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Midterm Outcomes of Transcatheter Aortic Valve Replacement in Dialysis Patients With Aortic Valve Stenosis

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Background: Little is known about late outcomes after transcatheter aortic valve replacement (TAVR) in dialysis patients.

Methods and Results: We enrolled 25 dialysis patients (mean age 76.5 years; mean STS score 14.7%; men 60.0%) with aortic valve stenosis undergoing TAVR at our institute. Cardiovascular mortality and stroke were defined according to the VARC-2 criteria, and major adverse cardiac and cerebrovascular events (MACCE) were investigated. Twenty-three patients (92.0%) were discharged, and the median hospital stay after TAVR was 9 days (IQR, 7.5–11 days). Mortality at 30 days was not observed. The overall survival rate at 1 and 3 years were 80.0% and 55.7%, respectively (follow-up period, 879±493 days; range, 40–1,826 days). At 1 and 3 years, rates of freedom from cardiovascular mortality, disabling stroke, and MACCE were 100% and 83.0%, 91.2% and 84.7%, and 69.8% and 39.9%, respectively. Three patients required redo-TAVR for valve dysfunction at 23, 36, and 38 months after the first TAVR, respectively (The rate of freedom from severe structural valve deterioration at 1 and 3 years was 100% and 85.9%, respectively).

Conclusions: Satisfactory in-hospital outcomes were achieved in dialysis patients after TAVR. Various problems, however, such as complications particular to dialysis patients and valve durability, remained at midterm follow-up. Further studies are recommended to solve these problems, and prudent preoperative assessments should be mandatory.

Key Words: Aortic stenosis; Dialysis; Transcatheter aortic valve replacement/implantation

Transcatheter aortic valve replacement (TAVR) for dialysis patients is not yet reimbursed in Japan because of poor evidence and data regarding outcomes after TAVR in these patients. We previously reported early outcomes of TAVR in 17 dialysis patients.[1] Although the early outcomes were significantly better compared with previous reports,[2–5] various complications particular to dialysis patients are common during follow-up according to the renal data registry of the Japanese Society for Dialysis Therapy.[6] In terms of the trend of causes of death in dialysis patients, the registry reported that infections are increasing, whereas heart failure is the leading cause of death. Furthermore, little is known about the long-term durability of transcatheter valves in these patients. It is therefore necessary to report on midterm and long-term outcomes after TAVR in dialysis patients. In the present study, we evaluated the midterm outcomes of 25 dialysis patients who underwent TAVR supported by advanced medical treatment (AMT) at the present institute.

Methods

Patients

From April 2012 to January 2016, we enrolled 25 patients with aortic stenosis (AS) with end-stage renal disease requiring dialysis, who underwent TAVR supported by AMT at the present institute. No patient was on peritoneal dialysis in this cohort. Severe AS was defined as aortic valve area $<0.8\,cm^2$ or an effective orifice area index $<0.5\,cm^2/m^2$, mean pressure gradient ≥40 mmHg, or peak aortic jet velocity ≥4.0 m/s. Patients with New York Heart Association class ≥II with an STS score ≥10% (if not, at least 1 surgeon and 1 cardiologist considered the patient not to be suitable for surgery due to comorbidities) were included. The complete list of exclusion criteria is given in **Supplementary Appendix 1**. All computed tomography was assessed using a dedicated workstation with 3mensio valve (3mensio Medical Imaging BV, Bilthoven, Netherlands; **Supplementary Appendix 2**). Operative techniques have been previously

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Table 1. Baseline Patient Characteristics

Characteristics	
Age (years)	76.5±5.1
Sex (male)	15 (60.0)
BSA (m^2)	1.50±0.16
BMI (kg/m^2)	21.1±2.6
NYHA	
III	11 (44.0)
IV	1 (4.0)
Hypertension	22 (88.0)
DM	5 (20.0)
Insulin dependence	3 (12.0)
COPD (≥moderate)	2 (8.0)
Dyslipidemia	14 (56.0)
PVD	12 (48.0)
Immunosuppressant agents	3 (12.0)
Previous cardiac surgery	8 (32.0)
Previous CABG	8 (32.0)
Pre-existing PMI	1 (4.0)†
Rhythm	
Sinus rhythm	21 (84.0)
Paroxysmal AF	1 (4.0)
Chronic AF	3 (12.0)
HD (years)	11.1±10.1
STS score (%)	14.7±10.5
EuroSCORE (%)	26.8±17.7
Echocardiography parameters	
mPG (mmHg)	44.5±14.5
AVA (cm^2)	0.78±0.16
EF (%)	59.6±11.8
AR grade ≥II	14 (56.0)
MR grade ≥II	14 (56.0)
TR grade ≥II	21 (84.0)
CT parameters	
Annular diameter (mm)	24.0±2.0
Valsalva diameter (mm)	31.2±3.4
Sinotubular junction diameter (mm)	26.8±2.5
Total calcium score (HU ≥650; mm^3)	549±277

Data given as n (%) or mean±SD. †Pre-existing implantable cardioverter defibrillator. AF, atrial fibrillation; AR, aortic regurgitation; AVA, aortic valve area; BMI, body mass index; BSA, body surface area; CABG, coronary artery bypass grafting; COPD, chronic obstructive pulmonary disease; CT, computed tomography; DM, diabetes mellitus; EF, ejection fraction; EuroSCORE, European System for Cardiac Operative Risk Evaluation; HD, hemodialysis; HU, Hounsfield unit; mPG, mean pressure gradient; MR, mitral regurgitation; NYHA, New York Heart Association; PMI, pacemaker implantation; PVD, peripheral vascular disease; STS, Society of Thoracic Surgeons; TR, tricuspid regurgitation.

Table 2. In-Hospital Outcomes

Outcomes	
Transapical TAVR	15 (60.0)
SAPIEN XT (THV9300)	18 (72.0)
In-hospital mortality	0 (0)
Acute MI	0 (0)
Disabling stroke	1 (4.0)
Access-related complications	1 (4.0)
Requirement for PPM	2 (8.0)
Conversion to SAVR	0 (0)
Length of ICU stay (days)	2.5±2.2
Restart of hemodialysis (days)	1.2±0.4
Length of hospital stay after TAVR (days)	9 (7.5–11)

Data given as n (%), mean±SD, or median (IQR). ICU, intensive care unit; MI, myocardial infarction; PPM, permanent pacemaker; SAVR, surgical aortic valve replacement; TAVR, transcatheter aortic valve replacement.

Table 3. Cause of Death

	No. deaths (n=15)
Infection	8 (53.3)
Gastrointestinal disease	3 (20.0)
Osteomyelitis	1 (6.7)
Pyogenic spondylitis	1 (6.7)
Pneumonia	1 (6.7)
Unknown	2 (13.3)
Cancer	1 (6.7)
Cardiovascular death	6 (40.0)
Heart failure	1 (6.7)
Cerebrovascular disease	1 (6.7)
Unknown	4 (26.7)

Data given as n (%).

described.[1] Aspirin was taken by all patients after TAVR. Additional antiplatelet agents and/or anticoagulation agents were taken based on patient background and medication(s) before TAVR. Patients underwent follow-up examinations, including transthoracic echocardiography, at the time of the procedure; at discharge from the hospital or at postoperative day 7; at 30 days, 6 months, and 12 months; and then annually. In the case of missing questionnaires or adverse events, telephone and personal consults were conducted. The mean duration of follow-up was 879±493 days. Follow-up was completed for the entire cohort. Cardiovascular mortality and stroke were defined according to Valve Academic Research Consortium-2 (VARC-2) criteria,[7] and major adverse cardiac and cerebrovascular events (MACCE) were defined as events requiring re-hospitalization due to heart failure or any cardiac and cerebrovascular event. In this study, the definition of valve dysfunction was adapted from the standardized definition of structural valve deterioration (SVD).[8] Definitions were as follows: severe SVD: (1) mean gradient ≥40 mmHg and/or ≥20 mmHg increase from baseline; AND/OR (2) peak velocity ≥4 m/s and/or ≥2 m/s increase from baseline; AND/OR (3) severe new or worsening intra-prosthetic aortic regurgitation (AR). Moderate SVD: (1) mean gradient ≥20 and <40 mmHg and/or ≥10 and <20 mmHg increase from baseline; AND/OR (2) peak velocity ≥3 and <4 m/s and/or ≥1.5 and <2 m/s increase from baseline; AND/OR (3) moderate new or worsening intra-prosthetic AR. The primary endpoint of this study was all-cause mortality, and the secondary endpoints were cardiovascular mortality, disabling stroke, valve-related complications such as valve thrombosis, major bleeding, and MACCE. Therapies for these patients were discussed at the multidisciplinary meetings attended by cardiac surgeons, cardiologists, and anesthesiologists.

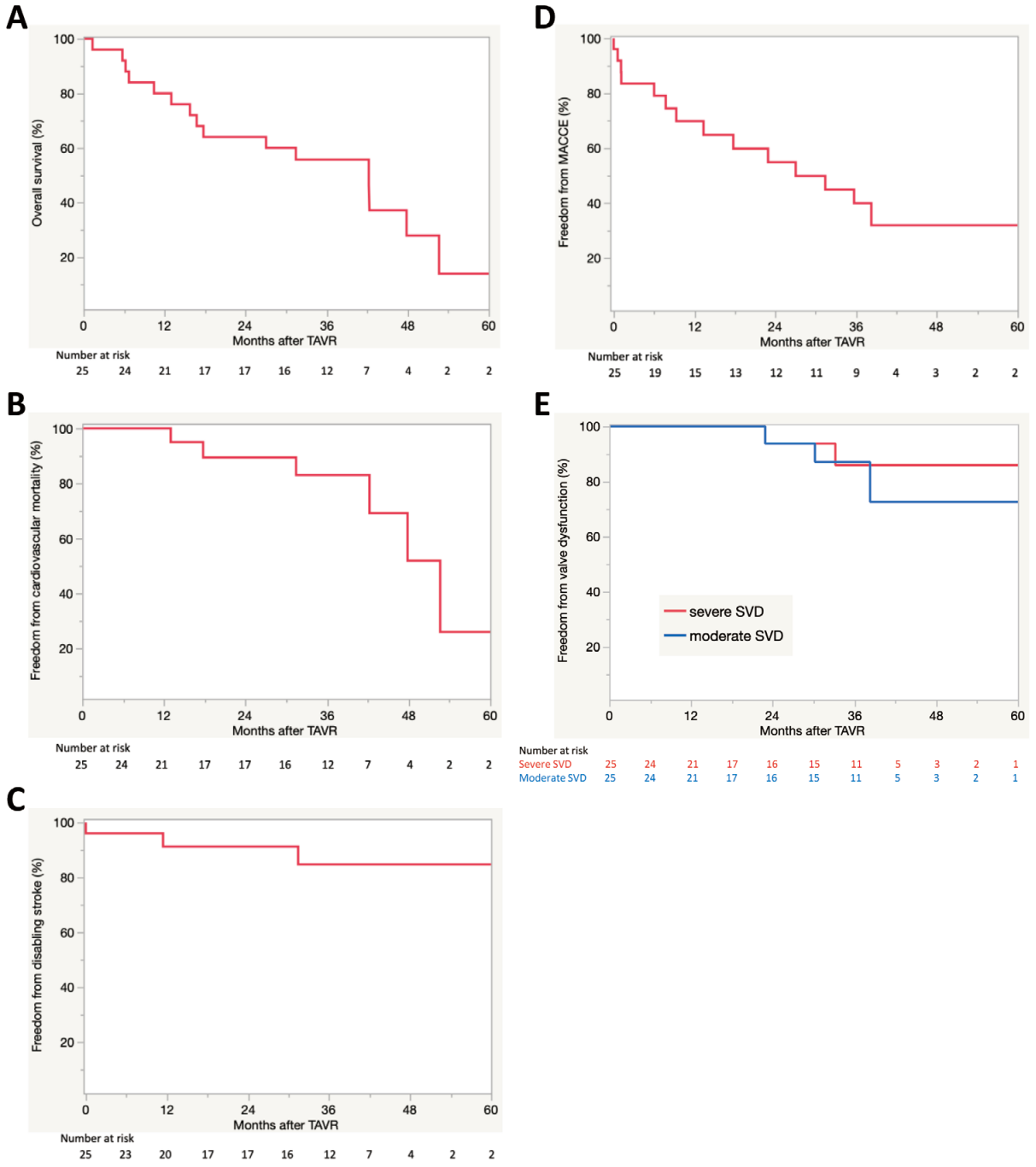

Figure. Kaplan-Meier analysis of late outcomes after transcatheter aortic valve replacement (TAVR): (**A**) overall survival rate; (**B**) freedom from cardiovascular mortality; (**C**) freedom from disabling stroke; (**D**) freedom from major adverse cardiac and cerebrovascular events (MACCE); and (**E**) freedom from valve dysfunction. SVD, structural valve deterioration.

This study was approved by the Institutional Review Board of Osaka University in Japan and all patients provided written informed consent.

Statistical Analysis

Continuous variables are presented as mean±SD or median (IQR), and categorical variables as n (%). Overall survival and freedom from cardiovascular mortality analyses were performed using the Kaplan-Meier method, with patient data censored as of the last date known to be alive. Logistic regression analysis was performed to examine predictors of late mortality. Freedom from disabling stroke, prosthetic valve dysfunction, and MACCE event analyses were also performed using the Kaplan-Meier method. One patient

Table 4. Indicators of Increased Late Mortality After TAVR

Subgroup	No. deaths (%)	HR (95%CI)	P-value
Age (years)			0.90
≥80	5/8 (62.5)	1.07 (0.33–3.14)	
<80	10/17 (58.8)	0.93 (0.32–3.06)	
Sex			1.0
Female	7/10 (70.0)	1.00 (0.35–2.99)	
Male	8/15 (53.3)	1.00 (0.34–2.89)	
BSA (m^2)			0.82
≥1.50	8/13 (53.3)	0.88 (0.30–2.59)	
<1.50	7/12 (58.3)	1.13 (0.39–3.32)	
BMI (kg/m^2)			0.34
≥20	12/17 (70.6)	1.81 (0.56–8.1)	
<20	3/8 (37.5)	0.55 (0.12–1.79)	
Duration of HD (years)			0.59
≥10	5/9 (55.6)	0.73 (0.20–2.20)	
<10	10/16 (66.7)	1.37 (0.45–5.01)	
DM (insulin dependent)			0.14
Yes	3/3 (100)	2.97 (0.65–10.3)	
No	12/22 (54.6)	0.33 (0.10–1.54)	
PVD			0.31
Yes	9/12 (75.0)	1.69 (0.61–5.05)	
No	6/13 (46.2)	0.59 (0.20–1.65)	
Previous CABG			0.15
Yes	6/8 (75.0)	2.29 (0.73–6.98)	
No	9/17 (52.9)	0.44 (0.14–1.37)	
EF (%)			0.064
≥50	11/21 (73.3)	0.28 (0.084–1.08)	
<50	4/4 (100)	3.55 (0.92–11.9)	
Total calcium (HU ≥650; mm^3)			0.037
≥500	10/13 (76.9)	3.25 (1.07–12.0)	
<500	4/11 (36.4)	0.31 (0.083–0.93)	
BNP (pg/mL)			0.037
≥1,000	7/9 (77.8)	3.23 (1.06–10.1)	
<1,000	8/16 (50.0)	0.31 (0.099–0.94)	
Alb (g/dL)			0.038
≥3.0	9/19 (47.4)	0.30 (0.10–0.93)	
<3.0	6/6 (100)	3.35 (1.08–9.67)	
STS (%)			0.23
≥12	7/10 (70.0)	1.91 (0.65–5.62)	
<12	8/15 (53.3)	0.52 (0.18–1.53)	

Alb, albumin; BNP, brain natriuretic peptide. Other abbreviations as in tables 1,2.

(patient 7) with severe paravalvular leakage due to delayed valve migration 13 months after TAVR was excluded from the analysis of valve dysfunction due to the potential for technical failure. Statistical analyses were performed using JMP Pro, version 14.0.0 (SAS Institute, Cary, NC, USA).

Results

Twenty-five dialysis patients who underwent TAVR at the present institution between April 2012 and January 2016 were enrolled in this study. The patients were considered to be inoperable or too high-risk for conventional aortic valve surgery. Mean age was 76.5 years, mean STS score was 14.7%, and 60% of participants were men. Previous coronary artery bypass grafting was identified in 8 patients (32.0%) and diabetes mellitus (DM)-related nephropathy in 5 (20.0%). Mean duration of dialysis was 11.1 years (range, 1–38 years). **Table 1** lists the demographic and baseline characteristics inclusive of comorbidities. **Table 2** lists the in-hospital outcomes. The transfemoral (TF) and transapical (TA) approaches were performed on 10 patients (40.0%; femoral, 9; iliac, 1) and on 15 patients (60.0%), respectively. The SAPIEN XT (THV 9300) and the SAPIEN (THV 9000) were implanted in 18 (72.0%) and in 7 patients (28.0%), respectively. In the cases of SAPIEN and SAPIEN XT, TA approach was performed in 4 (57.1%) and in 11 patients (61.1%), respectively. All bioprostheses were successfully implanted and there was no conversion to surgical aortic valve replacement (SAVR). Mean intensive care unit stay was 2.5 days, and conventional dialysis (non-continu-

Table 5. Valve Dysfunction After TAVR During Follow-up

Patient ID no.	THV	Postoperative anticoagulants and antiplatelet agents	Dysfunction	Valve durability (months)	Outcome
1	SAPIEN (THV9000)	DAPT	Severe stenosis	23	Alive (SAVR for re-stenosis 8 months after TAV-in-TAV)
8	SAPIEN XT (THV9300)	SAPT	Severe stenosis+ moderate AR	38	Death (unknown reason 7 months after TAV-in-TAV)
12	SAPIEN XT (THV9300)	SAPT	Severe stenosis+ moderate AR	35	Alive (13 months after TAV-in-TAV)

DAPT, dual antiplatelet therapy; SAPT, single antiplatelet therapy; TAV-in-TAV, transcatheter aortic valve in transcatheter aortic valve; THV, transcatheter heart valve. Other abbreviations as in tables 1,2.

ous hemodiafiltration) was reinitiated at postoperative day 1 in 20 patients (80.0%) and at postoperative day 2 in 5 (20.0%). A total of 23 patients (92.0%) were discharged, and the median hospital stay after TAVR was 9 days (IQR, 7.5–11 days). Mortality at 30 days and hospital mortality were not observed.

Fifteen patients died during the follow-up, and **Table 3** lists the causes of death in detail. The overall survival rate at 1 and 3 years was 80.0% and 55.7%, respectively (follow-up period, 879±493 days; range, 40–1,826 days; **Figure A**). In contrast, freedom from cardiovascular mortality at 1 and 3 years was 100% and 83.0%, respectively (**Figure B**). Severe paravalvular leakage due to delayed valve migration 13 months after the first TAVR occurred in 1 patient with previous coronary artery bypass grafting (patient 7). On retrospective investigation using CT, this was found to be caused by an initial lower site of implantation, as previously reported.[1] Although re-TAVR (transcatheter AVR in transcatheter aortic valve: TAV-in-TAV) was performed, this patient died from heart failure 6 months after re-TAVR. One patient (patient 5) died from subarachnoid hemorrhage 31 months after TAVR. On logistic regression analysis, lower left ventricular function, greater amount of calcium on the aortic root, higher B-type natriuretic peptide, and lower albumin were associated with increased late mortality (**Table 4**). Freedom from disabling stroke at 1 and 3 years was 91.2% and 84.7%, respectively (**Figure C**). One patient (patient 3) was hospitalized for gastrointestinal bleeding (life-threatening bleeding) 1 month after TAVR. Freedom from MACCE at 1 and 3 years was 69.8% and 39.9%, respectively (**Figure D**).

Valve Dysfunction

Table 5 lists valve dysfunctions during follow-up. Three patients required redo-TAVR (TAV-in-TAV) for valve dysfunction at 23, 36, and 38 months after first TAVR, respectively. Of these, 1 patient (patient 1) underwent SAVR using a mechanical prosthesis for re-stenosis of the transcatheter valve 8 months after re-TAVR. Freedom from moderate and severe SVD at 3 years was 87.1% and 85.9%, respectively (**Figure E**). Of the 3 patients with valve dysfunction, 1 patient (patient 1) has been given dual antiplatelet therapy and the others (patients 8 and 12) have been given single antiplatelet therapy after TAVR. One patient (patient 22), who had taken only aspirin, required an anticoagulation agent for prosthesis thrombosis. The symptoms and valve function improved after anticoagulation treatment.

Discussion

The present study has reported satisfactory early outcomes of TAVR in dialysis patients, but various problems occurred in the midterm outcomes. The in-hospital mortality after TAVR in dialysis patients was reported to be approximately 10–15%,[2–5] which was poorer compared with that of non-dialysis patients.[2,4,5] In contrast, Alkhalil et al concluded that TAVR and SAVR in dialysis patients had similar in-hospital mortality.[3] They also mentioned, however, that TAVR was associated with a shorter length of stay, lower hospitalization costs, fewer in-hospital complications, and higher rates of hospital discharge. Although the present study was not a comparative study, satisfactory outcomes such as short hospital stay after TAVR (median, 9 days) and high rate of hospital discharge (92.0%) were achieved even with extremely high-risk patients.

Little is known, however, about late outcomes after TAVR in dialysis patients. At 1 and 3 years, the overall survive rate and the rate of freedom from MACCE in this study were 80.0% and 55.7%, 69.8% and 39.9%, respectively. These outcomes were relatively poorer compared with those in non-dialysis patients according to the 5-year outcomes of the first pivotal clinical trial of TAVR in Japan (PREVAIL JAPAN; the overall survival rate and the rate of freedom from MACCE at 1 and 3 years were 85.3% and 63.6%, 74.0 and 59.9%, respectively).[9] These differences may be explained by the extremely high-risk cohort (mean STS score, 14.7%) in this study. Regarding the causes of death in this study, infection was the leading cause (53.3%), whereas heart failure was relatively low (6.7%). This trend is somewhat similar to the current trend in Japanese dialysis patients: the Japanese Society for Dialysis Therapy renal data registry[6] reported that infections are increasing, whereas heart failure is the leading cause of death. This indicates that important problems particular to dialysis patients still remain, even though TAVR could prevent heart failure. Of 8 patients who died from infection, 5 (62.5%) died from gastrointestinal diseases (gastrointestinal perforation) or orthopedic diseases (osteomyelitis and pyogenic spondylitis). Gastrointestinal complications in dialysis patients are associated with amyloid deposition in the gastrointestinal wall (gastrointestinal amyloidosis),[10] and osteomyelitis was caused by arteriosclerosis obliterans. Furthermore, dialysis patients are generally prone to infection for various reasons. Leakage of nutrients due to the dialysis membrane and/or poor intake of nutrients due to dietary restrictions are possible reasons. Leukocyte dysfunction and skin infection have also been reported. In this study, on Cox regression hazard analysis, hypoalbumin-

emia was a predictor of all-cause mortality, meaning that preoperative nutritional status might affect late outcome. This study, however, could not detect or examine these factors due to the small number of patients.

Valve selection in SAVR in dialysis patients is still controversial. In terms of durability of surgical bioprostheses, surgeons have believed that mechanical valves are superior to bioprosthetic valves because a rapid degeneration of bioprostheses was observed in these patients after SAVR.[11] Because, however, these patients are considered to have a higher rate of bleeding events, mechanical prostheses requiring anticoagulants have been limited to younger patients. In contrast, little is known about the long-term durability of transcatheter valves in dialysis patients, while 5-year durability of transcatheter valve in non-dialysis patients were reported.[12,13] The PARTNER trial reported no valve dysfunction for 5 years and PREVAIL JAPAN reported that valve dysfunction was observed in only 1 patient (3.1% at 5 years).[9] In contrast, Overtchouk et al noted that chronic renal failure led to a higher risk of transcatheter bioprosthetic dysfunction.[14] In the present study, early valve dysfunction was found in 3 patients. One patient (patient 1) required a TAV-in-TAV for stenosis of transcatheter valve approximately 2 years after TAVR, but because re-stenosis occurred in the second valve, this patient ultimately underwent SAVR using a mechanical valve, considering the limitations of bioprostheses. Another 2 patients had severe AS and moderate AR, which occurred approximately 3 years after TAVR. Because TAV-in-TAV was not reimbursed, dialysis patients who are older and/or patients with a relative short life expectancy should be considered as candidates for TAVR. Therefore, prudent preoperative assessments should be mandatory when deciding on the indication for TAVR in dialysis patients.

Postoperative anticoagulants and antiplatelet agents are still controversial in transcatheter valve therapy.[14–16] Recently, only anticoagulant agents were reported to prevent bioprosthetic transcatheter valve dysfunction.[14] Hemorrhagic events, however, are reported to be more frequent with their use, particularly in dialysis patients.[17,18] Therefore, aspirin is taken by patients after TAVR primarily, and additional antiplatelet agents and/or anticoagulation agents should be taken only according to patient background.

In this study, cost-effectiveness was not investigated because these patients underwent TAVR supported by AMT. Alkhalil et al reported that TAVR in dialysis patients was associated with a lower hospitalization cost compared with SAVR.[3] Further studies including randomized trials are needed, however, to assess the cost-effectiveness of this treatment, given that the cost of the device differs between countries.

Study Limitations

This study had several limitations. It was a single-center study with a non-randomized design, with a small number of enrolled patients and a short follow-up period. Also, the cohort included a small number of DM-related nephropathy patients (5 patients, 20.0%). This condition is significantly associated with early and midterm mortality in dialysis patients.[11,19,20] Moreover, in this study, the TA approach was used in 57.1% of the SAPIEN cases and in 61.1% of the SAPIEN XT cases. This may indicate that dialysis patients have poor access compared with non-dialysis patients. The devices in this study, however, were first-generation devices. Therefore, a clinical trial using SAPIEN 3 in dialysis Japanese patients is needed.

Conclusions

Satisfactory in-hospital outcomes after TAVR were achieved in 25 dialysis patients. Problems such as complications particular to dialysis patients and valve durability, however, remained at midterm follow-up. Further studies involving randomized trials are needed to solve these problems, and prudent preoperative assessments should be mandatory.

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Disclosures

The authors declare no conflicts of interest.

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Supplementary Files

Please find supplementary file(s);
http://dx.doi.org/10.1253/circj.CJ-19-0101