Endovascular Aortic Aneurysm Repair with the Zenith Endograft in Patients with Ectatic Iliac Arteries

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Endovascular aortic aneurysm repair (EVAR) in patients with ectatic iliac arteries is feasible; however, most studies have reported experience from single institutions where distal flare techniques with endograft components were used on an ''off-label basis.'' The Zenith endovascular graft allows adequate seal in ectatic common iliac arteries (CIAs) with diameters up to 20 mm. To determine whether large or ectatic CIAs are a risk factor for early and late endograft failure, we analyzed data from the Zenith U.S. multicenter trial. Among 352 patients receiving the endograft in the Zenith u.s. clinical study, 156 patients (44%) had at least one ectatic iliac artery (maximum diameter between 14 and 20 mm), whereas 22 (6.3%) had bilateral CIAs of normal diameter (< 14 mm). Variables analyzed included those defined by the reporting standards for EVAR (SVS/AAVS) as well as iliac-related outcome and indications for secondary iliac interventions. Univariate (Kaplan-Meier [KM] receiver operating characteristics curve, and Cox regression analyses were used to determine the association between CIA diameter and iliac-related complications. The median follow-up period was 24 months. Technical success was similar (>99%) for patients with ectatic and normal CIAs. Only one late type I distal endoleak was reported and was attributed to failure of distal iliac seal in a patient with ectatic CIAs. Freedom from iliac-related secondary intervention (IRSI) was not significantly different between the groups (KM, log-rank test, $p = 0.98$) with rates at 1, 12, and 24 months of 98%, 97%, and 95% for patients with ectatic CIAs, and 100%, 95%, and 95% for patients with normal iliac arteries, respectively. Moreover, Cox regression analysis revealed that the maximum CIA diameter was not a significant predictor of freedom from IRSI (hazard ratio, 0.98; 95% confidence interval, 0.7-1.4; $p = 0.98$). In patients with large CIAs, indications for IRSI included distal type I endoleak (1, 0.6%), type III endoleak (1, 0.6%), graft limb occlusion (4, 2.6%), and device stenosis (1, 0.6%). The only IRSI in a patient with normal CIAs was performed for device stenosis (4.6%). In conclusion, the Zenith endograft is effective for EVAR in patients with ectatic CIAs. Moreover, the presence of large CIAs was not associated with an increased risk of adverse iliac-related outcome or subsequent IRSI. Long-term surveillance, however, is mandatory, as IRSIs may be necessary.

INTRODUCTION

The Cook Zenith AAA endovascular graft (endograft) was approved for endovascular aneurysm repair (EVAR) of abdominal aortic aneurysms (AAA) by the United States Food and Drug Administration (FDA) in 2003. An FDA pivotal study entitled the Zenith US. multicenter trial, be-

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gun in January 2000 to assess the safety and effectiveness of the Zenith endograft prior to its approval.[1] Of note, the Zenith endograft was the first available and now approved device with designed components that allow adequate seal in ectatic common iliac arteries (CIAs) with diameters up to 20 mm.[2] The U.S. Clinical study data submitted for revision by the FDA's Circulatory System Devices Panel included patients with iliac artery distal fixation sites >10 mm in length and 7.5 to 20 mm in diameter (measured outer wall to outer wall).[1] However, stratified analyses including only patients with ectatic iliac arteries, i.e., CIAs with a >14 mm but <20 mm, have not been performed.

Before approval of the Zenith endograft, available endografts did not allow distal implantation with adequate seal in CIAs larger than 14 mm. There were then only two possibilities for EVAR in patients with ectatic CIAs. One option included extension of the endograft into a smaller external iliac artery (EIA), which required coil embolization of the ipsilateral hypogastric artery (HA).[3-6] The second option became known as the "bell-bottom" technique,[7] in which large-diameter stent grafts, usually aortic extension cuffs, are used to achieve adequate distal seal in ectatic CIAs.[8] Several single-center studies showed that this technique was safe and effective, although follow-up was limited.[7-9] The main concern with this technique was the possible subsequent enlargement of the ectatic CIAs that could result in distal seal failure, thereby increasing the risk of distal attachment site endoleaks, leg endograft migration, and aneurysm rupture.

The aim of this study was to evaluate the outcome of patients with ectatic CIAs who have undergone EVAR with the Zenith endograft. For this purpose, stratified analyses of data collected for the Zenith U.S. multicenter trial were performed to determine endograft failure related to the presence of ectatic CIAs.

METHODS

Among 352 patients who underwent EVAR with the Zenith endograft and were enrolled at 15 centers within the United States, 178 patients (51 %) had bilateral CIAs with a maximum diameter ≤ 20 mm. Iliac artery ectasia was defined according to the reporting standards and was defined as a maximum diameter of the CIA >14 mm and < 20 mm.[10] Patients with CIA aneurysms extending into the origin of the internal iliac artery, i.e., CIAs with diameter larger than 20 mm (n = 174), were not included in this study. In these instances aneurysmal CIAs were excluded from the arterial circulation through iliac leg extensions with distal fixation sites at the level of EIAs of normal diameter.

The Zenith device description and information about the study design, procedural techniques, and follow-up have been described in detail before.[1,2] Briefly, a prospective, nonrandomized, case-control study was performed to compare conventional open repair of AAAs with EVAR in patients who would otherwise be candidates for open surgical aneurysm repair. Two additional study arms included high-physiologic risk patients and roll-in patients treated with the Zenith endograft, whose data were processed in a registry format. Patient clinical and procedural characteristics as well as follow-up results of all patients undergoing EVAR with the Zenith endograft at 15 centers within the United States were prospectively collected. Clinical characteristics and demographic information, imaging and procedure-related data, and follow-up data were prospectively collected. Imaging information was analyzed at an assigned core laboratory (The Cleveland Clinic foundation, Cleveland, OH), whereas clinical events were interpreted by a clinical events committee (Harvard Clinical Research Institute, Boston, MA). Institutional review board approval for the trial and informed consent from each patient were required and obtained at all participating centers.

Iliac leg endografts used in the U.S. clinical study required iliac artery distal fixation sites >10 mm in length and 7.5-20 mm in diameter (measured outer wall to outer wall). Device diameters were oversized by 10% to 15% larger than the measured arterial diameter. Bilateral hypogastric preservation was attempted in all cases, but unilateral hypogastric patency was always mandatory. A compliant balloon was used for sequential inflations at the distal attachment sites.

Clinical evaluation, computed tomography (CT) scan, and four-view abdominal radiography were obtained at the time of discharge and 30 days, 6 months, 12 months, and yearly thereafter. CT scans were evaluated to determine maximum aneurysm diameter, migration of the endograft components, patency of the hypogastric arteries, and presence of distal attachment site endoleaks. For the purpose of this study, outcome variables and changes in aortic aneurysms were defined according to the current EVAR reporting standards prepared and revised by the Ad Hoc Committee for Standardized Reporting Practices in Vascular Surgery (SVS/AAVS).[11,12]

Descriptive statistics for categorical variables are presented as relative frequencies (percent). Univariate analysis of categorical variables was per-