



Dovell, G., Rogers, C. A., Armstrong, R., Harris, R. A., Hinchliffe, R. J., & Mouton, R. (2020). The effect of mode of anaesthesia on outcomes after elective endovascular repair of abdominal aortic aneurysm. *European Journal of Vascular and Endovascular Surgery*. https://doi.org/10.1016/j.ejvs.2020.01.031

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Link to published version (if available): 10.1016/j.ejvs.2020.01.031

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European Journal of Vascular & Endovascular Surgery

The effect of mode of anaesthesia on outcomes after elective endovascular repair of abdominal aortic aneurysm.

--Manuscript Draft--

Manuscript Number:	EJVES13837R
Article Type:	Original Article-Observational Study
Keywords:	Elective Endovascular Aneurysm Repair; Anaesthesia; Abdominal Aortic Aneurysm
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Abstract:	Background: Endovascular aneurysm repair (EVAR) is the most commonly used method to repair abdominal aortic aneurysm. EVAR can be performed using a variety of anaesthetic techniques including general anaesthetic (GA), regional anaesthetic (RA) and local anaesthetic (LA) but little is known about the effect each of these anaesthetic modes have on patient outcome. Methods: Data from the United Kingdom National Vascular Registry were analysed. All patients undergoing elective, standard infra-renal EVAR between 1st January 2014 and the 31st December 2016 were included. Patients with a symptomatic aneurysm treated semi-electively were excluded. The primary outcome was in-hospital death within 30-days of surgery. Secondary outcomes included postoperative complications and length of hospital stay. Time-to-event outcomes were compared using Cox Proportional Hazards regression adjusted for confounders including British Aneurysm Repair score and chronic lung disease. Results: A total of 9783 patients received an elective, standard infra-renal EVAR (GA n=7069, RA n=2347 and LA n=367) across 89 hospitals. RA and/or LA was used in 82 hospitals. There were 64 in-hospital deaths within 30-days, 50 (0.9% mortality at 30-days, 95% confidence interval [0.7%, 1.2%]) GA, 11 (0.6% [0.3%, 1.1%]) RA and 3 (1.5% [0.5%, 4.7%]) LA. The mortality was significantly lower in the RA group compared to the GA group (adjusted hazard ratio RA/GA: 0.37 [0.17,0.81] (p=0.03); LA/GA: 0.63 [0.15, 2.69]). Median length of stay was 2 days, but patients were discharged from hospital more quickly in the RA and LA groups compared to the GA (adjusted hazard ratio RA/GA: 1.10 [1.03, 1.17]; LA/GA: 1.15 [1.02, 1.29]). Pulmonary complications occurred with similar frequency (overall 2.4%, adjusted odds ratio RA/GA: 0.93 [0.66, 1.32]; LA/GA: 0.82 [0.41, 1.63]). Conclusion: 30-day mortality was lower with RA compared to GA, but mode of anaesthesia was not associated with increased complications for patients undergoing elective, standard infra-renal EVAR.

Editor-in-Chief:

You have addressed most comments and, in particular, well emphasized the limitations of your study.

Your revised manuscript reads very well and carries valuable and timely information for our readership.

Thank you for your time and expertise.

Before I accept it, you should:

- in the bibliography, list all references according to our instructions for authors. You obviously need to add volume and pages (not issue numbers). I.e. 2019:58,32-40.

This has been corrected, thank you for highlighting.

- in the section "what does this study add", fully spell all abbreviations at first use.

Thank you, we have corrected accordingly. Changes in the manuscript. Redline copy lines 34-35.

Thanks for your efforts and for submitting your work to our journal.

Reviewer 1:

The authors have corrected the last details, but they have also introduced a major error in the list of references by removing the issue and page numbering, leaving only the year of publication.

Is it really so difficult to read the instructions for authors and follow those?

Thank you for highlighting, we have corrected the bibliography.

There is only a red-line version of the manuscript in the resubmission, making it difficult to understand if they really intended this change?

Otherwise I have no further issues.

Thank you for helping us significantly improve the quality of our manuscript.

Reviewer 4:

Thank you for clarifying the study limitations.

Thank you for helping us significantly improve the quality of our manuscript.

MULTIPLE CHOICE QUESTION FOR EJVES Elective EVAR Paper

Question A:

Please select the correct answer.

The current European <u>Society for Vascular Surgery (ESVS)</u> guidance guidelines on choice of mode of anaesthesia for elective infra renal EVAR recommends......

- 1. Local anaesthetic for elective EVAR.
- 2. Regional anaesthetic for elective EVAR
- 3. General anaesthetic for elective EVAR.
- 4. General anaesthetic for patients with chronic lung disease
- 5. Hospitals should use their local routine practice when choosing a mode of anaesthesia

Questions B:

Regarding choice of anaesthesia for elective EVAR, please select the correct answer.

- 1. There is strong evidence that using local anaesthesia reduces pulmonary complications post elective EVAR.
- 2. Higher volume centres do a higher proportion of EVAR cases using local aesthetic.
- 3. There is equipoise in the published literature regarding the choice of mode anaesthesia for elective EVAR and its effect on mortality and post-operative complications.
- 4. The mortality benefit of using local anaesthesia in a ruptured EVAR can be extrapolated to the elective setting.
- 5. Patients treated with regional anaesthesia or local anaesthesia stay in hospital longer than those treated with general anaesthesia.

MULTIPLE CHOICE QUESTION FOR EJVES Elective EVAR Paper

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- 3. General anaesthetic for elective EVAR.
- 4. General anaesthetic for patients with chronic lung disease
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Questions B:

Regarding choice of anaesthesia for elective EVAR, please select the correct answer.

- 1. There is strong evidence that using local anaesthesia reduces pulmonary complications post elective EVAR.
- 2. Higher volume centres do a higher proportion of EVAR cases using local aesthetic.
- 3. There is equipoise in the published literature regarding the choice of mode anaesthesia for elective EVAR and its effect on mortality and post-operative complications.
- 4. The mortality benefit of using local anaesthesia in a ruptured EVAR can be extrapolated to the elective setting.
- 5. Patients treated with regional anaesthesia or local anaesthesia stay in hospital longer than those treated with general anaesthesia.

1	The e	ffect of mode of anaesthesia on outcomes after elective endovascular
2	repair	of abdominal aortic aneurysm.
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16	Submi	ssion Category: Original article
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What does this study add to the existing literature and how will it influence future clinical practice? This study supports the previously observed mortality benefit of regional anaesthetic (RA) technique for elective, standard infra-renal endovascular aneurysm repair (EVAR). Patients treated with local anaesthetic (LA) or LA and RA technique were discharged from hospital sooner. The previously observed reduction in pulmonary complications associated with LA technique in elective EVAR was not reproduced in this cohort. This retrospective analysis of a contemporary national database contributes to the evolving evidence base and clinical equipoise surrounding the choice of anaesthetic technique for EVAR.

ABSTRACT

62 Background:

Endovascular aneurysm repair (EVAR) is the most commonly used method to repair abdominal aortic aneurysm. EVAR can be performed using a variety of anaesthetic techniques including general anaesthetic (GA), regional anaesthetic (RA) and local anaesthetic (LA) but little is known about the effect each of these anaesthetic modes have on patient outcome. The aim of this study was to assess the effect of anaesthetic technique on early outcomes following elective EVAR.

Methods:

Data from the United Kingdom National Vascular Registry were analysed. All patients undergoing elective, standard infra-renal EVAR between 1st January 2014 and the 31st December 2016 were included. Patients with a symptomatic aneurysm treated semi-electively were excluded. The primary outcome was in-hospital death within 30-days of surgery. Secondary outcomes included postoperative complications and length of hospital stay. Time-to-event outcomes were compared using Cox Proportional Hazards regression adjusted for confounders including British Aneurysm Repair score (a validated aneurysm risk prediction score which is calculated using age, sex, creatinine, cardiac disease, electrocardiogram, previous aortic surgery, white blood cell count, serum sodium, abdominal aortic aneurysm diameter and ASA grade) and chronic lung disease.

Results:

A total of 9783 patients received an elective, standard infra-renal EVAR (GA n=7069, RA n=2347 and LA n=367) across 89 hospitals. RA and/or LA was used in 82 hospitals. There were 64 in-hospital deaths within 30-days, 50 (0.9% mortality at 30-days, 95% confidence interval [0.7%, 1.2%]) in the GA group, 11 (0.6% [0.3%, 1.1%]) in the RA group and 3 (1.5% [0.5%, 4.7%]) in the LA group. The mortality rate differed between groups (p=0.03) and was significantly lower in the RA group compared to the GA group (adjusted hazard ratio RA/GA: 0.37 [0.17,0.81]; LA/GA: 0.63 [0.15, 2.69]). The median length of stay was 2 days for all modes of anaesthesia, but patients were discharged from hospital more quickly in the RA and LA groups compared to the GA group (adjusted hazard ratio RA/GA: 1.10 [1.03, 1.17]; LA/GA: 1.15 [1.02, 1.29]). Overall, 20.7% of patients experienced one or

90	more complications (GA group: 22.1%; RA group: 16.8%, LA group: 17.7%) and pulmonary
91	complications occurred with similar frequency in the three groups (overall 2.4%, adjusted odds ratio
92	RA/GA: 0.93 [0.66, 1.32]; LA/GA: 0.82 [0.41, 1.63]).
93	
94	Conclusion:
95	30-day mortality was lower with RA compared to GA, but mode of anaesthesia was not associated
96	with increased complications for patients undergoing elective, standard infra-renal EVAR.
97	
98	Keywords: Elective Endovascular Aneurysm Repair, Anaesthesia, Abdominal Aortic Aneurysm
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INTRODUCTION

The majority of elective abdominal aortic aneurysm (AAA) repairs are now performed using the endovascular aneurysm repair (EVAR) technique. EVAR has become the preferred method for elective surgical repair of AAA in the United Kingdom (UK) with 70% of elective AAA repairs performed using EVAR.¹

It is possible to carry out EVAR under different types of anaesthesia, including general (GA), regional (RA) and local anaesthesia (LA). Non-randomized studies have suggested potential patient benefit when local and/or regional techniques are used for EVAR.^{2,3} However, these studies included a mix of elective and emergency patients and results did not distinguish between elective and emergency EVAR.^{4,5,6} A recent systematic review examining mode of anaesthesia for EVAR (39,744 patients from 22 non-randomized studies) reported a lower unadjusted risk of death after emergency EVAR with LA compared to GA, but trends in elective EVAR were less clear.⁷ There are no randomized controlled trials to guide practice in this area therefore the best choice of anaesthetic technique remains unknown.

There is emerging evidence from a recent randomized study (IMPROVE trial) that outcomes are better using LA in those patients presenting as an emergency with a rupture. A post-hoc subgroup analysis of a cohort of 186 patients who underwent emergency EVAR demonstrated a significantly reduced 30-day mortality for patients operated under LA compared to surgery under GA (odds ratio 0·27, 95% confidence interval (CI) 0·10, 0·70, after adjustment for potential confounding factors).8

The beneficial effect of LA in emergency EVAR observed in the IMPROVE trial was confirmed by a recent analysis of the UK National Vascular Registry (NVR), demonstrating a significant reduction in mortality in patients receiving ruptured AAA repair by EVAR under LA compared to GA (adjusted hazard ratio 0.62, 95% CI 0.45 to 0.85; P = 0.003).9

The NVR captures data on more than 90% of AAA procedures in the UK. It provides a unique opportunity to examine the practice and outcomes of elective EVAR in a pragmatic real-world setting.¹⁰ The aim of this study was to quantify the use of different modes of anaesthesia for elective

EVAR across all UK vascular centres, and to examine whether the observed benefit associated with

LA for emergency EVAR was replicated in UK elective EVAR practice.

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METHODS

National Vascular Registry

The NVR was commissioned as part of the National Clinical Audit and Patient Outcomes Programme, by the Healthcare Quality Improvement Partnership (HQIP), to measure quality of care and outcomes for patients receiving vascular interventions in the National Health Service (NHS). 1,10 Data submission forms part of the revalidation of NHS vascular surgeons and is therefore mandated. The NVR dataset is externally validated by comparing case ascertainment with Hospital Episode Statistics (HES); all NHS trusts in England are obliged to contribute to the HES dataset to ensure financial probity. 11 The internal validity of the NVR is assessed using range and consistency checks, and by extensive data scrutiny, including checking data values with individual hospitals. The NVR also includes patients from Scotland, Wales and Northern Ireland, and equivalent case ascertainment comparisons are made with the Scottish Morbidity Record (SMR01), Patient Episode Database for Wales and the Hospital Activity Statistics for each demographic area respectively. As such the internal and external validity of the registry is satisfactory. The NVR remains the largest recognized register of AAA cases in the UK. Permission was obtained from HQIP for the NVR to release anonymized patient data under a data sharing agreement between HQIP and the University of Bristol.

Study population

The study population comprised of consecutive UK patients who underwent elective EVAR for an AAA between the 1st January 2014 and the 31st December 2016. Patients who were symptomatic, underwent complex EVAR, received EVAR for an indication other than AAA (for example dissection) and those patients undergoing a revision EVAR were excluded.

The endovascular procedure performed is recorded at the time of surgery according to a range of Office of Population Censuses and Surveys (OPCS) codes in the NVR. Surgeons select whether the procedure was simple, complex or revision EVAR. Cases were excluded on the basis of this section;

164 therefore, if a standard 'simple' EVAR was used in a patient with juxta renal aneurysm it is analysed 165 as a standard infra-renal EVAR. 166 The NVR case ascertainment rate for elective AAA over the period 2014 to 2016 was 89%. 1,10 167 168 Mode of anaesthesia 169 170 The modes of anaesthesia recorded in the NVR include GA, LA and RA. The NVR does not specify 171 the exact quintessence of GA, RA or LA nor does it specify cases where a procedure was initiated 172 under LA and then converted to GA (or RA) later in the procedure. 173 174 Data collection 175 176 Data items included in the NVR and available for analysis are summarized in Appendix 1. Data items 177 were prospectively selected for extraction from the NVR. The NVR only collects data during the index 178 hospital admission until discharge from the hospital where the vascular surgical procedure was 179 carried out. Therefore, this could mean discharge home, or to a referring hospital or to a rehabilitation 180 hospital. 181 182 The British Aneurysm Repair (BAR) score, which includes data on age, sex, serum creatinine, cardiac 183 disease, electrocardiogram, previous aortic surgery, white blood cell count, serum sodium, AAA 184 diameter and ASA grade, was calculated from the available data. The BAR score is a validated risk 185 prediction score that provides an estimate of the risk of in hospital mortality for patients undergoing 186 elective AAA repair.¹² The BAR score is summarised in Figure 1. 187 188 Study outcomes 189 190 The primary outcome for this study was in-hospital mortality to 30-days. Patients who were 191 discharged from hospital alive were censored at last follow-up or 30-days if followed up beyond 30-192 days. Secondary clinical outcomes included post-operative length of hospital stay (LOS), intensive 193 care unit (ICU) admission, duration of ICU stay, post-operative complications, namely cardiac,

pulmonary and cerebral complications, renal failure, postoperative bleeding, endoleak and readmissions following discharge. We had not intended to consider readmissions, this was added in response to reviewer feedback. Secondary process outcomes included uptake of LA or RA for EVAR technique for elective AAA repair across UK vascular centres.

Statistical analysis

Continuous data are summarized as mean and standard deviation (SD) or median and interquartile range (IQR) if the distribution is skewed. Categorical data are summarized as a number and percentage. Patients undergoing EVAR are grouped by mode of anaesthesia, LA, GA or RA. Standardized mean differences (RA versus GA and LA versus GA) were calculated to quantify the differences in the baseline characteristics and aortic morphology between groups.

Cox proportional hazards regression was used to compare time-to-event outcomes, i.e. time from surgery to in-hospital death within 30-days, discharge from ICU (for the subset admitted to ICU) and discharge from hospital after surgery, by mode of anaesthesia. Patients who did not experience the event of interest were censored at discharge, 30-days or death as appropriate. Pulmonary complications were compared using logistic regression. This analysis was added following the publication of Van Orden et. al. report on pulmonary complications.¹³ All analyses were adjusted for presence of chronic lung disease (included because of an observed imbalance across the groups), BAR score¹² and hospital to reduce the effect of confounding. For time-to-event outcomes the analysis was stratified by hospital. For the analysis of pulmonary complications hospital was included as a random effect. BAR score was fitted as a continuous variable. For the analysis of postoperative hospital stay the effect of BAR score changed over time and to accommodate this BAR score was modelled separately for each of days 1, 2, 3 and 4+ after surgery. Results are reported as hazard ratios (time-to-event outcomes) or odds ratios (binary outcome) with 95% confidence intervals (CI) comparing RA to GA and LA to GA. P-values are calculated for the overall effect of mode of anaesthesia, except where indicated otherwise. Other outcomes are described but not formally compared. Missing data are described in the footnotes of tables.

224 All analyses were performed in Stata version 15.1 (StataCorp LP, College Station, Tex). 225 226 RESULTS 227 The NVR captured data on 20,936 patients undergoing AAA repair between January 2014 and 228 December 2016, 13,354 of whom received endovascular repair of their AAA. Of the 13,354 patients 229 undergoing EVAR for AAA, 9783 (73.2%) received an elective, standard infra-renal EVAR. Most 230 patients undergoing EVAR received GA (7069, 72.3%) with 2347 (23.9%) receiving RA and 367 231 (3.8%) receiving LA (Figure 2). 232 233 Hospital use of the three modes of anaesthesia 234 EVAR procedures were carried out in 89 hospitals across the UK, 54 hospitals used all three methods 235 of anaesthesia, 23 used GA or RA only, 3 used GA or LA only, 7 used GA alone and 2 used RA 236 alone. There was a trend towards higher volume centres performing more procedures under LA or 237 RA, however there was no increase in the proportion of cases performed under LA or RA as caseload 238 increased (Table 1, Figure 3). 239 240 Patient characteristics 241 Table 2 summarizes patient demographics and co-morbidity by mode of anaesthesia. Over 88% of 242 patients had co-morbidities and 7% of patients were considered American Society of 243 Anaesthesiologists (ASA) IV or V. BAR score was 1.1%, 0.98% and 1.44% for the RA, GA and LA 244 groups respectively. The median AAA diameter was 60mm (IQR 56-68mm). With the exception of 245 chronic lung disease, which was lower in the GA group (1662, 23.5%) compared to the LA (133, 246 36.2%) and RA (886, 36.9%) groups, patient characteristics were similar across the three groups, as 247 indicated by a standardized mean difference of <0.2 for the factors examined. 248 249 Clinical outcomes 250 Overall, the mortality rate at 30-days following elective, standard infra-renal EVAR was 0.86% (95% 251 confidence interval 0.67% to 1.11%). There were 64 in-hospital deaths within 30-days of surgery, 50 252 in the GA group (0.9%, 95% CI 0.7%-1.2%]), 11 in the RA group (0.6%, 95% CI 0.3%-1.1%) and 3 253 (1.5%, 95% CI 0.5%-4.7%) in the LA group (Figure 4). After adjustment for confounders including

BAR score (Figure 1), chronic lung disease and hospital, the risk of death within 30-days differed significantly between the groups (p=0.03) and was significantly lower with RA compared to GA, (adjusted hazard ratio RA versus GA: 0.37, 95% CI 0.17-0.81; LA versus GA: 0.63, 95% CI 0.15-2.69) (Figure 5).

Overall, 31.9% (2461 patients) were admitted to ICU post-operatively (Table 3). Amongst the subset admitted to ICU, the time to discharge was similar in the three groups, p=0.41, (Figure 5). In contrast, after adjustment for confounding (including BAR score, chronic lung disease and hospital), there was evidence to suggest that patients in the RA and LA groups were discharged from hospital more quickly than those in the GA group; adjusted hazard ratio RA versus GA: 1.10, 95% CI 1.03-1.17; LA versus GA: 1.15, 95% CI 1.02-1.29; p=0.003, Figure 5). Pulmonary complications were recorded most frequently, occurring in 237 patients (2.4%) and was similar in the three groups (Figure 5). Endoleak was recorded in 1537 cases (15.7%), with type 2 endoleak occurring most frequently, in 985 cases (63.3%) (Table 3).

DISCUSSION

The main finding from this observational analysis of data from the UK NVR is that the 30-day in hospital mortality for elective, standard infra-renal EVAR was significantly lower in the RA group compared to the GA group (Figure 5). Mortality was also lower in the LA group, but not significantly so. Patient groups were similar in demographics and co-morbid status. Complication rates were low and similar between groups, but patients in the RA and LA groups were more likely to be discharged earlier than those in the GA group.

The use of local, regional and general anaesthesia techniques for EVAR is well established in both the elective and emergency settings. 14 Recent evidence supports the use of LA for emergency EVAR of ruptured AAA: both the observational analysis of the IMPROVE trial and the analysis of the UK NVR demonstrated statistically significant reductions in mortality associated with the use of LA. 8,9 The effect of mode of anaesthesia on outcomes following elective EVAR is unknown. The 2019 ESVS Clinical Practice Guidelines on the Management of Abdominal Aorto-Iliac Artery Aneurysms

recommends that anaesthesia for elective EVAR be chosen according to local hospital routine practice as well as individual patient preference and assessment. These recommendations are based on evidence from a small retrospective analysis published in 2015 (ENGAGE study)¹⁵, which demonstrated that there was no significant difference in mortality between the three modes of anaesthesia.¹⁶ Conversely, a recent systematic review comparing mortality across different modes of anaesthesia for EVAR found that there may be some evidence to suggest that mode of anaesthesia, in particular RA for elective EVAR and LA for emergency EVAR, is associated with improved outcomes.⁷ The lack of high-quality randomised data however, introduces a significant risk of bias. An observational analysis of the IMPROVE trial found that patients treated with EVAR for ruptured AAA using LA were discharged home sooner, as well as their discharge destination being more often directly home, when compared to GA.⁸

Other contemporary authors have examined postoperative complications following EVAR and their relationship to mode of anaesthesia. In recent analysis of the Vascular Quality Initiative from the United States, the authors concluded that the use of LA for percutaneous elective EVAR was associated with fewer pulmonary complications (OR 2.8; 95% CI 1.49-5.43; p=0.002).¹³ There remain difficulties in this subject concerning firstly, the decision making and patient selection behind the choice of mode of anaesthesia, and secondly, the ambiguity in definitions of RA, GA and LA, particularly with regards to the addition of varying degrees of sedation to local or regional techniques.^{7,9}

The lower mortality rate observed with RA for elective EVAR is replicated in this UK NVR cohort of 9,783 patients undergoing elective, standard infra-renal EVAR. There was a trend towards a mortality benefit for the LA group but this did not reach statistical significance. The reduction in pulmonary complications with the use of LA reported by Van Orden et. al. ¹³ was not seen in this cohort; indeed, the rate of pulmonary complications was similar in the three groups (figure 5). Conversely this analysis does support the finding from the IMPROVE trial analysis as patients undergoing EVAR with LA or RA technique were discharged sooner.

The use of LA and RA technique in elective EVAR has been widely adopted throughout the UK with 82 of the 89 hospitals performing at least one procedure under LA or RA. There was a trend towards the higher volume centres were performing more procedures under LA or RA, however the proportion of cases performed under LA or RA did not increase with caseload (Figure 3). Interestingly the highest volume centre performed most of its elective EVAR under GA (97% of cases). This is contrary to the findings in emergency EVAR where high volume centres were performing more cases under LA.9

As with any registry data, the NVR is limited by its observational nature, the data collected and the data completeness. Whilst there are measures in place to ensure the internal and external validity of the NVR, including range checks and ratifying case ascertainment with HES data (estimated to be 89%),¹ the database is not independently externally validated, and HES data can be unreliable, this therefore limits the validity of the database. The authors were unable to cross reference the NVR with another external database to ensure its validity and this is important to consider when interpreting the findings. Despite this significant limitation the data remains valuable and is intended to generate clinical equipoise within the literature and lead to further high-quality randomised studies.

Although we were able to account for patient factors through the inclusion of the BAR score and the presence of chronic lung disease in our analyses, there are other potential confounding factors that may influence the choice of mode of anaesthesia and outcome that were not included and are not captured in the registry. Missing data are minimal in this cohort (<2%), with the exception of post-operative ICU admission, and multiple imputation was not considered necessary. Data on post-operative ICU admission was missing in 1675 GA, 363 RA and 46 LA cases which may suggest that the true numbers admitted to ICU postoperatively are lower than reported here.

The decision-making process surrounding the choice of anaesthetic technique for individual patients remains unclear and is a potential source of significant selection bias. For example, the method of vascular access (percutaneous or open cut-down) may influence the choice of anaesthetic technique and subsequent complications. It was not possible to investigate these factors as this information is not captured by the NVR. Furthermore, there remains ambiguity and inconsistency in the definition of

anaesthetic techniques, particularly when intravenous sedation is used alongside LA or RA techniques. In a study conducted by Verhoeven et. al. up to 13% of patients receiving LA EVAR also received intravenous sedation or analgesia,¹⁷ but these data are not recorded by the NVR. Even within GA different outcomes have been reported for total intravenous anaesthesia techniques when compared with volatile anaesthetics.¹⁸ In addition, the NVR does not record when a procedure was converted from one mode of anaesthesia to another, adding a further potential source of bias.

The NVR only collects mortality during the index hospital admission and any post-discharge deaths within 30-days will have been missed. Any missing or inaccurate mortality datapoints could potentially significantly affect the results as the numbers of deaths in each group are small. However, it must be noted that in multiple high profile EVAR trials there is a negligible difference between 30-day and inhospital mortality, suggesting that this is unlikely to be the case. 19-22 Further to this, it is also possible that some post-operative complications within the perioperative period have not been captured. With regards to the LA group, it may simply be too small to demonstrate significant differences in mortality and morbidity. The NVR may have irreparable flaws in its conception but, despite these limitations, the data remains valuable and represents the largest individual cohort of elective EVAR analysed by mode of anaesthesia.

Conclusions

This study contributes to the expanding evidence base surrounding the choice of anaesthetic technique for elective EVAR. It supports the current literature, ratifying the observed mortality benefit associated with RA technique in elective EVAR but does not replicate the observed reduction in pulmonary complications observed with LA technique in elective EVAR. This work is valuable in demonstrating the equipoise surrounding the choice of anaesthetic technique for elective EVAR and the need for a high quality randomized controlled trial comparing the different anaesthetic techniques.

373	Ackno	wledgements
374	The au	thors express their thanks to all the Vascular Surgeons and patients who have contributed data
375	to the N	National Vascular Registry. Thanks to Sam Waton from the Clinical Effectiveness Unit, Royal
376	College	e of Surgeons of England, for performing the data retrieval from the National Vascular Registry.
377		
378	Disclo	sure: The authors declare no conflict of interest.
379		
380	Fundir	ng information: This study was supported through an Infrastructure grant from the David
381	Telling	Charitable Trust.
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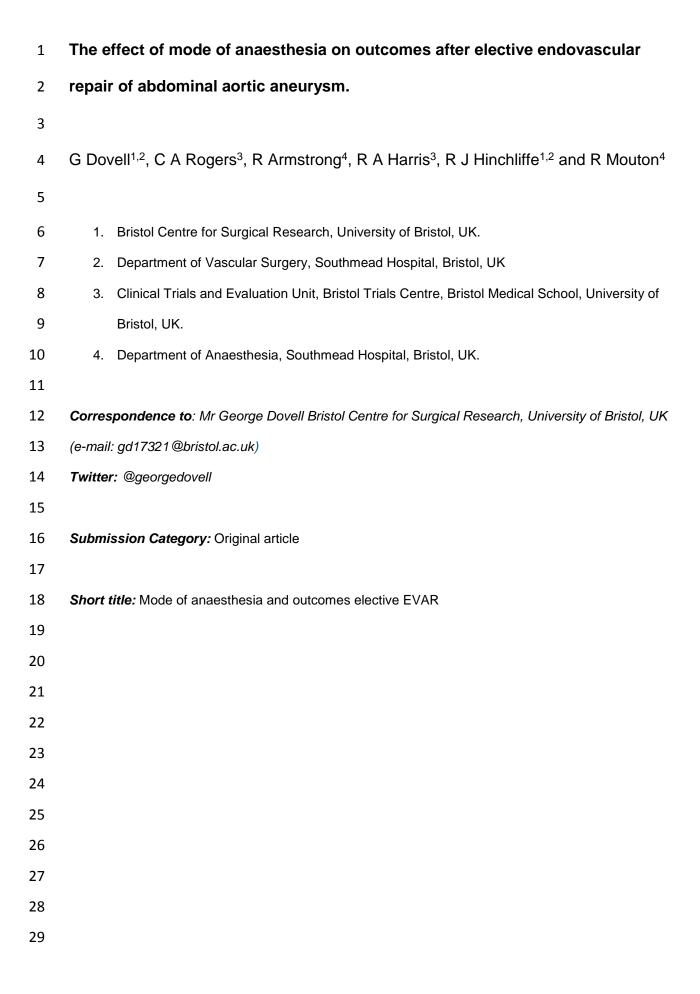
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What does this study add to the existing literature and how will it influence future clinical practice? This study supports the previously observed mortality benefit of regional anaesthetic (RA) technique for elective, standard infra-renal endovascular aneurysm repair (EVAR). Patients treated with local anaesthetic (LA) or RA technique were discharged from hospital sooner. The previously observed reduction in pulmonary complications associated with LA technique in elective EVAR was not reproduced in this cohort. This retrospective analysis of a contemporary national database contributes to the evolving evidence base and clinical equipoise surrounding the choice of anaesthetic technique for EVAR.

ABSTRACT

62 Background:

Endovascular aneurysm repair (EVAR) is the most commonly used method to repair abdominal aortic aneurysm. EVAR can be performed using a variety of anaesthetic techniques including general anaesthetic (GA), regional anaesthetic (RA) and local anaesthetic (LA) but little is known about the effect each of these anaesthetic modes have on patient outcome. The aim of this study was to assess the effect of anaesthetic technique on early outcomes following elective EVAR.

Methods:

Data from the United Kingdom National Vascular Registry were analysed. All patients undergoing elective, standard infra-renal EVAR between 1st January 2014 and the 31st December 2016 were included. Patients with a symptomatic aneurysm treated semi-electively were excluded. The primary outcome was in-hospital death within 30-days of surgery. Secondary outcomes included postoperative complications and length of hospital stay. Time-to-event outcomes were compared using Cox Proportional Hazards regression adjusted for confounders including British Aneurysm Repair score (a validated aneurysm risk prediction score which is calculated using age, sex, creatinine, cardiac disease, electrocardiogram, previous aortic surgery, white blood cell count, serum sodium, abdominal aortic aneurysm diameter and ASA grade) and chronic lung disease.

Results:

A total of 9783 patients received an elective, standard infra-renal EVAR (GA n=7069, RA n=2347 and LA n=367) across 89 hospitals. RA and/or LA was used in 82 hospitals. There were 64 in-hospital deaths within 30-days, 50 (0.9% mortality at 30-days, 95% confidence interval [0.7%, 1.2%]) in the GA group, 11 (0.6% [0.3%, 1.1%]) in the RA group and 3 (1.5% [0.5%, 4.7%]) in the LA group. The mortality rate differed between groups (p=0.03) and was significantly lower in the RA group compared to the GA group (adjusted hazard ratio RA/GA: 0.37 [0.17,0.81]; LA/GA: 0.63 [0.15, 2.69]). The median length of stay was 2 days for all modes of anaesthesia, but patients were discharged from hospital more quickly in the RA and LA groups compared to the GA group (adjusted hazard ratio RA/GA: 1.10 [1.03, 1.17]; LA/GA: 1.15 [1.02, 1.29]). Overall, 20.7% of patients experienced one or

90	more complications (GA group: 22.1%; RA group: 16.8%, LA group: 17.7%) and pulmonary
91	complications occurred with similar frequency in the three groups (overall 2.4%, adjusted odds ratio
92	RA/GA: 0.93 [0.66, 1.32]; LA/GA: 0.82 [0.41, 1.63]).
93	
94	Conclusion:
95	30-day mortality was lower with RA compared to GA, but mode of anaesthesia was not associated
96	with increased complications for patients undergoing elective, standard infra-renal EVAR.
97	
98	Keywords: Elective Endovascular Aneurysm Repair, Anaesthesia, Abdominal Aortic Aneurysm
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99	

INTRODUCTION

The majority of elective abdominal aortic aneurysm (AAA) repairs are now performed using the endovascular aneurysm repair (EVAR) technique. EVAR has become the preferred method for elective surgical repair of AAA in the United Kingdom (UK) with 70% of elective AAA repairs performed using EVAR.¹

It is possible to carry out EVAR under different types of anaesthesia, including general (GA), regional (RA) and local anaesthesia (LA). Non-randomized studies have suggested potential patient benefit when local and/or regional techniques are used for EVAR.^{2,3} However, these studies included a mix of elective and emergency patients and results did not distinguish between elective and emergency EVAR.^{4,5,6} A recent systematic review examining mode of anaesthesia for EVAR (39,744 patients from 22 non-randomized studies) reported a lower unadjusted risk of death after emergency EVAR with LA compared to GA, but trends in elective EVAR were less clear.⁷ There are no randomized controlled trials to guide practice in this area therefore the best choice of anaesthetic technique remains unknown.

There is emerging evidence from a recent randomized study (IMPROVE trial) that outcomes are better using LA in those patients presenting as an emergency with a rupture. A post-hoc subgroup analysis of a cohort of 186 patients who underwent emergency EVAR demonstrated a significantly reduced 30-day mortality for patients operated under LA compared to surgery under GA (odds ratio 0·27, 95% confidence interval (CI) 0·10, 0·70, after adjustment for potential confounding factors).8

The beneficial effect of LA in emergency EVAR observed in the IMPROVE trial was confirmed by a recent analysis of the UK National Vascular Registry (NVR), demonstrating a significant reduction in mortality in patients receiving ruptured AAA repair by EVAR under LA compared to GA (adjusted hazard ratio 0.62, 95% CI 0.45 to 0.85; P = 0.003).9

The NVR captures data on more than 90% of AAA procedures in the UK. It provides a unique opportunity to examine the practice and outcomes of elective EVAR in a pragmatic real-world setting.¹⁰ The aim of this study was to quantify the use of different modes of anaesthesia for elective

EVAR across all UK vascular centres, and to examine whether the observed benefit associated with

LA for emergency EVAR was replicated in UK elective EVAR practice.

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METHODS

National Vascular Registry

The NVR was commissioned as part of the National Clinical Audit and Patient Outcomes Programme, by the Healthcare Quality Improvement Partnership (HQIP), to measure quality of care and outcomes for patients receiving vascular interventions in the National Health Service (NHS). 1,10 Data submission forms part of the revalidation of NHS vascular surgeons and is therefore mandated. The NVR dataset is externally validated by comparing case ascertainment with Hospital Episode Statistics (HES); all NHS trusts in England are obliged to contribute to the HES dataset to ensure financial probity. 11 The internal validity of the NVR is assessed using range and consistency checks, and by extensive data scrutiny, including checking data values with individual hospitals. The NVR also includes patients from Scotland, Wales and Northern Ireland, and equivalent case ascertainment comparisons are made with the Scottish Morbidity Record (SMR01), Patient Episode Database for Wales and the Hospital Activity Statistics for each demographic area respectively. As such the internal and external validity of the registry is satisfactory. The NVR remains the largest recognized register of AAA cases in the UK. Permission was obtained from HQIP for the NVR to release anonymized patient data under a data sharing agreement between HQIP and the University of Bristol.

Study population

The study population comprised of consecutive UK patients who underwent elective EVAR for an AAA between the 1st January 2014 and the 31st December 2016. Patients who were symptomatic, underwent complex EVAR, received EVAR for an indication other than AAA (for example dissection) and those patients undergoing a revision EVAR were excluded.

The endovascular procedure performed is recorded at the time of surgery according to a range of Office of Population Censuses and Surveys (OPCS) codes in the NVR. Surgeons select whether the procedure was simple, complex or revision EVAR. Cases were excluded on the basis of this section;

164 therefore, if a standard 'simple' EVAR was used in a patient with juxta renal aneurysm it is analysed 165 as a standard infra-renal EVAR. 166 The NVR case ascertainment rate for elective AAA over the period 2014 to 2016 was 89%. 1,10 167 168 Mode of anaesthesia 169 170 The modes of anaesthesia recorded in the NVR include GA, LA and RA. The NVR does not specify 171 the exact quintessence of GA, RA or LA nor does it specify cases where a procedure was initiated 172 under LA and then converted to GA (or RA) later in the procedure. 173 174 Data collection 175 176 Data items included in the NVR and available for analysis are summarized in Appendix 1. Data items 177 were prospectively selected for extraction from the NVR. The NVR only collects data during the index 178 hospital admission until discharge from the hospital where the vascular surgical procedure was 179 carried out. Therefore, this could mean discharge home, or to a referring hospital or to a rehabilitation 180 hospital. 181 182 The British Aneurysm Repair (BAR) score, which includes data on age, sex, serum creatinine, cardiac 183 disease, electrocardiogram, previous aortic surgery, white blood cell count, serum sodium, AAA 184 diameter and ASA grade, was calculated from the available data. The BAR score is a validated risk 185 prediction score that provides an estimate of the risk of in hospital mortality for patients undergoing 186 elective AAA repair.¹² The BAR score is summarised in Figure 1. 187 188 Study outcomes 189 190 The primary outcome for this study was in-hospital mortality to 30-days. Patients who were 191 discharged from hospital alive were censored at last follow-up or 30-days if followed up beyond 30-192 days. Secondary clinical outcomes included post-operative length of hospital stay (LOS), intensive 193 care unit (ICU) admission, duration of ICU stay, post-operative complications, namely cardiac,

pulmonary and cerebral complications, renal failure, postoperative bleeding, endoleak and readmissions following discharge. We had not intended to consider readmissions, this was added in response to reviewer feedback. Secondary process outcomes included uptake of LA or RA for EVAR technique for elective AAA repair across UK vascular centres.

Statistical analysis

Continuous data are summarized as mean and standard deviation (SD) or median and interquartile range (IQR) if the distribution is skewed. Categorical data are summarized as a number and percentage. Patients undergoing EVAR are grouped by mode of anaesthesia, LA, GA or RA. Standardized mean differences (RA versus GA and LA versus GA) were calculated to quantify the differences in the baseline characteristics and aortic morphology between groups.

Cox proportional hazards regression was used to compare time-to-event outcomes, i.e. time from surgery to in-hospital death within 30-days, discharge from ICU (for the subset admitted to ICU) and discharge from hospital after surgery, by mode of anaesthesia. Patients who did not experience the event of interest were censored at discharge, 30-days or death as appropriate. Pulmonary complications were compared using logistic regression. This analysis was added following the publication of Van Orden et. al. report on pulmonary complications.¹³ All analyses were adjusted for presence of chronic lung disease (included because of an observed imbalance across the groups), BAR score¹² and hospital to reduce the effect of confounding. For time-to-event outcomes the analysis was stratified by hospital. For the analysis of pulmonary complications hospital was included as a random effect. BAR score was fitted as a continuous variable. For the analysis of postoperative hospital stay the effect of BAR score changed over time and to accommodate this BAR score was modelled separately for each of days 1, 2, 3 and 4+ after surgery. Results are reported as hazard ratios (time-to-event outcomes) or odds ratios (binary outcome) with 95% confidence intervals (CI) comparing RA to GA and LA to GA. P-values are calculated for the overall effect of mode of anaesthesia, except where indicated otherwise. Other outcomes are described but not formally compared. Missing data are described in the footnotes of tables.

224 All analyses were performed in Stata version 15.1 (StataCorp LP, College Station, Tex). 225 226 RESULTS 227 The NVR captured data on 20,936 patients undergoing AAA repair between January 2014 and 228 December 2016, 13,354 of whom received endovascular repair of their AAA. Of the 13,354 patients 229 undergoing EVAR for AAA, 9783 (73.2%) received an elective, standard infra-renal EVAR. Most 230 patients undergoing EVAR received GA (7069, 72.3%) with 2347 (23.9%) receiving RA and 367 231 (3.8%) receiving LA (Figure 2). 232 233 Hospital use of the three modes of anaesthesia 234 EVAR procedures were carried out in 89 hospitals across the UK, 54 hospitals used all three methods 235 of anaesthesia, 23 used GA or RA only, 3 used GA or LA only, 7 used GA alone and 2 used RA 236 alone. There was a trend towards higher volume centres performing more procedures under LA or 237 RA, however there was no increase in the proportion of cases performed under LA or RA as caseload 238 increased (Table 1, Figure 3). 239 240 Patient characteristics 241 Table 2 summarizes patient demographics and co-morbidity by mode of anaesthesia. Over 88% of 242 patients had co-morbidities and 7% of patients were considered American Society of 243 Anaesthesiologists (ASA) IV or V. BAR score was 1.1%, 0.98% and 1.44% for the RA, GA and LA 244 groups respectively. The median AAA diameter was 60mm (IQR 56-68mm). With the exception of 245 chronic lung disease, which was lower in the GA group (1662, 23.5%) compared to the LA (133, 246 36.2%) and RA (886, 36.9%) groups, patient characteristics were similar across the three groups, as 247 indicated by a standardized mean difference of <0.2 for the factors examined. 248 249 Clinical outcomes 250 Overall, the mortality rate at 30-days following elective, standard infra-renal EVAR was 0.86% (95% 251 confidence interval 0.67% to 1.11%). There were 64 in-hospital deaths within 30-days of surgery, 50 252 in the GA group (0.9%, 95% CI 0.7%-1.2%]), 11 in the RA group (0.6%, 95% CI 0.3%-1.1%) and 3 253 (1.5%, 95% CI 0.5%-4.7%) in the LA group (Figure 4). After adjustment for confounders including

BAR score (Figure 1), chronic lung disease and hospital, the risk of death within 30-days differed significantly between the groups (p=0.03) and was significantly lower with RA compared to GA, (adjusted hazard ratio RA versus GA: 0.37, 95% CI 0.17-0.81; LA versus GA: 0.63, 95% CI 0.15-2.69) (Figure 5).

Overall, 31.9% (2461 patients) were admitted to ICU post-operatively (Table 3). Amongst the subset admitted to ICU, the time to discharge was similar in the three groups, p=0.41, (Figure 5). In contrast, after adjustment for confounding (including BAR score, chronic lung disease and hospital), there was evidence to suggest that patients in the RA and LA groups were discharged from hospital more quickly than those in the GA group; adjusted hazard ratio RA versus GA: 1.10, 95% CI 1.03-1.17; LA versus GA: 1.15, 95% CI 1.02-1.29; p=0.003, Figure 5). Pulmonary complications were recorded most frequently, occurring in 237 patients (2.4%) and was similar in the three groups (Figure 5). Endoleak was recorded in 1537 cases (15.7%), with type 2 endoleak occurring most frequently, in 985 cases (63.3%) (Table 3).

DISCUSSION

The main finding from this observational analysis of data from the UK NVR is that the 30-day in hospital mortality for elective, standard infra-renal EVAR was significantly lower in the RA group compared to the GA group (Figure 5). Mortality was also lower in the LA group, but not significantly so. Patient groups were similar in demographics and co-morbid status. Complication rates were low and similar between groups, but patients in the RA and LA groups were more likely to be discharged earlier than those in the GA group.

The use of local, regional and general anaesthesia techniques for EVAR is well established in both the elective and emergency settings. ¹⁴ Recent evidence supports the use of LA for emergency EVAR of ruptured AAA: both the observational analysis of the IMPROVE trial and the analysis of the UK NVR demonstrated statistically significant reductions in mortality associated with the use of LA. ^{8,9} The effect of mode of anaesthesia on outcomes following elective EVAR is unknown. The 2019 ESVS Clinical Practice Guidelines on the Management of Abdominal Aorto-Iliac Artery Aneurysms

recommends that anaesthesia for elective EVAR be chosen according to local hospital routine practice as well as individual patient preference and assessment. These recommendations are based on evidence from a small retrospective analysis published in 2015 (ENGAGE study)¹⁵, which demonstrated that there was no significant difference in mortality between the three modes of anaesthesia.¹⁶ Conversely, a recent systematic review comparing mortality across different modes of anaesthesia for EVAR found that there may be some evidence to suggest that mode of anaesthesia, in particular RA for elective EVAR and LA for emergency EVAR, is associated with improved outcomes.⁷ The lack of high-quality randomised data however, introduces a significant risk of bias. An observational analysis of the IMPROVE trial found that patients treated with EVAR for ruptured AAA using LA were discharged home sooner, as well as their discharge destination being more often directly home, when compared to GA.⁸

Other contemporary authors have examined postoperative complications following EVAR and their relationship to mode of anaesthesia. In recent analysis of the Vascular Quality Initiative from the United States, the authors concluded that the use of LA for percutaneous elective EVAR was associated with fewer pulmonary complications (OR 2.8; 95% CI 1.49-5.43; p=0.002).¹³ There remain difficulties in this subject concerning firstly, the decision making and patient selection behind the choice of mode of anaesthesia, and secondly, the ambiguity in definitions of RA, GA and LA, particularly with regards to the addition of varying degrees of sedation to local or regional techniques.^{7,9}

The lower mortality rate observed with RA for elective EVAR is replicated in this UK NVR cohort of 9,783 patients undergoing elective, standard infra-renal EVAR. There was a trend towards a mortality benefit for the LA group but this did not reach statistical significance. The reduction in pulmonary complications with the use of LA reported by Van Orden et. al. ¹³ was not seen in this cohort; indeed, the rate of pulmonary complications was similar in the three groups (figure 5). Conversely this analysis does support the finding from the IMPROVE trial analysis as patients undergoing EVAR with LA or RA technique were discharged sooner.

The use of LA and RA technique in elective EVAR has been widely adopted throughout the UK with 82 of the 89 hospitals performing at least one procedure under LA or RA. There was a trend towards the higher volume centres were performing more procedures under LA or RA, however the proportion of cases performed under LA or RA did not increase with caseload (Figure 3). Interestingly the highest volume centre performed most of its elective EVAR under GA (97% of cases). This is contrary to the findings in emergency EVAR where high volume centres were performing more cases under LA.9

As with any registry data, the NVR is limited by its observational nature, the data collected and the data completeness. Whilst there are measures in place to ensure the internal and external validity of the NVR, including range checks and ratifying case ascertainment with HES data (estimated to be 89%),¹ the database is not independently externally validated, and HES data can be unreliable, this therefore limits the validity of the database. The authors were unable to cross reference the NVR with another external database to ensure its validity and this is important to consider when interpreting the findings. Despite this significant limitation the data remains valuable and is intended to generate clinical equipoise within the literature and lead to further high-quality randomised studies.

Although we were able to account for patient factors through the inclusion of the BAR score and the presence of chronic lung disease in our analyses, there are other potential confounding factors that may influence the choice of mode of anaesthesia and outcome that were not included and are not captured in the registry. Missing data are minimal in this cohort (<2%), with the exception of post-operative ICU admission, and multiple imputation was not considered necessary. Data on post-operative ICU admission was missing in 1675 GA, 363 RA and 46 LA cases which may suggest that the true numbers admitted to ICU postoperatively are lower than reported here.

The decision-making process surrounding the choice of anaesthetic technique for individual patients remains unclear and is a potential source of significant selection bias. For example, the method of vascular access (percutaneous or open cut-down) may influence the choice of anaesthetic technique and subsequent complications. It was not possible to investigate these factors as this information is not captured by the NVR. Furthermore, there remains ambiguity and inconsistency in the definition of

anaesthetic techniques, particularly when intravenous sedation is used alongside LA or RA techniques. In a study conducted by Verhoeven et. al. up to 13% of patients receiving LA EVAR also received intravenous sedation or analgesia,¹⁷ but these data are not recorded by the NVR. Even within GA different outcomes have been reported for total intravenous anaesthesia techniques when compared with volatile anaesthetics.¹⁸ In addition, the NVR does not record when a procedure was converted from one mode of anaesthesia to another, adding a further potential source of bias.

The NVR only collects mortality during the index hospital admission and any post-discharge deaths within 30-days will have been missed. Any missing or inaccurate mortality datapoints could potentially significantly affect the results as the numbers of deaths in each group are small. However, it must be noted that in multiple high profile EVAR trials there is a negligible difference between 30-day and inhospital mortality, suggesting that this is unlikely to be the case. 19-22 Further to this, it is also possible that some post-operative complications within the perioperative period have not been captured. With regards to the LA group, it may simply be too small to demonstrate significant differences in mortality and morbidity. The NVR may have irreparable flaws in its conception but, despite these limitations, the data remains valuable and represents the largest individual cohort of elective EVAR analysed by mode of anaesthesia.

Conclusions

This study contributes to the expanding evidence base surrounding the choice of anaesthetic technique for elective EVAR. It supports the current literature, ratifying the observed mortality benefit associated with RA technique in elective EVAR but does not replicate the observed reduction in pulmonary complications observed with LA technique in elective EVAR. This work is valuable in demonstrating the equipoise surrounding the choice of anaesthetic technique for elective EVAR and the need for a high quality randomized controlled trial comparing the different anaesthetic techniques.

373	Ackno	wledgements
374	The au	thors express their thanks to all the Vascular Surgeons and patients who have contributed data
375	to the N	National Vascular Registry. Thanks to Sam Waton from the Clinical Effectiveness Unit, Royal
376	College	e of Surgeons of England, for performing the data retrieval from the National Vascular Registry.
377		
378	Disclo	sure: The authors declare no conflict of interest.
379		
380	Fundir	ng information: This study was supported through an Infrastructure grant from the David
381	Telling	Charitable Trust.
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NOTES TO TYPESETTER

In Figure 4, please change '30-day' to '30 day'. Change the x-axis label to read 'Time – d'. Please insert a thin space after the first digit in all values of four numbers.

In Figure 5, please place all 'vs' in italics. Insert a space on either side of all '='. For 95% CI values, please replace the commas with closed up en dashes (e.g. 0.15-2.69). Change the p values (from top to bottom): p = .03; p = 81; p = .003; p = .41.

<Short title>Mode of Anaesthesia and Outcomes Effects After Elective EVAR

The Effect of Mode of Anaesthesia on Outcomes After Elective Endovascular Repair of Abdominal Aortic Aneurysm

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WHAT THIS PAPER ADDS

This study supports the previously observed mortality benefit of regional anaesthetic (RA) technique for elective, standard infrarenal endovascular aneurysm repair (EVAR). Patients treated with local anaesthetic (LA) or RA were discharged from hospital sooner. The previously observed reduction in pulmonary complications associated with LA in elective EVAR was not reproduced in this cohort. This retrospective analysis of a contemporary national database contributes to the evolving evidence base and clinical equipoise surrounding the choice of anaesthetic technique for EVAR.

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Objective: Endovascular aneurysm repair (EVAR) is the most commonly used method to repair abdominal aortic aneurysms. EVAR can be performed using a variety of anaesthetic techniques, including general anaesthetic (GA), regional anaesthetic (RA), and local anaesthetic (LA), but little is known about the effects that each of these anaesthetic modes have on patient outcome. The aim of this study was to assess the effect of anaesthetic technique on early outcomes after elective EVAR. Methods: Data from the UK's National Vascular Registry were analysed. All patients undergoing elective, standard infrarenal EVAR between 1 January 2014 and 31 December 2016 were included. Patients with a symptomatic aneurysm treated semi-electively were excluded. The primary outcome was in hospital death within 30 days of surgery. Secondary outcomes included postoperative complications and length of hospital stay. Time to event outcomes were compared using Cox proportional hazards regression adjusted for confounders, including British Aneurysm Repair score (a validated aneurysm risk prediction score that is calculated using age, sex, creatinine, cardiac disease, electrocardiogram, previous aortic surgery, white blood cell count, serum sodium, abdominal aortic aneurysm diameter, and American Society of Anaesthesiologists grade) and chronic lung disease. **Results:** A total of 9 783 patients received an elective, standard infrarenal EVAR (GA, n = 7 069; RA, n=2 347; and LA, n=367) across 89 hospitals. RA and/or LA was used in 82 hospitals. There were 64 in hospital deaths within 30 days, 50 (0.9% mortality at 30 days, 95% confidence interval [CI] 0.7 – 1.2) in the GA group, 11 (0.6%, 95% CI 0.3 – 1.1) in the RA group, and three (1.5%, 95% CI 0.5 – 4.7) in the LA group. The mortality rate differed between groups (p = .03) and was significantly lower in the RA group compared with the GA group (adjusted hazard ratio [aHR] RA/GA 0.37 [95% CI 0.17 -0.81]; LA/GA 0.63 [95% CI 0.15 - 2.69]). The median length of stay was two days for all modes of anaesthesia, but patients were discharged from hospital more quickly in the RA and LA groups than those in the GA group (aHR RA/GA 1.10 [95% 1.03 – 1.17]; LA/GA 1.15 [95% CI 1.02 – 1.29]). Overall, 20.7% of patients experienced one or more complications (GA group, 22.1%; RA group, 16.8%; LA group, 17.7%) and pulmonary complications occurred with similar frequency in the three groups (overall 2.4%, adjusted odds ratio RA/GA 0.93 [95% CI 0.66 – 1.32]; LA/GA 0.82 [95% CI 0.41 - 1.63).

Conclusion: Thirty day mortality was lower with RA than with GA, but mode of anaesthesia was not associated with increased complications for patients undergoing elective, standard infrarenal EVAR.

Keywords

Abdominal aortic aneurysm, Anaesthesia, Elective endovascular aneurysm repair

INTRODUCTION

The majority of elective abdominal aortic aneurysm (AAA) repairs are now performed using endovascular aneurysm repair (EVAR). EVAR has become the preferred method for elective surgical repair of AAA in the UK, with 70% of elective AAA repairs performed by EVAR.¹

It is possible to carry out EVAR under different types of anaesthesia, including general (GA), regional (RA), and local anaesthesia (LA). Non-randomised studies have suggested a potential patient benefit when local and/or regional techniques are used for EVAR.^{2,3} However, these studies included a mix of elective and emergency patients, and results did not distinguish between elective and emergency EVAR.⁴⁻⁶ A recent systematic review examining mode of anaesthesia for EVAR (39 744 patients from 22 non-randomised studies) reported a lower unadjusted risk of death after emergency EVAR with LA *versus* GA, but trends in elective EVAR were less clear.⁷ There are no randomised controlled trials to guide practice in this area and therefore the best choice of anaesthetic technique remains unknown.

There is emerging evidence from a recent randomised study (Immediate Management of Patients with Rupture: Open Versus Endovascular Repair [IMPROVE] trial) that outcomes are better using LA in those patients presenting as an emergency with a rupture. A post hoc subgroup analysis of a cohort of 186 patients who underwent emergency EVAR demonstrated a significantly reduced 30 day mortality for patients operated on under LA compared with surgery under GA (odds ratio [OR] 0.27, 95% confidence interval [CI] 0.10 - 0.70, after adjustment for potential confounding factors).⁸ The beneficial effect of LA in emergency EVAR observed in the IMPROVE trial was confirmed by a recent analysis of the UK National Vascular Registry (NVR), demonstrating a significant reduction in mortality in patients undergoing ruptured AAA repair by EVAR with LA compared with GA (adjusted hazard ratio [aHR] 0.62, 95% CI 0.45 - 0.85; p = .003).⁹

The NVR captures data on > 90% of AAA procedures in the UK. It provides a unique opportunity to examine the practice and outcomes of elective EVAR in a pragmatic real world setting. The aim of this study was to quantify the use of different modes of anaesthesia for elective EVAR across all UK vascular centres, and to examine whether the observed benefit associated with LA for emergency EVAR was replicated in UK elective EVAR practice.

METHODS

NVR

The NVR was commissioned as part of the National Clinical Audit and Patient Outcomes Programme, by the Healthcare Quality Improvement Partnership (HQIP), to measure quality of care and outcomes

for patients receiving vascular interventions in the National Health Service (NHS). ^{1,10} Data submission forms part of the revalidation of NHS vascular surgeons and is therefore mandated. The NVR dataset is externally validated by comparing case ascertainment with Hospital Episode Statistics (HES); all NHS Trusts in England are obliged to contribute to the HES data set to ensure financial probity. ¹¹ The internal validity of the NVR is assessed using range and consistency checks, and by extensive data scrutiny, including checking data values with individual hospitals. The NVR also includes patients from Scotland, Wales, and Northern Ireland, and equivalent case ascertainment comparisons are made with the Scottish Morbidity Record (SMR01), Patient Episode Database for Wales, and the Hospital Activity Statistics for each demographic area, respectively. As such, the internal and external validity of the registry is satisfactory. The NVR remains the largest recognised register of AAA cases in the UK. Permission was obtained from HQIP for the NVR to release anonymised patient data under a data sharing agreement between HQIP and the University of Bristol.

Study population

The study population comprised consecutive UK patients who underwent elective EVAR for an AAA between 1 January 2014 and 31 December 2016. Patients who were symptomatic, underwent complex EVAR, received EVAR for an indication other than AAA (e.g., dissection), and those undergoing a revision EVAR were excluded.

The endovascular procedure performed is recorded at the time of surgery according to a range of Office of Population Censuses and Surveys codes in the NVR. Surgeons select whether the procedure was simple, complex, or revision EVAR. Cases were excluded on the basis of this section; therefore, if a standard "simple" EVAR was used in a patient with juxtarenal aneurysm it is analysed as a standard infrarenal EVAR.

The NVR case ascertainment rate for elective AAA over the period 2014 – 2016 was 89%. 1,10

Mode of anaesthesia

The modes of anaesthesia recorded in the NVR include GA, LA, and RA. The NVR does not specify the exact quintessence of GA, RA, or LA, nor does it specify cases where a procedure was initiated under LA and then converted to GA (or RA) later in the procedure.

Data collection

Data items included in the NVR and available for analysis are summarized in Appendix S1 (see Supplementary Material). Data items were prospectively selected for extraction from the NVR. The NVR only collects data during the index hospital admission until discharge from the hospital where the

vascular surgical procedure was carried out. Therefore, this could mean discharge home, to a referring hospital, or to a rehabilitation hospital.

The British Aneurysm Repair (BAR) score, which includes data on age, sex, serum creatinine, cardiac disease, electrocardiogram, previous aortic surgery, white blood cell count, serum sodium, AAA diameter, and American Society of Anaesthesiologists (ASA) grade, was calculated from the available data. The BAR score is a validated risk prediction score that provides an estimate of the risk of in hospital mortality for patients undergoing elective AAA repair. The BAR score is summarised in Figure 1.

Study outcomes

The primary outcome for this study was in hospital mortality to 30 days. Patients who were discharged from hospital alive were censored at last follow up or 30 days if followed up beyond 30 days. Secondary clinical outcomes included postoperative length of hospital stay, intensive care unit (ICU) admission, duration of ICU stay, postoperative complications (namely cardiac, pulmonary, and cerebral complications), renal failure, postoperative bleeding, endoleak, and re-admissions following discharge. It was not intended to consider re-admissions; this was added in response to reviewer feedback. Secondary process outcomes included uptake of LA or RA for EVAR for elective AAA repair across UK vascular centres.

Statistical analysis

Continuous data are summarised as mean \pm standard deviation (SD) or median (interquartile range [IQR]) if the distribution was skewed. Categorical data are summarised as n (%). Patients undergoing EVAR were grouped by mode of anaesthesia (LA, GA, or RA). Standardised mean differences (RA vs GA and LA vs GA) were calculated to quantify the differences in the baseline characteristics and aortic morphology between groups.

Cox proportional hazards regression was used to compare time to event outcomes, that is, time from surgery to in hospital death within 30 days, discharge from ICU (for the subset admitted to ICU), and discharge from hospital after surgery, by mode of anaesthesia. Patients who did not experience the event of interest were censored at discharge, 30 days, or death as appropriate. Pulmonary complications were compared using logistic regression. This analysis was added following the report of Van Orden *et al.* on pulmonary complications. All analyses were adjusted for presence of chronic lung disease (included because of an observed imbalance across the groups), BAR score, and hospital to reduce the effect of confounding. For time to event outcomes the analysis was stratified by hospital. For the analysis of pulmonary complications hospital was included as a random effect. BAR score was

fitted as a continuous variable. For the analysis of postoperative hospital stay the effect of BAR score changed over time; to accommodate this BAR score was modelled separately for each of days 1, 2, 3, and 4+ after surgery. Results are reported as hazard ratios (time to event outcomes) or ORs (binary outcome) with 95% CIs comparing RA with GA and LA with GA. *P* values were calculated for the overall effect of mode of anaesthesia, except where indicated otherwise. Other outcomes are described but not formally compared. Missing data are described in the table footnotes.

All analyses were performed in Stata version 15.1 (StataCorp, College Station, TX, USA).

RESULTS

The NVR captured data on 20 936 patients undergoing AAA repair between January 2014 and December 2016, 13 354 of whom received endovascular repair of their AAA. Of the 13 354 patients undergoing EVAR for AAA, 9 783 (73.3%) received an elective, standard infrarenal EVAR. Most patients undergoing EVAR received GA (n = 7 069; 72.3%) with 2 347 (24.0%) receiving RA and 367 (3.8%) receiving LA (Fig. 2).

Hospital use of the three modes of anaesthesia

EVAR procedures were carried out in 89 hospitals across the UK; 54 hospitals used all three methods of anaesthesia, 23 used GA or RA only, three used GA or LA only, seven used GA alone, and two used RA alone. There was a trend towards higher volume centres performing more procedures under LA or RA; however, there was no increase in the proportion of cases performed under LA or RA as case load increased (Table 1, Fig. 3).

Patient characteristics

Table 2 summarises patient demographics and comorbidity by mode of anaesthesia. Over 88% of patients had comorbidities and 7% of patients were considered to be ASA grade IV or V. BAR score was 1.1%, 0.98%, and 1.44% for the RA, GA, and LA groups, respectively. Median AAA diameter was 60 mm (IQR 56 – 68 mm). With the exception of chronic lung disease, which was lower in the GA group (n = 1 662; 23.5%) than in the LA (n = 133; 36.2%) and RA (n = 886; 36.9%) groups, patient characteristics were similar across the three groups, as indicated by a standardised mean difference of < 0.2 for the factors examined.

Clinical outcomes

Overall, the mortality rate at 30 days after elective, standard infrarenal EVAR was 0.9% (95% CI 0.67 – 1.11). There were 64 in hospital deaths within 30 days of surgery: 50 in the GA group (0.9%, 95%

CI 0.7 - 1.2), 11 in the RA group (0.6%, 95% CI 0.3 - 1.1), and three (1.5%, 95% CI 0.5 - 4.7) in the LA group (Fig. 4). After adjustment for confounders, including BAR score (Fig. 1), chronic lung disease, and hospital, the risk of death within 30 days differed significantly between the groups (p = .03) and was significantly lower with RA compared with GA (aHR RA vs GA 0.37 [95% CI 0.17 - 0.81]; LA vs GA 0.63 [95% CI 0.15 - 2.69]) (Fig. 5).

Overall, 31.9% (2 461 patients) were admitted to the ICU postoperatively (Table 3). Among the subset admitted to ICU, the time to discharge was similar in the three groups (p = .41) (Fig. 5). In contrast, after adjustment for confounding (including BAR score, chronic lung disease, and hospital), there was evidence to suggest that patients in the RA and LA groups were discharged from hospital more quickly than those in the GA group (aHR RA vs GA 1.10 [95% CI 1.03 – 1.17]; LA vs GA 1.15 [95% CI 1.02 – 1.29]; p = .003) (Fig. 5). Pulmonary complications were recorded most frequently, occurring in 237 patients (2.4%) and was similar in the three groups (Fig. 5). Endoleak was recorded in 1 537 cases (15.7%), with type 2 endoleak occurring most frequently, in 985 cases (63.3%) (Table 3).

DISCUSSION

The main finding from this observational analysis of data from the UK NVR is that the 30 day in hospital mortality for elective, standard infrarenal EVAR was significantly lower in the RA group compared with the GA group (Fig. 5). Mortality was also lower in the LA group, but not significantly so. Patient groups were similar regarding demographics and comorbidity status. Complication rates were low and similar between groups, but patients in the RA and LA groups were more likely to be discharged earlier than those in the GA group.

The use of LA, RA, and GA techniques for EVAR is well established in both elective and emergency settings. ¹⁴ Recent evidence supports the use of LA for emergency EVAR of ruptured AAA: both the observational analysis of the IMPROVE trial and the analysis of the UK NVR demonstrated statistically significant reductions in mortality associated with the use of LA. ^{8,9} The effect of mode of anaesthesia on outcomes following elective EVAR is unknown. The 2019 ESVS Clinical Practice Guidelines on the Management of Abdominal Aorto-Iliac Artery Aneurysms recommend that anaesthesia for elective EVAR be chosen according to local hospital routine practice, as well as individual patient preference and assessment. These recommendations are based on evidence from a small retrospective analysis published in 2015 (ENGAGE study), ¹⁵ which demonstrated that there was no significant difference in mortality between the three modes of anaesthesia. ¹⁶ Conversely, a recent systematic review comparing mortality across different modes of anaesthesia for EVAR found that there may be some evidence to suggest that mode of anaesthesia, in particular RA for elective EVAR and LA for emergency EVAR, is associated with improved outcomes. ⁷ However, the lack of high

quality randomised data introduces a significant risk of bias. An observational analysis of the IMPROVE trial found that patients treated with EVAR for ruptured AAA using LA were discharged home sooner, as well as their discharge destination being more often home, when compared to GA.⁸

Other contemporary authors have examined postoperative complications following EVAR and their relationship to mode of anaesthesia. In recent analysis of the Vascular Quality Initiative from the USA, the authors concluded that the use of LA for percutaneous elective EVAR was associated with fewer pulmonary complications (OR 2.8, 95% CI 1.49 - 5.43; p = .002).

There remain difficulties in this subject concerning, firstly, the decision making and patient selection behind the choice of mode of anaesthesia, and, secondly, the ambiguity in definitions of RA, GA, and LA, particularly with regard to the addition of varying degrees of sedation to local or regional techniques.^{7,9}

The lower mortality rate observed with RA for elective EVAR is replicated in this UK NVR cohort of 9 783 patients undergoing elective, standard infrarenal EVAR. There was a trend towards a mortality benefit for the LA group, but this did not reach statistical significance. The reduction in pulmonary complications with the use of LA reported by Van Orden *et al.*¹³ was not seen in this cohort; indeed, the rate of pulmonary complications was similar in the three groups (Fig. 5). Conversely, this analysis does support the finding from the IMPROVE trial analysis as patients undergoing EVAR with LA or RA technique were discharged sooner.

The use of LA and RA in elective EVAR has been widely adopted throughout the UK, with 82 of the 89 hospitals performing at least one procedure under LA or RA. There was a trend towards the higher volume centres performing more procedures under LA or RA; however, the proportion of cases performed under LA or RA did not increase with case load (Fig. 3). Interestingly, the highest volume centre performed most of its elective EVAR under GA (97% of cases). This is contrary to the findings in emergency EVAR, where high volume centres were performing more cases under LA.

As with any registry data, the NVR is limited by its observational nature, the data collected, and the data completeness. While there are measures in place to ensure the internal and external validity of the NVR, including range checks and ratifying case ascertainment with HES data (estimated to be 89%),¹ the database is not independently externally validated, and HES data can be unreliable, therefore limiting the validity of the database. The authors were unable to cross reference the NVR with another external database to ensure its validity and this is important to consider when interpreting the findings. Despite this significant limitation the data remain valuable and are intended to generate clinical equipoise within the literature and lead to further high quality randomised studies.

Although the present study was able to account for patient factors through the inclusion of the BAR score and the presence of chronic lung disease in our analyses, there are other potential

confounding factors that may influence the choice of mode of anaesthesia and outcome that were not included and are not captured in the registry. Missing data are minimal in this cohort (< 2%), with the exception of postoperative ICU admission, and multiple imputation was not considered necessary. Data on postoperative ICU admission were missing in 1 675 GA, 363 RA, and 46 LA cases, which may suggest that the true numbers admitted to ICU postoperatively are lower than reported here.

The decision making process surrounding the choice of anaesthetic technique for individual patients remains unclear and is a potential source of significant selection bias. For example, the method of vascular access (percutaneous or open cut down) may influence the choice of anaesthetic technique and subsequent complications. It was not possible to investigate these factors as this information is not captured by the NVR. Furthermore, there remains ambiguity and inconsistency in the definition of anaesthetic techniques, particularly when intravenous sedation is used alongside LA or RA. In a study conducted by Verhoeven *et al.*, ¹⁷ up to 13% of patients receiving LA EVAR also received intravenous sedation or analgesia, ¹ but these data are not recorded by the NVR. Even within GA different outcomes have been reported for total intravenous anaesthesia techniques when compared with volatile anaesthetics. ¹⁸ In addition, the NVR does not record when a procedure was converted from one mode of anaesthesia to another, adding a further potential source of bias.

The NVR only collects mortality during the index hospital admission and any postdischarge deaths within 30 days will have been missed. Any missing or inaccurate mortality data points could potentially significantly affect the results as the numbers of deaths in each group are small. However, it must be noted that in multiple high profile EVAR trials there is a negligible difference between 30 day and in hospital mortality, suggesting that this is unlikely to be the case. ^{19–22} Further to this, it is also possible that some postoperative complications within the peri-operative period have not been captured. With regard to the LA group, it may simply be too small to demonstrate significant differences in mortality and morbidity. The NVR may have irreparable flaws in its conception but, despite these limitations, the data remain valuable and represent the largest individual cohort of elective EVAR analysed by mode of anaesthesia.

Conclusions

This study contributes to the expanding evidence base surrounding the choice of anaesthetic technique for elective EVAR. It supports the current literature, ratifying the observed mortality benefit associated with RA in elective EVAR but does not replicate the observed reduction in pulmonary complications observed with LA in elective EVAR. This work is valuable in demonstrating the equipoise surrounding the choice of anaesthetic technique for elective EVAR and the need for a high quality randomised controlled trial comparing the different anaesthetic techniques.

ACKNOWLEDGEMENTS

The authors express their thanks to all the vascular surgeons and patients who have contributed data to the National Vascular Registry (NVR). Thanks to Sam Waton from the Clinical Effectiveness Unit, Royal College of Surgeons of England, for performing the data retrieval from the NVR.

CONFLICTS OF INTEREST

None.

FUNDING

This study was supported by an Infrastructure Grant from the David Telling Charitable Trust.

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SUPPLEMENTARY MATERIAL

Appendix S1. Data available from the National Vascular Registry.

Table 1. Hospital use of anaesthesia according to abdominal aortic aneurysm (AAA) caseload Regional anaesthesia Local anaesthesia General anaesthesia Used for Used for Not used for Used for Not used for Not used for elective elective elective elective elective elective EVAR (n =EVAR (n =EVAR (n =EVAR (n =EVAR (n =EVAR (n =79) 87) 2) 10) 57) 32) Total AAA 21.5 (9.3– 40.7 (22.0-3.8 (1.0–6.5) 41.3 (25.3– 19.3 (6.5– 53.0 (35.0-71.3) 71.3) 38.3) 77.0) 33.2) (average cases/year) 46.3 (31.0-**EVAR AAA** 37.3 (20.7– 2.0 (1.0-3.0) 39.0 (23.0-17.8 (6.5– 20.2 (8.9– 29.0) 64.7) 30.7) (average 53.7) 55.7) cases/year) 37.7 (22.0– 3.8 (1.0–6.5) 38.7 (22.7– 19.0 (6.5– 50.3 (32.7-21.0 (9.3-Total elective 65.7) 65.7) 38.0) 71.3) 30.5) AAA (average cases/year) EVAR 34.7 (20.0– 2.0 (1.0–3.0) 35.3 (21.0– 17.5 (6.5– 42 (28.7– 19.5 (8.9– elective 49.7) 50.3) 27.7) 59.7) 28.2) AAA(average cases/year)

Data are presented as median (interquartile range). EVAR= endovascular aneurysm repair.

Table 2. Patient and operative characteristics of patients receiving elective standard infrarenal endovascular aneurysm repair (n = 9.783)

	GA (n = 7)	RA $(n = 2 347)$	LA $(n = 367)$	SMD	SM
	069)			RA	D
				vs	LA
				GA	vs
					GA
Demographics		1	I		
$Mean \pm SD age - y^*$	76.2 ± 7.2	77.0 ± 7.3	77.5 ± 7.4	0.11	0.19
Male	6 229 (88.1)	2077 (88.5)	327 (89.1)	0.01	0.03
Smoker					
Current or stopped	1 361 (19.3)	420 (17.9)	60 (16.4)	-0.04	_
< 2 mo					0.07
Ex	4 455 (63.0)	1 540 (65.6)	256 (69.8)	0.05	0.15
Never	1 251 (17.7)	387 (16.5)	49 (13.4)	-0.03	_
					0.12
ASA grade					
I (normal)	65 (0.9)	20 (0.9)	1 (0.3)	-0.01	_
					0.08
II (mild disease)	1 789 (25.3)	498 (21.2)	58 (15.8)	-0.10	_
					0.24
III (severe, not life	4 808 (68.0)	1 633 (69.6)	236 (64.3)	0.03	_
threatening)					0.08
IV (severe, life	403 (5.7)	195 (8.3)	70 (19.1)	0.10	0.41
threatening)					
V (moribund	2 (0.0)	1 (0.0)	2 (0.5)	0.01	0.10
patient)					
Cardiovascular risk factors	1		1		
Comorbidity on	6 219 (88.0)	2 142 (91.3)	335 (91.3)	0.11	0.11
admission (any)					
Diabetes	1 146 (16.2)	401 (17.1)	67 (18.3)	0.02	0.05
Hypertension	4 874 (68.9)	1 655 (70.5)	270 (73.6)	0.03	0.10
	1	1	1	1	ь

Stroke	503 (7.1)	147 (6.3)	32 (8.7)	-0.03	0.06
Ischaemic heart disease	2 864 (40.5)	1 014 (43.2)	187 (51.0)	0.05	0.21
Chronic heart failure	361 (5.1)	181 (7.7)	59 (16.1)	0.11	0.36
Chronic renal disease	938 (13.3)	373 (15.9)	58 (15.8)	0.08	0.07
Chronic lung disease	1 662 (23.5)	866 (36.9)	133 (36.2)	0.29	0.28
AAA anatomy*		•	-	•	
AAA diameter – mm [†]	60 (56–66)	60 (56–65)	60 (57–68)	0.02	0.10
Neck length – mm [‡]	23 (17–30)	24 (17–30)	23 (17–30)	-0.01	_
					0.03
Neck diameter – mm [§]	24 (22–27)	24 (22–26)	24 (21–27)	-0.07	_
					0.10
Common iliac artery	15 (13–18)	15 (13–18)	15 (12–18)	-0.02	_
diameter – mm					0.06
BAR score¶	0.98 (0.56–	1.10 (0.63–	1.44 (0.78–	0.14	0.43
	1.76)	2.00)	2.62)		

Data are presented as n (%) or median (interquartile range). GA = general anaesthesia; RA = regional anaesthesia; LA = local anaesthesia; SMD = standardised mean difference; AAA = abdominal aortic aneurysm. *Data missing for 32 patients (GA: 25; RA: 6; LA: 1). †Data missing for one patient (GA: 1; RA: 0; LA: 0). ‡Data missing for 212 patients (GA: 195; RA: 13; LA: 4). *Data missing for 208 patients (GA: 191; RA: 13; LA: 4). *Data missing for 206 patients (GA: 190; RA: 13; LA: 3). *Data missing for 104 patients (GA: 88; RA: 12; LA: 4).

Table 3. Postoperative outcomes for elective endovascular aneurysm repair			
	GA $(n = 7\ 069)$	RA $(n = 2 347)$	LA (<i>n</i> = 367)
Outcomes	L	1	1
In hospital death	50 (0.9)	11 (0.6)	3 (1.5)
within 30 d*			
7 d mortality	0.57 (0.4–0.8)	0.3 (0.1–0.6)	0.4 (0.1–2.6)
30 d mortality	0.9 (0.7–1.2)	0.6 (0.3–1.1)	1.5 (0.5–4.7)
Postoperative LOS –	2.0 (2.0–4.0)	2.0 (1.0-4.0)	2.0 (1.0-4.0)
$d^{\dagger,\ddagger}$			
Admitted to ICU§	1 618 (30.0)	720 (36.3)	123 (38.3)
If yes, ICU stay –	1.0 (1.0–2.0)	1.0 (1.0–2.0)	1.0 (1.0–2.0)
$d^{\dagger,\ddagger}$			
Re-admission within	340 (5.8)	142 (6.8)	34 (10.9)
30 days of			
discharge*,‡			
Complications [‡]	GA $(n = 7.068)$	RA (<i>n</i> = 2 346)	LA (<i>n</i> = 367)
Cardiac	136 (1.9)	36 (1.5)	8 (2.2)
complications			
Pulmonary	163 (2.3)	63 (2.7)	11 (3.0)
complications			
Cerebral	12 (0.2)	6 (0.3)	1 (0.3)
complications			
Renal failure	98 (1.4)	38 (1.6)	5 (1.4)
Bleeding	74 (1.0)	15 (0.6)	4 (1.1)
No. of			
complication			
S			
0	5 504 (77.9)	1 953 (83.2)	302 (82.3)
1	1 439 (20.4)	357 (15.2)	57 (15.5)
2	101 (1.4)	31 (1.3)	6 (1.6)
3	23 (0.3)	5 (0.2)	0 (0.0)
4	1 (0.0)	0 (0.0)	2 (0.5)

Endoleak	1 231 (17.6)	276 (11.8)	48 (13.1)
Endoleak type [¶]	1	1	
1	368 (29.9)	79 (28.6)	17 (35.4)
2	776 (63.0)	185 (67.0)	24 (50.0)
3	29 (2.4)	5 (1.8)	2 (4.2)
4	27 (2.2)	2 (0.7)	3 (6.3)
Unclassified	31 (2.5)	5 (1.8)	2 (4.2)

- Data are presented as n (%) or percentage (95% confidence interval) unless otherwise stated.
- 3 GA = general anaesthesia; RA = regional anaesthesia; LA = local anaesthesia; LOS = length
- of stay; ICU = intensive care unit. *GA: n = 5.825; RA: n = 2.074; LA: n = 313. †Data are
- 5 median (interquartile range). ‡Estimated using survival methods with patients censored if they
- died in hospital. Excluding patients that died in theatre. GA: <math>n = 6.992; RA: n = 2.343; LA:
- n = 367. ¶GA: n = 1 231; RA: n = 276; LA: n = 48.

Figure 1. British Aneurysm Repair score. 12 29 30 Figure 2. Elective endovascular aneurysm repair (EVAR): study profile. AAA = abdominal 31 aneurysm repair. *n = 2306/7520 for ruptured AAA. 32 33 34 Figure 3. Number of elective standard infrarenal endovascular aneurysm repair procedures 35 by hospital. LA = local anaesthesia; GA = general anaesthesia; RA = regional anaesthesia. 36 **Figure 4.** In hospital mortality to 30 days. RA = regional anaesthesia; GA = general 37 38 anaesthesia; LA = local anaesthesia. 39 40 **Figure 5.** Comparison of outcomes between groups. LA = local anaesthesia; GA = general anaesthesia; RA = regional anaesthesia; HR = hazard ratio; CI = confidence interval; OR = 41 42 odds ratio; ICU = intensive care unit.

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FIGURE LEGENDS

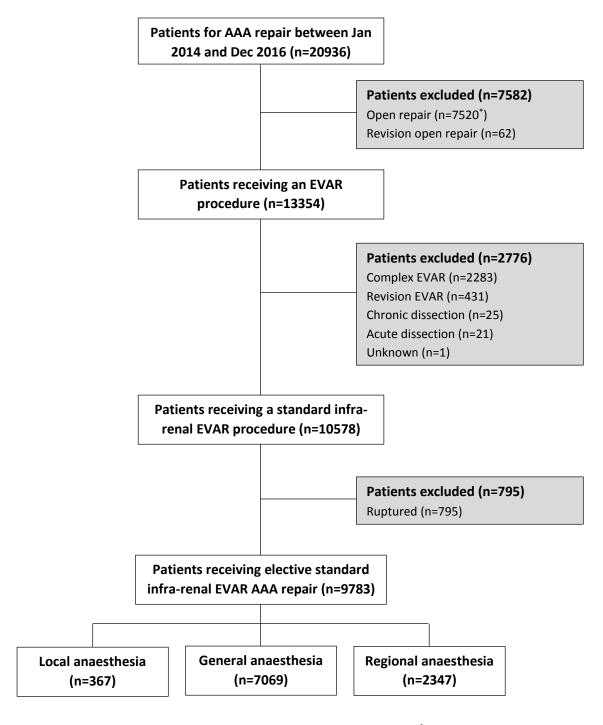
Figure 1. British Aneurysm Repair Score 12

Risk Factors	
Type of Repair	Open / EVAR
Age	Years
Gender	Male / Female
Serum Creatinine	Normal (≤120umol/L)
	Abnormal (> 120umol/L)
Cardiac Disease (Ischaemic Heart Disease or Cardiac Failure)	No / Yes
Abnormal ECG	No / Yes
Previous aortic surgery or stent	No / Yes
White cell count (x 10^9)	Normal (≥3.0 and ≤11.0)
	Abnormal (<3.0 or >11.0)
Serum sodium (mmol/L)	Normal (≥135 and ≤145)
	Abnormal (<135 or >145)
AAA diameter (cm)	Continuous variable
ASA grade	I, II, III, IV

EVAR= Endovascular Aneurysm Repair. ECG= Electrocardiogram. AAA= Abdominal aortic aneurysm. ASA= American Society of Anaesthesiologists.

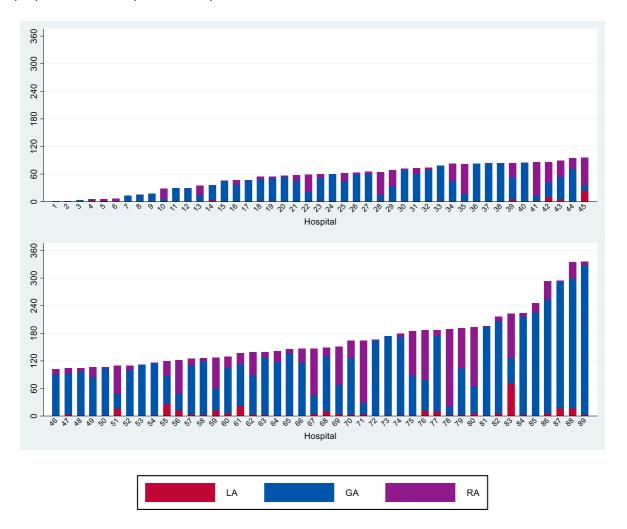
Reference 12: Grant SW, Hickey GL, Grayson A D, Mitchell DC, McCollum CN, National risk prediction model for elective abdominal aortic aneurysm repair. Br J Surg. 2013; 100:645-653.

Figure 2. Elective EVAR: study profile



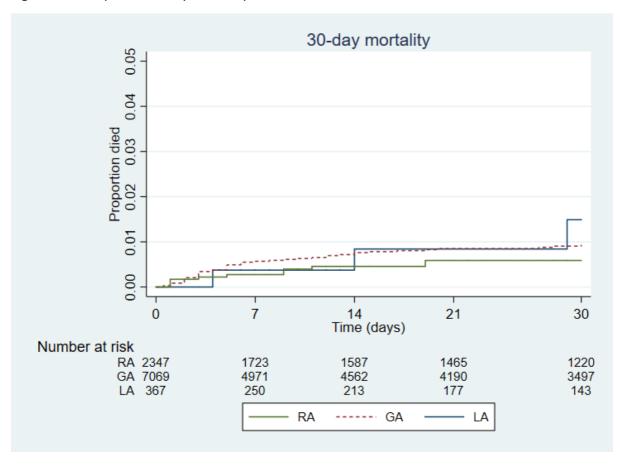
AAA= abdominal aortic aneurysm. EVAR= endovascular aneurysm repair. * 2306/7520 for ruptured AAA.

Figure 3. Number of elective standard infra-renal EVAR procedures by hospital, with hospital on the X axis and number of cases on the Y axis. Each bar is divided into colours which represent the proportion of cases performed by mode of anaesthesia.



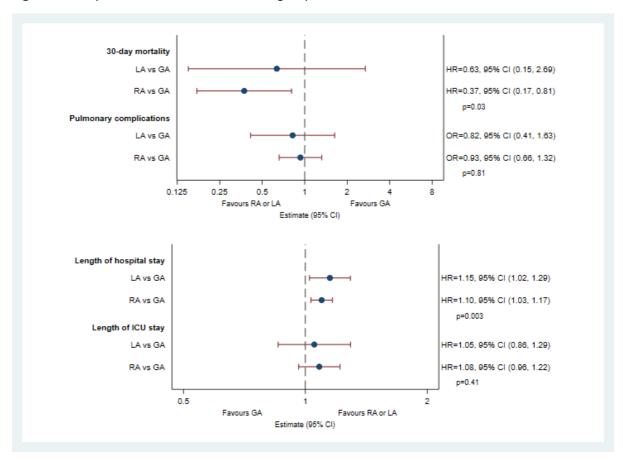
EVAR= Endovascular aneurysm repair. RA= Regional Anaesthesia. GA= General anaesthesia. LA= Local anaesthesia.

Figure 4. In-hospital mortality to 30-days.



RA= Regional Anaesthesia. GA= General anaesthesia. LA= Local anaesthesia.

Figure 5. Comparison of outcomes between groups.



RA= Regional Anaesthesia. GA= General anaesthesia. LA= Local anaesthesia. HR= Hazard Ratio. OR= Odds Ratio. ICU= Intensive care unit. CI= Confidence interval.

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Risk Factors		Formatted: English (United Kingdom)
Type of Repair	Open / EVAR	Formatted: English (United Kingdom)
Age	Years	Formatted: English (United Kingdom)
Gender	Male / Female	Formatted: English (United Kingdom)
Serum Creatinine	Normal (≤120umol/L)	Formatted: English (United Kingdom)
	Abnormal (> 120umol/L)	
Cardiac Disease (Ischaemic Heart Disease or Cardiac Failure)	No / Yes	Formatted: English (United Kingdom)
Abnormal ECG	No / Yes	Formatted: English (United Kingdom)
Previous aortic surgery or stent	No / Yes	Formatted: English (United Kingdom)
White cell count (x 10^9)	Normal (≥3.0 and ≤11.0)	Formatted: English (United Kingdom)
	Abnormal (<3.0 or >11.0)	
Serum sodium (mmol/L)	Normal (≥135 and ≤145)	Formatted: English (United Kingdom)
	Abnormal (<135 or >145)	
AAA diameter (cm)	Continuous variable	Formatted: English (United Kingdom)
ASA grade	I, II, III, IV	Formatted: English (United Kingdom)
		Formatted: English (United Kingdom)
VAR= Endovascular Aneurysm Repair, ECG= Electrocardiogram. AAA=	Abdominal aortic aneurysm. ASA=	Formatted: Font: 10 pt, English (United Kingdom)
merican Society of Anaesthesiologists,	Formatted: English (United Kingdom)	
Reference 12: Grant SW, Hickey GL, Grayson A D, Mitchell DC	Formatted: English (United Kingdom)	
nodel for elective abdominal aortic aneurysm repair. Br J Surg. 2013;	Formatted: Font color: Auto, English (United Kingdom	
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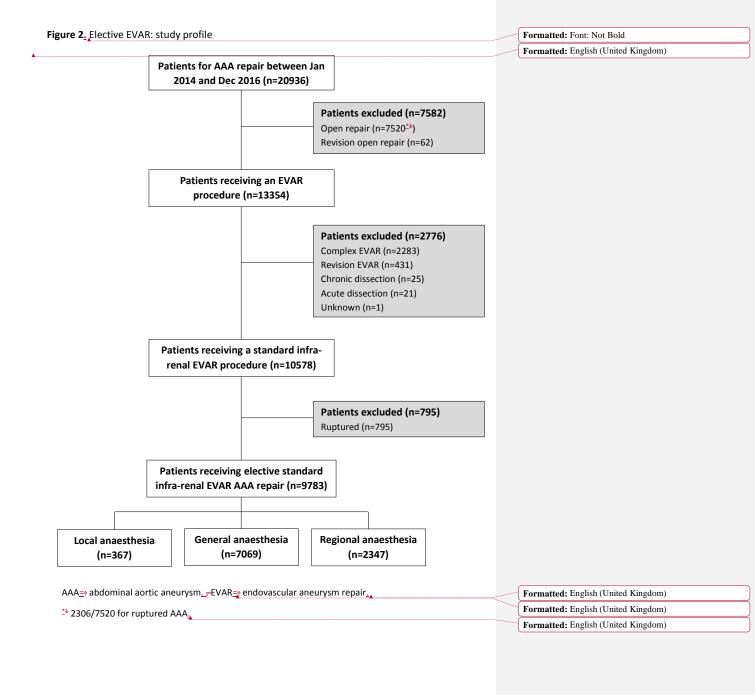
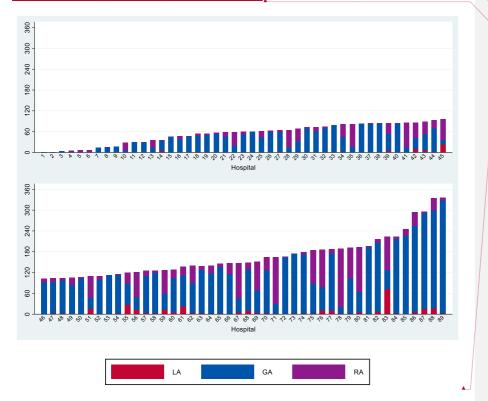


Figure 3. Number of elective standard infra-renal EVAR procedures by hospital, with hospital on the X axis and number of cases on the Y axis. Each bar is divided into colours which represent the proportion of cases performed by mode of anaesthesia.



EVAR= Endovascular aneurysm repair. RA= Regional Anaesthesia. GA= General anaesthesia. LA= Local anaesthesia.

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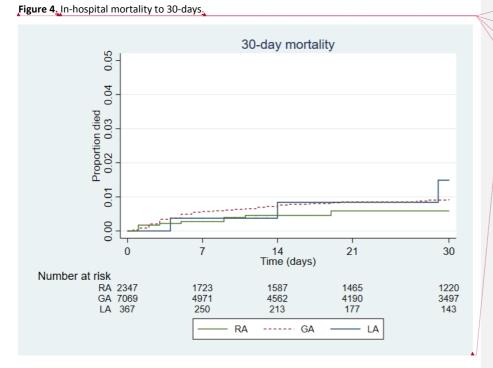
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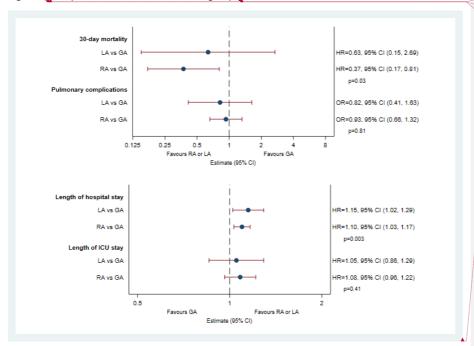
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RA= Regional Anaesthesia. GA= General anaesthesia. LA= Local anaesthesia. RA — regional anaesthesia, GA— general anaesthesia, LA local anaesthesia

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Figure 5. Comparison of outcomes between groups.



RA= Regional Anaesthesia. GA= General anaesthesia. LA= Local anaesthesia. HR= Hazard Ratio. OR= Odds
Ratio. ICU= Intensive care unit. Cl= Confidence interval. RA — regional anaesthesia, GA — general
anaesthesia, LA local anaesthesia, HR— hazard ratio, OR— odds ratio, ICU— intensive care

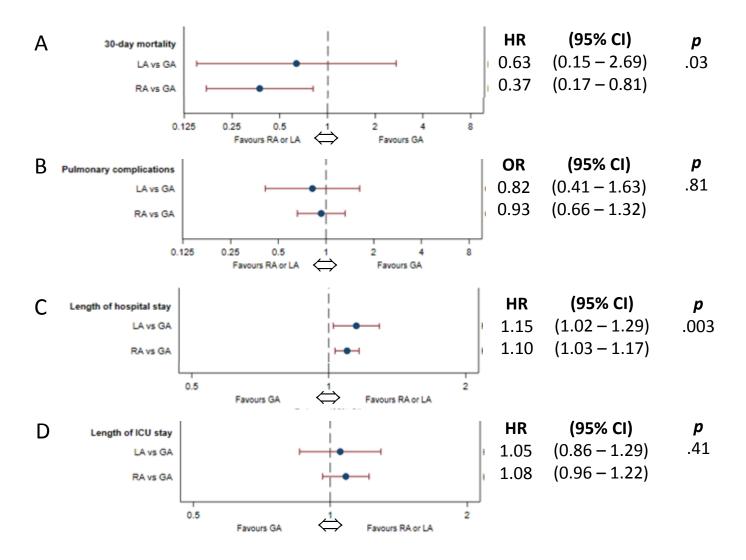
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Risk factors	
Type of repair	Open/EVAR
Age	Years
Sex	Male/female
Serum creatinine	Normal (≤ 120 μmol/L)
	Abnormal (> 120
	μmol/L)
Cardiac disease (ischaemic heart disease or cardiac failure)	No/yes
Abnormal ECG	No/yes
Previous aortic surgery or stent	No/yes
White cell count $-\times 10^9$	Normal (\geq 3.0 and \leq
	11.0)
	Abnormal (< 3.0 or >
	11.0)
Serum sodium – mmol/L	Normal (≥ 135 and ≤
	145)
	Abnormal (< 135 or >
	145)
AAA diameter – cm	Continuous variable
ASA grade	I, II, III, IV

EVAR = endovascular aneurysm repair; ECG = electrocardiogram; AAA = abdominal aortic aneurysm; ASA = American Society of Anaesthesiologists.

Figure 2.

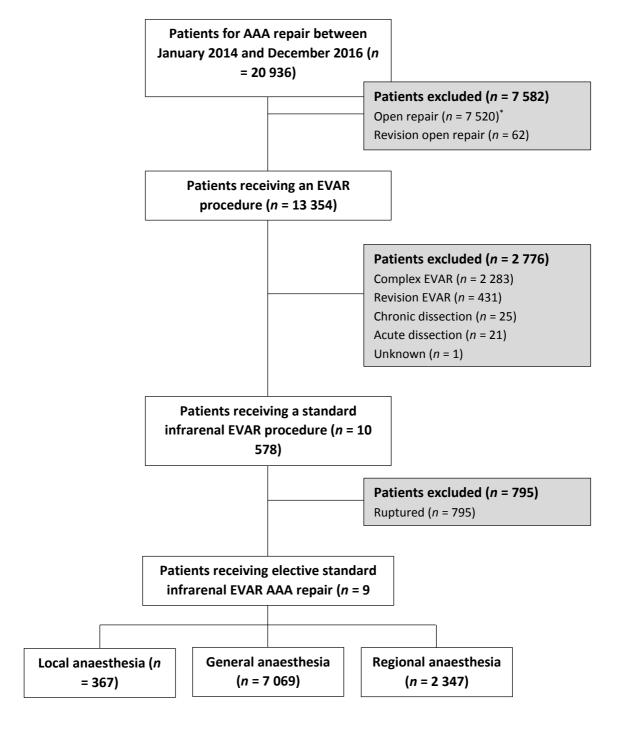


Figure 3.

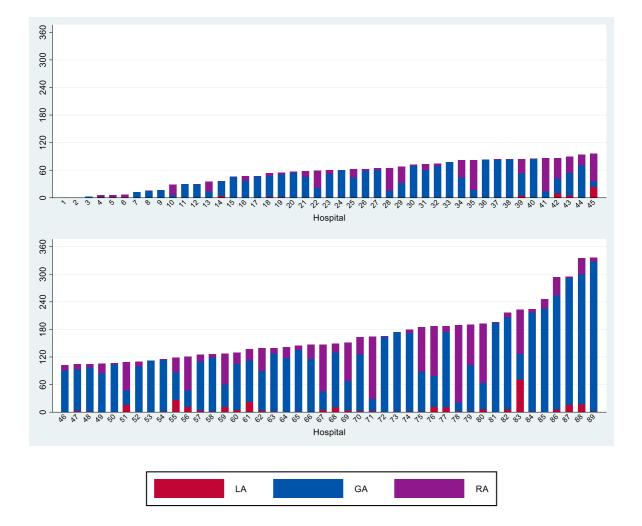


Figure 4.

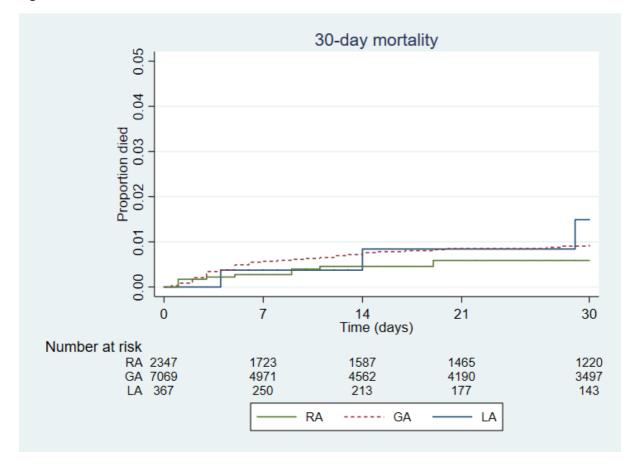


Figure 5. Comparison of outcomes between groups.

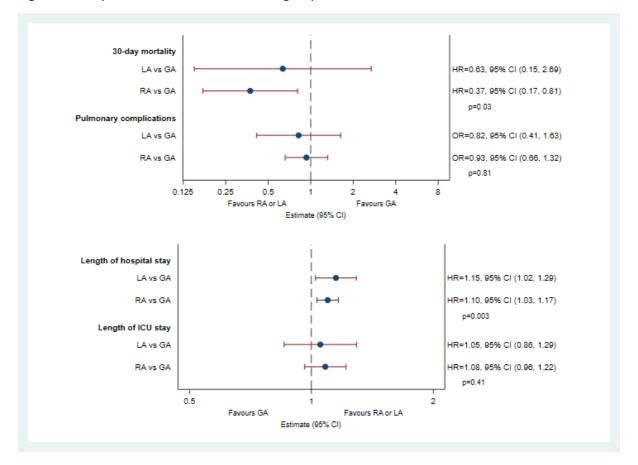


Table 1. Hospital use of anaesthesia according to abdominal aortic aneurysm (AAA) caseload.

	General A	naesthesia	Regional A	Anaesthesia	Local Anaesthesia		
	Used for elective EVAR (n=87)	Not used for elective EVAR (n=2)	Used for elective EVAR (n=79)	Not used for elective EVAR (n=10)	Used for elective EVAR (n=57)	Not used for elective EVAR (n=32)	
Total AAA (average cases/year)	40.7 (22.0, 71.3)	3.8 (1.0, 6.5)	41.3 (25.3, 71.3)	19.3 (6.5 <i>,</i> 38.3)	53.0 (35.0, 77.0)	21.5 (9.3, 33.2)	
EVAR AAA (average. cases/year)	37.3 (20.7, 53.7)	2.0 (1.0, 3.0)	39.0 (23.0, 55.7)	17.8 (6.5, 29.0)	46.3 (31.0 <i>,</i> 64.7)	20.2 (8.9, 30.7)	
Total elective AAA (average cases/year)	37.7 (22.0, 65.7)	3.8 (1.0, 6.5)	38.7 (22.7, 65.7)	19.0 (6.5, 38.0)	50.3 (32.7, 71.3)	21.0 (9.3, 30.5)	
EVAR elective AAA (average cases/year)	34.7 (20.0, 49.7)	2.0 (1.0, 3.0)	35.3 (21.0, 50.3)	17.5 (6.5, 27.7)	42 (28.7 <i>,</i> 59.7)	19.5 (8.9, 28.2)	

Data are presented as median (Interquartile range). AAA= Abdominal aortic aneurysm. EVAR= Endovascular aneurysm repair.

Table 2. Patient and operative characteristics of patients receiving elective standard infra-renal EVAR (n=9783)

		Anae	neral sthesia 7069	Anae	gional sthesia 2347	Ana	ocal esthesia =367	SMD RA vs GA	SMD LA vs GA
DEMOGRAPH									
Age (years) [‡] Male	Mean (SD)	76.2 6229	(7.2) (88.1)	77.0 2077	7.3 (88.5)	77.5 327	(7.4) (89.1)	0.11 0.01	0.19 0.03
Smoker	Current or stopped <2 months	1361	(19.3)	420	(17.9)	60	(16.4)	-0.04	-0.07
	Ex	4455	(63.0)	1540	(65.6)	256	(70.1)	0.05	0.15
	Never	1251	(17.7)	387	(16.5)	49	(13.4)	-0.03	-0.12
ASA grade	I: Normal	65	(0.9)	20	(0.9)	1	(0.3)	-0.01	-0.08
	II: Mild disease	1789	(25.3)	498	(21.2)	58	(15.8)	-0.10	-0.24
	III: Severe, not life- threatening	4808	(68.0)	1633	(69.6)	236	(64.3)	0.03	-0.08
	IV: Severe, life- threatening	403	(5.7)	195	(8.3)	70	(19.1)	0.10	0.41
	V: Moribund patient	2	(0.0)	1	(0.0)	2	(0.5)	0.01	0.10
CARDIOVASCU	JLAR RISK FACTORS*								
Comorbidity o	n admission (any)	6219	(88.0)	2142	(91.3)	335	(91.3)	0.11	0.11
Diabetes		1146	(16.2)	401	(17.1)	67	(18.3)	0.02	0.05
Hypertension		4874	(68.9)	1655	(70.5)	270	(73.6)	0.03	0.10
Stroke		503	(7.1)	147	(6.3)	32	(8.7)	-0.03	0.06
Ischaemic hea	rt disease	2864	(40.5)	1014	(43.2)	187	(51.0)	0.05	0.21
Chronic heart	failure	361	(5.1)	181	(7.7)	59	(16.1)	0.11	0.36
Chronic renal	disease	938	(13.3)	373	(15.9)	58	(15.8)	0.08	0.07
Chronic lung d	lisease	1662	(23.5)	866	(36.9)	133	(36.2)	0.29	0.28
AAA ANATON	1Y [†]								
AAA diameter	(mm) [¶]	60	(56, 66)	60	(56, 65)	60	(57, 68)	0.02	0.10
Neck length (n	nm) [§]	23	(17, 30)	24	(17, 30)	23	(17, 30)	-0.01	-0.03
Neck diamete	r (mm)×	24	(22, 27)	24	(22, 26)	24	(21, 27)	-0.07	-0.10
Common iliac diameter (mm	•	15	(13, 18)	15	(13, 18)	15	(12, 18)	-0.02	-0.06
BRITISH ANEU	IRYSM REPAIR SCORE (BAR	SCORE) †							
BAR score		0.98	(0.56, 1.76)	1.10	(0.63, 2.00)	1.44	(0.78 <i>,</i> 2.62)	0.14	0.43

Data are presented as n (%)* or median (Interquartile range) † unless otherwise stated. RA= Regional Anaesthesia. GA= General Anaesthesia. LA = Local Anaesthesia. SMD = Standardized mean difference. EVAR = Endovascular aneurysm repair. AAA= abdominal aortic aneurysm.

Missing data (GA, RA, LA): ‡ Data missing for 32 patients (25, 6, 1), ¶ data missing for 1 patient (1, 0, 0), § data missing for 212 patients (195, 13, 4), $^{\times}$ data missing for 208 patients (191, 13, 4), $^{\sim}$ data missing for 206 patients (190, 13, 3), $^{\bullet}$ data missing for 104 patients (88, 12, 4)

Table 3. Post-operative outcomes for elective EVAR.

			Anaesthesia 7069	_	Anaesthesia 2347	Local Anaesthesia n=367		
OUTCOMES			7003		2347		1-307	
In hospital death	within 30-days [†]	50	(0.9)	11	(0.6)	3	(1.5)	
7-day mortality§		0.57	(0.4, 0.8)	0.3	(0.1, 0.6)	0.4	(0.1, 2.6)	
30-day mortality	•	0.9	(0.7, 1.2)	0.6	(0.3, 1.1)	1.5	(0.5, 4.7)	
Post-op LOS								
(days) *¶		2.0	(2.0, 4.0)	2.0	(1.0, 4.0)	2.0	(1.0, 4.0)	
Admitted to		1618	(30.0)	720	(26.2)	123	(20.2)	
ICU^ [†]		1010	(30.0)	720	(36.3)	125	(38.3)	
If yes, ICU stay		1.0	(1.0, 2.0)	1.0	(1.0, 2.0)	1.0	(1.0, 2.0)	
(days) *¶								
Readmission with	nin 30 days of	340	(5.8)	142	(6.8)	34	(10.9)	
discharge [†]	+							
COMPLICATIONS			7068		2346		n=367	
Cardiac complica	tions	136	(1.9)	36	(1.5)	8	(2.2)	
Pulmonary		163	(2.3)	63	(2.7)	11	(3.0)	
complications			` ,		` '		` ,	
Cerebral complications		12	(0.2)	6	(0.3)	1	(0.3)	
Renal failure		98	(1.4)	38	(1.6)	5	(1.4)	
Bleeding		74	(1.4)	36 15	(0.6)	4	(1.4)	
bleeding		74	(1.0)	13	(0.0)	4	(1.1)	
Number of	None	5504	(77.9)	1953	(83.2)	302	(82.3)	
complications	1	1439	(20.4)	357	(15.2)	57	(15.5)	
	2	101	(1.4)	31	(1.3)	6	(1.6)	
	3	23	(0.3)	5	(0.2)	0	(0.0)	
	4	1	(0.0)	0	(0.0)	2	(0.5)	
Endoleak [‡]		1231	(17.6)	276	(11.8)	48	(13.2)	
Endoleak type	Type 1	368	(29.9)	79	(28.6)	17	(35.4)	
,,	Type 2	776	(63.0)	185	(67.0)	24	(50.0)	
	Type 3	29	(2.4)	5	(1.8)	2	(4.2)	
	Type 4	27	(2.2)	2	(0.7)	3	(6.3)	
	Unclassified	31	(2.5)	5	(1.8)	2	(4.2)	

Data are presented as n (%)[†], percent (95% confidence interval)[§] and median (Interquartile range)[¶] unless otherwise stated. RA= Regional Anaesthesia. GA= General Anaesthesia. LA = Local Anaesthesia. LOS= Length of Stay. ICU= Intensive care unit. EVAR= Endovascular aneurysm repair. * estimated using survival methods with patients censored if they died in hospital. ^ excluding patients that died in theatre. [‡]GA: n=6992 RA: n=2343 LA: n=367. GA: n=1231 RA: n=276 LA: n=48.

Appendix 1

Data available from the NVR registry.

Hospital code, sex, age at time of surgery, mode of admission, weight, height, AAA size, previous aortic operation, comorbidities (diabetes, hypertension, chronic lung disease, ischaemic heart disease, chronic heart failure, chronic renal disease, stroke), smoking status, white cell count, sodium, potassium, creatinine, albumin, haemoglobin, abnormal ECG, ASA grade, pre-operative medication, month and year of procedure, day of procedure, start time, AAA status, type of repair, anaesthetic type, procedure code 1, EVAR exclusion, type of EVAS device, neck angle, neck diameter, neck length, extended EIA, CIA diameter, type of complex EVAR, iliac branch, endoleak type, endoleak intervention, endoleak intervention success, AAA clamp site, AAA graft type, direct arterial monitoring, intraoperative cardiac output monitoring, postoperative coagulopathy, postoperative core temperature ≥ 36°C, patient reported severe pain within 1 hour of surgery, postoperative vomiting within 3 hours, destination after surgery, critical care stay, return to theatre within admission, re-admission to higher level of care, postoperative complications (cardiac, respiratory, cerebral, renal failure, haemorrhage, limb ischaemia, paraplegia, bowel ischaemia, puncture site haematoma, false aneurysm, vessel perforation, distal embolus), discharge status (alive of discharge), re-admission to hospital within 30 days, date clinic appointment attended, reason for no follow-up, length of stay, post-operative length of stay, vascular specialist 1, vascular specialist 2, vascular specialist 3.

Table 1. Hospital use of anaesthesia according to AAA abdominal aortic aneurysm (AAA) caseload.

	General A	naesthesia	Regional A	Anaesthesia	Local Anaesthesia		
	Used for elective EVAR (n=87)	Not used for elective EVAR (n=2)	Used for elective EVAR (n=79)	Not used for elective EVAR (n=10)	Used for elective EVAR (n=57)	Not used for elective EVAR (n=32)	
	Median (IQR)	Median (IQR)	Median (IQR)	Median (IQR)	Median (IQR)	Median (IQR)	
Total AAA (average cases/year)	40.7 (22.0, 71.3)	3.8 (1.0, 6.5)	41.3 (25.3, 71.3)	19.3 (6.5, 38.3)	53.0 (35.0, 77.0)	21.5 (9.3, 33.2)	
EVAR AAA (average. cases/year)	37.3 (20.7, 53.7)	2.0 (1.0, 3.0)	39.0 (23.0, 55.7)	17.8 (6.5, 29.0)	46.3 (31.0, 64.7)	20.2 (8.9, 30.7)	
Total elective AAA (average cases/year)	37.7 (22.0, 65.7)	3.8 (1.0, 6.5)	38.7 (22.7, 65.7)	19.0 (6.5, 38.0)	50.3 (32.7, 71.3)	21.0 (9.3, 30.5)	
EVAR elective AAA (average cases/year)	34.7 (20.0, 49.7)	2.0 (1.0, 3.0)	35.3 (21.0, 50.3)	17.5 (6.5, 27.7)	42 (28.7, 59.7)	19.5 (8.9, 28.2)	

Cases/year)

Data are presented as median (Interquartile range). AAA= Abdominal aortic aneurysm. EVAR= Endovascular aneurysm repair.

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Table 2. Patient characteristics and operative characteristics of patients receiving elective standard infra-renal EVAR (n=9783)

		Anae	Anaesthesia Anaest		Anaesthesia An		- <u>Local</u> esthesia =367)	SMD RA vs GA	SMD ← <u>LA vs</u> <u>GA</u>	Formatted Table
DEMOGRAPHY	•		(7.0)				(= 4)			Formatted: Superscript
Age (years) ≛ △ Male	Mean (SD)	76.2 6229 /7 069	(7.2) (88.1) %	77.0 2077 /2 347	7.3 (88.5) %	77.5 327 / 367	(7.4) (89.1) %	0.11	0.19	
Smoker	Current or stopped months		<u>(</u> 19.3 <u>)</u> %	420 /23 4 7	<u>(</u> 17.9 <u>)</u> %	60 /3	<u>(</u> 16.4 <u>)</u> %	-0.04	-0.07	
	Ex	4455 /7 067	<u>(</u> 63.0 <u>)</u> %	1540 /2 347	<u>(</u> 65.6 <u>)</u> %	256 / 365	<u>(</u> 70.1 <u>)</u> %	0.05	0.15	
	Never	1251 /7 067	<u>(</u> 17.7 <u>)</u> %	387 /23 47	<u>(</u> 16.5 <u>)</u> %	49 /3 65	(13.4) %	-0.03	-0.12	
ASA grade	I: Normal	65 /706 7	<u>(</u> 0.9 <u>)</u> %	20 /234 7	<u>(</u> 0.9 <u>)</u> %	1 /36 7	<u>(</u> 0.3 <u>)</u> %	-0.01	-0.08	
	II: Mild disease	1789 /7 067	<u>(</u> 25.3 <u>)</u> %	498 /23 4 7	<u>(</u> 21.2 <u>)</u> %	58 /3	<u>(</u> 15.8 <u>)</u> %	-0.10	-0.24	
	III: Severe, not life- threatening	4808 /7 067	<u>(</u> 68.0 <u>)</u> %	1633 /2 347	<u>(</u> 69.6 <u>)</u> %	236 / 367	<u>(</u> 64.3 <u>)</u> %	0.03	-0.08	
	IV: Severe, life- threatening	403 /70 67	<u>(</u> 5.7 <u>)</u> %	195 /23 4 7	<u>(</u> 8.3 <u>)</u> %	70 /3 67	<u>(</u> 19.1 <u>)</u> %	0.10	0.41	
	V: Moribund patier	t 2 /7067	<u>(</u> 0.0 <u>)</u> %	1 /2347	<u>(</u> 0.0 <u>)</u> %	2 /36 7	<u>(</u> 0.5 <u>)</u> %	0.01	0.10	
CARDIOVASCUL	AR RISK FACTORS									Formatted: Superscript
Comorbidity on	admission (any)	6219 /7 069	<u>(</u> 88.0 <u>)</u> %	2142 /2 347	<u>(</u> 91.3 <u>)</u> %	335 / 367	<u>(</u> 91.3 <u>)</u> %	0.11	0.11	
Diabetes		1146 /7 069	<u>(</u> 16.2 <u>)</u> %	401 /23 47	<u>(</u> 17.1 <u>)</u> %	67 /3 67	<u>(</u> 18.3 <u>)</u> %	0.02	0.05	
Hypertension		4874 /7 069	<u>(</u> 68.9 <u>)</u> %	1655 /2 347	<u>(</u> 70.5 <u>)</u> %	270 / 367	<u>(</u> 73.6 <u>)</u> %	0.03	0.10	
Stroke		503 /70	<u>(</u> 7.1 <u>)</u> %	147 /23 4 7	<u>(</u> 6.3 <u>)</u> %	32 /3 67	<u>(</u> 8.7 <u>)</u> %	-0.03	0.06	
Ischaemic heart	disease	2864 /7 069	<u>(</u> 40.5 <u>)</u> %	1014 /2 347	<u>(</u> 43.2 <u>)</u> %	187 / 367	<u>(</u> 51.0 <u>)</u> %	0.05	0.21	
Chronic heart fa	illure	361 /70	<u>(</u> 5.1 <u>)</u> %	181 /23 4 7	<u>(</u> 7.7 <u>)</u> %	59 /3 67	<u>(</u> 16.1 <u>)</u> %	0.11	0.36	
Chronic renal di	sease	938 /70 69	<u>(</u> 13.3 <u>)</u> %	373 /23 4 7	<u>(</u> 15.9 <u>)</u> %	58 /3 67	<u>(</u> 15.8 <u>)</u> %	0.08	0.07	
Chronic lung dis		1662 /7 069	<u>(</u> 23.5 <u>)</u> %	866 /23 4 7	<u>(</u> 36.9 <u>)</u> %	133 / 367	<u>(</u> 36.2 <u>)</u> %	0.29	0.28	
AAA ANATOMY										
AAA diameter (r	- (IQK)	60	(56, 66)	60	(56, 65)	60	(57, 68)	0.02	0.10	Formatted: Superscript
Neck length (mr	(IQK)	23	(17, 30)	24	(17, 30)	23	(17, 30)	-0.01	-0.03	
Neck diameter (- (IQK)	24	(22, 27)	24	(22, 26)	24	(21, 27)	-0.07	-0.10	Formatted: Superscript
Common iliac ar diameter (mm)	~ (IQR)	15	(13, 18)	15	(13, 18)	15	(12, 18)	-0.02	-0.06	
BRITISH ANEUR	YSM REPAIR SCORE	•							-	
BAR score (%)	Media (IQR)	0.98	(0.56, 1.76)	1.10	(0.63, 2.00)	1.44	(0.78, 2.62)	0.14	0.43	Formatted: Font: 11 pt, Superscript

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Data are presented as n (%)* or median (Interquartile range) __unless otherwise stated. RA= Regional Anaesthesia. GA= __General Anaesthesia. LA = Local Anaesthesia. SMD = Standardized mean difference. EVAR = Endovascular aneurysm repair. AAA= abdominal aortic aneurysm. RA = regional anaesthesia, GA = general anaesthesia, LA local anaesthesia. SMD = Standardized Mean Difference

Missing data (GA, RA, LA):

△ Data missing for 32 patients (25, 6, 1), ♣ data missing for 1 patient (1, 0, 0), ♣ data missing for 212 patients (195, 13, 4), ★ data missing for 208 patients (191, 13, 4), ← data missing for 206 patients (190, 13, 3), ♣ data missing for 104 patients (88, 12, 4)

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Table 3. Post-operative outcomes for elective EVAR.

		GA-<u>Ge</u> Anaesi (n=70	thesia	RA-Regional Anaesthesia (n=2347)			Anaesthesia =367)	Formatted Table	
OUTCOMES									
In hospital death		58		13		4		Formatted Table	
In hospital death wi	thin 30-days±	50	(0.9)	11	(0.6)	3	<u>(1.5)</u>		
7-day mortality [§]	% (95% CI)	0.57 %	(0.4, 0.8)	0.3 %	(0.1, 0.6)	0.4%	(0.1, 2.6)		
30-day mortality§	% (95% CI)	0.9%	(0.7, 1.2)	0.6 %	(0.3, 1.1)	1.5 %	(0.5, 4.7)		
Post-op LOS (days <u>) *1</u>	Median (IQR)*	2.0	(2.0, 4.0)	2.0	(1.0, 4.0)	2.0	(1.0, 4.0)		
Admitted to ICU^±		1618 /5394	<u>(</u> 30.0 <u>)</u> %	720 /1984	<u>(</u> 36.3 <u>)</u> %	123 /321	<u>(</u> 38.3 <u>)</u> %		
If yes, ICU stay (days) <u>*</u> ¶	Median (IQR)*	1.0	(1.0, 2.0)	1.0	(1.0, 2.0)	1.0	(1.0, 2.0)		
Readmission within discharge [±]	30 days of	340 /5825	<u>(</u> 5.8 <u>)</u> %	142 /2074	<u>(</u> 6.8 <u>)</u> %	34 /313	<u>(</u> 10.9 <u>)</u> %		
COMPLICATIONS ¹		<u>n=70</u>	<u> 268</u>	<u>n=2</u>	<u>346</u>	<u>n</u> :	<u>=367</u>		
Cardiac complicatio	ns	136 /7068	<u>(</u> 1.9 <u>)</u> %	36 /2346	<u>(</u> 1.5 <u>)</u> %	8 /367	<u>(</u> 2.2 <u>)</u> %	Formatted Table	
Pulmonary complications		163 /7068	<u>(</u> 2.3 <u>)</u> %	63 /2346	<u>(</u> 2.7 <u>)</u> %	11 /367	<u>(</u> 3.0 <u>)</u> %		
Cerebral complications		12 /7068	<u>(</u> 0.2 <u>)</u> %	6 /2346	<u>(</u> 0.3 <u>)</u> %	1 /367	<u>(</u> 0.3 <u>)</u> %		
Renal failure		98 /7068	<u>(</u> 1.4 <u>)</u> %	38 /2346	<u>(</u> 1.6 <u>)</u> %	5 /367	<u>(</u> 1.4 <u>)</u> %		
Bleeding		74 /7068	<u>(</u> 1.0 <u>)</u> %	15 /2346	<u>(</u> 0.6 <u>)</u> %	4 /367	<u>(</u> 1.1 <u>)</u> %		
Number of	<u>None</u>	<u>5504</u>	(77.9)	<u>1953</u>	(83.2)	<u>302</u>	(82.3)		
<u>complications</u>	<u>1</u>	<u>1439</u>	(20.4)	<u>357</u>	(15.2)	<u>57</u>	<u>(15.5)</u>		
	<u>2</u>	<u>101</u>	(1.4)	<u>31</u>	(1.3)	<u>6</u>	<u>(1.6)</u>		
	<u>3</u>	<u>23</u>	(0.3)	<u>5</u>	(0.2)	<u>0</u>	<u>(0.0)</u>		
	<u>4</u>	<u>1</u>	(0.0)	<u>0</u>	(0.0)	<u>2</u>	(0.5)		
Endoleak <u></u>		1231 /6992	<u>(</u> 17.6 <u>)</u> %	276 /2343	<u>(</u> 11.8 <u>)</u> %	48 /363	<u>(</u> 13.2 <u>)</u> %	Formatted Table	
Endoleak type-	Type 1	368 /1231	<u>(</u> 29.9 <u>)</u> %	79 /276	<u>(</u> 28.6 <u>)</u> %	17 /48	<u>(</u> 35.4 <u>)</u> %		
	Type 2	776 /1231	<u>(</u> 63.0 <u>)</u> %	185 /276	<u>(</u> 67.0 <u>)</u> %	24 /48	<u>(</u> 50.0 <u>)</u> %		
	Type 3	29 /1231	<u>(</u> 2.4 <u>)</u> %	5 /276	<u>(</u> 1.8 <u>)</u> %	2 /48	<u>(</u> 4.2 <u>)</u> %		
	Type 4	27 /1231	<u>(</u> 2.2 <u>)</u> %	2 /276	<u>(</u> 0.7 <u>)</u> %	3 /48	<u>(</u> 6.3 <u>)</u> %		
	Unclassified	31 /1231	<u>(</u> 2.5 <u>)</u> %	5 /276	(1.8)%	2 /48	<u>(</u> 4.2 <u>)</u> %		

Data are presented as n (%)[†], percent (95% confidence interval)[§] and median (Interquartile range)[¶] unless otherwise stated. RA= Regional Anaesthesia. GA= General Anaesthesia. LA = Local Anaesthesia. LOS= Length of Stay. ICU= Intensive care unit. EVAR= Endovascular aneurysm repair.RAlocal anaesthesia, LOS – length of stay; ICU – Intensive care unit

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 $^{^{}st}$ estimated using survival methods with patients censored if they died in hospital $_{\mbox{\scriptsize --}}$

[^] excluding patients that died in theatre. <u>†GA: n=6992 RA: n=2343 LA: n=367. GA: n=1231 RA: n=276 LA: n=48.</u>

Appendix 1

Data available from the NVR registry.

Hospital code, sex, age at time of surgery, mode of admission, weight, height, AAA size, previous aortic operation, comorbidities (diabetes, hypertension, chronic lung disease, ischaemic heart disease, chronic heart failure, chronic renal disease, stroke), smoking status, white cell count, sodium, potassium, creatinine, albumin, haemoglobin, abnormal ECG, ASA grade, pre-operative medication, month and year of procedure, day of procedure, start time, AAA status, type of repair, anaesthetic type, procedure code 1, EVAR exclusion, type of EVAS device, neck angle, neck diameter, neck length, extended EIA, CIA diameter, type of complex EVAR, iliac branch, endoleak type, endoleak intervention, endoleak intervention success, AAA clamp site, AAA graft type, direct arterial monitoring, intraoperative cardiac output monitoring, postoperative coagulopathy, postoperative core temperature ≥ 36°C, patient reported severe pain within 1 hour of surgery, postoperative vomiting within 3 hours, destination after surgery, critical care stay, return to theatre within admission, re-admission to higher level of care, postoperative complications (cardiac, respiratory, cerebral, renal failure, haemorrhage, limb ischaemia, paraplegia, bowel ischaemia, puncture site haematoma, false aneurysm, vessel perforation, distal embolus), discharge status (alive of discharge), re-admission to hospital within 30 days, date clinic appointment attended, reason for no follow-up, length of stay, post-operative length of stay, vascular specialist 1, vascular specialist 2, vascular specialist 3.

Appendix 1

Data available from the NVR registry.

Hospital code, sex, age at time of surgery, mode of admission, weight, height, AAA size, previous aortic operation, comorbidities (diabetes, hypertension, chronic lung disease, ischaemic heart disease, chronic heart failure, chronic renal disease, stroke), smoking status, white cell count, sodium, potassium, creatinine, albumin, haemoglobin, abnormal ECG, ASA grade, pre-operative medication, month and year of procedure, day of procedure, start time, AAA status, type of repair, anaesthetic type, procedure code 1, EVAR exclusion, type of EVAS device, neck angle, neck diameter, neck length, extended EIA, CIA diameter, type of complex EVAR, iliac branch, endoleak type, endoleak intervention, endoleak intervention success, AAA clamp site, AAA graft type, direct arterial monitoring, intraoperative cardiac output monitoring, postoperative coagulopathy, postoperative core temperature ≥ 36°C, patient reported severe pain within 1 hour of surgery, postoperative vomiting within 3 hours, destination after surgery, critical care stay, return to theatre within admission, re-admission to higher level of care, postoperative complications (cardiac, respiratory, cerebral, renal failure, haemorrhage, limb ischaemia, paraplegia, bowel ischaemia, puncture site haematoma, false aneurysm, vessel perforation, distal embolus), discharge status (alive of discharge), re-admission to hospital within 30 days, date clinic appointment attended, reason for no follow-up, length of stay, post-operative length of stay, vascular specialist 1, vascular specialist 2, vascular specialist 3.