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Retrograde Approach as an Alternative to Antegrade Approach in Peripheral Arterial Angioplasty for Treatment of Critical Lower Limb Ischemia

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Abstract: Background: Peripheral arterial disease (PAD) is a worldwide problem that has the potential to cause loss of limb or even loss of life. The prevalence of this vascular global problem in the general population is increased nowadays with increasing of prevalence of its risk factors as diabetes mellitus, hypertension, smoking, hyperlipidemia and others. **Objective:** to determine the feasibility (technically and outcome) of retrograde approach after failure of antegrade technique in peripheral arterial angioplasty for the treatment of critical lower limb ischemia. **Patients and Methods:** In this study, we worked on 25 patients who failed to be revascularized antegrade. Variant of accesses was created; popliteal, anterior tibial and posterior tibial. Ultrasound-guided puncture was needed in some of these cases. **Results:** Technically, 24 out of the 25 patients (96%) showed technical success, as the puncture was done and the lesion was crossed and treated adequately through a retrograde access. At the end of the 6-month period of follow up, the mean of ABI increased from 0.38 before the intervention to 0.68, this 0.3 rising in the ABI is significant and means that the procedure had a satisfactory outcome in short-term follow up period. **Conclusion:** The retrograde peripheral angioplasty whatever through popliteal artery or trans-tibial is feasible, safe, and successful in treating infra-inguinal arterial lesions when indicated, with satisfactory results during a short-term period of follow up.

[Alaa Abdulhamid ElAshry, Ramez Mounir Wahba, Hamdy Abdelazeem Abo ElNeel Abdelhameed and Mohamed ElSayed Ahmed Hassa. **Retrograde Approach as an Alternative to Antegrade Approach in Peripheral Arterial Angioplasty for Treatment of Critical Lower Limb Ischemia.** *Nat Sci* 2020;18(1):25-30]. ISSN 1545-0740 (print); ISSN 2375-7167 (online). http://www.sciencepub.net/nature. 5. doi:10.7537/marsnsj180120.05.

Keywords: Peripheral arterial disease, Critical limb ischemia, Angioplasty

1. Introduction

Peripheral arterial disease (PAD) is a group of disorders that characterized by narrowing or occlusion of the lower limb arteries resulting in a gradual reduction of blood perfusion to the limbs. (1)

Peripheral arterial disease (PAD) is a worldwide problem that has the potential to cause loss of limb or even loss of life. (2). The prevalence of this vascular global problem in the general population is about 12–14%, affecting up to 20% of those >70 years old. (3) The process of aging increases the symptomatic PAD incidence from about 0.3% per year in men aged 40–55 years to about 1% per year in those over 75 years. (4) In the 21st century, it became a clear problem in developing countries, which needs to be addressed. The prevalence of PAD is equal in both genders. (5)

PAD manifests as insufficient tissue perfusion. The progress of the disease is contributed to risk factors such as diabetes mellitus, hypertension, smoking, hyperlipidemia, and lack of exercise. (3)

Patients with PAD commonly suffer from ischemic heart diseases and visceral and cerebrovascular insufficiency. It is estimated that less than one-third of them will need intervention for their limbs, surgical or radiologic. However, studies show that patients with symptomatic PAD have at least a 30% risk for death from myocardial infarction or cerebrovascular disease within five years. Therefore, peripheral arterial diseases considered as an independent risk factor for cardiovascular death. (6)

Patients with symptomatic PAD and critical limb ischemia (CLI) have an increased risk for death and cardiovascular insults, especially in those with CLI who carry a high risk of limb loss. Advances in therapeutic modalities; medical, surgical, and endovascular techniques have shown excellent outcomes in those patients. (7)

Patients suffering from chronic lower limb ischemia are usually high-risk surgical patients because of their many co-morbidities. Therefore, open surgical revascularization is not suitable for many of them. Fortunately, percutaneous angioplasty offered a suitable treatment option for this group of patients as it performed under local anesthetic infiltration.

Furthermore, for patients with infra-popliteal occlusive disease, percutaneous endovascular intervention has become the first option of treatment for these challenging lesions. [8]

During angioplasty, multiple options for arterial access are available. The most commonly used site is the common femoral artery, through ipsilateral or contralateral cross-over. If the common femoral artery (CFA) access is not suitable, alternatively, a retrograde ipsilateral approach can be used through the distal superficial femoral artery (SFA), popliteal, tibials, or the dorsalis pedis arteries. Another use for the retrograde technique is the inability to return to the true lumen after creation of a subintimal plane during trials to pass the wire. The suggested re-entry devices are expensive and their use is complicated. Therefore, they can be replaced by different retrograde approaches. [9]

Popliteal artery access from a retrograde approach has grown in use as an alternative to antegrade crossing of SFA occlusions through femoral puncture. The dis-advantage of the need to change the patient's position in this retrograde approach is overcome now by performing the procedure while the patient is supine. However, it is suitable only for SFA lesions but not when coexistence of other lesions. [10]

On the other hand, the retrograde access seems to be a potentially effective alternative for endovascular therapy of infra-inguinal arterial lesions when the antegrade procedure is not suitable. [11]

Aim of The Work

The aim of this study is to determine the feasibility (technically and outcome) of retrograde approach after failure of antegrade technique in peripheral arterial angioplasty for the treatment of critical lower limb ischemia.

2. Patients and Methods

This is a prospective study conducted over a period of 11 months. Patients included in this study admitted for intervention and follow up at Electricity Hospital between November 2018 and July 2019.

In this study, we worked on 25 patients in Electricity Hospital who fulfilling inclusion criteria of this study, the selected group of patients were suffering from critical lower limb ischaemia; who complaining from rest pain or tissue loss (ischaemic ulcer or gangrene).

After verification of the inclusion and exclusion criteria, a written informed consent for the collection of personal and medical data was obtained for each patient before enrollment in this study.

Inclusion criteria: Patient complaining of critical limb ischemia with one or more of the following presentations; rest pain, arterial ulcer or gangrene, irrespective to patient's age or gender. Failure of antegrade recanalization for one of the following reasons: Inability to recognize the ostium of the occluded artery. Failure to pass the occlusion. Creation of a subintimal plane and failure of re-entry into the true lumen after subintimal dissection.

Exclusion criteria: Patient complaining from claudication only. Stenotic lesions (no total occlusion). Supra-inguinal lesions (iliac).

Procedure and hospitalization: All eligible patients underwent careful history taking and clinical examination to collect clinical data before the procedure. This consisted of medical history and comorbidities, medication record, physical examination and clinical categorization of critical limb condition (Rutherford 4, 5 & 6), including ABI calculation using hand-held doppler. Evidence of disease was assessed by color-flow duplex ultrasound study followed by CT angiography, then the patients were prepared for endovascular revascularization. Initially, while the patient is supine and after complete aseptic condition, antegrade access is obtained through femoral artery puncture ipsilateral or contralateral. When 6-F sheath was in place, 5000 units of heparin were administered intravenously, then a 0.035 hydrophilic guide wire was inserted trying to pass the targeted lesion, which varies in our cases from infra-inguinal to infra-popliteal segments. The guide wire is introduced trying to pass the occlusion, failure of passing occurs sometimes. In other situations, a subintimal plane may be created with in-ability to re-entry to the true lumen. In infra-popliteal disease, we could find difficulty in identification of the ostium of an artery, and that prevent the wire to pass to the targeted artery. In these conditions, the decision of retrograde access creation was taken.

Retrograde Interventions details: First, it was ensured that the antegrade femoral approach, either ipsilateral or contralateral, had failed**.**

Procedure of the tibial puncture: After skin preparation and obtaining complete aseptic condition around the ankle joint, the vertebral (angiographic) catheter that used during the antegrade attempt was placed close to the proximal end of the occlusion, to allow optimal contrast flow distal to the lesion and visualize the tibial arteries to guide its puncture. The puncture site is achieved by looking for a disease-free segment of the artery just above the ankle joint. When accessing the ATA, the foot was positioned in plantar flexion, while it has to be everted during PTA puncture. The needle was inserted while injecting the contrast from above by the assistant. In some difficult-puncture cases, the ultrasound-guided puncture was done.

Procedure of the popliteal puncture: With the patient in a lateral position, and after skin preparation and toweling, an initial ultrasound imaging was

performed to identify the popliteal artery and its relation to the popliteal vein. the popliteal artery was punctured just above the femorotibial joint line.

Technique of retrograde approach: After successful access creation, usually a 0.035′ hydrophilic guide wire was introduced through the popliteal retrograde access, while in ATA or PTA, the first choice was the 0.014′ hydrophilic wire then 0.018′, to decrease risk of vessel injury. The wire passed through the occlusion and back into the lumen above the lesion. The guide wire was manipulated and entered into the tip of the vertebral catheter, and then through and out of it at the femoral access site. Then, the vertebral catheter was pushed down over the wire beyond the lesion as far as the distal entry of the wire to the vessel. The wire was removed then reinserted from above with its soft tip through the vertebral catheter, and advanced distally in the vessel beyond the retrograde puncture site. Dilatation was done using an appropriately-sized balloon according to the vessel affected, advanced from the femoral site. Repeated dilatation was performed for any residual stenosis over 30%, or for flow-limiting dissection. A bare-metal stent was placed in cases with immediate post-dilatation restenosis, or in case of significant dissection.

All patients discharged on duel antiplatelet consisting of aspirin 75 mg and clopidogrel 75 mg, they also received a statin.

Follow up: The improvement in symptoms according to Rutherford classification, achievement of pulses, and ankle brachial index (ABI) were recorded the next day before discharge, and after 1 month, after 3 months, and after 6 months. An increase in ABPI more than 0.15 mmHg before discharge was considered a success. [12] Patients who presented with foot ulcers underwent follow up of their ulcer condition, with recording heal promotion post revascularization. CT angiography was performed if there a possibility of restenosis or occlusion. Complications, if present, were recorded.

Study endpoint:

Technical end-points: Failure to access popliteal artery or one of the tibial arteries. Failure to cross the targeted lesion from the retrograde approach. Flow-limiting dissection that cannot be corrected.

Follow up end-points: Arterial thrombosis before discharge. Restenosis >50% at any time during 6 months follow-up. Non-improved arterial ulcers after a significant period of follow up. Six-month follow-up of the successful cases (The 1ry end-point).

Statistical Analysis:

The sample size of the study was calculated using PASS program, setting alpha error at 5% and confidence interventional width at 0.15. Based on the primary endpoint of the study (feasibility of retrograde peripheral angioplasty), and in light of 100% success of the previous study of [13] the needed sample is 25 cases, taking in consideration 20% drop out rate.

3. Results

Fig. (1): Rising of ABI-mean values pre and post intervention.

Table (1): Risk factors percentage of the studied population.

Risk Factor	Number of patients (%)
Smoking	17 (68%)
DM	18 (72%)
Hypertension	21 (84%)
Ischemic heart disease (IHD)	13 (52%)
Cerebrovascular accident (CVA)	6 (24%)

Table (2): ABI changing among different visits.

At presentation	*ABI follow-up*	On discharge	After 1-month	After 3-months	After 6-months
0.38	**Mean**	0.62	0.65	0.66	0.68
0.029	**Standard Deviation**	0.075	0.08	0.09	0.1
---	**P-Value**	0.0001	0.0001	0.0001	0.0001

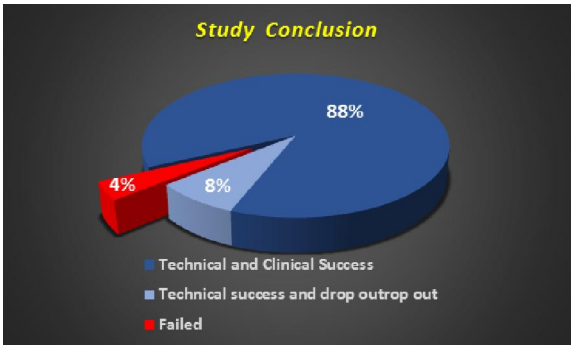

Fig. (2): Success percentage of the study showing 96% success in lesion treatment, with 8% (2 cases) drop out during follow up after successful intervention.

4. Discussion

Recently, endovascular intervention is the first option of treatment for peripheral arterial diseases. Efforts have been made to increase the success rate of this modality of treatment, by developing new devices and techniques that enable the surgeon to overcome the challenges faced during the procedure. [16]

Retrograde access is a promising alternative method for patients in whom conventional antegrade endovascular technique failed to achieve recanalization of the SFA, popliteal, and/or tibial arteries. During the period of our study, no patient underwent retrograde revascularization from the start, as most of cases completed successfully with antegrade access. That indicates that the antegrade approach, when feasible, is the preferred method. This was reflected in other studies as ***Rogers et al.*** [14] where 13 patients were included. This may suggest a general consensus that revascularization by puncturing the run-off vessel is not justified as a first option, as its failure may endanger the more feasible antegrade option. [15]

All of the patients of this study presented with critical limb ischemia, which includes one of the following; rest pain, ischemic foot ulcer or dry gangrene of the toes. This agrees with the observation made in previous studies, as all patients included in the study by ***Botti et al.,*** [16] presented with CLI. Also, all patients studied by ***Walker*** [17] had critical limb ischemia. This severe form of ischaemia is compatible with the recognized severity of the lesion and its calcification and explains the failure to cross the lesion from the start, but it is not clear why it is easy to cross the same lesion from below.

Regarding the access site, the popliteal artery was the artery of choice for access in (28%) of the patients, who characterized by chronic total occlusion of SFA with no significant tibial disease, as done in ***Noory et al.,*** [18].

Between the two tibial arteries, PTA was punctured in 12 (48% of all cases and 67% of tibial accesses) patients, in comparison to 6 (24% of all cases and 33% of tibial accesses) patients accessed through ATA. This agrees with the observation made in previous studies, as it was the access artery in 67% of patients in the study of ***Botti et al.,*** [16] and in 85% of cases in the study of ***Rogers et al.*** [14] but this disagrees with ***Mustapha et al.,*** [19] a study that worked on a bigger group of patients and showed 52% of patient obtained ATA access in comparison to 34% of PTA. That means that both ATA and PTA are accessible and the choice for access depends on the operator experience and the degree of run-off observed during the intervention. That also repeal the suggestion of ***Reffat et al.,*** [12] who said that the PTA is the preferable artery for access as the distal part of the PTA is the last segment to be affected by atherosclerosis process in chronic ischemia. To be mentioned. The peroneal artery is not excluded from our study, but it wasn't chosen as an access site in any patient.

The puncture was successful in all patients. This 100% success rate was also recorded by ***Botti et al.,*** [16] and by ***Hua et al.,*** [20]. Ultrasound guidance was used while obtaining the access in some of cases in our study. It was used in all 7 cases of popliteal punctures as it is safer and associated with fewer complications, as the study of ***Yilmaz et al.*** [21] confirmed. ATA and PTA were punctured initially after injection of dye to localize the position of the artery. In cases of poor distal run-off and ill-identified vessel, the US was used to ovoid multiple punctures and time wasting revealed by ***Gür et al.*** [22]. That was done in 4 (25%) patients out of 12 of PTA punctures, while ATA puncture was obtained under US usage just in one (16.6%) case of the six cases.

After obtaining retrograde access, the targeted lesion was successfully crossed, exteriorized (without snaring), treated in all patients but one, when a chronic total occlusion in the SFA cannot be crossed after obtaining ATA access. A stent was deployed if indicated. The technical success rate equals (96%). Such high success rates (>90%) were also recorded by others such as ***Dumantepe*** [23] (93%), ***Noory et al.,*** [18] (98%) and ***Gür et al.*** [22] (100%). This high success rate confirms that the retrograde approach is feasible and successful when indicated.

The patients included in our study were followed up for six months for their symptoms, foot ulcers, and ABI improvement. Only one patient died during the period of follow up period, two months post-intervention, and another patient was disconnected. All remaining patients were showed significant dramatic relieve of previously presented rest pain

post- intervention and during the period of follow up. Patients who was presented with foot ulcers show significant improvement up to complete healing at the end of the six-month period of follow up. That agrees with many of studies such as in ***Dumantepe*** [23].

During the follow-up period, the mean ABI improved from 0. 38 before intervention to 0.62 on the next day before patient's discharge. This increased to 0.65 after the first month, to 0.66 after three months, and to 0.68 at the end of the sixth month post-intervention. That means the mean improvement after the period of follow up = (0.3). This change in the mean of ABI was statistically significant. Other studies done on retrograde intervention in critical limb ischemia show close results; (0.33) in ***Ye et al.,*** [24] and (0.38) in ***Wei et al.,*** [25].

In this study, only minor complications were reported, in the form of non-significant subcutaneous hematoma. These complications are of those expected during the antegrade approach and were not specific to the retrograde maneuver. No major complications were recorded for 6 months. This low rate of complications confirmed the early suggestions regarding the safety of the procedure. [14]

5. Conclusion

The retrograde peripheral angioplasty whatever through popliteal artery or trans-tibial is feasible, safe, and successful in treating infra-inguinal arterial lesions when indicated, with satisfactory results during a short-term period of follow up.

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9/11/2019