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Open versus Endo: Early Experience with Endovascular Abdominal Aortic Aneurysm Repair beyond the Clinical Trials

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ABSTRACT

Objective: To analyze and compare open (OR) versus endovascular (EVAR) abdominal aortic aneurysm repair at our institution.

Methods: EVAR was attempted in 256 patients at the University of Tennessee Medical Center, Knoxville, between December 1999 and November 2002. One hundred forty patients underwent attempted EVAR, and 116 underwent OR. All patients were included on an intent-to-treat basis, and results were reviewed retrospectively. Statistical methods included the Student *t* test and chi-square analysis.

Results: Patients were age matched between the 2 groups (70.2 years versus 69.0 years; *P* = .936). Patients in the OR group had significantly higher American Society of Anesthesiologists classes than the EVAR group (2.96 versus 3.07; *P* = .006). However, there was no difference between the groups, OR versus EVAR, with respect to the presence of chronic obstructive pulmonary disease (55% versus 46%; *P* = .129), coronary artery disease (69% versus 66%; *P* = .638), diabetes mellitus (12% versus 18%; *P* = .167), mean left ventricular ejection fraction (51.8% versus 53.9%; *P* = .28), or mean preoperative creatinine level (1.2 mg/dL versus 1.1 mg/dL; *P* = .167). Tobacco use was more prevalent in the OR group (78.4% versus 64.2%; *P* = .013), and known carotid artery disease was more prevalent in the EVAR group (20.0% versus 6.9%; *P* = .003). The EVAR group had significantly shorter lengths of stay (4.2 versus 9.0 days; *P* = .000), intensive care unit days (0 versus 3.2; *P* = .000), time in the operating room (119.6 minutes versus 225.7 minutes; *P* = .000), and estimated blood loss (189.1 mL versus 897.9 mL; *P* = .000). Mean aneurysm size was larger in the OR group (5.6 cm versus 4.9 cm; *P* = .000). Perioperative complications occurred in 31 patients in the OR group and 5 in the EVAR group (*P* = .000). Two perioperative deaths occurred in the OR group and none in the EVAR group. As of this writing there has been no significant difference in all-cause mortality in the 2 groups (OR 9.6% versus EVAR 8.0%; *P* = .651). Seven patients in the EVAR group needed secondary interventions. Six were managed with endovascular techniques, and 1 underwent femoral-femoral bypass.

Conclusions: Patients who undergo EVAR have significantly less morbidity and mortality in the perioperative period than do equally matched patients undergoing open repair. In midterm follow-up (2-5 years), mortality is no different. Morbidity conferred by the need for secondary intervention in the endovascular group is minimal.

INTRODUCTION

Abdominal aortic aneurysm is a common disease, having a prevalence as high as 36.2 cases per 100,000 members of the population. This rate increases to almost 6% in persons older than 80 years [Uflacker 2001]. In March 1951 Charles Dubost, a French surgeon, performed the first repair of an abdominal aortic aneurysm. Since then, open repair has been the mainstay of therapy. However, despite advances in technology and techniques, morbidity and mortality remain high. Population-based reports show that major morbidity and mortality rates remain as high as 8%. The morbidity and mortality of open repair coupled with the lethal natural history of aortic aneurysm have driven the development of a less invasive repair.

In 1991 Parodi described "exclusion of an abdominal aortic aneurysm by placement of an intraluminal, stent-anchored, Dacron prosthetic graft using retrograde cannulation of the common femoral artery" [Parodi 1991]. In September 1999 the US Food and Drug Administration approved 2 devices for endoluminal repair of abdominal aortic aneurysm (EVAR). Although it was anticipated that the endovascular approach would significantly decrease the mortality rate for aneurysm repair, multicenter clinical trials did not show improvement [Moore 2003, Ohki 2001]. Soon after, endovascular techniques demonstrated they were a means of aneurysm repair with improved morbidity [Moore 1999, May 2001, Ohki 2001, Zarins 2001, Faries 2002]. Secondary interventions, however, have been required in as many as 19% of patients [Conners 2002]. Comparisons have been made

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between endovascular repair and conventional open repair (COR) [Moore 1999, May 2001]. However, few reports have come from centers not involved in the clinical trials. Are the results of the clinical trials reproducible? Or are results even better with the technology in a more mature form? We compared EVAR and COR in a single-center experience.

PATIENTS AND METHODS

Elective abdominal aortic aneurysm repair was performed in 256 patients between December 1999 and November 2002. Of those, 140 patients underwent attempted EVAR, and 116 underwent COR. In the EVAR group, devices were implanted in 139 patients. AneuRx devices (Medtronic/AVE, Santa Rosa, CA, USA) were implanted in 121 patients and Ancure (Guidant, Menlo Park, CA, USA) devices in the other 18. In the COR group, most repairs were made through a transperitoneal approach. Selection for COR versus EVAR was based primarily on aneurysm morphology. To be considered for EVAR, patients had to have proximal neck diameters of 26 mm or less, lengths of 10 mm or greater, and neck angulation of less than 60 degrees. Patients were also excluded from EVAR if it was believed it would be unlikely or difficult to obtain adequate follow-up information.

With respect to EVAR, success was defined by the reporting standards for EVAR set for the by the Ad Hoc Committee of the Joint Vascular Societies [Ahn 1997]. Technical success was defined as successful access to the arterial system from a remote site, successful deployment of the graft with secure proximal and distal fixation, no perigraft endoleak for more than 48 hours, and a patent graft in a surviving patient at 30 days. Clinical success was defined as lack of aneurysm sac enlargement (>0.5 cm), lack of persistent endoleak longer than 6 months, and lack of any secondary intervention or surgical conversion. Secondary success was continued clinical success after use of endovascular techniques in the treatment of a late graft complication.

A retrospective chart review was carried out on all patients included in this study. All patients were included on an intent-to-treat basis. Results were analyzed with SPSS statistical software using the Student *t* test and chi-square analysis. The follow-up period was up to 36 months.

RESULTS

Mean patient age in the EVAR group was 70.2 years, versus 69.0 for the COR group ($P = .936$). Of note, patients in the COR group had significantly higher mean American Society of Anesthesiologists scores than the EVAR group (2.96 versus 3.07; $P = .006$). However, there were no significant differences between the 2 groups with respect to the presence of chronic obstructive pulmonary disease (55% versus 46%; $P = .129$), coronary artery disease (69% versus 66%; $P = .638$), diabetes mellitus (12% versus 18%; $P = .167$), mean left ventricular ejection fraction (51.8% versus 53.9%; $P = .28$), and mean preoperative creatinine concentration (1.2 mg/dL versus 1.1 mg/dL; $P = .167$). Smoking was more prevalent in the COR group (78.4% versus 64.2%; $P = .013$), and carotid artery disease was more prevalent in the EVAR group (20% versus 6.9%; $P = .003$). Mean aneurysm size was significantly larger in the COR group (5.6 cm versus 4.9 cm; $P = .000$) (Table 1).

Table 1. Surgical Risk Factors*

	COR	EVAR	*P*
Mean age, y	70.2	69.0	.936
Mean ASA score	3.07	2.96	.006
COPD, n	62 (46%)	64 (55%)	.129
CAD, n	80 (69%)	90 (66%)	.638
Diabetes, n	14 (12%)	25 (18%)	.167
Mean LVEF, %	51.8%	53.9%	.28
Mean preoperative creatinine concentration, mg/dL	1.2	1.1	.167
Mean aneurysm size, cm	5.6	4.9	.000
Tobacco use, n	91 (78%)	86 (64%)	.013
Carotid disease, n	8 (6.9%)	27 (20%)	.003

*COR indicates conventional open repair; EVAR, endovascular aneurysm repair; ASA, American Society of Anesthesiologists; CAD, coronary artery disease; LVEF, left ventricular ejection fraction.

Technical success was achieved in 139 patients undergoing EVAR, a success rate of 99.2%. The single technical failure occurred as the iliac vessels could not be traversed. In this patient, comorbidities precluded open repair, and the patient did not undergo another attempt at repair. Secondary interventions were required in 7 (5%) of the patients. Two of these patients underwent successful embolization of type II endoleaks. The first patient had an increase in size of the aneurysmal sac of 1 cm over 1 year. The second patient began having significant back pain approximately 20 months after undergoing aneurysm repair. He had a known type II leak, and his symptoms prompted emergency embolization of the leak. It was later found that the pain was due to a metastatic lesion to the spine. The other 5 interventions were for limb occlusion, 2 cases of occlusion occurring in the perioperative period. Four of the cases of occlusion were managed with thrombectomy and stenting. One patient underwent femoral-femoral bypass. This patient had the first limb occlusion in our experience. In retrospect, he likely could have been managed with endovascular techniques.

Shorter lengths of stay were required for the EVAR group (4.2 days) compared with patients needing open repair (9.0 days) ($P = .000$). There were no days spent in the intensive care unit for those in the EVAR group; however, the mean number of days in the ICU for the COR group was 3.2 ($P = .000$). The EVAR group had significantly less time in the operating room (119.6 minutes versus 225.7 minutes; $P = .000$) and estimated blood loss (189.1 mL versus 897.9 mL; $P = .000$) (Table 2).

There were 33 perioperative complications in the COR group versus only 6 in the EVAR group ($P = .000$) (Table 3). After follow-up there was no significant difference in all-cause mortality: 9.6% in the COR group, 8.0% in the EVAR group ($P = .651$). There were no aneurysm-related deaths in either group. In the EVAR group there were no cases of delayed rupture or need for open conversion.

Table 2. Postoperative Data*

	COR	EVAR	*P*
Length of stay, d	9	4.2	.000
ICU days, n	3.29	0	.000
OR time, min	225.7	119.6	.000
Estimated blood loss, mL	897.9	189.1	.000

*COR indicates conventional open repair; EVAR, endovascular aneurysm repair; ICU, intensive care unit; OR, operating room.

DISCUSSION

EVAR has been demonstrated to effectively reduce risk of rupture with decreased perioperative morbidity [Harris 2000, Makaroun 2001, Zarins 2001, Faries 2002]. However, there have been reports sounding a cautionary note regarding midterm durability and high rates of secondary interventions. Some reports reveal secondary intervention rates as high as 10% to 19% and perioperative mortality rates ranging from 1% to 8% [Ahn 1997, Ohki 2001, Uflacker 2001, Faries 2002]. These numbers can be concerning given that conventional open repair traditionally carries an approximately 5% perioperative mortality rate. Again, all of these published reports were from centers involved in the clinical trials.

Certainly, the early experience with endovascular repair carried higher failure rates due to inexperience with techniques and prototypical devices. Our technical and clinical success rates were higher than usually reported. Okhi et al [2001] reported a technical success rate of 88.7%. That rate is significantly lower than our technical success rate of 99.2%. We attribute these improved outcomes to a matured learning curve and evolved technology. Our patients benefited from technology and techniques that other centers pioneered. We anticipate improved implantation success, less perioperative morbidity and mortality, and a decreased number of secondary interventions as the technology evolves.

Table 3. Perioperative Complications*

	COR	EVAR
Congestive heart failure	8	0
Arrhythmia	5	0
Pneumonia	5	0
Respiratory failure	3	0
Renal failure	3	0
Wound infection	0	3
Pulmonary embolus	2	0
Ischemic colitis	2	1
Graft-related complication	0	2
Myocardial infarction	1	0
Urinary tract infection	1	0
Prolonged ileus	1	0
Death	2	0

*COR indicates conventional open repair; EVAR, endovascular aneurysm repair.

Endoluminal techniques have significantly improved the perioperative morbidity and mortality of abdominal aortic aneurysm repair. Although all-cause mortality is not significantly different, we showed significant reductions in hospital stay, need for critical care setting, operating room time, blood loss, perioperative complications, and number of deaths.

CONCLUSIONS

In this series, EVAR conferred significantly less morbidity than open repair and had zero mortality. Secondary interventions were required in only 5% of patients, and all but one patient could be managed with endovascular techniques. There were no delayed ruptures and no immediate or later conversions to open repair. These results indicate that endovascular repair may become the new standard of therapy for abdominal aortic aneurysm.

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