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ENDOVASCULAR TREATMENT OF INFRA-AORTIC ATHEROSCLEROTIC ARTERIAL DISEASE

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Endovascular therapy has an important and definitive role for patients with critical limb ischemia. It easily revascularizes inflow and outflow lesions with minimal morbidity and mortality. One hundred and thirteen patients with critical limb ischemia underwent endovascular procedures either alone or combined with surgical bypass (n=29) with no procedure-related mortality. All patients had angioplasty while 8 of 12 patients with aortic bifurcation disease, 22 of 28 with iliac disease, and 28 of 44 with femoropopliteal disease had stent placement as well. Initial success rates were 100% for the aortic bifurcation group, 96.3% for the iliac group, and 90.7% for the femoropopliteal group. Two-year patency rates were 83.3% for the aortic bifurcation group, 85.2% for the iliac group, and 72.1% for the femoropopliteal group. Twenty nine patients underwent simultaneous iliac endovascular and infrainguinal bypass procedures. This group included 21 angioplasty of the common iliac artery with stent placement in 16 patients and 8 angioplasties of the external iliac artery with stent placement in 4. Femoropopliteal bypass was performed in 18 patients using vein grafts in 14 patients and synthetic polytetrafluoroethylene grafts in 4 patients. Femorotibial bypass was performed in 11 patients using vein grafts. The initial success rate for this simultaneous endovascular and surgical bypass was 93.1% and the 2-year patency rate was 75.9%. Our results demonstrate that endovascular therapy is a low-risk procedure with satisfactory initial and 2-year success rates.

Keywords: percutaneous transluminal angioplasty - stents – critical limb ischemia

INTRODUCTION

Percutaneous transluminal angioplasty (PTA) and stent placement is an accepted and successful method of treating patients with peripheral arterial disease.(1) Many of these patients have coexisting coronary artery disease, and surgical revascularization poses risks of perioperative myocardial infarction and cardiovascular death. Percutaneous treatment can preserve the surgical options and is often used as an adjunct to surgery by addressing inflow lesions and limiting the extent of surgical reconstruction.(2)

The purpose of endovascular intervention for critical limb ischemia is to salvage a functioning foot. Effective treatment of both the inflow and the outflow lesions may be necessary in most patients because of the multisegment nature of the disease. This is particularly relevant in diabetic patients.(2) Restoration of straight-line flow to the pedal arch by endovascular intervention alone or in combination with surgical bypass in one or more tibial arteries is necessary for clinical success. Dilatation of a proximal lesion when the distal artery is severely diseased will not yield lasting clinical benefit in limb salvage patients.(3, 4, 5) The purpose of this study is to evaluate our results with endovascular therapy for the treatment of patients with critical limb ischemia.

PATIENTS AND METHODS

Between January 1999 and January 2004, 113 patients underwent endovascular treatment for their critical limb ischemia. Demographic data and risk factors were defined according to the criteria prepared by the Ad Hoc Committee on Reporting Standards (Society of Vascular Surgery / International Society of Cardiovascular Surgery [SVS/ISCVS]).(6) Patient population and cardiovascular risk factors are shown in (Table I) . Patients suspected of having

lower extremity arterial disease according to the history and physical examination underwent screening color-doppler US examination and accordingly most patients were arranged to undergo diagnostic angiography and endovascular procedure at the same session.[7] All patients had clinical picture consistent with critical limb ischemia or disabling claudication (as defined below.) Clinical follow-up consisted of pulse examination and color-duplex evaluation of treated vessels.

Definitions

Critical limb ischemia was defined as[1] persistent, recurring rest pain of more than 2 weeks duration and requiring regular analgesia, and an ankle systolic pressure < 50 mmHg, and/or[2] ulceration, gangrene, or non-healing wounds of the foot with ankle systolic pressure <50 mmHg.[2]

Cardiovascular risk factors assessed were heart disease determined by history of MI, angina, arrhythmia, or congestive heart failure; hypertension defined as blood pressure > 140/90 mmHg, or requiring medication to control blood pressure; diabetes mellitus determined by history and blood glucose levels; kidney disease defined as serum creatinine > 1.5 mg/dl.

Technical success was defined as recanalization with antegrade flow at the conclusion of the procedure[1] and residual stenosis of less than 30% on arteriography compared with the distal artery.[8] Residual stenoses that seemed significant were recrossed and redilated.[9] Technical failure was defined as the inability to cross the lesion with a guidewire leading to termination of the procedure or residual stenosis greater than 30% at angiography immediately after PTA.[10, 11]

Technique of Angioplasty

All patients received antiplatelet therapy with 650 mg of aspirin daily which was started at least 24 hours before angioplasty and was continued indefinitely. A cushion elevates the ipsilateral buttock to lengthen the femoral vessels. Around the puncture site 10 cc of Xylocaine 2% is given. A 2-mm stab wound is made with an 11 blade and an antegrade or retrograde puncture of the ipsilateral femoral artery is performed.[12] The ipsilateral entry into the arterial system permits maximal control of guidewires and catheters. A 6-F or 7-F (for stent placement) sidearm sheath is introduced and passed over a gently curved J guide wire into the superficial femoral artery for antegrade procedures or into the iliac artery for ipsilateral retrograde or contralateral antegrade procedures. The sidearm sheath allows interim contrast injection while leaving the guidewire in place across the lesion.[13] Once the sheath is localized in the desired vessel, the patient is systemically heparinized with 5,000 units of heparin [14]. Additional 2,000-unit boluses of heparin was given if the procedure exceeds 1 hour. Under fluoroscopic guidance, a preliminary angiogram of the limb was taken using diluted (1:1) contrast medium (urograffin 60%) to locate the target lesions and mark them with external markers (e.g., needles or hemostats applied to the drapes). A variety of guidewires of diameter 0.18-0.35 inch were used to cross the lesions including the hydrophilic guide wire Glidewire (Terumo, Piscataway, NJ). For lesions involving the aortic bifurcation, bilateral femoral approach and the "kissing balloon" technique were used.[15] Angioplasty was then carried out using balloon catheters with diameter equal to the diameter of the adjacent normal arterial segment, with dilatation up to 10 mm in iliac arteries, 6 mm in SFA, 5 mm in the popliteal artery, 4 mm in proximal infrapopliteal vessels and 3 mm if more distal.[7, 16] The balloon was inflated manually until balloon deformity (waist) was relieved. Inflation was maintained for 30-40 seconds to minimize the interruption to distal flow. The balloon was then deflated for 10 seconds and reinflated for another 30-40 seconds. When angioplasty of the entire diseased segment of the vessel was completed, the balloon catheter was withdrawn proximally and an arteriogram was obtained to assess the result. The sheath was removed at the completion of the procedure and hemostasis was achieved by manual compression.

RESULTS

One hundred and thirteen patients underwent endovascular treatment for their critical limb ischemia. Results of angioplasty and stent placement in this group of patients are summarized in (Table II). One hundred and thirteen patients with critical limb ischemia underwent endovascular procedures either alone (n=84) or combined with surgical bypass (n=29). There was no procedure-related mortality. Twelve patients with aortic bifurcation disease underwent PTA using kissing balloon technique (Fig 1) and stents were placed in 8 patients. Twenty eight patients with iliac disease had PTA alone or with stent placement in 22 patients (Fig 2). Forty four patients with femoropopliteal disease underwent PTA, of whom 28 had stent placement as well (Figs 3, 4). Initial success rates were 100% for the aortic bifurcation group, 96.3% for the iliac group, and 90.7% for the femoropopliteal group. Two-year patency rates were 83.3% for the aortic bifurcation group, 85.2% for the iliac group, and 72.1% for the femoropopliteal group. Twenty nine patients underwent simultaneous iliac endovascular and infrainguinal bypass procedures. This group included 21 angioplasty of the common iliac artery with stent placement in 16 patients and 8 angioplasties of the external iliac artery with stent placement in 4. Femoropopliteal bypass was performed in 18 patients using vein graft in 14 patients and synthetic polytetrafluoroethylene graft in 4 patients. Femorotibial bypass was performed in 11 patients using vein grafts. The

initial success rate for this simultaneous endovascular and surgical bypass was 93.1% and the 2-year patency rate was 75.9%. The indications of stent placement in this study were as follow: 3 for dissection, 24 for residual stenosis, and 86 were placed primarily.

Table I: ***Patient population and cardiovascular risk factors***

Characteristic	*No. (%)*
Male/female	73/40
Mean age (yrs)	57 ± 6.9
Heart disease	39 (34.5)
Hypertension	48 (42.4)
Diabetes mellitus	43 (38.1)
Cigarette smoking	49 (43.3)
Kidney disease	15 (10.6)
Cerebro-vascular disease	0
Clinical ischemic category	
Severe claudication	84 (74.3)
Rest pain	18 (15.9)
Minor tissue loss	7 (6.1)
Major tissue loss	4 (3.5)

Table II: ***Results of PTA and stent placement***

Characteristics	*Limbs (%)*	*Stents No.*	*Initial Success*	*2-y Patency*
Aortic bifurcation	12 (10.61)	8	100%	83.3%
Iliac endovascular alone	28 (24.77)	22	96.3%	85.2%
Common iliac artery	17			
External iliac artery	11			
Stenosis	22			
Occlusion	6			
Iliac, combined	29 (25.66)	20	93.1%	75.9%
Common iliac artery	21	16		
External iliac artery	8	4		
Femoropopliteal, total	44 (38.93)	28	90.7%	72.1%
short stenosis	19			
medium stenosis	13			
2 stenoses	7			
occlusion	5			
good runoff	34			
poor runoff	9			
Total	113 (100)	78 (69)		

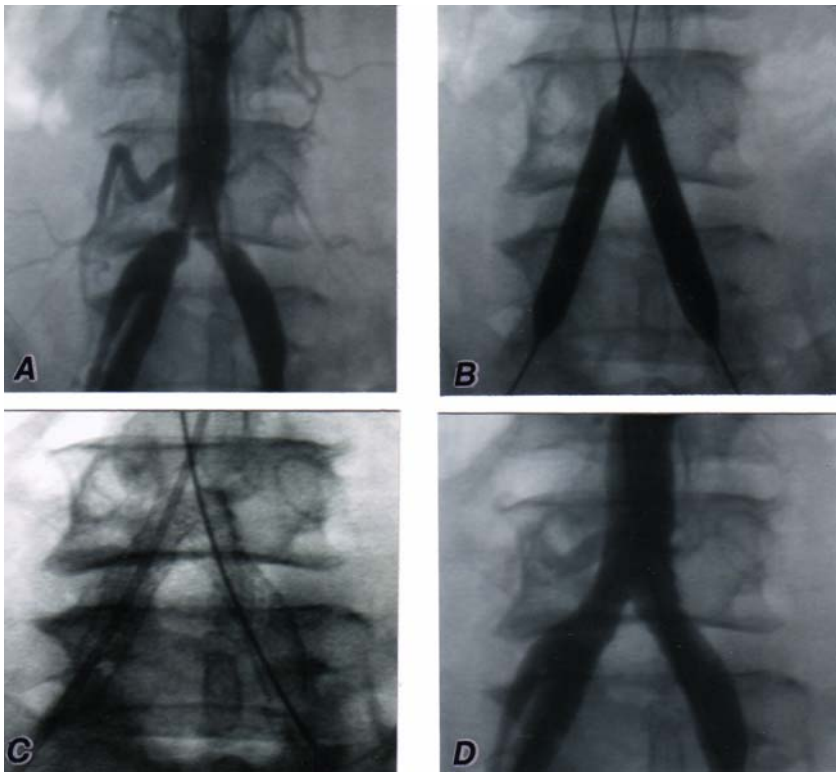

Figure 1:. A, *Severe aortic bifurcation disease.* **B**, *Bilateral angioplasty using kissing balloon technique.* **C**, *Bilateral stents placed (kissing stents).* **D**, *Angiogram showing no residual stenosis.*

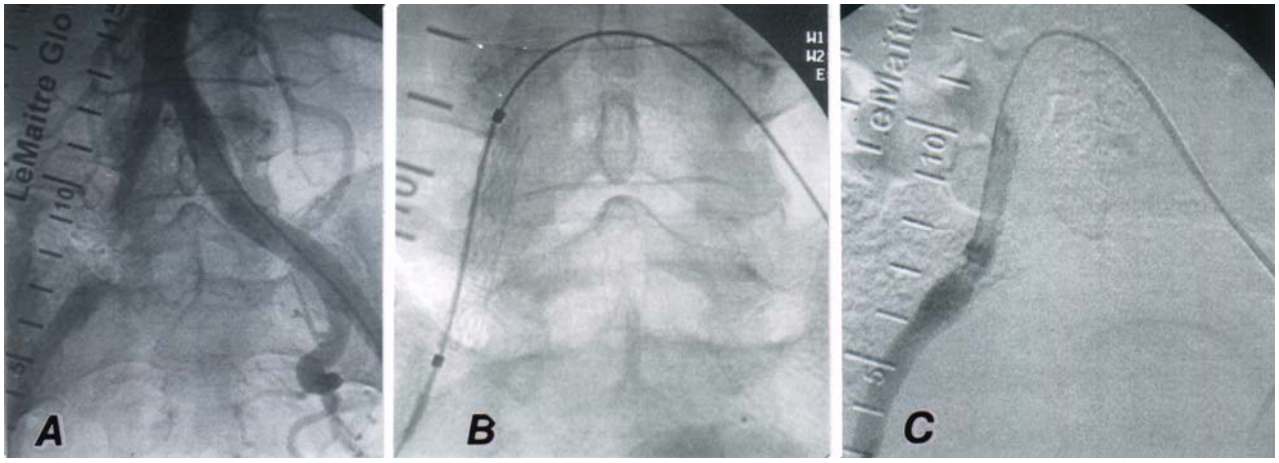

Figure 2:. A, *Stenosis of the right common iliac artery.* **B**, *Contralateral access with crossing the aortic bifurcation, balloon angioplasty and stent placement.* **C**, *Angiogram showing no residual stenosis.*

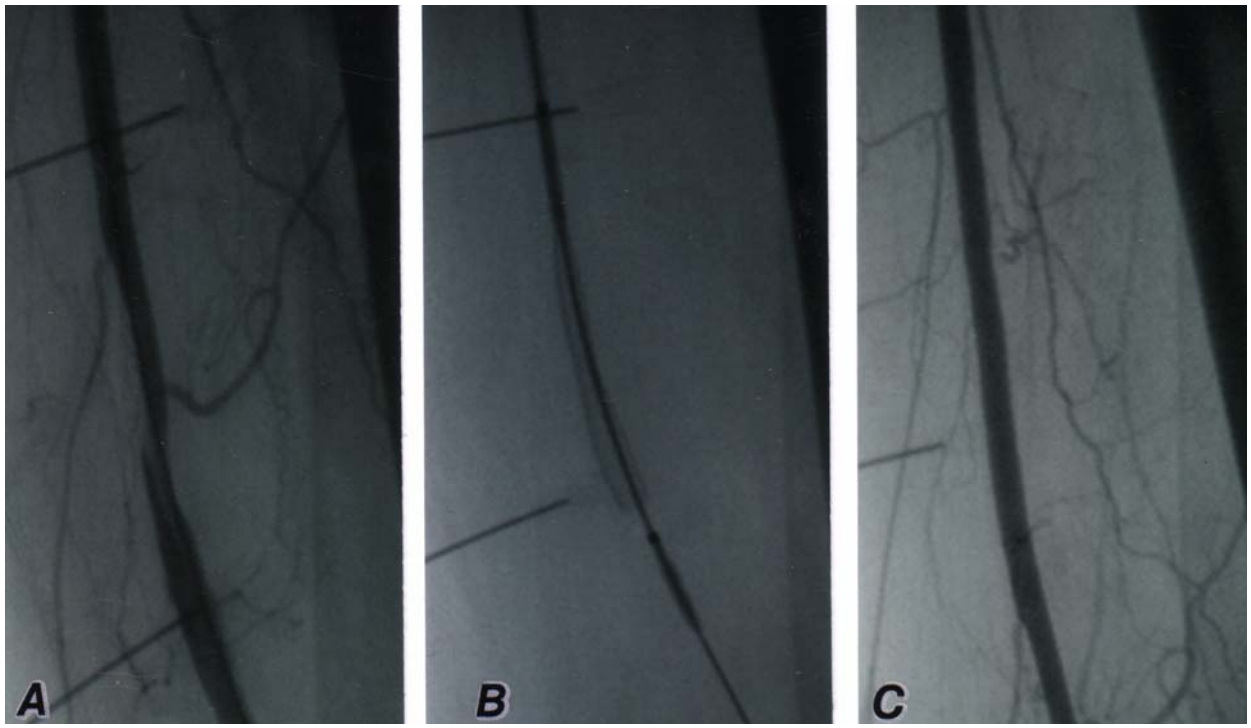

Figure 3:. A, ***Post-PTA dissection of left SFA.*** **B,** ***Stent placement.*** **C,** ***Post-stent angiogram.***

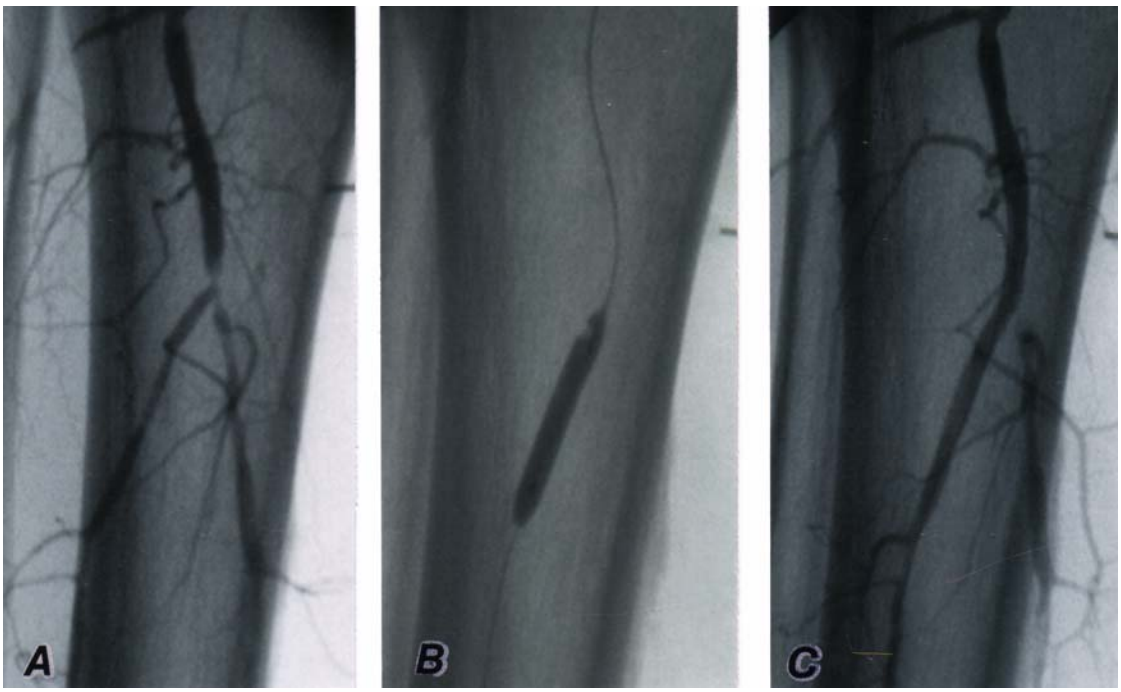

Figure 4:. A, ***Angiogram shows high-grade stenosis of the tibioperoneal trunk, the posterior tibial artery is occluded distally.*** **B,** ***PTA of the peroneal artery orifice.*** **C,** ***Angiogram showing good outcome.***

DISCUSSION

The role of percutaneous transluminal angioplasty and stent placement in the management of patients with peripheral arterial disease is increasing.[17] It has been reported that percutaneous transluminal angioplasty, with or without stent, is one of the most commonly performed percutaneous interventional radiological procedures. During the first 6 months of 1999, 3619 iliac angioplasties were performed and 1208 iliac stents inserted in England and Wales. The indications for intervention include lifestyle-limiting intermittent claudication, rest pain/gangrene and to improve inflow prior to infrainguinal surgical or percutaneous revascularization.[18]

PTA is a low-risk procedure and does not "burn any bridges" since anatomic failure may be amenable to repeat PTA and when surgical bypass is needed to treat clinical failure following PTA, the nature of the surgical bypass is unchanged by the preceding PTA.[7] Endovascular therapy has particularly an important and definitive role for patients with critical limb ischemia (CLI), many of whom have multisegmental arterial disease and associated comorbidities. By easily revascularizing inflow and outflow lesions with minimal morbidity and mortality, endovascular interventions significantly improve distal extremity perfusion pressure.[5]

Intravascular stents are used as a means of improving the results of balloon angioplasty by compressing disrupted atheroma, intima, and media against the vessel wall and thereby maintaining the integrity of the balloon dilated arterial lumen[19]

Endovascular treatment for aortoiliac disease

Iliac artery PTA and stenting have been established as a viable alternative to treating aortoiliac occlusive disease due to its low risk compared with surgery.[20, 21, 22] Data from different studies reported technical success and 3-year patency rates for PTA of iliac artery stenoses in 1,264 patients were 95% and 66%, respectively, for PTA of iliac artery occlusions in 291 patients were 84% and 60%, respectively, for stents in iliac artery stenosis in 1,365 patients were 99% and 74%, respectively, and for stents in iliac artery occlusions in 187 patients were 82% and 64%, respectively.[2] The initial success rate and 2-year patency rate in our patient population are similar to those reported in the literature.

Moreover, the results of a multicenter randomized comparison of PTA alone versus PTA plus stent in iliac lesions has demonstrated conclusively that iliac stent implantation results in a significantly higher patency rate at 4 and 5 years, with low incidence of procedural failure and complications.[23, 24, 25] Nicholson reported a major decrease in embolization rate after they adopted primary stenting of iliac angioplasty for the treatment of iliac occlusions.[18] These studies demonstrated that the role of vascular stents in the treatment of atherosclerotic disease in the iliac arteries has been reasonably well established.

Combined endovascular and surgical revascularization

Endovascular intervention has been combined with open surgery to treat lower extremity ischemia caused by multilevel occlusive disease.[26] This multilevel arterial disease, most often present in patients with critical ischemia, has been shown to respond poorly to treatment of only the SFA or popliteal disease.[7] Consequently, iliac artery PTA and stenting became a valuable adjunct to distal bypass either to improve inflow and outflow, or to reduce the extent of traditional surgical intervention. Both staged and simultaneous approaches appear to be safe and effective, and excellent results have been published for each. The 5-year primary patency rate for combined reconstructions ranges from 61% to 80%.[26, 27]

Consequently, the utility of femoro-femoral grafting became extended for use with bilateral iliac disease in which the occlusion of the proposed donor iliac artery was focal and amenable to angioplasty. Abu Rahma et al found that the combined use of iliac balloon angioplasty and stenting and femorofemoral bypass grafting is effective and durable and can be performed simultaneously, if the donor iliac stenosis length is 5 cm or less.[28] Liu et al reported a short-term (mean of 5 months) patency rate in 11 of 12 limbs with combined iliac PTA and stents and 9 femoropopliteal bypass and 3 femoro-femoral-popliteal bypass.[29] Another experience was reported by Schneider et al who combined intraoperative balloon angioplasty of the inflow superficial femoral artery with popliteal to distal bypass graft and found that this technique is a reasonable alternative to longer, femoral origin bypass graft in selected diabetic patients with gangrene.[30]

In our group of patient we performed iliac PTA and stenting simultaneously with distal femoropopliteal and Femorotibial bypass. The 2-year patency rate in our patients with combined endovascular and distal bypass is 75.9% which compares favorably with published results.

Endovascular treatment for infrainguinal disease

Substantial experience has demonstrated the effectiveness and safety of infrainguinal angioplasty. However, neither the initial success rate nor the long-term patency is as high as it is for iliac procedures.[26] Patients with isolated aortoiliac disease tend to be younger and have a low likelihood of coronary heart disease comorbidity, whereas those with femoropopliteal disease, infragenicular

disease, or multilevel disease tend to have the lowest ankle brachial pressure index and the highest likelihood of coronary heart disease comorbidity. In a recent review of the published results of PTA in stenoses and occlusions of the femoropopliteal arteries, the technical success and 3-year patency rates in 1,241 patients were 90% and 51%, respectively.[2]

Several studies have documented that certain factors are associated with worse outcomes. These factors include diabetes mellitus, critical ischemia, long-segment stenosis than focal lesions, eccentric versus concentric lesions, occlusion versus stenosis, and poor runoff.[2, 7, 10, 31] Other studies suggested that the inferior results of femoropopliteal PTA compared with iliac PTA are due to the presence of intimal flaps and elastic recoil which leads to early failures and restenosis related to intimal hyperplasia which account for the late failures.[32, 33]

Nonetheless, the role of infrainguinal PTA in the management of severe leg ischemia continues to be controversial.[16] This controversy may be in part due to the unfavorable results obtained in early studies before 1990. Earlier results of angioplasty, however, bore little relevance to the results that could now be achieved due to improved techniques and instrumentation. Moreover, differences in reporting make it difficult to easily estimate the true effectiveness of infrainguinal PTA.[2]

A group of investigators believe that infrainguinal PTA should be performed only in patients with short stenosis and/or with prohibitive surgical risk.[8, 34, 35, 36] Parsons et al reported their experience with PTA for the treatment of limb threatening ischemia in 1998 and found that one-year patency rates of PTA performed below the inguinal ligament are inferior to the patency rates of arterial bypass grafts, even when these bypasses are performed with a prosthetic material and recommended that PTA should not be considered as a primary treatment modality for patients with infrainguinal arterial occlusive disease who also have limb-threatening ischemia, except in unusual circumstances. They found also that the results of their study confirmed the utility of common iliac PTA in treating either occlusions or stenoses in the limb-salvage setting, and that PTA can be effective either as the sole therapy or to provide inflow for a needed infrainguinal bypass graft.[31] Currie et al also reported poor results of femoropopliteal PTA for severe limb ischemia with 42% primary limb survival rate at 2 years and recommended that PTA of long occlusions of the femoropopliteal segment should be avoided except in patients who have either a shortened life expectancy or who are unfit for bypass surgery.[37]

On the other hand, a more liberal use of infrainguinal PTA was supported by many investigators.[5, 14, 38, 39, 40] London et al demonstrated that, in a selected group of patients with lower limb critical ischemia, PTA can be a successful therapeutic option with a low complication rate, high technical success rate and a 77 per cent 2-year symptomatic patency rate. In their study, patients who have suitable lesions or who are unfit for bypass surgery were selected for PTA.[17] Ray et al also supported the use of angioplasty for treating the severely ischemic leg, especially when used to achieve ulcer healing. They argue that the high technical success and low mortality rate of less than 0.5 per cent compared with 3-9 per cent death rate following surgery for limb-threatening ischemia makes the procedure an attractive option. They also found that restenosis is often clinically unimportant because the short period of improved peripheral perfusion is sufficient to heal ulcers and that less flow is required to maintain healed tissues.[16]

Bakal et al in a study of PTA of infrapopliteal arteries performed for limb salvage in 53 patients concluded that infrapopliteal artery angioplasty will almost always yield beneficial clinical results when nonobstructed flow to the foot is restored (i.e., straight-line flow via one of the infrapopliteal arteries), but angioplasty will yield a response in only about one third of cases in the presence of obstruction distal to the dilatation site as a result of increasing flow to collaterals proximal to distal occlusions. They also found that in no case did an angioplasty complication preclude bypass surgery that the original vascular anatomy would have permitted.[3] Bakal et al feel, as do others, that liberal use of systemic heparin during angioplasty of peripheral vessels is probably more crucial than its use in angioplasty of higher flow vessels, such as the iliac arteries.[3, 41, 42] Sivananthan et al reported encouraging results of PTA of tibial arteries in 18 patients with claudication and 20 patients with rest pain or tissue loss. They achieved 96% technical success rate, 58% clinical improvement at a mean of 21 months and cumulative patency rate of 54% at 25-36 months. They recommended that PTA should be the first treatment option in patients with infrapopliteal arterial disease needing intervention, whenever technically feasible.[43]

Finally, in a meta-analysis of balloon dilation and stent implantation for treatment of femoropopliteal arterial disease, Muradin et al found that balloon dilation and stent implantation for claudication and stenosis yield similar long-term patency rates. For more severe femoropopliteal disease, the results of stent implantation seem more favorable. They concluded that stent placement is a useful bailout procedure to save a failed femoropopliteal balloon dilation procedure.[44] These results were confirmed by other studies.[23, 45, 46, 47] However, others recommend that primary stent placement should be reserved for use in patients with suboptimal results of PTA.[48]

CONCLUSION

PTA has become an established technique for the treatment of peripheral arterial disease in patients amenable to endovascular therapy. PTA is a safe and effective treatment for lower-limb critical ischemia and with increasing technical expertise and the development of new techniques such as subintimal angioplasty it is expected that PTA will play an increasingly important role.[1, 49]

Our results show that endovascular therapy has a good initial and 2-year outcome in this group of patients with critical limb ischemia. These results are comparable to results of published reports. Our results demonstrate also that intraoperative iliac artery PTA and stent placement can be safely and effectively performed simultaneously with infrainguinal revascularization for multilevel atherosclerotic occlusive disease.

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