Endovascular Treatment of Peripheral Artery Disease with Expanded PTFE-Covered Nitinol Stents: Interim Analysis from a Prospective Controlled Study

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Abstract

Purpose: Current covered peripheral stent designs have significant drawbacks in terms of stent delivery characteristics and flexibility. The aim of this study was to analyze the technical performance, safety and initial clinical efficacy of expanded polytetrafluoroethylene (PTFE)-covered nitinol stents for arteriosclerotic peripheral artery disease.

Methods: Eighty-two patients underwent implantation of PTFE-covered nitinol stents for iliac and/or femoral obstructions. The study was conducted prospectively in seven European centers and one Canadian center. Patients were controlled clinically and by duplex ultrasound follow-up. Data up to discharge were collected in 79 patients. Seventy-four patients have thus far received 1 month follow-up and 32 patients, 6 month follow-up examinations.

Results: The average lesion length measured 47 mm for the common and external iliac arteries and 50 mm for the femoral arteries. The mean severity of the stenoses was reduced from 94% to 4% in the iliac arteries and from 98% to 7% in the femoral arteries after stent placement and dilatation. One device deviation (inadvertent stent misplacement) and one puncture-related severe adverse event with formation of a pseudoaneurysm occurred. There were occlusions of the stent in five patients. No infections were noticed.

Conclusion: The interim analysis of this trial using PTFE-covered nitinol stents indicates that a strategy using primary implantation of this stent type is technically feasible, has an acceptable safety profile and is effective from a short-term perspective.

Key words: Angioplasty, transluminal—Iliac artery, stenosis and obstruction—Femoral artery, stenosis and obstruction—Stents and prostheses—Stents, covered

Percutaneous transluminal angioplasty (PTA) has become a well-established and routine intervention for the treatment of arteriosclerotic peripheral artery disease [1]. There are a number of inherent limitations to current PTA procedures, one of the most common being suboptimal PTA either from vessel recoil or due to dissection. One of the more recent treatment modalities used to overcome such limitations of PTA is peripheral artery stenting [2, 3]. Recent data suggest that intravascular stents may improve the immediate results after angioplasty with regard to postangioplasty recoil and may lead to longer-term vessel patency despite morphologic evidence of injury and dissection of the vessel wall [4, 5]. Endovascular stents may also help to manage complications after angioplasty [6, 7]. However, postprocedural subacute occlusions and restenosis, which often involve the stented segments, play a major role. This holds especially true in the
stent treatment of iliofemoral occlusions and long-segment femoral stenoses. Uncovered stents reduce recoil, but may fail when neointimal proliferation becomes excessive. Generally, long-term results depend on the degree, frequency and progression of neointimal hyperplasia. Covered stents have the potential to overcome this limitation by providing a barrier against neointimal hyperplasia, thus potentially increasing stent patency [8].

The aim of this study was to investigate the technical feasibility and initial clinical outcome of the recently developed expanded polytetrafluoroethylene (PTFE)-covered nitinol self-expanding stent for endovascular treatment of iliofemoral artery stenosis and occlusion.

Materials and Methods

Subjects

Eighty-two patients with iliac and/or femoral obstructions were treated with PTFE-covered nitinol stents between March 2000 and June 2001 in five European centers, one Australian Center, and one Canadian center. The procedures were performed in accordance with the respective institutional guidelines. All subjects gave written informed consent. Indications for stent placement were high-grade (>70% diameter stenosis) iliac (n = 45) and femoral (n = 37) stenosis or occlusion. For the exact locations of the lesions see Fig. 1.

Device Description

In all patients PTFE-covered nitinol stents were used (Cordis, Johnson & Johnson, Waterloo, Belgium). The stents were self-expanding, covered with a PTFE tube, and encapsulated between two nickel/titanium alloy frameworks designed to maintain vessel patency after deployment in the peripheral vasculature. Stents were available in lengths between 40 and 80 mm and diameters between 6 and 10 mm. The stent frameworks were made from a laser cut hypo-tube. The delivery system consisted of an inner shaft and an outer sheath locked together with a Tuohy-Borst valve. The self-expanding stent was positioned between the inner sheath and the outer sheath. Two radiopaque markers were located on the inner sheath (distal and proximal to the undeployed stent) and on the tip of the outer sheath.

Preinterventional Diagnostic Investigation

Biplanar angiographic views were obtained using digital subtraction technique before and after stent placement (Fig. 2A, B). For measurement of distances and severity of stenosis a graded 5 Fr catheter or wire was used only if deemed necessary, as it was not mandated by protocol.

Implantation

All patients were treated under local anesthesia in the angiography suite. Placement of the stents was performed using a 9 Fr (diameter of stent-graft 6–9 mm) or 10 Fr (diameter of stent-graft 10 mm) sheath. The stents were targeted according to the predeployment angiography. Peri-interventional medication included unfractionated heparin (5000 IU i.a., followed by 20 000 IU/24 hr i.v.) and aspirin (100 mg p.o.). After hospital discharge the patients were prescribed clopidogrel (75 mg p.o.) for 6 weeks and aspirin (100 mg p.o.).

Statistical Analysis

All variables are expressed as means ± SD or as numbers of patients and percentages. Paired t-tests or Wilcoxon signed rank tests, if appropriate, were used to compare the ankle-brachial indices and the peak systolic velocity values over time. Probability values given are based on two-sided analyses of test results. A significance level of 5% was used.