Early mortality and safety after transcatheter aortic valve replacement using the SAPIEN 3 in nonagenarians

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Abstract

Background Transcatheter aortic valve replacement (TAVR) has been performed for many elderly patients with severe aortic stenosis (AS). The SAPIEN 3 is one of the latest balloon-expandable prosthesis. This study aimed to investigate the early clinical outcomes after TAVR using the SAPIEN 3 in nonagenarians.

Methods A total of 97 consecutive patients underwent TAVR for severe AS between December 2015 and December 2016. Of these, 85 consecutive patients who underwent TAVR using the SAPIEN 3 were included. According to the age, patients were classified into age ≥ 90 years group (17 patients) or age < 90 years group (68 patients). The clinical outcomes including all-cause mortality and composite endpoint of early safety at 30 days were evaluated.

Results The Society of Thoracic Surgeons score in age ≥ 90 years group was higher than age < 90 years group (12.3 ± 6.1% vs. 8.5 ± 5.1%, P < 0.01). There was no significant difference in 30-day mortality between the two groups. However, the life-threatening bleeding and major vascular complications in age ≥ 90 years group were greater than age < 90 years group (11.8% vs. 1.5%, P = 0.04 and 11.8% vs. 1.5%, P = 0.04, respectively). The composite endpoint of early safety at 30 days was similar between the two groups. Multivariate logistic regression analysis showed that prior myocardial infarction was an independent predictor of the composite endpoint of early safety (odds ratio: 4.76, 95% confidence interval: 1.02–22.21, P = 0.047).

Conclusions The early mortality and safety after TAVR using the SAPIEN 3 in nonagenarians were similar and acceptable despite of higher operative risk.

Keywords: Nonagenarians; SAPIEN 3; Transcatheter aortic valve replacement;

1 Introduction

The number of patients with severe aortic stenosis (AS) has been increasing, which significantly reduces quality of life and survival in the elderly.[1] However, the elderly patients with severe symptomatic valve disease are not referred to surgery because of significant multiple comorbidities or advanced age.[2] Transcatheter aortic valve replacement (TAVR) has emerged as a viable treatment option for patients with severe AS who are inoperable or at high surgical risk, prolonging survival and improving quality of life in the majority of patients.[3] Previous study has reported outcomes of TAVR in the very elderly and higher short-time mortality rate.[4] The development of novel transcatheter heart valves and further iterations of delivery systems and prosthesis have contributed to decrease in complications rates in TAVR.[5] The Edwards SAPIEN 3 Transcatheter Heart Valve (Edwards lifesciences, Irvine, CA) is one of the latest development balloon-expandable prosthesis. The SAPIEN 3 can diminish vascular complication and paravalvular regurgitation.[6] However, there is little information about the early clinical outcomes after TAVR using the SAPIEN 3 in nonagenarians. Thus this study investigated the early clinical outcomes after TAVR using the SAPIEN 3 in nonagenarians.

2 Methods

2.1 Patients

Between December 2015 and December 2016, a total of 97 consecutive patients underwent TAVR for severe AS at Englewood Hospital and Medical Center. Symptomatic severe AS was defined as having an aortic valve area (AVA)
based on supra-annular aortography. Prosthesis position and (TEE) for procedural guidance. Device positioning was received fluoroscopy and transeosophageal echocardiography to patient anatomy, comorbidities, and physician discretion. The access approach was determined by CT scans based on patient size was measured for the appropriate size of valve. The access approach was determined by CT scans based on patient anatomy, comorbidities, and physician discretion.

TAVR was performed under general anesthesia and received fluoroscopy and transesophageal echocardiography (TEE) for procedural guidance. Device positioning was based on supra-annular aortography. Prosthesis position and function were evaluated by TEE. After the procedure, aortography was performed to verify the absence of coronary ostial obstruction and assess the degree of aortic regurgitation. Vascular access site closure was achieved by two Proglide devices (Abbott Vascular, Abbott Park, IL). Aortography was performed to detect ilio-femoral complications. And all patients were further evaluated postprocedural echocardiographic findings after TAVR by TTE.

Three commercially available valves were used at the same period in this study. The SAPIEN 3 and SAPIEN XT (Edwards lifesciences, Irvine, CA) are balloon-expandable prostheses and deployed under rapid pacing. The SAPIEN XT was used in the valve-in-valve cases for prior surgical aortic valve replacement. The CoreValve (Medtronic, Minneapolis, MN) is a self-expandable prosthesis. The CoreValve was preferred when high risks for annular rupture or repeated rapid pacing were anticipated. The CoreValve was used in 10 cases. Patients who were used the SAPIEN XT and CoreValve were excluded to eliminate the differences of prosthesis in this study.

Postprocedural antiplatelet therapy for patients without indication for oral anticoagulation consisted of low-dose of aspirin and clopidogrel 75 mg daily.

2.2 Procedure

Eligibility for TAVR was established by the local heart team including interventional cardiologists and cardiothoracic surgeons. Each patient underwent extensive preoperative evaluation to assess risk factors. Based on preoperative imaging, including CT scans and echocardiography, annulus size was measured for the appropriate size of valve. The access approach was determined by CT scans based on patient anatomy, comorbidities, and physician discretion.

TAVR was performed under general anesthesia and received fluoroscopy and transesophageal echocardiography (TEE) for procedural guidance. Device positioning was based on supra-annular aortography. Prosthesis position and function were evaluated by TEE. After the procedure, aortography was performed to verify the absence of coronary ostial obstruction and assess the degree of aortic regurgitation. Vascular access site closure was achieved by two Proglide devices (Abbott Vascular, Abbott Park, IL). Aortography was performed to detect ilio-femoral complications. And all patients were further evaluated postprocedural echocardiographic findings after TAVR by TTE.

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Postprocedural antiplatelet therapy for patients without indication for oral anticoagulation consisted of low-dose of aspirin and clopidogrel 75 mg daily.

2.3 Clinical outcome

Baseline demographic and clinical data along with in-hospital outcomes were obtained by review of the medical records and procedural reports. Clinical follow-up data were obtained from outpatient record reviews. Mortality, myocardial infarction, stroke and transient ischemic attack, bleeding, acute kidney injury, vascular complication were defined according to the Valve Academic Research Consortium-2 (VARC-2).[8] The composite endpoint of early safety at 30 days included all-cause death, all stroke, life-threatening bleeding, acute kidney injury stage 2 or 3, coronary artery obstruction requiring intervention, major vascular complication and valve-related dysfunction requiring repeat procedure.

2.4 Statistical analysis

Statistical analysis was performed with SAS version 9.4 (SAS Institute, Cary, NC). Continuous variables are expressed as mean ± SD and categorical variables as frequency (%). Continuous variables were compared using Student’s t-test or analysis of variance. Categorical variables were compared with chi-square statistics or Fisher’s exact test. Multivariate logistic regression analysis was used to identify independent predictors of the composite endpoint of early safety at 30 days. Univariate analysis of factors affecting the composite endpoint of early safety was performed using factors in Tables 1–3. Variables with P < 0.20 in univariate analysis were included in the multivariate analysis. P < 0.05 was considered significant.

3 Results

Baseline clinical characteristics are presented in Table 1. Weight, body mass index and body surface area in age ≥ 90 years group were lower than in age < 90 years group. Patients aged ≥ 90 years with past history of coronary artery disease and prior myocardial infarction were less than patients age < 90 years with those. On the other hand, the Society of Thoracic Surgeons score in age ≥ 90 years was significantly higher than age < 90 years group (12.3 ± 6.1% vs. 8.5 ± 5.1%, P < 0.01). There was no significant difference in prevalence of New York Heart Association class III or IV between the two groups.

The echocardiographic and angiographic characteristics before TAVR are listed in Table 2. AVA and mean aortic valve gradient, left ventricular ejection fraction on transthoracic echocardiogram and cardiac catheterization before TAVR were similar between the two groups. The preva-
Table 1. Baseline characteristics.

|                                | Nonagenarians; age ≥ 90 yrs (n = 17) | Others; age < 90 yrs (n = 68) | P value |
|--------------------------------|-------------------------------------|-------------------------------|---------|
| Age, yrs                       | 92.7 ± 2.2                          | 81.5 ± 6.3                    | < 0.0001|
| Male                           | 8 (47.1%)                           | 38 (55.9%)                    | 0.51    |
| Height, cm                     | 167.3 ± 13.7                        | 168.1 ± 12.4                  | 0.82    |
| Weight, kg                     | 60.0 ± 10.7                         | 74.6 ± 16.6                   | < 0.001 |
| Body mass index, kg/m²         | 21.6 ± 3.6                          | 26.4 ± 4.8                    | < 0.001 |
| Body surface area, m²          | 1.67 ± 0.19                         | 1.84 ± 0.24                   | < 0.01  |
| New York Heart Association class III/IV | 11 (64.7%)                       | 41 (60.3%)                    | 0.74    |
| Peripheral artery disease      | 6 (35.3%)                           | 19 (27.9%)                    | 0.55    |
| Coronary artery disease        | 7 (41.2%)                           | 46 (67.6%)                    | 0.04    |
| Prior myocardial infarction    | 1 (5.9%)                            | 25 (36.8%)                    | 0.01    |
| Prior percutaneous coronary intervention | 2 (11.8%)                       | 28 (41.2%)                    | 0.02    |
| Prior pacemaker implantation   | 0                                   | 1 (1.5%)                      | 0.62    |
| Prior cerebrovascular event    | 4 (23.5%)                           | 22 (32.4%)                    | 0.48    |
| Prior cardiac surgery          | 3 (17.6%)                           | 17 (25.0%)                    | 0.52    |
| Hypertension                   | 16 (94.1%)                          | 60 (88.2%)                    | 0.48    |
| Dyslipidemia                   | 14 (82.4%)                          | 58 (85.3%)                    | 0.76    |
| Diabetes mellitus              | 2 (11.8%)                           | 24 (35.3%)                    | 0.06    |
| Atrial fibrillation            | 7 (41.2%)                           | 20 (29.4%)                    | 0.35    |
| Current smokers                | 0 (0.0%)                            | 9 (13.2%)                     | 0.11    |
| Chronic obstructive pulmonary disease | 2 (11.8%)                       | 10 (14.7%)                    | 0.76    |
| Chronic kidney disease         | 7 (41.2%)                           | 28 (41.2%)                    | > 0.99  |
| Society of Thoracic Surgeons score, % | 12.3% ± 6.1                        | 8.5% ± 5.1%                   | < 0.01  |

Laboratory data

|                                |                                |                                |         |
|--------------------------------|--------------------------------|--------------------------------|---------|
| Serum creatinine, mg/dL         | 1.02 ± 0.28                    | 1.51 ± 1.63                    | 0.23    |
| Serum albumin, g/dL             | 3.7 ± 0.4                      | 3.9 ± 0.4                      | 0.08    |
| Hemoglobin, g/dL                | 12.3 ± 1.6                     | 12.1 ± 1.4                     | 0.55    |

Medication

|                                |                                |                                |         |
|--------------------------------|--------------------------------|--------------------------------|---------|
| Aspirin                        | 15 (88.2%)                     | 66 (97.1%)                     | 0.12    |
| Clopidogrel                     | 11 (64.7%)                     | 51 (75.0%)                     | 0.39    |
| Antitrombin K                   | 4 (23.5%)                      | 9 (13.2%)                      | 0.29    |

Data are presented as mean ± SD or n (%).

Table 2. Baseline echocardiographic and angiographic characteristics.

|                                | Nonagenarians; age ≥ 90 yrs (n = 17) | Others; age < 90 yrs (n = 68) | P value |
|--------------------------------|-------------------------------------|-------------------------------|---------|
| Baseline echocardiographic     |                                     |                               |         |
| Left ventricular ejection fraction | 58.8% ± 11.7%                   | 58.4% ± 9.7%                   | 0.89    |
| Aortic valve area, cm²         | 0.62 ± 0.11                       | 0.69 ± 0.17                    | 0.13    |
| Indexed aortic valve area, cm²/m² | 0.38 ± 0.09                     | 0.35 ± 0.08                    | 0.30    |
| Peak velocity, m/s             | 4.09 ± 0.53                       | 4.12 ± 0.83                    | 0.90    |
| Peak gradient, mmHg            | 68.6 ± 17.8                       | 68.3 ± 21.8                    | 0.96    |
| Mean gradient, mmHg            | 41.5 ± 12.6                       | 43.9 ± 15.1                    | 0.55    |
| Aortic regurgitation ≥ moderate | 3 (17.6%)                       | 9 (13.2%)                      | 0.64    |
| Mitral regurgitation ≥ moderate | 10 (58.8%)                      | 25 (36.8%)                     | 0.10    |
| Pulmonary hypertension ≥ moderate | 6 (35.3%)                      | 12 (17.6%)                     | 0.11    |
| Baseline cardiac catheterization |                                    |                               |         |
| Coronary artery disease        | 2 (11.8%)                        | 28 (41.2%)                     | 0.02    |
| Multivessel disease            | 1 (5.9%)                         | 8 (11.8%)                      | 0.48    |
| Left ventricular ejection fraction, % | 51.3% ± 13.6%                 | 56.7% ± 9.3%                   | 0.11    |
| Aortic valve area, cm²         | 0.60 ± 0.22                      | 0.67 ± 0.24                    | 0.33    |
| Mean gradient, mmHg            | 41.5 ± 16.1                      | 43.7 ± 19.8                    | 0.72    |
| Systolic pulmonary artery pressure, mmHg | 46.8 ± 15.4                  | 45.8 ± 12.6                    | 0.78    |

Data are presented as mean ± SD or n (%).

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Table 3. Procedural and postprocedural echocardiographic characteristics.

| Procedural                                                                 | Nonagenarians: age ≥ 90 yrs (n = 17) | Others: age < 90 yrs (n = 68) | P value |
|----------------------------------------------------------------------------|--------------------------------------|-------------------------------|---------|
| Transfemoral approach                                                     | 17 (100.0%)                          | 68 (100.0%)                   | NA      |
| Predilatation                                                             | 15 (88.2%)                           | 61 (89.7%)                    | 0.86    |
| Postdilatation                                                            | 6 (35.3%)                            | 23 (33.8%)                    | 0.91    |
| Procedure time, min                                                        | 87.4 ± 37.3                          | 76.5 ± 31.6                   | 0.22    |
| Fluoroscopy time, min                                                      | 14.5 ± 6.6                           | 14.1 ± 8.2                    | 0.87    |
| Contrast medium volume, mL                                                 | 123.5 ± 69.3                         | 126.9 ± 45.3                  | 0.81    |
| Valves size                                                                |                                      |                               |         |
| 20 mm                                                                     | 3 (17.6%)                            | 6 (8.8%)                      | 0.67    |
| 23 mm                                                                     | 6 (35.3%)                            | 24 (35.3%)                    |         |
| 26 mm                                                                     | 6 (35.3%)                            | 24 (35.3%)                    |         |
| 29 mm                                                                     | 2 (11.8%)                            | 14 (20.6%)                    |         |
| Postprocedural echocardiographic                                          |                                      |                               |         |
| Left ventricular ejection fraction                                         | 62.4% ± 10.6%                        | 61.3% ± 10.1%                 | 0.70    |
| Effective orifice area, cm²                                               | 1.85 ± 0.35                          | 1.61 ± 0.35                   | 0.36    |
| Indexed effective orifice area, cm²/m²                                     | 1.14 ± 0.15                          | 0.90 ± 0.22                   | 0.16    |
| Peak velocity, m/s                                                        | 2.29 ± 0.43                          | 2.31 ± 0.44                   | 0.89    |
| Peak gradient, mmHg                                                        | 20.5 ± 8.7                           | 21.6 ± 10.1                   | 0.73    |
| Mean gradient, mmHg                                                        | 11.1 ± 4.7                           | 11.7 ± 5.0                    | 0.72    |
| Aortic regurgitation ≥ moderate                                            | 0                                    | 3 (4.4%)                      | 0.38    |
| Mitral regurgitation ≥ moderate                                            | 10 (58.8%)                           | 24 (35.3%)                    | 0.08    |
| Pulmonary hypertension ≥ moderate                                          | 5 (29.4%)                            | 15 (22.1%)                    | 0.54    |

Data are presented as mean ± SD or n (%). NA: not applicable.

The procedural and postprocedural echocardiographic characteristics are presented in Table 3. The SAPIEN 3 could be implanted in all patients by transfemoral approach. There was no significant difference in procedural characteristics and valve size with the two groups. Furthermore, there was no significant difference in mean aortic valve gradient and the presence of aortic regurgitation moderate or severe after TAVR between the two groups.

The postprocedural clinical outcomes at 30 days after TAVR defined by VARC-2 were shown in Table 4. There was no significant difference in 30-day mortality between the two groups (0 vs. 4.4%, P = 0.38). On the other hand, the life-threatening bleeding and major vascular complications in age ≥ 90 years group were greater than age < 90 years group (11.8% vs. 1.5%, P = 0.04 and 11.8% vs. 1.5%, P = 0.04, respectively). However, the composite endpoint of early safety at 30 days was similar between the two groups (17.6% vs. 10.3%, P = 0.40) (Figure 1).

Table 4. Postprocedural outcomes at 30 days.

|                        | Age ≥ 90 yrs (n = 17) | Age < 90 yrs (n = 68) | P value |
|------------------------|-----------------------|-----------------------|---------|
| Hospital stay after procedure, day | 4.1 ± 1.2            | 4.3 ± 4.0             | 0.87    |
| All-cause mortality     | 0                     | 3 (4.4%)              | 0.38    |
| Hospitalization for congestive heart failure | 1 (5.9%)            | 2 (2.9%)              | 0.56    |
| Myocardial infarction   | 0 (0.0%)              | 1 (1.5%)              | 0.62    |
| Stroke and transient ischemic attack | 0 (0.0%)        | 1 (1.5%)              | 0.62    |
| Life-threatening bleeding, Major bleeding | 2 (11.8%)          | 1 (1.5%)              | 0.04    |
| Red blood cells transfusion | 3 (17.6%)          | 6 (8.8%)              | 0.29    |
| Acute kidney injury stage 2/3 | 1 (5.9%)            | 4 (5.9%)              | > 0.99  |
| Major vascular complications | 2 (11.8%)          | 1 (1.5%)              | 0.04    |
| Minor vascular complications | 2 (11.8%)          | 8 (11.8%)             | > 0.99  |
| New pacemaker implantation | 2 (11.8%)          | 6 (8.8%)              | 0.71    |
| Ventricular fibrillation  | 0                     | 2 (2.9%)              | 0.47    |
| Conversion to open surgery   | 0                     | 0                     | NA      |
| Cardiogenic shock         | 0                     | 2 (2.9%)              | 0.47    |
| Acute coronary obstruction | 0                     | 0                     | NA      |
| Cardiac tamponade         | 0                     | 0                     | NA      |
| Repeat procedure          | 0                     | 0                     | NA      |

Data are presented as mean ± SD or n (%). NA: not applicable.
4 Discussion

The present study investigated the early clinical outcomes after TAVR using the SAPIEN 3 in nonagenarians. The Society of Thoracic Surgeons score in nonagenarians was significantly higher than younger patients. There was no significant difference in 30-day mortality between nonagenarians and others. However, the life-threatening bleeding and major vascular complications in patients aged ≥ 90 years was greater than patients aged < 90 years. The composite endpoint of early safety at 30 days including all-cause death, all stroke, life-threatening bleeding, acute kidney injury stage 2 or 3, coronary artery obstruction requiring intervention, major vascular complication and valve-related dysfunction requiring repeat procedure was similar between nonagenarians and others.

As the prevalence of severe symptomatic AS increases with age, the need for treatment of nonagenarians with this disease has become more frequent.[9] Previous study has shown that surgical aortic valve replacement can be safe in octogenarians.[10] However, nonagenarians are more frail and have more comorbid conditions compared with younger cohorts, and surgical aortic valve replacement might be precluded in nonagenarians.[11] Previous trials demonstrated that TAVR significantly reduced mortality compared to medical therapy and was comparable to surgical aortic valve replacement among high-risk patients.[12,13]

Yamamoto, et al.[14] previously demonstrated that no statistically significant difference was found between TAVR patients aged ≥ 90 years and aged < 90 years with respect to the 30-day mortality rates (15% vs. 6%, P = 0.22). On the other hand, in the insights from the Society of Thoracic Surgeons/American College of Cardiology TVT (Transcatheter Valve Therapy), a 30-day mortality rate of 8.8% after TAVR in nonagenarians, and the mortality rate for nonagenarians remained higher than that of 5.9% observed in younger patients.[4] In the present study, a 30-day mortality rate was 0 after TAVR using the SAPIEN 3 in nonagenarians although the Society of Thoracic Surgeons score was high.

The SAPIEN 3 is the improved generation of balloon-expandable prostheses and has been designed to address the problem of paravalvular aortic regurgitation and to deliver with a lower profile.[15] In the Placement of Aortic Transcatheter Valves (PARTNER) trial, paravalvular aortic regurgitation was more frequent after TAVR than after surgery and moderate or severe paravalvular aortic regurgitation was seen in 11.8% of patients implanted with the previous balloon-expandable prosthesis.[12] Patients with moderate or severe paravalvular aortic regurgitation have the lower short-term survival than those with trivial or mild paravalvular aortic regurgitation.[16,17] In this study, moderate or severe paravalvular aortic regurgitation was shown in 3.5% of all patients after TAVR using the SAPIEN 3. There was no significant difference in moderate or severe paravalvular aortic regurgitation between nonagenarians and others (0 vs. 4.4%; P = 0.38).

Increased age might heighten the risk of particular post-procedural complications.[4] In the PARTNER trial for high risk patients, the TAVR cohort had higher rates of 30-day complications compared with surgical patients, with rates of major vascular events (11.0% vs. 3.2%, P < 0.001).[13] In the present study, major vascular complications were demon-

Table 5. Predictors of composite endpoint of early safety.

| Variable                  | Univariate OR (95% CI) | P value | Multivariate OR (95% CI) | P value |
|---------------------------|------------------------|---------|--------------------------|---------|
| Prior myocardial infarction| 4.13 (1.05–16.15)      | 0.04    | 4.76 (1.02–22.21)        | 0.047   |
| Atrial fibrillation       | 2.41 (0.63–9.16)       | 0.19    | 2.47 (0.54–11.35)        | 0.25    |
| Hemoglobin                | 0.73 (0.45–1.16)       | 0.18    | 0.73 (0.43–1.23)         | 0.23    |
| Left ventricular ejection fraction | 0.96 (0.97–1.16) | 0.19    | 0.97 (0.97–1.17)         | 0.19    |
| Procedure time            | 1.02 (1.01–1.03)       | 0.04    | 1.01 (0.99–1.03)         | 0.19    |
strated in 3.5% of all patients after TAVR using SAPIEN 3. The major vascular complications in age ≥ 90 years group were greater than age < 90 years group although there was no significant difference in minor vascular complications between the two groups. The SAPIEN 3 could reduce vascular complications, but more attention to major vascular complications was necessary for TAVR procedure in nonagenarians.

In this study, the life-threatening bleeding in patients aged ≥ 90 years was greater than those aged < 90 years. Previous study reported that life-threatening and major bleeding after TAVR occurred in approximately 15% and 20% of TAVR procedures. Toggweiler, et al. showed that marked reductions in bleeding and vascular complications could be achieved with careful patient selection and advanced interventional techniques. On the other hand, despite lower body mass index in age ≥ 90 years group than age < 90 years group, the antiplatelet therapy was similar between the two groups in the present study. Thus, the reduction of antiplatelet medication might be important to reduce the risk of bleeding in nonagenarians of lower body mass index.

Previous study indicated that New York Heart Association class and logistic EuroSCORE were independent predictive factors of cumulative 30-day mortality in octogenarians and nonagenarians. In the present study, prior myocardial infarction was an independent predictor of the composite endpoint of early safety at 30 days. This might be associated with cardiac dysfunction and prior antiplatelet therapy. The necessity for proper antiplatelet therapy after TAVR according to baseline characteristics was considered.

The early mortality and safety after TAVR using the SAPIEN 3 in nonagenarians was evaluated in this study. Despite higher operative risk of TAVR in patients aged ≥ 90 years, the composite endpoint of early safety at 30 days was similar between nonagenarians and younger populations. A possible explanation for this observation might be the advancement of TAVR in regard to valve design improvement, increased operator experience and improved procedural pre-planning. The use of the SAPIEN 3 for TAVR might be useful in nonagenarians.

There are some limitations in the present study. The sample size is small and this is a single-center nonrandomized study. In this study, the use of a self-expandable prosthesis was not included to eliminate the differences of prosthesis. However, there might be a selection bias between devices. This was a retrospective study with a small number of patients. This might be associated with no significant difference in all-cause mortality between the two groups. In the present study, the assessment of quality of life such as the Kansas City Cardiomyopathy Questionnaire before and after TAVR was not evaluated. This study was included only early clinical outcomes. Further studies with a larger number of patients and longer follow-up are required to evaluate usefulness of TAVR using the SAPIEN 3 in nonagenarians to predict the clinical events.

In conclusions, the early mortality after TAVR using the SAPIEN 3 in nonagenarians was similar in younger population despite of higher operative risk. The life-threatening bleeding and major vascular complications after TAVR were greater in nonagenarians. However, the early safety after TAVR using the SAPIEN 3 in nonagenarians was similar and acceptable.

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