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Predictors of 1-Year Survival After Endovascular Aneurysm Repair

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WHAT THIS PAPER ADDS

This article provides a comprehensive analysis of factors predicting 1-year all-cause survival after endovascular aneurysm repair (EVAR), something that has not been reported previously. We consider that 1 year is a reasonable and minimum amount of time that a patient undergoing elective surgery should expect to survive and therefore obtain benefit from the procedure. This study helps to identify which patients have a significantly elevated risk of dying within that first year after surgery. Surgeons could use this information to ensure that patients have understood and considered the risks and benefits of their elective EVAR prior to surgery.

Objective/background: The purpose of this study was to determine the preoperative variables that best predict 1-year survival following elective endovascular aneurysm repair (EVAR), a period of time that would suggest the patient had benefited from the procedure. Most EVAR survival studies focus on early and late survival; scant information is available for 1-year survival.

Methods: Data from two Australian audits of EVAR (1999–2001 and 2009–13) were combined ($n = 1,647$). Preoperative variables included routine demographic data, clinical health assessments, computed tomography-derived anatomical data, and all-cause mortality. Univariate and multivariate logistic regressions determined which variables best predicted 1-year survival.

Results: One-year survival after EVAR was 93.7% (1,544/1,647) and 30-day survival was 98.4% (1,620/1,647). Univariate analyses found that nine preoperative variables were significantly associated with 1-year survival. Five variables were included in the final multivariate model: American Society of Anesthesiologists physical status, aneurysm diameter, creatinine, respiratory assessment, and severity of iliac artery calcification (receiver–operator curve 0.717, $R^2 = .117$). Predicted 1-year survival ranged from 98.6% to 68.0%, based on differences in aneurysm size and patient comorbidities.

Conclusion: Personalised 1-year survival risk enables surgeons and patients to consider seriously the risks and benefits of EVAR prior to surgery.

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INTRODUCTION

Survival after repair of an abdominal aortic aneurysm (AAA) is unarguably the most important end point for patients considering elective surgery and one they will need to balance against their likelihood of surviving without an operation. Estimates for risk of rupture per year based on the size of aneurysm are imprecise but are quoted as follows: <4 cm, <0.2%; 4–4.9 cm, 0.3–0.6% in men and 1.0–3.0% in women; 5–5.9 cm, 3.0–15.0%; 6.0–6.9 cm, 10.0–20.0%; 7.0–7.9 cm, 20.0–40.0%; ≥8 cm, 30.0–50.0%. However, risk can vary depending on pre-existing conditions and rates of aneurysm expansion.[1,2]

Undergoing elective endovascular aneurysm repair (EVAR) carries a risk. Two systematic reviews comparing endovascular and open repair found 30-day mortality to be lower after EVAR than after open repair (1.4% vs. 4.2%) but had no survival advantage thereafter and was associated with an increased rate of complications and reinterventions.[3,4] The UK EVAR-1 and EVAR-2 trials reported 30-day mortality to be 1.8% for healthier patients (EVAR-1) and 7.3% for less fit patients (EVAR-2), showing a marked survival differential between healthier and sicker patients.[5] It has previously been shown that the factors that most strongly influenced 3- and 5-year survival are aneurysm diameter, American Society of Anesthesiologists (ASA) status, age, and creatinine.[6,7] Three-year survival varied between 91% for younger patients with low ASA status, creatinine, and aneurysm size and 44% for older, less fit patients.[8]

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Reliable figures for 1-year survival after EVAR have been less well documented than early and late survival, but published figures suggest ranges between 82% and 98% (details and references given in Table S1; see Supplementary Material). Hence, it is possible that a patient with a 6% risk of rupture could have an 18% risk of dying in the year after the procedure. In such a case the risk in that year outweighs the benefit, a factor that patients and clinicians may want to consider preoperatively. Highlighting the specific factors that most strongly influence 1-year survival after EVAR could help clinicians and patients decide whether, under certain circumstances, an intervention is an unnecessary burden. Not only is 1 year a reasonable period that a patient might expect to survive, but it is also more statistically reliable than early death (within 30 days of the procedure) as there are more deaths at 12 months. However, a note of caution about modelling is warranted: the ability to predict actual time of death for an individual is imprecise. The aim here is to provide a useful guide as to which aneurysm patients may have an elevated risk of dying within 1 year.

METHODS

Data and definitions

This study was a retrospective review of two prospectively maintained datasets from two Australian audits of EVAR, which were combined for analysis. Patients underwent elective EVAR procedures between November 1999 and May 2001 (AUS-01)[6] and between January 2009 and May 2013 (AUS-13). The majority (76%) of the grafts were Zenith grafts (Cook, Bloomington, IN, USA) and the aorto-bi-iliac-bifurcated configuration was used in >90% of cases. Clinical data were self-reported by the surgeon or a staff member. Data from the AUS-13 dataset were also independently audited. All patients were followed for 1 year and date of death was supplied by the Australian Institute of Health and Welfare National Death Index (NDI), which captures all deaths in Australia. One-year survival was calculated from date of the primary EVAR procedure. Preoperative variables, their definitions and assumptions made when combining the data, are shown in Table S2 (see Supplementary Material).

Information regarding iliac artery calcification and tortuosity was collected from preoperative computed tomography (CT) scans according to individual clinician opinion of severity (none, mild, moderate, severe). In the AUS-13 group, this was for both iliac arteries (common and external on both sides); in the AUS-01 group one global measurement was provided for left and right iliac arteries. For comparison purposes the iliac system with the most severe grading was selected.

Ethics approval

Ethics approval for AUS-01 was obtained from the Ethics Committee for the Royal Australasian College of Surgeons. The AUS-13 trial obtained state-wide and institutional ethics approval from all 25 participating institutions. Ethics approval to link datasets with the NDI was provided by the institutions and independently by the NDI ethics committee.

Statistical analysis

Data were tabulated as means and ranges or percentages. Student *t* tests and proportions tests ("stats" prop.test function) were used to compare the two datasets.[9] Each preoperative variable was plotted against 1-year survival rates for the overall dataset and the two datasets separately. For continuous variables (such as age) data were divided into deciles to assess model fit graphically. If the direction of the relationship for a variable was inconsistent across the two datasets it was not included in the multivariate model.

The binomial outcome variable, 1-year survival (survive or not), was used to predict the survival rate for each level of the independent (preoperative) variables. Preoperative variables were truncated at the 2.5% and 97.5% percentiles to provide a reasonable portion at each end of the range and hence more statistically robust estimates. Truncation ranges were as follows: age 60—88 years; maximum aneurysm diameter 43—85 mm; creatinine 60—208 μmol/L; infrarenal neck diameter 18—31 mm; infrarenal neck length 10—57 mm; aortic neck angle <90°; white cell count 4.5—13.1 × 10^9/L; aneurysm angle <80°. For example, age <60 were treated as 60 years and ages >88 were treated as 88 years.

Cardiac assessment groups 1 and 2 had similar 1-year survival rates, as did respiratory assessment groups 1 and 2 and calcification groups 1 and 2. Each of these indices were merged for the purposes of this study. These adjustments generally improved R^2 and/or receiver—operator curves (ROC). For multivariate models only preoperative variables with >1,000 total patient records (61%) were included.

For rigour, Cox proportional hazards survival models and binomial logistic regression were performed using Frank Harrell's "lrm" and "cph" functions from the "rms" library. For Cox proportional hazards models survival was truncated at 1 year. The proportional hazards assumption was tested using "cox.zph" function from the "survival" library.[10] ROC, odds ratios (OR) and hazards ratios (HR) were reported. Missing data were omitted from analysis rather than being imputed. Owing to missing preoperative variables, not all regressions included the same number of patients. Backwards stepwise regression using the "fastbw" function from rms library and the Akaike's Information Criterion were used to select which variables should be included in multivariate 1-year survival model.[9,11]

The le Cessie—van Houwelingen—Copas—Hosmer unweighted sum of squares test statistic was used to assess goodness of fit in logistic regression models.[12,13] The test was applied using the "residuals.lrm" function.[11] Final models were internally validated using 1,000 bootstrap samples with replacement.[14] The bias corrected Somers'