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Transcatheter aortic valve implantation versus surgical aortic valve replacement in Chinese patients with intermediate and high surgical risk for aortic stenosis: a decision analysis on effect, affordability and cost-effectiveness

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ABSTRACT

Objective Examine the cost-effectiveness of transcatheter aortic valve implantation (TAVI) versus surgical aortic valve replacement (SAVR) for Chinese patients with severe aortic stenosis (AS) at intermediate and high surgical risk.

Design A two-phase model, comprising a 1-month decision tree to simulate perioperative outcomes and a 5-year Markov model with monthly cycles to simulate long-term outcomes, has been developed to evaluate the cost-effectiveness of TAVI compared with SAVR for Chinese patients with AS at intermediate and high risk. The event rates for both phases are sourced from the Placement of Aortic Transcatheter Valves IA and IIA trials, while the cost inputs and utility values are sourced from local sources or published literature. Adjustments for inflation were made using consumer price indexes for healthcare to enhance precision. To ensure the reliability and robustness of the model, sensitivity analyses were conducted to assess their impact on outcomes.

Setting China healthcare system perspective.

Participants A hypothetical cohort of Chinese patients with AS in intermediate and high surgical risk.

Interventions TAVI versus SAVR.

Outcome measures Cost, quality-adjusted life-years (QALYs), life-years gained and incremental cost-effectiveness Ratio (ICER).

Result For both intermediate- and high-risk AS patients, offering TAVR resulted in high healthcare costs but moderate benefits compared with SAVR. Specifically, in the intermediate-risk population, TAVR led to a 0.34 QALY increase over SAVR, with an incremental cost of $16 707.58, resulting in an ICER of $49 176.60/QALY. Similarly, in the high-risk population, TAVR showed a 0.15 QALY increase over SAVR, with an incremental cost of $18 093.52, leading to an ICER of $122 696.37/QALY. However, both ICERs exceeded the willingness-to-pay threshold of $37 654.50/QALY. Sensitivity analyses confirmed the model's stability under parameter uncertainty.

Conclusion TAVI was deemed not cost-effective compared with SAVR for patients with AS at intermediate or high surgical risk in the Chinese healthcare system.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ From the perspective of Chinese healthcare system, we built a two-phase model, comprising a decision tree and a Markov model, by using the latest clinical data to to investigate the cost-effectiveness of transcatheter aortic valve implantation and surgical aortic valve replacement in intermediate- and high-risk patients with aortic stenosis.

⇒ In the two-phase model, the decision tree simulated the short-term outcomes during the surgery, while the Markov model simulated the long-term outcomes over a 5-year period.

⇒ The 1-month cycle length and 5-year time horizon were chosen to align with the clinical trial's duration and to avoid extrapolation.

⇒ This study used the most recent 5-year clinical data, and the entire simulation process was based on existing data, thereby avoiding simulation errors caused by extrapolation models.

⇒ In this study, the utility values for intermediate- and high-risk patients with AS are the same, which could potentially introduce some bias into the results.

Lowering valve costs was considered an effective approach to improve the cost-effectiveness of TAVI.

INTRODUCTION

Globally, the prevalence of aortic stenosis (AS) is estimated to be around 2–3%, but in individuals over the age of 65, this rate can exceed 10%.[1 2] In China, the prevalence across different age groups—18–44, 45–54, 55–64, 65–74 and ≥75 years—is 0.07%, 0.18%, 0.23%, 0.41% and 0.56%, respectively (p<0.001).[3 4] If left untreated, severe AS patients with 3 years of symptoms face a high mortality rate of approximately 75%.[5–7] Surgical aortic valve replacement (SAVR)

remains the mainstream treatment option, but many patients are considered inoperable due to factors such as frailty, comorbidities or advanced age.[8] Transcatheter aortic valve implantation (TAVI) has emerged as the preferred treatment for patients aged 80 years and older with severe AS and as an alternative for high-risk patients requiring valve treatment, according to the American Heart Association/American College of Cardiology and European government guidelines based on the Placement of Aortic Transcatheter Valves (PARTNER) trials.[9–12] TAVI has demonstrated better clinical outcomes, reduced re-hospitalisations, shorter length of stay and higher overall resource utilisation compared with SAVR in high-risk and intermediate-risk patients with AS.[10 13 14] In China, there are approximately 200 000 AS patients awaiting treatment every year. Since its introduction in 2010 and the approval of two domestic valves in 2017, cardiac interventional therapy has entered a new era.[15] The third generation of transcatheter aortic valves, such as the Edwards SAPIEN 3, has been included in provincial medical insurance catalogues, with a price reduction of over 40% since being approved for the Chinese market by the National Medical Products Administration in 2020.[16] Besides efficacy, the relatively higher cost of value-based TAVI poses a significant economic burden, necessitating pharmacoeconomic evaluation. Therefore, our goal is to conduct a cost-effectiveness analysis of TAVI versus SAVR in treating intermediate-risk and high-risk AS patients from a healthcare system perspective in China.

METHODS

Material and methods

This economic analysis used clinical efficacy and safety data from the PARTNER IA and PARTNER IIA trials, health state utilities and cost data from published literature and local public databases.

The decision tree model is typically used for short-term decision analysis, whereas the Markov model is employed to simulate the long-term progression of diseases, such as the evaluation of long-term treatment effects for chronic conditions. This study developed a two-phase decision-analytic model using TreeAge Pro software (version 2022,https://www.treeage.com/) based on published data, simulating a hypothetical cohort of AS patients.[17] The model was used to assess the cost-effectiveness of TAVI versus SAVR for both intermediate and high surgical risk patients with AS. In the two-phase model, the decision tree simulated the short-term outcomes during the surgery, while the Markov model simulated the long-term outcomes over a 5-year period. In both the decision tree and Markov model, patients may experience stroke, myocardial infarction (MI) or death. Patients who did not experience any events were considered event-free. After the decision tree, surviving patients remain at risk of experiencing new MI or stroke events in the Markov health states. In cases where patients experienced MI or stroke, they were transitioned to the 'post-MI' or 'post-stroke' states. The hypothetical cohort in the model was assumed to have similar characteristics to the populations of the PARTNER IA and PARTNER IIA trials, which reported a mean age of 81 years for AS patients.[10 11] A 1-month cycle length and a 5-year time horizon were chosen to align with the clinical trial's duration and avoid extrapolation.

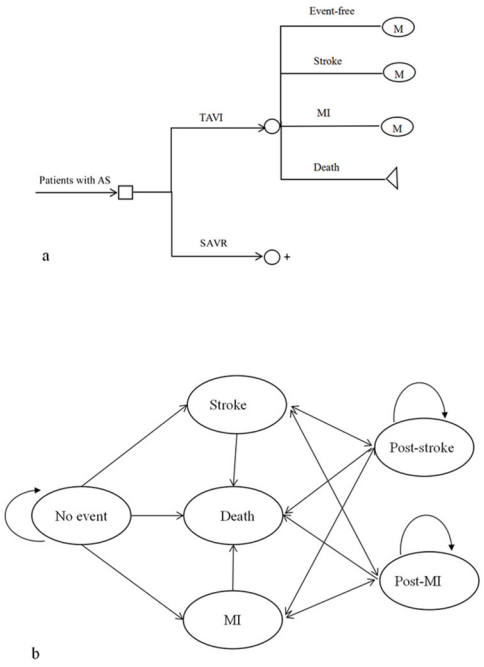

Figure 1 Simplified diagram of the model: (A) 1-month decision tree model; (B) Markov model. AS, aortic stenosis; MI, myocardial infarction. SAVR, surgical aortic valve replacement; TAVI, Transcatheter aortic valve implantation.

The model was based on data from PARTNER IA and PARTNER IIA trials,[10 11] and figure 1 illustrates the diagram of the model. Both the 1-month decision tree model (figure 1a) and the Markov model (figure 1b) were employed to assess cumulative healthcare costs reported in 2021 US dollars and cumulative effectiveness measured by life-years (LYs) gained and quality-adjusted life-years (QALYs) for each treatment arm. The cost-effectiveness of TAVI was evaluated using incremental cost-effectiveness ratios (ICERs), with an ICER below the willingness-to-pay (WTP) threshold of $37 654.50 per QALY (equivalent to 3 times China's per capital gross domestic product (GDP) in 2021) considered cost-effective.[18–20]

This economic analysis used clinical efficacy and safety data from the PARTNER IA and PARTNER IIA trials, health state utilities and cost data from published literature and local public databases. Since our study involved the use of existing data and did not involve human subjects, it was exempted from the institutional review board approval. Additionally, our study adhered to the Guidelines for Pharmacoeconomic Evaluation in China.[18]

Clinical and utility inputs

In our analysis, QALYs were calculated as utilities-discounted LYs. These utilities were determined based on the transition probabilities and varied according to

Table 1 Utilities applied to model events

The baseline (QALY)	TAVI	SAVR	Distribution	Data source
First year	0.80 (0.73–0.87)	0.71 (0.63–0.79)	Beta	24
Second year and beyond	0.89 (0.86–0.92)	0.78 (0.72–0.84)	Beta	24
Disutility of MI	0.147 (0.140–0.155)		Beta	25 26
Disutility of post-MI	0.039 (0.037–0.041)		Beta	25 26
Disutility of stroke	0.226 (0.215–0.237)		Beta	25 26
Disutility of post-stroke	0.069 (0.063–0.071)		Beta	25 26

MI, myocardial infarction; QALY, quality-adjusted life-year; SAVR, surgical aortic valve replacement; TAVI, transcatheter aortic valve implantation.

treatment strategies. We employed three source of data: PARTNER IA study for the SAVR high-risk population, PARTNER IIA study for the SAVR intermediate-risk population and published studies.[10 11 21–23] To construct a parametric survival model, we incorporated clinical outcomes such as all-cause mortality, major stroke incidences and MI (see online supplemental table 1).[10 11 21–23]A constant monthly incidence rate of clinical events was assumed between specific time points (eg, 30 days, 1 year, 2 years, 3 years and 5 years after the index procedure). The monthly transition probabilities of each clinical outcome were derived using the formula: p=1 s(t)/S(t-1), where S(t) represented the survival probability of the event at time t. Recurrent probabilities for MI and stroke in patients after the first month were estimated using the same formula above and were assumed to remain constant in all non-death health states. Utility scores were obtained from an economic study that used the European Quality of Life Group's 5-dimension 5-level questionnaire to assess the health-related quality of life for patients undergoing TAVI or SAVR procedures.[24] For simplicity, we assumed that the utilities were the same for both populations. Disutility scores for MI, stroke, post-MI and post-stroke were derived from reported economic studies.[25 26] Joint utilities were calculated using the following formula: Uij=Ui Uj, where Ui and Uj represent the utility for disease i and j, respectively.[27] To avoid double-counting, disutility associated with adverse events (AEs) were not included. All inputs for measuring QALYs are summarised in table 1.

Cost inputs

The direct costs in this analysis were collected from the perspective of the Chinese healthcare system and encompassed expenses associated with TAVI or SAVR procedures (including the cost of the valve, surgery and other materials), post-procedural inpatient care (including medication, nursing care, examinations, treatment, physicians, hospitalisation and laboratory tests), treatment for AEs and follow-up visits. Real-world data were obtained from a retrospective analysis conducted at a local comprehensive hospital between January 2021 and April 2022. A total of 111 patients with AS without any other underlying disease were included, with 65 receiving TAVI treatment and 46 receiving SAVR treatment. Additionally, based on market share data research, a weighted average analysis of the three most commonly used valves during TAVI or SAVR procedures resulted in average costs of $33 675.28 and $6667.75, respectively (online supplemental table 2). It is worth noting that patients who underwent SAVR often required blood transfusions post-surgery, and their costs were accounted for in the analysis. Other costs, including the management of stroke, MI, post-stroke and post-MI, were taken from previous literature.[28] To align with current clinical practice, patients who experienced cardiovascular disease (CVD) events and subsequently died were recommended for end-of-life care prior to death. The treatment cost related to CVD events was assumed to be the same for both populations and sourced from the literature.[29] Furthermore, patients who underwent TAVI or SAVR were charged for 75 mg one time per day clopidogrel and aspirin for the first 6 months after their procedure at a monthly cost of $12.90.

The model also accounted for costs related to AEs, including major bleeding, major vascular complications, new permanent pacemaker implantation, acute kidney injury and atrial fibrillation. These costs were calculated as a frequency-weighted sum and incorporated into the first cycle of the model using data from published literature (refer to table 2 for details).[28 30–34] As per local guidelines, routine outpatient follow-up was conducted in the first month, followed by visits at 6 months and annually thereafter, regardless of the type of treatment received.[35] All cost data were adjusted for inflation using the healthcare consumer price indexes based on the National Bureau of Statistics of China. The values were then converted to 2021 US dollars using an exchange rate of $1 = ¥6.4515.[19] The healthcare consumer price indexes in China from 2017 to 2021 were 1.06, 1.043, 1.24 and 1.018, respectively. The geometric mean based on these figures was used as the discount rate in our analysis. Future costs, LYs and QALYs were discounted at the same rate of 2.88% (1–8%).

Sensitivity analyses

To address the uncertainty in model parameters, both deterministic sensitivity analysis (DSA) and probabilistic sensitivity analysis (PSA) were conducted. In DSA, all parameters, including costs, event probabilities and utilities were varied independently within a range of ±30% of the baseline values or within plausible ranges available from published literature.[36 37] This allowed us to assess the potential impact of these variations on the ICER. The

Table 2 Summary of costs and proportion of model inputs in actual practice

Parameter	TAVI (range)	SAVR (range)	Distribution	Source
During the procedure ($)				
Valve	33 675.28 (23 572.70–43 777.86)	6667.75 (4667.43–8667.08)	Lognormal	Estimated
Surgery	1357.22 (950.05–1764.39)	1764.86 (1235.40–2294.32)	Lognormal	Estimated
Other materials that other than valve	3607.25 (2525.08–4689.43)	7783.36 (5448.35–10 118.37)	Lognormal	Estimated
Postprocedural inpatient care ($)				
The medication	1813.83 (1269.68–2357.98)	4894.20 (3425.94–6362.46)	Lognormal	Estimated
Nursing care	177.18 (124.03–230.33)	303.12 (212.18–394.06)	Lognormal	Estimated
Examination	2028.92 (1420.24–2637.60)	2113.00 (1479.10–2746.90)	Lognormal	Estimated
Treatment	951.22 (665.85–1236.59)	1214.67 (850.27–1579.07)	Lognormal	Estimated
Physicians	50.02 (35.01–65.03)	132.07 (92.45–171.69)	Lognormal	Estimated
Laboratory test	1007.20 (705.04–1309.36)	1976.64 (1383.65–2569.63)	Lognormal	Estimated
Hospitalisation	123.48 (86.44–160.52)	202.91 (142.04–263.78)	Lognormal	Estimated
Transfusion	NA	481.28 (336.90–625.66)	Lognormal	Estimated
The cost of oral clopidogrel and aspirin	12.9 (9.03–16.77)		Lognormal	Estimated
Stroke	1642.78 (1149.95–2135.61)		Lognormal	28
Post-stroke	37.46 (26.22–48.70)		Lognormal	28
MI	4281.91 (2997.34–5566.48)		Lognormal	28
Post-MI	37.46 (26.22–48.70)		Lognormal	28
Bleeding	2389.16 (1672.41–3105.91)		Lognormal	28
CVD events	12 061.48 (8443.04–15 679.92)		Lognormal	29
AKI	1066.48 (746.54–1386.42)		Lognormal	30
New PPI	12 617.23 (8832.06–16 402.40)		Lognormal	31
AF	9387.84 (571.45–12 204.19)		Lognormal	32
Major vascular complication	24 018.38 (16 812.87–31 223.89)		Lognormal	33
Follow-up cost ($/cycle)				
First month after the procedure	56.36 (39.45–73.27)		Lognormal	Estimated
Sixth month after the procedure	288.87 (202.21–375.53)		Lognormal	Estimated
Annually thereafter	56.36 (39.45–73.27)		Lognormal	Estimated
Incidence in intermediate-risk population (%)				
Bleeding	21.1 (14.77–27.43)	48.6 (34.02–63.18)	Beta	34
AKI	3.4 (2.38–4.42)	10.0 (7.00–13.00)	Beta	34
New PPI	15.1 (10.57–19.63)	13.5 (9.45–17.55)	Beta	34
AF	11.7 (8.19–15.21)	30.79 (21.49–39.91)	Beta	34
Major vascular complication	9.6 (6.72–12.48)	5.1 (3.57–6.63)	Beta	34
CVD events	56.2 (39.34–73.06)	60.3 (42.21–78.39)	Beta	34
Incidence in high-risk population (%)				
Bleeding	26.6 (18.62–34.58)	34.4 (24.08–44.72)	Beta	22
AKI	8.6 (6.02–11.18)	8.5 (5.95–11.05)	Beta	22
New PPI	9.7 (6.79–12.61)	9.1 (6.37–11.83)	Beta	22
AF	NA	NA		22
Major vascular complication	11.9 (8.33–15.47)	4.7 (3.29–6.11)	Beta	22
CVD events	64.2 (44.94–83.46)	62.1 (43.47–80.73)	Beta	22
Other				
Discount rate	0.0288 (0–0.08)		Normal	19

AF, atrial fibrillation; AKI, acute kidney injury; CVD events, cardiovascular disease events; MI, myocardial infarction; PPI, permanent pacemaker implantation; SAVR, surgical aortic valve replacement; TAVI, transcatheter aortic valve implantation.

results were presented using tornado diagrams to visualise the sensitivity of the model to each parameter.

In PSA, appropriate probability distributions (eg, beta distribution for utilities and proportions, lognormal distribution for costs, normal distribution for discount rate) recommended by the ISPOR-SMDM Modeling Good Research Practices Task Force were assigned to the parameters.[38] Then, 1000 Monte Carlo simulations were conducted to estimate the overall impact of parameter uncertainty on the results. The results of PSA were shown as cost-effectiveness acceptability curve (CEAC), which illustrate the probability that each treatment is cost-effective at different WTP thresholds .

Patient and public involvement statement

None.

RESULT

Base case result

From the Chinese healthcare system perspective, the base-case analysis revealed that TAVI treatment was associated with higher cost but better health outcomes compared with SAVR treatment for both intermediate- and high-risk AS patient populations. In the intermediate-risk population, TAVI was estimated to provide an additional 0.34 discounted QALY at an extra cost of $16 707.58, resulting in an ICER of $49 176.60 per QALY gained. For the high-risk population, TAVI was projected to generate an additional 0.15 discounted QALY at an additional discounted cost of $18 093.52, yielding an ICER of $122 696.37 per QALY gained. However, both of these ICERs exceeded the WTP threshold of $37 654.50/QALY, indicating that TAVI may not be considered cost-effective within these populations. Detailed information on the base-case analysis for each population can be found in table 3.

Table 3 Summary of cost ($) and outcome results in base case analysis

	In intermediate-risk population		In high-risk population	
Items	**TAVI**	**SAVR**	**TAVI**	**SAVR**
Mean costs ($)				
No-event state	46 947.46	29 983.72	46 671.09	29 526.02
Stroke state	2138.06	2593.40	2651.89	1790.58
MI	1479.45	1324.96	201.47	686.76
The procedure costs	43 297.91	26 917.07	43 523.18	25 871.31
Non-device costs	10 235.49	9908.75	11 088.75	10 647.09
Total costs	53 533.40	36 825.82	54 611.93	36 518.40
Mean LYs				
No-event state	2.82	2.96	2.08	2.15
Stroke state	0.39	0.34	0.51	0.51
MI	0.34	0.28	0.05	0.14
Total	3.54	3.57	2.64	2.80
Mean QALYs				
No-event state	2.43	2.24	1.77	1.62
Stroke state	0.31	0.24	0.41	0.35
MI	0.28	0.20	0.04	0.10
Total	3.02	2.68	2.23	2.08
ICERs ($/QALY)*	49 176.60	NA	122 696.37	NA

*Compared with SAVR
LYs, life-years; MI, myocardial infarction; QALY, quality-adjusted life-year gained; SAVR, surgical aortic valve replacement ; TAVI, transcatheter aortic valve implantation.

Sensitivity analysis

The DSA results are presented in online supplemental figure S1. For patients at intermediate risk, the parameter with the highest influence on ICER was the price of the valve in TAVI group (online supplemental figure S1a). When the valve price was reduced by 13.7% from its original price, the resulting ICER would be fall below the WTP threshold of $37 654.50/QALY. In the defined ranges, all parameters except for the valve price failed to produce an ICER lower than the WTP threshold. In the case of high-risk patients, the top three sensitive parameters were the utility at month 1 and month 12 in the SAVR arm and the cost of valve in TAVI arm (online supplemental figure S1b). However, none of these parameters alone were resulted in an ICER below the WTP threshold. The lowest ICER of $57 956.38/QALY was achieved when the price of the valve in the TAVI arm was reduced by 30%, highlighting the significant impact of pricing on the cost-effectiveness analysis.

Online supplemental figure S2a presents the CEAC of PSA for patients at intermediate-risk. At the Presupposed WTP threshold, the probability of TAVI being cost-effective compared with SAVR was 27.1%. The probability exceeded 50% at the WTP threshold of $49 176.60/QALY. In online supplemental figure S2b, the probability of TAVI being cost-effective for the high-risk population is shown with increasing WTP threshold. At the WTP threshold of $37 654.50/QALY, the probability of TAVI being cost-effective compared with SAVR was only 3.4%. However, at the WTP threshold of $122 696.3/QALY, the probability reached 50%, indicating that beyond this threshold, TAVI became the cost-effective treatment strategy.

DISCUSSION

To ensure a thorough assessment of the economic implications of new treatment strategies, especially in resources-constrained countries, comprehensive cost-effectiveness analyses are essential. To the best of our knowledge, this is the first cost-effectiveness analysis of TAVI from the perspective of the Chinese healthcare system by combining real-world cost information with time-to-event information from the PARTNER 1A and PARTNER 2A trials.

The results indicated that TAVI in intermediate and high surgical risk patients with AS had ICERs of $49 176.60 and $122 696.37 per QALY gained, respectively. These ICERs were considered not cost-effective at a WTP threshold of $37 654.50/QALY. The primary reasons for the high ICERs were the high procedure costs especially the device costs of TAVI compared with SAVR and the marginal improvement in QALYs as simulated mortality in TAVI exceeded SAVR at 5-year post-implantation. DSAs showed that the ICERs ranged from $21 879.29 to $76 473.91 per QALY gained in the intermediate-risk group and from $52 582.63/QALY to $541 942.59/QALY in the high-risk group. When the price of TAVI valve was discounted by more than 13.7%, the ICER fell below the WTP of $37 564.50/QALY, making TAVI cost-effective for the intermediate-risk population. While for the high- risk population, the lowest ICER was achieved when there was a 30% reduction in the cost of TAVI valve. Encouragingly, since 2017, the National Healthcare Security Administration has conducted negotiations with pharmaceutical companies regarding medical instruments and drugs, and many instruments, such as coronary stents, have been included in the National Reimbursement Drug List, resulting in average price reductions of 93%.[39] These valve negotiations could be an effective way to make TAVI more affordable and widely accessible in China. Additionally, alternative payment models such as bundled payments or performance-based payments can be explored to incentivise healthcare service providers to deliver high-quality and efficient care while controlling costs. Furthermore, the recommended ICER threshold for medical technologies is typically 3 times the country's per capital GDP.[17 18] However, due to the unbalanced economic development in China, there are significant variations in per capital GDP among which province-level administrative units differ significantly. For example, in 2021, it ranged from $6362.24 in Gansu province to $28 517.40 in Beijing city.[19] This implies that TAVI may be cost-effective in certain affluent regions.

The limited research on the economic evaluation of TAVI in China is primarily due to the relatively new clinical evidence. However, several published economic evaluations from Canada, France, Italy, Japan, Australia and the UK have shown that TAVI is a cost-effective strategy when compared with SAVR (see online supplemental table 3), which is inconsistent with our current findings.[17 40–45] There are two main reasons that may account for this disparity. First, the extrapolation of all-cause mortality from the 2-year PARTNER trials might have overestimated the benefits of TAVI, as the 5-year all-cause mortality rate was found to be higher in TAVI group than in SAVR group. This suggests that the long-term benefits of TAVI may not be as favourable as initially anticipated. Second, the relatively less developed economic conditions in China, compared with countries like the ones mentioned above, may contribute to the lower cost-effectiveness of TAVI in China. The economic factors and healthcare system differences between countries can significantly impact the results of economic evaluations. It is worth noting that the cost-utility analysis of TAVI in the Australian population emphasises its effectiveness, primarily attributed to its greater benefit in the moderate AS population. By intervening at an earlier stage of the disease, TAVI can potentially prevent the progression of AS to severe stages, consequently reducing the necessity for more invasive and costly interventions in the future. This, in turn, may result in patients gaining more QALYs. However, four other studies conducted in Singapore, Thailand, the USA and Belgium found ICERs above the WTP threshold, showing inconsistency in the cost-effectiveness of TAVI in both intermediate and high surgical risk groups.[24 34 46 47] The benefits of TAVI treatment include shorter hospitalisation and lower complication costs compared with SAVR; however, the cost savings from these benefits are not sufficient to offset the high cost of the TAVI valve.

Furthermore, as TAVI is a relatively new procedure, the long-term durability of the valve and the potential need for repeat procedures in the future may further impact its cost-effectiveness over time. The longevity and efficacy of the TAVI valve will be critical factors to consider in assessing the cost-effectiveness of this treatment option. Another important factor to consider is the risk profile of patients undergoing TAVI or SAVR. While TAVI may be a more suitable option for patients who are at high surgical risk, those who are at intermediate risk may not derive as much benefit from TAVI. Consequently, the cost-effectiveness of TAVI may vary depending on the risk profile of the patient population being evaluated. In general, the economic evaluation of TAVI is complex and multifaceted, with various variables impacting its cost-effectiveness. Therefore, continued research and evaluation of TAVI in different patient populations and healthcare systems are essential to ensure its appropriate adoption and utilisation in clinical practice. It is crucial to understand the specific context and characteristics of each country or healthcare system when interpreting the results of economic evaluations of TAVI.

Strengths and limitations

Our study has several strengths. First, the two-stage decision analysis model employed allows for a comprehensive evaluation of the intervention. The decision tree component helps in simulating short-term perioperative outcomes, providing insights into the immediate impacts of initial decisions. Subsequently, the Markov model enables the projection of long-term health state transitions and treatment effects, facilitating the assessment of long-term cost-effectiveness. This integrated approach yields comprehensive analysis results, thereby enhancing support for policy-making and medical decision-making. Second, it fills the knowledge gap in the field of TAVI cost-effectiveness and provides valuable data for decision-makers. Third, this study used the most recent 5-year clinical data, and the entire simulation process was based on existing data, thereby avoiding simulation errors caused

by extrapolation models. Finally, we made use of a significant amount of real-world economic data and directly compared the cost-effectiveness of TAVI versus SAVR using a Markov model. This study has the following limitations: first, the utility values used in this study are not derived from an Asian population, which may lead to bias in the study results. However, we conducted DSA and PSA, and the results showed that the utility values did not affect the robustness of the study results. Second, this study only conducted cost-effectiveness analysis for patients at intermediate and high surgical risk, and the results may not be applicable to other patient populations. In addition, the data sources and model parameters used in the study may also have an impact on the results.

CONCLUSIONS

TAVI may not prove to be a cost-effective treatment choice for patients with intermediate and high risks of AS in China when compared with SAVR. This is primarily due to the elevated procedural expenses, particularly those associated with the devices. To enhance the cost-effectiveness of TAVI, a pivotal strategy lies in diminishing the price of the valves through diverse approaches.

Although the results of this study are not very ideal, with the rapid development of medical technology in China, continuous innovations and optimisations in TAVI devices are expected to further reduce surgical risks and costs. The impact of these technological advancements on clinical outcomes and cost-effectiveness, particularly in reducing device costs, shortening postoperative recovery periods and decreasing complications, will be a key focus of future research. Second, long-term follow-up studies are crucial. This study provides an initial cost-effectiveness analysis based on existing short- and medium-term follow-up data, but longer-term data is essential for a comprehensive evaluation of the effects of TAVI and SAVR. Future studies should consider longer follow-up periods to thoroughly analyse the long-term cost-effectiveness of these two treatment methods, including the incidence of long-term complications, valve durability and changes in patients' quality of life. The accumulation of long-term data will allow for more precise guidance in clinical and economic decision-making.

For policymakers, while improving the payment system, promoting a nationwide early screening programme for aortic stenosis is critical. Particularly in high-risk elderly populations, early screening helps to make timely clinical decisions in the early stages of the disease, thereby reducing later treatment costs and significantly improving patient outcomes.

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