


# Impact of Procedure Volume on the Outcomes of Surgical Aortic Valve Replacement

Vera Oettinger<sup>1,2</sup>  Klaus Kaier<sup>2,3</sup> Constantin von zur Mühlen<sup>1,2</sup> Manfred Zehender<sup>1,2</sup>  
Christoph Bode<sup>1</sup> Friedhelm Beyersdorf<sup>4</sup> Peter Stachon<sup>1,2,\*</sup> Wolfgang Bothe<sup>4,\*</sup>

<sup>1</sup> Department of Cardiology and Angiology I, University Heart Center Freiburg, Medical Center – University of Freiburg, Faculty of Medicine, University of Freiburg, Freiburg, Germany

<sup>2</sup> Center for Big Data Analysis in Cardiology (CeBAC), Department of Cardiology and Angiology I, University Heart Center Freiburg, Medical Center – University of Freiburg, Faculty of Medicine, University of Freiburg, Freiburg, Germany

<sup>3</sup> Institute of Medical Biometry and Statistics, Faculty of Medicine and Medical Center – University of Freiburg, Freiburg, Germany

<sup>4</sup> Department of Cardiac and Vascular Surgery, University Heart Center Freiburg, Medical Center – University of Freiburg, Faculty of Medicine, University of Freiburg, Freiburg, Germany

**Address for correspondence** Vera Oettinger, MD, MSc, Department of Cardiology and Angiology I, University Heart Center Freiburg, Medical Center – University of Freiburg, Hugstetter Str. 55, 79106 Freiburg, Germany (e-mail: vera.oettinger@uniklinik-freiburg.de).

Thorac Cardiovasc Surg 2024;72:173–180.

## Abstract

**Background** Literature demonstrated that procedure volumes affect outcomes of patients undergoing transcatheter aortic valve implantation. We evaluated the outcomes of surgical aortic valve replacement.

**Methods** All isolated surgical aortic valve replacement procedures in Germany in 2017 were identified. Hospitals were divided into five groups from  $\leq 25$  (very low volume) until  $> 100$  (very high volume) annual procedures.

**Results** In 2017, 5,533 patients underwent isolated surgical aortic valve replacement. All groups were of comparable risk (logistic EuroSCORE, 5.12–4.80%) and age (66.6–68.1 years). In-hospital mortality and complication rates were lowest in the very high-volume group. Multivariable logistic regression analyses showed no significant volume–outcome relationship for in-hospital mortality, stroke, postoperative delirium, and mechanical ventilation  $> 48$  hours. Regarding acute kidney injury, patients in the very high-volume group were at lower risk than those in the very low volume group (odds ratio [OR] = 0.53,  $p = 0.04$ ). Risk factors for in-hospital mortality were previous cardiac surgery (OR = 5.75,  $p < 0.001$ ), high-grade renal disease (glomerular filtration rate  $< 15$  mL/min, OR = 5.61,  $p = 0.002$ ), surgery in emergency cases (OR = 2.71,  $p = 0.002$ ), and higher grade heart failure (NYHA [New York Heart Association] III/IV; OR = 1.80,  $p = 0.02$ ). Risk factors for all four complication rates were atrial fibrillation and diabetes mellitus.

**Conclusion** Patients treated in very low volume centers ( $\leq 25$  operations/year) had a similar risk regarding in-hospital mortality and most complications compared with very

## Keywords

- ▶ surgical aortic valve replacement
- ▶ volume–outcome relationship
- ▶ caseload
- ▶ in-hospital mortality
- ▶ complications
- ▶ transcatheter aortic valve implantation

\* These authors share the last authorship.

received

November 9, 2021

accepted after revision

March 14, 2022

article published online

August 2, 2022

© 2022. Thieme. All rights reserved.

Georg Thieme Verlag KG,

Rüdigerstraße 14,

70469 Stuttgart, Germany

DOI [https://doi.org/](https://doi.org/10.1055/s-0042-1754352)

10.1055/s-0042-1754352.

ISSN 0171-6425.

high-volume centers (>100 operations/year). Only in the case of acute kidney injury, very high-volume centers showed better outcomes than very low volume centers. Therefore, surgical aortic valve replacement can be performed safely independent of case volume.

## Introduction

In a recent publication, a minimum volume of 50 procedures per center and year was found to be suitable to allow for sufficient routine and thus better in-hospital outcomes in patients undergoing transcatheter aortic valve implantation (TAVI).<sup>1</sup> Volume–outcome relationships have also been published for various cardiac operations such as coronary artery bypass graft (CABG),<sup>2–4</sup> mitral valve replacement,<sup>3</sup> or surgical aortic valve replacement (SAVR).<sup>5–7</sup> In earlier studies, Nimptsch and Mansky<sup>5</sup> found a slightly lower in-hospital mortality rate with higher annual case numbers in patients undergoing SAVR, but since then TAVI has developed rapidly.<sup>8–10</sup> The indication, which was initially limited to patients with isolated aortic valve stenosis and very high operative risk, has been increasingly expanded<sup>11–14</sup> and, consequently, has led to altered profiles of patients undergoing SAVR.<sup>15</sup>

It may be speculated that these alterations could affect patient outcomes with respect to the center volume. Therefore, we performed an analysis of all SAVR procedures conducted in German hospitals in 2017. We analyzed in-hospital mortality and complications with regard to the case numbers of the respective centers. Furthermore, we investigated other influencing factors on in-hospital outcomes.

## Patients and Methods

### Data and Measures

Since 2005, data on all hospitalizations in Germany have been available for scientific use via the Diagnosis Related Groups (DRG) statistics collected by the Research Data Center of the Federal Bureau of Statistics (DESTATIS). These hospitalization data, including diagnoses and procedures, are a valuable source of representative nationwide data on the in-hospital treatment of patients. This database represents a virtually complete collection of all hospitalizations in German hospitals that are reimbursed according to the DRG system. From this database, we extracted data on all isolated SAVR procedures conducted in the latest available year 2017. Isolated SAVR procedures were defined using the German Operation and Procedure Classification (OPS) codes with the inclusion of all aortic valve procedures and the exclusion of concomitant procedures at the mitral valve, tricuspid valve procedures, CABG procedures, and maze procedures (see ►Supplementary Table S1 [available in the online version only]). As described previously,<sup>9</sup> patients with a baseline diagnosis of pure aortic regurgitation (main or secondary diagnosis other than International Classification of Diseases, Tenth Revision [ICD-10] codes I35.0, I35.2, I06.0, I06.2) and those with concomitant cardiac surgery or

percutaneous coronary intervention were not included in this analysis.

The respective patients were classified into five groups, starting with  $\leq 25$  procedures per center and year (very low volume) and ending at >100 procedures (very high volume). By choosing these groups, we were able to compare hospitals with, on the one hand, very low and, on the other hand, very high annual case numbers. In addition, these five volume groups were chosen as categorical values instead of continuous ones to be able to make clear and practicable recommendations. Furthermore, we wanted to investigate whether especially centers with very low volume of  $\leq 25$  operations/year achieve different outcomes than the larger centers. For calculating *p*-values and risk adjustment, centers with  $\leq 25$  cases per year were therefore used as reference.

The analysis focused on five different end points: in-hospital mortality, stroke, acute kidney injury (AKI), postoperative delirium, and mechanical ventilation exceeding 48 hours. Stroke and AKI were defined using ICD-10 codes (secondary diagnosis I63\* or I64 and N17\*, respectively). In-hospital mortality and length of mechanical ventilation were part of DESTATIS' main set of variables. All other comorbidities were defined by existing anamnestic or acute distinctive codes.

For calculation of the estimated logistic European System for Cardiac Operative Risk Evaluation (EuroSCORE), we were able to populate all fields except for critical preoperative state and left ventricular function, which were not available in the dataset provided by DESTATIS. In these, we assumed an inconspicuous state (i.e., no critical preoperative state and no left ventricular dysfunction) and thus calculated a best-case scenario.

### Statistical Analysis

In descriptive analyses of baseline characteristics and outcomes, groups were compared using chi-square tests or unpaired *t*-tests. To determine the impact of procedure volumes on the various end points, multivariable logistic regression analyses were performed. Beside procedure volume categories, a total of 21 baseline patient characteristics were included as potential confounders (as described previously<sup>9</sup>; all covariates listed in ►Table 1). Cluster-robust standard errors were used to account for the correlation of error terms of patients treated in the same hospital. No adjustment for multiple testing was performed. Thus, *p*-values may not be interpreted as confirmatory but are descriptive in nature and inferences drawn from the 95% confidence intervals may not be reproducible. All analyses were performed using Stata 16.0 (StataCorp, College Station, Texas, United States).

**Table 1** Baseline characteristics and in-hospital outcomes of patients treated with isolated SAVR in 2017

	≤25 procedures (very low)	26–50 procedures (low)	51–75 procedures (medium)	76–100 procedures (high)	>100 procedures (very high)	p-Value (≤25 vs all other groups)
N	154	849	949	1,139	2,442	
Logistic EuroSCORE, mean/SD	5.12/4.27	5.06/4.35	5.02/4.39	4.96/4.60	4.80/4.04	0.744
Age in years, mean/SD	66.59/9.63	67.05/9.75	68.05/9.56	67.78/9.74	67.39/10.11	0.253
Female, %	31.17%	34.63%	33.40%	35.56%	37.14%	0.242
NYHA II, %	12.34%	12.25%	9.48%	11.41%	21.87%	0.226
NYHA III or IV, %	31.82%	30.15%	34.56%	39.16%	27.89%	0.998
CAD, %	20.13%	20.97%	19.60%	19.58%	20.52%	0.976
Hypertension, %	70.13%	63.72%	52.58%	53.73%	57.41%	0.001
Previous MI within 4 mo, %	– <sup>a</sup>	0.59%	0.63%	0.70%	0.82%	– <sup>a</sup>
Previous MI within 1 y, %	0%	0%	0.32%	0.26%	0.49%	0.472
Previous MI after 1 y, %	– <sup>a</sup>	2.36%	2.32%	1.84%	1.68%	– <sup>a</sup>
Previous CABG, %	1.95%	2.24%	1.16%	1.32%	1.02%	0.488
Previous cardiac surgery, %	5.19%	7.07%	3.06%	4.04%	3.60%	0.521
Peripheral vascular disease, %	2.60%	3.53%	4.74%	4.92%	5.32%	0.196
Carotid disease, %	7.14%	4.95%	4.74%	4.57%	4.42%	0.139
COPD, %	11.04%	9.78%	11.28%	10.18%	7.45%	0.403
Pulmonary hypertension	9.09%	10.25%	6.95%	8.96%	11.83%	0.678
Renal disease, GFR < 15 mL/min, %	– <sup>a</sup>	1.06%	1.26%	0.97%	0.33%	– <sup>a</sup>
Renal disease, GFR < 30 mL/min, %	– <sup>a</sup>	0.71%	0.84%	0.70%	1.31%	– <sup>a</sup>
Atrial fibrillation, %	40.91%	39.34%	37.72%	43.55%	42.38%	0.917
Diabetes mellitus, %	25.97%	22.85%	25.71%	23.79%	22.77%	0.479
Emergency, %	17.53%	9.66%	11.49%	6.58%	3.03%	<0.001
In-hospital mortality	1.95%	2.24%	2.11%	2.19%	0.98%	0.741
Stroke	2.60%	2.36%	3.37%	2.28%	1.64%	0.583
AKI	12.34%	7.66%	8.01%	7.90%	6.27%	0.026
Postoperative delirium	9.74%	11.31%	15.70%	16.33%	9.66%	0.384
Ventilation > 48 h	7.14%	7.30%	13.38%	6.67%	4.95%	1.000

Abbreviations: AKI, acute kidney injury; CABG, coronary artery bypass graft; CAD, coronary artery disease; COPD, chronic obstructive pulmonary disease; EuroSCORE, European System for Cardiac Operative Risk Evaluation; GFR, glomerular filtration rate; MI, myocardial infarction; N, number of procedures; NYHA, New York Heart Association; SAVR, surgical aortic valve replacement; SD, standard deviation.

<sup>a</sup>Any information allowing the drawing of conclusions about a single patient or a specific hospital was censored by DESTATIS to guarantee data protection.

## Results

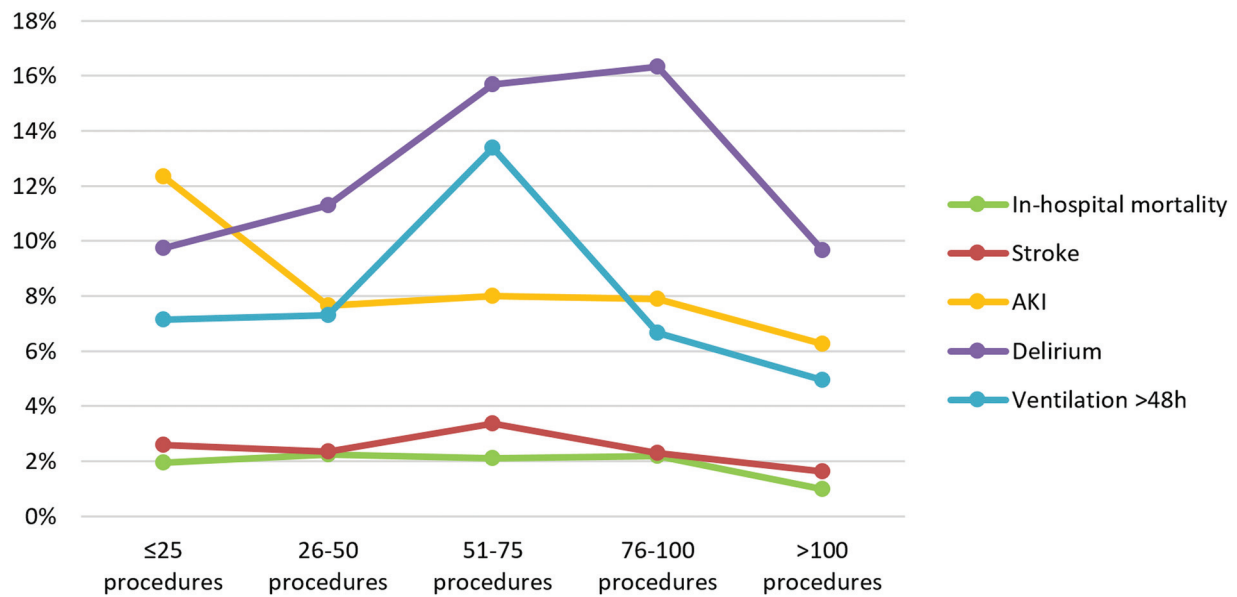
### Baseline Characteristics

In 2017, 5,533 patients underwent isolated SAVR in Germany. Of these, 154 were treated in the very low volume group (≤25 cases/year) and 2,442 in the very high-volume group (>100 cases/year; ▶Table 1). Also, 81.87% were accounted for hospitals with >50 procedures per year. Patients in all groups had a comparable, slightly falling preprocedural risk with higher volume according to the mean logistic EuroSCORE (5.12% in the very low volume group vs 4.80% in very high) and a comparable mean age (66.6–68.1 years over all groups). About one-

third was female (35.62% on average). Unadjusted in-hospital mortality and all observed complication rates (stroke, AKI, delirium, ventilation > 48 hours) were lowest in the very high-volume group (▶Fig. 1). Most common comorbidities were arterial hypertension (57.15% on average), atrial fibrillation (41.32% on average), and heart failure (NYHA [New York Heart Association] III/IV; 31.81% on average).

### Volume–Outcome Relationship

Using centers with ≤25 cases per year as reference, data showed slight differences for in-hospital mortality between groups with regard to procedure volume that are not



**Fig. 1** Unadjusted in-hospital outcomes per hospital category in 2017. AKI: acute kidney injury.

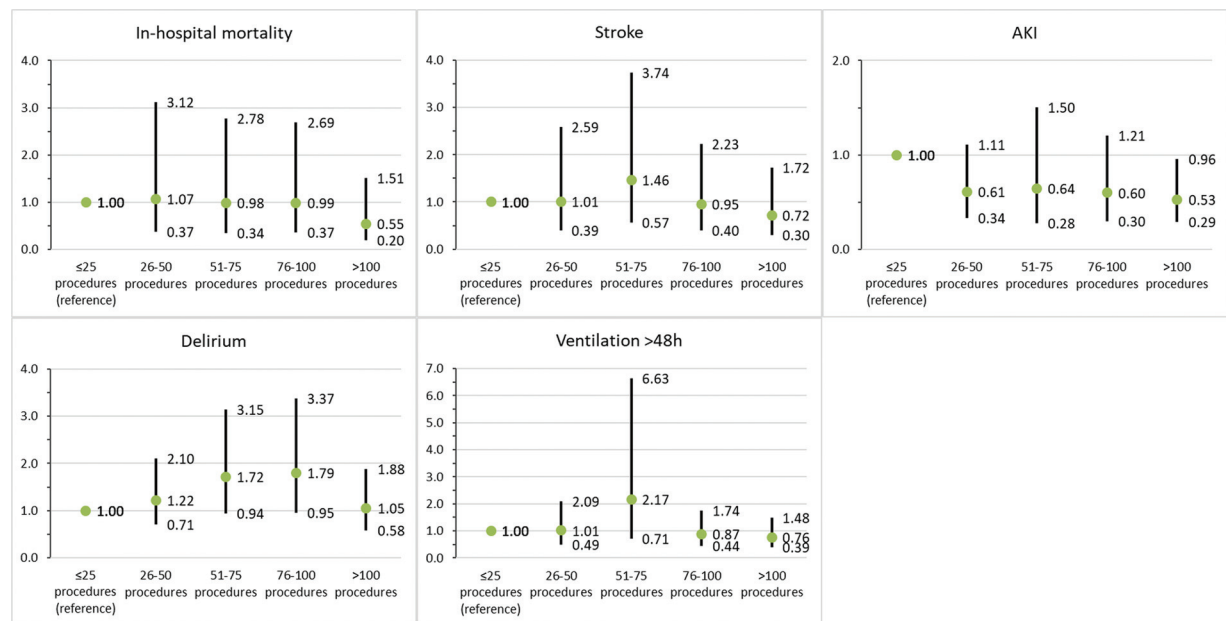
significant after risk adjustment (>100 procedures: adjusted odds ratio [OR] = 0.55,  $p = 0.24$ ; ► **Supplementary Table S2** [available in the online version only]).

Considering in-hospital complications, multivariable logistic regression analyses showed no significant inverse volume–outcome relationship for the end points stroke, postoperative delirium, and mechanical ventilation > 48 hours. Regarding the end point AKI, patients treated in hospitals of the very high-volume group were at a lower risk than patients treated in the very low volume group (OR = 0.53,  $p = 0.04$ ). Also, slight differences re-

garding the very high-volume group that are not significant were seen in stroke and ventilation > 48 hours (► **Fig. 2**).

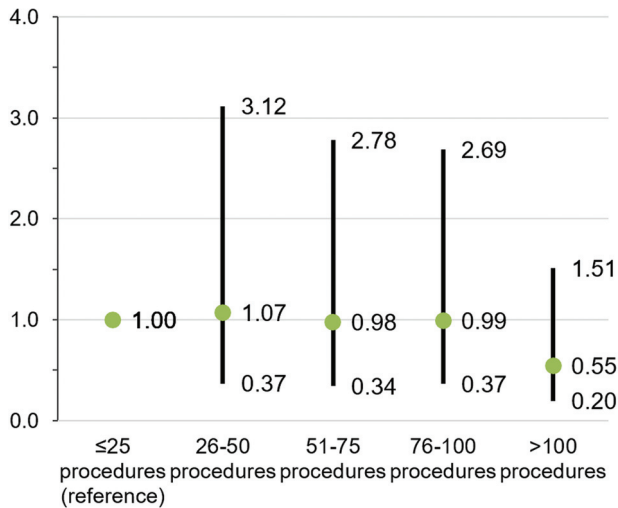
### Influencing Factors

A significantly higher in-hospital mortality was observed in patients with previous cardiac surgery (OR = 5.75,  $p < 0.001$ ) and a high-grade renal disease with glomerular filtration rate (GFR) < 15 mL/min (OR = 5.61,  $p = 0.002$ ). Furthermore, surgery in emergency cases was a significant predictor of higher mortality (OR = 2.71,  $p = 0.002$ ), as well as age (OR



**Fig. 2** Risk-adjusted odds ratios for in-hospital outcomes per hospital category in 2017. Risk-adjusted odds ratios (green marks) and 95% confidence intervals (black lines), divided up according to the number of SAVR procedures treated per hospital in 2017. AKI, acute kidney injury.

**Risk-adjusted odds ratios and 95% confidence intervals for in-hospital mortality per hospital category in 2017**



= 1.03,  $p = 0.03$ ). Also, patients with higher grade heart failure (NYHA III/IV) had a significantly higher mortality rate (OR = 1.80,  $p = 0.02$ ), while those with a lower grade heart failure (NYHA II) tended to have a lower one (OR = 0.24,  $p = 0.06$ ).

Significant risk factors on all four in-hospital complications were atrial fibrillation (stroke: OR = 1.72,  $p = 0.01$ ; AKI: OR = 2.04,  $p < 0.001$ ; delirium: OR = 1.77,  $p < 0.001$ ; ventilation > 48 hours: OR = 2.19,  $p < 0.001$ ) and diabetes mellitus (stroke: OR = 1.69,  $p = 0.007$ ; AKI: OR = 1.54,  $p < 0.001$ ; delirium: OR = 1.39,  $p = 0.002$ ; ventilation > 48 hours: OR = 1.39,  $p = 0.003$ ).

Diverging results were found for age (stroke: OR = 0.95,  $p < 0.001$ ; AKI: OR = 1.02,  $p = 0.004$ ; delirium: OR = 1.04,  $p < 0.001$ ; ventilation > 48 hours: OR = 1.00,  $p = 0.59$ ), previous cardiac surgery (stroke: OR = 0.17,  $p = 0.03$ ; AKI: OR = 4.40,  $p < 0.001$ ; delirium: OR = 0.84,  $p = 0.52$ ; ventilation > 48 hours: OR = 3.17,  $p < 0.001$ ), chronic obstructive pulmonary disease (stroke: OR = 0.45,  $p = 0.03$ ; AKI: OR = 1.51,  $p = 0.009$ ; delirium: OR = 1.25,  $p = 0.10$ ; ventilation > 48 hours: OR = 1.48,  $p = 0.05$ ), pulmonary hypertension (stroke: OR = 0.10,  $p < 0.001$ ; AKI: OR = 1.83,  $p = 0.003$ ; delirium: OR = 0.72,  $p = 0.13$ ; ventilation > 48 hours: OR = 1.09,  $p = 0.65$ ), and emergency admissions (stroke: OR = 0.32,  $p = 0.01$ ; AKI: OR = 2.32,  $p < 0.001$ ; delirium: OR = 0.95,  $p = 0.78$ ; ventilation > 48 hours: OR = 1.40,  $p = 0.07$ ).

As also seen in in-hospital mortality, a higher grade heart failure (NYHA III/IV) was related to a significantly higher rate of AKI (OR = 1.95,  $p = 0.002$ ) and ventilation > 48 hours (OR = 1.67,  $p = 0.002$ ), while a lower one showed a significantly lower rate of ventilation > 48 hours (OR = 0.53,  $p = 0.007$ ) and slight, although not significant, differences toward lower rate of stroke (OR = 0.53,  $p = 0.08$ ).

Furthermore, significant risk factors on at least one in-hospital complication were EuroSCORE (stroke: OR = 1.29,  $p < 0.001$ ; delirium: OR = 1.05,  $p = 0.02$ ), coronary artery dis-

ease (ventilation > 48 hours: OR = 1.44,  $p = 0.005$ ), and higher grade renal disease (GFR < 15 mL/min, ventilation > 48 hours: OR = 3.40,  $p = 0.001$ ; GFR < 30 mL/min, AKI: OR = 4.54,  $p < 0.001$ ; ventilation > 48 hours: OR = 1.91,  $p = 0.01$ ).

Lower rates of some in-hospital complications were observed in female patients (stroke: OR = 0.37,  $p < 0.001$ ; delirium: OR = 0.56,  $p < 0.001$ ), patients with previous CABG (AKI: OR = 0.36,  $p = 0.02$ ; ventilation > 48 hours: OR = 0.32,  $p = 0.009$ ), and patients with carotid disease (ventilation > 48 hours: OR = 0.49,  $p = 0.01$ ).

## Discussion

We analyzed all isolated SAVR procedures in Germany in 2017 to examine possible influences of annual hospital case numbers and baseline characteristics on in-hospital outcomes of SAVR. Interestingly, in this specific cohort, and in contrast to patients undergoing TAVI,<sup>1</sup> patients treated in very low volume centers (≤25 SAVR/year) had a similar risk with regard to in-hospital outcomes compared with patients treated in very high volume centers (>100 SAVR/year). The difference between TAVI and SAVR may be due to a longer learning curve over many decades in treating patients surgically.

The present data show that the largest amount of SAVR procedures is performed in higher volume centers, which was also found for TAVI in Germany.<sup>1,16</sup> Surprisingly, we observed a decrease of the EuroSCORE in centers with higher operation numbers. This could be due to a different therapy choice and allocation to SAVR or alternatively TAVI in very high versus very low volume centers, based on a decision by the heart team. Since TAVI is mostly performed in high-volume centers,<sup>1,16</sup> this could result in particularly patients with a higher risk receiving TAVI, if possible, and consequently the average risk in SAVR is lower, especially in higher volume centers. In addition, the present results show that very low volume centers treat significantly more emergency cases, which most likely also contributes to the higher EuroSCORE in very low volume centers.

Unadjusted in-hospital mortality and all observed complication rates (stroke, AKI, delirium, ventilation > 48 hours) were lowest in the very high volume group. After risk adjustment, data showed no significant difference between groups for in-hospital mortality and most complications (stroke, delirium, ventilation > 48 hours). For AKI, patients treated in the very high-volume group were at a lower risk than those treated in the very low one. Therefore, our results indicate that patients treated with SAVR in very low volume centers were of comparable risk for in-hospital outcomes, which is in contrast to the volume–outcome relationships described in the literature for TAVI.<sup>1,16–19</sup> This difference could be due to the fact that SAVR is a standard surgical operation and an integral part of surgical training with decades of experience. In contrast, TAVI is usually only offered at specialized centers. In addition, surgical learning effects in SAVR result from the sum of different operations, whereas TAVI is a special procedure that can only be partially compared with other catheter-based procedures such as



coronary angiography. Furthermore, taking into account the only small differences seen between very low and very high-volume centers in SAVR, the team performance seems very important. Also, the indication of TAVI, which was initially limited to patients with isolated aortic valve stenosis and very high operative risk, has been increasingly expanded<sup>11–14</sup> and, consequently, has led to altered profiles of patients undergoing SAVR<sup>15</sup> toward more selected patients who are younger and have fewer comorbidities as well as a lower operative risk.

It is also interesting that very low volume centers treat significantly more emergency cases than the other volume groups and still achieve good results. It is worth considering that SAVR is performed in very low volume centers by a limited number of experienced surgeons, which leads to good outcomes. However, in higher volume centers, there might be several residents in training, leading to mixed results. Furthermore, especially in very high-volume centers, there may be many experienced surgeons, which in turn leads to good results. This could also explain the slightly higher complication rates in the intermediate groups. In this context, it should be mentioned again that our study ultimately analyzed the performance of the centers and not of individual operators. Center experience therefore plays a major role.

Since the available data showed only minor differences in the outcomes between higher and lower volume centers, no specific threshold or ideal number of cases can be derived. Centers with lower volumes could also play an important role, e.g., in emergency cases and in regions with comparatively few hospitals.

Volume–outcome relationships for SAVR have been analyzed in several studies in the past. Nimptsch and Mansky<sup>5</sup> examined the volume–outcome relationship for SAVR in Germany between 2009 and 2014. They found an influence in favor of high-volume centers regarding the adjusted in-hospital mortality of 2.4% in the very high-volume quintile versus 3.1% in the very low volume quintile. The difference is significant but <1%. Other factors such as in-hospital complications were not investigated.

Brescia et al<sup>6</sup> investigated the volume–outcome relationship in Michigan, United States, between 2012 and 2016. They found better results in high-volume centers in terms of lower episode payments and shorter length of stay. However, the authors did not compare in-hospital outcomes such as mortality or complications as done in our data.

He et al,<sup>7</sup> in a systematic review and meta-analysis from 2020, examined six studies on SAVR. They summarize a volume–outcome relationship for short-term mortality in favor of high-volume hospitals. However, the authors themselves note that some of the analyzed studies show observation periods that lie far in the past until 1994, ending in 2011. Since the studies examined results from an era before or at the beginning of TAVI, a comparison with today's results and a transfer to the present are limited because of current technical innovations and also possible synergy effects between SAVR and TAVI.

Those synergy effects are described, e.g., by Jack et al.<sup>20</sup> They explain, based on a comparison of outcomes after SAVR

in hospitals with TAVI and those without in the United States, that centers with simultaneous TAVI achieve better results after SAVR in the form of mortality and discharge disposition than without. A positive influence through the involvement of an interdisciplinary heart team as well as possible differences in patient choice in centers with TAVI option is discussed. In a similar way, Singh et al<sup>21</sup> concluded that centers with simultaneous TAVI offer better results after SAVR in terms of mortality and complications than without. Thus, the availability of TAVI seems to have a positive influence on the management of patients with aortic valve stenosis. They also discuss the importance of a heart team because of easier joint decision making as well as improved patient selection, procedural performance, and complications management.

Furthermore, Khera et al<sup>22</sup> discussed that not only case number but also other factors such as risk are important because volume alone would lead to a misclassification of performance.

Our data show that EuroSCORE is a risk factor for complication rates. This seems logical, as those patients with higher EuroSCORE are generally sicker overall. The same applies to the relationship that risk of both mortality and complications increases with higher grade heart failure (NYHA III/IV). Also, a higher grade renal disease is a relevant risk factor; depending on the severity, it increases the risk of AKI and ventilation or even mortality.

Especially atrial fibrillation and diabetes mellitus are significantly associated with higher risk for all four in-hospital complications (stroke, AKI, delirium, ventilation > 48 hours). In-hospital mortality was not affected by either. López-de-Andrés et al<sup>23</sup> analyzed the influence of diabetes mellitus on mortality. They found a constant rate for mechanical valves and even a falling one for bioprostheses. Length of hospital stay was significantly longer in patients with diabetes mellitus. Ram et al<sup>24</sup> showed no impact of diabetes mellitus on in-hospital as well as 1- and 3-year mortality, but 5- and 10-year mortality was significantly higher in patients with diabetes mellitus. However, no complication rates were investigated.

Patients with certain baseline characteristics such as previous CABG or carotid disease achieved lower rates of in-hospital complications. This could be explained by the fact that these patients with certain isolated baseline characteristics possibly are already being treated and regular check-ups take place. They are therefore assigned to SAVR in time and are optimally prepared for it, e.g., with regard to previous medication. As a result, the outcomes are better afterward.

Female gender was found to be a protective factor, particularly for stroke and delirium, but also in a nonsignificant range for the other observed outcomes. This is surprising because female gender is generally considered a risk factor for SAVR<sup>25</sup> and also is taken into account in various risk scores such as logistic EuroSCORE, EuroSCORE II, or Society of Thoracic Surgeons (STS) score.<sup>26–29</sup> This can also be an indication of a possibly shifted patient profile between TAVI and SAVR compared with a time before or at the beginning of TAVI. Since female patients appear more

suitable for TAVI,<sup>30</sup> only selected female patients may receive SAVR.

## Limitations

There are certain limitations beyond those typical of retrospective studies, in accordance with previous analyses.<sup>1,16</sup> First, in administrative data coding errors are almost unavoidable. However, approximately 20% of DRG are reviewed by independent physician teams from health insurances, so overall reliability should be good. Furthermore, risk adjustment included parameters whose reliability cannot be fully secured, and we cannot guarantee that all parameters of relevance are included in the model. For example, no information about the type of valves or devices used in individual procedures is available in the dataset. Therefore, this information could not be used for risk adjustment. Also, information regarding the experience of surgeons would be highly relevant for the analysis but is unavailable, so we can only compare hospitals in Germany but not surgeons. In addition, we only looked at the summed-up results of patient cases per center for 1 year, so no conclusions can be drawn about the learning curve of hospitals or individual surgeons. Finally, the study only analyzed isolated SAVR, so combined operations, e.g., with CABG, were not considered. This makes sense from a clinical perspective, but may make it hard to compare with other datasets and may lead to bias in hospital volume and outcome.

## Conclusion

Patients treated in very low volume centers had a similar risk regarding in-hospital mortality and most complications compared with very high-volume centers. Only in the case of AKI, patients in the very high-volume group were at lower risk than those in the very low one. Hence, SAVR can be performed safely independent of case volume in the era of TAVI. Risk factors for in-hospital mortality after SAVR were previous cardiac surgery, high-grade renal disease (GFR < 15 mL/min), surgery in emergency cases, higher grade heart failure (NYHA III/IV), and age.

### Note

This article was presented at the 87th Annual Meeting of the German Cardiac Society (DGK), Congress Center Rosengarten Mannheim, Rosengartenplatz 2, 68161 Mannheim, Germany, online, April 7–10, 2021.

### Ethical Approval Statement

Our study did not involve direct access by the investigators to data on individual patients but only access to summary results provided by the Research Data Center. Therefore, approval by an ethics committee and informed consent were determined not to be required, in accordance with German law. All summary results were anonymized by DESTATIS. In practice, this means that any information allowing the drawing of conclusions about a single patient or a specific hospital was censored by

DESTATIS to guarantee data protection. Moreover, to prevent the possibility to draw conclusions to a single hospital, the data are verified and situationally censored by DESTATIS in those cases.

### Data Availability Statement

Data are available upon reasonable request. The patients' data are stored on the server of the Federal Bureau of Statistics and are not available due to data protection. The calculated raw data are sent anonymized to the scientist.

### Funding

This work was supported by the “German Heart Foundation/German Foundation of Heart Research.”

### Conflict of Interest

None declared.

### Acknowledgment

Peter Stachon and Wolfgang Bothe share the last authorship. Within the University Heart Center Freiburg at the Medical Center – University of Freiburg, there is an excellent cooperation between cardiologists and cardiovascular surgeons. The “Center for Big Data Analysis in Cardiology (CeBAC)” is led by the Department of Cardiology and Angiology I within the institution. Here, the outstanding expertise of the Department of Cardiac and Vascular Surgery is used in joint collaboration to illuminate this topic on SAVR in the best possible way, which also results in a shared last authorship.

## References

- Oettinger V, Kaier K, Heidt T, et al. Outcomes of transcatheter aortic valve implantations in high-volume or low-volume centres in Germany. *Heart* 2020;106(20):1604–1608
- Gutacker N, Bloor K, Cookson R, et al; as part of the ECHO collaboration. Hospital surgical volumes and mortality after coronary artery bypass grafting: using international comparisons to determine a safe threshold. *Health Serv Res* 2017;52(02):863–878
- Reames BN, Ghaferi AA, Birkmeyer JD, Dimick JB. Hospital volume and operative mortality in the modern era. *Ann Surg* 2014;260(02):244–251
- Kim LK, Looser P, Swaminathan RV, et al. Outcomes in patients undergoing coronary artery bypass graft surgery in the United States based on hospital volume, 2007 to 2011. *J Thorac Cardiovasc Surg* 2016;151(06):1686–1692
- 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(09):e016184
- Brescia AA, Syrjamaki JD, Regenbogen SE, et al. Transcatheter versus surgical aortic valve replacement episode payments and relationship to case volume. *Ann Thorac Surg* 2018;106(06):1735–1741
- 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
- Cribier A. Development of transcatheter aortic valve implantation (TAVI): a 20-year odyssey. *Arch Cardiovasc Dis* 2012;105(03):146–152

- 9 Reinöhl J, Kaier K, Reinecke H, et al. Effect of availability of transcatheter aortic-valve replacement on clinical practice. *N Engl J Med* 2015;373(25):2438–2447
- 10 Gaede L, Kim WK, Blumenstein J, et al. Temporal trends in transcatheter and surgical aortic valve replacement : an analysis of aortic valve replacements in Germany during 2012–2014. *Herz* 2017;42(03):316–324
- 11 Mack MJ, Leon MB, Thourani VH, et al; PARTNER 3 Investigators. Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients. *N Engl J Med* 2019;380(18):1695–1705
- 12 Popma JJ, Deeb GM, Yakubov SJ, et al; Evolut Low Risk Trial Investigators. Transcatheter aortic-valve replacement with a self-expanding valve in low-risk patients. *N Engl J Med* 2019;380(18):1706–1715
- 13 Stachon P, Kaier K, Zirlik A, et al. Risk-adjusted comparison of in-hospital outcomes of transcatheter and surgical aortic valve replacement. *J Am Heart Assoc* 2019;8(07):e011504
- 14 Kuck K-H, Bleiziffer S, Eggebrecht H, et al. Konsensuspapier der Deutschen Gesellschaft für Kardiologie (DGK) und der Deutschen Gesellschaft für Thorax-, Herz- und Gefäßchirurgie (DGTHG) zur kathetergestützten Aortenklappenimplantation (TAVI) 2020. *Der Kardiologe* 2020;14:182–204
- 15 Fujita B, Ensminger S, Bauer T, et al; GARY Executive Board. Trends in practice and outcomes from 2011 to 2015 for surgical aortic valve replacement: an update from the German Aortic Valve Registry on 42 776 patients. *Eur J Cardiothorac Surg* 2018;53(03):552–559
- 16 Kaier K, Oettinger V, Reinecke H, et al. Volume-outcome relationship in transcatheter aortic valve implantations in Germany 2008–2014: a secondary data analysis of electronic health records. *BMJ Open* 2018;8(07):e020204
- 17 Vemulapalli S, Carroll JD, Mack MJ, et al. Procedural volume and outcomes for transcatheter aortic-valve replacement. *N Engl J Med* 2019;380(26):2541–2550
- 18 Badheka AO, Patel NJ, Panaich SS, et al. Effect of hospital volume on outcomes of transcatheter aortic valve implantation. *Am J Cardiol* 2015;116(04):587–594
- 19 Kim LK, Minutello RM, Feldman DN, et al. Association between transcatheter aortic valve implantation volume and outcomes in the United States. *Am J Cardiol* 2015;116(12):1910–1915
- 20 Jack G, Arora S, Strassle PD, et al. Differences in inpatient outcomes after surgical aortic valve replacement at transcatheter aortic valve replacement (TAVR) and non-TAVR centers. *J Am Heart Assoc* 2019;8(22):e013794
- 21 Singh V, Badheka AO, Patel SV, et al. Comparison of in-hospital outcomes of surgical aortic valve replacement in hospitals with and without availability of a transcatheter aortic valve implantation program (from a nationally representative database). *Am J Cardiol* 2015;116(08):1229–1236
- 22 Khera R, Pandey A, Koshy T, et al. Role of hospital volumes in identifying low-performing and high-performing aortic and mitral valve surgical centers in the United States. *JAMA Cardiol* 2017;2(12):1322–1331
- 23 López-de-Andrés A, Perez-Farinos N, de Miguel-Díez J, et al. Impact of type 2 diabetes mellitus in the utilization and in-hospital outcomes of surgical aortic valve replacement in Spain (2001–2015). *Cardiovasc Diabetol* 2018;17(01):135
- 24 Ram E, Kogan A, Levin S, et al. Type 2 diabetes mellitus increases long-term mortality risk after isolated surgical aortic valve replacement. *Cardiovasc Diabetol* 2019;18(01):31
- 25 Goel H, Kumar A, Garg N, Mills JD. Men are from mars, women are from venus: factors responsible for gender differences in outcomes after surgical and trans-catheter aortic valve replacement. *Trends Cardiovasc Med* 2021;31(01):34–46
- 26 Roques F, Michel P, Goldstone AR, Nashef SA. The logistic EuroSCORE. *Eur Heart J* 2003;24(09):881–882
- 27 Nashef SA, Roques F, Sharples LD, et al. EuroSCORE II. *Eur J Cardiothorac Surg* 2012;41(04):734–744, discussion 744–745
- 28 Dewey TM, Brown D, Ryan WH, Herbert MA, Prince SL, Mack MJ. Reliability of risk algorithms in predicting early and late operative outcomes in high-risk patients undergoing aortic valve replacement. *J Thorac Cardiovasc Surg* 2008;135(01):180–187
- 29 Rosenhek R, Lung B, Tornos P, et al. ESC Working Group on Valvular Heart Disease Position Paper: assessing the risk of interventions in patients with valvular heart disease. *Eur Heart J* 2012;33(07):822–828, 828a, 828b
- 30 Williams M, Kodali SK, Hahn RT, et al. Sex-related differences in outcomes after transcatheter or surgical aortic valve replacement in patients with severe aortic stenosis: insights from the PARTNER trial (Placement of Aortic Transcatheter Valve). *J Am Coll Cardiol* 2014;63(15):1522–1528