Primary stenting versus balloon angioplasty in treating superficial femoral artery lesions

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Abstract

Background: The superficial femoral artery (SFA) is the site of> 50% of atherosclerotic plaques that develop in the human vascular tree. These lesions were previously amenable only to surgical bypass, but now the endovascular therapy altered this line of treatment. However, still there is a debate in using primary stents to treat such lesions.

Aim of the study: To compare primary stenting versus simple balloon angioplasty in treating SFA TASC II type A orB lesions.

Patients and methods: 40 patients presented by chronic lower limb ischemia were divided randomely into 2 groups. Each involved 20 patients. Group I was treated by primary stenting and group II by simple balloon angioplasty. The lesions treated belonged to TASC II (type A or B) lesions. Follow up at 6 months and one year was done as regards the patency and development of restenosis.

Results: The mean lesion length treated was 10.1 em ±3 em. 30% of the lesions were complete occlusions. The patency in both groups was 100% along the whole period of the study. 10% of group I and 25% of group II developed restenosis at 6 months. At the end of the first year, a total of 20% of group I and 56.2% group II developed restenosis >50%.

Conclusion: Primary stenting of SFA lesions (TASC II type A or B) is recommended as it improves the one year outcome as regards development of restenosis.

Keywords: Angioplasty, stenting, SFA.

Introduction:

Atherosclerosis is the most common cause of symptomatic arterial occlusion in human vascular tree: one of its most common sites is the femoropopliteal segment where more than 50% of atherosclerotic plaque lesions occur. The lesions may be focal, discrete or may involve the entire 30 em length of the vessel. Stenoses, occlusions or both may be present, although occlusions are three times more common than stenoses.[1]

The superficial femoral artery (SFA) is one of the longest arteries in the body. It has two major flexion points, the hip and the knee. The presence of few collateral vessels, many forces exerted on the SFA include torsion, compression, extention and flexion exert significant stress on the SFA.[2]

Endovascular therapy has dramatically altered the treatment of peripheral arterial disease (PAD). Lesions previously thought amenable only to open surgical bypass can now be successfully managed percutaneously.[3]

Atherosclerotic lesions with complex morphology such as calcified lesions, eccentric stenoses and plaques with ulceration or focal aneurysm, are prone to develop complications, when treated by balloon angioplasty alone, as elastic recoil, dissection and/or significant residual stenosis (which occur in up to 30% of cases). This results in unsatisfactory long term patency rates. Accordingly, primary stenting (stent placement without prior balloon angioplasty) is more effective in treating such lesions.[4]

For more than a decade, femoropopliteal stent implantation remained a bailout procedure after complicated balloon angioplasty. But the introduction of self-expanding nitinol stents once again, changed the treatment strategy of femoropopliteal disease.[5]

Self-expanding nitinol stents have improved radial strength with shape-memory characteristics that promots crush recoverability. They also have reduced foreshortening which allows precise placement. These properties led to better patency rates compared to earlier stent designs encouraging the use of primary stenting of SFA lesions.6

Aim of the study:

The aim of the study was to compare primary stenting versus simple balloon angioplasty in treating SFA lesions as regards the patency and restenosis over one year of trea1ment

Patients and methods:

Study design:

A randomized controlled study was conducted in Ain Shams University hospitals involving 40 patients comparing primary stenting to simple balloon angioplasty for the SFA atherosclerotic occlusive diseases.

The patients were divided into 2 equal groups, each included 20 patients that were randomely treated as follows:

Group1:In whom primary stenting of the SFA was done.

Group II: In whom simple balloon angioplasty was performed.

All patients enrolled in the study had the following inclusion criteria.

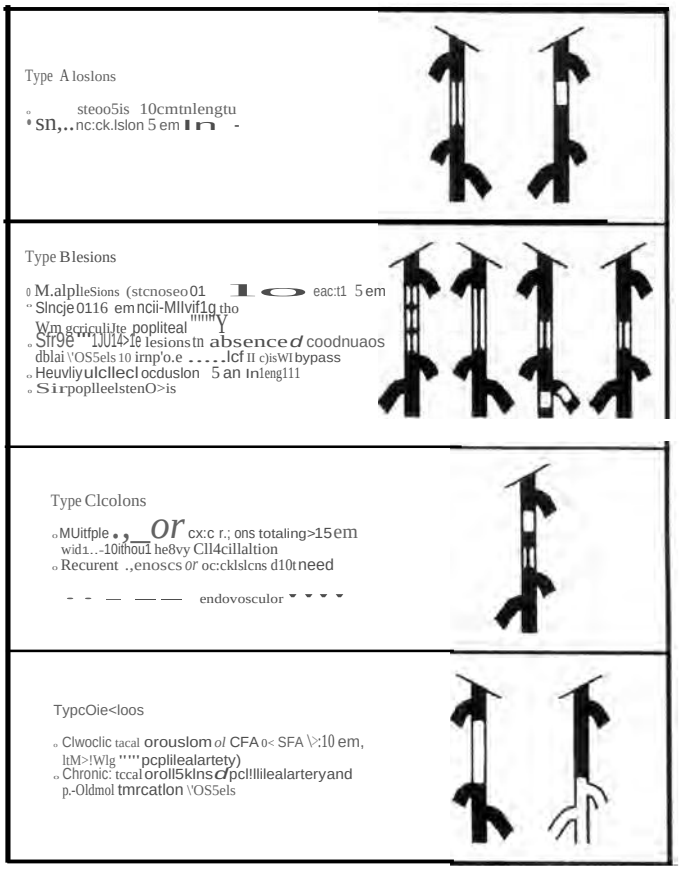
1- The presentation was critical limb ischemia (CLI) or very short distance claudication interfering with their life style. CLI was defined by the European consensus document as the presence of ischemic rest pain requiring opiate analgesia for at least 2 weeks, ankle systolic presSltt'e lower than *50* mmHg and/or toe systolic pressure lower than 30 mmHg or presence of ulceration or gangrene.

2- The lesion was type A or B according to classification of trans-atlantic inter-soceity consensus (TASC) IF femoropopliteal lesions, as shown in Table(l).

3- All lesions involved were atherosclerotic.

4- All patients had normal renal functions.

Table (1): Clllssification of trans-atlantic intN-soceity consensus (TASC) HfemoropoplituJ lesions.



Any patient not fulfilling any of these criteria, was excluded from the study.

A preoperative evaluation was done for all patients involving:

1- Risk factors for atherosclerosis including: smoking, diabetes mellitus, hypertension, dyslipidemia, obesity, coronary artery disease, and cerebral vascular disease.
2- Kidney function tests (S. creatinin , Bl. Urea) to exclude preoperative renal impairment.
3- Bleeding profile.
4- Clinical evaluation of the limb including the ankle brachial index (ABI).
5- Multi-slice CT angiography including the lower abdominal aorta and the lower limb arteries to delineate the lesions.

A loading anti-platelet therapy namely, clopidogrel, was given 24 hours before the procedure which was continued at least one year after the procedure[8]

Procedures:

An access to the lesion was obtained through an antegrade common femoral artery (CFA).[9] Retrograde CFA access was used in obese patients or if the lesion was in the proximal third of the SFA.[3]

A single-wall puncture needle (16 or 18 gauge) accommodating up to 0.35 inch guide wire was used. Then a 6 French sheath was introduced to obtain an access port to the artery.

After confirming an intra-arterial access, systemic anticoagulation was obtained with 50-100 IU/kg of intravenous heparin.

The lesion was crossed using a 0.035 inch hydrophilic guide wire.This may be aided by a 4 or 5 F diagnostic multipurpose catheter that improves the steerability of the wire and provides additional support for crossing the lesion.

In group I, a self-expandable nitinol stent of 6 mm diameter was used to cover the lesion. The stent was placed without prior balloon angioplasty.[4] Thena 6 mm balloon was inflated inside the stent to obtain an optimum result as detected by imaging control **Figure(l).**

In group II, a simple balloon angioplasty using 6 mm balloon was used to dilate the lesion controlled by intra-operative imaging **Figure(2).**

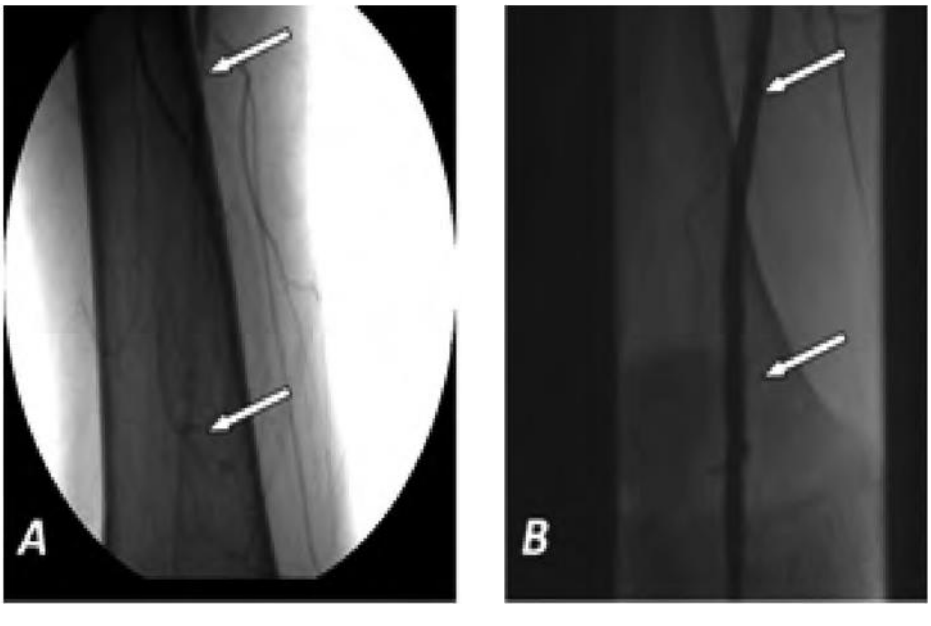


Figure (1): Primary stenting of occluded lower third of right SFA:
A. Pre-stenting angiogram showing occluded lower third of right SFA (arrows)
B. Past-stenting angiogram showing successfUl revascularization (site of the stent marked by arrows)

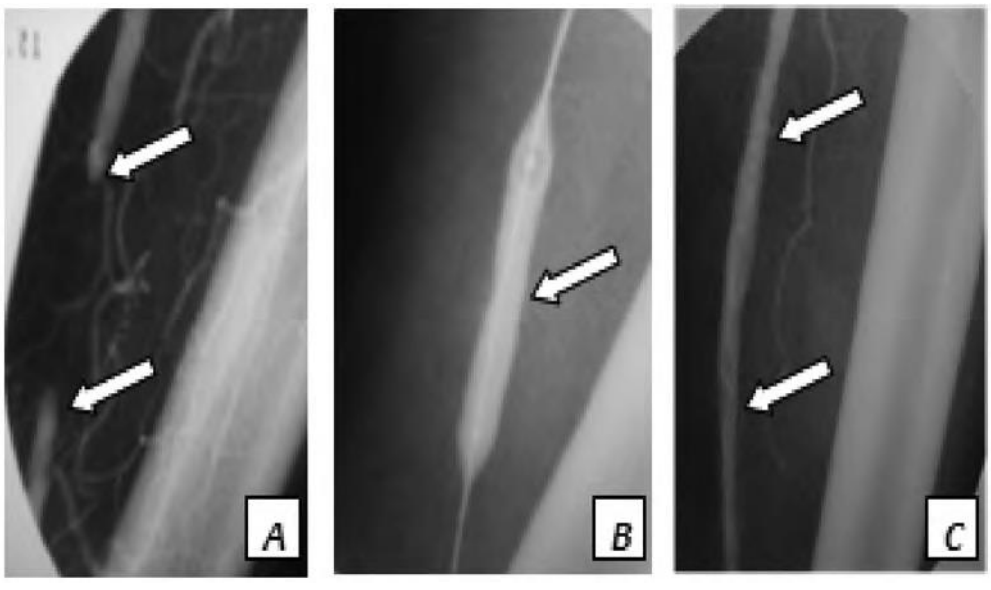


Figure (2): Simple hal/on angioplasty of7 em.occlusion of left SFA:
A. Pre-stenting angiogram showing occluded 7 em. segment of left SFA (arrows)
B. Balloon dilatation of the occluded segment (an-ow showing the waist of the balloon)
C. *Past-stenting angiogram showing successful revascularization (arrows)*

Postoperative follow up:

1- Clopidogrel was given for all patients one year postoperatively.
2- Immediate postoperative clinical response (technical success) was evaluated using the clinical response of the preoperative presentation and the ABI.
3- Patency of the procedure was assessed at 6 and 12 months by arterial duplex.
4- A multi-slice CT angiography was done if duplex was inconclusive.

The success of theprocedure was considered when there was freedom from> 500/o restenosis in the target vessel.

Results:

40 patients with SFA lesions were enrolled in the study, that were divided randomely into two equal groups:group (20 patients), treated by primary stenting and group n(20 patients), treated by simple balloon angioplasty.

Of the 40 patients, 30 (75%) were males and 10 (25%) were females. Their ages ranged from (42-93 years) with a mean age of67.7 years. 32 patients (80%) were diabetics, 27 patients (67.5%) were hypertensive, 30 patients (75%) were smokers, 28 patients (70%) had dyslipidemia, 16 patients (40%) were obese, 25 patients (62.5%) bad coronary artery disease, and 8 patients (20%) had cerebral vascular disease. There was no statistical significant difference between both groups as regarding demographic data and atherosclerotic risk factors.

32 patients (80%) presented by tissue loss in the form of ischemic ulcers or foot gangrene. The remaining 8 patients (20%) had short distance claudication. The ABI ranged from 0.2-0.5. There was no statistical significant difference between both groups regarding the clinical presentation of patients.

The preoperative multi-slice CT angiography revealed a mean lesion length of 10.1±3 em. 70% (28 patients) had diffuse disease (multiple or single stenosis in the affected segment) and 30% (12 patients) bad complete occlusion. All the lesions were confined to the SFA with good distal (tibial arteries) run off. Also, there was no statistical significant difference between the two groups considering CT angiography findings.

4 patients (20%) from group II, required secondary stenting due to suboptimal results of simple balloon angioplasty (in the form of residual stenosis > *SO%*, recoil or flow limiting dissection). However, these patients were excluded from the study. So, at the end of the study, group II were analyzed as 16 patients only.

Revascularization of SFA was associated with good clinical response in all patients of the two groups. After treatment, claudication and rest pain disappeared, and foot ulcers and/or minor amputation stumps healed.

Table (1): Results at 6 months after treatment.

Group	Complete occlusion	Restenosis >50%
Group I (20 patients)	Non	2(10%)
Group n(16 patients)	Non	4(25%)

P value > 0.05

As shown in Table(2): after 6 months of treatment, patency of the treated arteries was 100% in both groups. 2 patients (10%) from group I and 4 patients (25%) from group II developed restenosis >50%, but this was not statistically significant. However, all of these restenosis were asymptomatic and no further interventions were required.

As demonstrated in Table(3): after 12 months of treatment, patency of the treated arteries was 100%. 5 patients (20%) in group I and 9 patients (56.2%) in group IT developed restenosis >50%, with aP-value of0.01, which is highly significant. One patient in group I and 3 patients in group nbecame symptomatic and required re-intervention.

Table (3): Results at 11 months after treatment.

Group	Complete occlusion	Restenosis >50%
Group I (20 patients)	Non	5 (20%)
Group II (16 patients)	Non	9 (56.2%)

P value> 0.01

Discussion:

Percutaneous transluminal interventional techniques have profoundly changed the management of vascular occlusive disease. The acceptance of such techniques was gradual and hard fought, and there was significant resistance from the surgical community. Today, there is a major shift from surgery to angioplasty in patients with peripheral arterial occlusive disease.IO

The SFA is one of the most common sites of PAD where more than 50% of atherosclerotic plaques occur. As these lesions are mostly complex, they are prone to develop complications when treated by simple balloon angioplasty.l.4

The endovascular treatment of SFA lesions remained in a debate, some documented the essential use of primary stenting although others documented the efficacy of simple balloon angioplasty and secondary stenting on demand as a line of choice in the management of such lesions.ll·12

This randomized controlled study involved 40 patients aiming to compare primary stenting versus simple balloon angioplasty in treating SFA lesions as regards patency and restenosis over one year postoperatively.

Diabetes mellitus, smoking, and dyslipidemia account for the most common risk factors for atherosclerosis in our community. They were present in 80%,75%, and 70%, respectively in our patients.

20% of our patients treated by simple balloon angioplasty (group II) developed intra-operative complications that required secondary stenting. This was less than those in ABSOLUTE trial,13 balloon angioplasty versus stenting with nitinol stents in the SFA, in which 32% required secondary stenting, but, it was more than those in FAST (femoral artery stenting trial),14 in which only 11% required

secondary stenting. This difference might be due to the short length of lesion treated in FAST (mean 4.5 em) , while in our study and in ASBOLUTE trial it was more than 10 em. The cause of use of secondary stenting was mainly flow limiting dissection or residual stenosis > 30%.

The 6 months follow up of our patients revealed no difference in patency in both groups (100% in both) and no significant difference in restenosis (I0% and 25% respectively). This was similar to the results in ABSOLUTE trial which was 23.5% and 43.4% respectively)3

However, at the end of the frrst year, there was high significant difference in the incidence of> 50% restenosis, it was 20% in group I and 56.2% in group II. These results were similar to many trials, as in ABSOLUTE triaJ13 which was 36.7% and 63.5% and RESILIENT (randomized study comparing the Edwards self-expanding life stent versus angioplasty alone) trial ,15 which detected restenosis in 20% and 62%, respectively.

Also, similar results were obtained in ASTRON trial16 (balloon angioplasty versus primary stenting of femoropopliteal arteries using self-expandable nitinol stents) which were 34.4% and 61.1%, respectively.

In the DURABILITY triaJ17 of the stented SFA lesions done, only 8.7% developed restenosis at 6 months and 27.7% at one year follow up.

However, in FAST trial,14 it was found that there was insignificant difference in both groups as regards the development of restenosis which was 32% and 39% , respectively denoting no benefit in using stent in SFA lesions with respect to restenosis prevention.

Table(4) summarizes the results of different trials compared to our study in using primary stenting (Group I) versus simple balloon angioplasty (Group II) in treatment of SFA lesions.

Table (4): Results of different trials compared to our study.

Group I (primary stenting) & Group II (simple balloon angioplasty)

Study	Restenosis at 6 months		Restenosis at 1 year	
	Group I	Group II	Group I	Group II
ABSOLUTE trial	23.5%	43.4%	36.7%	63.5%
RESILIENT trial	Not available	Not available	20%	62%
ASTRON trial	Not available	Not available	34.4%	61.1%
DURABILITY trial	Not available	Not available	8.7%	27.7%
FAST trial	Not available	Not available	32%	39%
Our study	10%	25%	20%	56.2%

So, most of the trials and our study, support the use of primary stenting in SFA lesions (TASC II type A or B lesions), which had superior results than simple balloon angioplasty as regards development of restenosis.

Conclusion:

Primary stenting of the SFA lesions described in TASC II (type A or B lesions) is recommended as an endovascular approach to treat these lesions because it improves the one year outcome as regards development of restenosis.

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