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Durability of iliac artery preservation associated with endovascular repair of infrarenal aortoiliac aneurysms

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ABSTRACT

Objective: This study evaluated and compared the long-term clinical outcomes of endovascular repair of infrarenal aortoiliac aneurysms (EVAR) vs EVAR with preservation of antegrade internal iliac artery (IIA) perfusion using iliac branched devices (EVAR-IBDs).

Methods: From October 1998 to August 2015, patients with infrarenal aortoiliac aneurysmal (AIA) disease at high risk for conventional open surgery were enrolled in a prospective physician-sponsored investigational device exemption trial. Clinical data of 75 patients treated with EVAR-IBD and 255 with standard EVAR were analyzed. Technical success, perioperative outcomes, mortality, device patency, endoleak rates, and reinterventions during a follow-up of 10 years were analyzed.

Results: There were 87 IBDs deployed in 75 patients. Technical success rate was 97%. Mortality at 30 days was 1.3%. Freedom from aneurysm-related mortality at 3, 5, and 10 years was 99%. Freedom from a type I or III endoleak at 3, 5, and 10 years was 99%. Freedom from secondary reinterventions at 3, 5, and 10 years was 86%, 81%, and 81%, respectively. Primary patency of the IBDs at 3, 5, and 10 years was 94%, 94%, and 77%, respectively. Twenty-four percent of patients underwent EVAR for concomitant AIA disease (EVAR-AIA), and 78% were managed by staged IIA embolization before EVAR. No statistically significant difference in freedom from aneurysm-related mortality, limb occlusions, or endoleak rates was identified in patients with EVAR-AIA vs EVAR-IBD ($P > .05$). There were significantly more secondary reinterventions in the EVAR-AIA group compared with the EVAR-IBD group (hazard ratio, 0.476, 95% confidence interval, 0.226-1.001; $P = .045$).

Conclusions: EVAR of infrarenal AIAs with preservation of antegrade flow to the IIA using IBDs is feasible with long-term sustained durability. Serious considerations should be given to the use of IBDs in patients with infrarenal AIAs meeting appropriate anatomic criteria. (J Vasc Surg 2017;■:1-9.)

Approximately 15% to 40% of abdominal aortic aneurysms are associated with aneurysmal disease of iliac artery.[1,2] Elective open repair of aortoiliac aneurysms (AIAs) carries a 4% to 6% mortality. Graft-related complications rarely occur after open repair, with reported primary patency rates of 95% to 100%.[3,4] Multiple strategies have been developed to address concomitant AIA disease during endovascular aortic aneurysm repair (EVAR). Embolization of the internal iliac artery (IIA), followed by distal extension of the endograft limb to the external iliac artery, remains the most commonly used technique. Unilateral embolization of the IIA carries a reported 26% to 41% risk of ischemic complications.[5] As a result, bell-bottomed (flared) iliac endograft limbs, parallel endografting, and branched endografts have been used to preserve antegrade IIA perfusion.

Historically, implantation of iliac branch devices (IBDs) in the United States was limited to investigational device research.[6] A commercially obtainable device has recently become available in the United States; however, long-term outcomes for these procedures are limited. The aim of this current evaluation was to examine the long-term outcomes of IBDs in patients with infrarenal AIAs. These outcomes were further compared to outcomes of patients undergoing standard infrarenal EVAR repair to assess morbidity associated with the addition of IBD to standard EVAR.

METHODS

A total of 388 patients with infrarenal AIA disease were prospectively enrolled in a physician-sponsored investigational device exemption (PS-IDE) trial beginning in October 1998 until August 2015. Enrolled patients were considered to be at high physiologic risk for conventional open surgery as determined by the operating surgeon.

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High-risk physiologic criteria, along with inclusion and exclusion criteria for enrollment, have been described previously.[7,8] All patients underwent clinical evaluation along with computed tomography angiography scans at 1 and 12 months after the procedure and yearly thereafter. This study was approved by the Institutional Review Board at the Cleveland Clinic Foundation. All patients agreed to participate in the study and signed an informed consent.

Study design and analysis. The PS-IDE trial consisted of three arms that enrolled patients undergoing EVAR of infrarenal aortic or AIAs using (1) a modular bifurcated device based on the Cook Medical (Bloomington, Ind) Zenith platform (EVAR, n = 255), (2) a custom-designed IBD by Cook Medical with different branch configurations for IIA preservation (EVAR-IBD, n = 82), or (3) an aortouni-iliac (AUI) endograft (n = 51). Patients treated with an AUI device were excluded from this analysis. Eight patients were enrolled under compassionate use (1 with an AUI endograft and 7 with EVAR-IBD) and were also excluded.

Concomitant AIA disease was present in 62 of the 255 patients undergoing EVAR (EVAR-AIA). An aneurysmal iliac artery was defined as common iliac artery >20 mm at its largest diameter (not amenable to achieving distal seal using iliac limbs manufactured by Cook Medical on indications for use). All iliac endograft limbs used for EVAR with the modular bifurcated device based on the Zenith platform were of the ESLE series by Cook Medical.

Technical details, indications for use, and design specifications of different IBDs used were described previously.[6] The previous report from our group, by Wong et al,[6] included outcomes of IBDs implanted as part of two separate PS-IDE trials that included complex thoracoabdominal aortic aneurysms repaired with fenestrated/branched endografts in combination with IBDs. As mentioned previously, this study is limited only to infrarenal AIAs.

The IBD was custom-designed and sized by four different surgeons in a modular fashion or in a bifurcated-bifurcated fashion, which was introduced later in the study (Fig 1). The bifurcated-bifurcated IBD consisted of a helical branch for the IIA integrated with a bifurcated aortic endograft constructed as a unibody device. The modular IBD consisted of two types of branch configurations for IIA perfusion, including an unsupported limb and a modified limb that was constructed with support rings within the helical branch.

All IBDs were implanted via bilateral open exposure of common femoral arteries. Device selection and techniques used to treat iliac artery aneurysmal disease was at the discretion of the operating surgeon. Because these devices were custom-designed and implanted as part of the PS-IDE, no indications for use existed at the time of the study.

Technical success was defined as deployment of the device with patent limbs free of device-related serious intraoperative adverse events. In accordance with our PS-IDE trial definitions, all deaths ≤30 days of operation were classified as aortic aneurysm-related deaths. Thus, the Kaplan-Meier analysis for aneurysm-related deaths reflects this definition. Morbidity at 30 days was defined as occurrence of myocardial infarction, stroke, acute kidney injury, respiratory failure (reintubation or pneumonia), major bleeding episode, aneurysm rupture, limb thrombosis or ischemia, or wound infection. Patency of the IBD was analyzed as a single unit. Therefore, occlusion of the external or internal iliac branch limb of IBD was evaluated similar to occlusion of the entire system.

ARTICLE HIGHLIGHTS

- **Type of Research:** Single-center prospective nonrandomized controlled study
- **Take Home Message:** Deployment of 87 iliac branched devices in 75 patients during endovascular repair of infrarenal aortic aneurysms had a technical success of 97%, low procedure-related mortality, patency of 94% at 5 years and 77% at 10 years, and better freedom from secondary interventions than a group of endovascular repair patients treated with internal iliac artery embolization.
- **Recommendation:** The authors recommend preservation of antegrade internal iliac artery flow using iliac branched devices in the treatment of aortoiliac aneurysms.

Statistics. Continuous variables are reported as mean ± standard deviation. Categoric variables are presented as number (%). Continuous variables were compared using the Student *t*-test or Wilcoxon rank sum test. *P* values are reported using the Fisher exact or χ^2 tests for comparison of categoric variables. Kaplan-Meier analysis was done for time-to-event of survival and freedom from endoleaks and secondary reinterventions per patient. The Kaplan-Meier analysis for limb patency does not take into account intrasubject correlation for the likelihood of contralateral limb occlusion. Therefore, patency of each IBD implanted was analyzed independently per device in patients with bilateral devices. A *P* value of <.05 was considered statistically significant. Unadjusted hazard ratios (HRs) were calculated using the log-rank test. Estimates of the 95% confidence interval (CI) were calculated based on exponential distribution of time-to-event measure. Statistical analysis was performed using SAS 9.4 software (SAS Institute Inc, Cary, NC).

RESULTS

From a cohort of 330 patients, 255 (77%) underwent EVAR, and 75 (23%) underwent repair with an EVAR-IBD.