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Case series: Role of balloon angioplasty in below the knee vessels treatment in diabetics

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Abstract

Background: Diabetes Mellitus is considered one of the major risk factors for limb loss due to ischemia, infection, and neuropathy. It has been estimated that 25% of diabetics will develop foot ulcers during the course of the disease and leads to amputation. Most ulcers are successfully treated as out-patient. However, infected and ischemic foot ulcers are major causes of diabetes-related hospitalization which costs greater than $1 billion annually and rising. Angioplasty is playing a very huge role in salvage of lower limbs in diabetic patients.

Methods: This prospective study included 20 diabetic patients presented to our Vascular Surgery Unit. It evaluates the short-term clinical outcomes and re-stenosis rate of PTA (Percutaneous Transluminal Angioplasty) procedures performed for the purpose of limb salvage. The procedure, possible complications, benefits, risks, and other alternative interventions were all explained to the patients and informed consent was obtained. All of the patients were diabetic for more than 15 years and 55 % treated with insulin, the rest by oral diabetes medications.

Results: PTA was successful in 19/20 patients. PSV (Peak Systolic Velocity) pre-procedure was 10.4 ± 1.39, post-procedure was 23.2 ± 2.7 with a P value <0.001. Primary Patency was the mean follow-up which was 24 hours after intervention, at 1 and 3 months. The major amputation rate was 10%, one patient was post failed procedure and above the knee amputation was done and the other patient was after 3 months due to severe infection and below knee amputation was done; the limb salvage rate was 90% (18 out of 20 limbs). The minor amputation was 50% (10/20, 1 transmetatarsal, 4 rays, and 5 toes). Ischemic ulcers were 25% (5 out of 20) and healed at 3rd month. Secondary Patency was the 6 months target-vessel re-stenosis rate which was 30% (6/20). No patients underwent a second PTA procedure because of recurrent CLI in the same limb.

Conclusion: Angioplasty should be considered the first line of treatment in the management of tibial arterial occlusive disease especially with high surgical risk patients, even patients TASC C and D. APSV (ankle peak systolic velocity) is an effective tool for short and even long-term patency.

Keywords

diabetes; below the knee vessels; tibial; balloon angioplasty; peak systolic velocity

Introduction

Diabetes mellitus is a significant contributing factor to limb loss due to a combination of ischemia, infection, and neuropathy [1]. According to the United Kingdom Prospective Diabetes Study (UKPDS), aggressive glycemic control is associated with a significant fall in diabetes endpoints and myocardial infarction; however, intensive glycemic treatment did not appear to reduce the risk of peripheral artery disease (PAD), underpinning the importance of cessation of smoking and other risk factor management [2].

Angioplasty is the first line of treatment of PAD, especially in diabetic patients. Surgery will be kept until the end of treatment lines, given the co-morbidities of diabetes and surgery complications [3].

Diagnosed diabetes is most prevalent in the middle-aged and elderly populations, with rates estimated at 11% for those persons aged 65 years and older [4,5]. It is estimated that 25% of patients with diabetes will develop a lower extremity ulcer during the course of their disease [6-8]. Several reports from population-based studies indicate an annual cumulative incidence for diabetic foot ulcers of 2–3% [9,10].

In one study of a large cohort of neuropathic patients, there was a 7% one-year incidence of first foot ulcer [11]. Reported foot ulcer prevalence in a variety of populations has ranged between 2% and 10% [7,9,11,12]. The cumulative effects of neuropathy, deformity, high plantar pressure, poor glucose control, duration of diabetes, and gender are all contributory factors for foot ulceration [13].

Methods

This prospective study to identify the patients with Critical Limb Ischemia (CLI), treated with PTA between March 2016 and December 2018 who satisfied the following inclusion criteria, diabetic patients with critical limb ischemia in the form of tissue loss or rest pain, presence of below the knee vessels lesions, and absence of proximal lesions or stenosis. We excluded non-diabetic patients, diabetic patients with intermittent claudication, and patients with proximal femoral lesions or stenosis.

Pre-operative evaluation of the patients including their medical history and physical examination, using Doppler US was done to all 20 patients and C.T. Angiography (CTA) to those who are suspected to have proximal lesions, 4 patients. Patients are classified according to the Trans-Atlantic Inter-Society Consensus (TASC) Classification as in table 1.

Table 1: Trans-Atlantic Inter-Society Consensus classification for infra-popliteal lesions [14].

Classification	Lesion characteristics
TASC A	Single stenosis <1 cm long
TASC B	Multiple focal stenoses <1 cm long or 1 or 2 stenoses <1 cm involving the trifurcation
TASC C	Stenoses 1 to 4 cm long, occlusion 1 to 2 cm long, or extensive stenosis involving the trifurcation
TASC D	Occlusion >2 cm long or diffusely diseased

Also, complete blood picture, kidney, and liver function tests, coagulation profile and blood glucose level were checked in all patients

The patients' blood sugar was controlled by insulin therapy and other medications were given.

The patients were then admitted one day before the procedure. A nephroprotection protocol was used in all patients with creatinine levels of >1.1 mg\dl. A 1.0 ml/Kg/hr saline infusion, 0.5 ml/Kg/h in patients with a history of heart failure, 12 hr before and 24 hr after the procedure and oral N-acetyl-cysteine 1200 mg twice daily on the day before and the day of the procedure.

Dual antiplatelet therapy with aspirin 81mg/day and clopidogrel 75mg/day. TcPo2 was assessed before and after the procedure.

Angiography and PTA

i. Both groins prepared using an antiseptic solution, povodin iodine. All equipment were checked including monitors, connections, and stents. The patient lies in a supine position and the procedures were performed under local anesthesia, Xylocaine 2%.

ii. An ipsilateral antegrade femoral access following anatomical localization of the CFA and sonar-guided in 2 patients using sheath 6 Fr. Was performed.

iii. 10.000 IU of heparin was routinely administered intra-arterially at the beginning, and additional heparin was given if the procedure took more than one hour.

iv. A balloon was introduced after injecting the dye intra-arterial.

v. Wires 0.35 Fr PTFE, V 0.18, PT2 0.14, balloons 3×8, 2.5×8 or 2.5×10 cm were used.

vi. The balloon was inflated at a pressure around 8 mm Hg for 2 minutes then proceed to the next lesion distally, and finally, inject dye to be sure that the vessel is patent.

vii. If the wire passed till the end of the vessel, we inflated the balloon retrograde and inject dye again.

viii. We injected routinely nitroglycerin intra-arterial at the end of the procedure.

ix. Finally, we did completion angiogram intra-operative.

x. At the end of the procedure, hemostasis was obtained by local compression.

Post procedures care: Patients were observed for postoperative complications.

Post-PTA treatment

- Surgical debridement of necrotic tissue and drain the abscess and phlegmon of the diabetic foot; broad-spectrum empiric antibiotic therapy until results of culture and sensitivity.

- Elective surgery was performed with the aim of reconstructing a stump suitable for proper walking. All of the patients received dual antiplatelet therapy for a minimum of 6 months (aspirin 81 mg and clopidogrel 75 mg per day); the treatment was not interrupted when surgical procedures were undertaken.

Statistical analysis

The statistician was hired. Data are expressed as mean ± SD along with a 95 % confidence interval (CI) as well as a percentage when appropriate. SPSS 16.0 with Mann- Whitney Test, T-Test, NPar Tests, and Wilcoxon Signed Ranks Test were used. A P value <0.05 was considered statistically significant.

Results

Our study included 20 diabetic patients with critical limb ischemia (CLI) presented to our outpatient clinic. Demographics of our patients are listed in table (2):

Table 2: Patients demographics and co-morbidity

	N= 20
Age	62.5± 6.5
Males	80 %
Smoking	60 %
Hypertensive	50 %
Hypercholesteremia	100%
Immobility	0%
Recent surgery	0%
Coronary artery disease	30 %
Treatment with insulin	55 %
Chronic Renal failure	0 %
TASC C	40 %
TASC D	60 %
N. of ATA	13
N. of PTA	17
N. of peroneal a.	10

ATA: Anterior Tibial Artery; PTA: Posterior Tibial Artery; TASC: Trans-Atlantic Inter-Society Consensus.

The mean age of the patients is 62.5 with SD 6.5. Male represented 80%. The mean duration of diabetes mellitus was more than 15 years, and 55% of the patients were treated with insulin. Mean glycated hemoglobin (HbA1c) was 7.6% ± 1.8%. Ten patients (50%) had arterial hypertension and 6 (30%) a history of coronary artery disease. 40% was TASC C, while 60% was TASC D. Number of Lesions in Tibial vessels was 40, anterior tibial artery involved was 13 vessels, posterior tibial artery involved was 17, while peroneal arteries involved was 10. PSV was evaluated before and after the procedure. PSV before the procedure was 10.4 with SD of 1.39, while after the procedure 23.2 with SD of 2.7, the P value was significant < 0.001

Table 3: statistics of PSV pre and post-intervention

PSV pre Mean ± SD	PSV post Mean ± SD	P value
10.4 ± 1.39	23.2 ± 2.7	<0.001*

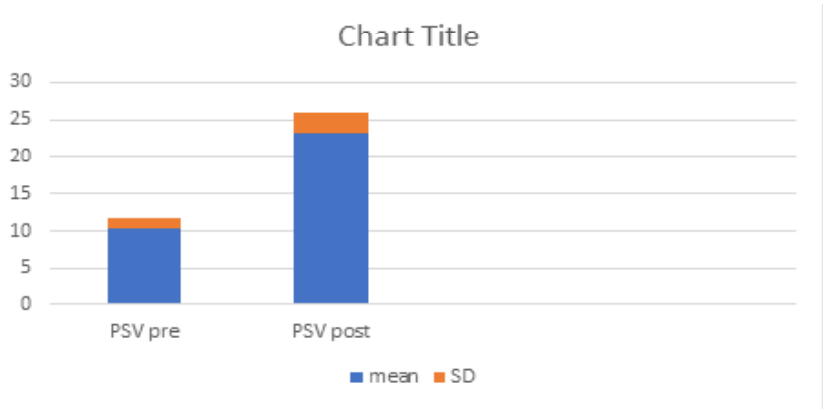

Figure 1: Pre & Post PSV

Follow-up

After discharge, the patients were seen in our out-patient clinic every week for the first month, monthly for the next 6 months. All of the patients received optimal medical treatment for vascular risk factors.

The patients who had not undergone a major amputation after 6 months were examined by a single operator using color duplex ultrasonography (US). PSV in the target- vessel was determined and compared with that in the preceding normal segment, also compared pre and post-procedure. A focal increase of at least 140% in the PSV, corresponding to a peak velocity ratio of >2.4, was considered indicative of >50% re-stenosis at that site.

The procedure was considered successful in 19 out of 20 patients. The procedure was unsuccessful in one patient, in whom PTA and ATA were totally occluded and there was perforation at the tibio-peroneal trunk. This patient was not suitable for surgical revascularization because of that distal vessels were unhealthy. Also, 1 patient experienced post-procedure hematoma and treated only by compression. One patient had early thrombosis of ant. tibial artery thrombectomy was done.

Primary Patency

The mean follow-up was, 24 hours after intervention, 1, 3 months. The major amputation rate was 10%. One patient was post failed procedure and above knee amputation was done, and another patient was post 3 months due to severe infection and below knee amputation was done. The limb salvage rate was 90%. The minor amputation rate was 50%, 1 transmetatarsal, 4 rays, and 5 toes. Ischemic ulcers were 25% and healed at 3rd month.

Secondary Patency

The 6 months target-vessel re-stenosis rate was 30%, 6 out of 20 patients. No patients underwent a

second PTA procedure because of recurrent CLI in the same limb.

End-points, definitions and outcome

The procedure was considered successful when it was possible to restore straight-line flow down to the foot circle in at least one crural artery with no significant residual stenosis (>30%).

The primary end-point of the study was the rate of limb salvage at follow-up, defined as an ability to maintain plantar standing.

The secondary end-points were

1. The 1-month improvement in most clinical complain.

2. The rate of US re-stenosis of the treated vessels after 6 months

3. The incidence of new re-vascularization interventions involving the same limb.

Discussion

Critical limb ischemia (CLI) is a manifestation of severe peripheral arterial disease, characterized by pain at rest, or by a non- healing ulcerative lesion of the foot or toes, or both, it is classified as Fontaine stage 3 and 4 or Rutherford stage 4, 5, and 6 and it is caused by insufficient blood flow due to a severe stenosis or occlusion of the supplying arteries [15,16].

One of the important aims of our study is to find the incidence of associated risk factors in our diabetic patients who had critical limb ischemia. To achieve this objective, we studied diabetic patients in our community with distinct demographic characteristics.

PAD is more common in diabetics and presents at a young age with minimal sex difference. It is usually multilevel, more distal and progresses faster to CLI [17].

Patients with DM have hyperglycemia, dyslipidemia and insulin resistance. These changes in the metabolism promotes development of atherosclerosis and development of PAD in the same way of development of coronary artery disease via inflammation and endothelial cell dysfunction. Hyperglycemia increases inflammation and leads to atherosclerosis. Dyslipidemia promotes leukocyte adhesions and coagulation and that would increase plaque burden, while insulin resistance will stimulate TNF-α and IL-6 and that will activate NF-κβ, leading to thrombogenesis, all of these changes put patients with diabetes at higher risk of PAD more than other population [18].

Diabetic patients are significantly less able to develop arterial collaterals and this explains why the majority of patients with CLI are diabetics, with the fact of that diabetics tend to have PAD as they tend to have atherosclerosis and fat droplets deposit on the arterial walls to develop atherosclerosis [18]. The incidence of male to female in our study is 4:1, smokers are 70%, and patients on insulin therapy are 55%.

Duration of D.M. in all patients is more than 15 years, hypertensive patients are 50%.

In our study, the age of the patient was ranging from 50 to 75 years most of them were males 80% indicating an increased incidence of tibial disease in males in our study however Keeling et al had the females representing most of the cases 53% of his 76 patient study [19].

This may be attributable to associated other risk factors as smoking as most of our patients are males.

All the patients were diabetic. Lopentalo et al. concluded that diabetes is an obvious risk factor in infragenicular atherosclerotic lesions most likely [20]. Ferraresi et al. concluded that of the 634 patients with CLI (Rutherford 5 and 6), 431 (68%) had diabetes mellitus [21].

Other risk factors as smoking in our study were 70% of cases & Hypertension 50%& with a history of coronary disease 30%. Lopentalo et al. also concluded that cigarette smoking and hypertension increased disease in iliac arteries but not below the knee arteries [20].

In this study, we excluded patients with claudication only, so the complaints of our patients were gangrene 60% (n=12) non-healing ulcer 25 % (n =5) and rest pain 15% (n=3).

Revascularization is necessary to save the limb and this can be performed surgically or percutaneously. When both treatments are possible, endovascular therapy is the ideal one; that avoids general anesthesia, poses lesser systemic stress and has fewer serious complications and similar clinical outcomes [22].

Patients with severe critical limb ischemia (CLI) due to long tibial artery occlusions are often poor candidates for surgical revascularization and frequently end up with lower limb amputation [15].

Percutaneous angioplasty of the infrapopliteal arteries has long been regarded as a difficult procedure because of the small caliber of the tibial arteries and the tendency to develop spasm [23].

Many technologies have been used in the tibial vasculature including angioplasty, cutting balloon angioplasty, cryoplasty, directional atherectomy, laser atherectomy, and stenting. Unfortunately, no literature to date has compared outcomes for these different technologies. Clearly, interventional therapy has worked in this arena, but we have yet to define who best to use these techniques on and what specific techniques to use [24].

The greatest advantage of interventional therapy for the tibial disease is that it minimizes the morbidity and mortality in patients with critical limb ischemia and should be used as a first-line treatment mode in the majority of patients, especially in those with significant medical co-morbidities, typically associated with treating CLI utilizing open operative therapies [25,26].

The primary goal in treating CLI is limb salvage and maintenance of quality of life, not patency, making endovascular treatment the ideal approach. For rest pain, ulceration and mild to moderate tissue loss,

endovascular therapy works exceedingly well [24,26].

We believe that establishing the continuity of blood flow to at least a one-foot artery is essential for the healing of ischemic foot lesions.

Graziani et al. usually attempt to provide, by endovascular treatment, direct straight-line flow to the foot through a native tibial artery, selecting, whenever possible, the anterior tibial artery for ischemic forefoot lesions and the posterior tibial for calcaneal lesions [27].

If neither the anterior nor the posterior tibial artery can be treated despite several intraluminal and subintimal crossing attempts, the alternative treatment may consist of providing direct flow along the peroneal artery. From the distal peroneal artery, some collateral branches arise for foot arteries. In particular, the posterior perforating branch connects the peroneal with the plantaris communis, whereas the anterior perforating branch links the peroneal to the dorsalis pedis [27,28].

In instances, a single stenotic vessel feeding the foot will be found with occlusion of the remaining tibial vessels. Prior to intervening on a single patent but a stenotic tibial vessel, attempts should be made to cross occluded vessels that reconstitute distally with a continuous flow to the foot even if it is at the pedal level [24].

Treating chronic total occlusions (CTO) prior to a single stenotic vessel with continuous runoff to the foot does not jeopardize the status of the limb when the crossing is unsuccessful. However, after opening a chronically occluded tibial artery, treatment of the stenotic vessels leads to more than one tibial vessel directly feeding the ischemic limb at the completion of the procedure [24].

Our protocol for management of these patients is that we did angioplasty for 20 diabetic patients after history taking, examination, admission one day before the procedure, laboratory and imaging investigations. After the procedure they were noticed for the presence of a pulse and if complications occurred as groin hematoma. Then discharged on clopidogrel and aspirin and come to our outpatient clinic for follow up three and six months. Post-intervention pulse was one of the predictors of clinical success. Post-intervention pulse was palpable following almost all cases.

The overall limb salvage rate of our study is 90%. In other studies, the limb salvage rate was 85.4% at 3 years, is considered higher than that previously quoted by Keeling et al. of 73% at 3.4 years [20,28] and compares to limb salvage rate of 84% at three years quoted by Giles et al. [29] because our limb salvage was during a shorter duration (less than one year).

PTA was considered successful in 19 patients (from 20 patients). The procedure was unsuccessful in one patient (one limb), in whom all of the three leg vessels were totally occluded. The reasons for the failures were an inability to cross a highly calcified chronic total occlusion and/or an inability to dilate the lesions properly with the balloon, so that patient had AKA.

This is clearly demonstrated by the fact that only one of our 19 patients underwent BKA due to severe infection, despite complete patency of the artery treated.

The limb salvage rate was 90% with a US re-stenosis rate of 30% during 6 months. It is noted that 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-canalization temporarily increases blood flow to the foot and has a positive effect in eradicating infection and healing ulcers and surgical wounds. As foot tissue healing reduces oxygen demand, less blood flow is generally required to maintain tissue integrity and keep the limb asymptomatic.

The effectiveness of PTA was demonstrated by the increase in PSV values after the procedure. This may explain the low rate of major amputations, as reported by Faglia et al. who looked specifically at the prognostic value of this index [30]. The P value was>0.001.

Rosemarie et al. stated that patients whose limb was saved after intervention more often had direct outflow to the dorsalis pedis artery. There was a trend toward a better clinical outcome in the case of direct flow to the pedal plantar arch after the intervention. These results confirm the importance of adequate outflow in both endovascular and surgical revascularization procedures. This implies that opening of the tibial arteries is not enough; the intervention should also focus on the improvement of outflow. Low-profile balloons and dedicated 0.14-in guidewires might help to target this outflow problem [15].

Our high rate of limb salvage at follow-up may have been due to our definition of successful PTA because, as reported by Faglia et al. the restoration of straight-line flow down to the foot in at least one crural artery is of paramount importance for short-term clinical success. Another explanation may be the combination of PTA and a good surgical approach to foot lesions (before and after the procedure), together with a strict clinical follow-up [30].

Follow-up re-stenosis in the surviving limbs was only ascertained by the Ultrasound. Although angiography is the gold standard for evaluating infrapopliteal arteries, US can be used to assess infrapopliteal artery patency if appropriate criteria are adopted.

In our study, the incidence of complications was 10%. There was one local extravasation hematoma, lead to a single small groin hematoma that was treated conservatively. One patient had early thrombosis of ant. tibial artery thrombectomy was done.

Conclusions

Angioplasty should be considered as the first line of treatment in the management of tibial arterial occlusive disease, especially with high surgical risk patients. Even those with TASC C and D can be managed effectively through angioplasty. APSV (ankle peak systolic velocity) is a more effective tool for short and even long-term patency.

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