Percutaneous Interventions for Lower Extremity Peripheral Vascular Disease

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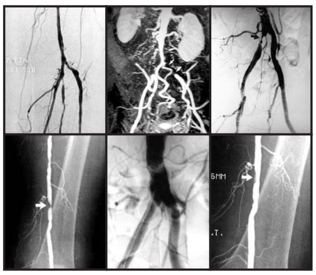
Peripheral vascular disease of the lower extremities is an important cause of morbidity that affects up to 10 million people in the United States. The primary care physician can easily identify patients who are at risk for the disease with a questionnaire and a relatively simple test—the ankle brachial index. More than 70 percent of patients diagnosed with the disease remain stable or improve with conservative management. Those who do not improve may undergo contrast angiography or magnetic resonance angiography, which may be used in planning for surgery or percutaneous intervention. Surgical bypass is the gold standard for extensive vascular occlusive disease, but endovascular interventions, including percutaneous transluminal angioplasty and stent placement, are being used more frequently, particularly in patients with significant comorbid conditions. **(Am Fam Physician 2001;64:1965-72.**



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Peripheral vascular disease (PVD) is a common condition with variable morbidity affecting mostly men and women older than 50 years. Based on incidence rates extrapolated to today's increasingly aging population, PVD affects as many as 10 million people in the United States.[1] As the population ages, the family physician will be faced with increasing numbers of patients complaining of symptoms of lower extremity PVD. Nearly one in four of the approximately 60,000 people screened annually through Legs for Life, a nationwide screening program, are determined to be at moderate to high risk of lower extremity PVD and are referred to their primary care physicians for diagnosis (data collected by the Society of Cardiovascular and Interventional Radiology).[2]

Intermittent claudication (pain while walking that abates during rest) is the most common symptom. Other symptoms include numbness or weakness in the legs, aching pain in the feet or toes while at rest, nonhealing ulcers on the leg or foot, cold legs or feet, and skin color changes of the legs or feet (particularly dependent rubor). Some patients, however, are asymptomatic.

More than 70 percent of patients experience no change or have an improvement in symptoms after five to 10 years of conservative management.[1] Twenty to 30 percent of patients develop more severe symptoms that require intervention. Fewer than 10 percent of patients require amputation.[1]

In most cases, the presence of PVD is a sign of systemic atherosclerosis, which puts these patients at high risk of stroke, myocardial infarction, and cardiovascular death. Risk factors for PVD include smoking, hypertension, hyperlipidemia, diabetes, family history of cardiac or vascular disease, obesity, and sedentary lifestyle.

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Diagnosis

Although a careful history and physical examination are the first steps to the diagnosis of PVD, they should not be relied on solely.

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ANKLE BRACHIAL INDEX

One of the most useful objective parameters to assess lower extremity arterial perfusion is the ankle brachial index (ABI), a test that can be performed in the physician's office. This study screens for hemodynamically significant disease and helps define its severity. The patient is placed in a supine position, and brachial and ankle systolic pressures are obtained. The protocol involves taking routine bilateral upper extremity pressure readings. The higher of the systolic pressures is used to calculate the ABI. (A lower arm pressure may indicate PVD of that arm.) Next, the cuff is placed on the lower right calf. The Doppler (usually required because ankle blood pressure may be inaudible with a stethoscope) is placed behind the medial malleolus to obtain the posterior tibial (PT) systolic pressure and then placed on the top of the foot to obtain the dorsalis pedis (DP) systolic pressure. The ABI is calculated by dividing the highest ankle systolic pressure (DP or PT) by the highest systolic pressure from either arm. The process is then repeated on the left ankle.

ABIs less than 1.0 are abnormal. The majority of patients with claudication have ABIs ranging from 0.30 to 0.90. Pain at rest or severe occlusive disease typically occur with an ABI less than 0.50. Indexes less than 0.20 are associated with ischemic or gangrenous extremities.

In diabetic patients with heavily calcified vessels, the arteries are frequently noncompressible. This results in an artifactually elevated ankle pressure, which can cause underestimation of disease severity. In these patients, toe pressure determinations more accurately reflect perfusion.[3] Noninvasive measures such as pulse volume recording (a subjective flow analysis performed in the vascular laboratory), duplex ultrasound scanning and exercise testing can be used to confirm the existence of vascular occlusive disease.

ANGIOGRAPHY

Standard angiography and magnetic resonance angiography (MRA) can provide anatomic definition of the occlusive disease. Whether to use MRA or angiography depends on several conditions, including certain patient factors, availability, and physician preference. MRA is one fourth as expensive as angiography, is noninvasive, and uses no

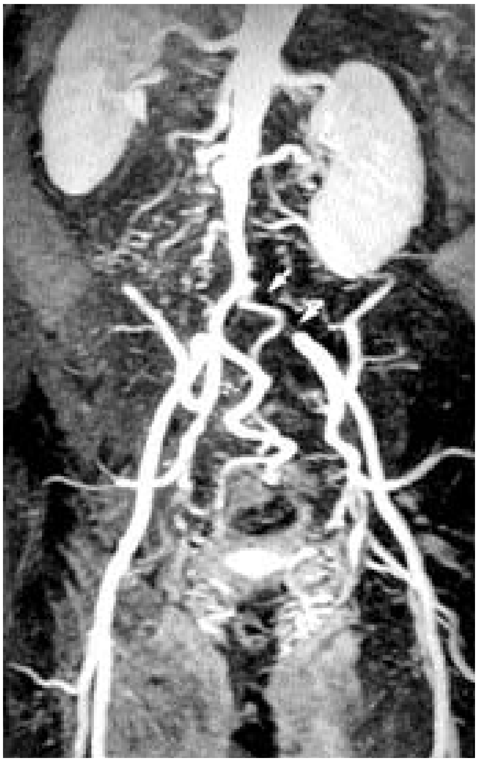

FIGURE 1. Abdominal magnetic resonance angiography. Distal abdominal aortic and bilateral common iliac artery occlusions appear as signal voids *(arrows denote left common iliac occlusion)*. The tortuous vessel that courses over the area of right common iliac signal void is an enlarged inferior mesenteric artery, a collateral pathway supplying the external iliac artery via the internal iliac artery.

ionizing radiation or contrast dye *(Figure 1)*. MRA can be beneficial in preoperative planning of lower extremity surgical revascularization. However, it can be challenging to interpret, because it is more susceptible to confounding artifacts such as patient motion, surgical clips, indwelling stents, and prostheses. Additionally, MRA is contraindicated in patients who have pacemakers and orbital metallic foreign bodies. In patients who may require angioplasty as a first-line treatment, angiography offers the possibility of diagnosis and treatment during a single procedure.

Treatment Options

Conservative treatment options, including cessation of tobacco use, exercise programs, and modifications in lipoprotein and cholesterol abnormalities, are the first line of defense against PVD. *Table 1* compares the use of angioplasty with bypass surgery in the treatment of PVD.

MEDICATIONS

Two prescription medications are approved by the U.S. Food and Drug Administration for treating intermittent claudication: pentoxifylline (Trental), an oral methylxanthine derivative, and cilostazol (Pletal), a phosphodiesterase III inhibitor. A recent randomized controlled trial[4] comparing the two drugs found cilostazol to be significantly more effective in improving walking distance than pentoxifylline, which was equivalent to placebo. However, cilostazol is associated with a greater frequency of minor side effects, including headache and diarrhea, and is contraindicated in patients with congestive heart failure.[5] Several drugs with phosphodiesterase III inhibitor activity (such as cilostazol) have shown decreased survival rates compared with placebo in patients with class III or IV failure.[6]

Antiplatelet/antithrombotic therapy also may be considered for use in these patients. Studies have shown that aspirin therapy may modify the natural history of chronic lower extremity PVD.[1] It also has been suggested that use of aspirin may prevent death and disability from stroke and myocardial infarction secondary to underlying disseminated atherosclerosis.[1]

Surgical bypass of severely occluded vessels has been considered the gold standard for use in symptomatic patients who do not respond to more conservative treatments.

TABLE 1

Angioplasty vs. Bypass Surgery for PVD of the Lower Extremities

Angioplasty

Advantages
- Offers faster recovery
- Requires shorter hospital stay
- Requires no general anesthesia
- Maintains all options for extremity revascularization
- Allows for preservation of the saphenous veins for future use (for extremity or coronary artery bypass)
- May be repeated if necessary
- May be combined with surgery to improve inflow or outflow of surgically placed grafts

Disadvantages
- Lower primary patency rates
- Reinterventions due to restenosis may be necessary
- Of limited use in the presence of multiple-level stenoses
- Cost-benefit ratio for severe advanced PVD is debatable

Bypass surgery

Advantages
- Considered the gold standard
- Has good long-term patency
- May be preferable to treat multiple stenoses if venous conduit available

Disadvantages
- A higher rate of morbidity
- Potential systemic complications
- Typically requires general anesthesia
- Requires harvesting of saphenous veins and upper extremity veins, precluding their use for coronary artery bypass

PVD = peripheral vascular disease.

A recent randomized controlled trial found that cilostazol was superior to pentoxifylline for treating intermittent claudication.

PERCUTANEOUS REVASCULARIZATION

Rapid advances in percutaneous revascularization techniques and equipment have significantly changed the patterns of vascular reconstruction, particularly when lifestyle modifications and drug therapies fail.[7]

For purposes of revascularization, PVD is considered in terms of inflow (aortoiliac) and outflow (infrainguinal) occlusive disease. In both cases, surgical revascularization represents the gold standard against which the results of percutaneous revascularization with angioplasty and stents are compared. Increasingly, combined surgical bypass and percutaneous endovascular treatment by the vascular/interventional radiologist, vascular surgeon, or interventional cardiologist are being used to optimize patient outcome while minimizing morbidity.

AORTIC REVASCULARIZATION

The iliac arteries are technically among the easiest vessels to approach percutaneously and are the largest peripheral lower extremity vessels with the highest flow rates. These factors optimize the outcome of percutaneous transluminal angioplasty (PTA) and stenting *(Table 2)*. Surgical bypass has a durable high rate of patency, reported as 93 percent at 42 months in a recent study,[8] but it is a major surgical procedure with potential for systemic complications in patients with preexisting significant comorbid conditions.

Before the first report of metallic stent deployment in peripheral arteries of humans in the late 1980s, angioplasty was the only means of percutaneous revascularization. A meta-analysis[9] of six PTA studies (1,300 patients) has established the high technical success of PTA for aortoiliac occlusive disease, with a combined immediate technical success for stenoses and occlusions of 91 percent.

Long-term success rates of PTA vary from 53 to 70 percent at five years, depending on the severity of disease and which diseased blood vessel was treated.[10]

In a quality-of-life study[11] of patients treated with PTA for iliac artery occlusive disease, walking distance improved by 20 percent 24 months after PTA. Physical functioning also improved, along with a significant decrease in pain.

TABLE 2
Characteristics of Best Candidates for Angioplasty and Stenting

Stenosis, rather than occlusion
Short-segment disease
Noncalcified lesions
Concentric stenoses
Large-vessel involvement
No coronary comorbidity or treated coronary disease
No diabetes
Claudication
Normal renal function
Good run-off (i.e., patent vessels distal to treated lesion)

NOTE: *Patients who have had their saphenous veins harvested for coronary artery bypass may be better candidates for percutaneous transluminal angioplasty than for synthetic bypass grafting, depending on the lesion and location.*

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The introduction of metallic stents has improved outcome in patients in whom PTA results were suboptimal. This technique has also opened the way for percutaneous treatment of complex, long-segment stenoses and occlusions, and the treatment of aortic bifurcation occlusive disease. Initial technical success of stent placement in aortoiliac occlusive disease is 96 percent, higher than that of PTA alone *(Figure 2)*.[9] Primary patency rates are 63 percent, and secondary patency rates are 86 percent at five years, respectively, approaching that of surgical bypass.[12]

Aortic bifurcation reconstruction, once the sole realm of surgical bypass, is now performed successfully using percutaneous techniques. In one study[12] that used bilateral iliac stents for treatment of aortic bifurcation disease with at least 12 months of follow-up, primary and secondary angiographic patency rates were attained in 89 and 93 percent of 28 patients, respectively—again approaching that of surgical bypass.[13]

In a quality-of-life study[11] of patients treated with primary stent placement for iliac artery occlusive disease, walking distance improved by 26 percent 24 months after treatment. Also, physical functioning improved and pain decreased.

The Veterans Administration Cooperative Study Group[14] found that, in a group of patients with claudication randomized to bypass surgery or angioplasty, no significant outcome difference was found at four years, but the early mortality rate was better with angioplasty. Angioplasty failure did not preclude performing subsequent bypass grafting or increase the rate of limb loss.[14] In a Swedish study[15] comparing angioplasty with surgery, significantly shortened length of hospital stay was found in patients undergoing angioplasty for claudication or chronic limb ischemia, compared with a surgery group. Similar success and complication rates were found at one year.[15] In a recent literature review and multivariate sensitivity analysis[16] evaluating quality adjusted life years as the main effectiveness measure, a Dutch-American study group favored angioplasty as the first-line treatment modality for claudication.

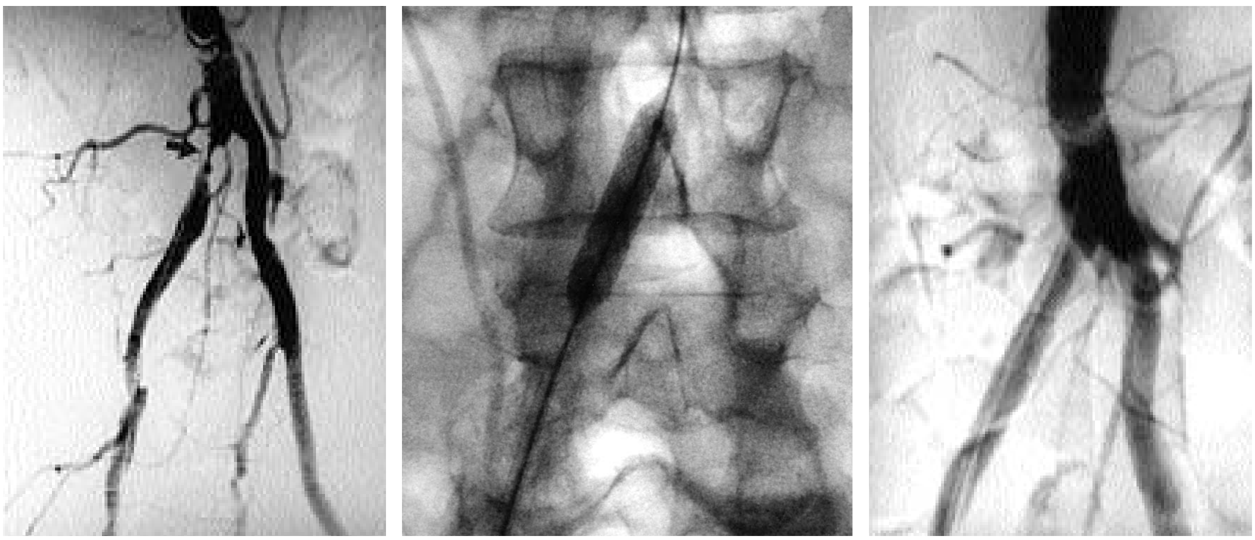

FIGURE 2. Digital subtraction pelvic arteriogram. *(Left)* There is a severe stenosis of the right common iliac artery *(arrow)*. *(Center)* Image hold. Deployment of a Palmaz stent mounted on an angioplasty balloon, seen in its fully expanded state. *(Right)* Magnification digital subtraction arteriogram centered at the aortic bifurcation. Following stenting, the right common iliac artery is widely patent.

INFRAINGUINAL REVASCULARIZATION

The role of infrainguinal angioplasty and stenting in the treatment of lower-extremity ischemia is more controversial than PTA and stenting for aortoiliac occlusive disease. Because of the small size of the infrainguinal vessels above and below the knee, dissections are more likely to be flow-limiting, spasm is more common, and relatively mild intimal hyperplasia or recoil of treated lesions may lead to recurrence of clinical symptoms. In contrast, infrainguinal surgical bypass carries a lower rate of morbidity than iliac bypass and retains a high patency rate.[17] Although percutaneous revascularization plays a less prominent role in the infrainguinal vasculature than in the aortoiliac system, it remains attractive as a minimally invasive alternative to surgical bypass, requiring shorter hospital stays and permitting faster recovery.

FIGURE 3. Lower extremity arteriogram at the level of the distal thigh. *(Left)* There is mild diffuse superficial femoral artery disease with a focal severe stenosis at the adductor canal *(arrow)*. *(Right)* Lower extremity arteriogram with magnification at the level of the distal thigh following percutaneous transluminal angioplasty with a 6 mm balloon. The angiographic appearance is significantly improved, with only mild residual stenosis *(arrow).*

Although dilatation of the common femoral and profunda femoral arteries is sometimes indicated, the most commonly treated femoropopliteal vessels are the superficial femoral artery (SFA) and popliteal artery *(Figure 3)*. The technical success rate of femoropopliteal PTA is high at 93 to 95 percent.[18,19] However, patency or clinical success rates, typically defined by symptomatic and hemodynamic improvement with an increase in ABI of at least 0.10, are considerably lower for the aortoiliac system. Cumulative primary patency for all lesions and all indications ranges from 26 to 45 percent at five years.[10,18,19]

Significantly higher patency rates have been achieved in patients with claudication when compared with those with critical ischemia.[18,19] In one study[20] of patients with femoropopliteal stenoses, successful PTA was reported in 16 to 53 percent of patients at five years, depending on the extent of disease.

In another study[16] comparing surgical with endovascular treatment for 65-year-old men with disabling claudication or chronic critical ischemia and femoropopliteal stenosis or occlusion, PTA increased quality-adjusted life expectancy by two to 13 months and resulted in decreased lifetime expenditures, compared with surgery. This same study used a decision analysis of cost and outcomes to evaluate six strategies for approaching infrainguinal occlusive disease in patients with claudication and with limb-threatening ischemia, including surgery, PTA, or both. In all patients, PTA was the best initial strategy, except in patients with femoropopliteal occlusion rather than stenosis who also had critical ischemia. For those patients, surgery was the best initial strategy.

In the femoral system, stenting has proved useful for treating initial PTA failure or early restenosis (within 90 days) after PTA. Pat-

FIGURE 4. Digital subtraction arteriogram at the level of the calf. *(Left)* Arrows delineate segmental occlusion of the anterior tibial artery and severe focal stenoses of the tibioperoneal trunk and posterior tibial artery. *(Right)* Digital subtraction arteriogram at the level of the calf following angioplasty for limb salvage. The anterior tibial artery occlusion has been recannalized and the tibioperoneal trunk and posterior tibial artery stenoses dilated, yielding a markedly improved angiographic appearance at each location *(arrows)*.

ency following stent placement in the SFA is higher for short-segment lesions. Primary patency rates of 75 to 81 percent at one year have been achieved for lesions averaging less than 4 cm.[21]

Infrapopliteal PTA *(Figure 4)* is generally reserved for use in patients with chronic, limb-threatening ischemia. In one study,[22] the cumulative primary success rates for all patients, including those with stenoses and occlusions and those who underwent concurrent femoropopliteal PTA, was 36 percent at three years. Limb salvage rates were considerably higher at 72 percent.

Further Information

A directory of physicians who perform endovascular techniques, patient information about PVD and details about the Legs for Life National Screening Week for PVD Leg Pain are available through the Society of Cardiovascular & Interventional Radiology, 10201 Lee Hwy., Suite 500, Fairfax, VA 22030; telephone, 800-488-7284; Web site, http://www.scvir.org.

The author indicates that she does not have any conflicts of interest. Sources of funding: none reported.

REFERENCES

1. Weitz JI, Byrne J, Clagett GP, Farkouh ME, Porter JM, Sackett DL, et al. Diagnosis and treatment of chronic arterial insufficiency of the lower extremities: a critical review. Circulation 1996;94:3026-49.
2. Becker GJ, McClenny TE, Kovacs ME, et al. The importance of increasing public and physician awareness of peripheral arterial disease. J Vasc Interv Radiol 2001, (in press).
3. Castañeda-Zuñiga WR, Tadavarthy SM. Interventional radiology. 2nd ed. Baltimore: Williams & Wilkins, 1992.
4. Dawson DL, Cutler BS, Hiatt WR, Hobson RW 2d, Martin JD, Bortey EB, et al. A comparison of cilostazol and pentoxifylline for treating intermittent claudication. Am J Med 2000;109:523-30.
5. U.S. Dept. of Health and Human Services, Food and Drug Administration. FDA approves new treatment for painful leg disorder. FDA talk paper T99-04, January 15, 1999. Retrieved September 2001, from: http://www.fda.gov/bbs/topics/ANSWERS/ANS00935.html.
6. Physicians' desk reference. 54th ed. Montvale, NJ: Medical Economics Company, 2000.
7. Whiteley MS, Ray-Chaudhuri SB, Galland RB. Changing patterns in aortoiliac reconstruction: a 7-year audit. Br J Surg 1996;83:1367-9.
8. Ballard JL, Bergan JJ, Singh P, Yonemoto H, Killeen JD. Aortoiliac stent deployment versus surgical reconstruction: analysis of outcome and cost. J Vasc Surg 1998;28:94-103.
9. Bosch JL, Hunink MG. Meta-analysis of the results of percutaneous transluminal angioplasty and stent placement for aortoiliac occlusive disease. Radiology 1997;204:87-96.
10. Johnston KW. Factors that influence the outcome of aortoiliac and femoropopliteal percutaneous transluminal angioplasty. Surg Clin North Am 1992;72:843-50.
11. Bosch JL, van der Graaf Y, Hunink MG. Health-related quality of life after angioplasty and stent placement in patients with iliac artery occlusive disease: results of a randomized controlled clinical trial. The Dutch Iliac Stent Trial Study Group. Circulation 1999;99:3155-60.
12. Cikrit DF, Gustafson PA, Dalsing MC, Harris VJ, Lalka SG, Sawchuk AP, et al. Long-term follow-up of the Palmaz stent for iliac occlusive disease. Surgery 1995;118:608-14.
13. Houston JG, McCollum PT, Stonebridge PA, Raza Z, Shaw JW. Aortic bifurcation reconstruction: use of the Memotherm self-expanding nitinol stent for stenoses and occlusions. Cardiovasc Intervent Radiol 1999;22:89-95.
14. Wilson SE, Wolf GL, Cross AP. Percutaneous transluminal angioplasty versus operation for peripheral arteriosclerosis. Report of a prospective randomized trial in a selected group of patients. J Vasc Surg 1989;9:1-9.
15. Holm J, Arfvidsson B, Jivegard L, Lundgren F, Lundholm K, Schersten T, et al. Chronic lower limb ischaemia. A prospective randomised controlled study comparing the 1-year results of vascular surgery and percutaneous transluminal angioplasty (PTA). Eur J Vasc Surg 1991;5:517-22.
16. Hunink MG, Wong JB, Donaldson MC, Meyerovitz MF, de Vries J, Harrington DP. Revascularization for femoropopliteal disease. A decision and cost-effectiveness analysis. JAMA 1995;274:165-71.
17. Treiman GS, Ichikawa L, Treiman RL, Cohen JL, Cossman DV, Wagner WH, et al. Treatment of recurrent femoral or popliteal artery stenosis after percutaneous transluminal angioplasty. J Vasc Surg 1994;20:577-87.
18. Hunink MG, Donaldson MC, Meyerovitz MF, Polak JF, Whittemore AD, Kandarpa K, et al. Risks and benefits of femoropopliteal percutaneous balloon angioplasty. J Vasc Surg 1993;17:183-94.
19. Stanley B, Teague B, Raptis S, Taylor DJ, Berce M. Efficacy of balloon angioplasty of the superficial femoral artery and popliteal artery in the relief of leg ischemia. J Vasc Surg 1996;23:679-85.
20. Martin DR, Katz SG, Kohl RD, Qian D. Percutaneous transluminal angioplasty of infrainguinal vessels. Ann Vasc Surg 1999;13:184-7.
21. Gray BH, Sullivan TM, Childs MB, Young JR, Olin JW. High incidence of restenosis/reocclusion of stents in the percutaneous treatment of long-segment superficial femoral artery disease after suboptimal angioplasty. J Vasc Surg 1997;25:74-83.
22. Lofberg AM, Lorelius LE, Karacagil S, Westman B, Almgren B, Berqgvist D. The use of below-knee percutaneous transluminal angioplasty in arterial occlusive disease causing chronic critical limb ischemia. Cardiovasc Intervent Radiol 1996;19:317-22.