ORIGINAL ARTICLE

Patency of Primary Stenting of Superficial Femoral Artery Steno-occlusive lesions at Jordan Royal Medical Services

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Abstract

Purpose: To evaluate the primary and assisted primary patency following primary stenting performed to treat superficial femoral artery (SFA) steno-occlusive disease in Jordan Royal Medical Services (JRMS).

Methods: This is a retrospective single-center study, done to analyze the primary and assisted primary patency of 131 primary stenting procedures for SFA steno-occlusive lesions (Trans Atlantic Inter-Society Consensus (TASC) A and B) using nitinol self-expandable stents performed in 117 patients over two years period (2007-2009). Patency was assessed by clinical examination, ankle-brachial pressure index, and colour duplex scanning over a mean period of one year.

Results: One year primary patency was 77% and 70% while one year assisted primary patency was 84% and 81% for TASC A and B lesions respectively. There was no procedure related periprocedural mortality.

Conclusion: Primary stenting of steno-occlusive (TASC A and B) lesions of SFA using nitinol stents is performed effectively in JRMS for patients encountering disabling intermittent claudication and critical lower limb ischemia with results comparable to international studies.

Keywords: Superficial Femoral Artery (SFA) disease, primary stenting, Trans Atlantic Inter-Society Consensus (TASC) classification, critical lower limb ischemia, disabling intermittent claudication.

Introduction:

Femoropopliteal segment is the most common site for peripheral arterial atherosclerotic disease[1,2]. The atherosclerotic plaque can involve the entire artery or it can be focal and discrete, reflecting the heterogenecity of lesions which are classified according to TASC classification into A, B, C and D lesions[3]. Endovascular techniques for recanalization of SFA spare the autologous saphenous vein, can be done with local anesthesia, and minimize the in-patient hospitalization.

Percutaneous transluminal angioplasty (PTA) for recanalization of the superficial femoral artery (SFA) can achieve initial technical success rates above 95% with low risk of complications[4,5,6]. However, recurrent stenoses at the treated segment occur in 40% to 60% at 1 year[4,7,8]. One -year restenosis rates above 70% have been reported after balloon angioplasty of lesions longer than 10 cm[5,9].

Stents can be placed at the time of successful angioplasty (primary stenting) or with failed angioplasty (secondary stenting) in the attempt of reducing the rate of restenosis. Balloon expandable stents can be deformed from trauma or external compression, making self-expandable stents preferred[10,11,12]. Randomized trials were recently published comparing PTA alone and PTA with stenting using nitinol stents[13,14,15]. Schillinger and Resilient Trials showed benefit of primary stenting at 12 and 24 months using the Dynalink/Absolute and Edwards Lifestent NT respectively[13,14]. We performed this retrospective study to compare our results of primary

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stenting using nitinol stents with the published results.

Methodology:

One hundred and thirty one primary stenting procedures for TASC (A and B) lesions of the SFA were performed in 117 patients in JRMS between January 2007 and January 2009. Lesions were classified as follows: 73 cases (56%) with TASC A and 58 cases (44%) with TASC B lesions. Procedures were performed either for disabling intermittent claudication in 68 cases(52%) or critical lower limb ischemia in 63 cases(48%). Aorto-iliac segments were free from significant flow limiting steno-occlusive lesions and there was at least one patent distal run off artery down to the foot in all patients. Most patients with extensive SFA disease (TASC C and D) were treated primarily with open surgical bypass procedure and were thus excluded from our study. (Table-1) shows demographics of the patients.

Procedures were performed in collaboration between the vascular surgery and interventional radiology departments at King Hussein Medical Center of the JRMS in Jordan. They were performed by retrograde puncture of the contra lateral common femoral artery (CFA). Six Fr sheath was used in all cases. A 0.038 hydrophilic wire was used to cross the lesions directed by an angle shaped vertebral catheter. Self expandable nitinol stents (Protégé , EV3 Inc) were used. Systemic heparinization was performed in all cases (80 UI/Kg). Location, degree and length of lesions were recorded according to TASC classification.

Table 1: *Patients demographics*

Characteristics	Patients
Age (years)	63 (range:42-81)
Male : Female	84:33 (72%:28%)
Hypertension	61 (52%)
Diabetes Mellitus	72 (62%)
Dyslipidemia	48 (41%)
Coronary artery disease	56 (48%)
Smoking history	93 (79%)
Disabling intermittent claudication	68 (52%)
Critical lower limb ischemia	63 (48%)
TASC A lesion	73 (56%)
TASC B lesion	58 (44%)

Ankle brachial pressure index (ABPI) was re-measured on the 2nd day before discharge and the patients were followed up in the vascular surgery clinic at one month, 6 months, 12 months and then annually by clinical examination, ABPI and duplex scan. Patients who developed recurrent flow limiting significant stenosis of more than 50% by duplex scan underwent a percutaneous transluminal angioplasty (PTA) procedure. Patients who failed the primary stenting or the follow up PTA procedure who sustained significant residual SFA stenosis or occlusion underwent surgical bypass procedure. Patients were followed up for a mean period of one year(12-24 months).

Patients whose SFA remained patent at one year without further intervention were included in the one year primary patency group. Patients who required secondary PTA procedure during the follow up period to maintain SFA patency were included in the one year assisted primary patency group.

Results:

Immediate technical success of the primary stenting was 98% (figures 1 and 2) with only three cases requiring subsequent surgical bypass procedure. During the follow up period, significant stenosis (ore than 50% demonstrated on duplex with increased velocities and change of Doppler waveform into monophasic flow) was detected in 26 cases (14 cases of TASC A lesions and 12 cases of TASC B lesions). Stent occlusion was detected in 3 cases (all were originally TASC B lesions). Patients who developed in- stent restenosis (ISR) underwent PTA which was successful in 11 cases. Patients with stent occlusion or those who failed secondary PTA underwent surgical bypass. Stent fracture was noticed in 3 cases. Major limb amputation was performed in 2 patients due to progressive soft tissue infection despite successful recanalization. No periprocedural mortality was encountered. Thirteen patients died during the follow up period. Eight patients lost follow up and therefore were ex-

Figure 1: *SFA TASC A lesion pre-stenting*

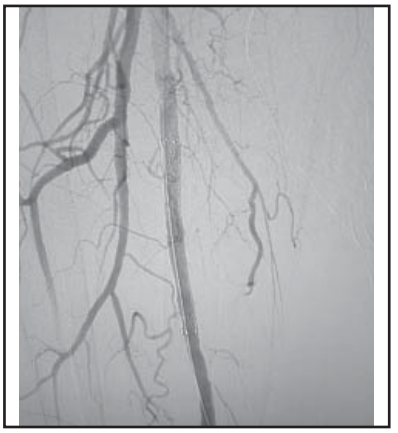

Figure 1: *TASC A lesion post stenting*

cluded from the results. One year primary patency was 77% and 70% while one year assisted primary patency was 84% and 81% for TASC A and B lesions respectively (Table- 2).

Discussion:

Percutaneous transluminal angioplasty (PTA) for recanalization of the superficial femoral artery was reported to have high one year primary patency rates as described by some International published trials (78% in Schillinger trial) making our results comparable to these studies[13,15,16]. In our study ISR occurred in higher frequency in TASC B than TASC A lesions reflecting probably the more advanced nature of TASC B lesions. Cases of ISR were often amenable for PTA contributing to a higher rate of primary assisted patency.

Stent occlusions with clinical deterioration were treated successfully with bypass surgery confirming that this initial endovascular approach did not compromise further surgical management after clinical stent failure. For patients with long-segment SFA disease requiring revascularization, bypass surgery using vein grafts still have to be considered as the most durable therapeutic option[4,15]. This is our policy in TASC C and D lesions although in some studies ,self-expandable nitinol platforms with drug-eluting properties has been mentioned as a possible adequate endovascular tool to challenge the results of surgical SFA revascularization in the near future[12,17,18].

Table 2: *One year primary and assisted primary patency*

TASC grade	One-year primary patency	One-year assisted primary patency
TASC A	77%	84 %
TASC B	70%	81%

Currently, poor surgical candidates with severe cardiovascular comorbidity may be considered for primary stenting of TASC C and D longer lesions. Furthermore, the intermediate term stent patency data are in the range of prosthetic SFA bypass grafts, and stenting has a considerably lower rate of complications making stenting an option of treatment for patients without available saphenous veins for a venous graft[6,15].

SFA stent fractures were first systematically described by Duda[18]. The cumulative length of the stented segment has been identified as the most important determinant for material fatigue and subsequent fracture[12,18,19,20]. Stent fracture might be more than the noticed three cases in our study because not all of our patients were screened for stent fracture. Still no serious sequelae of the fractures other than restenosis were observed in this study.

Conclusion:

Primary stenting for SFA steno-occlusive lesions using nitinol self expandable stents in patients suffering from disabling intermittent claudication or critical lower limb ischemia is performed effectively in the JRMS with one year primary and assisted primary patency rates comparable to international studies.

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