Outcomes after transcatheter aortic valve implantation: a single centre registry of 350 consecutive cases

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Summary

Introduction: The Valve Academic Research Consortium (VARC) consensus document on outcome reporting in transcatheter valves has recently been revised. We used these VARC-2 standardised endpoint definitions to report transcatheter aortic valve implantation (TAVI) outcome at our institution.

Methods: The study included 350 consecutive patients undergoing TAVI at the University Hospital Zurich between May 2008 and November 2012. The Edwards SAPIEN (n = 158; 45%), the Medtronic CoreValve (n = 189, 54%), and the Medtronic Engager (n = 3, 1%) prostheses were implanted via either the transfemoral (83%) or the transapical (17%) access. Mean follow-up was 389 ± 405 days.

Results: Device success within 72 hours was achieved in 88% of patients without significant differences between access sites (p = 0.89) and prosthesis types (p = 0.24). Device failure was due to procedural mortality in 12 (3.4%) patients. In survivors, implantation of more than one prosthesis or malpositioning of the prosthesis was observed in six (1.7%) patients, an increased transvalvular pressure gradient >20 mm Hg in four (1.1%) patients, and moderate aortic regurgitation in 19 (5.4%) patients, respectively. Severe aortic regurgitation was observed in one (0.3%) patient. All-cause mortality was 9.1% at 30 days (12.0% in the first half of the patients vs 6.3% in the second half; p = 0.07), and 21.2% at 1 year. The composite endpoint "early safety" was met in 67 (19.1%) patients at 30 days (23% in the first half of the patients vs 15% in the second half; p = 0.04). Stroke was observed in 2.9%, life-threatening bleeding in 4.6%, vascular complications in 7.4% and acute renal failure in 5.7% of patients. Coronary obstruction was rarely observed (0.9%). Valve-related dysfunction requiring repeat procedure occurred in two (0.6%) patients. With multivariate regression analysis, major and life-threatening bleeding within 30 days (hazard ratio [HR] 4.74, 95% confidence interval [CI] 2.03–11.07, p <0.001), chronic obstructive pulmonary disease (HR 3.41, 95% CI 1.71–6.81, p = 0.001), and baseline New York Heart Association (NYHA) functional class III or IV (HR 3.08, 95% CI 1.18–8.5, p = 0.02) were found to be the strongest independent predictors of all-cause mortality at total follow-up.

Conclusion: According to the newly revised VARC-2 standardised endpoint definitions, device success was met in 88% of patients, and the composite endpoint "early safety" was reached in 19% of patients. These results compare very favourably with the international experience using this novel technique. Thus, in selected patients with severe aortic stenosis TAVI is a valid therapeutic option.

Introduction

In individuals above 75 years of age, aortic valve calcification is a common condition with a prevalence of almost 40% [1]. Among these, moderate to severe aortic stenosis (AS) is observed in 5% [2]. With the growing elderly population in Western societies, the prevalence of AS will increase further in the near future. For symptomatic patients, surgical aortic valve replacement (SAVR) is the standard of care as a result of proven long-term efficacy and safety [3, 4]. However, a

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substantial number of patients is not referred for SAVR because of a high operative risk, severe comorbidities or advanced age [5–7]. Patients with severe symptomatic AS managed conservatively have an extremely poor prognosis with an average survival of two to four years.[5, 7]. In recent years, transcatheter aortic valve implantation (TAVI) has extended the therapeutic options in these patients, and has become an established alternative to SAVR [8, 9]. In the randomised PARTNER trial (Placement of AoRTic traNscathetER valve trial), superiority to standard medical therapy in nonoperable patients, and noninferiority to open heart surgery in high surgical risk patients has been demonstrated in terms of all-cause and cardiovascular mortality, rehospitalisation and cardiac symptoms [10, 11]. Favourable clinical and haemodynamic outcomes for up to 5 years after successful TAVI have been reported in different registries, with survival rates over 70% at two years follow-up [12, 13, 14, 15].

For the comparison of devices, implantation techniques and TAVI centers, standardised outcome reporting is essential. Hence, in January 2011, the first Valve Academic Research Consortium (VARC) definitions were published in order to harmonise outcome reporting for transcatheter valves [16]. These consensus definitions have already been widely adopted in clinical and research practice. With increasing experience with this technique, certain definitions were considered unsuitable or ambiguous, with need for adaption or extension [13, 17]. Accordingly, the revised standardized endpoint definitions were proposed in October 2012 [17]. In this consensus manuscript, outcome measures and composite endpoints were redefined to make them more suitable for present and future needs, in particular for clinical trials.

The aim of this study was to report TAVI experience of the Zurich University Hospital in accordance with the recently revised VARC-2 endpoint definitions.

Methods

Patients and procedures

The present analysis includes 350 consecutive patients undergoing TAVI at the Zurich University Hospital between May 2008 and November 2012. Indications for TAVI included severe symptomatic AS (mean transaortic systolic pressure gradient of ≥40 mm Hg, or an aortic valve area of <1.0 cm^2 or <0.6 cm^2/m^2) in individuals not eligible for SAVR because of an increased risk of mortality. Preprocedural patient assessment included transthoracic (TTE) and transoesophageal echocardiography (TEE), coronary angiography and multislice computed tomography (MSCT). All patients were evaluated by a multidisciplinary heart team consisting of cardiologists, cardiac surgeons, cardiac anaesthesiologists and imaging specialists [11].

Initially, the procedures were performed in the car-diac catheterisation laboratory, but since April 2011 all procedures were performed in a newly installed hybrid operating room. The procedure was performed under general anaesthesia with the exception of nine patients operated upon with local anaesthesia because of specific comorbidities. Prior to the implantation of the prosthesis, balloon valvuloplasty was performed under burst rapid right ventricular pacing.

Outcome reporting according to the VARC-2 endpoint definitions

Outcome was reported according to the revised VARC-2 standardised endpoint definitions [17]. These definitions include complication rates and clinical endpoints, partially summarised in the composite endpoints device success and "early safety". In brief, device success is defined as the absence of procedural mortality, correct positioning of a single prosthetic heart valve into the proper anatomical location and intended performance of the prosthetic heart valve (no prosthesis-patient mismatch, mean aortic valve gradient <20 mm Hg or peak velocity <3 m/s, and no moderate or severe aortic regurgitation). The composite endpoint "early safety" includes all-cause mortality, disabling and nondisabling stroke, life-threatening bleeding, acute kidney injury stage 2 or 3 including renal replacement therapy, coronary artery obstruction requiring intervention, major vascular complications, and valve-related dysfunction requiring repeat procedure (balloon valvuloplasty, TAVI or SAVR) [17]. Data were collected retrospectively from baseline and postinterventional case records as well as from angiographic and echocardiographic findings. The study was approved by the local ethics committee and all patients gave written informed consent.

Statistical analysis

Continuous variables are presented as mean ± standard deviation (SD). Categorical variables are given as numbers and proportions. Normality of distribution was assessed with the Shapiro-Wilk test. Continuous variables were tested for differences with the unpaired t-test or the Mann-Whitney U-test as appropriate. Categorical variables were tested for differences with the Pearson's chi-square-test or the Fisher's exact test as appropriate. Time-to-event relations were constructed on the basis of all available follow-up data, presented as Kaplan-Meier curves. For the Cox model, univariate analysis of predictors of the outcome variable (cumulative all-cause mortality) were tested, hazard ratios (HR) and 95% confidence intervals (CIs) of baseline and procedural characteristics are given. All variables with a p-value of <0.05 in univariate analysis were included in a multivariate model by the backward Wald method to determine independent predictors of the outcome variable. A two-sided p-value of <0.05 was considered statistical significant. All statistical analyses

were performed with the use of SPSS version 21 (SAS Institute Inc, Cary, NC).

Results

Patient characteristics

In total, 350 consecutive patients with severe symptomatic AS underwent TAVI (mean age, 82.4 ± 7.1 years; 48.9% male) from May 2008 to November 2012 at the Zurich University Hospital. Mean systolic pressure gradient was 43 ± 19 mm Hg. Most patients presented with symptoms of congestive heart failure (n = 259, 74%), angina (n = 60, 17%), or syncope (n = 31, 9%). At baseline, most patients were in NYHA class III or IV (n = 253; 72%). Patients were at high surgical risk, with a logistic EuroScore >20% in most of them. Patients who were not at increased surgical risk as estimated by the logistic EuroScore had specific comorbidities or surgical contraindications not incorporated in this risk score such as very advanced age >88 years (15%; n = 52), porcelain aorta (8%; n = 27) or immunosuppressive therapy (7%; n = 23).

The following three prostheses were used: the Medtronic CoreValve (26, 29 and 31 mm; n = 189, 54%), the Edwards SAPIEN (23, 26, and 29 mm; n = 158,

Table 1
Baseline characteristics. Results are presented as mean and SD, or numbers and percentages.
CABG = coronary artery bypass grafting; COPD = chronic obstructive pulmonary disease; LVEF = left ventricular ejection fraction; NT-pro BNP = N-terminal pro-brain-natriuretic peptide; NYHA = New York Heart Association.

Baseline characteristics	
Age, years	82.4 ± 7.1
Male	171 (49)
Body mass index (kg/m²)	26.3 ± 4.4
Coronary artery disease	203 (58)
Pevious CABG	78 (22)
Previous valve surgery	19 (5)
Diabetes mellitus	83 (24)
Hypertension	266 (76)
Atrial fibrillation	103 (29)
Previous pacemaker	38 (11)
COPD	69 (20)
Peripheral vascular disease	81 (23)
Cerebrovascular disease	80 (23)
Pulmonary hypertension >60 mmHg	44 (13)
Porcelain aorta	27 (8)
NYHA class III and IV	95 (27)
Log Euroscore (%)	22.1 ± 13.8
Creatinine (µmol/L)	115 ± 69
NT-proBNP (ng/L)	5257 ± 8470
LVEF (%)	55±13
Aortic valve gradient (echo; mmHg)	43 ± 19
Aortic valve area (cm²)	0.72 ± 0.19

Table 2
Procedural characteristics. Results are presented as numbers and percentages.

Procedural characteristics	
Access site	
transapical	61 (17)
transfemoral	289 (83)
Valve type	
Edwards SAPIEN	158 (45)
Medtronic CoreValve	189 (54)
Engager	3 (1)
Prosthesis size	
23 mm	73 (21)
26 mm	153 (43)
29 mm	104 (30)
31 mm	20 (6)
Type of anesthesia	
general anesthesia	341 (97)
local anesthesia	9 (3)

45%), and the Medtronic Engagr (formerly Ventor Embracer; 26 mm; n = 3, 0.8%) prosthesis. The size of the prosthesis was selected on the basis of aortic annulus dimensions measured in preprocedural MSCT and TEE studies. Access was either transfemoral (n = 289, 83%) or transapical (n = 61, 17%). Mean follow-up was 389 ± 405 days. Baseline characteristics are summarised in table 1 and procedural characteristics in table 2.

VARC-2 composite endpoints: device success and early safety

Device success within 72 hours was achieved in 88% of patients without significant differences between access sites (p = 0.89) and prosthesis types (p = 0.24). Device failure was due to procedural mortality (within 72 hours) in 12 (3.4%) patients. In survivors, implantation of more than one prosthesis or malpositioning of the prosthesis was observed in 6 (1.7%) patients and prosthesis valve dysfunction in 24 (6,9%) patients. Prosthetic valve dysfunction was due to an increased transvalvular pressure gradient >20 mm Hg in 4 (1.1%) patients and due to moderate aortic regurgitation in 19 (5.4%) patients. Severe aortic regurgitation was observed in one (0.3%) patient. Mean aortic valve gradient decreased from 43 ± 19 mm Hg at baseline to 10 ± 3 mm Hg 1 month after valve replacement (p = 0.001), and remained stable for up to 3 years of follow-up.

In the whole patient cohort, all-cause mortality was 9.1% at 30 days [18]. Causes of death at 30 days were cardiovascular in 96.8% (31 of 32) of patients. One patient died from a disabling stroke, all other patients died of cardiovascular causes according to the VARC-2 criteria. Stroke was observed in 2.9% of patients, life-threatening bleeding in 4.6%, vascular complications in 7.4% and acute renal failure in 5.7%. Coronary

obstruction was rarely observed (0.9%). Valve-related dysfunction requiring a repeat procedure occurred in two (0.6%) patients. The combined endpoint "early safety" at 30 days was met in 67 (19.1%) patients (fig. 1).

Myocardial infarction not due to coronary obstruction was observed in 2.0% of patients at 30 days, and was periprocedural in 1.4%. Conversion to open heart surgery and unplanned use of cardiopulmonary bypass was rare (1.7% and 2.3%, respectively). Cardiac tamponade occurred in 2.3% of patients, and was due to annulus rupture in 0.6%. TAVI-related complications are summarised in table 3.

New left bundle-branch block was observed in 21.1% of patients at 30 days follow-up, with increased incidence after implantation of the Medtronic Core Valve prosthesis (28.2%) compared with the Edwards SAPIEN prosthesis (12.0%; p = 0.001). Permanent pacemaker implantation within 30 days was needed in 18.9% of patients, with an increased need after implantation of the Medtronic CoreValve prosthesis (25.5%) compared with the Edwards SAPIEN prosthesis (10.8%; p = 0.004).

Figure 1
The combined endpoint "early safety" at 30 days.
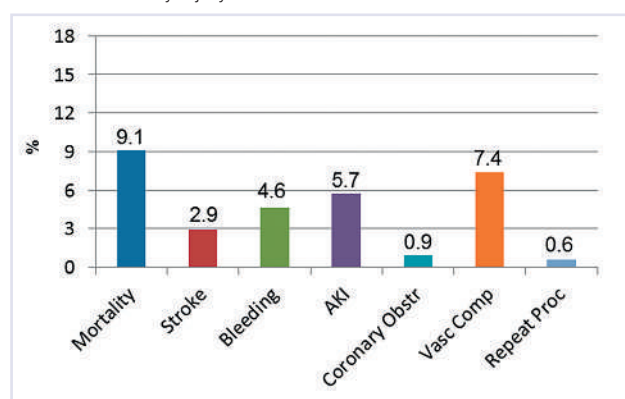AKI = acute kidney injury.

Table 3
TAVI-related complications. CPB = cardiopulmonary bypass;
TAV = transcatheter aortic valve.

TAVI-related complications	
Myocardial infarction	7 (2.0)
periprocedural	5 (1.4)
Conversion to open surgery	6 (1.7)
Unplanned use of CPB	8 (2.3)
Cardiac tamponade	8 (2.3)
Annulus rupture	2 (0.6)
Endocarditis	0 (0)
Valve thrombosis	3 (0.9)
Valve malpositioning	8 (2.3)
TAV-in-TAV deployment	2 (0.6)

Procedural learning curve

Device success at 72 hours was 84% in the first 175 patients, and 91% in the second (p = 0.02). All-cause mortality was 9.1% at 30 days (12% in the first half of the patients and 6.3% in the second half; p = 0.07).[18] Major vascular complications and acute kidney injury decreased from 9.7% to 5.1% (p = 0.29), and from 6.9% to 4.6% (p = 0.36), respectively, without reaching statistical significance. Overall, the combined endpoint "early safety" at 30 days was met in 19.1% of participants. Of note, "early safety" decreased significantly from 23% in the first 175 patients to 15% in the second (p = 0.04). The need for permanent pacemaker implantation within 30 days was 22.3% in the first half of patients and 15.4% in the second half (p = 0.10).

Symptomatic improvement

At baseline, 4% (n = 14) of patients were in NYHA class I, 24% (n = 83) in NYHA class II, 53% (n = 187) in NYHA class III and 19% (n = 66) in NYHA class IV. At 30 days, 1 year, and 2 years follow-up, most patients were in NYHA class I and II (p <0.001 vs baseline; fig. 2). Nine percent of patients required rehospialisation because of congestive heart failure or other valve-related complications within the first year after TAVI. Up to 1 year after the procedure, 61/106 (58%) patients were living independently at home.

Overall survival

The Kaplan-Meier survival analysis is depicted in fig. 3. Survival was 79% at 1 year, 69% at 2 years, and 53% at 3 years. Most deaths were observed within the first 6 months after the procedure. In our patient cohort, no significant survival differences were observed between prosthesis types (p = 0.23), access sites (p = 0.07), gender (p = 0.27) and presence or absence of coronary artery disease (p = 0.39).

Figure 2
Symptoms at baseline and after transcathetheter aortic valve implantation (TAVI).
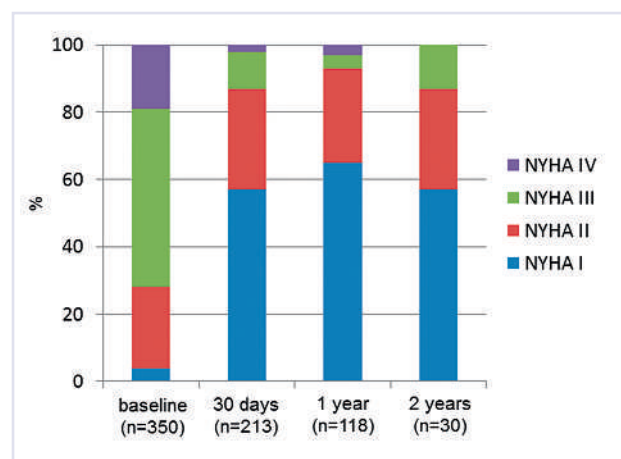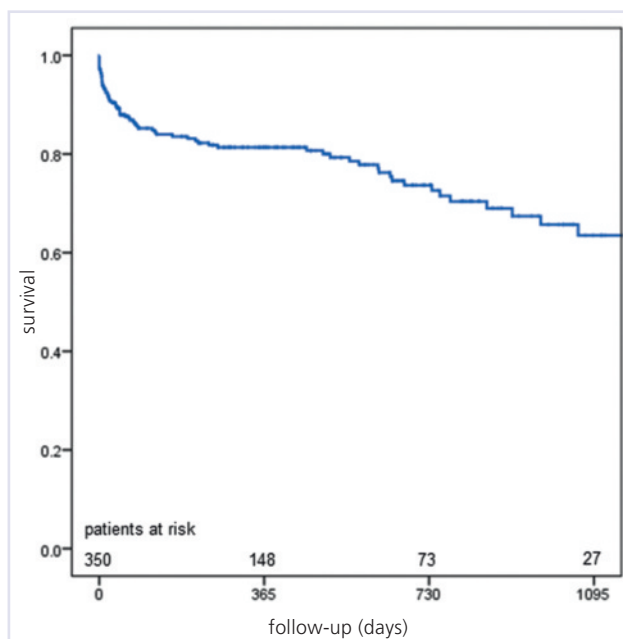NYHA = New York Heart Association.

Figure 3
Kaplan-Meier survival curve. Overall survival in the whole patient cohort.

Predictors of all-cause mortality

In a univariate Cox regression analysis, predictors of all-cause mortality in descending order of HR were major vascular complications (HR 4.17, 95% CI 2.33–7.49, p <0.001), major and life-threatening bleeding within 30 days (HR 3.86, 95% CI 2.15–6.93, p <0.001), baseline NYHA class III or IV symptoms (HR 2.64, 95% CI 1.36–5.15, p = 0.004), chronic obstructive pulmonary disease (HR 1.92, 95% CI 1.17–3.16, p = 0.01), atrial fibrillation (HR 1,74, 95% CI 1.10–2.76, p = 0.02), baseline creatinine levels (HR 1.01, 95% CI 1.00—1.01, p <0.001) and baseline N-terminal pro brain natriuretic peptide (NT-proBNP) (HR 1.00, 95% CI 1.00–1.00, p = 0.001).

In a multivariate Cox regression analysis, major and life-threatening bleeding within 30 days (HR 4.74, 95% CI 2.03–11.07, p <0.001), chronic obstructive pulmonary disease (HR 3.41, 95% CI 1.71–6.81, p <0.001) and NYHA class III or IV at baseline (HR 3.08, 95% CI 1.18–8.05, p = 0.02) were the strongest independent predictors of all-cause mortality. Further predictors in-

Table 4
Cox regression analysis of all-cause mortality.
CABG = coronary artery bypass grafting; LBBB = left bundle-branch block; LVEF = left ventricular ejection fraction; NYHA = New York Heart Association.

Cox Regression Analysis of All-Cause Mortality						
	Univariate Analysis			**Multivariate Analysis**		
Variable	**HR**	**95% CI**	**P-value**	**HR**	**95% CI**	**P-value**
Use of Medtronic CoreValve prosthesis	1.36	0.85–2.18	0.20			
Transapical access	1.54	0.93–2.55	0.1			
Age (>80 years)	1.16	0.71–1.91	0.55			
Female sex	0.84	0.67–1.06	0.13			
Diabetes mellitus	1.17	0.69–1.97	0.56			
Hypertension	1.43	0.80–2.56	0.23			
Atrial fibrillation	**1.74**	**1.10–2.76**	**0.02***	1.41	0.75–2.65	0.29
Chronic obstructive pulmonary disease	**1.92**	**1.17–3.16**	**0.01***	**3.41**	**1.71–6.81**	**0.001***
Peripheral vascular disease	1.20	0.73–1.98	0.46			
Cerebrovascular disease	0.91	0.54–1.52	0.72			
Coronary artery disease	1.34	0.82–2.18	0.23			
Previous CABG	1.03	0.60–1.74	0.93			
Previous valve surgery	0.72	0.23–2.28	0.57			
LogEuroSCORE (>20%)	1.15	0.65–2.03	0.63			
NYHA class III/IV	**2.64**	**1.36–5.15**	**0.004***	**3.08**	**1.18–8.05**	**0.02***
NT-proBNP (pg/ml)	**1.00**	**1.00–1.00**	**<0.001***	**1.00**	**1.00–1.00**	**0.03***
Creatinine (µmol/l)	**1.01**	**1.00–1.01**	**<0.001***	**1.00**	**1.00–1.01**	**0.02***
LVEF (<35%)	1.84	0.98–3.44	0.06			
Moderate to severe aortic regurgitation	1.26	0.73–2.18	0.41			
Major/life-threatening bleeding (30 days)	**3.86**	**2.15–6.93**	**<0.001***	**4.74**	**2.03–11.07**	**<0.001***
Major vascular complications (30 days)	**4.17**	**2.33–7.49**	**<0.001***	0.75	0.22–2.53	0.64
New permanent pacemaker	0.77	0.43–1.40	0.40			
New LBBB	1.51	0.89–2.55	0.12			

cluded increased NT-proBNP (HR 1.00, 95% CI 1.00–1.00, p = 0.03), and creatinine levels (HR 1.00, 95% CI 1.00–1.01, p = 0.02). Uni- and multivariate predictors of all-cause mortality at total follow-up are summarised in table 4.

Discussion

This study reports the Zurich University Hospital TAVI experience in accordance with the revised VARC-2 standardised endpoint definitions. During the past 5 years, TAVI was performed with favourable clinical outcome as assessed using VARC-2. Indeed, the composite endpoint "device success" was met in 88%, and the composite endpoint "early safety" occurred in 19% of patients.

Device success was high without any differences between access sites or prosthesis types. The difference from previously reported success rates of up to 97% in other registries is explained by the fact that the VARC-2 standardised endpoint definitions for the first time include absence of procedural mortality within 72 hours [17, 19, 20].

Complication rates observed in the patient cohort treated at the Zurich University Hospital are comparable to previously reported ones [13, 21]. Mortality in the whole patient cohort was 9.1% at 30 days without any differences between access sites or prosthesis types. Indeed, 30-day mortality rates ranging from 5.4% to 12.7% have been reported, with a marked decrease over time with the growing experience of operators, centres and the field at large [20, 22, 23]. The survival rates in our patient cohort are comparable to other registries, with the majority of deaths occurring within the first 3 months after the procedure [14, 24]. In the United Kingdom TAVI Registry survival was 92.9% at 30 days and 73.7% at 2 years [19]. Subgroup analyses in TAVI patients have demonstrated that a worse survival was observed in nontransfemorally treated patients, which may at least in part be explained by the more adverse risk profile in those patients, including peripheral artery disease among other problems [17]. Causes of death were cardiovascular in most patients; in accordance with the VARC-2 criteria, death of unknown cause and death caused by noncoronary vascular conditions including stroke are classified cardiovascular [17]. Stroke rates of 2.9% are comparable to rates in other registries. Indeed, mostly silent cerebrovascular events after TAVI are a major concern. In a magnetic resonance imaging study, cerebral defects were reported in over 80% of TAVI patients [25]. These findings underline the importance of stroke prevention and support the development of novel embolism protection devices in the context of TAVI. In our patient cohort, new left bundle-branch block was observed in 21% of patients, with an increased incidence with the Medtronic CoreValve prosthesis as compared

with the Edwards SAPIEN prosthesis. This difference has been attributed to the longer prosthesis skirt of the device comprising the conduction system; however, compression of the left ventricular outflow tract by the dilatory balloon has also been debated [26, 27, 28]. In previous reports, the incidence of TAVI-induced left bundle-branch block varies considerably with incidences between 7% and 83% [26, 27, 29, 30].

In our patient cohort, the strongest independent predictors of all-cause mortality were chronic obstructive pulmonary disease, NYHA class III or IV symptoms at baseline, and major or life-threatening bleeding within the first 30 days after TAVI. Major and life-threatening bleeding has clearly been associated with an increased mortality at 30 days, as well as during 3 years of follow-up [10, 15, 31]. Chronic obstructive pulmonary disease and NYHA functional class III or IV symptoms have previously been identified as strong independent predictors of mortality in multivariate models, as were reduced left ventricular ejection fraction or the presence of significant aortic regurgitation [12, 19, 32]. Impaired renal function, new left bundle-branch block and the use of transapical access were further predictors of mortality after TAVI in most studies [15, 19, 30, 32]. In our patient cohort, these results could not be confirmed, which might be largely owing to the retrospective nature of the registry and the smaller number of patients included compared with multicentre registries. Interestingly, in contrast to patients undergoing SAVR, previous cardiac surgery does not seem to influence survival after TAVI. Indeed, consistent with our results, both previous coronary artery bypass grafting (CABG) and previous SAVR were not identified as mortality predictors after TAVI [19, 24, 30, 33]. In the Transcatheter Valve Treatment Sentinel Pilot Registry, advanced age predicted higher mortality in a multivariate analysis [21]. However, in accordance with our patient cohort, other registries failed to show this association [19, 24, 33]. These findings underline the observation that additional comorbidities rather than mere age itself determine long-term survival in those patients [15].

In line with worldwide TAVI experience, we observed a learning curve with this technique since its introduction at our institution in May 2008. The combined endpoints device success and "early safety", including most important complications after TAVI, were significantly reduced in the second half of patients compared with the first half. Thirty-day-mortality, major vascular complications, the need for new permanent pacemaker implantation, as well as acute kidney injury following TAVI, tended to be lower in the second half of the patients, albeit without reaching statistical significance. Learning curves in transcatheter valve implantation have been investigated in detail at other centres [34, 35]. Gurvitch et al showed a clear reduction in 30-day mortality from 13.3% in the first half of the

patients to 5.9% in the second half [35]. Trends in TAVI outcome including significant reductions in major vascular complications, life-threatening bleedings and acute kidney injury, as well as improved 1-year surviva, have recently also been demonstrated by the PRAGMATIC Plus initiative [36]. These impressive results demonstrate that both operator and centre experience, as well as constant device optimisation, importantly affect outcome after TAVI. Furthermore, next generation prosthesis designs already on the horizon may address unresolved issues such as aortic regurgitation or conduction disturbances in near future.

VARC standardised endpoint definitions introduced into research practice in January 2011 have established a novel standard in outcome reporting, thereby improving comparison of complications with transcatheter valves. The revised version includes some changes in outcome definitions and composite endpoints including device success, clinical efficacy and time-related valve safety [17]. These endpoint definitions warrant a concise and systemic analysis of outcome measures in this high-risk patient population, and might further strengthen a standardised reporting of complications.

Limitations of this study are its retrospective nature and the relatively small number of patients, which might affect the validity of the regression analysis. However, this registry defines characteristics and outcomes in a real-world patient population treated with TAVI in Switzerland.

In conclusion, our data confirm the safety and feasibility of TAVI in an elderly high-risk patient population. Reporting TAVI-outcome according to the newly revised VARC-2 standardized definitions, device success is met in 88% of patients, and the composite endpoint "early safety" is observed in 19% of patients.

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