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Perioperative Results and Complications in 15,964 Transcatheter Aortic Valve Replacements

Prospective Data From the GARY Registry

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ABSTRACT

BACKGROUND Transcatheter aortic valve replacement (TAVR) has evolved into a routine procedure with good outcomes in high-risk patients.

OBJECTIVES TAVR complication rates were evaluated based on prospective data from the German Aortic Valve Registry (GARY).

METHODS From 2011 to 2013, a total of 15,964 TAVR procedures were registered. We evaluated the total cohort for severe vital complications (SVCs), including the following: death on the day of intervention, conversion to sternotomy, low cardiac output that required mechanical support, aortic dissection, and annular rupture; technical complications of the procedures (TCOs), such as repositioning or retrieval of the valve prosthesis and embolization of the prosthesis; and other complications.

RESULTS Mean patient age was 81 ± 6 years, 54% of the patients were women, the median logistic Euroscore I was 18.3, the German aortic valve score was 5.6, and the Society of Thoracic Surgeons score was 5.0. Overall in-hospital mortality was 5.2%, whereas SVCs occurred in 5.0% of the population. Independent predictors for SVCs were female sex, pre-operative New York Heart Association functional class IV, ejection fraction <30%, pre-operative intravenous inotropes, arterial vascular disease, and higher degree of calcifications. TCOs occurred in 4.7% of patients and decreased significantly from 2011 to 2013. An emergency sternotomy was performed in 1.3% of the patients; however, multivariate analysis did not identify any predictors for conversion to sternotomy.

CONCLUSIONS The all-comers GARY registry revealed good outcomes after TAVR and a regression in complications. Survival of approximately 60% of patients who experienced SVCs or who required sternotomy underlines the need for heart team–led indication, intervention, and follow-up care of TAVR patients. (J Am Coll Cardiol 2015;65:2173–80)

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ABBREVIATIONS AND ACRONYMS

AV = aortic valve

IQR = interquartile range

EF = ejection fraction

MI = myocardial infarction

NYHA = New York Heart Association

PCI = percutaneous coronary intervention

s/p = status post

STS = Society of Thoracic Surgeons

SVCs = severe vital complications

TAVR = transcatheter aortic valve replacement

TCO = technical complications of the procedure

Over the past 10 years, transcatheter aortic valve replacement (TAVR) has reached widespread clinical acceptance as treatment for elderly and high-risk patients with aortic stenosis (1,2). After an initial learning curve, the clinical outcomes of patients after TAVR procedures have improved in parallel with a steady decrease in complication rates (3). This may be explained by the increasing clinical experience of the physicians who perform the implantations, improvements in patient screening using specific imaging strategies (including computed tomography assessment of the target areas), better patient selection that excludes less feasible patients from these therapies, and technical improvements in the individual transcatheter valve prostheses and their application systems (4–8).

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Despite all of these achievements, TAVR procedures are associated with a considerable remaining risk. Complications such as malposition or displacement of the valve prosthesis, hemodynamic instability requiring cardiocirculatory support, coronary artery occlusions, aortic annular ruptures, aortic dissections, ventricular perforations, arrhythmias, aortic regurgitation, sternotomy, stroke, death, or need for permanent pacemaker implantation have been reported, among others (9,10). At present, these risks vary between 3% and 8% depending on the risk profiles of the patients, the overall clinical experience of the teams, and the type of analyses (i.e., whether they are calculated for selected trials or all-comers experiences) (11–15). The overall assessment of a relatively new therapeutic procedure like TAVR should be based on population-wide results, which can only be gathered by specific clinical registries. Analysis of such registry data will paint a more realistic picture of the performance and complication rates of a new procedure in the "real world."

Taking these findings into consideration, we analyzed the acute and in-hospital incidence of specific complications associated with TAVR procedures from the all-comers German Aortic Valve Registry (GARY). We specifically focused on the potential for a decrease in complications over time due to a learning curve effect and on the potentially predictive risk factors that could be associated with specific complications.

METHODS

GARY was designed as an all-comers registry for patients treated for aortic valve disease from July 2010 to 2015. Details have been reported previously (16–18). All-comers data from 88 sites are included in this registry. All contributing sites had sufficient previous clinical experience with TAVR procedures. In total, 4% of the procedures were performed at sites without a department of cardiac surgery but with a cardiac surgeon on standby.

Registry data, derived in part from the mandatory quality control, were carefully entered into the database and then checked for completeness and consistency. Thereafter, the database was finalized for the analysis. All further calculations were compiled at an independent medical research institution, the BQS Institute for Quality and Patient Safety (Düsseldorf, Germany). Acute complications from 2011 to 2013 were analyzed in the subset of 15,964 patients who underwent TAVR. Most patients underwent retrograde transfemoral TAVR (n = 11,292; 70.7%) or anterograde transapical TAVR (n = 4,304; 27%), whereas 368 patients (2.3%) were treated by an alternative access route. In-hospital outcome data of these patients were analyzed.

Complications were defined according to their complexity and the direct consequences for the patient. We evaluated the following groups:

- All patients, total;
- Severe vital complications (SVCs): death on the day of intervention, conversion to sternotomy, acute percutaneous coronary intervention (PCI), low cardiac output requiring mechanical circulatory support, cardiac tamponade requiring treatment, aortic dissection, or annular rupture;
- Technical complications of the procedures (TCOs): repositioning or retrieval of the valve prosthesis, valve-in-valve procedure, valve embolization, or closure of a paravalvular leak;
- Other complications: aortic regurgitation, new-onset pacemaker implantation, stroke, major vascular complications, and major bleeding;
- Conversion to sternotomy; and
- In-hospital death.

Multiple parameters were prospectively included in the database and subsequently analyzed regarding their potential impact on observed complications.

Pre-operative patient characteristics included female sex, age, logistic Euroscore, German aortic valve (AV) score, Society Thoracic Surgeons (STS) score (2008 valve mortality model), body mass index, New York Heart Association (NYHA) functional status, coronary artery disease, status post (s/p) myocardial infarction (MI), s/p PCI, previous cardiac surgery, pulmonary hypertension, hypertension, diabetes, atrial fibrillation, chronic obstructive pulmonary

disease, ejection fraction (EF), cardiac decompensation, cardiogenic shock, renal replacement therapy, long-term renal replacement therapy, on ventilator, neurological dysfunction, inotropes, arterial vascular disease, peripheral arterial vascular disease, aortic valve opening area, mean and maximum aortic valve pressure gradient, degree of aortic valve calcification, mitral regurgitation ≥2°, porcelain aorta, previous valvuloplasty, previous pacemaker/defibrillator, bicuspid aortic valve, degree of aortic stenosis and regurgitation, and tricuspid regurgitation.

We also analyzed the following procedural/operative data: elective procedure, general anesthesia, access for TAVR, balloon dilation, rapid pacing for implantation, cardiopulmonary bypass used, conversion to open heart surgery, cardiac tamponade, major vascular complication, residual aortic regurgitation ≥2°, new-onset pacemaker implantation, stroke, major bleeding, duration of the procedure, radiation time, and contrast dye use.

STATISTICS. The primary endpoint of the study was intrahospital mortality; SVCs and TCOs were secondary endpoints. Categorical variables are presented in percentages, and continuous scaled variables are presented as mean ± SD. Score results are given as median and interquartile range (IQR). A univariate analysis was performed using the chi-square test for categorical variables and the Mann-Whitney U test and Kruskal-Wallis test for continuous variables. Two-sided p values < 0.05 were considered statistically significant. The variables confirmed to be associated with an endpoint were included in a backward stepwise logistic regression analysis for identifying independent predictors for primary and secondary endpoints. All test statistics and backward stepwise procedures were performed using the statistical computer package SPSS version 22 (SPSS Inc., Chicago, Illinois).

RESULTS

A total of 15,964 patients were included in this analysis. The mean age was 80.9 ± 6.1 years, and 54.1% were women. A balloon-expandable prosthesis (SAPIEN XT, SAPIEN 3, Edwards Lifesciences Inc., Irvine, California) was used in 8,390 patients (52.6%), a self-expandable Corevalve prosthesis (Medtronic Inc., Minneapolis, Minnesota) was used in 6,026 patients (37.7%), and other self-expandable prostheses were used in 1,548 patients (9.7%). The main baseline clinical and echocardiographic data are given in Table 1. Patients who experienced SVCs or TCOs, required sternotomy, or who died had significantly higher values for the EuroSCORE, German AV score, and STS score. Procedural and post-operative data are listed in Table 2.

TABLE 1 Baseline Clinical and Echocardiographic Characteristics

TAVR 2011-2013	Total (N = 15,964)	SVC (n = 792)	TCO (n = 748)	Sternotomy (n = 201)	Death (n = 828)
Patients	100.0	5.0	4.7	1.3	5.2
Female	54.1	59.5*	47.6*	59.2	53.4*
Age, yrs	80.9 ± 6.1	81.0 ± 6.2	81.0 ± 6.0	80.5 ± 5.6	81.6 ± 6.3
Log Euroscore	18.3 (11.0–30.5)	21.0* (12.0–36.2)	21.5* (12.7–35.6)	20.6 (11.4–36.0)	24.7* (14.4–44.2)
German AV score	5.6 (3.3–9.1)	6.1* (3.8–11.0)	6.1* (3.3–10.4)	5.8* (3.7–10.9)	8.1* (4.6–14.3)
STS score	5.0 (3.4–7.7)	5.7* (3.8–8.7)	5.5* (3.8–8.0)	5.5*(3.8–8.2)	6.9* (4.6–11.4)
NYHA functional class III- IV	86.1	88.0	86.1	88.6	90.2*
CAD	55.1	58.0	58.2	50.2	61.8*
Previous cardiac surgery*	21.0	23.0	25.1*	19.4	23.3
Pulmonary hypertension	35.7	35.6	35.9	34.2	45.4*
COPD requiring medication	14.2	12.8	13.8	11.9	16.2
EF <30%	9.5	12.8*	13.6*	8.5	16.3*
Renal replacement therapy	5.0	4.8	5.2	5.5	8.2*
PVD	19.5	22.3*	19.7	22.4	30.1*
Aortic orifice area, cm^2	0.70 ± 0.28	0.67 ± 0.3*	0.73 ± 0.3	0.70 ± 0.3	0.69 ± 0.3*
Pmean, mm Hg	44 ± 17	45 ± 18	42 ± 17*	46 ± 18	42 ± 19*

Values are %, mean ± SD, or median (interquartile range). *p < 0.05 versus total.

AV = aortic valve; CAD = coronary artery disease; COPD = chronic obstructive pulmonary disease; EF = ejection fraction; NYHA = New York Heart Association; Pmean = mean aortic pressure gradient; PVD = peripheral vascular disease; STS = Society of Thoracic Surgeons; SVC = severe vital complications; TAVR = transcatheter aortic valve replacement; TCO = technical complications.

TABLE 2 Procedural and Post-operative Data

TAVR 2011-2013	Total (N = 15,964)	SVC (n = 792)	TCO (n = 748)	Sternotomy (n = 201)	Death (n = 828)
In-hospital mortality	5.2	40.8*	17.1*	42.3*	100.0*
CPB used	2.4	28.7*	13.9*	56.7*	13.6*
Conversion to open heart surgery	1.3	25.4*	12.0*	100.0*	10.3*
Cardiac tamponade	1.0	20.7*	3.9*	31.5*	8.0*
Transfemoral approach	70.7	66.3*	79.0*	67.7	58.6*
Transapical approach	27.0	31.3*	20.2*	30.3	37.6*
Other complications					
Residual aortic regurgitation ≥2°	5.8	10.7*	12.8*	16.7*	12.0*
New-onset pacemaker implantation	17.5	13.3*	25.2*	12.8	13.9*
Stroke	1.5	4.2*	4.1*	3.5*	6.3*
Major vascular complication	4.1	8.0*	10.3*	7.0*	8.0*
Major bleeding	26.3	54.7*	40.3*	70.1*	59.8*

Values are %. *p < 0.05 versus total.
CPB = cardiopulmonary bypass; other abbreviations as in Table 1.

COMPLICATIONS. Table 3 provides the overall incidence of complications from 2011 to 2013. An average 5% of the patients (n = 792) experienced SVCs, with a significant decrease in SVCs from 6.8% (in 2011) to 4.9% (in 2012) and 3.9% (in 2013) (p < 0.001). TCOs occurred in 4.7% of patients and showed a similarly significant decline over the years from 5.3% (in 2011) to 5.0% (in 2012) and 4.0% (in 2013) (p = 0.003). The overall survival of patients was 59.2% after a SVC (n = 469/792) and 82.9% after a TCO (n = 620/748). The number of patients who required sternotomy showed a slight regression at 1.6% (in 2011), 1.2% (in 2012), and 1.1% (in 2013) without statistical significance (p = 0.133). There was some regression in the proportion of patients who died in hospital at 5.9% (in 2011), 5% (in 2012), and 4.9% (in 2013) without reaching statistical significance (p = 0.078).

A total of 828 patients (5.2%) died during the procedures or during the hospital stay (Tables 1 to 3). Among those, 160 patients (1% of the total patient population) died on the day of intervention. Patients who died were significantly different from all other patients; they were frequently men; in NYHA functional classes III to IV; had coronary artery disease, s/p MI, s/p PCI, pulmonary hypertension, diabetes, atrial fibrillation, EF <30%, cardiogenic shock or decompensation; were receiving renal replacement therapy; were on ventilators; were receiving intravenous inotropes; and had arterial and peripheral vascular disease, mitral regurgitation ≥2°, porcelain aorta, or had undergone previous balloon valvuloplasty. They also had a higher logistic Euroscore, German AV score, STS score, mean and maximum gradients, and smaller aortic opening areas. Patients who died periprocedurally had significantly higher rates of general anesthesia, cardiopulmonary bypass, conversion to open heart surgery, cardiac tamponade, intraprocedural vascular complications, and residual aortic regurgitation ≥2°, as well as longer procedural duration.

TABLE 3 Overall Incidence of Complications

Year	TAVR Total 15,964 (100%)	SVC 792 (5.0%)	TCO 748 (4.7%)	Sternotomy 201 (1.3)	Death 828 (5.2%)
2011	3,945 (100)	270 (6.8)	209 (5.3)	62 (1.6)	232 (5.9)
2012	5,531 (100)	270 (4.9)	279 (5.0)	65 (1.2)	277 (5.0)
2013	6,488 (100)	252 (3.9)	260 (4.0)	74 (1.1)	319 (4.9)
p value	-	<0.001	0.003	0.133	0.078

Values are n (%).
Abbreviations as in Table 1.

Multivariate independent predictors of death included (Table 4) residual aortic regurgitation ≥2°, peripheral vascular disease, mitral regurgitation >2°, EF <30%, pulmonary hypertension, NYHA functional class IV, body mass index <22 kg/m^2, low cardiac output, cardiogenic shock, TCOs, sternotomy, post-operative stroke, post-operative new-onset dialysis, post-operative MI, post-operative ischemia, aortic dissection, annular rupture, tamponade, PCI due to complications, and bleeding. Multivariate analysis showed that the transapical approach was not an independent predictor of death.

A total of 792 patients (5%) experienced at least 1 SVC (Tables 1 and 2). These 792 patients were 81 ± 6 years old, 59.5% were women, the logistic Euroscore was 21.0 (IQR 12.0 to 36.2), the German AV score was 6.1 (IQR 3.0 to 11.0), and the STS score was 5.7 (IQR 3.8 to 8.7). The observed SVCs were conversion to sternotomy (n = 201; 1.3%), PCIs (n = 70; 0.4% of the total patient population), low cardiac output that required mechanical circulatory support (n = 228; 1.4%), tamponade (n = 164; 1%), aortic dissection (n = 33; 0.2%), and aortic annular rupture (n = 68; 0.4%).

There were significantly higher numbers of patients with SVCs who had the following pre-operative patient characteristics: female sex; logistic Euroscore; German AV score; NYHA functional class IV; EF <30%; cardiac decompensation or cardiogenic shock; pre-procedural use of inotropes; arterial vascular disease; peripheral vascular disease; smaller aortic valve orifice area; maximum pressure gradient; heavy degree of calcifications; mitral regurgitation ≥2°; previous balloon valvuloplasty; and grade IV aortic stenosis (Table 1). Patients with SVCs also had a significantly higher incidence of these

procedural parameters: nonelective procedures; use of general anesthesia; use of cardiopulmonary bypass; conversion to open heart surgery; tamponade; vascular complications; residual aortic regurgitation ≥2°; prolonged procedural duration; and longer radiation time (Table 2).

In univariate and multivariate logistic regression analyses, female sex, NYHA functional class IV, EF ≤30%, the need for preoperative inotropic medication, peripheral vascular disease, a higher degree of aortic valve calcification, and aortic stenosis of 4° were independent predictors of the occurrence of SVCs (Table 5).

Technical complications occurred in 748 patients (4.7%) (Table 2). This included valve-in-valve implantation (n = 295; 1.8% of the total population), repositioning of the valve prosthesis (n = 161; 1%), retrieval of the valve prosthesis (n = 146; 0.9%), closure of a paravalvular leak (n = 50; 0.3%), device embolization (n = 55; 0.3%; 43 of those had another TCO in parallel), and sequential valve implantation (n = 84; 0.5%).

Patients who experienced TCOs were significantly different from all other patients concerning these variables; they were less frequently women; had a higher logistic Euroscore and a higher German AV score; had a higher incidence of previous cardiac surgery; more frequently had an EF <30%; were more frequently on ventilators; more frequently received inotrope therapy; had lower mean and maximum pressure gradients; had lower degree of calcifications; and more frequently exhibited grade 4 aortic stenosis and aortic regurgitation (Table 1). Periprocedural results revealed that patients with TCOs had significantly higher rates of cardiopulmonary bypass, conversion to open heart surgery, tamponade, intraprocedural vascular complications, residual aortic regurgitation ≥2°, longer duration of the procedure, increased radiation time, and increased contrast dye use (Table 2). They also had significantly lower rates of balloon dilation and rapid pacing for implantation.

In the multivariate assessment, independent predictors for TCOs were male sex, EF <30%, neurological dysfunction, cardiac decompensation, and intravenous inotrope therapy (Table 5). In addition, a learning curve was apparent because the incidence of TCOs decreased over the years (Table 3).

Residual aortic regurgitation ≥2° occurred in 5.8% of patients, with a significant decrease from 6.3% (in 2011) to 6.1% (in 2012) and 5.1% (in 2013) (p < 0.001). New-onset pacemaker implantation occurred in 17.5% of patients, with a similar decline from 19.5% (in 2011) to 17.3% (in 2012) and 16.5% (in 2013) (p = 0.008). Stroke was diagnosed in 1.5%, and declined from 2.0% (in 2011) to 1.3% (in 2012) and 1.4% (in 2013) (p = 0.014). Major vascular complications occurred in 4.1% and showed a similarly significant decline over the years, from 5.4% (in 2011) to 2.7% (in 2012) and 4.4% (in 2013) (p < 0.001). Major bleeding (≥2 red blood cell units) was present in 26.3% of the patients (Table 2), with a significant decline from 30.6%

TABLE 4 Odds Ratios for Death Derived From Multivariate Analysis

	OR	95% CI	p Value
Residual aortic regurgitation ≥2°	1.885	1.372–2.588	0.000
PVD	1.443	1.156–1.800	0.001
Mitral regurgitation >2°	1.324	1.079–1.624	0.007
EF <30%	1.573	1.184–2.092	0.002
Pulmonary hypertension	1.353	1.106–1.655	0.003
NYHA functional class IV	1.288	0.999–1.661	0.051
Body mass index <22 kg/m^2	1.586	1.227–2.049	0.000
Low cardiac output	8.850	6.039–12.971	0.000
Cardiogenic shock	1.952	1.296–2.941	0.001
Technical complications	1.638	1.155–2.323	0.006
Sternotomy	2.078	1.208–3.573	0.008
Post-operative stroke	3.574	2.301–5.550	0.000
Post-operative new-onset dialysis	10.519	8.137–13.599	0.000
Post-operative myocardial infarction	23.146	10.877–49.251	0.000
Post-operative ischemia	2.101	1.085–4.068	0.028
Aortic dissection	5.594	2.023–15.470	0.001
Annular rupture	7.058	3.202–15.559	0.000
Tamponade	3.743	2.121–6.606	0.000
PCI due to complications	2.841	1.253–6.439	0.012
Bleeding	5.005	3.961–6.325	0.000

CI = confidence interval; OR = odds ratio; PCI = percutaneous coronary intervention; other abbreviations as in Table 1.

TABLE 5 Odds Ratios for Various Complications Derived From Multivariate Analysis

	OR	95% CI	p Value
Independent predictors for SVC			
Female	1.37	1.16–1.62	0.0002
NYHA class IV	1.46	1.19–1.79	0.0003
LVEF ≤30%	1.33	1.05–1.70	0.0183
IV inotropes	3.88	2.92–5.16	0.0000
Arterial vascular disease	1.23	1.04–1.45	0.0159
Higher degree of calcification	1.28	1.07–1.52	0.0059
Higher degree of aortic stenosis	1.36	1.14–1.62	0.0007
Independent predictors for TCO			
Year of procedure	0.882	0.803–0.969	0.009
Male	1.287	1.106–1.499	0.001
LVEF <30%	1.39	1.11–1.74	0.005
Neurological dysfunction	1.43	1.17–1.74	0.000
Cardiac decompensation	1.21	1.04–1.41	0.015
IV inotropes	2.22	1.59–3.11	0.000

IV = intravenous; LVEF = left ventricular ejection fraction; other abbreviations as in Tables 1 and 4.

(in 2011) to 27.0% (in 2012) and 23.0% (in 2013), ($p < 0.001$). Patients who experienced SVCs or TCOs, who died, or who required sternotomy had significantly higher rates of residual aortic regurgitation ≥2°, stroke, major vascular complications, and major bleeding.

Conversion to sternotomy was required in 201 patients (1.3%), with some regression over time that did not reach statistical significance ($p = 0.133$) (Table 3). Patients who required sternotomy presented with a significantly higher incidence of a high German AV score and receipt of intravenous inotropic therapy and had a significantly lower incidence of a porcelain aorta (Table 1). They underwent elective procedures less frequently; were treated with general anesthesia more frequently; had a higher use of cardiopulmonary bypass; more frequently experienced tamponade, intraprocedural vascular complications, and aortic regurgitation ≥2°; and had longer procedural duration and radiation time (all $p < 0.05$) (Table 2). Survival of patients who required conversion to sternotomy was 57.7% ($n = 116/201$).

Univariate and multivariate analyses of these data excluded any predictors for the potential occurrence of sternotomy during a TAVR procedure.

Stroke occurred in a total of 1.5% (242/15,964) of the patients (Table 2). It was significantly more frequent in patients who experienced SVCs (4.2%; $p < 0.001$), in patients with TCOs (4.1%; $p < 0.001$), in patients who required sternotomy (3.5%; $p = 0.034$), and in patients who died (6.3%; $p < 0.001$).

SCORES. The logistic Euroscore I was 18.3 (IQR: 11.0 to 30.5), the German AV score was 5.6 (IQR: 3.3 to 9.1), and the STS score was 5.0 (IQR: 3.4 to 7.7) for the overall population. All score values were significantly higher in patients with SVCs, TCOs, or who died (all $p < 0.001$). According to all 3 scores, a regression in risk profiles was observed over the years, The Euroscore I went from a median of 20.2 (in 2011) to 18.6 (in 2012) and 16.9 (in 2013); the German AV score went from 5.8 (in 2011) to 5.6 (in 2012) and 5.2 (in 2013); and the STS score decreased from 5.2 (in 2011) to 5.0 (in 2012) and 4.9 (in 2013) (all $p < 0.001$).

DISCUSSION

The clinical application of new therapeutic techniques like TAVR is usually associated with heightened enthusiasm and new perspectives, because improved therapeutic options can be offered, especially to elderly and high-risk patients with relevant aortic stenosis. However, despite all the optimism, potential complications of a new procedure like TAVR have to be critically evaluated as well. We have several options to evaluate specific outcomes and potential complications of TAVR procedures, including well-documented randomized clinical trials that may include a selected patient population only (19–21), single- or multicenter nonrandomized studies (22), and broader registry data (23–26) that may lack some information on potential specific clinical details. In this regard, we believe that, despite all limitations a clinical registry may have, particularly with concerns about data quality, the magnitude and variety of data in this prospective registry allowed us to obtain a clear clinical picture of the advantages of the new TAVR therapies and their potential complications. In addition, because TAVR therapies have been performed in Germany with large numbers of patients since 2008, the GARY registry data from the year 2010 onward permitted the assessment of real-world outcomes for patients who underwent any invasive therapy for aortic valve disease without any major effects from the early learning curve (16–18).

Our present analysis yielded several major findings. First, we determined that TAVR therapy is safe with acceptable complication rates in an all-comers and high-risk patient population. The GARY registry provided substantial data on 15,964 patients that underline these findings. We also found that the numbers of SVCs and TCOs significantly decreased over the years, but remained at approximately 4% (Central Illustration). The reduction in complications could be explained by continuous learning, improved patient screening and appropriate selection, and technical progress that included improved prosthetic heart valves and application systems. Our analysis further revealed significant, independent predictors for the occurrence of complications, especially patient sex, reduced EF, and arterial vascular disease, among others.

In addition, the 1.3% incidence of conversion to sternotomy was acceptably low without any significant changes over the years. Predictors for this complication were not identified, despite a very large number of patients. Finally, the overall in-hospital death rate of 5.2% was acceptable and did not change significantly over the years examined. Twenty independent predictors for death were determined, as summarized in Table 3.

SVC, TCO, AND OTHER COMPLICATIONS. SVCs during TAVR procedures included major challenges for the entire heart team involved in treating these patients. Therefore, it was encouraging to observe that there was a significant decrease in SVCs over the years. However, the current incidence of these complications is still appreciable and remains at approximately 4%, despite the large clinical

experience that is available throughout Germany at many specific sites that perform TAVR procedures. Based on these numbers, we suggest that TAVR should remain a heart team-led procedure performed by anesthesiologists, cardiologists, and cardiac surgeons. The continuing use of experienced heart teams, together with optimal infrastructure and standard operating processes, will be the only way forward to further minimize and eventually manage such complications.

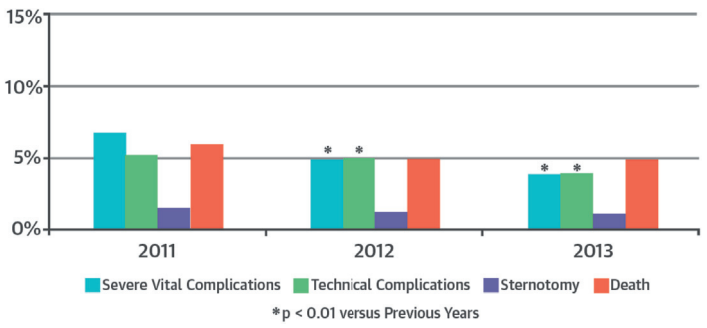
The significant decrease in TCO rates that were observed in this analysis most certainly reflect several factors that are associated with current TAVR therapies: 1) there is an increasing awareness of specific patient assessment, screening, and pre-operative imaging that has led to a good matching of the chosen valve prosthesis to the individual patient; 2) the clinical experience of many TAVR physicians has increased steadily, and together with good heart team cooperation, has led to a continuous improvement for most of the procedures; and 3) significant technical developments with newer generation valve prostheses and steadily improved application systems, which lead to smaller profiles, easier positioning, and improved valve placement, have been established. All of these changes clearly took place over time and have led to improved outcomes with regard to technical complications, even in complex TAVR procedures.

The presence of aortic valve regurgitation ≥2° was acceptably low (5.8%) in this all-comers population, especially because this condition is associated with increased mortality in the intermediate postoperative period (27,28). The incidence of new-onset pacemaker implantation of 17.5% was rather high, and was shown to be associated with TAVR and with the choice of prosthetic valve to be implanted (29). However, for the acute performance of the procedures, we believe that this is only of minor importance.

SURVIVAL AFTER COMPLICATIONS. Overall survival rates were 59.2% (SVCs), 82.9% (TCOs), and 57.7% (sternotomy). In view of some significant complications that were present especially in the SVC, TCO, and sternotomy groups, these survival rates were quite encouraging. Without direct heart team therapy on site, some of these patients might have died; therefore, to decrease complications and optimize outcomes TAVR should be performed by an established heart team with an appropriate infrastructure.

STUDY LIMITATIONS. There were several limitations to the present study, and these were especially related to the nature of a registry: all-comers data could only be captured by a registry, but such data might lack some of the details as well as the correlated adjudication that a randomized trial might have.

CENTRAL ILLUSTRATION **TAVR Perioperative Results and Complications**



Walther, T. et al. J Am Coll Cardiol. 2015; 65(20):2173–80.

From 2011 to 2013, a total of 15,964 transcatheter aortic valve replacement (TAVR) procedures were registered in the German Aortic Valve Registry (GARY). After evaluating the total cohort for severe vital complications (SVCs), technical complications of the procedures (TCOs), and other complications, including sternotomy and death, it was determined that the incidence of SVCs and TCOs decreased significantly from year to year, but remained at approximately 4%. No changes were observed for need for sternotomy (approximately 1.2%) and for in-hospital death (approximately 5%).

CONCLUSIONS

In the all-comers GARY registry, patients attained good outcomes after TAVR and experienced a regression in complications over time. SVCs and TCOs of TAVR procedures remained at 4%, need for sternotomy remained at 1.2% without any predictors, and the in-hospital death rate remained at 5% in this high-risk population. However, survival rates, particularly for patients who experienced SVCs or who required sternotomy were promising (approximately 60%), which demonstrated the continuing need for heart team-led indication, intervention, and follow-up care of TAVR patients.

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PERSPECTIVES

COMPETENCY IN PRACTICE-BASED LEARNING: In Germany, a registry of all TAVR procedures found that in-hospital mortality occurred in 5% of cases, other life-threatening complications in 4%, and conversion to open cardiac surgery in 1.2% of patients. Technical complications associated with adverse clinical outcomes diminished in relation to length of experience in performing the procedure.

TRANSLATIONAL OUTLOOK: Further research is needed to identify clinical features that predict the need for conversion to sternotomy, allowing initial recommendation of surgical valve replacement for these patients and further reduction in complication rates for those undergoing TAVR.

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