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**ORIGINAL ARTICLE**

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GENERAL ADULT CARDIAC

# 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

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## Abstract

**OBJECTIVES:** Surgical aortic valve replacement (sAVR) is coming under close scrutiny with the recent upswing in the use of less invasive approaches. The aim of this analysis was to identify current trends in patient selection, procedural characteristics and outcomes after sAVR in Germany.

**METHODS:** We analysed data from 42 776 patients included in the German Aortic Valve Registry who underwent sAVR with and without coronary artery bypass surgery (CABG) between 2011 and 2015. Baseline, procedural and short-term outcome parameters were analysed.

**RESULTS:** Of all registered patients, 26 618 (62.2%) underwent isolated sAVR and 16 158 (37.8%) sAVR + CABG. The median age was 72 years, and the median Society of Thoracic Surgeons Predicted Risk of Mortality (STS PROM) was 2.3%. From 2011 to 2015, there was a decline in STS PROM (2.4–2.2%, $P < 0.001$) and a decline in risk factors, such as pulmonary hypertension (9.1–3.2%, $P < 0.001$), occlusive arterial disease (19.6–17.7%, $P = 0.003$), mitral regurgitation $\geq 2^{\circ}$ (10.6–7.6%, $P < 0.001$) and New York Heart Association Class III/IV (65.3–59.2%, $P < 0.001$). In-hospital mortality was 2.3%, 1.3% had disabling stroke, 0.4% residual aortic regurgitation $\geq 2^{\circ}$, and the incidence of new-onset pacemaker/implantable cardioverter–defibrillator implantation was 3.9%. There was an increase in the use of biological valves in patients <65 years (50.1–65.7%, $P < 0.001$), and the proportion of rapid deployment valves increased significantly (1.5–8.4%, $P < 0.001$) over the investigated time period.

**CONCLUSIONS:** Both isolated sAVR as well as sAVR + CABG resulted in excellent in-hospital outcomes based on >42 000 patients treated between 2011 and 2015. The implementation of alternative treatment strategies has resulted in palpable changes in patient and device selection.

**Keywords:** German Aortic valve RegistrY • Surgical aortic valve replacement • Coronary artery bypass graft • All comers

† The first two authors contributed equally to this study.

## INTRODUCTION

For many decades, surgical aortic valve replacement (sAVR) was the only effective treatment option to increase life expectancy in patients with severe aortic valve disease. In recent years, transcatheter aortic valve implantation (TAVI) has been established as a less invasive alternative [1, 2]. In parallel, techniques of sAVR have been refined by the implementation of less invasive approaches such as ministernotomy or lateral minithoracotomy. Furthermore, rapid deployment valves (RDVs) have been introduced that obviate the need for suture placement along the entire annular perimeter, resulting in reduced operating times [3]. All of these developments are aimed at reducing the invasiveness of the procedures and improving haemodynamic function. As a consequence, there is now an ongoing debate on the best option for treatment of aortic stenosis, with consideration of the individual surgical risk and comorbidities necessitating additional procedures [4, 5]. To adequately assess this issue, it is critical to analyse contemporary results of sAVR procedures and take into account these technical refinements, recent demographic developments and real-world clinical practice.

Recent data on outcomes after sAVR are limited to reports of randomized controlled trials (RCTs) comparing sAVR and TAVI [5, 6], registry data of recently introduced surgical valves [7, 8] or small all-comers registries [9]. However, these reports are inherently biased by patient selection or small patient groups ($n < 500$) and, therefore, do not adequately reflect the real-world situation. In this regard, large all-comers registries are an invaluable source of information as they reflect real-world practice. The German Aortic Valve RegistrY (GARY) provides such all-comers data and has been accumulating data on the invasive treatment of aortic stenosis since 2011. We aimed to analyse contemporary practice and outcomes based on 42 776 patients registered in GARY who underwent sAVR with or without coronary artery bypass grafting (CABG) between 2011 and 2015.

## MATERIALS AND METHODS

GARY is a prospective multicentre all-comers registry initiated in 2010. All consecutive patients of the participating centres who were admitted for an elective surgery/procedure and gave written informed consent were enrolled. Registry data of >90 000 patients with aortic valve disease who were treated with sAVR, aortic valve reconstruction, TAVI or balloon valvuloplasty at 85 participating centres were entered into a dedicated database and subsequently checked for completeness and plausibility. Detailed descriptions of GARY have been published previously [10, 11].

In this analysis, all patients undergoing sAVR with or without concomitant CABG between 2011 and 2015 were analysed. Patients undergoing one or more additional cardiac procedures (defined as mitral, tricuspid or pulmonic valve replacement, repair or valvulotomy; replacement of the ascending aorta; closure of ventricular and atrial septal defects; ablation and other rare procedures) were excluded. Baseline, procedural and outcome characteristics were compared over the years for the entire study population as well as for the 2 groups defined as patients undergoing isolated sAVR and those undergoing sAVR + CABG. Patient risk profiles were estimated using the Society of Thoracic Surgeons Predicted Risk of Mortality (STS PROM) score, the logistic EuroSCORE (logES) and the German Aortic Valve score (GER AV score) for all 5 years as well as the EuroSCORE II (ESII) from 2012 onwards. The STS PROM was calculated in both groups according to the respective procedures, e.g. for isolated sAVR (STS PROM AVR) and combined sAVR + CABG (STS PROM COMB). In-hospital outcomes were assessed based on (but not limited to) the updated Valve Academic Research Consortium-2 criteria [12].

### Statistical analysis

All continuous variables were presented as median (25th–75th percentile) and compared between independent groups with the Mann–Whitney *U*-test or the Kruskal–Wallis test. Categorical data were expressed as absolute and relative frequencies and compared between independent groups with the $\chi^2$ test or the Fisher's exact test. To compare baseline and procedural characteristics, and in-hospital outcomes over the investigated time period, the values of 2011 were compared with those of 2015. For the ESII and echocardiographic parameters, values of 2012 and 2015 were compared. A 2-sided *P*-value of <0.05 was considered statistically significant for all analyses. All statistical analyses were performed with IBM SPSS Statistics for Windows (version 19.0.; IBM Corp., Armonk, NY, USA).

## RESULTS

### Patient demographics

Between 2011 and 2015, 99 293 patients who underwent invasive treatment of aortic valve disease at 85 German centres were prospectively enrolled into GARY. Of these, 26 618 patients underwent isolated sAVR and 16 158 sAVR + CABG (Fig. 1). The median age of the entire study population was 72 (65–77) years with a median STS PROM of 2.3% (1.5–3.6%) and logES of 5.8% (3.5–10%) (Table 1). In the isolated sAVR group, the median age was 71 (62–76) years, the median STS PROM AVR was 1.9% (1.2–2.9%) and logES was 5.4% (3.1–8.9%). The sAVR + CABG group was older [74 (69–78) years, $P < 0.001$ vs sAVR] and presented with higher risk scores with

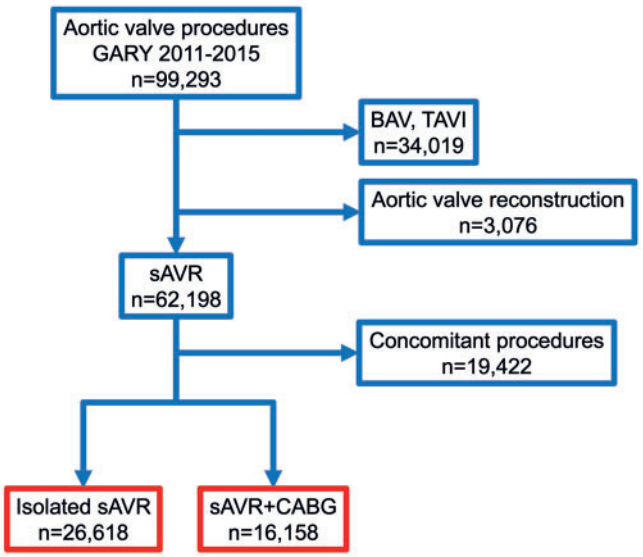


**Figure 1:** Flow chart of patient inclusion. BAV: balloon aortic valvuloplasty; CABG: coronary artery bypass surgery; GARY: German Aortic Valve RegistrY; sAVR: surgical aortic valve replacement; TAVI: transcatheter aortic valve implantation.

**Table 1:** Baseline characteristics of the entire study population and of the isolated sAVR and sAVR + CABG groups

| | sAVR all (*n* = 42 776) | isolated sAVR (*n* = 26 618) | sAVR + CABG (*n* = 16 158) | *P*-value (isolated sAVR vs sAVR + CABG) |
|---|---|---|---|---|
| Age (years) | 72 (65–77) | 71 (62–76) | 74 (69–78) | <0.001 |
| Female | 34.8 (14 877) | 39.3 (10 459) | 27.3 (4418) | <0.001 |
| BMI (kg/m$^2$) | 28 (25–31) | 28 (25–31) | 28 (25–31) | 0.41 |
| NYHA Class III/IV | 62 (26 507) | 59.8 (15 919) | 65.5 (10 588) | <0.001 |
| CAD | 49.3 (21 074) | 20.1 (5357) | 97.3 (15 717) | <0.001 |
| Previous MI | 9.5 (4071) | 5.1 (1353) | 16.9 (2718) | <0.001 |
| Previous PCI | 12 (5118) | 8.6 (2277) | 17.6 (2841) | <0.001 |
| Previous cardiac surgery | 7.2 (3070) | 8.7 (2309) | 4.7 (761) | <0.001 |
| Previous BAV | 0.4 (145) | 0.4 (107) | 0.2 (38) | 0.004 |
| Occlusive arterial disease | 18.3 (7824) | 14.6 (3876) | 24.5 (3948) | <0.001 |
| Central | 8.4 (3583) | 5.7 (1503) | 12.9 (2080) | <0.001 |
| Peripheral | 7 (2996) | 4.4 (1164) | 11.4 (1832) | <0.001 |
| COPD with medication | 6.4 (2730) | 6.3 (1681) | 6.5 (1049) | 0.47 |
| Pulmonary hypertension | 5.1 (2131) | 5 (1296) | 5.3 (835) | 0.16 |
| Diabetes mellitus | 9.4 (4017) | 7.9 (2095) | 11.9 (1922) | <0.001 |
| Renal dysfunction | | | | |
| Creatinine >2 mg/dl | 1.9 (812) | 1.7 (442) | 2.3 (370) | <0.001 |
| Chronic dialysis | 1.1 (482) | 1 (263) | 1.4 (219) | <0.001 |
| Atrial fibrillation | 9.9 (4216) | 9.5 (2542) | 10.4 (1674) | 0.01 |
| Pacemaker/ICD | 4.2 (1776) | 4.2 (1122) | 4 (654) | 0.4 |
| LVEF | | | | |
| Poor (<30%) | 4.4 (1889) | 3.9 (1033) | 5.3 (856) | |
| Medium (30–50%) | 22.2 (9507) | 19.9 (5284) | 26.1 (4223) | <0.001 |
| Good (>50%) | 73.4 (31 380) | 76.3 (20 301) | 68.6 (11 079) | |
| AVA (cm$^2$) | 0.8 (0.6–0.9) | 0.7 (0.6–0.9) | 0.8 (0.6–0.9) | <0.001 |
| MPG (mmHg) | 45 (34–55) | 47 (36–57) | 41 (30–52) | <0.001 |
| PPG (mmHg) | 71 (55–87) | 75 (59–90) | 67 (50–82) | <0.001 |
| MR ≥ 2° | 8.7 (3567) | 8.3 (2134) | 9.2 (1433) | 0.002 |
| TR ≥ 2° | 3.5 (1418) | 3.5 (893) | 3.5 (525) | 0.62 |
| Risk scores | | | | |
| STS PROM (%) | 2.3 (1.5–3.6) | | | |
| STS PROM AVR (%) | | 1.9 (1.2–2.9) | | |
| STS PROM COMB (%) | | | 3.1 (2.2–4.7) | |
| logES (%) | 5.8 (3.5–10) | 5.4 (3.1–8.9) | 6.7 (4.3–11.6) | <0.001 |
| ESII (%) | 2.3 (1.4–4.4) | 1.7 (1.1–3.2) | 3.6 (2.3–6.3) | <0.001 |
| GER AV score (%) | 1.5 (0.9–2.6) | 1.4 (0.8–2.1) | 1.8 (1–2.9) | <0.001 |

Values of various parameters are given in % (*n*) or median (25th–75th percentile) in respective units.
AVA: aortic valve area; BAV: balloon aortic valvuloplasty; BMI: body mass index; CABG: coronary artery bypass surgery; CAD: coronary artery disease; COPD: chronic obstructive pulmonary disease; ESII: EuroSCORE II; GER AV: German aortic valve; ICD: implantable cardioverter–defibrillator; logES: logistic EuroSCORE; LVEF: left ventricular ejection fraction; MI: myocardial infarction; MPG: mean pressure gradient; MR: mitral regurgitation; NYHA: New York Heart Association; PCI: percutaneous coronary intervention; PPG: peak pressure gradient; sAVR: Surgical aortic valve replacement; STS PROM AVR: isolated sAVR; STS PROM COMB: combined sAVR + CABG; STS PROM: Society of Thoracic Surgeons Predicted Risk of Mortality; TR: tricuspid regurgitation.

a median STS PROM COMB of 3.1% (2.2–4.7%) and logES of 6.7% (4.3–11.6%) ($P < 0.001$ vs sAVR). The details are listed in Table 1.

## Trends in patient demographics

From 2011 to 2015, the various surgical risk scores decreased by 0.1–0.7% ($P < 0.05$ for all scores), which was driven by a decrease in age and comorbidities (Fig. 2 and Supplementary Material, Table S1). Concordant trends were observed in the isolated sAVR (Supplementary Material, Fig. S1 and Table S2) and sAVR + CABG groups (Supplementary Material, Fig. S2 and Table S3).

## Valve type selection and trends in valve type selection

Overall, the proportion of mechanical valves implanted was 10%, whereas 86.3% of patients received conventional biological valves and 3.7% received RDVs (Table 2). From 2011 to 2015, there was a significant decline in the use of mechanical valves (12.7–8.9%) and conventional biological valves (85.8–82.8%) and an increase in the use of RDVs (1.5–8.4%) ($P < 0.001$ for all valve types; Supplementary Material, Table S4). Similar changes were observed in the isolated sAVR and sAVR + CABG groups, although the increase in RDVs was more pronounced in the isolated sAVR group (1.7–9.4% vs 1.1–6.7%, respectively; Supplementary Material, Tables S5 and S6). The proportion of conventional biological valves implanted in patients aged <65 years increased significantly from 50.1% in 2011 to 65.7% in 2015 ($P < 0.001$; Fig. 3). In patients aged ≥65 years, implantation of conventional biological valves remained relatively constant (96.2–88.8%, $P < 0.001$), whereas the proportion of RDVs increased markedly from 1.7% in 2011 to 10.4% in 2015 ($P < 0.001$; Fig. 3). Similar trends were observed in the 2 procedure groups with the most pronounced increase in RDV implantations observed for patients aged ≥65 years undergoing isolated sAVR (Supplementary Material, Figs S3 and S4).

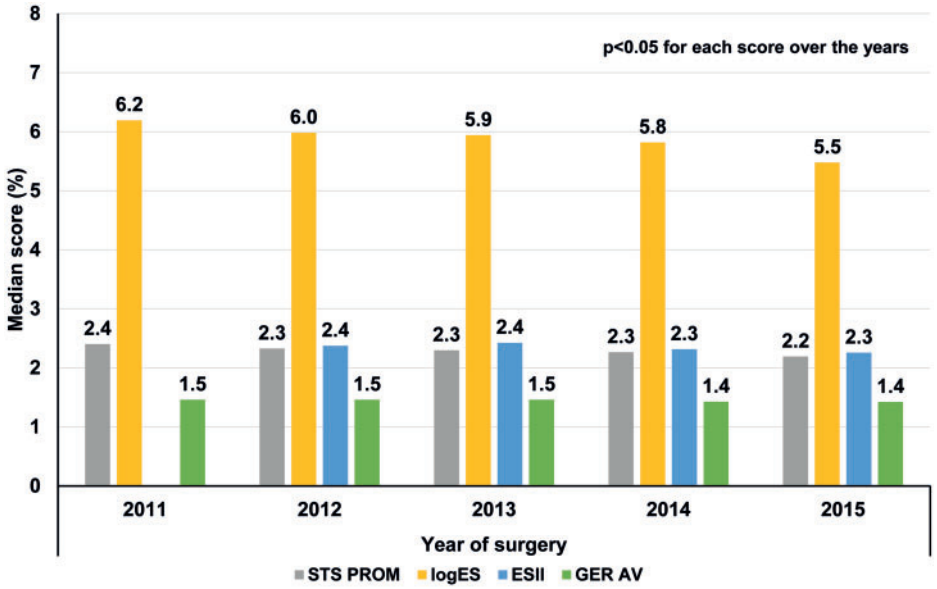


**Figure 2:** Risk scores stratified by the year of surgery for the entire study population. ESII: EuroSCORE II; GER AV: German aortic valve; logES: logistic EuroSCORE; STS PROM: Society of Thoracic Surgeons Predicted Risk of Mortality.

**Table 2:** Procedural characteristics of the entire study population and of the isolated sAVR and sAVR + CABG groups

| | sAVR all (*n* = 42 776) | isolated sAVR (*n* = 26 618) | sAVR + CABG (*n* = 16 158) | *P*-value (isolated sAVR vs sAVR + CABG) |
|---|---|---|---|---|
| Urgency | | | | |
| Elective | 84.3 (36 049) | 86.4 (22 994) | 80.8 (13 055) | <0.001 |
| Urgent/emergent | 15.7 (6727) | 13.6 (3624) | 19.2 (3103) | |
| Access | | | | |
| Conv. sternotomy | 85.3 (36 477) | 76.5 (20 364) | 99.7 (16 113) | <0.001 |
| Other | 14.7 (6299) | 23.5 (6254) | 0.3 (45) | |
| Operating times | | | | |
| Procedure time (min) | 182 (147–230) | 161 (135–195) | 223 (185–270) | <0.001 |
| Bypass time (min) | 95 (75–122) | 84 (68–105) | 116 (94–145) | <0.001 |
| Cross-clamp time (min) | 68 (53–87) | 60 (48–75) | 83 (67–103) | <0.001 |
| Type of prosthesis | | | | |
| Mechanical | 10 (4087) | 13 (3310) | 5 (777) | <0.001 |
| Biological | 86.3 (35 411) | 82.5 (20 937) | 92.5 (14 474) | <0.001 |
| RDV | 3.7 (1528) | 4.4 (1125) | 2.6 (403) | <0.001 |
| CABG data | | | | |
| Number of grafts | | | | |
| 1 | | | 42.9 (6920) | |
| 2 | | | 37.5 (6057) | |
| ≥3 | | | 19.6 (3157) | |
| Central anastomoses | | | | |
| 0 | | | 29.1 (4708) | |
| 1 | | | 49.3 (7970) | |
| ≥2 | | | 21.5 (3479) | |
| Peripheral anastomoses | | | | |
| 1 | | | 40.2 (6445) | |
| 2 | | | 30.6 (4913) | |
| 3 | | | 20.5 (3292) | |
| ≥4 | | | 8.7 (1388) | |

Values of various parameters are given in % (*n*) or median (25th–75th percentile) in respective units.
CABG: coronary artery bypass surgery; Conv. sternotomy: conventional sternotomy; RDV: rapid deployment valves; sAVR: Surgical aortic valve replacement.

## Outcomes and trends in outcomes

Overall in-hospital mortality was 2.3%, which remained stable throughout 2011–15 (2.5–2.3%, $P = 0.38$). There was a decline in the incidence of transient ischaemic attacks (1–0.6%, $P = 0.003$) and bleeding complications requiring transfusion of ≥4 units (25.7–13%, $P < 0.001$) from 2011 to 2015. The rate of new pacemaker/implantable cardioverter–defibrillator implantation (∼4%),

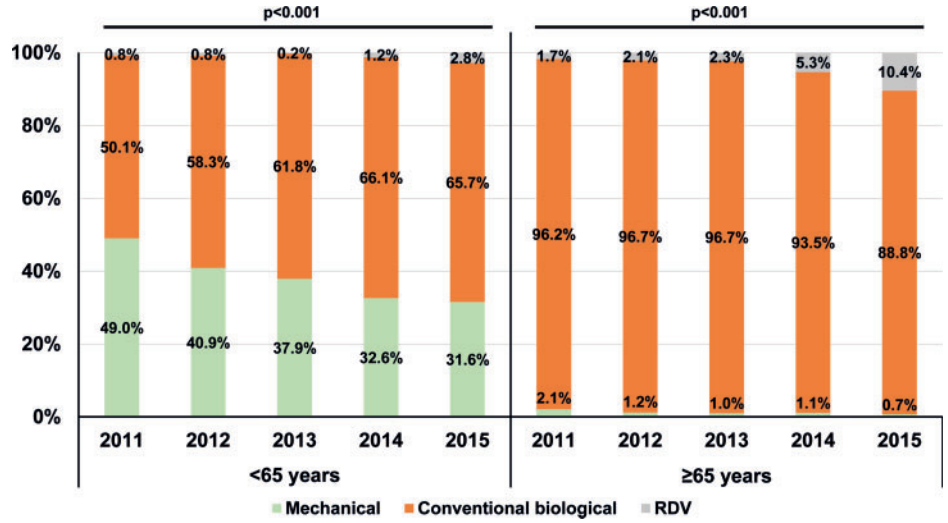


**Figure 3:** Type of implanted prostheses stratified by patient age and year of implantation for the entire study population. RDV: rapid deployment valve.

**Table 3:** In-hospital outcomes of the entire study population and of the isolated sAVR and sAVR + CABG groups

| | sAVR all ($n$ = 42 776) | isolated sAVR ($n$ = 26 618) | sAVR + CABG ($n$ = 16 158) | $P$-value, (isolated sAVR vs sAVR + CABG) |
|---|---|---|---|---|
| Mortality | 2.3 (994) | 1.7 (461) | 3.3 (533) | <0.001 |
| New-onset Afib | 5.1 (1943/37 759) | 4.9 (1170/23 711) | 5.5 (773/14 048) | 0.02 |
| New pacemaker/ICD | 3.9 (1609) | 4.1 (1058) | 3.6 (551) | 0.003 |
| Laparotomy | 0.3 (132) | 0.3 (68) | 0.4 (64) | 0.01 |
| Sepsis | 1.6 (669) | 1.2 (307) | 2.2 (362) | <0.001 |
| Neurological | | | | |
| TIA | 0.8 (349) | 0.7 (195) | 1 (154) | 0.01 |
| Disabling stroke | 1.3 (556) | 1 (272) | 1.8 (284) | <0.001 |
| Myocardial infarction | 0.5 (233) | 0.4 (112) | 0.7 (121) | <0.001 |
| Bleeding ≥4 units | 20.9 (8794) | 16.3 (4279) | 28.3 (4515) | <0.001 |
| New-onset dialysis | | | | |
| Temporary | 2.8 (1163) | 2.2 (589) | 3.6 (574) | <0.001 |
| Chronic | 0.3 (117) | 0.2 (56) | 0.4 (61) | 0.001 |
| Access site infection | 0.3 (136) | 0.3 (69) | 0.4 (67) | 0.01 |
| ICU stay (days) | 2 (1–4) | 2 (1–3) | 2 (1–5) | <0.001 |
| Hospital stay (days) | 10 (8–13) | 10 (8–13) | 11 (8–14) | <0.001 |
| Discharge echocardiography | | | | |
| MPG (mmHg) | 12 (9–16) | 12 (9–16) | 11 (8–15) | <0.001 |
| MPG ≥15 mmHg | 32.7 (7958) | 35.1 (5419) | 28.5 (2539) | <0.001 |
| PPG (mmHg) | 22 (16–29) | 22 (17–29) | 21 (16–27) | <0.001 |
| Residual AR | | | | |
| 0 | 91.7 (30 451) | 91 (18 881) | 92.8 (11 570) | |
| 1 | 7.9 (2636) | 8.6 (1788) | 6.8 (848) | <0.001 |
| ≥2 | 0.4 (136) | 0.4 (87) | 0.4 (49) | |

Values of various parameters are given in % ($n$) or median (25th–75th percentile) in respective units.
Afib: atrial fibrillation; AR: aortic regurgitation; CABG: coronary artery bypass surgery; ICD: implantable cardioverter–defibrillator; ICU: Intensive care unit; MPG: mean pressure gradient; PPG: peak pressure gradient; sAVR: surgical aortic valve replacement; TIA: transient ischaemic attack.

disabling stroke (∼1.3%) and residual aortic regurgitation (AR) ≥2° (∼0.5%) remained constant ($P$ = n.s. for all) (Table 3, Fig. 4 and Supplementary Material, Table S7).

In-hospital mortality was 1.7% for the sAVR group and 3.3% for the sAVR + CABG group; this outcome measure remained constant between 2011 and 2015 in both groups. In both groups, the incidence of new pacemaker implantation (sAVR ∼4%, sAVR + CABG ∼3.5%), disabling stroke (∼1% and ∼1.8%) and residual AR ≥2° (∼0.4% for both groups) remained stable (Table 3, Supplementary Material, Figs S5 and S6, Tables S8 and S9).

The risk of these complications increased with the surgical risk (Fig. 5). In the isolated sAVR group in-hospital mortality was 1.2% for the low-risk subgroup (STS PROM AVR <4%), 3.9% in the intermediate-risk subgroup (STS PROM AVR 4–8%) and 11.1% in the high-risk subgroup (STS PROM AVR >8%); the incidence of other complications was also elevated with increasing risk (Supplementary Material, Fig. S7). A similar increase of in-hospital mortality rates was observed in the sAVR + CABG group with 1.5%, 5.4% and 11.6% in the 3 risk categories, respectively (Supplementary Material, Fig. S8).

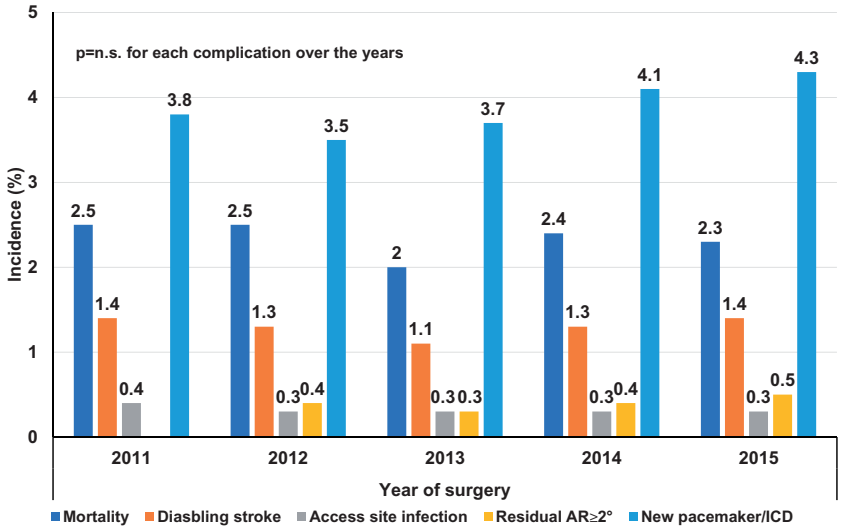


**Figure 4:** In-hospital outcomes stratified by the year of surgery for the entire study population. AR: aortic regurgitation; ICD: implantable cardioverter–defibrillator.

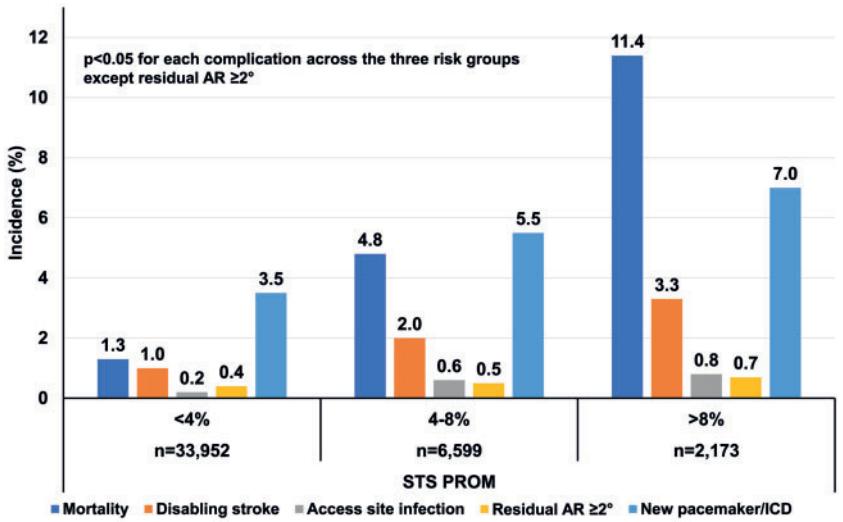


**Figure 5:** In-hospital outcomes stratified by patient STS PROM for the entire study population. AR: aortic regurgitation; ICD: implantable cardioverter–defibrillator; STS PROM: Society of Thoracic Surgeons Predicted Risk of Mortality.

## DISCUSSION

This analysis from GARY provides a comprehensive overview of current practice and clinical outcomes in the field of sAVR. This is the first report concerning such a large patient population during a time period when TAVI was already established and was being reimbursed as a treatment option for aortic valve stenosis in Germany. In addition, newer valve concepts such as RDVs had been introduced during this period. By evaluating data from 42 776 patients treated in the years from 2011 to 2015, we were able to detect therapeutic trends, draw conclusions and give recommendations on the best practice for patients with aortic stenosis. Several key findings can be drawn from this analysis: (i) sAVR is suitable for a variety of patients in different risk groups and produces good results; (ii) the combination of sAVR and CABG also yields excellent in-hospital outcomes with low mortality, pacemaker and residual AR rates; (iii) our data show a clear trend towards the use of biological valves in younger patients and (iv) an increasing fraction of patients being treated with RDVs.

Our analysis shows that sAVR can be applied to a wide range of patients and can yield very good outcomes. Compared with a similar analysis of the STS all-comers database, we observed lower in-hospital mortality and disabling stroke rates across all risk groups after isolated sAVR [13]. This may be related to the fact that our data included patients treated during a more recent time period (GARY 2011–15, STS 2002–10) when older and higher risk patients were already treated with TAVI. However, compared with recent outcomes after isolated sAVR in RCTs (e.g. PARTNER 2 and SURTAVI), our subgroup of intermediate-risk patients showed a higher short-term mortality rate [5, 14]. This finding is most likely related to the inevitable practice, in which RCTs are typically limited by strict inclusion criteria, leading to investigation of patient cohorts that do not necessarily reflect the broad majority of patients encountered in everyday practice. In addition, operator experience and expertise are usually high in RCTs, whereas these factors are not considered in this all-comers analysis. Therefore, large all-comers registries such as GARY provide an essential complementary framework to better interpret the results from RCTs and assess

their relevance for clinical decision-making and guidance of future studies. Considering these limitations of RCTs, we interpret the mortality rates observed in our study of GARY patients as acceptably low. The incidence of in-hospital complications such as residual AR, perioperative myocardial infarction, neurological events or permanent pacemaker implantation also occurred at a low level. Even in the high-risk subgroup (defined as STS PROM >8%), the incidences of residual AR ≥2° (approximately 1%) and permanent pacemaker implantation (<9%) were lower than generally reported after TAVI [5, 15–17]. In low- and intermediate-risk patients, sAVR yields excellent results and can still be considered a very safe and effective treatment strategy, whereas in high-risk patients who are ineligible for TAVI (e.g. for anatomic reasons), sAVR represents a therapeutic alternative with an acceptable safety profile.

For patients requiring concomitant intervention for coronary artery disease, our study shows that the combination of sAVR and CABG also yields excellent in-hospital outcomes with low mortality, pacemaker and residual AR rates. For this patient cohort, the preferred treatment strategy is under debate, especially for patients presenting with a high surgical risk. While sAVR + CABG has been the standard of care, the advent of TAVI has resulted in the implementation of fully percutaneous strategies to treat aortic stenosis and concomitant coronary artery disease [18–20]. For the time being, it seems important to carefully weigh the advantages and limitations of sAVR and TAVI as well as CABG and percutaneous coronary interventions to determine the best treatment option for the individual patient. The excellent in-hospital outcomes observed in GARY emphasize the fact that sAVR in combination with CABG can be performed with a satisfactory safety profile and that alternative treatment strategies should be compared with the benchmark data of sAVR + CABG.

GARY data show a clear trend towards biological valves in patients <65 years. While in 2011, about half of patients <65 years received a mechanical valve, this proportion decreased by almost 20% within 4 years. This trend has also been reported in other registries [21, 22] and is most probably related to the recent availability of transcatheter valve-in-valve (ViV) procedures as a less invasive alternative to redo sAVR in case of a subsequent degeneration of bioprostheses. Currently, experience with ViV procedures is growing rapidly and mid-term outcomes are well documented [23]. These results are encouraging and suggest that in high-risk patients, a ViV procedure can be a feasible alternative to redo sAVR. Based on these data, a recommendation towards biological valves in younger patients seems at least debatable. However, analyses of the Valve-in-Valve International Database as well as recent *in vitro* data emphasize that outcomes after ViV procedures are mainly determined by the type and size of the previously implanted bioprosthesis and the transcatheter heart valve to be implanted [24, 25]. Such technical factors are therefore critically important considerations for optimization of this multistage, long-term treatment strategy. In addition, transcatheter ViV and redo sAVR have so far not been compared in an RCT design. Moreover, previous reports (including RCTs and propensity score-matched analyses) comparing mechanical with biological prostheses in patients aged 50–69 years have yielded conflicting results that do not allow for a clear recommendation towards mechanical or biological valves [26–29]. Importantly, no study has demonstrated a survival benefit related to the use of biological valves but rather that these are, at best, non-inferior to mechanical valves. We, therefore, conclude that despite this clear trend towards biological valves, valve type selection continues to be a complex decision process—especially in borderline age groups—and that more data are needed for a clear recommendation in specific patient groups.

Another trend we identified is that an increasing fraction of patients are being treated with RDVs. This increase was particularly pronounced between 2013 and 2015 and preferentially affected older patients aged ≥65 years. Interestingly, RDVs were more often implanted in patients undergoing isolated sAVR than those undergoing sAVR + CABG, which was somewhat surprising as it has been postulated that patients undergoing complex cardiac surgery with expected prolonged operating times would especially benefit from RDVs [30]. Recently published trials with these devices have shown promising results but are mostly limited to single-arm observational studies. The implementation of a new procedure without the presence of trials that provide solid comparative data with the standard of care in our view bears a certain risk. Such trials are also necessary to clearly define a patient group that benefits from this therapy. Our observation that RDVs are currently being implanted in different patient groups in our view emphasizes the uncertainty regarding their optimal use. The currently ongoing PERSIST-AVR trial (NCT02673697) is aimed at randomizing more than 1200 patients for sAVR ± CABG with an RDV or a conventional biological valve. The outcome of this trial will shed more light on the potential advantages of RDVs, but the results are not expected before 2019.

### Limitations

We acknowledge some limitations of this study. First, centre participation in GARY is voluntary. However, the fact that most centres in Germany do participate compensates for this limitation, and the overall patient number is high enough to yield meaningful results. Second, due to patient selection, a direct comparison with other registries or clinical trials should only be made with caution. In the future, sophisticated statistical models (e.g. propensity score matching) may provide the possibility to pool data from large registries and adequately compare large databases.

## CONCLUSION

In summary, data from GARY show that sAVR can be performed with low in-hospital mortality and complication rates based on more than 42 000 patients treated with isolated sAVR or in combination with CABG in the very recent time period when TAVI was fully established and reimbursed. The recent introduction of alternative treatment strategies has already resulted in palpable effects on patient and device selection. sAVR still represents the treatment modality of choice in most patients suffering from aortic stenosis, and alternative treatment options will have to be compared with this gold standard. The findings of our study provide a solid basis for further investigations and discussion in this interesting and rapidly evolving field.

## SUPPLEMENTARY MATERIAL

Supplementary material is available at *EJCTS* online.

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