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Original Research Article

Impact of endovascular pedal arteries revascularization on wound healing in patients with critical limb ischemia

Mohamed M. El Yamany, Hatem H. Mohamed, Meera R. Boulos*, Sherif A. Reffat

Department of Surgery, Vascular and Endovascular Unit, Suez Canal University Hospital, Ismailia, Egypt

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***Correspondence:**
Dr. Meera R. Boulos,
E-mail: meeraboulos@gmail.com

ABSTRACT

Background: Critical limb ischemia (CLI) is the final consequence of peripheral arterial disease (PAD). The management of this complex patient population often warrants a multidisciplinary approach with collaboration between endovascular interventionist, vascular surgeons, podiatrist, infectious disease, and wound care specialist. Objective of the study was to evaluate the impact of endovascular pedal arteries revascularization on wound healing in patients with critical limb ischemia.
Methods: This was an interventional study conducted on 30 consecutive CLI patients underwent infra-genicular endovascular revascularization who attended to the outpatient department and emergency, Suez Canal university hospital complaining of symptoms of critical lower limb ischemia involving the foot (rest pain, ulcer and gangrene), during the period study from June 2017 till January 2019. Full detailed history, full examination, lab investigation, radiological imaging was done.
Results: The pain intensity decreased from 7 to 4 post-procedural at 2nd day post-op, then to 3 at one week follow up and then it totally disappeared at one month follow up visit. The remaining patients who had incomplete PAA reported faster relieve of pain and more dramatic improve over time as it was totally relieved post procedural by time of discharge. The overall mean time required to achieve wound healing was 15±8 weeks.
Conclusion: Successful pedal artery revascularization significantly improved wound healing in patients with CLI. Endovascular revascularization is effective to facilitate healing of wounds in CLI and can be performed without significant complications.

Keywords: CLI, Endovascular revascularization, Wound healing, Pain score

INTRODUCTION

PAD is an abnormal narrowing of arteries, most commonly affects the thigh and the legs, but other arteries may also be involved such as those of the arms, neck, or kidneys.[1,2]

Patients with PAD are at increased risk for coronary heart disease, and all-cause mortality. This risk is independent of traditional risk factors, including age, sex, smoking, systolic blood pressure, plasma lipids, fasting glucose, body mass index, and preexisting clinical cardiovascular disease. Risk of mortality as a consequence of coronary heart disease is 3 to 6 times higher in subjects with PAD than in subjects without PAD, even after accounting for traditional risk factors.[3]

Patients with lower extremity PAD experience substantial functional disability due to claudication, rest pain, and minor or major tissue loss. The number of patients requiring lower limb revascularization for limb ischemia are likely to increase significantly worldwide as a result

of ageing populations, the increasing prevalence of diabetes, and the failure so far to significantly reduce global tobacco consumption. Lower extremity occlusive disease may range from exhibiting no symptoms to limb-threatening gangrene.[4]

Rutherford and Fontaine classifications of CLL (chronic lower limb ischemia) help to establish uniform standards in evaluating and reporting the results of diagnostic measurements and therapeutic interventions.[5]

CLI is a major cause of morbidity and mortality worldwide. There are some reports that the atherosclerotic pattern in diabetic patients affects the tibial vessels yet tends to spare the pedal vasculature and thereafter pedal angioplasty is still doubtful.[6,7] Although this may be true in many cases, the experience has demonstrated frequent involvement of the pedal vessels, including the pedal arch. In a subset of patients with critical limb ischemia, particularly in longstanding type 1 diabetic patients and patients on dialysis, a predominance of disease involving the pedal vessels can exist with relative sparing of the tibial vessels, patients present with rest pain and/or non-healing ulceration comprise approximately 1 to 2% of the PAD population.[8]

A strong understanding of the pedal arch anatomy and its multiple connections is important for the physician performing not only pedal arch interventions, but tibial interventions as well. Familiarity with the arch anatomy increases procedural success rates in tibial intervention, as it gives the operator another collateral pathway to approach the target occlusion in a retrograde fashion.[9]

Although it has been suggested that revascularization of the pedal arch may benefit wound healing for these reasons.[10] An Angio some-directed revascularization strategy has clearly been shown to improve wound healing and limb salvage rates in both surgical and endovascular series.[11,12] This study aims to evaluate the Impact of endovascular pedal arteries revascularization on wound healing in patients with CLI.

METHODS

The present study was an interventional study. This study took place in the vascular surgery unit, surgical department, Suez Canal university hospital, Ismailia, Egypt, during the period from June 2017 till January 2019.

All the patients attended the outpatient department and emergency, SCUH complaining of symptoms of critical lower limb ischemia involving the foot (rest pain, ulcer and gangrene).

All patients signed written informed consent with explaining the aim of study before the study initiation. Approval of the study protocol was obtained by ethical scientific committee of Suez Canal university hospital. Maintained the privacy of participants and confidentiality of data by: each patient has a special file with code number. All pictures were taken only of sites of surgery and covering of the face and unnamed and also for any was assured patients privacy.

All patients included in this study were selected according inclusion and exclusion criteria as follow: inclusion criteria included both sexes ages from 18-80 years old. All patients with CLI involving the foot present with one or more of the following: Rest pain not relieved for 2 weeks, Ulcer of toes or forefoot not healed for 6 weeks and gangrene of toes or forefoot. Patients with normal or non-significant stenosis at common iliac artery, common femoral artery and upper superficial femoral artery are suitable for ante-grade trans-femoral pedal arteries angioplasty.

Exclusion criteria excluded patients refuse to be included in the study. All arterial lesions associated with A-V malformation and aneurismal dilatation, patients presented with proved vasculitis, patients who are not fit for angioplasty as: patients with chronic liver disease if there is prolonged PT and patients with heart failure if the patient is orthopneic and cannot lay on table for long time) and patients with impaired renal function.

The following data obtained from all patients: demographic data: the patient's name, age, sex, address, occupation and phone number and clinical presentation: limiting claudicating (category 3), rest pain (category 4), minor tissue loss (category 5) and major tissue loss (category 6), according to Rutherford classification).

Pain was assessed according to pain scales presented in the Table 1.[13]

Table 1: Pain scale.

Rating	Pain level
0	No pain
1-3	Mild pain (Nagging, annoying, interfering little with daily living activities)
4-6	Moderate pain (interferes significantly with ADL)
7-10	Severe pain (disabling; unable to perform ADL)

The pain scale will be completed with the help of the researcher.

Risk factors are like diabetes, ischemic heart disease, hypertension, hyperlipidemia, atrial fibrillation, chronic liver disease, chronic renal disease, smoking, and cerebro vascular stroke.[17,18] Any allergies to contrast (for angiography).

Trophic changes (Loss of hair, dry, shiny skin, nail changes, wasting), presence of ulcer, presence of

gangrene, warmth of the skin, capillary refill, pulses and grades (Femoral artery, popliteal artery, anterior tibial artery, posterior tibial artery and dorsalis pedis artery, bilaterally), measure the ankle-brachial pressure index (ABPI), bilaterally (ATA, PTA).

The ulcer (wound) was assessed for size and depth and by using the following classification: texas diabetic wound classification.[14]

Table 2: Texas diabetic wound classification.

Stages	Grading
Stage A: No infection or ischemia	Grade 0: Epithelialized wound
Stage B: Infection present	Grade 1: Superficial wound
Stage C: Ischemia present	Grade 2: Wound penetrates to tendon or capsule
Stage D: Infection and ischemia present	Grade 3: Wound penetrates to bone joint.

Laboratory investigations: Complete blood count (CBC) and fasting blood sugar for non-diabetic patient and HB A1C for diabetic patients, and Bleeding profile as prothrombin time (PT), partial thromboplastin time (PTT), international randomized ratio (INR) and serum creatinine.

Radiological: All patients did compute tomography angiography (CTA) as a primary choice.

Technique of pedal artery angioplasty

Patient fasted for 4 hours pre-operative, and Procedure was performed under local anesthetic (5-10 ml of 1% lignocaine).[15,16]

Site of arterial puncture: ante-grade puncture of the ipsilateral common femoral artery. Procedure: Every case was studied individually, the procedure was done in operation room under complete aseptic technique, and mobile C arm (Philips flat panel C arm 15 KW) with vascular imaging capabilities. Patients was placed supine. The ipsilateral common femoral artery was punctured using a single-piece 18-gauge needle. After selective wiring of the superficial femoral artery, an 11-cm-long, 6-F Terumo introducer sheath (Terumo interventional systems, somerset, NJ) was placed. Heparin 50 IU/ kilo was given IV, half of the dose was given when the procedure continued for more than one hour. Baseline angiography was performed to obtain pictures of the femoro-popliteal tract, as well as below the knee vessels (BTK) and foot vessels.

Regarding on table pre procedural angiography; all cases had diseased infra- genicular vessels. According to Kawarada classification which described three types of pedal arch disease, we found that all cases had absent pedal arch (APA); as they had neither of the dorsalis pedis artery nor none of the plantar arteries were patent and the circulation of the foot was established through collateral vessels.

A 0.018 inch (Boston scientific, V-18 control wire, 0.018×300 cm) hydrophilic guide-wire was advanced into the occluded pedal artery with the support of a microcatheter 0.018 in all presenting cases as the 1st choice. V-14 (Boston scientific, V-14 control wire, 0.014×300 cm) was tried after V-18 failure confirmed.

The use of appropriate X-ray equipment capable of subtraction angiography and magnification is crucial to carefully navigate the wire through the anastomotic connections between the dorsalis pedis and plantar artery (figure 10 A, 10 B). A very useful trick is to bring the balloon catheter to the distal dorsalis pedis or plantar artery and then to inject contrast locally to assess a possible road of connection. The availability of a low-profile, dedicated balloon catheter is then very important to follow the wire through tortuous vessels. Local injection through the balloon catheter can also be used to confirm the correct intraluminal position before inflation.

Specifically, two approaches can be attempted in each patient: antegrade recanalization of the anterior tibial artery and the dorsalis pedis followed by retrograde recanalization of the plantar artery and then of the distal posterior tibial artery or antegrade recanalization of the posterior tibial artery and the plantar artery followed by retrograde recanalization of the dorsalis pedis and then of the distal anterior tibial artery.[4,5]

Figure 1: (A) Contralateral oblique. (B) Ipsilateral cranial foot orientation.

The inflation should last between 60 and 180 seconds. The balloon size for foot vessels and plantar arch is usually 2.5 mm. After inflation, the balloon was retrieved, while leaving the guidewire in place, to perform digital subtraction angiography and appraise post-percutaneous transluminal angioplasty (PTA) results. If angiographic success is apparent, the guidewire was retrieved, and final control angiography was performed. Otherwise, subsequent inflations at higher pressure or with larger

balloons was performed for any residual stenosis greater than 30%.

On table post-procedural angiography of the foot was used to divide the patients into the following three groups according to the post-procedural angiography status of the pedal arch: complete pedal artery angioplasty (complete PAA), incomplete pedal artery Angioplasty (incomplete PAA) group, and non-complete pedal artery angioplasty (non PAA) group. After the procedure, homeostasis was achieved with manual compression of the accessed PA (7-10 minutes), followed by a compressive bandage was performed in all procedures. Technical success was defined as restored patency with no stenosis greater than 30% as per reporting standards. A poor result was defined as improvement in patency but with stenosis greater than 30% whilst failure will be defined as no change in patency or failure to cross the lesion.

Post procedural medication: All patients were medicated on: LMWH (low molecular weight heparin) for 3 days and dual anti platelets for 3 months with Clopidogrel (75 mg/day), acetylsalicylic acid (150 mg/day).

Follow-up for both groups

ABI, symptoms, pulses and duplex were assessed in these intervals: next day, after one week and every month till 6 months post procedural. An increase in the ABIP >0.015 was considered as accepted success. Complications such as infection, hematomas, thrombosis, aneurysm formation was recorded if present.

Statistical analysis

Results were tabulated and statistically analyzed by using a personal computer using Microsoft excel 2016 and SPSS v. 21 (SPSS Inc., Chicago, IL, USA**.** Statistical analysis was done using: Descriptive: e.g. percentage (%), mean and standard deviation. Analytical: that includes: chi-squared (χ^2), and paired t test. P value less than 0.05 was considered statistically significant.

RESULTS

In the current study, the ratio of male to female patients nearly equal; 16 men (53.3%) and 14 women (46.7%) with a mean age of 61.63±8.865 years. Out of the 27 patients who were diabetics, 17 of them (63%) had diabetic foot wounds. According to Texas university diabetic wound classification, found that 11 of these patients (36.7%) had D3 wounds at presentation, while 6 patients (22.2%) had D1 wounds. As shown in figure 2.

Regarding the presenting symptoms, 6 of the patients (20%) presented with ischemic rest pain (Rutherford class 4) which was of grade 7 according to pain scale, three patients among the latter group had associated toes discoloration. We also found that 21 patients (70%) presented with minor tissue loss (Rutherford class 5), while only 3 patients (10%) presented with superficial heel gangrene (Rutherford class 6). As shown in figure 2.

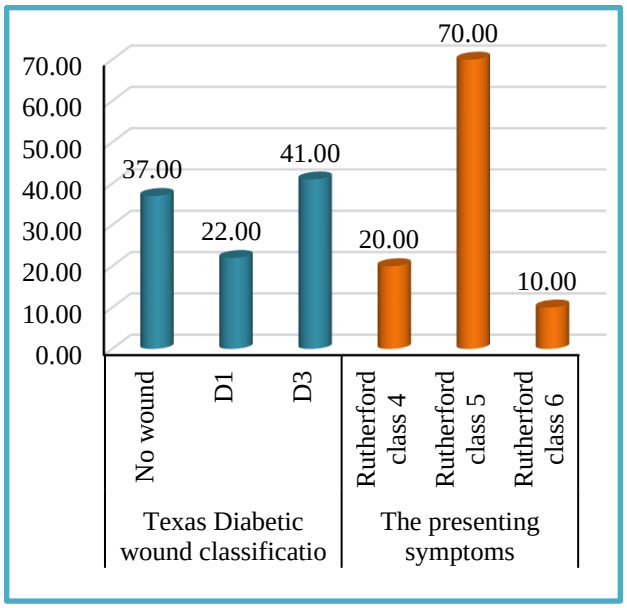

Figure 2: Distribution of the patients according to Texas diabetic wound classification and presentation as Rutherford class.

Out of the 21 patients who presented with minor tissue loss, 15 patients (63%) presented with big toe gangrene or ulcer only, 4 patients (17%) presented with other toes gangrene or ulcers, 2 patients (8%) presented with forefoot gangrene or ulcers. All 3 patients presented with major tissue loss, presented with dry gangrenous eschar over the heel with free X ray. Regarding the examination, all patients had bilateral palpable femoral pulsations. Regarding the presenting limb; 16 out of the 30 patients (53%) had palpable popliteal pulsations before the intervention, and no pulses were felt distally in all of them. On the other hand, for the non-presenting limb, contralateral popliteal pulse was palpable in the 20 patients (66.6%). No distal pulsations were felt in any of them, figure 3.

Regarding pre-op serum creatinine, all presenting cases had baseline normal creatinine function, except 2 cases (6.7%) among all 30 cases had 1.5 baseline creatinine function for which they were kept on pre and post procedural renal protocol. 24-hour post procedural serum creatinine was normal as well. All endovascular interventions were performed in our endovascular operating room under local anesthesia. Access was achieved through an IPSI-lateral common femoral artery using 6 Fr sheath.

According to Kawarada classification found that all of the 30 patients (100%) had absent pedal arch (APA); as they had neither of the dorsalis pedis artery nor any of the plantar arteries were patent.[37] Circulation to the foot was maintained through collateral vessels.

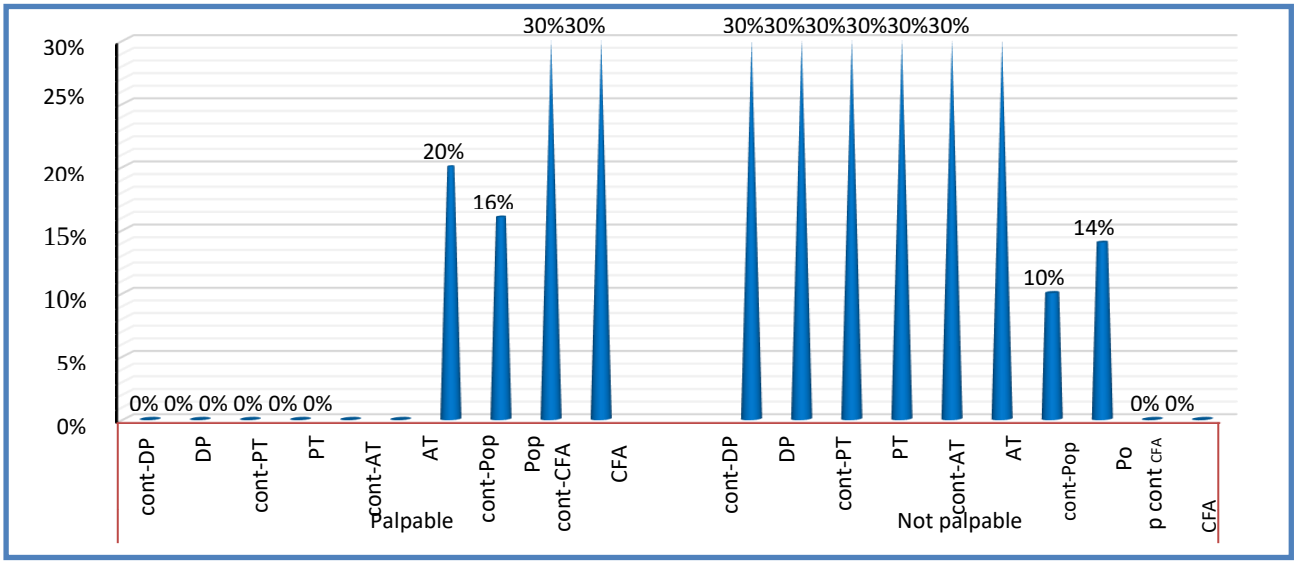

Figure 3: Distribution of the patients according to the pulsations contralateral.

Regarding the cases where significant distal SFA lesion was found; balloon dilatation of the vascular lesion was done first then followed by the same fore- mentioned diagnostic angiography procedure.

In this study, 5 patients among 8 cases who had non-PAA (62.5%) and 9 patients (75%) among 12 cases who had incomplete PAA had associated foot wounds or infection obscuring distal access site. As shown in Figure 4.

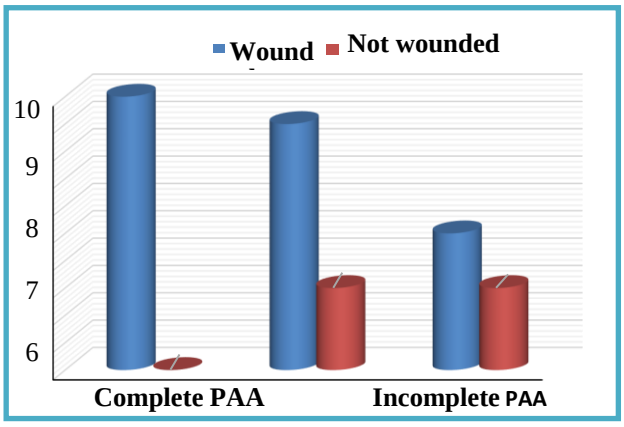

Figure 4: Distribution of patients according to post-procedural angiography findings; PAA: pedal artery angioplasty.

Used a supporting 0.018- and 0.014-inch micro-catheters (Rubicon, Boston scientific, 0.018 in/0.014 in × 150 cm) while advancing fore mentioned types of guide-wires into occluded pedal arteries in all 30 presenting patients. Used a low profile dedicated 2.5 mm balloon catheter (sterling balloon dilatation catheter, 2.5 mm×100 mm, 150 cm) in 22 cases. A 2.5 mm balloon was advanced following wire provided that lesion was crossed. Balloon dilatation of pedal vessels was performed for 1-3 min duration. Complete and incomplete PAA was achieved in 10 and 12 patients consecutively. On other hand, 3 mm balloon catheter (mustang balloon dilatation catheter, 3.0 mm×120 mm, 150 cm) was used in all tibial angioplasty. On table post-procedural angiography of foot was used to divide patients according to pedal arch status into following 3 groups; 10 patients (33%) had successfully PAA, while 12 patients (40%) had incomplete PAA. 8 patients (27%) had failed pedal artery angioplasty (non-PAA) and ended up with tibial angioplasty (Figure 5).

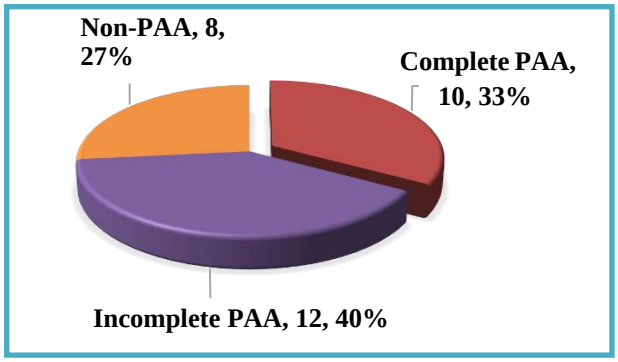

Figure 5: Distribution of patients according to post-procedural angiography findings; PAA: pedal artery angioplasty.

In 17 patients (57%), two or more vessels were treated, no intra- operative access site complication was recorded. 24 of patients (80%) underwent ATA revascularization; whether alone or associated with other infra- genicular vessels. 20 patients (67%) had treated PTA, 9 patients (30%) had treated DPA, 9 patients (30%) had treated PA, 7 patients had dilated med and lat planter vessels. However, out of the 30 patients, only 5 cases (16.7%) had associated distal SFA lesions that were treated as well during intervention.

Among all 24 patients (80%) presented with tissue gangrene or foot wounds, 15 patients (50%) had big toe amputation; in 8 (26.6%) cases out of the latter group we were able to achieve complete PAA along with ATA and PTA dilatation, while in 2 cases (6.6%) out of them we were able to achieve incomplete PAA in form of ATA and DPA dilatation. In remaining 5 (16.6%) patients we were able to achieve non-PAA as they had whether ATA and PTA dilation or isolated PTA dilatation only. All 4 patients presented with other toes wounds had incomplete PAA; in 2 of them (6.6%) who had 2nd toe amputation we were able to achieve ATA and DPA dilatation, while in the remaining 2 patients (6.6%) who had 4th toe amputation were able to achieve ATA, DPA and PTA dilatation.

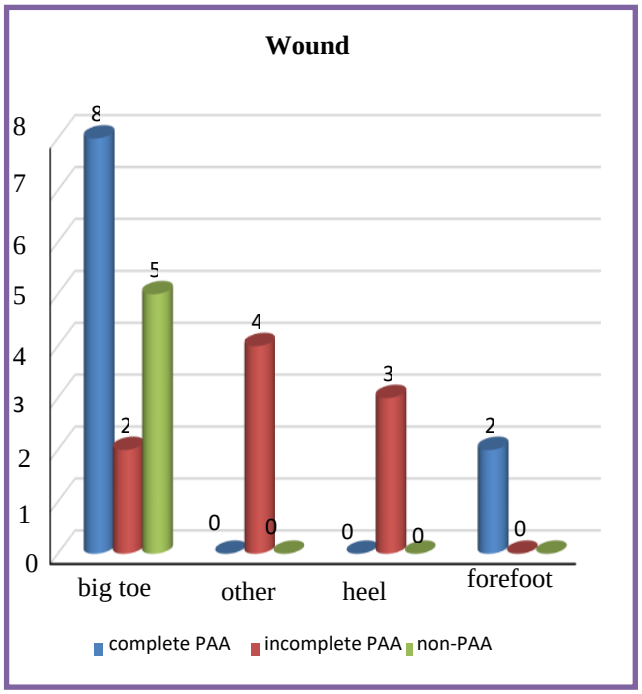

Figure 6: Distribution of patients with PAA according to their wound site.

In both 2 patients who presented with forefoot dry gangrene we were to achieve complete PAA along with PTA and ATA dilatation. In all 3 (10%) patients who presented with heel superficial gangrenous patches were to achieve incomplete PAA as they had balloon dilatation of both ATA and DPA. As shown in figure 6.

Regarding, during 6 months follow-up period, 6 patients with rest pain (grade 7) at presentation reported total relieve of symptoms post procedural. 3 patients among them had non-PAA. These patients reported gradual relieve of ischemic rest pain. According to pain scale, pain intensity decreased from 7-4 post- procedural at 2nd day post-op, then to 3 at one week follow up and then it totally disappeared at one month follow up visit. On other hand, the remaining patients who had incomplete PAA reported faster relieve of pain and more dramatic improve over time as it was totally relieved post procedural by time of discharge, (p=0.008, significant) (figure 7).

Concerning, during follow-up, healing of lesions whether partial or complete was achieved in all 21 patients (70%) with minor tissue loss (Rutherford class 5). Overall mean time required to achieve wound healing was 15±8 weeks. Complete PAA, incomplete PAA, and non-PAA groups, mean time to healing was 9±1.7 weeks, 14.2±2.1 weeks, and 29.2±2.1 weeks, p value=0.001, significant.

Among all 24 patients (80%) presented with minor tissue loss (Rutherford classb5), healing within 3 months from procedure was achieved in all 10 patients with complete PAA, 4 patients with incomplete PAA (16.7%), while none of patients with non-PAA had developed complete healing during our 6 months follow up period, (p=0.000, significant). However, remaining incomplete PAA patients had achieved complete wound healing by end of 4th month. Nevertheless, all 5 non-PAA patients (40%) showed slowly progressive wound healing but didn't achieve complete healing within 6 months follow up period, (p=0.000, significant), Figure 8.

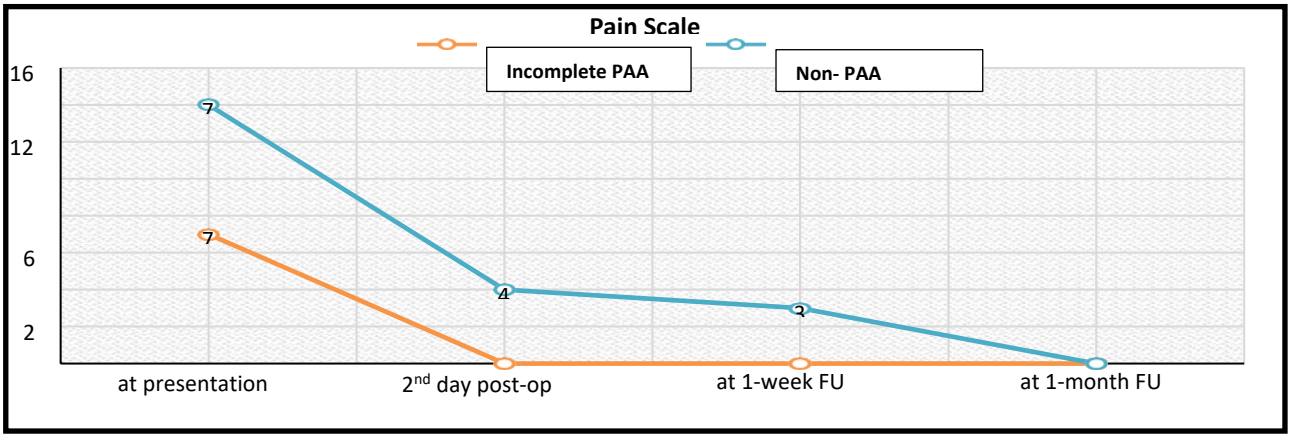

Figure 7: Comparison between the 2 groups regarding time required to achieve total rest pain relievers; PAA: pedal artery angioplasty.

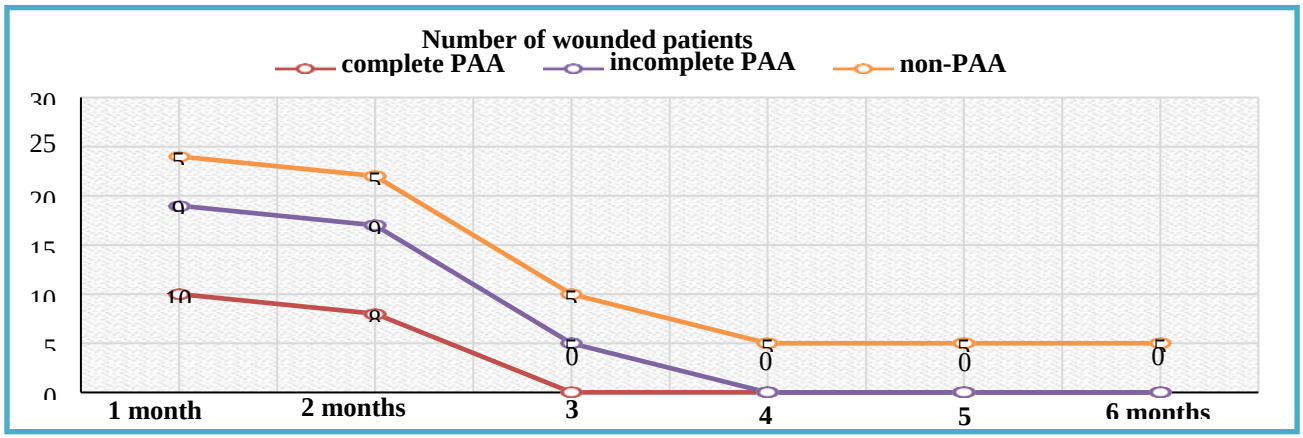

Figure 8: Comparison of the three groups regarding time required to achieve complete tissue healing; PAA: pedal artery angioplasty.

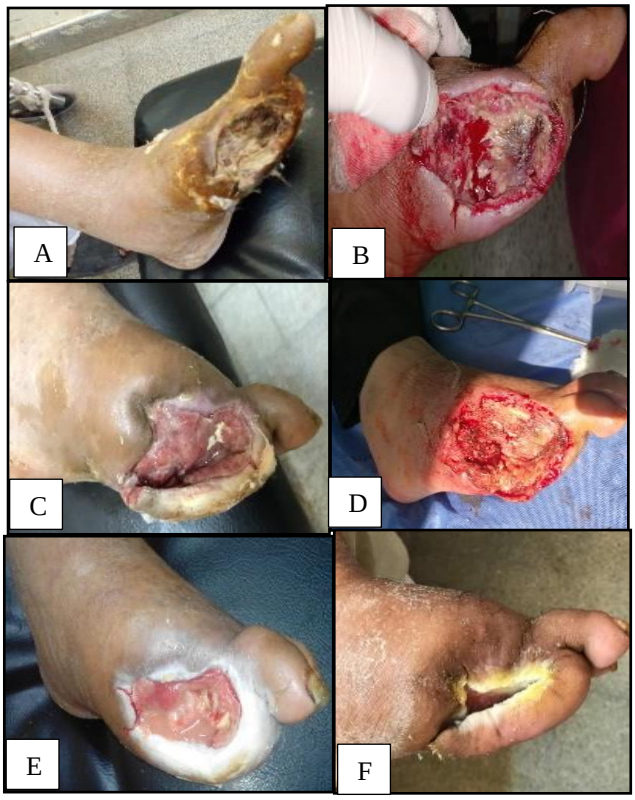

Figure 9: Progression tissue healing; patient with CLI presented with wet gangrenous big toe amputated stump, incomplete PAA was performed, regular follow up visits results slowly progressive tissue healing of wound and complete healing at 4 months. (A) At presentation. (B): post incomplete PAA debridement. (C): At 1-week FU. (D): At 1-month FU, wet gangrenous 2nd toe, surgically amputated.

During the follow-up, neither of the recovered patients reported recurrence of symptoms nor loss of the previously retrieved distal pulse. Only one patient started to develop infective gangrene of the adjacent toe which was treated by surgical debridement for the infective toes.

None of the patients developed neither extensive foot infection nor gangrene nor required major limb amputation. The following are 2 case examples that underwent PAA.

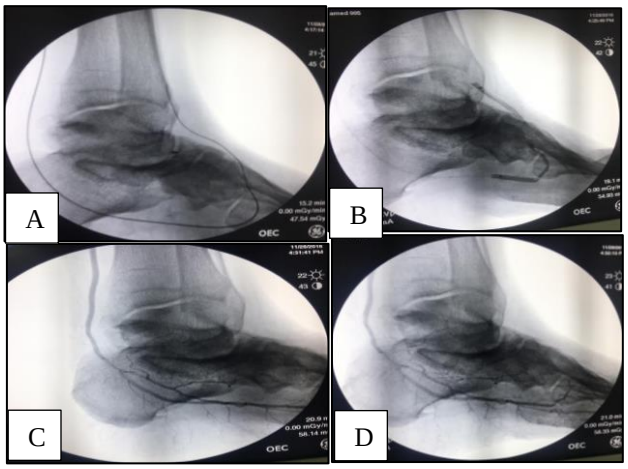

Figure 10: Incomplete pedal arch angioplasty; patient with CLI and extensive pedal-plantar arch disease, successful crossing of the lesion and balloon dilatation with good angiographic appearance of the medial and lateral planter arteries through PTA.

Case A: About 55 years old male patient, diabetic, hypertensive and smoker. He Presented with ischemic infected unhealed Lt big toe amputated stump. O/E; he had bilateral palpable femoral pulsations, non-palpable pop nor Tibial pulsations, he had ABPI over LT ATA, PTA 0.5, RT ATA, PTA 0.9. Duplex revealed distal SFA occlusion, occluded PTA, ATA. Ballooning angioplasty of distal SFA, PTA and planters; incomplete PAA was achieved. ABPI post-operative over ATA 0.8, PTA 1 (palpable). During his 1-month FU periodic visits, 2nd toe wet gangrene noted and toe amputation was performed. The patient showed similar results over her periodic FU visits after one week up to 6 months. Complete wound

healing occurred within 4 months, As shown in figure 9 and 10.

DISCUSSION

CLI 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.[20] CLI is the advanced stage of peripheral artery disease (PAD), which results from a progressive thickening of an artery's lining (caused by a buildup of plaque). This buildup of plaque, also known as atherosclerosis, narrows or blocks blood flow, reducing circulation of blood to the legs, feet, or hands.[10] The re-establishment of pulsatile flow to the pedal and plantar arches in below the knee region is a key factor to foot and limb salvage.[11.12]

The demographic data and risk factors of the studied patients were as expected for this type of disease.[31,32] Although the sample size was small, but diabetes, hypertension and hyperlipidemia all were prevalent among the studied group of patients. Most of the patients in this study were diabetics (90%), hypertensive (67%) and dyslipidemia (90%); which is similar to Ali et al which is a similar research conducted here at Egypt.[30]

In this study, 6 of the patients (20%) presented with ischemic rest pain (Rutherford class 4) which was of grade 7 according to pain scale, three patients among the latter group had associated toes discoloration. Also found that 21 patients (70%) presented with minor tissue loss (Rutherford class 5), while only 3 patients (10%) presented with superficial heel gangrene (Rutherford class 6), also showed that limb-threatening infections were observed in 123 limbs (47.9%). Nakama et al also showed that 128 involved limbs (49.8%) underwent surgical debridement or minor amputation.**[21]** Nevertheless, all 24 patients (80%) in our study presented with tissue gangrene or foot wounds underwent aggressive wound management as well. That implies that all patients involved presented with CLI.

This is common in similar studies in the same community.[22] Which may reflect an awareness or financial problems that prevent the patient from seeking medical advice in early stage of this disease. This, most probably, should affect the outcome of management for such cases, making the comparison of interventional outcome with the international publications difficult.

A V-18 control guidewire was advanced into the occluded pedal artery with the support of a microcatheter in all 30 presenting cases as our 1st choice. Succeeded to cross the occluded pedal arch in 8 cases (26.6%) and complete PAA was achieved. Also managed to achieve incomplete PAA in 7 patients (23.3%) using V-18 as 1st choice as well. V-14 was tried after V-18 failure confirmed. A second trial to achieve complete PAA in the fore-mentioned 7 cases using V-14 was done but unfortunately failed. Manzi et al studies all showed that the procedure was performed using 0.014- inch hydrophilic guide-wire as their 1st choice mainly in all cases.[23,24] However, Nicola et al showed that they successfully achieved complete PAA in 42 patients (30.7%), incomplete PAA in 60 patients (43.8%), and non-PAA in 35 patients (25.5%).[33]

Angio some-oriented direct revascularization, which might improve the blood supply toward target wounds, is a widespread strategy.[25,26] However, other studies showed that the effectiveness of the Angio some concept is still controversial.[27] Based on the fact that in patients with pedal artery disease, original Angio some mapping is already destroyed, and the blood supply toward the target wounds depends on the patency of the newly developed collateral channels.[21] These results are consistent with those of Azuma et al and Attinger et al as well.[28,29]

Multi-vessel infra-popliteal revascularization has also been suggested as an effective procedure to gain sufficient perfusion in the foot. However, this strategy is also controversial, especially in patients with pedal artery disease. This was explained by Nakama et al which suggested that due to the existence of pedal artery disease, the blood supply through the percutaneously recanalized infra-popliteal artery cannot directly reach the target wounds.[21] Therefore, direct blood supply is ultimately dependent on the condition of the pedal arteries. Re-establishment of the destroyed pedal artery might be necessary to enable the efficacy of these strategies.

These conclusions are consistent with our results. This study showed that complete healing has been achieved in those who underwent pedal arch recanalization whether complete or partial. On the other hand, none of the patients who had only infra-popliteal revascularization and failed PAA had accomplished complete wound healing by the end of our 6 months follow up period. Nevertheless, the latter group showed slowly progressive wound healing.

Fully agree with these conclusions and believe that in cases where the arterial pedal arch is completely intact, the infra-genicular artery perfused is irrelevant to the healing of tissue loss due to presence of multiple arterial-arterial connections between the three main arteries of the leg, rendering the angiosome principle irrelevant, too. Therefore, in this study, the angiosome-oriented revascularization strategy wasn't intended.

This study shows that patients who underwent PAA showed a higher rate of complete wound healing and shorter time to heal than patients without PAA. These results are agreeing with Utsunomiya et al showed in their study that patient provided with a direct flow to the target wound had a superior limb salvage and amputation-free survival in comparison with the patients with above-the-ankle angioplasty.[34]

Other studies, showed that diabetic patients with CPA/IPA seemed to have better outcomes in terms of wound healing and limb salvage. Their outcomes in a diabetic population that underwent peripheral endovascular revascularization were similar to those obtained by us.[33]

Their studies showed that complete wound healing was achieved in 35 patients with CPA (83.3%), 34 patients with IPA (56.7%), and in 13 patients with APA (37.1%) with a significant difference ($p<0.001$). Manzi et al reported the clinical outcomes obtained in 135 patients with CLI who were treated by balloon angioplasty of the foot vessels by using the pedal-plantar loop technique; immediate success evaluated with a significant improvement in the transcutaneous oxygen tension was maintained at one year in the majority of the patients.[35-37]

No complications were recorded up to one month, this may be because of the small sample size, but confirms the early suggestions regarding the safety and efficacy of the procedure.

CONCLUSION

Successful pedal artery revascularization (PAR) significantly improved wound healing in patients with CLI. Thus, efforts should be made to revascularize the pedal arteries, especially when the pedal arch is completely absent.

Recommendations

Endovascular revascularization is effective to facilitate healing of wounds in CLI and can be performed without significant complications. The pedal plantar loop technique is a safe and feasible technique, and appears to provide a proper revascularization of the foot arteries. Further studies in this research area with larger sample size, more equipment, and different techniques and longer follow up period.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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