ORIGINAL ARTICLE

REVASCULARIZATION OF DIABETIC PATIENTS WITH CHRONIC LOWER LIMB ISCHEMIA; ENDOVASCULAR VERSUS OPEN SURGERY

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Abstract

Aim: This study assessed the efficacy of endovascular versus surgical revascularization in diabetic patients with chronic lower limb ischaemia (LLI).

Methods: This prospective study, with 1-year follow up, was conducted in the vascular surgery department, Assiut University Hospitals, Egypt from September 2009 to January 2012 in a consecutive series of 161 patients with chronic LLI.

Results: Peripheral angioplasty (PTA) was performed in 107 (66.5%) patients and bypass graft (BPG) in 54 (33.5%). Technical success was 94.4% for the endovascular group and 88.9% for the BPG group. The overall 1 year patency rate was 74.2% after PTA and 70.8% after BPG. One year amputation and mortality rates for PTA were 9.3% and 10.3% respectively and for BPG were the same (14.8%).

Conclusion: Revascularization by PTA is highly feasible in diabetics with chronic LLI. The feasibility of revascularization by BPG is lower and was performed when PTA was not feasible. Diabetic patients often have comorbidities that make minimally invasive treatment modalities look more favorable.

Keywords: Diabetes mellitus, critical limb ischaemia, peripheral revascularization, endovascular surgery, open vascular surgery.

INTRODUCTION

Diabetes mellitus is one of the major risk factors of peripheral arterial occlusive disease (PAOD).(1-3) and affects the arterial tree in a centrifugal pattern.(4,5) Its prevalence is particularly high in patients with chronic critical lower limb ischemia (CLI).(6,7) Inspite of the gloomy course of CLI, there is no doubt that arterial revascularization improves the prognosis, even in diabetic patients.(8,9)

In patients with diabetes, the risk of PAD increases with age, duration and severity of diabetes, and the presence of peripheral neuropathy.(10,11) Patients with diabetes aged ≥40 years are two to three times more likely to suffer from PAD than those without diabetes, and as many as one-third of patients with diabetes may have concomitant lower extremity Ischemia.(12-14)

Unfortunately, patients with diabetes are also prone to develop PAD at earlier ages, have more progressive and severe disease, and are more likely to undergo surgery and amputation for CLI.[14-16]

In fact, foot problems remain the most common cause of hospitalization among diabetics.[17] It is widely recognized that aggressive revascularization is essential to salvage many of the limbs that present with CLI.[18]

In the past, most of these patients with significant limb ischemia have been treated with surgical revascularization. However, with rapid advances in catheter-based technology, there has been a significant shift toward endovascular interventions.[19] Endovascular interventions have gained widespread acceptance as primary and secondary treatments for CLI, and many believe there is little need for open bypasses for CLI. Despite this, some patients presenting with CLI require traditional lower extremity bypass procedures at some point for successful limb salvage.[20]

Definitive high-level evidence on which to base treatment decisions, with an emphasis on clinical and cost effectiveness, is still lacking. Treatment decisions in CLI are individualized based on life expectancy, functional status, anatomy of the arterial occlusive disease, and surgical risk.[21]

The purpose of this prospective study was to evaluate the efficacy of revascularization either by peripheral transluminal angioplasty (PTA) or bypass graft (BPG) as the first-line treatment for chronic lower limb ischemia in diabetes patients.

PATIENTS AND METHODS

This study was conducted prospectively on 161 patients with lower limb arterial disease presented to the Vascular surgery Department, Assiut University Hospital, Egypt from September 2009 to January 2012.

All patients underwent history taking and blood analysis (complete blood count, coagulation profile, and blood urea nitrogen and serum creatinine). This consisted of a complete noninvasive vascular work-up, including measurements of ankle-brachial index (ABI), and imaging studies consisting of duplex scan or computed tomography angiography. Grading of the severity of ischemia followed the classification system proposed by Rutherford et al.[22]

Our strategy is "to treat patients with chronic CLI by endovascular means whenever technically possible rather than to operate".

The intervention decision was determined by clinical presentation, urgency of therapy, general condition of the patient, including presence of limiting comorbidities as well as anatomic distribution and morphologic nature of vascular lesions, availability of autologous veins, and access for endovascular therapy.

Inclusion criteria for this study were ambulatory diabtic patients presenting with disabling claudication or critical limb ischemia who had either critical stenosis / stenoses or occlusion(s). Inclusion criteria for PTA were: 1. consecutive multiple stenoses, 2. calcified occlusions up to 10 cm long of aortoiliac lesions and more than 15 cm of SFA lesions 3. Multiple level diseases. 4. As a hybrid technique to improve inflow for a distal bypass. While indications for open surgery were: 1. Failure of endovascular intervention. 2. Iliac lesions extending to CFA. 3. Total SFA occlusion from its origin or extended to the infragenicular popliteal artery or tibial trifurcation.

On the other hand exclusion criteria included: patients with extensive necrosis or irreversible ischemic damage requiring primary amputation, and chronic lower limb ischemia in non-ambulatory patients.

Revascularization Procedures

PTA procedure

The procedure was performed under local anaesthesia through an antegrade puncture of the ipsilateral common femoral artery. Contralateral femoral approach was chosen in the following condition: If obstructions were present in the iliac, common femoral artery or proximal SFA, sever obesity and high femoral bifurcation. A six French gauge sheath was positioned and a preliminary angiographic study was performed. Then balloon dilatation or vessel recanalization was done. Stents were employed if dissection or suboptimal results occurred. No stents employed in the infra popliteal arteries. Vessel recanalization was considered successful when direct flow was obtained in the treated vessel, with no significant residual stenosis < 30% along the whole artery.

During the procedure, 5000 IU of sodium heparin was infused into the arterial lumen. If vessel spasm occurred, 0.1–0.2 mg of nitroglycerine was infused as an intra-arterial bolus. Intra-arterial thrombus was managed by catheter aspiration and / or streptokinase and heparin infusion.

A nephroprotection protocol was used in patients with renal insufficiency: 1500 ml saline was infused the day before and the day after the procedure. In patients with an ejection fraction ≤ 40%, 20 mg of furosemide were injected intravenously at the end of each hydration. Creatinine value was determined the day before and after the PTA.

All the patients were prescribed clopidogrel 75 mg / day for 30 days and subsequently acetyl salicylic acid 150 mg / day indefinitely.

Open surgical procedure

The choice of proximal and distal bypass graft depended on the angiographic picture and aimed at obtaining at least one patent artery continuous to the foot. The autogenous great saphenous vein was employed if present and in good condition. If venous conduit could not be used, prosthetic material (polytetrafluoroethylene; PTFE) was employed and the peripheral anastomosis consisted of a venous patch using the Taylor´s technique, or ‘‘composite’’ bypass with interposition of distal venous segments.

Limb salvage

In patients complaining of rest pain without foot ulcers, the disappearance of pain with discontinuation of analgesic therapy was considered as successful limb salvage. In patients with foot lesions, limb salvage was considered successful if plantar standing was maintained, even when achieved by a tarsal-metatarsal amputation. In patients in whom treatment did not relieve rest pain or the gangrene extended above the Chopart joint, a major amputation (above-the ankle) was proposed and performed. Any major amputation was deemed as a failure.

Follow-up

Assessment of the peripheral circulation was performed at baseline and at 1, 6, and 12 months by clinical examination and duplex ultrasound. After hospital discharge, all patients with foot ulcer were examined weekly until the ulcer healed and monthly thereafter in the absence of recurrence. The CLI recurrence in the treated arteries was assessed only in the case of pain recurrence or if the ulcer worsened. Duplex scanning was done and if positive, the patient underwent a repeat angiographic evaluation and a further PTA, if possible.

In cases of morphological restenosis, significant stenoses at duplex scanning without pain or ulcer worsening or recurrence, we did not perform any revascularization.

The graft patency was assessed with clinical examination and ultrasound study at 30 days, 3, 6, 12 months. Peak systolic velocity and anastomosis morphology were assessed by ultrasound study. Finally, inflow is compared with pre-operative condition. Repeated imaging studies were limited to patients where anastomotic stenosis or additional arterial lesions were suspected clinically or hemodynamically.

Statistical methods

Continuous and normally distributed variables are reported as mean ± standard deviation. Categoric variables are presented as numbers (percentages). Chi-square test was used to compare qualitative data between groups. Mann-Whitney test was used to compare quantitative data between different groups. A value of $P < 0.05$ was considered to indicate statistical significance and P value <0.001 was considered statistically highly significant. All analyses were performed using the SPSS 16.0.1 OG software (SPSS Inc, Chicago, Ill).

RESULTS

During the study period 161 consecutive patients with 161 chronic ischaemic limbs were treated. The study included 119 males and 42 females, with a mean age of 61±7.8, mean ABI was 0.35±0.14 in the endovascular group and 0.32±0.09 in the surgical group. All patients are diabetic, 45 patients (27.9%) were smokers, 78 patients (48.4%) were hypertensive, one third of cases with abnormal lipid profile, and 16 patients (9.9%) with renal insuufficiency. The demographic data are summarized in Table 1.

Table 1. Demographic data.

Variable	Frequency (n=161)	Percentage %
Age	Mean 61±7.8	
Sex		
males	119	73.9%
females	42	26.1%
Smoking	45	27.9%
Hypertension	78	48.4%
Dyslipidemia	54	33.3%
Renal insufficiency	16	9.9%

Table 2 shows information on the clinical assessment of the patients according to Rutherford categories; disabling claudication (Rutherford 3), rest pain (Rutherford 4), and tissue loss (Rutherford 5 and 6). Imaging studies recorded 116 limbs (72%) had good distal run off (2-3 patent runoff arteries), and 28% had poor distal run off (0-1 patent runoff vessel). 123 limbs (76.4%) had occlusion, but stenoses were recorded in 38 limbs.

Table 2. Shows information on the clinical assessment of the patients according to Rutherford categories; disabling claudication (Rutherford 3), rest pain (Rutherford 4), and tissue loss (Rutherford 5 and 6). Imaging studies recorded 116 limbs (72%) had good distal run off (2-3 patent runoff arteries), and 28% had poor distal run off (0-1 patent runoff vessel). 123 limbs (76.4%) had occlusion, but stenoses were recorded in 38 limbs.

Variables		Frequency (n=161)	Percentage %
Clinically	Rutherford category		
	- Category 3	1	0.6%
	- Category 4	20	12.4%
	- Category 5,6	140	87%
Distal run off			
- Good		116	72%
- Poor		45	28%
Type of lesion			
- Occlusion		123	76.4%
- Stenosis		38	23.6%

The level of occlusion were aorto-iliac in 16 patients, femoropopliteal occlusions in 95 patients and infrapopliteal in 20 patients while 30 patients were presented by multiple level disease (Table 3).

Table 3 Shows disease distribution either single or multilevel disease.

Level of occlusion	Frequency (n=161)	Percentage %
Single level:	131	81.4%
- Aorto-iliac segment	16	10%
- Femoropopliteal segment	95	59%
- Infrapopliteal segment	20	12.4%
Multilevel	30	18.6%

In this study the patients were divided into 2 groups, endovascular group (107/161) and surgical group (54/161). In endovascular group; PTA without stent was performed in 81.3% of the patients and stents deployed in 18.7%. In surgical group; autologous vein was used in 51.8% of patients, and prosthetic grafts in 48.2% (Table 4).

Table 4. Shows operative data of each group.

Procedure	Frequency	Percentage %
Endovascular	107	66.5%
PTA	87	81.3%
Stent deployment	20	18.7%
Open surgery	54	33.5%
Autologous vein	28	51.8%
Prosthetic graft	26	48.2%

Technical success and 1 year patency rate in the endovascular group was higher than that of surgical group, but with no significant difference (Table 5,6).

Table 5. Shows the technical success and 1 year patency rate in each group.

Procedure	Technical success	P value	1year patency rate	P value
Endovascular group	101/106 (94.4%)	0.2376	75/101 (74.2%)	0.8250
Surgical group	48/54 (88.9%)		34/48 (70.8%)	

Table 6. Shows technical success and 1 year patency rate in each level of occlusion.

Variables		Endovascular	Open surgery
Technical success	Single level disease:		
	Aorto-iliac	10 / 11 (90.9%)	5 / 5 (100%)
	Femoropopliteal	57 / 59 (96.6%)	34 / 36 (94.4%)
	Infrapopliteal	13 / 14 (92.8%)	5 / 6 (83.3%)
	Multilevel disease	20 / 23 (86.9%)	5 / 7 (71.14%)
1year patency rate	Single level disease:		
	Aorto-iliac	8 / 10 (80%)	4 / 5 (80%)
	Femoropopliteal	45 / 57 (78.9%)	25 / 34 (73.5%)
	Infrapopliteal	10 / 13 (76.9%)	3 / 5 (60%)
	Multilevel disease	12 / 20 (60%)	3 / 5 (60%)

ABI was false high (>1.3) in 54 patients, the mean value of ankle pressure in the remaining patients was increased significantly in both groups (Table 7).

Table 7. Shows pre- and postoperative ABI in each group.

ABI	Endovascular (n= 75)	Open surgery (n= 32)	P-value1
	Mean ± SD	Mean ± SD	
Pre-operative	0.35 ± 0.14	0.32 ± 0.09	
Immediate post-operative	0.82 ± 0.19	0.82 ± 0.13	1
After 1 year	0.77 ± 0.23	0.75 ± 0.20	0.669
P-value2	0.000*	0.000*	
P-value3	0.000*	0.000*	

* Statistical significant difference (P < 0.05).

Table 8. Shows the complications and the mortality rate in each group. In endovascular group there were 5 intraprocedural complications; 4 were arterial thrombosis; the remaining one was dye hypersensitivity, there were 2 postprocedural complications in the form of groin haematoma and retroperitoneal haematoma. In surgical group there were 3 intraprocedural complications in the form of graft thrombosis, and another 3 postprocedural complications; in form of postoperative graft thrombosis, secondary hemorrhage, and postoperative wound infection. 30 days mortality rate in the endovascular group were 2.8% (3 patients); one from anaphylactic shock, and the remaining two cases from postoperative myocardial infarction. In surgical group, mortality rate was 7.4% (4 patients); one patient from sepsis, and the remaining 3 patients from cardiac causes (heart failure and myocardial infarction).

Variable		Endovascular (n= 107)		Open surgery (n= 54)	
		No.	%	No.	%
Complications	Intraprocedural	5	4.7%	3	5.5%
	postprocedural	2	1.9%	3	5.5%
Mortality rate	30 days	3	2.8%	4	7.4%
	One-year	11	10.3%	8	14.8%

During the follow up period, 18 major amputations were performed; 10 of them in the endovascular group due to extension of gangrene above the Chopart joint; and 8 major amputation were performed for the surgical group due to acute graft failure (5 cases), extension of gangrene (one case), and anastomotic site infection with secondary hemorrhage in the remaining 2 cases.

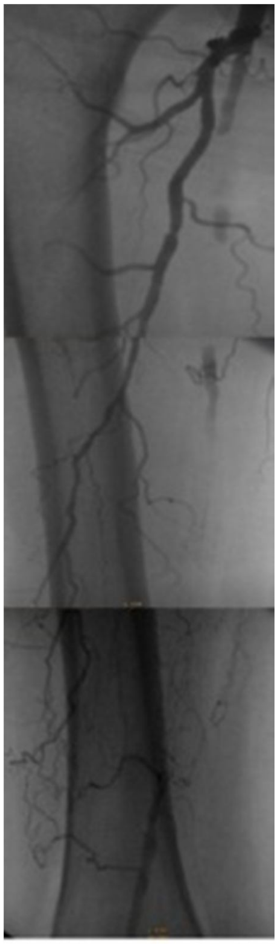

Fig 1a. Pre-operative angiogram; SFA occlusion.

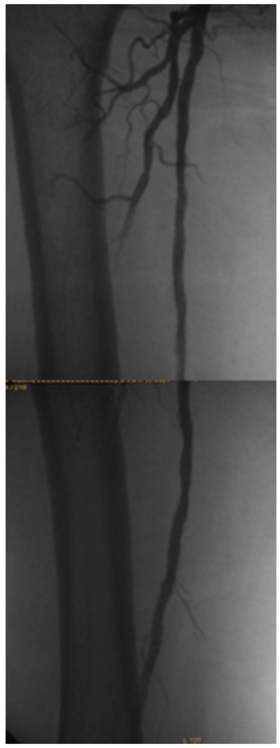

Fig1b. Post PTA angiogram.

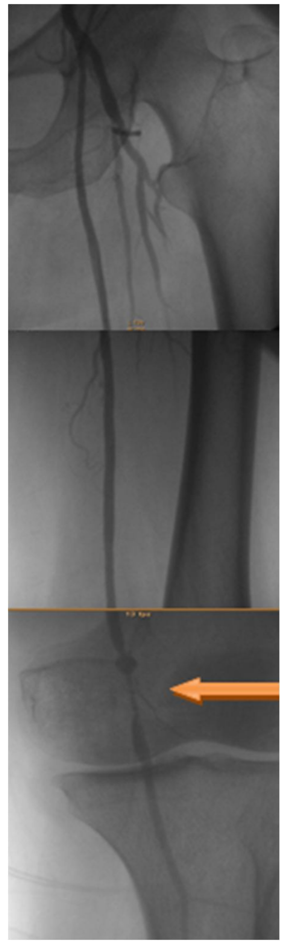

Fig 2a. Femoropopliteal bypass by vein graft (failing graft; stenosis of distal anastomosis).

Fig 2b. After PTA.

Fig 3a. Pre-operative angiogram; Multilevel disease, SFA stenosis, occlusion of popliteal and PT arteries.

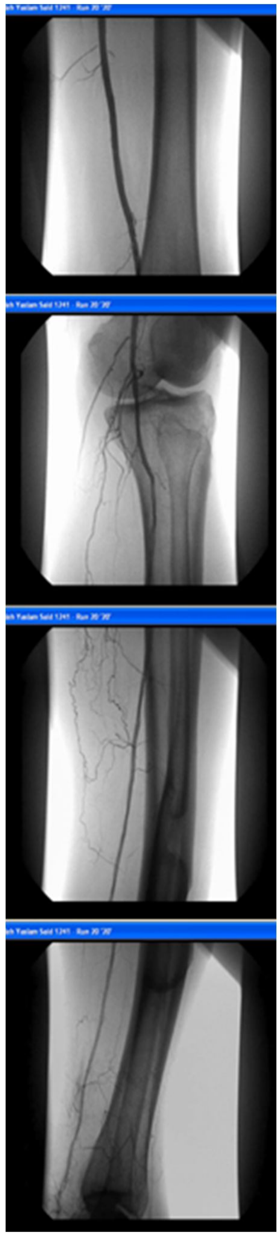

Fig 3b. Post PTA angiogram.

Fig 4a Femoro distal bypass by composite graft (failing graft; stenosis of distal anastomosis).

Fig 4b. After PTA.

Fig 5a Pre-operative angiogram; occlusion of Rt. Iliac artery and stenosis of lt. iliac artery.

Fig 5b Post kissing balloon angiogram, dissection of lt. iliac artery.

Fig 5c. Angiogram after stent deployment.

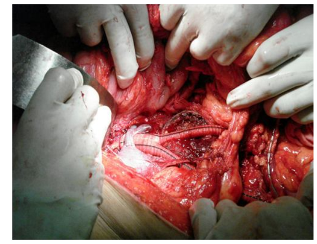

Fig 6. Aorto-bifemoral bypass.

DISCUSSION

PAD is an underrecognized complication of diabetes.(23) CLI is an even more underrecognized complication.(24,25) For diabetic patients, the onset of CLI is a dramatic event; risk of major amputation and death is considerable. The proper management of CLI could improve the amputation outcome.(26)

The aim of the revascularization procedure is to provide sufficient blood flow to relieve rest pain and heal skin lesions. The ideal revascularization procedure is one that avoids general anesthesia, poses a lesser systemic stress and has fewer serious complications.(27) Both surgical bypass and endovascular revascularization are currently accepted forms of treatment. Arterial bypass surgery has traditionally been the main treatment with a well-documented long-term patency and limb salvage rate. However, technical and anatomical limitations such as the availability of the long vein graft and the presence of infection near the site of planned distal anastomosis often make surgery technically challenging and difficult. Additionally, patients often have multiple co-morbidities such as cardiovascular disease, and other pathologies associated with diabetes. Their co-morbidities increase general anesthesia risk and lead to poor tolerance for prolonged surgery.(28) Concerns about impaired healing of surgical wounds, increased risks of infection, or silent CAD are important factors to refuse surgery.(29) PTA is thus an attractive alternative in this subset of patients. The rates of endovascular revascularization significantly increased from 7.8% before 2005 to 79.9% after 2005. The rates of surgical revascularization significantly declined from 92.2% to 20.1% before and after 2005, respectively.(19,30)

In the present study PTA was done to 66.5% of the patients and BPG was done to 33.5%. Dick et al(29) in their study also reported that 64.3% underwent PTA and 13.5% BPG and 22.2%, neither PTA nor BPG could be performed. Other studies reported higher rates of PTA, 74.5% underwent PTA and 20.6% underwent BPG.(26) Faglia et al(31) also reported that PTA was performed in 85.6% limbs, and BPG was performed in 11.1% limbs in which PTA was not feasible.

Diabetic patients tend to have an accelerated form of atherosclerosis and show faster progression of intimal hyperplasia at anastomoses or angioplasty sites. The consequences are earlier and higher rates of restenoses, which become even more pronounced in vessels with a smaller calibre.(4-7) Some authors remain doubting about whether diabetic patients really benefit from arterial revascularization at all, whereas others recommend surgery because of unacceptably high restenosis rates after distal PTA. However, technical feasibility, safety and interventional success of PTA have been established for CLI in a number of series, including diabetic patients.(27,32) Results were equivalent to nondiabetic patients and were achieved by aggressive therapeutic measures and refinement of catheter techniques.(29)

ABI was false high (>1.3) in 54 limbs (33.5%), the mean value of ankle pressure in the remaining patients was increased significantly in both groups. Faglia et al(31) also reported that ankle-pressure could not be measured in 202 out of 360 limbs (56.0%): in particular, this was due to the lack of patent arteries in the foot in 123 (34.2%) limbs, and to the presence of arterial calcifications in the remaining 79 (21.9%) limbs. The mean value of ankle pressure after PTA also increased significantly from 66.9 ±16.5 mmHg to 123.8± 27.5 mmHg (p=0.03).

The overall 1 year patency rate in the endovascular group was higher than that of surgical group, 74.2% and 70.8% respectively, but with no significant difference. Similary, another study recorded that during a mean follow up of 5.93 + 1.28 years the patency rate was 77.3% for PTA group and 68.2% after BPG.(26) Faglia et al(31) reported a first episode of CLI recurrence occurred in 53 (18.2%) of PTA patients, a second episode in 15 patients, and a third episode in 3 patients. The mean of 16.1+ 5.7 months, was the interval time after the first PTA. They also reported that BPG failure occurred in 16 (40.0%) patients after a mean of 6.2+5.9 months, 8 of these received a PTA, 1 a further BPG, 7 patients that could not sustain further revascularization either by PTA or BPG required major amputations. The rate of CLI recurrence was significantly higher in BPG group: p = 0.007. On the other hand, others reported a higher 1 year patency rate for BPG (56%) than that of PTA (45.9%).[29] Also, Romiti et al.[33] published a meta-analysis of 30 studies. At 3 years, Primary patency was much better for bypass (72%) than angioplasty (49%) but these studies reported that the limb salvage remained the same in both groups.

Recent data suggest that the early and mid-term outcomes of endovascular treatment in CLI appear acceptable in well selected patients and experienced centers. De novo stenosis within the vein graft conduit occurs in 30% to 40% of patients within the first 2 years of bypass, mandating a program of surveillance and reintervention to preserve long-term patency. Most importantly, distal bypass surgery for limb salvage is one of the most technically demanding procedures in vascular surgery, and there is significant variability in training, experience, and skill level among practitioners. It is likely that this plays a significant role in local practice patterns as well as in the outcomes realized.[34]

Endovascular therapy should be considered in those patients with good runoff, especially if there is a lack of conduit or the patient is a poor surgical candidate. Open surgery can be reserved for endovascular treatment failure or even as part of a hybrid procedure. In addition, major tissue loss has a better chance of healing with endovascular treatment if more than one tibial artery can be revascularized. With minor tissue loss, open the tibial artery that supplies the correct angiosome.[18]

In the present study, the 1 year patency rate for iliac disease was the same (80%) for both groups. Similarly, other study has compared open surgery with angioplasty in symptomatic iliac occlusive disease. There was no difference in patency and limb salvage rates at a median follow-up of 4 years. The authors concluded that the lower morbidity and mortality rate in the angioplasty group supported the concept of an angioplasty-first strategy because the outcomes of the two treatments did not differ.[35] In a second, nonrandomized comparative study, no significant differences were observed between the groups for late complications. However, the cumulative primary patency rate for bypass grafts was significantly better than for iliac stents at 18 months (93% vs 73%), 30 months (93% vs 68%), and 42 months (93% vs 68%).[36]

The 1 year patency rate for femoropopliteal PTA was 78.9% and was 76.9% for infrapopliteal PTA while the patency rate for multiple levels was 57.1%. The patency rates for femoropopliteal bypass, infrapopliteal bypass and femorodistal bypass for multiple levels were 73.5%, 60% and 50% respectively. In a comparison of results for above-the-knee versus below-the-knee (BTK) angioplasty in CLI patients, 2-year primary patency and limb salvage were 75% and 90%, respectively, for femoropopliteal angioplasty and 60% and 76% for BTK angioplasty.[37] There was a concurrent, comparative bypass group with 2-year primary patency and limb salvage for femoropopliteal bypass of 69% and 87%, respectively, and 53% and 57% for infrapopliteal bypass. Comparing the results of tibial angioplasty with popliteal to distal bypass in a meta-analysis of 30 studies showed that primary patency was better with bypass (72% v 49% at 3 years), but that limb salvage was about the same (82% in both groups at 3 years).[38] It is reported that long-term patency rates of tibial angioplasty are not as good as bypass, but limb salvage rates seem to be about the same and it offers faster recovery, shorter length of stay, and fewer major complications.[18]

Compared with the data reported in the literature, our series of revascularized patients required decidedly fewer major amputations in both the early and follow-up periods.[39] This is most likely due to the ability of our diabetic foot center to perform both endoluminal and surgical revascularization techniques, thus providing ≥95% of the patients with vessel revascularization. The rate of amputation is consistently lower in patients that received revascularization compared with patients that could not undergo revascularization.[40] An excellent diagnostic ability and an adequate postrevascularization ulcer management program are also required.[41]

In open surgery, an early failure of a bypass attempt often means a higher risk of limb loss as opposed to late failure. However, this is not demonstrated in early failed endovascular interventions. They reported that in the diabetic patient, the implications of a failed femoral to distal bypass carry a 50% chance of limb loss.[42]

We recorded a limb salvage rate of 90.7% after PTA during 1-year follow up with amputation rate of 9.3% while after surgery we reported a limb salvage of 85.2% during 1-year follow up with amputation rate of 14.8%. Near similar results reported by Faglia et al[26] who stated that After PTA, six major amputations were required within 30 days and 34 (8.2%) were performed during follow-up (5.93+1.28 years). After BPG, three major amputations were required within 30 days and 24 (21.1%) were performed during follow-up (5.93+1.28 years). At 30 days, there was no significant difference in the major amputation rates between group of PTA and BPG groups, but during the follow-up, there was a significant difference. However, another study recorded higher limb salvage after surgery, 86.3% during 1-year follow up with amputation rate of 13.7%, than the limb salvage after PTA, 80.1% during 1-year follow up with amputation rate of 18.9%.[29]

The limb salvage rate was the same in endovascular and open surgery in the diabetic group (33, 42). It has been postulated that endovascular therapy may increase limb salvage despite poorer long term patency as long as patency is maintained until the wound closes. However, this has not been evaluated in any prospective or systematic fashion in endovascular interventions. In open revascularization, late graft failure in operations performed for tissue loss results in recurrent wounds. Faglia[26] also observed similar amputation rates for the two procedures in the early period, but during the follow-up, the BPG group had a higher amputation rate than the PTA group. Angioplasty creates no leg incisions that might jeopardize the level of subsequent limb amputation, and thus this would seem to be a no-lose proposition for patients with amenable arterial lesions.[43]

The one year mortality rates were 10.3% and 14.8% for PTA and surgery groups respectively. Recent reports in the literature and in particular the recent Cochrane review, have reported that surgical and endoluminal revascularizations had similar outcomes in terms of mortality and major amputation rates.[44,45] Faglia et al[26] reported that the total death incidence per year of 12.53%. The annual death incidence was not different between patients who received PTA and those who received BPG. Faglia 2012[31] also reported that during 2 years follow-up 61 patients dead: 50 (16.2%) in PTA group, 11 (27.2%) in BPG group.

However, there are important limitations and risks to surgical procedures that should be considered, including postoperative morbidity, which is significant (20%). Wound complications are not infrequent (10% to 20%) and may necessitate prolonged hospitalization and additional procedures. Systemic complications such as cardiac, pulmonary, and renal are also not rare, and recovery in such cases may be prolonged.[34] The most obvious advantage to this minimally invasive therapy, PTA, is the low complications and morbidity associated with treatment.[43]

The best attempt to compare primary open and endovascular interventions was the BASIL (Bypass Versus Angioplasty in Severe Ischemia of the Leg) trial. The investigators randomized 452 patients, 42% of them had diabetes, with severe limb ischemia to surgery-first or balloon angioplasty first treatment strategies, and had long-term follow-up to 5 years or more in most patients. Most of the patients randomized in BASIL had moderate to severe disease either above or below the knee, and commonly only a single segment was treated. Isolated tibial angioplasty was rarely performed, and 25% of the bypass grafts were prosthetic. All of these technical factors would tend to weigh in favor of better outcomes for angioplasty. At 1 year, there was no difference in amputation-free or overall survival. They concluded that angioplasty should be used first for patients with significant comorbidities and with a life expectancy of ≤2 years, moreover, long-term results favored surgery if there is a “good” vein and a medically fit patient. However, for patients who survived 2 years (70% of the cohort), there was a survival advantage associated with the bypass first assignment and a trend to improved amputation-free survival. The BASIL authors concluded that bypass surgery with vein offered the best long-term outcomes, and is the preferred treatment for patients expected to survive 2 years or longer (approximately 70% of their cohort). They also reported that prosthetic bypass was associated with poor results and, therefore, angioplasty might be preferred when possible in patients lacking adequate venous conduit.[46]

Endovascular intervention for the treatment of limb ischemia has become the first line of therapy in many centers. Undoubtedly, in our analysis, we have seen a rapid growth of endovascular revascularization during the last 5 years, which has led to a significant decline in surgical revascularization. There are several reasons for the rapid growth of endovascular revascularization. First, endovascular interventions fall under the broad category of minimally invasive surgery, making it more attractive to patients. Similarly; patients with claudication who would have avoided surgery in the past now elect to have endovascular revascularization because of the minimally invasive nature of these procedures. Second, to sustain long-term patency, we might need to perform repeat endovascular interventions. This translates to the fact that patients may undergo multiple endovascular revascularizations as opposed to a single surgical bypass. Furthermore, patients who underwent previous surgical revascularization might have had endovascular interventions to sustain graft patency, increasing the number of endovascular interventions in these patients and have shown significant improvement in terms of limb salvage rates.[19]

Beyond different opinions and different published data, it is clear that if only one of these two procedures is available, the revascularization rates and subsequently the rates of limb salvage will be lower than when both procedures are available. The results obtained in our study population confirm this consideration, since an efficient revascularization was achievable in about 80% of the patients treated with PTA only and in about 60% of the patients treated with BPG only, while the complementary employ of both procedures allowed to revascularize 96% of the patients. However, in our protocol, the BPG was performed only when PTA was impossible; this may have selected patients with more severe arteriopathy. Nevertheless, the most important message that emerged from this study regarding the treatment of diabetic patients with CLI was the enormous difference in the amputation rate between patients that received and those that did not receive revascularization; this difference was evident in both the early and the late follow-up periods. This showed that a successful revascularization was more important than the type of revascularization used.[26]

Conclusions: Revascularization by PTA is highly feasible in diabetics with LLI. The feasibility of revascularization by BPG is lower and was performed when PTA was not feasible. Diabetic patients often have comorbidities that make minimally invasive treatment modalities look more favorable. PTA is considered the first choice revascularisation procedure as it is safe and effective for limb salvage in a high percentage of diabetic patients. Clinical restenosis was an infrequent event and PTA could successfully be repeated in most cases.

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