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Predictive Risk Factors for Restenosis after Remote Superficial Femoral Artery Endarterectomy

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Abstract *Objectives:* Restenosis following remote superficial femoral artery endarterectomy (RSFAE) remains a challenging problem. The determinants predicting failure are lacking. This study investigated patient characteristics with predictive value for restenosis during the first year after RSFAE.
Design: A prospective cohort study.
Materials and methods: A total of 90 patients post-RSFAE were studied for the occurrence of restenosis (peak systolic velocity ratio ≥ 2.5) in the first 12 months postoperatively. At baseline, clinical parameters were recorded. Vessel size was measured on the basis of plaque perimeter in the culprit lesion and lumen diameter on perioperative digital subtraction angiography.
Results: In 57 patients (63%), a restenotic lesion was diagnosed within 12 months following surgery. Patients with longer time interval between start of ischaemic walking complaints and RSFAE revealed a significantly higher incidence of restenosis (hazard ratio (HR) = 1.3 (1.05–1.52) per 4 years). Small plaque perimeter and small superficial femoral artery (SFA) diameter on angiography were significantly associated with restenosis (HR = 0.54 (0.34–0.88) per 10 mm and HR = 0.46 (0.27–0.78) per 1.5 mm, respectively). In multivariate analysis, age, duration of ischaemic walking complaints and lumen diameter were independently associated with increased risk of restenosis after RSFAE.
Conclusions: This study provides evidence that age, vessel size and duration of ischaemic walking complaints before RSFAE are predictive values for restenosis after RSFAE.

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Remote superficial femoral artery endarterectomy (RSFAE) is established as a minimally invasive treatment option for long occlusions, defined as TransAtlantic Inter-Society Consensus (TASC)[1] C and D lesions of the superficial femoral artery (SFA). RSFAE has comparable primary-assisted and secondary patency rates to prosthetic supragenicular bypass surgery.[2] Besides, hospital stay is shorter and consequences of possible re-obstructions are less severe in patients treated with RSFAE.[2,3]

A drawback of RSFAE is the restenosis rate in the first year postoperatively caused by neo-intimal hyperplasia, with more than 80% of all restenoses occurring in the first year after surgery. Restenosis within the first year has been associated with a higher risk for occlusion. The restenotic lesions are equally distributed in the endarterectomised SFA, including the distal part of the SFA with the stented transection zone.[4]

The determinants predicting failure after RSFAE are lacking. The general risk factors for cardiovascular disease are not successful in discriminating the risk for restenosis. The extent and severity of the treated lesion and technical considerations are determinants of failure after percutaneous interventions or bypass surgery.[5] However, these clinical characteristics have not yet been proven to be of value for predicting restenosis after RSFAE. The objective of this study was to investigate patient characteristics that have a predictive value for restenosis during the first year after RSFAE.

Materials and Methods

Study population

All patients in the current study were included in the Athero-Express Biobank, an ongoing vascular biobank with a longitudinal study design that has been described previously.[6] Dissected femoral plaques, obtained by endarterectomy in two participating Dutch teaching hospitals, were collected and examined histopathologically. In addition, clinical baseline characteristics of all included patients were obtained. The medical ethics boards of both participating hospitals approved the study, and all patients provided written informed consent.[6]

In both hospitals, patients suffering from SFA obstructions were treated by use of the same protocol. Patients without improvement or worsening of their complaints after supervised exercise, and patients with critical ischaemia primarily, were discussed in a multidisciplinary meeting. If the patients did have a suitable greater saphenous vein (>3 mm), TASC C lesions, assessed as too complicated for percutaneous intervention, and TASC D lesions were treated with a venous supragenicular bypass. If the patients with extensive TASC C and TASC D SFA lesions did lack a suitable greater saphenous vein, they were treated primarily with RSFAE. Only when RSFAE failed that patients received a prosthetic supragenicular bypass.

A total of 90 consecutive patients who underwent RSFAE between February 2003 and October 2007 were selected. All patients underwent unilateral RSFAE with or without an additional open endarterectomy of the common femoral artery. All patients presented with intermittent claudication, critical ischaemia or tissue loss (Rutherford category 3–5)[7] due to long-segment occlusion (TASC C and D lesions) of the SFA.

At baseline, clinical preoperative, perioperative and postoperative parameters were obtained from the Athero-Express medical database. Missing data were obtained from medical files or referral letters. The preoperative evaluation included a magnetic resonance angiography (MRA).

RSFAE technique

This minimally invasive debulking technique has been described previously.[8] In summary, the SFA is exposed through a small groin incision. After anticoagulation with heparin, the proximal SFA is clamped, and a longitudinal arteriotomy is made in the proximal SFA. The intima core is dissected, between the lamina elastica interna and the circular fibres of the media, using the Vollmar dissector (Vollmar Dissector, Aesculap®, San Francisco, CA, USA), until it reaches the distal limit of the atheroma in the SFA. The Vollmar dissector is then exchanged for the Mollring Cutter® (LeMaître Vascutek, San Jose, CA, USA). This device can transect and remove the entire desobstructed intimal core, all under fluoroscopic guidance. After the SFA is debulked, the distal transaction zone is secured by a stent and a completion angiography is performed to check the patency of the SFA and outflow arteries.

Atherosclerotic plaque

The excised plaques were directly transferred to the laboratory, processed and examined as described previously.[6] The atherosclerotic lesions were dissected into 5-mm segments, and the segment with the greatest plaque area was defined as the disease-causing lesion. This segment was fixed in formaldehyde 4%, decalcified for 1 week in ethylenediaminetetraacetic acid and embedded in paraffin. The segments adjacent to the causative lesion were snap-frozen in liquid nitrogen and stored at −80 °C for future analysis.[6]

Arterial size

Cross sections of the elastin von Gieson staining of the harvested atherosclerotic plaques were captured by digital image microscopy (AnalySiS version 3.2, Soft Imaging GmbH, Munster, Germany), and the perimeter of the plaque was measured in each cross section by tracing the internal elastic lamina (Fig. 1). As the studied femoral atherosclerotic plaques are dissected between the internal elastic lamina and the circular fibres of the media, we assumed that the perimeter of the dissected atherosclerotic plaque (the perimeter of the internal elastic lamina) is a measure of preoperative artery size.

The diameter of the arterial lumen was also measured on angiography performed at the end of the procedure as a measure for residual lumen size. All angiographies were stored in an electronic database, and all patients received an aSpire® stent (LeMaitre Vascular, San Jose, CA, USA) to secure the transaction zone in the distal SFA. The distance between two nitinol frames of the double-helix