Endovascular treatment of TASC D lesions in the femoropopliteal arterial disease; (Feasibility and midterm results)

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Abstract

Introduction: The aim of this study: is to evaluate the feasibility and clinical outcome for three months of endovascular treatment of TASC D femoropopliteal atherosclerotic occlusive disease in patient who were presenting with life style limiting claudication and in patients with critical limb ischemia. **Methods:** This was a prospective non randomized cohort study of patients with life style limiting claudication and patients with critical limb ischemia due to TASC D atherosclerotic femoropopliteal occlusive disease in patient with multiple comorbidities. **Results:** 30 patients were included in this study: 22patients were male, 8 patients were females. The primary and secondary patency rates at three and six months was 92.6%, 63% and 96.2%, 70.4% respectively. The limb salvage rate was 87.5%.**Conclusion:** The results made the first endovascular approach as a good alternative approach to bypass surgery in patients who are considered at high risk for surgery or in patients with lack of vein conduit. Closed surveillance and repeated intervention are important to maintain the patency of treated segment.

Key words: Critical limb ischemia (CLI), intermittent claudication(IC), Transatlantic society consensus document (TASC)

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 age[(1)].

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 arteries[(2)]

For decades, surgical revascularization has been the traditional treatment for a variety of the infrainguinal occlusive lesions[(3)]. Limitations of open bypass surgery include the need for general anesthesia, longer length of hospital stay, lack of vein conduit, and greater morbidity, particularly in patients presenting with critical limb ischemia[(4)]. In recent years, percutaneous 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 consent, representing a less invasive treatment option. Technical success rates range from 80

to 95% has progressively improved, due to the introduction of specifically designed guide wires and low-profile balloon catheters[5].

The advantages of a percutaneous interventional procedure over bypass surgery are: avoidance of the complications of general anaesthesia, 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 more readily repeated than surgery, with the possibility of offering future surgical intervention if needed[6].

Patients and Methods:

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 of 1/9/2013 to 31/11/2014. The procedure, possible complications, benefits, risks and other alternative interventions were all explained to the patients and an informed consent was obtained.

Inclusion criteria:

We have chosen All patients with chronic ischemia (incapacitating claudication), or critical limb ischemia (Rest pain, tissue loss, and gangrene) i.e. {≥ Rutherford stage III or Fontaine stage IIb} due to TASC- D Atherosclerotic femoropopliteal occlusive disease i.e. (chronic total occlusion of CFA or SFA > 20 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 or a leg ulcer prohibiting distal graft implantation), or patient refused surgery. Any proposed interventions should not endanger the chances for later surgical bypass or reconstruction in case it failed.

Exclusion criteria:

1)- Severe renal impairment.
2)- Lifestyle-non limiting claudication.
3)- Patients for whom antiplatelet therapy, anticoagulants, or thrombolytic drugs are contraindicated
4)- Patients suffering from non-atherosclerotic occlusive disease e.g. arteritis & entrapment syndrome.

For each patient detailed history taking and clinical examination were performed including: Age and gender, Major risk factors for atherosclerosis including; Diabetes Mellitus, smoking, hypertension and ischemic heart disease were recorded.

Routine laboratory tests results were performed including; the complete blood picture, kidney and liver function tests, coagulation profile, blood glucose level and the lipid profile.

Duplex scans for those patients were revised for:

- Anatomical site of the lesion and its length.
- Run-off status distal to the affected segment.

All patients were treated by a vascular surgeon in angiosuite. Lesions were defined by angiography according to the TASC II classification. Run-off vessels were defined as the number of patent crural vessels after the procedure in continuation with the treated femoropopliteal segment. Demographic, clinical and intra-operative variables were entered into a specific database by the operating team. Data were collected in a computerized database and was analyzed prospectively

Technique:
The patients lie in the supine position and a local anesthetic is given, except the transpopliteal access where the patient lies on prone or lateral decubitus position.

A)-Arterial access:
1)- Antegrade, ipsilateral common femoral artery puncture is preferred unless the lesion is very close (less than 1 cm) to the SFA origin.
2)- Contralateral femoral puncture and perform a cross over technique.
3)- 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 choice out of the above options will usually depend on the anatomy and operator preference.The standard arterial puncture needle is Single-wall puncture Seldinger needle which is used for most procedures.

B)- Angiography

C)- Crossing the Lesion:
The standard tools for recanalization of occlusions consist of a 0.035 hydrophilic guidewire and an angled-tip catheter, (e.g. 4F Berenstein), Once the lesion has been crossed, the catheter should be advanced beyond the lesion, the wire removed and contrast injected to ensure that the catheter is within the lumen.

D)- Deploying the Balloon/Stent :
Angioplasty was done with semi complaint balloon. Angioplasty was considered successful if there is rapid forward flow through the treated segment with no residual stenosis greater than 30% or flow limiting dissection

If there is residual stenosis or flow limiting dissection, the balloon catheter was re-inserted and prolonged inflation was maintained. If angiographic results were suboptimal, stent was inserted. A self-expanding stent should be used. This is because balloon-mounted stents are subjected to external pressure and will not re-expand if they are compressed. The stent should be oversized by 1 mm relative to the diameter of the SFA. The stent should be long enough to cover the lesion with 5–10 mm coverage of the normal artery on either side of the lesion.

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

Primary outcome parameters:
1)- Technical success proved by completion angiogram.
2)- Distal pulse retrieval.

Secondary outcome parameters:
1)- Limb Salvage.
2)- Disappearance of the rest pain.
3)- Healing of the wounds.
4)- Improvement of the claudication distance

Clinical follow-up consisted of pulse examination and evaluation of the ulcer or amputation site healing or resolution of infection.Duplex ultrasound was performed at within 48h, 30 days, and at 3months.Clinical outcomes, primary patency, secondary patency and complications following SA were reported according to the 'Recommended standards for reports' by (Rutherford et al., 1997). Technical success was defined as continuous arterial patency to the popliteal artery without any obvious flow-limiting lesions (absence of a stenosis >50%). Clinical success was defined as healing of ulcer or minor amputation site or resolution of rest pain.

Results
The patient's age ranged from 49 and 81 years with a mean age of 64.3±7.4 years.

Table (1): Patient demographic 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	21	70%
Smokers	13	44.8%
IHD	10	33.3%
Stroke	2	6.7%
ESRD	1	3.3%

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).14 patients (47, 3%) were investigated with arterial duplex scan while 16 patients (52.7%) were investigated with MSCT.

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%).

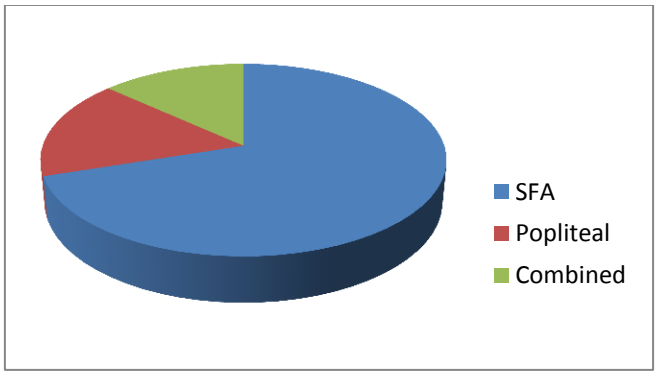

Fig (1): Different sites for femoropopliteal occlusion

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 contralateral (crossover) approach was used in 20 cases (66.7%).

NB: 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 subinti-

mally (66.7%), In 7 cases; the lesion was crossed intraluminally (23.3%); while in three cases (10%), there was a failure to cross the lesion.

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Angioplasty was done in all cases with conventional plain balloons Selective stenting was done in 17 cases only (63%). The stent diameters ranged from 4 to 6 mm with mean stent diameter (5.9±0.5 mm. The stent length ranged from 60 to 150 mm with mean stent length (102±28 mm). Self-expandable nitinol stents were the only stents used for selective stenting (100%).

Additional sites for angioplasty and stenting were done in 9 cases; Tibial angioplasty for the Infrapopliteal tibial vessels in 8 cases (26.7%), Primary CIA stenting in one case (3.7%). Auxiliary procedures were done in 9 patients (33.3%); debridement was done in 4 patients (14.8%) while transmetatarsal amputation (TMA) was done for toes gangrene in 5 patients (18.5%).

No major complications in the form of acute thrombosis, distal embolization, retroperitoneal bleeding or major amputation. 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 access site thrombosis (sheath was removed and cleared and any residuals were aspirated by 6F catheter.

Immediate technical success was achieved in 27 cases (90%).Technical failure to cross the lesion occurred in three cases only (10%)
After excluding the three cases in which we failed to cross the lesion)
At 3 months: 25cases (92.6%) remainned patent while 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 reoccluded and then converted to open bypass surgery. The target vessel was the anterior tibial artery (single runoff) which was not altered by the reapeated endovascular intervention, the other case (3.7%): 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 motality (3.7%) unrelated to our endovascular procedure. **At 6 months;** 25 cases completed follow up.

Table (2): Patency rates at 3 and 6 months

Follow up	Primary patency	Secondary patency
3months	92.6%	96.2%
6months	63%	70.4%

The overall limb salvage rate in our study was 87.5%.

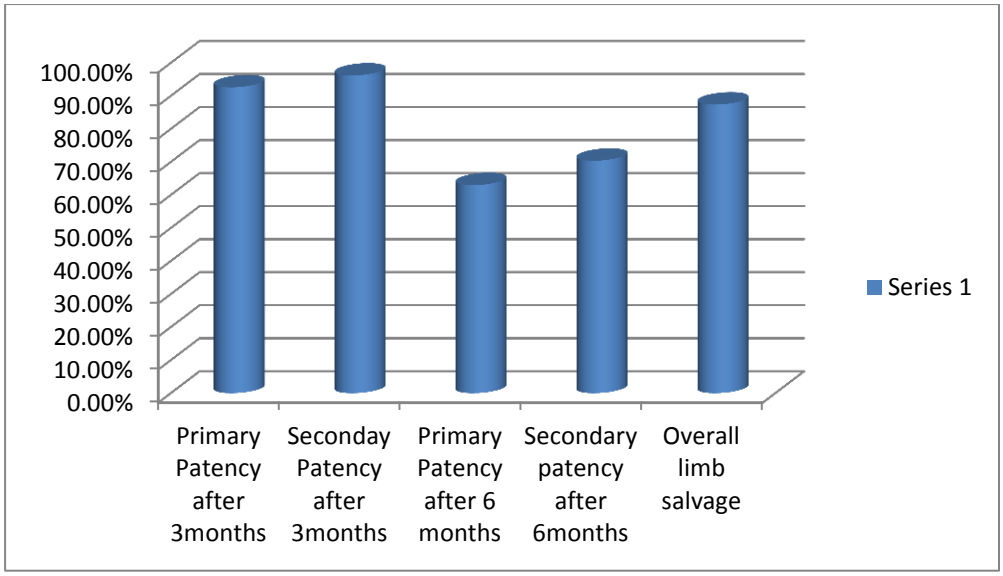

Fig. (2): Outcome (Patency and limb salvage rates)

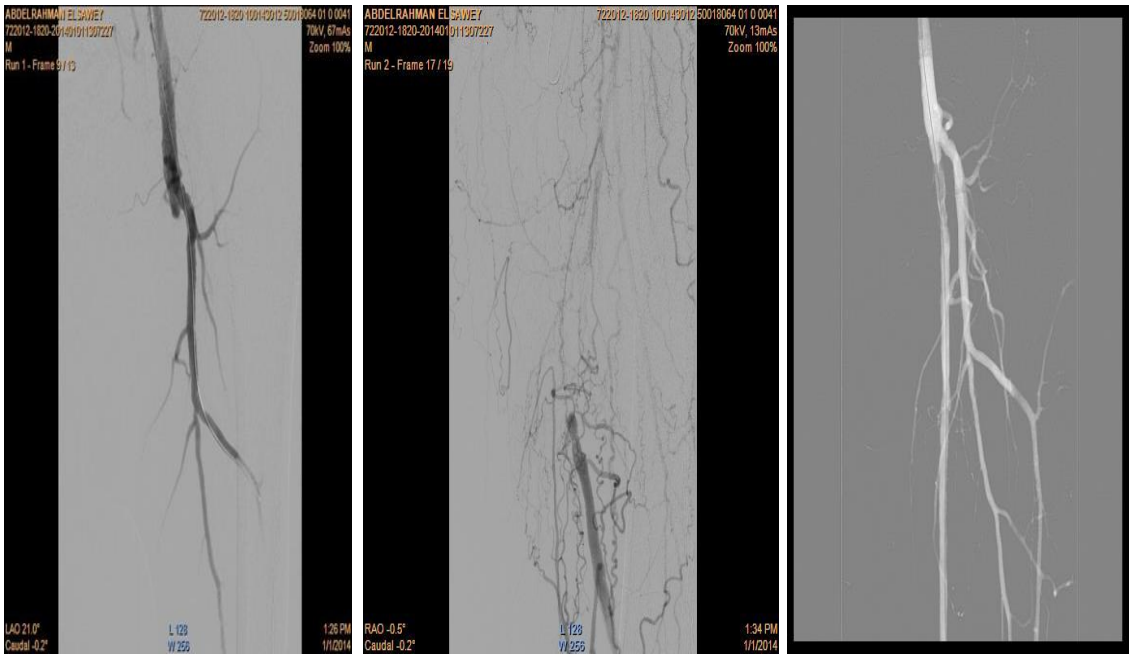

Fig. (3): SFA occlusion and result after SFA angioplasty

Discussion

Current TransAtlantic InterSociety Consensus Document on Management of Peripheral Arterial Disease (TASC II) recommendations advocates tradetional surgical therapy for the treatment of more complex TASC D lesions[7].

Patients with more complex TASC D lesions often present with CLI and suffer from significant comorbid medical conditions placing them at high risk for traditional open surgical bypass. Advances in endovascular techniques have significantly contributed to overcoming these technical limitations, making it possible to treat even the most complex occlusive lesion with minimally invasive techniques[8].

In our study we discuss the role of simple endovascular techniques in

treating TASC D femoropopliteal artery atherosclerotic occlusive diseases.

Indication of intervention in our study was life style limiting claudication in 6 Patients (20%); and critical limb ischemia in 24 patients (80%).

The study done by Baril et al, showed also predominance of patient presented with CLI about 70.9% compared to 29.1% of patients suffering from life style limiting claudication[9].

In our study the majority of cases were male (73.3%) with mean age of 63 years old. In Baril et al., study over 79 TASC D limbs in 74 patients; revealed that the average of male gender was 53% and the mean age of all patients included in the study was 76 years old[9] .

So, the percent of male gender in our study is higher in comparison to other studies on patients with symptomatic chronic occlusive lower limb ischemia. On the other hand, we had lower mean age. This could be explained by the fact that we are a developing country with low health care standards in comparison to the developed countries and that leads to low life expectancy in the general population.

Regarding risk factors, in our study; 13 patients were smokers (44.8%), hypertension was present in 21 patients (70%), and diabetes mellitus in 26 patients (88.7%).

In Baril et al., the average of the percentages were 52% for smoking, 82% for hypertension, and 38% for diabetes mellitus.

In comparison to Baril et al, we had more diabetic and this may be related to the fact that 70.9% of the patient group in Baril et al study had critical limb ischemia and we had 80% in our patient group suffering from critical limb ischemia. More over the incidence of diabetes is very high in our country.

In our study, retrograde access was used in two cases due to failure of antegrade recanalization. Guidewire passed subintimally in 20 patients (66.7%) while in only 10 patients (23.3%) the guidewire passed transluminally. 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 femoropopliteal occlusive disease in 95 limbs without re-entery devices[10]. Rabellino et al reviewed 234 limbs, 52% of which were TASC D lesions and reported initial technical success of 97%[11].

In our study 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 our study, one case of mortality unrelated to the procedure during the follow up period. Four patients (13.3%) in our study developed procedure related complications inform of groin hematoma, vessel perforation, and access thrombosis.

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 period in their study.

In our study we selectively put stents across the recanalized segment in nearly all cases. Treiman et al, demonstrated that routinely placing stents across the entire recanalized segment could contribute to a high rate of late failure[12].

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 stents. This would suggest that the routine use of stents in the femoro-popliteal region cannot be supported as a primary procedure[13].

In our study, the overall patency rate at 3 months was 96.2% and at 6 months the patency rate was 70.4%. Baril et al, reported cumulative patency of 89% at 3 months and 82% at 6 months.
The overall limb salvage in our study was 87.5 % 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.

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 groups[14].

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.

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 years and at the study of Min-yi et al was 4 years.

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.,.

In our study we just used the simplest endovascular tools. Evolving endovascular strategies like drug-eluting stents and drug coated balloons, and the use of stent grafts are currently being evaluated in the primary treatment of femoropopliteal 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:

Endovascular intervention for TASC D atherosclerotic femoropopliteal occlusive diseases is feasible and can be applied as first approach with comparable midterm results.

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