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Cohort Study

Trans-pedal access for endovascular revascularization in complex infra-popliteal lesions in critically ischemic limb: A cohort study

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ABSTRACT

Background: critical limb ischemia is one of the most challenging cases we face nowadays with high risk for amputation, retrograde trans-pedal angioplasty offers an alternative technique after failure of traditional ante-grade angioplasty.

Patients and Methods: 96 patients underwent trans-pedal or trans-tibial retrograde angioplasty after failure of the traditional ante-grade angioplasty with the aid of US, 21-gauge needle and 0.018 wire through sheath-less approach as a last chance for revascularization.

Results: clinical success or improvement in 77 cases (80.2%), and in other 19 cases (19.8%) there was no clinical success or improvement. The technical success was achieved in 81 cases with percentage of (84.4%), and not achieved in 15 cases (15.6%) only.

Conclusions: Retrograde Trans-pedal angioplasty is an efficient, safe, and practical procedure with a high technical success and a relatively minimal procedural adverse effect.

1. Introduction

Critical limb ischemia (CLI) with tissue loss leads to severe morbidity and mortality; CLI patients have a 1-year survival rate of 75% with a major amputation rate of 30%, but survival without major amputation is just 45%. Endovascular re-vascularization surgery is a feasible alternative either as a primary mode of care or in patients where distal bypass is not possible, either for anatomic or other purposes [1]. Lower extremity endovascular interventions are typically carried out using common femoral artery access contralateral retrograde or ipsilateral ante-grade, and less frequently brachial approach. However, the traditional ante-grade method fails in up to 20% of cases due to the inability to cross the target lesions [2]. An alternative technique has been proposed for retrograde access via pedal vessels and was first described by Iyer in 1990. Several retrospective case series have shown that this can be a theoretically successful solution. However, most of such researches record only short-term follow-up, and the patient cohorts mentioned typically fail to involve cases with a higher possibility of more advanced occlusive diseases, including those with ESRD [3]. As for all vascular lesions, the lesion crossing with the guide wire tip in an intraluminal portion beyond its a need for endovascular care to start the revascularization process. Crossing these lesions can be difficult, last but not least because of the calcification of BTK arteries found in patients with diabetes and ESRD at an above average frequency. In addition, as stated about the coronaries, due to the fibrous tissue material, the proximal cap of a lesion may be more solid than the distal one. This may explain why – when using modern equipment – only 20% of tibial is used Lesions might not be tackled efficiently from an ante-grade trans-femoral route [4].We found it necessary to record the current initial prospective study with this procedure by utilizing US guidance and a dedicated pedal access system for the treatment of BTK occlusions, because the literature as regards; retrograde Trans-pedal access is limited. The aim of this study is to carefully evaluate Retrograde Trans-pedal access revascularization technique for Complex infra-popliteal Arterial Disease. As regard to primary patency and amputation free survival rates and 30 days' mortality and morbidity.

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2. Methods

2.1. Registration

Our study registered at clinical trials.gov by this identifying number. NCT05436405.

2.2. Ethical approval

Approved by Institutional Research Board- IRB/August 2018 (MS.18.08.257–2018/08/16).

2.3. Study design

Cohort study and the work has been reported in line with the STROCSS criteria [5].

2.4. Settings and time frame of research

The study was done in vascular surgery department at Mansoura University Hospital (tertiary teaching hospital) between March 2018 and April 2020.

2.5. participants

96 patients undergoing endovascular BTK (Below The Knee) revascularization after failure of traditional ante-grade ipsilateral transfemoral approach and consequently underwent retrograde Trans-pedal or transtibial access to provide endovascular management for the lesions.

We include all patients aged from (18–80) years, males and female, with 1ry lesion (without previous trial of angioplasty or bypass) and 2ry lesion (after previous trial of angioplasty or bypass), also we include the patients with fountain classification (stage IIB, stage III, stage IV) and patients with Rutherford classification (grade I “category 3", grade II, Category 4”, grade III, Category 4&category 5. All patients gave written consent.

We excluded patients with untreated osteomyelitis, mixed lesions with other comorbidities (CVI &Lymphoedema), vasculitis or Buerger’s dis. Also, who can’t give consent (mentally retarded patients) or those with behavioral disorders were excluded.

Patients had been evaluated through the ABPI and duplex US examination: immediately, 3 mo, 6 mo, and 1 year following the surgery.

We contacted our patients by direct phone calls.

3. Methods – intervention and considerations

3.1. Pre-interventional considerations

History data: included patient’s demographics, underlying medical conditions, any previous surgery, transplanted kidney and other associated morbidity.

Examination: Full arterial assessments included pulse examination, and the ABPI (ankle brachial pressure index).

Laboratory: Blood picture, Blood sugar level, Kidney functions, Liver functions and Coagulation profile.

Imaging: Duplex ultra-sonographic (US) examination and CTA.

Medications: full heparinization was done routinely during intervention.

3.2. Intervention and intra-interventional considerations

Using a 21-gauge needle with insertion of 0.018-inch wire by sheathless technique (Fig. 1) or by utilizing a micro puncture access set. A duplex-guided access has a great importance in terms of evaluation of the pedal as well as tibial blood vessels. Such vessel is recognized using the US probe. Color flow is utilized for identification of the objective artery flow, after that color disappeared while the needle is utilized for accessing the anterior vascular surface by utilizing duplex US (Figs. 2 and 3), such approach performed in 54 patients. There are technical points worth mentioning utilizing such procedure: usage the smallest ready US as the major ones are bulky and may have a role in interference with the access process. In addition, marked vascular calcification may induce marked shadow making the identification very hard to be detected. In such conditions, a fluoroscopy might enable a good possibility for efficient access. In addition, it was suggested to utilize micro-puncture needle supposed to have echogenic pattern as the tip of regular needle is very hard to visualize utilizing the duplex US probe. Also, use of straight fluoroscopy or road mapping may offer a better chance for successful access, as we mentioned before, this method is done in 31 cases (Figs. 4 and 5). Appropriate section of the actual place of vascular access is essential for the successfulness of such procedure. Generally, a patent vessel is selected to be the access situation. A micro-puncture needle is utilized for access. Occasionally, bending the needle tip has the ability to make the possibility of vascular evaluation easy which has great importance if the access point in the ATA beyond the ankle.

Fig. 1. Successful puncture of posterior tibial artery.

Another method is open method (cut down) on tibial vessels, this

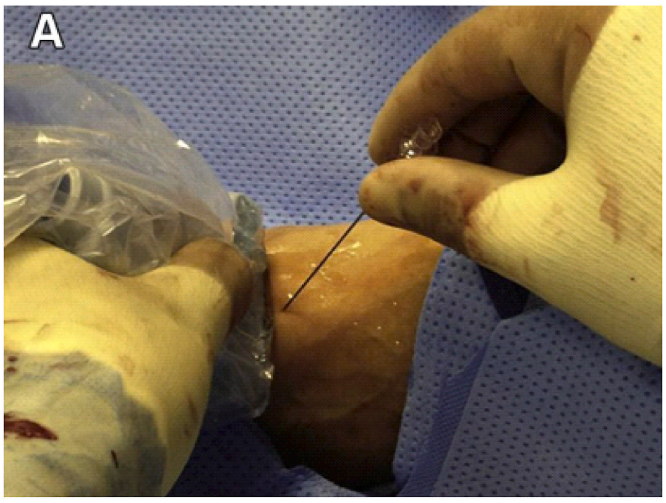

Fig. 2. Duplex guided puncture of anterior tibial artery.

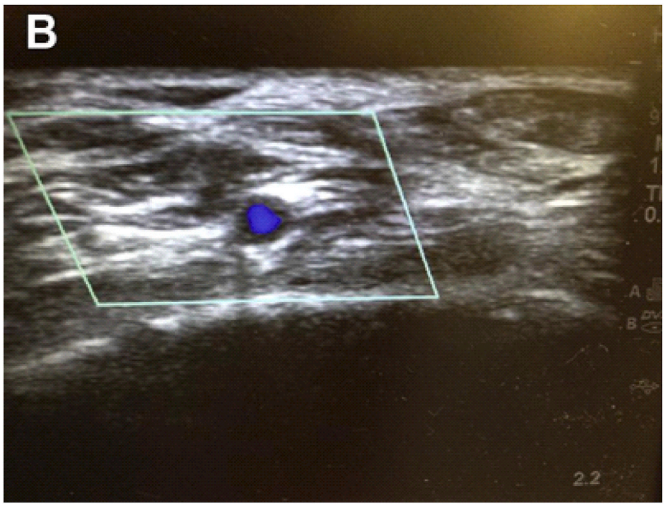

Fig. 3. View of the posterior tibial artery by intra-operative duplex.

method is done in 11 cases. Following evaluating the artery, established by back hemorrhage, the micro puncture access wire is introduced via the needle into the vessels underneath fluoroscopic guide in a retrograde fashion. The needle is removed and micro puncture set (4F) or the balloon itself is passed over the wire to secure the access. According to micro puncture introducer set it includes a 21- gauge, 7- cm echogenic needle, 10 – cm long micro puncture 4-french introducer and 2.9F inner caliber permitting passage of the equipment. When the retrograde introducers are in position, the case is completely heparinized to prevent any thrombus development throughout the interference process. An exchange dimension 0.018-inch wire was utilized to try passing across the disorder in a retrograde manner, it has very accurate outcomes crossing the obstruction for combination of a small sufficient diameter with adequate body support to permit crossing of the obstruction calcified in several patients. The V18 ™ Control Wire Guide Wire is specifically beneficial at such condition. It has a hydrophilic tip which may assist in sliding via the blockade with mild frictions, and simultaneously the wire has sufficient stiffness to pass across the overall occlusion. In sometimes, the usage of the 0.018 system only aiming for crossing isn't sufficient. Such condition specifically develops when there are prolonged occlusions and when there is marked calcification. In such patients, additional reinforcement is required for the platform to permit the crossing. Thus, up-sizing to a 0.035 system might help in disorder

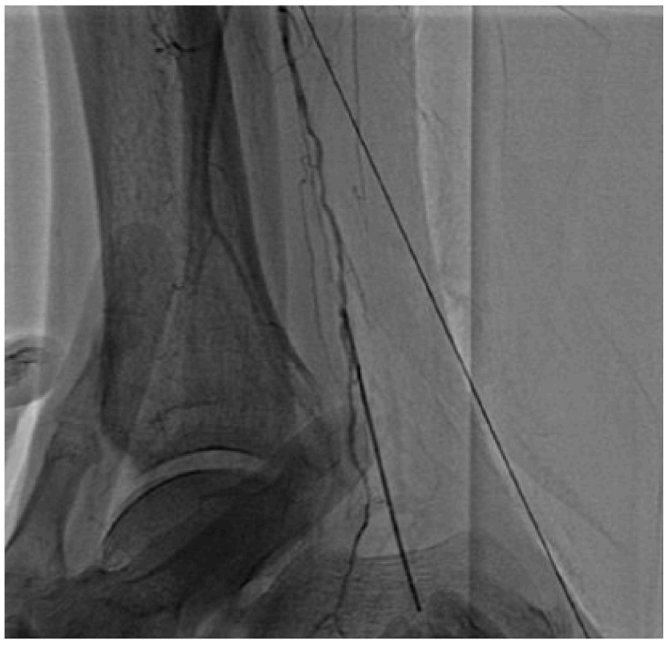

Fig. 4. Retrograde puncture of PTA via road-mapping aid.

Fig. 5. Retrograde puncture of ATA via road-mapping aid.

crossing. When we pass through the disorder, an angiogram from below is conducted to prove the situation in the actual lumen beyond the disorder. Then the procedure was done by ballon angioplasty and stenting when needed. The 0.018-inch system and wire were removed and hemostasis secured via digital compression for 8 min or by ante-grade balloon dilatation at the site of puncture for about 2–3 min.

4. Statistics and data interpretation

Data were analyzed using IBM SPSS Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp. Qualitative data were described using number and percent and compared using Chi-Square test Fischer exact test and Monte Carlo test as appropriate. Quantitative data were described using median mean, standard deviation for parametric data after testing normality using Kolmogrov-Smirnov test. Student t-test was used to compare 2 independent groups. Kaplan-Meier test; used to calculate overall survival and disease-free survival with using log rank χ^2 to detect effect of risk factors affecting survival. Significance of the obtained results was judged at the (0.05) level.

5. Results

5.1. Participants

96 patients with CLI presented by complex infra-popliteal lesions were admitted during the period between March 2018 and April 2020. The present study was carried out on 96 patients with complex infra-popliteal lesion in vascular surgery department of university hospitals in which ante-grade trans-femoral approach is tried.

5.2. Outcomes

Total number of the cases was 96 cases, with average age between (50–81) years with mean 63.89 years. 33 cases were female (34.4%) and 63 cases were males (65.6%), 48 cases were smoker (50%). The majority of the cases were diabetic as following, 59 cases were diabetic (61.5%). 60 cases were dyslipidemia (62.5%). Also, 60 cases were hypertensive with percentage of (62.5%). The majority of cases (58 cases) were cardiac patients (60.4%). As regard operative history for whole cases: 66 cases with no previous surgical history (68.8%), Ten case (10.4%) with previous history of Bypass of the same limb and Thrombectomy of the same limb, 12 cases (12.5%) with previous history of Angioplasty of the same limb, Major Amputations of the opposite limbs had been done in eight cases (8.3%).

On the Examination of the patient, half of the cases 48 cases (50%) classified as stage III Fontaine Classification; and the other half were stage IV Fontaine Classification. According to Rutherford Classification: 48 cases (50%) classified as (Grade II, Category 4: Rest pain), 36 cases (37.5%) reported at (Grade III, Category 5: Minor tissue loss (ischemic ulceration not Exceed ulcer of digits of foot) and 12 cases (12.5%) classified as (Grade III, Category 6: Major tissue loss (sever ischemic ulcer exceed Level of TM joint or frank gangrene of limb).

As for indications of the procedure: 33 cases (34.4%) were referred for rest pain, 35 cases (36.5%) were referred for ischemic ulcer, 28 cases (29.2%) were referred for gangrene. (Table 1).

According to access site for distal puncture: 57 cases were accessed through Anterior tibial artery (ATA) (59.4%), 39 cases (40.6%) were accessed through Posterior tibial artery (PTA). Most cases (54 cases) (56.3%) were punctured by duplex guided method, while 31 cases (32.3%) were punctured by Fluoroscopic guided or road mapping method but 11 cases (11.5%) were punctured by Open method. (Table 2).

In terms of anatomical arteries which are affected: 44 cases (45.8%) had tibial arteries (TA) affected, 29 cases had affected tibial and popliteal arteries (TA, PA) (30.2%), and 23 cases had affected tibial, popliteal and superficial femoral arteries (TA, PA, SFA) (24%).

Table 1
Patients demographics.

Age		Mean 64	Count	Layer N %
Gender	Female		33	34.4%
	Male		63	65.6%
Smoking status	Non smoker		48	50.0%
	Smoker		48	50.0%
Diabetes mellitus	Non-Diabetic		37	38.5%
	Diabetic		59	61.5%
Dyslipidemia	No Dyslipidemia		36	37.5%
	Dyslipidemia		60	62.5%
Hypertension	No Hypertension		36	37.5%
	Hypertensive		60	62.5%
Cardiac Status	Non-Cardiac diseases		38	39.6%
	Cardiac diseases		58	60.4%
Operative HX	No Previous Operations		66	68.8%
	Bypass or Thrombectomy of the same limb		10	10.4%
	Angioplasty of the same limb		12	12.5%
	Major Amputations of the opposite sites		8	8.3%
Indications	Rest Pain		33	34.4%
	Ulcer		35	36.5%
	Gangrene		28	29.2%
Fontaine Classification	Stage III		48	50.0%
	Stage IV		48	50.0%
Rutherford Classification	Grade II, Category 4: Rest pain		48	50.0%
	Grade III, Category 5: Minor tissue loss (ischemic ulceration not Exceed ulcer of digits of foot		36	37.5%
	Grade III, Category 6: Major tissue loss (sever ischemic ulcer exceed Level of TM joint or frank gangrene of limb)		12	12.5%

According to the type of the lesion: 28 cases (29.2%) had an arterial lesion in the form of multiple Stenotic Segments, 24 cases (25%) had an arterial lesion in the form of long Segment Total Occlusion, and 44 cases (45.8%) had an arterial lesion in the form of short segment total occlusion. The technical success was achieved in 81 cases with percentage of (84.4%), and not achieved in 15 cases (15.6%) only (Table 2).

On the follow up for the patients there was clinical success or improvement in 77 cases (80.2%), and in other 19 cases (19.8%) there was no clinical success or improvement. About the incidence of pedal vascular complications, there was 79 cases without any complications with percentage of (82.3%), while there were 9 cases (9.2%) with perforations, and 8 cases (8.3%) with spasm. And about incidence of major adverse events (MAEs) on follow up: 81 cases with no MAEs with percentage of (84.4%), Mortality within 3 months reported in 8 cases with percentage of (8.3%), and major amputations reported in 7 cases with percentage of (7.3%) of the patients (Table 2).

In terms ABPI values that indicated, 8 cases had (ABPI = .00) with percentage of (8.3%), 8 cases had (ABPI = .10) with percentage of (8.3%), 8 cases had (ABPI = .20) with percentage of (8.3%), 16 cases had (ABPI = .50) with percentage of (16.7%), 25 cases had (ABPI = .40) with percentage of (26%), 31 cases had (ABPI = .30) with percentage of (32.3%) of the patients (Table 3&4).

6. Discussion

CLI patients are prone to higher risk of limb loss (amputation) and cardiovascular events. The main aim of CLI management is to decrease the limb amputation. CLI patients which caused by IP diseases, are mainly elderly, diabetics, or ESRD/Dialysis patients [6].Such cases are at a higher possibility of amputation than those with both FP and IP disease [7]. One of the commonest challenges in CLI cases due to IP disease is the severely calcified arteries. Such severely calcified disorders have heterogeneous distributions of calcium densities which induce

Table 2
Patients method and results.

		Anatomical Arteries			total	%	P
		TA	TA, PA.	TA, PA, SFA			
		Count	Count	Count			
Access Site	ATA	27	19	11	57	59%	0.24
	PTA	17	10	12	39	41%	
Method of Puncture	Duplex-guided access	20	22	12	54	56.3%	0.48
	Fluoroscopic guided or road mapping	17	3	11	31	32.3%	
	Open method	7	4	0	11	11.5%	
Type of Lesions	Short Segment Total Occlusion	25	15	4	44	46%	0.73
	Long Segment Total Occlusion	13	0	11	24	25%	
	Multiple Stenotic Segments	6	14	8	28	29%	
Intervention Success	Successful	32	29	20	81	84%	0.13
	Unsuccessful	12	0	3	15	16%	
Clinical Success	Successful	32	25	20	77	80%	0.16
	Non-Successful	12	4	3	19	20%	
Pedal Vascular Complications	NO Complications	32	24	23	79	82.3%	
	Arteriovenous Fistula	0	0	0	0	0%	
	Thrombosed	0	0	0	0	0%	
	Pseudo-aneurysm	0	0	0	0	0%	
	Perforations	9	0	0	9	9.4%	
	Spasm	3	5	0	8	8.3%	
MAE	No MAEs	40	29	12	81	84.4%	
	Mortality within 3 months	0	0	8	8	8.3%	
	Major Amputations	4	0	3	7	7.3%	

TA = Tibial arteries, PA=Popliteal artery, SFA=Superficial femoral artery.

Table 3
Ankle Brachial pressure index results (ABPI).

ABPI	preoperative	Post operative	Z
median ABI	0.3	0.58	<0.0001

Table 4
Ankle Brachial Pressure Index Results (ABPI) according to clinical outcomes.

Outcome	median ABPI (preoperative)	median ABPI (Post operative)	Z
No MAEs	0.3	0.6	<0.0001
Mortality within 3 months	0.3	0.3	0.18
Major Amputations	0.1	0.05	0.7

heterogeneous distributions of resistance, which throughout interference induce higher possibility of plaque rupture, dissection as well as embolus formation [8].

Several studies have been illustrated the tibio-pedal approach to improve limb salvage in patients with critical limb ischemia (CLI) at a low reported complication rate. [9].

Three etiologies for a successful retrograde passage of a BTK CTO were established; firstly, the distal CTO cap is usually very soft and thus it is easy to enter, particularly if concave-shaped [10]secondly, from below the distance to the objective disorder is shorter, and together with a minor access vessel, might give additional reinforcement for the guide wire as well as different devices which were utilized. Thirdly, collaterals don't misguide the wire as easily if coming from below due to the angle and diameter of collaterals at the upper obstruction end [11].

In our study, we report 24 cases with CLI managed with Tibio-pedal approach due to superficial location (if open method used) and easy US penetration. The CLI patients with infrainguinal affection usually have severely calcified arteries. These severely calcified lesions had been attributed to DM, hypertension, Dyslipidemia and ESRD, [12]. Where the typical presentations of infra-popliteal (IP) disease in diabetics; are long, multilevel lesions [13].

In our study, the majority of the cases were diabetic, hypertensive (62.5%) and dyslipidemia (62.5%) so we faced Calcifications in infra inguinal affection. As regard Hosam El-Sayed et al. study; almost two thirds reported a history of tobacco use, and 76% were diabetic, 95% was hypertensive [14].

As regard indications of procedure: In our study, half of the cases indicated for rest pain (50%) and other half for tissue loss (37.5% for ulcer, 12.5% for gangrene), Hosam El-Sayed et al., reported in his study 19% of cases indicated for claudications, 5% for rest pain, 76% "majority of cases" for tissue loss [13], DM, CAD and HTN were present with percentage (94%), as reported in the literature [12],*also,* Zoltan Ruzsa et al., reported in his study that 53% 0f cases indicated for gangrene (majority), 37% for ischemic rest pain, 16% for ulcer [15].

Zoltan Ruzsa et al. had reported 35% 0f cases classified as (Grade II, Category 4: Rest pain), 65% of cases reported as (Grade III, Category 5: Minor tissue loss (ischemic ulceration not Exceed ulcer of digits of foot) [14]In our study, on the Examination of the patient, 12 cases (50%) classified as (Grade II, Category 4: Rest pain), 9 cases (37.5%) reported as (Grade III, Category 5: Minor tissue loss (ischemic ulceration not Exceed ulcer of digits of foot) and 3 cases (12.5%) classified as (Grade III, Category 6: Major tissue loss (sever ischemic ulcer exceed Level of TM joint or frank gangrene of limb).

Hosam El-Sayed et al. concerned that the major access site was dorsalis pedis artery (57%), ATA (19%), PTA (24%) [13],also, J. P. Goltz et al. reported that the dorsalis pedis artery and distal ATA are most common access site (81.25%), distal PTA represent (18.75%) of the cases [12]In our study, the access site for distal puncture was ATA (58.3%), PTA (37.5%), peroneal artery (4.2%).

As regard operative history for whole cases: 17 cases with no previous surgical history (70.8%), Two cases (8.4%) with previous history of Bypass or Thrombectomy of the same limb, 3 cases (12.5%) with previous history of Angioplasty of the same limb, Major Amputations of the opposite limbs had been done in two cases (8.3%). Zoltan Ruzsa et al. reported in his study 41% 0f cases underwent previous PTA, 11% of cases underwent previous vascular operation as "Bypass or Thrombectomy", 10% of cases with Hx. Of previous major amputation, 38% of cases with no previous surgical history [14].

Rational for utilizing retrograde Tibio-pedal access as a substation to ante-grade procedure is because it permits rapid therapy and short procedural time with minimal observation period within the hospitals.

Tibial arteries have minor calibers, making them more liable for vasospasm as well as thrombus development. Although such challenges

are decreased markedly with the usage of various protocols developed to reduce such adverse effects, the hazard is remaining a concern. Advantage as well as disadvantages must be evaluated cautiously. Using DAPT and anti-hyperlipidemic measures to keep the patency, and integrity of the vessels, and to minimize cardiac morbidities is essential.

The technical success was described as intra-vascular positioning of the pedal access vascular sheath through the objective vessels following retrograde puncture of the dorsal pedal artery as established by retrograde angiogram.

In our study, The technical success was achieved in 20 cases with percentage of (83.3%), and not achieved in 4 cases (16.7%) only, however technical success rate of crossing of 82% was similar to previously published data ranging from 75 to 100% as reported by [15], also, Andrej Schmidt, MD et al. in his study reported the retrograde access success in 98.6**%** [16], the procedure success rates were very high (>95%) as reported in the study of [17]. Hosam El-Sayed et al. in his study reported that the technical success rate of 67% was low, compared with earlier studies. In Botti et al.'s series of 6 patients, technical success was 100%; Rogers et al. and Montero-Baker et al. reported similar success rates of 85% and 86%, respectively. [18].

The main reason for procedural failure is the difficulty to perform re-entry following retrograde passage of the CTO. Thus, the usage of more procedures like the dual-balloon procedure or by usage of angulated catheters to break intimal flap [19]On the other hand, Mustapha and his colleagues recorded the primary etiology for failure as access location is calcification and successive difficulty to puncture the pedal vessel [20]. Incapability for evaluating the pedal vessel and failure to perform re-entry after retrograde sub-intimal disorder passing, were documented by Sabri et al. as the primary etiologies for failed procedure [21].

About the incidence of pedal vascular complications, in our study there was 20 cases without any complications with percentage of (83.3%), while there were 2 cases (8.3%) with perforations, and 2 cases (8.3%) with spasm. J. P. Goltz et al. in his study reported minor complications at pedal access site as hematoma and spasm (12.5%) while (87.5%) of cases without any complications [12].also, Zoltan Ruzsa et al. reported one tibial artery occlusion (4%), spasm (6%) in the investigated population and Tibial artery perforation was observed in (2%) [14].

The main drawback of the current study was the relatively small sample size which is difficult to be regarded as a general result.

7. Conclusion

Retrograde Tibio-pedal arterial access procedure can accomplish higher proportion of limb salvage rates with low morbidity and mortality utilizing highly skilled operators and advancements in current resources. Retrograde Tibio-pedal arterial access, as an initial primary procedure for endovascular intervention in CLI patients limited to infra popliteal vessels, is an efficient, safe, and practical procedure with a high technical success proportion and a relatively minimal procedural adverse effect proportion.

Declarations

The authors have nothing to declare as well as no boundaries or connection to any companies including those from which the devices utilized were used. No funds whatsoever were received at any time during the period of the trial.

Please state any sources of funding for your research

None.

Ethical approval

MS.18.08.257–2018/08/16.

Mansoura university.

Consent

No case reports.
But we had informed consent for the patients.

Registration of research studies

Name of the registry:
Unique Identifying number or registration ID: Hyperlink to your specific registration (must be publicly accessible and will be checked): MS.18.08.257–2018/08/16Mansoura university

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Declaration of competing interest

None declared.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.amsu.2022.104215.

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