

## Role of Angioplasty in Management of TASC-D Femoropopliteal Disease in Patients with Critical Limb Ischemia

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### ABSTRACT

**The aim** of this study was to evaluate the feasibility and durability of endovascular therapy (ET) and its role in limb salvage in patients with TASC D femoropopliteal lesions who presented by critical limb ischemia (CLI). **Background:** traditional treatment of TASC D femoropopliteal lesions in patients presenting with CLI has been used to be risk factor modification and bypass surgery. However, many of these patients have multiple comorbidities making them high risk for surgical intervention. On the other hand, advances in endovascular techniques and equipments, have made ET possible and with tolerable operative trauma. **Patients and Methods:** This is a retrospective case series analysis for all patients presenting with critical limb ischemia and TASC D femoropopliteal lesions in Kasr AlAini teaching hospitals in the period from August 2013 to March 2015, for whom endovascular management was attempted to improve blood flow to the popliteal trifurcation because of high risk of open revascularization ASA American society of anaesthesiologists(ASA) category 3 and 4. **Results:** Fifty patients were treated for TASC D lesions with mean age of 62.9 years and male preponderance of 76%. Seventy two percent of the patients presented with tissue loss and 28% by rest pain. The mean lesion length was 18.8cm. Two cases necessitated the use of re-entry device (Outback, Cordis Corporation, Miami Lakes, Florida, USA). Sixty five percent of patients had their lesions stented. Technical success was achieved in 92% of patients. There was one perioperative mortality and two wire perforations and one arteriovenous fistula (between the superficial femoral artery and vein) that were managed conservatively without further complications or surgical intervention and one retroperitoneal hematoma that was managed conservatively. There were ten (22.2%) major amputations during the follow-up seven of which (15%) in the first three months post-operative the other three were in the next 3 months. Primary patency was 73% (33/45) at 3 months and 55.5 % (25/45) at 6 months, however limb salvage was 84.4% (38/45) at 3 months and was 77.7 % (35/45) at 6 months. **Conclusion:** ET of TASC D femoropopliteal lesions is safe and effective in limb salvage in this moribund set of patients. Restenosis and reocclusion is common in these complex, lengthy lesions, regular follow-up by arterial duplex and ankle brachial index (ABI) is mandatory to early treat any restenosis before occlusions occur

**Key Words:** TASC D, femoropopliteal, critical limb ischemia

### INTRODUCTION

According to TASC II which was published in 2007, [1] TASC D femoropopliteal lesions are best treated with bypass surgery. This recommendation was based on the literature available at that time. There were no comparative trials of endovascular vs surgical revascularization to provide evidence based specific recommendation for one over the other. Due to the marked decrease in morbidity and mortality associated with endovascular therapy (ET) [2], [3], [4], and the higher morbidity of bypass surgery in the form of wound complications, infection and secondary hemorrhage, anesthetic

complications and perioperative mortality related to cardiovascular ischemic events [5], there has been widespread enthusiasm among surgeons and interventional radiologists to extend the ET to include TASC D lesions. Major advances in wire technology, reentry devices, retrograde punctures , low profile balloons, interwoven stents and long nitinol superficial femoral artery (SFA) stents drug coated balloons and stents and covered stents and atherectomy devices, all have made ET for TASC D femoropopliteal lesions possible and with tolerable surgical trauma. Currently, the optimal treatment for patients with TASC D femoropopliteal lesions remains ill defined.

## PATIENTS AND METHODS

This is a retrospective case series study done on fifty patients admitted in Kasr AlAini teaching hospital in the period from August 2013 to March 2015. Patients presenting with critical limb ischemia due to TASC D lesions and high risk for surgery i.e ASA (American society of anaesthesiologists) category 3 and 4 or don't have an available good quality autogenous conduit for bypass were included initially in our study. Patients with renal insufficiency (serum creatinine > 2 mg/dl & creatinine clearance <60 ml/min) or acute ischemia or intermittent claudication were excluded.

Full clinical history, patients' demographics and comorbidities were recorded and patients were clinically examined for proper assessment of their condition. All patients had imaging to ensure there was a sufficient inflow into the infrainguinal circulation, nature and length of lesion and distal runoff. The first line investigation was Doppler ultrasound but some patients with ambiguous duplex study had CT angiography. A loading dose of clopidogrel 300 mg was given the night of the procedure and aspirin 75 mg was started. Diabetic patients on Metformin were converted to another antihyperglycaemic agent 24 hours before and continued for 48 hours after the procedure. All procedures were done in the interventional angiography suite by vascular surgeons and accomplished under local infiltration anesthesia without sedation.

A common femoral access was established. Antegrade access was planned in all infrainguinal lesions except if the lesion was in proximal SFA or if there was an associated lesion in the iliac artery. In such instance, contralateral femoral access with crossover was used. Six Fr sheath was used in all cases. Standard digital subtraction techniques were employed to maximize image quality while minimizing use of contrast agent.

TASC D lesions were defined as chronic total occlusions of the SFA >20 cm and involving the popliteal artery or chronic total occlusions of the popliteal artery and proximal trifurcation vessels. Administration of systemic heparin (80 U/kg) was done before all interventions and 18 U/Kg units every extra hour. All lesions were crossed by subintimal approach with standard angled Terumo guidewire 0.035" (Terumo Tokyo, Japan) and

five Fr Bernstein catheter (Boston Scientific, NY, USA) was used. A popliteal puncture was used in cases of failed reentry followed by rendezvous technique as described by Andrej Schmidt et al in 2012<sup>[6]</sup>, a re-entry device, Outback LTD (Outback, Cordis Corporation, Miami Lakes, Florida, USA) was used only if reentry from the popliteal puncture was not successful. Re-entry was confirmed with contrast injection prior to balloon angioplasty.

Low profile balloon catheter (with a length as close as possible to the length of the lesion to minimize number of inflations and minimize dissections) was inserted over the guidewire; multiple inflations (of 1 minute minimum each) were done from distal to proximal with short semicompliant balloons. Non-compliant balloons were selectively used for resistant lesions (where failure of fully opening the waist). Longer inflation (>3 min) was adopted if dissections occurred or if wire perforations or AV fistula occurred. Stents were used selectively when there was flow limiting dissection or elastic recoil or residual lesion >30%. All stents utilized were nitinol self-expandable stents (E.Luminexx, Bard, Tempe AZ, USA). Whenever multiple stents were utilized, a minimum overlap zone of 5mm was achieved.

Angiographic success of the procedure was defined as satisfactory completion angiogram with no flow limiting dissection nor residual lesion >30% of the proximal healthier artery. Clinical success was defined as restoration of palpable distal pulse, reperfusion warmth, improvement of venous filling time and disappearance of rest pain; if any. In case of contralateral sheath, it was replaced with short straight sheath of the same size at the end of the procedure. The sheath was removed 4 hours after the procedure and the puncture site was controlled by manual compression for an average period of 15 minutes after the sheath was removed.

All patients were kept on daily dose of 150 mg aspirin and 40 mg statin after the procedure. Clopidogrel at a dose of 75 mg/day was added for a period of 3 months whenever a stent(s) were used. In diabetics clopidogrel and acetyl salicylic acid were prescribed for at least 1 year. The complications were recorded. Debridement of foot lesions or minor amputations were done before hospital discharge. Patients were scheduled for follow up at 3 and 6 months in the outpatient

clinic to assess their pulses, healing of the wounds. Duplex ultrasound was integrated component of the follow up.

An independent statistician performed all advanced statistical analyses. The endpoints of the study were the Primary patency and limb salvage that were calculated using survival curve analysis.

## RESULTS

During the period of the study, 50 patients suffering CLI and TASC D femoropopliteal lesions were treated. Their demographics and risk factors are listed in table 1

**Table 1:** Demographics and risk factors

<i>Males / female</i>	<i>Male: 38 (76%)</i>	<i>female: 12 (24%)</i>
Mean Age	62.6 ± 9.6 years	
Smoking	43 (86%)	
Diabetic	45 (90%)	
Hypertension	37 (74%)	

The presenting symptoms and indications for intervention are listed in table 2.

**Table 2:** Presenting symptoms and indications for intervention

<i>Rest pain (Rutherford IV)</i>	<i>14 (28%)</i>
Minor tissue loss (Rutherford V)	30 (60%)
Major tissue loss (Rutherford VI)	6 (12%)

The mean lesion length was 18.8cm( range 14-22 cm). Post procedure runoff was scored according to the SVS criteria such that a higher score implies worse runoff <sup>[7]</sup>. Nineteen limbs (38%) had runoff score > 10 and 31 (62%) had runoff score <5 .

Contralateral retrograde femoral access was used in 33 patients, whereas, antegrade ipsilateral femoral approach was in 17. Adjunct to the contralateral retrograde femoral access, a retrograde popliteal access was added in four patients.

There were 6 cases of failed reentry , 4 cases underwent successful popliteal punctures and wire crossing was successful while the other 2 cases necessitated the use of re-entry device (Outback, Cordis Corporation, Miami Lakes, Florida, USA). Sixty five percent of patients had their lesions stented.

Technical success was achieved in 92% (46/50) of patients who underwent endovascular management of TASC D lesions. Three cases of failed crossing due to failure of the transpopliteal access and unavailability of reentry device and 1

case of acute intraprocedure thrombosis constituted the 8% technical failure. There was one periprocedure death. This occurred in a 67-year-old female patient with multiple comorbidities (diabetic, hypertensive, previous stroke), seven days following a successful endovascular intervention, by massive cerebrovascular stroke.

Wire perforation occurred in two cases and was successfully managed by balloon dilatation for 3 minutes. Arteriovenous fistula (between the superficial femoral artery and vein) occurred in one patient and closed upon 3 minutes balloon inflation. Neither perforations nor fistula required insertion of covered stent. A retroperitoneal hematoma developed in another case. This was managed conservatively by transfusion of 2 units of packed RBC'S and 2 units of fresh frozen plasma and withholding of anticoagulant administration and close monitoring of vital signs. Follow up CT scan revealed diminution in the size of the hematoma and its complete resolution after two weeks.withholding anticoagulation did not affect the success of the revascularization. Of the 36 patients with tissue loss 26 underwent minor amputations and 10 had debridement only.

Follow up was for 6 months and included all patients except the four patients who failed the technique and one patient who passed away one week after the procedure.

After 3 months follow up, 12 cases had their revascularized segment occluded, seven of which underwent major amputation for unsalvageable limbs and five had viable limbs and recurrent ischemic manifestations (three cases underwent

redo endovascular intervention successfully and the other two cases underwent successful femoropopliteal bypasses with reversed saphenous veins).

After 6 months eight more revascularized segments had been occluded, three underwent major amputation for unsalvageable limbs due to delayed presentation and five had viable limbs and recurrent ischemic manifestations (four cases underwent redo endovascular intervention successfully and the other one case underwent successful femoro-posterior tibial bypass with reversed saphenous veins).

Primary patency was 73% (33/45) at 3 months and 55.5 % (25/45) at 6 months. Limb salvage was 84.4% (38/45) at 3 months and was 77.7 % (35/45) at 6 months

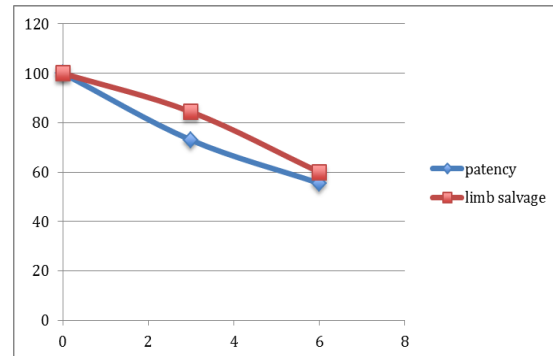


Fig. 1: Kaplan-Meier curve of patency and limb salvage



Fig. 2: A: TASC D long SFA occlusion. B: subintimal wire crossing. C: PTA .D: completion angiography



**Fig. 3:** A: P2 popliteal occlusion. B: post angioplasty



**Fig. 4:** A :acute thrombosis of infrapopliteal vessels in one of the complicated cases. B: another case of wire perforation that was managed successfully with three minutes balloon dilatation

## DISCUSSION

Traditional treatment of TASC D femoropopliteal lesions in patients presenting with critical limb ischemia (CLI) is risk factor modification and bypass surgery.<sup>[1]</sup>

However, many patients with such complex lesions typically have multiple comorbidities including advanced coronary artery disease and cerebrovascular disease, making them high risk for surgical intervention<sup>[5]</sup>

Furthermore, advances in endovascular techniques and equipment, have made ET possible with tolerable surgical trauma. Therefore, treatment strategies for patients with TASC D femoropopliteal lesions has shifted. However, this enthusiasm for endovascular therapy has been mired by significant rates of restenosis and occlusion particularly in these advanced lesions.<sup>[8]</sup>

The aim of this study was to evaluate the feasibility, durability and limb salvage rate of ET in CLI due to TASC D femoropopliteal lesions.

All Our cases presented with CLI. It has been shown that patients with critical limb ischemia have low 5 years survival rate due to multiple comorbidities and that amputation rate within 1 year is very high and so these patients are considered high risk for open surgery with high risk of mortality related to perioperative cardiovascular and/or cerebrovascular events as all our cases were ASA category 3 or 4. In a recent review of data obtained through the National Surgical Quality Improvement Program (NSQIP) on patients undergoing infrainguinal bypass, major complications occurred in 18.7% patients, including a 9.4% rate of wound infections<sup>[5]</sup>. Furthermore, major systemic complications occurred in 5.9% of patients<sup>[5]</sup>.

Claudicants were excluded from our study as the patency after ET for complex TASC D lesion does not last long<sup>[8]</sup>. Therefore, ET for TASC D lesions among claudicants is considered cost ineffective. Patients with renal insufficiency (serum creatinine >2 mg/dl & creatinine clearance <60 ml/min) were excluded from our study.

All lesions were crossed subintimally as described by Bolia<sup>[2]</sup> with standard hydrophilic 0.035", guidewire (Terumo, Tokyo, Japan) supported with 5Fr Bernstein catheter. Spontaneous reentry occurred in 40 cases and 6 case failed reentry, 4 cases had successful retrograde access of the popliteal artery in the prone position and the 2 failed cases of reentry even from the popliteal puncture a reentry catheter was used. This was similar to others as Setacci et who reviewed 145 patients with TASC II C and D lesions that were treated with subintimal angioplasty and selective use of a re-entry device and reported a technical success rate of 83.5% with a 16.5% usage rate of a re-entry device<sup>[8]</sup>.

Zeller et al in 2014 compared drug coated balloons (DCB) vs DES (drug eluting stents) in 228 patients of which 50% had TASC D femoropopliteal disease and used DCB in 131 patients and DES in 97 cases, has shown that restenosis rate in DCB was 29.3% and was 30.4% in DES cohort in 1 year follow up. [9] We have not used DCB or DES and this may contribute to the high early recurrence associated with POBA (26% recurrence after 3 months and 44.4% recurrence after 6 months).

Heparin-bonded covered stents has been shown by Lammer et al in 2013 to be superior to bare metal stents in long femoropopliteal lesions > 20cm.<sup>[10]</sup> We have not used either type of stents and this may also contribute to early in-stent restenosis.

Two cases of wire perforation and one AV fistula, did not need covered stent, and were managed only with balloon dilatation for 3 minutes. One case of retroperitoneal hematoma was managed conservatively. Congruent to what many authors have shown, there was no major complications or mortality related to the procedure among our cases.<sup>[2], [3], [4]</sup>

Although 25% of treated femoropopliteal segments lost patency after 3 months, yet the limb salvage rate was 82%. After 6 months 44.4 % of cases had lost patency however, this did not affect

the limb salvage (77.7%) due to the situational perfusion enhancement concept.

Long-term patency may not be crucial in patients with tissue loss. In such instances, a patency long enough to cover the time required for a given wound to heal is more imperative.

Seven cases were salvaged with redo endovascular therapy of the previously treated lesion (target lesion revascularization), this also emphasizes that ET can be repeated easily when necessary. Close surveillance using frequent noninvasive testing including both arterial duplex and ABI measurement in combination with clinical assessment is helpful in maintaining patency of these lesions. Because management of restenosis is much easier and less likely to be limb threatening than occlusions, this has also been shown by many authors as Baril et al in 2008<sup>[3]</sup> and Tze et al in 2015<sup>[11]</sup>

This study has a number of limitations, the most important of which is its retrospective nature. Patients who did not undergo successful primary interventions were excluded from the study analysis. The follow-up period is limited, and longer-term follow-up will be necessary to determine the durability of these interventions.

## CONCLUSION

ET of TASC D femoropopliteal lesions is safe and effective in limb salvage in this often moribund set of patients. Restenosis and reocclusion is common in these complex, lengthy lesions. Regular follow-up by arterial duplex and ABI is mandatory to treat any restenosis early before occlusions occur, as occlusions are not always benign and may present with acute ischemia with unsalvageable limbs. Further studies to evaluate the role of DCB and DES on the long-term results of ET in TASC D femoropopliteal lesions are required.

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