Outcome of patients with severe aortic stenosis undergoing ad hoc transcatheter aortic valve implantation without invasive pre-evaluation

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Summary

Aims: To investigate the feasibility and safety of TAVI without prior invasive assessment.

Methods and Results: A total of 489 patients underwent TAVI for treatment of severe aortic stenosis between July 2007 and April 2012 and were included in a prospective single-centre registry. Of 437 patients (90%), pre-procedural evaluation included right and left heart catheterisation, whereas 49 patients (10%) were scheduled to undergo TAVI without prior invasive assessment. Among patients without invasive assessment, coronary angiography was performed immediately before TAVI within the same intervention. Baseline patient characteristics and calculated risk scores were comparable between groups. Coronary artery disease was detected in 64% and 49% of patients with and without invasive assessment, respectively (p = 0.06), and resulted in more frequent use of concomitant percutaneous coronary intervention among patients without invasive assessment (15% vs 27%, p = 0.04). Clinical outcome at 30 days revealed no significant differences between patients with and without invasive assessment in terms of all-cause mortality (6.0% vs 4.1%, HR 1.40, 95% CI 0.33–5.92, p = 0.65), myocardial infarction (0.5% vs. 0%, p = 1.00), and major stroke (2.6% vs. 4.2%, HR 0.61, 95% CI 0.14–2.75, p = 0.52). Major bleeding was more frequent among patients undergoing invasive assessment as compared to those without invasive assessment (28.9% vs. 14.3%, RR 2.02, 95% CI 1.00–4.07, p = 0.05).

Conclusions: In selected patients, TAVI without prior invasive assessment may result in similar risk of ischaemic events compared to TAVI among patients with invasive assessment despite the more frequent use of concomitant PCI.

Key words: aortic stenosis; TAVI; pre-evaluation; ad hoc.

Funding / potential competing interests: Thomas Pilgrim: TP received honoraria from Medtronic and Biotronik. Stephan Windecker: Research grants to the institution from: St. Jude Medical, Biotronik, Medicines Company, Abbott, Medtronic, Edwards Lifesciences, Honoraria from: Astra Zeneca, Eli Lilly, Abbott, Biotronik, Boston Scientific, Bayer HealthCare. Fabian Nietlispach: FN is consultant for Ewards Lifesciences, St. Jude Medical and Direct Flow. Christoph Huber: Dr. Huber is proctor for Edwards Lifesciences and for Symetis as well as consultant for Medtronic. Bernhard Meier: Research grants to the institution of Abbott, Edwards, Medtronic, and St. Jude, and advisory board of Medtronic and St. Jude. Dr. Wenaweser: Proctoring and lecture fees from Medtronic, Edwards and Boston Scientific. Research grant from Medtronic to the institution (University of Berne).

Background

Comprehensive assessment of patients with severe aortic stenosis at increased risk for surgical aortic valve replacement guides selection of an appropriate treatment strategy tailored to the comorbidities, anatomic conditions and preferences of individual patients [1, 2]. Candidates for Transcatheter Aortic Valve Implantation (TAVI) routinely undergo non-invasive assessment by means of transoesophageal echocardiography, computed tomography (CT) angiography as well as invasive assessment by means of complete left and right heart catheterisation to determine the haemodynamic state, anatomic suitability for a transcatheter strategy, and concomitant coronary artery disease. Non-invasive assessment of the valvular dimensions and measurement of the peripheral access diameter allow for reliable sizing of the valvular dimensions and are useful to guide the selection of the most appropriate access route and device size. Functional assessment of myocardial ischaemia is, however, complicated by the presence of severe aortic stenosis and selective coronary angiography is the recommended standard (Class IC) for the comprehensive evaluation of coronary artery disease prior to aortic valve replacement therapy.

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Coronary artery disease has been documented in up to two thirds of patients with severe aortic stenosis [3, 4–9] and has not been associated with adverse outcome after TAVI [4]. Percutaneous coronary revascularisation may be considered among patients with a large area at risk and impaired left ventricular function. Observational studies suggest that concomitant or staged revascularisation by means of PCI is feasible and safe [4, 7–9].

The rationale for the present study is based on the assumption, that non-invasive assessment prior to TAVI is reliable and may avoid the need for invasive assessment among patients with a low probability of coronary artery disease. The objective of the study was to investigate the safety and feasibility of TAVI without invasive assessment in selected patients (ad hoc TAVI).

Methods

Patient population

In August 2007, we initiated a single-centre registry enrolling all consecutive patients undergoing TAVI. Selection of an adequate treatment strategy for patients with severe aortic stenosis at increased risk for surgical aortic valve replacement was determined in the heart team composed of interventional cardiologists and cardiac surgeons. Treatment allocation has been described previously in detail [2]. Patients undergoing TAVI for degenerated aortic bioprosthesis were excluded for the purpose of the present analysis. The registry was approved by the local ethics committee and all subjects gave written, informed consent.

Procedures

The selection of patients undergoing TAVI without invasive assessment was determined by several factors: (1.) explicit qualification for TAVI rather than surgery, (2.) increasing experience of the operators, (3.) low-suspicion for the presence of significant coronary artery disease on clinical grounds, (4.) detailed analysis of valvular anatomy as determined on non-invasive measurements. Three approved devices for TAVI, the Medtronic CoreValve (Irivine, California, USA), the Edwards Sapien (Irvine, California, USA), and the Symetis prosthesis (Ecublens, Switzerland), were implanted through transfemoral, transsubclavian or transapical access, respectively. The procedure has been described in detail previously [2]. In patients without invasive assessment prior to TAVI, coronary angiography was performed within the same intervention immediately before TAVI. Routine peri-procedural antithrombotic management consisted of unfractionated heparin (70 U/kg), acetylsalicylic acid 100 mg qd and clopidogrel (300 mg loading one day prior to the procedure followed by 75 mg qd for 3–6 months).

Data collection

All patients included into the registry were followed routinely by clinic visits or telephone interviews at one month, one year, and yearly thereafter. Documentation of potential adverse events was collected from treating hospitals, cardiologists, and primary care physicians. Independent event adjudication was performed by a clinical event committee consisting of an interventional cardiologist and a cardiac surgeon.

Definitions

Patients were categorised not to have had an invasive assessment prior to TAVI in the absence of heart catheterisation within six months prior to the procedure. Clinical endpoints were documented in accordance with the criteria formulated by the Valve Academic Research Consortium (VARC) [10]. Adverse events were recorded beginning at the time of the procedure and did not include adverse events related to invasive assessment or staged PCI prior to TAVI. Any death due to a proximate cardiac cause or death of unknown cause, as well as all procedure-related deaths and death caused by non-coronary vascular conditions such as cerebrovascular disease, pulmonary embolism, or other vascular disease was documented as a cardiovascular death. Peri-procedural myocardial infarction was defined by new ischaemic signs in combination with elevated cardiac biomarkers (two or more post-procedure samples that were >6–8 hours apart with a 20% increase in the second sample and a peak value exceeding ten times the 99th percentile upper reference limit (URL), or a peak value exceeding five times the 99th percentile URL with new pathological Q waves in at least two contiguous leads) within 72 hours after the index procedure. Major stroke was recorded in case of a rapid onset of focal or global neurological deficit of ≥24 hours duration requiring therapeutic intervention, or documentation of a new intracranial defect using MRI or CT-scan. Bleeding events were defined as life-threatening or disabling, and major. Life-threatening or disabling bleeding comprised (1.) bleeding into a critical area or organ such as the pericardial space, or (2.) bleeding causing hypovolemic shock or requiring vasopressors or surgery, or (3.) bleeding with an overt source of bleeding with a decrease in haemoglobin ≥5 g/dl or packed red blood cells (PRBC) transfusion ≥4 units. Major bleeding included overt bleeding associated with a decrease in haemoglobin level ≥3.0 g/dl. Access-related vascular injuries leading to either death, need for blood transfusions (≥4 units), percutaneous or surgical intervention, or irreversible end-organ damage were documented as major. Minor vascular complications included failure of percutaneous access site closure resulting in interventional or surgical correction. Kidney injury was defined using the modified RIFLE classification (Risk, Injury, Failure, Low output, End-stage kidney disease) and was based upon changes in serum creatinine within

72 hours after the procedure. Stage 1 was documented in the presence of an increase of serum creatinine to 150% to 200% (or an increase of ≥26.4 µmol/l), stage 2 was defined as an increase of baseline creatinine to 200% to 300%, and stage 3 was recorded in case of an increase in creatinine of ≥300% with an acute increase of at least 44 µmol/l.

Statistical analysis

All statistical analyses were performed with SPSS statistics version 17.0. Comparisons between continuous variables expressed as mean ± standard deviation (SD) were performed by means of ANOVA test or student's t-test as appropriate. Categorical data are presented as frequency (percentages), and are compared using the chi-square and Fishers exact tests as appropriate. Hazard Ratios (HR) with 95% confidence intervals (CI) were derived from Cox regressions for death, cardiovascular death, cerebrovascular events, myocardial infarction and their composites, whereas risk ratios were calculated using Poisson regressions with robust error variances for bleeding, acute renal failure, access site complications, VARC safety endpoint and any composite involving these outcomes. RR and HR for endpoints with zero outcomes are not reported. A p value <0.05 was considered statistically significant.

Results

A total of 489 patients underwent TAVI for severe aortic stenosis between July 2007 and April 2012 with the Medtronic CoreValve (n = 268), the Edwards SAPIEN (n = 218) or the Symetis (n = 3) bioprosthesis. After exclusion of three patients undergoing emergency TAVI due to decompensated heart failure, 49 patients (10%) were scheduled to undergo TAVI without prior invasive assessment, 10 of whom (20%) had undergone heart catheterisation at a mean duration of 762 ± 480 days prior to TAVI. All patients scheduled for TAVI without invasive assessment were treated as intended a priori. TAVI was never deferred because of coronary findings in the angiography immediately prior to TAVI. Figure 1 demonstrates a steady increase in the number of patients undergoing TAVI without invasive assessment in parallel with the increase in the total volume of TAVI procedures. Baseline characteristics of all patients are summarised in table 1 and did not show significant differences between patients with or without invasive assessment, respectively. The mean age was 82 ± 6 years and logistic EuroScore amounted to 23 ± 14%. Coronary artery disease was recorded in 62% of patients with a trend towards a lower prevalence among patients without invasive assessment (invasive assessment 64% versus without invasive assessment 49%; p = 0.06) (fig. 2). Significant coronary artery disease was established in 13 of 36 patients (36%) who had never undergone heart catheterisation before. Nine

Figure 1
Numbers of TAVI performed per year (according to quartiles).

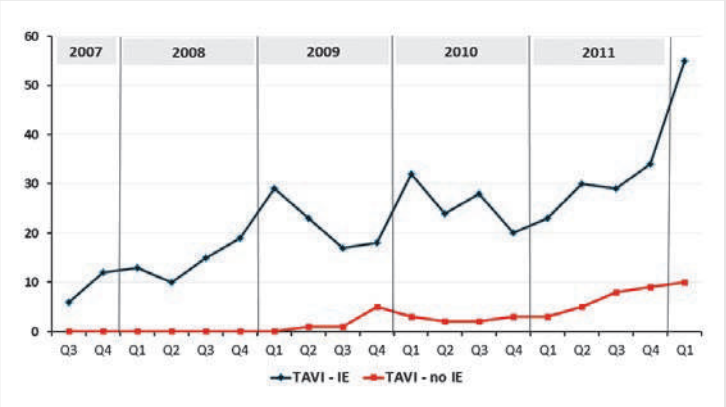

Figure 2
Coronary artery disease and revascularisation stratified by strategy of pre-evaluation.

Patient Population	TAVI n=486*		
Evaluation	Invasive Assessment n=437/486 (89%)		No Invasive Assessment n=49/486 (11%)
Coronary Artery Disease	Yes n=278/437 (64%)	No n=159/437 (36%)	Yes n=24/49 (49%)	No n=25/49 (51%)
Revascularization	Yes n=115/437 (26%)	No n=322/437 (74%)	Yes n=13/49 (27%)	No n=36/49 (73%)
Staged PCI	Yes n=50/437 (11%)		n.a.	
Concomitant PCI	Yes n=65/437 (15%)		Yes n=13/49 (27%)	

*exclusion of 3 patients undergoing emergency TAVI

Figure 3
All-cause mortality through one year as a function of pre-evaluation.

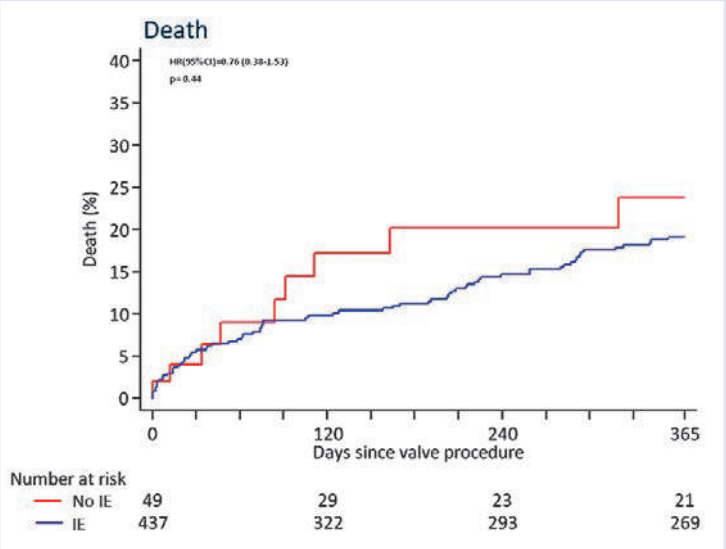

Table 1
Baseline clinical characteristics. Depicted are means ± SD with p-values from t-tests, or counts (%) with p-values from chi-square or Fisher's tests. *STS = Society of Thoracic Surgeons.

			Invasive pre-evaluation		
		All patients	**IE**	**No IE**	**p-value**
		N = 486	**N = 437**	**N = 49**	
Age (years)		82.4 ± 5.8	82.4 ± 5.7	83.2 ± 6.1	0.35
Female gender, n (%)		268 (55%)	239 (55%)	29 (59%)	0.65
Body mass index (kg/m²)		26.16 ± 4.93	26.19 ± 5.00	25.86 ± 4.30	0.65
Cardiac risk factors	Diabetes mellitus, n (%)	129 (27%)	118 (27%)	11 (22%)	0.61
	Hypercholesterolemia, n (%)	302 (62%)	276 (63%)	26 (53%)	0.17
	Hypertension, n (%)	397 (82%)	356 (81%)	41 (84%)	0.84
	Current smoker, n (%)	51 (11%)	49 (11%)	2 (4%)	0.21
Past medical history	Previous myocardial infarction, n (%)	79 (16%)	72 (16%)	7 (14%)	0.84
	Previous coronary artery bypass graft, n (%)	83 (17%)	77 (18%)	6 (12%)	0.43
	Previous percutaneous coronary intervention, n (%)	122 (25%)	118 (27%)	4 (8%)	0.003
	Previous stroke, n (%)	39 (8%)	33 (8%)	6 (12%)	0.26
	Peripheral vascular disease, n (%)	106 (22%)	100 (23%)	6 (12%)	0.101
	Chronic obstructive pulmonary disease, n (%)	87 (18%)	79 (18%)	8 (16%)	0.85
Clinical features	Systolic pulmonary pressure (mm Hg)	50.8 ± 16.9	50.9 ± 16.9	49.6 ± 16.4	0.62
	Coronary artery disease, n (%)	302 (62%)	278 (64%)	24 (49%)	0.061
	Single vessel disease, n (%)	105 (22%)	98 (22%)	7 (14%)	0.27
	Double vessel disease, n (%)	72 (15%)	66 (15%)	6 (12%)	0.83
	Triple vessel disease, n (%)	127 (26%)	116 (27%)	11 (22%)	0.61
	Atrial fibrillation, n (%)	139 (29%)	120 (28%)	19 (39%)	0.13
	Left ventricular ejection fraction (%)	52.2 ± 14.8	52.5 ± 14.8	50.2 ± 14.2	0.31
	Aortic valve area (cm²)	0.61 ± 0.2	0.60 ± 0.2	0.69 ± 0.2	0.012
	Mean transaortic gradient (mm Hg)	43.4 ± 17.2	43.6 ± 17.1	41.4 ± 17.8	0.40
Symptoms	New York Heart Association (NYHA) Functional Class				0.32
	NYHA I+II, n (%)	162 (34%)	149 (34%)	13 (27%)	0.34
	NYHA III+IV, n (%)	321 (66%)	286 (66%)	35 (73%)	0.34
Risk assessment	Logistic EuroScore (%)	23.2 ± 13.5	23.2 ± 13.1	23.2 ± 16.7	0.98
	STS* score (%)	6.6 ± 4.4	6.5 ± 4.3	7.3 ± 5.1	0.22

of these 13 patients underwent concomitant PCI. In the remaining 4 patients, two had diffuse three vessel disease without high-grade stenosis, one patient had a stenosis in a non-dominant right coronary artery, and one patient underwent staged PCI seven months after TAVI for the treatment of a significant stenosis of the right coronary artery and the left circumflex artery.

The overall rate of revascularisation was comparable in both groups (26% with invasive assessment vs. 27% without invasive assessment, p = 1.00). Concomitant percutaneous revascularisation was performed more frequently among patients without as compared to patients with invasive assessment (27% versus 15%; p = 0.04); however, 11% of the latter group had undergone revascularisation in a prior intervention (table 2,

Figure 4
Occurrence of death, myocardial infarction and major stroke within 30 days as a function of pre-evaluation.

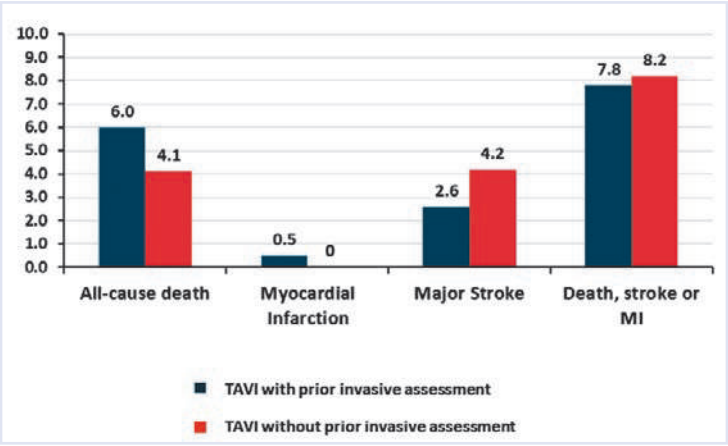

Table 2
Procedural characteristics. Depicted are means ± SD with p-values from t-tests, or counts (%) with p-values from chi-square or Fisher's tests.

			Invasive pre-evaluation		
		All patients	**IE**	**No IE**	**p-value**
		N = 486	**N = 437**	**N = 49**	
Procedure time (min)		79.2 ± 35.7	79.1 ± 35.8	80.3 ± 34.7	0.82
Fluoroscopy time (min)		20.1 ± 10.9	19.7 ± 11.0	23.1 ± 9.6	0.043
Amount of contrast (ml)		248.4 ± 98.5	243.6 ± 96.2	291.7 ± 108.2	0.001
General anaesthesia, n (%)		187 (40%)	173 (41%)	14 (30%)	0.158
New-onset of atrial fibrillation, n (%)		36 (7%)	35 (8%)	1 (2%)	0.159
Access route	Femoral, n (%)	382 (79%)	338 (77%)	44 (90%)	0.044
	Apical, n (%)	98 (20%)	93 (21%)	5 (10%)	0.089
	Subclavian, n (%)	6 (1%)	6 (1%)	0 (0%)	1.000
Valve type	Medtronic CoreValve, n (%)	264 (54%)	241 (55%)	23 (47%)	0.293
	Edwards Sapien Valve, n (%)	219 (45%)	193 (44%)	26 (53%)	0.289
	Symetis Acurate TA, n (%)	3 (1%)	3 (1%)	0 (0%)	1.000
Revascularisation	Concomitant PCI, n (%)	78 (16%)	65 (15%)	13 (27%)	0.041
	Staged PCI, n (%)	50 (10%)	50 (11%)	0 (0%)	0.006
Procedural specifications	VARC device success, n (%)	412 (85%)	372 (85%)	40 (82%)	0.530
	Post TAVI – need for permanent pacemaker, n (%)	120 (25%)	112 (26%)	8 (16%)	0.167
	Post TAVI – aortic regurgitation ≥2	56 (12%)	51 (12%)	5 (11%)	1.000
	Implantation of a second valve, n (%)	8 (2%)	5 (1%)	3 (6%)	0.038

fig. 2). Clinical outcomes at 30 days and 1 year are shown in table 3 and figure 3. There were no differences in terms of all-cause mortality (6.0% vs. 4.1%, HR 1.40, 95% CI 0.33–5.92, p = 0.65), myocardial infarction (0.5% versus 0%, p = 1.00), or major stroke (7.8% vs. 8.2%, HR 0.61, 95% CI 0.14–2.75, p = 0.52) (fig. 4). Rates of acute kidney injury were similar, and there were no differences in the occurrence of the VARC combined safety endpoint (24.5% with invasive assessment vs. 26.5% without invasive assessment, RR 0.92, 95%CI 0.56–1.51, p = 0.75). Major bleeding was more frequent among patients undergoing invasive assessment (28.9% vs. 14.3%, RR 2.02, 95% CI 1.00–4.07, p = 0.05), which was not related to major vascular access site complications after TAVI (8.5% vs. 8.2% RR 1.04, 95% CI 0.34–2.79, p = 0.94).

Discussion

The key findings of this analysis can be summarised as follows: (1.) clinical outcome of selected patients undergoing TAVI was comparable between patients with and without invasive assessment. (2.) Patients without invasive assessment more frequently underwent concomitant revascularisation procedures without an increased risk of peri-procedural ischemic events. (3.) TAVI without invasive assessment was not associated with an increased risk of renal failure despite a higher amount of contrast agent administered.

During the past decade, TAVI has gained broad acceptance as a valuable treatment alternative for patients with severe aortic stenosis at increased risk for surgical aortic valve replacement. In order to be implemented into routine clinical practice, novel procedures need to transition to a simplified treatment selection algorithm. Improvements of the delivery system, smaller sheath diameters and imaging tools to facilitate valve sizing and positioning have contributed to the continuing success of TAVI interventions. A reduction of the multimodality evaluation to assess the suitability for TAVI may be anticipated as logical next step in this development towards simplification of the pre-interventional process. We report our experience of patients undergoing ad hoc TAVI without invasive assessment. The selection of patients undergoing TAVI without invasive assessment was performed on an individual basis. A comparison of baseline characteristics of patients with and without invasive assessment did not yield a clear selection pattern.

Peri-procedural and clinical outcomes throughout one year were comparable between patients with and without invasive assessment. Rates of mortality, myocardial infarction, and stroke were in the range of previously published data [3, 5, 6]. Most importantly, we did not observe a higher risk of peri-procedural mortality or myocardial infarction due to the unknown coronary status and burden of ischemia prior to the TAVI procedure. There was no case of newly detected severe coronary artery disease which precluded TAVI. In one

Table 3
Clinical outcomes at 30 days and 1 year of follow-up. Depicted are events (with percentages from life-tables in brackets) and IE vs. No IE (reference) Hazard ratios HR (95% CI) or Risk ratios RR (95% CI). HR from Cox regressions for death, cardiovascular death, cerebrovascular events, myocardial infarction and their composites. RR from Poisson regressions with robust error variances for bleeding, acute renal failure, access site complications, VARC safety endpoint and any composite involving these outcomes. RR and HR involving zero outcomes not reported.

		Invasive pre-evaluation			
		IE	No IE	HR or RR (95%CI)	p-value
		N = 437	N = 49		
30 days follow-up	All causes of death, n (%)	25 (6.0)	2 (4.1)	1.40 (0.33–5.92)	0.65
	Cardiovascular death, n (%)	20 (4.8)	2 (4.1)	1.12 (0.26–4.80)	0.88
Cerebrovascular events	Major stroke, n (%)	11 (2.6)	2 (4.2)	0.61 (0.14–2.75)	0.52
	Minor stroke, n (%)	2 (0.5)	0 (0.0)	–	1.00
	Transient ischaemic attack, n (%)	0 (0.0)	0 (0.0)	–	
	Myocardial infarction, n (%)	2 (0.5)	0 (0.0)	–	1.00
Bleeding	Life-threatening, n (%)	70 (16.0)	4 (8.2)	1.96 (0.75–5.15)	0.17
	Major, n (%)	126 (28.9)	7 (14.3)	2.02 (1.00–4.07)	0.050
	Acute renal failure (VARC stage 3), n (%)	15 (3.4)	3 (6.1)	0.56 (0.17–1.87)	0.35
	Renal failure VARC stage 2 (n/%)	4 (0.8)	3 (0.7)	1 (2.0)	0.35
	Renal failure VARC stage 1 (n/%)	51 (10.5)	44 (10.1)	7 (14.3)	0.33
Access site complications	Major, n (%)	37 (8.5)	4 (8.2)	1.04 (0.39–2.79)	0.94
	Minor, n (%)	45 (10.3)	5 (10.2)	1.01 (0.42–2.42)	0.98
	VARC safety endpoint, n (%)	107 (24.5)	13 (26.5)	0.92 (0.56–1.51)	0.75
	all causes of death or stroke, n (%)	32 (7.3)	4 (8.2)	0.89 (0.31–2.52)	0.83
	All causes of death, stroke, or MI, n (%)	34 (7.8)	4 (8.2)	0.95 (0.34–2.67)	0.92
1 year follow-up	All causes of death, n (%)	72 (19.1)	9 (23.9)	0.76 (0.38–1.53)	0.44
	Cardiovascular death, n (%)	48 (12.9)	7 (17.2)	0.67 (0.30–1.49)	0.33
Cerebrovascular events	Major stroke, n (%)	15 (3.9)	3 (7.4)	0.52 (0.15–1.78)	0.29
	Minor stroke, n (%)	2 (0.5)	0 (0.0)	–	1.00
	Transient ischaemic attack, n (%)	2 (0.7)	0 (0.0)	–	1.00
	Myocardial infarction, n (%)	6 (1.8)	0 (0.0)	–	1.00
	All causes of death or stroke, n (%)	82 (21.5)	11 (27.8)	0.71 (0.38–1.33)	0.28
	All causes of death, stroke, or MI, n (%)	85 (22.3)	11 (27.8)	0.74 (0.40–1.39)	0.35

case, a staged PCI procedure was performed several months after TAVI. All other cases with newly detected coronary artery disease could be treated concomitantly without peri-procedural myocardial infarction or significant kidney damage which adds evidence to the concept of incidental PCI being feasible in selected TAVI patients [4, 9].

Cerebrovascular accidents deserve particular attention as the risk may be increased due to additional procedures, prolonged procedure times with indwelling catheters and need for additional anticoagulation. Our observational data summarised in this study did not reveal a significant difference with respect to this adverse event although a numerical difference was apparent.

Post-procedural renal impairment directly correlates with the amount of contrast medium used during the intervention [11]. Severe deterioration of renal function after the procedure impacts on morbidity and mortality and deserves prevention [12]. In our cohort without invasive assessment a higher amount of contrast agent was used without apparent impact on renal function and comparable rates of renal impairment. This finding is somewhat biased due to the selection of patients with low risk for renal failure in the group without invasive assessment. The benefit of a single procedure (TAVI combined with PCI) needs to be carefully weighed against the risk of renal failure and cerebrovascular events. Staged invasive diagnosis and treatment need to be spaced weeks apart to minimise renal jeopardy.

We observed an increased rate of bleeding complications among patients with invasive assessment prior to TAVI. This finding may be explained by an increased vascular vulnerability related to a second arterial puncture within few days to weeks, although it is not reflected in the higher rate of access site complications. No difference with regard to the severity of post-interventional aortic regurgitation was observed between patients with or without IE, respectively, corroborating the hypothesis that aortic root assessment by transoesophageal echocardiography and CT angiography

does suffice. This analysis has several limitations. First, the number of patients treated without IE is limited and allocation to either of the two evaluation strategies was performed in a non-randomised fashion. Findings must therefore be interpreted in the context of clinical decision making within the heart team. Second, one in every four patients from the group without invasive assessment had a coronary angiography within months to years prior to the intervention, and the status of coronary artery disease was therefore not unknown in all patients. Third, the role of invasive assessment is directly related to the importance of coronary artery disease in patients with symptomatic severe aortic stenosis, which remains to be determined in larger patient cohorts.

Conclusion

TAVI without prior invasive assessment may result in similar risk of ischaemic events compared to TAVI among patients with invasive assessment in selected patients. This ad hoc strategy did not increase the risk of peri-procedural ischaemic events or kidney damage despite a higher rate of concomitant PCI in comparison to patients with invasive assessment.

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