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" *Trans-Tibial Retrograde Approach for Below Knee Angioplasty in Chronic Critical Limb Ischemia"*

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ABSTRACT:

Background: patients presented mostly with critical total occlusion (CTO) in infra-genicular (IG) vessels; with medical illness recommend the endovascular approach for management. In the study, the retrograde trans-tibial approach is recommended after failure of the antegrade approach. The aim of the study was to assess the clinical outcomes of limb patency of critical limb ischemia (CLI) because of IG occlusive diseases by retrograde trans-tibial approach. **Patients and methods:** Through the period that started from December 2019 to October 2022. Rretrograde trans-tibial approach after failure of the antegrade approach was recommended on 26 patients complaining of CLI because of IG occlusive disease. Success of the procedure achieves by tibial revascularization and patency rate within the 12 month post intervention and record complications. **Results:** 26 patients were involved in the study, comprising 20 (76.9%) males and 6 (23.1%) females. Mean age ± SD was 64.4 ± 14.7 years. (88.5%) were diabetic, 93.3% hypertensive, 61.5% coronary heart disease, and 69.2% were smokers. Patients with CLI were 11 (42.3%) patients attended with a severe limiting claudication, 7 (26.9%) patients were attended with ischemic rest pain and 8 (30.8%) patients were attended with minor tissue affections (tissue ulcer or toe gangrene). The primary patency was after one month was 89%, after 3 months was 85%, after 6 months 81% while after 12 months was 79%, with no significant complications. **Conclusions:** Retrograde tibial access revascularization of IG vessel lesion is accessible and time saving in comparison with the antegrade approach if failed with acceptable complications.

Keywords: infra-genicular occlusion, retrograde, critical limb ischemia, antegrade, trans-tibial.

Introduction:

Regardless the increasing of success rate of infra-genicular (IG) angioplasty in patients presented with lower limb ischemia, that mentioned in different researches. [1–3]

Complex, hard calcification and complete obstruction could be in many cases. [4] The endovascular approach gives different modalities of treatment to accomplish acceptable success. [5]

Although, the antegrade approach usually used and recommended to overpass (CTO); about 30% in superficial femoral artery (SFA) and 50% for Infra-popliteal occlusions fail to cross the lesions. [1, 2]

For the purpose of limb salvage, best medical treatment (BMT) is recommended for revascularization of IG region and management of

atherosclerotic risk factors. The infra-genicular bypass using vein graft is considering the most recommended way of treatment. [6] although, the presence of multiple lesions along the course of tibial vessels in addition to absence of accessible healthy vein graft are considered obstacles for surgical bypass. [7]

Presence of chronic illnesses as respiratory, circulatory, renal and cardiac diseases are also considered resistance factors for the bypass graft. Out of this need, revascularization by peripheral angioplasty has been exceedingly used with rising prevalence. [8]

The starting trial of retrograde approach was announced by Iyer et al. [9] Using approach by achieving the recommended clinical outcomes was done through the tibial vessels. [10–15] The retrograde technique through tibial access could be considered as an adjunctive approach with technical success due to possibility to cross those uphill lesions from distal than proximal. [16]

Occurrence of CTO usually following to upgrading significant stenosis, associated with higher calcification in proximal part than distally. [17] For that, the rising rate of success to cross the tibial lesions through retrograde approach than antegrade. So, the crossing of the lesion will be starting with softer distal part to the harder proximal part. [18, 19]

In addition to the retrograde approach will be closer to the tibial lesions than the antegrade one. This gives priority for advanced control and manipulation of the crossing wire to bypass the occluded segment. [20]

Methods:

A prospective interventional study was done during the period from December 2019 to October 2022. The study was done in El-Rahma specialized hospital, Lotus specialized hospital and Omar Ibn El-Khattab specialized hospital in Port Said. El-Wady specialized hospital, Giza, Egypt. The aim was to assess the role of retrograde trans-tibial access for infra genicular angioplasty in ischemic patients after failure of antegrade approach and detect the complications that could be happened.

26 patients were involved in the research, and assessed through the following, Full medical history. Ankle brachial pressure index (ABPI) for

vascular assessment. Full laboratory investigations will be done for all patients including complete blood picture, serum glucose and clotting time. Liver, renal, cardiac and respiratory laboratory assessment will be done. Duplex ultrasound (DUS) in addition to computed tomography angiography for assessment of vascular tree from abdominal aorta downwards.

There were multiple risk factors associated with occurrence of critical lower limb ischemia, and increasing the liability of extensive tibial atherosclerosis and causing increasing the rate of failure of antegrade crossing tibial lesion approach. Most of patients were complaining of uncontrolled diabetes mellitus, hypertension, ischemic heart disease, smoking and hypercholesterolemia. **(21)**

The clinical assessment of presenting patients in the study, depending on administration of anticoagulants and peripheral vasodilators. Evaluation of drug sensitivity and allergy was done. Examination of the vascular tree and evaluation of chronic trophic changes in foot was done. **(22)**

All patients included in the study present with CTO in infra-genicular region of tibial vessels, with distal run-off, for possibility of entrance through retrograde approach, after failure of antegrade approach because of **(1)** Inability of entrance and get the access because of flush occlusion or common femoral artery (CFA) occlusion. **(2)** Failure of lumen re-entry from subintimal plan along the vessel. **(3)** Difficult to cross the lesion in different ways “true lumen or subintimal plan”. **(4)** Presence of distal run-off of tibial vessels, as patient distal vessel is necessary for possibility to access and puncture the tibial arteries (PTA or DPA).

The patients that excluded from the study were; **(1)** Asymptomatic Patients presented with chronic ischemia. **(2)** Patients not in need for retrograde approach as succeeded proximal access. **(3)** No distal run off could be detected. **(4)** Attending Patients with (Rutherford 6), or extensive site infection prevent entrance and could promote to amputation. **(5)** Refusal to participate in the study.

Technique of the Procedure:

All patients included were given 300 mg clopidogrel 75 mg as loading before intervention. [23] Proximal "trans-femoral access" antegrade approach will be tried first, in case of difficulty to cross the tibial lesion and failure to reach the distal run-off even by ipsilateral or contra-lateral side.

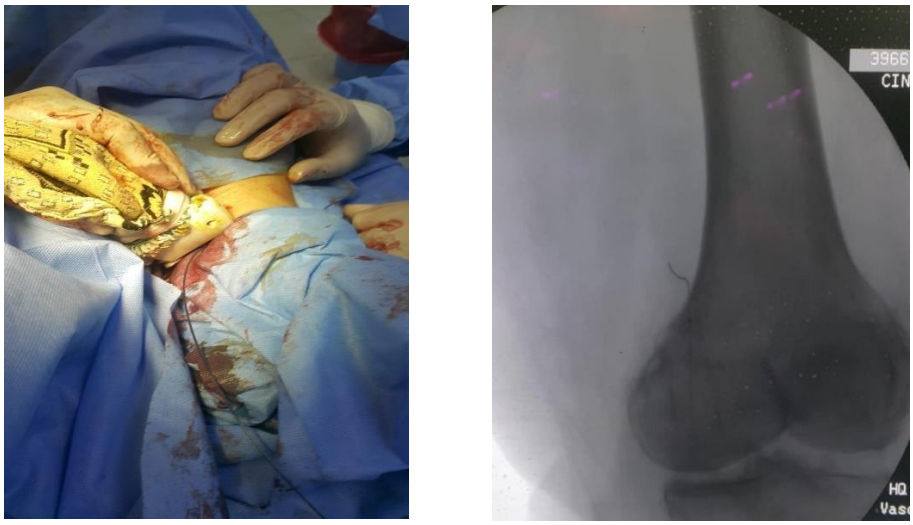
The next trial is retrograde approach through the tibial vessels anterior tibial artery (ATA) which is more recommended or posterior tibial artery (PTA) less recommended. All tibial access entrance will be gained by the guidance of fluoroscopy by injection through the proximal catheter which is most near to proximal part of occluded segment, to facilitate detection of run-off and could gain road map imaging. Even in the obese patients are punctured visualized by ultrasound guidance, allowing cannulation.

After entrance through the tibial access (PTA or DPA), retrograde direct insertion of hydrophilic Tueromo 0.035, or using 0.18 (V 18 TM) wire in other patients guided DUS or guided fluoroscopy. Crossing over the lesions supported by percutaneous sheath or wire directly supported by low profile balloon catheter. After crossing the distal tibial lesion upwards, Wire reception by the proximal sheath by entrance through the proximal Bernstein catheter or enter by straightway proximal to the sheath. Antegrade overriding the wire intraluminal balloon angioplasty. Withdraw of the tibial wire from the distal access upward, with compression of the puncture to stop bleeding.

Nitroglycerine 200 μg will be intended for tibial injection through the antegrade catheter for management of peripheral tibial vasospasm, and post intervention angiography will be done for assessment of procedural success in all cases. ABPI assessment will be done in all patients. [24]

All patients will be kept on dual antiplatelet post intervention including ASA (150 mg/day) and cilostazol (100 mg BPD/day) for the next 6 months. Then, most recommended will keep them long-life daily ASA. [23]

Figure (1): The direct retrograde entrance through LT-PTA (posterior tibial artery) at the ankle level (A, B), and pass upward crossing the tibial occlusion (C).



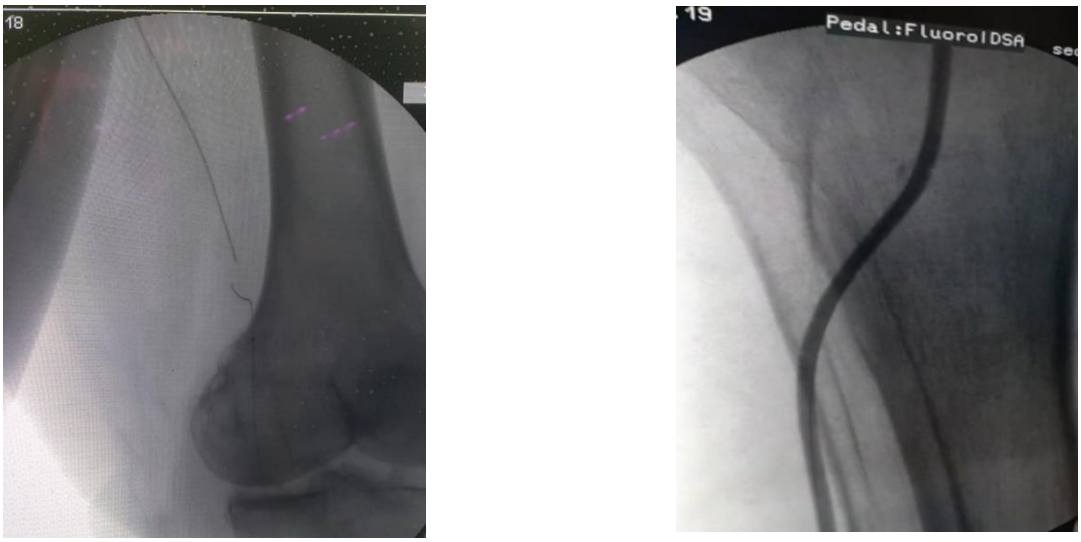


Figure (2) : direct puncture of the LT PTA guided duplex ultrasound, cross the lesion with double wires (retrograde / antegrade) approaches. Then, balloon dilatation of popliteal and tibial artery.

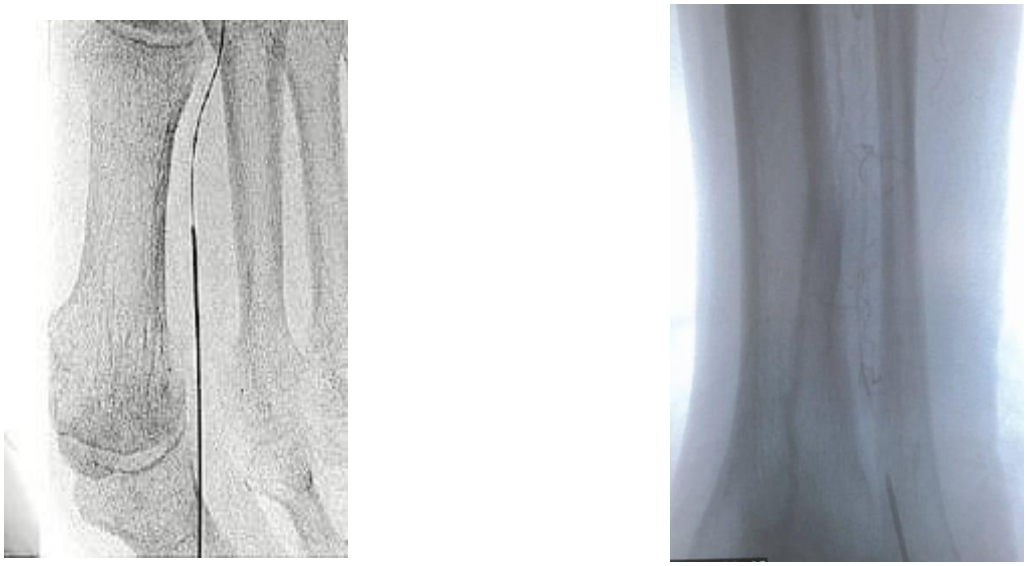


Figure (3) : direct puncture of dorsalis pedis artery and anterior tibial artery in retrograde approach.

The two accessible ways through the foot as ideal access arteries for possibility of retrograde angioplasty are PTA and DPA through the foot are ideal access arteries for retrograde angioplasty. Because of being superficial and more accessible even in high Body Mass Index (BMI) patients in addition

to a readily visualized by ultrasound guidance, allowing their proper cannulation.

The choice of which pedal vessel to be cannulated for retrograde recanalization, following the angiosome connotation is the recommended and the preferred tibial vessel that results in in-line flow to the affected soft tissue, because of being demonstrated to positively impact on limb salvage in the direct in parallel to indirect flow. [16, 36] The peroneal access is not recommended even though was mentioned in different studies [37] because of the surgical anatomy in the deep posterior compartment of the leg with difficult cannulation with sequel of difficult post intervention hemostasis, with well-formed hematoma up to and potential compartment syndrome.

No life-threatening consequences were reported. The only major complication was the acute occlusion of the tibial vessel after an ineffective retrograde approach.

Deterioration of the clinical condition might be predictable. So, open thrombectomy with in situ pedal bypass will be recommended. Then. The patient‟s condition will be better which is not faced during the study. Using of the 4- F sheath might result in trauma to the pedal vessel in addition to the low blood flow resulting from failed recanalization of the occluded segment participated in the access thrombosis. So, it‟s recommended to abandon using of 4-F sheaths for distal access and enter directly by wire and balloon catheter.

Clinical outcome:

Assessment of success by increasing of the ABPI > 0.15 mmHg post intervention next day, will be accepted and considered success of procedure. Arterial duplex was done on regular basis for all patients at 1, 3 and 6 months. If susceptible to restenosis (> 30%) or occlusion during follow up, CTA will be done for re-evaluation of the vascular tree.

The end points of the study were In case of difficult to access the tibial vessel, In-accessible to cross the tibial lesion from distal end, When not suitable for correction of restenosis > 30%, limited dissection and post follow up for 12 months with the recommended results.

Statistical Analysis:

Chi-square test will be utilized to deal with different variables, and assess their significant, and affect the study success SPSS v26 (IBM, Chicago, IL, USA) was used for statistical analysis using the Shapiro-Wilks test and histograms. Parametric quantitative data were done by using mean and standard deviation (SD) and the comparison by unpaired student t-test. A Kaplan–Meier curve will be for comparing primary patency rates after retrograde tibial procedure. The statistical significance will be when P value <0.05. The statistical analysis will be using SPSS 16.0 software.

The study was revised by Ethical Research Committee (ERC), Faculty of Medicine, Port-said University to obtain ERN, according to ethical research bylaws, and got ERN: MED (1/11/2022) s. no (65) SPS/VSC_006. The patient gave informed consent before any intervention was done.

Results:

Through the period that started from December 2019 to October 2022, a total of 26 patients who fulfilled the inclusion and exclusion criteria of the study for the process of retrograde trans-tibial access for tibial revascularization after difficulty to cross the lesions in antegrade approach.

It was recorded through the study that, 20 (76.9%) patients were males and 6 (23.1%) patients were females. The ages were ranged between (52 to 72 years), with a mean age ± SD 64.4 ±14.7 years. Body mass index (BMI) was 27.6. The study recorded 18 (69.2%) patients were smokers. 23 (88.5%) were diabetic on insulin treatment, while 24 (93.3%) patients were hypertensive on regular treatment. 16 (61.5%) patients had diagnosed coronary heart disease and 2 patients had done coronary bypass surgery (CABG). 14 (53.8%) patients were on regular treatment of hypercholesterolemia, Table(1).

Risk factors		**Rate**	**%**
Age (mean ± SD)		64.4 ± 14.7	-
BMI (kg/m^2)		27.6	-
Gender	Male	20	76.9%
	Female	6	23.1%
Smoking		18	69.2%
Diabetes		23	88.5%
Hypertension		24	93.3%
CHD		16	61.5%
CRF		3	11.5%
hypercholesterolemia		14	53.8%

Table (1): Rate of patients related to risk factors.

Note: SD, standard deviation; BMI, Body mass index; CHD, coronary heart disease; CRF, Chronic renal failure.

According to the presenting manifestations, 11 (42.3%) patients attended with a severe limiting claudication, 7 (26.9%) patients were attended with ischemic rest pain and 8 (30.8%) patients were attended with minor tissue affections (tissue ulcer or toe gangrene), table (2).

Rutherford classifications	**Description**	Number	(%)
Rutherford stage **3**	Severe claudication	11	(42.3%)
Rutherford stage **4**	Ischemic rest pain	7	(26.9%)
Rutherford stage **5**	Minor tissue affection	8	(30.8%)

Table (2): Rutherford classifications between participants in the study.

After failure of the first trial of antegrade approach, the retrograde procedure was completed by accessing the PTA in 14 patients (53.8%), the ATA were in 10 patients (38.5%) and through the peroneal artery in 2 patients (7.7%). In all of the 29 patients, one of the tibial arteries was punctured, wired and lesions were crossed successfully, table (3).

Access of entrance	**Rate**	**%**
ATA	10	38.5 %
PTA	14	53.8 %
Peroneal artery	2	7.7 %

Table (3): The different tibial access of entrance.

The pre-intervention mean ABPI was 0.39 while post-intervention mean was improved to 0.78. After one week of retrograde angioplasty the progress reach to 0.83. After 3 months of intervention, the mean was 0.85 up to 6 months. After 12 months, the mean ABPI was 0.82. The improved ABPI along the study and follow up was statistically significant, Figure(1).

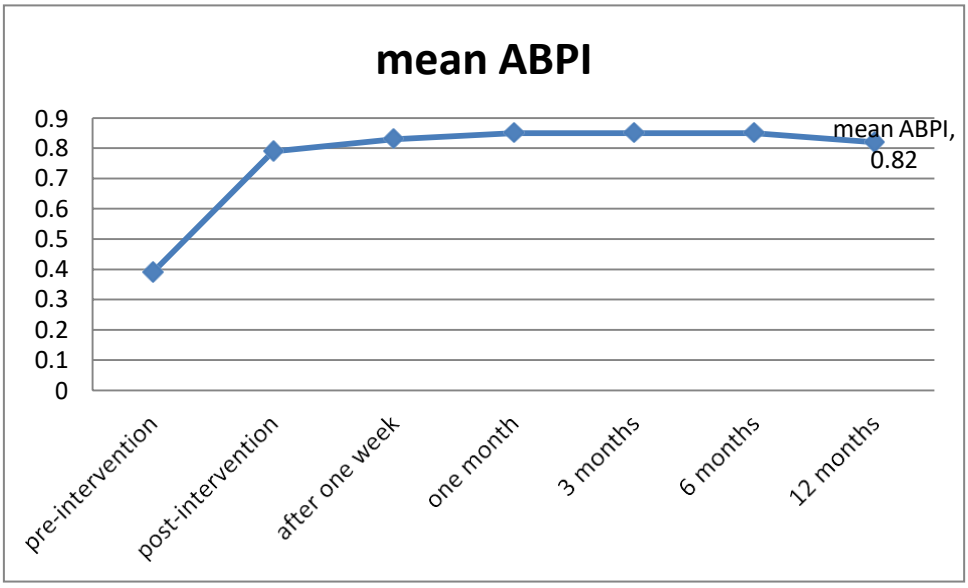
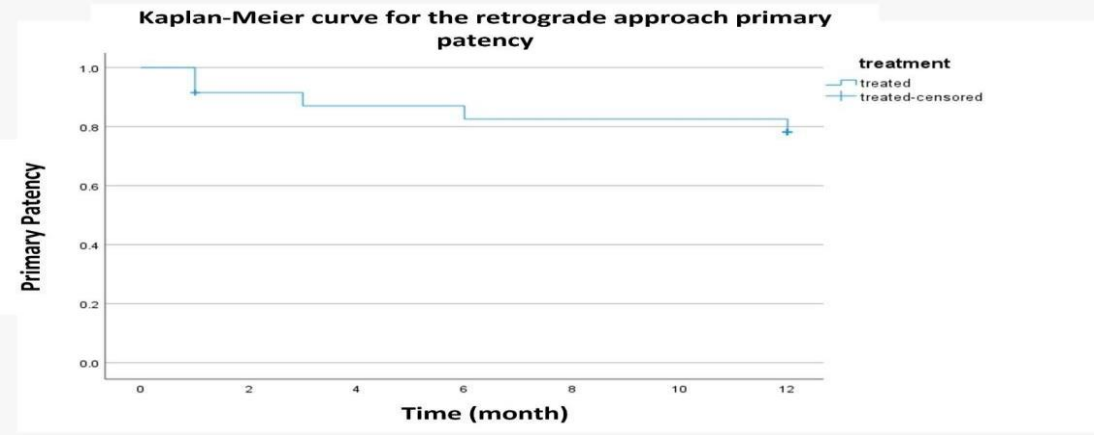


Figure (4): the mean of ABPI before and after intervention along the study.

The complications that were faced during the study post intervention, Puncture site ecchymosis noticed in 4 (15.4%) patients and resolved conservatively using thrombex cream. Perforation of tibial vessel occurred in two (7.7%) patients and managed using balloon for homeostasis and control bleeding in addition to external light compression to stop leakage. Puncture site inflammation occurred in one (3.8%) patient and treated using topical and systemic antibiotic. No thrombosis nor deep venous thrombosis occurred during the study, table (4).

Table (4): Complications were faced during the study.

A Kaplan–Meier curve was done to show the primary patency rate post retrograde angioplasty after one month was 89% , after 3 months was 85%, after 6 months 81% while after 12 months was 79%, Figure (2).



Complications	Rate	%
Puncture site ecchymosis	4	15.4%
Perforation of tibial vessel	2	7.7%
Puncture site inflammation	1	3.8%
Puncture thrombosis	0	0
DVT	0	0

Figure (5): Kaplan-Meier curve for the primary patency rate during the study.

Discussion:

Recently, the endovascular approach considered the recommended method of management of peripheral vascular disease (PVD). Advanced trials and techniques were spent to facilitate and support surgeons in all challenges for management of IG occlusive diseases for increasing the rate of success of this approach of management.

The occurrence of PAD with restricted to the tibial vessels with more liability to limb loss, because of the more extensive distal atherosclerosis with poor circulation to the foot and severe comorbidities prohibiting open surgical bypass. [25] Although interventional management for the CLI patients is formerly considered recommended option of management by some surgeons, [26] distal tibial occlusion could be difficult to be revascularized by endovascular technique, and failure of the antegrade approach in IG chronic total occlusions is significant. [1, 27]

The main cause of failure of endovascular management is mostly the difficulty of the guidewire to cross the tibial lesions, in addition to unsuccessful re-entry again of the wire through the true lumen distal to the occluded segment. [19]

Retrograde trans-tibial access could be utilized even without trial of antegrade approach as and almost consuming less time of the procedure [23]. Lupattelli et al. [28] did not recommend dealing with the retrograde trans-tibial approach from beginning to obviate significant access site complications.

Although, the trans-tibial approach for management of IG arterial occlusion has been mentioned in small researches. [9, 14] The retrograde trans-tibial access is accepted and recommended because of; the diameter of tibial vessels (2-3 mm) might help the wire and increase cross-over of the catheter through the tibial lesion, the proximal end of IG occluded segment (cap) is more difficult than distal end of the lesion which is easier to access and softer. heavy calcification in the proximal end in comparison with the distal end because of the sedimentation of calcium along blood stream which explains the difference. In addition to in CTO tibial lesion is nearer to the entrance puncture, which enable for facility of pushability, upward force through the lesion, and ease of torque handling. [17] Finally, the retrograde approach might be more recommended specially in patients with BMI more than 35 or with difficult or infected groin as antegrade approach is not reasonable. [27]

There are difficulties faced during the retrograde trans-tibial access approach as more liability to vasospasm and site puncture thrombosis with risk of occluded the run-off because of the smaller in diameter. So, this approach is un-routinely used specifically challenging in resistant cases.

According to the presenting symptoms, all the patients presented with CLI. So, target patients in the study were in this form of Rutherford (IV and V). The previous researches including Botti et. al, [29], Roger et. al, [30], Montero-Baker et. al, [31] and Walker et. al, [32] presented all cases with critical limb ischemia.

The using of anticoagulants during the procedure considered a matter of care [10], using heparin intra-arterial injection to keep the activated clotting time between 250 to 300 s. during the intervention. [11] This protocol could reduce the possibilities of access site complications, as help in controlling the puncture site during the maneuver. Fusaro et. al, [12] mentioned that the introduction of tibial balloon for controlling the puncture site to achieve hemostasis. During our study, we depended on external manual compression of the punctured artery during the intervention and were effective and sufficient.

Gandini et al. [13] had mentioned using a 4-F sheath through the pedal access during the study. Botti et al. [11] only used the dilator of a 4-F sheath to facilitate crossing the tibial vessels, beside reduced the choice of tools to support guidewire pathway through the tibial lesion. Spinosa et al. [10] used a 3-F sheath or only a 3-F dilator. Fusaro et al. [12] used a sheath-less technique by presenting a 0.018-inch guidewire with the needle for crossing the lesion over-lying balloon catheter, with pushability of 0.018-inch guidewires better than a 0.014-inch guidewire. Thus, abandoning the usage of a sheath during the procedure.

During the study, the entrance of the retrograde guidewire through the antegrade inserted sheath in comparison with previous researches, which used snare for this step by several authors, [13, 33,] while, insertion of the retrograde guidewire into a 4- to 5-F catheter proximally inserted until exit outside. [34] Spinosa et al. [27] mentioned that, this approach was helpful and better as less usage of contrast and less time consuming and less in cost. Fusaro et al. [15] mentioned that dilatation of the tibial occlusion using a retrograde balloon before the antegrade balloon is better in treatment. In spite of this maneuver could simplify the management but the pedal balloon might result in creasing the liability to vessel access injury, leaking or thrombosis. [8-10] So, need to care about

outcomes and avoid occurrence by controlling the cannulation site post-procedure and manage the event as mentioned above.

Ruzsa et al. [35] entered through DPA and PTA access by fluoroscopy and did not deal with peroneal vessel access. Bazan et al. [16] also used DPA and PTA ankle access using DUS guidance and did not attempt peroneal access. The past studies mentioned abandoning peroneal artery access because of its deep position in posterior compartment of the leg, with inaccessible bleeding control by pressure, and liability for occurrence of organized hematoma. Reciprocally, El-Sayed et al. [38] used ATA, PTA and peroneal artery as a retrograde access, guided by DUS. according to the angiosome distribution of the leg.

Conclusion:

The difficulty to cross the CTO tibial lesions through the true lumen during the antegrade angioplasty approach was recorded as high as 20% of the time. [27, 35] Retrograde trans-tibial approach for endovascular treatment of patients presented with CLI as considered less invasive, better results and minimal complications. Since the successful results of antegrade approach is recorded as 80%. [15] The retrograde approach showed higher success rate in tibial lesions with patency of all limbs of the study.

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