# Evaluation of length of stay after transfemoral transcatheter aortic valve implantation with SAPIEN 3 prosthesis A French multicentre prospective observational trial

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# Evaluation of Length of Stay after Transfemoral Transcatheter Aortic Valve Implantation with Sapien 3 prosthesis: A French Multicenter Prospective Observational Trial

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## ABSTRACT

**Background:** It was previously shown that complications decrease after transfemoral (TF) transcatheter aortic valve implantation (TAVI) and that early discharge is feasible and safe in selected populations.

**Aims: T**o evaluate length of stay (LOS) and reasons of prolonged hospitalization after TF TAVI in unselected patients.

**Methods:** Patients with severe aortic stenosis who had TF-TAVI with SAPIEN-3 prosthesis using exclusively local anesthesia were prospectively and consecutively included in 5 French high volume centers. LOS was calculated from TAVI procedure to discharge. Reasons of prolonged hospitalization (i.e., > 3 days) were evaluated.

**Results:** Between 2017 and 2018, 293 patients were included with a mean age of 82.4±6.5 years and a mean logistic EuroSCORE of 13.7±9.0 %. In-hospital mortality was 1.4%. The median LOS was 5 (3-7) days and was extremely variable among centers (from 2 to 7 days). Sixty-four (21.8%) patients were discharged within 3 days after TF TAVI. Reported reasons for prolonged hospitalization were complications in 62.2%, loss of autonomy in 3.1%, refusal of discharge in 2.2%, and logistic reasons in 0.9%. In 31.6% of cases, the investigators reported no apparent reasons.

**Conclusions:** The results of our study suggest that LOS after TF TAVI, using SAPIEN-3 prosthesis and a minimalist approach, remains extremely variable among centers. In almost a third of cases, hospitalization was prolonged without any apparent reason. Efforts may be made to educate centers to reduce LOS.



**Key words**: Aortic stenosis, TAVI, SAPIEN-3, Length of stay

## INTRODUCTION

Transcatheter aortic valve implantation (TAVI) is playing a growing role in the management of aortic stenosis (AS). Initially limited to inoperable and high-risk patients, indications for TAVI have extended to intermediate-risk patients, especially when a femoral approach is feasible (1, 2).

After the procedure, patients remain hospitalized to check for complications before being discharged. Currently, there are no recommendations regarding the minimum duration of in-hospital monitoring (3) and practices are extremely heterogeneous. We and others have shown that complications decrease and that early discharge home (i.e., within 3 days after the procedure) is feasible and safe (4-11) after transfemoral (TF) TAVI. Prolonged unjustified hospitalization can expose patients to potential iatrogenic complications and increased healthcare costs.

In France, a slight decrease in median length of stay (LOS) was observed between FRANCE 2 (2010-2011) and FRANCE TAVI (2013-2015) registries [9 (7-13) vs. 8 (6-11) days, $p<0.001$] (12, 13). Our objective was to evaluate prospectively LOS and reasons for late discharge after elective TF TAVI in a contemporary setting using exclusively the latest generation of balloon-expandable prosthesis implanted using local anesthesia in 5 French high-volume centers in consecutive patients eligible for discharge home.

## METHODS

### Study design

Between May 2017 and January 2018, the FAST-TAVI non-randomized, prospective, study enrolled 293 consecutive patients from five French high-volume centers (Rouen University Hospital-Charles Nicolle, Paris University Hospitals-Bichat Claude Bernard, Jacques Cartier private hospital, Brest University Hospital, and Rennes University Hospital). The study was approved by the CPP Ile de France V and was registered on clinicaltrials.gov (NCT02956915).

All patients provided written informed consent before the procedure.

Inclusion criteria consisted of stable patients with severe symptomatic AS who had scheduled TF-TAVI with the SAPIEN-3 prosthesis (Edwards Lifesciences, Irvine, CA, USA), using exclusively local anesthesia.

Exclusion criteria were the use of other than Edwards SAPIEN-3 transcatheter aortic valve devices, TF-TAVI requiring general anesthesia or surgical cut-down, TF-TAVI performed in unstable patients or on an urgent/emergent basis, non-TF routes of valve delivery (eg. transapical, transaortic, transcarotid), and patients for whom re-adaptation post-TAVI was not anticipated.

Patients were treated with Edwards SAPIEN 3 prosthesis via a femoral approach using local anesthesia and sedation on demand, as previously described (14). In-hospital and follow-up data were entered in a dedicated database.

EQ-5D 3 level (EQ-5D-3L) and EQ visual analogue scale (EQ VAS) were used to evaluate patients' health status before and one month after TAVI. The EQ-5D-3L descriptive system comprises the following five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has three levels: no problems, some

problems, extreme problems. Patients were asked to indicate their health status by ticking (or placing a cross) in the box next to the most appropriate statement in each of the five dimensions. The EQ VAS records the respondent's self-rated health on a vertical, visual analogue scale where the endpoints are labelled 'best imaginable health status' and 'worst imaginable health status'. The EQ-5D-3L index values were calculated using Crosswalk index calculator.

When LOS was longer than 3 days, investigators reported the main reason of prolonged hospitalization as follow: occurrence and type of complications, loss of autonomy during hospitalization, refusal of discharge by the patient or his/her family, logistic reason (delay to obtain echocardiography before discharge or an ambulance), and no apparent reason.

Clinical follow-up was carried out during pre-scheduled outpatient clinic visits or by telephone contact at 1-month post-TAVI. Clinical outcomes were defined according to Valve Academic Research Consortium-2 criteria (3).

**End-points**

LOS and reasons for prolonged hospitalization beyond 3 days were the primary end-points. Secondary end-points included: incidence of early discharge/prolonged hospitalization, safety of early discharge by the 30-day combined endpoint of mortality or rehospitalization at 30-days after TF-TAVI procedure, and predictors of prolonged hospitalization.

**Statistical analysis**

LOS was calculated from TAVI procedure (day 0) to discharge. Qualitative variables were expressed as percentage, and quantitative variables as mean ± SD or median ($25^{th}$ to $75^{th}$ interquartile range). Distribution of quantitative variables was evaluated using a Shapiro test.

Comparison of numerical variables was performed with the Student t test or Wilcoxon rank-sum test, depending on variable distribution. The chi-square test or Fisher's exact test was used to compare qualitative variables. Patients were analyzed in 2 groups for comparison purposes: those discharged within 3 days (early discharge group) versus those discharged > 3 days after the procedure (late discharge group). A logistic regression multivariable analysis was used to assess independent correlates of late discharge. The model was built on the basis of the univariate association between the variable and late discharge with a $p<0.10$. 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 23.0; IBM, Armonk, New York).

## RESULTS

### Baseline and procedural characteristics

Baseline and procedural characteristics of the studied population are summarized in Tables 1 and 2, respectively. Briefly, the mean age of the studied population was 82.4 ± 6.5 years and the mean logistic EuroSCORE was 13.7 ± 9.0 %. All the patients had severe AS and TAVI indication was decided by the local heart team. Patients included were contra-indicated or at increased risk for surgery. EQ-5D-3L before TAVI is shown in Table 3. EQ-5D-3L index and EQ VAS values were 0.76 ± 0.20 and 60.4 ± 17.8, respectively. One patient had structural valve deterioration of bioprosthetic surgical valve treated by valve-in-valve. All the patients were implanted with Edwards SAPIEN-3 prosthesis using local anesthesia, mostly without pre-dilatation (60.8%). Post-dilatation was required in 17 (5.8%) patients and a second valve was used in 1 (0.3%) patient. Device success was obtained in 261 (89.1%) patients.

### In-hospital outcomes

In-hospital complications and echocardiographic data after TAVI are summarized in Tables 4 and 5, respectively. As shown in Table 4, the occurrence of a major complication was rare. The three most frequent complications were conduction disturbances (30.0%), vascular (mostly minor, 29.5%), and infectious complications (5.1%). In-hospital mortality was low (1.4%). Four patients died during hospitalization with one case of tamponade related to annulus rupture, one case of coronary occlusion, one case of asystole and one case of refractory heart failure. The mean and median LOS were 6.1 ± 5.1 days and 5 (3-7) days, respectively. Sixty-four (21.8%) patients were discharged early (within 3 days after TAVI). The median LOS and the proportion of patients early discharged were extremely variable

among centers (Table 6). The majority of patients were discharged home, 85.3% (n=250). Others were discharged to a rehabilitation center (7.8%, n=23) or another institution (5.4%, n=16). The proportion of patients discharged home was higher in the early versus the late discharge group (92.2% vs. 84.9%), although the difference was not significant (p=0.10). The proportion of patients discharged home was significantly higher in those without any complications (92.4% vs. 80.6%, p=0.04). Two hundred and twenty-five (76.8%) patients had prolonged hospitalization (> 3 days). Interestingly, EQ-5D-3L index (0.75 ± 0.20 vs. 0.76 ± 0.20, p=0.74) and EQ VAS values (58.6 ± 18.9 vs. 61.1 ± 17.4, p=0.33) before TAVI were not significantly different in patients discharged early or late (Table 7). The most frequently reported reasons for the prolongation of hospitalization are reported in Table 8 and were the occurrence of complications in 62.2%. The most common complication was any conduction disturbance in 32% followed by vascular (23.6%), bleeding (6.7%), arrhythmia (4.4%), and infectious (3.6%) complications. Other reported reasons included loss of autonomy during hospitalization in 3.1%, patient or family refusal in 2.2%, and logistic reasons in 0.9%. Interestingly, no apparent reason was reported in 31.6% of cases.

Univariate and multivariable analysis of predictors of prolonged hospitalization are reported in Table 9. Low transaortic gradient, high logistic EuroSCORE, conductive disturbances (LBBB or 3$^{rd}$ degree AV block), and any vascular complications were independently associated with prolonged hospitalization whereas a pacemaker before TAVI was a protective factor.

**30-day outcomes**

None of the patients were lost to follow-up**.** One patient in the late discharge group died after a hip fracture and 19 patients were re-admitted between discharge and 30-day follow-up. The proportion of patients re-admitted was similar between early and late

discharge groups (6.2% vs. 6.7%, p=1). The 30-day occurrence of death or re-admission was not significantly different in patients discharged early or late (6.8% vs. 6.7%, p=1). EQ-5D-3L analysis after TAVI is shown in additional Table 4. EQ-5D-3L index (0.76 ± 0.20 vs. 0.81 ± 0.20, p<0.0001) and EQ VAS values (60.6 ± 17.0 vs. 67.1 ± 16.3, p<0.0001) were significantly improved at 30-day follow-up as compared to baseline in the overall population. Improvement of ED-5Q-3L and EQ VAS values was similar in patients discharged early or late (p=0.98 and 0.30, respectively).

## DISCUSSION

This prospective multicenter French FAST-TAVI study aimed to evaluate LOS and reasons/predictors of prolonged hospitalization after TF TAVI using exclusively the SAPIEN-3 prosthesis and a minimalist approach in unselected patients eligible for discharge home. The main results of our study may be summarized as follows: 1) LOS remains extremely variable among centers; 2) Predictive factors of late discharge were lower trans aortic gradient, higher logistic EuroSCORE, and complications (vascular and particularly conductive disturbances) whereas pacemaker before TAVI was a protective factor; 3) In almost a third of cases, hospitalization was prolonged without any apparent reason.; 4) When possible, early discharge is safe without alteration of health status.

Currently, LOS after TAVI remains high and extremely variable in France as compared to those reported in other countries. In contrast, complications decrease and it has been shown that early discharge home (i.e., within 3 days after the procedure) is feasible and safe (4-11) after transfemoral (TF) TAVI. In our study, all the procedures were performed in high-volume centers with more than 10 years of TAVI experience. All the patients were consecutive, stable and eligible for discharge directly home. TAVI was performed via a femoral approach using exclusively the latest generation of balloon-expandable prosthesis and local anesthesia. Compared to previous registries published in France, median LOS decreased to 5 days and 21.8% of patients were discharged early (within 3 days) after TAVI (12, 13). Moreover, LOS was extremely variable among the five centers since the lowest median LOS was 2 days and the highest was 7 days. Furthermore, the proportion of patients discharged early was also extremely variable among centers from 3.7% to 73.8%. It should therefore be possible to further reduce LOS since the results of some centers in France, Italy and North

America support the feasibility of programs favoring early discharge (within 2 or 3 days) after TAVI without safety concerns (5-11).

Reasons and predictive factors of prolonged hospitalization were closely similar. As expected, complications (in particular any vascular complications and high degree conductive disturbances) after TAVI were the most frequent reasons and the most powerful predictive factors of prolonged hospitalization. Very rarely is the prolongation of hospitalization related to a loss of autonomy or a wish of the patient or family. On the other hand, no apparent reason was reported to justify prolonged hospitalization in almost one third of cases in our study. This suggests that some centers have no established strategy for reducing LOS after TAVI and/or have other than medical considerations to decide when patients should be discharged. There are many potential explanations for prolonged hospitalization (see below) but there are probably also economic reasons since the reimbursement rate in France for TAVI procedures was lower when LOS is less than 4 days during the study. On the other hand, very few pre-operative variables were predictive of prolonged hospitalization and self-reported health status was similar in patients discharged early or late. This suggests that co-morbidities and patient status have a low impact on LOS in elective TF TAVI procedures. Taking into account all these considerations, it appears that early discharge is often feasible in TF TAVI elective procedures using a minimalist approach and a balloon-expandable prosthesis in the absence of complications in patients judged eligible for discharge home. Moreover, it was previously demonstrated that early discharge is safe and does not increase the risk of death or readmission at 30 days and does not alter health status (5-11).

We believe that further efforts should therefore be made to reduce unnecessary and potentially deleterious prolonged hospitalization after TF TAVI. Measures allowing a

reduction of LOS include, on the one hand, logistical measures (forecast of the potential date of discharge in the absence of per procedural complications, programming before the procedure echocardiography within 24 hours after the procedure, synergy between the different medical and paramedical professionals to reduce LOS, etc.) and on the other hand, standardized procedures for the prevention, monitoring, and treatment of complications.

**Limitations**

The results of our study were obtained in TF procedures using SAPIEN-3 prosthesis and local anesthesia and should not be extrapolated to procedures using non-femoral approach, other transcatheter heart valve devices, general anesthesia, or performed in unstable patients. Furthermore, although the FAST TAVI registry was observational, it is possible that LOS was influenced by a surveillance bias (Hawthorne effect).

**Conclusions**

The results of our study suggest that LOS after TF TAVI, using SAPIEN-3 prosthesis and a minimalist approach, remains extremely variable among centers. In almost a third of cases, hospitalization is prolonged without any apparent reason. Efforts are therefore probably necessary to educate centers to further reduce LOS after TF TAVI.

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**Conflict of interest**

Eric Durand and Bernard Iung are consultants for Edwards Lifesciences, Thierry Lefevre is proctor for Edwards Lifesciences, Dominique Himbert is proctor for Edwards Lifesciences and Medtronic, and Bernard Chevalier is proctor for Medtronic.

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## REFERENCES


1. Baumgartner H, Falk V, Bax JJ, et al; ESC Scientific Document Group. 2017 ESC/EACTS Guidelines for the management of valvular heart disease. Eur Heart J 2017;38:2739-91.

2. Nishimura RA, Otto CM, Bonow RO, et al. 2017 AHA/ACC Focused Update of the 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation 2017;135:e1159-95.

3. Kappetein AP, Head SJ, Généreux P, et al. Updated standardized endpoint definitions for transcatheter aortic valve implantation: the Valve Academic Research Consortium-2 consensus document. J Am Coll Cardiol 2012;60:1438-54.

4. Durand E, Borz B, Godin M, et al. Transfemoral aortic valve replacement with the Edwards SAPIEN and Edwards SAPIEN XT prosthesis using exclusively local anesthesia and fluoroscopic guidance: feasibility and thirty-day outcomes. JACC Cardiovasc Interv 2012;5:461-7.

5. Durand E, Eltchaninoff H, Canville A, et al. 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.

6. Serletis-Bizios A, Durand E, Cellier G, et al. A Prospective Analysis of Early Discharge After Transfemoral Transcatheter Aortic Valve Implantation. Am J Cardiol 2016;118:866-72.

7. Barbanti M, Capranzano P, Ohno Y, et al. Early discharge after transfemoral transcatheter aortic valve implantation. Heart 2015;101:1485-90.

8. Kamioka N, Wells J, Keegan P, et al. Predictors and clinical outcomes of next-day discharge after minimalist transfemoral transcatheter aortic valve replacement. JACC Cardiovasc Interv 2018;11:107-15.

9. Kotronias RA, Teitelbaum M, Webb JG, et al. Early versus standard discharge after transcatheter aortic valve replacement: a systematic review and meta-analysis. JACC Cardiovasc Interv 2018;11:1759-71.

10. Barbanti M, van Mourik MS, Spence MS, et al. Optimizing Patient Discharge Management after Transfemoral Transcatheter Aortic Valve Implantation: The Multicentre European FAST-TAVI Trial. EuroIntervention. 2019. pii: EIJ-D-18-01197. doi: 10.4244/EIJ-D-18-01197.

11. Wood DA, Lauck SB, Cairns JA, et al. 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: The 3M TAVR Study. JACC Cardiovasc Interv 2019;12:459-69.

12. Auffret V, Lefevre T, Van Belle E, et al; FRANCE TAVI Investigators. Temporal trends in transcatheter aortic valve replacement in France: FRANCE 2 to FRANCE TAVI. J Am Coll Cardiol 2017;70:42-55.

13. Gilard M, Eltchaninoff H, Iung B, et al; FRANCE 2 Investigators. Registry of transcatheter aortic-valve implantation in high-risk patients. N Engl J Med 2012;366:1705-15.

14. Durand E, Borz B, Godin M, et al. Transfemoral aortic valve replacement with the Edwards SAPIEN and Edwards SAPIEN XT prosthesis using exclusively local anesthesia and fluoroscopic guidance: feasibility and 30-day outcomes. JACC Cardiovasc Interv 2012;5:461-7.

**Table 1.** Baseline characteristics

| Variables | Overall population (N=293) | Early discharge (N=64) | Late discharge (N=225) | P |
|---|---|---|---|---|
| Age, years | 82.4 ± 6.5 | 82.5 ± 5.7 | 82.3 ± 6.8 | 0.86 |
| Male, n (%) | 173 (59) | 40 (62.5) | 132 (58.7) | 0.61 |
| Hypertension | 203 (69.3) | 46 (71.9) | 155 (68.9) | 0.81 |
| Diabetes | 78 (26.6) | 14 (21.9) | 62 (27.6) | 0.21 |
| Dyslipidemia | 153 (52.2) | 33 (51.6) | 118 (52.4) | 0.85 |
| BMI, $Kg/m^2$ | 27.3 ± 4.9 | 26.7 ± 4.0 | 27.5 ± 5.1 | 0.29 |
| Myocardial infarction, n (%) | 26 (8.9) | 5 (7.8) | 20 (8.9) | 1 |
| PCI, n (%) | 59 (20.1) | 16 (25) | 41(18.2) | 0.11 |
| CABG, n (%) | 18 (6.1) | 2 (3.1) | 16 (7.1) | 0.37 |
| History of SAVR, n (%) | 1 (0.3) | 1 (1.6) | 0 (0) | 0.38 |
| History of SMVR, n (%) | 2 (0.7) | 0 (0) | 2 (0.9) | 1 |
| Atrial fibrillation, n (%) | 75 (25.6) | 20 (31.2) | 80 (35.6) | 0.80 |
| Prior pacemaker, n (%) | 34 (11.6) | 12 (18.8) | 22 (9.8) | 0.02 |
| NYHA, n (%)<br>- I<br>- II<br>- III<br>- IV<br>- unknown | <br>5 (1.7)<br>141 (48.1)<br>120 (41.0)<br>8 (2.7)<br>19 (6.5) | <br>2 (3.1)<br>27 (42.2)<br>28 (43.7)<br>1 (1.6)<br>6 (9.4) | <br>3 (1.3)<br>112 (49.8)<br>91 (40,4)<br>7 (3.1)<br>12 (5.3) | 0.56 |
| EQ-5D-3L | 60.4 ± 17.7 | 58.2 ± 18.9 | 61.1 ± 17.4 | 0.27 |
| CHF before TAVI, n (%) | 20 (6.8) | 5 (7.8) | 15 (6.7) | 0.78 |
| Logistic EuroSCORE, % | 13.7 ± 9.0 | 10.2 ± 4.6 | 14.8 ± 9.7 | <0.0001 |
| PAD, n (%) | 14 (4.8) | 2 (3.1) | 11 (4.9) | 0.74 |
| Stroke, n (%) | 18 (6.1) | 2 (3.1) | 15 (6.7) | 0.38 |
| COPD, n (%) | 32 (10.9) | 3 (4.7) | 29 (12.9) | 0.07 |
| Creatinine clearance | 57.1 ± 23.3 | 53.6 ± 26.0 | 58.1 ± 22.5 | 0.18 |
| Liver cirrhosis, n (%) | 9 (3.1) | 1 (1.6) | 8 (3.6) | 0.69 |
| History of cancer, n (%) | 49 (16.7) | 11 (17.2) | 38 (16.9) | 0.97 |
| Chest irradiation, n (%) | 7 (2.4) | 2 (3.1) | 5 (2.2) | 0.65 |
| Mean aortic gradient, mmHg | 50.4 ± 16.0 | 44.2 ± 12.2 | 51.8 ± 15.8 | <0.0001 |
| Aortic valve area, $cm^2$ | 0.73 ± 0.23 | 0.8 ± 0.1 | 0.7 ± 0.2 | 0.005 |
| PASP, mmHg | 43.1 ± 13.9 | 36.6 ± 11.5 | 44.8 ± 14.0 | <0.0001 |
| LVEF, % | 56.9 ± 12.2 | 59.0 ± 11.7 | 56.1 ± 12.4 | 0.11 |

**Abbreviations.** BMI: body mass index, PCI: percutaneous coronary intervention, CABG: coronary artery bypass surgery, SAVR: surgical aortic valve replacement, SMVR: surgical mitral valve replacement, CHF: congestive heart failure, PAD: peripheral arterial disease, COPD: chronic obstructive pulmonary disease, PASP: Pulmonary arterial systolic pressure LVEF: left ventricular ejection fraction.

**Table 2**. Procedural characteristics

| **Variables** | **Overall population (N=293)** | **Early Discharge (N=64)** | **Late Discharge (N=225)** | **P** |
|---|---|---|---|---|
| Sapien 3 diameter, n (%) | | | | 0.23 |
| - 20-mm | 1 (0.3) | 1 (1.6) | 0 (0) | |
| - 23-mm | 82 (28.0) | 18 (28.1) | 62 (27.6) | |
| - 26-mm | 126 (43.0) | 30 (46.9) | 97 (43.1) | |
| - 29-mm | 81 (27.6) | 15 (23.4) | 66 (29.3) | |
| Valve-in-valve | 1 (0.3) | 1 (1.6) | 0 (0) | 0.22 |
| Without pre-dilatation | 178 (60.8) | 37 (57.8) | 139 (61.8) | 0.54 |
| Post dilatation | 17 (5.8) | 5 (7.8) | 12 (5.3) | 0.55 |
| Second valve | 1 (0.3) | 0 (0) | 0 (0) | |
| Device success, n (%) | 261 (89.1) | 57 (89.1) | 204 (90.7) | 0.94 |
| X ray duration, min | 14.8 ± 6.7 | 13.5 ± 6.5 | 15.1 ± 6.6 | 0.13 |
| Volume of iodine contrast, ml | 97.7 ± 40.4 | 122.5 ± 33.9 | 90.8 ± 39.4 | <0.0001 |

**Table 3.** EQ-5D-3L analysis before TAVI

| EQ-5D Dimension | Overall population (N=293) | Early discharge (N=64) | Late discharge (N=225) | P |
|---|---|---|---|---|
| **Mobility, %** | | | | 0.29 |
| - Level 1 | 45.5 | 51.5 | 43.8 | |
| - Level 2 | 46.9 | 43.8 | 47.8 | |
| - Level 3 | 2.8 | 4.7 | 2.2 | |
| - Unknown | 4.9 | 0 | 6.3 | |
| **Self-care, %** | | | | 0.18 |
| - Level 1 | 79.5 | 81.3 | 79.0 | |
| - Level 2 | 12.2 | 15.6 | 11.2 | |
| - Level 3 | 3.5 | 3.1 | 3.6 | |
| - Unknown | 4.9 | 0 | 6.3 | |
| **Usual activities, %** | | | | 0.005 |
| - Level 1 | 52.1 | 57.8 | 50.4 | |
| - Level 2 | 33.7 | 23.4 | 36.6 | |
| - Level 3 | 9.4 | 18.8 | 6.7 | |
| - Unknown | 4.9 | 0 | 6.3 | |
| **Pain/discomfort, %** | | | | 0.06 |
| - Level 1 | 47.6 | 40.6 | 49.6 | |
| - Level 2 | 38.5 | 48.4 | 35.7 | |
| - Level 3 | 9.0 | 10.9 | 8.5 | |
| - Unknown | 4.9 | 0 | 6.3 | |
| **Anxiety/depression, %** | | | | 0.21 |
| - Level 1 | 48.8 | 51.6 | 48.7 | |
| - Level 2 | 36.2 | 40.6 | 35.7 | |
| - Level 3 | 9.6 | 7.8 | 9.4 | |
| - Unknown | 5.5 | 0 | 6.3 | |
| **EQ-5D-3L index** | 0.76 ± 0.20 | 0.75 ± 0.20 | 0.76 ± 0.20 | 0.74 |
| **EQ VAS values** | 60.4 ± 17.8 | 58.6 ± 18.9 | 61.1 ± 17.4 | 0.33 |

**Table 4.** In-hospital complications after TAVI

| Variables | Overall population (N=293) | Early discharge (N=64) | Late discharge (N=225) | P |
|---|---|---|---|---|
| **Death**, n (%) | 4 (1.4) | 0 (0) | 0 (0) | |
| **Tamponade**, n (%) | 3 (1.0) | 0 (0) | 2 (0.9) | 1 |
| **Valve migration**, n (%) | 0 (0) | 0 (0) | 0 (0) | |
| **Cardiac surgery**, n (%) | 1 (0.3) | 0 (0) | 0 (0) | |
| **Conduction disturbances**, n (%) | | | | |
| - Any | 88 (30.0) | 6 (9.4) | 81 (36) | <0.0001 |
| - De novo persistent LBBB | 48 (16.4) | 2 (3.1) | 46 (20.4) | <0.0001 |
| - 1st degree AV block | 17 (5.8) | 2 (3.1) | 15 (6.7) | 0.38 |
| - 2nd degree AV block | 6 (2.0) | 0 (0) | 6 (2.7) | 0.34 |
| - 3rd degree AV block | 34 (11.6) | 2 (3.1) | 31 (13.8) | 0.01 |
| - PPI | 43 (14.7) | 1 (1.6) | 41 (18.2° | <0.0001 |
| **Rhythm disorder**, n (%) | | | | |
| - Supraventricular | 7 (2.4) | 0 (0) | 7 (3.1) | 0.35 |
| - Ventricular | 3 (1.0) | 0 (0) | 3 (1.3) | 0.53 |
| **Myocardial infarction**, n (%) | 1 (0) | 0 (0) | 0 (0) | |
| **Vascular complications**, n (%) | | | | |
| - Any | 76 (25.9) | 2 (3.1) | 72 (32) | <0.0001 |
| - Minor | 72 (24.6) | 2 (3.1) | 69 (30.7) | |
| - Major | 4 (1.4) | 0 (0) | 3 (1.3) | |
| - Needing stent graft | 10 (3.4) | 1 (1.6) | 9 (4) | 0.47 |
| - Needing vascular surgery | 12 (4.1) | 0 (0) | 11 (4.9) | 0.13 |
| **Stroke**, n (%) | | | | |
| - Any | 10 (3.3) | 0 (0) | 10 (4.4) | 0.12 |
| - Minor | 1 (0.3) | 0 (0) | 1 (0.4) | |
| - Major | 1 (0.3) | 0 (0) | 1 (0.4) | |
| - TIA | 8 (2.7) | 0 (0) | 8 (3.6) | 0.21 |
| **Hemorrhagic complications**, n (%) | | | | |
| - Any | 19 (6.5) | 1 (1.6) | 17 (7.6) | 0.14 |
| - Life-threatening/disabling | 3 (1.0) | 0 (0) | 2 (0.9) | |
| - Major | 4 (1.4) | 0 (0) | 4 (1.8) | |
| - Minor | 12 (4.1) | 1 (1.6) | 11 (4.9) | |
| - Needing transfusions | 7 (2.4) | 0 (0) | 7 (3.1) | 0.35 |
| **Acute kidney injury**, n (%) | | | | |
| - None | 282 (96.2) | 63 (98.4) | 216 (96) | |
| - Stage 1 | 8 (2.7) | 1 (1.6) | 7 (3.1) | 0.79 |
| - Stage 2 | 2 (0.7) | 0 (0) | 1 (0.4) | |
| - Stage 3 | 1 (0.3) | 0 (0) | 1 (0.4) | |
| - Hemodialysis | 0 (0) | 0 (0) | 0 (0) | |
| **Infectious complications**, n (%) | | | | |
| - Any | 15 (5.1) | 0 (0) | 14 (6.2) | 0.04 |
| - Pulmonary | 3 (1.0) | 0 (0) | 2 (0.9) | 1 |
| - Urinary | 4 (1.4) | 0 (0) | 4 (1.8) | 0.58 |
| - Others | 8 (1.7) | 0 (0) | 8 (3.6) | 0.21 |

**Abbreviations.** LBBB: left bundle branch block, AV: atrio-ventricular, PPI: permanent pacemaker implantation. Four patients died during the hospitalization and are note included in the early and discharge groups.

**Table 5.** Echocardiographic data after TAVI

| **Variables** | **Overall population (N=289)** | **Early discharge (N=64)** | **Late diescharge (N=225)** | **P** |
|---|---|---|---|---|
| Mean Gradient, mmHg | 12.4 ± 4.3 | 12.1 ± 3.9 | 12.6 ± 4.4 | 0.48 |
| Mean Gradient > 20 mmHg, n (%) | 17 (5.9) | 3 (4.7) | 14 (6.2) | 1 |
| Aortic valve area, $cm^2$ | 1.9 ± 0.5 | 2.0 ± 0.5 | 1.8 ± 0.5 | 0.08 |
| Aortic regurgitation, n(%) | | | | 0.54 |
| - None | 161 (54.9) | 39 (60.9) | 122 (54.2) | |
| - Grade 1 | 104 (35.5) | 23 (35.9) | 81 (36) | |
| - Grade 2 | 20 (6.8) | 2 (3.1) | 18 (8) | |
| - Grade 3 | 1 (0.3) | 0 (0) | 1 (0.4) | |
| - Grade 4 | 0 (0) | 0 (0) | 0 (0) | |
| - unknown | 3 (1.0) | 0 (0) | 3 (1.3) | |
| Mitral regurgitation, n(%) | | | | 0.70 |
| - None | 116 (39.6) | 25 (39.1) | 91 (40.4) | |
| - Grade 1 | 131 (44.7) | 33 (51.6) | 98 (43.6) | |
| - Grade 2 | 32 (10.9) | 5 (3.9) | 27 (12) | |
| - Grade 3 | 3 (1.0) | 1 (1.6) | 2 (0.9) | |
| - Grade 4 | 0 (0) | 0 (0) | 0 (0) | |
| - unknown | 7 (2.4) | 0 (0) | 7 (3.1) | |
| LVEF, % | 58.8 ± 11.7 | 62.0 ± 10.1 | 57.9 ± 12.0 | 0.02 |
| PASP, mmHg | 38.4 ± 11.2 | 33.7 ± 10.0 | 38.9 ± 11.0 | 0.02 |

**Table 6.** LOS and proportion of patients early discharged in the 5 participating centers

| **Centers** | **A** | **B** | **C** | **D** | **E** |
|---|---|---|---|---|---|
| **LOS** | | | | | |
| Median (IQR) | 2 (2-4) | 7 (4.5-12) | 6 (4-8) | 4 (3-6) | 7 (5-8) |
| Mean (SD) | 3.2 ± 0.3 | 8.7 ± 1.0 | 7.0 ± 0.8 | 5.0 ± 0.5 | 7.6 ± 0.6 |
| **% early discharge** | 72.6 | 12.5 | 3.1 | 9.4 | 4.7 |

**Abbreviations.** LOS: length of stay

**Table 7.** EQ-5D-3L analysis one month after TAVI

| EQ-5D Dimension | **Overall (N=289)** | **Early discharge (N=64)** | **Late discharge (N=225)** | **P** |
|---|---|---|---|---|
| **Mobility, %** | | | | 0.36 |
| - Level 1 | 57.3 | 59.4 | 56.7 | |
| - Level 2 | 30.9 | 31.2 | 30.8 | |
| - Level 3 | 1.4 | 3.1 | 0.9 | |
| - Unknown | 10.4 | 6.3 | 11.6 | |
| **Self-care, %** | | | | 0.51 |
| - Level 1 | 75.3 | 76.5 | 75.0 | |
| - Level 2 | 12.2 | 15.6 | 11.2 | |
| - Level 3 | 2.1 | 1.6 | 2.2 | |
| - Unknown | 10.4 | 6.3 | 11.6 | |
| **Usual activities, %** | | | | 0.36 |
| - Level 1 | 56.9 | 59.4 | 56.2 | |
| - Level 2 | 25.0 | 23.4 | 25.4 | |
| - Level 3 | 7.3 | 10.9 | 6.3 | |
| - Unknown | 10.8 | 6.3 | 12.1 | |
| **Pain/discomfort, %** | | | | 0.22 |
| - Level 1 | 51.0 | 48.4 | 51.8 | |
| - Level 2 | 33.3 | 35.9 | 32.6 | |
| - Level 3 | 5.2 | 9.4 | 4.0 | |
| - Unknown | 10.4 | 6.3 | 11.6 | |
| **Anxiety/depression, %** | | | | 0.39 |
| - Level 1 | 58.7 | 57.8 | 58.9 | |
| - Level 2 | 26.4 | 32.8 | 24.6 | |
| - Level 3 | 4.5 | 3.1 | 4.9 | |
| - Unknown | 10.4 | 6.3 | 11.6 | |
| **EQ-5D-3L index** | 0.81 ± 0.20 | 0.80 ± 0.22 | 0.81 ± 0.20 | 0.55 |
| **EQ VAS values** | 67.1 ± 16.3 | 65.5 ± 18.3 | 67.7 ± 15.6 | 0.39 |

**Table 8**. Reported reasons for prolonged hospitalization (i.e. > 3 days)

| Variables | Late discharge group (N=225) |
|---|---|
| **At least one Complication, n (%)** | **140 (62.2)** |
| - Conduction disturbance | 72 (32) |
| - Vascular | 53 (23.6) |
| - Bleeding | 15 (6.7) |
| - Arrhythmia | 10 (4.4) |
| - Infection | 8 (3.6) |
| - Neurological (stroke, confusion) | 6 (2.7) |
| - Heart failure | 4 (1.8) |
| - Others | 9 (4) |
| **Loss of autonomy, n (%)** | **7 (3.1)** |
| **Refusal, n (%)** | **5 (2.2)** |
| - Patient | 2 (0.9) |
| - Family | 3 (1.3) |
| **Logistic reasons, n (%)** | **2 (0.9)** |
| - Absence of ambulance | 1 (0.4) |
| - No echocardiography possible at discharge | 1 (0.4) |
| **No reason, n (%)** | **71 (31.6)** |

**Table 9**. Predictors of prolonged hospitalization

| | **Univariate** | | **Multivariable** | |
|---|---|---|---|---|
| | **Hazard Ratio (95% CI)** | **p** | **Hazard Ratio (95% CI)** | **p** |
| **Pacemaker before TAVI** | **0.38 (0.16–0.89)** | **0.03** | **0.24 (0.06–0.99)** | **0.05** |
| COPD | 3.06 (0.90–10.38) | 0.07 | 0.99 (0.15–6.47) | 0.99 |
| **Logistic EuroSCORE** | **1.10 (1.04–1.15)** | **0.001** | **1.17 (1.03–1.32)** | **0.01** |
| **Mean aortic gradient** | **0.96 (0.94–0.98)** | **0.001** | **0.94 (0.89–0.98)** | **0.008** |
| LVEF | 0.98 (0.96–1.01) | 0.09 | 1.00 (0.95–1.06) | 0.89 |
| PASP >40 mmHg | 3.17 (1.57–6.38) | 0.001 | 2.35 (0.73–7.55) | 0.15 |
| **Conductive disturbances** | **8.06 (1.90–34.17)** | **0.005** | **9.32 (1.00–90.83)** | **0.05** |
| **Vascular complications** | **14.70 (3.49–61.71)** | **<0.0001** | **23.56 (2.46–225.79)** | **0.006** |

**Abbreviations.** COPD: chronic obstructive pulmonary disease, LVEF: left ventricular ejection fraction, PASP: pulmonary arterial systolic pressure.