

Role Of Subintimal Angioplasty In Recanalization Of TASC B&C Lesions Of The Superficial Femoral Artery

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ABSTRACT

A prospective study aimed to evaluate the role of subintimal angioplasty in recanalization of TASC B&C lesions of superficial femoral artery, regarding the feasibility, the durability and the complications. Fifty seven patients with femoropopliteal occlusive disease were subjected to percutaneous angioplasty either transluminal or subintimal. Patients were followed up both clinically and by duplex scanning at 1,6 and 12 months after the procedure. Patient and Method: Among of the 57 patients 26 had percutaneous transluminal angioplasty (PTA) while 31 had subintimal angioplasty (SIA). Lesions were TASC B in 20 cases and TASC C in 37 cases. Diabetes was the main co-morbidity in 41 cases (72%). Gangrene was the main presentation in 24 cases (42.1%). Calcifications were present in 23 cases (40%). Single distal runoff was present in 21 cases (36.8%). Results: Patency rate after one year of follow up as determined by clinical evaluation was 85.1%, 83.3% in SIA and PTA cases respectively whereas duplex study showed popliteal triphasic flow in 85.1%, 62.2% in SIA and PTA cases respectively. At the end of one year follow up, Re-occlusion of the SFA occurred in sixteen patients, Twelve (75%) of them were diabetics and seven (43.7%) of them had heavy SFA calcifications. Eleven of occluded SFA cases had only one distal run off vessel. Conclusion: We recommend SIA to be considered in treatment of SFA lesions especially after failure of transluminal crossing and with long heavy calcified ones. SIA is technically feasible, safe, and provides satisfactory revascularization with nearly same results as percutaneous angioplasty (PTA). Calcification is one of the intra operative factors that affects technical difficulty and again long term (one year or more) patency especially in the SIA.

Keywords: Subintimal angioplasty, superficial femoral artery, TASC B&C..

INTRODUCTION

Peripheral arterial disease (PAD) is a common manifestation of atherosclerosis. The prevalence of PAD continues to increase, with recent data suggesting that almost 30% of at-risk populations have PAD. The less invasive nature of the endovascular surgery for treating critical limb ischemia and claudication and the reports of excellent patency in selected cases have encouraged the increasing use of this modality as a primary treatment of lower extremity arterial stenoses and occlusions.⁽¹⁾ Angioplasty of long stenotic lesions or chronic total occlusions in the superficial femoral (SFA) and popliteal arteries may be suboptimal. Implantation of stent in this region has a high restenosis rate. Changes in arterial flexion with daily activity can result in fatigue and fracture of metallic stents in the femoropopliteal arterial system.⁽²⁾ Recent studies have shown that Subintimal angioplasty (SIA) can produce good results not only in chronic critical limb ischemia but also in intermittent

claudication. SIA can now help to extend the scope of endovascular therapy to include a large number of femoropopliteal and tibial arteries occlusions who were considered to be unsuitable for angioplasty. In addition SIA can be used to re-open occluded native vessels following graft occlusion. The technique of SIA is simple, inexpensive, has low complication rates, good primary success rates, and good long-term outcomes.⁽³⁾

PATIENTS AND METHODS

This prospective study included 57 patients presented to the vascular surgery department in Kasr Al Aini and New Kasr Al Aini teaching hospitals with femoropopliteal disease for whom endovascular revascularization was done, between January 2010 and January 2014.

The study aimed to evaluate the role of subintimal angioplasty in recanalization of TASC B&C lesions of superficial femoral artery, regarding the feasibility, the durability and the

complications. by comparing the outcomes of these cases with those who had transluminal angioplasty.

The procedure, possible complications, benefits, risks and other alternative interventions were all explained to the patients and an informed consent was obtained. The aim was to evaluate the role of subintimal angioplasty in recanalization of TASC B&C lesions of superficial femoral artery, regarding the feasibility, the durability and the complications.

History taking, general and local limb examination followed by categorization of chronic lower limb ischemia was done according to the categorization of the Society of Vascular Surgery / International Society of Cardiovascular Surgery (SVS- ISCVS) for chronic lower limb ischemia. Then, routine laboratory tests and duplex scanning were obtained.

Inclusion Criteria:

Lifestyle limiting claudication (category 3; severe claudication). Critical limb ischemia (category 4; ischemic rest pain, resting ankle pressure was less than 40 mmHg, category 5; minor tissue loss, nonhealing ulcer or focal gangrene with diffuse pedal oedema and category 6; major tissue loss extending above tarso-metatarsal TM level). Patients with TASC B (multiple lesions each less than 5 cm in length, single occlusion less than 15 cm in length not involving the infrageniculate popliteal artery or heavily calcified occlusion less than 5 cm in length) or TASC C (multiple lesions totaling more than 15 cm in length).

Exclusion Criteria:

TASC A (Single stenosis <10 cm in length or Single occlusion <5 cm in length) and TASC D (Chronic total occlusion of the common femoral artery or SFA >20 cm in length involving the popliteal artery). Acute limb ischaemia. Haemodynamically significant Aortic stenosis or Aortic occlusion. Aneurysmal disease and arteriovenous fistula AVF. Known patients with intolerance or hypersensitivity to study medications or contrast agents.

Technique:

A loading dose of clopidogrel 300 mg was given the night of the procedure, both groins were prepared using an antiseptic solution (Povidone iodine 10%). All equipment were checked. The patient lies in the supine position and a local

anaesthetic is infiltrated at the artery puncture (xylocaine 2%).

Femoral access was adopted either ipsilateral antegrade (in lesions involving the mid to distal femoro-popliteal arteries) or contralateral retrograde (in lesions of the proximal SFA and in obese patients) based on the data obtained from the duplex or diagnostic angiographic study.

All PTA procedures were performed using a 0.035 "hydrophilic wire to cross the lesion. A balloon catheter suitable in length and diameter to the artery to be treated was used. Indications for stent deployment were flow-limiting dissection, or evident immediate vessel recoil.

Failure of transluminal crossing indicated using of SIA technique, only a very small stump (5 mm or less) of proximal SFA was required to start the dissection plane. Catheters with an angled tip, 4 or 5-French were useful to direct the end of the guidewire towards the vessel wall to break into the subintimal space for SFA lesions.

Angiographic success was defined as good flow with less than 30% residual stenosis measured at the narrowest point of vascular lumen. Technical failure was considered when failure to recanalize the occluded segment (failure to cross the lesion or to make re-entry) or downstream embolization into a critical runoff vessel. Immediate clinical success was defined as regain of pulse, revascularization warmth, oedema and disappearance of rest pain.

Most patients were discharged on the second day following the procedure after receiving instructions on risk factors control and treatment including Aspirin 150 mg/ day for life, Clopidogrel 75 mg/ day for at least 3 months. and Atrovastatin. Patients were advised for supervised walking exercise, foot care and protection and proper shoeing. Wound care and debridement, minor amputation were performed whenever indicated before hospital discharge.

Clinical follow-up and duplex examination at 1, 6, and 12 months after the procedure were done. It included follow-up of pulse examination, evaluation of the claudication pain and rest pain, evaluation of ulcer or amputation site healing or resolution of infection. Clinical success was defined as improvement of claudication pain, resolution of rest pain, healing of ulcer or minor amputation (up to transmetatarsal amputation).

Any additional endovascular procedures to maintain or restore patency of the vascular

channel were recorded, as well as all open surgical revisions, bypasses, and major amputations performed through the one year follow up.

Complications were divided into major and minor. Major complications included death, major bleeding, acute thrombotic occlusion, distal embolization or artery rupture. Minor complications included hematoma, treated dissection, dye extravasation (wire perforation), arteriovenous fistula or peripheral emboli.

RESULTS

This study included 57 patients (57 limbs) who were admitted to the vascular surgery department in Kasr Al Aini and new Kasr Al Aini teaching hospitals with critical limb ischaemia or incapacitating claudication due to femoropopliteal occlusive disease who fulfilled the selection criteria.

Patients were technically divided into two main groups: Percutaneous Transluminal Angioplasty (PTA-26patients) group and SIA group (SIA-31patients) (those whom transluminal crossing was failed and Subintimal Angioplasty technique was adopted) group based on the technique of the crossing of the lesion.

The demographic findings in this study are shown in (table1) while the main presenting symptoms are shown in (table2).

Table (1): Demography of the study

Male : Female		31 : 26	55:45 %
Age	<50	4	7
	50-60	20	35
	60-70	22	38.5
	>70	11	19
Comorbidities	NO.		%
Diabetes	41		72%
Hyperlipidimia	36		63%
Smoking	27		47.3%
Ischemic heart disease	10		17.5%
Hypertension	36		63%

Table (2): Presenting symptoms of the study.

Groups	P.T.A.		S.I.A.		Total	
	No.	%	No.	%	No.	%
Presenting symptom						
Intermittent claudication	7		5		12	21
Gangrene	14		10		24	42.1
Tissue loss	4		6		10	17.5
Rest pain	1		10		11	19.2

According to TASC classification, the B&C lesions, calcifications, no. of distal runoff vessels and additional proximal lesions are shown in (table3) while technique of recanalization and calcification are shown in (table4)

Table (3): Study of the lesion description

	No	%	
TASC B	20	35	
TASC C	37	65	
Calcification	23	40	
No. of distal run off vessels	0	4	7.5
	1	21	36.8
	2	17	30
	3	15	26.3
Additional proximal lesion	3	5.2	

Table (4): Technique of recanalization.

	P.T.A.		S.I.A.	
	No.	%	No.	%
TASC B	17/26	65	9/31	29
TASC C	9/26	35	22/31	71
Calcification	6/23	26	17/23	74

Failure of re-entry to the true lumen had occurred in three patients of the subintimal angioplasty group. Balloon angioplasty with or without stenting was done for the lesions after successful crossing. Balloon dilatation and stenting was done for the additional iliac artery lesions in three patients while balloon angioplasty to infra-popliteal vessels was done in eighteen patients to ensure adequate distal outflow to the femoro-popliteal segment.

Immediate success with good flow and palpable popliteal pulse was obtained in 94.7% (54patients) while failure of re-entry to the true lumen occurred in three cases in the subintimal group. One of them with gangrene was scheduled for femoro-popliteal bypass while the two others with claudication, control of risk factors and medical treatment were advised. Wire perforation occurred in 4 cases to which 3 minutes balloon dilatation tamponading was done. Arteriovenous fistula occurred in one patient to which balloon dilatation tamponading was done. No major complications in the form of death, major bleeding, acute thrombotic occlusion, distal embolization or artery rupture had occurred.

After one month, all patients (26) who were treated via P.T.A. route had improvement of their symptoms except two patients with gangrene that

had disappeared popliteal pulse due to reocclusion of the S.F.A. to which redo angioplasty with stenting was done but they had above knee amputation due to spreading infective gangrene. (**table5**).

After six months, the patient with rest pain and another one with ulcer had recurrence of their symptoms due to S.F.A. reocclusion to which redo angioplasty with stenting was done but six months later, they had another recurrence to which medical treatment and local wound care were advised (**table5**).

After twelve months, one patient had recurrence of gangrene due to S.F.A. reocclusion to which subintimal angioplasty was done while another patient had recurrence of claudication to which control of risk factors and medical treatment were advised (**table5**).

The primary patency rate was 92.3,84.6 and 76.9% at 1,6 and 12 months respectively while the secondary patency rate was 80.7% at 12months. The limb salvage rate was 92.3% all through the period of follow up (**table5**).

After one month. The 28 patients who were treated via S.I.A. route had improvement of their symptoms. After six months, one patient with rest pain had recurrence of his symptoms due to severe S.F.A. stenosis and tibial arteries lesions to which S.F.A. stenting and tibials angioplasty were done but he had below knee amputation six months later due to severe tibial arteries disease. Another patient with gangrene had recurrence of his symptoms to which above knee amputation was done due to S.F.A. reocclusion and spreading infective gangrene (**table5**).

After twelve months, one patient with gangrene and another one with ulcer had recurrence of their symptoms due to significant S.F.A. stenoses to which S.F.A. stenting was done (**table5**).

The primary patency rate was 90.3,83.8 and 77.4% at 1,6 and 12 months respectively while the primary assisted patency rate was 83.8% at 12months. The limb salvage rate was 83.8% at the end of the period of follow up (**table5**).

Table (5): Clinical follow up after 1,6&12 months.

After	1 month		6months		12months	
	PTA	SIA	PTA	SIA	PTA	SIA
Improvement of claudication	7/7	3/5	7/7	3/3	6/7	3/3
Resolution of rest pain	1/1	10/10	0/1	9/10	0/1	9/10
Healing ulcer	4/4	6/6	3/4	6/6	3/4	5/6
Healing gangrene	12/14	9/10	12/12	8/9	11/12	7/8
No improvement or Recurrence	2/26	3/31*	2/24	2/28	4/24	4/27

* Three cases with failure of reentry

After one month, the duplex finding showed that all patients (26) who were treated via P.T.A. route had patent S.F.A. with popliteal triphasic flow except two patients who had S.F.A. reocclusion causing recurrence of their gangrene. Above knee were done for both of them (**table6**).

After six months, six of 24 patients had S.F.A. occlusion or significant stenoses leading to symptoms recurrence in two of them (one with ulcer and the other with rest pain). two patients with claudication and two patients with ulcer still

had healed ulcer in spite of their S.F.A. reocclusion by duplex(**table6**).

After twelve months, nine of 24 patients of the P.T.A. group had S.F.A. reocclusion or significant stenoses leading to symptoms recurrence in four of them (one patient with gangrene, one with ulcer, another with rest pain and the last one with claudication). Two patients with claudication and three patients with ulcer still had healed ulcer in spite of their S.F.A. reocclusion by duplex (**table6**).

Table (6): Duplex findings during 1,6 &12 months follow up.

After	1 month		6months		12months	
	PTA	SIA	PTA	SIA	PTA	SIA
Groups						
Popliteal triphasic flow	24/26	27/28	18/24	25/28	15/24	23/27
Occluded or stenosed S.F.A.	2/26	1/28	6/24	3/28	9/24	4/27
Duplex finding only	0/26	1/28	4/24	1/28	5/24	1/27
With no Symptoms recurrence						

The 28 patients who were treated via S.I.A. route (after exclusion of 3cases of failed re-entry) had patent S.F.A. with popliteal triphasic flow after one month except one patient with rest pain who had S.F.A. moderate stenosis but remained asymptomatic. After six months, three patients of 28 had S.F.A. occlusion or significant stenoses leading to symptoms recurrence in two of them (one patient with gangrene and the other one with rest pain). One patient with ulcer still had healed ulcer in spite of S.F.A. reocclusion by duplex. After twelve months, four of 27 patients of S.I.A. group had S.F.A. reocclusion or significant stenoses leading to symptoms recurrence in three of them (one patient with gangrene, another with rest pain and the last one

with ulcer). One patient with ulcer still had healed ulcer in spite of his S.F.A. reocclusion by duplex.

In the P.T.A. group, 19 patients out of 26 had critical limb ischemia. After one year, seventeen of them had their limbs salvaged while two patients had major amputation.

In the S.I.A. group, 23 patients out of 28 had critical limb ischemia. After one year, 21 of them had their limbs salvaged while two patients had major amputation.

There were sixteen patients with S.F.A. reocclusion after one year. Twelve (75%) of them had diabetes. Seven (43.7) of them had heavy S.F.A. calcifications. Eleven of occluded SFA cases have only one distal run off vessel.

Case 1:

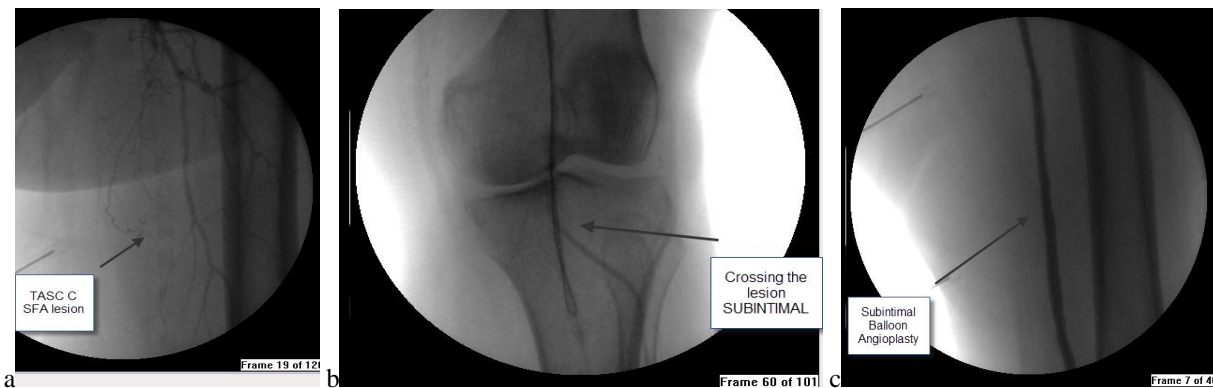


Figure 1: (a) TASC C S.F.A. lesion. (b) Subintimal crossing. (c) Flow after dilatation.

Case 2:

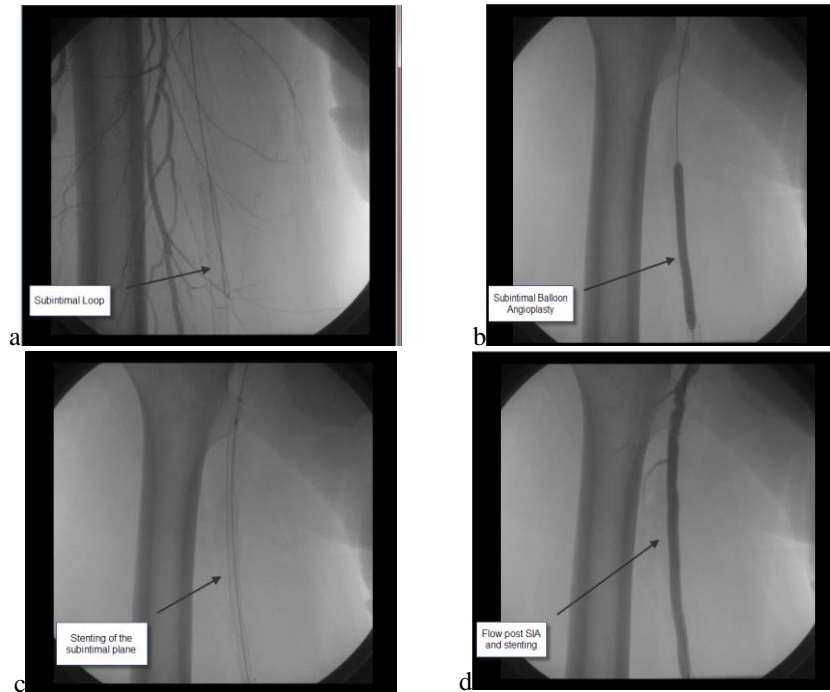


Figure 2: (a) TASC C S.F.A. lesion with wire passing subintimally. (b) Balloon dilatation. (c) Stent deployment. (d) Flow after treatment.

Case 3:

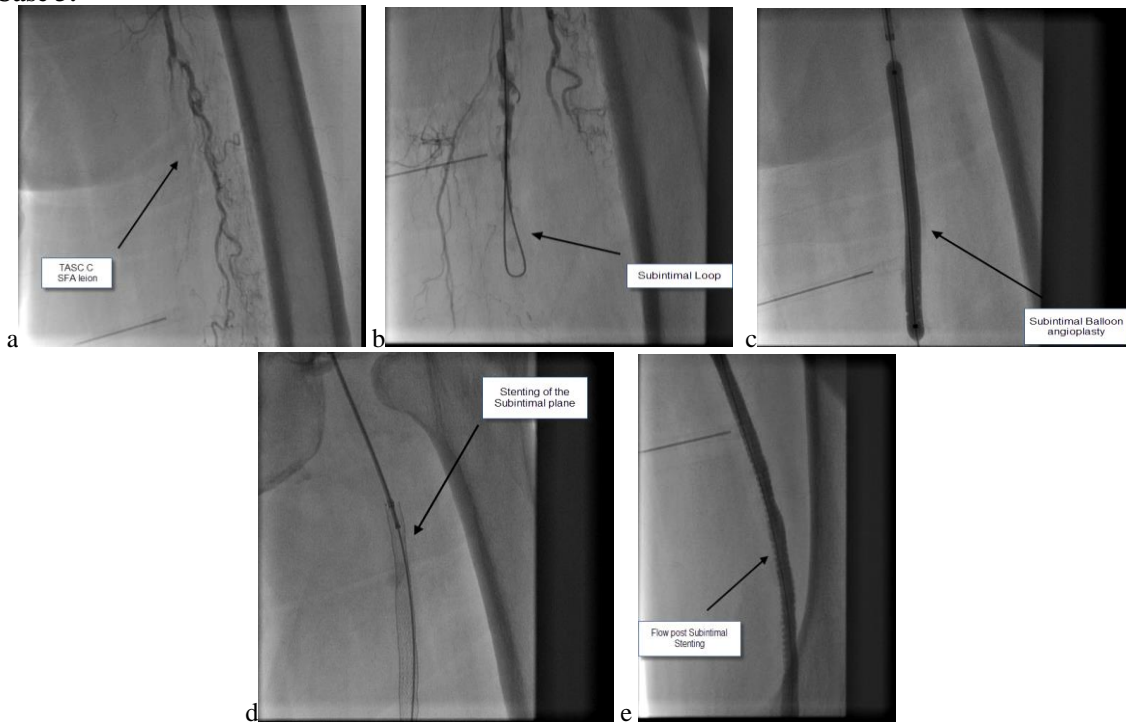


Figure3: (a) TASC C S.F.A. (b) Wire Subintimal (c) dilatation (d) Stenting (e) Flow after treatment.

DISCUSSION

The increasing longevity has led to deal with patients with more coexistent illnesses, which often increase the risk of intervention for PAD. Endovascular management of long SFA occlusions showed improved outcome, long-term patency and complication rates after the subintimal femoropopliteal recanalization published by *London et al.* with one year patency rates of 71%, indicated a new safe approach to this problem that merits consideration.⁽⁴⁾

In this study, an attempt to evaluate the different techniques of crossing the superficial femoral artery lesions (TASC B and TASC C) in patients with critical limb ischaemia or incapacitating claudication regarding the feasibility, durability and complications. For lesions that were not easily crossed by the hydrophilic guide wire intra-luminal; a trial of subintimal passage was performed. This ends up in two main groups in our study, the PTA cases, and the SIA cases

Patients with peripheral arterial disease present with significant medical co-morbidities that shape not only their perioperative risk, but also their longevity and patency rate. 72.% of patients had diabetes mellitus which is significantly higher than the arab world prevalence being 40%⁽⁵⁾ where 63.1% had hyperlipidaemia which is four times higher than the normal worldwide percent 15.3%⁽⁶⁾ and hypertension that coincides with what mentioned that the lifetime risk of hypertension exceeds 50% in most populations, then comes smoking 47.5% which is higher than the decreasing incidence worldwide reaching 24.5%⁽⁷⁾ and coronary artery disease 17% which is slightly less than the worldwide range being 25%.⁽⁸⁾ However, this can be contributed to the high incidence of diabetes in our study that can mask the CAD symptoms.

In spite of the fact that the main complaint in the current study was gangrene (42.1%), twenty one percent of patients were treated for incapacitating claudication which is much less than the world wide presentation being (54%)⁽⁹⁾. In our study, critical limb ischaemia patients (79%) were significantly higher compared to only (21%) presented by incapacitating claudication. The high prevalence of critical limb ischemia with gangrene being the most common

symptom may be due to the socioeconomic difference between the Western and the Egyptian community, and the nature of late presentation of patients to our center.

A total of 37 cases (65%) were classified by the Trans-Atlantic Inter-Society Consensus as class C, while 20 cases (35%) were classified as TASC B, with significant higher cases in SIA than PTA group, this is attributed to the nature of the lesions as it is technically easier to introduce the wire intra-luminal through multiple stenoses and short segment occlusions (TASC B), while it is easier for the wire to be introduced subintimally in long segment lesions (TASC C), a fact that was highly recommended by *Schmieder et al.*⁽¹⁰⁾ not only in TASC C but in both TASC C and D. Twenty three patients (40%) had calcified SFA lesions.

Our immediate technical success was to obtain good antegrade flow and palpable popliteal pulse. This was achieved in 54 (94.7%) cases, compared to 92% in other studies⁽¹¹⁾ the remaining 3 cases (5.3%) were considered as a failure due to failure of re-entry. One of them with gangrene was scheduled for surgical bypass, and the two cases with claudication, control of risk factors and medical treatment were advised.

After one year, patients with claudication had symptomatic improvement in 83% of the PTA group, compared to 100% in the SIA group, this being higher than the published studies that range between (68% *Eric et al.*⁽¹²⁾ to 76% *Tisi et al.*⁽¹³⁾ in the SIA cases). Ulcer healing occurred in 75% in the PTA group, compared to 83.3% in the SIA group, lower than *Antusevas et al.*⁽¹⁴⁾ with (84.6% in PTA cases, and 90.5% in SIA cases). Healing after minor amputation and/or proper debridement of gangrene occurred in 91.6% in PTA group, compared to 87.5% in the SIA group, with better results (85% in PTA cases and 80% in the SIA cases) published by *Mousa et al.*⁽¹⁵⁾

An ultrasound examination was performed after 1, 6, and 12 months. All examinations were performed in the same vascular laboratory, using the same ultrasound machines (Ultramark IU-22 and HDI 3500 ATL-Philips, Eindhoven, Holland). The B-mode imaging frequency was 7 MHz, and the pulsed-wave Doppler frequency 4 MHz.. ABI was not used due to inaccuracy with the high percentage of diabetes in our study, nor the peak systolic velocity due to technical difficulty.

During our 12 months follow up period, patency rates in SIA group at 1, 6, 12, months were 96.4%, 89.2%, and 85.1% respectively compared to 92.3,75 and 70.8% in the PTA group. SIA patency was significantly higher than that of PTA especially after 12 months. This "one year" patency results are higher than those of *A. Antusevas et al.*⁽¹⁴⁾ with patency rates in SIA group at 1, 6, 12 months were 84.9%, 68.5% and 65.8% respectively and in PTA group were 81.3%, 45.3% and 38.7% with even highly significant patency rate in favor of SIA. However, our SIA patency rate is significantly higher than other studies⁽¹²⁾ being 72%, 58% at 6, 12 month respectively. In addition, the results of SIA group is to be considered comparable to those of PTA group regarding that those lesions failed to be crossed transluminally, the fact that those lesions are considered to be more difficult than the PTA group.

With regard to the possible risk factors that might affect the patency rate, diabetes is the most important significant factor affecting patency after one year with 75% (12 patients out of 16) , which conforms with many publishing papers as^(12,16,17) where *Setacci et al.*⁽¹⁸⁾ added renal insufficiency and smoking to diabetes but *London et al.*⁽⁴⁾ concluded that smoking is an independent risk factors for reocclusion.

At 12 months follow up, 12 (75%) cases from total of 16 occluded cases had calcified lesions, which indicates that calcification is a significant poor prognostic factor for long term patency in both PTA and SIA techniques, keeping in mind that *Bolia et al.*⁽¹⁹⁾ stated that extensive calcifications should not be treated by the subintimal technique, however *Antusevas et al.*⁽¹⁴⁾ concluded that SFA calcifications can cause technical failure of recanalization but don't affect the primary patency rate. *Joye*⁽²⁰⁾ suggested that calcification in the wall of the occluded artery makes recanalization difficult and predisposes to technical failure, but *Laxdal et al.*⁽²¹⁾ *Tisi et al.*⁽¹³⁾ *Clair et al.*⁽²²⁾ and *Lipsitz et al.*⁽²³⁾ could not confirm this effect.

After 12 months follow up, out of sixteen occluded cases, eleven patients (68.7%) had only one distal run off vessel, while the remaining five cases (31.3%) had two or three distal run off vessels. This indicates that more than one distal run off vessel is an important significant prognostic factor for long term patency. This is

similarly comparable to *Johnston et al.*⁽²⁴⁾ *Hunink et al.*⁽²⁵⁾ *Lazaris et al.*⁽¹⁶⁾ shows that more than one vessel distal run off significantly affects the patency after one year. However, *London et al.*⁽⁴⁾ stated that more than one distal run off vessel is not a prognostic reliable factor for long term patency.

CONCLUSION

SIA is technically feasible, safe, and provides satisfactory revascularization with nearly same results as PTA. We recommend SIA to be considered in treatment of SFA lesions especially after failure of transluminal crossing and with long heavy calcified ones. Early post-procedural follow up is particularly important for identifying factors associated with poor patency and for the prevention of SFA re-occlusion.

Calcification is one of the intra operative factor that affects technical difficulty and again long term (one year or more) patency especially in the SIA, and further studies ,that we couldn't do in this thesis are needed to evaluate primary stenting at the calcified SIA cases as a prophylactic measure to prevent SFA re-occlusion.

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