THE ENDOVASCULAR OPTIONS FOR MANAGEMENT OF SUPERFICIAL FEMORAL ARTERY OSTIAL LESIONS

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Abstract

Objectives: The aim of this work is to evaluate the different techniques of crossing the superficial femoral artery osteal occlusion in patients with critical limb ischemia or incapacitating claudication regarding the feasibility, patency, clinical success, limb salvage rates and complications.

Subjects and Methods: This was a prospective study conducted on 55 patients presenting to the vascular surgery unit of Beni Suef University Hospitals between January 2020 and December 2021.

Results: Lower limb pulse examination after the procedure revealed that 39 (70.9%) cases regained their pedal pulse, 12 (21.8%) cases regained only popliteal pulse and in 4 (7.27%) had no regaining of distal pulse due to technical failure.

Conclusion: Recent advanced endovascular facilities like drug eluting balloons and flexible stents are giving us promising future outcomes in the management of these lesions. Recurrence is not uncommon in PAD cases. The lesions characteristics, associated comorbidities, the presence of stent and run off vessels are playing important role of rate of recurrence. Regular follow-up depending on clinical assessment and non-invasive arterial investigations is a cornerstone in the management plan.

Keywords: Lower limb peripheral arterial disease, endovascular, drug eluting balloons, popliteal pulse.

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1. INTRODUCTION

Lower limb peripheral arterial disease (PAD) patients are complaining form functional limitation due to claudication, rest pain and the loss of tissue integrity in their lower limbs. The procedures of lower limb revascularization for limb ischemia are increasing significantly worldwide recently because of ageing populations, the people with atherosclerosis risk factors are also increasing **[1].**

Open surgical options for revascularization was the main line of management for achieving limb salvage in last decades; however, the morbidity and mortality rate in these procedures was significant **[2].**

Endovascular interventions has been known to be parallel to open surgical interventions in achieving limb salvage with a good patient survival **[3].**

The sub-intimal angioplasty techniques have great role in management of CLI cases. The efficacy of sub-intimal angioplasty techniques in limb salvage makes them an ideal first line management to long and/or totally chronic occlusive lesions of the SFA **[4].**

Endovascular surgeons who manage patients with critical lower limb ischemia are usually have a challenge with long lesions, multi-level diseases vessels or totally chronically occlusive lesions especially in the superficial femoral artery (SFA). SFA chronic total occlusions (CTOs), especially in the ostial segment, present the greatest operator challenge **[5].**

Although there are some clear advantages of sub-intimal dissection, it is unquestionable that a true lumen CTO crossing would be preferred because it is less complex and cumbersome and has a lower likelihood of procedural complications **[6].**

In about 15% to 25% of the cases, standard techniques using the cross over and the antegrade approach can`t cross total superficial femoral artery occlusions.

Furthermore, long superficial femoral artery occlusions without visible patent proximal stump can be catheterized using this technique **[7].**

The aim of this work was to evaluate the different techniques of crossing the superficial femoral artery osteal occlusion in patients with critical limb ischemia or incapacitating claudication regarding the feasibility, patency, clinical success, limb salvage rates and complications.

2. PATIENTS AND METHODS

This was a prospective study conducted on 55 patients presenting to the vascular surgery unit of Beni Suef University Hospitals between January 2020 and December 2021.

The study group includes patients with symptomatic atherosclerotic occlusive disease of osteal segment of SFA.

The aim of our study was to evaluate the different endovascular techniques of management the SFA osteal lesions in cases with critical limb ischemia or incapacitating claudication regarding the feasibility, patency, clinical success, limb salvage rates and complications.

Inclusion criteria: Cases are presenting with critical lower limb ischemia, cases are presenting with incapacitating claudication, all cases have osteal SFA lesions (no stump or stump < 1 mm) that determined by arterial duplex, CT arteriography or direct angiography and clinically and laboratory fitness for the procedure.

Exclusion criteria: Cases with lifestyle non limiting claudication, acute ischemia of the lower limb, non-salvageable lower limbs requiring primary major amputations, SFA lesions associated with arterial-venous malformation, SFA lesions associated with aneurysmal dilatation, connective tissue disorders or immunological disease and contraindications of contrast injection as sensitivity or renal impairment.

METHODOLOGY:

Data collection: Detailed and careful history taking was done for all cases including: Name, age and gender, complaint and present history, major risk factors for atherosclerosis including; Diabetes mellitus, smoking, hypertension, hyperlipidemia and ischemic heart disease, previous surgical or endovascular interventions and history of regular medications or allergies. Meticulous general examination of all cases included vital signs, bilateral carotid arteries pulse examination and auscultation for bruit, groin examination.

Pre-procedural investigations: Routine laboratory investigations as complete blood count, renal functions tests, hepatic functions tests, coagulation profile, blood glucose levels and lipid profile. Arterial scanning of lower limb tests were done either CTA or duplex scanning before the procedure for accurate diagnosis of the site and length of the lesion and the distal run off vessels. ECHO examination only for cases with history of cardiac disease. X ray foot was required only for cases of foot ulcers, infection or gangrene.

Technique of endovascular interventions:

Pre-intervention preparation: Cases were admitted to the vascular surgery unit of Beni-Suef University hospitals one day before or on the same day of the procedure: All cases signed an approved informed consent. Also, they were made fully aware about the intervention steps, expected benefits, risks, alternative interventions and possible complications.

Arterial access: The initial arterial accesses were obtained via the contra-lateral CFA using crossover sheaths. The contra-lateral CFA access was not available in some cases, trans-brachial access was tried.

Angiography: After the arterial access was punctured, a 6F sheath was inserted and free arterial flow was allowed to confirm the proper position of the sheath. 5000 IU of unfractionated heparin was administered through the arterial sheath. Angiography was done to confirm data obtained by pre procedural investigations using nonionic low osmolar contrast diluted to 50% with normal saline.

Crossing the lesion: The osteal SFA lesion was crossed by multiple techniques and equipment designed to each case. The common tools for recanalization of stenosis and occlusions consist of a 0.035 hydrophilic guide wire and an angled-tip catheter. Intraluminal technique was the initial technique for crossing SFA osteal lesions.

Angioplasty: A balloon catheter was selected for proper diameter and length. The balloon was directed over the guide wire to the distal end of the lesion. The balloon was inflated until any waist on the balloon had been abolished. Inflation time was two to three minutes. This step may be repeated until the whole lesion had been dilated.

End point: The endpoint of the intervention was unrestricted forward contrast flow through the managed SFA without evidence of significant (more than 30%) residual stenosis. At the end of the intervention, the arterial sheath should be removed and hemostasis was performed by manual compression for fifteen to twenty minutes.

Intervention outcome: The angiographic success was defined as unrestricted forward contrast flow through the managed SFA without evidence of significant (more than 30%) residual stenosis. Clinical success was defined as regain of pulse, revascularization warmness, edema and improvement of rest pain. Technical failure was defined as interventions couldn't to gain re-entry or had a restricted contrast flow through the managed arteries.

Follow up: All cases were followed with regular visits at one, three and six months or when new complaints arise. Follow up was performed by clinical examination with or without imaging studies if needed in cases of absent pulse, diminished pulse or recurrence of symptoms. Demographic data, clinical signs and symptoms, risk factors data, procedure data, intra and post-operative complications, primary and secondary outcomes were recorded. Also, any additional endovascular interventions 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 six months follow up.

Statistical analysis: Data were fed to the computer and analyzed using IBM SPSS software package version 20.0**. (**Armonk, NY: IBM Corp**)** Qualitative data were described using number and percent. Kolmogorov-Smirnov test was used to verify the normality of distribution Quantitative data were described using range (minimum and maximum),

mean, standard deviation, median and interquartile range (IQR). Significance of the obtained results was judged at the 5% level.

3. Results

This is a prospective study conducted on 55 patients presenting to the vascular surgery unit of Beni Suef University Hospitals between January 2020 and December 2021.

There were 29 (52.7%) patients of the studied cases were at age <65 years old and 26 (47.3%) patients were at age ≥65years old. The mean age was 65.82 ± 9.52 SD with range (49.0 - 95.0). There were 40 (72.7%) patients of the studied cases were males and 15 (27.3%) patients were females. **Table (1)**

Table (1): Distribution of the studied cases according to demographic data

Demographic data	No.	%
Age (years)		
<65	29	52.7
≥65	26	47.3
Min. – Max.	49.0 - 95.0	
Mean ± SD.	65.82 ± 9.52	
Median (IQR)	64.0 (59.50 – 71.0)	
Sex		
Male	40	72.7
Female	15	27.3

SD: Standard deviation IQR: **Inter Quartile Range**

According to TASC II classification, TASC II B were the most common cases by 40%, followed by TASC II D by 21.8% of cases and TASC II C cases by 20%. TASC II a cases were the least common by 18.2% only. **Figure (1)**

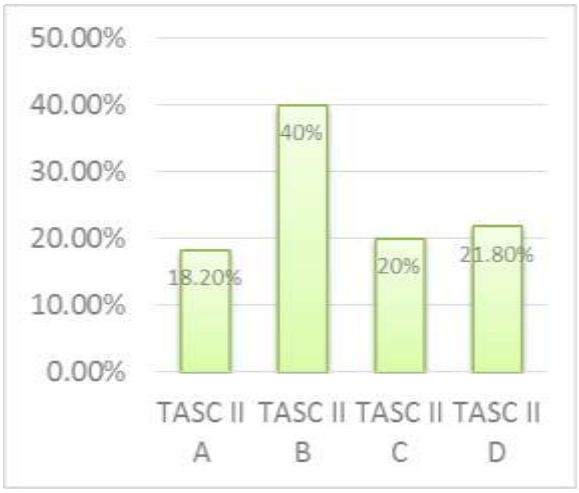

Fig (1): Distribution of the studied cases according to TASC II classification.

According to techniques of lesion crossing, there were 27 (49.1%) intra-luminal procedures, 25 (45.5%) sub-intimal procedure and in 3 (5.5%) cases had failed. **Table (2)**

Table (2): Distribution of the studied cases according to techniques of lesion crossing

	No.	%
Intraluminal	26	47.3
Sub-intimal	25	45.5
Failed	4	7.2

Selective stenting was done in 20 (36.4%) procedures only and 35 (63.3%) procedures were done without stenting. **Table (3)**

Table (3): Distribution of the studied cases according to stenting

Stent	No.	%
No	35	63.6
Yes	20	36.4

Lower limb pulse examination after the procedure revealed that 39 (70.9%) cases regained their pedal pulse, 12 (21.8%) cases regained only popliteal pulse and in 4 (7.27%) had no regaining of distal pulse due to technical failure. **Table (4)**

Table (4): Distribution of the studied cases according to technical success and regaining of distal pulse

	No.	%
Technical success		
No	4	7.3
Yes	51	92.7
Regaining of distal pulse		
No	4	7.3
Pedal pulse	39	70.9
Popliteal pulse	12	21.8

Review of our study showed that there was only 1 (1.8%) case of the studied cases complicated by CIN which responded to medical treatment within two weeks. Also, there were 6 cases (10.9%) developed access site hematoma, all of them managed by conservative treatment. Only 1 case (1.8%) complicated by access site pseudo-aneurysm managed by duplex guided compression. The majority of cases (87.3%) had no complications. **Table (5)**

Table (5): Distribution of the studied cases according procedure complications

	No.	%
CIN		
No	54	98.2
Yes	1	1.8
Access complications		
No complications	48	87.3
Mild Hematoma	6	10.9
Pseudo aneurysm managed by compression	1	1.8

Regular and careful follow up was scheduled for all cases in this study at one, three and six months after the procedure. The patency was kept in 51 (100%), 49 (96.07%) and 40 (78.43%) of all technical successful cases in one, three and six months respectively. The limb salvage was achieved in 51 (100%), 50 (98.04%) and 45 (88.23%) of all technical successful cases in one, three and six months respectively. **Table (6)**

Table (6): Distribution of the studied cases according to patency rate and limb salvage at 3 periods

	1 month		3 months		6 months		Q	p
	No.	%	No.	%	No.	%		
Patency rate								
No	**0**	**0**	**2**	**3.93**	**11**	**21.57**	**19.500***	**<0.001***
Yes	**51**	**100**	**49**	**96.07**	**40**	**78.43**		
Limb salvage								
No	**0**	**0**	**1**	**1.96**	**6**	**11.77**	**11.143***	**0.004***
Yes	**51**	**100**	**50**	**98.04**	**45**	**88.23**		

Q: Cochran's test
P: p value for comparing between the studied Periods
***: Statistically significant at p ≤ 0.05**

In this study, we lost only 3 (5.88%) cases during follow up due to death not related to the endovascular procedures. One case within three months and 2 cases within six months after the interventions. **Figure (2)**

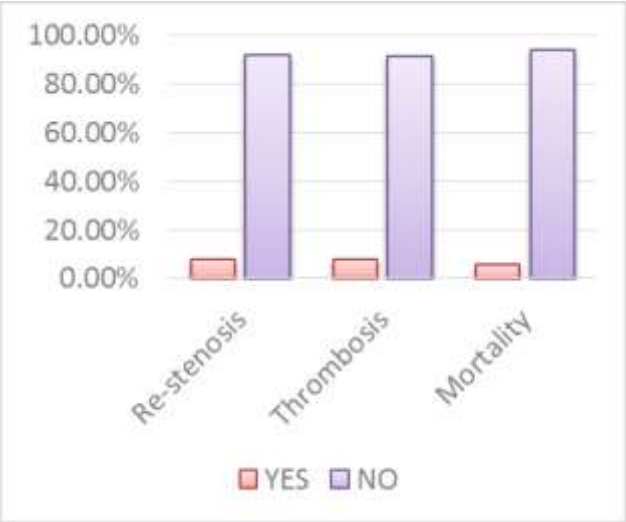

Fig (2): Distribution of the studied cases according to Post procedural complications.

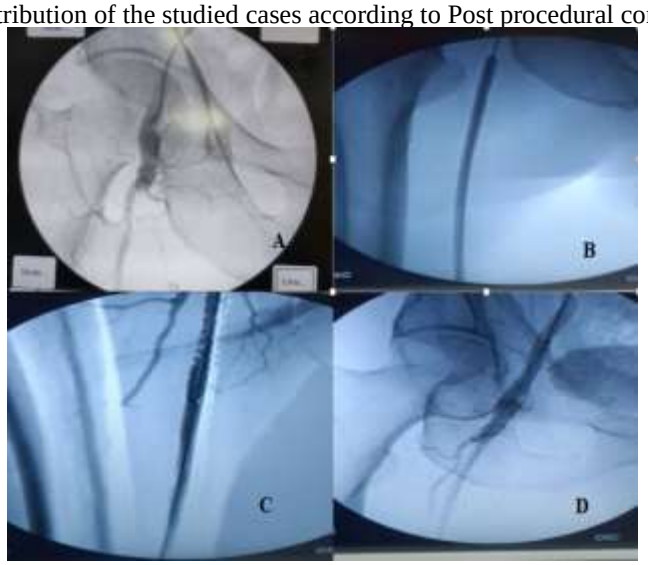

Fig (3): Case No. 1 with osteal SFA TASC II D occlusion managed by contra-lateral SFA access. Fig (A) is showing no stump of the SFA. Fig (B) is showing balloon dilatation of proximal SFA lesion after sub-intimal crossing of the lesion. Fig (C) and (D) are showing good contrast flow after stenting and successful revascularization.

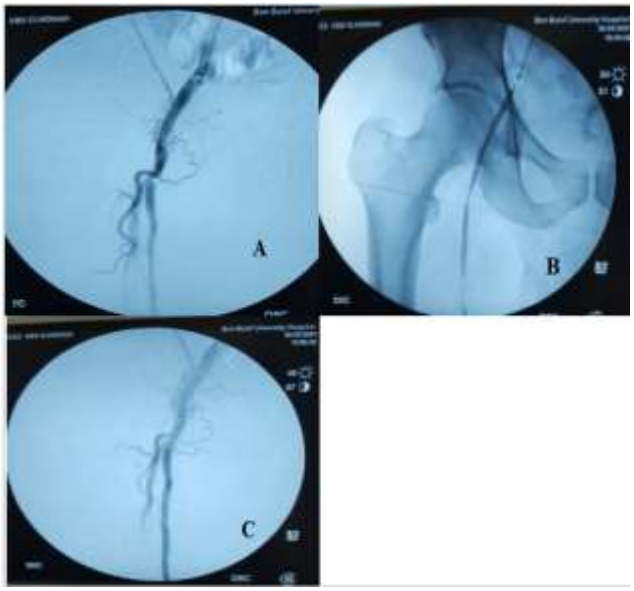

Fig (4): Case No. 2 with osteal SFA TASC II A lesion managed by contra-lateral SFA access. Fig (A) is showing osteal SFA stenosis lesion less than 10 cm in length without SFA stump. Fig (B) is showing balloon dilatation of proximal SFA lesion after intra-luminal crossing of the lesion. Fig (C) is showing good contrast flow through the SFA after successful revascularization.

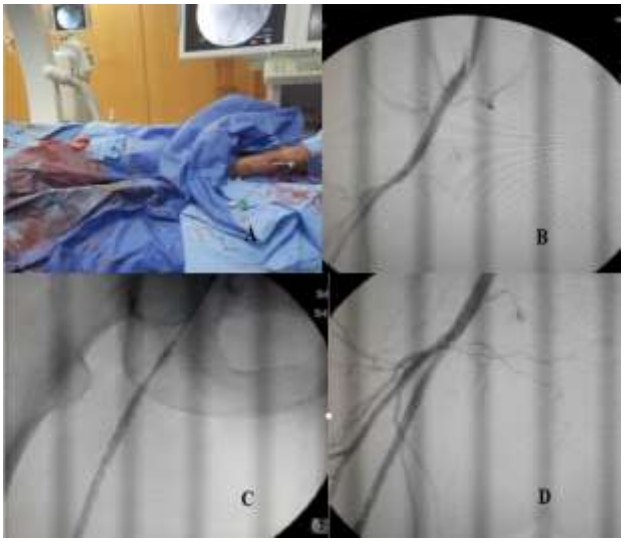

Fig (5): Case No. 3. Fig (A) is showing trans-pedal retrograde access. Fig (B) is showing osteal SFA TASC II B occlusion. Fig (C) is showing balloon dilatation of proximal SFA lesion after sub-intimal crossing of the lesion. Fig (D) is showing good contrast flow through the SFA after stenting and successful revascularization.

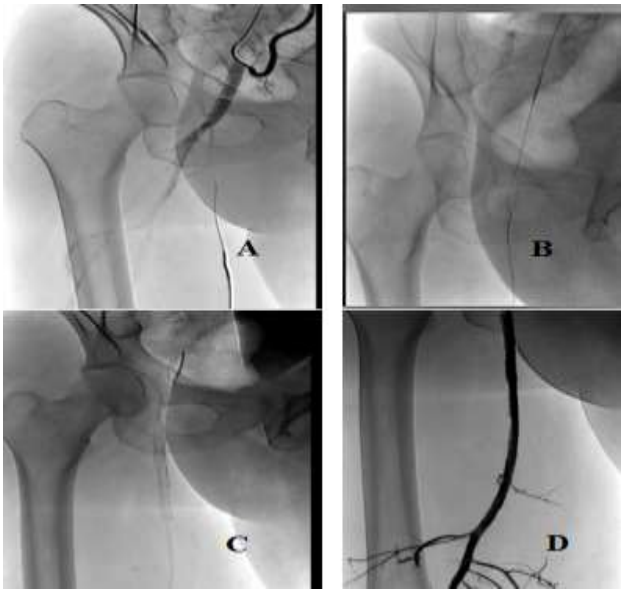

Fig (6): Case No. 4. Fig (A) is showing trans-popliteal retrograde access in case of osteal total occlusion of the SFA TASC II D. Fig (B) is showing successful wire crossing through the lesion. Fig (C) is showing stent insertion in the proximal SFA segment. Fig (D) is showing good contrast flow through the SFA after stenting and successful revascularization.

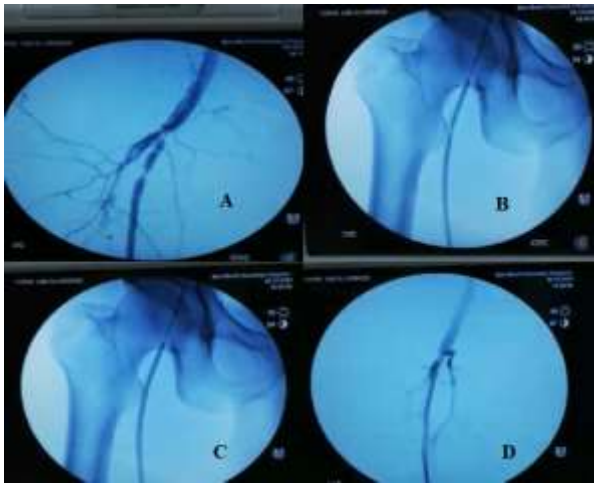

Fig (7): Case No. 5 with osteal SFA TASC II B lesion managed by contra-lateral SFA access. Fig (A) is showing multiple osteal SFA stenosis lesions, each one is less than 5 cm in length without SFA stump. Fig (B) and (C) are showing balloon dilatation of proximal SFA lesions after intra-luminal crossing of these lesions. Fig (D) is showing good contrast flow through the SFA after successful revascularization.

4. DISCUSSION

Nowadays, huge improvement in endovascular techniques and tools give the endovascular specialists the ability to manage these cases by variable procedures with promising results **[8].**

Our study was performed on 55 cases with symptomatic PAD due to osteal SFA lesions to evaluate the different endovascular techniques of management regarding the feasibility, patency, clinical success, limb salvage rates and complications.

The mean age in our study was 65.82 ± 9.52 SD years. Approximately, all data from the recent epidemiological studies referring increased incidence of PAD in elderly population. In 2021, Criqui and his colleagues reported that a systematic review of thirty-four researches (22 from high-income countries and 12 from low- and middle-income countries) explained that the incidence of PAD was about 5% at 40 to 44 years of age and about 12% at 70 to 74 years of age in both males and females **[9].**

The evidence of gender difference in PAD is less clear with differences between studies varying from marked male prevalence, equal prevalence to sometimes higher female prevalence. Male prevalence in our study was 72.7%. Utsunomiya and his associates evaluated gender difference in 616

inpatient with CLI and found 66% of patients are male. The marked difference of gender prevalence between studies may be due to the significant difference of life style between the cases in each study **[10].**

Ten cases (18.2%) in our study have history of previous revascularization procedures. Ruzsa and her team mentioned that they had 28% of cases in their study with previous revascularization procedures **[11]. [12]** reported 36.1% of their cases had previous history of peripheral vascular interventions

The presentation of cases in our study is varying between Fontaine stages IIB, III and IV. The distribution of these presentations is 14.5%, 32.7%, and 52.7% respectively. The distribution of presentations was 44%, 20%, 36% respectively by **[13]**. The study by **[14]**, it was 11%, 56% and 33% respectively. Also, distribution of presentations was 6.6%, 32.1% and 61.3% respectively by **[15]**.

In this study, all cases have osteal SFA lesions. We are classifying the lesions according to the TASC II classification. There are 10 cases (18.2%) TASC II A, 22 cases (40%) TASC II B, 11 cases (20%) TASC II C and 12 cases (21.8%) TASC II D. When this classification applied by **[15]**, they reported 7%, 18%, 35% and 40% respectively. **[16]** reported 33%, 51%, 11% and 5% respectively.

Our study conducted on 55 lower limbs, 25 cases 25% affected right side and 30 cases 30% affected left side. The study done by Farshidmehr and his team, they had 24 cases (45%) with right-sided lesions, 22 cases (40%) with left-sided lesions, and only 9 (15%) with bilateral lesions **[16]**.

Ismail and O.A., [18] mentioned that the access site in their study was contralateral CFA access (75%), trans-popliteal access (11.67%), trans-pedal access (13.33%). **[19]** had contralateral CFA access (88.5%), trans-brachial (1.9%) and trans-popliteal (9.6%) and.

Technical successes are defined as continuous arterial patency to the SFA without any obvious flow-limiting lesions (residual stenosis more than 30% or flow limiting dissection) or major extravasation. In our study, 51 cases (92.7%) have successful technical intervention. On the other hand, 4 cases (7.3%) are failed. The technical success rate was 83.3%, 96.3% and 100% by **[18].**

In 2021, Hamdy Hassan and his coworkers reported that the mean hospital stay was 1.6±0.35. While in 2018, Doshi and his coworkers reported that the mean hospital stay was 3 days (1-7). That is similar to the mean hospital stay in our study which is 1.53 ± 0.81 **[20].**

During the follow up of the studied cases, the patency was kept in technical successful cases at one, three and six months in 100%, 96.07% and 87.43% of cases respectively. These results agree with results of similar studies as **[21]** recorded that the patency rate was 100%, 91% and 86% at one, three and six months respectively. Also, **[22]** recorded that the patency rate in their study was 100%, 82% and 78% at one, three and six months respectively.

Regarding limb salvage after endovascular management of CLI, our study referred promising results regarding this target. We have 100%, 98.04% and 88.23% limb salvage rate at one, three and six months respectively. **[23]** had also promising results as 95%, 91% and 86% limb salvage rate at one, three and six months respectively.

During the follow up program, we discovered loss of patency in 4 (7.84%) cases of technical successfully group lost their primary patency due to re-stenosis at the 6th month follow up. All them had successful another endovascular revascularization procedures. Another 4 (7.84%) cases of the technical successful group in this study developed acute thrombosis. Only one case after 3 months and the other three cases after 6 months. Only one case had successful revascularization re-intervention by thrombolytic management. The remaining three cases underwent major amputation.

Eleissawy and his team discovered 12% cases with re-stenosis and 16% cases with acute thrombosis during the follow up visits **[13]**.

In this study, we lost only 3 (5.88%) cases during follow up due to death not related to the endovascular procedures. One case within three months and 2 cases within six months after the interventions.

5. Conclusion and Recommendations

Recent advanced endovascular facilities like drug eluting balloons and flexible stents are giving us promising future outcomes in the management of these lesions. Recurrence is not uncommon in PAD cases. The lesions characteristics, associated comorbidities, the presence of stent and run off vessels are playing important role of rate of recurrence. Regular follow-up depending on clinical assessment and non-invasive arterial investigations is a cornerstone in the management plan.

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