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Midterm Outcomes after Endovascular Therapy in Claudicant Patients

Intermittent claudication (IC) is the most common clinical manifestation in patients with peripheral vascular disease (PVD). Between 25-33% of PVD patients will present symptoms of IC; (1) however, major amputation rate in these patients will not be >3.3%. (2) The main purpose for the treatment of these patients is to improve quality of life and reduce complications. Traditionally, pharmacological therapy and supervised exercise have been the first-line treatment. Today, with the development of endovascular treatment, a new alternative arises, given the low morbidity and mortality rates and the positive short- and mid-term outcomes.

The purpose of this study was to analyze the technical success, complications, and clinical outcomes in a group of patients with symptoms of IC undergoing endovascular treatment. A descriptive, retrospective analysis was performed on 90 patients in whom 115 limbs were consecutively treated between September 2010 and January 2015.

Inclusion criteria for the analysis of these patients were vascular IC Rutherford grade I, II, and III. Of the 115 limbs treated, 19.2% were grade II, and 80.8% were grade III. Clinical follow-up was performed at 1, 3, 6, and 12 months, and annually through questioning and physical examination. Technical success was defined as residual stenosis <30% without flow-limiting dissection of the treated arterial segment.

Complications were divided into major -requiring open invasive treatments- or minor -requiring conservative or percutaneous treatments. The course of symptoms was divided into four groups. Asymptomatic group: patients had no symptoms of IC; symptomatic improvement group: patients with reduced Rutherford classification by one or more degrees; no improvement group: patients without clinical changes; and increased-symptom group: patients with IC increased by one degree in the classification.

The femoral, contralateral, or ipsilateral access was the elective approach. Retrograde approaches were used in 4 limbs (3.5%) due to failed recanalization. Primary nitinol self-expanding stent (nSES) follow by percutaneous transluminal angioplasty (PTA) was the technique of choice. Drug-eluting balloon angioplasty (DEB-PTA) was the treatment of choice for stenotic lesions, while occlusive lesions were approached with PTA with stent or DEB implantation, depending on the result. Table 1 shows the characteristics of the study population.

Among the 115 limbs considered for treatment, this was performed in the aortoiliac region in 45 (39%) and in the femoropopliteal region in 70 (61%). Infraarterial vessel PTA was also performed in 9 limbs (7.8%) (Table 2). Technical success was reached in 114 (99.1%) of the 115 limbs treated. One hundred percent technical success was obtained in TASC A-B lesions, and 98.2% in TASC C-D lesions. In one of the limbs with femoropopliteal TASC D lesion, distal approach was possible due to gross calcifications. Percutaneous transluminal angioplasty with nSES was used in 82 of the 115 limbs (71.3%); 23 (20%) were treated with DEB, and 10 (8.7%) with conventional PTA.

Complications occurred in 7 cases (6%): 4 (3.4%) were pseudoaneurysms treated with embolization with thrombin injection and 3 (2.6%) were hematomas, not requiring treatment.

Mean follow-up was 18 months (1-36 months) in 111 (96.5%) limbs. Among these, 104 (93.7%) were asymptomatic, 4 (3.6%) had symptomatic improvement, and 3 (2.7%) showed no clinical changes. During follow-up, 60.6% of the patients abandoned their smoking habit.

A total of 10 (8.7%) reoperations were performed in the 115 limbs treated. Four (40%) of these reoperations were in TASC A-B patients and 6 (60%) in TASC C-D patients. In turn, 8 (80%) of these reinterventions were on the femoropopliteal region, and 2 (20%) in the aortoiliac region, resulting in a reoperation rate of 4.4% for iliac lesions, and 11.42% for femoropopliteal lesions (p Fisher=0.311).

We can say that the natural history of patients with claudication is “benign”; however, at 5 years, between 10% and 20% of those without revascularization will progress to critical ischemia with an amputation rate of 2-5%. (2) Accordingly, treatment is based on management of risk factors, supervised exercise, and pharmacological treatment, a therapeutic approach that is effective only in 25-30% of cases. Cilostazol as drug therapy improves walking distance by 50%, but 15% of the patients stop treatment due to its adverse events. (3) Moreover, supervised exercise training in patients with severe limiting claudication does not increase significantly walking distance.

Shalger et al. reported a group of claudicant patients whose mean walking distance before treatment was 102 (66-155) meters, and increased to 154 (97-230) meters after exercise training. (4) In the work by Hobbs et al., the distance before supervised exercise

<table>
<thead>
<tr>
<th>Table 1. Risk Factors</th>
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<tbody>
<tr>
<td>Factor</td>
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<tr>
<td>Kidney disease</td>
</tr>
<tr>
<td>DM</td>
</tr>
<tr>
<td>HTN</td>
</tr>
<tr>
<td>Dyslipidemia</td>
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<td>Heart disease</td>
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<tr>
<td>Smoker</td>
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<td>Ex-smoker</td>
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DM: Diabetes mellitus. HTN: Hypertension.

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training was 111 (60-237) meters, and after exercise it increased to 124 (74-352) meters. (5)

In our series, 93.7% of the limbs treated at a mean follow-up of 18 months were asymptomatic, 3.6% presented improved symptoms, and 2.7% showed no clinical changes. It is important to point out that 81% of the patients in this series were Rutherford grade III. The therapeutic arterial current available has improved the technical success rate and patency of the treated lesions—a key point in claudicant patients—, since the relapse of symptoms is directly associated with restenosis or occlusion of the treated segment, as well as the development of new lesions. In our caseload, technical success was 99.1%, regardless of classification and arterial territory of the limbs treated.

Conventional balloons, DEB, covered stents with and without eluting drugs, and atherectomy are among current endovascular alternatives. Regarding covered stents, McQuade et al. presented a randomized study comparing the patency of prosthetic bypass grafting versus Viabahn covered stent for the treatment of extensive femoropopliteal lesions, and found no statistically significant differences in primary patency at 4-year follow-up. (6) Recently, Tepe et al. carried out a multicenter randomized study to compare the outcomes of DEB angioplasty versus conventional balloon, reporting a primary patency of 82.2% and 52.4% at 12 months, respectively. (7)

In our experience, none of the 23 limbs treated with DEB required reoperation, and remained asymptomatic during the follow-up period. Therefore, we could say that endovascular therapy for IC patients performed by experienced groups is safe and effective, with low morbidity and mortality rate. The indication of endovascular therapy in these patients should be agreed between doctor and patient based on the expectations and functionality of each person. Nonetheless, endovascular therapy should be considered as the treatment of choice in patients whose medical treatment is unsuccessful or insufficient for their expectations.

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REFERENCES

Malpositioned Pacemaker Lead Mimicking Left Myocardial Injury
Pacemaker implantation is a common practice, with minimum prevalence of associated complications. However, inadvertent left-sided lead placement is one of them, which though rare, may have serious consequences as atrial thromboembolism.

We report the case of a 73-year-old hypertensive female patient, with no history of coronary heart disease, with ostium secundum atrial septal defect (ASD), severe pulmonary arterial hypertension (PAH) and right heart dilatation, and no other cardiovascular history. A DDD pacemaker had been implanted in another center due to extreme bradycardia in acute AF conversion, 30 days before consultation.

The patient presented with FC III precordial, burning pain of moderate intensity, spreading at rest, radiating to the back and the right arm, and relieved with opioid analgesics. Upon consultation, the patient was asymptomatic and normotensive, with no signs of congestive heart failure (CHF), jugular venous distention or Kussmaul’s sign.

The electrocardiogram (ECG) showed ST-segment depression in V2 and V3 with negative T-waves (Figure 1A). No other ECG abnormalities were noted over previous ECGs (the patient had deviation of the axis and right bundle branch block associated with her history of ASD and PAH. Successive records showed ST segment resolution (Figure 1B). Elevated serum cardiac enzymes (CPK and cTnI) were observed in the appropriate time window.

Table 2. Distribution of lesions by territory and technical success

<table>
<thead>
<tr>
<th>TASC</th>
<th>Aortoiliac (n=45)</th>
<th>Femoropopliteal (n=70)</th>
<th>Technical success (Global 99.1%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>14 (31%)</td>
<td>19 (27.1%)</td>
<td>100%</td>
</tr>
<tr>
<td>B</td>
<td>11 (24%)</td>
<td>19 (27.1%)</td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>3 (6.7%)</td>
<td>8 (11.4%)</td>
<td>98.2%</td>
</tr>
<tr>
<td>D</td>
<td>17 (37.8%)</td>
<td>24 (34.4%)</td>
<td></td>
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