

STRUCTURAL: FOCUS ON TAVR

Predictors and Clinical Outcomes of Next-Day Discharge After Minimalist Transfemoral Transcatheter Aortic Valve Replacement



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ABSTRACT

OBJECTIVES This study sought to investigate predictors and safety of next-day discharge (NDD) after transcatheter aortic valve replacement (TAVR).

BACKGROUND Information about predictors and safety of NDD after TAVR is limited.

METHODS The study reviewed 663 consecutive patients who underwent elective balloon-expandable TAVR (from July 2014 to July 2016) at our institution. We first determined predictors of NDD in patients who underwent minimalist transfemoral TAVR. After excluding cases with complications, we compared 30-day and 1-year outcomes between NDD patients and those with longer hospital stay using Cox regression adjusting for the Predicted Risk of Mortality provided by the Society of Thoracic Surgeons. The primary endpoint was the composite of mortality and readmission at 1 year.

RESULTS A total of 150 patients had NDD after TAVR and 210 patients had non-NDD. Mean age and the Society of Thoracic Surgeons Predicted Risk of Mortality were 80.7 ± 8.8 years and $6.6 \pm 3.7\%$, respectively. Predictors of NDD were male sex (odds ratio [OR]: 2.02; 95% confidence interval [CI]: 1.28 to 3.18), absence of atrial fibrillation (OR: 1.62; 95% CI: 1.02 to 2.57), serum creatinine (OR: 0.71; 95% CI: 0.55 to 0.92), and age (OR: 0.95; 95% CI: 0.93 to 0.98). As expected, 84% of patients with complications had non-NDD. After excluding cases with complications, there was no difference in hazard rates of the 30-day composite outcome between NDD and non-NDD (hazard ratio: 0.62; 95% CI: 0.20 to 1.91), but the hazard of the composite outcome at 1 year was significantly lower in the NDD group (hazard ratio: 0.47; 95% CI: 0.27 to 0.81). This difference in the composite outcome can be explained by the lower hazard of noncardiovascular related readmission in the NDD group.

CONCLUSIONS Factors predicting NDD include male sex, absence of atrial fibrillation, lower serum creatinine, and younger age. When compared with patients without complications with a longer hospital stay, NDD appears to be safe, achieving similar 30-day and superior 1-year clinical outcomes. (J Am Coll Cardiol Intv 2018;11:107-15) © 2018 Published by Elsevier on behalf of the American College of Cardiology Foundation.

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**ABBREVIATIONS
AND ACRONYMS****AF** = atrial fibrillation**CI** = confidence interval**CRBBB** = complete right
bundle branch block**HR** = hazard ratio**MDCT** = multidetector
computed tomography**NDD** = next-day discharge**OR** = odds ratio**PPM** = permanent pacemaker**PROM** = Predicted Risk of
Mortality**STS** = Society of Thoracic
Surgeons**TAVR** = transcatheter aortic
valve replacement

One of the advantages of transcatheter aortic valve replacement (TAVR) compared with surgical aortic valve replacement is early recovery after the procedure (1,2). The “minimalist approach” with conscious sedation and local anesthesia using transthoracic echocardiography guidance has made early discharge more feasible after TAVR (3,4). Previous reports have identified predictors of early discharge (within 3 days) from baseline

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characteristics and complications of the procedure (1,5,6). In this study of patients undergoing minimalist TAVR, we assessed patient characteristics to investigate predictors of next-day discharge (NDD) using only

characteristics of patients at baseline. We also hypothesized that among patients with no complications the outcomes of NDD would be similar to those of non-NDD and thus we compared the 30-day and 1-year composite outcomes of mortality and readmission between NDD patients and non-NDD patients to evaluate safety of NDD.

METHODS

We reviewed 663 consecutive patients who underwent elective TAVR at our institution from July 2014 to July 2016 (Figure 1). All patients had severe aortic stenosis and were deemed eligible for TAVR by a multidisciplinary heart team. From this cohort, we selected those patients who underwent transfemoral TAVR under conscious sedation and local anesthesia (minimalist approach) with either a SAPIEN XT (Edwards Lifesciences, Irvine, California) or SAPIEN 3 valve (Edwards Lifesciences). We only included patients in this study that had pre-procedural 3-dimensional imaging with multidetector computed tomography (MDCT). Determination of patient discharge was made based on patients' characteristics and clinical status at the timing of discharge by physician.

Our study had 2 objectives. First, we aimed to identify predictors of NDD in patients undergoing TAVR using the minimalist approach. Predictors were identified from patients' physiologic baseline

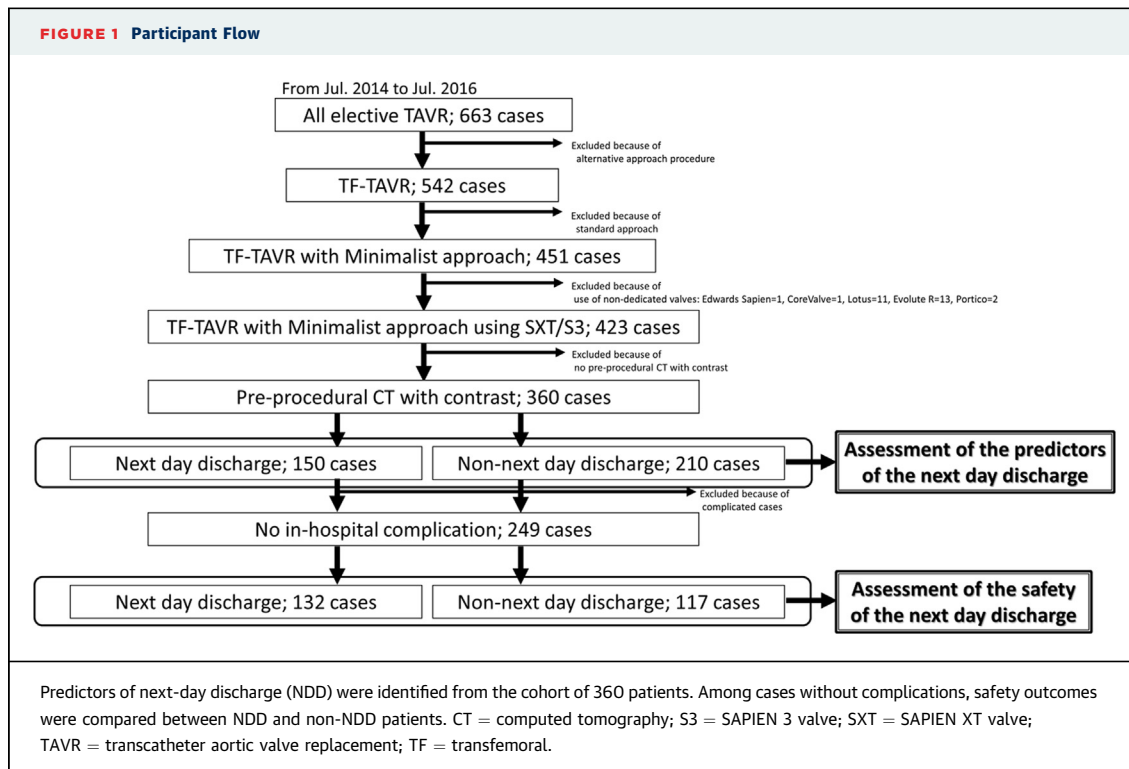
characteristics and anatomical characteristics seen on MDCT before the procedure. Second, we sought to compare the 30-day and 1-year composite outcomes of mortality and readmission between NDD and non-NDD patients. We excluded patients with complications to allow a fair comparison between groups. Complications were defined according to the Valve Academic Research Consortium-2 consensus document and included intraprocedural complications, such as vascular complications, bleeding, stroke, or a new complete heart block, and post-procedural complications (Online Table 1) (7). The primary endpoint was the composite of mortality and readmission at 1 year. Secondary endpoints included the composite of mortality and readmission at 30 days. Cardiovascular readmission was defined as readmission due to reasons related to cardiovascular diseases.

Procedural details and perioperative care at our institution have been described previously (3). Operators determined the valve type and size according to the findings of pre-procedural MDCT. Implanting technique was standard among operators. Baseline characteristics, outcomes, and complications were reported according to the Society of Thoracic Surgeons (STS) adult cardiac surgery data specifications, Valve Academic Research Consortium-2 criteria, or European Association of Echocardiography/American Society of Echocardiography recommendations, as appropriate (7-9). Definition of coronary artery disease followed the definition of “Coronary Anatomy/Disease Known” in the STS definition. Frailty was assessed according to previously published definitions (10).

For imaging, pre-procedural and post-procedural echocardiographic variables were expressed according to the guidelines of the American Society of Echocardiography (9,11). Contrast MDCT imaging was analyzed using a dedicated workstation and 3mensio valve software version 9.0 (Pie Medical Imaging BV, Philipsweg, the Netherlands) by 2 experienced investigators blinded to the clinical data. The distribution of aortic valve calcification was analyzed separately. The annulus was defined as 2 mm inferior and 3 mm superior to the annular plane, and the left ventricular outflow tract was defined as 5 mm inferior to the annular plane. Leaflet calcification was

board for Medtronic. Dr. Guyton has served as the national principal investigator on the Edwards Lifesciences TMVR early feasibility trial. Dr. Thourani has served as a consultant for Edwards Lifesciences, Abbott Vascular, Gore Vascular, and Boston Scientific. Dr. Babaliaros is a consultant for and has received research grant support from Abbott Vascular and Edwards Lifesciences. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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measured from 3 mm superior to the annular plane to the end of the leaflet using an empirical cutoff of 550 HU (12,13). A left ventricular outflow tract “finger” of calcification was defined as calcification extending from the annular plane toward the left ventricle more than 5 mm. The sheath to femoral artery ratio and the sheath to external iliac artery ratio were defined as the ratio of the minimal femoral artery diameter to sheath outer diameter and the ratio of the minimal external iliac artery diameter to sheath outer diameter, respectively (14). Skin-to-vessel diameter was defined as vertical distance from the surface of the artery to surface of the skin at the center of the femoral head. When calcification covered the surface of the artery at the puncture site, we defined it as a “calcium cap” at the puncture site. Circumferential calcium was assessed at the minimal lumen lesion.

All patient information and follow-up data were collected from the electronic medical record (operative record, procedure log, and chart review) and our local database or confirmed by direct phone contact with patients or their family. The Emory University Institutional Review Board approved this study.

STATISTICAL ANALYSIS. Continuous variables are summarized as mean ± SD or as median (interquartile range), and means were compared using 2-sample Student *t*-tests for reasonably normally distributed

variables or Wilcoxon rank sum tests for variables with skewed distributions. Categorical variables are reported as count (proportion) and proportions were compared using the chi-square test or Fisher exact test. Frailty data were available among patients who underwent frailty assessment. To determine predictors of NDD, first single-predictor logistic regression models were initially fit to assess the association of each individual predictor with NDD. Next, stepwise regression was used; a significance level of 0.20 was required for a variable to enter or remain in the model. When comparing NDD and non-NDD, patients who experienced complications were excluded and Cox regression models were built adjusted for the STS Predicted Risk of Mortality (PROM) score. Kaplan-Meier curves were drawn to graphically compare survival distributions of the 2 groups, with the composite of death and readmission as the outcome. A subsequent competing risk analysis using the method developed by Fine and Gray was used to compare the relative incidence of death, cardiovascular admission, and noncardiovascular admission between the NDD- and non-NDD-matched groups (15). Tests of hypotheses were 2-sided and conducted at a 0.05 level of significance. All statistical analyses were performed using SAS software version 4.2 (SAS Institute, Cary, North Carolina).

TABLE 1 Baseline Characteristics

	Overall (N = 360)	NDD (n = 150)	Non-NDD (n = 210)	p Value
Age, yrs	80.7 ± 8.8	79.0 ± 8.7	82.0 ± 8.6	<0.001*
Male	200 (55.6)	95 (63.3)	105 (50.0)	0.01*
Body mass index, kg/m ²	27.8 ± 5.6	28.2 ± 5.3	27.5 ± 5.8	0.11
Body surface area, m ²	1.9 ± 0.3	2.0 ± 0.3	1.9 ± 0.3	0.04*
Hypertension	351 (97.5)	146 (97.3)	205 (97.6)	0.86
Dyslipidemia	345 (95.8)	144 (96.0)	201 (95.7)	0.89
Diabetes mellitus	143 (39.7)	60 (40.0)	80 (39.5)	0.93
Insulin dependent	46 (12.8)	22 (14.7)	24 (11.4)	0.36
Serum creatinine, mg/dl	1.4 ± 1.7	1.2 ± 1.0	1.6 ± 2.1	0.02*
Dialysis	16 (4.4)	3 (2.0)	13 (6.2)	0.06
Lung disease (≥ moderate)	65 (18.1)	25 (16.7)	40 (19.0)	0.56
Liver disease	13 (3.6)	3 (2.0)	10 (4.8)	0.17
Immunocompromised	30 (8.3)	13 (8.7)	17 (8.1)	0.85
History of endocarditis	3 (0.8)	1 (0.7)	2 (1.0)	0.77
Cerebrovascular disease	138 (38.3)	58 (38.7)	80 (38.1)	0.91
Peripheral vascular disease	90 (25.0)	35 (23.3)	55 (26.2)	0.54
History of peripheral bypass graft	8 (2.2)	1 (0.7)	7 (3.3)	0.15
Coronary artery disease	196 (54.4)	75 (50.0)	121 (57.6)	0.15
History of myocardial infarction	106 (29.4)	41 (27.3)	65 (31.0)	0.46
History of CABG	93 (25.8)	45 (30.0)	48 (22.9)	0.13
History of PCI	124 (34.4)	46 (30.7)	78 (37.1)	0.20
History of heart failure	348 (96.7)	147 (98.0)	201 (95.7)	0.23
History of SAVR	14 (3.9)	10 (6.7)	4 (1.9)	0.02*
NYHA functional class IV	139 (38.6)	49 (32.7)	90 (42.9)	0.05
STS PROM, %	6.6 ± 3.7	5.5 ± 3.1	7.4 ± 3.9	<0.001*
Frailty†	50 (20.5)	14 (13.6)	36 (25.5)	0.02*

Values are mean ± SD or n (%). *Significant values. †Frailty had 32% missing values, as not all patients were assessed (n = 244).

CABG = coronary artery bypass grafting; NDD = next day discharge; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; SAVR = surgical aortic valve replacement; STS-PROM = Society of Thoracic Surgeons Predicted Risk of Mortality.

TABLE 2 Baseline Cardiac Parameters

	Overall (N = 360)	NDD (n = 150)	Non-NDD (n = 210)	p Value
Electrocardiogram				
Atrial fibrillation	132 (36.7)	46 (30.7)	86 (41.0)	0.046*
Paroxysmal atrial fibrillation	82 (22.8)	29 (19.3)	53 (25.2)	0.19
Chronic atrial fibrillation	50 (13.9)	17 (11.3)	33 (15.7)	0.24
Atrial fibrillation with CHA ₂ DS ₂ -VASc ≥ 4	126 (35.0)	44 (29.3)	82 (39.0)	0.06
Complete right bundle branch block†	37 (11.3)	10 (7.1)	27 (14.4)	0.04*
Complete left bundle branch block†	21 (6.4)	10 (7.1)	11 (5.9)	0.64
Previous device implantation	49 (13.6)	17 (11.3)	32 (15.2)	0.29
Echocardiogram				
Mean aortic valve gradient, mm Hg	42.8 ± 13.6	42.3 ± 13.9	43.2 ± 13.3	0.28
Aortic valve area, cm ²	0.78 ± 0.29	0.82 ± 0.37	0.75 ± 0.21	0.14
Aortic insufficiency (≥ moderate)	72 (20.0)	28 (18.7)	44 (21.0)	0.59
Mitral regurgitation (≥ moderate)	95 (26.4)	33 (22.0)	62 (29.5)	0.11
Tricuspid regurgitation (≥ moderate)	82 (22.8)	29 (19.3)	53 (25.2)	0.19
Left ventricular ejection fraction, %	52.5 ± 13.1	52.2 ± 11.4	52.8 ± 14.2	0.15
Right ventricular systolic pressure, mm Hg	42.6 ± 13.7	40.9 ± 13.0	43.7 ± 14.1	0.04*
Right ventricular ejection fraction (≥ moderate)	24 (6.7)	9 (6.0)	15 (7.1)	0.67

Values are n (%) or mean ± SD. *Significant values. †Number of bundle branch block was counted among the cases without previous permanent pacemaker (n = 311).

CHA₂DS₂-VASc = congestive heart failure, hypertension, age ≥ 75 years, diabetes mellitus, stroke or transient ischemic attack or thromboembolism, vascular disease, age 65 to 74 years, sex category; NDD = next-day discharge.

RESULTS

We identified 360 patients (NDD = 150 and non-NDD = 210) who met the study's inclusion criteria. Baseline characteristics are listed in **Table 1**. NDD patients were younger, less frail, and more likely to be men than were non-NDD patients. Additionally, they had larger body surface area, lower serum creatinine level, and lower mean STS PROM. Among cardiac parameters (**Table 2**), NDD patients had less atrial fibrillation (AF) and complete right bundle branch block (CRBBB). Right ventricular systolic pressure was also lower in the NDD group than in the non-NDD group. MDCT parameters were similar between the groups with respect to aortic valve calcification and peripheral vessel measurements. However, the sheath to femoral artery ratio was slightly larger in the NDD group (**Online Table 2**). Procedural details and in-hospital outcomes are listed in **Table 3**. STS PROM of complicated cases was significantly higher than those of noncomplicated cases (complicated cases $7.34 \pm 4.18\%$ vs. noncomplicated cases $6.27 \pm 3.42\%$; $p = 0.03$). The less frail demographics of our cohort might have led to 90% of patients being directly discharged to home.

Using the entire sample, predictors of NDD were identified (**Figure 2**). Male sex (odds ratio [OR]: 2.02; 95% confidence interval [CI]: 1.28 to 3.18), absence of AF (OR: 1.62; 95% CI: 1.02 to 2.57), serum creatinine (OR: 0.71 for each increase of 1.0 mg/dl; 95% CI: 0.55 to 0.92), and age (OR: 0.95 for each increase of 1.0 year; 95% CI: 0.93 to 0.98) predicted NDD. A logistic regression model predicting NDD using these predictors was fit and the area under the receiver-operating characteristic curve (0.67) was found to be not significantly different from that obtained using STS PROM (0.67) (**Figure 3**).

As expected, 84% of patients with procedural complications had non-NDD (**Table 4**). After excluding 111 patients who experienced a complication during the procedure or in the first 24 h after the procedure (**Online Table 1**), outcomes were similar between groups at 30 days, with no mortality observed at 30 days (**Table 5**). The primary composite endpoint at 1 year was significantly lower in the NDD group than in the non-NDD group when adjusted for STS PROM (hazard ratio: 0.47; 95% CI: 0.27 to 0.81). The Kaplan-Meier curve revealed superior outcome in the NDD group compared with non-NDD group (**Figure 4**). Incidence of mortality and cardiovascular readmission was not different between groups (HR: 0.71; 95% CI: 0.12 to 4.19; and HR: 0.68; 95% CI: 0.33 to 1.43, respectively), but the relative incidence of noncardiovascular readmission

was lower among NDD patients (HR: 0.47; 95% CI: 0.27 to 0.81).

DISCUSSION

This study demonstrates 2 major findings: 1) predictors of NDD are male sex, absence of AF, lower serum creatinine, and younger age; and 2) among patients without complications in the first 24 h post-procedure, there was no difference in mortality at 30 days and better composite outcomes for NDD patients at 1 year. We identified variables that may help clinicians assess their patients' likelihood of NDD after TAVR with a balloon-expandable valve. The safety of NDD could not be assessed in earlier studies from baseline variables because those studies included patients with procedural complications that likely delayed discharge. Therefore, in this study it was critical to perform the analysis in a homogenous population of minimalist, transfemoral TAVR with balloon-expandable devices and no complications from the procedure.

PREDICTORS OF NDD. In this study, we found male sex was the strongest positive predictor of NDD. Previous reports have shown that male sex is associated with fewer vascular complications and bleeding after TAVR than is female sex due to anatomic differences, leading to a slightly longer hospital stay for women (16-18). However, female sex has been previously reported to be associated with better short- and midterm outcomes after TAVR in older-generation devices (17,19). The presence of the sex disparity in our study is intriguing and stresses the need for further examination of sex differences among TAVR patients using current-generation devices.

Pre-existing AF was a negative predictor of NDD, although its impact on length of stay after TAVR remains controversial (20-23). Some papers have reported that pre-existing AF is associated with worse long-term outcomes including death and bleeding complications, but it was not associated with negative short-term outcomes (20-22). Consistent with those reports, there was no statistically significant relationship between pre-existing AF and in-hospital complications in our study. However, patients with AF may have other confounding issues after TAVR, such as need for anticoagulation and variable heart rates, which may lead to prolonged hospitalization. Additional research may be warranted to investigate the impact of AF on early discharge.

It is no surprise that higher serum creatinine is a negative predictor of NDD. Patients with renal dysfunction often need a longer stay because of

TABLE 3 Procedure Detail and In-Hospital Outcomes

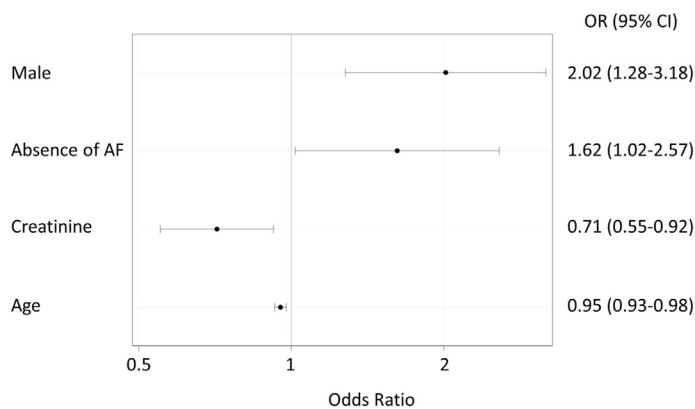
	Overall (N = 360)	NDD (n = 150)	Non-NDD (n = 210)	p Value
Procedure detail				
Total laboratory time, h	160.1 ± 50.2	152.9 ± 37.1	165.2 ± 57.4	0.08
Fluoroscopy time, min	23.9 ± 8.6	23.6 ± 8.6	24.2 ± 8.6	0.40
Contrast volume, ml	149.5 ± 60.3	149.7 ± 57.2	149.4 ± 62.3	0.63
Valve type				
SAPIEN XT	99 (27.5)	36 (24.0)	63 (30.0)	0.21
SAPIEN 3	261 (72.5)	114 (76.0)	147 (70.0)	
Covered index	1.12 ± 0.15	1.12 ± 0.16	1.12 ± 0.15	0.83
In-hospital outcomes				
Device success	300 (83.3)	125 (83.3)	175 (83.3)	1.00
Vascular complication				
Major vascular complication	10 (2.8)	0 (0.0)	10 (4.8)	0.01*
Minor vascular complication	21 (5.8)	5 (3.3)	16 (7.6)	0.08
Bleeding complication				
Life-threatening or major bleeding	12 (3.3)	1 (0.7)	11 (5.2)	0.02*
Life-threatening bleeding	5 (1.4)	0 (0.0)	5 (2.4)	0.06
Major bleeding	7 (1.9)	1 (0.7)	6 (2.9)	0.14
Minor bleeding	29 (8.1)	9 (6.0)	20 (9.5)	0.23
Stroke				
Major stroke	2 (0.56)	0 (0.0)	2 (0.95)	0.23
Minor stroke	6 (1.7)	1 (0.7)	5 (2.4)	0.21
New conduction disturbance†				
New complete heart block†	24 (7.3)	2 (1.4)	22 (11.8)	0.0004*
New pacing device implantation†	20 (6.4)	2 (1.5)	18 (10.1)	0.002*
Peak serum troponin I, ng/ml	2.34 ± 2.76	1.82 ± 1.66	2.68 ± 3.25	0.02*
Discharge location				
Home	343 (95.3)	150 (100.0)	193 (91.9)	
Subacute rehabilitation facility	9 (2.5)	0 (0.0)	9 (4.3)	
Nursing home	3 (0.8)	0 (0.0)	3 (1.4)	
Other acute care hospital	1 (0.3)	0 (0.0)	1 (0.5)	
In-hospital death	4 (1.1)	0 (0.0)	4 (1.9)	

Values are mean ± SD or n (%). *Significant values. †Incidence of new conduction disturbance, complete heart block, and pacing device implantation was counted and analyzed among the cases without previous pacing device (n = 311).
 NDD = next day discharge.

perioperative hydration or need for in-hospital management (24-29).

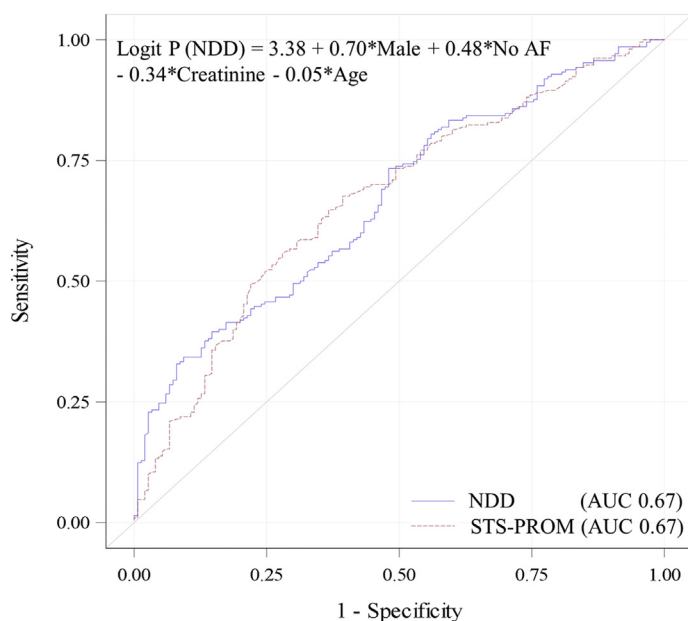
Our model predicted NDD just as well as the model based on STS PROM. Both models have an area under the receiver-operating characteristic curve of 0.67, even as STS PROM is based on a model with several variables and our NDD model uses only 4 preoperative variables. Of course, STS PROM was designed for 30-day mortality, and our model used NDD as the dependent variable.

SAFETY OF NDD. One obvious question concerning the safety in NDD is the possibility of late appearing heart block and need for permanent pacemaker (PPM) implantation. In our study, consistent with previous reports, patients with pre-existing CRBBB needed significantly more new PPM immediately after TAVR (10 of 33 cases, 30.3%) than did those without CRBBB (10 of 278 cases, 3.6%; p < 0.001) (30,31). However,

FIGURE 2 Predictors of Next-Day Discharge After Transcatheter Aortic Valve Replacement Based on Entire Sample

Odds ratio (OR) for age is the OR comparing groups that differ in age by 1 year; OR for serum creatinine compares 2 groups that differ in serum creatinine by 1.0 mg/dl. AF = atrial fibrillation; CI = confidence interval.

new PPM was not a predictor in the multivariate analysis, but was in the univariate analysis. This result could be attributed to low incidence of PPM implantation (6.4%) in our entire cohort compared with previous reports (30,32). The low incidence of

FIGURE 3 Receiver-Operating Characteristic Curves of NDD and STS PROM

The identified predictors (male sex, absence of AF, serum creatinine [mg/dl], and age [years]) were used for building a logistic model predicting NDD. AUC = area under the curve; STS PROM = Society of Thoracic Surgeons Predicted Risk of Mortality; other abbreviations as in Figures 1 and 2.

PPM implantation might have obscured the influence of CRBBB (32,33). There was only 1 patient who required new PPM after discharge within 30 days. The patient was in the non-NDD group, had a pre-existing CRBBB. Thus, late post-discharge PPM was only 1 of 360 (0.28% of the entire cohort of patients).

In the safety analysis after excluding the complicated patients, none of the patients had evidence of high degree of heart block at discharge and there was no 30-day mortality in either group. As the rate of readmission at 30 days after minimalist TAVR was reported to be 10.7% by a different group, our results of 30-day composite endpoint (mortality and readmission 6.1%) are similar and support that a NDD strategy is reasonable (34).

OUTCOMES OF NDD. There have been no previous reports regarding influence of early discharge on long-term outcome. The NDD patients had better outcomes at 1 year than did the non-NDD patients, though this finding probably reflects a healthier cohort in the NDD group (Table 4). Although the reason for the discrepancy in the composite outcome at 1 year is mainly driven by noncardiovascular readmission, other confounding variables cannot be entirely ruled out.

STUDY LIMITATIONS. First, this was a single-center, retrospective, nonrandomized observational analysis. It included only transfemoral balloon-expandable TAVR population. Second, in the analysis of predictors of NDD, the non-NDD group consisted not only of patients who were discharged after next day, but also 4 patients who died in the peri-operative period. This allowed our study to be closer to an intention-to-treat analysis, and makes this study a prediction model rather than simple comparison of length of stay. Third, we only included patients in this study who had pre-procedural MDCT to avoid the disadvantage of a lack of preprocedural evaluation of anatomical features. Thus, some patients with chronic kidney disease who could not undergo MDCT were excluded. In addition, there is no validation cohort for our predictors. A prospective study using our predictors will be needed to confirm our results. Finally, we tried to investigate the relationship between family support and patients' discharge though we could not include it into our predictor model, as it is difficult to precisely quantify family support or measure the accurate influence of family support over patient's discharge. Nevertheless, it cannot be denied these social factors affect clinical decision-making processes. Further studies are necessary to assess influence of social support on patients' discharge.

TABLE 4 Baseline Characteristics After Exclusion of Complicated Cases

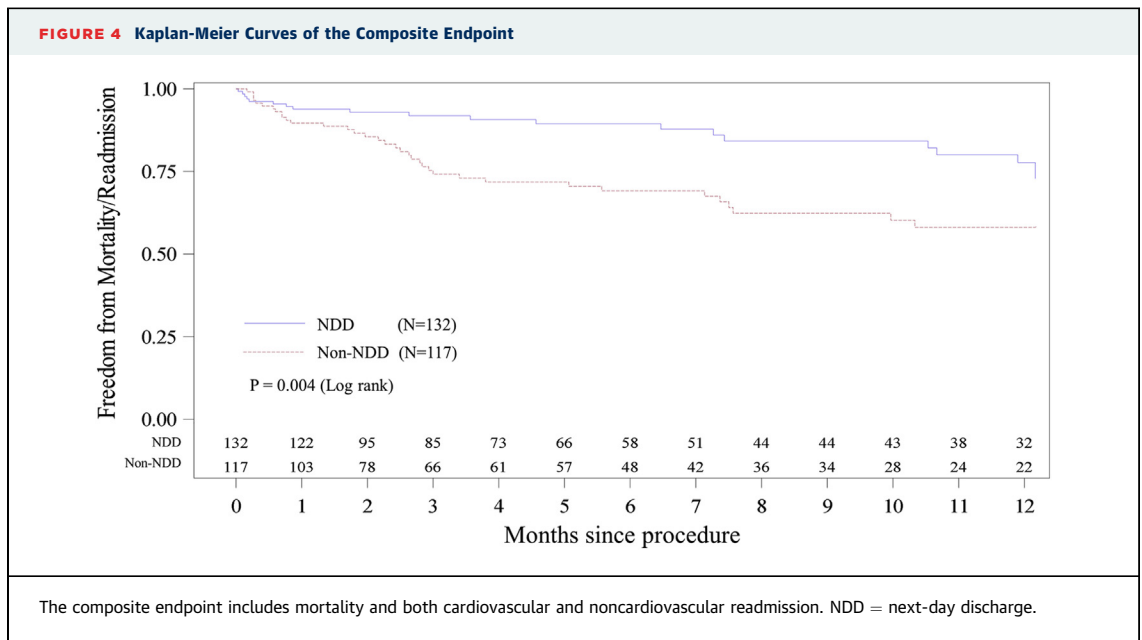
	Overall (N = 249)	NDD (n = 132)	Non-NDD (n = 117)	p Value
Age, yrs	80.5 ± 8.6	79.3 ± 8.2	81.8 ± 8.9	0.01*
Male	132 (53.0)	83 (63.9)	49 (41.9)	0.001*
Body mass index, kg/m ²	27.8 ± 5.4	28.0 ± 5.3	27.6 ± 5.5	0.41
Body surface area, m ²	1.94 ± 0.27	1.96 ± 0.25	1.91 ± 0.29	0.12
Hypertension	243 (97.6)	129 (97.7)	114 (97.4)	1.00
Dyslipidemia	238 (95.6)	128 (97.0)	110 (94.0)	0.26
Diabetes mellitus	101 (40.6)	55 (41.7)	46 (39.3)	0.71
Insulin dependent	30 (12.0)	20 (15.2)	10 (8.5)	0.11
Serum creatinine, mg/dl	1.32 ± 1.20	1.19 ± 1.06	1.45 ± 1.33	0.01*
Dialysis	10 (4.0)	3 (2.3)	7 (6.0)	0.20
Lung disease (≥ moderate)	45 (18.1)	23 (17.4)	22 (18.8)	0.78
Liver disease	10 (4.0)	3 (2.3)	7 (6.0)	0.20
Immunocompromised	21 (8.4)	12 (9.1)	9 (7.7)	0.69
History of endocarditis	3 (1.2)	1 (0.8)	2 (1.7)	0.60
Cerebrovascular disease	91 (36.5)	49 (37.1)	42 (35.9)	0.84
Peripheral vascular disease	58 (23.3)	32 (24.2)	26 (22.2)	0.71
History of peripheral bypass graft	2 (0.8)	0 (0.0)	2 (1.7)	0.22
Coronary artery disease	128 (51.4)	67 (50.8)	61 (52.1)	0.83
History of myocardial infarction	72 (28.9)	39 (29.5)	33 (28.2)	0.82
History of CABG	58 (23.3)	39 (29.5)	19 (16.2)	0.01*
History of PCI	78 (31.3)	42 (31.8)	36 (30.8)	0.86
History of heart failure	242 (97.2)	129 (97.7)	113 (96.6)	0.71
History of SAVR	8 (3.2)	7 (5.3)	1 (0.9)	0.07
NYHA functional class IV	84 (33.7)	38 (28.8)	46 (39.3)	0.08
STS PROM, %	6.27 ± 3.42	5.50 ± 3.08	7.13 ± 3.60	<0.001*
Frailty†	36 (21.4)	14 (15.2)	22 (28.9)	0.03*

Values are mean ± SD or n (%). *Significant values. †Frailty had 32% missing values, as not all patients were assessed (n = 168).
 Abbreviations as in Table 1.

TABLE 5 Midterm Outcomes in Uncomplicated Patients

	Overall (N = 249)	NDD (n = 132)	Non-NDD (n = 117)	Unadjusted HR (95% CI)	Unadjusted p Value	STS PROM Adjusted HR (95% CI)	STS PROM Adjusted p Value
30-day outcomes							
Mortality	0 (0.0)	0 (0.0)	0 (0.0)	–	–	–	–
Readmission							
CV readmission	11 (4.4)	6 (4.6)	5 (4.3)	1.07 (0.33-3.49)	0.92	0.97 (0.30-3.12)	0.95
Non-CV readmission	11 (4.4)	2 (1.5)	9 (7.7)	0.19 (0.04-0.91)	0.04	0.25 (0.05-1.18)	0.08
Stroke	0 (0.0)	0 (0.0)	0 (0.0)	–	–	–	–
30-day composite endpoint†	22 (8.8)	8 (6.1)	14 (12.0)	0.49 (0.21-1.20)	0.12	0.62 (0.20-1.91)	0.41
1-yr outcomes							
Mortality	8 (3.2)	2 (1.5)	6 (5.1)	0.64 (0.11-3.82)	0.45	0.71 (0.12-4.19)	0.71
Readmission							
CV readmission	29 (11.6)	12 (9.1)	17 (14.5)	0.63 (0.30-1.31)	0.21	0.68 (0.33-1.43)	0.31
Non-CV readmission	23 (9.2)	6 (4.6)	17 (14.5)	0.30 (0.12-0.76)*	0.01*	0.31 (0.12-0.76)*	0.01*
Stroke	0 (0.0)	0 (0.0)	0 (0.0)	–	–	–	–
1-yr composite endpoint†	56 (22.5)	20 (15.2)	36 (30.8)	0.44 (0.26-0.76)*	0.003*	0.47 (0.27-0.81)*	0.006*

Values are n (%) unless otherwise indicated. *Significant values. †Composite endpoint includes mortality and both cardiovascular (CV) and non-CV readmission.
 CI = confidence interval; STS PROM = Society of Thoracic Surgeons Predicted Risk of Mortality.



CONCLUSIONS

We found that predictors of NDD after elective TAVR with a balloon-expandable valve were male sex, absence of AF, lower serum creatinine, and younger age. NDD patients had similar 30-day and better 1-year clinical outcomes (readmission and mortality) compared with non-NDD patients. Although superior NDD outcomes are likely attributed to selected patient characteristics, NDD in patients without in-hospital complications may be appropriate after transfemoral balloon-expandable TAVR.

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PERSPECTIVES

WHAT IS KNOWN? Uncomplicated TAVR procedures have made early discharge more feasible. However, predictors, safety, and outcomes of NDD are unknown.

WHAT IS NEW? Our results revealed predictors of NDD were male sex, lower serum creatinine, absence of AF, and younger age. In addition, we also demonstrated the safety of NDD. A strategy of NDD in patients without in-hospital complications may be appropriate after transfemoral balloon-expandable TAVR.

WHAT IS NEXT? A validation cohort will be needed to confirm the predictors identified in this study and to apply NDD to wider population.

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APPENDIX For supplemental tables, please see the online version of this article.