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 BAV patients were 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...
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 rupture, and other severe periprocedural complications. 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 $\geq 20$ms 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 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                  | 72.00         | 76.00         | <0.001  |
| Male, n (%)       | 222 (56.2)             | 137 (61.4)    | 85 (49.4)     | 0.022   |
| BMI, median (IQR), kg/m² | 22.90               | 25.70         | 23.10         | 0.125   |
| NHYA III/IV, n (%) | 296 (74.9)             | 160 (71.7)    | 136 (79.1)    | 0.122   |
| Early day discharge, n (%) | 297 (75.2)     | 169 (75.8)    | 128 (74.4)    | 0.846   |
| Post-dilatation, n (%) | 248 (62.8)         | 159 (71.3)    | 89 (51.7)     | <0.001  |
| Pre-dilatation, n (%) | 364 (92.2)         | 217 (97.3)    | 147 (85.5)    | <0.001  |
| Pre TTE data | | | | |
| Hypertension, n (%) | 204 (51.6)             | 104 (46.6)    | 100 (58.1)    | 0.030   |
| 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   |
| Aortic dissection, n (%) | 7 (1.8)              | 4 (1.8)       | 3 (1.7)       | 1.000   |
| Annular rupture, n (%) | 3 (0.8)              | 2 (0.9)       | 1 (0.6)       | 1.000   |
| Coronary obstruction, n (%) | 5 (1.3)            | 2 (0.9)       | 3 (1.7)       | 0.658   |
| Length of stay since TAVR, median (IQR), days | 2.00 (1.00, 4.00) | 2.00 (1.00, 4.00) | 2.00 (1.00, 4.00) | 0.377 |
| Maximum velocity, mean ± SD, m/s | 4.53 ± 2.25 | 4.53 ± 2.25 | 4.53 ± 2.25 | <0.001 |
| Mean Gain, median (IQR), mmHg | 64.80 (52.00, 76.00) | 66.00 (54.00, 70.00) | 64.67 (57.23, 71.50) | 0.850 |
| Post-dilatation, n (%) | 71 (18.2)             | 34 (15.2)     | 38 (22.1)     | 0.106   |
| Pre-dilatation, n (%) | 129 (32.9)            | 65 (29.4)     | 64 (37.4)     | 0.660   |
| Pre TTE data | | | | |
| Day after TAVR (n = 395) | 103 (26.1)          | 57 (25.5)     | 46 (26.8)     | 0.912   |
| Day after TAVR (n = 223) | 57 (25.5)           | 34 (15.2)     | 23 (13.0)     | 0.912   |
| Day after TAVR (n = 172) | 46 (26.8)           | 23 (13.0)     | 23 (13.0)     | 0.912   |
| 3. Discussion

The present study demonstrated the feasibility and safety of the next-
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 patients are warranted to confirm the findings in our study.

In conclusion, we found a similar rate of NDD in BAV patients who underwent 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.

**Table 2 (continued)**

|                           | All Patients (n = 172) | BAV (n = 101) | TAV (n = 71) | p Value |
|---------------------------|------------------------|--------------|--------------|---------|
| EF, median (IQR), %       | 62.50                  | 62.70        | 62.00        | 0.780   |
|                          | (58.40, 65.35)         | (59.00, 65.35) | (58.10, 66.35) |         |

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.

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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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