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Outcome of Single Tibial Artery Angioplasty in Critical Limb Ischemia

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Abstract: Peripheral arterial disease (PAD) presents with 12% to 20% of the elderly patients (aged 65 years and older). Critical limb ischemia (CLI) represents the most severe form of PAD; which is a severe obstruction of the arteries which markedly reduces blood flow to the extremities (hands, feet and legs) and has progressed to the point of severe pain and even skin ulcers or sores. In daily practice, CLI patients often have significant lesions in both the anterior tibial artery (ATA) and the posterior tibial artery (PTA). In patients who have progressed to CLI, revascularization of the affected extremity through endovascular intervention plays a crucial role in staving off limb loss, prolonging survival, and improving their quality of life. The aim of this work was to evaluate the outcomes and advantages of single tibial artery angioplasty in critical limb ischemia. In this one arm observational prospective study; 40 patients were selected from the Department of Vascular Surgery- Ain Shams University Hospital from the period of June to December 2018. Patients were subjected to Duplex study and Computerized tomography (CT) angiography for investigation. Patients were treated by single vessel infra-popliteal PTA with or without stent and balloon. Post-intervention medical treatment included: **Anti-coagulants & Anti-platelets. Outcome within one month. Complications, Length of stay in hospital & Mortality.**

- Wound healing at three and six months (Complete or Incomplete).

Our results showed that:

1. The mean of age was 60.525 ± 4.013 years. 26 patients (65%) were male while 14 patients (35%) were female. BMI was 23.075 ± 4.299 kg/m^2

2. Regarding the past medical history, hypertension was found in 30 patients (75%). Diabetes mellitus was found in 32 patients (80%). Smoking was found in 28 patients (70%). Cardiac diseases were found in 27 patients (67.5%). Renal diseases were found in 16 patients (40%). COPD was found in 8 patients (20%).

3. Four patients (10%) had no prior intervention in this study while 9 patients (22.5%) had suprapopliteal angioplasty and 12 patients (30%) had infrapopliteal angioplasty. Bypass was done in 11 patients (27.5%) while 4 patients (10%) had minor amputations.

4. The indications for intervention among the studied cases were rest pain in 3 patients (7.5%), ulcer in 16 patients (40%) and gangrene in 21 patients (52.5%).

5. The anterior tibial artery was targeted for revascularization in 18 patients (45%) while the posterior tibial artery was the target in 14 patients (35%). The peroneal artery was revascularized in 8 patients (20%).

6. Intraoperatively, complications occurred in 7 patients (17.5%); perforation occurred in 4 patients (10%) while dissection occurred in 3 patients (7.5%). The mean length of hospital stay among the patients was 2.95 ± 1.358 days.

7. No complications were encountered during follow-up in 28 patients (70%). Restenosis was found in 4 patients (10%) while thrombosis was found 6 patients (15%). Kidney problems were encountered in 2 patients (5%) due to contrast administration.

8. During follow-up, complete wound healing was found in 24 patients (60%) while incomplete healing was encountered in 16 patients (40%).

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Keywords: Outcome, Single Tibial Artery Angioplasty, Critical Limb Ischemia

1. Introduction

Peripheral arterial disease (PAD) is increasing in prevalence worldwide affecting 12% to 20% of the elderly (aged 65 years and older). Critical limb ischemia (CLI) represents the most severe form of

PAD **(Roger et al., 2012).**

Critical limb ischemia occurs as a result of reduced arterial blood flow resulting in: (1) ischemic limb pain at rest, (2) non- healing ischemic ulceration, or (3) gangrene **(Arain and White, 2008).**

Despite continuous technical advances, treatment of critical limb ischemia of lower limbs remains a challenging situation. Expressive incidence of major amputations compromises the quality of life of these patients **(Casella et al., 2010).**

Achieving single vessel inflow to the wound is an acceptable end point of PVI for CLI with tissue loss. In daily practice, CLI patients often have significant lesions in both the anterior tibial artery (ATA) and the posterior tibial artery (PTA) **(Kobayashi et al., 2016).**

In patients who have progressed to CLI, revascularization of the affected extremity through endovascular intervention plays a crucial role in staving off limb loss, prolonging survival, and improving their quality of life. This study will show the outcome of single tibial artery angioplasty in critical limb ischemia.

Aim of the Work

The aim of the present study is to show the outcome of single tibial artery angioplasty in critical limb ischemia.

2. Patients and Methods

This is a one arm observational prospective study and patients will be selected according to inclusion and exclusion criteria, using PASS program, setting alpha error of 5% and confidence interval width of 0.15 and result from prevous study of **(Kobayashi et al., 2016)**. Based on this, the needed sample is forty patients at the Department of Vascular Surgery- Ain Shams University Hospital.

Inclusion criteria

Patients with critical lower limb ischemia due to tibial disease.

Exclusion criteria

Patients with critical lower limb ischemia at another anatomical sites:

Aorto-iliac segment.
Femoral segment.
Femero-popliteal segment.

Pre-intervention evaluation:

Patient criteria.

Age.
Gender.

Clinical assessment and history.

History of comorbidities:

Coronary artery disease.
Hypertension.
Diabetes mellitus.
chronic renal in sufficiency.
Myocardial infarction.
Congestive heart failure.
Chronic obstructive heart disease.
Smoking.

History of perior intervention:

Percutaneous trans-luminal angioplasty (PTA).
Bypass.
Minor amputation.
Infra-popliteal PTA.

Indication for intervention:

Rest pain.
Ulcer.
Gangerene.

Laboratorial and radiological investigation.

Duplex study

Computerized tomography (CT) angiography as a primary choice.

Intervention:

Patients will be treated by single vessel infra-popliteal PTA with or without stent.

Post-intervention

Post-intervention medical treatment:

Anti-coagulants.
Anti-platelets.
Outcome within one month:
Complications.
Length of stay in hospital.
Mortality.
Wound healing at three and six months:
Complete.
Incomplete.

Statistical analysis

Data was collected and entered to the computer using SPSS (Statistical Package for Social Science) program version 16.0, SPSS Inc., Chicago, Illinois, USA for statistical analysis. Data was entered as numerical or categorical, as appropriate. Quantitative data was shown as mean, SD, and range. Qualitative data was expressed as frequency and percent at 95% confidence interval (95% CI).

3. Results

In this one arm observational study, forty patients with critical limb ischemia due to tibial disease were enrolled. Results and data analysis are presented in the following tables and figures.

The following table **(Table 1)** shows the demographic data of the studied cases.

Table (1): Demographic data of the studied cases (N=40)

Demographic Data	Number of patients (N=40)	Percentage
Age (Years)		
Mean± SD	60.525 ± 4.013	
Range	51-72	
Sex		
Male	26	65%
Female	14	35%
BMI (kg/m^2)		
Mean± SD	23.075 ± 4.299	
Range	14-32	
Past Medical History		
Hypertension	30	75%
Diabetes Mellitus	32	80%
Smoking	28	70%
Cardiac disease	27	67.5%
Renal Disease	16	40%
COPD	8	20%
History of prior intervention		
No	4	10%
Suprapopliteal PTA	15	37.5%
Suprapopliteal Bypass	17	42.5%
Minor amputations	4	10%

Data in N (%), mean±SD

In this study, the mean of age was 60.525 ± 4.013 years. 26 patients (65%) were male while 14 patients (35%) were female **(Figure 1)**. BMI was 23.075 ± 4.299 kg/m^2.

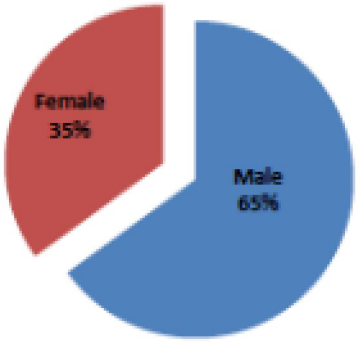

Figure (1): Sex distribution (N=40)

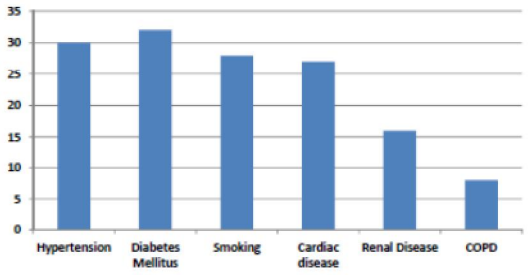

Figure (2): Past Medical History (N=40)

Regarding the past medical history **(Figure 2)**, hypertension was found in 30 patients (75%). Diabetes mellitus was found in 32 patients (80%). Smoking was found in 28 patients (70%). Cardiac diseases were found in 27 patients (67.5%). Renal diseases were found in 16 patients (40%). COPD was found in 8 patients (20%).

Four patients (10%) had no prior intervention in this study while 9 patients (22.5%) had suprapopliteal angioplasty and 12 patients (30%) had infrapopliteal angioplasty. Bypass was done in 11 patients (27.5%) while 4 patients (10%) had minor amputations **(Figure 3)**.

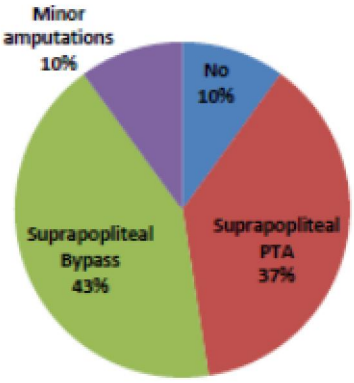

Figure (3): History of prior intervention (N=40)

The following table **(Table 2)** shows the details of operative data among the studied cases.

The indications for intervention among the studied cases were rest pain in 3 patients (7.5%), ulcer in 16 patients (40%) and gangrene in 21 patients (52.5%) **(Figure 4)**.

In this study, the anterior tibial artery was targeted for revascularization in 18 patients (45%) while the posterior tibial artery was the target in 14 patients (35%). The peroneal artery was revascularized in 8 patients (20%) **(Figure 5)**.

Table (2): Operative Data (N=40)

Operative Data	Number of patients (N=40)	Percentage
Indications for intervention		
Rest Pain	3	7.5%
Ulcer	16	40%
Gangrene	21	52.5%
Revascularized Artery		
Anterior Tibial Artery	18	45%
Posterior Tibial Artery	14	35%
Peroneal artery	8	20%
Intraoperative Complications		
No	33	82.5%
Perforation	4	10%
Dissection	3	7.5%
Length of Hospital stay (Days)		
Mean± SD	2.95 ± 1.358	
Range	2-6	

Data in N (%), mean±SD

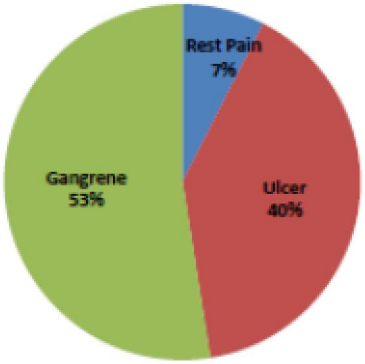

Figure (4): Indications for intervention (N=40)

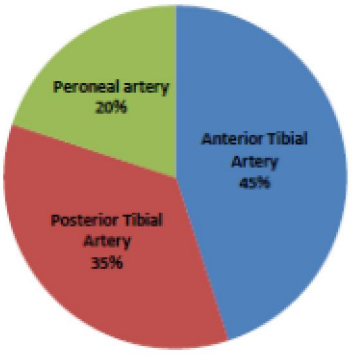

Figure (5): Revascularized artery (N=40)

Intraoperatively, complications occurred in 7 patients (17.5%); perforation occurred in 4 patients (10%) while dissection occurred in 3 patients (7.5%) **(Figure 6)**. The mean length of hospital stay among the patients was 2.95 ± 1.358 days.

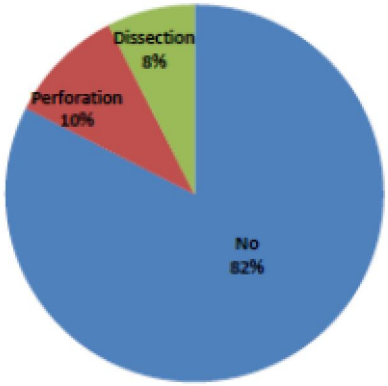

Figure (6): Intraoperative complications (N=40)

The following table **(Table 3)** shows the details of the follow-up among the studied cases.

Table (3): Follow-up Data (N=40)

Follow-up Data	Number of patients (N=40)	Percentage
Complications		
No	28	70%
Restenosis	4	10%
Thrombosis	6	15%
Kidney problems	2	5%
Wound Healing		
Complete wound healing	24	60%
Delayed wound healing	8	20%
Minor amputation	4	10%
Major amputations	4	10%

Data in N (%)

No complications were encountered during follow-up in 28 patients (70%). Restenosis was found in 4 patients (10%) while thrombosis was found 6 patients (15%). Kidney problems were encountered in 2 patients (5%) due to contrast administration **(Figure 7)**.

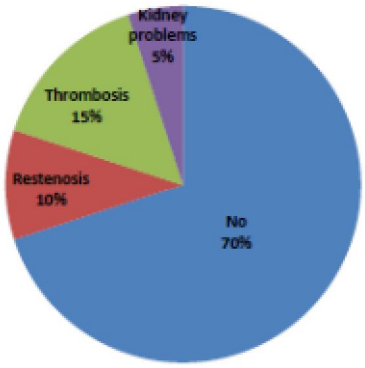

Figure (7): Complications (N=40)

During follow-up, complete wound healing was found in 24 patients (60%) while incomplete healing was encountered in 16 patients (40%) **(Figure 8)**.

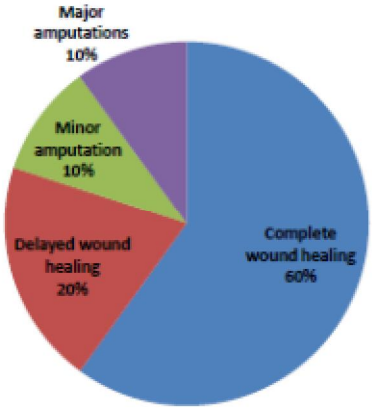

Figure (8): Wound Healing (N=40)

4. Discussion

Critical limb ischemia is a clinical syndrome of ischemic pain at rest and/or ischemic tissue loss such as non-healing ulcers or gangrene, related to peripheral arterial disease of the lower limbs. Its importance is due to the much higher risks of limb loss and cardiovascular events than asymptomatic peripheral artery disease and intermittent claudication **(Thukkani & Kinlay, 2015).**

Peripheral arterial disease (PAD) is increasing in prevalence worldwide affecting 12% to 20% of the elderly (aged 65 years and older). Critical limb ischemia (CLI) represents the most severe form of PAD **(Alguire & Scovell, 2018).**

The poor prognosis demands more rapid assessment, a greater role for wound care, and the earlier use of revascularization. As a result, a multidiscipline approach involving specialists in endo-vascular revascularization, open surgical revascularization, podiatry, wound care and other specialties is often required to maximize patient outcomes **(Kinlay, 2016).**

CLI is usually the result of multi-segmental PAD with impaired blood flow in peripheral tissues. In some cases, the simultaneous presence of impaired cardiac output may worse the peripheral perfusion in CLI patients. The reduced oxygenation and nutrition of peripheral tissues may cause claudication or rest pain, even if this typical symptom of PAD may be reduced or absent in diabetic patients with neuropathy. Furthermore, diabetic CLI patients show usually distal arterial lesions characterized by the involvement of the vessel below the knee (BTK), and often the first signs of PAD are claudication, rest pain, ulceration, necrosis or gangrene **(Abu Dabrh et al., 2015).**

Endovascular procedures are well-accepted approaches to treat patients with critical limb ischemia (CLI) according to the latest guidelines. The aim of revascularization in these patients is fast ulcer healing and prevention of amputation and death. Balloon angioplasty compared to surgical bypass allows

multivessel revascularization using a less invasive approach and achieves similar outcomes. Restenosis is the main limiting factor of this treatment, with a rate of 42% at 1-year follow-up. Several approaches have been evaluated to improve these outcomes in the past decade, including drug-coated balloons (DCB) **(Jaff et al., 2015).**

Longer calcified lesions which are typically observed in CLI patients had the worst outcomes probably related to the barrier effect of the calcified atherosclerotic plaque. This calcification prevents penetration of drugs to the vessel wall, reducing the efficacy of DCB **(Bosiers et al., 2017).**

Achieving single vessel inflow to the wound is an acceptable end point of PVI for CLI with tissue loss. In daily practice, CLI patients often have significant lesions in the anterior tibial artery (ATA), peroneal and the posterior tibial artery (PTA) (**Kobayashi et al., 2017).**

This is why the study was selected to be conducted to show the outcome of single tibial artery angioplasty in critical limb ischemia in Ain Shams University Hospitals. The study was prospective thesis study included forty patients with single tibial artery revascularization was targeted pre-intervention due to single distal run-off and patients with only single tibial artery revascularization could be achieved due to failure of revascularization of the other tibial artery. The duration of the study had been 6 months.

The main results of the study were as following:

The mean of age was 60.525 ± 4.013 years. 26 patients (65%) were male, while 14 patients (35%) were female. BMI was 23.075 ± 4.299 kg/m2.

These results are in agreement with finding reported by **Ghoneim et al. 2018** as they found that prospective study included 180 patients, with age range from 42 to 86 years and mean age of 62 years; 55% were male patients.

Our results showed that regarding the past medical history, hypertension was found in 30 patients (75%); diabetes mellitus was found in 32 patients (80%); smoking was found in 28 patients (70%). Cardiac diseases were found in 27 patients (67.5%). Renal diseases were found in 16 patients (40%) in the form of elevated kidney functions (serum creatinine above 1.4 mg/dl) due to atherosclerosis of renal blood vessels and peri-reneal causes (dehydration). Chronic obstructive pulmonary disease (COPD) was found in 8 patients (20%). Four patients (10%) had no prior intervention in this study where 9 patients (22.5%) had suprapopliteal angioplasty and suprapopliteal Bypass was done in 11 patients (27.5%) while 4 patients (10%) had minor amputations.

These results were in agreement with finding reported by **Ghoneim et al. 2018** as they reported that most of the patients are diabetics and male.

Patel et al. 2016 reported that 63 % were diabetic, 39 % were smokers and 71 % were hypertensive in the endovascular group.

Muir et al. 2017 reported that 116 patients were identified as having undergone a tibial endovascular intervention. Ninety-two had concomitant aortoiliac or femoropopliteal interventions; after excluding those patients, we identified 24 limbs that were treated for isolated below-knee popliteal, tibial, and/or peroneal occlusive disease using an endovascular modality.

Enzmann et al. 2018 reported that there were 61 tibiodistal vein bypasses for critical limb ischemia performed in 23 years. Indications for tibiodistal bypass was Rutherford category 5 in 41 cases (67%) and category 6 in 20 cases (33%).

Our results show that the indications for intervention among the studied cases were rest pain in 3 patients (7.5%), ulcer in 16 patients (40%) and gangrene in 21 patients (52.5%). In this study, the anterior tibial artery was targeted for revascularization in 18 patients (45%) while the posterior tibial artery was the target in 14 patients (35%). The peroneal artery was revascularized in 8 patients (20%).

Ghoneim et al. 2018 reported that of the 180 patients, 60 patients had single peroneal vessel runoff, whereas 120 patients had a single tibial runoff.

Biagioni et al. 2018 reported that successful recanalis-ation was achieved in 95.8%, 86.2%, 86.9%, and 92.5% for the tibio- peroneal trunk, anterior tibial, posterior tibial, and Peroneal artery respectively.

Del Giudice & Gandini, 2019 reported that a total of 19 lesions averaging 123.5±44.9 mm in length were treated in the infrapopliteal arteries. Eight of 19 lesions were chronic total occlusions; 11 lesions had severe calcifications. Distal runoff was present in all target vessels. Eight patients underwent planned minor amputations before the study procedure.

Faglia et al. 2005 reported that PTA was performed in 993 patients (83.6%) and in the remaining 195 (16.4%) was not feasible due the complete calcified occlusion of the vessel which did not permit balloon catheter passage.

Our results showed that intraoperatively, complications occurred in 7 patients (17.5%); perforation occurred in 4 patients (10%) due to calcified atherosclerotic vessels controlled by conservative treatment (manual compression to stop extravasation) adjunctive endoscopic vascular surgery consisting of balloon tamponade may be required with persistent extravasation or development of haematoma, preservation of the patency was achieved in one of these patients while the other 3 patients were referred for surgical intervention.

Dissection occurred in 3 patients (7.5%) and treated by sustained inflation of a low pressure balloon as the wire was still crossing through the area of

dissection and can be also treated by excision with a directional atherectomy device, failure of recanalization occurred in 2 patients (were planned for surgical intervension) while one patient had successful recanalization.

The mean length of hospital stay among the patients was 2.95 ± 1.358 days. No complications were encountered during follow-up in 28 patients (70%). Restenosis was found in 4 patients (10%) and all were planned for further endovascular balloon angioplasty while thrombosis was found in 6 patients (15%) mostly due to occluded arch then treated by thrombolysis & thrombectomy using wire guided fogarty, 2 of these 6 patients had successful recanalization while the rest 4 patient were planned for major and minor amputation. Kidney problems were encountered in 2 patients (5%) due to contrast administration. Then limb salvage is decided for most patients with successful revascularization.

Another groin complications such as haematoma, pseudoanurysm, and groin infection were treated conservatively.

Our results are supported by finding reported by Patel et al. 2016 as they reported that the most common perioperative/ procedural complication In the endovascular group they were acute kidney injury (4•0 %), arterial rupture (3•2 %), arterial dissection requiring an unplanned stent (3•2 %), pseudoaneurysm (2•4 %) and groin bleeding requiring surgical intervention (2•4 %).

Ghoneim et al., 2018 reported that the mortality rate along 2 years was 10 and 5% in groups P and T, respectively. Limb salvage rate along 2 years was 68.8% in group P and 79.8% in group T (P<0.036). The primary and secondary patency rates over 2 years in group P were 31.3 and 54.2%, respectively, and in group T were and 62.4%, respectively.

In contrary to our results, a retrospective analysis by **Soares et al. 2016** showed a higher incidence of renal failure when treating more than one artery.

Palena et al. 2018 reported that limb salvage rate was 100%, and 90.4% of patients achieved the combined endpoint of reduction in ulcer size/depth or complete healing. Lutonix drug-coated balloons (LDCB) had superior efficacy (MALE + post-operative death, amputation free survival, freedom from re-intervention, limb salvage and survival rates), while attaining superior or equivalent safety (Major Adverse Limb Events, major adverse cardiovascular events and Amputation) endpoints for the overall, modified clinical and anatomical high-risk groups.

Bosiers et al. 2017 reported that seven patients died; cause of death was unknown in 3 and no autopsy was performed. The other 4 died of kidney failure, stroke, a hypoglycemia coma at home, and worsening general condition.

Vraux & Bertoncello, 2006 reported that there were 7 complications including 2 embolisms, 1 perforation and 4 haematomas.

Faglia et al. 2005 observed that during the follow-up; six patients who had a PTA and a healed ulcer underwent subsequent procedures in another institution: one PTA, two above and two below the knee amputations. One subject died suddenly the night following PTA. One patient underwent an above the knee amputation due to acute distal thrombosis not suitable for surgical revascularisation. Thirty-two complications required a specific therapy or a prolonged hospital stay.

Feiring et al. 2004 reported that one-month major adverse events (MAEs) were defined as death, myocardial infarction, major unplanned amputation, need for surgical revascularization, or major bleeding. Clinical success was defined as improved resting ankle brachial index by ≥ 0.10, relief of resting pain, healing of ulceration or amputation, and improvement of claudication.

Our results show that during follow-up, complete wound healing was found in 24 patients (60%) while delayed wound healing was encountered in 8 patients (20%), major amputations occurred in 4 patients (10%) and minor amputation occurred in 4 patients (10%).

The result according to each single artery. Posterior tibial artery angioplasty had the best result in related to wound healing (84-88%), the peroneal artery (75-80%) and the anterior tibial artery (72-78%). Trials for arch angioplasty were successful in 78%.

Zhan et al. 2015 demonstrated that revascular-ization had a significant effect on the improvement of wound healing time, particularly in clinical stage 3 patients (mean wound healing time of 238 days without revascularization vs. 94 days with revascularization; P = 0.008.

Bosiers et al. 2017 reported that only 12 of 61 patients had nonhealing wounds.

Vraux & Bertoncello, 2006 reported that the technical success rate was 78% (31/40). Nine technical failures were treated by conventional surgery or angioplasty of another diseased tibial vessel. The clinical success rate was 68% (27/40).

Feiring et al. 2004 reported that technical success was 94% for de novo lesions and there were no MAEs. Ankle brachial indexes increased for all groups (CLI = 0.32 ± 0.13 to 0.9 ± 0.14 and LLC = 0.65 ± 0.09 to 0.95 ± 0.12; P ≤ 0.0001, pre vs. post). Relief of rest pain and healing of ulcerations and amputations were seen in 96% (47 of 49) of patients with CLI who underwent successful intervention.

Conclusion and Recommendation

Conclusions

The achievement of single vessel inflow to the wound has been considered as an acceptable end point of infrapopliteal PVI for CLI patients.

Study limitations & Recommendation

1. The sample size of the present study was relatively small. In the future, a prospective randomized study with sufficient sample size should be performed to definitively confirm the present findings.

2. Balloon angioplasty was performed for infrapopliteal intervention because balloon angioplasty is one of favourable option available during the study period.

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