

CLINICAL AND RADIOLOGICAL OUTCOME OF INFRA-POPLITEAL BALLOON ANGIOPLASTY IN MANAGEMENT OF ISCHEMIC LIMB WITH DIABETIC FOOT: IMMEDIATE AND SHORT-TERM ASSESSMENT

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ABSTRACT:

Objective: To evaluate the clinical and radiological outcome after infrapopliteal angioplasty for diabetic patients with ischemic foot.

Patients and Methods: Twenty diabetic patients with critical limb ischemia had 34 infrapopliteal lesions were treated with transluminal balloon angioplasty. Follow up was scheduled at 3 months, 6 months and 12 months following the procedure for clinical improvement and color Doppler evaluation. Primary patency was defined as persistent patency without any re-intervention including angioplasty, surgical procedure performed on or at the margins of the treated lesion, or amputation

Results: The mean age of the study population was 62.4±12.1 years, with (75%) male and (25%) female patients. The total number of the affected limbs was 34 limbs. The most frequently observed initial presentation of the limb was resting pain (64.7%), followed by gangrenous change (52.9%) and non-healing ulcer (38.2%). The **primary** technical success rate in 88.2% (30/34) of lesions. The lesions were stenotic (n= 19) or occluded (n= 11). Out of 30 lesions with initial technical success, the patency rate was 86.6% at 3 months, 80% at 6 months, and 66.6% at 12 months. Major amputation was carried out for 3 patients (15%), one above and 2 below the knee. Minor amputation was carried out for 7 patients (35%).

Conclusion: Infrapopliteal angioplasty showed remarkable immediate and short term effect in treatment of ischemic diabetic foot; however through 12 months follow up the patency rate is declined by time and may need re-intervention.

KEYWORDS:

Ischemia

Diabetes mellitus

Angioplasty

Infrapopliteal lesions.

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INTRODUCTION:

Critical limb ischemia (CLI) represents the extreme of the peripheral arterial occlusive disease spectrum and is associated with high morbidity and mortality. Limb salvage often requires infrapopliteal revascularization¹. The preferred method for

revascularization of symptomatic infrapopliteal arterial occlusive disease (IPAD) has traditionally been open vascular bypass². However, patients with CLI are often aged and not optimal candidates for surgical bypass due to medical co-morbidities with increasing perioperative mortality rates and a poor autogeneous conduit^{3,4}.

As an alternative method of revascularization, infrapopliteal angioplasty is preferred by patients with visible stumps, good runoff of distal outflow vessels or high surgical risk. However, it had been regarded as an inferior treatment option compared to surgical bypass due to bulky catheters, lack of low caliber wires and general lack of clinical experience which frequently resulted in peri-procedural complications^{3,5}. The newly developed devices and technical advances have widened the therapeutic spectrum of angioplasty to more distal and complex lesions with lower complication rates^{6,7}.

Diabetes mellitus is becoming increasingly common in CLI presentations featuring prolonged foot inflammation or tissue necrosis. This currently involves frail patients at high perioperative risk and affected by numerous vascular comorbidities^{8,9}. In diabetic subjects with CLI, some studies revealed that successful revascularization reduces the rate of major amputation^{10,11}. However, other investigators reported that diabetic patients had an unfavorable 2-year primary patency compared with non-diabetic patients after infrapopliteal angioplasty¹².

The aim of this study was to assess the clinical and radiological success for infrapopliteal angioplasty of patient with ischemic diabetic foot.

PATIENTS AND METHODS:

Patient Characteristics:

Between April 2007 and January 2010, twenty diabetic patients with critical limb ischemia had 34 infrapopliteal lesions were treated with transluminal balloon angioplasty in Interventional Radiology Unit in Minia University Hospital.

Percutaneous trans-luminal angioplasty procedure:

All patients received anti-platelet therapy (clopidogril loading dose 300mg) at least 24 hours before angioplasty, followed by 75 mg and 150 mg of acetyl salicylic acid daily and continued indefinitely. All cases were done in the angiography suite. Complete sterilization with antiseptic solution, 10 cc of lidocaine 2% is infiltrated around the puncture site and a 2-mm incision is made with a blade.

Femoral puncture was done through either ipsi-lateral anti-grade or contra-lateral approach of the common femoral artery. A 6-F sidearm sheath is introduced and passed over a gently curved J guide wire, the sidearm sheath allows interim contrast injection while leaving the guide wire in place across the lesion. Once the sheath is localized in the femoral artery, the patient is systemically heparinized with 10,000 units of unfractionated heparin. Under fluoroscopic guidance, introduction of 4F diagnostic catheter (vertebral catheter) over 0.35 hydrophilic guide wire till the level of the upper popliteal artery. A preliminary angiogram of the limb was taken using non ionic contrast medium (Ultravist) to locate the target lesions and mark them with external markers (e.g., needles). A variety of hydrophilic guide wires of diameter 0.35 or 0.18 were used to cross the lesions as (Terumo, Zip wire, V18 wires). Angioplasty was then carried out using balloon catheters with diameter equal to the diameter of the adjacent normal arterial segment (usually 3mmx10cm)..

The balloon was inflated manually using inflator device until balloon deformity (waist) was relieved through a pressure ranged from 6 to 10 atmospheric pressure. Inflation was

maintained for 60 to 120 seconds to minimize the interruption to distal flow. The balloon was then deflated. When angioplasty of the entire diseased segment of the vessel was completed, the balloon catheter was withdrawn proximally and an arteriogram was obtained to assess the result. The sheath was removed at the completion of the procedure over the guide wire and hemostasis was achieved by manual compression.

Follow-up:

Follow up was scheduled at 3 months, 6 months and 12 months following the procedure for: clinical improvement according to Rutherford categorization by absent resting pain and/or progressive tissue healing; and color Doppler evaluation by ankle peak systolic velocity. Peak systolic velocity (PSV) in the target-vessel was determined and compared with that in the preceding normal segment. A focal increase of at least 140% in the PSV was considered indicative of >50% restenosis at that site¹³.

Primary patency was defined as persistent patency without any re-intervention including angioplasty, surgical procedure performed on or at the margins of the treated lesion, or amputation. Minor amputation was defined as transmetatarsal or more distal amputation of the lower extremity¹⁴.

RESULTS:

Demographic and Clinical Characteristics:

Demographic and clinical characteristics of the studied 20 diabetic patients are listed in Table 1. The mean age of the study population was 62.4 ± 12.1 years, with (75%) male

and (25%) female patients. Many patients had co-morbid risk factors including hypertension (80%), hyperlipidemia (75%), and history of current smoking (60%), coronary artery disease (20%), and chronic renal failure (10%). There were 14 cases (70%) with bilateral lesions, thus the total number of the affected limbs was 34 limbs. The most frequent presenting symptoms were rest pain (64.7%), followed by gangrenous change (52.9%) and non-healing ulcer (38.2%).

Angioplasty procedure:

No patient died during hospitalization for PTA. No puncture site haematoma required blood transfusion or surgery. Immediate evaluation showed primary technical success rate in 88.2% (30/34) of lesions. The angiographic characteristics of the successfully treated vessels are shown in Table 2. There were 4 technical failures due to 3 unsuccessful attempts to insert the guidewire, and 1 heavy calcified lesion. The lesions were stenotic (n= 19) or occluded (n= 11). The mean length of treated stenotic vessels was 92 ± 71 mm, and the mean length of treated occluded vessels was 170 ± 90 mm.

Outcome:

In all patients successfully treated with PTA the pain disappeared. During the follow up period with color Doppler (Fig. 1), out of 30 lesions with initial technical success, the patency rate was 86.6% (26/30) at 3 months, 80% (24/30) at 6 months, and 66.6% (20/30) at 12 months. Major amputation was carried out for 3 patients (15%), one above and 2 below the knee. Minor amputation was carried out for 7 patients (35%).

Table 1: Demographic and clinical characteristics of the studied diabetic patients (N=20).

Variable	No. of cases	Percent (%)
Total number	20	100%
Bilateral disease	14	70%
Male	15	75%
Female	5	25%
Age (years); mean±SD	62.4±12.1	
Co-morbidity factors:		
-Hypertension	16	80%
-Hyperlipidemia	15	75%
-Current smoking	12	60%
-Coronary artery disease	4	20%
-Chronic renal failure	2	10%
Resting Pain **	22	64.7%
Gangernous changes **	18	52.9%
Non-healing ulcers **	13	38.2%

** Total number of the affected limbs = 34.

Table 2: Characteristics of lesions with primary technical success (N=30).

Artery	No. (%)	Stenosis (n)	Mean length ± SD (mm)	Occlusions (n)	Mean length ± SD (mm)
Anterior tibial	11 (36.6%)	8	119±110	3	233±104
Posterior tibial	7 (23.3%)	4	114±103	3	201±98
Peroneal	8 (26.6%)	4	111±92	4	173±69
Pedal artery	3 (10%)	2	68±33	1	74
Plantar artery	1 (3.3%)	1	52±19	0	0
Total	30 (100%)	19	92±71	11	170±90

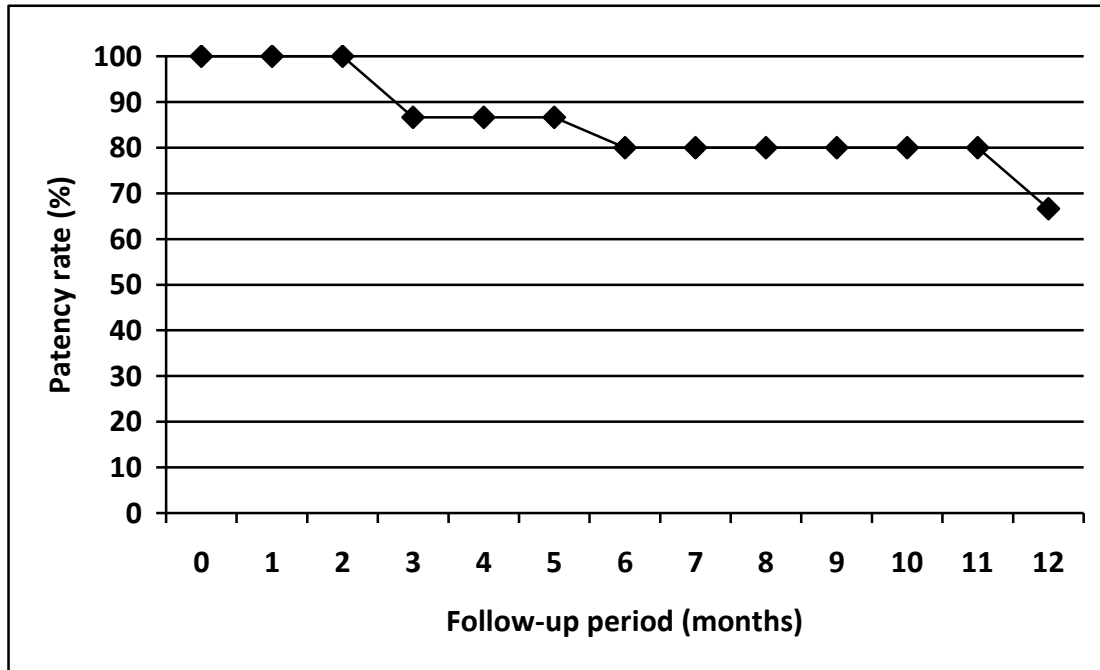
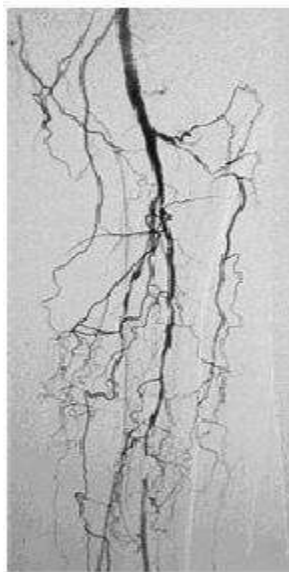


Fig. (1): Patency rate of 30 lesions during 12 months of follow-up after angioplasty.

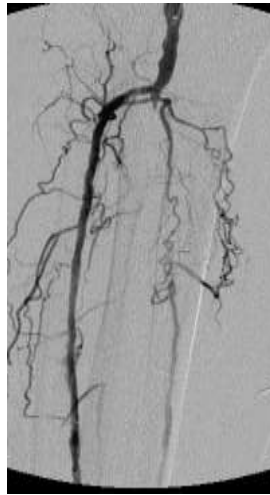


(A)



(B)

Fig. (2): Arteriogram obtained in a 65-years-old diabetic patient with nonhealing ulcers and CLI. (A) Total occlusion of the anterior and posterior tibial arteries, narrowing and occlusion of the peroneal artery. (B) Good flow straight to the foot is restored.



(A)



(B)

Fig. (3): Arteriogram obtained in a 55-years-old diabetic patient with non-healing ulcers and CLI. (A) Total occlusion of the posterior tibial artery.(B) Complete recanalization of the occluded posterior tibial artery.



(A)



(B)

Fig. (4): A. Diabetic patient with non-healing foot ulcers and CLI. B. Good response and near-total healing after three months post- angioplasty.

DISCUSSION:

Diabetic patients are more likely to develop CLI and its serious complications including gangrene, and to have higher morbidity and mortality^{15,16}; also, diabetes mellitus is one of the possible determinant factors of graft failure in patients with CLI¹⁷. For these reasons, infrapopliteal angioplasty is currently proposed as the primary treatment for CLI in diabetic patients¹⁸⁻²¹. Infrapopliteal angioplasty, however, has been criticized because of the small diameter and length of the treated vessel, both of which have a tendency towards a high restenosis rate; furthermore, it is not clear whether the clinical success of infrapopliteal angioplasty is due solely to technical success²²⁻²⁵.

In this study, the primary technical success rate was 88.2%. In the study by Tan et al.,²⁶ the technical success was achieved in 90% (38 out of 42 patients). A relatively low technical success rate (70%) in a recent study by Ryu et al.,²⁷ may be attributed to a high proportion of suboptimal results (22%). Most of the suboptimal results involved diffuse and heavily calcified lesions, and had 30% to 50% of residual stenosis despite repeated balloon dilatation. Another study by Ryu et al.,¹² compared the outcomes of infrapopliteal angioplasty between diabetic patients and non-diabetic patients with CLI, showed significant differences between the 2 groups in technical success rate (66% in diabetic vs. 84% in non-diabetic).

In this study, the patency rate was 86.6% at 3 months, 80% at 6 months, and 66.6% at 12 months. This result reflects a decline of patency rate by time, however the long-term complete patency of the treated vessel

is less important in such patients than in those with coronary, carotid or renal arterial disease: the re-canalisation temporarily increases blood flow to the foot and has a positive effect in eradicating infection and healing ulcers and surgical wounds²⁸, thus the rate of major amputations in this study still low after 12 months of angioplasty.

There are differences in primary patency between studies in literature that may be due to the heterogeneity of the patient groups rather than to the differences in angioplasty technique. This study has noted a higher primary patency compared with a study by Ferraresi et al.,²⁸ who reported re-stenosis rate of 42% and patency rate of 58% in a long-term study. Another previous study²⁹, however, found a higher primary patency (88%) compared with our study.

In our study, major amputation after 12 months of follow-up was carried out in 15% of the studied diabetic patients. This rate in the subjects who successfully underwent PTA is very low in comparison to other studies in literature^{30,31}. In the study by Kuusela et al.,³² there was a high rate of major amputations at 3, 6, and 12 months that was 23%, 31%, and 35%, respectively, with a tendency of increased frequency among patients treated for more severe ischemia. However, the study by Faglia et al.,³³ showed a very low rate of major amputations in 10 patients (5.2%) out of the 191 patients with ischemic diabetic foot who underwent PTA. Those authors believe that PTA revascularization has increased the likelihood of successfully performing minor amputations, which they consider as being limb-salvage procedures in subjects with large loss

of tissue or gangrene who would otherwise most likely have undergone a major amputation³⁴. Another study by Faglia et al.,³⁵ reported that major amputations were performed in 15 out of 24 patients (62.5%) with occlusion of all the infrapopliteal arteries, and in 7 out of 186 patients (3.7%) in whom only the peroneal artery was patent, with an overall major amputations rate of 5.2% (22 out of 420 patients).

In conclusion, infrapopliteal angioplasty is a less-invasive, safe and reproducible method, and could be a better strategy for CLI patients with comorbidities who are at high surgical risk. It reduces the rate of major amputations; however through 12 months follow up the patency rate is declined by time. More aggressive treatment with advanced devices and more clinical experience are required as it may lead to better results.

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النتائج الإكلينيكية و الإشعاعية بعد إجراء رأب الشرايين تحت الركبة باستخدام القسطرة لعلاج الأطراف المصابة بنقص التروية الدموية في وجود القدم السكرية : تقييم النتائج الفورية وقصيرة الأجل

الهدف من الدراسة: تقييم النتائج الإكلينيكية و الإشعاعية بعد إجراء رأب الشرايين تحت الركبة باستخدام القسطرة لعلاج الأطراف المصابة بنقص التروية الدموية في وجود القدم السكرية.

المرضى و طرق البحث: خلال فترة الدراسة تم علاج 20 مريضا بداء السكري يعانون من نقص شديد في التروية الدموية للطرف السفلي لديهم 34 إصابة بالشرايين تحت الركبة و ذلك باستخدام رأب وعائي بالقسطرة المتصلة بالبالون. تم إجراء متابعة للنتائج الإكلينيكية و الإشعاعية للمرضى عند الشهر الثالث و الشهر السادس و بعد اكتمال عام من إجراء التدخل العلاجي. تم تحديد عدم انسداد الشرايين بشكل أولي إذا ما خلا التجويف الشرياني من أي انسداد دون أي تدخل بما في ذلك إعادة القسطرة، والإجراءات الجراحية للإصابات التي تم علاجها أو إجراء بتر.

النتائج: كان متوسط عمر المرضى محل الدراسة 62 عاما ، كان منهم (75%) ذكورا و (25%) إناثا وكان العدد الإجمالي للأطراف المتضررة 34 طرفا. وجد الألم بالطرف السفلي أثناء الراحة كأكثر الأعراض الأولية شيوعا بين المرضى (7,64%)، تلاه وجود الغرغرينا (9,52%) والقرح غير الملتهمة (2,38%)، وقد وصلت نسبة النجاح التقني إلى 88,2% من المرضى محل الدراسة. كانت الإصابات على هيئة ضيق بالشرايين في 19 مريضا و انسداد في 11 مريضا، و كان معدل تسليك الشرايين 86,6% في 3 أشهر، 80% في 6 أشهر، و66,6% في 12 شهرا. وقد أجريت عمليات البتر الكبرى ل 3 من المرضى (15%)، واحدة فوق و 2 تحت الركبة، وأجريت عمليات بتر بسيطة ل 7 من المرضى (35%).

الاستنتاج: أظهر إجراء رأب الشرايين تحت الركبة باستخدام القسطرة نتائج جيدة بشكل فوري و خلال المدى القصير عند استخدامه لعلاج الأطراف المصابة بنقص التروية الدموية في وجود القدم السكرية، إلا أن معدل توسع الشرايين تناقص خلال 12 شهرا من المتابعة.