Transcatheter Aortic Valve Implantation Versus Surgical Aortic Valve Replacement for Severe Aortic Stenosis in Patients With Chronic Kidney Disease Stages 3b to 5

Paola D'Errigo, MS, Claudio Moretti, MD, Fabrizio D'Ascenzo, MD, Stefano Rosato, MS, Fausto Biancari, MD, Marco Barbanti, MD, Francesco Santini, MD, Marco Ranucci, MD, Antonio Miceli, MD, Corrado Tamburino, MD, Francesco Onorati, MD, Gennaro Santoro, MD, Claudio Grossi, MD, Danilo Fusco, MS, and Fulvia Seccareccia, MS, on behalf of the OBSERVANT Research Group

National Centre for Epidemiology, Surveillance and Health Promotion, Istituto Superiore di Sanità, Rome; Division of Cardiology, Città della Salute e della Scienza, University of Turin, Turin; Department of Surgery, University of Oulu, Oulu, Finland; Division of Cardiology, Ferrarotto Hospital, University of Catania, Catania; Division of Cardiac Surgery, IRCCS San Martino, University Hospital, Genova; Department of Cardiothoracic and Vascular Anesthesia and ICU, IRCCS Policlinico San Donato, San Donato Milanese, Milan; Cardiothoracic Center, Istituto Clinico Sant'Ambrogio, Gruppo Ospedaliero San Donato, Milan; Division of Cardiac Surgery, University of Verona Medical School, Verona; Division of Cardiology, Careggi Hospital, Florence; Division of Cardiac Surgery, ASO S. Croce e Carle, Cuneo; and Department of Epidemiology of Lazio Regional Health Service, Rome, Italy

Background. **There are scarce data on outcomes after transcatheter aortic valve implantation (TAVI) and surgical aortic valve replacement (SAVR) in patients with renal failure.**

Methods. **We evaluated the impact of renal failure on outcomes after TAVI and SAVR and compared the results of these procedures in patients with chronic kidney disease stages 3b to 5 from the Observational Study of Effectiveness of AVR-TAVI Procedures for Severe Aortic Stenosis Treatment (OBSERVANT) study.**

Results. **Chronic kidney disease (CKD) stages 3b to 5 was associated with an increased risk of mortality after either TAVI or SAVR compared with CKD stages 1 to 3a. Among 170 propensity score–matched pairs with CKD stages 3b to 5, patients who underwent TAVI had a significantly higher rate of permanent pacemaker implantation, vascular damage, and mild to moderate paravalvular regurgitation, and tended to have a higher 30-day mortality (7.1% versus 2.9%; $p = 0.09$). Thirty-day mortality after transapical TAVI was 7.1%. SAVR had a significantly higher rate of blood transfusions, stroke, and acute kidney injury. At 2 years, patients undergoing TAVI had somewhat higher all-cause mortality (31.2% versus 23.4%; $p = 0.118$), major cardiac and cerebrovascular events (37.2% versus 31.0%; $p = 0.270$), and a lower risk of dialysis (12.4% versus 21.2%; $p = 0.052$) compared with SAVR.**

Conclusions. **CKD stages 3b to 5 increases the risk of mortality after TAVI and SAVR. In this subset of patients, SAVR was associated with somewhat better early and late survival. The risk of acute kidney injury was higher after SAVR. These findings suggest that CKD stages 3b to 5 does not contraindicate SAVR. Strategies to prevent severe acute kidney injury should be implemented with either SAVR or TAVI.**

(Ann Thorac Surg 2016;102:540–8)

Chronic kidney disease (CKD) has been shown to be associated with increased postoperative mortality after cardiac operations [1]. Patients with decreased kidney function are also at risk of postoperative acute kidney injury [1–3]. Such a complication can be triggered by the extent of the procedure and the use of cardiopulmonary bypass in patients undergoing cardiac operations [4] and by the use of ionized contrast agent in patients undergoing transcatheter aortic valve implantation (TAVI) [5, 6]. In turn, acute kidney injury has a negative impact on outcome after cardiac procedures [5, 7–10].

The aim of the present study was to evaluate the impact of different stages of CKD on outcomes after either TAVI or surgical aortic valve replacement (SAVR) and to compare the early and intermediate results of these 2 treatment methods in patients with moderate to severe CKD.

Accepted for publication Jan 28, 2016.

Address correspondence to Mr Rosato, National Centre for Epidemiology, Surveillance and Health Promotion, Istituto Superiore di Sanità, Via Giano della Bella 34 00161 Rome, Italy; email: stefano.rosato@iss.it.

The Appendix can be viewed in the online version of this article [http://dx.doi.org/10.1016/j.athoracsur.2016.01.109] on http://www.annalsthoracicsurgery.org.

0003-4975/$36.00
http://dx.doi.org/10.1016/j.athoracsur.2016.01.109

Patients and Methods

Study Design and Data Collection

The Observational Study of Effectiveness of AVR-TAVI Procedures for Severe Aortic Stenosis Treatment (OBSERVANT) is a national observational prospective multicenter cohort study that enrolled consecutive patients with aortic valve stenosis undergoing TAVI or SAVR at 93 Italian cardiology/cardiac surgery centers between December 2010 and June 2012. Details on the study design, patient eligibility criteria, and data collection modalities have been reported elsewhere [11, 12]. In the participating hospitals, both procedural treatments (SAVR or TAVI, or both) could be offered to patients with aortic valve stenosis (see Appendix for the complete list of executive working group, participating centers, and investigators). The study protocol was approved by the Local Ethics Committee (ASL 2 Melegnano) of the coordinating Institution (Policlinico San Donato), and the patients gave informed consent for the scientific treatment of their data in an anonymous form. Patients undergoing TAVI received an Edwards SAPIEN XT (Edwards Lifesciences, Irvine, CA) or a CoreValve (Medtronic, Inc, Minneapolis, MN) bioprosthesis.

The study population included all consecutive adult patients admitted with a diagnosis of severe aortic valve stenosis who required an aortic valve replacement. A dedicated data sheet for data collection on both procedures was developed. Data on demographic characteristics, health status before intervention, comorbidities, and complete information on the type of intervention were collected in a standardized online data sheet on a password-protected website. Collected data were stored and analyzed at the Italian National Institute of Health.

For the purposes of the present analysis, patients with porcelain aorta or hostile chest, those undergoing any combined procedure (coronary revascularization or intervention on other heart valves), and those who underwent emergency procedures were excluded. Estimated glomerular filtration rate (eGFR) was obtained using the formula proposed by Levey and colleagues [13]. Severity of baseline renal failure was graded according to 6 different stages of increasing severity of eGFR [14]. Postoperative acute kidney injury was graded in 3 stages according to the Acute Kidney Injury Network (AKIN) definition, taking into consideration only the baseline and postoperative serum creatinine levels [15].

Outcome End Points and Follow-Up

All-cause mortality up to 2 years was the primary outcome measure. Secondary outcome end points were in-hospital adverse events such as stroke, vascular complications, red blood cell transfusion, and acute kidney injury. Stroke was defined as any focal deficit lasting longer than 24 hours or focal deficit lasting less than 24 hours with abnormal neuroimaging studies. Vascular complications were defined as any access site complication requiring surgical or percutaneous treatment. Acute kidney injury was classified in 3 stages according to the AKIN definition, taking into account only the peak postoperative serum creatinine level obtained within 48 hours of the procedure [15]. Other secondary outcome end points were major adverse cardiac and cerebrovascular events (MACCE) at 2 years. MACCE were defined as the composite of death from any cause, stroke, myocardial infarction, percutaneous coronary intervention, and coronary artery bypass grafting. An administrative follow-up was set up for each enrolled patient through a record linkage with the National Hospital Discharged Records database (for in-hospital events) and with the Tax Registry Information System (for information on life status). This approach guarantees a very low rate of loss to follow-up.

Statistical Analysis

Statistical analyses were performed using the SAS statistical package, version 9.2 (SAS Institute Inc, Cary, NC) and IBM SPSS Statistics, version 22 (SPSS Inc, Chicago, IL). Continuous variables are presented as mean ± standard deviation and were compared using a Student's t test. Categorical variables are presented as counts and percentages and were compared with the χ^2 test or Fisher's exact test as appropriate.

Operative deaths were not excluded from survival analyses. Time-to-event variables were described using Kaplan-Meier estimates and compared using the log-rank test. Adjusted survival analysis was performed using the Cox proportional hazards method. We evaluated the prognostic impact of CKD stages by adjusting CKD stages for all covariates included in the Appendix using a Cox proportional hazards method in a backward

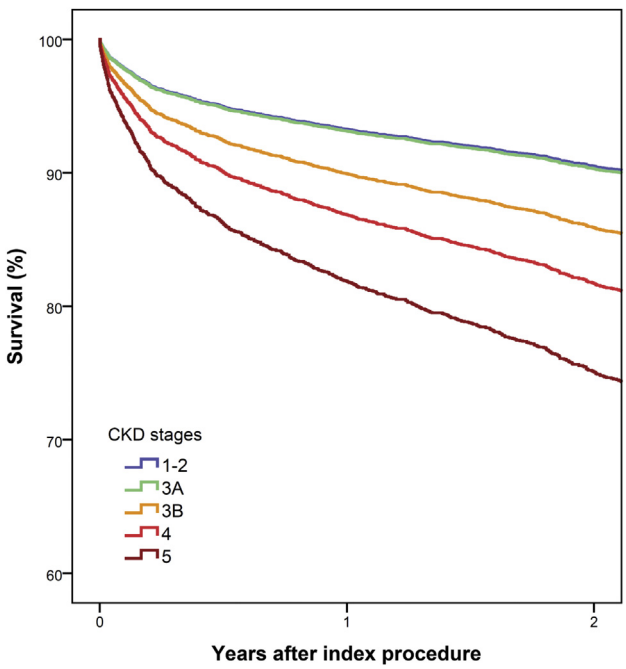

Fig 1. Cox-adjusted analysis of the impact of baseline chronic kidney disease (CKD) stages on the intermediate all-cause mortality in patients undergoing transcatheter or surgical aortic valve replacement for severe aortic stenosis.

Table 1. Baseline Clinical Characteristics of Propensity Score–Matched Pairs

Characteristic	SAVR n = 170	TAVI n = 170	*p* Value	Standardized Difference
Age (y)	79.5 ± 6.2	80.3 ± 7.0	0.20	0.12
Male sex	107 (62.9)	108 (63.5)	0.90	0.01
Hemoglobin (mg/d)	11.7 ± 1.6	11.2 ± 1.6	0.008	0.30
BMI (kg/m^2)	27.4 ± 4.3	26.8 ± 4.9	0.29	0.11
Diabetes mellitus	54 (31.8)	57 (33.5)	0.73	0.04
eGFR (mg/min/1.73 m^2)	32.9 ± 9.5	33.0 ± 9.0	0.88	0.02
Chronic dialysis treatment	7 (4.1)	9 (5.3)	0.62	0.06
Smoking history	19 (11.5)	19 (11.5)	1.00	0.00
Pulmonary disease	33 (19.4)	33 (19.4)	1.00	0.00
Oxygen dependency	3 (1.8)	8 (4.7)	0.13	0.17
Neurologic dysfunction	7 (4.1)	6 (3.5)	0.78	0.03
Chronic liver disease	11 (6.5)	9 (5.3)	0.65	0.05
Active neoplastic disease	2 (1.2)	3 (1.8)	0.65	0.05
Peripheral arteriopathy	40 (23.5)	41 (24.1)	0.90	0.01
Pulmonary hypertension	20 (12.6)	21 (13.2)	0.85	0.02
Previous cardiac operation	14 (8.2)	13 (7.6)	0.84	0.02
Previous operation on the aorta	6 (3.5)	6 (3.5)	0.78	0.00
Previous BAV	5 (2.9)	5 (2.9)	1.00	0.00
Previous AMI	23 (13.5)	23 (13.5)	1.00	0.00
Previous PCI	29 (17.1)	24 (14.1)	0.45	0.08
Coronary artery disease				
1-vessel disease	20 (11.8)	20 (11.8)		
2-vessel disease	8 (4.7)	10 (5.9)	0.96	0.06
3-vessel disease	8 (4.7)	7 (4.1)		
NYHA class				
I	8 (4.7)	9 (5.3)		
II	60 (35.3)	63 (37.1)	0.97	0.05
III	78 (45.9)	74 (43.5)		
IV	24 (14.1)	24 (14.1)		
Unstable angina	8 (4.7)	7 (4.1)	0.80	0.03
Frailty score (moderate to severe)	19 (11.7)	21 (12.9)	0.75	0.04
Critical preoperative state	9 (5.3)	11 (6.5)	0.65	0.05
Urgent procedure	9 (5.3)	10 (5.9)	0.82	0.03
EuroSCORE II (%)	6.5 ± 8.1	7.1 ± 8.5	0.50	0.08

Continuous variable are reported as the mean and standard deviation; categorical variables are reported as counts and percentages.

p values refer to the McNemar test for dichotomous variables, the Stuart-Maxwell test for categorical variables, and the *t* test for paired samples for continuous variables.

AMI = acute myocardial infarction; BAV = balloon aortic valvuloplasty; BMI = body mass index; eGFR = estimated glomerular filtration rate; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; SAVR = surgical aortic valve replacement; TAVI = transcatheter aortic valve implantation.

fashion. Once we observed that the risk of midterm mortality was significantly higher in patients with CKD stages 3b to 5, we included them in the final analysis. Because observational studies do not provide randomization, the propensity score method was applied to select 2 groups of patients undergoing SAVR and TAVI, respectively, with similar baseline characteristics. Therefore, patients with CKD stages 3b to 5 were the subjects of 1-to-1 propensity score matching comparing SAVR and TAVI. The propensity score was estimated using a nonparsimonious logistic regression model, with the treatment method as the dependent variable [16] and all measured potential confounders as covariates. The following variables were included: age, sex, previous percutaneous coronary intervention, previous balloon aortic valvuloplasty, previous cardiac operation, previous operation on the aorta, chronic dialysis treatment, diabetes, chronic obstructive pulmonary disease, previous myocardial infarction, peripheral arteriopathy, eGFR, critical preoperative state, unstable angina, neurologic dysfunction, pulmonary hypertension (systolic pulmonary arterial pressure >60 mm Hg), chronic liver disease, active neoplastic disease, New York Heart Association class, frailty score (Geriatric Status Scale [17]), left ventricular ejection fraction, coronary artery disease, urgency status, and mitral regurgitation.

Table 2. Preoperative Echocardiographic Measurements

Variable	SAVR n = 170	TAVI n = 170	*p* Value	Standardized Difference
LVEF				
>50%	120 (72.3)	123 (74.1)		
30%–50%	42 (25.3)	41 (24.7)	0.70	0.09
<30%	4 (2.4)	2 (1.2)		
Mitral valve regurgitation				
Mild	85 (50.0)	80 (47.1)		
Moderate	42 (24.7)	42 (24.7)	0.59	0.15
Severe	7 (4.1)	4 (2.4)		
Aortic valve pattern				
Aortic valve area (cm^2)	0.7 ± 0.3	0.7 ± 0.3	0.10	0.19
Peak gradient (mm Hg)	81 ± 24	83 ± 23	0.56	0.07
Mean gradient (mm Hg)	50 ± 16	51 ± 14	0.53	0.07
Annulus diameter (mm)	21.3 ± 1.9	22.0 ± 2.2	0.01	0.35

Continuous variables are reported as mean and standard deviation; categorical variables are reported as counts and percentages.

p values refer to the McNemar test for dichotomous variables, the Stuart-Maxwell test for categorical variables, and the *t* test for paired samples for continuous variables.

LVEF = left ventricular ejection fraction; SAVR = surgical aortic valve replacement; TAVI = transcatheter aortic valve implantation.

Pairs of patients undergoing TAVI and SAVR and having the same probability score (nearest neighbor method; caliper = 0.2*DS [logitPs]) [18] were matched. To evaluate the balance between the matched groups, we used the *t* test for paired samples for continuous variables, the McNemar test for dichotomous variables, the Stuart-Maxwell test for categorical variables, and analysis of the standardized differences before and after matching. The same tests were used to compare periprocedural adverse events. Differences in the outcome of propensity score–matched pairs were evaluated by the Kaplan-Meier method with the Klein-Moeschberger stratified log-rank test. A *p* value less than 0.05 was considered statistically significant.

Results

This study included 5,475 patients who underwent either isolated TAVI or isolated SAVR. Cox proportional hazards analysis showed that when adjusted for treatment method and all baseline variables listed in the Appendix, CKD stage 3b (hazard ratio [HR], 1.52; 95% confidence interval [CI], 1.25–1.86), stage 4 (HR, 2.02; 95% CI, 1.57–2.60), and stage 5 (HR, 2.87; 95% CI, 2.04–4.03) were associated with significantly increased risk of midterm all-cause mortality after either TAVI or SAVR compared with CKD stages 1 and 2 (Fig 1). Because CKD stage 3a (HR, 1.02; 95% CI, 0.84–1.25) had a survival similar to that of CKD stages 1 and 2, further analyses were performed only in patients with CKD stages 3b to 5.

Table 3. Periprocedural Adverse Events in Propensity Score–Matched Pairs

Periprocedural Adverse Events	SAVR n = 170	TAVI n = 170	*p* Value
Valve migration	0	1 (0.6)	0.32
Stroke	6 (3.6)	0 (0)	0.01
Shock	11 (6.6)	5 (3.0)	0.13
Cardiac tamponade	5 (3.0)	9 (5.3)	0.25
Permanent pacemaker	5 (3.0)	29 (17.6)	<0.0001
Major vascular damage	0 (0)	10 (6.2)	0.001
Infection	15 (9.6)	10 (6.4)	0.27
Wound	6 (3.5)	2 (1.2)	
Lung or other organs	7 (4.1)	8 (4.7)	0.26
Sepsis	2 (1.2)	0 (0)	
Emergency PCI	0 (0)	0 (0)	. . .
Red blood cell transfusions	113 (69.8)	66 (40.7)	<0.0001
No of red blood cell transfusions	2.3 ± 3.2	0.9 ± 1.6	<0.0001
Paravalvular regurgitation			
Mild	13 (7.6)	65 (38.2)	
Moderate	6 (3.5)	19 (11.2)	<0.0001
Severe	. . .	. . .	
Acute kidney injury[a]	67 (48.9)	49 (35.8)	0.038
AKIN Stage 1[a]	43 (31.4)	30 (21.9)	
Stage 2[a]	3 (2.2)	4 (2.9)	0.16
Stage 3[a]	21 (15.3)	15 (10.9)	
De novo dialysis[a]	27 (18.4)	15 (10.2)	0.073
Mean transvalvular gradient (mm Hg ± SD)	13.6 ± 5.9	10.5 ± 4.7	<0.0001
ICU stay	4.9 ± 11.0	3.2 ± 3.9	0.049
30-day mortality	5 (2.9)	12 (7.1)	0.09

[a] Excluding 16 pairs of patients with previous dialysis.

Continuous variables are reported as mean and standard deviation; categorical variables are reported as counts and percentages.

p values refer to the McNemar test for dichotomous variables, the Stuart-Maxwell test for categorical variables, and the *t* test for paired samples for continuous variables.

ICU = intensive care unit; PCI = percutaneous coronary intervention; SAVR = surgical aortic valve replacement; SD = standard deviation; TAVI = transcatheter aortic valve implantation.

Study Population

From the entire cohort, 1,057 patients (19.3%; 505 patients undergoing SAVR and 552 patients undergoing TAVI, 89 of them with a transapical approach) had CKD stage 3b to 5. Baseline characteristics of these patients are summarized in the Appendix Table.

Propensity score matching generated 170 pairs of patients with similar baseline characteristics, as confirmed by a standardized difference less than or equal to 0.1 in almost all baseline and echocardiographic variables, as well as a similar EuroSCORE II (TAVI, 7.1% ± 8.5% versus SAVR 6.5% ± 8.1%; $p = 0.50$) (Tables 1 and 2). Twenty-eight TAVIs were performed through a transapical approach.

Early Outcomes

Patients who underwent TAVI tended to have higher 30-day mortality (7.1% versus 2.9%; $p = 0.09$). The

Table 4. Adverse Events at 2-Year Follow-Up

Late Events	SAVR n = 170 (%)	TAVI n = 170 (%)	*p* Value
Death from any cause	23.4	31.2	0.118
Stroke	8.5	8.9	0.982
Acute myocardial infarction	4.4	2.6	0.366
PCI	1.2	0.6	0.569
CABG	0	0	. . .
MACCE	37.2	31.0	0.270
Dialysis	21.2	12.4	0.052

Data are reported as Kaplan-Meier estimates at the specific time point.

CABG = coronary artery bypass grafting; MACCE = major adverse cardiac and cardiovascular events (death from any cause, stroke, acute myocardial infarction, coronary revascularization); PCI = percutaneous coronary intervention; SAVR = surgical aortic valve replacement; TAVI = transcatheter aortic valve implantation.

observed/expected ratio of 30-day mortality was 0.44 for SAVR and 1.00 for TAVI. Thirty-day mortality after transapical TAVI was 7.1%. TAVI was associated with a significantly higher risk of permanent pacemaker implantation (17.6% versus 3.0%; $p < 0.0001$), major vascular damage (6.2% versus 0%; $p < 0.0001$), and paravalvular regurgitation (mild, 38.2% versus 7.6%; moderate to severe, 11.2% versus 3.5%; $p < 0.0001$).

SAVR was associated with a significantly higher risk of blood transfusions (69.8% versus 40.7%; $p < 0.0001$), stroke (3.6% versus 0%; $p = 0.01$), and longer stay in the intensive care unit (4.9 ± 11.0 days versus 3.2 ± 3.9 days; $p = 0.049$).

After excluding 16 patients receiving preoperative dialysis, the risk of AKIN acute kidney injury was significantly higher in patients undergoing SAVR compared with patients undergoing TAVI (48.9% vs 35.8%; $p = 0.038$). In particular, the risk of AKIN acute kidney injury stage 3 was 15.3% after SAVR and 10.9% after TAVI ($p = 0.37$). However, the risk of de novo dialysis was similar (SAVR, 18.4%, versus TAVI, 10.2%; $p = 0.073$) (Table 3).

Midterm Outcomes

At 2 years, the risk of mortality and other cardiovascular adverse events was similar in the study groups (Table 4). Although patients undergoing TAVI had a slightly higher all-cause mortality risk (31.2% versus 23.4%; stratified log-rank test $p = 0.118$), the difference did not reach statistical significance. The risk of MACCE was similar after TAVI and SAVR (37.2% versus 31.0%; stratified log-rank test $p = 0.270$) (Table 4; Fig 2). After patients receiving preoperative chronic dialysis were excluded from the analysis, the rate of any renal replacement therapy at 2 years was 21.2% after SAVR and 12.4% after TAVI (stratified log-rank test $p = 0.052$) (Table 4). Although such a difference almost reached statistical significance, no data were available to assess whether renal replacement therapy in these patients was temporary or chronic.

Comment

The present findings indicate that renal failure is a major determinant of midterm survival in patients undergoing either SAVR or TAVI. Although the impact of subclinical renal failure in surgical patients is not new [19], this study suggests that only an eGFR less than 45 mL/min/1.73 m^2 has a negative prognostic impact in patients undergoing aortic valve replacement. Two previous studies confirm these findings [20–22] on the lack of prognostic impact of CKD stage 3a in patients undergoing aortic valve replacement and indicate, as originally observed by Go et al. [23], a marked rise in the risk of mortality only in patients with CKD stages 3b to 5.

An important finding of this study is the rather high prevalence of CKD stages 3b to 5, a condition that is associated with an increased operative risk in patients undergoing either TAVI or SAVR (Appendix). These findings are of clinical relevance because both TAVI and SAVR (likely through different mechanisms) expose these patients to an excessive risk of acute kidney injury, which in turn has a negative prognostic impact [5, 7–11]. We observed a significantly increased rate of acute kidney injury in patients undergoing SAVR compared with that in patients undergoing TAVI. This translated to a decreased risk of renal replacement treatment after TAVI at 2 years. However, no data were available to differentiate temporary from chronic dialysis in these patients, and this prevents us from evaluating whether the severe acute kidney injury had permanent consequences. In any case, the risk of renal replacement therapy was substantial in both study groups. We speculate that a strategy of reducing the amount of contrast agent used in patients undergoing TAVI as well as decreasing the duration of cardiopulmonary bypass using increased perfusion pressure and normothermia, avoiding low intraoperative hematocrit, and avoiding significant bleeding and blood transfusions are measures that may reduce the risk of acute kidney injury in these high-risk patients [24–26].

This study showed that SAVR is associated with a favorable 30-day mortality rate, which tended to be lower than that in TAVI. Interestingly, the observed early mortality was similar to that after TAVI and much lower than the predicted rate after SAVR (observed/predicted ratio: SAVR, 0.42 versus TAVI, 1.0). The difference in mortality persisted up to 2 years after the procedure but did not reach statistical significance.

SAVR was associated with a significantly higher risk of stroke immediately after the surgical procedure compared with TAVI, but the difference between the groups disappeared at intermediate follow-up. Conversely, TAVI was associated with a significantly increased risk of atrioventricular block requiring implantation of a permanent pacemaker and of mild to moderate paravalvular regurgitation, both being the Achille's tendon of this treatment method. Furthermore, TAVI was associated with a lower mean transvalvular gradient compared with SAVR. Although such a difference is statistically significant, this is hardly of clinical

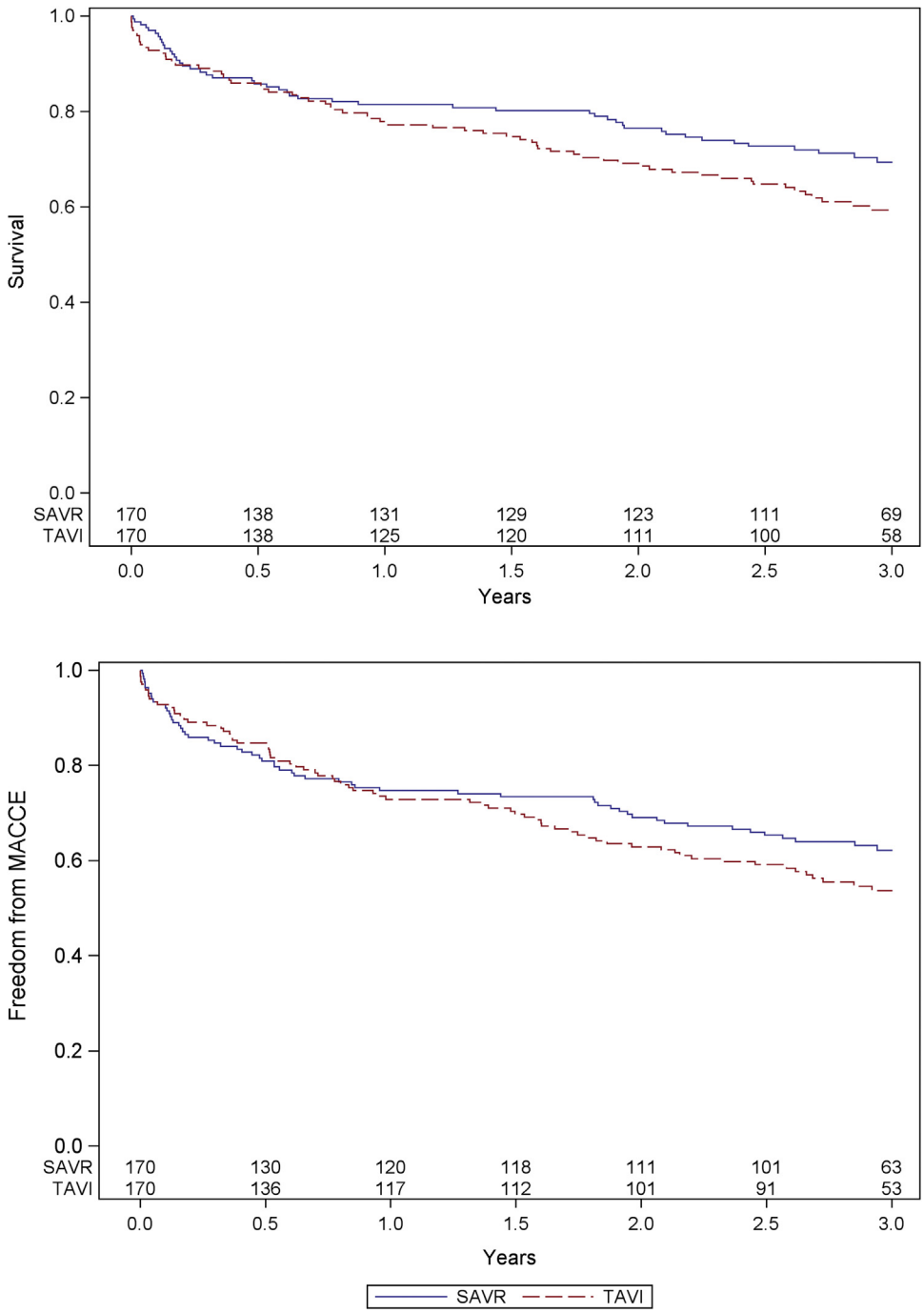

Fig 2. Intermediate survival and freedom from major adverse cardiac and cerebrovascular events (MACCE) in propensity score–matched pairs of patients with chronic kidney disease (CKD) stages 3b to 5 after transcatheter aortic valve implantation (TAVI) or surgical aortic valve replacement (SAVR) for severe aortic stenosis.

significance because the mean transvalvular gradient after SAVR was rather low. This finding can be explained by the use of stented valve prostheses in SAVR.

These present results do not confirm the findings by Nguyen and associates [27], who showed an advantage of TAVI in patients with an eGFR less than 60 mL/min/1.73 m^2. These authors observed that TAVI was associated with excellent outcomes, and renal failure was not predictive of adverse outcomes. The opposite was proved for patients who underwent SAVR. However, Nguyen and associates [27] did not perform a formal comparative analysis of SAVR versus TAVI in patients with renal failure, and their results reflect the experience of a single institution.

Study Limitations

The present study has a number of limitations that should be acknowledged. First, the nonrandomized nature of this study can lead to incorrect conclusions because of the influence of unassessed confounding variables. However, it has been argued that a well-conducted observational cohort study can provide the same level of internal

validity as randomized controlled trials [28]. Conversely, the results of "real world" clinical registries may provide unselected data, which can reach higher levels of external validity compared with randomized clinical trials. To compensate for the baseline imbalance between the study groups, we applied a propensity score adjustment, which represents the best available method for analyzing observational data.

Severe postoperative acute kidney injury requiring chronic dialysis is a severe complication after cardiac interventions. However, we do not have data to assess whether temporary and permanent renal replacement therapy was needed in these patients.

Another limitation of the present study is that the outcome events were not defined according to Valve Academic Research Consortium criteria [29]. The reason is that such definitions are specifically designed to define complications after TAVI. Therefore they may be misleading when used to illustrate complications after SAVR, likely resulting in their overestimation. The 2-year follow-up prevents conclusive results on the very long-term durability of these methods in these high-risk patients. Finally, this analysis included only patients who underwent isolated SAVR or TAVI, and it is unknown whether these results also apply to patients undergoing concomitant coronary artery bypass operations or percutaneous coronary intervention.

Conclusions

The results of this multicenter observational study showed that patients with CKD stages 3b to 5 have increased mortality after either TAVI or SAVR compared with patients with CKD stages 1 to 3a. In this subset of patients, SAVR is associated with somewhat better early and late survival. The risk of early postoperative acute injury is higher after SAVR. These findings suggest that when the operative risk is not prohibitive, SAVR is not contraindicated in patients with CKD stages 3b to 5. Strategies to prevent severe acute kidney injury should be implemented with either SAVR or TAVI.

The authors wish to thank Gabriella Badoni for her technical support in the organizational phases of the study.

The OBSERVANT Study was supported by a grant (Fasc. 1M30) from Italian Ministry of Health and Istituto Superiore di Sanità.

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INVITED COMMENTARY

Chronic kidney disease (CKD) moved from 27th to 18th in the list of causes of deaths worldwide over 2 decades, according to the 2010 Global Burden of Disease Study, and it is a known risk factor for cardiovascular disease. Mortality due to cardiovascular disease is 10 to 30 times higher in patients receiving dialysis than in the general population [1]. Patients have increased aortic valve calcification, and their native valves tend to degenerate faster [2]. Patients with CKD have increased operative risk and therefore are not considered ideal candidates for aortic valve replacement. However, more patients with CKD are undergoing surgical aortic valve replacement (SAVR) and transcatheter aortic valve replacement (TAVR) procedures. TAVR has found recent success that is challenging SAVR for treating CKD patients with aortic stenosis (AS) [3]. Two questions remain: can a patient's CKD stage be used as a prognostic factor for adverse outcomes in their SAVR or TAVR procedures, and is SAVR or TAVR more efficacious in patients with advanced renal failure?

This study compared the short-term and intermediate-term outcomes in patients with CKD stages 3b–5 who were undergoing SAVR versus TAVR for severe AS [3]. Data collection was from the OBSERVANT database, a nationwide Italian cohort. The short-term TAVR results showed higher mortality, permanent pacemaker implantation, and major vascular damage. However, SAVR showed an elevated risk of acute kidney injury (AKI), stroke, blood transfusions, and longer intensive care unit stays at 30 days. Notably, there were no significant differences in mortality or in major adverse cardiac and cerebrovascular events at 2 years.

The need to clarify the benefits and risks of SAVR versus TAVR for AS patients with CKD is greater than ever. This study supports other findings that renal function can be used as a prognostic variable, inasmuch as mortality increased with CKD stages 3b–5 versus stages 1–3a. Additionally, it refutes our group's study supporting TAVR in patients with worsening glomerular filtration rates. We found that the incidence of new dialysis and renal failure increased with deteriorating renal function in SAVR patients [4]. The TAVR group did not demonstrate this relationship.

A few limitations exist for this study. The lack of long-term data, as acknowledged by the authors, limits the usefulness of the study. Understanding the implications beyond 2 years would certainly be relevant to the decision to perform SAVR versus TAVR in CKD patients, particularly because CKD is associated with a higher incidence of structural valve deterioration. Another confounder is the mix of transapical (TA) and transfemoral TAVRs in the analysis. Previous studies have shown that patients who have undergone the TA approach tend to be a higher-risk cohort associated with worse outcomes. Therefore, the risk of AKI in the short term may be overstated in the SAVR population because of an overall reduced risk in the TAVR population. In fact, another study found that TA was the only independent predictor of AKI [5].

Current data comparing SAVR and TAVR have largely excluded patients with severe renal disease, limiting our understanding in this important patient subset [6]. This study addresses the heart of the matter by focusing specifically on patients with severe CKD, and it is the only study to analyze TAVR in CKD patients stratified by CKD stage. The study provides evidence to support the use of CKD stages as a prognostic tool for evaluating a patient's risk. Although the evidence provided for the efficacy of SAVR versus TAVR for CKD patients differs from that in previous studies, it adds important information to a limited body of knowledge and serves as a solid platform for future research. Additional research is needed to clarify the most effective modality to treat AS in this growing patient subset.

Tom C. Nguyen, MD
Matthew D. Terwelp, MD

University of Texas Houston - Memorial Hermann
6400 Fannin St
Ste 2850
Houston, TX 77004
email: tom.c.nguyen@gmail.com

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0003-4975/$36.00
http://dx.doi.org/10.1016/j.athoracsur.2016.02.049