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Safety and predictors of next day discharge after elective transfemoral transcatheter aortic valve replacement☆

Sulaiman Rathore [a], Yevgeniy Latyshev [a], Sheree Emore [a], Joseph Rowe [b], Jason Foerst [a,*]

[a] Cardiology Section, Carilion Clinic/Virginia Tech-Carilion School of Medicine, Roanoke, VA, USA
[b] Section of Cardiothoracic Surgery, Carilion Clinic/Virginia Tech-Carilion School of Medicine, Roanoke, VA, USA

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ABSTRACT

Objectives: We sought to determine the predictors of next-day discharge (NDD) for selected patients undergoing elective transfemoral transcatheter aortic valve replacement (TF-TAVR).
Background: Techniques have rapidly evolved over the last several years to simplify TF-TAVR allowing for a subset of patients to be discharged the next day.
Methods: Baseline and procedural characteristics, in-hospital and 30-day follow-up outcomes, complications and readmission rates of 100 TF-TAVR cases were assessed. Patients selected for NDD all met the following criteria: no procedural complications, same day ambulation, strong family support with home supervision, and access to our valve coordinator post discharge.
Results: There were 22 patients in NDD and 78 in later-day discharge (LDD) groups respectively. The mean length of stay was 3.4 days for LDD. There were no significant differences in baseline, pre-procedural characteristics, or frailty indices of the two groups. However, there were more baseline oxygen dependent patients in LDD ($p = 0.004$). Procedural characteristics included more balloon expandable valves ($p = 0.005$), less fluoroscopy time ($p = 0.008$), and higher use of moderate sedation ($p = 0.0001$) in NDD group. There were more minor vascular complications ($p = 0.04$) and new permanent pacemaker implantations ($p = 0.016$) in the LDD group. There were no vascular complications, stroke or blood transfusions in the NDD group. The 30-day re-admission and mortality rates were similar in both groups. In logistic analyses only moderate sedation was a strong predictor of next day discharge after TF-TAVR ($p = 0.003$).
Conclusion: Carefully selected patients without complications following TF-TAVR can be discharged safely the next day.

1. Introduction

Transcatheter aortic valve replacement (TAVR) was approved in the United States in late 2011 based on large randomized trials [1,2] with first generation balloon expandable valves. TAVR is rapidly becoming standard therapy for patients at high surgical risk for treatment of aortic stenosis, and is included in the latest ACC/AHA guidelines for management of valvular heart disease [3]. Historically, most centers used general anesthesia, transesophageal echocardiography, invasive hemodynamic monitoring, and indwelling urinary catheters to perform TAVR. This standard has changed, as there is evidence that TAVR can be performed safely with minimal sedation and transthoracic echocardiographic guidance, with difference in outcomes such as shorter hospital stay [4–7]. This "minimalist" approach has decreased cost and length of stay for patients undergoing TAVR [8]. Similarly, pathways to reduce length of stay by developing a fast track protocol have been described for transfemoral transcatheter aortic valve replacement (TF-TAVR) [9]. Likewise, improvements in procedural techniques, delivery system profile, and valve design have reduced complications [10,11]. These procedural changes of less general anesthesia, early removal of pulmonary artery catheters, central lines and bladder catheters, and early ambulation post-procedure have simplified elective TF-TAVR allowing for a subset of patients to be discharged the next day. We retrospectively analyzed our database to compare the characteristics and safety of next-day discharge (NDD) to later-day discharge (LDD) after elective TF-TAVR.

2. Methods

Our TAVR program started in May of 2012 with first generation balloon expandable valves delivered via transfemoral or transapical, our

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* Corresponding author at: Virginia Tech-Carilion School of Medicine, 2001 Crystal Springs Ave, Suite 203, Roanoke, VA 24014, USA.
E-mail address: JRFoerst@CarilionClinic.org (J. Foerst).

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program now implants both balloon expandable and self-expanding valves using all suitable access approaches based on patient characteristics. Recent improvements in transcatheter valve technology have allowed for the majority of our patients to be treated with a percutaneous transfemoral approach. In 2015 we transitioned away from general anesthesia and the majority of our cases were performed under monitored anesthesia care (MAC) without central lines or bladder catheters. Thus, we elected to focus on elective TF-TAVR procedures from January 2014 through December 2015. All patients were formally evaluated in the Structural Heart and Valve Clinic where they underwent baseline frailty assessments with the Kansas City Cardiomyopathy Questionnaire (KCCQ), Edmonton Frailty Score (EFS), 5-meter walk and 30-day Surgical Thoracic Society (STS) predicted risk of mortality (PROM). Patients generally would have a second visit within a week for cardiac catheterization and first cardiothoracic surgical evaluation. A third visit occurred the following week for a gated computed tomography study to assess the aortic annulus and iliofemoral anatomy, and a second cardiothoracic surgical consultation for assessment of surgical risk. All patients were reviewed at our multi-disciplinary valve conference, and the elective TF-TAVR case was usually scheduled within a week. All patients were recovered in a post-anesthesia care unit and transferred to the coronary care unit (CCU) where nurses were instructed to remove any central or arterial lines and bladder catheters as soon as possible. Patients were encouraged to ambulate within 6 h if there were no procedural complications. Careful electrocardiographic monitoring was performed in CCU for early detection of conduction disturbances and a permanent pacemaker was systematically implanted in patients with persistent complete atrioventricular block 24–48 h after TF-TAVR. Complications and procedural outcomes were defined according to the Valvular Academic Research Consortium-2 consensus document [12]. Patients with persistent left bundle branch block without a previous permanent pacemaker were not eligible for NDD. Patients selected for NDD all met the following criteria: no major procedural complications, same day ambulation, strong family support with home supervision and ready access to our valve coordinator the day after discharge. All patients had 30 day follow-up and were enrolled in the STS/TVT Registry™.

3. Statistics

Baseline, procedural, in-hospital and 30-day follow up data were entered prospectively in our database. A retrospective analysis of our TAVR database was performed. The study population was divided into 2 groups based on length of stay (LOS). Length of stay was calculated from the TAVR procedure (day 0) to discharge. Patients discharged on day 1 constituted NDD group and patients discharged on day 2 or after constituted the LDD group. Categorical variables were expressed as percentages and continuous variables were expressed as mean ± SD. Comparison of categorical variables was done by using Pearson's chi-square test or Fisher's Exact test and continuous variables were compared by using Student's *t*-test.

A multivariable logistic regression was used to assess the independent correlates of NDD. The model was built on the basis of the univariate association between the variable and NDD with a $p = 0.05$ and an elimination $p = 0.1$. All statistical tests were 2 sided. Differences were considered statistically significant at a p value ≤ 0.05. All data were analyzed using SPSS software (version 22.0; IBM, Armonk, New York).

4. Results

4.1. Baseline and pre-procedural characteristics

From January 2014 to December 2015 we performed 144 TAVR procedures of which there were 6 transapical, 6 direct aortic, 14 urgent/emergent TF TAVR and 100 elective TF TAVR. Among the 100 elective TF TAVR patients, there were 22 (22%) patients in NDD and 78 (78%) patients in LDD groups respectively. The post-procedure LOS was 1 day for NDD vs 3.4 days for LDD ($p = 0.0001$). The distribution of LOS after elective TF-TAVR is shown in Fig. 1. The mean LOS was 3.3 days in year 2014 and 2.5 days in year 2015 ($p = 0.1$) respectively as shown in Fig. 2. There were 60 (60%) patients discharged within 48 h post procedure.

Baseline characteristics of both groups are shown in Table 1. Overall the mean age was 80.6 (±8.5) years and 49% of patients were men. There were no significant differences in the baseline characteristics such as age ($p = 0.56$), gender (male, $p = 0.28$), diabetes ($p = 0.84$), body mass index ($p = 0.43$), creatinine ($p = 0.26$), previous permanent pacemaker ($p = 0.08$), baseline hemoglobin ($p = 0.41$) and heart failure class 3 or greater ($p = 1.0$). There were more home oxygen dependent patients in LDD group ($p = 0.004$).

Pre-procedural echocardiographic parameters are shown in Table 2. There was no significant difference between the two groups in mean aortic valve gradient ($p = 0.46$), aortic valve area ($p = 0.98$) or ejection fraction ($p = 0.49$).

There was no significant difference in frailty indices of the two groups (Table 3) including STS 30-day PROM ($p = 0.52$), KCCQ score ($p = 0.56$), 5-m walk ($p = 0.16$) and EFS ($p = 0.13$).

4.2. Procedural characteristics and outcomes

There was no difference in valve size between the two groups but there was more use of balloon expandable valves ($p = 0.005$) and monitored anesthesia care sedation ($p = 0.0001$) in NDD patients. The fluoroscopy time was also less in NDD group ($p = 0.008$) as compared to LDD group (Table 4).

At 30-day follow up visit, the echocardiogram showed a slightly higher mean aortic valve gradient in NDD group ($p = 0.002$). There was no difference in aortic valve area, ejection fraction and paravalvular regurgitation between the two groups (Table 5). Among the frailty indices between the two groups, KCCQ ($p = 0.001$) and EFS ($p = 0.02$) had a greater improvement in NDD while there was no difference in five meter walk test ($p = 0.08$) at 30 days (Table 6).

There were more procedural complications in the LDD group (Table 7): 2 (2.8%) strokes ($p = 0.31$), 8 (10.3%) minor vascular complications ($p = 0.04$), 11 (14.1%) new permanent pacemaker implants ($p = 0.016$) and 5 (6.4%) patients requiring blood transfusions ($p = 0.11$) vs none in the next-day discharge group. There was a higher drop in post procedure hemoglobin next day defined as delta hemoglobin in LDD group ($p = 0.009$). The 30-day re-admission rates for any reason were similar with 3 (13.6%) in the next-day discharge vs 8 (10.3%) in the later day discharge group ($p = 0.66$). The CCU time

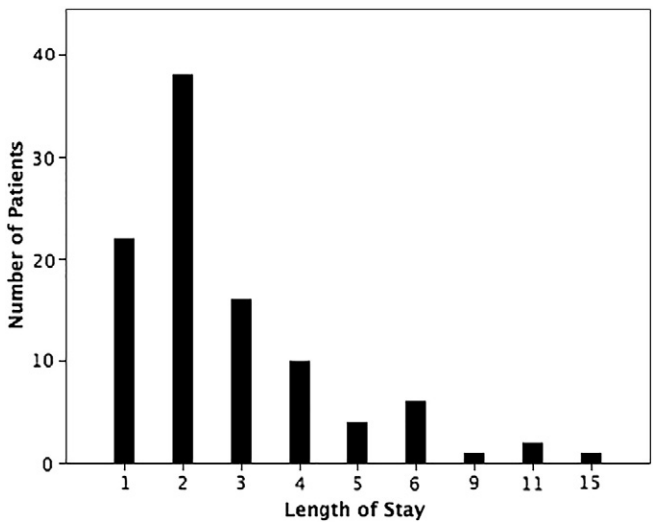

Fig. 1. Graphical representation of length of stay (days) in overall population.

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