# Subintimal angioplasty of chronic total superficial femoral artery occlusions in critical lower limb ischemia patients: the single center experience

Khaled Attalla, Ahmed El Badawy, Ashraf El Naggar, Bahgat Thabet

Department of Vascular Surgery, Assiut University Hospital, Assiut, Egypt

Correspondence to Dr. Khaled Attalla, PhD, Department of Vascular Surgery, Assiut University Hospital, 71-515, Assiut, Egypt.
Tel: 01009554420
e-mail: khaled67@yahoo.com

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**Objective**
The aim of this article was to report our results of subintimal angioplasty (SIA) of long superficial femoral artery (SFA) occlusions and try to appreciate factors that affect patency following this type of intervention in critical lower limb ischemia (CLI) patients.

**Patients and methods**
The current series was conducted prospectively over a 1-year period. Forty cases, 40 limbs (mean age = 65.8 years old) with long SFA occlusion (>15 cm) and patent popliteal artery continuous with at least one leg artery runoff were included. Exclusion criteria were: renal impairment, nonatherosclerotic occlusions (thrombosis, dissection, or compression), short SFA occlusions (<15 cm), or non-SIA revascularization intervention. Results were considered successful with primary technical success combined with improving ischemic rest pain or healing wounds following minor amputations. Nonrecanalization or major amputations were considered failures. One-year patency and salvage rates were calculated. Factors that affected patency such as patent leg arteries and TASC grading were analyzed.

**Results**
Results were considered successful in 34 (85%) patients and failure was noticed in six (15%) cases. At the end of the first follow-up year, the primary patency rate was 75% and the salvage rate was 87.5%. The 1-year patency rate was higher in TASC C patients (85.7%) in comparison with TASC D cases (69.2%). The patency rate was 50% or less with one patent leg artery and 80% or more with two or three patent leg arteries.

**Conclusion**
SIA is a good alternative for recanalization of chronic long SFA total occlusions in CLI patients with acceptable 1-year patency rates. Number of patent leg arteries is an important determinant of durable procedures.

**Keywords:**
critical limb ischemia, subintimal angioplasty, total superficial femoral artery occlusion

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## Introduction

During the last two decades major changes have taken place in the diagnostic and treatment techniques for peripheral arterial disease (PAD). In the past, the main treatments for PAD were thrombectomy, endarterectomy, and bypass surgery [1,2]. Today occlusions can be corrected by means of percutaneous transluminal angioplasty, subintimal angioplasty (SIA) [3], laser angioplasty [4], thrombolysis, and endovascular stenting [5].

Lower limb SIA is now a well-known technique which can achieve recanalization of long occluded arterial segments [6]. It has been proposed as an alternative to lower limb bypass procedures, especially in patients with critical lower limb ischemia (CLI) [7]. Much of the criticism about this technique is based on its patency rate compared with bypass procedures [8]. It is often stated that the ~50% [9] primary patency rate at 12 months postintervention is quite low compared with the almost 80–90% [10] rate for bypass procedures.

However, despite the relatively high reocclusion rate, SIA allows an exceptionally good limb salvage rate in patients with limb threatening ischemia [11].

Since the introduction of the technique of SIA which was first described by Bolia *et al.* [12] for the treatment of long occlusive lesions, the indications remain variable and controversial. Subintimal recanalization however, in some centers, is the procedure of choice even for fitter patients with severe PAD [13]. Advantages of this technique compared with surgical bypass are reduced morbidity and mortality, reduced anesthesia requirements and potential reduction in hospital length stay and cost [14]. In the current study, we report our results of SIA of long superficial femoral artery (SFA) occlusions and try to appreciate factors that affect patency following this type of intervention in CLI patients.

## Patients and methods

The current series was conducted prospectively over a 1-year period. CLI patients with long SFA occlusions (>15 cm) and patent popliteal artery continuous with at least one leg artery as the distal runoff were included. CLI is defined according to the SVS/ICSVS reporting standards, with rest pain and/or tissue loss [15]. Forty cases, 40 limbs (mean age = 65.8 years old) were included for a limb salvage procedure. Our Institutional Review Board approved the informed consent that was given by all participants included in the current study.

### Management strategy

Following clinical evaluation, all CLI patients presenting to our center performed multidetector computed tomography (MDCT) angiography serving TASC grading [16]. TASC C and D cases were potential candidates for our study. Trying endo-first is our treatment approach for CLI patients requiring a revascularization procedure.

During the same study period, 151 patients were excluded as a result of renal impairment, nonatherosclerotic occlusions (thrombosis, dissection, or compression), short SFA occlusions (<15 cm), or non-SIA revascularization procedures. In the current series, all included patients were pretreated with combined acetylsalicylic acid 100 mg and clopidogrel 75 mg daily. Clopidogrel was continued for at least 30 days after the intervention and aspirin was continued indefinitely.

The technique of SIA has been described by Bolia *et al.* [12] Contralateral retrograde femoral access was performed in all cases using a 6Fr introducer sheath that was replaced by a crossover 55 cm long sheath (BRITE TIP Interventional Sheath Introducer; Cordis Corporation, 430 Route 22 East Bridgewater, NJ 088071831, U.S.) positioned in the common femoral artery.

A 0.035-inch Stiff hydrophilic J tip wire (glide wire; Terumo) combined with a 4-Fr angled tip catheter (glidecatheter; Terumo Corporation 2-44-1 Hatagaya, Shibuya-Ku, Tokyo, Japan) approached the arterial occlusion. The wire was intentionally introduced into the subintimal plane guided by the angled catheter directed to the arterial wall. The wire/catheter combination is then advanced into the occlusion. Entry into the subintimal space is confirmed by injection of a small volume of dilute contrast medium and in addition the guide wire moves freely when the subintimal space has been entered.

When the catheter tip is 2 : 3 cm from the distal end of the occlusion, the J-wire is manipulated to form a large loop and the true arterial lumen re-entered by the forward pressure on the loop [17].

There was no need for re-entry devices in all cases of the current series. The return point was the first part of the popliteal artery in 29 (72.5%) cases and its second part in 11 (27.5%) patients. The catheter was then replaced with a 5-Fr 5 or 6 mm diameter balloon catheter (Wanda; Boston Scientific Manufacturing Company, Marlborough, MA, USA) inflated throughout the entire length of the subintimal passage at 10 : 12 atmospheres for 60 s (Fig 1). If there is a residual stenosis of greater than 30% then the dilatation is repeated using slightly higher pressures and if the problem persisted, stenting was performed.

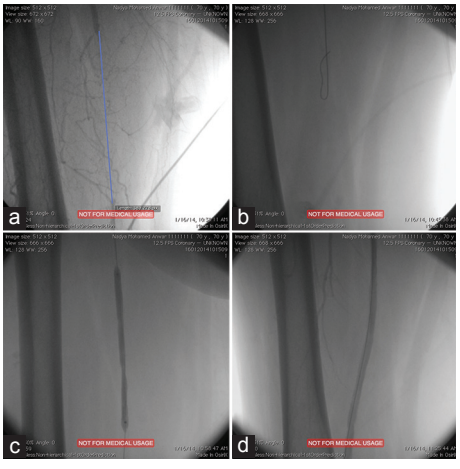
### Appreciation of results and follow-up

Results were considered successful with primary technical success combined with improving ischemic rest pain or healing wounds following minor amputations. Nonrecanalization or major amputations were considered failures. All patients were followed up at regular intervals (3, 6, and 12 months) with clinical assessment, ABI measurements and duplex arterial mapping. One-year patency and salvage rates were calculated. Factors that affected patency such as patent leg arteries and TASC grading were analyzed.

## Results

Forty cases were included in the current series for assessment of SIA of long SFA occlusions and factors affecting patency rates following this type of intervention.

**Figure 1**




(a) Long chronic superficial femoral artery (SFA) occlusion with return of the dye in the proximal popliteal (P1) artery. (b) Looping of the wire in the subintimal space. (c) Ballooning after traversing the lesion. (d) Final.

All included patients presented with rest pain (25%) or ischemic toe gangrene (75%). The current study included 27 (67.5%) men and 13 (32.5%) females. Twenty-eight (70%) patients were diabetic, 24 (60%) cases were hypertensive, and 22 (55%) patients were suffering from ischemic heart disease. Out of 40 included patients, 14 (35%) cases were of TASC C and 26 (65%) patients were of TASC D occlusions.

Following intervention, stenting was not deemed necessary in any of the current study cases. Results were considered successful in 34 (85%) patients and failure was noticed in six (15%) cases. At the end of the first follow-up year, the primary patency rate was 75% and the salvage rate was 87.5%. Further interventions were needed in seven (17.5%) cases. Table 1 shows types of performed procedures. We found that the three (7.5%) cases where thrombectomy was performed underwent major amputation of their ischemic limbs in the follow-up periods.

When analyzing factors affecting the patency rate in the current series with different variables, none of the factors predisposing to atherosclerosis was found to affect the SIA outcome in our study.

We found that the 1-year patency rate was higher in TASC C patients (85.7%) in comparison with TASC D cases (69.2%) (Table 2). Table 3 demonstrates the relation between the state of distal runoff presented as the number of patent leg arteries and the 1-year patency rate. We noticed that the patency rate was 50% or less with one patent leg artery and 80% or more with two or three patent leg arteries.

**Table 1 Interventions following subintimal angioplasty performed in the current series**

| Procedure performed | Frequency [*n* (%)] |
|---|---|
| Thrombectomy | 3 (7.5) |
| Bypass | 2 (5) |
| Perforation, surgical repair | 1 (2.5) |
| Amputation | 1 (2.5) |

**Table 2 The relation between TASC II staging and the patency rate in the current series**

| Recanalized segment | TASC C [*n* (%)] | TASC D [*n* (%)] |
|---|---|---|
| Not patent | 2 (14.3) | 8 (30.8) |
| Patent | 12 (85.7) | 18 (69.2) |

## Discussion

With the improved endovascular armamentarium, introduction of new materials, better patient selection, and refined indications, it's necessary to continuously report results of specific promising interventions such as SIA that offer an important revascularization alternative for a subset of CLI patients.

The current single center, nonrandomized, prospective study included 40 CLI cases to report our results of SIA of long SFA occlusions. We reported 85% primary technical success in the current series. The technical success of SIA is generally high and varies between 78 and 90% in different reports [8,11,18]. According to the literature, infrapopliteal occlusions have a less favorable technical success rate when compared with the femoropopliteal occlusions [8,9,18].

The selection of patients suitable for SIA has to be defined clearly to avoid failures. Reekers and Bolia and Aleksynas and Kaupas found that arterial calcification was predictive of technical failure [6,19]. Bolia *et al.* [12] in addition, stated that the extensive calcification, recent (3 : 6 months) occlusions, and distal atherosclerotic disease should not be treated with subintimal recanalization. In the current study, we encountered failure in six cases. We could not return to the true lumen distal to the occlusion as a result of heavy calcification in three patients. In the other three cases, thrombosis developed in the recanalized segment.

The 1-year primary patency rate in our study was 75% and the salvage rate was 87.5%. London *et al.* [17] in their series reported a 1-year patency rate of 71% in three prospective studies. Florenes and colleagues [20,21] presented 12 month overall patency rates for SIA ranging from 53 to 70%. Lazaris *et al.* [22] reported a limb a salvage rate of 92% in their series of 46 CLI patients.

Variability in reporting patency rates among different studies is attributed to the different patients' characteristics, affected arterial segments and factors that could affect outcome and patency. In the current study, we report our results for a homogenous group of CLI patients with SFA lesions of more than 15 cm length and expected return points at the first or second part of the popliteal artery.

**Table 3 The relation between the state of distal runoff and the 1-year patency rate**

| Recanalized segment | ATA [*n* (%)] | PTA [*n* (%)] | Peroneal artery [*n* (%)] | ATA and PTA [*n* (%)] | ATA and peroneal a [*n* (%)] | PTA and peroneal a [*n* (%)] | Patent 3 leg vessels [*n* (%)] |
|---|---|---|---|---|---|---|---|
| Not patent | 3 (50) | 4 (66.7) | 1 (50) | 0 | 0 | 2 (18.2) | 0 |
| Patent | 3 (50) | 2 (33.3) | 1 (50) | 2 (100) | 4 (100) | 9 (81.8) | 9 (100) |

ATA, anterior tibial artery; PTA, posterior tibial artery.

With regard to the possible factors that might determine the patency rate of SIA, we found that the number of patent crural vessels after the procedure was the most important. We noticed that the patency rate was 50% or less with one patent leg artery and 80% or more with two or three patent leg arteries.

Lazaris *et al.* [23] reported that patients with two or three patent runoff vessels after the angioplasty have a 81% 1-year patency compared with 25% with one patent runoff vessel. London *et al.* [17] reported a similar result in patients with only femoropopliteal occlusion treated by SIA. Similar results have also been reported by other investigators for percutaneous transluminal infrainguinal angioplasty [24,25].

We reported in the current study a 1-year patency rate of 85.7% in TASC C patients in comparison with 69.2% in TASC D cases. The length of the recanalized occluded arterial segment was also found to be related to the patency rate of SIA in the study conducted by Lazaris and colleagues. They found that for every 10 cm of recanalized occlusion there is about a 1.22 risk of reocclusion after the angioplasty [23]. Also, London *et al.* [17] considered that the risk of reocclusion of a femoropopliteal SIA increases by 1.73 for every 10 cm of occlusion length. Comparable results have also been reported by other investigators for percutaneous transluminal infrainguinal angioplasty [25].

Despite the fact that a small number of patients is considered our main study limitation, our results support the reported data that the number of runoff vessels and the length of occlusion are the main determinants of SIA patency. This knowledge could improve SIA patency rates, as a recanalization of more than one vessel is often achievable [23].

SIA is a good alternative for recanalization of chronic long SFA total occlusions in CLI patients with acceptable 1-year patency rates. Number of patent leg arteries is an important determinant for durable procedures.

## Acknowledgements

### Conflicts of interest

None declared.

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