

Current Results of Surgical Aortic Valve Replacement: Insights From the German Aortic Valve Registry

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Background. Conventional aortic valve replacement (AVR) remains the therapy of choice for many patients with severe aortic valve disease. The unique German Aortic Valve Registry (GARY) allows the comparison of contemporary outcomes of AVR with those of transcatheter AVRs. We report here real-world, all-comers outcomes of AVR, including combined AVR and coronary bypass grafting (AVR+CABG).

Methods. A total of 34,063 patients who received AVR (22,107 patients, 39% female; mean age 68.0 ± 11.3 years, mean logistic European System for Cardiac Operative Risk Evaluation, 8.6%) or AVR+CABG (11,956 patients, 28% female; mean age 72.6 ± 7.8 years, mean logistic European System for Cardiac Operative Risk Evaluation, 10.7%) between 2011 and 2013 were analyzed and followed up to assess the 1-year outcome.

Results. In-hospital mortality was 2.3% for AVR and 4.1% for AVR+CABG. Other important outcome

variables include stroke (AVR, 1.2%; AVR+CABG, 1.9%) and new pacemaker implantation (AVR, 4.4%; AVR+CABG, 3.6%). Survival at 1 year was 93.2% for AVR and 89.4% for AVR+CABG. Total stroke rates at 1 year were 1.6% for AVR and 2.0% AVR+CABG. Quality of life assessment indicated that most patients were in New York Heart Association Functional Classification I or II (AVR, 86%; AVR+CABG, 84%) and that they were satisfied with the overall postoperative course (AVR, 88%; AVR+CABG, 87%).

Conclusions. Contemporary surgical AVR yields excellent outcomes with low in-hospital mortality, a low overall complication rate, and good 1-year outcome for all risk groups. Accordingly, conventional AVR remains an important therapeutic option for many patients.

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Conventional surgical aortic valve replacement (AVR) is considered the therapy of choice for many patients with severe aortic valve disease according to common guidelines. During the past decade, however, transcatheter AVR (TAVR) has emerged as a minimally invasive alternative for high-risk patients [1–3]. The first randomized studies confirmed acceptable outcomes for certain selected high-risk and inoperable patients [4, 5] for both the transvascular and the transapical approach

compared with conservative or surgical management. Meanwhile, the number of TAVR procedures performed in Europe, notably in Germany, has increased, and the

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growing experience as well as better valve prostheses and delivery systems have led to stable and improved TAVR results [6]. In the light of these circumstances, the German Aortic Valve Registry (GARY) was designed to allow the evaluation of contemporary outcomes of AVR and TAVR.

Several national European registries focus only on TAVR patients [7–9]. In the current literature, there is also a strong focus on this young technology, and recent advances in the conventional operation and the excellent hemodynamic performance of modern bioprostheses tend to be neglected [10, 11]. Current results from a large, multicenter, all-comers, all-surgical aortic valve disease patient population have not appeared in the literature to date.

Against this backdrop, the German Cardiac Society and the German Society for Thoracic and Cardiovascular Surgery inaugurated the GARY. The goal was to gather clinical information on all current transcatheter and conventional aortic valve procedures, including patients being treated for coronary disease, currently being performed in Germany. Here we report the results of all patients who received conventional AVR or AVR and coronary artery bypass grafting (AVR+CABG) between 2011 and 2013 who were included in the GARY.

Patients and Methods

The GARY

The GARY was conceived to obtain a real-world picture of current practice for the treatment of aortic valve disease and to gather reliable data on the short-term and long-term outcomes of different aortic valve treatment strategies. Included are all patients undergoing interventional treatment (ie, AVR including the Ross procedure, aortic valve repair, aortic valvuloplasty, and transvascular and transapical TAVR). Currently more than 80,000 patients have signed informed consent preoperatively. The GARY protocol has been described in detail previously [12, 13].

Statistics

Patients were divided into two groups: conventional AVR and AVR+CABG. In both groups, the results are

presented separately for all patients in the group and for elective patients only, defined as nonurgent, non-decompensated, and nonendocarditis.

Categorical variables are presented in absolute values and percentages and continuously scaled variables as mean \pm standard deviation. Time-to-event curves for death were calculated using Kaplan-Meier methods with the date of death estimated if the exact date was unknown. The European System for Cardiac Operative Risk Evaluation (EuroSCORE) was used to stratify risk groups.

Number of Centers and Patients

From 2011 to 2013, 49,660 patients from 95 centers were included in the registry; of whom, 34,063 patients (69%) underwent surgical AVR. The in-hospital outcome data refer to these patients.

The 1-year-follow-up has been completed for patients treated in 2011 and 2012. This includes 13,639 patients undergoing AVR and 7,382 patients undergoing AVR+CABG. Follow-up is 98.3% complete regarding the living status of those patients at 1 year.

To put the numbers for surgical AVR into the right context, some basic facts for TAVR patients included in the GARY during the same time period are given in Table 1.

Results

Patient Characteristics

Mean age was 68.0 years for AVR patients and 72.6 years for AVR+CABG patients, and the mean logistic EuroSCORE was 8.6% for AVR and 10.7% for AVR+CABG. As expected for an all-comers registry, patients of all age and risk groups were included. The relatively high TAVR penetration in Germany, however, can be attributed to the lower incidence of specific high-risk comorbidities in the surgically treated population compared with data from other registries [14]. All patient characteristics are summarized in Table 2, and the valvular specifications are reported in Table 3.

In-Hospital Mortality Rate

The in-hospital mortality rate was 1.8% for elective AVR (2.3% for all AVR patients) and was 3.3% for elective

Table 1. Basic Facts for Elective Transapical Aortic Valve Replacement Patients Included in the German Aortic Valve Registry, 2011 to 2013

Variable ^a	Transvascular AVI			Transapical AVI		
	2011 (n = 2,074)	2012 (n = 3,123)	2013 (n = 3,902)	2011 (n = 998)	2012 (n = 1,297)	2013 (n = 1,407)
Age, y	81.0 \pm 6.2	81.3 \pm 5.7	81.3 \pm 5.9	80.2 \pm 6.1	80.3 \pm 6.4	80.0 \pm 6.3
Age \geq 75 years	85.8	89.4	89.6	83.3	84.1	83.7
Logistic EuroSCORE	23.4 \pm 16.1	21.7 \pm 15.1	19.6 \pm 13.9	23.1 \pm 15.7	22.4 \pm 15.3	22.7 \pm 15.0
In-hospital mortality	86 (4.1)	115 (3.7)	121 (3.1)	68 (6.8)	74 (5.7)	94 (6.7)

^a Continuous data are shown as mean \pm standard deviation and categorical data as number (%) or as percentage.

AVI = aortic valve implantation; EuroSCORE = European System for Cardiac Operative Risk Evaluation.

Table 2. Preoperative Patient Characteristics, 2011 to 2013

Variable ^a	AVR		AVR+CABG	
	Elective (n = 18,378)	Total (N = 22,107)	Elective (n = 9,433)	Total (N = 11,956)
Female	7,272 (39.6)	8,545 (38.7)	2,658 (28.2)	3,360 (28.1)
Age, y	68.2 ± 11.0	68.0 ± 11.3	72.5 ± 7.8	72.6 ± 7.8
Age ≥75 y	32.2	32.0	45.3	45.7
Logistic EuroSCORE	7.3 ± 7.0	8.6 ± 9.8	9.2 ± 8.2	10.7 ± 10.7
BMI, kg/m ²	28.2 ± 4.9	28.1 ± 5.0	28.2 ± 4.5	28.1 ± 4.5
NYHA III-IV	10,806 (58.8)	13,496 (61.0)	6,139 (65.1)	8,074 (67.5)
CAD	3,382 (18.4)	4,147 (18.8)	9,144 (96.9)	11,570 (96.8)
Previous MI	4.5	4.9	14.2	16.7
Previous PCI	8.0	8.0	17.6	17.7
Previous cardiac operation	1,357 (7.4)	2,068 (9.4)	455 (4.8)	669 (5.6)
Pulmonary hypertension	2,183 (12.0)	2,870 (13.1)	1,095 (11.7)	1,508 (12.8)
Diabetes (insulin dependent)	1,346 (7.3)	1,679 (7.6)	1,025 (10.9)	1,385 (11.6)
Atrial fibrillation	2,743 (14.9)	3,467 (15.7)	1,400 (14.8)	1,872 (15.7)
COPD requiring medication	1,111 (6.0)	1,398 (6.3)	615 (6.5)	818 (6.8)
LVEF				
>0.50	75.1	73.3	69.3	66.6
0.30–0.50	21.4	22.4	25.8	27.4
<0.30	3.5	4.3	4.9	6.1
Renal replacement therapy	375 (2.0)	503 (2.3)	249 (2.6)	340 (2.8)
Chronic renal replacement therapy	192 (1.0)	264 (1.2)	115 (1.2)	171 (1.4)
Neurologic dysfunction				
Central or peripheral	1,207 (6.6)	1,656 (7.5)	799 (8.5)	1,095 (9.2)
Arterial vascular disease	3,259 (17.7)	4,023 (18.2)	2,352 (25.0)	3,107 (26.0)
Peripheral arterial vascular disease	721 (3.9)	949 (4.3)	1,002 (10.6)	1,331 (11.2)
Previous pacemaker/ICD	4.8	5.2	4.7	5.0

^a Continuous data are shown as mean ± standard deviation and categorical data as number (%) or as percentage.

AVR = aortic valve replacement; BMI = body mass index; CABG = coronary artery bypass graft; CAD = coronary artery disease; COPD = chronic obstructive pulmonary disease; EuroSCORE = European System for Cardiac Operative Risk Evaluation; ICD = implantable cardioverter defibrillator; LVEF = left ventricular ejection fraction; MI = myocardial infarction; NYHA = New York Heart Association; PCI = percutaneous coronary intervention.

AVR+CABG (4.1% for all AVR+CABG patients). The in-hospital mortality rate stratified by age and risk profile is reported in Table 4. The total numbers in some subgroups are low, and therefore, the results must be interpreted with caution. The mortality rate is lower than previously reported for the low-risk groups (eg, 1.2% for patients aged <70 years old and logistic EuroSCORE <10%) and does not depend on age alone.

Other In-Hospital Outcomes

The stroke rate was as low as expected, at 1.0% for elective AVR patients and 1.9% for AVR+CABG patients. Approximately 6% of the patients had new-onset atrial fibrillation, and 4% needed a new-onset pacemaker implantation. Other complications are summarized in Table 5.

One-Year Survival

At the 1-year follow-up interview, 92.5% of the elective AVR patients were alive, 6.0% were known to have died, and the status was unknown for 1.5%; and for elective AVR+CABG, 88.8% were alive, 9.7% had died, and status

was unknown for 1.7% (Table 6). Figure 1 depicts the cumulative mortality for the four subgroups.

Complications During Follow-Up

The overall complication rate during the first year after the operation was low, as reported by the interviewed patients. The total stroke rate (including in-hospital strokes) was between 1.4% and 2.0%. About one-third of the patients were readmitted to a hospital during the first year, but this was due to the original procedure only in a small proportion. All other complications are reported in Table 7.

Quality of Life

Almost 85% of the interviewed patients in all groups were in New York Heart Association Functional Classification I or II; that is, more than 92% were in better health or at least had the same clinical condition than before the operation (Table 7). This clinical status is in accordance with the subjective evaluation of the patients who described their general status of health as better or at least the same as before the operation (Fig 2), and thus, only a

Table 3. Valvular Characteristics, 2011 to 2013

Variable ^a	AVR		AVR+CABG	
	Elective (n = 18,378)	Total (N = 22,107)	Elective (n = 9,433)	Total (N = 11,956)
EOA, cm ²	0.84 ± 0.58	0.86 ± 0.61	0.84 ± 0.42	0.85 ± 0.45
Pmean, mm Hg	45.5 ± 18.6	44.6 ± 19.2	41.7 ± 17.0	41.1 ± 17.4
Pmax, mm Hg	72.0 ± 28.4	70.6 ± 29.4	66.2 ± 25.7	65.2 ± 26.3
Degree of calcification				
Low	5.90	6.30	4.80	5.20
Average	20.30	19.70	23.10	22.70
Heavy	65.40	63.10	67.20	66.50
Bicuspid aortic valve	18.30	17.80	7.80	7.60
Aortic stenosis				
None	10.80	13.60	6.00	7.10
Grade I	2.20	2.70	1.80	2.20
Grade II	5.40	5.60	10.20	10.60
Grade III	63.30	61.20	64.90	64.20
Grade IV	18.20	16.90	17.10	16.00
Aortic regurgitation				
None	31.00	30.00	34.20	33.50
Grade I	38.30	37.00	42.00	41.40
Grade II	16.40	16.80	16.30	16.60
Grade III	12.20	13.60	6.50	7.30
Grade IV	2.10	2.50	1.00	1.20
Regurgitation				
Mitral ≥2	13.60	15.20	12.90	14.30
Tricuspid (≥moderate)	6.40	7.20	5.30	6.00

^a Continuous data are shown as mean ± standard deviation and categoric data as percentage.

AVR = aortic valve replacement; CABG = coronary artery bypass graft; EOA = effective orifice area; MI = myocardial infarction; P = pressure.

small number of patients (less than 3.5%) were not satisfied at 1 year (Fig 3).

Time Dependence

A slight trend to healthier patients was observed during the surveillance period. However, the differences were marginal, reflecting that TAVR was available and fully reimbursed since 2009 in Germany. By 2011 TAVR had already reached a high penetration. Interestingly, the percentage of implanted sutureless valves remained very low. This technology obviously was not able to gain ground (Table 8).

Comment

The spectrum of therapeutic options for aortic valve disease has widened during the past decade. In parallel with a relatively stable number of conventional surgical procedures on the aortic valve, an exponential growth in the rate of catheter-based valve implantations has been observed. This has occurred particularly in countries with no restrictions on health care cost reimbursement during the past 5 years; accordingly, these procedures account for 30% to 40% of all AVRs in Germany. Today, TAVR has become a routine clinical procedure for patients at high

risk for conventional surgical procedures. This has led to a 50% increase overall in patients treated for aortic stenosis, whereas absolute numbers of conventional surgical AVR remain almost the same as before the TAVR era.

Several clinical trials have addressed this development. The randomized Placement of Aortic Transcatheter Valve (PARTNER B) trial demonstrated superiority of TAVR over conventional therapy in inoperable patients [4], whereas noninferiority was observed compared with conventional AVR in patients at high risk for surgery (PARTNER A) [5]. A second randomized comparison even showed a higher survival rate with TAVR in patients with an increased risk for surgical AVR after 1 year [6].

Tamburino and colleagues [15] recently published a comparison of the 1-year outcomes of TAVR vs surgical AVR. In this retrospective study with a relatively small number of patients, no differences between the groups concerning the primary end point of major adverse cardiac and cerebrovascular events were found after risk adjustment. However, the 30-day mortality rate in the surgical group was unusually high, whereas the late mortality rate in the TAVR group was higher [15].

Presently, there is an ongoing discussion on potential risk creep with TAVR, challenging conventional

Table 4. Perioperative Mortality Stratified by Age and European System for Cardiac Operative Risk Evaluation for Elective Operations, 2011 to 2013^a

AVR						
	Age, y					
EuroSCORE	<70	70–74	75–79	80–84	≥85	Total
<10%						
Total number of patients	7,220	3,535	2,612	826	47	14,240
In-hospital mortality	84 (1.2)	57 (1.6)	44 (1.7)	10 (1.2)	1 (2.1)	196 (1.4)
10%–20%						
Total number of patients	406	621	933	534	125	2,619
In-hospital mortality	9 (2.2)	20 (3.2)	28 (3.0)	15 (2.8)	2 (1.6)	74 (2.8)
>20%						
Total number of patients	90	197	339	255	67	948
In-hospital mortality	6 (6.7)	8 (4.1)	12 (3.5)	18 (7.1)	4 (6.0)	48 (5.1)
Total						
Total number of patients	7,716	4,353	3,884	1,615	239	17,807
In-hospital mortality	99 (1.3)	85 (2.0)	84 (2.2)	43 (2.7)	7 (2.9)	318 (1.8)
AVR+CABG						
<10%						
Total number of patients	2,230	1,915	1,671	545	40	6,401
In-hospital mortality	42 (1.9)	40 (2.1)	33 (2.0)	11 (2.0)	3 (7.5)	129 (2.0)
10%–20%						
Total number of patients	202	437	691	507	108	1,945
In-hospital mortality	12 (5.9)	19 (4.3)	26 (3.8)	24 (4.7)	3 (2.8)	84 (4.3)
>20%						
Total number of patients	46	160	282	217	63	768
In-hospital mortality	6 (13.0)	18 (11.3)	30 (10.6)	13 (6.0)	7 (11.1)	74 (9.6)
Total						
Total number of patients	2,478	2,512	2,644	1,269	211	9,114
In-hospital mortality	60 (2.4)	77 (3.1)	89 (3.4)	48 (3.8)	13 (6.2)	287 (3.1)

^a Categorical data are shown as number (%) or as indicated.

AVR = aortic valve replacement; CABG = coronary artery bypass graft; EuroSCORE = European System for Cardiac Operative Risk Evaluation.

Table 5. Postoperative Outcome Variables, 2011 to 2013

Variable ^a	AVR		AVR+CABG	
	Elective (n = 18,378)	Total (N = 22,107)	Elective (n = 9,433)	Total (N = 11,956)
In-hospital mortality	338 (1.8)	503 (2.3)	311 (3.3)	496 (4.1)
Transient ischemic attack	168 (0.9)	213 (1.0)	116 (1.2)	150 (1.3)
Stroke	189 (1.0)	263 (1.2)	177 (1.9)	231 (1.9)
Myocardial infarction	68 (0.4)	79 (0.4)	57 (0.6)	81 (0.7)
Atrial fibrillation (new-onset persisting at discharge)	856 (5.5)	1,049 (5.7)	490 (6.2)	624 (6.4)
New pacemaker/ICD implantation	609 (4.1)	771 (4.4)	269 (3.5)	348 (3.6)
Dialysis (new onset)				
Temporary	467 (2.6)	693 (3.2)	356 (3.9)	542 (4.7)
Chronic	47 (0.3)	66 (0.3)	32 (0.3)	48 (0.4)
Post-op length of stay				
In-hospital, d	11.7 ± 8.8	12.2 ± 9.4	13.0 ± 9.9	13.4 ± 10.7
Intensive care, d	3.5 ± 8.5	3.8 ± 8.5	4.7 ± 7.8	4.9 ± 8.0

^a Categorical data are shown as number (%) and continuous data as mean ± standard deviation.

AVR = aortic valve replacement; CABG = coronary artery bypass graft; ICD = implantable cardioverter defibrillator.

Table 6. Follow-Up Status at 1 Year, 2011 to 2012

Survival status at 1-year follow-up	AVR		AVR+CABG	
	Elective (n = 11,364)	Total (N = 13,639)	Elective (n = 5,798)	Total (N = 7,382)
Patient alive, No. (%)	10,516 (92.5)	12,485 (91.5)	5,146 (88.8)	6,454 (87.4)
Patient deceased (date of death not considered), No. (%)	677 (6.0)	941 (6.9)	554 (9.6)	801 (10.9)
Survival status unknown	171 (1.5)	213 (1.6)	98 (1.7)	127 (1.7)
Kaplan-Meier 1-year mortality, %	5.90	6.80	9.20	10.60
Patients with 1-year follow-up interview, No. (%)	9,430/10,516 (89.7)	11,101/12,485 (88.9)	4,541/5,146 (88.2)	5,700/6,454 (88.3)

AVR = aortic valve replacement; CABG = coronary artery bypass graft.

operations for the treatment of intermediate-risk and low-risk patients. Two randomized clinical studies comparing patients with intermediate risk are currently under way (Surgical Replacement and Transcatheter Aortic Valve Implantation [SURTAVI] [16], PARTNER II [17]). In these discussions, results for the conventional operation are often extrapolated from older studies because of a lack of contemporary real-world outcome data. However, a large number of publications on TAVR are available that demonstrate improving results in that field. This can lead to distortions in the overall picture of AVR and was one of the reasons for the inauguration of the GARY.

Although randomized clinical trials offer the best evidence for the effectiveness of any new therapeutic approach, one has to keep in mind that patient inclusion

into such trials is usually quite selective. Routine clinical decision making needs to focus on all-comers outcomes, most importantly because physicians are confronted with an all-comers population and not selected patient groups in everyday clinical practice. Therefore, an all-comers registry such as the GARY provides a realistic picture of clinical results and can thus reliably guide future clinical decision making. A similar data analysis drawn from the comprehensive The Society of Thoracic Surgeons database was published by Thourani and colleagues [14] earlier this year showed similar outcomes in the low-risk groups. The lower mortality rate for the intermediate-risk and high-risk patients in the GARY might be explained with the already very high transcatheter aortic valve implantation penetration in Germany.

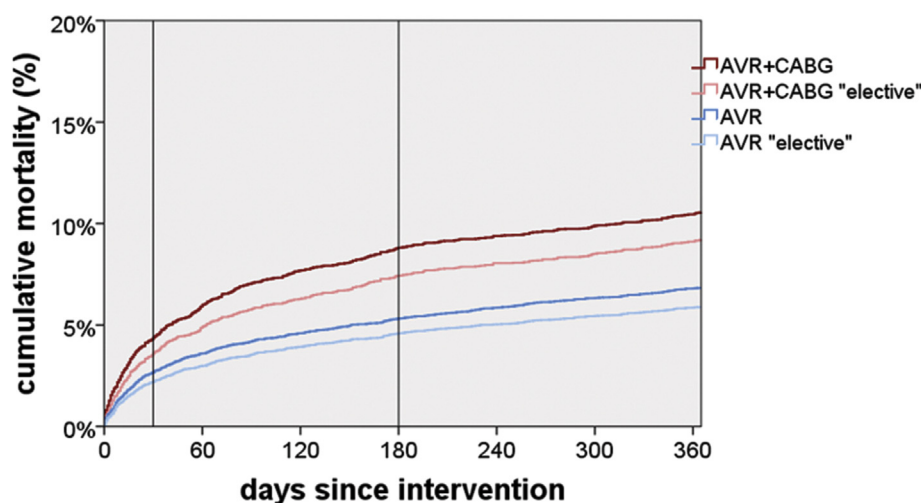


Fig 1. Kaplan-Meier mortality curves patients undergoing aortic valve replacement (AVR) for all four subgroups (AVR+CABG = AVR and coronary artery bypass grafting, red line; AVR+CABG elective, pink line; AVR, blue line; AVR elective, light blue line; sAVR = surgical aortic valve replacement.)

Death	sAVR (el.)	sAVR	sAVR+CABG (el.)	sAVR+CABG
In-hospital	1.9%	2.3%	3.5%	4.4%
180 Days	4.6%	5.3%	7.4%	8.8%
365 Days	5.9%	6.8%	9.2%	10.6%

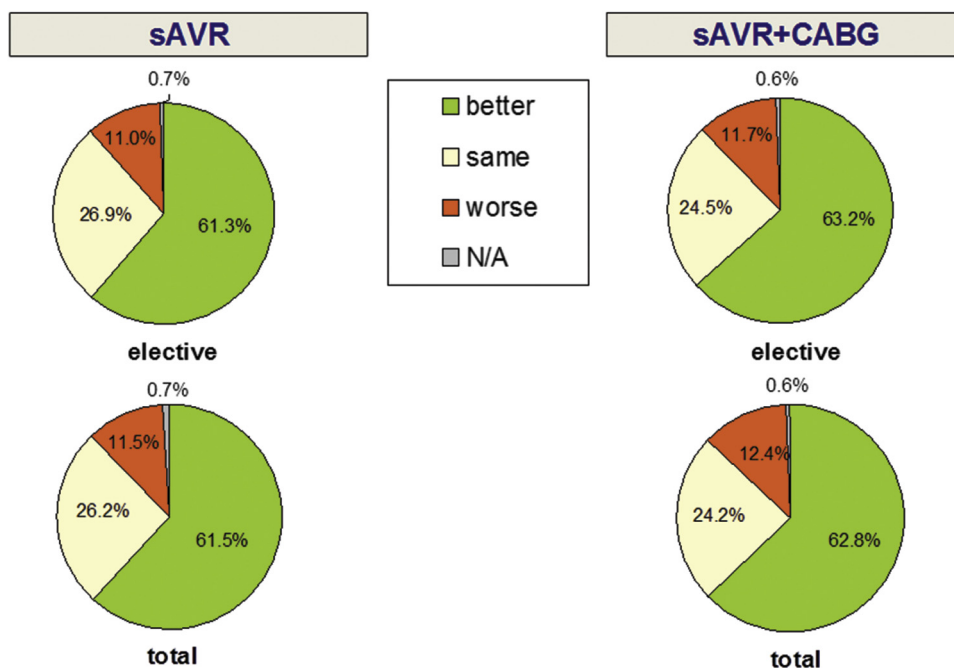
Table 7. Adverse Events During the First Year, 2011 to 2012

Variable ^a	AVR		AVR+CABG	
	Elective (n = 9,430) ^b	Total (N = 11,101) ^b	Elective (n = 4,541) ^b	Total (N = 5,700) ^b
Total with				
Transient ischemic attack	132 (1.4)	158 (1.4)	85 (1.9)	110 (1.9)
Stroke	135 (1.4)	176 (1.6)	91 (2.0)	116 (2.0)
Myocardial infarction	37 (0.4)	43 (0.4)	30 (0.7)	41 (0.7)
New-onset pacemaker/ICD	622/9,013 (6.9)	764/10,578 (7.2)	270/4,334 (6.2)	349/5,430 (6.4)
Repeat hospital stay	2,697 (28.6)	3,238 (29.2)	1,414 (31.1)	1,822 (32.0)
For complications of the procedure	544 (5.8)	653 (5.9)	286 (6.3)	354 (6.2)
For cardiovascular problems	1,059 (11.2)	1,297 (11.7)	522 (11.5)	683 (12.0)
PCI after discharge	52 (0.6)	63 (0.6)	49 (1.1)	63 (1.1)
CABG after discharge	14 (0.1)	19 (0.2)	18 (0.4)	24 (0.4)
NYHA				
I	50.60	50.30	48.60	48.10
II	35.40	35.30	35.70	36.00
III	12.60	12.90	14.20	14.30
IV	0.90	1.00	1.10	1.10
Unknown	0.50	0.50	0.40	0.50
NYHA at 1 year vs pre-op				
Better	67.40	68.10	68.30	69.70
Same	25.30	24.70	24.80	23.60
Worse	6.80	6.70	6.50	6.30
Unknown	0.50	0.50	0.40	0.50

^a Data are shown as number (%) or as percentage. ^b Patients with 1-year-follow-up interview.

AVR = aortic valve replacement; CABG = coronary artery bypass graft; ICD = implantable cardioverter defibrillator; NYHA = New York Heart Association; PCI = percutaneous coronary intervention.

Fig 2. Patients' subjective evaluation (better, green; same, yellow; worse, red; not available [N/A], gray) of general status of health 1 year postoperatively. (CABG = coronary artery bypass grafting; sAVR = surgical aortic valve replacement.)



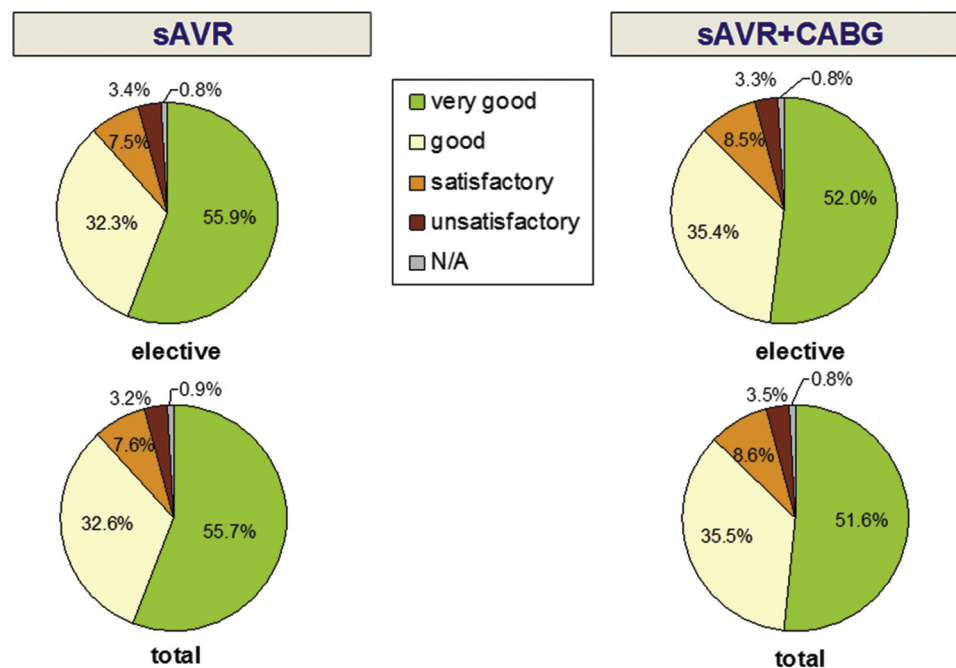


Fig 3. Patients' overall satisfaction (very good, green; good, yellow; satisfactory, orange; unsatisfactory, brown; not available [N/A], gray) with the procedure and postoperative course after 1 year. (CABG = coronary artery bypass grafting; sAVR = surgical aortic valve replacement.)

Table 8. Time Dependence of Basic Facts for Surgical Aortic Valve Replacement, 2011 to 2013

Variable ^a	2011 (n = 5,465)	2012 (n = 5,962)	2013 (n = 6,951)
Pre-op patient characteristics			
Female	2,170 (39.7)	2,369 (39.7)	2,733 (39.3)
Age, y	68.5 ± 11.0	68.1 ± 11.1	68.1 ± 11.0
Age ≥75 y	1,824/5,459 (33.4)	1,893/5,951 (31.8)	2,200/6,941 (31.7)
Logistic EuroSCORE	7.7 ± 7.6	7.3 ± 6.9	7.0 ± 6.6
NYHA III-IV	3,282 (60.1)	3,425 (57.4)	4,099 (59.0)
Previous cardiac surgery	430/5,431 (7.9)	442/5,922 (7.5)	485/6,940 (7.0)
Diabetes (insulin dependent)	445/5,462 (8.1)	420/5,953 (7.1)	481/6,947 (6.9)
Atrial fibrillation	814 (14.9)	889 (14.9)	1,040 (15.0)
COPD (requiring medication)	332/5,462 (6.1)	353/5,957 (5.9)	426/6,950 (6.1)
Peripheral arterial vascular disease	240/5,458 (4.4)	236/5,952 (4.0)	245/6,950 (3.5)
Post-op in-hospital data			
In-hospital mortality	100 (1.8)	119 (2.0)	119 (1.7)
Transient ischemic attack	42 (0.8)	59 (1.0)	67 (1.0)
Stroke	63 (1.2)	61 (1.0)	65 (0.9)
Myocardial infarction	20 (0.4)	29 (0.5)	19 (0.3)
New-onset atrial fibrillation	262/4,598 (5.7)	271/5,009 (5.4)	323/5,853 (5.5)
New-onset pacemaker/ICD implantation for pre-op sinus rhythm	193/4,410 (4.4)	193/4,821 (4.0)	223/5,621 (4.0)
Dialysis (new onset)			
Temporary	149/5,328 (2.8)	154/5,837 (2.6)	164/6,838 (2.4)
Chronic	13/5,328 (0.2)	17/5,837 (0.3)	17/6,838 (0.2)
Type of valve prosthesis used			
Mechanical	866 (15.8)	887 (14.9)	949 (13.7)
Biological			

(Continued)

Table 8. Continued

Variable ^a	2011 (n = 5,465)	2012 (n = 5,962)	2013 (n = 6,951)
Stented	4,151 (76.0)	4,467 (74.9)	5,319 (76.5)
Stentless	365 (6.7)	425 (7.1)	514 (7.4)
Suture free	0 (0)	60 (1.0)	131 (1.9)
Other	11 (0.2)	11 (0.2)	10 (0.1)
Not specified	72 (1.3)	112 (1.9)	28 (0.4)

^a Categorical data are shown as number (%) and continuous variables as mean \pm standard deviation.

COPD = chronic obstructive pulmonary disease; EuroSCORE = European System for Cardiac Operative Risk Evaluation; ICD = implantable cardioverter defibrillator; NYHA = New York Heart Association.

The data shown here clearly demonstrate that conventional surgical techniques can be applied to all risk groups with very good outcomes that are similar to or better than those reported in recent publications [10, 11]. The low mortality rates and low overall complication rates support the position that conventional AVR is and remains the gold standard for patients with aortic stenosis who are at low and intermediate risk.

Limitations

The major limitation of this study is that patient inclusion is voluntary rather than mandatory. Compensating for this limitation is that the overall patient number is high enough to yield some meaningful results stemming from contemporary practice.

Owing to patient selection, a direct comparison of these results with results from other registries or clinical series should be made only with caution. In addition, it should be considered that the good outcome of conventional AVR was achieved in an environment where most of the high-risk patients were scheduled for TAVR by the heart teams. Nonetheless, the GARY and the surgical results of this study deliver a solid basis for further discussions in this interesting and rapidly evolving field.

Conclusions

Surgical AVR resulted in a low in-hospital mortality rate and a low overall complication rate and in good 1-year outcomes for all risk groups. These all-comers registry data therefore clearly indicate that conventional AVR remains the therapy of choice for lower-risk patients with aortic stenosis.

References

1. Cribier A, Eltchaninoff H, Bash A, et al. Percutaneous transcatheter implantation of an aortic valve prosthesis for calcific aortic stenosis: first human case description. *Circulation* 2002;106:3006–8.
2. Walther T, Simon P, Dewey T, et al. Transapical minimally invasive aortic valve implantation: multicenter experience. *Circulation* 2007;116:1240–5.
3. Webb JG, Chandavimol M, Thompson CR, et al. Percutaneous aortic valve implantation retrograde from the femoral artery. *Circulation* 2006;113:842–50.
4. Leon MB, Smith CR, Mack M, et al. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. *N Engl J Med* 2010;363:1597–607.
5. Smith CR, Leon MB, Mack MJ, et al. Transcatheter versus surgical aortic-valve replacement in high-risk patients. *N Engl J Med* 2011;364:2187–98.
6. Adams DH, Popma JJ, Reardon MJ, et al. Transcatheter aortic-valve replacement with a self-expanding prosthesis. *N Engl J Med* 2014;370:1790–8.
7. Zahn R, Gerckens U, Grube E, et al. Transcatheter aortic valve implantation: first results from a multi-centre real-world registry. *Eur Heart J* 2011;32:198–204.
8. Moat NE, Ludman P, de Belder MA, et al. Long-term outcomes after transcatheter aortic valve implantation in high-risk patients with severe aortic stenosis: The U.K. TAVI (United Kingdom Transcatheter Aortic Valve Implantation) registry. *J Am Coll Cardiol* 2011;58:2130–8.
9. Gilard M, Eltchaninoff H, Jung B, et al. Registry of transcatheter aortic-valve implantation in high-risk patients. *N Engl J Med* 2012;366:1705–15.
10. Botzenhardt F, Eichinger WB, Guenzinger R, et al. Hemodynamic performance and incidence of patient-prosthesis mismatch of the complete supraannular Perimount Magna bioprosthesis in the aortic position. *Thorac Cardiovasc Surg* 2005;53:226–30.
11. Bavaria JE, Desai ND, Cheung A, et al. The St. Jude Medical Trifecta aortic pericardial valve: results from a global, multicenter, prospective clinical study. *J Thorac Cardiovasc Surg* 2014;147:590–7.
12. Beckmann A, Hamm C, Figulla HR, et al. The German Aortic Valve Registry (GARY): a nationwide registry for patients undergoing invasive therapy for severe aortic valve stenosis. *Thorac Cardiovasc Surg* 2012;60:319–25.
13. Hamm CW, Mollmann H, Holzhey D, et al. The German Aortic Valve Registry (GARY): in-hospital outcome. *Eur Heart J* 2014;35:1588–98.
14. Thourani VH, Suri RM, Gunter RL, et al. Contemporary real-world outcomes of surgical aortic valve replacement in 141,905 low-risk, intermediate-risk, and high-risk patients. *Ann Thorac Surg* 2015;99:55–61.
15. Tamburino C, Barbanti M, Capodanno D, et al. Comparison of complications and outcomes to one year of transcatheter aortic valve implantation versus surgical aortic valve replacement in patients with severe aortic stenosis. *Am J Cardiol* 2012;109:1487–93.
16. van Mieghem NM, Head SJ, van der Boon RM, et al. The SURTAVI model: proposal for a pragmatic risk stratification for patients with severe aortic stenosis. *EuroIntervention* 2012;8:258–66.
17. Bourantas CV, Farooq V, Onuma Y, Piazza N, Van Mieghem NM, Serruys PW. Transcatheter aortic valve implantation: new developments and upcoming clinical trials. *EuroIntervention* 2012;8:617–27.