Endovascular vs open repair for ruptured abdominal aortic aneurysm

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Objective: Endovascular repair (EVAR) of ruptured abdominal aortic aneurysm (rAAA) has become first-line therapy at our institution and is performed under a standardized protocol. We compare perioperative mortality, midterm survival, and morbidity after EVAR and open surgical repair (OSR).

Methods: Records were retrospectively reviewed from May 2000 to September 2010 for repair of infrarenal rAAAs. Primary end points included perioperative mortality and midterm survival. Secondary end points included acute limb ischemia, length of stay, ventilator-dependent respiratory failure, myocardial infarction, renal failure, abdominal compartment syndrome, and secondary intervention. Statistical analysis was performed using the t-test, chi-square test, and logistic regression calculations. Midterm survival was assessed with Kaplan-Meier analysis and Cox proportional hazard models.

Results: Seventy-four infrarenal rAAAs were repaired, 19 by EVAR and 55 by OSR. Despite increased age and comorbidity in the EVAR patients, perioperative mortality was 15.7% for EVAR, which was significantly lower than the 49% for OSR (odds ratio, 0.19; 95% CI, 0.05-0.74; P = .008). Midterm survival also favored EVAR (hazard ratio, 0.40; 95% CI, 0.21-0.77; P = .028, adjusted for age and sex). Mean follow-up was 20 months, and 1-year survival was 60% for EVAR vs 45% for OSR. Mean length of stay for patients surviving >1 day was 10 days for EVAR and 21 days for OSR (P = .004). Ventilator-dependent respiratory failure was 5% in the EVAR group vs 42% for OSR (odds ratio, 0.08; 95% CI, 0.01-0.62; P = .001).

Conclusions: EVAR of rAAA has a superior perioperative survival advantage and decreased morbidity vs OSR. Although not statistically significant, overall survival favors EVAR. We recommend that EVAR be considered as the first-line treatment of rAAAs and practiced as the standard of care. (J Vasc Surg 2012;56:15-20.)

Endovascular repair (EVAR) of abdominal aortic aneurysms (AAAs) was introduced in the 1990s as an alternative to open surgical repair (OSR) for patients with high operative risk. Randomized, controlled trials (RCT) report lower perioperative morbidity and mortality with elective EVAR compared with OSR. Endovascular repair for rAAA (rEVAR) was introduced in 1994 by Marin et al and has been increasing nationwide since the first case series of 12 patients was reported by Ohki et al and Hinchcliffe et al. Hinchcliffe et al published the only RCT in 2006, demonstrating equivalent results and challenging the benefit of rEVAR. Lack of statistical power due to small sample size is a frequently cited criticism. Although a few RCTs are ongoing, such as under standardized protocols that used rEVAR as first-line therapy. Mehta et al reported an 18% mortality rate after rEVAR compared with the traditional 40% to 50% for OSR. EVAR is first-line therapy for patients with rAAAs at our institution, and a formal protocol is practiced to expedite evaluation and treatment. The purpose of this study was to determine if perioperative morbidity and mortality are lower after rEVAR, compared with OSR, at our institution. We also evaluated length of stay (LOS), midterm survival, and institutional use of rEVAR during the past 5 years.

METHODS

We performed a retrospective review of rAAA repairs at Beth Israel Deaconess Medical Center from May 2000 to September 2010. Suprarenal and juxtarenal aneurysms were excluded. Preoperative characteristics were compared between rEVAR and OSR, including age, sex, coronary artery disease, and history of congestive heart failure, atrial fibrillation, chronic obstructive pulmonary disease, chronic renal insufficiency (glomerular filtration...
rate < 60 mL/min/1.73 m²), hypertension, and diabetes. Primary end points included perioperative mortality (in-hospital or ≤ 30 days) and midterm survival. Our rAAA protocol was initiated in 2007. Perioperative mortality was compared between rEVAR and OSR patients before and after the protocol was initiated.

Secondary end points included LOS, acute renal failure requiring dialysis, ventilator-dependent respiratory failure (VDRF) requiring ≥7 days of ventilator support, acute limb or acute mesenteric ischemia, myocardial infarction (MI), abdominal compartment syndrome, and secondary intervention for wound infection or seroma, bowel resection, thrombectomy, conversion to OSR, coil embolization of type II endoleak, and closure of abdominal wounds. Preoperative hemodynamic stability and intraoperative estimated blood loss (EBL) were assessed. Because our protocol includes permissive hypotension, permitting a systolic blood pressure (SBP) < 100 mm Hg, the definition of instability included SBP < 90 mm Hg, administration of vasoactive medications to maintain SBP ≥ 90 mm Hg, intubation before arrival to the operating room, or SBP < 100 mm Hg with depressed mental status.

Our rupture protocol involves notification through a central paging system of on-call staff, including vascular/endovascular surgeons, cardiovascular anesthesiologists, endovascular nurses with catheter-based experience, and radiology technicians. Early notification facilitates immediate preparation for direct patient transfer to the operating suite on arrival, if necessary. The protocol is designed to enable rapid evaluation of aneurysm anatomy and transfer to the hybrid operating/endovascular suite. Communication between departments for expeditious treatment is paramount and has been emphasized in previously published protocols.18 If the patient is hemodynamically stable enough to delay surgery, direct transfer to the computed tomography (CT) scanner occurs with surgical staff in attendance. If the patient’s anatomy is favorable for rEVAR, grafts are sized and selected from available inventory, which contains most of the available components of two different stent graft systems. Patients who are too unstable to undergo a CT scan are transferred directly from the helicopter or ambulance to the endovascular suite.

Ultrasound-guided access into the common femoral arteries is achieved before induction of anesthesia to allow for sheath and wire placement into the aorta. Aortic balloon occlusion is initiated, if hemodynamic instability is present, as previously described.19,20 Two Perclose ProGlide suture-mediated closure devices (Abbott Laboratories, Abbott Park, Ill) are fired (Perclose technique) to avoid the need for surgical femoral artery exposure. We routinely use ultrasound-guided access and the Perclose technique during elective EVAR repairs to facilitate rapid and consistent technical results during rAAA repair. If unstable, percutaneous closure can be delayed until the repair has been completed.

The main body device is delivered through the femoral artery sheath, contralateral to the side with the occlusion balloon and deployed after the balloon is deflated and withdrawn. If needed, an additional occlusion balloon can be placed through the main body device once it is deployed to maintain proximal control while cannulating and deploying the contralateral iliac limb. Zenith Flex (Cook, Bloomington, Ind) and Gore Excluder (W. L. Gore and Associates, Flagstaff, Ariz) endografts were used primarily to perform rEVAR and were selected based on surgeon experience and preference.

After graft deployment and fixation, the proximal occlusion balloon is deflated and removed, and an aortogram is performed and reviewed for endoleak. The sheaths are removed over a wire, and Perclose sutures are pushed down over a wire left in the femoral artery. If hemostasis is achieved, the wire is removed and the sutures are secured. If persistent bleeding occurs, additional Perclose ProGlide devices may be deployed, or the sheath may be replaced for hemostasis, allowing subsequent open repair.

OSR of rAAAs is performed in a standard fashion with a midline transperitoneal or retroperitoneal incision, based on surgeon preference. If a transperitoneal approach is performed, the abdominal wall is frequently left open to minimize the development of abdominal compartment syndrome. Closure of the abdomen is usually delayed 48 to 72 hours.

Statistical analysis of preoperative characteristics, perioperative outcomes, and mortality was performed using t-test, χ² test, the Fisher exact test, and logistic regression calculations. Midterm survival was assessed with Kaplan-Meier analysis and Cox proportional hazard models. Statistical analysis was performed with SAS software (SAS Institute Inc, Cary, NC). Statistical significance was assigned at the value of P < .05.

RESULTS

Between May 2000 and September 2010, 74 rAAAs were repaired, comprising 19 rEVAR and 55 OSR. Patients were generally excluded for an infrarenal aortic neck < 5 mm, diameter greater than the largest available main body graft at the time performed, or severe iliac occlusive arterial disease. Two rAAAs were repaired with EVAR before our protocol was initiated in 2007. The average patient age was 78 years for rEVAR and 76 years for OSR (P = .44). Women comprised 26% of rEVAR and 49% of OSR (odds ratio [OR], 0.37; 95% confidence interval [CI], 0.12-1.2; P = .75). Balloon occlusion was required in 32% of rEVAR and 49% of OSR (OR, 0.92; 95% CI, 0.57-1.5; P = .83). Ruptures were considered unstable in 50% of patients in the rEVAR group vs 57% in the OSR group (OR, 0.85; 95% CI, 0.3-2.3; P = .75). Balloon occlusion was required in 11% of rEVAR patients and in 16% of OSR patients (P = .32). Since initiation of the formal protocol in 2007, one patient was deemed too unstable to undergo a CT scan and was transported directly to the hybrid operating room. An
occlusion balloon was inflated within the aorta, an aortogram was performed, and the aneurysm was successfully excluded with a bifurcated endograft. However, the patient died on the table due to cardiac arrest.

Perioperative mortality was 15.7% for rEVAR and 49% for OSR (OR, 0.19; 95% CI, 0.05-0.74; \( P = .008 \)). Mid-term survival also favored rEVAR (hazard ratio, 0.40; 95% CI, 0.21-0.77; \( P = .028 \), adjusted for age and sex, Fig 1). Mean follow-up was 20 months, and 1-year survival was 60% for EVAR vs 45% for OSR. Mean LOS for patients surviving \( >1 \) day was 10 days for rEVAR and 21 days for OSR (\( P = .004 \)).

Postoperative complications, including acute renal failure requiring hemodialysis, acute limb ischemia, mesenteric ischemia, and MI, were similar between the two groups (Table II). One MI occurred after rEVAR resulting in death, and four MIs occurred after OSR, with one death. One rEVAR was complicated by acute limb ischemia, recognized before leaving the operating room. A common femoral thrombectomy and patch angioplasty was performed, resulting in limb salvage. One OSR was complicated by bilateral limb ischemia, requiring bilateral lower extremity thrombectomy. Limb salvage was achieved, but the patient died several days later of multiorgan system failure. VDRF was significantly lower in the rEVAR group, with a rate of 5% compared to 42% for OSR (OR, 0.08; 95% CI, 0.01-0.62; \( P = .001 \)). EBL was 0.4 liters in the rEVAR group and 2.9 liters in the OSR group (\( P = .0005 \)). The number of packed red blood cell (pRBC) units transfused was also compared because calculated blood loss for OSR patients includes both internal hematoma and operative hemorrhage, whereas only externalized blood was calculated for rEVAR. An average of 3.42 units of pRBC were transfused for rEVAR vs 10.4 units for OSR (\( P = .00005 \)).

Secondary interventions were required in 37% of rEVAR patients, including wound debridement for infection or seroma, coil embolization of type II endoleak, and conversion to OSR, compared with 33% of OSR patients (\( P = .74 \)), who required colectomy for mesenteric ischemia, thrombectomy for acute limb ischemia, graft revision for infection, and abdominal wound closure for compartment syndrome. Delayed closure of the abdominal wound occurred in 25% of OSR patients, often prophylactically, according to surgeon preference, whereas none of the rEVAR patients underwent decompressive laparotomy (\( P = .57 \)).

The annual combined volume of rEVAR and OSR for rAAA is reported in Fig 2. EVAR use has been increasing since the rAAA protocol was initiated in 2007. Overall mortality was 54.1% before the protocol (2000-2007) compared with 27% after the protocol (2007-2010; OR 3.29; 95% CI, 1.2-8.7; \( P = .014 \)).

There were no immediate conversions in the rEVAR group. One patient underwent elective conversion \( \sim 1 \) month after rEVAR because of a small type I endoleak recognized on completion aortogram. Although no extravasation was visualized, there was concern for potential, persistent aneurysm sac pressurization. After optimizing cardiac and pulmonary function, elective OSR was performed. The patient is alive and has recently recovered from the elective repair of a thoracic aneurysm. A second patient with an unrecognized type I endoleak after rEVAR presented with aortic rupture \( \sim 1 \) month after repair. An OSR was performed. The patient was discharged on postoperative day 28 but died on day 38.

**DISCUSSION**

Previous RCTs demonstrate lower rates of morbidity and mortality in patients undergoing elective EVAR compared with OSR counterparts.\(^ {17-23} \) Currently, a growing number of single-institution studies and national and international reviews report that perioperative mortality is also lower for patients undergoing rEVAR.\(^ {13,18,24-26} \) Our institution reflects the nationwide trend of increasing rEVAR use, which presently is \( >65\% \) of rAAA repairs. However, our rEVAR repairs are performed under a formal protocol that includes availability of endovascular staff, rapid evaluation of aneurysm anatomy, a hybrid operating room suite, and priority toward rEVAR.\(^ {6,27} \) These resources are required to practice under a similar protocol and may be justified by an adequate volume of rAAA, as well as other vascular emergencies treated with a catheter-based intervention. For this reason, it may be appropriate to centralize rAAA repair to tertiary centers that are able to provide these specialized resources. EVAR for rAAA under this standardized protocol resulted in lower rates of perioperative mortality, which was 15.7% for rEVAR and 49% for OSR. This is comparable to results published by Mehta et al\(^ {18} \) of 18% EVAR and 51% OSR. Our mortality rate was more than three times lower in the rEVAR group, despite higher rates of preoperative chronic renal insufficiency and congestive heart failure.

Hinchliff et al\(^ {9} \) published results from a RCT in 2006 with equivalent mortality in rEVAR (53%) and OSR (53%) groups. However, more than two-thirds of patients were...
excluded from the study because of hemodynamic instability or staff unavailability. There were 13 patients in the rEVAR group and only 11 completed rEVAR, due to OSR crossover or preoperative death. Previous studies published by Giles et al.\textsuperscript{10,24} used the American College of Surgeons National Surgical Quality Improvement Program (NSQIP) and NIS databases to examine perioperative outcomes and reported a perioperative survival advantage for rEVAR, albeit higher mortality rates of 24% for NSQIP and 39.9% for NIS.\textsuperscript{6} Although the NIS study did not have access to hemodynamic data or aneurysm anatomy, potentially contributing to selection bias, the NSQIP study did include hemodynamic parameters in a limited fashion.

Criticism toward similar studies has been directed at the imbalance of hemodynamically stable patients, with more favorable aneurysm anatomy, in the rEVAR cohorts. We demonstrate a similar percentage of hemodynamic instability in both groups, as well as exclusion of juxtarenal or suprarenal aortic aneurysms in the OSR cohort. Giles et al.\textsuperscript{10} reported decreased total AAA- and rAAA-related mortality in the post-EVAR era using the NIS database. Overall rAAA mortality before rEVAR use and initiation of the rupture protocol was 54%, compared with the postprotocol overall mortality of 27%. This suggests that our improved perioperative mortality is not due to the selection of patients with favorable anatomy or hemodynamics.

Postoperative complications reflecting technical differences between rEVAR and OSR, such as acute limb and mesenteric ischemia, were similar. Significantly more women were treated with OSR than rEVAR. The reason for this is unclear from our data; however, this may be due to a smaller iliac diameter or less favorable aortic neck anatomy. LOS and VDRF were much lower in the rEVAR group, possibly as a result of less intraoperative blood loss, smaller postoperative fluid shifts, and reduced production of inflammatory mediators. EVAR may also expedite recovery.

Table II. Perioperative outcomes for patients undergoing endovascular repair (EVAR) and open surgical repair (OSR) for ruptured abdominal aortic aneurysms (rAAAs)

<table>
<thead>
<tr>
<th>Perioperative outcomes</th>
<th>EVAR (%)</th>
<th>OSR (%)</th>
<th>OR (95% CI)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perioperative mortality, %</td>
<td>15.7</td>
<td>49.1</td>
<td>0.19 (0.05-0.74)</td>
<td>.008</td>
</tr>
<tr>
<td>Length of stay &gt;1 day, average days</td>
<td>9.6</td>
<td>20.5</td>
<td></td>
<td>.004</td>
</tr>
<tr>
<td>VDRF, %</td>
<td>5.3</td>
<td>41.8</td>
<td>0.07 (0.01-0.62)</td>
<td>.001</td>
</tr>
<tr>
<td>ARF requiring dialysis, %</td>
<td>10.8</td>
<td>14.6</td>
<td>0.69 (0.13-3.6)</td>
<td>.65</td>
</tr>
<tr>
<td>Acute limb ischemia, %</td>
<td>5.3</td>
<td>5.5</td>
<td>0.96 (0.09-9.9)</td>
<td>.97</td>
</tr>
<tr>
<td>Mesenteric ischemia, %</td>
<td>5.3</td>
<td>9.1</td>
<td>0.56 (0.06-5.1)</td>
<td>.58</td>
</tr>
<tr>
<td>Myocardial infarction, %</td>
<td>5.3</td>
<td>10.9</td>
<td>0.45 (0.05-4.0)</td>
<td>.44</td>
</tr>
<tr>
<td>Estimated blood loss, liters</td>
<td>0.40 ± 0.29</td>
<td>2.9 ± 1.7</td>
<td></td>
<td>.0005</td>
</tr>
<tr>
<td>Secondary intervention, %</td>
<td>36.8</td>
<td>32.7</td>
<td>1.20 (0.4-3.6)</td>
<td>.74</td>
</tr>
<tr>
<td>Delayed abdominal wound closure, %</td>
<td>0</td>
<td>25</td>
<td>0.74 (0.3-1.7)</td>
<td>.57</td>
</tr>
</tbody>
</table>

ARF, Acute renal failure; CI, confidence interval; OR, odds ratio; VDRF, ventilator-dependent respiratory failure.

Fig 1. Kaplan-Meier curves show survival analysis of patients treated with endovascular (EVAR) and open surgical repair (OSR) for ruptured abdominal aortic aneurysms (rAAAs) during a 2-year period. Survival at 1 year is 60% for EVAR and 45% for OSR (adjusted hazard ratio, 0.40; P = .028).
and lessen VDRF by reducing pain associated with large abdominal incisions.

None of the rEVAR patients required laparotomy for compartment syndrome, which may be because we require evidence of elevated inspiratory peak airway pressures or marginal urinary output combined with bladder pressures >30 mm H2O. Delayed abdominal closure occurred in 25% of OSR patients for compartment syndrome. However, this was frequently performed prophylactically according to surgeon preference and therefore shows a bias toward rEVAR. We agree with prior suggestions that a high index of suspicion should be maintained to allow prompt decompressive laparotomy if there is evidence of compartment syndrome.

Overall survival curves show superiority for rEVAR vs OSR (hazard ratio, 0.40; 95% CI, 0.21–0.77). Survival at 1 year was not statistically significant, likely due to small numbers of patients with 1-year follow-up. Although the midterm survival benefit is not as large as the perioperative survival, it is still significant. Ongoing rEVAR mortality is observed past the perioperative period and increased mortality risk persists until ~3 months. Characterization of these patients may help identify those who are able to survive rEVAR but who decompensate during recovery from the rupture event due to comorbid illnesses. We believe this hypothesis is supported by the findings of Egorova et al,28 who published similar results after review of the Medicare Inpatient Standard Analytical File, including >43,000 patients. Late survival (>90 days) benefit was not as pronounced as in the perioperative period but was significant when cohorts were matched. Survival advantage persisted out to 4 years of follow-up.28

Our study is limited by small sample size and short follow-up. Nonetheless, we were able to duplicate the results published by similar institutions and demonstrated the feasibility of rEVAR when performed under a standardized protocol. Institutions should have significant experience with elective EVAR as well as the infrastructure and inventory to create a standardized treatment algorithm. Our study is retrospective and not randomized to control for bias.

**CONCLUSIONS**

Ongoing debate regarding the need for RCTs continues, but given the mounting evidence for survival advantage in patients undergoing rEVAR, RCTs may be unnecessary. Given the superior perioperative survival advantage, favorable overall survival, and decreased morbidity of rEVAR, we recommend it be practiced as the standard of care for patients with rAAAs.

**AUTHOR CONTRIBUTIONS**

Conception and design: AN, MS, RH
Analysis and interpretation: AH, FP, MW, MS, AN
Data collection: JS, RH, AN
Writing the article: AN
Critical revision of the article: MS, FP, MW, AH
Final approval of the article: AN, MS
Statistical analysis: AN, TS, JS
Obtained funding: FP, MS
Overall responsibility: MS

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