ORIGINAL ARTICLE

Outcomes of Transcatheter Aortic Valve Implantation under Transfemoral Approach Versus Alternative Approach in King Chulalongkorn Memorial Hospital

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Background: The transfemoral approach (TF) is the access of choice for transcatheter aortic valve implantation (TAVI). However, approximately 10% of patients have anatomy or comorbidity unsuitable for TF.

Objective: To analyze the outcomes of an alternative approach compared with TF in the authors' institute.

Materials and Methods: A retrospective analysis of patients undergoing TAVI in King Chulalongkorn Memorial Hospital between December 2010 and 2021 was conducted. The present study compared the baseline characteristics, outcomes, and complications of TAVI procedures, including one-year mortality, according to whether they were performed through a TF or alternative approach.

Results: Among 210 patients that underwent TAVI, 188 (89.6%) were in the TF group and 22 (10.4%) were in the alternative group with seven in the trans-subclavian, nine in the transapical, and six in the transaortic. The mean age of the population was 81 years. Patients in the alternative group had more severe disease (median logistic EuroSCORE-II 19.67 versus 10.01, p<0.001). Other baseline characteristics were not different between groups. According to the Valve Academic Research Consortium 3 (VARC-3) criteria, there were higher mortality and complication rates in the alternative group but no statistical differences regarding 30-day mortality of TF at 2.1% versus alternative at 9.1% (p=0.121) and 1-year mortality of TF at 5.3% versus alternative at 13.6% (p=0.143). Hospitalization times were significantly longer in the alternative group (median hospital stay in days of TF 4 versus alternative 10, p=0.013). Although no statistical significance was found, there were trends towards a higher rate of valve malposition for TF at 3.7% versus alternative at 13.6%, and major vascular complications for TF at 1.6% versus alternative at 9.1%.

Conclusion: The authors' institute data demonstrates alternative approach TAVI was associated with a similar mortality rate and post-procedural complication rate compared with transfemoral TAVI, except for a trend toward a higher rate of valve malposition and major vascular complications. The alternative approach TAVI may be favored in patients with high or prohibitive surgical risk unsuitable for transfemoral TAVI.

Keywords: Transcatheter aortic valve implantation; TAVI; Alternative approach; Transfemoral; Operative outcomes

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Aortic stenosis (AS) is the most commonly acquired valvular heart disease in the elderly. It is present in about 5% of the population at age 65, increasing in prevalence with advancing age[1]. Surgical aortic valve replacement has been used for decades as the gold standard treatment for AS. However, at least 30% of patients with severe symptomatic AS are considered inoperable due to a high surgical risk secondary to complex comorbidities[2].

Transcatheter aortic valve implantation (TAVI) is a procedure in which a bioprosthetic valve is inserted through a catheter and implanted within the diseased native aortic valve, paving the way for a minimally invasive alternative to surgical aortic valve replacement. Since its introduction in 2002, TAVI has become a widely adopted treatment modality for the treatment of severe AS[3].

The transfemoral (TF) TAVI is the approach of choice for patients due to its ease of use, the ability for early mobility, allowance of awake procedures, fast-track protocols, and avoidance of

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surgical incisions. It is also associated with the most favorable clinical outcomes. Its superiority as a first-line approach has been confirmed in numerous registries and international guidelines[4,5], and in the PARTNER high- and intermediate-risk studies, where significantly improved clinical outcomes were demonstrated for the TF approach over the transthoracic approach[6-8].

However, the TF approach cannot be performed in 10% to 15% of patients due to anatomically unsuitable conditions such as iliofemoral arteriopathy, tortuosity, severe calcifications, aortic aneurysms, or previous vascular surgery. A recent analysis of the Transcatheter Valve Therapy Registry showed 7.6% of TAVI required a non-transfemoral, alternative approach[9].

Alternative approaches can be categorized into transthoracic and peripheral approaches, facilitated by either surgical or percutaneous techniques. Transthoracic approaches include transapical and direct aortic approach. Peripheral options include trans-axillary, trans-carotid, trans-subclavian, and trans-caval access. However, no randomized trial has compared the outcome of TAVI according to the access site, and observational study-derived comparisons have been limited by the difference in patient characteristics between the groups, patients with more severe disease undergoing an alternative approach.

The retrospective study took place in a tertiary care hospital with a large volume of TAVI cases in Thailand. The study was designed to compare the results of TF and alternative TAVI approaches, including survival outcomes and periprocedural complications, followed by Valve Academic Research Consortium 3 (VARC-3) criteria.

Materials and Methods

Study population

The study population was derived from all patients that underwent TAVI in King Chulalongkorn Memorial Hospital, Bangkok, Thailand, between December 2010 and December 2021. In-patient, out-patient medical records, and operative records of the patients were retrospectively reviewed. Patients who lost to follow-up were contacted via telephone by investigators.

The inclusion criteria were patients with symptomatic severe AS that underwent TAVI. Exclusion criteria were patients whose operative notes could not be retrieved and patients who had incomplete medical records.

The authors usually used the TF approach TAVI. However, the authors chose the alternative approach, decided by the heart team in TAVI conference, for patients not suitable for TF, such as too small or calcified access vessels. Furthermore, the authors considered an alternative approach by trans-subclavian before trans aortic, and trans apical was the last choice for an alternative approach.

The present study was approved (COA No. 1743/2022) by the Institutional Review Board of the Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand, in compliance with the International Guidelines for Human Research Protection, such as the Declaration of Helsinki, the Belmont Report, the CIOMS Guidelines and the International Conference on Harmonization in Good Clinical Practice (ICH-GCP).

Data collection

Preoperative demographic data including gender, age, body mass index (BMI), dyspnea grading (New York Heart Association; NYHA), history of congestive heart failure (CHF) and myocardial infarction (MI), co-morbidity, cardiovascular disease, previous cardiac intervention, surgical risk by STS score and EUROscore-II model, and echocardiographic data (left ventricular ejection fraction, aortic valve area, and mean pressure gradient) were collected. Intraoperative data, including the types and sizes of trans-catheter heart valves, anesthetic strategy, and types of access routes were collected. Postoperative course data, including complications, length of stay (LOS), and intensive care unit (ICU) stay were collected. Follow-up data included all-cause death and stroke at 30 days and at 1-year follow-up. TAVI approaches were classified into two groups, the TF approach and the alternative approach.

Outcomes were site-reported, and standard definitions were used to enter the data. Major complications, including post-TAVI aortic regurgitation, vascular and access-related complications (major and minor complications), new conduction disturbances with permanent pacemaker implantation (PPM), valve-related complications, and post-interventional arrhythmias were defined according to VARC-3 criteria.

Endpoint

The primary outcomes were 30-day and 1-year post-procedural mortality. Secondary outcomes included ICU and hospital LOS, stroke (major or minor stroke or transient ischemic attack), post-

procedural paravalvular leakage (PVL) of moderate or greater, need for PPM, vascular and access-related complications (major and minor complications), valve-related complications, and post-interventional arrhythmias.

Statistical analysis

The IBM SPSS Statistics for Windows, version 22.0 (IBM Corp., Armonk, NY, USA) was used to perform statistical analysis. Nominal data were expressed as percentages. Continuous data were expressed as mean ± standard deviation (SD) and median (IQR). The authors used the Kolmogorov-Smirnov test and the Shapiro-Wilk test to determine whether the present data follows a normal or non-normal distribution. Differences in continuous and categorical variables between groups were assessed using an independent sample t-test or Mann-Whitney U test and chi-square test or Fisher's exact test, respectively. A p-value of less than 0.05 was considered significant.

Results

The baseline characteristics of the two populations were similar as regards gender, age, cardiovascular comorbidity, and other comorbidities such as hypertension, diabetic mellitus, chronic kidney disease, chronic lung disease, cirrhosis, previous cardiac intervention and surgery, NYHA classification, and pre-operative echocardiographic data (Table 1). However, the alternative approach group had a higher number of coronary artery diseases compared with the TF approach. Of note, the alternative approach group had a statistically significantly higher logistic EuroSCORE-II at 19.76%, compared with the TF approach group at 10.01% ($p<0.001$). Even median STS score was not statistically different as STS scores of TF and alternative approach were 5.26 (3.60 to 8.24) and 6.96 (4.47 to 11.41), respectively ($p=0.143$).

In the present study population, two types of anesthetic techniques were used in TAVI, including general anesthesia (GA) and local anesthesia with sedation. In the TF approach group, there were 135 patients (71.8%) that underwent TAVI under local anesthesia with sedation and 53 patients (28.2%) that were under GA. In contrast, in the alternative approach group, there were 21 patients (95.5%) that underwent TAVI under GA, but only one patient who was trans-subclavian TAVI under local anesthesia with sedation. Therefore, there were statistically significant differences in using different anesthesia. The alternative approach usually used GA and the TF approach used local anesthesia with sedation ($p<0.001$).

In the present study population, both the TF approach group (188 patients) and the alternative approach group (22 patients), used two types of transcatheter heart valves, including balloon expandable valves and self-expandable valves. In the alternative approach group, which included trans apical for nine patients (40.9%), trans-subclavian for seven patients (31.8%), and trans aortic for six patients (27.3%), there were 13 patients (59%) that used self-expandable valves and nine patients (41%) that used balloon expandable valves. In the TF approach group, there were 166 patients (88.3%) that used the self-expandable valve, and 19 patients (10.1%) that used the balloon expandable valve, and only three patients (1.6%) that used the mechanical expandable valve (Lotus valve, by Boston Scientific). There was a statistically significant difference that the surgeons were more likely to use self-expandable valves such as Hydra valve (by SMT), CoreValve™ and Evolut™ R (by Medtronic) in the TF approach group.

In the TF approach group, the 30-day mortality rate was 2.1% (0% to 7.03%). This is well below the EuroSCORE-II predicted mortality of 10.01%, and the 1-year mortality rate was 5.3% (0% to 11.63%) (Table 2). The rate of moderate or severe PVL was 11.7%, and the rate of transcatheter heart valve malposition was 3.7%. These valve-related complications were corrected with a valve-in-valve procedure. The rate of post-TAVI stroke was 3.2%. Only 1.6% of the patients had major vascular complications. The need for PPM rate was 17.5% in this group of patients (Table 3).

In the alternative approach group, the mortality rate at 30 days was 9.1% (0% to 22.41%), and at 1 year was 13.6% (0% to 28.11%) (Table 2). There was a higher mortality rate at 30 days compared to the TF approach group, but not a statistically significant difference ($p=0.121$). The rate of post-TAVI stroke was 0%. There was a need for PPM for 4.5%, and post TAVI moderate or severe PVL for 4.5%, which were all lower than the TF approach (Table 3). There were higher rates of transcatheter heart valve malposition at 13.6% and major vascular complications at 9.1%, compared to TF without having statistically significant difference (valve malposition, $p=0.074$ and major vascular complications, $p=0.086$).

However, the TF approach population had a statistically significant faster recovery than the

Table 1. Characteristics of patient

Characteristics	Transfemoral approach (n=188)	Alternative approach (n=22)	p-value
Age (year); mean±SD	81.61±8.004	82.14±6.190	0.759
Sex; n (%)			0.498
Female	101 (53.7)	14 (63.6)	
Male	87 (46.3)	8 (36.4)	
Cardiovascular comorbidity; n (%)			
Coronary artery disease	109 (58.0)	20 (90.9)	0.002
Atrial fibrillation	25 (13.3)	4 (18.2)	0.517
Complete heart block with pacemaker	15 (8.0)	0 (0.0)	0.376
Stroke	26 (13.8)	6 (27.3)	0.115
Peripheral arterial disease	6 (3.2)	2 (9.1)	0.199
Other comorbidities; n (%)			
Hypertension	128 (68.1)	14 (63.6)	0.640
Diabetes mellitus	80 (42.6)	11 (50.0)	0.506
Chronic kidney disease	41 (21.8)	4 (18.2)	1.000
Chronic lung disease	16 (8.5)	1 (4.5)	1.000
Liver disease (cirrhosis)	6 (3.2)	0 (0.0)	1.00
Previous cardiac intervention/surgery; n (%)	102 (54.3)	15 (68.2)	0.260
Percutaneous coronary intervention (PCI)	68 (36.2)	13 (59.1)	0.062
Coronary bypass graft (CABG)	31 (16.5)	5 (22.7)	0.548
Permanent pacemaker implantation (PPI)	18 (9.6)	0 (0.0)	0.227
Surgical risk score; median (IQR)			
STS score	5.26 (3.60 to 8.24)	6.96 (4.47 to 11.41)	0.143
EURO score II	10.01 (4.09 to 22.38)	19.67 (15.95 to 49.26)	<0.001
Preoperative echocardiographic data; median (IQR)			
Aortic valve area (cm^2)	0.62 (0.51 to 0.78)	0.57 (0.50 to 0.88)	0.837
Mean pressure gradient (mmHg)	43 (36 to 52)	42.5 (40 to 60.5)	0.748
Left ventricular ejection fraction (%)	64 (48 to 75)	61 (43.5 to 64.5)	0.114
NYHA classification; n (%)			
NYHA class III-IV	127 (68.3)	16 (72.7)	0.810
Type of anesthesia; n (%)			<0.001
General anesthesia	53 (28.2)	21 (95.5)	
Local anesthesia	135 (71.8)	1 (4.5)	
Type of transcatheter heart valve; n (%)			
Balloon expandable valve	19 (10.1)	9 (40.9)	0.001
Self-expanding valve	166 (88.3)	13 (59.1)	0.001
Mechanical expandable valve	3 (1.6)	0 (0.0)	1.000

NYHA=New York Heart Association; SD=standard deviation; IQR=interquartile range

Table 2. 30 days and 1-year all-cause mortality

All-cause mortality	Transfemoral approach (n=188)	Alternative approach (n=22)	p-value
30 days mortality; n (%)	4 (2.1)	2 (9.1)	0.121
1-year mortality; n (%)	10 (5.3)	3 (13.6)	0.143

Compare proportion (%) using chi-square

alternative approach population, with an ICU length of stay in the TF group of four days versus nine point five days in the alternative approach group (p=0.01), and hospital length of stay in the TF group at four days versus ten days in the alternative approach group (p=0.013).

When directly comparing both groups, the alternative approach group seemed not inferior to

Table 3. Length of stay and post-procedural complications

Variable	Transfemoral approach (n=188)	Alternative approach (n=22)	p-value
Length of stay (days); median (IQR)			
ICU length of stay	4 (3 to 9)	9.5 (4.25 to 13.50)	0.010
Hospital length of stay	4 (3 to 9.5)	10 (4.25 to 13.50)	0.013
Post-TAVI aortic regurgitation; n (%)			
No or mild PVL	166 (88.3)	21 (95.5)	
Moderate or severe PVL	22 (11.7)	1 (4.5)	0.479
Cardiac conduction disturbance; n (%)			
Permanent pacemaker implantation	33 (17.5)	1 (4.5)	0.216
Valve-related complication; n (%)			
Transcatheter heart valve malposition	7 (3.7)	3 (13.6)	0.074
Post-TAVI stroke; n (%)	6 (3.2)	0 (0.0)	1.000
Vascular and Access complication; n (%)			
Major vascular complication	3 (1.6)	2 (9.1)	0.086
Minor vascular complication	13 (6.9)	0 (0.0)	0.369
Arrhythmia; n (%)	7 (3.7)	2 (9.1)	0.240

ICU=intensive care unit; TAVI=transcatheter aortic valve implantation; PVL=paravalvular leakage; IQR=interquartile range

the TF approach except in aspects of heart valve malposition, major vascular complications, and ICU and hospital length of stay.

Discussion

The present study showed no significant differences in outcomes between patients with severe AS treated with the TF approach and the alternative approaches, including trans-subclavian, transaortic, and transapical approach. However, the TF technique offers advantages to patients in shorter ICU and hospital LOS. The alternative approach technique is a well-established approach for patients unsuitable for TF approach TAVI.

In the present study, mortality and morbidity were not significantly different when compared between the TF TAVI and the alternative approach, which was different from previous studies. The transapical technique provided a higher rate of mortality and morbidity compared to the TF technique. This may be because an aortic puncture and the often-friable apex of the left ventricle puncture can cause troublesome bleeding after the procedure[6,10].

Studies[10,11] recommended the transaortic approach over the transapical approach because the upper hemi sternotomy can quickly and easily be converted to a full median sternotomy, allowing rapid control of any problem. Furthermore, the data suggests that the transaortic group provided a slight trend toward lower mortality compared to the transapical approach[10,11].

Important complications such as moderate or severe PVL, valve malposition, arrhythmia and the need for PPM, post-TAVI stroke, and vascular complications were not statistically significant different between both groups. In the TF approach group, the rate of moderate or severe PVL was 11.7%, and the need for PPM rate was 17.5%. In contrast, in the alternative approach group, post TAVI moderate or severe PVL was 4.5% and need for PPM was 4.5%, which were all lower than the TF approach. These may be related to valve type because there were more than 85% of patients in the TF approach group using the self-expandable valve while there were about 50% in the alternative approach group. However, the alternative approach is trending to be inferior to the TF approach in terms of valve malposition and vascular complications, although it was not statistically significant. The trend of the need for PPM is going down in the later part of the authors' cohort. This may be due to our more extensive experience with the TAVI procedure.

A previous study showed that there was a 0.9% to 2.1% stroke rate in patients who underwent transaortic or transapical approach TAVI[10]. In the present study population, there were no patients in the alternative group who had a post-procedure stroke, thus 0%.

Limitation

There were limitations to the present study. First, the study was a single-center retrospective study, which may not provide data for the general population. Second, the authors did not have the

valve-specific data. The valves mostly used were the Hydra valve in the self-expandable valve group, which included 77 patients (40.9%), and the Edwards SAPIEN valve in the balloon-expandable valve group for all cases. These may be potentially confounding factors in the present study. Third, the management of the TAVI patient depended on the hospital heart team's decision-making and the resources. These could not provide accurate results for the general TAVI population. The last point to consider is that the alternative approach group had a relatively small sample size, which may have led to underpowered statistical measurements in some aspects.

Conclusion

Although there was no statistical significance in mortality between the two approaches at 30 days and one year, there was a trend toward a worse outcome in the alternative approach group. This could be due to the small sample size. The present study results suggested that TF access remains the default access for TAVI, and alternative access can be considered when TF cannot be done with acceptable results.

What is already known on this topic?

TF TAVI is the approach of choice for patients with symptomatic severe AS who are considered inoperable or at high surgical risk of undergoing surgical aortic valve replacement. Transthoracic or peripheral artery access was used as an alternative approach in patients who were unsuitable for TF. However, there are no randomized trials and limited studies comparing the outcomes of TAVI according to the access sites.

What does this study add?

This study showed that the alternative approach TAVI is associated with a similar 30-day and 1-year mortality rate and post-procedural complications when compared with TF TAVI. Although the alternative approach has a trend toward a higher rate of major vascular complications and valve malposition, there were no statistically significant differences. So, it can be considered in patients who are unsuitable for TF TAVI.

Conflicts of interest

The authors declare no conflict of interest.

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