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Association of Chronic Kidney Disease With In-Hospital Outcomes of Transcatheter Aortic Valve Replacement

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ABSTRACT

OBJECTIVES This study sought to determine the association of chronic kidney disease (CKD) with in-hospital outcomes of transcatheter aortic valve replacement (TAVR).

BACKGROUND CKD is a known independent risk factor for worse outcomes after surgical aortic valve replacement (SAVR). However, data on outcomes of patients with CKD undergoing TAVR are limited, especially in those on chronic dialysis.

METHODS The authors used data from the 2012 to 2014 National Inpatient Sample database to identify all patients ≥18 years of age who underwent TAVR. International Classification of Diseases-Ninth Revision-Clinical Modification codes were used to identify patients with no CKD, CKD (without chronic dialysis), or end-stage renal disease (ESRD) on long-term dialysis. Multivariable logistic regression models were constructed using generalized estimating equations to examine in-hospital outcomes.

RESULTS Of 41,025 patients undergoing TAVR from 2012 to 2014, 25,585 (62.4%) had no CKD, 13,750 (33.5%) had CKD, and 1,690 (4.1%) had ESRD. Compared with patients with no CKD, in-hospital mortality was significantly higher in patients with CKD or ESRD (3.8% vs. 4.5% vs. 8.3%; adjusted odds ratio [no CKD as reference]: 1.39 [95% confidence interval: 1.24 to 1.55] for CKD and 2.58 [95% confidence interval: 2.09 to 3.13] for ESRD). Patients with CKD or ESRD had a higher incidence of major adverse cardiovascular events (composite of death, myocardial infarction, or stroke), net adverse cardiovascular events (composite of major adverse cardiovascular events, major bleeding, or vascular complications), and pacemaker implantation compared with patients without CKD. Acute kidney injury (AKI) and AKI requiring dialysis were associated with several-fold higher risk-adjusted in-hospital mortality in patients in the no CKD and CKD groups. Moreover, the incidence of AKI and AKI requiring dialysis did not decline during the study period.

CONCLUSIONS Patients with CKD or ESRD have worse in-hospital outcomes after TAVR. AKI is associated with higher in-hospital mortality in patients undergoing TAVR and the incidence of AKI has not declined over the years. (J Am Coll Cardiol Intv 2017;10:2050–60) © 2017 by the American College of Cardiology Foundation.

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Transcatheter aortic valve replacement (TAVR) is approved for treatment of severe symptomatic aortic stenosis in the United States in patients who are considered intermediate or high risk for surgical aortic valve replacement (SAVR) (1,2). Impaired renal function, either in the form of chronic kidney disease (CKD) (referred to as chronic kidney disease not requiring dialysis) or end-stage renal disease (ESRD) (referred to as CKD requiring long-term dialysis), is associated with accelerated calcification, and these patients tend to present with severe aortic stenosis at a younger age (3,4). Limited information is available regarding outcomes in patients with ESRD undergoing TAVR as these were excluded from the PARTNER (Placement of Aortic Transcatheter Valves) and the U.S. CoreValve trials (5–9). A combined analysis from the PARTNER trial and continued access registries reported that severe renal impairment (glomerular filtration rate [GFR] ≤30 ml/min/1.73 m^2) was associated with higher 1-year mortality after TAVR (10). Multicenter prospective registries from other countries have reported similar findings but have been limited by under-representation of the ESRD population (11–13).

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The objective of this study was to assess the in-hospital outcomes of patients with CKD or ESRD undergoing TAVR in the United States following commercial approval. We also examined the incidence of acute kidney injury (AKI) and the association of AKI with in-hospital mortality in patients without ESRD. In addition, we assessed the temporal trends in the proportion of patients with CKD or ESRD undergoing TAVR and their in-hospital mortality over a 3-year period.

METHODS

DATA SOURCE. Data were obtained from the 2012 to 2014 National Inpatient Sample (NIS) database files. The NIS is sponsored by the Agency for Healthcare Research and Quality as a part of the Healthcare Cost and Utilization Project. It is the largest publicly available all-payer inpatient care database in the United States and includes data on ~8 million hospitalizations each year from ~1,000 hospitals in participating states (n = 46 in 2014). A 20% sample of discharges is included from all Healthcare Cost and Utilization Project participating hospitals. Discharge weights are provided for each record and can be used to obtain national estimates (14).

STUDY POPULATION. We used the International Classification of Diseases-9th Revision-Clinical Modification (ICD-9-CM) codes 35.05 and 35.06 to identify all patients age ≥18 years who underwent TAVR (n = 41,025). Patients with CKD were identified using ICD-9-CM codes 585.1, 585.2, 585.3, 585.4, 585.5, and 585.9. Patients with ESRD were identified using the diagnosis code for CKD requiring long-term dialysis (585.6) or the procedure codes for hemodialysis (39.95) or peritoneal dialysis (54.98), except when dialysis was performed for AKI (ICD-9-CM diagnosis codes 584.5 to 584.9). This approach has been used by previous studies using the NIS database to accurately identify patients with CKD or ESRD (15,16). In administrative databases, ICD-9-CM coding for chronic renal insufficiency has been shown to have a sensitivity of 81.9%, specificity of 98.6%, positive predictive value (PPV) of 71.2%, and negative

ABBREVIATIONS AND ACRONYMS

AKI = acute kidney injury
CI = confidence interval
CKD = chronic kidney disease
ESRD = end-stage renal disease
GFR = glomerular filtration rate
ICD-9-CM = International Classification of Diseases-9th Revision-Clinical Modification
LOS = length of stay
MACE = major adverse cardiovascular event(s)
MI = myocardial infarction
NACE = net adverse cardiovascular event(s)
NIS = National Inpatient Sample
NPV = positive predictive value
OR = odds ratio
PPM = permanent pacemaker
PPV = positive predictive value
TAVR = transcatheter aortic valve replacement

the data monitoring committees of the Cleveland Clinic, Duke Clinical Research Institute, Harvard Clinical Research Institute, Mayo Clinic, Population Health Research Institute; has received honoraria from the American College of Cardiology (Senior Associate Editor, *Clinical Trials and News*, ACC.org), Belvoir Publications (Editor in Chief, *Harvard Heart Letter*), Duke Clinical Research Institute (clinical trial steering committees), Harvard Clinical Research Institute (clinical trial steering committee), HMP Communications (Editor in Chief, *Journal of Invasive Cardiology*), *Journal of the American College of Cardiology* (Guest Editor; Associate Editor), Population Health Research Institute (clinical trial steering committee), Slack Publications (Chief Medical Editor, *Cardiology Today's Intervention*), Society of Cardiovascular Patient Care (Secretary/Treasurer), and WebMD (CME steering committees); has served as the Deputy Editor for *Clinical Cardiology*; has served as the chair of the NCDR-ACTION Registry Steering Committee and VA CART Research and Publications Committee; has received research funding from Amarin, Amgen, AstraZeneca, Bristol-Myers Squibb, Chiesi, Eisai, Ethicon, Forest Laboratories, Ironwood, Ischemix, Lilly, Medtronic, Pfizer, Roche, Sanofi, and The Medicines Company; has received royalties from Elsevier (Editor, *Cardiovascular Intervention: A Companion to Braunwald's Heart Disease*); has served as a site co-investigator for Biotronik, Boston Scientific, and St. Jude Medical (now Abbott); has served as a trustee of American College of Cardiology; and has performed unfunded research for FlowCo, Merck, PLx Pharma, and Takeda. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose. A part of this study was presented as an abstract at the American College of Cardiology 66th Annual Scientific Sessions in Washington, DC, on March 18, 2017. Dr. Gupta and Dr. Goel contributed equally to this manuscript.

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TABLE 1 Baseline Characteristics of Patients Undergoing TAVR

	Overall (n = 41,025)	No CKD (n = 25,585)	CKD (n = 13,750)	ESRD (n = 1,690)	p Value: CKD vs. No CKD	p Value: ESRD vs. No CKD
Age, yrs	81.1 ± 8.5	80.9 ± 8.8	82.3 ± 7.2	75.3 ± 9.9	<0.001	<0.001
Women	47.7	52.5	40.0	37.3	<0.001	<0.001
Race					<0.001	<0.001
White	81.3	83.2	79.4	68.3		
African American	3.6	2.8	3.9	13.9		
Hispanic	3.5	3.4	3.6	4.4		
Asian or Pacific Islander	1.0	0.8	1.4	1.8		
Native American	0.2	0.2	0.2	0.6		
Other	3.4	3.2	3.6	3.8		
Missing	7.0	6.5	7.9	7.1		
Comorbidities						
Smoking	3.1	3.4	2.7	0.9	<0.001	<0.001
Dyslipidemia	64.6	63.7	67.5	53.8	<0.001	<0.001
Known CAD	68.3	65.8	73.3	64.5	<0.001	0.27
Prior myocardial infarction	13.1	12.2	14.8	13.3	<0.001	0.18
Prior PCI	18.9	18.3	20.1	17.8	<0.001	0.59
Prior CABG	22.3	21.1	24.9	18.9	<0.001	0.006
Prior TIA/stroke	10.4	10.2	11.0	8.9	0.013	0.08
Atrial fibrillation	44.7	43.2	48.0	38.8	<0.001	<0.001
Heart failure	74.1	69.6	81.8	79.6	<0.001	<0.001
Diabetes mellitus	34.6	30.9	39.7	47.9	<0.001	<0.001
Hypertension	79.5	75.4	86.1	86.4	<0.001	<0.001
Obesity	14.1	13.6	15.3	13.0	<0.001	0.51
Peripheral vascular disease	29.7	27.4	33.4	34.3	<0.001	<0.001
Carotid artery disease	7.3	7.3	7.4	6.2	0.91	0.08
Dementia	5.1	5.5	4.8	2.7	0.003	<0.001
Prior PPM	10.5	10.3	10.9	9.2	0.07	0.13
Prior ICD	2.9	2.1	4.3	3.3	<0.001	0.003
Anemia	26.2	20.9	32.4	56.8	<0.001	<0.001
Chronic pulmonary disease	33.2	32.9	34.5	27.5	0.001	<0.001
Coagulopathy	23.8	21.7	27.2	28.4	<0.001	<0.001
Hypothyroidism	20.3	20.1	21.5	14.5	0.001	<0.001
Liver disease	2.4	2.1	2.6	5.3	0.003	<0.001
Fluid and electrolyte disorder	26.6	24.0	30.0	38.8	<0.001	<0.001
Cancer	3.7	4.0	3.2	2.7	<0.001	0.007
Neurologic disorders	6.4	6.8	5.6	5.9	<0.001	0.15
Hospital characteristics						
Hospital region					<0.001	<0.001
Northeast	25.3	26.4	23.2	25.7		
Midwest	22.2	21.0	24.5	19.8		
South	34.4	34.6	33.3	39.6		
West	18.2	18.0	18.9	14.8		
Bed size					<0.001	<0.001
Small	4.9	4.7	5.3	4.1		
Medium	16.3	14.8	18.7	19.2		
Large	78.8	80.5	76.0	76.6		
Teaching hospital	88.9	89.3	88.0	89.6	<0.001	0.67
Primary expected payer					<0.001	<0.001
Medicare	90.1	89.3	91.6	89.1		
Medicaid	1.1	1.1	0.7	2.7		
Private insurance	7.1	7.8	5.9	5.9		
Self-pay	0.5	0.5	0.4	0.8		
Other	1.2	1.3	1.4	1.5		

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TABLE 1 Continued

	Overall (n = 41,025)	No CKD (n = 25,585)	CKD (n = 13,750)	ESRD (n = 1,690)	p Value: CKD vs. No CKD	p Value: ESRD vs. No CKD
Median household income					<0.001	<0.001
0–25th percentile	20.6	19.9	21.3	25.7		
26–50th percentile	24.5	24.7	24.2	25.1		
51–75th percentile	25.4	24.9	26.2	25.4		
76–100th percentile	29.5	30.6	28.3	23.7		
Procedural characteristics						
Transapical TAVR	20.0	20.9	18.2	21.3	<0.001	0.66
PCI during hospitalization	3.4	3.5	3.0	5.9	0.011	<0.001
Use of MCS	2.4	2.0	2.7	5.6	<0.001	<0.001

Values are mean ± SD or %.

CAD = coronary artery disease; CABG = coronary artery bypass grafting; CKD = chronic kidney disease; ESRD = end-stage renal disease; ICD = implantable cardioverter-defibrillator; MCS = mechanical circulatory support; PCI = percutaneous coronary intervention; PPM = permanent pacemaker; TAVR = transcatheter aortic valve replacement; TIA = transient ischemic attack.

predictive value (NPV) of 99.2% (17). Patients without codes for CKD or ESRD were assigned to the no CKD group.

PATIENT AND HOSPITAL CHARACTERISTICS. Baseline patient-level characteristics included were demographics (age, sex, race, primary expected payer, median household income for patient's zip code) and relevant comorbidities (smoking, dyslipidemia, known coronary artery disease, prior myocardial infarction [MI], prior percutaneous coronary intervention [PCI], prior coronary artery bypass grafting, prior transient ischemic attack or stroke, atrial fibrillation, heart failure, diabetes mellitus, hypertension, obesity, peripheral vascular disease, chronic renal failure, carotid artery disease, dementia, prior permanent pacemaker [PPM], prior implantable cardioverter-defibrillator, anemia, chronic pulmonary disease, coagulopathy, hypothyroidism, liver disease, fluid and electrolyte disorders, cancer, and neurologic disorders) (18,19). Hospital-level characteristics were census region, bed size, and teaching status. Procedural characteristics were TAVR access site (endovascular vs. transapical), PCI during hospitalization, and use of mechanical circulatory support devices. A list of ICD-9-CM and Clinical Classification Software codes used to identify comorbidities and procedural characteristics is included in Online Table 1.

OUTCOMES MEASURED. Our primary outcome of interest was all-cause, in-hospital mortality. In-hospital complications included MI, stroke, major bleeding, major vascular complications, new requirement for PPM, and conversion to SAVR. Major adverse cardiovascular events (MACE) were defined as a composite of death, MI, or stroke. Net adverse cardiovascular events (NACE) were defined as a composite of MACE, major bleeding, or major vascular complications. A list of ICD-9-CM codes used to define complications is included in Online Table 1. Other secondary outcomes examined were length of stay (LOS) and discharge disposition in patients surviving the hospitalization.

We further examined the incidence of AKI and AKI requiring dialysis as additional outcomes in patients in the no CKD and CKD groups. Patients with AKI were identified using ICD-9-CM diagnosis codes 584.5 to 584.9. AKI requiring dialysis was identified by the additional presence of the ICD-9-CM procedure code for hemodialysis (39.95). ICD-9-CM codes for AKI have been shown to have a sensitivity of 35.4%, specificity of 97.7%, PPV of 47.9%, and NPV of 96.1%. ICD-9-CM diagnosis of AKI requiring dialysis has been shown to have a sensitivity of 90.4%, specificity of 93.8%, PPV of 94.0%, and NPV of 90.0% (20).

STATISTICAL ANALYSIS. Weighted data were used for all analyses. Baseline patient-level, hospital-level, and procedural characteristics of patients with CKD or ESRD were compared with those with no CKD using the Pearson chi-square test for categorical variables and Student *t* test for continuous variables.

Multivariable logistic regression models were used to compare in-hospital mortality and in-hospital complications among the 3 study groups, using the no CKD group as the reference. Regression models were constructed using generalized estimating equations to account for clustering of outcomes within hospitals. To compare average LOS among the study groups, we used multivariable linear regression

TABLE 2 In-Hospital Outcomes in Patients Undergoing TAVR

	Overall (n = 41,025)	No CKD (n = 25,585)	CKD (n = 13,750)	ESRD (n = 1,690)
In-hospital mortality				
%	4.2	3.8	4.5	8.3
Unadjusted OR (95% CI)	—	Ref.	1.21 (1.09–1.34)	2.29 (1.91–2.76)
Adjusted OR (95% CI)*	—	Ref.	1.39 (1.24–1.55)	2.58 (2.09–3.13)
Major adverse cardiovascular events				
%	8.7	8.3	9.0	11.8
Unadjusted OR (95% CI)	—	Ref.	1.09 (1.01–1.17)	1.48 (1.27–1.72)
Adjusted OR (95% CI)*	—	Ref.	1.22 (1.12–1.32)	1.56 (1.32–1.84)
Net adverse cardiovascular events				
%	24.4	22.9	25.9	34.0
Unadjusted OR (95% CI)	—	Ref.	1.18 (1.12–1.23)	1.74 (1.56–1.93)
Adjusted OR (95% CI)*	—	Ref.	1.23 (1.16–1.29)	1.96 (1.74–2.20)
Acute myocardial infarction				
%	2.7	2.5	2.9	3.6
Unadjusted OR (95% CI)	—	Ref.	1.15 (1.02–1.31)	1.44 (1.10–1.88)
Adjusted OR (95% CI)*	—	Ref.	1.19 (1.03–1.36)	1.26 (0.93–1.69)
Stroke				
%	2.6	2.8	2.3	2.1
Unadjusted OR (95% CI)	—	Ref.	0.80 (0.70–0.92)	0.73 (0.52–1.02)
Adjusted OR (95% CI)*	—	Ref.	0.96 (0.83–1.11)	0.86 (0.59–1.23)
Major bleeding				
%	14.7	13.1	16.8	21.6
Unadjusted OR (95% CI)	—	Ref.	1.34 (1.26–1.42)	1.83 (1.62–2.07)
Adjusted OR (95% CI)*	—	Ref.	1.35 (1.27–1.44)	2.13 (1.85–2.44)
Vascular complications				
%	5.5	5.4	5.4	7.1
Unadjusted OR (95% CI)	—	Ref.	0.99 (0.91–1.09)	1.34 (1.10–1.62)
Adjusted OR (95% CI)*	—	Ref.	1.01 (0.91–1.11)	1.38 (1.12–1.70)
Requirement for PPM†				
%	12.0	11.2	13.2	15.2
Unadjusted OR (95% CI)	—	Ref.	1.21 (1.13–1.30)	1.42 (1.23–1.65)
Adjusted OR* (95% CI)	—	Ref.	1.15 (1.07–1.24)	1.53 (1.31–1.79)

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models, using log-transformed LOS as the dependent variable. Variables entered into the regression models were demographics (age, sex, race, primary expected payer, median household income for patient's ZIP code), all comorbidities listed in Table 1, hospital characteristics, and use of transapical TAVR. Data were complete on all covariates except race (7.0% missing), median household income (1.7% missing), and primary expected payer (0.1% missing). Missing values were replaced with the dominant category for primary expected payer and median household income, whereas missing values for race were treated as a separate category in the regression models. This approach has been used in prior studies (16,21). The incidence of AKI and AKI requiring dialysis in patients with CKD versus no CKD and the association of AKI and AKI requiring dialysis with in-hospital mortality was examined using similar multivariable models.

Temporal trends in proportion of patients with no CKD, CKD, and ESRD undergoing TAVR was examined using the Cochran-Armitage test. To determine if in-hospital mortality in the 3 study groups changed over the study period, we constructed regression models with calendar year as a categorical variable, using 2012 as the reference. Temporal trends in AKI and AKI requiring dialysis in the no CKD and CKD groups were examined similarly. All the aforementioned variables were included in these regression models.

Last, we constructed a stepwise logistic regression model to identify independent predictors of in-hospital mortality in ESRD patients undergoing TAVR. All the clinically relevant patient-level variables were entered into the model (i.e., age, sex, all comorbidities, and use of transapical TAVR).

Statistical analysis was performed using SPSS Statistics 21.0 (IBM Corporation, Armonk, New York). All p values were 2-sided with a significance threshold of <0.05. Categorical variables were expressed as percentage and continuous variables as mean ± SD or median (interquartile range) as appropriate. Odds ratios (ORs) and 95% confidence intervals (CIs) were used to report the results of regression models.

RESULTS

BASELINE CHARACTERISTICS. Of 41,025 patients undergoing TAVR from 2012 to 2014, 25,585 (62.4%) had no CKD, 13,750 (33.5%) had CKD, and 1,690 (4.1%) had ESRD. Compared with patients with no CKD (mean 80.9 ± 8.8 years of age), patients with CKD (mean 82.3 ± 7.2 years of age) were older, whereas those with ESRD were younger (mean 75.3 ± 9.9 years of age). Compared with patients with no CKD, those with CKD or ESRD were less likely to be women or white and more likely to be African American or Hispanic. The prevalence of smoking, dementia, and cancer was highest in patients with no CKD; the prevalence of dyslipidemia, known coronary artery disease, prior MI, prior PCI, prior coronary artery bypass grafting, atrial

fibrillation, heart failure, obesity, prior implantable cardioverter-defibrillator, chronic pulmonary diseases, or hypothyroidism was highest in patients with CKD; and diabetes mellitus, hypertension, peripheral vascular disease, anemia, coagulopathy, liver disease, and fluid or electrolyte disorders were most prevalent in patients with ESRD. Compared with patients with no CKD, those with CKD or ESRD were less likely to have private insurance and more likely have median household income in the lowest quartile ($p < 0.05$ for all).

The use of transapical TAVR was lower in patients with CKD (18.2%; $p < 0.001$) and similar in patients with ESRD (21.3%; $p = 0.66$) compared with patients with no CKD (20.9%). PCI during the TAVR hospitalization and use of mechanical circulatory support devices were most common in ESRD patients (Table 1).

IN-HOSPITAL OUTCOMES. Compared with patients with no CKD, in-hospital mortality was significantly higher in patients with CKD or ESRD (3.8% vs. 4.5% vs. 8.3%; $p < 0.001$). Even after multivariable risk adjustment for differences in baseline characteristics, patients with CKD or ESRD had higher in-hospital mortality compared with those in the no CKD group (adjusted OR: 1.39 [95% CI: 1.24 to 1.55] for CKD and 2.58 [95% CI: 2.09 to 3.13] for ESRD) (Table 2). Also, patients with ESRD had 2-fold higher adjusted odds of in-hospital mortality compared with CKD patients (adjusted OR: 2.15 [95% CI: 1.74 to 2.65]).

When stratified by TAVR access site, both patients with CKD or with ESRD had higher risk-adjusted in-hospital mortality than those in the no CKD group among those undergoing endovascular TAVR. However, among patients undergoing transapical TAVR, only ESRD patients had higher risk-adjusted in-hospital mortality compared with patients with no CKD (Online Table 2).

Patients with CKD or ESRD had a higher incidence of MACE (8.3% vs. 9.0% vs. 11.8% [no CKD vs. CKD vs. ESRD]; $p < 0.001$) and NACE (22.9% vs. 25.9% vs. 34.0%; $p < 0.001$) compared with those with no CKD. Compared with the no CKD group, the crude incidence of acute MI was higher both in patients with CKD or ESRD (2.5% vs. 2.9% vs. 3.6%; $p < 0.001$); however, after multivariable risk adjustment, this difference was significant only for the CKD group. There was no difference in risk-adjusted incidence of stroke in patients with CKD or ESRD compared with those with no CKD.

Compared with patients with no CKD, major bleeding complications were much more frequent in patients with CKD or ESRD (13.1% vs. 16.8% vs. 21.6%; $p < 0.001$). Vascular complications were more common in ESRD patients. New requirement for PPM was more common both in patients with CKD or ESRD compared with those with no CKD. Conversion to SAVR was almost 3-fold more common in patients with ESRD compared with those with no CKD. Average LOS was longer both in patients with CKD or ESRD (Table 2).

Among patients surviving to discharge, patients with CKD or ESRD were less likely to be discharged home and more likely to be discharged to a skilled nursing facility (Online Figure 1).

TABLE 2 Continued

	Overall (n = 41,025)	No CKD (n = 25,585)	CKD (n = 13,750)	ESRD (n = 1,690)
Conversion to SAVR				
%	0.4	0.3	0.4	0.9
Unadjusted OR (95% CI)	–	Ref.	1.28 (0.91–1.81)	2.86 (1.64–4.97)
Adjusted OR* (95% CI)	–	Ref.	1.31 (0.89–1.94)	2.56 (1.41–4.65)
Length of stay‡				
Mean ± SD, days	8.0 ± 7.3	7.4 ± 6.6	8.6 ± 7.6	12.4 ± 11.5
Median (IQR), days	6 (4–9)	6 (4–8)	6 (4–10)	8 (5–16)
Unadjusted parameter estimate (95% CI)	–	Ref.	1.06 (1.05–1.06)	1.18 (1.16–1.19)
Adjusted parameter estimate (95% CI)*	–	Ref.	1.05 (1.05–1.06)	1.13 (1.11–1.15)

*Adjusted for demographics (age, sex, race), hospital characteristics (region, bed size, teaching status), all comorbidities listed in Table 1, and use of transapical approach. †Patients with prior PPM or ICD (n = 5,475) were excluded for this analysis. ‡Unadjusted and adjusted parameter estimates reported for length of stay represent the antilog of the β coefficients [exp(β)] obtained from the log-transformed linear regression models.

CI = confidence interval; IQR = interquartile range; OR = odds ratio; SAVR = surgical aortic valve replacement; other abbreviations as in Table 1.

TABLE 3 Incidence of AKI and AKI Requiring Dialysis in Patients Undergoing TAVR

	Overall	No CKD	CKD
AKI			
%	18.8	10.6	34.1
Unadjusted OR (95% CI)	–	Ref.	4.34 (4.12–4.58)
Adjusted OR (95% CI)*	–	Ref.	4.70 (4.42–5.00)
AKI requiring dialysis			
%	1.2	0.6	2.4
Unadjusted OR (95% CI)	–	Ref.	3.91 (3.23–4.73)
Adjusted OR (95% CI)*	–	Ref.	3.55 (2.88–4.38)

Patients with ESRD were excluded for this analysis. *Adjusted for demographics (age, sex, race), hospital characteristics (region, bed size, teaching status), all comorbidities listed in Table 1, and use of transapical approach.

AKI = acute kidney injury; other abbreviations as in Tables 1 and 2.

TABLE 4 Association of AKI and AKI Requiring Dialysis With In-Hospital Mortality in Patients Undergoing TAVR

No CKD		
	No AKI	AKI
In-hospital mortality, %	2.2	17.3
Unadjusted OR (95% CI)	Ref.	9.34 (8.18-10.67)
Adjusted OR (95% CI)*	Ref.	7.40 (6.36-8.60)
	No AKI requiring dialysis	AKI requiring dialysis
In-hospital mortality, %	3.5	56.3
Unadjusted OR (95% CI)	Ref.	35.86 (26.05-49.36)
Adjusted OR (95% CI)*	Ref.	15.01 (9.99-22.57)
CKD		
	No AKI	AKI
In-hospital mortality, %	2.3	9.0
Unadjusted OR (95% CI)	Ref.	4.26 (3.59-5.05)
Adjusted OR (95% CI)*	Ref.	3.61 (2.99-4.35)
	No AKI requiring dialysis	AKI requiring dialysis
In-hospital mortality, %	3.9	28.8
Unadjusted OR (95% CI)	Ref.	9.83 (7.63-12.67)
Adjusted OR (95% CI)*	Ref.	7.23 (5.44-9.62)

*Adjusted for demographics (age, sex, race), hospital characteristics (region, bed size, teaching status), all comorbidities listed in Table 1, and use of transapical approach.

Abbreviations as in Tables 1–3.

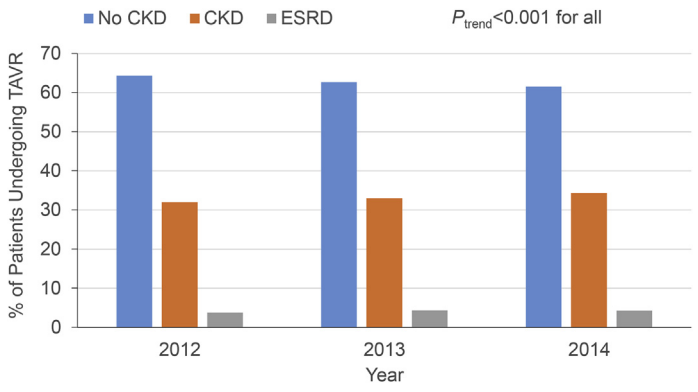
AKI AND AKI REQUIRING DIALYSIS. The incidence of AKI (34.1% vs. 10.6%; $p < 0.001$) and AKI requiring dialysis (2.4% vs. 0.6%; $p < 0.001$) was significantly higher in patients with CKD vs. those with no CKD (Table 3). Importantly, AKI and AKI requiring dialysis were associated with higher risk-adjusted in-hospital mortality both in patients with no CKD and CKD. However, the odds of excess in-hospital mortality associated with AKI and AKI requiring dialysis were substantially higher in patients with no CKD than in CKD patients. Specifically, AKI was associated with almost 7-fold higher (17.3% vs. 2.2%; $p < 0.001$) and AKI requiring dialysis with 15-fold higher (56.3% vs. 3.5%; $p < 0.001$) risk-adjusted in-hospital mortality in patients with no CKD; whereas in patients with CKD, AKI was associated with almost 4-fold higher (9.0% vs. 2.3%; $p < 0.001$) and AKI requiring dialysis with 7-fold higher (28.8% vs. 3.9%; $p < 0.001$) risk-adjusted in-hospital mortality (Table 4).

TRENDS. Of the total number of patients undergoing TAVR, the proportion of those with CKD or ESRD increased from 2012 to 2014 ($p_{trend} < 0.001$) (Figure 1). Compared with 2012, crude in-hospital mortality decreased during the study period in all the 3 study groups (Figure 2). However, risk-adjusted in-hospital mortality of patients in the no CKD group was similar in 2013 and 2014 compared with 2012. On the contrary, risk-adjusted in-hospital mortality of patients with CKD was significantly lower in 2013 and 2014 compared with 2012. Among patients with ESRD, risk-adjusted in-hospital mortality was lower in 2014 compared with 2012 (Table 5).

The risk-adjusted incidence of AKI was higher in 2013 and 2014 compared with 2012 in patients with no CKD, whereas it was higher in 2013 and similar in 2014 in CKD patients. The incidence of AKI requiring dialysis remained unchanged during the study period both in patients with no CKD and CKD (Table 6).

PREDICTORS OF IN-HOSPITAL MORTALITY IN ESRD PATIENTS. In stepwise logistic regression analysis, age (adjusted OR: 1.04 [95% CI: 1.02 to 1.06], dyslipidemia (adjusted OR: 0.59 [95% CI: 0.41 to 0.85]), prior PCI (adjusted OR: 0.35 [95% CI: 0.18 to 0.67]), coagulopathy (adjusted OR: 3.14 [95% CI: 2.19 to 4.50]), and use of transapical TAVR (adjusted OR: 1.94 [95% CI: 1.31 to 2.87]) were identified as independent predictors of in-hospital mortality in ESRD patients undergoing TAVR.

FIGURE 1 Temporal Trends in Proportion of Patients With No CKD, CKD, or ESRD Undergoing TAVR



CKD = chronic kidney disease; ESRD = end-stage renal disease; TAVR = transcatheter aortic valve replacement.

DISCUSSION

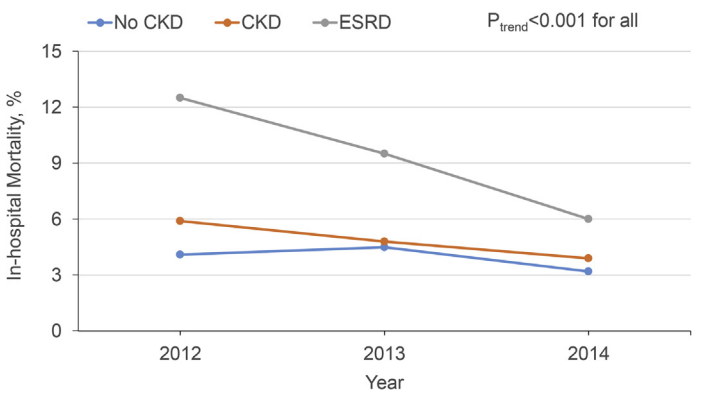
In this nationwide study of ~41,000 patients undergoing TAVR in the United States from 2012 to 2014, we report the following findings. First, there was a temporal increase in the proportion of patients with CKD or ESRD undergoing TAVR. Second, patients with CKD or ESRD had higher in-hospital mortality than those with no CKD, with the odds of higher in-hospital mortality compared with patients with no CKD being substantially higher for ESRD patients. Importantly, the rate of adjusted in-hospital mortality in patients with

CKD and ESRD decreased over the study period. Third, the incidence of in-hospital MACE, NACE, PPM, and major bleeding was significantly higher in patients with CKD or ESRD compared with those with no CKD. Last, AKI and AKI requiring dialysis were associated with higher adjusted in-hospital mortality both in patients with no CKD or CKD. However, whereas the incidence of AKI increased slightly during the study period, that of AKI requiring dialysis remained unchanged.

With the growing indications and increase in the number of TAVR procedures and the intent to extend TAVR to even lower-risk patients, it is important to identify clinical risk factors independently associated with outcomes. Presence of renal dysfunction is one such variable; however, its association with in-hospital outcomes in TAVR patients has been controversial. Among the high-risk and inoperable PARTNER trial patients, Thourani et al. (10) reported significantly increased mortality and rehospitalization at 1-year in those with GFR <30 ml/min/1.73 m^2 compared with those with a normal GFR, with no difference in the rates of MI or major bleeding; however, there were only 9 patients with ESRD. Another study evaluating 2,929 consecutive patients undergoing TAVR in the FRANCE-2 (FRench Aortic National CoreValve and Edwards) registry reported similar findings in patients with CKD or ESRD (n = 96) at 30 days and 1-year. There were no significant differences in the Valve Academic Research Consortium defined complications such as MI, stroke or bleeding (12). In the UK-TAVI (UK Transcatheter Aortic Valve Implantation) registry of 3,980 patients undergoing TAVR from 2007 to 2012, every 10-ml/min/1.73 m^2 decrease in GFR was associated with an 8% increase in in-hospital mortality (13). Highest mortality was noted in patients with CKD stage 4 or with ESRD. In one of the larger studies of 5,000 Medicare patients who underwent TAVR in the United States from 2011 to 2012, 30-day mortality was 2-fold higher in patients (n = 224) on dialysis compared with those not on dialysis (22). Multiple other studies have reported similar findings; however, the majority of them included <100 patients with ESRD. Our study includes the largest cohort of patients with CKD or ESRD undergoing TAVR. Our results are similar to previous studies showing significantly higher in-hospital mortality in patients with CKD or ESRD compared with those without CKD (23). However, we also noted a higher incidence of MACE, NACE, major bleeding, and new requirement for PPM in this group, reflecting a very high-risk subgroup of patients undergoing TAVR. The difference from previous studies with respect to a statistically significant increase in the incidence of in-hospital complications in patients with CKD or ESRD is probably due to the larger sample size of our study or because patients identified as having CKD using ICD-9-CM codes may just reflect a higher risk subgroup. Furthermore, we also found that average LOS was longer and discharge to a skilled nursing facility more common in patients with CKD or ESRD.

We found that in-hospital mortality after TAVR in patients with ESRD was significantly higher compared with patients with CKD or those with no CKD after adjusting for clinical risk factors and other confounders. We found similar results in subgroup analysis in patients undergoing endovascular or transapical TAVR. Moreover, transapical TAVR was

FIGURE 2 Temporal Trends in Unadjusted In-Hospital Mortality in Patients With No CKD, CKD, or ESRD Undergoing TAVR



Abbreviations as in Figure 1.

TABLE 5 Trends in In-Hospital Mortality of Patients Undergoing TAVR

	2012	2013	2014
No CKD			
In-hospital mortality, %	4.1	4.5	3.2
Unadjusted OR (95% CI)	Ref.	1.11 (0.93–1.32)	0.78 (0.66–0.93)
Adjusted OR (95% CI)*	Ref.	1.00 (0.83–1.21)	0.84 (0.70–1.01)
CKD			
In-hospital mortality, %	5.9	4.8	3.9
Unadjusted OR (95% CI)	Ref.	0.80 (0.65–0.99)	0.64 (0.52–0.79)
Adjusted OR (95% CI)*	Ref.	0.74 (0.59–0.92)	0.68 (0.55–0.84)
ESRD			
In-hospital mortality, %	12.5	9.5	6.0
Unadjusted OR (95% CI)	Ref.	0.73 (0.47–1.15)	0.45 (0.29–0.71)
Adjusted OR (95% CI)*	Ref.	0.79 (0.46–1.33)	0.63 (0.40–0.99)

*Adjusted for demographics (age, sex, race), hospital characteristics (region, bed size, teaching status), all comorbidities listed in Table 1, and use of transapical approach.

Abbreviations as in Tables 1 and 2.

TABLE 6 Trends in Incidence of AKI and AKI Requiring Dialysis in Patients Undergoing TAVR

	2012	2013	2014
No CKD			
AKI			
%	9.4	11.8	10.3
Unadjusted OR (95% CI)	Ref.	1.28 (1.14–1.44)	1.10 (0.98–1.23)
Adjusted OR (95% CI)*	Ref.	1.20 (1.06–1.36)	1.14 (1.01–1.28)
AKI requiring dialysis			
%	0.6	0.6	0.6
Unadjusted OR (95% CI)	Ref.	1.07 (0.68–1.67)	1.01 (0.66–1.55)
Adjusted OR (95% CI)*	Ref.	1.15 (0.69–1.89)	1.00 (0.61–1.63)
CKD			
AKI			
%	33.1	37.5	32.2
Unadjusted OR (95% CI)	Ref.	1.21 (1.09–1.35)	0.96 (0.87–1.06)
Adjusted OR (95% CI)*	Ref.	1.20 (1.07–1.35)	1.02 (0.91–1.13)
AKI requiring dialysis			
%	2.2	2.6	2.3
Unadjusted OR (95% CI)	Ref.	1.15 (0.83–1.59)	1.05 (0.77–1.42)
Adjusted OR (95% CI)*	Ref.	1.23 (0.87–1.76)	1.34 (0.96–1.87)

*Adjusted for demographics (age, sex, race), hospital characteristics (region, bed size, teaching status), all comorbidities listed in Table 1, and use of transapical approach.

Abbreviations as in Tables 1 and 2.

found to be an independent predictor of in-hospital mortality in ESRD patients. A recent analysis of 96 ESRD patients enrolled in the U.S. CoreValve Expanded Use Study reported an extremely high mean Society of Thoracic Surgeons score of 16 and 30% mortality at 1 year, with the majority of deaths attributable due to noncardiovascular causes. Notably, valve performance and hemodynamics were stable in patients who survived up to 1 year (24). A subanalysis from the STS/TVT (Society of Thoracic Surgeons/Transcatheter Valve Therapy) registry also showed a significantly higher 1-year mortality in patients with ESRD compared with those with a creatinine of <2 mg/dl (25). These findings underscore ESRD as an independent risk factor for in-hospital mortality after TAVR. Increased morbidity and mortality related to the procedure is most likely secondary to extensive calcification in the vasculature, aorta, and aortic annulus predisposing to bleeding and vascular complications and paravalvular leak. Accordingly, we also noted a significantly higher conversion rate of TAVR to SAVR in patients with ESRD.

Risk-adjusted in-hospital mortality in patients with CKD or ESRD decreased during the study period, reflecting improvements in valve design, implantation technique, more operator experience, and likely better risk stratification. This in contrast to patients with no CKD, in whom the decreasing trend in in-hospital mortality was not statistically significant after multivariable risk adjustment.

The incidence of AKI was significantly higher in patients with CKD with 34% of the patients experiencing AKI versus 10.6% of the patients without CKD. AKI requiring dialysis was noted in 2.4% of the patients with CKD and 0.6% of patients with no CKD. In-hospital mortality rates in patients experiencing AKI requiring dialysis were 56.3% and 28.8% for the no CKD and CKD groups, respectively, substantially higher than those in patients who were on chronic dialysis before TAVR (8.3%). The worrisome trends of a slight increase in incidence of AKI and no change in the incidence of AKI requiring dialysis over the 3-year study period are concerning. Urgent efforts are required to accurately identify the risk factors of AKI in patients undergoing TAVR. Moreover, application of various methods such as judicious contrast use, avoiding hypotension, and avoiding long rapid pacing runs to minimize the incidence of AKI are imperative.

STUDY LIMITATIONS. Patients with CKD or ESRD were identified using ICD-9-CM codes. The ICD-9-CM diagnosis for CKD, although highly specific, has a sensitivity of ~80% (17). Therefore, it is likely that patients with milder degrees of CKD were classified as not having CKD and is the probable reason behind the proportion of patients with CKD in our study being lower than other contemporary TAVR cohorts (10,13,25). Similarly, whereas the administrative diagnosis of AKI requiring dialysis is both highly sensitive and specific, that of AKI, although highly specific, has a modest sensitivity of ~35%. However, Waikar et al. (20) reported significant variations in the sensitivity of ICD-9-CM diagnosis of AKI, with the sensitivity being higher in patients ≥75 years of age, which comprised ~80% of our TAVR cohort. Therefore, the incidence of AKI in our study (18.8%) was similar to that reported by previous studies (ranging from 15% to 55%) (26,27). Because we did not have detailed clinical and laboratory data on body mass index and serum creatinine to calculate GFR, outcomes could not be stratified according to CKD stages. Comorbidities were extracted based on ICD-9-CM codes, and therefore severity of comorbidities could not be accounted for. Information on Society of Thoracic Surgeons scores and key prognostic data such as left ventricular ejection fraction were not available. Data on TAVR valve type and size, procedural success, and post-procedural hemodynamics were not available. The NIS in an inpatient database, and therefore data on long-term mortality were lacking. Last, given the retrospective design, the possibility of residual

measured or unmeasured confounding cannot be eliminated.

CONCLUSIONS

In this analysis of a nationally representative, unselected cohort of ~41,000 patients undergoing TAVR in the United States, we found that patients with CKD or ESRD had higher in-hospital mortality and a higher incidence of in-hospital complications compared with those without CKD. The proportion of patients with CKD or ESRD undergoing TAVR increased during the study period. Parallel with this trend, we observed favorable temporal trends in risk-adjusted in-hospital mortality both in patients with CKD or with ESRD. AKI, especially with new requirement for dialysis, was associated with alarmingly high in-hospital mortality, particularly in those without pre-existing CKD. Moreover, we observed that the incidence of AKI increased slightly, whereas that of AKI requiring dialysis remaining unchanged during the study period. Future studies should focus on identifying methods for optimally risk stratifying patients with ESRD undergoing evaluation for TAVR. Also, concerted efforts are required to define strategies to reduce the risk of AKI in patients undergoing TAVR.

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PERSPECTIVES

WHAT IS KNOWN? Patients with CKD or ESRD have worse outcomes after SAVR. Previous studies on outcomes of patients with chronic renal insufficiency undergoing TAVR were limited by under-representation of the ESRD population.

WHAT IS NEW? Patients with CKD or ESRD have higher in-hospital mortality and higher incidence of in-hospital complications after TAVR. Adjusted in-hospital mortality both in patients with CKD or with ESRD has decreased over the years. Although AKI, especially with new requirement for dialysis, is associated with several-fold higher in-hospital mortality in patients undergoing TAVR, its incidence has not declined.

WHAT IS NEXT? Future studies are needed to risk stratify patients with ESRD undergoing TAVR evaluation optimally and also to define strategies to minimize risk of AKI in patients undergoing TAVR.

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KEY WORDS acute kidney injury, chronic kidney disease, end-stage renal disease, in-hospital mortality, major adverse cardiovascular event(s), transcatheter aortic valve replacement

APPENDIX For supplemental tables and a figure, please see the online version of this article.