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Kidney function change after transcatheter aortic valve replacement in patients with diabetes and/or hypertension

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Aortic stenosis (AS) is a progressive heart valve disease occurring predominantly in older patients. According to a survey in a western country, the prevalence of AS is nearly 6.4% in patients over 75 years old (Carabello and Paulus, 2009). Transcatheter aortic valve replacement (TAVR) is an alternative method for AS patients. Previous studies have described how up to 66% of TAVR patients have concomitant baseline kidney dysfunction (Ferro et al., 2015; Gargiulo et al., 2015). The majority of patients can benefit from the TAVR procedure with the recovery of kidney function. The TAVR procedure releases the obstruction of the left ventricle caused by severe AS, and the increased cardiac output may be reasonably responsible for recovery of the kidney function (Ewe et al., 2010; Dauerman et al., 2016). Kidney dysfunction is most commonly attributed to diabetes and hypertension (HTN) (Chen et al., 2019). A few studies have reported kidney function change after TAVR in baseline chronic kidney disease (CKD) patients (Beohar et al., 2017; Azarbal et al., 2019; Okoh et al., 2019). However, no study has focused on kidney function change after TAVR in the diabetic or hypertensive population. Therefore, we aimed to investigate kidney function

change during the TAVR procedure in patients with diabetes mellites (DM) and/or HTN.

A total of 410 consecutive severe AS patients were included, who underwent the TAVR procedure between March 1, 2013 and May 30, 2019 and who had self-expandable, balloon-expandable, and mechanically expandable valves. After excluding patients with baseline dialysis, severe kidney dysfunction (CKD stage 5: estimated glomerular filtration rate (eGFR) of <15 mL/min), and patients who died within 48 h, 399 patients were enrolled in the study. Preoperative assessment was done comprehensively and TAVR procedures were determined by an interdisciplinary heart team. All patients who had TAVR underwent both pre- and post-procedural hydrations based on their respective individual cardiac performances. Blood and glycemia were well-control under the expert guidance of a specialist if necessary before the procedure. More detailed information about the procedure was reported in a previous study (Fan et al., 2020).

The outcome of the present study was defined according to the Valve Academic Research Consortium (VARC)-2 criteria (Kappetein et al., 2012). Data collection included baseline characteristics, procedural data, and pre-discharge outcomes. Baseline characteristics consisted of baseline clinical, laboratory, echocardiographic, and computed tomographic data. Kidney function tests were performed before and after the TAVR procedure in all patients. The Cockcroft-Gault formula was used for eGFR at the baseline and pre-discharge (24–48 h before discharge) for all patients.

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According to a previous study, for CKD patients, a 10% change of eGFR between discharge and baseline may reflect a fluctuation of kidney function (Okoh et al., 2019). We divided the patients into three groups according to the percent change in eGFR post-TAVR: (discharge eGFR–baseline eGFR)/baseline eGFR×100%. Patients with improved, declined, and no kidney function changes represented $\geq 10\%$, $\leq -10\%$, and between -10% and 10% changes in eGFR, respectively. Patients were classified as having DM and/or HTN if they had been diagnosed with either condition at baseline, as reported on the “diagnosed conditions” electronic case report form.

Continuous variables following normal distribution were presented as mean±standard deviation (SD) and compared using analysis of variance (ANOVA). Otherwise, the skewed variables were presented as median (interquartile range (IQR)), and the Kruskal-Wallis test was used. Categorical data were presented as count (percentage) and compared with the Chi-square test. $P < 0.05$ was considered statistically significant. Statistical analysis was performed using SPSS software (Version 20.0, SPSS Inc., Chicago, Illinois, USA) and the figures were created in GraphPad Prism (Version 6.0, GraphPad Software, San Diego, California, USA).

Of the 399 patients who had TAVR from March 1, 2013 to May 30, 2019, 242 (60.7%) were diabetic and/or hypertensive patients. Among these 242 diabetic and/or hypertensive patients, 93 patients (38.4%) showed an improvement, 117 patients (48.3%) showed no changes, and 32 patients (13.2%) showed a decline in eGFR of more than 10%. In the other 157 non-diabetic and non-hypertensive patients, 77 patients (49.0%) showed an improvement, 68 patients (43.3%) showed no changes, and 12 patients (7.6%) showed a decline in eGFR of more than 10%. The kidney function change between these diabetic and/or hypertensive patients and non-diabetic or non-hypertensive patients was on the very borderline of statistical significance ($P=0.059$). The eGFR change in two groups is shown in Fig. 1.

The baseline demographics and clinical characteristics of diabetic and/or hypertensive patients in this study are shown in Table 1. There was no significant difference observed for age, sex, body mass index (BMI), New York Heart Association (NYHA) III/IV, or proportion of DM and/or HTN. Patients with declined and improved kidney function had significantly higher Society of Thoracic Surgeons (STS) scores compared

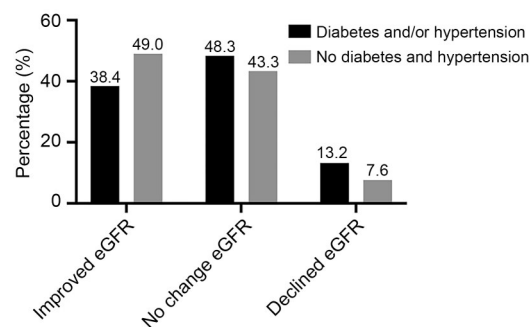


Fig. 1 Percentages of estimated glomerular filtration rate (eGFR) changes in diabetic and/or hypertensive patients versus non-diabetic and non-hypertensive patients.

with unchanged kidney function patients (7.41 (3.52–10.97) and 7.04 (4.52–9.91) vs. 5.09 (3.58–8.34), $P=0.003$). The incidence of peripheral vascular disease was higher in declined kidney function patients compared with improved and unchanged patients (40.6% vs. 26.9% and 14.5%, $P=0.003$). Previous histories of smoking, dyslipidemia, DM, atrial fibrillation, chronic obstructive pulmonary disease (COPD), percutaneous coronary intervention (PCI), or other clinical diseases did not differ significantly. The patients with improved kidney function had higher creatinine (93.0 (74.5–121.0) vs. 75.0 (61.5–94.5) vs. 66.5 (54.3–95.3) $\mu\text{mol/L}$, $P < 0.001$) and lower eGFR (45.0 (33.9–60.3) vs. 57.4 (43.4–70.7) vs. 56.6 (44.2–76.8) mL/min per 1.73 m², $P < 0.001$) than patients with unchanged and declined kidney function.

Values for echocardiographic parameters did not differ between the three groups for transvalvular mean gradient, max transvalvular velocity, left atrial size, left ventricular size, or pulmonary artery systolic pressure besides aortic valve area and left ventricular ejection fraction (LVEF). The improved kidney function patients had lower LVEF (55.1% (40.9%–62.0%) vs. 60.4% (53.4%–66.1%) vs. 59.9% (52.9%–67.8%), $P=0.002$) compared with the unchanged and declined kidney function patients. Moreover, the unchanged kidney function patients had higher aortic valve area (0.64 (0.50–0.75) vs. 0.55 (0.43–0.71) vs. 0.52 (0.44–0.68) cm², $P=0.028$) compared with the improved and declined kidney function patients. All baseline characteristics of patients are shown in Table 1.

The three groups showed no difference in contrast volume used, fluoroscopy time, procedural time, or hospital stay. The intensive care unit (ICU) stay was also comparable without statistically significant differences (1 (0–1) vs. 0 (0–1) vs. 0 (0–1) d, $P=0.062$).

Table 1 Baseline characteristics of diabetic and/or hypertensive patients in this study

Characteristics	DM and/or HTN			P
	Improved (n=93)	No change (n=117)	Declined (n=32)	
Age (year)	79.0 (74.0–82.0)	77.0 (72.5–82.5)	78.0 (72.3–82.0)	0.745*
Male	54 (58.1%)	68 (58.1%)	15 (46.9%)	0.509
BMI (kg/m ²)	23.23±3.56	23.32±3.20	23.74±3.57	0.757
NYHA III/IV	85 (91.4%)	104 (88.9%)	28 (87.5%)	0.804
STS	7.04 (4.52–9.91)	5.09 (3.58–8.34)	7.41 (3.52–10.97)	0.003*
Smoker	12 (12.9%)	15 (12.8%)	2 (6.3%)	0.604
Dyslipidemia	24 (25.8%)	27 (23.1%)	6 (18.8%)	0.709
DM and HTN				0.114
DM	11 (11.8%)	10 (8.5%)	5 (15.6%)	
HTN	53 (57.0%)	84 (71.8%)	16 (50.0%)	
Combined	29 (31.2%)	23 (19.7%)	11 (34.4%)	
PVD	25 (26.9%)	17 (14.5%)	13 (40.6%)	0.003
Atrial fibrillation	17 (18.3%)	25 (21.4%)	2 (6.3%)	0.147
COPD	20 (21.5%)	24 (20.5%)	8 (25.0%)	0.864
Prior PCI	11 (11.8%)	19 (16.2%)	7 (21.9%)	0.381
Prior CABG	0	0	1 (3.1%)	0.132
Prior MI	2 (2.2%)	2 (1.7%)	0	1.000
Prior PPI	2 (2.2%)	3 (2.6%)	1 (3.1%)	1.000
Prior stroke	6 (6.5%)	9 (7.7%)	0	0.159
Prior angina	16 (17.2%)	21 (17.9%)	4 (12.5%)	0.816
Syncope	12 (12.9%)	8 (6.8%)	2 (6.3%)	0.302
GI bleeding	2 (2.2%)	1 (0.9%)	2 (6.3%)	0.167
Pulmonary HTN	8 (8.6%)	5 (4.3%)	1 (3.1%)	0.434
Pure AS	57 (61.3%)	78 (66.7%)	26 (81.3%)	0.115
Creatinine (μmol/L)	93.0 (74.5–121.0)	75.0 (61.5–94.5)	66.5 (54.3–95.3)	<0.001*
eGFR (mL/min per 1.73 m ²)	45.0 (33.9–60.3)	57.4 (43.4–70.7)	56.6 (44.2–76.8)	<0.001*
LVEF (%)	55.1 (40.9–62.0)	60.4 (53.4–66.1)	59.9 (52.9–67.8)	0.002*
MG (mmHg)	53.0 (41.0–65.8)	51.0 (42.0–62.0)	57.0 (45.0–69.0)	0.219*
AVA (cm ²)	0.55 (0.43–0.71)	0.64 (0.50–0.75)	0.52 (0.44–0.68)	0.028*
Maximum velocity (m/s)	4.79 (4.21–5.30)	4.70 (4.20–5.20)	4.96 (4.34–5.23)	0.365*
LVEDD	5.14±1.04	4.93±0.76	4.79±0.89	0.095
LA	4.30±0.68	4.24±0.72	4.17±0.60	0.606
PASP	37.5 (31.0–54.5)	34.0 (29.3–45.8)	38.0 (29.0–51.0)	0.299*

* Kruskal-Wallis test was used. Data are presented as mean±standard deviation (SD), median (interquartile range (IQR)), or number (percentage). AS: aortic stenosis; AVA: aortic valve area; BMI: body mass index; CABG: coronary artery bypass grafting; COPD: chronic obstructive pulmonary disease; DM: diabetes mellitus; LVEF: left ventricular ejection fraction; eGFR: estimated glomerular filtration rate; GI: gastrointestinal; HTN: hypertension; LA: left atrial; LVEDD: left ventricular end-diastolic diameter; MG: mean gradient (1 mmHg=0.133 kPa); MI: myocardial infarction; NYHA: New York Heart Association; PASP: pulmonary artery systolic pressure; PCI: percutaneous coronary intervention; PPI: permanent pacemaker implantation; PVD: peripheral vascular disease; STS: Society of Thoracic Surgeons.

However, for the prevalence of blood transfusion, the declined kidney function patients had a higher rate than the other two groups (21.9% vs. 6.0% vs. 17.2%, $P=0.015$). The declined kidney function patients had a higher frequency of new pacemaker implantation (25.0% vs. 9.4% vs. 9.7%, $P=0.075$) than the unchanged and improved kidney function groups; however, it did not reach statistical significance. Of more concern,

patients with declined kidney function had higher rates of in-hospital mortality (12.5% vs. 1.7% vs. 0%, $P=0.002$) and 30-d mortality (15.6% vs. 1.7% vs. 0%, $P<0.001$), which were mainly caused by in-hospital (6.3% vs. 1.7% vs. 0%, $P=0.068$) and 30-d (9.4% vs. 1.7% vs. 0%, $P=0.009$) cardiovascular mortalities (Table 2).

In multivariable linear models, age, male, peripheral vascular disease, baseline LVEF, aortic valve area,

Table 2 Peri-procedural and follow-up clinical outcomes

Characteristics	DM and/or HTN			P
	Improved (n=93)	No change (n=117)	Declined (n=32)	
Contrast volume (mL)	125 (110–156)	120 (108–150)	120 (98–150)	0.524*
Fluro time (min)	22 (18–33)	22 (18–32)	27 (16–32)	0.911*
Procedural time (min)	83 (55–119)	70 (49–110)	95 (60–133)	0.229*
Proglide	84 (90.3%)	107 (91.5%)	25 (78.1%)	0.133
ICU stay (d)	1 (0–1)	0 (0–1)	0 (0–1)	0.062*
Hospital stay (d)	8 (7–11)	8 (7–10)	9 (7–14)	0.115*
Stroke	2 (2.2%)	3 (2.6%)	3 (9.4%)	0.156
Blood transfusion	16 (17.2%)	7 (6.0%)	7 (21.9%)	0.015
Vascular complication	4 (4.3%)	7 (6.0%)	3 (9.4%)	0.507
New atrial fibrillation	5 (5.4%)	6 (5.1%)	1 (3.1%)	0.861
New pacemaker	9 (9.7%)	11 (9.4%)	8 (25.0%)	0.075
Unplanned CPB	4 (4.3%)	1 (0.9%)	2 (6.3%)	0.113
Echocardiography				
Mean gradient (mmHg)	11.0 (9.0–15.0)	10.0 (8.5–14.0)	10.0 (8.0–14.5)	0.638*
AVA (cm ²)	1.54±0.36	1.57±0.38	1.57±0.24	0.812
Maximum velocity (m/s)	2.37 (2.05–2.70)	2.30 (2.02–2.60)	2.20 (2.00–2.60)	0.575*
LVEF (%)	56.1 (47.0–62.8)	61.5 (55.3–66.7)	60.7 (55.3–64.9)	0.001*
LVEF change (%) [#]	3.1 (–5.0–15.5)	–0.4 (–7.3–10.5)	0.8 (–10.4–14.9)	0.343
Mortality				
In-hospital	0	2 (1.7%)	4 (12.5%)	0.002
30-d	0	2 (1.7%)	5 (15.6%)	<0.001
Cardiovascular mortality				
In-hospital	0	2 (1.7%)	2 (6.3%)	0.068
30-d	0	2 (1.7%)	3 (9.4%)	0.009

* Kruskal-Wallis test was used. [#] LVEF change from baseline: (predischarge LVEF–baseline LVEF)/baseline LVEF×100%; Data are presented as mean±standard deviation (SD), median (interquartile range (IQR)), or number (percentage). AVA: aortic valve area; CPB: cardiopulmonary bypass; DM: diabetes mellitus; HTN: hypertension; ICU: intensive care unit; LVEF: left ventricle ejection fraction.

baseline left ventricular end-diastolic diameter (LVEDD), baseline eGFR, pre-discharge ICU stay, blood transfusion, new pacemaker implantation, and unplanned cardiopulmonary bypass (CPB) before discharge were included. In these models, LVEF ($P=0.001$), baseline eGFR ($P<0.001$), and unplanned CPB ($P=0.010$) were the independent predictors of eGFR change between before discharge and baseline (Table S1).

To our knowledge, this is the first study that investigated the prognosis of kidney function change in patients with DM and/or HTN undergoing the TAVR procedure. We found that (1) declined kidney function patients are significantly associated with higher mortality in hospital and at 30 d; (2) improved kidney function—concurrently with a higher STS score, lower LVEF, and smaller aortic valve area—is ubiquitous in baseline diabetic and/or hypertensive patients, though its prevalence in the improved population is lower than that in the non-diabetic and non-hypertensive

population; (3) LVEF, baseline eGFR, and bleeding are independent predictors of improved versus declined kidney function after TAVR.

In the present study, 38.4% of diabetic and/or hypertensive patients had an improvement in kidney function which was lower than 49.0% in non-diabetic and non-hypertensive patients. Previous studies observed a 52% incidence of improved kidney function in baseline renal dysfunction patients after TAVR (Beohar et al., 2017; Okoh et al., 2019). Though the procedure itself may bring some risk of renal injury by the usage of contrast, nearly half of patients benefited more from the procedure. This phenomenon reveals that the release of pressure afterload by TAVR plays a more prominent role in the recovery of type 2 chronic cardiorenal syndrome whose cause may be multifactorial such as through reduced cardiac output, elevated venous pressure, or renin–angiotensin–aldosterone system (RAAS) activation (Rangaswami et al., 2019). In our study, the

observed rate of recovered kidney function was lower in diabetic and/or hypertensive patients. The phenomenon reveals that even diabetic and/or hypertensive patients, whose comorbidities may influence the recovery of kidney function, benefited from the TAVR procedure.

The presence of DM and/or HTN has been associated with impaired kidney autoregulation, which is consistent with a previously reported study (Schewel et al., 2017). The pathophysiological mechanism may be related to the negative influence of DM and/or HTN on kidney autoregulation (Abuelo, 2007). AS patients with uncontrolled or controlled HTN by medication may have irreversible renal damage due to excessive activation of RAAS and decreased afferent arteriolar resistance (Rieck et al., 2012). Moreover, AS patients with DM came up, not only with a more pronounced metabolic syndrome but also with an increased incidence of generalized atherosclerosis (Banovic et al., 2019). Though a previous study by Schewel et al. (2017) could not find any evidence for the influence of DM on the incidence of acute kidney injury (AKI), their data showed a numerically increased rate in AKI among those diabetic patients with severe renal failure (eGFR<30 mL/min per 1.73 m²). A meta-analysis by Mina et al. (2017) showed that DM was associated with increased AKI and one-year mortality after TAVR. Overall, it is reasonable to state that the rate of recovery for kidney function is lower in diabetic and/or hypertensive patients compared with previous studies.

Okoh et al. (2019) found that female gender, baseline liver dysfunction, and preoperative left ventricular ejection fraction are associated with immediately declining or improving kidney function in baseline renal dysfunction patients. Data from the Placement of Aortic Transcatheter Valves (PARTNER) 1 trial and registry reported by Boehar et al. (2017) showed that female gender and baseline left ventricular mass are predictors of declined or improved kidney function. Multivariable logistic regression in a previous study by Azarbal et al. (2019) found that moderate to severe lung disease, eGFR<50 mL/min per 1.73 m², and previous aortic valve surgery are the independent predictors of acute kidney recovery, while patients with DM, baseline anemia, and STS>6.1 are likely to develop AKI. Though the included population was different, our study identified four independent predictors of improved versus declined eGFR in diabetic and hypertensive patients. We have found that LVEF, baseline eGFR, and

a lower incidence of unplanned CPB may indicate the potential improvement of kidney function.

Our study revealed that patients with lower LVEF may be likely to improve kidney function after TAVR. This finding supports the concept that after the release of the pressure afterload, the LVEF recovers and the low perfusion state in the kidney is eliminated. Therefore, it can be observed that lower LVEF patients had a greater prevalence of improved kidney function. Our findings are similar to previous results. Lower eGFR patients were more likely to develop kidney function improvement and higher STS scores may increase the risk of kidney function injury (Azarbal et al., 2019). Thus, the clinical avoidance of TAVR in these severe kidney dysfunction patients may not be reasonable given the enormous potential for improvement in this high-risk group. Moreover, it is reasonable that a lower incidence of unplanned CPB during the TAVR procedure may help the recovery of kidney function. Unplanned CPB is one of the severe peri-procedural complications that is associated with AKI after cardiac surgery (Fischer et al., 2002). The exposure of blood to non-endothelial lined surfaces during CPB can induce a systemic inflammatory response, coagulopathy, hemodilution, generation of thrombin, inflammatory reaction, and postoperative bleeding leading to declined kidney function (Thongprayoon et al., 2015).

Findings from the present study showed the relationship between declined kidney function change and higher mortality in diabetic patients and/or patients who underwent TAVR. The previous study by Okoh et al. (2019) showed that in-hospital, 30-d, and one-year mortalities were associated with declined kidney function change significantly. Our study confirmed that the detrimental effect on all-cause and cardiovascular mortality persisted in diabetic and/or hypertensive patients.

This study is a retrospective single-center study with large differences in the number of patients (93 vs. 117 vs. 32 patients), and therefore there are still some limitations inherently present in such a study. Patients with baseline eGFR of <15 mL/min per 1.73 m² and those on dialysis were excluded from the present study because the fluctuations in eGFR of these diabetic and/or hypertensive patients were not accurate. The present study only considered an immediate improvement change as improved or declined kidney function change in eGFR defined by pre-discharge value. Long-term follow-up was not considered in

our study, which would have been valuable for further study to see whether it would persist in the long term as well. The study is likely not adequately powered to detect differences in some clinical endpoints in the improved or declined kidney function groups compared with the group who experienced no change for a limited number of patients. Moreover, as a retrospective study, anti-hypertensive and anti-diabetic therapy, hemoglobin A1c, or blood control situation was not recorded in the databases. We used a clinically meaningful definition of improved or declined eGFR; however, other definitions such as absolute increase or decrease of serum creatinine of 0.3 mg/dL could also be used as the VARC definition (Kappetein et al., 2012).

The frequency of recovery of kidney function in diabetic and/or hypertensive severe symptomatic AS patients is lower than that in non-diabetic and non-hypertensive patients. Nearly 40% of diabetic and/or hypertensive patients experience an intermediate improvement after TAVR. Patients with declined renal function suffer worse outcomes in mortality, mainly in cardiovascular mortality.

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Author contributions

Jiaqi FAN and Changjie YU designed the research. Kaida REN and Wanbing LIN conducted experiments. Stella NG, Xinping LIN, Lihan WANG, Qifeng ZHU, Yuxin HE, and Jubo JIANG recruited patients, collected data, and entered the data. Jiaqi FAN and Zexin CHEN did the statistical analysis. Xianbao LIU and Jian'an WANG undertook a critical revision of the manuscript. All authors have read and approved the final manuscript and, therefore, have full access to all the data in the study and take responsibility for the integrity and security of the data.

Compliance with ethics guidelines

Jiaqi FAN, Changjie YU, Kaida REN, Wanbing LIN, Stella NG, Zexin CHEN, Xinping LIN, Lihan WANG, Qifeng ZHU, Yuxin HE, Jubo JIANG, Xianbao LIU, and Jian'an WANG declare that they have no conflicts of interest.

All procedures followed were in accordance with the ethical standards of the responsible committee on human

experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008 (5). Informed consent was obtained from all patients for being included in the study.

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Supplementary information

Table S1