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Clinical and haemodynamic evolution of lesions treated by means of atherectomy with SilverHawk in the femoropopliteal sector

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ABSTRACT

The objective of the work is to study the clinical and haemodynamic evolution, over 1 year, in patients with femoropopliteal arterial pathology treated by means of atherectomy with the SilverHawk device.
Materials and methods: Nineteen (19) patients were treated between December 2008 and May 2009, collecting data on sex, age, comorbidity and clinical degree, with prospective monitoring over 12 months of clinical symptoms, physical examination and ecodoppler, obtaining results on diameter and peak systolic velocity at different arterial levels.
Results: Of the 19 patients, 14 were men and 5 women, with a mean age of 70 years, hypertensive (73%), diabetic (63%) and smokers (63%). Six (6) presented disabling claudication and 13 critical ischemia with advanced distal trophic lesions in 5. A good arteriographic result was obtained in 12 cases, a stent was placed on the superficial femoral artery in 5 due to suboptimal outcome. Contrast extravasation was observed in 2, with femoropopliteal bypass performed and one exclusion with endoprosthesis for repair. In the ecodoppler after 1, 3, 6 and 12 months, a progressive reduction in lumen diameter and peak intraarterial systolic velocity was observed, particularly on the distal superficial femoral artery. After one year, 7 patients (36.8%) were symptom-free, 5 (26.3%) presented mild or moderate intermittent claudication and 1 patient (5.3%) presented localised distal trophic lesion. Four (4) major amputations were performed, in 2 the knee was preserved, there were 3 thromboses due to the procedure, a secondary endovascular procedure was performed in one case and a femoropopliteal bypass in another, and there were 2 non procedure-related deaths.
Discussion: atherectomy with SilverHawk achieves an improvement in clinical degree, with a good rate of extremity salvage in patients with critical ischemia. In the first year, the ecodoppler shows evolution of the arteriopathy, without this necessarily meaning a clinical worsening.

1. Introduction

The increase in the population's life expectancy is giving rise to an increase in the prevalence of peripheral obstructive arteriopathy, significantly affecting patient quality of life.

Up until several years ago, the surgical treatment of arteriopathy at infrainguinal level by means of bypass was regarded as the "gold standard" [1]. In recent years, different devices for the performance of endoluminal treatment of infrainguinal lesions have been developed and perfected, such as balloon angioplasty with or without stent, cryoplasty, directional atherectomy, laser atherectomy, remote endarterectomy [2].

The endoluminal treatment of peripheral arteriopathy provides lower morbidity and mortality, with good permeability results with regard to bypass revascularisation [3], hence in many centres it has become the first option in the treatment of infrainguinal lesions.

In 1987, a directional atherectomy was introduced, namely the Simpson device, with a complex mechanism whose results were poorer than expected [4]. In 2003, the Food and Drug Administration (FDA) approved a new, easy-to-manage infrainguinal directional atherectomy device, the SilverHawk Plaque Excision System (Fox Hollow Technologies, Redwood City, CA), which features a carbide blade that eliminates material from the damaged arterial wall, and unlike balloon angioplasty and stent placement, which expand the arterial lumen mechanically, this device does not use a balloon, thus reducing barotrauma, minimising vessel wall trauma [5–11]. Several works describe

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the SilverHawk atherectomy device and the results it presents [12–22].

The objective of our work is to study clinical and haemodynamic evolution over 12 months, with measurements performed by ecodoppler of femoropopliteal arterial pathology treated with atherectomy with SilverHawk device.

2. Materials and methods

A prospective study was performed over 12 months with 19 patients with femoropopliteal arterial lesions treated by atherectomy between December 2008 and May 2009. The SilverHawk device (Fox Hollow Technologies, Redwood City, CA) was used for the atherectomy. Data were collected on age, gender, cardiovascular risk factors, comorbidity and clinical degree according to the classification described by Rutherford et al. [23].

All the patients were studied preoperatively by means of arteriography, the lesions were classified according to the TASC criteria [1], the number of distal aperture vessels was considered, and whether it was stenosis or arterial occlusion.

The atherectomies were performed in the operating theatre by a vascular surgeon by means of anterograde homolateral femoral access. Data were obtained on the device, and different-sized devices – MS, LL or LX – were used, according to the diameter of the vessel to be treated; and the use of the distal filter, the criteria for the use of the filter were on plaques that were more susceptible to emboly and when the patient presented poor distal aperture. A balloon angioplasty and/or stent placement was performed in the same operation when significant residual stenosis was observed (>30%).

Technical success was regarded as a final arteriographic image with correct arterial rechannelling, residual stenosis <30% and the absence of contrast extravasation; clinical success was the improvement of clinical degree, healing of distal lesions and when major amputation of the extremity was not required.

These patients were monitored after 1, 3, 6 and 12 months, evaluating clinical symptoms, physical examination, ankle-arm index, antiaggregant and/or anticoagulant treatment and an exploration was performed by means of an ecodoppler of the infrainguinal arterial axis of the operated extremity, the data on peak systolic velocity and diameter of the intraarterial lumen at different levels were collected: the common femoral artery, the superficial femoral in its proximal segment, the superficial femoral artery before Hunter's canal and the popliteal infragenicular artery before the anterior tibial origin. A Philips Envisor C HD ecodoppler with a multifrequency probe of 3–12 MHz was used for the study. The ecodoppler was performed by the same explorer.

Primary permeability was defined as the absence of thrombosis of the treated arterial segment by means of ecodoppler study in monitoring, and salvage of an extremity through not having to perform a major amputation, either at supracondylar or infrapatellar level.

The statistical analysis was performed with the SPSS program version 16.0, the Student's t was used to analyse the quantitative variables and the Chi-square test to study the qualitative variables. The Kaplan–Meier method was used for survival analysis. A $p < 0.05$ was regarded as a statistically significant difference.

3. Results

Of the 19 patients studied, 14 (73.7%) were men and 5 (26.3%) women, with a mean age of 70 years (range 50–89). They presented the following cardiovascular risk factors: 73.7% hypertension, 63.2% with diabetes, 63.2% smokers and 31.6% with dyslipemia, with a record of ischemic heart disease in 31.6%, chronic bronchitis in 15.8% and chronic renal failure in 15.8% (Table 1).

Table 1
Demography and comorbidity (n, %).

Men	14 (73.7%)
Women	5 (26.3%)
Age	70 years (50–89)
Hypertension	14 (73.7%)
Diabetes	12 (63.2%)
Smokers	12 (63.2%)
Dyslipemia	6 (31.6%)
Heart disease	6 (31.6%)
Bronchitis	3 (15.8%)
CKD	3 (15.8%)

CKD: chronic kidney disease.

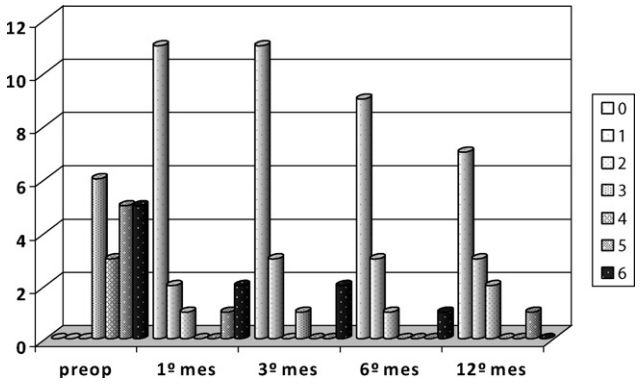

Fig. 1. Clinical evolution of patients according to the Rutherford category in the preoperative phase, 1st, 3rd, 6th and 12th month.

The preoperative clinical symptoms presented by the patients were 6 with severe intermittent claudication (degree 3), 3 with pain at rest (degree 4), 5 with trophic lesion or localised gangrene (degree 5) and 5 with advanced gangrene (degree 6) and with a mean ankle-arm index of 0.36.

The arteriographic lesions treated according to the TASC classification were 9 type A (47.4%), 8 type B (42.1%) and 2 type C (10.5%); 12 were lesions that produced stenosis and 7 occlusions; the superficial femoral artery was affected in 14 cases, the popliteal artery in 2 and both in 3. In 2 patients, distal runoff was to 3 vessels, to 2 vessels in 3, to 1 vessel in 8 and in 6 patients there was severe distal involvement with divergent collateral circulation.

The MS device was used in 12 cases, LS in 6 and LX in 1; the distal filter was used in 6 cases and a nithinol stent was placed in 5. Contrast extravasation arose as a complication in 2 patients, requiring the implantation of an covered stent and the performance of a femoropopliteal bypass in each one of the cases for arterial repair. Postoperative treatment in 13 patients was with clopidogrel, oral anticoagulation in 3, in one case it was combined with 100 mg adiro and in another with clopidogrel, with adiro at a dose of 300 mg in one and with triflusal in one.

The clinical evolution presented by patients in the controls after 1, 3, 6 and 12 months is represented in Fig. 1. After 1 year, 7 patients (36.8%) were symptom-free, 2 of them required amputation below the knee and another one presented thrombosis of the superficial femoral artery on the ecodoppler, 5 (26.3%) mild-moderate intermittent claudication (Rutherford degree 1–2) and 1 patient (5.3%) localised distal trophic lesion (degree 5).

The mean preoperative ankle-arm index was 0.36, which increased in the exploration after the 1st month to 0.76, the mean index after one year was still above preoperative level (0.58), and comparing the preoperative mean to the mean after one year there