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Original Research Article

Endovascular revascularization of multilevel arterial disease in patients with critical limb ischemia

Asser Abd El Hamid Goda*

Department of Vascular Surgery, Sohag university hospital, Sohag university, Sohag city, Sohag state, Egypt

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***Correspondence:**
Dr. Asser Abd El Hamid Goda,
E-mail: assergoda@yahoo.com

ABSTRACT

Background: Critical limb ischemia (CLI) occurs due to progressive obstructive nature of atherosclerosis disease. Nowadays, there is widespread use of endovascular revascularization procedures for restoration of blood flow in CLI. The aim this study is evaluation of the efficacy of endovascular intervention for multilevel arterial disease in patients with critical limb ischemia.
Methods: This prospective study was included CLI patients due to multilevel arterial disease who underwent endovascular revascularization between January 2016 and January 2017 in our institution. Study end points were limb salvage and wound healing.
Results: The mean age of patients was (61.7±7.47) years, with 13 (61.9%) men. Eight limbs were identified as Rutherford category 4 (38.1%), ten limbs as Rutherford category 5 (47.6%), and three limbs as Rutherford category 6 (14.3%). Limb salvage rate was (90.5%) at 1 year. Wound healing rate was 80.9%.
Conclusions: This study proved that endovascular revascularization of multilevel arterial disease for patients with critical limb ischemia is effective.

Keywords: Critical limb ischemia, Endovascular revascularization, Multilevel arterial disease

INTRODUCTION

Both increasing the life expectancy and prevalence of diabetes mellitus lead to increased incidence of peripheral artery disease, especially CLI.[1] Critical limb ischemia (CLI) occurs due to progressive obstructive nature of atherosclerosis disease, that leads to marked reduced blood flow.[2,3] CLI patients may lose their limbs or may undergo fatal complications of sepsis and gangrene if the limb is not vascularized.[4] Twenty five percentages of CLI patients are at risk of mortality and another 25% are at risk of amputation, if they are not timely revascularized.[5] Even in developed countries, primary foot amputation is considered the management of 25% of the patients with CLI.[6] Urgent revascularization of CLI patients following adequate diagnosis is a cornerstone step in treatment of CLI patients to obtain good outcome.[4] The role of either endovascular intervention (EVI) or bypass surgery is established as revascularization modalities for patients with CLI.[5]

Revascularization strategies changed from traditional bypass surgery to endovascular intervention due to technological advances and patients preference (7,8&9). Endovascular revascularization is preferred to surgical bypass for selected lesions, because it is performed under local anaethesia, it enables the vascular surgeon to treat patients who are at high risk of anaethesia, it has low mortality and it has acceptable midterm assisted patency and limb salvage rates.[5] Nowadays, there is widespread use of endovascular revascularization procedures for restoration of blood flow in CLI due to new advancement

in techniques and devices and due to presence of proved evidence regarding its safety and clinical effectiveness.[9-13]

The aim of this study was to evaluate the efficacy of endovascular intervention for multilevel arterial disease in patients with critical limb ischemia. This aim is proved by limb salvage rate and healing rate.

METHODS

This prospective study was conducted at Vascular Surgery Departments in Sohag University Hospitals between January 2016 and January 2017 following approval by the Scientific Ethics Committee. The study included 21 patients presented by critical limb ischemia due to multi-level atherosclerotic occlusive disease affecting the infra-inguinal arteries. Written informed consent was obtained from the entire patients after verification of the inclusion and exclusion criteria and before start of the procedure.

Inclusion criteria

Patients with critical limb ischemia.
Patient is willing to comply with specified follow-up evaluations at the specified times.

Exclusion criteria

- Patients have renal impairment.
- Lower limb claudication only.
- Patients with uncorrected bleeding disorders.

Hemodynamically unstable patient at onset of the procedure. Patients presented with critical limb ischemia due to non-atherosclerotic occlusive disease e.g. atheroembolic/thromboembolic disease, thrombosis resulting from hypercoagulable states, vasculitides, thromboangiitis obliterans, cystic adventitial disease, Buerger's disease, popliteal entrapment syndrome, trauma.

Baseline clinical examination is done for all eligible patients to collect clinical data before the procedure, which is consisted of medical history, physical examination and clinical category of critical limb ischemia according to the Rutherford classification.

The disease distribution and severity were assessed by color-flow duplex ultrasound imaging and CT angiography. Procedural angiography is done for final assessment of the severity of lesion.

Interventions details

Arterial Access was accomplished using 6 F Introducer Sheath. Antegrade, ipsilateral common femoral artery puncture was preferred for femoropopliteal lesion and for infrapopliteral artery lesions. Both contralateral femoral puncture and cross over technique and retrograde ipsilateral puncture of the popliteal artery were performed when the lesion was very close (less than 1 cm) to the SFA origin. The lesions were crossed using a hydrophilic guide wire over an angled-tip diagnostic catheter. For femoropopliteal arterial lesions 0.035 inch hydrophilic guide wires were used but, for infrapopliteal arterial lesions hydrophilic 0.018 inch guide wires were used Angioplasty balloons length selected to match the length of the lesion and the diameter of the non-diseased artery adjacent to the lesion on CT or angiography. Balloon inflation pressures ranged from 4 to 16 atmospheres and were repeated routinely two to three times (for at least 60s) at the same segment. Stents in SFA lesions were placed for flow-limiting dissections or suboptimal angioplasty results (residual stenosis >30%). If a stent is indicated, a self-expanding stent was used. Post procedure angiography: Completion angiography was done immediately after the endovascular procedure (Fig 1-8).

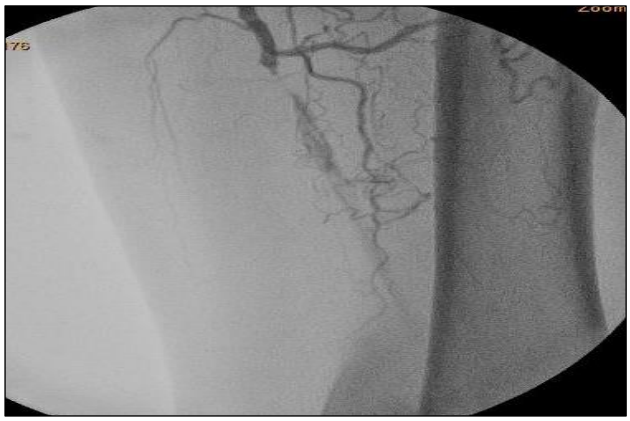

Figure 1: SFA lesion.

Figure 2: Infrapopliteal lesion.

Debridement of all gangrenous and necrotic tissue if present was performed immediately after the end of the endovascular procedure. The patients were given dual oral antiplatelet therapy (aspirin 75 mg/day and clopidogrel 75 mg/day) for at least one year and aspirin for life-long.

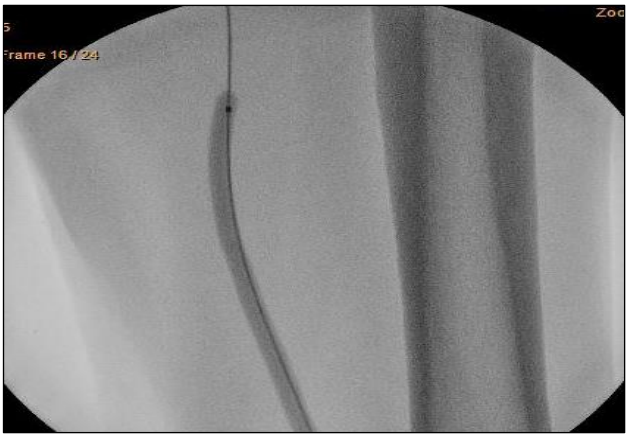

Figure 3: SFA angioplasty.

Figure 4: SFA and popliteal angioplasty.

Figure 5: Infrapoliteal angioplasty.

Follow up

Before the patients discharge from the hospital, 1, 3, 6, 9 and 12 months after endovascular intervention, all the patients were evaluated by clinical examination.

By clinical examination we looked for:

- Wound healing
- Absence of rest pain
- Absence of tissue necrosis and gangrene

Figure 6: Infrapopliteal angioplasty.

Figure 7: Normal SFA flow.

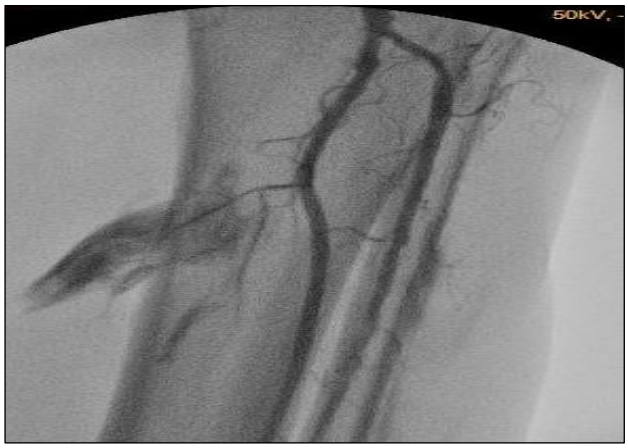

Figure 8: Normal ATA, Peroneal A flow.

Duplex imaging and CTA were done for patients presented with return CLI symptoms.

Endpoint

Endpoints are limb salvage and wound healing

Definitions

Limb salvage was defined as prevention of major amputation.[14]

Major amputation was defined as limb loss below or above the knee.[14]

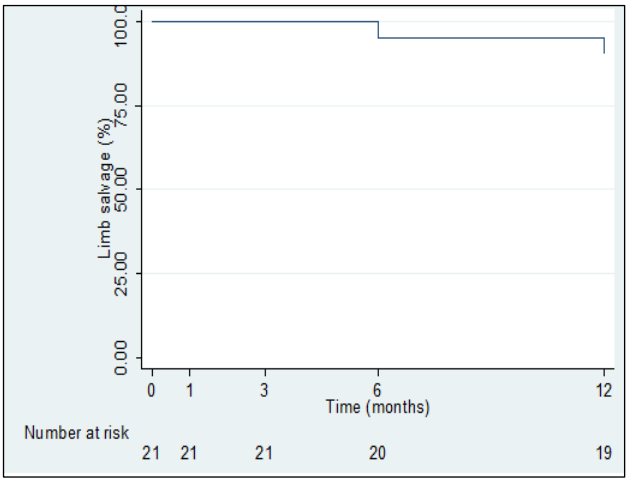

Figure 9: Kaplan-Meier curve of limb salvage.

Statistical analysis

Data are presented as mean±standard deviation for continuous variables and data are presented as counts (percentages) for categorical variables. The limb salvage rate (LSR) was estimated using Kaplan-Meier method.

RESULTS

During the study period, 21 patients with 21 critically ischemic limbs underwent multi-level arterial endovascular intervention.

The baseline characteristics of the study patients

The mean age of the study population was (61.7±7.47) years, with 13 (61.9%) men. Many patients had risk factors like diabetes mellitus (85.7%), hypertension (61.9%), and smoking (42.8%).

Also, many patients had significant comorbidities including cerebrovascular stroke (9.5%), coronary artery disease (33.3%), and chronic renal failure (4.7%). Eight (38.1%) limbs were identified as Rutherford criteria 4, ten (47.6%) limbs as Rutherford criteria 5, and three (14.3%) limbs as Rutherford criteria 6 (Table 1).

Table 1: The baseline characteristics of the study patients.

Total number of patients	21
Demographic characteristics of patients	
Age	61.7±7.47
Male gender	13 (61.9%)
Risk factors	
Diabetes	18 (85.7%)
Hypertension	13 (61.9%)
Smoking	9 (42.8%)
Comorbid diseases of patients	
Cerebrovascular stroke	2 (9.5%)
Coronary artery disease	7 (33.3%)
Chronic renal failure	1 (4.7%)
Clinical presentation of patients	
Rest pain, ulcer (Rutherford criteria 4)	8 (38.1%)
Minor tissue loss (Rutherford criteria 5)	10 (47.6%)
Major tissue loss (Rutherford criteria 6)	3 (14.3%)

Data expressed as the mean value ± SD or percentage of patients.

Angiographic finding of the study patients

Both femoropopliteal and infrapopliteal lesions were present in (71.4%) but femoropopliteal lesions only were present in (28.6%). Femoropopliteal lesions were classified according to the TASC II system. Fourteen (66.7%) lesions were identified as TASC II A, four (19%) lesions as TASC II B, two (9.5%) as TASC II C, and one (4.8%) as TASC II D. infrapopilteal lesions were classified according to on the number of affected infrapopliteal arteries because most cases with long segmental occlusion or total occlusion are classified to class D on TASC system. Five (33.3%) patients had single infrapoplitel artery affection, eight (53, 3%) patients had two infrapopliteal arteries affection, and two (13.3%) patients had three infrapopliteal arteries affection (Table 2).

Table 2: Angiographic finding of the study patients.

Lesion distribution	
FP and IP	15 (71.4%)
FP	6 (28.6%)
FP lesions (21 limbs)	
TASC II A	14 (66.7%)
TASC II B	4 (19%)
TASC II C	2 (9.5%)
TASC II D	1 (4.8%)
IP lesions (15 limbs)	
One IP artery affection	5 (33.3%)
Two IP arteries affection	8 (53.3%)
Three IP arteries affection	2 (13.3%)

Outcomes of the study patients

Limb salvage rate was 90.5 % (19/21) at 1 year (Fig 9). During the follow up, 2 patients required major amputation. Amputation was done for the first patient at

6th month and at 12th month for the second patients. Wound healing rate was in this study was successful in 80.9% (17/21) of patients.

DISCUSSION

Both increasing the life expectancy and prevalence of diabetes mellitus lead to increased incidence of peripheral artery disease, especially CLI.[1] Prompt revascularization is considered the o ptimal treatment of CLI.[15] The ideal revascularization procedure is the one that 'avoids a general anesthesia, poses a lesser systemic stress, and has fewer serious complications.[9]

This study is a single-center experience of the effectiveness of endovascular treatment for multilevel arterial disease with critical limb ischemia that is proved by limb salvage and wound healing. The follow-up period is 12 months which is comparable to other recent studies.[3,11]

The LSR in this study was 90.5% (19/21) at one year which is comparable to LSR in other literatures.[2,11,16,17] Bae et al reported in retrospective study on 189 limbs with CLI treated with multilevel endovascular revascularization that LSR was 94.8% at 1 year.[2] Another study was done by Conrad on 409 CLI patients.[11] The patients underwent infrainguinal PTA±stent for CLI management. The LSR in that study was 88.4% at one year. Kanolkar reported in study included 34 patients underwent endovascular reconstruction of popliteal and infrapopliteal arteries for CLI that the Limb salvage rate was (97%) at 3-month.[16] O'Brien Irr et al reported in study in which analysis of 106 infrainguinal interventions for CLI was done that limb salvage rate was 83% at 2 years in patients with tissue loss.[17]

Wound healing rate in this study was successful in 80.9% which is comparable to wound healing rate in other literatures.[2,18] Bae et al reported that wound healing was successful in 85% and failed in 15%.[2] Okamoto et al reported that wound healing was 87% in study included 211patients with CLI caused by infrainguinal disease treated by endovascular intervention.[18]

Wound healing rate in this study was more than that reported in other literatures.[6,17] Kanolkar reported that successful wound healing occurred in 11 (35%) patients with an additional 7 (21%) patients showing clinical improvement in their wounds.[16] O'Brien-Irr et al reported that wound healing rate was 50% with a mean healing time of 7 months.[17]

CONCLUSION

Endovascular revascularization of multilevel arterial disease is effective for patients with critical limb ischemia, where it provides high LSR and wound healing rate. Endovascular revascularization for CLI patients should be chosen as first-line therapy.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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