Association of Hospital Volume with Perioperative Mortality of Endovascular Repair of Complex Aortic Aneurysms

A Nationwide Cohort Study

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Objective: We evaluate nationwide perioperative outcomes of complex EVAR and assess the volume-outcome association of complex EVAR.

Summary of Background Data: Endovascular treatment with fenestrated (FEVAR) or branched (BEVAR) endografts is progressively used for excluding complex aortic aneurysms (complex AAs). It is unclear if a volumeoutcome association exists in endovascular treatment of complex AAs (complex EVAR).

Methods: All patients prospectively registered in the Dutch Surgical Aneurysm Audit who underwent complex EVAR (FEVAR or BEVAR) between January 2016 and January 2020 were included. The effect of annual hospital volume on perioperative mortality was examined using multivariable logistic regression analyses. Patients were stratified into quartiles based on annual hospital volume to determine hospital volume categories.

Results: We included 694 patients (539 FEVAR patients, 155 BEVAR patients). Perioperative mortality following FEVAR was 4.5% and 5.2% following BEVAR. Postoperative complication rates were 30.1% and 48.7%, respectively. The first quartile hospitals performed <9 procedures/ yr; second, third, and fourth quartile hospitals performed 9–12, 13–22, and ≥23 procedures/yr. The highest volume hospitals treated significantly more complex patients. Perioperative mortality of complex EVAR was 9.1% in hospitals with a volume of <9, and 2.5% in hospitals with a volume of ≥13 (P = 0.008). After adjustment for confounders, an annual volume of ≥13 was associated with less perioperative mortality compared to hospitals with a volume of <9.

Conclusions: Data from this nationwide mandatory quality registry shows a significant effect of hospital volume on perioperative mortality following complex EVAR, with high volume complex EVAR centers demonstrating lower mortality rates.

Keywords: complex AAA, endovascular, mortality, volume-outcome

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Since the inception of endovascular treatment of abdominal aortic aneurysms (AAAs), endovascular management of complex aortic aneurysms has been of interest, as open surgical procedures are associated with significant mortality and morbidity.[1,2] Complex aortic aneurysms are defined as those including the renal or visceral segment of the aorta.[3] Traditionally, complex aortic aneurysms were treated with open surgical repair (OSR), including suprarenal or supravisceral clamping, since the first generation endografts were unsuitable to treat these aneurysms.[3] Due to reduced mortality and morbidity,[3,4] treatment with fenestrated endovascular aortic aneurysm repair (FEVAR) or branched endovascular aortic aneurysm repair (BEVAR) is progressively used for excluding complex aortic aneurysms.[5,6] Nowadays, many patients with complex aortic aneurysms, including those who are unfit for OSR, are successfully treated with FEVAR or BEVAR (complex EVAR).[7] Vascular registry data are essential to assess outcomes of new procedures.[8] This is especially relevant for complex EVAR, since randomized controlled trials have not been performed on this matter. Literature on data of FEVAR/BEVAR exists, albeit predominantly from centres of excellence.[2,9] Nationwide outcomes of FEVAR or BEVAR reflecting daily clinical practice have not been reported yet.

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FEVAR and BEVAR are considered technically complex procedures, performed in a fragile patient category. The potential influence of hospital volume on perioperative outcomes of these interventions is, therefore, a subject of interest,[4,10] especially since an increase in hospital volume has been shown to improve outcomes in other aortic interventions.[11–13] In contrast to AAA repair, both the most recent European Society for Vascular Surgeon (ESVS) guidelines and Society for Vascular Surgery (SVS) guidelines do not advise a minimum caseload per year for complex EVAR.[14–17] Research has established that a volume–outcome relationship exists in open juxtarenal AAA repair[18] and in thoracoabdominal aortic aneurysm repair,[19,20] but it is unclear if a volume–outcome relationship exists in FEVAR[4,10] or BEVAR patients.

This study evaluated the nationwide perioperative outcomes of patients who underwent complex EVAR (FEVAR or BEVAR) using data from a mandatory nationwide quality registry. Furthermore, we assessed the association of hospital volume with perioperative mortality of complex EVAR.

METHODS

Study Design and Data Source

The dataset was retrieved from the Dutch Surgical Aneurysm Audit (DSAA), which is a mandatory and prospective quality registry of aneurysm surgery performed by vascular surgeons. Since 2013, the DSAA prospectively registers all primary abdominal aortic interventions in the Netherlands. Since 2016, endovascular complex aortic aneurysm repair (complex EVAR), including FEVAR and BEVAR, secondary aortic surgery, and/or thoracic or thoracoabdominal aortic aneurysm repair are registered as well. Data verification was conducted through a random sample of hospitals, indicating high reliability of the data.[21,22] Case-ascertainment was 98.4% in a subgroup of 14 hospitals investigated, and completeness of data was verified including mortality and complications.[21,22] The steering committee of the DSAA approved the study protocol. Ethical approval or informed consent was not required for this study according to Dutch law as the data were anonymised. The data in our study was retrospectively analysed and reported according to the STROBE Statement.[23]

Study Population

All patients that underwent endovascular repair (FEVAR and BEVAR) for an intact complex aortic aneurysm and who were registered in the DSAA between January 1, 2016 and December 31, 2019 were included in this study. Patients that underwent endovascular aortic arch repair were not included in this study. Patients were excluded when data was missing in variables date of birth, date of surgery, sex, and survival status at the time of discharge or 30-days postoperatively. For analyses regarding the total hospital volume of EVAR, all endovascular aortic interventions that were performed in those hospitals that performed complex EVAR between January 1, 2016 and December 31, 2019 were included as well.

Definitions

A patient receiving surgery in two planned stages was included twice in the DSAA and was allocated to the group (FEVAR or BEVAR) of the first intervention. For patient characteristics, length of hospital stays and length of stay at the ICU, the details of the first intervention were reported, for other perioperative outcomes, the outcomes of both stages were reported as one outcome. Variables 'Cardiac comorbidity' and 'Pulmonary comorbidity' were based on the V-POSSUM[24] from 2016–2018, and were based on ICD–10 codes in 2019 (Supplemental Digital Content Table 1, http:// links.lww.com/SLA/D560). The details in these variables were stratified per patient into the categories 'absent' or 'present'.

Hospital Volume

Hospital volume of complex EVAR (FEVAR and BEVAR) was calculated per year and over the 4-year study period, and was reported as the number of patients that underwent an intervention. Hospital volume of total endovascular aortic interventions (per year and over the 4-year study period) was defined as the number of patients that underwent FEVAR and BEVAR, and the total number of all endovascular aortic interventions (which included all endovascular repairs for ruptured aortic aneurysms, and conventional EVARs and TEVARs). Patients were stratified into quartiles based on the (annual) volume of the hospital in which they underwent complex EVAR to determine the cut–off points for the categories of hospital volumes.

Outcomes

The primary outcome of this study was perioperative mortality. Perioperative mortality was defined as 30-day mortality and inhospital mortality and included mortality following both stages of complex EVAR when applicable. Secondary outcomes were other perioperative outcomes that occurred within 30 days after complex EVAR (postoperative complications, intraoperative complications, length of stay at ICU, length of hospital stay, reinterventions, readmissions, major complication, and failure to rescue), the association between hospital volume and perioperative mortality, and other factors associated with perioperative mortality. Major complications were defined as either intraoperative or perioperative complications that caused a prolonged stay (threshold: FEVAR: >7 days, BEVAR: >9 days), reintervention, or death.[25] Failure to rescue was defined as the number of patients that died perioperatively divided by the number of patients with a major complication.[25] The annual and overall hospital volume of complex EVAR, all endovascular aortic interventions, FEVAR, and BEVAR, were examined to assess the association between hospital volume and perioperative mortality.

Statistical Methods

Patients and aneurysm characteristics and outcomes of both FEVAR and BEVAR were analysed using descriptive statistics. Patient and aneurysm characteristics and outcomes were stratified according to the quartiles of the annual hospital volume of complex EVAR. Differences in categorical variables were tested with Chi-square tests or Fisher exact tests. The distribution of continuous variables was examined with histograms and Q-Q plots. T-tests were used for normally distributed variables and Mann-Whitney *U*-tests otherwise. A *P*-value of ≤ 0.050 was considered statistically significant.

Univariable and multivariable logistic regression analyses were performed to examine the association between annual hospital volume (based on quartiles) of complex EVAR and perioperative mortality and to identify factors associated with mortality. Covariates used for this analysis were age, sex, pulmonary and cardiac comorbidity, creatinine, haemoglobin, referral, aneurysm diameter, location of the aneurysm, type of surgery, urgency, procedure, number of targeted vessels, and annual hospital volume. The lowest quartile of hospital volume

TABLE 1. Patient Characteristics, Aneurysm Morphology, and Operative Data of Patients Following Complex EVAR (FEVAR and BEVAR)

	Complex EVAR*	FEVAR	BEVAR
Number of patients	694	539	155
Number of interventions	705	545	160
Number of hospitals	28		
Age, yr	73.5 ± 6.6	73.8 ± 6.7	72.3 ± 6.2
Sex: female	128 (18.4)	69 (12.8)	59 (38.1)
Preoperative pulmonary comorbidity			
Absent	453 (66.3)	362 (68.2)	91 (59.9)
Present	230 (33.7)	169 (31.8)	61 (40.1)
Unknown/missing	11	8	3
Preoperative cardiac comorbidity			
Absent	160 (23.2)	129 (24.1)	31 (20.1)
Present	530 (76.8)	407 (75.9)	123 (79.9)
Unknown/missing	4	3	1
Preoperative creatinine, μmol/L	95 [79–114]	96 [82–114]	88 [72–115]
Unknown/missing	26	23	3
Preoperative hemoglobin, mmol/L	8.5 ± 1.0	8.6 ± 1.0	8.3 ± 1.0
Unknown/missing	21	20	1
Aneurysm diameter, mm	63.7 ± 9.4	62.8 ± 9.2	66.8 ± 9.5
Unknown/missing	6	5	1
Location of the aneurysm			
Abdominal: juxtarenal or infrarenal	396 (57.2)	379 (70.6)	17 (11.0)
Abdominal: suprarenal	65 (9.4)	58 (10.8)	7 (4.5)
Thoracoabdominal	231 (33.4)	100 (18.6)	131 (84.5)
Abdominal: unspecified/aorto–iliac	2	2	0
Type of surgery			
Primary	527 (75.9)	409 (75.9)	118 (76.1)
Secondary aortic intervention	167 (24.1)	130 (24.1)	37 (23.9)
Pathogenesis: primary repair			
Atherosclerosis	460 (87.3)	358 (87.5)	102 (86.4)
Inflammatory	4 (0.8)	4 (1.0)	0 (0.0)
Infectious	4 (0.8)	2 (0.5)	2 (1.7)
Dissection	12 (2.3)	7 (1.7)	5 (4.2)
Connective tissue disease	2 (0.4)	2 (0.5)	0 (0.0)
Unknown	45 (8.5)	36 (8.8)	9 (7.6)
Pathogenesis: secondary aortic intervention			
Infected prosthesis	2 (1.2)	1 (0.8)	1 (2.7)
Endoleak	88 (52.7)	77 (59.2)	11 (29.7)
False aneurysm	7 (4.2)	7 (5.4)	0 (0.0)
New aneurysm†	18 (10.8)	12 (9.2)	6 (16.2)
Progression of aneurysmatic disease	52 (31.1)	33 (25.4)	19 (51.4)
Urgency			
Elective	682 (98.3)	536 (99.4)	146 (94.1)
Urgent intact	12 (1.7)	3 (0.6)	9 (5.9)
Number of targeted vessels			
1–2	136 (19.6)	126 (23.4)	10 (6.5)
3	252 (36.4)	218 (40.5)	34 (21.9)
≥ 4	305 (44.0)	194 (36.1)	111 (71.6)
Unknown/missing	1	1	0

Values are presented as n (%), mean (SD), or median (interquartile range).
*Complex EVAR: FEVAR and BEVAR.
†aneurysm on different anatomical location than for which the primary procedure was done.

was used as the reference category. Variables with a *P*-value ≤0.10 in univariable analysis and variables that were considered clinically relevant were included in the multivariable analysis, and outcomes were reported in (adjusted) odds ratios with 95%–CI confidence intervals. Moreover, a multivariable logistic regression model with a restricted cubic spline using 4 knots that account for a non-linear relationship was created to visualize the association between annual hospital volume of complex EVAR and mortality.[26] The associations between hospital volume (continuous and based on quartiles) of all endovascular aortic interventions, hospital volume of FEVAR, hospital volume of BEVAR, and perioperative mortality were examined with univariable analyses.

All analyses were carried out using R, version 4.0.2.

RESULTS

In total, 15817 patients that underwent 16335 interventions in 61 Dutch hospitals were registered in the DSAA between January 1, 2016 and December 31, 2019. In these patients, 706 complex EVAR repairs were registered. After excluding one patient with an unknown survival status, 705

TABLE 2. Perioperative Outcomes of Patients Following Complex EVAR (FEVAR and BEVAR)

	Complex EVAR*	FEVAR	BEVAR
Number of patients	694	539	155
Perioperative mortality	32 (4.6)	24 (4.5)	8 (5.2)
Postoperative complication	232 (33.4)	162 (30.1)	70 (45.2)
Abdominal complication	30 (4.3)	25 (4.6)	5 (3.2)
Pulmonary complicaton	59 (8.5)	44 (8.2)	15 (9.7)
Cardiac complication	30 (4.3)	22 (4.1)	8 (5.2)
Neurological complication	55 (7.9)	32 (5.9)	23 (14.8)
Paraplegia	21 (3.0)	13 (2.4)	8 (5.2)
Stroke	7 (1.0)	4 (0.7)	3 (1.9)
Prosthesis/reconstruction related	17 (2.4)	11 (2.0)	6 (3.9)
Rebleeding	21 (3.0)	13 (2.4)	8 (5.2)
Renal	36 (5.2)	30 (5.6)	6 (3.9)
Wound	14 (2.0)	9 (1.7)	5 (3.2)
Arterial occlusion	26 (3.7)	16 (3.0)	10 (6.5)
Infection	22 (3.2)	10 (1.9)	12 (7.7)
Other	56 (8.1)	39 (7.2)	17 (11.0)
Intraoperative complication	91 (13.1)	64 (11.9)	27 (17.4)
Cardiopulmonary resuscitation/myocardial infarction	1 (0.1)	0 (0.0)	1 (0.6)
Occlusion of side branch	15 (2.2)	12 (2.2)	3 (1.9)
Type 1 endoleak	17 (2.5)	13 (2.4)	4 (2.6)
Type 3 endoleak	7 (1.0)	4 (0.7)	3 (1.9)
Other	49 (7.1)	35 (6.5)	16 (10.3)
Intraoperative mortality	1 (0.1)	1 (0.2)	0 (0.0)
Missing	1	1	0
Length of stay at ICU	1 [0–2]	1 [0–1]	2 [1–3]
Missing	2	2	0
Length of hospital stay	5 [3–7]	4 [3–7]	6 [4–10]
Missing	9	7	2
Reinterventions	81 (11.7)	48 (8.9)	33 (21.3)
Endovascular	21 (3.0)	12 (2.2)	9 (5.8)
Percutaneous	6 (0.9)	3 (0.6)	3 (1.9)
Endoscopic	1 (0.1)	1 (0.2)	0 (0.0)
Thoraco–laparoscopic	28 (4.0)	16 (3.0)	12 (7.7)
Open	69 (9.9)	16 (3.0)	9 (5.8)
Readmission	69 (9.9)	52 (9.6)	17 (11.0)
Major complication	159 (22.9)	112 (20.8)	47 (30.3)
Failure to rescue	32/159 (20.1)	24/112 (21.4)	8/47 (17.0)

Values are presented as n (%), or median (interquartile range). The specific complications included in the categories of postoperative complications are shown in Supplemental Digital Content Table 2, http://links.lww.com/SLA/D561.

*Complex EVAR: FEVAR and BEVAR.

complex EVAR repairs from 28 hospitals were included in this study. In 11 patients, two interventions were registered (median time between these two interventions was 70 days, IQR 33.5–118 days), and thus 694 patients were included for further analysis. Of these patients, 539 underwent FEVAR, and 155 underwent BEVAR. For analyses regarding the overall hospital volume of endovascular aortic interventions, 6438 other endovascular aortic interventions were included (Fig. 1).

Patient and Aneurysm Characteristics

An overview of the patient characteristics of all patients as well as stratified for FEVaR and BEVAR is shown in Table 1. The mean age of the FEVAR patients was 73.8 years, and the mean age of BEVAR patients was 72.3 years. In FEVAR patients, 12.8% were female, and in BEVAR patients, 38.1% were female. Most patients had cardiac comorbidity (FEVAR: 75.9%, BEVAR; 79.9%). The majority of the patients were referred by another hospital (FEVAR: 50.3%, BEVAR: 67.7%). Inthe FEVAR group, most patients (70.6%) were treated for a juxtarenal or infrarenal aneurysm, and in the BEVAR group, most patients were treated for a thoracoabdominal aneurysm (84.5%). Of all patients, 75.9% underwent a primary repair, mainly due to atherosclerosis (87.3%).

Perioperative Outcomes

Table 2 shows that the perioperative mortality was 4.5% following FEVAR and 5.2% following BEVAR. Postoperative complication rates were 30.1% following FEVAR and 45.2% following BEVAR. Of all FEVAR patients, 5.9% had a neurological complication (2.4% paraplegia, 0.7% stroke), while 14.8% had a neurological complication following BEVAR (5.2% paraplegia, 1.9% stroke). Intraoperative complications occurred in 11.9% following FEVAR and in 17.4% following BEVAR. The median length of hospital stay was 4 days following FEVAR and 6 days following BEVAR. The reintervention rate was 8.9% following FEVAR and 21.3% following BEVAR.

Hospital Volumes

Fig. 2 shows the number of patients that underwent FEVAR and BEVAR per hospital. The median annual hospital volume of complex EVAR was 13 patients [IQR 9–23], and the median hospital volume during the 4-year study period was 55 patients [IQR 35–76]. Supplemental Digital Content Figure 1, http://link-s.lww.com/SLA/D558 shows the number of endovascular aortic interventions in hospitals that performed FEVAR and BEVAR. The median overall hospital volume of all endovascular aortic interventions was 304 interventions

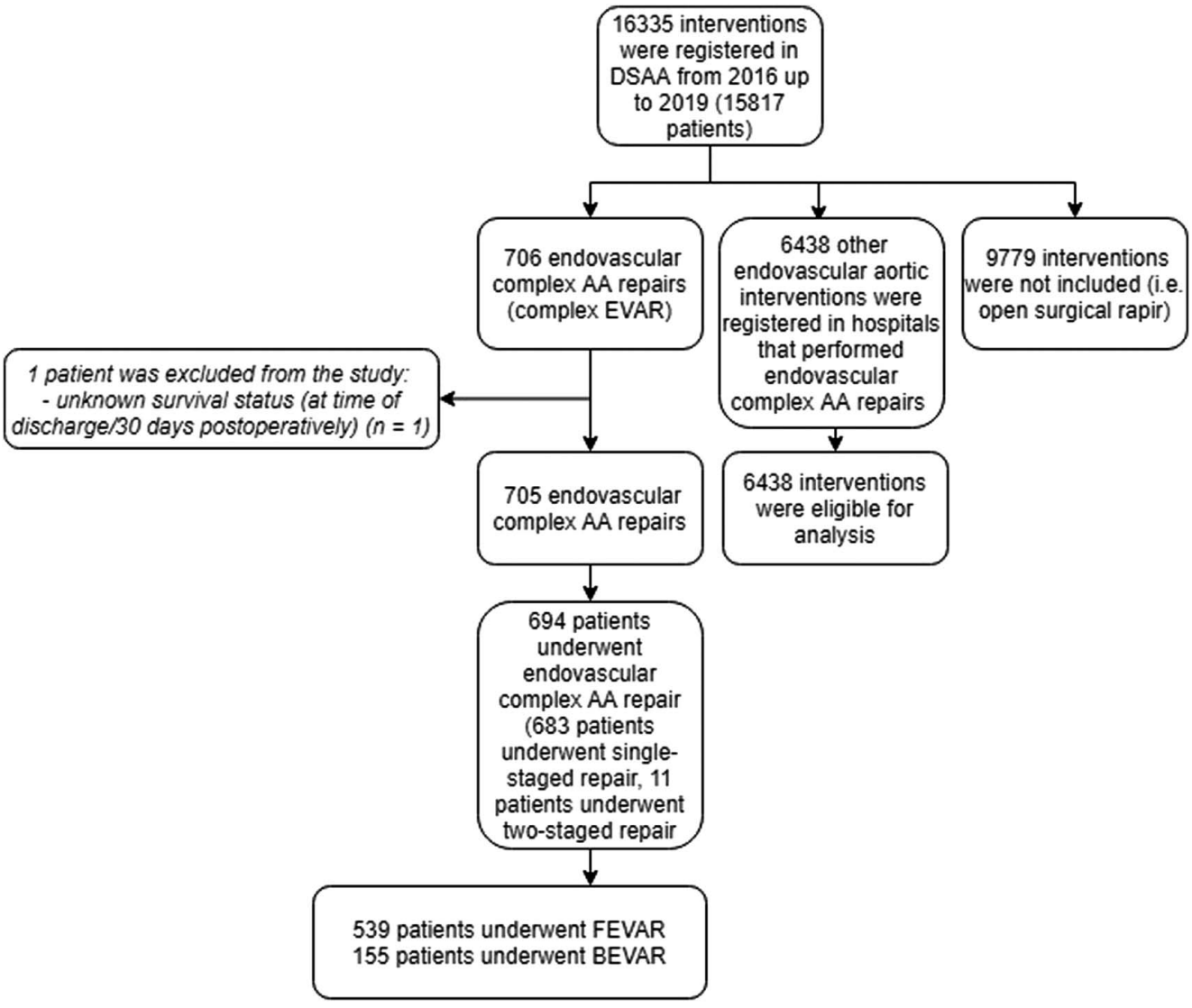

FIGURE 1. Flow chart of included patients that underwent complex EVAR (FEVAR and BEVAR).

(IQR 207–357), and the median annual hospital volume was 72 interventions (IQR 52–90). Details regarding volume of FEVAR and BEVAR per hospital are shown in Supplemental Digital Content Table 3, http://links.lww.com/SLA/ D562.

Patient and Aneurysm Characteristics and Perioperative Outcomes, Stratified per Quartile of Annual Hospital Volume of Complex EVAR

Patient and aneurysm characteristics and perioperative outcomes, stratified per quartile of annual hospital volume of complex EVAR, are shown in Supplemental Digital Content Table 4, http:// links.lww.com/SLA/D563. In 2019, 13/23 hospitals treated less than 9 patients. In hospitals with an annual volume of <9, 9.5% of the patients were female, while in hospitals with an annual volume of ≥23,24.9% were female. The percentage of cardiac comorbidity was higher in hospitals with a higher annual volume. In hospitals with an annual volume of ≥23, 66.2% of the patients were referred by another hospital. Hospitals with a higher annual volume performed more BEVAR and more secondary aortic interventions than lower– volume hospitals. Perioperative mortality rates were 9.1% in hospitals with an annual volume <9, 5.4% in hospitals with an annual volume of 9–12, and 2.5% in hospitals with an annual volume of 1322 and ≥23 (P = 0.008) (shown in Supplemental Digital Content Figure 2, http://links.lww.com/SLA/D559). The percentage of postoperative complication rates did not differ between the hospital volume categories (35.2%, 31.0%, 33.7%, and 33.3% in hospitals with an annual volume of <9, 9–12, 13–12, and ≥23). Also, the percentage of major complications and failure to rescue did not differ statistically significantly between the hospital volume categories (Supplemental Digital Content Table 4, http://links.lww.com/SLA/ D563).

Association of Annual Hospital Volume of Complex EVAR with Mortality

Factors associated with mortality following univariable and multivariable analysis are shown in Table 3. An annual volume of complex EVAR of 13–22 and ≥23 was significantly associated with

TABLE 3. Univariable and Multivariable Analyses to Assess Whether Annual Hospital Volume of Complex EVAR (FEVAR + BEVAR) is Associated With Increased Perioperative Mortality of Complex EVAR

		Univariable analysis		Multivariable analysis	
	No. of patients	**OR (95%–CI)**	***P***	**aOR (95%–CI)**	***P***
Annual volume of complex EVAR					
<9	165	Ref.		Ref.	
9–12	129	0.57 (0.21–1.41)	0.24	0.44 (0.16–1.12)	0.096
13–22	199	0.26 (0.08–0.68)	0.010	0.11 (0.02–0.37)	0.001
≥23	201	0.26 (0.08–0.67)	0.010	0.14 (0.04–0.42)	<0.001
Age, yr		1.03 (0.98–1.09)	0.256		
Sex					
Male	566	Ref.		Ref.	
Female	128	2.30 (1.35–3.85)	0.002	3.37 (1.77–6.43)	<0.001
Pulmonary comorbidity					
Absent	453	Ref.		Ref.	
Present	230	1.91 (0.92–3.94)	0.081	1.75 (0.79–3.85)	0.164
Missing	11				
Cardiac comorbidity					
Absent	160	Ref.			
Present	530	1.04 (0.46–2.65)	0.935		
Missing	4				
Preoperative creatinine		1.003 (0.998–1.007)	0.151		
Preoperative haemoglobin		0.85 (0.53–1.04)	0.085	0.77 (0.53–1.13)	0.177
Referral					
General practitioner	124	Ref.			
Emergency department	10	1.86 (0.09–12.22)	0.582		
Other hospital	373	0.80 (0.34–2.11)	0.625		
Medical specialist in own hospital	181	0.67 (0.22–2.01)	0.469		
Missing	6				
Aneurysm diameter		1.03 (0.996–1.07)	0.074	1.05 (1.00–1.09)	0.024
Location of the aneurysm					
Abdominal: juxtarenal or infrarenal	396	Ref.			
Abdominal: suprarenal	65	0.75 (0.11–2.74)	0.711		
Thoracoabdominal	231	1.53 (0.72–3.21)	0.256		
Type of surgery					
Primary	522	Ref.			
Secondary aortic intervention	167	0.72 (0.26–1.66)	0.473		
Urgency					
Elective	682	Ref.			
Urgent intact	12	1.91 (0.10–10.29)	0.542		
Procedure*					
FEVAR	539	Ref.		Ref.	
BEVAR	155	1.17 (0.48–2.55)	0.711	0.71 (0.24–1.82)	0.492
Number of targeted vessels					
1–2	136	Ref.			
3	252	0.45 (0.14–1.38)	0.158		
≥ 4	305	1.22 (0.52–3.20)	0.656		
Missing	1				

CI indicates confidence interval; OR, odds ratio; aOR, adjusted odds ratio.
*Included in multivariable analysis due to clinical relevance.

less mortality compared to an annual volume of <9 after adjustment for confounders (13–22: aOR 0.11, 95%–CI 0.02–0.37, ≥23: aOR 0.14, 95%–CI 0.04–0.42, ref: <9). Other factors associated with mortality were female sex (aOR 3.37, 95%–CI 1.77–6.43) and aneurysm diameter (aOR 1.05, 95%–CI 1.00–1.09). Fig. 3 shows the restricted cubic spline, which visualizes the non–linear association between annual hospital volume and mortality of complex EVAR after adjustment for confounders.

Association of (Annual and Overall) Hospital Volume of FEvAr, BEVAR, and all Endovascular Aortic Interventions with Mortality

Supplemental Digital Content Table 5, http://links.lww.com/ SLA/D564 shows that an overall volume of complex EVAR of 3554, 55–75, and ≥76 in 4 years was associated with less mortality compared to an overall volume of <35. In FEVAR patients, a higher overall volume, as well as a higher annual volume, were associated with less mortality in FEVAR patients. In BEVAR patients, no associations between hospital volume and mortality were found, likely due to a low number of BEVAR patients. An overall volume of 207–303 total endovascular aortic interventions was associated with less perioperative mortality of complex EVAR compared to an overall volume of ≤207, while higher overall volumes (304–346, ≥347) were not associated with less mortality compared to an overall volume of 207–303. Moreover, a higher annual volume of total endovascular aortic interventions was not associated with less mortality of complex EVAR.

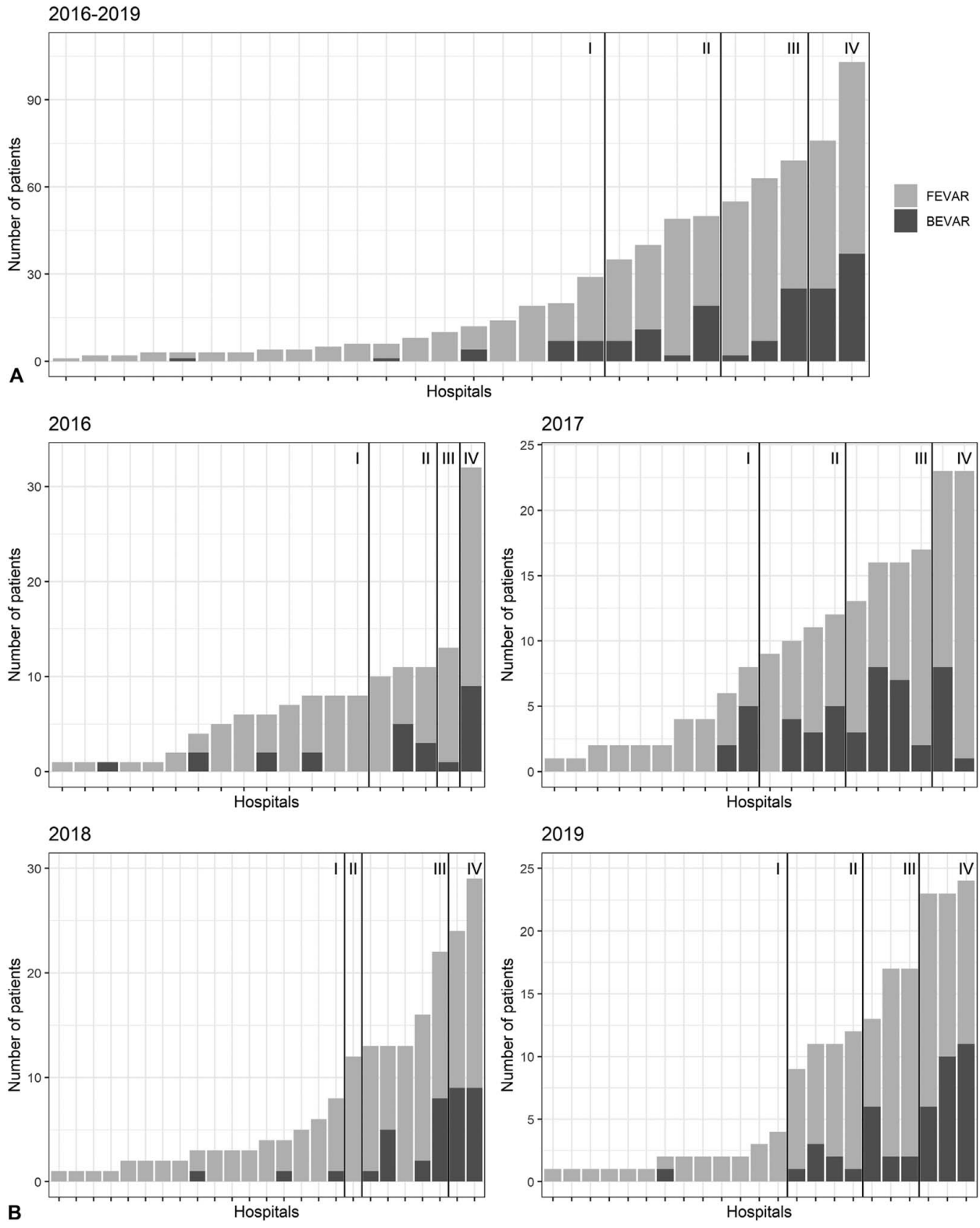

FIGURE 2. (A) Overall number of patients per hospital that underwent complex EVAR (FEVAR and BEVAR), including quartiles of overall hospital volume (I: <35, II: 35–54, III: 55–75, IV: ≥76). (B) Annual number of patients per hospital that underwent complex EVAR (FEvAr and BEVaR), including quartiles of annual hospital volume (I: <9, II: 9–12, III: 13–22, IV: ≥23).

DISCUSSION

This population-based study that includes data from a nationwide mandatory quality registry describes the association between hospital volume and mortality in patients that underwent complex EVAR (FEVAR and BEVAR). In the entire cohort, the perioperative mortality rate was 4.6%. In the Dutch setting, perioperative mortality rates of complex EVAR were 2.5% in hospitals with an annual volume of complex EVAR of 13 or more, while perioperative mortality rates were 9.1% in hospitals with an annual volume of less than 9. After adjustment for confounders, an annual hospital volume of complex EVAR of 13–22 and ≥23 was significantly associated with lower perioperative mortality compared to an annual hospital volume of <9.

The perioperative mortality as reported in our study seems to be consistent with the literature. However, no results of complex EVAR from a mandatory nationwide quality registry have been published previously, which makes it challenging to make a valid comparison with other studies as smaller cohort studies are more prone to selection bias and heterogeneity in reporting. Furthermore, these former studies mainly describe outcomes from centers of excellence. A meta-analysis reporting on endovascular TAAA repair (branched or fenestrated endografts) described hospital mortality or 30-day mortality of 7.4%,[27] and a meta-analysis describing FEVAR of juxtarenal aneurysms reported a pooled early postoperative mortality of 3.3%.[28] Recent published large observational cohort studies, not included in the meta-analyses, reported perioperative mortality rates of 1.8–3.9% following FEVAR[9,24,29] and 2.7% following a physician modified endograft,[29] while mortality rates of F/BEVAR for thoracoabdominal aortic aneurysms as reported by German administrative data were 9.2%.[19] Although our study also includes less favourable results of low-volume hospitals, the 4.6% overall mortality rate is in line with previous literature but could potentially improve further with centralisation of care.

Previous studies reporting the association between hospital volume and mortality in complex EVAR (FEVAR and BEVAR) did not show any hospital volume-outcome relationship. One observational study that compared low-volume (< 4 FEVAR/year) and high-volume (4–6 FEVAR/year) hospitals did not demonstrate a hospital volume-outcome relationship of FEVAR,[4] and a recent systematic review found no evidence of whether hospital volume affects mortality in FEVAR patients.[10] Our study describes the results of complex EVAR from a mandatory nationwide registry and examines the association between hospital volume and perioperative mortality of complex EVAR. This nationwide study design is important in revealing the association between hospital volume and mortality as no minimum number of complex EVAR was required in the Netherlands during the study period, and consequently, many low- volume hospitals were included. Furthermore, the substantial risk of complex EVAR on perioperative mortality might also have played a role in revealing a volume-outcome relationship.[30] Other studies reporting on thoracic aortic aneurysms (TAAs) and thoracoabdominal aortic aneurysms (TAAAs) did describe the influence of hospital volume on perioperative outcomes. A high annual hospital volume (≥13) of thoracic aortic aneurysms (TAAs), treated with FEVAR/BEVAR, open surgical repair, or hybrid, was significantly associated with less mortality.[19] Moreover, lower morbidity and mortality was shown in high volume hospitals (annual volume > 22) performing complex EVAR including TEVAR for thoracoabdominal aortic aneurysms .[20] Also, a low annual hospital volume (< 9) of open juxtarenal repair was associated with higher perioperative mortality.[18]

Several studies have shown associations between the number of aortic interventions and outcomes.[12,13,31] Since infrarenal endovascular aneurysm repair has been centralized in the United Kingdom, mortality rates following these interventions have dropped from 1.5% to 0.9% following EVAR and from 5.4% to 4.0% following OSR.[11] Defining the optimal threshold or cut-off is difficult and might differ between countries.[32–34] Therefore, it is vital to investigate the volume-outcome associations of complex EVAR in specific healthcare systems. Other countries (USA, UK, Germany) do not have any specific requirements for a minimum hospital volume of complex EVAR.[35,36] The reason for this is that there is no scientific data on this subject, as our paper is the first describing a volume-outcome relationship for complex endovascular aortic procedures. The data derived from this study seems to indicate that one should not perform fewer than nine complex procedures per hospital annually in the Netherlands and that an annual volume of at least 13 complex EVAR procedures seems to result in better outcomes. Furthermore, in our spline diagram the reduction of mortality is even observed until 20 cases per year. Therefore, as in many surgical procedures and outcomes: annual caseload does matter. Above this volume, there is very little incremental benefit in perioperative mortality by increasing center volume. In addition, a minimum number of total endovascular aortic interventions does not seem to be essential for low mortality rates of complex EVAR. Complex EVAR procedures are technically complex procedures, and it could be hypothesized that specific expertise from the vascular surgeon and team in treating complex EVAR is more important than a high institutional knowledge created by a high volume of standard EVAR. Finally, although failure to rescue appeared higher in low-volume hospitals (38.5%), the difference in failure to rescue between the volume categories was not statistically significant. This could be a result of treating more complex aneurysmal disease as well as patients with more comorbidities in higher volume hospitals masking the true effect of failure to rescue on hospital mortality. It is described that in intact AAA-repairs, an increase in hospital volume is significantly associated with less failure to rescue, which could be caused due to prompt recognition and management of complications in large volume hospitals.[31]

Spinal cord ischemia as well as cerebral embolism are the most feared complications following management of thoracic aortic aneurysms[15] and complex aortic aneurysms.[37] Previous studies have reported paraplegia rates of 4.1% and 5.2% following FEVAR and BEVAR,[27,37] which is in accordance with our present results. Also, the stroke rates following FEVAR and BEVAR reported by this study were consistent with the literature.[38,39] The reintervention rate is frequently reported when endovascular repair is compared with open surgical repair. Interestingly, this study reported a considerable number of reinterventions within 30 days following BEVAR (21.3%). Although the DSAA included some details regarding the nature of the reinterventions, the exact cause of the reinterventions remains unclear. Future improvement seems possible, given the high rate of reinterventions. Multivariable analysis showed that female sex was associated with higher perioperative mortality following complex EVAR, which was not consistent with current literature that describes that females have similar mortality rates as males following fenestrated-branched EVAR for treatment of TAAA.[40] Although we found that high-volume hospitals treated more female patients than low-volume hospitals, mortality rates were lower in high-volume hospitals. The number of targeted vessels was not associated with mortality, which was in agreement with previous studies,[41,42] but contrary to another study

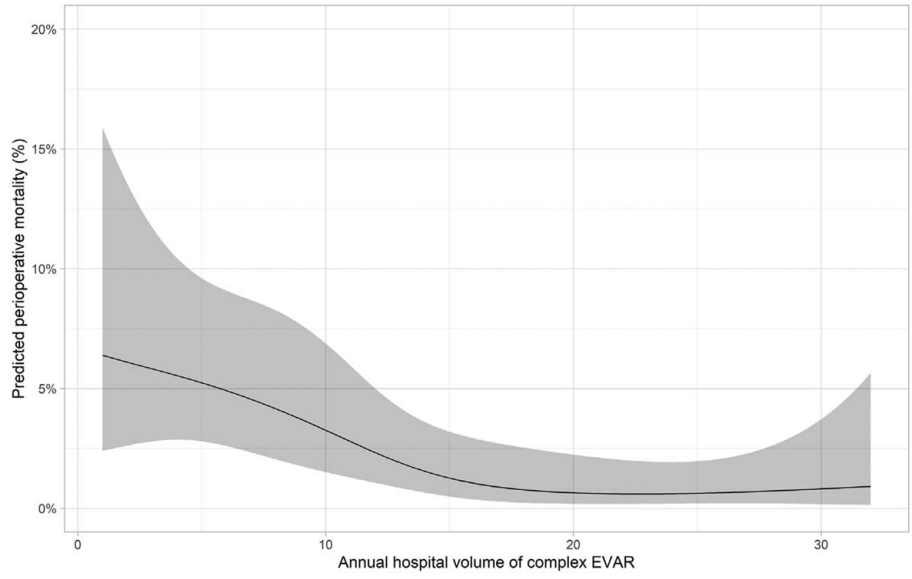

FIGURE 3. Association between annual hospital volume and perioperative mortality for complex EVAR (FEVAR and BEVAR): restricted cubic spline (4 knots), including adjustment for confounders.

that suggests that incorporating additional visceral vessels is significantly associated with increased mortality.[43] Our study showed that low-volume hospitals treated aneurysms with less targeted vessels than high-volume hospitals, suggesting that low-volume hospitals treat less extensive aneurysms. Furthermore, as previously reported,[44] our study did not find an association between preoperative creatinine and perioperative mortality. Future studies are needed to verify factors associated with perioperative mortality.

The strength of this study is the unique nationwide study design using data from a mandatory quality registry. One limitation is that our data is retrieved from a nationwide quality registry, which is not primarily designed for scientific purposes and registers a limited number of variables. Consequently, the description of clinical and aneurysm characteristics is limited, and therefore, we could not report this study according to the reporting standards of endovascular aortic repair of aneurysm involving the renal-mesenteric arteries.[16] Secondly, the definitions of variables 'location of the aneurysm', 'FEVAR', and 'BEVAR' in the DSAA might have been interpreted differently by treating physicians, which could have induced selection bias. The reported location of the aneurysm might have been influenced by interobserver variability as some clinicians could have reported the location of the aneurysm by the anatomic extent of the aortic disease, while others might have reported it by the extent of the repair. Moreover, patients who received an endograft with a combination of fenestrations and branches are registered in either the FEVAR or BEVAR category, based on local clinical opinion, although this probably includes very few patients. Therefore, we choose to report the volume-outcome association of the entire cohort of FEVAR and BEVAR patients. Thirdly, we could only report on hospital volume and not on surgeon volume, as surgeon volume is not registered in the DSAA. For open AAA surgery, a lower surgeon annual volume was associated with higher 30-day mortality.[11]

In conclusion, this nationwide population-based study with data from 539 FEVAR and 155 BEVAR patients provides an unique overview of perioperative outcomes following FEVAR and BEVAR, including a significant effect of hospital volume of complex EVAR on perioperative mortality with high volume complex EVAR centers showing lower mortality. An annual caseload of at least 9 complex EVAR procedures seems to be the minimum requirement to significantly reduce mortality in this group of patients, while an annual volume of at least 13 seems to result in better outcomes. At 20 cases, the optimum annual caseload and mortality is achieved, suggesting this should be our national threshold.

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