Short-term outcome of infrapopliteal percutaneous transluminal angioplasty for isolated infrapopliteal lesions in patients with critical limb ischemia

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Objective
The aim of this study was to evaluate the efficacy of percutaneous transluminal angioplasty for isolated infrapopliteal (IP) arterial disease in patients with critical limb ischemia (CLI).
Patients and methods
This prospective study included all CLI patients with IP disease who underwent primary IP angioplasty between January 2014 and January 2016 in our institution. Study endpoints were technical success rate, primary patency, secondary patency, limb salvage, and wound healing.
Results
The mean age of patients was 64.6±13.5 years, with 23 74% men. Twenty limbs were identified as Rutherford category 4 (48%), 16 limbs as Rutherford category 5 (38%), and six limbs as Rutherford category 6 (14%). Initial technical success was 90.5%. Among 38 limbs with initial technical success, primary patency and secondary patency rate were, respectively, 60.5 and 75% at 1 year. Limb salvage rate was 86.8% at 1 year. Wound healing rate was 76.3%. Wounds were completely healed in 15.8%, improved in 60.5%, stable in 13.2%, and worse in 10.5%.
Conclusion
Percutaneous transluminal angioplasty is effective and preferred procedure for IP angioplasty for patients who presented with CLI.

Keywords:
angioplasty, critical limb ischemia, isolated infrapoplital angioplasty

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Introduction

Critical limb ischemia (CLI) is a condition that represents the most advanced form of peripheral artery disease [1]. The recent reports showed that about half of CLI was due to isolated infrapopliteal (IP) lesions [2]. CLI attributable to pure IP lesions might be thought as the most severe form of the peripheral artery disease [3]. Patients with CLI due to infrapopliteal arterial occlusive disease are a high-risk group in which the current reported amputation and mortality rates at 1 year are 25% and 20–25%, respectively [4]. Endovascular treatment is increasingly being used as the preferred method of revascularization in patients with infrapopliteal arterial disease suffering from CLI [5].

The aim of this prospective study was to evaluate the efficacy of percutaneous transluminal angioplasty (PTA) for IP arterial disease in patients with CLI. This aim is proved by detection of short-term results of primary patency, secondary patency, limb salvage, and healing rate.

Patients and methods

This prospective study was carried out in the Vascular Surgery Department, Faculty of Medicine, Sohag. All patients gave their formal consent. The protocol was approved the Ethical committee of the faculty. The study included all CLI patients with IP disease who underwent primary IP angioplasty between January 2014 and January 2016.

Exclusion criteria

(1) CLI patients presenting with functionally unsalvageable limbs with spreading ischemic ulcer or gangrene past the ankle requiring primary major amputation.
(2) CLI patients with iliac artery lesions or femoral artery lesions or multilevel lesions.

The institutional review board has approved the study and written informed consent was obtained from all patients before the procedure.

Preprocedure assessment

All patients were subjected to history taking, clinical examination, and radiological imaging.

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Preprocedure medication

Dual antiplatelet therapy [aspirin (100 mg/day), clopidogrel (75 mg/day), or cilostazol (200 mg/day)] was initiated for all patients 1 week before PTA.

Technique

Six French sheath was placed after ipsilateral puncture of the common femoral artery under local anesthesia. Intra-arterial bolus of 5000 IU of heparin was given. Infrapopliteal lesions were passed with a 0.018 hydrophilic guide wire. Balloon angioplasty was performed using 2.5 mm diameter balloon to avoid arterial injury and the diameter was increased to 3 or 3.5 mm according to the diameter of the artery.

When multiple stenosis or occlusions were noted in below-the-knee arteries, the aim was to dilate all arteries. However, if it was difficult to open all infrapopliteal arteries, the priority was to achieve direct flow to the tissue site based on the angiosome concept.

Postprocedure angiography

Completion angiography was performed immediately after the angioplasty procedure.

Debridement of extensive gangrene was mostly performed immediately after the end of the angioplasty procedure.

Postprocedure medication

The patients were given dual antiplatelet therapy for 3 months after PTA.

Follow-up

Before the patient's discharge from the hospital and at 1, 3, 6, and 12 months after PTA, all patients were evaluated with clinical examination and duplex imaging.

On clinical examination I looked for the following:

(1) Wound healing.
(2) Absence of rest pain.
(3) Absence of tissue necrosis and gangrene.

On duplex imaging I looked for target vessel restenosis, which was diagnosed by measuring the peak systolic velocity (PSV) in the target segment of the vessel and compared with the PSV in the preceding normal segment of the same vessel. A focal increase in PSV in the target segment of the vessel of at least 140% greater than the preceding normal segment was considered indicative of more than 50% restenosis at that site.

CTA was performed for patients who presented with return of symptoms of CLI associated with restenosis or occlusion of the treated arterial segment for more detailed anatomical information needed for reintervention (Figs 1 and 2).

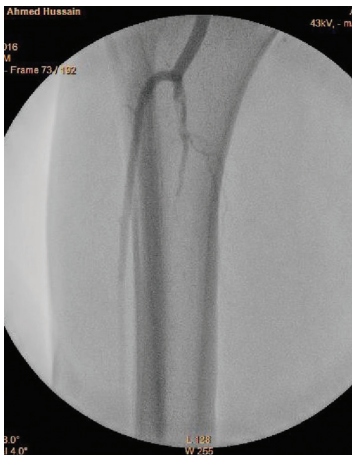
Endpoint

Primary endpoints were technical success rate, primary patency, and secondary patency.

Secondary endpoints were limb salvage and wound healing.

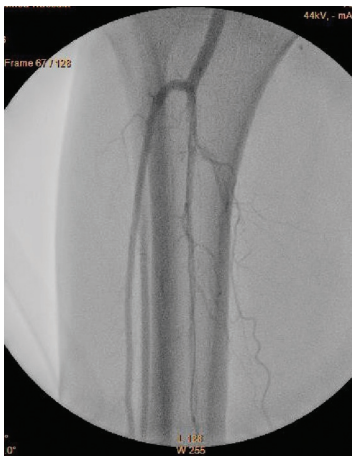
Technical success was defined as a residual stenosis less than 30% with sufficient antegrade flow and achieving straight-line flow from the aorta down to either a patent dorsalispedis or plantar artery at final angiography [6].

Figure 1



Pre intervention angiography

Figure 2



Post intervention angiography

Primary patency was defined as the absence of occlusion or significant restenosis within the treated segment [7].

Secondary patency was defined as patency that was achieved utilizing secondary endoluminal procedures, which involved recanalizing occluded arterial segments [5,8].

Limb salvage was defined as prevention of major amputation [9].

Major amputation was defined as limb loss below or above the knee [9].

Minor amputation was defined as a transmetatarsal amputation or more distal level amputation of the lower extremity [9].

Wound healing was documented as complete, improved, stable, or worse [10].

Statistical analysis

Data are presented as mean±SD for continuous variables and data are presented as counts (percentages) for categorical variables. The primary patency rate, the secondary patency rate, and the limb salvage rate were estimated using the Kaplan–Meier method.

Results

During the study period, 31 patients underwent PTA for 42 limbs. The baseline characteristics of the study patients are shown in Table 1. The mean age of the study population was 64.6±13.5 years, with 23 (74%) men. Many patients had significant comorbidities, including hypertension (68%), diabetes mellitus (71%), cerebrovascular stroke (13%), coronary artery disease (55%), and renal failure (16%). Moreover, 19 (61%) patients had a history of smoking. Twenty limbs were identified as Rutherford category 4 (48%), 16 limbs as Rutherford category 5 (38%), and six limbs as Rutherford category 6 (14%).

Table 1 The baseline characters of the study patients

Total number of patients	31
Demographic characteristics of patients	
Age	64.6±13.5
Male	23 (74)
Comorbid disease of patients	
Hypertension	21 (68)
Diabetes mellitus	22 (71)
Cerebrovascular stroke	4 (13)
Coronary artery disease	17 (55)
Chronic renal failure	5 (16)
Smoker	19 (61)
Clinical category of limbs (42)[a]	
Rutherford criteria+ 4	20 (48)
Rutherford criteria+ 5	16 (38)
Rutherford criteria+ 6	6 (14)

Data expressed as the mean±SD or *n* (%) of patients. [a]Rutherford classification reference [7].

Angiographic findings of the study patients

Angiographic findings of the study patients are shown in Table 2. A total 91 lesions were treated in 42 limbs of 31 patients. Anterior tibial artery was the most commonly affected artery with 45 (49.5%) lesions, followed by the posterior tibial artery with 27 (29.7%) lesions, the peroneal artery with 16 (17.5%) lesions, and, lastly, the tibioperoneal trunk with three (3.3%) lesions. Sixty-five of total 91 (61.5%) lesions were stenotic lesions. The lesion length was 9.7±7.8 cm.

Outcome variables of the study patients

Outcome variables of the study patients are shown in Table 3. Initial technical success was achieved in 38 (90.5%) limbs. Among 38 limbs with initial technical success, primary patency and secondary patency rates were, respectively, 60.5 and 75% at 1 year. During the follow-up, eight patients underwent successful repeated angioplasty.

Limb salvage rate was 86.8% at 1 year. During the follow-up, five patients required major amputation. Amputation was performed for two patients after intervention at 30 days and for the three other patients amputation was performed later. Four of

Table 2 Angiographic findings of the study patients

	n (%)
Affected arteries	
Anterior tibial art	45 (49.5)
Posterior tibial artery	27 (29.7)
Peroneal artery	16 (17.5)
Tibioperoneal trunk	3 (3.3)
Type of lesions	
Stenosis	56 (61.5)
Occlusion	35 (38.5)
Lesion length (cm)	9.7±7.8

Table 3 Outcome variables of the study patients

Outcome of the study patients	*n*/*N* (%)
Technical success	38/42 (90.5)
Primary patency	23/38 (60.5)
Secondary patency	6/8 (75)
Limb salvage	33/38 (86.8)
Wound healing	29/38 (76.3)

these patients presented with thrombosis of the treated artery and one patient presented with wound infection despite patent treated arteries. Wound healing rate was 76.3%. Wounds were completely healed in 15.8%, improved in 60.5%, stable in 13.2% and worse in 10.5%.

Discussion

The development of the endovascular techniques has resulted in an increase in the endovascular infrapopliteal revascularization. Endo vascular treatment (EVT) has become commonplace as the revascularization strategy for infrapopliteal lesions in patients with CLI [11].

Balloon angioplasty remains the most appropriate endovascular treatment modality for infrapopliteal disease, even with severe disease and suboptimal runoff [12].

In this study, we intentionally selected CLI patients with IP disease to demonstrate the efficacy of angioplasty alone on this type of arterial disease and demonstrate its effect on the healing process. The primary patency rate and secondary patency rate in this study were, respectively, 60.5 and 75% at 1 year.

Our results in terms of primary patency rate and secondary patency rate can be considered comparable to those reported in the literature [13]. Romiti *et al.* [13] reported in meta-analysis study including 30 studies (2557 cases) published between 1990 and 2006, dealing with PTA performed for IP lesion, a primary patency rate 58% and a secondary patency rate 74% at 1 year.

Our results are lower than those reported by Tartaglia *et al.* [14] and included 101 diabetic patients who underwent infrapopliteal angioplasty. Tartaglia *et al.* [14] reported that the primary patency rate and secondary patency rate were 67 and 83% at 1 year, although diabetes as a risk factor was present in all cases of Tartaglia *et al.* [14] study, it was present only in 71% of patients in this study. This can be explained by comparing the lesion length in the two studies. The mean length of lesions in this study is 9.7 cm, but in the study by Tartaglia *et al.* [14] it was 4.5 cm.

Moreover, our results are lower than those reported by Ryu *et al.* [9]. Ryu *et al.* [9] reported that, among 82 CLI who underwent infrapopilteal angioplasty with initial technical success, the primary patency rate was 70.7% at 1 year; however, the secondary patency rate was not delineated. Rye *et al.* [9] did not demonstrate the lesion length in the treated arteries to know the severity of the atherosclerotic disease of the treated arteries.

Our results are higher than those reported by Giles *et al.* [10], which included 176 consecutive limbs that underwent infrapopliteal angioplasty for CLI. Giles *et al.* [10] used stents for lesions refractory to PTA. The primary patency rate at 1 year in the study by Giles *et al.* [10] was 53%; however, the secondary patency was not delineated. Giles *et al.* [10] attributed the low patency rate in their study to presence 29% of patients with TASC D lesion, which had adverse impact on restenosis, as reported by Kudo *et al.* [15].

Moreover, our results are higher than that reported in the study by Fernandes *et al.* [6], which included 54 limbs of isolated tibial disease. The primary patency rate and secondary patency rate at 1 year were 37 and 65%, respectively.

The incidence of limb salvage in the current study was 86.8%, at 1 year. Our result in terms of limb salvage can be considered comparable to those reported in the literature [10,13,14]. Romiti *et al.* [13] reported that the limb salvage rate was 85% at 1 year. Giles *et al.* [10] and Tartaglia *et al.* [14] reported that the limb salvage rate was 84% at 1 year. Our result is lower than that reported by Rye *et al.* [9]. Rye *et al.* [9] reported that the limb salvage rate was 97.6% at 1 year. In contrast, our result is higher than that reported by Fernandez *et al.* [2]. Fernandez *et al.* [2] reported that the limb salvage rate in the group of isolated tibial disease was 81 and 74.8% at 9 and 12 months, respectively.

The healing rate in the current study was 76.3% at 1 year. According to wound healing classification documented in our study, the incidence of complete wound healing was 15.8%, that of improved wound healing was 60.5%, stable wound size with no healing was 13.2%, and worse wound healing was 10.5%. Healing rate in the current study can be considered comparable to that reported in the literature [14]. Tartaglia *et al.* [14] reported that the healing rate was 78% at 1 year. According to the Armstrong classification, healing rate was 100% when wound depth was grade 1, 91% when grade 2, 88% when grade 3, and 30% when grade 4. Our results are higher than those reported in other studies [8,10]. Giles *et al.* [10] reported that the healing rate was 57% at 1 year. According to wound healing classification documented in the study by Giles *et al.* [10], complete wound healing was 0%, improved wound healing was 57%, stable wound size with no healing was 22%, and worse

wound healing was 21%. Moreover, Fernandez *et al.* [2] reported that wound healing or improvement was 69% in the isolated tibial arteries group. The mean overall follow-up was 12.6±5.3 months.

Study limitations

First, this study was conducted in a single center and with a relatively small study population. Further multicenter studies with large numbers of patients are required to confirm the present results. Second, this is a short-term follow-up study. Further long-term follow-up study of the patients should be considered.

Conclusion

PTA is an effective procedure for IP angioplasty for patients who presented with CLI and gives good results in terms of primary patency, secondary patency, limb salvage, and healing rate along short-term follow-up. These results encourage the usage of PTA as a preferred procedure for IP angioplasty, but more studies with long-term follow-up are needed.

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Conflicts of interest

There are no conflicts of interest.

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