Transcatheter aortic valve replacement in patients with chronic kidney disease: a multi-centre retrospective study

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Background: Chronic kidney disease (CKD) is a common comorbid condition in patients undergoing transcatheter aortic valve replacement (TAVR). Reported outcome studies on the association of baseline CKD and mortality is currently limited.

Objectives: To determine the prevalence of chronic kidney disease in patients undergoing TAVR and analyse their overall procedural outcomes.

Methods: This retrospective observational study was conducted at 43 publicly funded hospitals in Hong Kong. Severe aortic stenosis patients undergoing TAVR between the years 2010 and 2019 were enroled in the study. Two groups were identified according to the presence of baseline chronic kidney disease.

Results: A total of 499 patients (228, 58.6% men) were enroled in the study. Baseline hypertension was more prevalent in patients with CKD (82.8%; $P = 0.003$). As for primary end-points, mortality rates of CKD patients were significantly higher compared to non-CKD patients (10% vs. 4.1%; $P = 0.04\%$). Gout and hypertension were found to be significantly associated with CRF. Patients with gout were nearly six times more likely to have CRF than those without gout (odds ratio = 5.96, 95% CI = 3.12–11.29, $P < 0.001$). Patients with hypertension had three times the likelihood of having CRF compared to those without hypertension (odds ratio = 2.83, 95% CI = 1.45–6.08, $P = 0.004$).

Conclusion: In patients with severe aortic stenosis undergoing TAVR, baseline CKD significantly contributes to mortality outcomes at long-term follow up.

Keywords: CKD, mortality, TAVR

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Introduction

Transcatheter aortic valve replacement (TAVR) is currently a prominent treatment option of aortic stenosis, with current volumes exceeding surgical aortic valve replacement[1,2]. Such therapeutic advancement led to expansion of its indication from low- to high- risk patients[3]. Patients with aortic stenosis are at accelerated risk of developing chronic kidney disease (CKD), further contributing to their higher mortality rates[4]. Such patients constitute a clinical challenge partly due to the rapid unpredictable progression of aortic stenosis and worse outcomes following aortic valve replacement[5]. Despite that, patients with advanced CKD and end-stage kidney disease have been excluded from randomized trials, contributing to higher challenges in therapeutic decision-making[6]. Cardio-renal syndrome has been proposed to contribute to the morbidity and mortality of such patients, verifying the role of TAVR in potentially reversing this cycle[7]. Yet, conflicting data has been reported in regards to procedural outcomes following TAVR in CKD[8]. Notably, recent data reveal a stable or improved course of renal function in 80% of patients following TAVR[9].

Since patients with baseline CKD contribute to a high yet understudied proportion of patients undergoing TAVR, it is essential to study procedural outcomes and distinguish factors associated with dismal events. Therefore, this study first examines

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mortality outcomes of CKD patients and analyses baseline factors associated with such outcomes.

Methods

This retrospective observational analysis was conducted at 43 publicly funded hospitals in Hong Kong between the years 2010 and 2019. Patients with severe aortic stenosis with a valve area of 1.0 cm or less, mean pressure gradient of 40 mmHg or greater, and a jet velocity of 4.0 m/s or higher were eligible for enrolment. A total of 449 severe aortic stenosis underwent TAVR and met the inclusion criteria. Patients were stratified into two groups according to the presence of baseline chronic kidney disease to allow for comparison. A comparison of baseline characteristics and echocardiographic parameters were used as independent predictors of procedural outcomes in the two cohorts. Among the demographic parameters, baseline comorbidities including hypertension, diabetes mellitus, hyperlipidemia, coronary artery disease, carotid stenosis and congestive heart failure were analysed. As for echocardiographic parameters, variables like ejection fraction, atrial enlargement, concentric left ventricular hypertrophy, pulmonary hypertension, and valvular lesions were used as independent variable. In terms of primary end-points, mortality rates following TAVR was compared between the two subgroups. This study was granted by the ethics committee for research studies.

Statistical analysis

Continuous variables were presented as mean and standard deviation, whereas categorical variables were presented as frequencies and percentages. Pearson's χ^2 test was used to analyse statistical differences in categorical variables. Continuous variables were analysed through linear model (ANOVA). A P value of less than or equal to 0.05 was used as a measure of statistical significance. Data were analysed using multivariate logistic regression to assess the association between chronic kidney disease and procedural outcomes.

Results

Table 1 shows the baseline characteristics of the study population stratified by baseline CKD. Among the total 499 patients, 50.8% were male, with a slightly higher percentage of males in the CKD group compared to the non-CKD group (58.6% vs. 49.6%, $P = 0.201$). Regarding comorbidities, both groups had similar rates of chronic coronary artery disease (CAD), diabetes, hyperlipidemia, acute coronary syndrome (ACS), and atrial fibrillation (AF), with no significant differences observed. However, the presence of Hypertension was notably higher among individuals with CKD compared to those without CKD (82.8% vs. 62.9%, $P = 0.003$). Similarly, a higher proportion of individuals with CKD experienced congestive heart failure (CHF) compared to those without CKD (31.0% vs. 24.8%, $P = 0.311$). Additionally, Carotid Stenosis was observed in a small percentage of cases, with a slightly higher prevalence in the CKD group (3.4%) compared to the non-CKD group (1.0%, $P = 0.133$); however, these difference among the groups were not statistically significant. Moreover, the mortality rate was notably higher in the CKD group compared to the non-CKD group (10.3% vs. 4.1%, $P = 0.040$).

HIGHLIGHTS

- Baseline chronic kidney disease is a common comorbid condition in patients undergoing transcatheter aortic valve replacement.
- Gout and hypertension were commonly associated with baseline chronic kidney disease in patients undergoing TAVR.
- Baseline chronic kidney disease predicts mortality outcomes at 5-year follow-up.

Table 2 provides a comprehensive overview of baseline echocardiographic parameters in patients under the study cohort. Among the assessed parameters, the left ventricular ejection fraction (LVEF) showed a numerical difference between the two groups, with the CKD group having a slightly lower mean LVEF (52.3 ± 12.0) compared to the non-CKD group (55.2 ± 11.9), although this difference did not reach statistical significance ($P = 0.088$). None of the other parameters, including left atrial enlargement (LAE), right atrial enlargement (RAE), bi-atrial enlargement (BAE), concentric left ventricular hypertrophy (Conc. LVH), pulmonary hypertension (PHT), mitral regurgitation (MR), mitral stenosis (MS), mitral annular calcification (MAC), aortic regurgitation (AR), tricuspid regurgitation (TR), and pulmonary regurgitation (PR), showed statistically significant differences between the two groups.

Moreover, CRF is analysed in relation to several factors in order to determine their potential impact on the likelihood of developing CRF (Table 3). Among all the variables, gout, hypertension and mortality showed significant association with CRF. The presence of gout showed a strong positive association with CRF, with patients having gout being nearly six times more likely to have CRF compared to those without gout [odds ratio (OR) = 5.96, 95% CI = 3.12–11.29, $P < 0.001$]. Additionally, Hypertension also exhibited a significant association with CRF, as patients with hypertension had approximately three times higher odds of having CRF compared to those without hyper-

Table 1				
Baseline clinical characteristics, mortality in the two subgroups.				
	Total (N = 449)	**CKD (N = 58)**	**No CKD (N = 391)**	**P**
Age, Mean ± SD	78.3 ± 7.8	79.7 ± 6.9	78.0 ± 7.9	0.124[a]
Sex (male), n (%)	228.0 (50.8)	34.0 (58.6)	194.0 (49.6)	0.201[b]
Chronic CAD, n (%)	121.0 (26.9)	17.0 (29.3)	104.0 (26.6)	0.664[b]
Diabetes, n (%)	138.0 (30.7)	18.0 (31.0)	120.0 (30.7)	0.958[b]
Hypertension, n (%)	294.0 (65.5)	48.0 (82.8)	246.0 (62.9)	*0.003[b]
Hyperlipidaemia, n (%)	143.0 (31.9)	20.0 (35.1)	123.0 (31.5)	0.583[b]
ACS, n (%)	21.0 (4.7)	2.0 (3.4)	19.0 (4.9)	0.635[b]
AF, n (%)	149.0 (33.2)	22.0 (37.9)	127.0 (32.5)	0.411[b]
Carotid stenosis, n (%)	6.0 (1.3)	2.0 (3.4)	4.0 (1.0)	0.133[b]
CHF, n (%)	115.0 (25.6)	18.0 (31.0)	97.0 (24.8)	0.311[b]
Mortality, n (%)	22.0 (4.9)	6.0 (10.3)	16.0 (4.1)	*0.040[b]

ACS, acute coronary syndrome; AF, atrial fibrillation; CHF, congestive heart failure; Chronic CAD, chronic coronary artery disease.
* Indicates statistically significant.
[a]Linear Model ANOVA.
[b]Pearson's χ^2 test.

Table 2

Baseline echocardiographic parameters in CKD and non-CKD patients.

	Total (N = 449)	CKD (N = 58)	No CKD (N = 391)	P
LVEF Mean ± SD	54.8 ± 12.0	52.3 ± 12.0	55.2 ± 11.9	0.088[a]
LAE, n (%)				0.091[b]
Normal	248.0 (55.2)	38.0 (65.5)	210.0 (53.7)	
Mild	166.0 (37.0)	15.0 (25.9)	151.0 (38.6)	
Moderate	24.0 (5.3)	5.0 (8.6)	19.0 (4.9)	
Severe	11.0 (2.4)	0.0 (0.0)	11.0 (2.8)	
RAE, n (%)				0.811[b]
Normal	417.0 (92.9)	55.0 (94.8)	362.0 (92.6)	
Mild	26.0 (5.8)	3.0 (5.2)	23.0 (5.9)	
Moderate	4.0 (0.9)	0.0 (0.0)	4.0 (1.0)	
Severe	2.0 (0.4)	0.0 (0.0)	2.0 (0.5)	
BAE, n (%)				0.246[b]
Normal	411.0 (91.5)	55.0 (94.8)	356.0 (91.0)	
Mild	35.0 (7.8)	2.0 (3.4)	33.0 (8.4)	
Severe	3.0 (0.7)	1.0 (1.7)	2.0 (0.5)	
Conc LVH, n (%)				0.911[b]
Normal	183.0 (40.8)	24.0 (41.4)	159.0 (40.7)	
Mild	252.0 (56.1)	33.0 (56.9)	219.0 (56.0)	
Moderate	12.0 (2.7)	1.0 (1.7)	11.0 (2.8)	
Severe	2.0 (0.4)	0.0 (0.0)	2.0 (0.5)	
PHT, n (%)				0.929[b]
Normal	422.0 (94.0)	55.0 (94.8)	367.0 (93.9)	
Mild	24.0 (5.3)	3.0 (5.2)	21.0 (5.4)	
Moderate	1.0 (0.2)	0.0 (0.0)	1.0 (0.3)	
Severe	2.0 (0.4)	0.0 (0.0)	2.0 (0.5)	
MR, n (%)				0.897[b]
Normal	82.0 (18.3)	10.0 (17.2)	72.0 (18.4)	
Mild	248.0 (55.2)	32.0 (55.2)	216.0 (55.2)	
Moderate	88.0 (19.6)	13.0 (22.4)	75.0 (19.2)	
Severe	31.0 (6.9)	3.0 (5.2)	28.0 (7.2)	
MS, n (%)				0.673[b]
Normal	411.0 (91.5)	52.0 (89.7)	359.0 (91.8)	
Mild	26.0 (5.8)	5.0 (8.6)	21.0 (5.4)	
Moderate	8.0 (1.8)	1.0 (1.7)	7.0 (1.8)	
Severe	4.0 (0.9)	0.0 (0.0)	4.0 (1.0)	
MAC, n (%)				0.189[b]
Normal	364.0 (81.1)	52.0 (89.7)	312.0 (79.8)	
Mild	82.0 (18.3)	6.0 (10.3)	76.0 (19.4)	
Severe	3.0 (0.7)	0.0 (0.0)	3.0 (0.8)	
AR, n (%)				0.663[b]
Normal	110.0 (24.5)	11.0 (19.0)	99.0 (25.3)	
Mild	231.0 (51.4)	33.0 (56.9)	198.0 (50.6)	
Moderate	86.0 (19.2)	12.0 (20.7)	74.0 (18.9)	
Severe	22.0 (4.9)	2.0 (3.4)	20.0 (5.1)	
TR, n (%)				0.893[b]
Normal	78.0 (17.4)	8.0 (13.8)	70.0 (17.9)	
Mild	257.0 (57.2)	35.0 (60.3)	222.0 (56.8)	
Moderate	77.0 (17.1)	10.0 (17.2)	67.0 (17.1)	
Severe	37.0 (8.2)	5.0 (8.6)	32.0 (8.2)	
PR, n (%)				0.629[b]
Normal	343.0 (76.4)	43.0 (74.1)	300.0 (76.7)	
Mild	102.0 (22.7)	15.0 (25.9)	87.0 (22.3)	
Moderate	4.0 (0.9)	0.0 (0.0)	4.0 (1.0)	

AR, aortic regurgitation; BAE, bi-atrial enlargement; Conc. LVH, concentric left ventricular hypertrophy; LAE, left atrial enlargement; LVEF, left ventricular ejection fraction; MAC, mitral annular calcification; MR, mitral regurgitation; MS, mitral stenosis; PHT, pulmonary hypertension; PR, pulmonary regurgitation; RAE, right atrial enlargement; TR, tricuspid regurgitation.
[a]Linear Model ANOVA.
[b]Pearson's χ^2 test.

Table 3

Odds ratio of chronic renal failure and independent variables.

Dependent: CRF	No	Yes	Odds ratio
Age			
Mean ± SD	78.0 ± 7.9	79.7 ± 6.9	1.03 (0.99–1.07, P = 0.124)
LVEF			
Mean ± SD	55.2 ± 11.9	52.3 (12.0)	0.98 (0.96–1.00, P = 0.089)
Gout			
Yes	34 (61.8)	21 (38.2)	5.96 (3.12–11.29, P < 0.001)
Hypertension			
Yes	246 (83.7)	48 (16.3)	2.83 (1.45–6.08, P = 0.004)
Carotid stenosis			
Yes	4 (66.7)	2 (33.3)	3.46 (0.47–18.13, P = 0.158)
Diabetes			
Yes	120 (87.0)	18 (13.0)	1.02 (0.55–1.82, P = 0.958)
Angina			
Yes	24 (92.3)	2 (7.7)	0.55 (0.09–1.91, P = 0.420)
TR			
Mild	222 (86.4)	35 (13.6)	1.38 (0.64–3.32, P = 0.438)
Moderate	67 (87.0)	10 (13.0)	1.31 (0.49–3.61, P = 0.596)
Death	16 (72.7)	6 (27.3)	2.70 (0.94–6.91, P = 0.047)

LVEF, left ventricular ejection fraction; TR, tricuspid regurgitation.

tension (OR = 2.83, 95% CI = 1.45–6.08, P = 0.004). The mortality rate of CKD patients was statistically higher compared to their counterparts (10% vs. 4.1%; P = 0.040), attributing impaired renal function to poor outcomes. If mortality data is compared to "non-CKD" patients, the odds ratio of mortality in CKD patients was reported as 2.7 (P = 0.047). The odds ratio plot of chronic kidney disease and independent variables is illustrated in Fig. 1. Among the baseline clinical risk factors, gout (OR = 6.29; P < 0.001) and hypertension (OR = 2.84; P = 0.004) were found to be statistically higher in patients with CKD. Other baseline clinical parameters of CKD patients including age, LVEF, carotid stenosis, diabetes, and TR were not associated with mortality.

Table 4 provides a comparative overview of mortality outcomes among CKD patients following TAVR, as reported by different studies. The findings highlight the importance of considering both short-term and long-term mortality risks in this patient population, which can vary significantly based on the specific study population and follow-up duration (30 days–5 years). These insights contribute to a better understanding of the clinical outcomes and prognosis for CKD patients undergoing TAVR procedures.
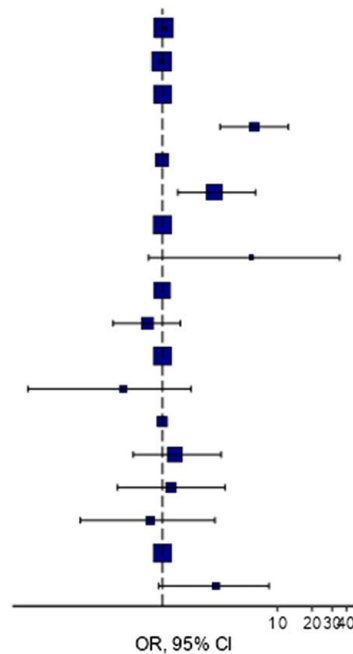
Discussion

Our cohort of 449 severe AS patients undergoing TAVR revealed the presence of baseline chronic kidney disease in 14% of the entire study population. Among the baseline clinical characteristics, the presence of hypertension and gout were frequent comorbidities in CKD patients. As for baseline echocardiography, the mean ejection fraction was found to be 52.3% among patients with CKD. The reported mortality at 5-year follow-up (10.3%) was statistically higher in patients with CKD, with an odds ratio of 2.7. Such results imply the role of renal function in predicting mortality outcomes following TAVR, further contributing to risk stratification of patients.

Transcatheter aortic valve replacement is a well-established alternative for patients at high risk for surgery, although definite

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Figure 1. Odds ratio plot of dependent and independent variables. LVEF, left ventricular ejection fraction; OR, odds ratio; TR, tricuspid regurgitation.

evidence addressing the accelerated risk of specific groups is lacking[12]. Patients with underlying chronic kidney disease are recognised as a group of uncertainty for such procedure, given the potential hazard of the use of iodinated contrast in such patients[14]. Despite the role of AVR in reversing the rapid progression of aortic stenosis in the setting of impaired renal function, existing data supporting its use is limited[15]. Previous studies reported the impact of baseline CKD on the overall procedural outcomes of TAVR, with conflicting data in different cohorts. In an analysis of 270 patients by Goebel *et al.*[16], the overall mortality rate at 30 days was not statistically different between CKD and non-CKD patients. In contrast, our cohort revealed a higher cumulative mortality in patients with CKD, signifying the role of impaired renal function with poor outcomes[17]. This was further replicated in the STS/ACC TVT registry of 44,778 patients, revealing higher mortality rates with advanced stages of CKD[18]. Moreover, a meta-analysis of 32 131 patients revealed a hazard mortality ratio of 1.69 in renal disease patients, with a higher mortality per unit decrease in serum creatinine[19]. Such data may influence clinical-decision making in terms of candidate selection and allows anticipation of specific outcomes.

On a positive note, compelling evidence supports the role of TAVR in improving the progression renal impairment in CKD patients. In an analysis of 410 patients, those with baseline CKD sustained higher rates of improvements in renal function after TAVR[20]. In addition, those who developed a stable or improved renal function after TAVR had favourable survival rates at 2-year follow-up[9]. A further analysis revealed a higher improvement in kidney function in patients with lower ejection fraction, primarily due to afterload relief and kidney reperfusion[20]. In addition,

patients with lower eGFR were more likely to develop improvements in renal function[21]. This finding supports the role of TAVR in patients with severe renal impairment, opposing the usual management of avoiding TAVR in such population[22]. It is essential to address the risk of acute kidney injury and requirement of renal replacement therapy (RRT) post TAVR, as pre-procedure GFR can predict the associated risk[23]. Notably, increasing CKD stage was associated with a higher risk of RRT, denoting the role of education and counselling paints during the therapeutic process[24]. Identifying mechanisms of renal injury may potentially allow preventative measures to halt the progressive worsening of renal function[25]. For instance, preoperative strategies in the form of hydration, n-acetyl-cysteine, or diuresis may decrease angiography-related renal outcomes[26,27].

Previously reported TAVR outcome studies outline the variable mortality rates in different population groups[28–31]. As for patients with CKD, reported mortality outcomes differ in each cohort, as outlined in Table 4. Future trials should drive focus on

Table 4			
Mortality outcomes of CKD patients post TAVR across different cohorts.			
Authors, year of publication	**Patients, *n***	**Primary end point**	**Outcome**
Yap *et al.*, 2020[10]	216	30 days mortality	21%
Ogami *et al.*, 2021[8]	3883	5 years mortality	69.9%
Hahn *et al.*, 2022[11]	643	In hospital mortality	5.1%
Gupta *et al.*, 2017[12]	13 750	In hospital mortality	4.5%
Rahman *et al.*, 2015[13]	129	30 days mortality	7.0%
Our analysis	58/499	5 years mortality	10%

CKD, chronic kidney disease; TAVR, transcatheter aortic valve replacement.

reporting TAVR related outcomes in the context of renal failure, given the highly associated comorbid condition. In addition, preventative strategies specific to ameliorate the risk of AKI should be additionally targeting CKD patients.

The limitations of this analysis is related to the retrospective nature of this study. In addition, interobserver variability in data acquisition including echocardiographic parameters may limit precision of data. Specific to this analysis, TAVR related end-points including AKI and post procedural complications were not captured.

Conclusion

Baseline chronic kidney disease is a common comorbid condition in patients undergoing transcatheter aortic valve replacement. Our analysis revealed a significant association between CKD and mortality outcomes at 5-year follow-up, denoting the role of renal function in candidate selection.

Ethics approval statement

This study was approved by the ethics committee and Ministry of Health.

Consent

Written informed consent was obtained from the patient for publication and any accompanying images. A copy of the written consent is available for review by the Editor-in-Chief of this journal on request.

Source of funding

No funding available for this study.

Author contribution

M.A.J. contributed to study concept or design, data collection, data analysis or interpretation, writing the paper. S.A. contributed to study concept or design, data collection, data analysis or interpretation, writing the paper. R.R. contributed to study concept or design, data collection, data analysis or interpretation, writing the paper. R.D. contributed to study concept or design, data collection, data analysis or interpretation, writing the paper. K.D. Z. contributed to study concept or design, data collection, data analysis or interpretation, writing the paper. P.S. contributed to study concept or design, data collection, data analysis or interpretation, writing the paper. A.A.S. contributed to study concept or design, data collection, data analysis or interpretation, writing the paper. M.A. contributed to study concept or design, data collection, data analysis or interpretation, writing the paper. P.A.B. contributed to study concept or design, data collection, data analysis or interpretation, writing the paper. G.L.B. contributed to study concept or design, data collection, data analysis or interpretation, writing the paper. J.A.B. contributed to study concept or design, data collection, data analysis or interpretation, writing the paper. G.T. contributed to study concept or design, data collection, data analysis or interpretation, writing the paper.

Conflicts of interest disclosure

No conflict of interest exists for any author on this manuscript.

Research registration unique identifying number (UIN)

This study was not a clinical trial. This study was registered through researchregistry.com: researchregistry9516.

Guarantor

Dr. Rajesh Rajan

Data availability statement

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

Provenance and peer review

Not commissioned, not externally peer-reviewed.

Patient consent statement

Patient consented was not mandated for this retrospective observational study. Permission to reproduce material from other sources: No material from other sources is included in this study.

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