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RESEARCH LETTER

Three-Year Outcomes of Endovascular Therapy for Aortoiliac Lesions

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Endovascular therapy (EVT) has advanced rapidly, thanks to recent developments in catheter devices, and EVT for aortoiliac lesions has now become commonplace.[1] However, no large-scale prospective studies have been performed to assess the efficacy of this therapy. We conducted a 3-year large-scale, multicenter, prospective, observational study of EVT for aortoiliac disease, named the OMOTENASHI (Observational Prospective Multicenter Registry Study on Outcomes of Peripheral Arterial Disease Patients Treated by Angioplasty Therapy for Aortoiliac Artery). The preliminary 1-year results were previously reported in this journal.[2] Here, we present the 3-year outcomes.

The OMOTENASHI registry enrolled 893 patients (1128 limbs) with symptomatic peripheral arterial disease (Rutherford classification categories 2–4) undergoing EVT for de novo aortoiliac lesions between April 2014 and April 2016 at 64 centers in Japan. Loss of primary patency was defined as ≥50% stenosis on computed tomography or angiography, peak systolic velocity ratio ≥2.5 on duplex ultrasound, or requirement for target vessel revascularization. The study was performed in accordance with the Declaration of Helsinki and approved by the ethics committee of each participating center. Written informed consent was obtained from each patient. Right-censored data on freedom from target vessel revascularization, limb salvage, and overall survival were analyzed using the Kaplan-Meier method, whereas interval-censored primary patency data were evaluated as the total number of cases divided by the number of cases at risk, at respective time points, with a tolerance of ±2 months. Statistical analyses were performed with R 3.6.0 (R Development Core Team, Vienna, Austria). Because of the sensitive nature of the collected data, we will not make them available to other researchers.

Baseline characteristics of the study population were published previously.[2] The 3-year clinical outcomes are summarized in the Table. Data on primary patency at 12, 24, and 36 months (±2 months) were available for 771, 584, and 441 limbs, respectively. With multiple imputation (5×) for missing data, the 3-year primary patency (95% CI) was estimated to be 71.4% (66.9%–76.0%) at 3 years. The 3-year cumulative rate of freedom from target vessel revascularization, limb salvage, and overall survival was 95.4% (94.0%–96.8%), 99.8% (99.5%–100.0%), and 90.7% (88.4%–92.9%), respectively. Mean ankle-brachial index was higher at 3 years than at baseline, and Rutherford category 0 accounted for 55.3% (45.8%–64.8%). Disease-specific health-related quality of life, evaluated using the Walking Impairment Questionnaire, was still significantly better at 3 years than at baseline, whereas the improvement of generic health-related quality of life, evaluated using the EuroQol-5 dimensions, lost statistical significance at 3 years (Table).

A subgroup of patients treated with plain balloon angioplasty had a lower 3-year patency rate than patients treated with stent implantation (42.0% [5.8%–78.2%] versus 71.9% [67.4%–76.5%]), although this difference did not reach statistical significance (P=0.10), possibly because of the small number of patients (n=20). The generalized linear mixed model with a logit link function, in which interinstitution

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Table. Three-Year Clinical Outcomes After Aortoiliac Endovascular Therapy

	Baseline	At 1 y	At 2 y	At 3 y
Per-limb outcome (n=1128)				
Primary patency	…	83.8% (81.5%–86.0%)	78.0% (74.4%–81.6%)	71.4% (66.9%–76.0%)
Freedom from TVR	…	98.5% (97.8%–99.3%)	96.5% (95.3%–97.7%)	95.4% (94.0%–96.8%)
Limb salvage	…	100.0% (100.0%–100.0%)	100.0% (100.0%–100.0%)	99.8% (99.5%–100.0%)
Ankle-brachial index	0.66 (0.65–0.67)	0.92 (0.91–0.94)*	0.91 (0.88–0.93)*	0.92 (0.90–0.93)*
Per-patient outcome (n=893)				
Overall survival	…	97.3% (96.2%–98.4%)	94.5% (92.8%–96.2%)	90.7% (88.4%–92.9%)
Rutherford classification				
Improved from baseline	…	94.0% (92.5%–95.4%)	91.2% (88.6%–93.8%)	89.2% (84.0%–94.3%)
Unchanged from baseline	…	4.8% (3.5%–6.1%)	6.5% (4.3%–8.8%)	6.6% (4.7%–8.5%)
Worsened from baseline	…	1.2% (0.5%–2.0%)	2.3% (0.0%–5.0%)	4.2% (0.0%–8.6%)
Category 0	…	66.9% (63.8%–70.0%)	58.7% (54.0%–63.4%)	55.3% (45.8%–64.8%)
WIQ				
Pain	43 (41–46)	82 (79–85)*	78 (75–81)*	75 (68–82)*
Distance	31 (28–33)	70 (67–74)*	67 (60–73)*	59 (53–64)*
Speed	33 (31–35)	65 (59–72)*	60 (50–69)*	48 (35–61)*
Climbing	35 (32–37)	68 (61–74)*	60 (53–67)*	54 (40–68)*
EQ-5D				
Utility score	0.70 (0.67–0.72)	0.83 (0.81–0.86)*	0.77 (0.74–0.79)*	0.68 (0.65–0.71)
Visual analogue scale	61 (59–63)	72 (69–76)*	68 (63–74)*	58 (52–65)

Data are point estimates (95% CIs). During a median follow-up of 2.89 y, 71 deaths were observed in a total of 893 patients, and 44 TVRs and 1 major amputation were observed in a total of 1128 limbs. Freedom from TVR, limb salvage (freedom from major amputation), and overall survival were estimated by Kaplan-Meier methods; other outcomes were estimated as the proportions or the mean values. Ankle-brachial index, WIQ, and EQ-5D at 1, 2, and 3 y were compared with baseline values. EQ-5D indicates EuroQol-5 dimensions; TVR, target vessel revascularization; and WIQ, Walking Impairment Questionnaire.

*$P<0.05$ vs baseline.

and intersubject variability were treated as random effects, identified femoropopliteal lesion and minimum stent diameter as independent risk factors for the 3-year restenosis in a subgroup with stent implantation (n=1108). Their adjusted odds ratios were 1.48 ([1.04–2.10] P=0.031) and 0.83 ([0.72–0.94] P=0.005) per 1-mm increase, respectively.

These 3-year results of our prospective multicenter study indicate the efficacy of EVT in patients with aortoiliac lesions. The primary patency rate was a little lower in this study than in previous retrospective studies.[3] However, the apparently high patency rates in those studies might have been due to patency being assessed using Kaplan-Meier analysis. This method was originally developed for right-censored data, and its application to interval-censored data such as patency could underestimate the event occurrence (ie, loss of patency) in retrospective studies. The rate of freedom from target vessel revascularization in the present study was 95.4%, higher than in previous studies, probably due to improvements in procedural techniques and devices.[3] It is also noteworthy that ankle-brachial index, the Rutherford classification, and disease-specific health-related quality of life kept improving throughout the 3 years. Our data confirmed that the efficacy of aortoiliac EVT is sufficient and clinically acceptable. Aortoiliac EVT as an add-on of exercise therapy and optimizing medical care would be worth taking into consideration in clinical practice.[4]

Independent predictors of 3-year loss of primary patency were coexisting femoropopliteal disease and smaller stent diameter, the same as those for 1-year loss of primary patency.[5] Restenosis factors seemed to be unchanged over time. These factors would correspond to an outflow lesion and a smaller aortoiliac vessel, both of which were identified as predictors of poor aortoiliac patency in previous retrospective studies.[3] Given that the presence of an outflow lesion indicates a decreased outflow vascular bed, additional clinically driven distal revascularization would be beneficial for maintaining aortoiliac patency.

In conclusion, we confirmed the long-term efficacy of aortoiliac EVT, supporting the recent recommendation that EVT can be a first-line treatment for aortoiliac disease.[1]

ARTICLE INFORMATION

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Disclosures

None.

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