Usefulness of the Symphony™ Nitinol Stent for Arteriosclerosis Obliterans

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The Symphony Peripheral Stent™ is a self-expanding stent made of thermal memory Nitinol wire. Stents were implanted in 39 lesions of 32 patients (26 men, 6 women) with atherosclerosis obliterans (ASO). The ankle–arm index (AAI), and vessel diameters evaluated by quantitative angiography were compared before and 6 months after treatment. Symphony Peripheral Stent™ implantation significantly improved the AAI from 0.50±0.4 to 0.9±0.2 (p<0.01), the minimum lumen diameter (MLD) from 2±1.5 to 5±1.4 mm (p<0.01) and percent diameter stenosis (%DS) from 69±20% to 16.5±8% (p<0.01). Re-evaluation of 33 of the 39 lesions 6 months after treatment revealed a low restenosis rate of 15%, an AAI of 0.8±0.3, MLD of 4.5±2 mm and %DS of 30±22%, so the Symphony Peripheral Stent™ is thus a promising choice for patients with ASO. (Circ J 2002; 66: 1000–1002)

Key Words: Atherosclerosis obliterans; Nitinol; Self-expandable stent; Transluminal angioplasty

Percutaneous transluminal angioplasty (PTA) has had a high success rate as a treatment for peripheral vascular disease, becoming an alternative to bypass surgery!–3 However, certain problems, such as occlusion and restenosis of the treated arteries, remain to be solved.

Intravascular stents are inserted to minimize the elastic recoil after balloon angioplasty and this additional treatment ensures immediate patency of the treated vessels for several months after the treatment.4–6 Stents are now classified into 2 types: mechanical expansion by an angioplasty balloon (eg, Palmaz stent) or self-expanding (eg, the Wallstent).

We used a new stent made of nitinol (Symphony™ Nitinol Stent, Boston Scientific Corporation) and report our clinical experience.

Methods

Materials

The Symphony™ Nitinol Stent is a tubular prosthesis constructed from a single strand of thermal memory nickel titanium alloy filament (0.23 mm in diameter). The wire is formed into several axially arranged hexagonal cells welded together at specified locations to form an integral structure.

The stent is delivered on the tip of a catheter covered with an outer sheath to protect and constrain the stent prior to deployment (Fig 1A). The outer diameter of the stent system is 7 French. For exact placement of the stent, there are 4 radiopaque markers on the proximal and distal ends of the outer sheath and the stent respectively. We used 2 sizes of stents: an unconstrained diameter of 8 mm and length of 44 mm, implanted in a vessel lumen of diameter 6–7 mm, and another with an unconstrained diameter of 10 mm and length of 40 mm for 7–9 mm vessels.

The delivery system has a unique shape (Fig 1B) with a double lumen structure: one is the guidewire lumen and the other is a flushing lumen, used for priming the stent capsule prior to use. The outer sheath is retracted by pulling a trigger on the proximal handle of the delivery system and as the outer sheath retracts, the stent begins to expand radially (Fig 1C). After removing the outer sheath completely, the stent undergoes ‘shape recovery’ (Fig 1D) and expands within the vessel.

Subjects

The protocol was approved by the ethics committee of National Toyohashi Higashi Hospital before the study began. Thirty-two patients (26 men, 6 women; mean age 70.6±7.8) were admitted for treatment of atherosclerosis obliterans (ASO): 19 (59%) were smokers, 11 (34%) had

(A) Constrained Symphony™ Stent on the delivery catheter. (B) The proximal handle of the delivery system. It has a double lumen (arrow) and a safety device (open arrow). (C) Expansion of the stent by retraction of the outer sheath. (D) The stent released from the outer sheath recovers its original shape.
diabetes, 17 (53%) had hypertension, 3 (9%) had hyperlipidemia, and, 7 (22%) had ischemic heart disease. Based on their symptoms, 11 patients were classified clinically as Fontaine stage I, 16 as stage IIa, 10 as stage IIb and, 2 as stage IV.

All patients underwent angiography after giving written informed consent; 39 target lesions (23 iliac artery lesions, 11 superficial femoral artery lesions, and 5 subclavian artery lesions) were treated. Based on their angiographical morphology, 26 (67%) lesions were classified as eccentric, 14 (36%) as calcified and 9 (23%) as total obstruction.

Patients were evaluated before and after the procedure and at follow-up. Quantitative angiography was performed on all lesions.

Interventional Procedures
At the beginning of the procedure, 5,000IU of heparin was injected and then 1,000IU each hour thereafter. The occluded segment of the artery was firstly recanalized with a guidewire and after dilatation with a balloon, the stent was advanced to cover the lesion. The proximal ends of the stent and the lesion were aligned first, then the stent position was adjusted using the radiopaque markers under fluoroscopic angiographic guidance. The stent was then fully released and implanted. In all lesions, after stent delivery, additional balloon angioplasty was performed to prevent the turbulent blood flow caused by incomplete apposition of the stent struts. The average Balloon Artery ratio was 1.2±0.25, and inflation pressure was 13±5 atm.

Initial results were classified by (1) procedural success, (2) clinical success and (3) Hemodynamic success.

(1) Procedural success was defined as 30% or less residual stenosis, and/or an increase of 50% or more in luminal diameter after the procedure without major complications.

(2) Clinical success was defined by the Fontaine classification, as in maintenance of stage I, and/or improvement by at least one stage.

(3) Hemodynamic success was defined as an increase of 0.1 or more in the ankle–arm index (AAI).

For the subclavian artery lesions, we compared the bilateral brachial systolic pressure index (brachial systolic pressure on the diseased side/on the healthy side) instead of the AAI and did not evaluate the change in the Fontaine classification. Restenosis was defined as the percent diameter stenosis of more than 50% at follow-up.

Statistical Analysis
Data are presented as the mean value ± SD. Statistical significance of continuous variables was determined with a two-tailed Student t test. Categoric variables were compared by the chi-square test or Fisher exact test, when appropriate. A p value less than 0.05 was considered statistically significant.

Results

Immediate Results
We implanted 74 stents in 39 lesions during this study (35 stents in 23 iliac artery lesions; 34 stents in 11 superficial femoral artery lesions and 5 stents in 5 subclavian artery lesions).

The initial procedural success rate was 95%, and the mean percentage diameter stenosis (%DS) improved to a significant degree before and after the procedure (Table 1). The mean pressure gradient across the lesion also improved from 52±39 mmHg to 2±4 mmHg. Procedural failures were the result of major complications.

The initial clinical success rate was 89%; 3 patients did not improve more than one stage in the Fontaine classification, and of those patients, 2 remained at stage IV. One patient at stage IIb improved only to IIa. In all patients with subclavian artery disease, the symptoms caused by limb ischemia disappeared.

The initial hemodynamic success rate was 92%; the AAI improved from 0.50±0.4 to 0.9±0.2 (p<0.001).

Major complications occurred in 2 patients: one had a cerebral hemorrhage that was treated with conservative medical therapy and only minor paralysis remained; the other had perforation of the external iliac artery during the post dilatation of the stenting lesion because of an oversized balloon with a Balloon Artery ratio of 1.35. We successfully treated this complication with a Palmaz stent covered with an autologous vein graft.

Minor complications occurred in 3 patients: 2 suffered from distal thromboses and one developed a groin hematoma after the procedure.

Follow-up
The mean follow-up period was 6.3±1.4 months: follow-up angiography was performed in 33 lesions (85%; 20 iliac artery lesions, 8 superficial femoral artery lesions and 5 subclavian artery lesions) of 27 patients.

Of the 5 patients for whom follow-up angiography was not performed, one died suddenly from causes unrelated to stenting, and 3 patients were lost to follow-up because of admission to another hospital for treatment of pneumonia.

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<th>Table 1 Quantitative Angiographic Measurements of ASO Lesions</th>
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<td>Lesion length (mm)</td>
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<td>Post procedure (n=39)</td>
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ASO, atherosclerosis obliterans; MLD, minimal lumen diameter; DS, diameter stenosis. *p<0.01; †p=0.05 vs baseline value of each group.
or cerebral infarction. The patient implanted with the Palmaz stent covered with an autologous vein graft was excluded from this study at follow-up.

Angiographical findings showed that the lumen of the stent was maintained (Table 1); patency was 97.0% and restenosis occurred in 5 lesions (15.2%). All restenosis lesions were localized in the superficial femoral artery. There was no significant increase in the mean pressure gradient (16±3 mmHg).

Target lesion revascularization (TLR) was performed in 7 lesions (21%); in 2 of these, although the %DS was less than 50%, there was stenosis on the distal side of the stented site, which decreased distal blood flow.

The clinical success rate was 81.8% and 18 patients maintained stage I of the Fontaine classification. None of the patients with subclavian artery disease complained of symptoms.

The hemodynamic success rate was 82%; the AAI was 0.8±0.3 and there was no significant difference in the AAI immediately after the procedure.

Discussion

We used a stent made of nitinol with a new delivery system and obtained satisfactory results in patients with ASO. In a prior study by Martin et al, the initial success rate and patency rate at 6 months for a Wallstent implanted in the iliac artery were 97% and 87%, respectively5 Similar results were reported by Gunther et al5,6 and Murphy et al7 in the iliac artery stenoses and occlusions with use of Wallstents: Three-year experience. J Vasc Inter Radiol 1996; 7: 21–27.

References