

# Short-term clinical outcomes among patients undergoing transcatheter aortic valve implantation in Switzerland: the Swiss TAVI registry

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## KEYWORDS

- aortic stenosis
- outcomes
- transcatheter aortic valve implantation

## Abstract

**Aims:** To evaluate short-term clinical outcomes following transcatheter aortic valve implantation (TAVI) using CE-mark approved devices in Switzerland.

**Methods and results:** The Swiss TAVI registry is a national, prospective, multicentre, monitored cohort study evaluating clinical outcomes in consecutive patients undergoing TAVI at cardiovascular centres in Switzerland. From February 2011 to March 2013, a total of 697 patients underwent TAVI for native aortic valve stenosis (98.1%), degenerative aortic bioprosthesis (1.6%) or severe aortic regurgitation (0.3%). Patients were elderly (82.4±6 years), 52% were females, and the majority highly symptomatic (73.1% NYHA III/IV). Patients with severe aortic stenosis (mean gradient 44.8±17 mmHg, aortic valve area 0.7±0.3 cm<sup>2</sup>) were either deemed inoperable or at high risk for conventional surgery (STS 8.2%±7). The transfemoral access was the most frequently used (79.1%), followed by transapical (18.1%), direct aortic (1.7%) and subclavian access (1.1%). At 30 days, rates of all-cause mortality, cerebrovascular events and myocardial infarction were 4.8%, 3.3% and 0.4%, respectively. The most frequently observed adverse events were access-related complications (11.8%), permanent pacemaker implantation (20.5%) and bleeding complications (16.6%). The Swiss TAVI registry is registered at ClinicalTrials.gov (NCT01368250).

**Conclusions:** The Swiss TAVI registry is a national cohort study evaluating consecutive TAVI procedures in Switzerland. This first outcome report provides favourable short-term clinical outcomes in unselected TAVI patients.

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## Introduction

Aortic valve stenosis is the most clinically relevant valvular heart disease in the elderly patient population and is associated with worse clinical outcomes once symptoms occur<sup>1</sup>. Surgical aortic valve replacement (SAVR) was for decades the standard treatment for patients with symptomatic, severe aortic stenosis, and resulted in effective alleviation of symptoms, improvement of health-related quality of life and overall prognosis<sup>2</sup>. Following the introduction of transcatheter aortic valve implantation (TAVI) in 2002 as a less invasive treatment for symptomatic severe aortic stenosis<sup>3</sup>, TAVI has evolved into a reliable therapeutic alternative with comparable results to SAVR in well-defined patient subgroups<sup>4-6</sup>. Currently, the indication for TAVI is limited to carefully selected patients deemed inoperable or at excessive risk for SAVR<sup>2</sup>. A successful TAVI procedure is preceded by a complex selection process of patients, requiring detailed imaging information of the aortic valve anatomy and the peripheral vasculature, and also a meticulous clinical assessment by an interdisciplinary Heart Team<sup>7,8</sup>.

In the era of the Heart Team, the Swiss Working Group of Interventional Cardiology in collaboration with the Swiss Society of Cardiac Surgery started a nationwide, prospective cohort study in 2011, with the intention of assessing the safety and efficacy of unselected and consecutive TAVI procedures in Switzerland. As the first TAVI in Switzerland was performed in August 2007, this registry mainly focuses on contemporary results of experienced cardiovascular centres in consecutive patients treated with TAVI in Switzerland.

## Methods

The Swiss TAVI registry is a national, prospective cohort study aiming for consecutive patient enrolment, data monitoring and endpoint adjudication by a dedicated clinical events committee according to the recommendations of the Valve Academic Research Consortium (VARC)<sup>9,10</sup>. The Swiss TAVI registry was designed to provide short-term clinical outcomes and long-term clinical data of TAVI patients treated with CE-approved devices.

The aim of the present report was to describe the clinical and procedural characteristics of patients treated with TAVI in Switzerland using different CE-approved devices and various access routes as well as to stratify short-term outcomes according to device type and access route. The study protocol was approved by the local cantonal ethics committee at each participating centre and all patients provided written informed consent. The Swiss TAVI registry is performed under the lead of the Swiss Cardiovascular Centre Bern at Bern University Hospital in cooperation with the Clinical Trials Unit Bern responsible for data management and independent statistical analysis.

## Patient population

A total of 697 patients were enrolled into the Swiss TAVI registry between February 2011 and March 2013, and eight centres participated during this first period of inclusion. Consecutive patient enrolment was mandatory. All participating centres are listed in the

**Online Appendix.**

Patients were eligible for inclusion in case of symptomatic, severe aortic stenosis, degenerated aortic bioprosthesis or severe aortic regurgitation treated with CE-approved TAVI devices. Patient screening and selection was recommended to be performed within a multidisciplinary Heart Team using detailed clinical and anatomical imaging information. The exclusion criterion for participation in the cohort study was the absence of cardiac surgery on-site.

## Procedure and devices

Transcatheter aortic valve procedures were performed using CE-approved devices only. During the inclusion period, the following CE-approved devices were available in Switzerland and used for patient treatment: Medtronic CoreValve® (Medtronic Inc., Minneapolis, MN, USA), Edwards SAPIEN XT (Edwards Lifesciences, Irvine, CA, USA), Symetis Acurate TA™ (Symetis, Lausanne, Switzerland), JenaValve (JenaValve Technology GmbH, Munich, Germany) and the Portico™ THV (St. Jude Medical, Minneapolis, MN, USA). There was no pre-specified recommendation regarding access route selection, and the decision as to general anaesthesia or conscious sedation was left to the discretion of the Heart Team and according to local expertise. In addition, there was no specific recommendation for the type and duration of antiplatelet or antithrombotic medication, which was left to the discretion of the operator and according to local expertise.

## Definitions and endpoints

The primary study endpoint with respect to procedural safety was all-cause mortality at 30 days of follow-up. Secondary outcome measures included cardiovascular mortality, cerebrovascular events, myocardial infarction, bleeding complications, vascular or access-related complications and acute kidney injury. Serious adverse events were site reported and checked for plausibility. All events were adjudicated by a clinical events committee, consisting of interventional cardiologists and cardiac surgeons according to the standardised endpoint definitions proposed by the Valve Academic Research Consortium (VARC)<sup>9</sup>.

## Data collection and quality control

Data were collected using standardised case-report forms available on a web-based database ([www.swisstaviregistry.ch](http://www.swisstaviregistry.ch)). The database was maintained by the Clinical Trials Unit at the University of Bern. Apart from baseline, procedural and in-hospital characteristics, the Swiss TAVI registry prospectively collects follow-up data at 30 days, 12 months and also after three and five years following the procedure. Follow-up was performed individually by each centre on the basis of phone calls or clinical visits. Central monitoring by an independent monitor and statistician was performed to verify completeness and accuracy of data entry at each site. Monitoring included all patients; however, no on-site monitoring or patient data validation was performed.

## Statistical analysis

Continuous data are reported as mean  $\pm$  standard deviation (SD), and categorical variables are reported as number of patients (% of patients) where appropriate. In-hospital events are reported as

counts of first occurrence per (sub-) type of event (% of all patients). Thirty-day event rates are reported using time-to-first-event data, graphically presented using Kaplan-Meier curves, with incidence rates calculated from life tables. Event rates at 30 days were compared for patients treated with transvascular vs. surgical access, and also within transfemoral patients comparing the two main devices Medtronic CoreValve and Edwards SAPIEN XT bioprosthesis, using Cox's regressions. Reported are crude hazard ratios (HR; with 95% confidence intervals) with p-value from Wald chi-square test, or continuity corrected risk ratios (RR; 95% CI) with p-value from Fisher's exact test in case of zero events. Reported are adjusted HR (95% CI), where groups are compared including adjustment for age, gender, previous cardiac surgery, peripheral vascular disease, and coronary artery disease. Two-sided p-values <0.05 were considered statistically significant. All analyses were performed with Stata version 12 (StataCorp, College Station, TX, USA).

## Results

### PATIENT POPULATION

A total of 697 patients underwent TAVI between February 2011 and March 2013 for native aortic valve stenosis (98.1%), degenerative aortic bioprosthesis (1.6%) and native aortic regurgitation (0.3%) and were entered in the Swiss TAVI registry. Elective treatment was performed in 94.9% of cases, while 5.1% of patients underwent urgent or emergent intervention due to haemodynamic instability. A multidisciplinary decision for TAVI was reached in 97.0% of procedures. Mean age was 82.4±6.2 years and 51.5% were female. Patients were highly symptomatic, with 73.1% presenting in NYHA functional Class III and IV. The mean aortic valve area was 0.74±0.3 cm<sup>2</sup> and the transvalvular mean gradient was 44.8±17.4 mmHg. Patients were considered to be at high surgical risk or inoperable with an estimated risk of mortality at 30 days of 20.2±12.7% according to the logistic EuroSCORE and 8.2±7.1% according to the STS score. Detailed information on baseline clinical characteristics are summarised in **Table 1**.

### PROCEDURAL CHARACTERISTICS AND RESULTS

Procedural characteristics and results are presented in **Table 2**. Most TAVI procedures were performed in the catheterisation laboratory (74.6%), the hybrid room (24.2%), and the operating room (1.1%) using either general anaesthesia (54.6%) or conscious sedation (45.4%). Transfemoral implantation was performed in 79.1%, transapical in 18.1%, the direct aortic access was used in 1.7% and the subclavian approach in 1.1%, respectively. The majority of patients received balloon aortic valvuloplasty prior to valve insertion (86.7%). The Medtronic CoreValve was implanted in 48.4%, the Edwards SAPIEN XT in 45.7%, JenaValve in 3.3%, the Symetis Acurate TA in 2.4%, and the Portico THV prosthesis in 0.1% of patients. Most patients received only one prosthesis (95.5%); however, more than one prosthesis was required in 4.5% of patients during the intervention. A total of three patients (0.4%) did not receive any TAVI prosthesis: one patient was treated with balloon aortic valvuloplasty only, one patient was converted to surgical aortic valve replacement due

**Table 1. Baseline characteristics.**

		All patients N=697
Age (years)		82.4±6.2
Female gender, n (%)		359 (51.5)
Body mass index (kg/m <sup>2</sup> )		26.3±5.0
Cardiac risk factors	Diabetes mellitus, n (%)	204 (29.3)
	Dyslipidaemia, n (%)	387 (55.5)
	Hypertension, n (%)	574 (82.4)
Past medical history	Previous pacemaker implantation, n (%)	69 (9.9)
	Previous myocardial infarction, n (%)	105 (15.1)
	Previous cardiac surgery, n (%)	104 (14.9)
	Previous stroke, n (%)	83 (11.9)
Clinical features	Peripheral vascular disease, n (%)	137 (19.7)
	Chronic obstructive pulmonary disease, n (%)	109 (15.6)
	Coronary artery disease, n (%)	390 (56.0)
	Left ventricular ejection fraction (%)	53.8±14.1
	Aortic valve area (cm <sup>2</sup> )	0.74±0.3
	Mean transaortic gradient (mmHg)	44.8±17.4
Symptoms on admission	New York Heart Association (NYHA) functional class	
	NYHA I or II, n (%)	186 (26.9)
	NYHA III or IV, n (%)	505 (73.1)
	Canadian Cardiovascular Society (CCS) angina class	
	No angina, n (%)	496 (71.2)
	CCS I or II, n (%)	114 (16.4)
	CCS III or IV, n (%)	87 (12.5)
Risk assessment	Log. EuroSCORE (%)	20.2±12.7
	STS score (%)	8.2±7.1

to heavy calcification of the native aortic valve, and one patient died following balloon aortic valvuloplasty and prior to any valve insertion. Conversion to surgery occurred in 0.9% of patients.

Information on the in-hospital course after TAVI is provided in **Table 3**. Cumulative mean duration of hospital length of stay was 10.7±6.1 days, comprising 1.1±2.4 days in the intensive care unit, 2.5±2.9 days in the intermediate or coronary care unit and on average 7.1±5.3 days in the general ward. The majority of patients were discharged to a rehabilitation clinic (43.5%), while one third of patients (28.9%) were discharged home and another quarter of patients were sent back to the referring hospital (24.1%).

### CLINICAL OUTCOMES

Short-term clinical outcomes within the first 30 days after TAVI are presented in **Table 4** (In-hospital clinical outcomes are provided in **Online Table 1**). Cumulative all-cause mortality was 4.8%. All deaths were due to cardiovascular causes. The overall rate of cerebrovascular accidents after 30 days was 3.3% with the majority being major strokes (2.5%). The myocardial infarction rate was less than 1%. TAVI was effective in symptomatic alleviation (**Figure 1**) showing a reduction of dyspnoea from 73.1% of patients in NYHA Class III/IV at baseline to 11.0% at 30-day follow-up. Two main subanalyses were performed:

**Table 2. Procedural characteristics.**

		All patients N=697
Procedure time (min)		75.8±37.9
Amount of contrast (ml)		215.0±107.5
General anaesthesia, n (%)		380 (54.6%)
Conversion from local to general anaesthesia, n (%)		16 (5.1%)
Procedure location	Catheterisation laboratory, n (%)	520 (74.6%)
	Operating room, n (%)	8 (1.1%)
	Hybrid room, n (%)	169 (24.2%)
Access site location	Femoral, n (%)	551 (79.1%)
	Apical, n (%)	126 (18.1%)
	Subclavian, n (%)	8 (1.1%)
	Direct aortic, n (%)	12 (1.7%)
Concomitant procedure	Percutaneous coronary intervention, n (%)	65 (9.3%)
Device features	Prior balloon aortic valvuloplasty, n (%)	604 (86.7%)
	Device implanted	
	Medtronic CoreValve, n (%)	336 (48.4%)
	Edwards SAPIEN XT, n (%)	317 (45.7%)
	Symetis Acurate, n (%)	17 (2.4%)
	JenaValve, n (%)	23 (3.3%)
	SJM Portico, n (%)	1 (0.1%)
Aortic regurgitation post TAVI	Grade 0, n (%)	170 (24.9%)
	Grade 1, n (%)	452 (66.3%)
	Grade 2, n (%)	55 (8.1%)
	Grade 3, n (%)	5 (0.7%)

Transvascular (transfemoral and transsubclavian) versus surgical access (transapical and transaortic): baseline and procedural characteristics according to access route are provided in the **Online Table 2** and **Online Table 3**. Clinical outcomes at 30 days of follow-up are summarised in **Table 5**. There were no differences with regard to cerebrovascular accidents, myocardial infarction, acute kidney injury and life-threatening bleeding complications between surgical access and transvascular patients; however, vascular access-site and access-related complications (0.7% vs. 14.7%;

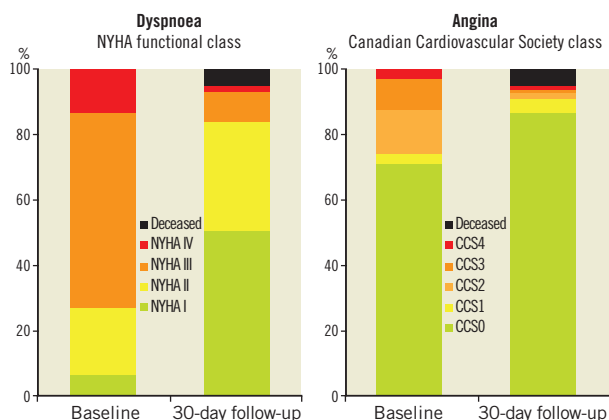
**Table 3. In-hospital course.**

		All patients N=697
Permanent pacemaker implantation, n (%)		137 (19.9%)
Any PRBC infusion during hospitalisation, n (%)		131 (18.9%)
Number of PRBC, median (interquartile range)		2.0 (1.0; 3.0)
Overall in-hospital stay after TAVI (days)		10.7±6.1
Stay at intensive care unit (days)		1.1±2.4
Stay at intermediate care (days)		2.5±2.9
Stay at general ward (days)		7.1±5.3
Patient discharged to	Home, n (%)	197 (28.9%)
	Referring hospital, n (%)	164 (24.1%)
	Rehabilitation clinic, n (%)	296 (43.5%)
	Nursing home, n (%)	6 (0.9%)
	Other, n (%)	18 (2.6%)
Medication	Aspirin exclusive, n (%)	67 (10.4%)
	Clopidogrel exclusive, n (%)	14 (2.2%)
	Oral anticoagulation exclusive, n (%)	54 (8.4%)
	Aspirin and clopidogrel, n (%)	355 (55.0%)
	Aspirin and oral anticoagulation, n (%)	71 (11.0%)
	Clopidogrel and oral anticoagulation, n (%)	38 (5.9%)

HR<sub>adjusted</sub> 0.05, 95% CI: 0.01-0.35) as well as major bleeding complications (3.7% vs. 9.6%; HR<sub>adjusted</sub> 0.33, 95% CI: 0.13-0.84) were found to be less frequent among surgical access patients. The increased rate of permanent pacemaker implantation between surgical access and transvascular treated patients (10.5% vs. 22.9%; HR<sub>adjusted</sub> 0.41, 95% CI: 0.23-0.72) is mainly explained by differences in device type and design, as permanent pacemaker implantation was found to be less frequent with the Edwards SAPIEN XT when compared with the Medtronic CoreValve. Furthermore, patients with surgical access were at higher risk of death after 30 days compared to patients treated by the transvascular route (**Figure 2**; 9.5% vs. 3.6%; HR<sub>adjusted</sub> 2.39, 95% CI: 1.13-5.04).

**Table 4. Clinical outcomes at 30 days.**

	All patients N=697
Mortality, n (%)	33 (4.8)
Cardiovascular mortality, n (%)	33 (4.8)
Cerebrovascular accident, n (%)	23 (3.3)
Major stroke, n (%)	17 (2.5)
Minor stroke, n (%)	4 (0.6)
TIA, n (%)	2 (0.3)
Myocardial infarction, n (%)	3 (0.4)
Spontaneous myocardial infarction, n (%)	1 (0.2)
Bleeding, n (%)	114 (16.6)
Life-threatening bleeding, n (%)	43 (6.3)
Major bleeding, n (%)	58 (8.4)
Minor bleeding, n (%)	13 (1.9)
Permanent pacemaker implanted, n (%)	140 (20.5)

**Figure 1. Symptom status at baseline evaluation and at 30-day follow-up after TAVI.**



**Table 5. Clinical outcomes of surgical and transvascular access patients at 30 days.**

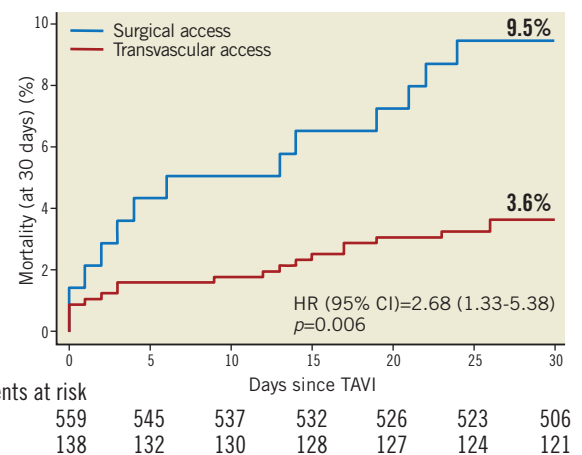
	Surgical access N=138	Transvascular N=559	Crude HR or RR (95% CI)	p-value	Adjusted HR (95% CI)	p-value
Mortality, n (%)	13 (9.5)	20 (3.6)	2.68 (1.33-5.38)	0.006	2.39 (1.13-5.04)	0.022
Cardiovascular mortality, n (%)	13 (9.5)	20 (3.6)	2.68 (1.33-5.38)	0.006	2.39 (1.13-5.04)	0.022
Cerebrovascular accident, n (%)	5 (3.7)	18 (3.2)	1.14 (0.42-3.06)	0.80	1.11 (0.39-3.18)	0.85
Major stroke, n (%)	5 (3.7)	12 (2.2)	1.70 (0.60-4.82)	0.32	1.66 (0.54-5.06)	0.37
Minor stroke, n (%)	0 (0.0)	4 (0.7)	0.45 (0.02-8.31)	1.00		
TIA, n (%)	0 (0.0)	2 (0.4)	0.81 (0.04-16.78)	1.00		
Myocardial infarction, n (%)	1 (0.7)	2 (0.4)	2.06 (0.19-22.68)	0.56	1.46 (0.11-18.89)	0.77
Acute kidney injury, n (%)	10 (7.4)	40 (7.3)	1.03 (0.51-2.06)	0.94	0.94 (0.46-1.94)	0.87
Stage 1, n (%)	4 (3.0)	22 (4.0)	0.74 (0.26-2.16)	0.59	0.72 (0.24-2.15)	0.55
Stage 2, n (%)	3 (2.2)	4 (0.7)	3.08 (0.69-13.78)	0.14	2.79 (0.55-14.11)	0.22
Stage 3, n (%)	3 (2.2)	14 (2.5)	0.88 (0.25-3.06)	0.84	0.75 (0.21-2.74)	0.66
Bleeding, n (%)	16 (11.8)	98 (17.7)	0.65 (0.38-1.10)	0.11	0.63 (0.37-1.10)	0.10
Life-threatening bleeding, n (%)	10 (7.4)	33 (6.0)	1.24 (0.61-2.51)	0.55	1.46 (0.70-3.04)	0.32
Major bleeding, n (%)	5 (3.7)	53 (9.6)	0.38 (0.15-0.94)	0.037	0.33 (0.13-0.84)	0.02
Minor bleeding, n (%)	1 (0.7)	12 (2.2)	0.34 (0.04-2.62)	0.30	0.31 (0.04-2.46)	0.23
Vascular access-site complications, n (%)	1 (0.7)	82 (14.7)	0.05 (0.01-0.35)	0.003	0.05 (0.01-0.35)	0.003
Major vascular complications, n (%)	0 (0.0)	45 (8.1)	0.04 (0.00-0.65)	<0.001		
Minor vascular complications, n (%)	1 (0.7)	38 (6.8)	0.11 (0.01-0.78)	0.027	0.12 (0.02-0.89)	0.038
Permanent pacemaker implantation, n (%)	14 (10.5)	126 (22.9)	0.43 (0.25-0.74)	0.003	0.41 (0.23-0.72)	0.002

Comparison of the two most frequently used devices using the transfemoral access only: clinical outcomes at 30 days according to device type are summarised in **Table 6**. No differences were observed with regard to major cardiac and cerebrovascular events (**Figure 3**). However, there was an increased risk of vascular access-site complications when using the Edwards SAPIEN XT prosthesis (19.8% vs. 11.1%; HR 1.80, 95% CI: 1.16-2.76), which was mainly due to major vascular complications (11.7% vs. 5.6%; HR 2.12, 95% CI: 1.17-3.84). In this patient population, there was no relationship between device size and vascular access-site complications among patients receiving the Edwards SAPIEN XT prosthesis (**Online Table 4**). In contrast, permanent pacemaker implantation was more frequently required after the implantation of the Medtronic CoreValve prosthesis (11.4% vs. 31.3%; HR 0.33, 95% CI: 0.21-0.51).

Additional subgroup analyses revealed a trend of a higher overall mortality among patients undergoing urgent TAVI in comparison with elective procedures (**Online Table 5-Online Table 7**). Moreover, patients receiving more than one prosthesis had a comparable outcome apart from a higher incidence of bleeding (**Online Table 8-Online Table 10**). Finally, patients discharged directly home (28% of the overall patient population) had very low event rates up to 30 days (mortality: 0%, myocardial infarction: 0.5%, cerebrovascular events: 0.5%) (**Online Table 11-Online Table 13**).

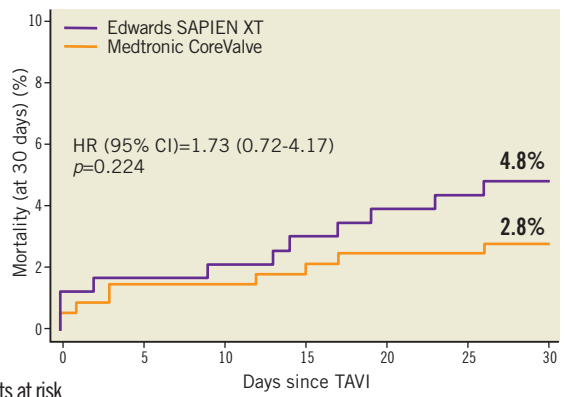
## Discussion

This first report of the Swiss TAVI investigators provides detailed information on in-hospital and 30-day clinical outcomes. The main findings are:



**Figure 2.** Cumulative incidence of all-cause mortality among patients undergoing TAVI according to type of access at 30-day follow-up. Of note, surgical access interventions include transapical and direct aortic access patients, and transvascular interventions include transfemoral and subclavian access patients. SA: surgical access

- Carefully selected patients undergoing TAVI with different devices and access routes showed favourable short-term clinical outcomes with lower mortality rates than predicted with the logistic EuroSCORE and the STS risk score.
- Comparison of different access routes suggests a higher risk of all-cause mortality via the transapical or transaortic route even in an adjusted analysis.
- A comparative analysis between the most frequently used devices (Medtronic CoreValve and the Edwards SAPIEN XT)



Patients at risk	0	5	10	15	20	25	30
CoreValve	324	317	313	312	308	307	295
Edwards SAPIEN XT	232	225	221	218	216	214	209

**Figure 3.** Cumulative incidence of all-cause mortality among patients undergoing transfemoral TAVI according to type of device implanted. Medtronic CoreValve and Edwards SAPIEN XT prosthesis implantations represent 94.1% of TAVI implantations in Switzerland.

**Table 6.** Clinical outcomes among transfemoral patients according to device selection.

	Edwards SAPIEN XT bioprosthesis N=232	Medtronic CoreValve N=324	HR or RR (95% CI)	p-value
Mortality, n (%)	11 (4.8)	9 (2.8)	1.73 (0.72-4.17)	0.22
Cardiovascular mortality, n (%)	11 (4.8)	9 (2.8)	1.73 (0.72-4.17)	0.22
Cerebrovascular accident, n (%)	9 (3.9)	9 (2.8)	1.41 (0.56-3.55)	0.47
Major stroke, n (%)	7 (3.0)	5 (1.5)	1.97 (0.62-6.19)	0.25
Minor stroke, n (%)	1 (0.4)	3 (0.9)	0.47 (0.05-4.51)	0.51
TIA, n (%)	1 (0.4)	1 (0.3)	1.41 (0.09-22.48)	0.81
Myocardial infarction, n (%)	0 (0.0)	2 (0.6)	0.28 (0.01-5.81)	0.51
Acute kidney injury, n (%)	14 (6.1)	26 (8.1)	0.76 (0.40-1.46)	0.41
Stage 1, n (%)	8 (3.5)	14 (4.4)	0.81 (0.34-1.92)	0.63
Stage 2, n (%)	1 (0.4)	3 (0.9)	0.47 (0.05-4.53)	0.51
Stage 3, n (%)	5 (2.2)	9 (2.8)	0.78 (0.26-2.34)	0.66
Bleeding, n (%)	39 (17.0)	58 (18.1)	0.95 (0.63-1.42)	0.80
Life-threatening bleeding, n (%)	12 (5.2)	21 (6.6)	0.80 (0.39-1.62)	0.54
Major bleeding, n (%)	26 (11.4)	27 (8.4)	1.38 (0.80-2.36)	0.24
Minor bleeding, n (%)	1 (0.4)	10 (3.1)	0.14 (0.02-1.09)	0.06
Vascular access-site and access-related complications, n (%)	46 (19.8)	36 (11.1)	1.80 (1.16-2.78)	0.008
Major vascular complications, n (%)	27 (11.7)	18 (5.6)	2.12 (1.17-3.84)	0.014
Minor vascular complications, n (%)	20 (8.6)	18 (5.6)	1.55 (0.82-2.93)	0.18
Permanent pacemaker implanted, n (%)	26 (11.4)	100 (31.3)	0.33 (0.21-0.51)	<0.001

demonstrates no significant difference with respect to mortality, major cardiac or cerebrovascular events. However, there was a threefold increased risk of permanent pacemaker implantation for the Medtronic CoreValve and an almost twofold increased risk of vascular access-site and access-related complications among patients receiving the Edwards SAPIEN XT bioprosthesis.

In this first analysis of the Swiss TAVI registry, the overall 30-day mortality rate remains below the estimated risk using the two most frequently used risk scores for the evaluation of TAVI patients. With an estimated risk of mortality of 8.2% according to the STS score and 20.2% according to the logistic EuroSCORE, the risk of TAVI patients in Switzerland is comparable to other European or national registries<sup>11-14</sup>, and confirms the overestimation of periprocedural risk for patient selection in contemporary clinical practice. While the STS score is currently used as the standard risk assessment tool in TAVI trials, the discrepancy between the estimated risk and the observed rate of mortality after a TAVI procedure is still remarkable and highlights the urgent need for a dedicated TAVI risk score for appropriate patient selection.

All deaths within the first 30 days after TAVI were adjudicated to be due to cardiovascular causes, and the rate of 4.8% compares favourably to the large-scale CoreValve ADVANCE study (4.6%, 30-day all-cause mortality)<sup>14</sup> and the SOURCE registry (8.5%, 30-day all-cause mortality)<sup>13</sup>, which are considered high-quality databases of contemporary TAVI experience with second-generation devices. While no significant difference was observed for all-cause mortality between the Edwards SAPIEN XT and the Medtronic CoreValve in the transfemoral cohort, there was a significantly higher risk for mortality among patients undergoing TAVI via a surgical access route. This observation was independent of baseline confounders and is consistent with previous reports from the SOURCE registry (transfemoral vs. transapical 4.3% vs. 9.9%)<sup>13</sup>, the FRANCE 2 registry (transfemoral vs. transapical 8.5% vs. 13.9%,  $p < 0.001$ )<sup>11</sup> and the UK TAVI registry (transfemoral vs. other routes 5.5% vs. 10.7%,  $p = 0.006$ )<sup>12</sup>. The reason for this difference is unclear, but is most probably related to the higher risk of patients in the surgical access group. Notably, the majority of TAVI centres in Switzerland follow a “transfemoral first” strategy and the transapical access remains second choice only for patients not eligible to be treated via a transfemoral access. Knowing this, a substantial selection bias to the disadvantage of transapical patients might be mirrored in the results of this report.

The incidence of cerebrovascular accidents in the periprocedural phase after TAVI was comparable to rates reported in other registries. In Germany, periprocedural stroke after TAVI is reported with an incidence rate of 1.7 to 2.3%<sup>15</sup>, whereas the stroke rates amounted to 3.4% in France<sup>11</sup>, 4.1% in the UK (in-hospital)<sup>12</sup>, and 5% in Belgium<sup>16</sup>. In contrast to a recent meta-analysis with more than 10,000 TAVI patients, indicating a decrease in cerebrovascular accidents among patients undergoing transapical TAVI (2.7% vs. 4.2%)<sup>17</sup>, the periprocedural stroke rate was similar among surgical access and transvascular patients in our patient population.

A 30-day rate of 3.3% of cerebrovascular accidents still appears relatively high and requires further action to minimise this risk. Technological improvement, more standardised procedural techniques and cerebral protection during the procedure may help in reducing these disabling adverse events. However, recent studies evaluating cerebral protection devices have so far failed to demonstrate a beneficial effect<sup>18</sup>. Last but not least, alternative antiplatelet and anticoagulation regimens (e.g., bivalirudin) might also be of help in this regard.

In this patient population, the Medtronic CoreValve was associated with a higher risk for permanent pacemaker implantation compared with the Edwards SAPIEN XT prosthesis, corroborating previous reports. Conversely, more vascular access-site complications were observed with the use of the Edwards SAPIEN XT as compared with the Medtronic CoreValve without differences in terms of bleeding. The latter observation is difficult to explain but is possibly related to the larger sheath size (outer diameter) when using the Edwards SAPIEN XT. Other confounding factors like vessel quality, tortuosity and calcification might also have contributed to this difference. Most importantly, the difference in permanent pacemaker implantation or vascular access-site complications did not translate into a higher risk of mortality.

## Limitations

Several limitations need to be acknowledged before interpreting the results of this study. First, as the Swiss TAVI registry was designed to generate data on contemporary clinical practice and outcomes with newer-generation devices in Switzerland, there is no information on the learning curve or the evolution of TAVI devices, procedures or outcomes over time. Second, clinical practice and expertise might be different in the participating centres. Finally, serious adverse event reporting within Swiss TAVI is left to the discretion of each centre and, although the monitoring process includes a systematic plausibility and inconsistency check, we are not able to exclude a certain underreporting of events and bias.

## Conclusion

The Swiss TAVI registry is a prospective, national cohort study assessing clinical outcomes of consecutive patients undergoing TAVI in Switzerland. This first report based on adjudicated events shows favourable short-term clinical outcomes in unselected TAVI patients.

### Impact on daily practice

The Swiss TAVI registry provides favourable clinical outcomes and reflects contemporary clinical practice with CE-approved TAVI devices in patients carefully selected by the Heart Team. The transfemoral route was the preferred access for the majority of patients and was associated with low rates of mortality and cerebrovascular events. However, further improvement of the technology is required to reduce the rate of vascular access-site and bleeding complications.

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## Conflict of interest statement

P. Wenaweser has received honoraria and lecture fees from Medtronic and Edwards Lifesciences and has received an unrestricted grant from Medtronic to the institution (University of Bern). F. Nietlispach serves as consultant to Edwards Lifesciences and St. Jude Medical. R. Jeger has received reimbursement for travel expenses from Medtronic, St. Jude Medical and Edwards Lifesciences. E. Ferrari is a proctor for Edwards Lifesciences. S. Toggweiler has received speaker's honoraria from Medtronic. T. Carrel has received fees as referee from Medtronic and Edwards Lifesciences. S. Noble serves as consultant for Medtronic. P. Jüni is an unpaid steering committee or statistical executive committee member of trials funded by Abbott Vascular, Biosensors, Medtronic and Johnson & Johnson. CTU Bern, which is part of the University of Bern, has a staff policy of not accepting honoraria or consultancy fees. However, CTU Bern is involved in design, conduct or analysis of clinical studies funded by Abbott Vascular, Ablynx, Amgen, AstraZeneca, Biosensors, Biotronic, Boehringer Ingelheim, Eisai, Eli Lilly, Exelixis, Geron, Gilead Sciences, Nestlé, Novartis, Novo Nordisc, Padma, Roche, Schering-Plough, St. Jude Medical, and Swiss Cardio Technologies. S. Windecker has received research contracts to the institution from Abbott, Boston Scientific, Biosensors, Cordis, Medtronic and St. Jude. C. Huber is a proctor for Symetis and Edwards Lifesciences, serves as consultant for Medtronic and has shares in Endoheart. All the other authors have no conflicts of interest to declare.

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## Online data supplement

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# Online data supplement

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**Online Table 1. In-hospital clinical outcomes.**

In-hospital clinical outcomes	All patients N=697
Mortality, n (%)	22 (3.2)
Cardiovascular mortality, n (%)	22 (3.2)
Cerebrovascular accident, n (%)	22 (3.2)
Major stroke, n (%)	17 (2.4)
Minor stroke, n (%)	3 (0.4)
TIA, n (%)	2 (0.3)
Myocardial infarction, n (%)	2 (0.3)
Periprocedural myocardial infarction, n (%)	2 (0.3)
Acute kidney injury, n (%)	49 (7.0)
Stage 1, n (%)	26 (3.7)
Stage 2, n (%)	7 (1.0)
Stage 3, n (%)	16 (2.3)
Bleeding, n (%)	105 (15.1)
Life-threatening bleeding, n (%)	37 (5.3)
Major bleeding, n (%)	56 (8.0)
Minor bleeding, n (%)	12 (1.7)
Vascular access-site and access-related complications, n (%)	82 (11.8)
Major vascular complications, n (%)	44 (6.3)
Minor vascular complications, n (%)	39 (5.6)
Permanent pacemaker implanted, n (%)	137 (19.7)
Depicted are number of first events with % of all patients (in-hospital events). All clinical outcomes were adjudicated.	

**Online Table 2. Baseline surgical vs. transvascular access.**

		Baseline characteristics of surgical access vs. transvascular access patients			
		Surgical access N=138	Transvascular N=559	Difference (95% CI)	p-value
Age (years)		81.6±5.8	82.6±6.2	-1.0 (-2.2; 0.2)	0.088
Female gender, n (%)		66 (47.8%)	293 (52.4%)	-4.6% (-13.9%; 4.7%)	0.34
Body mass index (kg/m <sup>2</sup> )		26.2±4.8	26.3±5.0	-0.14 (-1.1; 0.8)	0.76
Cardiac risk factors	Diabetes mellitus, n (%)	42 (30.4%)	162 (29.0%)	-1.5% (-10.0%; 7.0%)	0.75
	Dyslipidaemia, n (%)	80 (58.0%)	307 (54.9%)	-3.1% (-12.3%; 6.2%)	0.57
	Hypertension, n (%)	119 (86.2%)	455 (81.4%)	-4.8% (-12.0%; 2.3%)	0.21
Past medical history	Previous pacemaker implantation, n (%)	11 (8.0%)	58 (10.4%)	2.4% (-3.2%; 8.0%)	0.52
	Previous myocardial infarction, n (%)	22 (15.9%)	83 (14.8%)	-1.1% (-7.8%; 5.6%)	0.79
	Previous cardiac surgery, n (%)	34 (24.6%)	70 (12.5%)	-12.1% (-18.7%; -5.5%)	0.001
	Previous stroke, n (%)	17 (12.3%)	66 (11.8%)	-0.5% (-6.6%; 5.5%)	0.88
Clinical features	Peripheral vascular disease, n (%)	58 (42.0%)	79 (14.1%)	-27.9% (-35.0%; -20.8%)	<0.001
	Chronic obstructive pulmonary disease, n (%)	25 (18.1%)	84 (15.0%)	-3.1% (-9.9%; 3.7%)	0.36
	Coronary artery disease, n (%)	96 (69.6%)	294 (52.6%)	-17.0% (-26.2%; -7.8%)	<0.001
	Left ventricular ejection fraction (%)	52.4±14.3	54.2±14.1	-1.88 (-5.0; 1.2)	0.23
	Aortic valve area (cm <sup>2</sup> )	0.7±0.3	0.74±0.3	-0.01 (-0.07; 0.05)	0.70
	Mean transaortic gradient (mmHg)	45.5±19.8	44.7±16.7	0.82 (-2.97; 4.61)	0.67
Risk assessment	Log. EuroSCORE (%)	22.5±13.1	19.6±12.5	2.89 (0.13; 5.66)	0.04
	STS score (%)	9.0±7.8	8.0±7.0	0.92 (-0.41; 2.25)	0.18

Depicted are means with standard deviations (p-value from t-tests) or counts (% of all patients; p-value from Fisher's or chi-square tests).

**Online Table 3. Procedure surgical vs. transvascular access.**

	Procedural characteristics surgical access vs. transvascular access patients			
	Surgical access N=138	Transvascular N=559	Difference (95% CI)	p-value
Procedure time (min)	83.3±41.4	73.9±36.8	9.4 (2.2; 16.6)	0.011
Amount of contrast (ml)	192.0±91.2	220.0±110	-28.0 (-49.4; -6.6)	0.010
General anaesthesia, n (%)	138 (100.0%)	242 (43.4%)	56.6% (48.3%; 64.9%)	<0.001
Procedure location				<0.001
Catheterisation laboratory, n (%)	95 (68.8%)	425 (76.0%)	-7.2% (-15.3%; 0.9%)	
Operating room, n (%)	7 (5.1%)	1 (0.2%)	4.9% (2.9%; 6.9%)	
Hybrid room, n (%)	36 (26.1%)	133 (23.8%)	2.3% (-5.7%; 0.3%)	
Concomitant procedure				
Percutaneous coronary intervention, n (%)	7 (5.1%)	58 (10.4%)	5.3% (-0.1%; 10.7%)	0.071
Device features				
Prior balloon aortic valvuloplasty, n (%)	129 (93.5%)	475 (85.0%)	-8.5% (-14.8%; -2.2%)	0.008
Device implanted				<0.001
Medtronic CoreValve, n (%)	12 (8.8%)	324 (58.2%)	-49.4% (-58.0%; -40.8%)	
Edwards SAPIEN XT, n (%)	85 (62.0%)	232 (41.7%)	20.4% (11.2%; 29.6%)	
Symetis Acurate, n (%)	17 (12.4%)	0 (0.0%)	12.4% (9.7%; 15.2%)	
JenaValve, n (%)	23 (16.8%)	0 (0.0%)	16.8% (13.7%; 19.9%)	
SJM Portico, n (%)	0 (0.0%)	1 (0.2%)	-0.2% (-0.9%; 0.5%)	
Aortic regurgitation post TAVI				0.24
Grade 0, n (%)	40 (29.6%)	130 (23.8%)	5.9% (-2.3%; 14.0%)	
Grade 1, n (%)	88 (65.2%)	364 (66.5%)	-1.4% (-10.3%; 7.6%)	
Grade 2, n (%)	6 (4.4%)	49 (9.0%)	-4.5% (-9.6%; 0.6%)	
Grade 3, n (%)	1 (0.7%)	4 (0.7%)	0.0% (-1.6%; 1.6%)	
In-hospital course				
Permanent pacemaker implantation, n (%)	12 (8.8%)	125 (22.7%)	13.9% (6.5%; 21.4%)	<0.001
Any packed red blood cell infusion during hospitalisation, n (%)	36 (26.1%)	95 (17.1%)	-9.0% (-16.3%; -1.7%)	0.021
Number of PRBC, median (interquartile range)	2.0 (1.0; 3.0)	2.0 (1.0; 3.0)	-0.58 (-2.05; 0.89)	0.51
Overall in-hospital stay after TAVI (days)	11.1±5.1	10.6±6.4	0.48 (-0.68; 1.63)	0.42
Stay at intensive care unit (days)	2.0±1.9	0.9±2.4	1.03 (0.59; 1.46)	<0.001
Stay at intermediate care (days)	1.1±2.4	2.9±3.0	-1.75 (-2.29; -1.22)	<0.001
Stay at general ward (days)	8.1±4.4	6.9±5.5	1.20 (0.20; 2.20)	0.019
Patient discharged to				0.001
Home, n (%)	30 (22.2%)	167 (30.6%)	-8.4% (-16.9%; 0.2%)	
Referring hospital, n (%)	23 (17.0%)	141 (25.8%)	-8.8% (-16.8%; -0.7%)	
Rehabilitation clinic, n (%)	74 (54.8%)	222 (40.7%)	14.2% (4.8%; 23.5%)	
Nursing home, n (%)	0 (0.0%)	6 (1.1%)	-1.1% (-2.9%; 0.7%)	
Other, n (%)	8 (5.9%)	10 (1.8%)	4.1% (1.1%; 7.1%)	

Depicted are means with standard deviations (*p*-values from ANOVAs) or counts (% of all patients; *p*-values from chi-square tests).

**Online Table 4. Access complications according to Edwards SAPIEN XT size.**

Vascular access-site complications according to device size among transfemoral access patients with the Edwards SAPIEN XT prosthesis					
	23 mm N=68	26 mm N=142	29 mm N=21	HR (95% CI)	p-value
<b>30-day follow-up - events</b>					
Vascular access-site complications, n (%)	14 (20.6)	29 (20.4)	3 (14.3)	0.90 (0.55-1.47)	0.67
Major vascular complications, n (%)	7 (10.3)	18 (12.7)	2 (9.5)	1.05 (0.55-2.00)	0.88
Minor vascular complications, n (%)	7 (10.3)	12 (8.5)	1 (4.8)	0.75 (0.35-1.60)	0.46

Depicted are number of first events censored at 30 days since procedure with % from Kaplan-Meier estimates. \*n: 1 patient with Edwards device size of 20 mm not shown. Hazard ratio (HR; with 95% confidence intervals) from Cox's regression with a p-value testing a linear effect from 23 mm (set as reference) to 29 mm.

**Online Table 5. Baseline urgent vs. elective treatment.**

	Baseline characteristics of urgent vs. elective patients				
	Urgent N=35	Elective N=657	Difference (95% CI)	p-value	
Age (years)	82.6±6.0	82.4±6.2	0.2 (-1.9; 2.3)	0.85	
Female gender, n (%)	19 (54.3%)	338 (51.4%)	2.8% (-14.2%; 19.9%)	0.86	
Body mass index (kg/m <sup>2</sup> )	26.0±5.2	26.4±5.0	-0.3 (-2.0; 1.4)	0.70	
Cardiac risk factors	Diabetes mellitus, n (%)	12 (34.3%)	192 (29.2%)	-5.1% (-20.6%; 10.5%)	0.57
	Dyslipidaemia, n (%)	19 (54.3%)	366 (55.7%)	1.4% (-15.5%; 18.4%)	0.86
	Hypertension, n (%)	28 (80.0%)	542 (82.5%)	2.5% (-10.5%; 15.5%)	0.65
Past medical history	Previous pacemaker implantation, n (%)	1 (2.9%)	67 (10.2%)	7.3% (-2.8%; 17.5%)	0.24
	Previous myocardial infarction, n (%)	6 (17.1%)	98 (14.9%)	-2.2% (-14.4%; 10.0%)	0.63
	Previous cardiac surgery, n (%)	3 (8.6%)	101 (15.4%)	6.8% (-5.4%; 19.0%)	0.34
	Previous stroke, n (%)	3 (8.6%)	80 (12.2%)	3.6% (-7.5%; 14.7%)	0.79
Clinical features	Peripheral vascular disease, n (%)	5 (14.3%)	130 (19.8%)	5.5% (-8.0%; 19.0%)	0.52
	Chronic obstructive pulmonary disease, n (%)	4 (11.4%)	103 (15.7%)	4.2% (-8.1%; 16.6%)	0.64
	Coronary artery disease, n (%)	24 (68.6%)	365 (55.6%)	-13.0% (-29.9%; 3.9%)	0.16
	Left ventricular ejection fraction (%)	46.9±17.6	54.2±13.8	-7.4 (-12.9; -1.8)	0.01
	Aortic valve area (cm <sup>2</sup> )	0.7±0.2	0.7±0.3	-0.06 (-0.17; 0.04)	0.22
	Mean transaortic gradient (mmHg)	44.1±18.6	44.8±17.4	-0.7 (-7.6; 6.2)	0.84
Risk assessment	Log. EuroSCORE (%)	29.2±19.8	19.4±11.6	9.8 (5.5; 14.0)	<0.001
	STS score (%)	12.1±9.7	8.0±6.9	4.1 (1.7; 6.5)	0.001

Depicted are means with standard deviations (p-value from t-tests) or counts (% of all patients; p-value from Fisher's or chi-square tests). In n: 5 patients the indication urgent/elective was missing and they were excluded from the analyses.



Online Table 6. Procedure urgent vs. elective treatment.

	Procedural characteristics of urgent vs. elective patients			
	Urgent N=35	Elective N=657	Difference (95% CI)	p-value
Procedure time (min)	76.3±31.0	76.0±38.2	0.4 (-14.0; 14.8)	0.96
Amount of contrast (ml)	221.1±87.8	214.4±108.4	6.7 (-31.5; 45.0)	0.73
General anaesthesia, n (%)	11 (31.4%)	365 (55.6%)	-24.2% (-41.1%; -7.3%)	0.008
Conversion from local to general anaesthesia, n (%)	3 (12.5%)	13 (4.5%)	-8.0% (-17.2%; 1.1%)	0.11
Procedure location				0.007
Catheterisation laboratory, n (%)	34 (97.1%)	481 (73.2%)	23.9% (9.2%; 38.7%)	
Operating room, n (%)	0 (0.0%)	8 (1.2%)	-1.2% (-4.9%; 2.4%)	
Hybrid room, n (%)	1 (2.9%)	168 (25.6%)	-22.7% (-37.3%; -8.2%)	
Access-site location				0.67
Femoral	30 (85.7%)	517 (78.7%)	7.0% (-6.8%; 20.9%)	
Transapical	5 (14.3%)	120 (18.3%)	-4.0% (-17.1%; 9.1%)	
Subclavian	0 (0.0%)	8 (1.2%)	-1.2 (-4.9%; 2.4%)	
Direct aortic	0 (0.0%)	12 (1.8%)	-1.8% (-6.3%; 2.6%)	
Concomitant procedure				
Percutaneous coronary intervention, n (%)	7 (20.0%)	57 (8.7%)	-11.3% (-21.2%; -1.5%)	0.035
Device features				
Prior balloon aortic valvuloplasty, n (%)	31 (88.6%)	568 (86.5%)	-2.1% (-13.8%; 9.5%)	1.00
Device implanted				0.56
Medtronic CoreValve, n (%)	18 (51.4%)	314 (48.0%)	3.4% (-13.6%; 20.5%)	
Edwards SAPIEN XT, n (%)	15 (42.9%)	301 (46.0%)	-3.2% (-20.2%; 13.8%)	
Symetis Acurate, n (%)	2 (5.7%)	15 (2.3%)	3.4% (-1.9%; 8.7%)	
JenaValve, n (%)	0 (0.0%)	23 (3.5%)	-3.5% (-9.6%; 2.6%)	
SJM Portico, n (%)	0 (0.0%)	1 (0.2%)	-0.2% (-1.5%; 1.1%)	
Aortic regurgitation post TAVI				0.96
Grade 0, n (%)	8 (22.9%)	161 (25.1%)	-2.2% (-17.0%; 12.5%)	
Grade 1, n (%)	24 (68.6%)	425 (66.2%)	2.4% (-13.8%; 18.5%)	
Grade 2, n (%)	3 (8.6%)	52 (8.1%)	0.5% (-8.9%; 9.8%)	
Grade 3, n (%)	0 (0.0%)	4 (0.6%)	-0.6% (-3.2%; 2.0%)	
In-hospital course				
Permanent pacemaker implantation, n (%)	4 (11.4%)	133 (20.4%)	8.9% (-4.7%; 22.5%)	0.28
Any packed red blood cell during hospitalisation, n (%)	11 (31.4%)	116 (17.8%)	-13.7% (-26.9%; -0.5%)	0.069
Number of PRBC, median (interquartile range)	1.0 (1.0; 3.0)	2.0 (1.0; 3.0)	-1.1 (-3.7; 1.5)	0.11
Overall in-hospital stay after TAVI (days)	12.7±9.3	10.6±5.9	2.0 (-0.06; 4.1)	0.057
Stay at intensive care unit (days)	1.5±2.6	1.1±2.3	0.4 (-0.5; 1.2)	0.39
Stay at intermediate care (days)	3.5±4.1	2.5±2.9	0.9 (-0.08; 1.9)	0.072
Stay at general ward (days)	7.8±8.8	7.1±5.1	0.8 (-1.1; 2.6)	0.41
Patient discharged to				<0.001
Home, n (%)	6 (18.2%)	191 (29.5%)	-11.3% (-27.2%; 4.6%)	
Referring hospital, n (%)	14 (42.4%)	150 (23.1%)	19.3% (4.3%; 34.2%)	
Rehabilitation clinic, n (%)	9 (27.3%)	287 (44.3%)	-17.0% (-34.4%; 0.3%)	
Nursing home, n (%)	0 (0.0%)	6 (0.9%)	-0.9% (-4.2%; 2.4%)	
Other, n (%)	4 (12.1%)	14 (2.2%)	10.0% (4.4%; 15.5%)	

Depicted are means with standard deviations (p-values from ANOVAs) or counts (% of all patients; p-values from chi-square tests). In n: 5 patients the indication urgent/elective was missing and they were excluded from the analyses.

**Online Table 7. Outcomes urgent vs. elective treatment.**

	Clinical outcomes of urgent vs. elective patients					
	Urgent N=35	Elective N=657	HR or RR (95% CI)	p-value	Adjusted HR or RR (95% CI)	p-value
<b>30-day follow-up - events</b>						
Mortality, n (%)	4 (11.6)	29 (4.5)	2.74 (0.96-7.81)	0.058	2.61 (0.91-7.52)	0.075
Cardiovascular mortality, n (%)	4 (11.6)	29 (4.5)	2.74 (0.96-7.81)	0.058	2.61 (0.91-7.52)	0.075
Cerebrovascular accident, n (%)	0 (0.0)	22 (3.4)	0.41 (0.03-6.62)	0.62		
Major stroke, n (%)	0 (0.0)	16 (2.4)	0.56 (0.03-9.15)	1.00		
Minor stroke, n (%)	0 (0.0)	4 (0.6)	2.06 (0.11-37.52)	1.00		
TIA, n (%)	0 (0.0)	2 (0.3)	3.70 (0.18-75.63)	1.00		
Myocardial infarction, n (%)	0 (0.0)	3 (0.5)	2.65 (0.14-50.32)	1.00		
Acute kidney injury, n (%)	4 (12.2)	45 (7.0)	1.80 (0.65-5.01)	0.26	1.59 (0.57-4.44)	0.38
Stage 1, n (%)	4 (12.2)	21 (3.2)	3.87 (1.33-11.29)	0.013	3.43 (1.16-10.10)	0.026
Stage 2, n (%)	0 (0.0)	7 (1.1)	1.23 (0.07-21.11)	1.00		
Stage 3, n (%)	0 (0.0)	17 (2.6)	0.53 (0.03-8.64)	1.00		
Bleeding, n (%)	7 (20.5)	103 (15.9)	1.37 (0.64-2.95)	0.42	1.48 (0.68-3.19)	0.32
Life-threatening bleeding, n (%)	3 (8.7)	37 (5.7)	1.60 (0.49-5.18)	0.44	1.60 (0.49-5.23)	0.44
Major bleeding, n (%)	3 (9.0)	55 (8.5)	1.07 (0.34-3.43)	0.90	1.23 (0.38-3.95)	0.73
Minor bleeding, n (%)	1 (3.0)	11 (1.7)	1.85 (0.24-14.29)	0.56	1.76 (0.22-13.79)	0.59
Vascular access-site and access-related complications, n (%)	8 (22.9)	73 (11.1)	2.09 (1.01-4.33)	0.048	2.09 (1.00-4.36)	0.05
Major vascular complications, n (%)	3 (8.6)	40 (6.1)	1.42 (0.44-4.60)	0.56	1.38 (0.43-4.51)	0.59
Minor vascular complications, n (%)	5 (14.3)	34 (5.2)	2.76 (1.08-7.06)	0.034	2.91 (1.12-7.53)	0.028
Permanent pacemaker implanted, n (%)	4 (12.4)	136 (21.1)	0.57 (0.21-1.53)	0.26	0.55 (0.20-1.48)	0.24

Depicted are number of first events with % of all patients (in-hospital events); and censored at 30 days since procedure with % from Kaplan-Meier estimates (30-day follow-up events). All clinical outcomes were adjudicated, except for pacemaker implantations. Cox's regression, reports hazard ratio (HR; with 95% confidence intervals). Continuity corrected RR (95% CI) with p-value from Fisher's exact test in case of zero events. Adjusted HR or RR: adjusted for age, gender, previous cardiac surgery, peripheral vascular disease, coronary artery disease. In n: 5 patients the indication urgent/elective was missing and they were excluded from the analyses.

Online Table 8. Baseline one vs. more than one prosthesis.

		Baseline characteristics comparing patients with one prosthesis vs. two or more prostheses			
		Two or more prostheses N=30	One prosthesis N=667	Difference (95% CI)	p-value
Age (years)		81.3±5.5	82.4±6.2	-1.1 (-3.3; 1.2)	0.35
Female gender, n (%)		14 (46.7%)	345 (51.7%)	-5.1% (-23.4%; 13.3%)	0.71
Body mass index (kg/m <sup>2</sup> )		26.5±5.2	26.3±5.0	0.1 (-1.7; 2.0)	0.88
Cardiac risk factors	Diabetes mellitus, n (%)	8 (26.7%)	196 (29.4%)	2.7% (-14.0%; 19.4%)	0.84
	Dyslipidaemia, n (%)	19 (63.3%)	368 (55.2%)	-8.2% (-26.4%; 10.1%)	0.45
	Hypertension, n (%)	22 (73.3%)	552 (82.8%)	9.4% (-4.5%; 23.4%)	0.22
Past medical history	Previous pacemaker implantation, n (%)	1 (3.3%)	68 (10.2%)	6.9% (-4.1%; 17.8%)	0.35
	Previous myocardial infarction, n (%)	3 (10.0%)	102 (15.3%)	5.3% (-7.8%; 18.4%)	0.60
	Previous cardiac surgery, n (%)	4 (13.3%)	100 (15.0%)	1.7% (-11.4%; 14.7%)	1.00
	Previous stroke, n (%)	5 (16.7%)	78 (11.7%)	-5.0% (-16.9%; 6.9%)	0.39
Clinical features	Peripheral vascular disease, n (%)	6 (20.0%)	131 (19.6%)	-0.4% (-14.9%; 14.2%)	1.00
	Chronic obstructive pulmonary disease, n (%)	4 (13.3%)	105 (15.7%)	2.4% (-10.9%; 15.7%)	1.00
	Coronary artery disease, n (%)	16 (53.3%)	374 (56.1%)	2.7% (-15.5%; 21.0%)	0.85
	Left ventricular ejection fraction (%)	58.9±12.9	53.6±14.1	5.4 (-0.6; 11.3)	0.076
	Aortic valve area (cm <sup>2</sup> )	0.78±0.3	0.74±0.3	0.04 (-0.06; 0.15)	0.42
	Mean transaortic gradient (mmHg)	51.8±19.0	44.5±17.3	7.3 (0.0; 14.6)	0.05
Risk assessment	Log. EuroSCORE (%)	15.8±8.7	20.4±12.8	-4.6 (-9.8; 0.6)	0.083
	STS score (%)	6.4±4.5	8.3±7.2	-1.9 (-4.5; 0.8)	0.16

Depicted are means with standard deviations (p-values from ANOVAs) or counts (% of all patients; p-values from chi-square tests).

Online Table 9. Procedure one vs. more than one prosthesis.

	Procedural characteristics comparing patients with one prosthesis vs. two or more prostheses			
	Two or more prostheses N=30	One prosthesis N=667	Difference (95% CI)	p-value
Procedure time (min)	114.1±65.3	74.1±35.4	40.0 (25.6; 54.1)	<0.001
Amount of contrast (ml)	309.5±107.1	210.7±105.5	98.8 (59.4; 138.2)	<0.001
General anaesthesia, n (%)	7 (23.3%)	373 (56.0%)	-32.7% (-50.8%; -14.6%)	0.001
Conversion from local to general anaesthesia, n (%)	2 (8.7%)	14 (4.8%)	-3.9% (-13.3%; 5.4%)	0.33
Procedure location				0.70
Catheterisation laboratory, n (%)	24 (80.0%)	496 (74.4%)	5.6% (-10.3%; 21.6%)	
Operating room, n (%)	0 (0.0%)	8 (1.2%)	-1.2% (-5.1%; 2.7%)	
Hybrid room, n (%)	6 (20.0%)	163 (24.4%)	-4.4% (-20.2%; 11.3%)	
Access-site location				0.12
Femoral	29 (96.7%)	522 (78.3%)	18.4% (3.5%; 33.3%)	
Transapical	1 (3.3%)	125 (18.7%)	-15.4% (-29.5%; -1.3%)	
Subclavian	0 (0.0%)	8 (1.2%)	-1.2% (-5.1%; 2.7%)	
Direct aortic	0 (0.0%)	12 (1.8%)	-1.8% (-6.6%; 3.0%)	
Concomitant procedure				
Percutaneous coronary intervention, n (%)	1 (3.3%)	64 (9.6%)	6.3% (-4.4%; 16.9%)	0.35
Device features				
Prior balloon aortic valvuloplasty, n (%)	25 (83.3%)	579 (86.8%)	3.5% (-9.0%; 15.9%)	0.58
Device implanted				<0.001
Medtronic CoreValve, n (%)	28 (93.3%)	308 (46.4%)	46.9% (28.9%; 65.0%)	
Edwards SAPIEN XT, n (%)	2 (6.7%)	315 (47.4%)	-40.8% (-58.8%; -22.7%)	
Symetis Acurate, n (%)	0 (0.0%)	17 (2.6%)	-2.6% (-8.2%; 3.1%)	
JenaValve, n (%)	0 (0.0%)	23 (3.5%)	-3.5% (-10.0%; 3.1%)	
SJM Portico, n (%)	0 (0.0%)	1 (0.2%)	-0.2% (-1.5%; 1.2%)	
Aortic regurgitation post TAVI				0.23
Grade 0, n (%)	6 (20.0%)	164 (25.2%)	-5.2% (-21.0%; 10.7%)	
Grade 1, n (%)	19 (63.3%)	433 (66.4%)	-3.1% (-20.4%; 14.3%)	
Grade 2, n (%)	4 (13.3%)	51 (7.8%)	5.5% (-4.5%; 15.5%)	
Grade 3, n (%)	1 (3.3%)	4 (0.6%)	2.7% (-0.4%; 5.8%)	
In-hospital course				
Permanent pacemaker implantation, n (%)	9 (30.0%)	128 (19.5%)	-10.5% (-25.2%; 4.1%)	0.16
Any packed red blood cell during hospitalisation, n (%)	8 (26.7%)	123 (18.6%)	-8.1% (-22.5%; 6.2%)	0.34
Number of PRBC, median (interquartile range)	2.0 (1.0; 3.5)	2.0 (1.0; 3.0)	3.9 (1.3; 6.6)	0.82
Overall in-hospital stay after TAVI (days)	13.6±9.7	10.6±5.9	3.0 (0.8; 5.3)	0.01
Stay at intensive care unit (days)	3.0±7.9	1.0±1.7	2.0 (1.1; 2.8)	<0.001
Stay at intermediate care (days)	2.6±2.8	2.5±2.9	0.1 (-1.0; 1.2)	0.85
Stay at general ward (days)	8.0±8.6	7.1±5.1	0.9 (-1.0; 2.9)	0.35
Patient discharged to				0.64
Home, n (%)	8 (26.7%)	189 (29.0%)	-2.4% (-19.0%; 14.3%)	
Referring hospital, n (%)	6 (20.0%)	158 (24.3%)	-4.3% (-20.0%; 11.4%)	
Rehabilitation clinic, n (%)	14 (46.7%)	282 (43.3%)	3.3% (-14.9%; 21.5%)	
Nursing home, n (%)	0 (0.0%)	6 (0.9%)	-0.9% (-4.4%; 2.5%)	
Other, n (%)	2 (6.7%)	16 (2.5%)	4.2% (-1.7%; 10.1%)	

Depicted are means with standard deviations (*p*-values from ANOVAs) or counts (% of all patients; *p*-values from chi-square tests).



Online Table 10. Outcomes one vs. more than one prosthesis.

	Clinical outcomes comparing patients with one prosthesis vs. two or more prostheses					
	Two or more prostheses N=30	One prosthesis N=667	HR or RR (95% CI)	p-value	Adjusted HR or RR (95% CI)	p-value
<b>30-day follow-up - events</b>						
Mortality, n (%)	2 (6.7)	31 (4.7)	1.48 (0.35-6.18)	0.59	1.71 (0.41-7.17)	0.46
Cardiovascular mortality, n (%)	2 (6.7)	31 (4.7)	1.48 (0.35-6.18)	0.59	1.71 (0.41-7.17)	0.46
Cerebrovascular accident, n (%)	0 (0.0)	23 (3.5)	0.47 (0.03-7.56)	0.62		
Major stroke, n (%)	0 (0.0)	17 (2.6)	0.63 (0.04-10.23)	1.00		
Minor stroke, n (%)	0 (0.0)	4 (0.6)	2.43 (0.13-44.12)	1.00		
TIA, n (%)	0 (0.0)	2 (0.3)	4.38 (0.21-89.27)	1.00		
Myocardial infarction, n (%)	0 (0.0)	3 (0.5)	3.13 (0.17-59.26)	1.00		
Acute kidney injury, n (%)	2 (6.9)	48 (7.3)	0.95 (0.23-3.91)	0.94	0.96 (0.23-3.94)	0.95
Stage 1, n (%)	2 (6.9)	24 (3.7)	1.92 (0.45-8.12)	0.38	1.89 (0.45-8.02)	0.39
Stage 2, n (%)	0 (0.0)	7 (1.1)	1.46 (0.09-24.98)	1.00		
Stage 3, n (%)	0 (0.0)	17 (2.6)	0.63 (0.04-10.23)	1.00		
Bleeding, n (%)	9 (30.2)	105 (15.9)	2.07 (1.05-4.09)	0.036	2.08 (1.05-4.13)	0.035
Life-threatening bleeding, n (%)	3 (10.0)	40 (6.1)	1.72 (0.53-5.57)	0.36	1.75 (0.54-5.67)	0.35
Major bleeding, n (%)	4 (13.9)	54 (8.2)	1.70 (0.62-4.71)	0.30	1.66 (0.60-4.63)	0.33
Minor bleeding, n (%)	2 (6.9)	11 (1.7)	4.27 (0.95-19.28)	0.059	4.81 (1.05-21.93)	0.042
Vascular access-site and access-related complications, n (%)	6 (20.1)	77 (11.6)	1.74 (0.76-4.00)	0.19	1.78 (0.77-4.09)	0.18
Major vascular complications, n (%)	4 (13.5)	41 (6.2)	2.19 (0.78-6.10)	0.14	2.24 (0.80-6.29)	0.13
Minor vascular complications, n (%)	2 (6.7)	37 (5.5)	1.20 (0.29-4.99)	0.80	1.22 (0.29-5.09)	0.78
Permanent pacemaker implanted, n (%)	9 (31.6)	131 (20.0)	1.65 (0.84-3.24)	0.15	1.64 (0.84-3.23)	0.15

Depicted are number of first events with % of all patients (in-hospital events); and censored at 30 days since procedure with % from Kaplan-Meier estimates (30-day follow-up events). All clinical outcomes were adjudicated, except for pacemaker implantations. Cox's regression, reports hazard ratio (HR; with 95% confidence intervals). Continuity corrected RR (95% CI) with p-value from Fisher's exact test in case of zero events.

Online Table 11. Baseline discharge home vs. others.

	Baseline characteristics for patients discharged home vs. others				
	Home N=197	Others N=500	Difference (95% CI)	p-value	
Age (years)	81.6±7.1	82.7±5.7	-1.1 (-2.1; -0.1)	0.036	
Female gender, n (%)	78 (39.6%)	281 (56.2%)	-16.6% (-24.8%; -8.4%)	<0.001	
Body mass index (kg/m <sup>2</sup> )	26.6±5.2	26.2±4.9	0.5 (-0.4; 1.3)	0.28	
Cardiac risk factors	Diabetes mellitus, n (%)	52 (26.4%)	152 (30.4%)	4.0% (-3.5%; 11.5%)	0.31
	Dyslipidaemia, n (%)	107 (54.3%)	280 (56.0%)	1.7% (-6.5%; 9.9%)	0.74
	Hypertension, n (%)	163 (82.7%)	411 (82.2%)	-0.5% (-6.8%; 5.8%)	0.91
Past medical history	Previous pacemaker implantation, n (%)	24 (12.2%)	45 (9.0%)	-3.2% (-8.1%; 1.8%)	0.21
	Previous myocardial infarction, n (%)	29 (14.7%)	76 (15.2%)	0.5% (-5.4%; 6.4%)	0.91
	Previous cardiac surgery, n (%)	36 (18.3%)	68 (13.6%)	-4.7% (-10.6%; 1.2%)	0.13
	Previous stroke, n (%)	15 (7.6%)	68 (13.6%)	6.0% (0.6%; 11.3%)	0.028
Clinical features	Peripheral vascular disease, n (%)	37 (18.8%)	100 (20.0%)	1.2% (-5.4%; 7.8%)	0.75
	Chronic obstructive pulmonary disease, n (%)	34 (17.3%)	75 (15.0%)	-2.3% (-8.3%; 3.7%)	0.49
	Coronary artery disease, n (%)	111 (56.3%)	279 (55.8%)	-0.5% (-8.8%; 7.7%)	0.93
	Left ventricular ejection fraction (%)	55.9±12.4	52.9±14.7	3.0 (0.2; 5.8)	0.034
	Aortic valve area (cm <sup>2</sup> )	0.8±0.3	0.7±0.2	0.1 (0.04; 0.1)	0.001
	Mean transaortic gradient (mmHg)	43.0±14.5	45.6±18.5	-2.6 (-6.0; 0.9)	0.14
Risk assessment	Log. EuroSCORE (%)	19.3±12.8	20.5±12.6	-1.2 (-3.8; 1.4)	0.36
	STS score (%)	7.7±7.2	8.4±7.1	-0.8 (-2.0; 0.4)	0.20

Depicted are means with standard deviations (p-values from ANOVAs) or counts (% of all patients; p-values from chi-square tests). In n: 16 patients the discharge location was unclear and assumed others.

Online Table 12. Procedure discharge home vs. others.

	Procedural characteristics for patients discharged home vs. others			
	Home N=197	Others N=500	Difference (95% CI)	p-value
Procedure time (min)	73.3±32.3	76.8±39.9	-3.5 (-9.9; 2.9)	0.29
Amount of contrast (ml)	212.8±103.6	215.9±109.1	-3.1 (-21.3; 15.1)	0.74
General anaesthesia, n (%)	113 (57.4%)	267 (53.5%)	3.9% (-4.4%; 12.1%)	0.40
Conversion from local to general anaesthesia, n (%)	0 (0.0%)	16 (6.9%)	6.9% (1.5%; 12.4%)	0.008
Procedure location				
Catheterisation laboratory, n (%)	141 (71.6%)	379 (75.8%)	-4.2% (-11.4%; 3.0%)	
Operating room, n (%)	2 (1.0%)	6 (1.2%)	-0.2% (-1.9%; 1.6%)	
Hybrid room, n (%)	54 (27.4%)	115 (23.0%)	4.4% (-2.7%; 11.5%)	
Access-site location				0.005
Femoral	161 (81.7%)	390 (78.0%)	3.7% (-3.0%; 10.5%)	
Transapical	29 (14.7%)	97 (19.4%)	-4.7% (-11.0%; 1.7%)	
Subclavian	6 (3.0%)	2 (0.4%)	2.6% (0.9%; 4.4%)	
Direct aortic	1 (0.5%)	11 (2.2%)	-1.7% (-3.8%; 0.5%)	
Concomitant procedure				
Percutaneous coronary intervention, n (%)	16 (8.1%)	49 (9.8%)	1.7% (-3.1%; 6.5%)	0.56
Device features				
Prior balloon aortic valvuloplasty, n (%)	173 (87.8%)	431 (86.2%)	-1.6% (-7.2%; 4.0%)	0.62
Device implanted				0.96
Medtronic CoreValve, n (%)	96 (48.7%)	240 (48.3%)	0.4% (-7.8%; 8.7%)	
Edwards SAPIEN, n (%)	90 (45.7%)	227 (45.7%)	0.0% (-8.2%; 8.3%)	
Symetis Acurate, n (%)	4 (2.0%)	13 (2.6%)	-0.6% (-3.1%; 2.0%)	
JenaValve, n (%)	7 (3.6%)	16 (3.2%)	0.3% (-2.6%; 3.3%)	
SJM Portico, n (%)	0 (0.0%)	1 (0.2%)	-0.2% (-0.8%; 0.4%)	
Aortic regurgitation post TAVI				
Grade 0, n (%)	55 (28.2%)	115 (23.6%)	4.6% (-2.6%; 11.8%)	
Grade 1, n (%)	133 (68.2%)	319 (65.5%)	2.7% (-5.2%; 10.6%)	
Grade 2, n (%)	7 (3.6%)	48 (9.9%)	-6.3% (-10.8%; -1.8%)	
Grade 3, n (%)	0 (0.0%)	5 (1.0%)	-1.0% (-2.4%; 0.4%)	
In-hospital course				
Permanent pacemaker implantation, n (%)	43 (21.8%)	94 (19.1%)	-2.7% (-9.3%; 3.9%)	0.46
Any packed red blood cell during hospitalisation, n (%)	21 (10.7%)	110 (22.2%)	11.5% (5.1%; 17.9%)	<0.001
Number of PRBC, median (interquartile range)	2.0 (1.0; 3.5)	2.0 (1.0; 3.0)	-0.5 (-2.3; 1.2)	0.74
Overall in-hospital stay after TAVI (days)	9.2±5.0	11.4±6.4	-2.2 (-3.2; -1.2)	<0.001
Stay at intensive care unit (days)	0.9±1.2	1.2±2.7	-0.3 (-0.7; 0.1)	0.19
Stay at intermediate care (days)	1.9±2.1	2.8±3.2	-0.9 (-1.4; -0.4)	<0.001
Stay at general ward (days)	6.4±4.6	7.4±5.6	-1.0 (-1.9; -0.1)	0.023

Depicted are means with standard deviations (p-values from ANOVAs) or counts (% of all patients; p-values from chi-square tests). In n: 16 patients the discharge location was unclear and assumed others.

Online Table 13. Outcomes discharge home vs. others.

	Clinical outcomes comparing patients discharged home vs. others					
	Home N=197	Others N=500	HR or RR (95% CI)	p-value	Adjusted HR or RR (95% CI)	p-value
<b>30-day follow-up - events</b>						
Mortality, n (%)	0 (0.0)	33 (6.7)	0.04 (0.00-0.65)	<0.001		
Cardiovascular mortality, n (%)	0 (0.0)	33 (6.7)	0.04 (0.00-0.65)	<0.001		
Cerebrovascular accident, n (%)	1 (0.5)	22 (4.5)	0.11 (0.02-0.84)	0.033	0.12 (0.02-0.92)	0.041
Major stroke, n (%)	1 (0.5)	16 (3.2)	0.16 (0.02-1.18)	0.072	0.17 (0.02-1.30)	0.088
Minor stroke, n (%)	0 (0.0)	4 (0.8)	0.28 (0.02-5.18)	0.58		
TIA, n (%)	0 (0.0)	2 (0.4)	0.51 (0.02-10.58)	1.00		
Myocardial infarction, n (%)	1 (0.5)	2 (0.4)	1.24 (0.11-13.66)	0.86	1.15 (0.10-13.14)	0.91
Acute kidney injury, n (%)	12 (6.1)	38 (7.8)	0.78 (0.41-1.50)	0.46	0.76 (0.39-1.46)	0.41
Stage 1, n (%)	9 (4.6)	17 (3.5)	1.33 (0.59-2.98)	0.49	1.22 (0.54-2.76)	0.64
Stage 2, n (%)	1 (0.5)	6 (1.2)	0.41 (0.05-3.41)	0.41	0.52 (0.06-4.43)	0.55
Stage 3, n (%)	2 (1.0)	15 (3.1)	0.33 (0.08-1.44)	0.14	0.31 (0.07-1.38)	0.12
Bleeding, n (%)	19 (9.7)	95 (19.3)	0.48 (0.29-0.79)	0.003	0.49 (0.30-0.81)	0.005
Life-threatening bleeding, n (%)	4 (2.0)	39 (7.9)	0.25 (0.09-0.70)	0.008	0.25 (0.09-0.71)	0.009
Major bleeding, n (%)	11 (5.6)	47 (9.6)	0.58 (0.30-1.11)	0.10	0.61 (0.32-1.19)	0.15
Minor bleeding, n (%)	4 (2.0)	9 (1.8)	1.10 (0.34-3.56)	0.88	1.06 (0.32-3.52)	0.92
Vascular access-site and access-related complications, n (%)	12 (6.1)	71 (14.2)	0.43 (0.23-0.78)	0.006	0.46 (0.25-0.84)	0.013
Major vascular complications, n (%)	5 (2.5)	40 (8.0)	0.31 (0.12-0.79)	0.015	0.35 (0.14-0.90)	0.029
Minor vascular complications, n (%)	7 (3.6)	32 (6.4)	0.56 (0.25-1.26)	0.16	0.57 (0.25-1.30)	0.18
Permanent pacemaker implanted, n (%)	43 (21.9)	97 (19.9)	1.11 (0.78-1.59)	0.56	1.02 (0.71-1.47)	0.90

Depicted are number of first events with % of all patients (in-hospital events); and censored at 30 days since procedure with % from Kaplan-Meier estimates (30-day follow-up events). All clinical outcomes were adjudicated, except for pacemaker implantations. Cox's regression, reports hazard ratio (HR; with 95% confidence intervals). Continuity corrected RR (95% CI) with p-value from Fisher's exact test in case of zero events. In n: 16 patients the discharge location was unclear and assumed others.