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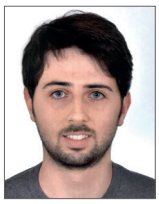
Predictors and safety of next-day discharge in patients undergoing transfemoral transcatheter aortic valve implantation



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KEYWORDS

- femoral
- no complication
- TAVI

Abstract

Aims: The aim of this study was to evaluate predictors and safety of next-day discharge (NDD) after transfemoral transcatheter aortic valve implantation (TF-TAVI) in unselected patients receiving either balloon-expandable or self-expanding devices.

Methods and results: From June 2007 to August 2018, 1,232 consecutive patients undergoing TF-TAVI were discharged alive from our institution. They had a mean age of 80.9±5.4 years and an intermediate estimated surgical mortality risk; they received either balloon-expandable (26.1%) or self-expanding prostheses (73.9%). We compared patients discharged within 24 hours from the procedure (n=160, 13.0%) with those discharged later, and accounted for confounding variables through a propensity matching adjustment. After adjustment, no differences in all-cause mortality (1.2% vs 0.0%, for NDD and no-NDD matched groups, respectively, p=0.16) or permanent pacemaker implantation (PPI) after TAVI (0.6% vs 0.6%, respectively) were encountered at 30 days. At one year, no difference in the composite endpoint of all-cause death and heart failure (HF) rehospitalisation was encountered (Kaplan-Meier [KM] estimates 91.9% vs 90.6% for NDD and no-NDD matched groups, respectively, p=0.69). After excluding patients with post-procedural major complications from the unmatched population, prior PPI (OR 2.06, 95% CI: 1.21-3.51; p<0.01) and availability of preprocedural computed tomography angiography (CTA) (OR 1.71, 95% CI: 1.15-2.54; p<0.01) were found to be predictors of NDD after TAVI.

Conclusions: NDD in unselected patients after TF-TAVI using either balloon-expandable or self-expanding devices was demonstrated to be a safe strategy up to one year in the absence of procedural complications. Patients with prior PPI and undergoing preprocedural CTA had a higher chance of NDD.

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Abbreviations

AS	aortic stenosis
CTA	computed tomography angiography
NDD	next-day discharge
PPI	permanent pacemaker implantation
TAV	transcatheter aortic valve
TAVI	transcatheter aortic valve implantation

Introduction

The PARTNER 3 and Evolut R Low Risk randomised trials established the role of transcatheter aortic valve implantation (TAVI) alongside surgery even for treatment of patients with severe aortic stenosis (AS) at low surgical risk[1,2]. Apart from clear contraindications for each type of intervention as assessed by local Heart Teams, bioprosthesis durability and patients' preference remain the main factors in the decision-making process for the treatment of severe AS in elderly patients. In recent years, some groups have been working on local programmes which incorporate specific preprocedural, periprocedural and post-procedural pathways aimed at simplification of the TAVI pathway. The objectives of these pathways are to identify a more efficient system for patient assessment screening, to optimise the TAVI procedure without compromising its safety, to accelerate patient recovery and mobilisation after the procedure and to minimise unnecessary use of medical resources[3-7].

The purpose of this study was to evaluate the safety of next-day discharge (NDD) after transfemoral TAVI (TF-TAVI) using either balloon-expandable or self-expanding transcatheter aortic valves (TAVs) in an all-comers population and to determine which patients are more suitable for this strategy.

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Methods

This was a single-centre, retrospective analysis obtained from a prospective local TAVI registry. All consecutive patients undergoing TF-TAVI in our institution were included. The TAVI procedures were all performed using a minimalist approach, under local anaesthesia and using only angiographic guidance with back-up transthoracic echocardiography. Transthoracic echocardiographic evaluation was performed immediately after the procedure and before discharge. Patients who died during the index hospitalisation were excluded from the analysis.

First, we reported in-hospital and 30-day outcomes of consecutive patients discharged alive from our institution considering the entire population categorised into two groups (NDD group vs no-NDD group); we accounted for any confounding variables through a propensity matching adjustment and evaluated 30-day outcomes and the one-year composite outcome of all-cause death and rehospitalisation for heart failure (HF) of the NDD and no-NDD matched groups.

Second, we assessed predictors of NDD among patients not experiencing periprocedural and in-hospital major or life-threatening complications, including in-hospital myocardial infarction (MI), stroke or transient ischaemic attack (TIA), major vascular complications, major or life-threatening bleeds, more-than-mild acute kidney injury (AKI), new-onset atrial fibrillation (AF) or permanent pacemaker implantation (PPI). All outcomes were reported according to Valve Academic Research Consortium-2 definitions[8]. The study participant flow chart is shown in **Figure 1**.

STATISTICAL ANALYSIS

Continuous variables are reported as mean±standard deviation (SD), whereas dichotomous parameters are reported as frequencies

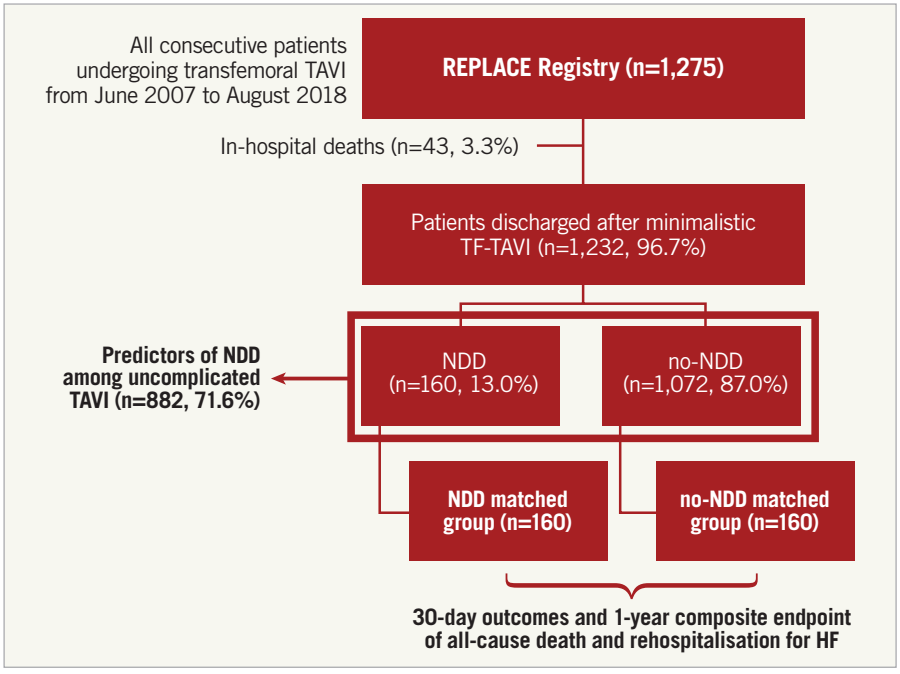


Figure 1. *Flow chart of study participants.*

and percentage. Comparisons were carried out using a Pearson's chi-square test and t-test for categorical and continuous variables, as appropriate. To adjust for potential bias in treatment assignment, two groups of patients with similar preprocedural characteristics were selected using propensity score (PS) matching with the nearest neighbour method using a non-parsimonious approach. Variables taken into account in the propensity score were: sex, age, body mass index (BMI), hypertension, severe renal impairment, chronic obstructive pulmonary disease (COPD), peripheral artery disease (PAD), prior PPI, Society of Thoracic Surgeons (STS) mortality score, echocardiographic left ventricle ejection fraction (EF) and computed tomography angiography (CTA) assessment. The standardised mean difference plot of PS matching is shown in **Supplementary Figure 1**. The matching algorithm used in this analysis is implemented in the PS Matching package, version 3.0.4 (IBM Corp., Armonk, NY, USA), whose details have been reported elsewhere. To account for the matched design, the baseline characteristics and the clinical outcomes after matching were analysed using Spearman's rank correlation and Mann-Whitney U tests between the two groups, as appropriate.

Two-step analysis was used to assess predicting factors. First, a single logistic regression was performed. Variables with a p-value <0.10 were entered into a multiple logistic regression analysis. The results were reported as odds ratio (OR) with a 95% confidence interval (CI).

All statistical tests were performed two-tailed, and a significance level of p<0.05 was considered to indicate statistical significance. The statistical software SPSS Statistics, Version 25.0 (IBM Corp.) was used for all statistical analyses.

CRITERIA FOR NEXT-DAY DISCHARGE

Patients were deemed suitable for an NDD strategy if they had: New York Heart Association (NYHA) Class ≤II; no chest pain attributable to cardiac ischaemia; no untreated major arrhythmias; no fever during the last 24 hours and no signs of an infectious cause; independent mobilisation and self-caring; preserved diuresis (>40 ml/hour during the preceding 24 hours); blood creatinine increase less than 0.3 mg/dL from baseline; stable haemoglobin in two consecutive samples (defined as a decrease of no more than 2 mg/dl); no PVL with aortic regurgitation less than moderate; no stroke/TIA; and no haemodynamic instability.

Results

From June 2007 to August 2018, 1,275 patients underwent TF-TAVI using different devices at our institution. For the purposes of the present analysis, 43 patients (3.3%) who died during the index hospitalisation were excluded from the study.

The study population comprised 1,232 consecutive patients discharged alive after TF-TAVI. Mean age was 80.9±5.4 years and the mean STS mortality score was 4.4±3.4%. TAVI was performed using either balloon-expandable (26.1%) or self-expanding (73.9%) TAVs. Baseline demographic, clinical, electrocardiographic, echocardiographic and preprocedural CTA characteristics of the entire population are summarised in **Table 1**. Data on the in-hospital length of stay (LoS) of the overall population across the study time period are presented in **Figure 2**.

One hundred and sixty patients (13.0%) were discharged within 24 hours after the procedure. At baseline, NDD patients had a lower incidence of prior stroke (1.3% vs 5.1%, p<0.01), pre-existing atrial fibrillation (AF) (12.6% vs 17.4%, p<0.05), and NYHA Classification III/IV (66.0% vs 74.8%, p<0.05), a higher incidence of prior pacemaker (PM) (16.4% vs 9.3%, p<0.05) and preprocedural computed tomography angiography (CTA) assessment (60.4% vs 44.8%, p<0.01), and a larger native aortic valve area (AVA) (0.7±0.2 vs 0.6±0.2 cm², p<0.01).

Table 1. Baseline characteristics of the entire all-comers population.

Baseline	Overall (n=1,232)	NDD (n=160)	no-NDD (n=1,072)	*p*-value
Age, years±SD	80.9±5.4	80.8±6.0	80.9±5.3	0.745
STS mortality, mean±SD	4.4±3.4	4.1±2.3	4.5±3.5	0.093
Female, n (%)	706 (57.3)	83 (52.2)	622 (58.0)	0.147
BMI, mean±SD	27.4±4.8	27.6±4.6	27.4±4.8	0.661
Hypertension, n (%)	1,060 (86.0)	134 (84.3)	925 (86.2)	0.428
Diabetes, n (%)	371 (30.1)	52 (32.7)	319 (29.7)	0.481
Prior PCI, n (%)	242 (19.6)	29 (18.2)	213 (19.9)	0.518
Prior CABG, n (%)	102 (8.3)	11 (6.9)	91 (8.5)	0.494
COPD, n (%)	312 (25.3)	34 (21.4)	278 (25.9)	0.214
Prior MI, n (%)	183 (14.8)	23 (14.5)	160 (14.9)	0.794
Prior stroke, n (%)	57 (4.6)	2 (1.3)	55 (5.1)	<0.010
Prior PPI, n (%)	126 (10.2)	26 (16.4)	100 (9.3)	0.018
Atrial fibrillation, n (%)	206 (16.7)	20 (12.6)	187 (17.4)	0.034
Severe renal impairment*, n (%)	176 (14.3)	18 (11.3)	159 (14.8)	0.138
NYHA Class III-IV, n (%)	909 (73.7)	105 (66.0)	803 (74.8)	0.025
Echo measurements				
LVEF, mean±SD	52.8±11.6	53.3±12.3	52.7±11.5	0.608
Mean aortic gradient, mean±SD	49.7±16.5	50.1±21.4	49.7±15.7	0.775
AVA, mean±SD, cm²	0.6±0.2	0.7±0.2	0.6±0.2	<0.010
More-than-mild MR, n (%)	422 (34.3)	49 (30.8)	373 (34.8)	0.289
More-than-mild TR, n (%)	295 (23.9)	32 (20.1)	263 (24.5)	0.184
Preprocedural CTA, n (%)	577 (46.8)	96 (60.4)	481 (44.8)	<0.010
Annulus perimeter, mean±SD, cm	7.3±1.1	7.2±1.4	7.3±1.0	0.499
Annulus area, mean±SD, cm²	4.2±0.9	4.2±1.0	4.2±0.8	0.991
Blood haemoglobin, mg/dL±SD	11.8±1.9	12.0±1.7	11.7±1.9	0.090

*GFR <30 ml/min according to the Cockcroft-Gault formula. AVA: aortic valve area; BMI: body mass index; CABG: coronary artery bypass grafting; COPD: chronic obstructive pulmonary disease; CTA: computed tomography angiography; LVEF: left ventricular ejection fraction; MI: myocardial infarction; MR: mitral regurgitation; NYHA: New York Heart Association; PCI: percutaneous coronary intervention; PPI: permanent pacemaker implantation; SD: standard deviation; STS: Society of Thoracic Surgeons; TR: tricuspid regurgitation

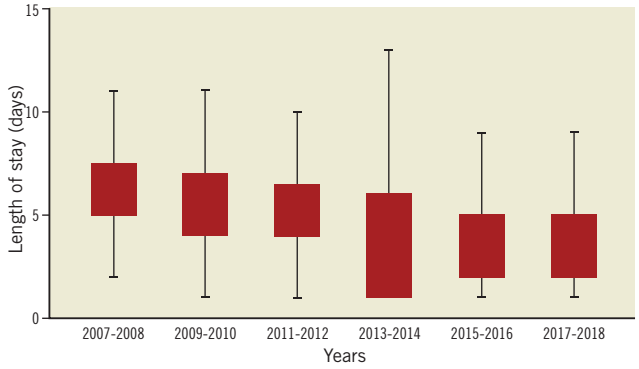


Figure 2. *Box plots of post-procedural length of stay (LoS) of the overall population across the study time period.*

All the baseline differences among NDD and no-NDD patients at baseline were resolved after propensity matching analysis **(Supplementary Table 1)**.

Procedural and in-hospital outcomes of the entire population are reported in **Table 2** and **Supplementary Table 2**, respectively. Data on transcatheter aortic valve use and NDD strategy across the study time period are presented in **Supplementary Figure 2**. Patients discharged at 24 hours after the procedure had a lower contrast volume usage (198±76 vs 217±88 ml, p=0.01). The ACURATE *neo*™ (Boston Scientific, Marlborough, MA, USA) valve was more frequently used in patients discharged within 24 hours (16.4% vs 8.9%, p=0.01), whereas the CoreValve® (Medtronic, Minneapolis, MN, USA) was used more frequently in those discharged later (26.4% vs 34.9%, p=0.02).

No cases of MI (0.0% vs 0.2%, p=0.51), disabling stroke (0.0% vs 0.7%, p<0.01) or major vascular complication (0.0% vs 10.5%, p<0.01) were reported among NDD patients.

Table 2. Procedural characteristics of the entire all-comers population.

Procedural	Overall (n=1,232)	NDD (n=160)	no-NDD (n=1,072)	*p*-value
Concomitant PCI, n (%)	74 (6.0)	12 (7.5)	62 (5.8)	0.834
Device success, n (%)	1,129 (91.7)	152 (95.0)	977 (91.2)	0.052
Contrast volume, ml±SD	214±86	198±76	217±88	0.012
TAV implanted				
Balloon-expandable TAVs, n (%)	321 (26.1)	43 (26.9)	278 (25.9)	0.786
Edwards SAPIEN XT, n (%)	132 (10.7)	13 (8.2)	118 (11.0)	0.233
Edwards SAPIEN 3, n (%)	189 (15.3)	29 (18.2)	160 (14.9)	0.263
Self-expanding TAVs, n (%)	911 (73.9)	117 (73.1)	794 (74.1)	0.786
Medtronic CoreValve, n (%)	416 (33.7)	42 (26.3)	374 (34.9)	0.019
Medtronic Evolut R, n (%)	315 (25.6)	37 (23.1)	278 (25.9)	0.550
Medtronic Evolut PRO, n (%)	38 (3.1))	8 (5.0)	30 (2.8)	0.385
Abbott Portico, n (%)	21 (1.7)	4 (2.5)	17 (1.6)	0.357
Boston ACURATE, n (%)	121 (9.8)	26 (16.2)	95 (8.9)	0.014

PCI: percutaneous coronary intervention; SD: standard deviation; TAV: transcatheter aortic valve

NDD patients showed lower rates of new-onset AF (3.8% vs 7.4%, p<0.01), PPI (2.3% vs 13.5%, p<0.01), AKI (2.5% vs 11.3%, p<0.01) and major or life-threatening bleeding (1.9% vs 20.2%, p<0.01).

The thirty-day outcomes of the entire population are reported in **Table 3**.

Table 3. 30-day outcomes of the entire all-comers population.

30-day outcomes	Overall (n=1,232)	NDD (n=160)	no-NDD (n=1,072)	*p*-value
All-cause death, n (%)	20 (1.6)	2 (1.2)	18 (1.7)	0.686
Cardiovascular death, n (%)	12 (1.0)	1 (0.6)	11 (1.0)	0.628
Myocardial infarction, n (%)	1 (0.1)	0 (0.0)	1 (0.1)	0.706
Disabling stroke, n (%)	11 (0.9)	0 (0.0)	11 (1.0)	<0.010
PPI*, n (%)	10 (0.8)	1 (0.6)	9 (0.8)	0.770
Rehospitalisation for HF, n (%)	14 (1.1)	0 (0.0)	14 (1.3)	<0.010
Echo measurements				
Mean gradient, mean±SD	8.9±4.7	7.9±4.0	9.0±4.8	<0.010
More-than-trace PR, n (%)	514 (41.7)	62 (39.0)	452 (42.2)	0.474

*PPI after discharge. HF: heart failure; PPI: permanent pacemaker implantation; PR: paravalvular regurgitation; SD: standard deviation

At 30 days, no differences in all-cause (1.2% vs 1.7%, p=0.69) and cardiovascular mortality (0.6% vs 1.0%, p=0.63), or PPI after discharge (0.6% vs 0.8%, p=0.77) were reported between the NDD and no-NDD cohorts. No cases of MI (0.0% vs 0.1%, p=0.71), disabling stroke (0.0% vs 1.0%, p<0.01) or HF rehospitalisation (0.0% vs 1.3%, p<0.01) were reported among NDD patients. Furthermore, patients discharged within 24 hours from TAVI showed a lower mean transvalvular gradient (7.9±4.0 vs 9.0±4.8 mmHg, p<0.01) at 30 days.

After propensity score-matching analysis, no difference regarding all-cause (1.2% vs 0.0% for NDD and no-NDD patients, respectively, p=0.16) and cardiovascular mortality (0.6% vs 0.0% for NDD and no-NDD patients, respectively, p=0.32) was reported between the two groups at 30 days. No cases of MI, disabling stroke or rehospitalisation for HF were reported for either group at 30 days. A trend towards lower rates of PPI after TAVI was observed in the NDD group (2.5% vs 6.9%, for NDD and no-NDD matched groups, respectively, p=0.06) **(Table 4)**.

At one year, no difference in all-cause mortality (6.3% vs 8.1%, p=0.52), stroke (0.6% vs 2.5%, p=0.18) or rehospitalisation for HF (2.5% vs 2.5%, p=1.00) was reported in the NDD and no-NDD matched groups **(Table 4)**. Survival analysis using the Kaplan-Meier (KM) method showed no difference in the composite endpoint of all-cause death and rehospitalisation for heart failure (KM estimates 91.9% vs 90.6% for NDD and no-NDD matched groups, respectively, $p_{log\text{-}rank}$=0.69) **(Figure 3)**.

After excluding patients with procedure-related complications (n=882; 71.6%), NDD patients had a lower incidence of

Table 4. 30-day and 1-year outcomes after propensity matching adjustment.

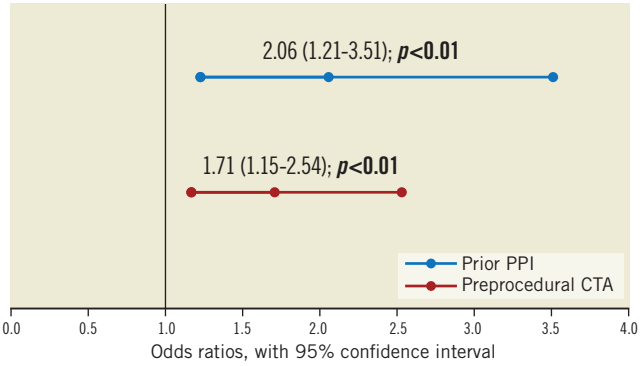
	Overall (n=320)	NDD (n=160)	no-NDD (n=160)	*p*-value
30-day matched outcomes				
All-cause death, n (%)	2 (0.6)	2 (1.2)	0 (0.0)	0.157
CV death, n (%)	1 (0.3)	1 (0.6)	0 (0.0)	0.317
Myocardial infarction, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	–
Disabling stroke, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	–
PPI*, n (%)	2 (1.2)	1 (0.6)	1 (0.6)	–
Rehospitalisation for HF, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	–
1-year matched outcomes				
All-cause death, n (%)	23 (7.2)	10 (6.3)	13 (8.1)	0.518
Any stroke, n (%)	5 (1.6)	1 (0.6)	4 (2.5)	0.177
Rehospitalisation for HF, n (%)	8 (2.5)	4 (2.5)	4 (2.5)	–

* PPI after discharge. CV: cardiovascular; HF: heart failure; PPI: permanent pacemaker implantation; SD: standard deviation

chronic obstructive pulmonary disease (COPD) (20.5% vs 28.4%, p<0.05), a higher incidence of prior PPI (16.4% vs 10.2%, p<0.05) and preprocedural CTA assessment (61.6% vs 40.8%, p<0.01), larger AVA (0.7±0.2 vs 0.6±0.2 cm^2, p<0.01) and higher values of haemoglobin at baseline (12.0±1.7 vs 11.6±1.9 mg/dL, p<0.05) **(Supplementary Table 3)**.

Logistic regression of baseline and procedural factors with NDD after TAVI considering patients without procedure-related complications is reported in **Supplementary Table 4**.

In a multivariate analysis, prior PPI (OR 2.06, 95% CI: 1.21-3.51, p<0.01) and preprocedural CTA assessment (OR 1.71, 95% CI: 1.15-2.54, p<0.01) were associated with discharge within 24 hours from the procedure in patients without procedural complications **(Figure 4)**.



	Univariate analysis, OR (CI)	*p*-value	Multivariate analysis, OR (CI)	*p*-value
Prior PPI	1.73 (1.05-2.85)	0.031	2.06 (1.21-3.51)	<0.01
Preprocedural CTA	2.34 (1.62-3.36)	<0.010	1.71 (1.15-2.54)	<0.01
Device success	2.53 (1.08-5.93)	0.033	1.42 (0.56-3.64)	0.46
Contrast volume (mL)	1.00 (0.99-1.00)	0.071	1.00 (0.99-1.00)	0.19
Prior stroke	0.42 (0.13-1.38)	0.153	0.54 (0.15-1.87)	0.33
More-than-mild MR	0.70 (0.48-1.04)	0.075	0.77 (0.49-1.20)	0.24
COPD	0.68 (0.44-1.06)	0.089	0.70 (0.42-1.16)	0.17
NYHA Class III-IV	0.72 (0.49-1.05)	0.086	0.75 (0.49-1.15)	0.19
Female sex	0.77 (0.54-1.10)	0.156	0.87 (0.57-1.32)	0.52
STS mortality score	0.96 (0.90-1.03)	0.234	1.00 (0.93-1.08)	0.97
Baseline Hb (mg/dL)	1.12 (1.02-1.24)	0.022	1.04 (0.92-1-17)	0.55
CoreValve TAV	0.48 (0.32-0-72)	<0.010	1.27 (0.74-2.19)	0.38
ACURATE *neo* TAV	2.14 (1.28-3.56)	<0.050	1.27 (0.70-2.29)	0.43

Figure 4. *Predictors of next-day discharge after TAVI among patients without procedure-related complications in an all-comers population.*

Discussion

To date, the majority of patients undergoing TAVI have been elderly and with many comorbidities; therefore, in most cases, a fast post-operative recovery was challenging to obtain. On the basis of the

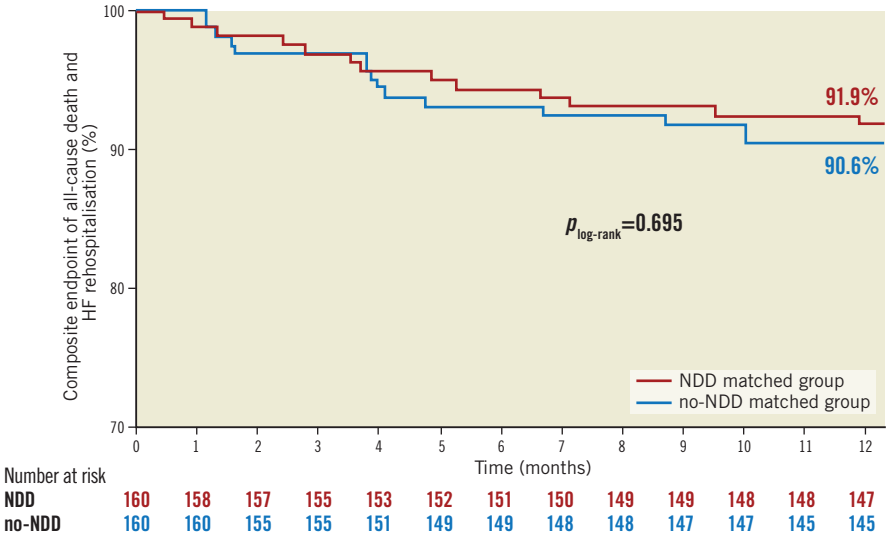


Figure 3. *Kaplan-Meier estimates of the composite endpoint of all-cause death and rehospitalisation for heart failure in NDD and no-NDD matched groups at one year.*

promising results of the latest trials in younger patients at low surgical risk, the indications for TAVI are expected to increase dramatically[1,2]. Hence, optimisation of the TAVI procedure and post-procedural pathways is an issue of paramount importance for the near future[5]. In recent years, the adoption of a minimalist approach (local anaesthesia and conscious sedation under fluoroscopic guidance) has permitted facilitating patients' mobilisation, shortening postoperative in-hospital stay, and reducing hospitalisation-related complications and costs[6,9-13]. Recently, two multicentre prospective trials assessed the safety and feasibility of early discharge of patients after TAVI, and an analysis from the Society of Thoracic Surgeons/American College of Cardiology (STS/ACC) Transcatheter Valve Therapy (TVT) registry reported a significant increase in mortality for patients with delayed discharge after TAVI[1,2,14].

The main findings of our study are as follows. First, early discharge within 24 hours following TF-TAVI using either balloon-expandable or self-expanding devices was feasible in an unselected, "all-comers" population, and was not associated with an increased risk of all-cause mortality or rehospitalisation for HF at one year. Second, among patients who did not experience procedure-related complications, those with prior PPI at baseline and who underwent preprocedural CTA assessment had a higher probability of being discharged within 24 hours.

Hospital stays after TAVI range from 3 to 11 days with an average LoS of at least 6 days in most contemporary trials and registries. The most frequent issues that usually prolong hospitalisations after TAVI are unnecessary prolonged immobilisation, bleeding, conduction disturbances, AKI, and the need for prolonged monitoring due to acute atrioventricular block which is by far the most important one. Early mobilisation promotes a rapid return to baseline status, reduces nosocomial complications, and decreases LoS in frail elderly patients. Several European and North American experiences, including ours, have demonstrated that discharge within 72 hours after TAVI in most of the patients did not compromise the safety of the procedure[3,12,13,15,16]. This analysis was meant to demonstrate that there is additional room for optimisation of the post-procedural period by discharging patients safely even the day after TAVI. The safety at 30 days of an NDD strategy after TAVI has already been explored in the 3M multicentre prospective trial and in a retrospective study by Kamioka et al. However, both studies included highly selected patients treated with a balloon-expandable TAV with a preprocedural CTA assessment, thus hiding a certain grade of selection in the patient population[12,13,15,17,18]. The results of the present study are important because the study included different TAVI devices and did not incorporate any selection criteria. Considering the overall population, at 30 days NDD patients showed similar rates of overall (1.2% vs 1.7%, p=0.69) and cardiovascular (0.6% vs 1.0%, p=0.63) mortality, MI (0.0% vs 0.1%, p=0.71) and PPI after discharge (0.6% vs 0.8%, p=0.77), and lower rates of disabling stroke (0.0% vs 1.0%, p<0.01) and HF rehospitalisation (0.0% vs 1.3%, p<0.01) compared to those discharged later. Nevertheless, these differences are probably related to the differences in baseline characteristics between the two cohorts. Indeed, after propensity-matching adjustment, an NDD strategy was not associated with an increased risk of overall (1.2% vs 0.0%, p=0.16) and cardiovascular mortality (0.6% vs 0.0%, p=0.32), stroke (0.0% vs 0.0%), pacemaker implantation (0.6% vs 0.6%) or rehospitalisation (0.0% vs 0.0%) at 30 days. At one year, an early discharge within 24 hours from the index procedure was confirmed to be a safe strategy, as no difference in the composite endpoint of all-cause death and rehospitalisation for HF was encountered ($p_{log\text{-}rank}$=0.69).

In our analysis, we also demonstrated that there was no correlation between using balloon-expandable (26.9% vs 25.9% for NDD and no-NDD patients, respectively) or self-expanding (73.1% vs 74.1% for NDD and no-NDD patients, respectively) devices for TAVI and NDD (p=0.79).

Analysing each TAV, although the ACURATE *neo* (16.4% vs 8.9%, p<0.05) and the CoreValve (26.4% vs 34.9%, p<0.05) were associated with NDD and no-NDD, respectively, neither of these devices was demonstrated to be an independent predictor of NDD after TAVI at multivariate analysis (p=0.43 and p=0.38, respectively). It might be hypothesised that the observed differences among TAVs simply reflect the tendency to shorten postoperative LoS during recent years **(Supplementary Figure 2)**[14]. In fact, the first-generation CoreValve was used at the beginning of our TAVI experience, when the procedure was less standardised and post-procedural management protocols more intensive, whereas the ACURATE *neo* was the latest device introduced in our practice, when TAVI had already become a streamlined and standardised procedure.

The majority of patients discharged within 24 hours after TAVI did not experience any procedure-related complications (n=146, 91.2%). In an exploratory analysis including only patients free from procedural complications, prior PPI and the presence of preprocedural CTA assessment were found to be predictors of NDD after TAVI.

This finding highlights the importance of pre-procedure planning with high-quality CTA, as it facilitates selecting the most suitable device considering the anatomy of the aortic root and iliofemoral vascular axes, thus permitting in particular a decrease in vascular complication rates[18].

The presence of prior PM implantation offers a protection in case of new-onset advanced atrioventricular disease block related to TAVI, avoiding the necessity of close rhythm monitoring after the procedure as well as additional immobilisation for PPI[19].

Finally, our study seems to support the feasibility and safety of shortening the LoS up to 24 hours after TAVI even for unselected patients. It also showed that pre-existing PM and preprocedural CTA assessment could help to identify patients who are eligible for this strategy. However, it has to be underlined that discharge timing in some European countries (e.g., Germany) actually clashes with the different reimbursement regimens of each national health system, as in many countries TAVI patients must stay hospitalised for an established minimum number of days after the procedure and therefore cannot benefit from the NDD strategy.

Limitations

The main limitation of our study lies in its single-centre, retrospective design with a relatively small sample size. Furthermore, the influence of unknown confounders cannot be excluded, despite propensity-matching adjustment.

Conclusions

A next-day discharge strategy for unselected patients after transfemoral TAVI was demonstrated to be a safe strategy in the absence of procedural complications. Patients with prior PPI at baseline and undergoing preprocedural CTA assessment had a higher chance of being discharged within 24 hours following the procedure. At one year, no difference in the composite endpoint of all-cause death and HF rehospitalisation was encountered between NDD and no-NDD matched groups.

Impact on daily practice

On the basis of the promising results of the latest trials on younger patients at low surgical risk, TAVI indications are expected to increase dramatically. Hence, optimisation of the TAVI procedure and post-procedural pathways is an issue of paramount importance for the near future. Recently, the multicentre, prospective 3M and FAST-TAVI trials assessed the safety and feasibility of early discharge (within three days) of selected patients after TAVI using a balloon-expandable device. In our study, we demonstrated that next-day discharge (NDD) of unselected patients undergoing minimalist, transfemoral TAVI is a safe strategy up to one year for those patients not experiencing procedural complications, regardless of the type of prosthesis implanted. Patients with a pre-existing PM at baseline and undergoing preprocedural CTA assessment had a higher chance of being discharged within 24 hours from the procedure.

Appendix. Study collaborators

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Conflict of interest statement

M. Barbanti is a consultant for Edwards Lifesciences and an advisory board member for Biotronik. C Tamburino has received speaker honoraria from Medtronic, Abbott Vascular, Edwards Lifesciences and Boston Scientific. The other authors have no conflicts of interest to declare.

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Supplementary data

Supplementary Figure 1. Standardised mean differences plot of variables included in propensity score matching.

Supplementary Figure 2. Data of transcatheter aortic valve use and next-day discharge (NDD) strategy across the study time period.

Supplementary Table 1. Baseline characteristics after propensity-matching adjustment.

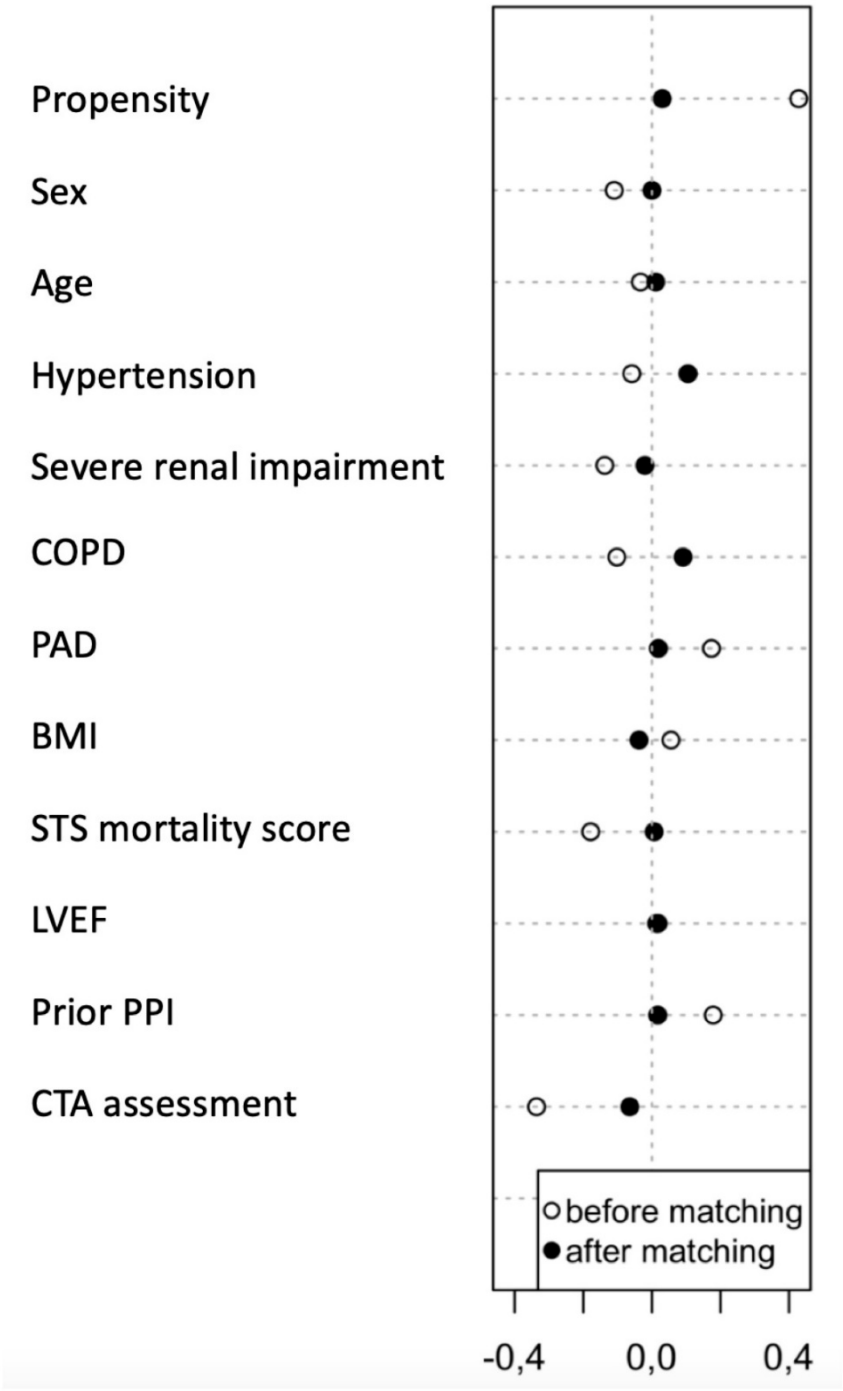
Supplementary Table 2. In-hospital outcomes of the entire all-comers population.

Supplementary Table 3. Baseline characteristics of patients who did not experience procedural complications.

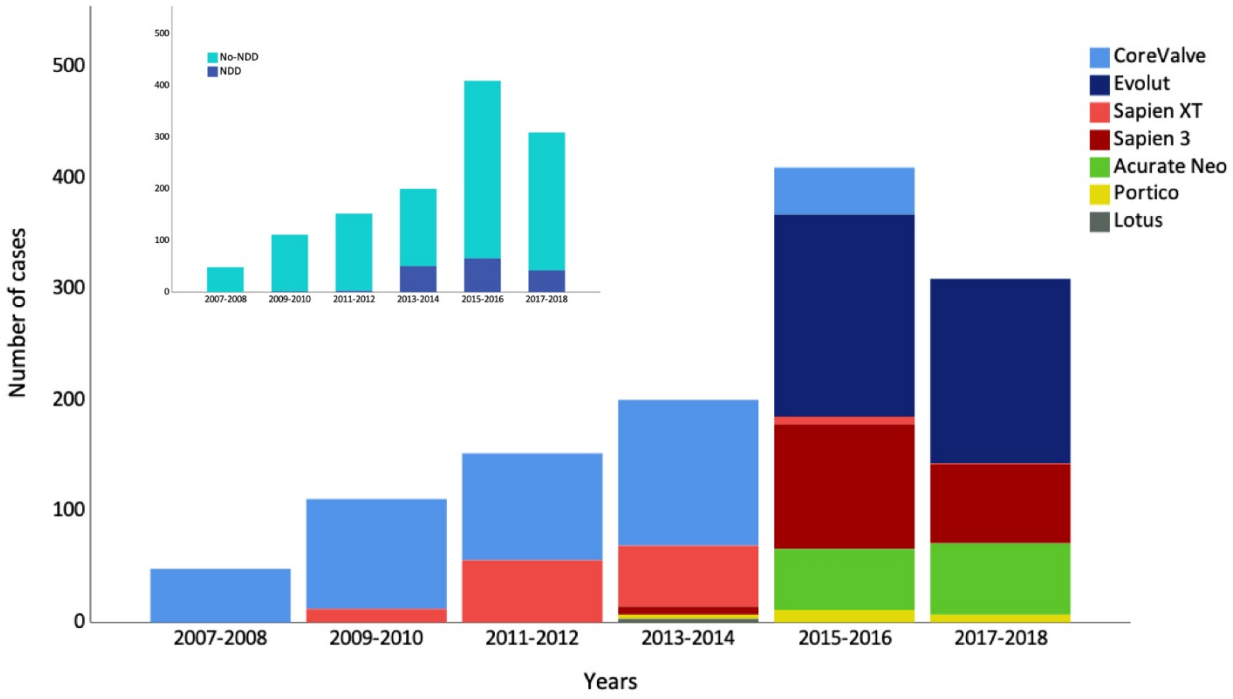
Supplementary Table 4. Logistic regression of baseline and procedural factors with next-day discharge after TAVI considering patients without procedure-related complications.

The supplementary data are published online at: https://eurointervention.pcronline.com/doi/10.4244/EIJ-D-19-01080

Supplementary data



Supplementary Figure 1. Standardised mean differences plot of variables included in propensity score matching.



Supplementary Figure 2. Data on transcatheter aortic valve use and next-day discharge (NDD) strategy across the study time period.

Supplementary Table 1. Baseline characteristics after propensity-matching adjustment.

Baseline	**Overall (n=320)**	**NDD (n=160)**	**no-NDD (n=160)**	***p*-value**
Age, years±SD	80.8±5.8	80.7±6.1	80.9±5.4	0.826
STS mortality, mean±SD	4.3±3.1	4.1±2.4	4.4±3.8	0.657
Female, n (%)	169 (52.8)	84 (52.5)	85 (53.1)	0.911
BMI, mean±SD	27.7±5.0	27.6±4.6	27.7±5.4	0.761
Hypertension, n (%)	270 (84.4)	136 (85.0)	134 (83.8)	0.759
Diabetes, n (%)	111 (34.7)	53 (33.1)	58 (36.3)	0.558
Prior MI, n (%)	51 (15.9)	23 (14.4)	28 (17.5)	0.447
Prior PPI, n (%)	58 (18.1)	26 (16.3)	32 (20.0)	0.386
Prior stroke, n (%)	8 (2.5)	3 (1.9)	5 (3.1)	0.475
Atrial fibrillation, n (%)	38 (11.9)	20 (12.5)	18 (11.3)	0.731
Severe renal impairment§, n (%)	36 (11.3)	17 (10.6)	19 (11.9)	0.724
NYHA Class III-IV, n (%)	220 (68.8)	108 (67.5)	112 (70.0)	0.631
Echo measurements				
LVEF, mean±SD	53.1±11.6	53.1±12.2	53.0±11.1	0.559
Preprocedural CTA, n (%)	196 (61.3)	98 (61.3)	98 (61.3)	-

§ GFR <30 ml/min according to the Cockcroft-Gault formula.

BMI: body mass index; CTA: computed tomography angiography; LVEF: left ventricular ejection fraction; MI: myocardial infarction; NYHA: New York Heart Association; SD: standard deviation; STS: Society of Thoracic Surgeons

Supplementary Table 2. In-hospital outcomes of the entire all-comers population.

In-hospital outcomes	**Overall (n=1,232)**	**NDD (n=160)**	**no-NDD (n=1,072)**	***p*-value**
Myocardial infarction, n (%)	2 (0.2)	0 (0.0)	2 (0.2)	0.513
Disabling stroke, n (%)	8 (0.6)	0 (0.0)	8 (0.7)	<0.01
PPI*, n (%)	134 (12.1)	3 (2.2)	131 (13.5)	<0.01
New-onset LBBB, n (%)	85 (6.9)	12 (7.5)	73 (6.8)	0.572
New-onset AF, n (%)	85 (6.9)	6 (3.8)	79 (7.4)	<0.01
Vascular complications				
Major, n (%)	113 (9.2)	0 (0.0)	113 (10.5)	<0.01
Minor, n (%)	107 (8.7)	20 (12.6)	88 (8.2)	0.096
Closure failure, n (%)	56 (4.5)	8 (5.0)	48 (4.5)	0.674
Bleeding				
Major or life-threatening, n (%)	220 (17.9)	3 (1.9)	217 (20.2)	<0.01
Minor, n (%)	87 (7.1)	9 (5.7)	78 (7.3)	0.511
Any AKI, n (%)	125 (10.1)	4 (2.5)	121 (11.3)	<0.01

* frequencies calculated among patients without prior pacemaker.

AF: atrial fibrillation; AKI: acute kidney injury; LBBB: left bundle branch block; PPI: permanent pacemaker implantation

Supplementary Table 3. Baseline characteristic of patients not experiencing procedural complications.

Baseline	**Overall (n=882)**	**NDD (n=146)**	**no-NDD (n=736)**	***p*-value**
Age, years±SD	80.9±5.3	80.8±6.0	81.0±5.1	0.801
STS mortality, mean±SD	4.3±3.3	4.0±2.2	4.3±3.6	0.111
Female, n (%)	500 (56.7)	75 (51.4)	425 (57.7)	0.156
BMI, mean±SD	27.3± 4.7	27.7±4.6	27.3±4.7	0.349
Hypertension, n (%)	746 (84.6)	123 (84.2)	623 (84.6)	0.873
Diabetes, n (%)	260 (29.5)	48 (32.9)	212 (28.8)	0.313
Prior PCI, n (%)	180 (20.4)	27 (18.5)	153 (20.8)	0.736
Prior CABG, n (%)	77 (8.7)	11 (7.5)	66 (9.0)	0.572
COPD, n (%)	239 (27.1)	30 (20.5)	209 (28.4)	0.049
Prior MI, n (%)	132 (15.0)	19 (13.0)	113 (15.5)	0.462
Prior stroke, n (%)	38 (4.3)	3 (2.1)	35 (4.8)	0.141
Prior PPI, n (%)	99 (11.2)	24 (16.4)	75 (10.2)	0.029
Atrial fibrillation, n (%)	143 (16.2)	19 (13.0)	124 (16.8)	0.391
Severe renal impairment§, n (%)	119 (13.5)	16 (11.0)	103 (14.0)	0.327
NYHA Class III-IV, n (%)	643 (72.9)	98 (67.1)	545 (74.0)	0.085
Echo measurements				
LVEF, mean±SD	52.3±11.9	53.4±11.7	52.1±11.9	0.223
Mean aortic gradient, mean±SD	50.4±16.8	50.5±21.8	50.3±15.7	0.897
AVA, mean±SD, cm²	0.6±0.2	0.7±0.2	0.6±0.2	0.003
More-than-mild MR, n (%)	317 (35.9)	43 (29.5)	274 (37.2)	0.074
More-than-mild TR, n (%)	218 (24.7)	29 (19.9)	189 (25.7)	0.137
Preprocedural CTA, n (%)	390 (44.2)	90 (61.6)	300 (40.8)	<0.01
Annulus perimeter, mean±SD, cm	7.3±1.2	7.2±1.4	7.3±1.1	0.254
Annulus area, mean±SD, cm²	4.3±0.9	4.2±1.0	4.3±0.9	0.582
Blood haemoglobin, mg/dL±SD	11.7±1.9	12.0±1.7	11.6±1.9	0.022

§ GFR <30 ml/min according to the Cockcroft-Gault formula.
AVA: aortic valve area; BMI: body mass index; CABG: coronary artery bypass grafting; COPD: chronic obstructive pulmonary disease; CTA: computed tomography angiography; LVEF: left ventricular ejection fraction; MI: myocardial infarction; MR: mitral regurgitation; NYHA: New York Heart Association; PCI: percutaneous coronary intervention; PPI: permanent pacemaker implantation; SD: standard deviation; STS: Society of Thoracic Surgeons; TR: tricuspid regurgitation

Supplementary Table 4. Logistic regression of baseline and procedural factors with next-day discharge after TAVI considering patients without procedure-related complications.

	Univariate analysis [OR (CI)]	*p*-value	Multivariate analysis [OR (CI)]	*p*-value
Prior PPI	1.73 (1.05-2.85)	0.031	2.06 (1.21-3.51)	<0.01
Preprocedural CTA	2.34 (1.62-3.36)	<0.01	1.71 (1.15-2.54)	<0.01
Device success	2.53 (1.08-5.93)	0.033	1.42 (0.56-3.64)	0.46
Contrast volume (mL)	1.00 (0.99-1.00)	0.071	1.00 (0.99-1.00)	0.19
Prior stroke	0.42 (0.13-1.38)	0.153	0.54 (0.15-1.87)	0.33
More-than-mild MR	0.70 (0.48-1.04)	0.075	0.77 (0.49-1.20)	0.24
COPD	0.68 (0.44-1.06)	0.089	0.70 (0.42-1.16)	0.17
NYHA III-IV	0.72 (0.49-1.05)	0.086	0.75 (0.49-1.15)	0.19
Female sex	0.77 (0.54-1.10)	0.156	0.87 (0.57-1.32)	0.52
STS mortality score	0.96 (0.90-1.03)	0.234	1.00 (0.93-1.08)	0.97
Baseline blood haemoglobin (mg/dL)	1.12 (1.02-1.24)	0.022	1.04 (0.92-1-17)	0.55
CoreValve TAV	0.48 (0.32-0-72)	<0.01	1.27 (0.74-2.19)	0.38
Acurate Neo TAV	2.14 (1.28-3.56)	<0.05	1.27 (0.70-2.29)	0.43

COPD: chronic obstructive pulmonary disease; CTA: computed tomography angiography; MR: mitral regurgitation; NYHA: New York Heart Association; PPI: permanent pacemaker implantation; STS: Society of Thoracic Surgery