Efficacy of multiple arterial levels of percutaneous transluminal angioplasty on limb salvage

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Background
Endovascular recanalization has become the preferred method of treatment for many patients with symptomatic femoropopliteal (FP) occlusive disease.
Aim
To study the efficacy of multiple level arterial angioplasty on limb salvage.
Patients and methods
This is a prospective, nonrandomized study that included 35 patients with critical lower limb ischemia due to multilevel arterial atherosclerotic occlusive disease treated with endovascular revascularization between August 2015 and July 2016 and followed up for 12 months. Primary outcome parameters included technical success proved by completion angiogram and distal pulse retrieval. Secondary outcome parameters included limb salvage, disappearance of the rest pain, wounds healing, and claudication distance improvement.
Results
Angiographically, 62.9% had both FP and infrapopliteal segment lesions while 37.1% had FP lesions only, and about 50% of our cases were Trans-Atlantic Society Consensus (TASC) II A. Technical success was recorded in 31 (88.6%) patients with failure to cross the lesion occurring in four (11.4%) patients. Cumulative limb salvage rates were 96.7, 90.3, and 80.6 at 3, 6, and 12 months, respectively.
Conclusion
The endovascular approach is safe and effective in the management of multilevel arterial atherosclerotic occlusive disease with high technical success rate and accepted percent of limb salvage for 1 year.

Keywords:
angioplasty, critical limb ischemia, infrapopliteal

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Introduction

Femoropopliteal (FP) segment involvement in occlusive peripheral arterial disease is extremely common and, in one series, was present in 80% of symptomatic patients undergoing angiography [1].

Endovascular recanalization has become the preferred method of treatment for many patients with symptomatic FP occlusive disease. Percutaneous transluminal angioplasty (PTA) with adjunctive stenting is a well validated and increasingly used technology, and it is the technique most frequently used for infrainguinal endovascular treatment. An alternative to transluminal angioplasty is subintimal angioplasty, also referred to as percutaneous intentional extraluminal revascularization. Novel technologies and refinements of previous technologies are enabling endovascular treatment for increasingly complex vascular pathology [2].

Device and technical developments provide high recanalization rates in total occlusions of more than 85% (range, 81–94%; SE, 2.9%) [3].

Recent technologic advances in endovascular therapy have extended the applicability of minimally invasive treatment for challenging superficial femoral artery lesions that were previously deemed unsuitable for endovascular repair. Current infrainguinal endovascular options include balloon angioplasty, subintimal angioplasty, angioplasty with selective stenting, and primary stenting. Several trials have been published; however, the debate continues about which endovascular treatment is preferable [4,5].

Aim

The aim of this study is to evaluate the efficacy of endovascular techniques for multilevel arterial occlusive disease on limb salvage.

Patients and methods

This is a prospective, nonrandomized study conducted at the Vascular Surgery Department at Zagazig University Hospitals and Vascular Surgery Department at Sohag University Hospitals in the period between August 2015 and July 2016. All procedures performed were in accordance with the ethical standards of the institutional research committee and with the Helsinki declaration. Informed consent was obtained from all participants included in the study.

The study group included 35 patients suffering from atherosclerotic occlusive disease affecting the infrainguinal arteries (multilevel lesions) presented by critical limb ischemia.

After verification of the inclusion and exclusion criteria, written informed consent for the collection of personal medical data was obtained for each patient before enrollment in the study.

Inclusion criteria

(1) Patient aged 18 years or more.
(2) Patients with critical limb ischemia.
(3) Patient willing to comply with the specified follow-up evaluations at the specified times.
(4) Patient (or his or her legal representative) understands the nature of the procedure and provides written informed consent.

Exclusion criteria

(1) Patients who have renal impairment.
(2) Lower limb claudication only.
(3) Patients with uncorrected bleeding disorders.
(4) Any patient considered to be hemodynamically unstable at the onset of the procedure.
(5) Patients suffering from nonatherosclerotic occlusive disease, for example, arteritis and entrapment syndrome.

Patients were eligible for enrollment in the study when they complied with all general inclusion criteria and all angiographic inclusion criteria and when none of the exclusion criteria were met. The procedure, possible complications, benefits, risks, and other alternative interventions were all explained to the patients.

All eligible patients underwent a baseline clinical examination which consisted of medical history, medication record, physical examination, and clinical category of critical limb ischemia according to the Rutherford classification and Trans-Atlantic Society Consensus (TASC) II classification.

Evidence of disease was assessed by color-flow duplex ultrasound imaging and computed tomography angiography. Final assessment of the lesion severity had to be confirmed by procedural angiography.

Interventions details

(1) Arterial access:
   (a) Antegrade, ipsilateral common femoral artery puncture is preferred unless the lesion is very close (<1 cm) to the superficial femoral artery (SFA) origin.
   (b) Contralateral femoral puncture and perform a cross-over technique.
   (c) Retrograde ipsilateral puncture of the popliteal artery, if there is an SFA occlusion flush with the vessel origin and the popliteal artery is patent.
(2) Angiography.
(3) Crossing the lesion:
   (a) The standard tools for recanalization of stenosis and occlusions consist of a hydrophilic guide wire and an angled-tip catheter, for example Bernstein.
   (b) Deploying the balloon/stent.
   (c) Balloon angioplasty.
   (d) Stent insertion – indications for stent insertion in the SFA segment are:
      (i) Elastic recoil.
      (ii) Flow-limiting dissection.
      (iii) Residual stenosis more than 30%.

Endpoint

(1) The endpoint of the procedure is unrestricted forward flow of contrast with no evidence of significant (>30%) residual stenosis.
(2) The runoff should be assessed at the end of the procedure for the occurrence of distal embolization caused by the PTA or stent insertion.
(3) As all the patients are being treated for critical ischemia, PTA of any relevant tibial lesions should be performed during the same procedure.
(4) When the procedure is completed, the arterial access sheath should be removed and hemostasis achieved by manual compression.
(5) After revascularization, debridement is done to remove all gangrenous and necrotic tissue if present.

Primary outcome parameters

(1) Technical success proved by completion angiogram (means good flow of the dye with no flow-limiting dissection or residual stenosis more than 30% and there is at least one patent runoff reaching the foot arch).
(2) Distal pulse retrieval.

Secondary outcome parameters

Limb salvage (means that the patient only underwent minor amputations in the foot without any major amputation) and proved by:

(1) Disappearance of the rest pain.
(2) Healing of the wounds.

Follow-up

Patients' follow-up visits are 1 week after the procedure, then every 3 months for 1 year. Clinical follow-up data were collected at 3, 6, 9, and 12 months. At each follow-up visit the patients were subjected to medication registration, physical examination, ABI measurements, clinical categorization of critical limb ischemia according to the Rutherford categorization, and wound healing assessment. Data were collected in table form sheets and analysis was done regarding all aspects of the procedures, results, and complications.

Statistical analysis

Data collected throughout history, basic clinical examination, laboratory investigations, and outcome measures were coded, entered, and analyzed using Microsoft Excel software (Microsoft Excel version 2010, SPSS: Statistical Package for the Social Sciences by IBM USA). Data were then imported into the statistical package for the social sciences (SPSS, version 20.0) software for analysis. P values less than 0.05 were considered statistically significant. The Pearson χ^2 test was used to compare categorical data. Independent t test was used to compare numerical data. Before analyzing numerical data, their distributions were sufficiently normal for the purpose of conducting a t test (i.e. skew$<$2.0 and kurtosis$<$9.0). Analysis of the long-term effectiveness in limb salvage over time was performed using the Kaplan–Meier model.

Results

Thirty-five patients suffering from Critical Limb Ischemia (CLI) underwent endovascular revascularization of FP and infrapopliteal (IP) arterial atherosclerotic occlusive disease in the period from July 2016 to December 2017. The mean age was 61 years with a SD of 7 years. Screening for risk factors for atherosclerotic disease has shown that 60% of the patients belonged to the male sex. The majority (88%) were diabetics, two-thirds (23) suffered from systemic hypertension, and 42% (15) were smokers. According to Rutherford classification for chronic lower limb ischemia, 19 (54%) patients presented with rest pain, while 10 (28%) and six (17%) patients suffered from minor and major tissue loss, respectively. Table 1 illustrates different demographic and clinical characteristics of the study patients.

Arterial lesions

Angiographically, the distribution of the arterial lesions involved the FP segment in 13 (37%) patients while lesions affecting both FP and IP segments were found in 22 (63%) patients (Fig. 1). FP lesions (35) were classified according to the TASC II system. IP lesions (22) were classified based on the number of affected crural arteries. Angiographic distribution and characteristics of the lesions are summarized in Table 2.

Angiographic results

Technical success was recorded in 31 (88.6%) patients with failure to cross the lesion occurring in four (11.4%) patients. Flush SFA occlusion (Fig. 2) was met in four (11.4%) cases at angiography, of which the technical failure rate reached 75%.

Follow-up

The 6 months' primary patency rates show statistically significant difference between the transluminal and subintimal approaches which were 73.3 and 13.3% retrospectively. The cumulative limb salvage rate (LSR) was 96.7, 90.3, and 80.6% at 3, 6, and 12 months, respectively (Fig. 3).

Discussion

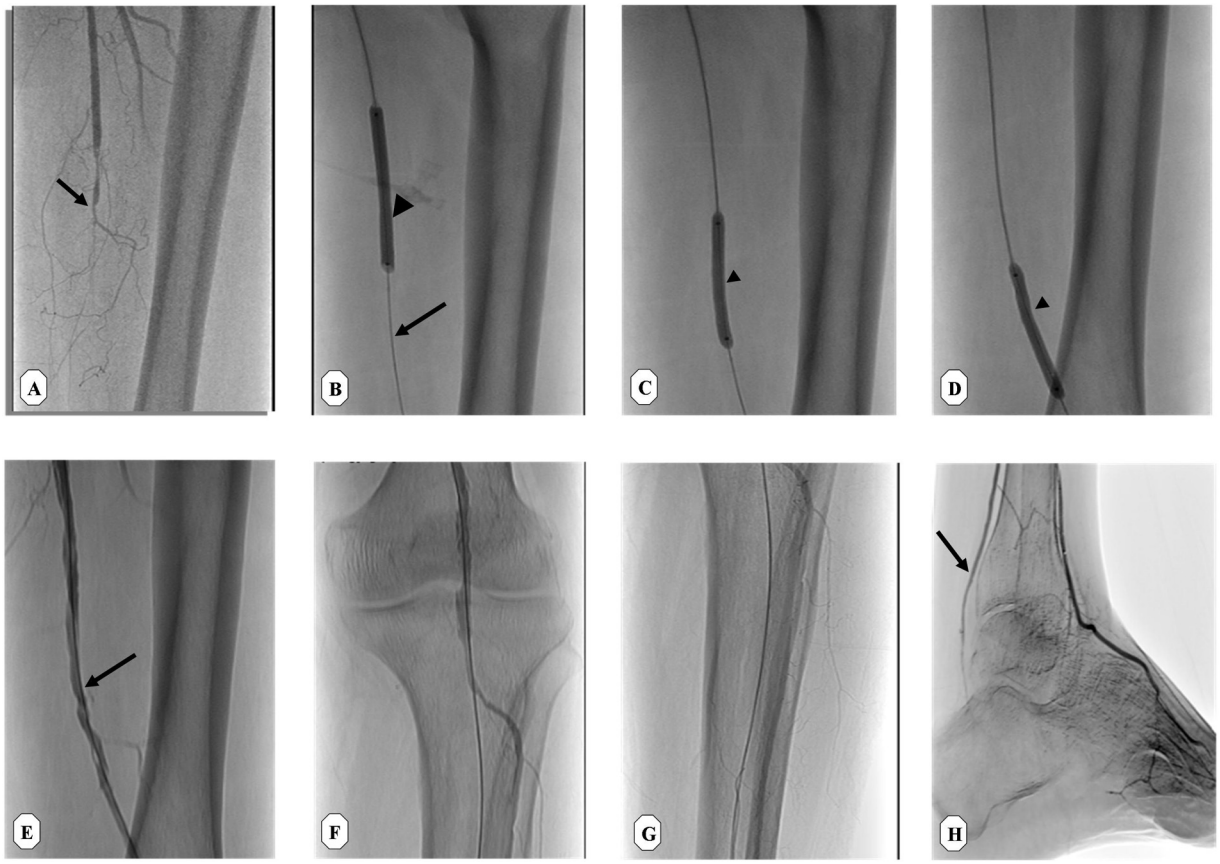
CLI is an advanced peripheral arterial disease which is marked by the development of rest pain, ulceration, or

Table 1 Demographic and clinical characteristics of patients

Variables	Patients (N=35)
Age	61.7±7.47
Male sex	21 (60)
Diabetes	31 (88.6)
Hypertension	23 (66)
Smoking	15 (42.8)
Clinical presentation	
Rest pain (Rutherford category 4)	19 (54.3)
Minor tissue loss (Rutherford category 5)	10 (28.6)
Major tissue loss (Rutherford category 6)	6 (17.1)

Data are presented as n (%) and mean±SD.

Figure 1



Technical success after femoropopliteal and infrapopliteal angioplasty. (a) Preprocedural angiography shows femoropopliteal segment occlusion (arrow). (b–d) Crossing the lesion with a 0.035-inch guide wire (arrow) followed by plain only balloon angioplasty of the occluded segment (arrow heads). (e) Superficial femoral artery (SFA) was recanalized successfully (arrow). (f, g) Transluminal crossing of the wire via the occluded posterior tibial artery (PTA). (h) Recanalized PTA (arrow) is evident.

Table 2 Lesion distribution and characteristics

Variables	*n* (%)
Lesion distribution	
FP+IP	22 (62.9)
FP	13 (37.1)
FP lesions (35 limbs)	
TASC II A	18 (51.4)
TASC II B	5 (14.3)
TASC II C	8 (22.9)
TASC II D	4 (11.4)
IP lesions (22 limbs)	
One IP artery affection	8 (36.4)
Two IP arteries affection	12 (54.5)
Three IP arteries affection	2 (9.1)

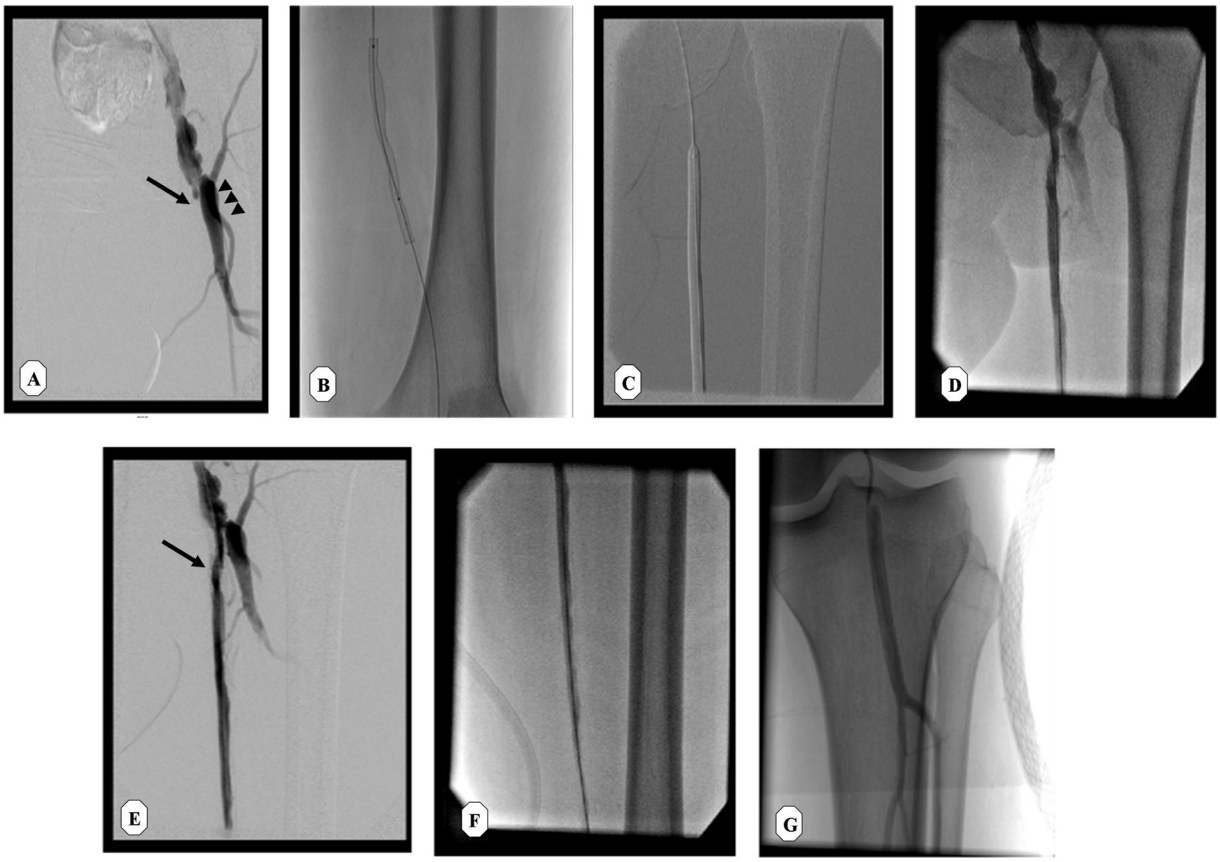
FP, femoropopliteal; IP, infrapopliteal; TASC, trans-atlantic society consensus.

gangrene and is associated with high morbidity and mortality rates [6]. CLI generally occurs in diabetics with extensive atherosclerotic disease of the IP vessels. Associated iliac, femoral, and popliteal lesions are present in most cases [7]. Without revascularization, patients often progress to amputation, even with aggressive local wound care [8]. In those patients, CLI resulted in major amputation in 73% with rest pain and in 95% with tissue loss at 1 year follow-up [9]. So, the optimal treatment for CLI patients is prompt revascularization, but careful planning is required, as patients often have multilevel arterial disease and multiple comorbidities [10].

The significant associated cardiovascular comorbidities have necessitated using minimally invasive therapeutic options, combining low interventional risks with satisfactory late outcomes. Endovascular technology is a less invasive percutaneous technique with reported clinical efficacy and clear periprocedural morbidity and mortality benefits which increasingly replaced the conventional operative strategies in high-risk patients [11].

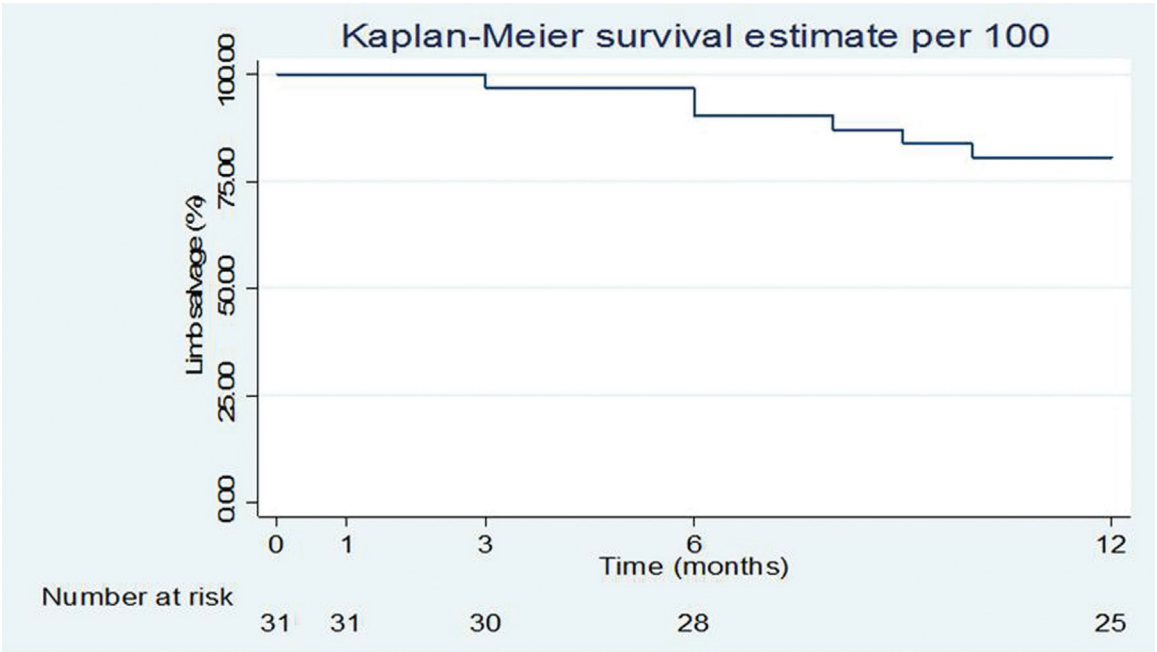
This study is a double-center experience of the effectiveness of endovascular treatment in CLI. It is designed to assess the safety of the transluminal angioplasty of multilevel arterial diseases and its efficacy on limb salvage and wound healing. In a series of 35 limbs with CLI, all cases had lesions affecting

Figure 2



Successful endovascular recanalization of femoropopliteal segmental occluded. (a) Preprocedural angiogram shows Superficial femoral artery (SFA) occlusion from its origin (arrow) with patent profunda femoris artery (arrow heads). (b, c) Crossing the lesion with a 0.035-inch guide wire followed by plain only balloon angioplasty of the occluded segment. (d, e) SFA was recanalized successfully (arrow). (f, g) Completion angiogram showing successful recanalization of the femoropopliteal segment with patent 3 crural arteries.

Figure 3



Kaplan–Meier curve shows event-free survival of limbs after endovascular revascularization for critical limb ischemia (CLI).

multiple arterial segments of which 63% underwent combined FP and IP endovascular recanalization.

Regarding the passage of the wire, in about 73.3% of the cases the wire crossed transluminally while in only about 13.3% the wire passed subintimally. The rate of subintimal crossing is low in comparison to other studies, which is thought to be attributed to the truth that more than 65% of FP lesions are TASC A and B.

Peregrin *et al*. [12] reached a technical success rate of 89% in a large retrospective study involving 1445 PTA procedures. Comparably, the majority (88%) of our patients successfully achieved linear flow to the foot in at least one artery. Flush SFA occlusion at angiogram was a significant factor associated with technical failure, in which the endovascular revascularization failed to cross the lesion in 75% of SFA flush occlusion cases.Preventing major amputation in CLI is arguably the most important goal and is predicated on the ability to restore and maintain linear arterial flow to the foot [7]. Primary LSR is defined as functional limb salvage after the first endovascular revascularization with no subsequent intervention. Studies have shown that the primary 1-year LSR ranged from 75 to 94% [13–17]. Our 1-year LSR exceeded 80% which is within the reported range in the literature.

Conclusion

An endovascular approach is safe and effective in the management of multilevel arterial atherosclerotic occlusive disease with high technical success rate and accepted percent of limb salvage for 1 year. Factors that influence the lesion crossing of the wire include length of the lesion, morphological characteristic and TASC II classification of the lesion, and operator experience.

The endovascular first approach is advisable in high-risk patients, who have a relatively short life expectancy. It is associated with low morbidity and short hospital stay, and subsequent surgical intervention is not prejudiced should it be necessary.

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Conflicts of interest
There are no conflicts of interest.

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