

Cost–Utility Analysis of Transcatheter Aortic Valve Implantation versus Surgery in High-Risk Severe Aortic Stenosis Patients in Thailand

Unchalee Permsuwan^{1,2}, Voratima Yoodee^{1,3}, Wacin Buddhari⁴, Nattawut Wongpraparut⁵, Tasalak Thonghong⁶, Sirichai Cheewatanakornkul⁷, Krissada Meemook⁸, Pranya Sakiyalak⁹, Pongsanae Duangpakdee¹⁰, Jirawit Yadee^{1,2}

¹Department of Pharmaceutical Care, Faculty of Pharmacy, Chiang Mai University, Chiang Mai, Thailand; ²Center for Medical and Health Technology Assessment (CM-HTA), Department of Pharmaceutical Care, Faculty of Pharmacy, Chiang Mai University, Chiang Mai, Thailand; ³Pharmaceutical Care Training Center (PCTC), Department of Pharmaceutical Care, Faculty of Pharmacy, Chiang Mai University, Chiang Mai, Thailand; ⁴Division of Cardiovascular Medicine, Department of Medicine, Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand; ⁵Division of Cardiology, Department of Medicine, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand; ⁶Division of Cardiology, Department of Internal Medicine, Faculty of Medicine, Chiang Mai University, Chiang Mai, Thailand; ⁷Division of Cardiology, Department of Internal Medicine, Faculty of Medicine, Prince of Songkla University, Songkhla, Thailand; ⁸Division of Cardiology, Department of Medicine, Faculty of Medicine Ramathibodi Hospital, Mahidol University, Bangkok, Thailand; ⁹Division of Cardio-Thoracic Surgery, Department of Surgery, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand; ¹⁰Division of Cardiovascular and Thoracic Surgery, Department of Surgery, Faculty of Medicine, Prince of Songkla University, Songkhla, Thailand

Correspondence: Jirawit Yadee, Department of Pharmaceutical Care, Faculty of Pharmacy, Chiang Mai University, 239 Suthep Road, Mueang Chiang Mai District, Chiang Mai, 50200, Thailand, Tel +66 5394-4351, Email jirawit.yadee@cmu.ac.th

Background: Transcatheter aortic valve implantation (TAVI) has been shown to be effective in treating patients with severe symptomatic AS who are high-risk population for conventional surgical aortic valve replacement (SAVR). This study aimed to evaluate the cost–utility of TAVI compared with SAVR for severe aortic stenosis with high surgical risk in Thailand.

Methods: Lifetime costs and quality-adjusted life years (QALYs) from societal and healthcare perspectives were estimated using a two-part constructed model. The study population consisted of 80-year-old severe AS patients with high surgical risk. Mortality and complication rates were obtained from landmark trials. All cost–related and utility data were based on Thai population. Costs and QALYs were discounted at a rate of 3% annually and presented as 2021 values. Incremental cost-effectiveness ratios (ICERs) were computed. Sensitivity analyses were performed both deterministically and probabilistically.

Results: The findings from a societal perspective revealed that TAVI treatment was associated with higher cost (THB 1,551,895 [USD 47,371.64] vs THB 548,438 [USD 16,741.09] and higher QALYs than SAVR treatment (3.15 vs 2.31 QALYs). The estimated ICER was THB 1,196,191/QALY (USD 36,513.78/QALY). For the healthcare system perspective, TAVI treatment resulted in a higher total cost than SAVR treatment (THB 1,451,317 [USD 44,301.49] vs THB 432,398 [USD 13,198.95]) with comparable gains in LY and QALYs from a societal perspective. The ICER was calculated to be THB 1,214,624/QALY (USD 37,076.42/QALY). TAVI was not cost-effective at the Thai willingness to pay (WTP) threshold of THB 160,000/QALY (USD 4884/QALY). The model was the most sensitive to changes in TAVI valve cost and TAVI or SAVR treatment utilities.

Conclusion: TAVI is not a cost-effective strategy in patients with severe AS who are at high surgical risk when compared to SAVR at the WTP of THB 160,000/QALY (USD 4884/QALY) from the perspectives of society and the healthcare system.

Keywords: cost–utility, transcatheter aortic valve implantation, transcatheter aortic valve replacement, severe aortic stenosis, high surgical risk

Introduction

Aortic stenosis (AS) is one of the most common valvular heart diseases.¹ The prevalence of AS and severe AS in people aged 75 years and older is 12.4% and 3.4%, respectively. Furthermore, the prevalence of AS is rising among the elderly.²

The mortality rate is high, particularly among patients who did not receive treatment.^{3,4} The risk of death while waiting for intervention in routine clinical practice ranges between 2.7% and 14%.⁵

Transcatheter aortic valve implantation (TAVI) has emerged as the preferred treatment option for elderly patients with severe AS who require valve replacement. It has been shown to be effective in treating patients with severe symptomatic AS who are inoperable and high-risk population for conventional surgical aortic valve replacement (SAVR).^{6–8} The American Heart Association/American College of Cardiology (ACC/AHA) recommends it as the first choice for patients with severe AS aged 80 years and older, and as an alternative for patients of any age who are high-risk patients, based on its survival benefit, symptom improvement, and hemodynamic outcomes.⁹ In addition, the European Society of Cardiology/European Association for Cardio-Thoracic Surgery (ESC/EACTS) clinical practice guidelines recently published the recommendation of TAVI as the treatment for patients with severe AS aged 75 years and older, or in those who are high-risk patients or unsuitable for surgery.¹⁰

As healthcare resources are limited in all countries including Thailand, the recommendations for costly health technologies such as drugs, vaccines, and medical devices may require country-specific evidence that supports the cost-effectiveness of the new health technology and informs the decision-making.

In Thailand, the health technology assessment (HTA) method has been used to investigate the cost-effectiveness of new interventions proposed by various stakeholders for the development of a health benefit package under the Universal Health Coverage Scheme (UHCS). TAVI was proposed in 2017 by a private sector and prioritized based on predefined criteria by a selection working group under the Subcommittee for the Development of the Benefit Package and Service Delivery (SCBP). Economic evidence has become an important piece of information to justify the costly benefit package before including into the Thailand's Universal Health Coverage Benefit Package (UHCBP). As a result, the goal of this study was to compare the cost-utility of TAVI versus SAVR for severe aortic stenosis with high surgical risk in Thailand.

Methods

This cost-utility analysis was conducted in accordance with the SCBP-approved national methodological and process guidelines, including the Thai HTA guideline.^{11–13} The detailed information on the health technology assessment process for UHCS in Thailand was provided in the [Supplement Materials](#) “Health technology assessment (HTA) process for the Universal Health Coverage Scheme (UHCS) in Thailand” section.

Model Description

A two-part constructed model was developed to represent the short-term and long-term consequences of TAVI or SAVR procedure ([Figure 1](#)). All severe AS patients would undergo either TAVI or SAVR procedure. During the short-term period or initial 30 days after procedure, a decision tree model was constructed to estimate the expected costs and quality-adjusted life-years (QALYs). Patients during this period were at risks of death or remained alive after procedure. Alive patients would be discharged without complication or had complications occurred within 30 days. Postoperative complications could be acute major stroke or early complications. Early complications included major vascular complications, major bleeding, atrial fibrillation, acute kidney injury, and permanent pacemaker implantation. A Markov model with an annual cycle length was used to analyze the lifetime costs and QALYs beyond 30 days after the short-term decision tree model. Patients without complications would enter the ‘No complications’ health state in the Markov model. Patients experiencing an acute major stroke would enter the “Post-stroke” health state. Patients experiencing early complications would enter to such a ‘Late complications’ health state. Patients in the “No complications” health state would move to acute major stroke or late complications or remained in the “No complications” health state in the next cycle. The model was run until all patients were absorbed by the “Death” health state.

Population

The cohort population was severe AS patients with high surgical risk. Patients with high surgical risk were considered based on the diagnosis of cardiologists and the risk stratification using the Society of Thoracic Surgeons (STS) score for surgical risk greater than 8%.¹⁴ However, in the case of a lower STS score than 8%, the clinical characteristics that were high risk for conventional surgical aortic valve replacement and/or clinical judgement by an interventional cardiologist or

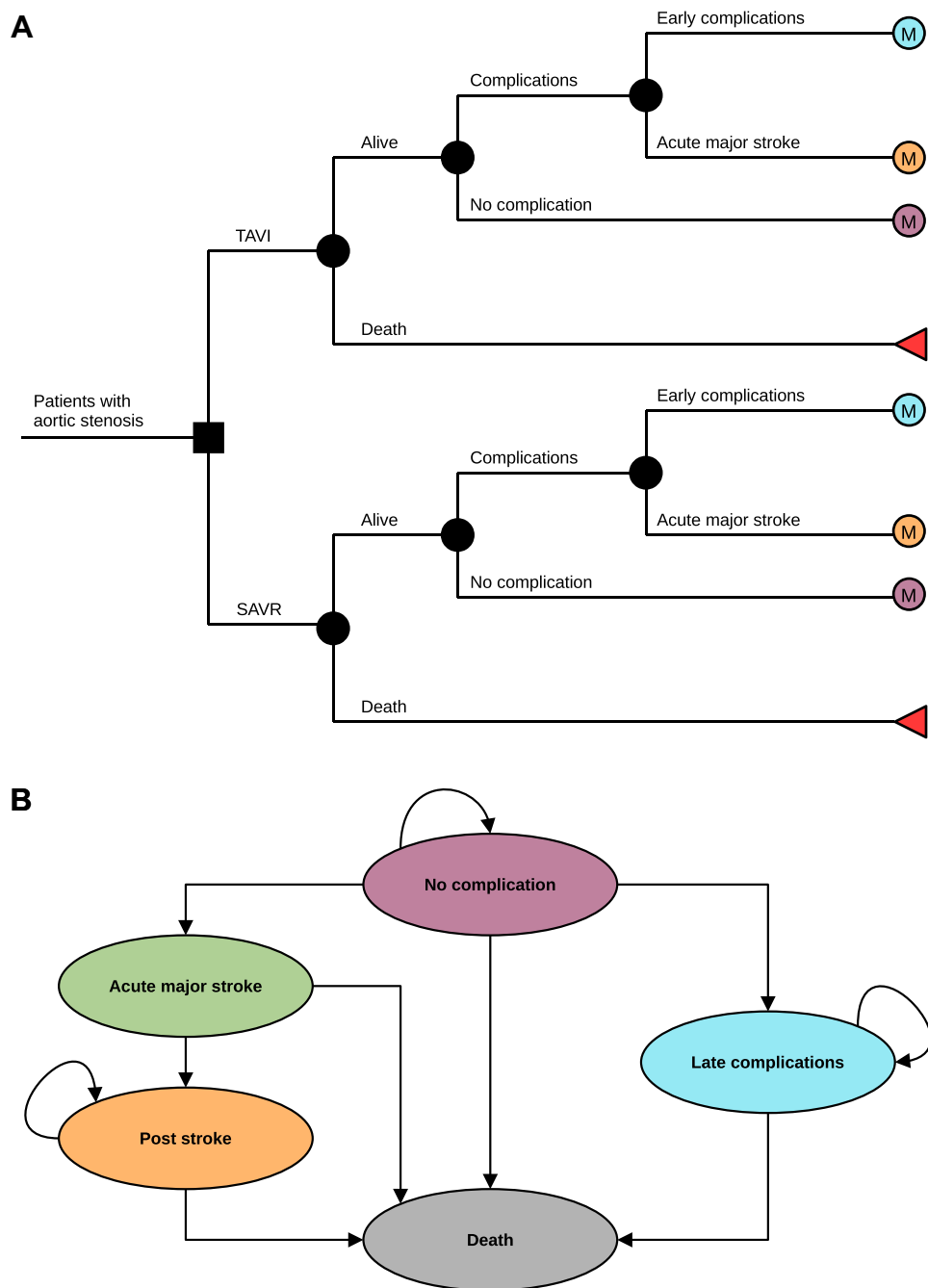


Figure 1 (A) Decision tree model for 30-day after undergoing the intervention. (B) Markov model for long-term complications. **Abbreviations:** SAVR, surgical aortic valve replacement; TAVI, transcatheter aortic valve implantation.

a multidisciplinary heart team were considered to receive TAVI instead of SAVR. In addition, the starting age of the cohort population at 80 years was chosen to reflect the average age of the severe AS patients in the general medical practice in Thailand.¹⁵

Intervention and Comparator

The intervention in this study was TAVI. There are five brands of TAVI valve available in Thailand: 1) Edwards Lifesciences (SAPIEN-3™), 2) Medtronic (CoreValve™ and Evolut R™), 3) Boston Scientific (LOTUS Edge™ and

ACURATE neo™), 4) Abbott Vascular (Portico™), and 5) Vascular Innovation (Hydra™). The access routes included both transfemoral and transapical. The comparator in this study was SAVR.

Input Parameters

Transitional Probabilities

Based on our findings from a systematic review, we calculated mortality and complication rates for patients undergoing TAVI and SAVR procedures from included clinical studies. Briefly, systematic literature search was conducted in four databases (PubMed, Scopus, Web of Science, and Embase) from inception to July 2021. The main search terms included “transcatheter aortic valve implantation”, “transcatheter aortic valve replacement”, “Self-expanding or balloon-expandable” and “randomized controlled trial”. To be included in this review, the article must meet the following inclusion criteria: 1) a randomized controlled trial of TAVI versus SAVR; 2) the sample was severe AS patients with high surgical risk based on the Society of Thoracic Surgeons Predicted Risk of Mortality (STS-PROM) greater than 8% or the logistic EuroSCORE greater than 20%; 3) Clinical outcomes were reported at 30 days, 1 year, or longer than 1 year; and 4) The study was published in English. Other study types such as non-randomized controlled trial, observational study, case report, and review article were excluded from this review. The flow diagram for literature review was shown in the [Supplementary Materials \(Figure S1\)](#).

The included clinical studies were 1) Transcatheter versus Surgical Aortic-Valve Replacement in High-Risk Patients trial (PARTNER Cohort A)⁸ and 2) Transcatheter Aortic-Valve Replacement with a Self-Expanding Prosthesis (US CoreValve).¹⁶ Pooled analyses for combining outcomes of all-cause death, major vascular complications, major bleeding, AF, AKI, and new permanent pacemaker implantation at 30 days and 1-year after TAVI or SAVR procedure were performed to obtain the probability data in the model. The 1-year probabilities were carried forwarded until the end of the model time horizon.

After 1-year period, age-specific mortality rate (ASMR) for Thai general population based on the data from the Ministry of Public Health¹⁷ adjusted by the risk of being severe AS was applied to the model. The odds ratio of 1-year mortality of severe AS compared with no AS was equal to 2.57 (95% confidence interval [CI], 2.42 to 2.74).¹⁸ The mortality rate was then converted to annual risks. Clinical input parameters following TAVI and SAVR procedures are listed in [Table 1](#).

Costs

Both societal and healthcare system perspectives were applied in this study. The costs comprised direct medical costs and direct non-medical costs. However, according to the HTA guideline in Thailand, indirect costs were not included to prevent double counting benefits, both in terms of costs and effectiveness of the interventions.¹⁹

Cost data were directly obtained from five large university-affiliated hospitals. Three hospitals are located in Bangkok, one is in the North and the other is in the South of Thailand. Direct medical costs including costs of procedure and complication treatment were derived from hospitals' electronic database. For direct non-medical costs, costs of

Table 1 Clinical Input Parameters: Short-Term and Long-Term Outcomes Following SAVR/TAVI

Parameters	Value (Range)		References
	SAVR	TAVI	
30-day outcomes			
Mortality	0.0608 (0.0547–0.0669)	0.0339 (0.0305–0.0373)	Smith CR, ⁸ Adams DH ¹⁶
Stroke	0.0256 (0.0230–0.0282)	0.0671 (0.0604–0.0739)	
No complication	0.1401 (0.1261–0.1541)	0.3845 (0.3461–0.4230)	
1-year outcomes			
Mortality	0.2032 (0.1829–0.2235)	0.1717 (0.1546–0.1889)	Smith CR, ⁸ Adams DH ¹⁶
Stroke	0.0495 (0.0445–0.0544)	0.0529 (0.0476–0.0582)	
Vascular complications	0.0196 (0.0176–0.0215)	0.0622 (0.0560–0.0684)	
Major bleeding	0.3760 (0.3384–0.4136)	0.2211 (0.1990–0.2432)	
Acute kidney injury	0.0844 (0.0760–0.0929)	0.0529 (0.0476–0.0582)	
Atrial fibrillation	0.1821 (0.1639–0.2004)	0.1027 (0.0924–0.1130)	
Pacemaker implantation	0.0545 (0.0491–0.0600)	0.0965 (0.0868–0.1061)	

Abbreviations: SAVR, surgical aortic valve replacement; TAVI, transcatheter aortic valve implantation.

accommodation, food, transportation, and caregivers were collected from severe AS patients who underwent TAVI or SAVR procedure from five hospitals. The ethical approval of the study was obtained from the Institutional Review Board of Central Research Ethics Committee (Certificate of Approval No. COA-CREC057/2020). All procedures were carried out in accordance with the applicable guidelines and regulations.

All cost data were adjusted for inflation using the medical care section of Thailand's consumer price index²⁰ and presented in 2021, and were converted from Thai Baht (THB) into the United States dollars (USD) using an exchange rate of THB 32.76 per USD, as of 17 November 2021.²¹ All cost data are listed in [Table 2](#).

Utility

Utility data were collected from severe AS patients who underwent TAVI or SAVR procedure using the Thai version of the European Quality of Life Group's 5-dimension 5-level (EQ-5D-5L) questionnaire²² at baseline, 1 month, and 1 year after procedure. Utility data are presented in [Table 2](#).

Study Outcomes

Lifetime total cost, life-years (LYs), quality-adjusted life-years (QALYs) which is the product of utility and LY, clinical benefits in terms of overall cause of death, incremental costs, LY gained, QALYs gained, and incremental cost-effectiveness ratio (ICER) were the outcomes of interest in this study.

Study Analyses

Base-Case Analysis

The base-case approach was used to calculate the incremental cost-effectiveness ratio (ICER) in THB per life year (LY) or QALY gained by dividing difference in total costs by the difference in outcomes of TAVI and SAVR. Lifetime costs and outcomes were discounted at an annual rate of 3% based on Thai HTA guideline.²³ TAVI treatment will be considered cost-effective if the estimated ICER is not greater than the threshold of 160,000 THB per QALY, or about 1.2 times per capita gross national income (GNI).²⁴

Sensitivity Analyses

Deterministic and probabilistic sensitivity analyses (PSA) were performed to assess the sensitivity of the results to the assumptions used and parameter values selected, as well as to determine the level of uncertainty surrounding the base-case results.

One-way sensitivity analysis was performed to evaluate the impact of altering each of the individual input parameters within its range to test the robustness of the model results. All input parameters including transitional probabilities, costs, and utility data were varied in the analysis. The lower and upper boundaries of its specified range such as standard deviation and standard error were used as the low and high values in the analysis. In the absence of specific ranges, transitional probabilities were varied by $\pm 10\%$ and costs were varied by $\pm 20\%$. In addition, according to the Thai HTA guideline, the discount rate varied from 0% to 6%.²³ The results of one-way sensitivity analysis are presented as a tornado diagram.

For the PSA, parameter value distributions were specified, and 1000 Monte Carlo simulations were run with random draws for each parameter distribution, with incremental costs and benefits calculated for each run.²⁵ A beta distribution was assigned for the probability and utility parameters. A gamma distribution was used for the cost parameters. All ICERs were plotted on the cost-effectiveness plane. A cost-effectiveness acceptability curve (CEAC) was generated to demonstrate the likelihood of TAVI being cost-effective at different willingness to pay values.

Table 2 Costs and Utility Inputs

Parameters	Value (Range)		References
	SAVR	TAVI	
Direct medical costs			
Intervention admission (THB per admission)			
Cost of valve	60,789 (48,631–72,946)	1,068,891 (855,113–1,282,670)	Hospital database
Cost of instrument	62,097 (49,677–74,516)	106,282 (85,026–127,538)	
Cost of ICU stay	3887 (3109–4664)	3887 (3109–4664)	
Cost of ward stay	18,314 (14,651–21,976)	12,209 (9767–14,651)	
Cost of food	3016 (2412–3619)	2262 (1809–2714)	
Inpatient costs of complications (THB per year)			
Stroke	123,874 (99,099–148,648)		Hospital database
Vascular complications	50,604 (40,483–60,725)		
Major bleeding	109,772 (87,818–131,727)		
Acute kidney injury	119,571 (95,656–143,485)		
Atrial fibrillation	186,291 (149,033–223,549)		
Pacemaker implantation	115,840 (92,672–139,008)		
Chronic renal failure	123,874 (99,099–148,648)		
Outpatient costs of complications (THB per year)			
Post-stroke	57,062 (45,649–68,474)		Hospital database
Vascular complications	467 (374–561)		
Major bleeding	21,247 (16,998–25,497)		
Acute kidney injury	6385 (5108–7662)		
Atrial fibrillation	5082 (4065–6098)		
Pacemaker implantation	6178 (4942–7414)		
Chronic renal failure	57,062 (45,649–68,474)		
Direct non-medical costs			
Intervention admission (THB per admission)			
Cost of transportation	1775 (1420–2130)	1775 (1420–2130)	Patient interview
Cost of food	3245 (2596–3894)	2434 (1947–2921)	
Cost of accommodation	7779 (6223–9335)	5834 (4668–7001)	
Cost of informal care	11,160 (8928–13,392)	8370 (6696–10,044)	
Outpatient follow-up visit (THB per year)			
Cost of transportation	4687 (3749–5624)	6007 (4806–7208)	Patient interview
Cost of food	1804 (1443–2164)	2312 (1849–2774)	
Cost of accommodation	3191 (2553–3829)	4090 (3272–4908)	
Cost of informal care	5631 (4504–6757)	7217 (5774–8660)	
In-patient admission (THB per year)			
Cost of transportation	2210 (1768–2652)	2612 (2090–3135)	Patient interview
Cost of food	678 (542–814)	801 (641–961)	
Cost of accommodation	2780 (2224–3336)	3285 (2628–3942)	
Cost of informal care	2704 (2163–3245)	3196 (2557–3835)	
Utility			
At 30-day after intervention	0.71 (0.63–0.79)	0.80 (0.73–0.87)	Patient interview
At 1-year after intervention	0.78 (0.72–0.84)	0.89 (0.86–0.92)	

Abbreviations: SAVR, surgical aortic valve replacement; TAVI, transcatheter aortic valve implantation; THB, Thai baht.

Results

Base-Case Analysis

The findings of the cost–utility analysis from a societal perspective revealed that TAVI treatment was associated with higher cost and better health outcomes than SAVR treatment. The total cost of TAVI treatment was THB 1,551,895 (USD 47,371.64), compared to THB 548,438 (USD 16,741.09) for SAVR treatment. The TAVI treatment was more effective in terms of LYs and QALYs than the SAVR treatment (3.65 vs 3.05 LYs and 3.15 vs 2.31 QALYs, respectively). These values resulted in ICERs of THB 1,672,226/LY (USD 51,044.76/LY) and THB 1,196,191/QALY (USD 36,513.78 QALY), which were both considerably higher than the Thai willingness to pay (WTP) threshold of THB 160,000/QALY or USD 4884/QALY.

For the healthcare system perspective, TAVI treatment resulted in a higher total cost than SAVR treatment (THB 1,451,317 [USD 44,301.49] vs THB 432,398 [USD 13,198.95]) with comparable gains in LY and QALYs from a societal perspective. The ICER was estimated to be THB 1,214,624/QALY (USD 37,076.42/QALY) (Table 3).

Sensitivity Analyses

Figure 2 demonstrates the results of a cost–utility analysis from a variety of one-way sensitivity as a tornado diagram. The model was the most sensitive to changes in TAVI valve cost and TAVI or SAVR treatment utilities. Furthermore, the cost of the TAVI valve was varied in order to determine the appropriate TAVI valve cost, which yielded an ICER lower than the Thai WTP threshold. The TAVI valve cost was estimated to be THB 199,655 (USD 6094.47), bringing the ICER below the WTP threshold of THB 160,000/QALY or USD 4884/QALY (Figure 3).

The scatter plot (Figure 4) on the cost-effectiveness plane revealed that all 1000 iterations were in the upper right quadrant. This meant that TAVI treatment was more costly and yielded more QALYs than SAVR treatment. The cost-effectiveness acceptability curve (Figure 5) depicted the likelihood of both treatment options at various WTP levels. TAVI treatment had a better chance of being cost-effective as the level of WTP increased.

Discussion

This study is the first economic evaluation using Thailand’s local available cost and utility data to compare the cost-utility of TAVI versus SAVR in high surgical risk patients with severe symptomatic AS. According to the findings of this study, the estimated ICER was THB 1,196,191/QALY (USD 36,513.78 QALY). Therefore, TAVI was not a cost-effective treatment

Table 3 Base-Case Results

Variables	TAVI	SAVR
Healthcare system perspective		
Total cost (THB/USD)	1,451,317 (44,301.49)	432,398 (13,198.95)
Life-years (years)	3.65	3.05
QALYs (years)	3.15	2.31
Incremental cost-effectiveness ratio		
THB/life-year (USD/life-year)	1,697,994 (51,831.31)	
THB/QALY (USD/QALY)	1,214,624 (37,076.42)	
Societal perspective		
Total cost (THB/USD)	1,551,895 (47,371.64)	548,438 (16,741.09)
Life-years (years)	3.65	3.05
QALYs	3.15	2.31
Incremental cost-effectiveness ratio		
THB/life-year (USD/life-year)	1,672,226 (51,044.76)	
THB/QALY (USD/QALY)	1,196,191 (36,513.78)	

Abbreviations: QALYs, quality-adjusted life-years; SAVR, surgical aortic valve replacement; TAVI, transcatheter aortic valve implantation; THB, Thai baht; USD, United States dollars.

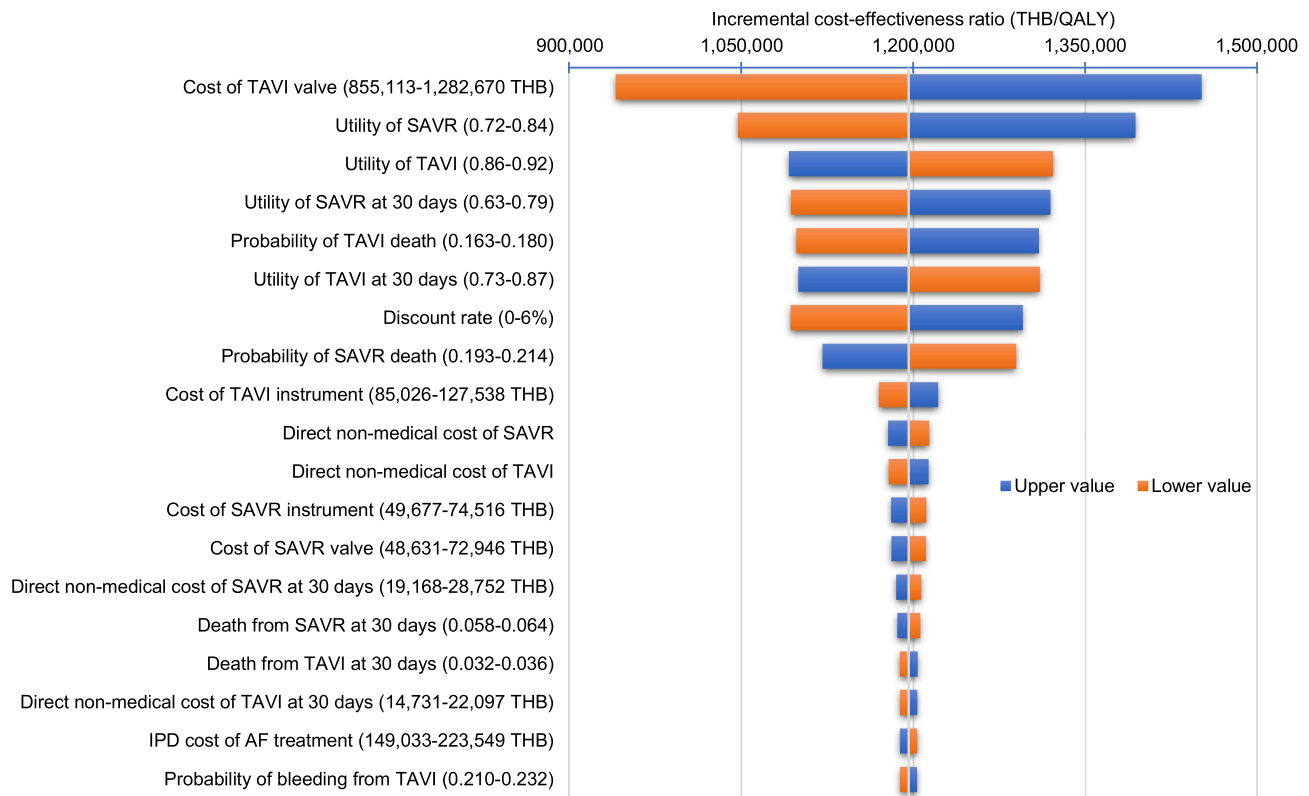


Figure 2 Tornado diagram of TAVI compared with SAVR.

Abbreviations: AF, atrial fibrillation; IPD, inpatient department; QALY, quality-adjusted life-year; SAVR, surgical aortic valve replacement; TAVI, transcatheter aortic valve implantation; THB, Thai baht.

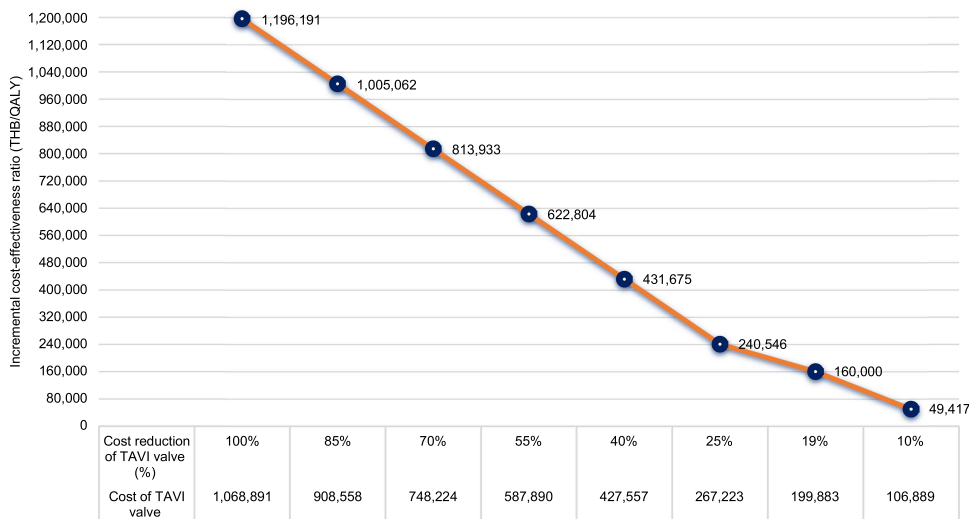


Figure 3 Threshold analysis varying cost of TAVI valve.

Abbreviations: QALY, quality-adjusted life-year; TAVI, transcatheter aortic valve implantation; THB, Thai baht.

for severe AS patients with high surgical risk at a ceiling ratio of THB 160,000/QALY (USD 4884/QALY). As the level of WTP increased, TAVI treatment had a better chance of being cost-effective.

Findings from the United States,²⁶ the United Kingdom,²⁷ Canada,^{28,29} the Netherlands,³⁰ and Japan³¹ revealed that TAVI was a cost-effective strategy compared with SAVR in severe AS patients with high surgical risk based on each

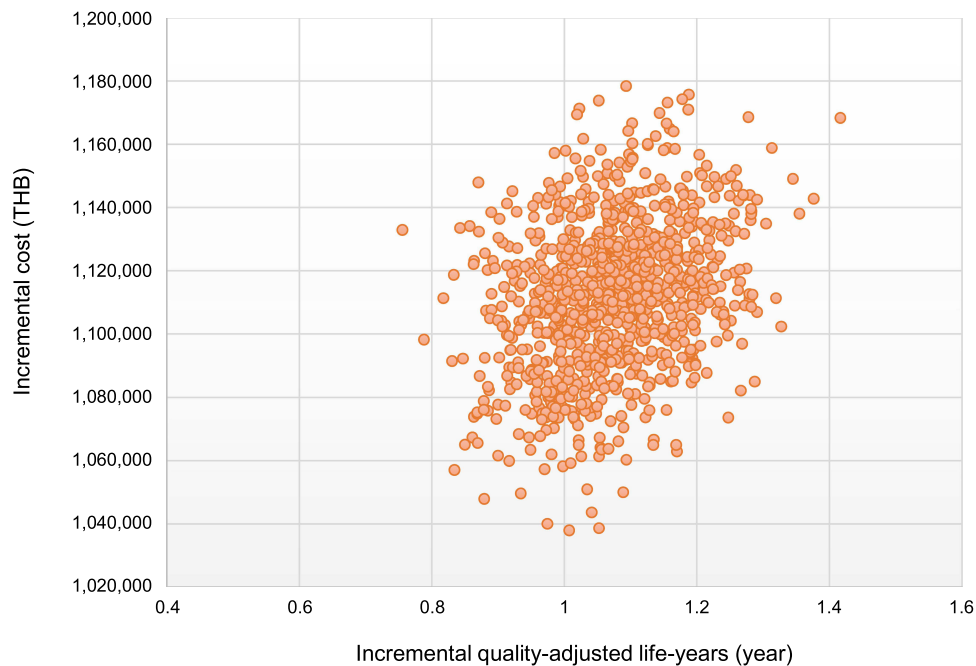


Figure 4 Scatter plots of 1000 iterations for TAVI compared with SAVR on a cost-effectiveness plane.

Abbreviations: SAVR, surgical aortic valve replacement; TAVI, transcatheter aortic valve implantation; THB, Thai baht.

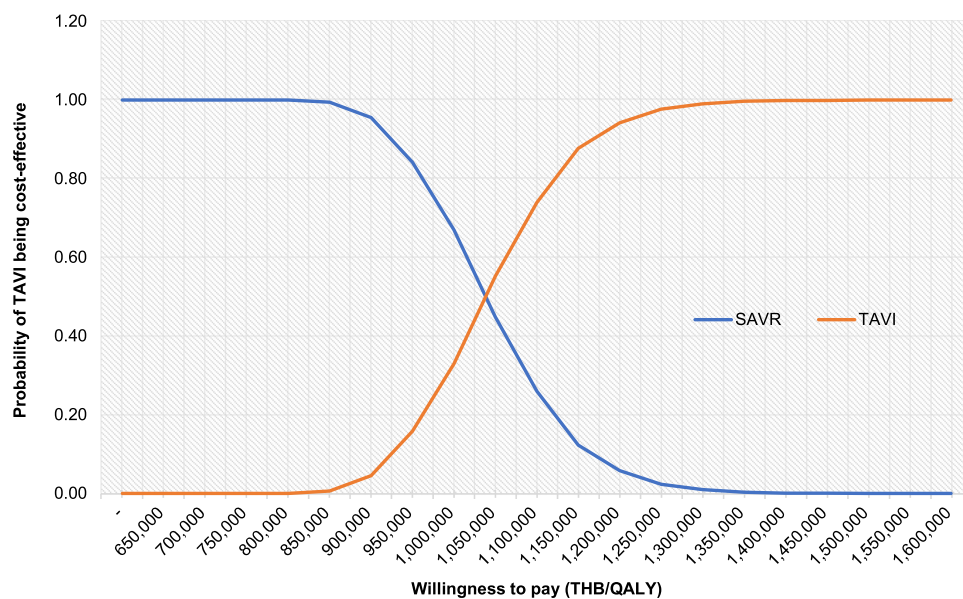


Figure 5 Cost-effectiveness acceptability curve of TAVI compared with SAVR.

Abbreviations: QALY, quality-adjusted life-year; SAVR, surgical aortic valve replacement; TAVI, transcatheter aortic valve implantation; THB, Thai baht.

country's respective acceptable WTP threshold. However, six studies conducted in the United States,^{32–35} Belgium,³⁶ and the United Kingdom³⁷ found the ICER above the WTP threshold, implying that TAVI was not cost-effective when compared to SAVR. This might be due to costly TAVI valve. TAVI treatment requires less length of stay of hospitalization and incurs less cost of complications than SAVR treatment; however, the benefit accrued from the cost savings mentioned above is not enough to offset the costly TAVI valve.

In this study, utility values had a significant impact on the ICER. These utility data were consistent with those from other countries, which showed that patients undergoing TAVI treatment had a higher utility value than those undergoing SAVR.

This study had several strengths. To begin, the analysis relied on Thailand-specific cost and utility data. The data were gathered directly from severe AS patients who underwent TAVI or SAVR procedures at five large university-affiliated hospitals. These data were useful in reflecting Thailand's general clinical practice. Next, this study was conducted in accordance with the process recommended by the SCBP and Thai HTA guideline. The study's findings were evaluated by the external reviewers for quality assurance. These procedures ensured the study's validity and usefulness.

However, several limitations in this study were taken into consideration. First, we modeled the parameters using clinical outcomes in terms of mortality and complications from the PARTNER Cohort A and CoreValve trials rather than Thailand's local patient outcomes' data. This is due to the fact that Thailand has a limited number of TAVI cases and no locally randomized trials. Second, because long-term clinical outcome data is not yet available, the extrapolation procedure assumed 1-year outcomes carried forward, implying some degree of uncertainty in the results. Third, TAVI has been performed in patients with severe AS in Thailand since the first-in-human implantation in 2009. The learning curve is an essential component of a successful TAVI procedure. We believe that the cost of TAVI treatment would decline from less complication and mortality with experience gain of interventional cardiologists in Thailand. Finally, the results might not estimate the economic burden due to TAVI in Thailand. Therefore, further study about budget impact analysis might be in need.

Conclusion

The finding of this study revealed that TAVI for patients with high-risk severe AS is not a cost-effective strategy compared with SAVR at the WTP of THB 160,000/QALY (USD 4884/QALY) from the perspectives of society and healthcare system.

Ethics Approval

The ethical approval was obtained from the Institutional Review Board of Central Research Ethics Committee (Certificate of Approval No. COA-CREC057/2020). All procedures were carried out in accordance with the applicable guidelines and regulations.

Consent to Participate

The study protocol was explained to all subjects. All subjects signed informed consent forms after agreeing to participate in the study.

Author Contributions

UP initiated the study design and methodology. WB, NW, TT, SC, KM, PS, and PD participated in patient enrollment and data acquisition. JY and UP performed the data analyses. JY, VY, and UP drafted the manuscript. All authors contributed to revising the article, have agreed on the journal to which the article was submitted, gave final approval of the version to be published, and agree to be accountable for all aspects of the work.

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Disclosure

All authors have no conflicts of interest to declare that are relevant to the content of this article.

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