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ORIGINAL ARTICLE
Cardiovascular Intervention

Impact of Vessel Diameter Measured by Preprocedural Computed Tomography Angiography on Immediate and Late Outcomes of Endovascular Therapy for Iliac Artery Diseases

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Background: We evaluated whether vessel diameters measured by preprocedural computed tomography angiography (CTA) affects the immediate and late outcomes of endovascular therapy for iliac artery diseases.

Methods and Results: A total of 254 patients who underwent endovascular treatment for iliac artery diseases were retrospectively evaluated. Minimum vessel diameters were measured on preprocedural CTA images at target lesions, common iliac arteries, and external iliac arteries (EIA). Predictors of immediate and late procedural outcomes were analyzed. Procedural failure or vessel-specific complications occurred in 29 patients (11%): wire passage failure (n=10), rupture (n=8), and distal embolization (n=11). Target lesion revascularization (TLR) was required in 6.0% at 2 years. Independent predictors of procedural failure or vessel-specific complications were small minimum vessel diameter of the target lesion (odds ratio [OR]=0.68, P=0.008) or EIA (OR=0.67, P=0.008), and chronic total occlusions (OR=3.78, P=0.036). Small minimum EIA diameter (hazard ratio [HR]=0.66, P=0.017) and chronic total occlusions (HR=4.45, P=0.024) were independent predictors of TLR in patients with technical success.

Conclusions: Small vessel diameter of the target lesion or EIA was an independent predictor of procedural failure or vessel-specific complications. Small vessel diameter, particularly of the EIA, was also associated with increased TLR after successful endovascular therapy for iliac artery lesions.

Key Words: Computed tomography; Complications; Failure; Iliac artery; Patency

A recent meta-analysis has demonstrated that computed tomography angiography (CTA) has high diagnostic accuracy with respect to the presence and extent of peripheral artery disease (PAD).[1] CTA, with duplex ultrasound and magnetic resonance angiography, is currently recommended as a noninvasive imaging strategy for localizing lower extremity arterial disease lesions and for considering the revascularization options.[2–4] Also, preprocedural CTA can provide 3D data on the diameters of diseased segments, in addition to the degree of stenosis, whereas fluoroscopic angiography only provides 2D information on luminal narrowing. However, the prognostic value of vessel diameter measured by CTA for outcomes of endovascular therapy has not been evaluated. Although endovascular therapy has achieved high technical success rates with excellent patency for iliac artery disease and its indication has been expanded to complex lesions,[4] the incidence of procedural failure and periprocedural complications has been reported to be 1–5% and 4–20%, respectively, frequencies that are still clinically significant.[5–12]

We therefore investigated whether vessel diameters measured by preprocedural CTA affects the immediate (procedural failure or vessel-specific complications) and late outcomes (the need of target lesion revascularization [TLR]) of endovascular therapy for iliac artery disease.

Methods

Subjects

Between 2005 and 2013, a total of 590 patients underwent endovascular therapy for symptomatic iliac artery disease. Of them, 92 with restenotic lesions, 16 with dissections, and 37 who were previously treated with stent grafts or bypass graft were excluded. Among the remaining 445

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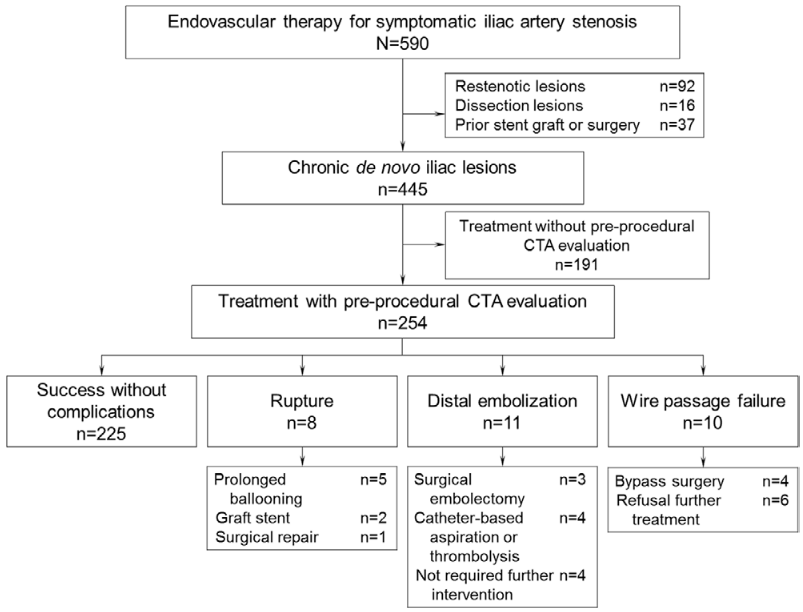

Figure 1. Study flowchart. CTA, computed tomography angiography.

patients with de novo lesions, 254 (57.1%) were evaluated by CTA prior to endovascular therapy and were included in the present study (**Figure 1**). The study protocol conformed to the 1975 Declaration of Helsinki. The institutional review board approved this study and waived the requirement for informed consent for this retrospective analysis.

Angioplasty Procedure

Systemic heparin (5,000 IU) was administered to achieve an activated clotting time >200s. For the treatment of occlusive iliac artery lesions, recanalization was generally performed using an antegrade approach, either from the contralateral femoral artery using a 7F contralateral Balkin sheath (Cook, Bloomington, IN, USA) or from the brachial artery using a 7F Shuttle sheath (Cook). If an antegrade approach failed to cross the lesions, an additional retrograde approach from the ipsilateral femoral artery was carried out. For long iliac artery occlusions, a subintimal approach using a 0.035-inch hydrophilic guide wire (Terumo, Tokyo, Japan) supported by a 5F Multipurpose catheter (Torkon NB; Cook) was performed as previously described.[9] All subintimal procedures were performed without the use of re-entry devices. For the treatment of nonocclusive stenotic iliac artery lesions, either an ipsilateral retrograde approach with a 7F introducer sheath (Terumo) or contralateral antegrade approach with a 7F contralateral Balkin (Cook) was used.

After the passage of a 0.035-inch guide wire, all target lesions were predilated and treated with primary stenting. Self-expandable nitinol stents were usually preferred for long-segment lesions and balloon-expandable stents were used for short- segment lesions or common iliac ostial lesions. Stent diameters ranged from 7 to 10 mm. All self-expandable stents were routinely postdilated to the reference vessel size. Additional post-stent dilation was performed for all stents in cases of residual stenosis >30%. In the presence of significant infrainguinal lesions, combined treatment was performed. Angioplasty in the tibial arteries was carried out only when patients had clinical signs of critical limb ischemia. After successful recanalization, patients received a combination of aspirin (100 mg/day) and either clopidogrel (75 mg/day) or cilostazol (200 mg/day) for at least 1 year. Thereafter, patients were given lifelong aspirin with or without cilostazol.

Analysis of Preprocedural CTA Images

All patients underwent preprocedural CTA using a dual-source CT scanner (SOMATOM Definition Flash; Siemens Medical Solutions, Forchheim, Germany), which produced a scan from the abdominal aortic bifurcation to the feet.[13] The start of the scan was determined by bolus triggering measured in the abdominal aorta. Nonionic contrast (iopamidol [Parmiray, 370 mg of iodine/mL; Dongkook Pharma, Seoul, Korea]; 100–150 mL at a rate of 3 mL/s) was intravenously injected, followed by 40 mL of saline at the same rate. Images were acquired in the arterial and delayed phases at 14 s and 100 s, respectively, after reaching 100 Hounsfield units at the abdominal aortic lumen. Scans were performed using helical acquisition with 100 kV, 170 mAs, slice thickness of 2 mm, and a field of view of 350–380 mm. All CTA images were analyzed blinded to the patients' clinical information. Vessel diameters on the CTA image were assessed at the target lesion, common iliac artery (CIA), and external iliac artery (EIA). In patients with bilateral lesions, the limb with the more severe stenosis was chosen. The minimum vessel diameters were measured perpendicular to the vessel centerline in cross-sectional images with the use of dedicated offline software (Vitrea 2.0; Vital Images, Minnetonka, MN, USA).

Follow-up

Patients were clinically followed at 1 month and then every 3 months regardless of technical success. For patients with technical success, noninvasive hemodynamic evaluations (ankle-brachial index [ABI], segmental pressures, pulse volume recordings) were performed before discharge from

Table 1. Baseline Characteristics of the Patients Undergoing Endovascular Therapy

	All (n=254)	Patients with failure or complications (n=29)	Patients with success without complications (n=225)	P value
Age (years)	67.5±9.3	65.1±11.2	67.8±9.0	0.142
Male	226 (89.0)	25 (86.2)	201 (89.3)	0.613
BMI (kg/m²)	22.8±3.2	22.6±2.1	22.9±3.3	0.629
Risk factors				
Hypertension	178 (70.1)	20 (69.0)	158 (70.2)	0.889
Diabetes mellitus	104 (40.9)	8 (27.6)	96 (42.7)	0.120
Dyslipidemia	114 (44.9)	13 (44.8)	101 (44.9)	0.995
CKD	46 (18.1)	4 (13.8)	42 (18.7)	0.521
CAD	159 (62.6)	15 (51.7)	144 (64.0)	0.198
Smoking	159 (62.6)	17 (58.6)	142 (63.1)	0.638
Clinical stage of PAD				0.028
Rutherford 2	93 (36.6)	3 (10.3)	90 (40.0)	
Rutherford 3	124 (48.8)	20 (69.0)	104 (46.2)	
Rutherford 4	25 (9.8)	5 (17.2)	20 (8.9)	
Rutherford 5	11 (4.3)	1 (3.4)	10 (4.4)	
Rutherford 6	1 (0.4)	0 (0.0)	1 (0.4)	
Critical limb ischemia	37 (14.6)	6 (20.7)	31 (13.8)	0.321
Discharge medication				
Aspirin	249 (98.0)	29 (100.0)	220 (97.8)	0.417
Clopidogrel	213 (83.9)	21 (72.4)	192 (85.3)	0.075
Cilostazol	77 (30.3)	11 (37.9)	66 (29.3)	0.343
Statin	179 (70.5)	19 (65.5)	160 (71.1)	0.534
ACEI or ARB	120 (47.2)	11 (37.9)	109 (48.4)	0.286

Values are n (%) or mean±SD. ACEI, angiotensin-converting enzyme inhibitor; ARB, angiotensin II receptor blocker; BMI, body mass index; CAD, coronary artery disease; CKD, chronic kidney disease; PAD, peripheral artery disease.

the hospital and regularly thereafter every 6 months or if there was symptom deterioration. Follow-up CTA or duplex ultrasound was performed routinely at 12 months. In addition, a noninvasive imaging study was performed if symptoms worsened by one clinical category or ABI decreased by >0.15 during follow-up.

Study Endpoints and Definitions

Technical success was defined as recanalization of the target lesion with absence of residual stenosis >30% or flow-limiting dissection. Vessel-specific complications were defined as target vessel-related complications such as bleeding, occlusion, thrombosis, intimal injury/dissection, severe vasospasm, pseudoaneurysm, arteriovenous fistula, vascular perforation or rupture, or arterial embolization remote from the puncture site.[14] Contrast-induced acute kidney injury was defined as >25% increase in serum creatinine level or >0.5 mg/dL within 2 days after intravascular administration of iodinated contrast medium when no other major kidney insult was identified. Primary patency was defined as treated lesions without restenosis >50%, as assessed by intra-arterial angiography, CTA, or duplex ultrasound. Peak velocity ≥180 cm/s or a lesion/adjacent segment velocity ratio >2.4 by duplex ultrasound was considered to be significant (>50%) restenosis. TLR was performed for restenosis >50% in cases of worsening symptoms or ABI decreased by >0.15.

Statistical Analysis

Continuous data are presented as mean±standard deviation, and categorical data are presented as number (percentage). Factors affecting procedural failure or occurrence of complications were determined by performing a logistic regression analysis using all clinical, angiographic, and preprocedural CTA variables listed in **Tables 1,2**. For the variables with P<0.1 in the univariate analyses, multivariate logistic regression analyses using the enter method were performed. For independent preprocedural CTA variables, the optimal cutoff value for prediction of procedure failure or occurrence of vessel-specific complications was determined by an analysis of the area (AUC) under the receiver-operating characteristic (ROC) curve.

Factors associated with TLR were determined by performing a univariate analysis using the Cox proportional hazards regression with all variables listed in **Tables 1,2**. All variables achieving P<0.1 in the univariate analysis were entered using the enter method into the multivariate analysis model. Kaplan-Meier survival curves were constructed by classifying subjects according to the optimal cutoff value found by area under the ROC curve analysis. TLR rates were estimated using the Kaplan-Meier survival analysis and compared using a log-rank test. Findings were considered significant at P<0.05. All statistical analyses were performed using SPSS 18.0 (SPSS Inc., Chicago, IL, USA).

Results

Baseline Characteristics

Clinical, angiographic, and preprocedural CTA characteristics according to the occurrence of failure or complications are summarized in **Tables 1,2**. With the exception of

Table 2. Angiographic, Preprocedural CTA, and Procedural Characteristics of the Patients Undergoing Endovascular Therapy

	All (n=254)	Patients with failure or complications (n=29)	Patients with success without complications (n=225)	P value
Bilateral lesions	92 (36.2)	16 (55.2)	76 (33.4)	0.024
Location of the lesion				0.011
CIA only	72 (28.3)	2 (6.9)	70 (31.1)	
EIA only	42 (16.5)	4 (13.8)	38 (16.9)	
CIA+EIA	140 (55.1)	23 (79.3)	117 (52.0)	
Lesions with EIA involvement	182 (71.7)	27 (93.1)	155 (68.9)	0.006
Femoropopliteal lesion	113 (44.5)	15 (51.7)	98 (43.6)	0.405
Lesion length (mm)	94.8±51.9	133.1±65.1	89.9±47.9	<0.001
Degree of stenosis (%)	90.3±12.3	99.0±3.9	89.1±12.6	<0.001
Chronic total occlusion	123 (48.4)	25 (86.2)	98 (43.6)	<0.001
TASC II classification				<0.001
A	55 (21.7)	1 (3.4)	54 (24.0)	
B	86 (33.9)	3 (10.3)	83 (36.9)	
C	73 (28.7)	8 (27.6)	65 (28.9)	
D	40 (15.7)	17 (58.6)	23 (10.2)	
C/D	113 (44.5)	25 (86.2)	88 (39.1)	<0.001
Moderate to severe calcification on fluoroscopy	162 (63.8)	17 (58.6)	145 (64.4)	0.539
Minimum vessel diameter on CTA (mm)				
Target lesion	7.6±2.2	6.1±2.3	7.7±2.1	<0.001
CIA	10.1±1.9	9.7±2.0	10.1±1.9	0.216
EIA	6.8±1.5	5.6±2.0	6.9±1.4	0.001
Preprocedural thigh-brachial index	0.7±0.2	0.6±0.2	0.7±0.2	0.132
Preprocedural ankle-brachial index	0.6±0.2	0.5±0.3	0.6±0.2	0.116

Values are n (%) or mean±SD. CIA, common iliac artery; CTA, computed tomography angiography; EIA, external iliac artery; TASC, TransAtlantic Inter-Society Consensus.

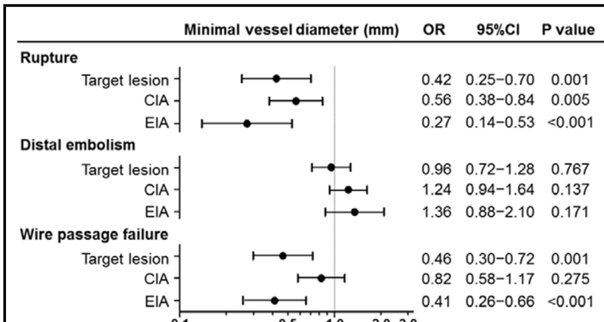

Figure 2. Vessel diameters measured by computed tomography angiography predicting rupture, distal embolization, and wire passage failure after endovascular therapy. CI, confidence interval; CIA, common iliac artery; EIA, external iliac artery; OR, odds ratio.

the clinical stage of PAD, clinical characteristics were similar between groups. The frequency of bilateral lesions requiring bilateral interventions was 36%. Chronic total occlusions and TASC (TransAtlantic Inter-Society Consensus) II classification C/D lesions were found in 48% and 45%, respectively. Moderate to severe calcium deposition on fluoroscopy containing longitudinal calcified lesions (obvious densities observed within the apparent iliac wall on the angiogram) >50% of the iliac segment was 64%. On preprocedural CTA images, the minimum diameter at the target lesion was 7.6±2.2 mm. Minimum CIA diameter was 10.1±1.9 mm, and minimum EIA diameter was 6.8±1.5 mm.

Immediate Outcomes

Technical success was achieved in 240 of 254 patients (94%). Procedural failure or vessel-specific complications occurred in 29 patients (11%), and included wire passage failure (n=10), arterial rupture (n=8), and distal embolization (n=11) (**Figure 1**). In 4 of the 10 patients with wire passage failure, the wire could not cross the lesion; in the remaining 6 patients, the wire crossed the lesion, but failed to enter the distal true lumen. Of the 10 patients with wire passage failure, 4 underwent bypass surgery, but the other 6 refused further treatment. Among the 8 patients with arterial rupture, prolonged ballooning was sufficient in 5 patients. However, graft stents were required in 2 patients, and surgical repair was needed in 1 patient. Among the 11 patients with distal embolization, 4 did not require any further interventions, but 7 underwent further management, including surgical embolectomy using a Fogarty catheter (n=3), thrombus aspiration using a catheter (n=2), and catheter-based thrombolysis (n=2). After the preprocedural CTA, 2 patients (0.8%) showed a transient serum creatinine elevation caused by contrast-induced acute kidney injury. The interval between the preprocedural CTA and the index procedure was 20.5±16.4 days. After the index procedure, 2 patients (0.8%) developed contrast-induced acute kidney injury. Of them, only 1 patient showed persistent elevation of serum creatinine. None of the patients required dialysis for renal failure.

Table 3. Predictors of Procedural Failure or Complications

	Univariate			Multivariate					
				Model 1			Model 2		
	OR	95% CI	P value	OR	95% CI	P value	OR	95% CI	P value
Bilateral lesions	2.41	1.10–5.28	0.027	1.41	0.42–4.67	0.578	1.21	0.36–4.01	0.760
Lesions with EIA involvement	6.10	1.41–26.35	0.015	0.93	0.16–5.48	0.936	2.56	0.45–14.55	0.289
Lesion length (mm)	1.01	1.01–1.02	<0.001	1.00	0.99–1.02	0.574	1.00	0.99–1.01	0.765
Chronic total occlusions	8.10	2.73–24.04	<0.001	3.78	1.09–13.05	0.036	3.27	0.94–11.42	0.063
TASC II classification C/D	9.73	3.28–28.91	<0.001	2.33	0.60–8.97	0.220	2.56	0.64–10.20	0.184
Minimum vessel diameter on CTA (mm)									
Target lesion	0.59	0.45–0.76	<0.001	0.68	0.50–0.90	0.008	–	–	–
CIA	0.87	0.71–1.08	0.213	–	–	–	–	–	–
EIA	0.54	0.41–0.72	<0.001	–	–	–	0.67	0.50–0.90	0.008

Variables with P<0.1 in the univariate analysis and vessel diameters on CTA are presented. Variables achieving P<0.1 were entered in the multivariate analyses using the enter method and the diameters of the target lesion and the EIA were entered separately for Models 1 and 2. CI, confidence interval; OR, odds ratio. Other abbreviations as in Table 2.

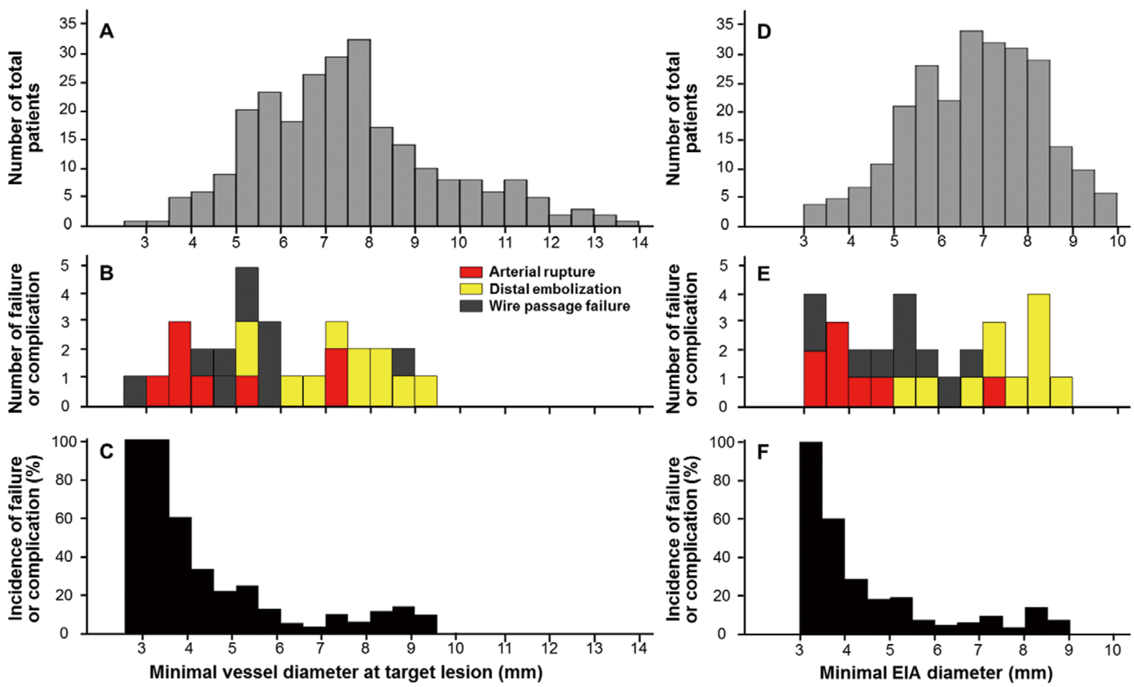

Figure 3. Number of patients (1st row), number of failures or complications (2nd row), and incidence of failure or complication (3rd row) according to minimum vessel diameter of target lesion (**A**–**C**) and EIA (**D**–**F**). EIA, external iliac artery.

Predictors of Procedural Failure and Vessel-Specific Complications

Predictors of rupture, distal embolization, and wire passage failure are presented in **Figure 2**. Independent predictors of overall procedural failure or vessel-specific complications (**Table 3**) included small minimum diameter at the target lesion (adjusted odds ratio [OR]=0.68, P=0.008), small EIA diameter (adjusted OR=0.67, P=0.008), and chronic total occlusion (adjusted OR=3.78, P=0.036). **Figure 3** shows the incidence of procedure failure or vessel-specific complications according to minimum diameter at the target lesion and EIA. The incidence of procedure failure or vessel-specific complications was higher in patients with small minimum vessel diameter at the target lesion and EIA. Arterial rupture and wire passage failure were particularly associated with small vessel diameter. The optimal cutoff value of minimum diameter at the target lesion and EIA for the determination of procedural failure or complications was 5.75 mm (AUC=0.723, sensitivity 85%, specificity 55%) (**Figure S1A**) and 5.35 mm (AUC=0.700, sensitivity 87%, specificity 56%), respectively (**Figure S1B**).

Predictors of TLR

Patients were followed for a median duration of 2.8 years

Table 4. Predictors of TLR in the Patients Undergoing Endovascular Therapy

	Chronic total occlusion	Minimum vessel diameter on CTA (mm)		
		Target lesion	CIA	EIA
Univariate analysis				
HR	6.30	0.86	0.69	0.56
95% CI	1.81–22.00	0.66–1.10	0.74–1.25	0.40–0.80
P value	0.004	0.229	0.760	0.001
Multivariate analysis				
HR	4.45	–	–	0.66
95% CI	1.22–16.25	–	–	0.47–0.93
P value	0.024	–	–	0.017

Variables with P<0.1 in the univariate analysis and vessel diameters on CTA are presented. Variables achieving P<0.1 were entered in the multivariate analyses using the enter method. HR, hazard ratio; TLR, target lesion revascularization. Other abbreviations as in Tables 2,3.

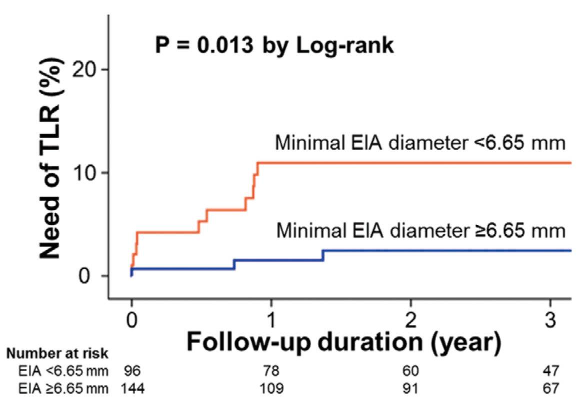

Figure 4. Kaplan-Meier survival curves of target lesion revascularization (TLR). Subjects were classified according to the optimal cutoff value found by the area under the receiver-operating characteristic curve analysis. All standard errors <10%. EIA, external iliac artery.

(interquartile range, 1.4–5.2 years). Among the 240 patients who completed endovascular therapy with technical success, 19 exhibited loss of patency of the target lesion during the follow-up period. Primary patency was 93.5% at 2 years, according to the Kaplan-Meier curves. Of these 19 patients, 17 underwent TLR, including repeat endovascular therapy (n=15) and surgical bypass (n=2). Clinical, angiographic, and preprocedural CTA characteristics according to the need of TLR are summarized in **Tables S1**,**S2**. Kaplan-Meier curves showed that TLR was required in 6.0% of patients at 2 years. On multivariate analysis, predictors of TLR after technical success were chronic total occlusion (hazard ratio [HR]=4.45, P=0.024) and small minimum EIA diameter (HR=0.66, P=0.017) (**Table 4**). Kaplan-Meier curves showed that TLR was significantly higher in patients with an EIA diameter <6.65 mm compared with those with a diameter ≥6.65 mm (P=0.013), where 6.65 mm was the optimal cutoff value for prediction of TLR (AUC=0.706, sensitivity 0.62, specificity 0.92) (**Figure 4**).

Discussion

The principal findings of the present study are that preprocedural CTA parameters, especially vessel diameter, can effectively predict immediate and long-term outcomes after endovascular therapy for iliac artery lesions. Small vessel diameters at the target iliac artery lesion or the EIA and total occlusion were independent predictors of procedural failure or vessel-specific complications. Small vessel diameter of the EIA and total occlusion were associated with increased TLR after successful endovascular therapy for iliac artery lesions. To our knowledge, there has not been a clinical study that investigated the value of CTA parameters for predicting immediate and late outcomes of iliac artery intervention.

Predictors of Procedural Failure or Complications

Procedural failure has been reported in up to 1–5% of patients, and the procedure-related complication rate has been shown to vary from 4% to 20%.[5–12] Complications such as arterial perforation or retroperitoneal bleeding, though rare, are life-threatening. Therefore, every effort should be made to avoid such serious complications. We often observe negative remodeling in cases of long-standing chronic total occlusion of the iliac arteries. With intra-arterial angiography, it is difficult to assess vessel diameter, especially when a long segment of the iliac artery is occluded. Dilation of such lesions with a balloon greater than the actual vessel diameter may result in arterial rupture. In this respect, CTA is advantageous compared with intra-arterial angiography because it can visualize the vessel wall of the occluded artery and allow accurate measurement of vessel size. In the present study, more complex lesion characteristics, such as bilateral lesions, lesions with EIA involvement, longer lesion length, chronic total occlusions and TASC II classification C/D, were related to procedural failure or the occurrence of vessel-specific complications, consistent with the TASC II guidelines and a previous study,[3,12] Moreover, we found that small vessel diameter at the target lesion, especially small EIA diameter, was an important predictor of failure or occurrence of complications, particularly rupture or wire passage failure. Therefore, information on target vessel diameter based on CTA or other imaging modalities and avoidance of overdilation beyond the vessel size may be critical in preventing serious complications.

Predictors of TLR

Previous studies have reported that female sex, diabetes, renal failure, balloon angioplasty without stenting, and combined outflow lesions are independent predictors of loss of primary patency.[15–18] In the present study, we found that small EIA diameter was also an important determinant of TLR. Similarly, Soga et al reported that reference vessel diameter <8.0 mm measured by angiography during the procedure was an independent predictor of restenosis. In our study, CIA diameter, unlike EIA diameter, did not affect TLR, possibly because of the relatively larger diameter of the CIA. The limits of the present study did not allow us to clarify the mechanisms linking EIAs with a small diameter to increased TLR. We speculate that residual stenosis, stent under-expansion, or relatively higher outward expanding force by the stent may contribute to increased risk of restenosis in small-diameter EIAs.

Study Limitations

First, this was a retrospective study of single-center registry data from a relatively small group of patients. Second, noninvasive testing during follow-up was less rigorous than would be achieved in a prospective study. Third, dialysis-independent patients with moderate to severe CKD were not proportionately represented in this study because the use of contrast-enhanced CT angiography was limited in this population.

Conclusions

Small vessel diameters on preprocedural CTA images were associated with adverse immediate and late outcomes after iliac artery intervention. Thus, preprocedural assessment using CTA may be beneficial for procedural success and prevention of complications or repeat revascularization.

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Conflict of Interests

There is no conflict of interest to declare.

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Supplementary Files

Supplementary File 1

Figure S1. Receiver-operating characteristics of minimum vessel diameter at the target lesion (**A**) and the EIA (**B**) for the determination of procedural failure or complications.

Table S1. Baseline characteristics of the patients with technical success according to the need for TLR

Table S2. Angiographic, preprocedural CTA, and procedural characteristics of the patients with technical success according to the need for TLR

Please find supplementary file(s);
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