Mid-term Outcomes following Emergency Endovascular Aortic Aneurysm Repair for Ruptured Abdominal Aortic Aneurysms

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A B S T R A C T

Objective: Emergency Endovascular Aortic Aneurysm Repair (eEVAR) is a rapidly evolving approach to ruptured Abdominal Aortic Aneurysms (rAAA). Yet longer-term outcomes following eEVAR remain unclear. This study compares mid-term outcomes of eEVAR and open rAAA.

Methods: A prospective database for all patients undergoing eEVAR and open rAAA from January 2006 to April 2010 was analysed. Patients were offered eEVAR if anatomically suitable.

Results: 52 patients (45 male, median age 78 years (62–92 years), underwent eEVAR, 50 patients (44 male, median age = 71 (62–95 years) underwent open rAAA repair. In-hospital mortalities were 12% (6/52) for eEVAR, 32% (16/50) for open repair. There were five re-interventions (10%) in the eEVAR group. The peri-operative survival benefits of eEVAR over open repair were maintained at 1 and 2 years post-operatively with open repair demonstrating a two-fold increased risk of mortality (Hazard ratio 2.2, Fisher Exact test, 95% Confidence Interval (CI) 1.108–4.62, \( p = 0.0122 \)). Overall survival was 81% at 1 year, 73% at 2 years for eEVAR, and 62% at 1 year and 52% at 2 years for open rAAA repair.

Conclusion: eEVAR is associated with excellent mid-term survival in this cohort. We would recommend eEVAR as the management of choice for rAAA in anatomically suitable patients where local facilities and expertise exist.

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Introduction

Mortality after open repair of ruptured abdominal aortic aneurysm (AAA) remains high, in excess of 40% for those offered surgery. Therefore Emergency Endovascular Aortic Aneurysm Repair (eEVAR) is rapidly becoming the treatment of choice for ruptured Abdominal Aortic Aneurysms (rAAA) where the facilities and expertise are available. There is good evidence to suggest that eEVAR is associated with reduced peri-operative mortality. The benefit of EVAR in elective patients over open repair is lost at 2-year follow-up. However, relatively little is known about longer-term outcomes following eEVAR. We hypothesized that eEVAR for rAAA is associated with lower mid-term mortality. Our aim of this study was to evaluate the mid-term outcomes of eEVAR compared to open rAAA carried out during this time period at our institution. We have endeavoured to report data in accordance with the contemporary British Society of Endovascular EVAR reporting standards.

Methods

A retrospective analysis of a prospectively collated database of all eEVARs and open rAAA repairs performed at our institution from January 2006 to April 2010 was conducted. The study period commenced at the outset of our emergency EVAR program and concluded after randomization into the IMPROVE trial was established in our unit. The study only included confirmed ruptures, with evidence of haematoma on pre-operative CT scan or at open surgery. Both iliac and aortic aneurysm ruptures were included. Patients routinely undergo a pre-operative CT scan for rAAA at our institution. Emergency EVAR was offered preferentially to patients where, anatomically suitable on pre-operative imaging and when the eEVAR team and appropriate stent-grafts were available. Physiological data including pre-operative blood pressure, heart rate and haemoglobin levels were collected prospectively and
entered into the National Vascular Database. Where this data was incomplete it was sort by retrospective review of hospital computer and case note records.

During the study period four vascular surgeons managed all ruptured aneurysms. Three surgeons were trained and experienced in both open and endovascular techniques. One offered only open repair, often without pre-operative CT imaging. Endovascular procedures were carried out by a team of vascular surgeons and interventional radiologists, with similar technique. Standard anatomical criteria for were used to assess suitability for EVAR, however strict adherence to device specific anatomical parameters, were left at the discretion of the operating surgeon. Our technique has developed overtime with the preference for aorto-uni-iliac endografts and fem–fem crossovers initially gradually being overtaken by the use of a bifurcated stent graft where possible. This modification in technique has occurred as our initial desire for a quick seal has been overtaken by the desire to provide a more anatomical and durable repair. Furthermore an initial approach involving both local and general anaesthetic has shifted to entirely local anaesthetic where possible. No supra–coeliac balloon occlusion catheters were used to achieve haemodynamic stability. After discharge patients who underwent EVAR were followed up in our EVAR surveillance program following a protocol of clinical examination and duplex at 6 weeks and 6 months, CT at 3 months and 1 year and subsequent annual duplex scanning and plain abdominal x-rays with selective CT imaging. Those who underwent open repair underwent clinical examination at 6 weeks and 6 months following discharge, with selective imaging as required and further follow-up at the discretion of the operating surgeon.

Statistical Analysis

Continuous variables are reported as median (inter-quartile ranges) and categorical variables as absolute number (%), unless stated otherwise. Baseline characteristics between the groups were compared using the chi-square or Mann–Whitney U test for categorical and continuous variables respectively. Survival was assessed using the Kaplan–Meier method. The survival curves were truncated at two years. Survival was compared between groups by using the log-rank test and a hazard ratio calculated. The 5% significance level was taken as significant and all p-values are two-sided. The statistical analyses were performed using Stata (Stata direct Ltd, Altrincham, UK).

Results

A total of 52 patients underwent eEVAR during this time period and 50 underwent open repair. Patients undergoing EVAR were significantly older (median 78 years, range 62–92 years) than those undergoing open repair (71 years, range 62–95 years) (p < 0.001). Operative characteristics for eEVAR patients are demonstrated in Table 1. Patient co-morbidities are shown in Table 2 demonstrating that the groups were well matched. There were 5 transfers (5%) from other hospitals all in the eEVAR group. Seventy six percent (38/50 patients) undergoing open rAAA repair had a pre-operative CT scan. Of the 12 patients in the study who did not have a pre-operative CT scan, 6 were considered only for open repair due to surgeon preference, with the remaining 6 (6%) considered too unstable for CT scanning (The mortality of the 12 patients treated by open repair without CT scanning was 3/12 or 25%). Overall 90 patients (88%) had pre-operative CT scanning. There were no significant differences in the pre-operative lowest systolic blood pressures between the patients undergoing open repair (median 94 mmHg) and those who had eEVAR (96 mmHg) p = 0.84, highest pre-operative heart rates (83 bpm open versus 90 bpm eEVAR), p = 0.4 or pre-operative haemoglobin levels (10.6 g/dl open versus 11.7 g/dl eEVAR, p = 0.06) suggesting that both groups were well matched for physiological and haemodynamic stability (Table 3).

The median length of stay was 11 days (IQR 7–25 days) in the eEVAR group and 16 days (IQR 8–26 days) in the open rAAA group. The median follow up was 31 months (Range 8–58 months) in the eEVAR group and 36 months (Range IQR 1–135 months) in the open rAAA group. No surviving eEVAR patients have been lost to follow-up.

Table 2

<table>
<thead>
<tr>
<th>Variable</th>
<th>eEVAR (n = 52)</th>
<th>Open (n = 50)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median age yrs range</td>
<td>78 (62–92)</td>
<td>71 (62–95)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Hypertension</td>
<td>23 (45%)</td>
<td>21 (42%)</td>
<td>0.754</td>
</tr>
<tr>
<td>Ischaemic heart disease</td>
<td>20 (39%)</td>
<td>16 (32%)</td>
<td>0.449</td>
</tr>
<tr>
<td>Renal failure</td>
<td>2 (4%)</td>
<td>2 (4%)</td>
<td>0.985</td>
</tr>
<tr>
<td>Cerebrovascular accident</td>
<td>4 (8%)</td>
<td>6 (12%)</td>
<td>0.508</td>
</tr>
<tr>
<td>Arhytmia</td>
<td>5 (9%)</td>
<td>3 (6%)</td>
<td>0.509</td>
</tr>
<tr>
<td>Diabetes</td>
<td>3 (6%)</td>
<td>2 (4%)</td>
<td>0.696</td>
</tr>
<tr>
<td>COPD</td>
<td>11 (21%)</td>
<td>5 (10%)</td>
<td>0.111</td>
</tr>
<tr>
<td>Malignancy</td>
<td>7 (14%)</td>
<td>8 (16%)</td>
<td>0.747</td>
</tr>
<tr>
<td>Post-operative</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory</td>
<td>10 (19%)</td>
<td>19 (38%)</td>
<td>0.068</td>
</tr>
<tr>
<td>Acute renal failure</td>
<td>11 (13%)</td>
<td>5 (10%)</td>
<td>0.786</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>2 (4%)</td>
<td>4 (8%)</td>
<td>0.427</td>
</tr>
<tr>
<td>Sepsis</td>
<td>5 (9%)</td>
<td>3 (6%)</td>
<td>0.509</td>
</tr>
<tr>
<td>Limb ischaemia</td>
<td>0 (0%)</td>
<td>2 (2%)</td>
<td>0.49</td>
</tr>
<tr>
<td>Wound infection</td>
<td>2 (4%)</td>
<td>1 (2%)</td>
<td>1.00</td>
</tr>
<tr>
<td>Bowel ischaemia</td>
<td>0 (0%)</td>
<td>3 (6%)</td>
<td>0.114</td>
</tr>
<tr>
<td>Any complication</td>
<td>18 (35%)</td>
<td>38 (76%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>In-hospital death</td>
<td>6 (12%)</td>
<td>14 (28%)</td>
<td>0.115</td>
</tr>
</tbody>
</table>

Table 3

<table>
<thead>
<tr>
<th>Variable</th>
<th>eEVAR</th>
<th>Open rAAA</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-operative lowest</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>systolic BP, mmHg</td>
<td>[41/50]</td>
<td>[42/52]</td>
<td></td>
</tr>
<tr>
<td>Heart rate bpm</td>
<td>[41/50]</td>
<td>[44/52]</td>
<td></td>
</tr>
<tr>
<td>Pre-operative highest</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>haemoglobin g/dl</td>
<td>[50/50]</td>
<td>[52/52]</td>
<td></td>
</tr>
</tbody>
</table>

Mortality

The in-hospital mortalities for eEVAR and open rAAA repair were 12% and 32% respectively. The in-hospital mortality and 30-day mortality were the same for the eEVAR group. In the open rAAA group the 30-day mortality was 28%. During the study period 9 patients with ruptured AAAs were palliated due to a combination medical co-morbidity, advanced age, poor quality of life and dementia.
The early mortality benefit of eEVAR was maintained at 1 and 2 years post-operatively $p = 0.012$ (Fisher Exact) with open repair demonstrating a two-fold increased risk of mortality (Hazard ratio 2.2 [95% CI 1.108–4.62, $p = 0.0122$]. A Kaplan–Meier survival curve is shown in Fig. 1. Overall survival was 81% at 1 year and 73% at 2 years for eEVAR, compared to 62% at 1 year and 52% at 2 years for open rAAA repair. There were a total of 14 deaths, 6 (12%) as inpatient and a further 8 (15.4%) during 2-year follow-up in the eEVAR group.

The causes of inpatient death were myocardial infarction, sepsis, mesenteric ischaemia and re-bleeding. The remaining two deaths were secondary to respiratory arrests, the inability to secure a definitive airway and consequent hypoxic brain damage. There were 8 deaths following discharge at 2 years. Two patients died of bronchopneumonia, three from malignancies, one from mesenteric ischaemia, one from sepsis secondary to a pressure sore, and the final cause of death remains unknown.

Re-interventions

There were a total of 5 patients who had re-interventions (9.6%) in the eEVAR group. The first patient had an iliac limb dislocation and consequent repressurisation of the sac, requiring an emergency bridging stent with good initial result. A further eight months later he presented with bilateral lower limb ischaemia and an axillo-femoral bypass was performed.

The second patient had a kink at the body graft and iliac limb interface, which was demonstrated on a routine surveillance CT. Though she was asymptomatic, a limb extension was deployed with no immediate complications. The third patient had a type 2 endoleak arising from an ilio-lumbar artery, 25 months post eEVAR on a routine surveillance scan. This was treated with a proximal aortic cuff. The last patient had an original aorto-uni-iliac and femoro–femoral crossover graft. This developed an infection and had to be removed with a consequent axillo-femoral bypass graft being performed in the open rAAA group 3 patients had re-interventions (6%). 2 patients had femoral embolectomies immediately post-operatively for distal emboli. One of these patients needed a subsequent above knee amputation within the same admission.

One patient in the open rAAA group had a Hartmans procedure as an inpatient for bowel ischaemia which was reversed after discharge. He subsequently had a leak from the distal end of his graft one year post-operatively. He presented to the Emergency Department with hypotension and collapse and was subsequently stented. Though the total number of patients who had re-interventions was 3, the total number of re-interventions in the open rAAA group was 5 (10%).

Complications

Complications after eEVAR and open repair are described in Table 2. Eleven patients required temporary renal replacement therapy after eEVAR, but only one needed long-term haemodialysis. There was one case of abdominal compartment syndrome, which required laparostomy.

Discussion

There is evidence to suggest that eEVAR is associated with a lower peri-operative mortality rate compared to open rAAA repair.2–4,7–9 Systematic reviews and meta-analyses have demonstrated a significant reduction in 30-day mortality with eEVAR with pooled odds ratio ranging from 0.45 to 0.82.10,11 However, these studies are non-randomized, and data from randomized controlled trials is awaited.

A peri-operative and inpatient mortality rate of 12% in our cohort of patients is extremely encouraging and certainly comparable to the current literature. Contemporary non-randomized studies of ruptured eEVAR have demonstrated peri-operative mortality rates ranging from 11 to 45%.8,12–16 However relatively little is known about mid-term results of eEVAR. Anain et al. reported one-year survival rates of 77%, though this was based on a retrospective study.17 Ockert et al. reported mid-term mortality rates of 17.2%, though this was based on a small cohort.18 Verhoeven et al. had a larger cohort of 175 patients and reported open repair mortality of 27.2% and EVAR mortality of 20% over a seven-year period.19

Hence based on the relatively sparse literature, our one year survival rates of 81% and 2 year survival rates of 73% are extremely encouraging as these take include inpatient mortality. Potentially the most important finding of this study is that eEVAR continues to have a significant survival advantage over open rAAA repair after 2 years. This is in contrast to survival after elective EVAR demonstrated in the DREAM and EVAR1 trials5,20 which showed that the peri-operative mortality benefit of EVAR was lost by two years. Furthermore this is despite the significantly older patients in the eEVAR group in this study. This is of interest particularly in view of the contemporary EVAR1 data suggesting that increasing age is significantly associated with graft–related complications.21 Life expectancy data for England for males aged 71 years and 78 years are 13.4 and 9.1 years respectively.22 It could be anticipated that the shorter life expectancy in the eEVAR group in this study would ameliorate its benefits overtime, but this is not apparent at two-years post-operatively.

Our results could be attributed to the fact that we have a joint approach involving dedicated interventional radiologists and vascular surgeons and commenced our eEVAR service six years after the establishment of our elective EVAR service. Both our expertise and technology of stent grafts has improved during this time, and challenged the previously stringent anatomical criteria for eEVAR. Earlier studies may not have the benefit of experience and contemporary technology and hence have reported significantly lower survival figures for eEVAR.23

We restricted our study to true ruptures only, to avoid selection bias. We did include ruptured common iliac aneurysms, though
these only comprised 13% of the eEVAR patients being in a tertiary centre, patients are often transferred from neighbouring hospitals. It could be argued that those patients who survive the transfer are physiologically selected to survive the operation. However only a minority of patients were transfers, accounting for a total of 5% of all patients. We recognize some weaknesses in this study, patients were offered eEVAR if anatomically suitable and therefore by definition had more favourable anatomy than those undergoing open repair therefore introducing a selection bias. It has also been suggested that patients who are offered eEVAR are likely to be more haemodynamically stable introducing a further bias. However we have shown both groups were well matched for pre-procedural blood pressures and heart rates. Furthermore the majority of the 50 open rAAA performed had a pre-operative CT scan (76%) which may also reflect a degree of haemodynamic stability. CT scanning of ruptured AAAs has not been demonstrated to affect mortality in a previous study of open repairs. Out of the twelve patients in the open rAAA group did not undergo CT scanning, 3 died as inpatients.

The significant difference in age in the open and eEVAR groups reflects the fact that some of the eEVAR patients would have not been offered open repair due to age related co-morbidity. We have previously demonstrated that the introduction of eEVAR has reduced our palliation rates for ruptured AAAs from 23.9% to 8.7% during this study period. This reduction suggests that the introduction of eEVAR has allowed us to treat more rAAA patients. Furthermore we have observed a slight increase in the proportion of patients undergoing eEVAR overtime. 

Our re-intervention rate of 9.6% is certainly low, compared to the current literature. Oranen et al. reported a re-intervention rate of 15% in their ruptured AAA group, which is at par with the reported re-intervention rate in elective EVAR patients. Previous studies report a lack of surveillance scanning which may account for under reporting of endoleaks. In contrast, all our patients were strictly followed up our surveillance programme. One of our patients who had a kink at the iliac limb and body interface on a surveillance CT scan was asymptomatic but was treated on the basis of our previous experience of limb dislocation. One of the strengths of this study is the complete outcome data including the cause of death data for all bar one eEVAR patient. In conclusion emergency EVAR is associated with excellent mid-term survival in this study with the significant reduction in operative mortality maintained at two years.

We would recommend eEVAR as the management of choice for rAAA in anatomically suitable patients where the local facilities and expertise exist. However results of this and other contemporary studies comparing open and EVAR for rAAA are potentially limited by selection bias. This may be overcome with the publication of results from the important ongoing multi-centred randomized controlled trials such as IMPROVE. Furthermore although our results are encouraging at two years, further follow-up is required after emergency eEVAR to prove its long-term efficacy.

Conflict of Interest/Funding

None.

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References