

Endovascular Treatment of TASC D Lesions in the Femoro-popliteal Arterial Disease; Feasibility and Short-term Results

Mohammed H. Eldessoki¹, Haitham A. Eldmarany², Ahmad Gamal¹

¹Professor of Vascular Surgery, Kasr Alaini Hospital, Cairo University

²Lecturer of Vascular Surgery, Kasr Alaini Hospital, Cairo University

ABSTRACT

Introduction: In recent years, endovascular treatment of long-segment superficial femoral artery (SFA) occlusive disease (> 15 cm) (Trans Atlantic Inter-society Consensus TASC lesions type C and D) has gained wider acceptance, representing a less invasive treatment option. Technical success rates have progressively improved to range from 80 to 95%, due to the introduction of specifically designed guidewires and low-profile balloon catheters. **Aim of the work:** Evaluation of the endovascular in treatment of TASC D femoro-popliteal occlusions in patients who might be at high surgical risk for open surgical interventions, as regarding: feasibility, clinical assessment of results, short-term patency and complications. **Method:** This is a prospective study conducted on patients presenting to the department of vascular and endovascular surgery, Kasr Alaini hospital, Cairo University along the period from September 2013 to December 2014. The aim of this study to assess the technical success and clinical outcome for six months after endovascular treatment of femoro-popliteal arterial disease TASC- D lesions in patients suffering from critical limb ischemia (CLI) and lifestyle-limiting claudication i.e. (Rutherford category III or more). **Results:** We received 30 patients; 22 males (73.3%) and 8 females (26.7%) with age range from 49 and 81 years (mean: 64.3±7.4 years). 6 patients (20%) presented with lifestyle limiting claudication (Rutherford 3), 13 patients (43.3%) presented with rest pain (Rutherford 4), 16 patients (53.3%), presented with non-healing ulcers (Rutherford 5) with or without rest pain and 8 patients (26.7%) presented with gangrene proximal to the metatarsal bones (Rutherford 6). All the lesions were TASC D femoro-popliteal occlusive disease (100%). Lesions were classified into three groups according to the site of the occlusion: 21 patients have SFA occlusion (70%), 5 patients have popliteal occlusion (16.7%), while 4 patients have combined SFA & popliteal occlusion (13.3%). 50 % (15 patients) have runoff on three vessels, 30 % (9 patients) have run off on two vessels, and 20 % (6 patients) have run off on one vessel. Angioplasty was done in all cases with conventional semi-complaint plain balloons. Selective stenting using self-expanding nitinol stents was done in 17 cases only (63%); the stents diameters ranged from 4 to 6 mm with mean stent diameter (5.9 ± 0.5 mm) and the stents length ranged from 60 to 150 mm with mean stent length (102 ± 28 mm). Additional sites for angioplasty and stenting were done in 9 cases; Tibial angioplasty for the Infrapopliteal tibial vessels in 8 cases (26.7%), and primary stenting for Common iliac artery (CIA) stenosis in one case only (3.7%). No major complications in the form of acute thrombosis, distal embolization, retroperitoneal bleeding or major amputation were observed. Minor complications occurred in 4 patients (13.3%); one patient (3.3%) has groin hematoma that was treated conservatively, two patients (6.7%) have minor perforation that was treated with prolonged balloon inflation and one patient (3.3%) has sheath thrombosis (sheath was removed and cleared and any residuals were aspirated by 6F catheter). Immediate technical success was achieved in 27 cases (90%). **Conclusion:** TASC D lesions can be treated using the simple endovascular means with acceptable results concerning limb salvage due to its ability to significantly improve distal extremity perfusion pressure with high technical success rates and minimal morbidity and mortality.

Keywords: Endovascular, TASC D Lesions, Femoro-popliteal, Feasibility

INTRODUCTION

Peripheral arterial disease (PAD) is a significant healthcare problem affecting the elderly population. Its incidence increases from

4% in population 40 years and older to 15% in patients over 70 years of age¹. Anatomically, approximately 30% of the arterial lesions are located in the iliac arteries, 70% in the femoro-popliteal and tibial tract. Isolated lesions below

the knee are present in only 15% of the cases. The most common clinical manifestation of PAD is intermittent claudication involving the pelvis, upper thigh and lower limb. Patients present with critical limb ischemia usually have multi-segmental disease with involvement of the infra-inguinal arteries². For decades, surgical revascularization has been the traditional treatment for a variety of the infra-inguinal occlusive lesions³. Limitations of open bypass surgery include the need for general anesthesia, longer length of hospital stay, lack of good quality vein conduit, and greater morbidity, particularly in patients presenting with critical limb ischemia⁴.

The interest in and overall usage of endovascular procedures for the treatment of lower extremity ischemia continues to grow at a rapid pace. An increasing number of centers throughout the world are gaining experience with angioplasty. Promising results have been reported with the application of this technique. Although primary patency rates compared with bypass surgeries are relatively low for patients undergoing angioplasty, limb salvage rates remain high. Re-occlusion after angioplasty frequently does not cause recurrence of symptoms, especially when a gangrenous lesion or ulcer has healed⁵. In recent years, endovascular treatment of long-segment superficial femoral artery (SFA) occlusive disease (> 15 cm) (Trans Atlantic Inter-society Consensus TASC lesions type C and D) has gained wider acceptance, representing a less invasive treatment option. Technical success rates range from 80 to 95% has progressively improved, due to the introduction of specifically designed guidewires and low-profile balloon catheters⁶.

According to the **BASIL** trial (Bypass versus Angioplasty in Severe Ischemia of the Leg) compared to surgery, percutaneous recanalization provides similar amputation-free survival rates, although it represents a less expensive and probably safer treatment option⁷. The main limitation of the interventional procedures is the relatively low mid- and long-term primary patency rates. The reported 5-year patency rate of femoro-popliteal angioplasty is about 40–55%, which is lower than the corresponding 5-year patency rates of bypass grafts, ranging from 40 to 75%, according to the site of the graft (better results obtained in above the knee procedures) and the type of conduits (significantly better

results with venous grafts compared to synthetic grafts)⁷. The advantages of a percutaneous interventional angioplasty procedures over bypass surgery are: avoidance of the complications of general anesthesia, making an incision in an ischemic leg and healing complications as well as less systemic stress (local anesthesia) and faster recovery and ambulation. Moreover, a redo procedure might be easier than surgery, with the advantage of offering future surgical intervention if needed⁸.

Aim of the work

Evaluation of the endovascular technique in treatment of TASC D femoro-popliteal occlusions in patients who might be at high surgical risk for open surgical interventions, as regarding: feasibility, clinical assessment of results, short-term patency and complications.

PATIENTS & METHOD

This is a prospective study conducted on patients presenting to the department of vascular and endovascular surgery, Kasr Alaini hospital, Cairo University along the period from September 2013 to December 2014. The aim of this study was to assess the technical success and clinical outcome at six months after endovascular treatment of femoro-popliteal arterial disease TASC- D lesions in patients suffering of critical limb ischemia (CLI) or lifestyle-limiting claudication i.e. (Rutherford category III or more). The procedure, possible complications, benefits, risks and other alternative interventions were all explained to the patients and an informed consent was obtained. We have chosen All patients with chronic ischemia (incapacitating claudication), or critical limb ischemia (Rest pain, tissue loss, and gangrene) i.e. { \geq Rutherford stage III or Fontaine stage IIb} due to TASC- D atherosclerotic femoro-popliteal occlusive disease i.e. (chronic total occlusion of CFA or SFA > 15 cm, involving popliteal artery or chronic total occlusion of popliteal artery involving the trifurcation vessels) who are considered at high risk for surgery due to their poor state of health or for anatomical reasons (an inadequate greater saphenous vein (GSV) or a leg ulcer prohibiting distal graft implantation), or patient's refusal of surgery. We excluded patients with severe renal impairment, lifestyle-non limiting claudication, patients suffering from non-atherosclerotic

occlusive disease e.g. arteritis & entrapment syndrome as well as patients for whom antiplatelet therapy, anticoagulants, or thrombolytic drugs are contraindicated. For each patient detailed history taking and clinical examination were performed including: Age, gender and predisposing risk factors for atherosclerosis. Duplex scans for those patients were revised for: 1) anatomical site of the lesion and its length, 2) run-off status distal to the affected segment. Some of our patients had multislice CT angiography (MSCT) (5 cases i.e. 25%) in addition to the duplex. Lesions were defined by angiography based upon the TASC II classification. Run-off vessels were defined as the number of patent crural vessels after the procedure in continuation with the treated femoro-popliteal segment. Demographic, clinical and intra-operative variables were entered into a designed database by the research team. Data were collected in a computerized database and was analyzed prospectively as regarding: patient's demographics, associated co-morbidities, presenting symptoms, type length & site of the femoro-popliteal lesions, numbers of distal run-off vessels, number of stents used, technical success rates and patency rates.

Technique:

Patients were admitted one day before or at the day of the procedure, a loading dose of clopidogrel (300 mg) was given the night of the procedure, both groins were prepared using antiseptic solution (povidone iodine). The patients lie in the supine position and a local anesthetic is given (xylocain 2%: 3-5mg/kg), except in the trans-popliteal access where the patient lie on prone or lateral decubitus position.

Three types of arterial access were used depending on the anatomy of the lesion and the operator preference; antegrade ipsilateral common femoral artery puncture was the most common access used (unless the lesion is very close to the SFA origin), contra-lateral femoral puncture with a cross over technique and retrograde ipsilateral puncture of the popliteal artery (if there is an SFA occlusion flush with the vessel origin and the popliteal artery is patent). The standard tools that we used for recanalization of stenoses and occlusions consist of a 0.035 hydrophilic guidewire and an angled-tip catheter, (e.g. 4F Berenstein or Vertebral catheters, Cordis®). Once the lesion has been crossed, the catheter is

advanced beyond the lesion, the wire removed and contrast injected to ensure that the catheter is within the true lumen. 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). The balloon was inflated to its nominal pressure until any waist on the balloon has been abolished. Inflation times vary from a few seconds to a few (1-3) minutes. In case of long lesions with no available suitable balloon lengths, after balloon deflation, the balloon catheter was withdrawn slightly and re-inflated with overlaps until the whole lesion has been covered.

Revascularization strategy:

In case of stenotic lesions; we tried to cross the lesion and perform balloon dilation using over the wire (OTW) a semi compliant plain balloon of suitable size and length. The balloon was chosen according to the diameter of the normal segment of the diseased target artery and the length should allow coverage of the whole lesion with 5-10 mm coverage of the normal artery on either side of the lesion. After balloon dilatation, the balloon catheter was then withdrawn completely, while keeping the guidewire in place across the lesion so that re-insertion of the balloon catheter or a stent can be performed if required. Angiography to assess the result was performed by injecting contrast medium through the side arm of the sheath. There should be rapid forward flow through the treated segment with no residual stenoses greater than 30%. If there were residual stenoses, the balloon catheter was re-inserted and re-inflated at the site of stenosis. If the balloon inflates fully, but the stenosis persists, indicating elastic recoil, insertion of a stent was deemed necessary. If there was a flow-limiting dissection, prolonged balloon inflation was performed to (tack down) the flap. In this case the balloon was kept inflated for up to 5 min. If this failed, a stent was indicated.

In case of CTO lesions; we tried first to cross the lesion intra-luminal but if the wire passed subintimal we followed the wire until bypassing the diseased segment and attempted to return to the true lumen without the need of re-entry devices. After initial balloon dilatation, if there was resistant elastic recoil (more than 30%) or flow-limiting dissection not corrected by prolonged balloon dilatation, a stent was indicated (selective stenting).

In all cases, if a stent was indicated, a self-expanding bare metal nitinol stent was used. This is because balloon-mounted stents are subjected to external pressure and will not re-expand if they are compressed. The stents were oversized by 1 mm relative to the diameter of the SFA. The stents used were chosen to be long enough to cover the lesion with 5–10 mm coverage of the normal artery on either side of the lesion.

Auxiliary procedures like tibial angioplasty were performed when needed to enhance and augment the outflow vessels. The wire was left across the lesion for access and an intra-arterial nitroglycerin (100-200 ug) was given, a check angiogram was performed and re-dilatation was done whenever required. The endpoint of the procedure was unrestricted forward flow of contrast with no evidence of significant (>30%) residual stenosis. The run-off was assessed at the end of the procedure for the occurrence of distal embolization caused by the PTA or stent insertion.

When the procedure was completed, the arterial access sheath was removed and hemostasis achieved by manual compression. Digital compression was held proximal to the skin puncture site for 15-20 minutes and mobilization was delayed for 12-24 hours. When more than 5000 IU of heparin were given, we delay sheath removal until activated clotting time (ACT) normalizes. Most patients were discharged on the second day following the procedure after receiving instructions on risk factors control and treatment including: **Enoxaparin** subcutaneously every 12 hours for 2 days, **Aspirin** 81 mg /day for life, **Clopidogrel** 75 mg /day for at least 3 months and **Atrovastatin** is given routinely (40 mg for 2 weeks then 20 mg for 6 months).

The patients received foot care consisting of wound dressing, minor debridement, limited amputations (up to trans-metatarsal amputation), infection control, and appropriate footwear before discharge.

Follow up:

Clinical follow-up consisted of pulse examination and evaluation of the ulcer or amputation site healing or resolution of infection. Clinical success was defined as healing of ulcer or minor amputation site or resolution of rest pain. An ultrasound examination was performed within 48 h and repeated at day 30 and 6 months. The clinical status of the patients and ABI index were

evaluated at the same intervals, except in patients with huge ulceration in the leg or calcified arteries, in whom ABI index was substituted by toe/ pressure measurement. The ultrasound examination measured the patency of the treated artery and any evidence of internal thrombus. All examinations were performed in the same vascular laboratory, using the same ultrasound machine. The B-mode imaging frequency was 7 MHz, and the pulsed-wave Doppler frequency 4 MHz. An insonation angle of 60° was used, with angle correction where necessary (40° - 60°). We attempted to maintain the insonation of 60° all the time in order to standardize the study methodology. Primary technical success was defined as continuous arterial patency to the popliteal artery without any obvious flow-limiting lesions (absence of a stenosis >50%). Clinical outcomes, primary patency, secondary patency and complications were reported according to the 'Recommended standards for reports' by (Rutherford et al., 1999)⁹.

The patency rate was based on a colour-flow ultrasound scan. A change in ABI of at least 0.10 was accepted as evidence of haemodynamic improvement (and a change of less than 0.10 was deemed to be a haemodynamic failure). In patients in whom the ABI could not be measured accurately (e.g., patients with diabetes and rigid calcified arteries) it was substituted by the toe / pressure (which is usually unaffected by such conditions) or any measurable pressure distal to the revascularization. Early mortality (<30 days) was reported. Limb salvage was defined as no amputation proximal to the metatarsus. Any above-the-ankle amputation was considered a failure of the revascularization procedure. All peri-procedural and post-procedural complications were evaluated and documented. 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.

RESULTS

We received 30 patients; 22 males (73.3%) with age range from 49 and 81 years (mean: 64.3±7.4 years). The associated co-morbidities and risk factors are shown in table 1.

Table (1): Patient's demographics and risk factors

Patients demographics		
Sex	M:F	22:8
Mean age	64.3±7.4 years	
Co-morbidity		
Diabetes Mellitus	26	86.7%
Hypertension		70%
Smokers	13	44.8%
IHD	10	33.3%
Stroke	2	6.7%

The presenting manifestations are shown in table 2.

Table (2): Clinical indication of patients for intervention

Claudication	6	20%
Rest pain	13	43.3%
Non-healed ulcers	16	53.3%
Gangrene	8	26.7%

Lesions were classified into three groups according to the anatomical site: 21 patients have SFA lesions (70%), 5 patients have popliteal lesions (16.7%), while 4 patients have combined SFA & popliteal lesions (13.3%).

50 % (15 patients) have runoff on three vessels, 30 % (9 patients) have run off on two vessels, and 20 % (6 patients) have run off on one vessel. The ipsilateral antegrade femoral approach was used in 10 cases (33.3%) and the contra-lateral (crossover) approach was used in 20 cases (66.7%). In two cases, an additional retrograde access was used: Percutaneous transpopliteal access in one case and through the anterior tibial artery in another case. One access was done in 28 patients (93.3%) while two accesses were used in two cases only. In 20 cases, the lesion was crossed subintimal (66.7%), In 7 cases; the lesion was crossed intra-luminal (23.3%); while in three cases (10%), there was a failure to cross the lesion. In all the lesions, hydrophilic 0.035 wire supported by vertebral catheter was used to cross the lesion. No re-entry devices were used in cases of subintimal crossing to get re-entry to the true lumen. In the three cases of failure, trial was done to cross the lesion with the stiff back end of the guidewire, and hence those three cases will be excluded from further patency and follow-up

analysis. Angioplasty was done in all cases with conventional plain balloons. Selective stenting using self-expanding nitinol stents was done in 17 cases only (63%); the stents used were all of the same type (Complete SE, Medtronic®) diameters ranged from 5 to 6 mm with mean stent diameter (5.9 ± 0.5 mm) and the stents length ranged from 60 to 150 mm with mean stent length (102 ± 28 mm). Additional sites for angioplasty and stenting were done in 9 cases; Tibial angioplasty for the Infrapopliteal tibial vessels in 8 cases (26.7%), and primary stenting for Common iliac artery (CIA) stenosis in one case only (3.7%). No major complications in the form of acute thrombosis, distal embolization, retroperitoneal bleeding or major amputation were detected. Minor complications occurred in 4 patients (13.3%); one patient (3.3%) has groin hematoma that was treated conservatively, two patients (6.7%) have minor perforation that was treated with prolonged balloon inflation and one patient (3.3%) has sheath thrombosis (sheath was removed and cleared and any residuals were aspirated by 6F catheter). Immediate technical success was achieved in 27 cases (90%). Patency rates (After excluding the three cases in which we failed to cross the lesion) are shown in table 3.

At 3 months, 25cases (92.6%) remained patent. 2 cases (7.4%) become occluded; one case (3.7%) have occluded popliteal artery at two months that was treated with stenting by self-expandable nitinol stent, then get re-occluded and then converted to open bypass surgery. The target vessel was the anterior tibial artery (single runoff) which was not altered by the repeated endovascular intervention. Another patient had acute stent thrombosis that was treated with catheter-directed thrombolysis (CDT) and then angioplasty followed by stenting for the underlying stenosis. At 4 months, one case of mortality (3.7%) unrelated to our endovascular procedure.

Of the 16 cases who presented with non-healing ulcer, 16 cases had successful angioplasty and underwent minor amputation after the angioplasty and the amputation stumps healed in 3months average. At the time of complete healing, 11 cases had the angioplasty SFA still patent. Of the 8 cases who presented with gangrene, 6 cases had successful subintimal angioplasty and underwent minor amputations after the angioplasty and the amputation stumps

healed in 3 months average. At the time of complete healing, 5 cases had the angioplasted SFA still patent while 2 cases of unsuccessful subintimal angioplasty (due to failure to cross the lesion) had undergone open surgical revascularization. The overall limb salvage rate in our study was 87.5%.

Table (3): Patency rates at 3 and 6 months

Follow up	Primary patency	Secondary patency
3 months	92.6% (25 cases)	96.2%
6 months	63% (17 cases)	70.4% (19 cases)

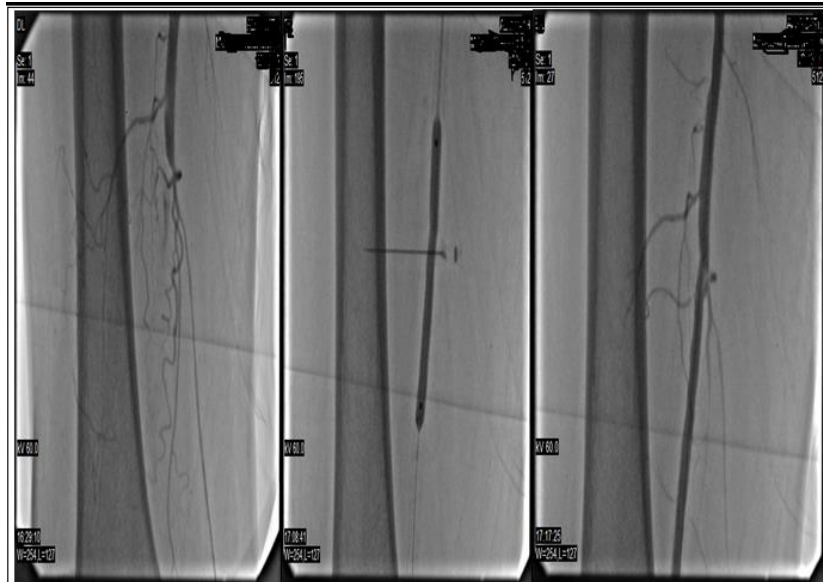


Fig. 1: Long segment chronic total occlusion affecting SFA that have been corrected by balloon angioplasty alone without the need for stent insertion

DISCUSSION

Femoro-popliteal segment involvement in occlusive peripheral arterial disease is extremely common and, in one series, was present in 80% of symptomatic patients undergoing angiography¹⁰. Current TransAtlantic InterSociety Consensus Document on Management of Peripheral Arterial Disease (TASC II) recommendations advocates traditional surgical therapy for the treatment of more complex TASC D lesions¹¹.

These lesions involve long femoro-popliteal segments, an independent predictor for treatment failure, and anatomically challenged regions (popliteal), which traditionally do not lend themselves to stenting. However, advances in endovascular techniques including the utilization of the subintimal technique and advances in technology, specifically, the development of re-entry devices and more flexible nitinol stents have

significantly contributed to overcoming these technical limitations, making it possible to treat even the most complex occlusive lesion with minimally invasive techniques especially that, patients with more complex TASC D lesions often present with severe CLI and suffer from significant co-morbid medical conditions placing them at high risk for traditional open surgical bypass¹².

In our study we discuss the role of simple endovascular techniques in treating TASC D femoro-popliteal artery atherosclerotic occlusive diseases. We used the contra lateral retrograde femoral access and ipsilateral femoral access according to the site of occlusion. As most of the occlusion affected the proximal part of the superficial femoral artery (SFA), so we used the contra lateral retrograde femoral access in 20 patients (66.7%); while in 10 patients, we used the ipsilateral antegrade femoral access due to

remote femoro-popliteal occlusion. We did not recognize much difference in wire pushability or torcability between ipsilateral antegrade femoral and contra lateral retrograde femoral approaches. In two cases only, we used the ipsilateral retrograde access; (trans-popliteal access and another access through the ATA. One case due to failure to get re-entry to the true lumen after subintimal crossing of SFA occlusion, and another case with popliteal and trifurcation occlusion and we failed for antegrade recanalization; so we decided for retrograde recanalization through percutaneous access to the ATA. Regarding the passage of the wire, in 20 patients (66.7%) the wire passed subintimal while in only 10 patients (23.3%) the wire passed transluminal. The overall technical success to pass the lesion was 90%. Min-yi et al., reported a technical success rate about 91% in endovascular recanalization of TASC D femoro-popliteal occlusive disease in 95 limbs without re-entry devices¹³. Rabellino et al reviewed 234 limbs, 52% of which were TASC D lesions and reported initial technical success of 97%¹⁴.

We did not face much difficulty in re-entering the true lumen; we did not use any re-entry devices due to lack of availability. In the three cases with technical failure, we didn't use retrograde trans-popliteal approach as a simple alternative technique for lesion crossing, so we think that 95% technical success can be achieved with simple endovascular techniques. Different techniques and new devices have been reported to facilitate re-entry into the true lumen. Two devices are currently available that facilitate true-lumen reentry [The OutBack LTD reentry catheter (Cordis) and the Pioneer catheter (Medtronic)]. We strongly recommend using these devices if being available as it achieves high success rate in safe re-entry to the true lumen, and may reduce the chance of vessel perforation and procedure times. Regarding the complications, there was one case of mortality (3.7%) during the follow-up period. Death was unrelated to the procedure, as the patient has multiple comorbidities. No patient required a major amputation during this follow-up period. Four patients (13.3%) in our study developed procedure related complications inform of groin hematoma, vessel perforation, and access thrombosis.

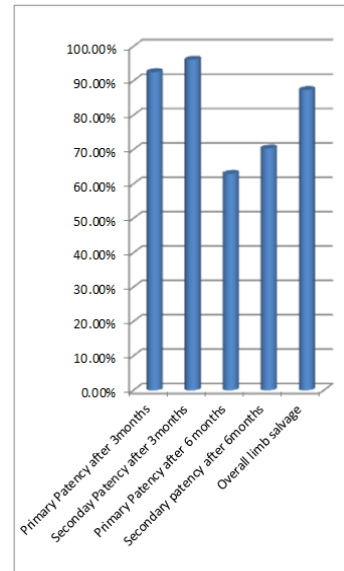


Fig. 2: Outcome (Patency and limb salvage rates)

Baril et al. reported procedure related complications in five patients (6.3%), mortality in 18 patients (24.3%), and no major amputation required during the follow-up period¹⁵. The short conventional balloons caused thrombosis when successive dilations are performed in a long segment lesion and had bad results which may give bad reputation of subintimal angioplasty in the past. Because of that most authors now use over the wire (OTW) long balloons to minimize the number of inflations. We also used OTW configuration as it offers better pushability, control, reduces number of inflations and minimizes complications.

Most institutions have routinely placed a stent across the re-canalized segment in an attempt to maintain patency and minimize the risk of stenosis or occlusion in the re-canalized segment. Others, however, have either used no stents or placed them selectively based on residual stenosis on completion imaging. Lipsitz and associates at Montefiore Medical Center in New York, reporting one of the largest experiences in this field, have treated 39 patients without stent placement¹⁶.

In our study we selectively put stents across the re-canalized segment in nearly all cases. Treiman et al. demonstrated that routinely placing stents across the entire re-canalized segment could contribute to a high rate of late failure¹⁷. Several recent studies have indicated the

superiority of stenting for SFA arterial disease, especially in long occlusive lesions. Laird et al. reported the 12-month results from the RESILIENT randomized trial, which showed that compared with balloon angioplasty alone, stenting is associated with better patency in treatment of moderate-length lesions in the SFA and proximal popliteal artery. They reported that target lesion revascularization was not observed in 87.3% of patients in the stent group and 45.1% of patients in the angioplasty group ($P < 0.0001$). Duplex ultrasound-derived primary patency at 12 months was better for the stent group (81.3% vs. 36.7%, $P < 0.0001$)¹⁸.

A meta-analysis done by Perrio and colleague about the role of superficial femoral artery (SFA) stents in the management of arterial occlusive disease concluded that no statistically significant difference in 1-year primary patency outcome between the patients undergoing PTA and those being treated with stents¹⁹.

This would suggest that the routine use of stents in the femoro-popliteal region cannot be supported as a primary procedure. However, there was a significant degree of heterogeneity among the studies, reflecting the poor quality of data available. Some of the earlier series are now effectively historical owing to the use of obsolete stents. As such, this conclusion may not reflect accurately the state-of-the-art as practiced in advanced centers and should be interpreted with caution. There are also not enough data to suggest which treatment modality in particular lesions would be most amenable to. The next generation of self-expanding stents will no doubt improve on the last, but potentially with increased cost; therefore, proving cost-effectiveness will be vital. In our study, the overall patency rate at 3 months was 85.15%, at 6 months the patency rate was 70.4%. Baril et al. reported cumulative patency of 89% at 3 months and 82% at 6 months¹⁵.

The overall limb salvage in our study was 86.6% 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 collaterals developed are enough for the tissue viability. Veith et al. suggesting comparable patency rates for AK-FPB with vein and e.PTFE grafts²⁰, however; multiple

studies have suggested that there is a significant difference in patency rates between PTFE and vein grafts in this location. Min-yi et al. reported primary rate of 89%, 62%, 52%, and 52% for endovascular intervention of TASC D femoro-popliteal lesion at 1, 2, 3, and 4 years respectively¹³.

Kedora et al., randomized 100 limbs to AK-FPB using PTFE graft vs. covered stent (mean covered SFA length, 25.6 ± 15 cm), and reported an identical 12-month primary patency rate of 74% and secondary patency of 84% in both groups²¹.

That means that endovascular intervention for TASC D femoro-popliteal lesions has almost similar patency rates (short and midterm results) especially when compared to bypass with synthetic PTFE graft; yet the long term results for five years is much better in the arm of bypass surgery.

It looks that patient who is at high risk for surgery, and those with lack of vein conduit should be offered endovascular intervention as a first line of treatment. However, it is to be noted that our follow up period was relatively short compared to other studies. The follow up period in the study of Baril et al., was 2 years¹⁵ and at the study of Min-yi et al., was 4 years¹³. We couldn't assess the difference in outcomes between claudicants and those with critical limb ischemia due to the fact that the vast majority of our patients had critical limb ischemia. Also, we didn't do comparison between routine and selective stenting. Our study was in the arm of angioplasty with selective stenting that makes our endovascular approach is an important bias. We have few number of patients included in this study; only 30 patients compared to 74 patient with 79 TASC D limbs in the study of Baril et al.¹⁵.

Although this study is prospective, it does not scrutinize all the variables that may have influenced the outcome of the procedure (e.g., calcification and run-off vessel number, as analyzed by other authors). Many studies have included the increase in the ABI as a parameter of improvement. However this was not possible in our study due to the fact that 86.7% of the patients were diabetics with a false high ABI. In our study we just used the simplest endovascular tools. Evolving endovascular strategies embrace new technologies in an attempt to improve the safety

and efficacy of revascularization procedures for lower extremity arterial occlusive disease. Drug-eluting stents and drug coated balloons, and the use of stent grafts are currently being evaluated in the primary treatment of femoro-popliteal segment disease for selected patients. Moreover, this study was not controlled and randomized and our first approach to endovascular therapy for such SFA lesions is probably an important bias as well.

CONCLUSION

TASC D lesions can be treated using the simple endovascular means with acceptable results concerning limb salvage due to its ability to significantly improve distal extremity perfusion pressure with high technical success rates and minimal morbidity and mortality.

REFERENCES

1. Taneja M, Tay KH, Dewan A, Sebastian MG, et al, 2010. Bare nitinol stent enabled recanalization of long-segment, chronic total occlusion of superficial femoral and adjacent proximal popliteal artery in diabetic patients presenting with critical limb ischemia. *Cardiovasc Revasc Med*.
2. Zeller T, 2007. Current state of endovascular treatment of femoro- popliteal artery disease.
3. Makato Sumi and Takao Ohki: Technique: Endovascular Therapeutic; Rutherford's Vascular Surgery, seventh edition, 2010; Chapter 85, Pages 1277-1294.
4. Conte MS, Bandyk DF, Clowes AW, et al; PREVENT III Investigators. Results of PREVENT III: a multicenter, randomized trial of edifoligide for the prevention of vein graft failure in lower extremity bypass surgery. *J Vasc Surg*. 2006;43:742-751.
5. Massimo Lenti, Enrico Cieri, Paola De Rango et al.: Endovascular treatment of long lesions of the superficial femoral artery: Results from a multicenter registry of a spiral, covered polytetrafluoroethylene stent. *J Vasc Surg*, 2007; 45:32-9.
6. Setacci C, Chisci E, de Donato G, Setacci F, Iacoponi F, Galzerano G. Subintimal angioplasty with the aid of a re-entry device for TASC C and D lesions of the SFA. *Eur J Vasc Endovasc Surg* 2009;38:76-87
7. Adam DJ, Beard JD, Cleveland T, Bell J, Bradbury AW, Forbes JF, et al. BASIL trial participants. Bypass versus angioplasty in severe ischemia of the leg (BASIL): multicentre randomized controlled trial. *Lancet* 2005; 366:1925-34.
8. Hameed Aamir, Gluege Michelle, and Reinhart Richard: Subintimal Angioplasty: To Stent or Not to Stent? *J INVASIVE CARDIOL* 2009; 21: 54-e156
9. Rutherford RB, Becker GJ. Standards for evaluating and reporting the results of surgical and percutaneous therapy for peripheral arterial disease. *J Vasc Inter Radiol* 1999; 2:169-74.
10. Fowkes FGR, Hously E, Cawood EH, Macintyre CC, Ruckley CV, Prescott RJ. Edinburgh Artery Study: prevalence of asymptomatic and symptomatic peripheral arterial disease in the general population. *Int JEpidemiol*.1991;20:384-392.
11. Norgren L, Hiatt WR, Dormandy JA et al.: TASC II Working Group. Inter-society consensus for the management of peripheral arterial disease (TASC II). *Eur J Vasc Endovasc Surg*, 2007; 33(suppl 1):S1-75.
12. Murabito JM, Evans JC, Nieto K, Larson MG, Levy D, Wilson PW. Prevalence and clinical correlates of peripheral arterial disease in the Framingham Offspring Study. *Am Heart J*. 2002;143:961-5.
13. Min-yi YIN, Mi-erJIANG, Xin-tian HUANG, Min LU, Xin-wu LU, Ying HUANG and Wei-min LI; Endovascular interventions for TransAtlantic InterSociety Consensus II C and D femoropopliteal lesions. *Chinese Medical Journal* 2013;126 (3).
14. Rabellino M, Zander T, Baldi S, Garcia Nielsen L, Aragon-Sanchez FJ, Zerolo I, et al. Clinical follow-up in endovascular treatment for TASC C-D lesions in femoropopliteal segment. *Catheter Cardiovasc Interv* 2009; 73:701-5.
15. Baril DT, Chaer RA, Rhee RY, Makaroun Ms, Marone Lk.; Endovascular interventions for TASC II D femoropopliteal lesions. *J Vasc Surg*. 2010; 51:406-412.
16. Lipsitz E.C., Okhi T., Veith F.J. et al. Does subintimal angioplasty have a role in the treatment of severe lower extremity ischemia? *J Vasc Surg*, 2003, 37: 386-91.

17. Treiman G.S, Treiman R., and Whiting J. Results of percutaneous subintimal angioplasty using routine stenting. *J Vasc Surg*, Volume 43, 2006, pp. 513–519.
 18. Laird JR, Biamino G, McNamara T, et al.: Cryoplasty for the treatment of femoropopliteal arterial disease: extended follow-up results. *J Endovasc Ther* 2006; 13 Suppl 2:II52–9.
 19. Perrio S., Holt P J.E, Patterson BO, Hinchliffe RJ, Loftus IM, and Thompson MM. Role of Superficial Femoral Artery Stents in the Management of Arterial Occlusive Disease: Review of Current Evidence *Vascular* April 1, 2010 vol. 18 no. 282-92.
 20. Veith FJ, Gupta SK, Ascher, White-Flores S, Samson SH, Scher LA, et al. Six-year, prospective multicenter randomized comparison of autologous saphenous vein and expanded polytetrafluoroethylene grafts in infrainguinal arterial reconstructions. *J Vasc Surg* 1986; 3:104-14.
 21. Kedora J, Hohmann S, Garrett W, Munschaur C, Theune B, Gable D. Randomized comparison of percutaneous Viabahn stent grafts vs prosthetic femoral-popliteal bypass in the treatment of superficial femoral artery occlusive disease. *J Vac Surg* 2007; 45:10-6.
-