Structural Heart
The Journal of the Heart Team

ISSN: 2474-8706 (Print) 2474-8714 (Online) Journal homepage: https://www.tandfonline.com/loi/ushj20

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To cite this article: Jordan R. Wooley, Anupama Vasudevan, Deborah Tabachnick, John J. Squiers, J. Michael DiMaio, Michael J. Mack & Elizabeth Holper (2019) Identification of Patient Factors Associated with Loss to Follow-Up at 1-Year Post Transcatheter Aortic Valve Replacement, Structural Heart, 3:1, 61-64, DOI: 10.1080/24748706.2018.1549373

To link to this article: https://doi.org/10.1080/24748706.2018.1549373

Published online: 29 Nov 2018.

STRUCTURAL HEART
2019, VOL. 3, NO. 1, 61–64
https://doi.org/10.1080/24748706.2018.1549373

ORIGINAL RESEARCH

Identification of Patient Factors Associated with Loss to Follow-Up at 1-Year Post Transcatheter Aortic Valve Replacement

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ABSTRACT

Background: Centers for Medicare and Medicaid Services requires for payment that transcatheter aortic valve replacement (TAVR) programs follow patients for at least 1-year post-procedurally and record outcomes in a data registry. We sought to identify which patient factors are associated with loss to follow-up 1 year after TAVR.

Methods: A retrospective study of 604 TAVR patients between January 2012 and April 2017 was conducted. Patients who suffered 1-year mortality (n = 67) were excluded. A step-wise logistic regression analysis was employed to identify risk factors associated with loss to follow-up 1 year after TAVR. Discriminatory ability and calibrating efficiency of the final model was assessed using receiver operating curve analysis and Hosmer-Lemeshow (HL) goodness-of-fit test, respectively.

Results: A total of 537 patients met inclusion criteria, with median age 82 years (range, 47–100) and 279 (51.9%) females. There were 79 (14.7%) patients without 1-year follow-up. After multivariable analysis, general anesthesia (OR 6.25, 95%CI 2.15–18.18), failure of the 5-meter walk test preoperatively (OR 2.73, 95%CI 1.31–5.7), any post-procedural complication (OR 1.81, 95%CI 1.08–3.03), distance in miles (for every 100 miles) between home address and hospital (OR 1.3, 95%CI 1.1–1.5) were predictive of loss to follow-up at 1 year. Higher albumin levels (OR 0.54, 95%CI 0.33–0.88) were protective against becoming lost to follow-up at 1 year. The area under the curve was 0.73 and the HL was $p = 0.75$.

Conclusions: Multiple factors are predictive of loss to follow-up at 1 year after TAVR. Although few factors are readily modifiable, they can be used to identify patients at increased risk for loss to follow-up after TAVR.

ARTICLE HISTORY Received 25 April 2018; Revised 3 October 2018; Accepted 8 November 2018

KEYWORDS Transcatheter aortic valve replacement (TAVR); follow-up; clinical quality

Introduction

Transcatheter aortic valve replacement (TAVR) is a common procedure for patients with severe aortic stenosis who are deemed intermediate or high risk for mortality after surgical aortic valve replacement (SAVR). Centers for Medicare and Medicaid Services (CMS) requires, as a condition for payment, that TAVR programs follow all patients and record outcomes for at least 1 year post-procedurally in a prospective, national, audited registry.[1–3] Most programs elect to use the STS/ACC TVT Registry to record up to 1-year outcomes including all-cause mortality, stroke, major vascular complications, and quality of life.[2] Additionally, routine follow-up allows physicians to monitor the performance of bioprosthetic TAVR valves over time for complications such as valve hemodynamic deterioration (VHD) and early leaflet thrombosis.[4,5] Physicians can also monitor for signs of aortic insufficiency (AI) and paravalvular leak (PVL), which can be detected via routine clinical surveillance, allowing earlier interventions when appropriate.

Despite the importance of maintaining follow-up with TAVR patients, many centers have had difficulty complying with the CMS requirement of maintaining 1-year follow-up data.[6,7] The factors contributing to a patient becoming lost to follow-up after TAVR are not well understood. We recently completed a quality improvement (QI) project at our institution to identify patients lost to follow-up after TAVR and, at minimum, determine their 1-year mortality status.[8] We sought to identify factors associated with loss to follow-up at 30 days and 1 year after TAVR prior to the implementation of this QI project.

Materials and methods

A retrospective analysis of 604 patients undergoing TAVR at The Heart Hospital Baylor Plano, Plano, Texas, USA between January 2012 and April 2017 was conducted to evaluate completeness of 30-day and 1-year follow-up. We have previously published the details regarding our multidisciplinary QI process to determine, at minimum, 1-year mortality status in all patients who have previously undergone TAVR at our center.[8] At the conclusion of this QI project, 1-year mortality status was known in 100% of patients. A total of 67 patients died within 1 year of TAVR and were excluded from the current analysis. Patients alive at 1 year were separated into two

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cohorts: those with and those without 1-year follow-up prior to the implementation of the QI project. The window for 1-year follow-up was defined as beginning 305 days after TAVR, based upon criteria used by the STS/ACC TVT Registry.

Data were collected from our site's Society of Thoracic Surgeons/American College of Cardiology (STS/ACC) Transcatheter Valve Therapy (TVT) Registry, and were supplemented by manual chart review. Lost to follow-up status was determined by the available data in our local STS/ACC TVT Registry and mirrors the definitions used to determine follow-up status by the registry. Patients whose follow-up status was recorded as "lost to follow-up," and thus had no lab values or echo data recorded in the registry, were classified as lost to follow-up. A 5-meter walk test (5MWT) of ≤ 6 s was classified as normal gait speed, while a 5MWT of > 6 s was classified as slow gait speed.[9] Patients were dichotomized between having no complications post-TAVR and those having one or more complications, as reported by our site's registry.

Analyses were conducted using STATA 14.2. Baseline characteristics were presented as proportions and counts for categorical variables and as median (range) for continuous variables. Comparisons were performed using Chi-square /Fisher exact tests for proportions and Wilcoxon rank-sum /Student's *t*-tests for continuous variables, as appropriate. A step-wise logistic regression analysis was employed to identify the risk factors associated with loss to follow-up at 1-year after TAVR. Those factors with a *p*-value of <0.05 on univariate comparisons were included in the logistic regression analysis to identify independent risk factors for loss to follow-up at 1 year. The discriminatory ability and calibrating efficiency of the final model was assessed using receiver operating curve analysis and Hosmer-Lemeshow (HL) goodness-of-fit test, respectively.

Results

A total of 604 consecutive patients underwent TAVR during the study period. Those patients who died within 1 year of TAVR (n = 67; 11%) were excluded from the analysis (Figure 1). The study population comprised of 537 living patients (51.9% female) with a median age of 82 years (range, 47–100). The population had a mean body mass index (BMI) of 27.2 kg/m^2 (range 12.5–59.2 kg/m^2), a mean Society of Thoracic Surgeons Predicted Risk of Mortality (STS-PROM) of 6.4% (range 0.6–-28.9%), and was 93.9% Caucasian (n = 504). Within the study population 94.6% (n = 508) of patients had hypertension, 41.9% (n = 225) had diabetes mellitus, and 21.4% (n = 115) had a pacemaker prior to undergoing TAVR. Post-operative complications included neurologic (n = 13), cardiovascular (n = 162), conduction (121), bleeding (n = 79), device malfunction (n = 14), and new requirement for dialysis (n = 6). Numerous patients experienced more than one post-operative complication. A total of 79 (14.7%) patients were lost to follow-up at 1 year (LTF patients), 18 of whom were lost to follow-up at 30 days as well. LTF patients had a higher mean STS-PROM (7.6% vs. 6.2%, $p = 0.002$), lower median serum albumin (3.5 g/dL vs. 3.7 g/dL, $p = 0.01$; normal range 3.4–5.0 g/dL), higher incidences of stroke (22.8% vs. 12.7%, $p = 0.02$), more likely to have prior aortic valve procedures (39.2% vs. 25.3%, $p = 0.01$), and more commonly had heart failure within the 2 weeks prior to the procedure (86.1% vs. 74.7%, $p = 0.03$). LTF patients also had increased use of general anesthesia (94.9% vs. 74.7%, $p = < 0.001$), more post procedural complications (46.8% vs. 33.4%, $p = 0.02$), were classified as having slow gait speed (70.9% vs. 36.7%, $p = < 0.001$), and lived farther from our site (114 vs. 46.5 miles, $p = < 0.001$) (Table 1).

By a multivariable analysis, general anesthesia, slow gait speed, post-procedural complications, living farther from the site, and lower albumin levels were independently predictive of loss to follow up at 1 year. The HL goodness of fit test indicated a good fit of this prediction model (0.75) and the area under the curve was found to be 0.73 (Table 2, Figure 2). A separate analysis was performed excluding patients lost to follow-up at 30-days (n = 18) with no appreciable change to the results.

Discussion

Given these results, we can begin to understand factors associated with those patients most likely to be lost to follow-up at 1 year. LTF patients shared several factors: lower serum

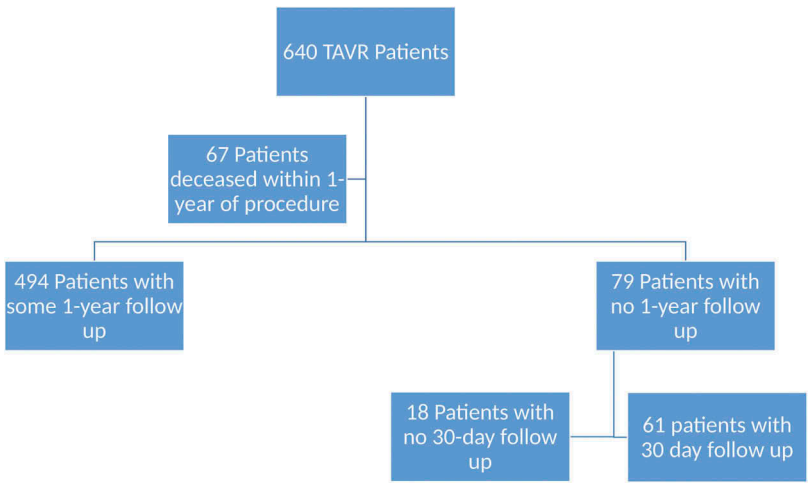

Figure 1. Patient CONSORT diagram.

Table 1. Patient characteristics.

	1-year follow-up (n = 458)	Lost to follow-up at 1-year (n = 79)	*p*-value
Age, years (range)	82 (54–100)	83 (47–95)	0.61
Male	221 (48.3%)	37 (46.8%)	0.81
Caucasian	429 (93.7%)	75 (94.9%)	0.67
BMI, kg/m^2 (range)	27.3 (12.5–59.2)	26.8 (16.2–57.0)	0.59
STS-PROM, % (range)	6.2 (0.6–28.9)	7.6 (2.1–23.8)	0.002
Albumin, g/dL, (range)	3.7 (1.0–7.8)	3.5 (1.0–4.5)	0.01
Prior pacemaker	96 (20.9%)	19 (24.1%)	0.54
Prior CABG	144 (31.5%)	32 (40.5%)	0.12
Prior aortic valve procedure	116 (25.3%)	31 (39.2%)	0.01
Prior stroke	58 (12.7%)	18 (22.8%)	0.02
Peripheral artery disease	135 (29.5%)	20 (25.3%)	0.45
Hypertension	414 (90.4%)	67 (84.8%)	0.13
Diabetes mellitus	192 (42.0%)	33 (41.8%)	0.97
Dialysis	4 (0.9%)	1 (1.3%)	0.55
Chronic lung disease	145 (31.8%)	27 (34.6%)	0.62
Prior myocardial infarction	124 (27.1%)	24 (30.4%)	0.54
Prior heart failure (2 weeks)	339 (74.7%)	68 (86.1%)	0.03
NYHA Class (III/IV)	343 (75.7%)	61 (78.2%)	0.63
Porcelain aorta	24 (5.2%)	9 (11.4%)	0.04
Slow gait speed	327 (71.9%)	69 (87.3)	0.004
General anesthesia	339 (74.7%)	75 (94.9%)	<0.001
Patients with post-operative complications*	153 (33.4)	37 (46.8%)	0.02
Distance, miles, (range)	46.5 (0–1469)	114 (5–1301)	<0.001

Notes. *Defined as any patient who experienced one or more neurologic, cardiovascular, conduction, bleeding, device malfunction, or new requirement for dialysis events that occurred post-procedure and prior to discharge.
Sources: STS/ACC TVT Registry, The Heart Hospital Baylor Plano, Plano, TX, USA; The Heart Hospital Baylor Plano Electronic Health Record
Abbreviations: CABG, coronary artery bypass graft; NYHA, New York Heart Association.

Table 2. Independent risk factors for loss to follow-up: Multivariable logistic regression analysis.

	Odds Ratio	Std. Err.	z	*p*-value	95%CI	
Slow gait speed	2.73	1.02	2.68	0.01	1.31	5.70
Distance from the hospital (every 100 miles)	1.30	0.08	4.03	<0.001	1.14	1.47
General anesthesia	6.25	3.40	3.36	<0.001	2.15	18.18
Albumin, g/dL, (range)	0.54	0.13	−2.49	0.01	0.33	0.88
Post-operative complications	1.81	0.47	2.26	0.02	1.08	3.03

albumin levels, slow gait speed, use of general anesthesia, and greater distance from the TAVR center. Knowing that these factors contribute to a patient's likelihood of not returning for a 1-year follow-up provides centers the opportunity to implement measures to prevent them becoming lost to follow-up.

Based upon identification of these patients at risk for becoming lost to follow-up, a TAVR center should develop proactive measures to ensure patient compliance with 1-year follow-up. Potential measure to implement include: pre-discharge education on the importance of follow-up post TAVR, providing the patient with both 30-day and 1-year follow-up appoint before leaving the hospital, creation of

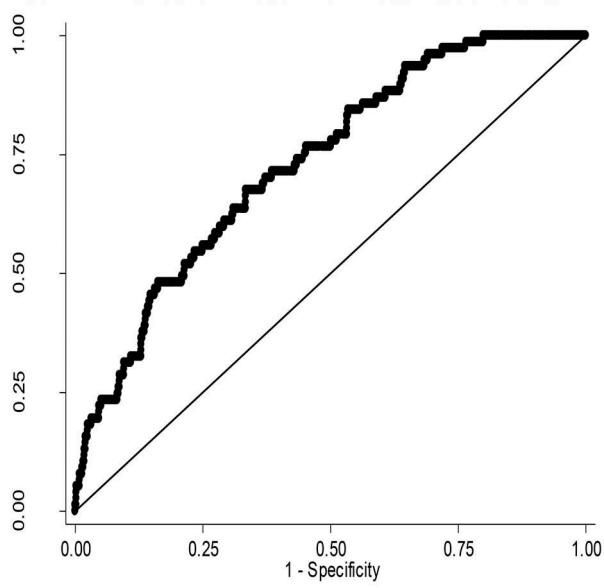

Figure 2. Receiver-operator curve for multivariable analysis derivation cohort.

a dedicated TAVR follow-up coordinator to maintain frequent phone contact with patients, developing robust relationships with referring and local cardiologists, and implementing mobile and home follow-up services.

TAVR centers and physicians are well aware of the importance of 1-year follow-up, but patients may not be. Patient education is an important tool for informing patients and making them active participants in managing their own health. Nurses and nurse practitioners play an important part in educating patients, especially at discharge. Advanced practice nurses such as the nurse practitioner can be valuable members of the heart team and often fill the role of TAVR coordinator at most TAVR centers.[10] This role involves organizing, assessing, and educating TAVR patients as well as coordinating inpatient and outpatient care, and can be vital in educating patients on the value of follow-up as well as coordinating follow-up at key time points post procedure.[10]

VHD, valve thrombosis, restenosis, and AI remain concerns for all TAVR patients and highlight the need for increased vigilance through routine follow-up. While we are unable to quantify the occurrence of these complications within our study population, a recent multicenter registry of 1,521 patients with a mean echocardiographic follow-up of 20 ± 13 months showed a 4.5% incidence of VHD (defined as ≥ 10 mm Hg increase in gradient from discharge to follow-up), indicating the importance of follow-up in the management of patients following TAVR.[4] The increased use of biological valves among patients < 60 years of age increases the likelihood of valve-in-valve TAVR procedures during their lifetime. In addition, the stability of the TAVR devices has been questioned given that the cusps are made from the same material used in conventional bioprostheses.[11] As the TAVR population continues to decrease in both STS-PROM and age, the likelihood of first time TAVR patients requiring another valve in their lifetime increases. Making patients aware of these potential risks associated with TAVR and the

importance of routine and regular follow-up can motivate patients to keep 1-year follow-up appointments and perhaps even beyond that.

Maintaining extended follow-up after TAVR is critically important to ensure optimal patient outcomes and to meet reimbursement criteria for CMS but has proven to be challenging for many TAVR centers. Factors predisposing patients to loss from follow-up are poorly understood. This study identified several independent risks factors for loss to follow-up at 1-year including prior stroke, slow gait speed, decreased preoperative serum albumin, use of general anesthesia, postoperative complications, and increased living distance from the hospital.

Limitations

Our study was subject to several limitations. It was limited to a single center and was retrospective in nature. Because of this, our event numbers are small, which limits our ability to investigate other potential predictors of becoming lost to follow-up. Additionally, our unique patient population may have factors that are not common to other sites, such as geographic location and risk profiles. This study was also limited by our inability to include socioeconomic factors such as household income, level of education, and social support. These factors were unavailable to us at the time of this study but could play a role in a patient's ability and/or motivation to return for follow-up at both 30 days and 1 year. Collecting and including these factors are important considerations for future work. While we were able to identify factors contributing to patients who were previously lost to follow-up, we have not fully applied our model to current patients, and thus, have not validated it. Moving forward, we plan to explore implementation of systems such as patient education, dedicated follow-up coordinators, and increased relationships with referring physicians to ensure that we do not lose these patients to follow-up.

Conclusion

Extended follow-up provides valuable data and surveillance for patients after TAVR. Developing a model that is predictive of patients becoming lost to follow-up provides TAVR centers with the ability to create a proactive approach or processes to improve follow-up compliance. Improving patient follow-up should facilitate improved surveillance and care for patients and, secondarily, will increase the amount of high quality data available for outcomes research, which has the potential to improve patient care on the population level.

Acknowledgments

We are grateful to Joy Fan for her efforts in gathering and organizing data necessary to complete this study.

Funding

None.

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Disclosure statement

Michael J. Mack, MD: Co-PI Partner Trial, Edwards Lifesciences, Co-PI Coapt Trial, Abbott Vascular, Executive Committee Apollo Trial, Medtronic. The other authors report no conflicta of interest.

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