

## Challenges Associated with the Integration of Endovascular Repair of Abdominal Aortic Aneurysms in a Community Hospital

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### ABSTRACT

**Purpose:** There has been considerable debate regarding the proper place for endovascular repair (ER) of abdominal aortic aneurysms (AAAs) versus traditional open repair (OR). Our study compared preoperative patient demographics and outcomes for elective, asymptomatic AAA repairs performed at our center over a 33-month period.

**Methods:** For this study, we selected 342 consecutive elective infrarenal AAA repairs performed between July 1, 2000, and March 31, 2003, at Riverside Methodist Hospital. The patients underwent either ER or OR, depending on patient and surgeon collaborative determinations. Ruptured and symptomatic AAAs were excluded from our study. Preoperative demographics, anesthesia, complications, and discharge status for the 2 groups were analyzed, and statistical analysis was done to determine statistically significant differences.

**Results:** The preoperative status of the ER and OR patient groups were essentially similar. There were only 3 significant differences between the 2 groups: alcohol use was higher for the OR group than for the ER group (12.0% versus 5.2%;  $P = .04$ ), and the incidence of type II diabetes mellitus and peripheral vascular disease were lower for the OR group compared with the ER group (6.7% versus 13.4% [ $P = .04$ ] and 18.3% versus 30.6% [ $P = .008$ ], respectively). The OR group used more general anesthesia than the ER group (99% versus 86%;  $P < .001$ ) and had more complications, including dysrhythmia (8.65% versus 1.59%;  $P = .005$ ), ileus (13.94% versus 0.79%;  $P < .0001$ ), infection (8.17% versus 0.0%;  $P = .0007$ ), respiratory complications (12.50% versus 1.59%;  $P = .0003$ ), and renal complications (5.29% versus 0.79%;  $P = .032$ ). The ER group had a higher rate of wound hematoma (4.76% versus 0.48%;  $P = .007$ ). ER patients also

had significantly less blood loss (379 mL versus 1930 mL;  $P < .001$ ), a better independent discharge status ( $P < .0001$ ), a shorter length of stay (1.8 days versus 8.2 days;  $P < .001$ ), and a lower mortality rate (0.75% versus 3.85%;  $P = .0954$ ).

**Conclusions:** From our study we cautiously continue to encourage the consideration of the ER of AAAs in our patient population while being mindful of its limitations.

### INTRODUCTION

The advent of endovascular repair (ER) of infrarenal abdominal aortic aneurysm (AAA) has revolutionized the burgeoning field of catheter-based treatment of vascular disease like no other development. ER offers several potential advantages over traditional/open AAA repair (OR), including a shorter hospital stay, less blood loss, a decreased operative time, rapid recovery, less use of the intensive care unit (ICU), and a lower surgical stress response [May 1998, Zarins 1999, Salartash 2001, Ligush 2002]. However, reports of persistent aneurysm growth, late rupture, persistent endotension, graft limb thrombosis, graft migration, and other late complications related to ER have appeared in the literature [Politz 2000, Baum 2001, Carpenter 2001]. The once rampant enthusiasm for ER has turned to cautious optimism for its use in cases for which the clinical therapeutic footprint should be minimized [Feigl 2001, Sapirstein 2001]. These increasingly reported outward events have led to cautionary recommendations regarding the limitation of ER to the patient at high risk [Bush 2001, Ohki 2001]. However, because no randomized prospective trials comparing ER with OR were conducted during the early evaluation of this new technology, meaningful data regarding risk stratification or the effect of ER in improving outcome relative to OR at varying levels of risk have yet to be published. Properly integrating this technology into mainstream community hospital practice has been difficult as clinicians have battled unbridled media enthusiasm that at times has lured patients from populations other than the high-risk cohort that would intuitively benefit the most. However, the definition of high risk remains nebulous at best, and thus the population most likely to benefit from ER can be inferred but not defined completely. At this point, therefore, it is not clear that the potential short-term superiority of ER justifies the

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abandonment of the well-established long-term durability conveyed by OR or that ER is superior to OR with regard to perioperative morbidity and mortality at equivalent levels of preoperative risk. With these points in mind, we compared the preoperative medical risk factors and perioperative outcomes of patients who underwent elective treatment of infrarenal AAA repair with ER or OR during a recent 33-month period at our institution to assess the potential advantages of ER versus OR.

## METHODS

During the study period, 342 consecutive patients underwent isolated OR of AAAs that were located below the level of the renal arteries and were not associated with simultaneous renal, mesenteric, or femoropopliteal revascularization. Patients who underwent repair of thoracoabdominal, suprarenal, pararenal, and symptomatic aortic aneurysms and patients who underwent aortic aneurysm repair with combined visceral or renal artery reconstructions were excluded from further consideration. Sixty-seven patients who underwent open operations for a ruptured AAA were also excluded.

Using established reporting standards, we abstracted data from the hospital record that included demographics, preoperative medical comorbidities, and American Society of Anesthesiologists (ASA) classification [Djokovic 1979]. Aneurysm size and extent were determined on the basis of dimensions obtained from abdominal computed tomography scanning. Postoperative complications were recorded according to recommended standards. Only major postoperative morbidity that led to increased hospital stay, need for reoperative therapy, permanent disability, or death was considered in the statistical analysis. Perioperative mortality was defined as all deaths occurring within 30 days of operation or within the same hospitalization period, regardless of interval.

Procedural selection (ER versus OR) was based on aneurysm morphology, clinical suitability for OR, and patient preference. Detailed imaging with 3-dimensional contrast-enhanced computed tomography and aortography was performed in all patients prior to surgery. Anatomical morphologic criteria for endoluminal grafting based on these investigations included the following: a proximal aneurysm neck with a 15-mm length or greater and a diameter of 28 mm or less; a proximal neck angulation of less than 75°; and iliac arteries with a degree of calcification, tortuosity, and diameter that was not considered prohibitive to the passage of the delivery catheter.

All patients who were anatomically suitable for ER were offered this treatment option in the context of their operative risk. The decision to perform ER was based on comorbidities that precluded OR ( $n = 40$ ) and patient/physician choice after collective consultation ( $n = 94$ ).

### Statistical Analysis

All statistical analyses were performed with Statistical Analysis Software, version 8 (SAS Institute, Cary, NC, USA). Dichotomous data (demographics, morbidity, and mortality) were analyzed according to the method of

Table 1. Demographics and American Society of Anesthesiologists (ASA) Classification Data of Patients Who Underwent Abdominal Aortic Aneurysm Repair\*

|                             | Surgery<br>(n = 208) | Stent Grafting<br>(n = 134) | P    |
|-----------------------------|----------------------|-----------------------------|------|
| Age, y                      |                      |                             |      |
| Mean                        | 70.8                 | 71.6                        | NS   |
| Range                       | 42-89                | 47-91                       | NS   |
| Male sex                    | 83.7%                | 89.5%                       | NS   |
| Female sex                  | 16.3%                | 10.5%                       | NS   |
| Smoking, presently          | 20.7%                | 22.4%                       | NS   |
| Smoking, formerly           | 38.5%                | 33.6%                       | NS   |
| COPD                        | 35.1%                | 32.1%                       | NS   |
| Hypertension                | 68.8%                | 70.2%                       | NS   |
| History of MI               | 26.9%                | 31.3%                       | NS   |
| Cerebrovascular accident    | 11.1%                | 6.7%                        | NS   |
| Diabetes mellitus, oral     | 6.7%                 | 13.4%                       | .04  |
| Diabetes mellitus, insulin  | 1.4%                 | 2.2%                        | NS   |
| Congestive heart failure    | 9.1%                 | 11.2%                       | NS   |
| Renal insufficiency         | 6.3%                 | 9.7%                        | NS   |
| Hyperlipidemia              | 45.7%                | 44.0%                       | NS   |
| Peripheral vascular disease | 18.3%                | 30.6%                       | .008 |
| Coronary artery disease     | 56.3%                | 50.0%                       | NS   |
| Alcohol use                 | 12.0%                | 5.2%                        | .04  |
| ASA risk category           |                      |                             |      |
| I to II                     | 4.1%                 | 4.2%                        | NS   |
| III                         | 75.0%                | 75.8%                       | NS   |
| IV                          | 20.4%                | 20.0%                       | NS   |
| Aneurysm size, cm           |                      |                             |      |
| Mean                        | 6.2                  | 5.1                         | NS   |
| Range                       | 4.5-10.2             | 4.8-7.5                     | NS   |

\*Statistical tests were considered statistically significant when the *P* value was less than .05. NS indicates not statistically significant; COPD, chronic obstructive pulmonary disease; MI, myocardial infarction.

aneurysm repair with chi-square and Fisher exact tests. All continuous variables were analyzed with the Student *t* test. Graded medical comorbidity and ASA classification data were analyzed with the nonparametric Wilcoxon rank sum test to take into account both the frequency and the severity of the condition/measure. All statistical tests were considered significant when the *P* value was less than .05.

### Patient Characteristics

As indicated in Table 1, this series includes 294 men (86%) and 48 women (14%) with ages ranging from 42 to 91 years (mean  $\pm$  SD,  $70.5 \pm 7.2$  years; median, 70 years). The mean aneurysm size was  $5.6 \pm 1.1$  cm. When the data were examined by method of operative repair, no significant differences were found among demographic factors, ASA classification, or aneurysm size other than the incidence of type 2 diabetes mellitus (13.4% for the ER group versus 6.7% for the OR group), peripheral vascular disease (30.6% for the ER group versus 18.3% for the OR group), and alcohol use (5.2% for the ER group versus 12% for the OR group).

**Technique of Endoluminal Aneurysm Repair**

Informed consent was obtained from each patient. All procedures were performed in a catheterization lab with operating department sterility specifications or in a standard operating room with the patient prepared and draped for a conventional open operation in the event that conversion to OR was required in cases of a failed endoluminal technique or the occurrence of serious complications.

Vascular surgeons were involved with all 134 procedures (100%), interventional radiologists were involved in 7 cases (5.2%), and interventional cardiologists were involved in 127 cases (94.8%). No outcome difference was seen on the basis of the number of cases performed or specialty involvement in the treatment procedures. Industry-related proctors were present in all cases.

The endografts used were AneuRx (Medtronic, Santa Rosa, CA, USA), Ancure (Guidant, Menlo Park, CA, USA), and Zenith (Cook, Bloomington, IN, USA). Antibiotics were administered as prophylaxis at the time of anesthesia induction. All patients underwent anticoagulation treatment with 10,000 U heparin administered intravenously after the access artery was exposed. Monitoring of anticoagulation status was not used, and full reversal with protamine was administered immediately following arterial repair. Access was restricted to the femoral arteries in 97 patients, and the common iliac arteries were used with an extraperitoneal approach in 3 patients. The techniques for the transfemoral and extraperitoneal iliac approaches have previously been described in detail. Fluoroscopic monitoring was used in the delivery and deployment of all endografts. On-table completion angiography was undertaken in all patients.

Contrast-enhanced computed tomography was performed in accordance with the manufacturers' guidelines, and the results were reported by the treating physicians and recorded in a central data registry. Most of these investigations were performed at the authors' institution. Those investigations that were not done at the authors' direction, and the resulting scans were viewed by them. Outcome measures for this study were survival and successful outcome after primary AAA repair. Success in the ER group was defined as continuing graft function without endoleak or conversion to OR. A decrease in maximum transverse diameter of the AAA after ER is also an important parameter in the assessment of success, and this diameter was monitored regularly. Persistent endoleak was classified as a failure, irrespective of whether successful secondary ER repair was subsequently achieved. A spontaneous seal of an endoleak with a demonstrated consistent reduction in maximum transverse diameter was classified as a success. Other outcome measures were length of hospital stay, length of ICU stay, and operative blood loss.

**Technique of Open Aneurysm Repair**

Nearly all AAA procedures (99%) were performed with general endotracheal anesthesia and the conventional technique of open aneurysm repair, usually with epidural analgesia for postoperative pain management. Although a midline transperitoneal incision was used preferentially, a retroperitoneal approach through the left flank was used whenever it

seemed to be more appropriate because of a "hostile" abdomen secondary to multiple previous celiotomies, a functioning colostomy, truncal obesity, serious chronic obstructive pulmonary disease, or the possibility that suprarenal cross-clamping might be necessary for the construction of a juxtarenal aortic graft (our database does not contain specific information regarding the choice of incisions). Collagen-impregnated Hemashield knitted polyethylene terephthalate (Dacron) grafts (Boston Scientific, Maple Grove, MN, USA) were implanted in all cases. Straight grafts were feasible in 30% of patients, and aortobiliac (n = 70), aortobifemoral (n = 20), or aortoiliac/femoral (n = 4) bifurcation grafts were used in the other cases (70%; Table 1).

**RESULTS**

Anesthesia and operative time data are presented in Table 2.

Nearly all patients (99%) who underwent OR were administered a general anesthetic, compared with only 86% of patients who underwent ER ( $P < .001$ ). Operative times were significantly shorter for ER (4.05 hours versus 2.37 hours;  $P = .005$ ), and shed blood loss was significantly less (1930 mL versus 379 mL;  $P < .001$ ).

The distributions of morbidity were similar for the 2 groups with the exception of a trend toward more wound complications in the ER group ( $P = .007$ ) and more infections ( $P = .0007$ ), dysrhythmias ( $P = .005$ ), and respiratory complications ( $P = .0003$ ) in the OR group. Cardiac complications were rare in both groups and in most cases were related to dysrhythmia. The perioperative mortality rate also trended higher in the OR group, but the difference did not achieve statistical significance (3.85% versus 0.75%;  $P = .0954$ ).

**Endoluminal Group**

ER was achieved in 133 (99%) of 134 patients. Conversion to OR was required in the remaining patient, who sustained a perforation of the common iliac artery. Secondary conversion to OR on a subsequent occasion was required in 1 patient. The cause of this secondary conversion was a contained ruptured AAA. Abdominal radiographs and angiography results indicated downward displacement of the proximal end of the prosthesis, which was confirmed during the OR. The patient recovered uneventfully.

**OR Group**

Eight perioperative deaths occurred in the 208 patients who underwent OR. Three deaths were caused by myocardial infarction, 3 were caused by arrhythmia and cardiac arrest,

Table 2. Operative Variables: Shed Blood Loss, Anesthesia, and Procedure Time

|                            | Surgery          | Stent Grafting | P     |
|----------------------------|------------------|----------------|-------|
| Shed blood loss, mL*       | 1930 (50-10,000) | 379 (30-2200)  | <.001 |
| Anesthesia, general/spinal | 99%/1%           | 86%/14%        | <.001 |
| Procedure time, h          | 4.05             | 2.37           | .005  |

\*Data are presented as the mean (range).

and 2 were caused by renal failure. There were no instances of graft failure in the OR group. Local vascular and remote/systemic complications are listed in Table 3.

### Comparison of Outcomes

Like other investigators, we found that perioperative outcome in the ER group was significantly affected with regard to shed blood loss (the data refer to blood shed at operation and not to blood replacement, thus avoiding the bias caused by the use of the cell saver in most patients), operative time, ICU use, and length of stay (Tables 2 and 3). It must be remembered, however, that departmental policy was for patients in the OR group to routinely go to the ICU. None of the patients who underwent successful ER required mechanical ventilation; however, the overall postoperative mortality rate was not significantly lower in the ER group (Table 4). The ER group also needed more perioperative interventions than did the OR group. No difference in morbidity or mortality rate was noted between patients with femoral artery access and those with iliac artery access.

## DISCUSSION

The emergence of ER has provided surgeons with a new technique that should improve patient outcomes. However, with the exception of higher incidences of preoperative diabetes mellitus and peripheral vascular disease, the ER and OR patients in our series showed similar preoperative medical risk factor profiles and had similar rates of morbidity and mortality after aneurysm repair. The results of our analysis leave us with questions as to how ER can most beneficially be applied in our patient population.

Some investigators argue that ER offers an earlier return to functional status. Although we did not specifically study that parameter, Aquino et al [2001] recently reported on a prospectively conducted quality-of-life assessment for patients who received either ER or OR. These investigators concluded that an earlier return to baseline function was detected in patients treated with ER than in those treated with OR. A closer dissection of their data, however, revealed these findings to be questionable. The groups were not randomly assigned to the 2 treatment arms and were clearly unmatched with respect to aneurysm extent. Of the 51 patients enrolled in their study, the 26 patients in the OR arm were deemed unsuitable for ER because of a short proximal neck ( $n = 10$ ), pararenal AAA ( $n = 6$ ), iliac aneurysm ( $n = 8$ ), or iliac occlusive disease ( $n = 1$ ). The mere fact that the OR group may have needed suprarenal clamping or more extensive iliac dissection with their well-established higher risks of renal, sexual, bladder, and bowel dysfunction makes any conclusions regarding postoperative quality of life in these investigators' 2 treatment arms difficult to justify. Indeed, on long-term follow-up, these investigators reported similar quality-of-life scores for the 2 groups, suggesting that the short-term benefits did not translate into a long-term advantage.

Although the rates of both significant perioperative morbidity and mortality trended higher in our study among patients treated with OR, these differences did not achieve

Table 3. Perioperative Morbidity Rates\*

|                             | Surgery<br>(n = 208) | Stent Grafting<br>(n = 134) | P      |
|-----------------------------|----------------------|-----------------------------|--------|
| Hematoma                    | 0.48%                | 4.76%                       | .007   |
| Pseudoaneurysm              | 0.0%                 | 0.0%                        | NS     |
| Thrombosis                  | 0.96%                | 2.38%                       | NS     |
| Acute myocardial infarction | 4.33%                | 0.79%                       | NS     |
| Retroperitoneal bleeding    | 1.44%                | 0.79%                       | NS     |
| Dysrhythmia                 | 8.65%                | 1.59%                       | .005   |
| Ileus                       | 13.94%               | 0.79%                       | <.0001 |
| Dissection                  | 0.0%                 | 0.79%                       | NS     |
| Infection                   | 8.17%                | 0.0%                        | .0007  |
| Surgical wound              | 1.44%                |                             |        |
| Respiratory                 | 4.33%                |                             |        |
| Urinary tract infection     | 1.9%                 |                             |        |
| Other                       | 0.48%                |                             |        |
| Endoleak type II            |                      | 21.43%                      |        |
| Endoleak type III           |                      | 0.79%                       |        |
| Cerebrovascular accident    | 0.0%                 | 0.79%                       | NS     |
| Respiratory complications   | 12.50%               | 1.59%                       | .0003  |
| Renal complications         | 5.29%                | 0.79%                       | NS     |
| Paralysis                   | 0.0%                 | 0%                          | NS     |
| Paresthesia                 | 0.96%                | 1.59%                       | NS     |
| Perforation                 | 0.0%                 | 0.79%                       | NS     |
| Sepsis                      | 0.96%                | 0%                          | NS     |
| Intent to treat/abandoned   | 0.0%                 | 0.79%                       | NS     |
| Congestive heart failure    | 3.37%                | 0.79%                       | NS     |
| Late conversion             |                      | 0.79%                       | NS     |
| Convert to open repair      |                      | 0.0%                        | NS     |
| Minor complications         | 28.85%               | 8.21%                       | <.0001 |
| Major complications         | 17.31%               | 5.97%                       | .0022  |

\*NS indicates not significantly different.

statistical significance. ER was associated with decreases in ICU use, operative time, and hospital length of stay. These results suggest that ER shortened operative times and hospital convalescence but did not have a beneficial effect on perioperative morbidity or mortality. We believe that the population most likely to benefit from ER is the relatively poorly defined "high-risk" patient group in whom the stress of OR would be poorly tolerated. In this regard, the study by Salartash et al [2001] is particularly important. Their study showed that ER was associated with a marked reduction in values of parameters of the postoperative stress response, compared with OR. Although these investigators' study group was relatively small, the findings are compelling. However, the study was not designed to correlate the stress response with perioperative outcomes, so how these data apply to the AAA population as a whole is unclear at this point. Although the patients who underwent OR in our study may be presumed to probably have had a higher stress response than those who underwent ER, it did not result in poorer perioperative outcomes.

Several centers with large endovascular experience have reported advantages of ER over OR, particularly with regard

Table 4. Discharge Status

|                       | Surgery<br>(n = 208) | Stent Grafting<br>(n = 134) | P      |
|-----------------------|----------------------|-----------------------------|--------|
| Home                  | 50.96%               | 82.84%                      | <.0001 |
| Home health           | 18.27%               | 6.72%                       | .0025  |
| Skilled/extended care | 17.79%               | 5.22%                       | .0007  |
| Died                  | 3.85%                | 0.75%                       | .0954  |

to resource use [Zarins 1999, Ligush 2002]. However, reports of significant postoperative morbidity have continued to surface in the literature [Politz 2000, Baum 2001], leading to a dampening of the once unbridled enthusiasm for ER. ER has instead been reserved for high-risk operative patients. Centers that participated in the phase II AneuRx trial reported early endoleaks in 38% of the patients. Although follow-up imaging indicated that only approximately a third of these endoleaks persisted for longer than 1 month, new endoleaks eventually occurred in another 9% of patients, and secondary procedures to correct endoleaks (4%) or graft limb occlusions (2%) ultimately were necessary for 6% of the patients [Zarins 2001]. According to Zarins et al, the presence of an endoleak has not influenced the cumulative 1-year survival rate (96%) or the 2-year aneurysm rupture rate (3%) in the phase II AneuRx trial. In Europe, however, both type I and type III endoleaks have significantly contributed to the cumulative rupture rate of 1% per year for AAAs treated with several proprietary stent grafts in the EUROSTAR registry [Harris 2000]. Several publications have attempted to explain these shortcomings [Zarins 2001], and 1 recent editorial has essentially condemned ER altogether [Collin 2001].

One of the original goals of this study was to define more accurately the high-risk AAA patient for whom ER appeared to be clearly beneficial, but the preoperative medical risk factor profiles in our 2 treatment arms were not significantly different. Becker et al [2001] recently reported on a large series of patients treated with ER and analyzed the outcomes on the basis of a risk-stratification system derived from published reports on OR. Although these workers' overall results appear to compare favorably with OR at each risk level, they did not compare ER with an ongoing or previously treated cohort of OR subjects at their institution with similar levels of risk. In a study designed to investigate the outcomes of patients who underwent ER on the basis of a retrospectively applied stratification of surgical risk, Bush et al [2001] found similar rates of perioperative morbidity and mortality for patients at high and low risks who underwent ER. In their conclusions, these investigators advocated caution regarding the use of ER for the otherwise ideal candidate for OR. We, too, have yet to define the patient population that will derive maximal benefit from ER. There is general acceptance that the gold standard for comparing 2 methods of treatment is a concurrent randomized study. However, when there is such a vast difference between the 2 methods and the level of discomfort experienced by the patients in each group, it has

become apparent that a randomized trial is impractical. There is virtually no way of preventing patients from withdrawing from a randomized study if they fail to draw the minimally invasive method that many patients seek. If the trial happens to be a multicenter one, there are similar problems with preventing patients from registering with several centers in a sequential manner until they draw the method of their choice.

Collective reviews have cited several series from referral centers in which the operative mortality rate (2%) is comparable with our own (3.58%) [Thomas 1988, Drott 1992], and the mortality rate in multicenter cooperative studies generally has been approximately 5% [Pilcher 1980, Ingoldby 1986]. Statewide audits have documented early mortality rates exceeding 7% for nonruptured AAAs but also have repeatedly shown that these rates are inversely related to the hospital volume and the experience of individual surgeons with aortic surgery [Ernst 1993]. The Dartmouth Atlas of Vascular Health Care has confirmed that this relationship between case volume and early outcome exists nationwide in the Medicare population, irrespective of the specialty designation of the surgeons performing the operations [Johnston 1989]. Recent investigations with the National Hospital Discharge Survey have the advantage of an extraordinarily large database but necessitate considerable editing even to discriminate between suprarenal and infrarenal aortic aneurysms [Sullivan 1990, Rutledge 1996]. Possibly because of differences in the way in which data were retrieved from the National Hospital Discharge Survey, these investigations have estimated that the overall mortality rates for AAA repair in the United States range as high as 4% to 8%. Comparing any of these data with the postoperative mortality rate for endovascular AAA repair at vetted trial centers could be misleading because, in addition to potential variability in the patient mix, the mortality rate of ER may prove to be much higher once this technique becomes as widely available as conventional surgical treatment. There is no immediate reason to assume, for instance, that low-volume stent grafting will be any safer in the future than low-volume open operations have been in the past.

Several limitations of our study bear mentioning. Clearly, our study is relatively small and lacks the power of a prospective, randomized, multi-institutional trial. The retrospective analysis of the data for the OR group may have underestimated the incidences of complications for this group. Regular follow-up and the use of contrast-enhanced computed tomography in the endoluminal group make it highly unlikely that any failures or complications would be overlooked. The OR group was not subjected to such scrutiny. It is possible that false aneurysms were overlooked. The chance of undetected failure from this cause, however, is probably small because the incidence of false aneurysm is low in the first 5 years after OR. In addition, one may argue that the surgical outcomes from our early ER procedures cannot be compared with our well-established, large OR experience. However, we did not have the learning-curve effect described by other investigators during their early ER efforts [Dorffner 1997]. We have been able to achieve a level

of technical success similar to that of larger series in their later phases of endograft deployment with regard to graft deployment, aneurysm exclusion, graft limb thrombosis, open conversion, and direct procedure-related mortality. The shortcomings of our study notwithstanding, it is important to recognize that the impact of a specific therapy on patient outcome is measured best not always with data from large series but rather in the ability of the individual surgeon to administer that therapy. Inasmuch as vascular surgeons critique their complication rates on their ability to maintain established procedural outcomes, it is imperative that the same be done with regard to this new technology as it applies to the treatment of AAA. It is important to recognize that most reports regarding ER come from large centers with extensive endovascular experience. Many of these centers have participated in the development of clinical trials evaluating these endovascular devices. As more vascular surgeons use ER for the treatment of their patients, it is essential that they analyze their results in an objective fashion to assess the impact of ER, or lack thereof, on their patient populations.

## CONCLUSION

What is the superior option for AAA repair in these groups of patients? There is no easy answer because nearly the entire literature on the topic of asymptomatic AAAs, including our study, is based on nonuniform patient populations who have a wide variety of surgical risks. With the exception of a small number of preoperative comorbidities, we detected minimal differences between the ER and OR patients at our institution with respect to preoperative medical risk factors. Relative to OR, ER was associated with significant decreases in operative times, ICU use, blood loss, and overall lengths of stay. Despite these advantages, that the endoluminal method is not free of major morbidity and mortality must be emphasized. ER was associated with similar rates of significant perioperative morbidity and mortality compared with OR. These results suggest that ER offers improvements in use of hospital and blood bank resources but no beneficial impact on overall complication rates when similar preoperative medical risks exist, especially when ER is used at medical centers where low morbidity and mortality rates are already established for OR. Furthermore, the definition of the high-risk patient who may potentially benefit from ER to the greatest degree remains imprecisely defined, and patients opting for the endoluminal method of repair should be made aware that the minimally invasive technique carries the disadvantage of a lifetime surveillance “contract” and a potentially higher failure rate. Other centers that perform ER should undertake such an analysis to assess its impact on their patients. To make the application of ER justifiable, any center that cares for a large number of patients with complex aortic pathologies and possesses considerable expertise in the open management of aneurysms should embrace catheter-based alternative therapy for AAA only if their highest-risk patients benefit significantly from the standpoint of perioperative complications.

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