Evaluating abdominal aortic aneurysm and carotid artery surgery in the Netherlands: variations in indication, treatment and outcomes measures

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CHAPTER 4

Dutch Surgical Aneurysm Audit: Volume and Outcome of Elective Open Aneurysm Repair

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ABSTRACT

Background and objectives

Endovascular aneurysm repair (EVAR) has become standard of care in the treatment of elective abdominal aortic aneurysms (AAA), with a decrease in procedural mortality to <1%. Consequently, elective open surgical repair (OSR) is performed only in a minority of patients with a mortality of around 5%. Aiming to improve procedural outcomes, we determined the patient characteristics associated with mortality after elective OSR for AAA in the Dutch population and evaluated the association between hospital volume of elective OSR and adjusted mortality in order to explore a possible volume standard.

Methods

In this observational retrospective study**,** all patients undergoing elective OSR for an AAA between 2013-2018 in the Netherlands and prospectively registered in the compulsory Dutch Surgical Aneurysm Audit (DSAA) were included. The primary outcome was mortality (30-days/in-hospital). To evaluate a possible association between patient characteristics and mortality, a multivariable logistic regression analysis was performed. Next the case-mix adjusted postoperative mortality over the period 2013-2018 was calculated per hospital and displayed in a funnel plot. Additionally, the association between hospital volume and mortality after OSR was investigated with a generalized linear mixed model, adjusted for patient characteristics.

Results

In a six-year timeframe, 3100 patients with an AAA underwent elective OSR, which represents 23% of all electively repaired AAA. The overall mortality was 5.0% (n=156). Patient characteristics independently associated with mortality were: female sex [OR 1.676, 95% CI 1.132-2.483], age (OR 1.067, 95% CI 1.040-1.096) pulmonary state (dyspnea OR 1.756, 95% CI 1.230-2.508), preoperative hemoglobin (OR 0.836, 95% CI 0.702-0.996) and creatinine level (OR 1.004, 95% CI 1.001-1.008).

Elective OSR was performed in 59 hospitals, with a volume in 6 years varying from 1-141 elective OSR procedures and a case-mix adjusted mortality varying from 0-16%(mean 5%). Fourteen hospitals had a significantly lower mortality than the national mean mortality while none performed significantly worse. Adjusted for patient characteristics, hospital volume was not significantly associated with postoperative mortality after elective OSR.

Conclusion

In the Netherlands, annual hospital volume of elective OSR is not significantly associated with adjusted postoperative mortality. Female sex, increasing age, pulmonary state, preoperative hemoglobin and creatinine were significantly associated with mortality after elective OSR.

INTRODUCTION

Endovascular aneurysm repair (EVAR) has become standard of care in the treatment of elective abdominal aortic aneurysms (AAA). Since the landmark trials, postoperative mortality after elective EVAR has even decreased to less than 1%.[1] This is in contrast to elective open surgical repair (OSR) where postoperative mortality remained unchanged: 5% mortality in the Netherlands and varying from 2.0% to 5.6% between other European countries.[2-5]

With EVAR as the preferred surgical treatment, almost 80% of all Dutch elective aneurysm patients is now undergoing EVAR.[2] This percentage of elective EVAR is comparable to other European countries.[6] Patients, not suitable for treatment with EVAR, undergoing elective OSR have therefore become a selected group of patients mostly with a more difficult anatomy of the aneurysm. Also, this group may include more patients at a greater risk for postoperative mortality, due to changed patient selection. So, the unchanged mortality rate of 5% after OSR might reflect an improvement of care of AAA patients treated by OSR.

A possible factor for improving postoperative outcomes after elective OSR is the hospital volume in which this procedure is performed. Previous studies showed a relationship between hospital volume and postoperative mortality in AAA surgery.[7,8] In the Netherlands, there is a minimum volume standard of 20 elective abdominal aortic aneurysm procedures (EVAR and OSR) a year per hospital. However, this minimum volume standard dates from the time that OSR was mainly performed. With the increased use of EVAR over the last decades, the use of OSR simultaneously has decreased. Due to this decrease, hospitals may not perform the surgical procedure sufficiently to maintain good quality of care, which may possible influence postoperative mortality.[9] However, although the American minimum standard has been set at 10 OSR procedures a year, the Dutch minimum standard has yet not been changed or stratified by type of surgical procedure.[10,11]

The aim of our study was to analyze the association between hospital volume of elective OSR and postoperative mortality, in order to explore a possible minimum volume standard for elective OSR. Furthermore, we evaluate which patient characteristics are associated with postoperative mortality after elective OSR in the current Dutch population

METHODS

Data source and patient selection

The dataset was derived from the Dutch Surgical Aneurysm Audit (DSAA). This compulsory nationwide audit was initiated in 2013 and prospectively registers all patients undergoing surgery for an aortic aneurysm or dissection. Data were registered via a web-based survey or provided by the hospital via a batch file. All patients with a juxta- or infrarenal abdominal aortic aneurysm undergoing primary elective open surgical repair between January 2013 and December 2018 were included for analyses. All patients with a thoracic or thoracoabdominal aortic aneurysm or dissection, a ruptured or acute symptomatic abdominal aortic aneurysm, elective abdominal aortic aneurysm undergoing EVAR and secondary aortic reintervention following a primary AAA repair were excluded. A minimal set of variables had to be registered to consider a patient eligible for further analysis: date of birth, date of surgery, type of surgical procedure and patient survival status (30 days/in-hospital). Verification of the DSAA data was carried out in 2015 by a third trusted party, through a random sample of hospitals and will be repeated in the near future.[12,13]

Primary outcome measure

The primary outcome of this study was postoperative mortality, 30-days and/or in-hospital. Patient characteristics were compared between patients with postoperative mortality and patients who survived after OSR, using T-tests for continuous variables and chi-square tests for categorical variables.

Multivariable logistic regression analysis

In order to evaluate possible associations between patient characteristics and postoperative mortality, a multivariable logistic regression analysis (enter model) at a p value of 0.05, was performed.

Patient characteristics included in this analysis were based on the elements of the V(p)-POSSUM predictive score: sex, age, maximal aneurysm diameter, pulmonary state, cardiac state, results of last preoperative electrocardiogram, preoperative hemoglobin and preoperative creatinine level.[14]

In case of missing data in continuous variables, the mean of each variable was imputed. Data was most frequently missing in preoperative creatinine (3.5%) and hemoglobin (2.6%). If data was missing in categorical variables, a category 'unknown' was added.

Additionally, to demonstrate the influence of certain patient characteristics and make them more useful to clinicians, mortality rates were stratified by the subgroups of combined patient characteristics that were most strongly associated with mortality.

Hospital selection: hospital volume

The annual volume of elective OSR was measured per hospital during a period of 6 years (2013-2018). Additionally, the ratio of elective OSR and EVAR volumes per hospital in this period was calculated. To evaluate the variation in postoperative mortality between hospitals, hospital volume of OSR was plotted against case-mix adjusted mortality rates in a funnel plot. The association between hospital volume of OSR per year and postoperative mortality was evaluated with a generalized linear mixed regression model, adjusted for all patient characteristics previously proven to be associated with postoperative mortality. As patients treated in the same hospital share many experiences, we have to account for the resulting correlation. Therefore, a random effect per hospital was added to the model. Patients operated in hospitals that stopped performing elective OSR (4 hospitals, N=41, 0.03%) were excluded from this analysis.

All statistical analyzes regarding the association between patient characteristics and mortality were performed using SPSS statistical software (version 24; IMB Corp, Armonk, NY). All statistical analyzes regarding the association between hospital volume and postoperative mortality were performed using R statistical software (version 3.4.0)

RESULTS

Between January 2013 and December 2018, 14364 patients underwent elective abdominal aortic aneurysm repair in the Netherlands and were registered in the DSAA. After exclusion of all patients undergoing revision surgery (n=692, 4.8%), patients undergoing EVAR (10567, 74%) and patients with incomplete data (n=5, 0.03%), 3100 patients with an AAA undergoing primary elective open surgical repair and eligible for analyses were included in the study.

The majority of the cohort consisted of males (n=2505, 80.8%) with a mean age of 70.8 years (SD 7.3). Of all patients undergoing elective OSR between 2013-2018, 156 (5.0%) patients died within 30 days postoperatively and/or during their initial hospital stay, with a highest mortality (7.1%) in 2015 and the lowest (3.8%) in 2017. Patient characteristic, compared between patients with postoperative mortality and patients who remained alive after elective OSR, are shown in table 1. Patients with postoperative mortality were more often female (27.6% vs 18.8%, p = 0.006) and on average 3.6 years older (p =<0.001) than patients who survived. Additionally, cardiac state, preoperative electrocardiogram, pulmonary state, preoperative hemoglobin and preoperative creatinine levels were significantly different between the two groups.

Patient characteristics associated with postoperative mortality

The multivariable logistic regression analysis for postoperative mortality after elective OSR is shown in table 2. Patient characteristics independently associated with postoperative mortality after elective OSR were: female sex [odds ratio (OR) 1.676, 95% confidence interval (CI) 1.132-2.483], age per year (OR 1.067, 95% CI 1.040-1.096) pulmonary state (dyspnea OR 1.756, 95% CI 1.230-2.508), preoperative hemoglobin (OR 0.836, 95% CI 0.702-0.996) and preoperative creatinine per unit (OR 1.004, 95% CI 1.001-1.008).

Table 1. Comparison of patient characteristics between patients with and without postoperative mortality

	Patients survived		Patients with postoperative mortality		
	N	%	N	%	P-value
Sex					0.006
Male	2392	81%	113	72%	
Female	552	19%	43	28%	
Age (mean, years)	70.6 SD 7.3		74.2 SD 6.6		<0.001
Year of surgery					0.193
2013	524	96%	23	4.2%	
2014	530	94%	32	5.7%	
2015	435	93%	33	7.1%	
2016	470	95%	26	5.2%	
2017	478	96%	19	3.8%	
2018	507	96%	23	4.3%	
Cardiac state					0.010
No failure	1235	42%	50	32%	
Hypertension, angina pectoris, use of diuretics/digoxin	1387	47%	77	49%	
Peripheral edema, use of coumarin, cardiomyopathy	200	6.8%	21	14%	
Raised CVP, cardiomegaly	39	1.3%	3	1.9%	
Unknown	83	2.8%	5	3.2%	
Preoperative ECG					0.021
No abnormalities	1662	57%	67	43%	
Atrial fibrillation	156	5.3%	12	7.7%	
Ischemia	67	2.3%	5	3.2%	
Other abnormalities	870	30%	61	39%	
Unknown ECG /No ECG performed	189	6.4%	11	7.1%	
Pulmonary state					<0.001
No dyspnea	2238	76 %	95	61%	
Mild dyspnea	616	21%	53	34%	
Severe dyspnea	90	3.1%	8	5.1%	
Aneurysm diameter					0.327
<55mm	536	18%	20	13%	
55-64mm	1471	50%	84	54%	
65-74mm	457	16%	27	17%	
>75mm	438	15%	21	14%	
Missing	42	1.4%	4	2.6%	
Preoperative laboratory results					
Hemoglobin (mean, mmol/L)	8.7 SD 0.98		8.3 SD 0.97		<0.001
Creatinine (median, mmol/L)	90 IQR 76-107		98 IQR 78-131		<0.001

Table 2. Patient characteristics independently associated with postoperative mortality

	Odds Ratio	95% Confidence interval
Sex		
Male	Ref.	
Female	1.676	1.132–2.483
Age (years)	1.067	1.040–1.096
Aneurysm diameter (mm)	1.002	0.988–1.016
Cardiac state		
No failure	Ref.	
Hypertension, angina pectoris, use of diuretics/digoxin	1.228	0.845–1.787
Peripheral edema, use of coumarin, cardiomyopathy	1.669	0.952–2.925
Raised CVP, cardiomegaly	1.154	0.329–4.047
Unknown	1.269	0.484–3.328
Preoperative ECG		
No abnormalities	Ref.	
Abnormalities	1.416	0.989–2.026
Unknown ECG /No ECG performed	1.553	0.796–3.030
Pulmonary state		
No dyspnea	Ref.	
Mild dyspnea	1.756	1.230–2.508
Severe dyspnea	1.792	0.823–3.901
Hemoglobin (mmol/L)	0.836	0.702–0.996
Creatinine (mmol/L)	1.004	1.001–1.008

Table 3 demonstrates, as a practical example, the differences in mortality rates between patients with and without patient characteristics most strongly associated with mortality. For example, the combined characteristics 'age of 75 years and higher' and 'pulmonary comorbidity' resulted in a mortality of 11.0% in males and 13.1% in females.

Hospital volume

Between 2013-2018 elective OSR was performed in 59 hospitals, in which the total volumes of OSR in this period varied from 1 to 141 procedures. Figure 1 shows the volume of OSR per hospital per 2-year period. The majority of hospitals is performing on average less then 10 elective OSR procedures a year and only 20 hospitals perform on average more than 10 elective OSR a year. Figure 2 shows the ratio of OSR and EVAR per hospital between 2013-2018. Out of all hospitals, 7 hospitals performed on average less than 20 AAA procedures (EVAR and/or OSR) a year. Four of these hospitals stopped performing elective OSR after 2015. The crude mortality percentages varied from 0-13.9% between hospitals. In figure 3, postoperative mortality is plotted against total hospital volume of OSR between 2013-2018, adjusted for patient characteristics. Case-mix adjusted mortality varied from 0-16% between hospitals, with the majority of hospitals performing within the confidence intervals no hospitals with a significantly higher postoperative mortality than the national mean of 5.0%. Fourteen hospitals had a significantly lower postoperative mortality than the national

Table 3. Postoperative mortality after elective OSR stratified by subgroups of patients.

	Male (n=2505)							Female (n=595)							
Dead	4.5% (n=113)							7.3% (n=43)							p = 0.006
	Age < 75 years (n=1706)			Age 75 years and older (n=799)				Age < 75 years (n=361)			Age 75 years and older (n=234)				
Dead	2.9% (n=50)			7.9% (n=63)			p = 0.000	5.8% (n=21)			9.4% (n=22)			p = 0.099	
	No pulmonary comorbidity (n=1330)	Pulmonary comorbidity (n=376)		No pulmonary comorbidity (n=581)	Pulmonary comorbidity (n=218)			No pulmonary comorbidity (n=249)	Pulmonary comorbidity (n=112)		No pulmonary comorbidity (n=173)	Pulmonary comorbidity (n=61)			
Dead	2.3% (n=31)	5.1% (n=19)	p = 0.006	6.7% (n=39)	11.0% (n=24)	p = 0.045		4.4% (n=11)	8.9% (n=10)	p = 0.090	8.1% (n=14)	13.1% (n=8)	p = 0.248		

Figure 1. Volume of elective OSR procedures per hospital in 2013-2018

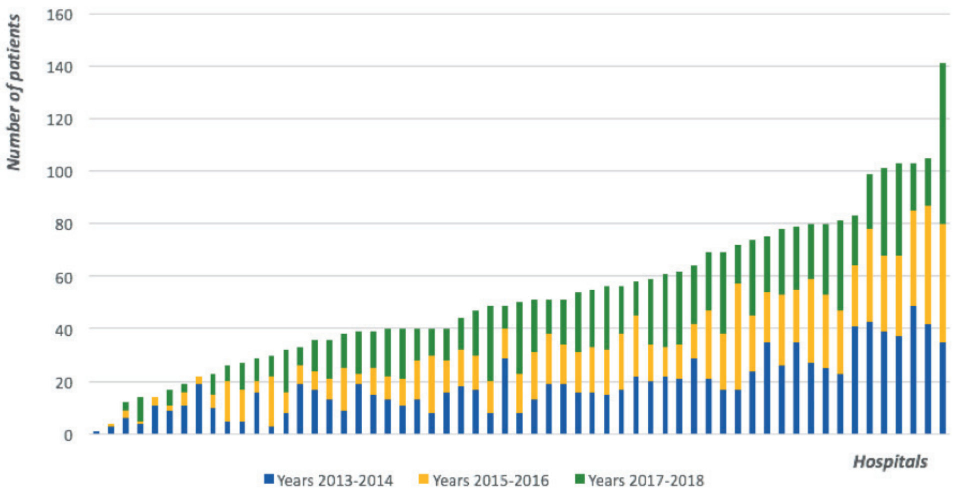
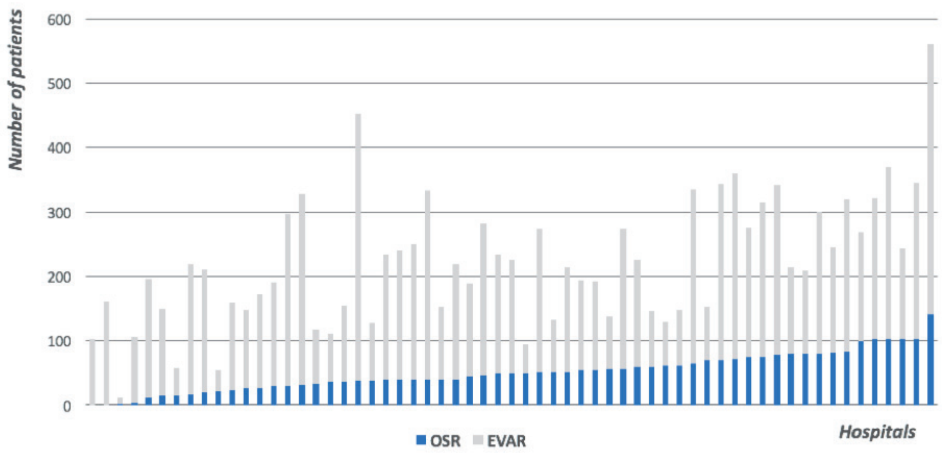


Figure 2. Ratio of elective OSR and EVAR per hospital between 2013-2018



mean, of which 6 hospitals had a total case load of less than 20 procedures in 6 years and a corresponding mortality of 0% and should therefore be left outside consideration. Using a generalized linear mixed model adjusting for sex, age, pulmonary state, preoperative hemoglobin and preoperative creatinine, we found no association between annual hospital volume and postoperative mortality (table 4).

Figure 3. Relation between hospital volume of OSR and case-mix adjusted postoperative mortality

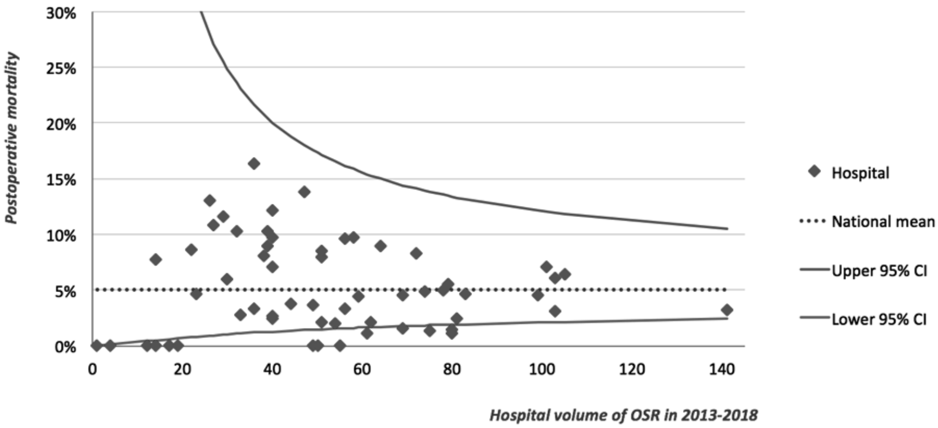


Table 4. The association between hospital volume of OSR per year and postoperative mortality.

Random effects	Variance	SD		
(intercept)	0.09895	0.3146		
Fixed effects	Estimate	SE	Z-value	P
(intercept)	-3.317	0.230	-14.397	<0.001
Volume	-0.009	0.015	-0.589	0.556
Age	0.066	0.013	4.952	<0.001
Gender				
Male	Ref.			
Female	0.439	0.200	2.198	0.028
Pulmonary state				
No dyspnea	Ref.			
Mild dyspnea	0.602	0.186	3.234	0.001
Severe Dyspnea	0.722	0.396	1.823	0.068
Preoperative hemoglobin	-0.191	0.090	-2.131	0.033
Preoperative creatinine	0.004	0.002	2.563	0.010

DISCUSSION

In the Netherlands, elective OSR was performed with a postoperative mortality of 5% (n=156) in 6 consecutive years. Patients with postoperative mortality were more often female, on average 3.6 years older, and had more cardiac and pulmonary co-morbidities, as well as preoperative elevated creatinine and decreased hemoglobin levels. Female sex, increasing age, pulmonary co-morbidities, preoperative hemoglobin and preoperative creatinine levels were independently associated with postoperative mortality after elective OSR. Elective OSR was performed in 59 hospitals in the Netherlands, in which the total elective OSR volume varied from 1 to 141. Although the adjusted postoperative mortality ranged from

0-16%, no hospitals had a significantly higher postoperative mortality. In a generalized linear mixed regression model, annual hospital volume of elective OSR was not associated with postoperative mortality after elective OSR in the current Dutch population.

Studies dated from the pre-EVAR era reported a postoperative mortality after elective OSR varying from 2.7-6.1%.[15-18] Since the introduction of EVAR, the use of elective OSR has decreased over time and as reported in this study is now only performed 22% of elective patients. In the current Dutch population, this group will predominantly consist of AAA patients not suitable for EVAR. With the emerge of national quality registries, nowadays trends in the use of surgical techniques and their outcomes can be monitored on a national level.[2,19] The current postoperative mortality after elective OSR is comparable to the reported mortality prior to the introduction of EVAR. This is remarkable considering that much progress has been made in surgical and perioperative care in the past 25 years. On the other hand, nowadays the OSR group consist of more patients with complex juxta and supra renal aneurysms. However, today one may question whether 5% is an acceptable mortality risk for an elective procedure.

Aiming to further reduce postoperative mortality after elective OSR, a possible solution could be found in the improvement of the selection of patients. Already in the pre-EVAR era, several models were formed, in which patient characteristics were used to predict postoperative mortality after (elective) open AAA surgery.[14,20-22] The widely-used Glasgow Aneurysm Score contained only a small selection of variables where other models, such as the POSSUM and Leiden score, were more extensive. Patient characteristics corresponding in these models were: age, myocardial disease, and renal failure. Notable is that the Leiden score was the only one that included sex as a predictive factor. As we hypothesized that the introduction of EVAR made patients undergoing elective OSR a select group of patients, we were interested in the factors associated with postoperative mortality in this current population. In addition to age and renal failure, sex, pulmonary comorbidities and preoperative hemoglobin were found to be associated with postoperative mortality.

The declining use of elective OSR and the absence of a minimum volume standard specific for elective OSR, has led to the situation in the Netherlands that 59 hospitals perform elective OSR with an annual volume that ranges between 1-33 procedures between hospitals. Since previous studies have demonstrated a relationship between hospital volume and outcomes, hospital volume seemed a logical variable to investigate for quality improvement within the DSAA.[23,24] Additionally, a minimum standard of 10 elective OSR per hospital per year is added in the latest SVS guideline.[10] In contrast to the previous studies, we found no statistically significant association between hospital volume of OSR per year and postoperative mortality in all (n = 3100) Dutch elective OSR patients operated in 59 hospitals over a 6-year period. A possible explanation for this difference is that in some previous studies single regression analysis were used, where in our opinion, mixed models would be more appropriate, as it accounts for the unmeasured factors corresponding between patients treated in the same hospital.[25] Additionally, the difference could be explained by the fact that some studies used the total procedural volume of OSR (elective and acute) as the OSR hospital volume, as the performance of acute OSR would contribute to the experience with OSR.[24] We have deliberately chosen to use only the number of elective OSR because we believe hospitals should perform OSR sufficiently in an elective setting to be able to perform OSR in ruptured patients. Furthermore, we have not included the number of EVAR procedure in this analysis, because this is a completely different intervention and the ratio of OSR/EVAR differs greatly between hospitals, as illustrated in figure 2.

The lack of a significant association between volume of OSR and postoperative mortality, could not substantiate a new volume standard for elective OSR for the Netherlands. However, this does not alter the fact that hospital volume is still an important topic of discussion within quality measurement. When a surgical procedure is performed relatively infrequently by a hospital, mortality or the absence of it says little about whether the next patient can be treated safely. A funnel plot might give the impression that all hospitals perform well, namely not significantly different from the national average, but actually we are not really sure. When lowering the mortality standard to an imaginary mortality of 3% (appendix 1), the confidence intervals only shift slightly downwards, so that fewer hospitals perform significantly better. However, the differences in outcome between hospitals do not change.

In the search for a suitable volume standard for elective OSR, we additionally turned the question around. Instead of looking at what volume is needed for better postoperative outcomes, we looked for the volume needed to show that hospitals are doing well enough and to be able to detect significant worsening of outcomes. As an example, appendix 2. shows the number of cases (per hospital) needed on the x-axis versus the power of detecting a difference in mortality, in which the lines represent the alternative mortality (6%, 7%, etc.) in a hospital compared to the average national mortality of 5%. The values at which the limits of such a statistical model should be set, remain to be discussed. Though, even with this method, the hospital volumes needed to observe differences in outcome are not feasible in the current practice, not even with more centralization of OSR care. Nevertheless, in a more centralized situation, with higher volume of OSR per hospital, it may be possible that an association between volume and postoperative mortality can be found. Additionally, in a shift towards more centralization of OSR surgery, it may also be conceivable that not all vascular surgeons within a team will still perform OSR, but only by those with sufficient exposure. However, as the DSAA focuses solely on the numbers results of the entire team rather than the individual surgeon, we have no data to support this notion.

CONCLUSION

In the Netherlands, elective OSR for AAA has a mortality of 5%. Female sex, increasing age, pulmonary state, preoperative hemoglobin and creatinine were independently associated with postoperative mortality. Annual hospital volume of elective OSR was not associated with postoperative mortality in the current population of the DSAA. Based on this study we cannot substantiate a minimum volume standard for elective OSR.

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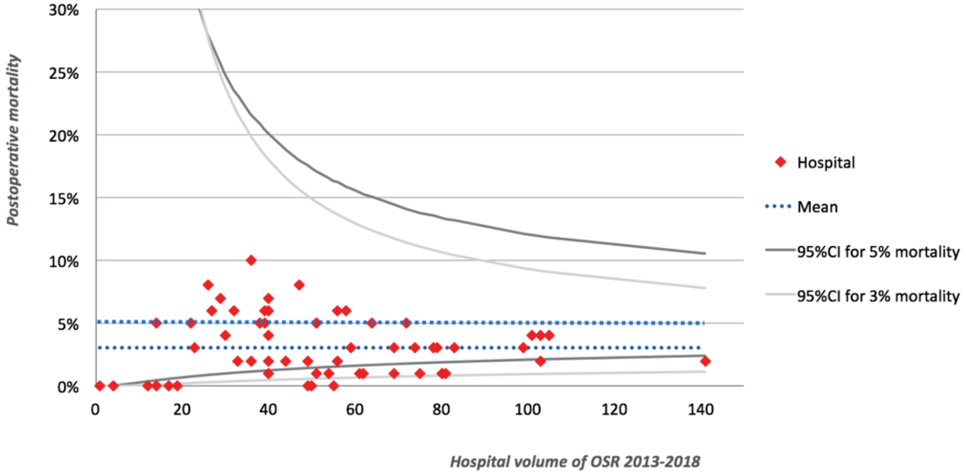
Appendix 1. Relation between hospital volume of OSR and case-mix adjusted postoperative mortality compared to the national mean of 3% and 5% mortality.



Appendix 2. Number of cases needed per hospital to detect alternative mortality rates compared to the current national mean of 5%