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PERIPHERAL

15-Year Patency and Life Expectancy After Primary Stenting Guided by Intravascular Ultrasound for Iliac Artery Lesions in Peripheral Arterial Disease

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ABSTRACT

OBJECTIVES The purpose of this study was to evaluate 15-year patency and life expectancy after endovascular treatment (EVT) with primary stenting guided by intravascular ultrasound (IVUS) for iliac artery lesions.

BACKGROUND Fifteen-year patency, factors causing restenosis, and survival after IVUS-guided EVT are unclear based on the TransAtlantic Inter-Society Consensus II (TASC-II) classification in peripheral arterial disease (PAD).

METHODS EVT was performed for 507 lesions in 455 patients with PAD. The 15-year endpoints were primary, primary-assisted, and secondary patency; overall survival; freedom from major adverse cardiovascular events (MACE); and freedom from major adverse cardiovascular and limb events (MACLE).

RESULTS The 5-, 10-, and 15-year primary and secondary patencies were 89%, 83%, and 75%, respectively, and 92%, 91%, and 91%, respectively. There were no significant differences among TASC-II categories.

CONCLUSIONS IVUS-guided stenting for the iliac artery had favorable 15-year patency in all TASC categories. Life expectancy after EVT was poor, but stenting is feasible for patients with PAD. (J Am Coll Cardiol Intv 2015;8:1893–901)

The therapeutic strategy for peripheral arterial disease (PAD) is generally selected based on the lesion type, using the morphological stratification in the Inter-Society Consensus for the Management of Peripheral Arterial Disease (TransAtlantic Inter-Society Consensus [TASC]) classification in the aortoiliac artery (1). Favorable results have been obtained with endovascular treatment (EVT) for iliac artery lesions compared with lesions of the femoral artery (2–4). However, there are few reports on very long-term patency after treatment of TASC type A to D lesions.

Intravascular ultrasound (IVUS) gives a high-resolution cross-sectional image for use during coronary and peripheral intervention, and the additional morphological information may decrease the restenosis rate after stent implantation (5–8). However, factors evaluated by IVUS that cause restenosis in long-term patency after EVT have not been analyzed in detail. PAD is a systemic disease with multiple

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ABBREVIATIONS AND ACRONYMS

CLI = critical limb ischemia

CTO = chronic total occlusion

EVT = endovascular treatment

IVUS = intravascular ultrasound

MACE = major adverse cardiovascular event(s)

MACLE = major adverse cardiovascular and limb event(s)

MLA = mean stent lumen area

PAD = peripheral arterial disease

TASC = TransAtlantic Inter-Society Consensus

atherosclerotic risk factors and poor long-term survival (1,9,10), and more information is needed on long-term outcomes after EVT for PAD. Therefore, in this study, we analyzed 15-year patency and life expectancy after IVUS-guided primary stenting for iliac artery lesions categorized using the TASC classification.

METHODS

PATIENTS. Patients with PAD admitted to Kitakanto Cardiovascular Hospital from June 1993 to December 2013 for EVT for subjective symptoms categorized as higher than Fontaine class II and with stenosis of the iliac artery ≥70% in angiography were included in a single-center prospective study. Written informed consent for participation in the study was obtained from all patients, and the protocol was approved by our institutional ethical committee before initiation of the study (4). A total of 874 patients were treated for infrarenal aortoiliac disease. Of these patients, 194 with intermittent claudication were treated with exercise rehabilitation and medication alone (1).

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Revascularization was performed in 680 patients with critical limb ischemia (CLI) or intermittent claudication whose symptoms were not improved or deteriorated after medication. EVT was performed for all type A and B lesions. Of patients with type C lesions, 4 with iliac lesions and severe calcified stenosis in the common femoral artery were excluded because EVT and endarterectomy were performed concurrently. Of patients with type D lesions, 18 were excluded because of severe calcified stenosis in the common femoral artery, as mentioned in the preceding text (n = 2), abdominal aortic aneurysm requiring stent graft placement (n = 4), severe calcified aortoiliac occlusion (n = 9), and aortoiliac occlusion requiring concomitant femoropopliteal bypass (n = 3). As a result, EVT was performed in 658 patients, of whom 203 were excluded because of treatment with angioplasty alone (n = 169; types A: 98, B: 57, C: 12, D: 2), restenotic lesions (n = 29), and primary stenting without adequate IVUS data (n = 5). Therefore, analysis of endpoints was finally performed in 455 patients who underwent primary stenting for de novo aortoiliac lesions.

ENDOVASCULAR TREATMENT. All patients received a bolus of 5,000 IU of heparin before treatment. The puncture site for arterial access was in the inguinal region of the femoral arteries, and EVT was performed through the iliac artery via an ipsilateral or contralateral route. All procedures for stent implantation were guided by IVUS. Images were acquired with an IVUS console (Volcano s5 Imaging system, Volcano Corp., San Diego, California, or CVIS, Boston Scientific, San Jose, California) and an IVUS catheter (Visions PV .018, 20 MHz, Volcano Corp., or Ultracross catheter, 30 MHz, Boston Scientific). After guidewire passage through the lesion, IVUS was performed at the lesion segment and at proximal and distal reference sites in the lesion segment with manual pullback. A lesion was classified as calcified on the basis of IVUS identification of an angle of calcification >180° in the plaque in the minimal lesion area. In cases with severely calcified lesions, minimal pre-dilation with balloon angioplasty was performed with Sterling or Wanda (Boston Scientific, Natick, Massachusetts) and Powerflex (Cordis, Fremont, California) balloon catheters. In most other cases, direct stent implantation was performed using

TABLE 1 Baseline Clinical Characteristics

Factor	All Patients (N = 455)	Type A/B (n = 312)	Type C/D (n = 143)	p Value
Number of lesions	507	364 (A/B: 231/133)	143 (C/D: 53/90)	
Age, yrs	71.8 ± 8.5	71.9 ± 8.3	71.6 ± 9.0	0.728
Male	399 (87.7)	275 (88.1)	124 (86.7)	0.667
Fontaine class, IIa/IIb/III/IV	128/274/5/48	117/171/2/22	11/103/3/26	<0.001
CLI	53 (11.6)	24 (7.7)	29 (20.2)	<0.001
Lesion length, cm	5.8 ± 4.9	4.2 ± 3.7	9.9 ± 5.2	<0.001
Chronic total occlusion	119 (23.5)	50 (13.7)	69 (48.3)	<0.001
Lesion location				
Common iliac artery	201 (39.6)	169 (46.4)	32 (22.4)	<0.001
External iliac artery	240 (47.3)	195 (53.6)	45 (31.5)	<0.001
Common to external iliac artery	54 (10.7)	0 (0)	54 (37.8)	<0.001
Aortoiliac artery	12 (2.4)	0 (0)	12 (8.4)	<0.001
Initial success	493 (97.2)	359 (98.62)	134 (93.3)	0.002
Number of stents	1.23 ± 0.20	1.07 ± 0.26	1.63 ± 0.59	<0.001
Stent type				<0.001
Balloon expandable	98 (19.3)	92 (25.2)	6 (4.2)	
Self-expandable	392 (77.3)	269 (73.9)	123 (86.0)	
Both	17 (3.4)	3 (0.8)	14 (9.8)	
ABI				
Pre-procedure	0.59 ± 0.02	0.63 ± 0.21	0.50 ± 0.26	<0.001
Post-procedure	0.90 ± 0.02	0.93 ± 0.20	0.87 ± 0.26	0.006
Angiographic stenosis, %				
Pre-procedure	78.5 ± 16.0	75.6 ± 15.0	85.8 ± 16.1	<0.001
Post-procedure	14.0 ± 9.5	13.0 ± 9.3	16.7 ± 9.6	<0.001
IVUS MLA, mm^2				
Pre-procedure	10.3 ± 8.5	11.6 ± 8.6	6.9 ± 6.9	<0.001
Post-procedure	34.9 ± 11.9	36.8 ± 12.3	30.0 ± 8.9	<0.001
Calcified lesion	97 (19.1)	66 (18.1)	31 (21.6)	0.361
Stent edge dissection	9 (1.8)	6 (1.6)	3 (2.1)	0.730
In-stent thrombosis	11 (2.2)	4 (1.1)	7 (4.9)	0.021
Stent fracture	6 (1.2)	5 (1.4)	1 (0.7)	0.861
Antiplatelet discontinuation	12 (2.4)	9 (2.6)	3 (2.1)	0.940

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