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Research article

# Short-Term Outcomes of Patients Undergoing Transcatheter Aortic Valve Replacement: Early Experience at Chulabhorn Cardiac Center

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## Abstract

**Background:** Transcatheter aortic valve replacement (TAVR) has emerged as an alternative treatment for severe aortic stenosis in the past few decades. Chulabhorn Cardiac Center initiated a TAVR program in 2019. We herein report the initial 30-day outcomes and complications of the first 60 patients who underwent TAVR in Chulabhorn Cardiac Center. **Methods:** This study involved the analysis of descriptive data for the first 60 patients who underwent TAVR from 2019 to 2021. The inclusion criteria were symptomatic severe aortic stenosis or asymptomatic severe aortic stenosis with an indication for valvular intervention according to current standard guidelines. The reported outcomes were retrospectively analyzed, including clinical outcomes, complications, and echocardiographic and hemodynamic changes pre- and post-TAVR. **Results:** Sixty patients (47% female) were enrolled in this cohort. Their median Society of Thoracic Surgeons score was 3.7. The procedural success rate was 100%. The median in-hospital and 30-day follow-up mean pressure gradient was 9.9 and 11.2 mmHg, respectively, with 46 (93.4%) patients reportedly developing no to mild paravalvular leakage after the procedure. No patients died within the first 30 days after the procedure. With regard to periprocedural complications, 13 (21.7%) patients underwent permanent pacemaker implantation after the TAVR procedure because of new-onset high-grade or complete atrioventricular block. Four (6.6%) patients developed ischemic stroke after the TAVR procedure. Three (5.0%) patients developed a major vascular complication according to the VARC definition, among whom only one (1.7%) patient required surgical correction. **Conclusion:** The immediate and 30-day outcomes in our initial 60 patients undergoing TAVR were favorable with a low complication rate.

**Keywords:** transcatheter aortic valve replacement (TAVR), transcatheter aortic valve implantation (TAVI), aortic stenosis, bioprosthetic heart valve, echocardiography, hemodynamics, treatment outcome, complication

## Background

Aortic stenosis is the most common valvular heart disease worldwide, with a prevalence of 1% to 2% among people aged >65 years and 12% among those aged >75 years.[1,2] Among people with aortic stenosis, 3.4% have severe aortic stenosis.[2] The gold standard treatment for severe aortic stenosis is surgical aortic valve replacement.[3,4] However, the risks of post-operative complications in high-risk populations can prevent these patients from proceeding to surgery. During the past decade, trans-catheter aortic valve replacement (TAVR) has emerged as an alternative treatment for severe aortic stenosis in high-risk populations,[5–7] and its indications may now extend to low-risk populations.[8,9] The standard treatment of severe aortic stenosis has shifted from surgical aortic valve replacement to TAVR, which is currently considered a standard treatment in high-risk populations.[3,4]

The Cardiology Center at Chulabhorn Hospital initiated a TAVR program in 2019, and more than 60 patients have been enrolled in the program to date. We herein report the 30-day outcomes and complications of our first 60 patients.

## Patients and Methods

All patients who underwent TAVR from 2019 to 2021 at Chulabhorn Cardiac Center were recruited for inclusion in the study analysis. The patients' data were reviewed by the TAVR conference committee, which comprised cardiovascular imaging specialists, interventionists, and cardiothoracic surgeons, to evaluate the feasibility of performing the procedure. All patients had either symptomatic severe aortic stenosis or asymptomatic aortic stenosis with an indication for aortic valve replacement according to current standard guidelines.[3,4] Routine left cardiac catheterization was performed prior to full evaluation by the TAVR conference committee to identify and properly treat significantly diseased coronary arteries. Computed tomography of the whole aorta and lower extremity vessels was also routinely performed to evaluate entry sites, intraoperative techniques, and optimal deployment views. Routine pre- and post-TAVR transthoracic or transesophageal echo-cardiography was performed and reviewed by cardiothoracic imaging specialists. If the TAVR conference committee reached a consensus on performing TAVR, the patients' preoperative, intraoperative, and postoperative data were collected. If the patients were lost to follow-up for any reason, the data were identified as "missing data" and excluded from the primary analysis. The missing data were later included in the sensitivity analysis after completion of the study and reported as supplementary data.

The study protocol was approved by the Committee for Medical Research Ethics, and all patients provided written informed consent in accordance with the revised Declaration of Helsinki.

The procedures were performed by one team comprising at least three operators (either interventionists or cardiothoracic surgeons). All patients underwent general anesthesia. A temporary pacemaker was placed in the right ventricular apex or wire pacing was placed in the left ventricular apex, and balloon valvuloplasty was then performed under rapid ventricular pacing followed by implantation of the valve. If the femoral artery was used as the access site, it was closed using a large-bore closure device (either ProGlide; Abbott Laboratories, Abbott Park, IL, USA or Angio-Seal; Terumo Corporation, Tokyo, Japan).

### *Definition of complications*

Ischemic stroke, transient ischemic accident, major vascular complications, and major bleeding were defined according to the consensus report of the Valve Academic Research Consortium (VARC-2).[10]

### *Statistical analysis*

Continuous variables are presented as mean ± standard deviation for parametric data and

as median and interquartile range for non-parametric data. Continuous variables were compared using the paired t test or the Mann–Whitney U test. All analyses were performed with Stata/MP 14.0 software (StataCorp, College Station, TX, USA).

## Results

Sixty patients, 29 (48.3%) of whom were female, were included in the analysis. Their mean age was 80 ± 5.7 years. The patients' baseline clinical characteristics are shown in Table 1. Of the 60 TAVR procedures, 59 were performed via the transfemoral approach and 1 was performed via the transaortic approach. The CoreValve system (Medtronic, Minneapolis, MN, USA) was used in 38 patients, and the Edwards Sapien system (Edwards Lifesciences, Irvine, CA, USA) was used in 22 patients. The procedural characteristics are shown in Table 2. Thirty-day follow-up data were completed for 52% of the 60 patients in our cohort.

The valve system most commonly used in our cohort was a self-expandable valve system (68.4%). The procedural success rate was 100%. This rate was later confirmed by intraprocedural pressure gradient measurement and echocardiographic two-dimensional/three-dimensional imaging, including Doppler measurement of the transvalvular gradient, which declined rapidly following valve deployment. The pre- and post-TAVR hemodynamic indices are presented in Table 2, and the baseline, in-hospital, and 30-day post-procedure echocardiographic parameters are shown in Table 3.

**Table 1.** Baseline Characteristics

| Characteristics | N = 60 |
|---|---|
| Female sex | 29 (48.3) |
| Age, years | 80 ± 5.7 |
| Body mass index, kg/m$^2$ | 22.5 ± 4.0 |
| Hypertension | 47 (78.3) |
| Diabetes mellitus | 18 (30.0) |
| Hyperlipidemia | 38 (63.3) |
| PAD | 2 (3.3) |
| CAD | 27 (45.0) |
| Previous TIA/stroke | 3 (5.0) |
| Estimated GFR, mL/min/1.73 m$^2$ | 41 ± 14.9 |
| Chronic kidney disease | |
| Stage 3a | 19 (31.7) |
| Stage 3b | 27 (45) |
| Stage 4 | 7 (11.7) |
| Stage 5 | 2 (3.3) |
| Previous CABG | 3 (5.0) |
| Previous aortic valve surgery | 1 (1.7) |
| COPD | 2 (3.3) |
| Atrial fibrillation | 8 (13.3) |
| STS score, points | 3.7 (3.1–5.8) |

Data are presented as n (%), mean ± standard deviation, or median (interquartile range).
PAD, peripheral artery disease; CAD, coronary artery disease; TIA, transient ischemic attack; GFR, glomerular filtration rate; CABG, coronary artery bypass grafting; COPD, chronic obstructive pulmonary disease; STS, Society of Thoracic Surgeons

**Table 2.** Procedural Characteristics

| Characteristics | N = 60 |
|---|---|
| Approach | |
| Transfemoral | 59 (98.3) |
| Transaortic | 1 (1.7) |
| Total dose of heparin, IU | 5000 (4000–5000) |
| Valve type | |
| Sapien 3, Edwards Lifesciences | 22 (36.7) |
| CoreValve Evolut R, Medtronic | 31 (51.7) |
| CoreValve Evolut Pro, Medtronic | 7 (11.7) |
| Valve size, mm | |
| 20 | 5 (8.3) |
| 23 | 6 (10.0) |
| 26 | 27 (45.0) |
| 29 | 17 (28.3) |
| 34 | 5 (8.3) |
| Predilatation | 44 (73.3) |
| Postdilatation | 13 (21.7) |
| Vascular closure of device site | |
| ProGlide, Abbott | 58 (96.7) |
| Angio-Seal VIP, Terumo | 26 (43.3) |
| Surgical repair | 1 (1.7) |
| Contrast dose, mL | 200 (170–300) |
| Hemodynamics before TAVR | |
| Systolic blood pressure, mmHg | 103 (93–116) |
| Diastolic blood pressure, mmHg | 46 (38–55) |
| LVEDP, mmHg | 14.5 (12–22) |
| Peak-to-peak pressure gradient, mmHg | 60.5 (42–81) |
| Mean pressure gradient, mmHg | 55.9 (44.1–75.7) |
| Hemodynamics after TAVR | |
| Systolic blood pressure, mmHg | 120 (103–131) |
| Diastolic blood pressure, mmHg | 49 (44–56) |
| LVEDP, mmHg | 16.5 (12–23) |
| Peak-to-peak pressure gradient, mmHg | 2 (2–6) |
| Mean pressure gradient, mmHg | 7.8 (3.3–12.9) |

Data are presented as n (%) or median (interquartile range).
TAVR, transcatheter aortic valve replacement; LVEDP, left ventricular end-diastolic pressure

The 30-day postprocedural in-hospital complications are listed in Table 4. According to the VARC-2 definition,[10] the composite endpoint of device success was 100%, the 30-day early safety event rate was 11.7%, and the 30-day clinical efficacy rate was 6.7%.

In terms of complications after TAVR, no periprocedural death occurred in our cohort. The most common periprocedural complication was high-grade/complete atrioventricular block, which was found in 13 (21.7%) patients and led to permanent pacemaker implantation; however, no patients had fatal events. Four (6.6%) patients developed ischemic stroke during the

periprocedural period. Three (4.9%) patients developed new-onset atrial fibrillation during the periprocedural period, mostly within 3 days; the latest onset was 5 days after the procedure. Three (5.1%) patients developed major vascular complications during the procedure; these complications were mostly non-fatal and could be corrected nonsurgically. Only two patients developed vascular complications requiring surgical correction. With regard to paravalvular leakage, most of the patients had trace to mild leakage. Only four (7.3%) patients had moderate regurgitation, and no severe regurgitation was reported in our cohort. Bleeding after the procedure was reported in 12 (20.0%) patients, and most of these cases were minor access site bleeding. Only one patient developed life-threatening bleeding at the vascular access site.

**Table 3.** Echocardiographic Parameters

| Echocardiography | Baseline (n = 60) | In-hospital (n = 60) | 30-day post-procedure (n = 31) |
|---|---|---|---|
| LVEF, % | 63.25 (55–70) | 63 (55.5–70.1) | 66.9 (57.4–70.8) |
| LVEF category | | | |
| Normal | 48 (80.0) | 50 (83.3) | 27 (87.1) |
| Mildly impaired | 4 (6.7) | 5 (8.3) | 3 (9.7) |
| Moderately impaired | 7 (11.7) | 3 (5.0) | 1 (3.2) |
| Severely impaired | 1 (1.7) | 2 (3.3) | 0 (0.0) |
| Diastolic dysfunction | | | |
| No diastolic dysfunction | 1 (1.7) | 0 (0.0) | 0 (0.0) |
| Grade 1 | 35 (58.3) | 42 (70.0) | 13 (41.9) |
| Grade 2 | 14 (23.3) | 10 (16.7) | 14 (45.1) |
| Grade 3 | 6 (10.0) | 2 (3.3) | 0 (0.0) |
| Undetermined | 4 (6.7) | 5 (8.3) | 2 (6.4) |
| Anatomy of aortic valve | | | |
| Tricuspid | 53 (88.3) | - | - |
| Bicuspid | 7 (11.7) | - | - |
| Peak aortic valve gradient, mmHg | 91.1 (73.5–108.8) | 19.4 (15.4–25.4) | 20.4 (13.9–23.3) |
| Mean aortic valve gradient, mmHg | 55.8 (45.2–69.8) | 9.9 (7.5–13.4) | 11.2 (7.9–12.7) |
| Aortic valve area, $cm^2$ | 0.6 ± 0.2 | - | |
| Effective orifice area, $cm^2$ | - | 1.8 ± 0.8 | 1.9 ± 0.7 |
| Effective orifice area index, $cm^2/m^2$ | - | 0.9 ± 0.4 | 0.8 ± 0.7 |
| Doppler velocity index | | 0.6 ± 0.2 | 0.6 ± 0.2 |
| Paravalvular leakage | - | | |
| None or trace | | 28 (46.7) | 14 (45.2) |
| Mild | | 28 (46.7) | 12 (38.7) |
| Moderate | | 4 (6.7) | 4 (12.9) |
| Severe | | 0 (0.0) | 1 (3.2) |

Data are presented as n (%), mean ± standard deviation, or median (interquartile range).
LVEF, left ventricular ejection fraction

**Table 4.** Thirty-day Post-procedural In-hospital Complications

| Complications | N = 60 |
|---|---|
| In-hospital mortality | 0 (0.0) |
| Cardiac arrest | 1 (1.7) |
| Valve dislodgement | 2 (3.3) |
| Myocardial infarction | 2 (3.3) |
| Coronary occlusion | 2 (3.3) |
| Respiratory failure | 5 (8.3) |
| Cardiogenic shock | 4 (6.7) |
| Major vascular complication | |
| False aneurysm | 1 (1.7) |
| Vessel perforation | 1 (1.7) |
| Vessel occlusion | 1 (1.7) |
| Acute kidney injury | 5 (8.2) |
| Ischemic stroke | 4 (6.6) |
| Infection | 10 (16.7) |
| Permanent pacemaker implantation | 13 (21.7) |
| New atrial fibrillation | 3 (5.0) |
| Major bleeding | |
| Access site | 1 (1.7) |
| False aneurysm | 1 (1.7) |
| Retroperitoneal | 1 (1.7) |
| Minor bleeding | |
| Access site | 7 (11.7) |
| Gastrointestinal | 2 (3.3) |

Data are presented as n (%).

## Discussion

We have herein reported favorable outcomes but quite low complication rates in our first 60 patients who underwent TAVR as part of the TAVR program at Chulabhorn Cardiac Center. The procedural success rate was 100%, and no patients died within the first 30 days. Seven patients in our cohort had a bicuspid aortic valve, for which TAVR is not recommended according to the current guidelines.[3,4] However, these seven patients developed no adverse clinical events, and echocardiography showed no signs of bioprosthetic valve dysfunction within 30 days after performing TAVR. Therefore, a bicuspid aortic valve may not be a contraindication for TAVR in appropriately selected patients.

In the PARTNER study,[6,7] which involved patients who had severe aortic stenosis with high and prohibitive risks, the 30-day mortality rate was 5%, the 30-day major stroke rate was 5%, the major vascular complication rate was 16%, and the major bleeding rate was 16%. In the PARTNER-2 study,[11] which involved patients who had severe aortic stenosis with intermediate risks, the 30-day mortality rate was 3.9%, the major stroke rate was 3.2%, the major vascular complication rate was 7.9%, and the major bleeding rate was 10.4%. In the PARTNER-3[8] and Evolut-Low Risk[9] studies, which involved patients with low-risk severe aortic stenosis, the 30-day mortality rate was 0.4% and 0.5%, the major stroke rate was 0.7% and 0.6%, the major vascular complication rate was 2.2% and 3.8%, and the major bleeding

rate was 3.6% and 2.4%, respectively. In the French transcatheter aortic valve implantation (FRANCE-TAVI) registry[12] of 3195 patients, the 30-day mortality rate was 9.7% and the 30-day stroke rate was 3.4%. Additionally, 5.0% of patients developed major vascular complications, 4.5% had major bleeding, and 15.6% required permanent pacemaker implantation.

Because our patient population mainly involved patients with low to intermediate risk as assessed by the Society of Thoracic Surgeons score, the 30-day in-hospital mortality and major complication rates were not inferior to, and some parameters were better than, the previous low- and intermediate-risk TAVR clinical trials and registries mentioned above.

Notably, this study involved only pilot data from a small population of patients with low to moderate risk as reflected by the baseline Society of Thoracic Surgeons score, and the procedures were performed by the same team at a single medical center. This might not reflect the situation of other medical centers in other parts of the world. The 30-day follow-up data in this initial report were largely missing because the data were acquired only from the patients who were followed up at Chulabhorn Cardiac Center; some of the patients were followed up in other hospitals. However, the clinical and echocardiographic data in other hospitals are being pursued and will be further analyzed in our final report.

## Conclusions

Compared with previous studies, our pilot study showed favorable outcomes and low complication rates among our first 60 patients undergoing TAVR. We attained a procedural success rate of 100% with no 30-day mortality in the first 60 patients undergoing TAVR at Chulabhorn Cardiac Center.


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