



Can Acute Kidney Injury After Transcatheter Aortic Valve Replacement Alone Predict Poor Prognosis in Diabetic Patients?

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Abstract

Aim: Transcatheter aortic valve implantation (TAVI) has become a well-recognized treatment option for patients with symptomatic severe aortic stenosis (AS) who are deemed to have a higher risk for surgical intervention. Due to underlying comorbidities, acute kidney injury (AKI) continues to be a common complication, especially in patients with diabetes mellitus after TAVR. The aim of this study is to evaluate the effect of postoperative AKI development in diabetic patients undergoing TAVR on the development of mortality and major adverse cardiac events (MACE) in these patients.

Material and Method: A total of 141 patients who underwent TAVR between January 2015 and January 2020 were grouped according to whether they developed AKI and whether they had MACE. MACE and 5-year mortality status were compared according to whether the patients developed AKI.

Results: A total of 35 patients were observed to develop AKI (24.8%). Additionally, MACE was observed in 36 patients (25.5%). Five-year mortality rates (42.9% vs. 15.1%; $p = 0.002$) and MACE rates (54.3% vs. 16%; $p < 0.001$) were significantly higher in the AKI group. Univariate and multivariate logistic regression analyses identified AKI as a significant independent predictor of MACE development, regardless of other associated parameters (OR = 3.92, 95% CI: 1.28–12.02; $p = 0.017$).

Conclusion: The most important result obtained in this study is that AKI development in diabetic patients who underwent TAVR with the diagnosis of advanced aortic stenosis has an effect on the development of MACE and long-term mortality independently of other parameters.

Keywords: Acute kidney injury, diabetes mellitus, TAVR, aortic stenosis, major adverse cardiac events

INTRODUCTION

The most common heart valve problem in adults is sclerotic aortic valve disease (AS). While it is seen at a frequency of less than 1% in individuals between the ages of 50 and 70, the rate increases with age, approximately threefold in individuals in the seventh decade, and reaches 10% in the population over the age of eighty [1]. This disease, which has a very low survival rate from the onset of symptoms, often requires surgery or percutaneous intervention [2].

Transcatheter aortic valve replacement (TAVR), which is proposed as a technique different from conventional surgery even in low-risk patients, is preferred in AS patients with high surgical risk [3,4]. However, most patients

undergoing TAVR have multiple parameters affecting their prognosis.

Chronic kidney disease (CKD) commonly accompanies severe aortic stenosis and diabetes mellitus, likely due to shared underlying causes. Impaired renal function contributes to aortic valve calcification. Due to underlying CKD and other comorbidities, acute kidney injury (AKI) continues to be a worse event after TAVR. Various studies have reported AKI rates following TAVI ranging between 5% and 42% [5,6]. Postprocedural AKI-related worse prognosis was demonstrated by multiple studies [7,8]. By impairing the status of the kidney through inflammation and microthrombosis, TAVR may lead to hemodynamic and

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organelle impairment. While numerous parameters were claimed for AKI following TAVR, no studies have specifically examined its impact on worse events and survival in diabetic patients with AKI.

This study sought to analyse the impact of postoperative AKI on survival and major adverse cardiac events (MACE) in diabetic patients undergoing TAVR.

MATERIAL AND METHOD

This study adhered to the ethical principles and guidelines set by the institutional research committee, following the 1964 Helsinki Declaration and its subsequent amendments or equivalent ethical standards. Approval for the study was granted by the Ethics Committee of University of Health Sciences Turkey, Bursa Yüksek İhtisas Training and Research Hospital (decision no: 2011-KAEK-25 2022/11-15).

Study Population

By screening 240 patients whose complete data were available between January 2015 and January 2020 and eliminating the patients according to the exclusion criteria, the non-prospective observational design included all diabetic patients who underwent non-invasive aortic valve replacement.

The study's exclusion criteria included: patients with (1) any infection, (2) a history of systemic autoimmune disorders, (3) a history of malignancy, (4) additional coronary balloon or stent implantation within the last week, (5) decompensated chronic renal failure, (6) undergoing dialysis treatment, and (7) missing clinical data.

One hundred and forty-one patients fulfilling the specified criteria were enrolled. In-hospital records and databases were analyzed by collecting the following data: demographic details, comorbid conditions, procedural aspects such as valve type and size, in-hospital complications, laboratory findings, and mortality during hospitalization.

Five-year mortality analyses were obtained from the hospital records of the patients included in the study. Detailed explanations were given to all patients, and their consent was obtained. They were assessed by a multidisciplinary heart team.

The logistic EuroSCORE model was utilized to estimate perioperative and short-term mortality risk for severe symptomatic AS. Procedural complications were categorized based on the VARC-2 criteria [9].

TAVI procedure

Patients admitted one day prior to the procedure with an estimated glomerular filtration rate (eGFR) below 60 mL/min received intravenous (IV) saline hydration for TAVI-associated contrast medium administration during TAVI.

Fluoroscopic imaging with contrast was used to ensure proper catheter and valve placement and to evaluate potential perivalvular aortic regurgitation.

TAVI devices were valve prostheses implanted via a femoral approach using self- or balloon-expanding systems.

The procedure was conducted using either local anesthesia or general anesthesia with endotracheal intubation.

Before the intervention, echocardiography and computed tomography modalities were used for prosthesis size determination.

Blood tests were monitored daily from admission until the third postoperative day and subsequently as needed until discharge.

Laboratory Analysis

In our study, blood samples, including complete blood hematological and biochemical tests, were measured at admission in all studied patients. eGFR was calculated according to the MDRD formula [10]. Patients with eGFR values below 60 mL/min/1.73 m² were considered as the renal dysfunction group. Decompensated patients with chronic renal failure and patients under dialysis treatment were excluded from the study.

Definitions

Mortality occurring between the procedure and hospital discharge was classified as in-hospital death. Data on 5-year mortality were retrieved from the hospital's electronic records. Diabetes mellitus was diagnosed based on fasting blood glucose levels or the use of oral antidiabetic medications or insulin, in accordance with the American Diabetes Association guidelines [11].

Acute renal injury was defined as an increase of one and a half times or more above the initial level within the first seven days, following KDIGO criteria, as endorsed by the VARC-3 [12]. Adverse cardiovascular events (MACE) included cardiovascular-related death, stroke, and hospitalizations due to cardiovascular complications.

Echocardiographic Measurements

Echocardiographic evaluations were obtained from patient records in the hospital archives. Evaluation of the parameters was performed based on the guidelines of the American Society of Echocardiography [13]. The pressure gradient measured echocardiographically is also called systolic pulmonary artery pressure (sPAP), and values above the 36 mmHg cut-off point of the tricuspid regurgitation pressure gradient identified individuals with pulmonary hypertension [14].

Statistical Analysis

Statistical analysis of the data was performed with the Statistical Package for the Social Sciences version 24.0 software program (IBM Corp., Armonk, NY, USA). Continuous variables are presented as the mean $\pm$ standard deviation if normally distributed, and as the median and interquartile range if not normally distributed. Inter-group differences of continuous variables were tested with the Student's t-test or Wilcoxon rank-sum test, depending on the distribution. To analyze categorical data, we used a Pearson χ^2 test (or Fisher's exact test if any expected cell count was <5), and we presented descriptive statistics as numbers and percentages.

Binary logistic regression analyses were conducted to assess the association between various parameters and MACE. NT-proBNP variables weren't normally distributed as shown by the Kolmogorov–Smirnov test, and were made usable in regression risk analysis by applying logarithmic transformation. Since a large number of predictor variables may increase the risk of reflecting the so-called "overfitting" features of the dataset into the model, it is known that variables that may be related to the condition of interest can be included in the analysis at a rate of 1/10 of the number of outcomes.

Therefore, we wanted to avoid multicollinearity due to the close correlation between variables used in the EuroSCORE calculation, such as age, gender, and creatinine clearance. The association was thus adjusted in the multivariable model, which included four variables (AKI, log NT-proBNP, female sex, and aortic valve area) for a total of 36 MACE events, by including our main variable of interest, AKI, and excluding EuroSCORE.

An odds ratio (OR) and 95% CI were calculated. Hazard ratios (HRs) and 95% CIs were also calculated. A p-value ≤ 0.05 was considered statistically significant. Statistical tests were two-sided.

RESULTS

The study enrolled 141 diabetic patients with severe aortic stenosis who underwent TAVR (median [IQR] age, 80 [75–83] years; 57 patients [40.4%] male) (Table 1). A total of 35 patients were observed to develop AKI (24.8%). Additionally, MACE was observed in 36 patients (25.5%).

In Table 1, AKI status is compared according to demographic, clinical, and laboratory characteristics. Among those with in-hospital mortality, only in the AKI group, 3 patients developed acute kidney injury with clinical deterioration requiring dialysis. Comparison of characteristics showed that the development of AKI was higher in females (p = 0.005). In addition, when comorbidities were examined, the incidence of hypertension was observed to be significantly higher in the AKI group (p < 0.001). No notable differences were observed between the two groups regarding other demographic features and comorbid conditions.

When the two groups were compared in terms of drug use, beta-blocker (p < 0.001) and statin (p = 0.001) use were found to be lower in the group with functionally intact kidneys. There was no difference between the groups in terms of antidiabetic treatment. An analysis of the patients' laboratory parameters was conducted, and platelet volume (p < 0.001), AST (p < 0.001), ALT (p = 0.002), eGFR (p < 0.001), and LDL cholesterol (p < 0.001) values were found to be significantly lower in the group that developed AKI. Baseline creatinine (p = 0.047) and NT-proBNP values (p < 0.001) were significantly higher in the AKI group.

When the two groups (with and without AKI) were compared according to preoperative echocardiographic parameters, LVEF (p < 0.001), aortic valve area (AVA) (p < 0.001), tricuspid annular plane systolic excursion (TAPSE) (p < 0.001), and systolic pulmonary artery pressure (sPAP) (p < 0.001) were significantly lower in the AKI group.

Preoperative moderate and severe mitral regurgitation (MR) (p = 0.002) and aortic regurgitation (AR) (p < 0.001) rates were higher in the renal impairment group.

Table 1: The baseline characteristics and laboratory investigations of all patients according to acute kidney injury

Variables	All patients n = 141	AKI		p
		Yes n = 35	No n = 106	
Age, years	80 (75-83)	76 (75-82)	80 (75-84)	0.072
Male sex	57 (40.4)	7 (20)	50 (47.2)	0.005
Body mass index, kg/m²	27.5 (25.7-28.6)	27.6 (27.6-28.6)	26.9 (25.7-28.7)	0.237
Hypertension	106 (75.2)	35 (100)	71 (67)	<0.001
Chronic kidney disease	39 (27.7)	7 (20)	32 (30.2)	0.282
Coronary artery disease	51 (36.2)	14 (40)	37 (34.9)	0.516
Previous stroke	9 (6.4)	2 (5.7)	7 (6.6)	0.917
Logistic EuroSCORE, %	33.3 ± 12.9	33.2 ± 4.3	33.4 ± 14.7	0.922
Acetylsalicylic Acid	76 (53.9)	16 (45.7)	60 (56.6)	0.329
B-Blocker	109 (77.3)	35 (100)	74 (69.8)	<0.001
ACE Inh	82 (58.2)	23 (65.7)	59 (55.7)	0.329
Statin	59 (41.8)	23 (65.7)	36 (34)	0.001
Diabetes treatment condition, %				
Untreated	13 (9)	5 (13)	8 (8)	0.185
OADs treated	78 (55)	13 (39)	65 (61)	
Insulin treated	23 (16)	8 (22)	15 (14)	
OADs +Insulin treated	27 (19)	9 (26)	18 (17)	
Hemoglobin, g/dl	12 ± 1.5	12.2 ± 1.2	12 ± 1.6	0.367
Platelet, g/L	214.6 ± 60.3	187.6 ± 41.3	223.5 ± 63	<0.001
Baseline creatinine, m/dl	1.15 ± 0.4	1.29 ± 0.5	1.11 ± 0.4	0.047
eGFR, ml/min/1.73 m²	57.3 ± 20.4	46.1 ± 10.3	61 ± 21.6	<0.001
AST, IU/L	29.3 ± 32.8	17.3 ± 2.3	33.2 ± 37	<0.001
ALT, IU/L	30.4 ± 63	13.5 ± 6.3	36 ± 71.8	0.002
LDL cholesterol, mg/dL	103.6 ± 30.6	90.7 ± 13.9	107.8 ± 33.3	<0.001
NT-pro BNP, pg/mL	2336 (957-4850)	10547 (1792-14743)	2336 (887-3484)	<0.001
Log (NT-pro BNP)	3.35±0.45	3.81±0.44	3.29±0.43	<0.001
Left-ventricular ejection fraction, %	43.8 ± 12	38.7 ± 7.3	45.5 ± 12.8	<0.001
Aortic valve area, cm²	0.66 ± 0.1	0.58 ± 0.1	0.69 ± 0.1	<0.001
Mitral regurgitation ≥ moderate	96 (68.1)	35 (100)	61 (57.6)	0.002
Aortic regurgitation ≥ moderate	63 (44.6)	28 (80)	35 (33)	<0.001
TAPSE, mm	20.7 ± 2.2	20.5±2.0	20.9 ± 2.5	<0.001
sPAB, mmHg	37.9 ± 11.4	29 ± 2	40.8 ± 11.7	<0.001

Data are presented as mean ± SD, median (interquartile range) or number (percentage) of patients. Abbreviations: ACE, angiotensin converting enzyme; AKI, acute kidney injury; AST, aspartate aminotransferase; ALT, alanine aminotransferase; eGFR, estimated glomerular filtration rate; EuroSCORE, The European System for Cardiac Operative Risk Evaluation; IQR, interquartile range; LDL, low-density lipoprotein; NT-pro BNP, N-terminal pro-B-type natriuretic peptide; OAD, oral antidiabetic; SD, standard deviation; sPAB, systolic pulmonary arterial pressure; TAPSE, tricuspid annular plane systolic excursion.

In Table 2, renal impairment was evaluated according to procedural and postprocedural status. When the type of valve used during TAVR was examined, it was observed that the self-expandable Portico™ valve was used in all patients in the AKI group, and this created a significant difference between the two groups (p < 0.001). In the group that developed AKI, the rate of patients who underwent post-dilatation was also significantly lower (p = 0.021), and the group that developed AKI received a significantly greater amount of contrast medium (p < 0.001). In addition, 5-year mortality rates (42.9% vs. 15.1%; p = 0.002) and MACE rates (54.3% vs. 16%; p < 0.001) were significantly different in the AKI group. The groups were found to be similar in terms of other endpoints.

Table 2: Procedural and postprocedural characteristics of all patients according to acute kidney injury

Variables	All patients n = 141	AKI		p
		Yes n = 35	No n = 106	
Procedural characteristics				
Type of valve				
SAPIENT™ XT	5 (3.5)	0	5 (4.7)	<0.001
ACURATE neoTM	26 (18.4)	0	26 (24.5)	
PorticoTM	72 (51.1)	35 (100)	37 (34.9)	
EvolutTM R	38 (27)	0	38 (35.8)	
Predilatation	31 (22)	12 (34)	19 (18)	0.059
Postdilatation	14 (9.9)	0	14 (13.2)	0.021
Volume of contrast agent, mL	144.6 ± 19.7	161.7 ± 23.6	139 ± 14.3	<0.001
Outcome parameters and summary of all MACE				
Severe AR after the procedure	27 (19)	7 (20)	20 (19)	1.000
Stroke	2 (1.4)	0	2 (1.9)	1.000
In-hospital mortality	8 (5.7)	4 (11.4)	4 (3.8)	0.105
5-year total mortality	31 (22)	15 (42.9)	16 (15.1)	0.002
MACE	36 (25.5)	19 (54.3)	17 (16)	<0.001

Data are presented as mean ± SD, median(interquartil range) or number (percentage) of patients. Abbreviations: AKI, acute kidney injury; AR, aortic regurgitation; MACE, major adverse cardiovascular events; SD, standard deviation.

Table 3 presents data based on the occurrence of MACE; the demographic, echocardiographic, and postprocedural characteristics of the patients were categorized according to their MACE status. When the demographic

characteristics of patients with MACE were examined, the rate of MACE was found to be higher in females ($p = 0.011$). In addition, logistic EuroSCORE values were significantly higher in the MACE group ($p = 0.027$). No difference was found in terms of other demographic characteristics.

When we focus on blood parameters, NT-proBNP values were found to be significantly different in patients with MACE compared to the non-MACE group ($p = 0.04$). Regarding echocardiographic parameters, the aortic valve area was smaller in the MACE group ($p = 0.017$).

An evaluation of post-procedural characteristics showed a higher incidence of AKI in the MACE group ($p < 0.001$).

Table 3. Basic characteristics, laboratory investigations, echocardiographic parameters, and postprocedural characteristics of TAVI patients by MACE status.				
Variables	All patients n = 141	MACE		p
		Yes n = 36	No n = 105	
Demographic characteristics				
Age, years	79 (73-83)	77 (74-81)	80 (73-83)	0.590
Female gender	84 (59.6)	28 (77.8)	56 (53.3)	0.011
Hypertension	106 (75.2)	31 (86.1)	75 (71.4)	0.116
Chronic kidney disease	39 (27.7)	9 (25)	30 (28.6)	0.830
Coronary artery disease	51 (36.2)	12 (33.4)	39 (37.1)	0.869
Previous stroke	9 (6.4)	4 (11.1)	5 (4.8)	0.233
Logistic EuroSCORE	33.3 ± 12.9	37.8 ± 14.2	31.8 ± 12.2	0.027
Laboratory data				
Hemoglobin, g/dL	12.0 ± 1.5	11.9 ± 1.2	12.1 ± 1.6	0.539
eGFR, ml/min/1.73 m ²	57.3 ± 20.4	53.7 ± 15.1	58.5 ± 22.0	0.147
NT-pro BNP, pg/mL	2336 (957-4850)	2336 (816-2919)	2049 (1078-6536)	0.040
Log (NT-pro BNP)	3.35±0.45	3.40±0.50	3.22±0.28	0.004
Echocardiographic parameters				
Left-ventricular ejection fraction, %	43.8 ± 12	41.7 ± 10.4	44.5 ± 12.5	0.183
Aortic valve area, cm ²	0.66 ± 0.1	0.62 ± 0.1	0.68 ± 0.1	0.017
Postprocedural characteristics				
AKI	35 (24.8)	19 (52.8)	16 (15.2)	<0.001
Severe aortic regurgitation after the procedure	27 (19.1)	5 (13.9)	22 (21)	0.464
Major vascular complications	10 (7.1)	0	10 (9.5)	0.065
Need for a permanent pacemaker	10 (7.1)	2 (5.6)	8 (7.6)	1.000
Data are presented as mean ± SD, median(interquartil range) or number (percentage) of patients. Abbreviations: AKI, acute kidney injury; eGFR, estimated glomerular filtration rate; EuroSCORE, The European System for Cardiac Operative Risk Evaluation; NT-pro BNP, N-terminal pro-B-type natriuretic peptide. SD, standard deviation.				

Table 4 presents an analysis of parameters linked to MACE development using both univariate and multivariate logistic regression. Univariate analysis identified AKI occurrence, preoperative aortic valve area, log NT-proBNP values, and female gender as significant factors associated with MACE.

We found that AKI was an independent predictor of MACE development, unlike other parameters, using multivariate logistic regression analysis (OR = 3.92, 95% CI: 1.28–12.02; $p = 0.017$).

Table 4. The univariable and multivariable regression model for detecting factors associated with the occurrence of MACE				
Variables	Univariable analysis		Multivariable analysis	
	OR (95% CI)	p	OR (95% CI)	p
AKI (yes)	6.22 (2.67-14.45)	0.001	3.92 (1.28-12.02)	0.017
Aortic valve area (before TAVI), cm ²	0.01 (0-0.38)	0.014	0.06 (0-5.38)	0.216
Log NT-proBNP, pg/ml*	3.16 (1.38-7.23)	0.006	0.97 (0.33-2.86)	0.953
Sex (Female)	3.06 (1.28-7.34)	0.012	2.68 (0.97-7.41)	0.060

Abbreviations: AKI, acute kidney injury; CI, confidence interval; NT-pro BNP, N-terminal pro-B-type natriuretic peptide; OR, odds ratio; TAVI, transcatheter aortic valve implantation
* The logarithm of the NT-pro BNP values were taken and included in the regression analysis

DISCUSSION

The key finding of this study is that AKI, which is one of the common conditions after TAVR and can develop due to a variety of causes, has an effect on the development of MACE and long-term mortality independently of other parameters. As far as we know, this is the first study to demonstrate the independent impact of AKI on MACE development and long-term mortality in diabetic patients.

Earlier research has demonstrated that AKI development after TAVR occurs at similar rates irrespective of chronic kidney disease [15]. Similarly, in our study, previous chronic kidney disease was not found to have an effect on the occurrence of AKI. Previously, the rate of AKI development after TAVR was shown to be between 11% and 41%, and in our study, similar to these studies, the rate of AKI was determined to be 24.8% [16,6].

In our study, it was determined that there are many factors affecting the development of AKI. These can be summarized as female gender, presence of hypertension, various drug use, some laboratory parameters, echocardiographically low left ventricular ejection fraction, aortic valve area, poor right ventricular function, and use of more contrast material during the procedure.

Previous studies have shown the effects of most of these factors in the occurrence of AKI, and for the purposes of our study, the relationships between these factors and the development of AKI were not detailed [17–19].

TAVR, being a less invasive technique, might be associated with less risk of AKI after TAVR. However, the mentioned technique is usually performed on patients with multiple comorbidities, and because of the use of contrast material and prolonged rapid ventricular pacing during the procedure, AKI is observed at a higher rate than expected. It was also shown that the risk of AKI was similar in surgical intervention and TAVR [2,20].

Anita Korczak et al. investigated AKI development and its relation with mortality and MACE in patients undergoing aortic valve intervention. In this study, the development of AKI was shown to be an important predictor of MACE [21]. Our study differs by specifically analyzing the relation between AKI and MACE in diabetic patients undergoing TAVR.

When other factors related to the development of MACE after TAVR were analyzed, it was revealed that female gender was associated with higher MACE rates. When the relationship between MACE after TAVR and gender was examined, the relationship between female gender and MACE was also shown in previous studies in the literature [22]. All of our patients were diabetic, and the relationship between the presence of diabetes and higher MACE rates has also been shown in previous studies in the literature [23].

Patients with elevated pre-procedural NT-proBNP levels were observed to have higher MACE rates. A previous study by Konstantinos C. Koskinas and colleagues showed a relationship between high NT-proBNP values and high MACE rates, similar to the results in our study [24].

Our study also found that patients with smaller aortic valve areas had a higher MACE rate. No prior research on this topic exists in the literature. However, our opinion on this subject is that in patients with smaller aortic valve areas, it becomes difficult to pass through the aortic valve during the procedure. As a result, the procedure duration extends, and the contrast material usage rises. We think that MACE rates

increase after the procedure due to these factors, but studies are needed to support this idea.

We believe that the relationship we found between AKI and MACE rates, and the observation of renal replacement requirement in clinical follow-up in those who died in the AKI group, are important. Our study may shed light on the necessity of renal replacement therapy under earlier and more flexible conditions in the special patient group (diabetic female patients with nephropathy, hypertension, and more severe valvular and cardiac involvement) who develop AKI after TAVI.

The major limitation of the study is its retrospective nature and a limited sample size from a single center. Additionally, the urine output criterion for AKI diagnosis was not considered due to incomplete medical records. Another limitation was that the duration and severity of diabetes were not taken into account.

CONCLUSION

We impress that AKI development, which is one of the frequently seen conditions in diabetic individuals who underwent TAVR for severe aortic stenosis, has an effect on the development of adverse events and survival independently of other parameters.

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Ethical approval: The study protocol received approval from Ethics Committee of University of Health Sciences Turkey, Bursa Yüksek İhtisas Training and Research Hospital (decision no: 2011-KAEK-25 2022/11-15).

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