From the Society for Clinical Vascular Surgery
2015 International Award

Outcomes of polytetrafluoroethylene-covered stent versus bare-metal stent in the primary treatment of severe iliac artery obstructive lesions

Michele Piazza, MD,[a] Francesco Squizzato, MD,[a] Gaya Spolverato, MD,[b] Luca Milan, MD,[a] Stefano Bonvini, MD,[a] Mirko Menegolo, MD,[a] Franco Grego, MD,[a] and **Michele Antonello, MD,[a]**
Padova, Italy

Objective: **This study compared early and midterm outcomes of polytetrafluoroethylene-covered stents (CSs) vs bare-metal stents (BMSs) in the primary treatment of severe TransAtlantic Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II) C and D iliac artery obstructive lesions.**
Methods: **Between January 2009 and June 2014, 128 patients underwent stenting of 167 iliac arteries; CSs were implanted in 82 iliac arteries (49%) and BMSs in 85 (51%). All patients were prospectively enrolled in a dedicated database. Thirty-day outcomes, mid-term patency, limb salvage, and survival were compared, and follow-up results were analyzed with Kaplan-Meier curves. Clinical presentation, lesion site, extension, and laterality were evaluated for their association with patency in the two groups using multiple logistic regressions.**
Results: **Patients were a mean age of 70 ± 10.3 years, The Society for Vascular Surgery comorbidity score was 0.89 ± 0.57, with no differences after stratification by CS and BMS ($P = .17$). Iliac lesions were classified by limb as TASC II C in 86 (51%) and D in 81 (49%). Comparing CS and BMS, technical success was 99% in both groups ($P = 1.0$); the 30-day cumulative surgical complications rate (7.3% vs 4.7%; $P = .53$), mortality (1.8% vs 0%; $P = .45$), and morbidity (1.8% vs 1.4%; $P = .99$) were equivalent. At 24 months (average 22 months; range, 30 days-56 months), primary patency of CS vs BMS was similar (93% vs 80%; $P = .14$), and this finding was maintained after stratification by TASC II C (97% vs 93%; $P = .59$) and D (88% vs 61%; $P = .07$); secondary patency was 98% vs 92% ($P = .22$), and limb salvage was 99% and 95% ($P = .35$) respectively. Multivariate analysis indicated that BMS in long-segment stenosis involving the common and external iliac arteries was a negative predictor of patency (odds ratio, 0.16; 95% confidence interval, 0.04-0.62; $P = .007$); within this subgroup of TASC II D lesions, primary patency at 24 months was significantly higher for CS than for BMS (88% vs 57%; $P = .03$).**
Conclusions: **Overall, the use of CSs for severe iliac lesions has similar early and midterm outcomes compared with BMS. In a subcategory of TASC II D lesions with long-segment severe stenosis of both the common and external iliac arteries, CS should be considered as the primary line of treatment. (J Vasc Surg 2015;62:1210-8.)**

Severe iliac occlusive disease, defined as TransAtlantic Inter-Society Consensus (TASC) for the Management of Peripheral Arterial Disease (II) C and D lesions,[1] often presents with bilateral involvement, extensive and complex lesions, and may be associated with multisegmental disease of the aorta and the infrainguinal arteries. In this setting, surgical repair still represents the gold standard in good-risk patients; however, several authors[2,3] have demonstrated that an endovascular approach can be justified, especially in high-risk patients, with acceptable midterm patency rates and low morbility. Although iliac percutaneous transluminal angioplasty (PTA) and stenting is now considered routine, the technical characteristics of the stent to be used are still debated. In particular for severe obstructive disease, factors as lesion characteristics, extension, and site may significantly modify long-term patency outcomes.

In addition, if we consider that the main cause for late failure is in-stent stenosis predominantly caused by intimal hyperplasia, the use of expanded polytetrafluoroethylene covered stents (CSs) rather than bare-metal stents (BMSs) may play a major role. Furthermore, in cases of severe iliac disease with long-segment extremely calcified lesions, the use of a CS allows pronounced balloon dilatation without the risk of complications related to arterial rupture.

Previous experiences[4-7] demonstrated a freedom of binary restenosis >90% at 1 year when a CS was used. In 2011, the Covered Versus Balloon Expandable Stent Trial (COBEST) multicenter randomized trial demonstrated an increased patency at 18 months in favor of CSs compared with BMSs in TASC C and D lesions.[8] However, that study made no distinctions in the target lesion sites; in

From the Vascular and Endovascular Surgery Division[a] and Department of Surgery, Oncology, and Gastroenterology,[b] School of Medicine, Padova University.
Author conflict of interest: none.
Presented at the Forty-third Annual Symposium of the Society for Clinical Vascular Surgery, Miami, Fla, March 29-April 2, 2015.
Additional material for this article may be found online at www.jvascsurg.org.
Correspondence: Michele Piazza, MD, Vascular and Endovascular Surgery Clinic, School of Medicine, Padova University, Via Giustiniani, 2, 35100 Padova, Italy (e-mail: mikpia79@hotmail.com).
The editors and reviewers of this article have no relevant financial relationships to disclose per the JVS policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.
0741-5214

http://dx.doi.org/10.1016/j.jvs.2015.05.028

addition, balloon-expandable and self-expanding BMSs were both compared with a single type of covered balloon-expandable stent. In the real-world practice, the use of a covered or uncovered stent in severe iliac disease is strictly related not only to the TASC II classification (C or D lesions) but also to the lesion quality, extension, and laterality.

The purpose of this study was to review our experience in the endovascular treatment of severe iliac artery obstructive disease (TASC II C and D) comparing CSs vs BMSs. Particular attention was given to technical outcomes and midterm procedural durability; furthermore, clinical presentation, lesion site, extension, and laterality were evaluated for their association with patency. The most current standards were used to define the different variables.

METHODS

This study did not require Institutional Review Board Approval according to Padova University guidelines on research ethics. The informed consent requirement was waived for this study.

Patient selection. A retrospective review was performed of all patients admitted to the Clinic of Vascular and Endovascular Surgery of Padova University who underwent iliac stenting for chronic obstructive disease between January 2009 and June 2014. All data were prospectively collected in a dedicated database. Only patients with TASC II C and D lesions were included. The study excluded patients who had undergone previous endovascular procedures of the iliac segment, those with associated aortic thrombosis, or those treated in emergency setting.

Patients were grouped by those who received a CS and those who received a BMS. In particular, group subdivision by patient was applied for demographics, risk factors, major medical postoperative complications, and survival. Only two of 128 patients (1.5%) underwent bilateral treatment, in which a CS was implanted in one side and a BMS in the contralateral iliac artery, and those were allocated in the CS patient group.

The subgroup division by limb was applied to define the clinical and anatomical spectrum, and surgical early and midterm outcomes. In three limbs (3%), a combination of CS and BMS was implanted: the CS was implanted for the treatment of the target iliac lesion and a short BMS across the hypogastric was used to maintain its patency; these were allocated in the CS limb group.

Treatment and definitions. Patient demographics and cardiovascular risk factors were evaluated. Operative comorbidity risk was evaluated using the Society for Vascular Surgery (SVS) comorbidity grading system[9] and the America Society of Anesthesiologist Physical Status Classification score. Chronic limb ischemia was defined by symptoms at presentation, based on the SVS/American Association for Vascular Surgery reporting standards.[10] The TASC II classification[1] was used to evaluate the extent of the iliac occlusive disease; furthermore, specific disease characteristics, such as target lesion sites, laterality, stenosis length, presence of occlusion, were evaluated. Associated femoropopliteal obstructive disease was recorded. The term "bilateral" was specifically used to classify all patients with bilateral obstructive disease requiring stenting. The term "aortic bifurcation" identified patients with occlusive disease of the distal aorta (below the inferior mesenteric artery) without complete thrombosis or bilateral proximal common iliac artery (CIA) disease.

The diagnosis of iliac obstructive disease was determined after physical examination supported by duplex ultrasound imaging or ankle-brachial index (ABI) measurements, or both; all patients underwent further imaging examinations by computed tomography (CT) scan or angiogram for diagnosis confirmation and careful evaluation of disease severity and extension. Common femoral artery (CFA) occlusive disease was classified according to CT imaging as mild (<50%), moderate (50%-74% stenosis), or severe (75%-99%) and occlusion. Endarterectomy was performed when the CFA stenosis was >50%.

Data regarding procedural details and perioperative and early postoperative (≤30 days after surgery) medical and surgical outcomes were collected. Date of the last follow-up, vital status, primary and secondary patency, and limb salvage-related information was also collected on all patients. Overall average length of follow-up was 22 months (range, 30 days-56 months), with a mean follow up of 20 months (35 ± 19 months) for CS and 31 months (42 ± 24 months) for BMS. Seventeen of 128 patients (13%) were lost during follow-up. The follow-up evaluation of patency of the treated iliac lesion included the presence of a palpable femoral pulse at physical examination, resolution of symptoms, and regular color-flow Doppler ultrasound imaging, and ABI of the iliac and femoral axis at 3, 6, and 12 months, and then yearly. Loss of patency was determined by the loss of previously palpable pulses, recurrence of symptoms, Doppler ultrasound findings of arterial stenosis, in-stent restenosis or occlusion (>50% stenosis defined as a >100% increase in the peak systolic velocity relative to the adjacent segments[10]), drop in the ABI >0.15, or a combination of these findings. Symptoms suggestive of failure or evidence of loss of patency were confirmed by CT angiogram or angiography. Primary and secondary patency and limb salvage were defined in accordance with the SVS guidelines.[11] Only major amputations, defined as at the level of the ankle or more proximal, were considered for outcomes. Survival was verified using the Padova Hospital Registry database.

Operative technique. An endovascular iliac approach was performed by members of the Vascular and Endovascular Surgery Division of Padova University. The choice of CSs vs BMSs was decided case-by-case at the discretion of the treating physician. If the artery was occluded, intraplaque or subintimal recanalization was obtained with the passage of a hydrophilic wire and catheter via an antegrade or retrograde approach; the access site was the ipsilateral CFA (68%), contralateral CFA (14%), or left brachial artery (18%). The stent covered the entire length