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# Factors Affecting Survival after Endovascular Aneurysm Repair: Results from a Population Based Audit

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***Objectives***. *To determine the effect of pre-operative factors on mid-term survival of patients enrolled in an Australian audit of endovascular aneurysm repair (EVAR).*
***Design***. *Prospective longitudinal national register (audit) of patients undergoing EVAR.*
***Methods***. *961 individuals who had elective or semi-urgent EVAR of abdominal aortic aneurysms were enrolled in the audit between November 1999 and May 2001. Data was contributed by 81 surgeons from 64 hospitals.*

*Kaplan-Meier survival analysis was used to determine survival rates and factors significantly influencing survival. Parametric survival analysis with log-exponential distribution was used to estimate expected 3 and 5 year survival for different ages, ASA, creatinine and aneurysm sizes.*
***Results***. *Overall survival was 93% at 1 year, 80% at 3 years and 67% at five years. Survival rates were found to be statistically associated with ASA, age, aneurysm size and creatinine levels. ASA has the largest effect. Five year survival rates for aneurysms ≥65 mm and <55 mm were 54% and 76% respectively. Pre-operative creatinine levels ≥ 160 μmol/L lowered the survival rate from 71% to 40%.*
***Conclusions***. *Survival for EVAR patients is strongly correlated with a number of pre-operative factors. This survival analysis provides a useful decision-making tool for surgeons particularly for individuals with smaller aneurysms.*

*Keywords: Aorta; Aneurysm; Abdominal/Australia/Medical audit/Data collection/Registries.*

## Introduction

In 1999, a report prepared for the Australian Government found that the long-term outcomes of endovascular aneurysm repair (EVAR) were not well defined.[1] As a consequence, the Government funded a longitudinal national audit of the procedure, undertaken by the Royal Australasian College of Surgeons (RACS), with the aim of using the results to provide additional information regarding the safety and efficacy of the procedure.

This paper is based on the statistical analysis of data during the seventh year of the audit, and presents information on the influence of preoperative factors on mid-term survival of EVAR patients. Mortality data was obtained from the National Death Index which contains the records for all deaths occurring in Australia from 1980.

Being a national audit, patients exhibit a wide range of aneurysm morphology and pre-operative patient characteristics. For instance, the Australian audit has previously highlighted that in ''real'' practice the procedure is frequently used on smaller aneurysms[2] despite evidence suggesting that conservative treatment is the preferred option for aneurysms smaller than 55 mm.[3,4,5]

The EVAR procedure has been used increasingly by vascular surgeons since its inception, despite ongoing uncertainty over its longer term durability and effectiveness. Figures provided by Medicare Australia show that in Australia the number of EVAR procedures performed in 2000 and 2006 within the private system more than doubled (from 237 in 2000 to 570 in 2006). At the same time the number of open repairs of abdominal aortic aneurysms decreased from 465 to 349 (25%).

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It is important that surgeons are familiar with the preoperative factors which may influence the survival of an EVAR patient.

## Methods

### *Ethics approval and governance*

Ethics approval for the audit was obtained from the Ethics Committee for the Royal Australasian College of Surgeons. A reference group of vascular surgeons provides advice on clinical aspects of EVAR repair. Participating surgeons obtained informed consent from patients.

### *Audit of EVAR*

Operative data for patients who underwent elective or semi-urgent EVAR between the 1 November 1999 and 16 May 2001 were collected from vascular surgeons and entered into a central Access (Microsoft) database. Cross-checking of private cases with Medicare Australia (formerly the Health Insurance Commission) indicated a compliance rate of >90%. Annual follow-up of all patients will continue until 2008. Mortality data for patients enrolled in the audit were obtained from the Australian Institute of Health and Welfare's National Death Index in November 2004, September 2005 and August 2006.

Using standard data forms, a range of pre-operative information was collected for items such as age, gender, ASA, aneurysm morphology, creatinine and suitability for open repair. Copies of data entry forms are available from the RACS website (http://www.surgeons.org/asernip-s/audit.htm). Patient fitness was measured using the American Society of Anaesthesiology (ASA) rating. Details of the procedure, additional procedures and any complications arising either immediately following the procedure or prior to discharge were collected. Follow-up data sought to identify graft related problems, changes in aneurysm size and additional aneurysm related procedures.

The main type of device deployed between 1999 and 2001 was the Zenith graft (Cook Australia) 82%. Other types of graft used were: Ancure (Guidant) 1.5%, AneurRx (Medtronic) 7%, Excluder (WL Gore) 4.5%, Talent (World Medical) 3.8% and Vanguard (Boston Scientific) 0.7%.

### *Data interpretation*

Peri-operative mortality is defined as death within 30 days of the procedure. Aneurysm-related death (ARD) is defined as any death occurring within 30 days of the primary or any secondary procedure or any ARD such as rupture occurring at any time following the primary procedure.

Independent statistical analyses were undertaken by the Commonwealth Scientific and Industrial Research Organisation (CSIRO) to evaluate the effect of pre-operative factors such as age, gender, smoking status, graft configuration and device type (manufacturer), ASA, pre-existing conditions, fitness for the open procedure, renal function (creatinine), aneurysm size, aortic neck and aneurysm angle and aortic neck length on survival and ARD. Some pre-operative variables were not selected for statistical analysis if they were subjective, ambiguous or highly incomplete (e.g. tortuosity and calcification).

Stratified, right censored, Kaplan-Meier Survival analysis was utilized to determine the survival rates and factors significantly influencing survival, using the log rank (Mantel-Haenszel) test. Freedom from ARD was similarly assessed.[6]

Survival curves and table (Table 2) were produced using rounded months until death, or until last known to be alive, for simplicity of interpretation. The last time a person is known to be alive is either the last date that the Australian Death Mortality Index registry was interrogated or the last follow-up date, whichever occurred later. Patients who are still alive are considered censored because we do not know how long they will survive.

The rounded months used for graphs and Table 2 were 0, 1, 3, 6, 12, 24, 36, 48, 60 and 72 months. S-Plus surv() function Version 6.2.1 2003 Insightful Corp. was used to produce survival table and curves.[7]

Parametric survival analysis with log-exponential distribution was used to estimate expected 3 and 5 year survival for different ages, ASA, creatinine and aneurysm sizes (Tables 3 and 4). Parametric survival analysis was seen to be a more appropriate method to estimate the survival rates for continuous variables (size, age, ASA and creatinine). The log exponential distribution was used because it has the lowest residual log likelihood and requires one less parameter estimate than other distributions such as Weibull, Gaussian, or logistic.

## Results

### *Preoperative and operative information*

A total of 961 patients who underwent EVAR during November 1999 and May 2001 were enrolled in the Australian audit. Data were contributed by

81 surgeons for procedures performed at 64 institutions. Some patient baseline characteristics are shown below and in Table 1. Additional baseline information is reported in the audit annual reports (http://www.surgeons.org/asernip-s/audit.htm) and in previous publications.[2,8]

The mean age (±SD) of patients at the time of the procedure was 75.0 ± 6.9 years. Twenty three percent (223/961) of patients were 80 years or older and 7% were under 65 years (70/961). Male patients predominated in the audit (86%, 828/961). Thirty four percent of patients were listed as healthy or had only mild systemic conditions (i.e. ASA I or II). The majority of patients were ASA III (559/945). The majority of patients had normal renal function, as measured by pre-operative creatinine < 120 μmol/L (66.6%, 604/907). 21.3% of patients had mid-range creatinine (120−159 μmol/L, 193/907) and 12.1% had high creatinine (≥160 μmol/L, 110/907). Females were significantly more likely to have had hypertension prior to surgery than males (77% vs 69%, $p = 0.04$). For age (t-Test: Two-Sample Assuming Unequal Variances) and ASA (Chi-squared test) the patient profiles were not significantly different when the data was analysed by gender.

Pre-operative aneurysm characteristics are shown by gender in Table 1.

When surgeons were asked to report the suitability of their patients for the open procedure their response indicated that 43% of their patients (411/961) were unsuitable candidates for open repair, the predominant reason stated being co-existent morbidities (77%, 316/411). Good prognostic indicators for a patient to be deemed suitable for open repair by their surgeon included ASA (ASA I and ASA II: 13% unsuitable v 51% suitable, $p < 0.001$), number of comorbidities (mean number 3.5 v 2.2; $p < 0.001$), age (76.4 years unsuitable v 74.1 years suitable, $p < 0.001$) and aneurysm size (59.9 mm unsuitable v 55.8 mm suitable, $p < 0.001$).

**Table 1. Preoperative aneurysm morphology**

| | Male | Female | Significant difference $p < 0.05$ |
|---|---|---|---|
| Mean aneurysm diameter [±SD]† | 57.9 [±10.5] | 54.7 [±9.0] | yes |
| Aneurysm diameter < 55 mm* | 42% (338/799) | 55% (73/132) | yes |
| Infrarenal neck length ≤ 15 mm* | 17% (128/747) | 19% (24/125) | No |
| Infrarenal neck diameter >28 mm* | 8% (61/751) | 6% (8/126) | No |
| Thrombus in neck* | 12% (90/755) | 12% (15/129) | No |
| Saccular aneurysm* | 21% (156/745) | 24% (30/123) | No |

* chi-squared test.
† t-Test: Two-Sample Assuming Equal Variances.

*Mid-term mortality and morbidity*

Early or peri-operative mortality for patients enrolled in the Australian audit was 1.8% (17/961). By August 2006, 40% (374/961) of audit patients had died.

2.5% of deaths were identified as aneurysm related (24/961). Aneurysm related deaths included death within 30 days of the original procedure (13), death due to rupture (9) or mortality within one month of a secondary procedure (2). A further 14 patients had the ICD-10 code = I714 "abdominal aortic aneurysm without rupture" (13), or I72.3 "aneurysm of iliac artery" (1) as the primary cause of death provided by the National Death Index. These two 'cause of death' descriptors are ambiguous and may not necessarily indicate ARD.

Overall, 23 patients had their EVAR converted to open repair (2.4%). Eight conversions happened during or soon after primary surgery (two following rupture). The mean time to late conversion was 36 months. Reasons for late conversions included rupture (3), enlargement of the aneurysm (4), infected graft (3), migration and endoleak (2), type I endoleak (1), thrombosed graft (1) and unspecified (1).

At August 2006, 16 patients had ruptured aneurysms (1.7%). Three "early" ruptures occurred within 30 days of the original procedure. One patient died and two survived following conversion to open repair. Thirteen "late" ruptures have been reported of which 9 patients died as a consequence, three patients survived following open repair and one survived following repeat endovascular repair.

Preoperative aneurysm size was significantly larger for the patients whose aneurysms ruptured (68.5 mm vs 57.3 mm, $p < 0.001$).

*Statistical analysis of results*

Table 2 shows the survival data for all patients enrolled in the audit.

Essentially 3 years following EVAR, 80% of patients can be expected to survive. Similarly, after five years 67% of patients can be expected to survive.

The angle of the aortic neck, infra-renal neck length, device brand, smoking status, graft configuration, aneurysm angle, and gender had non-significant effects on survival (i.e. $p > 0.05$). Four factors were shown to statistically significantly impact on survival: age, ASA, creatinine and aneurysm size as shown in Figs. 1−4. Each factor was found to contribute

**Table 2. Survival table for all patients.**

| Time (months) | Number entering this interval | Number of deaths | Proportion surviving | Survival Standard error | Lower 95% CI | Upper 95% CI |
|---|---|---|---|---|---|---|
| 0 | 961 | 3 | 99.7% | 0.2% | 99.3% | 100.0% |
| 1 | 958 | 16 | 98.0% | 0.4% | 97.1% | 98.9% |
| 3 | 942 | 9 | 97.1% | 0.5% | 96.0% | 98.2% |
| 6 | 933 | 14 | 95.6% | 0.7% | 94.3% | 96.9% |
| 12 | 919 | 29 | 92.6% | 0.8% | 91.0% | 94.3% |
| 18 | 890 | 33 | 89.2% | 1.0% | 87.2% | 91.2% |
| 24 | 857 | 30 | 86.1% | 1.1% | 83.9% | 88.3% |
| 36 **3 yr** | 827 | 57 | **80.1%** | 1.3% | 77.6% | 82.7% |
| 48 | 770 | 56 | 74.3% | 1.4% | 71.6% | 77.1% |
| 60 **5 yr** | 714 | 68 | **67.2%** | 1.5% | 64.3% | 70.3% |
| 72 | 646 | 47 | 62.3% | 1.6% | 59.3% | 65.5% |
| 96 | 243 | 12 | 59.3% | 1.7% | 56.0% | 62.7% |

statistically significantly to a model of survival with each $p < 0.001$. Three and five year survival rates are shown on each figure. Infrarenal neck diameter was statistically significant for 3 year survival (0.006), but not 5 year survival ($p = 0.093$).

Age statistically significantly contributes to the survival model which already accounts for ASA ($p < 0.001$), using a likelihood ratio test[7] comparing survival models of ASA, with and without age. Aneurysm size ($p = 0.001$) similarly was found to statistically significantly contribute to explain the variation in survival rates, when added to a model which already included age and ASA. Creatinine ($p < 0.001$) further statistically significantly contributed to explain the variation in survival rates, when added to a model which already included age, size and ASA.

Tables 3 and 4 show predicted survival of patients after EVAR at three years and five years, for patients with particular preoperative aneurysm size, ASA, creatinine and age. These tables show the effect of all four variables on survival in contrast to their singular effect shown in the figures. The best case scenario shown in Tables 3 and 4 is for a young patient (70 years) with low ASA, a small aneurysm (50 mm) and with low creatinine (85 μmol/L). We expect 91% of such patients to survive 3 years and expect 85% patients to survive 5 years (i.e. 15% expected to die within 5 years). The worst case scenario shown in Tables 3 and 4 is for an older patient (83 years), with high ASA (IV), with a large aneurysm(74 mm) and with high creatinine(125 μmol/L). For this worst case we expect 44% patients to survive 3 years and only 25% to survive 5 years (i.e. 75% expected to die within 5 years).

Grey shading in Tables 3 & 4 indicates unreliable estimates, showing where there were less than 10 people in the region estimated. These have been included for completeness, but should not be treated as accurate estimates of survival rates.

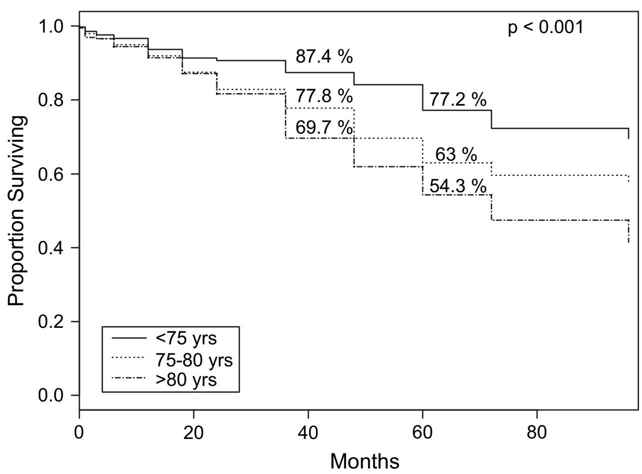


**Fig. 1.** Age.

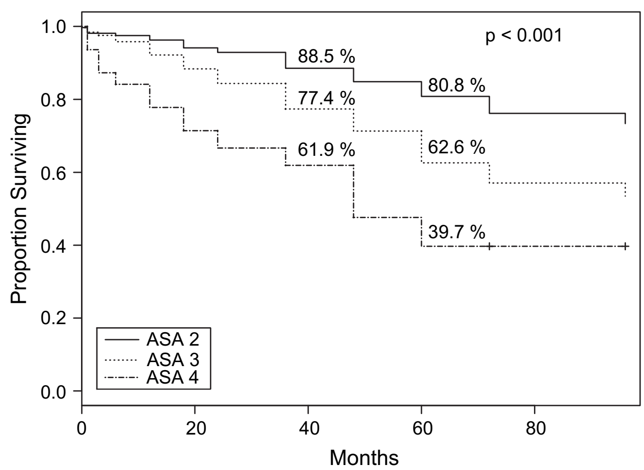


**Fig. 2.** ASA.

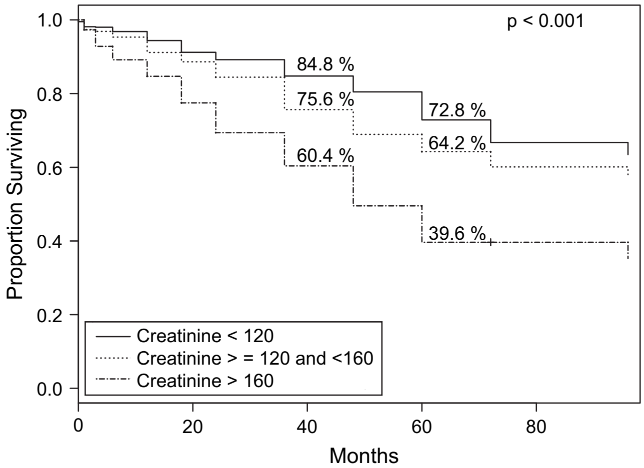


**Fig. 3.** Renal function (creatinine).

*Aneurysm related deaths*

Stratified, right censored, Kaplan-Meier survival analysis was used to determine which factors significantly influenced ARD. Results indicated that ASA ($p = 0.002$), aneurysm size ($p = 0.001$) and infrarenal neck length ($p = 0.001$) all significantly contributed to a model of freedom from ARD. Gender, age, aortic neck angle, device, graft type, infrarenal neck diameter, smoking status, aneurysm angle and creatinine were not found to statistically significantly predict ARD. Finding significant differences despite the small number of (24) of ARD, implies these have a strong effect. Table 5 shows the direction and magnitude of these affects; the observed ARD rates are reported.

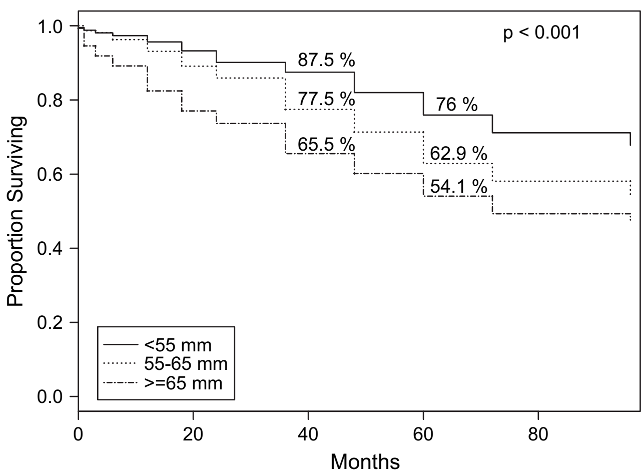


**Fig. 4.** Size of aneurysm.

**Table 3. Survival at three years predicted by ASA, age and aneurysm size**

| ASA | Max Diameter | Age (years) | | | | | |
|---|---|---|---|---|---|---|---|
| | | 70 years | | 77 years | | 83 years | |
| | | Creatinine (μMoles/Litre) | | | | | |
| | | 85 | 125 | 85 | 125 | 85 | 125 |
| ASA II | 50 mm | 91% | 88% | 87% | 84% | 83% | 79% |
| | 58 mm | 89% | 87% | 86% | 82% | 81% | 77% |
| | 74 mm | 87% | 83% | 82% | 77% | 77% | 71% |
| ASA III | 50 mm | 86% | 82% | 81% | 76% | 75% | 69% |
| | 58 mm | 84% | 80% | 78% | 73% | 72% | 66% |
| | 74 mm | 80% | 75% | 73% | 67% | 66% | 59% |
| ASA IV | 50 mm | 79% | 74% | 72% | 65% | 64% | 56% |
| | 58 mm | 76% | 71% | 69% | 62% | 60% | 52% |
| | 74 mm | 71% | 64% | 62% | 54% | 53% | 44% |

Shading denotes estimates with low certainty. Sample sizes <10 in those regions.

## Discussion

The management of abdominal aortic aneurysms remains controversial and this is particularly true for sicker patients (ASA III and IV) with smaller aneurysms (<55 mm). The data presented here provides robust information which can help inform clinicians in their decision-making process for patients with abdominal aortic aneurysms.

Being population based, the Australian audit has been able to closely follow a large heterogeneous group of EVAR patients for over six years. For example 44% of the 961 patients were treated for aneurysms smaller than 55 mm and 65% were ASA III or IV.

The 30-day mortality for EVAR cases submitted to the Australian audit was 1.8% which is similar to results reported elsewhere.[9]

In this Australian study, the overall three year survival post EVAR is 80% and 67% at five years.

**Table 4. Survival at five years predicted by ASA, age and aneurysm size**

| ASA | Max Diameter | Age (years) | | | | | |
|---|---|---|---|---|---|---|---|
| | | 70 years | | 77 years | | 83 years | |
| | | Creatinine (μMoles/Litre) | | | | | |
| | | 85 | 125 | 85 | 125 | 85 | 125 |
| ASA II | 50 mm | 85% | 81% | 79% | 74% | 74% | 68% |
| | 58 mm | 83% | 79% | 77% | 72% | 71% | 64% |
| | 74 mm | 79% | 74% | 72% | 65% | 64% | 57% |
| ASA III | 50 mm | 77% | 72% | 70% | 63% | 62% | 54% |
| | 58 mm | 75% | 69% | 67% | 60% | 58% | 50% |
| | 74 mm | 69% | 62% | 60% | 52% | 50% | 41% |
| ASA IV | 50 mm | 67% | 60% | 57% | 49% | 48% | 39% |
| | 58 mm | 64% | 56% | 53% | 45% | 43% | 34% |
| | 74 mm | 56% | 48% | 45% | 36% | 34% | 25% |

Shading denotes estimates with low certainty. Sample sizes <10 in those regions.

**Table 5. Aneurysm Related Deaths**

| | |
|---|---|
| ASA I or II | 1% (4/305) |
| ASA III | 3% (16/568) |
| ASA IV or V | 8% (5/63) |
| Aneurysm diameter ≤ 50 mm | 0% (1/253) |
| Aneurysm diameter 50–55 mm | 2% (5/225) |
| Aneurysm diameter > 55 mm | 4% (18/441) |
| Infrarenal neck length <12 mm | 9% (6/66) |
| Infrarenal neck length 12–20 mm | 2% (7/306) |
| Infrarenal neck length >20 mm | 2% (11/476) |

Missing data was omitted. Hence totals < 961.

We found, however, that a number of pre-operative factors are strongly predictive of mid-term survival. The most powerful single predictor of survival is ASA status, with ASA II individuals having an 81% 5 year survival , ASA III a 63% survival and ASA IV patients a 40% 5 year survival. Whilst allocation of individuals to various ASA groups is somewhat arbitrary, it is clear that a global assessment of co-morbidities predicts long-term survival. Similar findings have been reported by Torsello *et al.* after Talent graft deployment.[10]

As expected, the survival analysis showed that age at the time of implantation is a strong predictor (5 year survival in patients less than 75 years of age is 77% versus 54% in those over 80 years) indicating strongly to clinicians the impact of patient selection on clinical outcome.

Renal impairment (reflected by a creatinine level ≥ 120 μmol/L) was also found to be a strong predictor of survival (Fig. 3). Whilst formal glomerular filtration rates were not calculated, it is clear that modest renal impairment is a potent predictor of long-term survival post EVAR. This is consistent with findings by Azizzadeh *et al.*[11] Similar effects of renal function on outcome of coronary bypass grafting in high risk individuals has been found[12] and in fact also in patients with ischaemic heart disease.[13]

Somewhat surprisingly however, we have also found that aneurysm size is a significant predictor of survival (5 year survival in patients with aneurysms <55 mm is 78%, versus 54% in aneurysms ≥ 65 mm) and this effect is independent of ASA and age. Two studies have reported worse mid-term outcomes for patients with larger preoperative aneurysms.[14,15] Ouriel *et al.* showed significantly worse 24-month survival for larger aneurysms (≥ 55 mm) than those less than 55 mm[14] The EUROSTAR collaborators also found that the midterm outcome for larger preoperative aneurysms resulted in more ARD, unrelated death and rupture.[15] Zarins *et al.* observed a significant increase in five year mortality in larger aneurysms.[16] It is not clear why this should be, and would appear to warrant further investigation.

Two large randomised controlled trials have demonstrated that surveillance is generally preferable to open repair for patients whose aneurysms are smaller than 55 mm.[3,4,5] This assessment is based on the rates of perioperative mortality and the risk of rupture for the smaller aneurysm. The risk of small aneurysms (40–50 mm) rupturing is around 1% per annum.[3,4,5,17,18] However, a significant proportion of aneurysms tend to expand over time, leading to increased risk of rupture (10–20% for aneurysms between 60 and 70 mm) and hence the inevitable requirement for intervention in a subset of patients.[17]

Given the increasing strength of evidence in favour of improved survival of patients with smaller aneurysms and the desire of vascular surgeons to use the EVAR procedure rather than open repair, there may be good reasons for re-evaluating these recommendations in selected subgroups of patients, especially where the expected rate of expansion can be predicted. However, the ongoing need for reintervention and continued aortic sac enlargement will also need to inform the decision making process.[19]

ASA, aneurysm size, and infrarenal neck length all significantly influenced ARD. It should be noted however that ARD only accounted for 2.5% of all deaths in the study group. This compares with a 3.1% of patients at twelve years reported by Brewster *et al.*[20] and 0.6% at seven years reported by Torsello *et al.*[10] It is probably reasonable to assume that with this Australian study 2.5% is a baseline figure and that additional deaths were aneurysm related, but not attributed at the time of death, where autopsies are rarely undertaken in older patients.

Brewster *et al.* found large pre-operative aneurysm size to be one predictor of ARD as well as renal insufficiency, which did not appear to be a predictor in our study.[20] The Eurostar collaborators found no independent association of risk factor variables with ARD.[21] The association of ARD with infra-renal neck length appears to be new and requires additional investigation.

The ability to readily link this patient group with the National Death Index will enable us to review further causes of mortality and especially ARD during the next two years of the study.

We have presented survival tables for patients at three and five years based on the Australian audit results with subgroups of patients based on aneurysm size, ASA, and age. The results clearly show the diminishing chance of survival for patients with larger aneurysms, increasing ASA, older age and elevated creatinine, and could be of use to clinicians and patients alike during their pre-operative decision making process.

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