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U. Ronellenfitsch^{1,2} · K. Meisenbacher² · M. Ante² · M. Grilli³ · D. Böckler²

¹ Department of Visceral, Vascular and Endocrine Surgery, University Hospital Halle (Saale), Halle (Saale), Germany

² Department of Vascular and Endovascular Surgery, University Hospital Heidelberg, Heidelberg, Germany

³ Information Services for Medicine and Health Care, Karlsruhe, Germany

Association between operation volume and postoperative mortality in elective endovascular repair of infrarenal abdominal aortic aneurysms: systematic review—continuation

Background and aim

For numerous operations there is evidence showing an inverse association between hospital and surgeon volumes on one side and perioperative mortality on the other side [1, 2]. Surgeon-related factors, such as individual experience as well as team-related factors, such as team composition, experience and availability of single team members, and institution-related factors such as the technical equipment and infrastructural framework play an important role in both associations [3, 4].

The first part of this systematic review assessed the association between volume per surgeon and per treating institution, and postoperative mortality for elective open repair of infrarenal abdominal aortic aneurysms (AAA) [5]. It showed that operations performed in high volume centers or by high volume surgeons

are associated with a lower mortality. The present second part of the review, relying on all evidence available in the literature, assesses if a corresponding association is also present for elective endovascular repair (EVAR).

Study design and methods

A detailed description of the study design and methods can be found in the first part of this work [5]. In brief, a review of several literature databases (PubMed, Cochrane Library, Web of Science Core Collection, Cinahl, Current Content Medizin CCMed and ClinicalTrials.gov) was done using a predefined search strategy for the period from database inception to 1 January 2018. For the present analysis, all studies comparing elective EVAR of infrarenal AAA done in a high volume center with EVAR done in a low volume center, or done by a high volume surgeon with EVAR done by a low volume surgeon were included. Inclusion criteria were that at least one of the outcomes overall postoperative mortality, hospital mortality or 100-day mortality or a combined endpoint, needed to be reported by the study. Regarding the definition of “high volume” and “low volume” centers and study design, there were no exclusion

criteria. The relevant data from single studies were extracted by both independent reviewers and were stored in a database. The specific definitions of high volume and low volume were taken from the respective studies. For studies comparing several groups with different case volume, e.g. quartiles, the group with the highest volume was compared with the group with the lowest volume. The association between volume and mortality was described with the effect measure reported in the respective publication, which usually was the odds ratio. Effect measures and corresponding 95% confidence intervals (CI) were transformed in a way that values below one reflected a lower mortality in the high volume group. Results were displayed descriptively. Given the heterogeneity of data and the diverging definition of high volume and low volume centers, a meta-analysis for quantifying a possible association between volume and mortality was not done.

Results

After literature review and de-duplication there were 1021 hits, of which eleven studies exclusively assessed the association of hospital volume with perioperative mortality, four studies assessed both

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the association of hospital volume and surgeon volume with perioperative mortality and one study exclusively assessed the association of surgeon volume with perioperative mortality. In total 16 studies were included.

The characteristics and results of the included studies on hospital volume are displayed in **Table 1**. They recruited patients between 1988 and 2014 and were published between 2008 and 2017. Of the 15 studies, eleven were conducted in the USA, three in Germany, and one in England. All studies had a retrospective design. The total number of patients included in the compared groups of the 15 studies was 643,343. In the eleven studies reporting case numbers for the single groups there were 76,126 patients in the high volume group and 211,344 patients in the low volume group. Four studies did not report group-specific case numbers. Study participants were predominantly male with a mean or median age between 73.4 and 77 years. The threshold used for defining low volume (either the value defining the group with the lowest volume if several groups were compared or the value above which the group was considered high volume if only two groups were compared) was between three and 50 EVAR cases per institution per year. Institutions with a volume between 18 and 115 annual EVAR cases were defined as high volume. Unadjusted mortality was between 0.36% and 6.88% in the low volume groups and between 0.08% and 2.88% in the high volume groups. Ten studies reported mortality as hospital mortality and four studies as 30-day mortality. One study did not specify the mortality indicator used and twelve studies found a significantly lower mortality in the high volume group. Three studies could not find a mortality difference between groups. Out of the 15 studies, ten did a multivariable analysis. The effect measures (odds ratio) were between 0.43 and 0.91.

Table 2 shows the characteristics and results of the five included studies on the association between volume per surgeon and postoperative mortality after EVAR for AAA. These studies recruited patients between 2001 and 2011 and were published between 2016 and 2018. All

studies were conducted in the USA and had a retrospective design. In total, in the four studies reporting group-specific patient numbers, there were 56,749 patients in the compared groups. Of these, 29,849 were in the low volume and 26,900 in the high volume groups. One study reported no group-specific patient numbers. Only two studies reported the sex and age distribution of the participants. The mean age was 74 and 77 years, respectively. The threshold used for defining low volume (either the value defining the group with the lowest volume if several groups were compared or the value above which the group was considered high volume in case only two groups were compared) was between four and eleven operated cases per surgeon per year. In studies comparing several groups, surgeons performing between five and 30 EVAR per year were classified as high volume. Unadjusted mortality was between 1.7% and 2.7% in low volume and between 1.6% and 2.4% in high volume groups. Three studies reported mortality as hospital mortality and two studies as 30-day mortality. No study found a significant mortality difference between the high volume and low volume groups. Three of the five studies conducted a multivariable analysis. The effect measures (odds ratio) were between 0.63 and 0.91.

Discussion

The present analysis results from a systematic review on a possible association between case volume per hospital and surgeon and perioperative mortality in elective repair of infrarenal AAA. While the first part of the work assessed OR, this second part looked at the evidence regarding EVAR.

The results show that there are differences in the association between volume and perioperative mortality between OR and EVAR. While there was an inverse association between hospital volume and mortality for EVAR, similar to that observed for OR, the five identified studies on the association between surgeon volume and mortality showed no association.

The reasons for these results, which differ from those for OR of AAA, are not

obvious. Undoubtedly, the number of studies assessing an association between volume per surgeon and perioperative mortality is much lower for EVAR than for OR. The single studies do, however, include large populations, which should lend a sufficient statistical power to the studies. Given that none of the studies showed an association, these results must be assumed valid in the sense that there is no relevant association between volume per surgeon and perioperative mortality. This finding is surprising because planning and performing EVAR is technically demanding. Consequently, one would expect that the operative outcome depends in a relevant way on the experience and continuous training of the surgeon [23, 24]. This is mirrored in the individual learning curve for EVAR [25]. When interpreting these results, it must be taken into account that there is no information from the single studies regarding the lifetime experience of the respective surgeon but only regarding the annual caseload at the time of data accrual. It is therefore possible that surgeons with a long experience are classified as low volume because they treat only a small number of patients annually in their current position. Moreover, the fact that not only vascular surgeons but also radiologists or angiologists perform EVAR could influence the association between individual caseload and perioperative mortality. Another explanation, which can also not be proven with the available data, is that a low caseload for EVAR leads to technical complications such as endoleaks; however, these would not influence perioperative mortality but long-term mortality, which was not assessed by the included studies. It must also be taken into consideration that all studies on the association between volume per surgeon and perioperative mortality were conducted in the USA. There are structural differences between the healthcare systems. In particular, surgeons in the USA are usually completely independent consultants and do not have direct supervision by or exchange on specific cases with a defined colleague (such as the two-man rule when planning EVAR). Thus, comparability to differently structured healthcare systems,

U. Ronellenfitsch · K. Meisenbacher · M. Ante · M. Grilli · D. Böckler

Association between operation volume and postoperative mortality in elective endovascular repair of infrarenal abdominal aortic aneurysms: systematic review—continuation**Abstract**

Background. Many surgical interventions show an inverse association between case volume per hospital/surgeon and perioperative mortality. In the first part of this systematic review it was shown that such an association also exists for the open treatment of infrarenal aortic aneurysms. The second part now examines a possible association with endovascular treatment of infrarenal aortic aneurysms.

Objective. In a systematic review, the data available on the association between the case volume per hospital/surgeon and perioperative mortality in elective endovascular treatment of infrarenal aortic aneurysms are presented.

Materials and Methods. Systematic research using defined keywords was carried out. All original works comparing elective endovascular treatment of an infrarenal aortic

aneurysm in a “high volume” center with a “low volume” center or by a “high volume” surgeon with a “low volume” surgeon, as defined in each study, were included.

Results. After deduplication, the literature search produced 1,021 hits. Of these, 16 publications fulfilled the inclusion criteria. With regard to the thresholds for the definition of high volume and low volume, there was marked heterogeneity between individual studies. Twelve of the 15 studies showed a significantly lower mortality in high volume than in low volume centers. The effect measures, usually odds ratios, were between 0.43 and 0.91. In the comparison between high volume and low volume surgeons, there was no difference in mortality in any of the five studies included.

Discussion. The available data on the association between case volume per hospital

and surgeon and the perioperative mortality in elective endovascular treatment of infrarenal aortic aneurysms consistently show that patients operated on in high volume centers have a lower mortality. The volume per surgeon seems to have no influence on perioperative mortality. To achieve the lowest perioperative mortality possible in endovascular treatment of infrarenal aortic aneurysms, centralization with high volume per hospital should be aimed for, taking into consideration the context of the health care system.

Keywords

Infrarenal aortic aneurysm · Endovascular aortic repair (EVAR) · Case volume · Postoperative mortality · Systematic review

Assoziation zwischen Operationsvolumen und postoperativer Mortalität bei der elektiven endovaskulären Versorgung infrarenaler abdomineller Aortenaneurysmen: systematische Übersichtsarbeit – Fortsetzung**Zusammenfassung**

Hintergrund. Eine Vielzahl chirurgischer Eingriffe weist eine inverse Assoziation zwischen Fallzahl pro Krankenhaus und Operateur und perioperativer Mortalität auf. Im ersten Teil dieser systematischen Übersichtsarbeit konnte gezeigt werden, dass eine solche Assoziation auch für die offene Versorgung infrarenaler Aortenaneurysmen besteht. Der zweite Teil untersucht nun eine mögliche Assoziation für die endovaskuläre Versorgung.

Ziel der Arbeit. In einer systematischen Übersichtsarbeit soll die verfügbare Datenlage zur Assoziation zwischen Fallzahl pro Krankenhaus und Operateur und perioperativer Mortalität bei der elektiven endovaskulären Versorgung infrarenaler Aortenaneurysmen dargestellt werden.

Material und Methoden. Eine systematische Literaturrecherche wurde mittels definierter Schlüsselwörter durchgeführt. Es wurden alle Originalarbeiten eingeschlossen, die die elektive endovaskuläre Versorgung eines

infrarenalen Aortenaneurysmas in einem „high volume“-Zentrum mit einem „low volume“-Zentrum oder durch einen „high volume“-Chirurgen mit einem „low volume“-Chirurgen, wie in der jeweiligen Studie definiert, verglichen.

Ergebnisse. Nach Deduplizierung erbrachte die Literatursuche 1021 Treffer. Von diesen erfüllten 16 Publikationen die Einschlusskriterien. Hinsichtlich der Schwellenwerte zur Definition von „high volume“ und „low volume“ zeigte sich eine deutliche Heterogenität zwischen den einzelnen Studien. So zeigten 12/15 Studien eine signifikant niedrigere Mortalität in „high volume“- verglichen mit „low volume“-Zentren. Die Effektmaße, in aller Regel Odds Ratios, lagen zwischen 0,43 und 0,91. Für den Vergleich von „high volume“- mit „low volume“-Chirurgen zeigte sich in keiner der fünf eingeschlossenen Studien ein Mortalitätsunterschied.

Diskussion. Die verfügbare Datenlage zur Assoziation zwischen Fallzahl pro Krankenhaus

und Operateur und perioperativer Mortalität bei der elektiven endovaskulären Versorgung infrarenaler Aortenaneurysmen zeigt übereinstimmend, dass in „high volume“-Zentren operierte Patienten eine niedrigere Mortalität aufweisen. Die Fallzahl pro Chirurg scheint keinen Einfluss auf die perioperative Mortalität zu haben. Um eine möglichst niedrige perioperative Mortalität bei der endovaskulären Versorgung infrarenaler Aortenaneurysmen zu erreichen, sollte unter Berücksichtigung des Kontextes des Gesundheitssystems eine Zentralisierung mit hohen Fallzahlen pro Krankenhaus angestrebt werden.

Schlüsselwörter

Infrarenales Aortenaneurysma · Endovaskuläre Behandlung von Aortenaneurysmen (EVAR) · Operationsvolumen · Postoperative Mortalität · Systematische Übersichtsarbeit

Table 1 Studies meeting the inclusion criteria and comparing postoperative mortality in elective endovascular repair of infrarenal abdominal aortic aneurysm in low and high volume groups, relating to the case volume per hospital. If fields are empty, the corresponding data were not reported in the publication. For studies dividing hospitals in one low and one high volume group, the volume threshold is presented. For studies dividing hospitals into several groups according to their case volume, the group with the lowest volume was compared with the group with the highest volume and the respective thresholds for both groups are presented. Odds ratios were transformed so that a value <1 reflects a lower mortality in the high volume group

Author (year of publication)	Place	Time	Significant mortality difference	Threshold high vs. low volume or lower threshold high volume	Lower threshold high volume	Patients low volume	Patients high volume or total population	Age (mean years) total population	Age (mean years) low volume	Age (mean years) high volume	Men low volume	Men high volume (or total population)	Mortality total population (%)	Mortality low volume (%)	Mortality high volume (%)	Mortality indicator	Odds ratio (95%-CI)	Multi-variable
Brooke B. S., et al. (2008) [6]	USA	2000–2005	No	50	–	1783	1337	75.69	75.30	76.20	1524	1123	–	2.02 (2000–2002), 1.91 (2003–2005)	1.16 (2000–2002), 0.63 (2003–2005)	HM	0.62 (0.22–1.70)	Yes
Dimick, J. B. and G. R. Upchurch, Jr. (2008) [7]	USA	2001–2003	Yes	–	–	–	26,750	–	–	–	–	–	–	–	–	–	0.60	No
Dua, A., et al. (2014) [8]	USA	1998–2011	Yes	–	–	–	113,485	–	–	–	–	–	–	–	–	HM	–	–
Egorova, N., et al. (2009) [9]	USA	2000–2006	Yes	6	–	6674	7924	–	–	–	55,485	–	–	2.30	1.40	30-day	0.69 (0.56–0.85)	Yes
Hicks, C. W., et al. (2016) [10]	USA	2010–2012	Yes	50	–	123,052	8856	73.70	–	–	108,417	–	–	–	–	HM	0.73 (0.54–0.99)	No
Holt, P. J., et al. (2009) [11]	England	2005–2007	Yes	8	115	416	320	–	73.40	73.50	359	262	–	6.88	2.88	HM	0.99 (0.98–0.99)	Yes
Ilonzo, N., et al. (2014) [12]	USA	1995–2011	Yes	3	18	–	195,928	–	–	–	–	–	–	0.36	0.08	30-day	–	No
Landon, B. E., et al. (2010) [13]	USA	2001–2004	Yes	10	50	–	22,830	–	–	–	–	–	–	2.50	1.45	30-day	–	Yes
McPhee, J. T., et al. (2011) [14]	USA	2003–2007	No	15	70	1828	1641	–	–	–	–	–	–	1.50	0.93	HM	0.43 (0.19–1.04)	Yes
Meltzer, A. J., et al. (2017) [15]	USA	2000–2011	Yes	33	82	4110	4210	–	–	–	10,141	–	–	1.60	1.30	30-day	0.56 (0.34–0.94)	Yes
Nimpisch, U. and T. Mansky (2017) [16]	GER	2009–2014	Yes	9	57	8462	8281	–	–	–	–	–	–	1.70	1.60	HM	0.91 (0.68–1.21)	Yes
Trenner, M., et al. (2014) [17]	GER	1999–2010	No	10	63	3173	2533	–	–	–	–	–	–	1.40	1.40	HM	–	–
Trenner, M., et al. (2017) [18]	GER	2005–2013	Yes	5	41	30,149	608	–	–	–	–	–	–	3.00	1.60	HM	0.62 (0.51–0.77)	Yes
Vogel, T. R., et al. (2011) [19]	USA	2005–2007	Yes	–	–	16,218	25,937	–	–	–	13,300	21,146	–	–	–	HM	0.74 (0.60–0.93)	Yes
Zettervall, S. L., et al. (2017) [20]	USA	2001–2008	Yes	9	49	15,479	14,479	–	77.00	77.00	12,693	12,018	–	1.90	1.40	HM	0.71 (0.59–0.83)	Yes

CI confidence interval, GER Germany, HM hospital mortality, USA United States of America, 30-day 30-day mortality

Table 2 Studies meeting the inclusion criteria and comparing postoperative mortality in elective endovascular repair of infrarenal abdominal aortic aneurysm in low and high volume groups, relating to the case volume per surgeon. If fields are empty, the corresponding data were not reported in the publication. For studies dividing surgeons in one low and one high volume group, the volume threshold is presented. For studies dividing surgeons into several groups according to their case volume, the group with the lowest volume was compared with the group with the highest volume and the respective thresholds for both groups are presented. Odds ratios were transformed so that a value <1 reflects a lower mortality in the high volume group

Author (year of publication)	Place	Time	Significant mortality difference	Threshold high vs. low volume or lower threshold high volume	Lower threshold high volume	Patients low volume	Patients high volume or total population	Age (mean years) total population	Age (mean years) low volume	Age (mean years) high volume	Men low volume	Men high volume (or total population)	Mortality total population (%)	Mortality low volume (%)	Mortality high volume (%)	Mortality indicator	Odds ratio (95% CI)	Multi-variable
Dua et al. (2016) [21]	USA	2007–2009	No	5	–	–	–	–	–	–	–	–	2.50	2.70	2.40	HM	–	–
Esce A., et al. (2018) [22]	USA	2000–2010	No	Median	–	8817	5642	74	74	–	7080	4531	–	1.90	1.60	30-day	–	–
McPhee, J. T., et al. (2011) [24]	USA	2003–2007	No	4	25	1584	1495	–	–	–	–	–	–	–	–	HM	0.63 (0.29–1.32)	Yes
Meltzer, A. J., et al. (2017) [25]	USA	2000–2011	No	11	30	4126	4375	–	–	–	–	–	–	1.70	1.60	30-day	0.73 (0.46–1.15)	Yes
Zettervall, S. L., et al. (2017) [30]	USA	2001–2008	No	6	28	15,322	15,388	–	77	77	12,564	12,772	–	1.80	1.60	HM	0.91 (0.77–1.11)	Yes

CI confidence interval, HM hospital mortality, USA United States of America, 30-day 30-day mortality

such as the German one is substantially limited. However, it cannot be explained by available data and thus remains unclear why, in contrast to EVAR, for OR there is a markedly higher perioperative mortality for patients operated on by a low volume as compared to a high volume surgeon.

Similarly to OR of AAA, there is an inverse association between hospital volume and perioperative mortality. Both the caseload and the mortality figures in the respective high volume and low volume groups show marked differences between the single studies. These can be explained by structural heterogeneity of the participating hospitals and the different definitions for low volume and high volume centers across studies.

The inverse association between hospital volume and perioperative mortality is, however, observed independently from the absolute threshold. Thus, a real class effect can be assumed. The observed mortality difference could be explained by the fact that the experience of the care team in its group-specific composition leads to better preparedness for critical situations and a proactive avoidance of mistakes as well as a timely and effective management of incident complications. With respect to quality models used in healthcare, a higher hospital volume would be associated with a higher process and treatment quality, which in turn are a necessary condition for a higher outcome quality [26].

Just like for OR of AAA, so-called failure to rescue could be one of the main reasons for the inverse association between hospital volume and perioperative mortality. It is defined as postoperative death due to a potentially treatable severe complication, such as hemorrhage, sepsis or respiratory failure [27]. For a number of operations, there is sufficient evidence that such a scenario manifests less frequently in high volume than in low volume hospitals [28]. Whereas such an association could also be shown for OR of AAA [29], so far no specific studies on the influence of hospital volume on failure to rescue in EVAR have been published. An association is, however, likely because characteristics associated with hospital volume and size probably play

an important role. One example is the around the clock availability of specific emergency diagnostics and of specialized and experienced staff. The prediction of the individual postoperative mortality risk after elective repair of infrarenal AAA is of importance. Risk scores, such as the DIGG risk score [30], can be of considerable help and, if used wisely, can improve outcome of EVAR. This score comprises patient-specific risk factors. Characteristics of the hospital and the operating surgeon, such as case volume, are not taken into account.

The designs employed in the included studies were limited to non-randomized, retrospective analyses. Albeit desirable, a randomization of patients to being treated in facilities or by surgeons with a high or low volume would be neither feasible nor ethically justifiable. Doubtlessly, retrospective studies have limitations with respect to data quality and an increased risk of selection bias. Yet, the case volume and overall mortality can be reliably ascertained. A selection bias in elective AAA repair would probably imply that patients with a particularly high perioperative risk tend to be treated in centers with a higher volume. Multivariable analyses can achieve at least a partial adjustment for differences in risk profiles. The assumed selection would lead to higher unadjusted mortality in high volume centers. A possible association between volume and outcome would thus be attenuated. Since most studies have nonetheless found a significant inverse association between hospital volume and perioperative mortality, a stable association can be assumed and a significant result due to selection bias appears unlikely.

In summary, this second part of the systematic review on the association between hospital and surgeon volume and perioperative mortality in EVAR for AAA yielded different results from the first part looking at OR. While the inverse association between hospital volume and perioperative mortality could be shown similarly to OR, no association between surgeon volume and perioperative mortality was found. The reasons underlying this different pattern cannot be identi-

fied with the available data. These results imply that a centralization of elective endovascular aortic surgery in high volume hospitals makes sense. A clearly defined threshold for what constitutes a high volume hospital cannot be inferred from the available studies because almost every study uses its own threshold. Moreover, thresholds are not readily transferable between different institutions and healthcare systems. Accordingly, national and international guidelines are heterogeneous in their recommendation of a minimum threshold per hospital for elective EVAR of infrarenal AAA. Whereas the guidelines of the US Society of Vascular Surgery (SVS) recommends a minimum of ten cases per year [31], the European Society for Vascular Surgery (ESVS) recommends in its guidelines that AAA should be treated only in centers with an annual volume of at least 30 cases [32]. This number is not specified regarding OR or EVAR. The German S3 guidelines [33] discuss minimum case numbers deduced from a number of meta-analyses and single studies. These range from eight to 60 annual cases and are mostly not presented specifically for OR or EVAR. The guidelines therefore recommend that infrarenal AAA be treated in specialized centers, without stipulating a defined minimum threshold for volume and without making a difference between OR and EVAR. In conclusion, a possible centralization should be done taking into account the characteristics of an established healthcare system.

Corresponding address

Prof. Dr. D. Böckler
Department of Vascular
and Endovascular Surgery,
University Hospital
Heidelberg
Im Neuenheimer Feld 420,
69120 Heidelberg, Germany
dittmar.boeckler@med.uni-
heidelberg.de

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Compliance with ethical guidelines

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