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ORIGINAL ARTICLE

THE RELATIONSHIP BETWEEN THE LENGTH OF OCCLUSION IN INFRAINGUINAL VESSELS IN CRITICAL LOWER LIMB ISCHAEMIA AND THE OUTCOME AFTER ENDOVASCULAR INTERVENTION

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Abstract

Critical limb ischemia (CLI) represents the most severe clinical manifestation of peripheral arterial disease. Patients suffering from CLI have traditionally been treated with surgical bypass to avoid major amputation. However, there are increasing data on the efficacy of endovascular revascularization procedures in achieving good leg salvage rate. The current study was designed to deal with 80 cases presented with critical lower limb ischemia involving the femoro-popliteal and infrapopliteal arteries. This study aims at reviewing the demographic features of patients presenting with CLI and reviewing the relation between the length of occlusion and clinical outcome after endovascular intervention, as regards the technical success rate and the short term follow up (patency rate and limb salvage rate). Patients were classified according to TASC II classification into TASC B (22.5%), TASC C (22.5%) and TASC D (55%). According to the length of the lesion <5 cm (17.5%), 5-10 cm (45%) and >10 cm (37.5%).All patients were offered a trial of revascularization by endovascular technique. Technical success was 97.5%. At 3, 6 and 12 months follow-up periods; overall Primary patency rates were 90%, 80% &72% respectively, Secondary patency rates were 95%, 91% &85% respectively, and Limb salvage rates were 92.5%, 87.5% and 83.75% respectively. Major amputation rate was 16.25%. It was concluded that, the length of the lesion, the multilevel disease and the single vessel runoff after angioplasty, all had their effect on the patency rates and the limb salvage rate.

INTRODUCTION

Critical lower limb ischemia -following the TASC II guidelines- is defined as: lower limb with more than two weeks of rest pain, ulcers, or tissue loss attributed to arterial occlusive disease.[1] The management of critical limb ischemia remains challenging due to the frequent patient comorbidities, diffuse vascular involvement, and high rates of restenosis and re-occlusion, and disease progression. Most patients presenting with CLI are old in age, atherosclerotic, diabetics and hypertensives. Most of them are heavy smokers, and with cardiac disease.[2-7] CLI also reflects an advanced, systemic form of atherosclerotic disease that renders the patient at high risk for complications after open surgical revascularization. A more aggressive percutaneous approach of revascularization for the treatment of infrainguinal occlusive disease evolved. It was found that endovascular therapy for CLI is associated with high rates of technical success (90%), low rates of periprocedural mortality (2%), and complication rates (5%) and that intermediate term (1-2 years) limb salvage rates of more than 80% are typical.[8] Furthermore, as balloon angioplasty does not usually preclude later bypass surgery, it can be attempted rather liberally as a first-line revascularization strategy.[9] The presence of multilevel disease affects the prognosis after angioplasty as every level by itself has its rate of

complications and re-stenosis. After completion of the angioplasty, the distal runoff also affects the prognosis. This study evaluated short-term results of endovascular treatment of infrainguinal arterial disease in patients with critical lower extremity ischemia, as regards the relation between the length of the lesion and the primary and secondary patency rates, and limb salvage rates.[10-12]

PATIENTS AND METHODS

This is a prospective study conducted on 80 patients who presented to our department of vascular and endovascular surgery, Kasr Al Ainy hospital, Cairo University from 10/2010 to 4/2012. The patients in this study presented with critical lower limb ischemia according to TASC II classification, and included femoro-popliteal and infra popliteal vessels occlusive disease.

Patients presenting with non-salvageable limbs requiring primary major amputation, acute thrombotic or embolic ischemia, aneurysms, trauma, arteritis or connective tissue disorders, were excluded from this study. All patients were subjected to detailed history taking, especially the history of rest pain, ulcers and gangrene, color and temperature changes, weakness and parasthesia. Past history of previous interventions and medical history was taken (previous surgeries, diabetes, hypertension, cardiac or renal disease, regular medications). Proper clinical evaluation; blood pressure, pulse, cardiological, neurological, & respiratory assessments were performed. Complete blood count, fasting blood glucose, coagulation profile, liver and renal function tests were done. Duplex study with ABI and peak systolic velocities was done in addition to conventional angiography or CTA of the arterial tree. An informed consent was signed by all included patients.

All endovascular procedures were done in our angiosuite under local anaesthesia. Proper hydration was insured by adequate fluid intake the day before the procedure. A loading dose of clopidogrel 300 mg was given the night of the procedure that is to be continued post-procedurally (if stents were used) at a maintenance dose of 75 mg daily. The first choice approach for lower limb intervention was ipsilateral antegrade puncture of the common femoral artery. Contralateral femoral approach was chosen if duplex scan showed iliac or common femoral artery stenosis >50%, proximal SFA lesion, severe obesity, high femoral bifurcation. A bolus of 5000 IU of unfractionated heparin was administered intra-arterial. An initial angiogram was done to confirm the pre-procedure duplex, determine the morphology of the lesion, and decide the plan of treatment. Through a 6F sheath, a guide wire (0.035 inch in SFA, 0.018 and 0.014 inch in infra-popliteal tree) was used to cross the lesion with or without the support of a guiding catheter, and balloon catheters (2.5-6 mm) were used for the dilatation of arteries. Stents were used selectively, particularly if dissection or suboptimal results persisted despite repeated, prolonged balloon inflations (in the SFA, 5-6 mm stents). In cases of vessel spasm Tridil 5 mg/ml (1 ml diluted in 10 ml saline) was given intra-arterially. Vessel recanalization was considered successful when direct flow was obtained angiographically in the treated vessel with or without retrieval of distal pulsation. Immediate evaluation was based on clinical assessment (pulse, capillary refill, and warmth) and angiography. The arterial sheath was routinely removed 2-3 hours after the procedure and digital compression was done for 15-20 minutes. Successful cases were discharged on the second day on a treatment of clopidogrel (only if a stent was used) 75mg/day, aspirin 150 mg/day.

The success of the procedure: Angiographic success defined as good flow with less than 30% residual stenosis at the narrowest point of the arterial lumen, and definitive clinical success in the form of regain of pulse, or clinical improvement (good capillary circulation, warmth, relief of symptoms and good healing of ulcer or minor amputation).

Follow-up protocol: The outcome was evaluated for every case by clinical examination and duplex was done 3, 6 and12 months later. Angiography was only done if there was deterioration of the clinical status or abnormal duplex findings.

RESULTS

This study was conducted on 80 patients with critical lower limb ischaemia in a period of eighteen months, and 1 year follow-up. The number of male patients was 54 (67.5%), while there were only 26 female patients (32.5%) of the cases. The co-morbities were diabetes, hypertension, smoking, cardiac diseases, COPD and stroke, with diabetes and hypertension being the most prevalent (92.5% and 90% respectively). Only 15% of the patients presented with rest pain, while 85% presented with tissue losses in the form of ulcers in (17.5%), gangrenous toes in (47.5%) and massive gangrene of the fore-foot not extending to the heel in (20%). According to TASC II classification; there were 18 patients with TASC B (22.5%), 18 with TASC C (22.5%) and 44 with TASC D (55%). The length of lesion was <5cms in (17.5 %), from 5 to 10 cms in (45%) and >10 cms in (37.5%). Most of the patients (80%) presented with single occlusion.

Antegrade access was used more than retrograde access (92.5% and 7.5% respectively). Stent was used in 35% of the patients in the superficial femoral artery only, the length of the stents ranged between 8 and 15 cm according to the length of the lesion. Technical success was 97.5%. The number of the distal runoff vessels after PTA is shown in table (1). Two cases (2.5%) had failed endovascular intervention and below knee amputation was done. Primary patency rate was 90%, 80% &72% at 3, 6 and 12 months follow-up respectively. Secondary patency rates were 95%, 91% &85% at 3, 6 and 12 months follow-up respectively.

Limb salvage rate in this study was 92.5%, 87.5% and 83.75% at 3, 6 &12 months follow-up respectively. Total number of patients who underwent major amputation (above and below knee amputations) throughout the study was 13 (16.25%), four of them above knee (30.7%) and the remaining 9 cases (59.3%) underwent below knee amputation. As regards below knee amputations; two were done after failure of endovascular dilatation (these were TASC D with very poor distal runoff). Seven cases with single runoff were done within 12 months follow-up period. As regards the 4 above knee amputations, they were done between 6-12 months followup period. Two due to spreading infection (with good vascularity), and two were patients with one-vessel runoff after successful angioplasty.

Table 1. Showing number of distal runoff vessels after PTA of the SFA.

No. of runoff vessels	Frequency	percentage
1	38	47.5%
2	12	15%
3	30	37.5%

Table 2. Showing 1ry and 2ry patency rates in relation to the length of the lesion.

Length of lesion	1ry patency		2ry patency	
	6 month	12 month	6 month	12 month
<5cm	92%	85%	95%	88%
5-10 cm	80%	70%	84%	78%
>10 cm	55%	0%	62%	34%

As regards the length of the lesion, we compared the results obtained from the study; cases with lesions < 5 cms had the best prognosis as regards patency rates and limb salvage. Cases with lesions' lengths between 5 and 10 cms had fair results. The worst results were obtained with lesions >10 cm length,1ry patency rate was 55% in 6 months period and 2ry patency rate dropped from 62% to 34% between the 6 to 12 months follow-up. As for lesions with <5 cm length lesions, 1ry and 2ry patency rates were 85% and 93% respectively at the 12 months follow-up (table 2).

Ninety two and a half percent (92.5%) of patients in this study were diabetics. Multilevel occlusions were found to be in 16 cases (20%). The primary patency rate for these cases dropped from 80% to 50% within 6 to 12 months follow-up. Secondary patency rate dropped from 90% to 70% within 6 to 12 months follow-up.

DISCUSSION

Specific considerations apply to CLI patients. CLI is characterized by multi-level disease, high burden of comorbidity and limited life span. Thus decision-making in revascularization strategies in CLI differs substantially from that in patients with claudication as; wound healing, limb salvage and maintained ambulation are different treatment aims than improved walking ability.

Long-term patency as such is probably of less importance. The choice of endovascular treatment may be supported by presence of major comorbidities and hence high risk for open interventions.[13] The prognosis is poor and patients have a high risk of major amputation and death, the 1-year amputation rate being over 20%, and the 1- and 5-year mortality around 20 and 40–70%, respectively.[5]

The age distribution in the current study ranged from 48 to 82 years old with mean 64.88. It reflects higher prevalence of CLI in the age group above 60 years old. This was less to some extent than mentioned in some studies[2-4,14,15] in which age ranged from 66 to 89 years old. This may be explained by high incidence of atherosclerosis with advance of age especially in the 6th decade of life.

In the current study male patient constituted about 67.5% while female were 32.5 % of all patients. The higher incidence in male population was mentioned also by,[2-5,6,7,15,16] where it ranged from 54 to 76%. The higher incidence in male may be attributed to the prevalence of predisposing factors (smoking, hyperlipedimia, stress of life& hypertension) in the male population.

In the current study the main associated co-morbidities were diabetes in 92.5%, smoking in 62.5%, hypertension in 90% and cardiac disease in 39.1%. Diabetes resembles a challenge due to the bad condition of the vessel wall,

the distribution of the arterial disease and moreover the microangiopathies that make the spread of infection more serious. In this study there was no specific classification for diabetics and non-diabetics but being represented by 92.5% of CLI patients included in this study, diabetes should be put into consideration.

The current study results are coinciding with the incidence of hypertension, cardiac and smoking mentioned in literature; this may be attributed to the increased incidence of atherosclerosis with these risk factors.

This study showed that, among patients with a more advanced limb ischemia grade, the prevalence of DM is often higher. Patients with DM tend to have a greater systemic vascular disease burden based on their comorbidities and also had increased rates of restenosis and significantly lower limb salvage rates than the non-diabetic patients despite having less complex lesions according to the TASC system of categorization. Similar results were obtained in a study by Bakken, et al., in 2007.[18] On the other hand, it was found that diabetes was not a negative predictor of wound healing or limb salvage.[19] It was found that in those patients deemed suitable for revascularization, there was no statistical significant difference in the limb salvage rate between diabetic and non-diabetic patient.[20]

It is commonly recognized that a more severe ischaemic state of the limb, more likely results in a higher major amputation rate. The need for major amputation is twofold higher in patients with ulcers or gangrene than in patients with only rest pain.[7] In the current study, it is found that presence of major tissue loss (forefoot or beyond) showed worse limb salvage rate (66.6%). In a study by Taylor etal,[21] it was argued that clinical success after lower extremity revascularization for ischemic tissue loss is determined by intrinsic patient factors and not by method of revascularization.

TASCII D infrainguinal lesions were found in 44 cases (55%). This reflects that CLI to occur needs extensive disease and long occlusion not simply short stenosis or occlusion and this was consistent with other studies[2,6,22] However it was mentioned that TASC A &B can cause CLI as diabetic patient had in addition microvascular deficiency (microangiopathy) because the presence of DM appears to reduce blood flow to the microvascular bed via arterio-venous fistulae leading to symptomatic disease with less advanced femoro-popliteal disease.[7,18]

In different studies on patients with critical limb ischemia where most patients would have been TASC II C or D, PTA was feasible in 84% and during a median follow-up of 23 month while the cumulative 5 year primary patency was 88%.[23-25] It was stated that endovascular interventions for TASC II D lesions can be safely performed with excellent hemodynamic improvement and limb salvage rates.

It was mentioned that five-year patency is 80% to 85% for ideal short segment lesions <5 cm, with patency decreasing to approximately 65% to 75% for stenosis in >5 cm. 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. Additionally, a system was recommended that depended on the length of lesion instead of the TASC for research applications and clinical management.[13] It was mentioned that short SFA lesions (<5cm) are preferably treated with angioplasty. Stenting of short lesions should only be performed when suboptimal results are obtained with PTA alone and the preferred treatment of intermediate SFA lesions (5—15cm) is PTA with primary bare nitinol stenting and in long SFA lesions (>15 cm) endovascular treatment (intraluminal or subintimal) with a stent graft seems acceptable when the patient's condition precludes an open procedure.[13] In the current study, lesions more than 10 cm were present in 37.5% of cases and SFA segment was the highest segment affected, and our results were almost similar to those mentioned in other studies. In the study by Taneja et al,[26] similar limb salvage rates like our study were obtained in CLI patients with long-segment occlusions treated with bare nitinol stents; and primary patency rates were rather low with 61.5% and 27% after 6 and 12 months, respectively. However, in a study by Antusevas et al,[27] there was no statistical significance between the length of lesion and technical failure.

Another limitation of TASC II classification is in management of infrapopliteal disease as the commonly encountered TASC D (occlusions longer than 2 cm or diffuse disease in the tibial and peroneal arteries) which indicates bypass surgery according to the TASC guideline, and few patients with CLI therefore are clinically indicated for angioplasty based on anatomical morphology. However, endovascular therapy (EVT) with traditional angioplasty currently is most widely used in the infrapopliteal region because it achieves technical and clinical success rate of up to 90% and 70%, respectively. Moreover, patients are commonly not suitable surgical candidates secondary to comorbidities and advanced age.

The TASC-based morphological classification of infrapopliteal lesions does not determine revascularization modality selection in current clinical practice.[7]

In the current study, multilevel occlusions were found to be in 16 cases (20%). The primary patency rate for these cases ranged from 80% in the 3 months follow up to 60% in the 18 months follow-up. Secondary patency rate dropped from 90% to 70% within 6 to 18 months follow-up.

Other studies,[28] showed that the 5-year primary patency rate for combined multilevel reconstructions ranged from (61%) to (80%). The endovascular treatment of multilevel disease is thought to result in worse outcomes compared with the treatment of single-

level disease of the femoropopliteal or aorto-iliac vasculature, because each lesion has its own failure rate that results in an additive effect. In addition, patients with multilevel disease are frequently older, have more co morbidities, and have lower baseline ankle-brachial indices than patients with single-level disease.[29]

Although runoff status is not simple to quantify, it has been identified as a significant prognostic factor in the outcome of endovascular intervention. This difference is accentuated in diabetic patients, who often have severe distal disease compromising runoff. In a study of PTA in diabetic patients, there was a 19% difference between groups with good runoff and poor runoff at 1 year (95% versus 76%), but at 5 years, there was an almost fourfold difference in patency; (77% versus 20%).[30] In the current study, it was found that 38 patients (47.5% of the cases) were with single vessel runoff. Nine (23.6%) of these patients underwent major amputations within the 3-12 months period, and 12 cases (15%) were with two vessels runoff. Two (16.6%) of them underwent major amputation within 6-12 months. And those with 3 vessels runoff didn't need major amputation in 12 months follow up period.

In this study, SFA stenting was done in 28 cases (35%) of total cases. Although stents have been increasingly used in the femoro-popliteal segment, no convincing data exist to show that primary stenting dramatically improves out-come. SFA is subjected to many external forces (torsion, compression, flexion, extension and contraction) that make stenting not popular. However after suboptimal balloon (as dissection occurs or residual stenosis or recoil), stenting can improve the outcome.[31]

Several concerns have been raised regarding the utilization of stents in infrapoliteal disease with respect to the risks of stent fracture, restenosis, thrombosis, and the possibly limited role of a focally acting endoprothesis in a diffusely diseased vessel.[13] In the current
study, no stenting of the infra-popliteal vessels was done.

In the current study; primary patency rate was 90%, 80% &72% at 3,6 and 12 months follow-up respectively. Secondary patency rates were 95%, 91% &85% at 3,6 and 12 months follow-up respectively. The limb salvage rate after 3,6 &12 months were 92.5%, 86.5% & 83.75% respectively. Our results were relatively consistent with other studies.[32,33]

It is now recognized that the patency of revascularization is not important as limb salvage and actually there is a population of asymptomatic patients with subclinical lower extremity ischemia and very low perfusion pressures. These patients become symptomatic only when they develop incidental foot ulceration and do not have the circulatory reserve to heal. A boost in arterial perfusion, even transiently, usually allows healing of the ulcer. Once the ulcer is healed, maintenance of enhanced perfusion is not critical, and recurrent ischemia is usually well tolerated as the patient resumes the subclinical ischemic state. Percutaneous intervention proponents therefore argue that inferior reconstruction patency rates after such interventions are inconsequential.[34] This makes the endovascular treatment an attractive method of treatment of patients with CLI who have multi-level disease, and high burden of co-morbidity.

In conclusion results of this study showed that, in relation to the length of the lesion, patency rates are significantly lower the longer the lesions, also TASC D cases have worse patency rates. As regards the limb salvage rates, there is no direct relation to the length of the lesion, microangiopathy might play a stronger role. Given a similar limb salvage rate in those undergoing revascularization procedures, diabetics should not be prejudiced against and the decision to amputate or treat conservatively rather than revascularise should be based on suitability for revascularizations, appropriate anatomy, and the presence of medical conditions other than diabetes. However, it was argued that clinical success after lower extremity revascularization for ischemic tissue loss is determined by intrinsic patient factors and not by method of revascularization. These data predict that future investigation efforts should be focused less on the method of revascularization and more on identification of patient cohorts at risk for failure regardless of the treatment method.

A system was recommended that depended on the length of lesion instead of the TASC for research applications and clinical management and also urge that future research should prove the applicability and reproducibility of the classification and the additional value of a potential subdivision of stenotic vs. occlusive lesions.

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