CLINICAL STUDY

A Decade of Outcomes and Predictors of Sac Enlargement after Endovascular Abdominal Aortic Aneurysm Repair Using Zenith Endografts in a Japanese Population

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ABSTRACT

Purpose: To present 10-year outcomes and risk factors for sac enlargement after endovascular aneurysm repair (EVAR) using the Zenith AAA Endovascular Graft (Cook, Inc, Bloomington, Indiana) in a Japanese population.

Material and Methods: During the period 1999–2011, 127 patients underwent elective EVAR using Zenith endografts at a single institution. A retrospective investigation looked at initial rates of technical success and complications, 10-year rate of freedom from all-cause and aneurysm-related mortality, freedom from secondary intervention and sac enlargement, and risk factors for second intervention and sac enlargement.

Results: The median age of the patients was 78 years, and the median follow-up time was 43 months. The initial technical success rate was 98.4% (125 of 127 patients). Major adverse events occurred in 7 of 127 (5.5%) patients. Rates of freedom from all-cause and aneurysm-related mortality at 1, 3, 5, and 10 years were 95%, 87%, 77%, and 39% (all-cause mortality) and 100%, 100%, 99%, and 93% (aneurysm-related mortality). Rates of freedom from secondary intervention at 1, 3, 5, and 10 years were 97%, 91%, 88%, and 70%. Rates of primary freedom from sac enlargement at 1, 3, 5, and 10 years were 99%, 87%, 75%, and 67%. Multivariate analysis revealed aneurysm sac diameter as an independent risk factor for a secondary intervention. Preoperative sac diameter combined with an angulated short (AS) proximal neck was a risk factor for sac enlargement.

Conclusions: The 10-year results of EVAR using Zenith endografts in a Japanese population were comparable to results from Western countries. Larger aneurysms and AS neck were predictors of sac enlargement after EVAR.

ABBREVIATIONS

AAA = abdominal aortic aneurysm, AR = angulated and reverse, AS = angulated and short, CIA = common iliac artery, EIA = external iliac artery, EVAR = endovascular aneurysm repair

The Zenith AAA Endovascular Graft (Cook, Inc, Bloomington, Indiana) for treatment of abdominal aortic aneurysm (AAA) was the first stent graft to be introduced into Japan. This graft consists of three modular devices with suprarenal fixation. A few articles have described the long-term outcomes after EVAR using Zenith endografts (1–3), but these studies did not target Asian populations. Several articles have described anatomic differences between Asian and Western populations, such as a shorter common iliac artery (CIA) and a higher prevalence of infrarenal neck angulation among Asians (4–8). Various studies in Western countries have evaluated the effects of hostile neck features on outcomes after EVAR. Some studies have associated infrarenal neck angulation with type Ia endoleaks or sac enlargement (9,10), whereas others have found an association between a short proximal neck and type Ia endoleaks (11). However, none of these studies have evaluated the impact of coexisting hostile neck features,

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such as infrarenal angulation with a short neck, which might further adversely affect outcomes. The present study assesses the long-term outcomes of EVAR using Zenith endografts in a Japanese population, focusing on the impact of proximal neck anatomic features and combinations.

MATERIALS AND METHODS

Patients

Between July 1999 and August 2011, 127 patients underwent elective EVAR with Zenith endografts. This was a retrospective review of prospectively collected clinical follow-up and imaging data and did not require institutional review board approval according to our institutional guidelines. All patients provided written informed consent to participate in all procedures associated with the study. The median age of patients was 78 years (range, 55–91 y), and the median follow-up time was 43 months (range, 3–143 mo). **Table 1** summarizes patient demographics.

The inclusion criteria for EVAR at our vascular center were (*a*) aneurysm sacs > 50 mm or sac > 40 mm with iliac artery aneurysms > 35 mm on the minor axis of the maximal aneurysm plane, (*b*) an increase in sac diameter of 5 mm within 6 months, or (*c*) saccular aneurysms of any size. Exclusion criteria were (*a*) circular thrombus or extensive calcification in the proximal neck, (*b*) proximal neck diameter > 30 mm, and (*c*) proximal neck length < 10 mm. Patients with isolated iliac or ruptured aneurysms were not included in this study.

Procedures and Hospital Stay

A team of interventional radiologists and vascular surgeons performed all EVAR procedures in an angiography suite using a fixed fluoroscopic unit. All patients received local anesthesia with conscious sedation. Access was achieved through cutdown of the bilateral femoral arteries.

Table 1. Patient Demographics and Clinical Factors

	No. (%)
No. patients	127
Age (y)	77 ± 6
Female	11 (9)
Comorbidities	
Diabetes mellitus	17 (13)
Hypertension	62 (49)
Hyperlipidemia	28 (22)
Coronary artery disease	43 (34)
Cerebrovascular disease	18 (14)
Chronic renal failure*	23 (18)
Smoking	42 (33)

*Serum creatinine > 1.5 mg/dL.

Image Acquisition and Follow-up

The follow-up protocol included a clinical examination, measurement of ankle-brachial index, biplanar plain abdominal radiography (anteroposterior and lateral projections), and nonenhanced arterial and delayed venous phase contrast-enhanced computed tomography (CT). Follow-up of patients using these modalities was usually performed at 1 week, 6 months, and 12 months after the procedures and annually thereafter. The origin of any type I or type III endoleaks and sac enlargement > 5 mm determined by contrast-enhanced CT were confirmed by digital subtraction angiography. Type II endoleaks were evaluated with digital subtraction angiography only when the aneurysmal sac enlarged > 5 mm.

Definition

Aneurysm morphology, technical success, change in aneurysm size, and complications were defined according to the reporting standards suggested by the Society for Vascular Surgery (12). In brief, we measured the minor axis of the maximal aneurysm plane on axial images of aneurysm sacs. A change in diameter of ≥ 5 mm from the first set of postoperative values determined from imaging was considered significant. Neck length, neck diameter, and aortic angulation were assessed for planning EVAR using an Aquarius-NetStation three-dimensional workstation (TeraRecon, Foster City, California). A hostile neck was defined as having one or more of the following four features: short neck, length 10–15 mm; infrarenal angulation, angle > 60 degrees; wide neck, neck diameter > 28 mm; and reverse taper. A reverse taper neck was defined as a proximal neck with gradual dilation of ≥ 2 mm within the first 10 mm below the lowest renal artery (13). A friendly neck was defined as having no hostile neck features. Infrarenal angulation combined with a short or a reverse taper neck was defined as angulated and short (AS) and angulated and reverse (AR), respectively (**Fig 1**), and a short neck combined with a reverse taper neck was defined as short and reverse. Stent graft migration was defined as > 10 mm downward displacement of the device. Significant kinking was defined as graft kinking that caused > 50% stenosis or ischemic limb symptoms. The treating physicians obtained all CT measurements.

Primary technical success was defined as successful access and deployment at the intended position without type I or III endoleaks, significant kinking, obstruction of flow, or a need for open conversion (12). An unplanned additional endovascular procedure, such as placement of an extra-large PALMAZ bare metal stent (Cordis Endovascular, Warren, New Jersey) or the need for unplanned main body extension to achieve aneurysm exclusion, was defined as an assisted primary technical success. Primary freedom from sac growth was defined as sac shrinkage or no change without additional

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