

PROPOSAL APPLICATION FORM

Peripheral Arterial Disease (PAD) project registration form

Title of research project: Different Endovascular Modalities of Treatment of Isolated Atherosclerotic Popliteal Artery Lesions

Short title (acronym):EMO-POP registry

Chief Investigator responsible for project

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Brief Project proposal –

Objectives:

Knee flexion continuously stresses the popliteal artery with high biomechanical forces. As a result, isolated atherosclerotic popliteal artery lesions are quite common in patients with peripheral arterial disease.

During the last years different endovascular modalities of treatment have been proposed to treat these lesions (standard balloon angioplasty, PTA; drug-coated balloon, DCB; atherectomy; stenting). In some papers a combination of more modalities have been reported (directional atherectomy with antirestenotic therapy, DAART).

Hypothesis and specific aims:

Aim of this study is to report the early and long-term outcomes of endovascular treatment of isolated atherosclerotic popliteal artery lesions comparing the different modalities of treatment in the framework of a multicenter retrospective registry.

PICO Summary:

Background including pilot data which might be available:

1. Tamashiro GA, Tamashiro A, Villegas MO, Dini AE, Mollón AP, Zelaya DA, Soledispa-Suarez CI, Díaz JA. Flexions of the popliteal artery: technical considerations of femoropopliteal stenting. J Invasive Cardiol 2011; 23: 431-433.
2. Stavroulakis K, Schwindt A, Torsello G, Stachmann A, Hericks C, Bosiers MJ, Beropoulos E, Stahlhoff S, Bisdas T. Directional Atherectomy With Antirestenotic

Therapy vs Drug-Coated Balloon Angioplasty Alone for Isolated Popliteal Artery Lesions. J Endovasc Ther 2017; 24: 181-188.

3. Rastan A, McKinsey JF, Garcia LA, Rocha-Singh KJ, Jaff MR, Harlin S, Kamat S, Janzer S, Zeller T. One-Year Outcomes Following Directional Atherectomy of Popliteal Artery Lesions: Subgroup Analysis of the Prospective, Multicenter DEFINITIVE LE Trial. J Endovasc Ther 2018; 25: 100-108.
4. Poulson W, Kamenskiy A, Seas A, Deegan P, Lomneth C, MacTaggart J. Limb flexion-induced axial compression and bending in human femoropopliteal artery segments. J Vasc Surg 2018; 67: 607-613.
5. Elens M, Verhelst R, Mastrobuoni S, Bosiers MJ, Possoz J, Lacroix V, Astarci P. Balloon Angioplasty Versus Bailout Stenting for Isolated Chronic Total Occlusions in the Popliteal Artery. Vasc Endovascular Surg 2019; 53: 126-131.

Rationale for current proposal, further pilot data which might be required and how that pilot data will be acquired:

This study is a retrospective multi-center European registry comparing outcomes of different modalities of treatment of isolated atherosclerotic popliteal artery lesions from high-volume vascular centers. Exhaustive information regarding patients' demographics/risk factors (including both anatomical data and cardiovascular risk-factors), procedural details, and latest available outcomes will be collected in a dedicated database.

Methods:

Inclusion criteria are:

- Endovascular treatment of isolated atherosclerotic stenosis or occlusion of popliteal artery in one or more segments (the popliteal artery segments are defined as follows: P1 segment, from intercondylar fossa to proximal edge of patella; P2 segment, from proximal edge of patella to knee joint space; P3 segment, from knee joint space to ostium of anterior tibial artery)

Exclusion criteria are:

- Redo procedures including in-stent restenosis
- Entrapment syndrome
- Popliteal aneurysm
- Concomitant endo or open treatment of the infrainguinal in-flow vessels (common femoral, superficial femoral arteries)
- Concomitant endo or open treatment of the out-flow-vessels (below-the-knee and foot arteries)

Anticipated problems and limitations:

Possible Data analysis:

- The primary outcomes measures are primary patency, secondary patency, and absence of target lesion revascularization (TLR)
- The secondary outcomes measures are acute technical success (residual stenosis <30%), 30-days morbidity, 30-days mortality, primary assisted patency, limb salvage

Specific support requested from RCPAD collaborating centres that will allow the completion of the project:

Each collaborating center will be expected to contribute a minimum of 15 patients with complete follow-up data. The aim is to enroll at least 500 patients.

A 4-month period will be offered to every collaborating center for the data collection.

The data will be analyzed by Nicola Troisi, Giovanni Torsello and Hany Zayed who will also prepare a manuscript for publication. This will be circulated to the main authors from each collaborating center for comments/suggestions prior to submission (at least one week to receive comments/suggestions).

Authorship will be granted based on the latest International Committee of Medical Journals Editors (ICMJE) guidance, available here: <http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>

Each institution will nominate one lead to help with data collection, and study-related communications, but there will be no limit to the number of authors (collaborative model).