

## Transluminal versus Subintimal Angioplasty for Management of Critical Limb Ischemia Patients with Femoropopliteal Occlusive Disease

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### ABSTRACT

**Aim:** comparison between intraluminal and subintimal angioplasty with special emphasis on technique, factors affecting the success and complications. **Methods:** This is a prospective non randomized study included 159 patients presented over two years starting from May 2014 to the vascular surgery department in Cairo University hospitals with critical chronic lower limb ischemia due to atherosclerotic femoropopliteal occlusive disease for whom percutaneous angioplasty was done. Patients presenting with non-salvageable limbs requiring primary major amputation and non atherosclerotic causes of CLI were excluded. **Results:** 75.5% of the lesions (120 cases) were crossed transluminally while 19.5% (31 cases) of the lesions were crossed subintimally. In 8 cases (5%) the lesion could not be passed. The overall technical success to pass the lesion was 95%. On 12 months follow up, 1ry patency, 2ry patency, limb salvage in intraluminal group are 56.8%, 60.2% and 66.1% respectively while in subintimal group 46.7%, 46.7% and 60% respectively. Subintimal was more in the TASC D, lesion more than 10 cm and in contralateral access ( P value was < 0.05). There was no statistically significant differences between intraluminal and subintimal angioplasty regarding the outcome ( Patency and limb salvage). **Conclusions:** The passage of the wire is affected by length of the lesion, the TASC II classification of the lesion and access site with the subintimal passage was more in Lesion more than 10 cm, TASC D lesions and in contralateral access. These factors can be used prospectively as predictors for passage of the wire whether intraluminal or subintimal. In spite of the technical differences between the intraluminal and subintimal passage, yet they show no significant statistical differences regarding the outcome (patency and limb salvage). Hence both should be used as part of vascular armamentarium for revascularization in such frail patients. **Keywords:** Critical limb ischemia; Limb salvage; femoropopliteal disease; subintimal angioplasty.

### INTRODUCTION

Critical limb ischemia (CLI) is characterized by multi-level disease, high burden of comorbidity and limited life span. The care of patients with CLI is not easy for the reason that many of them have considerable co-morbidities.<sup>(1)</sup>

Successful revascularisation decreases the major amputation rate in patients with critical limb ischemia (CLI). The effectiveness of peripheral bypass grafts and percutaneous transluminal angioplasty in accomplishing limb salvage has been known.<sup>(2)</sup> Femoropopliteal segment involvement in occlusive peripheral arterial disease is extremely common and, in one series, was present in 80% of symptomatic patients underwent angiography. However; the

optimal approach for treating this artery is still debated.<sup>(3)(4)</sup>

The recent technologic advances in endovascular therapy have extended the applicability of minimally invasive treatment for challenging superficial femoral artery lesions that were previously deemed inappropriate for endovascular therapy. 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.<sup>(5)</sup>

In our protocol for the treatment of all patients with TransAtlantic Inter-Society Consensus (TASC) criteria of CLI, PTA is the first choice revascularization procedure. In this study, we review the efficacy of angioplasty in

the femoropopliteal segment with special emphasis on the role of selective stenting. We try to compare between intraluminal and subintimal angioplasty with special emphasis on technique, factors affecting the success and complications. We try to review specifically the role of subintimal angioplasty and difficulties specific to the femoropopliteal segment is included with the use of simple techniques.

## PATIENTS AND METHODS

### Patient selection

This study is a prospective, non-randomized study performed at the Department of Vascular Surgery in Cairo University hospitals along the period of two years starting from May 2014. The study group included patients suffering from critical limb ischemia due to atherosclerotic occlusive disease affecting the femoropopliteal segment. The inclusion and exclusion criteria are shown in table 1.

**Table 1: Inclusion and exclusion criteria**

<b>Inclusion criteria:</b>
<b>A) General inclusion criteria:</b>
<ul style="list-style-type: none"> <li>▪ Patients with critical limb ischemia (Patient presents a score of 4 to 6 after Rutherford classification).</li> <li>▪ Patient is willing to comply with specified follow-up evaluations at the specified times.</li> <li>▪ Patient (or his or her legal representative) understands the nature of the procedure and provides written informed consent.</li> </ul>
<b>B) Angiographic inclusion criteria:</b>
<ul style="list-style-type: none"> <li>▪ The target lesion is located within the native femoropopliteal artery with or without any other lesions in the arterial tree.</li> <li>▪ The target lesion has angiographic evidence of stenosis or restenosis 50% or more or occlusion.</li> <li>▪ Target vessel diameter visually estimated is between 4mm and 6.5 mm.</li> <li>▪ There is angiographic evidence of at least one vessel runoff to the foot.</li> </ul>
<b>Exclusion criteria:</b>
<ul style="list-style-type: none"> <li>▪ Severe renal impairment.</li> <li>▪ Patients for whom antiplatelet therapy, anticoagulants, or thrombolytic drugs are contraindicated.</li> <li>▪ Patients with uncorrected bleeding disorders.</li> <li>▪ Life expectancy of 12 months or less.</li> <li>▪ Any patient considered to be hemodynamically unstable at onset of the procedure.</li> <li>▪ Patients suffering from non-atherosclerotic occlusive disease e.g. arteritis &amp; entrapment syndrome.</li> </ul>

Chronic critical lower limb ischemia was defined following the TASC II guidelines as: lower limb with more than two weeks of rest pain ,ulcers ,or tissue loss attributed to arterial occlusive disease .<sup>(6)</sup>

Patients presenting with non-salvageable limbs requiring primary major amputation and non atherosclerotic causes of CLI were excluded from this study. The decision of amputation was taken on basis of severe tissue loss when whole foot lost or non reconstructable arterial occlusion after adequate study either by angiography or CTA.

Endovascular treatment was the first choice modality of treatment in revascularization of all patients. Open surgery was offered selectively for patient whom endovascular failed or complicated and for long TASC II D lesions in fit patients

according to American Society of Anesthesia (ASA) score. Surgery was preferred in extensive disease (occlusions of whole length of the SFA and also upper popliteal occlusion and runoff on lower pop in fit patient and available vein).

**Pre-procedure assessment:** All patients were subjected to history taking, physical examination and radiological imaging (duplex and CTA).

**Consent:** Detailed explanation of the procedure, its indications, methods, risks& outcome was done. After which an informed consent was signed by all included. Approval from ethical committee in Cairo university General surgery department was taken before the beginning of the study.

### Technique:

All endovascular procedures were done in angi suite under local anesthesia.

Antegrade, ipsilateral common femoral artery puncture is the preferred access. Contralateral femoral puncture and a cross over technique was used when the lesion is very close (less than 2 cm) to the SFA origin, obesity and in hostile groin. Retrograde ipsilateral puncture of the popliteal artery & brachial access were also used in selected cases. After gaining access, an initial diagnostic angiogram was done.

The standard tools for recanalization of stenoses and occlusions consisted of a hydrophilic guidewire and an angled-tip catheter, e.g. Berenstein. Once the lesion has been crossed, the catheter was advanced beyond the lesion, the wire removed and contrast injected to ensure that the catheter is within the lumen.

The transluminal approach is intended to be used in all patients trying not to make a loop with the wire tip. When the intraluminal approach fails we used the subintimal approach. In our study we are aiming to use the simplest devices due to financial issues and no reentry devices were used nor available. Then after the procedure, patients are categorized in two groups: patients with intraluminal passage of the wire and patients with subintimal passage of the wire.

A balloon catheter, selected for appropriate diameter and length, is advanced over the wire to the distal extent of the lesion (or proximal lesion if the approach is via the popliteal artery). In our study the indications for stent insertion in the SFA segment are elastic recoil, flow-limiting dissection & residual stenosis more than 30%.

#### **The procedure outcome**

The outcome was evaluated for every case immediately post-procedure, and 3, 6 and 12 months later. Immediate evaluation was based on clinical assessment (pulse, capillary refill, and warmth) and angiography. Follow up was according to clinical re-assessment and duplex. The success of the procedure was determined by the following:

- Angiographic success defined as good flow with less than 30% residual stenosis at the narrowest point of the arterial lumen.
- Clinical success which may be:
  - Definitive success in the form of regain of pulse.

- Clinical improvement (good capillary circulation, warmth, relief of symptoms and good healing of ulcer or minor amputation).

▪ **PRIMARY ENDPOINT** : technical success , primary patency , secondary patency

▪ **SECONDARY END POINT** : limb salvage , disappear of the rest pain and wound healing

**Follow up:** clinical success was diagnosed by clinically presence of distal pulse, improvement of patient symptoms and healing of tissues imaging: duplex was done routinely for all patients on their follow up

**Data collection and statistical analysis:** Double-data entry was performed in an electronic database to generate descriptive data summaries. Data were statistically described in terms of mean  $\pm$  standard deviation ( $\pm$  SD), median and range, or frequencies (number of cases) and percentages when appropriate. Comparison of numerical variables between the study groups was done using Student t test for independent samples. For comparing categorical data, Chi square ( $\chi^2$ ) test was performed. Exact test was used instead when the expected frequency is less than 5. p values less than 0.05 was considered statistically significant. All statistical calculations were done using computer programs SPSS (Statistical Package for the Social Science; SPSS Inc., Chicago, IL, USA) version 15 for Microsoft Windows. All periprocedural and post procedural complications were evaluated and documented

## **RESULTS**

Over 2 years, 159 patients (159 limbs) with symptomatic femoropopliteal arterial occlusive disease met the inclusion criteria. Among the 159, 61.6% were male (98 patients). Patients are categorized according to the passage of the wire into intraluminal group and subintimal group.

Demographic features and associated co morbidities are shown in table 2. Diabetes and hypertension were the main associated co morbidities in both groups. Presenting symptoms were shown in table 3. The main presenting symptoms were tissue loss in both groups. Lesion morphology and TASC II classification were shown in table 4 and 5.

**Table (2): Clinical presentation**

<i>Clinical presentation</i>	<i>Intraluminal NO120 (%)</i>	<i>Subintimal NO 31 (%)</i>
Rutherford IV	32 ( 26.7%)	5 (16.1%)
Rutherford V	66 (55%)	14 (45.2%)
Rutherford VI	19 ( 15.8%)	12 (38.7%)

**Table (3): TASC classification**

<i>TASC II</i>	<i>Intraluminal NO 120 (%)</i>	<i>Subintimal NO 31 (%)</i>
A	14 (11.7)	0
B	35 (29.2)	2 (6.5%)
C	23 (19.2)	2 (6.5%)
D	48 (40%)	27 (87.1%)

**Table 5: Lesion length**

<i>Lesion length</i>	<i>Intraluminal NO 120 (%)</i>	<i>Subintimal NO 31 (%)</i>
Less than 5 cm	39 (32.5%)	2 (6.5%)
Between 5 and 10 cm	24 (20%)	2 (6.5%)
More than 10 cm	57 (47.5%)	27 (87.1%)

Runoff vessels analysis shows that 68 patients had 3 vessels runoff (42.8%), 11 patients had 2 vessels runoff (6.9%) and 80 patients with single runoff (50.3%). Subintimal was more in the TASC D, lesion more than 10 cm and in contralateral access (P value was <0.05). As shown in table 6, SI was more in the cases where contralateral access used.

**Table 6: Access used**

<i>Access used</i>	<i>Intraluminal NO 120 (%)</i>	<i>Subintimal NO 31 (%)</i>
Ipsilateral	103 (85.8%)	16 (51.7%)
Contralateral	16 (13.3%)	12 (38.7%)
Other	1 brachial (0.8%)	3 contralateral and popliteal (9.7%)

75.5% of the lesions (120 cases) were crossed transluminally while 19.5% (31 cases) of the lesions were crossed subintimally. In 8 cases (5%) the lesion could not be passed. The overall technical success to pass the lesion was 95%.

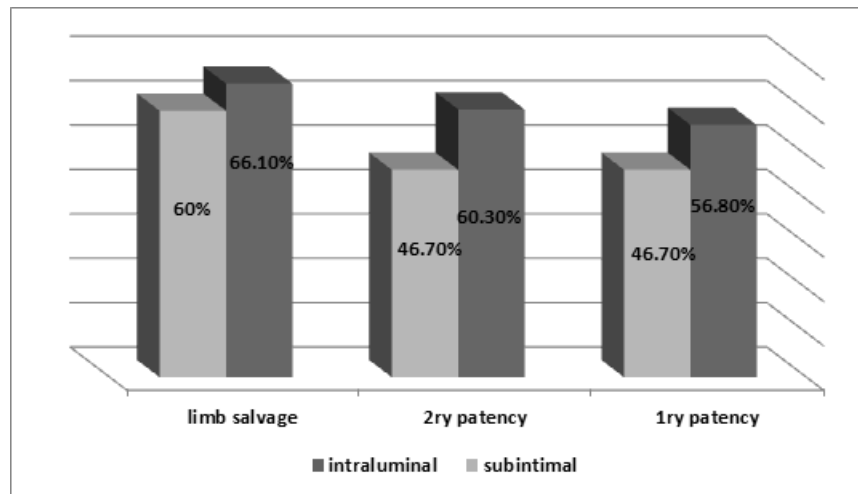
The mortality rate was 1.3% (2 cases). The complications were present in 56 patients (37%). The complications were summarized in table (7). All access hematomas were mild to moderate in size and were treated conservatively. Dissections were evaluated and were stented if they were flow limiting. There were two cases with recoil that necessitated stenting.

**Table (7): Complications**

<i>Complication</i>	<i>Transluminal</i>		<i>Subintimal</i>	
	<b>Number</b>	<b>Percent</b>	<b>Number</b>	<b>Percent</b>
Access hematoma	2	1.3%	0	–
Dissection	28	18.5%	20	13.2%
Recoil	0	–	2	1.3%
Perforation	1	0.7%	0	–
Thrombosis	1	0.7%	2	1.3%
Angina	1	0.7%	0	–

There were 8 cases with failure to cross the lesion, 3 cases complicated with acute thrombosis and open surgery was done, and one case had acute angina on table so the intervention was aborted and the patient transferred to ICU and the limb died so primary amputation was done and the other 4 cases were referred to surgery. 145 patients completed the 6 months follow up, 135 patients completed the 12 months follow up and 92 patients completed the 24 months follow up.

On 12 months follow up, 1ry patency, 2ry patency, limb salvage in intraluminal group are 56.8%, 60.2% and 66.1% respectively while in subintimal group 46.7%, 46.7% and 60% respectively with no statistical differences. (P value 0.560). (Fig 1)



## DISCUSSION

Critical leg ischemia (CLI) leads to considerable morbidity and mortality and lead to the consumption of considerable health and social care resources in developed and developing countries. Specific considerations apply to CLI patients and decision-making in revascularization strategies in CLI differs from that in patients with claudication. In CLI, different treatment aims at wound healing, limb salvage and maintained ambulation rather than improved walking ability in claudicants. Moreover long-term patency as such is probably of less importance. This makes the choice of endovascular treatment may be supported even if act as temporary revascularization till wound healed. <sup>(7)</sup> <sup>(1)</sup> Femoropopliteal segment involvement in occlusive peripheral arterial disease is extremely common and, in one series, was present in 80% of symptomatic patients undergoing angiography. <sup>(3)</sup>

In our protocol for the treatment of all patients with TransAtlantic Inter-Society Consensus (TASC) criteria of CLI, PTA is the first choice revascularization procedure. In this study, we

review the efficacy of angioplasty in the femoropopliteal segment with special emphasis on the role of selective stenting. We try to compare between intraluminal and subintimal angioplasty (SIA) with special emphasis on technique, factors affecting the success and complications. We try to review specifically the role of subintimal angioplasty and difficulties specific to the femoropopliteal segment is included with the use of simple techniques.

Although SIA is currently widely used and worldwide experience with the technique is growing, there is still considerable doubt regarding the method and its results. This is mainly due to lack of evidence from randomized clinical trials comparing SIA with intraluminal angioplasty. However, SIA is known to yield high percentages of technical success and acceptable long-term clinical patency and limb-salvage rates.

Although subintimal passage of the lesions were happened to a lesser extent in this study. However no one can deny the success of subintimal in limb salvage in CLI characterized by long total occlusions. Hynes et al. have reported the number of attempted

revascularisations to have doubled since the introduction of the subintimal angioplasty.<sup>(8)</sup> Subintimal angioplasty has also provided a new method of managing occlusions, which has substantially improved the entire field but specifically has changed lower extremity revascularization.<sup>(9)</sup>

These results were recently confirmed by Bolia et al. and Setacci et al. with primary success rates of 80% and 83.5% and limb salvage rates of 85% and 88% at 1 year, respectively.<sup>(10)</sup>  
(11)

lesions more than 10 cm in length was a predictor for more subintimal passage of the wire (about one third of the cases with lesion length more than 10 cm with P value < 0.05). Arterial calcification, poor runoff, diabetes, treatment for chronic limb ischemia as opposed to claudication, and lesion length are the variables most frequently postulated to affect patency. Although occlusions are thought to be more difficult to treat than stenosis, results have been conflicting.<sup>(12) (13) (14)</sup>

TASC II D lesions were predictor of the more subintimal passage of the wire with statistically significant. (P value < 0.05). The high percentage of TASC D cases reflect that the CLI to occur need extensive disease and long occlusion not simply short stenosis or occlusion and the same time reflect the difficulties in management of such difficult lesions and the technical success of PTA and could be used as the 1st choice.<sup>(15)</sup>

Regarding the runoff vessels about 50% of our cases had single runoff vessel and this is may be due to the fact that more than 90% of our patients were diabetics. While the average percent of patients suffering from critical limb ischemia in the meta-analysis done by Antoniou et al., (2013) was 66%.<sup>(16)</sup> This may reflect the difficulties in management of our patients. The endovascular treatment of multilevel disease is thought to result in worse outcomes compared with the treatment of single-level disease of the femoropopliteal vasculature, because each lesion has its own failure rate that results in an additive effect.<sup>(17)</sup>

This study did not use several other techniques described for use in difficult passage for long femoropopliteal lesions. Retrograde passage through popliteal access has been used mainly for flush SFA occlusion after failure of cross over passage. Usually the retrograde puncture of the popliteal artery was done by using

duplex ultrasonography, and SI-PTA is performed from the distal SFA to the proximal SFA, which is opposite the direction used for the standard approach. The retrograde SFA SI-PTA approach has a reported patency rate of 62% at 1 year.<sup>(18)</sup> There is another technique described by Balas et al, which approaches flush occlusions of the SFA with a combination of open surgery and endovascular techniques.<sup>(19)</sup>

Regarding the passage of the wire, in about 75.5% of the cases the wire passed transluminally while in only about 19.5% of the cases the wire passed subintimally with 5% failure to cross the lesion.

A major concern of the popularity of endovascular interventions, especially in complex lesions, is the potential alteration of the level for subsequent open procedures after failed endovascular intervention. Joels et al. have reported that the problem of alteration of the level of a subsequent open procedure after failed endovascular intervention is acceptable and even when the level alters it does not necessarily change clinical outcome.<sup>(20)</sup>

In a study done by Köchera, et al., in 2010 aiming at retrospective assessment in mid-term outcomes of subintimal angioplasty of chronic arterial occlusions in femoro-popliteal region,, Technical success was achieved in 86.46% . Primary patency rate was 83.1%, 67.5% , 58% and 48.4% at 6, 12, 24 and 36 months respectively and the study concluded that subintimal recanalisation is a simple and safe procedure for treatment of chronic peripheral arterial occlusions with high primary technical success rate, acceptable primary patency rate, low percentage of complications and mortality is as low as nil.<sup>(21)</sup>

However, there is a serious disadvantage of PSA, which may make the patient worse rather than better. There is a potential risk of damage to important collaterals distal to the occlusion when these are included in the dissected portion. When important collaterals are compromised without achieving a haemodynamically viable channel in the main artery, the patient's distal circulation will be compromised and urgent bypass surgery will be required to restore circulation to the distal leg. It is therefore crucially important that a dissection is not extended too far distal to the occlusion, particularly early on in a doctor's experience.<sup>(22)</sup> But in a study done by Treiman et

al where they do support the concept that failed recanalization does not alter or jeopardize subsequent bypass.<sup>(12)</sup>

In the current study, the overall technical success to pass the lesion was 95%. Antoniou et al., reported 91% technical success in the endovascular group with no significant heterogeneity among the studies. Taking into consideration the usage of simple endovascular tools and avoidance of reentry devices, we think that 95% technical success using the simplest endovascular tools for treating critical limb ischemia patients is satisfactory.<sup>(16)</sup> In a study done by Myers and coworkers shows similar rate with initial technical success rate of 92.6% and the patency rate of 82.3% at 6 months.<sup>(23)</sup>

The overall primary patency rate in our study at 12 months was 54.7% in comparison to about 62% in three randomized trials and four observational studies and this inferior result may be due to the fact that most of our patients were diabetic with TASC II C or D category and with long total occlusions. (16) The primary patency rate at 24 months for the transluminal approach was 56.8%, while for the subintimal approach was 46.7%, so there was no statistical significance between the two approaches (P value 0.55). In the study of Sidhu et al., The cumulative primary patency at 6 and 12 months was 90% and 73%, respectively and Primary patency of SA is lower compared to surgical bypass, especially that with autogenous vein. The secondary patency rate at 12 and 24 months was 94% and 85%, respectively (24)

Data regarding primary patency rates at 1 year after SIA vary widely. A recent meta-analysis of several SIA studies, including 1549 and 2810 limbs, respectively, estimated that 1-year primary patency rate was approximately 50%.<sup>(25)</sup>

The overall limb salvage in our study was 64.9% and the reason beneath the fact that the limb salvage is higher than patency rates is that all of the cases had critical limb ischemia and endovascular intervention may provide sufficient blood supply needed for healing then by the time the vessels is occluded the demand of blood supply is decreased and the collateral developed is enough for the tissue viability. Limb salvage is the most widely accepted clinical outcome measure in the CLI population. The limb salvage at 12 months for the transluminal approach was 66.1%, while for the subintimal approach was

60%, so there was no statistical significance between the two approaches (P value 0.58).

In the analysis of amputation free and overall survival by treatment received for the BASIL trial done by Bradbury et al., (2010), they found that there were no differences in amputation free survival or in the overall survival between transluminal and subintimal angioplasty.<sup>(7)</sup>

Regarding the complications the mortality rate was 1.3% and the overall complication rate was 37%. It is noticed that in our study there is a high percent of dissection (about 31%) and this is may be due to the fact that more than half of our cases are TASC II D and more than 90% of our cases are diabetics leading to the presence of heavily calcifications.

In metaanalysis done by Markos et al. Overall complication rates of SIA are reported as between 6% and 17%. Definitions of complications differ widely, and there is very limited evidence about factors affecting the complication rate. The complication rate of SIA is no higher than for PTA, and the risk of major adverse events is lower in SIA than surgery. The amputation rate after SIA was reported as 2.2% in patients with CLI.<sup>(26)</sup>

The comparison between subintimal and intraluminal is difficult and unfair as both are used in different situations as regard the patency rate. First, the lesion morphology after angioplasty is different. The atherosclerotic plaque remains in the flow channel after intraluminal angioplasty, whereas a subintimal flow channel is devoid of exposed plaque except at entry and re-entry points. This could alter arterial wall remodeling after SIA from those observed with IBA. Hence, the role of neo-intimal hyperplasia after stent placement in a subintimal channel is unknown. Second, the types of lesions in each group are different. Whereas IBA can be used for segments with stenosis or short occlusions, SIA is used for segments with short or long occlusions. Also, as suggested by the worsening stent results with increasing TASC lesion, the majority of SIA are performed for TASC C and D lesions. Hence, the results from IBA stents can't be readily extrapolated to SIA. Second, it has been our view that stents may hinder any secondary interventions. Our study, however, shows that re-interventions can be undertaken with similar success rates as those limbs without stents. Third, one putative benefit

of SIA is the maintenance of and possible opening up of collaterals. 17 The fate of these collaterals could be jeopardized by placing stents. In our study, there was a trend for SIA patients receiving stents (35%) to require more open bypass surgery than those without stents (17%) at 2 years ( $P = .06$ ). This trend could reflect our bias that endovascular reinterventions may be more difficult after stent failure. Hence, patients with failed stents may undergo open bypass surgery without an endovascular salvage attempt. Finally, Treiman's study lined the whole subintimal channel with stents, whereas we selectively placed stents in segments as needed. Hence, comparisons of SIA with stent cannot be made between the studies. The benefits and drawbacks of either approach are uncertain and remain an important question to address.<sup>(27)</sup>

#### Limitation of study

##### Study limitation

- There are some limitations of the present study.
- First, this is non randomized study. Therefore, there may be a bias in selection of patients
- Second, the results of the present study were derived from a single-center experience with a high work volume where certain techniques have been routinely adopted for many years as a first choice. It is therefore likely that the selection of techniques with its own limitations may differ largely from centers with another experience.
- Third, in most of our patients computed tomographic angiogram or a magnetic resonance angiogram was not a baseline performed before the intervention. An extensive use of these diagnostic tools might have impact on the decision process.
- Fourth, we have economic problem that hinder us from using the more recent technology as reentry devices and special recanalization device. But this is may be a point of power that we are obliged to seek less costly techniques to overcome this factor.

In addition, this study included treated segments from the proximal SFA to the tibial vessels. This heterogeneous data could make interpretation of outcomes more difficult.

Finally, we have lost some patients on follow up. This may be attributed to socioeconomic factors and lack of proper insurance system. So

the lower mortality rate in this study cannot be taken with certainty.

**Conflict of interest:** Non

## CONCLUSION

1. The passage of the wire is affected by length of the lesion, the TASC II classification of the lesion and access site with the subintimal passage was more in Lesion more than 10 cm, TASC D lesions and in contralateral access.
2. These factors can be used prospectively as predictors for passage of the wire whether intraluminal or subintimal
3. In spite of the technical differences between the intraluminal and subintimal passage, yet they show no significant statistical differences regarding the outcome (patency and limb salvage). Hence both should be used as part of vascular armamentarium for revascularization in such frail patients.

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