Predictors of Early and Late Mortality after Transcatheter Aortic Valve Implantation: A Multicenter Retrospective Chinese Study

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Abstract

Background: Patients undergoing TAVR constitute a high-risk population given their comorbidities and out-of-hospital mortality rates remain high despite significant improvements in the overall procedural outcomes. **Objectives:** The objective of this study was to determine the early and late mortality rates following transfemoral transcatheter aortic valve replacement (TAVR) and identify the risk factors for poor outcomes. **Methods:** This study population examined patients extracted from 43 publicly funded hospitals in Hong Kong between 2010 and 2019. The study constitutes retrospective analysis of mortality outcomes for severe aortic stenosis patients undergoing TAVR. The primary end points include out-of-hospital 30-day, 1-year, 1–2-year, and 2–5-year mortality rates. **Results:** A total of 448 patients underwent TAVR and were included into the study. The rates of mortality following TAVR were 1.7%, 3.3%, 1.3%, and 0.22% at 30 days, 1, 1–2, and 2–5 years, respectively. Age and chronic renal failure (CRF) were concluded to be associated with postprocedural mortality. Further analysis of the baseline echocardiographic parameters revealed a higher prevalence of right atrial enlargement (RAE) and tricuspid and pulmonary regurgitation in the deceased subgroup. **Conclusion:** We report the 30-day, 1-, 1–2-, and 2–5-year all-cause mortality for TAVR of 1.7%, 3.3%, 1.3%, and 0.22% at 30 days. Factors associated with a higher prevalence of mortality include age, CRF, RAE, and tricuspid and pulmonary regurgitation.

Keywords: Aortic stenosis, mortality, transcatheter aortic valve replacement

Introduction

In patients with severe aortic stenosis (AS) at high risk for surgical aortic valve replacement (SAVR), transcatheter aortic valve replacement (TAVR) is a valid alternative in improving the survival outcomes.[1] Nevertheless, mortality outcomes following TAVR have had a considerable impact over candidate selection and eligibility criteria.[2] Scoring tools such as the society of thoracic surgeons (STS) and EuroSCORE II, which have been established to stratify patients at high risk for surgery, were additionally established in predicting mortality following TAVR.[3] Previous studies delineated varying mortality rates in patients undergoing TAVR, with a focus on predictors of poor outcomes.[4,5] The PARTNER study, which included severe AS patients at high risk for surgery, revealed an all-cause mortality rate of 42.5%.[4] Further studies reported predictors of mortality outcomes following TAVR, with baseline kidney disease, liver disease, atrial fibrillation (AF), and malignancy constituting the main predictor variables.[5] Since patients undergoing TAVR constitute a high-risk population given their comorbidities and frailty, it is essential to predict their mortality with an increasing focus on risk factors for such poor outcomes.[6] Therefore, this

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study examines the early and late mortality following TAVR, in addition to the identification of factors associated with the dismal outcomes.

Methods

We enrolled a total of 450 AS patients undergoing TAVR due to high risk associated with conventional SAVR. Specifically, high risk was defined as an STS/EuroSCORE II of 8% or higher, including those above 75 years of age. The study population was extracted from 43 publicly funded hospitals in Hong Kong between 2010 and 2019. All data were extracted from an electronic database of AS patients undergoing TAVR. Baseline echocardiography was performed at admission to define the severity of underlying valvular lesion and risk stratification. Inclusion criteria included severe AS patients as defined by echocardiographic criteria: aortic valve area <1 cm^2, a mean aortic valve gradient of ≥40 mmHg, or a peak aortic jet velocity of ≥4.0 m/s. This retrospective study divided patients into two cohorts: deceased or alive to allow the comparison of predictors of mortality.

Baseline characteristics with echocardiographic parameters were used as independent variables of procedural outcomes. Besides the demographic characteristics of patients undergoing TAVR, comorbidities include hypertension, diabetes mellitus, hyperlipidemia, coronary artery disease (CAD), chronic renal failure (CRF), carotid stenosis, and congestive heart failure (CHF). Among the echocardiographic parameters, variables such as ejection fraction, atrial enlargement, concentric left ventricular hypertrophy, pulmonary hypertension, and valvular lesions were assessed. In terms of primary end points, mortality at 30 days, 1 year, 1–2 years, and 2–3 years was used as dependent variables.

Statistical analysis

Continuous variables were presented as mean and standard deviation, whereas categorical variables were presented as frequencies and percentages. The Pearson's Chi-squared test was used to analyze the statistical differences in categorical variables. Continuous variables were analyzed through a linear model ANOVA. $P \leq 0.05$ was used as a measure of statistical significance. Data were analyzed using multivariate logistic regression to assess the association between demographic characteristics and mortality [Table 1].

Survival analysis

A Kaplan–Meier survival probability plot is illustrated in Figure 1. Each plot represents the cumulative incidence of survival stratified by ejection fraction.

Results

A total of 448 patients (50.7% of males, 50.3% of females) represented the study cohort. Two patients were excluded from the analysis due to data insufficiency during the follow-up period. Patients were subdivided into two groups (426 alive, 22 dead) to allow for the comparison. Baseline characteristics of the two subgroups were well-balanced, as delineated in Table 2. The overall mean age of the cohort was 78.3 ± 7.8 years. Among the baseline comorbidities, hypertension (65.4%), AF (33.3%), and diabetes mellitus (30.6%) were the most prevalent. In terms of predictors of mortality, old age was significantly associated with mortality (81.5 years vs. 78.1 years; $P = 0.046$). The distribution of age in deceased patients is further detailed in Figure 2. Furthermore, CRF was more prevalent in the deceased subgroup (27.3% vs. 12%; $P = 0.036$). However, there were no statistically significant differences between other baseline characteristics such as male gender (49.8% vs. 68.2%; $P = 0.092$), AF (32.6% vs. 45.5%; $P = 0.213$), CHF (24.6% vs. 40.9%; $P = 0.088$), diabetes mellitus (30.3% vs. 36.4%; $P = 0.546$), or chronic CAD (26.8% vs. 27.3%; $P = 0.958$).

Table 1: Binary logistic regression

Predictor	Estimate	SE	*Z*	*P*
Intercept	−8.5983	2.9019	−2.9630	0.003
Age	0.0638	0.0352	1.8124	0.070
Gender				
Male-female	0.8372	0.4863	1.7217	0.085
ACS				
Yes-no	0.3443	1.1244	0.3062	0.759
CRF				
Yes-no	0.8905	0.5345	1.6660	0.096
BAE				
Mild-normal	−1.3124	1.1119	−1.1803	0.238
Severe-normal	−15.3785	1259.0123	−0.0122	0.990
TR				
Mild-normal	−0.7478	0.6525	−1.1461	0.252
Moderate-normal	0.2043	0.7252	0.2818	0.778
Severe-normal	1.5784	0.7260	2.1742	0.030

Estimates represent the log odds of "Death=Dead" versus "Death=Alive," R^2=0.133. ACS: Acute coronary syndrome, CRF: Chronic renal failure, BAE: Biatrial enlargement, TR: Tricuspid regurgitation

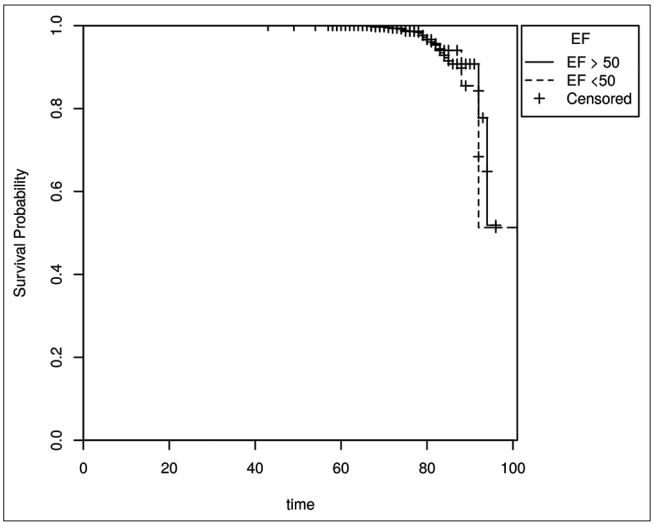

Figure 1: Cumulative incidence of all-cause mortality stratified by EF. EF: Ejection fraction

Table 2: Clinical characteristics and demographics of the study population (*n*=448)

Characteristic	Total (*n*=448), *n* (%)	Alive (*n*=426), *n* (%)	Dead (*n*=22), *n* (%)	*P*
Age (years), mean±SD	78.3±7.8	78.1±7.8	81.5±7.1	0.046*
Gender (male)	227 (50.7)	212 (49.8)	15 (68.2)	0.092
CAD	120 (26.8)	114 (26.8)	6 (27.3)	0.958
Diabetes mellitus	137 (30.6)	129 (30.3)	8 (36.4)	0.546
Hypertension	293 (65.4)	278 (65.3)	15 (68.2)	0.779
Hyperlipidemia	143 (31.9)	138 (32.4)	5 (22.7)	0.343
CRF	57 (12.7)	51 (12.0)	6 (27.3)	0.036*
ACS	21 (4.7)	20 (4.7)	1 (4.5)	0.974
Atrial fibrillation	149 (33.3)	139 (32.6)	10 (45.5)	0.213
Carotid stenosis	6 (1.3)	6 (1.4)	0	0.575
CRF	114 (25.4)	105 (24.6)	9 (40.9)	0.088

*Statistical significance. Linear model ANOVA. Pearson's Chi-squared test. SD: Standard deviation, CAD: Coronary artery disease, ACS: Acute coronary syndrome, CRF: Chronic renal failure, CRF: Congestive heart failure

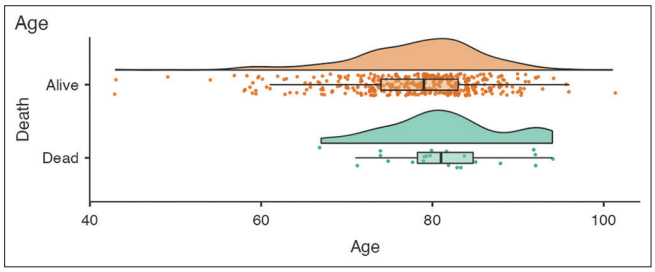

Figure 2: Distribution of age in the deceased subgroup

Baseline echocardiographic was correspondingly compared in both subgroups, as shown in Table 3. The mean ejection fraction for the total study population was 54.8% ± 12%. Among the structural abnormalities, right atrial enlargement (RAE) was more prevalent in the diseased subgroup (P = 0.016). Valvular lesions, including mitral, aortic, tricuspid, pulmonary regurgitation, and mitral stenosis were further subdivided according to the severity. Among the valvular lesions, severe tricuspid regurgitation (TR) was more frequent in the deceased subgroup (27.3% vs. 7.2%; P = 0.004). In addition, mild (36.4% vs. 22%) and moderate (4.5% vs. 0.7%) pulmonary regurgitation were more likely to be recorded in the deceased subgroups compared to alive patients.

The primary end point was the rates of all-cause mortality following TAVR at 30 days, 1 year, 1–2 years, and 2–5 years as shown in Table 4. At 30 days following the procedure, the overall mortality rate was 1.7% for the total study population. Follow-up at 1 year, 1–2 years, and 2–5 years revealed a mortality rate of 3.3%, 1.3%, and 0.22%, respectively. The overall cumulative mortality for this cohort at 5 years was reported as 4.82%.

Discussion

The main results obtained from this cohort of 450 AS undergoing TAVR can be summarized as follows. First, among the baseline characteristics, age and CRF were concluded to be associated with postprocedural mortality. Further analysis of baseline echocardiographic parameters revealed a higher prevalence of RAE and tricuspid and pulmonary regurgitation in the deceased subgroup. In regard to primary end points, the rates of mortality were 1.7%, 3.3%, 1.3%, and 0.22% at 30 days, 1, 1–2, and 2–5 years, respectively.

The average age of patients within the deceased subgroup was 81.5 years, which was correspondingly associated with worse outcomes. In a nationwide database of 84,017 patients undergoing TAVR, patients aged 80–89 and older had an increased risk of readmissions, complications, and mortality compared to patients <70 years of age.[7] One-third of patients under the deceased arm in our cohort had chronic kidney disease (CKD), additionally posing a higher risk of mortality. This was further replicated in a meta-analysis of 4992 patients, in which early all-cause mortality was significantly associated with a preoperative diagnosis of CKD, mainly at stages 3–5.[8] On a positive note, the postprocedural renal outcomes were associated with a stable course or with improvements in more than 80% of the patients.[9]

Preoperative echocardiography was additionally analyzed for markers of poor prognosis, among which the presence of RAE and tricuspid and pulmonary regurgitation was concluded as predictors of mortality. As for valvular lesions, TR was previously reported in 80% in a cohort of 34,576 patients undergoing TAVR, with a corresponding increase in mortality with an increasing severity.[10] Such outcomes underline the necessity of combined therapy through SAVR and tricuspid valve annuloplasty or transcatheter tricuspid techniques.[11] As per the current guidelines, tricuspid valve annuloplasty is recommended in patients undergoing open-heart surgery for other cardiac indications (class 1 recommendation).[12] In terms of disease progression, TR progression to moderate and severe was observed in 5.4% of patients post-TAVR, further highlighting the role of combined aortic and tricuspid valve therapy in such patients.[13] The prevalence of PH was 9.1% in the deceased subgroup, compared to a prevalence of 30% in a Japanese registry of 1872 patients.[14] Data derived from the OCEAN-TAVI report that periprocedural PH can be utilized for risk stratification, with an increasing mortality in patients with residual PH.[15] The role of TAVR in regression of PH

Table 3: Baseline echocardiographic parameters of the study population (*n*=448)

Characteristic	Total (*n*=448), *n* (%)	Alive (*n*=428), *n* (%)	Dead (*n*=22), *n* (%)	*P*
LVEF, mean±SD (%)	54.8±12.0	54.9±11.9	52.0±12.3	0.269
LAE				
Normal	249 (55.3)	236 (55.1)	13 (59.1)	0.131
Mild	166 (36.9)	159 (37.1)	7 (31.8)	
Moderate	24 (5.3)	24 (5.6)	0	
Severe	11 (2.4)	9 (2.1)	2 (9.1%)	
RAE				
Normal	418 (92.9)	401 (93.7)	17 (77.3)	0.016*
Mild	26 (5.8)	22 (5.1)	4 (18.2)	
Moderate	4 (0.9)	3 (0.7)	1 (4.5)	
Severe	2 (0.4)	2 (0.5)	0	
BAE				
Normal	412 (91.6)	391 (91.4)	21 (95.5)	0.778
Mild	35 (7.8)	34 (7.9)	1 (4.5)	
Severe	3 (0.7)	3 (0.7)	0	
Conc. LVH				
Normal	184 (40.9)	174 (40.7)	10 (45.5)	0.879[2]
Mild	252 (56.0)	241 (56.3)	11 (50.0)	
Moderate	12 (2.7)	11 (2.6)	1 (4.5)	
Severe	2 (0.4)	2 (0.5)	0	
PHT				
Normal	423 (94.0)	403 (94.2)	20 (90.9)	0.852
Mild	24 (5.3)	22 (5.1)	2 (9.1)	
Moderate	1 (0.2)	1 (0.2)	0	
Severe	2 (0.4)	2 (0.5)	0	
MR				
Normal	83 (18.4)	80 (18.7)	3 (13.6)	0.513
Mild	248 (55.1)	235 (54.9)	13 (59.1)	
Moderate	88 (19.6)	85 (19.9)	3 (13.6)	
Severe	31 (6.9)	28 (6.5)	3 (13.6)	
MS				
Normal	412 (91.6)	392 (91.6)	20 (90.9)	0.738
Mild	26 (5.8)	25 (5.8)	1 (4.5)	
Moderate	8 (1.8)	7 (1.6)	1 (4.5)	
Severe	4 (0.9)	4 (0.9)	0	
MAC				
Normal	365 (81.1)	345 (80.6)	20 (90.9)	0.476
Mild	82 (18.2)	80 (18.7)	2 (9.1)	
Severe	3 (0.7)	3 (0.7)	0	
AR				
Normal	111 (24.7)	104 (24.3)	7 (31.8)	0.478
Mild	231 (51.3)	223 (52.1)	8 (36.4)	
Moderate	86 (19.1)	81 (18.9)	5 (22.7)	
Severe	22 (4.9)	20 (4.7)	2 (9.1)	
TR				
Normal	79 (17.6)	75 (17.5)	4 (18.2)	0.004*
Mild	257 (57.1)	250 (58.4)	7 (31.8)	
Moderate	77 (17.1)	72 (16.8)	5 (22.7)	
Severe	37 (8.2)	31 (7.2)	6 (27.3)	
PR				
Normal	344 (76.4)	331 (77.3)	13 (59.1)	0.043*
Mild	102 (22.7)	94 (22.0)	8 (36.4)	
Moderate	4 (0.9)	3 (0.7)	1 (4.5)	

*Statistical significance. Linear model ANOVA. Pearson's Chi-squared test. LVEF: Left ventricular ejection fraction, LAE: Left atrial enlargement, RAE: Right atrial enlargement, BAE: Biatrial enlargement, Conc. LVH: Concentric left ventricular hypertrophy, PHT: Pulmonary hypertension, MR: Mitral regurgitation, MS: Mitral stenosis, MAC: Mitral annular calcification, AR: Aortic regurgitation, TR: Tricuspid regurgitation, PR: Pulmonary regurgitation, SD: Standard deviation

was detected in 46% of the patients, consequently leading to a lower risk of all-cause mortality at a long-term follow-up.[16] RAE was additionally found to be associated with mortality in our cohort, corresponding to the findings of PARTNER B cohort at 1-year follow-up.[4]

Multiple trials have established the survival benefit of TAVR over SAVR, expanding its indications for low and high surgical risk patients.[17-19] Despite such improvements in survival, out-of-hospital mortality still poses a considerable impact over the procedural outcomes. The evaluation of mortality at 30 days in our cohort revealed a rate of 1.7%, comparable of a mortality rate of 2.2% from a cohort of 106,749 patients.[20] Validation of a risk adjustment model for 30-day mortality after TAVR that accounts for clinical factors and preprocedural health status has been established, allowing for an objective tool for predicting mortality.[21] A literature review of TAVR outcomes at 30 days revealed mortality rates ranging from 1.6% to 12.7%, as shown in Table 5.[22-29] Several risk factors were independently associated with all-cause and cardiovascular mortality, including age, gender, lower left ventricular ejection fraction and hemoglobin, AF/flutter, lung disease, aortic insufficiency, oxygen use, with inhospital complications.[22] A lower Kansas City Cardiomyopathy Questionnaire score was additionally associated with mortality, emphasizing the role of baseline illness and disability in predicting poor outcomes.[30]

Concurrent CAD is common among patients undergoing TAVR, with a recorded prevalence of 65%.[31] In this cohort, 26.8% of enrolled cases had a baseline diagnosis of chronic CAD, corresponding to shared risk factors of such conditions.[32] Preprocedural coronary angiography is considered the standard of care for the evaluation of significant coronary artery lesions and vascular access. The ACTIVATION trial has recently determined the impact of percutaneous coronary intervention (PCI) and no-PCI before TAVR, with results revealing similar rates of deaths between the two treatment arms. On another note, a 40% reduction in bleeding was observed in patients who did not undergo PCI, potentially contributing to a reduction in bleeding access site-related outcomes.[33]

In summary, we report the early and late mortality rates of 450 patients undergoing TAVR, with a mortality rate of 1.7% at 30 days. The introduction of TAVR has evolved the management of patients deemed high risk of surgery, potentially improving the survival outcomes of patients at different ranges of severity. A steady progress in TAVR outcomes has been recognized in patients at high-, intermediate-, and low-risk, with reported mortality rates of 3.4%, 3.9%, and 0.5%, respectively.[34] Such considerable improvements direct broadening the indications of TAVR, potentially reversing the need for surgery in all surgical candidates.[35] The limitations of this analysis are related to the retrospective nature of the study, including selection bias and interobserver variability for the clinical and echocardiographic parameters performed by different cardiologists. In addition, clinical end points, including in- and out-of-hospital postoperative complications, were not captured. Furthermore, the underlying etiology of mortality outcomes was not specified, hindering the attribution of specific risk factors.

Table 4: Follow-up out-of-hospital mortality rates at 30 days, 1 year, 1–2 years, and 2–5 years

Mortality	Number of deaths	Percentage of total patients
30-day	8	1.7
1 year	15	3.3
1–2 years	6	1.3
2–5 years	1	0.22
Total	22	4.88

Conclusion

In this Hong Kong registry of 450 patients, we identified a 30-day and 1-year all-cause mortality rates of 1.7% and 3.3%, respectively. We identified several factors associated with mortality outcomes, including age, CRF, RAE, with pulmonary and TR.

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Nil.

Conflicts of interest

There are no conflicts of interest.

Table 5: Literature review of 30-day mortality outcomes among different cohorts

	Number of patients	Percentage of 30-day mortality	Country	Type of study
Bahaa *et al*., 2021[27] (Egypt registry)	96	4.16	Egypt	Cohort
Rodés-Cabau *et al*., 2010[10] (Canadian registry)	345	10.40	Canada	Clinical trial
Sabaté *et al*., 2010–2011[11] (Spain registry)	1416	8	Spain	Cohort
Eltchaninoff *et al*., 2011[12] (France registry)	244	12.70	France	Multicenter study
Tamburino *et al*., 2011[14] (Italy registry)	663	5.40	Italy	Cohort
Zahn *et al*., 2011[15] (Germany registry)	697	12.4	Germany	Comparative study
Smith *et al*., 2011[16] (USA registry)	699	3.4	USA	Randomized control trial
Al Balool *et al*., 2022[4]	61	1.6	Kuwait	Retrospective observational study
Our study, 2022	450	1.7	China	Retrospective observational study

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