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RESEARCH LETTER

One-Year Outcomes of Endovascular Therapy for Aortoiliac Lesions

Yasutaka Yamauchi, MD, PhD
Mitsuyoshi Takahara, MD, PhD
Yoshiaki Shintani, MD
Osamu Iida, MD
Teruyasu Sugano, MD, PhD
Yoshito Yamamoto, MD
Daizo Kawasaki, MD, PhD
Masahiko Fujihara, MD
Keisuke Hirano, MD
Hiroyoshi Yokoi, MD
Akira Miyamoto, MD, PhD
Masato Nakamura, MD, PhD
on behalf of the OMOTENASHI investigators

Although endovascular therapy (EVT) is widely used as first-line treatment for aortoiliac lesions,[1] no large-scale prospective studies have been performed to assess the efficacy and safety of this therapy. Accordingly, we are conducting a 3-year large-scale multicenter prospective observational study of EVT for aortoiliac disease, and we report the 1-year results here.

The OMOTENASHI (Observational Prospective Multicenter Registry Study on Outcomes of Peripheral Arterial Disease Patients Treated by Angioplasty Therapy for Aortoiliac Artery) registry is being conducted at 64 centers in Japan to clarify the 3-year clinical outcomes of aortoiliac EVT in real-world practice. The study registered 893 patients (1128 limbs) with symptomatic peripheral arterial disease (Rutherford classification categories 2, 3, or 4) undergoing EVT for de novo aortoiliac lesions between April 2014 and April 2016. The study was performed in accordance with the Declaration of Helsinki and was approved by the ethics committee of each participating center. Written informed consent was obtained from each patient. Baseline characteristics of the study population, initial clinical outcomes, 1-year clinical outcomes, and the 1-year changes of health-related quality of life (HRQOL) are summarized in the Table. Continuous variables are presented as the mean±SD and categorical variables are presented as numbers (percentages), unless otherwise mentioned. Statistical analyses were performed with R version 3.1.0 (R Development Core Team, Vienna, Austria).

The patients were aged 73±9 years. The Rutherford class was 2, 3, and 4 in 42%, 51%, and 7%, respectively, and 36% of the limbs had chronic total occlusion. Mean total stent length was 82.1±48.5 mm and mean stent diameter was 9.1±1.3 mm. Initial technical success (<30% residual angiographic stenosis) was achieved in 99.4% (1121 of 1128 limbs). The 30-day rate of major adverse events (all-cause death, myocardial infarction, stroke, and target vessel revascularization) was 0.9% (8/893 patients).

Data on primary patency at 12 months (±2 months) were available for 631 limbs. Restenosis (≥50% stenosis on computed tomography or angiography, peak systolic velocity ratio ≥2.5 on duplex ultrasound, or requirement for target vessel revascularization) was confirmed in 68 of the 631 limbs. With multiple imputation (50×) for missing data, the 1-year primary patency rate of the study population was estimated to be 86.2% (95% CI, 83.3% to 89.2%). As a sensitivity analysis, parametric survival analysis of interval-censored data using the Weibull distribution gave a 1-year primary patency rate of 87.8% (85.5% to 89.9%). The Kaplan-Meier estimate of the 1-year rate of freedom from target vessel revascularization was 98.4% (97.6% to 99.2%; 707 limbs at risk at 1 year), whereas the corresponding overall survival and freedom from major adverse cardiovascular events (a composite of all-cause death, myocardial infarction, and stroke) rates were 97.0% (95.8% to 98.2%; 569 patients at risk) and 96.2% (94.9% to 97.5% 564 patients at risk), respectively.

Key Words: angiography ■ angioplasty ■ peripheral arterial disease ■ quality of life ■ stents

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Table. Baseline Characteristics and 1-Year Results of the OMOTENASHI Registry

Baseline Characteristics			
Age, y			73±9 (n=893)
Male sex			83% (743/893)
Current smoker			35% (316/893)
Hypertension			94% (839/893)
Dyslipidemia			82% (730/893)
Diabetes mellitus			48% (426/893)
Renal failure on dialysis			13% (113/893)
Rutherford category: 2/3/4			42%/51%/7% (377/453/63)
TASC II class: A/B/C/D			46%/23%/13%/18% (415/202/112/164)
Chronic total occlusion (per limb)			36% (401/1128)
Ankle-brachial index (per limb)			0.66±0.21 (n=1102)
Femoro-popliteal lesion (per limb)			37% (380/1033)
Endovascular procedure (per limb)			
Time: ≤1 h/1–2 h/≥2 h/Staged			57%/29%/11%/2% (507/262/102/22)
Stent: BE/SE/both/angioplasty alone			6%/91%/2%/2% (63/1023/22/20)
Total stent length, mm*			82.1±48.5 (n=1108)
Mean stent diameter, mm*			9.1±1.3 (n=1108)
Pre-ballooning			71% (803/1128)
Post-ballooning			92% (1038/1128)
Initial clinical outcome			
Initial technical success (per limb)			99.4% (1121/1128)
Ankle-brachial index (per limb)			0.91±0.19 (n=909)
30-D MAE (per patient)			0.9% (8/893)
Clinical outcomes at 1 y			
Primary patency (per limb)			86.2% (83.3%–89.2%)
Freedom from TVR (per limb)			98.4% (97.6%–99.2%)
Freedom from MACE (per patient)			96.2% (94.9%–97.5%)
Overall survival (per patient)			97.0% (95.8%–98.2%)
Mean HRQOL scores (per patient)			
EQ-5D	Utility score	Baseline	0.71 (0.69–0.73)
		1 y after EVT	0.80 (0.78–0.83)*
	VAS	Baseline	61 (59–63)
		1 y after EVT	70 (68–72)*
WIQ	Pain	Baseline	44 (42–47)
		1 y after EVT	81 (77–84)*
	Distance	Baseline	29 (27–32)
		1 y after EVT	68 (65–72)*
	Speed	Baseline	32 (29–35)
		1 y after EVT	60 (56–63)*
	Climbing	Baseline	33 (31–36)
		1 y after EVT	64 (61–68)*

Data are the mean±SD, frequency (percentage), or point estimate (95% CI). The primary patency rate and mean HRQOL values were estimated with multiple imputation (n=50) for missing data, whereas the freedom from TVR rate, freedom from MACE rate, and overall survival rate were estimated by the Kaplan-Meier method. Data on primary patency at 12 mo (±2 mo) were available for 631 limbs. Data on the EQ-5D utility score at baseline (before EVT) and at 12 mo (±2 mo) were available for 318 and 325 patients, respectively. Corresponding data on the EQ-5D VAS and the WIQ score for pain, distance, speed, and climbing were available for 299 and 271, 316 and 296, 274 and 268, 260 and 231, and 268 and 262 patients, respectively. BE indicates balloon-expandable stent; EQ-5D, EuroQol 5 Dimensions; EVT, endovascular therapy; HRQOL, health-related quality of life; MACE, major adverse cardiovascular events; MAE, major adverse events; SE, self-expandable stent; TVR, target vessel revascularization; and WIQ, Walking Impairment Questionnaire.

*P<0.001 vs baseline.

This study also assessed HRQOL by using Japanese versions of EuroQol 5 Dimensions[2] and the Walking Impairment Questionnaire.[3] The statistical significance of the 1-year changes was tested after multiple imputation (50×) for missing data, revealing that all HRQOL scores showed significant improvement at 1 year after EVT (Table).

These 1-year results of our ongoing prospective multicenter study indicate that EVT shows acceptable safety and efficacy in patients with aortoiliac lesions. The initial technical success rate was higher than in previous retrospective studies,[4] despite a higher prevalence of chronic total occlusion, suggesting a contribution of recent technical advances. The primary patency rate was somewhat lower in this study compared with previous retrospective studies.[4] However, the patency rate was assessed by the Kaplan-Meier method in previous studies. Patency data are interval censored because patency or freedom from restenosis cannot be confirmed without examination, so restenosis will be overlooked if patency is not evaluated periodically. The Kaplan-Meier method was originally developed for right-censored data rather than interval-censored data, and analysis of interval-censored data by this method yields artificially high event-free rates. Indeed, Kaplan-Meier analysis of the current OMOTENASHI registry data yielded a 1-year primary patency rate of 95.2%, which was almost 10% higher than our result (86.2%). Improvement of HRQOL after EVT in this study was consistent with the results of the CLEVER trial (Claudication: Exercise Versus Endoluminal Revascularization),[5] which showed that HRQOL was significantly improved after stent implantation compared with supervised exercise therapy with optimal medical care, whereas walking performance at 18 months was similar between stenting and exercise. In conclusion, 1-year data from our ongoing multicenter prospective study indicate acceptable safety and efficacy of aortoiliac EVT, supporting the recent recommendation that EVT can be a first-line treatment for aortoiliac disease.[1] To confirm the long-term safety and efficacy of EVT, the 3-year OMOTENASHI registry results are awaited.

ARTICLE INFORMATION

Data sharing: We will not make our data available to other researchers.

Correspondence

Yasutaka Yamauchi, MD, PhD, Cardiovascular Center, Takatsu General Hospital, 1-16-7 Mizonokuchi, Takatsu-ku, Kawasaki-shi, Kanagawa, 213-0001, Japan. Email qqfw76rd@bell.ocn.ne.jp

Affiliations

Cardiovascular Center, Takatsu General Hospital, Kanagawa, Japan (Y. Yamauchi, A.M.). Department of Diabetes Care Medicine, Osaka University Graduate School of Medicine, Japan (M.T.). Department of Cardiology, Shin-Koga Hospital, Fukuoka, Japan (Y.S.). Cardiovascular Center, Kansai Rosai Hospital, Hyogo, Japan (O.I.). Department of Cardiovascular Medicine, Yokohama City University Hospital, Kanagawa, Japan (T.S.). Department of Cardiovascular Medicine, Iwaki Kyoritsu General Hospital, Fukushima, Japan (Y. Yamamoto). Department of Internal Medicine, Morinomiya Hospital, Osaka, Japan (D.K.). Cardiovascular Center, Kishiwada Tokushukai Hospital, Osaka, Japan (M.F.). Division of Cardiology, Saiseikai Yokohamashi Tobu Hospital, Kanagawa, Japan (K.H.). Cardiovascular Center, Fukuoka Sanno Hospital, Japan (H.Y.). Division of Cardiovascular Medicine, Toho University, Ohashi Medical Center, Tokyo, Japan (M.N.).

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Disclosures

None.

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