

Outcome after transvascular transcatheter aortic valve implantation in 2016

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Aims

We analysed the number of procedures, complications, and in-hospital mortality rates of all patients undergoing transvascular transcatheter aortic valve implantation (TV-TAVI) in comparison to isolated surgical aortic valve replacement (iSAVR) from 2014 to 2016 in Germany.

Methods and results

All aortic valve procedures performed in Germany are mandatorily registered in a quality control program. More than 15 000 TV-TAVI procedures were performed in 2016 in Germany. Especially the number of post-procedural complications declined within the last few years, including new pacemaker implantations (2015: 12.6% vs. 2016: 11.4%, $P = 0.002$) and vascular complications (2015: 8.5% vs. 2016: 7.1%; $P < 0.001$). Thus, in 2016 the overall in-hospital mortality rate after TV-TAVI was 2.6%, which is for the first time numerically below that of iSAVR, which was 2.9% ($P = 0.19$). A stratified analysis according to the German aortic valve score shows a lower observed than expected in-hospital mortality rate for TV-TAVI (O/E 0.68). Additionally, the in-hospital mortality was significantly lower after TV-TAVI than after iSAVR in the very high- (11.3% vs. 23.6%; $P < 0.001$), in the high- (4.1% vs. 9.2%; $P < 0.001$), and in the intermediate-risk group (3.0% vs. 4.6%; $P = 0.016$) and was similar to that of iSAVR in low-risk patients (1.6% vs. 1.4%; $P = 0.4$).

Conclusion

The overall in-hospital mortality after TV-TAVI was numerically lower than after iSAVR in 2016 for the first time. In the low risk group in-hospital mortality was similar, whereas in all other risk groups in-hospital mortality after TV-TAVI was significantly lower than after SAVR. This is likely to contribute to a redefinition of the standard of care in the future.

Keywords

TAVI • Aortic valve replacement • Outcome • Mortality • Surgery • AKL score

Introduction

Transcatheter aortic valve implantation (TAVI) is emerging as the standard of care for patients with severe aortic stenosis.¹ Whereas a decade ago TAVI was only a treatment option for patients at high or prohibitive risk for surgical aortic valve replacements,^{2–5} real-world data from large cohorts have confirmed that particularly transvascular (TV) TAVI provides excellent outcomes in all risk categories and has shown a decline in the number of complications over the years.^{6–11} This initiated a paradigm shift towards treating

intermediate-risk patients with TAVI rather than with isolated surgical aortic valve replacement (iSAVR) in routine clinical practice in the years 2012–14, even in the absence of data from randomized trials.^{10,12} Recently, both the PARTNER-2 and the Sur-TAVI trials confirmed TAVI to be non-inferior to surgery in patients with severe aortic stenosis at intermediate surgical risk.^{13,14} Therefore, the newly published guidelines of the European Society of Cardiology (ESC) propose to perform TAVI rather than iSAVR in patients ≥ 75 years presenting with a STS-Score $\geq 4\%$ or a logistic EuroSCORE I $\geq 10\%$ when feasible with a transfemoral approach.¹

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Here, we analyse the newest data provided by the mandatory quality assurance program on all TV-TAVI procedures performed in Germany in 2016 to gain insights into the latest developments of this approach, including patients' risk profiles, procedural success, complication rates, and outcomes, and compare the data with that of previous years and with that of conventional iSAVR.

Methods

Source of data

All aortic valve procedures performed in Germany, including those that are transcatheter based, are legally required to be registered with the Institute for Quality Assurance and Transparency in Healthcare (IQTIG), an independent governmental organization, as part of a mandatory quality control program. Therefore, these data reflect the real-world scenario in Germany and allow an evaluation of the overall development of aortic valve replacement, a comparison of current patient selection practices for aortic valve replacement with respect to demographics and risk scores, and an assessment of these results within the framework of the recently published data of previous years.^{10–12} Data are routinely transferred to the IQTIG by all sites conducting aortic valve replacements using standardized electronic data entry. The data quality is controlled at different levels, including on-site visits and structured interviews of the institutions. The underlying control mechanisms comprise testing for plausibility, completeness, concordance, and accuracy using a well-validated system. The data validation procedures are documented in the yearly publication of the Federal Joint Committee (Gemeinsamer Bundesausschuss) in charge of quality control of health care in cooperation with the health insurance companies in Germany.^{10,11,15} Aortic valve procedures are divided into iSAVR, SAVR, TV-TAVI (transfemoral, direct aortic, and trans-subclavian access), and transapical (TA) TAVI. The data set includes 125 parameters such as baseline clinical characteristics, comorbidities, procedural as well as post-procedural complications, and in-hospital outcome. The complete data set is pooled in a national database that is publicly available.¹⁵ The data for this study derive from the official IQTIG report.

Definition of clinical outcomes

Clinical outcomes such as post-procedural myocardial infarction or aortic regurgitation are defined according to the Valve Academic Research Consortium (VARC) 2 criteria and have been described previously.¹⁶ Aortic regurgitation after TAVI is quantified angiographically at the end of the procedure. Aortic regurgitation after iSAVR is assessed with echocardiography.

AKL score for risk prediction of isolated aortic valve procedures

Both the logistic EuroScore I (log ES I)¹⁷ and the German AV score (AKL score)¹⁸ were calculated from baseline characteristics and documented comorbidities.¹⁸ Whereas various scores for risk estimation in patients undergoing heart surgery in general are known to overestimate the mortality of patients undergoing isolated aortic valve procedures,^{17,19–21} the AKL score is the only score developed for isolated aortic valve replacement and includes results of surgical as well as TAVI procedures. The AKL score is calculated from 17 variables including age, gender, body mass index (two risk classes), New York Heart Association class (NYHA), American Society of Anesthesiologists (ASA) classification, angina, critical pre-operative status including cardiac shock and cardiopulmonary resuscitation, pulmonary hypertension, heart rhythm, left

ventricular ejection fraction (LVEF), redo procedure, endocarditis, coronary artery disease, peripheral arterial disease, diabetes mellitus, renal failure, and emergency procedure.¹⁸ Because of its reliable prediction of mortality after surgical and TAVIs, the AKL score is used to calculate the expected mortality and therefore the observed/expected mortality ratio. The individual parameters used in deriving the AKL score are annually risk-adjusted according to the results of the previous report and are publicly available.¹⁵ Due to this risk adjustment it maintains its high predictive value. In the present study, patients were categorized into four risk groups based on their AKL scores: low (<3%), intermediate (≥3% and <6%), high (≥6% and <10%), and very high (≥10%).

Statistical analysis

Categorical variables were analysed by the Pearson's χ^2 test using a series of 2×2 tables. The alpha level of statistical significance was 0.05.

Results

In 2016, a total of 15 050 TV-TAVI procedures were carried out in Germany. This represents an increase of 14.6% over 2015, which is less of an increase than in previous years (*Figure 1*). Baseline characteristics were complete in 99.9% (15 029/15 050). The AKL score could only be calculated for these patients. Data on procedural complications were complete in 100% and on post-procedural complications in 99.9% ($n = 15 043$).

Baseline characteristics

Baseline characteristics of TV-TAVI patients were similar in 2016 compared with the previous years. Most (59.7%) patients were still between 80 and 89 years old, resulting in an overall mean age of 81.0 years (*Table 1*). Fewer patients presented with an elevated pulmonary artery pressure ($P = 0.007$), or had had prior heart surgery ($P = 0.02$) than in 2015. Significantly more patients treated with TV-TAVI in 2016 were described to be completely asymptomatic ($P = 0.001$) or in NYHA class II ($P = 0.01$) compared with 2015 ($P = 0.001$; *Table 1*). There was also a slight decrease in the number of patients with very low left ejection fraction of <30% ($P = 0.02$). Nevertheless, patients treated with TV-TAVI show overall a relatively constant risk profile over the year, which is reflected in the similar distributions of the different risk groups according to the log ES I over the years ($P > 0.05$; *Figure 2*).

Procedural characteristics

The procedure time continuously decreased over the years, with a mean time of 71.5 min being reported for 2016 (-10.0% vs. 2014). Likewise, the radiation time (-24.4% vs. 2014) and the amount of contrast medium (-8.2% vs. 2014) were reduced from 2014 to 2016 (*Table 2*).

The frequency of intra-procedural complications increased slightly in 2016 compared with 2015 ($P = 0.003$). This increase was mainly driven by a higher rate of intra-procedural vascular complications ($P < 0.001$). Angiographically assessed aortic regurgitation $\geq 2^\circ$ decreased slightly from 2015 to 2016 (0.5% vs. 0.6%; $P = 0.047$). The incidence of all the other complications remained stable or decreased without statistical difference between 2015 and 2016 ($P \geq 0.05$; *Table 2*).

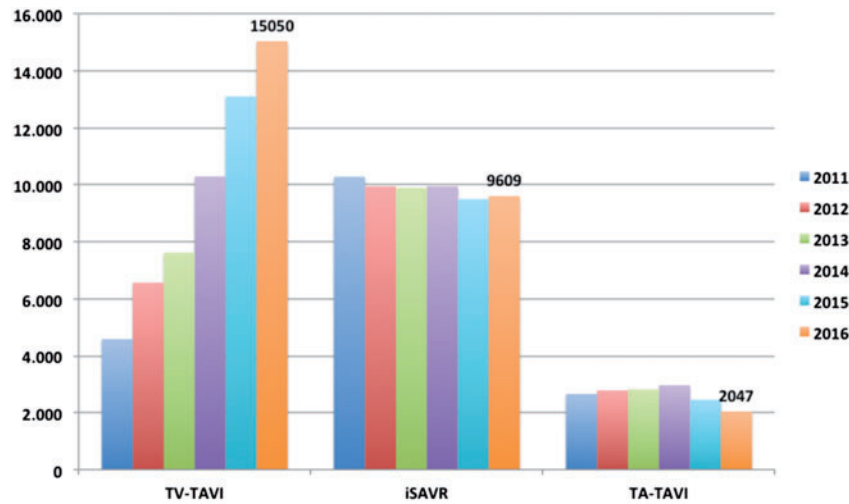


Figure 1 Numbers of procedures for transvascular transcatheter aortic valve implantation, transapical transcatheter aortic valve implantation, and isolated surgical aortic valve replacement 2011–2016.

Table 1 Baseline criteria and comorbidities of patients undergoing transvascular transcatheter aortic valve implantation 2014–2016 and isolated surgical aortic valve replacement in 2016

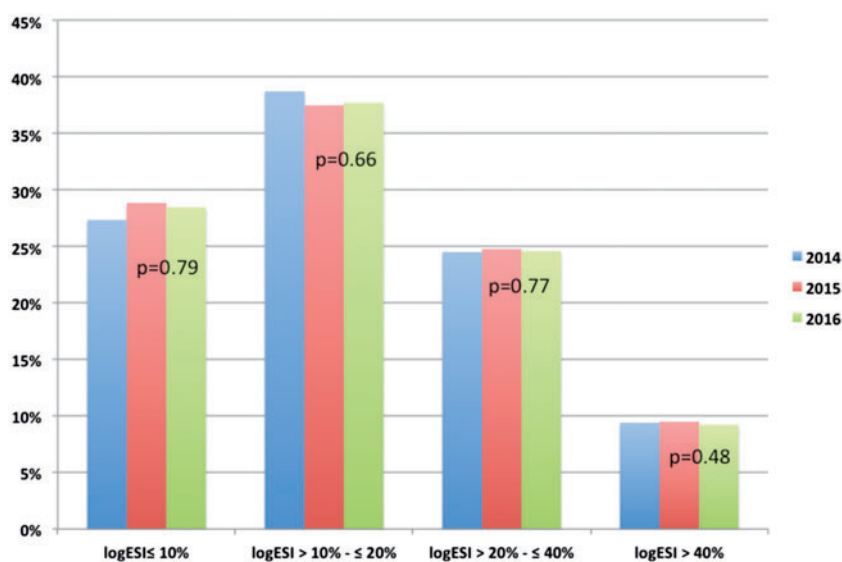
	TV-TAVI 2014 n = 10 286	TV-TAVI 2015 n = 13 123	TV-TAVI 2016 n = 15 043	P-value TV-TAVI 2015 vs. 2016	iSAVR 2016 n = 9579	P-value: TV-TAVI 2016 vs. iSAVR 2016
Age						
<50 years	0.1% (6)	0.2% (20)	0.1% (20)	0.67	6.3% (603)	<0.001
50–59 years	0.5% (51)	0.5% (68)	0.7% (102)	0.08	14.8% (1419)	<0.001
60–69 years	3.1% (317)	3.3% (431)	3.6% (547)	0.11	26.2% (2512)	<0.001
70–79 years	32.3% (3326)	31.3% (4113)	30.5% (4584)	0.12	42.2% (4038)	<0.001
80–89 years	57.9% (5954)	58.9% (7735)	59.7% (8981)	0.20	10.2% (976)	<0.001
≥90 years	6.1% (632)	5.8% (756)	5.4% (809)	0.16	0.3% (31)	<0.001
Median age	82.0 (IQR 78–85)	82.0 (IQR 78–85)	81.0 (IQR 78–85)		71.0 (IQR 61–76)	
Comorbidities						
Lung disease	22.2% (2279)	21.4% (2800)	21.7% (3260)	0.50	15.3% (1467)	<0.001
Renal RT	3.3% (334)	2.8% (373)	4.0% (600)	<0.001	1.4% (132)	<0.001
PHT	48.2% (5049)	53.8% (7062)	52.2% (7852)	0.007	18.7% (1858)	<0.001
31–55 mmHg	34.7% (3566)	38.8% (5094)	36.6% (5512)	<0.001	15.4% (1479)	<0.001
>55 mmHg	13.5% (1388)	14.0% (1832)	15.1% (2275)	0.006	3.3% (311)	<0.001
PPM pre-op	11.0% (1127)	11.6% (1519)	11.4% (1709)	0.57	3.8% (366)	<0.001
ICD pre-op	1.7% (179)	1.8% (232)	1.7% (253)	0.58	1.0% (99)	<0.001
Prior heart surgery	17.2% (1772)	16.7% (2189)	15.7% (2359)	0.02	9.7% (931)	<0.001
LVEF ≤ 30%	9.7% (995)	9.5% (1245)	8.7% (1307)	0.02	4.7% (450)	<0.001
LVEF 31–50%	27.9% (2867)	28.9% (3798)	28.3% (4254)	0.27	21.3% (2042)	<0.001
CAD	54.5% (5599)	56.0% (7352)	55.9% (8403)	0.78	23.8% (2284)	<0.001
1-Vessel	18.7% (1918)	19.3% (2530)	19.1% (2867)	0.64	12.2% (1167)	<0.001
2-Vessel	14.1% (1448)	15.2% (1994)	15.1% (2268)	0.78	6.1% (583)	<0.001
3-Vessel	21.7% (2233)	21.6% (2828)	21.7% (3268)	0.72	5.6% (534)	<0.001
Left main disease ≥50%	4.3% (437)	4.5% (585)	4.3% (639)	0.39	0.9% (83)	<0.001
Diabetes, total	33.4% (3436)	32.9% (4317)	32.6% (4903)	0.68	24.7% (2365)	<0.001
Insulin therapy	14.1% (1452)	12.8% (1681)	13.2% (1989)	0.31	8.3% (790)	<0.001

Continued

Table 1 Continued

	TV-TAVI 2014 n = 10 286	TV-TAVI 2015 n = 13 123	TV-TAVI 2016 n = 15 043	P-value TV-TAVI 2015 vs. 2016	iSAVR 2016 n = 9579	P-value: TV-TAVI 2016 vs. iSAVR 2016
NYHA I	2.4% (248)	1.9% (248)	2.3% (348)	0.01	6.5% (625)	<0.001
NYHA II	12.8% (1699)	13.0% (1699)	14.0% (2104)	0.01	35.5% (3398)	<0.001
NYHA III	72.6% (9382)	71.9% (9382)	69.8% (10 493)	0.001	51.6% (4938)	<0.001
NYHA IV	12.2% (1794)	13.7% (1794)	14.0% (2098)	0.50	6.5% (618)	<0.001

CAD, coronary artery disease; DM, diabetes mellitus; ICD, defibrillator; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; PHT, pulmonary hypertension; PPM, permanent pacemaker; renal RT, renal replacement therapy; iSAVR, isolated surgical aortic valve replacement; TAVI, transcatheter aortic valve implantation; TV, transvascular.

**Figure 2** Classification of patients undergoing transvascular transcatheter aortic valve implantation according to the logistic EuroScore I.

Post-procedural complications

The overall rate of post-procedural complications decreased in 2016 relative to the previous years (Table 3). Importantly, this includes a significant decrease in the frequency of new permanent pacemaker implantations ($P = 0.002$) as well as a decrease in post-procedural vascular complications ($P < 0.001$) and in the number of cardiopulmonary resuscitations ($P = 0.005$; Table 3).

Outcome after transvascular transcatheter aortic valve implantation

In-hospital mortality decreased further to 2.6% in 2016 (vs. 3.8% in 2014 and 3.4% in 2015; Figure 3). Whereas this decrease was not significant in previous years, it showed statistical significance from 2015 to 2016 ($P < 0.001$).

The observed (O) mortality in 2016 was significantly lower than the expected (E) mortality calculated with the AKL score ($P < 0.001$), resulting in an O/E mortality ratio of 0.68 (Table 4). When stratified into the four risk groups according to the AKL score (low,

intermediate, high, and very high risk), the decrease in mortality from 2015 to 2016 was apparent in all risk groups using the same risk model for both years (Table 4). The O/E ratio was < 1 in patients in all risk groups (Table 4). A significant difference in the O/E mortality ratio was observed throughout all risk groups (low-risk group $P = 0.01$; intermediate-risk group $P = 0.004$, and high- and very high-risk groups $P < 0.001$). This low O/E ratio was especially pronounced in the high- and very high-risk groups (0.61 and 0.54, respectively).

Comparison with isolated surgical aortic valve replacement

Over the last few years, the number of isolated iSAVR procedures was more or less stable ($n = 9609$ in 2016; Figure 1). Of these, 6.7% were implanted sutureless and 9.1% minimally invasive. Patients undergoing iSAVR were younger than TV-TAVI patients ($P < 0.001$) and showed a significantly lower rate of comorbidities such as pulmonary hypertension ($P < 0.001$), coronary artery disease ($P < 0.001$), or diabetes mellitus ($P < 0.001$; Table 1). This results in a higher surgical

Table 2 Procedural details and complications of patients undergoing transvascular transcatheter aortic valve implantation 2014–16 and isolated surgical aortic valve replacement 2016

	TV-TAVI			P-value: TV-TAVI 2015 vs. 2016	iSAVR 2016 n = 9609	P-value: TV-TAVI 2016 vs. iSAVR 2016
	2014 n = 10 299	2015 n = 13 132	2016 n = 15 050			
Procedure time (min)	70 (IQR 55–95)	65 (IQR 51–89)	61 (IQR 50–81)		160 (IQR 135–196)	
Radiation time (min)	14 (IQR 10–20)	13 (IQR 9–18)	12 (IQR 9–18)		—	—
Contrast medium (mL)	120 (IQR 90–142)	120 (IQR 90–137)	116 (IQR 90–152)		—	—
Intra-procedural complications						
At least one complication	8.8% (906)	6.4% (846)	7.4% (1107)	0.003	1.2% (119)	<0.001
Device malpositioning	1.2% (125)	0.7% (91)	0.8% (116)	0.45	0.2% (15)	
Coronary obstruction	0.3% (34)	0.2% (32)	0.2% (27)	0.24	0.1% (7)	0.03
Aortic dissection	0.2% (22)	0.2% (27)	0.1% (21)	0.18	0.04% (4)	0.02
Annulus rupture	0.3% (27)	0.3% (39)	0.2% (31)	0.13	0.03% (<=3)	<0.001
Pericardial tamponade	0.8% (85)	0.8% (105)	0.7% (103)	0.26	0% (0)	<0.001
LV decompensation	0.7% (70)	0.5% (66)	0.5% (80)	0.74	0.2% (16)	<0.001
Cerebral emboli	0.2% (19)	0.1% (16)	0.1% (22)	0.58	0.02% (<3)	<0.001
Aortic regurgitation $\geq 2^\circ$	1.0% (100)	0.6% (83)	0.5% (69)	0.047	0.1% (13)	<0.001
Device embolization	0.3% (261)	0.2% (247)	0.2% (279)	0.87	0.01% (<3)	<0.001
Arrhythmia	0.3% (29)	0.2% (27)	0.2% (32)	0.90	0.3% (32)	0.07
Vascular complications	3.2% (330)	2.1% (269)	3.2% (481)	<0.001	0.4% (42)	<0.01

LV, left ventricle.

Table 3 Procedural complications after transvascular transcatheter aortic valve implantation 2014–16 and isolated surgical aortic valve replacement 2016

	TV-TAVI			P-value TV-TAVI 2015 vs. 2016	iSAVR 2016 n = 9579	P-value: TV-TAVI 2016 vs. iSAVR 2016
	2014 n = 10 286	2015 n = 13 132	2016 n = 15 043			
Post-procedural vascular complications	8.3% (854)	8.5% (1117)	7.1% (1065)	<0.001	0.73 (69)	<0.001
Vascular rupture	0.5% (52)	0.4% (58)	0.4% (52)	0.20	—	—
Dissection	1.3% (132)	1.5% (191)	1.3% (193)	0.22	—	—
Bleeding	4.1% (429)	4.1% (535)	3.1% (462)	<0.001	—	—
Haematoma	3.1% (407)	3.8% (491)	3.3% (500)	0.06	—	—
Ischaemia	0.6% (66)	0.7% (96)	0.6% (95)	0.31	—	—
New pacemaker/ICD	14.6% (1499)	12.6% (1649)	11.4% (1713)	0.002	3.0% (266)	<0.001
Myocardial infarction	0.3% (35)	0.4% (48)	0.2% (36)	0.05	0.4% (36)	0.05
Low cardiac output	2.3% (235)	1.9% (253)	1.7% (254)	0.13	3.9% (372)	<0.001
Cardiopulmonary resuscitation	2.7% (277)	2.6% (334)	2.1% (308)	0.006	2.4% (230)	0.006
Cerebrovascular complication (bleeding or ischaemia)	2.0% (209)	2.2% (285)	2.2% (329)	0.35	1.8% (172)	0.03
Renal replacement therapy	3.8% (393)	3.4% (441)	3.0% (457)	0.12	4.96% (475)	<0.001
Revision surgery/re-thoracotomy	2.87% (192)	2.7% (227)	1.64% (246)	0.54	6.2% (596)	<0.001

ICD, implantable cardioverter defibrillator.

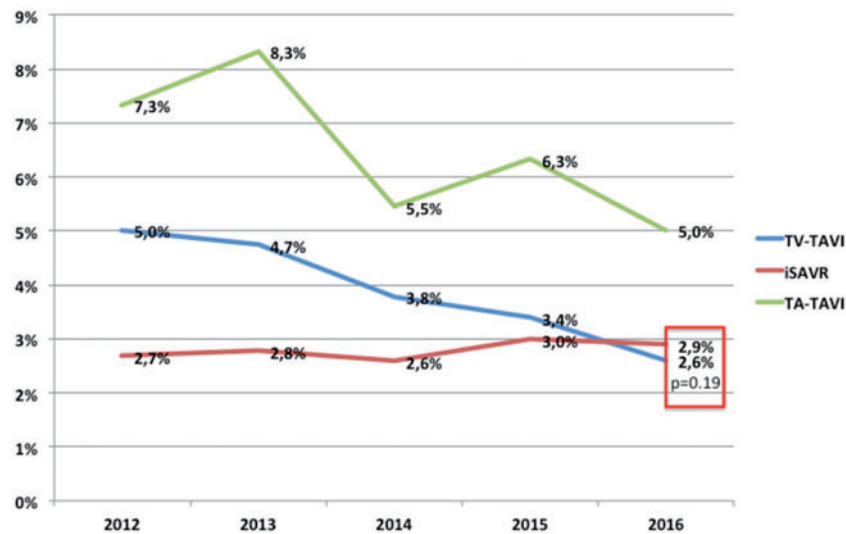


Figure 3 Overall in-hospital mortality after transcatheter aortic valve implantation, transapical transcatheter aortic valve implantation, and isolated surgical aortic valve replacement 2014–2016.

Table 4 Mortality after isolated surgical aortic valve replacement, transcatheter aortic valve implantation, and transapical transcatheter aortic valve implantation: use of AKL score 2016 for the years 2015 and 2016

	iSAVR 2015	iSAVR 2016	TV-TAVI 2015	TV-TAVI 2016	P-value: iSAVR vs. TV-TAVI 2016	TA-TAVI 2015	TA-TAVI 2016	P-value: TV- vs. TA-TAVI 2016
Overall patient numbers (n)	9475	9544	13 108	15 029		2448	2036	
Observed; % (95% CI)	3.0% (2.6–3.3)	2.9% (2.6–3.3)	3.4% (3.1–3.7)	2.6% (2.4–2.9)	0.19	6.3% (5.4–7.3)	5.0% (4.1–6.0)	<0.001
Expected; % (95% CI)	2.7% (2.3–3.0)	2.9% (2.5–3.2)	3.9% (3.6–4.2)	3.9% (3.6–4.2)		4.5% (3.7–5.3)	4.7% (3.8–5.6)	
Observed–expected	0.35%	0.06%	-0.52%	-1.24%		1.84%	0.29%	
Observed/expected	1, 13	1, 02	0, 87	0, 68		1, 41	1, 06	
Patient distribution according to AKL 2016; % (n)								
AKL 0–<3%	85.9% (8125)	83.7% (7987)	56.2% (7370)	56.2% (8449)	<0.001	45.8% (1121)	41.0% (834)	<0.001
AKL 3–<6%	7.7% (726)	8.6% (825)	31.1% (4072)	31.3% (4711)	<0.001	37.0% (906)	39.1% (797)	<0.001
AKL 6–>10%	2.5% (235)	3.3% (316)	8.1% (1061)	8.0% (1203)	<0.001	10.9% (267)	12.9% (263)	<0.001
AKL ≥ 10%	3.9% (371)	4.4% (416)	4.6% (605)	4.4% (666)	0.79	6.3% (154)	7.0% (142)	<0.001
Expected mortality per risk class according to AKL 2016; % (95% CI)								
AKL 0–<3%	1.3% (1.1–1.6)	1.3% (1.1–1.6)	2.1% (1.8–2.4)	2.1% (1.8–2.4)		2.2% (1.3–3.0)	2.2% (1.2–3.1)	
AKL 3–<6%	4.0% (2.6–5.4)	4.0% (2.7–5.3)	4.1% (3.5–4.7)	4.1% (3.5–4.6)		4.1% (2.9–5.5)	4.1% (2.8–5.5)	
AKL 6–>10%	7.8% (4.3–11.1)	7.7% (4.7–10.5)	7.5% (6.9–9.1)	7.5% (6.0–9.0)		7.6% (4.3–10.6)	7.6% (4.4–10.8)	
AKL ≥ 10%	25.3% (20.9–29.8)	26.0% (21.7–30.2)	18.7% (15.6–21.8)	18.5% (15.5–21.4)		18.0% (12.1–24.3)	17.4% (11.3–23.7)	
Observed mortality per risk class according to AKL 2016; % (95% CI)								
AKL 0–<3%	1.4% (1.2–1.7)	1.4% (1.2–1.7)	1.9% (1.6–2.2)	1.6% (1.3–1.8)	0.40	4.1% (2.9–5.3)	1.8% (0.9–2.7)	0.62
AKL 3–<6%	5.4% (3.7–7.0)	4.6% (3.2–6.0)	3.2% (2.7–3.7)	3.0% (2.5–3.4)	0.014	5.9% (4.3–7.4)	4.9% (3.4–6.4)	0.004
AKL 6–>10%	8.1% (4.6–11.6)	9.2% (6.0–12.4)	7.0% (5.4–8.5)	4.1% (3.0–5.2)	<0.001	8.6% (5.2–12.0)	9.5% (6.2–13.6)	<0.001
AKL ≥ 10%	29.7% (25.0–34.3)	23.6% (19.5–27.6)	16.9% (13.9–19.8)	11.3% (8.9–13.7)	<0.001	21.4% (14.9–17.9)	16.2% (10.1–22.3)	0.10

risk of patients undergoing TV-TAVI according to the AKL score (Table 4). Patients undergoing iSAVR showed lower rates of procedural complications than patients undergoing TV-TAVI ($P < 0.001$; Table 2). Following iSAVR, patients had lower rates of post-procedural vascular complications ($P < 0.001$), pacemaker implantation ($P < 0.001$), and cerebrovascular complications ($P = 0.03$) but higher rates of renal replacement therapy ($P < 0.001$), low cardiac output ($P < 0.001$), and cardiopulmonary resuscitation ($P = 0.006$). Significantly more patients undergoing iSAVR needed rethoracotomy due to various reasons such as bleeding, haematoma, or infections ($P < 0.001$; Table 3).

The in-hospital mortality after iSAVR remained stable over the years, with a rate of 2.9% in 2016 [3.0% in 2015 ($P = 0.75$); Figure 3]. The observed and expected mortality after iSAVR in 2016 calculated with the AKL score did not differ significantly ($P = 0.83$). The overall *O/E* ratio of patients undergoing iSAVR in 2016 was 1.02, which is slightly lower than the value of 1.13 in 2015 (Table 4). The only risk group with an *O/E* ratio slightly below 1 were the patients at very high risk who represent 4.4% of all patients undergoing iSAVR (Table 4).

The overall in-hospital mortality rate was numerically lower after TV-TAVI than after iSAVR (2.6% vs 2.9%; $P = 0.19$). Stratification into the risk groups according to the AKL score showed significantly lower mortality rates for TV-TAVI vs. iSAVR in intermediate-risk ($P = 0.014$), high-risk ($P < 0.001$), and very high-risk ($P < 0.001$) patients. There was no significant mortality difference in the low-risk group (1.6% vs. 1.4%; $P = 0.4$).

Comparison with transvascular transcatheter aortic valve implantation

During the last few years the number of TA-TAVI procedures was stable. ($n = 2047$ in 2016; Figure 1). Patients undergoing TA-TAVI had a higher rate of comorbidities such as lung diseases ($P < 0.001$), reduced LVEF ($P < 0.001$), coronary artery disease ($P < 0.001$), and diabetes ($P = 0.003$), and more often had had prior heart surgery ($P < 0.001$), but they had a lower rate of pulmonary hypertension ($P < 0.001$; see Supplementary material online, Table S1). Patients undergoing TA-TAVI were therefore at higher surgical risk according to the AKL score than patients undergoing TV-TAVI in 2016 (Table 4). Mortality after TA-TAVI in 2016 was significantly higher than after TV-TAVI ($P < 0.001$; Figure 3). This significant difference was apparent in the intermediate ($P = 0.004$) and high-risk group ($P < 0.001$) but not in the low ($P = 0.62$) and in the very high-risk group ($P = 0.10$; Table 4).

Discussion

The present analysis of all TV-TAVI procedures performed in Germany in 2016 in comparison with recent years shows that (i) the total number of TV-TAVI procedures continued to increase markedly; (ii) the patient selection according to comorbidities and the log ES I did not change significantly; (iii) the peri- and post-procedural complications and consequently the in-hospital mortality after TV-TAVI further declined in 2016. The overall in-hospital mortality rate after TV-TAVI was numerically lower than after iSAVR for the first time in 2016. In all but the low-risk group the mortality rate was

significantly lower than after iSAVR; in the low-risk group similar rates were observed for the two procedures.

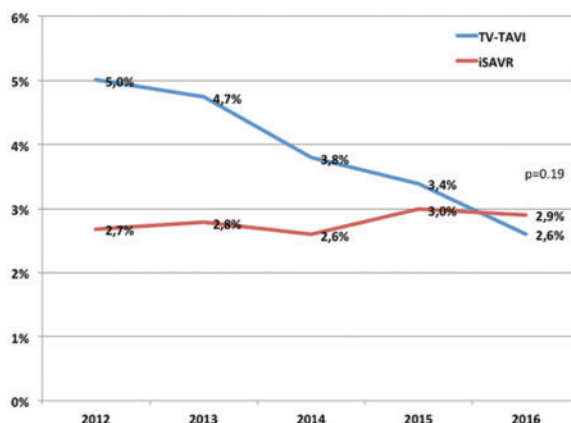
Recently published randomized trials showed very promising results for patients being treated with TAVI procedures instead of iSAVR.^{3,4,13,14} Whereas these results were widely accepted for high-risk patients already since 2012,²² the treatment of intermediate- and low-risk groups with TAVI is still a matter of debate.¹ Nonetheless, the number of TV-TAVI procedures increased in 2016 in comparison to previous years, with more than 15 000 TV-TAVI procedures being carried out as compared with the more-or-less stable number of 9600 iSAVR procedures. This increase was not driven by a relaxation of the traditional selection criteria, as clearly demonstrated by an unaltered risk profile of the TV-TAVI patients during the last few years. Therefore, it must be concluded that the overall increase in the number of patients who were treated for aortic valve disease in 2016 was due to patients who would not otherwise have received replacement therapies at all. This development may well be explained by a better awareness among both physicians and patients of the minimally invasive treatment options, although a recent survey did propose that awareness is still insufficient within the European population.²³

The patient population treated with TV-TAVI today consists not only of high-risk patients but includes also a significant share (87.5% patients with an AKL score $< 6\%$) of patients with either intermediate or even low risk for surgical valve replacement. The debate on the preferred treatment option for these patients is still on-going in the surgical and cardiological community. Therefore, it is of utmost importance to closely monitor both the results of randomized trials as well as the results obtained from routine clinical practice. Mandatory quality assurance programs such as that employed here may be of great help in comparing the results of the different approaches. As described for GARY⁷ and in the analyses of previous years,^{10,11} the positive trend continued in 2016, showing a further decline especially in post-procedural complications such as aortic regurgitation, device embolization, permanent pacemaker implantation, and vascular complications. The consistently declining rate of complications after TAVI can be attributed to the still on-going learning process and improved valve technology.^{24,25}

Thus, for the first time the overall in-hospital mortality was numerically lower in patients treated with TV-TAVI than in patients treated with iSAVR (2.6% vs. 2.9%) despite a difference of 13 years in mean age and a considerably higher risk profile of TAVI patients. These differences were statistically significant in the intermediate-, high-, and very high-risk group as stratified by the AKL score. Remarkably, the low-risk group—representing for both treatment options the group with the most patients—did not show a significant difference in mortality between iSAVR and TV-TAVI.

To integrate the higher age and risk profile of TV-TAVI patients, focus should be placed on the *O/E* ratios for the different risk groups, which underlines the very good results after TV-TAVI. In all risk groups, including the low-risk group, the *O/E* ratio for patients after TV-TAVI was remarkably lower than for patients after iSAVR.

Our results reveal in addition that a considerable portion of TV-TAVI procedures is still performed in patients at high operative risk and that the indication has not already been excessively expanded to lower-risk populations. Nevertheless, according to the results of our large cohort showing a lower in-hospital mortality for TV-TAVI in



Take home figure Overall in-hospital mortality after transcatheter aortic valve implantation (TV-TAVI) and after isolated surgical aortic valve replacement (iSAVR) 2012–2016.

intermediate-risk patients and taking into account the recently published randomized trials confirming these data for a follow-up period of up to 2 years,^{13,14} an even wider broadening of the indication for TV-TAVI appears reasonable than as stated in the newly published guidelines.¹ Even in low-risk patients TAVI might be a good therapy option.

Limitations

Our analysis has several limitations. Firstly, the data derives only from German hospitals and therefore does not necessarily reflect practices in other countries. Second, only in-hospital mortality was assessed. Long-term follow-up data are needed to confirm the relevance of the data. Third, data on the exact prosthesis implanted as well as detailed data on the access site especially for TV-TAVI can't be derived from the IQTIG data. Fourth, we want to emphasize the *de novo* calculation of the AKL score every year. On one hand, this makes the score more precise than other scores, but on the other hand it leads to a different classification of patients every year. Therefore, all data that are based on the AKL score can be compared between different years in only a limited way. Nonetheless, it is important to mention that our comparisons between the different treatment options were made exclusively on the basis of the same underlying risk model. Fifth, we focused on patients who could be treated using the transcatheter approach. Finally, although these data are not derived from a registry they are still not comparable to data from randomized controlled trials. This counts especially for the fact that individual data is not given and therefore statistical analysis is only possible in a simplistic way. Given that data quality control is mandatory; however, the completeness of the data may surpass that of other real-world data sets.

Conclusions

The number of TV-TAVI procedures performed in Germany is still increasing from year to year. The in-hospital mortality decreased over the last few years, and in 2016 it was for the first time numerically lower than the respective mortality rate after iSAVR. In the low

risk group in-hospital mortality was similar, whereas in all other risk groups in-hospital mortality after TV-TAVI was significantly lower than after sAVR. This translates to remarkably good results after TV-TAVI, not only for patients at high and intermediate risk but also for patients in the low risk group, which may therefore stimulate a further widening of the TV-TAVI indication spectrum.

Supplementary material

Supplementary material is available at *European Heart Journal* online.

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