

*Research Article***Outcome of angioplasty and selective stenting of TASC D femoro-popliteal lesions**

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Abstract

Introduction: The aim of this study: is to evaluate the results of angioplasty and selective stenting approach for endovascular treatment of TASC D femoropopliteal lesions. **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 six months were 63%, 70.4% respectively. The limb salvage rate was 87.5%. **Conclusion:** The results made angioplasty and selective stenting as a feasible with good clinical outcomes compared to bypass surgery for treatment of complex femoropopliteal lesions.

Key words: Critical limb ischemia (CLI), Intermittent claudication(IC), Transatlantic society consensus document (TASC), Best medical therapy (BMT)

Introduction:

Peripheral artery disease (PAD) is a common circulatory problem, which refers to the obstruction of blood flow in the arteries exclusive of the coronary and cerebral vessels. Patients with PAD may suffer from claudication, ischemic rest pain, ischemic ulcerations and limb loss which consequently results in a poor quality of life and a high rate of depression.⁽¹⁾

Treatment of PAD comprises conservative management for symptoms of claudication, such as risk factor modification, exercise therapy, antithrombotic therapy, and catheter-based or surgical revascularization for patients with critical limb ischemia (CLI).⁽²⁾

Endovascular treatment is an attractive alternative to open surgical procedures

for PAD due to the less procedural risk resulted by it.⁽³⁾

Several studies showed that routine stenting may results in equivalent long term outcomes compared to angioplasty and selective stenting; yet it can even contribute to high rates of late failure.⁽⁴⁾

The aim of this study was to assess the clinical outcome of angioplasty and selective stenting of TASC- D lesions in patients suffering of critical limb ischemia (CLI) and lifestyle-limiting claudication i.e. (Rutherford category III or more).

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.

Inclusion criteria:

We have chosen All patients with chronic ischemia (incapacitating claudication) that failed to respond to BMT for six months, 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 femoropopliteal occlusive disease i.e. 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 patient refused surgery.

Exclusion criteria:

- 1)- Lifestyle-non limiting claudication.
- 4)- Patients suffering from non-atherosclerotic occlusive disease e.g. arteritis & entrapment syndrome.

Patient demographics including: age and gender, and major risk factors for atherosclerosis including; Diabetes Mellitus, smoking, hypertension and ischemic heart disease were recorded.

Duplex scans for those patients were revised to identify the anatomical site of lesion, its length and the runoff state.

Data were collected in a computerized database and was analyzed prospectively.



Fig (1): patient with critical limb ischemia (Gangrenous toes)

Technique:

- The patients lie in the supine position except the transpopliteal access where the patient lies on prone or lateral decubitus position.
- The procedure started with ipsilateral antegrade femoral access if the lesion is distally, contralateral femoral access if the lesion is very close (less than 1 cm) to the SFA origin, and retrograde access

in case of flush SFA occlusion or failed antegrade femoral recanalization.

- The lesion was crossed by slanted tools 0.035 hydrophilic guidewire and an angled-tip catheter, (e.g. 4F Berenstein)
- Angioplasty was done with semi compliant 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. The stent should be oversized by 1 mm relative to the diameter of the SFA.

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

Primary outcome measures is technical success while the Secondary outcome measures are amputation free survival, improvement of at least one category in the Rutherford classification (Resolution of rest pain, improvement on the claudication distance, and ulcer healing)

Follow-up done clinically and by duplex ultrasound within 48h, 30 days, and at 6 month.

Data were statistically described in terms of mean standard deviation (SD), median and range, or frequencies (number of cases) and percentages when appropriate .

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 peri-procedural and post-procedural complications were evaluated and documented.

Results:

The patient's age ranged from 49 and 81 years with a mean age of 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).

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.

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. .

In 20 cases, the lesion was crossed subintimally (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.

Angioplasty was done in all cases with plain old balloons Selective stenting was done in 17 cases only (63%). The stent diameters ranged from 4 to 6 mm. The stent length ranged from 60 to 150 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 procedure related complications. 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%)

One case of mortality (3.7%) unrelated to our endovascular procedure at 4 month.

Conversion to bypass surgery done in one case (3.7%).

At 6 months; 25 cases completed follow up.

The primary and secondary patency rates were 63%, 70.4% respectively at 6 months respectively. The overall limb salvage rate in our study was 87.5%.

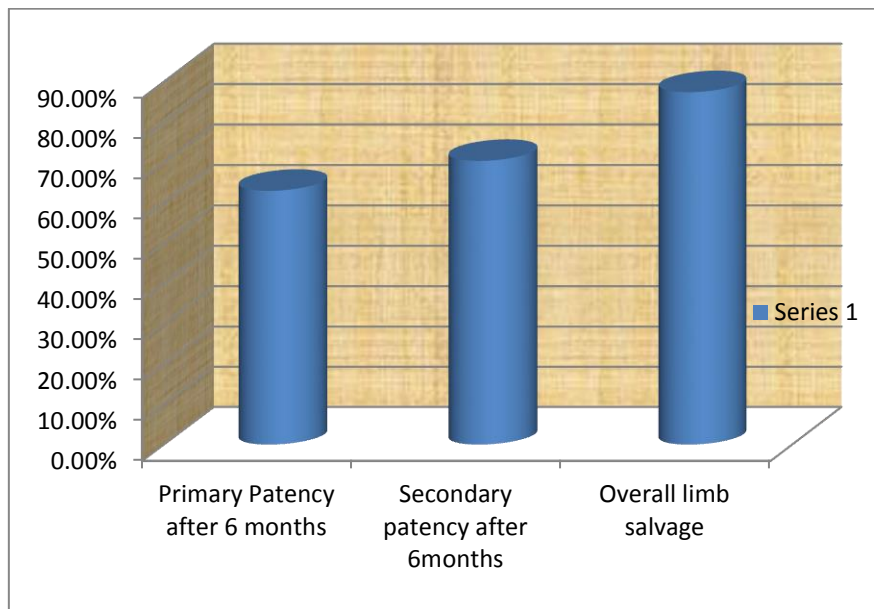


Fig. (2): Outcomes (Patency and limb salvage rates)

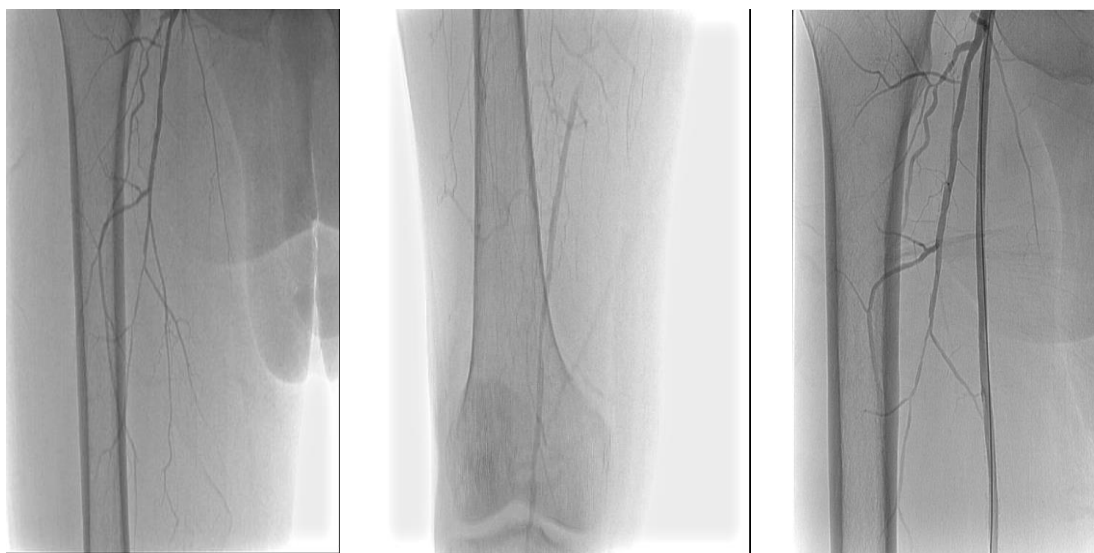


Fig. (3): SFA occlusion and result after angioplasty.

Discussion:

TASC-II recommendations advocate traditional surgical therapy for the treatment of complex lesions of femoropopliteal segments.⁽³⁾ However, advances in endovascular techniques including the utilization of the subintimal technique and advances in technology, have significantly enabled the treatment of even the most complex occlusive lesion with minimally invasive techniques and yielded favorable outcomes.⁽⁵⁾

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

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%.

Yin-My et al., reported a technical success rate about 91% in endovascular recanalization of TASC D femoropopliteal occlusive disease in 95 limbs

without re-entry devices.⁽⁵⁾ Rabellino et al., reviewed 234 limbs, 52% of which were TASC D lesions and reported initial technical success of 97%⁽⁶⁾.

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⁽⁷⁾. Hasaballah et al reported procedure related complications in 8 patients (14%), with no mortality after endovascular treatment of 48 limbs with TASC D femoropopliteal occlusive diseases⁽⁸⁾.

The preferential use of primary stenting versus selective stenting during endovascular treatment for longer

lesions (TASC-IIC and D lesions) is still controversial. Surowiec et al., have shown that there was no difference in outcomes (patency or limb salvage) between patients in whom primary stenting was used compared to those in whom selective stenting was used⁽⁹⁾.

In the study of Chalmers et al., the primary end point of 12-month binary restenosis was not significantly reduced by a strategy of primary stenting compared with balloon angioplasty in long SFA lesions⁽¹⁰⁾. This is similar to the findings of the FAST study, but in contrast to the ABSOLUTE and ASTRON studies^(11, 12, and 13).

Hasaballah et al., reported outcome of angioplasty and selective stenting in endovascular treatment of 48 patients with TASC D femoropopliteal lesions. Stent were selectively inserted in 15(26%) patients because of suboptimal angiographic results with primary patency rate at 6 months was 80%⁽⁸⁾.

In our study, balloon angioplasty-enabled recanalization is still the preferred first-line endovascular therapy because of its lower cost. In the present study, 17(63%) patients underwent selective stenting because of a suboptimal angiographic result or a flow-limiting dissection.

In our study, the overall patency rate 6 months was 70.4%. Baril et al, reported cumulative patency of 82% at 6 months⁽⁷⁾. Hasaballah et al., reported primary patency rate of 80.9%⁽⁸⁾. Surowiec et al., reported primary patency rate of 50% (37-70%) at 6 months after primary stenting of TASC D femoropopliteal lesions which quite similar to our results⁽⁹⁾.

The overall limb salvage in our study was 87.5%. Taneja et al. reported that

the overall limb salvage rate at the 1-year follow-up was 81%⁽¹⁴⁾.

We have limitation in this study; 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 have control group. 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 did not do analysis on predictors of worse patency. In other studies; Hasaballah et al., reported that sex, risk factors, number of run off vessels and Rutherford staging did not find any statistically significant effect on the 1-year primary patency rate. Baril et al., in their series, reported that smokers were at a higher risk for restenosis and occlusion

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.

Although we had short term data of follow up; endovascular intervention for TASC D lesions can be performed safely with acceptable patency, limb salvage rates and should be considered first approach for patients at high risk for surgery. Further data are still needed to show the difference in outcomes between primary and selective stenting for TASC D femoropopliteal lesions.

Conclusion:

Our experience showed that endovascular treatment of TASC D femoropopliteal artery occlusion by angioplasty and selective stenting has a high technical success rate with good acceptable medium-term patency and limb salvage rates

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الملخص العربي

نتائج التوسيع بالبالون و الدعامات الانتقائية

لعلاج انسدادات الشريان الفخذي المابضى تاسك (د)

في الفترة الاخيرة حدث تقدم ملحوظ في علاج انسدادات الشريان الفخذي المابضى الطويلة باستخدام البالون و الدعامات الطرفية مما جعله حل جيد و مماثل للمرضى الغير قادرين على تحمل الحل الجراحي الذي يحمل بطبيعته درجة وفاة اعلى مقارنة بالعلاج باستخدام القسطرة الطرفية.

لا زال هناك خلاف بين استخدام الدعامات اوليا في علاج انسدادات الشريان الفخذي المابضى الطويلة او استخدامها انتقائيا في استمرار وجود ضيق اكثر من 30% او وجود انشطار بجدار الشريان بعد اجراء التوسيع بالبالونة الطرفية.

تتضمن هذه الرسالة 30 مريضا تم علاجهم بمستشفيات جامعة القاهرة و مستشفى الساحل التعليمي في الفترة ما بين اغسطس 2013 إلى نوفمبر 2014 بسبب انسداد بالشريان الفخذي طولة على الاقل 20 سم او انسداد بالشريان المابضى طبقا لتاسك (د) نتيجة تصلب الشرايين والذي ادى الى غرغرينا وجروح و قرح غير ملتئمة أو الام اثناء السير.

هدف هذه الدراسة هو الوقوف على مدى كفاءة و أمان تقنية علاج الأنسداد الطويل في الشريان الفخذي والمأبضي بالبالون و الدعامات الانتقائية.

وقد أظهرت دراستنا معدل نجاح تقني وصل إلى 90% من مجموع الحالات في النجاح في عبور الأنسداد باستخدام السلك المرشد.

و خلال سنة شهور كان معدل انفتاح مجرى الاوعية من مجموع عدد الحالات التي نجحنا فيها هو 70.4% وعند الانتهاء من الدراسة تبين ان معدل انقاذ الطرف السفلى و هو 87.5%.

عند المقارنة بباقي الدراسات التي استخدمت الدعامات اوليا في علاج انسدادات الشريان الفخذي المابضى الطويلة لم يتضح وجود فرق في خلال سنة اشهر من اجراء القسطرة الطرفية العلاجية.

ينقص هذه الدراسة التي قمنا بها هو قلة عدد المرضى الذين اجرينا عليهم هذه الدراسة و هم ثلاثون مريضا و مدة الدراسة كانت ستة اشهر و هي اقل مقارنة بالدراسات الاخرى التي امتدت دراسة النتائج الى اربعة سنوات بالاضافة الى عدم القدرة على معرفة اذا كانت هناك بعض العوامل التي تؤثر على نتيجة توسيع الشرايين مثل السن و الجنس و الوضع الاكلينيكي للمريض قبل اجراء القسطرة و عدد الشرايين المفتوحة اسفل الركبة.

بالرغم من ذلك يتضح من خلال هذه النتائج ان علاج الانسدادات الطويلة للشريان الفخذي و المابضى باستخدام القسطرة التداخلية العلاجية هي طريقة ممكنة وفعالة مما يجعلها بديل كفاء للتدخل الجراحي.