Results from the Prospective Registry of Endovascular Treatment of Abdominal Aortic Aneurysms (RETA): Mid Term Results to Five Years


Sheffield Vascular Institute, Northern General Hospital, Herries Road, Sheffield S5 7AU, UK

Objectives. To assess the mid-term outcomes up to 5 years following endovascular repair of abdominal aortic aneurysms (EVAR), following its initial introduction into practice in the UK.

Design. A prospective voluntary Registry of Endovascular Treatment of Aneurysms (RETA) collected demographic and risk factor data, short term (30 day) outcomes and follow up outcomes up to 5 years from the 41 centres that initially undertook EVAR in the UK.

Results. Short term outcomes (30 days): 90.4% of aneurysms were successfully excluded, 6.1% had persistent endoleaks and 5.8% of patients had died. Follow up was obtained from 30 days up to 5 years (mean 3.1 years). Returns rates for requested follow up data were 87% at 1 year and 77, 65, 52 and 51% at 2, 3, 4 and 5 years, respectively. Ninety percent of deaths at follow up were unrelated to the stent-graft or aneurysm. Persistent proximal type I endoleak was associated with significant mortality both from attempted open repair or from rupture if untreated. Other endoleaks were more benign. Complications related to the aneurysm or device occurred at an average rate of 15% per annum. The most common complications were secondary endoleaks or graft migration. Endovascular treatment was preferred if treatment was necessary for graft complications. The cumulative freedom from secondary procedure (Kaplan–Meier) were 87, 77, 70, 65 and 62% at 1, 2, 3, 4 and 5 years of follow up, respectively.

Conclusions. Registry data provides useful information to guide the design of more formal trials. Collecting follow up from voluntarily submitted data is difficult. The registry data remains well ahead of the trial data, but indicate that long term follow up is required in these trials, because of the high rate of complications seen at follow up.

Keywords: EVAR; Endovascular aneurysm repair; Stent-grafting.

Introduction

The Registry for Endovascular Treatment of Aneurysms (RETA) was established to collect data on endovascular abdominal aortic aneurysm repair (EVAR) from UK centres as this new approach to treating abdominal aortic aneurysm (AAA) was introduced into UK practice. Since, its inception on the 1st of January 1996¹ a total of 1823 cases have been submitted to the Registry. One thousand cases were submitted to the Registry prior to the introduction of the UK randomized trials (EVAR 1 and 2) in 2000. The majority of EVARs were subsequently performed within these trials. Cases submitted to RETA after this time were performed outside the trial, usually early in a centre’s experience, to allow entry into the trials. As a result the RETA dataset became less representative of current UK practice. The main value of the Registry then became the collection of long-term outcome for those cases treated early in UK practice.

This paper presents data for the first 1000 cases submitted to the Registry, and though major short-term outcomes are briefly presented, these do not differ greatly from results published previously on a smaller cohort.¹ The focus of this paper is on mid-term EVAR durability and patient outcome.

Methodology

Details of the Registry, submitting centres and datasets are discussed in the previous paper.¹ A simple one-page follow-up form was sent out to the each centre on
an annual basis, this follow up data could be returned by post, fax or via e-mail. Original submission of data was voluntary, and return of follow up data was dependent on the submitting centre in the majority of cases. Centres that failed to return forms were sent a further form, followed by a telephone reminder. The returned follow up data was manually entered into an Access database.

Statistical analysis was performed using the SPSS® for Windows™ statistical software. The analysis that is presented divides patients into subgroups defined by stent-graft type, fitness for open repair and aneurysm diameter. Stent-graft type were divided into the aorto-uni-iliac stent-graft with a crossover graft (AUIC) and the aortic tube or bifurcated stent-graft (AT/BI).

Patients corresponding to the American Society of Anaesthesiology (ASA) grade I–III were deemed ‘fit’ for open repair and those corresponding to ASA IV–V were deemed ‘unfit’. Patients with hostile abdomens or other contraindications to open repair, but ASA I–III were, included in the ‘fit’ group. Subgroups of ‘small’ AAA <6 cm diameter and ‘large’ AAA >6 cm were analysed separately.

Statistical testing used Chi-squared test of independence (for categorical data) and t-tests (for continuous data) to assess differences in baseline data. Logistic regression was used to compare differences in outcomes adjusting for available confounders for defined subgroups. The variables used in the logistic regression model were: fitness for repair, indication for repair, age, device type and aneurysm diameter. Results are presented as odds ratios (OR). These represent the increased (or decreased) odds (with 95% confidence intervals) of an outcome in the first group compared to the second group. Kaplan–Meier analysis was used for the analysis of long-term outcomes.

**Patient Demographics**

One thousand cases were submitted to the Registry from 41 centres between 1st January 1996 and March 3rd 2000. The number of cases per centre ranged from 2 to 143 (median 16). The number of centres and cases increased each year until the EVAR trial began. The indication for repair was elective asymptomatic abdominal aortic aneurysm (AAA) in 83.2%, elective symptomatic in 13.5%, acute non-rupture in 1.6% and stable rupture in 1.4%.

Overall, 3.2% of patients received an AT, 26.3% an AUIC and 70.2% a BI (missing data n=3). There were relatively few ATs in the Registry and their use fell out of favour in the first 2 years because of distal endoleaks. AUICs built ‘in-house’ were the commonest stent-graft used at the beginning of the Registry but these have now been superseded by commercially available and CE marked devices. The devices used are detailed in Table 1. The increase in the proportion of BI stent-grafts is also reflected in the fact that more than 60% of endovascular repairs were performed in the operating theatre when the Registry commenced, but by 1998 more than 60% were undertaken in the radiology suite. The proportion of patients having the procedure under loco-regional anaesthesia also increased.

The median aneurysm diameter was 6 cm (range 2.5–15) with a median infra-renal neck length of 2.4 cm. Overall 42% were classified as large (>6 cm). There were significantly more large aneurysms in the AUIC group (132/253, 52.3%) compared to the AT/BI group (288/735, 39.7%), OR 1.65, 95% CI 1.24–2.2, p<0.001. Patients with larger aneurysms were also more unfit (95/559, 17% vs 125/420, 29.8%, OR 2.1, 95% CI 1.5–2.8, p<0.001)

A total of 22.7% patients were considered unfit for open repair (missing data n=3). Of the fit patients, 67 (8.8%) were considered fit but unsuitable for open repair. There was a significantly higher proportion of unfit patients in the AUIC group (96/263, 36.5%) compared to the AT/BI group (130/174, 17.7%). The increased odds of being unfit in the AUIC group was 2.67 (95% CI 1.95–3.65, p<0.001).

The median age of the patients was 73 years (range 44–93) with a male: female ratio of 9:1. There was no difference in age (72 vs 73 years) between those treated with an AUIC and those treated with an AT/BI, respectively. Nor was there any difference in age between fit and unfit patients (72 vs 72 years).

**Short Term Results**

Overall, 77.2% of endovascular repairs resulted in successful exclusion of the aneurysm, without complications, by the end of the procedure (missing data n=4). The success rate was the same for both stent-graft types (Table 2). Additional endovascular procedures were required significantly more often in the AT/BI group (p=0.003). However, conversion to open repair occurred more frequently in the AUIC group (p=0.001). The overall conversion rate was 3.3% but this fell significantly from 13/143 (9.1%) in 1996 to 1/335 (0.3%) in 1999 (p=0.002) (Fig. 1). Mortality following immediate conversion was 30%, but rose to 66.7% for unfit patients.

Post-procedure complications within 30 days occurred in 27.8% of cases (Table 3). There were significantly more complications in the AUIC group.
At 30 days, 90.4% of aneurysms had been successfully excluded, 6.1% had persistent endoleaks and 5.8% of patients had died. There were significantly more deaths in the AUIC group, (33/263, 12.5% vs 24/726, 3.3%, OR 2.6, 95% CI 1.4–4.8, \( p < 0.001 \)). There were also significantly more deaths in unfit patients (33/223, 14.8% vs 25/769, 3.3%, OR 3, 95% CI 1.6–5.5, \( p < 0.001 \)). The higher mortality rate in the AUIC group remained significant even after adjusting for available confounding influences such as the higher proportion of unfit patients within this subgroup (Fig. 2). The mortality rate halved from 15/143 (10.5%) in 1996 to 15/335 (4.5%) in 1999 but this failed to achieve significance (Fig. 1). The mortality rate in women (5.7%) was significantly higher than men (1.9%) (\( p < 0.01 \)). Persistent endoleaks and mortality were significantly higher in those with larger aneurysms (\( p < 0.0001 \) and \( p < 0.0046 \), respectively). The median length of stay was longer for patients in the AUIC group (mean 8 vs 5 days, \( p = 0.001 \) after adjusting for confounders).

**Fate of Primary Endoleaks**

Endoleaks\(^2\) were identified in 146 cases either during the primary procedure or at 30 day follow up. Proximal anastomotic (PA) type I endoleaks\(^2\) at the end of the primary procedure were the most common reported and occurred in 54 cases (Fig. 3). Most (51/54) were identified immediately post-procedure and three at imaging at 30 days follow up. Most had urgent treatment, either immediately the endoleak was identified or within a few days. Of these 54 endoleaks, 11 were converted to open repair immediately (three deaths) and two were converted later (both survived). Six had operative banding, but this was only successful in two cases (three deaths). Proximal cuffs were successful in 11/12 cases (one death at 3 months due to rupture from a persistent leak). In three patients a second stent-graft repaired the leak and PTA was successful in 2/3 cases. Sixteen patients had no immediate treatment and three died of rupture at 10 days, 16 days and 4 months. Overall 19 patients had a persistent PA endoleak, with or without treatment and 4 (21%) subsequently died of rupture within 1 year. Operative repair was attempted in 20 cases, resulting in six deaths (mortality rate 30%).

Collateral (type II) endoleaks\(^3\) were the next most common endoleak reported and occurred in 44 cases (35 visible immediately and nine within 30 days). Twenty-three of these had occluded spontaneously by 30 days. At 1 year, four of the remaining patients had been successfully treated by embolisation or laparoscopic clipping and 11 had spontaneously occluded. Only two cases had persistent endoleak at 1 year. No follow up was available for three cases. One patient with an apparently sealed collateral endoleak and an excluded aneurysm on follow up CT died of AAA rupture 10 months post-procedure.

Distal anastomotic (DA) type I endoleaks at the end of the primary procedure occurred in 19 cases (14 detected immediately and five within 30 days). Of these, seven spontaneously sealed by imaging at 30 days, one was embolised and three had extension stent-grafts placed prior to discharge. Of the seven persistent DA endoleaks, three were treated within 1 year and remained excluded at follow up or death.

### Table 1. Endoprosthesis type

<table>
<thead>
<tr>
<th>Device</th>
<th>Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ancure (Guidant EVT Europe)</td>
<td>60 (6)</td>
</tr>
<tr>
<td>AneurX (Medtronic)</td>
<td>254 (25.4)</td>
</tr>
<tr>
<td>Bard device (Bard UK)</td>
<td>11 (1.1)</td>
</tr>
<tr>
<td>Baxter device (Baxter)</td>
<td>1 (0.1)</td>
</tr>
<tr>
<td>Excluder (Gore)</td>
<td>19 (1.9)</td>
</tr>
<tr>
<td>Giatourco-Dacron ('Home made')</td>
<td>123 (12.3)</td>
</tr>
<tr>
<td>Giatourco-PTFE ('Home made')</td>
<td>17 (1.7)</td>
</tr>
<tr>
<td>Hol B Endostent</td>
<td>1 (0.1)</td>
</tr>
<tr>
<td>Ivanchev-Malmo ('Home made')</td>
<td>2 (0.2)</td>
</tr>
<tr>
<td>Palmaz/PTFE ('Home made')</td>
<td>64 (6.4)</td>
</tr>
<tr>
<td>Stenford (Stenford, France)</td>
<td>2 (0.2)</td>
</tr>
<tr>
<td>Talent (Medtronic)</td>
<td>117 (11.7)</td>
</tr>
<tr>
<td>Vanguard (Boston Scientific)</td>
<td>174 (17.4)</td>
</tr>
<tr>
<td>Zenith (Cook, UK)</td>
<td>144 (14.4)</td>
</tr>
<tr>
<td>Missing</td>
<td>11 (1.1)</td>
</tr>
<tr>
<td>Total</td>
<td>1000 (100)</td>
</tr>
</tbody>
</table>

### Table 2. Immediate outcomes

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>All</th>
<th>AT/BI</th>
<th>AUIC</th>
<th>OR (95% CI)</th>
<th>( p ) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aneurysm excluded</td>
<td>769/996 (77%)</td>
<td>566/733 (77%)</td>
<td>203/263 (77%)</td>
<td>1.1 (0.8–1.6)</td>
<td>0.5</td>
</tr>
<tr>
<td>Additional endovascular procedures</td>
<td>110/996 (11%)</td>
<td>94/733 (13%)</td>
<td>16/263 (6%)</td>
<td>0.4 (0.2–0.7)</td>
<td>0.003</td>
</tr>
<tr>
<td>Additional endovascular procedures</td>
<td>52/996 (5%)</td>
<td>40/733 (6%)</td>
<td>12/263 (4%)</td>
<td>0.7 (0.3–1.4)</td>
<td>0.3</td>
</tr>
<tr>
<td>Conversion to open repair</td>
<td>33/996 (3%)</td>
<td>13/733 (2%)</td>
<td>20/263 (8%)</td>
<td>5.0 (2.3–10.8)</td>
<td>0.0001</td>
</tr>
</tbody>
</table>

AT/BI, aortic tube and bi-iliac devices; AUIC, aorto-uni-iliac devices; aneurysm exclusion, no flow into aneurysm sac angiographically at end of procedure.
Four cases had open repair (OR) because of persistent or recurrent DA endoleak (one death at OR). There were no rupture-related deaths in this group at follow up.

Occluder endoleaks occurred in four cases. Two had occluded spontaneously within 30 days, one was successfully surgically banded and the other successfully embolised. There were no ruptures reported for these cases.

Midgraft (type III) endoleaks occurred in 15 cases. Fourteen were excluded at available follow up with no treatment. One case required a further stent-graft for fabric tear, with no recurrence at follow up. The site of endoleak was stated on the registry form for 10 cases. There were no ruptures reported at follow up in these patients.

Mid-term Results

At the time of data analysis 90% of cases had reached the 4 year follow up point and 55% had reached the 5 year follow up point, giving a mean follow up of 3.1 years (range 30 days–5 years) Despite the best efforts of the Registry co-ordinator voluntary data submission resulted in returns rates for requested follow up data of 87% at 1 year and 77, 65, 52 and 51% at 2, 3, 4 and 5 years, respectively.

Mortality in the first year post-procedure was 11%. Most deaths (90% n = 82) were due to co-morbid conditions, the most common being cardiac-respiratory disease or malignancy, i.e. unrelated to graft complications. Six deaths were related to AAA rupture, three of these were detailed above as they had primary proximal type I endoleaks. One other had a secondary DA type I endoleak, the other two cases had apparently excluded aneurysms at follow up CT scanning. In subsequent years the mortality rates were 10, 7, 10 and 8%, at 2, 3, 4 and 5 years post-procedure, respectively. As previously most deaths were not related to graft complications, though five other fatal ruptures were reported, one other patient ruptured with an associated secondary proximal endoleak, and survived open repair, one patient died following surgery for secondary endoleak and two patients died as a result of overwhelming sepsis and infected stent-grafts. The cumulative risk of rupture (Kaplan–Meier) was 2% at the 5 year follow up point.

Overall 253 complications related to the device or aneurysm were reported, occurring in 13, 14, 15, 16 and 16% at 1, 2, 3, 4 and 5 year follow up intervals, respectively. Fifty-four percent (n = 139) of these were

Table 3. In-hospital complications

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>All</th>
<th>AT/BI</th>
<th>AUIIC</th>
<th>OR (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any complication</td>
<td>272/976 (28%)</td>
<td>175/716 (24%)</td>
<td>97/268 (37%)</td>
<td>1.57 (1.1–2.1)</td>
<td>0.006</td>
</tr>
<tr>
<td>Technical complication</td>
<td>55/976 (6%)</td>
<td>31/716 (4%)</td>
<td>24/268 (9%)</td>
<td>2.1 (1.2–3.7)</td>
<td>0.013</td>
</tr>
<tr>
<td>Wound complication</td>
<td>78/976 (8%)</td>
<td>55/716 (8%)</td>
<td>23/268 (9%)</td>
<td>1.1 (0.6–1.8)</td>
<td>0.84</td>
</tr>
<tr>
<td>Renal failure</td>
<td>40/976 (4%)</td>
<td>21/716 (3%)</td>
<td>19/268 (7%)</td>
<td>2.1 (1.1–4.2)</td>
<td>0.03</td>
</tr>
<tr>
<td>Colonic ischaemia</td>
<td>6/976 (0.6%)</td>
<td>4/716 (0.6%)</td>
<td>2/268 (0.8%)</td>
<td>1.1 (0.2–6.7)</td>
<td>0.9</td>
</tr>
<tr>
<td>Other medical complications</td>
<td>147/976 (15%)</td>
<td>92/716 (13%)</td>
<td>55/268 (21%)</td>
<td>1.5 (1.01–2.2)</td>
<td>0.045</td>
</tr>
</tbody>
</table>

AT/BI, aortic tube and bi-iliac devices; AUI, aorto-uniliac devices.
secondary endoleaks or graft migration, with secondary collateral (type II) endoleak the most common problem reported. Many collateral endoleaks were not treated, but other types of endoleak and proximal graft migration were usually treated using endovascular techniques, such as embolisation or further stent-grafts. Graft or limb occlusions and/or kinks were the next most common problem accounting for 18% (n=45) of device or AAA complications. Limb or graft occlusion often required a surgical bypass procedure. Increasing size of the sac remnant with no endoleak was also reported in a number of cases, and though most cases were kept under close observation conversion to OR was reported in 25% (n=5/20) of cases. Overall open repair was reported for 23 cases to treat complications, though it was unclear from submitted registry forms if all cases were formal late conversions to repair the abdominal aortic aneurysm or more limited surgical procedures to deal with a specific graft or limb complication. During later years of follow up graft distortion and suture breaks were widely reported, though most did not require treatment as they were not necessarily associated with endoleak or graft migration.

Follow up of secondary complications and their treatment showed that on average 39% (n=65) of reported complications persisted, with a third of these having some form of intervention for the complication and a further 3% (n=7) had recurrence of the original complication requiring further treatment. As a result, for those patients treated for secondary complications only an average of 33% (n=57) survived with no further problems.

Using Kaplan–Meier analysis the cumulative freedom from endoleak was 88, 80, 76, 71 and 68% and the cumulative freedom from secondary procedure rates were 87, 77, 70, 65 and 62% at 1, 2, 3, 4 and 5 years of follow up, respectively (Fig. 4).

Fig. 2. Comparison of 30 day mortality rates for patients deemed fit or unfit for open repair, by graft type (AUIC vs AT/BI). There were significantly more deaths in unfit patients (33/223, 14.8% vs 25/769, 3.3%, OR 4.9, 95% CI 2–12, p<0.001). The higher mortality rate in the AUIC group remained significant after adjusting for the higher proportion of unfit patients.

Fig. 3. Fate of primary proximal anastomotic type I endoleaks.
Discussion

The overall short term outcome results for EVAR from RETA show a 30 day mortality of 5.8%, which is not clearly better than that reported for open repair. However, the data represents an early experience. Nearly 25% of patients were considered unfit for open repair and another 25% received AUIC stent-grafts that were fabricated in-house, due to an initial lack of commercially available alternatives. The mortality rate of a group more comparable to those being offered open repair, i.e. fit patients treated with AT/BI stent-grafts, was 1.7%, and this is very similar to the early results of the EVAR and DREAM trials which reported procedure related mortality of 1.4 and 1.7%, respectively in patients who were fit for open repair and randomised to EVAR.4,5 The fall in conversion rates and mortality with time reflects advances in stent-graft design, better patient selection and improved mentoring of new centres.

RETA shows that larger aneurysms have worse 30 day outcomes with fewer large aneurysms excluded and a higher mortality. This is important, particularly for unfit patients who tend to present when their aneurysms are larger. This may be related to these aneurysms being more technically challenging, though there was no increase in the rate of technical complications in larger aneurysms, but there was a trend towards an increased need for conversion to open repair. It may be that the larger aneurysms had wider necks and available stent-grafts were undersized, but these data were not collected in the Registry.

It is recognised that AUIC devices can be used to treat a larger proportion of aneurysms6 and we have shown that those treated with it tend to be older, more unfit and to have larger aneurysms. Comparisons with the AT/BI group remain difficult in the context of a registry because these differences confound direct comparison of the two groups. Conversions to open repair and technical complications were more frequent in the AUIC group and even after adjustment for available confounding influences the morbidity and mortality rates were higher for those treated with AUIC devices. Also, after adjustment, patients treated with an AUIC device had a significantly longer hospital stay. This is probably related to the surgical crossover graft that is required for this type of device.

The mortality rate post-procedure was about 10% per annum, fairly typical for patients with arterial disease. Most deaths at follow up were unrelated to stent-graft complications, mostly due to cardiac disease or malignancy. Between 30 days and 1 year, six ruptures (1%) were reported. Of these, three had primary proximal type I endoleaks that had persisted despite attempts at endovascular treatment and one had a documented secondary endoleaks. The annual rupture rate was about 1% per year in the first couple of years post-procedure, giving a cumulative risk of rupture of 2% at 5 years post-procedure. All but one rupture was fatal, and proximal type I endoleaks, if not corrected, were particularly associated with a poor outcome, emphasising the need to correct these endoleaks whenever possible. It should be noted that two deaths were attributed to systemic sepsis thought to be secondary to stent-graft infection. With the move towards deployment of stent-grafts in the radiology or endovascular suites, this underlines the importance of theatre-quality asepsis in these environments.

There was an overall primary endoleak rate of over 14% (146 endoleaks). Of these the most common were endoleaks from the proximal anastomosis or from collaterals. Of the 19 persistent proximal endoleaks at 30 days 21% lead to AAA rupture during follow up. This appears to justify an aggressive approach to treatment of type I proximal anastomotic endoleaks, when they occur. However, surgical treatment of this group of patients resulted in perioperative mortality in 30%, and the mortality rate of converting patients deemed unfit was 66.7%. This suggests that unfit patients must be counselled about the poor chances of survival should endovascular repair fail and conversion become necessary. This mortality from conversion to open repair is higher than that reported in other series.7 Patients did better if an endovascular treatment, such as cuffing was feasible, but if conversion is necessary, and it can be deferred for a few days, such an approach seems sensible to allow recovery from the primary procedure and related nephrotoxicity, but undue delay should be avoided. Other primary endoleaks had a more benign course with a reasonable

![Cumulative freedom from endoleak obtained using Kaplan–Meier analysis.](image-url)
chance of sealing spontaneously, though one patient with an apparently sealed collateral (type II) endoleak and an excluded aneurysm at follow up died of AAA rupture 10 months post-procedure. Similarly the Eurostar Registry has found that rupture can occur with no obvious endoleak or complication, and this probably accounts for the conversion to OR of five cases in RETA with increasing size of the AAA sac, but no identifiable endoleak. The Eurostar Registry has also found associations between collateral endoleaks and continued aneurysm expansion, and the risk of rupture with an increasing size of the AAA sac. More frequent surveillance and/or intervention is, therefore, warranted in such cases.

Most of the uncertainty surrounding EVAR relates to the long term complications of the procedure. It is, therefore, vital that the durability of the devices and the long-term outcomes of these cases are subjected to rigorous assessment. In this cohort, reported complications related to the aneurysm or device occurred at an average rate of 15% per annum. These data are similar to results for early generation devices from the Eurostar Registry. Many of these complications were secondary endoleaks, and often these could be treated using endovascular techniques. However, follow-up of these secondary problems suggest that many recur or persist, and only about 30% of patients survive with no further problems. Therefore, although most complications can be treated successfully, continued long-term surveillance is required. The cost of this surveillance, and subsequent treatment, may outweigh the short-term benefits of EVAR, but only a long term cost analysis is possible as part of the EVAR trials would confirm this. Also, a large proportion of the stent-grafts in the Registry were first generation devices that were fabricated in-house or second-generation devices that have been withdrawn due to failure of structural integrity, or superseded by devices with improvements in design. It remains to be seen whether third-generation devices suffer from the same problems. The initial data suggests that they may be better in this respect.

As a first step registries can be of value in the assessment of new treatments. Regulatory organisations such as the UK National Institute for Clinical Excellence (NICE) will often accept that, in the absence of formal trials, registries can act as a means of assessment of new treatments or technologies. In the case of EVAR, NICE specifically recommends that all patients undergoing EVAR should either be treated as part of a randomised trial or entered into a registry. However, it is important to understand the limitations of Registry data. The only way to eliminate confounding and obtain clear results when comparing interventions is to use randomisation. Data submission to registries is usually voluntary which risks bias in the data submitted. Furthermore follow-up data becomes increasingly difficult to obtain. Despite the best efforts of the Registry co-ordinator the returns rate we present in this paper fell from 87% at 1 year to 51% at 5 years. It is very difficult to ensure data is submitted and it is not possible to make this compulsory. If a large amount of data is submitted it is likely to be representative of practice at the time it is collected, but the results presented can only ever represent the best estimates within the limitations of the data collected. In the case of RETA this cohort of cases represents the early experience in the UK with early device designs, with problems of incomplete data follow up.

However, if these problems are borne in mind then registry data can provide useful insight into the results of new treatments, and can be used in planning trials and to generate hypotheses to be tested. Indeed, results from RETA were used in the planning of the EVAR trials and as an audit tool to assess centres for trial entry. The outcomes from the randomised trials will provide more definitive results of EVAR in fit and unfit patients. However, continued follow-up of the 1000 patients within the RETA cohort remains vital. The duration of follow-up is a long way ahead of the long term complications of the procedure. It is, therefore, vital that the durability of the devices and the long-term outcomes of these cases are subjected to rigorous assessment. In this cohort, reported complications related to the aneurysm or device occurred at an average rate of 15% per annum. These data are similar to results for early generation devices from the Eurostar Registry. Many of these complications were secondary endoleaks, and often these could be treated using endovascular techniques. However, follow-up of these secondary problems suggest that many recur or persist, and only about 30% of patients survive with no further problems. Therefore, although most complications can be treated successfully, continued long-term surveillance is required. The cost of this surveillance, and subsequent treatment, may outweigh the short-term benefits of EVAR, but only a long term cost analysis as part of the EVAR trials would confirm this. Also, a large proportion of the stent-grafts in the Registry were first generation devices that were fabricated in-house or second-generation devices that have been withdrawn due to failure of structural integrity, or superseded by devices with improvements in design. It remains to be seen whether third-generation devices suffer from the same problems. The initial data suggests that they may be better in this respect.

As a first step registries can be of value in the assessment of new treatments. Regulatory organisations such as the UK National Institute for Clinical Excellence (NICE) will often accept that, in the absence of formal trials, registries can act as a means of assessment of new treatments or technologies. In the case of EVAR, NICE specifically recommends that all patients undergoing EVAR should either be treated as part of a randomised trial or entered into a registry. However, it is important to understand the limitations of Registry data. The only way to eliminate confounding and obtain clear results when comparing interventions is to use randomisation. Data submission to registries is usually voluntary which risks bias in the data submitted. Furthermore follow-up data becomes increasingly difficult to obtain. Despite the best efforts of the Registry co-ordinator the returns rates we present in this paper fell from 87% at 1 year to 51% at 5 years. It is very difficult to ensure data is submitted and it is not possible to make this compulsory. If a large amount of data is submitted it is likely to be representative of practice at the time it is collected, but the results presented can only ever represent the best estimates within the limitations of the data collected. In the case of RETA this cohort of cases represents the early experience in the UK with early device designs, with problems of incomplete data follow up.

However, if these problems are borne in mind then registry data can provide useful insight into the results of new treatments, and can be used in planning trials and to generate hypotheses to be tested. Indeed, results from RETA were used in the planning of the EVAR trials and as an audit tool to assess centres for trial entry. The outcomes from the randomised trials will provide more definitive results of EVAR in fit and unfit patients. However, continued follow-up of the 1000 patients within the RETA cohort remains vital. The duration of follow-up is a long way ahead of the randomised trials and highlight the potential problems that occur long term, as well as providing a benchmark to show changes in outcome over time. The collection and analysis of data from this and similar registries should facilitate the early identification, quantification and correction of device-related problems.

**Key Messages**

- Short term outcomes (30 days): 90.4% of aneurysms were successfully excluded, 6.1% had persistent endoleaks and 5.8% had died.
- Conversion rates and mortality fell with time reflecting better patient selection, advances in stent-graft design, and improved mentoring of new centres.
- A higher mortality rate in the AUIC group remained significant after adjusting for the higher proportion of unfit patients.
- Most deaths at follow up were unrelated to the stent-graft or aneurysm. Persistent proximal endoleak was associated with significant mortality both from attempted open repair or from rupture if untreated.
- Complications related to the aneurysm or device
occurred at a rate of approximately 15% per annum. Many of these complications were secondary endoleaks, many of which could be successfully treated by endovascular means.

- Long term costs of stent-graft surveillance, and secondary treatment, may outweigh the short-term benefits of EVAR.
- Voluntary Registries complement, but do not replace, Randomised Controlled Trials.
- Data collection for voluntary registries is problematic, with achieved returns rates for requested follow up data of 87% at 1 year and 77, 65, 52 and 51% at 2, 3, 4 and 5 years, respectively.

Acknowledgements

Data was submitted from the following centres (co-ordinator): Royal United Hospital, Bath (Dr Hardman); Belfast City Hospital, Belfast (Ms K. McGuigan); Belfast Royal Victoria Hospital, Belfast (Ms T. Dennison); Birmingham Heartlands Hospital, Birmingham (Mr M.X. Gannon); Blackburn Hospital, Blackburn (Mr Hardy); Bristol Royal Infirmary, Bristol (Mr Smith); Charing Cross Hospital, London (Ms L. Brown); Countess of Chester Hospital Chester, (Miss L. DeCossart); Derriford Hospital, Plymouth (Ms C. Cosgrove); Edinburgh Royal Infirmary, Edinburgh (Mr Shearman); Freeman Hospital, Newcastle (Ms V. Wealeans); Gartnavel Hospital, Glasgow (Ms J. Innes); Glasgow Royal Infirmary, Glasgow (Dr McCarter); Gloucester Royal Hospital, Gloucester (Mr Earnshaw); Guys Hospital, London (Ms A. Aukett); Hull Royal Infirmary, Hull (Ms J. Bryce); Leeds General Infirmary, Leeds (Mr M. Gough); Leicester Royal Infirmary, Leicester (Prof Naylor, Mrs B. Hughes); Manchester Royal Infirmary, Manchester (Dr Chalmers); Ninehills Hospital, Dundee (Mr Griffiths); North Manchester General Hospital, Manchester (Mr Tait); Queen’s Medical Centre, Nottingham (Mr S. MacSweeney); Queen Elizabeth Hospital Gateshead (Ms J. Coleman); Royal Bournemouth Hospital, Bournemouth (Ms S. Baker); Royal Cornwall Hospital, Truro (Ms N. Sinclair); Royal Free Hospital, London (Ms P. Morris-Vincent); Royal Lancaster Infirmary, Lancaster (Mr P. Wilson); Royal Liverpool Hospital, Liverpool (Mrs J. West); St George’s Hospital, London (Dr R. Morgan); St James Hospital, Leeds (Prof J. Scott); St Mary’s Hospital, London (Ms M. Kerle); Sheffield Vascular Institute, Sheffield (Mrs M. Ireland, S. Ayers); South Cleveland Hospital, Middlesborough (Dr Leen); Southampton General Hospital, Southampton (Dr O’Durny); Southern General Hospital, Glasgow (Mr Welch); Swansea Hospitals, Swansea (Dr Roberts); University College Hospital, London (Ms D. Broadley); University Hospital of Wales, Cardiff (Mr Whiston); University Hospital, Birmingham (Mr Simms); Walsgrave Hospital, Coventry (Mr Higman); Withington Hospital, Manchester (Dr R. Ashleigh).

Financial support has been provided by the BSIR and VSCBI and by the following device companies, BARD UK Ltd, WL Gore (UK) Ltd, Medtronic Ltd, Cook (UK) Ltd and Boston Scientific Ltd, and Cordis (UK).

References


Accepted 29 March 2005