Eur J Vasc Endovasc Surg (xxxx) xxx, xxx

EJVES Open Access

The Relationship Between Hospital Procedure Volume and Outcomes After Endovascular or Open Surgical Revascularisation for Peripheral Arterial Disease: An Analysis of Health Insurance Claims Data

Jenny Kuchenbecker [a], Frederik Peters [a], Thea Kreutzburg [a], Ursula Marschall [b], Helmut L'Hoest [b], Christian-Alexander Behrendt [a,c,*]

[a] Research Group GermanVasc, University Medical Centre Hamburg-Eppendorf, Hamburg, Germany
[b] BARMER, Wuppertal, Germany
[c] Brandenburg Medical School Theodor Fontane, Neuruppin, Germany

WHAT THIS PAPER ADDS

German hospital quality reports on annual procedure volume and longitudinal health insurance claims data providing outcomes beyond discharge were linked for the first time to compile a large cohort of 64 871 individual patients who underwent 88 187 hospitalisations for symptomatic peripheral arterial disease in Germany. While previous studies have been mostly limited to peri-procedural short term outcomes, the current study additionally explored the complex relationship between hospital volume and midterm outcomes after one year, indicating that higher volume was associated with reduced risk of amputation after both endovascular and open surgical revascularisation and with a lower mortality risk after open surgical revascularisation.

Objective: There is a paucity of data on the relationship between hospital procedure volume and outcomes after inpatient treatment of symptomatic peripheral arterial disease (PAD). This study aimed to generate meaningful hypotheses to support the ongoing discussion.

Methods: Data derived from BARMER, Germany's second largest insurance provider, were linked with nationwide hospital procedure volumes from mandatory hospital quality reports. All endovascular (EVR) and open surgical revascularisations (OSR) provided to patients ($\geq$ 40 years) with symptomatic PAD between 1 January 2013 and 31 December 2018 were included. Hospital volume was defined as the number of procedures performed by a hospital in the previous calendar year (in quartiles). Freedom from re-intervention, amputation, and overall mortality rate within 12 months after discharge were analysed using multivariable Cox proportional hazards models. In hospital mortality was determined by generalised estimating equations logistic regression models.

Results: There were 88 187 revascularisations (72.4% EVR; EVR: 72.7 years and 45.2% females; OSR: 71.9 years and 41.9% females) registered by 668 hospitals. No statistically significant association was found between 12 month freedom from re-intervention and hospital volume (EVR: 4; quartile HR 1.05; 95% CI 0.94 – 1.16. OSR: 4; quartile HR 1.05; 95% CI 0.92 – 1.21). Patients with OSR had a decreased hazard of 12 month mortality in a high volume hospital compared with a low volume hospital (HR 0.85; 95% CI 0.73 – 0.98), but not with EVR (HR 1.03; 95% CI 0.91 – 1.16). Patients who were treated in hospitals with highest volumes showed decreased hazards of 12 month freedom from amputation when compared with low volume hospitals (EVR: HR 0.72; 95% CI 0.52 – 0.99. OSR: HR 0.61; 95% CI 0.44 – 0.85).

Conclusion: This large retrospective analysis of insurance claims suggests that higher procedure volume is associated with lower major amputation rates, although there is a need for standardisation of the definition of volume stratification. Future studies should address the impact of subsequent outpatient care and surveillance to further examine the complex interaction between treatment and outcomes.

Keywords: Amputation, Endovascular techniques, Health services, Peripheral arterial disease, Procedure volume, Quality of care, Research
Article history: Received 10 March 2022, Accepted 29 November 2022, Available online XXX

INTRODUCTION

The impact of hospital procedure and case volumes on outcomes has been extensively discussed for several cardiovascular populations.[1–4] Most vascular surgery studies have rather focused on carotid and aortic procedures,[5–9] while the available evidence concerning interventions for patients with lower extremity peripheral arterial disease

* Corresponding author. Head of Research Group GermanVasc, Department of Vascular and Endovascular Surgery, Asklepios Clinic Wandsbek, Asklepios Medical School, Hamburg, Germany.
E-mail address: behrendt@hamburg.de (Christian-Alexander Behrendt).
@VASCevidence

https://doi.org/10.1016/j.ejvs.2022.11.022

(PAD) remains scarce. Moreover, most conclusions in previous publications were derived from administrative and clinical registries, which were often limited to periprocedural short term outcome data. That might be more acceptable after certain procedures, but it seems important to compare midterm outcomes after invasive treatment of patients with symptomatic PAD.[10]

With approximately 237 million patients and countless procedures every year,[11,12] PAD plays an important part in the everyday clinical practice of vascular surgeons and other medical specialties involved in its treatment. Considering the huge disease burden for global healthcare systems, it seems interesting that only a few and mainly historical studies have addressed the volume—outcome relationship in the PAD field with inconsistent conclusions, while valid guidelines do not contain specific recommendations.[13–23]

Beyond the unequivocal meaning of patient reported outcomes for the treatment of this patient population, major adverse limb and cardiovascular events count as commonly accepted indicators of outcome quality after invasive revascularisation for symptomatic PAD.[24,25] Hence, the comparison between lower extremity amputation and re-intervention rates and mortality may be used to benchmark outcomes between facilities.

This study aimed to analyse the relationship between hospital procedure volumes and midterm outcomes after revascularisation in symptomatic PAD.

METHODS

This retrospective observational study examined German health insurance claims data linked to hospital quality reports.[26] Random sampling and additional needs based reviews by the medical service of German statutory health insurance providers (Medizinischer Dienst der Krankenversicherung, MDK) were regularly applied to assure high internal and external data validity.

Hospital procedure volume

Hospital procedure volumes were extracted from mandatory hospital quality reports covering all facilities in Germany. German hospitals were obliged to submit a biennial hospital specific quality report between 2005 — 2014; this report has been requested annually by the authorities since 2014. This information is being increasingly used for analysing the relationship between hospital volume and health outcomes.[27] Amongst general information on the hospitals, such as staffing, number of beds, and total number of patients treated, the annual number of procedures performed by operation and procedure codes and international classification of disease diagnoses (ICD-GM codes) were extracted from these reports. The selected operation and procedure codes for both endovascular (EVR) and open surgical revascularisation (OSR) were summed, respectively, for each clinic and reporting year as the annual procedure volume. The annual procedure volume for each procedure type (EVR *vs.* OSR) was divided into quartiles by sorting the procedure volume in ascending order and separating the cumulative sum to generate four groups of equal size. Resulting quartile thresholds varied between years and are displayed in Supplementary Fig. S1.

Study population

Hospital cases were selected from the database of BARMER, Germany's second largest insurance provider. The database comprises longitudinal inpatient and outpatient information of about 9 million insured persons and is widely used for health services research.[26,28] Further details on the specifics of the BARMER cohort and German healthcare system have been described previously.[29] Inclusion criteria included any in hospital stay for symptomatic PAD treated by either an EVR or OSR (see Supplementary Table S1 for specific coding) between January 1 2013 and December 31 2018. Eligible PAD patients were categorised in Fontaine stages 2, 3, and 4. To establish a more homogeneous cohort, only patients aged $\geq$ 40 years on admission were included. The longitudinally linked data were collected for each patient on a hospital case level, enabling inclusion of all eligible cases (hospitalisations) per patient. To adjust for case severity, longitudinal information on medical history up to five years before each hospital stay was extracted from previous inpatient and outpatient claims data (lookback). Hybrid cases (both EVR and OSR during the same procedure), cases with incomplete five year lookback, and cases without specification of the revascularised leg or lesion level were excluded.

Data linkage

The nine digit institution code provides a unique identifier for each hospital in Germany and was used in this study to interlink information extracted from hospital quality reports covering all hospitals and claims data. For each case, the hospital information of the previous calendar year was used. Cases with missing information due to incomplete data on the previous year (e.g., newly founded hospital, mergers, or acquisitions with change in institution code) were excluded.

Declaration of Helsinki

The study complied with the Declaration of Helsinki 2013. All analyses were based on a factual anonymised administrative database so that neither locally appointed ethics committee approval nor informed consent was applicable.

Study outcomes

Study outcomes were 12 month freedom from re-intervention (defined as subsequent EVR or OSR in the index leg and same lesion level). Lesion levels were categorised in aorto-iliac, femoropopliteal, and crural (below the knee) revascularisations. Additional outcomes were 12 month freedom from major amputation, 12 month overall survival after discharge, and in hospital mortality. An amputation was considered if it affected the index leg or either leg if the patient had procedures on both legs during the hospital stay.

Please cite this article as: Kuchenbecker J et al., The Relationship Between Hospital Procedure Volume and Outcomes After Endovascular or Open Surgical Revascularisation for Peripheral Arterial Disease: An Analysis of Health Insurance Claims Data, European Journal of Vascular and Endovascular Surgery, https://doi.org/10.1016/j.ejvs.2022.11.022

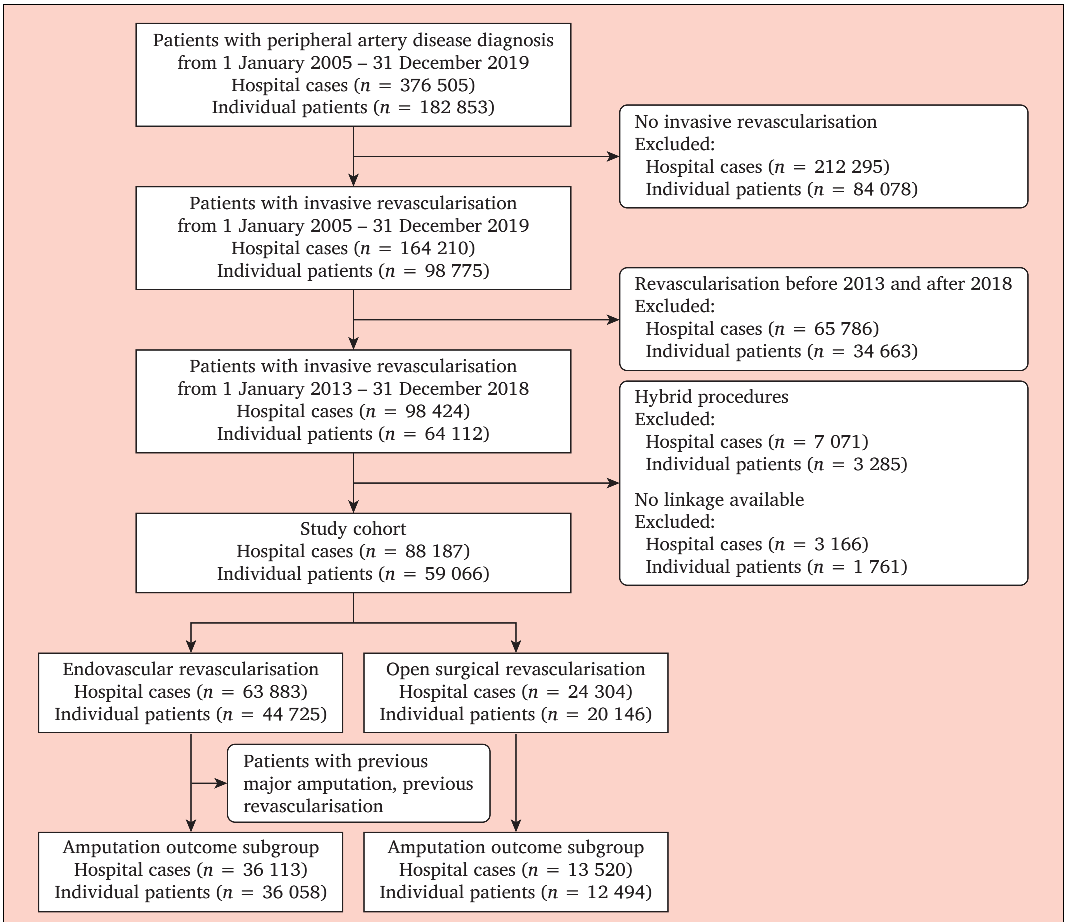

Figure 1. Flowchart of inclusion criteria for selection of patients aged ≥ 40 years with symptomatic peripheral artery disease, treated with endovascular or open surgical revascularisation in Germany between 2013 – 2018.

Statistical analysis

To detect erroneous outliers in hospital quality reports, the hospital procedure volume and total number of patients treated were studied for each hospital over time using modified Z scores with a critical value of 3.5.[30] Hospitals with Z scores above the critical value were excluded for the specific year (1.7% of hospitals).

For a summary of baseline characteristics, continuous variables are shown as mean ± standard deviation or median with interquartile range depending on their distribution. Categorical variables are presented as percentages. Cases with missing data in general patient information were excluded using listwise deletion, resulting in complete case analysis (< 0.5% of all cases).

The outcomes were analysed using separate multivariable Cox proportional hazards models clustered by hospital and stratified by Fontaine stage. The proportional hazards assumption was assessed graphically and tested with the Grambsch—Therneau test.[31] Analysis of freedom from major amputation included only patients without prior major amputation and was performed at patient level using only the first inpatient admission during the study time to avoid an overestimation of amputation events. Patients who had changed their insurance provider during follow up were considered right censored in the Cox proportional hazards models. In hospital death was examined using generalised estimating equations in the form of logistic models with binomial variance functions to account for observations clustered by hospital.

Each model was adjusted for the patient's sex, number of prescribed medications in the year prior to admission, previous prescriptions for antithrombotic, lipid lowering, or antihypertensive drugs, and information on the hospital such as quartile of procedure volume, geographic location (North-West, South-West, East Germany), and hospital size using a quotient of procedure volume divided by the total number of patients treated. Additionally, models were adjusted for number of endovascular or open surgical procedures during stay, length of stay, number of days with surgeries, emergency department admission, and number of affected lesion levels and legs. In addition to these variables, comorbidities were selected from Elixhauser comorbidity groups by elastic nets and varied between models.[32,33] Each model was amended by variables based on clinical relevance. The model for in hospital mortality also contained the van Walraven score that summarises the comorbidity burden into a weighted sum score based on the Elixhauser groups.[34] The adjusted variables are displayed in Supplementary Table S2. The alpha level was set at 5%. Statistical analysis was performed using SAS 9.4 (SAS

Please cite this article as: Kuchenbecker J et al., The Relationship Between Hospital Procedure Volume and Outcomes After Endovascular or Open Surgical Revascularisation for Peripheral Arterial Disease: An Analysis of Health Insurance Claims Data, European Journal of Vascular and Endovascular Surgery, https://doi.org/10.1016/j.ejvs.2022.11.022

Table 1. Characteristics of the study population of 59 066 patients with symptomatic peripheral arterial disease of the lower limbs, shown separately by endovascular or open surgical revascularisation

Characteristics	Endovascular procedure	Open surgical procedure
Hospital cases – *n*	63 883	24 304
Individual patients – *n*	44 725	20 146
Hospitals – *n*	640	571
Female sex	28 864 (45.29)	10 192 (41.9)
Age – y	72.70 ± 10.30	71.87 ± 10.05
Fontaine stage 2	37 765 (59.1)	11 550 (47.5)
Fontaine stage 3	6 324 (9.9)	4 775 (19.6)
Fontaine stage 4	19 794 (31.0)	7 979 (32.8)
Lipid lowering medication	38 235 (59.9)	14 185 (58.4)
Antithrombotic medication	40 214 (62.9)	15 057 (62.0)
Antihypertensive medication	56 056 (87.7)	20 975 (86.3)
Emergency department admission	11 362 (17.8)	6 009 (24.7)
Procedures involving both legs	5 759 (9.0)	1 778 (7.3)
Treatment of lesion below the knee	21 349 (33.4)	6 724 (27.7)
Number of lesion sites, right/left leg and three lesion levels	1.32 ± 0.54	1.43 ± 0.62
Median van Walraven Score	10 [3, 19]	11 [4, 20]

Data are presented as *n* (%), mean ± standard deviation, or median [interquartile range] unless stated otherwise.

Institute, North Carolina, USA) and R version 4.0.3 (The R Foundation for Statistical Computing, Vienna, Austria). A list of R packages that were used can be found in Supplementary Table S3.

RESULTS

The study cohort consisted of 88 187 cases (55.9% intermittent claudication) comprising 59 066 individual patients who underwent invasive revascularisation in 668 hospitals

Table 2. Baseline characteristics of the included 59 066 patients with symptomatic peripheral arterial disease of lower limbs who underwent endovascular revascularisation for symptomatic peripheral arterial disease by hospital procedure volume in quartiles

Variable	1st Quartile	2nd Quartile	3rd Quartile	4th Quartile
Hospitals – *n*	483	228	137	59
Patients – *n*	16 248	12 919	10 811	8 695
Procedures	236 [124, 385]	748 [650, 869]	1 279 [1 128, 1 481]	2 286 [1 993, 2 755]
Female sex	9 369 (45.4)	7 639 (45.7)	6 515 (45.4)	5 341 (43.8)
Age – y	72.66 ± 10.40	72.72 ± 10.27	72.88 ± 10.30	72.53 ± 10.17
Fontaine stage 2	11 936 (57.8)	10 127 (60.6)	8 229 (57.4)	7 473 (61.3)
Fontaine stage 3	2 075 (10.0)	1 560 (9.3)	1 446 (10.1)	1 243 (10.2)
Fontaine stage 4	6 648 (32.2)	5 018 (30.0)	4 660 (32.5)	3 468 (28.5)
Lesion				
Aorto-iliac	5 243 (25.4)	4 418 (26.4)	3 509 (24.5)	3 187 (26.2)
Femoropopliteal	12 888 (62.4)	10 776 (64.5)	9 425 (65.7)	8 380 (68.8)
Crural	6 801 (32.9)	5 326 (31.9)	5 130 (35.8)	4 092 (33.6)
Van Walraven score	10.00 [3.00, 18.00]	10.00 [3.00, 18.00]	11.00 [4.00, 19.00]	11.00 [4.00, 18.00]
Congestive heart failure	7 367 (35.7)	6 037 (36.1)	5 267 (36.7)	4 232 (34.7)
Cardiac dysrhythmias	8 276 (40.1)	6 690 (40.0)	6 080 (42.4)	4 931 (40.5)
Hypertension	19 081 (92.4)	15 527 (92.9)	13 386 (93.4)	11 339 (93.1)
Chronic pulmonary disease	9 002 (43.6)	7 350 (44.0)	6 395 (44.6)	5 440 (44.6)
Uncomplicated diabetes	10 322 (50.0)	8 307 (49.7)	7 291 (50.9)	5 986 (49.1)
Complicated diabetes	8 759 (42.4)	6 965 (41.7)	6 177 (43.1)	5 077 (41.7)
Renal failure	7 884 (38.2)	6 727 (40.3)	6 307 (44.0)	5 320 (43.7)
Liver disease	4 725 (22.9)	3 687 (22.1)	3 300 (23.0)	2 815 (23.1)
Obesity	5 867 (28.4)	4 810 (28.8)	4 230 (29.5)	3 401 (27.9)
Prior stroke or TIA	3 237 (15.7)	2 473 (14.8)	2 331 (16.3)	1 884 (15.5)
History of coronary artery disease	10 751 (52.0)	8 764 (52.5)	7 681 (53.6)	6 576 (54.0)
Prior myocardial infarction	2 407 (11.7)	1 961 (11.7)	1 826 (12.7)	1 544 (12.7)
Dyslipidaemia	16 146 (78.2)	13 427 (80.4)	11 675 (81.4)	10 229 (84.0)
Antihypertensives in previous year	18 009 (87.2)	14 710 (88.1)	12 644 (88.2)	10 693 (87.8)
Lipid lowering drugs in previous year	11 800 (57.1)	9 824 (58.8)	8 662 (60.4)	7 949 (65.2)
Antithrombotic drugs in previous year	12 585 (60.9)	10 375 (62.1)	9 254 (64.6)	8 000 (65.7)
Emergency department admission	3 797 (18.4)	3 215 (19.2)	2 459 (17.2)	1 891 (15.5)
Number of prior medications	10.00 [6.00, 15.00]	10.00 [7.00, 15.00]	11.00 [7.00, 15.00]	10.00 [7.00, 15.00]

Data are presented as *n* (%), mean ± standard deviation, or median [interquartile range] unless otherwise stated. TIA = transient ischaemic attack.

Please cite this article as: Kuchenbecker J et al., The Relationship Between Hospital Procedure Volume and Outcomes After Endovascular or Open Surgical Revascularisation for Peripheral Arterial Disease: An Analysis of Health Insurance Claims Data, European Journal of Vascular and Endovascular Surgery, https://doi.org/10.1016/j.ejvs.2022.11.022

Table 3. Baseline characteristics of the included 59 066 patients with symptomatic peripheral arterial disease of the lower limbs who underwent open surgical revascularisation for symptomatic peripheral arterial disease by hospital procedure volume in quartiles

Variable	1st Quartile	2nd Quartile	3rd Quartile	4th Quartile
Hospitals – n	391	211	150	76
Patients – n	7 920	5 797	5 414	5 173
Procedures	207 [116, 312]	566 [499, 631]	839 [767, 926]	1 265 [1 134, 1 581]
Female sex	3 180 (40.2)	2 368 (40.8)	2 339 (43.2)	2 305 (44.6)
Age – y	71.70 ± 10.13	71.89 ± 10.01	72.01 ± 9.99	71.95 ± 10.04
Fontaine stage 2	3 745 (47.3)	2 666 (46.0)	2 599 (48.0)	2 540 (49.1)
Fontaine stage 3	1 543 (19.5)	1 161 (20.0)	1067 (19.7)	1 004 (19.4)
Fontaine stage 4	2 632 (33.2)	1 970 (34.0)	1 748 (32.3)	1 629 (31.5)
Lesion				
Aorto-iliac	1 621 (20.5)	1 313 (22.6)	1 499 (2.7)	1 536 (29.7)
Femoropopliteal	6 542 (82.6)	4 814 (83.0)	4 478 (82.7)	4 416 (85.4)
Crural	2 091 (26.4)	1 593 (27.5)	1 553 (28.7)	1 487 (28.7)
Van Walraven score	11.00 [4.00, 19.00]	11.00 [4.00, 19.00]	11.00 [4.00, 19.00]	12.00 [5.00, 20.00]
Congestive heart failure	2 853 (36.0)	2 123 (36.7)	1 915 (35.4)	1 923 (37.2)
Cardiac dysrhythmias	3 128 (39.5)	2 317 (40.0)	2 117 (39.1)	2 115 (40.9)
Hypertension	7 272 (91.8)	5 341 (92.1)	5 016 (92.6)	4 727 (91.4)
Chronic pulmonary disease	3 660 (46.2)	2 757 (47.6)	2 523 (46.6)	2 515 (48.6)
Uncomplicated diabetes	3 658 (46.2)	2 622 (45.2)	2 344 (43.3)	2 240 (43.4)
Complicated diabetes	2 950 (37.2)	2 162 (37.3)	1 944 (35.9)	1 861 (36.0)
Renal failure	2 740 (34.6)	2 064 (35.6)	2 000 (36.9)	1 987 (38.4)
Liver disease	1 852 (23.4)	1 319 (22.8)	1 252 (23.1)	1 237 (23.9)
Obesity	2 068 (26.1)	1 463 (25.2)	1 363 (25.2)	1 355 (26.2)
Prior stroke or TIA	1 202 (15.2)	872 (15.0)	811 (15.0)	762 (14.7)
History of coronary artery disease	4 122 (52.0)	3 096 (53.4)	2 849 (52.6)	2 753 (53.2)
Prior myocardial infarction	995 (12.5)	826 (14.2)	663 (12.2)	665 (12.8)
Dyslipidaemia	6 134 (77.4)	4 510 (77.8)	4 247 (78.4)	4 131 (79.9)
Antihypertensives in previous year	6 841 (86.4)	4 999 (86.2)	4 703 (86.9)	4 432 (85.7)
Lipid lowering drugs in previous year	4 570 (57.7)	3 465 (59.8)	3 183 (58.8)	2 967 (57.4)
Antithrombotic drugs in previous year	4 892 (61.8)	3 639 (62.8)	3 341 (61.7)	3185 (61.6)
Emergency department admission	2 008 (25.4)	1 400 (24.2)	1 296 (23.9)	1 305 (25.2)
Number of prior medications	10.00 [6.00, 14.00]	10.00 [6.00, 15.00]	10.00 [6.00, 14.00]	10.00 [6.00, 15.00]

Data are presented as *n* (%), mean ± standard deviation, or median [interquartile range] unless otherwise stated. TIA = transient ischaemic attack.

(Figure 1); the mean age was 72.5 years and 44.3% were female. Follow up was censored at one year, resulting in a median follow up of 365 days (mean 336 days). The data were stratified by procedure type, resulting in 63 883 cases with EVR and 24 304 with OSR (Table 1). For analyses of freedom from major amputation, patients with previous major amputations were excluded, leading to a sample of 36 113 EVR and 13 520 OSR cases (Fig. 1).

A minority of cases involved procedures performed on both legs (9.0% for EVR and 7.3% for OSR) and fewer patients were revascularised below the knee (33.4% for EVR and 27.7% for OSR). Patients who underwent OSR presented with more comorbidities and more often with chronic limb threatening ischaemia (52.4%) when compared with EVR. Baseline characteristics stratified by procedure type and hospital volume quartiles can be found in Table 2 and Table 3. Information on frequency of outcome events is given in Supplementary Table S4. Additional sensitivity analyses are given in Supplementary Table S5.

Midterm 12 month outcomes

Analyses of re-interventions did not show a significant association with hospital procedure volume for both procedure types. The risk of major amputation was statistically significantly lower after a procedure in a high volume hospital for both procedure types with an HR of 0.72 (95% CI 0.52 – 0.99) for EVR and 0.61 (95% CI 0.44 – 0.85) for OSR. Patients treated by OSR in high volume hospitals enjoyed better survival (HR 0.85; 95% CI 0.73 – 0.98) when compared with the reference. No statistically significant difference in midterm survival was found for patients with EVR (Figs 2 and 3).

Short term peri-procedural mortality rate

For EVR patients, the second quartile showed a statistically significant increase of in hospital mortality compared with the first quartile (OR 1.28; 95% CI 1.03 – 1.58) (Figs 2 and 3). Sensitivity analyses were confirmative (Supplementary Table S3).

DISCUSSION

In this analysis of insurance claims from Germany, data were included on almost 65 000 individuals who underwent more than 88 000 hospitalisations for the invasive treatment of symptomatic PAD between 2013 and 2018. For the

Please cite this article as: Kuchenbecker J et al., The Relationship Between Hospital Procedure Volume and Outcomes After Endovascular or Open Surgical Revascularisation for Peripheral Arterial Disease: An Analysis of Health Insurance Claims Data, European Journal of Vascular and Endovascular Surgery, https://doi.org/10.1016/j.ejvs.2022.11.022

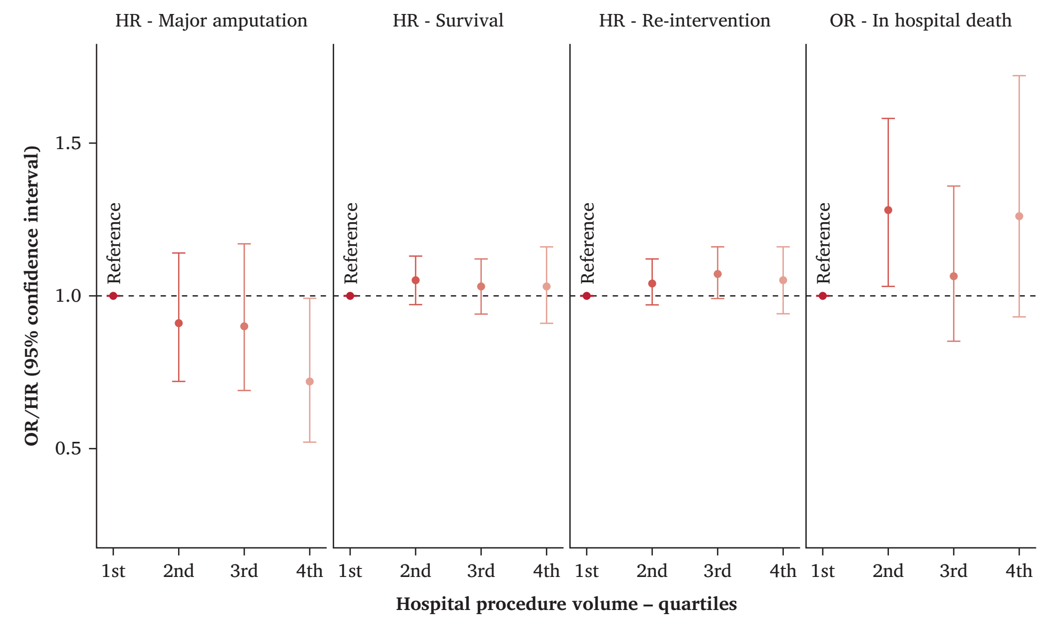

Figure 2. Outcomes after 63 883 endovascular procedures for patients with symptomatic peripheral arterial disease of the lower limbs, shown separately for each quartile of annual hospital volume (reference: first quartile), adjusted for patient and procedure characteristics, medication, comorbidities, and prior treatment in Germany between 2013 – 2018. HR = hazard ratio; OR = odds ratio.

first time, it linked available statistical data on annual procedure volume with patient related midterm outcomes to determine the complex relationship between volume and outcome. It adjusted for patient and procedure characteristics, medication, comorbidities, and prior inpatient and outpatient information, while all analyses were stratified by the index approach. Interestingly, patients who underwent both EVR and OSR in a high volume centre were at lower risk of major amputation in the longer term, while an additional survival benefit was observed during 12 months after OSR in high volume centres.

Few articles have addressed the aspects of case or procedure volume in relation to outcomes after invasive treatment of PAD. In two recently published articles by Iida

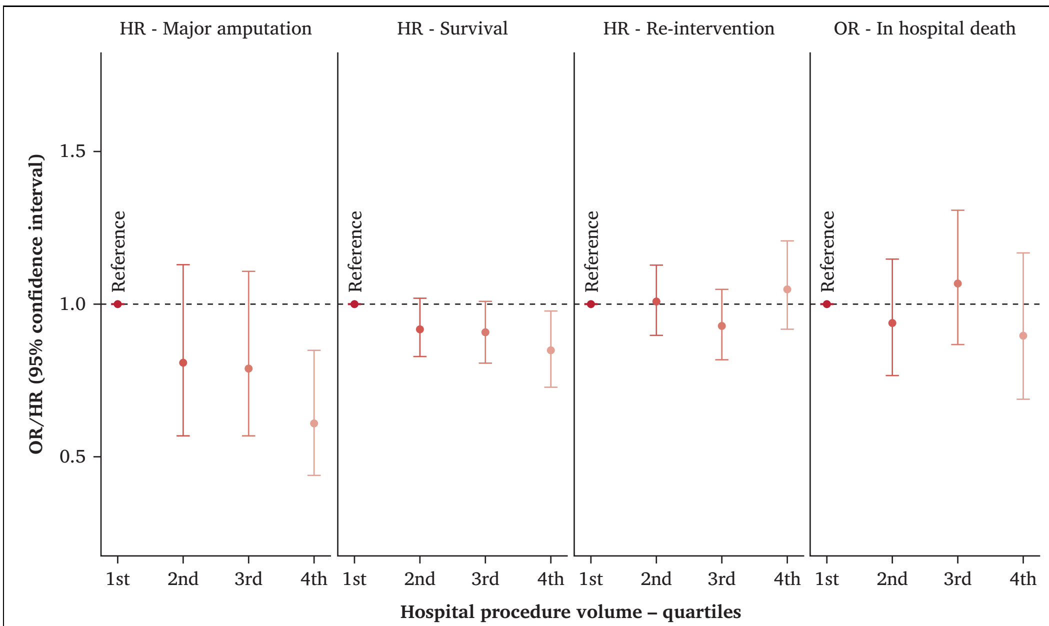

Figure 3. Outcomes after 24 304 open surgical procedures for patients with symptomatic lower limb peripheral arterial disease, shown separately for each quartile of annual hospital volume (reference: first quartile), adjusted for patient and procedure characteristics, medication, comorbidities, and prior treatment in Germany between 2013 – 2018. HR = hazard ratio; OR = odds ratio.

Please cite this article as: Kuchenbecker J et al., The Relationship Between Hospital Procedure Volume and Outcomes After Endovascular or Open Surgical Revascularisation for Peripheral Arterial Disease: An Analysis of Health Insurance Claims Data, European Journal of Vascular and Endovascular Surgery, https://doi.org/10.1016/j.ejvs.2022.11.022

et al., the authors used data from multicentre registries in Japan.[17,18] While 0.3% of the nationwide cohort encountered critical in hospital complications after EVR for symptomatic PAD, a higher institutional volume was statistically significantly associated with a lower risk of events.[17] A propensity score matched analysis of 236 pairs revealed that lower institutional volume was associated with higher 12 month re-stenosis rate after aorto-iliac stenting for PAD, while comparable in hospital outcomes were observed.[18]

More than 20 years ago, four different research groups used data derived from Scandinavian registries and databases from the UK and USA.[13–16] The study design and cohorts widely differed. Kantonen *et al.* found that surgeon's caseload and hospital volume affected amputation rates but not the mortality rate in patients operated on for chronic limb threatening ischaemia.[14] In contrast, Troeng *et al.* reported that experience of the surgeon and the type of hospital were less important after an operation for chronic leg ischaemia.[13] Using data from the Oxford region, Michaels *et al.* concluded that districts with high rates of distal arterial reconstructions performed fewer amputations and that more widespread use of reconstructive surgery would result in substantial reductions in the number of leg amputations.[15] Bates *et al.* had access to data from the Veterans Affairs programmes; their study did not show an association between higher amputation case volume and short term mortality, while no data on revascularisation procedures were available.[16]

While the latter studies included rather small cohorts, Moxey *et al.* used large hospital episode statistics data from the UK comprising a total of 27 660 femoropopliteal bypass and 4 161 femorodistal bypass procedures. A positive volume—outcome relationship was found for these procedures with benefits in terms of mortality and limb salvage both during the short and midterm follow up.[21] In an approach to summarise the available evidence, Awopetu *et al.* conducted a systematic review and concluded that higher volume hospitals were associated with reduced amputation and mortality rates after lower limb vascular surgery; however, the authors also emphasised that these data were not conclusive due to significant heterogeneity.[35] Besides the fact that all these previous studies applied heterogeneous study designs, they partially included historical cohorts while the field of PAD treatment rapidly developed during the past two decades.

More recently, Scali *et al.* used data from the Society for Vascular Surgery Vascular Quality Initiative registry comprising a total of 25 852 procedures with sufficient one year follow up (2003 — 2019). A higher volume was associated with diminished midterm survival, while increasing practice experience in years was more significantly associated with a reduction of in hospital complications and the risk of major adverse limb events compared with the volume. In contrast, neither experience nor volume had any significant association with early mortality.[19]

Interestingly, the results from the current study overall confirmed the inconsistency in previous studies. The rather distinct benefits in terms of major amputation rate were accompanied by a survival benefit only after open surgical procedures.

Strengths

This study explored the role of hospital volume in the context of PAD in Germany based on an innovative linkage of data extracted from hospital quality reports and insurance claims data. A particular strength was the longitudinal design, which enabled a current or history of chronic diseases and prior treatment to be taken into account, and also outcomes occurring beyond discharge to be considered.

Limitations

Although the data offer a valuable insight into the effect of hospital volume on patient outcomes, they have some limitations. The administrative data used for the current study were not primarily collected for research purposes and it cannot be excluded that systematic coding errors appeared. Extensive data cleaning involving internal validation and Z scores with median absolute deviation was performed. Furthermore, the issue of residual confounding in observational research remains unsolved. Hence it seems important to question clinical relevance against statistical significance. Despite the large sample size of the study, in hospital death is a rare event after lower extremity revascularisation, which therefore leads to broad confidence intervals. Lastly, the complex association between hospital volumes, surgeons' teaching curriculum, who treats patients in an academic centre, and other aspects certainly deserve more attention, as the available information were limited in the current study. To date, 36 university medical centres exist beside more than 1 600 general hospitals in Germany. If a non-academic hospital is registered as a teaching hospital, it does not follow commonly accepted assumptions concerning surgical training and there is no central registry for this information.[36–38]

The results of the current study emphasise that the vascular community should further explore the possible relationship between case volume and outcomes in the PAD field. In times of increasing centralisation of procedures in vascular surgery, it appears reasonable to consider all the different areas of clinical expertise.

Conclusions

This large analysis of health insurance claims revealed that a higher case volume was associated with lower major amputation rate in the longer term after both endovascular and open surgical revascularisation for symptomatic PAD. Furthermore, midterm survival was better after open surgical revascularisation in high volume facilities. These results confirm previous data emphasising that the vascular community should expand considerations of centralisation to domains other than aortic repair. Beyond the pressing need for a standardisation of definition of volume stratification,

Please cite this article as: Kuchenbecker J et al., The Relationship Between Hospital Procedure Volume and Outcomes After Endovascular or Open Surgical Revascularisation for Peripheral Arterial Disease: An Analysis of Health Insurance Claims Data, European Journal of Vascular and Endovascular Surgery, https://doi.org/10.1016/j.ejvs.2022.11.022

future projects should aim to derive appropriate thresholds for the treatment of patients with PAD.

CONFLICTS OF INTEREST

None.

ACKNOWLEDGEMENTS

The authors are grateful for the scientific support from BARMER. This work was supported by the German Federal Joint Committee (grant number 01VSF18035 to CAB).

APPENDIX A. SUPPLEMENTARY DATA

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ejvs.2022.11.022.

REFERENCES

1 He J, Zhang Z, Wang H, Cai L. The relation between volume and outcome of transcatheter and surgical aortic valve replacement: a systematic review and meta-analysis. *Cardiovasc Ther* 2020;**2020**: 2601340.
2 Ando T, Villablanca PA, Takagi H, Briasoulis A. Meta-analysis of hospital-volume relationship in transcatheter aortic valve implantation. *Heart Lung Circ* 2020;**29**:147–56.
3 Gaudino M, Bakaeen F, Benedetto U, Rahouma M, Di Franco A, Tam DY, et al. Use rate and outcome in bilateral internal thoracic artery grafting: insights from a systematic review and meta-analysis. *J Am Heart Assoc* 2018;**7**. e009361.
4 Nguyen YL, Wallace DJ, Yordanov Y, Trinquart L, Blomkvist J, Angus DC, et al. The volume-outcome relationship in critical care: a systematic review and meta-analysis. *Chest* 2015;**148**:79–92.
5 Henebiens M, van den Broek TA, Vahl AC, Koelemay MJ. Relation between hospital volume and outcome of elective surgery for abdominal aortic aneurysm: a systematic review. *Eur J Vasc Endovasc Surg* 2007;**33**:285–92.
6 Shackley P, Slack R, Booth A, Michaels J. Is there a positive volume-outcome relationship in peripheral vascular surgery? Results of a systematic review. *Eur J Vasc Endovasc Surg* 2000;**20**:326–35.
7 Holt PJE, Poloniecki JD, Loftus IM, Thompson MM. The relationship between hospital case volume and outcome from carotid endartectomy in England from 2000 to 2005. *Eur J Vasc Endovasc Surg* 2007;**34**:646–54.
8 Budtz-Lilly J, Bjorck M, Venermo M, Debus S, Behrendt CA, Altreuther M, et al. Editor's Choice - The impact of centralisation and endovascular aneurysm repair on treatment of ruptured abdominal aortic aneurysms based on international registries. *Eur J Vasc Endovasc Surg* 2018;**56**:181–8.
9 Trenner M, Kuehnl A, Salvermoser M, Reutersberg B, Geisbuesch S, Schmid V, et al. Editor's Choice - High annual hospital volume is associated with decreased in hospital mortality and complication rates following treatment of abdominal aortic aneurysms: secondary data analysis of the nationwide German DRG statistics from 2005 to 2013. *Eur J Vasc Endovasc Surg* 2018;**55**:185–94.
10 Sillesen H, Debus S, Dick F, Eiberg J, Halliday A, Haulon S, et al. Long term evaluation should be an integral part of the clinical implementation of new vascular treatments - an ESVS Executive Committee position statement. *Eur J Vasc Endovasc Surg* 2019;**58**:315–7.
11 Song P, Rudan D, Zhu Y, Fowkes FJI, Rahimi K, Fowkes FGR, et al. Global, regional, and national prevalence and risk factors for peripheral artery disease in 2015: an updated systematic review and analysis. *Lancet Global Health* 2019;**7**:1020–30.
12 Behrendt CA, Sigvant B, Kuchenbecker J, Grima MJ, Schermerhorn M, Thomson IA, et al. Editor's Choice - International variations and sex disparities in the treatment of peripheral arterial occlusive disease: a report from VASCUNET and the International Consortium of Vascular Registries. *Eur J Vasc Endovasc Surg* 2020;**60**:873–80.
13 Troëng T, Bergqvist D, Janson L. Incidence and causes of adverse outcomes of operation for chronic ischaemia of the leg. *Eur J Surg* 1994;**160**:17–25.
14 Kantonen I, Lepäntalo M, Luther M, Salenius P, Ylönen K. Factors affecting the results of surgery for chronic critical leg ischemia – a nationwide survey. Finnvasc Study Group. *J Vasc Surg* 1998;**27**: 940–7.
15 Michaels JA, Rutter P, Collin J, Legg FM, Galland RB. Relation between rates of leg amputation and distal arterial reconstructive surgery. Oxford Regional Vascular Audit Group. *BMJ* 1994;**309**: 1479–80.
16 Bates EW, Berki SE, Homan RK, Lindenauer SM. The challenge of benchmarking: surgical volume and operative mortality in Veterans Administration Medical Centers. *Best Pract Benchmarking Healthc* 1996;**1**:34–42.
17 Iida O, Takahara M, Kohsaka S, Soga Y, Fujihara M, Mano T, et al. Impact of institutional volume on critical in-hospital complications adjusted for patient- and limb-related characteristics: an analysis of a nationwide Japanese registry of endovascular interventions for PAD. *J Endovasc Ther* 2020;**27**:739–48.
18 Iida O, Takahara M, Yamauchi Y, Shintani Y, Sugano T, Yamamoto Y, et al. Impact of hospital volume on clinical outcomes after aortoiliac stenting in patients with peripheral artery disease. *J Atheroscler Thromb* 2020;**27**:516–23.
19 Scali ST, Martin AJ, Neal D, Berceli SA, Beach J, Suckow BD, et al. Surgeon experience versus volume differentially affects lower extremity bypass outcomes in contemporary practice. *J Vasc Surg* 2021;**74**:1978–86.
20 Karthikesalingam A, Hinchliffe RJ, Loftus IM, Thompson MM, Holt PJ. Volume-outcome relationships in vascular surgery: the current status. *J Endovasc Ther* 2010;**17**:356–65.
21 Moxey PW, Hofman D, Hinchliffe RJ, Poloniecki J, Loftus IM, Thompson MM, et al. Volume-outcome relationships in lower extremity arterial bypass surgery. *Ann Surg* 2012;**256**:1102–7.
22 Conte MS, Bradbury AW, Kolh P, White JV, Dick F, Fitridge R, et al. Global vascular guidelines on the management of chronic limb-threatening ischemia. *Eur J Vasc Endovasc Surg* 2019;**58**: S1–109.
23 Aboyans V, Ricco JB, Bartelink MEL, Bjorck M, Brodmann M, Cohnert T, et al. Editor's Choice - 2017 ESC Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases, in collaboration with the European Society for Vascular Surgery (ESVS). *Eur J Vasc Endovasc Surg* 2018;**55**:305–68.
24 Hischke S, Rieß HC, Bublitz MK, Kriston L, Schwaneberg T, Härter M, et al. Quality indicators in peripheral arterial occlusive disease treatment: a systematic review. *Eur J Vasc Endovasc Surg* 2019;**58**:738–45.
25 Riess HC, Debus ES, Schwaneberg T, Hischke S, Maier J, Bublitz M, et al. Indicators of outcome quality in peripheral arterial disease revascularisations - a Delphi expert consensus. *VASA* 2018;**47**:491–7.
26 Peters F, Kreutzburg T, Kuchenbecker J, Marschall U, Remmel M, Dankhoff M, et al. Quality of care in surgical/interventional vascular medicine: what can routinely collected data from the insurance companies achieve? *Gefässchirurgie* 2020;**25**:19–28.
27 Nimptsch U, Mansky T. Hospital volume and mortality for 25 types of inpatient treatment in German hospitals: observational study using complete national data from 2009 to 2014. *BMJ Open* 2017;**7**:e016184.
28 Behrendt CA, Sedrakyan A, Peters F, Kreutzburg T, Schermerhorn M, Bertges DJ, et al. Editor's Choice - long term survival after femoropopliteal artery revascularisation with paclitaxel coated devices: a propensity score matched cohort analysis. *Eur J Vasc Endovasc Surg* 2020;**59**:587–96.
29 Peters F, Kreutzburg T, Kuchenbecker J, Debus E, Marschall U, L'Hoest H, et al. A retrospective cohort study on the provision and

outcomes of pharmacological therapy after revascularization for peripheral arterial occlusive disease: A study protocol. *BMJ Surg Interv Health Tec* 2020;**2**:e000020.

30 Iglewicz B, Hoaglin D. The ASQC basic references in quality control: statistical techniques. *How to detect and handle outliers (Mykytka EF. ASQC Quality Press* 1993;**16**:1−87.

31 Grambsch PM, Therneau TM. Proportional hazards tests and diagnostics based on weighted residuals. *Biometrika* 1994;**81**: 515−26.

32 Elixhauser A, Steiner C, Harris DR, Coffey RM. Comorbidity measures for use with administrative data. *Med Care* 1998;**36**:8−27.

33 Quan H, Khan N, Hemmelgarn BR, Tu K, Chen G, Campbell N, et al. Validation of a case definition to define hypertension using administrative data. *Hypertension* 2009;**54**:1423−8.

34 van Walraven C, Austin PC, Jennings A, Quan H, Forster AJ. A modification of the Elixhauser comorbidity measures into a point system for hospital death using administrative data. *Med Care* 2009;**47**:626−33.

35 Awopetu AI, Moxey P, Hinchliffe RJ, Jones KG, Thompson MM, Holt PJ. Systematic review and meta-analysis of the relationship between hospital volume and outcome for lower limb arterial surgery. *Br J Surg* 2010;**97**:797−803.

36 Patel MS, Fong ZV, Wojcik BM, Noorbakhsh A, Wilson SE, Chang DC. Hospital teaching status and readmission after open abdominal aortic aneurysm repair. *Ann Vasc Surg* 2018;**50**:186−94.

37 Pei KY, Zhang Y, Sarac T, Davis KA. Comparison of outcomes in below-knee amputation between vascular and general surgeons. *Ann Vasc Surg* 2018;**50**:259−68.

38 Goka EA, Phillips P, Poku E, Essat M, Woods HB, Walters SJ, et al. The relationship between hospital or surgeon volume and outcomes in lower limb vascular surgery in the United Kingdom and Europe. *Ann Vasc Surg* 2017;**45**:271−86.

Please cite this article as: Kuchenbecker J et al., The Relationship Between Hospital Procedure Volume and Outcomes After Endovascular or Open Surgical Revascularisation for Peripheral Arterial Disease: An Analysis of Health Insurance Claims Data, European Journal of Vascular and Endovascular Surgery, https://doi.org/10.1016/j.ejvs.2022.11.022