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# INFRAPOPLITEAL ENDOVASCULAR INTERVENTION IN PATIENTS WITH CRITICAL LIMB ISCHEMIA AND ISOLATED BELOW-THE-KNEE LESIONS: A SINGLE-INSTITUTIONAL EXPERIENCE.

Cardiology

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## ABSTRACT

Recent development in endovascular intervention hardwares has made it the first choice strategy for the management of complex below-the-knee (BTK) and below-the-ankle (BTA) disease in critical limb ischemia (CLI). We retrospectively investigated 36 patients (31 males and 05 females, mean age 48 ± 18 years) with BTK disease presenting with CLI undergoing infrapopliteal endovascular intervention at a single center in northern India between January 2017 and December 2018. Infrapopliteal percutaneous transluminal angioplasty (PTA) was performed on the primary target lesion, which was decided by the wound location based on the angiosome concept. All patients were followed up at regular intervals with clinical assessment of wound healing and peripheral pulses as well as ankle brachial index measurement and duplex imaging. Technical success rate was 89%. Primary patency rates were 94% at 6 months and 81% at 1 year. Infrapopliteal endovascular intervention with BTK angioplasty in patients with CLI is effective and safe in terms technical success rate and primary patency rate.

## KEYWORDS

BTK intervention, Critical limb ischemia, Tibial PTA, Infrapopliteal arterial disease.

## INTRODUCTION:

Critical limb ischemia (CLI) is a limb and life threatening condition with an alarmingly increasing incidence rate in north Indian population, particularly among adults who are smokers and tobacco chewers. Infrapopliteal arterial occlusive disease is a leading cause of CLI. Recent development in endovascular intervention hardwares has made it the first choice strategy for the management of complex below-the-knee (BTK) and below-the-ankle (BTA) disease in CLI. We present the immediate and medium term clinical results of infrapopliteal endovascular intervention in patients with CLI and isolated BTK lesions in north Indian population.

### Material and Methods:

For this study, we retrospectively analyzed the subset of patients in our peripheral artery disease registry with isolated BTK disease presenting with CLI who underwent angiosome-targeted infrapopliteal endovascular intervention (n=36; 31 males and 05 females) at Uttar Pradesh University of Medical Sciences between January 2017 and December 2018. The procedure was explained to all the patients, as well as the possible complications, and written informed consents were obtained.

Indication for endovascular intervention was technical inoperability by peripheral bypass surgical procedure due to poor saphenous vein, inadequate distal runoff or landing zone. Exclusion criteria were acute total occlusions, significant coexisting suprapopliteal lesions, no distal reconstitution of any of the three leg arteries and extensive infection or tissue loss above ankle joint.

All patients were assessed clinically and investigated with a combination of imaging (duplex ultrasound, digital subtraction or computed tomography angiography) and physiologic measurements (ankle-brachial index and toe pressure) prior to treatment. A retrograde contralateral 'crossover' approach was preferred for diagnostic angiography to delineate any coexistent significant inflow lesions (iliac, femoral or popliteal) which were treated first and BTK revascularization was done a few weeks later, as a staged procedure if required, and such patients were excluded from the study.

All the patients had CLI (Rutherford category 4 to 6) with infrapopliteal target artery stenosis or chronic total occlusions (CTO) [Trans Atlantic Inter-Society Consensus (TASC) B, C & D lesions] and mean lesion length of 189 ± 82mm. CLI was defined as Rutherford category 4 (Ischemic rest pain), category 5 (Minor tissue loss-nonhealing ulcer, focal gangrene) or category 6 (Major tissue loss-extending above transmetatarsal level) with a reduced ankle-brachial index (ABI) to a level of ≤0.4, an ankle systolic pressure of <50 mmHg or a toe pressure of <30 mmHg in category 4 patients; or ABI≤0.5, ankle systolic pressure of <70 mmHg or a toe pressure of <50 mmHg in category 5 and 6 patients.(1) Most of the patients were on DAPT (Ecospirin 150mg plus Clopidogrel 75mg) and Cilostazol 100mg for at least a month pre-intervention with no symptomatic improvement.

All patients were followed up at regular intervals (weekly for a month, fortnightly for 3 months, and then at 6 and 12 months) with clinical assessment of wound healing and peripheral pulses as well as ABI measurement and duplex imaging. Any further treatments including surgical debridement and amputation procedures during follow up period were recorded. Study end points were technical success rate (defined as successful restoration of inline flow to the foot supplying the area of tissue loss and complete recanalization with residual stenosis of <30 %), primary patency rates at 6months and 1year and limb salvage (defined as freedom from major lower extremity amputation, above ankle or below knee). Partial success was defined as successful recanalization of the tibial vessel but with limited flow into the plantar arch.

### Intervention Procedure:

Endovascular procedures were performed in a dedicated angiographic suite under local anesthesia, sterile draping and continuous monitoring. Loading dose of Ecospirin 300mg plus Clopidogrel 150mg was given 2 hours before procedure to all the patients who were not on DAPT preoperatively for at least a week. Antegrade ipsilateral CFA access was established with 5 French introducer sheaths ('Avanti', Cordis). Selective arteriography and/or digital subtraction angiography was obtained to delineate the lesions, which were classified based on the TASC II anatomic classification system for infrapopliteal arterial disease.(2) Heparin was given intra-arterially to maintain an activated clotting time of 200 - 250 seconds.

We performed infrapopliteal percutaneous transluminal angioplasty (PTA) on the primary target lesion, which was decided by the wound location based on the angiosome concept. The cases where recanalization of the target artery failed, intraluminal or subintimal, PTA was attempted on another infrapopliteal non target artery. In patients with extensive wounds, PTA was performed for two or three infrapopliteal arteries regardless of the angiosomal supply.

Intraluminal negotiation of the primary target lesion was attempted initially with 0.014"/ 0.018" guidewire ('V-14, V-18', Boston Scientific) with the support of a 4F MPA diagnostic catheter or a low profile 2.0-2.5mm PTA balloon catheter, guided by roadmap. In cases with failed intraluminal negotiation in chronic total occlusions (CTO), subintimal tracking of the wire was attempted (n=10). Our initial attempt was antegrade guidewire passage in all the patients, failing which retrograde doppler guided puncture or pedal-plantar looping technique was attempted. After successful crossing of the lesion, intraluminal position of the catheter/ balloon tip was verified by contrast injection, catheter was exchanged with an appropriate PTA balloon catheter and angioplasty was done with nominal inflation for 3 minutes.

PTA balloon dimensions were chosen according to reference vessel diameter and lesion length by visual or quantitative vessel analysis. Low profile 4Fr, over-the-wire (OTW), 0.018" wire compatible, semi compliant PTA balloon catheters ('Sterling', Boston Scientific) were used for angioplasty. Drug coated balloons (DCB) ('Ranger', Boston Scientific) were used in TASC II C and D lesions. No stent or atherectomy device was used in our cohort.

Post angioplasty, a cocktail of nitroglycerine, diltiazem and heparin was used to flush the vessels to relieve spasm. All attempts were made to improve tibial runoff up to the plantar arch with additional below-the-ankle angioplasty of significant distal stenosis or occlusions. After completion angiography, the femoral sheath was removed and manual compression applied for 10 minutes. No haemostatic device was used. Post procedural care: DAPT (tablet Ecospirin 150mg plus Clopidogrel 75mg) for 12 weeks followed by Ecospirin 150 mg thereafter. Aggressive risk factor modification therapy for diabetes, hypertension, dyslipedemia, smoking and sedentary lifestyle was advised. Wound care protocol was strictly adhered to.

## RESULTS:

Between January 2017 and December 2018, 36 patients (31 males and 05 females; mean age 48 ± 18years) with isolated BTK disease presenting with CLI underwent angiosome-targeted PTA at our center. Among the cardiovascular risk factors, smoking/ tobacco chewing was associated in 78%, which is a significant health problem in this part of our country. Hypertension (22%), hyperlipidemia (14%) and diabetes (11%) were the major comorbidities. Rutherford category 5 (53%) dominated the clinical presentation at our centre with most of the patients presenting late after disease onset. (Table 1)

**Table 1: Baseline patient characteristics**

| | N | % |
|---|---|---|
| No. of patients | 36 | |
| Mean age ± S.D.(years) | 48 ± 18 | |
| Males | 31 | 86 |
| Females | 05 | 14 |
| Cardiovascular risk factors | | |
| Hypertension | 08 | 22 |
| Smokers/ Tobacco chewers | 28 | 78 |
| Diabetes | 04 | 11 |
| Hyperlipidemia | 05 | 14 |
| Coronary artery disease | 02 | 05 |
| Renal disease | 02 | 05 |
| Stroke | 01 | 03 |
| Clinical presentation (Rutherford Category) | | |
| Category 4 | 05 | 14 |
| Category 5 | 19 | 53 |
| Category 6 | 12 | 33 |
| Ankle-brachial index (on admission) 0.38 ± 0.16 | | |

TASC-C lesions predominated among the BTK involvement with the mean lesion length of the target tibial artery being 189 ± 82mm (CTO and stenosis >70%).

Angiosome-targeted PTA procedures were done in anterior tibial artery (ATA) ± dorsalis pedis artery (DPA) (28%), posterior tibial artery (PTA) ± common plantar artery (CPA) / lateral plantar artery (LPA) (44%), peroneal artery (06%) and a combination of two vessels in 22% of the cases. PTA procedures were extended BTA, if necessary, to establish inline flow to the plantar arch (PA). (Table-2)

**Table 2: Angiographic and procedural data**

| | N | % |
|---|---|---|
| No. of legs | 36 | |
| Mean procedural time ± S.D. (minutes) for revascularization | 75 ± 38 | |
| Mean lesion length ± S.D. (mm) | 189 ± 82mm | |
| TASC Classification of BTK lesions | | |
| TASC-B | 12 | 33 |
| TASC-C | 18 | 50 |
| TASC-D | 06 | 17 |
| Angiosomal artery targeted for PTA | | |
| ATA ± DPA/PA | 09 | 28 |
| PTA ± CPA/LPA/PA | 14 | 44 |
| Peroneal artery | 02 | 06 |
| Combination of two arteries | 07 | 22 |
| Intervention procedure | | |
| Intraluminal PTA | 21 | 66 |
| Subintimal PTA | 11 | 34 |
| Retrograde PTA by distal puncture | 04 | 12 |
| Retrograde PTA by 'pedal plantar loop' technique | 03 | 09 |
| Transcollateral revascularization | 01 | 03 |
| PTA | 24 | 75 |
| PTA + DCB | 08 | 25 |
| Balloon for PTA of infrapopliteal arteries, 4Fr compatible | | |
| Mean diameter ± S.D. (mm) | 2.5 ± 0.5 | |
| Mean length ± S.D. (mm) | 150 ± 50 | |
| PTA for a longer inflation time of 4 minutes (second dilatation) | | |
| Suboptimal angioplasty | 04 | 12 |
| Flow limiting flap or dissection | 02 | 06 |
| Fluoroscopy time (minutes) | 24 ± 14 | |
| Total contrast (ml) | 50 ± 25 | |

In 02 cases with subintimal negotiation, reentry into the true lumen distally failed, despite all maneuvers. Both these patients were managed by doppler guided distal puncture and retrograde revascularization. In 02 cases with flush occlusion of anterior tibial artery at popliteal artery bifurcation, antegrade negotiation failed following which distal ATA puncture under doppler guidance and retrograde revascularization was done successfully.

In 06 cases antegrade negotiation of guidewire, intraluminal or subintimal, into the tibial vessel failed due to ostial occlusion/ dense fibrotic occlusion, and retrograde revascularization by 'pedal plantar loop' technique was successfully performed in 03 cases out of these. (Table 2)

In 04 cases of suboptimal angioplasty and 02 cases with flow limiting dissection, a second dilatation with balloon for a longer inflation time of 4 minutes was performed. No bailout stenting was done. One procedure required transcollateral revascularization. In 05 patients with B/L L.L. involvement BTK angioplasty was done in a staged manner after 2-4 weeks.

Subjective improvement in pain was observed all the patients post procedure. There was no access site related complication. All the patients were discharged in 4-12days.

Technical success rate was 89%. Primary patency rates were 94% at 6 months and 81% at 1 year. Target lesion revascularization rate was 06% at 6 months (02 patients with restenosis underwent PTA with drug coated balloons and both these cases were patent 6 months post procedure). Partial success was achieved in 04 cases with successful recanalization of the tibial vessel but with limited flow into the plantar arch and distally, all of these improved clinically and underwent limited amputation of the gangrenous toes and forefoot with successful stump healing.

## DISCUSSION:

PTA is an established alternative to surgical bypass in peripheral arterial disease with lower perioperative morbidity and mortality, high technical success and equivalent limb salvage rates.(3-5) Though the BASIL trial suggested that bypass should be offered first over balloon angioplasty in patients with available venous conduits who are expected to live longer than two years, this study was not specific to infrapopliteal disease encompassing all infrainguinal disease. Many further series have demonstrated similar survival and limb salvage rates in bypass and PTA group.(6-8)

Recent development in endovascular intervention hardwares like low-profile PTA balloon catheters, dedicated guidewires for negotiating CTO, guide catheters, drug coated balloons etc. has made it the first choice strategy for the management of complex BTK and BTA disease in CLI. Dedicated PTA balloons of 1.5 to 2.0 mm calibre suitable for plantar arch or plantar arteries are now available conferring an insurmountable lead to endovascular interventions vis a vis open surgical procedures.

Technical success rates of infrapopliteal PTA are reported to be as high as 80-100 %.(9-10) Up to 80 % 2-year limb salvage rates after PTA are reported, but this depends on the clinical and anatomical extent of disease.(11) Factors to be considered when choosing between PTA and bypass surgery for BTK disease should include the anatomic extent and location of the disease and the anticipated morbidity and mortality of the procedure, which seems lower with endovascular treatment than with bypass surgery.(12)

As shown in our case series, infrapopliteal endovascular intervention in patients with CLI is effective and safe in terms of primary procedure success. Our initial attempt was intraluminal negotiation of guidewire in most of the patients, failing which subintimal intervention was tried. Failure of antegrade negotiation of guidewire necessitated the utilization of various techniques like doppler guided distal puncture, 'pedal plantar loop' technique across the plantar arch and transcollateral revascularization techniques. This explains our excellent technical success rate of 89% despite the fact that 67% of the cases done were TASC- C & D lesions.

Primary patency rates in our study were 94% at 6 months and 81% at 1 year. Our emphasis is always on establishing in-line flow up to the plantar arch, preferably via the angiosomal artery, failing which via the non-target artery, which ensures a respectable primary patency rate even after one year. Patient's poor compliance with post procedure treatment and persistent tobacco consumption, which is a significant health problem in north India, also influences the primary patency rate.

During the follow-up period of 15.2 ± 5.4 (range 10-21) months, the ABI increased from an initial 0.38 ± 0.16 at admission to 0.92 ± 0.12 at discharge and was 0.88 ± 0.14 at 6 months and 0.85 ± 0.18 at 1 year.

Complete wound healing was 91% at 6 months. All the patients showed limitation of spread of gangrene with formation of clear line of demarcation. 06 patients underwent limited amputation of the gangrenous toes and forefoot with successful stump healing. No major amputation was performed. There was no mortality in the follow up period.

Presence of diabetes, hypertension and renal impairment were negative predictors for long term patency and wound healing. Positive predictors of wound healing were technical success and preserved flow to the foot via a tibial artery.

### Study limitations:

There were certain limitations to our study. This was a retrospective observational study with a small sample size; hence the potential for selection and information bias exists. Also since our series represents the experience of one operating endovascular surgeon at a single institution, the results are subject to the influence of specific intra-institutional referral patterns, surgeon experience and patient selection preferences. The pre and post procedure medical management protocol was not uniform; it was rather tailored to specific patient profile. The small sample size, heterogeneity of treated tibial segments, the medium term follow up, endovascular first approach and tailored post procedure medical management protocol as per patient profile should be considered in the interpretation of these results.

## CONCLUSIONS:

Infrapopliteal endovascular intervention with BTK angioplasty in patients with CLI is effective and safe in terms technical success rate and primary patency rate. Periprocedural adjunctive procedures and secondary interventions may be necessary to maintain target vessel patency. The procedure is safe with no major access site complications. With competitive immediate and mid-term results, it can be considered the primary revascularization strategy in these patients.

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