Chapter 4

Spinal – Extradural

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INTRODUCTION

History

Spinal injections were first used in the mid-19th century to produce anesthesia for surgical procedures. Over the next century, new needles were developed and our anatomical understanding of the spine was enhanced. This mixture of progressive thoughts led to the development of epidural stimulation in the mid-1960s. This new therapy involved placing a lead with electrodes over the spine and creating an electrical current with a power source. Dr Norman Shealy reported the first successful case in 1967, in a patient with neuropathic cancer pain. In that case, a lead was placed in the intrathecal space. The lead was crudely designed, the energy source was archaic and the overall system was rudimentary, but the outcome was positive. These are important considerations since we are now dealing with much more advanced tools. Critical historic steps since that time have included the development of multicontact leads, a better understanding of anode and cathode field shaping, better computer modeling, totally implantable generators, rechargeable systems, miniaturization, and the development of prospective controlled studies. It is the purpose of this chapter to give an overview of the use of spinal cord stimulation (SCS) in modern medicine, and to examine the place of this therapy in the treatment algorithm.

General indications

An implantable neuromodulation system is indicated for spinal cord stimulation (SCS) as an aid in the management of chronic, intractable pain of the trunk and/or limbs. The best outcomes occur in patients with neuropathic, as opposed to nociceptive, pain syndromes, although many patients have mixed pain patterns that require both SCS, and additional treatments of muscle, joint and visceral pain. In the past, the best outcomes were confined to patients with unilateral

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pain in a single extremity. Fortunately, recent improvements in technology, specifically the development of multiple lead systems with greater ability to steer current, drive current deeper to the cord layers, and impact new neural pathways, have enhanced outcomes for more complex pain presentations, including axial low back pain, bilateral extremity pain, visceral pain from the chest, abdomen and pelvis, and vascular pain syndromes.

Patient selection for spinal cord stimulation

Patient selection is the most important aspect for impacting a good outcome in those who undergo SCS. The most relevant issues are patient characteristics, and disease state causing the pain syndrome.

Patient characteristics

Several factors are predictive of a potential poor outcome in SCS. While these factors do not indicate an absolute contraindication, they should be considered carefully in the decision process to implant a patient.

1. Abuse or abnormal behavior with opioids suggesting abuse or diversion.
   a. Dose escalation without doctor's consent.
   b. Lost or stolen prescriptions.
   c. Early refill requests.
   d. Doctor shopping.
2. Presence of psychiatric and psychological disease.
   a. Untreated severe depression or anxiety.
   b. Untreated psychosis.
   c. Personality disorders such as borderline disorder.
3. Inability to understand risks and benefits of SCS.
4. Presence of bleeding abnormalities.
   a. Presence of drugs that impact bleeding.
   b. Disease states that lead to increased risk.
5. Presence of infection at the site of implant or systemically.
6. Physician impression that the patient is a poor candidate.

Disease-specific characteristics

The other major issue involved in the selection process is choosing the patient with the proper disease state and indication. Published literature has evolved on several patient groups who have undergone stimulation with both successful and less than optimal results. We can learn from this information to select patients in a more informed manner. This is also helpful to identify patients who are less likely to have an optimal outcome. The best outcomes may be expected in patients who have pain characterized by burning, crawling, stabbing, or shooting pain in the extremities after spinal surgery, those with spinal nerve entrapment from mechanical spinal diseases, complex regional pain syndrome type I and II, peripheral nerve injury, and painful neuropathies

of various causes. Another group who have shown great promise are those that suffer from refractory angina, ischemic pain of the extremity, and pain related to peripheral vascular disease or vasospasm. Axial back pain once mystified the interventional pain physician and played a major role in SCS failure. With the advent of new percutaneous arrays, paddle multicolumn arrays, and combined epidural and peripheral nerve stimulation, more modern studies are reporting improved results, decreased opioid consumption, and improved return to work and to active duty in the armed services. Many other patient groups have been reported to be successfully treated with spinal cord stimulation, including intercostal neuralgia, spinal cord injury, focal peripheral nerve injury, phantom pain or neuropathic pain after trauma, and chest wall pain.

The achievement of parasthesia in the area of pain is thought to be an essential component in achieving a good outcome with relief of pain. In some patients, a good area of stimulation coverage is achieved, but pain relief is not achieved to a degree that would lead to an acceptable outcome by the patient. In some cases, the physician may be able to predict a probable failure of the implantable theory. Patient groups who have a less than optimal chance of a good outcome include those with spinal cord injury, central pain after stroke or traumatic brain injury, perirectal pain, pelvic pain, and nerve root transaction or brachial plexus or lumbar plexus injury.

Once the patient is selected for an epidural stimulator placement, the physician should be adept at placing the lead, anchoring the lead, and placing the generator. The next section will review these concepts.

EPIDURAL SPINAL CORD STIMULATION: THE PROCEDURE

Patient education is an important part of the procedure. The patient and their caretaker should be made aware of the risk of infection, bleeding, epidural hematoma, epidural abscess, lead failure, generator failure, and failure of the therapy. This education process can be part of the informed consent process. It is helpful for the patient to consult with anesthesiologists prior to moving forward with the procedure. Prior to the trial, preoperative antibiotics are given thirty to sixty minutes prior to incision, or skin puncture. This antibiotic regimen is recommended prior to the trial and standard for the permanent [14]. The implanter should consult with the local infectious disease physician for recommendations regarding local antibiotic resistant organisms. Some clinicians have chosen to use chlorohexidine baths or intranasal bacitracin prior to implant, particularly in high risk patients.

The anesthesiologist is helpful in achieving the implant. Ideally, the patient should be comfortable, but remain conversant during the procedure. In the cervical spine, the need to have the patient alert and conversant should be the standard of care.

The optimal positioning for the patient for lumbar thoracic implants is to have the abdominal area padded to alleviate lumbar lordosis. This position allows

for ideal opening of the intralaminar spaces. Cervical placement is assisted by proper positioning which involves having the arms to the side, padding of the chest, and slight neck flexion. The well-positioned patient makes the procedure easier to achieve, reduces risks, and improves fluoroscopic guidance.

After proper positioning, achieving sterile technique is critical. Standard prep solutions include alcohol, povidone-iodine or chlorhexidine. Some clinicians prefer to finalize their preparation with a binding type of prep stick that clings to the skin or with clinging impregnated drapes.

Fluoroscopic guidance is utilized throughout the procedure, and an attention to safety to radiation exposure is very important. This is very important for the long-term health of the doctor. The use of fluoroscopy can be used in a pulsed fashion as opposed to continuous exposure, which will limit the exposure. Lateral and anterior-posterior views are critical to assure proper placement of the needle and leads. The spinal level of entry depends on the patient's anatomy and doctor preference. Previous back surgery usually precludes epidural entry at lower lumbar levels. Entry at L1–L2, T12–L1 may facilitate better lead control when placing the leads at the desired level (Fig. 4.1). Entry into the epidural space above the level of the conus medullaris may facilitate easier lead placement, however, there is potentially greater risk of spinal cord injury at any level above L2.

FIGURE 4.1 Recommended paramedian approach to epidural needle placement.

Once the entry level is determined, the skin is anesthetized with local anesthetic. Common choices include bupivicaine 0.25% or more commonly lidocaine 1% with epinephrine and sodium bicarbonate. The sodium bicarbonate is often added with a 1:9 ratio (i.e. 1 ml of sodium bicarbonate in with 9 ml of lidocaine). The sodium bicarbonate hastens the onset of topical analgesia and decreases the burning sensation of the local anesthetic. The use of epinephrine optimizes vasoconstriction and reduces bleeding. Careful attention should be used to avoid deep local infiltration which can lead to an unintentional spinal injection.

A 14-gauge modified-Tuohy (provided with the lead kit) or bent tip needle should be used to enter the epidural space with a loss-of-resistance (LOR) technique, or hanging drop technique. Some instructors have recommended using a lead wire to identify the epidural space, but this method has not been studied and may increase the risk of wet tap or accidental spinal cord injury. There is no literature to support the use of air, saline or a combination in the syringe used to find the epidural space by loss of resistance. Some have theorized that saline may lead to current disbursement and change programming, but that has never been shown to be the case in a prospective fashion. [15,16]

The needle-entry point at the skin should be just medial to the pedicle, one and one-half to two vertebral bodies below the intended interlaminar entry site (Fig. 4.2). The ideal needle angle should be less than 30 degrees to the skin, but

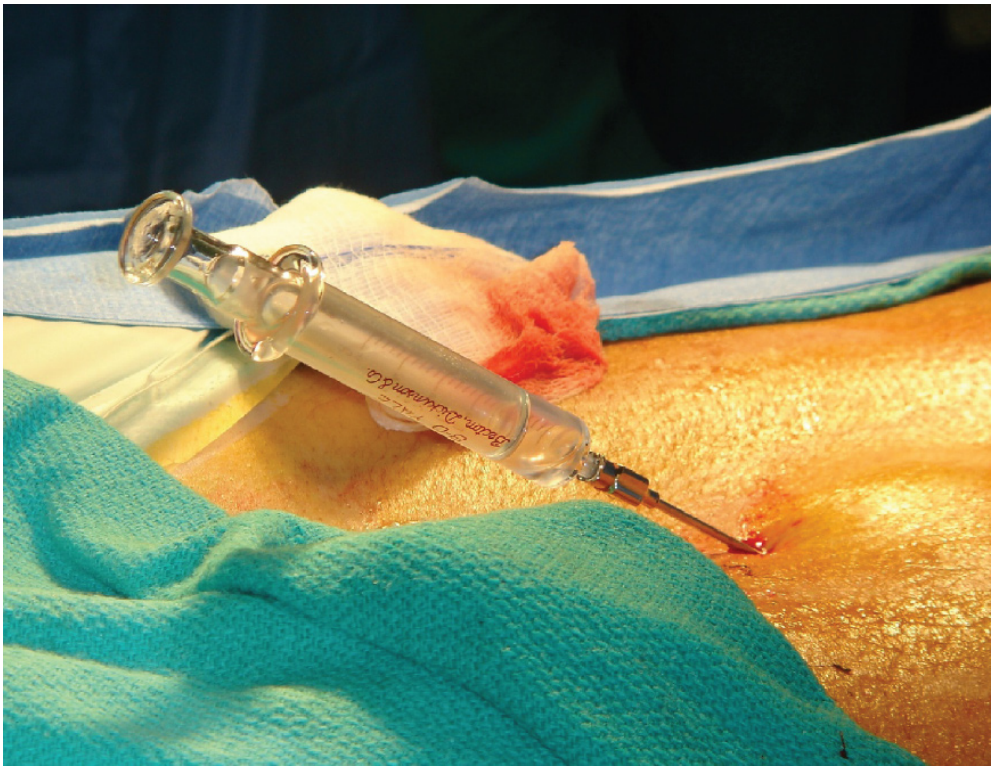

FIGURE 4.2 Loss of resistance technique to identify the epidural space.

this may vary based on body habitus and spinal anatomy. The orientation of the bevel on needle entry into the epidural space has been debated, but no clear instruction has been documented in the literature.

Placement of the lead(s) must be performed with fluoroscopic guidance. It is recommended that the practitioner use a low-dose, pulsed technique or intermittent fluoroscopy to reduce radiation exposure. The implanter should always keep their hands out of the direct path of the fluoroscopic beam when passing the leads. The initial target for the leads should be based on the pain pattern (Table 4.1). The use of a single lead, dual leads, or tripolar arrays are at the discretion of the implanter. Studies have shown the ability to treat axial and bilateral radicular pain with a single lead, but these studies have been short term, and have been criticized by some because of the inability to maintain stimulation on a long-term basis with the minimal capability to change programming [17]. Recent studies have shown improvements in axial back and extremity coverage using dual eight leads, staggering lead arrays, and targeting based on anatomical targets. [10,18,19]

New smaller rechargeable generators have made the percutaneous epidural lead more attractive, since the energy requirements can be increased without exhausting the battery as quickly. Some older studies showed that paddle leads were superior to percutaneous leads because of limited ability to increase energy and programs. Newer generators allow for multiple high energy programs that can be cycled in continuous patterns. These changes have negated some, but not all advantages of paddle leads. Persistent advantages include the capability to place the lead in areas where a percutaneous lead could not be easily placed, the ability to overcome scar tissue, and the ability to target deeper spinal cord structures with programming.

Placement of the internal programmable generator and tunneling of the leads is an important part of the percutaneous permanent implant. The physician should closely examine the patient to determine the ideal location for the generator. Factors to consider include size of the generator, location of bony landmarks,

TABLE 4.1 Sensory mapping in spinal cord stimulation

Location of pain	Approximate lumbar spinal cord stimulator lead placement
Low back	T7–T10
Buttock	T10–T12
Anterior thigh	T10–T12 slightly lateral
Posterior thigh	T10–L1
Foot	T11–L1

and patient skin condition such as lesions or infected areas. With all factors being equal the generator should be as close to the lead implant site as possible.

The pocket is made by making an incision to the subcutaneous tissue and then by blunt dissection to the appropriate size. The pocket should be 110 to 120% of the volume of the device to allow room to close without excessive dead space for fluid or seroma accumulation. The tunneling rod should be used with care to avoid inadequate or excessive tissue depth. Once tunneled a strain relief loop should be at both the lead placement site and the pocket.

EPIDURAL STIMULATION TO TARGET SPECIFIC DISEASE STATES

Specific disorders

The patient with failure of surgery of the lumbar or cervical spine; the patient with inoperable lumbar or cervical radiculopathy

Failed back surgery syndrome (FBSS) is defined as persistent or worsening pain of the trunk, back, neck, arms, legs, or multiple areas after attempted surgical correction of spinal disease. This diagnosis, commonly used to describe multiple patients with varying pain patterns, represents a diverse group of patients. These patients may have varying pain generators and mechanisms of pain production including nerve injury or mechanical pain. The patient may also suffer from chemical radiculitis, mechanical pain from joints or muscle, spinal or foraminal narrowing, scar around a nerve or spinal structure or inflamed arachnoid tissues.

Comparative prospective randomized evidence-based studies support the effectiveness of spinal cord stimulation as a comparative treatment of failed back surgery syndrome. In a very well done study, North identified failed back surgery patients with recurrent disk disease that were felt to be surgically correctible or an acceptable candidate for spinal cord stimulation. Randomization treatment was grouped into repeat surgery or spinal cord stimulation. The results of this study were favorable for SCS. SCS proved to be superior to repeat surgery when measured by global satisfaction and analgesia ($P > 0.01$). The crossover analysis also favored the stimulation group versus the repeat surgery group ($P = 0.02$) [38]. This study suggests that spinal cord stimulation is an effective alternative to repeat surgery in patients who have failed previous lumbar surgery, and should be considered to be a first line treatment in this complex group of patients.

Reviewing past studies in SCS one finds that the success rate has been very positive in those suffering from radicular neuropathic limb pain. Radiculopathy is a prime indication for the procedure. Axial back pain stimulation has proven to be more challenging. The difficulty in relieving axial low back pain centers on the fact that the nerve fibers that must be stimulated are located in the deep lateral areas of the dorsal columns near the dorsal root entry zone and the nerve

root. In order to achieve stimulation of these deep lateral fibers, the nerve fibers of the dorsal nerve roots at the level of the stimulator are often activated causing painful nerve stimulation and involuntary motor function. This problem has been lessened by new multicolumn stimulation patterns that allow depolarization of the nerve roots, and focused current into the deeper lateral fibers. This gives a greater ability to focus current on the midline fibers and lateral fibers without subsequent stimulation of the nerve roots. In a prospective study, the combination of an increased number of leads and advanced programming led to improved success in patients suffering from axial pain [37]. Continued work on lead constructs and engineering models for both computer analysis and clinical studies are critical to future advancement.

Studies have shown that the earlier the patient is implanted after the failure of back or neck surgery, the better the chance of a good outcome [5].

Lead placement

In patients with single limb radicular pain, the lead may be placed to the midline or slightly off midline to the effected side between T8 and L1 to achieve good coverage in the lower body. The targets in the neck are often C2 to C7. The risk of one lead is migration or scarring under the lead, with limited programming to correct for these changes in the coverage. Dual lead systems may improve the overall long-term outcome [35]. Crossing over the midline with one or two leads may allow for coverage of the axial region and the limbs (Fig. 4.3).

Complex regional pain syndrome (CRPS)

Complex regional pain syndrome was formally known as reflex sympathetic dystrophy, or causalgia. This problem has led to loss of function, severe pain, and tremendous expense to society [40–42]. The goal of SCS in this population is multifaceted and includes pain relief, improved blood flow in those who have vasoconstriction, global satisfaction, and increased ability to tolerate rehabilitation. Achieving these goals will lead to a reduction in muscle atrophy, preservation of movement, and maintenance of strength via physical therapy and home exercise.

The success of spinal cord stimulation for CRPS is well supported by high powered statistical studies. In a prospective, randomized trial of 36 CRPS patients, the patients that were implanted with a permanent stimulator showed long-term pain reduction and improvements in quality of life, and global satisfaction. At long-term follow up of 5 years, the group undergoing SCS and physical therapy had persistent good outcomes with pain reduction [69–71].

One common thread in all studies regarding SCS for CRPS includes the importance of moving forward with the therapy early in the course of the disease. Once the process spreads to other body parts, or the patient develops contractures, the chance of a good outcome diminishes [43–45].

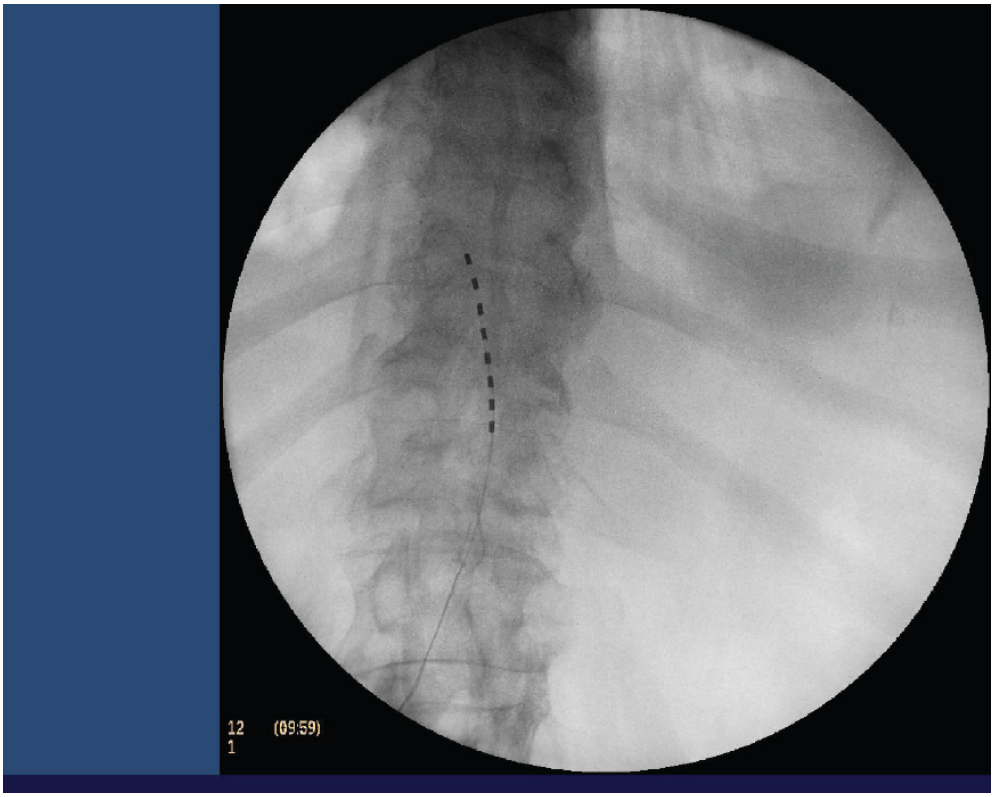

FIGURE 4.3 Ideal lead placement to achieve bilateral stimulation of the spinal cord by crossing the radiological and anatomical midline.

Lead placement

The lead target depends on the site of the CRPS symptoms. For the upper extremity, placement is recommended just ipsilateral to midline at the C2–C7 levels. For the lower extremity, placement is recommended just ipsilateral to midline at the T8–L1 levels. In patients where the foot is an involved area, the implanter should consider placing the lead at the T12–L1 level. This may require crossing the midline, and entering the spine two to three levels lower with the needle. Sensory mapping studies can be used to target initial lead placement, but the lead should be adjusted based on patient response (see Table 4.1).

Examples of this concept would be to place the lead at T12/L1 for the foot or T10/T11 for the knee. In complex cases involving multiple body parts, the implanter may choose multiple leads and, in some cases, more than one generator. The use of high-frequency stimulation (greater than 500 Hz) may also add some benefit [46].

Peripheral neuropathy

The burning, stinging pain of peripheral neuropathy is very amenable to SCS. Many of these patients respond to anticonvulsants or selective serotonin reuptake inhibitor (SSRI) medications. These drugs are very costly and often

lose effect over time or cause unacceptable side effects. SCS can be much more cost effective over time, and can avoid the issue of end-organ effects of systemic medications. Many studies showing improvement of pain in neuropathic limb pain include these patients with neuropathies [29].

Lead placement

The targets for these leads for peripheral neuropathy are similar to that of the other syndromes noted above and are based on pain pattern. In some cases, in order to achieve stimulation, the lead must be placed in the area of the nerve root at L5–S1.

Post-herpetic neuralgia (PHN)

Severe nerve pain can develop in the area of previous herpes zoster activation. This chronic and severe problem is caused by an eruption of dormant Herpes varicella virus living in the dorsal root ganglia. This can lead to a chronic disruption of the nerve with abnormal activation of the A-delta and C fibers. Studies on the efficacy of SCS have been mixed in this condition. It does appear that the outcomes have improved over time with evolution of new technology and better programming. The efficacy may be due to direct stimulation at the cord level, but it also has been theorized to be due to restoration of blood flow due to vasodilatation, changes in the sympathetic nervous system, or improved blood flow to the nerve [48,49,50]. In patients who fail SCS for this condition, the implanter may consider peripheral nerve stimulation, or intrathecal drug delivery.

Lead placement

The most common array for this condition in the epidural space involves placement of one lead off midline in the ipsilateral side two levels above the lesion with a second lead in the lateral ipsilateral space one level above the lesion. New targets are needed to improve the outcome in this patient group.

Peripheral vascular disease (PVD) and ischemic pain

Neuropathic pain secondary to ischemia is a Food and Drug Administration (FDA) approved indication in the USA. The use of SCS for treatment of peripheral vascular disease has been a common use in Europe. The mechanism of action for the ability of spinal cord stimulation to relieve ischemic pain is not proven, but many have theorized it causes a change in sympathetic tone and thus increases blood flow [49,50]. Spinal cord stimulation improves microcirculation and increases capillary density and increases red blood cell velocity through capillary beds [51,52]. The current literature does show improved function in walking and function with SCS and may also improve wound healing in lesions of equal to or less than 3 cm^2 [53]. The presence of wet gangrene is a relative contraindication to placement of a SCS device in these patients.

Studies in the USA have used SCS with mixed results. The European evidence indicates improved function, improved wound healing, and improved pain scores when SCS is used early in the treatment protocol. Considering this information, the use of SCS for ischemic limb pain and peripheral vascular disease should be considered earlier in the course of treatment.

Lead placement

Leads should be placed to target the entire extremity. The most common locations would be T10– T12 for lower extremity ischemia, or C3– C6 in the upper extremity.

Angina

SCS has anti-anginal and anti-ischemic effects on the myocardium and may impact survival and function in the patient with intractable angina. Some have theorized the mechanism to be segmental inhibition of the activity on the sympathetic nervous system to the heart, causing an increase in microcirculation, improved metabolism, and a reduction in myocardial demand of oxygen [54]. SCS has been shown to improve achievable cardiac work load, increase time to ischemia and angina and improve function while not blunting the patient's ability to identify significant ischemic symptoms [55,56,57].

Lead placement

The lead for angina is placed at C7–T2 in most cases with a goal of producing a parasthesia in the chest wall, and left arm.

Visceral pain

Recent work by Kapural, Deer, and colleagues has shown improved pain relief with SCS in those suffering from visceral abdominal pain syndromes. Pain generation may develop secondary to ischemia to the bowel, adhesions, chronic pancreatitis, or post operative pain syndromes [58,72]. Other reports have shown an improvement in symptoms using SCS with or without opioids than to opioids alone in patients with chronic pancreatitis [59].

Lead placement

The lead for abdominal visceral pain has most commonly been reported at T5 or T6.

Pelvic pain

Common causes of pelvic pain include interstitial cystitis, endometriosis, and post-surgical scarring. Many of these patients are treated with high dose opioids with poor results. SCS has been used successfully in these cases after failure of more urological or gynecological treatments. The success of treatment for pain

in the interstitial cystitis patient has led to an expansion of these therapies to patients with other causes of pelvic pain.

Lead placement

Most implanters now use dual octapolar leads placed over the S2, S3, and S4 nerves bilaterally. In some patients this will lead to improved pain and improved bladder volumes. Leads can be placed antegrade through the sacral hiatus, retrograde from the lumbar spine downward, or directly through the sacral hiatus (Figs 4.4 and 4.5). Leads can be placed by a paddle approach via sacrotomy at the upper sacrum [61,62].

Based on the information noted above we can make conclusions about patients who may have the best chance of a good outcome [10]:

High probability of a good outcome:

- Chronic cervical or lumbar radicular pain syndromes
- Complex regional pain syndrome, types 1 and 2
- Painful peripheral mononeuropathies
- Angina pectoris refractory to conventional surgical bypass and medical management
- Painful ischemic vascular disease refractory to medical management or surgical intervention.

Moderate chance of success with SCS:

- Axial low back pain
- Pelvic pain
- Visceral pain syndromes of the abdomen
- Post-herpetic neuralgia.

Difficult to achieve good outcomes with SCS:

- Neuropathic pain following spinal cord or brain injuries, nerve root avulsions
- Iatrogenic nerve root destruction
- Phantom limb pain.

CONTRAINDICATIONS TO SCS

Prior to moving forward with SCS the implanter should consider the contraindications to implanting a SCS device.

Contraindications

- Uncorrected coagulopathies
- Current sepsis/infection with fever
- Implantable cardiac defibrillator
- Inability to control device or lack of patient cooperation
- Thoracic syrinx.

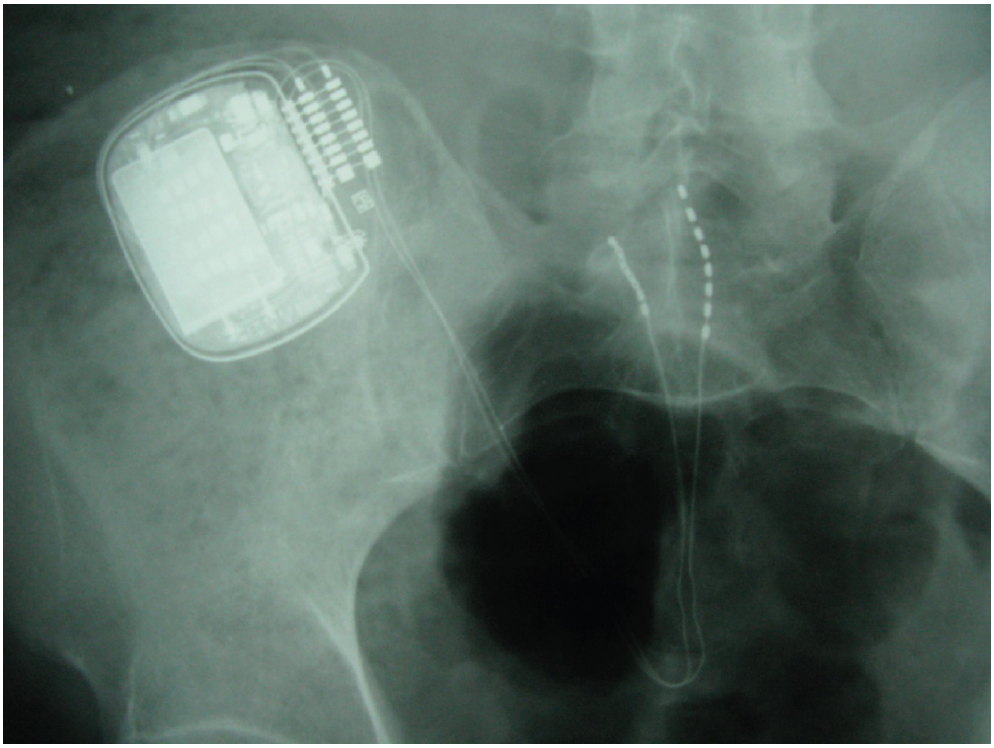

FIGURE 4.4 Stimmulation of the sacral nerve roots.

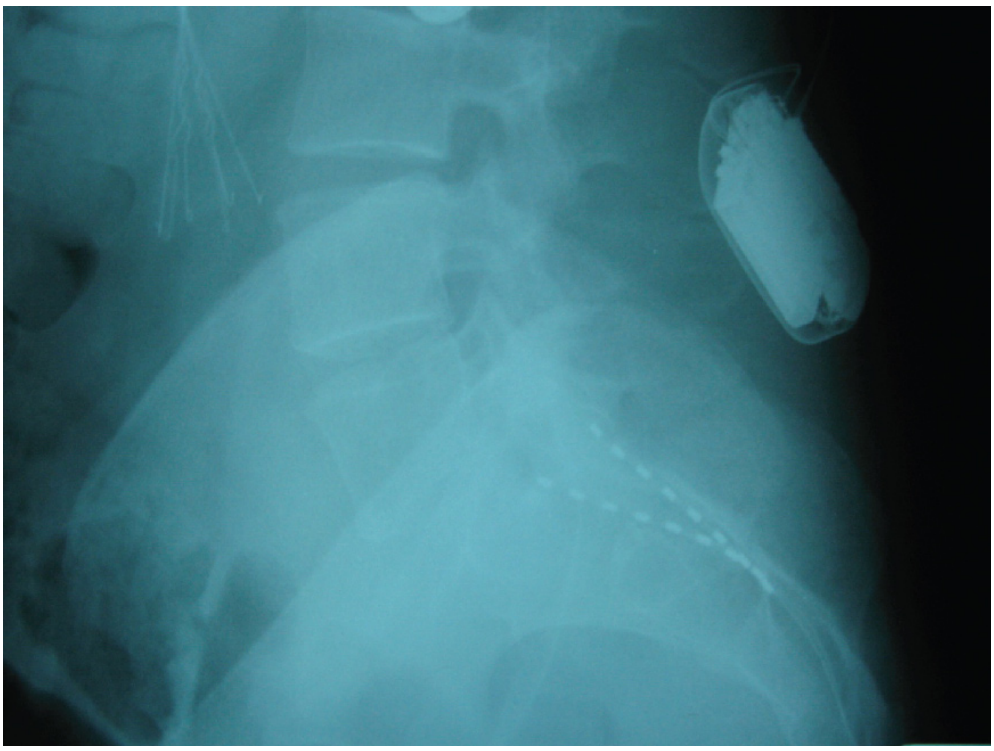

FIGURE 4.5 Lateral view of sacral nerve root stimmulation.

Relative contraindications

- Thoracic stenosis (if <10 mm for a percutaneous lead [10])
- Patients who may require serial MRI evaluations (e.g. multiple sclerosis)
- Demand cardiac pacemaker: most pacemakers are now compatible with SCS but the cardiologists should be consulted prior to permanent implant.

PROGRAMMING THE EPIDURAL LEADS

With each implant several factors are critical to success. These include patient selection, proper needle and lead placement, and proper programming. The ability to program a lead depends on the position of the lead and the number of contacts. The detailed description of programming is very complex, but each implanter should know basic concepts. The cathode is the negatively charged electrode that impacts the shape and depth of the field. The anode is the positively charged electrode that disperses current and makes the field broader, but less focused. In order to drive current towards a specific portion of the cord, the cathode should be activated over the target. The target can be more specifically impacted by minimizing the number of cathodes and surrounding this electrode with two or more anodes.

Complications

Like other surgical procedures, the implantation of SCS systems can be associated with complications. The risks of the procedure must be weighed against the potential benefits. The majority of devices are placed and maintained without complications but, when they do occur, the most common complications are infection, post dural puncture headache, increased impedance from epidural scarring, bleeding, spinal cord injury, nerve injury, lead fracture, and lead migration.

Of these complications, the most common problem is lead migration. The movement of the lead laterally or vertically may result in loss of stimulation, and the need for surgical revision. The incidence of these complications has varied in the reported literature, but appears to range from 1% to 23% with the most likely number incidence being 13.5%. Lead fracture appears to be the second most common complication. [20].

Inadvertent dural puncture appears to occur in less than 1% of patients, and leads to post dural puncture in less than 1% of patients. There appears to be no reason to abandon the procedure in cases where a dural puncture has occurred as long as the patient is stable and has no parasthesias.

Infection is a potential complication of SCS. Patients with high risk of infection should be optimized medically prior to implant. Preoperative blood sugar control, preoperative chlorhexidine baths, intravenous antibiotics 30 minutes prior to incision or needle placement, intraoperative antibiotic irrigation, and careful wound closure may be helpful in reducing these risks. Early

identification and aggressive treatment of superficial wound infections may prevent more extensive infection and help avoid expensive loss of the device.

Bleeding is a rare but serious complication of SCS. The majority of bleeds are superficial in the wound or pocket of insignificant consequence. In the event of an epidural bleed, a hematoma can develop. This can lead to serious injury to the neural structures and paraplegia if not addressed rapidly. Diagnosis is made by clinical suspicion and confirmed by CT. Treatment is surgical drainage.

Prevention of significant bleeding is based on reducing trauma and modification of oral medications that can impact bleeding in the perioperative period. Many patients are on these drugs because of cardiac, neurological or hematological problems. The treating cardiologists, neurologist, or family doctor should make decisions on the appropriateness of discontinuing these medications. The American Society of Regional Anesthesia and Pain Medicine establish and update guidelines on the issue of anticoagulants at regular intervals [21].

Spinal cord injury, nerve injury, and cord contusion are risks of spinal cord stimulation. These risks can be reduced by using a shallow needle entry, gentle lead placement, and avoidance of forcing leads past areas of resistance. Keeping the patient alert and conversant may also reduce the risk of injury.

Complications around the generator are another potential source of difficulty for the implanted patient. Fluid collection around the generator is a common complication. This problem, called seroma, can lead to swelling, redness and pain. The problem can be differentiated from infection by lack of fever, minimal white blood cell elevation, and lack of malaise. The incidence of seroma formation may be reduced by minimizing tissue trauma by blunt dissection techniques, by making the pocket prior to lead placement so the wound can be packed to reduce small venous bleeders, by creating an appropriately sized device pocket (generator blanks or spacers may help in this process), and by maximizing health in those with protein deficiency prior to surgery. Seroma may be treated by observation, pressure dressings, aspiration or by incision and drainage.

Another rare but important complication is placing the generator at a depth that is not optimal. The generator that is placed to deep will be unable to communicate with the transdermal telemetry equipment and a generator that is too superficial may lead to erosion. Hand held telemetry should be performed on the generator prior to leaving the sterile environment of the operating room. Since manufacturers vary on recommended depth, the corporate technician should be consulted if any questions exist regarding appropriate depth.

The other area of concern in the immediate postoperative period is wound dehiscence. The implanting physician should be vigilant in closing the tissue levels carefully to avoid lack of tissue congruency. The occurrence of wound dehiscence often leads to loss of the generator and, in most cases, the entire system.

CONCLUSION

The placement of computerized leads into the epidural space above the nerve and spinal cord can lead to changes in the patient's neurophysiology that eventually leads to changes in the pain perception and other neural reactions that can lead to major changes in the disease process and functional loss resulting from the rampages of pain and ischemia. These devices should be considered to be a major part of the treatment algorithm for chronic pain.

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