The AURORAA registry: 4 year results using interwoven nitinol stents for extensive distal femoropopliteal occlusive disease

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Introduction

Endovascular treatment of popliteal and distal superficial femoral artery lesions is increasingly growing. The Supera stent was limited by insufficient radial strength/flexibility to maintain vessel patency and scaffolding and to prevent recoil, stent kinking and fractures (with high prevalence of in-stent re-stenosis, restenosis and occlusion). There was a need for "dedicated" stents, that provide the combination of sufficient strength and flexibility and that can deal with high mechanical stress, created by the flexion-extension, compression, elongation and rotational forces; especially at the level of the knee. For this reason the Supera device Fig.2, a 0.014/0.018-inch guidewire compatible, sheath based delivery system is already been tested and investigated on safety and durability. The retrieved data showed a superior radial strength, flexibility, durability, conformability, scaffolding and fracture resistance in combination with excellent patency rates compared to the "classic bare slotted nitinol tubed stents".

The aim of this study was to see if those results could be reproduced in "real world" conditions with patients with extensive atherosclerotic lesions.

Methods

Patients, after endovascular treatment of lesions at the level of the distal superficial femoral artery (SA) and/or popliteal artery, who needed stent placement due to flow limiting dissection, recoil or calcifications, were treated with a Supera implantation. Before device delivery, every patient received a proper vessel preparation with a 1-to-1 balloon angioplasty (2 min inflation time) to obtain sufficient space for a complete stent deployment. The Supera has a unique design with six pairs of closed-end, interwoven nitinol wires in a helical pattern, giving it extraordinary characteristics: very flexible, kink, fracture and crush resistant together with great radial force and improved strength. The device is deployed by advancing a ratchet-like mechanism actuated by a thumb slide distally while the stent handle is held stationary. The stent is then pushed out, while the catheter is pulled back. This is completely different as the "traditional" pull back systems and makes the deployment "operator depended".

Results

From June 2010 till July 2012 we followed 117 patients treated with the Supera stent in a single centre-physician-initiated, prospective, non-randomised, follow-up study (patient characteristics: table 1). Most of the lesions were TASC II C & D lesions, with involvement of the distal SFA and popliteal artery and with occlusive and calcified disease. The average lesion length was 14 cm with an average stent length of 16 cm. Technical success rate was around 96% (table 2). Follow up done by duplex ultrasound (PSVR: 2.5). Seven (5.9%) patients died of non-interventional causes and 2 (1.7%) patients needed a major amputation. Six months primary patency was more than 90%. Twelve months primary patency was around 81%. Patency rates remained high in following long-term follow up: 70.08% after 36 months (table 3).

We observed further more no stent fractures or flow limiting kinking in this very difficult "to stent" area (distal superficial femoral artery & popliteal artery).

Conclusions

• The Supera stent can be a solution when the use of a "classic" nitinol stent is not indicated or favourable, especially in the femoropopliteal area or areas with extreme mechanical stress.

• Implantation of the Supera system is safe and effective, with high patency rates and no stent fractures, despite the very difficult regions to treat.

• This is of course highly important in patients with chronic CLI, the elderly, the chronic ill with high comorbidity, and those with extensive (calcified) plaque burden.

• This self-expansible system, that mimics and adapts to the vascular features, can be a necessary complement in your tool box due to its special characteristics.

References


7.報告書"四回経過観察について" "四回経過観察について" "四回経過観察について" "四回経過観察について" "四回経過観察について" "四回経過観察について" "四回経過観察について" "四回経過観察について" "四回経過観察について" "四回経過観察について" "四回経過観察について" "四回経過観察について" "四回経過観察について" "四回経過観察について" "四回経過観察について" "四回結