jaa Just accepted article

EuroIntervention

Title: Predictors and Safety of Next-Day Discharge in Unselected Patients Undergoing Transfemoral Transcatheter Aortic Valve Implantation.

Authors: Giuliano Costa, M.D; Marco Barbanti, M.D; Andrea Picci, M.D; Denise Todaro, M.D; Ketty La Spina, M.D; Emanuela Di Simone, M.D; Paolo D'Arrigo, M.D; Enrico Criscione, M.D; Roberto Valvo, M.D; Claudia Reddavid, M.D; Wanda Deste, M.D; Carmelo Sgroi, M.D; Corrado Tamburino, M.D, PhD

DOI: 10.4244/EIJ-D-19-01080

Citation: Costa G, Barbanti M, Picci A, Todaro D, La Spina K, Di Simone E, D'Arrigo P, Criscione E, Valvo R, Reddavid C, Deste W, Sgroi C, Tamburino C. Predictors and Safety of Next-Day Discharge in Unselected Patients Undergoing Transfemoral Transcatheter Aortic Valve Implantation. *EuroIntervention* 2020; Jaa-738 2020, doi: 10.4244/EIJ-D-19-01080

Manuscript submission date: 03 December 2019

Revisions received: 29 January 2020, 17 February 2020

Accepted date: 20 February 2020

Online publication date: 25 February 2020

Predictors and Safety of Next-Day Discharge in Unselected Patients Undergoing Transfemoral Transcatheter Aortic Valve Implantation

Authors: Giuliano Costa, MD[1*], Marco Barbanti, MD[1*], Andrea Picci, MD[1], Denise Todaro, MD[1], Ketty La Spina, MD[1], Emanuela Di Simone, MD[1], Paolo D'Arrigo, MD[1], Enrico Criscione, MD[1], Roberto Valvo, MD[1], Claudia Reddavid, MD[1], Wanda Deste, MD[1], Carmelo Sgroi, MD[1], Corrado Tamburino, MD, PhD[1]

[1]Division of Cardiology, Policlinico-Vittorio Emanuele Hospital, C.A.S.T., University of Catania, Catania, Italy

*Giuliano Costa and Marco Barbanti equally contributed to this work.

***A list of study collaborators can be found in the appendix**

Short Title: Next-day discharge after TAVI in unselected patients

Corresponding author

Marco Barbanti, MD, email: mbarbanti83@gmail.com

Division of Cardiology, Policlinico-Vittorio Emanuele Hospital, University of Catania

Via Santa Sofia 78, Catania, Italy

ABSTRACT

Aim: To evaluate predictors and safety of next-day discharge (NDD) after transfemoral transcatheter aortic valve implantation (TF-TAVI) in unselected patients receiving either balloon- 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, and received either balloon-(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) and permanent pacemaker implantation (PPI) after TAVI (0.6% vs. 0.6%) were encountered at 30 days. At 1 year, no difference in composite endpoint of all-cause death and heart failure (HF) rehospitalization was encountered (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 pre-procedural computed tomography angiography (CTA) (OR:1.71; 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- or self-expanding devices demonstrated to be a safe strategy up to 1 year in absence of procedural complications. Patients with prior PPI and undergoing pre-procedural CTA had a higher chance of NDD.

CONDENSED ABSTRACT

From June 2007 to August 2018, 1,232 consecutive, intermediate-risk patients undergoing TF-TAVI were discharged alive from our Institution. They received either balloon- (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. NDD in unselected patients after TF-TAVI using either balloon- or self-expanding devices demonstrated to be a safe strategy up to 1 year in absence of procedural complications. Patients with prior PPI and undergoing pre-procedural CTA had a higher chance of NDD.

CLASSIFICATIONS: femoral, TAVI, no complication

ABBREVIATIONS: AS, Aortic Stenosis; TAVI, Transcatheter Aortic Valve Implantation; TAV, Transcatheter Aortic Valve; NDD, Next-day discharge; PPI, Permanent Pacemaker Implantation; CTA: Computed Tomography Angiography

INTRODUCTION

The PARTNER 3 and Evolut R Low Risk randomized trials established the role of transcatheter aortic valve implantation (TAVI) alongside to 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, bioprostheses durability and patients' preference remain the main factors in decision-making process on the treatment of severe AS in elderly patients. In recent years some groups have been working on local programs, which incorporated specific pre-, peri- 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 optimize the TAVI procedure without compromising its safety, to accelerate patient's recovery and mobilization after the procedure and to minimize unnecessary use of medical resources [3–7].

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

METHODS

This is a single-center, retrospective analysis obtained from a prospective local TAVI registry. All consecutive patients undergoing transfemoral TAVI in our institution were included. TAVI procedures were all performed using a minimalistic approach, under local anaesthesia and using only an angiographic guidance with back-up transthoracic echocardiogram. Transthoracic echocardiographic evaluation was performed immediately after the procedure and before the discharge. Patients who died during the index hospitalization 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 categorized in 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 1-year composite outcome of all-cause death and rehospitalization for heart failure (HF) of NDD and no-NDD matched groups.

Second, we assessed predictors of NDD among patients not experiencing peri-procedural and in-hospital major or life-threatening complications, including in-hospital myocardial infarction, stroke or transient ischemic 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 Valve Academic Research Consortium-2 definitions [8]. Study participant flow was reported in **Figure 1**.

Continuous variables were reported as mean ± standard deviation (SD) whereas dichotomous parameters as frequencies and percentage. Comparisons were made 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 pre-procedural 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 permanent pacemaker implantation (PPI), Society of thoracic surgeons (STS) mortality score, echocardiographic left ventricle ejection fraction (EF) and computed tomography angiography (CTA) assessment. The standardized mean difference plot of PS matching was reported in **Supplementary Figure 1**. The matching algorithm used in this analysis is implemented in the PS Matching package (IBM SPSS Statistics, USA, vers. 3.0.4) whose details have been reported elsewhere. To account for the matched design, the baseline characteristics and the clinical outcomes after matching were analysed using the Spearman's rank correlation and Mann-Whitney U tests among the three 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 entered a multiple logistic regression analysis. 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 IBM SPSS Statistics 25.0 was used for all statistical analyses.

Criteria for next-day discharge

Patients were deemed suitable for a next-day discharge strategy if they had: 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 mobilization 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. For the purposes of the present analysis, 43 patients (3.3%) who died during the index hospitalization 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- (26.1%) or self-expanding (73.9%) TAVs. Baseline demographic, clinical, electrocardiographic, echocardiographic and pre-procedural CTA characteristics of the entire

population are summarized in **Table 1**. Data of in-hospital length of stay (LoS) of overall population across study time-period are presented in **Figure 2**.

One hundred-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), NYHA classification III/IV (66.0% vs. 74.8%, p<0.05), higher incidence of prior pacemaker (PM) (16.4% vs. 9.3%, p<0.05), pre-procedural computed tomography angiography (CTA) assessment (60.4% vs. 44.8%, p<0.01) and larger native aortic valve area (AVA) (0.7±0.2 vs 0.6±0.2 mmHg, p <0.01).

All the baseline differences among NDD and no-NDD patients at baseline were solved 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 of transcatheter aortic valves' use and next-day discharge (NDD) strategy across 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 Boston Acurate Neo valve was more frequently used in patients discharged within 24 hours (16.4% vs. 8.9%, p=0.01), whereas Medtronic CoreValve was used more frequently in those discharged later (26.4% vs. 34.9%, p=0.02).

No cases of myocardial infarction (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.

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

Thirty days outcomes of the entire population are reported in **Table 3**.

At 30-day, no differences in all-cause (1.2% vs. 1.7%, p=0.69) and cardiovascular mortality (0.6% vs. 1.0%, p=0.63), and PPI after the discharge (0.6% vs. 0.8%, p=0.77) were reported between

NDD and no-NDD cohorts. No cases of myocardial infarction (0.0% vs. 0.1%, p=0.71), disabling stroke (0.0% vs. 1.0%, p<0.01) or HF rehospitalization (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 myocardial infarction, disabling stroke and rehospitalization for HF were reported for both groups 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, NDD and no-NDD matched groups reported no difference in all-cause mortality (6.3% vs. 8.1%, p=0.52), stroke (0.6% vs. 2.5%, p=0.18) and rehospitalization for HF (2.5% vs. 2.5%, p=1.00) (**Table 4**). Survival analysis using Kaplan-Meier method showed no difference in the composite endpoint of all-cause death and rehospitalization 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 chronic obstructive pulmonary disease (COPD) (20.5% vs. 28.4%, p<0.05), higher incidence of prior PPI (16.4% vs. 10.2%, p<0.05) and pre-procedural CTA assessment (61.6% vs. 40.8%, p<0.01), larger AVA (0.7±0.2 vs 0.6±0.2 mmHg, 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.**

At a multivariate analysis, prior PPI (OR 2.06 [CI 1.21-3.51], p<0.01) and pre-procedural CTA assessment (OR 1.71 [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**).

DISCUSSION

To date, the majority of patients undergoing TAVI was such aged and with many comorbidities that in most cases a fast post-operative recovery was challenging to obtain. On the basis of the promising results of latest trials on younger patients at low surgical risk, TAVI indications are expected to increase dramatically [1,2]. Hence, optimization of TAVI procedure and post-procedural pathways is an issue of paramount importance for the upcoming future [5]. In the last years, the adoption of a minimalistic approach (local anaesthesia and conscious sedation under fluoroscopic guidance) has permitted to facilitate patients' mobilization, to shorten post-operative in-hospital stay, and to reduce hospitalization-related complications and costs [6,9–13]. Recently, two multicenter 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: first, early discharge within 24 hours following transfemoral TAVI using either balloon- or self-expanding devices was feasible in an unselected, "all-comers" population, and was not associated with an increased risk of all-cause mortality and rehospitalization for HF at one year; second, among patients not experiencing procedure-related complications, those with prior PPI at baseline and undergoing pre-procedural CTA assessment had a higher probability to be 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 hospitalizations after TAVI are: unnecessary prolonged immobilization, bleeding, conduction disturbances, and acute kidney injury, being the need for prolonged monitoring due to acute atrio-ventricular block by far the most important one. Early mobilization promotes rapid return to baseline status, reduces nosocomial complications, and decreases length of stay in the frail elderly. Several European and North American experiences, including ours, demonstrated that discharge within 72 hours after

TAVI in most of the patients did not preclude the safety of the procedure [3,12,13,15,16]. This analysis was meant to demonstrate that there is additional room for an optimization of the post-procedural period by discharging safely patients even the day after TAVI. The safety at 30 days of next-day discharge strategy after TAVI has been already explored in the 3M multicenter prospetive 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 pre-procedural CTA assessment, thus hiding a certain grade of selection in patients population [12,13,15,17,18]. The results of the present study are important because it included different TAVI devices and does not incorporate any selection criteria. Considering the overall population, 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 the 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 rehospitalization (0.0% vs. 1.3%, p<0.01) compared to those discharged later at 30 days. Nevertheless, these differences are probabily related to the differences in baseline characteristics between the two cohorts. Indeed, after propensity matching adjustment 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%) and re-hospitalisation (0.0% vs. 0.0%) at 30 days. At 1-year, an early discharge within 24 hours from the index procedure confirmed to be a safe strategy, as no difference in the composite endpoint of all-cause death and re-hospitalization for HF was encoutered ($p_{log\text{-}rank}$=0.69). In our analysis, we also demonstrated that there was no correlation between using balloon- (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 next-day discharge (p=0.79). Analysing each TAV, although Acurate Neo (16.4% vs. 8.9%, p<0.05) and CoreValve (26.4% vs. 34.9%, p<0.05) were associated with NDD and no-NDD respectively, none of these devices demonstrated to be an indipedent predictor of next day discharge after TAVI at multivariate analysis (p=0.43 and p=0.38, respectively). It might be hypothesized that observed differences

among TAVs simply reflect the tendency to shorten post-operative length of stay (LoS) during latest years **(Supplementary Figure 2)** [14]. In fact, first generation CoreValve was used at the beginning of our TAVI experience, when the procedure was less standardized and post-procedural management protocols more intensive, whereas Acurate Neo was the last device introduced in our practice, when TAVI had already become a streamlined and standardized procedure.

The majority of patients discharged within 24 hours from 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 pre-procedural CTA assessment were found to be predictors of next-day discharge after TAVI.

This finding higlights the importance of preprocedure planning with high-quality CTA, as it allows to choose the most suitable device considering the anatomies of aortic root and ileo-femoral vascular axes, thus permitting in particular to decrease vascular complication rates [18].

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

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

Limitations

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

CONCLUSIONS

Next-day discharge strategy for unselected patients after transfemoral TAVI demonstrated to be a safe strategy in absence of procedural complications. Patients with prior PPI at baseline and undergoing pre-procedural CTA assessment had a higher chance to be discharged within 24 hours from the procedure. At 1 year, no difference in the composite endpoint of all-cause death and HF rehospitalization was encountered between NDD and no-NDD matched groups.

FUNDING

None.

APPENDIX

Collaborators:

Angelo Giuffrida, MD (Division of Cardiac Surgery, Policlinico-Vittorio Emanuele Hospital, C.A.S.T., University of Catania, Catania, Italy)

Valeria Garretto, MD; Gianbattista Privitera, MD; Maria Teresa Cannizzaro, MD; Cristina Inserra, MD (Division of Radiology, Policlinico-Vittorio Emanuele Hospital, C.A.S.T., Catania, Italy)

Pierfrancesco Veroux, PhD (Division of Vascular Surgery, Policlinico-Vittorio Emanuele Hospital, C.A.S.T., University of Catania, Catania, Italy)

DISCLOSURES

Marco Barbanti is consultant for Edwards Lifesciences and is an advisory board member for Biotronik. Corrado Tamburino received speaker honoraria from Medtronic, Abbott Vascular, Edwards Lifesciences and Boston Scientific. All other authors have no conflict of interest to declare.

IMPACT ON DAILY PRACTICE

On the basis of the promising results of latest trials on younger patients at low surgical risk, TAVI indications are expected to increase dramatically. Hence, optimization of TAVI procedure and post-procedural pathways is an issue of paramount importance for the upcoming future.

Recently, multicenter, prospective 3M and FAST-TAVI trials assessed the safety and feasibility of early discharge (within 3 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 minimalistic, transfemoral TAVI is a safe strategy up to 1 year for those patients not experiencing procedural complications, regardless the type of the prosthesis implanted. Patients with a pre-existing PM at baseline and undergoing pre-procedural CTA assessment had a higher chance to be discharged within 24 hours from the procedure.

Table 1. Baseline characteristics of entire all-comers population

Baseline	**Overall (n=1232)**	**NDD (n=160)**	**N-NDD (n=1072)**	**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(%)	1060(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)	<0.01
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 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	0.6±0.2	0.7±0.2	0.6±0.2	<0.01
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

Pre-procedural CTA, n(%)	577(46.8)	96(60.4)	481(44.8)	<0.01
Annulus Perimeter, mean±SD	7.3±1.1	7.2±1.4	7.3±1.0	0.499
Annulus Area, mean±SD	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

Abbreviations: STS, Society of Thoracic Surgery; **BMI**, Body Mass Index; **PCI,** Percutaneous Coronary; **CABG,** Coronary Artery Bypass Grafting; **COPD**, Chronic Obstructive Pulmonary Disease; **MI,** Myocardial Infarction; **PPI,** Pacemaker Implantation; **NYHA,** New York Heart Association; **LVEF,** Left Ventricular Ejection Fraction; **AVA**, Aortic Valve Area; **MR**, Mitral Regurgitation; **TR**, Tricuspid Regurgitation; **CTA,** Computed Tomography Angiography; **SD**, Standard Deviation

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

Table 2. Procedural characteristics of entire all-comers population

Procedural	**Overall (n=1232)**	**NDD (n=160)**	**N-NDD (n=1072)**	**p-value**
Concomitant PCI, n (%)	74(6.0)	12(7.5)	62(5.8)	0.834
Device success, n (%)	1129(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-expandable TAVs, n(%)	911(73.9)	117(73.1)	794(74.1)	0.786
Medtronic CoreValve, n(%)	416(33.7)	42(26.4)	374(34.9)	0.019
Medtronic Evolut R, n(%)	314(25.5)	37(23.2)	278(25.8)	0.550
Medtronic Evolut PRO, n(%)	30(2.5)	5(3.1)	25(2.3)	0.595
Abbott Portico, n(%)	21(1.7)	4(2.5)	17(1.6)	0.357
Boston Acurate, n(%)	121(9.8)	26(16.4)	95(8.9)	0.014

Abbreviations: PCI, Percutaneous Coronary; **TAV,** Transcatheter Aortic Valve; **SD**, Standard Deviation

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

30-day outcomes	**Overall (n=1232)**	**NDD (n=160)**	**N-NDD (n=1072)**	**p-value**
All-cause death, n(%)	17(1.4)	2(1.2)	18(1.7)	0.686
Cardiovascular death, n(%)	10(0.8)	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)	<0.01
PPI*, n(%)	10(0.8)	1(0.6)	9(0.8)	0.77
Rehospitalization for HF, n(%)	14(1.1)	0(0.0)	14(1.3)	<0.01
Echo measurements				
Mean Gradient, mean±SD	8.9±4.7	7.9±4.0	9.0±4.8	<0.01
More-than-trace PR, n(%)	514(41.7)	62 (39.0)	452 (42.2)	0.474

Abbreviations: PPI, Pacemaker Implantation; **HF,** Heart Failure, **PR,** ParaValvular Regurgitation; **SD**, Standard Deviation

*PPI after discharge

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

	Overall (n=320)	**NDD (n=160)**	**N-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)	-
Rehospitalization 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
Rehospitalization for HF, n(%)	8(2.5)	4(2.5)	4(2.5)	-

Abbreviations: CV, CardioVascular**; PPI,** Pacemaker Implantation; **HF,** Heart Failure; **SD**, Standard Deviation

*PPI after discharge

FIGURE LEGENDS

Figure 1. Participants flow

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

Figure 3. Kaplan-Meier estimates of the composite endpoint of all-cause death and rehospitalization for heart failure in NDD and no-NDD matched groups at 1 year.

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

REFERENCES

1. Mack MJ, Leon MB, Thourani VH, Makkar R, Kodali SK, Russo M, Kapadia SR, Malaisrie SC, Cohen DJ, Pibarot P, Leipsic J, Hahn RT, Blanke P, Williams MR, McCabe JM, Brown DL, Babaliaros V, Goldman S, Szeto WY, Genereux P, Pershad A, Pocock SJ, Alu MC, Webb JG, Smith CR. Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients. *N Engl J Med*. 2019;380:1695–705.
2. Popma JJ, Michael Deeb G, Yakubov SJ, Mumtaz M, Gada H, O'Hair D, Bajwa T, Heiser JC, Merhi W, Kleiman NS, Askew J, Sorajja P, Rovin J, Chetcuti SJ, Adams DH, Teirstein PS, Zorn GL, Forrest JK, Tchétché D, Resar J, Walton A, Piazza N, Ramlawi B, Robinson N, Petrossian G, Gleason TG, Oh JK, Boulware MJ, Qiao H, Mugglin AS, Reardon MJ. Transcatheter aortic-valve replacement with a self-expanding valve in low-risk patients. *N Engl J Med*. 2019;380:1706–15.
3. Barbanti M, Capranzano P, Ohno Y, Attizzani GF, Gulino S, Immè S, Cannata S, Aruta P, Bottari V, Patanè M, Tamburino C, Di Stefano D, Deste W, Giannazzo D, Gargiulo G, Caruso G, Sgroi C, Todaro D, Di Simone E, Capodanno D, Tamburino C. Early discharge after transfemoral transcatheter aortic valve implantation. *Heart*. 2015;101:1485–90.
4. Olsen SJ, Fridlund B, Eide LS, Hufthammer KO, Kuiper KK, Nordrehaug JE, Skaar E, Norekvål TM. Changes in self-reported health and quality of life in octogenarian patients one month after transcatheter aortic valve implantation. *Eur J Cardiovasc Nurs*. 2017;16:79–87.
5. Barbanti M, Gulino S, Costa G, Tamburino C. Optimization and simplification of transcatheter aortic valve implantation therapy. *Expert Rev Cardiovasc Ther*. 2018;16.
6. Awad W, Mathur A, Baldock L, Oliver S, Kennon S. Comparing post-operative resource consumption following transcatheter aortic valve implantation (TAVI) and conventional aortic valve replacement in the UK. *J Med Econ*. 2014;17:357–64.
7. Rathore S, Latyshev Y, Emore S, Rowe J, Foerst J. Safety and predictors of next-day discharge after elective transfemoral transcatheter aortic valve replacement. *Cardiovasc*

Revascularization Med. 2017;18:583–7.

8. Pieter Kappetein A, Head SJ, Généreux P, Piazza N, Van Mieghem NM, Blackstone EH, Brott TG, Cohen DJ, Cutlip DE, Van Es GA, Hahn RT, Kirtane AJ, Krucoff MW, Kodali S, Mack MJ, Mehran R, Rodés-Cabau J, Vranckx P, Webb JG, Windecker S, Serruys PW, Leon MB. Updated standardized endpoint definitions for transcatheter aortic valve implantation: The Valve Academic Research Consortium-2 consensus document. *EuroIntervention*. 2012;8:782–95.
9. Reynolds MR, Magnuson EA, Wang K, Lei Y, Vilain K, Walczak J, Kodali SK, Lasala JM, O'Neill WW, Davidson CJ, Smith CR, Leon MB, Cohen DJ. Cost-Effectiveness of Transcatheter Aortic Valve Replacement Compared With Standard Care Among Inoperable Patients With Severe Aortic Stenosis: Results From the Placement of Aortic Transcatheter Valves (PARTNER) Trial (Cohort B). *Circulation*. 2012;125:1102–9.
10. Reynolds MR, Magnuson EA, Lei Y, Wang K, Vilain K, Li H, Walczak J, Pinto DS, Thourani VH, Svensson LG, Mack MJ, Miller DC, Satler LE, Bavaria J, Smith CR, Leon MB, Cohen DJ. Cost-Effectiveness of Transcatheter Aortic Valve Replacement Compared With Surgical Aortic Valve Replacement in High-Risk Patients With Severe Aortic Stenosis. *J Am Coll Cardiol*. 2012;60:2683–92.
11. Attizzani GF, Alkhalil A, Padaliya B, Tam C-C, Lopes JP, Fares A, Bezerra HG, Medallion B, Park S, Deo S, Sareyyupoglu B, Parikh S, Zidar D, Elgudin Y, Popovich K, Davis A, Staunton E, Tomic A, Mazzurco S, Avery E, Markowitz A, Simon DI, Costa MA. Comparison of Outcomes of Transfemoral Transcatheter Aortic Valve Implantation Using a Minimally Invasive Versus Conventional Strategy. *Am J Cardiol*. 2015;116:1731–6.
12. Barbanti M, van Mourik MS, Spence MS, Icovelli F, Martinelli GL, Muir DF, Saia F, Bortone AS, Densem CG, van der Kley F, Bramlage P, Vis M, Tamburino C. Optimising patient discharge management after transfemoral transcatheter aortic valve implantation: the multicentre European FAST-TAVI trial. *EuroIntervention*. 2019;15:147–54.

13. Wood DA, Lauck SB, Cairns JA, Humphries KH, Cook R, Welsh R, Leipsic J, Genereux P, Moss R, Jue J, Blanke P, Cheung A, Ye J, Dvir D, Umedaly H, Klein R, Rondi K, Poulter R, Stub D, Barbanti M, Fahmy P, Htun N, Murdoch D, Prakash R, Barker M, Nickel K, Thakkar J, Sathananthan J, Tyrell B, Al-Qoofi F, Velianou JL, Natarajan MK, Wijeysundera HC, Radhakrishnan S, Horlick E, Osten M, Buller C, Peterson M, Asgar A, Palisaitis D, Masson J-B, Kodali S, Nazif T, Thourani V, Babaliaros VC, Cohen DJ, Park JE, Leon MB, Webb JG. The Vancouver 3M (Multidisciplinary, Multimodality, But Minimalist) Clinical Pathway Facilitates Safe Next-Day Discharge Home at Low-, Medium-, and High-Volume Transfemoral Transcatheter Aortic Valve Replacement Centers. *JACC Cardiovasc Interv*. 2019;12:459–69.

14. Wayangankar SA, Elgendy IY, Xiang Q, Jneid H, Vemulapalli S, Khachatryan T, Pham D, Hilliard AA, Kapadia SR. Length of Stay After Transfemoral Transcatheter Aortic Valve Replacement. *JACC Cardiovasc Interv*. 2019;12:422–30.

15. Kamioka N, Wells J, Keegan P, Lerakis S, Binongo J, Corrigan F, Condado J, Patel A, Forcillo J, Ogburn L, Dong A, Caughron H, Simone A, Leshnower B, Devireddy C, Mavromatis K, Guyton R, Stewart J, Thourani V, Block PC, Babaliaros V. Predictors and Clinical Outcomes of Next-Day Discharge After Minimalist Transfemoral Transcatheter Aortic Valve Replacement. *JACC Cardiovasc Interv*. 2018;11:107–15.

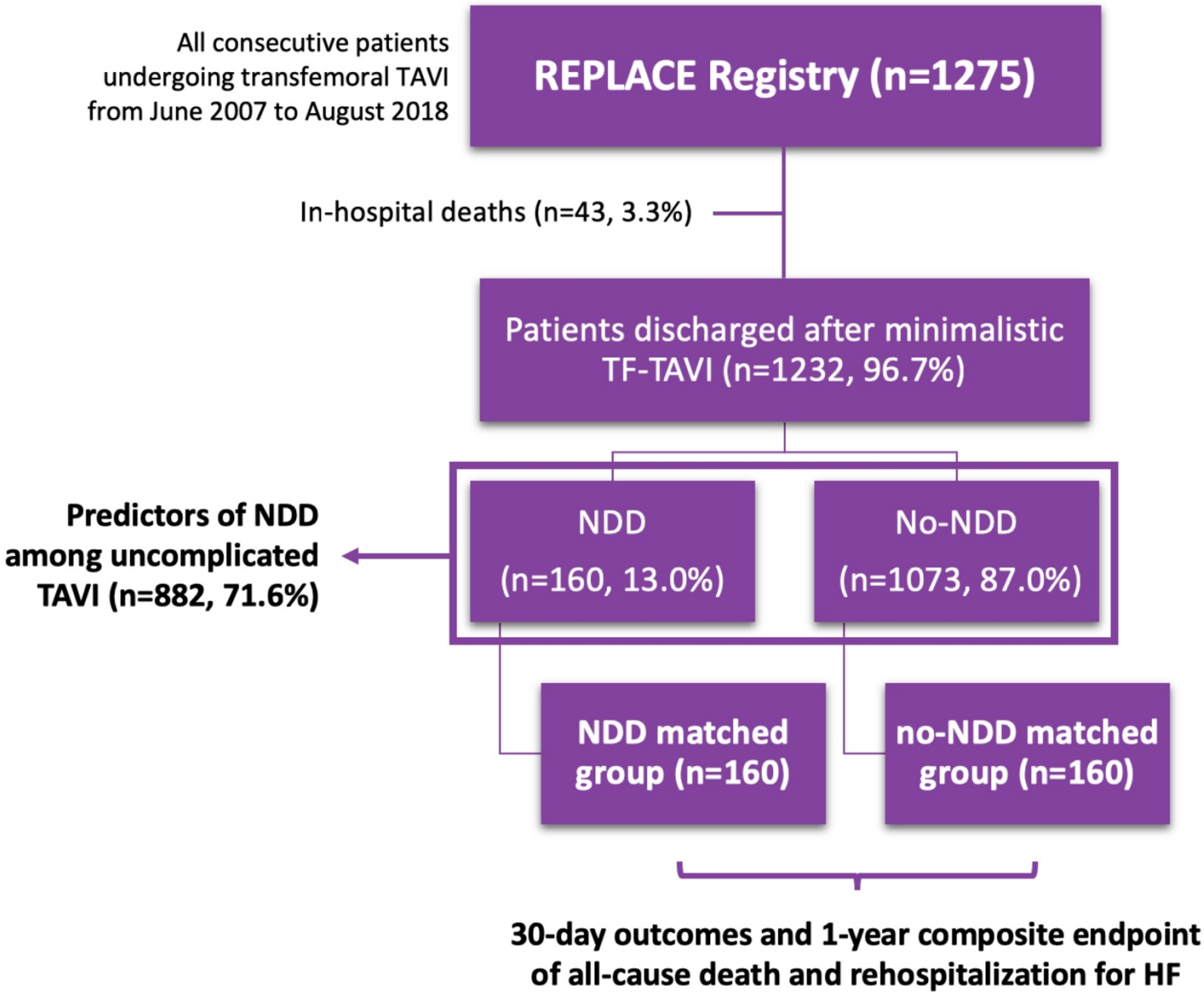
16. Durand E, Eltchaninoff H, Canville A, Bouhzam N, Godin M, Tron C, Rodriguez C, Litzler PY, Bauer F, Cribier A. Feasibility and safety of early discharge after transfemoral transcatheter aortic valve implantation with the Edwards SAPIEN-XT prosthesis. *Am J Cardiol*. 2015;115:1116–22.

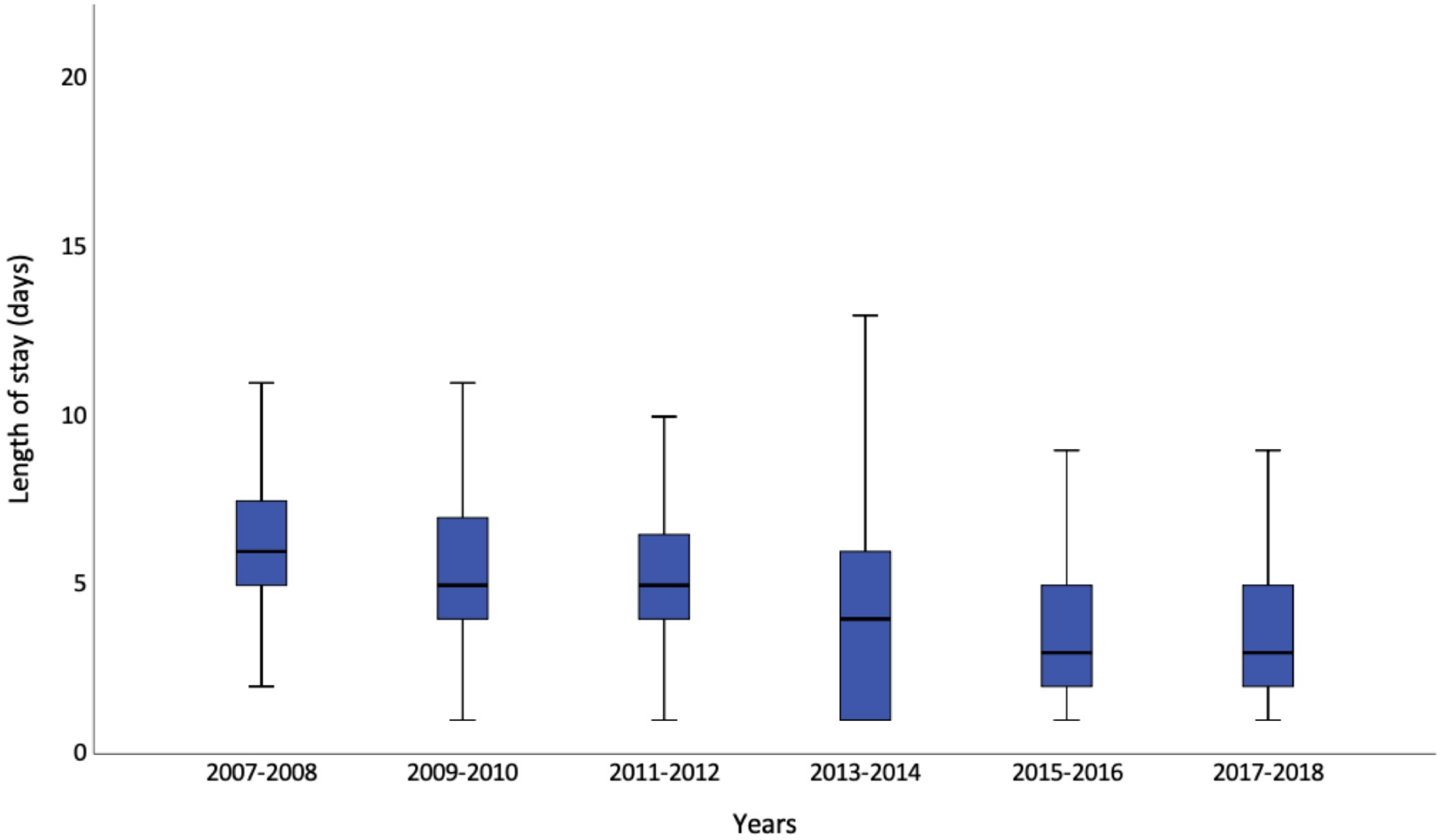
17. Kotronias RA, Teitelbaum M, Webb JG, Mylotte D, Barbanti M, Wood DA, Ballantyne B, Osborne A, Solo K, Kwok CS, Mamas MA, Bagur R. Early Versus Standard Discharge After Transcatheter Aortic Valve Replacement. *JACC Cardiovasc Interv*. 2018;11:1759–71.

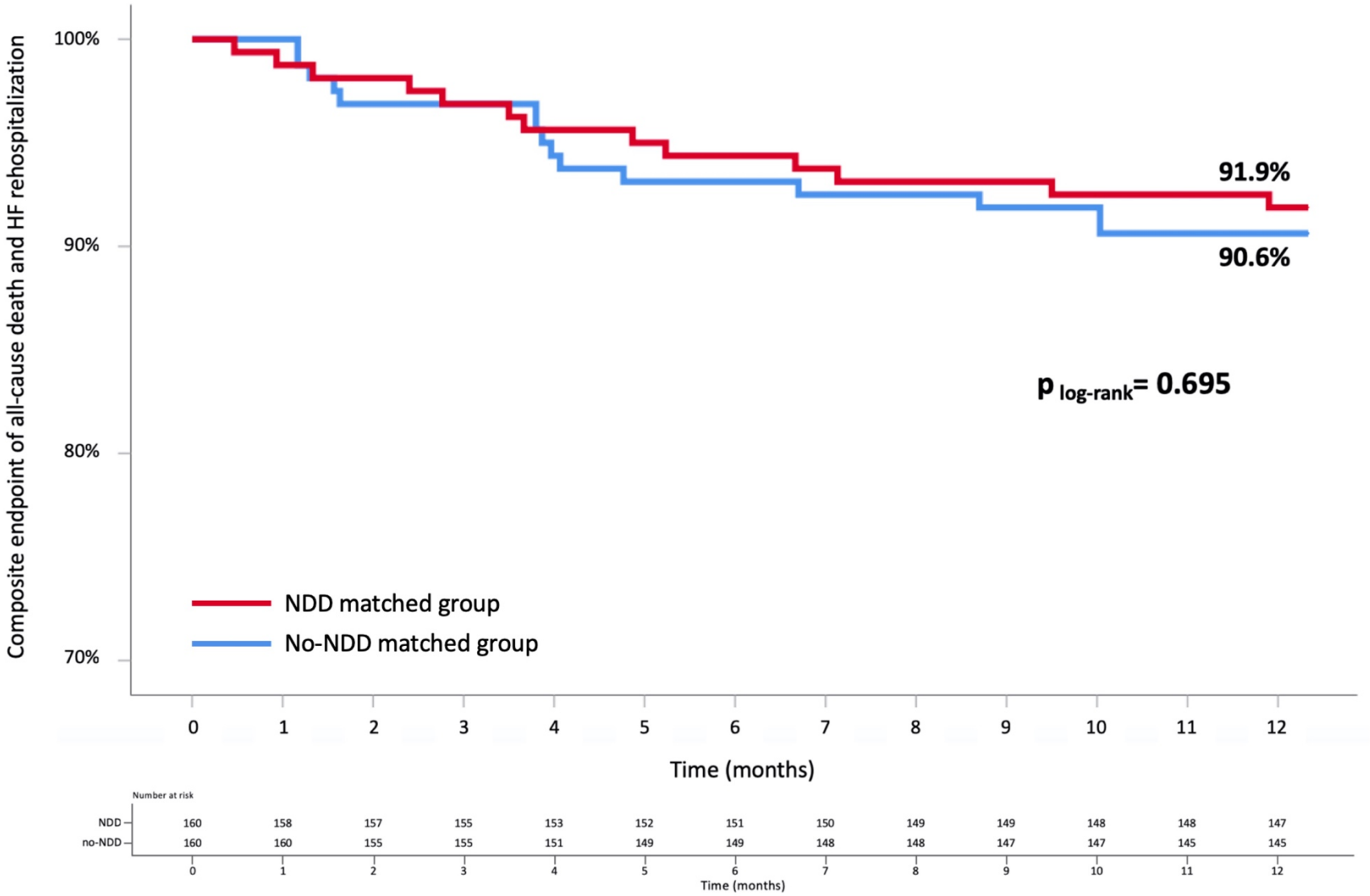
18. Alkhouli M, Winkler L, Tallaksen RJ. Computed Tomography Assessment for Transcatheter

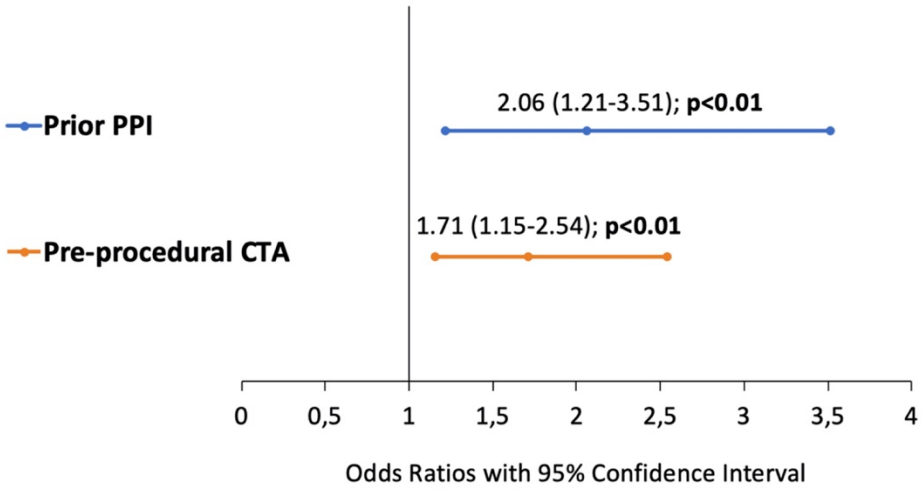
Aortic Valve Replacement. *Interv Cardiol Clin*. 2018;7:301–13.

19. Costa G, Zappulla P, Barbanti M, Cirasa A, Todaro D, Rapisarda G, Picci A, Platania F, Tosto A, Di Grazia A, Sgroi C, Tamburino C, Calvi V. Pacemaker dependency after transcatheter aortic valve implantation: incidence, predictors and long-term outcomes. *EuroIntervention*. 2019;15:875–83.









	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
Pre-procedural 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 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)	<0.01	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

SUPPLEMENTARY FIGURE LEGENDS

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

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

Supplementary Table 1. Baseline characteristics after propensity matching adjustment

Baseline	**Overall (n=320)**	**NDD (n=160)**	**N-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 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
Pre-procedural CTA, n (%)	196 (61.3)	98 (61.3)	98 (61.3)	-

Abbreviations: STS, Society of Thoracic Surgery; **BMI**, Body Mass Index; **MI,** Myocardial Infarction; **NYHA,** New York Heart Association; **LVEF,** Left Ventricular Ejection Fraction; **CTA,** Computed Tomography Angiography; **SD**, Standard Deviation.

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

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

In-hospital outcomes	**Overall (n=1232)**	**NDD (n=160)**	**N-NDD (n=1072)**	**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 complication				
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

Abbreviations: PPI, Pacemaker Implantation; **LBBB,** Left Bundle Branch Block; **AF**, Atrial Fibrillation; **AKI,** Acute Kidney Injury.

*frequencies calculated among patients without prior PM

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

Baseline	Overall (n=882)	NDD (n=146)	N-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 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	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

Pre-procedural CTA, n (%)	390 (44.2)	90 (61.6)	300 (40.8)	<0.01
Annulus Perimeter, mean±SD	7.3±1.2	7.2±1.4	7.3±1.1	0.254
Annulus Area, mean±SD	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

Abbreviations: STS, Society of Thoracic Surgery; **BMI**, Body Mass Index; **PCI,** Percutaneous Coronary; **CABG,** Coronary Artery Bypass Grafting; **COPD**, Chronic Obstructive Pulmonary Disease; **MI,** Myocardial Infarction; **PPI,** Permanent Pacemaker Implantation; **NYHA,** New York Heart Association; **LVEF,** Left Ventricular Ejection Fraction; **AVA**, Aortic Valve Area; **MR**, Mitral Regurgitation; **TR**, Tricuspid Regurgitation; **CTA,** Computed Tomography Angiography; **SD**, Standard Deviation

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

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
Pre-procedural 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

Abbreviations: STS, Society of Thoracic Surgery; **COPD**, Chronic Obstructive Pulmonary Disease; **PPI,** Permanent Pacemaker Implantation; **NYHA,** New York Heart Association; **MR**, Mitral Regurgitation; **CTA,** Computed Tomography Angiography