

Short-Term Outcomes of Transcatheter Aortic Valve Implantation Versus Surgical Aortic Valve Replacement in Kidney Transplant Recipients (from the US Nationwide Representative Study)



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Kidney transplant recipients (KTRs) are considered high-risk patients for surgical interventions. Transcatheter aortic valve implantation (TAVI) has been introduced as an alternative to surgical aortic valve replacement (SAVR) in patients with aortic stenosis (AS) at high operative risk. However, the outcomes of TAVI compared with SAVR KTRs have not been well-studied in nationally representative data. Patients with prior history of functioning kidney transplant who were hospitalized for TAVI and SAVR between January 2012 and December 2017 were identified retrospectively in the Nationwide Readmissions Database. Our study included 762 TAVI and 1,278 SAVR KTRs. Compared with SAVR, TAVI patients generally had higher rates of co-morbidities with lower risk of in-hospital mortality (3.1% vs 6.3, $p = 0.002$), blood transfusion (11.5% vs 38.6%, $p < 0.001$), acute myocardial infarction (3.9% vs 6.5%, $p = 0.16$), acute kidney injury (24.5% vs 42.1%, $p < 0.001$), sepsis (3.9% vs 9.5%, $p < 0.001$) and discharge with disability (42.6% vs 68.4%, $p < 0.001$). However, the rate of permanent pacemaker implantation was significantly higher in TAVI group (11.4% vs 3.9%, $p < 0.001$). Of note, in-hospital stroke and 30-day readmission were comparable between both groups. These findings were confirmed after adjusting for other co-morbidities. TAVI is growing as a valid and safe alternative for KTRs with severe AS. © 2020 Elsevier Inc. All rights reserved. (Am J Cardiol 2021;144:83–90)

Kidney transplant recipients (KTRs) are classified as high-risk patients for cardiac surgery. According to the United States Renal Data System, 14% of KTRs who undergo valvular heart surgery die before hospital discharge.¹ The worse prognosis of these patients after cardiac surgery may be attributed to comorbid conditions, impaired renal function, and being on immunosuppressive drugs (which is not included in the EuroSCORE assessment).^{1,2} It is clear from the published literature that a well-powered comparison between transcatheter aortic valve implantation (TAVI) and surgical aortic valve replacement (SAVR) in KTRs is lacking and that the outcomes of TAVI in this population are not yet clear. The current analysis was performed to compare the outcomes of TAVI versus SAVR in KTRs, using data from the large Nationwide Readmission Database (NRD).

Methods

We performed a retrospective cohort study following the STROBE checklist and using the NRD database released by the Healthcare Cost and Utilization Project (HCUP) of the Agency for Healthcare Research and Quality (AHRQ).³ The NRD is a nationally representative database of hospital admissions in United States (US) non-federal hospitals. It includes up to 17 million discharges each year in up to 27 states, accounting for about 57% of all hospitalizations in the US and providing discharge weights that can be used to provide national US estimates.⁴ The need for an institutional review board approval was waived for this study because of the anonymized and de-identified nature of the publicly available data in the NRD.

We used weighted estimates of NRD to include patients with a history of a kidney transplant who underwent an AVR (transcatheter or surgical) between January 2012 and December 2017. In order to identify patients within our inclusion criteria, ICD-9 (International Classification of Diseases-9th Edition-Clinical Modification) codes were used before October 2015, whereas ICD-10 codes were used starting from October 2015. Supplementary Table 1 lists ICD codes used for these selections.

We assessed in-hospital outcomes including length of hospital stay (LOS), mortality, stroke, infective endocarditis (IE), permanent pacemaker (PPM) implantation, blood transfusion, acute myocardial infarction (AMI), acute kidney injury (AKI), sepsis, and discharge with disability among patients who underwent TAVI or SAVR. The NRD

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categorizes patient disposition into the following categories: (1) routine discharge, (2) transfer to a short-term hospital, skilled nursing facility, intermediate care facility, or other facilities, (3) home health care, and (4) discharge against medical advice. "Discharged with disability" was defined as any disposition category not reported as routine discharge.⁵ We then followed patients for 30-days after discharge to assess 30-day outcomes, including readmission, stroke, PPM implantation, and mortality. For 30-day outcomes calculation, we excluded patients who died during the index admission and patients who were discharged in December of each year, to allow for at least 30 days of follow-up. When assessing outcomes' predictors, we grouped patients with CKD stages I-II with patients with no CKD for the following reasons: (1) CKD stage I-II are considered clinically normal from a nephrology point of view, (2) the relatively low number of these patients (Table 1), (3) the high chance of underreporting CKD stages I-II in NRD because of being considered normal clinically.

Categorical variables were presented as numbers and percentages and were compared using the Chi-square test. Continuous variables were presented as median (interquartile range [IQR]), or mean (standard deviation [SD]), and were compared using Student's t-test or the Mann-Whitney U test. Categorical variable cells with a number of patients less than 11 were suppressed in compliance with the privacy protection policy of the HCUP Data Use Agreement. Predictors of in-hospital mortality, in-hospital stroke and discharge with disability were examined using multivariable logistic regression models. All variables of patient characteristics were included as covariates in the multivariable analyses. All tests were 2-sided with a significance level of 0.05. All statistical analyses were conducted using IBM SPSS Statistics, version 26 (IBM Corp., Armonk, New York).

Results

Our study included 2,040 KTR patients who underwent an AVR procedure, of which 762 underwent TAVI, and 1,278 underwent SAVR. KTRs represented 0.4% and 0.3% of all TAVI and SAVR patients in the NRD, respectively. TAVI patients were more likely to have CHF, hypertension, liver disease, DM, dyslipidemia, obesity, a history of myocardial infarction, and a history of a stroke and/or TIA, but less likely to have atrial fibrillation and atrial flutter (Table 1). Although the number of SAVR procedures in KTRs remained stable over the study period, the number of TAVI procedures significantly raised from 137 in 2012 to 2014 to 625 in 2015 to 2017 (Figure 1).

Rates of in-hospital mortality, IE, AMI, AKI, sepsis, blood transfusion, and discharge with disability were all higher following SAVR, whereas the rates of PPM implantation were higher following TAVI. The rates of 30-day outcomes did not differ between TAVI and SAVR (Table 1). A subgroup analysis TAVI patients based on the approach (transapical vs endovascular) is presented in supplementary Table 2.

Interestingly, rates of post-TAVI in-hospital stroke decreased from 12.4% during the period 2012 to 2014 to 3.2% during the period 2015 to 2017, while post-SAVR in-

Table 1

Baseline characteristics and outcomes of renal transplant patients (n = 2,040)

Variable	TAVI (n=762)	SAVR (n=1,278)	p value
Age (years) median (IQR)	72 (65-76)	63 (55-69)	<.001
Men	523 (68.6%)	867 (67.8%)	.695
Women	239 (31.4%)	412 (32.2%)	
Chronic kidney disease stage			<.001
None	405 (53.1%)	590 (46.2%)	
I-II	33 (4.3%)	31 (2.4%)	
III	134 (17.6%)	229 (17.9%)	
IV	58 (7.6%)	43 (3.4%)	
V	17 (2.2%)	13 (1%)	
ESRD on dialysis	115 (15.1%)	373 (29.2%)	
Atrial fibrillation	235 (30.8%)	466 (36.4%)	.011
Atrial flutter	28 (3.7%)	106 (8.3%)	<.001
Congestive heart failure	540 (70.9%)	569 (44.5%)	<.001
Hypertension	678 (89%)	1,110 (86.8%)	.165
Liver disease	66 (8.7%)	42 (3.3%)	<.001
Diabetes mellitus	409 (53.7%)	526 (41.1%)	<.001
Carotid artery disease	29 (3.8%)	43 (3.4%)	.621
Dyslipidemia	533 (69.9%)	696 (54.4%)	<.001
Peripheral vascular disease	152 (19.9%)	225 (17.6%)	.195
Aortic atherosclerosis	21 (2.8%)	45 (3.5%)	.368
Obesity	122 (16%)	161 (12.6%)	.034
Smoker	205 (26.9%)	306 (23.9%)	.139
Alcohol abuse	-*	22 (1.7%)	.007
Old myocardial infarction	118 (15.5%)	76 (5.9%)	<.001
History of stroke/TIA	96 (12.6%)	101 (7.9%)	.001
CHA2DS2-VASc score, mean (SD)	4.1 (1.4%)	3 (1.3%)	<.001
Hospital characteristics			
Hospital location and teaching status			<.001
Metropolitan non-teaching	65 (8.8%)	195 (15.9%)	
Metropolitan teaching	667 (90.7%)	1,025 (83.5%)	
Urban	-*	-*	
Hospital bedsize			<.001
Small	12 (1.6%)	70 (5.7%)	
Medium	127 (17.3%)	260 (21.2%)	
large	596 (81.1%)	897 (73.1%)	
In-hospital outcomes			
Length of stay (days)	4 (2-8)	10 (6-17)	<.001
Median (IQR)			
Mortality	24 (3.1%)	81 (6.3%)	.002
Stroke	38 (5%)	53 (4.1%)	.377
Infective endocarditis	-*	102 (8%)	<.001
Permanent pacemaker implantation	87 (11.4%)	50 (3.9%)	<.001
Blood transfusion	88 (11.5%)	493 (38.6%)	<.001
Acute myocardial infarction	30 (3.9%)	83 (6.5%)	.016
Acute kidney injury	187 (24.5%)	538 (42.1%)	<.001
Sepsis	30 (3.9%)	122 (9.5%)	<.001
Discharge with disability [†]	314 (42.6%)	819 (68.4%)	<.001
30-day outcomes [‡]			
30-day readmission	126 (21.8%)	237 (21.8%)	.181
30-day stroke	-*	-*	.757
30-day Permanent pacemaker implantation	-*	-*	.112
30-day in-hospital mortality	-*	19 (1.8%)	.093

* Cells with n≤10 were suppressed with (-).

[†] This analysis excluded patients who died within index hospitalization.

[‡] These analyses excluded patients who died within index hospitalization and those discharged in December each year, to allow for at least 30 days of follow-up.

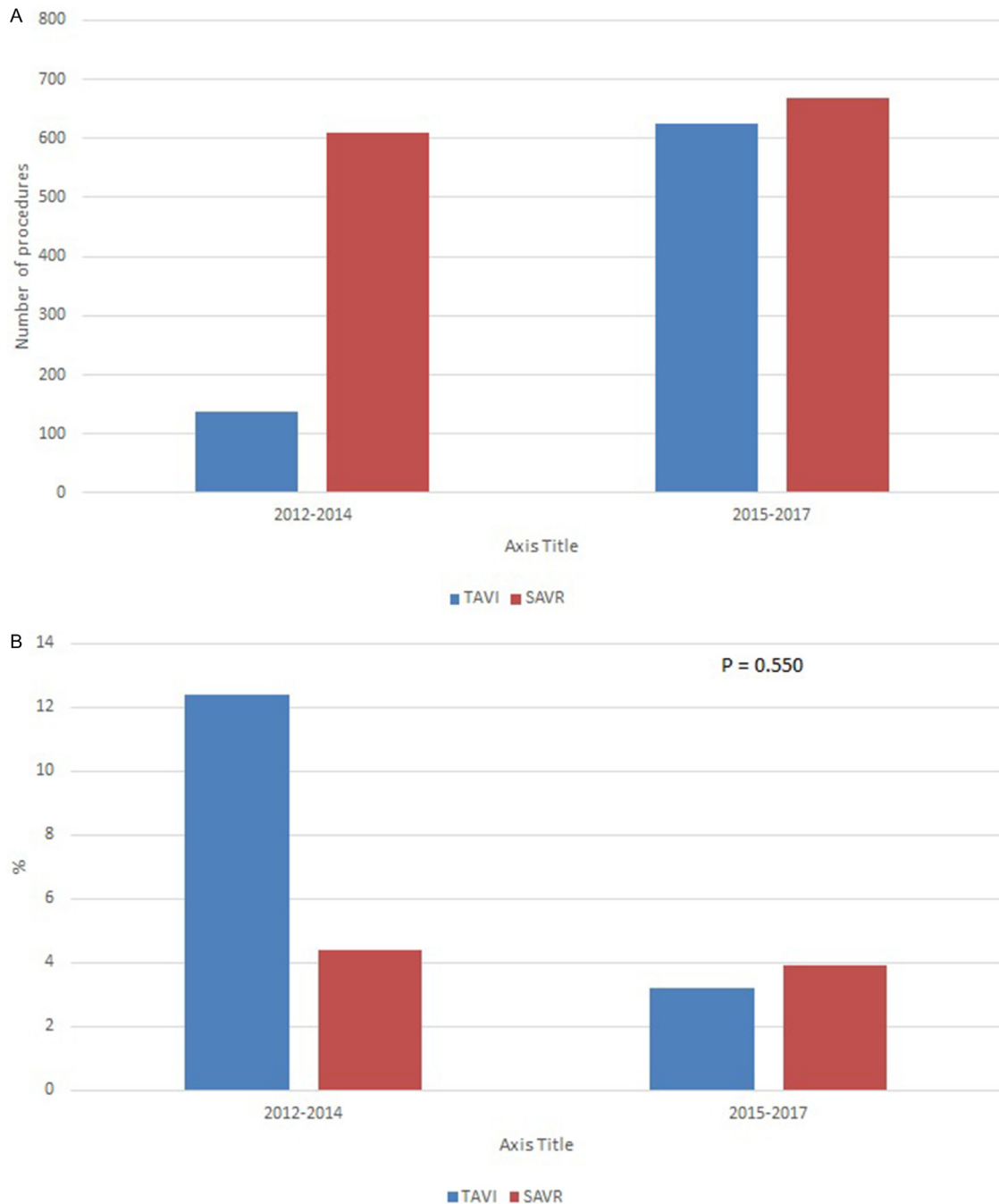


Figure 1. Trends of (A) TAVI and SAVR in kidney transplant patients, (B) stroke, (C) AMI, and (D) in-hospital mortality in kidney transplant patients following TAVI versus SAVR.

hospital stroke decreased from 4.4% during the period 2012 to 2014 to 3.9% during the period 2015 to 2017 (Figure 1). Supplementary Table 3 summarizes the characteristics and outcomes of TAVI patients during both these periods. Table 2

After adjusting for age, gender, chronic kidney disease, and all other co-morbidities, TAVI was associated with a lower risk of the composite outcome (in-hospital stroke and/or mortality) when compared with SAVR (OR = 0.641, 95% CI [0.427 to 0.960], $p = 0.031$) (Supplementary Table

4). Additionally, TAVI was associated with a significantly lower risk of discharge with a disability when compared with SAVR (OR = 0.194, 95% CI [0.151 to 0.249], $p < 0.001$) (Supplementary table 4) (Figure 2).

Discussion

Using contemporary nationwide data, our main findings suggest that TAVI in KTRs is a safe alternative to SAVR with favorable short-term outcomes. To our knowledge,

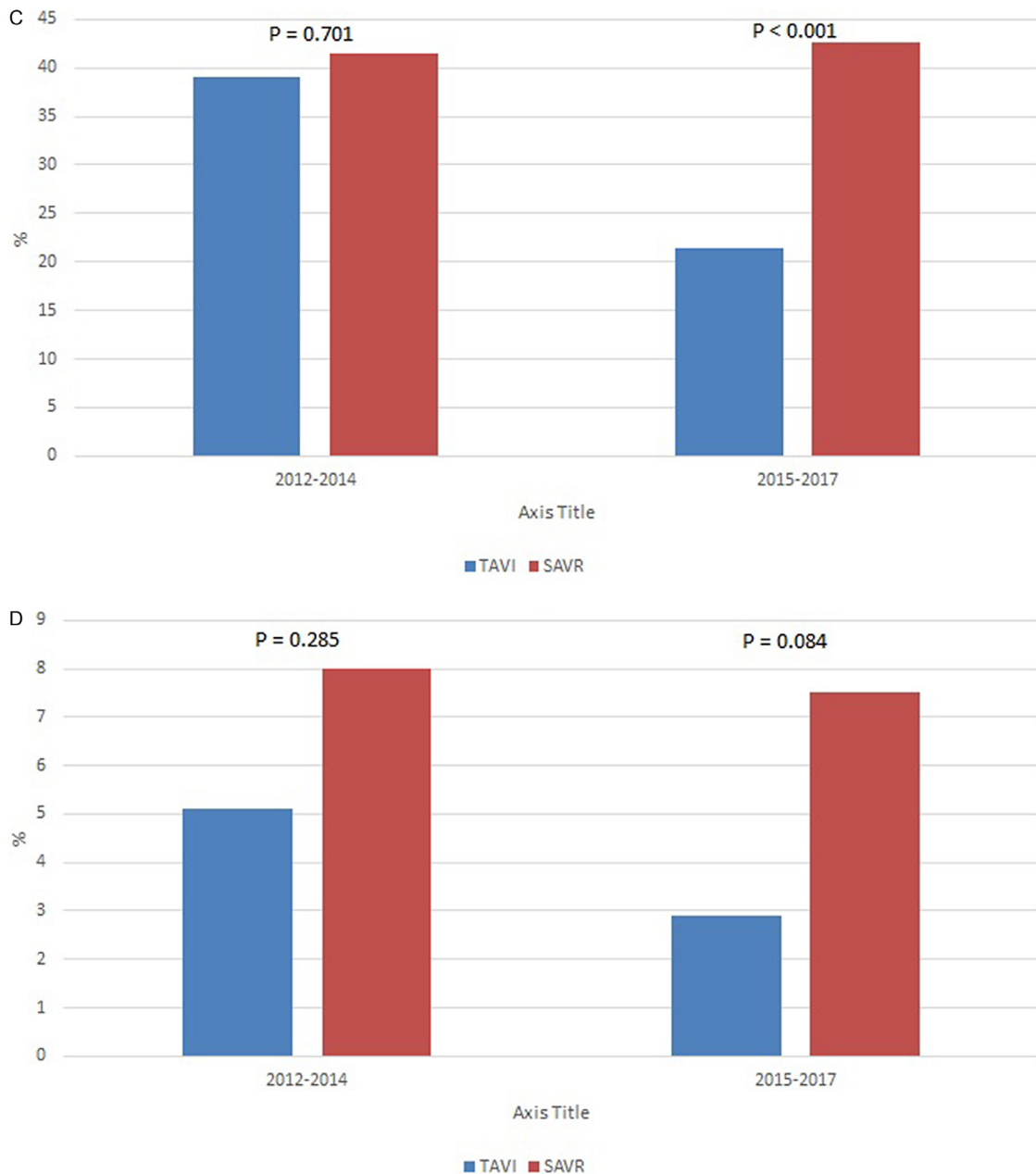


Figure 1. Continued

there have been few published reports focusing on outcomes of aortic valve replacement (AVR) in KTRs.⁶⁻⁹ In respect of both SAVR and TAVI, very limited studies addressed outcomes of SAVR and TAVI in the unique KTRs population.^{6,8,10,11}

In the present study, KTRs who underwent TAVI were older and had higher frequencies of several comorbidities compared with SAVR. Despite that, TAVI was associated with significantly lower rates of in-hospital complications. In terms of in-hospital mortality among KTRs, previous reports recorded rates ranging from 0% to 18.6% following SAVR^{1,11-16} compared with 0% to 4% following TAVI.^{6,10,11} However, the

sample sizes of KTRs studied in these reports was considerably small (Table 3). Similarly, our analysis found a lower in-hospital mortality of 3.1% in TAVI group compared with 6.3% in SAVR group.

Focusing on in-hospital stroke, we found no significant difference between the entire SAVR and TAVI cohort, especially in later years. This may be attributed to increasing operator experience with TAVI besides the introduction of newer devices and additional stroke preventive measures as transcatheter cerebral embolic protection devices. Given the chronic prothrombotic state and the faster progression of aortic valve calcifications in KTRs compared with the general population, additional measures should be directed

Table 2
Studies of surgical and transcatheter valve replacement in kidney transplant recipients

Author, Year	Study period	Total (n) kidney transplant recipients	Type of surgery (isolated AVR, combined CABG/AVR) / Access approach	In-Hospital Mortality (n), %	30-day Mortality in valve replacement group	Overall survival in 5 years among valve replacement group
<i>Surgical Aortic Valve Replacement</i>						
Dresler et al, 1997 ¹⁸	1970- 1994	45	Total (n=14) Isolated AVR (n=13), CABG/AVR (n=3)	(n=2), 14.3%	-	-
Mitruka et al, 1997 ²²	1986-1993	40	Total (n=19); combined (CABG/AVR) (n=3), Isolated AVR (n=16)	(n=1) 5.2%	-	-
Ono and colleagues, 2002 ¹⁷	1988-2001	46	Total (n=11); AVR (n=9), CABG/AVR (n=2)	(n=2), 18.2%	-	67.9%
Deb et al, 2006 ²⁰	1986-2001	34	Total (n=11)	0%	-	82% +- 8%
Musci et al, 2007 ²¹	1988-2006	16	Total (n=11); AVR (n=9), MVR/AVR (n=2)	(n=2), 18.2%	-	81%
Sharma et al, 2010 ¹	1991-2004	1335	Total (n= 1335); AVR (66%), MVR/AVR (9%).	15.0 % in non-tissue AVR, 11.4% in tissue AVR	-	-41.7% in tissue valves -37.2% in non-tissue valves
Fox et al, 2013 ¹⁶	2010-2011	18	Total (n=18); isolated AVR (n=7), combined CABG/AVR (n=11)	(n=1), 9.1%	(n=2), 11.1%	-
Rocha et al, 2014 ¹⁹	1999-2010	92	Total (n=20); Isolated AVR (7), MVR/AVR (1), CABG+ AVR (12)	-	(n=5), 25%	52.8%
<i>Transcatheter Aortic Valve Implantation</i>						
F Fox et al, 2013 ¹⁶	2010-2011	8	Transfemoral access (n=6), 75%	0%	0%	-
Rashid et al, 2017 ¹⁵	2006-2016	8	Transfemoral access (n=8), 100%	0%	0%	-
Witberg et al, 2019 ¹¹	2008-2017	72	Transfemoral access (n=50) 80.6%	(N=3), 4.2%	-	-

AVR = Aortic valve replacement; CABG = Coronary artery bypass graft; MVR = Mitral valve replacement.

towards reducing such risk irrespective of the type of AVR performed.^{17,18}

AKI following AVR is associated with significantly worse patient outcomes in terms of hospital cost, mortality and LOS.¹⁹ Among our TAVI cohort, we reported an AKI incidence of 24.5%, which is lower than the figures reported by Al-Rashid et al (50%)¹⁰ and Witberg et al (19.4%).⁶ The latter study identified the need for initiating long term hemodialysis as an independent predictor of long-term mortality. Despite the 8-fold risk of requiring hemodialysis in KTRs post-TAVI compared with the overall TAVI population and 3-fold risk compared with CKD patients, as shown by Witberg et al,⁶ this risk remains significantly lower when compared with KTRs patients undergoing SAVR as demonstrated by our analysis. This increased risk among SAVR group might be attributed to the cardiopulmonary bypass induced renal ischemia and ischemia-reperfusion factor.²⁰ In addition, our findings of SAVR patients' increased incidence of after-operative blood transfusion compared with TAVI owing to the less-invasive nature of TAVI seem to be contributing to the hypo perfusion-induced renal ischemia and excessive use of vasopressors as discussed by Merchant and colleagues.²¹

Post-operative IE has been associated with poor outcomes in both SAVR and TAVI patients. In a post-hoc analysis of the PARTNER trials, Summers and colleagues reported no difference in terms of after-operative IE between SAVR and TAVI.²² But as we mentioned earlier, the KTRs have been excluded from previous clinical trials. This is the first report showing a lower risk of early IE in KTRs following TAVI compared with SAVR. This can be partly explained by the less-invasive nature of the TAVI, combined with shorter LOS compared with SAVR.

In our study, the requirement of PPM was higher after TAVI compared with SAVR. Indeed, PPM is a common complication post TAVI regardless of pre-existing CKD.²³ In efforts to minimize paravalvular leakage in TAVI, operators try to achieve better sealing of the aortic annulus, which might damage the conduction system. We were unable to identify the type of valves used owing to the nature of the NRD publicly available data. Despite the higher PPM in TAVI, we noted shorter LOS and lower discharge with disability and 30-day readmission rates. Likewise, Fox et al reported showed shorter ICU and hospital stays in favor of TAVI in KTRs.¹¹

Given the fact that kidney transplantation is among the most common solid organ transplants in the 21st century in

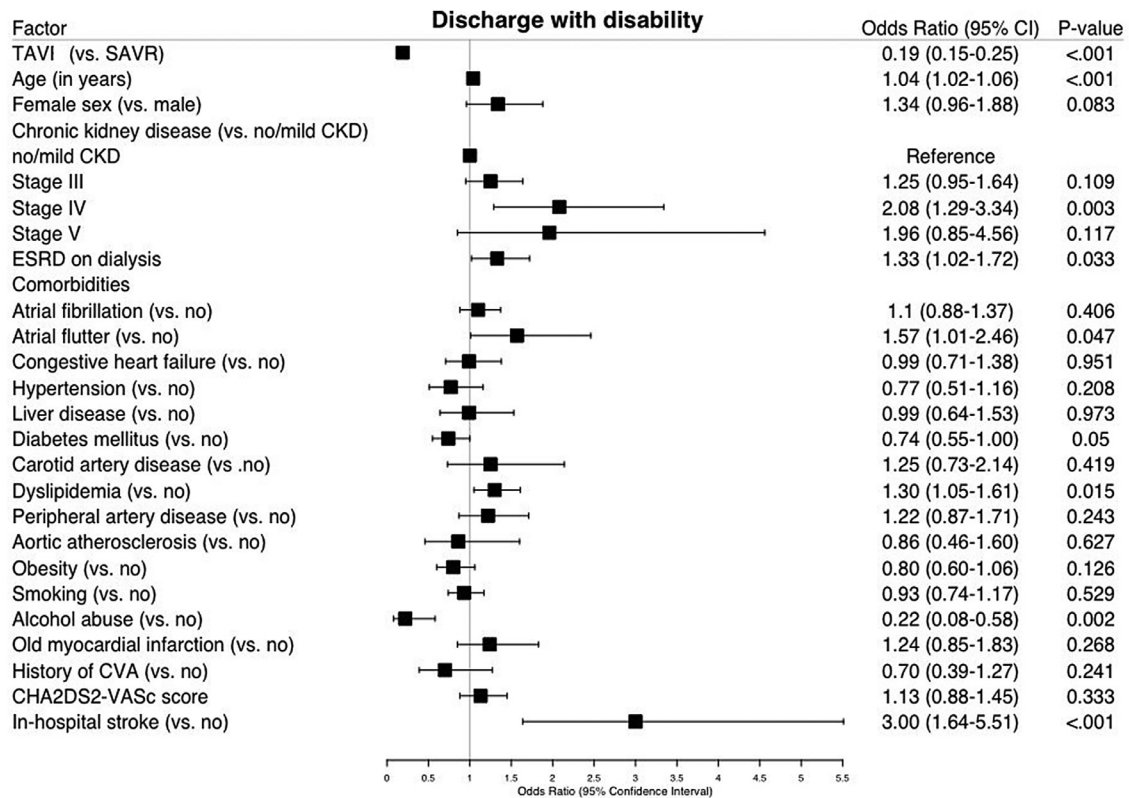


Figure 2. Forest plot showing the predictors of discharge with disability in KTRs undergoing aortic valve replacement.

the United States,²⁴ coinciding with the growing use of TAVI, it is expected that the proportion of KTRs undergoing TAVI will continue to grow. Therefore, additional strategies should be directed towards improving TAVI outcomes in this unique population. Despite the comparable rates of in-hospital stroke among KTRs with both TAVI and SAVR in our study, the risk remains high compared with the general population. The utilization of transcatheter cerebral embolic protection devices might aid in reducing the in-hospital stroke risk. Indeed, the SENTINEL device demonstrated that 99% of the filters had captured embolic material during TAVI.²⁵ Of note, pre-operative planning with the use of non-contrast Magnetic Resonance Imaging or the Zero Contrast or low contrast dose approach has been beneficial in patients with renal insufficiency towards decreasing post-operative AKI risk.²⁶

Our study has several limitations worth noting. First, the retrospective observational design of our study subjects it to the potential bias of coding errors. Second, our study lacks more granular data including detailed echo data, such as the mean gradient and aortic valve area, procedural details, such as the type of valve used in TAVI (self- versus balloon-expandable) and SAVR (bioprosthetic versus mechanical), medications including heart failure therapies and anti-thrombotic drugs, which could affect outcomes like stroke and bleeding. Such unmeasured factors may influence the results of multivariable analyses. Yet, our population-based study derives its strength from a large nationwide cohort that examined outcomes of TAVI versus SAVR, utilizing multiple statistical methods to ensure a

robust analysis with the goal to shed light on the understudied high-risk population of KTRs.

In KTRs with AS, TAVI provides better short-term outcomes compared with SAVR with the exception of PPM. Despite KTRs being a high-risk population for invasive procedures, they are likely to benefit from AVR with additional measures directed towards lowering post-operative AKI and PPM risk. More studies focusing on the mid and long-term outcomes in KTRs are warranted.

Disclosure

The authors declare no conflict of interest.

Ethical Approval

This study was exempted from the institutional review board's approval because it used anonymized and de-identified data in a publicly available database.

Credit Author Statement

Omar M. Abdelfattah and Anas M. Saad: Conceptualization, Data curation, Formal analysis, Methodology, Project administration, Writing – original draft; Abdelrahman Aboshouk, Mohamed Hassanein, and Toshiaki Isogai: Conceptualization, Methodology, Writing - original draft; Mohamed M. Gad and Keerat Rai Ahuja: Visualization, Software, Writing – review & editing; James Yun and Amar Krishnaswamy: Conceptualization, Supervision,

Validation, Writing – review & editing; Samir Kapadia: Conceptualization, Supervision, Validation, Writing - review & editing, Project administration, Resources.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this study.

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Supplementary materials

Supplementary material associated with this article can be found in the online version at <https://doi.org/10.1016/j.amjcard.2020.12.048>.

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