ORIGINAL ARTICLE

Role of infrapopliteal angioplasty in diabetic and non-diabetic patients

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KEYWORDS
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Critical limb ischemia;
Diabetes mellitus;
Infrapopliteal arteries

Abstract
Objective: To compare the outcomes of infrapopliteal angioplasty between diabetic patients and non-diabetic patients with critical limb ischemia.

Patients and methods: From March 2014 to December 2014, infrapopliteal angioplasty was performed on 60 limbs (43 men and 17 women with mean age 70.13 years) with the CLI (Fontaine’s grade III or IV). The number of diabetic patients was 40 (66.66%). Follow-up included clinical examination for rest pain improvement and ischemic ulcer healing, and duplex-documented target vessel patency or re-stenosis at discharge and at 3 months.

Results: The technical success rate was 100% in diabetic and non-diabetic groups. The ulcer healing rate was 33/37 (89.18%) in diabetic patients vs. 14/15 (93.3%) in non-diabetic patients. And the re-stenosis and re-occlusion rates of treated vessels after 3 months were 10.0% in diabetic vs. 5.0% in non-diabetic groups.

Conclusion: There were no significant differences between the 2 groups in the technical success rate, but the 3 months clinical success rate and the primary patency rate were better in non-diabetic than in diabetic patients with no significant differences.

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1. Introduction

Peripheral vascular diseases (PVD) in diabetic patients constitutes a major clinical problem and is associated with higher morbidity and mortality (1). Diabetic patients are 5-fold more likely to develop critical limb ischemia (CLI) than non-diabetic patients (2). One serious complication of PVD is gangrene, which accounts for up to 50% of lower limb amputations in diabetic patients in the Western world (2).
Percutaneous transluminal angioplasty (PTA) is a practical method of revascularization in treating the critical limb ischemia (CLI) (3,4) in peripheral vascular diseases (PVD), and replacing the surgical bypass which was considered as a standard method due to its better anatomical and clinical durability relative to the other revascularization methods (5,6).

Some studies revealed that infrapopliteal revascularization in diabetic patients with CLI reduces the rate of amputation, these studies dealt with heterogeneous stages of ischemia such as resting pain or tissue lesions, and furthermore, the most frequently treated vessels were the distal Popliteal artery and the Tibio-peroneal trunk (7,8).

In a later study, the successful endovascular procedure led to a high percentage of limb salvage at long-term follow-up in the patients with ischemic diabetic foot and isolated below-knee lesions (9).

The aim of the works was to compare the outcomes of infrapopliteal angioplasty between the diabetic and non-diabetic patients with CLI.

2. Patients & methods

This study was done between March 2014 and December 2014, and 60 limbs in 60 patients with CLI (40 diabetic) and (20 non-diabetic) had infrapopliteal arterial lesions, were treated with balloon angioplasty. All procedures were done in Istituto DI Cura Città’ DI Pavia (Italy) in the angiographic room on GE innova 3100, USA.

2.1. Patients

2.1.1. Demographic data

- In the diabetic group 26 patients were males and 14 females, their mean age was 71.43 ± 2.41 years and more than half of this group had hypertension (72.5%), 47.5% were smokers and 40.0% had dyslipidemia, while in the non-diabetic group 17 were males and 3 females, 50.0% of patients had hypertension and were smokers as well as 25.0% had dyslipidemia.

2.1.2. Inclusion criteria

- Patients with critical limb ischemia, having a Fontaine's stage III (ischemic rest pain) or Fontaine's stage IV (ischemic leg or foot ulcers).
- Patients have single or multiple segments of stenosis (> 50%) or occlusions involving the infrapopliteal arteries.
- The presence of associated femoro-popliteal diseases did not exclude the patient from the study.

2.1.3. Exclusion criteria

- Acute limb ischemia.
- Active bleeding or bleeding diathesis.
- Recent hemorrhagic stroke or any other CNS abnormality with increased risk of hemorrhage.
- Previous implanted stent at the index site.
- When Acetylsalicylic acid (aspirin), Clopidogrel (Plavix) and Heparin are contraindicated.
- Known allergy to iodinated contrast media.
- Renal disease under medical treatment (serum creatinine > 3 mg/dL).

2.1.4. Patients are classified according to Fontaine's clinical classification (10) into 4 stages

- Stage I: Asymptomatic, incomplete blood vessel obstruction.
- Stage II A: Claudication at a distance of greater than 200 m.
- Stage II B: Claudication at a distance of less than 200 m.
- Stage III: Rest pain, mostly in the feet.
- Stage IV: Necrosis and/or gangrene of the limb.

Patients those included in this study are stages III and IV.

2.1.5. All included lower limb arteries are examined by Doppler ultrasound before angioplasty procedures

2.2. Methods

2.2.1. Pre-procedural medications

All patients received oral antiplatelet in form of salicylic acid (150 mg) and Plavix (75 mg) twice daily and good hydration by normal saline for 6 h before the procedure.

2.2.2. The procedure

The procedure was done under local anesthesia 10 cc of lidocaine 2% infiltrated around the puncture site. Femoral puncture was done through either ipsi-lateral anti-grade or contra-lateral approach of the common femoral artery.

A 5-F sheath is introduced and passed over a guide wire, to perform a preliminary angiographic study using diluted (50%) non-ionic contrast medium from the sidearm sheath. Once the sheath is localized in the femoral artery, the patient is systemically heparinized with intra-arterial bolus of 5000 units of unfractionated heparin.

Selective angiography of the infrainguinal and infrapopliteal arteries was performed with a 5-F multipurpose diagnostic catheter. After obtaining the pre-interventional angiography, the lesions of the femoral and popliteal artery (if present) were treated to establish good inflow to the calf by angioplasty.

Afterward a hydrophilic guidewire (Aqua Liner Angled .018" × 150 cm) with a steerable soft atrumatic tip was then used to pass intraluminally in the infrapopliteal lesions, if failed we dissect the intima by subintimal approach in an antegrade direction.

After crossing the lesion, dilation using Bantam® PTA catheter with a diameter of 3 mm and a length of 130 mm by 6 atmospheres for 60 s was performed with an inflator device. Vessel recanalization was considered successful when direct flow was obtained in the treated vessel, with no significant residual stenosis along the whole artery.

The sheath was removed at the completion of the procedure over the guide wire and hemostasis was achieved by manual compression.
2.2.3. Post-procedural medications

All patients received 150 mg acetylsalicylate (ASA) indefinitely on a lifetime basis plus 75 mg Plavix for 1 month.

2.3. Follow-up

Follow-up was scheduled at 1 day and 3 months post procedures for the following: clinical improvement according to Fontaine's classification by absent resting pain and/or progressive tissue healing, and Duplex Ultrasound 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% re-stenosis at that site (11).

3. Results

* In the diabetic group 26 patients were males and 14 females, their mean age was 71.43 ± 2.41 years and more than half of this group had hypertension (72.5%), 47.5% were smokers and 40.0% had dyslipidemia, while in the non-diabetic group 17 were males and 3 females, 50.0% of patients had hypertension and were smokers as well as 25.0% had dyslipidemia.

* In the diabetic group the anterior tibial artery was the most affected artery in 20 patients (50.0%) followed by the posterior tibial artery in 8 patients (20.0%), while in non-diabetic patients the posterior tibial artery was the most affected artery in 8 patients (40.0%), followed by the anterior tibial and peroneal arteries in 4 patients of each artery (20.0%).

* Out of 40 diabetic patients, 92.5% of patients had ischemic skin ulcer and 20.0% had rest pain. Out of 20 non-diabetic patients, 15 patients had ischemic skin ulcer (25.0%) and 9 patients had rest pain (45.0%) with significant difference between the two groups (Table 1).

* 60 infrapopliteal arterial lesions were treated in 60 patients with no major complication requiring surgical intervention after PTA.

* Follow-up with Doppler ultrasound 1 day post procedures “Initial technical success” was achieved in 60 limbs by (100%). Follow-up with clinical examination after 3 months “primary clinical success” revealed persistent ischemic ulcer in 4 diabetic patients and in one non-diabetic patient with significant difference between the two groups (P < 0.03). Doppler ultrasound of the treated vessels after 3 months “primary patency rate” revealed high frequency of re-stenosis and re-occlusion in diabetic patients than in the non-diabetic patients but with no significant difference, Table 2.

Sample of cases attached is shown in Figs. 1-4.

4. Discussion

Although bypass surgery using outflow vessels below the ankle should be considered the standard treatment in patients with CLI due to infrapopliteal arterial disease (12), this requires a good vein conduit and at least one open foot artery and is associated with considerable perioperative mortality, postoperative complications, myocardial infarction, and early reoperation for graft thrombosis (13).

Diabetic patients are more likely to develop CLI and its serious complications including gangrene, and to have higher morbidity and mortality (1,2).

Diabetes mellitus is the possible determinant factor of graft failure in patients with CLI (14).

For these reasons, infrapopliteal angioplasty is currently proposed as the primary treatment for CLI in diabetic patients (4,7).

Infrapopliteal angioplasty is a critical procedure because of the small diameter and length of the treated vessel, both of which have a tendency toward a high re-stenosis rate;

<table>
<thead>
<tr>
<th>Item</th>
<th>D.M “n = 40”</th>
<th>Non-D.M “n = 20”</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1- Age “ys.”</td>
<td>71.43 ± 2.41</td>
<td>68.38 ± 2.5</td>
<td>P &lt; 0.03*</td>
</tr>
<tr>
<td>2- Sex:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Male</td>
<td>26</td>
<td>17</td>
<td>85.0%</td>
</tr>
<tr>
<td>• Female</td>
<td>14</td>
<td>3</td>
<td>15.0%</td>
</tr>
<tr>
<td>3-Co-morbidity:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• H.T</td>
<td>29</td>
<td>10</td>
<td>50.0%</td>
</tr>
<tr>
<td>• Smoking</td>
<td>19</td>
<td>10</td>
<td>50.0%</td>
</tr>
<tr>
<td>• Dyslipidemia</td>
<td>16</td>
<td>5</td>
<td>25.0%</td>
</tr>
<tr>
<td>4- Distribution of vs.:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Anterior tibial A.</td>
<td>20</td>
<td>4</td>
<td>20.0%</td>
</tr>
<tr>
<td>• Tibio-peroneal A.</td>
<td>2</td>
<td>1</td>
<td>5.0%</td>
</tr>
<tr>
<td>• Posterior tibial A.</td>
<td>8</td>
<td>8</td>
<td>40.0%</td>
</tr>
<tr>
<td>• Peroneal A.</td>
<td>7</td>
<td>4</td>
<td>20.0%</td>
</tr>
<tr>
<td>• Pedal A.</td>
<td>2</td>
<td>2</td>
<td>10.0%</td>
</tr>
<tr>
<td>• Plantar A.</td>
<td>1</td>
<td>1</td>
<td>5.0%</td>
</tr>
<tr>
<td>5- Symptoms:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Rest pain.</td>
<td>3</td>
<td>5</td>
<td>25.0%</td>
</tr>
<tr>
<td>• Ischemic ulcer.</td>
<td>32</td>
<td>11</td>
<td>5.0%</td>
</tr>
<tr>
<td>• Rest pain + Ulcer</td>
<td>5</td>
<td>4</td>
<td>20.0%</td>
</tr>
</tbody>
</table>
furthermore, it is not clear whether the clinical success of infra-
popliteal angioplasty is due solely to technical success (15,16). The technical success rate in the present study was 100% in diabetic and non-diabetic groups. In the study by Hyeon et al. (17) there were also no significant differences between the 2 groups in the technical success rate (78% of diabetic vs. 84% in non-diabetic (P = 0.133)).

In the present study, the 3 months clinical success rate revealed that the ulcer healing was better in non-diabetic group (89.1% in diabetics vs. 93.3% in non-diabetics) with significant difference (P < 0.03). Also, in the study by Hyeon et al. (17) it was shown that the ulcer healing was better in non-diabetic group but with no significant differences between the 2 groups.

As regards the patency rate after 3 months, the present study showed that the patency of treated infrapopliteal vessels was better in non-diabetic than in diabetic groups (95.0% vs. 90.0%) respectively with no significant difference. Bosiers et al. (18) found that the 3-months patency rate was unfavorable in diabetic patients compared with non-diabetic patients; otherwise, the other outcomes (clinical success rate, limb salvage and overall survival) showed no significant differences between the 2 groups.

In this study, the occlusive peripheral arterial disease (PVD) in diabetic patients is characterized by long, multiple, calcified

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Follow-up after infrapopliteal angioplasty in diabetic and non-diabetic groups.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item</td>
<td>D.M “n = 40” %</td>
</tr>
<tr>
<td>1-Clinical signs after 3 mos:</td>
<td></td>
</tr>
<tr>
<td>● Rest pain improvement</td>
<td>8/8</td>
</tr>
<tr>
<td>● Ulcer healing</td>
<td>33/37</td>
</tr>
<tr>
<td>2- “1 day” post procedure Doppler ultrasound:</td>
<td></td>
</tr>
<tr>
<td>● Patent</td>
<td>40</td>
</tr>
<tr>
<td>● Re-stenosis</td>
<td>–</td>
</tr>
<tr>
<td>● Re-occlusion</td>
<td>–</td>
</tr>
<tr>
<td>3- “3 mos” post procedure Doppler Ultrasound:</td>
<td></td>
</tr>
<tr>
<td>● Patent</td>
<td>36</td>
</tr>
<tr>
<td>● Re-stenosis</td>
<td>1</td>
</tr>
<tr>
<td>● Re-occlusion</td>
<td>3</td>
</tr>
</tbody>
</table>

* P < 0.05 significant.

Fig. 1 Arteriogram obtained in a 55-years-old diabetic patient with non-healing ulcers and CLI. (a) Total occlusion of the anterior tibial artery and non-visualized posterior tibial artery. (b) Complete transluminal recanalization of the occluded anterior tibial artery.

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In this study, the occlusive peripheral arterial disease (PVD) in diabetic patients is characterized by long, multiple, calcified
obstructions and complete occlusion more than stenotic lesions. This may explain the tendency toward lower primary patency in diabetic patients during 3 months follow-up. Diabetic patients with CLI had poor collateral distribution due to the depression of arteriogenic and collateral growth in response to ischemia particularly in below the knee arteries, Faglia et al. (19).

In diabetic patients, it is advisable to achieve direct blood flow to the foot by an anterior or posterior tibial artery revascularization, because the peroneal artery anatomically ends above the ankle and its collaterals to the foot are usually poorly developed.

5. Conclusion

Infrapopliteal angioplasty has acceptable clinical outcome and is feasible as the primary choice of treatment in diabetic patients with CLI. Diabetes mellitus is a risk factor significantly affecting the 3-months clinical success rate, but is not significantly affecting the technical success and the 3-months patency rate.

Conflict of interest

The authors declare that there are no conflict of interests.

References


