

‘Real world’ experience with EVAR-a retrospective cohort study of 239 endoluminal grafts in a Scottish vascular centre

Abstract

Endovascular aneurysm repair (EVAR) for abdominal aortic aneurysm (AAA) continues to evolve. We present a review of Scottish and international data of perioperative and long-term mortality after AAA repair and detail our departmental experience for elective endoluminal grafting.

Keywords: abdominal aortic aneurysm, endovascular aneurysm repair, mortality, restrictions, mortality

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Abbreviations: EVAR, endovascular aortic aneurysm repair; AAA, abdominal aortic aneurysm; TS, thrombosis

Introduction

Endovascular aortic aneurysm repair (EVAR) is now well established as the most frequently performed method of infra renal abdominal aortic aneurysm (AAA) repair. Given certain restrictions on patient fitness and aortic aneurysm morphology, EVAR gives durable repair and offers lower short-term mortality rates compared to open surgery.¹ It is debatable whether the mortality benefits of EVAR last in the intermediate and long term;¹ while EVAR offers a clear operative mortality benefit over open repair in patients fit for both procedures, this early benefit may not translate into a long-term survival advantage² either because of late device-related reintervention or because of the death of the patient from other causes. Despite this, EVAR remains the current preferred method of operative repair by patients with threshold aneurysms compared to open surgery.³ Clear survival benefit has been shown in elective AAA repair thanks to advances in surgical technique and intensive care, being shown to have a mortality of 10.7% as recently as 1994⁴ dropping to ~5% in the small aneurysm trial in 1998.⁵ The recent advances in EVAR mean that perioperative mortality may be as low as 1.7% in randomized series.¹ EVAR is well studied and understood in a controlled trial population and from registry data. European vascular surgery centers have contributed to the EUROSTAR project, providing multi-centered outcome data regarding endovascular repair of infra-renal aortic aneurysms.⁶ EUROSTAR data from 2846 patients indicates that secondary intervention was performed in 247 patients (8.7%) at a mean of 12 months after the initial procedure; the cumulative incidence of such interventions was 6, 9, 12 and 14 percent at 1, 2, 3 and 4 years respectively.⁷ These rates are similar to those reported in the main UK and European RCTs.⁸ However, such registry data represents a selected population with relatively strict inclusion criteria; RCT data such as that from the EVAR-1⁹ and IMPROVE¹⁰ trials reveal a more “real world” picture. The EVAR-1 trial,⁹ a seminal study in randomized treatment of AAA comparing both open repair and EVAR, showed that EVAR is associated with late complications

related to stent degradation, migration and thrombosis. We were therefore keen to study our own outcomes since the introduction of EVAR in NHS Lanarkshire throughout 2006-2015. We sought to examine our own outcomes.

Materials and methods

The details of all patients undergoing endoluminal grafting between 2006 and 2015 were collected through accessing health board PACS and clinical portal systems. Data including urgency of implant (emergency/elective), date of implant, patient age at implant, and type of graft were collected. Patient survival at 30 days, 1 year, 3 years and 5 years was collected. Information on early or late re-intervention or graft-related complications, endoleaks, and explants was recorded. Patients undergoing emergency or urgent implantation for rupture or acute aortic syndrome were excluded from analysis, as were those undergoing complex endovascular interventions such as fenestrated, chimney or iliac branch procedures. Concurrently, data on overall mortality and readmission was obtained from the Scottish Office for verification.

Results

Number of procedures

In total, 239 patients underwent EVAR between the study period of 7/19/2006 and 12/9/2015. These were confirmed to be elective implants. An average of 23.9 patients was operated on each year since the department commenced its first EVAR. This number of EVAR procedures performed each year is as follows, as summarized in Figure 1: 2006: 1 patient, 2007: 7 patients, 2008: 29 patients, 2009: 20 patients, 2010: 29 patients, 2011: 37 patients, 2012: 25 patients, 2013: 29 patients, 2014: 31 patients, 2015: 31 patients.

Age of patients undergoing EVAR

Of the 239 patients undergoing EVAR during the study period, septuagenarians were the most frequent recipients, with a median age of 72.8 years at implant and a range of 53 years to 92 years old. Patients were divided into each decade of life as follows, as summarized

in Figure 2: heptogenarians 9patients, hexogenarians 72patients, septuagenarians 108patients, octogenarians 49patients, and a single nonogenarian.

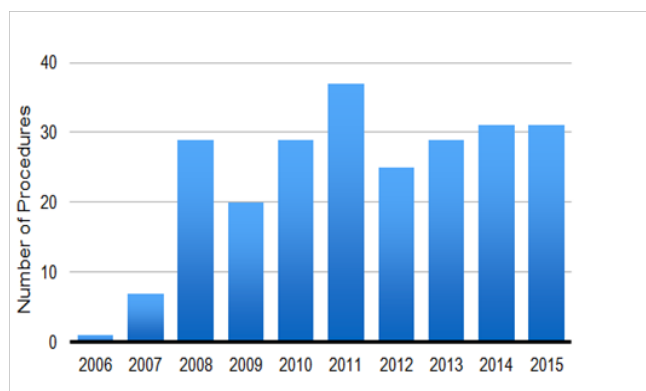


Figure 1 Number of EVAR procedures per year.

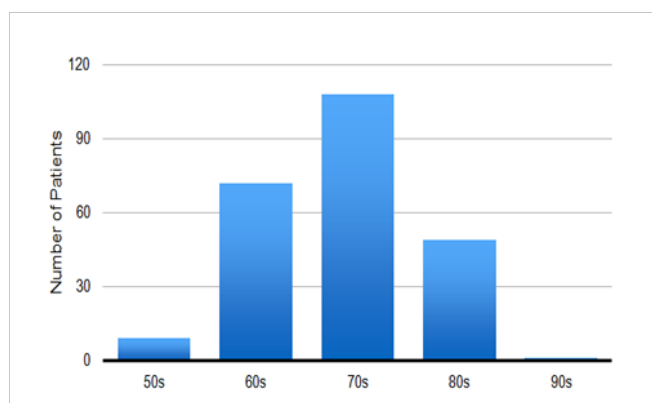


Figure 2 Ages of patients undergoing EVAR.

Mortality data

Mortality data was calculated at 30 day, 1 year, 3 year and 5 year intervals.

Peri-operative mortality-30 day's survival: In the 30 day post operative period, 1 death occurred, with 238 patients surviving. This gives a 30 day peri-operative mortality of 0.41%. It should be noted that this death occurred in a patient in his early 60s with a significant pre-operative cardiac history.

1year: Of the 239 patients undergoing EVAR during the study period, 26 patients had not yet reached 1year post-op. This left 213 patients for analysis. Of this group (N=213), 209 patients were alive at 1year, with 4 patients dying. This gives a 1 year survival of 98.09% and a mortality of 1.91% (2dp).

3year: Of the 239 patients undergoing EVAR during the study period, 85 patients had not yet reached 3years post-op. This left 154 patients for analysis. Of this group (N=154), 129 were alive at 3years with 25

patients dying. This gives a 3year mortality of 16.23(2dp).

5year: Of the 239 patients undergoing EVAR during the study period, 127 patients had not yet reached 5years post-op. This left 112 patients for analysis. Of this group (N=112), 67 patients were alive at 5years with 45 patients dying. This gives a 5year mortality of 35.43% (2dp) (Figure 3).

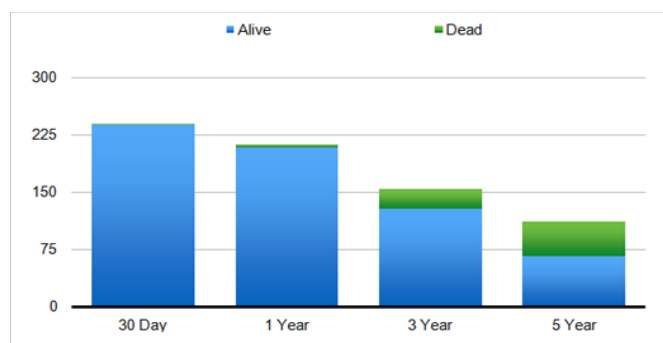


Figure 3 Mortality status for available patients post-EVAR; absolute numbers.

Survival probability statistics

Of the 239 patients undergoing EVAR during the study period, 213 patients had reached 1year post-op, 154 patients had reached 3years and 112 patients had reached 5years. Assuming all 239 patients are enrolled, Kaplan-Meier survival probability estimates can be used to model 5 year survival estimates for this group, assuming those patients unavailable for analysis (i.e not yet post-op) are censored. Survival probability estimates for 30day, 1year, 3year and 5year intervals, with upper and lower confidence intervals, are shown in Table 1.

Incidence of post-implant complication

Patients were identified in whom, on the latest follow-up CT angiogram or on clinical portal, a suboptimal radiographic or clinical problem was present. These included expensive endoleaks, graft limb thrombosis, graft limb occlusion, graft migration, rupture and explants. Non-expensive endoleaks and non-occlusive thrombus, both typically benign entities, were not classified as complications. Thus, 40patients with complications were identified (Figure 4).

Complications of limb ischaemia: 17patients with occluded graft limbs were treated expectantly as claudicates with no limb threat. Of patients with limb threat, adjunctive stenting was performed 4times, 2femoral thrombectomies were required, re-ballooning of graft required twice, and 3 fem-fem crossover grafts were required. Overall, 11patients required re intervention for limb threat.

Complications of expansile endoleak: It is departmental policy to intervene on expansile endoleaks if the patient remains fit. 7patient's required trans-arterial coil or Onyx embolisation, with two of these also requiring CT-guided Onyx administration. 4 grafts required to be explanted; two for unforeseeable rupture and two for refractory endoleak. There was no 30-day mortality in any of these patients (Table 2).

Table 1 Kaplan-Meier survival probability estimates

Time period	At risk	Censored	Died	Survival probability estimate	0.95 confidence interval (lower limit)	0.95 confidence interval (upper limit)
30Days	239	0	1	0.995816	0.973278	0.999782
Year 1	238	26	3	0.983264	0.954847	0.994625
Year 3	209	59	21	0.884467	0.835358	0.920796
Year 5	129	42	20	0.74734	0.68643	0.800131

Table 2 Overall survival was calculated at 30days, 1,3 and 5years and compared to the EVAR-1 trial participants

Survival	EVAR 1 trial endovascular recipients	NHSL EVAR recipients
30day	98.20%	99.50%
1year	93.50%	98.30%
3year	81.50%	88.40%
5year	68.50%	74.70%

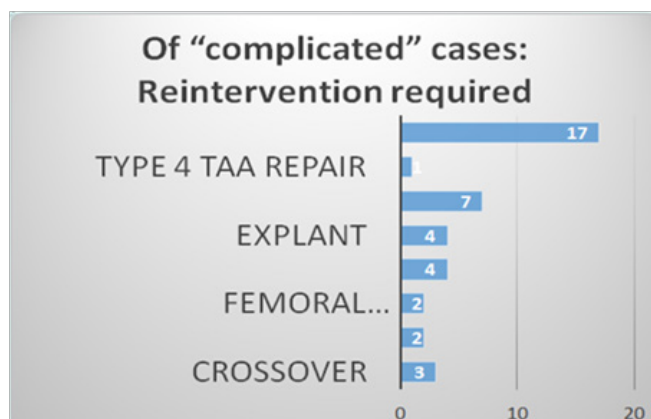


Figure 4 Complications of limb ischaemia.

Conclusion

EVAR is a rapidly developing subspecialty of endovascular surgery. Since the original EVAR-1 trial data, the discipline has become increasingly refined. Developments in graft technology, delivery systems, quality of preoperative CT planning, and increasing expertise within the scrub team mean that the procedure should become safer over time. Conversely, the success of EVAR may mean that it is offered to patients considered high-risk or unfit for open surgery with a corresponding potential increase in morbidity and mortality. It is therefore of great importance that threshold AAA patients are treated on the basis of individual patient fitness, aortic morphology and with multidisciplinary support for the implanting physician. This will ensure optimal patient-centered outcomes. The NHSL data compare favorably to the EVAR-1 trial data. Lanarkshire

has a high prevalence of cardiovascular disease and relatively low life expectancy, therefore lower survival rates might be expected compared to a randomized trial population. The data would suggest that this does not seem to be the case. Furthermore, the EVAR-1 data was obtained in patients judged to be fit for both open and endovascular repair, on the grounds of co morbidity and aortic morphology. It has been the policy of NHSL to perform EVAR if morphology was acceptable, as long as the patient was fit for EVAR. This probably more accurately reflects UK and general western vascular practice, and implies that our data set is representative of widespread preoperative decision making. Overall, the data suggest that EVAR is performing well and that the multidisciplinary approach to patient selection, work-up, implantation and follow-up should continue.

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Ethical approval

Ethical Approval was granted by the NHS Lanarkshire clinical Quality department, project number 4745.

Conflict of interest

Authors declare there is no conflict of interest in composing this manuscript.

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