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Evaluating Clinical Outcomes of Performing Endovascular Treatment for Patients Presenting with Severe Intermittent Claudication or Critical Limb Ischemia Due to TASC D Lesions

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Abstract

Background: **Peripheral arterial disease (PAD) is a prevalent medical condition, reaching 20% among males in the 7th decade, the associated morbidity and even mortality is more with critical limb ischemia (CLI) than with Intermittent Claudication (IC). Endovascular interventions have become more popular than open measures in treating PAD with less complications and more success rates.** ***Aim:*** **to evaluate the clinical outcomes of performing percutaneous transluminal angioplasty (PTA) in patients presenting with severe IC or CLI due to Trans-Atlantic Inter-Society Consensus (TASC)-D lesions.** ***Patients and Methods:*** **forty five patients with TASC D PAD were selected randomly; they performed PTA with balloon dilation with or without stenting for the lesions.** ***Results:*** **The mean age was 61.5 years, 74% males & 26% females. 28.9% presented with IC and 71.1% with CLI. The mean pre-intervention ABI was 0.45, reaching 0.69 after interventions (statistical significant improvement). Restenosis developed in 24.4% of the cases.** ***Conclusion:*** **Endovascular interventions for TASC II D lesions can be safely (minimal complications) performed with excellent hemodynamic improvement and limb salvage rates in this often medically unfit population.**

Key words: Peripheral Arterial Disease,TASC classification

Introduction

The prevalence of peripheral arterial disease (PAD) has been evaluated in several epidemiologic studies and is in the range of 3% to 10%, increasing to 15% to 20% in persons over 70 years[1]. Chronic lower extremity ischemia is associated with severe morbidity and increased mortality, mainly from associated cardiovascular events[2]. The natural history of critical limb ischemia has been well studied, demonstrating that patients with critical limb ischemia (CLI) have a much poorer prognosis compared to patients with intermittent claudication (IC)[3]. A resting ABI of <0.90 is caused by hemodynamically significant arterial stenosis and is most often used as a hemodynamic definition of PAD. In symptomatic individuals, an ABI <0.90 is approximately 95% sensitive in detecting arteriogram-positive PAD and almost 100% specific in identifying healthy individuals[4]. Although operative bypass is still considered the

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"gold standard" for treating peripheral arterial disease, over the last decade endovascular interventions have become more popular and now represent the vast majority of peripheral arterial treatments being performed. Open bypass is associated with an unacceptable morbidity and mortality that is not encountered to the same extent with endovascular techniques[3,5]. However, outcomes of endovascular intervention are dependent upon the location and nature of the lesion, as well as possibly the technologies available to treat the lesion and the experience of the surgeon. In correctly selected patients, endovascular techniques should be the primary management employed for critical limb ischemia[5]. Endovascular intervention in arterial disease is less invasive and therefore carries a lower risk profile. Endovascular approaches to limb salvage currently represent 70% of total interventions[6,7]. Endovascular treatment has multiple benefits. Patients with CLI may not have appropriate bypass targets due to the nature of their disease, or they may not have adequate saphenous vein to provide as a bypass conduit. Additionally, patients with CLI have abundant medical co morbidities that make them poor operative candidates. Therefore, endovascular therapy may be the only option for these patients who would otherwise not be amenable to surgical bypass[8]. The role of endovascular intervention depends on the Trans Atlantic Inter-Society Consensus (TASC) classification of lower extremity arterial lesions. TASC classification of lesions is based upon a review of the world literature, and the success rates for types of procedures in various lower extremity vascular beds[9]. Femoral-popliteal lesions that are TASC A; either a single stenosis <10 cm in length, or a short stenosis of <5 cm in length[10]. TASC B lesions are characterized as multiple lesions (stenoses or occlusion) each less than 5 cm, a single stenosis or occlusion <15 cm not involving the infrageniculate popliteal artery, a single or multiple lesions in the absence of continuous tibial vessels to support a bypass, heavily calcified occlusion <5 cm in length, or a single popliteal stenosis[11,12]. TASC C lesions; multiple stenoses or occlusions totaling >15 cm with or without heavy calcification or recurrent stenoses or occlusions that need treatment after two endovascular interventions[13], TASC D lesions (chronic total occlusions of CFA or SFA >20 cm involving the popliteal artery, or chronic total occlusion of popliteal artery and proximal trifurcation vessels) are more extensive and have less success with endovascular repair[12,14]. It was recommended that patients with TASC C and D lesions undergo surgical management if they are adequate operative candidates. As more research is being undertaken, the indication for endovascular treatment is being expanded to include infrapopliteal disease[15]. Evaluations focused on pulse changes, healing status of prior tissue loss, evolution of symptoms, adherence to antiplatelet therapy, and control of risk factors[16]. The modification of the TASC data to the TASC II data indicates that we continue to push the boundaries of what lesions may respond favorably to percutaneous intervention[17]. Many of us believe that with endovascular intervention we rarely burn bridges while providing revascularization with minimal morbidity. Continued endovascular innovations help us push these boundaries but sometimes at exponential expense[18]. The purpose of this study is to evaluate the clinical outcomes of performing percutaneous angioplasty PTA in patients presenting with severe IC or CLI due to TASC D lesions.

Patients and Method

This study used the interventional design;

using 45 randomly selected patients attending the vascular surgery clinic in the Suez Canal University hospital. All the included cases showed CT angiographic evidence of TASC D lower limb lesions and presented with either intermittent Claudication or critical limb ischemia. All the cases under study were examined before intervention regarding their personal and medical history, presentation, ABI of the affected limb, full laboratory tests and pre-CTA. The studied cases performed percutaneous transluminal angioplasty with balloon dilation for the stenosed segments; stenting was performed if dilation was non-satisfactory. Follow up was performed for all cases regarding post-intervention ABI, symptoms, complications and peripheral pulsations. This was assessed just before discharge and after 3, 6, 9 and 12 months.

Results

During the time period reviewed, they were 45 patients, 34 patients (74%) male and 11 patients (26%) female, with the male to female ratio about 3: 1. Regarding the age, the youngest patients aged 50 years old and the oldest 75 years old, the age (mean±SD) was (61.58±5.315). The maximum number of patients 18 (40%) were in the age group 60-65, while the least number of patients 2 (4.4%) were in the age group 70-75 and 75-80, (Figure 1). Regarding the risk factors, 36 patients (87.3%) were diabetics, 38 patients (84.4%) were hypertensive, 37 patients (80.4%) had ischemic heart disease and 5 out of those 37 patients (13.5%) had coronary stents. Regarding the hyperlipidemia, 17 out of the twenty three patients (37.8%) were positive, 26 male patients of the 34 male patients were smokers, while all the females denied smoking, (Figure 2). Regarding the presenting symptoms, 13 patients (28.9%) presented with limiting claudication, 23 patients (51.1%) presented with ischemic rest pain and 9 patients (20%) with toes gangrene or atrophic changes, (Figure 3).

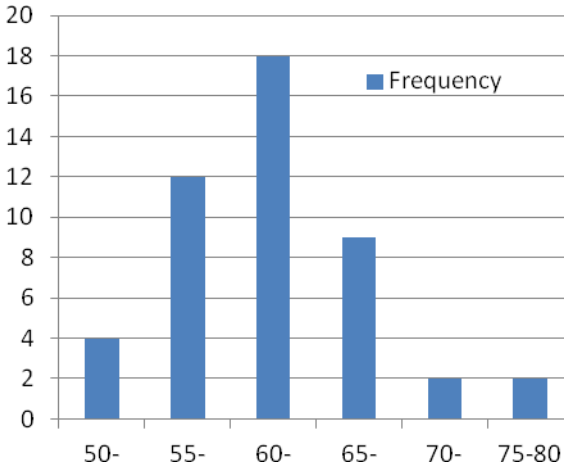

Figure 1: Distribution of patients' age in years

Regarding history taking from patients, The maximum number of patients were complaining for 2 month were 19 patients(42.2%), and the least number were 4 patients complaining for 4 month, and the (mean±SD) was (6.53±2.34), (Figure 4). Regarding CTA; the maximum number of patients were presented with Unilateral occlusions of both CIA and EIA and patients presented with total occlusions of CFA or SFA (>20 cm, with popliteal artery) 11 patients (24.4%) for each group, then presented with total occlusion of popliteal artery and proximal trifurcation vessels were 8 patients (17.8%), then patients presented with multiple lesions involving the unilateral CIA, EIA and CFA 7 patients (15.6%), then presented with bilateral occlusions of EIA were 6 patients (13.3%), and the least number of patients were presented with Aorto-iliac occlusion were 2 patients (4.4%), (Figure 5). Regarding the examination, the maximum number of presenting patients had an ABI (0.4-0.5) group were 18 patients (40%), then patients had an ABI (0.5-0.6)

group were 14 patients (31.1%), and the least number of patients had an ABI (0.6-0.7) group were 2 patients (4.4%), and the measuring of ABI (mean±SD) were 0.4532±0.07559, (Figure 6). Regarding the examination after finish-ing the intervention, the maximum number of patients had an ABI (0.8-0.9) group were 16 patients (35.6%), then had an ABI (0.7-0.8) were14 patients (31.1%), and the least number of patient was one patients (2.2%), with the (mean±SD) was 0.695±0.1181, (compared to pre-examination; P<0.05) (Figure 7).

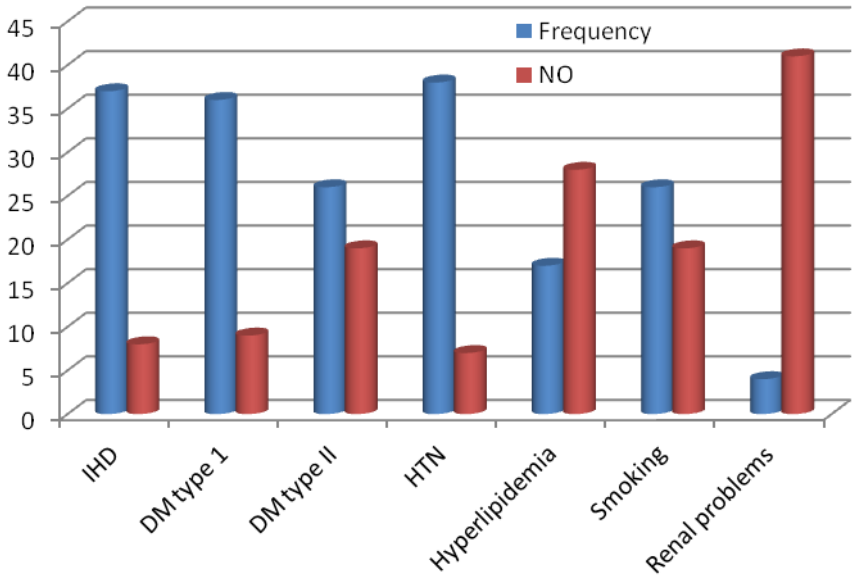

Figure 2: Distribution of the patients according to the risk factors
DM: diabetes, HTN: Hypertension, IHD: Ischemic Heart Disease

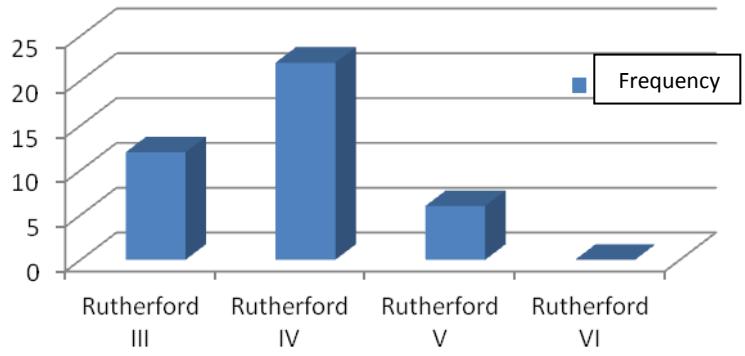

Figure 3: Distribution of the patients according to their presentation

Regarding the presenting symptoms, 13 patients (28.9%) presented with limiting claudication, 23 patients (51.1%) presented with ischemic rest pain and 9 patients (20%) with toes gangrene or atrophic changes, (Figure 3). Regarding history taking from patients, The maximum number of patients were complaining for 2 month were 19 patients (42.2%), and the least number were 4 patients complaining for 4 month, and the (mean±SD) was (6.53±2.34), (Figure 4). Regarding CTA; the maximum number of pa-

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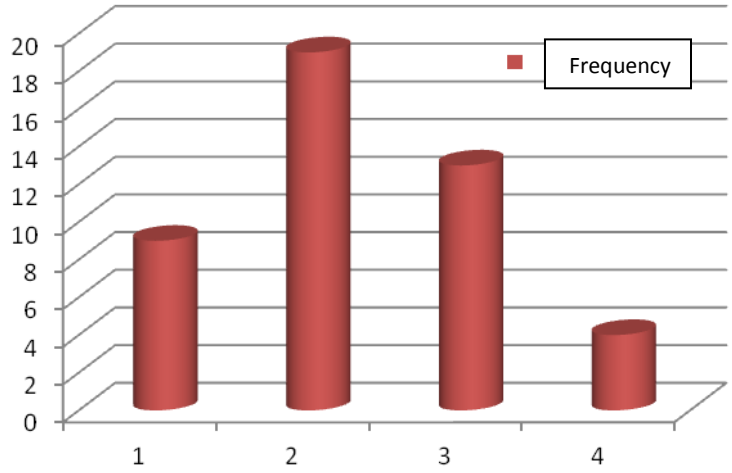

Figure 4: Distribution of duration of complaint

Regarding examination and investigations after the intervention, 11 patients (24.4%) had occurrence of re-stenosis, (Figure 8). Regarding evaluation of the patient's status after intervention, 3 patients (27.3%) re-stenosed within 3 month, 5 patients (45.5%) re-stenosed within 3 to 6 month, one patient (9.1%) re-stenosed within 6 to 9 month, 2 patients (18.2%) re-stenosed within 9 to 12 month, (6.55±3.32, Figure 9). Regarding the sheet of intervention, about 26 patients (57.8%) used balloon for dilatation, while 19 patients (42.8%) used balloon and stenting (Figure 10). Regarding the site of re-stenosis, 3 patients (27.3%) had iliac re-stenosis, 3 patients (27.3%) had femoro-popliteal (f/p) re-stenosis, both of them in 2 patients (18.2%), 3 patients (27.3%) with femoro-distal re-stenosis, P<0.05, (Figure 11). Regarding the follow up and evaluation of patients, one patient occluded after one month of intervention, three patients after three month and six patients occluded after one year, (Table 1).

Discussion

Conventional treatment of advanced PAD in patients presenting with lifestyle-limiting claudication and CLI has been risk factor medication and surgical intervention, respectively. However, 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. However, this enthusiasm for endovascular therapy has been tempered by significant rates of re-stenosis and occlusion particularly for more advanced lesions.

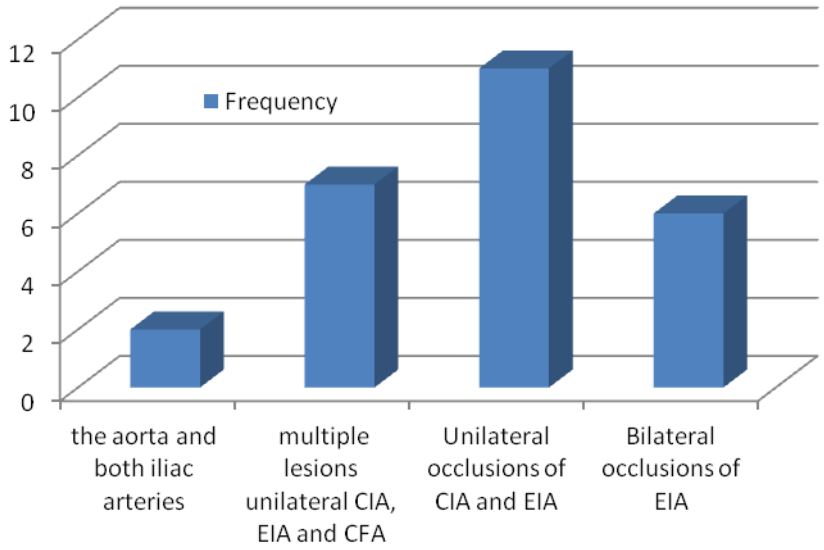

Figure 5: Distribution of the lesions in aorta and iliac arteries.

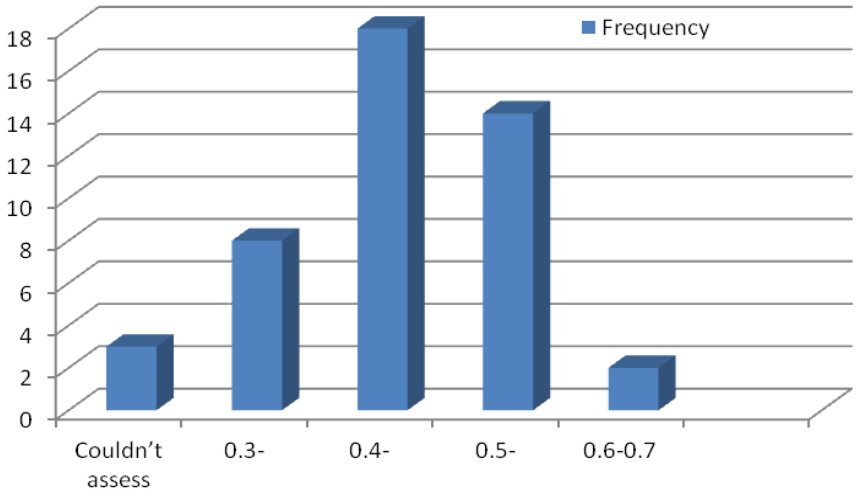

Figure 6: Distribution of ABI before intervention

Concomitantly, patients with such complex lesions typically have multiple comorbidities including advanced coronary artery disease and cerebrovascular disease, mak-

ing them high risk for surgical intervention. The treatment of TASC D lesions relies on particular techniques as well as equipment to optimize technical success. In particular, these lesions, by definition are often quite long, which may require the use of stiff wires to optimize the ability to push across these lesions. Furthermore, as demonstrated in this series, four limbs required an antegrade approach to improve pushability and assist in crossing longer lesions. In addition to crossing ability, TASC D lesions are more complex in that re-entry may be difficult secondary to calcification or due to a suboptimal anatomic location. Limb salvage in our series was excellent, with no major amputations during the follow-up time.

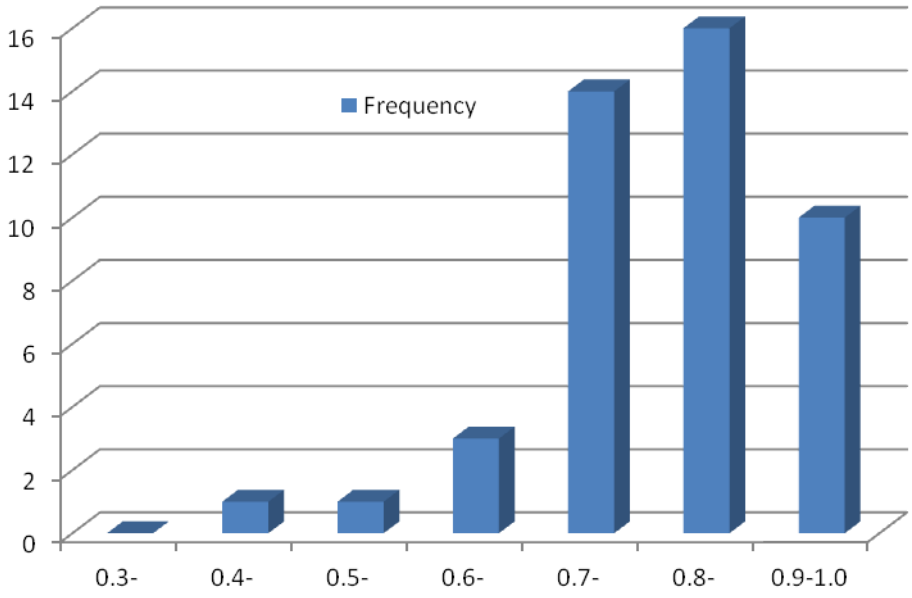

Figure 7: Distribution of ABI after finishing intervention

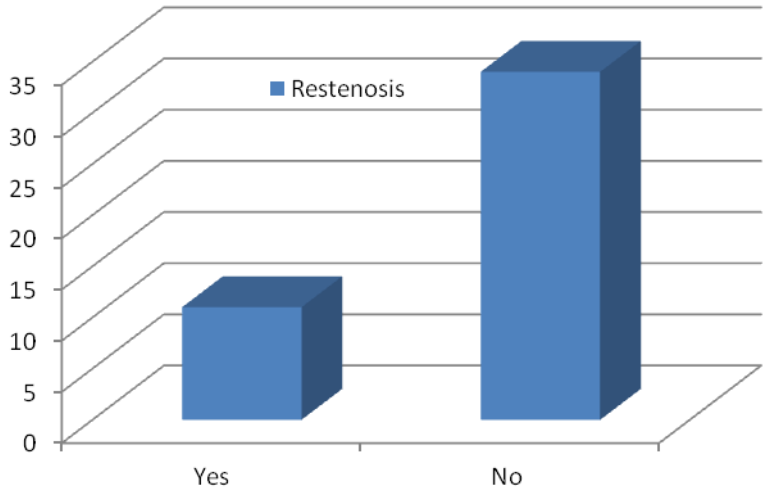

Figure 8: Distribution of patients regarding to restenosis

There was a 15% rate of minor amputations, not unexpected given the extent of arterial disease treated. Furthermore, 89% of patients who presented with tissue loss went

on to significant or complete wound healing during follow-up. During a follow-up period with a mean of approximately 12 months, nearly one-fourth of the population expired. This highlights the fact that patients with advanced PAD are at very high risk of death from cardiovascular events, not only perioperatively but also in the months to years following their diagnosis of PAD as well. Data from the Reduction of Atherothrombosis for Continued Health (REACH) dataset established that patients with known PAD had a 21.1% incidence of cardiovascular death, myocardial infarction, stroke, or hospitalization for an atherothrombotic event compared to 15.2% for patients with a diagnosis of coronary artery disease alone or 14.5% for patients with a diagnosis of cerebrovascular disease alone in the first year following their initial diagnosis[11].

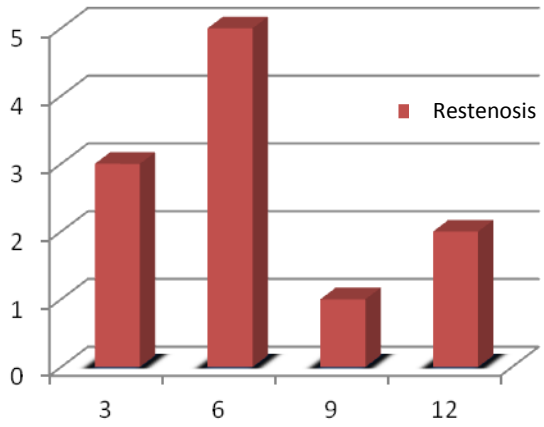

Figure 9: Distribution of patients regarding to time of restenosis in months

Predictors of re-stenosis/occlusion in this study were cerebrovascular disease, hypercholesterolemia, the presence of a popliteal stent, and patients who were current or former smokers. We have previously demonstrated hypercholesterolemia to be a predictor of re-stenosis in TASC B and C lesions, but the exact mechanism remains ill-defined.

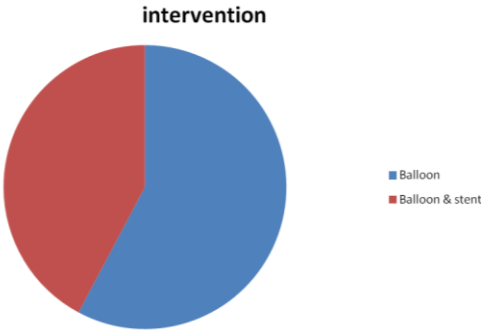

Figure 10: Distribution of participants regarding to type of intervention

Given the significant contribution of tobacco use to atherosclerotic disease, it is not surprising that smokers were at a higher risk for re-stenosis and occlusion as has been previously demonstrated. 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 re-stenosis, 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 re-stenosis. 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. Minor complications were reported by others in the form of non significant haematoma and distal embolisation that was treated by suction[19]. These complications are also expected during the antegrade transfemoral approach. Saim Yilmaz et al reported a massive thigh haematoma after transpopliteal approach, this was following the use of a Closer suture-mediated device[20]. Elias Noory et al has used the Starclose and Perclose (Abbott Vascular Devices, USA), and the AngioSeal (St. Jude Medical, USA) and did not record complications[19].

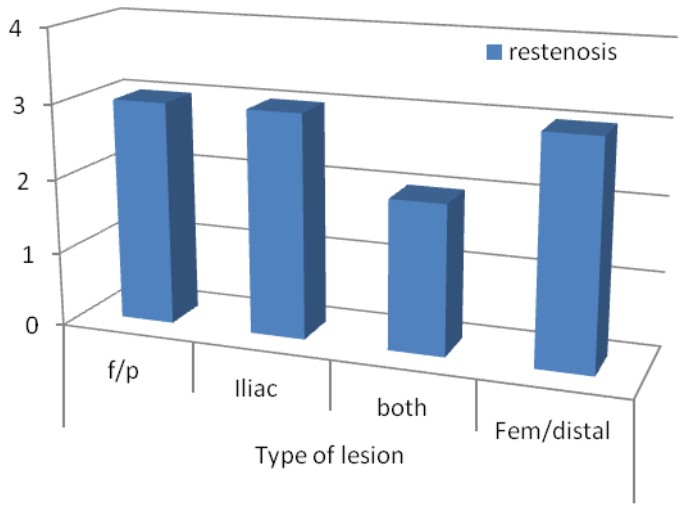

Figure 11: Relation between site of lesion and the restenosis

Table 1: Relation between number of occluded arteries and duration

Duration in month	0	1	3	6	9	12
Number of patent vasculature	45	44	42	42	40	39

However, in the presenting study, only manual compression was used as suggested in other literatures to be sufficient[21]. This study has a number of limitations, the most important of which is its retrospective nature. 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 un dergo successful primary interventions were excluded from the analysis.

Conclusion

Endovascular interventions for TASC II D lesions can be safely performed with excellent 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 non-invasive arterial studies. Cerebrovascular disease, hypercholesterolemia, the presence of a popliteal stent, and tobacco use all appear to be associated with higher rates of recurrence. Further follow-up is necessary to determine the long-term efficacy of these interventions.

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