From the Eastern Vascular Society

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).

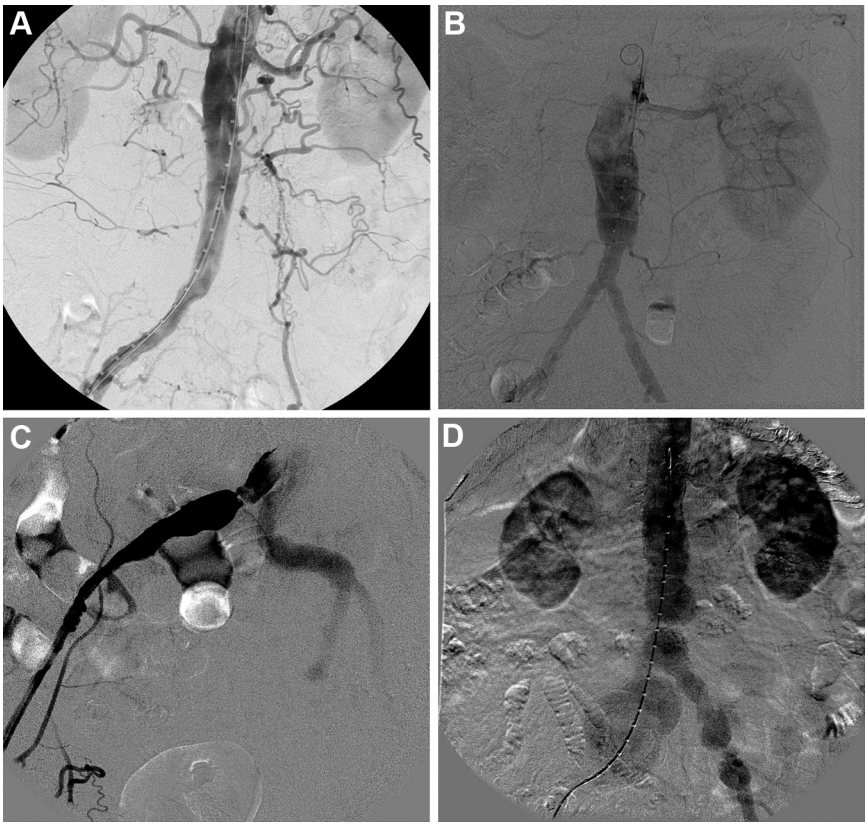

Fig. A, Unilateral iliac occlusion. **B,** A severely narrowed aortic segment. **C,** Severe iliac occlusive disease. **D,** Complex iliac aneurysms.

Table I. Anatomic indications for aortouni-iliac (*AUI*) device use

Indications for AUI device use	*N = 128, No. (%)*
Unilateral iliac occlusion	30 (23)
Narrow aorta	58 (45)
Severe iliac occlusive disease	28 (22)
Severe iliac tortuosity	29 (23)
Iliac aneurysm	19 (15)
Multiple indications	38 (30)

Procedures. Procedural data are summarized in Table III. Successful deployment was achieved in all AUI cases, but duration of total implantation time, including both fluoroscopy and femoral-femoral bypass, was significantly longer than for BIF cases (110.9 ± 54.9 minutes vs 99.2 ± 44.3 minutes; $P = .02$). A greater percentage of AUI patients underwent repair under general anesthesia compared with the BIF patients (81% vs 64%; $P < .1$). Intraoperative blood loss was higher for the AUI group (247.8 ± 259.6 mL vs 204.2 ± 210.0 mL; $P < .01$), although the absolute difference of less than 50 mL did not appear to be clinically significant.

Detailed data on femoral-to-femoral bypass grafts were not recorded consistently in the ENGAGE Registry. In the IDE study, one patient had a pre-existing femoral-to-femoral bypass graft, whereas all others had a new bypass as part of the procedure. In the IDE trial, no adverse events directly attributable to the femoral-to-femoral grafts were reported in the first 12 months.

Outcomes. Table IV summarizes the 30-day and 1-year outcomes. Mean hospital days were comparable between the two groups. However, AUI patients spent more time in the intensive care unit than BIF patients did (19.6 ± 80.0 hours vs 9.0 ± 34.8 hours; $P = .01$). Overall 30-day mortality was 2%, which was not different from the BIF mortality of 1% ($P = .21$). Except for higher myocardial infarction and respiratory failure rates, 30-day outcomes of the AUI cohort were similar to those of the BIF cohort.

At 1 year, aneurysm-related mortality was only 2% (two of 128) for the AUI cohort. Overall mortality illustrating the high systemic disease burden in these patients was 11%, however, which was still comparable to that of the BIF group (7%; $P = .10$). The bowel ischemia rate in the AUI group was 2% compared with <1% in patients who received a BIF graft ($P = .03$). This may be related to more vascular disease and more complex iliac anatomy and internal iliac artery exclusions in the AUI group. Similarly, the myocardial infarction rate at 1 year was 6% in the AUI group compared with 2% in the BIF cohort. There

Table II. Baseline demographics and comorbidities

	AUI group (n = 128)	*BIF group (n = 1305)*	P *value*
Demographics			
Female	19% (24/128)	10% (131/1305)	<.01
Mean age ± SD, years	73.7 ± 7.9	73.1 ± 8.1	.42
Baseline comorbidities			
Tobacco use	52% (66/127)	49% (622/1275)	.49
Hypertension	82% (103/126)	76% (985/1290)	.18
Hyperlipidemia	74% (92/124)	63% (781/1235)	.01
Diabetes mellitus	24% (31/127)	20% (251/1288)	.19
Cancer	21% (26/126)	21% (275/1287)	.83
Alcoholism	7% (9/127)	4% (45/1272)	.04
Cardiac disease	65% (83/128)	53% (689/1304)	.01
Myocardial infarction	40% (49/123)	26% (327/1259)	<.01
Arrhythmia	27% (34/127)	19% (243/1278)	.04
Angina	29% (37/127)	15% (192/1279)	<.01
Congestive heart failure	9% (12/127)	7% (90/1273)	.34
Coronary artery disease	60% (73/122)	36% (458/1267)	<.01
Chronic obstructive pulmonary disease	50% (62/125)	26% (332/1287)	<.01
Renal insufficiency	20% (25/127)	15% (189/1295)	.13
Carotid artery disease	27% (30/113)	12% (134/1113)	<.01
Cerebrovascular/neurologic disease	21% (27/128)	15% (189/1304)	.05
Transient ischemic attack	7% (9/127)	5% (63/1293)	.28
Cerebrovascular accident	5% (6/127)	5.9% (77/1299)	.58
Vascular disease	73% (93/128)	37% (484/1304)	<.01
Previous AAA	6% (7/128)	1% (13/1298)	<.01
Previous TAAA	1% (1/123)	2% (23/1255)	.18
Peripheral vascular disease	49% (61/125)	18% (233/1290)	<.01
ASA classification			
Class 1	4% (5/128)	6% (75/1304)	.37
Class 2	19% (24/128)	44% (570/1304)	<.01
Class 3	55% (70/128)	42% (548/1304)	<.01
Class 4	23% (29/128)	9% (111/1304)	<.01
SVS/ISCVS classification			
SVS 0	1% (1/122)	0.0% (0/1265)	<.01
SVS 1	10% (12/122)	14% (182/1265)	.16
SVS 2	48% (58/122)	52% (652/1265)	.40
SVS 3	42% (51/122)	34% (431/1265)	.09

AAA, Abdominal aortic aneurysm; *ASA,* American Society of Anesthesiologists; *AUI,* aortouni-iliac; *BIF,* bifurcated; *ISCVS,* International Society for Cardiovascular Surgery; *SD,* standard deviation; *SVS,* Society for Vascular Surgery; *TAAA,* thoracoabdominal aortic aneurysm.

Table III. Procedural results

Operative results	*AUI group (n = 128)*	*BIF group (n = 1305)*	P *value*
Preimplantation coil embolization of hypogastric artery	6% (8/128)	4% (53/1305)	.24
Duration of implant time ± SD, minutes	110.9 ± 54.9	99.2 ± 44.3	.02
General anesthesia	81% (103/128)	64% (828/1304)	<.01
Estimated blood loss ± SD, mL	247.8 ± 259.6	204.2 ± 210.0	<.01
Volume of contrast material ± SD, mL	123.5 ± 59.8	132.0 ± 69.6	.19
Fluoroscopy time ± SD, minutes	19.9 ± 19.3	21.2 ± 12.3	.29
Freedom from intraoperative death	100% (128/128)	100% (1305/1305)	NA
Freedom from type I/III endoleak	96% (123/128)	99% (1290/1300)	<.01
Stent graft kinking	0% (0/128)	1% (13/1297)	.26
Stent graft twisting	0% (0/128)	1% (7/1296)	.42
Conversion to open surgery	0% (0/128)	0% (2/1305)	.61
Aneurysm rupture	0% (0/128)	0% (1/1305)	.75

AUI, Aortouni-iliac; *BIF,* bifurcated; *NA,* not applicable; *SD,* standard deviation.

were no migrations, ruptures, fractures, or open conversions up to 1 year.

No statistically significant differences were seen in 30-day and 1-year endoleak rates among the graft configurations. Both groups had comparable rates of secondary endovascular procedures at 30 days and 1 year. No reinterventions were required for any of the femoral-to-femoral bypass grafts in the IDE study up to 1 year. The total AUI cohort's secondary endovascular reintervention rates were 2% at 30 days and 8% at 1 year (Table V). This was similar to the BIF cohort's rate of 5% ($P = .19$).

Table IV. The 30-day and 1-year outcomes

	AUI group (n = 128)	*BIF group (n = 1305)*	P *value*
Thirty-day outcomes			
Mean hospital stay ± SD, days	6.2 ± 6.7	5.9 ± 6.3	.61
Mean ICU stay ± SD, hours	19.6 ± 80.0	9.0 ± 34.8	.01
Mortality	2% (3/128)	1% (14/1305)	.21
Bowel ischemia	1% (1/128)	0% (4/1305)	.36
Myocardial infarction	4% (5/128)	1% (13/1305)	<.01
Paraplegia	0% (0/128)	0% (0/1305)	NA
Procedural blood loss >1000 mL	3% (4/128)	1% (17/1305)	.11
Renal failure	1% (1/128)	0% (4/1305)	.36
Respiratory failure	2% (2/128)	0% (2/1305)	<.01
Stroke	1% (1/128)	0% (4/1305)	.53
Endoleaks	14% (17/119)	12% (150/1209)	.56
Conversion to open surgery	0% (0/128)	0% (1/1305)	.72
Aneurysm rupture	0% (0/128)	0% (0/1305)	NA
Secondary endovascular procedure	2% (3/128)	1% (17/1305)	.36
One-year outcomes			
All-cause mortality	11% (14/128)	7% (91/1305)	.10
Bowel ischemia	2% (2/123)	0% (4/1290)	.03
Myocardial infarction	6% (7/123)	2% (23/1289)	<.01
Paraplegia	0% (0/122)	0% (0/1289)	NA
Procedural blood loss >1000 mL	3% (4/123)	2% (19/1289)	.14
Renal failure	2% (3/123)	1% (16/1289)	.27
Respiratory failure	4% (5/124)	0% (4/1290)	<.01
Stroke	2% (2/123)	1% (11/1290)	.39
Stent graft migration	0% (0/127)	0% (1/1289)	.75
Stent graft occlusion	3% (4/127)	3% (43/1289)	.91
Stent graft kinking	2% (3/127)	2% (27/1289)	.84
Endoleaks	7% (9/121)	9% (112/1290)	.64
Conversion to open surgery	0% (0/128)	1% (7/1305)	.42
Aneurysm rupture	0% (0/128)	0% (3/1305)	.59
Secondary endovascular procedure	8% (10/128)	5% (67/1305)	.19
AAA diameter decrease	46% (45/99)	42% (416/996)	.48

AAA, Abdominal aortic aneurysm; *AUI,* aortouni-iliac; *BIF,* bifurcated; *ICU,* intensive care unit; *NA,* not applicable; *SD,* standard deviation.

Table V. Secondary endovascular procedure details of aortouni-iliac (*AUI*) cohort

Subject ID	*Date of initial implant*	*Date of secondary procedure*	*Time to secondary procedure, days*	*Reason for secondary procedure*	*Group*
15009-002	2010-01-07	2010-01-14	7	Stent graft kink	AUI (ENGAGE)
20005-009	2010-07-06	2010-07-13	7	Resolve type I endoleak	AUI (ENGAGE)
05003-001	2010-11-05	2010-11-23	18	Occlusion stent graft	AUI (ENGAGE)
50300-002	2010-10-05	2010-11-11	37	Stent graft occlusion	AUI (ENGAGE)
11002-014	2010-07-07	2010-09-15	70	Resolve type I endoleak	AUI (ENGAGE)
05001-057	2010-06-18	2010-09-03	77	Infected anastomotic aneurysm left femoral artery	AUI (ENGAGE)
10201-029	2010-05-19	2010-08-18	91	Resolve type I endoleak	AUI (ENGAGE)
10209-030	2010-07-01	2010-12-13	165	Resolve stent graft occlusion (right iliac) by implanting surgical axillobifemoral bypass graft	AUI (ENGAGE)
05006-020	2010-11-10	2011-05-03	174	Resolve type II endoleak, resolve aneurysm expansion	AUI (ENGAGE)
008-010	2011-02-28	2011-12-05	280	Stenosis of AUI stent graft	AUI (IDE)

ENGAGE, Endurant Stent Graft Natural Selection Global Postmarket Registry; *IDE,* Investigational Device Exemption.

Both configurations show equivalent and significant reduction of sac diameter at 1 year (46% in AUI cohort and 42% in BIF cohort).

DISCUSSION

AUI devices for EVAR initially gained favor because of simpler deployment of straight grafts compared with BIF stent grafts when cannulation of the contralateral gate was necessary, leading to its popularity for use in ruptured AAAs.[6,7] As BIF endografts have rapidly evolved with varying delivery profiles and increased trackability, the use for AUI endografts has shifted toward overcoming the complex anatomy of select patients with AAAs. Narrow aortic bifurcations and iliac artery disease, including tortuosity, aneurysms, and stenosis, continue to limit BIF endograft use; thus, EVAR with an AUI device with

femoral-to-femoral crossover continues to have an important role in specific anatomic cases.[8,9] Patients in this study often had multiple indications for AUI stent use for EVAR, but the majority had an occluded iliac artery or a small aortic diameter that would not allow safe deployment of two limbs required of BIF endografts. Without the availability of AUI devices, the alternative options are either open aneurysm repair, accompanied by increased morbidity and mortality rates in elderly patients or those with comorbid conditions,[10,11] or forcing a BIF graft to aggressively accommodate the difficult anatomy. Neither option is desirable, and some surgeons have opted on occasion to occlude the contralateral limb opening of a BIF device, effectively creating an AUI configuration.

The anatomic review in this study allows a better understanding of the current usage trends in AUI devices, and the comparison to patients with BIF grafts performed in similar settings with similar data collection defines the patient populations better and suggests expected outcomes in both. Although the majority of AAA exclusions in the ENGAGE Registry were with the BIF device, the AUI configuration was selected by operators in about 7% of patients, giving an estimate for the proportion of patients who may benefit from this configuration in a general EVAR population. It is notable that considerably more women seem to be suitable for the AUI device than for BIF configuration EVARs, illustrating the difficult iliac anatomy exhibited in women who present for the treatment of their AAAs.

Indications for the AUI configuration obviously vary among users, depending on familiarity with the device and availability of other alternatives. Thus, recommendations for the use of an AUI device cannot be generalized and have to be based on the clinical and anatomic setting. The configuration is clearly ideal for a unilateral iliac occlusion or severe stenotic iliac disease and should be recommended as a suitable option for endovascular repair with good outcomes. The other indications identified in this review, such as severe iliac tortuosity, complex iliac aneurysms, and a narrow calcified aortic bifurcation, are obviously more relative indications in which the AUI configuration with femoral-to-femoral bypass can be a suitable alternative in the absence of other better options. The commercial availability of AUI devices clearly provides additional options for the treating physician.

Despite these limited but well-established indications, limited data exist on comparative outcomes for AUI endografts in these challenging patients, especially compared with sister studies of BIF endografts.

Our review suggests that EVAR with AUI devices can be highly successful technically in patients with difficult anatomy and feasible, albeit with higher myocardial infarction and respiratory complication rates, in this patient population with increased baseline comorbidities.

The high technical success rate and low operative mortality and morbidity in this study show a significant improvement from earlier estimates of the AUI and BIF device comparisons, such as the Ancure endografts. More recent comparisons have shown similar trends as were illustrated in our study. Jean-Baptiste et al reviewed midterm results after the use of BIF and AUI configurations of the Zenith (Cook) graft during a 4-year period: 124 patients with an AUI configuration were compared with 323 patients who received the BIF configuration. Technical success rate for the AUI configuration was good at 94% but lower than that for the BIF configuration (99%; $P = .002$). As expected, the 30-day mortality rate was marginally higher in the AUI group compared with the BIF group (3.2% vs 1.5%; $P = .2$). With a longer observation period than in our study, more secondary procedures were necessary in the AUI cohort (11% vs in 5%; $P = .01$).[12] Similar outcomes were reported in another midterm comparison of AUI vs BIF configuration EVARs comparing 21 patients with the Endofit AUI endograft (LeMaitre Vascular, Burlington, Mass) and 86 patients with the Talent bifurcated endograft. Small numbers aside, mortality from the AUI configuration was 1.6%.[13] Although the secondary endovascular reintervention rates trended higher for the AUI group in our report, and more so compared with open AAA repair,[14] endoleaks were not significantly different between the two cohorts, and the AUI device configuration allowed aneurysm exclusion in patients who otherwise may not have been suitable for EVAR with a BIF device, with similar rates of morbidity and mortality. A longer period of observation would of course be necessary to evaluate these variables further.

Decreasing profiles, increased operative experience, and more commercial offerings continue to improve EVAR outcomes in challenging anatomies. Although some techniques, such as kissing balloons in the aortic bifurcation, and endografts such as the AFX Device (Endologix, Irvine, Calif) may be suitable in smaller aortic bifurcations, these solutions do not address all such anatomies, including those with occluded or severely diseased iliac arteries, aneurysms, or other challenging outflow anatomy.[15] The present series provides reassurance that use of the AUI configuration may provide a reasonable alternative for such patients with improved outcomes over historical series. Despite no major differences between the AUI and BIF cohorts in ASA class 3/4 in the EVT/Guidant multicenter trial, early results were inferior with the use of the AUI device, giving pause to operators. The current series provides a slightly different picture: with more Endurant AUI patients classified as ASA class 3/4, similar outcomes were achieved.[1] The results are also encouraging compared with open surgical control procedures in good-risk patients from pooled data of IDE clinical trials, which reveal a 30-day mortality of 1.4%.[16] In addition, patients experience a reduction in blood loss, intensive care unit length of stay, and overall hospital stay.[1]

The population of AUI patients has a higher burden of comorbid disease, and a higher proportion received a general anesthetic, probably because of the femoral-to-femoral bypass graft. Complications due to general anesthesia and the increased prevalence of cardiorespiratory disease in the baseline AUI population are likely to have contributed

to the longer stays in the intensive care unit compared with the BIF patients. The more significant surgical burden of the AUI procedure as well as the increased prevalence of preoperative cardiac ischemic disease and chronic obstructive pulmonary disease is probably responsible for the noted increase in postoperative myocardial infarctions and respiratory failure. The favorable results reported from this retrospective review suggest that the AUI configuration is a valid option for patients with complex aortoiliac anatomy and may be preferable to open repair when a BIF graft cannot be deployed. In addition, the technical ease of deploying a one-sided device compared with a complicated BIF modular approach should not be underemphasized, especially in urgent clinical scenarios including ruptured aneurysms.[17] As with all EVAR patients, follow-up is essential to monitor graft complications. However, in patients with AUI endografts, additional attention should be paid to the patency and complications of femoral-to-femoral bypass grafts. Five-year primary patency rates of femoral-to-femoral bypass grafts placed for occlusive disease range from 55.8% to 73%.[18-21] In a recent study of crossover bypasses performed for aneurysms in conjunction with an AUI configuration, primary and secondary patency rates were 98% and 100%, respectively, with a mean follow-up of 15.8 months.[9] Studies suggest that femoral-to-femoral bypass grafts placed for aneurysmal disease have an overall higher patency rate than those placed for other indications,[22,23] but follow-up surveillance and secondary interventions maintain higher primary and primary-assisted patency.[24]

Limitations. A significant limitation of the study is that the indication for use of the AUI device has been inferred by the authors from anatomic reviews and not by having the operators declare their reason for selecting this modality over other available treatment options. Another limitation is the clinical comparison of two groups that are clinically and anatomically distinct and for which treatment options are not equivalently applicable. However, the prospectively collected data that were carefully monitored, audited, and externally reviewed provide the opportunity to place outcomes in perspective in these populations of patients. Furthermore, with a significant imbalance in the number of patients enrolled in each cohort, statistical inference is limited by type II error. In addition, more complex statistical analysis, such as logistic regression or propensity score matching, could not be performed as patient-specific data for both cohorts were not coded to run such an analysis.

CONCLUSIONS

Patients with current anatomic indications for an AUI device do have an increased perioperative cardiac and pulmonary morbidity, but early outcomes demonstrate the relative safety and effectiveness of the procedure, similar to patients treated with a BIF configuration. The AUI configuration appears to extend EVAR feasibility to several hostile anatomies that otherwise would not be easily amenable to EVAR.

AUTHOR CONTRIBUTIONS

Conception and design: MM
Analysis and interpretation: MK, MM
Data collection: TF, JT, GP, SE, DB, MM
Writing the article: MK, MM
Critical revision of the article: MK, TF, JT, GP, SE, DB, MM
Final approval of the article: MK, TF, JT, GP, SE, DB, MM
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REFERENCES

1. Moore WS, Brewster DC, Bernhard VM. Aorto-uni-iliac endograft for complex aortoiliac aneurysms compared with tube/bifurcation endografts: results of the EVT/Guidant trials. J Vasc Surg 2001;33(Suppl):S11-20.
2. Crago AM, Singh N, Deaton DH, Neville RF, Laredo J. Endovascular repair of a common iliac artery aneurysm using the Cook Zenith abdominal aortic aneurysm Endovascular Graft Converter. Vasc Endovascular Surg 2008;42:54-7.
3. Bockler D, Fitridge R, Wolf Y, Hayes P, Silveira PG, Numan F, et al. Rationale and design of the Endurant Stent Graft Natural Selection Global Postmarket Registry (ENGAGE): interim analysis at 30 days of the first 180 patients enrolled. J Cardiovasc Surg (Torino) 2010;51:481-91.
4. Keats AS. The ASA classification of physical status—a recapitulation. Anesthesiology 1978;49:233-6.
5. Rutherford RB, Baker JD, Ernst C, Johnston KW, Porter JM, Ahn S, et al. Recommended standards for reports dealing with lower extremity ischemia: revised version. J Vasc Surg 1997;26:517-38.
6. Hinchliffe RJ, Braithwaite BD. A modular aortouniiliac endovascular stent-graft is a useful device for the treatment of symptomatic and ruptured infrarenal abdominal aortic aneurysms: one-year results from a multicentre study. Eur J Vasc Endovasc Surg 2007;34:291-8.
7. Peppelenbosch N, Geelkerken RH, Soong C, Cao P, Steinmetz OK, Teijink JA, et al. Endograft treatment of ruptured abdominal aortic aneurysms using the Talent aortouniiliac system: an international multicenter study. J Vasc Surg 2006;43:1111-23; discussion: 1123.
8. Clouse WD, Brewster DC, Marone LK, Cambria RP, Lamuraglia GM, Watkins MT, et al. Durability of aortouniiliac endografting with femorofemoral crossover: 4-year experience in the Evt/Guidant trials. J Vasc Surg 2003;37:1142-9.
9. Rehring TF, Brewster DC, Cambria RP, Kaufman JA, Geller SC, Fan CM, et al. Utility and reliability of endovascular aortouniiliac with femorofemoral crossover graft for aortoiliac aneurysmal disease. J Vasc Surg 2000;31:1135-41.
10. Johnston KW. Multicenter prospective study of nonruptured abdominal aortic aneurysm. Part II. Variables predicting morbidity and mortality. J Vasc Surg 1989;9:437-47.
11. Dardik A, Lin JW, Gordon TA, Williams GM, Perler BA. Results of elective abdominal aortic aneurysm repair in the 1990s: a population-based analysis of 2335 cases. J Vasc Surg 1999;30:985-95.
12. Jean-Baptiste E, Batt M, Azzaoui R, Koussa M, Hassen-Khodja R, Haulon S. A comparison of the mid-term results following the use of bifurcated and aorto-uni-iliac devices in the treatment of abdominal aortic aneurysms. Eur J Vasc Endovasc Surg 2009;38:298-304.
13. Dalainas I, Moros I, Gerasimidis T, Papadimitriou D, Saratzis N, Gitas CG, et al. Mid-term comparison of bifurcated modular endograft versus aorto-uni-iliac endograft in patients with abdominal aortic aneurysm. Ann Vasc Surg 2007;21:339-45.
14. De Bruin JL, Baas AF, Buth J, Prinssen M, Verhoeven EL, Cuypers PW, et al. Long-term outcome of open or endovascular repair of abdominal aortic aneurysm. N Engl J Med 2010;362:1881-9.

15. Carpenter JP, Garcia MJ, Harlin SA, Jordan WD, Jung MT, Krajcer Z, et al. Contemporary results of endovascular repair of abdominal aortic aneurysms: effect of anatomical fixation on outcomes. J Endovasc Ther 2010;17:153-62.
16. Lifeline registry of endovascular aneurysm repair: long-term primary outcome measures. J Vasc Surg 2005;42:1-10.
17. Ohki T, Veith FJ, Sanchez LA, Cynamon J, Lipsitz EC, Wain RA, et al. Endovascular graft repair of ruptured aortoiliac aneurysms. J Am Coll Surg 1999;189:102-12; discussion: 112-3.
18. Criado E, Burnham SJ, Tinsley EA Jr, Johnson G Jr, Keagy BA. Femorofemoral bypass graft: analysis of patency and factors influencing long-term outcome. J Vasc Surg 1993;18:495-504; discussion: 504-5.
19. Dick LS, Brief DK, Alpert J, Brener BJ, Goldenkranz R, Parsonnet VA. 12-year experience with femorofemoral crossover grafts. Arch Surg 1980;115:1359-65.
20. Perler BA, Williams GM. Does donor iliac artery percutaneous transluminal angioplasty or stent placement influence the results of femorofemoral bypass? Analysis of 70 consecutive cases with long-term follow-up. J Vasc Surg 1996;24:363-9; discussion: 369-70.
21. Schneider JR, Besso SR, Walsh DB, Zwolak RM, Cronenwett JL. Femorofemoral versus aortobifemoral bypass: outcome and hemodynamic results. J Vasc Surg 1994;19:43-55; discussion: 55-7.
22. Thompson-Fawcett M, Moon M, Hands L, Collin J. The significance of donor leg distal runoff in femorofemoral bypass grafting. Aust N Z J Surg 1998;68:493-7.
23. Ohki T, Marin ML, Veith FJ, Lyon RT, Sanchez LA, Suggs WD, et al. Endovascular aortounifemoral grafts and femorofemoral bypass for bilateral limb-threatening ischemia. J Vasc Surg 1996;24:984-96; discussion: 996-7.
24. Stone PA, Armstrong PA, Bandyk DF, Keeling WB, Flaherty SK, Shames ML, et al. Duplex ultrasound criteria for femorofemoral bypass revision. J Vasc Surg 2006;44:496-502.

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