

## The Relationship Between Aortic Aneurysm Surgery Volume and Peri-Operative Mortality in Australia

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### WHAT THIS PAPER ADDS

This study is the first to have examined the effect of hospital and surgeon operative volume on peri-operative mortality after aortic aneurysm repair in Australia. Its findings differ from similar studies performed before centralisation in the UK and North American populations, in that it found no correlation between volume and mortality outcomes for standard and complex EVAR (including fenestrated, branched, and chimney EVAR). However, there was an inverse relationship between peri-operative mortality and hospital volume for thoracic EVAR, as well as surgeon volume for open aortic repair, suggesting that in Australia TEVAR should be performed by high volume hospitals and open repair by high volume surgeons.

**Objectives:** Operative caseload is thought to be associated with peri-operative mortality following intact aortic aneurysm repair. The aim was to study that association in the Australian setting, which has a unique healthcare provision system and geographical population distribution.

**Methods:** The Australasian Vascular Audit database was used to capture volume measurements for both individual surgeon and hospital and to separate it into quintiles (1, lowest, to 5, highest) for endovascular (EVAR), open surgical repair (OSR), and subgroups of repair types between 2010 and 2016. Multivariable logistic regression modelling was used to assess the impact of caseload volumes on in hospital mortality after adjustment for confounders.

**Results:** Volume counts were determined from 14,262 aneurysm repair procedures (4121 OSR, 10,106 EVAR). After exclusions, 2181 OSR (161 complex, 2020 standard) and 7547 EVAR (6198 standard, 1135 complex, 214 thoracic (TEVAR)) elective cases were available for volume analysis. Unadjusted mortality after EVAR was unaffected by either surgeon (Quintile 1, 1.0%; Quintile 5, 0.9%;  $p = .28$ ) or hospital volume (Quintile 1, 0.8%; Quintile 5, 1.3%;  $p = .47$ ). However, univariable analysis of the TEVAR subgroup revealed a significant correlation with hospital volume (Quintiles 1–2 vs. Quintiles 3–5;  $p = .02$ ). Univariable analysis for OSR demonstrated a marginal, non-significant value for surgeon (Quintile 1, 4.0%; Quintile 5, 3.6%;  $p = .06$ ), but not hospital volume (Quintile 1, 4.7%; Quintile 5, 4.0%;  $p = .67$ ). After adjustment for confounders hospital volume remained a significant predictor of peri-operative TEVAR mortality (Quintile 1–2 vs. 3–5; OR 5.62, 95% CI 1.27–24.83;  $p = .02$ ) and surgeon volume a predictor following standard OSR (Quintile 1–2 vs. Quintile 3–5; OR 2.15, 95% CI 1.21–3.83;  $p = .01$ ).

**Conclusions:** There is an inverse correlation between both surgeon volume of open aortic aneurysm repair, hospital volume of thoracic endovascular aneurysm repair and in hospital mortality. These findings suggest that in Australia TEVAR should be performed by high volume hospitals and OSR by high volume surgeons.

**Keywords:** Aortic aneurysm, Mortality, Vascular surgical procedures, Post-operative complications, Health impact assessment

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## INTRODUCTION

Since the first reports of endovascular aortic aneurysm repair (EVAR) there has been widespread acceptance of the technique.<sup>1–3</sup> Elective EVAR now surpasses open surgical repair (OSR) as the most common treatment method for abdominal aortic aneurysm (AAA).<sup>4</sup> This is due to its minimally invasive nature, which results in reduced morbidity and peri-operative mortality.<sup>5–9</sup>

A body of evidence has identified a relationship between individual surgeon, hospital case volume, and peri-operative outcomes.<sup>10</sup> Several North American and British studies have investigated volume outcome relationships in aortic surgery,<sup>4,11–19</sup> finding that higher surgical volumes are associated with lower peri-operative risk. It is thought that the same inverse relationship may be more pronounced with complex aortic surgery, which has increased procedural complexity and higher peri-operative risk. Those relationships have not been studied in Australia.

Australia played a central role in the advancement of several first generation EVAR devices during their early development.<sup>20–22</sup> Standard and custom made aortic stent grafts were planned and manufactured, with local proctor training provided to international vascular surgeons who were early adopters of the technique. Moreover, there was an active fenestrated and complex EVAR training program available to local surgeons which ensured most were well placed to incorporate these procedures into their own practice. Without regulatory body restriction both standard and complex EVAR procedures were broadly integrated into practice within the Australian vascular surgery community.<sup>23</sup> This meant that surgeon and hospital caseload volumes were often lower than those overseas, where more selective introduction of EVAR in to large specialty centres was commonplace.<sup>24–27</sup> It may be that applying results of volume outcome studies from other continents may not be justified.

The aim of this study was to determine the relationship between individual surgeon and hospital caseload volume with peri-operative mortality for elective aortic aneurysm repair in Australia. Furthermore, more complex subgroups of open surgery and endovascular aortic aneurysm repair were included in that same volume outcomes analysis.

## METHODS

Approval for this study was granted by the institutional ethics committee. The committee determined that individual patient consent was not required, as there was no personally identifiable material within the dataset.

### Study population

The Australasian Vascular Audit (AVA) database was used to capture all elective and emergency aortic surgical repair procedures between 1 January 2010 and 31 December 2016.<sup>23</sup> The AVA is a nationwide, individual, total practice audit mandated for all members of the Australian and New Zealand Society for Vascular Surgery (ANZSVS) who perform specified (endo) vascular procedures. It captures quality

assurance and outcomes data (complications and mortality but not cause of death) for each hospital admission. Members of the ANZSVS are required to enter their operative activity for all hospitals in which they conduct audited index vascular procedures (<http://www.anzsvs.org.au/audit/>).<sup>23,28</sup>

Study patients included all those who underwent standard and complex EVAR for abdominal aortic aneurysm, thoracic endovascular aortic aneurysm repair (TEVAR) for isolated thoracic aortic aneurysm, standard and complex OSR for intact aneurysm disease of the abdominal aorta. Complex EVAR was defined as endovascular repair of any abdominal  $\pm$  iliac aneurysm disease which included a combination of endovascular branches (BEVAR), fenestrations (FEVAR), or chimney grafts (CHEVAR) for visceral (or iliac) branch arteries. Complex OSR was defined as open repair of the same that involved the use of a suprarenal aortic clamp, interposition or bypass graft to any visceral branch, surgery for infected aneurysms, or explantation of an existing endograft. These included juxtarenal, suprarenal, mycotic aneurysm repair, and open conversion for a failed EVAR procedure.

Thoraco-abdominal, ruptured, and urgent symptomatic aortic aneurysms were excluded from the analysis because of the confounding effect of their high mortality rate.

### Volume metrics

Individual surgeon and hospital volumes were independently assessed using counts from the period ( $\leq$  12 months) that preceded any given operation. Each surgeon was identified by the unique identification code allocated by the AVA general manager. This meant that the surgeon volumes derived for each patient, aggregated all operations performed by the treating surgeon in all the institutions in which they worked. Only the lead operator under whose name the patient was admitted was identified for deriving volume. Data from the first 12 months of the study period (January to December 2010) was used to calculate volume only and did not contribute to the outcomes dataset. Data from 2011 to 2016 were used to calculate both volume and peri-operative mortality. While peri-operative outcomes were only evaluated for elective surgery, the total calculated volume counts were taken from all aortic aneurysm procedures, including elective, urgent, and emergency procedures.

To assist with analysis and interpretation of results, surgeon and hospital volumes were stratified into quintiles, using cut offs which allocate surgeons/hospitals to five groups of approximately equal size (Table 1). The same method has been used consistently and validated in several similar volume outcome studies.<sup>4,19,29</sup> Volume quintiles were calculated separately for EVAR and open surgery as a whole and five subgroups: standard EVAR, complex EVAR, TEVAR, standard OSR, and complex OSR. All EVAR and all OSR case volumes were used to separate into volume quintiles for each of the subgroups. A further binary analysis (Quintiles 1–2 vs. 3–5), in addition to quintile

**Table 1.** Definition of volume quintiles for surgeons and hospitals (number of procedures per year) for EVAR and open repair subgroups between 2010 and 2016

Quintile	EVAR						Open repair			
	Standard EVAR (n = 6198)		Complex EVAR (n = 1135)		TEVAR (n = 214)		Standard OSR (n = 2020)		Complex OSR (n = 161)	
	Hospital	Surgeon	Hospital	Surgeon	Hospital	Surgeon	Hospital	Surgeon	Hospital	Surgeon
1	0–10	0–6	0–14	0–8	0–15	0–6	0–4	0–2	0–5	0–2
2	11–18	7–10	15–23	9–11	16–21	7–11	5–10	3–4	6–9	3–5
3	19–26	11–13	24–33	12–15	22–31	12–14	11–17	5–6	10–15	6–8
4	27–39	14–18	34–46	16–20	32–43	15–18	18–29	7–10	16–27	9–12
5	40–96	19–42	47–95	21–37	44–91	19–28	30–71	11–28	28–43	13–28

EVAR = endovascular aortic aneurysm repair; TEVAR = thoracic endovascular aortic aneurysm repair; OSR = open surgical aortic aneurysm repair.

assessment, was performed for all subgroups to mitigate the risk of type II error for smaller subgroups. Volumes were calculated as mean annual volume for the recorded period prior to each operation and were noted to vary slightly over the annual study periods.

### Endpoints

The primary endpoint was peri-operative mortality, defined as in hospital death before discharge regardless of cause or time post procedure. Length of stay was recorded as a secondary endpoint.

### Statistical analysis

The AVA database was thoroughly screened for missing, miscoded, and duplicated data by two independent researchers (M.S. and S.P.), then cross checked by a third (R.V.). Miscoded and implausible data were excluded from the analysis. Hospital and surgeon volumes were examined over time for each procedural subgroup and then compared with admission characteristics. Chi-square tests were used to compare categorical variables and ANOVA was used to compare continuous, normally distributed variables. The primary focus was on the magnitude of the differences (rather than statistical differences) to determine the potential for confounding due to imbalanced patient group characteristics and therefore the extent to which the statistical model was required to perform adjustment.

Separate multilevel, multivariable logistic regression models were then estimated with surgeon and hospital volume as the primary predictor to estimate the overall effect of each. Next, models were estimated with both surgeon and hospital volume as predictors to isolate the independent effect of each, controlling for the other. All models included year of surgery as well as baseline patient demographic and clinical characteristics, which included age, gender, smoking status, comorbidities (diabetes, hypertension, ischaemic heart disease, respiratory disease, creatinine level), to control for the potential confounding effect. Candidate predictors which were considered in the preliminary statistical analysis but excluded from the final model due to lack of correlation, include hospital teaching

status, hospital rural status, and patient insurance type. Calculation was made of odds ratios (OR) and 95% confidence intervals (CI). In each case the highest volume quintile was used as the reference group.

All multilevel models included random effects for surgeon and hospital to account for the correlation of measures among patients who were treated by the same surgeon within the same hospital, to obtain estimates for the appropriate standard error.

Statistical analyses were completed using SAS 9.4 software (SAS Institute Inc., Cary, NC, USA).

### RESULTS

Volume counts were determined from 14,262 individual patients with aortic aneurysm who underwent 4121 (29.0%) OSR and 10,106 (71.0%) EVAR procedures over a seven year period between 2010 and 2016. The OSR group included data from 97 hospitals and 185 individual surgeons. Over that same period there were greater numbers performing EVAR, with 117 hospitals and 201 surgeons included in the analysis. After removal of emergency surgery, duplicates, incomplete data, and outcome data from 2010 (which was used for volume calculations only), there were 2181 OSR (87 deaths, 4.0%) and 7547 EVAR (78 deaths, 1.0%) for the volume outcomes analysis. Within the OSR group, 161 patients were classified as complex (7.4%; peri-operative mortality 13.0%), with the remaining 2020 classified as standard OSR (92.6%; peri-operative mortality 3.3%). The EVAR group consisted of 1135 complex EVAR (15.3%; peri-operative mortality 2.6%), 214 TEVAR (2.8%; peri-operative mortality 5.6%) and 6198 standard EVAR (81.8%; peri-operative mortality 0.5%). Quintile volume definitions for individual surgeon and hospitals related to each of those aortic surgery subgroups are given in [Table 1](#).

### Demographics and comorbidities

The mean age for the all EVAR group was  $75.4 \pm 8.0$  years (range 24–102 years). There was variation in the proportion of patients within the hospital and surgeon volume categories over individual years ([Table 2](#)); however, those variations appeared to be small in magnitude. Similarly, there was interquintile variation in hospital volume for the

**Table 2.** Patient demographics according to volume quintiles for all endovascular aortic aneurysm repair

Variables	Hospital volume			p-value	Surgeon volume			p-value
	Low (Quintile 1)	Median (Quintiles 2–4)	High (Quintile 5)		Low (Quintile 1)	Median (Quintiles 2–4)	High (Quintile 5)	
Procedures per year	0–11	12–40	41–96		0–6	7–19	20–42	
Year (% of quintile)								
2011	14.9	17.3	17.8	< .001	16.7	14.2	25.3	< .001
2012	14.6	17.3	15.1		14.9	15.9	18.9	
2013	16.6	14.5	21.3		16.9	16.8	14.1	
2014	17.7	17.8	15.4		16.9	17.7	16.6	
2015	17.7	15.9	14.6		16.4	16.6	13.6	
2016	18.5	17.3	15.8		18.3	18.8	11.4	
Patients analysed, n	1532	4472	1543		1454	4626	1467	
Age (mean years)	75.9	75.5	73.9	< .001	75.0	75.2	75.8	.01
Male (%)	87.6	84.5	85.5	.014	86.7	84.8	85.7	0.19
Diabetes (%)	15.0	15.4	18.7	.006	16.5	16.4	14.2	0.11
Hypertension (%)	83.6	87.4	91.1	< .001	86.4	87.5	87.8	0.49
IHD (%)	53.1	54.2	59.1	.001	55.3	54.1	56.9	0.17
Creatinine > 150 µmol/L (%)	7.9	8.5	7.5	0.37	8.0	8.2	8.3	0.95
Respiratory (%)	1.2	1.4	1.4	0.89	1.5	1.3	1.5	0.61
Smoker (current or Ex) (%)	72.9	78.7	77.3	< .001	79.8	75.7	79.8	.001
Length of stay in days (mean/median)	4.5/3.0	4.9/3.0	5/3.0	.02	4.8/3.0	4.9/3.0	4.7/3.0	.86 <sup>a</sup>

The bold values represent significant p values at the 0.05 threshold.

IHD = ischaemic heart disease.

<sup>a</sup> Kruskal–Wallis test.

proportion of most recorded comorbidities; however, those absolute differences were small to moderate, with marginal clinical significance. However, high volume hospitals were more likely to operate on slightly younger, diabetic patients with hypertension and ischaemic heart disease. There was very little interquintile variation in the surgeon volume analysis. A demographic summary of all EVAR procedures included in the analysis is given in Table 2.

The mean age for the all OSR group was  $71.6 \pm 8.3$  years (range 21–95 years). There appeared to be variation in the volume proportions across the study period with most of the high volume surgeon and hospital procedures taking place between 2011 and 2013 (Table 3). There was no interquintile variation between comorbidities when analysed by hospital volume and very few when surgeon volume was analysed. Patients of high volume surgeons were more likely to be older males, and less likely to have hypertension; however, once again those absolute differences between groups were small and unlikely to introduce significant bias. A summary of all OSR procedures included in the analysis is given in Table 3.

### Effects of volume on peri-operative mortality

The median number of EVAR operations performed was 12 (range 0–42) by surgeon and 23 (range 0–96) by hospital. Those same values for subgroups were standard EVAR 12 (range 0–42) of 22 (range 0–96), complex EVAR 14 (0–37) of 28 (0–95), and TEVAR 13 (0–28) of 27 (0–91) for individual surgeon and hospital, respectively. Unadjusted mortality rates for EVAR procedures analysed as a single group showed no significant association with either surgeon (Quintile 1, 1.0%; Quintile 2, 0.7%; Quintile 3, 1.4%; Quintile

4, 0.8%; Quintile 5, 0.9%;  $p = .28$ ) or hospital volume (Quintile 1, 0.8%; Quintile 2, 1.0%; Quintile 3, 0.8%; Quintile 4, 0.9%; Quintile 5, 1.3%;  $p = .47$ ) (Fig. 1). When subgroups were analysed separately there appeared to be an inverse association between TEVAR hospital volumes and mortality (Quintile 1, 13.6%; Quintile 2, 7.3%; Quintile 3, 2.3%; Quintile 4, 2.2%; Quintile 5, 2.4%;  $p = .17$ ) (Fig. 2A). That difference was highly significant on univariable analysis of binary groups (Quintiles 1–2 vs. Quintiles 3–5;  $p = .02$ ). There were no discernible associations observed for the other EVAR subgroups (standard and complex EVAR) (Fig. 2A and B).

The median number of OSR operations performed was six (range 0–28) by surgeon and 14 (range 0–71) by hospital. Those same values for subgroups were standard OSR 6 (range 0–28) of 14 (range 0–71) and complex OSR 7 (0–28) of 12 (0–43) for individual surgeon and hospital, respectively. When a single group encompassing all OSR surgery was analysed using a univariable analysis there was a marginal, but non-significant association between unadjusted mortality rates for surgeon (Quintile 1, 4.0%; Quintile 2, 6.6%; Quintile 3, 2.7%; Quintile 4, 3.0%; Quintile 5, 3.6%;  $p = .06$ ); and no relationship with hospital volume (Quintile 1, 4.7%; Quintile 2, 4.5%; Quintile 3, 4.0%; Quintile 4, 2.8%; Quintile 5, 4.0%;  $p = .67$ ) (Fig. 1). When the subgroups were analysed separately there appeared to be an association between complex OSR and mortality which suggested that mortality increased with hospital volume (Quintile 1, 6.3%; Quintile 2, 14.7%; Quintile 3, 10.3%; Quintile 4, 14.7%; Quintile 5, 18.8%;  $p = .52$ ), however this was not statistically significant. All other subgroups demonstrated non-linear relationships (Fig. 2C and D).

**Table 3.** Patient demographics according to volume quintiles for all open aortic aneurysm repair

Variables	Hospital				Surgeon			
	Low (Quintile 1)	Median (Quintiles 2–4)	High (Quintile 5)	p-value	Low (Quintile 1)	Median (Quintiles 2–4)	High (Quintile 5)	p-value
Procedures per year	0–4	5–28	29–71		0–2	3–10	11–28	
Year (% of quintile)								
2011	17.7	17.5	29.2	< .001	17.8	17.7	27.5	< .001
2012	20.7	15.0	24.8	–	13.6	16.3	26.4	
2013	15.7	17.1	20.6		12.9	18.3	19.7	
2014	12.7	19.2	7.9		20.0	16.5	10.1	
2015	17.2	17.0	9.3		19.3	17.0	8.2	
2016	16.0	14.1	8.2		16.4	14.1	8.2	
Patients analysed, n	401	1352	428		450	1254	477	
Age (mean years)	71.5	71.3	72.1	0.17	70.9	71.3	72.4	.01
Male (%)	82.0	82.5	81.8	0.94	78.2	83.1	83.9	.04
Diabetes (%)	12.0	12.5	11.2	0.77	11.6	11.6	14.0	0.37
Hypertension (%)	83.3	83.4	84.4	0.88	86.2	84.1	79.5	.01
IHD (%)	43.9	45.2	48.4	0.39	43.1	44.9	49.7	0.1
Creatinine >150 µmol/L (%)	7.2	6.1	7.9	0.38	6.2	6.0	9.0	0.07
Respiratory (%)	7.7	7.7	8.9	0.72	6.7	8.1	8.6	0.51
Smoker (Current or Ex) (%)	77.6	81.8	83.4	0.07	83.1	80.5	82.0	0.43
Length of stay in days (mean/median)	10.8/9	10.6/8	11.4/8	0.07	10.4/8.0	11/8.0	10.8/8.0	.25 <sup>a</sup>

The bold values represent significant p values at the 0.05 threshold.

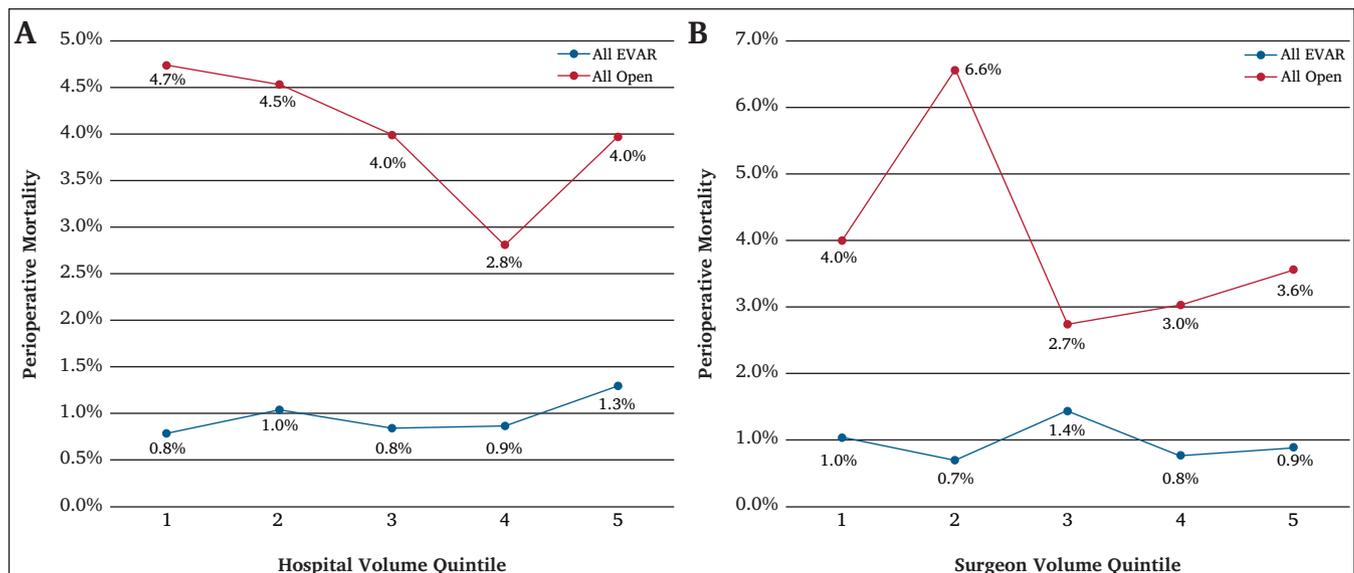
IHD = ischaemic heart disease.

<sup>a</sup> Kruskal–Wallis test.

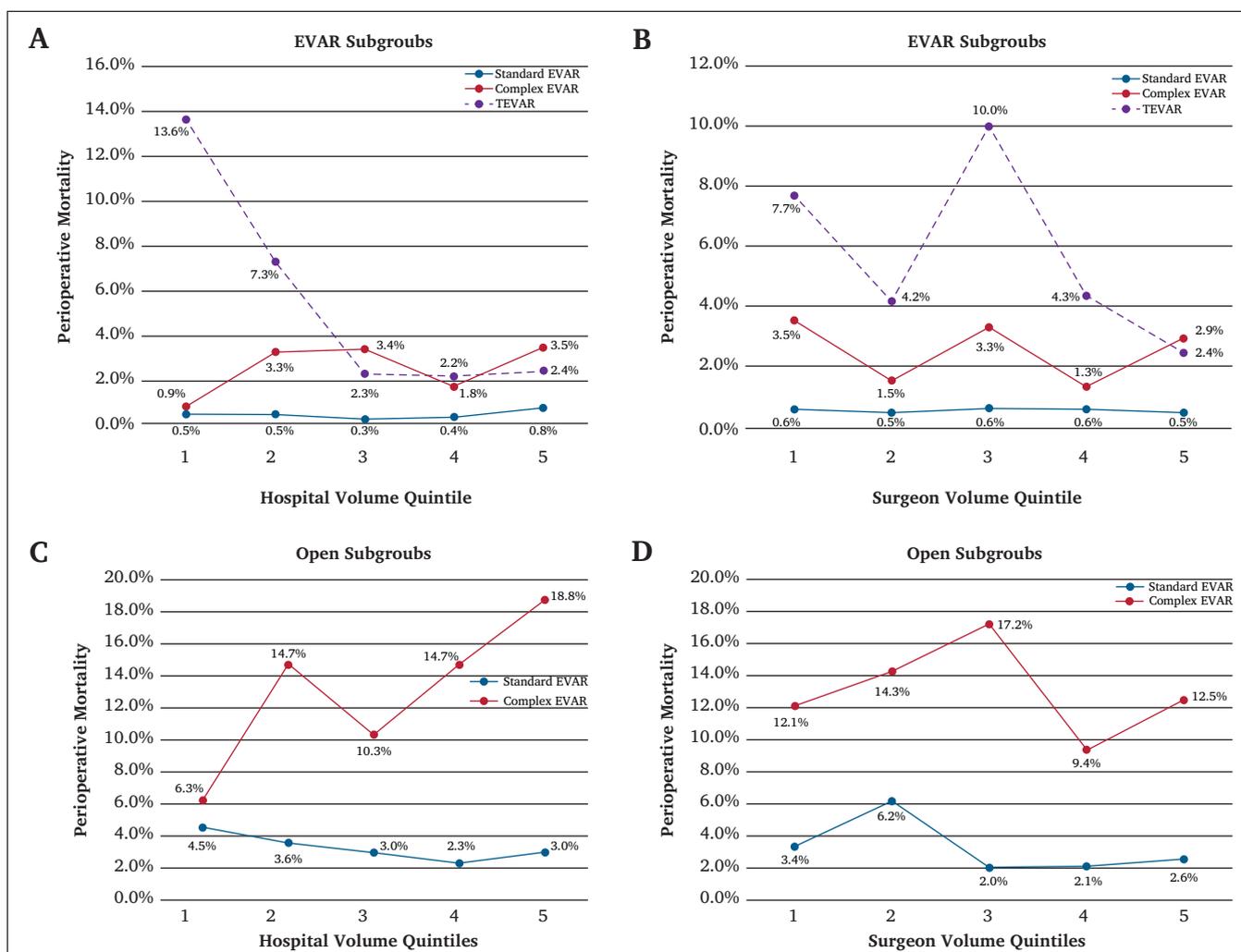
After adjustment for patient demographics, comorbidities and hospital volume for surgeon volume associations (and surgeon volume for the hospital volume analysis) two inverse associations were confirmed. Hospital volume for TEVAR procedures was strongly associated with decreasing perioperative mortality, both with adjustment for surgeon volume (Quintile 1–2,  $n = 0–21$ , vs. 3–5,  $n = 22–91$ ; OR 5.62, 95% CI 1.27–24.83;  $p = .02$ ) and without (Quintile 1–2 vs. 3–5; OR 5.58, 95% CI 1.25–24.98;  $p = .03$ ). Individual surgeon volume had no such association. When OSR was analysed there was an inverse association observed between surgeon volume and mortality for standard (but not complex)

aortic surgery (Quintiles 1–2,  $n = 0–4$ , vs. Quintiles 3–5,  $n = 5–28$ : OR 2.15, 95% CI 1.21–3.83;  $p = .01$ ). Adjusted odds ratios for all quintiles vs. the reference group of Quintile 5 are given for all aortic repair subgroups in Table 4.

There were also important negative findings observed. Both univariable and multivariable regression of volume stratified by quintiles and by binary classification methods (Quintile 1–2 vs. Quintile 3–5) found no significant associations between mortality and volume in both the standard and complex EVAR subgroups. Furthermore, univariable and multivariable regression of quintiles and continuous measurements of surgeon and hospital volume in OSR, EVAR,



**Figure 1.** Unadjusted peri-operative mortality rates for all Open Repair vs. all endovascular aortic aneurysm repair (EVAR), by hospital (A) and surgeon volume (B).



**Figure 2.** Unadjusted peri-operative mortality rates for endovascular aortic aneurysm repair (EVAR) subgroups by hospital (A) and surgeon volume (B). Unadjusted mortality rates for Open Repair subgroups by hospital (C) and surgeon volume (D). TEVAR = thoracic endovascular aortic aneurysm repair.

and subgroups identified no significant association with length of stay in patients who were alive at discharge.

**DISCUSSION**

This is the first Australian study to have analysed the relationship between case volume and peri-operative outcomes following elective aortic aneurysm surgery. Elective EVAR was found to be significantly safer than OSR, with overall mortality outcomes consistent with that of the international published literature (peri-operative mortality 1.0% for EVAR and 4.0% for OSR).<sup>8,30–32</sup> The complete EVAR, and EVAR subgroup analysis showed no association between operative volume (hospital and surgeon) and peri-operative mortality in patients who received standard and complex endovascular repair. However, hospital volume in the TEVAR subgroup showed a strong inverse correlation with mortality. Furthermore, patients receiving OSR had a significant association between individual surgeon volume (not hospital) and reduced peri-operative mortality. Subgroup analysis revealed that association was driven by standard rather than complex OSR surgery.

The European Society for Vascular Surgery guidelines recommend that AAA repair be undertaken within centres of sufficient caseload and experience.<sup>32</sup> They state that relationships between volume and peri-operative outcomes exist for both EVAR and OSR, and base their recommendations on a body of published research from a single centre that analysed results from the United Kingdom and performed meta-analysis of the international literature.<sup>15,33–35</sup> They make a specific threshold based recommendation: that AAA only be performed in hospitals that reach a minimum threshold of 50 elective, infrarenal aneurysm repair cases per annum, by OSR or EVAR.<sup>32</sup> Recently published guidelines for the Society for Vascular Surgery have similar, but less stringent, threshold recommendations.<sup>31</sup> Basing their recommendations on North American studies of risk adjusted Medicare data, they also acknowledged the relationship between hospital volume and peri-operative outcomes.<sup>4,18,30,36</sup> They state that outcomes improve when a hospital volume exceeds 30 EVAR cases per annum and recommend a minimum annual volume of 10 cases, conditional on a documented peri-

**Table 4.** Adjusted odds ratios regarding perioperative mortality for Quintiles 1–4 vs. Quintile five (reference group) by aortic aneurysm repair groups and subgroups

	Surgeon volume (crude) OR (95% CI)	Surgeon volume (adjusted for hospital volume) OR (95% CI)	Hospital volume (crude) OR (95% CI)	Hospital volume (adjusted for surgeon volume) OR (95% CI)
<b>Quintile 1 vs. 5</b>				
All EVAR	1.46 (0.66–3.25)	1.59 (0.70–3.60)	0.63 (0.26–1.50)	0.56 (0.23–1.35)
Standard EVAR	1.40 (0.45–4.30)	1.68 (0.52–5.39)	0.56 (0.23–1.35)	0.42 (0.12–1.44)
Complex EVAR	1.43 (0.47–4.32)	1.64 (0.53–5.11)	0.22 (0.04–1.11)	0.22 (0.04–1.13)
TEVAR	3.19 (0.24–42.94)	5.50 (0.31–98.33)	9.02 (0.75–108.87)	9.17 (0.61–137.76)
All Open	1.48 (0.70–3.15)	1.18 (0.48–2.89)	1.93 (0.87–4.28)	1.51 (0.59–3.88)
Standard Open	1.59 (0.66–3.80)	1.37 (0.50–3.73)	1.87 (0.81–4.33)	1.31 (0.50–3.40)
Complex Open	1.14 (0.13–10.32)	3.86 (0.11–133.78)	0.24 (0.02–3.73)	0.06 (0.00–3.27)
<b>Quintile 2 vs. 5</b>				
All EVAR	0.89 (0.38–2.07)	0.95 (0.40–2.24)	0.82 (0.38–1.76)	0.74 (0.34–1.61)
Standard EVAR	1.03 (0.32–3.28)	1.14 (0.35–3.73)	0.74 (0.34–1.61)	0.46 (0.15–1.40)
Complex EVAR	0.45 (0.11–1.85)	0.55 (0.13–2.32)	0.91 (0.29–2.80)	0.90 (0.28–2.82)
TEVAR	1.57 (0.11–22.57)	2.05 (0.11–37.08)	2.79 (0.22–35.42)	2.38 (0.16–35.66)
All Open	<b>2.83 (1.40–5.70)<sup>a</sup></b>	<b>2.47 (1.10–5.54)<sup>b</sup></b>	1.51 (0.72–3.17)	1.16 (0.49–2.75)
Standard Open	<b>3.25 (1.47–7.20)<sup>a</sup></b>	<b>3.00 (1.21–7.43)<sup>b</sup></b>	1.61 (0.69–3.78)	1.13 (0.44–2.91)
Complex Open	0.84 (0.09–8.09)	2.13 (0.08–60.19)	1.13 (0.14–9.34)	0.38 (0.01–8.06)
<b>Quintile 3 vs. 5</b>				
All EVAR	1.78 (0.86–3.68)	1.89 (0.90–3.96)	0.67 (0.30–1.47)	0.63 (0.29–1.39)
Standard EVAR	1.47 (0.46–4.72)	1.58 (0.49–5.11)	0.63 (0.29–1.39)	0.31 (0.09–1.05)
Complex EVAR	1.12 (0.38–3.32)	1.30 (0.43–3.95)	0.86 (0.29–2.56)	0.87 (0.29–2.58)
TEVAR	3.46 (0.27–44.85)	2.28 (0.13–40.13)	0.71 (0.03–14.89)	0.53 (0.02–13.17)
All Open	1.03 (0.44–2.42)	0.96 (0.38–2.43)	1.21 (0.57–2.60)	0.97 (0.41–2.25)
Standard Open	0.99 (0.36–2.71)	0.99 (0.34–2.89)	1.11 (0.47–2.66)	0.84 (0.32–2.16)
Complex Open	1.02 (0.12–8.69)	0.94 (0.08–10.97)	0.63 (0.06–6.79)	0.33 (0.01–8.06)
<b>Quintile 4 vs. 5</b>				
All EVAR	0.88 (0.38–2.03)	0.92 (0.40–2.13)	0.62 (0.29–1.33)	0.60 (0.28–1.30)
Standard EVAR	1.40 (0.46–4.27)	1.52 (0.49–4.72)	0.60 (0.28–1.30)	0.42 (0.14–1.26)
Complex EVAR	0.46 (0.11–1.85)	0.50 (0.12–2.04)	0.46 (0.13–1.67)	0.47 (0.13–1.73)
TEVAR	1.66 (0.11–24.56)	2.65 (0.16–45.22)	1.29 (0.06–25.89)	1.12 (0.05–25.02)
All Open	1.15 (0.53–2.49)	1.16 (0.52–2.56)	0.83 (0.37–1.86)	0.76 (0.33–1.74)
Standard Open	1.01 (0.40–2.58)	1.03 (0.39–2.71)	0.83 (0.32–2.14)	0.73 (0.27–1.93)
Complex Open	0.47 (0.04–5.29)	0.42 (0.03–6.32)	0.75 (0.10–5.55)	0.75 (0.08–6.76)

EVAR = Endovascular aortic aneurysm repair; TEVAR = Thoracic endovascular aortic aneurysm repair; OR = odds ratio; CI = confidence interval.

<sup>a</sup>  $p < .01$ .

<sup>b</sup>  $p < .05$ .

operative mortality and/or conversion to open repair rate less than 2%. For open surgical repair their recommendation is also for a minimum of 10 cases per year and less than 5% documented peri-operative mortality. They acknowledge the changing landscape of OSR, with a shift in practice toward EVAR and warn against extrapolating from data of the pre-endovascular era when open surgical skills were likely to have been more adept. The results here differ from the European and North American studies which underscore those recommendations, suggesting that there may be geographical differences in patient populations, vascular surgery training, and/or treatment practice of aneurysm disease which limit their generalisability.

The main difference between the current findings and those other studies<sup>4,15,18,30,33–37</sup> was that peri-operative mortality after EVAR was found to have no association with hospital or surgeon volume in the current study. This may be partially explained by the evolution of the discipline of vascular surgery and the EVAR procedure itself within

Australia. Structural changes to the discipline and the training of vascular specialists took place in the 1990s, formally separating the specialty from general surgery in 1995. In contrast, that separation process took place much later in both the United States (2005) and the UK (2013). It facilitated a restructuring of the curriculum, gave vascular surgeons greater control over continuing education, and made it possible to conduct specialty specific board certification. Those changes assisted the rapid acquisition of new skills in the image guided, catheter based treatment of vascular disease. Occurring at a time when endovascular therapy was developing rapidly, these simultaneous events assisted the specialty in taking ownership of those less invasive treatment methods for aortic aneurysm. Moreover, Australia played a key role in the development of EVAR, which included contributions to the design of various EVAR delivery systems,<sup>38</sup> force analysis research,<sup>39,40</sup> the development of bifurcated,<sup>41</sup> fenestrated, and branched stent grafts,<sup>20,21,42</sup> and the term endoleak.<sup>43</sup> This had the effect of

encouraging widespread acceptance of the technique, which was embraced by the vascular surgical community. A phenomenon which was clearly evident in a Vascunet (Subcommittee of the European Society of Vascular Surgery) analysis of elective AAA repair in nine countries between 2005 and 2009 showed that Australia performed the greatest proportion of EVAR over that six year period (56%).<sup>44</sup>

The current study included an a priori analysis of complex EVAR subgroups, including fenestrated EVAR, branched EVAR, chimney EVAR, and TEVAR, as these high risk, highly skilled procedures would be the most likely to benefit from higher operator and hospital volumes. However, with the exception of hospital volumes for TEVAR no association was found between surgeon volume, hospital volume, and peri-operative mortality in these groups. This is a reassuring finding, which may be explained by Australia adopting complex, fenestrated EVAR, and branched EVAR procedures at an early stage in their development. Led by local pioneers, these complex procedures were rigorously proctored throughout the vascular community, with a focus on concentration of experience and collaboration. The practice of multiple contributing specialist operators attending each operation was, and still is, commonplace. Multidisciplinary, multi-operator support is likely to have played a role in the excellent outcomes observed for complex EVAR procedures, which were unaffected by volume.

In distinction from those treatments for abdominal aortic disease, it may be that TEVAR benefits the most from multidisciplinary aortic planning meetings, as well as the hospital based protocols, systems of care, and well resourced intensive care units which are found in larger volume centres. Not only is TEVAR associated with higher mortality risk than those other complex procedures, it has a higher risk of stroke and spinal paraplegia, complications which may benefit from well developed, cross discipline, hospital systems to prevent them progressing to mortality. The results suggest that Australian hospital centres should be performing an annual volume of  $\geq 22$  EVAR procedures (Quintile 3–5) to maintain an acceptable standard of peri-operative mortality following TEVAR. TEVAR should be avoided in low volume hospital centres and concentrated within large tertiary centres by creating a hub and spoke model of referral. Centralisation of TEVAR as a quality assurance strategy has the potential to improve patient mortality outcomes by removing low volume, high mortality outliers and should be carefully considered by the vascular specialty and government health policy advisors.

The finding that individual surgeon OSR volume is associated with lower peri-operative mortality is consistent with other studies.<sup>4,12,13</sup> Specifically, it suggests that an individual Australian surgeon must have an annual volume five or more open repairs (Quintile 3–5) to maintain acceptable standards of peri-operative mortality. This was independent of hospital volume, which had no such association and reflects the high skill level required for this surgery as well as the significant peri-operative risk. While concentrating experience in OSR has the potential to reduce peri-operative mortality it may be possible for individual tertiary hospitals to develop internal

strategies to mitigate the risk of low volume surgeons. A single “open aortic” surgeon who performs all OSR within a hospital, either alone or in conjunction with the referring surgeon, would, facilitate the highest quality care with very little structural change to the current provision of services model and is one that is recommended.

The study has added to the existing literature in demonstrating a convincing relationship between volume and in hospital mortality for TEVAR, and OSR, but no other form of EVAR. This raises doubt as to whether data derived from geographies such as North America and the UK can be applied to diverse and distant regions like Australia, which may have unique local geographic and specialty related factors that make them ill suited to direct comparison. Furthermore, in finding no relationship between caseload volume and mortality rates after complex EVAR it has been demonstrated, for the first time, that for these most complex endovascular procedures volumes are unlikely to play a major role in determining outcome. These procedures may be performed safely in a low volume environment with appropriate proctoring, support, and collaboration.

There are limitations to this study which warrant discussion. Firstly, like any database derived study, it is subject to the quality of the data entered and is therefore prone to bias resulting from errors of fact, coding, transcription, omission, and duplication. However, internal validation of the collected AVA data is performed every three years and shows that it is reliable, with only 2.6% of fields incorrect.<sup>45</sup> Second, compared to other large population studies the sample size and the relative case volume of the higher quintile operators was relatively small, albeit proportional to the smaller population of Australia. This is reflected in the broad confidence intervals observed in the subgroup analysis, which raise the possibility of an underpowered analysis and type II error. However, the ample clinical data recorded in the AVA database has given scope for a more detailed study of potentially relevant and/or confounding variables. Despite the mandatory nature of the AVA as an individual practice audit designed to capture all aortic aneurysm surgery and peri-operative outcomes, external validation has revealed that only 63% of all vascular procedures were captured in its first two years.<sup>45</sup> Those non-compliance proportions have changed little over the period since, and it is therefore likely that the dataset is incomplete. That fact may lead to selection bias; however, most studies which rely on clinical registry data contain a similar degree of bias. Those which are based on US Medicare data are incomplete due to the restriction of patients within that database to those older than 65 years, and data losses related to invalid provider numbers and inadequate surgeon identifiers.<sup>4,11,12,14,18</sup> Those based on the National Inpatient Sample (NIS) are also incomplete due to the very nature by which that dataset is composed.<sup>13,19</sup> It is derived from a 20% random sample of all hospital discharges in the United States stratified by geographic region, hospital bed size, teaching status, urban vs. rural location, and hospital ownership. As not all US states record surgeon information, data analysis is limited to approximately 60% of total AAA

repairs.<sup>13</sup> While specific case ascertainment rates cannot be determined, these limitations are certain to have introduced significant bias into studies like this one which have used those two platforms. Even studies from the UK, derived from a broad based national healthcare scheme with well established national statistics networks are imperfect.<sup>15,17,33,37</sup> The National Health Service datasets are derived from registries with case ascertainment rates which range between 72% and 96%, and also have the potential to introduce selection bias.<sup>46</sup> The AVA is a more complete and less biased method of prospective data collection than both the NIS and US Medicare databases, while less complete than the NHS Hospital Episodes Statistics. While it suffers from the same limitations as all registry based studies, it is valid as the most complete and rigorously conducted study of aortic surgery outcomes in the Australian population to date. Finally, the AVA tool records in hospital mortality and may have missed patients who died after discharge but within the conventional 30 day definition of peri-operative death. As a result, the incidence of mortality, the primary endpoint, may have been underestimated.

## CONCLUSION

The evaluation of health outcomes is fundamental to all advanced healthcare systems. This study has demonstrated an inverse correlation between individual surgeon volume of open infrarenal aortic aneurysm repair, as well as hospital volume of thoracic endovascular aortic repair with peri-operative mortality. No such association was seen for other types of endovascular aortic aneurysm repair. These data suggest that TEVAR in Australia should be performed at high volume hospitals and open aortic aneurysm repair by high volume surgeons.

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## CONFLICTS OF INTEREST

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## APPENDIX A. SUPPLEMENTARY DATA

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ejvs.2018.09.019>.

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