The outcome of a combination of superficial femoral artery angioplasty with infragenicular angioplasty in the treatment of critical lower limb ischemia

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Background/aim
As endovascular disease with significant femoropopliteal or infragenicular arterial lesions largely affects the outcome in critical limb ischemia (CLI), the aim of this study is to examine the impact of dealing with distal outflow infragenicular arterial lesions on the outcome of CLI in terms of patency and limb salvage rates.

Patients and methods
A prospective study was carried out of all endovascular interventions performed for patients with CLI encountering femoropopliteal and tibial arterial lesions between February 2012 and January 2014; the patients were randomly divided into two groups. The first group included patients who received a concomitant tibial intervention and the second group included those who received femoropopliteal interventions alone. The duration of follow-up was 12 months, which was within the period of this study.

Results
Endovascular procedures were used to treat 54 patients with a runoff score of greater than 10. The first group included 29 patients and the second group included 25 patients with CLI. Primary success reached 89.6% in the first group and 96% in the second group. Primary patency rates at 12 months were 59 and 51% in both groups, respectively, whereas secondary patency rates at 12 months were 70 and 52% in both groups, respectively, with no statistically significant difference. The limb salvage rate over 12 months was better in the first group (83%) than in the second group (76%).

Conclusion
Although simultaneous superficial femoral artery with tibial angioplasty did not yield a significant increase in patency rates, the better limb salvage rates make interventional treatment for infragenicular arteries a key part of the vascular specialist armamentarium when treating CLI.

Keywords:
angioplasty, critical, infragenicular, ischemia, runoff

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Introduction

Critical ischemia that causes rest pain and tissue loss remains a significant problem for vascular surgeons and is associated with significant perioperative morbidity and mortality [1].

Infrapopliteal peripheral arterial disease may occur in isolation or in conjunction with proximal-level disease. Patients with multilevel disease are frequently older, have multiple comorbidities, show increased vascular compromise, and might fare worse after an endovascular intervention than patients with isolated disease of the aortoiliac or femoropopliteal [2]. The impact of infragenicular interventions, which should axiomatically improve distal runoff and thus improve the outcome of superficial femoral artery (SFA) interventions, has not been examined widely.

The aim of this study is to clarify the role of an infragenicular intervention in patients with critical lower limb ischemia (CLI) and femoropopliteal interventions on the outcome in terms of short-term results.

Patients and methods

The study was carried out prospectively on 54 patients with Rutherford class 4–6 categories of chronic limb ischemia who presented to the Vascular Surgery Unit in Zagazig University Hospitals with CLI during the period from February 2012 to January 2014.

All patients were preferentially offered an endovascular intervention as the first option. All patients were reviewed by computed tomographic (CT) angiography or conventional angiography, where all arterial lesions were categorized according to TASC I, II classifications. Runoff vessels in all patients were reviewed; poor runoff greater than 10 according to the modified criteria of

Society for Vascular Surgery (SVS) was selected [3]. Major exclusion criteria included a life expectancy of less than 12 months; cerebrovascular event or myocardial infarction within 3 months of presentation; inability to walk for any reason; and serum creatinine level greater than 2 mg/dl.

Endovascular approach

All procedures were performed under local anesthesia. Ipsilateral antegrade access was most commonly performed, whereas contralateral retrograde common femoral access was selectively used in cases of ipsilateral ileac artery, common femoral artery, or flush SFA lesions. Interventions were performed under systemic heparinization (100 U/kg). For complete occlusions, our practice is to cross the lesions in a subintimal plane. Balloon diameter was selected on the basis of the angiographic measurements of the nondiseased arterial segment proximal and distal to the lesion.

The use of stents depended on operator preference, where secondary stenting was in areas of flow limiting dissections, intimal flaps, or residual significant stenoses. Stenting of the origin of SFA, the retro and infrageniculate popliteal, and the tibials were generally avoided.

Restenosis was determined on noninvasive testing, which confirmed recurrent disease by ankle-brachial index (ABI) decrease of greater than 0.15, or evidence of stenoses by duplex ultrasound scan, irrespective of symptom status, and was confirmed by CT angiography only in patients with recurrent symptoms or failed healing of foot lesions.

Follow-up was attempted by duplex ultrasound surveillance, which was routinely performed on all patients at 1, 3, and 6 months after the procedures; patients were then evaluated at 6-month intervals.

Statistical analysis

All statistical tests were performed using SPSS version 17; continuous variables were presented as mean ± SDs. Datasets were compared using Mann–Whitney *U*-test or a paired *t*-test; a *P* value of less than 0.05 was considered significant. Twelve-month primary patency, secondary patency, and limb salvage rates were calculated using the Kaplan–Meier test. Multivariable Cox proportional hazards regression was used to develop predictive models.

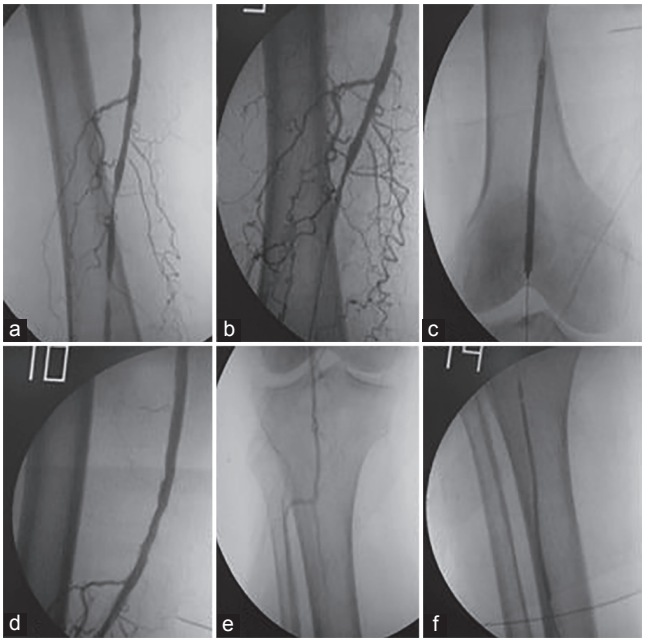
Results

Endovascular procedures were performed on 54 patients with CLI, with poor runoff defined by a runoff score of greater than 10 according to a modification of the SVS criteria. Overall mean age of the patients was 55.3 ± 8.9 years; 64% of patients were men in the first group versus 56.6% in the second group. Demographic criteria and patient comorbidities are reported in Table 1. There was no statistical difference in the comorbidities between both groups. Presenting symptoms were similar between both groups, where rest pain was 27.5 versus 36% and tissue loss was 72.5 versus 64% (*P* = 0.441). Figure 1 shows combined femoropopliteal and peroneal artery recanalization. Table 2 shows a summary of endovascular procedures.

Table 1 Demographic criteria and patients' comorbidities in both groups

Demographic criteria	Group I [*n* (%)]	Group II [*n* (%)]	*P* value
Mean age (years)	56.4 ± 8.9	54.04 ± 8.8	0.312
Male sex	16 (64)	17 (58.6)	
Diabetes	23 (79.3)	20 (80)	0.514
Hypertension	18 (62)	17 (68)	0.885
Ischemic heart disease	10 (34.4)	9 (36)	0.908
Smoking	13 (44.8)	11 (44)	0.817
Heart failure	2 (6.8)	3 (12)	0.523
Hyperlipidemias	10 (34.4)	8 (32)	0.126
Symptoms			
Rest pain	8 (27.5)	9 (36)	0.441
Tissue loss	21 (72.5)	16 (64)	

Figure 1



Combined femoropopliteal and peroneal artery recanalization. (a) Femoropopliteal occlusion. (b) Passage of hydrophilic wire through the proximal lesion. (c) Balloon dilatation of the lesion. (d) Complete recanalization of the proximal lesion. (e) Passage of the wire through peroneal artery occlusion. (f) Balloon dilatation of the distal lesion in the peroneal artery.

The primary patency rates at 12 months were 59 and 51% in both groups, respectively (log rank test, $P = 0.364$), whereas secondary patency rates at 12 months were 70 and 52% in both groups, respectively, with no statistically significant difference ($P = 0.191$). The limb salvage rate over 12 months was better in the first group (83%) than the second group (76%), as shown in Figs 2–4.

The acute failure rates (failure to traverse an occlusion or occlusion within 30 days) were 10.3 and 8% in both groups, respectively (Tables 3 and 4).

Table 2 Summary of endovascular procedures

Procedures	Group I [*n* (%)]	Group II [*n* (%)]	*P* value
Transluminal	19 (65.5)	21 (84)	0.002
Subintimal	12 (41.3)	7 (28)	0.314
Stent use	15 (51.7)	12 (48)	0.787
Adjunctive ileac procedures	7 (24.1)	10 (40)	0.215

By Cox regression analysis, factors that contributed toward decreased survival were the presence of hyperlipidemia (relative risk 0.325, 0.063–1.677, $P = 0.01$) and diabetes (relative risk 2.520, 0.680–9.337, $P = 0.004$) as shown in Table 5.

In the first group, there were three cases with primary failure; femorodistal bypass was performed for two cases and one case with heart failure resulted in above-the-knee amputation (AKA). In the second group, there were only two cases with primary failure; in one case, we failed to cross the occlusion either by transluminal or by subintimal routes, and this patient had recent myocardial infarction and ended by AKA. In the other patient, we failed to re-enter the true lumen, and bypass was offered and performed.

Nine patients in each group presented during the follow-up period with recurrent rest pain, tissue loss,

Table 3 Mean and median for survival time for primary patency

Procedures	Mean[a]				Median			
	Estimate	SE	95% confidence interval		Estimate	SE	95% confidence interval	
			Lower bound	Upper bound			Lower bound	Upper bound
Infragenicular angioplasty	9.569	0.715	8.168	10.970	12.000	0.000		
No infragenicular angioplasty	8.720	0.770	7.210	10.230	10.000	0.624	8.776	11.224
Overall	9.176	0.522	8.152	10.200	12.000	0.000		

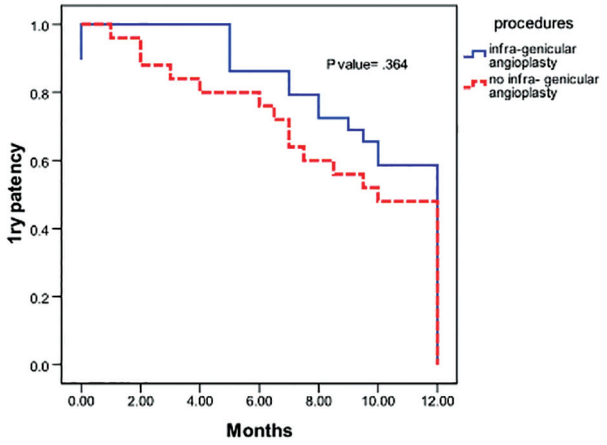
[a]Estimation is limited to the largest survival time if it is censored.

Table 4 Mean and median for survival for secondary patency

Procedures	Mean[a]				Median			
	Estimate	SE	95% confidence interval		Estimate	SE	95% confidence interval	
			Lower bound	Upper bound			Lower bound	Upper bound
Infragenicular angioplasty	10.121	0.702	8.745	11.496	12.000	0.000		
No infragenicular angioplasty	9.340	0.691	7.985	10.695	12.000	0.000		
Overall	9.759	0.493	8.793	10.725	12.000	0.000		

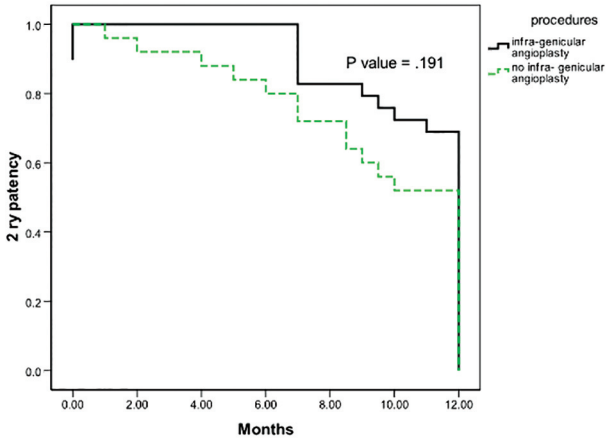
[a]Estimation is limited to the largest survival time if it is censored.

Figure 2



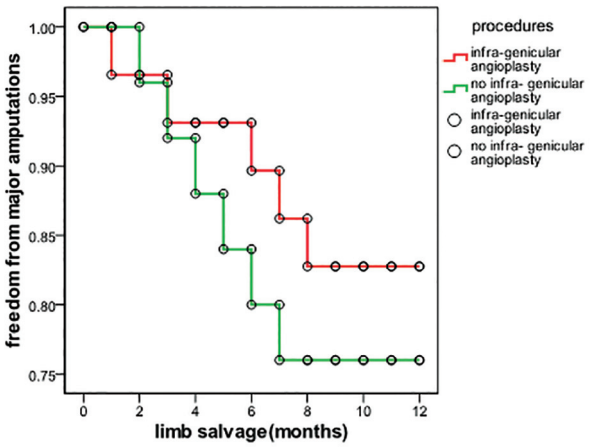
Primary patency rates among both groups at 12 months.

Figure 3



Secondary patency rates among both groups at 12 months.

Figure 4



Limb salvage rates among both groups.

or failure of wound healing, with decreases in ABI of greater than 0.15. Table 6 shows the causes of recurrent symptoms investigated by arterial duplex and subsequent CT angiography when needed in salvageable cases. A decision was made as follows:

(a) Reintervention at the same lesion, proximal or distal to it,
(b) Bypass surgery, or
(c) Major amputation when the condition did not allow a limb salvage procedure.

During the follow-up period, four patients underwent major amputations in the first group (one between 1 and 3 months, two between 3 and 6 months, and one case between 6 and 12 months) because of worsening leg pain, intractable wound infection, or gangrene; three of them were AKA and the other one was below-knee amputations. Six patients underwent major amputations in the second group (three between 1 and 3 months, three between 3 and 6 months, and no cases between 6 and 12 months).

Discussion

Angioplasty of the infragenicular vessels has had limited application as a primary revascularization strategy for patients with CLI for a long time [4,5], with its limitation being the requirement for revascularization of inflow lesions and the low likelihood of success in terms of correction of tibioperoneal outflow lesions [6].

Smolock *et al.* [7] reported that improved medical management and therapies later in the time period may have led to a variation in the results as their study

Table 5 Cox regression analysis for factors associated with decreased survival

Factor	*B*	SE	Wald	*d.f.*	Significance	Exp (*B*)
Hyperlipidemias	−2.140	0.830	6.651	1	0.010	0.118
Diabetes	1.827	0.630	8.411	1	0.004	6.216

Table 6 Outcome during the follow-up and secondary procedures

Out come of procedure	Group I [*n* (%)]	Group II [*n* (%)]
Causes of recurrent symptoms		
Restenosis	4 (13.7)	3 (12)
In-stent restenosis	2 (6.8)	0
Occlusion	2 (6.8)	3 (12)
Progression of proximal disease	0	2 (8)
Progression of distal disease	1 (3.4)	1 (4)
Subsequent interventions		
Lesion reintervention	2 (6.8)	3 (12)
Proximal intervention	1 (3.4)	2 (8)
Distal intervention	1 (3.4)	0
Bypass	3 (10.3)	2 (8)

period was over 5 years, with the appearance of new modalities in treatment that were not available during our study, which had shorter duration.

Many previous studies have failed to show an overall correlation between distal arterial runoff score and limb salvage rates [8–10]. One limitation of these studies is that they did not include many patients with extremely compromised outflow (tibial runoff score>10, using the standardized SVS system). Others have shown that scores reflecting blind outflow are a marker for limb loss [11,12]. These data would suggest that limb salvage after an endoluminal intervention is dependent on runoff. With one exception, Lee and Katz [13] reported that the number of patent tibial vessels has no effect on the primary patency of primarily stented femoral and popliteal arteries; otherwise, most studies addressing the issue of multilevel disease favor better anatomic outcomes when all levels are treated with an endovascular intervention [14,15].

One of the criticisms of our study is that one group of patients was deprived of more correction of distal lesions; however, all patients in that group with primary success had increased ABI, regaining popliteal pulsations, with satisfactory results without involving more complex tibial lesions, which was attempted without randomization between both groups.

Davies *et al.* [11] reported that patency and target lesion revascularization is negatively affected by worsening runoff in patients who are treated with SFA percutaneous interventions, and free from recurrent

symptoms and limb salvage are decreased gradually as runoff scores worsen, and reported that patients with compromised and poor runoff may not benefit from a percutaneous intervention. In our study we found that correction of SFA and popliteal lesions without attacking more nasty complex lesions distal to the trifurcation led to a great benefit for the majority of patients in the second group, especially when combined with medical treatment, and the patients did not lose something, where bypass options and reintervention options still preserved to be performed if needed during follow-up periods.

Because of financial problems and because not all patients are covered by insurance, there were obstacles in the selection of the endovascular route from the start, and we did not include atherectomy or re-entry devices during recanalization of total arterial occlusions.

Conclusion

Although concomitant tibial angioplasty appears not to result in significant clinical benefit to SFA angioplasty with a nonsignificant increase in primary or secondary patency rates in CLI, better limb salvage rates make interventional treatment for infragenicular arteries a key part of the vascular specialist armamentarium, with low morbidity and mortality, especially in those with significant medical comorbidities.

Acknowledgements

Conflicts of interest

None declared.

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