Guidelines for Percutaneous Transluminal Angioplasty

Society of Interventional Radiology Standards of Practice Committee[1]

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PERCUTANEOUS transluminal angioplasty (PTA) and other methods of revascularization have recently undergone explosive growth. Great interest and acceptance by patients, referring physicians, and third-party payers have led to the wide application of the technique in the treatment of vascular disease. However, because of the pace of development, confusion has arisen over the proper indications for the various procedures and the relative roles of percutaneous and conventional surgical procedures.

To clarify the appropriate use of these techniques, the Standards of Practice Committee of the Society of Cardiovascular and Interventional Radiology has developed these guidelines. In their formulation, an initial review of the pertinent scientific literature was performed to determine the reported indications and results of percutaneous and standard surgical procedures. Because of the wide disparity in study designs and reporting methods, a direct analysis of the literature could not be the only basis for developing guidelines. Rather, the literature was used as a basis for developing a consensus among practicing interventionalists that could serve as a guide to the appropriate use of surgical and nonsurgical therapies in the treatment of vascular disease.

It is important to remember that these are only guidelines. For any given patient, alternative treatment may be valid and, in fact, preferred for sound clinical reasons. In addition, certain surgical or percutaneous procedures require that the individual be highly trained or unusually skilled in the specific technique. Practitioners are cautioned to recognize the level of skill and experience they possess and weigh the appropriateness of therapy in that light. Finally, these guidelines are intended to define in a general way the current standard of care and should not be used to discourage innovation or new developments in properly controlled clinical research protocols. They will be reviewed and updated periodically, as our knowledge of the therapy of vascular disease advances.

DEFINITIONS

Before the results of angioplasty are evaluated and used to guide therapy, it is necessary to define terms that can be used to measure outcome. For the purposes of this discussion, the following definitions will be used.

Success Rate

The success rate is the percentage of patients with an initial positive outcome from the procedure. The success rate has two components: technical and clinical. Technical success is the substantial relief of stenosis or occlusion with residual narrowing of 20% or less, significant hemodynamic improvement, and no major morbidity. Clinical success is the complete relief of or substantial improvement in presenting symptoms. The determinants of clinical success are different in each vascular distribution and will be defined in each subsection.

Patency Rate

The patency rate is the percentage of patients who have undergone an initially successful procedure for whom flow at the treatment site and symptomatic improvement are uninterrupted in any specified time period. Patency is ended when there is recurrence of symptoms to the same degree as present previously, with angiographic or noninvasive evidence indicating recurrence in the same vessel segment.

DETERMINANTS OF SUCCESS

There are many factors that will alter the prospects for a successful procedure, and these will significantly alter the technical and clinical success rates.

The technical success rate is directly related to the features of the lesion treated, specifically the length, morphology, and whether it is a stenosis or an occlusion in general the shorter the lesion, the greater the technical success rate. Thus, in most series, initial results are best with lesions of 3 cm or less. Those 3–10 cm in length are associated with a somewhat lower rate of success, and those over 10 cm have the lowest success rates. Also, technical success is higher with stenoses

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than with occlusions, given equal length. The morphology of the lesion is also a factor in technical success. Concentric lesions are easier to treat than eccentric lesions, and treatment results may be more uniformly acceptable. The location of the lesion within the vessel affects the technical success. Lesions at the origins of vessels or at branch points may not respond as well to balloon dilation or may result in branch occlusions. Finally, the pathologic features of the lesion are a factor in the technical success rate. In the renal arteries, treatment of fibromuscular disease is associated with a higher rate of technical success than treatment of atherosclerosis. Vessels with myointimal hyperplasia associated with vein graft stenosis are more difficult to dilate than those with atherosclerosis and the former often require use of higher balloon pressures. The presence of calcium in a lesion reduces the efficiency of most lasers and atherectomy devices. Calcified lesions can be dilated with baloons but generally require higher inflation pressures and may have a slightly lower technical success rate.

Clinical success depends on the performance of a technically satisfactory procedure, but it also depends on the type of lesion and the overall extent of disease. In most vascular distributions, atherosclerosis is the primary process treated, and factors other than the disease process determine the relative clinical success rates. However, in the renal arteries the disease process is directly related to the success rate; vessels with fibromuscular dysplasia have a better outcome than vessels with atherosclerotic disease. The extent of the vascular disease is perhaps the most important consideration. Clinical success is highest when minimal disease is present elsewhere.

DETERMINANTS OF PATENCY

The most important determinants of long-term patency of a vessel treated with angioplasty are the vascular distribution of the lesion and the extent of vascular disease. In broad terms, better patency is seen in larger vessels, short-segment disease, and cases in which minimal vascular disease is present elsewhere. In addition, the control of cardiovascular risk factors improves the long-term outcome.

When the long-term benefits of percutaneous angioplasty are evaluated, it must be remembered that clinical recurrence of symptoms is often due to progression of disease in an area other than that treated. In addition, the opportunity usually exists to re-treat the same segment, with prolongation of clinical benefit at moderate additional cost and morbidity. Therefore, comparative long-term patency rates between percutaneous and conventional surgical therapies must be evaluated with consideration of the total cost, time lost, and morbidity. Even in cases in which long-term benefit from a single percutaneous procedure may be less than that from the corresponding surgical procedure, retreatment will often result in lower total cost and morbidity, with equal or superior clinical benefit.

SPECIFIC VASCULAR LESIONS

The decision whether to perform a surgical bypass or revascularize a segment with percutaneous techniques is a complicated one. All the previously mentioned factors must be considered along with the general medical status of the patient. In addition, the availability of qualified vascular surgeons and interventionalists and the specific skills of each must be weighed. The local standard of care will vary according to the training and experience of the practitioners in the community. In the most general terms, surgical bypass is best untaken in patients with advanced vascular disease who are reasonable surgical risks. Percutaneous techniques have their greatest application in less advanced disease and in those patients who are poor operative risks.

The following sections discuss specific guidelines for percutaneous angioplasty in each vascular distribution. In each section there is a brief overview of the clinical indications for therapy. Clinical success will be defined in each case. The overview also briefly discusses the surgical alternatives to the percutaneous procedures. Each type of vascular lesion will then be classified into one of four categories as defined below. Any lesions for which percutaneous therapy is contraindicated will be listed in each section.

Lesion Categories

Category 1

Category 1 lesions are those for which balloon angioplasty alone is the procedure of choice. Treatment of these lesions results in a high technical success rate and will generally result in complete relief of symptoms or normalization of pressure gradients.

Category 2

Category 2 lesions are well-suited for angioplasty. Treatment results in complete relief of or significant improvement in symptoms, pulses, or pressure gradients. This category includes lesions treated with percutaneous procedures that will be followed by surgical bypass to treat multilevel vascular disease.

Category 3

Category 3 lesions are amenable to percutaneous therapy, but because of disease extent, location, or severity, percutaneous treatment has a moderate chance of initial technical success or long-term benefit compared with surgical bypass. However, PTA may be performed, generally because of patient risk factors or because of the lack of suitable bypass material.

Category 4

Category 4 lesions are found with extensive vascular disease. Percutaneous therapy has a very limited role because of a low technical success rate or poor long-term benefit. In very high-risk patients, or when no surgical procedure is applicable, PTA may have some place.

Brachiocephalic Angioplasty

When to treat stenotic lesions of the brachiocephalic vessels is controversial. The complexity of the extracranial brachiocephalic vasculature and the many potential collateral vessel pathways make the significance of a specific stenosis difficult to predict. Multiple vessels may be diseased, further complicating the decision of which or how many vessels to treat.

The symptoms that most commonly lead to arteriographic evalua-

tion of the brachiocephalic vessels are ischemic stroke, transient ischemic attack, amaurosis fugax, dizziness, vertigo, and arm claudication. Asymptomatic carotid bruit, indicating severe stenosis, may also be depicted on duplex ultrasound scans.

Surgical treatment for occlusive disease of the brachiocephalic vessels includes a variety of intra- and extrathoracic procedures, including carotid endarterectomy, carotid-subclavian bypass, axillary-axillary bypass, and vertebral artery ligation. Carotid endarterectomy has a very low morbidity, but more complex surgical revascularization may be associated with 5%–10% mortality and a serious complication rate of 15%–25%.

A limited number of series on angioplasty of the subclavian and brachiocephalic arteries has been reported. Pooling the data from these yields a technical success rate of 88% and a complication rate of 5% in 182 procedures. The long-term clinical success has been reported in 46 patients, with an 80% patency rate at an average of 2 years follow-up. This technique has most often been applied in patients presenting with "subclavian steal syndrome." The very high success rates and low morbidity make percutaneous therapy the preferred procedure.

Because of the very low morbidity associated with carotid endarterectomy when performed by experienced surgeons, carotid angioplasty should be limited to hemodynamically significant lesions with difficult surgical access, such as at the origin of the common carotid artery or the upper cervical carotid artery. Lesions in these regions are best treated during a surgical procedure to allow control of debris related to the procedure. The procedure should be limited to patients with definite neurologic or visual symptoms attributable to that vascular distribution. Treatment for asymptomatic lesions is controversial, and no recommendation can be made at this time. While percutaneous carotid angioplasty has been reported, the risk of ischemic neurologic injury is unknown, and therefore it should not be performed outside controlled clinical trials. Similarly, while vertebral angioplasty has been performed with few complications to date, this procedure should be undertaken only by individuals with experience in complex angioplasty.

Subclavian or brachiocephalic angioplasty should be limited to stenoses that produce specific vertebrobasilar symptoms (vertigo, gait disturbance, or amaurosis fugax), severe arm claudication, or a combination of these symptoms. This should be supported by objective evidence of diminished flow. A secondary indication is to provide inflow to extraanatomic grafts, such as axillofemoral grafts or internal mammary coronary grafts.

Carotid or vertebral occlusions are contraindications to angioplasty.

Clinical Success

Clinical success for carotid angioplasty is defined as resolution of presenting neurologic or visual ischemic symptoms.

Clinical success for brachiocephalic or subclavian angioplasty is defined as (*a*) complete resolution of or substantial improvement in ischemic symptoms believed secondary to steal phenomenon from cerebral circulation and (*b*) resolution or substantial improvement of arm claudication or weakness, with a decrease in the brachial artery pressure differential to less than 10 mm Hg.

Lesion Classification

Category 1.—Category 1 lesions of the subclavian and brachiocephalic arteries are stenoses that are isolated, 3 cm or less in length, and with plaque that does not involve the right carotid artery or either vertebral artery orifice.

Category 2.—Category 2 lesions are defined separately for the subclavian and brachiocephalic, carotid, and vertebral arteries. Category 2 lesions of the subclavian and brachiocephalic arteries include (*a*) stenoses that are isolated, greater than 3 cm in length, and with plaque that does not involve the right carotid artery or either vertebral orifice; (*b*) stenoses dilated to provide inflow to surgical grafts; and (*c*) bypass graft anastomotic stenoses in cases in which the risk of cerebral embolization is low.

Category 2 lesions of the carotid artery are atherosclerotic, with difficult surgical access (at the origin of the common carotid artery or high cervical internal carotid artery) and with surgical exposure and control of the vessel.

Category 2 lesions of the vertebral arteries are focal proximal lesions that require minimal manipulation.

Category 3.—Category 3 lesions of the subclavian and brachiocephalic arteries are short-segment occlusions (less than 5 cm) that often involve the origin of the subclavian and brachiocephalic arteries.

Category 4.—Category 4 lesions of the subclavian and brachiocephalic arteries are stenoses that involve the origin of the carotid and vertebral arteries or long-segment occlusions (greater than 5 cm).

Renal Angioplasty

Renovascular hypertension is difficult to diagnose. Both essential hypertension and renal artery stenoses are common in the adult population, and it has been difficult to identify the 4% of the hypertensive population that has a renovascular basis for their disease. There is no standard algorithm for noninvasive screening of the hypertensive population. Instead, evaluation for the presence of renal artery stenosis is usually prompted by sudden onset or worsening of hypertension, diastolic hypertension in a young person, hypertension that responds only to drugs that block the renin-angiotensin system, or hypertension in the presence of a flank bruit. The discovery of a hemodynamically significant renal artery stenosis in this population constitutes an indication for therapeutic intervention.

Another subgroup of patients who can benefit from renal artery revascularization are those who have deterioration of renal function with evidence of renal ischemia. Although criteria for pursuing arteriographic evaluation of this group are poorly defined, patients with worsening renal function and a concomitant decrease in the size of one or both kidneys may benefit from treatment. Response to balloon dilation is greatest in cases in which the serum creatinine level is less than 3.0 mg/dL (265 μmol/L) and there are bilateral stenoses.

The greatest success with renal angioplasty has been in patients with fibromuscular dysplasia, with improvement or cure in over 90% of patients with medial involvement. Atherosclerosis will also respond well to PTA when the stenosis does not involve the

aortic wall and renal artery ostium. Postoperative stenoses in native kidneys or transplants will respond to balloon dilation, but use of high-pressure balloons may be required, and patency may be shorter than that for other lesions. However, because surgical repair is often difficult in these patients and the outcome is uncertain, percutaneous therapy is preferred.

Angioplasty of renal artery occlusions has a low rate of technical success, and surgery may be preferred in patients with low operative risk. Dilation of vessels arising from aneurysmal or severely diseased aortic segments may be associated with higher rates of embolization, and balloon angioplasty has a limited role.

Clinical Success

Clinical success in the treatment of renovascular hypertension is defined in terms of cure and improvement. Cure is defined as diastolic blood pressure of less than 90 mm Hg without administration of antihypertensive medication. Improvement is defined as (*a*) diastolic blood pressure less than 90 mm Hg with administration of equal or reduced doses of medication or (*b*) diastolic blood pressure greater than 90 mm Hg but less than 110 mm Hg with at least a 15-mm decrease from measurements obtained before angioplasty while the patient is receiving a similar or decreased medication regimen.

Clinical success for renal failure is defined as a decrease in serum creatinine to normal levels or 20% below levels obtained before angioplasty.

Lesion Classification

Category 1.—Category 1 lesions include those that result from fibromuscular renal artery disease, renal artery transplant stenosis, and atherosclerosis. Atherosclerotic lesions are unilateral, short (less than 3 cm) stenoses that do not involve the renal artery ostium.

Category 2.—Category 2 lesions are (*a*) atherosclerotic bilateral stenoses that do not involve the renal artery ostia, (*b*) postoperative anastomotic and non-anastomotic stenoses that complicate surgical revascularization, or (*c*) stenoses associated with worsening renal function and decreasing renal mass in patients with a serum creatinine level of less than 3.0 mg/dL (265 μmol/L).

Category 3.—Category 3 lesions are (*a*) atherosclerotic stenoses involving the renal artery ostia; (*b*) non-atheromatous lesions involving the proximal renal arteries, including neurofibromatosis, Takayasu arteritis, and abdominal coarctation (midaortic syndrome); (*c*) stenoses associated with worsening renal function, that is, in patients with unilateral stenosis, serum creatinine levels greater than 3.0 mg/dL (265 μmol/L), and for whom dialysis is imminent; or (*d*) renal artery occlusions.

Category 4.—Category 4 lesions are renal artery stenoses in vessels that arise from an aneurysmal or severely diseased aortic segment or stenoses associated with renal artery aneurysm.

Visceral Angioplasty

Angioplasty of the nonrenal visceral vessels is an unusual procedure because of the rarity of true abdominal angina. Symptoms include chronic postprandial pain, nausea, vomiting, and diarrhea. Invariably there is weight loss, and patients often develop a fear of eating. However, these symptoms are not specific, and other gastrointestinal causes must be excluded. Many of these patients undergo angiography as a last resort, after an exhaustive and negative evaluation. The presence of a stenosis or the occlusion of a single vessel is generally not sufficient to require treatment as collateral flow may allow patients to be asymptomatic. Usually, two visceral vessels must be diseased before the patient will have symptoms that warrant therapy. Occasionally, a patient will have acute symptoms and will not be operable because of other risk factors. These patients may benefit from percutaneous therapy.

Arcuate ligament compression of the celiac or other vessels is a contraindication for PTA.

Clinical Success

Clinical success for visceral angioplasty is defined as complete or substantial relief of symptoms of abdominal angina.

Lesion Classification

Category 1.—There are no lesions for which angioplasty is clearly the procedure of choice, as there are too few patients reported in the literature to support that conclusion. This may change as experience increases.

Category 2.—Category 2 lesions are short-segment (less than 3 cm) atherosclerotic or fibromuscular stenoses of the celiac or superior mesenteric arteries that do not involve the origin.

Category 3.—Category 3 lesions are long stenoses (greater than 3 cm) of the celiac or superior mesenteric arteries that do not involve the origins or ostial lesions of the superior mesenteric or celiac arteries.

Category 4.—Category 4 lesions are occlusions of visceral vessels, inferior mesenteric artery stenoses or occlusions, or lesions in patients with clinical evidence of acute mesenteric ischemia.

Aortic Angioplasty

Percutaneous angioplasty of the infrarenal abdominal aorta has been performed on small numbers of patients with excellent results. Patients with severe focal stenosis in an infrarenal aorta with otherwise minimal disease have the best clinical results. Treatment of patients with severe diffuse atherosclerotic disease of the aorta has not been advocated. The dilation of stenoses greater than 4 cm in length has been reported in small numbers of patients, and while the initial results have been encouraging, the data supporting the percutaneous treatment of long-segment aortic stenosis are insufficient to recommend it categorically.

Treatment of aortic stenosis may be performed in those patients with claudication of the legs or buttocks. Many of the patients may also have impotence. Patients with atheroembolic symptoms (blue toe syndrome) might also benefit, but the data on the percutaneous therapy in this group are very limited.

Clinical Success

Clinical success for abdominal aortic angioplasty is defined as complete or substantial relief of symptoms, alleviation of the systolic pressure gradient across the lesion, or the normalization of femoral pulses.

Lesion Classification

Category 1.—Category 1 lesions are short-segment (less than 2 cm) steno-

ses of the infrarenal abdominal aorta, with minimal atherosclerotic disease of the aorta otherwise.

Category 2.—Category 2 lesions are medium-length (2–4 cm) stenoses of the infrarenal abdominal aorta, with mild atherosclerotic disease of the aorta otherwise.

Category 3.—Category 3 lesions are (*a*) long-segment (greater than 4 cm) stenoses of the infrarenal abdominal aorta, (*b*) aortic stenoses with atheroembolic disease (blue toe syndrome), or (*c*) medium-length (2–4 cm) stenoses of the infrarenal abdominal aorta, with moderate to severe atherosclerosis of the aorta otherwise.

Category 4.—Category 4 lesions are aortic occlusions and aortic stenoses associated with an abdominal aortic aneurysm.

Iliac Angioplasty

PTA has proved to be an effective technique for treatment of symptomatic atherosclerotic disease in the iliac arteries, with 5-year patency rates (80%–90%) approaching those of surgical bypass procedures. The success of iliac angioplasty is dependent on many factors, including the lesion length, presence of occlusion or stenosis, adequacy of distal runoff, and the presence of dense calcification in the lesion. Overall technical success of 90%–95% can be anticipated with proper selection of patients with category 1 or 2 stenoses. Patency at 3–5 years of 80%–85% for ideal short-segment lesions can be expected, with patency decreasing to approximately 75% for stenoses in category 3. Although longer lesions can be successfully dilated, the long-term patency is lower, and surgical treatment would be preferred in patients with low surgical risk factors.

Total occlusion of an iliac artery has been considered a contraindication to PTA because of the risk of distal embolus or contralateral embolization after dislodgement of atheromatous material or clot. While recent reports are more optimistic concerning percutaneous therapy, they have failed to place sufficient emphasis on the role of thrombolytic therapy prior to balloon angioplasty. Before percutaneous therapy is attempted on total iliac occlusions, a trial of intraarterial thrombolytic therapy should be made. The lesions discussed below will be categorized according to their appearance *after* thrombolytic therapy. Similarly, all iliac occlusions should be considered for a trial of thrombolytic therapy unless the patient's medical history clearly indicates the lesion is chronic.

Several recent studies have defined a subgroup of patients with unilateral blue toe syndrome and hemodynamically significant stenoses for whom percutaneous therapy has been beneficial. While treatment of these lesions should be approached with care, atheroemboli should not be considered a contraindication to angioplasty.

Although the presence of dense calcification increases the difficulty of angioplasty, these lesions can be successfully dilated with newer balloon technology. Due to the increased risk of arterial rupture, aneurysms adjacent to stenoses are best treated surgically.

PTA is indicated in patients with appropriate lesions as defined below and clinical symptoms of peripheral vascular insufficiency. These symptoms include claudication that limits performance of daily activities, ischemic rest pain, gangrene, ischemic ulceration or tissue loss, or atheroembolism (blue toe syndrome).

Clinical Success

Clinical success in the iliac segment is defined as relief of or substantial improvement in symptoms, alleviation of the systolic gradient across the lesion, or the normalization of the femoral pulse.

Lesion Classification

Category 1.—Category 1 lesions are stenoses less than 3 cm in length that are concentric and noncalcified.

Category 2.—Category 2 lesions are stenoses 3–5 cm in length or calcified or eccentric stenoses less than 3 cm in length.

Category 3.—Category 3 lesions are stenoses 5–10 cm in length or chronic occlusions less than 5 cm in length after thrombolytic therapy.

Category 4.—Category 4 lesions are (*a*) stenoses greater than 10 cm in length, (*b*) chronic occlusions greater than 5 cm in length after thrombolytic therapy (*c*) extensive bilateral aortoiliac atherosclerotic disease, or (*d*) iliac stenoses in patient with abdominal aortic aneurysm or other lesions requiring aortic or iliac surgery.

Femoropopliteal Angioplasty

More than any other vascular segment, technical success and patency in the femoropopliteal artery depend on the characteristics of the lesion treated. Recent developments in the treatment of femoropopliteal disease hold promise for improvement in the technical success and patency rates of percutaneous therapy. However, until longer follow-up is available on results with many of the newer devices, therapeutic decisions will continue to rely on the extensive data available on balloon angioplasty and surgical revascularization. The following categorization of the lesions reflects that experience.

The indications for treatment of the femoropopliteal arteries are similar to those in the iliac vessels. Claudication that limits lifestyle, rest pain, and ischemic ulceration are indications for therapy. Atheroembolic disease (blue toe syndrome) caused by unilateral atheroembolic disease that otherwise meets the criteria may be treated percutaneously. Vessels with acute ischemic symptoms and angiographic evidence of fresh thrombus generally should not be dilated directly. Thrombolytic therapy may be appropriate. Any lesions that are treated with thrombolytic therapy should be categorized after therapy is complete.

Clinical Success

Clinical success in the femoropopliteal segment is defined as relief of or substantial improvement in symptoms, increase in the ankle-brachial index of at least 0.15, and/or normalization of the popliteal pulse, thigh/calf pulse volume recording, or Doppler pressure. For category 4 lesions, pressure or pulse may not return to normal, and success is defined as relief of or substantial improvement in symptoms.

Lesion Classification

Category 1.—Category 1 lesions are single stenoses or occlusions, up to 3 cm in length, that are not at the origin of the superficial femoral artery or the distal portion of the popliteal artery.

Category 2.—Category 2 lesions are (*a*) single stenoses or occlusions, 3–10 cm in length, not involving the distal

popliteal artery; (*b*) heavily calcified stenoses up to 3 cm in length; (*c*) multiple lesions, each less than 3 cm, that are either stenoses or occlusions; or (*d*) single or multiple lesions in cases in which there is no continuous tibial runoff to improve inflow for distal surgical bypass.

Category 3.—Category 3 lesions are (*a*) single lesions, 3–10 cm in length, involving the distal popliteal artery; (*b*) multiple focal lesions, each 3–5 cm, that may be heavily calcified, or (*c*) single lesions, either stenoses or occlusions, with a length greater than 10 cm.

Category 4.—Category 4 lesions are complete common and/or superficial femoral artery occlusions or complete popliteal and proximal trifurcation occlusions.

Infrapopliteal Angioplasty

The recent advances in catheter and guide wire technology have allowed safe and efficacious application of angioplasty techniques in the anterior tibial, posterior tibial, and peroneal arteries. However, the risks are somewhat greater in these vessels than in the larger, more proximal arteries. The indications for intervention in these vessels are more limited and should be applied judiciously. It is unusual for short-segment stenoses or occlusions to occur as isolated disease in these vessels. Because of the advanced stage of the disease at presentation, the most common symptoms are ischemic rest pain, ischemic ulceration, or gangrene. Generally, these procedures are only indicated in this population with severe symptoms. However, severe claudication that prevents minimal ambulation may be an acceptable indication, particularly if more than one tibial vessel is to be treated. Mild to moderate claudication generally is not an indication for treatment of these vessels; treatment at other levels generally relieves the symptoms, and the risk of occlusion is unacceptably high for this group of patients.

Clinical Success

Clinical success in the infrapopliteal vessels is defined as resolution of or significant improvement in ischemic rest pain or healing of ischemic ulcerations after completion of treatment including any accompanying proximal percutaneous or surgical therapy.

Lesion Classification

Category 1.—Category 1 lesions are single focal stenoses of tibial or peroneal vessels that are 1 cm or less in length.

Category 2.—Category 2 lesions are (*a*) multiple focal stenoses of tibial or peroneal vessels, each 1 cm or less in length; (*b*) one or two focal (1 cm or less) stenoses at the tibial trifurcation; or (*c*) tibial or peroneal stenosis treated at femoropopliteal bypass.

Category 3.—Category 3 lesions are moderate-length (1–4 cm) stenoses or moderate length (1–2 cm) occlusions of tibial or peroneal vessels or extensive stenoses of the tibial trifurcation.

Category 4.—Category 4 lesions are tibial or peroneal occlusions longer than 2 cm or diffusely diseased tibial or peroneal vessels.

Angioplasty of Bypass Grafts

Balloon angioplasty is a safe and effective means of treating many stenoses that develop in or near bypass grafts. While there is variable long-term patency according to the underlying disease process, dilation can often extend the life of grafts for years. These patients may have slowly recurring ischemic symptoms, but they are often asymptomatic. Their lesions are often discovered at routine follow-up, with diminished pulses or noninvasive vascular testing results. Generally, the ankle-brachial index will decrease by 0.2, the pulse volume recording will drop by 5 mm Hg, or the flow velocity within the graft will decrease. Another subset of patients present with acute graft occlusion, and after treatment with a thrombolytic agent, the underlying stenosis is discovered.

While the pathologic features of these stenoses may vary to some degree, myointimal hyperplasia is the most common cause. This may occur within the graft or at the anastomosis. The stenosis usually occurs within the 1st year (77% of cases). Hypertrophy of a venous valve can also cause stenosis and is usually seen in the 1st year. Graft failure or occlusion within the 1st week after surgery usually indicates a technical problem that should be treated with a second operation. Graft failure after the 1st year may be due to either myointimal hyperplasia or recurrent atherosclerosis, either above or below the bypassed segment. Vein grafts usually respond well to balloon dilation, and percutaneous treatment of short lesions is usually indicated.

Atherosclerotic lesions that occur within native vessel above or below the bypass are not included here and therapy should be decided with the categories from the appropriate vascular distribution. The lesions that are categorized below are assumed to have developed after the perioperative period.

Lesion Classification

Category 1.—Category 1 lesions are focal stenoses of the distal anastomosis of a femoropopliteal or femorotibial vein bypass or focal stenoses of the proximal or distal anastomosis of a saphenous vein aortorenal bypass.

Category 2.—Category 2 lesions are (*a*) focal stenoses of the proximal anastomosis of a saphenous vein femoropopliteal or femorotibial bypass, (*b*) short-segment (up to 5 cm) stenoses occurring within vein bypasses, (*c*) stenoses associated with aortobifemoral or aortobi-iliac bypasses, or (*d*) stenoses associated with prosthetic extraanatomic bypasses.

Category 3.—Category 3 lesions are moderate-length (greater than 5 cm) stenoses of vein bypass grafts.

Category 4.—Category 4 lesions are long-segment (greater than 10 cm) stenoses in vein bypass grafts or stenoses associated with anastomotic aneurysms.

Intraoperative Angioplasty

Recently, there has been a growing tendency to perform vascular interventional procedures in operating rooms. Most of these procedures can be done more quickly, economically, and safely in angiography suites with percutaneous techniques and local anesthesia. The routine use of surgical cutdown and general or regional anesthesia adds considerably to the expense and risk of the procedure, without any additional benefit. For these reasons, the routine use of surgical suites for the performance of vascular interventional procedures is not warranted.

However, intraoperative procedures are occasionally required and are indicated in certain circumstances. The most common reason is limited percutaneous vascular access, such as with lesions proximal or dista1 to an occluded segment that is simultaneously treated by means of bypass or endarterectomy. Lesions for which percutaneous access might introduce an unacceptable risk, such as those in the carotid artery, are another indication for surgical access for therapy. In each case, the risks of a separate percutaneous procedure must be weighed against that of a combined procedure, particularly when the combined procedure may be performed with inferior imaging equipment in an operating room.

Outpatient Angioplasty

Outpatient angioplasty has been reported in a small number of patients. While there have been few complications to date, the total number of patients reported is small. There are serious problems with the generalized use of the procedure on an outpatient basis. First, only a small number of patients will have the support system required to closely monitor symptoms after the procedure. While serious complications are unusual, many can be disastrous unless immediately recognized. Delay in appropriate therapy may result in limb or organ loss. In addition, the initial ambulation of the patient after the procedure should be carefully supervised. It is preferred that these procedures be performed in an acute care hospital, where immediate operative intervention is possible and where these procedures can be entered into the hospital's quality assurance program and monitored appropriately. For these reasons, the committee feels that all patients undergoing percutaneous vascular intervention should be observed in an acute care environment overnight.

New Devices for Vascular Intervention

A variety of new devices for vascular intervention have been developed in recent years, in an attempt to increase the technical success rate of or extend the patency resulting from percutaneous vascular procedures. Many of these devices are considerably more expensive than balloon catheters, and may require a high level of expertise for a successful result. Procedures with these devices should be directly compared with conventional balloon procedures and/or the corresponding surgical procedures in trials prior to broad clinical use. These devices should be selected and used on the basis of proved benefit.

In this publication, new interventional devices are not specifically recommended nor discouraged. The guidelines are designed to outline those patients who should undergo percutaneous therapy and those who should not. How new devices fit into practice has not yet been shown with the available scientific data, and no recommendation on their use can be made at this time.

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Brachiocephalic Angioplasty

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