Figure 192.3 Mirror therapy with reflection of the non-affected extremity. The affected extremity is behind the mirror.

laterality followed by explicit motor imagery in which the patient imagines moving their limbs with the help of images and pictures usually in a way which evokes pain, and the final step is mirror therapy as detailed above. GMI decreases pain and improves functional outcomes in CRPS patients.[53,56]

Ultimately, physical and psychological therapy should be patient-centered and focused on reducing pain and improving function of the affected limb, and are considered the mainstay of CRPS treatment.

Pharmacological

Anti-inflammatory/Immunomodulators

Nonsteroidal anti-inflammatory drugs (NSAIDs) and corticosteroids have been used to treat CRPS with mixed results. Their effect is thought to be mediated by decrease in inflammatory mediators such as prostaglandins. NSAIDs have shown mixed results in patients with neuropathic pain with one trial showing no benefit in CRPS patients.[57] Systemic corticosteroids have been tested in various trials with many showing positive results.[58,59] In a randomized clinical trial involving 60 patients, prednisolone was compared with piroxicam (NSAID) and showed greater improvement in symptoms.[58] In another study, 58 patients with post-stroke CRPS were given a high loading dose of prednisolone with 96% of patients showing improvement.[59] One-half of patients were continued on low-dose prednisolone and showed further improvement in symptoms as compared to the patient group who was taken off prednisolone.[59] Steroids are particularly helpful in acute CRPS when inflammation is at its peak, and longer treatment courses or use of steroids in chronic CRPS have not been proven to be efficacious. Other anti-inflammatory and immune-modulating drugs like selective cyclooxygenase (COX)-2 inhibitors, infliximab, etanercept (tumor necrosis factor [TNF]-α inhibitor) and thalidomide (TNF-α and interleukins 1 & 6 inhibitor) have shown some benefit in case reports and smaller trials, however, more data is required before their use can be recommended.[60,61]

N-Methyl-D-Aspartic Acid Receptor Antagonists

NMDA receptor antagonists (ketamine, amantadine, and dextromethorphan) have been evaluated for neuropathic pain and CRPS with mixed results. Ketamine can potentially reverse central sensitization resulting in pain alleviation; however, toxicity of ketamine at the required therapeutic dose limits its use in CRPS.[62]

Neuropathic Pain Medications

Gabapentin has been shown to be effective in acute and chronic neuropathic pain conditions and is widely used to treat CRPS patients, and associated with marked reductions in pain and improvement in sensory deficits.[63–65] Tricyclic antidepressants such as amitriptyline have also been used effectively to treat neuropathic pain conditions including CRPS. A randomized clinical trial (RCT) compared gabapentin and amitriptyline in a pediatric CRPS population, and showed similar reduction in pain and improvement in sleep over a 6-week period.[65] Anticonvulsant drugs such as carbamazepine, oxcarbazepine and phenytoin have also been used to treat neuropathic pain.[66–69] Carbamazepine has been studied specifically in CRPS patients showing significant pain reduction.[66] Oxcarbazepine is usually used in place of carbamazepine due to favorable risk profile and has shown to be comparable to carbamazepine in treating neuropathic conditions; however, it has not been tested in CRPS patients specifically.[67] Other anticonvulsants such as phenytoin, lamotrigine and topiramate have been used in various neuropathic conditions, however evidence in CRPS is lacking.[68,69]

Opioids

Opioids inhibit central nociceptive neurons and have been used to treat neuropathic pain, but there is no evidence of their benefit in CRPS patients. An RCT evaluated control release morphine in CRPS and found no difference in pain relief when compared to placebo.[70] While direct benefit of opioids in CRPS is questionable, they are used as part of a broader pain relief strategy and their use should be dictated on a case-by-case basis, while keeping tolerance and long-term adverse reactions in mind.[70,71]

Anti-hypertensives and Adrenergic Antagonists

Since sympathetic nervous system dysfunction plays an important part in CRPS, adrenergic agonist and antagonist drugs have been proposed to treat CRPS. However, results have been mixed.[72,73] In a case series, topical administration of the alpha-2 adrenergic agonist clonidine was reported to relieve hyperalgesia and allodynia but in a subsequent systematic review, evidence in support of clonidine was lacking.[72,73] Phenoxybenzamine is an alpha-adrenergic antagonist and has been associated with pain remission especially when administered in early stages of CRPS.[74] Other antihypertensives such as the calcium-channel blocker nifedipine has been used to manage vasoconstriction-induced symptoms in early CRPS.[75]

Calcitonin and Bisphosphonates

Bone resorption and remodeling occurs in advanced CRPS leading to osteoporosis and osteopenia. Bone density loss is further compounded by disuse of the affected extremity. Bisphosphonates (alendronate, ibandronate, risedronate, zoledronate, etidronate, pamidronate, etc.) are a class of drugs which inhibit osteoclastic activity thereby reducing bone resorption and increasing bone density.[76,77] Adami et al. reported reduction in

pain, tenderness and swelling of the affected extremity in 20 patients given intravenous alendronate.[77] Calcitonin is a polypeptide which preserves bone mass and has been found to be effective in treating acute and chronic pain. However, results in CRPS patients have been mixed.[78,79] In a double-blind randomized study of 66 patients, intranasal calcitonin added to physiotherapy was associated with improved pain as compared to placebo plus physiotherapy.[78]

SYMPATHETIC BLOCKADE – CENTRAL/PERIPHERAL/REGIONAL

As autonomic dysregulation and exaggerated cathecholamine response contribute to the pain in CRPS, stellate ganglion and lumbar sympathetic nerve block (SNB) have been used to control pain in upper and lower extremities, respectively. The success of the block is assessed by an increase in temperature in the affected extremity, without a sensory or motor block, reduced pain, improved range of motion, and decreased allodynia.[80] Positive results after sympathetic nerve block have been reported in 85% of patients in nonrandomized studies, although fewer patients (60%) reported long-term relief.[81,82] However, RCTs comparing SNB with placebo did not show any difference in pain outcomes,[83,84] and a Cochrane review[85] including 12 studies (461 patients) could not support or refute the use of SNB for the treatment of CRPS. Despite the lack of strong evidence supporting SNB for CRPS, these procedures are commonly performed by interventional pain specialists. SNB is performed in early CRPS after failure of conservative management, and a series of 3–6 blocks is recommended. Maximum benefit occurs in 3 months, and sympathectomy should be considered in patients with persistent pain. In patients who get complete pain relief after sympathetic blocks, and continue to have disabling pain, sympathectomy can be considered after 3 blocks.

Stellate Ganglion Block Technique

With the patient's head extended backwards on a pillow, the 6th transverse process is felt with the finger inserted between the sternocleidomastoid muscle and the trachea. With one finger on the 6th transverse process, a fine needle is inserted until it reaches the transverse process, and withdrawn 2–3 mm. Then, 15 mL of 0.25% bupivacaine is injected.

Lumbar Sympathetic Blockade Technique

Lumbar sympathetic blockade is obtained with a single injection of 15 mL of bupivacaine (Marcaine) at the level of L2. Some advocate using two or even three needles, with one inserted at L2 and the others at L3 and L4.

NEUROAXIAL THERAPY

Epidural administration of clonidine has been proposed for pain control by reducing the sympathetic nervous activity. In a small randomized control trial (N = 26), patients receiving clonidine had significant improvement of pain over placebo.[86] Intrathecal injection of various agents has been studied in four small randomized trials,[87–90] and steroid or glycine did not show any benefit, and further trials are needed to investigate intrathecal clonidine, adenosine and baclofen before their use can be recommended.

SYMPATHECTOMY

In patients who fail medical management, and if they responded to a series of 3–6 sympathetic blocks with >50% pain reduction lasting more than 24 hours, sympathectomy using chemical, radiofrequency or surgical excision can be considered.

Chemical Sympathectomy

Chemical sympathectomy involves injection of alcohol or phenol to induce sclerosis of the sympathetic chain. The technique is similar to the sympathetic block with three needles placed against the bodies of L2, L3 and L4 with the needle tip barely touching the vertebral body in lateral view, and lying over the bodies on anteroposterior view. After placing the needles, 3 mL of alcohol, or 3 mL of 6.5%–7% phenol dissolved in water are injected through each needle. The durability depends on the extent of disruption of sympathetic chains and does not preclude surgical sympathectomy if this fails, although it may be more difficult due to inflammation and scarring. It is also associated with painful neuralgias.

Radiofrequency Ablation

Radiofrequency ablation has been used to ablate the stellate ganglion and the lumbar sympathetic chain. It is considered to be more precise than chemical ablation, however it requires general anesthesia, and the response rate is not as complete and durable as surgical sympathectomy. It also causes inflammation, making subsequent sympathectomy more difficult.

Percutaneous radiofrequency thermal lumbar sympathectomy and lumbar sympathetic neurolysis with phenol were compared in a randomized trial involving 20 patients with lower extremity CRPS.[91] In both groups, the initial pain scores (8–9/10) fell to 4/10 after 1 day and remained between 3 and 5 over 4 months. One patient in the phenol group had postsympathectomy neuralgia, whereas "unpleasant sensation" score was higher in the radiofrequency group. However, due to the risk of phenol leaking with potential risk of neuritis, which is not uncommon, and occasional reported risk of paralysis, most interventionalists reserve the use of phenol for terminal cancer cases.[92]

Surgical Sympathectomy

Surgical sympathectomy has traditionally been performed via an open surgical approach but recently minimally invasive endoscopic approaches have been used, particularly for cervicodorsal sympathectomy. Patients should be informed about the potential complications (including early postsympathectomy

neuralgia), as well as expectations of outcomes following sympathectomy.

Cervicodorsal Sympathectomy

The preganglionic neurons supplying the face, neck and upper extremity originate from C7 through T5, and the efferent fibers form multiple synapses in the stellate and thoracic ganglia. A direct fiber tract from the T2 sympathetic ganglion to the brachial plexus (the nerve of Kunz) is also present in many patients as a frequent variation. Thoracic sympathetic ganglia are located laterally in the posterior mediastinum, and each trunk enters the thorax anterior to the rib, and behind the medial arcuate ligament. The first thoracic ganglion may fuse with the inferior cervical ganglion in front of the neck of the first rib to form the stellate ganglion. Autonomic denervation of the upper extremity requires both cervicodorsal sympathetic chain and periarterial sympathectomy at multiple levels. Typically, T2, T3 and T4 ganglia are included in the dorsal sympathectomy, although some recommend including lower third of the stellate ganglion (C7, C8, T1) in the excision, in order to prevent Horner syndrome.

Open Surgical Cervicodorsal Sympathectomy

Supraclavicular, transthoracic and axillary approaches have been described. These approaches are rarely used in contemporary practice and only when thoracoscopic approach is contraindicated. The supraclavicular approach is the easiest to perform with access to the extrapleural space, bilaterally if needed. However, due to manipulation of the stellate ganglion, Horner syndrome is frequently observed, which is usually temporary. The transaxillary approach provides exposure to T2–T4 and has less risk of Horner syndrome, although it may cause significant neuralgias.

Thoracoscopic Dorsal Sympathectomy

The procedure is performed in lateral thoracotomy position on a beanbag using single lung ventilation. Three 5-mm ports are placed in a triangular fashion in the 2nd, 3rd and 4th intercostal spaces. The sympathetic chain is visualized below the pleura over the posterior ribs as a whitish, multinodular cord. The sympathetic chain is traced to the level of the first rib, and the inferior margin of the stellate ganglion is seen, which is covered by apical fat. The T2 ganglion is under the second and third ribs. The pleura is incised longitudinally, and the T2 is transected below the stellate ganglion, and is grasped, and the nerve connections and adjacent nerves of Kuntz are divided and carried down to T4 or 5, and excised. The intercostal nerves 1–5 are blocked with 0.5% bupivacaine for postoperative pain control. The lung is reexpanded, and a 14- to 16-F tube is inserted while the two port sites are closed, and the tube is removed under negative pressure and the port site is closed. Postoperative chest X-ray is obtained to ensure absence of pneumothorax. Patients are typically discharged 1–2 days after surgery.

Lumbar Sympathectomy

The preganglionic fibers arise from the lateral gray substance of the thoracoabdominal spinal cord, and emerge via the ventral roots of the thoracic and lumbar nerves and reach the sympathetic chain via the white rami communicantes. After synapsing with the sympathetic ganglia cells, the postganglionic fibers course through the gray rami communicantes and join the somatic nerves. The sympathetic innervation of the leg is through L1–4 ganglia. The lower extremity receives its preganglionic fibers from the upper lumbar nerves, through the lumbar sympathetic trunks, which are located anterolaterally on the vertebral bodies. The number of lumbar ganglia varies from three to five. Complete sympathetic denervation should include division of preganglionic fibers at their origin, as well as intercommunicating fibers in addition to the appropriate ganglia, typically L2–4.

Open lumbar sympathectomy can be performed via a transperitoneal or retroperitoneal approach. A transverse skin incision is extended from the rectus muscle to the midaxillary line between the costal margin and the iliac crest. The preperitoneal fat is reached after muscle splitting, and carried posteriorly with blunt dissection, taking care not to enter the peritoneum. The psoas muscle is visualized, and the ureter must also be mobilized anteriorly and medially. Then the lumbar chain is palpated as a firm cord anterolaterally on the vertebral bodies, between the psoas muscle and the vena cava on the right, and aorta on the left. Crossing lumbar veins and arteries are ligated. The sympathetic chain is elevated using a hook, and the chain is divided between the first and second ganglia, avoiding the first ganglion to minimize the risk of sexual dysfunction. The L1 ganglia typically lies behind the diaphragmatic crura. The second to fourth ganglia are removed with the ends clipped, and sent for frozen examination for verification of ganglion cells (Fig. 192.4).

Laparoscopic Lumbar Sympathectomy

Laparoscopic lumbar sympathectomy can also be performed by a transperitoneal (anterior) or retroperitoneal approach. In the extraperitoneal approach, initially a 12 mm incision is made between the iliac crest and the costal margin in the midaxillary line, and the retroperitoneum is reached after bluntly separating the external and internal oblique muscles, and a cut in transverse muscle, and balloon distension is used to dissect the retroperitoneum, followed by placing a 10-mm port and three or four 5-mm ports. The psoas muscle, ureter, genitofemoral nerve and the gonadal vessels are visualized, and the sympathetic chain is visualized medial to the psoas muscle, under the vena cava on the right and adjacent to the aorta on the left side. The sympathetic chain is dissected along the vertebral column and the overlying lumbar veins are clipped and divided. The sympathetic ganglia L2–4 and the chain is removed using laparoscopic forceps and microcoagulating scissors. In the anterior approach, after obtaining pneumoperitoneum, the colon and kidney are medially rotated to gain access to the sympathetic chain.

Complications

Neuralgia of the thigh is the most common complication after thoracodorsal lumbar sympathectomy, which occurs in up

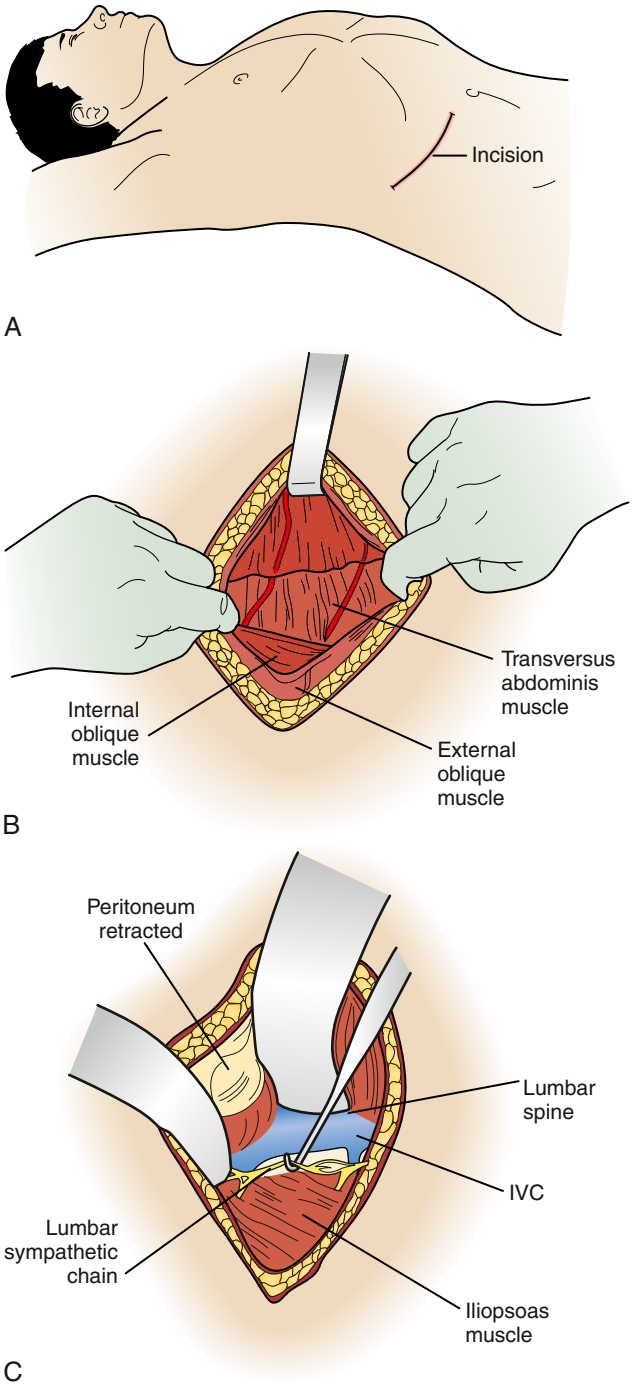


Figure 192.4 Open Lumbar Sympathectomy. (**A**) Patient positioning and incision; (**B**) muscle splitting and retraction of the inferior vena cava (IVC) (**C**), to expose the sympathetic chain.

to one-third of patients. Pain is located in the scapula after thoracic, and anterolateral thigh after lumbar sympathectomy. The pain typically starts 1–3 weeks after sympathectomy, is not affected by activity and is worse at night. The pain is typically temporary and resolves spontaneously in 2–3 months in the majority of patients.[93,94] Other complications include compensatory sweating of the lower back and face, pneumothorax, bleeding due to azygos vein or intercostal artery injury and long thoracic nerve injury causing winged scapula after thoracic sympathectomy. Additionally, genitofemoral nerve injury, ureter and bowel injury, and bleeding from lumbar vein injury can occur after lumbar sympathectomy. Retrograde ejaculation can occur in up to 25%–50% of patients after bilateral lumbar sympathectomy, but is rare after unilateral sympathectomy, especially if the L1 ganglion is preserved.[95]

SPINAL CORD STIMULATION

Spinal cord stimulation (SCS) has been used for CRPS, in which electrodes are placed surgically or percutaneously into the dorsal epidural space at the level of the nerve roots innervating the painful area.[96] An electrical current is supplied by the electrode from a pulse generator located in a subcutaneous pocket, which can be placed in various locations (gluteal, abdominal, axillary, paravertebral). A variety of mechanisms of action have been proposed, including inhibition of neural induction at the dorsal horn and supraspinal structures,[97,98] sympathetic inactivation and peripheral vasodilatation,[99] antidromic release of calcitonin gene-related peptide and nitric oxide from small-fiber sensory fibers.[100] In an RCT comparing SCS and physiotherapy to physiotherapy alone, Kemler et al.[101] showed improvement in pain up to 2 years, but there was no difference at 5 years with 42% of patients in SCS groups experiencing complications. Overall, SCS has been reported to be associated with clinically meaningful pain relief in about 40%–50% of patients.[101,102] The variation in response rate may be due to lack of precision, paresthesias, as well as the mechanism of action not being targeted by the technique. The lack of precision of SCS may be due to variations in stimulation with position changes, segmentation of spinal sensory input, shunting of energy by the cerebrospinal fluid and lead migration.[103] In addition to lack of efficacy, SCS can also be complicated by infections, injury to dura and device failure.[104]

Dorsal Root Ganglion Stimulation

Dorsal root ganglion (DRG) houses the somas of the primary sensory neurons, and is located between every spinal nerve and the spinal cord on the posterior root. The somas process and transmit sensory information from the periphery to the central nervous system. Pathological changes in the DRGs have been hypothesized to play a role in the pathophysiology of CRPS.[105] Anatomically, peripheral stimuli associated with pain symptoms can be narrowed down to one or two spinal level DRGs. Therefore, stimulation of the relevant DRG modifies pain signaling from the periphery for only the affected dermatomes. Neurostimulation of the DRG has been shown to have a higher success rate than SCS.[106] In a multicenter RCT involving patients with lower extremity CRPS, significantly more patients in the DRG arm achieved ≥50% pain relief as compared to the SCS group along with greater improvements in quality of life and psychological disposition.[106] Further studies are needed to verify the superiority of DRG stimulation.

AMPUTATION

Amputation of the affected limb should only be considered for patients with severe or recurrent infections, and severe dysfunction, and not for pain control, due to very high risk of persistence or recurrence of pain.[107]

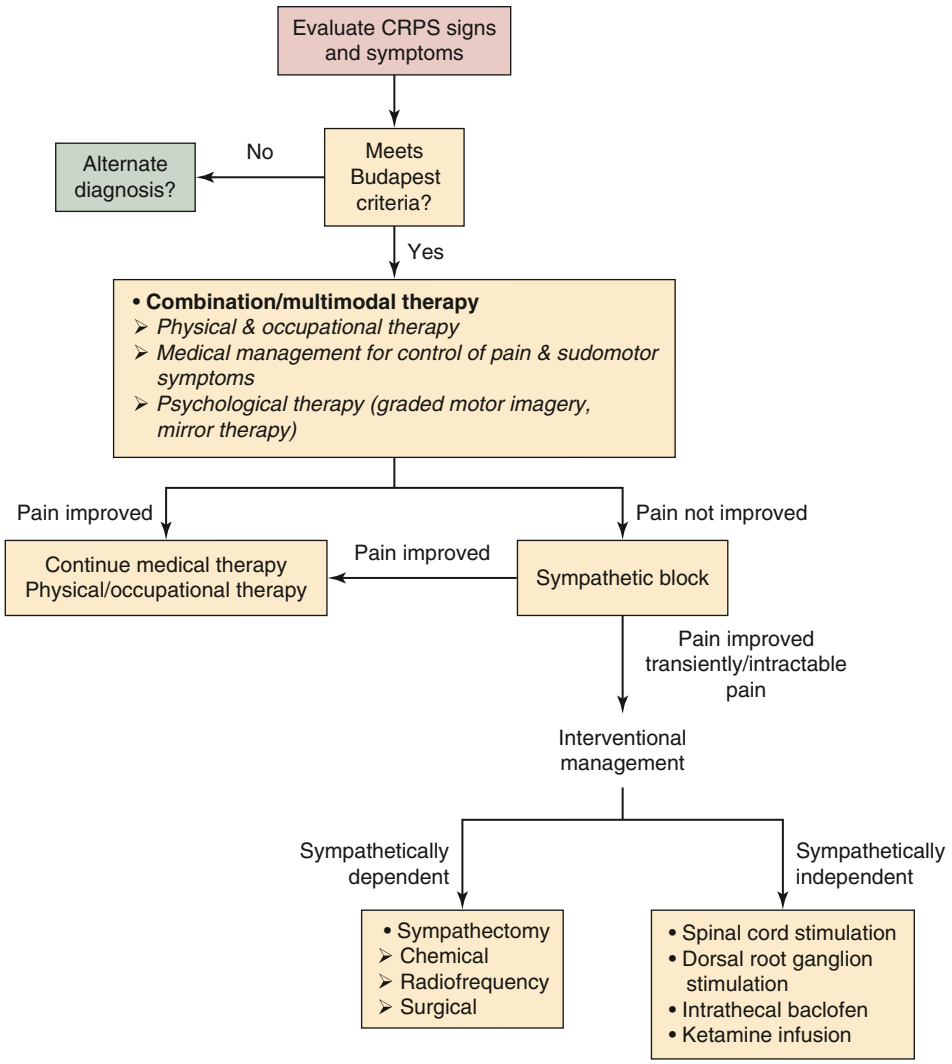
PREVENTION

Vitamin C may decrease the rate of CRPS by inhibiting inflammatory pathways. However, results have been mixed. In one RCT, vitamin C was associated with a significant decrease in CRPS rate (2.4% vs. 10.1%).[108] However, another more recent RCT showed no difference in functional outcomes, rate of CRPS and bone healing.[109] Furthermore, a recent meta-analysis of three trials did not show vitamin C to reduce risk of CRPS after distal radial fractures.[110] Although the quality of evidence is low, due to some positive results, vitamin C is still recommended in some guidelines to decrease the rate of CRPS after wrist, foot, and ankle surgery.[111]

LIMITATION OF DATA/FUTURE DIRECTIONS

While evidence to guide treatment of CRPS remains limited, increasing work over the last couple of decades has improved our understanding of the disease and its underlying pathophysiology. The CRPS patient population is heterogeneous with variable clinical presentations, reflecting different underlying pathophysiological features, which explains the variable response to treatments in clinical practice and research studies. Moreover, evidence in CRPS II is even more limited. Given this variability, it is difficult to design trials and results of even well-designed trials may not be applicable to all patients. Most clinicians adopt an experimental approach and effective treatment is implemented by a trial and error approach. Most of the time, effective symptom control is achieved by combining multimodal therapies. Additional studies investigating combination therapy in CRPS are necessary to better delineate effective treatment strategies in this challenging patient population.

CHAPTER ALGORITHM



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193 CHAPTER

Current Role of Sympathectomy (Upper and Lower)

NELSON WOLOSKER and PAULO KAUFFMAN

INTRODUCTION

Cervical sympathectomy was first performed to treat a patient with hyperhidrosis by Kotzareff in 1920.[1] Subsequently, Diez performed the first lumbar sympathetic chain ganglia resection to treat a patient with thromboangiitis obliterans (TAO) in 1924, and reported 100% success in treating 150 cases of upper limb TAO.[2] Leriche in 1924 performed this procedure to treat Raynaud disease. Subsequently, open surgery evolved with a number of procedures to resect the sympathetic ganglia: supraclavicular (cervical),[3] axillary transthoracic,[4] dorsal (posterior),[5] dorsal midline,[6] and anterior transthoracic.[7] By the end of the 1930s, the main indications for cervicothoracic sympathectomy had started to be delineated: hyperhidrosis,

TAO, and vasospastic conditions. Until the 1960s, due to a lack of revascularization techniques, lumbar sympathectomy was considered the only alternative, widely used to treat lower limb peripheral artery diseases.

After the development of the thoracoscope, introduced by Jacobaeus in 1910,[8] Hughes in 1942 performed the first thoracoscopic sympathectomy.[9] Kux, in 1953, was the first to publish a large experience with this method.[10] However, despite the good results, for unknown reasons this technique did not achieve international acceptance until the end of the 1980s.[11] In the 1990s, technological innovation with advances in low profile optical systems and instruments for thoracoscopic surgery made it possible to perform video-assisted thoracoscopic sympathectomy (VATS),[12] with low morbidity, good cosmetic results, decreased incidence of Horner syndrome and short hospital stay.[13]

ANATOMY

Sympathetic Ganglia

The motor sympathetic route is formed by three neurons (Fig. 193.1). The cell body of the first neuron is located in the sudomotor and vasomotor centers, mainly in the hypothalamus. Its axon projects along the dorsal longitudinal and spinovestibular fascicles to the cell body of the second neuron (preganglionic neuron), which is located in the intermediolateral nucleus of the spinal gray matter, between the first thoracic and second lumbar vertebrae. Its axon (the preganglionic fiber) exits the medulla through the ventral root of the spinal nerves and, through the white communicating branch, projects to the paravertebral ganglion, where it forms a synapse with the cell body of the third neuron, the postganglionic neuron. Its axon (the postganglionic fiber) leaves the sympathetic chain through the gray communicating branch into the spinal nerve and is distributed peripherally. The ganglia are also interconnected longitudinally by axons from preganglionic neurons that run rostrally or caudad to the neighboring ganglia of the chains.

As in the somatic nervous system, the axon of the preganglionic neuron exits the segment in which its soma is located. There is one sympathetic paravertebral ganglion (G) for each spinal segment. The sympathetic fiber that originates from the ganglion innervates the area of the spinal nerve corresponding to that segment. Thus the second ganglion (G2) supplies sympathetic innervations for the structures of the second dermatome (D2).

In the neck, there are normally three ganglia in the sympathetic chain. The superior cervical ganglion results from the fusion of the first four sympathetic cervical ganglia; it is located at the level of the transverse process of the second and third cervical vertebrae and supplies the head and neck. The middle cervical ganglion is located at the level of the sixth cervical vertebra. The inferior cervical ganglion is generally fused with the first thoracic ganglion (G1) to form the cervicothoracic ganglion (stellate ganglion), which is located anterior to the head of the first rib and covered by the pleura.

In the thoracic region, the ganglia of the sympathetic chain are positioned anteriorly to the transverse processes of the thoracic vertebrae and are covered by the parietal pleura. They are fewer in number than the spinal thoracic nerves because of the fusion of the first thoracic ganglion with the inferior cervical ganglion, fusion of the last thoracic ganglion with the first lumbar ganglion, and fusion of the thoracic ganglia with each other.

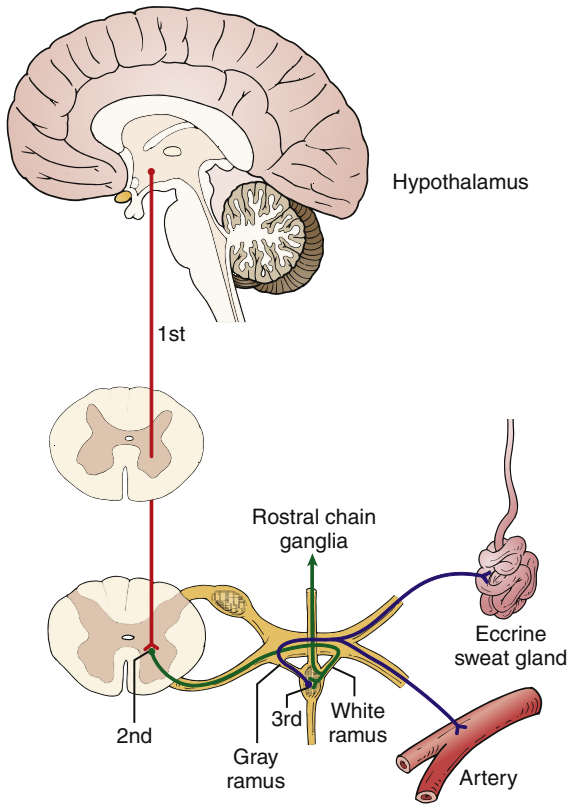

Figure 193.1 The Motor Sympathetic Route. The cell body of the first neuron is located in the sudomotor and vasomotor centers, the second neuron (preganglionic neuron) is located in the intermediolateral nucleus of the spinal gray matter, and the third neuron (postganglionic neuron) is located in the paravertebral ganglia.

The greater, lesser, and least splanchnic nerves are formed by preganglionic fibers originating from the 5th to 12th thoracic medullary segments. They cross the corresponding sympathetic ganglia without forming synapses with them and end in the celiac, aorticorenal, and superior and inferior mesenteric ganglia. The major splanchnic nerve plays a particularly important role in visceral pain because of the large numbers of visceral afferent fibers it contains. Hence splanchnicectomy may be employed to treat unmanageable visceral pain, particularly in pancreatic diseases (cancer and pancreatitis).[14] In the past, thoracolumbar sympathectomies were performed to treat hypertension, a technique currently abandoned with the advent of modern antihypertensive drugs.

Sympathetic Innervation of the Upper Limbs

The preganglionic fibers responsible for the innervation of the upper limbs originate from the second to eighth thoracic medullary segments, most of them below the fourth segment. The fibers enter the paravertebral sympathetic chain through the

white communicating branches of the corresponding ganglia and have an ascending pathway in which a synapse is formed with cells located in the second thoracic ganglion, the stellate ganglion, and probably the middle cervical ganglion. It is of surgical interest that no preganglionic fibers enter the sympathetic chain above the first thoracic ganglion, which participates in innervation of the limb in only 10% of the cases.

In most patients, the thoracic sympathetic trunk is located in the middle of the intercostal space, on the bottom edge of the top rib or the top edge of the bottom rib.[15–17] Therefore when one sections the sympathetic chain on two consecutive ribs, there is a high probability that one is making the sympathetic ganglion between them dysfunctional.[18]

Several anatomic landmarks have been used to determine the exact location of sympathetic interruption, including the thoracic ganglion (G), the vertebral level, and the intercostal space. More recently, a rib-oriented nomenclature has been suggested that refers to the rib level (R) instead of the vertebral level for sympathetic interruption.[18] This decision was based on too many patients having mediastinal fat that can obscure clear identification of the specific ganglia and because there are many anatomic variations in the ganglion anatomy. Information about the technique used for ganglionic interruption should also be included in the nomenclature, stating whether clipping, cauterization, or segment removal is performed. For this chapter, we use the ganglionic level as anatomic reference.

Sympathetic Innervation of the Lower Limbs

Sympathetic preganglionic fibers responsible for the innervation of the lower limbs originate from the 12th thoracic medullary segment to the 2nd lumbar segment and reach the sympathetic chain by white rami communicantes, all having descendant paths.

Postganglionic fibers originate in cells of the lumbar and sacral ganglia. The fibers destined for the lumbar plexus come from the first three lumbar ganglia and those destined for the sacral plexus come from the fourth lumbar nerve and sacral ganglia. Therefore, all postganglionic fibers that follow the sciatic nerve originate on ganglia located under the third lumbar nerve, since the greater number of synapses occur on the fourth lumbar nerve.

It is known that there are no rami communicantes under the second lumbar ganglion; therefore, the removal of the second and third lumbar sympathetic ganglia interrupts all preganglionic fibers to the sciatic nerve and consequently to the cutaneous territory located under the knee except the saphenous nerve territory, which originates from the lumbar plexus. To obtain thigh denervation it is necessary to remove the first lumbar ganglion. The removal of the fourth lumbar ganglion does not amplify the scope of denervation but interrupts the many postganglionic fibers destined for the sciatic nerve.

Sympathetic Innervation of the Ocular Structures

The sympathetic preganglionic fibers controlling the smooth muscles of the eye are rostral, from anterior roots of G1 and G2. The fibers enter the sympathetic chain by the corresponding ganglia but do not form synapses. The synapses are subsequently formed when they ascend to the superior cervical ganglion. The postganglionic fibers head toward the ocular–pupillary apparatus through the carotid plexus. Consequently resection of the stellate ganglion causes Horner syndrome (enophthalmos, myosis, and palpebral ptosis).

Sympathetic Innervation of the Cephalic Segment

Sympathetic innervation of the head and neck originates from the first to fifth thoracic medullary segments. The preganglionic fibers ascend the sympathetic chain and form synapses with the first thoracic ganglion and the inferior cervical ganglion. Most of the postganglionic fibers responsible for innervation of the face originate from G2, which implies that craniofacial sweating diminishes through G2 ablation.

Sympathetic Innervation of the Heart

Sympathetic innervation of the heart is supplied from the higher three heart nerves (superior, medial, and inferior) arising from the three cervical ganglia and from the sixth or seventh thoracic paravertebral ganglia. Most fibers converge at the cardiac plexuses. These nerves are more abundant in the fourth and fifth thoracic segments than at higher levels.

PHYSIOLOGY

The sympathetic chain supplies the smooth muscles of the blood vessels through adrenergic fibers and the sweat glands through cholinergic fibers. The vascular system differs from other systems in its lack of antagonistic innervation between sympathetic and parasympathetic vasoconstrictor fibers; thus vasodilation results from a decrease in sympathetic activity.

The autonomic nervous system has a considerable influence on vessels with a more developed smooth muscle layer of the vessel wall in relation to its caliber. Hence arterioles are most affected by sympathetic activity and the autonomic nervous system has great influence on skin circulation but is of little importance in great vessels and muscular arteries.

Eccrine sweat glands, which are responsible for hyperhidrosis, are innervated by the nonmyelinic C fibers of the sympathetic nerves, and acetylcholine is the chemical mediator. Local or systemic administration of cholinergic agents induces sweating, whereas the use of atropine blocks it. Although sweating in the palmar and plantar regions may result from emotional stimuli and abundant sweating is observed under clinical conditions in which catecholamines are released by the adrenal glands, administration of adrenergic agents by any route does not stimulate the sweat glands.[8] Blocking of preganglionic fibers does not stop sweating caused by stimulation of the postganglionic fibers, nor does the local administration of cholinergic agents. However, if postganglionic fibers are cut, such secretion will no longer occur through local stimulation by any pharmacologic agent. This is an exception to Cannon's

law (which states that when one unit in a series of efferent neurons is destroyed, increased irritability to chemical agents is developed in the structure that has been isolated and the effect is greater in the part that is directly denervated). Heating of the skin may cause sweating in this situation through an unknown mechanism.

Different neural centers control the various types of sweat glands in a reflex manner. Thus emotional sweating is controlled by a cortical center, thermal sudoresis by a hypothalamic center, gustatory sudoresis by medullary nuclei, and spinal sweating by cells of the intermediate-lateral region of the spinal cord.

The nerve centers and pathways that control emotion-induced sweating are not fully known, although it seems that they are located in the frontal lobe. Emotion-induced stimuli can increase sweating, especially in the palmar and plantar regions. Under baseline conditions, few impulses pass to the sweat glands, and nonsensory sweating (perspiration) is always present, partly because of the activity of the glands and partly because of loss of water through the epidermis.

INDICATIONS FOR CERVICOTHORACIC AND LUMBAR SYMPATHECTOMY

The current indications for cervicothoracic sympathectomy are limited to essential hyperhidrosis,[19] selected cases of critical hand ischemia,[20] complex regional pain syndrome (CRPS) (see Ch. 192, Complex Regional Pain Syndrome),[21] clinically refractory long QT syndrome,[22] and Raynaud syndrome (see Ch. 142, Raynaud Phenomenon).[23] The current indications for lumbar sympathectomy are limited to essential plantar hyperhidrosis and rare and selected cases of chronic critical ischemia of the legs with no conditions or revascularization.[24] Other less frequent indications are selected cases of Raynaud syndrome and CRPS.[25,26]

Idiopathic Hyperhidrosis

Hyperhidrosis, the production of excessive quantities of sweat believed to be the result of stimulation of the sympathetic nervous system at the central level, occurs mainly in the palms of the hands, armpits, soles of the feet and face, but it can also affect the abdomen, chest, back, inguinal regions and lower limbs in a symmetric manner. Hyperhidrosis manifests frequently in more than one site. Only 15% of patients have a single site of excessive sweating. The main complaint is palmar sweating. When there are two sites of sweating, the most frequent combination is palmo-plantar, and when there are three, the most frequent combinations are palmo-planto-axillary and axillary-palmo-plantar. In the literature, authors always refer to the type of patient complaint based on the site with the highest interference, regardless of the secondary sites, but we must keep in mind that in most cases the manifestations are multiple.[27] Hyperhidrosis has unknown etiology, may arise during childhood, but it is more intense during adolescence, a transitional period of life with potential psychological stress associated with triggers of hormonal and sexual maturation. It may persist into adulthood but decreases in intensity in some patients.[28]

Hyperhidrosis affects approximately 3% of the population; in 13% to 57% of patients it can be associated with a family history of hyperhidrosis.[29,30] Climate is not an etiologic factor, but hot weather exacerbates sweating.[31]

Palmar hyperhidrosis generally takes on greater clinical significance than the others because it creates significant problems within the educational, social, professional, and affective spheres, which can worsen any emotional issues that may already exist for such patients.[32,33]

Plantar hyperhidrosis is frequently associated with palmar or axillary hyperhidrosis and is worsened by the use of closed shoes, which hinder evaporation and favor skin maceration. The constant dampness provides additional conditions for malodorous fungal or bacterial infections.[34]

Axillary hyperhidrosis tends to appear at puberty, with the increased production of sexual hormones. Symptoms of axillary hyperhidrosis are disabling both professionally and socially for almost all patients who seek surgical treatment.[35] Likewise, craniofacial hyperhidrosis and facial rubor may cause social phobia.[36–38]

Nonsurgical treatment should initially be attempted in all cases of hyperhidrosis. If results are inferior to patient expectations, sympathectomy should be considered. Besides oxybutynin,[39] other consistent alternatives include botulinum toxin injection[40] and glycopyrrolate.[41] Sympathectomy is indicated for patients who do not experience an improvement in quality of life despite appropriate nonoperative treatment and are willing to accept the risks involved in surgical treatment (mainly compensatory hyperhidrosis).[42]

Ischemia of the Hand

Selected patients with ischemic hand pain or finger ulcers, particularly those with TAO and distal arterial obstruction, may benefit from sympathectomy (see Ch. 139, Thromboangiitis Obliterans).[20,43,44] Cervicodorsal sympathectomy has been used selectively in cases of critical hand ischemia to improve cutaneous vasodilation, control ischemic rest pain and vasomotor phenomena, and support healing of the skin in patients unresponsive to conservative management. However, no randomized trial comparisons with other treatments are available, and because the disease can be improved by smoking cessation, it is difficult to judge the benefit of sympathectomy from published studies.[45]

Complex Regional Pain Syndrome

CRPS, also known as causalgia, reflex sympathetic dystrophy (RSD), posttraumatic pain syndrome, shoulder–hand syndrome, and Sudeck atrophy, is a term that has been used since 1994. It describes ① regional pain condition that often occurs after injury, ② disproportionate to the inciting event, and is associated with ③ signs of vasomotor dysfunction and sudomotor activity.[46] When CRPS is left untreated, hyperalgesia, allodynia, signs of vasomotor dysfunction, and edema can be

seen initially. After 3 to 6 months, there is increased pain, and sensory dysfunction and motor or trophic changes (or both) develop (dystrophic stage). Finally the pain decreases, but there are still sensory disturbances (atrophic stage).[47,48] Sympathetic blockade with local anesthesia has been used to control pain in selected patients. If it is effective, this technique can be repeated, together with physical therapy to recover functionality of the limb.[49] Peridural or intrathecal infusions of anesthetic drugs can be used in selected patients who do not respond to conservative treatment. Because of proximity to receptor sites, the therapeutic effect of intrathecal drug application lasts longer and the rate of systemic side effects is reduced. However, there are catheter-related technical problems, such as catheter dislocation, obstruction, kinking, and disconnection or rupture, as well as drug-related side effects.[50]

Spinal cord stimulation is efficacious in CRPS type I that is resistant to medication or other treatments. High-frequency transcutaneous electrical nerve stimulation and repetitive transcranial magnetic stimulation are noninvasive and suitable as preliminary or add-on therapies and provide satisfactory pain relief to many patients, including those resistant to medication or other therapies.[51]

Chemical sympathectomy with phenol or alcohol seems to have at best a temporary effect limited to cutaneous allodynia. Because studies reported to date include few patients and poorly defined outcomes, well-designed studies on the effectiveness of the procedure are needed.[52,53]

Sympathectomy can be used in selected patients who do not respond to nonsurgical treatment or in those who have good but transient benefit from pharmacologic sympathetic blockade.[54]

Long QT Syndrome

Long QT syndrome is an idiopathic congenital disorder of ventricular repolarization, with prevalence of at least 1 in 2000 live births, characterized by a lengthened QT interval on the electrocardiogram associated with a high incidence of severe tachyarrhythmia, syncope, and sudden death. It often occurs at a young age. There is no clinical or radiologic evidence of heart disease. Severe episodes typically occur during intense physical exercise or emotional crises, which leads to the supposition that the sympathetic nervous system plays an active part in the genesis of the problem. The mortality rate in untreated patients reaches as high as 78%. Beta-blockers are effective in preventing such crises in 75% to 80% of the cases.[55] Sympathectomy is only potentially indicated in patients who, even with appropriate clinical treatment, continue to have syncopal crises (about 20%–25% of these patients).[56,57]

Raynaud Syndrome

Raynaud disease and phenomenon are exaggerated responses to cold temperature or emotional stress characterized by episodic spasm of arterioles, usually in the digits, with intermittent pallor or cyanosis, precipitated by exposure to cold, emotional upset, or drugs. The treatment of Raynaud syndrome is essentially nonoperative. Sympathectomy has been used in few patients who, despite adequate clinical treatment, continue to have severe symptoms or trophic lesions with poor healing. However, it is difficult to judge the benefit because randomized trials have not been performed and the natural history is variable.[20]

SURGICAL TECHNIQUES

Open Surgery for Cervicothoracic Sympathectomy

Until the 1990s and before VATS, open surgery was the "gold standard" for cervicodorsal sympathectomy. Several approaches are available for open surgery, each with its own advantages and disadvantages. There are three main approaches, the paravertebral, transthoracic, and supraclavicular routes. Today the open technique is indicated only when VATS cannot be accomplished for technical reasons or an associated open operation is being performed.

The paravertebral route, mainly used by neurosurgeons, offers wide exposure of the sympathetic chain. However, it involves extensive dissection and the sectioning of several muscle bunches and requires a long period of recovery.[58]

The transthoracic axillary approach has the advantages of superior exposure, easier access to the sympathetic chain for wide incisions, lower risk of Horner syndrome, and good cosmetic results. The main complication is postsympathetic neuralgia, which is long-lasting and extends the recovery time.[59]

The supraclavicular approach requires an extrapleural access and thus allows the procedure to be completed bilaterally in a single operation. The resulting scar becomes virtually invisible in a short time, convalescence is fast with little pain, hospital stay is short, and surgical complication rates are low. The disadvantage is that the stellate ganglion is the point of reference for identifying the sympathetic chain, and its simple manipulation can result in Horner syndrome, although in most cases transitory.[60]

Video-Assisted Thoracoscopic Sympathectomy

VATS is currently considered the gold standard for cervicothoracic sympathectomy. Several approaches (one port, two ports, three ports, four ports, lateral, dorsal) are available, each with its own advantages and disadvantages.[61–63] An easy and practical technique (two ports) is described in the following paragraphs.

Instrumentation

The basic equipment includes a 15-degree angled thoracoscope, video camera with monitor, DVD recorder, light source, video endoscopic instruments, electrocautery (harmonic or not), and nerve hook and vascular clips.

Anesthesia

The patient usually undergoes double-lumen endotracheal general anesthesia, which makes it possible to stop the patient's ventilation and consequently to collapse the lung on the side that

will undergo surgery. When necessary, bronchoscopy is used to verify tube positioning. A double-lumen endotracheal tube is used in patients undergoing resection of the fourth ganglion of the thoracic sympathetic chain. When thermoablation is performed on the second or third ganglion, a single-lumen tube may be used in conjunction with adequate control over lung ventilation. Long-acting anesthetic agents are avoided to allow immediate extubation at the end of the procedure.

Positioning

Positioning the patient properly is essential, since patients placed in inappropriate positions usually present with transient paresis of the upper limb, which although temporary, takes months to disappear, leading to great discomfort and stress for patients. The patient is placed in dorsal decubitus semiseated position with the trunk raised approximately 45 degrees. Two small pads are placed under the shoulders to create a space between the axillae and the surgical table and to bring the shoulders forward, thereby avoiding distention of the brachial plexus when the arms are positioned in 90 degrees of abduction on the arm rests. Another pad under the knees and a securing strap at the hip level allow the legs to be positioned comfortably and stabilize the patient on the surgical table when it is rotated laterally to bring the sites for surgery forward (right or left).

Technique

In patients with hyperhidrosis, which represent more than 95% of the cases and in which thermoablation of only the third or fourth sympathetic ganglion is performed, two mini-incisions about 1 cm in length are made. The first incision is made on the anterior axillary line at the level of the fourth or fifth intercostal space to introduce a video camera. The second incision at the second or third intercostal space on the medial axillary line is used to introduce the surgical instruments (electric or ultrasonic bistoury, scissors, dissecting forceps, retractable hook, and aspirator) into the pleural cavity (Fig. 193.2). In cases where the stellate ganglion must be resected, a third mini-incision is made anterior to the posterior axillary line to facilitate the dissection.

Trocars 5.5 mm in diameter are introduced into all the incisions to keep the pathway open and protect the structures of the thoracic wall. Carbon dioxide insufflation into the pleural cavity has been used in some centers to improve surgical access. However, this may cause cardiovascular compromise even when it is used at low pressure.[64] To avoid these complications, we have preferred to use open pneumothorax, which has proved to be sufficiently satisfactory.

The sympathetic chain is identified through the parietal pleura as a whitish, longitudinal, multinodular cord that forms a slight prominence in the lateroposterior region of the thoracic vertebrae, above the heads of the costal arches (Fig. 193.3). In elderly patients or individuals with a greater degree of fatty tissue, the sympathetic chain sometimes becomes difficult to distinguish. In such cases the chain is identified by touch with the endosurgical instruments (Fig. 193.4). The parietal pleura is sectioned above the chain and is also dissected by blunt separation. The communicating branches are coagulated and sectioned to the extent desired (Fig. 193.5). The chain is then sectioned above the costal arches and the segment isolated is cauterized (Fig. 193.6). Application of vascular clips to the main sympathetic trunk instead of thermoablation is an alternative.

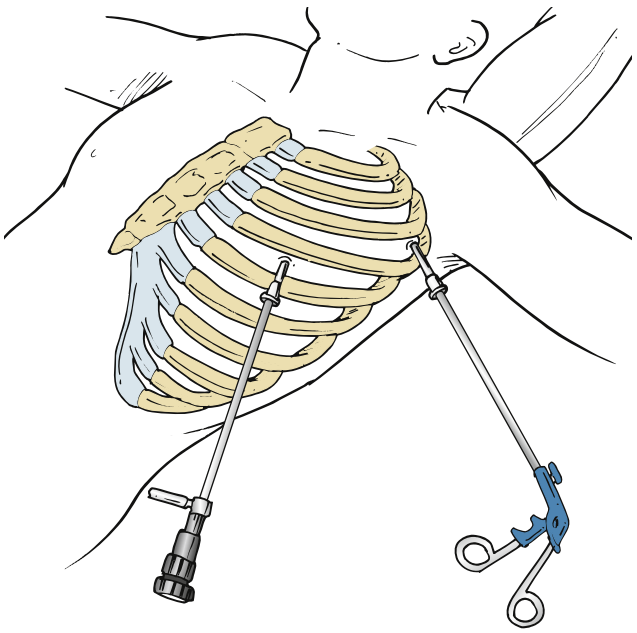

Figure 193.2 Port placement: one in the fourth or fifth intercostal space on the anterior axillary line and one in the medial axillary line in the second or third intercostal space.

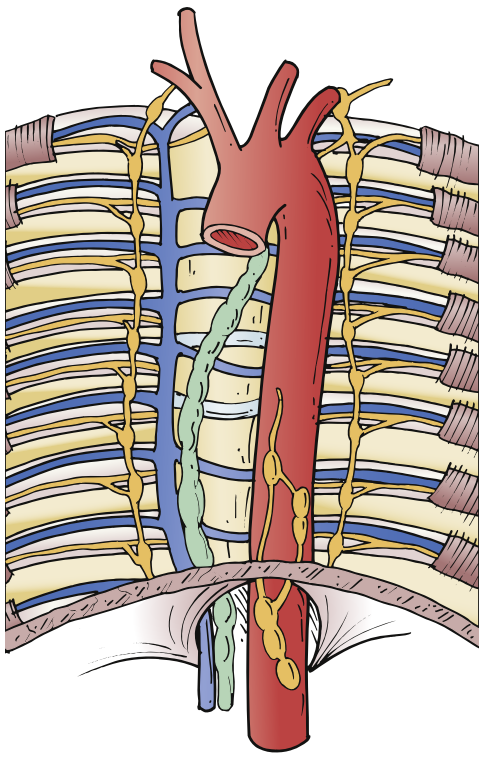

Figure 193.3 Sympathetic chain *(yellow)* coursing above the heads of the costal arches. The stellate ganglion is located anterior to the head of the first rib, the T2 ganglion is between the second and third ribs, the T3 ganglion is between the third and fourth ribs, and the T4 ganglion is between the fourth and fifth ribs.

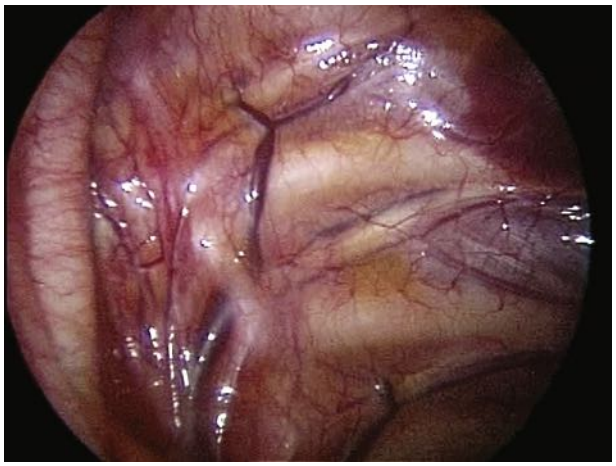

Figure 193.4 Thoracoscopic normal anatomy of the sympathetic chain.

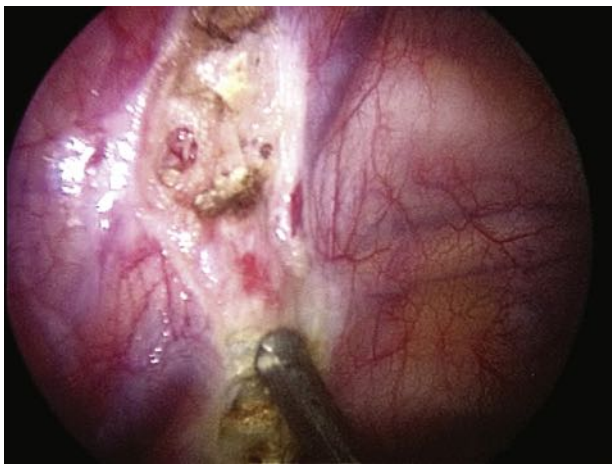

Figure 193.5 Sympathetic chain sectioned above and below the ganglia.

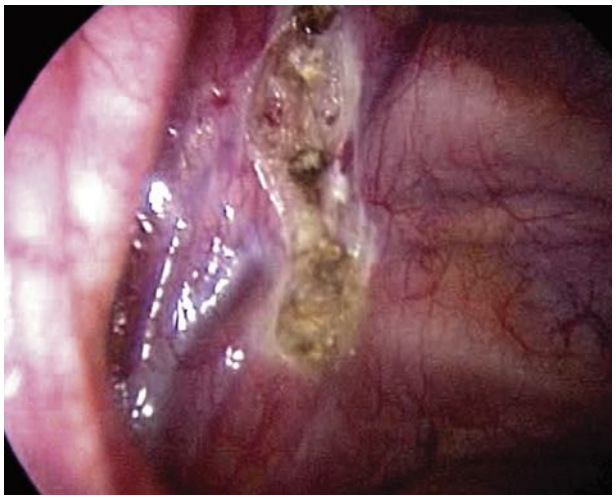

Figure 193.6 Sympathetic chain cauterized.

After hemostasis is achieved, a 14- or 16-F aspiration probe is placed through the upper trocar and connected to a negative-pressure aspirator. The anesthetist is then asked to ventilate the collapsed lung until complete expansion has been achieved. This can be verified by direct viewing on the video monitor. The video camera and aspirating probe are then removed and the corresponding incision is sutured. Occlusive bandages are left on the surgical incisions for 24 hours. In the postanesthesia recovery room, chest radiography is obtained to confirm and inspect expansion of the lung and check for possible residual pneumothorax.

Lumbar Sympathectomy

Open surgery performed through anterolateral extraperitoneal access provides a wide surgical field and allows for the execution of bilateral surgery with no need to change the patient's position on the surgical bed. An alternative to conventional surgery is sympathetic denervation through retroperitoneoscopy; minimal morbidity, short convalescence time, and similar effectiveness to open surgery have been reported.[65,66] The endoscopic technique, although feasible, is not widely performed today since the indications of lumbar sympathectomy are infrequent so that a small number of procedures are being performed.

Chemical sympathectomy, which consists in blocking the sympathetic nerve with phenol, has increased in application since Reid et al. in 1970 showed the procedure to be safe and effective in a large number of patients.[67] It is a fairly long-lasting method and as an advantage has the possibility to be repeated whenever necessary. Postsympathectomy neuralgia occurred in 9% of the cases in Reid et al.'s experience, a complication that is relatively frequent with surgical sympathectomy.

Technical Difficulties in Video-Assisted Thoracoscopic Sympathectomy

Pleural adhesions are found fairly frequently during thoracoscopy (3%–7%). Firm and extensive pleural adhesions caused by previous pleuropulmonary diseases may make it impossible to perform VATS. In such cases, open surgery is the best option. Unfortunately such adhesions cannot be diagnosed preoperatively by routine chest radiography.[68]

The presence of an azygos lobe is an infrequent anatomic variation that involves an accessory pulmonary lobe at the apex of the lung, making it difficult or sometimes impossible to carry out VATS, particularly when the surgeon is not prepared for this contingency.[69] Preoperative chest radiography may identify this anomaly.[70]

Technical Alternatives for Video-Assisted Thorascopic Sympathectomy

Alternatives to ganglia resection are interruption of the chain without the removal of ganglia (sympathicotomy)[71] and blockade by endoscopic clipping,[72–74] a technique that can be reversed, within 10 days after intervention, by removal of the clips.[75,76] In both techniques, transmission of sympathetic impulses from the lower sympathetic ganglia through the stellate ganglia to the limbs is interrupted.

Sympathicotomy and thoracoscopic clipping are also acceptable. Early results are comparable to those of sympathectomy, but long-term results are unknown. Sympathicotomy is a good alternative when the anatomy is not appropriate for sympathectomy (large veins over the sympathetic chain). Clipping

of the trunk has the potential benefit of unclipping (reverse operation) in case of intolerable compensatory hyperhidrosis. Large-scale prospective studies with long-term follow-up are needed in both techniques.

New alternatives based on emerging technology have been introduced for performing sympathectomy using an embryonic natural orifice: the transumbilical endoscopic surgery with a flexible endoscope. This novel procedure can reduce postoperative pain and afford even better cosmetic benefits by hiding the surgical incision in the umbilicus. It seems to be a safe and an efficacious alternative to the conventional approach.[77–79] Another option recently described is the use of robotics, although there is little experience reported to date.[80]

Contraindications to Video-Assisted Thoracoscopic Sympathectomy

The contraindications to VATS are lung infections that evolve with pleural effusion and require puncture or drainage, lung diseases that cause dense pleural adhesions (such as tuberculosis), previous thoracic surgery, thoracic radiotherapy, sinus bradycardia, and clinical conditions in which endotracheal anesthesia is contraindicated.[81] Obesity has also been considered a contraindication to VATS. Although overweight patients have a high degree of satisfaction with the operation, it may be difficult to identify the sympathetic chain when it is covered by a greater layer of adipose tissue. In addition, such patients have a higher risk of severe compensatory hyperhidrosis.[82]

TARGET GANGLIA

The extent of thermoablation, resection, or interruption of the sympathetic chain is an important subject in dealing with thoracic sympathectomy (Table 193.1).[83]

With improvements in surgical techniques for the treatment of hyperhidrosis, therapeutic success has been achieved even when sympathectomy is performed at levels distant from the stellate ganglion (G3 and G4 ganglia). This has corresponded to a significant reduction in the complications that were most feared before the advent of VATS: Horner syndrome and compensatory hyperhidrosis.

Lumbar sympathectomy is a predominantly preganglionic type of surgery, since the fourth ganglion is not manipulated, because the majority of the pre- and postganglionic fibers synapse are in this level. It is generally agreed that resection of the first three lumbar ganglia produces denervation of the whole corresponding lower limb. However, some have advocated removal of the second and third lumbar ganglia only, this approach limits the sympathetic denervation to the territory located under the knee, although the clinical results are similar to those obtained by longer resection. Further, saving of the first lumbar sympathetic chain, at least one side, prevents interference with the normal mechanisms of male ejaculation. In practice we found that the arrangement of the ganglia in this chain varied considerably. There are cases where the first three ganglia are perfectly identified and others where there are only two ganglia separated by a long chain segment. There have also been a few cases where there was only one identifiable ganglion, giving the impression that all of them had merged into one. Our approach has been to remove the chain from the crus of diaphragm to the level of the fourth lumbar vertebra, saving the first ganglion, which usually is included in diaphragmatic pillar fibers.[84,85]

TABLE 193.1 Denervation Levels for Different Indications

Disease	Denervation Level
Palmar hyperhidrosis	G4 or G3
Axillary hyperhidrosis	G4
Craniofacial hyperhidrosis	G2
Facial rubor	G2
Plantar	L2 and L3
Complex regional pain syndrome	Stellate ganglion, G2, and G3
Vascular disease	Stellate ganglion, G2, and G3
Raynaud syndrome	Stellate ganglion, G2, and G3
Long QT syndrome	Left side, from the stellate ganglion to G4 or G5

Palmar Hyperhidrosis

In cases of palmar hyperhidrosis, physicians initially used to resect G2 and G3 ganglia with good results (anhidrosis); however, it was a difficult procedure associated with a high incidence of Horner syndrome and severe compensatory hyperhidrosis.[86] Subsequently, on the basis of the principle that interruption of the transmission of sympathetic impulses from the lower sympathetic ganglia through stellate ganglia resolves hyperhidrosis, thermoablation of G2 accelerated this procedure and gave similar results. However, intervention on the G2 ganglion resulted in a high rate of compensatory hyperhidrosis (in more than 75% of the cases) because an extensive area is denervated, including the cephalic, cervical, and upper limb segments. This collateral effect has been responsible for dissatisfaction in 4% of patients.[87] To minimize this problem, thermoablation of G2 was initially replaced by thermoablation of G3 and currently G4, which has led to similar results of palmar anhidrosis but considerably decreased compensatory hyperhidrosis,[88] probably due to preservation of sympathetic tonus in the cephalic segment.

Patients who undergo G3 ablation usually have totally dry hands and need to use skin moisturizers, whereas patients who undergo G4 ablation have continued low levels of sweating (not hyperhidrosis but a little greater than normal physiologic levels), which is considered to be a therapeutic success.[89–91] In order to reduce the incidence of compensatory sweating (CS), some authors have studied the two-stage

operative treatment, which consists of the initial approach of the dominant limb followed by contralateral limb surgery at a later time. The results are interesting, since almost half of the patients consider themselves satisfied with treatment only on the dominant side, requesting that the other side not be treated later. In this approach, there is lower degree of CS than patients operated on both sides simultaneously.[92] Prospective and randomized studies are being carried out to better elucidate this topic.

Axillary Hyperhidrosis

Resection of the second to fourth ganglia of the thoracic sympathetic chain was the first step in treating axillary hyperhidrosis.[93] It was replaced by thermoablation on G3 and G4[94] and then by single G4 thermoablation,[95] which results in excellent therapeutic success (anhidrosis), less severe compensatory hyperhidrosis, and a higher rate of satisfaction.

Craniofacial Hyperhidrosis or Facial Rubor

Sympathetic denervation of the face and head can be obtained by thermoablation of the G2 ganglion. Sympathetic blockade of G3 with the use of clips is an alternative for these patients.[96]

Complex Regional Pain Syndrome, Vascular Disease, and Raynaud Syndrome

Sympathetic denervation of the upper limb must be as complete as possible if sympathectomy is used for these conditions. Hence the stellate ganglion, G2, and G3 should be included.[86] To avoid incomplete denervation of the limb, the communicating branches of T1 and the nerve of Kuntz have to be ablated as well.[97] This approach is always associated with the presence of Horner syndrome.

Long QT Syndrome

Sympathectomy is performed only on the left side, from the stellate ganglion to G4 or G5.[56,98,99]

RESULTS

Hyperhidrosis

The success rate in the abolition of hyperhidrosis (i.e., anhidrosis) is very high and ranges from 96% to 100% for palmar hyperhidrosis,[100,101] from 63% to 100% for axillary hyperhidrosis,[102] and from 87% to 100% for craniofacial hyperhidrosis.[24] In addition, quality-of-life analyses have demonstrated an "overall satisfaction" of around 90% 5 years after sympathectomy.[103–106]

Although it is nonspecific for the treatment of plantar hyperhidrosis, which is usually associated with palmar or axillary hyperhidrosis, VATS was shown to immediately reduce plantar sweating in more than 80% of patients; however, there is a reduction to smaller degrees of improvement (60%) during the 1-year period after surgery.[107] There is no convincing anatomic–physiologic explanation for this improvement. Perhaps correction of palmar hyperhidrosis by the intervention leads to a greater emotional equilibrium, thereby lowering sympathetic nervous stimuli to the feet.

Recurrence of palmar or axillary hyperhidrosis has been reported in 1% to 13% of surgically treated patients and in 2% of the patients with craniofacial hyperhidrosis.[108] The main cause of the recurrence is technical failure. Reoperation is usually successful.[109] Weak adhesions are found in these situations, but they do not cause significant difficulties for the procedure.

Transitory occurrence of sweating of variable intensity in the denervated segment during the first postoperative week (third to fifth postoperative days) is observed in 13% of the cases. It lasts for a maximum of 36 hours and is caused by the release of neurotransmitter at the end of the sympathetic postganglionic fibers as they degenerate.[110,111]

One adverse effect from sympathectomy is gustatory sudoresis. Its incidence is variable (ranging from 6% to 32%), and it is probably related to eating habits in different regions. In most cases it is of light to moderate intensity and does not interfere with quality of life.[112]

CH consists of an increase in the severity of sweating in locations that were previously normal. This is the most frequent and most feared side effect of thoracic sympathectomy. It is present in almost all patients, and when severe (in 1%–4% of the cases), it is considered the main cause of patient dissatisfaction.[42] It occurs mainly on the abdomen, back, and thighs and becomes more uncomfortable on hot days, during physical exercise, and in hot work environments.[113] It may diminish over time, or the patient may learn to live with it.[114] CH has a high correlation with the level and extent of resection.[115] The higher the interruption or resection of the sympathetic chain, the more afferent fibers responsible for inhibition of sweating would be harmed, thereby causing a considerable increase in the quantity and intensity of CH. By performing thermoablation only in G4 ganglia for palmar or axillary hyperhidrosis, there is a significant decrease in the quantity and intensity of compensatory hyperhidrosis,[116,117] which leads to an improvement in quality of life. Another risk factor for CH is a high body mass index (BMI); this is why patients with a BMI greater than 25 should not be operated on.[118] Because of the importance of compensatory hyperhidrosis, it is necessary to attempt medical treatment with anticholinergic drugs first and to operate only on those individuals who do not obtain significant results.[119] Furthermore, it is necessary to alert all patients with hyperhidrosis to this risk before they choose sympathetic denervation or an alternative technique and that treatment with anticholinergics is the best alternative for compensatory hyperhidrosis, although reasonable results are achieved in only half of these patients.[120,121] The rate of compensatory hyperhidrosis and its severity are tolerated better by children, and their

postoperative satisfaction is higher than that of adolescents and adults. Therefore VATS is indicated for children as early as possible.[122,123]

Another alternative that has been used in attempts to reduce the occurrence and intensity of CH is utilization of the two-stage unilateral or even the unilateral sympathectomy for the treatment of hyperhidrosis. With these procedures, the incidence and intensity of hyperhidrosis appears to be lower.[124–127]

Patients with poorer quality-of-life evaluations before surgery presented higher levels of improvement after sympathectomy. VATS is therefore considered an efficient therapeutic alternative for patients with initially poor quality-of-life evaluations.[128]

Vascular Diseases

Sympathectomy is seldom used at present to treat vascular insufficiency because of the availability of bypass and endovascular procedures. When sympathectomy is used, it is performed for digital and palmar obstructions associated with necrotic lesions of the fingers.[129] In selected patients, sympathectomy has been reported to decrease pain and to assist in clinical treatment.[130,131]

Complex Regional Pain Syndrome

VATS is highly effective in reversing symptoms when it is performed early in the evolution of CRPS, at which time it has a success rate of 80% to 90%.[54] However, sympathectomy is ineffective if it is delayed until after joint contracture or nerve atrophy has occurred.[132] It should be used cautiously in clinical practice, in carefully selected patients, and only after other treatment options have failed.[25]

Long QT Syndrome

Favorable results from left thoracic sympathectomy in high-risk patients (preventing complications) have been demonstrated in the literature since the 1970s. VATS is associated with a significant reduction in the incidence of aborted cardiac arrest and syncope in high-risk patients with long QT syndrome compared with pre–left cardiac sympathetic denervation events, but changes in the QT interval after sympathectomy are variable and the clinical results cannot be fully predicted.[133] In a group of high-risk patients undergoing left cardiac sympathetic denervation, 46% remained asymptomatic; syncope occurred in 31%, aborted cardiac arrest in 16%, and sudden death in 7%.[134,135]

Raynaud Syndrome

The results of sympathetic denervation in cases of Raynaud syndrome are transitory.[136] Vasospastic episodes reappear within a short time, and dissatisfaction with the procedure is observed in almost 50% of patients.[137] This has led some authors to no longer recommend sympathectomy for such patients.[138]

BOX 193.1 Complications Associated with Thoracoscopic Sympathectomy

Common

Compensatory sweating (70%–100%)
Segmental atelectasis (1%–5%)
Pneumothorax (1%–5%)
Subcutaneous emphysema (1%–2%)

Rare (<1% of Cases)

Horner syndrome
Hemothorax
Pleural effusions
Injury to the vagus nerve
Injury to the phrenic nerve
Injury to the subclavian artery and vein

COMPLICATIONS OF VIDEO-ASSISTED THORACOSCOPIC SYMPATHECTOMY

Although VATS is a minimally invasive and safe procedure, it is not free of significant risk or death, and a mortality rate of 0.045% has been reported.[139,140] A detailed summary of complications is provided in Box 193.1.

Pneumothorax

The most common perioperative complication is pneumothorax. Most patients (75%) have some residual gas in the thorax at the end of the surgery. Small amounts of residual air in the pleural cavity remaining after sympathectomy are absorbed. However, when pulmonary fistulas are present, 1% to 3% of patients may require thoracic drainage.[139] Tension pneumothorax after surgery is rare. It results from direct injury to the lung at the time of trocar insertion or from tearing of an apical adhesion when the lung is depressed.[141] Apical bullae may occasionally be found; they may rupture during anesthesia when high pulmonary insufflation pressure is used at the completion of the procedure. This complication can be prevented by careful reinsufflation at the end of the operation.[142] Subcutaneous emphysema around the trocar insertion site confined to the thoracic wall may occur in 2% to 7% of patients.[143] Treatment is conservative in the absence of pneumothorax.

Hemorrhage

Significant intraoperative hemorrhage is rare and mostly originates from intercostal vein disruption during dissection of the sympathetic chain. It may also occur at the trocar insertion site. Laceration of the subclavian artery and intercostal artery pseudoaneurysms requiring thoracotomy have been reported.[144]

Chylothorax

Chylothorax is an extremely rare complication resulting from laceration of the main or accessory thoracic duct.[145]

Cardiac Complications

Transitory bradycardia during sympathectomy occurs in 1.2% of the patients,[146] but it is usually self-limited and does not require intervention. Recovery takes place after a few minutes of clinical observation. Extensive thoracic sympathectomy may have a beta-blocker effect, leading to a moderate decrease in heart rate at rest and during maximal exercise.[147,148] Intraoperative cardiac arrest has been reported in only two patients during the surgical procedure, but they were both successfully resuscitated.[149]

Neurologic Complications

Severe postoperative pain is a common event, presenting in more than 95% of cases. It occurs independently of the electrocautery type. Most patients report acute pain, especially when breathing in deeply, for some hours after the operation, but a significant number complain of pain of lower intensity that is more constant in the dorsal region, which may occasionally require nonsteroidal anti-inflammatory agents for 2 weeks along with analgesics as necessary.[150]

Paresis and paresthesia in the upper limbs occurred in 2.9% of the patients as a result of tension of the brachial plexus caused by their position on the surgical table.[151] In most patients, these manifestations regressed within 3 days to 3 weeks.[152] Horner syndrome is a side effect from complete sympathetic denervation of the upper limb when the stellate, G2, and G3 ganglia are resected.[153] However, in cases of hyperhidrosis in which only G3 or G4 is manipulated, this complication is rare.[154]

CAUSES OF FAILURE

Incomplete Denervation

Late activation of the intermediate ganglia (microscopic aggregates of ganglion cells distributed in the communicating branches or in the anterior roots of the cervical and brachial spinal nerves) may explain failures in the sympathetic denervation of the upper limbs.[7] In these cases, resympathectomy is an effective procedure, and it improves the quality of life in patients with primary hyperhidrosis who failed after the first surgery.[109]

Regeneration

There is no evidence of regeneration of the sympathetic ganglion cells. However, if only the axis cylinder is sectioned, regeneration of new fibers from the ganglion cell may occur. This may have a negligible effect in operations where the paravertebral ganglia are removed.[59]

Functional Reorganization (Collateral Nerve Sprouting)

Degenerated fibers produce humoral substances that stimulate closely intact nerves to establish connections with denervated ganglion cells.[155] Hence cutting of only the preganglionic fibers responsible for the innervation of the upper limbs (the fibers that pass by the stellate ganglion on their pathway to the superior cervical ganglion) would give rise to favorable conditions for sprouting in the stellate ganglion.[156] Furthermore, there may be a functional connection between these branches and the ganglion cells in the spinal nerves, which would explain the return of sympathetic activity in the limb.

REVERSAL OF SYMPATHECTOMY

A small subset (currently less than 1%) of patients submitted to VATS for hyperhidrosis develop postoperative intense compensatory hyperhidrosis that is perceived as more debilitating than their initial complaints; therefore they seek medical assistance to reverse the sympathetic blockade. Studies in this area are still scarce, and the initial outcomes are poor, probably because of technical flaws.[157]

Promising technical advances with robotics technology have been achieved through implantation of a nerve graft using 10-0 nylon sutures on the epineurium.[158–160]

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A complete reference list can be found online at www.expertconsult.com.

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194 CHAPTER

Abdominal Vascular Tumors and their Management

BERNARDO C. MENDES and THOMAS C. BOWER

INTRODUCTION

Over the past 20 years, surgical treatment of primary and secondary malignancies involving the arteries and veins has become more aggressive.[1–6] This is due in part to careful patient selection, improvement in surgical techniques and critical care, and the lack of curative adjuvant therapies. Diagnosis is rarely made at an early stage in which surgical resection would be broadly applicable. This chapter reviews patient selection, surgical principles and management, and the technical aspects of resection and replacement of major central and peripheral arteries and veins.

TUMOR TYPES

Tumors of the arteries and veins are classified by their origin. In general, primary tumors arise from the smooth muscle of the media and rarely from the intima, except for aortic sarcoma. Primary aortic tumors are very rare, and usually classified by morphology and arterial layer of origin. Salm describes these tumors as polypoid or intraluminal, intimal, and adventitial.[7] In contrast, Wright et al. classify the polypoid and intimal types as intimal tumors, and those of the adventitia as mural tumors.[8] Polypoid intimal tumors grow intraluminally and have a propensity to embolize, whereas other intimal sarcomas are infiltrative, growing along the endothelial surface and may cause large vessel branch occlusion. Adventitial or mural tumors grow beyond the confines of the aorta and invade adjacent structures. The majority of aortic sarcomas are of the intimal type with equal distribution among the aortic segments. Staats and colleagues reported the clinicopathological features of 26 aortic and iliofemoral sarcomas. The abdominal (13 patients) and thoracic aorta (8 patients) were the most common sites. Interestingly, the diagnosis was not suspected clinically in any case. Prognosis is poor because of metastatic disease. Pathologically, the tumors were poorly differentiated in 13 patients and undifferentiated in 7. The other tumors secondarily invaded adjacent arteries, and included osteosarcoma, myxofibrosarcoma and myxoid sarcoma.[9] Secondary arterial involvement also occurs with head and neck, lung, musculoskeletal, colorectal, pancreatic, gynecologic, and retroperitoneal carcinomas or sarcomas.[10–13] At times, benign tumors such as ganglioneuroma encase the aorta or its branches (Fig. 194.1).

Primary and secondary tumors of the superior and inferior vena cava (IVC) are shown in Box 194.1. Primary tumors of the superior vena cava or peripheral veins are much less common than those of the IVC,[1,5,14–17] with the former affected more by secondary malignancies. Venous leiomyosarcoma is the most common primary tumor (PVL), is more frequent than its arterial counterpart, tends to be polypoid or nodular, and growth is usually intraluminal. Aggressive PVLs invade through the adventitia and may involve adjacent organs.[18,19] PVL of the IVC represents one-third of surgical cases. Similar to aortic sarcoma, distant metastases occur early with primary IVC leiomyosarcoma, and are present in at least one half of patients at diagnosis.[1,20,21] These factors adversely affect survival.[1]

Retroperitoneal sarcoma is the most common malignancy to invade the infrarenal IVC, but it can involve any caval segment. Bowel or solid organ cancers may invade the adjacent IVC segment. For example, cancers of the liver, pancreas, kidney, or adrenal glands can invade the suprarenal segment.[18] Another form of a secondary malignancy is when the tumor grows through the draining vein into the IVC or SVC as tumor

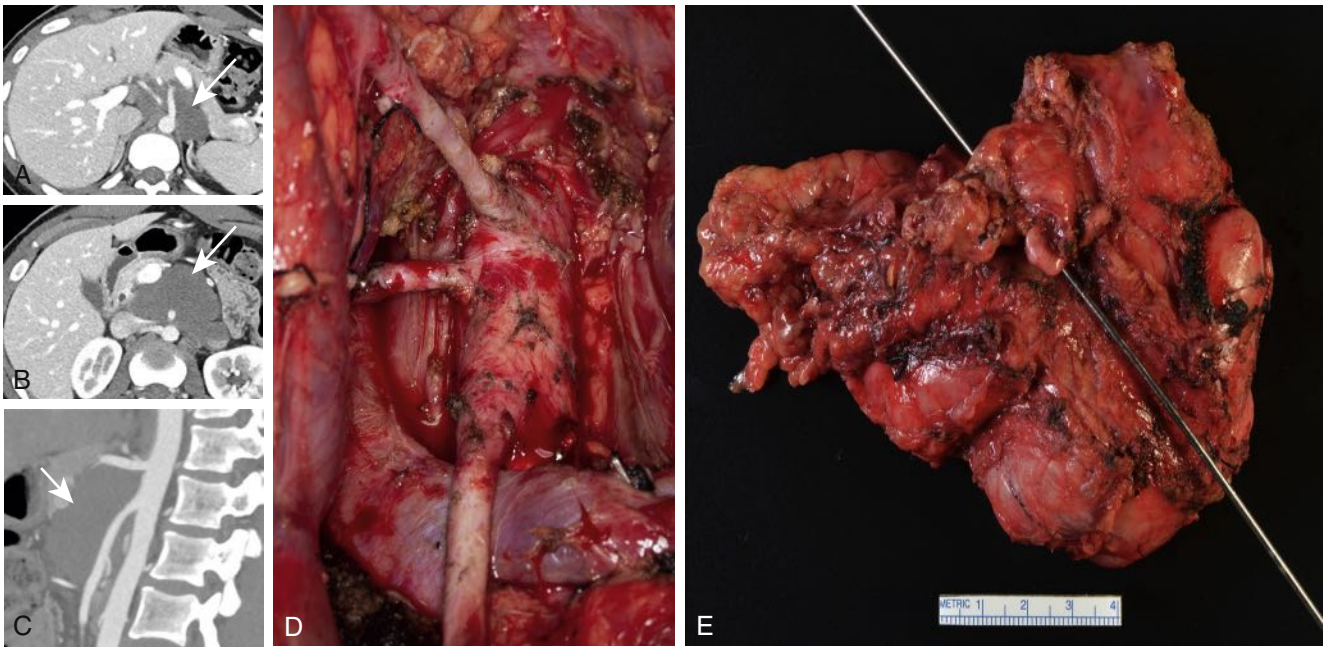


Figure 194.1 Axial (**A**, **B**) and sagittal (**C**) CT images of young patient with a large ganglioneuroma wrapped around the celiac, common hepatic and superior mesenteric arteries. The common hepatic artery had a separate origin from the aorta. The tumor partially encased the left renal vein and artery. Intraoperative photograph (**D**) showing the skeletonized paravisceral aorta, celiac, common hepatic and superior mesenteric arteries, and the left renal vein at the bottom of the picture. The specimen is shown in **E**.

BOX 194.1 Tumors of the Vena Cava

Primary leiomyosarcoma
Secondary SVC tumors
- Lung cancer with mediastinal adenopathy
- Lymphoma
- Follicular or medullary thyroid cancer
- Teratoma
- Thymoma
- Angiosarcoma
- Synovial cell carcinoma

Secondary IVC tumors
- Retroperitoneal soft tissue tumors
  - Liposarcoma
  - Leiomyosarcoma
  - Malignant fibrous histiocytoma
- Hepatic tumors
  - Cholangiocarcinoma
  - Hepatocellular carcinoma
  - Metastatic (e.g., colorectal)
- Pancreaticoduodenal cancers

Secondary IVC tumors that may have tumor thrombus
- Renal cell carcinoma
- Pheochromocytoma
- Adrenocortical carcinoma
- Sarcomas of uterine origin
  - Leiomyomatosis
  - Endometrial stromal cell
- Germ cell tumors
  - Embryonal
  - Teratocarcinoma

thrombus (Fig. 194.2). Several cancers behave this way, with the most frequent being renal cell carcinoma (RCC). Approximately 4%–15% of patients with RCC have tumor thrombus which is limited to the renal vein–caval confluence in nearly half of this group, extends into the suprarenal IVC in 40% of patients, and involves the right heart in the remainder.[22–28]

CLINICAL PRESENTATION AND EVALUATION

Aortic sarcomas present in several ways. Arterial obstruction by tumor emboli is a recognized presentation,[8,29–33] with the extremities and brain commonly affected.[33,34] Intimal or mural sarcomas have been misdiagnosed as aneurysms, focal dissection, an inflammatory process mimicking vasculitis, or an atherosclerotic lesion. Interestingly, there are reports of aortic sarcoma originating within an aneurysm sac post-EVAR, or immediately adjacent to a polyester aortic graft.[35–38] Similar to other advanced malignancies when diagnosis is made, the most common symptoms are nonspecific, such as malaise, fatigue and unintentional weight loss.

Primary venous leiomyosarcoma involves the IVC more than the peripheral veins, presents in women more than men, and occurs over a wide age range, with a mean age of 50 to 60 years.[1,14,15,20,39] Similar to primary aortic sarcoma, early detection is rare. Abdominal pain is the most common symptom, although many patients have nonspecific symptoms. Metastases are present in 50% or more of patients when diagnosis is made.[5,15,19] Cardiac symptoms, hepatic vein outflow obstruction causing Budd–Chiari syndrome, renal vein outflow obstruction, or muscle or nerve involvement may occur with primary or secondary venous malignancies. Lower extremity deep vein thrombosis or edema is more common with peripheral vein tumors.[40]

A multidisciplinary team is needed to manage these patients. Involvement of a medical or surgical oncologist guides adjuvant and surgical therapies. For example, neoadjuvant treatment now is offered to select patients with locally advanced pancreatic adenocarcinoma and vascular involvement to improve their candidacy for surgical resection. If response is noted and staging laparoscopy proves negative, radical resection is undertaken and may involve the portal vein and/or hepatic or superior mesenteric artery revascularization[41] (Fig. 194.3) (see Ch. 195, Vascular Reconstruction in Oncologic Surgery).

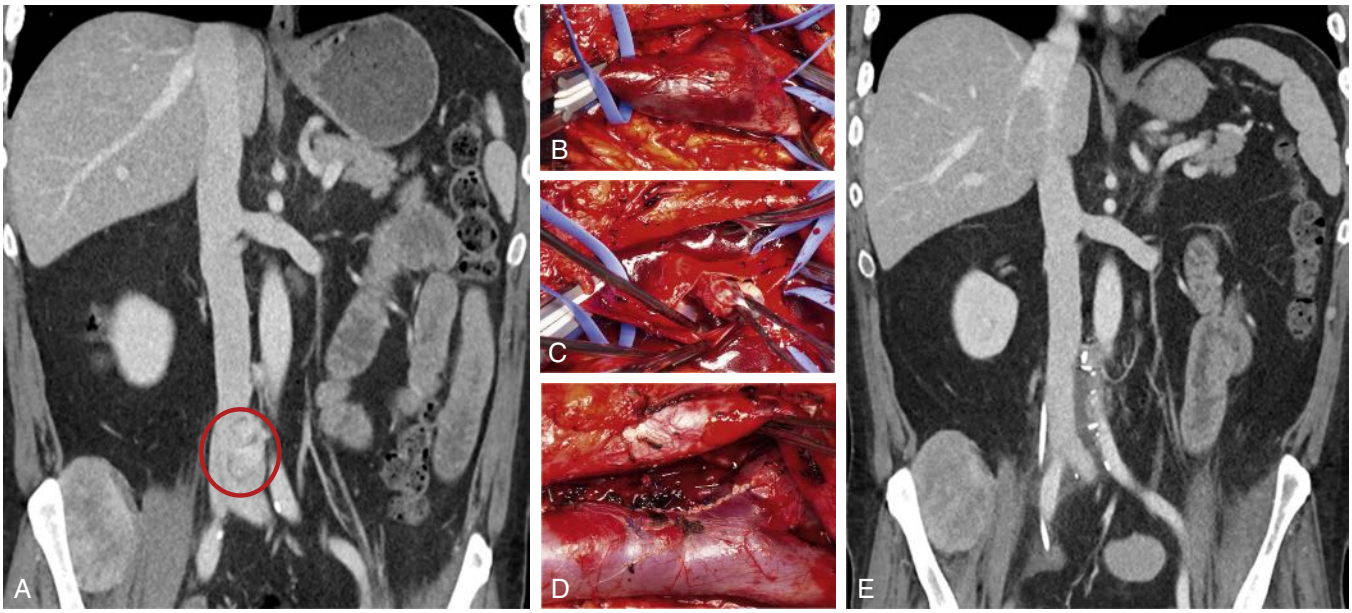


Figure 194.2 Patient with metastatic papillary thyroid cancer growing from a lumbar vein into the lower vena cava near the iliac vein–caval confluence as shown in the CT image (**A**, red circle). The tumor had to be removed to allow systemic therapy to treat his disease. The tumor was removed by opening the vena cava and upper left common iliac vein on the left anterolateral wall and at the lumbar vein–caval confluence. Both the lumbar vein defect and the vena cava were closed primarily (**B–D**). Postoperative CT scan at 6 months showing a widely patent vena cava and upper common iliac veins (**E**).

Figure 194.3 Intraoperative photograph demonstrating an aorta to common hepatic artery interposition graft utilizing the left superficial femoral artery (SFA) as a conduit. The SFA was replaced with a 6-mm ringed PTFE graft.

Oncologic, hepatobiliary, urologic, orthopedic, neurologic, and cardiothoracic surgeons often team with the vascular surgeon in operative planning and execution. Evaluation is directed at definition of tumor type, its local extent, the presence of distant metastases, and the severity of arterial or venous obstruction. Moreover, patient comorbidity and performance status (physical fitness) affect decision making for operation. In general, surgical therapy is offered to patients with localized disease, good cardiopulmonary, hepatic and renal function, and few if any limitations in daily activities (performance status scores of 0 or 1).[16]

Computed tomography (CT) and magnetic resonance imaging (MRI) are used to define location and extent of tumor, the presence of distant metastases, and to plan operation. Arterial and venous phase imaging is important. Properly-timed CT venography supplants the need for standard venography. MRI remains the imaging study of choice to differentiate an intracaval mass as tumor versus bland thrombus. Some groups, including our own, have used MRI to determine the likelihood of venous wall invasion by intracaval tumor thrombus. Psutka et al. and Zini and colleagues have shown that residual tumor thrombus on the caval wall increases risk of recurrence and mortality.[27,28] Such preoperative differentiation influences operative planning and the need for caval replacement. Positron-emission tomography (PET) is selectively used to define distant metastases for many primary and secondary tumors, and has been used to diagnose aortic sarcoma.[42–44] Transesophageal echocardiography and ultrasound imaging are used selectively, depending on tumor type and location, particularly if CT or MRI inadequately image venous tumors. The Mayo Clinic group routinely obtains lower extremity ultrasonography of the deep veins for any patient with an IVC, iliac or extremity venous tumor to exclude occult deep vein thrombosis. The authors have found 3D modeling an invaluable tool for operative planning when tumors are in close proximity to major vessels, soft tissues, bone and/or nerves (Fig. 194.4).

Medical risk assessment is focused on organ system function. Transthoracic echocardiography or cardiac stress studies, pulmonary function tests, and bloodwork for liver and renal function are commonly obtained. If major liver resection is anticipated, it is important to address the volume of liver remnant in order to avoid postoperative hepatic dysfunction. Physical fitness is essential if a major aortic, vena cava, or central artery

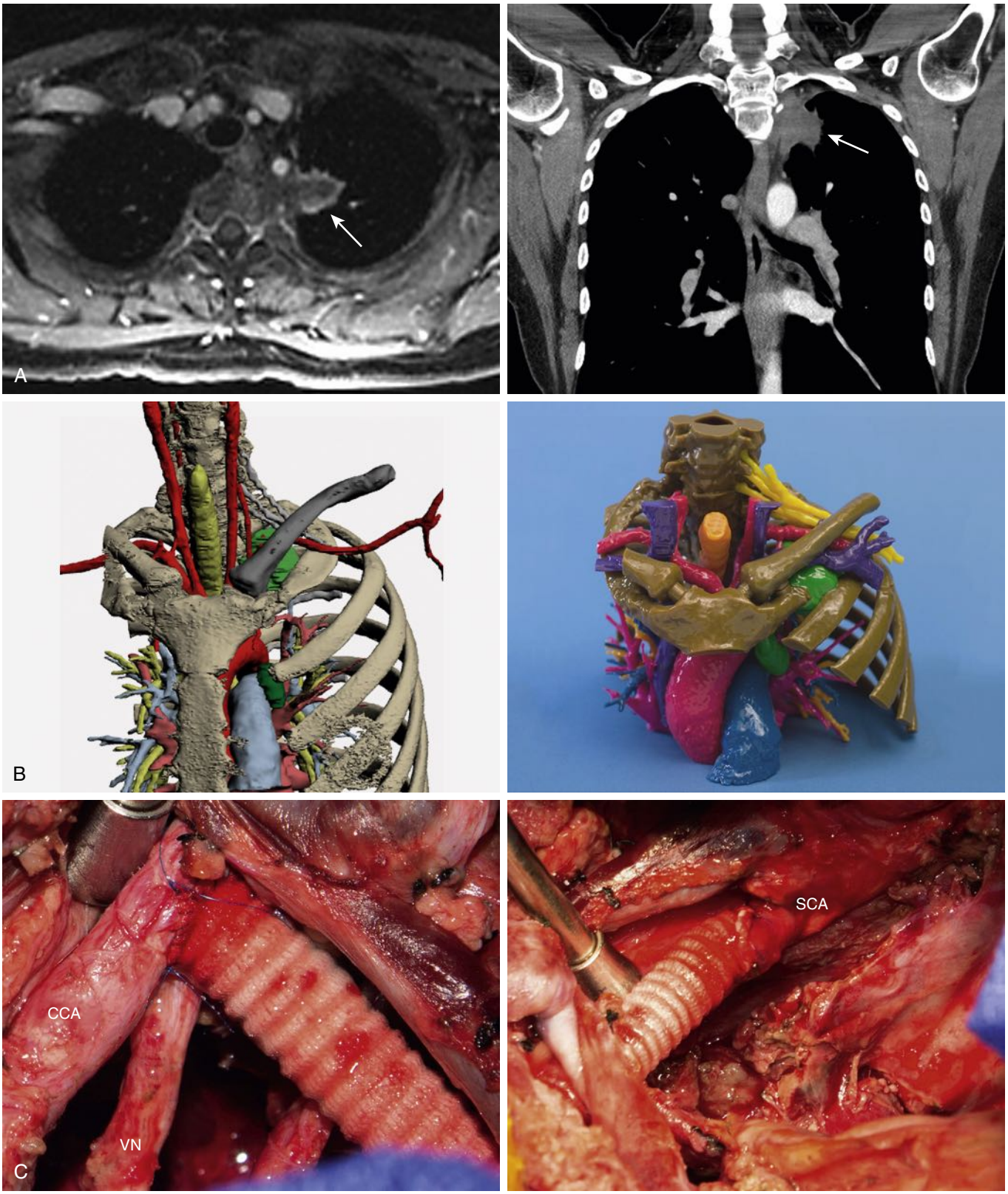


Figure 194.4 Left Pancoast tumor encasing subclavian artery (**A**) and 3D modeling (**B**) showing relationship of the tumor (green), to the adjacent artery (red), veins (purple), brachial plexus (yellow), and bony structures (tan). The mass was resected which required replacement of the subclavian artery as shown in (**C**). *CCA*, common carotid artery; *SCA*, subclavian artery; *VN*, vagus nerve.

or vein replacement is required. The risk of major adverse events and the capacity for patients to recover from surgery is negatively impacted if they have significant comorbidities or limitations in daily activities (performance score ≥2). Patients with poor cardiopulmonary, liver or renal function, or physical debility, should not be offered operation in our opinion.

TREATMENT

The operative approach and treatment depends on type, location and extent of the tumor; and the extent of venous obstruction and location of collaterals for patients with primary or secondary venous tumors. As with any vascular reconstruction, adequate exposure is essential, so the incision and approach must be chosen carefully and with input from the entire surgical team. 3D modeling is helpful when the tumor is in a difficult area, such as the thoracic inlet or outlet, the mediastinum, or the pelvis. Choice of incision is straightforward for most neck, mediastinal and extremity operations, but varies when vascular reconstruction is needed in the abdomen. The use of midline, bilateral subcostal, modified Makuuchi or thoracoabdominal incisions are determined based on size and location of the tumor, body habitus including the costal flare, extent of the anticipated vascular replacement and where control of the aorta, vena cava or branch vessels is needed. For example, a bilateral subcostal incision can be used to approach the upper abdominal aorta, visceral and renal arteries, portal vein, or the suprarenal vena cava if the costal margin is wide. A full midline incision provides similar access and may be preferable for individuals with a narrow costal margin. Either incision can be extended with a sternotomy for patients with RCC or similar cancers when tumor thrombus involves the right heart. This combination of incisions also is useful for patients with malignant obstruction of the suprahepatic and retrohepatic IVC in which there is venous congestion of the liver.[1,4,5,14,16,18,45] A Makuuchi incision is favored by some surgical oncologists when radical pancreatic resection and vascular reconstruction is necessary.[41] A low right thoracoabdominal incision (8th or 9th interspace) affords excellent exposure of the vena cava and liver for patients with large malignant tumors involving the retrohepatic IVC.

A number of secondary tumors can be separated from major arteries or veins when there is a tissue plane between the tumor and vessel on preoperative imaging. Others, such as ganglioneuroma or germ cell, can often be separated from the arteries and veins without the need for vascular reconstruction even in the absence of a tissue plane on CT or MRI (see Fig. 194.1). In general, primary or patch closure of an arterial or venous defect post tumor resection is preferred over graft replacement, as long as the repair does not compromise the vessel lumen. A prosthetic or bovine patch is useful for repair of the aorta, iliac, or peripheral artery. Aortic, supra-aortic trunk, carotid, visceral and iliac artery replacement is done with prosthetic unless resection involves the aerodigestive tract. In the latter situation, our preference is for native artery or cryopreserved artery allografts matched to the size of the resected artery.[46–48] because they seem to resist infection or anastomotic dehiscence better than saphenous or femoral vein in the authors' experience. Replacement of the thoracic or abdominal aorta or the iliac arteries in a contaminated field is done with a cryopreserved allograft, with the suture lines buttressed by fascia lata. This approach is similar to that which we use for explantation of infected aortic endovascular devices. The superficial femoral artery (SFA) is an excellent conduit when the carotid artery requires replacement during head and neck cancer resection complicated by pharyngeal or tracheal involvement. Similarly, the SFA works well for hepatic and/or superior mesenteric artery replacement in select patients who undergo resection for locally advanced pancreatic cancer (see Fig. 194.3). The harvested SFA is replaced with a prosthetic interposition graft.[41] If a cryopreserved femoral artery allograft is used, we believe it best if the diameter is 7 mm or larger, as graft stenosis can occur in smaller size allografts. Surgeons have used a thoracic aortic stent graft to facilitate resection of lung cancers involving the aortic wall to obviate the need for aortic cross-clamping. Tumor resection follows stent-graft placement, and the aortic wall defect is buttressed with a patch.[49,50]

Our preference for vena cava, innominate or common iliac vein replacement is a large diameter externally supported polytetrafluorethylene (ePTFE) graft.[5,16,18] The external support resists compression in the mediastinum or abdomen. Cryopreserved aortic allografts have been used by the authors to replace the IVC or iliac veins if concomitant intestinal resection is done. Others have used cryopreserved vein or bovine pericardial tube grafts in similar circumstances.[51–54] Portal vein replacement can be done with prosthetic; or left renal, jugular, femoral, or spiral saphenous vein.[55–57] Patch venoplasty is preferred over large vein segmental resection and replacement whenever possible, and our preference is to use bovine pericardium. We accept as much as 60% involvement of the circumference of the IVC in which to resect and patch, provided the resection is limited to a small segment (4 cm to 7 cm length). It is imperative that the diameter of the patch be of adequate width to avoid stenosis. The diameter necessary is easily calculated based on the circumference of the normal vena cava, which geometrically is a cylinder. A 20-mm diameter IVC in which 50% of the vein wall is resected will require a patch 30 mm in diameter (π or 3 × vein diameter × % of the wall to be replaced; for this case, the calculation is made as 3 × 20 × 0.5) (Fig. 194.5).[18]

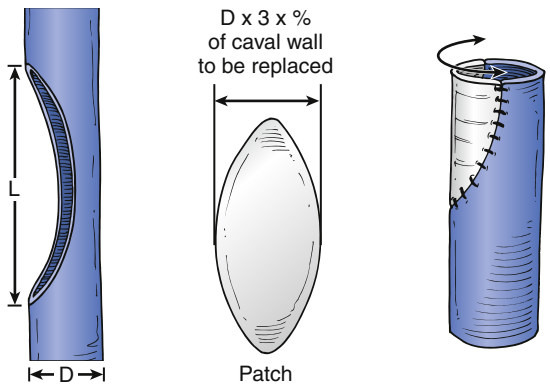


Figure 194.5 If closure of a caval defect will narrow the vein, a bovine pericardial patch is used. The diameter of the patch is estimated from the percentage circumference resected from the normal vena cava. See diagram for calculation. In most cases, the patch assumes a wide elliptical or near circular configuration.

Peripheral artery or vein replacement is done with prosthetic, saphenous vein alone or in a spiral or panel graft configuration, or with cryopreserved artery or vein. Choice of conduit is dependent on the size of the vessel and the length needed for reconstruction, and availability of autogenous conduit. If both artery and vein replacement is necessary, venous reconstruction is usually done first (Fig. 194.6).

With chronic infrarenal IVC or long segment iliac or peripheral vein occlusion, vein replacement may not be necessary if collaterals are not ligated during tumor resection.[22,58–61] Temporary arterial or venous shunting or bypass may help maintain distal perfusion during resection of large musculoskeletal tumors before definitive vascular reconstruction can be done.

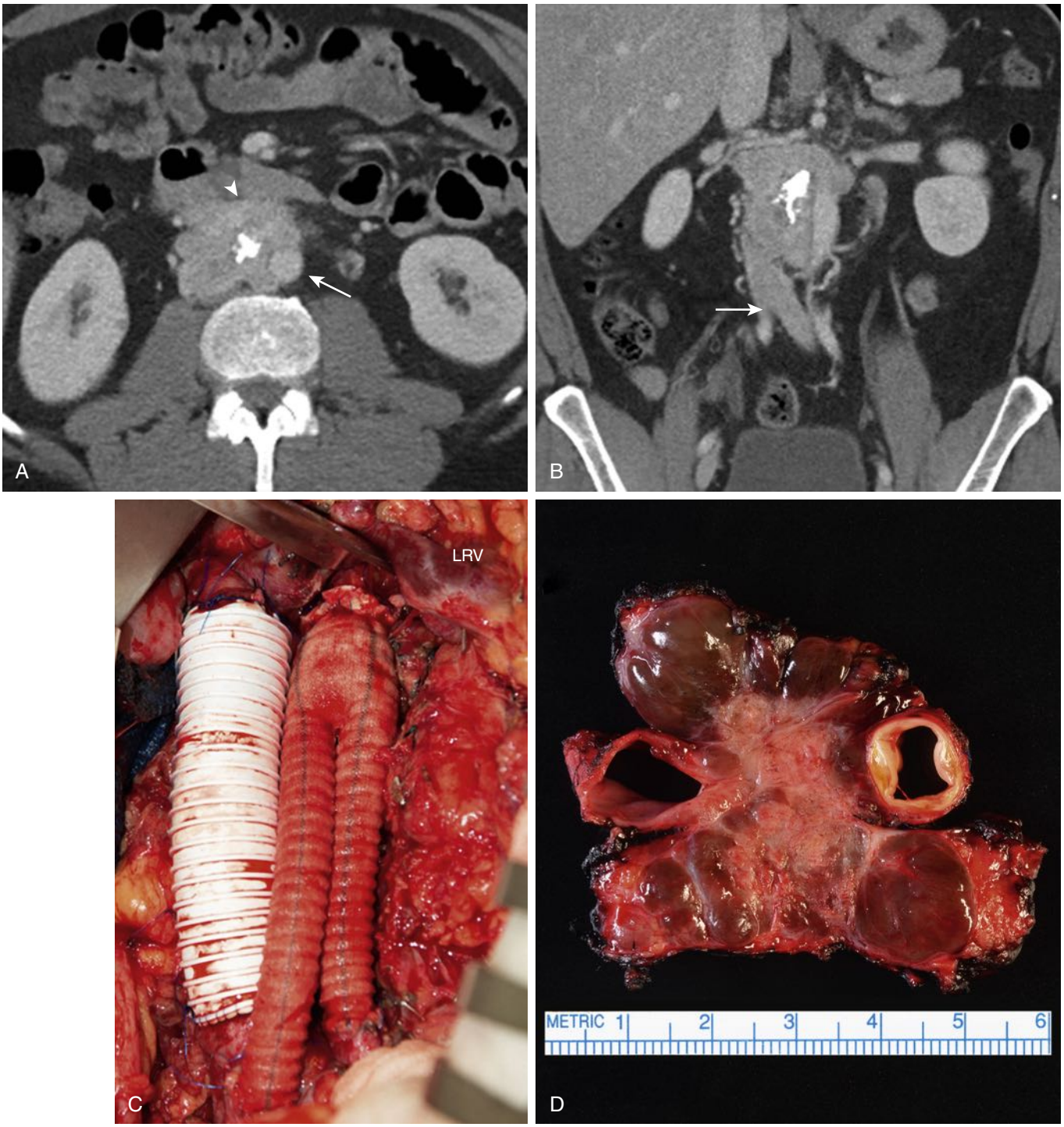


Figure 194.6 Paraganglioma encasing the infrarenal vena cava (**A**, *arrowhead*) with partial involvement of the aortic wall (**A**, *arrow*), as shown on CT in (**A** and **B**), and on pathologic specimen in (**D**). The tumor extended to near the caval bifurcation, as shown by the *arrow* in (**B**). The vena cava and the aorta required reconstruction (**C**). *LRV*, left renal vein.

INFERIOR VENA CAVA REPLACEMENT

At the Mayo Clinic, any segment of the IVC is replaced if the majority of its circumference requires resection to achieve tumor-free margins, and the vein is only partially obstructed by the malignancy. We and others use 16-mm or 20-mm ePTFE grafts for large vein replacement provided the surgical field is not contaminated or the aerodigestive tract violated. Patency rates are at least 88% at 5- and 10-year follow-up among more than 120 patients with IVC graft replacement.[5] The only drawback with this graft is that the maximum diameter is 20 mm, which is sometimes small for the vena cava. Cryopreserved aortic allograft, femoral vein panel graft, and bovine pericardial tube grafts have been utilized in the few patients who required concomitant intestinal resection (Fig. 194.7).[62] The UCLA group favors graft diameters smaller than the native IVC because of the theoretical increase in blood flow velocity through the graft, which may enhance patency.[4,63] PTFE grafts are readily available and resist visceral compression. The rings of the graft are kept in immediate proximity to the anastomoses whenever possible, to avoid late stenosis in the unsupported segment.[64]

Infrarenal IVC replacement is straightforward, with the primary challenge being control of the iliac vein–caval confluence if resection extends to the caval bifurcation (Fig. 194.8). There are a number of thin-walled or broad-based iliolumbar or sacral veins which cause troublesome bleeding if injured. This venous anatomy is highly variable, but often there is a large right iliolumbar vein at the junction of L5–S1. We long ago abandoned the use of arteriovenous fistulas to enhance patency for grafts in this position, given the good results seen with postoperative anticoagulation.[4,5,16,18,65] Resection of the pararenal IVC segment has been done without graft replacement but carries a risk of renal failure, particularly if one kidney is resected with the tumor. Our preference is to reconstruct or reimplant remnant renal veins, including the left one, even if the branches of the left renal vein are preserved. The added operative time is little when compared to the consequence of renal failure from ligation of the left renal vein if a right nephrectomy has been done.

Special adjuncts are helpful when the retrohepatic or suprahepatic IVC requires resection and graft replacement, particularly if concomitant major liver resection and/or hepatic vein reconstruction is necessary (Fig. 194.9). Total vascular isolation (TVI), selective use of venovenous or cardiopulmonary bypass to maintain hemodynamics or protect the organs, choice of clamp position, ischemic preconditioning of the liver during hepatic resection, and ligation of the afferent and efferent lobar vessels during parenchymal division have all been utilized in our experience.[3–5,16,18,65–67] The specific steps of retrohepatic IVC replacement and concomitant liver resection are highlighted in previous publications by the authors.[18,65,67,68] TVI is initiated once the surgical team is prepared to transect the vena cava to complete the *en bloc* tumor resection. A temporary period of suprahepatic IVC clamping in patients without caval tumor thrombus helps determine the need for venovenous bypass. Generally, patients with good cardiopulmonary function tolerate systolic pressures of 100 mm Hg or higher without the need for venovenous bypass. If the initial test clamp results in lower pressures, intravenous volume loading is necessary. If the 100 mm Hg target is not achieved within a few minutes, the clamp is released. A cannula is then placed into the infrarenal IVC at the gonadal vein confluence and secured. Blood is circulated through an extracorporeal pump system to the jugular vein via a previously inserted large bore catheter. Clamp sequence is the IVC below the tumor, the inflow to the liver (portal triad) and the suprahepatic IVC. In patients with retrohepatic tumor thrombus who need TVI, the clamp sequence is similar. However, a suprahepatic test clamp is not performed because inadvertent dislodgement of the thrombus could occur if the blood pressure drops and the clamp needs to be removed to restore normal hemodynamics. The systolic blood pressure is adjusted as each clamp is applied, targeting 100 mm Hg or higher. If the upper caval anastomosis is to the suprahepatic segment, at or near the remnant hepatic vein, the anastomosis is challenging because the PTFE graft is stiff and the vein can be fragile. Placement of the suprahepatic clamp in the immediate supra-diaphragmatic extrapericardial position affords additional length and size of the vein orifice. A parachute technique may facilitate this anastomosis. One or more clamps are placed on the graft caudal to the anastomosis to allow hepatic venous drainage, but only after forebleeding is allowed by temporary release of the hepatic artery and portal vein clamp prior to completion of the anastomosis. Graft length is an important consideration, as the tendency is to cut the graft too long. This mistake is obviated by checking graft length during maximum inhalation and exhalation. We cut the graft primarily based on the inhalation length, as the upper and lower IVC will stretch. Reestablishment of blood flow is done after back-bleeding and forebleeding of the IVC has been performed with the patient in a head-down position, the lungs inflated to 30 mm Hg pressure, and the graft filled with heparinized saline. The anastomosis is completed, the lower caval clamp is released and the graft de-aired to avoid embolism. To date, the warm liver ischemia time has been well tolerated by patients with these *in situ* reconstructive techniques.[3,16,66,67]

A few patients with infiltrative leiomyosarcomas or secondary tumors of the retrohepatic IVC occlude hepatic vein outflow and the liver becomes very congested. Mobilization of the liver and isolation of the suprahepatic IVC is risky because the liver parenchyma tears and bleeds easily. In these circumstances, cardiopulmonary bypass (CPB) and cooling have been utilized. The liver is fully mobilized once CPB is instituted. An atriotomy allows examination of the upper extent of the tumor. The IVC is transected, the tumor and cava resected with buttons cut around the hepatic veins. It is imperative that frozen section show tumor-free margins. The remnant hepatic veins are reimplanted onto the caval graft, and it is placed in anatomic position and sewn to the cavoatrial junction and the infrahepatic IVC (Fig. 194.10). The challenges are proper alignment of the hepatic veins on the graft, as they are not anatomically linear in orientation; and assurance the hepatic vein–graft suture lines and the raw liver surface are hemostatic in advance of the IVC–graft anastomoses due to the inherent coagulopathy with CPB and hypothermia.

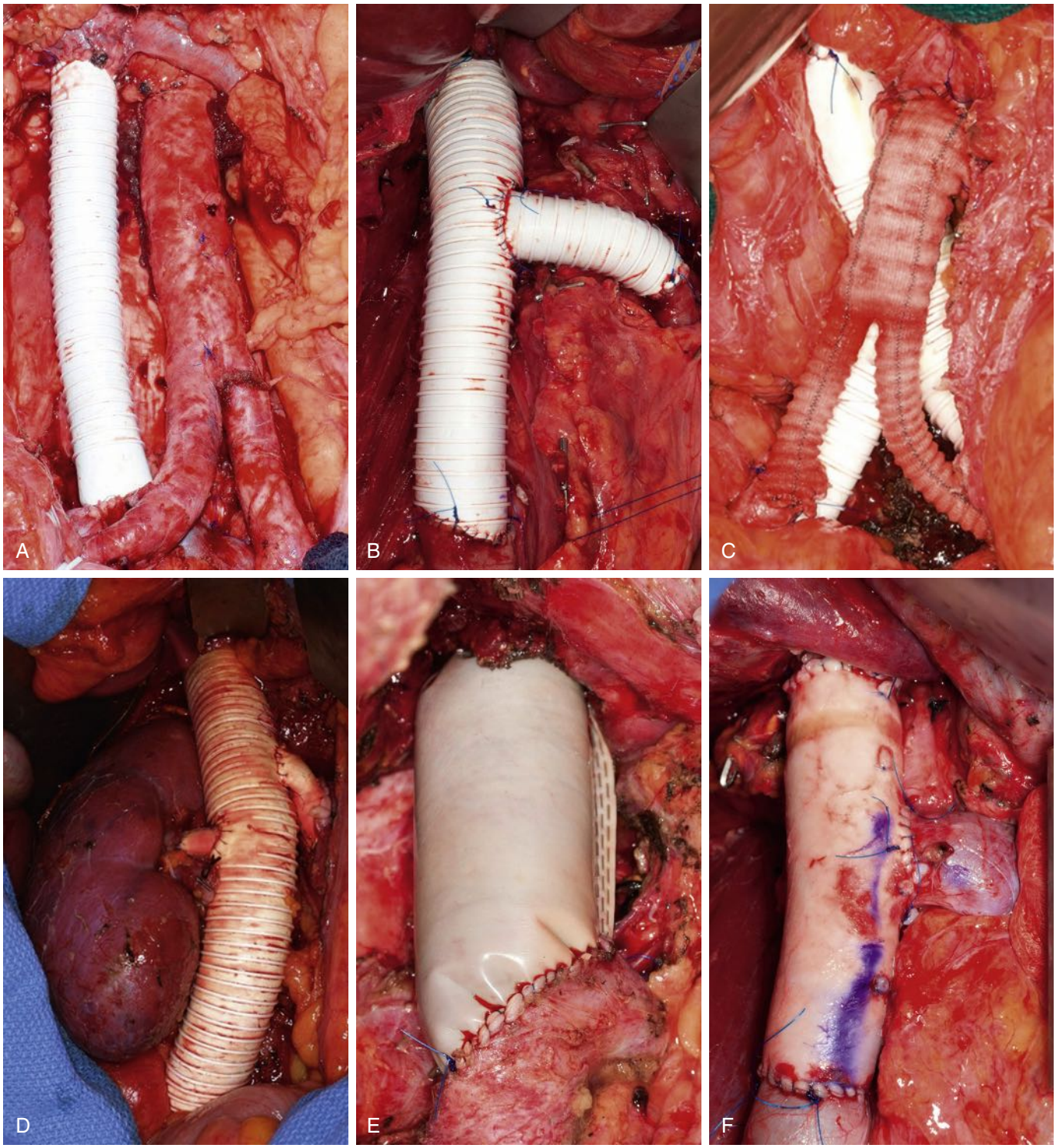


Figure 194.7 Inferior vena cava (IVC) and branch vein reconstructions can be done in many ways. (**A**) An infrarenal IVC graft. (**B**) Reconstruction of the infrahepatic and infrarenal IVC with a prosthetic interposition graft to the remnant left renal vein. (**C**) Bifurcated grafts used to reconstruct the infrarenal IVC, aorta and common iliac arteries. Both renal veins were reconstructed together with caval replacement in (**D**). A bovine pericardial tube graft was used to reconstruct the infrahepatic IVC as shown in (**E**). A cryopreserved aortic allograft was used for caval replacement in (**F**) as there was duodenal wall invasion. The remnant left renal vein was reimplanted.

Others prefer *ex situ* hepatic resection and autotransplantation of the hepatic remnant if a complex vascular reconstruction is needed and long warm hepatic ischemia time is anticipated. *Ex situ* techniques allow time to perform difficult vascular anastomoses while protecting the liver, but are fraught with higher perioperative mortality and liver failure rates than *in situ* reconstructions. Moreover, there is a low, but real risk of liver failure necessitating orthotopic liver transplantation. Further refinement in surgical

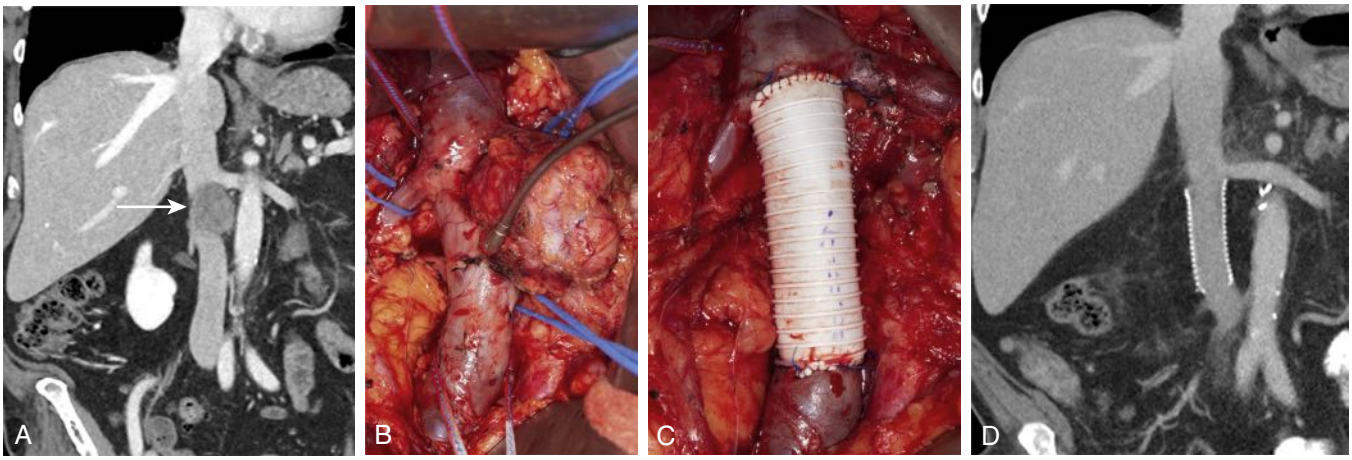


Figure 194.8 Preoperative coronal CT image (**A**) of a primary venous leiomyosarcoma involving the upper infrarenal vena cava near the renal vein–caval confluences. An intraoperative photograph (**B**) shows the tumor mobilized, and the renal veins and vena cava above and below the tumor controlled. (**C**) The vena cava was replaced with a ringed PTFE graft, with the upper anastomosis incorporating portions of both renal veins. (**D**) A 9-month's postoperative CT venogram showing a widely patent graft.

Figure 194.9 Preoperative CT angiogram (**A–C**) showing a large, primary venous leiomyosarcoma involving the liver and IVC near the right hepatic vein–caval confluence (*arrows*). The patient underwent *en bloc* resection and retrohepatic IVC reconstruction with a ringed PTFE graft. The specimen in (**D**) shows that most of the tumor was intraluminal but with invasion into the left lobe. Postoperative CTA 1 year later showing a widely patent IVC graft and right hepatic vein (**E**).

technique, methods to mitigate ischemic liver injury, and new or better neoadjuvant therapies are needed to broaden applicability and improve outcomes in these patients.[3,16,66,67]

OUTCOMES

Patient outcome is dictated by operative risk; performance status; tumor type, location, and stage; and whether arterial and/or venous involvement is managed by primary closure, a patch or an interposition graft.

Given the rarity of primary aortic or peripheral arterial malignancies, few surgical series are available.[12,29,34,69–71] The Mayo Clinic group reported outcomes in 13 patients diagnosed with primary angiosarcoma of the heart, aorta or supra-aortic trunks spanning a 26-year period. Metastatic disease was present in 10 patients when the

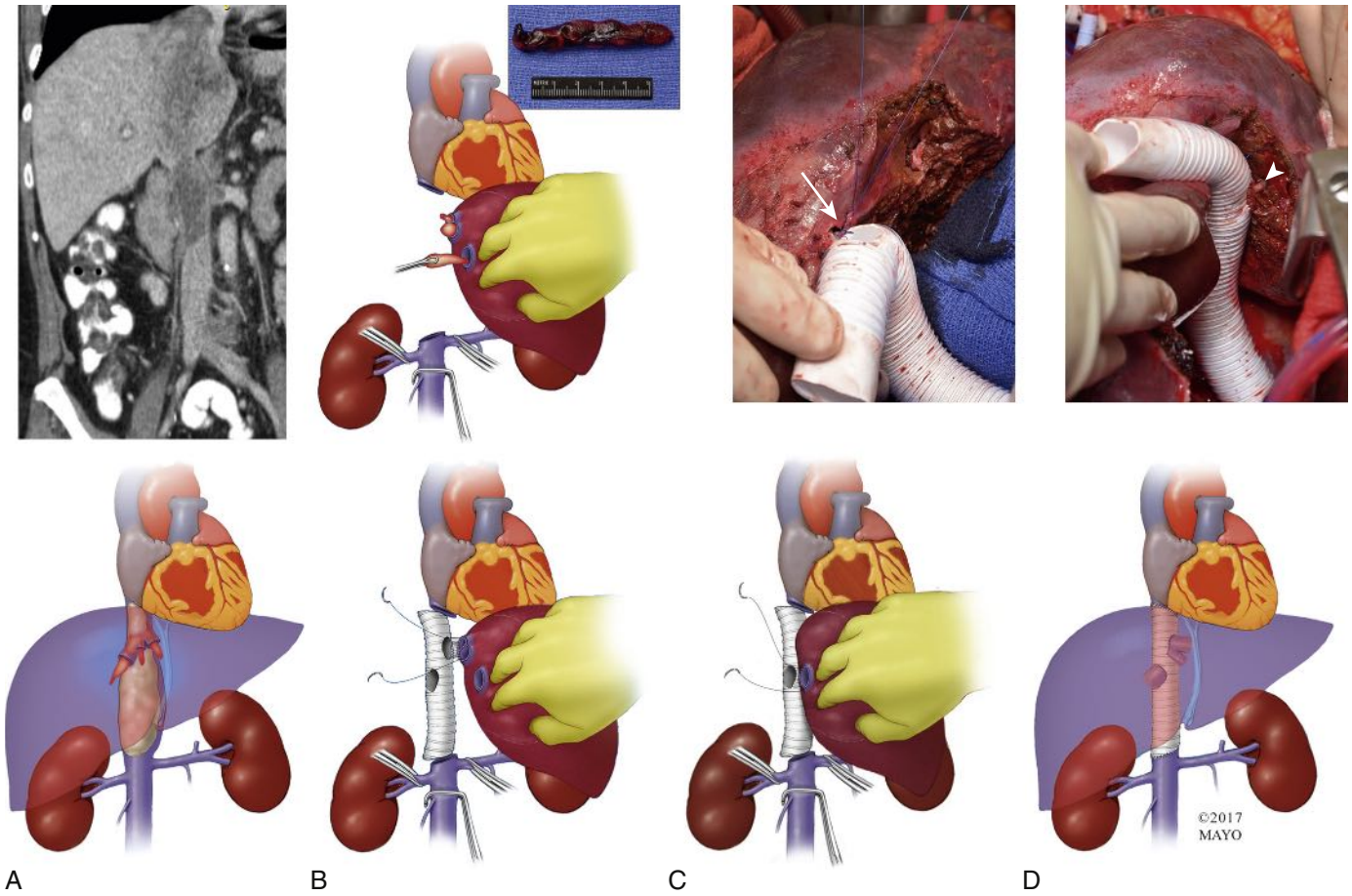


Figure 194.10 Infiltrative retrohepatic caval leiomyosarcoma extending from the cavoatrial junction to the renal vein–caval confluence as depicted vertically in panel (**A**). The tumor invaded the hepatic veins causing thrombosis of them with resultant hepatic congestion. Operation was done with cardiopulmonary bypass. The tumor was resected and the liver rotated to allow removal of bland thrombus from each of the hepatic veins and some of their branches, as shown in panel (**B**). The left and middle hepatic veins were reimplanted onto the externally supported PTFE graft (bottom, panel **B**; top, panel **C**). The right hepatic vein was reimplanted next (bottom, panel **C**; and top, panel **D**). Note the hepatic veins are not linearly oriented. The liver was placed in anatomic position, and the upper and lower caval anastomoses completed as shown in (**D**), bottom panel.

diagnosis was made, and only nine proved to have resectable disease. Five of the nine patients underwent aortic resection and reconstruction and two each were treated by thromboendarterectomy or pericardiectomy and atrial septal resection with patch closure of the defect (Fig. 194.11). One patient had biopsy only. There were no early deaths but overall median survival was just 8 months. The surgically treated aortic sarcoma patients had median survival of 14 months, ranging from one month to 75 months.[29] Carpenter et al. reported outcomes for 60 patients surgically treated for tumors arising from or secondarily involving the aorta or other major arteries.[12] Iliac artery involvement was noted in 37 patients (62%) and sarcoma was the most common pathology. Twelve patients required aortic resection, eight treated with graft replacement, and the others with a patch or primary closure. Early mortality was 5%. There were two intraoperative deaths and another one from cardiac arrest within 24 hours of surgery. Two deaths were in patients with aortic tumors, and the third in a patient with sacral malignancy in which the aorta and iliac arteries required mobilization. The latter patient died from coagulopathy induced by bone and soft tissue hemorrhage. Graft patency was excellent over a mean follow-up of 20.5 months, excepting one patient with a superficial femoral artery graft rupture and another prosthetic common iliac graft thrombosis.[12] A recent single center series and systematic review reported five cases of primary aortic tumors and analyzed an additional 218 cases from the literature. Median overall survival was 8 months, with 1-, 3- and 5-year survival rates at 26%, 7.6%, and 3.5%, respectively. Chronic hypertension, fever, back pain, asthenia, and peripheral embolization predicted a poor outcome, while histologic subtypes did not significantly impact outcomes. The combination of surgery and adjuvant treatment (chemotherapy and/

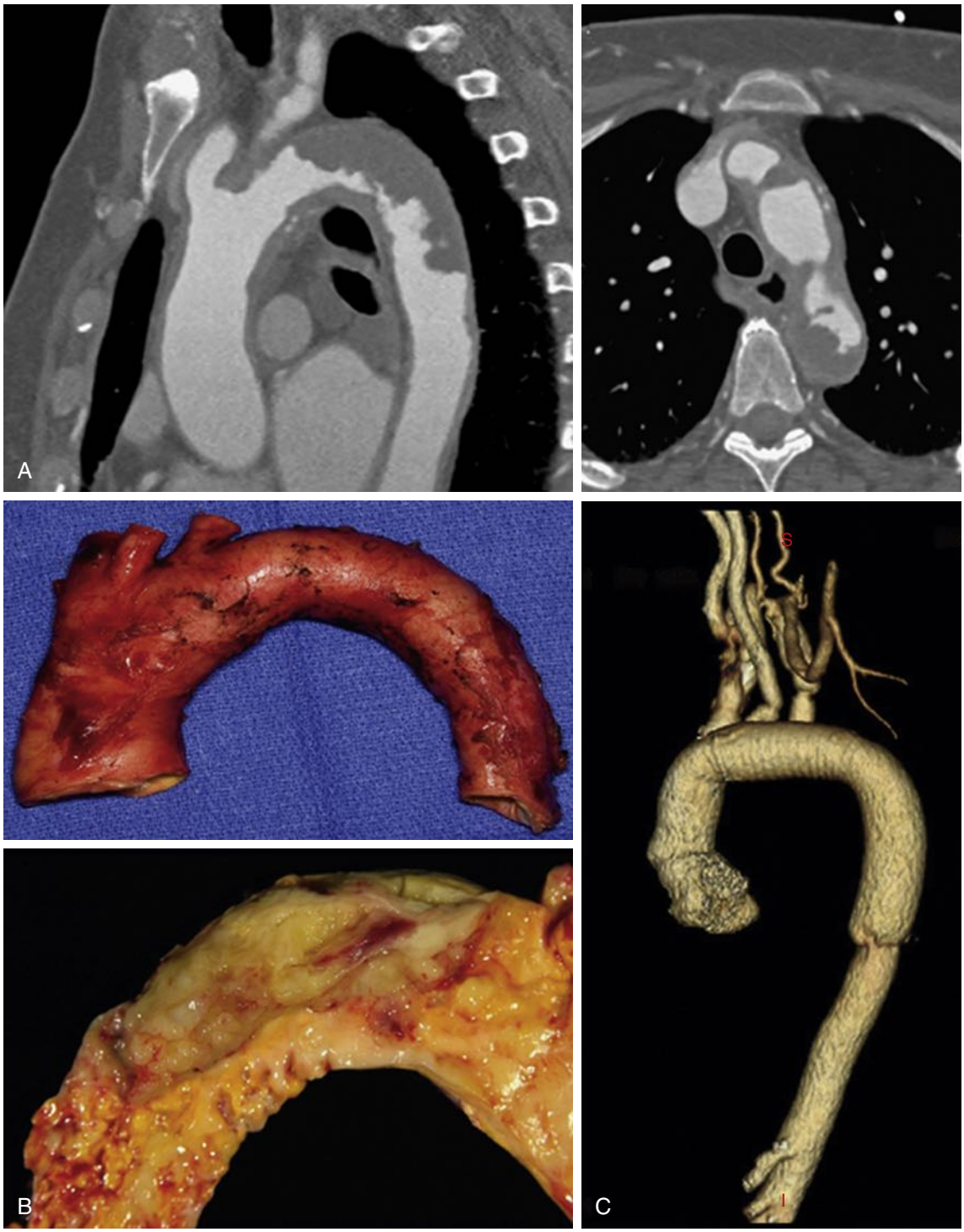


Figure 194.11 Sagittal and axial CT images of an intimal sarcoma of the aortic arch and proximal descending thoracic aorta (**A**). Pathologic specimens (**B**) show no gross invasion through the adventitia but extensive intimal tumor. Postoperative CT angiogram (**C**) showing widely patent aortic graft with reconstructed supra-aortic trunks. (Modified from Fatima J, et al. *J Vasc Surg* 2013;57(3):756–764.)

or radiotherapy) improved median survival to 12 months (8–24) compared to 8 months with medical therapy alone, 7 months with surgical treatment alone and 2 months without treatment ($P = 0.001$).[71]

En bloc celiac axis and tumor resection with arterial reconstruction has been increasingly utilized for select patients undergoing resection for locally advanced pancreatic adenocarcinoma. A Mayo Clinic series of 90 such patients

who responded positively to modern neoadjuvant chemotherapy was recently reported. Arterial and venous revascularization was performed in 62% and 66%, respectively. Arterial conduits were polyester early in the study, but now are either autologous superficial femoral or cryopreserved femoral artery. Major morbidity was high at 55% and 90-day mortality was 10% for the entire cohort. However, mortality declined to 4% in the last 50 cases as an understanding of which patients do better with total versus partial pancreatectomy was gained. Median overall survival was 36 months, better in patients who had neoadjuvant chemotherapy. The authors concluded that celiac axis resection should be considered in fit patients with objective neoadjuvant chemotherapy responses at specialized centers.[41] Comparison of outcomes for patients treated for IVC malignancies is difficult because tumor types vary, and surgeons lump patients treated by primary IVC closure or patch angioplasty with those who need segmental resection and graft replacement. Moreover, location of the IVC tumor influences risk.[19] The physiologic stress of a retrohepatic IVC graft replacement, particularly if major liver resection is needed and/or hepatic veins require concomitant reconstruction, varies significantly from an individual who needs replacement of the infrarenal IVC. Mortality was 20% in the Kieffer series, but tumor size was large and 14 of the 20 patients had suprarenal IVC involvement, including five with invasion into the hepatic veins or heart.[15] By comparison, Ito et al. reported no mortality among 20 patients surgically treated for PVL, but only five patients had graft replacement and only one had tumor above the hepatic veins.[14] Similarly, an Italian report had low mortality among 11 patients treated with graft replacement of the infrarenal IVC.[1,72] Contemporary series from Quinones-Baldrich et al., Hemming and colleagues, and Glebova and associates document low mortality despite increasingly complex operations (Table 194.1).[1–6,14,15,45,62,67,73–76] Overall 5-year survival has reached 50% in some series for primary or secondary IVC tumors. Among 124 patients treated at the Mayo Clinic by segmental IVC resection and graft replacement, overall 5-year survival was 52% and disease-free survival was 32%. The local progression-free survival was 66%.[5] Other series report similar results. Although surgical resection may improve survival in select patients, more effective adjuvant therapies are needed if additional survival advantage is to be seen.

The greatest survival benefit is seen in patients surgically treated for RCC with intracaval tumor thrombus. Five-year survival rates between 40% and 60% are noted in several series, with sarcomatoid features, lymph node involvement, perinephric fat infiltration, distant metastasis, and residual tumor adherent to the IVC wall after thrombectomy adversely impacting outcome.[22–25,27,28,77–80] Extent of tumor thrombus is not as important a survival predictor as distant metastases or vascular margin status. Five-year disease-specific survival reaches 40% to 71% for patients undergoing radical nephrectomy and IVC tumor thrombectomy in the absence of metastases, but falls considerably to between 6% and 28% when metastatic disease is present.[26,27] Among a cohort of 304 patients, Psutka and colleagues noted a 1.5-fold increase in mortality at 5 years if vascular margins were positive on pathologic analysis.[26,27]

Concomitant liver resection increases the complexity of the operation significantly. Sarmiento and colleagues reported outcomes of 19 patients who underwent partial hepatectomy and segmental IVC resection and reconstruction. Cholangiocarcinoma was the most common tumor and affected nine patients, followed by metastasic lesions in five, sarcomas in three and hepatocellular carcinoma in two. Major hepatectomies (≥3 segments) were performed in 15 patients. Hepatic vascular isolation was needed in 13 patients, and all but one patient had IVC replacement with a PTFE graft. Despite a high complication rate (42%), there was only one perioperative death (5%). Median overall survival was 38 months.[67] These results are corroborated by a more recent publication by Hemming and colleagues.[3] In that study, concomitant liver and IVC resection was performed in 60 patients, mostly for primary hepatic tumors. Six patients required an *ex vivo* procedure, while the remaining 54 needed varying degrees of vascular isolation of the liver. IVC graft replacement was needed in 38 patients. Perioperative mortality was 8%. Long-term survival was 89% at 1 year and 35% at 5 years. These results support aggressive resection of hepatic tumors with IVC involvement.[3,66,67]

Adjuvant therapies have evolved slowly for most primary or secondary IVC malignancies. Tyrosine-kinase inhibitors seem effective treatment for patients with RCC, though have not significantly impacted survival in patients with intracaval tumor thrombus.[81–84] An R0 tumor resection is always the goal, but select patients with retroperitoneal or IVC sarcomas may have the risk of locally recurrent disease lowered by radiation therapy. Some authors have shown local tumor control to be improved by a combination of external beam and intraoperative radiation therapy in select patients.[75,85–88] The application of preoperative proton beam radiation therapy is in its infancy, although this treatment causes perivascular inflammation and/or a soft tissue rind in our experience.

Malignant obstruction of the superior vena cava is most often caused by lung cancer with mediastinal adenopathy. Lymphoma, thyroid cancer, thymoma and teratoma are the other etiologies. Most patients with malignant SVC obstruction are not surgical candidates, and treatment is palliative with stenting of the vein. If patients with localized disease undergo segmental SVC or innominate vein resection, our preference for venous reconstruction is a prosthetic graft (ePTFE).

Single center experience with peripheral vein reconstruction for malignancy is rarer than that of the IVC. Sun and associates from the Mayo Clinic reported the results of 28 reconstructions in 27 patients with iliac (19), lower extremity (6) and upper extremity (3) venous tumors spanning from

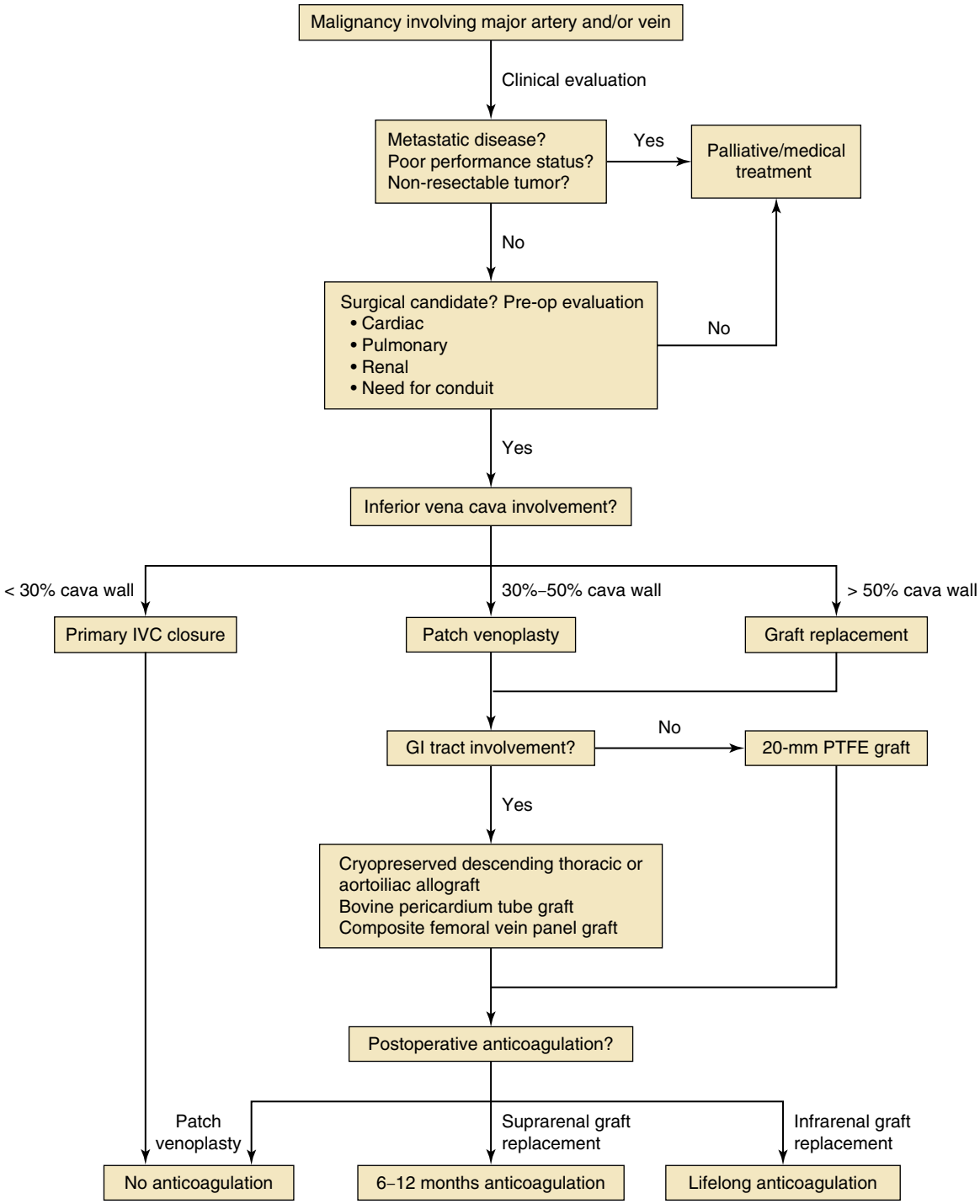
TABLE 194.1 Contemporary Series of Primary and Secondary Inferior Vena Cava Malignancies

		TYPE		LOCATION			TUMOR SIZE (cm)			
	N			IR	SR/RH	SH	Liver Resection	Median	Graft	Early mortality *n* (%)
Sarmiento (2003)	19	Cholangiocarcinoma Metastatic Sarcoma HCC	9 5 3 2	0	19	0	19	–	18	1 (5)
Kieffer (2006)	20	PVL		3	13	4	4	21	13	4 (20)
Ito (2007)	20	PVL		6	13	1	1	10.7	5	0
Kuehnl (2007)*	35	PVL Secondary	6 20	5 (4)	7 (3)	14 (2)	–	–	–	2 (6)
Delis (2007)	12	Colorectal HCC Cholangiocarcinoma	6 4 2	0	12	0	12	–	12	0
Quinones-Baldrich (2012)	47	PVL Secondary	30 17	9	18		–	11.6	27**	0
Hemming (2013)	60	Cholangiocarcinoma HCC Metastases Other tumors	26 16 13 5	–	–	–	60	–	38	5 (8)
Benkirane (2014)	26	RCC	26	–	–	–	–	10	26	1 (3.8)
Fabre (2014)	37	PVL RCC Adrenocortical Sarcoma HCC Other tumors	2 11 8 6 2 8	8	15	14	–	–	14	2 (5.4)
Glebova (2016)	63	RCC Sarcoma Germ cell tumor Paraganglioma Adrenocortical Other tumors	31 13 6 4 3 6	18	44	–	–	11.1	21	2 (3)
Illuminati (2016)	18	PVL		–	–	–	–	–	18	0
Bower† (2015)	110	PVL Secondary	36 74	28	14	1	32	10.5	110	2 (2)

*9 SVC and 26 IVC tumors. The location of the 9 patients with grafts shown in parentheses.
**8 entire IVC replaced with hepatic/renal vein reimplantation; 6 had suprarenal and pararenal IVC replaced with 7 renal vein reimplantations; 4 had infrarenal and pararenal IVC replaced with 4 renal vein reimplantations
†Multiple segments in remainder
HCC, hepatocellular carcinoma; *IR*, infrarenal segment; *PVC*, primary venous leiomyosarcoma; *RCC*, renal cell carcinoma; *SH*, suprahepatic segment; *SR/RH*, suprarenal–retrohepatic segment.

2000 through 2015. Prosthetic grafts were used in 17 patients, vein grafts in seven, and a cryopreserved graft in one, with the remaining three reconstructions performed with a patch. Early outcomes were good with no 30-day mortality and few graft-related complications (infection in three). At a median follow-up of 4.4 years, 2- and 5-year primary patency rates were both 61%. Graft thrombosis occurred in five patients, four with prosthetic grafts, yielding an overall freedom from graft thrombosis of 87% at 5 years.[40] Similar results have been shown by others.[89]

CHAPTER ALGORITHM



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Bower TC, Nagorney DM, Cherry KJ, et al. Replacement of the inferior vena cava for malignancy: an update. *J Vasc Surg*. 2000;31(2):270–281.

The paper provides an in-depth analysis of the types and locations of the IVC tumors, analysis of outcomes, and detailed surgical techniques.

Fatima J, Duncan AA, Maleszewski JJ, et al. Primary angiosarcoma of the aorta, great vessels, and the heart. *J Vasc Surg*. 2013;57(3):756–764.

The Mayo Clinic experience in 13 patients diagnosed with primary angiosarcoma of the heart, aorta, or supra-aortic trunks spanning a 26-year period. Five of the nine patients underwent aortic resection and reconstruction and two each were treated by thromboendarterectomy or pericardiectomy and atrial septal resection with patch closure of the defect. There were no early deaths but overall median survival was just 8 months. The surgically treated aortic sarcoma patients had median survival of 14 months, ranging from 1 month to 75 months.

Hemming AW, Mekeel KL, Zendejas I, et al. Resection of the liver and inferior vena cava for hepatic malignancy. *J Am Coll Surg*. 2013;217(1):115–124.

A large series of 60 patients treated with concomitant liver and inferior vena cava resection for primary and secondary hepatic tumors. A detailed technical description of different variations of the operation is provided. Ex vivo reconstruction was performed in six patients, and the other 54 procedures were performed with varying degrees of vascular isolation. The IVC was reconstructed in 38 patients using a tube graft. Perioperative mortality was 8% and actuarial 1- and 5-year survival rates were 89% and 35%.

Pouliot F, Shuch B, LaRochelle JC, et al. Contemporary management of renal tumors with venous tumor thrombus. *J Urol*. 2010;184(3):833–841.

This paper summarizes the contemporary management of patients with renal cell cancer and venous tumor thrombus. The authors provide comparative outcome data between the largest studies with regard to median survival, disease-specific survival, and impact of metastases or no metastases on disease-specific survival.

Quinones-Baldrich W, Alktaifi A, Eilber F. Inferior vena cava resection and reconstruction for retroperitoneal tumor excision. *J Vasc Surg*. 2012;55(5):1386–1393.

The UCLA group describes 47 patients treated with IVC resection and tumor excision between 1990 and 2011. The majority of tumors were sarcomas, of which 30 were primary to the IVC. Eleven patients had primary repair, 9 had patch angioplasty, and 27 had circumferential resection and IVC replacement with a PTFE graft. Eighteen of the reconstructions with grafts included more than one caval segment. There was no mortality and a 10.6% major morbidity rate.

Salm R. Primary fibrosarcoma of aorta. *Cancer*. 1972;29(1):73–83.

Landmark paper on the morphologic types of aortic tumors.

Wachtel H, Gupta M, Bartlett EK, et al. Outcomes after resection of leiomyosarcomas of the inferior vena cava: a pooled data analysis of 377 cases. *Surg Oncol*. 2015;24(1):21–27.

This is a large pooled data analysis on IVC leiomyosarcomas. The dominant predictors of survival included margin status, tumor size, and radical resection.

A complete reference list can be found online at www.expertconsult.com.

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CHAPTER 195

Vascular Reconstruction in Oncologic Surgery

KATHERINE GIULIANO and JAMES H. BLACK III

PANCREATIC MALIGNANCIES

Pancreatic cancer is currently the fourth leading cause of cancer death within the United States with 56,770 new cases and 45,750 deaths estimated for 2019.[1] Five-year survival remains poor at an estimated 10%.[2] Improving long-term survival is therefore the goal of care, with surgery as a pivotal portion of multidisciplinary care. Preoperative surgical resectability can be classified as follows: *unresectable* (metastatic disease, encasement of the superior mesenteric artery [SMA] or hepatic arteries, lack of venous reconstructive options); *borderline resectable* (superior mesenteric vein [SMV]/portal vein [PV] tumor–vessel interface ≥180 degrees of vessel wall circumference, and/or reconstructable occlusion; SMA tumor–vessel interface <180 degrees of vessel wall circumference; celiac artery tumor–vessel interface <180 degrees of vessel wall circumference; common hepatic artery tumor–vessel interface without involvement of proper hepatic artery and/or celiac artery); or *resectable*.[3,4] Recent definitions of borderline resectable disease also include serum carbohydrate antigen (CA) 19-9 levels (with >500 units/mL concerning for unproven distant metastases or lymph node metastases) and Eastern Cooperative Oncology Group (ECOG) performance status (surgical resection for borderline tumors recommended in patients with ECOG status of two or more).[4]

Neoadjuvant chemotherapy and radiation may reduce the extent of vascular involvement in borderline disease, but continued involvement necessitates vascular resection and reconstruction as part of the pancreaticoduodenectomy. In an analysis of over 10,000 pancreatectomies from the National Inpatient Sample database, patients with vascular reconstructions (4% of all) experienced increased major complications, but no difference in mortality.[5] Even with increased morbidity, vascular resection represents the only curative option for patients with borderline resectable disease. Indeed, patients who undergo pancreaticoduodenectomy with vascular resection have equivalent postoperative survival to those who undergo pancreaticoduodenectomy alone and superior survival to those with unresectable disease.[6]

Among patients undergoing resection of the pancreatic head when there is potential for a venous resection/reconstruction, one should consider an artery-first approach.[7,8] Our preference is to dissect and ligate all SMA branches/perivascular connective tissue to the pancreas prior to undertaking SMV/PV clamping or venous resection. In brief, this technique can be accomplished by rotating the specimen to the left by widely mobilizing the right colon to fully expose the duodenum in its entirety and dividing the perivascular connective tissue along the SMA in a parallel fashion from caudal to cranial. Attachments

between the SMA and uncinate are divided to expose the lateral border of the PV–SMV. After the specimen has been freed from the SMA the only tissue remaining should be venous attachments. Benefits include not only the potential for lower blood loss and facilitation of an *en bloc* resection but also increased mobility of the specimen and ease of venous resection.

Venous Resection and Reconstruction

The surgeon should have a clear understanding of the need for venous reconstruction based on high quality preoperative cross-sectional imaging (triple contrast phase along with thin cuts through the pancreas). Assessment of SMV/PV infiltration by a pancreatic tumor is best assessed on the portal venous phase.[9] Imaging findings highly sensitive for detection of PV/SMV invasion include radiologic absence of a fat plane between the tumor and the vessel, length of tumor involvement of greater than 5 mm, venous occlusion with formation of collateral vessels, presence of a "teardrop sign" in the SMV ("tethering" of the SMV by the tumor), and irregularity of the wall of the blood vessel (Fig. 195.1). Imaging findings highly sensitive for unresectability include circumferential involvement of a vessel by more than 180 degrees (see Fig. 195.1).

True venous involvement of the SMV, PV, or their confluence can be confirmed either at the time of tunneling under the pancreatic neck or following the creation of the tunnel (at the time the surgeon is controlling vessels from the SMV/PV, SMA to the head of the pancreas and uncinate process). Vein resections can either be performed by excising the right lateral portion of the SMV or PV or a segment of the SMV, after gaining venous control. Generally, options to proceed include locally resecting a portion of the right lateral aspect of the SMV/PV (tangential resection) and repairing either with interrupted sutures in a transverse fashion or with a saphenous vein patch, segmental resection and primary anastomosis, or segmental *en bloc* resection of tumor and vein followed by placement of an interposition graft (Fig. 195.2).[6] Data suggest SMV or PV resection with primary end-to-end reconstruction or transverse

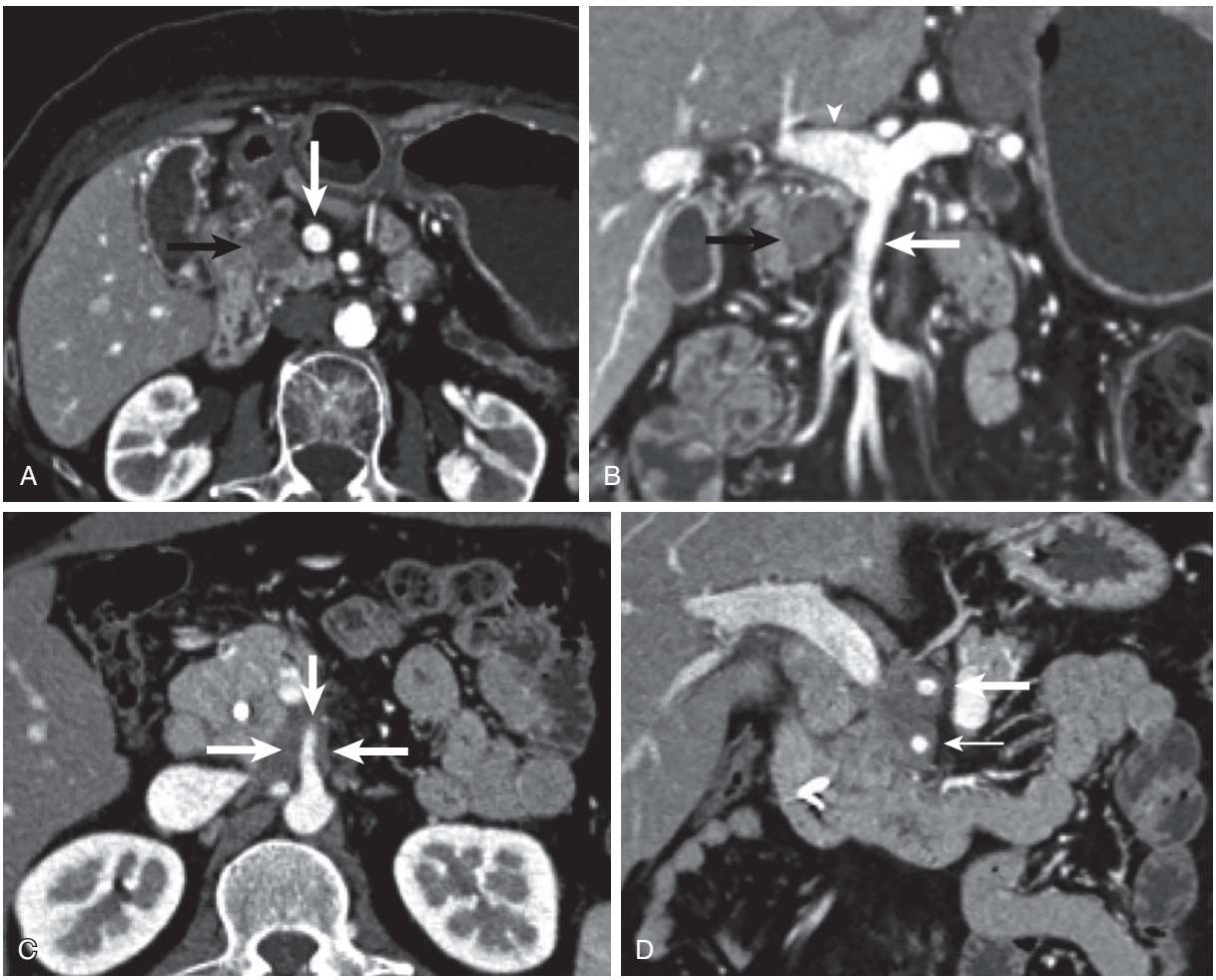

Figure 195.1 Portal Vein Invasion is Evaluated on Preoperative Computed Tomography (CT) Imaging. (**A**) Axial slice of CT scan demonstrating a resectable lesion in the head of the pancreas *(black arrow)* with preservation of the fat plane circumferentially around the portal vein *(white arrow)*. (**B**) Coronal slice of CT scan demonstrating resectable lesion in the head of the pancreas with preservation of the fat plane around the vessel. (**C**) Axial slice of CT scan demonstrating an unresectable pancreatic mass with greater than 180-degree loss of the fat plane around the portal vein and circumferential encasement of the superior mesenteric artery (SMA). (**D**) Coronal slice of CT scan demonstrating an unresectable pancreatic tumor with complete encasement of portal vein *(large arrow)* and SMA *(small arrow)*.

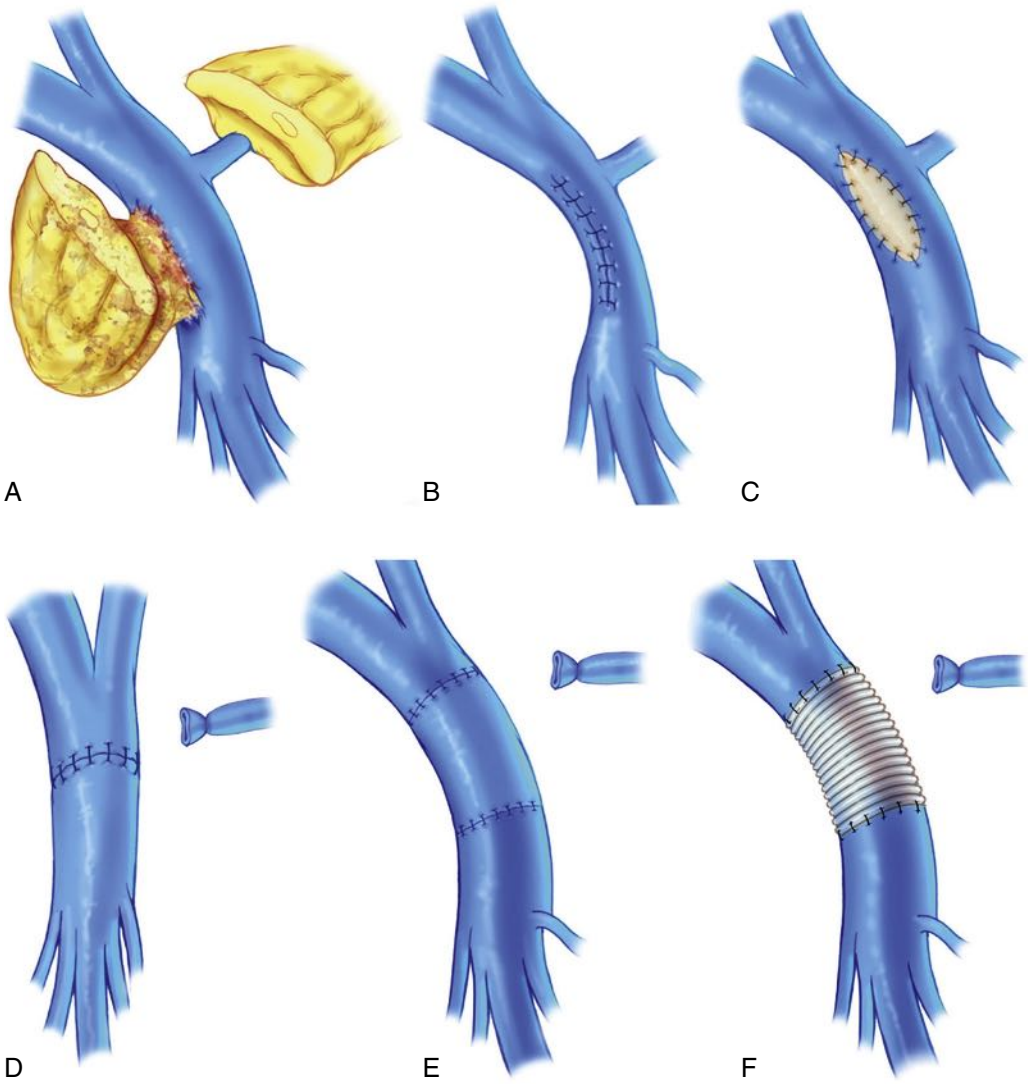

Figure 195.2 Methods of Portal Vein and Superior Mesenteric Vein Resection and Reconstruction During Pancreatectomy. (**A**) Appearance of the pancreatic parenchyma in relation to the portal vein (PV)/superior mesenteric vein (SMV) illustrating involvement of the blood vessel in the usual anterolateral location. (**B**) Primary PV/SMV repair using venorrhaphy. (**C**) Vein patch angioplasty. (**D**) Primary end-to-end anastomosis. (**E**) Interposition graft placement using autologous vein. (**F**) Interposition graft placement using prosthetic.

venorrhaphy results in a greater patency rate as compared to lateral/longitudinal venorrhaphy, patch venoplasty or interposition grafting for short (<3 cm) reconstructions.[10,11] In a series of 173 patients undergoing PV reconstruction among 6522 patients who underwent pancreatectomy over a 45-year period at the Johns Hopkins Hospital, use of prosthetic grafts (as well as long operative times) was a risk factor for postoperative PV thrombosis.[12]

As a general principle, it is of paramount importance to critically analyze the site of tumor infiltration of the vein preoperatively and intraoperatively. Wide mobilization of the liver and retroperitoneum will allow approximately a 3-cm gap to be bridged by a primary end-to-end repair. Proximal vein involvement can typically be handled more easily, as the vessel diameter is large enough to create a sufficient anastomosis. However, in cases of venous involvement distal to the first jejunal branch, the decreasing diameter of the SMV may limit the technical possibility to perform a venous resection.[13] Occasionally, however, the SMV, PV, splenic vein (SV), and confluence will all be involved by tumor. This pattern of venous invasion may be found when resecting tumors of the pancreatic neck or medial aspect of the head of the pancreas. In such cases when all three venous structures are involved, a total pancreatectomy with SMV to PV reconstruction can be considered. In this setting, the venous gap may exceed 3 cm and interposition grafting may be required.

Tangential Superior Mesenteric Vein/Portal Vein Reconstruction with Saphenous Vein Patch

Tangential resection (right lateral SMV/PV partial resection) is well-suited for when there is involvement of the medial aspect of the SMV/PV junction opposite to the splenic vein. Although certain circumstances preclude this technique and a formal segmental resection must be performed, if possible a tangential resection should be utilized. Key technical aspects of this procedure include proximal and distal control of the SMV/PV and splenic vein with vascular clamps, achieving a grossly negative margin of vein and constructing a vein patch. If there is a question of leaving a positive margin, a segmental resection should be utilized. Additionally, if only a small portion of the vein is required for resection, the vascular clamps

can be applied in a "V" format, angling in behind the involved area of vein. If a larger portion of the vein is required, a Satinsky clamp can be applied parallel to the vein. Close communication with the anesthesia team at the time of PV clamping is important to avoid potential hypotension and any diminished mesenteric venous flow.

The great saphenous vein (GSV) should always be harvested prior to PV clamping in order to expedite the reconstruction and limit the amount of portal flow disruption. It is paramount to plan and prioritize sequential steps to allow for safe and efficient venous repair. GSV harvest is accomplished by exposing the previously prepped groin and creating a longitudinal incision medial to the femoral artery. The GSV is then identified at its junction with the femoral vein (saphenofemoral junction), mobilized distally for an appropriate length of 5–6 cm, and ligated proximally and distally; this segment of GSV is then removed and placed in heparinized saline.

To complete the vein patch, the GSV should be opened longitudinally, cut to size and spatulated. The valves should be lysed to avoid directional flow issues. Following clamping, the patch is then grafted using 5-0 or 6-0 polypropylene suture in a running technique. Finally, an air knot of one-third the diameter of the PV is tied in order to allow for venous distention (see Fig. 195.2C).

Segmental Resection and Primary Anastomosis

Segmental resection with primary end-to-end anastomosis has proven to have the highest patency rates of all reconstruction methods. Certain factors must be appropriate in order to complete a primary end-to-end anastomosis following a segmental resection. First and foremost, the anastomosis must be created without tension. This can be facilitated by mobilization of the SMV (along the root of the small bowel mesentery) and PV (superior to the pancreas) by ligating and dividing small branches along the length of these vessels. Additionally, further length on the PV can be gained through hepatic mobilization; the right and left liver should be mobilized by incising the triangular and cardinal ligaments along with the hepatocolic and falciform ligaments. If further length is required, the midgut can also be mobilized by creating a dissection plane immediately anterior to the wall of the aorta and IVC. Such preparatory steps should precede the interruption of portal venous flow to avoid venous congestion.[14]

Proximal and distal control of the PV and SMV is obtained with pediatric vascular clamps, the vein transected, and the specimen removed. The previous mobilization maneuvers should permit a tension-free primary anastomosis. The anastomosis is undertaken utilizing a running 5-0 or 6-0 polypropylene suture on the back wall and simple suture repair on the front wall. Finally, an air knot of one-third the diameter of the PV is tied in order to allow for venous swelling and to prevent an hour-glass formation of the anastomosis. Typically, a segmental defect of ≤2–3 cm can be repaired with a primary anastomosis using these principles (see Fig. 195.2D for schematic and Fig. 195.3C for intraoperative photograph).

Segmental Resection and Interposition Grafting

When segmental resections of the PV or the SMV longer than 3 cm is required, we recommend the use of a vascular conduit as an interposition graft (see Fig. 195.2E and F for schematic and Fig. 195.3D for intraoperative photograph). Conduit selections include: autologous vein (left renal vein, internal jugular [IJ] vein), cryopreserved vein, bovine pericardium, peritoneum, or synthetic grafts, but cryopreserved vein, bovine pericardium, peritoneum, and synthetic grafts are not considered optimal conduits for PV reconstruction. Although saphenous vein is an excellent material for patch angioplasty, it is not an ideal conduit for PV/SMV reconstruction owing to size mismatch. Our conduit preference for interposition grafting in the setting of pancreatectomy is autologous vein utilizing the left renal vein or splenic vein.

Left Renal Vein Graft

Traditionally, the left renal vein has been used to repair venous structures (PV, IVC or hepatic vein) during resection of hepatic hilar cholangiocarcinomas. Extrapolating this technique to the pancreas offers distinct advantages for venous reconstruction. Importantly, previous experience has confirmed the safety of left renal vein ligation distal to the insertion of the left adrenal and gonadal veins, which provide collateral venous drainage for the left kidney.[15,16] Proximally, the vein is divided flush with the IVC, which generally provides a 3- to 4-cm venous interposition graft (Fig. 195.4). Division of the vein is undertaken with a linear (transverse anastomosis) stapling device. Following harvest, the venous segment should be maintained in heparinized saline until reconstruction. Interposition reconstruction should then be undertaken with 5-0 or 6-0 polypropylene suture in a running technique in an end–end fashion without spatulation (see Fig. 195.2E and Fig. 195.3D). Advantages to the left renal vein graft include the ability to expose the vein within the same operative field, eliminating a second operative field as would be required to harvest the IJ vein. Additionally, the caliber and wall thickness of the vein is similar to the PV, therefore providing ease in handling and suturing.[15,16]

Internal Jugular Vein Graft

IJ vein graft remains a valid option for segmental reconstruction. However, unlike the left renal vein, a separate surgical field is required. Harvest of the IJ vein is performed with the patient's head turned away from the surgeon and the neck slightly extended. An incision on the anterior border of the sternocleidomastoid muscle (SCM) is created and taken down to the carotid sheath. This can be facilitated by retracting the SCM laterally. Next, the carotid sheath should be entered and the facial vein ligated between ties. Next, the vagus nerve should be identified, keeping it free from injury. An appropriate length of IJ vein is then chosen and ligated between ties. Following harvest, the venous segment should be maintained in heparinized saline until reconstruction.

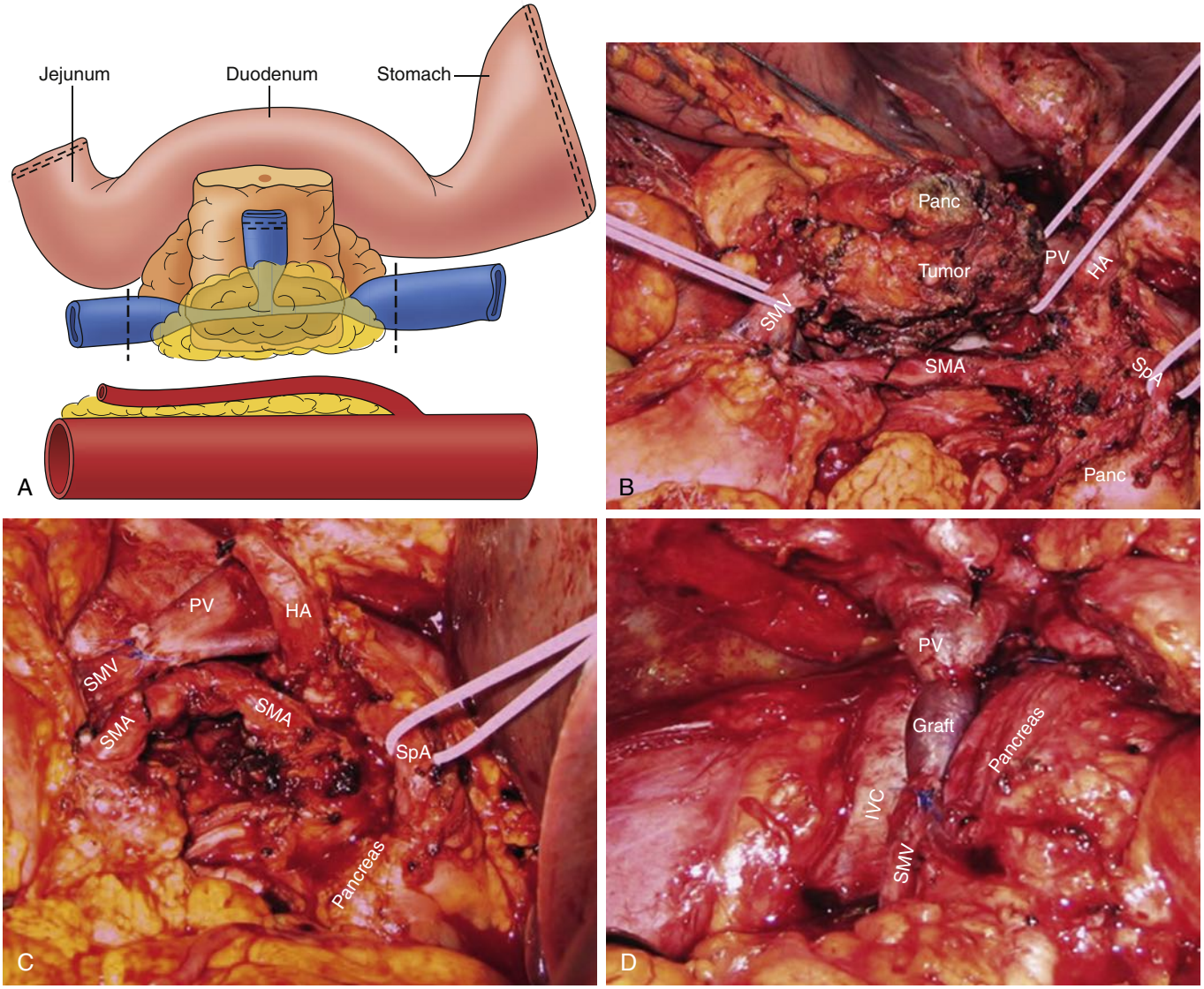

Figure 195.3 Portal Vein and Superior Mesenteric Vein Resection and Reconstruction During Pancreatectomy. (**A**) Schematic of a pancreatic tumor adherent to the superior mesenteric vein (SMV), portal vein (PV), and splenic vein. (**B**) Intraoperative image after completion of the dissection, with the tumor remaining attached only to the SMV/PV. After *en bloc* resection, venous reconstruction options include: (**C**) completed segmental resection with primary anastomosis between the SMV and PV, or (**D**) completed segmental resection with autologous vein grafted anastomosis. *Panc,* pancreas; *PV,* portal vein; *SMV,* superior mesenteric vein; *HA*, hepatic artery; *SMA,* superior mesenteric artery; *SpA*, splenic artery; *IVC*, inferior vena cava. (From Strasberg SM, Sanchez LA, Hawkins WG, Fields RC, Linehan DC. Resection of tumors of the neck of the pancreas with venous invasion: the "Whipple at the Splenic Artery (WATSA)" procedure. *J Gastrointest Surg*. 2012;16:1048–1054.)

Interposition reconstruction should then be undertaken with 5-0 or 6-0 polypropylene suture in a running technique in an end–end fashion without spatulation (see Fig. 196.2E and Fig. 196.3D).

Splenic Vein Preservation Versus Ligation

Splenic vein preservation is possible, but it significantly limits the mobilization of the PV and may prevent primary anastomosis of the SMV/PV following segmental resection if the tumor is opposite the splenic vein orifice. Thus, pancreatectomy with SMV/PV end-to-end anastomosis may be the best option when all three vessels are encased. If there is excess distance to bridge, choosing a segment of splenic vein from the distal pancreas to use as a secondary splenic vein graft can be performed.[6] Recent data suggests that pancreaticoduodenectomy with SMV–PV confluence resection and splenic vein resection can be safely conducted, and preservation of the left gastric vein–PV and/or inferior mesenteric vein–splenic vein confluences may reduce the risk of left-sided portal hypertension postoperatively.[17]

Postoperative Considerations and Oncologic Outcomes

There is no standardized practice for the use of anticoagulation or antiplatelet therapy postoperatively, with significant

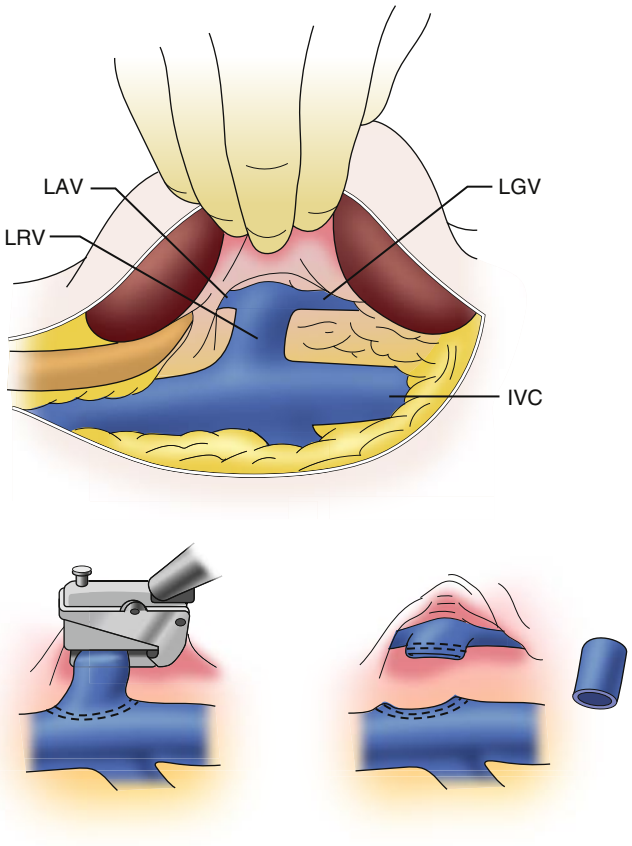

Figure 195.4 Harvesting Left Renal Vein (LRV) **Conduit.** The vein is divided at the junction of the left gonadal vein (LGV) and the left adrenal vein (LAV), which will provide left kidney venous drainage. It is then divided flush with the inferior vena cava (IVC) to a provide a 3- to 4-cm venous interposition graft. (Used with permission Mayo Foundation for Medical Education and Research. All rights reserved.)

inter-center heterogeneity.[18] Generally speaking, patients do not require anticoagulation with heparin, but the use of antiplatelet therapy with aspirin is more common. In one series of 90 patients who underwent vein resection/reconstruction during pancreatectomy, prophylactic aspirin was used in 69% but was not protective against thrombosis.[10] Doppler ultrasound imaging on postoperative day 2 or 3 can be useful to detect any flow abnormalities that may require additional anticoagulation. Reported rates of venous thrombosis after reconstruction are as high as 26% but vary according to the repair.[10,18] By repair type, one case series reported thrombosis rates of 0% for transverse venorrhaphy and primary repair, 25% for longitudinal venorrhaphy, 31% for patch repair, and 44% for interposition grafting at a median follow-up of 316 days.[10]

With respect to oncologic efficacy, the literature documents equivalent survival between those who undergo SMV/PV resection and those who do not.[5,6,19,20] A meta-analysis of 19 studies comparing 661 patients with venous resections during pancreatectomy to 2247 patients without venous resections found no difference in perioperative morbidity, mortality, or 5-year survival.[21] Therefore in properly selected patients, venous resection during pancreaticoduodenectomy should be undertaken if technically feasible.

Arterial Resection

Historically, arterial resection was associated with high morbidity and was therefore considered a contraindication. When the tumor has arterial involvement, however, pancreatectomy with arterial resection and reconstruction represents the only potential option for a R0 resection.[19,22] Arterial resection and reconstruction remains controversial. Several small case series have been published to describe outcomes after arterial resection; while they suggest feasibility and safety of the technique, the oncologic benefit remains unclear. For instance, Zhang et al. describe 21 patients who underwent pancreatectomy with arterial resection. All had an R0 resection, there were no intraoperative complications, three patients died postoperatively from hemorrhage due to pancreatic fistula, and median postoperative survival was 11.6 months for the patients with pancreatic adenocarcinoma.[22] Perinel et al. compared a cohort of patients who underwent planned arterial resection and reconstruction during pancreatectomy with those who required only venous resection and those who required no vascular resection. The primary selection criteria for arterial resection was the possibility of achieving a complete resection based on the extent of axial encasement, the absence of tumor invasion at the origin of celiac trunk and SMA, and a free distal arterial segment

to allow for reconstruction. Six SMA, two celiac trunk, four common hepatic artery, and two replaced right hepatic artery resections were undertaken with the preferred arterial reconstruction being a splenic artery transposition. There were no statistically significant differences in the incidence, grade, and type of complications in the three groups, but 7/14 and 2/14 patients in the arterial resection group developed metastatic and loco-regional recurrences, respectively.[23]

Celiac Axis Resection/Appleby Procedure

Involvement of the celiac axis by pancreatic body tumors is no longer considered an absolute contraindication to resection. In highly selected patients, resection is feasible and relies on collateral circulation through the gastroduodenal artery (GDA) to maintain hepatic arterial perfusion. However, in the setting of locally advanced pancreatic adenocarcinoma, multidisciplinary care is essential, and the patient likely requires systemic therapy prior to the consideration of surgical exploration. If resection is deemed appropriate and the celiac axis remains grossly involved with tumor after neoadjuvant therapy, an Appleby procedure can be performed. This allows for *en bloc* resection of the common hepatic, celiac, and splenic arteries in combination with a distal pancreatectomy and splenectomy. Of paramount importance, adequate flow through the GDA must be determined prior to celiac axis resection and preserved to allow for continued hepatic arterial perfusion via retrograde flow to the proper hepatic artery.

Resectability is determined by the adequacy of retrograde blood flow through the GDA after isolating the celiac axis, common hepatic artery, and GDA. The common hepatic artery is clamped, and flow in the proper hepatic artery and GDA is assessed by palpation and Doppler. The presence of a strong pulse/signal will allow resection to proceed. Once deemed resectable, the common hepatic artery is clamped and divided. The pancreas is divided at the pancreatic neck, then the celiac axis is clamped and divided. Standard distal pancreatectomy and splenectomy can then ensue.

HEPATIC AND BILIARY MALIGNANCIES

Despite advances in novel chemotherapeutics, biologic agents and immunotherapy, the best chance for cure and long-term survival for hepatic and biliary malignancies is surgical resection with negative margins. Even with improvements in regional hepatic therapies, patients who are deemed unresectable have overall worse survival than those who have a chance at curative resection. However, regional nodal involvement often determines oncologic outcome beyond a technically successful resection. Historically, vascular invasion for hepatic and biliary tumors was considered a contraindication to surgical resection, as the risks of an operative intervention were felt to far outweigh the benefits.

With technical advances over time, however, combined hepatectomy and vascular resection as a means to obtain negative margins for many hepatobiliary malignancies has become acceptable. Most of the published literature on vascular resection and surgical outcomes comes from hilar cholangiocarcinoma (Klatskin tumors) due to the infiltrative nature of this malignancy (involvement of adjacent vascular structures within the hilum). Therefore this chapter uses hilar cholangiocarcinoma as an example to demonstrate the fundamental elements and operative approach of oncologic vascular surgery and reconstruction in hepatic and biliary malignancies. These principles also apply to primary IVC malignancies as well as renal, adrenal, retroperitoneal, and abdominal malignancies that can secondarily involve the IVC.

Cholangiocarcinoma is the most common cancer of the biliary tree, but it is overall rare, accounting for 3% of gastrointestinal cancers.[24] It is considered unresectable if there is: bilateral segmental ductal extension, unilateral atrophy with either contralateral segmental ductal or vascular inflow involvement, or unilateral segmental ductal extension with contralateral vascular inflow involvement.[24] Those that are resectable still present unique challenges as the disease can extend longitudinally along the hepatic ducts and obtaining a negative margin is often difficult. Resection of the involved intra- and extrahepatic bile ducts in conjunction with hepatic resection has become the standard of care.[24–26] The infiltrative nature of the tumor and the anatomic proximity of a Klatskin tumor to the PV, hepatic arteries, and IVC predisposes it to vascular involvement. Hepatic surgeons must therefore be facile in perihepatic vascular reconstruction of the PV, hepatic artery, or retrohepatic IVC in cases of locally advanced cholangiocarcinoma.

These combined resections are associated with higher morbidity and mortality, and management at high volume centers within a multidisciplinary team experienced in both surgical and perioperative management of these diseases is highly recommended.

General Considerations and Surgical Principles

In the management of hilar cholangiocarcinoma, tumor resectability must first be defined preoperatively. This includes cross-sectional imaging with either triphasic computed tomography (CT) or magnetic resonance imaging/cholangiopancreatography (MRI/MRCP) to assess the extent of vessel involvement. Variant vascular anatomy and ductal vascular relationships must be defined for preoperative planning for successful resection and vascular reconstruction. It is paramount to confirm vessel accessibility above and below the tumor level for vascular anastomosis.

The general principles of vascular reconstruction apply. It is essential to preoperatively address the need for vascular access, ability to establish proximal/distal control, and select appropriate conduits for vessel reconstruction in each patient. Guidelines for liver resections include having a postoperative future liver remnant (FLR) of greater than 0.6% of total body weight (greater in the pretreated or cholestatic liver), or an estimation of the future liver remnant function of greater than 2.3%/min/m^2.[27,28] It is therefore recommended to obtain volumetric assessment preoperatively to avoid postoperative complication and liver insufficiency/failure, even more so in planned

resections in conjunction with vascular reconstruction. In cases of borderline FLR, preoperative portal vein embolization (PVE) has been used as an important adjunct. In such cases, PVE should be performed 4 to 6 weeks before resection to allow time for adequate hypertrophy.[29]

Portal Vein Reconstruction

Reconstruction of the PV in conjunction with hepatectomy was first described in the Western literature by Blumgart in 1990 for hilar cholangiocarcinoma.[30] Several years after, Neuhaus and colleagues described an extended bile duct resection consisting of *en bloc* eradication of the entire biliary tree by a no-touch technique combining total hepatectomy, partial pancreaticoduodenectomy, extended lymphadenectomy, and liver transplantation.[31,32]

PV resection is the most common vascular resection performed for hilar cholangiocarcinoma and considered a means to obtain negative margins, which is associated with a better chance of long-term survival.[33] In one series of 52 hepatectomies with portal vein resection, 69.2% had histologic portal vein invasion. In those who didn't have occult invasion, however, the distance between the leading edge of the cancer cells and the outer layer of the adventitia was most often less than 1 mm. The authors therefore recommend *en bloc* portal vein resection when the portal bifurcation in involved on inspection in the operation room.[34]

Preoperative planning and understanding the portal venous anatomy as well as the position of the hepatic artery is key for successful outcomes. In general, primary end-to-end anastomosis is preferred compared to interposition grafting. To perform a primary anastomosis, complete mobilization of the proximal main PV to the level of the pancreas is recommended. For right-sided hepatectomies, a minimum of 0.8–1.0 cm of PV before its branching point is required for clamp placement and anastomosis between the main and left PV (Fig. 195.5).

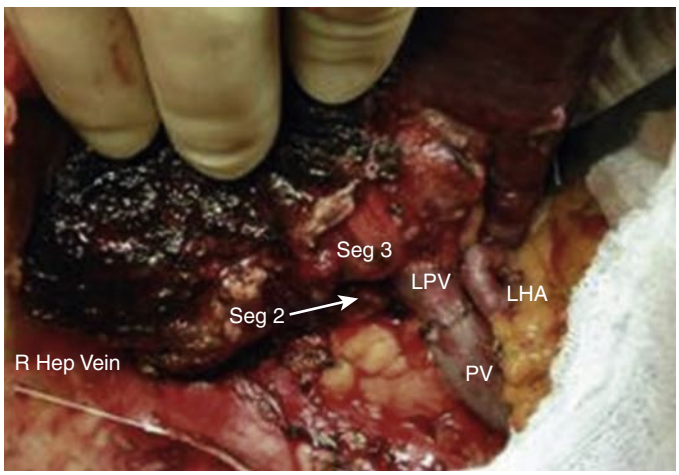

Figure 195.5 Portal Vein Reconstruction During Hepatectomy. The tumor has been resected with a right trisectionectomy with bile duct resection and PV resection. The main PV has been anastomosed to the left PV. *LHA,* left hepatic artery; *LPV,* left portal vein; *PV,* portal vein; *R Hep Vein,* right hepatic vein. (From Berumen J, Hemming A. Vascular reconstruction in hepatic malignancy. *Surg Clin North Am.* 2016;96:283–298.)

Anastomosis of the left PV can almost always be performed in an end-to-end fashion as the left PV is accessible and should be performed before the liver itself is transected. If needed, the anastomosis can be performed after parenchymal transection.

As left-sided resections usually require a more extended resection, the right posterior sectoral branch becomes the general target for anastomosis, although anastomosis can be to the right PV if possible. This reconstruction is usually performed after transection of the liver. If the main PV does not reach, common autologous vein grafts including left renal, femoral, jugular, and even hepatic vein from the resected liver can be used. If no native veins are available, synthetic or cryopreserved grafts can be used but, if possible, should be avoided due to risk of infection and thrombosis.[25,35,36]

Long-term survival following hepatectomy with PV resection depends entirely on the ability to achieve negative margins. Hence, with aggressive surgical care, the number of resectable and, therefore, curable patients has increased over time. Morbidity of combined resection with concomitant vascular reconstruction has improved over the last decade. Several studies have shown that patients undergoing combined hepatectomy and PV resection with negative margins have similar outcomes to patients with negative margins undergoing hepatic resection alone.[34,35,37,38]

Hepatic Artery Resection

In contrast to PV resection, data on hepatic artery reconstruction is more limited and long-term survival benefits have not been clearly described.[39] However, an increasing number of series have successful outcomes of hepatectomies and PV/hepatic artery reconstruction in a selected patient population.

In most cases in which a hepatic artery resection in indicated, the artery is involved at its bifurcation and thus necessitates combined PV resection. Prior to any arterial reconstruction, it is of highest importance to review the anatomic variation in case native vessels are needed. As with the PV reconstruction, assessment of adequate clamping space for proximal and distal control sites and options for suitable grafts need to be made preoperatively. Arterial reconstruction is most often performed after completion of PV reconstruction, but an arterial reconstruction-first approach has also been described in the literature.[40] When arterial reconstruction occurs after PV reconstruction, this is usually done after the specimen is removed and the liver is transected. To perform a tension-free end-to-end primary anastomosis, the artery must be fully mobilized. The preferred conduit for interposition graft is the GSV (Fig. 195.6).[35,41] Other options include the radial or splenic artery, however these should only be considered in the absence of a suitable saphenous vein.

Early reports of hepatic artery resection with hepatectomy for cholangiocarcinoma demonstrated worse long-term outcomes with a higher operative mortality of up to 55%.[39,42,43] Indeed, a 2013 meta-analysis of 24 studies concluded that arterial resection results in higher morbidity and mortality with no proven benefit.[42] More recent outcomes from high volume centers with experience, however, have shown acceptable

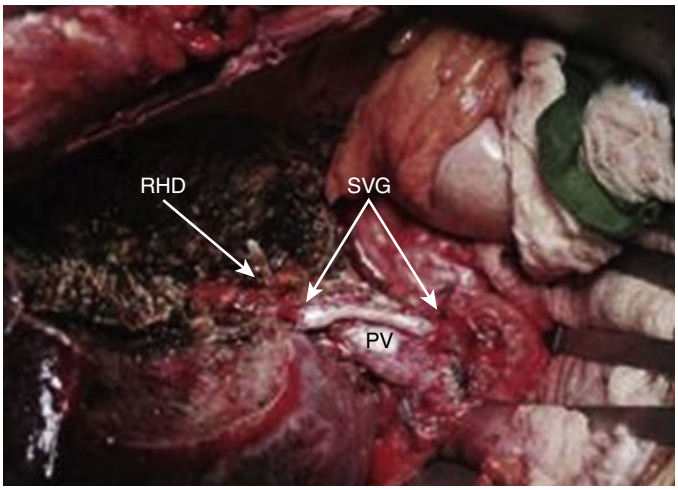

Figure 195.6 Hepatic Artery Reconstruction During Hepatectomy. Extended left hepatectomy for hilar cholangiocarcinoma has been performed. The hepatic artery has been resected with a saphenous vein graft placed from the proper hepatic artery to the right hepatic artery several millimeters before it divides into anterior and posterior divisions. *PV,* portal vein; *RHD,* right hepatic duct; *SVG,* saphenous vein graft. (From Berumen J, Hemming A. Vascular reconstruction in hepatic malignancy. *Surg Clin North Am.* 2016;96:283–298.)

results combining arterial and PV reconstruction.[36,44–46] Nagino et al. report the largest series of 50 patients who underwent combined PV and arterial reconstructions with an operative mortality rate of only 2%. With advanced microsurgical techniques, 32 of their cases were performed in a primary end-to-end fashion, 11 with a saphenous vein and radial artery interposition graft, and 2 using a left or right gastric artery. R0 resection was achieved in 66%, with 1-, 3-, 5-year survival rates of 78%, 36%, and 30%, respectively.[36] Other authors similarly report no difference in postoperative complications or overall survival when propensity matching to patients undergoing hepatectomy without arterial resection,[45] comparable rates of R0 resection with those undergoing hepatectomy alone or with PV resection (although higher rates of lymph node metastases),[46] and even a series of 26 patients who underwent hepatic artery resection without reconstruction.[47]

Inferior Vena Cava Resection

IVC involvement has traditionally been a contraindication to resection for hepatic and biliary malignancies given the poor postoperative outcomes. However, with improved techniques for liver resection and perioperative management, tumors involving the IVC and hepatic veins are now considered resectable in select patients with hepatic malignancies with acceptable morbidity and mortality.

Caval reconstruction depends, as with any other vascular reconstruction, on the degree and extent of involvement. If feasible, primary resection with a side-bite clamp with primary anastomosis or patch repair can be considered (Fig. 195.7A and B).[48,49] Otherwise, complete replacement of the vena cava with a synthetic or biologic graft should be considered (Fig. 195.7C for schematic and Fig. 195.8A for intraoperative photograph). In cases of contamination of the operative field by bowel contents, it may be necessary to reconstruct the IVC utilizing autologous vein (saphenous, jugular, or femoral) assembled in a spiral fashion in order to achieve a conduit of adequate caliber to match the native IVC (see Fig. 195.7D for schematic and Fig. 195.8B for intraoperative photograph). For complete caval replacement, the IVC should be exposed above and below the tumor and resection can be performed along with the parenchymal resection after vascular control has been obtained. We routinely administer systemic anticoagulation intraoperatively using intravenous heparin (100 U/kg) administered prior to vascular cross-clamping and dosed to maintain an activated clotting time greater than 250 seconds until restoration of venous flow is achieved. Primary end-to-end repair may be feasible with a resected portion up to 3 cm. However, larger defects should be reconstructed using synthetic or biologic graft material. Reconstructive options include an interposition graft with a large caliber (18–22 mm) polytetrafluoroethylene (PTFE) ringed graft or a bovine pericardium patch if the caval defect is less than one-third the circumference. There is no clinical evidence that using synthetic material leads to higher risks of infection in these vascular reconstructions.[50–53]

IVC resection and reconstruction has been associated with higher morbidity and mortality rates, but this risk has been accepted given its benefits in experienced hands and lack of alternative curative approaches.[51,53] The largest series by Hemming and colleagues included 60 patients over a study period of 16 years.[54] In their study, defects of greater than 5 cm were repaired with autologous vein, bovine pericardium, or Gore-Tex. More than half of their patient population required full reconstruction with a Gore-Tex graft. Perioperative mortality was 8% and 3-year survival 35%. Others have reported similar operative mortality, with an 8.1% mortality rate when pooling 111 patients from 13 total studies. Patency of the graft on follow-up was 98.2%.[55] These results demonstrate that combined liver and IVC resection can be beneficial in fit and highly selected patients, but these radical resections should only be executed at highly specialized centers with experienced hepatobiliary surgery and liver transplantation and capacity of perioperative ICU and interventional radiology.

SOFT TISSUE SARCOMA

Soft tissue sarcoma (STS) is a rare, heterogeneous group of tumors of mesenchymal origin, comprising over 50 histologic subtypes and representing 1% of all adult cancers.[1,56,57] The underlying oncogenesis of these tumors varies widely amongst the various subtypes. The most commonly affected site is the extremity (approximately 40% of cases)[56]; however, STS may arise anywhere in the body. STS is often locally aggressive and as such often involves multiple anatomic structures. Complete surgical resection is the mainstay of treatment and the only potentially curative therapy. Owing to the infiltrative nature of these tumors, local recurrence had historically been the pitfall of treatment and highlights the need to achieve wide, microscopically negative margins.[58–60] Management is best handled at high volume centers within a multidisciplinary team experienced in both surgical and medical treatment of this disease.

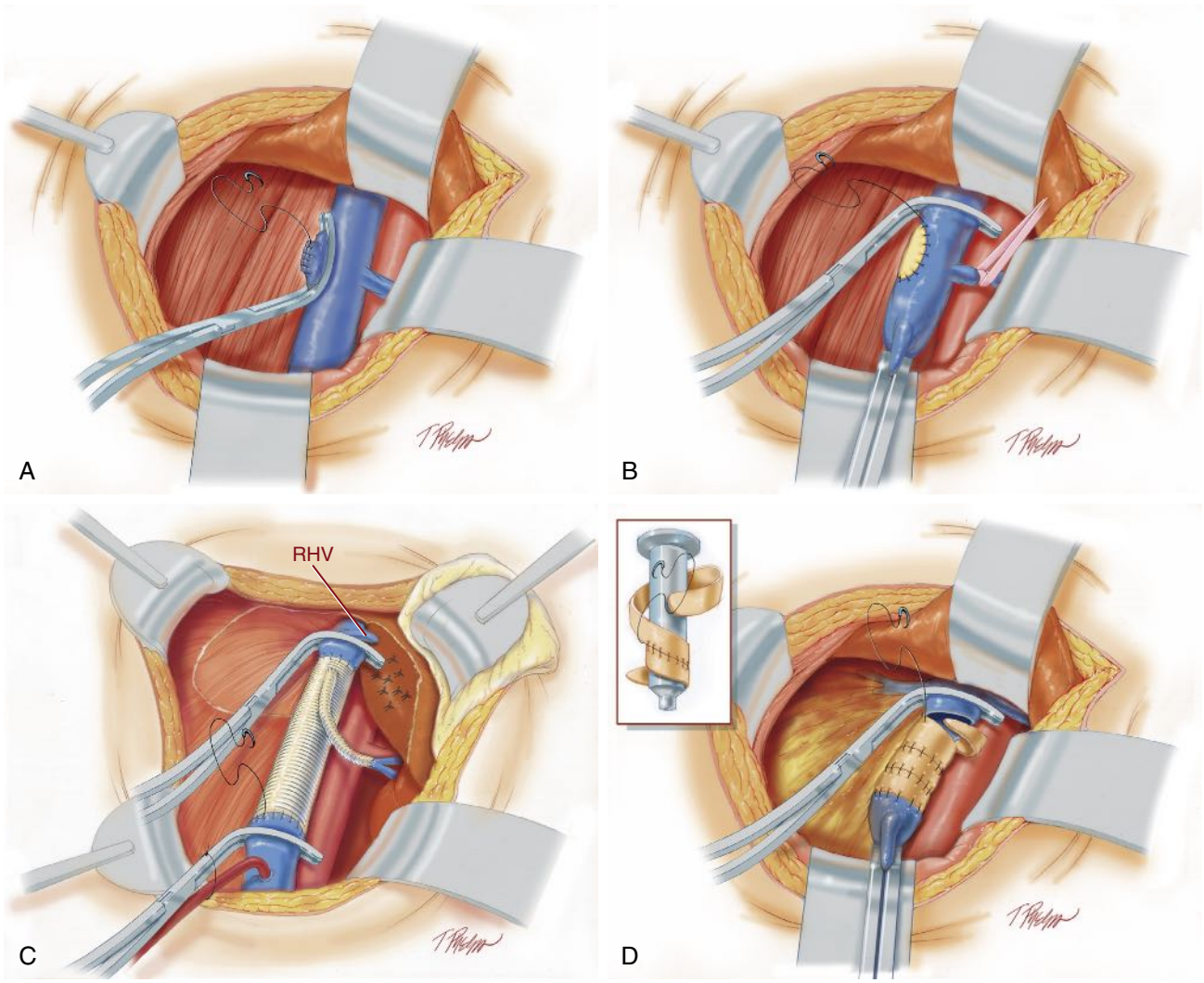

Figure 195.7 Methods of Inferior Vena Cava Reconstruction. (**A**) Primary repair. (**B**) Patch repair. (**C**) Graft reconstruction. (**D**) Spiral vein graft reconstruction. *RHV,* right hepatic vein.

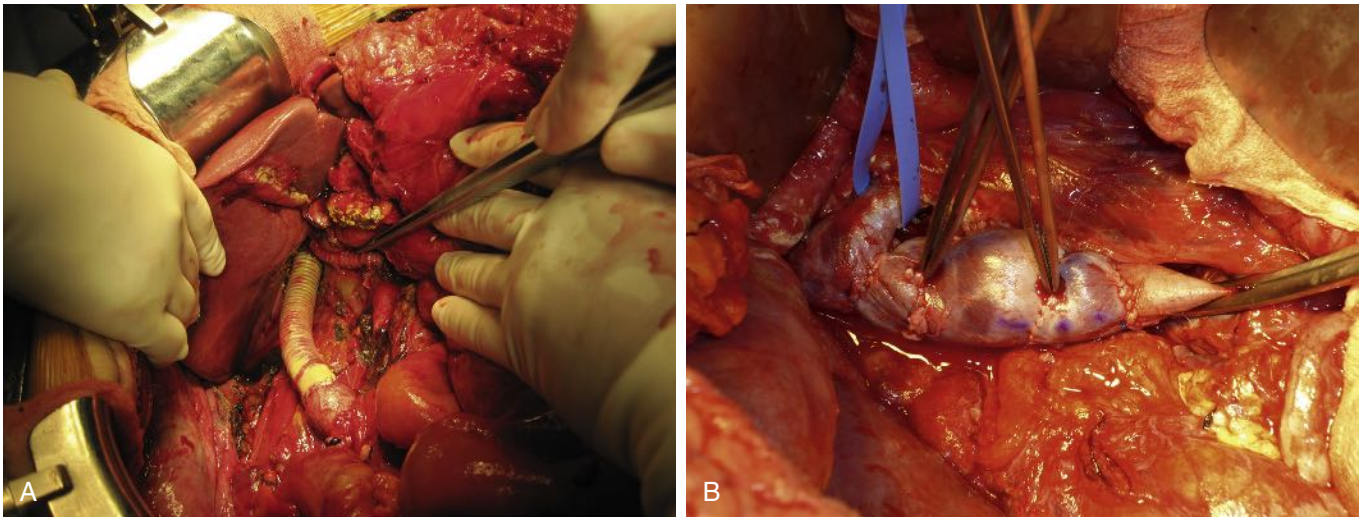

Figure 195.8 Intraoperative photographs of inferior vena cava reconstructions including (**A**) prosthetic interposition graft with reimplantation of left renal vein and (**B**) spiral vein reconstruction using an autologous vein graft.

The surgical management of STS is further complicated when major vasculature is involved. Any major blood vessel or vascular bundle may require resection in order to remove all disease. Amputation was historically considered the ideal procedure to achieve local control of extremity STS.[61,62] Since the hallmark study by Rosenberg and colleagues in 1982 demonstrating similar oncologic outcomes of limb-preserving surgery in combination with adjuvant radiation as compared to amputation alone, limb preservation has become the modern standard of care, but often requires major vessel resection and reconstruction.[63,64] Both resection and reconstruction require careful planning among a team of experienced oncologic and vascular surgeons given the complex anatomy and locations of these tumors.

General Considerations and Surgical Principles

Management of STS requiring concomitant vascular reconstruction begins with a standard oncologic workup, including appropriate staging. Each case should be individualized to the specific histologic type and managed within a multidisciplinary team. When vascular reconstruction is necessary, cross-sectional imaging with either contrast-enhanced CT or MRI is sufficient to delineate anatomic details such as involved vessels, modification to normal blood flow patterns, development of collaterals, and presence of intravascular thrombus. MRI is particularly useful in defining involvement of soft tissues adjacent to vascular structures.[65] Adjuvant imaging modalities such as duplex ultrasonography can be helpful in select cases but often do not add significant information to the operative plan.

Considerations that are essential to address preoperatively include the need for vascular access, ability to establish proximal/distal vascular control, possible endovascular adjuncts, and specific strategies for reconstruction of the involved blood vessels. Technique, extent of vascular resection, and choice of conduit vary widely among the literature and are often based on surgeon preference.[64,66–70] The most common materials utilized for oncovascular reconstructive surgery are summarized in Box 195.1. Short- and long-term patency rates of vascular bypass in STS resection are comparable to those performed for atherosclerosis. Preoperatively, embolization of vessels perfusing hostile surgical fields such as large pelvic tumors has been employed to help manage predicted intraoperative bleeding.[71] Postoperative endovascular interventions may also be utilized to provide secondary patency and extend the life of a functioning vascular conduit.

The extent of vascular resection and subsequent reconstruction is based upon the extent of the lesion, the predicted patient morbidity, and the preoperative anatomy. When curative resection is the goal, all involved vascular structures must be completely removed to achieve negative margins. In difficult anatomic regions where dissection may lead to massive hemorrhage and vascular involvement is unclear, the decision can be made to shave the tumor away from major vessels as opposed to a formal resection (Fig. 195.9). Although in some instances safer, this technique may leave behind residual microscopic disease along the adventitia. For arterial resections, reconstruction must always be performed given the inevitability of limb ischemia if adequate perfusion is not restored. If less than 50% of the vessel circumference is resected, patch angioplasty is an acceptable option. More extensive lesions require formal arterial bypass.

Venous resection with subsequent reconstruction is less definitively managed, with multiple options based on the clinical scenario. Veins which are chronically occluded or in the periphery of the surgical field can be sacrificed via ligation without significant effect on preservation of the limb\and this is well tolerated.[72] Likewise, preoperative imaging displaying abundant venous collaterals can allow for ligation of major veins with similarly good outcomes. Without evidence of collaterals or preoperative occlusion, the decision to reconstruct major veins is debated in the literature. Proponents of venous reconstruction cite that it adds very little morbidity to the overall procedure, while simultaneously acting as prophylaxis to severe postoperative venous hypertension with sequelae similar to that of a post-thrombotic syndrome.[73] Arguments

BOX 195.1 Materials Utilized for Arterial/Venous Reconstruction

Autologous vein
- Great saphenous vein
- Femoral vein
- Splenic vein
- Jugular vein
- Left renal vein

Cadaveric, cryopreserved vein
Cadaveric, cryopreserved artery
Bovine pericardium
Synthetic conduit
- Polytetrafluoroethylene (PTFE)
- Polyethylene terephthalate (Dacron)

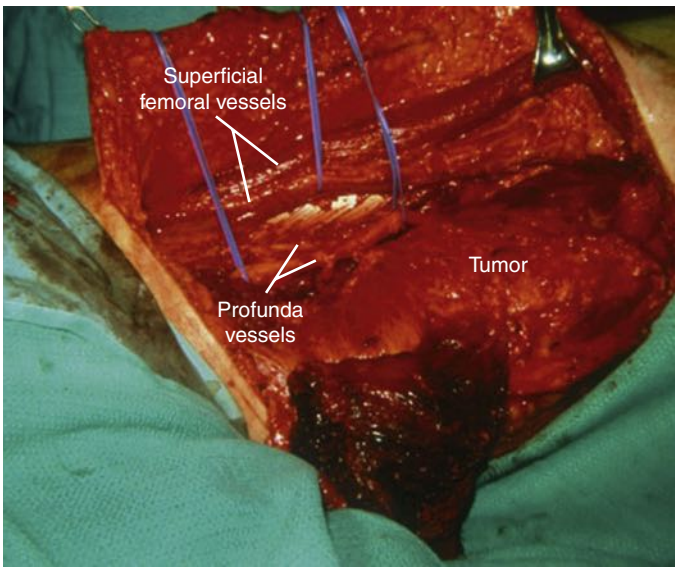

Figure 195.9 Dissection of a medial thigh sarcoma away from the superficial femoral and profunda femoris arteries. (From Karakousis C. Tumor in the medial thigh. In: *Atlas of Operative Procedures in Surgical Oncology*. New York: Springer Science + Business Media; 2015, Ch. 48, p. 327, Fig. 48.8.)

against venous reconstruction include reports of high rates of occlusion, similar incidence of postoperative edema with or without venous reconstruction, and the ability to manage any postoperative edema with medical treatments such as limb elevation and compression.[64,74,75] If a flap repair is used to cover the surgical defect, functional venous collaterals may also develop in the postoperative period and render venous reconstruction unnecessary. Overall, it is acceptable to perform venous reconstruction when indicated but is not a surgical necessity.

Extremity Soft Tissue Sarcoma

The extremity is the most common location of STS. Historically, 40% of STS cases localized to the extremity resulted in amputation.[76] At that time, recurrence rates were 30% after wide resection and exceeded 60% after local excision. Since the advent of adjuvant radiotherapy and improvements in chemotherapy, limb-sparing procedures evolved to become the standard of care.[63] Importantly, limb salvage with vascular reconstruction offers comparable local tumor control and overall survival as compared to amputation.[72,74] Functional outcomes and quality of life are improved with limb-sparing procedures, which is particularly important given the relatively young mean age of patients with STS.[77]

Any major upper or lower extremity vessel may be involved in STS, and thus thorough knowledge of both the vascular anatomy and possible bypass options is a prerequisite to optimal patient outcomes. In order to achieve negative margins, the extent of the resection may be more significant than originally planned based on preoperative imaging. Thus, the ability to be flexible in regards to an operative plan is also paramount. The predominant site of STS is the lower extremity and therefore the vast majority of resections subsequently involve a lower extremity bypass. Upper extremity vascular resection and reconstruction is rare, with multiple options for arterial reconstructions of the extremity reported in the literature.[70,78,79]

Choice of conduit in vascular reconstruction of the extremity after STS resection is based upon surgeon preference. For arterial reconstructions, most centers utilize autologous vein whenever possible as it provides lower rates of infection.[64,75] The GSV is the most commonly used autologous conduit given its length and ease of accessibility; however, several reports have illustrated good outcomes with the femoral vein as well.[70,80] When possible, the graft should be harvested from the contralateral limb so as not to worsen limb edema on the side of the primary resection, which commonly disrupts native venous tributaries and lymphatics. In a study of 17 limb salvage surgeries with vascular resection and reconstruction for extremity STS, Park et al. found superior patency of autologous vein conduit as compared to synthetic graft, as did Nishinari et al. in a series of 25 patinets.[64,81] Autologous vein conduit is therefore preferable for reconstruction whenever possible.

Outcomes with respect to vascular reconstructions for limb preservation are exceedingly good, as evidenced by limb salvage rates of over 90% in nearly all published studies. Overall, the most common morbidities related to vascular reconstructions after STS resection are wound infection, skin flap necrosis, limb edema, hematoma, and graft thrombosis. Five-year arterial patency approaches 85%.[63,71,72,81] Early arterial thrombosis is quite rare but necessitates reintervention to restore perfusion to the extremity, which typically involves revision and/or complete reconstruction of the vascular conduit. Venous patency rates are more variable and less well characterized. In general, thrombosis is more common in venous reconstructions secondary to the low flow state of this system. The clinical significance of these events is typically negligible, as most episodes of venous thrombosis are successfully managed with systemic anticoagulation alone. A recent series reports a 5-year venous patency of 75%.[82]

Patients with STS who undergo limb-preserving surgery with adjuvant radiotherapy have similar long-term outcomes as those who undergo limb amputation. Five-year overall survival ranges from 40% to 68%.[64,73,82] The success of STS resection is incumbent upon complete removal of disease, and vascular reconstructions allow removal of involved vessels to achieve an R0 resection. With current limb-preserving techniques and radiotherapy, local recurrence has diminished from as high as 65% historically to approximately 16% in the current era.[58,59,64]

Retroperitoneal Soft Tissue Sarcoma

Retroperitoneal STS represents a particularly challenging surgical disease, which is only further complicated when the aorta, IVC, or both are involved. Retroperitoneal STS comprises 15% of all cases of sarcoma.[83] As with other anatomic locations, these tumors are locally aggressive and invade nearby structures. These tumors are often asymptomatic until they achieve a sufficient size to cause compression of local structures, and as such typically involve multiple organs. Multivisceral resections (defined as the removal of two or more organs) are frequently required to achieve negative margins.[66,69] When the aorta or IVC are involved, additional concerns arise as both structures must be resected if a curative surgery is planned.

Preoperative workup must focus specifically on identifying the extent of vascular and solid organ involvement. Tumors may present anywhere from the aortic hiatus and retrohepatic IVC superiorly to the common iliac bifurcation inferiorly. Extension into the pelvis makes adequate exposure and safe dissection more difficult, and in some cases impossible. When the aorta or IVC are involved, consideration must be given to the possible need for cardiopulmonary or veno-venous bypass. The potential need for postoperative renal replacement therapy (RRT) must also be considered if the renal vasculature requires resection or a formal nephrectomy is a possibility. Based on the extent of the tumor, a tentative but specific operative plan must be developed in order to make preparations for the vascular reconstruction.

With respect to vascular reconstruction, involvement may comprise the artery alone, vein alone, or a combination of the

two. Similar to vessels in the extremity, if less than 50% of the vessel circumference is resected, angioplasty (primary or patch) is a reasonable option. Both synthetic and autologous materials can be used for this purpose. In the setting of bowel resection, which is common in retroperitoneal STS, some centers opt to avoid synthetic materials.[84] If greater than 50% of the vessel circumference is involved, a formal resection and reconstruction must be performed to avoid compromising flow. Both the aorta and the IVC may be reconstructed utilizing autologous or synthetic conduits.[85] Given the large diameter of both vessels, synthetic conduits are generally the first-line choice. These offer several advantages, including avoidance of donor site morbidity, ease of matching vessel diameter, and a shorter procedure. For situations in which IVC reconstruction is exceedingly difficult or dangerous, the IVC can be ligated. Up to half of these patients will develop subsequent venous hypertension and lower extremity edema if collaterals are poor.[86,87] Similarly to reconstructions in the extremity, the two exceptions to this are if occlusive thrombus is present proximal to the resected vein segment preoperatively, or if significant venous collaterals have been identified on cross-sectional imaging. In either of these scenarios, the IVC can be ligated without significant sequelae.

Postoperative management after retroperitoneal STS resection has the potential for high morbidity given the multivisceral nature, extensive dissection required to achieve negative margins, and prolonged time spent in the operating room to perform the necessary vascular reconstruction. Mortality is notably rare (estimated 4%) but is certainly a more significant concern as compared to resection of extremity STS.[69] Patency of the reconstructed aorta and IVC is very good as a result of the large diameter of these vessels, with overall graft patency rates of approximately 89% for artery and 94% for vein at a median of 19.3 months follow-up.[69] Common early postoperative morbidities include hemorrhage, wound infection, prolonged ileus, and renal insufficiency.

Oncologic outcomes for retroperitoneal STS involving major blood vessels are comparable to those of the extremity only if complete resection with negative surgical margins (R0) is achieved. In the largest series to date assessing retroperitoneal STS resection with major blood vessel involvement, R0 resection yielded 2- and 5-year survival rates of 90% and 66.7%, respectively. However, patients with an R1 resection had mean survival of 21 months, and R2 resections had 8 months mean survival. Local recurrence in this series approximated 18% for complete resections.[69] Neoadjuvant and adjuvant therapies vary widely among centers, but nearly all patients will receive some variant of adjunctive treatment.

SUMMARY

The PV, SMV, and IVC may be safely and expeditiously resected as an adjunct to tumor resection in appropriate candidates. The safety and feasibility of these techniques have been well established on the basis of institutional experiences from multiple centers, and they facilitate a higher rate of R0 resections in pancreatic and hepatobiliary malignancies, soft tissue sarcomas, as well as other tumors of the IVC, kidneys, adrenals, and abdomen. Arterial resection for the treatment of pancreatic and hepatobiliary malignancies remains more controversial but can be safely performed in high-volume centers. Vascular reconstruction – venous and arterial – is also utilized in the treatment of extremity STS, permitting limb-salvage with equivalent outcomes to amputation when combined with radiation and chemotherapy.

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A complete reference list can be found online at www.expertconsult.com.

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196 CHAPTER

Chronic Exertional Compartment Syndrome

ELINA QUIROGA, NITEN SINGH, and AMIR GHAFFARIAN

Chronic exertional compartment syndrome (CECS) is a nonatherosclerotic cause of claudication that is often referred to a vascular surgeon. As the name implies, it is exercise-induced leg pain that usually presents in young, active patients such as athletes and military personnel. Symptoms are generally confined to the compartment of the leg that is affected and are reproducible to timing, distance, and the intensity of exercise.

HISTORY

CECS was first described in 1912 by Edward Wilson during an expedition to the South Pole.[1] In his diary, he described his symptoms, which are consistent with anterior compartment syndrome. Various descriptions were offered until G. E. Mavor published his article regarding a professional soccer player in Aberdeen, Scotland, who complained of pain in the anterior compartments of both legs during exercise. In addition, he had paresthesias associated with the pain in his foot. Mavor ultimately performed the first published fasciotomy for CECS. Interestingly, his repair was completed with a fascia lata graft to close the defect. The operation worked so well that after he performed it on the contralateral leg, the patient was able to resume his soccer career.[2]

ETIOLOGY

The exact mechanism is unknown but CECS is believed to arise from increased compartment pressure (ICP) resulting in transient muscular ischemia within the enclosed myofascial space during endurance training.[3,4] In contrast to an acute compartment syndrome, in which the pressure remains elevated, in CECS the pressure dissipates over time and the symptoms resolve. Theories that have been proposed to explain the development of ischemia include arterial spasm, microcirculatory obstruction, and arteriolar and venous collapse due to pressure disturbances.[5] Studies on normal muscle reveal a 20% increase in muscle size secondary to increased blood volume and exercise.[6] In addition, fascial thickening and muscle hypertrophy have been postulated to account for this syndrome.[7] However, some studies, including those by Amendola, have found that pain is not related to ischemia on nuclear medicine blood flow imaging; in their study of patients with CECS utilizing MRI did not find ischemic changes in all of the patients with elevated pressures.[8]

EPIDEMIOLOGY

Risk factors include anabolic steroid use, with resultant muscle hypertrophy and abnormal biomechanics during running that favor increased load-bearing by various compartments of the leg.[9,10] The estimated prevalence of CECS in patients with exercise-induced leg pain is 10% to 60% in relation to the diagnostic criteria utilized.[11] In a study of 150 athletes with exercise-induced leg pain, CECS was the most common condition (34%), followed by stress fracture of the tibia, accounting for 25%.[12] Most patients with CECS present with pain in the anterior and lateral compartments and 70% to 80% of these

individuals will experience bilateral symptoms. Studies have not revealed a difference in males and females. The median age of presentation is 20 years.[13] The condition is often seen in military personnel and recruits. Waterman and colleagues reviewed the military health database over an 8-year period and their study showed an average annual incidence of 0.49 per 1000 at-risk person-years. They identified 611 patients who underwent 754 surgical procedures, and of these procedures, 77.4% involved only the anterior or lateral compartment. Symptom recurrence after treatment was 44.7%, and 27.7% of these individuals were unable to return to full activity. Surgical failure was associated with perioperative complications, activity limitations, and persistence of preoperative symptoms. The investigators concluded that CECS was a substantial contributor to lower extremity disability in the military population.[14] In a systematic review among athletes, runners and soccer players were most prone to develop CECS. In addition, the presence of deep posterior compartment syndrome in this young population is associated with higher rates of surgical failure.[15]

DIFFERENTIAL DIAGNOSIS

A history of reproducibly developing pain in a compartment of the leg with exercise in a young, active person is typically seen. The pain can be described as burning or aching. In patients referred to a vascular specialist, the main diagnosis that should be considered is popliteal entrapment syndrome (PES) (see Ch. 144, Nonatheromatous Popliteal Artery Diseases). Although patients may describe similar symptoms as seen in CECS, often a diminished pulse is not noted with provocative maneuvers; subsequent noninvasive studies will generally fail to identify popliteal compression. Other etiologies of exercise-induced leg pain – such as stress fracture and medial tibial stress syndrome (shin splints) – can be ruled out by physical examination, X-ray imaging, and bone scintigraphy. Other nonatherosclerotic etiologies that should be considered include cystic adventitial disease of the popliteal artery and thromboangitis obliterans (Buerger disease) (see Ch. 139, Thromboangiitis Obliterans). Both of these conditions, along with atherosclerosis, are not generally seen in this young, active population.

ANATOMY

The leg is divided into four compartments: anterior, lateral, superficial, and deep posterior. The structures located within the anterior compartment include the deep peroneal nerve, anterior tibial artery, tibialis anterior, and extensor muscles of the toes. The lateral compartment contains the superficial peroneal nerve and the peroneus longus and brevis muscles. The superficial posterior compartment contains the gastrocnemius and soleus muscles and the sural nerve. The deep posterior compartment contains the tibial nerve, posterior tibial artery, peroneal artery, tibialis posterior muscle, and flexors of the toes.

CLINICAL PRESENTATION AND DIAGNOSIS

CECS should be suspected in a young, active patient with reproducible symptoms that occur with endurance training and resolve with rest (see Chapter Algorithm). In this patient population, in addition to the symptoms already described, exercise history may reveal neurologic symptoms based on the involved compartment. For example, for the most common compartments affected, the patient may describe weakness with dorsiflexion (anterior compartment, deep peroneal nerve), numbness of the dorsum of the foot (lateral compartment, superficial posterior compartment), or, more rarely, weakness of plantarflexion (posterior compartment, tibial nerve).

Physical examination is unrevealing at rest. The individual compartments may feel firm or be tender to deep palpation, and fascial hernias may be present as well.[3] Neurologic examination should focus on the suspected, specific compartment and nerve involved to identify chronic irritation. The pulse examination and resting ankle–brachial indices will be normal in these individuals.

The definitive diagnosis of CECS is established by invasive measurement of intracompartmental pressures (ICMPs). A handheld device is available (Stryker catheter, Kalamazoo, MI) that allows rapid measurement (Fig. 196.1). With this device, the pressure can be measured in the compartments of interest. The classic diagnostic criteria described by Pedowitz are as

Figure 196.1 Intracompartmental Pressure Measurement.

follows: ICMP before exercise 15 mm Hg; 1 minute after exercise, greater than 30 mm Hg; and 5 minutes after exercise, greater than 20 mm Hg.[16] The exercise regimen described in studies is often variable and inconsistent. A more recent protocol developed by Roscoe in the United Kingdom involves continuously measured ICMP before, during, and after participants exercise on the treadmill. A standardized exercise protocol was utilized, and the investigators compared patients with a suspicion for CECS with healthy volunteers. The protocol included measuring beyond 5 minutes of exercise and to maximal tolerable pain as the individuals tested went through three phases of exercise carrying a weighted backpack and with varying grades on the treadmill. When the investigators compared their technique, they found a higher sensitivity and specificity for the diagnosis of CECS when measurements are continued through exercise.[11]

Recent studies have investigated the use of MRI to diagnose CECS. Ringler performed a validation study with MRI in 76 patients referred for pain induced by lower extremity exercise; as a result, 23 patients met the clinical diagnostic criteria for CECS. Utilizing a T2-weighted intensity ratio of 1.54 and correlating with ICMP measurements, the sensitivity of MRI was 87% and specificity was 62%. Others have also had promising results with MRI and described the benefit of visualizing fascial thickening and edema as well muscle hypertrophy.[17] Other modalities such as near-infrared spectroscopy (NIRS) have been investigated as well. This technique is able to noninvasively measure the tissue oxygen saturation with a sensitivity similar to that of MRI.[18] All of these modalities are promising, but ICMP is the current "gold standard" for the diagnosis of CECS.

MANAGEMENT

Nonsurgical

Most patients are initially offered a trial of decreasing or stopping the physical activities that trigger the symptoms. Cessation of eliciting activities usually resolves all symptoms; but in this patient population, who are often high-performance athletes, it is not a realistic option. Multiple nonsurgical interventions have been described for the treatment of CECS, including the use of insoles and orthotics to correct excessive pronation, running on softer surfaces, physical therapy, icing, warm therapy, nonsteroidal anti-inflammatory drugs, and even local lidocaine injections.[10,13,19] All nonsurgical treatments have had little success; surgical intervention with compartment decompression is the only reliable option that can return these patients to prior activity levels.

Surgical

Surgical compartmental release is accepted as the only effective treatment of CECS. The goal of the intervention is to decrease the ICMP by increasing the volume of the affected compartments. Multiple fasciotomy techniques have been used, including subcutaneous and endoscopic fasciotomy, as well as fasciectomy, with similar results. This outpatient procedure can be performed under local, regional, or general anesthesia. A compressive dressing is usually applied in the operating room, and we prescribe graded compression stockings (15–20 mm Hg) for the first 14 days after the surgery for patient comfort.

Anterior and Lateral Compartment Fasciotomy

Following the technique described by Rorabeck in 1983, the compartments are released by using two 4-cm vertical skin incisions separated by a 15-cm skin bridge. The incisions are centered between the fibula and the crest of the tibia and a plane is developed between both incisions. Decompression of the anterior and lateral compartments is achieved by retracting the skin and incising the fascia 1 cm medial and lateral to the intermuscular septum (Fig. 196.2A). A similar decompression can be achieved by performing a single 5-cm skin incision over each compartment and incising the underlying fascia subcutaneously with Metzenbaum scissors (Fig. 196.3). Another

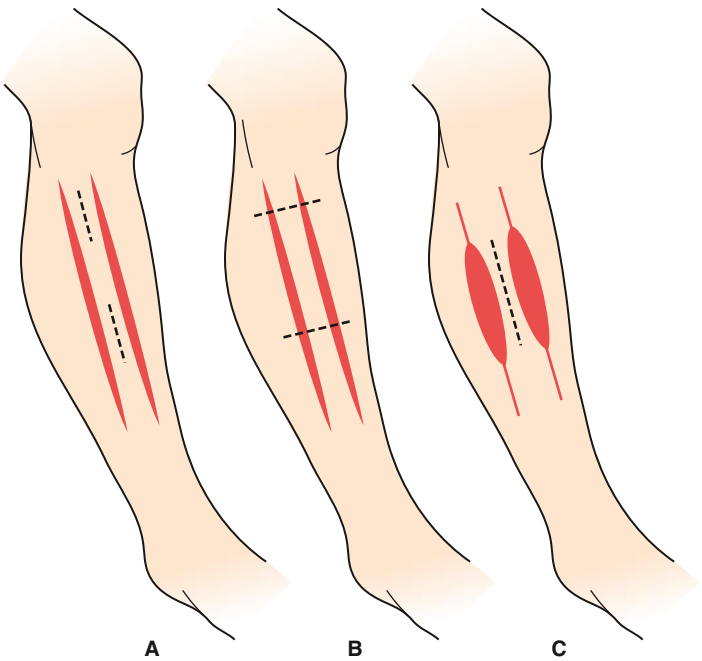


Figure 196.2 Schematic Representation of Alternate anterior and Lateral Compartment Release Techniques. See text for details. *Dotted line:* skin incision.

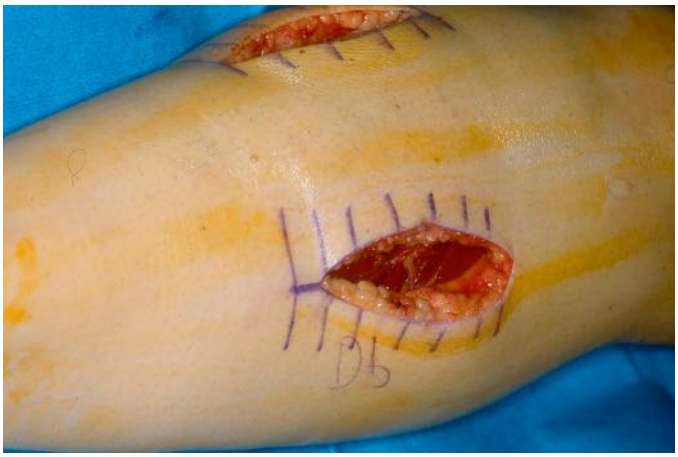


Figure 196.3 Anterior and Lateral Compartment Fasciotomy.

technique employs two transverse skin incisions to perform subcutaneous fasciotomy of the anterior and lateral compartments (see Fig. 196.2B).

Open fasciectomy of the anterior and lateral compartments is performed using a single incision lateral to the edge of the tibia. After raising subcutaneous flaps of appropriate length, the fascia of both the anterior and lateral compartments is exposed and an approximately 6- by 2-cm ellipse of fascia is removed. This procedure is usually combined with fasciotomies performed by incising the fascia proximally and distally in order to achieve complete compartment release while the fascia overlying the intermuscular septum is left intact (see Fig. 196.2C).

Posterior Compartments Release

One or two vertical incisions are made behind the posteromedial edge of the tibia. The greater saphenous vein and the saphenous nerve are identified, mobilized if needed, and protected during the procedure. The fascia is incised and, in order to decompress the deep posterior compartment, the tibial attachments of the soleus are taken down so as to expose the deep posterior compartment fascia. The fascia overlying the deep posterior compartment is incised, exposing the flexor digitorum longus and decompressing the compartment.

Endoscopic Compartmental Release

Similar to the technique of subfascial endoscopic perforator surgery (SEPS), endoscopic compartmental release has been described. A transverse incision is made in the proximal leg just medial to the fibular head and a dissection plane is created into the loose areolar tissue just superficial to the fascia where the balloon dissector is inserted. The balloon is advanced to the distal leg and inflated in order to create a cavity within the fascial cleft. The fascia overlying the anterior and lateral compartments is released under direct visualization.[20]

To release the superficial and deep posterior compartments, a skin incision is made proximally on the medial aspect of the leg; the balloon is advanced into the loose subcutaneous tissue just above the fascia, inflated, and removed after developing the cavity. Using endoscopic scissors and under direct visualization, the fascia overlying the superficial posterior compartment as well the fascia of the deep posterior compartment are released directly off the edge of the tibia.[20]

POSTOPERATIVE MANAGEMENT AND COMPLICATIONS

The patient is instructed to perform range-of-motion and stretching exercises, and we do not place limitations on weight bearing postoperatively. Patients are encouraged to ambulate early after the procedure. Vigorous activities such as running and participating in team sports are not recommended for the first 2 weeks to ensure skin healing. Activities are gradually advanced and the patient is expected to return to full activity in 6 to 8 weeks.

The most frequent complication is postoperative neurologic dysfunction, specifically superficial peroneal neuritis, which affects up to 5% of patients. Infection, seroma, hematoma, DVT, and wound dehiscence are rare in this patient population.

OUTCOMES

Although surgical treatment is accepted as the only effective treatment option for CECS, outcomes are not universally positive. Furthermore, there is no standardized tool, questionnaire, or metric to report the efficacy of the intervention, making the evaluation of success across published cases series difficult. Earlier reports described resolution of symptoms in almost 100% of cases, but recent papers report success rates below 50%.[21,22] In the military population, 25% of patients are unable to return to active duty even after surgical treatment.[14] Interestingly, 84% of patients are satisfied with the results of the procedure at short- and midterm follow-up.[15] Overall, the estimated clinical success rate of compartmental release for CECS is around 66%.[15]

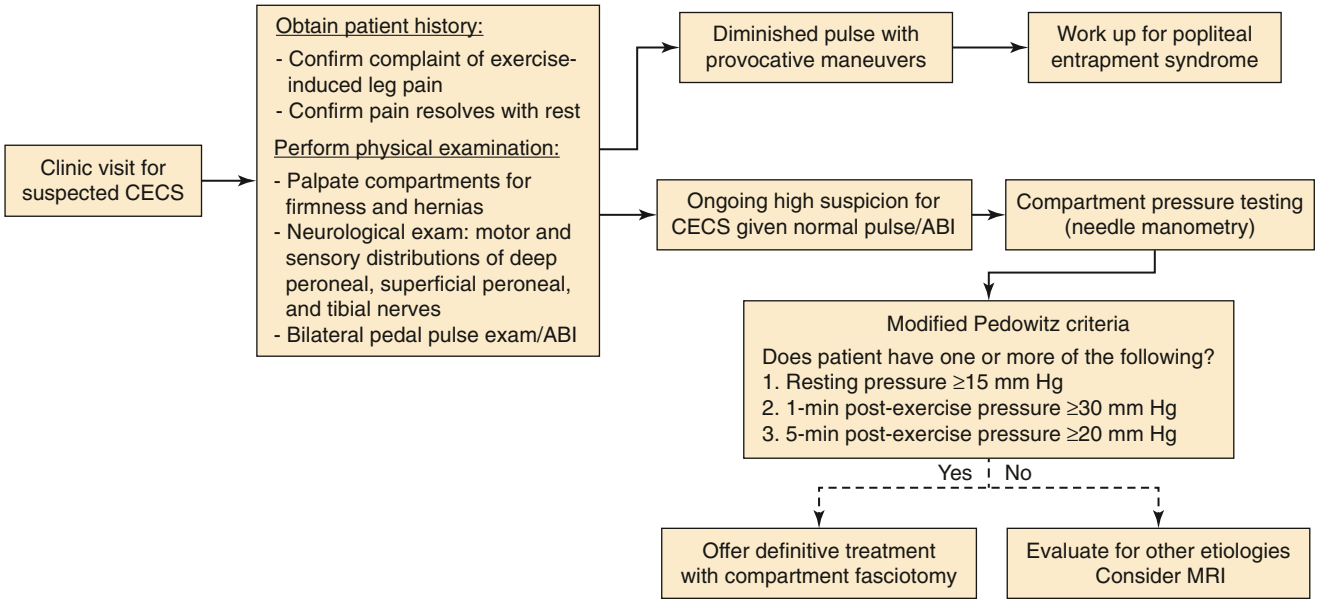
Recurrent symptoms are reported by 5% to 10% of patients, and approximately 6% of patients undergo revision surgery.[23] Incomplete or inadequate compartment decompression, as well as extensive scarring are the usual reasons for revision surgery.

Multiple studies have investigated predictors of surgical failure after all of the described procedures (fasciotomy, fasciectomy, endoscopic fasciotomy), which have yielded similar results. Based on anatomy, the diagnosis of CECS of the posterior compartment is associated with the poorest outcomes.[23,24] Satisfaction after the procedure and return to the previous level of activity does not correlate with preoperative ICMP values.[23] However, chronicity and a longer duration of symptoms are associated with worse outcomes. Poor outcomes have also been found among female athletes, but the underlying reason for this finding is unknown.[24]

CONCLUSION

CECS is an unusual cause of claudication in the young patient, and every vascular surgeon should understand the presentation, diagnosis, and treatment of this pathology. In contrast to older patients with claudication due to atherosclerosis, the symptoms of CECS occur with more strenuous exercise, and we should understand that cessation of activity is not a reasonable recommendation for this patient population. However, it is also important to appreciate that even though the procedure is not complex, the surgical outcomes are not uniformly positive.

CHAPTER ALGORITHM



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Waterman BR, Laughlin M, Kilcoyne K, et al. Surgical treatment of chronic exertional compartment syndrome of the leg. *J Bone Joint Surg Am*. 2013;95:592–596.

Study involving the review of 611 patients in the military with a description of outcomes and symptom recurrence.

A complete reference list can be found online at www.expertconsult.com

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CHAPTER 197

Development of a Multispecialty Practice and Operation of Multispecialty Cardiovascular Centers

MICHAEL R. GO, JEAN E. STARR, and BHAGWAN SATIANI

INTRODUCTION

A service line strategy has long been used by medical centers to counter inefficiency in provision of multidisciplinary care, improve quality, and capitalize on high-frequency diseases with well-reimbursed treatments. Common examples are neuroscience, cancer, and wound care services. The concept of a vascular service line has existed since World War II,[1] and organized cardiovascular (CV) centers have existed in civilian hospitals since the 1980s.

However, service line strategies involving multiple specialties can be a challenge in academic medical centers (AMCs), where departmental silos can splinter the care of a single patient. For example, vascular disease can be managed by vascular surgery, vascular medicine, interventional radiology, and cardiology.[2] These difficulties may also arise in community hospitals, where turf battles between private groups may exist.

Currently, the multispecialty CV center remains a priority of health system leaders,[3] but the forces shaping their evolution are changing rapidly in the contemporary healthcare environment. Successful multispecialty CV centers are adapting, whereas others are losing market share. Vascular diseases in particular represent a strategic priority for CV centers because of the projected growth in demand for services, disruptive technology, prevailing poor care coordination, and a lack of integration with cardiac disorders.[4] In this chapter, we review early examples of multispecialty CV centers and the impact of changes in market forces, consider development and operational aspects, appraise trends within existing CV centers, and look to the future.

EARLY EXAMPLES OF MULTISPECIALTY CARDIOVASCULAR CENTERS

An early concept of a vascular center was described by Elkin and DeBakey in 1943:

The problem of supplying competent specialized care by experienced personnel for large numbers of casualties with vascular injuries was resolved in World War II by the establishment in the Zone of Interior of vascular centers to which surgeons experienced in vascular surgery were attached and in which other surgeons could be trained. To these centers were sent patients with vascular injuries and diseases. The establishment of these centers made it possible to carry out the necessary treatment of such patients with an economy of equipment, personnel, and effort which would have been impossible had the patients been scattered through a large number of hospitals. It also permitted the observation of patients with vascular injury and disease in numbers far beyond those of any similar previous experience. Careful and detailed records were kept and analysis of data derived therefrom permitted deductions and conclusions which could not be gained from the small series of cases previously observed by surgeons in civilian practice.[1]

Even in the midst of war, these surgeons had the foresight to recognize and address the challenges and opportunities facing a service line strategy, all the while paying equal attention to the clinical care, teaching, and research missions. The War Department set up the first vascular center at Ashford General Hospital in West Virginia. It was, indeed, a true multispecialty CV center consisting of a surgeon, assistant surgeon, two medical officers, a cardiologist, a physiotherapist, and an officer to supervise reconditioning after treatment had concluded.

Modern CV centers do not have to deal with the volumes of military injuries that Ashford General Hospital did but instead must navigate an increasingly complex environment with a shifting regulatory landscape, decreasing reimbursement, demands for transparency and quality measures, and interspecialty competition. However, CV centers are well suited for multispecialty collaboration. Emphasis on one organ system, high volumes and visibility, and a major source of revenue for health systems, have led to initiatives to undertake new care models with reimbursement tied to varying incentives through novel strategies, such as Medicare demonstration projects. With increasing employment of all CV specialties by health systems, the task of getting multiple specialties to agree on protocols and quality metrics has become possible. Modern vascular centers that employed CV specialists arose in the 1980s and include the Mayo Vascular Center.[5]

The birth of the Mayo Vascular Center in 1987 arose from the recognition that because multiple clinical departments were involved in the diagnosis and treatment of most vascular diseases, diagnostic testing suites and physician clinics became physically and administratively distinct and spread across the campus. As the Mayo Vascular Center developed a national referral base, these separations introduced significant inefficiency. The strategic vision of the founders of the Center prioritized a "one-stop" patient experience and openness to any interested specialties. This represented an early recognition of patient satisfaction as a quality metric, as well as the potential for competition between specialties in the vascular space.

Initially, large private health systems were unable to duplicate the Mayo experience, which is unique both geographically as well as organizationally, following a foundation model for physician–hospital alignment.[6] However, as the fee-for-service model evolved into the health maintenance organization (HMO) era in the 1980s and 1990s, then to the present value-based payment (VBP) system in which cost containment and value are emphasized, academic, private, and foundational model CV centers have found success, and their strategic visions have dramatically changed and increased in complexity.

FORCES SHAPING THE EVOLUTION OF CONTEMPORARY MULTIDISCIPLINARY CARDIOVASCULAR CENTERS

The United States spends more than any other country on healthcare, and US healthcare expenditures are expected to exceed 20% of the gross domestic product.[7] Inefficiencies in US healthcare are widely viewed as opportunities to contain costs, particularly in the government-sponsored Medicare and Medicaid programs. Regulators and the public are increasing focus on value, transparency, and definitions of quality. Total demand for CV services is increasing rapidly as the population ages, while a specialty physician shortage looms.[4,8] What started out as a marketing tactic aimed at increasing market share has now evolved into a holistic focus on quality, efficiency, transparency, patient satisfaction, and cost, almost all driven by changing reimbursement systems. Health systems still continue to fight for market share to compensate for diminishing revenue. This is the difficult environment in which the contemporary multidisciplinary CV center must succeed. Hospital systems and physicians alike should weigh the advantages and disadvantages before undertaking the process of CV center formation (Table 197.1).

Changes in Demographics and Care Delivery

The number of board-certified vascular surgeons in the United States has remained relatively stable, and in 2010 there were, by one estimate, fewer than 3000. This number is projected to grow linearly over the next decades to approximately 3500 in 2040.[9] Simultaneously, the general population will continue to expand rapidly, and the elderly population even more quickly over the coming years. Vascular surgeons are one of the smaller physician workforces, yet they take care of a disease process that is one of the leading causes of death in the United States. A vascular surgeon shortage looms, and this has and will continue to shape the makeup of the vascular provider pool and the modes of delivery of vascular care.[8] Because vascular care is also provided by cardiologists, interventional radiologists, and vascular

TABLE 197.1 Pros and Cons of Establishing a Multidisciplinary Cardiovascular (CV) Center

Pros	Cons
• Common CV disease process • Demand for CV care is increasing • Ease of access for patients with multiple medical problems • Ease of access for referring physicians • Improved relationship and influence with payers • Decreased duplication of services and expenses • Improved quality oversight • Consolidated marketing strategy • Development of a CV scorecard to measure success	• Consolidation of services may require capital expenditures for physical facility • Physician engagement may be difficult due to diminished autonomy and interspecialty conflicts • May be seen as hostile to medical education and research • Change in reporting structure (especially academic medical centers) • Difficulties in aligning compensation among specialists • Challenges to aligning procedural privileging • Patients still require other services so not completely self-reliant

TABLE 197.2 Essential Components of a Multidisciplinary Cardiovascular (CV) Center

1. Medical/surgical specialties:
   a. Vascular and endovascular surgery
   b. Cardiothoracic surgery
   c. Cardiology: interventional and noninvasive
   d. Radiology: interventional and noninterventional
   e. Vascular medicine
   f. Anesthesiology
   g. Podiatry
   h. Neurology/neuroradiology
   i. Endocrinology (including lipid metabolism)
   j. Wound care specialist
2. Vascular nursing
3. Noninvasive vascular laboratory
4. Noninvasive cardiac laboratory
5. Rehabilitation: cardiac and vascular diseases
6. Prevention and wellness screening programs
7. Research
8. Education

medicine specialists, a multidisciplinary CV center makes an ideal organization in which to provide comprehensive services to patients with a common pathology (Table 197.2).

Although still relatively rare before the age of 50 years, by age 80 the prevalence of peripheral arterial disease (PAD) rises to 20%. By 2030, 180,000,000 people are estimated to have at least one risk factor for PAD.[9] Thus, as the elderly population continues to expand faster than younger segments, the prevalence of PAD will continue to increase sharply, and the number of PAD procedures will increase accordingly (Fig. 197.1). Furthermore, the elderly are living longer, requiring treatment over longer periods of time, and are accumulating more comorbidities that affect PAD risk and treatment outcomes.[10]

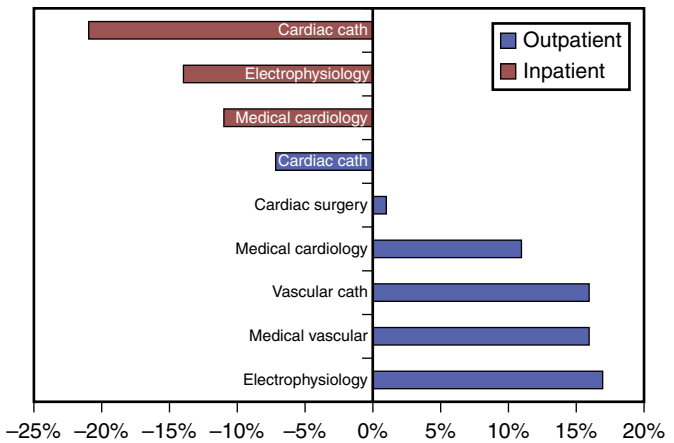

Figure 197.1 Cardiovascular Volume Growth Projections by Subservice Line 2013 to 2018.

Despite these demographic changes, management of these aging and increasingly complex patients is moving increasingly into the outpatient arena. The rate of inpatient PAD interventions declined from 209.7 to 151.6 per 100,000 Medicare beneficiaries between 2006 and 2011, whereas the rate of outpatient interventions increased from 184.7 to 228.5.[11] With the shift to outpatient care, significant increases in office-based procedures are also occurring (see Ch. 198, Development and Successful Operation of an Outpatient Vascular Center).

Paradoxically, medical innovation has largely focused on inpatient treatments. Costs for inpatient care continue to rise and make up the majority of Medicare expenditures for PAD[12]; this highlights the disconnect between increasing outpatient volumes and a focus on inpatient care. Given the push by multiple stakeholders, it is likely that financial incentives for outpatient care, preventive medicine, and population health management will drive the design of multispecialty CV centers in the future. For example, the safety, patient satisfaction, and financial viability of endovascular procedures performed in the outpatient setting has already been established (See Ch. 198, Development and Successful Operation of an Outpatient Vascular Center).[13]

Competition

Market forces have played a significant role in the evolution of many multispecialty centers that focus on common or historically well-reimbursed diseases including CV, orthopedic, and neurologic diseases, especially in the outpatient setting (Fig. 197.2). For example, in the 1990s, the number of programs offering coronary artery bypass grafting (CABG) increased by 30%. More than 80% opened within 30 miles of an existing program, and 55% opened within 10 miles. Every new program established in a freestanding "heart" facility opened within 20 miles of an existing program. New cardiac surgery programs established from 1993 to 2004 led to little increased access and substantial duplication of services.[14] At the same time, CABG volume overall was decreasing and there was mounting evidence that centers with lower CABG volumes

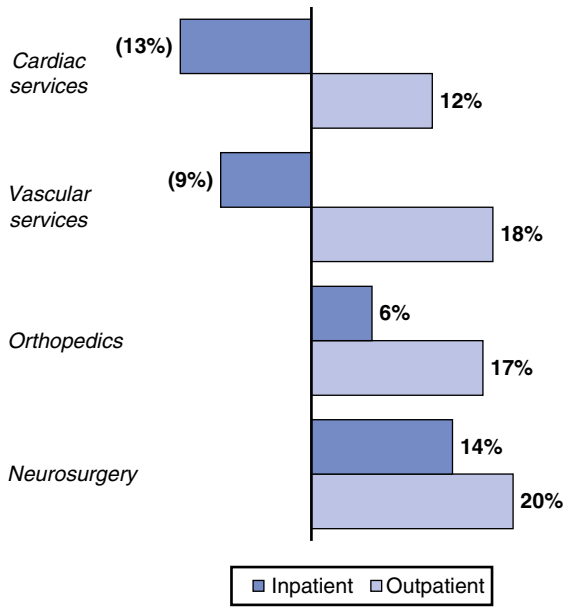

Figure 197.2 All Payer Growth in Major Service Line Volume Projections 2014 to 2019. The left side shows negative growth and the right side shows positive growth.

had poorer outcomes.[15] Ultimately, the competition in this environment made it very difficult for many CABG programs to maintain durable independent success.

The evolution of disruptive technology, such as endovascular aneurysm repair (EVAR), has also increased competition among multispecialty CV centers. In many regions, as EVAR diffused from early adopters to academic centers to the community, the total volume of EVAR cases became distributed over an increasing number of centers. Again, this was in spite of data suggesting that high-volume centers had better outcomes.[16] The rapid growth of programs in proximity, decreasing procedural volumes, and the need for volume at individual centers to maintain quality outcomes and financial success has led to intense competition, but has not necessarily improved access to specialty care in all communities.[8]

Reimbursement and Quality of Care

Assorted reimbursement models have been proposed and implemented rapidly as our healthcare system struggles to balance cost, outcomes, and value. Pay-for-performance models offer only modest incentives for quality improvement over fee-for-service models and drive the use of evidence-based practice while emphasizing patient satisfaction (see Ch. 200, Alternative Payment Models in Vascular Surgery). The assumption is that higher quality leads to fewer encounters, more durable outcomes, and therefore lower cost; an assumption that may not be valid and also one that depends heavily on the definition of quality. The definition of quality can vary significantly, particularly if one moves from an individual perspective to a community or population perspective. Individual patient outcomes have always been the physician's measure of quality. Quality and value were viewed as synonymous. However, in this era of cost containment, the definition of value has evolved to include much more. Not only are patient outcomes a part of this new value equation but so is patient (customer) satisfaction and experience, efficiency, and cost management. To this end, calculating the value of a multispecialty CV system has become important to the public, payers, and regulators.

As part of the trend toward financial transparency and value estimation, Medicare in 2008 began the Physician Feedback Program. Not yet publicly reported, this program collects data on quality, cost, and resource use on a hospital and provider level and provides participants with their data in comparison to their peers. In addition to this reporting, a Value Based Payment (VBP) modifier is in development, which would provide for differential payment for fee-for-service Medicare services based on quality of care and costs incurred by providers. With all this currently or soon-to-be publicly available data, multispecialty CV centers must balance meeting metrics while staying true to their core mission.

DEVELOPMENT OF A MULTISPECIALTY CARDIOVASCULAR CENTER

To position themselves to provide for population health, successful health systems are altering their strategies. Optimizing CV specialist access at high-volume, critical locations is important so that there is a balance between offering access at outreach sites yet not short-changing primary sites.[17] Ideally, the right patients should be seen by the right specialist at the right time in the most cost-effective manner. Although "on demand" presence is rarely possible because of limited physician capacity, considerable management skills are needed to use CV specialists appropriately. This may include streamlining scheduling practices, reducing no-shows, and prioritizing patient convenience by offering hours convenient for them.

When multiple specialties are involved, there is always going to be jockeying for an advantage between groups. Managing these highly charged conflicts takes a skillful leader. Experience, temperament, and trust are prime attributes to seek in any leader, but especially in a complex, changing environment. A physician coleader working with an administrator may provide the best value (Fig. 197.3). Almost 75% of surveyed CV centers had either a "dyad" (physician leader and an administrator) or a "triad" (administrator and two physician specialists) leading the center.[18] The team leading a CV center, as a whole, must possess critical skills such as project management, strategic and operational awareness, financial proficiency, and competence in addressing quality-of-care issues. The biggest challenges are aligning incentives and achieving shared values and expectations so that all stakeholders agree to be accountable to each other. It is essential that these are written down and agreed upon by all members. Stakeholders will desire a sense of fairness in any agreement.

In AMCs, the duality of reporting to the academic department as well as the CV center creates confusion regarding accountability.[2] Although it may be possible to eliminate the duplicate reporting in nonacademic, highly integrated health systems, long-standing barriers and fear of disruption of traditional cost-accounting systems make it difficult in AMCs.

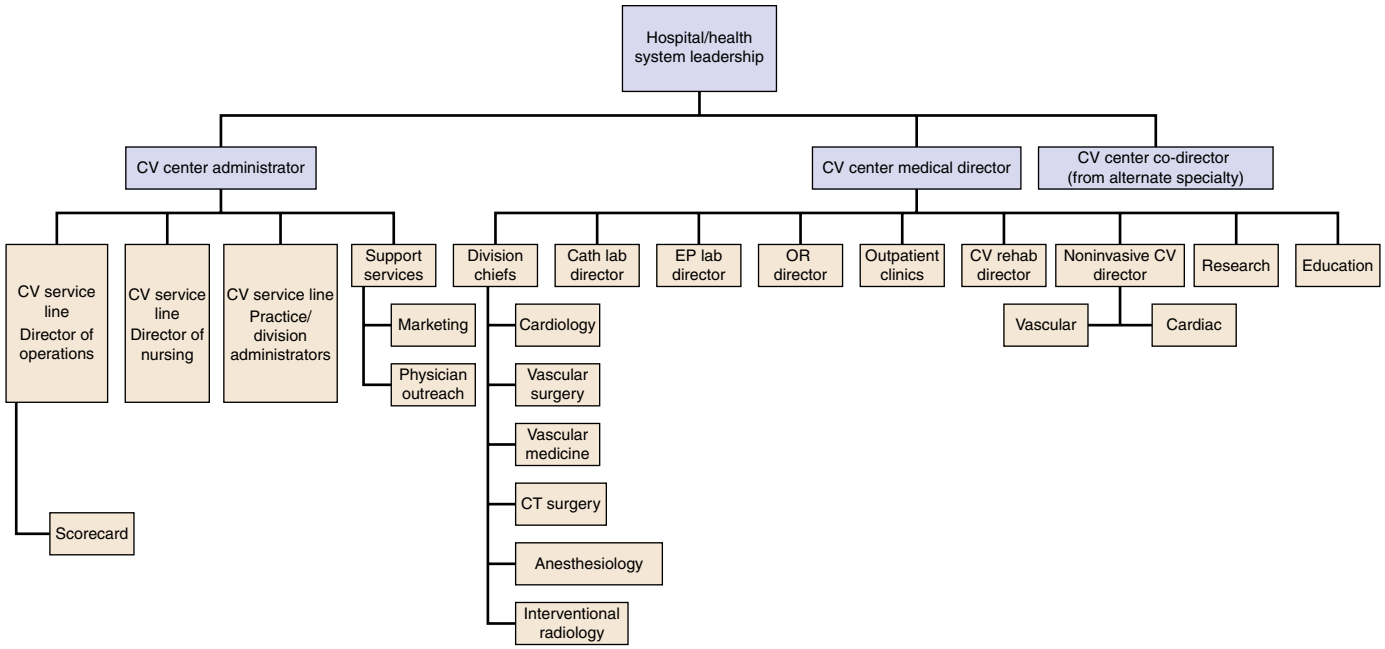

Figure 197.3 Suggested Governance of a CV Center (Dyad or Triad). *CT,* cardiothoracic; *CV,* cardiovascular; *EP,* electrophysiology; *OR,* operating room.

Another pitfall in a CV center is agreeing on privileges for procedures because procedural volumes required for "competence" vary by specialty. Agreement must be reached by reviewing relevant specialty guidelines and favoring a higher bar, then negotiating to train each other to achieve competence. This can happen only if incentives for compensation are transparent, fair, based upon valid benchmarks, and agreed upon unanimously. After internal competition between specialties is eliminated or minimized, all specialists can concentrate on growing the business regardless of who does the work.

Finances and Compensation

As more CV specialists become fully employed by health systems, the financial management must itself be completely integrated. A dedicated budget and a single profit and loss statement for all CV operations must be in place. This allows the pressures on revenues such as increasing costs, decreasing reimbursement, more risk-based payments, and changing payer mix to affect all specialties. Although volume, commonly measured by work relative value units, is still the dominant component of physician compensation, an increasing share is tied to quality of care and performance. If the CV center is designing a compensation system to align multiple specialties, shared incentives must be encouraged so that some percentage of compensation is based on team, unit, service line, or system performance. Similarly, at-risk incentives may include metrics such as quality measures, use, readmissions, patient access, cost control, good citizenship, and outreach activities. As an example, if there is a group performance incentive, a CV specialist who travels to an outreach site and generates referrals for others in the group while her own procedural productivity suffers should share equally in the group bonus if productivity targets are met or exceeded. These incentives should be perfectly transparent to all the involved clinicians. Multispecialty collaboration is unlikely to succeed if a specialty or individual feels that their income is more at risk than the others.

Operational Issues

A culture of excellence is vital for a CV center to succeed but requires a commitment from physician and nursing staff. Because of the competition for CV patients both locally and regionally, CV centers need to differentiate themselves based upon quality outcomes, price, access, reputation, and rankings. Achieving well-known designations for excellence requires the organizational commitment of everyone from leadership to support staff, in addition to investment in personnel and computer resources. Commonly CV desired designations include: US News and World report (Heart and Heart Surgery category);[19] Health Grades,[20] which gives out specialty awards annually; Thomson Reuters, which publishes hospitals that meet certain CV benchmarks with its top 100;[21] Intersocietal Accreditation Commission accreditation for vascular laboratories, echocardiography and nuclear medicine;[22] and American Heart Association recognition for ST-elevation myocardial infarction referral centers. Many insurance companies and professional society databases also confer various awards for excellence in specialty care.[23] These designations require sophisticated computer programs and staff to enter, collect, analyze, and report data.

The governance structure of the CV institute must ensure that responsibility and accountability for the service line is designated to clearly appointed personnel. The "dyad" model combines the clinical experience of a physician with a skilled administrator. The difficulty in executing a vision or strategic

plan occurs because of ambiguous lines of responsibility. Regardless, the structure must allow proper representation of all parties (see Fig. 197.3).

There are several options for designing an operations hierarchy. Several layers of vertical bureaucracy existing in most hospitals are not well suited to single service line organizations. A matrixed structure allows expedited decision-making, quicker execution of strategic plans, and better patient outcomes and quality of care. However, this reporting structure consists of a CV leader but no clear and direct responsibilities for all the divisions or departments within the service line.[24] This model requires all parties to be cooperative at all levels, and obtaining consensus may delay time-sensitive decisions. In an integrated operating structure most, if not all, reports occur directly to leaders of a service line or subservice line within a CV center. This structure is more complex because of the number of personnel and functions reporting to very few individuals, but decision making can be more efficient. There is no "one-size-fits-all" governance hierarchy that will work in every system. The management structure chosen must fit the local culture while satisfying basic organizational needs.

AMCs have traditionally operated with a hierarchical structure partly because the decision-making power rests with a dean and a department chair and partly because AMCs are cautious about taking risks with new models of care. However, foundation model-based institutions such as the Mayo Clinic have changed to patient-centric, integrated models of care in view of the move to value-based reimbursement, more emphasis on quality of care, increased transparency, and regulatory pressures. In bringing several specialties in CV centers into a single service line, many challenges are faced because of disruption of the existing power structure, medical education, resident training, and most importantly internal competition and compensation models. Not all AMCs are well suited for disruptive change.[25] Skilled leadership is required to integrate clinical, research, education, and administrative functions into a tightly knit, efficient unit focused on patient care, best outcomes, growth, and external competition.

THE CURRENT STATE OF MULTISPECIALTY CARDIOVASCULAR CENTERS

A survey of CV center administrators showed that AMCs, nonteaching community hospitals, and teaching community hospitals each constitute one-third of all CV centers.[18] Half of CV centers are associated with greater than 500 beds, and 60% are either regional or multistate systems, suggesting the need for organizational resources and capacity. It must be recognized that the creation of a larger entity such as a CV center poses new challenges in terms of governance and operations to any healthcare system, which should be anticipated (Table 197.3).

To better understand the current status of multidisciplinary CV centers in this country, existing community and AMC program administrators and lead physicians were contacted

TABLE 197.3 Challenges and Solutions for Cardiovascular (CV) Centers

Challenge	Possible Solutions
Appropriate leadership	1. Select a knowledgeable, representative, and accepted leadership unit in place 2. Establish a culture of integrity, transparency, and accountability 3. Mission and vision statements after input from all stakeholders 4. Responsibilities are specific and not ambiguous
Organizational chaos	1. Require physician leadership training 2. Integrate employed and affiliated physicians 3. Fashion a systemwide service line 4. Integrate inpatient and outpatient services 5. Control costs associated with newly formed service line associated center
Interspecialty silos and conflicts	1. Minimize internal competition while maximizing referrals and volumes for all 2. Avoid cannibalization 3. Design a transparent, fair compensation system that rewards not only individual productivity but team goals
Turf battles	1. Affirm a multispecialty team approach to cardiovascular diseases 2. Broad agreement to train each other when possible 3. Train multidisciplinary nurse specialists, patient schedulers, and other care givers 4. Cross-specialty strategy, privileging, and quality of care committee 5. Educate trainees on the advantages of cooperation
Integration	1. Common charge-master and pool technical and professional revenue 2. Single profit and loss statement 3. Cross-specialty practice guidelines and value analysis 4. Compensation incentives partly based upon group or subservice line performance and system goals 5. Physicians completely embedded in the governance model
Variation in care among specialties	1. Standardization of clinical and operational protocols 2. Institute a standing multidisciplinary quality assurance (mortality and morbidity) and case monitoring conference 3. Participate in national registries such as Vascular Quality Initiative (VQI) by the Society for Vascular Surgery or National Surgical Quality Improvement Program (NSQIP) by the American College of Surgeons or similar program

for telephone interviews. Designations for current CV centers range from "center of excellence" and "service line" to "institute," implying varying degrees of integration. Service lines tend to bring together specialties with a common clinical focus under one administrative umbrella, with the aim of initiating cost-savings maneuvers and promoting collaboration among specialists. Centers of excellence seem to venture beyond operational integration and clinically cooperate on various levels with regard to physical facilities, scheduling, and referrals. Institutes imply the highest level of integration with financial interdependence between the member specialties and an increased level of collective fiscal responsibility by the specialties.

The impetus to establish a multidisciplinary CV center varies but was generally consistent with the reasons stated earlier. Administrators tended to cite business reasons as motivators, such as greater procedural volume, access to patients, and better bargaining power with payers. Improved system accessibility for patients and better patient outcomes were also mentioned. Although physicians claimed these same patient-centered inspirations, preservation of specialty specific referrals and practice patterns remained important to them. Despite this, most CV centers were inclusive of cardiology and vascular surgery; cardiothoracic surgery, interventional radiology, neurology, neurosurgery, and vascular medicine were involved on a more varying basis. Overall, CV centers seemed to have a higher level of integration when a variety of physicians were engaged at the inception of the CV center and improved patient care was the ultimate objective.

The presence of a common CV center administrator was a typical theme encountered during phone interviews, but this person's responsibilities and decision-making authority varied from functioning as a simple coordinator to one with full strategic and operational capabilities. Physician leadership was always incorporated to some degree but ranged from one to several directors, typically from a variety of specialties. Commonly, a cardiologist was the appointed physician leader. The amount of physician responsibility also ranged from an assigned title to involvement in operations including active planning and frequent team meetings.

Many CV centers approached were still in a state of continued development and refinement of their programs. The more recent adapters tended to have service line-type programs by aligning the involved specialties through administrative functions. This included managing personnel issues and processing requests for new equipment acquisition, among many other tasks. Individual specialties maintained their separate financial structures and oversight programs (quality, physician recruitment, reimbursement, etc.). Clinical activities were typically also independent, although there were some CV centers whose specialists shared a common outpatient clinic or inpatient procedural area.

In general, academic divisions contacted continued to report and be accountable to their respective departments. It was rare to encounter an AMC where individual divisions had traded the traditional departmental structure for a disease-based configuration, unless special circumstances existed, such as a previously established multispecialty practice or the availability of a large amount of external funding. Departments also seemed unwilling to sacrifice their components (and sometimes the more lucrative ones) to a disease-specific center. Community hospitals tended to have similar concerns, with specialists remaining loyal to their private practices and groups, rather than wanting to create a whole new financial structure and give up total operational and fiscal control.

However, irrespective of the base structure of a CV center, most have developed some type of tool for measuring success. Key performance indicators (KPIs) are the norm in CV centers operated by both academic and community hospital systems, whether they are administrative or clinical (Table 197.4). A scorecard should be built based on the organization's mission, vison, and values in order to better communicate strategy to the key stakeholders. KPIs should be reviewed regularly to gauge success. Examples of CV scorecard projects are endless and may include increasing local/regional market share, improving patient throughput in the ambulatory setting, employer of choice programs, and reintervention rates for endovascular interventions.

Healthcare marketing is a specialty and in competitive markets is a multi-million-dollar budget item for CV centers. Although there are several important metrics in gauging success of marketing plans, market share is a critical number to follow over time. Market penetration is monitored by analyzing patients served, discharges, and revenue in specific regions. Occasionally in CV centers that exist largely in name only, without true integration in operations and finance, care givers themselves may be unaware that a named CV center exists, making one wonder how effective their marketing plans have been. This emphasizes the importance of staff engagement on all levels to promote a healthier patient experience and the success of centers of excellence.

FUTURE DIRECTIONS

Coincident with increasing mergers and acquisitions of hospitals and health systems will come consolidation of services focused on reducing variations in care and eliminating wasteful tests and procedures, all to produce better quality healthcare with reduced cost.[26] Specialties providing care to the vascular patient will be persuaded to work together with greater efficiency, and physicians will be credentialed according to experience and skills rather than specialty-specific requirements. Difficult as it may be, sharing of knowledge must be mutually acknowledged as a necessity. Best practices and specialty guidelines must be shared and disseminated throughout all clinical areas.

On the surface, the multidisciplinary CV center seems well suited to achieve success in bundled and accountable care reimbursement models. By giving providers defined payments for "episodes of care," bundling emphasizes clinical performance and the use of evidence-based medicine but also rewards efficiency of care delivery and multispecialty cooperation. Systems that can achieve quality outcomes with the least redundancy and waste should succeed. Furthermore, by including continuums of care in certain "episodes" (e.g., defining an episode as

TABLE 197.4 Key Performance Indicators in Creating a Cardiovascular (CV) Scorecard

Focus	Focus of Metrics	Examples of Metrics
Customer	1. Patient 2. Employee 3. Referring physician	• Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS), care pathways, average wait times to access • Attrition rate, satisfaction survey metrics • Referral rates, survey metrics
Clinical/education	1. Quality 2. Research 3. Education	• Outcomes by specialty, shared performance measures, concurrence with guidelines, door to door times, core measures met • Grant volumes and dollars, presentations, publications • Peer-reviewed publications • Scientific presentations – local, regional and national • Performance in "in-training" and board examinations • Results of accreditation site visits • Outcomes of National Resident Matching Program (NRMP)
Organizational	1. Leadership 2. Strategy/business development 3. Financial performance 4. Marketing initiatives 5. Operational efficiency	• Quality of care indicators, financial performance, market share • Market share, payer mix, physician alignment • Inpatient and outpatient volumes, accounts receivables, physician productivity, monitoring of value-based payments, net profitability measures by specialty, return on investment • Patient intake by geographical area and zip code, success of differentiation strategies, online analytics (bounce and conversion rates) • Case mix index, supply chain efficiency, readmission rates, no show rates, unit or procedure room use rates, staff productivity

admission through a surgery and then 90 days post-discharge), systems are forced to invest not only in procedural or inpatient care but also post-acute and outpatient care. The Bundled Payments for Care Improvement Initiative (BPCI) sponsored by the Center for Medicare and Medicaid Innovation (a product of the Affordable Care Act) has targeted 48 disease areas in which to roll out bundled payments; fully one-third are CV diseases.

The Accountable Care Organization (ACO) model further broadens the scope of cost-containment efforts to the community and population level. Instead of individual episodes of care, disease outcomes at the population level are emphasized. Successful treatment of chronic outpatient diseases and delivery of effective preventative care are rewarded. In addition to the quality care delivery and system efficiency incentivized by bundled payments, effective resource use across a community, geographic region, or population is rewarded by the ACO. In 2018, low-revenue physician-led ACOs performed much better with seven times Medicare savings per beneficiary compared to hospital-led high-revenue ACOs.[27] As of January 2020, there are 558 Medicare ACOs serving more than 12.3 million beneficiaries.[28] Besides large health systems, physicians are leading consolidation of single or multispecialty vascular and cardiac groups and are also well positioned to succeed in competing for the CV patient. Each of these evolving reimbursement models rewards a different type of multispecialty CV system, and development of a successful center requires intimate knowledge of the local and national reimbursement environment and the direction in which it is likely to move.

Patients increasingly affected by cost shifting to higher deductibles will move toward being better consumers, seeking out online reviews about quality and price transparency. Nonemergency procedures performed in the expanding outpatient arena will compete for price and quality. Similarly, Hospital Consumer Assessment of Healthcare Providers and Services (HCAHPS) metrics now used as part of value-based reimbursement will likely also begin to be used in outpatient centers. CV centers of the future will also join the technology revolution by allowing vascular patients to access their electronic medical records, including imaging and test results. Consumer expectations for access to care are also changing quickly. The ease of access to services at one click for transportation, groceries, laundry, and retail care has changed consumer behavior to where "on-demand" access is expected. Similarly, online scheduling convenience will be expected and require upgrading scheduling platforms and physician portals. The concept of a "just in time" strategy to decrease waste and improve efficiency will become common as health systems grapple with innovative ways of using technology to increase access to vascular specialists at multiple locations.

CONCLUSION

Factors that should lead to the long-term success of any CV center are those that characterize the best health systems today: enlightened leadership, excellent patient care, demonstrated outcomes and quality, cutting-edge research and innovation, and committed physicians who have access to the latest technology. The successful CV center of the future must be multidisciplinary and patient-centered, empower physicians and other leaders to participate fully in governance and business decisions, design quality of care guidelines, and abandon siloed care, and move to collaborative models. Only then will there be a truly shared commitment to collaborative growth in the construction of the CV center of the future.

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A complete reference list can be found online at www.expertconsult.com.

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198 CHAPTER

Development and Successful Operation of an Outpatient Vascular Center

KRISHNA MOHAN JAIN

INTRODUCTION

Endovascular procedures have traditionally been performed in the hospital where the patient was observed overnight following the procedure; this gradually transitioned to the patient being discharged on the same day.[1] Once the safety and efficacy of these procedures was established in the hospital-based setting, studies were conducted by multiple investigators that documented the safety, cost efficiency, and clinical efficacy of conducting endovascular procedures in a dedicated office sertting.[2–4] The Deficit Reduction Act of 2005 included the provision for the Center for Medicare and Medicaid Services (CMS) to reimburse endovascular procedures in the office setting. Same-day discharge of the patient after these procedures helps reduce the cost of the procedure.[1] Other insurance companies followed CMS policy, and now provide the

same coverage. Thus, endovascular procedures can now be performed in outpatient vascular centers. There are three types of outpatient centers that a patient may consider for endovascular procedures: a hospital-associated outpatient center, an ambulatory surgery center (ASC), or an office-based endovascular center (OEC). OEC is also referred to as office-based lab (OBL).

Outpatient vascular centers can be established by a hospital or by office-based practitioners. In hospital-developed outpatient centers, the hospital is paid under the outpatient prospective payment system, and each physician bills separately for professional services rendered. At a privately-owned ASC, the "facility fee" is paid to the ASC for the surgical procedure and the provider is paid the "facility rate" based on the surgical procedure performed. In an office setting, Medicare and other insurance companies pay at the "nonfacility" rate. This nonfacility fee is a combination of technical and professional fees. An office-based center or laboratory is defined as a procedural suite within an office and is an extension of the office where patients are seen and treated. The office-based center is not specialty specific and the elements described in this chapter can be applied to all specialties. ASC is governed by different rules and can be built in partnership with nonmedical organizations. There is some variation in the procedures that can be performed in the office as compared to the ASC. For example, coronary artery angioplasty can be performed in an ASC but not in an OEC. The payment for the same procedure done in OEC or ASC differs since different payment structures are used for reimbursement in different sites of service. This chapter will discuss the office-based endovascular center in detail.

TABLE 198.1 Comparison of Ambulatory Surgery Center and Office-Based Labs

	ASC	Office-Based Lab
Payment methods	Bill facility fee and professional fee	Global payment (nonfacility)
Procedures allowed	All ASC-approved procedures can be performed	Limited number of procedures
Physician usage	Other practitioners can use	Only practitioners seeing the patients in that office
Ownership	Multiple physicians can own it	Lab must typically be owned by physicians who are seeing patients and operating on them
Licensing	CMS and state license required	No license needed
Capital investment	Higher capital outlay for construction and equipment	Reasonable capital outlay
Size of facility	Bigger facility required	Depending on expected volume, smaller space can suffice
Regulations	Comply with federal and state laws	Comply with state laws
Services cost	Higher professional services cost at outset	Minimal cost
Staffing cost	Higher staffing cost; different staffing ratio	Office staff can be used in addition to added personnel
Monthly cost	Higher monthly cost	Lower cost
Accreditation requirements	Accreditation required	Not required except in certain states
Certification requirements	Certificate of Need required in many states	No Certificate of Need required
Transfer regulations	Need to provide hospitals documentation that includes information about their operation and their patient population.	Not needed, desirable if the practitioner is not a surgeon

ASC, Ambulatory Surgery Center; *CMS*, Center for Medicare and Medicaid Services.

REGULATIONS

Office-based centers, in contrast to ASCs, do not have well-defined regulations guiding their operation. Instead, the centers are mostly regulated by state law (Table 198.1), because there are currently no federal guidelines for an office-based center. These regulations mostly pertain to anesthesia, radiology, and the Occupation Safety and Health Administration (OSHA). Increasing number of states are passing laws to regulate these centers. Many of them require the lab to be certified. ASC is regulated by specific federal and state laws. To receive payment from CMS for procedures done in the ASC the facility must be certified by one of the deemed organizations.

Anesthesia

Regulations pertaining to anesthesia depend on the degree of sedation administered to the patient. In most states there is no requirement for an anesthesiologist to be present for minimal to moderate sedation. Many states, including New York,[5] require the presence of anesthesiology personnel if moderate to severe sedation is needed for the procedures being performed. Different accrediting bodies may also have specific requirements regarding anesthesia that must be followed for the center to be accredited.

Radiology

Each state has different regulations governing the radiology suite in the office. Not all states require lead lining of the lab if a C-arm is being used. Some states mandate that only a

certified radiology technician can operate the C-arm. The lab should follow the state law related to C-arm inspection, lead lining, staffing, and training regulations. In addition, there may be regulations governing the integrity of lead aprons and dosimeters.

Occupation Safety and Health Administration

OSHA regulations need to be followed diligently. This requires compliance training, policies and procedures, employee handbooks, and forms for recording incidents (needlesticks, etc.). The complete set of regulations can be found at www.osha.gov.

COMPONENTS FOR SUCCESS

Office for Patients

Office-based outpatient interventional centers are defined as locations where patients traditionally see physicians or surgeons to diagnose and discuss their clinical condition. The office must meet the basic requirements of space and personnel, such as examination rooms for patients to be seen, and nursing staff to provide patient care, among other requirements.

Noninvasive Vascular Lab

A noninvasive vascular lab is needed to support the office-based practice and the endovascular laboratory suite. An ultrasound machine that can reliably perform imaging of the venous system and peripheral arterial system including the aorta, carotid, and visceral arteries is required. The same machine can be used to access arteries and veins in the endovascular suite. A Doppler machine is necessary to obtain wave forms and measure ankle and toe pressures to assess circulation in the extremities. Additionally, the appropriate equipment is required to conduct photoplethysmography of digital vessels to check the digital circulation in patients with conditions such as Raynaud phenomenon, vascular steal in dialysis patients, and distal occlusive disease in diabetics. The lab should be certified by the Intersocietal Accreditation Commission or the American College of Radiology.

Endovascular Lab

Almost all percutaneous endovascular procedures currently performed in the hospital can be safely conducted in the office-based lab.[2,6] Because there are limited resources in the office as compared to a hospital, patient selection is crucial in optimizing results and diminishing potential complications. The absolute contraindications to treating a patient would be the need for general anesthesia, the need for hospital admission due to comorbidities, the expected need for prolonged observation post procedure, or severe allergy to dye.[3] Relative contraindications for patients would include the weight of patient exceeding 400 pounds or a patient with decreased pain tolerance, if conscious sedation is not available. Endovascular repair of an aortic aneurysm and carotid stenting cannot be performed in an office-based lab and are not reimbursable in the office-based setting. In a pilot study (not published), endovascular repair of infrarenal aneurysms was safely done in the office-based lab in appropriately selected patients. However, until a larger study is conducted, this procedure should not be performed in the office-based setting.

Types of Procedures

Hemodialysis Access-Related Procedures

The outpatient management of the dialysis access patient population is discussed in Chapter 199 (Development and Operation of Outpatient Dialysis Access Centers), and only a brief overview of the spectrum of procedures is provided in this chapter (see Ch. 177, Hemodialysis Access: Failing and Thrombosed). Insertion of catheters should be avoided as much as possible due to the inherent complications of infection and stenosis caused by the catheters.[7] Patients needing urgent dialysis without a functioning access will need catheters, however, and these can be easily placed in the office setting. Midlevel operators can be trained to remove catheters.

Indications for performing a fistulogram in this setting include: (1) decreased blood flow; (2) increased venous pressure; (3) increased bleeding after removal of the needle; (4) ultrasound-proven hemodynamically significant stenosis; (5) inability to access the vein; (6) increased recirculation time; or (7) decreased urea clearance. There is no indication for doing a fistulogram on a predetermined schedule.[8] Stenoses identified can be treated in the outpatient setting with either angioplasty and the selective placement of bare or covered stents, such as for elastic recoil.[9–11] Laser atherectomy of stenoses at the dialysis access stent is currently not FDA approved, so it should not be performed. Coil embolization to occlude venous branches contributing to "steal" can be performed in the outpatient setting.[12] Balloon-assisted maturation of a fistula may be performed but at this time there is no reimbursable code for this procedure.[13,14] Intravascular ultrasound (IVUS) may be helpful in determining the degree of stenosis and appropriate sizing of devices.[15]

Declotting of a fistula can be carried out using percutaneous,[16] chemical, or mechanical thrombectomy,[17] and underlying stenoses can then undergo angioplasty following recanalization.[18]

Central venous stenoses due to previous catheters or the presence of a pacemaker/defibrillator on the ipsilateral side can be treated in the outpatient center, typically using bare metal or covered stents.[19,20] Likewise, arterial inflow stenoses can be corrected by angioplasty using a retrograde approach through the access or by using an antegrade approach via the femoral artery in the outpatient center.

Peripheral Arterial Procedures

Arteriography may be performed for carotid artery disease, renal artery stenosis, lower or upper extremity ischemia, aneurysmal disease or visceral ischemia. A diagnostic arteriogram can be performed and reimbursed for any vessel in the body except the coronary arteries. If this procedure is performed in an ASC, however, it is reimbursed. The procedure can be done

via a femoral, brachial,[21] radial,[22] or tibial approach.[23] Femoral artery access is the most common approach. Prior to the procedure, kidney function should be assessed and in cases where renal function is compromised, an appropriate hydration protocol should be used. In patients with moderate to severe renal impairment, CO_2 angiography should be performed.[24] In cases of morbid obesity or hostile groin, a brachial, radial or tibial approach can be used. The complication rate is higher with the brachial approach as compared to radial access.[21] Closure devices are used based on physician preference. Although there is no significant decrease in post-procedure bleeding when these devices are used, the time to discharge is often diminished.[25]

Visceral and renal angioplasty and stent placement can be performed for appropriate indications.[26,27] Angioplasty and stenting of iliac arteries results in satisfactory long-term results. Atherectomy at this anatomical location is not proven to be clinically beneficial and is not reimbursable.[28] Likewise, carotid stenting is not reimbursable and aortic angioplasty is seldom indicated.

Interventions for superficial femoral, popliteal, and infrapopliteal arterial disease are the most common procedures performed in many labs. Documentation of prior medical management and noninvasive vascular lab studies is recommended to justify the intervention. Angioplasty, stenting,[29] and atherectomy[30–33] are all performed in these vessels in the outpatient setting. A recent paper from an office-based endovascular center demonstrated the efficacy of atherectomy in infrainguinal arteries.[33] Drug-eluting balloons, new design stents, and drug-coated stents being increasingly utilized.[34–37] A retrograde tibial approach is being used to cross lesions when an antegrade method fails, or in the case of a hostile groin.[38,39] Stenoses in the subclavian,[40] axillary, brachial, radial, and ulnar arteries can be managed by angioplasty and stenting when indicated.

Venous Procedures

Venous stenosis in the iliac and femoral veins due to post-thrombotic obstruction or external compression, can be detected using venography and IVUS, and treated in the outpatient center. Neglén et al.[41] have demonstrated long-term patency of venous stents and sustained clinical symptom relief, and Ganelin et al. demonstrated the safety of this procedure in an office-based setting.[42] FDA-approved stents are now available for treating venous stenoses. The stents needed are usually large, ranging from 14 to 28 mm in diameter, which requires stocking larger balloons than usually kept in the lab. IVUS is proving to be more accurate than venography in diagnosing venous stenoses.[43] Thrombolytic therapy of iliac vein thrombosis will likely soon be considered safe in the office setting. Finally, vena cava filters can be inserted and removed safely in the office-based lab.[44,45] It may be possible to improve retrieval rate of filters when the procedure is carried out in the OBL.[45]

Port Insertions

Ports for chemotherapy, nutrition, or antibiotic therapy can be inserted in an office-based lab as long as the patient is not on Coumadin.[6]

Venous Center

Use of an outpatient venous center to primarily manage superficial venous reflux has gained wide acceptance among physicians and patients, utilizing endovenous ablation, microphlebectomy, sclerotherapy, and evolving new techniques like foam and glue injections for truncal venous insufficiency.[46,47] The venous center can be developed with or without an accompanying endovascular center. A combined venous and endovascular center can be beneficial since some patients may also be candidates for interrogation of iliac and femoral veins through venography and intravenous ultrasound and subsequent treatment with angioplasty and stenting. Providing treatment for all types of vascular conditions at one location improves the safety and convenience for the patient.

Additional Services

Vascular Medicine

Management of peripheral vascular disease starts with medical management, and following intervention it is crucial to continue optimal medical management. While many if not most vascular surgeons devote considerable part of their time in the medical management of their patients with peripheral artery disease (PAD), in a busy practice a vascular medicine specialist can dedicate 100% of his/her time to the management of the risk factors in patients with PAD.[48] A vascular medicine specialist can coordinate programs dedicated to helping patients stop smoking, manage weight and participate in supervised exercise therapy. In light of the continuous introduction of new drugs to treat hypertension, diabetes, and hyperlipidemia, a vascular medicine service supporting the OBL can ensure patients are provided the most current medical treatment available and provide the personalized care these patients need to improve their health.

Wound Care Center

Ideally a vascular center would work closely with a wound care center.[49] Patients seen in the office with wounds can have the extremity revascularized in the office-based setting followed by wound care in the wound care center. If the practice is large enough, it can also own the wound center. Wound centers may also refer new patients into the vascular practice. If the limb can be revascularized in the office-based lab, followed by wound management in the wound care center, this can avoid a hospital admission, which is inherently more expensive and less user friendly. Many wound centers are operated by podiatrists and multidisciplinary collaboration with podiatrists can help improve limb salvage.[50]

Screening Program

Providing a screening program should be part of the comprehensive services provided to the patient population with vascular disease.[51] Since 2007, Medicare has reimbursed for abdominal aortic aneurysm (AAA) screening in men over 55 years of age with a family history of AAA, all men above the age of 65, and women 65 years or older with a family history of AAA or history of smoking. Specific screening guidelines vary among clinical societies. PAD screening and carotid screening

are often done in tandem. In the Life Line screening program, the prevalence of PAD and carotid artery disease was 4.1% and 3.9%, respectively.[52] As many as 18.8% of patients with PAD also have carotid artery disease. Providing a screening program for vascular diseases in an office vascular center increases the awareness of disease among patients in addition to positioning the practice as a leader in managing PAD, both of which benefit the practice. Recently, however, the benefit of a screening program has been questioned.[53]

BUILDING A CENTER

Business Plan

Before embarking on development of an outpatient office-based endovascular suite, it is crucial to have a business plan.[4] This involves collecting clinical data, financial analysis, creating a pro forma, and projections. The physician needs to assess the current volume of percutaneous procedures in each category that can be performed in the office, and anticipate what new procedures will be offered once the endovascular suite is opened. A realistic expectation of growth based on the last 3 years of clinical practice should be determined. The capital expense and cost of disposable items and devices needs to be calculated and accounted for based upon the anticipated volume of patients. The largest expenses relate to the purchase of a building, capital equipment, cost of devices, and the cost of labor. For new practitioners, it may be advisable to build the practice prior to opening an office-based lab.

Building

The endovascular center needs to physically be in conjunction with the existing office space. A typical center is usually 2500 to 3500 square feet in area. The center will need the following areas: (1) a reception area, which can be combined with existing reception spaces; (2) a preoperative and recovery room with one or two reclining chairs for dialysis patients, and three to five beds for peripheral and venous procedures; (3) an endovascular suite (one or two depending on the anticipated patient volume) that is lead lined; (4) a storage area for equipment and supplies; (5) a decontamination area; (6) a manager/coordinator's office; and (7) a nurses' station. Design of the procedure room will depend on the machine being used for imaging. If a fixed system is planned, a bigger room with higher ceiling will be required to accommodate the machine. If the center wants to operate as an ASC or as an ASC/OBL, there are very specific building requirements that need to be followed.

Equipment

One of the biggest challenges facing the startup of the lab is financing. Most labs choose to buy the necessary equipment outright. However, many companies are willing to lease the capital equipment to the lab. A list of equipment necessary for the endovascular suite and venous center can be found in Tables 198.2 and 198.3, respectively. For radiology equipment, another consideration is the choice between a C-arm and a fixed system, which depends on personal preference, types of cases anticipated, and the cost of the equipment. Currently available C-arms with vascular software provide adequate image quality for almost all procedures performed in the office. One limitation is morbidly obese patients and C-arms convey increased risk of radiation

TABLE 198.2 Equipment for the Endovascular Suite

In the Lab
C-arm/Fixed overhead system
Radiolucent table
Power injector
Ultrasound machine
Monitoring equipment
Overhead surgical light
Surgical instruments
Arm board
Portable oxygen tanks
Suction machine
Procedure table for instruments
Preoperative and Postoperative Area
Wheelchair
Reclining chair
Beds/stretcher
AED
Monitors
Crash cart
Miscellaneous
Furniture
Computers
Blanket warmer
Autoclave
Emergency battery backup
Lead aprons, hats, and glasses
PACS image storing
Emergency generator
Storage racks
Data collection software
EHR

AED, automated external defibrillator; *EHR,* electronic health record; *PAC,* picture archiving and communication.

TABLE 198.3 Equipment for the Venous Center

Radiofrequency ablation machine/Laser machine/Other modality
Table
Pump
Ultrasound machine

exposure to the patient, physician, and staff. Therefore, appropriate measures should be taken to limit the radiation exposure.[54,55] Fixed systems may be better for renal and visceral artery interventions, procedures in morbidly obese patients, and carotid angiography. However, for dialysis-related cases a fixed system is harder to use because of positioning of the patient in relationship to the X-ray tube. It is better to buy new equipment rather than used or refurbished equipment because the success of the center depends upon the functionality of these pieces of equipment. Purchase of equipment to perform ultrasound is highly recommended because ultrasound guidance for entering vessels during arterial and venous procedures is known to decrease complication rates.[56] One of the complications of these procedures is post-procedure bleeding, which is the most common cause for transfer to the hospital after femoral artery catheterization.

Supplies and Medications

Various supplies and medications are required for a functional endovascular center (Tables 198.4 and 198.5). The amount and brand of these supplies to be stocked is at the discretion of the endovascular center and the procedures that the center plans to perform. Inventory control is crucial to the financial success of the center.

TABLE 198.4 Supplies

Preparation for Procedure
Surgical packs
Lead apron
Lead lined and sterile gloves
Booties, lead lined hats, and regular hats
Arterial and Venous Procedures
Vascular access kit
Catheter and wires
Sheaths
Support catheters
Crossing devices
Angioplasty balloons
Stents (bare metal and covered)
Atherectomy device
Inflation device
Intravenous ultrasound catheter
Closure device
Snare
Dialysis Related Procedures
Dialysis permanent and temporary catheters
Over the wire Fogarty catheter
Other Procedures
Ports
Stents
Intracaval filters
Filter retrievable kits

Staffing

Acquiring new staff for the endovascular or venous center depends on the current number of staff members in the office. Some of the tasks, like scheduling, billing, and patient registration, can be performed by the current staff. The staff needed exclusively for the lab include a manager (if there is no business manager in the office), two registered nurses, a scrub technician, a radiology technician/medical assistant trained in using the C-arm, and another medical assistant to interact with patients and carry out miscellaneous duties in the pre- and post-procedure area. If an anesthesiologist is providing sedation, they will have their own staff.

Electronic Health Record, Picture Archiving and Communication System

Data management in the office is currently mandated by government and private insurance companies. It is important to have an electronic health record (EHR) and data management tool that can seamlessly interact. The data management tool should be able to provide patient demographics, risk factors, clinical findings, procedures performed, outcomes. The system should allow seamless entry of data in a registry. For the functioning of the lab, the data management system should be able to track procedures, inventory, supplies used per procedure, clinical monitoring, image management, and billing. The clinical, business, and quality indicators have to align seamlessly. Total transparency is critical to the success

TABLE 198.5 Medications

Contrast solution
Intravenous fluid
Hydrocodone
Diazepam
Fentanyl
Naloxane
Versed
Flumazenil
Heparin
Protamine sulfate
Local anesthetic agent
Other drugs if anesthesiology is providing sedation
Drugs as per ACLS protocol
Insulin
Antibiotic
Local hemostatic agents

of the lab; payers will need to see this data to reimburse for services provided by the office. Since there is no peer review for office-based procedures, payers are inherently suspicious of the performance of unnecessary procedures. Only a strong data management program can support the appropriateness of billing. All of the images produced during procedures need to be stored and archived for quality, follow-up, and legal requirements in a picture archiving and communication system (PACS). Ideally the data should be accessible from a remote site as well.

The EHR should have the following elements: (1) full history and physical exam including vascular exam, noninvasive vascular lab findings, indication for the procedure, pre- and post-procedure medications including antiplatelet drugs, anticoagulants, and statins; (2) procedure notes including site verification, type of anesthesia, vital signs during the procedure, the amount of radiation, and the amount of contrast; (3) equipment used including wires, catheters, balloons, stents, and other devices; (4) technical details of the procedure and medications administered; (5) a report generated for billing purposes; (6) a note for the referring provider; and (7) documentation of follow-up visits/phone calls to assess the outcomes of the procedure.

Biomedical and Electrical

There should be enough plugs and power to supply all electrical equipment in the room. Some devices may need a 220-V connection. There should also be an emergency generator. All equipment should be serviced at recommended intervals and have a sticker to identify the date of the last service. Portable oxygen should be available. A portable suction machine should also be available; wall suction is not required.

Accreditation

There are currently no organizations equipped to specifically accredit office-based endovascular centers. Various labs have received accreditation from different entities like The Joint Commission (JACHO), Accreditation Association for Ambulatory Health Care (AAAHC), and the American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF). To ensure safe, effective, consistent, and comparable care at all office-based endovascular centers, an organization needs to be developed to specifically accredit these labs. Some of the principles used by the JACHO and other agencies could also apply in certifying these labs. All the procedures performed are percutaneous and no body cavities are opened. The procedures are very similar in nature and do not require elaborate, complex, or varied monitoring tools. In the accreditation process, none of these organizations look at indications and outcomes, which should be considered to assess the appropriateness of care and ensure the safety and efficacy of the procedure. In order to satisfy the regulatory burden in a cost-effective manner, oversight of these centers by a specific organization is essential. This challenge is currently being addressed through the development of a vascular center certification program developed by the Society for Vascular Surgery (SVS).

MANAGING A CENTER

Medical Records

With an EHR, medical records should be completed in a timely manner. These records include history and physical, preoperative plan and discussion with the patient, informed consent, procedure notes, record of anesthesia, post-procedure recovery records, and follow-up. By law, patients must have access to some part of their records via the Internet. Inaccurate medical records can result in poor or dangerous care of the patient and have legal ramifications.

Policies and Procedures

The policy and procedures manual is the brain of your practice. It defines your best practices, and describes the conduct of the procedure and standard set by the lab to be followed for optimal outcomes.[57] A clear definition and description of the procedures, equipment needed to carry out the procedure, and conduct of the procedure should be detailed in the manual. If there is a complication, there should be a plan established to manage each complication. This would include emergency protocols and transfer protocols. If there are state or accreditation body requirements, these will be defined in the manual and should be followed accordingly.

Coding Compliance

Overcoding and undercoding are both illegal under federal law. Every year there are changes in coding for office-based procedures. The lab should have a certified coder who remains updated with the various changes. Periodic audits performed internally or by a third party are highly recommended because the cost of inaccurate coding is significant.

Billing

Billing can be done internally or outsourced depending on the current practice of the office. If the billing is outsourced, it is critical to ensure the billing is done in a timely manner and there is appropriate follow-up with insurance companies and patients in case an insurance company requires more data to be submitted. The charges should be set in a reasonable manner with the Medicare allowable charges in mind. A policy should be established for dealing with overdue bills. Special attention should be paid to bills greater than 90 days past due. If preauthorization from the insurance company is required, it should be obtained before the procedure is performed; otherwise the insurance company will not pay and a potentially very dissatisfied patient will be left with the bill. Because patients are more frequently required to provide copayments, the lab should take these into account when

assessing cash flow and have payment policies that can be discussed with the patients in advance.

Data Management

Data within a medical practice exists in many forms, including administrative and clinical records, which consist of both image and text files. A good EHR is crucial in providing quality care. There is need for software that can manage office notes, ultrasound and X-ray images, medications, inventory, billing outcomes, and be able to transmit data to a registry. The data should be contemporaneous, easy to access, and in a format that can be analyzed. Most of the commercially available generic EHRs are not suited to good data management, and thus there is a need for new carefully designed data management software.

Quality Control

To ensure the quality of the practice, data should be analyzed at regular intervals. There should be monthly meetings of physicians and staff to look at patient satisfaction and all untoward incidents and complications. Root cause analysis should be carried out for major or unexpected complications and appropriate measures should be taken to avoid them in the future.

The data should be compared to national results published in peer-reviewed journals. Indications for the procedure should be clearly delineated and should follow the published guidelines. If the lab is part of a registry,[58] data should be compared to other centers to make sure there are no significant deviations. Some states have regulations that require reporting of serious complications, unplanned transfer to the hospital, transmission of blood-borne pathogens, and any deaths that occur within 30 days of the procedure.

Outcome Management

Outcome measurement is important for quality control, marketing and success of the practice. When establishing a practice, one can quote the results from the literature to patients while obtaining informed consent. As the practice matures, patients will want to know the results from the specific practice or a specific physician. With appropriate data collection, the operators in the lab should be able to provide these results. Outcomes can only be measured if the patient has appropriate follow-up after the procedure. The best marketing tool one can have is one's results. If the lab is a part of a registry, outcomes can be compared internally between practice physicians and externally with other labs. Measurement of outcomes should include success of the procedure, complications, death, and long-term follow-up. Appropriate outcomes are well defined in the literature and should be comparable to the procedures being carried out in the hospital. One goal of the office-based lab should be to surpass the hospital outcomes because there is inherent efficiency in the office. The Vascular Quality Initiative, under the auspices of the SVS, has become an important tool in measuring outcomes in a hospital setting[58] and is currently being adapted to office-based endovascular labs. To maximize your revenue under Merit-based incentive payment system by CMS, it is important to have good outcomes and patient satisfaction.

Management of Complications

There are very few published reports documenting the incidence of complications observed in the office-based setting.[59] However, complications should be similar to those encountered in the hospital setting (Table 198.6). Due to limited resources, there should be written protocols to manage complications. In the most comprehensive report published,[6] the overall complication rate in 6458 procedures was 0.8%. The specific rates were: venous 2.2%; diagnostic aortogram 1%; arteriogram and intervention 2.7%; fistulogram 0.5%; catheters 0.3%; and venous filter related 2%. Twenty-six patients out of 2822 required hospital transfer and 10 patients needed an operation. As expected, operative site bleeding/hematoma was the most common reason to transfer the patient. There was no 30-day mortality related to the procedures. Others have also published data supporting the safety of these procedures in the office-based setting.[2,54] A protocol should be established concerning how serious complications will be handled. Specific personnel should be identified as responsible for calling 911 to enable patient transfer to the hospital. Ideally, the patient should be transferred to the hospital where the vascular surgeon has privileges. If a nonvascular surgeon is performing the procedure and the patient needs to be transferred, the interventionist should

TABLE 198.6 Types of Complications Observed Following Endovascular Procedures

Access Site Complications	Target Site Complications	Anesthesia Complications	Cardiac Complications	Device Related Complications	Other Complications
Active bleeding	Rupture	Hypoxia	Myocardial infarction	Retained wire	Syncope
Pseudoaneurysms	Dissection	Need to intubate	Arrhythmia	Broken catheter	Seizure
Hematoma	Occlusion			Catheter embolization	Renal failure
Closure of vessel	Thromboembolism			Stent migration	
Embolism					
Infection					

have an arrangement with the receiving hospital or a vascular surgeon to manage any complications. A written transfer agreement with the hospital is not required. Periodic mock drills should be carried out to manage a potential life- or limb-threatening event.

Marketing

All marketing is local and the key to any marketing program is communication The easiest and most cost-effective (free) method to communicate your message is to interact with local referring physicians. To market the vascular center, the center needs to know and communicate its own outcomes, strengths, and weaknesses. You need a strategy to address your weaknesses. Data should be collected and shared appropriately with referring physicians and patients. The age-old mantra of the 3 As – availability, affability, and ability – is key. If a patient's dialysis access is clotted and you can take care of it "now," so that the patient does not miss a dialysis treatment, you will have developed a strong relationship with the nephrologist and the dialysis center. With staff and patient turnover, the success of your practice relies on successful marketing, which is an ongoing process. If the patient and the referring physician have a good experience with you and your staff, they will become your ambassadors. The physician and the staff should dress professionally, act professionally, provide information in a brochure and online, and be polite and accessible. The center should be clean and inviting, a place where patients would like to return.

Avenues for Marketing

It is important to let referring physicians know what you do. Personal contact can be made by phone or in person. A brochure sent to the referring physician with information pertaining to the procedures done in the center is an inexpensive way of keeping physicians aware of your center's capabilities. You should send selected images of the procedure to the referring physician. It is an effective way to showcase your ability and provides follow-up. The center could also create a newsletter for physicians, which can serve as a continual reminder of the care you provide.

You can also communicate your message at a variety of meetings, such as physician meetings, social meetings (i.e., rotary club), or patient-oriented meetings. You could also arrange educational meetings for physicians, other midlevel providers, and patients. In addition, the local newspaper is always looking for articles about the latest advances in medicine. You could write an article or arrange for an interview regarding a new procedure you are offering. Approach these stations and offer your services to educate the public. If a new technology becomes available, arrange for an interview. Advertising in print media is declining rapidly as the penetration of this media is on the decline. However, if a newspaper has a strong presence in your community, an advertisement may be worthwhile, although it likely has decreasing returns. Advertising on radio is more cost-effective than TV, and may be particularly effective in marketing a venous center.

This role of the internet continues to grow at a fast pace (see Ch. 203, Online Branding and Marketing a Vascular Surgery Practice). A comprehensive website is essential to any modern-day practice. It should include pertinent information about the center and educational material about the procedures you perform. The site should be regularly assessed for accuracy and updated as the medical information evolves. There are various social media outlets that can be used for advertising. It is best to work with marketing people who understand this medium (see Ch. 206, Social Media in Vascular Surgery).

If you know your data and you are doing clinical research, you can publish it, which is another avenue for marketing what you do and how well you do it. Currently, there is very little data in the published literature reporting the outcomes of office-based endovascular procedures, thus various organizations are willing to support genuine research efforts.

If you decide to advertise, you need to follow certain guidelines as advocated by the American Medical Association (AMA) Code of Medical Ethics, Opinion 5.02. Be careful to abide by federal regulatory standards that apply to commercial advertising, and make only objective and factually supportable claims about experience, competence, and quality. Avoid aggressive high-pressure tactics and refrain from using testimonials that do not reflect typical patient outcomes. Be careful when claiming to have treated a particular ailment successfully in a large number of cases, because this can imply a certainty of results or create unjustified patient expectations. Finally, eschew claims of unique medical skills unless this is true for a particular geographic area.

Radiation Safety

Radiation safety[55,60] is an important part of all the safety measures undertaken in the office-based lab. Appropriate precautions need to be taken to minimize exposure of the patient, operator, and staff in the room. This includes appropriate lead shielding as required for the room and that all personnel need to wear appropriate lead-lined aprons, thyroid shield, head cover, and lead-lined glasses. Lead-lined gloves should be used under the sterile gloves when there is great likelihood of radiation exposure to the hands, i.e. procedures on dialysis access. Everyone should pass a radiation safety test every 2 years and records should be maintained. Radiation badges should be worn and checked at regular intervals. If the operator is also performing endovascular procedures in the hospital, the radiation dose received by the operator in the hospital should be combined to keep total exposure within safe limits.

Patient Satisfaction

It is paramount for the success of these centers to achieve a very high patient satisfaction rate. In a patient satisfaction survey administered in the author's office-based laboratory, two questions were asked: (1) were they satisfied, and (2) will they return to the office if another procedure is needed; in this survey the patient satisfaction rate was 98% to 99%.[6] There were many reasons patients cited for being highly satisfied: they see

BOX 198.1 Sample Patient Satisfaction Survey

Using the number scale described below, please circle the appropriate number to indicate your agreement with each statement:
1. Highly disagree
2. Moderately disagree
3. Agree
4. Moderately agree
5. Highly agree

Were you satisfied with our care?
1 2 3 4 5
If you need another procedure will you come back to our office?
1 2 3 4 5
Have you had a similar procedure in the hospital?
Yes/No
If yes, where will you prefer to have your next procedure?
Hospital/Office
If not in the office, what are the reasons?
Poor pain control
Did not feel safe
Staff was not competent
Other reason:_____

the same staff every time; there is no hospital maze to navigate; no hospital registration; no pre-procedure workup in most patients; the time spent in the center is significantly less than in the hospital; access is easier for the patient; and the results are comparable with a hospital-based procedure. The main reason patients may not be satisfied is occasional poor pain control in the office-based setting if conscious sedation is not used judiciously. There are currently no standard surveys available that assess patient satisfaction in these centers. An example of a patient satisfaction survey can be found in Box 198.1.

Evaluation of the Center by Physicians

A quarterly evaluation of marketing efforts, screening programs, outcomes, complications, rates of hospital transfer, and financial data should be performed by the physicians in the group. At these meetings, the minutes should be documented and maintained. In case of a sentinel event, an emergency meeting of all parties concerned, including the medical director of the center, should occur. If the center is failing to meet its own goals, root cause analysis should be conducted and any appropriate actions should be taken. A quarterly profit/loss report is crucial for the financial viability of the center. As new devices come to the market, a cost/benefit analysis should be completed before procuring the device for the center. Processes should be streamlined to enhance the effectiveness of the center. Various operators should have a consensus about device use to minimize the number of products on the shelf. Finally, the center should not offer inferior care as compared to the community standard, based on cost.

FUTURE

The future of the outpatient vascular center is bright. As healthcare payers continue to demand efficiency and institute a value-based payment system, office-based care will have an increased demand because it has proven to be safe, cost-effective, and patient-friendly. In the future, payments to physicians will be made under the Medicare Access and Children's Health Insurance Program (CHIP) Reauthorization Act, Public Law No. 114-10 Act (MACRA). Physician payment is being provided through a new merit-based incentive payment system (MIPS). An increasing number of patients are demanding outpatient services as demonstrated by the success of ASCs providing endoscopy, plastic, and ophthalmology services. However, there is a paucity of data supporting the efficient use of outpatient vascular centers. When the inpatient hospital services get overwhelmed by a pandemic like the one caused by COVID-19, an office-based center or an ASC with proper precautions can continue to provide care. As more data becomes available, the value of these centers will be recognized by patients and payers alike, making these centers the preferred location for treatment of peripheral arterial and venous disease.

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This paper showed the feasibility of same day discharge after peripheral angioplasty without increasing adverse outcomes.

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A complete reference list can be found online at www.expertconsult.com.

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CHAPTER 199

Development and Operation of Outpatient Dialysis Access Centers

JOHN R. ROSS and TERRY F. LITCHFIELD

INTRODUCTION

Hemodialysis is the perfect example of bioengineering being applied to medicine to preserve the life of the patient with an otherwise fatal disease. Unfortunately, the interface between the biomechanical mechanism in the patient, i.e., the vascular access, is defective. Problems related to the vascular access are a major cause of hospitalization of the dialysis patient, contribute approximately 20% of the cost of caring for these cases, and contribute significantly to their morbidity and mortality. Evidence-based dialysis vascular access planning, creation and problem management are critical in allowing the end-stage renal disease patient to realize their longevity potential. This process is being increasingly performed in outpatient dialysis access centers (DAC). In the past 20 years, dialysis access procedures have gradually shifted from a hospital-based, open surgical approach to endovascular treatment with approximately 50% of the cases being performed outside of the hospital setting.

THE COMPLETE INTEGRATED ACCESS CONCEPT

The issues related to the establishment of planning, placement, and management of the dialysis access clinical structure include how, where, and who selects the renal replacement therapy (RRT) option including the dialysis type and modality, timing of access placement, and who places and maintains the dialysis access. The lack of, and the difficulty of performing, randomized studies with multiple confounding factors in the heterogeneous and rapidly changing ESRD population demographics only partly explains the dialysis access conundrum. In addition, there are rapidly developing and competing technologies, the wide spectrum of the professional experience, bias, and socioeconomic forces to make the ESRD problems multivariate and complex. The dialysis access conundrum is further magnified by the several specialties involved in providing dialysis access clinical care. Most would agree that a patient-centered dialysis access decision-making algorithm is desirable. The issue is not who places the access but who does it right, every time, to everyone, and everywhere.[1] A related confounding factor is the widely different professional experience with which we make decisions about the best treatment of the patient. This makes the decision-making process complex and related not only to the skills and knowledge level of the practitioner, but also to his or her specialty.

THE DIALYSIS ACCESS CENTER

The dialysis access center's structure takes many forms (Video 199.1), summarized below:

- **One physician office** referral patterns likely affect treatment choices and outcomes. The Fistula First movement favored

this setting. Ideally, physicians with limited resources have developed referral patterns to centers as needed to best serve the patient-centered algorithm concept.

- **Outpatient dialysis access center** with capability to perform access repair, maintenance and replacement including vascular access procedures to maintain the current access. Since the graft option is not favored or used in appropriate patients; limitations are present but less significant than in the single provider situation. Ideally, these centers have developed collaborative arrangements with centers that offer new access creation.
- **The complete dialysis access center** performs all dialysis access procedures (creation, maintenance, salvage and abandoning), including peritoneal dialysis. It is often hospital affiliated with available specialties (i.e., MRI, CT, ICU) as needed. The complete access center also acts as a referral for complicated cases. This center has dedicated technologists for ultrasound and radiology giving the ability to deliver all dialysis access needs in one visit setting. The complete dialysis access center also has teaching for nurses and technologists and hands-on simulation and clinical training programs for physicians with certifications issued (Fig. 199.1).

Whether the DAC is structured as a stand-alone hospital-associated outpatient facility (Place of Service (POS) 22), an ambulatory surgical center (POS 24) or a physician office–based facility (POS 11), they share certain basic characteristics. It is located outside of the hospital, generally in a location convenient to dialysis facilities and the patient population being served. The DAC is a dedicated facility specifically designed, equipped, staffed, and operated for the management of the dialysis vascular access. Typically, these facilities work in close coordination with the dialysis community with strong engagement from the patients involved. Because the DAC is dealing with vascular access management in a relatively closed population, many of which require recurrent visits, a team approach is developed with close coordination between the physicians and staff of the facility and that of the dialysis clinics along with a personal familiarity with the individual patients being cared for.

SIZE

The DAC is generally between 3500 and 15,000 square feet in size and is built to healthcare facility standards to promote patient safety and efficient operations (Fig. 199.2). The common areas of development in each of these include convenient parking, a patient friendly/accessible waiting room, adequate space for nursing assessment and patient intake, pre- and post-procedure patient areas, patient changing room, procedure/operating room(s), storage areas, nursing station and recovery area along with administrative areas for the center manager, physician with break rooms and restrooms for the staff and patients. The use of good lighting and large hallways with aesthetically pleasing artwork support a healing healthcare environment. Comfortable seating areas for patients (including bariatric sized chairs) are important features for patients and their accompanying family members.

COMPUTERIZED DATA SYSTEM

DAC design and planning should include the hardware, software, and peripheral equipment necessary for data management. Data is essential to the operation of the facility for

Figure 199.2 San Diego Vascular Access Center.

Figure 199.1 The complete dialysis access center has its own physical building (**A**), ideally attached to a hospital with access to acute dialysis, advanced radiology services (i.e., CT, MRI), and several spatial operating suites (**B**) fully equipped for anesthesia, mobile C-arms. The access center serves as a referral point for a larger geographic area in a collaborative spirit where patients are triaged and treated in one visit ("same day shopping").

managing billing and collections, maintenance of patient records, and monitoring outcomes and performance. The selection of an Electronic Health Record (EHR) system is a difficult but essential undertaking with a major capital expense associated with its implementation.

PROCEDURE ROOM

The procedure room should be equipped in much the same way as a standard operating room but greatly simplified. The number of procedure rooms necessary when planning the DAC will depend upon the size of the patient population being supported and the number of resulting cases being performed. Since these procedures are done with only sedation/analgesia, anesthesia equipment is not needed unless a complete DAC is envisioned including surgical placement. An operating table suitable for use with fluoroscopy is necessary. A portable C-arm with a vascular package is the preferred equipment for these types of procedures. A radiology PAC system is important for maintaining patient medical records. Good surgical lighting, patient monitoring equipment and other minor equipment is necessary. Good ultrasound equipment is also important for evaluating vascular access, measuring blood flow and use for central venous dialysis catheter placement.

As an outpatient center, the DAC must have adequate supplies available for procedures. This should include an adequate size range and variety of basic interventional devices such as sheaths, guidewires, and catheters. "Bail-out" supplies must also be available, items such as stents, embolectomy catheters, embolization coils, and endovascular snares. However, with a limited number of operators performing limited types of procedures, economy in supply management is possible. Simplification and avoiding duplication are important. The key factors for supply choice should be safety, efficacy, efficiency, and price in that order. To assure economy, operator preference should only enter the equation when all other factors are the same.

STAFF OF THE DAC

Typically, one full-time equivalent (FTE) physician can generally handle 8 to 10 cases per day, depending upon the complexity of the case. If more cases are anticipated based upon the size of the patient population being served, additional physician operators will be required. For surgical placement, a qualified surgeon with experience in dialysis access is critical. The specialty certification of the physician is not important; however, there are three traits that are essential for optimal dialysis vascular access management. The physician must (1) be familiar with and understand the dialysis patient and their unique needs and requirements, (2) be knowledgeable concerning dialysis vascular access issues and problems, and evidence-based techniques and procedures necessary for their management, and (3) have clinical expertise in performing the necessary procedures.

In addition to being the operating physician, in some cases the interventionalist takes on the role of manager and becomes the "face" of the center to the community. As such, he/she should be available for education, training and presentations related to dialysis vascular access to the dialysis community, physicians, dialysis unit staff and patients.

In addition to 1 FTE physician per operating room, DAC staffing should include at least 2–4 registered nurses (RNs), 2–4 radiology technologists (RTs), and an individual to manage the front desk of the facility and act as an access coordinator. This staffing is related to case volume and the number of operating/procedure rooms. In most of these facilities one of the individuals, either an RN or RT, is the facility manager overseeing the operational aspects of the center. For larger centers, you will need an administrator to handle the regulatory and operations needs of a larger DAC. In addition, each member of the DAC staff is generally assigned one or more roles other than their job-specific duty. These are roles such as infection control preventionist, safety officer, radiation safety officer, and materials management/supply chain coordinator, to name a few. These additional roles are performed when there are no patients in the facility. All staff should be advanced cardiac life support (ACLS) certified. Billing, coding, and collections are typically performed offsite.

It is important that the nurses, technologists, and access coordinator be knowledgeable about dialysis vascular access and understand the problems of the dialysis patient. They must be capable of working closely together and work quickly since the window of treatment opportunity with sedation/analgesia is short and because many patients must get back to the dialysis clinic for their scheduled treatment. Constancy of communication with the dialysis facilities being served is extremely important.

PROCEDURE SUCCESS AND SAFETY OF THE DAC

Before a procedure requiring sedation/analgesia that has typically been performed in the hospital setting is moved to a freestanding outpatient facility, especially procedures performed on patients classified as American Society of Anesthesiology (ASA) physical status class III and IV, it is important to assure that it can be performed successfully and safely. A series of studies have been performed to evaluate this issue.

In a study of 14,067 cases treated in a DAC designed to evaluate the effectiveness and safety of procedures being performed, the reported success rate for the total procedure profile was 96%,[2] which was higher than that reported for the same procedures performed in the hospital setting. The procedure complication rate was 3.5% (the Society of Interventional Radiology threshold is 5%) with more than 90% of these being minor complications requiring no treatment and having no adverse sequelae.

Since almost all of the procedures performed in the DAC are done with sedation/analgesia with no anesthesiologist present, a study was conducted involving 12,896 cases to determine the level of safety associated using this strategy.[3] Sedation/analgesia was achieved using either midazolam only, fentanyl only or a combination of both agents. The level of sedation was

Patients treated in the DAC have lower PMPM payments; fewer infections; septicemia-related hospitalizations; unrelated hospitalizations; and an overall lower mortality rate than those treated in the HOPD ($P<0.001$)

	DAC (n=64,018)	HOPD (n=64,018)	Difference (DAC – HOPD)
Dialysis vascular access-related PMPM payment (including dialysis and drugs)	**$4704**	**$5159**	**–$454*****
Outcomes per patients			
Average number of related and unrelated hospitalizations	4.0	4.3	–0.3***
Average number of infections	0.21	0.28	–0.07***
Average number of septicemia hospitalizations	0.16	0.17	–0.01***
Outpatient dialysis treatments per week	2.8	2.8	0.0**
All-cause mortality rate during episode	44.6%	50.2%	11.1%***
Episode length (years)	2.4	2.2	0.2***

Source: Dobson DaVanzo Analysis of USRDS Data 2006-2009.
**Statistically significant at $P<0.01$ ***Statistically significant at $P<0.001$

Figure 199.3 Dialysis access centers have better outcomes and lower costs. *DAC,* dialysis access center; *HOPD,* hospital outpatient department; *PMPM,* per member per month.

sedation/analgesia as classified by ASA, equivalent to a level between 4 and 5 on the Ramsay Sedation Scale. The frequency of procedural-related complications in this cohort was 3.1% (more than 90% were minor) and the frequency of complications related to sedation was 0.14% (18 cases), the majority of which were either a temporary drop in oxygen saturation below 90% or a temporary period of hypotension. No serious complications related to sedation occurred.

The staff of the DAC facility spends much of the day in the procedure room performing procedures that involve the use of fluoroscopy resulting in radiation exposure to them and their patients. Many hemodialysis patients require repetitive procedures resulting in the additive effects of radiation exposure. Vascular access procedures are somewhat unique in that the interventionalist is working and acquiring images in the same anatomical area. By necessity, they are near the primary radiation beam and at times their hands may actually be within the beam. While the levels of radiation exposure involving a mobile C-arm as used in the DAC are significantly less than those of a fixed C-arm typically used in the hospital setting, radiation safety is still extremely important. Studies involving radiologists performing these types of procedures have shown relatively low levels of radiation exposure; however, most of the physicians working in the DAC are not radiology trained. In order to evaluate the level of radiation exposure associated with procedures performed in the DAC, a study was performed looking at each of the major procedures.[4] The numbers of cases involved by procedure ranged from 500 to 6000. The levels of radiation exposure were found to be 3 to 8 times lower than those reported for these procedures in the hospital setting.[4]

In order to evaluate the effect of vascular access treatment at a DAC on the overall patient population being served, over 27,000 cases treated at the DAC were compared with the same number of cases treated in the hospital setting.[5] The comparison was made using propensity score matching for demographic profile on an individual patient basis. It was found that patients treated in the DAC had significantly better outcomes including fewer related hospitalizations, vascular access-related infections, septicemia-related hospitalizations and a lower mortality rate (Fig. 199.3).

PATIENT SATISFACTION

Virtually all studies that have been published note that, like other service lines, patient satisfaction is improved when medical care is moved from the hospital to the outpatient environment. The convenience of the location and the focused attention to their individual needs results in an increased level of patient satisfaction and engagement. Both emergent and elective procedures can be performed in a timelier fashion. Because the facility is dealing only with dialysis access dedicated to the needs of the individual patient, greater attention to customer service and a more focused level of quality assurance and improvement is possible. Because many of the procedural needs of the patients are recurrent, staff–patient relationships develop that add to patient engagement and satisfaction. This relationship also makes it possible for the DAC to provide a higher level of patient education which is important to their overall medical care.

ECONOMICS

The size of the dialysis patient population being served is critically important in evaluating the economic feasibility of establishing a DAC. Typically, 1 to 1.5 procedures per dialysis patient per year can be anticipated. It has been estimated that 4 patients per day is the minimum economic break-even point. Therefore, a minimum patient population in the range of 700 to 800 is required. The primary procedures performed in the DAC are AVF angioplasty, AVG angioplasty, AVF thrombectomy, AVG thrombectomy, tunneled catheter placement and tunneled catheter exchange. In an established DAC with an experienced operator the mean time required for these procedures has been reported to be 24 minutes, 18 minutes, 55 minutes,

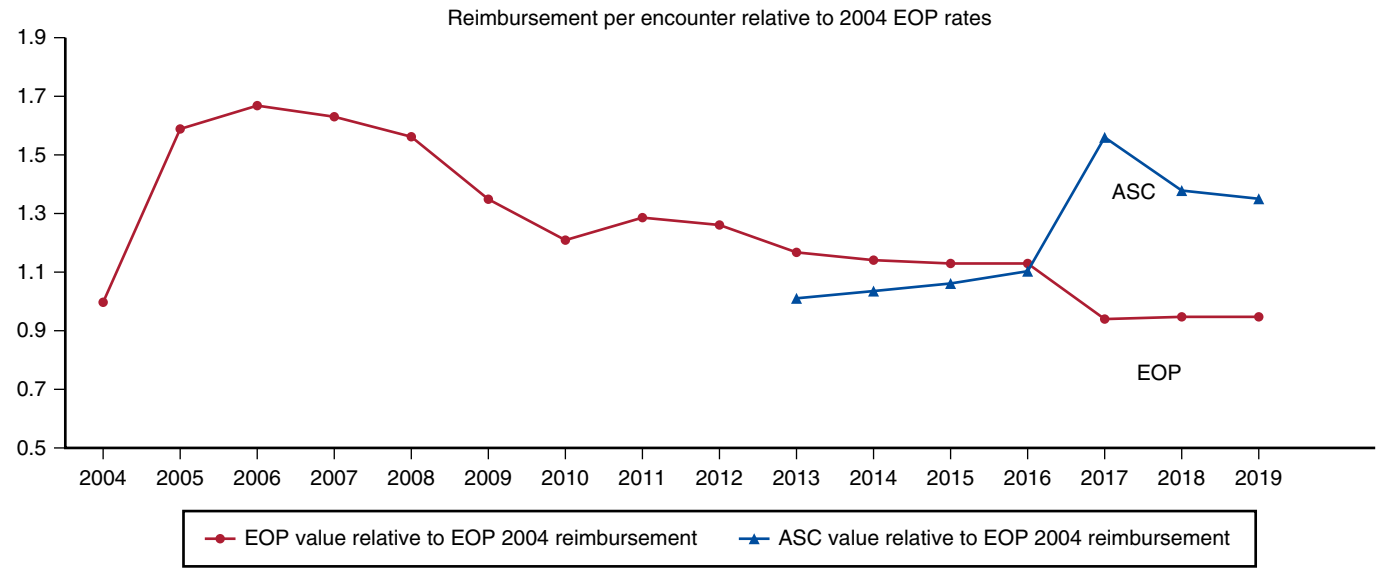

Figure 199.4 Vascular Access Outpatient Reimbursement Trend.

37 minutes, 27 minutes, and 19 minutes, respectively.[6] The time required for turnover in the procedure room must be added to this to determine the total time required per case. A single procedure room can generally accommodate approximately 8 to 10 cases each day, dependent upon the complexity of the case. For the complete DAC offering surgery and PD catheter placement, those numbers are small averaging less than 0.25 procedures per dialysis patient per year.

The reimbursement for dialysis access procedures in a DAC has been on a downward trend for the past few years (Fig. 199.4), with more than 25% of the physician office–based facilities (POS 11) suffering business failures since the 2017 revaluation and the development of new CPT codes related to dialysis access repair and maintenance. There is a national advocacy group (Dialysis Vascular Access Coalition) along with the specialty societies that work tirelessly to educate and advocate with policy makers related to the importance of outpatient dialysis vascular access. The work of this group that created optimism that some degree of improvement may be possible.

REGULATORY AND ADVOCACY

The Kidney Disease Outcomes Quality Initiative (KDOQI) has published national benchmarks related to Vascular Access[7] and the most recent update (2019) provides the latest in evidence-based outcomes standards when treating access dysfunction. In 2019/2020, the National Kidney Foundation launched a new initiative to update the clinical evidence relating to vascular access with its *Kidney Disease Outcomes Quality Initiative (KDOQI) Clinical Practice Guideline for Vascular Access*. While the updated KDOQI guidelines continue to recognize the paramount importance of fistulas, the guidelines also recognize that newer technologies (e.g., peritoneal) and earlier interventions (e.g., a permanent functioning fistula created at the CKD, or "pre-ESRD" stage) mean that a patient's vascular access needs are likely to involve multiple modalities over the course of a patient's life. In addition, the Centers for Medicare and Medicaid (CMS) has created quality metrics for dialysis units that bonus or penalize dialysis centers for access care, with bonus points and payment for AV fistula use and penalties for hemodialysis catheter use. The United States Renal Data System[8] annually publishes the ESRD outcomes for all patients in the US, including a chapter on vascular access. The lofty goals of the Advancing American Kidney Health, an Executive Order from the US President, has as goals, more than 50% of the dialysis patients treated at home or transplanted by 2025, so we may expect increased interest in peritoneal dialysis procedures in these centers as more patients seek home treatment.

CONCLUSION

Patients requiring lifelong renal replacement therapy (RRT) are uncommon; about 1:100,000. It is a highly complex challenge with a huge financial burden to society. RRT should be seen and managed as a single entity, with the patient's lifetime vascular access needs planned early in a holistic way considering the four modalities (transplant, PD, HD, palliation), all of which they may end up using during their lifetime. RRT is multi-layered and complex. This chapter concentrates on the outpatient dialysis vascular access center where the patient can have access created, repaired, maintained and replaced providing the setting for *creation, maintenance, salvage,* and *abandonment* of dialysis vascular access. The outpatient facility for dialysis vascular access has evolved into a mainstay of dialysis access care and has been shown to provide consistently reliable and efficient care. Safety, outcomes, and patient satisfaction appear to be superior to those procedures performed in hospitals. Challenges regarding the growth and survival of these centers are now largely focused around public policy, regulations, and the erosion of reimbursement schedules. With the 2019 President's

Executive Order Advancing American Kidney Health, the outpatient access center may have an opportunity to play an even more pivotal role as scarce resources are allocated to delivery systems that favor efficiency, effectiveness, safety, quality, and patient engagement.

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CHAPTER 200

Alternative Payment Models in Vascular Surgery

JEFFREY EDWARDS and BRAD JOHNSON

INTRODUCTION

Alternative payment models were introduced with the Quality Payment Program, which was established with the Medicare Access and Children's Health Insurance Plan (CHIP) Reauthorization Act of 2015 (MACRA). Prior to MACRA, payments for Medicare services were set by the Sustainable Growth Rate (SGR). Under the SGR law, spending increases were capped in accordance with growth in the Medicare population with a modest allowance for inflation. In practice, this did not allow for an increase in service utilization by healthcare providers, and the reimbursement for each unit of service had to be adjusted downward to hold costs relatively constant. In order to prevent large decreases in the Physician Fee Schedule, Congress had to pass a new law annually to authorize the current fee schedule and prevent large cuts in payments to providers. MACRA was passed with strong bipartisan support, passing the House of Representatives with a 392–37 vote and the Senate with a 92–8 vote, and is not part of the Affordable Care Act.

The objectives of MACRA are defined by the Centers for Medicare and Medicaid Services (CMS) as follows:

- To improve beneficiary population health
- To improve the care received by Medicare beneficiaries
- To lower costs to the Medicare program through improvement of care and health
- To advance the use of healthcare information between allied providers and patients
- To educate, engage, and empower patients as members of their care team
- To maximize Quality Payment Program (QPP) participation with a flexible and transparent design, and easy-to-use program tools
- To maximize QPP participation through education, outreach, and support tailored to the needs of practices, especially those that are small, rural, and in underserved areas
- To expand alternative payment model (APM) participation
- To provide accurate, timely, and actionable performance data to clinicians, patients, and other stakeholders
- To continuously improve QPP, based on participant feedback and collaboration.

The QPP started on January 1, 2017 and is designed to reward high-value, high quality Medicare clinicians with payment increases, while penalizing those providers who do not meet performance standards. There are two participation tracks with the QPP – the Merit-based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (AAPM). Clinicians who bill Medicare Part B more than $30,000 per year and/or provide care for more than 100 Medicare patients per year must participate in either MIPS (increased to $90,000 and 200 patients in 2018) or AAPM to avoid a negative adjustment to their reimbursements. When QPP became active in 2017, there were no advanced payment models (APMs) with a vascular focus that qualified as a Medicare AAPM, thus the majority of vascular surgeons have had to participate in MIPS.[1,2]

MERIT-BASED INCENTIVE PAYMENT SYSTEM

MIPS has four components: Quality, Promoting Interoperability (PI; previously called Advancing Care Information), Improvement Activities (IA), and Cost. Each of the four components is scored to create a final composite score that determines reimbursement rate. While data collection began in the performance year 2017, QPP rates did not go into effect until 2019. In the first year, quality comprised 60% of the score, PI comprised 25%, and IA comprised 15% (Cost was not included initially to allow for additional data collection and to enable planning for future years).[1,2] It is important to note that specific measures of each component may change on an annual basis reflecting policy changes.

The Quality performance category replaced the former Physician Quality Reporting System (PQRS), and it pertains to the quality of care delivered based on performance measures created by CMS. Clinicians pick six measures (out of 300) which best fit their practice (https://qpp.cms.gov/mips/overview). One example of a vascular surgery quality measure is the "percentage of patients 18 years and older undergoing infra-inguinal lower extremity bypass who are prescribed a statin medication at discharge."[1,2] This has created unexpected challenges for vascular surgeons in academic practices or large multi-specialty groups, as the six allowable measures are selected for the entire group. For example, they may select measures on total knee replacements, depression, etc., that do not pertain to the care of vascular surgery patients. Efforts by the Society for Vascular Surgery (SVS) to allow for reporting by the vascular surgery practices within the larger group have thus far been unsuccessful.

The Promoting Interoperability (PI) performance category was previously known as the Advancing Care Information performance category. This focuses on patient engagement and the electronic exchange of health information using certified electronic health record technology (CEHRT). PI replaced the Medicare Electronic Health Record (EHR) Incentive Program for Eligible Clinicians and is satisfied by proactively sharing information with other healthcare providers or the patient. Examples include sharing test results, encounter summaries, and therapeutic plans with patients or other healthcare facilities.[1]

Improvement Activities is a new performance category, which collects information regarding actions taken to improve a clinician's care processes, enhance patient engagement, and increase access to care. This category creates an inventory which allows the provider to choose the activities appropriate to their practice, and includes over 90 activities in nine subcategories. Examples include expanded practice access, population management, care coordination, beneficiary engagement, patient safety, and practice assessment.[1,2]

The Cost performance category replaced the Value-based Payment Modifier, and is calculated by CMS as the cost of care provided. MIPS uses these cost measures to gauge the total cost of care during the year and during individual patient encounters. This metric was incorporated into clinicians' MIPS score beginning in 2018 and weighted at 10% of the total MIPS score. The first two cost measures were: (1) Medicare Spending Per Beneficiary (MSPB) and (2) Total Per Capita Cost (TPCC). The MSPB cost measure was designed to evaluate efficiency of care during a hospital stay, and includes a global period starting 3 days prior to hospitalization and ending 30 days after discharge. The TPCC cost measure evaluates overall efficiency of a provider's care, and is calculated using all Medicare beneficiaries under a provider's care. Episode-based cost measures are currently in development, with additional categories being added each year.[2] Vascular surgery episode-based cost measures were first introduced in the performance year 2020 and include Hemodialysis Access Creation and Revascularization for Lower Extremity Chronic Critical Limb Ischemia.[1] These episode-based cost measures are a critical component of the QPP MIPS APM model, as the MIPS cost performance category was weighted at 30% of the final MIPS score beginning in the performance year 2019.[1–3]

ACCOUNTABLE CARE ORGANIZATION

ACOs as defined by CMS are groups of doctors, hospitals, and other healthcare providers, who come together voluntarily to give coordinated high-quality care to their Medicare patients.

The goal of coordinated care is to ensure that patients get the right care at the right time, while avoiding unnecessary duplication of services and preventing medical errors.

When an ACO succeeds both in delivering high-quality care and spending healthcare dollars more wisely, the ACO will share in the savings it achieves for the Medicare program.[4]

In 2011, CMS approved 32 Pioneer Accountable Care Organizations; of which 19 remained active through 2015. On July 7, 2013, the Centers for Medicare and Medicaid Services announced the results of the Pioneer ACO demonstration with 19 of 32 producing a shared savings. The Pioneer ACOs earned an estimated $76 million. While ACOs have the ability to improve coordination of care and reduce cost they are difficult to organize and require significant startup costs. Furthermore, a successful ACO requires an adequate number of primary care physicians and a robust electronic medical record (EMR). As with MIPS in larger academic practices, due to the small number of vascular surgeons and their procedures, they have a relatively small effect on system quality and costs. Vascular surgery-specific APMs in lower extremity revascularization, aortic aneurysm repair, etc., have been proposed, which would allow more control over which data points can be attributed to vascular surgery quality and cost analyses.[4]

ROLE OF SOCIETIES/ADVOCACY IN THE DEVELOPMENT OF ALTERNATE PAYMENT MODELS

The SVS has been involved with the development of alternative payment models since the MACRA was authorized in 2015. Because of the Vascular Quality Initiative (VQI), SVS had already developed quality measures to improve outcomes in the care of the vascular patient. These measures and the data

from VQI were subsequently used by the SVS Quality Performance and Measures Committee (QPMC) to present to the National Quality Forum for approval. For example, Measure 465 – Perioperative antiplatelet therapy for patients undergoing CEA – was approved and used by Medicare in the QPP. These measures were further utilized by the VQI to become a MIPS Qualified Clinical Data Registry (QCDR), enabling vascular surgeons to report their outcomes to MIPS via VQI.

The Centers for Medicare & Medicaid Services (CMS) and its contractor (Acumen, LLC) on April 5, 2017 invited the SVS QPMC to participate in a listening session on the development of episode-based cost measures for the Merit-based Incentive Payment System (MIPS) in the Quality Payment Program. In June of 2017, members of the SVS Quality Measures and Performance Committee (QMPC) and Coding Committee along with two vascular surgeons in private practice attended a two day session in Washington DC to help create an episode-based cost measure – Revascularization for Lower Extremity Chronic Critical Limb Ischemia. This was followed by the development in the second wave of cost measures, Hemodialysis Access Creation.

CREATION OF A VASCULAR SURGERY ADVANCED ALTERNATE PAYMENT MODEL

As the SVS leadership realized that Medicare was planning to initiate value-based payment reform, the SVS convened an APM Taskforce. The Taskforce's mission was to support the ability of vascular surgeons to participate in value-based vascular care that would qualify as an Advanced APM under the QPP, thus receiving the 5% bonus payments and the higher conversion factor update associated with successful participation. A secondary goal was to develop a more in-depth understanding of the methodology and implications of bundled payment in vascular surgery. The Taskforce includes broad representation across committees with a wide array of expertise. This includes the Clinical Practice Council, the Government Relations Committee, the Coding and Reimbursement Committee, and the Quality and Performance Measures Committee.

The SVS APM Taskforce selected peripheral artery disease (PAD) as an initial clinical condition for APM modeling due to its prevalence and rising cost of care. PAD is a global health problem that consumes in excess of $20 billion of healthcare expenditure in the United States annually. In 2015, the SAGE Group, a research and consulting company, noted that there were 20 million people in the United States with PAD and estimated that this would increase to 25 million by 2030.[5–7]

In the PAD APM model, a revascularization procedure would trigger the collection of data on costs and quality and 90 days of subsequent care. The Taskforce realized the complexities in determining the quality outcomes along with the costs, which include clinical services such as imaging, readmission and home health services. Evaluation of quality process measures include ankle–brachial index (ABI) measurement, optimal medical therapy initiation, smoking cessation, and glycemic control. Clinical outcome measures, on the other hand, measure the treatment results. In PAD, meaningful outcomes include amputation rates, mortality rates, hospitalization durations, and readmission rates. Costs of caring for PAD patients are difficult to control as multiple stakeholders such as podiatry, cardiology, interventional radiology, primary care, endocrinology, and ancillary care providers (home health agencies, rehabilitation centers, wound centers, etc.) are involved in the postoperative care. While the Taskforce has realized the difficulty of developing a PAD APM, its creation will provide a comprehensive model for improving patient outcomes while decreasing costs. Current efforts have been hindered by significant personnel and financial costs, however the taskforce continues to work towards the development of the APM.[8]

CONCLUSION

CMS seeks to incentivize high value care with alternative payment models which reward high quality care while minimizing cost. These efforts to improve quality care and reduce cost mean that Alternative Payment Models will certainly not disappear and only become more prominent in our care of vascular surgery patients. MACRA currently incentivizes providers to satisfy their QPP requirements through APMs, however eligibility requirements exclude many vascular providers, so they must participate in MIPS. The development of vascular-specific APMs is complex and influenced by a changing financial and political landscape, but participating in the QPP is vital to the long-term viability of vascular surgeons given the high proportion of Medicare patients in most practices. Vascular surgeons must continue our participation in the development of these models and demonstrate to CMS that we can provide the best quality care at the least cost in caring for the vascular surgery patient.

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201 CHAPTER

Improving Quality and the Value of a Vascular Registry to the Practice

LARRY W. KRAISS, PHILIP P. GOODNEY, ADAM W. BECK, FRED A. WEAVER, and JENS ELDRUP-JORGENSEN

INTRODUCTION

Registries contain large bodies of information, generally collected in the course of routine clinical practice. The usefulness or value of that information depends on many issues but primarily whether it is used for a purpose consistent with the intent of the registry and whether the registry data are regarded as valid. This chapter summarizes the characteristics of registries, and examines how they might – or might not – add value to the practice of vascular surgery. A comprehensive review of medical registries is also available for those who wish more detail.[1]

THE DEFINITION OF A MEDICAL REGISTRY

Although most practitioners intuitively understand the concept, it is useful to unambiguously define a medical registry. Some have applied the term to almost any database that collects information about patients or clinical events. However, there are specific characteristics that make a collected data set a true registry. The most useful definition was advanced by Solomon et al. in 1991 and subsequently subscribed by many others: a systematic collection of a clearly defined set of health and demographic data for patients with specific health characteristics, held in a central database for a predefined purpose.[2,3]

Understanding the predefined purpose of the registry is paramount, as this *Inclusion Principle* will govern downstream decisions about what data should be collected.[4] In other words, what characteristic(s) of a patient or medical event qualifies it for registry inclusion?[5] The diversity of medical registries arises from the various reasons or predefined purposes for their existence.

One way of operationalizing this definition has been termed the **MDR-OK** model:[5]

Mergeable data facilitates aggregation of information submitted from various individual sources that can be combined into a larger, more representative, dataset.

Data set standardization means that the same characteristics are collected on every patient or case included in the registry. The predefined purpose of the registry will inform the process of selecting the characteristics to be collected for later analysis. Adherence to collecting a clearly defined standardized data set should reduce the subsequent problem of missing information during analyses. Completeness of data collection is a key factor in determining the quality or external validity of a registry.

Rules for data collection provide guidelines for translating raw source data into definitions established by the registry. These guidelines are typically contained in a protocol and data dictionary developed during conception of the registry. Observance of these rules will ensure that data in the registry are reproducible and consistent, even if collected by different people at different times in different locations about different patients or events. The degree to which these rules are complied with affects the consistency of a registry, which is a measure of internal validity. Examples of this process are mapping blood pressure information into a registry data element such as "Hypertension" or creatinine values into a data element termed "Renal Insufficiency."

The aforementioned characteristics are fundamental to a medical data registry. Several additional features may enhance the value of a registry:

Observation over time means that a registry collects longitudinal patient data, which are then linked to the initial patient record.

Knowledge of outcomes may allow a registry to indicate which characteristics collected as part of the initial registry record are more or less likely to lead to a particular clinical outcome. It is important to recognize that the outcome in question must be as carefully defined and standardized as any of the initial data elements. Outcomes assessment may be determined actively by their specific addition to the registry by its participants or passively by linkage to administrative data. An example of the latter is tracking vital status by using a common identifier such as a social security number to link the initial registry record with the Social Security Death Index. Registries are becoming increasingly sophisticated in developing relationships and linkages with administrative data sources (see Linkage with Administrative Datasets to Monitor Device-Related Outcomes, below).

WHY REGISTRIES EXIST

Like virtually all physicians, vascular surgeons strive to provide the best outcomes for their patients. To do this, information is needed about which procedures or treatments work best for which patients at which times. It is an axiom of quality improvement that "you can't improve what you don't measure." Registries measure activities that occur during routine clinical care, as opposed to information derived from randomized clinical trials, which are in reality experiments designed to answer specific questions or test explicitly stated hypotheses.

Further, in recent years, many payers have restricted the use of new or evolving technology unless the results of these procedures are followed carefully in registries.[6,7] For example, the FDA has also used medical registries for the purpose of post-approval device surveillance of TEVAR and TAVR devices.[8,9]

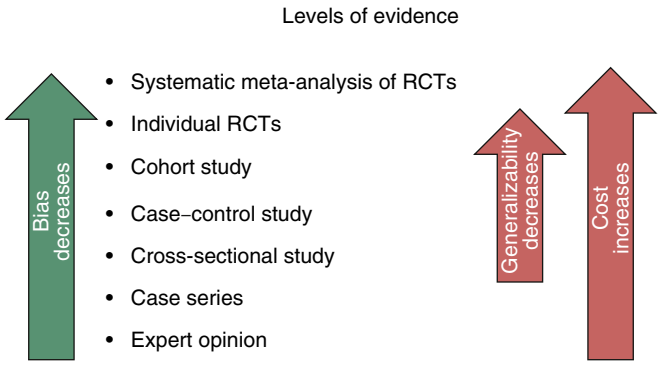


Figure 201.1 Relationship of bias in medical evidence relative to generalizability and cost. Cohort, case–control and cross-sectional studies are often based on registry data. *RCT,* randomized controlled trial.

There is a well-recognized hierarchy of medical evidence based primarily on whether the conclusion delivered by a particular type of study is felt to be biased (Fig. 201.1).[10,11] Systematic meta-analyses of related randomized controlled trials (RCTs) are regarded as the highest quality evidence followed by individual RCTs themselves. However, RCTs have numerous drawbacks. Randomization is unethical in situations where clinical equipoise does not exist, no matter how valuable or useful the answer might be. The highly restrictive inclusion/exclusion criteria of RCTs may raise questions about whether the results apply to the broader population of patients seen in routine clinical practice. RCTs are rarely powered to detect safety signals.

The disadvantages of RCTs create the niche and rationale for medical registries. Randomization is not a prerequisite for enrollment, so there are rarely ethical objections. Maintaining confidentiality of protected health information is usually the major concern with registries. Systematic and broad registration of patients or events according to the predefined inclusion principle should make registry-based results more generalizable to everyday patients and minimize selection bias. The large case volume accumulated by many registries allows detection of relatively low-frequency events that are unlikely to be recognized in an RCT or in a single center's experience. Broad participation also facilitates benchmarking, which is the comparison of an individual or group's performance to the average performance (or best performance) of the rest of the group.

DETERMINANTS OF THE VALUE OF A REGISTRY

The *quality* of data collected and maintained by a registry is the greatest determinant of that registry's value.[4] Two major attributes of registry data quality are recognized: **completeness** and **accuracy**.[3]

Completeness is a measure of the extent to which all data eligible for registry entry have actually been included. Since one of the major advantages of registries is their increased

representativeness or broad inclusion of relevant cases, any concern that a registry's data is not inclusive or representative will lower its value and raise questions of selection bias. Lack of completeness is a threat to a registry's *external* validity or generalizability. These issues may be more likely to affect procedure-based as opposed to disease-based registries, as well as those that depend on self-reported data as opposed to data entry by a third party or automatic process.[12] Lack of completeness would severely compromise the value of a registry established for the purpose of public reporting. Another issue that may affect a registry's external validity is cost of participation. If cost becomes a barrier to participation, data that are entered into the registry may be less representative, again raising the possibility of selection bias.[12]

Accuracy refers to the degree to which registered data conform to reality, or a predetermined gold standard.[3] Flaws in data accuracy will primarily affect a registry's *internal* validity or confidence that conclusions based on registered information are free from bias or error.

An appropriately focused auditing strategy or policy should be a feature of all high-quality registries. The nature and scale of the audit should be consistent with the registry's purpose and will ideally test for both completeness and accuracy.[13] Concerns about validity pertain to all types of registries, whether they exist primarily for research or other clinical purposes. For instance, a registry's signal about poor clinical outcomes may be dismissed if there is suspicion that the underlying data are suspect.[14]

There is also a tension between registry complexity and both internal and external validity. Typically, the more complex registries will collect and contain more clinical information, theoretically increasing their value since they can analyze the relationship of more clinical characteristics with outcomes than registries that contain simpler data sets. A hierarchy of data for arthroplasty registries has been described that can be extrapolated to other clinical, procedure-based registries.[15]

- Level 1 – Simple demographics, date of procedure, dx, type of procedure, medical device info, surgeon and hospital identifier
- Level II – Patient clinical characteristics, surgical technique, intraoperative events/processes
- Level III – Patient Reported Outcomes (PROs), clinical or functional outcomes, economic data
- Level IV – Radiographic assessments (possibly by a central imaging core).

Obviously a registry collecting Level III or IV information will have much richer data and be able to address a wider variety of clinical questions than a registry that only contains Level I information. At first glance, it may appear to deliver greater value. However, a complex registry that strives to collect detailed information but sacrifices representativeness or has quality issues because of complicated or confusing data entry processes may ultimately not be as useful as a simpler registry. In general, a registry should be no more complex than necessary to meet its stated purpose.

At inception and throughout its life cycle, a registry must address and balance multiple issues that create tension between its value and validity. Although registries are not typically as costly as RCTs, they are frequently not subsidized or externally funded. Thus even a relatively low-cost registry may be very expensive for some centers or groups.

WHERE REGISTRIES FIT AS MEDICAL EVIDENCE

As noted above, there is a hierarchy of medical evidence ranging from systematic reviews of randomized controlled trials regarded as the most authoritative to isolated case reports regarded as least authoritative. RCTs are so highly regarded because they are prospectively designed as focused clinical experiments and the randomization allocation minimizes the possibility that the trial outcomes will be affected by confounding influences. However, RCTs cannot address every issue for which we need data to help guide clinical decision making.

While data from registries do not represent the highest level of evidence, they do provide valuable information that cannot be obtained from any other source. There are essentially three types of studies that leverage registry data: cohort analysis, case–control and cross-sectional studies (Fig. 201.1; Table 201.1).[15]

Differences between registry data and those collected in the course of a randomized controlled trial are important to recognize.[4] First, subject enrollment into a trial is a strictly controlled event occurring only after stringent assessment of carefully defined, prospectively applied inclusion and exclusion criteria. Enrollment criteria for registry entry are usually not so strict giving registries a "real-world" flavor, but the inclusion of ineligible subjects may corrupt the relationship between a particular characteristic and outcome. Also, treatment allocation in a registry is almost never random, so the factors governing the choice of one type of treatment over another are frequently unknown.

Since the participants in randomized trials are so valuable, follow-up for adverse events and clinical outcomes is typically active and aggressive. This type of information may only find its way into registries passively and can produce problems with missing data in terms of outcomes of interest. Further, outcome ascertainment in a formal trial is frequently blinded to the treatment allocation but not necessarily so in a registry. When an outcome of interest such as mortality is definitive and not open to interpretation, linkage to administrative databases may alleviate this problem. For less definitive outcomes, the possibility of ascertainment bias remains a significant issue in registries.

Registry data are often affected by various confounders (e.g., selection bias, ascertainment bias, inconsistent treatment protocols and others that may not be recognized), so data analysis can be complicated. Numerous statistical methods to account for known confounding have been developed, including adjustment techniques, regression analysis, instrumental variable analysis, and various types of propensity-matching.[15]

For the clinician evaluating a registry-based article, a standardized approach can be useful to help determine the quality of the conclusions as they may impact practice, as outlined in Table 201.2.[4]

TABLE 201.1 Types of Registry-Based Studies

Study Design	Level of Evidence (for a Registry Study)	Sample Selection	Advantages	Disadvantages
COHORT	High	An "exposure" defines the cohort, which is then followed prospectively for an "outcome" of interest	Temporal relationship between "exposure" and "outcome" established	Bias still possible but largely related to the structure of the registry
CASE–CONTROL	Medium	An "outcome" defines the cohort of cases. Controls are matched to cases based on prespecified matching criteria	Useful to study possible exposures associated with rare outcomes	No temporal relationship established between exposure and outcome; selection bias possible when selecting matching criteria for controls
CROSS-SECTIONAL	Low	Inclusion of a subject in the sample determined by existence of either the exposure or the outcome	Can establish prevalence of a practice/condition or the mere coexistence of the exposure and outcome	No temporal relationship established

TABLE 201.2 Standardized Assessment of Registry-based Studies

Characteristic	Criteria for Evaluation
Generalizability	Are the enrollment criteria clearly specified? If so, are the registry patients similar to my patients?
Relevance	Is the purpose of the registry clearly stated, and are the data pertinent to the question being posed?
Quality	Does the registry have procedures in place to assess the accuracy and completeness of its data? This information is typically found in a publication describing the registry and its operation, frequently cited in the Methods section
Meaningful outcomes	How objective are the criteria used to define the outcome of interest? Were outcomes determined systematically? This is especially important if a comparison group is included. There should be an equal opportunity or likelihood to identify the outcome in the comparison group
Follow-up	This property is closely related to the previous question. Poor or inconsistent follow-up will result in many instances of missing data
Characterization of the comparison group	Cohort and case–control registry studies compare outcomes between different groups of subjects. It is important to understand whether these groups are different in ways other than the defined exposure variable. This is typically the area where many of the more sophisticated statistical and analytic techniques are applied, because the subjects were not assigned to the case or control groups randomly

A *randomized registry trial* is an effort to leverage the existing infrastructure of high-quality registries and still gain the powerful advantages of randomization.[16] A randomized registry trial is a clinical experiment targeting a specific question conducted within the context of a registry, thus avoiding the time-consuming and expensive task of creating the infrastructure necessary to answer the question. During a randomized registry trial, a "randomization module" unique to the question at hand is applied at the time of registry entry. Randomized registry trials still require informed consent and equipoise regarding the risks or benefits to the patient of allocation to one group or the other.

Probably the best example of a randomized registry trial is the TASTE (Thrombus Aspiration in ST Elevation MI) study performed in Scandinavia.[17,18] This study randomized patients experiencing STEMI to a specific attempt at thrombus aspiration during percutaneous coronary intervention (PCI) versus standard PCI alone. Enrollment was relatively straightforward, since STEMI patients in Scandinavia are typically entered into the Swedish Web System for Enhancement and Development of Evidence-Based Care in Heart Disease Evaluated According to Recommended Therapies (SWEDEHEART), a well-developed registry. Following informed consent, patients were randomly allocated to thrombus aspiration or standard PCI. The outcome was "hard" (mortality at 30 days) and ascertained by querying SWEDEHEART. Most patients agreed to participate, and the incremental cost of enrolling a patient in the TASTE study, as opposed to just the underlying registry, was $50.[18] Thrombus aspiration was found not to provide a survival advantage, compared with standard PCI for STEMI.[17]

EXISTING VASCULAR SURGERY REGISTRIES

Vascular Quality Initiative

The Vascular Quality Initiative (VQI), sponsored and administered by the Society for Vascular Surgery (SVS), is the

largest vascular-focused registry family in the United States, with >850 participating centers, >5100 providers from multiple specialties, and >800,000 cases entered in 12 distinct procedure-related registries as of October 2021 (Fig. 201.2).[19] The purpose of the VQI registries is to provide information regarding indications, patient characteristics, procedure performance, and clinical outcomes that will support quality improvement efforts.[20] The participating centers are also organized into 18 regional groups, which have in-person semiannual meetings to facilitate more informal sharing of best practices and lessons learned (see Fig. 201.2).[21]

The SVS VQI is organized as a Patient Safety Organization (PSO), which is a legal entity defined by the Patient Safety Act of 2005. As long as VQI meets certain statutory requirements concerning confidentiality and operates according to the rules specified by the statute, institutions participating in the PSO can transmit protected health information to the registry without obtaining informed consent. By law, a PSO's primary purpose must be quality improvement, so there are also provisions in the Patient Safety Act that promote transparent reporting of adverse outcomes and prevent use of the data for disciplinary or corrective action. Information regarding clinical outcomes and processes of care – also termed Patient Safety Work Product – can only be publicly distributed in de-identified fashion. Public comparison of performances between identified centers or providers is also prohibited.

VQI participants enter clinical data into a commercially operated web-based data platform. The method of data collection is not prescribed, allowing flexibility in workflows that can be tailored to each individual center. Thus some centers have providers enter data at the point of care, others rely on employed data coordinators, and some use commercial data abstraction services.

As mentioned earlier, completeness of case capture and accuracy are the key determinants of registry validity. The VQI requires that all cases eligible for registry entry be submitted – a process that is audited by the review of claims records. The lack of a requirement for individual patient-informed consent also facilitates completeness of case capture. The VQI engages in two types of auditing for accuracy: a newly implemented random audit schedule that will examine each center approximately once every three years. Statistically targeted auditing is performed periodically when centers or specific case records are identified to be potential outliers.

Another important distinctive feature of the VQI is a requirement for follow-up of outcomes approximately one year after the procedure. While this requirement significantly raises the effort necessary to participate in the VQI (increased complexity), the registry can thus provide information about which patients undergoing vascular intervention are most likely to have sustained benefit (as opposed to simply surviving the perioperative period). Since many vascular procedures are performed for preventive (e.g., asymptomatic carotid stenosis or intact AAA) or lifestyle (e.g., claudication) indications, knowing which patients are likely to survive long enough to benefit from the intervention is critical information during preoperative decision making.

Regularly scheduled feedback to participants is provided in the form of semi-annual benchmark reports, many of which are risk-adjusted.

The SVS VQI and American College of Cardiology National Cardiovascular Data Registry recently announced an intersociety collaboration merging their corresponding vascular registries into a single database to be co-branded by both groups and operated by the SVS PSO.[22,23]

American College of Surgeons National Surgical Quality Improvement Program

The National Surgical Quality Improvement Program (NSQIP) is operated by the American College of Surgeons (ACS) and is patterned after the earlier Veterans Administration Surgical Quality Improvement Program (VASQIP).[24–26] In its current form, it offers several options for participation, depending on the size of the hospital and associated resources for data collection. NSQIP contains a procedure-targeted vascular module.[27] Under this option, a hospital collects 100% of procedures performed defined by a specific subset of vascular CPT codes. Procedure data are abstracted by trained personnel who are periodically audited by NSQIP. A number of procedure-relevant outcomes are captured, but follow-up is limited to 30 days after surgery. Feedback to participants is provided in the form of semi-annual risk-adjusted benchmark reports.

National Veterans Administration Surgical Quality Improvement Program

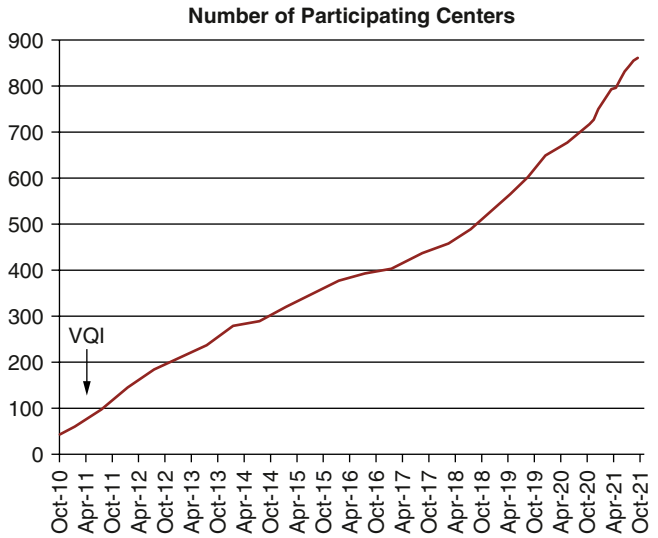
This registry served as the prototype for the American College of Surgeons National Surgical Quality Improvement Program mentioned previously.[24] The two programs function very similarly, except that this program is restricted to United States Veterans Affairs hospitals.

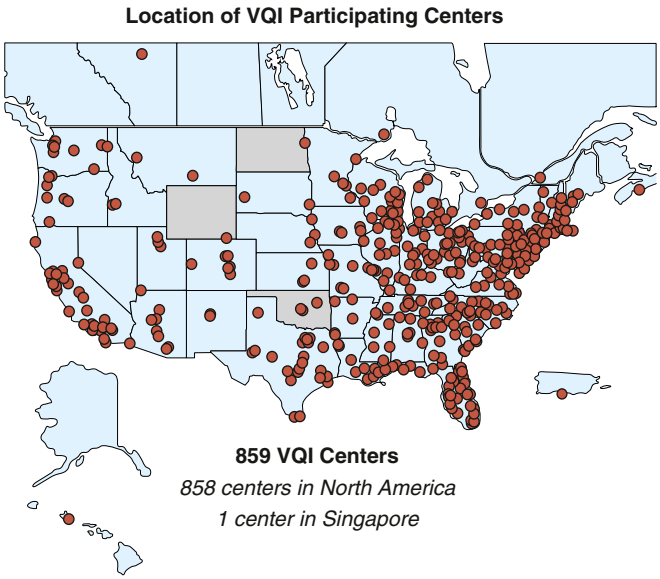
Vascunet

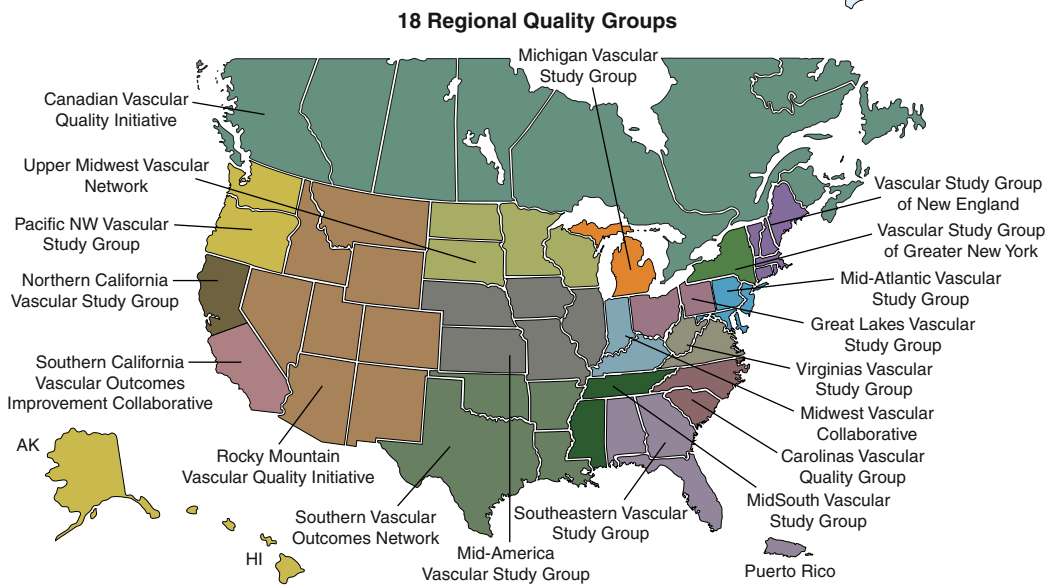
Vascunet is a collection of international registries (or audits) organized under the auspices of the European Society for Vascular Surgery.[28,29] The participating countries are Australia, Brazil, Croatia, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Italy, New Zealand, Norway, Poland, Portugal, Romania, Russia, Serbia, Spain, Sweden, Switzerland, and the United Kingdom.[30] Each country operates its own registry, which can vary in types of procedures and data elements collected, as well as length of follow-up. Case registration is not always mandatory.

For the Scandinavian registries, vital status and relatively long-term follow-up can be obtained through linkage with national administrative databases.[31] Although not comprehensive nor covering all countries participating in Vascunet, formal auditing for data capture and consistency have been performed in Hungary,[32] Sweden[33] and Malta[34] with acceptable results.

For some registries reporting is mandatory, and for others it is voluntary. In the United Kingdom, reporting is mandatory and data are collected for the purposes of public reporting of







Total procedures captured (as of 11/1/2021)	883,561
Peripheral vascular intervention	297,475
Carotid endarterectomy	165,504
Infra-inguinal bypass	70,610
Endovascular AAA repair	68,115
Hemodialysis access	67,060
Carotid artery stent	64,244
Varicose vein	49,558
Supra-inguinal bypass	22,869
Thoracic and complex EVAR	22,849
Lower extremity amputations	22,831
IVC filter	16,502
Open AAA repair	15,620
Vascular medicine consult	267
Venous stent	57

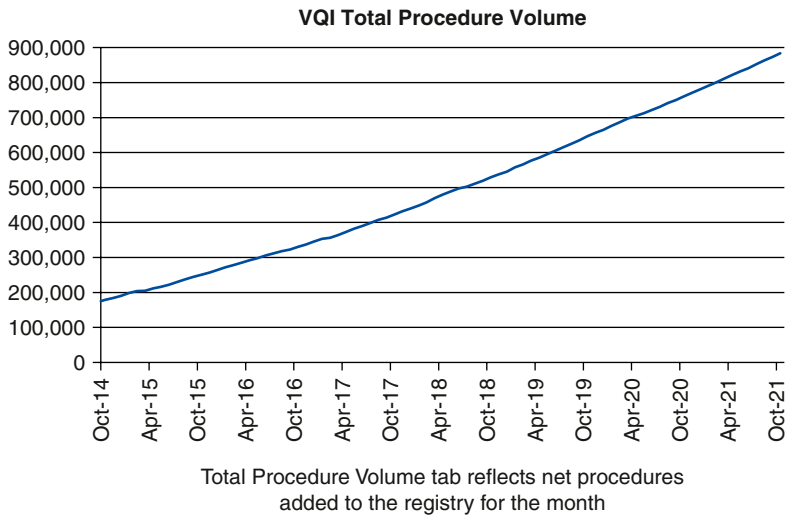


Figure 201.2 Status of the Society for Vascular Surgery Patient Safety Organization as of October 2021. There were >850 participating centers from North America and Singapore organized into 18 regional quality groups. *EVAR*, endovascular aneurysm repair. (From https://www.vqi.org/wp-content/uploads/VQI-Summary-Slides-October-2021.pdf.[19])

outcomes following AAA, carotid endarterectomy (CEA), and lower extremity procedures. Public reports for both hospitals and individual consultant surgeons are released.[35]

The Vascunet collaboration has published several articles describing variation in indications and outcomes for AAA,[36–38] popliteal aneurysm,[39] infrainguinal bypass surgery,[40] and CEA.[41,42] Other reports have highlighted the challenges of reconciling and harmonizing data from numerous national registries in order to properly leverage the large numbers of cases that can be pooled by such collaborations.[43]

International Consortium of Vascular Registries

The ICVR began in 2014 as a collaboration between the SVS VQI and Vascunet.[44] The ICVR currently includes 14 countries including the United States (SVS VQI) and registries across Europe, New Zealand and Australia. The organization has set out to share their international experience with quality improvement, evaluation of best practices and vascular device evaluation and has bi-annual meetings to discuss ongoing collaborative projects.

The central idea of the ICVR is to provide a collaborative platform through which vascular health can be evaluated and improved internationally. The group has a number of important publications demonstrating variation in AAA[44] and carotid disease[45] practice internationally, and ongoing projects to evaluate the performance of endovascular aortic repair (EVAR) devices in the treatment of ruptured aneurysms, volume-outcomes studies to determine best practices related to yearly volume of open and endovascular AAA treatment,[46] among many other projects.

A key challenge of collaboration across many country registries is harmonization of variables and data definitions, which has been central to the early work of ICVR. Members of ICVR have used Delphi methodology to do so with peripheral arterial disease and acute limb ischemia[47] and are currently performing similar projects across other vascular procedures, including complex endovascular aortic repair.

ROLE OF MEDICAL REGISTRIES IN QUALITY IMPROVEMENT

Using Feedback from Registries to Improve Outcomes

Most registries established for QI purposes (VQI, ACS-NSQIP, VASQIP) return information to their participants in the form of benchmarking (crude and risk-adjusted) reports. ACS-NSQIP and VQI also make available de-identified data sets that allow focused QI research into a particular topic. VQI also facilitates customized querying of an individual site's own data through an online analytics engine incorporated into the web-based data entry platform.

Within the context of the SVS VQI, information from the registries serves as the substrate for separate and distinct quality improvement efforts. The VQI is governed by its participants, who commission the Patient Safety Organization (owned and operated by the SVS) to analyze the registry data in order to uncover variations in practice performance and clinical outcomes in order to identify opportunities to improve vascular care. The VQI communicates these findings to its participants in the form of Center Opportunity Profile for Improvement (COPI) reports, along with other report formats informing individual providers and centers of their performance in selected areas, such as smoking cessation counseling, prescription of antiplatelet/statin medication at discharge or follow-up imaging after EVAR.

An individual COPI report focuses on a particular clinical issue or outcome such as surgical site infection (SSI) after lower extremity bypass or stroke/death following carotid intervention. A multivariable model predicting the outcome of interest is developed based on nationwide data from the relevant VQI registry. This multivariable model is then used to predict the likelihood of the outcome occurring for a given center, which is then compared with the observed frequency of the outcome at that center, in the form of an observed/expected (O/E) ratio. Individualized feedback to participating centers is then provided, along with information regarding the rates of risk factors or clinical characteristics associated with the outcome of interest. When these risk factors or clinical characteristics are modifiable, the center could potentially improve its performance through attention to these particular factors through a change in processes of care. For other risk factors that may not be modifiable (e.g., patient comorbidities), knowledge of these characteristics could assist in optimizing patient selection for a particular procedure or making the informed consent process more relevant for an individual patient.

The impact of the VQI COPI report for SSI after lower extremity bypass remains an excellent example of how this process can work to improve performance.[48] Among VQI centers, significant variation in the occurrence of SSI was noted, ranging from 0% to 30% (Fig. 201.3). The multivariable model identified low ABI, increased operative time, transfusions, and use of a nonchlorhexidine skin preparation agent as risk factors for SSI; the latter three are potentially modifiable process measures (Fig. 201.4). Each center received a COPI report specifying that center's O/E ratio for SSI, whether it was significantly different as well as information about the prevalence of modifiable risk factors in their patient population (see Fig. 201.4).

Following the release of the SSI COPI report, there was a significant increase in use of chlorhexidine for skin preparation, a reduction in transfusions, and reduced operating time. There was a trend toward reduced SSI, which was not statistically significant nationwide. However, there was a statistically significant decline in SSI among centers that had the greatest increase in chlorhexidine usage (Fig. 201.5).

The VQI has released other COPI reports focusing on length of stay (LOS) after elective CEA and endovascular aneurysm repair (EVAR), with corresponding reductions in LOS among participating centers (Fig. 201.6).

The initial experience with VASQIP showed a relatively dramatic improvement in surgical quality (27% and 45%

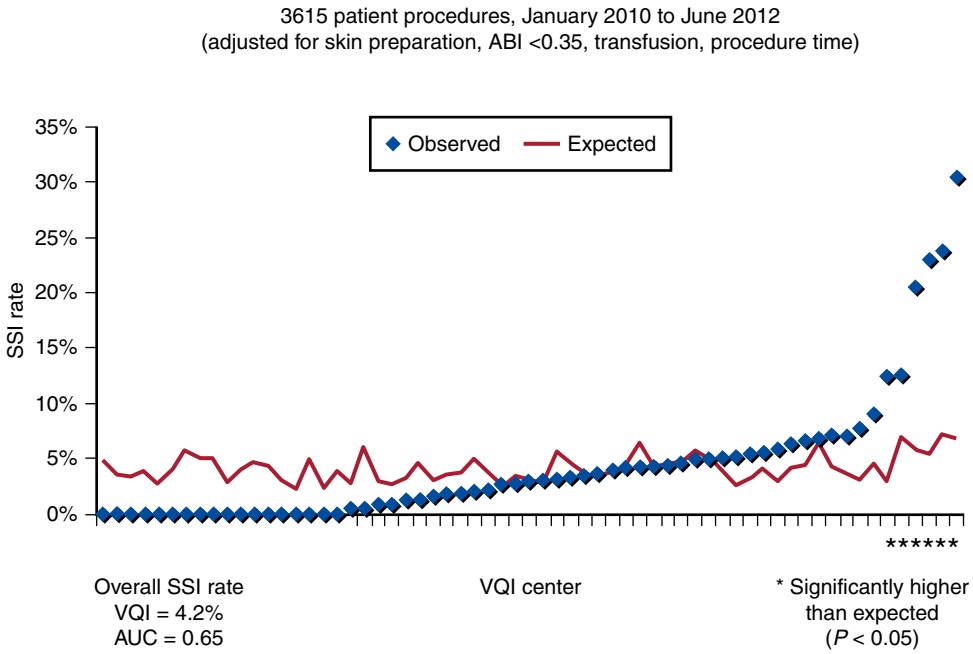


Figure 201.3 Variation in surgical site infection (SSI) following lower extremity bypass in individual vascular quality initiative (VQI) centers between January 2010 and June 2012. Rates of SSI ranged from 0% to 30%. Six centers were statistical outliers with high O/E ratios *(asterisks)*. Independent risk factors for SSI after lower extremity bypass in the VQI between January 2010 and June 2012. (From Kalish JA, Farber A, Homa K, et al. Factors associated with surgical site infection after lower extremity bypass in the Society for Vascular Surgery (SVS) Vascular Quality Initiative (VQI). *J Vasc Surg*. 2014;60:1238–1246)

Variable	*OR*	*95% CI*	*P*
ABI <0.35	1.54	1.03–2.30	<0.04
Procedure time >220 minutes	2.11	1.05–4.23	<0.04
Transfusion >2 units pRBCs	3.30	2.17–5.02	<0.001
Chlorhexidine w/wo alcohol prep	0.53	0.35–0.79	0.002

ABI, ankle–brachial index; *CI*, confidence interval; *OR*, odds ratio; *pRBCs*, packed red blood cells; *w/wo*, with or without.

COPI	VQI wound infection rate			3.6%	**SVS PSO**
	Center name				
	Your center's number of procedures			21	
	Your center's wound infection rate			28.6%	
	Your center's wound infection expected rate			5.9%	
	Observed rate vs. expected rate			Rates significantly different $P < 0.01$	
	Predictors of wound infection			**Your center**	
VQI Average	Chlorhexidine skin prep **60%**	Transfusion ≥3 units **5.8%**	Procedure time >220 minutes **50%**	Improvement opportunity	
	Higher is better	**Lower is better**	**Lower is better**		
Your center	57%	33%	71%	Significantly higher infection rate than expected. Switch to chlorhexidine. Reduce number of transfusions.	

Note: This patient safety work product generated within the SVS PSO, LLC, is considered privileged and confidential.

Figure 201.4 Example of Center Opportunity Profile for Improvement (COPI) report regarding surgical site infection (SSI) after lower extremity bypass to a fictional Vascular Quality Initiative (VQI) center. In this center's case, the observed (28.6%) to expected (5.9%) SSI rate is statistically high ($P < 0.01$). Increasing chlorhexidine use, reducing transfusions, and shortening procedure times represent opportunities for changes in the process of care that would be predicted to lower future SSI rates. *SVS PSO,* Society for Vascular Surgery Patient Safety Organization. (Courtesy Society for Vascular Surgery Patient Safety Organization.)

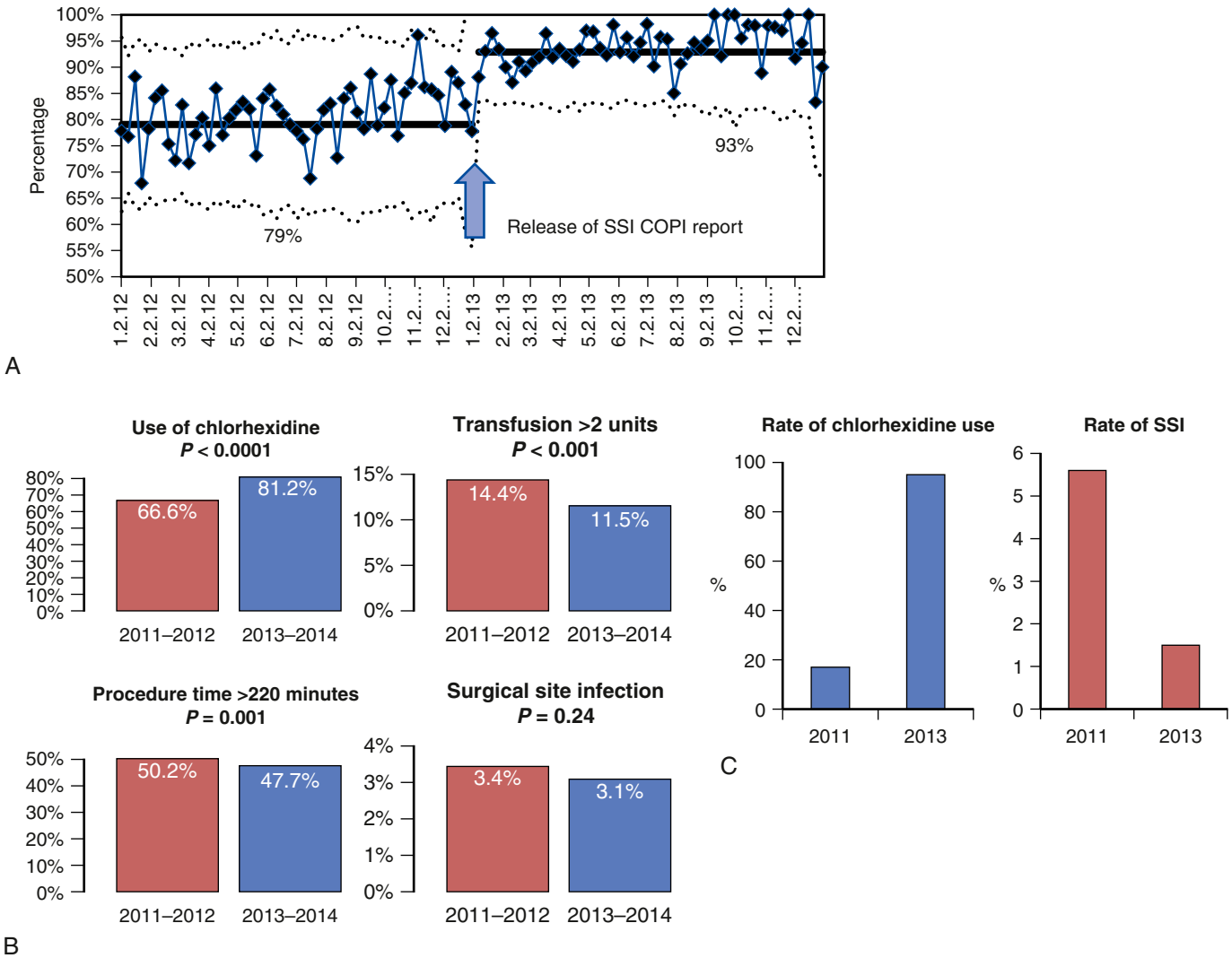


Figure 201.5 **Impact of Surgical Site Infection Center Opportunity Profile for Improvement (SSI COPI) Report in the Vascular Quality Initiative (VQI).** (**A**) Statistical process control chart showing the rate of chlorhexidine use across the VQI before and after the release of the SSI COPI report *(blue arrow)*. (**B**) There were significant beneficial changes in chlorhexidine use, transfusion practice, and procedure time following release of the SSI COPI report. Coincidentally, SSI rates across the VQI decreased, but not to a statistically significant degree. (**C**) Among select VQI centers who had the greatest increase in chlorhexidine use (low to high utilizers), a statistically significant decrease in SSI rate was observed. (Courtesy Society for Vascular Surgery Patient Safety Organization.)

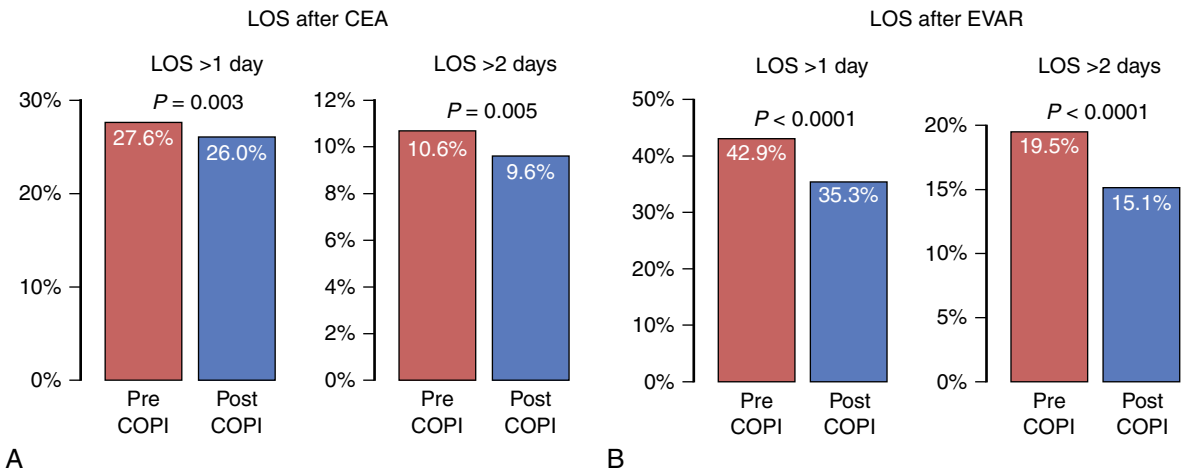


Figure 201.6 Impact of Center Opportunity Profile for Improvement (COPI) reports focusing of length of stay (LOS) after carotid endarterectomy (CEA; **A**) and elective endovascular aneurysm repair (EVAR; **B**). (Courtesy Society for Vascular Surgery Patient Safety Organization.)

reductions in 30-day mortality and major morbidity, respectively) within the VA system, coinciding with delivery of individualized feedback regarding outcomes.[49] It is very common to see reports of improved quality connected to registry participation.[12] However, these reports typically are not controlled for secular trends in overall improvement in care, and the observed quality improvement may not be a direct result of registry participation.

There is now increasing recognition that simply providing information about a center's performance may not result in consistently improved performance.[14] Two recent reports that did control for an overall secular improvement in care indicated that the rate of improvement in mortality or major morbidity among centers participating in NSQIP did not exceed the observed rate of improvement in the same outcomes among centers that did not participate in NSQIP.[50,51] Similar findings have been published regarding VQI participation.[52] The current interpretation of these potentially sobering reports is that some form of organized quality improvement process must be implemented in response to the data to truly drive improved performance.[14,53] Such QI processes may take the form of Plan-Do-Study-Act (PDSA) cycles, LEAN, or Six Sigma programs operating at the local center level. So while robust reliable data, often collected through a registry, is *necessary* for quality improvement, it may not be *sufficient*.[14]

COMPLIANCE WITH CLINICAL PRACTICE GUIDELINES

Professional societies publish clinical practice guidelines (CPGs) to decrease the gap between evidence and current practice, to reduce inappropriate variability in practice and to be readily available resources that provide recommendations for different clinical scenarios.[54,55] The degree to which CPG are used to guide practice has been difficult to measure. The SVS Document Oversight Committee responsible for developing the society's CPG and VQI collaborated to use registry data to assess compliance with AAA CPG.[56]

The SVS AAA guidelines contain 111 recommendations, but only ten were measurable in a meaningful way using the VQI open AAA and EVAR registries.[57] Within VQI, compliance with these 10 guidelines was quite variable (see Table 201.3). In general, compliance with guidelines based on higher quality evidence was associated with improved outcomes. When centers were graded on overall compliance with AAA guidelines, those with better compliance experienced reduced SSI and mortality. VQI now provides centers with periodic reports detailing their compliance with CPG.

Key take-home messages from this analysis were that registries can increase the value of CPG by demonstrating the effect of compliance on outcomes. CPG writing groups and

TABLE 201.3 VQI Assessment of AAA Guideline Compliance and Effect on Clinical Outcomes

Guideline	Level of Evidence (GRADE)	Overall Compliance (%; by case)	Variation in Compliance (%; by center)	Effect of Compliance on Clinical Outcomes
Size criteria for repair (≥55 mm in men; ≥50 mm in women)	1A	EVAR, 71.3 OAAA, 83.1	EVAR, 36–92 OAAA, 40–100	EVAR – Increased in-hospital mortality, any adverse event, 1-year reintervention OAAA – Increased respiratory complications, any adverse event
Preserved perfusion of at least one internal iliac artery	1A	EVAR, 99.2 OAAA, 96.8	EVAR, 75–100 OAAA, 51–100	EVAR – Decreased MACE OAAA – None
Perioperative antibiotics	1A	EVAR, 93.8 OAAA, 93.3	EVAR, 27–100 OAAA, 60–100	EVAR – Decreased SSI, in-hospital mortality, any adverse event OAAA – None
Cell salvage	1B	EVAR, NA OAAA, 92.3	EVAR, NA OAAA, 25–100	EVAR – NA OAAA – Decreased 1-year mortality
Smoking cessation	1C	EVAR, 54.6 OAAA, 40.1	EVAR, 13–100 OAAA, 0–83	EVAR – Decreased respiratory complications, in-hospital mortality, 1-year mortality, any adverse event OAAA – Decreased respiratory complications, 1-year mortality
Stress test	2B	EVAR, 43.7 OAAA, 60.3	EVAR, 0–100 OAAA, 6–100	EVAR – Decreased 1-year mortality, any adverse event OAAA – None
Case volume guideline (≥10/year)	2C	EVAR, 95.8 OAAA, 68.3	EVAR, 78% met guideline OAAA, 51% met guideline	EVAR – None OAAA – Decreased in-hospital mortality
Altered incision for pulmonary disease	2C	EVAR, NA OAAA, 29.0	EVAR, NA OAAA, not presented	EVAR – NA OAAA – None
Door-to-intervention <120 minutes for RAAA	Ungraded	EVAR, 61.9 OAAA, 69.0	EVAR, 8–100 OAAA, 30—100	EVAR – Increased SSI, MACE OAAA – Increased MACE

relevant registries should coordinate definition of registry variables to increase the ability to measure guideline compliance.[57] Finally, registry data may provide feedback to CPG groups that some guidelines, especially those based on low quality evidence, are not associated with improved outcomes and should be retired.

LINKAGE WITH ADMINISTRATIVE DATASETS TO MONITOR DEVICE-RELATED OUTCOMES

The VQI Vascular Implant Surveillance and Interventional Outcomes Network (VISION) is a partnership between the Society for Vascular Surgery's Vascular Quality Initiative (VQI) and the Medical Device Epidemiology Network (MDEpiNet).[58]

VISION is a project that links clinically enriched VQI registry data to Medicare claims to generate novel registry claims linked data sets for long-term follow-up analysis, especially related to implanted devices such as stent grafts, etc.

The datasets combine the clinical detail from the VQI with long-term outcome variables derived from Medicare claims. Matched VQI-VISION datasets are available for EVAR, OAAA, PVI, TEVAR, CAS, INFRA and SUPRA datasets. For each dataset, the following VQI–Medicare derived outcomes are available:

1. Date of death – determined using the Denominator File in Medicare Claims, an exceedingly accurate form of determination of date of death
2. A procedure-specific adverse outcome, such as stroke, aortic rupture, amputation
3. A measure of re-intervention, such as re-intervention after EVAR
4. Readmission
5. Post-procedure imaging
6. Cost.

By combining registry-based detail with long-term follow-up in Medicare claims, VISION data allows long-term follow-up for the outcomes described above.[59–62] For example, data from VISION-VQI has shown that re-intervention rates are higher for black patients treated with endovascular aneurysm repair (Fig. 201.7A), and that women have poorer survival than men after AAA repair (Fig. 201.7B).[62] This linkage with Medicare claims allowed follow-up to be determined for VQI patients up to 10 years after the index procedure. It is unlikely that VQI centers could have followed these patients actively on their own for this period of time, illustrating the unique benefit of linkage with administrative data.

The center-specific nature of VQI data also allows VISION to generate center-specific feedback reports called Survival, Reintervention and Surveillance (SRS) Reports and to analyze device performance and long-term outcomes of vascular surgical techniques. Future work for VISION aims to expand the nature of the efforts to ensure VQI provides the most accurate studies possible of long-term outcomes after vascular care.

PUBLIC REPORTING OF REGISTRY DATA

There is a strong presumption that the public has a right to information about surgical quality performance in order to make the most informed choices regarding where to obtain healthcare. To this end, public reporting of surgical outcomes may be desirable. On the other hand, there is concern that public access to quality performance information will reduce the willingness of providers and centers to be forthright when discussing adverse events, thereby compromising quality improvement efforts that are widely thought to be enhanced by assurances of confidentiality.[63–65]

When evaluating a registry, it is important to know whether the data are used for public reporting, as there may be conditions applied to the collection and reporting of the data that will affect its validity and the overall confidence in the data. Information about how outliers are identified and confirmed should be available to both participants and consumers of the information. At a minimum, reports of mortality and morbidity should be risk-adjusted so that hospitals and providers caring for sicker, more complex patients are not unfairly labeled as subpar because of the expected higher incidence of adverse outcomes occurring in this higher risk population.

Two prominent examples of public reporting of cardiovascular outcomes are the New York State Cardiac Registries[66] and the Vascular Services Quality Improvement Program (VSQIP) in the United Kingdom, covering AAA, CEA, and lower extremity PAD procedures.[67,68] Registration of all eligible patients is mandatory in both programs and both programs report both hospital-specific and surgeon-specific risk-adjusted outcomes.

Following the onset of public reporting, risk-adjusted cardiac surgery mortality in New York fell 41%.[66] In an attempt to determine if public reporting in New York was associated with a differential impact on mortality, comparison with other states who did not publicly report outcomes showed that New York's outcomes were significantly better, with a calculated odds ratio for short-term mortality of 0.66.[66] There is some controversy as to whether public reporting has produced risk aversion (thus potentially denying high-risk patients needed care) among New York hospitals and surgeons; data have been published supporting both sides of the issue.[66]

Similar concerns have been raised in the United Kingdom, and some have advanced strong arguments specifically against surgeon-specific outcomes reporting.[68] Important points include the fact that case numbers for individual surgeons are much lower than hospital-specific numbers, leading to greater statistical uncertainty. Also, they note the possibility of risk aversion and unfair attribution of any particular patient's death to an individual surgeon in an era where team-based care is increasingly emphasized and recognized as correlating with patient outcomes.

Defenders of public reporting recognize that such a practice introduces unwanted incentives to maximize the risk profile or under-report mortality. Rigorous external auditing assessing both completeness and accuracy is necessary to maintain the

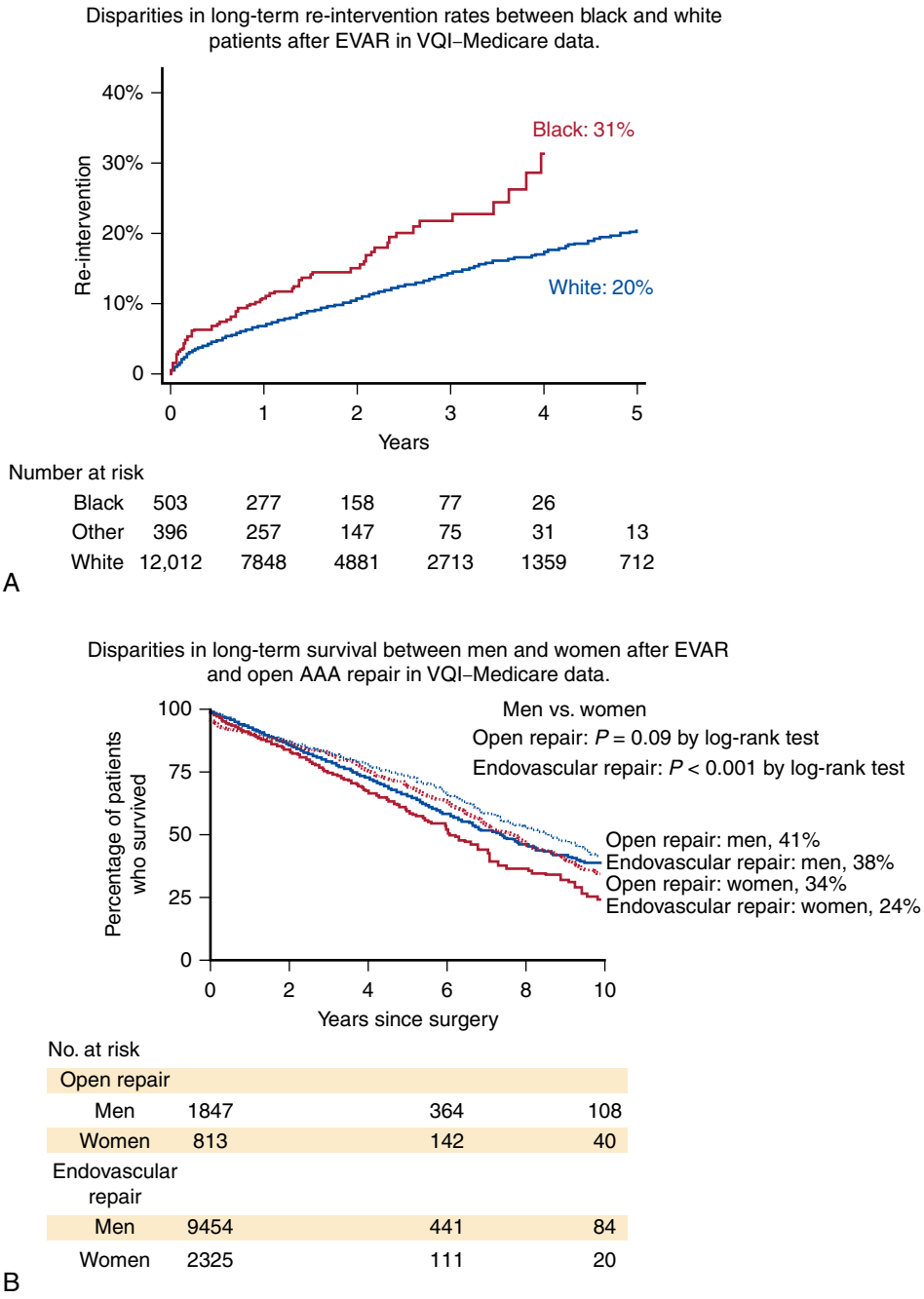


Figure 201.7 Linkage of VQI registry data with Medicare claims data allows long-term (5–10 years) follow-up after AAA repair. (**A**) Reintervention rates 4–5 years after EVAR are higher in black patients than white patients. (**B**) Women experience poorer long-term survival 10 years after AAA repair (either EVAR or open). *EVAR*, endovascular aneurysm repair. (Courtesy Goodney PP, VISION. From Ramkumar N, Goodney PP, Cronenwett JL. Open versus endovascular repair of abdominal aortic aneurysm. *N Engl J Med*. 2019;381(11):e24.)

confidence of both public and the healthcare community in these registries.[66] A recent analysis of the effect of public reporting of colorectal surgical outcomes in the United Kingdom found no evidence of risk aversion or "gaming" of clinical data but did show an associated reduction in 90-day mortality following implementation of public reporting.[69] Some registries have taken the approach of allowing voluntary reporting by individual centers although it is unlikely that institutions would voluntarily publicize inferior outcomes.[70] The absence of some centers from these public compilations of voluntarily reported outcomes then assumes certain uncomfortable implications.

Registries such as the SVS VQI are organized under legislation (Patient Safety Act of 2005) that specifically prohibits the public release of hospital- or surgeon-specific outcomes as well as any comparison of outcomes between different centers or practitioners. PSOs are intentionally designed to foster the free exchange of information between hospitals and providers in order to promote the transparency and dissemination of best practices/lessons learned. The primary purpose of the SVS VQI is to improve quality, not to inform the public of the specific performance of individual hospitals or surgeons.

THE FUTURE OF MEDICAL REGISTRIES

In our opinion, medical registries – even more specifically vascular registries – are here to stay. The information they provide is distinctly different from formal RCTs. Their data represent a real-world experience that can be extremely valuable, assuming the data contained in the registry are credible.[71] Many important clinical questions can only be answered by the systematic collection of clinical data obtained during the routine delivery of vascular care – especially information that allows characterization of relatively low-frequency events unlikely to be seen in statistically valid numbers by any single center or practitioner.[12]

Cost remains the primary challenge facing clinical registries. The more complex registries collect and analyze information at a granular level that can support detailed and valuable analyses. But the more complex registries are more expensive in terms of infrastructure, as well as the time and effort required by sites to enter the data. As the value of registries is increasingly recognized by regulatory agencies and industry and third-party payers, it is possible that the cost of participation will be subsidized.[12] Alternatively, participation may be motivated by policies of payers or regulatory agencies that will give preferred patient access or reimbursement status to registry participants.

Patient-reported outcomes (PROs) are increasingly considered when determining the value of surgical procedures and vascular surgery is no different.[72] Incorporation of PROs into registry data adds another important real-world perspective. Allowing patients to provide this information directly may invest them in the value of the registry and may enhance the completeness of a registry. Greater inclusion of PROs in registries and innovative ways of directly involving patients in registries is part of the future.

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A complete reference list can be found online at www.expertconsult.com.

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CHAPTER 202

Health and Wellness for the Vascular Surgeon

DAWN M. COLEMAN

INTRODUCTION

The epidemic of physician burnout has been declared a public health crisis, and a growing focus for occupational intervention. Symptoms of burnout are particularly problematic among surgeons and surgical trainees in comparison to the general population (53% vs. 26%).[1–5] Burnout is characterized by emotional exhaustion, depersonalization, and a diminished sense of personal accomplishment and arises from a chronic disparity between people and their work setting.[6] The 2019 11th Revision of the International Classification of Diseases (ICD-11) has newly specified burnout as an occupational phenomenon, in contrast to a medical condition. Personal ramifications of such may include broken relationships, alcohol and substance abuse, depression, suicidal ideation and suicide.[7] Physicians have higher rates of suicide than the general population, with relative risks of 1.1–3.4 for men, and 2.5–5.7 for women.[8,9] Moreover, compared with white male professionals, physicians' proportionate mortality ratio is higher for suicide than for all other causes of death.[8,10]

Burnout also threatens quality of patient care, safety, patient satisfaction, productivity, and physician retention (i.e., turnover and premature retirement).[11–16] A recent meta-analysis, which included 47 studies of over 42,000 physicians, revealed physician burnout to be associated with an increased risk of patient safety incidents, poorer quality of care due to low professionalism, and reduced patient satisfaction.[13] A survey of over 7900 surgeons revealed 9% reporting concern that they had made a major medical error in the last 3 months.[12] More than 70% of surgeons attributed the error to individual rather than system level factors and further analysis revealed a direct association between burnout scores and the likelihood of committing a major medical error. By multivariate analysis, a positive depression screen and burnout were factors independently associated with perceived medical errors, and this relationship persisted into longitudinal studies independent of fatigue.

Burnout is a major driver of physician turnover and multiple large, national studies of US physicians have indicated that burnout is one of the largest factors determining whether or not physicians intend to leave their current position over the next 24 months.[11,17–19] Burnout has also been linked to premature retirement by surgeons and has been shown to decrease professional work effort in prospective, longitudinal studies.[20,21] As one example, a 2014 survey of American physicians revealed that 1 in 5 US physicians intend to reduce their clinical work hours in the next year, and 1 in 50 US physicians intend to leave medicine altogether in the next 2 years to pursue a different career.[11] Physician turnover results in direct costs associated with recruitment alongside lost revenue during recruitment, onboarding, and the time it takes for a new physician to reach optimal efficiency in a new system.[14] Historical studies suggest that the cost to replace a physician is 2 to 3 times the physician's annual salary, and likely higher for subspecialty physicians. It has been estimated that physician burnout results in $4.6 billion/year related to physician turnover, and reduced productivity (approximately $7600 per

employed physician/year).[22] These direct costs of turnover fail to account for the disruptive impact of turnover on patients, other members of the care team, and the organization's culture and reputation.

BURNOUT IN VASCULAR SURGERY

Vascular surgeons appear to be at high risk for occupational burnout, as supported by a study of US surgeons across 14 surgical specialties which identified vascular surgeons as having the second highest rate of burnout and the lowest level of career satisfaction.[23] Approximately one-third of vascular surgeons in this study reported symptoms of depression and, when compared to other surgical specialties, vascular surgeons report the highest incidence of suicidal ideation. Moreover, vascular surgeons were the most likely (36%) to suggest they "would not become a surgeon again" in comparison to general surgeons (32%), cardiothoracic surgeons (27.5%), urologic surgeons (26%), orthopedic surgeons (20%), and pediatric surgeons (15.6%). Vascular surgeon burnout may compromise the recruitment of trainees and new physicians into the specialty in addition to the retention of existing vascular surgeons.[11,24] These risks are especially poignant given the impending workforce challenges described by a 2016 U.S. Department of Health and Human Services Report on Surgical Supply and Demand projecting a 520 full-time equivalent (FTE) deficit of vascular surgeons by 2025.[11,25,26]

In a 2018 survey of 2905 active Society for Vascular Surgery (SVS) members, 41% of respondents met criteria for burnout, as defined by high emotional exhaustion and/or depersonalization scores.[27] Importantly, 37% endorsed symptoms of depression in the past month and 8% indicated they had considered suicide in the last 12 months. Based on multivariable analysis, age, work-related physical pain, and work–home conflict were independent predictors for burnout. Unpublished data from the same survey data stratified results by gender noting a similar prevalence of burnout among men and women at approximately 40%. However, the prevalence of suicidal ideation within the past year was significantly (twofold) higher for women than men (12.9% for women vs. 6.6% for men). Furthermore, conflict between work–life balance was greater in women than in men, with women reporting more time spent working at home on the electronic medical record (6.4 vs. 4.7 hours; $P < 0.0001$) and other nonclinical work-related tasks (6.5 vs. 5.4 hours; $P < 0.05$) compared to men. Predictors of burnout in women in the survey included not enough family time and work-related pain. In addition, work-related pain was an independent predictor for suicidal ideation for both men and women. Taken together, symptoms of burnout and depression are common among vascular surgeons, and there are gender-based differences driving career dissatisfaction and burnout.

OPTIMIZING HEALTH AND WELLNESS

Physician burnout is multifactorial, attributed to key drivers that encompass: (1) meaning in work; (2) excessive workload; (3) inefficient work environment and/or inadequate support; (4) problems with work–life integration; (5) loss of autonomy and control; (6) culture and values; and (7) community at work. These drivers fall into three major domains: *efficiency of practice* and *a culture of wellness* are primarily organizational responsibilities, while *maintaining personal resilience* is primarily the obligation of the individual physician.[28] These domains reciprocally influence the others necessitating a balanced approach to building a stable platform that will drive sustained improvements in physician well-being and the overall performance of our healthcare system. Growing data support that physicians are not resilience-deficient, and that burnout rates are substantial even among the most resilient physicians, further supporting efforts to address system issues in the clinical care environment to reduce burnout and promote physician well-being.[29]

The aforementioned drivers of burnout and wellness are each influenced by national, organizational, work unit, and individual factors. Organizations have the opportunity to make profound and effective changes with limited investment. A systematic review and meta-analysis of 15 randomized controlled trials and 37 observational studies supported that individual-focused interventions (i.e., mindfulness, self-care training, stress management) and structural organizational interventions (i.e., duty hour restrictions, clinical work process optimizations) can successfully reduce burnout domain scores.[30]

Shanafelt et al. have previously proposed a framework of shared responsibility to drive system-level solutions across nine domains[7]:

1. Acknowledge and assess the problem
2. Harness the power of leadership
3. Develop and implement targeted work unit interventions
4. Cultivate community at work
5. Use rewards and incentives wisely
6. Align values and strengthen culture
7. Promote flexibility and work–life integration
8. Provide resources to promote resilience and self-care
9. Facilitate and fund organizational science.

Each domain warrants independent consideration.

Acknowledge, Accept, and Measure the Problem

By defining the issue and being willing to listen, organizational leadership demonstrates that a problem is recognized, while starting to build the necessary trust for physicians and leaders to work in partnership to make progress.[7] Organizations measure mission critical metrics like patient volume, quality/safety, patient satisfaction. It would follow that assessing individual wellness metrics, aggregated at the work unit level, facilitates intentional interventions, attention, and resource allocation. Organizations may find value in assessing wellness and burnout dimensions alongside other key organizational performance metrics, especially as physician well-being is equally important to the health and long-term viability of the organization. There are a variety of candidate dimensions of well-being for organizations to assess, many with national benchmarks for U.S. physicians and comparisons available for the general population.

The Maslach Burnout Inventory (MBI) is an introspective psychological inventory consisting of 22 items pertaining to occupational burnout, and a validated burnout assessment tool. The MBI measures three dimensions of burnout: emotional exhaustion, depersonalization, and personal accomplishments. An analysis of 84 published studies that report sample-specific reliability estimates for the three MBI scales found that the scales have strong reliability.[31,32] The MBI has also been validated for human services populations and general work populations.[33,34] Burnout is commonly measured using the emotional exhaustion (EE) and depersonalization (DP) scales.[35–37] Beyond composite well-being measures, additional available standardized assessment tools assess achievement, professional fulfillment, engagement, fatigue, stress, and quality of life.[21,38–52]

Harness the Power of Leadership

Leadership has a direct effect on the professional satisfaction of physicians.[7] Data supports that the leadership behaviors of the physician supervisor critically impacts the well-being of the physicians they lead.[38,53] A 2013 survey of >2800 physicians queried items evaluating their opinion of the leadership qualities of their immediate supervisor (i.e., division or department chair).[53] A significant decrease in emotional exhaustion and depersonalization was noted with increasing composite leadership scores, alongside a significant increase in overall satisfaction noted with increasing composite leadership scores. A 1-point increase in leadership score (60-point scale) was associated with a 3.3% decrease in the likelihood of burnout ($P < 0.001$) and a 9.0% increase in satisfaction ($P < 0.001$) for individual physicians after adjusting for age, sex, and specialty.

In part, effective leaders recognize individual physician talents, and can identify what motivates them. Physicians that spend 20% of their professional effort focused on the dimension of work they find most meaningful have a lower risk for burnout and each 1% reduction below this threshold increases the risk of burnout.[54] Organizations must prioritize leadership selection, development and regular assessment and be willing to make leadership changes when necessary for those that continue to receive low leadership behavior scores from those they lead despite appropriate support, coaching, and mentorship.[7] While leadership development directly impacts the individual surgeon, it also positively affects institutional culture, a critical component to determining effective strategies for collaboration in team-based approaches to health care.[55–59]

Develop and Implement Targeted Interventions

Combining these first two strategies of assessment and leadership can assist organizations to overcome the variability in drivers of burnout and dissatisfaction across specialties and work units.[7,60] Information on the prevalence of burnout, engagement, and satisfaction at the division/department level (strategy 1) allows leaders to identify "high-opportunity work units," defined by metric performance in comparison to benchmarks. A stepwise process for targeted work-unit interventions has been proposed that rests on a leadership consulting team of physicians and administrators with expertise in leadership and physician engagement working directly with physician and work-unit leaders.[7] The process transitions away from generalities regarding burnout and rather brings focus on the specific issue(s) at the local work unit as the team works to identify, develop, and implement an initial intervention. Importantly, this approach transforms the physician's mindset from that of a "victim" in a broken system to an engaged and empowered partner working constructively with leaders to shape their own future.

Cultivate Community at Work

Both formal and informal peer support is critical in helping physicians navigate unique occupational challenges associated with their professional identify.[61–64] Unfortunately, natural and organic peer support can be challenged continuously by increasing productivity expectations and rising clerical burden resulting in physician isolation.[7] A 2012 Mayo Clinic randomized trial reported that providing physicians with 1 hour of protected time twice a month to meet with a small group of colleagues and discuss topics related to the experience of physicianhood improved meaning in work and reduced burnout.[65] A follow-up trial evaluated a revised format to make these COMPASS (COlleagues Meeting to Promote And Sustain Satisfaction) groups more cost-effective and scalable, again, reporting that these meetings with colleagues led to an improvement in both meaning in work and burnout for participants.[66]

"Second victim syndrome" refers to a healthcare provider involved in an unanticipated adverse patient occurrence that experiences psychological and emotional trauma related to the event.[67] Second victims may feel personally responsible for the unexpected patient outcomes, believe they failed their patients, and/or second-guess their clinical skills, knowledge base and career choice and be left with persistent feelings of fear, guilt, anger, embarrassment, and humiliation for months or years.[68] Risk factors for second victim syndrome include: (1) residents in training; (2) burnout; (3) female gender; (4) less experience; (5) feelings of being unrewarded or overwhelmed; (6) and work–life imbalance.[69]

Data supports the role of peer support as an intervention for second victim syndrome, specifically as understanding and empathy from a peer facilitates reassurance.[62,70–72] Peer support can help affirm the surgeon's worth to the group, re-build confidence and trust in their skills, and helps with "normalization" of the individual to return to their routine after a traumatic event ultimately promoting the continuation of productive careers while building healthy stress management behaviors into individuals and the system.[72] Central components to the peer support of second victims center around "rapid response teams," that engage the clinician with intent, self-identifying as peers within 24 hours of the event.[62,69,71–75] These rapid responding peers ask questions about the surgeon's "coping" experience (i.e., if they are sleeping, getting exercise), give them an outlet to talk about feelings and fears, help to affirm their worth, emphasize how the second victim is "not defined" by

the event, and proactively change the isolation that often results from a critical event.

Use Rewards and Incentives Wisely

Healthcare organizations often link physician financial compensation to productivity, either wholly or in part (i.e., structured productivity incentive bonus).[76–78] Physicians in an equally efficient practice environment primarily increase productivity or revenue by shortening the time spent per patient, ordering more tests/procedures, or working longer.[14] The first two approaches may erode quality of care, and the latter may increase the risk of physician burnout. Growing evidence does suggest that productivity-based compensation increases the risk of physician burnout, especially as physicians may be vulnerable to overwork due to high levels of education debt, their desire to "do everything for their patients," unhealthy role modeling by colleagues, and normalization of extreme work hours during the training process.[79–81]

Salaried compensation models may offer a beneficial alternative. Additional incentives may be individualized, empowering physicians to create concurrent and professional fulfillment. Examples may include enhanced scheduling flexibility to optimize work–life integration, and protected time to pursue personally meaningful aspects of work.

Align Values and Strengthen Culture

An organization's culture, values, and principles are mission critical; as such organizations must: (1) be mindful of factors that influence culture; (2) assess ways to keep values fresh; and (3) periodically take stock of whether actions and values are aligned.[14] More than ever, academic medicine faces intense competition, narrower margins, and decreased federal funding as medical schools are becoming increasingly involved with large, expanding health systems.[82] It has recently been reported that academic health systems typically expand to support their business goals, rather than their academic mission and that changes in governance sometimes disempower departmental leadership, shift traditional compensation models, and redirect research programs resulting in cultural conflict.[82] In contrast, others cross-subsidize surgical departments' research and training missions while concurrently expanding their clinical footprint, enabling them to improve standards of care and enhanced opportunities for researchers and trainees. Alignment between medical school and health system goals enabled some surgical department leaders to take advantage of their health systems' reach and resources in order to support their academic missions.

Recognizing also that exponential advances in scientific discovery mandate increasingly specialized clinical expertise, healthcare is most effectively delivered by high-performance interdisciplinary teams whose collective skill set, diverse perspectives, shared lived experiences and judgment may be more effective than hierarchical or bureaucratic forms of healthcare delivery in terms of efficiency and quality of care for patients.[83] Team-based care is a foundation of contemporary healthcare redesign models, and surgeons must be proactive in assuming leadership positions.[84] Diverse high performance teams require a culture of equity that is open, supportive and inclusive to support team members to leverage cognitive diversity which offers a performance advantage, improving collective understanding and optimizing high-complexity problem-solving. Diverse teams have been shown to outperform homogenous teams, and this diversity, supplemented with equity and inclusion, yield a superior creative culture. In short, organizations should consider honest self-assessment of culture with consideration to foundational principles like physician leadership, compensation (i.e., salaried physicians), physician–administrator partnership, a multidisciplinary approach to team-based care, "term limits" for all leaders, and organizational policies that cultivate long tenure and low turnover and diversity, equity and inclusion.

Promote Flexibility and Work–Life Integration

While individual risk factors for burnout are multi-faceted, work–life integration may be the most commonly reported, and perhaps the most critical contributor. The idea that one should restrict the amount of time spent at work dates back to manufacturing laws in the late 1800s when laborers worked unregulated hours in manufacturing plants. By 1938, the *Fair Labor Standards Act* established a 44-hour work week, while excluding certain professions including physicians who were assumed to be continuously "on call." In the 1980s, the Women's Liberation Movement brought "work–life balance" back to societal forefront to accommodate the growing number of women in the workforce. Flexible schedules and maternity leave were popularized initially for women expected to balance professional and domestic responsibilities, and thereafter quickly expanded to include both men and women such that personal–professional life balance, flexibility in schedule management and increased work and life satisfaction dominated the late 20th century.

Physicians are nearly twice as likely to be dissatisfied with work–life integration as US workers in other fields, a problem that is likely, in part, explained by differences in work hours.[14] Approximately 45% of physicians work more than 60 hours per week compared with less than 10% of US workers in other fields.[85] The high work hours expected of a full-time position in medicine challenge physicians to integrate their personal and professional lives; these challenges may be compounded for women physicians due to different cultural and societal expectations.

Although the vascular surgery workforce is increasingly diversifying, women represent a minority and consistently report lower satisfaction with work–life integration.[86] Data show that women experience work–home conflict at greater rates than men, in part due to multiple gender differences in domestic and parenting responsibilities.[87] Women with younger children have particularly more home responsibilities, and are more likely to be in a dual-career household posing greater challenges balancing work and home responsibilities and perhaps more often facing conflict between their own and their

partner's career advancement.[16,88–90] Survey data from the American College of Surgeons indicates that a significantly larger proportion of women surgeons with children (57%) felt child rearing slowed their career advancement in comparison to men (20%).[16] A contemporary analysis of personal life factors and surgical career satisfaction reaffirmed that fewer women report career satisfaction in comparison to men, more conflicts between professional and personal life and greater domestic (inclusive of both household and childcare) responsibilities.[86] Importantly, these authors identified the factor with the strongest association with career satisfaction was a higher degree of collegial support of work–life integration efforts.

Providing all physicians with the option to adjust professional work effort allows them to tailor their work hours to meet both personal and professional obligations.[77,78,91–93] Evidence suggests that reducing professional work hours can help individual physicians recover from burnout.[94] Supportive workplace culture considerations could include: accommodation of requests for individualized schedules (i.e., facilitate autonomy and flexibility)[7]; options for formal leave, flexible vacation time and paid time off, options for sabbaticals, and career sharing; avoidance of early or late meetings that may interfere with personal responsibilities[95]; onsite childcare, extended hour and drop-in childcare, subsidized childcare for minor illnesses that preclude attendance at school or daycare[96]; flexibility and compassion when work–life integration conflicts arise; team-building exercises and protected time for small-group discussions, and incentivizing teamwork and holding team leaders accountable for maintaining a positive workplace culture.[65]

Provide Resources to Promote Resilience and Self-Care

Individually focused institutional offerings like tools for self-calibration, resources to promote self-care and training in skills that promote resilience must be coupled with sincere efforts to address the system-based issues contributing to burnout.[14] Although burnout is primarily a system-level problem driven by excess job demands and inadequate resources and support, not an individual problem triggered by personal limitations, data well supports that organizational interventions can reduce burnout and that even modest investments can make a difference.[30] A systematic review and meta-analysis including five randomized controlled trials and nine cohort studies reported a significant absolute reduction in burnout from 54% to 44% with interventions that spanned the work environment (i.e., shortening rotation length, modifications to the work process and shortened resident shifts) and individual-focused interventions (i.e., small group curricula, stress management, self-care training, communications skills training and belonging-interventions).[30]

The U.S. Army Ready and Resilient Campaign (R2C) is an example of resiliency training as a comprehensive plan implemented to address the immediate and enduring needs of the Total Army (i.e., Active, Reserve and National Guard Soldiers, Families and Army Civilians). The campaign is working to instill a cultural change by directly linking personal resilience to readiness and emphasizing the responsibility of people at all levels to build and maintain resilience. The Ready and Resilient Campaign builds upon physical, emotional and psychological resilience in our soldiers, families and army civilians so they improve performance to deal with the rigors and challenges of a demanding profession. Master resiliency training curriculum in the U.S. Army is based on materials developed by the University of Pennsylvania (Penn Resilience Program).[97] The curriculum encompasses resilience and performance-enhancing skills and perhaps most relevant, the resilience module highlights six core competencies: (1) self-awareness; (2) self-regulation; (3) optimism; (4) mental agility (i.e., flexible thinking, willingness to try new strategies); (5) character strengths (i.e., how to identify in self and others); (6) connection (i.e., building strong relationships, communication, empathy and willingness to ask/offer help).

Most recently, there is emerging data supporting the use of coaching interventions to optimize physician well-being and minimize distress and burnout. Coaching is distinct from mentorship and peer support. It involves inquiry, encouragement, and accountability to increase self-awareness, motivation, and the capacity to take effective action. Importantly, coaches do not need to be physicians or directly involved in healthcare, and professional coaching can be tailored to focus on the aspects desired by recipients to assist individuals in their effort to navigate their professional life, their choices, and the direction of their career.[98–101] A recent multisite, single-institution pilot randomized clinical trial included 80 physicians within 5–30 years of practice working in the departments of medicine, family medicine, and pediatrics.[98] Physicians were randomized to intervention ("coaching") or no intervention, with consideration given to years in practice, work site, and primary care vs. subspecialty practice. Participants completed a baseline and 5-month survey, corresponding to the end of the intervention. Participants randomized to the coaching group received a 1-hour initial professional coaching session followed by five 30-minute professional coaching sessions occurring at a goal frequency of every 2 to 3 weeks within 5 months (total of 3.5 coaching hours at a cost of approximately $1400 per person). Credentialed professional coaches were engaged from an established international professional coaching company with expertise in coaching physicians. All coaching sessions were performed by telephone. The initial coaching session focused on creating the relationship, assessing needs, identifying values, setting goals, and creating an action plan. Subsequent sessions followed the same general structure and the topics individuals could request coaching on were unscripted and individualized. Participants randomized to the intervention group were expected to see the same number of patients as their colleagues who were not in the intervention group. There were no statistically significant differences in baseline burnout symptoms, quality of life, resilience, job satisfaction, engagement, or meaning at work at baseline between individuals randomized to coaching and those randomized to the control group. After 6 months of professional coaching, there was an absolute reduction in emotional exhaustion and overall burnout scores. Moreover, coaching improved overall quality of life and resilience.

ERGONOMIC CHALLENGES IN VASCULAR SURGERY

Occupational pain has a tremendous economic and psychological impact on the U.S. workforce, and specifically surgery given its requisite high mental workload, repetitive movements, and the ergonomic challenges that come from prolonged standing, body posturing and physical exertion to manipulate tissue and devices intrinsic to the performance of such a vocation. A recent SVS survey of 775 members evaluated the physical pain and wellness of active vascular surgeons by body type and type of vascular procedure using the Borg pain scale.[102] Survey responses identified that after a full day of open surgery, the majority of the responding vascular surgeons are in a moderately strong amount of pain (mean score, 4.4 ± 2.3) and after a full day of endovascular procedures, most vascular surgeons are in a moderately strong amount of pain (mean score, 3.9 ± 2.4). While pain after open surgery is greatest in the neck, after endovascular surgery pain is highest in the lower back. Almost 40% of surgeons have sought medical care for work-related pain, with 8% taking time away from the operating room and 10% required surgery or other significant medical procedures. Importantly, of the 39 retirees captured with this survey, one-quarter ended their careers owing to physical disabilities from work-related pain and half of the responding active vascular surgeons felt that physical discomfort will affect the longevity of their careers. Finally, high work-related physical discomfort was significantly associated with burnout.

The science of ergonomics aims to optimize performance and well-being, with the field applied extensively in both the military and industry to minimize error and injury. There is growing interest in the ergonomics of surgery, from which data supports strategies to reduce the risk of developing work-related pain that may include exercise, posture awareness, yoga, regular stretching, and microbreaks during surgery.[103–105] A microbreak incorporates scheduled work periods followed by a shorter, scheduled break from work, and frequently involve posture correction and establishing a relaxed stance to decrease muscle sympathetic activity.[106] Other ergonomic opportunities include adjusting the height of the table and monitor to reduce neck strain, padded floor mats, footwear and support stockings, and wearing custom-fit lead.

SURGICAL TRAINING

Vascular trainees are not immune to burnout. The Association of Program Directors in Vascular Surgery (APDVS) found that over 60% of current vascular surgery trainees and recent graduates indicated experiencing one or more symptoms of distress on a weekly basis.[107] The frequency of distress was associated with older age and with the presence of an advanced degree. The most recent data from the 2018 Annual Training Survey of the APDVS identified modifiable risk factors for burnout amongst vascular surgery trainees to include: the clinical learning environment (specifically feeling appropriately challenged, appropriately integrating learning and clinical productivity, and having a supportive learning environment), longitudinal mentorship and specific coping strategies.[107]

Distinct domains of the learning environment have been proposed to influence surgical resident well-being, a conceptual model that forms the framework for the SECOND (*S*urgical *E*ducation *C*ulture *O*ptimization through targeted interventions based on *N*ational comparative *D*ata)[108] Trial – a study designed to optimize the surgical training environment and promote well-being.[109] This model introduces three unique domains to surgical training including faculty relationships and engagement, resident comradery and mistreatment. These domains specifically address the hierarchical nature of surgical residency that profoundly complicates workplace relationships while the model emphasizes that while individual factors play a role in resident well-being and burnout, these factors must be viewed in the context of the learning environment. Important 2018 ABSITE survey data of 7409 residents spanning 262 programs identified more than 50% of general surgery residents reported some form of mistreatment including gender discrimination (32%), racial discrimination (17%), verbal or physical abuse (30%), and/or sexual harassment (10%).[110] All types of mistreatment were reported with higher frequency by women, of whom 65% reported discrimination and 20% reported sexual harassment. Weekly symptoms of burnout were described by 38%, and importantly those that reported mistreatment at least a few times per month were more likely to have symptoms of burnout (OR 2.94) and suicidal ideation (OR 3.07).

Until now, training programs have had limited ability to assess/benchmark their trainees' wellness and access to strategies for improvement. The SECOND Trial seeks to fill these gaps.[108] The SECOND Trial generates confidential reports of each program's residents' wellness, benchmarked against other programs, based upon a survey administered after the annual in-training exam (VSITE/ABSITE); all programs participating in the SECOND Trial receive this data. Intervention arm programs receive reports with enhanced detail about their Learning Environments and gain access to the SECOND Trial's Wellness Toolkit of successful interventions from surgical programs throughout the country, along with implementation support. At the conclusion of the trial in 2022, access will be extended to all participants. In partnership with the APDVS and the Vascular Surgery Board–American Board of Surgery (VSB-ABS), the SECOND Trial investigators have extended the trial to vascular surgery training programs at institutions with general surgery programs enrolled in the SECOND Trial.

CONCLUSION

To enhance recruitment and retention to secure our future vascular surgery workforce and deliver the highest quality care that our vascular patients and their families deserve, it is critical to minimize team member burnout and depression, and maximize job satisfaction, work–life integration and overall well-being. To do this, we must commit resources to promoting member health and wellness in a longitudinal manner.

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203 CHAPTER

Online Branding and Marketing a Vascular Surgery Practice

YOUNG LEE and ANIL HINGORANI

INTRODUCTION

Marketing has shifted from being frowned upon and avoided, to being acceptable for building and maintaining a vascular surgery practice, to now becoming an essential.[1] Increasing competition amongst vascular surgeons as well as physicians in other specialties,[2] patient consumerism, growth of elective/ambulatory procedures, and presence of business entrepreneurs in healthcare services are all factors that necessitate marketing. Vascular surgery practices largely rely on patient referrals from other physicians; therefore, marketing creates awareness of the vascular surgeon's expertise and commitment not only for the patients but also for the referring physicians.[3]

Branding is an important component of marketing and is defined based on the notion of a label or a symbol. By creating a logo or catchphrase, a vascular surgery practice can build its own branding identity. The relationship between the consumer (i.e., patient) and the provider (i.e., physician), the value added for the patient, and the exchange (i.e., cost and benefit) between the physician and the patient are the three main constructs of branding.[4]

In the recent decade, social media has revolutionized the practice of medical marketing by creating a network connecting patients, physicians and other health systems. Moreover, social media presence of the vascular surgery field is increasing.[5–7] Thus, online branding and marketing through social media is a necessary part of developing, growing, and maintaining a vascular surgery practice.

This chapter outlines guidelines for marketing a vascular practice, with emphasis on social media marketing, how to conduct a market analysis, methods to attract referring physicians/hospitals and how to assess referral patterns within the practice community, development and use of educational tools in marketing, strategies in modern advertising using social media and web presence, ways to deal with negative feedback and the pitfalls of social media, and how to implement online

marketing to strengthen a vascular surgery practice. By understanding these principles, vascular surgeons can effectively expand and maintain their practice while establishing their expertise to the patients and the referring physicians.

MARKETING A VASCULAR PRACTICE

Marketing is any promotional activity aimed at promoting an idea, organization or service. This requires understanding the needs and wants of the patients (i.e., customers) and tailoring your practice's service to meet those needs. To set up an effective marketing plan for a vascular practice, the practice needs to identify groups of patients who share common wants or needs and develop positioning statements that will demonstrate what your practice will offer to each of your target groups. You must also identify and market yourself and your practice's unique strengths and niche (i.e., dialysis access, wound care/limb salvage, noninvasive vascular laboratory, varicose veins) that only you and your practice can fill.[8] Vascular practices can incorporate the traditional marketing mix of the 4Ps that businesses use as part of their marketing plan: product, price, promotion, and place.[3]

- **Product** refers to the actual service being provided. In vascular surgery, this could mean endovascular services, noninvasive vascular studies, vein services, etc.
- **Price** is the list price of the services including any discounts.
- **Promotion** is the advertising, promotions, sales force, and public relations used to reach a defined target market. For example, direct marketing to potential patients can be used to distribute information about the vascular practice.
- **Place** describes the locations at which your service is available to the patients.

Next, the practice must outline specific campaign objectives, marketing activities, timeline, and budget. It is important to perform a marketing analysis in order to set goals that can be evaluated for improvement with time and must be realistic and attainable. First, you must assess the population of potential patients, the competition, and referrers. When developing your marketing plan, you should analyze the competitors nearby (i.e., competing vascular surgeons, interventional cardiologists, interventional radiologists, general surgeons, neurosurgeons, etc.) as well as which procedures they are performing and where (i.e., operating rooms, interventional radiology suites, cardiac cath labs). You need to assess the current market area and explore whether there are new areas to be explored. In addition, you should investigate whether the patients are staying locally for the services or travelling elsewhere and if there are patients with vascular diseases that are not being treated.[9] All of this information will guide you in attracting potential patients and keeping existing patients to maintain and build your practice efficiently. Your marketing goals can be achieved via both internal and external marketing.[3]

Internal Marketing

Internal marketing is when the practice advertises itself by providing positive patient experiences. It is the most effective type of marketing and at no cost. When the providers and staff within the practice afford extra care and effort, patients in turn recognize the enhanced level of care and return for follow-up care or new issues. Furthermore, the satisfied patients will promote the practice by positive word of mouth to their relatives and friends. Simple ways to internally market the practice and positively enhance your patients' experiences are to document special events, hobbies/interests or birthdays and mention them at office visits, provide a 2-minute call on the way home from the office to follow-up with the patients, and leave the patients with the impression that you and your practice are grateful in the trust they have put in you.[3]

The effort placed by the staff within the practice is equally as important in internal marketing as the staff are a representation of you and your practice. Patients will often interact with the office staff as they schedule their appointments and settle billing issues. Selecting staff that share your values, including them in strategic decisions to enhance patient care and experiences within the practice, setting tangible goals to gauge success, and rewarding positive outcomes is critical to the success of the practice.[3]

External Marketing

External marketing is advertisements, promotions, public relations and other forms of communications, such as social media, which will be discussed later in the chapter. Patient requests can be the deciding factor of the referrals by primary care and specialists to your practice. Educating potential patients about less familiar topics in vascular diseases and surgery may be useful.[3] The SVS website provides patient education fliers on various vascular diseases, interventions, and surgeries, that may be downloaded in the offices and handed to patients or accessed by patients on the website itself.[10] Vascular practices can use their websites and social media sites to provide links to these fliers, which are available in both English and Spanish.

Educational marketing can also be achieved within the practice. For example, within the waiting area, the fliers mentioned above can be available for the patients to read while waiting to be seen by the providers. Short educational segments can also be presented on television screens in the waiting area of the vascular practice. These activities show that the practice is interested in engaging with the patients and providing them with readily accessible resources.

Generating positive public relations is another way to market your vascular practice. Sponsoring free lectures and/or workshops on various vascular interventions to nurses, medical spas, and salons or providing free screenings at a retirement home are ways to develop good relationships with potential patients. In addition, your practice can also participate in community outreach such as health fairs to target more potential patients.[3]

Marketing to Referrers and Assessing Referral Patterns

When marketing a vascular practice, it is essential to remember referrers as part of your target audience. This includes hospitals

BOX 203.1 Relationship-Building Tools with Referrers

- Provide easy contact with your practice and to set up an appointment for one of their patients.
- Provide the expected communication by the referrers after assessing and treating their patients. *(Some referrers will want summaries while others will want details)*
- Follow up with the referrers.
- Maintain communication with the referrers and the referred patients. *(Provide updates through the practice website or social media sites)*
- Maintain professionalism and be courteous to all employees when providing service at an institution outside of your practice. *(Interns, residents, and fellows are future referrers. Employees will often seek medical attention from providers they know and are comfortable with)*
- Maintain a database of the referrers. *(Provide special treatment to the top referrers)*
- Be active in professional organizations – create more awareness about your practice and your expertise.
- Create business cards with your credentials and practice information along with a customized *referral brochure* accessible from the SVS website[11] to distribute to hospitals, referring physicians and employers. *(The referral brochures can be emailed to referring physicians or hospitals to be distributed)*
- Periodically survey the referring physicians and improve your service based on the feedback.

and referring physicians. Referrers are looking for vascular specialists who are able to provide the best care for their patients, good communication about their patients, and easy scheduling access for their patients. In order to attract referrers, you must first target the referring physicians. This can be achieved by lunches/dinners offering continuing medical education (CME), with phone calls or by distributing referral fliers/business cards, online websites or social media advertising, or providing hospital in-service presentations or grand rounds.[9] Another option is to take stipended vascular calls at a local hospital to increase your profile within the community.[8] Outlined in Box 203.1 are easy ways to build relationships with the referrers.[3,8]

Once referrers are established within your practice, it is important to assess the referral patterns within your practice and community in order to retain and bring in more referrers to maintain and continuously grow your practice.

BRANDING A VASCULAR PRACTICE

Part of marketing a practice is to create a brand associated with the practice. A brand is a name, logo, or catchphrase or a combination intended to identify the one specific practice differentiating them from other practices. Branding is a strategy used to develop a unique identity or "brand" for your vascular practice. In order to maintain the "image" of the brand, the practice must ensure that their patient interaction is positive.

In addition, the Society for Vascular Surgery provides the "SVS member logo" (Fig. 203.1) that can be used in conjunction with your practice name or logo. This is available at no cost to all SVS members on the SVS website[12] and can be used to promote your affiliation with SVS as part of the marketing strategy. Moreover, marketing the Vascular Board certifications of the surgeons within the practice boosts the credibility of the providers and their training for the services provided. Providing information about the surgeons' memberships in various vascular societies and their role within the societies can market the providers' expertise and continued involvement in trending vascular services.

Figure 203.1 The Society for Vascular Surgery Member Logo.

WHAT IS SOCIAL MEDIA?

Social media is defined as web-based and mobile technologies used to turn communication into interactive dialogues.[5] This platform provides opportunities for people to connect electronically and informally by making introductions, sharing experiences, building communities and linking common interests compared to printed/video content advertisements which provide only one-directional interaction. Moreover, social media allows viewers to review the advertisement and content repeatedly as well as freely share and redistribute content amongst the users.[13] Popular social media sites include Facebook, Twitter, Instagram, Pinterest, and YouTube.[5,14] The top social media sites commonly used by physicians are LinkedIn, Facebook, YouTube, and Twitter; thus, these sites would be effective in developing a referral base with other physicians.[13] Furthermore, to facilitate easy access to the vascular practice's social media site, links should be included in the practice's official website.

Social media marketing uses these networking sites to promote commercial enterprises. In the United States, nearly 70% of adults use at least one social media site and they spend more than 6 hours per day on digital media.[13,15] The advantages of marketing using social media include enormous reach and accessibility with minimal cost (especially compared to traditional marketing media: television, magazines, and newspapers). Moreover, social media is easy to use, therefore, this type of marketing would allow a vascular surgery practice to quickly assert itself as a trusted expert and establish an immediate line of communication with the practice's patients. As a result, the networking outreach capabilities of social media are vast when marketing a vascular surgery practice.[5,14,16]

However, there are some limitations of social media marketing. The information can be easily edited and negative comments posted often lack credibility and accountability. The effective ways to deal with negative feedback are discussed later in this chapter.

Popular Social Media Platforms

Facebook is the largest social media platform in the world, with more than 2.9 billion users and it is used by half of the United

States, population daily.[5,15] Thus, it is the best social media application to reach patients, families, and departmental employees.[7] Patients may share their vascular care experiences on their personal Facebook page, which allows the vascular practice an avenue for free advertising to the patient's network of friends.[5] Vascular practices can also design their own public Facebook page and attract existing or potential patients with engaging and educational content about the practice, the procedures offered, and the common disease processes. Institutional or departmental websites are often linked through Facebook and most practices with Facebook pages will post contents two to three times per week.[7]

YouTube is a powerful tool that uses online video technology and has over two billion users in the world. It is used to target mainly patients and families. Instead of paying thousands of dollars producing a promotional video to air on television, any vascular practice may produce its own video and publish it on its own channel, to which patients can subscribe.[5,7] Subscribers will receive notifications when new content is uploaded. Educational material about specific vascular conditions and content about new advances in patient care and research are presented in YouTube videos. In addition, each of the videos can include the practice's name and logo for branding purposes. Clinics may post as much as they want at no additional cost. An employee familiar with social media navigation or an outside company may be hired to optimize the practice's social media content in order to get more patients or potential clients to watch the videos and gain their interest.[5] Most users will post new videos several times every month.

Not only can social media provide an avenue to reach out to current or potential patients, it can provide unparalleled networking opportunities between clinicians. An example is Twitter, which allows communication through text-based interactions (Tweets), delivering microbursts of information online. Each Tweet has a 280-character limit, and photographs, links, and videos can be included. The Tweets can be viewed by all followers or by any user following the hashtags included in the post.[7] Each photograph posted increases the retweeting rate by 35%.[13] Twitter has become the preferred social media engagement tool amongst medical professionals and has allowed physicians to reach other providers in the same or other specialties. The wide use of Twitter in the medical community allows vascular surgeons to manage their professional brand and provide access to networking opportunities, which can include referring physicians.[7]

Image-based platforms, such as Instagram, share photographs among users; Instagram is one of the most widely used social media applications in the world. Users are able to post images or videos and an accompanying caption (2200 character limit), which can include searchable hashtags. This is well suited for educational content. Anyone following the user or searching the specific hashtag can view the post. The Instagram posts can be interactive because users can post comments or questions below the caption. Most users will post daily or multiple times per week.[7]

GUIDELINES FOR SOCIAL MEDIA MARKETING

When using social media marketing to build, grow and maintain a vascular surgery practice, it is important for the surgeons to establish their brand as a valuable expert. The aim would be to provide more for the patients than what is received in return. For marketing purposes, Facebook and YouTube provide the widest reach of patients.[7] The SVS website provides ads for Facebook, Twitter and Doximity that can be customized with photos from your practice. Each of these ads will have the "SVS member logo" signifying your membership status with the Society of Vascular Surgery. These ads can be uploaded onto your social media accounts and used to market your practice.[11]

A well-designed social media page needs to have the vascular practice's complete, updated, and correct contact information. An abundance of photos and videos are important because visual content receives 4 to 10 times more fan engagement. To engage a larger audience, a call to action to follow the practice's posts and share with friends on the social media page will allow more social media networking through the patient's own social media friends. Be sure to have applications on the social media site to book an appointment with the clinicians at the vascular practice and a link to connect to the practice's official website. In addition, having a link to the social media sites on the website is also becoming standard. Easy-to-enter contests and promotions on the site will also attract the viewers.[5,16]

However, it is important to avoid having the vascular practice's social media page overflowing with lists of specials, discount offers, and self-praising messages by adhering to "The Social 80/20." Clinics should provide free interesting information at least 80% of the time on the social media page, while not asking for something from the patients more than 20% of the time. This allows the patients to be receptive to the social media site and its message because they have been consistently exposed to appealing and interesting content by the clinician publishers who have established themselves as experts in the field.[5] Engaged patients will further the growth of the practice's social media following by sharing the content with their friends. This community of followers becomes a true asset to the vascular practice and its brand.

The guidelines in Box 203.2 are provided to aid vascular surgeons in using social media marketing for their practices.

Methods to Attract Referring Physicians on Social Media

Patient referrals from other physicians are essential for building, maintaining and expanding a vascular surgery practice.[3] Thus, the target audience for social media marketing should also include referring physicians. With increasing numbers of physicians online,[13] it is important to use social media marketing to demonstrate and help the referrers understand a vascular surgeon's expertise and skillset in treating the entire disease entity. For professional branding and to reach colleagues in other specialties, Twitter provides a better avenue for interaction.[7] In

BOX 203.2 Social Media Marketing Guidelines

- Align the social media marketing strategy with the practice's general marketing principles *(Who is this practice?)*
- Create a solid "branding statement" *(Why is this practice unique?)*
- Create one logo for all of the social media sites *(to associate with the brand of the practice)*
- Select the appropriate social media channels *(2–3 maximum for easier maintenance)*
- Outline five things patients need to know about the practice *(Why should the patient believe in the practice?)*
- Create visually attractive social media homepages *(Align visually with the look, feel, and brand of the practice)*
- Continuously create engaging content both informative and educational to the patients and the referring physicians *(<20% should be promotional)*
- Keep the content on homepages accurate, concise, broad, and general *(avoids negative misinterpretation of the information)*
- Include case pictures or videos to demonstrate visually the types of procedures performed *(always obtain informed consent from the patients and eliminate patient identifiers)*
- Include concise and honest patient testaments *(allows other existing or potential new patients to relate more personally to the practice)*
- Maintain and update social media homepages with a minimum of weekly updates *(keeps the audience engaged and anticipating new content)*

BOX 203.3 Methods to Attract Referring Physicians Using Social Media

- Present information on new techniques to diagnose and treat patients (*demonstrates the vascular practice's ability to stay current in treatment options*)
- List the practice's recent publications (*highlights interests and strengths of the practice*)
- Post interesting and/or challenging cases and include how the surgeon navigated through those situations (*allows referrers to understand the complexity of vascular surgery and the need for an expert surgeon to treat their patients*)
- Provide interactive cases (*engages referrers and helps educate them*)
- Promote new studies that the practice is part of to recruit new patients (*promotes the practice as being progressive and a leader in the field*)
- Publicize new medications for patients to try to treat or improve symptoms of their disease

particular, the vascular surgeon should use searchable hashtags related to the case or pathology Tweeted to attract other clinicians searching or following the same hashtag. Box 203.3 provides methods to attract referring physicians and educate them in the vascular surgeon's ability to treat their patients.

Social Media Marketing "Don'ts"

Although social media marketing significantly grows a vascular practice given its incredibly broad audience, there are a few things physicians should avoid doing. Providing educational, informative, engaging content using social media channels is important in maintaining current or prospective patients' interests; however, the information should always be general and broad. Specific communications that can be misconstrued as medical advice should be avoided and the practitioners should seek an opinion from their legal professional.[5] Physicians should also avoid glamorization of procedures and avoid employing sensationalism on the practice's social media posts.[17]

The vascular practice's social media presence is a professional one; thus, any religious or political preferences should be avoided since patient populations are diverse and these contents may offend the viewer. In addition, a patient–physician social relationship should not be started and maintained online. These posts may be circulated without the physician's knowledge and the relationship violates the code of ethics. Furthermore, do not allow patients access to personal profiles and social media sites.[16,17]

Online professionalism should always be maintained. To guide physicians, one should always adhere to departmental, institutional and professional society guidelines set for social media presence. Therefore, it is important to become acquainted with these guidelines prior to establishing a social media presence for marketing.

HOW TO DEAL WITH NEGATIVE FEEDBACK AND PITFALLS OF SOCIAL MEDIA

While social media is useful in marketing a vascular surgery practice, there are potential pitfalls that need to be addressed. Because the internet is a public forum, negative comments and internet trolls (people intentionally antagonizing online by posting inflammatory and digressive, disruptive, or off-topic messages to evoke emotional responses) cannot be avoided.[7] Moreover, patients may rely on social media as the mainstay of communication rather than directly communicating with their vascular surgeons and these communications can be edited and altered at any time. This could lead to a potential delay in diagnoses and treatment. Lastly, violation of patient privacy could become a legal issue.[15,16]

Negative feedback is inevitable; therefore, it is important to never ignore or delete feedback but rather address the issues in a timely and sincere manner. Insincere apologies to maintain a good social media façade should be avoided. Furthermore, responding in the right frame of mind is key to avoiding further conflict that could arise from emotional responses. By being aware of the negative feedback (i.e., set internet alerts with the vascular surgery practice or surgeon name), the practitioner can be quick to acknowledge the negative comment likely posted by a frustrated patient. Trying to see the comment from the patient's point of view and starting appropriate dialogue can further help resolution. It is better to steer the conversation away from the public limelight and proceed privately. Most importantly, apologize if at fault and be sure the response is personal, not automated. Follow up with concrete actions to resolve the issue to avoid future discontent. Lastly, if the negative comment is left by an internet troll, ignore him/her or post facts that support truths without engaging.[13]

Another pitfall of social media is the difficulty in verifying the validity of the information posted. Due to the "viral" nature of social media, it is a powerful platform for spread of false information. Sharing common perceptions and values leads to a groupthink mentality thereby amplifying similar opinions despite the truth.[7] Therefore, it is the physician and the practice's duty to provide accurate and correct educational content for the patients engaging in their social media content.

ADHERING TO THE AMERICAN MEDICAL ASSOCIATION CODE OF ETHICS

When using social media marketing, the vascular surgeon must always adhere to the American Medical Association (AMA) Code of Ethics.[15] First and foremost, clinicians should always maintain patient privacy and confidentiality and avoid posting any identifiable patient information without informed consent. Moreover, patients should be aware that information posted on the social media site online is likely permanent.[13,18]

Even with privacy settings, practitioners should post content on social media with caution because once on the web, the information is traceable even if the content is removed after being posted. Therefore, clinicians should perform routine monitoring of professional and personal information on various social media sites to ensure accuracy of the information posted.[13,18]

According to the AMA, patient–physician interaction online must maintain the appropriate boundaries of the patient–physician relationship in accordance with professional ethical guidelines. Physicians can further maintain professional boundaries by having separate professional and personal social media accounts. If a physician notices inappropriate and unprofessional content posted by colleagues, they are responsible for bringing that content to the individual's attention so that it can be removed unless the behavior significantly violates the norms, in which case the matter should be reported to the appropriate authoritative channels.[13,18]

Lastly, physicians should understand and recognize that content posted online may negatively affect their reputation amongst peers and have potential consequences for their medical careers. Unfortunately, this can undermine public trust in the medical field. Box 203.4 summarizes the guidelines for following the AMA code of ethics when using social media for professional use.[13,18]

BOX 203.4 Guidelines for Following the AMA Code of Ethics

- Avoid all patient confidentiality breeches (*review all photographs and videos before posting, for any identifying features*)
- Obtain informed consent when posting patient information (*include permanence of online content and lack of control over audience*)
- Prohibit patient incentives for allowing postings of their photographs
- Follow institutional guidelines (*if the practice is part of an institution*)
- Maintain separate personal and professional social media accounts
- Must keep responsible communication on social media sites *(adhere to HIPAA regulations, maintain professional boundaries of patient–physician relationship)*

BUDGETING FOR MARKETING

A budget is important to plan before implementing marketing strategies. The United States Small Business Administration recommends allocating approximately 7%–8% of total revenue in marketing for businesses with revenues less than $5 million.[18] The Society for Vascular Surgery recommends spending 5%–10% of your practice's gross income on advertising if you are in a competitive market area and 1%–5% if you are in a less competitive area.[8] This budget should cover both brand development costs and business promotion costs. In 2020, the marketing budget was about 9%–16% of the total revenue for business to consumer firms.[19] However, these numbers do not represent just advertisement costs but also includes hiring staff or outside sources to maintain the practice's website and engage current and new patients through social media.[20,21]

IMPLEMENTATION

Online branding of a vascular surgery practice should start with its own personal website. The easiest way to do this is to hire a professional with experience and credibility in working with the healthcare community. The website should be easy to navigate for patients. Furthermore, it can provide links to the social media networks for further marketing. The "viral" qualities of social media demonstrate the power of the Internet to spread information quickly and maximize the power of advocacy to tremendous levels. This is why many medical practices employ professional social media marketing companies that aid in developing strategic and tactical plans to take advantage of these opportunities, keep current with the changes, and ensure that the practice "brand" is ahead of the competition.[4–5,14]

The majority of the marketing content should include providing interesting and educational information for the patients about their disease processes and maintaining promotional information at a minimum, which will engage the patients (i.e., consumers) and, in return, they will be more receptive to the promotional messages. More specifically, the content may include frequently asked questions (FAQs), visit information, procedure information (including videos and photos), and specific information about the practice and the staff.[5,16] Content creation requires time, however platforms such as Facebook, Instagram and Twitter allow for short content which can be created at the point of thought while a 5-minute YouTube video may take up to 4–8 hours to produce and upload.[7] These are considerations when determining whether a social media manager should be hired or if it is sufficient to designate staff who are fluent social media users to maintain the vascular practice's social media presence for marketing.

By providing a continuous and frequent flow of interesting, educational information on the practice's social media sites, the patients following will actually look forward to the contents

and will likely share this with their family and friends, enlarging the practice's patient base. Moreover, this establishes the vascular surgeon as the expert in his or her field, which attracts other physicians who may become a referral base in addition to potential patients. The information provided should be kept broad and general when communicating with patients using social media networks, and care taken to maintain the patients' privacy and to avoid violating The Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulations.[17]

CONCLUSION

Social media marketing can elevate a vascular surgeon's practice if accomplished appropriately. It is a useful marketing strategy during this digital age, given the magnitude of users, to increase referrals, expand patient base, and create a positive reputation. However, it is important to recognize that this marketing strategy alone does not grow a vascular practice. A vascular surgery practice must first establish its vision and create its own brand. Ultimately developing and maintaining a trusting relationship between the patients, the physician referrers, and the vascular surgeon is the key to developing and maintaining a vascular practice.

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CHAPTER 204

Telemedicine in Vascular Surgery Practice

JOHN W. HALLETT Jr.

INTRODUCTION

Telehealth technologies offer opportunities to improve the access to vascular care and enhance continuity of care. Many vascular surgeons are already using store-and-send options to review CT images generated at distant hospitals to triage symptomatic aortic pathology. This capability allows referring physicians to access expeditiously the expertise of larger aortic centers. Recently, the COVID-19 pandemic forced all medical and surgical practices to adapt to telehealth systems to evaluate and follow patients.[1,2] The adoption of telehealth over the past two decades has been slow but is now accelerating.

Other examples of tele-technologies impacting cardiovascular care include home monitoring of blood pressure, blood glucose, cardiac rhythm, and INR measurements for chronic oral anticoagulation. In addition, some advanced vascular wound care centers review images recorded remotely by patients and healthcare providers on cellphones and transmitted for review and advice. Although many of these communications do not meet current Protected Health Information (PHI) security recommendations, the practice is still common.

In this chapter, we review briefly the history of vascular telehealth. The impact of the COVID-19 pandemic has increased the urgency of using telemedicine. Various options are evolving, and the reimbursement schemes continue to adapt. Although several simple methods of telehealth are discussed, we present a more advanced telehealth option for vascular care that has been developed over 5 years: the remote or distant vascular patient consult or office visit. This model of vascular telehealth may be conducted at an affiliated regional multispecialty clinic, an emergency department, or hospital equipped with telehealth transmission equipment and trained tele-presenters.

Finally, we review data on patient satisfaction and also emphasize the challenges of establishing a vascular telehealth program. We share lessons learned. Establishing an effective vascular telehealth program requires attention to several principles. The details of technology and reimbursement will change, but the key principles will remain. These concepts facilitate success in caring for patients via telehealth technologies.

HISTORY OF VASCULAR TELEHEALTH

In the past several decades, the concept of telehealth to evaluate and treat vascular patients emerged, especially in rural areas.[3] Virtual wound care evaluation was instituted in some practices. Transporting CT scan images from rural areas to major medical centers became common, allowing vascular surgeons to quickly evaluate aortic catastrophes such as ruptured aneurysms and arterial dissections.[4] Virtual postoperative visits have also added to improved outcomes.[5,6]

Although the benefits of quicker access were clear, past services were not reimbursed for the most part. Before the COVID-19 pandemic, a more analytical look at vascular telehealth began to appear. The savings in time and expense for travel by patients was documented.[5] Patient satisfaction was high, and Medicare and some private payers began to reimburse for visits beyond a certain geographic distance, usually 25–50 miles.

The COVID-19 pandemic catapulted telehealth for all kinds of medical care to the forefront. Prior to the pandemic, less than 1% of vascular care was facilitated by tele-technologies. At the peak of the COVID-19 pandemic, up to 60%–70% of vascular surgery clinic visits became virtual. At the time of this writing, the rate of virtual clinic visits is in the 30%–40% range, and will probably remain at this new set point.[2] Certainly patients appreciate the convenience of telehealth, and vascular specialists are learning a more focused, efficient style of practice.

THE STRATEGIC URGENCY

The aging population is rapidly multiplying the number of patients with vascular disease. The prevalence of peripheral arterial disease, aortic aneurysms, carotid artery disease, and venous thromboembolism with post-phlebitic syndrome is increasing. Unfortunately, these demographic changes in vascular disease are occurring concurrent with a growing healthcare provider shortage.[7] Over 40% of vascular surgeons are over 55 years of age. Their retirement in the next decade, without adequate residency graduation replacement, may strain clinical access to care. Consequently, tele-technologies have become obvious as a partial solution to this issue.

The COVID pandemic propelled the need for telemedicine for all specialties. In-person clinics were suddenly reduced. Many practices reported that patient visits and procedures were reduced by 25%–50%. The use of advanced telehealth carts in clinics was essentially lost because patients would not come to the office. Consequently, vascular surgeons resorted to smartphones and apps, like doxy.me. Insurers agreed to reimburse for telecommunication visits by almost any device and any location including home, although the reimbursement for smartphone calls was less than more formal telemedicine visits in a remote clinic.

DEVELOPING THE OPTIMAL TELEHEALTH PRACTICE

Most vascular practices are likely to adopt several telecommunication methods *IF* reimbursement covers all of them. All of these methods have their pros and cons.

The simplest is using a smartphone to interact directly with a patient. FaceTime can add some visual information. Vital signs depend on whether the patient has in-home monitors, e.g., for blood pressure, heart rate, blood glucose. Any medication reconciliation has to be done by the provider. Finally, reliable broadband in remote rural areas can be problematic, and reimbursement for time spent interacting with the patient plus review of chart and documentation is relatively low for the time spent. Nonetheless, the immediacy of access is excellent for both the patient and the provider.

The next level of telehealth options is a variety of stand-alone vendors. Some examples include: doxy.me, DrFirst.com, careclix.com, medici.md, myremedy.com, snap,md/technology/, zipnosis.com, zoom.us/healthcare. In addition, during the COVID-19 crisis, covered healthcare providers were allowed to use popular applications for video chat, including Apple FaceTime, Facebook Messenger video chat, Google Hangouts video, Zoom, or Skype. Each of these has some unique functionality, connection to electronic health records (EHRs), and billing mechanisms.

Finally, the most sophisticated telehealth systems are advanced mobile telehealth carts that are used in clinic, emergency department, and hospital wards. These devices are generally set up by a medical assistant or nurse who reconciles history and medications, records vital signs, and can perform explicit parts of a physical exam with an electronic stethoscope, EKG, and continuous wave Doppler to provide arterial sounds. These carts are more expensive than less advanced telecommunication systems (e.g., smartphones and stand-alone computer programs) mentioned previously. However, they allow for a more complete exam, provide high-definition images, and the visits are reimbursable at parity with an in-person visit if properly documented.

The next section discusses the complexities of organizing the most advanced telehealth systems that are likely to become more prevalent in the future. In addition to the larger telehealth mobile carts, smaller portable telemedicine units are under development and will be ideal for home or nursing home visits.

ORGANIZATIONAL STEPS AND REQUIRED RESOURCES

The organizational steps and resources required to build a vascular telehealth system are relatively complex and require the coordination of providers, information technology experts, scheduling personnel, and billing staff. Each has to work concomitantly over time to bring an advanced telehealth system to fruition and to maintain it.

Step 1: Development of Institutional Infrastructure

Developing an advanced telehealth systems requires an institutional vision and financial commitment. The major source of the most sophisticated state telehealth systems has been funding from state legislatures. One pioneering example is South Carolina, where the legislature established the South Carolina Telehealth Alliance in 2013. They allocated millions of dollars to fund the development of a telemedicine program across the state, especially for quick access to expert university-medical-center expertise for acute stroke in every rural hospital. In 2017, the Federal Government began to recognize national

Telehealth Centers of Excellence. The expectation has been that these centers would develop and share the best models for telemedicine with the nation. Many states have been making similar investments in telehealth, and one should search for ALL sources of funding available for a regional program, e.g., https://www.telehealthresourcecenter.org.

Consequently, our most important strategic message is simple: telehealth development requires significant personnel and financial resources. Telehealth must have an organizational strategic vision before individual patients and providers can benefit from its opportunities. Smaller practices will need to ascertain what level of personnel and investment can be made, and perhaps they may align with larger healthcare systems to contract resources.

The ideal multispecialty telehealth center remains in a large healthcare system that can fund a full-time administrative director, a dedicated physician director, and a diversified clinical and technical staff. The support staff must have expertise in information technology, telehealth equipment, care-system organization, scheduling, billing, regulatory requirements, outcomes analysis, and legislative lobbying. Ideally, a telehealth center should be located in a dedicated space with offices, teaching labs, and tele-offices for providers to see patients at remote sites.[8] Such a center can support multiple specialties without duplicating efforts.

Step 2: Identification of Physician Champions

Physician champions are critical to the successful development of a telehealth program! Often, they are early adopters of disruptive technologies. Telehealth is still seen by some providers and some patients as an uncertain change. The skepticism is not unlike the initial pushback by surgeons to laparoscopic operations and by vascular surgeons to endovascular therapy. There was even a time when cardiovascular physicians questioned the value of statins. However, all of these major paradigm shifts develop relatively slowly over a few years. Often patients eventually demand the changes faster than physicians. Then, the adoption rate accelerates rapidly. With the recent COVID-19 pandemic, telemedicine has been thrust into rapid acceleration.

Step 3: Selection of Telehealth Clinical Sites

Many vascular practices have outreach clinics, which may be a several-hour drive from the main office. Such sites often provide convenient access for both follow-up and new patient encounters. The main challenge for the provider is travel time which generally is nonproductive unless the provider is chauffeured, an additional cost no matter how one measures it.

Established rural clinic sites are the logical locations at which to initiate a regional vascular telehealth program. Some rural communities may already have telehealth capabilities for stroke triage or pediatric consults. Ideally, a shared multispecialty clinic site with telehealth connectivity and trained tele-presenters (certified medical assistants or nurses) reduces startup and sustainable costs. Rural communities often request specialty consultations from several specialties, such as cardiology, neurology, pulmonary medicine, rheumatology, neurosurgery, and vascular surgery. Consequently, a central site in a rural community shared by several providers in collaboration with local medical facilities is a pragmatic economic model for everyone.

If a potential telehealth site does not exist, partnering with a rural health system is recommended. They may have available space and support staff for a multispecialty clinic, and they may have some level of IT support to collaborate. Some states already provide state funding to support rural telehealth projects.

Finally, most payers previously required a specific distance between the telehealth provider and the patient. This distance was often 25–50 miles. With the recent COVID-19 pandemic, geographic conditions have generally been eliminated. It is always wise to check with local and regional payers to be certain about what geographic limits are in place.

Medicare and private payors are also considering the value of telehealth home visits that would be reimbursed. During the COVID-19 pandemic, the location of the visit became inconsequential to billing as long as the provider documented the type of televisit and applied appropriate coding. For example, indigent patients in sprawling urban areas may have difficulty with transportation within a congested city. So, both rural and urban areas need telehealth reimbursement. Telehealth should be the most convenient and rapid access for any patient anywhere.

In addition to specialized telehealth clinic sites, the use of portable, smaller telehealth systems may allow visiting nurses to link vascular patients at home with specialists at vascular practices or centers. The technological advances and the reimbursement options are likely to accelerate in the next few years, expanding the ability of vascular specialists to triage or manage patients remotely. These changes will not only increase access to care but also optimize the use of physician time.

Step 4: Establishment of Appropriate Equipment and Exam Protocols

At the remote clinic site, certain equipment is key. We recommend a mobile telehealth cart that is easily moved in and out of the exam room or hospital room. Consequently, using rooms that can comfortably accommodate the exam table/bed, the patient, the telehealth cart, and necessary staff plus family members is important. Some exam rooms are simply too small for optimal telehealth care. A critical part of starting up a telehealth site is pretesting all of the equipment and staff in the exam room before launch.

Initially, we used the Avizia TM telehealth platform for this vascular cart model. This platform/card incorporates a 24-inch LED screen with built-in WiFi connectivity. The control panel is simple with icons that are intuitive. The equipment initiates and is ready to use within 10 seconds. All of the components of this system are manufactured and maintained by Avizia, which makes any maintenance and repair easier. Other systems are built using components from several vendors, which

Figure 204.1 Patient undergoing a telemedicine consult with advanced telehealth cart displaying both patient and provider images, electronic medical record, and with auxiliary connections for a stethoscope and a continuous-wave Doppler.

complicates troubleshooting problems and repairing them. However, other telehealth carts are also available, and we recommend consulting an established telemedicine center to get their latest recommendations (Fig. 204.1).

To this basic cart or platform, one must add the accessories needed to provide the history and physical exam necessary for a comprehensive vascular evaluation. So, can an adequate vascular exam be accomplished by telehealth? Generally, yes.

Vital signs are easily recorded and transmitted. Cardiac rhythm can be recorded and examined. The general appearance of the patient is seen clearly by high-resolution cameras. Magnifying cameras can not only show lesions at a closer and more magnified quality (1080 pixels) but also record and store for later review or transmission to other consultants. For venous disease with swelling, it is easy to measure leg and thigh diameter with a simple measuring tape and record the findings.

Auscultation of the heart, lungs and arteries may seem challenging. However, several stethoscopes have been adapted to telehealth stations. We have tried them all and finally decided that the best quality of sound occurred with the Thinklabs One™. This digital stethoscope provides direct analog audio output, requires no special software, and integrates into almost any videoconferencing system. For over a decade, this system has performed reliably with telehealth cart systems. Other stethoscopes were evaluated and may be acceptable: 3M™ Littmann R Model 3200 and the Cardiomin E-Scope II.

The telepresenter must be trained and guided to where the stethoscope should be placed for auscultation of cervical bruits, heart sounds and murmurs, abdominal and femoral bruits, and breath sounds. A high-fidelity headset improves hearing all sounds during auscultation.

At first, the extremity arterial exam appears problematic. Most certified medical assistants and nurses have limited training and experience in pulse exam. However, they can be trained to detect arterial Doppler flow. One Doppler option is a commercially available and relatively inexpensive continuous-wave Doppler: the Parks 811 unit known and used by many vascular surgeons for generations. The next step in standardizing the Doppler exam may be software that guides any examiner to the optimal angle of insonation. The signal would then be processed and interpreted automatically as triphasic (normal), biphasic (moderate arterial obstruction), and monophonic (severe arterial obstruction).

The peripheral venous exam is relatively easy. Leg imaging with the exam camera is clear. Varicose veins, stasis skin changes, leg ulcers, and telangiectasia can be photographed and stored for review or transmission to insurance companies. The medical assistant or nurse can easily measure leg or thigh diameter with a measuring tape.

In addition, the abdominal vascular exam can be simplified to detect occult aneurysms. For men with a belt size less than 40 inches and for women with a waist size less than 35 inches, tele-presenters can be trained to simply lay the palm of their hand just above the umbilicus in the relaxed abdomen. Generally, large abdominal aortic aneurysms (AAA greater than 5.5 cm) are palpable as pulsating masses. Ultrasound can be confirmatory. Also, they can listen with an electronic stethoscope in the midline between the xyphoid and umbilicus for bruits, which would be audible to the remote provider. Most remote clinic sites are located near a radiology department or vascular lab where aortic ultrasound can be performed to investigate any abnormal findings. (Males over 65 who have ever smoked should be screened by ultrasound for AAA.)

Finally, a comprehensive vascular exam flow sequence (Box 204.1) can standardize the training and performance of the physical exam for the tele-presenters. Pertinent neurological and orthopedic exam can also be guided by the physician as the tele-presenter tests these systems. It is important to ask the tele-presenter whether they observe anything else about the patient that needs to be recorded and discussed. The comprehensive vascular exam can be demonstrated by the medical assistant to the provider in about 5 minutes as the assistant becomes skilled at the essential exam elements (Box 204.1).

Step 5: Team Organization and Training

Telehealth patient encounters are a team effort. Several members are critical at both ends of the encounter. At the origination (patient) site is the usual receptionist team that checks in and rooms the patient. They are important in reassuring the patient that the visit with the provider will be similar to a direct patient visit.

The telehealth presenter is usually a certified medical assistant or nurse. Training this individual is critical. They must be familiar with the electronic medical record, using the telehealth cart to connect the patient with the provider, and the skills to perform the essential parts of the physical exam for the provider, e.g., auscultation of the heart and Doppler arterial exam of pedal pulses. A structured exam format is helpful for both training and exam (Box 204.1).

At the reception (physician/provider) site, the provider needs a workspace equipped with a high-fidelity computer monitor and camera to view the patient and to be seen by the patient. A separate adjacent computer screen is ideal for

BOX 204.1 Sequence of a Comprehensive Vascular Exam for a Telehealth Visit Performed by Tele-presenter (Certified Medical Assistant or Other Qualified Provider at Site of Patient)

1. Record blood pressure, heart rate, oxygen saturation, and weight BEFORE calling the provider for the telehealth visit.
2. Call the telehealth provider and begin the visit by introducing the patient to the healthcare provider doing the telehealth visit. Assure that both the patient and provider have a good audio connection.
3. With the patient sitting, check the radial pulse in BOTH arms for any irregularity (especially an irregular heart rate suggesting atrial fibrillation, a common cause of arterial embolism.)
4. Place electronic stethoscope over the anterior mid-neck (carotid artery) and record any bruits.
5. Palpate for a carotid artery pulse and note present or absent.
6. Place the stethoscope over the upper right lateral border of the upper sternum to listen for any murmur over the aortic valve. (Aortic stenosis can be a critical risk factor for sudden cardiac death, especially under general anesthesia.)
7. Listen to the chest and note any disturbance in breathing (e.g., wheezing or rales).
8. Have the patient lie back into the supine position with knees flexed to relax the abdominal muscles. Listen for any abdominal bruits in the midline, halfway between the xyphoid process of the lower sternum and the umbilicus.
9. With the abdomen relaxed, the tele-presenter places her/his relaxed palm of the hand in the midline, just above the umbilicus. Note any pulsatile mass suggesting an abdominal aortic aneurysm. In male smokers over 65, order a screening abdominal aortic ultrasound to check for aneurysm.
10. Examine the lower extremities for swelling, ulcers, or any foot sores. Measure the calf and thigh circumference of any patient with leg swelling. Photograph any wounds, foot sores, or other discoloration and insert in the electronic medical record.
11. Palpate for dorsalis pedis and posterior tibial pulses and note present or absent. Use continuous-wave Doppler to record arterial signals IF pulses are NOT present and consider further vascular lab testing.
12. Have the patient sit comfortably to discuss exam findings with the healthcare provider at the remote reception site.

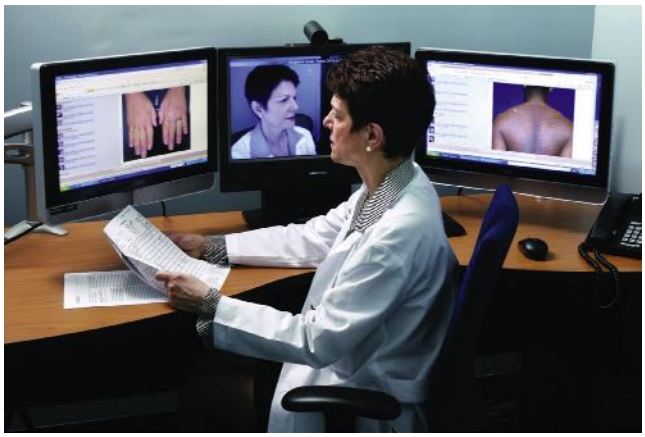

Figure 204.2 Healthcare provider doing a telemedicine consult using multiple screens to examine the patient, interact with the patient, and update the electronic medical record. (Courtesy of University of Miami Miller School of Medicine.)

keeping the electronic medical record open for review of any tests, documentation of the encounter, and electronic orders (Fig. 204.2). This system requires a program, e.g., Jabber™, to connect securely the origination and reception sites.

The provider is also helped in orientation at initial clinics by a technical assistant who can troubleshoot problems with the provider. This assistance helps to assure a successful encounter for both the patient and provider team. Minimizing any discouraging obstacles is key to adoption by all.

Once the team is organized and trained in individual roles, a team practice session(s) is essential. These sessions identify problems that can be rectified before actual launch of the telehealth service. Team "huddles" and practice sessions may need to be repeated after initial telehealth consults or clinics to correct details that optimize the system. A standardized format for all telehealth encounters, regardless of specialty, creates a better system for all.

Step 6: Credentialing

In general, providers must not only be licensed in the state where the patient service originates but also credentialed in the medical facility of origination of the patient consult. Licensing has been loosened recently with the COVID-19 pandemic. One must ascertain whether services are billable across state lines. Specific state guidelines should be reviewed as well as medical malpractice coverage stipulations. Usually, a rural hospital will accept *by proxy* the credentialing from the home medical institution of the provider.

Step 7: Patient Appointment Scheduling

Scheduling patients for telehealth encounters can be challenging. Emergency services such as acute stroke consults requires a central coordinating center plus on-call stroke neurologists to answer the consult expeditiously. Our model for vascular telehealth has been focused initially on a defined clinic at a remote location where nearly all patients are established or new consults for chronic issues. However, more pressing problems, e.g., progressive critical limb ischemia can be triaged by telehealth visits.

The specific system of arranging a telehealth consult may depend on whether the provider practice uses centralized or individual physician-office scheduling. Regardless of how scheduling is done, the schedulers must be trained and scripted to explain the nature of the telehealth encounter, answer general questions, and be encouraging that this method of care will satisfy the patient's and family expectations. Attention to detail in creating an optimal scheduling system for telehealth cannot be overemphasized.

Step 8: Coding and Billing

Reluctance to adopt telehealth patient visits had been based partly on concerns that the effort would not be reimbursed.

For most insurers, reimbursement is available. The rates are in parity with direct visits provided that the visit meets the requirements specified by state and insurer guidelines. The essential requirements generally focus on: (1) direct interactive video connection and (2) documentation of the type of visit (formal telehealth station at a clinic, stand-alone systems (e.g., doxy.me) or a simple smartphone FaceTime). With the COVID pandemic, the previous distance requirement for a telehealth reimbursable visit has become less important. For example, the note may begin with: "This telemedicine consult was requested by the referring healthcare provider and completed using real-time videoconferencing with the patient. The exam was performed via real-time video conferencing with the use of examination peripherals and the assistance of a telehealth provider."

In coding the note, the same criteria for a direct patient encounter are used. For Medicare and Medicaid patients, a GT modifier is added (Interactive Telecommunication, GT). For private payors, a different modifier (e.g., 95) will be necessary. Institutions launching a telehealth patient–consult system should contact all insurers to verify documentation requirements for payment. Several state and national legislative proposals are underway to assure reimbursement for all telehealth care provided by licensed providers, whether the patient is near or far and regardless of the patient location, e.g., ER, hospital, home or chronic care facility.

Step 9: Launch Day

Like any new venture, the first day is a big deal for everyone. We recommend scheduling only 6–8 patients for the first clinic or two. This allows everyone time to comfortably adapt to the format. Subsequently, scheduling 12–14 consults at 30-minute intervals works well in our experience. Telehealth remote vascular clinics are NOT ideal for the usual larger clinic where multiple rooms are underway concomitantly, often with nurses, medical assistants, advanced practice providers or residents assisting in seeing 25–50 patients or more.

The addition of vascular lab tests to the visit can also be challenging. We offer patients the opportunity to have tests BEFORE the clinic day. If vascular testing is performed on the clinic visit day, the patient should have the testing arranged at least one hour prior to the telehealth encounter to assure that the visit is on time and the provider has reviewed the study and interpretation.

Step 10: Patient and Staff Quality Improvement Input

After each telehealth clinic, the clinical team should give input on what went well and what could be improved. This feedback should be recorded in detail within 24 hours so that suggestions are fresh and accurate. In addition, a brief survey for patient satisfaction should be considered. Combining feedback from the patient, family and providers is essential to process change and quality improvement. Our results show a high level of patient satisfaction with a telehealth format.

PATIENT SATISFACTION WITH TELEMEDICINE

With telehealth being relatively new to most vascular surgery practices, patient satisfaction surveys are limited. However, one survey consultant, Press Gainey, has provided data from patients during the COVID-19 pandemic in 2020.[9] Several generalizations are appearing: (1) vascular surgery telehealth encounters have results similar to other specialties; (2) none of the telehealth scores are as low as patient perception of the traditional waiting room experience for in-person visits; and (3) the overall likelihood to recommend is lower than in-person clinic visits.

More specifically, 84%–90% of patients highly rated the convenience of a telehealth visit, i.e., not having to travel and generally connecting at a convenient time. Eighty three percent rated team coordination and communication of a telehealth visit as 5/5 positive for a telehealth visit compared to 57%–63% for a waiting-room experience. Overall likelihood to recommend was 71% for telehealth compared to 89% for in-person visits.

Three areas for improvement were identified as potential ways to improve the telehealth experience: (1) better connection stability (increased broadband in rural areas); (2) better digital literacy of both patients, their families, and healthcare providers; and (3) more efficient and reliable workflow systems. However, all the data support that telehealth provides a strong relationship between the patient and the provider.

BARRIERS AND CHALLENGES TO ESTABLISHING TELEHEALTH PROGRAMS

The two primary barriers to telehealth were once (1) technology to conveniently schedule and conduct a telehealth visit and more importantly (2) lack of reimbursement. Both barriers have been lessened in recent years, especially when the COVID-19 pandemic made in-person visits problematic.

Many options exist currently to connect the patient with the provider. These options are evolving rapidly and will have changed by the time this chapter is in print. Nonetheless, an excellent source of the *many* telemedicine options is published periodically by the Massachusetts Medical Society (http://www.massmed.org/Patient-Care/COVID-19/Telehealth-Vendor-Options/). This noncommercial review examines the functionality and pricing of both electronic health record options integrated into a variety of EHRs. It also reviews stand-alone telehealth choices. With so many different needs by the diversity of vascular centers and private practice, one should review the option(s) that provide the functionality and pricing that fits best.

The challenges still persist around (1) making the connective technology not only easier to use but widely available, especially in rural and indigent urban areas, (2) sustained enthusiasm

by providers to use telehealth, and (3) reimbursement that is not geographically or location based.

Experts also foresee telehealth providing better continuous or synchronized care. With better home monitors for vital signs, blood chemistries, electrocardiography, and hopefully peripheral perfusion monitoring, providers could be alerted when a problem exists, to allow them to contact the patient immediately for urgent care. A textbook by Shawn Valenta, a nationally recognized telemedicine innovator, will appear by 2022 on *Telehealth Service Implementation Models* (Springer Publishers) and will guide healthcare providers in various options for the best telehealth systems for their practices and for continuity of care of their patients.

CONCLUSIONS

Launching a telehealth remote vascular clinic or consultation service is a relatively complex and time-intensive process. However, the recent COVID-19 pandemic has accelerated the urgency for telehealth in all specialties. Reimbursement has been broadened to many forms of telecommunication and for nearly any location. From the simple use of a smartphone for a FaceTime call to a stand-alone option (e.g., doxy.me) to sophisticated telehealth carts in special clinics, vascular surgeons have significantly increased their use of telehealth for initial evaluation and long-term care.

This chapter also presents a 10-step process to successfully start a sustainable vascular clinic model with high patient satisfaction. These principles should be applicable in most healthcare systems. This ten-step system has been confirmed by recent strong patient satisfaction scores.

Finally, several observations appear applicable to any vascular surgery practice and especially vascular centers. An organizational investment in supportive staff, equipment, and physician leadership facilitates a successful program. The steps are not sequential but concomitant in development. A physician champion is critical in pulling all of these concomitant activities together in the final format before launching the clinic. In addition, organizing and training the telehealth team must be a priority before offering the telehealth service. The clinical equipment, credentialing, scheduling process, coding and billing, and reimbursement issues have generally been solved. The key ingredient to the program's successful launch and sustainability remains physician leadership and perseverance. Telehealth technologies will become an increasingly important part of the access and continuity of vascular care.

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A complete reference list can be found online at www.expertconsult.com.

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205 CHAPTER

Internet-Based Surveillance of Vascular Disease and Reconstructions

CHARLIE CHENG, YUSUF CHAUHAN, TRAVIS VOWELS, and JEAN BISMUTH

INTRODUCTION

Technology has transformed the delivery of healthcare, both in-person and remotely, over the past 30 years. The World Health Organization (WHO) defines telemedicine (TM) or telehealth (TH) as "The delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities."[1] This very broad definition of TH includes the use of secure messaging, mobile applications, and telephone and videoconferencing to evaluate new patients preoperatively, follow existing patients after surgery, proctor surgical cases, monitor for changes in electroencephalogram or transcranial doppler during carotid endarterectomy, observe patients for seizure activity, or attend local, regional, and national meetings for continuing medical education, remotely from the comfort of the healthcare provider's office.[2] We recognize that historically some have used the term "TM" to refer specifically to the diagnosis and treatment of patients by physicians and the broader term "TH" to include all components, activities, and services provided by all healthcare providers including techs, nurses, advanced practice providers (APPs), pharmacists, and physicians using telecommunications technology.[1]

Nowhere does TH have the potential to transform and impact clinical practice as it does in tertiary and quaternary referral centers where patients come from hundreds or even thousands of miles away for treatment by a subject matter expert or subspecialist. TH can extend the availability of these experts to patients in rural communities or those with mobility restrictions or small children.[2] These may be particularly important and valuable in the postoperative setting. In vascular surgery we treat many elderly patients who are at particular risk and may benefit from the opportunity to be followed remotely. TM refers not just to the office consultations we have become so accustomed to during the COVID-19 era, but also to the possibilities that technological evolution has afforded for the assessment of the postoperative cardiovascular patient.

The COVID-19 pandemic has created a monumental surge in the need for our ability to monitor our patients' recovery from surgery, especially in our high-risk groups with multiple medical comorbidities. The use of TH in vascular surgery specifically is as accurate and effective as on-site evaluations for a variety of vascular problems, including abdominal aortic aneurysms, cerebrovascular disease, and lower extremity

occlusive disease.[3,4] This chapter examines the use of TH in the diagnosis, treatment, and surveillance of the vascular surgery patient.

HISTORY OF VIRTUAL MEDICINE

For the first half of the 20th century, telephone was the only platform available for use by clinicians to share health information over long distances.[5] The first radiological images were reportedly sent via the telephone line in the 1940s and shortly thereafter, the National Aeronautics and Space Administration (NASA) was credited with pioneering efforts to develop and pave the way for modern-day telecommunications. Initially concerned about the effects of zero gravity on astronauts, NASA scientists developed ways of monitoring vital signs of astronauts in space as well as diagnosing and treating medical emergencies from the earth as they arose in space.[5]

With the explosion of the internet and world wide web in the 1990s came the ability of healthcare professionals to exchange medical images and information with the click of a mouse. As early as 1993, transcontinental surgical consultations were made possible via the internet.[6] That same year, the American Telemedicine Association was founded with the purpose of accelerating the adoption of TH and ensuring access to safe, effective, and appropriate healthcare by all individuals. Today, with the advancement of mobile and electronic technologies, telemedicine has been made more accessible. Most families have at least one digital device, such as smartphone and webcam, that can provide communication between patient and healthcare provider.[7] In a report by the Pew Research in 2019, 90% of Americans use the internet.[8] In addition, 81% of Americans own a smartphone, nearly 75% own desktop or laptop computers, and roughly 50% own tablet computers or e-readers.[8] These digital devices provide easy accessibility to the internet. With impressive gains in internet speeds and capacity, synchronous telemedicine is now possible via real-time live videos. One of the limitations of telemedicine is physical examination of the patients, although even that is changing rapidly. Recently, remote patient monitoring (RPM) is made possible by the availability of digital stethoscopes, ophthalmoscopes, otoscopes and wearable biosensors for vital signs. RPM has further improved the telemedicine experiences for both patients and providers. In 2016, the Food and Drug Administration (FDA) gave a 510(k) clearance to TytoCare Inc's digital stethoscope. The company introduced an artificial intelligence (AI) powered diagnostic support solution, providing clinicians with advanced insights for informed remote diagnoses and launched an FDA-cleared fingertip (SpO_2) device that enables users to check blood oxygen saturation levels and heart rate at home. The ability to do this has also been implemented in the National Health Service (NHS) in the United Kingdom, where Arc Health has partnered with the NHS with a similar ability to perform general physical exams with an online tool. Even very accessible applications within the popular smartphones can detect arrhythmias, heart rate and blood pressure, features which can give us important indications of poor postoperative outcomes.

TELEHEALTH PRIOR TO COVID-19

The advancement of electronic technologies and internet speed has led to the rapid increase in the utilization of telemedicine. From 2010 to 2017, there was an increase in the percentage of US hospitals using telemedicine to connect patients from 35% to 76%.[9] Furthermore, the American Medical Association reported that the insurance claims for telemedicine increased by 53% from 2016 to 2017.[10]

Telemedicine is increasingly being used in surgical specialties, and showing promise as part of the solution to an impending provider shortage. The Association of American Medical Colleges projects that there will be a shortage of up to 30,500 surgeons by 2030.[11] It is crucial that surgeons and other physicians find strategies to effectively address this provider shortage and deliver high-quality, convenient care to their patients. In vascular surgery, telemedicine provides equal or superior quality of care compared with traditional in-person consultations for management of varicose veins.[12] Furthermore, these authors also demonstrated high patient satisfaction for virtual vascular clinic with point-of-care ultrasound.[13] A medical staff was present at the satellite locations to obtain the patient's vital signs. A vascular surgeon interacted with patients via real-time video conferencing, and patients' information was entered in the electronic medical record. The remote vascular surgeon evaluated the patient via videoconference interview and visual physical examination, reviewed laboratory and imaging results, discussed medical management or surgical intervention, and determined treatment plans with the patient.

COVID-19 PANDEMIC AND TELEHEALTH EVOLUTION

In the US, the Stafford Act, enacted in the middle of March 2020, helped to expedite the adoption of telemedicine. It permitted Medicare & Medicaid Services (CMS) to extend access and reimbursement for telemedicine services. Other US insurers also rapidly expanded medical coverage to include telemedicine and some states waived their licensure requirements for care provided beyond state boundaries.[14] Soon, the American Medical Association (AMA) developed a new resource for physicians to get advice via telemedicine, providing best practices for medical practitioners in adopting a broad range of virtual technologies including telemonitoring, telecare, and telemedicine. These steps helped to transition vascular surgery to internet-based medicine for new outpatient consultations, routine patient surveillances, and postoperative follow-up visits.

The Australian government funded telemedicine services, known as the "Better Access Initiative" program, prior to the COVID-19 pandemic to address the health needs of remote and rural patients during emergency situations such as bushfires and long-term drought.[15] In response to COVID-19, the Australian Government provided extra funded services that allowed for a greater range of telemedicine services to be delivered.[16] Similarly, the United Kingdom's NHS introduced the adoption of video consultations by health centers to lessen the

number of people who visit hospitals and decrease the potential for transmission.[16]

Telehealth technologies have also expanded into other clinical areas. Mobile integrated healthcare programs and community paramedicine have decreased the need for transportation to the emergency department by having physicians provide digital support to patients who call via emergency channels, such as through 911 calls. Mobile health (mHealth) applications using mobile and wearable devices for remote monitoring allow patients to access medical information and physicians to provide support for non-emergency or chronic health problems. Artificial intelligence and machine learning decision-making applications are being used to improve the accuracy of COVID-19 detection and diagnosis. Robotic technologies are being used in China to serve patients in isolation facility or quarantine centers. Health and fitness applications have exploded during this time of social isolation to provide diet plans, calorie counters, and various real-time or pre-recorded follow-along exercise videos.

Natural disasters and epidemics in the past have posed many challenges in providing healthcare. Technological advances have provided new options and innovative solutions to address both the needs of patients with COVID-19 and other people who need healthcare services. Telehealth has provided many benefits that include minimizing the hazard of direct person-to-person exposure, access to healthcare from remote areas, guidance of expert physicians to less experienced medical practitioners, more efficient healthcare during times of workforce reduction and limited resources, disease containment via patient tracking and quarantine, and improved epidemiological research. The COVID-19 pandemic has transformed the care of patients and healthcare delivery around the world in 2020.

FEATURES SPECIFIC TO POSTOPERATIVE CARE IN VASCULAR SURGERY

TH appears to have created an unprecedented increase in accessibility of healthcare. Many of the advantages of TH visits over traditional clinic visits can be traced back to increased accessibility and convenience of visits with primary and specialty care.

Distance, Time, and Cost

TH has been observed to create avenues of convenience with regards to both distance traveled and time consumed from the patient's day. One study based out of the Michigan metropolitan area demonstrated that their patients had an average round-trip of 31.2 miles/39 minutes.[17] The comparison grows stark when including difficult to quantify variables such as rush hour traffic, parking availability, and check-in times. Between travel time to healthcare facilities, waiting room time, and time actually obtaining medical care, Americans spend an average of 123 minutes per visit, with an average face-to-face time with a physician of 20.5 min.[18] TM appointments may virtually eliminate travel and waiting times, dramatically increasing the proportion of patients' face-to-face time with their physicians.[19] In a study of general surgery postoperative patients, a time reduction of 85% was demonstrated when including travel times in the duration of the clinic encounter.[20]

From the patient's standpoint, the primary aim of telemedicine is to increase access to care and enhance the convenience of healthcare services. Telemedicine may provide specialty care to populations where it may otherwise not be available, such as those living in rural areas, deployed on military assignments, or in prisons. In addition, patients who have previously had difficulty making it to their appointments, such as those who are disabled, elderly, or lacking transportation, can now receive healthcare.[19]

Distance and time savings can be further extrapolated to extraneous costs, which are not typically calculated towards the cost of healthcare or included in a patient's deductible. Fuel costs for travel can compose a significant expense. Parking at more urban hospitals and clinics can often be pricy and difficult to navigate. For patients without independent transportation, public or private transportation may incur significant costs in addition to the costs of their clinic visit. Unpaid sick leave, childcare, and the need for additional family members to accompany patients to clinic represent additional intangible costs of traditional visits over which TH provides a benefit.

Triage and Follow-Up

TH has been explored extensively for its use in postoperative surgical care across a wide variety of surgical specialties including general, plastic, orthopedic, trauma, burn, transplant, and vascular surgery. Studies reporting clinical outcomes demonstrated equivalence or only slightly increased complications in TH patients.[21] Easy accessibility to a surgeon through TH may reduce emergency room visits and re-admissions. Patients who are not sure of the severity of their symptoms may find it easier to coordinate a virtual visit prior to being directed to an in-clinic visit, the emergency room, or a direct admission. In evaluating vascular surgery patients with surgical site infections following arterial revascularization with groin incisions, patients assigned to the TH group found no significant differences in short-term readmissions. TH patients from the same vascular surgery group were however found to have increased general satisfaction with their care.[22] In our own practice, we assist patients with setting up smartphone applications for virtual visits. For patients without problems in smartphone usage or internet connections, we saw improved patient compliance and decreased missed appointments.

BARRIERS AND LIMITATIONS

Technological achievements have led to increasing adoption of TH overall; however, it is notable that adoption within vascular surgery and surgery in general initially remained slow. A number of barriers, real or perceived, may be attributed to the initial slow uptake; however, the COVID-19 pandemic has caused rapid adoption. Unfortunately, barriers remain against

full adoption of TH for all patients and it remains to be seen whether TH will ever completely supplant the traditional clinic visit. Despite the barriers, at a minimum, TH is a valuable tool to triage patients to an appropriate clinic visit.

Distance

As TH increases accessibility for patients remote from vascular surgery practices, a certain subset of patients remains isolated from this expanded availability. Roughly 60% of rural Americans are noted to have access to a broadband connection at home as opposed to 75%–80% for urban and suburban households. Similar discrepancies are present with ownership of a laptop, smartphone, or other handheld camera-enabled device permitting appropriate virtual examination. For rural residents who do own an appropriate device, rural broadband is also less likely to be up to par with regards to bandwidth and connection fidelity.[23] Poor audio-visual quality, lag time, and disconnection present significant barriers to carrying out an effective virtual visit.

Technology Anxiety

Appropriate access to TH technology does not necessarily translate to a willingness or ability among patients to utilize TH. Many vascular diseases manifest primarily in the elderly and they may have decreased trust in virtual visits with a perceived lack of empathy. Elderly patients may also lack the dexterity or the technical expertise to operate their assigned TH portal.[24] Oftentimes, due to glitches and/or confusion with the TH portal, camera-based visits have to be downgraded to basic triage phone calls with in-person clinic follow-up. In our experience, we have noted that accompanying family members are frequently necessary in order to facilitate the TH visit.

Physical Examination

Perhaps the largest barrier to TH adoption from the surgical standpoint remains the lack of ability to perform an adequate physical examination of the patient. The traditional pre-clinic routine of obtaining vital signs is only possible if the patient has the necessary equipment to monitor and record on their own. Though many clues regarding the patient's condition can be gleaned from a combination of live video and still photos, post-processing, data compression, and poor lighting conditions may significantly impede qualitative observation. In addition, differences between a patient's subjective descriptions of what they are experiencing may be vastly different from their physical exam findings. The reality is we always do a physical examination, even via video. We simply use our power of observation better. The information to be gained by looking through the camera at someone is significant, and really no different than what we do in the initial twenty seconds of an office visit. We assess general appearance, skin tone, rate of breathing, gait, discomfort and so forth. A video assessment is no different in that we can identify whether they're sitting up or lying in bed, pale, presence of tachypnea, shortness of breath along with all the aforementioned features. Some patients with disabling conditions or range-of-motion limitations postoperatively may lack the dexterity or comfort with providing complete visual inspection of their symptoms, but then again that gives some indication of overall condition and recovery.

With TH, the classical teaching of "inspection, palpation, percussion, and auscultation" becomes limited to only inspection and subjective evaluation. A number of symptoms related to vascular disease require physical exams with provoked or palpated observations. Descriptive physical exam signs such as "tenderness to palpation," "fluctuance," "bruit," or provoked tests such as the "Allen's test" are impossible to elicit virtually and may lead to inadvertent missed diagnoses. Yet technology today is rapidly allowing us to perform some of these specific tasks remotely. For example, although proper trials have not been performed, the ability to remotely obtain foot temperature via infrared sensors can give us an indirect appreciation of whether a vascular reconstruction has failed or not.[25] Having a baseline at the time of a femoral tibial bypass or a superficial femoral artery stent has the potential for us to detect a deviation from that on follow-up with such technology. So although we can in no way ask a patient to perform a remote ultrasound of that bypass, indirect measures of patency exist.

Screening and Surveillance Studies

The Society for Vascular Surgery (SVS) guidelines on follow-up after surgical intervention are thorough, but unfortunately without a strong level of evidence.[26] One thing that is absolutely unambiguous to those treating patients with vascular disease, is that to achieve good outcomes, follow-up is necessary. Although a good clinical exam including palpation of pulses is elemental, there is no doubt that imaging plays a central role in our surveillance of vascular disease, monitoring endovascular and open surgical reconstruction patency and ultimately determinants of failure. In the era of COVID-19 much focus has been placed on being able to perform clinical follow-up remotely, but is that an achievable reality in our specialty? Certainly, other specialties have excelled in that respect, for example cardiology with a number of implantable devices to modern cardiac function. During a 6-year study period, Brooke et al. found that a remarkably low number of patients had the recommended imaging follow-up.[27] This of course is outside of the COVID-19 period, so we could speculate about the rationalization behind this, but this likely does not come as a surprise to most clinicians. As an example, it was found that only 50%–58% of patients returned for follow-up after an aortic aneurysm repair.[27]

We suspect that much of this is multifactorial in nature with reasons such as geographic limitations, cost of studies, inadequate education of patients, etc. The reality is, unless we have almost 100% compliance in post-procedural surveillance imaging, we have no true estimate for how much surveillance is needed to maintain satisfactory outcomes.

There are currently online applications to monitor vascular events with patients logging in and providing information. Programs such as these can be run independent of a physician

by a nurse and should be able to alert the team to a vascular event. Yet, in the case of a surgical/endovascular reconstruction, a vascular event can be catastrophic as this may indicate failure. Unfortunately, this process is entirely dependent on patient motivation and so technology penetration will certainly be marred by lack of patient input. Telemonitoring "kits" have been used in a number of specialties postoperatively. Gräfitsch et al. used such a kit to monitor postsurgical recovery after abdominal wall surgery. Adherence to the protocol was largely maintained, but due to the nature of these procedures only short-term follow-up is typically necessary.[28] As is well-known, patients with vascular disease are for the most part long-term patients with a quite rigorous imaging surveillance requirement. Most remote applications to monitor the postsurgical patient are primarily focused on preventing postoperative complications, death and unplanned hospital readmissions. Nevertheless, a high degree of acceptance was achieved by McGillion et al. in an off-the-shelf wearable device able to register a number of vitals including blood pressure, heart rate, blood sugar, weight, and activity.[29] The inability to adequately monitor postsurgical patients with current available systems is by all accounts a major consideration impacting postoperative morbidity and mortality. A study from 2014 demonstrated that for four vascular procedures, lower extremity bypass, endovascular aortic aneurysm repair, open aortic aneurysm repair and carotid endarterectomy, the overall (planned and unplanned) readmission rates were 16.4%, 8.2%, 8.1%, and 8.0%, respectively.[30] The implementation of some form of remote monitoring has significant implications from the standpoint of data infrastructure and security, processing, analysis, and interpretation as well as ethical and legal. Innovative tools, such as that by Neville et al., may be the wave of the future.[31] The notion of a "smart" graft (Fig. 205.1), or potentially even a "smart" stent that could alert vascular surgeons to a potential failure, would be a leap forward in our ability to monitor our postoperative patients remotely without the need for repeated imaging. The perfect triad could then be a measurement of flow, monitoring of vitals and an interactive video platform, which could open up to opportunities to examine postoperative wounds for example. Utopia may not be so far away, but we must remember that the patient population may serve as a barrier insofar as there may be a gap in understanding the technology. Additionally, geography could interfere with cellular, Bluetooth and/or Wi-Fi reception required for these devices.

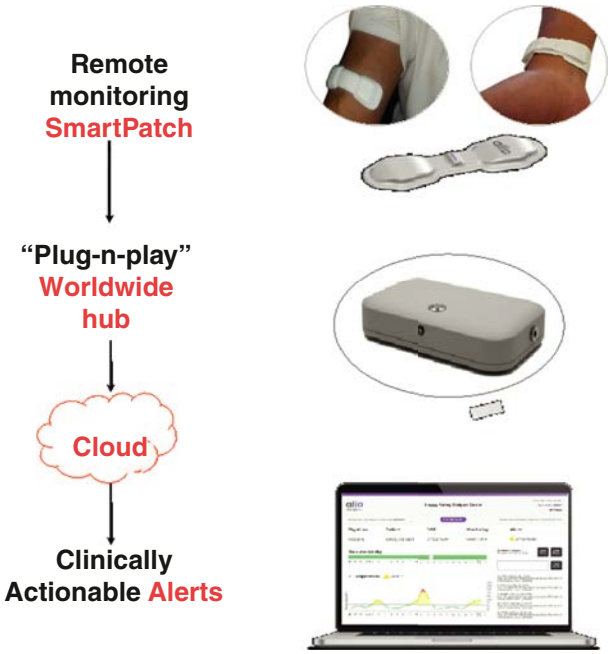

Figure 205.1 Alio SmartPatch. (Published with permission from Richard Neville, MD.)

CONCLUSION AND FUTURE DIRECTIONS

The increase in value-based care in conjunction with the increased availability and acceptance of TH has opened a number of avenues for innovation and expansion of TH services in vascular surgery. Patients and physicians who have become comfortable with TH throughout the COVID-19 pandemic may wish to assign a large portion of their healthcare interactions to virtual environments. The rapid growth in companies providing dedicated TH apps and devices will only further facilitate TH utilization.

With a longer-term outlook, TH can be expected to expand from clinic visits to interventions. Research into remote tools to evaluate the results in our patients continues to flourish and is likely to achieve substantial penetration in the near future. In our practice we have been able to reduce readmissions after surgery substantially using our nurse practitioner to follow closely with phone calls. We anticipate that being able to evaluate the patient's overall condition objectively by remote digital processes promises to further this trend of reduced readmissions and likely improved outcomes. Each healthcare system is very different and as some capital purchase is necessary from either the insurance provider or a national healthcare system, there are certainly some assumptions that may not reflect reality.

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CHAPTER 206

Social Media in Vascular Surgery

JON P. ORLINO and MATTHEW R. SMEDS

BACKGROUND

History of Social Media

Social media is defined as "forms of electronic communication through which users create online communities to share information, ideas, personal messages, and other content."[1] Early social networking websites can be traced back to the end of the 20th century with sites such as Classmates and SixDegrees, with expanding popularity in the early 2000s with Friendster and Myspace.[2] However, the social media culture as we know it today was rooted in the rising popularity of Facebook since its launch in 2004 and has grown to encompass multiple different platforms in addition to social networking such as photo and video sharing, blogging, and collaborative projects. It is estimated that more than 70% of American adults use at least one social media platform, with the 18- to 29-year-old age group being the highest utilizers, and companies, societies, and professional groups have all started to embrace this technology as ways to share information.[3] This usage has increased significantly over the last 15 years, with Facebook and YouTube having the highest number of users according to the Pew Research Center (Fig. 206.1 and Table 206.1).[4]

Social Media Use in Vascular Surgery

The specialty of vascular surgery is no stranger to the incorporation of evolving technology into daily practice and much of its success over the decades has been due to the welcoming of new technologies into the specialty. Social media has become exponentially popular over the past 20 years and medical professionals have seen success in utilizing it as a tool to improve health education, increase one's recognition and reputation, promote one's medical business, and establish professional

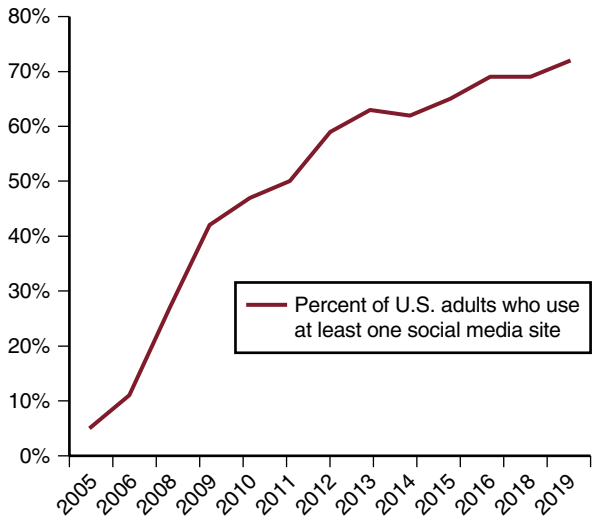

Figure 206.1 Percentage of U.S. adults who use at least one social media site per year according to the Pew Research Center.

TABLE 206.1 Social Media Platforms Most Commonly Used by U.S. Adults

Social Media Platform Used	Percentage of U.S. Adults Who Use Social Media Platforms
YouTube	73%
Facebook	69%
Instagram	37%
Pinterest	28%
LinkedIn	27%
Snapchat	24%
Twitter	22%
WhatsApp	20%
Reddit	11%

Percentage of U.S. adults who use social media platforms as of February 2019, according to the Pew Research Center.

connections.[5] Many individual vascular surgeons, practices, divisions, training programs and institutions have adopted the use of social media for these benefits. Even vascular surgical societies and journals have begun to establish their social media presence. The Society for Vascular Surgery has created accounts on platforms such as Facebook, Twitter, YouTube, and LinkedIn in addition to its own website,[6] as have multiple other regional and national societies. While the usage of this technology in the field of vascular surgery has not been extensively studied, failing to capitalize on this communication tool may prove to be a missed opportunity. However, with the advent of the incorporation of social media platforms into the practice of vascular surgery, a new set of risks, ethical challenges, and potential downfalls have surfaced. This chapter outlines the main platforms of social media available today, provides potential usages for each site, and discusses risks and concerns with social media use in vascular surgery practice.

SELECT AVAILABLE SOCIAL MEDIA PLATFORMS AND DIFFERENCES IN THEIR USAGE

Facebook

Facebook is a social networking site that focuses on establishing online relationships among people. Originally aimed at networking college students, the site has grown to more than 2.5 billion users worldwide and is open to anyone at least 13 years of age.[7] It is one of the most commonly used social media outlets, and networking within the site can occur in one of several ways after creation of an online profile. Individuals can search for people they know or wish to network with and request to be their "friend." They can then post text updates, pictures, videos, links, or other multimedia that their Facebook friends (or other people depending on the post's privacy setting) are able to view, react to or comment on. Facebook users are also able to connect with other users through direct text or video messaging. In addition, individuals can formulate or join restricted or private common-interest groups in which members can post and share updates. Depending on the group's settings, membership to the group may be restricted to those who are either invited in by existing members or request to join. The group's administrator must then grant access in order for an individual to join the group. Members of private Facebook groups are then able to view, react to and comment on existing group posts or add their own posts. The personal profiles of members of a private group may be restricted in such a way that other group members cannot view their full profiles unless granted access. This platform is particularly appealing for the creation of patient support groups in which disease-specific groups can offer each other information, support, and different treatment opportunities such as clinical trials.[8] From an institutional or business perspective, Facebook can provide targeted advertising based off user demographics, making it appealing as a branding or marketing tool.[9]

Twitter

Twitter is a social media site launched in 2006 on which users can post short messages known as tweets. Other users can then read these tweets, like or comment on them, or share them (known as retweeting). Considered a microblogging service, tweets are limited to 280 characters as of 2017, prior to which the limit had been 140 characters.[10] Users can choose to follow other users, of which there are over 300 million,[11] but can see postings by any user by searching for the user or by searching for posts by searchable keywords called "hashtags" (which are preceded by the # sign). Anyone can comment on any post, making the platform useful for information dissemination, but also a prime domain for cyber-bullies or "bots," accounts that can post content without human input.[12] Both the number of vascular surgery tweets and the number of users tweeting about vascular surgery topics have dramatically increased since 2015, with students, vascular surgery trainees, vascular surgeons,

other physicians, patients, vascular surgery societies, academic institutions, and journals all occupying this space.[13]

YouTube

YouTube is an online video-sharing website created in 2005 and currently owned by Google.[14] Users can create their own channels where they are able to upload videos which can be searchable and viewed by the online general public. Viewers, in addition, are able to subscribe to a channel as well as like or comment on a video. They also have the ability to share the link to a YouTube video on other social media websites. Popularity is usually gauged by the number of views for a video or the number of subscribers for a channel. Videos on this platform are searchable by keywords and are a powerful way to deliver education to patients, vascular surgery trainees, or other members of the public regarding providers, disease processes, or resources as provided by an institution or provider. However, this platform is also a potential propagator of misinformation. Multiple studies have demonstrated the presence of substandard information on various different topics, which may lead to patient confusion, misunderstanding, or false expectations.[15,16]

Instagram

Created in 2010, Instagram is a social networking application primarily geared towards the sharing of photos and short videos.[17] This social media application was purchased by Facebook in 2012 for $1 billion. Known for its feature to apply photographic filters to images, Instagram allows its users to like or comment on posts and follow other users, including public figures and celebrities. This application also includes the capability of direct messaging between users and uses searchable keywords identified by hashtags (#). With currently over 1 billion Instagram accounts,[18] users have the potential to gain followers to expand their visibility and influence, and may be a tool that could be used by healthcare providers in education, branding, and marketing, particularly for medical specialties that are "visually-rich" such as plastic surgery and dermatology.[19] The ability to post pictures makes it appealing for education in vascular surgery where surgical techniques or radiographic findings may be displayed. Posts on this platform may be linked to an individual's other social media accounts such as Facebook.

WhatsApp

WhatsApp Messenger was founded in 2009 and was initially intended to allow users to update their status, and was designed to have the unique ability to enable push notifications to other users regarding status changes. What was intended as a status update application developed into a cross-platform instant messaging service. The application utilizes web-based instant messaging capabilities, which enable users to communicate with each other around the world instantly. This is different from typical cellular based short-messaging system (SMS) texting, which relies on a cellular network. Users may send text messages or voice messages, and share images, documents and other media with individuals or groups. WhatsApp also allows voice and video calls free of charge. Facebook purchased WhatsApp in 2014 for $19 billion.

LinkedIn/Doximity/ResearchGate

These social networking platforms were developed with the aim of creating professional connections between individuals. LinkedIn is a networking application with an employment-centered focus, connecting employers with job seekers. Employers may post job offerings and potential employees have the opportunity to upload their resume or curriculum vitae. Users can also post professional accomplishments or changes in their work responsibilities, and this site is often used as a way to meet people within similar fields. Doximity is an online networking platform specifically intended to connect members of the medical community. Similarly, ResearchGate is a site meant to connect researchers in order to share research ideas and develop collaborative opportunities. Users can search for research topics being studied by other users, and then reach out to these users for collaboration or copies of research that has been posted.

Wikipedia/Medical Blogging

Wikipedia was created to develop a free online encyclopedia in which articles are created and revised by editors in an open collaborative fashion. The site has grown to become one of the largest and most popular online reference sites with over 53 million articles, and is used frequently by patients, students, and healthcare professionals to find information in an easy to access manner.[20] Blogs are a form of online journals where sites, such as Blogger, LiveJournal, and Tumblr, allow users to post entries and opinions about topics of the author's choosing. Blogs are typically updated regularly and written in an informal or conversational style.

USES OF SOCIAL MEDIA FOR THE VASCULAR SURGEON

Surgical Education

The paradigm of surgical education has been evolving as an increasing proportion of individuals from the millennial generation enter surgical training and ultimately surgical practice. Defined as being born between 1981 and 1996,[21] millennials grew up in the digital age and therefore not only embrace, but expect technology to be a part of their daily lives. A new learning theory of Connectivism has emerged to explain learning in the digital age, with knowledge acquisition occurring through networking, information sharing, and pattern recognition.[22] Digital platforms, including online versions of textbooks and journals, have become a preferred learning modality for many individuals of the millennial generation, who expect quick and easy access to information via cellular phones and online applications. Surgical

educators need to therefore adapt to these changes in learning methods and acknowledge technology as a mainstay in education. The various social media platforms, as a component of this technology, have an untapped potential as learning adjuncts, which have only begun to be explored. It still remains to be seen how to optimally utilize and study the effects of social media on education and how each individual social media platform can be used as an effective educational tool. A recent study deploying a gamified and structured daily question of the day posted via Twitter to participating surgical residents at a single institution, was shown to increase ABSITE scores.[23] This was postulated to be not as much a result of the questions themselves but that the daily posts encouraged and provided a framework for learners to engage in further discussions and self-learning on the topics. Similarly, postings on social media by prominent surgeons of interesting or challenging cases often garner significant discussion in the comments by followers which may contribute to education of participants. In addition to Twitter, podcasts, blogs, YouTube, and wikis have been studied in graduate medical education as tools to engage learners and enhance education, but most with only moderate improvement in results.[24]

In particular, surgical videos have become an integral part of surgical education as they allow learners to visually experience the steps of a procedure prior to performing a live operation and may provide an additional level of depth not seen with text or even a series of static images. In a survey of general surgery faculty, residents, and graduating medical students entering surgical training programs, the overwhelming majority (90%) reported using videos for surgical preparation.[25] Specifically, YouTube was reported as the most commonly used source, and among trainees, the preferred source of surgical videos, likely due to the platform's accessibility and ease of searchability for video content. However, vascular surgery as a specialty has yet to develop a major presence on YouTube even for frequently performed vascular surgical procedures. For example, among YouTube videos for carotid endarterectomy, more videos were associated with cardiac surgery and neurosurgery than with vascular surgery.[26] Similarly, there are fewer videos by vascular surgeons on percutaneous common femoral artery access compared to interventional cardiologists or interventional radiologists.[27] As with all social media, issues exist regarding the quality of the educational product being produced on sites such as YouTube. Just as there is no-one directing participants to appropriate content, there is no-one policing this content to ensure it is accurate. Consequently, there exists a need to ensure and provide high-quality and technically appropriate YouTube videos for vascular and other surgical trainees who rely on this platform as a considerable adjunct to their education.

Patient Education

Patients, too, have turned to the internet and social media as a primary source of information on medical conditions and their consequent treatment options, to gain advice from other patients suffering with the same disease, and to receive social support.[28] These social networks allow patients the opportunity to network and connect with others in similar situations, follow or comment on mutual accounts and postings, and interact and connect via online social media groups. Studies have shown that Facebook support groups can have a positive impact on a patient's overall care and feeling of satisfaction.[29] Other forms of social media have been demonstrated to decrease patients' anxiety and increase their knowledge of treatment options available.[30] In addition to sharing healthcare information with public forums for advice or social support, social media can also be used to exchange medical information with healthcare providers. A recent study demonstrated usage of social media for health communication has increased significantly over the past 10 years, with those in the younger age groups more likely to use this method of communication.[31]

However, as increasing numbers of patients turn to the internet and social media for guidance, the vast wealth of information available can be overwhelming and confusing. Unfortunately, unlike for most medical professionals, members of the general public are usually poorly equipped to discern between a source that is accurate and reliable versus one that is of poor quality. As the realm of social media is one that is largely not peer reviewed, this can commonly lead to patients being misinformed or developing unrealistic expectations for their medical conditions. Multiple studies have sought to examine the quality of information available on certain social media platforms for specific disease states, such as prostate cancer, gallbladder disease, or kidney stones.[32] Although there have been some mixed results, many of these found social media to be poor sources of information for patients. One particular study analyzing the quality of information available on YouTube on varicose vein treatments found that a quarter of associated YouTube videos were deemed of poor informational and scientific quality.[32] Moreover, a large majority of videos strongly advocated for a particular treatment with only a small minority (6.6%) remaining neutral. Albeit the production of many of these videos is primarily geared towards advertising, patients look to them seeking unbiased information. As it is unrealistic to expect patients to avoid using social media as a source of information, efforts to direct vascular patients to reputable social media resources should be a key goal for vascular surgeons and vascular surgery as a specialty. This goal can be achieved in two components. First, vascular surgical societies need to facilitate increased production of high-quality and unbiased resources on common vascular diseases for patients and publish or provide links to them on the various social media platforms.[32] Second, individual surgeons should promote these resources to their patients so as to direct them appropriately. Frequently, patients may be afraid to actively request for additional information from their physician and rather, turn to the convenience of the World Wide Web for this. Following these steps would maximize the exposure of patients to appropriate social media sources.

Self-Promotion, Marketing, and Practice Building

Given the potential to connect with an infinite number of individuals, social media has clearly emerged as a new avenue for

marketing and self-promotion for both individual practitioners as well as for practices and institutions. Among surgical specialties, plastic surgery has become a pioneer in social media marketing likely due to its focus on cosmesis and natural means to share before and after photos. While there exists minimal data studying the success of vascular surgery in this realm, several key principles can be extrapolated from that of the plastic surgery experience to capitalize on social media marketing in order to maximize self-promotion and career development. There has been some data to suggest that the return on investment from utilization of social media platforms, specifically Facebook and Instagram, rivals that of traditional advertising methods such as billboards, radio, and television, especially with early branding of start-up practices.[33] Social media was also found to be superior to other methods of internet marketing such as online review sites, Google, or a practice's main website. Although the monetary value that a social media campaign can bring to a practice is difficult to quantify, usage of social media to develop one's brand can be beneficial. Social media may be particularly good at marketing treatment of unusual/uncommon conditions, as online groups for these diagnoses often form to disseminate information and provide support. An analysis of referral patterns for chronic compartment syndrome and popliteal entrapment syndrome at an institution noted that over the past 20 years there has been a decrease in physician referral of these patients with an increase of non-physician-associated referrals due to social media and internet searches, suggesting these platforms may be a good source of potential patients.[34]

Cultivating a successful online social media brand for an individual surgeon or practice necessitates several components. The social media account and its consequential activity need to reflect the identity and values of a practice or institution.[35] This may include sharing details of the individual practitioners, describing services offered, and creating posts that reflect the culture of the practice and how a patient may be treated at the practice.[36] A surgeon should think about the type of social media activity they will likely and most frequently be engaging in, such as text-based posts, images, videos, and/or networking in order to select the most appropriate social media platforms to join.[35,37] They should also consider the audience that they plan on reaching, whether it is a particular subset of a patient population or other medical professionals, and consider which social media outlets that audience is most likely utilizing.[36] Even seemingly smaller details in account creation such as the account handle or username should not be overlooked as these can affect searchability, recognizability, and ease of remembrance.

Collaboration for Patient Care and Research

Many social media applications provide a forum for vascular surgeons to network with each other and other health professionals. This allows them the almost effortless capability to share information and collaborate on several different fronts. This may occur on more broad-based platforms, such as Facebook, Twitter, and Instagram, or more focused ones, such as ResearchGate. It is quite easy to post a complex, difficult, or interesting case that may have a few reasonable management options and poll one's peers for the most popular one. Research ideas may also be proposed in efforts to find collaborators at other institutions. Social media use, especially Twitter, has become popular at academic conferences, allowing participants to reflect on and develop online conversations about presented information.[35] Social media may also be utilized in campaigns to increase awareness and recruitment into clinical trials as well as to direct patients to sites such as clinicaltrials.gov.[6] Ultimately, having a social media presence often gets one's name out to the community, solidifying a reputation, and encouraging engagement, which may result in subsequent collaboration.

Recruitment

Usage of social media as a tool for outreach and recruitment to vascular surgical training programs or for new team members of a vascular surgery group is indispensable and necessary for the success of the specialty. In an age where the applicant pool consists overwhelmingly of millennials, social media may serve as a primary source in many individuals' introduction to the specialty. This will only become more evident in coming years as the applicant pool will be joined by members of Generation Z, defined as being born between 1997 and 2012[38] and characterized by having increased dependence on social media and online access compared to previous generations. However, the social media presence of vascular surgery programs is currently insufficient and could be improved upon. While nearly all training programs and institutions have a developed website, the content found on these websites is highly variable and often outdated, as it is typically more laborious to update the content regularly. Only a small portion of US vascular surgery training programs (13%) have associated social media accounts, based on a study performed in 2018.[39] In creating their websites, vascular surgery groups should assume this to be the sole source of information for an interested applicant, and therefore need to make them as comprehensive as possible as well as easy to navigate. Social media accounts offer an additional avenue for potential applicants to stumble upon a program and can adjunctively provide applicants snapshots of various aspects of a particular program through its postings. However, it is impossible to publish every detail about a group solely on a social media account, and as such, they should always include a way to prompt viewers to the program's main website for further information.

Not only can social media be used to promote individual training programs but also to attract surgery residents and medical students to the specialty itself. Other online sources, such as videos and webinars, have been created in a nationwide campaign to increase interest in the specialty of vascular surgery and these have been shown to be beneficial to students to increase understanding of the path to becoming a vascular surgeon as well as to increase an interested student's knowledge in the steps for successfully matching into a vascular surgery training program.[40] Social media serves a role in maximizing exposure of these resources to students. Even social media accounts of individual vascular surgeons, practices, or institutions

should make it a goal to intermittently provide links or bring attention to the existence of these sources as they occur so as to increase awareness to the specialty.

Use of social media for recruitment of participants in research has also been studied. While there is minimal data to support it as the most effective way to find patients for clinical trials, there is some evidence that suggests it may be particularly useful for hard-to-reach populations or observational studies.[41] Other researchers have utilized these platforms to obtain survey participants utilizing groups of interest within social media.

RISKS, PITFALLS, AND CONCERNS WITH SOCIAL MEDIA USE

Privacy and HIPAA Violations

Surgical patients are particularly at risk for having their information disseminated over social media whether in the form of a picture, video of their procedure, or description of demographic data. In a study of a single academic center, 53% of medical students, 86% of residents, and 32% of faculty reported having ever shared some aspect of a patient's health information over social media.[42] While doing so in the right context does have its benefits, utilizing social media must maintain patient safety and confidentiality as its highest priority, as with any other aspect of the practice of medicine. The Health Insurance Portability and Accountability Act (HIPAA) is well known to many healthcare providers and regulates the use of patient information in order to maintain patient confidentiality. According to HIPAA, the disclosure of "individually identifiable health information" or "protected health information" (PHI) is restricted to certain specified uses.[43] Such protected information commonly includes identifiers such as name, birth date, social security number, or medical record number. Use of PHI outside of the permitted use requires authorization by the patient. In keeping with this regulation, de-identified information is frequently utilized in publications if needed. The same standard applies to social media posts as it does to peer-reviewed journals. It is recommended, however, to minimize the use of de-identified information to that which is necessary in the context of the social media post. Users also need to be cautious to the potential that a set of de-identified information, including pictures and video, can become individually identifiable information when presented together as a whole. Finally, regardless of a posting's appropriateness in regards to HIPAA regulations, individual institutions may have their own rules regarding social media posts that involve patients. Potential utilizers of social media should be aware of their organization's guidelines prior to making any patient-specific postings.

Misinformation and "Online Consultation"

Dissemination of misleading information through social media can have detrimental effects on patients, learners, and the public. Peer review, the gold standard of scientific information presentation, does not occur on the platforms currently being used, and those who post can obtain instant "credibility" based off the number of likes, re-postings, and engagements. Furthermore, anyone can post anything without identifying any credentials or verifying sources that they report. In a recent study, it was determined that the rate and speed of false information was 10 times greater than the rate and speed of true information on Twitter.[44] When this spread of misinformation occurs, the onus is on providers who utilize social media to provide correction. It has been shown that "social correction" of erroneous posts can be effective in not only correction of misinformation but also limiting of misperceptions.[45] These corrective posts should refute the false claims and, if possible, provide reference to appropriate sources for their response. Physicians in general need to be cognizant of the power of this technology in propagating responses and should avoid providing online consultation to patients. The comments given to an individual, while perhaps being appropriate for that individual, may be propagated, taken out of context, and further disseminated.[19]

Professionalism and Damage to Personal or Employers' Reputation

As members of the medical community, vascular surgeons, those in training and those out in practice alike, are expected to maintain a certain level of professionalism both in and out of the hospital setting. This expectation also extends to one's online presence, which should be treated no differently than one's behavior out in public. However, distinguishing between what is professional and what is unprofessional, especially with regards to posts on social media, is not so straightforward. While there are behaviors that are universally seen as unprofessional, such as the use of illicit drugs, illegal behavior, and HIPAA violations, what is considered an unprofessional social media post has become a controversial and highly debated topic.[46,47] Nonetheless, one needs to be cognizant and cautious of the potential that exists for a social media post to be perceived as unprofessional. Vascular surgeons should assume that their online activity can be easily accessed by the general public. Patients, too, are turning to internet sources to gain more information about their healthcare provider in order to gauge a level of trustworthiness for their surgeon. Even a single post that is viewed negatively can tarnish the reputation of a surgeon as well as the reputation of the institution or practice they represent. As a general rule of thumb, vascular surgeons should not post something on social media that they would not want a patient or colleague to see, regardless of the post's privacy settings. Understanding your audience and knowing who can view your posts on different social media platforms are critical in being able to deliver a message effectively.

Risk with Social Media Use for Pre-Employment Screening

Social media has the potential to become a valuable asset in the recruitment process of vascular surgery residencies and fellowships or for the hiring of potential partners or staff in a vascular practice. However, it too, can have its pitfalls. A small but

significant number of training programs have already turned to social media as a tool to gain more information about their residency applicants. Multiple studies have shown that 16%–18% of residency program directors have reported visiting the social media profile of a residency applicant and up to 60% of those report that the applicant's online activity affects their rank list position.[48–50] While it may be enticing to use social media to rule out grossly unprofessional behavior or to delve deeper into the personality of an applicant, caution needs to be taken in establishing a practice of "social media stalking" as part of the application process. The action may be well intentioned, but its use can be considered an invasion of privacy. The formal application is meant to provide a comprehensive but unbiased overview of an applicant's accomplishments and qualifications. Visiting social media profiles of applicants may reveal details of their personal lives such as religious or political affiliation, marital status, sexual orientation, etc., that can subject people making decisions on hires to certain biases that the formal application process is meant to protect.

Cyber-Bullying and Trolling

An internet troll aims to antagonize others online by deliberately posting inflammatory, irrelevant, or offensive comments or other disruptive content.[51] On social media, this can be done by real people or by fake accounts created for this purpose. Trolling can be considered a form of the broader action of cyberbullying in which aggressive acts intentionally target victims through electronic means.[52] Unfortunately, encountering an online troll is an inevitable occurrence for any social media user, vascular surgeons included. Users may discover comments on their social media posts or be tagged/mentioned in the posts of a trolling social media account intended to ignite comment wars that perpetuate without any constructive purpose. Vascular surgeons should be cautious in engaging with or giving in to these trolls. At the least, trolling may be seen as an annoyance, but in more severe cases, it can be used to disseminate false information or harm the reputation of a surgeon or a surgical practice. Therefore, quick recognition of trolling activity and consequent action must be undertaken to minimize this risk. This may include deleting the inciting comment, blocking the user on that social media platform, providing correcting information in subsequent posts, and reporting the user to the application's administration to be flagged.

Loss of Intellectual Property

The sharing of ideas and collaboration among vascular surgeons and other professionals over social media can be a helpful medium. However, this potentially may put any posted intellectual property at risk. Many social media platforms attempt to address the protection of intellectual property in their Terms of Service. Twitter states that in posting on their site "you agree that such content will not contain material subject to copyright or other proprietary rights, unless you have necessary permission or are otherwise legally entitled to post the material."[53] Facebook, in its Terms of Service, reports "you may not use our products to do or share anything … that infringes or violates someone else's rights, including their intellectual property rights."[54] These applications further outline the right to remove any content that is found to be in violation of copyright or intellectual property rights. However, this does not prevent the social media sites from utilizing or disseminating the posted content themselves, as stated in their Terms of Service. In posting on social media sites, vascular surgeons should consider any posted content as public knowledge and disseminate any information accordingly. The content may ultimately be protected by intellectual property law but the hassle of going through the legal process of enforcing it may not be worth it. Additionally, consumers of social media must realize that ideas they express in these forums are open to use by others with minimal protection, whether this be an idea for a research project, or an interesting surgical technique. Thus, vascular surgeons should recognize that any ideas they put forth are subject to use.

DO'S AND DON'TS OF SOCIAL MEDIA – TIPS FOR VASCULAR SURGEONS

Social media, if used correctly, can be a helpful tool for a practicing surgeon in regards to branding/promotion, education, and the dissemination of ideas. Some things to consider if you use social media either personally or professionally:

DO become familiar with how to use and navigate whichever social media platform or application you choose to engage in. If this is overwhelming, you may consider investing in professional assistance in developing your personal or your practice's social media presence.

DO link your *professional* social media accounts to each other. Links to all associated social media accounts should be provided on your practice's main website. Likewise, every social media account should contain links to your website as well as to your other social media accounts.

DO consider creating separate personal and professional social media accounts to minimize exposure of your personal life to the online general public. Utilize each platform's privacy settings to maintain this privacy as needed, and **DON'T** link your personal accounts with your professional accounts. Also **DON'T** assume your personal account is free of any risk and still manage your personal account accordingly.

DO follow the guidelines of your practice or institution for proper social media use. If guidelines do not exist, encourage their development. Practices and institutions should provide education and training to their employees regarding the professional and ethical use of social media.

DO acknowledge the shifting paradigm in surgical education with increased use of technology and embrace the benefits social media can have on surgical training.

DO utilize hashtags to increase post visibility in certain social media platforms, notably Twitter and Instagram. Hashtags are keywords that are included in social media posts preceded by the # symbol (e.g. #vascularsurgery), which unify posts of

specific themes and topics. Users are able to search for, view, and follow posts containing a specific hashtag. This allows posts the potential to be disseminated to more users who may be viewing other similar posts.

DO know your audience and identify your goals of social media usage. Your goals and expectations will dictate both your message and the platform you decide to use.

DO post regularly, but **DON'T** post too frequently. Maintaining one's social media presence requires consistent use in order to remain visible to followers and the online community. However, posting too frequently can be overwhelming to followers who may choose to unfollow or hide a social media account's activity because of this. It is recommended to post at least once per week but no more than once per day.

DON'T stalk the social media accounts of potential training program applicants as a means for determining rank list position.

DON'T utilize social media as a means for telemedicine. Patients may directly reach out for medical advice. Providers may clarify or explain general information but should not provide individualized medical advice to patients over social media. However, **DO** have a plan for when this occurs to encourage an in-office consultation or if they are not local, to provide resources to seek referral with their local vascular surgeon.

DON'T disseminate individually identifiable patient information on social media posts. This is against HIPAA and the law! Be judicious in the use of other patient information such as age, gender, photos, video, etc.

DON'T utilize social media as a means to deceive and mislead viewers with inaccurate information. For the medical professional, a fine line can exist between promoting one's brand or services while still providing unbiased information. This includes the altering of photos or videos to the extent of showcasing exaggerated results.

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CHAPTER 207

The Quality and Fidelity of Vascular Information on the Internet

QI YAN, JOHN A. TREFFALLS, and MARK G. DAVIES

ROLE OF THE INTERNET IN MEDICINE

The internet has become an essential medium of communication and a popular disseminator of verifiable and non-verifiable information. In recent times, it has replaced many in-person contacts within the healthcare sector. With the volume of information now freely published and available and topics easily searchable, patients are increasingly using the internet to locate providers, to seek to reduce costs, to gain personal health-related knowledge, to communicate with physicians, to link with social support, to offer and to exchange advice in support groups, and foster self-care.[1] Healthcare providers and organizations have adapted to this increasing utilization of the internet to promote their brands and services, engage with the public, educate and interact with patients and caregivers, and even recruit patients to clinical trials.[2,3] Additionally, the internet has improved communication between physicians by creating and widening professional networking, enhancing the sharing of medical knowledge, speeding the dissemination of research, and promoting the debate on healthcare policy and practice issues.[2] An example of the insertion of social media into professional activities is that the American College of Surgeons 2015 Clinical Congress had over 55 million impressions on Twitter from 15 thousand tweets generated by nearly 3 thousand users, a more than 10-fold increase compared to the 2013 Congress.[4] With the internet permeating throughout every aspect of medicine and healthcare, a better understanding of the quality and fidelity of the information that is currently available for both patients and their providers on the subjects of vascular diseases, their therapies and their outcomes is essential.

The use of direct-to-patient telehealth, where physicians are able to interact with patients via phone calls or video conferencing to treat minor illnesses, has rapidly grown in recent years, and has increased access to healthcare for many patients. In 2015, there were approximately 1.25 million virtual visits, a number that continues to grow with increasing access to the internet and with changes in insurance and medical board policies.[5] This new medium of doctor–patient interaction increases convenience for the patient, alters the physicians' conventional approach to the interactions and may represent an overall move towards more consumer-orientated, patient-centered care. However, while little is known about how these virtual visits are viewed by patients or physicians, or how they affect overall costs, anecdotal evidence suggests greater patient satisfaction, reduced costs and enhanced value especially for simple diagnoses and therapies. It is important to note that there are studies that have questioned the safety and efficacy of telehealth, finding that virtual visits result in an increased number of missed diagnoses and fewer orders for guideline-suggested diagnostic testing compared to in-person visits.[6,7] The current COVID-19 pandemic mandated changes in care will provide a rich dataset to explore all aspects of virtual care and help inform further developments in the field.

Social media has transformed modern communication, allowing millions of people around the world to rapidly interact using the internet. Social media has also changed how physicians communicated with each other. Twitter is increasingly being used by surgeons to share interesting case information, including imaging, with colleagues across the globe as a means to educate, seek outside opinion, build personal and institutional brand, and enhance reputation. Additionally, new research findings and respective commentary can now be rapidly disseminated to others via open fora, which may be moderated or unmoderated for quality and accuracy. Many claim that sharing patient imaging or case details, even if de-identified, can be traced back to specific patients and thus constitutes a violation of Health Insurance Portability and Accountability Act (HIPAA). Multimedia platforms allow physicians, trainees, and other healthcare workers to engage with each other, representing an enhancement in education and networking ability. The use of public social media platforms such as Twitter, Instagram, and LinkedIn and commercial multimedia platforms such as Zoom, Teams, Webex and GoToMeeting are now integral to the professional communities of healthcare. See Chapter 206 (Social Media in Vascular Surgery) for more detailed information on the impact of social media in the practice of vascular surgery.

INTERNET FOR PATIENT EDUCATION

According to the Pew Research Center survey in 2011, 80% of internet users have looked up information about health topics, which translates to 59% of all US adults in the current population.[8] Multiple participants in the health care space (hospitals or health organizations, professional organizations, and industries selling medical devices) have websites that target the consumer patients with the goal of education, as well as self-promotion, advertising and direct-to-consumer marketing. There is also an abundance of open-access medical news websites promoting health information that targets patients directly. The quantity of this freely available health information, much of which is not peer-reviewed, can be empowering to patients. Less than a third of patients that search for health information online do so unrelated to a clinic visit; the remainder of patients who search are split between seeking information before or after a clinic visit.[4] Patients that search and read about their condition before a clinic visit have a better understanding of their disease and are better able to participate in shared decision-making on their care.[9] For patients that search for health information after a clinic visit, web-based information is a useful supplement to the verbal communication with their physician and can reinforce key information and assist in consolidating shared decision-making.[10]

However, the lack of quality control and regulation of online health information creates an environment where patients can readily access inaccurate or unreliable information. This has the potential to lead to delays in healthcare, engender mistrust in their providers, result in noncompliance, and potentially waste resources as physicians spend more time correcting misconceptions or being forced into defensive medical practices. Additionally, while the average American citizen accessing the internet has the reading ability of 7th–8th grade level, most websites are written at a more advanced level, greatly hindering patient comprehension.[11]

The DISCERN instrument is a measurement tool designed to help health consumers and information providers assess the quality of written information about healthcare treatment options. Another available tool, the Health on the Net Foundation Code of Conduct (HONcode) for medical and health websites, addresses the reliability and credibility of information. In a recent review by Daraz et al. of 153 studies evaluating the quality of websites oriented for patients from 2008 to 2018, DISCERN and HONcodes were the two most used quality assessment tools (Table 207.1).[12] Of the 87 studies (5693 websites) that used DISCERN, website qualities ranged between *good* to *very good,* but no websites were categorized as *excellent.*[9] Of the 74 studies that used HONcode, 18% (1004) were HONcode certified.[12] Government organization websites are graded *very good* by DISCERN, while academic organizations receive a rating of *good,* and media-related sources were ranked *poor.*[12]

TABLE 207.1 A Summary of Website Quality Rating Tools

Instrument Name	Description	Principles of the Instrument
DISCERN	Questionnaire with 16 questions rated on a 5-point scale[69] Organized into 3 sections.	Is the publication reliable? How good is the quality of information on treatment choices? Overall rating of the publication?
HONcode	Code of conduct to provided quality health information[70,71] Websites evaluated and certified by the HON Foundation HONcode seal demonstrates intention to publish objective and transparent information	Authority, Complementarity, Confidentiality, Attribution, Justifiability, Transparency, Financial disclosure, Advertising
Ingledew	Validated tool that incorporates important dimensions of instruments like HONcode, DISCERN, and *JAMA* benchmark with other criteria identified as important to patients[72]	Affiliation, Accountability, Interactivity, Structure and organization, Readability, Content quality
JAMA benchmark	Four benchmarks established by the American Medical Association[73]	Authorship, Attribution, Currency, Disclosure
LIDA	Evaluates design and content of health websites with a series of questions that are scored on a 0–3 point scale for a total score of 144[74]	Accessibility, Usability, Reliability
Michigan score	University of Michigan Consumer Health Website Checklist is a questionnaire with 43 questions with a total possible point of 80[75] 0–25 is considered poor, 26–40 weak, 51–60 average, 61–70 good, and 71–80 excellent	Authority, Currency, Information, Scope/Selection, Audience, Value, Accuracy, Advertising, Navigation, Speed, Access

In an older review of broader topics on the internet, Eysenbach et al. found that the percentage of inaccuracies were higher in studies that used a higher level of evidence.[13] Studies that did not report the criterion standard or those that used personal opinions found an average of 15.4% of the websites to be inaccurate.[13] In contrast, those that used literature, textbooks, or expert consensus found inaccuracies in 35.3% of websites and those using clinical guidelines found 38.3%.[13] Most studies (55, 70%) in the review conducted by Eysenbach et al. concluded that information quality is a problem on the internet, and there are no evidence-based guidelines on the acceptable quality of web-based medical information.[13] However, studies on clinical vascular topics of interest to patients make up only a small percentage of studies in these reviews. In Daraz et al., only 3 out of 153 studies were related to vascular surgery.[12] In comparison, the most popular field of study, orthopedic surgery, had 24 studies followed by internal medicine with 17 studies.[12] In Eysenbach et al., only 2 out of 79 studies were vascular surgery related.[13] Soot et al. evaluated the accuracy and quality of patient-oriented information on the internet for three common vascular diseases, abdominal aortic aneurysm (AAA), carotid endarterectomy (CEA), and leg ischemia, using self-developed criteria as early as 1999.[14] They found that overall quality was low, with a third of websites presenting misleading or unconventional information.[14]

Since the publication of Soot et al., several more studies have been published related to AAA, carotid disease, varicose veins, venous malformation, hemodialysis access, lymphedema, and lastly vascular surgery in general (Tables 207.2 and 207.3).[12–20] These studies used various evaluation criteria

TABLE 207.2 Characteristics and Findings of Studies Evaluating Online Patient Education Resources in Vascular Surgery

Study	*N*	Topic	Findings
Soot, 1999	59	AAA (17)	IS: mean 39.8 out of 100
		CEA (19)	IS: mean 44.8 out of 100
		Leg ischemia (23)	IS: mean 24.8 out of 100
Libertiny, 2000	41	Varicose veins	Median (IQR) IS: 21.5 (7.5–48.5) out of 100
Bailey, 2012	55	AAA	Median IQR Michigan score: 36 (25–56) out of 80 FRE: 39 (29–47)
Grewal, 2012	189	CEA	LIDA total: mean 63.9% LIDA accessibility: mean 72.6% LIDA usability: mean 58.9% LIDA reliability: mean 50.2% FRE: mean 53.5% GFI: mean 12.3
		EVAR	LIDA total: mean 66.2% LIDA accessibility: mean 76.9% LIDA usability: mean 60.2% LIDA reliability: mean 52.3% FRE: mean 50.5 GFI: mean 12.1
		Varicose veins	LIDA total: mean 65.4% LIDA accessibility: mean 77.8% LIDA usability: mean 63.6% LIDA reliability: mean 43.8% FRE: mean 58.6 GFI: mean 10.7
Alsafi, 2013	36	Vascular surgery	1/36 scored above 90% LIDA accessibility: mean 84% LIDA usability: mean 53% LIDA reliability: mean 53% FRE: 1/36 scored above 60
Keogh, 2014	100	CEA (50)	Median (range) LIDA total: 82% (62%–94%) LIDA accessibility: 83% (57%–98%) LIDA usability: 75% (50%–100%) LIDA reliability: 87% (33%–100%)
		Carotid stenting (50)	Median (range) LIDA total: 83% (56%–98%) LIDA accessibility: 83% (57%–98%) LIDA usability: 83% (58%–100%) LIDA reliability: 84% (47%–100%)

Continued

TABLE 207.2 Characteristics and Findings of Studies Evaluating Online Patient Education Resources in Vascular Surgery—cont'd

Study	*N*	Topic	Findings
Tran, 2017	10	Lymphedema	SMOG: 14 Complexity score (PMOSE/iKIRSCH): 6.7 ("low" complexity, 8th–12th grade education) Suitability score: 45% (40%–69% means adequate)
Pass, 2018	20	Sclerotherapy for venous malformations	Mean (range) FRE: 44 (24.2–70.1) *JAMA* benchmark total: 2.05 out of 4 benchmarks *JAMA* authorship: 8/20 websites *JAMA* attribution: 5/20 websites *JAMA* disclosure: 17/20 websites *JAMA* currency: 11/20 websites HONcode: 0/20 websites
Cheun, 2018	63	Hemodialysis access	16% of the websites were written at a college reading level or higher Educational content: mean 2.8 out of 7.8
Yan, 2020	103	Varicose veins	Quality score: 22.5 (5.9) out of 42 Accountability 5.7 (4.5) out of 16 Interactivity 2.4 (0.9) out of 6 Structure 3.6 (0.8) out of 5 Content 11.6 (3.8) out of 15 FK grade level: 10 (2) grade SMOG: 10 (1) grade

AAA, abdominal aortic aneurysm; *CEA*, carotid endarterectomy; *EVAR*, endovascular aortic repair; *FRE*, Flesch Reading Ease; *FK grade level*, Flesch–Kincaid grade level; *GFI*, Gunning Fox Index; *IQR*, interquartile range; *IS*, information score, a composite score on content ranging from 0 to 100 developed by Soot et al.; *PMOSE/iKIRSCH*, scores material based on structure (1–4), density (1–10), and dependency (0–1), include lists, charts, and graphical display; *SMOG*, Simple Measure of Gobbledygook.

TABLE 207.3 Evaluation of Written Internet Resources for Patients with Vascular Disease

	Information	Composite Score	Accessibility	Accountability	Usability	Reliability	Readability
AAA	Fair	Average		Fair			Poor
Amputation	Average	Average		Average	Average		Fair
Carotid stenting		Excellent	Excellent		Excellent	Excellent	
CEA	Fair	Good	Good		Good	Good	Fair
DVT	Average	Average		Average	Average		Fair
Hemodialysis	Fair						16% were poor
Leg ischemia	Poor						
Lymphedema							Poor
PE	Average	Average		Average	Average		Fair
Sclerotherapy for venous malformation				Average			Poor
Thoracic outlet syndrome	Good	Average		Fair	Average		Fair
Varicose veins	Average	Average	Good	Fair	Average	Average	Fair
Vascular surgery			Excellent		Average	Average	97% below Average

Poor: 0%–20%; Fair: 20%–40%; Average: 40%–60%; Good: 60%–80%; Excellent: 80%–100%.
Readability: Poor – FRE score 0–49 or text easily understandable by college students using other readability formulas; Fair – FRE score 50–59, or text easily understandable by high school students; Average – FRE score 60–69 or text easily understandable by 8th graders; Good – FRE score 70–79 or text easily understandable by 6th and 7th graders; Excellent – FRE score 80 or above or text easily understandable by 5th graders or younger.

including the Michigan Consumer Health Website Evaluation Checklist, LIDA tool, *Journal of the American Medical Association (JAMA)* benchmarks, HONcode, a comprehensive website evaluation tool developed by Ingledew, and an information score developed by Soot et al.[15–19] Although the studies conducted by Grewal et al. and Keogh et al. both evaluated carotid endarterectomy using the LIDA tool, Grewal et al. found acceptable accessibility (73%) but poor usability (59%) and reliability (50%).[10] In contrast, Keogh et al. found websites to be acceptable across all three domains (83% for accessibility, 75% for usability, and 87% for reliability).[17] The varying results using the same tool on the same topic could reflect improved website quality between the time interval that the two studies were published, low reliability across raters, or other differences in their methods. Significant variations in evaluation tools used by each study and lack of available guidelines for acceptable information quality for each evaluation tool makes it difficult to draw conclusions from these studies. However, most of these studies have consistently demonstrated significant variability in quality between websites.[11,14–19] Additionally, all studies have demonstrated that online, patient-oriented resources are very difficult to read as they are written in language that is too advanced for the average patient.[11–21] Tran et al. assessed not only readability but also complexity and density of data as well as text design, vocabulary, and organization and found that in the case of lymphedema, online resources are too sophisticated for the average US adult and thus fail to achieve their goal of informing the patient.[21]

Complementary to the availability of written materials online, video services have risen in popularity as information sources. YouTube has become a popular platform for patient education, with more than a third of patients watching health-related videos.[22] YouTube videos oriented for patients are less studied than traditional websites. Radonjic et al. evaluated patient-oriented YouTube videos for abdominal aortic aneurysm (AAA) using the DISCERN instrument, the *JAMA* benchmark, and an adapted AAA-specific score and found that videos scored poorly across all three assessment tools.[23] Similar to online written materials discussed above, videos made for the purpose of educating patients would benefit from a peer review process. Additionally, these videos should ensure completeness by updating information to align with current guidelines.[23] Patients would benefit from assistance from providers with navigating the information found on YouTube, such as a list of reliable videos or channels.

Patients place significant trust in online health information, which can influence their treatment decisions, the questions they pose to their providers, and even the decision to visit a provider.[24] However, studies examining patient-oriented material online have consistently shown significant variations in quality. Thus, it is essential that physicians are familiar with information available on the internet in order to effectively communicate with patients, clarify misconceptions, and provide high-quality websites or videos to interested patients. Additionally, webmasters, especially from healthcare organizations and professional societies, should be aware of the criteria for high-quality websites and videos and should improve any areas of deficiency (Table 207.4).

TABLE 207.4 Best Practices

Clearly identify author, credential and affiliation
Use citation and cite reliable work such as journal article or peer-reviewed sites
Disclose date of creation and modification
Disclose sponsorship or advertisement
Optimize structure of the text and webpage
Improve interactivity by allowing discussion forum, multimedia, educational support, and contact information for editorial team or author
Accurate content
Appropriate readability

Aside from open access online resources, the electronic patient portal is an alternative means for patients to access important medical information. The patient portal allows patients to access their health information such as lab results, securely message the provider, schedule appointments, enter health metrics such as blood pressure, and view provider-nominated educational materials.[25] However, the current utilization of electronic patient portals is generally low. While 88% of hospitals and 87% of healthcare professionals utilize patient portals, only 15%–30% of patients have electronically accessed their health information.[26] A study by Urowitz et al. showed that patients think positively of the Health Library, a component of patient portals that allows access to educational materials, and thought access to credible health information increased their awareness.[27] However, some patients had significant difficulties with navigating the Health Library and finding the right information, with many expressing desire for providers to refer specific information from the Health Library.[27] Increased provider participation in the patient portal, such as sending patients relevant health educational materials, may encourage patient use and improve the quality of online information accessed by their patients.

INTERNET FOR PHYSICIAN EDUCATION

Online resources can make important contributions to physician training in the current digital age. Studies on available open access resources for physicians have focused on two key issues: (1) training program website quality, (2) YouTube videos for vascular procedures.

Training Program Website for Recruitment

Even as early as 1998, the majority of applicants rely on training program websites to decide on which programs to apply.[28]

Since then, numerous studies have confirmed the vital role program websites play in the entire application process, from the initial application to the final ranking.[9,29–31] A study by Huang et al. reviewed the presence, accessibility, comprehensiveness, and quality of vascular surgery training program websites.[32] The study found that integrated vascular residency and independent vascular fellowship websites were not uniformly accessible, did not have comprehensive content (averaging only 34% of the content items), and were below the accepted quality in terms of content, organization, design, and user friendliness.[32] In a study comparing program websites of integrated vascular surgery (VS), interventional radiology (IR), and cardiothoracic surgery (CTS) residencies, integrated VS residency websites had more content than IR but less content than CTS.[33] There were key differences in the availability of online content offered by residencies recruiting from the same pool of applicants.[33] Vascular surgery residencies and fellowships should be mindful of their program website design and the information it offers. A well-designed program website can be a promotional tool to attract highly competitive applicants. Accurate and comprehensive information about the program and city may allow a more efficient selection of a program that is the best "fit."

YouTube as Preparation Resource

Almost all (95%) surgical trainees and senior medical students use videos in preparation for operations, with YouTube as the most frequent source (95%).[34] However, a study that evaluated the quality of 160 online videos of laparoscopic cholecystectomy found poor operative quality with very few videos showing an adequate critical view of safety.[35] Only a few studies have been conducted on vascular-related topics, but these studies consistently found that only a very small percentage of the videos were of high quality.[36–39] YouTube videos of vascular procedures showed incomplete educational content, technical variations between specialties, and inaccurate information or information against the guidelines. A study on YouTube videos of amputations showed that these videos, on average, only scored 58% on 11 educational items deemed necessary by the author.[36] In a recent study that evaluated carotid endarterectomy videos, only 8 out of 46 (17.4%) of the videos were considered high quality – defined by including English-language captions or narration and demonstrating key steps of the procedure (division of the common facial vein, exposure of the common, external and internal carotid arteries, vascular control and clamping, arteriotomy, endarterectomy, and arteriotomy closure).[39] There were no high-quality videos for eversion endarterectomy.[39] Additionally, there were significant practice differences between videos posted by neurosurgeons who exclusively performed primary repair versus vascular surgeons or cardiac surgeons where patch angioplasty was routinely used.[39] A study on common femoral artery access also showed a similar variation of video content by specialty.[38] All videos by vascular surgeons showed ultrasound-guided access, which is recommended by current guidelines, but videos by interventional cardiology and radiology predominately showed landmark-guided accesses.[38] A significant number (82.9%) of YouTube videos had inaccuracies such as wrong positioning in a review of videos describing the removal of central venous catheters.[37] Of the videos on the YouTube channel of Society for Vascular Surgery (SVS), only a small portion (17.9%) were related to procedures.[40] Additionally, the SVS official video channel focuses heavily on career development and patient education.[38] It would benefit trainees for professional organizations or academic centers to publish more peer-reviewed operative videos on open access platforms such as YouTube.

e-Learning

Using technology and online platforms for teaching and learning, known as "e-learning," emerged as early as the 1950s.[41] However, this modality is more popular in undergraduate medical education compared to graduate medical education in the US. e-Learning offers flexibility, which minimizes the disruption of clinical responsibilities and allows residents to devote more time to the operating room. Additionally, e-learning allows residents to access the material at their own pace. Trainees desire the ability to select subjects in parallel to their clinical experience rather than having a rigidly supervised timetable. Major concerns regarding e-learning include high quantity of work, circumvention of duty hour limits, and a loss of socialization. Additionally, faculty adoption and support of e-learning is crucial to its success. Implementation of e-learning takes significant leadership, resident input, professional staff support, and faculty engagement.[42,43] However, e-learning reduces longitudinal faculty time in preparation and delivery and allows standardization of delivery across cohorts of learners.[44] e-Learning resources for trainees from reputable sources such as the SCORE curriculum and official platforms of individual programs can reduce the need for other non-peer-reviewed sources that may contain inaccurate information, such as YouTube videos from independent users.

INTERNET FOR PHYSICIAN RATING AND SPECIALTY RATING

Physician rating websites (PRWs) have experienced a significant growth since their inception.[45–49] PRWs display providers' practice information such as clinical expertise, office locations, office hours, insurance accepted and outcomes available. Additionally, PRWs display reviews from patients, which can be quantitative or qualitative (narrative comments). However, data that PRWs contain is not evenly distributed among medical specialties. While orthopedic surgeons are highly represented with well over 90% of surgeons with reviews on the most popular PRWs, only a fifth of radiologists have at least one review across five PRWs.[50–54] Currently, there is no published study evaluating the digital footprint of vascular surgeons on PRWs. In our unpublished work, we found that 87% of vascular surgeons had been reviewed at least once across 16 PRWs, and most (90%) of the profiles are accurate in terms of practice specialty and location. However, the density of review is very low, and no physicians responded to any reviews, including negative reviews.

Limited physician participation is likely due to the fear of violating the Health Insurance Portability and Accountability Act (HIPAA) and difficulty validating patient complaints because of anonymity. The American Medical Association (AMA) recommends that physicians speak in general terms when responding online and communicate specifics offline and securely if possible.[55] Additionally, the AMA recommends politely asking patients to write reviews because the majority of reviews will be positive.[55] While anonymity provides a safe environment for honest reviews of deficiencies, it does allow false-negative reviews from competitors or self-written positive reviews to promote their own practices.[56] This makes soliciting authentic patient reviews more important.

In a review of PRWs around the world, the US has the largest number of commercial PRWs, however the quality of these websites varied highly.[57] This large number of PRWs in the US contributes to the dilution of reviews seen across the sites. Interestingly, the number of PRWs has been decreasing over time, 33 were counted in 2010 versus 28 in 2018 in two studies by the same author.[56,58] This natural consolidation of PRWs should improve review density and PRW quality. PRWs will likely continue to gain popularity as the digital generation ages to become the main patient population. The majority (70%) of the top 10 search results of specific physicians on Google yield third-party physician information websites, including PRWs.[59] Vascular surgeons must embrace social media and PRWs and navigate these online platforms to promote the specialty as well as individual practices.

INTERNET AND BRAND

Social media are tools based on the World Wide Web that allow users to create and exchange information.[60] Social media are powerful promotional tools because of the advantages of access to a large number of consumers, the presence of transparency, the wide global reach, the ability to boost web page traffic, and the ability to promote brand name.[61] Seventy percent of US healthcare organizations use social media.[2] A study on social media presence of hospitals found significant positive correlations between reputation score and total US News and World Report score, of both adult and children's hospitals, with the number of Twitter followers and Facebook followers.[62] Gould et al. looked at returns on investment in social media promotion of a new startup plastic surgery practice and found relatively high return as measured by referrals.[63] Many professional medical associations, such as the Society for Vascular Surgery (SVS), also maintain active social media accounts across various platforms. About 18% of dermatology journals and 47% of dermatology professional organizations had Facebook profiles and 17% of journals and 29% of professional organizations were on Twitter in 2017. The most popular professional dermatology society on Facebook had 155,380 likes, and the most popular professional dermatology society on Twitter had 27,576 followers. In comparison, SVS has 6886 followers currently on Twitter and 7210 likes on Facebook.[64] The difference in popularity could be related to the size of the professional body, the nature of the treatments offered leading to difference in patient followers, the engagement of its members or the popularity of organization globally.

Social media use by individual physicians depends on their specialties and practice settings. Half of plastic surgeons use social media regularly in their professional practice, while only around a quarter of gynecologists and a third of pediatric orthopedic surgeons, oncologists and primary care physicians use social media for professional reasons.[1,65,66] Surgeons in the private practice setting and plastic surgeons with aesthetic dominant practices were more likely to use social media.[65–67] A significantly higher portion of private practice plastic surgeons use social media for branding, patient acquisition, and public education compared to salaried plastic surgeons.[67] Over half of private practices would measure the number of patient referrals from social media as a marker of return on investments in social media.[67] For plastic surgeons that use social media, 34% found a positive impact on their practices, with the main benefits of increasing the exposure of their practices, providing a low-cost means of advertising, capturing new referrals, and receiving positive feedback through social media websites.[66] Similar research is currently lacking in vascular surgery, which could explain why vascular surgeons have not placed the same weight on social media. Hawkins et al. recommended maintaining active social media profiles as Google search algorithms will prioritize these compared to third-party sites such as PRWs, which physicians have little control over.[68] More studies on the utilization of the internet in the field of vascular surgery are needed and recommendations regarding social media use from professional societies would be beneficial.

CONCLUSION

The internet and social media play essential roles in healthcare in the digital age. Currently literature regarding the information available to both patients and medical professionals in the field of vascular surgery is lacking. The digital footprint of vascular surgeons on various social media platforms and PRWs is not known. As the internet and social media continue to rapidly grow, it is imperative that we better understand its effect on our specialty.

Take-Away Points

- The internet has permeated through every aspect of medicine and healthcare.
- Current open access patient education material, both written material and videos, displays significant variation in quality.
- Provider awareness of available information on the internet can improve communication with patients, clarify misconceptions, and provide high-quality websites or videos to interested patients.
- YouTube videos for vascular trainees can contain inaccurate information; peer-reviewed operative videos on open access platforms will be beneficial to trainees.
- Vascular surgeons' engagement on physician rating websites is low.
- Social media platforms can be used for branding, patient acquisition, and public education. Vascular surgeons should embrace social media and physician rating websites and navigate these online platforms to promote the specialty as well as individual practices.

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A complete reference list can be found online at www.expertconsult.com.

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