Does the Midterm Outcome of the Redo Endovascular Intervention Provide Satisfactory Results?

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ABSTRACT

The aim of the study was to demonstrate the feasibility and midterm patency of redo endovascular procedures for recurring symptomatic ischemia after previously successful endovascular revascularization. This is a case series study done among patients admitted in kasr AlAini teaching hospital in the period between August 2013 till May 2014, presenting with recurrent chronic ischemia after previously successful endovascular procedure. Patient demographics, indications for intervention, technique, patency and limb salvage and complications were recorded and analyzed. Results have shown that the mean age was 65 years and most of the cases were claudicants (50%) and having rest pain (45%).Technical success was 90% and limb salvage rate was 93.75% at 6 months although patency was 56.25%. Complications occurred in 6 cases. Redo endovascular intervention is an acceptable option for patients with critical limb ischemia (CLI) with multiple morbidities, short life expectancy and it can be repeated safely. But not recommended for young fit patients with intermittent claudication due to its very short midterm result, as durability of reintervention is further compromised and bypass for young fit patient with adequate single segment great saphenous vein (GSV) is better.

INTRODUCTION

Although open surgical bypass provides the most durable option for limb salvage in patients with (CLI) but it has substantial morbidity and mortality[HYPERLINK \l "Var" 1].The morbidity and mortality associated with endovascular therapy has been found to be less than that reported with traditional open surgical bypass.2]

Thus, many centers prefer to initially treat (CLI) patients with a less-invasive endovascular intervention instead of open bypass[HYPERLINK \l "Kud" 2]. Results of the Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) trial suggest that overall differences in amputation-free survival after endovascular intervention vs. bypass are insignificant3]

With the increase of use of endovascular procedures, the number of patients coming back with recurrent ischemia is increasing. Surgical management is the standard in these recurrent cases. However with increased experience and advancement of technology, there is greater enthusiasm of trying to manage these challenging cases with endovascular techniques again[HYPERLINK \l "Sul09" 4]

PATIENTS AND METHODS

This is a prospective case series study done among patients admitted in kasr AlAini teaching hospital in the period between August 2013 till May 2014.

Patients presented with critical limb ischemia or lifestyle limiting claudication 1 month or more after previously successful endovascular procedure were included in our study. Patients with renal insufficiency or acute ischemia were excluded.

The patients were subjected to history taking for the previous intervention criteria and were clinically examined for proper assessment of their condition.

Duplex ultrasound (DUS) was done, a decline in Ankle Brachial pressure Index (ABI) of 0.15 or more from the previous post intervention ABI or peak systolic velocity ratio (PSVR) of 2.4 or more or re-occlusion of the previously treated lesion was considered a proof for recurrence. CT angiography was done in selected cases with inadequate duplex study.

A loading dose of clopidogrel 300 mg was given the night of the procedure, both groins were

prepared using an antiseptic solution (povedine iodine 10%). All equipment were checked.

The patient lies in the supine position and a local anesthetic is infiltrated at the artery puncture (xylocaine 2%). A femoral access was established. Antegrade access was planned in all infra-inguinal lesions except if the lesion was in proximal superficial femoral artery (SFA) or if the lesion was in the iliac artery, contralateral femoral access with crossover was used. Six Fr sheath was used in all cases.

Lesions were crossed by 0.018" guide wire with catheter support, if failed, subintimal approach with standard angled Terumo guidewire (0.035") was considered. Low profile balloon catheter was inserted over the guidewire, multiple inflations done from distal to proximal. Non compliant balloon were selectively used for resistant lesions. Longer inflation (>3 min) was adopted if dissections occurred. Stents were used selectively when there was flow limiting dissection or elastic recoil or residual lesion >30%.

Angiographic success of the procedure was defined as satisfactory completion angiogram with no flow limiting dissection nor residual lesion >30% of the proximal healthier artery. Clinical success was defined as restoration of palpable distal pulse, reperfusion warmth and improved venous filling time. Sheath was removed at the end of the procedure if only 5000iu of heparin was given, after a duration of two hours. If more than 5000iu of heparin was given or the duration was less than 2 hours, then the patient was discharged to the ward with the sheath inside, removed after 6 hours and normalization of the APTT.

The complications occurred were recorded. Debridement of foot lesions or minor amputations were done before discharge.

Patients were scheduled for follow up at 1,3 and 6 months in the outpatient clinic to assess their pulses, healing of the wounds or improvement in claudication distance. DUS was done at 1,3 and 6 months.

RESULTS

This is a case series study included twenty patients with recurrent lower limb ischemia after they had successful endovascular procedure one month or more before. They were done at Kasr AlAini teaching hospital in the period between August 2013 - May 2014.Their demographics and risk factors are listed in table 1

Table 1: Demographics and risk factors

Males / female	**No 17/3**	**85%/ 15%**
Age		
55-59	2	10%
60-64	8	40%
65-70	10	50%
Smoking	13	65%
Diabetic	13	65%
Hypertension	18	90%
Cerebrovascular disease	7	35%
Ischemic heart disease	15	75%

The presenting symptoms and indications for intervention are listed in table 2 and sites of lesions are listed in table 3

Table 2: Presenting symptoms and indications for intervention

Rest pain	10	50%
Intermittent claudication	9	45%
Tisuue loss	1	5%

Table 3: Site of the lesions

EIA restenosis	2	10%
SFA restenosis after POBA	4	20%
SFA instent restenosis	3	15%
SFA reocclusion after POBA	4	20%
SFA denovo stenosis	3	15%
SFA denovo occlusion	1	5%
IPD reocclusion	1	5%
IPD recurrent stenosis	2	10%

EIA :external iliac artery, SFA :superficial femoral artery.
IPD :infrapopliteal disease, POBA: plain old balloon angioplasty.

Restenosis of the same lesion occurred in 11 patients (7 in SFA, 2 in EIA and 2 in IPD) while re-occlusion occurred in 5 patients (4 in SFA and

1 in IPD). Denovo stenosis occurred in SFA of 3 patients while denovo occlusion occurred in SFA of one patient.

Antegrade ipsilateral femoral access was used in 15 cases and 3 retrograde contralateral femoral access with crossover for 3 femoral lesions and 2 retrograde femoral access for 2 iliac lesions.

Crossing transluminal with 0.018" guidewire and microcatheter support was successful in (6) of the successful cases and in (12) of the successful cases were crossed subintimally with standard angled tip hydrophylic 0.035" guidewire.

Stenting was done in 11 cases (55%) : (2) cases with EIA restenosis, (3) cases with SFA instent stenosis, (4) cases with SFA reocclusion and (2) cases with SFA flow limiting dissection.

Technical success was 90% (18) cases with 2 failed cases. One case with failed crossing in a claudicant patient and continued on conservative management without limb deterioration. The another case had acute thrombosis in a patient with IPD during the procedure and he had below the knee amputation.

Complications occurred in 6 cases, 3 cases developed small groin hematomas that were managed conservatively and resolved spontaneously with observation. One case developed femoral artery pseudoaneurysm managed by successful duplex guided compression and one case developed contrast induced nephropathy which was temporary and resolved after 10 days with just good hydration and did not need dialysis and the last complication was the patient that developed acute thrombosis during the procedure that could not be managed by endovascular means.

All patients were followed for 6 months except one case which was missed. At one month : one patient died after he developed myocardial infarction and one patient developed spreading infection after previous forefoot amputation and he had a lifesaving below the knee amputation. At 3 months, the outcome was the same at one month follow up and there were no changes.

At 6 months : 6 patients had the target lesion of revascularization occluded. 3 cases of SFA instent stenosis and the 3 IPD cases. But the occlusion did not affect limb salvage as all foot lesions were healed by this time.

Table 4: Limb salvage rate and patency rate

	Limb salvage	**Patency**
1 month	15/16 (93.75%)	16/16 (100%)
3months	15/16(93.75%)	16/16 (100%)
6 months	15/16(93.75%)	9/16 (56.25%)

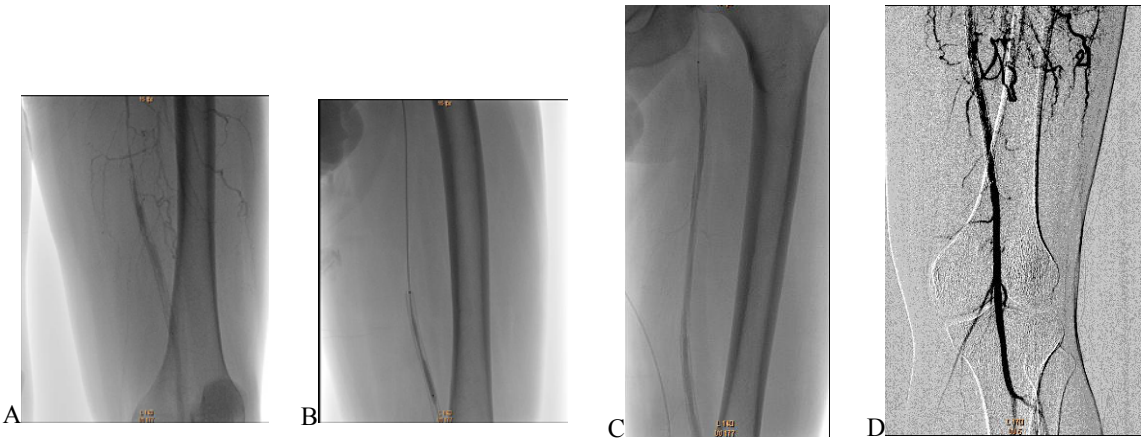

Figure 1 : A case of occluded popliteal stent. A: shows the occluded stent; B: PTA of the stent, lead to unsatisfactory result; C: new proximal stent overlapping the old one with good flow; D : good angiographic result.

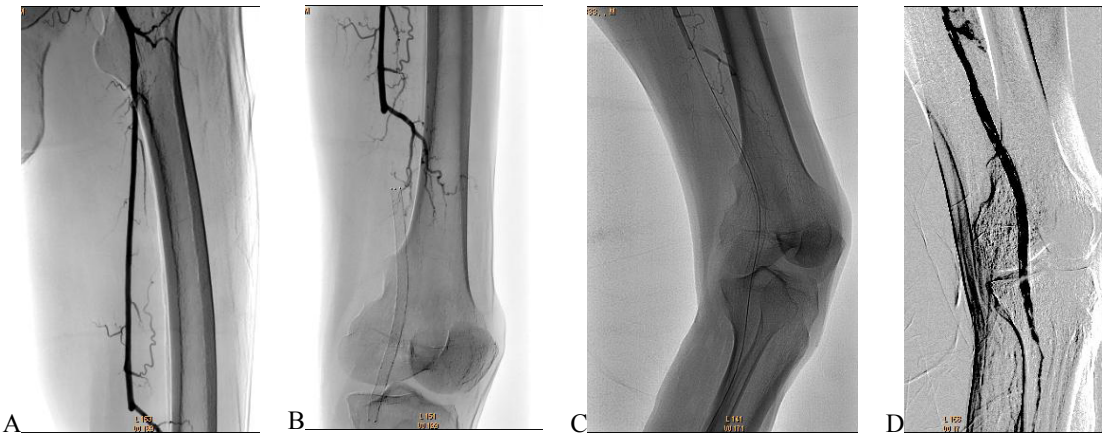

Figure 2: A case of popliteal stent occlusion. A : occlusion of SFA few cm above the stent ;B : lower extent of the stent in P3 ;C :PTA of the stent ; D : result after PTA , another proximal overlapping stent was inserted (not shown)

DISCUSSION

Treatment of recurrent symptomatic or limb threatening ischemia by open surgical bypass is the standard line due to its high durability especially with great saphenous vein, but is also associated with high morbidity as anesthesia complications, wound complications as well as CVS in the early postoperative period which may increases the mortality related to the procedure.[1] Moreover, in many studies, the hospital stay in open surgery is longer than endovascular procedures which in turn makes the costs not significantly lower than that of endovascular procedures.[5]

Morbidity and mortality after endovascular procedures is far less than surgery which made many surgeons offer and prefer endovascular 1st policy especially in this aged highly moribund patient population even if the midterm result are still lower than that of bypass[2].The opinion is based on 2 concepts the 1st is the situational perfusion enhancement which states that the wound needs higher perfusion during the healing process than in the healed state and so after healing, even if restenosis or reocclusion occurs, there may be no need for further intervention. This is clearly demonstrated in the higher limb salvage rates compared to patency rates in other studies[6] including our study. The 2nd concept is that endovascular intervention can be repeated easily with acceptable midterm patency and limb salvage as shown in our study.

The aim of this study was to demonstrate the feasibility and midterm patency of redo endovascular procedures in symptomatic recurrent ischemia after previously successful endovascular revascularization. Our study population was similar to most other studies showing the classic risk factors of atherosclerosis.[6][1]

Only 5 % of our patients had tissue loss, that explains why our limb salvage rate was very good (93.75%) as the most important risk factor for limb loss after endovascular procedure is tissue loss which is usually associated with multilevel occlusion and poor runoff[7].

Two of our cases were recurrent EIA stenosis after <6 months of previous intervention which shows that stenting should be strongly considered in iliac artery stenosis especially if there are no tools of pressure gradient measurement across the lesion. Also the patency of the same lesions in our study of more than 6 months after insertion of stents, further emphasizes this concept.[8].

Results of SFA POBA has been shown to be poor and that PTA without drug coated balloons (DCB) is unacceptable option except for the very focal (<5cm) lesion as shown in 4 cases of early recurrence of SFA lesion post POBA only. [9]

SFA instent stenosis remains a big challenge to endovascular techniques. Three of our cases developed instent stenosis in <6 months. All of the cases in our study were managed by instent stenting, all occluded by<6 months of follow up which shows that stenting is not the ideal treatment for this problem. Several studies have shown that debulking [10] and DCB [8] [11] may

improve the results but still the bypass should be considered in these cases if they are fit and have an adequate vein.

Four cases of denovo SFA lesions showed that control of risk factors of atherosclerosis is even more important than treatment at the target lesion, it has been shown by[9] that control of risk factors, improves survival as patients with intermittent claudication has 5years survival rate of 70% which is comparable to many cancers[12].

Sixty six percent of our lesions(N=12/18) were crossed by SIA, but the main problem was reentry at the end of the occlusion without disturbing any collateral and without crossing the knee in SFA cases which is sometimes difficult. That's why we prefer intraluminal approach with 0.018"GW and catheter support but unfortunately it was successful only in 30% of the cases. This correlates well with what is reported in the literature about the superiority of the subintimal crossing of long occlusions[13] ,[14] and [4]

Our technical success rate was (18/20) 90% which is comparable to most studies, [15][16] showing that redo endovascular intervention is feasible and can be repeated easily.

Three of our cases developed groin hematoma and one had pseudoaneurysm (20%) which may show that the policy of on table removal of the sheath without Aptt (activated partial thromboplastin time) may be inappropriate. But as the three hematomas were small and resolved spontaneously, this shows that endovascular intervention is a safe procedure.

Limb salvage rate was 93.75%.at 6 months as compared to patency rate (56.25%) which demonstrates the concept of situational perfusion enhancement[4]

CONCLUSION

Redo endovascular intervention is an acceptable option for patients with CLI with multiple morbidities, short life expectancy, can be repeated safely. But not recommended for young fit patients with intermittent claudication due to its very short midterm result, as durability of reinvention is further compromised and bypass for young fit patient with adequate single segment GSV is better.

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