Clinical Outcomes of Transcatheter Aortic Valve Implantation for Native Aortic Valves in Patients with Low Coronary Heights

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Purpose: Acute coronary occlusion is a rare but fatal complication that may occur during trans-catheter aortic valve implantation (TAVI) and appears more frequently in patients with low coronary heights. We evaluated the feasibility of self-expanding valves in patients with low coronary heights undergoing TAVI.

Materials and Methods: TAVI for native aortic valve stenosis was conducted in 276 consecutive patients between 2015 and 2019 at our institute. Using multi-detector computed tomography (MDCT), information on the aortic valve, coronary arteries, and vascular anatomy in 269 patients was analyzed. Patients with low coronary heights were defined as those with coronary heights of 10 mm or less during MDCT analysis.

Results: Among the 269 patients, 29 (10.8%) patients had coronary arteries with low heights. The mean coronary height was 8.9±1.2 mm in the left coronary artery. These patients with low coronary heights were treated with self-expandable (n=28) or balloon-expandable (n=1) valves. Prophylactic coronary protection with a guidewire, balloon, or stent prepositioned down at-risk coronary arteries was not pursued in all patients. No acute coronary occlusion occurred in any of these patients during TAVI. Five patients (17.9%) died during follow-up (average of 553.8 days), including four from non-cardiogenic causes and one from a cardiogenic (aggravation of heart failure) cause.

Conclusion: A considerable number of patients with low coronary heights were observed among TAVI candidates in this study. Use of a self-expandable valve may be feasible for successful TAVI without acute coronary occlusion in patients with low coronary heights.

Key Words: Aortic valve stenosis, trans-catheter aortic valve replacement, coronary artery disease.

INTRODUCTION

Several randomized trials have demonstrated the safety and effectiveness of trans-catheter aortic valve implantation (TAVI) in patients with symptomatic severe aortic stenosis who were at low- to high-risk for adverse outcomes during conventional surgical aortic valve replacement.[1-7] Despite the wide expansion of indications for TAVI, however, the potential for various procedure-related complications still exists, including vascular/bleeding events, stroke, permanent pacemaker implantation, emergent conversion to open-heart surgery, and acute coronary occlusion.[2-9] Among these TAVI-related complications, acute or delayed coronary occlusion is a rare but devastating complication, with an overall mortality rate greater than 50%.[10,11] Previous studies have reported that the anatomical predictors for acute coronary occlusion during TAVI are a low height (≤10 mm) for the ostium of coronary arteries from aortic annuls and a small aortic sinus of Valsalva (≤30 mm).[10-13] The risk of acute coronary

occlusion may also depend on the type of TAVI valves used (e.g., self-expandable vs. balloon-expandable) and the conduct of TAVI in a native aortic valve or valve-in-valve context.[10-13] In this study, we sought to evaluate the feasibility of self-expanding valves in patients with low coronary heights undergoing TAVI for symptomatic severe stenosis.

MATERIALS AND METHODS

Between 2015 and 2019, 276 consecutive patients underwent TAVI for symptomatic severe native aortic valve stenosis at our institute. Also, two patients underwent TAVI for severe valve-in-valve stenosis during the same study period; however, these two patients were excluded from the analysis of this study. Among the 276 patients who underwent TAVI in the native aortic valve, multi-detector computed tomography (MDCT) was performed in 269 patients. The remaining seven patients did not undergo pre-TAVI MDCT because TAVI was performed in an emergent situation. Information on the aortic valve, coronary arteries, and vascular anatomy from the 269 patients was analyzed. Patients with low coronary heights were defined as those with coronary heights of 10 mm or less between the annular plane and the most inferior aspect of the coronary ostia during MDCT analysis.[10-12] This study complied with the principles of the Declaration of Helsinki and the study protocol was approved by the Institutional Review Board of Severance Hospital (IRB No: 1-2009-0018, 1-2011-0099). Written informed consent was obtained from all patients. For every patient, a multidisciplinary heart team including interventional cardiologists, imaging cardiologists, cardiothoracic surgeons, and anesthesiologists made decisions regarding eligibility for TAVI, choice of vascular approach, and type of anesthesia. The choice of transcatheter aortic valve type was made at the discretion of the operating interventional cardiologists. The implantation techniques for both valves have been described previously.[14,15] Early safety outcomes (at 30 days) and follow-up clinical outcomes were analyzed according to the Valve Academic Research Consortium-2 consensus.[16] The early safety outcomes included all-cause mortality, all stroke, life-threatening bleeding, acute kidney injury of stages 2 or 3, acute coronary occlusion requiring intervention, major vascular complications, and valve-related dysfunction requiring repeat procedure.

Continuous variables are reported as means±standard deviations. Categorical variables are reported as numbers (percentage).

RESULTS

Among 269 patients who underwent TAVI for symptomatic severe native aortic stenosis, 29 patients (10.8%) demonstrated low coronary heights ≤10 mm. The baseline clinical characteristics of the patients whose coronary height was ≤10 mm and >10 mm are described in Table 1. In patients whose coronary heights were ≤10 mm, the mean age of the included patients was 80.6±5.5 years, and most patients were female (n=24 patients; 82.8%). Pre-TAVI echocardiographic and MDCT findings for the patients whose coronary height was ≤10 mm and >10 mm are presented in Table 2. In patients whose coronary height ≤10 mm, the mean annulus area was 407.1±67.7 mm^2, and the mean perimeter diameter was 71.6±6.5 mm. The mean coronary height was 8.9±1.2 mm in the left coronary artery and 14.7±2.6 mm in the right coronary artery. Among the 29 patients with low coronary heights, the TAVI valve was delivered through the femoral artery under general anesthesia with the use of transesophageal echocardiography in 27 patients and

Table 1. Baseline Clinical Characteristics

	Total study population n=269	Patients without a low coronary height n=240	Patients with a low coronary height n=29	*p* value
Age (yr)	81.5±5.6	81.6±5.6	80.6±5.5	0.352
Male	132 (49.1)	127 (52.9)	5 (17.2)	<0.001
Follow-up duration (days)	438±363.7	422.4±352.8	553.8±425.4	0.121
STS-PROM score (%)	7.1±8.7	7.0±9.0	7.4±5.6	0.830
Hypertension	226 (84)	203 (84.6)	23 (79.3)	0.464
Diabetes mellitus	111 (41.3)	100 (41.7)	11 (37.9)	0.700
Coronary artery disease	164 (61)	147 (61.3)	17 (58.6)	0.784
Prior percutaneous coronary intervention	68 (25.3)	60 (25)	8 (27.6)	0.762
Prior acute myocardial infarction	28 (10.4)	24 (10)	4 (13.8)	0.528
Chronic obstructive airways disease	42 (15.6)	37 (15.4)	5 (17.2)	0.798
Prior cerebrovascular accident	53 (19.8)	50 (20.8)	3 (10.3)	0.203
Prior permanent pacemaker	5 (1.9)	4 (1.7)	1 (3.4)	0.502
Chronic kidney disease	138 (51.3)	124 (51.7)	14 (48.3)	0.730

STS-PROM, Society of Thoracic Surgeons Predicted Risk of Mortality.
Data are presented as mean±standard deviation or n (%).

Table 2. Echocardiographic and Multi-Detector Computed Tomography Findings

	Total study population n=269	Patients without a low coronary height n=240	Patients with a low coronary height n=29	*p* value
Multi-detector computed tomography				
Native aortic annulus				
Area (mm²)	429.8±67.6	432.8±67.3	407.1±67.7	0.142
Perimeter (mm)	74.9±6.1	75.3±5.9	71.6±6.5	0.004
Minimum diameter (mm)	20.7±2.1	20.8±2	20.2±2.7	0.244
Mean diameter (mm)	23.7±2.0	23.9±2.0	22.7±2.1	0.005
Native aortic root				
Sinus of Valsalva diameter (mm)	31.6±3.5	32±3	28.3±4.9	<0.001
Sinotubular junction diameter (mm)	28.2±3.1	28.2±3.1	27.9±3.7	0.620
Height of right coronary artery (mm)	16.7±2.6	17.0±2.5	14.7±2.6	<0.001
Height of left coronary artery (mm)	13.5±2.7	14.0±2.3	8.9±1.2	<0.001
Pre-TAVI echocardiography				
Left ventricular ejection fraction (%)	59.8±15.2	59.9±15.4	58.8±13.8	0.712
Aortic valve				
Peak pressure gradient (mm Hg)	81.0±26.5	79.3±26.2	95.2±25.0	0.002
Mean pressure gradient (mm Hg)	49.5±17.6	48.4±17.3	59.1±17.0	0.002
Mean aortic valve area (cm²)	0.7±0.2	0.7±0.2	0.6±0.2	0.007
Post-TAVI echocardiography				
Left ventricular ejection fraction (%)	61.8±14.1	61.8±14.5	62.3±10.8	0.832
Aortic valve				
Peak pressure gradient (mm Hg)	19.5±9.2	19.3±9	21.0±10.8	0.368
Mean pressure gradient (mm Hg)	9.9±4.9	9.8±4.7	10.9±6.0	0.279
Effective orifice area (cm²)	2.0±0.53	2.1±0.53	2.0±0.5	0.321

TAVI, trans-catheter aortic valve implantation.
Data are presented as means±standard deviations.

local anesthesia with sedation in two patients. Twenty-eight patients were treated with a self-expandable valve (CoreValve, Evolut R, or Evolut Pro; Medtronic, Minneapolis, MN, USA), and one patient was treated with a balloon-expandable valve (Sapien 3; Edwards Lifesciences, Irvine, CA, USA). Prophylactic coronary protection with a guidewire, balloon, or stent prepositioned down at-risk coronary arteries was not completed in all patients. No case of acute coronary occlusion occurred in any patient during TAVI. The effective orifice area of the aortic valve increased from 0.6±0.2 cm² pre-TAVI to 2.0±0.5 cm² post-TAVI (Table 2). In 240 patients with a coronary height >10 mm, a self-expandable valve was used in 147 patients, a balloon-expandable valve in 84 patients and a mechanically expanded valve (Lotus; Boston Scientific, Marlborough, MA, USA) in 9 patients. Clinical outcomes seen during hospitalization and the follow-up period for the patients whose coronary height was ≤10 mm and >10 mm are presented in Table 3. In patients whose coronary height was ≤10 mm, life-threatening or major bleeding and minor bleeding occurred in 1 (3.4%) and 2 (6.9%) patients, respectively. There was no instance of all-cause death during hospitalization. Permanent pacemakers were implanted in 6 patients (20.7%). The average follow-up duration after discharge was 553.8±425.4 days. Death occurred in 5 patients

(17.9%) during follow-up (average of 553.8 days): the cause was non-cardiogenic in 4 patients and cardiogenic (aggravation of heart failure) in one patient.

DISCUSSION

Coronary artery obstruction is a rare but fatal intra- or post-TAVI complication that may occur in less than 1% of patients who undergo TAVI.[10] The reported incidence of coronary obstruction differs according to valve type and procedure type: 0.34% in the context of a self-expandable valve vs. 0.81% in the context of a balloon-expandable valve (*p*=0.023) and 0.62% in a native aortic valve case vs. 2.48% in a valve-in-valve case (*p*=0.045).[10] Delayed coronary obstruction might be divided into two types according to the timing of onset of this event after TAVI as early (<7 days) and late (>7 days) coronary obstruction,[11] with cardiac arrest or ST-elevation myocardial infarction constituting the clinical presentation in early delayed coronary obstruction and stable or unstable angina constituting the clinical presentation in late delayed coronary obstruction.[11] The potential mechanism of early delayed coronary obstruction might be correlated with the displacement of a calcified native valve leaflet.[10-12]

Table 3. Clinical Outcomes

	Total study population n=269	Patients without a low coronary height n=240	Patients with a low coronary height n=29	*p* value
In-hospital outcomes				
Life-threatening or major bleeding	5 (1.9)	4 (1.7)	1 (3.4)	0.502
Minor bleeding	38 (14.1)	32 (13.3)	6 (20.7)	0.283
Acute kidney injury	40 (14.9)	35 (14.6)	5 (17.2)	0.711
Stage I	22 (8.2)	20 (8.4)	2 (6.9)	
Stage II	6 (2.2)	5 (2.1)	1 (3.4)	
Stage III	12 (4.5)	10 (4.2)	2 (6.9)	
All-cause death	18 (6.7)	18 (7.5)	0 (0)	0.127
Cardiogenic death	11 (4.1)	11 (4.6)	0 (0)	0.239
Noncardiogenic death	7 (2.6)	7 (2.9)	0 (0)	0.351
Stroke	9 (3.4)	7 (2.9)	2 (6.9)	0.450
Myocardial infarction	1 (0.4)	1 (0.4)	0 (0)	0.727
Acute coronary obstruction	0 (0)	0 (0)	0 (0)	-
New permanent pacemaker	34 (12.7)	28 (11.7)	6 (20.7)	0.170
Follow-up outcomes				
All-cause death	24 (8.9)	19 (7.9)	5 (17.2)	0.096.
30-day cardiogenic death	1 (0.4)	1 (0.4)	0 (0)	0.728
30-day noncardiogenic death	1 (0.4)	0 (0)	1 (3.4)	0.004
1-year cardiogenic death	2 (0.7)	1 (0.4)	1 (3.4)	0.073
1-year noncardiogenic death	20 (7.4)	17 (7.1)	3 (10.3)	0.527
Myocardial infarction	0 (0)	0 (0)	0 (0)	-
Coronary obstruction	0 (0)	0 (0)	0 (0)	-
New permanent pacemaker	4 (1.6)	4 (1.9)	0 (0)	0.467
Re-hospitalization	18 (7.4)	16 (7.4)	2 (6.9)	0.955

Data are presented as n (%).

The predominant mechanism of late delayed coronary obstruction might be linked to bioprosthetic valve endothelialization with some degree of obstruction or embolization of unknown thrombus.[10-12] When coronary obstruction occurs following TAVI, percutaneous coronary intervention is the preferred treatment option.[10] The literature suggests 30-day mortality rates reach 50% in patients with coronary artery bypass graft surgery, 22.2% in patients with successful percutaneous coronary intervention, and 100% in patients without successful percutaneous coronary intervention.[10]

Early coronary obstruction occurs more frequently in patients treated with a balloon-expandable valve than those treated with a self-expandable valve.[10,17,18] A recent study reported that partial obstruction and complete obstruction of the left coronary ostium on follow-up computed tomography occurred in 33.6% and 2.1% of patients, respectively, who underwent TAVI with balloon-expandable valve.[19] The risk factors for early coronary obstruction were a narrow aortic sinus of Valsalva (<30 mm) and low coronary height (<10 mm).[10-13] One German registry study with 86 patients who had low coronary heights (mean height of 6.4±1.1 mm) reported that coronary obstruction occurred in three patients: two of these individuals underwent a valve-in-valve procedure and the third patient was treated with a Lotus

valve.[20] All patients except one with low coronary heights in the present study (8.9±1.2 mm) were successfully treated with self-expandable valves. There was no occurrence of acute coronary occlusion even without prophylactic coronary protection of at-risk coronary arteries.

Coronary protection and chimney stenting have been found to prevent coronary artery obstruction during TAVI.[11,21,22] One recent study adopted chimney stenting for the prevention of coronary artery obstruction during TAVI in 60 (0.5%) of 12800 TAVI procedures.[21] Among these 60 patients, 42 patients (70%) underwent TAVI due to a degenerative surgical bioprosthesis. Ultimately, 3 patients (5%) died, 13 patients (21.6%) experienced myocardial infarction, and 14 patients (23.3%) exhibited cardiogenic shock during 30 days of follow up.[21] The proportion of the chimney coronary stent that protruded into the aorta comprised 49.7% of the total stent length.[21] The presence of a protruding chimney coronary stent between the TAVI valve and native coronary artery ostium might be involved with turbulent blood flow or hemodynamic deterioration in the aortic sinus of Valsalva and play a substantial role as a nidus for thrombus formation in the future. Therefore, a more prolonged duration of dual antiplatelet therapy or (single or dual) antiplatelet therapy plus anticoagulant therapy might be required to prevent

thrombus formation in the coronary stent or TAVI valve. However, a prolonged duration of antiplatelet and/or anticoagulant therapy might translate to a subsequent increase in bleeding risk among patients treated with TAVI and chimney stent implantation. The absence of coronary protection was the only predictor of 30-day death, myocardial infarction, and/or cardiogenic shock in a recent study.[21] Another study reported preventive stent implantation across the coronary ostia was associated with good mid-term survival and a low rate of stent thrombosis in patients who underwent TAVI and were at high risk for delayed coronary occlusion.[23] Meanwhile, another novel approach, the bioprosthetic or native aortic scallop intentional laceration to prevent iatrogenic coronary artery obstruction (BASILICA) technique, was developed to prevent coronary artery obstruction in high-risk patients during TAVI.[24] When using the BASILICA technique, equipment, such as an electrosurgery pencil and electrosurgery generator for laceration, is required. In addition, this procedure includes many unfamiliar steps, and side effects of anatomical limitations and stroke have been reported.[24]

The favorable clinical outcomes and lack of acute coronary occlusion in the patients with low coronary heights treated with self-expandable valves in this study might be explained as follows. First, TAVI was performed exclusively in patients with native aortic valve stenosis and not in those with degenerative surgical bioprosthesis stenosis. Second, because self-expandable valves have the capacity to retrieve the valve, we may check the possibility of acute coronary occlusion again immediately before complete deployment of the valve during the real TAVI procedure. Finally, the specific configuration of self-expandable valves with a concave appearance at the mid-portion of the valve provide more sufficient space with which to avoid acute coronary occlusion relative to balloon-expandable valves, which exhibit a flat appearance at the mid-portion of the valve. Therefore, the use of self-expandable valves may be considered in patients with low coronary height for prevention of occurrence of acute coronary occlusion. Subsequent need for coronary protection may be determined according to aortographic findings during pre-dilation of aortic valve with balloon. When there are significant impairments of coronary blood flow, coronary protection may be required. Otherwise, coronary protection may not be necessary.

This study has several limitations. This was a single-center retrospective study, and the number of included patients was too small. There was also an insufficient number of control patients who were treated with balloon-expandable valves. MDCT analysis, such as leaflet length, calcification volume of leaflet, and virtual valve to coronary ostial distance, which can affect coronary obstruction, was insufficient in this study. There also may have been a limitation with adequate coronary access in future coronary events in patients receiving self-expandable valve implantation.

In conclusion, 29 patients (10.8%) with low coronary heights

were observed among TAVI candidates. The use of self-expandable valves may be feasible to promote successful TAVI without acute coronary occlusion in patients with low coronary heights.

AUTHOR CONTRIBUTIONS

Conceptualization: Hyeongsoo Kim. Data curation: Hyeongsoo Kim, Seung-Jun Lee, Sung-Jin Hong, Chi-Young Shim, Chul-Min Ahn, Jung-Sun Kim, Byeong-Keuk Kim, Geu-Ru Hong, and Young-Guk Ko. Formal analysis: Hyeongsoo Kim. Funding acquisition: Myeong-Ki Hong. Investigation: Hyeongsoo Kim. Methodology: Hyeongsoo Kim and Myeong-Ki Hong. Project administration: Hyeongsoo Kim. Supervision: Donghoon Choi, Yangsoo Jang, and Myeong-Ki Hong. Writing—original draft: Hyeongsoo Kim. Writing—review & editing: Hyeongsoo Kim and Myeong-Ki Hong. Approval of final manuscript: all authors.

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