Economic Evaluation of Transcatheter Aortic Valve Replacement Compared to Surgical Aortic Valve Replacement in Chinese Intermediate-Risk Patients

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Background: Aortic stenosis (AS) is a severe disease that causes heart failure and sudden death. Transcatheter aortic valve replacement (TAVR) and surgical aortic valve replacement (SAVR) are both recommended for patients with intermediate surgical risk, but the cost-effectiveness of TAVR compared to SAVR in China has not been investigated.

Methods: A combined decision tree and Markov model were conducted to compare the cost-effectiveness of TAVR versus SAVR with a 5-year simulation. The primary outcome was the incremental cost-effectiveness ratio (ICER), a ratio of incremental costs to incremental quality-adjusted life-year (QALY). One-way sensitive analysis and probabilistic sensitivity analysis (PSA) were conducted to test the robustness of the model.

Results: After a simulation of 5 years, the costs of TAVR and SAVR were 54,573 and 35,002 USD, respectively, and the corresponding effectiveness was 2.826 versus 2.712 QALY, respectively. The ICER for the TAVR versus SAVR comparison was 170,056 USD/QALY, which was three times higher than the per capita gross domestic product (GDP) in China. One-way sensitive analysis showed that the cost of the TAVR device impacted the ICER. The TAVR could be cost-effective only in the case where its cost is lowered to 29,766 USD.

Conclusion: TAVR is currently not cost-effective in China, but it could be cost-effective with a reduction of costs to 29,766 USD, which is approximately 65% of the current price.

Keywords: TAVR, SAVR, economic evaluation, cost-effectiveness, aortic stenosis
INTRODUCTION

Aortic stenosis (AS) is a severe disease that causes heart failure and sudden death (1, 2). A retrospective survey conducted in China showed that the prevalence of AS was 0.16% in inpatients younger than 65 years old and that it was 0.41 and 0.56% in those aged 65–74 and over 75 years old (3). Another study conducted in China found that 0.39–0.66% of outpatients aged over 65 years who received echocardiography were diagnosed with severe AS (4). As the Chinese population is entering an aging society, the burden of AS is increasing.

Surgical aortic valve replacement (SAVR) has always been the optimal treatment for patients with AS across different risk stratifications (5, 6). However, several important clinical studies regarding transcatheter aortic valve replacement (TAVR) (7–10) have demonstrated the efficacy and safety of TAVR all over the world (11, 12). It is estimated that more than 306,000 patients with AS have undergone TAVR in the United States (13). The number of patients with AS who have undergone TAVR in China is much lower but is increasing at a fast rate.

In patients with AS who are at intermediate risk for surgery, it has been demonstrated that TAVR has similar efficacy as that of SAVR (9). The 2021 European Society of Cardiology (ESC) guidelines for valvular heart disease recommended that SAVR and TAVR are both first-line treatments for patients at intermediate-risk (6). In clinical practice, whether a treatment can be widely used depends not only on its effectiveness but also on whether it is cost-effective. The collective purchase policy launched by the Chinese government allows only cost-effective drugs or medical devices to be widely used in Chinese hospitals, but an economic evaluation comparing TAVR versus SAVR is lacking. Thus, the present study aimed to investigate the cost-effectiveness of TAVR compared to SAVR among Chinese patients at intermediate-risk.

MATERIALS AND METHODS

Overview

The basic structure of the model consisted of two parts, namely, a 30-day decision tree and a 59-month Markov model. Patients who entered the model would first enter the decision tree, and TAVR or SAVR was performed. After 30 days, the patients would enter a Markov model with a simulation of 59 months. The summary simulation period was 60 months. The starting age was 80 years old, and the simulation cycle was 5 years, which was similar to that in the PARTNER 2 study.

Model Structure

In the 30-day decision tree model, patients allocated to the TAVR or SAVR group may experience one or several complications of the procedure, including death, disabling stroke, non-disabling stroke, myocardial infarction (MI), major vascular complication, major bleeding, acute kidney injury (AKI), permanent pacemaker implantation, and new atrial fibrillation (AF). After that, the patients would enter a Markov model with a simulation of 59 months, and every patient entering the Markov model would transit among five states, including no events, post-AF, post-disabling stroke, post-non-disabling stroke, and death. The cycle period in the Markov model was 1 month, and there were 59 cycles in summary. The detailed model is displayed in Figure 1.

Input Parameters

Clinical Data

The clinical data analyzed in our study was mainly derived from the PARTNER 2 study (Placement of aortic transcatheter valves II - XT intermediate and high risk) (9, 14). For periprocedural complications within 30 days, the corresponding data were directly extracted from a published article. For data between
1 month and 5 years post-procedure, they were transformed into probability per month. Considering that the probabilities of complications and death within 1, 2, and 5 years may vary, we separately calculated the data between these periods. The non-cardiovascular mortality in the Markov model was obtained from the China National Bureau of Statistics\(^1\). As the AF incidence was much higher in patients with a procedure than without a procedure, the AF incidence was accessed from the PARTNER 2 study. However, the mortality of AF was obtained from a study conducted in a Chinese population (15), and the mortality of stroke was also derived from a Chinese cohort study. The key input parameters in this study are listed in Table 1.

### Costs

The key costs are displayed in Table 1. The costs of TAVR are shown in USD, including the TAVR device costs, medicine costs, diagnosis costs, and other costs, and the overall costs of SAVR are also shown in USD. Different from previous studies, the costs in the present study were derived from a domestic article, and the costs of intensive care unit (ICU) or ward stay were covered in the medicine and other costs. The costs of stroke, AF, MI, major bleeding, AKI, and permanent pacemaker were obtained from a published article. Because there are no explicit costs of major vascular complications, we consulted two experts in this field and adopted the value of 5,000 USD as its cost. All the costs were discounted at 0.037 annually, which was the mean medical consumer price index (CPI) in the past 5 years in China. The range of costs was extracted from a published article. If the costs could not be extracted from a published article, we adopted 0.5 fold and 2 fold as the lower and higher limits, respectively. All the costs were converted from Chinese renminbi (RMB) to USD at a ratio of 6.5, which was the mean ratio in 2021.

### Utilities

If there were utilities for the Chinese population, we adopted the domestic value; otherwise, we adopted the commonly used utilities. The base utilities of post-procedure were obtained from a published article investigating the utilities of TAVR and SAVR, and we adopted the disutility for complications including AF, bleeding, major vascular complications, non-disabling stroke, and AKI. The utility for disabling stroke was a fixed value of .39, which is commonly used in published studies.

### Outcomes

The primary outcome of this study was the incremental cost-effectiveness ratio (ICER), representing the incremental costs per quality-adjusted life-year (QALY). As there was no specific willing-to-pay (WTP) threshold in China, we selected three times the per capita GDP in China in 2021 as the WTP, which was 37,500 USD. The TAVR would be considered cost-effective if the ICER was less than 37,500 USD/QALY; otherwise, it would be thought as not cost-effective. In addition, if the TAVR was not cost-effective, the cost leading to cost-effectiveness would be calculated.

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\(^1\)http://www.stats.gov.cn/
## TABLE 1 | Periprocedural complications incidence and transition probabilities in the model.

| Periprocedural complications incidence in TAVR (30 days) | Base | SD  | Range low | Range high | Source |
|---------------------------------------------------------|------|-----|-----------|------------|--------|
| AF                                                      | 0.091| 0.009| 0.073     | 0.109      | (14)   |
| AKI                                                     | 0.013| 0.004| 0.006     | 0.02       | (14)   |
| Bleeding                                                | 0.104| 0.01 | 0.085     | 0.123      | (14)   |
| Death                                                   | 0.039| 0.006| 0.027     | 0.051      | (14)   |
| Disabling stroke                                        | 0.032| 0.006| 0.021     | 0.043      | (14)   |
| Major vascular complication                             | 0.079| 0.008| 0.062     | 0.096      | (14)   |
| MI                                                      | 0.012| 0.003| 0.005     | 0.019      | (14)   |
| Non-disabling stroke                                    | 0.023| 0.005| 0.014     | 0.032      | (14)   |
| PPM                                                     | 0.085| 0.009| 0.068     | 0.102      | (14)   |

| Periprocedural incidence in SAVR (30 days)              | Base | SD  | Range low | Range high | Source |
|---------------------------------------------------------|------|-----|-----------|------------|--------|
| AF                                                      | 0.264| 0.014| 0.237     | 0.291      | (14)   |
| AKI                                                     | 0.031| 0.005| 0.02      | 0.042      | (14)   |
| Bleeding                                                | 0.434| 0.016| 0.404     | 0.464      | (14)   |
| Death                                                   | 0.041| 0.006| 0.029     | 0.053      | (14)   |
| Disabling stroke                                        | 0.043| 0.006| 0.031     | 0.055      | (14)   |
| Major vascular complication                             | 0.05 | 0.007| 0.037     | 0.063      | (14)   |
| MI                                                      | 0.019| 0.004| 0.011     | 0.027      | (14)   |
| Non-disabling stroke                                    | 0.018| 0.004| 0.01      | 0.026      | (14)   |
| PPM                                                     | 0.069| 0.008| 0.053     | 0.085      | (14)   |

| Transition probabilities of no event to AF in TAVR (per month) | 2–12 months | 0.001 | /  | / | / | (14) |
|----------------------------------------------------------------|-------------|------|----|---|---|-----|
| 13–24 months                                                  | 0.0011      | /    | /  | / | / | (14) |
| 25–60 months                                                 | 0.0014      | /    | /  | / | / | (9)  |

| Transition probabilities of no event to AF in SAVR (per month) | 2–12 months | 0.001 | /  | / | / | (14) |
|----------------------------------------------------------------|-------------|------|----|---|---|-----|
| 13–24 months                                                  | 0.0001      | /    | /  | / | / | (14) |
| 25–60 months                                                 | 0.0011      | /    | /  | / | / | (9)  |

| Transition probabilities of no event to non-disabling stroke in TAVR (per month) | 2–12 months | 0.0007 | /  | / | / | (14) |
|----------------------------------------------------------------|-------------|------|----|---|---|-----|
| 13–24 months                                                  | 0.0003      | /    | /  | / | / | (14) |
| 25–60 months                                                 | 0.0005      | /    | /  | / | / | (9)  |

| Transition probabilities of no event to non-disabling stroke in SAVR (per month) | 2–12 months | 0.0007 | /  | / | / | (14) |
|----------------------------------------------------------------|-------------|------|----|---|---|-----|
| 13–24 months                                                  | 0.0003      | /    | /  | / | / | (14) |
| 25–60 months                                                 | 0.0003      | /    | /  | / | / | (9)  |

| Transition probabilities of no event to disabling stroke in TAVR (per month) | 2–12 months | 0.0017 | /  | / | / | (14) |
|----------------------------------------------------------------|-------------|------|----|---|---|-----|
| 13–24 months                                                  | 0.0011      | /    | /  | / | / | (14) |
| 25–60 months                                                 | 0.0011      | /    | /  | / | / | (9)  |

| Transition probabilities of no event to disabling stroke in SAVR (per month) | 2–12 months | 0.0014 | /  | / | / | (14) |
|----------------------------------------------------------------|-------------|------|----|---|---|-----|
| 13–24 months                                                  | 0.0005      | /    | /  | / | / | (14) |
| 25–60 months                                                 | 0.0007      | /    | /  | / | / | (9)  |

| Cardiovascular mortality in TAVR (per month) | 2–12 months | 0.0036 | /  | / | / | (14) |
|----------------------------------------------------------------|-------------|------|----|---|---|-----|
| 13–24 months                                                  | 0.0027      | /    | /  | / | / | (14) |
| 25–60 months                                                 | 0.0067      | /    | /  | / | / | (9)  |

| Cardiovascular mortality in SAVR (per month) | 2–12 months | 0.0047 | /  | / | / | (14) |
|----------------------------------------------------------------|-------------|------|----|---|---|-----|
| 13–24 months                                                  | 0.0029      | /    | /  | / | / | (14) |
| 25 and 60 months                                             | 0.0057      | /    | /  | / | / | (9)  |

| Non-cardiovascular mortality for aged 80–85 (per month) | 2–12 months | 0.0026 | /  | / | / | (15) |
|----------------------------------------------------------------|-------------|------|----|---|---|-----|
| 13–24 months                                                  | 0.0016      | /    | /  | / | / | (28) |
| 25 and 60 months                                             | 0.0011      | /    | /  | / | / | (28) |
| Transition probability of AF to stroke (per month)            | 0.0005      | /    | /  | / | / | (28) |
| Transition probability of AF to disabling stroke (per month)  | 0.0024      | /    | /  | / | / | (28) |
TABLE 2 | Utilities and costs in the model.

| Utility                      | Base  | SD   | Range low | Range high | Sources |
|------------------------------|-------|------|-----------|------------|---------|
| No event in TAVR <7 months   | 0.74  | 0.24 | /         | /          | (19, 22) |
| No event in TAVR 7–12 months | 0.76  | 0.2  | /         | /          | (19, 22) |
| No event in TAVR >12 months  | 0.75  | 0.22 | /         | /          | (19, 22) |
| No event in TAVR <7 months   | 0.68  | 0.24 | /         | /          | (19, 22) |
| No event in TAVR 7–12 months | 0.75  | 0.27 | /         | /          | (19, 22) |
| No event in TAVR >12 months  | 0.74  | 0.23 | /         | /          | (19, 22) |
| Disabling stroke             | 0.39  |      | 0.31      | 0.52       | (29)    |
| Non-disabling stroke         | –0.161| 0.054| /         | /          | (22)    |
| AF                           | –0.038|      | –0.038    | 0          | (24)    |
| AKI                          | –0.177|      | –0.177    | 0          | (24)    |
| Bleeding                     | –0.447|      | –0.447    | 0          | (24)    |
| Major vascular complication  | –0.046|      | –0.046    | 0          | (24)    |
| Myocardial infarction        | –0.1  |      | –0.1      | 0          | (33)    |

Costs

- TAVR device: 45526 USD
- TAVR diagnosis: 2016 USD
- TAVR medicine: 2025 USD
- TAVR others: 824 USD
- SAVR device: 15580 USD
- SAVR diagnosis: 2076 USD
- SAVR medicine: 8182 USD
- SAVR others: 1401 USD
- Non-disabling stroke event: 1096 USD
- Non-disabling annual cost: 329 USD
- Disabling stroke event: 1379 USD
- Disabling stroke annual cost: 516 USD
- Myocardial infarction event: 732 USD
- Major vascular complication: 2750 USD
- Major bleeding: 69 USD
- Atrial fibrillation (AF): 14124 USD
- AF annual cost: 945 USD
- Stroke death: 458 USD
- Discount rate: 0.037

26,794 USD, the ICER would be 12,500 USD/QALY, which is equal to the current per capita GDP in China, and the ICER would be 37,500 USD/QALY (three times greater than the current per capita GDP in China) when the TAVR price is 29,766 USD.

DISCUSSION

To the best of our knowledge, the present study is the first to investigate the cost-effectiveness of TAVR vs. SAVR in Chinese patients with AS. We found that in the intermediate surgical risk population, TAVR is not currently cost-effective in China, and TAVR could be cost-effective only when the TAVR device cost is decreased to 29,766 USD. Thus, if the TAVR device cost is lowered to 26,794 USD, TAVR would be highly cost-effective.

Some studies have reported that TAVR is cost-effective in their countries (16–19). However, in the present study, we concluded that TAVR is not currently cost-effective in China due to several reasons. First, the costs of the TAVR device vary among different regions, ranging from 17,268 USD to 45,526 USD (20, 21). In Canada, the cost is 17,268 USD, but the cost is approximately 45,526 USD in China, resulting in an ICER of 170,056 USD/QALY, which is higher than the per capita GDP in China. However, if we adopted the Canadian TAVR device cost in our analysis, the cost of TAVR would be less but the effect would not change. Second, as China is the largest developing country, the per capita GDP is only 12,500 USD, which is lower than that in the United States, Canada, Australia, and Japan, which may cause a lower threshold of WTP. The ICER of 170,056 USD/QALY may be accepted in the United States and Australia with a per capita GDP of more than 60,000 USD, but it cannot be currently accepted in China. Third, there is a difference in the composition of surgical costs between China and other countries. In China, the TAVR device costs account for over 90% of the overall costs, and the proportion of device costs is much higher in China than in other countries (21). In the USA, the proportion of the TAVR device costs is less than 65% of the total costs, and in Australia and Canada (20, 22), the proportion of the TAVR device costs is lower than 60%. The unique situation in China leads to the fact that TAVR is not currently cost-effective in China.

Compared to SAVR, TAVR achieves similar clinical outcomes (7–9). In inoperative patients, TAVR may significantly reduce mortality and other outcomes (23), but in patients with high risk or intermediate risk, the published clinical trials have indicated that TAVR displays similar efficacy to that of SAVR (7, 14). The improvement of TAVR versus SAVR may lie in the relief of

TABLE 3 | Base case and scenario analysis based on different TAVR device cost.

| Arm              | TAVR/SAVR costs (USD) | Summary Costs (USD) | Summary Effectiveness (QALY) | Incremental Cost (USD) | Incremental Effectiveness (QALY) | ICER (USD/QALY) |
|------------------|-----------------------|---------------------|----------------------------|------------------------|-------------------------------|----------------|
| Base case        | SAVR 15580            | 35001               | 2.71                       | /                      | /                             | /              |
|                  | TAVR 45526            | 54573               | 2.83                       | 19571                  | 0.115                         | 170056         |
| Scenario 1       | TAVR 33846            | 43266               | 2.83                       | 8265                   | 0.115                         | 71813          |
| Scenario 2       | TAVR 17268            | 27219               | 2.83                       | –7782                  | 0.115                         | –67621         |
| Scenario 3       | TAVR 26794            | 36439               | 2.83                       | 1438                   | 0.115                         | 12500          |
| Scenario 4       | TAVR 29766            | 39316               | 2.83                       | 4315                   | 0.115                         | 37500          |
symptoms, indicating that patients who underwent TAVR may achieve higher utilities than those who received SAVR, especially in the periprocedural period (24). In the PARTNER 2 study, the periprocedural mortality is 6.1% in the TAVR group versus 8.0% in the SAVR group, but these differences are not statistically significant. When the follow-up period is extended to 5 years, the mortalities in TAVR and SAVR groups are 47.9% and 43.4%, respectively (9, 14). A previous meta-analysis conducted by our team has also demonstrated that TAVR has similar efficacy to that of SAVR regardless of the follow-up period (10). A similar efficacy but higher costs may suggest that TAVR is not cost-effective in China. In addition, the durability of TAVR should be investigated. However, studies thus far have shown that TAVR is safe. The durability of SAVR needs to be evaluated for at least 10 years of follow-up (25), but the longest reported follow-up period of TAVR is only 6 years (26).

**FIGURE 2** | Tornado diagram based on the one-way sensitivity analysis.
One-way sensitive analysis showed that the costs of the TAVR device had the largest impact on the ICER. The PSA showed that TAVR was cost-effective only with a 5% probability. These results indicated that under current costs, TAVR is not cost-effective. The scenario analysis showed that when the costs of the TAVR device are decreased to 29,766 USD, the TAVR could be cost-effective. If the costs of TAVR are lowered to 26,794 USD, TAVR would be highly cost-effective. The Chinese government has launched a collective purchase project, which requires that only cost-effective drugs or medical devices
Transcatheter aortic valve replacement is not currently cost-effective in China. However, TAVR could be cost-effective with a reduction of costs to 29,766 USD, which is approximately 65% of the current price.

**DATA AVAILABILITY STATEMENT**

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author/s.

**AUTHOR CONTRIBUTIONS**

LQ and CZ came up with the idea and designed the protocol. WZ and YL synthesized the data and drafted the manuscript. YL and HW participated in the data collection and data analysis. All authors approved the final version of the manuscript.

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