Clinical Investigation

JOURNAL OF ENDOVASCULAR THERAPY
A SAGE Publication
An official publication of the ISEVS

Journal of Endovascular Therapy
1–7

DOI: 10.1177/1526602820949872
www.jevt.org
SAGE

Intravascular Ultrasound Imaging During Aortoiliac Stenting: No Impact on Outcomes at 1 Year

Takuya Tsujimura, MD[1], Mitsuyoshi Takahara, MD, PhD[2], Osamu Iida, MD[1], Yasutaka Yamauchi, MD, PhD[3], Yoshiaki Shintani, MD[4], Teruyasu Sugano, MD, PhD[5], Yoshito Yamamoto, MD[6], Daizo Kawasaki, MD, PhD[7], Hiroyoshi Yokoi, MD[8], Akira Miyamoto, MD, PhD[3], Toshiaki Mano, MD, PhD[1], and Masato Nakamura, MD, PhD[9] on behalf of the OMOTENASHI Investigators

Abstract

Purpose: To investigate the effect of intravascular ultrasound (IVUS) imaging use on clinical outcomes after aortoiliac stenting in patients with peripheral artery disease (PAD). **Materials and Methods:** Subjects for this retrospective analysis were derived from the OMOTENASHI registry database, which contained 803 symptomatic PAD patients (Rutherford categories 2–4) who were treated with self-expanding stent implantation for aortoiliac atherosclerotic lesions at 61 centers in Japan between January 2014 and April 2016. Of the 803 patients, 545 (67.9%) patients (mean age 73±9 years; 453 men) underwent IVUS-supported stent implantation and were compared with the 258 patients (mean age 73±8 years; 217 men) treated without IVUS. A propensity score analysis of 138 matched pairs was conducted to compare treatment strategies and clinical outcomes between patients having IVUS-supported endovascular therapy and those treated without IVUS. **Results:** Endovascular strategies and postoperative medications were not significantly different between the IVUS and no-IVUS groups. A procedure time under 1 hour was less frequent in the IVUS group, which had a longer fluoroscopy time. The 12-month restenosis rate was not significantly different between the 2 groups [10.2% (95% CI 6.9 to 14.9%) vs 10.3% (95% CI 5.4 to 18.6%), p=0.99]. There was no interaction between baseline characteristics and the association of IVUS use with restenosis risk. **Conclusion:** Propensity score matching analysis revealed that duration and fluoroscopy time during IVUS-supported procedures were significantly longer than in cases without IVUS use, whereas the 12-month restenosis rate was not significantly different between the groups. IVUS use in aortoiliac lesions may be unnecessary.

Keywords

aortoiliac vessels, endovascular treatment/therapy, iliac artery, intravascular ultrasound, restenosis, stent

Introduction

The incidence of lower limb peripheral artery disease (PAD) is high worldwide, and the number of patients with PAD is increasing.[1] Endovascular therapy (EVT) for symptomatic lower extremity ischemia has become widespread, and thanks to technological advances, it is now recommended in the latest guidelines.[2–4] In particular, several reports have shown the safety and efficacy of EVT for aortoiliac lesions.[5–7] Intravascular ultrasound (IVUS) imaging is widely applied during catheter-based interventions to provide a 360-degree cross-sectional view of blood vessels before and after treatment.[8] Previous studies in femoropopliteal lesions reported the association of IVUS with better clinical outcomes after EVT.[9–12] A quarter-century ago, Buckley et al[13] analyzed 71 iliac lesions (52 patients) after balloon angioplasty and balloon-expandable stent implantation and reported that IVUS use significantly improved long-term patency. However, it is unknown whether or not IVUS use during aortoiliac EVT would be beneficial now that endovascular devices have dramatically improved and self-expanding stent implantation has become a mainstream therapy for aortoiliac atherosclerotic lesions. Thus, this study sought to determine the influence of IVUS use on clinical outcomes after aortoiliac stenting for patients with symptomatic PAD in current real-world settings.

Materials and Methods

A clinical database of the OMOTENASHI (Observational, Prospective, Multicenter Registry Study on Outcomes of Peripheral Arterial Disease Patients Treated By Angioplasty Therapy in Aortoiliac Arteries) registry collected symptomatic PAD patients (Rutherford categories 2–4) undergoing EVT for aortoiliac lesions between January 2014 and April 2016 in Japan. For the current analysis, data were extracted on 803 patients who underwent self-expanding stent implantation at 61 centers with known institutional volume (number of EVTs performed during 2014 and 2015). Higher-volume centers were defined as the highest tertile of the procedure volume (≥611 EVTs per 2 years).

Of the 803 patients selected for the study, 545 (67.9%) patients (mean age 73±9 years; 453 men) underwent IVUS-supported stent implantation and were compared to the 258 patients (mean age 73±8 years; 217 men) treated without IVUS. The baseline characteristics of the groups are shown in Table 1.

The groups were compared overall and after propensity score matching. The primary endpoint was 12-month restenosis, defined as ≥50% stenosis on computed tomography or angiography or a peak systolic velocity ratio ≥2.5 on duplex ultrasonography.[14] Cases that required target vessel revascularization (TVR) were considered to have restenosis. Secondary outcomes included (1) initial technical success, defined as angiographic residual stenosis <30% after balloon dilation or stent implantation; (2) post-EVT ankle-brachial index (ABI); (3) 30-day major adverse events (MAEs: all-cause death, myocardial infarction, stroke, or TVR); (4) 12-month TVR; (5) 12-month major adverse cardiovascular events (MACE: a composite of all-cause death, myocardial infarction, and stroke); (6) 12-month major adverse limb events (MALE: a composite of major amputation of the treated limb and TVR); and (7) 12-month all-cause death. Major amputation referred to above the ankle. TVR, MAE, MACE, and MALE were determined by an independent Clinical Events Committee (CEC) whose members had relevant expert knowledge and were not directly involved in this study. The CEC assessed TVR by analysis of angiographic images.

This study was performed in accordance with the Declaration of Helsinki and was approved by the ethics committee of each participating center. Written informed consent for the EVT and use of anonymized data was obtained from each patient.

Statistical Analysis

Data on baseline characteristics are presented as mean ± standard deviation for continuous variables and count/sample (percentage) for categorical variables, if not otherwise mentioned. The differences in baseline characteristics between groups were crudely tested using the Welch *t* test for continuous variables, the Fisher exact test for dichotomous variables, and the Mann-Whitney *U* test for ordinal categorical variables.

Propensity score matching was performed to minimize the intergroup difference in baseline characteristics for comparison of treatment strategies, endovascular procedures, and clinical outcomes. Patients with bilateral iliac lesions had 1 limb selected randomly for analysis. The propensity score was developed using a logistic regression model with the following explanatory variables: age, sex, body mass index, smoking, hypertension, dyslipidemia, diabetes mellitus, regular dialysis, myocardial infarction, Rutherford category, ABI, TransAtlantic Inter-Society Consensus (TASC) II class, chronic total occlusions (CTOs), femoropopliteal lesion, use of CO_2 contrast, guidewire selection, total stent length, mean stent diameter, and institutional volume. Matching was performed on the logit of the propensity score within the caliper of 0.2 standard deviations of the logit of the propensity score. To maximize the statistical power to detect intergroup prognostic differences, as many matched samples as possible in the IVUS group were extracted to one in the no-IVUS group. After matching, intergroup differences were analyzed with stratification by the pairs; weighted descriptive statistics are reported. The differences in binary and continuous outcomes were assessed using the generalized linear mixed model with a logit-link function and the linear mixed model for continuous outcomes (matched pair

[1]Cardiovascular Center, Kansai Rosai Hospital, Amagasaki, Japan
[2]Department of Metabolic Medicine, Osaka University Graduate School of Medicine, Suita, Japan
[3]Cardiovascular Center, Takatsu General Hospital, Kawasaki, Japan
[4]Department of Cardiology, Shin-Koga Hospital, Kurume, Fukuoka, Japan
[5]Department of Cardiovascular Medicine, Yokohama City University Hospital, Yokohama, Japan
[6]Department of Cardiovascular Medicine, Iwaki Kyoritsu General Hospital, Fukushima, Japan
[7]Cardiovascular Division, Department of Internal Medicine, Morinomiya Hospital, Osaka, Japan
[8]Cardiovascular Center, Fukuoka Sanno Hospital, Fukuoka, Japan
[9]Division of Cardiovascular Medicine, Ohashi Medical Center, Toho University, Tokyo, Japan

Corresponding Author:
Osamu Iida, Kansai Rosai Hospital Cardiovascular Center, 3-1-69 Inabaso, Amagasaki, Hyogo 660-8511, Japan.
Email: iida.osa@gmail.com

Table 1. Baseline Characteristics of the Study Population Before and After Matching.[a]

	Before Matching				Matched Groups		
Variable	IVUS (n=545)	No IVUS (n=258)	SD, %	p	IVUS (n=540)	No IVUS (n=138)	SD, %
Age, y	73±9	73±8	2.5	0.74	73±9	73±9	0.6
Men	453/545 (83.1)	217/258 (84.1)	2.7	0.76	460/540 (85.1)	116/138 (84.1)	2.9
BMI, kg/m^2	22.7±3.3	22.3±3.3	12.0	0.11	22.3±3.2	22.2±3.1	5.0
Current smoking	198/545 (36.3)	86/258 (33.3)	6.3	0.43	171/540 (31.7)	42/138 (30.4)	2.8
Hypertension	513/545 (94.1)	244/258 (94.6)	1.9	0.87	500/540 (92.5)	131/138 (94.9)	9.9
Dyslipidemia	441/545 (80.9)	216/258 (83.7)	7.4	0.38	434/540 (80.4)	112/138 (81.2)	1.9
Diabetes mellitus	258/545 (47.3)	130/258 (50.4)	6.1	0.45	275/540 (51.0)	66/138 (47.8)	6.3
Regular dialysis	56/545 (10.3)	40/258 (15.5)	15.7	0.036	72/540 (13.3)	21/138 (15.2)	5.6
Myocardial infarction	72/545 (13.2)	32/258 (12.4)	2.4	0.82	60/540 (11.1)	15/138 (10.9)	0.8
Rutherford category				0.98			
2	235/545 (43.1)	99/258 (38.4)	9.7		201/540 (37.3)	52/138 (37.7)	0.9
3	257/545 (47.2)	153/258 (59.3)	24.5		315/540 (58.3)	82/138 (59.4)	2.2
4	53/545 (9.7)	6/258 (2.3)	31.5		24/540 (4.4)	4/138 (2.9)	8.1
Ankle-brachial index	0.65±0.20	0.69±0.22	15.8	0.042	0.65±0.20	0.66±0.21	3.7
(missing data)	11/545 (2.0)	3/258 (1.2)	6.8	0.57	12/540 (2.3)	3/138 (2.2)	0.6
TASC II class				<0.001			
A	217/545 (39.8)	145/258 (56.2)	33.2		266/540 (49.3)	71/138 (51.4)	4.4
B	124/545 (22.8)	59/258 (22.9)	0.3		124/540 (22.9)	33/138 (23.9)	2.5
C	79/545 (14.5)	23/258 (8.9)	17.4		67/540 (12.4)	15/138 (10.9)	4.9
D	125/545 (22.9)	31/258 (12.0)	29.1		83/540 (15.4)	19/138 (13.8)	4.7
CTOs	221/545 (40.6)	55/258 (21.3)	42.5	<0.001	162/540 (30.0)	40/138 (29.0)	2.1
Femoropopliteal lesion	185/545 (34.0)	106/258 (41.2)	14.8	0.077	219/540 (40.6)	61/138 (44.0)	6.9
(missing data)	19/545 (3.5)	42/258 (16.3)	43.9	<0.001	41/540 (7.6)	13/138 (9.4)	6.6
Use of CO_2 contrast	38/545 (7.0)	6/258 (2.3)	22.2	0.007	28/540 (5.1)	5/138 (3.6)	7.3
0.035-inch wire first	68/545 (12.5)	172/258 (66.7)	132.9	<0.001	203/540 (37.6)	55/138 (39.9)	4.6
(missing data)	2/545 (0.4)	0/258 (0.0)	8.6	≥0.99	0/540 (0.0)	0/138 (0.0)	0.0
0.035-inch wire final	42/545 (7.7)	162/258 (62.8)	141.0	<0.001	159/540 (29.4)	45/138 (32.6)	6.9
(missing data)	2/545 (0.4)	0/258 (0.0)	8.6	≥0.99	0/540 (0.0)	0/138 (0.0)	0.0
Total stent length, mm	84.9±50.7	73.4±36.9	25.8	<0.001	76.4±46.4	77.7±39.3	3.0
Stent diameter, mm	9.1±1.3	9.3±1.2	15.7	0.036	9.2±1.3	9.2±1.3	0.1
Treated at higher-volume centers[b]	139/545 (25.5)	142/258 (55.0)	63.1	<0.001	205/540 (38.0)	57/138 (41.3)	6.8

Abbreviations: BMI, body mass index; CTO, chronic total occlusion; IVUS, intravascular ultrasound; SD, standard difference; TASC II, TransAtlantic Inter-Society Consensus II.

[a]Continuous data are presented as the mean ± standard deviation; categorical data are given as the count/sample (percentage).

[b]Greater than or equal to 611 procedures per 2 years.

treated as a cluster), respectively. For missing data, a multiple imputations method (50 times) was adopted. The odds ratios (ORs) for 1-year restenosis (loss of patency) and the assessment of interaction effects were estimated using the generalized linear mixed model with a logit-link function after stratifying the propensity score by quintiles. Time-to-event outcomes were analyzed using the Kaplan-Meier method and the log-rank test; estimates are reported with their 95% confidence intervals (CI). $P<0.05$ was considered significant. All statistical analyses were performed with R (version 3.1.0; R Development Core Team, Vienna, Austria).

Results

Baseline characteristics and procedure details of the groups differed before matching (Table 1). The IVUS group had fewer patients on regular dialysis (10.3% vs 15.5%, p=0.036) and a significantly lower mean ABI (0.65±0.20 vs 0.69±0.22, p=0.042), but a higher prevalence of TASC II class D lesions (22.9% vs 12.0%, $p<0.001$) and CTOs (40.6% vs 21.3%, $p<0.001$). In the IVUS group, CO_2 contrast agent was used more often (7.0% vs 2.3%, p=0.007), and a 0.035-inch guidewire was less frequently selected first (12.5% vs 66.7%, $p<0.001$). Implanted stents in these

Table 2. Treatment Strategies, Endovascular Procedures, and Clinical Outcomes in the Matched Groups.[a]

	IVUS	No IVUS	p
Endovascular treatment			
Predilation	78.2% (74.1% to 81.7%)	71.6% (63.2% to 78.7%)	0.11
Postdilation	97.0% (95.2% to 98.2%)	99.3% (95.0% to 99.9%)	0.17
Distal protection	1.7% (0.6% to 4.4%)	1.5% (0.4% to 5.4%)	0.89
Hemostasis device use	43.7% (39.6% to 47.9%)	50.7% (42.4% to 59.0%)	0.14
Procedure time ≤1 hour	46.9% (42.0% to 51.9%)	71.6% (63.3% to 78.7%)	<0.001
Contrast agent volume, mL	102 (97 to 107)	105 (95 to 115)	0.59
Fluoroscopy time, min	34 (32 to 36)	22 (17 to 26)	<0.001
Medications			
Aspirin	74.2% (69.9% to 78.1%)	75.2% (67.0% to 81.9%)	0.82
Thienopyridine	75.2% (71.4% to 78.6%)	75.4% (67.5 to 81.8%)	0.97
Dual antiplatelet therapy	58.7% (54.5% to 62.8%)	60.1% (51.8 to 68.0%)	0.76
Anticoagulants	8.9% (6.8% to 11.6%)	10.1% (6.1% to 16.4%)	0.65
Cilostazol	25.2% (21.7% to 29.0%)	25.4% (18.8% to 33.3%)	0.97
Statins	51.6% (47.3% to 55.9%)	51.5% (43.1% to 59.7%)	0.97
Postoperative outcomes			
Technical success	99.8% (0 to 100.0%)	99.4% (0% to 100.0%)	0.37
Ankle-brachial index	0.91 (0.89 to 0.93)	0.91 (0.88 to 0.95)	0.75
30-day MAE	0.7% (0.3% to 2.0%)	0.7% (0.1% to 5.0%)	0.98
12-month clinical outcomes			
Restenosis	10.2% (6.9% to 14.9%)	10.3% (5.4% to 18.6%)	0.99
TVR	2.4% (0 to 5.1%)	1.6% (0 to 3.7%)	0.95
MACE	4.0% (0.5% to 7.5%)	2.5% (0 to 5.2%)	0.45
MALE	2.4% (0 to 5.1%)	1.6% (0 to 3.7%)	0.95
All-cause death	3.7% (0.3% to 7.0%)	0.8% (0 to 2.3%)	0.18

Abbreviations: IVUS, intravascular ultrasound; MACE, major adverse cardiovascular events; MAE, major adverse events; MALE, major adverse limb events; TVR, target vessel revascularization.
[a]Continuous data are presented as the weighted mean; categorical data are given as the weighted proportion. The 95% confidence interval is in parentheses.

patients were longer (84.9±50.7 vs 73.4±36.9 mm, p<0.001) and smaller in diameter (9.1±1.3 vs 9.3±1.2 mm, p=0.036). The IVUS group was less likely to be treated at the higher-volume centers (25.5% vs 55.0%, p<0.001).

The propensity score matching extracted 138 pairs (138 patients in the no-IVUS group and 540 patients in the IVUS group), with no remarkable intergroup differences in baseline characteristics (Table 1). As shown in Table 2, procedure times ≤1 hour were less frequent in the IVUS group [46.9% (95% CI 42.0% to 51.9%) vs 71.6% (95% CI 63.3% to 78.7%), p<0.001] and the fluoroscopy time was longer [34 minutes (95% CI 32 to 36) vs 22 minutes (95% CI 17 to 26)]. Endovascular strategies and postoperative medication were not significantly different between the IVUS and no-IVUS groups (Table 2). Data on 30-day MAE (0.7% in both groups) were available in all 803 patients. The 12-month restenosis rate [available in 457 patients (56.9%)] was not significantly different between the groups [10.2% (95% CI 6.9% to 14.9%) vs 10.3% (95% CI 5.4% to 18.6%), p=0.99]. Other clinical outcomes were also comparable (Table 2). There was no significant interaction between the baseline variables and the association of IVUS with restenosis risk (Table 3).

Discussion

IVUS is a device providing cross-sectional, high-resolution tomographic images of the vessel wall and is widely used as an imaging device.[8] With its improved technology, IVUS offers detailed real-time information, increasing the understanding of arterial architecture and pathology. Therefore, the frequency of IVUS use during percutaneous coronary intervention and EVT has been increasing to evaluate lesions and decide treatment strategy.

When analyzing the entire study population, a substantial difference was found in baseline characteristics between the IVUS and no-IVUS groups. For example, IVUS was generally used in more complicated lesions, such as TASC II C/D, CTOs, and longer lesions that required a longer stent. Interventionists might have been more likely to use IVUS to assess lesion morphology, wire route, and landing zone for these complicated cases. By the same token, use of CO_2

Table 3. Interactions of Baseline Characteristics on the Association of IVUS With Restenosis Risk.

Variable	Subgroup	OR (95% CI)	p for interaction
Overall		1.12 (0.59 to 2.14)	
Age	<75 years	1.38 (0.44 to 4.31)	0.59
	≥75 years	1.38 (0.44 to 4.31)	
Sex	Female	1.92 (0.25 to 14.5)	0.58
	Male	1.06 (0.54 to 2.10)	
Body mass index	<22 kg/m^2	1.32 (0.55 to 3.15)	0.63
	≥22 kg/m^2	1.04 (0.42 to 2.57)	
Current smoking	No	1.43 (0.59 to 3.46)	0.29
	Yes	0.79 (0.32 to 1.94)	
Hypertension	No	0.86 (0.08 to 8.86)	0.80
	Yes	1.14 (0.59 to 2.22)	
Dyslipidemia	No	2.62 (0.45 to 15.4)	0.27
	Yes	0.97 (0.49 to 1.94)	
Diabetes mellitus	No	1.51 (0.50 to 4.59)	0.58
	Yes	0.96 (0.43 to 2.16)	
Regular dialysis	No	1.19 (0.58 to 2.44)	0.84
	Yes	0.95 (0.21 to 4.32)	
Myocardial infarction	No	1.28 (0.62 to 2.66)	0.30
	Yes	0.65 (0.17 to 2.40)	
Rutherford category	2	1.30 (0.42 to 4.04)	0.82
	3/4	1.07 (0.50 to 2.29)	
TASC II class	A to C	1.12 (0.56 to 2.25)	0.79
	D	0.91 (0.22 to 3.73)	
Chronic total occlusion	No	1.01 (0.45 to 2.31)	0.92
	Yes	1.06 (0.33 to 3.44)	
Femoropopliteal lesion	No	1.64 (0.59 to 4.56)	0.41
	Yes	0.91 (0.38 to 2.20)	
Total stent length	<100 mm	1.08 (0.50 to 2.34)	0.93
	≥100 mm	1.14 (0.38 to 3.42)	
Mean stent diameter	<9.0 mm	1.25 (0.47 to 3.35)	0.66
	≥9.0 mm	0.95 (0.42 to 2.15)	
Aspirin use	No	1.31 (0.32 to 5.41)	0.85
	Yes	1.09 (0.55 to 2.16)	
Thienopyridine use	No	1.05 (0.38 to 2.93)	0.80
	Yes	1.23 (0.55 to 2.76)	
Dual antiplatelet therapy	No	1.03 (0.42 to 2.50)	0.75
	Yes	1.22 (0.52 to 2.87)	
Anticoagulant use	No	1.09 (0.55 to 2.13)	0.86
	Yes	1.30 (0.17 to 10.2)	
Cilostazol use	No	1.26 (0.61 to 2.63)	0.50
	Yes	0.84 (0.27 to 2.60)	
Statin use	No	1.30 (0.57 to 3.00)	0.60
	Yes	0.97 (0.40 to 2.36)	
Use of CO_2 contrast	No	1.21 (0.62 to 2.38)	0.15
	Yes	0.22 (0.02 to 2.01)	
0.035-inch wire first	No	1.09 (0.41 to 2.90)	0.77
	Yes	1.35 (0.50 to 3.61)	
0.035-inch wire final	No	1.18 (0.45 to 3.12)	0.91
	Yes	1.30 (0.37 to 4.56)	
Predilation	No	0.72 (0.23 to 2.21)	0.29
	Yes	1.46 (0.66 to 3.23)	
Procedure time ≤1 hour	No	0.58 (0.21 to 1.58)	0.31
	Yes	1.12 (0.48 to 2.62)	
Contrast agent	<100 mL	1.18 (0.48 to 2.91)	0.71
	≥100 mL	1.04 (0.43 to 2.50)	
Fluoroscopy time	<30 min	0.88 (0.40 to 1.92)	>0.99
	≥30 min	0.88 (0.29 to 2.65)	
Hemostasis device use	No	1.49 (0.56 to 3.97)	0.34
	Yes	0.77 (0.32 to 1.84)	

Abbreviations: CI, confidence interval; IVUS, intravascular ultrasound; OR, odds ratio; TASC II, TransAtlantic Inter-Society Consensus II.

contrast was more frequent in the IVUS group, so operators may have used IVUS to acquire more detailed information during EVT in patients at risk of nephrotoxicity.

The lower prevalence of regular dialysis in cases having IVUS support could have been due to operators not choosing to use IVUS because the procedure takes longer and could consequently increase the risk of complications in patients on regular dialysis. Surprisingly, IVUS was less frequently used in higher-volume centers, which suggests that interventionists in higher-volume centers were more experienced and intuitively realized that IVUS afforded relatively little benefit in aortoiliac interventions.

However, the feasibility, effectiveness, and safety of IVUS during revascularization in PAD patients with aortoiliac lesions are still inconclusive. Our group previously reported that IVUS use in femoropopliteal stenting for TASC II A-C lesions improved the primary patency rate.[9] A propensity score matching analysis demonstrated that the Kaplan-Meier estimates of the 5-year primary patency rate were 65% and 35% in the IVUS and no-IVUS groups, respectively ($p<0.001$).[9] By contrast, in the present study, IVUS use during aortoiliac stenting was not associated with primary patency. One possible explanation would be that EVT per se achieves a high primary patency rate in iliac lesions, so IVUS use did not further improve patency.

Although Buckley et al[13] long ago demonstrated a significant improvement in iliac artery patency by using IVUS, their endovascular strategies were different from ours. In their study, only balloon-expandable stents were implanted, whereas we analyzed the efficacy of IVUS use during self-expanding stent implantation. Balloon-expandable stents are generally short in length, whereas longer self-expanding stents are available. Based on this difference, balloon-expandable stents are more likely to be deployed using a spot-stenting strategy, just focally covering the most severe lesion, while self-expanding stents typically fully cover the lesions, including moderate stenosis, in the clinical setting. Therefore, there is less residual stenosis in the target vessels after self-expanding stent implantation. In addition, because of their high elasticity, self-expanding stents can avoid stent malapposition, which is one of the risk factors for restenosis. From these reasons, we extrapolated that stable results could be expected by using self-expanding stents regardless of IVUS support. These differences in stent type might be related to the different effects of IVUS use on primary patency.

Because of recent advancements in endovascular devices and techniques, perioperative adverse events are now substantially reduced.[2,7,15,16] The present study confirmed that the incidence of 30-day MAE was very low (<1%). Furthermore, although this registry included some challenging lesions, both groups achieved an almost 100% technical success rate. These excellent postoperative outcomes regardless of IVUS use may be the result of recent developments in devices and technical procedures that

have standardized aortoiliac interventions. On the contrary, procedure and fluoroscopy times were significantly longer in patients treated under IVUS support. Thus, it may not be necessary to use IVUS during EVT for aortoiliac lesions owing to the greater procedure time, radiation exposure, and cost.

Limitations

This study was not a randomized controlled trial; however, propensity score matching was employed to reduce bias as much as possible. The assessment of restenosis was not conducted under core laboratory review. The data on 12-month restenosis were available in only 56% of the study population, although the multiple imputation method was employed to address this issue. The poor compliance with the follow-up protocol might have been because iliac stenting dramatically improves a patient's symptoms making them less inclined to visit the hospital if they are asymptomatic.

The study analyzed only patients treated with self-expanding stents, and it is unknown whether similar results would be obtained with other devices, such as balloon-expandable stents or stent-grafts. Patients with chronic limb-threatening ischemia and tissue loss were excluded because they generally have a poor prognosis. Therefore, the result of the current study might not apply to patients with severe disease. Finally, IVUS parameters were not evaluated in detail because the data were not collected in the OMOTENASHI registry. Further investigations are necessary.

Conclusion

Propensity score matching analysis revealed that procedure and fluoroscopy times in patients having EVT with IVUS support were significantly longer than in those without IVUS use, whereas the 12-month restenosis risk was not significantly different between the 2 groups. IVUS use in aortoiliac lesions appears to not be necessary.

Acknowledgments

The authors convey their greatest appreciation to the staff who offered continuing support and constant encouragement.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

ORCID iDs

Takuya Tsujimura https://orcid.org/0000-0002-3128-1357
Osamu Iida https://orcid.org/0000-0001-6829-7304
Yoshiaki Shintani https://orcid.org/0000-0001-5860-3021

References

1. Selvin E, Erlinger TP. Prevalence of and risk factors for peripheral arterial disease in the United States: results from the National Health and Nutrition Examination Survey, 1999-2000. *Circulation*. 2004;110:738–743.
2. Aboyans V, Ricco JB, Bartelink MEL, et al. 2017 ESC Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases, in collaboration with the European Society for Vascular Surgery (ESVS): document covering atherosclerotic disease of extracranial carotid and vertebral, mesenteric, renal, upper and lower extremity arteries endorsed by: the European Stroke Organization (ESO), The Task Force for the Diagnosis and Treatment of Peripheral Arterial Diseases of the European Society of Cardiology (ESC) and of the European Society for Vascular Surgery (ESVS). *Eur Heart J*. 2018;39:763–816.
3. Gerhard-Herman MD, Gornik HL, Barrett C, et al. 2016 AHA/ACC Guideline on the Management of Patients With Lower Extremity Peripheral Artery Disease: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *J Am Coll Cardiol*. 2017;69:1465–1508.
4. Conte MS, Pomposelli FB, Clair DG, et al. Society for Vascular Surgery practice guidelines for atherosclerotic occlusive disease of the lower extremities: management of asymptomatic disease and claudication. *J Vasc Surg*. 2015;61(3S):2S–41S.
5. Soga Y, Iida O, Kawasaki D, et al. Contemporary outcomes after endovascular treatment for aorto-iliac artery disease. *Circ J*. 2012;76:2697–2704.
6. Krankenberg H, Zeller T, Ingwersen M, et al. Self-expanding versus balloon-expandable stents for iliac artery occlusive disease: the Randomized ICE Trial. *JACC Cardiovasc Interv*. 2017;10:1694–1704.
7. Yamauchi Y, Takahara M, Shintani Y, et al. One-year outcomes of endovascular therapy for aortoiliac lesions. *Circ Cardiovasc Interv*. 2019;12:e007441.
8. Nissen SE, Yock P. Intravascular ultrasound. Novel pathophysiological insights and current clinical applications. *Circulation*. 2001;103:604–616.
9. Iida O, Takahara M, Soga Y, et al. Efficacy of intravascular ultrasound in femoropopliteal stenting for peripheral artery disease with TASC II class A to C lesions. *J Endovasc Ther*. 2014;21:485–492.
10. Mori S, Hirano K, Nakano M, et al. Intravascular ultrasound measurements after drug-eluting stent placement in femoropopliteal lesions: determining predictors of restenosis. *J Endovasc Ther*. 2015;22:341–349.
11. Kurata N, Iida O, Shiraki T, et al. Impact of stent-to-vessel diameter ratio on restenosis in the superficial femoral artery after endovascular therapy. *Circ J*. 2018;82:1412–1417.

12. Miki K, Fujii K, Fukunaga M, et al. Impact of post-procedural intravascular ultrasound findings on long-term results following self-expanding nitinol stenting in superficial femoral artery lesions. *Circ J*. 2013;77:1543–1550.
13. Buckley CJ, Arko FR, Lee S, et al. Intravascular ultrasound scanning improves long-term patency of iliac lesions treated with balloon angioplasty and primary stenting. *J Vasc Surg*. 2002;35:316–323.
14. Legemate DA, Teeuwen C, Hoeneveld H, et al. Value of duplex scanning compared with angiography and pressure measurement in the assessment of aortoiliac arterial lesions. *Br J Surg*. 1991;78:1003–1008.
15. Indes JE, Tuggle CT, Mandawat A, et al. Effect of physician and hospital experience on patient outcomes for endovascular treatment of aortoiliac occlusive disease. *Arch Surg*. 2011;146:966–971.
16. Iida O, Soga Y, Takahara M, et al. Perioperative complications after aorto-iliac stenting: associated factors and impact on follow-up cardiovascular prognosis. *Eur J Vasc Endovasc Surg*. 2014;47:131–138.