Popliteal Artery Stenting is A Controversial Treatment, A Study Analysis

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ABSTRACT

Purpose: *To evaluate the efficacy & complications of popliteal artery stenting as a treatment for popliteal occlusive or aneurysmal diseases.* ***Materials & Methods:*** *54 patients were exposed to popliteal artery stenting either for occlusion or aneurysmal lesions from January 2012 to December 2015, we analyzed the data of these procedures as regard the patency rates (primary & secondary) and the complications incidence including stents fracture & acute thrombosis.* ***Results:*** *54 patients were treated by stenting of popliteal artery. 50 patients had popliteal artery occlusive lesions & the remaining 4 were treated for aneurysmal disease. The primary techniqual success after popliteal artery stenting was 100%. One year primary & secondary patency rate was 64.7%% & 70.5 % respectively. We had two non-procedure related mortality (3.7%). The total major amputation rate was 16.6%. The total stents fracture rate was 24% at one year.* ***Conclusion:*** *Popliteal artery stenting can be a good option of treatment for the aneurysmal dilation with low incidence of complications while for the atherosclerotic occlusive lesions; stents should be deployed as an selective and not as primary option. With new development of stents manufacture e.g. Supera, primary popliteal artery stenting can be considered but prospective randomized large studies are needed to document the efficacy.*

Key Words: *Popliteal artery, stenting, aneurysmal, occlusive disease*

INTRODUCTION

The aging of the population increases the prevalence of the endovascular interventions in the last 20 years. Since the endovascular procedures are often used as a first option for treatment in most of the peripheral occlusive diseases so it is becoming increasingly important to determine which modes of therapy are the most effective & cost benefit [1-3].

While the results of PTAs of iliac lesions have approached that of open procedures, the same cannot be said for infrainguinal vessels. Routine treatment of self-expandable stainless-steel stents has been shown to be no more durable than angioplasty alone[4]. More recent data, however, suggest that particularly for longer lesions of the superficial femoral artery (SFA), patency rates after systematic primary stenting are significantly higher than after balloon dilation and provisional stenting[5]. In fact, recent data from studies on nitinol stent implantation in the SFA have reported encouraging patency rates of 60% to 80% at 12 months.

The popliteal artery, unlike the SFA, has unique characteristics because it is highly exposed to biomechanical forces resulting from repetitive flexion of the knee,[6-7]. Concerns have been expressed that the implantation of stents, particularly in the popliteal artery, may be complicated by an unacceptable risk of stent fracture, [8].

For the previously mentioned factors, non–stent-based solutions for the popliteal artery may seem appealing, very few data are available, and stenting may still be required in a high percentage of patients after initial angioplasty procedures [8]. With the new advances in stents technology, new generation of stents (e.g. Supera stents , Abbot USA) can be deployed safely as a primary option at the popliteal artery [5-8].

MATERIALS & METHODS

From January 2012 till December 2015, 54 Cases of popliteal artery stenting were done. 50 Of these interventions for popliteal artery occlusive disease and the remaining 4 cases for

aneurysmal dilatation. Follow up data of all cases for 1 year postoperatively was collected from data base at our vascular department. Follow up included the primary & secondary patency rates at one year post interventions. Also all cases with popliteal stents were exposed to follow up by X ray at 1, 6, and 12 months for detection of any stent fracture. Acute stent thrombosis was detected during follow up & immediate interventions were done by thrombolytic therapy or with distal bypass. The rate of limbs salvage for critical limbs ischemia was reordered and the incidence of major amputations either below or above knee was addressed at this study.

Technique of interventions: -

All cases were done in angio suite under local anesthesia. Ipsilateral or contra lateral approach was done according if there is concomitant high significant lesions at iliac, CFA or proximal SFA. Cannulation of the artery by 6F sheath and immediate heparin bolus at dose of 100 IU/Kg body weight was administrated at the sheath. 0.35 Treumo standard angled wires were used in most of the cases. This wire was replaced by hard stiff tip 0.14 wire in cases with total occlusion of popliteal artery or associated with tibial vessels occlusion e.g. Victory (Boston scientific, USA). Transluminal angioplasty was the preferred technique in most of the cases but with failure for crossing the lesions, sub-intimal angioplasty was carried on. Re-entry at the true lumen was done by using different types of catheters e.g. shuttle catheter (Cook). Balloon angioplasty was done by using semi compliant balloons with 1 mm less in diameter than the native vessel as measured on fluoroscopy. Exception for this rule, in the situation we used the Supera stents (Abbott), the popliteal artery was dilated by a balloon with a diameter which is equal or larger than the native vessel diameter by 1 mm to avoid the stretch of the stent. Selective stenting was the routine technique. The stents were deployed if there was blood flow limiting dissection or immediate of recoil of the lesions in spite of two times dilatation. Primary stenting was done in selected cases with total occlusion in which Supera stents were deployed. Different types of stents were used but all of them were self-expandable nitinol ones. Self-expandable grafts stents (Viahaban) were used in cases with long popliteal occlusion. Cases with popliteal artery aneurysms, Viahaban (graft stents) were used to cover the aneurysm with safe landing zone (1 cm above & below the aneurysm). The graft stents size was 1 mm bigger than the native vessel diameter and then followed by balloon dilatation of the stent to avoid the endo-leak of the aneurysm. Closure of the arterial puncture was done by using closure device in the contralateral approach but in the cases with ipsilateral approach, manual compression was carried on.

Follow up protocol: -

The primary techniqual success was defined at this study as complete recanalization of the artery with residual stenosis is less than 30%. Follow up of all cases were carried on at 1, 6, & 12 months by duplex examination to detect the patency rate. The duplex criteria of restenosis that necessities reinterventions included reduction of the diameter of the vessel by 50% or more and increase the Peak systolic velocity (PSV) at the stenotic area more than 200 cm/sec. during follow up of patients who suffering of unhealed ulcers or amputated wounds and showed any clinical signs of deterioration of the wounds, immediate duplex examination was done to evaluate the distal vasculature flow. If secondary intervention was required in cases with restenosis, follow up duplex examination was done at the second day of the intervention to confirm the patency and PSV at distal vessels. X ray follow up at the knee area to detect fracture of the stents was done at 1, 6, & 12 months period and any fracture was detected, even without presence of significant comprise of blood flow, another stent was deployed at this fractured area.

RESULTS

All demographic features are listed in the **table 1**. The mean age is 63 years old.

Demographic feature	*Number of patients (%)*
Male gender	37/54 (68.5%)
Diabetes	42/54 (77.7%)
Hypertension	31/54 (57.4%)
IHD	19/54 (35.1%)
Renal impairment	11/54 (20.3%)
CRF (on Haemodialysis)	6/54 (11.1%)
Dyslipidemia	44/54 (81.4%)
Autoimmune disease (vasculitis)	3/54 (5.5%)
Smoking	40/54 (74%)

The presenting symptoms of the patients were illustrated in **table 2**. The most common

presentation at the time of intervention was unhealed ulcer of the foot.

Presenting symptom	*Number of patients (%)*
Intermittent claudication	4/54 (7.4%)
Rest pain	9/54 (16.6%)
Unhealed foot ulcer	25/54 (46.2%)
Gangrenous toe(s) or foot	13/54 (24%)
Asymptomatic aneurysm	3/54 (5.5%)

The degree of stenosis or occlusion was classified according to TASC II classifications. **Table 3** showed the degree of the lesions among the patients who are suffering of occlusive disease.

TASC classification (only Pop atherosclerotic lesions)	*Number of patients (%)*
A	1/50 (2%)
B	21/50 (42%)
C	13/50 (26%)
D	11/50 (22%)

The concomitant lesions sites at the vascular tree are shown in **table 4.** Most of cases (%) had SFA stenotic lesions

Associated lesions site	*Number of patients (%)*
Iliac	9/54 (16.6%)
CFA	3/54 (5.5%)
SFA	28/54 (51.8%)
Tibial	44/54 (81.4%)
Aortic aneurysm	1/54 (1.8%)

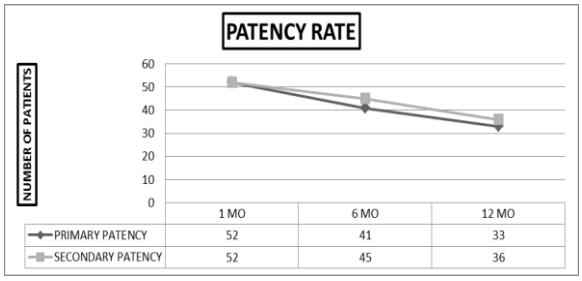
The tibial runoff was addressed in all cases and graded from 0-3 according the number patent distal vessels. **Table 5** showed the grades of distal runoff.

Grade of runoff	*Number of vessels*	*Number of patients (%)*
0	0	8/54 (14.8%)
1	1	23/54 (42.5%)
2	2	13/54 (24%)
3	3	10/54 (18.5%)

Different types of stents were used in this study as in listed in **table 6**. All of the deployed stents were self-expandable ones. 6 graft stents (Viahaban) were deployed, 4 for the cases for popliteal artery aneurysms & the remaining 2 for cases with long occlusive disease with total SFA occlusion.

Type of stent	*Number of patients (%)*
Smart (Cordis)	7/54 (12.9%)
Protégé (EV3)	22/54 (40.7%)
Complete (Medtronic)	10/54 (22.2%)
Maris plus (invatec)	5/54 (9.2%)
Supera (Abbott)	4/54 (7.4%)
Viahaban (Gore)	6/54 (11.1%)

The primary techniqual success was 100%. The primary patency rate was 52/54 (96.2%) %, 41/52 (78.8%) & 33/51 (64.7%) at 1, 6, & 12 months respectively and secondary patency rate was 52/54 (96.2%), 45/52 (86.5%) & 36/51 (70.5%) at 1, 6, & 12 months respectively. Two patients died with first 6 months follow up due to acute cardiac ischemia (2/54, %) & one patient was lost during the follow up after one month. The rate of major amputation at this study was 9/54 (16.6%) in 24 months follow up. **Figure 1** showed the patency rate



Two major complications were recorded in this study; stent fracture and acute stent thrombosis. The rate of stent fracture is listed in **table 7**. The total numbers of fractured stents at 1 year follow up was 13 stents out 51, (25.49%). In 7 occasions it was grade I fracture, while it was Grade II in 2 occasions and grade IV in 4.

Stent fracture follow	**Number of patients**

up / months	(%)
1	2/54 (1.8%)
6	5(+2)/51 (13.7%)
12	6(+7)/51 (25.49%)

Correlation between the stent type & the incidence of the fracture showed that the highest incidence in the protégé type (EV3) (7 stents). Both Smart (Cordis) & Maris plus stents had incidence of 2 stents fracture out of 5 (40%) while Viahaban (Gore) had one out of 6 (16.7%) & complete (Medtronic) had one stent facture out of 10 stents deployed with incidence of (10%). The Supera stents had 0% fracture.

We also had 4 cases of acute stent thrombosis was (7.4%). In three incidences, thrombosis was related to the occurrence of stent fracture and those 3 patients had an urgent femoro-distal bypass, two of them were successful and one failed ended in a major amputation. In the 4th incidence thrombosis was not related to stent fracture and it was managed successfully by thrombolytic therapy over 48 hours.

DISCUSSION

Endovascular revascularization strategies of the superficial femoral and popliteal arteries have evolved rapidly over the last decade. Despite very high immediate technical success rates, the major drawbacks are still poor long-term patency. Data are generally scarce, particularly for long, complex lesions, and comparative analyses for different treatment concepts are lacking. Maintaining long-term patency after recanalization of complex femoropopliteal lesions remains one of the greatest challenges of endovascular therapy [9].

Although the wider use of nitinol stents has generally improved the procedural outcomes compared with balloon angioplasty,[9–11] lesion morphology remains the most important factor in the long term, with more favorable results achieved with short stenoses[12] than with long lesions or complete occlusions. One of the limitations of endovascular stenting for long femoropopliteal lesions is the incidence of stent fractures, which has been correlated with the length of the stented segment[13], although the mechanisms of stent fractures remain unclear, the non-physiological stiffening of the arterial segment by the stent may result in kinking and eventual fracture. Minor stent fractures may be relatively benign; in contrast, major stent fractures with complete separation of their fragments are the cause of restenosis and repeat interventions[14,15]. Therefore, the elimination of stent fractures and kinking might further improve the outcome of femoropopliteal stenting, particularly for long, complex lesions. Another limitation of conventional or standard slotted tube nitinol stents is their relatively low resistive radial strength. In particular, when implanted for complex, severely calcified lesions, eccentric plaques, or total occlusions, these stents may incompletely expand. A 30% residual stenosis is a standard criterion of technical success, which is achieved in 90% to 95% of procedures [16].

In our study, the primary techniqual success is 100% and this matches with most of the studies for the high immediate techniqual success but the primary patency rate at one year is 64.4% and this goes with the poor drawbacks of the mid-term & long-term patency of the popliteal stenting. However, shortcomings (e.g., stent fractures and incomplete stent expansion due to heavy calcification) were identified [17,18] particularly in longer stented segments and complex lesion morphologies. Our study also showed high incidence of stent fracture, 24% especially with long length stent.

The development of novel stent designs with high radial force and flexibility, such as the interwoven nitinol stents, (Supera stent) has addressed these issues. This matches with our study that showed 0% fracture rate with Supera stents but the main problem in this study, the small numbers of Supera stents that was included in this study (4 stents) and to prove the efficacy of this stent type for fracture resistance, a large numbers of this stent type should be included in further studies. In a recent study by Bausback et al.[19] involving recanalization of chronic femoropopliteal occlusions after failed guidewire re-entry, a, 30% residual stenosis was achieved in only 57% of cases. It is noteworthy that the failure to achieve a, 30% residual stenosis was associated with a significant decrease in long-term primary patency. While the patients included in our study were distinctly more challenging than average (more patients with TASC D lesions were included), these observations highlight the need for superior mechanical characteristics of the stent to achieve higher procedure success rates. The

woven nitinol wire design of the SUPERA stent used in this study satisfies to a large extent the requirements for a self-expanding SFA stent, namely, flexibility, compliance, resistance to fracture and kinking, and very high radial strength. Despite the challenging study population (21% total occlusions and primarily severe to critical limb ischemia), a 100% technical success rate was achieved, which resulted in significant clinical improvement. To achieve these excellent implantation results, we had to be precise during the stent implantation process than would be required with standard laser-cut nitinol stents. First, careful attention was paid to properly matching the stent diameter (1:1) to the reference vessel diameter to ensure that the stent could be deployed close to its nominal diameter, where it reaches its highest radial strength. It is of interest that only one patient in our study required open bypass surgery. The reasons are multifactorial. Many primary treatment failures were salvaged by repetitive endovascular procedures. A number of patients with open ulcerations or limited gangrene were able to heal their lesions before the failure of their percutaneous interventions. Moreover, to ensure optimal compliance of the vessel during stent deployment, the artery was systematically predilated using a balloon catheter with a diameter that was at least equal to the reference vessel diameter. Similarly, the primary and secondary patency rates of 64.7% and 70.5% at 12 months, respectively, are very encouraging and compare favorably with the reported literature. Limitations The main limitations of this study are its retrospective design, the absence of a randomized control group.

CONCLUSION

Popliteal artery stenting can be a good option of treatment for the aneurysmal dilation with low incidence of complications while for the atherosclerotic occlusive lesions; stents should be deployed as selective and not as primary option. With new development of stents manufacture e.g. Supera, primary popliteal artery stenting can be considered but prospective randomized large studies are needed to document the efficacy.

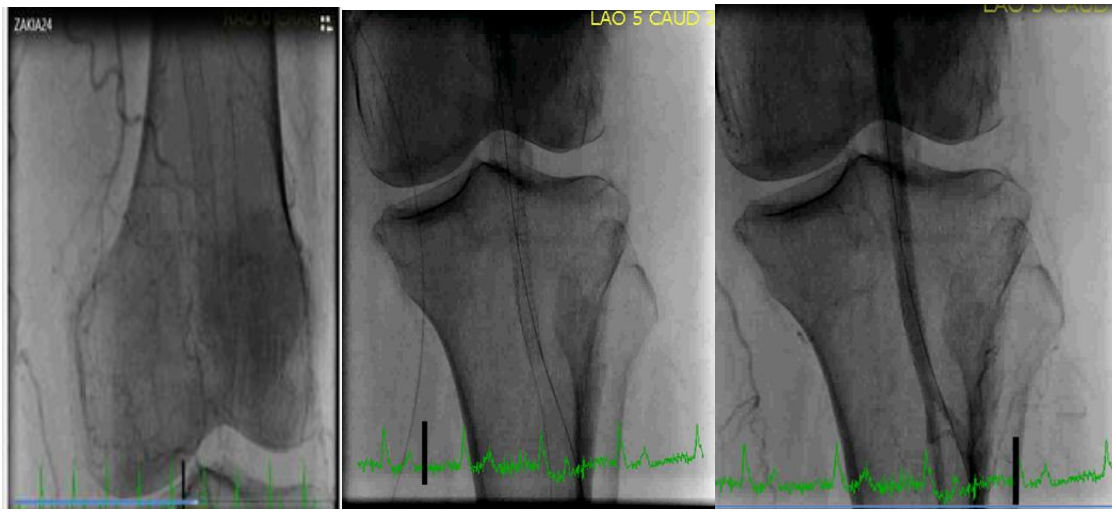


Fig. 2: Showed a case of total popliteal occlusion (TASC D) with Supera stent deployment

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