Clinical application and early outcomes of the aortouni-iliac configuration for endovascular aneurysm repair

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Objective: **The objective of this study was to review the current anatomic indications for and early results of aortouni-iliac (AUI) devices for endovascular aneurysm repair.**

Methods: **A total of 128 patients receiving an Endurant (Medtronic Inc, Minneapolis, Minn) AUI device in the U.S. Investigational Device Exemption trial (44 patients) or the Endurant Stent Graft Natural Selection Global Postmarket Registry (84 patients) were reviewed. Preoperative computed tomography imaging of patients in the Investigational Device Exemption trial and case report forms of Registry patients were used to determine anatomic indications. Baseline characteristics and early results were compared with those of 1305 patients receiving a bifurcated (BIF) device in sister studies.**

Results: **The indication for the AUI device was unclear from case report forms in two Registry cases. The remaining 126 patients had a unilateral iliac occlusion in 30 (23%), a severely narrowed aortic segment in 58 (45%), severe iliac occlusive disease in 28 (22%), severe iliac tortuosity in 29 (23%), or complex iliac aneurysms in 19 (15%). Two patients had a previous aortobifemoral graft; 38 patients (30%) had multiple indications. The AUI cohort included more women than the BIF group did (19% vs 10%; $P < .01$) and had more severe comorbidities. Successful deployment was achieved in all AUI cases. The 30-day mortality was 2% (BIF cohort, 1%; $P = .21$). More AUI patients underwent repair under general anesthesia (81% vs 64%; $P < .01$), and procedures were longer (110.9 ± 54.9 minutes vs 99.2 ± 44.3 minutes; $P = .02$). Except for longer intensive care unit stays (19.6 ± 80.0 hours vs 9.0 ± 34.8 hours; $P = .01$) and higher myocardial infarction rates (4% vs 1%; $P < .01$), outcomes of the AUI cohort were similar to those of the BIF cohort. There were no migrations, ruptures, fractures, or open conversions at up to 1-year follow-up.**

Conclusions: **The AUI configuration extends endovascular aneurysm repair feasibility to several hostile anatomic conditions. Despite increased comorbidities in the recipient patient population and associated higher rates of postoperative myocardial infarction and respiratory complications, early outcomes with the new generation of AUI devices are acceptable and comparable to those after treatment with BIF configurations. (J Vasc Surg 2014;60:1452-9.)**

Despite considerable early benefits over open surgical procedures, endovascular aneurysm repair (EVAR) does not apply to all patients and is limited to abdominal aortic aneurysms (AAAs) with defined anatomic requirements. The majority of EVAR procedures are performed with bifurcated (BIF) devices with limbs into both iliac arteries. The use of an aortouni-iliac (AUI) configuration in conjunction with a femorofemoral crossover graft has been advocated intermittently for hostile and complex distal aortic and iliac anatomy as well as for ruptured aneurysms and salvage of some BIF graft complications. There is a paucity of clinical information, however, about the application and outcomes of elective AAA repair with an AUI device, in part owing to the lack of a specifically designed and approved endograft for this configuration in the last decade. The last approved AUI device in the United States, part of the Ancure (Guidant, Menlo Park, Calif) endograft family, was distributed for only 2 years before being withdrawn in 2004 as the company abandoned the AAA market.[1] In recent years, the Zenith Renu (Cook Medical, Bloomington, Ind) stent graft was developed to salvage migrated endografts but has been used more liberally in the repair of aortic and iliac aneurysms.[2] The recent introduction of the Endurant AUI stent graft (Medtronic Inc, Minneapolis, Minn) for the management of AAA provides the opportunity to re-examine this approach and its place in our modern treatment strategy through data from the U.S. Investigational Device Exemption (IDE) trial and the Endurant Stent Graft Natural Selection Global Postmarket Registry (ENGAGE).

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METHODS

Study population. The U.S. IDE trials of the Endurant system enrolled patients at 26 U.S. centers, leading to the U.S. Food and Drug Administration approval of the BIF device in December 2010 and of the AUI device in April 2013. The international Global Postmarket ENGAGE Registry initiated in March 2009 is prospectively enrolling patients treated with an Endurant endograft in real-world practice from 79 sites in more than 30 different countries.[3] These studies were sponsored by the device manufacturer as is standard practice for IDE studies and postmarket registries. This review included all patients receiving an Endurant AUI stent graft in either the IDE or ENGAGE cohorts. Baseline characteristics and results were compared with those of patients receiving the BIF device in the same studies. The same comorbidity and outcome data points were used uniformly across all cohorts.

Clinical data were obtained from audited clinical research forms collected by the sites. The research team at each site determined the presence or absence of a specific background disease state on the basis of the medical history and physical examination findings obtained at study enrollment. All preoperative computed tomography scans of IDE AUI patients stored at a core laboratory and all case report forms of Registry patients were reviewed to determine anatomic indications for AUI device use. Outcomes at 30-day and 1-year follow-up were collected. All sites obtained Investigational Research Board (IRB) approval before participation or, in the case of 16 ENGAGE sites, provided a written statement that they had confirmed with their IRB that neither approval nor notification was needed. All subjects gave informed consent, approved by the IRB.

Clinical measures. Baseline characteristics included demographic factors as well as American Society of Anesthesiologists (ASA) classification and Society for Vascular Surgery/International Society for Cardiovascular Surgery risk classification.[4,5] Procedural data included preimplantation adjunctive procedures as well as the type of anesthesia used, estimated periprocedural blood loss, volume of contrast material used, total fluoroscopy time, and technical measures of device deployment. Clinical results were recorded at 30 days and 1 year, including mortality, major adverse events, presence and type of endoleaks, stent graft kinking/occlusion, conversion to open surgery, aneurysm rupture, and secondary procedures. Major adverse events for the purposes of a safety end point were defined as death, bowel ischemia, myocardial infarction, paraplegia, procedural blood loss >1000 mL, renal failure, respiratory failure, and stroke.

Detailed data on femoral-to-femoral bypass grafts were not recorded consistently in the ENGAGE Registry. Complications of femoral-to-femoral bypass grafts and reinterventions were reported in the IDE study as procedure-related complications.

Anatomic indications. The indications for AUI device use were categorized as follows: unilateral iliac occlusion, severe iliac occlusive disease, severe iliac tortuosity, complex iliac aneurysms, or severely narrow or calcified aortic segment precluding deployment of two iliac limbs (Fig, *A-D*). Unilateral iliac occlusion was defined as a complete occlusion of either the common or external iliac segment or both. Severe iliac occlusive disease and severe iliac tortuosity were defined as stenosis or tortuosity that limits the safe passage of delivery sheaths. Complex iliac aneurysms were defined as those that are multiple and large with no suitable landing zones in the common iliac arteries on both sides. A severely narrow or calcified aortic segment was defined as a distal aortic diameter <16 mm for more than 1 cm in length, precluding the safe deployment of two iliac limbs.

Statistical analysis. Statistical analyses were performed with Stata 12 (StataCorp, College Station, Tex). Continuous variables are reported as means ± standard deviation and were compared by the Student *t*-test or Mann-Whitney *U* test; categorical data were reported as a percentage and compared by χ^2 tests. Statistical significance was assumed at $P < .05$. *P* values were not adjusted for multiple testing because the tests for each of the outcomes were planned analysis to test the research hypothesis set a priori.

RESULTS

Of the 128 AUI device patients (mean age, 73.7 ± 7.9 years), 44 were enrolled in the U.S. IDE trial and 84 in the ENGAGE Registry; these patients were compared with 1305 BIF device patients (mean age, 73.1 ± 8.1 years). The U.S. IDE trial enrolled 150 patients, and the Global Postmarket ENGAGE Registry enrolled 1155 patients.

Anatomic indications. The IDE studies do not provide a good estimate of how often an AUI device was needed as the denominators are not known. However, with all configuration options available in the ENGAGE Registry, an AUI configuration was selected in 7% of patients on the basis of anatomic considerations (84 of 1239 patients).

The indication for the AUI device was unclear from case report forms in two Registry cases. The remaining 126 patients had a unilateral iliac occlusion in 30 (23%), a narrow aortic segment in 58 (45%), severe iliac occlusive disease in 28 (22%), severe iliac tortuosity in 29 (23%), or iliac aneurysms in 19 (15%). Two patients had a previous aortobifemoral graft without iliac occlusions, and 38 (30%) had multiple indications (Table I).

Demographics. Baseline characteristics of the AUI group of patients compared with the BIF group are in Table II. The patients were similar in age, but the AUI cohort included significantly more women (19% vs 10%; $P < .01$) and had more severe comorbidities, including an increased incidence of cardiac disease, chronic obstructive pulmonary disease, carotid artery disease, cerebrovascular disease, and peripheral vascular disease. More patients in the AUI cohort were also classified as ASA class 4 and Society for Vascular Surgery 3 than in the BIF cohort (23% vs 9%, $P < .01$, and 42% vs 34%, $P = .09$, respectively).