The Effect of Stenting on Patency and Limb Salvage in Cases of TASC D Femoropopliteal Disease in Critical Limb Ischemia

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Abstract

The aim was to evaluate the effect of stenting on patency and limb salvage in cases of TASC D femoropopliteal disease in critical limb ischemia patients.

This prospective study included 51 patients presented to the Vascular Surgery Department in Kasr Al-Aini and New Kasr Al-Aini Teaching Hospitals with femoropopliteal disease for whom endovascular revascularization was done, between January 2013 and January 2014.

Patients and Methods: Angiography was performed under systemic heparin administration (5000 IU) through the sheath. SIA, trying to achieve re-entry. If reentry was not successful, a transpopliteal approach is used and if still reentry was not successful a reentry device is used.

Once the lesion is crossed, the guiding catheter is exchanged for a 5- or 6-mm-diameter 5-French balloon catheter. Refractory stenoses may require placement of Self-Expandable Peripheral Nitinol Stents in the affected region. During the procedure, a systemic 1000 IU Heparin was given per hour.

Clinical follow-up and duplex examination at 1 month, 6 months, and 12 months after the procedure were done. It included follow-up of pulse examination, evaluation of the claudication pain and rest pain, evaluation of ulcer or amputation site healing or resolution of infection.

Results: Technical success was achieved in 90.2% of patients who underwent endovascular of TASC D lesions. Patients who underwent failed attempts at endovascular intervention for a TASC D lesion were not included in the subsequent outcomes analysis. Seventeen limbs (31.3%) required an ante grade approach to facilitate successful recanalization.

Follow-up length was 12 months excluding five patients who were technically failed one patient who expired in the hospital one week post operative. Another one died during follow-up.

There were 26.5% major amputations during the follow-up 14.3% in the first three months post operative. 18.4% above knee amputation 4.1% below knee amputation 4.1%

30 limbs (59%) experienced restenosis (21 limbs) or occlusions (9 limbs). By survival curve analysis, primary patency was 75% at 6 months and 45.5% at 12 months. 20 limbs (40%) underwent reintervention during the follow-up time. All patients had duplex findings consistent with restenosis or occlusion prior to reintervention.

The mean time to reintervention was 6 months. 5 limbs (10%) required multiple reinterventions including 2 limbs which underwent 3 reinterventions, 3 limbs which underwent 2 reinterventions, secondary patency rates by survival curve analysis were 59.1% at 12 months. Of the 28 limbs which suffered occlusion, 7 limbs underwent successful endovascular salvage, 2 were observed following complete wound healing in the affected limb, and 3 went on to surgical bypass. Among the patients who underwent surgical bypass, there were 2 femoral-to-below-knee popliteal artery bypasses performed for early occlusions (at 6 months), endovascular interventions. Secondary patency rates by survival curve analysis were 59.1% at 12 months. There was no significant difference in primary, assisted primary, or secondary patency between patients who underwent their initial intervention for CLI (p=.84, p=.73, and p=.42, respectively).

Key Words: Angioplasty – Femoropopliteal – TASC D – Stent – Critical ischemia.

Introduction

PERIPHERAL Arterial Disease (PAD) is a common manifestation of atherosclerosis. The prevalence of PAD continues to increase, with recent data suggesting that almost 30% of at-risk populations have PAD. The alternatives for treatment of PAD are rapidly expanding. These new options include surgical techniques, and endovascular therapy. Endovascular intervention has been proposed as a more safe and effective alternative to lower extremity arterial bypass surgery for treating critical limb ischemia and claudication. The less invasive nature of the endovascular surgery and the reports of excellent patency in selected cases have resulted in increasing the use of this modality as a primary treatment of lower extremity arterial stenosis and occlusions. TASC D femoropopliteal
The Effect of Stenting on Patency & Limb Salvage in Cases of TASC D disease was long considered as contraindication to endovascular therapy but with advances in techniques and equipments, decreased morbidity and mortality associated with endovascular therapy, there was increased enthusiasm in extending endovascular therapy to TASC D lesions. The role of stents in long occlusions of the femoropopliteal segment has been subject of debate due to increased fracture rates and suspicious durability. In this study we will evaluate the short and long term patency and limb salvage effects associated with stenting of long femoropopliteal occlusions.

Patients and Methods

This prospective study included 51 patients presented to the Vascular Surgery Department in Kasr Al-Aini and New Kasr Al-Aini Teaching Hospitals with femoropopliteal disease for whom endovascular revascularization was done, between January 2013 and January 2014.

The procedure, possible complications, benefits, risks and other alternative interventions were all explained to the patients and an informed consent was obtained.

The aim was to evaluate the effect of stenting on patency and limb salvage in cases of TASC D femoropopliteal disease in critical limb ischemia patients.

Clinical evaluation was carried out for all patients including detailed history taking and examination. Major risk factors for atherosclerosis including; diabetes mellitus, smoking, hypertension, hyperlipidaemia and ischemic heart disease were recorded.

Routine laboratory tests were done. Duplex scanning was done to all patients before intervention with proper comment on the site and length of the lesion and the distal run off vessels.

Patients with critical limb ischemia and TASC D femoropopliteal disease were included in the study. Patients with acute limb ischemia. Or aortic lesion and AVF were excluded from the study.

Patients were admitted one day before or on the day of the procedure, a loading dose of clopidogrel 300mg was given the night of the procedure, local anaesthetic is given (xylocaine 2%). Femoral access was either ipsilateral antegrade (in lesions involving the mid to distal femoro-popliteal arteries) or contralateral retrograde (in lesions of the proximal SFA and in obese patients) based on the lesion site in the femoropopliteal segment from the finding of the duplex.

Transpopliteal was used in flush occlusions of SFA if antegrade crossing was not successful.

Angiography was performed under systemic heparin administration (5000IU) through the sheath. SIA, using a 0.035 "hydrophilic wire was done. only a very small stump (5mm or less) of proximal SFA is required to start the dissection plane. Catheters with an angled tip, 4 or 5-French are useful to direct the end of the guidewire towards the vessel wall to break into the subintimal space for SFA lesions.

The guidewire is manipulated to a form a U-shaped loop of ideally 3-5cm in length. The leading edge of the loop is then used to advance the dissection distally. The catheter provides support while it and the guidewire are advanced distally along the length of the occlusion. The guidewire is advanced first, followed by the catheter.

If the guidewire fails to advance further due to resistance, the catheter should then be advanced to provide support to one arm of the loop. This allows the dissection to be continued until the distal end of the occlusion is reached. Once this point has been reached, it is recommended to shorten the loop length to 2-3cm. Further advancement of the guidewire can then result in the guidewire loop reentering the true lumen.

Adjunctive procedures such as a slight twisting or screwing action can help to re-enter the true lumen. Re-entry is marked by a sudden decrease in the resistance to forward pressure on the guidewire, and can be confirmed by advancing the catheter into the distal artery and injecting a small volume of contrast medium. A relatively disease-free vessel distal to the stenosis or occlusion is favorable to achieving re-entry.

Once the lesion is crossed, the guiding catheter is exchanged for a 5-or 6-mm-diameter 5-French balloon catheter. The entire length of the subintimal channel is then dilated, in a distal-to-proximal direction using short (5 -10 seconds) inflations of approximately 10-12 atmospheres. Flow is assessed by the injection of small volumes of contrast medium, and flow impairment can be treated with repeated balloon inflation. Any residual stenosis of greater than 30% is repeatedly balloon dilated, including the use of higher inflation pressures. Refractory stenoses may require placement of self-expandable peripheral nitinol stents in the affected
region. During the procedure, a systemic 1000 IU Heparin was given per hour.

Immediate clinical success was defined as regain of pulse, revascularization warmth, oedema and disappearance of rest pain.

Angiographic success defined as good flow with less than 30% residual stenosis measured at the narrowest point of vascular lumen.

Technical failure: Procedures with failure to gain re-entry or obtain an acceptable flow through the occlusion. The arterial sheath was routinely removed immediately after the procedure and digital compression was held proximal to the skin puncture site for 15-20 minutes. Mobilization was delayed for 12-24 hours. If more than 5000 IU of heparin were given, we delay sheath removal until a PTT normalizes.

Most patients were discharged on the second day following the procedure after receiving instructions on risk factors control and treatment including Aspirin 150mg/day for life, Clopidogrel 75mg/day for at least 3 months and atrovastatin according to the presence or absence of dyslipidemia.

The patients received foot care consisting of wound dressing, minor debridments, limited amputations, infection control, and appropriate footwear before discharge.

Follow-up:

Clinical follow-up and duplex examination at 1 month, 6 months, and 12 months after the procedure were done. It included follow-up of pulse examination, evaluation of the claudication pain and rest pain, evaluation of ulcer or amputation site healing or resolution of infection.

Clinical success was defined as improvement of claudication pain, resolution of rest pain, healing of ulcer or minor amputation (up to transmetatarsal amputation).

Any additional endovascular procedures to maintain or restore patency of the vascular channel were recorded, as well as all open surgical revisions, bypasses, and major amputations performed through the one year follow-up.

Complications were divided into major and minor. Major complications included death, need for emergency surgery, major bleeding or acute thrombotic occlusion. Minor complications included hematoma, treated dissection, dye extravasation or peripheral emboli.

Results

This study included 51 patients who were admitted to the Vascular Surgery Department in Kasr Al-Aini and new Kasr Al-Aini Teaching Hospitals with critical limb ischaemia due to femoropopliteal occlusive disease who fulfilled the selection criteria.

Patient population:

During the time period reviewed, a total 51 patients were treated with TASC D lesions. All of these limbs were Rutherford classification 4/5, that were treated for CLI 36 were for rest pain and 15 were for tissue loss.

The mean age was 62.6±9.6 years. A male predominance (76%) was noted, and the typical comorbid features associated with PAD were identified 88% were diabetics 73% hypertensive 84% smokers. Mean lesion length was 188.6 mm.

The ipsilateral femoral approach was used in 17 patients thirty limbs contralateral retrograde four limbs ipsilateral retrograde trans popliteal one limb bilateral femoral access, the curved tipped hydrophilic 0.035" guide wire (Terumo, Japan) crossed the lesion via subintimal route except 3 cases transluminal route.

Failure of re-entry to the true lumen had occurred in two patients (4.1%) of the subintimal angioplasty group necessitated the use of a re-entry device.

Technical success was achieved in 90.2% of patients who underwent endovascular of TASC D lesions. Patients who underwent failed attempts at endovascular intervention for a TASC D lesion were not included in the subsequent outcomes analysis.

There was one periprocedural death. This occurred in a 67-year-old female patient with multiple comorbidities. Seven days following a successful endovascular intervention, from massive cerebrovascular stroke. Immediate complications occurred following five interventions (10.2%). Wire perforation occurred in 2 cases to which 3 minutes balloon dilatation tamponading was done. Arteriovenous fistula occurred in one patient to which balloon dilatation tamponading was done, acute thrombosis in one case retro peritoneal hematoma in one case.

Follow-up:

Follow-up length was 12 months excluding five patients who were technically failed one patient
who expired in the hospital one week post operative. Another one died during follow-up.

There were 26.5% major amputations during the follow-up 14.3% in the first three months post operative. 18.4% above knee amputation 4.1% below knee amputation 4.1% 30 limbs (59%) experienced restenosis (21 limbs) or occlusions (9 limbs). By survival curve analysis, primary patency was 75% at 6 months and 45.5% at 12 months. 20 limbs (40%) underwent reintervention during the follow-up time. All patients had duplex findings consistent with restenosis or occlusion prior to reintervention.

The mean time to reintervention was 6 months. 5 limbs (10%) required multiple reinterventions including 2 limbs which underwent 3 reinterventions, 3 limbs which underwent 2 reinterventions, secondary patency rates by survival curve analysis were 59.1% at 12 months. Of the 28 limbs which suffered occlusion, 7 limbs underwent successful endovascular salvage, 2 were observed following complete wound healing in the affected limb, and 3 went on to surgical bypass. Among the patients who underwent surgical bypass, there were 2 femoral-to-below-knee popliteal artery bypasses performed for early occlusions (at 6 months), endovascular interventions. Secondary patency rates by survival curve analysis were 59.1% at 12 months. There was no significant difference in primary, assisted primary, or secondary patency between patients who underwent their initial intervention for CLI \( p = 0.976 \), \( p = 0.861 \), \( p = 0.832 \), respectively).

**Risk factors for restenosis/occlusion:**

Significant predictors or restenosis/occlusion included the presence of DM (diabetes mellitus), patients who were current or former smokers. Patients with less than two infrapopliteal runoff vessels trended toward being a predictor of restenosis/occlusion and lastly stents placement and effect on patency, data were statistically described in terms of frequencies (number of cases) and percentages. The study groups was done. \( p \)-values less than 0.05 was considered statistically significant. All statistical calculations were done using computer programs.

The following diagrams shows the effect of risk and predictor values over the results with special consideration to D M, run off and stents placement that shows its effect but un fortunately non significant \( p \)-values.

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**Primary patency:**

<table>
<thead>
<tr>
<th>% of pts</th>
<th>No stent</th>
<th>Stent</th>
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<tbody>
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<td>120%</td>
<td>100.0%</td>
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<td>100%</td>
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<td>60%</td>
<td>75.0%</td>
<td>75.0%</td>
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<td>40%</td>
<td>45.5%</td>
<td>59.1%</td>
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**Secondary patency:**

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<th>% of pts</th>
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<td>74.2%</td>
<td>54.2%</td>
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<tr>
<td>40%</td>
<td>42.9%</td>
<td>29.9%</td>
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**Comment:**

- Better results were obtained with stent.
Comment:
- Amputations were less with stent. It reached to 17.4% compared to 50% in cases without stent.

Case:

Fig. (5): (A) TASC C S.F.A. lesion with wire passing subintimally. (B) Balloon dilatation. (C) Stent deployment. (D) Flow after treatment.
**Discussion**

Due to increasing longevity, patients now present with more coexistent illnesses, which often increase the risk of surgery for PAD. Today, many lesions can be treated by endovascular methods which are less invasive, can be performed under local anaesthesia and without need for surgical incisions [1].

In this study, the aim was to evaluate the effect of stenting on patency and limb salvage in cases of TASC D femoropopliteal disease in critical limb ischemia patients.

With advances in endovascular techniques and equipment, the treatment paradigm for patients with PAD has shifted. In particular, patients with anatomically favorable lesions have demonstrated excellent outcomes with endovascular therapy and are often managed with an aggressive endovascular posture [2-5].

Our overall technical success, was 90.2% this is not dissimilar from other studies which have looked at combined outcomes of endovascular treatment of TASC C and D lesions AS Donald T. Baril et al., who reviewed 74 patients with 79 limbs TASC II D lesions who were treated with subintimal angioplasty and selective use of a re-entry device and reported a technical success rate of 89%. This is less than their previous reported 98% technical success for TASC B and C lesions [4,6].

However, Setacci et al., reviewed 145 patients with TASC II C and D lesions who 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. Rabellino et al., reviewed 234 limbs, 52% of which were TASC II D lesions and reported initial technical success of 97%. In addition to the technical limitations, there is also a degree of surgeons’ judgment contributing to lower technical success rates [7,8].

Unlike bypass, endovascular intervention may be performed with minimal physiologic impact on this often critically ill patient population. In our current series, there was no systemic complication directly related to the procedure with local complications in 5 cases in the form of perforation, a V fistula retroperitoneal hematoma and thrombosis all managed successfully. 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 [9].

Restenosis and occlusion continue to complicate endovascular interventions in nearly all arterial beds. Previous studies have demonstrated worse outcomes with more advanced TASC classification, and TASC D classification, alone has been shown to be a predictor of restenosis [3,4,10,11].

Although not directly comparable given the retrospective nature of the two studies, Donald. Baril et al., previously reported data on TASC B and C femoropopliteal lesions demonstrated assisted-primary patency rates of 89.3% at 12 months and 87.1% at 24 months and secondary patency rates of 94.0% at 12 months and 94.0% at 24 months. Comparatively, for the TASC D limbs in there later series, the assisted-primary and secondary patency rates were 88.4% at 12 months and 74.2% at 24 months and 92.6% at 12 months and 88.9% at 24 months, respectively. (Donald et al., 2010). In our series, the primary and secondary patency rates were 45.5% and 59.1% at 12 months respectively limb salvage was 73.5% in 12 months given the long length of these lesions or their popliteal location, such patency rates are not unexpected [4,6].

However, it should be noted that the majority of these restenoses can be treated using endovascular techniques. Furthermore, a large number of the limbs that go on to occlusion can be salvaged through an endovascular approach. Close surveillance using frequent noninvasive testing including arterial duplex in combination with a clinical assessment appear to be helpful in maintaining patency of these lesions [6].

Predictors of restenosis/occlusion in this study were DM, runoff vessels and stents placement. Schillinger et al., state that the presence of a stent in the popliteal segment places a rigid stent at an area of repetitive motion and stress, leading to an increased rate of restenosis, with or without the presence of a stent fracture. Although prospective, randomized data regarding this are lacking, from our experience and that of others, avoidance of extending stents into the distal SFA and proximal popliteal appears to be beneficial in reducing restenosis. Initial undersizing of balloons, long inflation times, and not routinely placing stents in nonflow-limiting dissections appear to be the best means of avoiding popliteal artery stent placement [2,6].

Gregory et al., [12] state that one-year primary and secondary patency for stent vs no-stent group
was 50% vs 45% (p = .73) and 70% vs 78% (p = .47), respectively. One-year limb salvage rate for the stent vs no-stent group was 85% vs 90% (p = .61). A stent diameter >7mm displayed a trend toward better patency 53% vs 37% for diameter ≤6mm (p = .08). None of these factors proved significant with multivariate analysis. Selective stents placed for suboptimal results after subintimal angioplasty produce similar patency rates to primary SIA without stents but better limb salvage.

In our study one-year primary and secondary patency for stent vs no-stent group was 54.2% vs 38.5% (p = .976) and 78.3% vs 42.9% (p = .861), respectively. One-year limb salvage rate for the stent vs no-stent group was 82.6% vs 50% (p = .832). But in effect of single or multible run off over primary, secondary patancy and limb salvage respectively was 35.7% vs 56.5% (p = .856) and 50% vs 73.9% (p = .866) and 50% vs 82% (p = .832).

This study has a number of limitations, patient selection and treatment modality were not standardized. Additionally, this was not designed as an intention-to-treat study and the primary goal of this review was to determine the outcomes and durability of successful endovascular interventions on TASC II D lesions. As such, patients who did not undergo successful primary interventions were excluded from the analysis. Furthermore, although data have been derived based on survival curve analysis, the follow-up, number of patients, time is limited, and longer-term follow-up will be necessary to determine the durability of these interventions.

Endovascular interventions for TASC II D lesions can be safely performed with fair hemodynamic improvement and limb salvage rates in this often medically unfit population.

Restenosis is not uncommon in these complex, typically lengthy lesions that mandate strict follow-up utilizing noninvasive arterial studies.

Stenting appear to improve primary and secondary patency and limb salvage.

References
الملخص العربي

القسطرة الطرفية بدأت في علاج انسداد الشريانين المزمن للطرف السفلي بديلًا عن العلاج الجراحي كونها أكثر أمانًا وأرخص سعرًا ويمكن القيام بها بخفة موضعية.

هذه دراسة شملت 15 مريض قد تم علاجهم بمستشفى قصر العيني ومستشفى قصر العيني التعليمي الجديد لمرضى انسداد الشريان الفخذي المائي في الحرق تاسك د في الفترة ما بين يناير 2012 إلى يناير 2014.

هدف هذه الدراسة هو تأثير الدعمات في التعامل مع انسداد الشريان الفخذي المائي الحرق تاسك د في حقيقة التقدم في الأدوية والأساليب.

مع القسطرة في الأدوية والطرق المستخدمة كانت النتائج الميدانية مبشرة من حيث النجاح في الإجتياز الأولي للإنسداد وإنقاذ الطرف السفلي من خطر الإجلال مع إنخفاض معدل الوفيات والمضاعفات التي تلت التدخل.

النجاح الفوري في الإجتياز للإنسداد كان 90% وفاز في 6 حالات تمثل 99% وبعد عام من التدخل كان بقاء الشرايين مفتوحة 45%.

وقد تم رفع هذه النسبة إلى 91% بعد التدخل الثاني في ذات العام وجعل إنقاذ الطرف السفلي من البتر كان 75% وحدثت بعض المضاعفات البسيطة مثل نزيف وتجلط بالشريان وناصر شرياني وردت تم التعامل معها بنجاح.

ويتير وضع دعمات بالشريان من المحدود لنجاح طول مدة عدم انسداد الشريان بعد القسطرة.

ويحتاج التدخل بالقسطرة لمرضى انسداد الشريان المائي الحرق تاسك د إلى المتابعة أكثر لتحديد مدى فعالية هذا التدخل على المدى البعيد وأيضًا يحتاج لضمن أكبر من المرضى ودراسات عن العائد من التدخل بالقسطرة ومقارنته بالتدخل الجراحي لتعظيم هذا النوع من العلاج للتعامل مع الحالات المتقدمة لنسداد الشريان الفخذي المائي الحرق المزمن تاسك د.