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Impact of Hospital Volume on Clinical Outcomes after Aortoiliac Stenting in Patients with Peripheral Artery Disease

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Aim: To investigate the impact of institutional volume on clinical outcomes after aortoiliac (AI) stenting in patients with symptomatic peripheral artery disease (PAD).

Methods: We analyzed the clinical database from the Observational prospective Multicenter registry study on the Outcomes of peripheral arTErial disease patieNts treated by AngioplaSty tHerapy in the aortoIliac artery (OMOTENASHI) registry. The volume of each institution was evaluated as the number of endovascular therapy (EVT) procedures performed in 2 years (2014–2015). High-volume centers were defined as being in the highest tertile of the procedural volume (≥ 611 EVT procedures in 2 years). Clinical outcomes, treatment strategies, and endovascular procedures were compared between high- and low-volume centers using a propensity score matching.

Results: The propensity score matching extracted 236 pairs of patients (as many patients treated at high-volume centers and 519 patients treated at low-volume centers), with no remarkable intergroup differences in the baseline characteristics. Patients treated at high-volume hospitals had a significantly lower 12-month restenosis rate than that of patients treated at low-volume hospitals (6.5% vs. 15.8%, $P=0.032$), although comparable outcomes between the two groups included the technical success rate (99.6% vs. 99.8%, $P=0.58$) and the rate of 30-day major adverse events (0.4% vs. 0.8%, $P=0.59$).

Conclusion: Institutional volume was associated with the 12-month restenosis rate after AI stenting for PAD, although comparable perioperative outcomes were also observed between high-volume and low-volume hospitals.

Key words: Endovascular treatment/therapy, Aortoiliac lesion, Institutional volume, Restenosis

Introduction

Stent-supported endovascular therapy (EVT) for aortoiliac (AI) lesions is now regarded as the first-line treatment with acceptable efficacy and safety and is widely applied to patients with peripheral artery disease (PAD) in real-world clinical practice[1-5].

Previous literature reported the association of the institutional volume with in-hospital outcomes in AI endovascular revascularization[6-9]. However, with the

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recent development of dedicated devices and an accumulation of experience in endovascular field, perioperative outcome has been dramatically improved and the incidence of in-hospital adverse events has been greatly declined[4, 5]. Recently, the incidence of in-hospital outcomes after EVT for AI lesions has become far lower than that after surgical reconstruction[10, 11], almost reaching a clinically negligible level. Given these situations, the next question raised in clinical practice is the volume–outcome association regarding a long-term outcome, i.e., patency after revascularization. However, whether the institutional volume is associated with primary patency after AI stenting in clinical practice remained so far unknown. The aim of the current study is to reveal the impact of institutional volume on clinical outcomes after AI stenting for patients with symptomatic PAD in today's real-world settings.

Methods

We analyzed a clinical database from the Observational prospective Multicenter registry study on the Outcomes of peripheral arTErial disease patieNts treated by AngioplaSty tHerapy in the aortoIliac artery (OMOTENASHI) registry. The OMOTENASHI study was conducted at 64 centers in Japan to register patients with symptomatic PAD (Rutherford category 2, 3, or 4) who were undergoing EVT for iliac lesions between January 2014 and April 2016. The institutional volume of each center was evaluated as the number of EVT procedures performed during the 2 years between 2014 and 2015. The data on the institutional volume were available in 61 of the 64 centers, at which 884 patients were registered with eligibility for the study. Of the 884 patients, 803 underwent self-expandable stent implantation. As described below, we conducted a propensity score matching. To keep subjects otherwise independent of one another during the analysis, a unilateral limb was randomly selected as the representative limb in patients with bilateral iliac lesions. High-volume centers were defined as being in the highest tertile of procedural volume (≥ 611 EVT procedures per 2 years). The tertile was based on the number of the registered patients, rather than that of the participating institutions. Consequently, 281 of the 803 patients (35%) were categorized as those treated at a high-volume center, whereas the remaining 522 patients (65%) were categorized as those treated at a low-volume center. Out of the 61 institutions, 11 institutions performed ≥ 611 EVT procedures (median: 1045 procedures; interquartile range: 838–1131 procedures) between 2014 and 2015, whereas the remaining 50 institutions performed < 611 procedures (median: 264 procedures; interquartile range: 212–381 procedures). Clinical outcomes, treatment strategies, and endovascular procedures were compared between high- and low-volume centers.

Endpoints

The primary perioperative endpoint was 30-day major adverse events (MAE), which included all-cause death, myocardial infarction, stroke, and target vessel revascularization (TVR). 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 ultrasound. The requirement for TVR, which was defined as any reintervention, including surgical or percutaneous approach for targeted vessel, was also included as restenosis. Restenosis was assessed for iliac territories and did not include femoropopliteal lesions.

Secondary endpoints included initial technical success, defined as angiographic residual stenosis < 30% after balloon dilatation or stent implantation, and 12-month TVR. TVR and MAE were determined by an independent clinical events committee (CEC) whose members were not directly involved in this study and had relevant expert knowledge. The CEC assessed TVR through an analysis of angiographic images.

Statistical Analysis

The baseline characteristics data are presented as the mean ± standard deviation (SD) for continuous variables and as the frequency (percentage) for categorical variables, if not otherwise mentioned. $P < 0.05$ was considered significant. The differences in baseline characteristics between groups were crudely tested by Welch's *t*-test for continuous variables, Fisher's exact test for dichotomous variables, and Mann–Whitney *U* test for ordinal categorical variables.

When treatment strategies, endovascular procedures, and clinical outcomes were compared between the patients treated at high-volume centers and those treated at low-volume centers, propensity score matching was performed to minimize the intergroup differences in baseline characteristics. The propensity score was developed using a logistic regression model. The following explanatory variables were included in the model: age, sex, body mass index, smoking, hypertension, dyslipidemia, diabetes mellitus, regular dialysis, myocardial infarction, ischemic stroke, medication use, the Rutherford classification, ankle–brachial pressure index, TASC II classification, chronic total occlusion, calcification, lesion localization, total stent length, mean stent diameter, femoropopliteal lesion,

and contralateral iliac lesion warranting revascularization. Matching was performed on the logit of the propensity score within the range of 0.2 SD of the logit of the propensity score. To maximize the statistical power and to detect intergroup prognostic differences, we extracted as many matched patients treated at a low-volume center to those treated at a high-volume center as possible. After matching, the intergroup differences were analyzed with stratification by matched pairs, and weighted descriptive statistics are reported. The difference in binary and continuous outcomes was assessed using a generalized linear mixed model with a logit-link function and a linear mixed model for continuous outcomes, in which a matched pair was treated as a cluster. For missing data, multiple imputation (50 times) was adopted. Time-to-event outcomes were analyzed by the Kaplan–Meier method and log-rank test. Point estimates are reported with their 95% confidence intervals. The estimation of odds ratios for 12-month restenosis (loss of patency) and the assessment of interaction effects were performed with stratification by quintiles of propensity score using a generalized linear mixed model with a logit-link function. All statistical analyses were performed with R version 3.1.0 (R Development Core Team, Vienna, Austria).

Results

The baseline characteristics are shown in **Table 1**. Patients treated at high-volume centers had a higher prevalence of regular dialysis (17.1% vs. 9.2%), arterial calcification (85.7% vs. 77.4%), common iliac artery lesions (73.7% vs. 62.5%), and contralateral iliac lesions warranting revascularization (35.6% vs. 25.1%), but they had a lower prevalence of male sex (79.7% vs. 85.4%), dyslipidemia (77.2% vs. 84.3%), thienopyridine use (63.0% vs. 79.1%), dual antiplatelet therapy (45.6% vs. 55.7%), statin use (42.0% vs. 55.6%), Rutherford category 2 (32.7% vs. 46.4%), and chronic total occlusion (28.8% vs. 36.8%). The mean diameter of implanted stents was significantly larger in patients treated at high-volume centers (9.4 ± 1.3 vs. 9.1 ± 1.2 mm). Data on 30-day MAE were available in all 803 patients (100%), whereas data on 12-month restenosis were available in 458 patients (57.0%).

Propensity score matching extracted 236 pairs (as many patients treated at high-volume centers and 519 patients treated at low-volume centers), with no remarkable intergroup differences in baseline characteristics (**Table 1**). **Table 2** summarizes the intergroup differences in endovascular strategies and clinical outcomes. During EVT, the rates of using a 0.035-inch wire and a hemostasis device were significantly more frequent at high-volume centers than at low-volume centers (44.2% [37.9 to 50.6%] vs. 19.7% [16.5 to 23.3%] and 52.1% [45.7 to 58.4%] vs. 41.8% [37.6 to 46.1%], respectively), whereas preballooning and intravascular ultrasound (IVUS) use were less frequent (59.7% [53.4 to 65.8%] vs. 80.0% [76.3 to 83.2%] and 52.5% [46.2 to 58.8%] vs. 77.5% [73.7 to 80.8%], respectively). A significantly larger volume of contrast agent was used at high-volume centers (108 [101 to 115] vs. 96 [91 to 101] ml), whereas the procedure time was ≤ 1 hour in more cases (68.6% [62.4 to 74.2%] vs. 50.5% [46.2 to 54.8%]), and the radiation time was shorter (27 [23 to 30] vs. 32 [29 to 34] min) at high-volume centers than at low-volume centers. The risk of 30-day MAE was not significantly different between the two groups (0.4% [0.1 to 2.9%] vs. 0.8% [0.3 to 2.0%], $P=0.59$), whereas 12-month restenosis was significantly less prevalent in patients treated at high-volume centers (6.5% [2.8 to 14.1%] vs. 15.8% [11.5 to 21.2%], $P=0.032$, **Fig. 1**). The association of institutional volume with restenosis risk was not significantly different between the subgroups of the population (**Table 3**).

Discussion

The current propensity score matching demonstrated that perioperative outcomes, including technical success and 30-day MAE, were not significantly different between high- and low-volume centers, whereas the 12-month restenosis rate was significantly lower at high-volume centers than at low-volume centers.

To date, in the field of percutaneous coronary intervention (PCI), several studies report that treatment in institutions and by operators with high case volumes favorably impacts long-term adverse outcomes, representing the volume–outcome relationship[12]. Accordingly, current clinical guidelines for coronary intervention recommend institutions and operators to experience >400 PCIs per year and ≥ 75 PCIs per year, respectively[13-16]. The latest clinical competence statement has relaxed the minimum requirements for PCI performance (>200 PCI procedures per year for institutions and ≥ 50 PCI procedures per year for operators) to reflect the recent decline in the number of PCI procedures performed[17].

In the field of peripheral intervention, previous studies reported a volume–outcome relationship regarding perioperative outcomes[7, 8]. Presumably based on those reports, clinical guidelines for selection of revascularization in complex AI lesions recommend

Table 1. Baseline characteristics of the study population before and after matching

Variable	Overall population (before matching)				Matched population		
	Patients treated at higher-volume centers (n = 281)	Patients treated at lower-volume centers (n = 522)	Standard difference (%)	P value	Patients treated at higher-volume centers (n = 236)	Patients treated at lower-volume centers (n = 519)	Standard difference (%)
Age (years)	73 ± 9	73 ± 9	1.5	0.84	73 ± 9	73 ± 9	0.7
Male sex	79.7%	85.4%	15.1	0.046	81.4%	81.7%	0.8
Body mass index (kg/m^2)	22.7 ± 3.4	22.5 ± 3.3	5.7	0.44	22.7 ± 3.3	22.7 ± 3.3	0.2
Current smoking	34.2%	36.0%	3.9	0.64	36.0%	36.0%	0.1
Hypertension	93.6%	94.6%	4.4	0.53	93.6%	94.0%	1.7
Dyslipidemia	77.2%	84.3%	18.0	0.016	78.0%	78.6%	1.5
Diabetes mellitus	45.9%	49.6%	7.4	0.34	46.2%	46.1%	0.3
Regular dialysis	17.1%	9.2%	23.5	0.001	15.7%	13.7%	5.5
Myocardial infarction	12.8%	13.0%	0.6	1.00	13.1%	12.5%	1.8
Ischemic stroke	13.2%	16.9%	10.3	0.19	12.7%	13.2%	1.4
Aspirin use	74.0%	74.3%	0.7	0.93	75.8%	74.6%	3.0
Thienopyridine use	63.0%	79.1%	36.1	< 0.001	67.4%	70.0%	5.6
Dual antiplatelet therapy	45.6%	55.7%	20.5	0.006	47.9%	49.8%	3.8
Anticoagulant use	7.1%	8.8%	6.3	0.50	7.6%	7.6%	0.2
Cilostazol use	27.0%	24.1%	6.7	0.39	28.0%	25.5%	5.6
Statin use	42.0%	55.6%	27.4	< 0.001	43.2%	46.9%	7.4
Rutherford classification				0.002			
Category 2	32.7%	46.4%	28.1		36.9%	34.2%	5.5
Category 3	60.9%	45.8%	30.6		56.8%	58.3%	3.2
Category 4	6.4%	7.9%	5.6		6.4%	7.4%	4.2
Ankle-brachial index	0.68 ± 0.23	0.66 ± 0.20	9.8	0.20	0.67 ± 0.22	0.66 ± 0.20	4.9
(missing data)	1.4%	2.1%	5.2	0.59	1.7%	1.3%	2.9
TASC II classification				0.49			
Class A	47.7%	43.7%	8.1		49.2%	46.1%	6.0
Class B	21.7%	23.4%	4.0		22.5%	23.3%	2.1
Class C	9.6%	14.4%	14.7		8.5%	10.0%	5.4
Class D	21.0%	18.6%	6.1		19.9%	20.5%	1.5
Chronic total occlusion	29.2%	38.3%	19.4	0.011	30.1%	33.6%	7.5
Calcification	87.1%	77.1%	26.5	0.001	86.8%	86.5%	1.0
(missing data)	0.4%	1.3%	10.8	0.27	0.4%	0.7%	3.6
Common iliac artery lesion	74.6%	62.5%	26.5	0.001	72.0%	71.0%	2.3
(missing data)	0.4%	0.0%	8.5	0.35	0.0%	0.0%	0.0
External iliac artery lesion	55.7%	62.3%	13.3	0.082	56.8%	57.1%	0.6
(missing data)	0.4%	0.0%	8.5	0.35	0.0%	0.0%	0.0
Ostium lesion	41.6%	36.6%	10.4	0.17	39.4%	41.4%	4.1
Total stent length (mm)	83.4 ± 46.2	80.2 ± 45.6	6.8	0.36	82.1 ± 45.1	81.7 ± 46.5	0.9
Mean stent diameter (mm)	9.5 ± 1.3	9.1 ± 1.2	29.5	< 0.001	9.4 ± 1.4	9.4 ± 1.3	5.6
Femoropopliteal lesion	37.8%	36.7%	2.3	0.81	37.9%	35.9%	4.2
(missing data)	17.1%	2.3%	51.6	< 0.001	7.2%	5.1%	8.8
Infrapopliteal revascularization	0.4%	0.4%	0.4	1.00	0.4%	0.3%	2.7
Contralateral iliac revascularization	35.6%	25.1%	23.0	0.002	31.4%	30.9%	1.0

Table 2. Endovascular procedures and clinical outcomes (after matching)

	Patients treated at higher-volume centers	Patients treated at lower-volume centers	*P* value
Endovascular treatment			
0.035-inch wire first selected	44.2% [37.9 to 50.6%]	19.7% [16.5 to 23.3%]	<0.001
0.035-inch wire finally used	36.9% [31.0 to 43.3%]	16.8% [13.8 to 20.2%]	<0.001
Pre-ballooning	59.7% [53.4 to 65.8%]	80.0% [76.3 to 83.2%]	<0.001
Number of stents used	1.3 [1.2 to 1.3]	1.2 [1.2 to 1.2]	0.22
Intravascular ultrasound use	52.5% [46.2 to 58.8%]	77.5% [73.7 to 80.8%]	<0.001
Distal protection	2.1% [0.9 to 5.0%]	3.1% [1.9 to 5.0%]	0.46
Hemostasis device use	52.1% [45.7 to 58.4%]	41.8% [37.6 to 46.1%]	0.008
Procedure time ≤ 1 hour	68.6% [62.4 to 74.2%]	50.5% [46.2 to 54.8%]	<0.001
Contrast agent volume (mL)	108 [101 to 115]	96 [91 to 101]	0.010
Radiation time (min)	27 [23 to 30]	32 [29 to 34]	0.019
Postoperative outcomes			
Technical success	99.6% [97.1 to 99.9%]	99.8% [98.6 to 100.0%]	0.58
30-day major adverse event	0.4% [0.1 to 2.9%]	0.8% [0.3 to 2.0%]	0.59
12-month clinical outcomes			
Restenosis	6.5% [2.8 to 14.1%]	15.8% [11.5 to 21.2%]	0.032
TVR	0.5% [0.0 to 1.6%]	2.1% [0.1 to 4.0%]	0.090

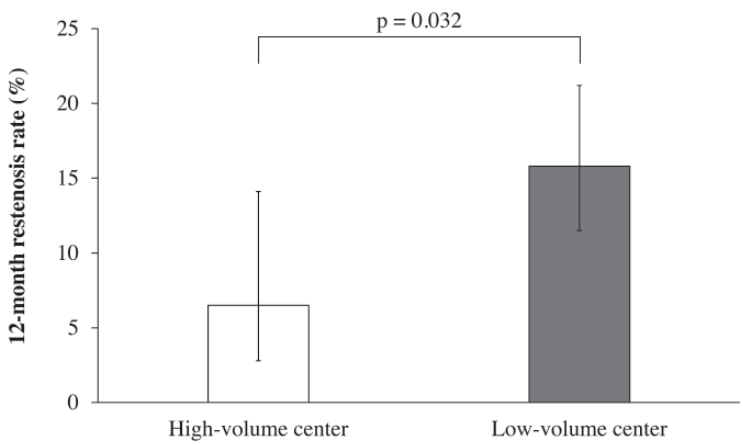

Fig. 1. Twelve-month restenosis rate between high- and low-volume centers

The incidence of 12-month restenosis was significantly lower in patients treated at high-volume centers (6.5% [2.8 to 14.1%] vs. 15.8% [11.5 to 21.2%], *P*=0.032).

that EVT be performed by an experienced team. However, recent distinct advancements in endovascular devices and techniques and perioperative adverse events were substantially decreased in incidence[4, 5, 8, 10, 11]. The current study reveals that the incidence rate of 30-day MAE was very low even in low-volume centers. Furthermore, although this registry included some challenging lesions (e.g., 20% were TASC II class D lesion and approximately 30% were CTO lesions), both classes of centers achieved an almost 100% technical success rate, which was much higher than that reported in previous studies[11]. This range may be the result of recent developments in devices (CTO-specific guidewire) and technical procedures (bilateral two-way approach [bilateral femoral or brachiofemoral approach]) for achieving standardized AI intervention. On the contrary, procedural time and radiation time were longer at low-volume centers than at high-volume centers, whereas low-volume centers used IVUS more frequently, with a lower amount of contrast agent used. These findings indicate potential technical and procedural differences between low- and high-volume centers, which may yield inter-center difference in medical resource use, although low-volume centers apparently achieved similar short-term outcomes compared with high-volume centers.

Table 3. Interaction effect on the association of institutional volume with restenosis risk

		Odds ratio of higher- versus lower-volume centers for 12-month restenosis	*P* for interaction			Odds ratio of higher- versus lower-volume centers for 12-month restenosis	*P* for interaction
Overall		0.46 [0.23 to 0.94]					
Age	<75 years	0.59 [0.25 to 1.37]	0.33	Rutherford classification	category 2/3	0.43 [0.21 to 0.92]	0.53
	≥ 75 years	0.33 [0.11 to 1.00]			category 4	0.85 [0.11 to 6.38]	
Sex	Female	0.66 [0.15 to 2.81]	0.62	TASC II classification	class A to C	0.45 [0.21 to 0.98]	0.86
	Male	0.44 [0.20 to 0.95]			class D	0.50 [0.14 to 1.74]	
Body mass index	<22 kg/m^2	0.41 [0.15 to 1.15]	0.90	Chronic total occlusion	No	0.56 [0.26 to 1.17]	0.55
	≥ 22 kg/m^2	0.50 [0.20 to 1.27]			Yes	0.36 [0.09 to 1.42]	
Current smoking	No	0.38 [0.14 to 1.02]	0.44	Total stent length	<100 mm	0.49 [0.22 to 1.11]	0.84
	Yes	0.61 [0.26 to 1.47]			≥ 100 mm	0.40 [0.13 to 1.26]	
Hypertension	No	0.77 [0.10 to 5.66]	0.58	Mean stent diameter	<9.0 mm	0.68 [0.26 to 1.78]	0.37
	Yes	0.45 [0.21 to 0.94]			≥ 9.0 mm	0.36 [0.13 to 1.00]	
Dyslipidemia	No	0.46 [0.12 to 1.72]	1.00	Femoropopliteal lesion	No	0.43 [0.13 to 1.36]	0.81
	Yes	0.45 [0.19 to 1.04]			Yes	0.46 [0.20 to 1.10]	
Diabetes mellitus	No	0.51 [0.20 to 1.29]	0.84	Contralateral iliac revascularization	No	0.44 [0.17 to 1.11]	0.98
	Yes	0.43 [0.16 to 1.16]			Yes	0.41 [0.15 to 1.14]	
Regular dialysis	No	0.44 [0.19 to 1.00]	0.96	Stent use	single	0.45 [0.21 to 0.96]	0.79
	Yes	0.37 [0.08 to 1.87]			multiple	0.53 [0.15 to 1.90]	
Myocardial infarction	No	0.45 [0.20 to 0.99]	0.70	Intravascular ultrasound use	No	0.55 [0.20 to 1.54]	0.66
	Yes	0.59 [0.15 to 2.31]			Yes	0.42 [0.14 to 1.29]	
Aspirin use	No	0.69 [0.19 to 2.48]	0.49	Hemostasis device use	No	0.41 [0.15 to 1.16]	0.62
	Yes	0.41 [0.18 to 0.90]			Yes	0.57 [0.24 to 1.37]	
Thienopyridine use	No	0.62 [0.25 to 1.54]	0.26	Pre-ballooning	No	0.49 [0.17 to 1.43]	0.93
	Yes	0.28 [0.09 to 0.87]			Yes	0.44 [0.18 to 1.08]	
Dual antiplatelet therapy	No	0.62 [0.27 to 1.42]	0.19	Procedure time ≤ 1 hour	No	0.53 [0.17 to 1.64]	0.97
	Yes	0.24 [0.07 to 0.86]			Yes	0.52 [0.22 to 1.25]	
Anticoagulant use	No	0.46 [0.22 to 0.98]	0.95	Contrast agent	<100 ml	0.48 [0.19 to 1.21]	0.94
	Yes	0.44 [0.07 to 3.01]			≥ 100 ml	0.42 [0.15 to 1.12]	
Cilostazol use	No	0.35 [0.14 to 0.83]	0.16	Radiation time	<30 min	0.68 [0.31 to 1.50]	0.28
	Yes	0.83 [0.29 to 2.37]			≥ 30 min	0.32 [0.09 to 1.11]	
Statin use	No	0.39 [0.16 to 0.97]	0.60				
	Yes	0.57 [0.21 to 1.54]					

Another important difference between low- and high-volume centers was the 12-month restenosis rate, which was significantly lower in the high-volume center group than in the low-volume center group. The subsequent interaction analysis confirmed that the superiority was irrelevant to the lesion complexity. Even when population was limited into non-complex AI lesions, 12-month restenosis rate in the low-volume center was still higher than that in the high-volume center. Although the true reasons for this significant difference remained unrevealed, some technical difference may be involved. One speculation regarding the superiority of high-volume centers in primary patency is that endovascular specialty or endovascular-specific skills, which is an unmeasurable parameter, rather than imaging modality or device selection, plays an important role in achieving better long-term outcomes after AI intervention. High-volume centers are expected to be superior in the endovascular technique. The current findings may demonstrate that the clinical guidelines' recommendation that hospital experience is important in EVT for complex AI lesions is still valid in the current clinical settings. The findings will also suggest the importance of hospital experience even in EVT for non-complex lesions. Our findings indicate that hospital volume may be a practical surrogate of quality for "any" AI endovascular intervention.

The current study has several limitations. First, this study was not a randomized controlled trial. However, propensity score matching based on pro-

spectively collected data was employed to reduce bias as much as possible. In addition, data on 12-month restenosis were available in only about a half of the study population, although we adopted the multiple imputation method to address this issue. Second, detailed information on lesion morphology and procedural information was limited. Third, the assessment for restenosis was not conducted under core laboratory review. Fourth, the data on operator volume and the number of AI EVT procedures at each center were unavailable. We were unable to assess the association between lower operator volume and increased risk of outcomes. Outcomes may be more properly evaluated according to the number of AI EVT procedures at each center, rather than the whole number of EVT procedures. Finally, only patients who underwent EVT using self-expandable stent were analyzed. In clinical practice, stents have several types, which will affect differences in restenosis rate and may likely influence the outcome than the hospital volume[18]. In the current study, patients not treated with self-expandable stent were consequently eliminated to simply evaluate the impact of hospital volume on outcomes.

Conclusion

Hospital volume was associated with a lower risk of 12-month restenosis after AI stent implantation for patients with symptomatic PAD, although low-volume centers achieved comparable technical success and 30-day major adverse events as high-volume centers did.

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Disclosures

None.

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