From the Southern Association for Vascular Surgery

The effect of demographic factors and lesion severity on iliac stent patency

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Objective: **The aim of our study was to perform a large multivariate analysis to identify demographic, anatomic, or procedural factors that affect iliac artery stent primary patency (PP).**

Methods: **Patients receiving iliac stents from 2007 to 2013 were retrospectively reviewed. Univariate analysis assessed cohort characteristics and their effect on PP. Variables considered significant (P < .05) were brought forward in the multivariate analysis.**

Results: **A total of 213 patients underwent primary iliac artery stenting, and 307 limbs were analyzed. The average age was 66 years (range, 38-93 years), 54% were male, and 55% were Caucasian. Indications for procedure were claudication in 68%, rest pain in 20%, and tissue loss in 12%. All TransAtlantic Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC) II classifications were included: 51% TASC II A, 25% TASC II B, 13% TASC II C, and 11% TASC II D. The treated anatomic locations were 27% isolated external iliac artery (EIA), 56% isolated common iliac artery, and 17% combined common iliac artery and EIA. Multivariate analysis found three factors were correlated with decreased PP: non-Caucasian race (hazard ratio [HR], 1.84; 95% confidence interval [CI], 1.08-3.13; P = .025), younger age (HR, 1.04; 95% CI, 1.01-1.08; P = .006), and presence of EIA occlusion (HR, 2.02; 95% CI, 1.05-3.89; P = .036). Overall, Kaplan-Meier analysis at 1 and 3 years revealed a PP of 86% and 53%, assisted PP of 98% and 89%, and secondary patency of 99% of 98%. Kaplan-Meier analysis showed PP at 1 year for was 91% Caucasian patients vs 77% for non-Caucasian (P = .001). PP was 75% in patients aged <60 years, 86% in patients aged 60-70 years, and 96% in patients aged >70 years, with a significant difference between all groups (P < .001). PP was significantly different for those with and without EIA occlusion (P = .002), with 1-year PP of 71% and 88%, respectively.**

Conclusions: **In our experience with a large number of iliac interventions, younger age, non-Caucasian race, and EIA occlusion were strong predictors for loss of PP. (J Vasc Surg 2015;62:645-53.)**

Approximately 8 million people in the United States suffer from peripheral arterial disease (PAD). Arterial disease can be identified in 20% of individuals aged ≥60 years. In addition to the increasing prevalence with older age, PAD prevalence also increases in the African American population.[1] As the incidence of PAD rises, it is becoming increasingly necessary to determine not only the most successful treatment options for PAD but also the procedural and patient characteristics that determine treatment success and treatment failure.

One element of patient characteristics that can affect treatment outcomes is the anatomic extent of PAD. There has been limited success in determining how lesion severity, especially TransAtlantic Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC) II classification, affects treatment outcomes in iliac disease. Sixt et al[2] found similar patency rates between all TASC II classifications undergoing endovascular therapy for aortoiliac occlusive lesions. Furthermore, how anatomic differences affect endovascular outcomes and patency is unclear. A study by Lee et al[3] investigating stenting of symptomatic iliac artery occlusive disease and limb ischemia showed no significant differences in patency rates between external iliac artery (EIA) and common iliac artery (CIA) lesions. In contrast, EIA lesions had significantly lower patency rates compared with CIA lesions in women undergoing stent placement and angioplasty.[4] Conflicting studies also exist addressing lesion length and the effect on patency. Norgren et al[5] and Scheinert et al[6] demonstrated that iliac occlusions >10 cm are associated with worse patency outcomes after recanalization and stenting. Conversely, lesion length as defined by TASC II classification was not an independent predictor of patency rates in 438 interventions for aortoiliac arterial obstructions.[2]

In addition to conflicting information about the anatomic factors that affect iliac stent patency, limited information is available on the effect of demographic factors, such as gender. Kudo et al[7] found male gender was an independent predictor for clinical failure after

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iliac angioplasty with selective stenting. However, Bechter-Hugl et al[8] found no difference in primary stent patency rates between men and women based on a cohort of 404 primary iliac artery percutaneous transluminal angioplasties with stent placement in 337 patients. Because of the incongruences within the literature on factors affecting iliac stenting, the purpose of our study was to further investigate anatomic, demographic, and procedural factors associated with iliac stent primary patency (PP) in a large cohort.

METHODS

A retrospective review was conducted using an electronic medical records (EMRs) search of Current Procedural Terminology (CPT; American Medical Association, Chicago, Ill) coding to identify all consecutive patients who underwent iliac stenting procedures between May 2011 and June 2013. Index iliac stenting patients were identified by CPT codes 37220, 37221, 37222, and 37223. Patients were identified by the index procedure or subsequent procedures through CPT codes, resulting in procedure dates ranging from June 2007 to October 2013. Excluded were patients with previous iliac angioplasty, iliac stenting, aortic dissection, total aortic occlusions, or endovascular or thoracic endovascular aortic repair, and also patients with insufficient data or follow-up of <30 days after the index procedure. CPT codes identified 525 patients during this time, 213 of which met the inclusion criteria as previously stated. The EMR review and waiver of consent was performed with approval of the Eastern Virginia Medical School Institutional Review Board and in compliance with the Health Insurance Portability and Accountability Act.

Demographic characteristics, lesion morphology, procedural information, and outcome data were obtained through the EMRs and compiled into a deidentified, password-protected Excel data sheet (Microsoft Corp, Redmond, Wash). Lesion severity was categorized using the 2007 TASC II classification system.[9] Limbs stented as a result of treatment of disease in the contralateral CIA were not assigned a TASC II classification, resulting in classifications in 288 of 307 limbs. Kissing stents placed contralateral to the symptomatic iliac were included in patency analysis because they were still subject to disease burden in the limb.

Data used to assign the TASC II classification were taken from the operative report and angiographic imaging. Attempts were made to collect lesion length. Unfortunately, unless an intraprocedural measurement tape or measurement guide was included in all the angiographic images, there was no way to accurately and consistently document lesion length. For this reason we included stent length, but not lesion length, because we were unable to accurately document this variable. For the minority of lesions requiring length for TASC II classification, length was inferred from stent size. Of the 288 classified lesions, 279 were accurately based on the pretreatment angiography.

Table I. Demographic characteristics of the study cohort

Variables[a]	*No. in cohort (N = 213)*
Age, years	65.9 ± 10.4
Male sex	115 (54.0)
Race	
Caucasian	118 (55.4)
Black	72 (33.8)
Asian	3 (1.4)
Other/unknown	20 (9.4)
Body mass index, kg/m^2	26.6 ± 5.9
Comorbidities	
Hypertension	180 (85)
Hyperlipidemia	120 (56.3)
Diabetes mellitus	83 (39)
Chronic kidney disease	26 (12.2)
Coronary artery disease	80 (37.6)
Chronic obstructive pulmonary disease	33 (15.5)
Current or former smoker	208 (97.7)
Active smoker[b]	114 (54.8)
Pack years[b]	34.8 ± 27.7
Statin use	155 (72.8)

[a]Continuous data are shown as mean ± standard deviation and categoric data as number (%).
[b]Of current or past smokers.

For each patient, all available data concerning infrainguinal vessel occlusive disease, including runoff and lesions, were recorded in the Excel data sheet. Infrainguinal arterial occlusive disease information was not available for all limbs due to the angiographic images that were saved or lack of information in the operative reports. Concerning the specific vessels, pathology information was present for the common femoral artery in 296 limbs, profunda femoral artery in 285 limbs, superficial femoral artery in 287 limbs, popliteal in 279 limbs, and lower leg runoff vessel in 201 limbs.

Technical success was defined as the presence of antegrade flow through the treated iliac lesion at completion of the procedure with <30% residual stenosis. If necessary, pullback pressures with resolution of the pressure differential or intravascular ultrasound (IVUS) imaging was used to determine technical success and lack of residual stenosis. The use of IVUS imaging and pullback pressure was under the discretion of the operating surgeon and was not lesion dependent. Primary, primary assisted, and secondary patency, and limb loss were defined by Society for Vascular Surgery[10] standards. Loss of PP was defined as any stent that required reintervention, occluded, or showed >75% stenosis on any imaging modality. Duplex ultrasound imaging identified >75% stenosis as a loss of reverse flow component or an end-diastolic velocity >100 cm/s. If duplex studies or results were unavailable due to lack of follow-up or difficulty due to body habitus or bowel gas, hemodynamic status was tracked through the ankle-brachial index (ABI) and subsequent angiograms.

The primary study end point was PP, and all preoperative variables were studied in univariate/multivariate analysis to determine the effect of variables on PP. Categoric variables were analyzed with χ^2 analysis or the Fisher exact