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Feasibility and safety of next-day discharge following transcatheter bicuspid aortic valve replacement

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ABSTRACT

Background: Decreased length of stay in the index hospitalization is a tendency in transcatheter aortic valve replacement (TAVR) era. In this study, we aim to evaluate the feasibility and safety of next-day discharge (NDD) in bicuspid aortic valve (BAV) patients following TAVR.

Methods: The study analyzed patients who received TAVR in 2019 to 2022. Thirty-day mortality and readmission rate were compared between BAV and tricuspid aortic valve (TAV) patients.

Results: The proportion of NDD was similar between the BAV and TAV group (45.3 % vs 41.3 %, $p = 0.487$). In NDD patients, the lower age (72.0 [67.0, 77.0] yrs vs 74.0 [70.0, 80.0] yrs, $p = 0.011$) and STS score (2.33 [1.56, 3.54] % vs 3.82 [2.38, 5.70] %, $p < 0.001$) were observed in the BAV group. The NDD BAV patients had higher proportion of post-dilatation (74.3 % vs 50.7 %, $p = 0.003$) when compared with the TAV patients. The NDD patients was safe with no death both in BAV and TAV patients at 30-day follow-up. Moreover, the readmission rate was comparable between BAV and TAV patients who discharged on the next day after TAVR (8.1 % vs 14.0 %, $p = 0.397$).

Conclusions: NDD after TAVR was feasible and safe in both BAV and TAV patients. The younger BAV patients with fast recovery deserve the next-day discharge after TAVR.

Transcatheter aortic valve replacement (TAVR) is widely utilized in overall risk profiles patients with severe aortic stenosis (AS) as a minimally invasive treatment. With the accumulated evidence and increasing knowledge of periprocedural complications, this percutaneous approach enables faster recovery after procedure and can facilitate earlier discharge. In the recent years, the length of hospital stay after TAVR has significantly decreased. In many high-volume centers with rich of procedural and management experience, early discharge (ED), next-day discharge (NDD), even same-day discharge (SDD) is quite common [1–4].

However, TAVR still face many difficulties in its development. One challenge is the bicuspid aortic valve (BAV). BAV used to be a relative contraindication for TAVR and have been excluded from the large randomized clinical trials [5–10]. BAV are less elliptical, with commissural fusion, irregularities in shape and heavier calcification, which may result in inadequate valve expansion, severe paravalvular leakage, annular rupture, and brain injury after TAVR [11–15]. Though, recently more and more studies have evaluated the safety and feasibility of TAVR in BAV patients, the length of stay after TAVR still remained from 2 days to 7 days [16–18].

Therefore, our study aims to evaluate the feasibility and safety of next-day discharge in BAV patients who received the TAVR procedure by comparing these patients with tricuspid aortic valve patients.

1. Methods

1.1. Study design and study population

The presented study is a retrospective analysis of the prospective study conducted in the Second Affiliated Hospital of Zhejiang University School of Medicine (TORCH registry, NCT02803294). Our center implemented a protocol for the next-day discharge of suitable TAVR candidates with specific criteria beginning in March 2019 [19]. The presented study included consecutive patients who underwent TAVR

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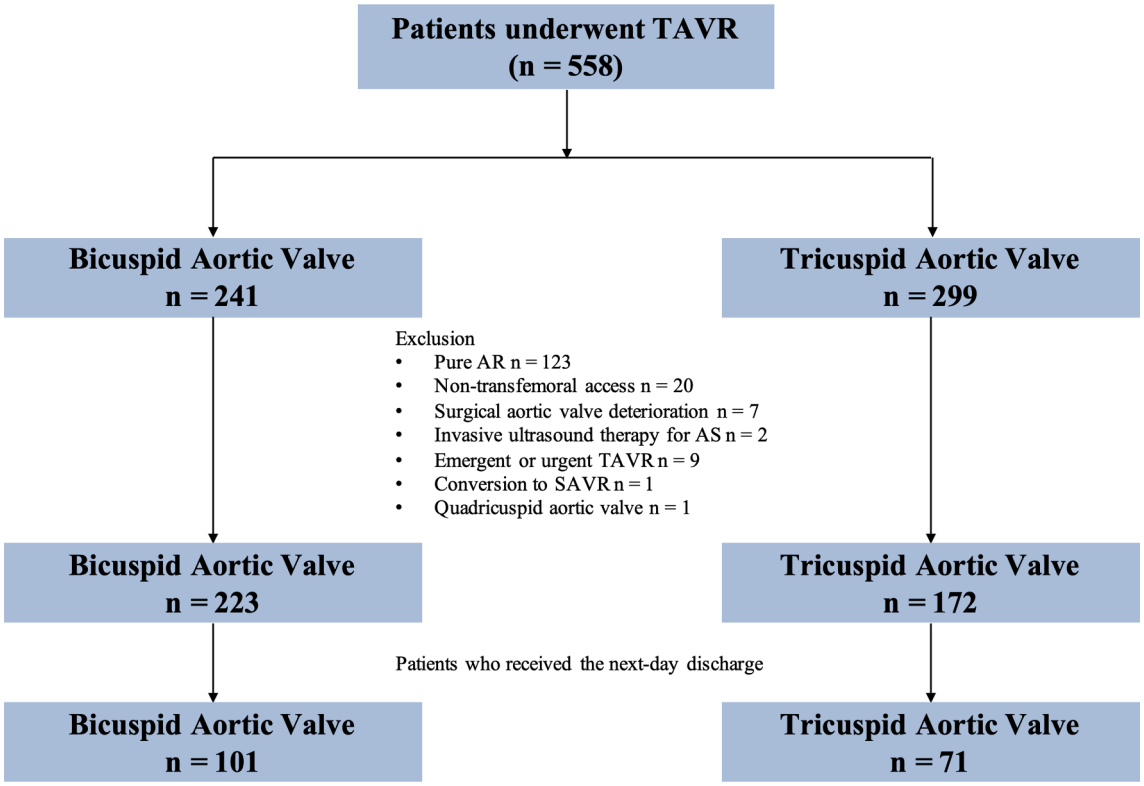

Fig. 1. Participant flow.

between March 2019 and April 2022. Data including the baseline characteristics, procedural variables, and follow-up data were stored in the database of the TORCH registry. The study was approved by the medical ethics committee of the Second Affiliated Hospital of Zhejiang University School of Medicine and carried out according to the principles of the Declaration of Helsinki. All patients provided written informed consent.

1.2. Periprocedural evaluation of TAVR candidates for NDD

We implemented selection criteria for NDD in TAVR candidates. If the TAVR candidate meet the criteria, the patients will go to the process of NDD. The main criteria for the NDD post-TAVR were: 1). Transfemoral TAVR with sedation plus local anesthesia; 2). No devasting complications, like coronary obstruction, annular rupture, and other severe periprocedural complications; 3). No any vascular complications during or after the procedure; 4). No any unstable situation, no usage of vasoactive agents or immunosuppressant or acute heart failure or cardiopulmonary resuscitation before or after procedure; 5). Without bone fracture or disabling stroke and can ambulation easily after procedure. If the patients meet the criteria of NDD process, the physicians and nurses of heart team will guide the patient in fast rehabilitation exercise. The patients will be assigned a smartwatch within 24 h before procedure. Patients and their families will be taught how to use the smartwatch to record single-lead ECG and multiple biometric parameters, store the data, and transfer it to the remote database through the application in smartphone.

1.3. Procedures and postprocedural management

Details of the TAVR procedure were determined by heart team discussion. Operators determined the valve type and size after discussion based on balloon sizing, annular size, and aortic root features. The mainly used valve were VenusA-Valve (Venus Medtech, Hangzhou, China), VitaFlow (Microport, Shanghai, China), Taurus One-Valve (Peijia Medical, Suzhou, China), and CoreValve (Medtronic, Minneapolis, Minnesota). Pre-dilatation and post-dilatation were decided by the cardiologist during the procedure if necessary. Transthoracic echocardiography was performed after TAVR to evaluate the hemodynamic and procedural outcomes. Patients received 12-lead ECG at baseline, immediately post-procedure, 4 h and 24 h after procedure, and daily thereafter during the index hospitalization if needed. If no increase in PR and QRS interval $\geq$ 20ms within the last two ECG before discharge, PR $<$ 240 ms and QRS $<$ 150 ms in the last ECG before discharge, and no transient and persisted high degree atrioventricular block and complete heart block occurred, the patients will be discharged on the next day. After discharge, patients will be monitored the evolution and development of the ECG and multiple biometric parameters remotely with the aid of smartwatch. A designated heart team member will contact the patients regularly and help the patients if they are in needed.

1.4. Outcomes definition and data collection

Baseline characteristics, including age, sex, body mass index, NYHA, STS score, history of smoke, dyslipidemia, diabetes mellitus, hypertension, syncope, chronic obstructive pulmonary disease, prior myocardial infarction, prior history of percutaneous coronary intervention and stroke were recorded and traced in the database of TORCH registry.

Outcomes were measured in hospital and 30-day follow-up. All outcomes were defined as the Valve Academic Research Consortium-3 (VARC-3) criteria [20]. Readmission was reported by patient themselves at 30-day follow-up.

1.5. Statistical analysis

Categorical data were presented as number (percentage). Continuous data were presented as mean $\pm$ SD for normal distribution and median [first quartile, third quartile] for skewed distribution. Student's *t* test or Mann-Whitney *U* test were used for normal or skewed distributed data respectively. Chi-square or fisher exact test was performed for the

Table 1
Baseline characteristics of the all patients in BAV versus TAV patients.

	All Patients (n = 395)	BAV (n = 223)	TAV (n = 172)	p Value
Age, median (IQR), y	73.00 (69.00, 79.50)	72.00 (68.00, 78.00)	76.00 (70.00, 82.00)	**<0.001**
Male, n (%)	222 (56.2)	137 (61.4)	85 (49.4)	**0.022**
BMI, median (IQR), kg/m^2	22.90 (20.45, 25.30)	22.70 (20.30, 25.05)	23.10 (21.00, 25.40)	0.125
NYHA III/IV, n (%)	296 (74.9)	160 (71.7)	136 (79.1)	0.122
STS, median (IQR)	3.22 (1.92, 5.80)	2.57 (1.57, 4.58)	4.04 (2.56, 7.04)	**<0.001**
Smoker, n (%)	99 (25.1)	60 (26.9)	39 (22.7)	0.398
Dyslipidemia, n (%)	66 (16.7)	39 (17.5)	27 (15.7)	0.736
Diabetes Mellitus, n (%)	72 (18.2)	34 (15.2)	38 (22.1)	0.106
Hypertension, n (%)	204 (51.6)	104 (46.6)	100 (58.1)	**0.030**
Syncope, n (%)	20 (5.1)	11 (4.9)	9 (5.2)	1.000
COPD, n (%)	77 (19.5)	48 (21.5)	29 (16.9)	0.302
Prior MI, n (%)	4 (1.0)	2 (0.9)	2 (1.2)	1.000
Prior PCI, n (%)	48 (12.2)	26 (11.7)	22 (12.8)	0.852
Prior Stroke, n (%)	21 (5.3)	11 (4.9)	10 (5.8)	0.872
Pre TTE data				
Max velocity, mean ± SD, m/s	4.71 ± 0.82	4.85 ± 0.78	4.53 ± 0.84	**<0.001**
Mean Gradient, median (IQR), mmHg	49.00 (40.00, 64.00)	52.00 (42.00, 66.00)	46.50 (36.00, 62.75)	**<0.001**
AVA, median (IQR), cm^2	0.66 (0.49, 0.82)	0.62 (0.46, 0.80)	0.69 (0.55, 0.85)	**0.001**
EF, median (IQR), %	60.80 (52.00, 65.30)	60.80 (53.00, 64.80)	60.45 (51.38, 66.60)	0.850
AR moderate/severe, n (%)	183 (46.3)	78 (35.0)	105 (61.0)	**<0.001**
Procedure				
Valve type				0.832
Self-expanding valve, n (%)	351 (88.9)	197 (88.3)	154 (89.5)	
Balloon-expandable valve, n (%)	44 (11.1)	26 (11.7)	18 (10.5)	
Valve size				0.328
≤26 mm, n (%)	257 (65.1)	140 (62.8)	117 (68.0)	0.687
>26 mm, n (%)	138 (34.9)	83 (37.2)	55 (32.0)	
Pre-dilatation, n (%)	364 (92.2)	217 (97.3)	147 (85.5)	**<0.001**
Post-dilatation, n (%)	248 (62.8)	159 (71.3)	89 (51.7)	**<0.001**
In-hospital outcomes				
Mortality, n (%)	8 (2.0)	7 (3.1)	1 (0.6)	0.145
MI, n (%)	2 (0.5)	2 (0.9)	0 (0.0)	0.507
Stroke, n (%)	12 (3.0)	7 (3.1)	5 (2.9)	1.000
Pacemaker implantation, n (%)	34 (8.6)	20 (9.0)	14 (8.1)	0.912
Coronary obstruction, n (%)	5 (1.3)	2 (0.9)	3 (1.7)	0.658
Annular rupture, n (%)	3 (0.8)	2 (0.9)	1 (0.6)	1.000
Aortic dissection, n (%)	7 (1.8)	4 (1.8)	3 (1.7)	1.000
Second valve deployment, n (%)	22 (5.6)	15 (6.7)	7 (4.1)	0.357
Vascular complications, n (%)	26 (6.6)	14 (6.3)	12 (7.0)	0.942
Length of stay since TAVR, median (IQR), days	2.00 (1.00, 3.00)	2.00 (1.00, 3.00)	2.00 (1.00, 4.00)	0.377
Next-day discharge, n (%)	172 (43.5)	101 (45.3)	71 (41.3)	0.487
Early day discharge, n (%)	297 (75.2)	169 (75.8)	128 (74.4)	0.846
30-day follow-up				
Mortality, n (%)	8 (2.1)	7 (3.3)	1 (0.6)	0.145
MI, n (%)	2 (0.5)	2 (0.9)	0 (0.0)	0.508
Stroke, n (%)	12 (3.2)	7 (3.3)	5 (3.1)	1.000
Pacemaker implantation, n (%)	45 (12.0)	26 (12.3)	19 (11.7)	1.000
Readmission, n (%)	39 (12.7)	19 (11.1)	20 (14.8)	0.428
Echocardiographic data				
Max velocity, mean ± SD, m/s	2.25 ± 0.52	2.25 ± 0.52	2.24 ± 0.52	0.790
Mean Gradient, median (IQR), mmHg	10.00 (8.00, 13.00)	10.00 (8.00, 13.00)	10.00 (7.00, 13.00)	0.471
AVA, median (IQR), cm^2	1.64 (1.40, 1.89)	1.62 (1.41, 1.90)	1.64 (1.40, 1.88)	0.955
EF, median (IQR), %	61.70 (57.15, 66.15)	62.00 (57.23, 66.47)	61.50 (57.00, 65.60)	0.442

Data are presented as no. (%), mean ± SD or median (interquartile range, IQR). AVA, aortic valve area; AR, aortic regurgitation; BAV, bicuspid aortic valve; BMI, body mass index; COPD, chronic obstructive pulmonary disease; CT, computed tomography; EF, ejection fraction; LM, left main artery; MI, myocardial infarction; NYHA, New York Heart Association; PCI, percutaneous coronary intervention; RCA, right coronary artery; STJ, sino-tubular junction; STS, Society of Thoracic Surgeons; TAV, tricuspid aortic valve; TTE, transthoracic echocardiography.

categorical data. A p value < 0.5 was considered as statistically significant.

2. Results

We finally consecutively enrolled 395 patients between March 2019 and April 2022. The patient flow was presented in the Fig. 1. Of them, 56.5 % were BAV patients, while the remaining were the TAV patients. The age (72.0 [68.0, 78.0] yrs vs 76.0 [70.0, 82.0] yrs, $p < 0.001$) and STS (2.57 [1.57, 4.58] % vs 4.04 [2.56, 7.04] %, $p < 0.001$) were lower in the BAV group compared with the TAV group. The proportion of hypertension was lower in the BAV group (46.6 % vs 58.1 %, $p = 0.030$). The data of the preprocedural echocardiography presented the characteristics of higher transvalvular maximum velocity (4.85 ± 0.78 m/s vs 4.53 ± 0.84 m/s, $p < 0.001$), higher transvalvular mean gradient (52.00 [42.00, 66.00] mmHg vs 46.50 [36.00, 62.75] mmHg, $p < 0.001$), lower aortic valve area (0.62 [0.46, 0.80] cm^2 vs 0.69 [0.55, 0.85] cm^2, $p = 0.001$), and lower prevalence of aortic regurgitation (35.0 % vs 61.0 %, $p < 0.001$) in the BAV patients. Moreover, BAV patients required more pre-dilatation (97.3 % vs 85.5 %, $p < 0.001$) and post-dilatation (71.3 % vs 51.7 %, $p < 0.001$) during the procedure.

The mortality was comparable between two groups (3.1 % vs 0.6 %, $p = 0.145$). Meanwhile, the mortality and follow-up data at 30-day were similar between these two groups. The readmission rate was comparable between BAV and TAV patients within 30-day follow-up (11.1 % vs 14.8 %, $p = 0.428$). The baseline characteristics, procedural data, in-hospital outcomes and 30-day follow-up data for all patients were presented in the Table 1.

There were 172 (43.5 %) patients who had the next-day discharge after TAVR, consisted by 101 (58.7 %) BAV and 71 (41.3 %) TAV patients. For patients who received the next-day discharge, similar with the former results, the lower age (72.0 [67.0, 77.0] yrs vs 74.0 [70.0, 80.0] yrs, $p = 0.011$) and STS score (2.33 [1.56, 3.54] % vs 3.82 [2.38, 5.70] %, $p < 0.001$) were observed in the BAV group. Meanwhile, the BAV patients had lower prevalence of AR regurgitation (29.7 % vs 64.8 %, $p < 0.001$). The BAV patients who received next-day discharge had higher proportion of post-dilatation (74.3 % vs 50.7 %, $p = 0.003$) when compared with the next-day discharged TAV patients. The patients who received the next-day discharge was safe with no death both in BAV and TAV patients at 30-day follow-up. Moreover, the readmission rate was comparable between BAV and TAV patients who discharged on the next day after TAVR (8.1 % vs 14.0 %, $p = 0.397$). The baseline characteristics, procedural data, in-hospital outcomes and 30-day follow-up data for patients who received the next-day discharge were presented in the Table 2.

3. Discussion

The present study demonstrated the feasibility and safety of the next-

Table 2
Baseline characteristics of the next-day discharge patients in BAV versus TAV patients.

	All Patients (n = 172)	BAV (n = 101)	TAV (n = 71)	p Value
Age, median (IQR), y	73.00 (68.00, 79.00)	72.00 (67.00, 77.00)	74.00 (70.00, 80.00)	**0.011**
Male, n (%)	93 (54.1)	59 (58.4)	34 (47.9)	0.227
BMI, median (IQR), kg/m^2	22.90 (20.67, 25.80)	23.10 (20.50, 26.00)	22.50 (21.05, 25.30)	0.716
NYHA III/IV, n (%)	124 (72.1)	71 (70.3)	53 (74.6)	0.650
STS, median (IQR)	2.69 (1.81, 4.54)	2.33 (1.56, 3.54)	3.82 (2.38, 5.70)	**<0.001**
Smoker, n (%)	37 (21.5)	23 (22.8)	14 (19.7)	0.771
Dyslipidemia, n (%)	31 (18.0)	20 (19.8)	11 (15.5)	0.601
Diabetes Mellitus, n (%)	30 (17.4)	17 (16.8)	13 (18.3)	0.962
Hypertension, n (%)	90 (52.3)	50 (49.5)	40 (56.3)	0.466
Syncope, n (%)	9 (5.2)	5 (5.0)	4 (5.6)	1.000
COPD, n (%)	38 (22.1)	24 (23.8)	14 (19.7)	0.658
Prior MI, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	NA
Prior PCI, n (%)	18 (10.5)	10 (9.9)	8 (11.3)	0.972
Prior Stroke, n (%)	7 (4.1)	6 (5.9)	1 (1.4)	0.242
Pre TTE data				
Max velocity, median (IQR), m/s	4.71 (4.32, 5.21)	4.72 (4.33, 5.19)	4.71 (4.24, 5.23)	0.939
Mean Gradient, median (IQR), mmHg	51.00 (42.00, 65.00)	51.00 (42.00, 65.00)	51.00 (42.00, 64.00)	0.703
AVA, median (IQR), cm^2	0.67 (0.51, 0.82)	0.69 (0.49, 0.84)	0.67 (0.54, 0.79)	0.826
EF, median (IQR), %	61.40 (56.70, 65.85)	61.70 (57.80, 65.50)	61.20 (56.55, 66.75)	0.745
AR moderate/severe, n (%)	76 (44.2)	30 (29.7)	46 (64.8)	**<0.001**
Procedure				
Valve type				0.556
Self-expanding valve, n (%)	156 (90.7)	90 (89.1)	66 (93.0)	
Balloon-expandable valve, n (%)	16 (9.3)	11 (10.9)	5 (7.0)	
Valve size				0.181
≤26 mm, n (%)	120 (69.8)	66 (65.3)	54 (76.1)	
>26 mm, n (%)	52 (30.2)	35 (34.7)	17 (23.9)	
Pre-dilatation, n (%)	163 (94.8)	97 (96.0)	66 (93.0)	0.491
Post-dilatation, n (%)	111 (64.5)	75 (74.3)	36 (50.7)	**0.003**
In-hospital outcomes				
Mortality, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	NA
MI, n (%)	0 (0.0)	0(0.0)	0 (0.0)	NA
Stroke, n (%)	3 (1.7)	1 (1.0)	2 (2.8)	0.570
Pacemaker implantation, n (%)	2 (1.2)	0 (0.0)	2 (2.8)	0.169
Coronary obstruction, n (%)	2 (1.2)	1 (1.0)	1 (1.4)	1.000
Annular rupture, n (%)	1 (0.6)	0 (0.0)	1 (1.4)	0.413
Aortic dissection, n (%)	3 (1.7)	0 (0.0)	3 (4.2)	0.069
Second valve deployment, n (%)	7 (4.1)	4 (4.0)	3 (4.2)	1.000
Vascular complications, n (%)	5 (2.9)	2 (2.0)	3 (4.2)	0.405
30-day follow-up				
Mortality, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	NA
MI, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	NA
Stroke, n (%)	3 (1.8)	1 (1.0)	2 (3.0)	0.565
Pacemaker implantation, n (%)	5 (3.0)	3 (3.0)	2 (3.0)	1.000
Readmission, n (%)	15 (10.5)	7 (8.1)	8 (14.0)	0.397
Echocardiographic data				
Max velocity, mean ± SD, m/s	2.29 ± 0.53	2.32 ± 0.53	2.25 ± 0.52	0.398
Mean Gradient, median (IQR), mmHg	11.00 (8.00, 13.00)	11.00 (8.00, 13.25)	10.00 (7.00, 13.00)	0.229
AVA, median (IQR), cm^2	1.62 (1.42, 1.83)	1.62 (1.43, 1.84)	1.62 (1.40, 1.80)	0.601
EF, median (IQR), %	62.50 (58.40, 66.35)	62.70 (59.00, 66.12)	62.00 (58.10, 66.60)	0.780

Data are presented as no. (%), mean ± SD or median (interquartile range, IQR). AVA, aortic valve area; AR, aortic regurgitation; BAV, bicuspid aortic valve; BMI, body mass index; COPD, chronic obstructive pulmonary disease; CT, computed tomography; EF, ejection fraction; LM, left main artery; MI, myocardial infarction; NYHA, New York Heart Association; PCI, percutaneous coronary intervention; RCA, right coronary artery; STJ, sino-tubular junction; STS, Society of Thoracic Surgeons; TAV, tricuspid aortic valve; TTE, transthoracic echocardiography.

day discharge in the BAV patients received the TAVR. Next-day discharge post-TAVR was observed in nearly half of the TAVR recipients in our center, of whom more than half were BAV patients.

In the presented study, NDD BAV patients were slightly younger with lower STS score compared with TAV patients. Consistent with previous studies, patients with BAV undergoing TAVR tend to be younger with less comorbidities and presented a lower risk profile in traditional risk assessment model. There was a double-edged sword as BAV patients were younger, had lower STS score accompanied with anatomical challenging (heavier calcification, horizontal aorta, ascending aorta dilation) [21]. Previous study showed that younger age was a predictor for NDD [22]. However, the younger BAV patients may face more challenge during the procedure. The data in recent paper only reported 6.7 % BAV patients in NDD patients [4]. In China, TAVR candidates have a significantly higher frequency of bicuspid valve morphology [23]. Therefore, we aimed to explore the feasibility and safety of NDD in high BAV frequently Chinese patients. In our study, we found that the NDD in both BAV and TAV patients was safe and feasible.

In our study, we implanted the NDD protocol with the aid of remote health management by smartwatch. For BAV patients who were discharged on the next-day, only 3 patients received the pacemaker implantation after discharge. Our previous work demonstrated that smartwatch can facilitate remote health care for patients discharged to home after TAVR. The majority of cardiac clinical events were detected by the smartwatch [24]. Therefore, for the younger BAV patients, smartwatch facilitated remote health care ensured the safety for NDD patients.

In our study, no death was observed during 30-day follow-up in NDD patients. Previous study had observed a greater trend towards a reduction of length of stay after TAVR with average LOS from 6.3 days to 4.6 days [25]. As the rapid development in recent years, more and more centers utilized the minimalist TAVR to achieve the NDD or EDD, even SDD post-TAVR [1–4]. The mortality within 30-day follow-up ranged from 0 % to 2.2 %. Similar, zero death in our NDD patients supported the safety of the NDD in both BAV and TAV patients, even the BAV patients may face more anatomical challenging requiring more pre-dilatation and post-dilatation during the procedure. Moreover, our data showed the comparable readmission rate between BAV and TAV NDD patients within 30-day follow-up. The overall readmission rate was similar with the previous studies varied from 5.7 % to 14.0 % in the patients discharged within 3 days since TAVR [1–4]. In our study, we observed 8.1 % of readmission in BAV NDD patients and 14.0 % of readmission in TAV NDD patients. The numerical higher rate of readmission in TAV NDD patients may be related with the higher age in TAV patients.

4. Conclusions

In conclusion, we found a similar rate of NDD in BAV patients who undergoing TAVR compared with TAV patients. NDD in BAV patients after TAVR was feasible and safe. Clinical studies with large population are warranted to confirm the findings in our study.

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Disclosures.

All authors have no disclosures to report.

Ethics approval.

The study was approved by the medical ethics committee of the Second Affiliated Hospital of Zhejiang University.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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