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Dialysis Following Transcatheter Aortic Valve Replacement: Risk Factors and Outcomes

An Analysis From the UK TAVI (Transcatheter Aortic Valve Implantation) Registry

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ABSTRACT

OBJECTIVES This study sought to determine the risk factors for post-transcatheter aortic valve replacement (TAVR) dialysis and to determine the impact of pre-TAVR or post-TAVR dialysis on mortality.

BACKGROUND TAVR is now established as an alternative treatment to surgical aortic valve replacement. Data examining the impact of dialysis on outcomes after TAVR are lacking.

METHODS The UK TAVI (Transcatheter Aortic Valve Implantation) Registry was established to report outcomes on all TAVR procedures performed within the United Kingdom (2007 to 2014). Data were collected prospectively on 6,464 patients with a median follow-up of 625 days.

RESULTS The proportion of patients on dialysis before TAVR has remained constant at 1.8%. After TAVR, the proportion of patients newly needing dialysis after TAVR has fallen from 6.1% (2007 to 2008) to 2.3% (2013 to 2014). The risk of new dialysis requirement after TAVR was independently associated with lower baseline renal function, year of procedure, impaired left ventricular function, diabetes, use of an Edwards valve, a nontransfemoral approach, need for open surgery, and moderate-to-severe aortic regurgitation after the procedure. Requirement for new dialysis after TAVR was associated with higher mortality at 30 days (hazard ratio: 6.44; 95% confidence interval: 4.87 to 8.53) and at 4 years (hazard ratio: 3.54; 95% confidence interval: 2.99 to 4.19; $p < 0.001$ for all) compared with patients without dialysis requirement.

CONCLUSIONS The proportion of patients needing dialysis after TAVR has decreased over time. Post-TAVR dialysis is associated with increased mortality. Factors identified with dialysis requirement after TAVR require further investigation.
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Transcatheter aortic valve replacement (TAVR) is now established as an effective treatment for patients with severe symptomatic aortic stenosis at high risk from a conventional cardiac surgical aortic valve replacement (SAVR). Factors such as advanced age, frailty, or high comorbidity are used routinely to identify patients at high or, in selected cases, intermediate-risk patients who may be better treated by TAVR rather than by SAVR (1). Worldwide, the use of TAVR is accelerating as registry and trial data indicate good medium term outcomes; over 100,000 procedures have now been performed (2).

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The prevalence of pre-procedural renal dysfunction in patients undergoing TAVR is high (50% to 60% with chronic kidney disease [CKD] stage 3 or worse) (3,4) and has been shown to be significantly associated with increased mortality (3,4) and acute kidney injury (AKI) (5) post-TAVR. However, although the reported new need for dialysis after TAVR has been examined in several studies (6–22), most are single center and report data on <300 patients with rates for post-procedure dialysis varying between 0% and 21%. A recent meta-analysis examining the impact of AKI after TAVR analyzed 13 studies and reported a rate of new dialysis of 5.8% (89 of 1,528 patients) (5). A high (9-fold increase) mortality at 1 year associated with the need for dialysis after TAVR was reported in a single study of 270 subjects (16). Data from the German TAVI-registry also suggested new dialysis requirement after TAVR was associated with higher mortality at 30 days but not at 1 year (23). To the best of our knowledge no study has yet compared outcomes of patients requiring dialysis support after TAVR with those already on dialysis before the procedure.

Given the wide variation in the reported rates of dialysis after TAVR and the potentially very high mortality associated with this complication, there is a need for better information based on larger datasets. Such datasets may also provide a better understanding of the risk factors associated with the need for post-procedural dialysis allowing the design of preventative strategies. The objectives of this study were first to define the incidence of dialysis requirement after TAVR in the United Kingdom, second to determine pre-procedural and periprocedural factors associated with the need for dialysis after TAVR, and third to compare outcomes in patients requiring dialysis after TAVR with subjects already established on dialysis and those without any dialysis requirement.

METHODS

DATABASE. The UK TAVI (Transcatheter Aortic Valve Implantation) registry has collected data on all TAVR procedures performed in the United Kingdom since 2007. The registry is managed by the National Institute for Cardiovascular Outcomes Research (NICOR) with clinical direction and strategy provided by the UK TAVI steering group (established in 2008). The UK TAVI registry dataset is collected using the web-based interface from NICOR, as previously described (24). Case ascertainment is performed by comparing the center's reported numbers of total procedures with the number of procedures uploaded to the NICOR. The national dataset between 2007 and 2014 was provided by NICOR: to the investigators. Range checks to look for extreme values and assessments of internal consistency were applied during upload. All data including periprocedural complications and complications up to hospital discharge were self-reported according to the definitions within the national dataset (1). Centers providing records with missing, extreme or inconsistent values were contacted and asked to check and modify records as appropriate. The pre-procedure estimated glomerular filtration rate (eGFR) was calculated using the Chronic Kidney Disease Epidemiology Collaboration formula with serum creatinine recalibrated to be traceable to an isotope-derived mass spectroscopy method (25). Patients not requiring dialysis support before the TAVR procedure were divided into 5 groups of GFR categories based on the widely used clinical classification (26): ≥60 ml/min/1.73 m^2 (eGFR category >60); 45 to 59 ml/min/1.73 m^2 (CKD stage 3a); 30 to 44 ml/min/1.73 m^2 (CKD stage 3b); 15 to 29 ml/min/1.73 m^2 (CKD stage 4); and <15 ml/min/1.73 m^2 (CKD stage 5). Patients were also divided in to 3 groups depending on their dialysis requirements: those patients who required dialysis before the TAVR procedure, those who newly required dialysis support after the TAVR procedure, and those who did not require dialysis support either before or after the TAVR procedure.

MORTALITY TRACKING. A robust independent system for tracking mortality exists in England and Wales (2 of the 4 countries in the United Kingdom covering 89% of the total UK population). The National Health Service Central Register performed case linkage to data held by the Office of National Statistics in May 2015 using each patient's unique National Health Service Number. Validated life

ABBREVIATIONS AND ACRONYMS

AKI = acute kidney injury

CI = confidence interval

CKD = chronic kidney disease

eGFR = estimated glomerular filtration rate

EuroSCORE = European System for Cardiac Operative Risk Evaluation

NICOR = National Institute of Cardiovascular Outcomes Research

OR = odds ratio

SAVR = surgical aortic valve replacement

TAVR = transcatheter aortic valve replacement

TABLE 1 Clinical and Procedural Characteristics of the Study Population According to Dialysis Requirements Before or After TAVR

	No Dialysis	Dialysis Before	Dialysis After	p Value*	p Value†
Number of TAVR procedures	6,145 (95.1)	117 (1.8)	202 (3.1)		
Male	3,258 (53.2)	75 (64.7)	117 (57.9)	0.197	0.284
Age, yrs	83 (77-87)	77 (71-82)	83 (77-87)	0.961	<0.001
Logistic EuroSCORE	17.8 (11.6-27.1)	29.0 (15.2-41.7)	21.0 (14.5-35.8)	<0.001	0.056
GFR, ml/min/1.73 m^2	45.1 (33.7-60.8)	N/A	31.5 (22.1-40.4)	<0.001	N/A
GFR categories/CKD stages					
eGFR >60 ml/min/1.73 m^2	1,545 (25.1)	N/A	13 (6.4)	<0.001	N/A
CKD stage 3	3,451 (56.2)	N/A	91 (45.0)		
CKD stage 4	991 (16.1)	N/A	80 (39.6)		
CKD stage 5	88 (1.4)	117 (100.0)	13 (6.4)		
Missing eGFR	70 (1.1)	N/A	5 (2.5)		
LVEF <30%	545 (8.9)	17 (14.5)	30 (14.9)	0.006	1.000
NYHA functional class III-IV	4,968 (81.2)	96 (82.8)	172 (85.1)	0.338	0.632
PVD	1,420 (23.2)	32 (27.6)	78 (38.6)	<0.001	0.051
Any CAD	2,580 (42.7)	49 (43.4)	105 (52.2)	0.007	0.158
Pre-existing AF	1,547 (25.4)	30 (25.9)	56 (27.7)	0.460	0.793
Previous cardiac surgery	1,931 (31.6)	37 (31.6)	59 (29.2)	0.490	0.704
Diabetes mellitus	1,378 (22.5)	34 (29.1)	70 (34.7)	<0.001	0.324
COPD	1,779 (29.1)	38 (32.5)	68 (33.8)	0.156	0.902
Previous stroke	1,038 (17.0)	28 (23.9)	43 (21.3)	0.128	0.580
Previous MI	1,317 (21.5)	28 (23.9)	57 (28.2)	0.030	0.433
AAC	1,066 (17.4)	28 (23.9)	38 (18.8)	0.199	0.001
Procedural characteristics					
Valve manufacturer					
Edwards	3,421 (56.0)	64 (54.7)	149 (73.8)	<0.001	0.001
Medtronic	2,477 (40.5)	48 (41.0)	51 (25.2)		
Other	216 (3.5)	5 (4.3)	2 (1.0)		
Nontransfemoral approach	1,524 (24.8)	31 (26.5)	99 (49.0)	<0.001	<0.001
General anesthetic	5,260 (85.9)	100 (85.5)	189 (93.6)	0.001	0.027
AR (moderate/severe)	450 (7.5)	9 (7.8)	34 (17.0)	<0.001	0.026
MI before discharge	30 (0.5)	0 (0)	1 (0.5)	0.968	1.000
Stroke before discharge	137 (2.2)	2 (1.7)	12 (5.9)	0.006	0.101
Tamponade	97 (1.6)	2 (1.7)	7 (3.5)	0.049	0.495
Conversion to open surgery	53 (0.9)	0 (0)	10 (5.0)	<0.001	0.016
Major vascular complication	366 (6.0)	4 (3.4)	18 (8.9)	0.098	0.070

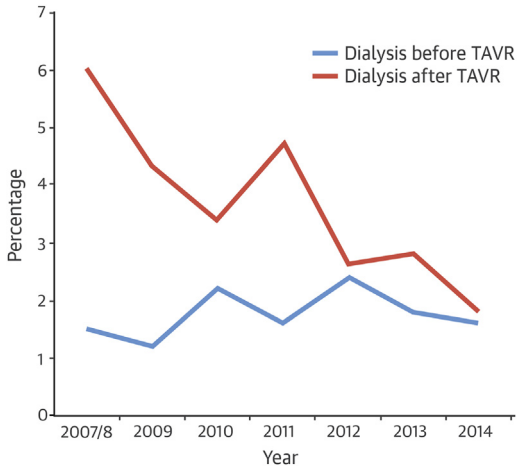
Values are n (%) or median (interquartile range). *Comparison between group requiring dialysis after and group with no dialysis requirement. †Comparison between group requiring dialysis before transcatheter aortic valve replacement (TAVR) and group with new dialysis requirement after TAVR.

AAC = ascending aortic calcification; AF = atrial fibrillation; AR = aortic regurgitation; CAD = coronary artery disease; COPD = chronic obstructive pulmonary disease; CKD = chronic kidney disease; eGFR = estimated glomerular filtration rate; EuroSCORE = European System for Cardiac Operative Risk Evaluation; GFR = glomerular filtration rate; LVEF = left ventricular ejection fraction; MI = myocardial infarction; N/A = nonapplicable; NYHA = New York Heart Association; PVD = peripheral vascular disease.

status was available in 6,464 of 7,364 patients (88%) who underwent a TAVR procedure between January 1, 2007, and December 31, 2014 consistent with proportion of patients from England and Wales. This cohort was used for all the survival analyses. All patients provided written informed consent for the TAVR procedure. NICOR: has support under section 251 of the NHS Act 2006. Under NHS research governance arrangements, formal ethical approval was not required for this study.

STATISTICAL ANALYSIS. Statistical analysis was performed using SPSS statistical software version 23.0 (IBM Corporation, Armonk, New York). Categorical data are presented as percentages and comparisons between groups were performed by the chi-square test or the Fisher exact test. Numerical data are presented as median (interquartile range) and comparisons were performed using the Mann-Whitney *U* test. All the variables used in the analysis had <5% of the values missing and were therefore treated as missing completely at random with casewise deletion. Logistic regression analysis was used to assess the relationship between pre- and perioperative factors and the need for dialysis post-procedure and in-patient mortality with the results expressed as an odds ratio (OR) with 95% confidence interval (CI). Time-to-event data analysis

FIGURE 1 Percentage of Patients on Dialysis Before TAVR and With New Requirement for Dialysis After TAVR (2007 to 2014)



The proportion of patients on dialysis undergoing transcatheter aortic valve replacement (TAVR) has remained constant over the study time period whereas the proportion of patients requiring dialysis for the first time after the procedure has declined.

for cumulative mortality at 30 days and 4 years were performed using the Cox proportional hazards model and the results expressed as a hazard ratio with 95% CI. Multivariable models were adjusted for sex, age, left ventricular ejection fraction <30%, New York Heart Association functional class III to IV, peripheral vascular disease, known coronary artery disease, pre-existing atrial fibrillation, previous cardiac surgery, diabetes mellitus, chronic obstructive pulmonary disease, previous stroke, previous myocardial infarction, ascending aortic calcification, valve manufacturer (Medtronic, Edwards, other) non-transfemoral route, use of general anesthetic, moderate-severe aortic regurgitation, myocardial infarction before discharge, stroke before discharge, cardiac tamponade, conversion to open surgery, and major vascular complication. Kaplan-Meier survival curves were drawn to assess differences between groups for the time-to-event data and estimate mortality rates. Comparisons were made using the log-rank statistic. For all tests, a value of $p < 0.05$ was considered significant.

RESULTS

PATIENT CHARACTERISTICS. Baseline demographic characteristics and risk factors of the study population divided by need for dialysis before or after TAVR are presented in Table 1. Of the 6,464 patients included in the study, 117 (1.8%) were on dialysis before the TAVR procedure with the proportion of patients remaining constant over time ($p = 0.704$) (Figure 1). Over the whole study period, 202 (3.1%) patients required dialysis for the first time after the TAVR procedure. The proportion of patients newly requiring dialysis post-TAVR has been declining over time with ($p < 0.001$) (Figure 1).

FACTORS ASSOCIATED WITH NEW REQUIREMENT FOR DIALYSIS AFTER TAVR PROCEDURE. In a univariable analysis, the logistic European System for Cardiac Operative Risk Evaluation (EuroSCORE) was associated with new requirement for dialysis after TAVR (OR: 1.02; 95% CI: 1.01 to 1.03; $p < 0.001$). The univariable and multivariable individual pre-procedural and periprocedural factors associated with the new need for dialysis are shown in Table 2. In the multivariable analysis the pre-procedural factors were a lower eGFR (as a continuous variable), year of operation, a left ventricular ejection fraction <30% and a diagnosis of diabetes mellitus. Procedural factors associated with a new requirement for dialysis were a nontransfemoral approach, conversion to open surgery, and use of an Edwards valve rather than a Medtronic valve. Having moderate-to-severe aortic regurgitation after the procedure was also associated with an increased risk for new dialysis after TAVR. The year of procedure was inversely associated with the risk of requiring dialysis after TAVR in both univariable and multivariable analyses (Table 2). Excluding cases performed 2007 to 2008 made no appreciable difference to the result. In a model incorporating the year of procedure and the logistic EuroSCORE as a composite measure of patient co-morbidity only, the year of procedure remained inversely associated with the need for dialysis after TAVR (OR: 0.85; 95% CI: 0.79 to 0.91; $p < 0.001$).

Stages of CKD were grouped into moderate-advanced CKD (stages 3b to 5) (OR: 4.27; 95% CI: 2.93 to 6.22; $p < 0.001$) and advanced CKD (stages 4 to 5) (OR: 4.02; 95% CI: 2.97 to 5.43; $p < 0.001$) and entered separately into the model replacing eGFR as a continuous variable. Both were independently associated with the need for dialysis post-TAVR and did not significantly alter the model.

The finding that use of the Edwards valve was associated with a higher risk of requiring dialysis after TAVR was unexpected. Therefore, we explored this relationship further. Patients receiving an Edwards valve were more comorbid with an increased risk profile as evaluated by the logistic EuroSCORE (Online Table 1). The proportion of patients with the

TABLE 2 Significant Logistic Regression Multivariable Associations of Need for Dialysis After Procedure (Patients on Dialysis Before Procedure Excluded From Analysis)

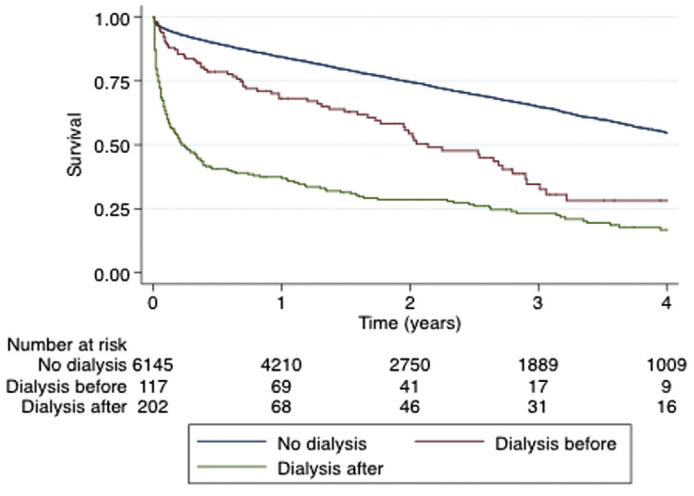
	Odds Ratio (95% CI)	p Value
Pre-procedural characteristics		
eGFR, ml/min/1.73 m^2	0.95 (0.94–0.96)	<0.001
Left ventricular ejection fraction <30%	1.53 (1.01–2.33)	0.048
Diabetes mellitus	1.63 (1.19–2.23)	0.002
Year of procedure	0.89 (0.82–0.96)	0.004
Procedural and post-procedural features		
Valve manufacturer		
Medtronic	1.00	
Edwards	1.92 (1.35–2.72)	<0.001
Other	0.71 (0.17–2.97)	0.637
Nontransfemoral approach	2.46 (1.81–3.34)	<0.001
AR post-procedure (moderate/severe)	3.012 (1.99–4.57)	<0.001
Conversion to open surgery	9.59 (4.39–20.96)	<0.001

Multivariable models adjusted for sex, age, LVEF <30%, NYHA functional status III to IV, PVD, known CAD, pre-existing AF, previous cardiac surgery, diabetes mellitus, COPD, previous stroke, previous myocardial infarction, AAC, valve manufacturer, nontransfemoral route, use of general anesthetic, moderate-severe AR after procedure, MI before discharge, stroke before discharge, cardiac tamponade, conversion to open surgery, and major vascular complication.

CI = confidence interval; other abbreviations as in Table 1.

variables found to be associated with the new need for dialysis after TAVR (Table 2) are presented in Online Table 1. Proportionately many more patients receiving an Edwards valve had a nontransfemoral approach (34.2% vs. 14.9%; p < 0.001) and more required conversion to open surgery (1.3% vs. 0.5%; p = 0.004). However, proportionately fewer patients receiving an Edwards valve had moderate-to-severe aortic regurgitation after the procedure (4.8% vs. 12.5%; p < 0.001). Given that the nontransfemoral approach has been consistently found to be associated with worse outcomes after TAVR and that the decision-making process for the choice of approach is difficult to quantify objectively, the logistic regression analyses were repeated excluding patients who underwent a nonfemoral approach. The full univariable and multivariable associations in this model are shown in Online Table 2. Use of an Edwards valve remained associated with an increased risk of requiring dialysis after the procedure (OR: 1.85; 95% CI: 1.09 to 3.14; p = 0.006).

FIGURE 2 Kaplan-Meier Curves for All-Cause Cumulative Survival



Study patients are divided according to the need for dialysis either before or after transcatheter aortic valve replacement (global log-rank test p < 0.001). Patients requiring dialysis after transcatheter aortic valve replacement had a higher mortality than both patients already on dialysis (pairwise log-rank test p < 0.001) and those with no dialysis requirement (pairwise log-rank test p < 0.001).

DIALYSIS REQUIREMENTS AND MORTALITY. The median follow-up period was 625 (268 to 1,208) days. Overall, 2,486 (37%) patients died during the follow-up period. In total, 314 (4.9%) patients died during the hospital admission. A total of 223 (3.7%) patients with no dialysis requirement, 9 (7.8%) patients on dialysis before the procedure, and 82 (40.6%) patients requiring dialysis after TAVR died in hospital (p < 0.001). The Kaplan-Meier cumulative survival curves are shown in Figure 2. The Kaplan-Meier mortality estimates in patients with no dialysis requirements were 0.06, 0.07, 0.08, 0.16, and 0.46 at 30 days, 60 days, 90 days, 1 year, and 4 years, respectively. These were significantly higher in patients requiring dialysis after the procedure at 0.35, 0.45, 0.50, 0.64, and 0.84 at the same time points (log-rank p < 0.001). Mortality was also higher in patients requiring dialysis after TAVR compared with those already on dialysis before the procedure (log-rank p < 0.001).

The univariable and multivariable associations of dialysis requirement before or after TAVR with overall mortality at 30 days and at 4 years are presented in Table 3 and Online Tables 3 and 4. Both dialysis requirements before and after TAVR were independently associated with mortality at all time periods. For new dialysis requirement after TAVR, none of these associations were significantly affected by further adjustment for eGFR as a continuous variable, or by categorization of CKD stages to moderate-advanced CKD or advanced CKD. Valve make was not associated with mortality at any time period in the multivariable analyses (Online Tables 3 and 4).

DISCUSSION

Between 2007 and 2014 the incidence of AKI requiring new dialysis after TAVR in the UK was 3.1%, but by

2013 to 2014 this had fallen to 2.1%. This decline was independent of patient comorbidities and procedural characteristics recorded in the dataset. Although most of the factors associated with the need for dialysis after TAVR were conventional risk factors for AKI, we found unexpectedly that use of an Edwards valve was independently associated with a greater need for new dialysis after the procedure. We have also shown that the new need for dialysis after a TAVR procedure is associated with higher mortality at 30 days, and 4 years after the procedure than that of patients on dialysis before TAVR and patients not requiring dialysis at all.

With 6,464 patients at risk, this study is by far the largest reporting the incidence rate of the need for dialysis after TAVR. This contrasts with a recent meta-analysis of AKI after TAVR that, although reporting on 24 studies (n = 5,971), found only 13 studies that gave the incidence of dialysis after TAVR with an at risk population of only 1,058 (5). The need for dialysis in this study was 5.8%, which is much higher than the figure in our analysis. This may, in part relate to the year of treatment. Our large population has allowed us to examine the incidence of the need for new dialysis over time. This has decreased significantly between 2007 and 2014. The decline appears to be independent of recorded pre-procedural individual risk factors and of the logistic EuroSCORE as a comorbidity score. Excluding cases undertaken in the first 2 years to allow for the unusually high risk of the early cases and a potential learning curve did not affect this finding. Although our study is not able to elucidate the reasons for this decline, possible explanations include changes in patient selection (with features not captured in the dataset), better procedural technique, and better periprocedural care optimizing factors such as patient hydration, anesthetics, and sedation.

In this study we have identified a number of factors that are well recognized to be associated with a higher risk of post-procedural AKI leading to dialysis including pre-procedural kidney function and diabetes mellitus. With respect to procedural characteristics, in addition to a nontransfemoral approach we found that the use of an Edwards valve was associated with an increased risk of new dialysis requirement after TAVR. This association remained significant even when adjusted for comorbidities. Furthermore, this association was still significant when procedures performed from the transfemoral approach were considered in isolation (i.e., patients undergoing a nontransfemoral approach were excluded from the analysis). Although the negative outcomes associated with use of a nontransfemoral approach have been well described (4,27,28), the association with the use of a particular valve or valve type has not. However, 1 retrospective, small study (n = 118) has also recently reported a higher rate of AKI associated with use of the Edwards valve compared with the Medtronic valve (29). This association is difficult to explain given the excellent results reported by multiple investigators using this device (27,30,31). It is notable that although the Edwards valve was associated with an increased risk of dialysis requirement after TAVR it was not associated with increased mortality. Although this study examines association and cannot show causation, possible mechanistic explanations require consideration. Possibilities include higher rates of microembolization to the kidneys during the procedure, transient reduced perfusion due to the brief period of hypotension that occurs during rapid pacing, and possible differences in radiographic contrast dose during valve positioning. Although the Edwards valve is loaded onto the deployment balloon in the descending aorta, this process does not involve significant contact with the aortic wall and seems unlikely to cause microembolization to renal arteries. The period of hypotension during rapid ventricular pacing is usually <1 min but it is possible that this insult might precipitate AKI in patients, with already compromised hemodynamics. Nevertheless, a previous study found no association between AKI and the number of pacing episodes (18). Unfortunately, the UK TAVI registry does not collect data on contrast use. Finally, the influence of unmeasured risk factors such as frailty and comorbid burden of disease that

TABLE 3 Cox-Regression Univariable and Multivariable Associations With 30-Day and 4-Year Mortality

Need for Dialysis Before or After TAVR	Univariable Analysis		Multivariable Analysis	
	Hazard Ratio (95% CI)	p Value	Hazard Ratio (95% CI)	p Value
At 30 days				
No	1.00		1.00	
Before	1.78 (0.91–3.45)	0.090	2.29 (1.17–4.46)	0.015
After	9.29 (7.15–12.08)	<0.001	6.44 (4.87–8.53)	<0.001
After*	9.27 (7.13–12.05)	<0.001	6.63 (5.00–8.77)	<0.001
At 4 yrs				
No	1.00		1.00	
Before	2.16 (1.68–2.77)	<0.001	2.46 (1.90–3.18)	<0.001
After	4.46 (3.79–5.24)	<0.001	3.54 (2.99–4.19)	<0.001
After*	4.45 (3.78–5.24)	<0.001	3.25 (2.73–3.87)	<0.001

Multivariable models adjusted for sex, age, LVEF <30%, NYHA functional class III to IV, PVD, known CAD, pre-existing AF, previous cardiac surgery, diabetes mellitus, COPD, previous stroke, previous MI, AAC, valve manufacturer, nontransfemoral route, use of general anesthetic, moderate-severe AR after procedure, MI before discharge, stroke before discharge, cardiac tamponade, conversion to open surgery, and major vascular complication. *Also adjusted for eGFR as a continuous variable with patients previously on dialysis excluded from the analysis.

CI = confidence interval; other abbreviations as in Table 1.

might be associated with use of an Edwards valve cannot be excluded. The wide experience and good results reported with the valve may have led operators to choose this valve in cases at higher risk for AKI. Low numbers of other balloon-expandable valves used in the United Kingdom during this time mean that it is not possible to determine whether this association is present for other balloon expandable valves.

The proportion of patients requiring dialysis for AKI after TAVR has decreased to a rate about equal to that after SAVR (5). Interestingly, a recent report of 133 patients (58% TAVR, 42% SAVR) has reported a greater risk of AKI in patients treated with TAVR, compared with patients undergoing SAVR (32). This may be a result of patient selection as well as differences in the procedural renal insults.

In this study, we have shown that a new requirement for dialysis after TAVR was associated with a >6-fold increased risk of mortality at 30 days compared with non-dialysis-requiring control subjects whereas patients established on dialysis before TAVR had a >2-fold increased risk. This difference suggests that the dialysis procedure itself accounts for only part of the excess mortality associated with the new use of dialysis. However, there is almost certainly an inherent selection bias in patients accepted for TAVR already requiring dialysis treatment. This assertion is supported by the observation that this group of patients had the lowest median age. The risks associated with AKI are long term, as evident from the increased risk of mortality present at 4 years. Whether interventions designed to prevent the need for dialysis after TAVR will improve outcomes requires further investigation (33).

STUDY STRENGTHS AND LIMITATIONS. The strengths are the inclusion of all consecutive patients treated in the UK. This is a large number of patients with a wide range of risk profiles. Indeed, our study is 6 times the size of a meta-analysis quantifying the risk of dialysis after a TAVR procedure. The UK TAVI Registry has captured every TAVR performed at all active units within the United Kingdom from the inception of the procedure in this country, and thus includes the entire "learning curve" and early experience of adopting centers without bias by center selection. The data collection shares the weaknesses of other national registry programs. There is a balance between the size of the dataset and the ability or willingness to collect it accurately. Thus potentially informative data, involving the need for prior balloon aortic valvuloplasty, contrast volume, recent contrast use for computed tomography angiography, bleeding, and recovery of renal function after dialysis might not have been included. Other than mortality tracking, the accuracy and completeness of the data are self-reported and other than range checks and checks for internal validity, there are no external validation processes in place. Also, apart from mortality, later clinical and quality-of-life follow-up is limited. We investigated estimated rather than measured GFR in this study, and although this was (and will likely remain) a practical necessity we acknowledge the imperfection of the estimated measure. As use of conscious sedation rather than general anesthetic for TAVR occurred in large numbers only after 2014 we are unable to comment on the impact of this evolving approach.

CONCLUSIONS

Although the risk of requiring dialysis after TAVR appears to be decreasing, the very high mortality associated with this complication means that it warrants further investigation of potentially preventable risk factors.

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PERSPECTIVES

WHAT IS KNOWN? The reported rates of dialysis post-TAVR differ widely and there is little information on outcomes after this complication.

WHAT IS NEW? The incidence of dialysis requirement post-TAVR has been decreasing over time but is associated with a very high mortality.

WHAT IS NEXT? Further studies are needed to assess interventions and procedural or technique changes designed to lower the risk of significant AKI resulting in the need for dialysis post-TAVR.

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KEY WORDS acute kidney injury, mortality, valve type

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