Anatomic Suitability of Aortoiliac Aneurysms for Next Generation Branched Systems

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Background: Preservation of internal iliac flow is an important consideration to prevent ischemic complications during endovascular aneurysm repair. We sought to determine the suitability of aortoiliac aneurysms for off-the-shelf iliac branched systems currently in clinical trial.
Methods: Patients undergoing abdominal aortic aneurysm repair from 2004 to 2013 at 2 institutions were reviewed. Centerline diameters and lengths of aortoiliac morphology were measured using three-dimensional workstations and compared with inclusion/exclusion criteria for both Cook and Gore iliac branch devices.
Results: Of the nearly 2,400 aneurysm repairs performed during the study period, 99 patients had common iliac aneurysms suitable for imaging review. Eighteen of the 99 (18.2%) patients and 25/99 (25.3%) patients fit the inclusion criteria and would have been able to be treated using the Cook and Gore iliac branch devices, respectively. The most common reason for exclusion from Cook was internal iliac diameter of <6 or >9 mm (68/99, 68.7%). The most common reason for exclusion from Gore was proximal common iliac diameter of <17 mm (39/99, 39.4%) and inadequate internal iliac artery diameter of <6.5 or >13.5 mm (37/99, 37.3%). Comparing the included patients across both devices, a total of 35/99 (35.4%) of patients would be eligible for the treatment of aortoiliac aneurysms based on anatomic criteria.
Conclusions: Only 35% of the aneurysm repairs involving common iliac arteries would have been candidates for the 2 iliac branch devices currently in trial based on anatomic criteria. The major common reason for exclusion is the internal iliac landing zone for both devices. Design modifications for future generation iliac branch technology should focus on diameter accommodations for the hypogastric branch stent and proximal and distal sizes of the iliac branch components. Familiarity with alternate branch preserving techniques is still needed in the majority of cases.

INTRODUCTION

Successful treatment of aortoiliac aneurysms involves branch vessel preservation and long-term protection from rupture. While endovascular aneurysm repair (EVAR) has eclipsed open surgery because of lower operative mortality and morbidity in anatomically suitable patients,[1–4] the durability of EVAR has been questioned because of the need for additional graft-related interventions and increase incidence of late aneurysm-related complications.[5,6] Long-term failure can occur because of the loss of seal at the proximal or distal attachment sites. In fact, Schanzer et al.[7] demonstrated that common iliac diameter of >20 mm was an independent predictor of late sac enlargement, as was use of the device outside the manufacturer's instructions for use (IFU). Furthermore, Benharash et al.[8] have demonstrated that iliac fixation is important in preventing late graft migration regardless of proximal attachment type.

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Table I. Summary of anatomic sizing criteria based on CT reconstruction for the 2 trials

Cook IBD exclusions	Gore IBE exclusions
CIA length <50 mm	Aorta-hypogastric length <165 or CIA length <40 mm
CIA diameter <20 mm	CIA diameter <25 mm
EIA length <20 mm	Proximal CIA diameter <17 mm
EIA diameter <8 mm	Distal CIA diameter <14 mm
IIA occluded or >50% stenosis	EIA length <10 mm
IIA aneurysm distal to landing zone	EIA diameter <6.5 or >25 mm
IIA length <10 mm	IIA length <10 mm
IIA diameter <6 or >9 mm	IIA diameter <6.5 or >13.5 mm

CIA, common iliac artery; EIA, external iliac artery; IIA, internal iliac artery or hypogastric.

The incidence of iliac artery involvement in abdominal aortic aneurysms (AAAs) is estimated at 20–30%.[9,10] Hence, nearly a third of all patients presenting with AAAs for repair might not fit within the IFU for standard EVAR device based on iliac diameters. A common approach to ensure appropriate landing zone for iliac components of endografts involves extension into the external iliac artery, with or without concomitant hypogastric artery embolization and coverage. While unilateral coiling has been demonstrated to have relatively low rates of complication,[11] sacrifice of the hypogastric artery, especially bilaterally, can have devastating sequelae including buttock claudication (28–42%), impotence (17–24%), colonic ischemia (3.4%), and spinal cord ischemia (0.1–0.3%).[12]

Given the significant morbidity associated with these complications, industry has developed branch technology for hypogastric preservation. The approval process in the United States has been slow, however, and several hypogastric preserving techniques have been developed in the interim. These include surgical correction of the iliac bifurcation,[13] surgeon-modified iliac stent graft components,[14] aortouni-iliac endografting with contralateral external iliac to hypogastric artery stent graft,[15] double barrel/snorkel/sandwich parallel endografts,[16–18] and trifurcated endografts.[19] While innovative, these techniques are, by definition, outside the IFU for current endograft technology and the long-term implications of utilizing components in such a manner is not known. Furthermore, they require unique endovascular equipment and techniques that are not available to most practices.

In response to the need to extend EVAR beyond the iliac bifurcation in up to 30% of patients, 2 iliac branched devices are currently being studied in pivotal trials in the United States. Several anatomic restrictions potentially limit wide applicability of these devices, and we sought to understand the impact of these 2 devices in contemporary practice. The purpose of this study was to evaluate the anatomic characteristics of aortoiliac aneurysms at 2 large academic practices and assess the suitability of these ''off-the-shelf'' systems being studied in clinical trials.

PATIENTS AND METHODS

Patients

Institutional review board approval was gained at both Stanford University and the University of Alabama at Birmingham to query prospective vascular databases for cases of EVAR requiring extension into the external iliac artery. Each patient included in the study must needed to have one preoperative computed tomography (CT) scan amenable to three-dimensional reconstruction.

Anatomic Measures

The inclusion/exclusion criteria (Table I) of the Gore Excluder (W. L. Gore & Associates, Flagstaff, AZ) Iliac Branch Endoprosthesis Trial (Gore IBE) and the Cook (Cook Medical, Inc., Bloomington, IN) Preserve-Zenith Iliac Branch Device Clinical Study (Cook IBD) were used to generate our anatomic measurements as depicted in Figure 1. All anatomic measurements were performed on AquariusNET™ Client or TeraRecon Workstation (TeraRecon, Inc., Foster City, CA) and maintained in an Excel (Microsoft, Inc., Redmond, WA) spreadsheet.

Automatic centerlines were utilized when CT angiography (CTA) were available. When only noncontrast scans were available, thin-cut CTs were used to create centerlines by hand. Distinct centerlines were created for each of the following: (1) aorto-external iliac bilaterally and (b) aorto-internal iliac bilaterally. Lengths and diameters were derived from these centerline measures. The measurements were performed and verified by the