Prespecified risk criteria facilitate adequate discharge and long-term outcomes after transfemoral transcatheter aortic valve implantation

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ORIGINAL RESEARCH

Prespecified Risk Criteria Facilitate Adequate Discharge and Long-Term Outcomes After Transfemoral Transcatheter Aortic Valve Implantation

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BACKGROUND: Despite the availability of guidelines for the performance of transcatheter aortic valve implantation (TAVI), current treatment pathways vary between countries and institutions, which impact on the mean duration of postprocedure hospitalization.

METHODS AND RESULTS: This was a prospective, multicenter registry of 502 patients to validate the appropriateness of discharge timing after transfemoral TAVI, using prespecified risk criteria from FAST-TAVI (Feasibility and Safety of Early Discharge After Transfemoral [TF] Transcatheter Aortic Valve Implantation), based on hospital events within 1-year after discharge. The end point—a composite of all-cause mortality, vascular access–related complications, permanent pacemaker implantation, stroke, cardiac rehospitalization, kidney failure, and major bleeding—was reached in 27.0% of patients (95% CI, 23.3–31.2) within 1 year after intervention; 7.5% (95% CI, 5.5–10.2) had in-hospital complications before discharge and 19.6% (95% CI, 16.3–23.4) within 1 year after discharge. Overall mortality within 1 year after discharge was 7.3% and rates of cardiac rehospitalization 13.5%, permanent pacemaker implantation 4.2%, any stroke 1.8%, vascular-access–related complications 0.7%, life-threatening bleeding 0.7%, and kidney failure 0.4%. Composite events within 1 year after discharge were observed in 18.8% and 24.3% of patients with low risk of complications/early (≤3 days) discharge and high risk and discharged late (>3 days) (concordant discharge), respectively. Event rate in patients with discordant discharge was 14.3% with low risk but discharged late and increased to 50.0% in patients with high risk but discharged in ≤3 days.

CONCLUSIONS: The FAST-TAVI risk assessment provides a tool for appropriate, risk-based discharge that was validated with the 1-year event rate after transfemoral TAVI.

REGISTRATION: URL: https://www.ClinicalTrials.gov; Unique identifier: NCT02404467.

Key Words: aortic stenosis ■ aortic valve implantation ■ discharge ■ risk ■ validation

Transcatheter aortic valve implantation (TAVI) has now become an accepted alternative to surgical aortic valve replacement across surgical risk groups.[1,2] However, despite the availability of guidelines for the performance of TAVI, current treatment pathways vary between countries and institutions,

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CLINICAL PERSPECTIVE

What Is New?

- After results from the FAST-TAVI (Feasibility And Safety of Early Discharge After Transfemoral [TF] Transcatheter Aortic Valve Implantation) registry demonstrated that prespecified risk criteria based on the rate of 30-day complications could identify patients with severe symptomatic aortic stenosis for whom early discharge was safe and effective and those patients who would benefit from late discharge, this analysis of the FAST-TAVI registry data aims to determine the appropriateness of the discharge criteria to predict out-of-hospital events during the first year after hospital discharge.
- A FAST-TAVI risk assessment provides a tool for an appropriate, risk-based discharge scheme that was revalidated on the basis of the 1-year event rate of adverse events after transfemoral TAVI.

What Are the Clinical Implications?

- While low-risk patients can be safely discharged early, patients with high risk based on outlined criteria need to stay in the hospital and are exposed to a considerable risk if they are discharged early.

Nonstandard Abbreviations and Acronyms

ED	early discharge
FAST-TAVI	Feasibility and Safety on Early Discharge After Transfemoral Transcatheter Aortic Valve Implantation
PPI	permanent pacemaker implantation
TAVI	transcatheter aortic valve implantation

which impacts on the mean duration of hospitalization after the procedure (range, 6–16 days).[3–7]

The adoption of well-standardized TAVI-specific clinical care pathways for patients can help to identify those candidates suitable for early discharge (ED; ≤3 days), without impacting on their overall clinical outcome.[4,8,9] In those patients at low risk for complications, there is no increase in 30-day mortality, stroke, bleeding, permanent pacemaker implantation (PPI), or readmission when discharged early.[4,9] In fact, ED can improve patient outcomes and quality of life after surgical and interventional procedures.[4] On the other hand, patients at high risk for ED may require prolonged hospitalization to avoid unattended adverse events. The length of hospital stay for patients after TAVI is a delicate balancing act that considers the individual patient's medical needs, the benefits of ED (eg, reduced hospital-acquired complications, accelerated patient recovery/mobility, and reduced hospital costs) and the benefits of late discharge (>3 days), for example, the timely detection of postprocedural complications.[10]

Results from the FAST-TAVI (Feasibility and Safety of Early Discharge After Transfemoral [TF] Transcatheter Aortic Valve Implantation) registry demonstrated that prespecified risk criteria based on the rate of 30-day complications could identify patients with severe symptomatic aortic stenosis for whom ED was safe and effective and those patients who would benefit from late discharge.[10,11] This analysis of the FAST-TAVI registry data aims to determine the appropriateness of the discharge criteria to predict out-of-hospital events during the first year after hospital discharge.

METHODS

The FAST-TAVI registry was an observational, prospective, multicenter project conducted at 5 sites in Italy, 2 sites in The Netherlands, and 3 sites in the United Kingdom. All centers involved had no administrative restrictions or reimbursement issues potentially affecting postprocedural length of hospital stay.[10,11] The registry was approved by the independent ethics review boards at each of the participating institutions. Patients and the public were not involved in the study design. All patients provided written informed consent. The data are available from the corresponding author upon reasonable request.

Patient Selection

Briefly, patients undergoing transfemoral TAVI with the SAPIEN 3 transcatheter heart valve (Edwards Lifesciences, Irvine CA) were enrolled. Valve selection was restricted to remove potential bias introduced by different valves on the rate of permanent pacemaker implantation (PPI) or other relevant complications. The local team at each institution adhered to medical judgment and standard, local practice regarding their decision to perform the TAVI procedure and the date to discharge their patient.

Discharge Criteria

According to the protocol, a list of prespecified criteria were considered after TAVI to define a low risk of complications after ED (Table 1) including New York Heart Association class ≤II; no chest pain attributable to cardiac ischemia; no untreated major arrhythmias; patients having complications on days 0 to 1, but free of signs or symptoms on day 3; no fever during the past 24 hours

Table 1. Discharge Risk Evaluation Criteria

Baseline, before TAVI • Independent mobilization and self-caring • No chest pain attributable to cardiac ischemia • No untreated major arrhythmias • New York Heart Association class
Status after TAVI • New York Heart Association class ≤II • No paravalvular leak with aortic regurgitation≥++; stroke/transient ischemic attack; hemodynamic instability • Patients having complications on days 0 to 1, but free of signs or symptoms on day 3 • No red blood cell transfusion during the past 72 h • Stable hemoglobin in 2 consecutive samples (defined as a decrease of no more than 2 mg/dL) • Preserved diuresis (>40 mL/h during the past 24 h) and no unresolved acute kidney injury type 3 (Valve Academic Research Consortium -2) • No fever during the past 24 h, no signs of an infectious cause (clinic and laboratory)

TAVI indicates transcatheter aortic valve implantation.

and no signs of an infectious cause; independent mobilization and self-caring; preserved diuresis (>40 mL/h during the preceding 24 hours); no unresolved acute kidney injury type 3 (according to Valve Academic Research Consortium-2 criteria); no red blood cell transfusion during the preceding 72 hours; stable hemoglobin in 2 consecutive samples; no paravalvular leak with aortic regurgitation less than moderate; no stroke/transient ischemic attack; and no haemodynamic instability.

Objectives

The primary objective was to determine the incidence of a composite of Valve Academic Research Consortium-2 criteria defined all-cause mortality, vascular access–related complications, PPI, stroke, rehospitalization for cardiac reasons, kidney failure, and major bleeding, occurring after patients were discharged alive from the hospital.[12,13] In this analysis, we aimed to determine the appropriateness of the discharge criteria to predict out-of-hospital events based on the above-mentioned composite end point during the first year after the intervention.

Statistical Analysis

The data are presented descriptively, using absolute values with percentages. Comparisons were made using a Pearson's chi-square or Fisher's exact test for categorical variables. A *P* value of <0.05 was considered statistically significant. Statistical analysis was performed using SPSS Version 24.0 (IBM Corporation, Armonk, NY).

RESULTS

Patient characteristics of the FAST-TAVI registry have previously been described in full detail.[10] Three patients were lost to follow-up between discharge and 30 days, and a further 14 patients between 30 days and 1 year, resulting in a completeness at the 1-year follow-up of 96.6% (Figure 1). Overall, 6 of the 502 patients died in the hospital (3 before and 3 after TAVI). Of the 496 patients discharged alive, 3 died between discharge and 30 days and a further 32 died between 30 days and 1 year.

Long-Term Outcomes for the Composite End Point

Of the patients discharged alive a total of 27.0% (95% CI, 23.3–31.2) reached the composite end point (Table 2); 7.5% (95% CI, 5.5–10.2) had complications during hospitalization before discharge and 19.6% (95% CI, 16.3–23.4) had complications within 1 year after being discharged.

The overall mortality within 1 year after discharge was 7.3%, and the rate of rehospitalization for cardiac reasons was 13.5% and PPI 4.2%. Any stroke was observed in 1.8% of patients, vascular access–related complications in 0.7%, life-threatening bleeding in 0.7%, and kidney failure in 0.4%.

Complications by Risk Category

After dividing patients into low risk of complications and high risk of complications, 21.6% and 46.2% of patients, respectively, reached the composite end point (*P*<0.001) (Table 3). The overall mortality was 6.4% and 10.5% in the low- and high-risk-of-complications groups, respectively (*P*=0.145). The most common complications in the low-risk group were rehospitalization for any reason (25.1%; including rehospitalization for cardiac reasons, 12.0%), PPI (7.7%), stroke (1.2%), and major vascular complications (0.9%). In the high-risk group, the most common complications were rehospitalization for any reason (32.1%, including rehospitalization for cardiac reasons, 16.5%), stroke (7.5%; *P*=0.002 versus low risk), PPI (22.6%; *P*<0.001 versus low risk) and major vascular complications (6.8%; *P*=0.002) and life-threatening bleeding (6.8%; *P*=0.001).

Risk-Based Discharge and Outcomes Within 1 Year

End points within 1-year after discharge as defined by the composite end point were observed in 18.8% (95% CI, 14.9–23.3) of patients with low risk of early discharge and actually discharged early. The end point rate was 24.3% (95% CI, 17.3–33.1) in patients with high risk of ED and actually discharged late. The 2 were considered concordant discharge (Figure 2).

The event rate in those patients with discordant discharge was 14.3% (95% CI, 5.0–34.6) for patients with low risk but discharged late and increased to 50.0% (95% CI, 15.0–85.0) in patients with high risk

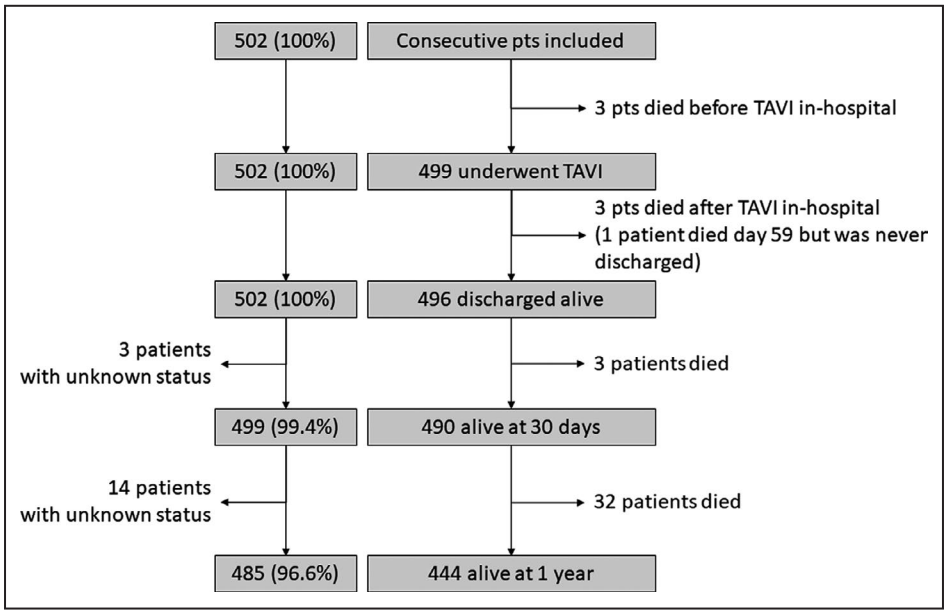

Figure 1. Patient flow.
FU indicates follow-up; and TAVI, transcatheter aortic valve implantation.

but discharged within the first 3 days. A statistical comparison of the high-risk early discharge group with the other categories was not significant (P=0.182) and would have required at least 36 high-risk early discharge patients (power 80%; alpha 5%). Rates of rehospitalization for cardiac reasons were within a range of 9.5% to 15.2% for all groups except for patients with high risk but ED, who were readmitted in 50.0% of cases (Table 4).

DISCUSSION

The current analysis demonstrates that the FAST-TAVI discharge criteria provide an effective tool for the appropriate discharge timing of patients after transfemoral TAVI. While low-risk patients can be safely discharged early, patients with high risk on the basis of the outlined criteria (Table 1) need to stay in the hospital and are exposed to a considerable risk if they are discharged

Table 2. 1-Year Outcomes of Patients Discharged Alive

	Before /After Discharge	Before Discharge	Events After Discharge	
	Events, n/N (%)	Events, n/N (%)	Events, n/N (%)	Proportion of Patients With an Event After Discharge (%)
Primary end point*	130/481 (27.0) (95% CI, 23.3–31.2)	36/481 (7.5) (95% CI, 5.5–10.2)	94/479 (19.6) (95% CI, 16.3–23.4)	72.3
Overall mortality	35/479 (7.3)	NA	35/479 (7.3)	100
Stroke/transient ischemic attack	18/453 (4.0)	4/453 (0.9)	14/452 (3.1)	77.8
Stroke	12/453 (2.6)	4/453 (0.9)	8/452 (1.8)	66.7
Transient ischemic attack	6/452 (1.3)	0/452 (0.0)	6/452 (1.3)	100
New PPI	52/450 (11.6)	33/450 (7.3)	19/450 (4.2)	36.5
Kidney failure	3/447 (0.7)	1/447 (0.2)	2/447 (0.4)	66.7
Major vascular complications	10/448 (2.2)	7/448 (1.6)	3/448 (0.7†)	30.0
Life-threatening bleeding	9/448 (2.0)	6/448 (1.3)	3/448 (0.7‡)	33.3
Rehospitalization (any reason)	127/466 (27.3)	NA	127/466 (27.3)	100
Cardiac reasons	63/465 (13.5)	NA	63/465 (13.5)	100

NA indicates not applicable; and PPI, permanent pacemaker implantation.
*The primary end point and objective of the study was to determine the incidence of a composite of all-cause mortality, vascular access–related complications, PPI, stroke, rehospitalization for cardiac reasons, kidney failure, and life-threatening bleeding.
†Occlusion of the femoral artery, sepsis caused by infected stent right groin, cardiac tamponade.
‡Subdural hematoma in 2 patients, cardiac tamponade.

Table 3. All Events Within 1 Year After Being Discharged Alive With a Complete Risk Categorization*

	Low Risk for Early Discharge, n/N (%)	High Risk for Early Discharge, n/N (%)	*P* Value
Primary end point†	77/357 (21.6)	54/117 (46.2)	<0.001
Overall mortality	23/358 (6.4)	12/114 (10.5)	0.145
Stroke/Transient ischemic attack	10/339 (2.9)	8/107 (7.5)	0.049
Stroke	4/339 (1.2)	8/107 (7.5)	0.002
Transient ischemic attack	6/339 (1.8)	0/106 (0)	0.343
PPI	26/337 (7.7)	24/106 (22.6)	<0.001
Kidney failure	1/337 (0.3)	2/103 (1.9)	0.138
Major vascular complications	3/338 (0.9)	7/103 (6.8)	0.002
Life-threatening bleeding	2/338 (0.6)	7/103 (6.8)	0.001
Rehospitalization (any reason)	88/350 (25.1)	35/109 (32.1)	0.152
Cardiac reasons	42/349 (12.0)	18/109 (16.5)	0.226

*In 7 patients, risk categorization is not available.

†The primary end point and objective of the study was to determine the incidence of a composite of all-cause mortality, vascular access–related complications, permanent pacemaker implantation (PPI), stroke, rehospitalization for cardiac reasons, kidney failure, and major bleeding.

early (50% events over 1 year). It was reassuring to see that this type of discordant discharge was rare in the participating centers.

TAVI has become the first-line therapy for patients with severe aortic stenosis or aortic regurgitation, as well as degenerated transcatheter or surgical bioprostheses. There are several challenges with this intervention that can affect procedure efficacy and patient survival including paravalvular leak, PPI, vascular access–related complications, and stroke.[3,14] Despite improvements in the TAVI procedure and with the availability of new devices, these posttreatment complications remain key concerns. With the use of more modern devices, the incidence of paravalvular leak after TAVI has steadily decreased and is now <5%.[14,15] Certain factors, for example, preexisting conduction disorders or anatomic features, that influence the need for PPI cannot be changed, but reducing the amount of mechanical trauma to the conduction system and periprocedural medical management has the potential to reduce the need for PPI.[15] Again, the incidence of vascular access–related complications associated with TAVI has been reduced by using computed tomography imaging and closure devices and by decreasing the profile of the delivery systems; finally, the incidence of stroke after TAVI has reduced to ≈3%, which is in line with surgical valve replacement.[14]

The aim of the FAST-TAVI registry was to provide a source of prospectively collected data that could be used to better understand the benefits and risks of ED after transfemoral TAVI, with the aim of improving clinical outcomes and quality of

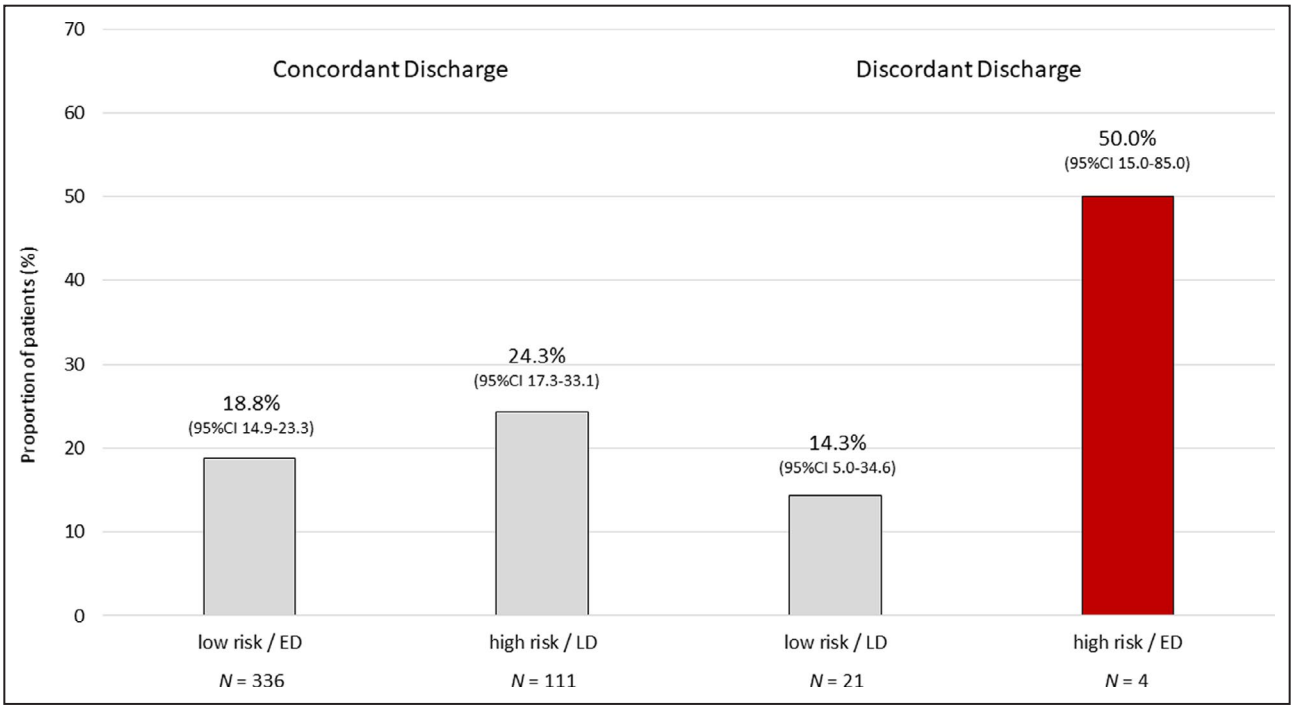

Figure 2. Composite complications* after discharge (1-year follow-up).
ED, early discharge within 3 days; LD, late discharge>3 days after the intervention. *The primary end point and objective of the study was to determine the incidence of a composite of all-cause mortality, vascular access–related complications, PPI, stroke, rehospitalization for cardiac reasons, kidney failure, and major bleeding.

Table 4. Out-of-Hospital Event Rate in Patients up to 1 Year Based on Different Risk and Discharged Categories*

	Concordant Discharge		Discordant Discharge	
	Low Risk of Early Discharge and Discharged ≤3 d, n/N (%)	High Risk of Early Discharge and Discharged> 3 d, n/N (%)	Low Risk of Early Discharge and Discharged >3 d, n/N (%)	High Risk of Early Discharge and Discharged ≤3 d, n/N (%)
Primary end point†	63/336 (18.8)	27/111 (24.3)	3/21 (14.3)	2/4 (50.0)
Overall mortality	23/337 (6.8)	11/110 (10.0)	0/21 (0)	1/4 (25.0)
Stroke/Transient ischemic attack	9/318 (2.8)	4/103 (3.9)	1/21 (4.8)	0/3 (0)
Stroke	3/318 (0.9)	4/103 (3.9)	1/21 (4.8)	0/3 (0)
Transient ischemic attack	6/318 (1.9)	0/103 (0)	0/21 (0)	0/3 (0)
PPI	12/316 (3.8)	4/103 (3.9)	0/21 (0)	1/3 (33.3)
Kidney failure	1/316 (0.3)	1/100 (1.0)	0/21 (0)	0/3 (0)
Major vascular complications	2/317 (0.6)	1/100 (1.0)	0/21 (0)	0/3 (0)
Life-threatening bleeding	2/317 (0.6)	1/100 (1.0)	0/21 (0)	0/3 (0)
Rehospitalization (any reason)	84/329 (25.5)	33/105 (31.4)	4/21 (19.0)	2/4 (50.0)
Cardiac reasons	40/328 (12.2)	16/105 (15.2)	2/21 (9.5)	2/4 (50.0)

PPI indicates permanent pacemaker implantation.
*This included all patients discharged alive (n=496) with outcomes and a complete risk categorization available.
†The primary end point and objective of the study was to determine the incidence of a composite of all-cause mortality, vascular access–related complications, PPI, stroke, rehospitalization for cardiac reasons, kidney failure, and major bleeding.

life for the patient. A predefined set of risk criteria as a guide to discharge decisions resulted in the appropriate selection of patients eligible for ED (because of a low risk of out-of-hospital complications) and the identification of patients benefitting from longer hospitalization (late discharge). This discharge strategy was associated with a low rate of adverse events (including PPI, vascular access–related complications, and stroke, as previously mentioned) and a low rate of rehospitalization for cardiac reasons.[10]

Other studies have also looked at the implications of ED after TAVI. One systematic review and meta-analysis concluded that ED following uncomplicated TAVI is safe in terms of 30-day mortality or the need for PPI following discharge,[16] which is in line with our previous findings.[10] Several studies have looked into specific factors associated with safe ED after TAVI and have concluded that various factors, for example, lower logistic EuroSCORE, smaller delta creatinine, not developing any complications after discharge, higher left ventricular ejection fraction, and better cognitive function, are associated with safe ED.[9,17] Other studies have looked into factors that necessitate late discharge (eg, the use of blood transfusions and PPI).[18,19] To the best of our knowledge, however, this is the first study that has looked at the longer-term impact of ED after TAVI. The data presented here confirm earlier, 30-day data showing that ED is safe and effective in a subset of patients identified with prespecified criteria and that this response is extended into the longer term (1 year after intervention).

By the very nature of the TAVI intervention, those patients selected for treatment are quite sick; a significant number of patients enrolled in this registry had additional comorbidities, and ≈10% of the patients had undergone prior cardiovascular interventions (eg, coronary artery bypass grafting and percutaneous coronary intervention).[10] Compared with the event rates seen before discharge (7.5% for the composite), the 1-year outcomes show that the overall rate of the composite end point has increased considerably (19.6% after discharge or 72.3%). While the majority of new PPI, major vascular complications, and life-threatening bleedings occurred early before discharge, other events were more likely to occur after discharge (stroke/transient ischemic attack, kidney failure). In addition, in those patients with a low risk of complications and ED, the rates of PPI have increased from 30-day to 1-year follow-up, whereas the rates of vascular access–related complications and stroke have marginally increased, which would be expected in such a patient population. Rates of these complications, however, all remain within acceptable levels after TAVI, confirming that ED is safe and effective in patient populations identified by prespecified criteria. Interestingly, the rates of rehospitalization for cardiac reasons have increased across all groups by up to 3-fold, and although this could be unrelated to the TAVI procedure itself or related to past cardiology procedures, more data are needed to understand the reasons behind this.

Hospital budgets are constantly under scrutiny, and efforts need to be made to become more economical without compromising on patient safety or

making decisions that will increase costs in the longer term through, for example, rehospitalisation or PPI. Previous studies have shown that ED is beneficial for the patient (accelerated patient recovery and mobilization) and is associated with a low risk of out-of-hospital complications, but it also has the potential to be advantageous for hospital budgets by reducing unnecessary length of hospital stay after TAVI.[10,19]

Limitations

The FAST-TAVI study was conducted in 3 European countries, which increases the applicability of the study findings to other countries, but there are likely differences in the healthcare systems (eg, the financial implications of ED) across these countries that are not considered in this study. In addition, standard procedural and after-care protocols are likely to vary among countries, and possibly among institutions within a single country. While this is an important limitation, it was the trigger for the identification of predefined common risk criteria in the FAST-TAVI registry.

CONCLUSIONS

The FAST-TAVI risk assessment provides a tool for an appropriate, risk-based discharge scheme that was revalidated based on the 1-year rate of adverse events after transfemoral TAVI. By applying the predefined discharge criteria, the timing of discharge can be optimized.

ARTICLE INFORMATION

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Disclosures

Dr Bramlage is the representative of the Institute for Pharmacology and Preventive Medicine, Cloppenburg. Dr Barbanti is consultant for Edwards Lifesciences and an advisory board member for Medtronic Inc. Dr Spence is a proctor for TF-TAVI and is a consultant for Edwards Lifesciences. Dr Muir is a proctor for Edwards Lifesciences. Dr Kurucova and Thoenes are employees of the funder Edwards Lifesciences. The remaining authors have no disclosures to report.

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