



Cost–effectiveness analysis of a resource-intensive approach versus minimally invasive strategy for high-risk transcatheter aortic valve replacement patients

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Aortic stenosis has a high mortality rate in patients who do not receive aortic valve replacement. Previously, transcatheter aortic valve replacement (TAVR) was an intervention reserved for individuals deemed high-risk for surgery. Since that time, TAVR has increasingly been offered to lower risk patients, yet it is unclear whether TAVR will meet an acceptable cost–effectiveness threshold in this group. In this cost–effectiveness study, we employed a decision tree model with Monte Carlo probability sensitivity analysis to determine the incremental cost (in US\$) per quality-adjusted life year (QALY) and life year (LY) of performing the TAVR procedure using the resource-intensive approach versus the minimally invasive strategy in high-risk surgical patients.

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Symptomatic aortic stenosis (AS) is a disease with a high mortality rate in patients who do not receive an aortic valve replacement [1–3]. Literature estimates suggest that 3.4% of the population >75 years of age has aortic stenosis [4]. Nearly a decade ago, transcatheter aortic valve replacement (TAVR), formerly an intervention reserved for high-risk individuals with severe symptomatic AS, was found to be superior to medical management. More recently, the PARTNER 3 trial demonstrated TAVR superiority with regards to 30-day mortality, stroke rate, new onset atrial fibrillation, and hospital length of stay even in low-risk patients [5]. As TAVR is increasingly offered to lower risk surgical patients, it will become important to assess the cost–effectiveness of the procedure across discretely defined risk groups, as 12-month cumulative costs of TAVR remain ~US\$10,000 more than surgical aortic valve replacement (SAVR), chiefly attributable to device cost [6,7]. It is unclear whether TAVR will meet an acceptable cost–effectiveness threshold in lower risk groups, where the relative higher cost of the TAVR procedure compared with traditional SAVR may outweigh the cost savings associated with a shorter hospital stay and fewer post-operative complications [7].

Most medical centers performing TAVR have historically employed a resource-intensive approach (RIA) that usually includes endotracheal intubation with general anesthesia, bladder catheterization, central line placement, invasive hemodynamic monitoring, trans-esophageal echocardiography (TEE) and cardiothoracic (CT) surgical back-up [8,9]. More recently, many hospitals in Europe and the USA have adopted a leaner, minimally invasive strategy (MIS) to TAVR staffing in an effort to decrease resource utilization, procedural costs and hospital length of stay (LOS) [10,11]. The MIS involves local anesthesia, minimal conscious sedation, transthoracic echocardiography (TTE) and is performed in a catheterization lab versus the hybrid operating room used with the RIA [10–12].

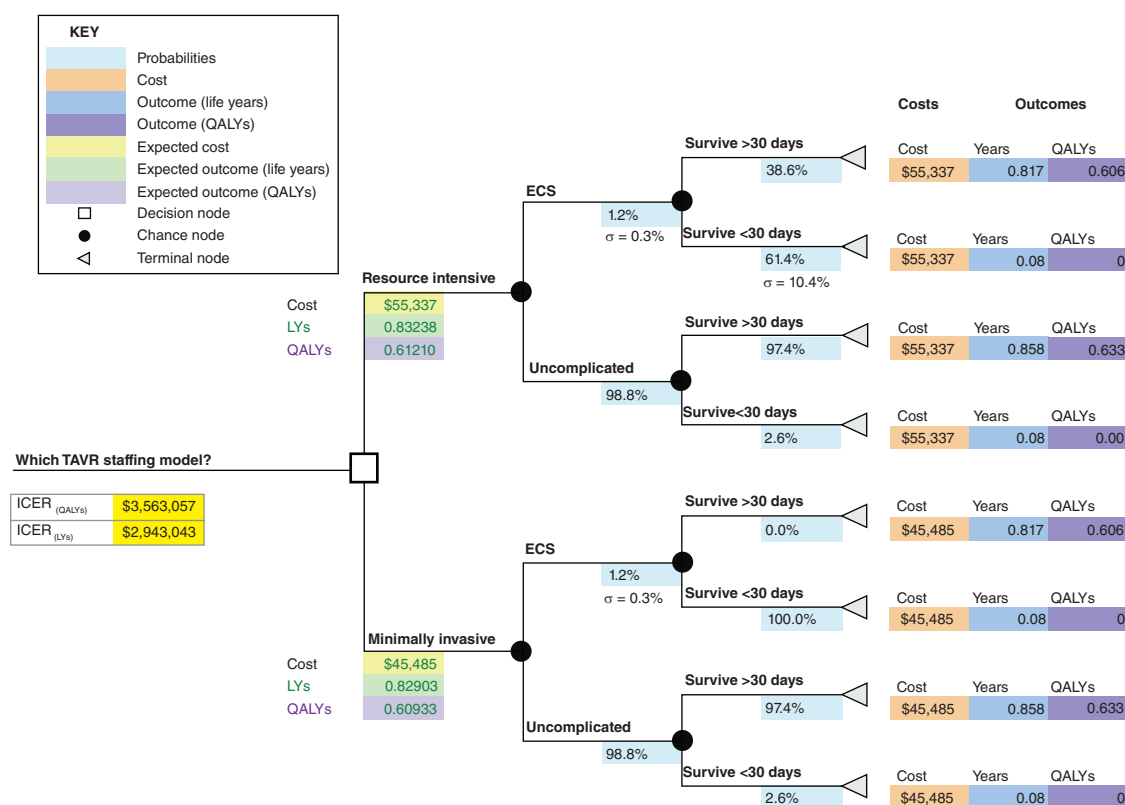


Figure 1. Decision tree model for transcatheter aortic valve replacement staffing approaches: expected value analysis.

ICER: Incremental cost–effectiveness ratio; LY: Life years QALY: Quality-adjusted life years; TAVR: Transcatheter aortic valve replacement.

Literature has shown MIS is associated with shorter post procedural length of stay, reduced costs and a success rate consistent with the RIA [10–12].

Although there are a myriad of staffing approaches to TAVR, there is no clear consensus on the best method to optimize cost and patient safety [13]. In this review, we performed a cost–effectiveness analysis of the MIS (excluding a cardiac anesthesiologist and direct cardiac surgery back-up) versus the resource-intensive staffing model for TAVR in the setting of the need for emergent cardiac surgery (ECS). The primary outcome of our model was the incremental cost–effectiveness ratio (ICER) [14,15]. The ICER is a normalizing ratio designed to represent the incremental cost of a healthcare intervention relative to additional benefits [16]. Mathematically, the ICER is the difference in costs between two interventions (ΔC) divided by the difference in effectiveness (ΔE) of two interventions.

The ICER does not indicate an absolute cost incurred by a hospital or institution, rather a theoretical cost necessary to achieve a given outcome versus an alternative intervention. Therefore, the ICER should inform healthcare policy decision makers about the efficient allocation of constrained healthcare resources [17].

Case study/methods

Model design & study population

We developed a probability decision tree model to assess the cost–effectiveness of MIS-TAVR versus RIA-TAVR (see Figure 1) [18]. Our underlying model variables (i.e. probabilities, health utilities and costs) are described below:

Probabilities

The probabilities at the chance nodes in our decision tree are based on data from published studies (see Table 1). Studies contributing probability data to our model had a weighted mean logistic EuroScore of 23.8. Probabilities were based on the following key assumptions:

Table 1. Weighted probabilities of emergent cardiac surgery conversion rate during transcatheter aortic valve replacement and 30-day mortality rate for patients undergoing emergent cardiac surgery.

Study name	Author (year)	ECS conversion %			30-day mortality % for patients undergoing ECS			Ref.
		No. of participants	$X_i = \text{ECS conversion \%}$	$W_i = \text{study weight}$	$X_{ij} = \text{30-day mortality \%}$	$W_{ij} = \text{study weight}$	$X_{ij+n} = \text{weighted 30-day mortality \%}$	
Emergent cardiac surgery during TAVI: a weighted meta-analysis of 9251 patients from 46 studies	Engelbrecht et al. (2013)	9251	1.10	79.18	67.10	76.49	51.32	[19]
ECS during TF- and TA-TAVI: incidence, reasons, management, and outcome of 411 patients from a single center[]	Griese et al. (2013)	n/a†	n/a†	n/a†	35.00	3.40	1.19	[13]
Outcome of patients after emergency conversion from TAVI to surgery	Hein et al. (2013)	1975	1.20	16.90	45.80	16.33	7.48	[20]
Severe intraoperative complications after transcatheter aortic valve implantation	Seiffert et al. (2013)	458	2.80	3.92	38.50	3.79	1.46	[21]
Totals‡		11,684		100.0		100	61.45	
Weighted standard deviation§				0.33			10.40	

†ECS in Griese et al. study was 4.9%. This was felt to be an outlier and therefore excluded from the weighted ECS conversion calculation.

‡Totals calculated for Weighted ECS Conversion % and 30 day mortality % as follows: Weighted ECS conversion % = $(w_i \cdot X_i) + (W_i + 1 \cdot X_i + 1) + (W_i + 2 \cdot X_i + 2) + (W_i + 3 \cdot X_i + 3)$.

§Example of Weighted Standard Deviation calculation as follows for ECS Conversion %: Weighted STDEV = $\text{SQRT}[(w_i \cdot (X_i - X_e)^2 + W_i + 1 \cdot (X_i - X_e)^2 + W_i + 2 \cdot (X_i - X_e)^2 + W_i + 3 \cdot (X_i - X_e)^2)]$.

ECS: Emergent cardiac surgery.

- We calculated weighted average probabilities based on the number of study participants in each paper contributing data.
- Studies contributing probability data contained transfemoral (TF) and transapical (TA) TAVR patients. We did not differentiate between access route when calculating our weighted probabilities as emergency cardiac surgery (ECS) conversion rates and 30-day mortality rates were similar between these two sub-groups in all studies [13,19–21].
- The probability of survival >30 days after ECS with MIS excluding CT surgical back-up is unknown [21]. We assumed a survival probability of 0% for this scenario in our base case to be conservative; however, real survival rates are likely greater than zero.
- The 30-day mortality rate for uncomplicated RIA and MIS cases was assumed to be 2.6% based on the PARTNER A trial [22].

Health utilities

Health outcomes, life years (LYs) and quality-adjusted life years (QALYs) for TAVR patients were taken from a published cost–effectiveness analysis of the PARTNER A trial (see Table 2) [7]. We assumed all patients who survived <30 days accumulated 0.08 life years (30 days) and zero QALYs. The LYs and QALYs for TAVR patients undergoing ECS who survived >30 days were assumed to be the same as regular SAVR patients in the PARTNER A trial [7].

Costs

Initial TAVR procedure hospitalization costs for the minimalist and resource-intensive approaches were determined from an outcomes and cost analysis study of TF-TAVR patients (see Table 2) [12]. Physician fees were not included in the model; therefore the cost difference was underestimated between the two staffing models in our analysis as more physicians were present during RIA-TAVR than MIS-TAVR.

Cost–effectiveness analysis

We computed the base case ICER using expected values from the two branches, MIS and RIA, of our decision tree. Expected values for costs and health utilities (i.e., life years and QALYs) were calculated by ‘rolling back’ the decision tree from right to left [23]. The final expected cost and health utility values were the sum of the products of the probability of events occurring and the outcomes (i.e., the health utilities and costs) of these events [23,24].

Next, the ICER was utilized to determine the cost–effectiveness of the RIA compared with the MIS, with C_1 and E_1 representing the cost and effect of the RIA, and C_0 and E_0 representing the cost and effect of the MIS.

$$\text{ICER} = \frac{\Delta C}{\Delta E} = \frac{C_1 - C_0}{E_1 - E_0}$$

Sensitivity analysis

We performed univariate sensitivity analyses of the key model variables to assess the relative impact of each variable on the model output (ICER). The key variables were manipulated while holding all other variables constant at their base values. See Table 3 for results of the univariate sensitivity analyses.

Next, we conducted a Monte Carlo Probability Sensitivity Analysis (PSA) to assess the effects of randomness on our model [25]. The Monte Carlo PSA involves assigning each model variable parameter inputs (mean and standard deviation) and an appropriate probability distribution [23]. We used the beta distribution for probabilities, the gamma distribution for costs, and the normal distribution for QALYs and life years (see Table 2) [24]. During each simulation of the model, random values for each variable are selected from the assigned probability distributions around the parameter inputs. We performed 5,000 simulation runs of our model (Figure 2A & B).

Results

The base case ICER calculated using expected value analysis of the decision tree was US\$3,563,057 per QALY $([\text{US\$55,337} - \text{US\$45,485}]/[0.61210 - 0.60933])$ and US\$2,943,043 per LY $([\text{US\$55,337} - \text{US\$45,485}]/[0.83238 - 0.82903])$. We assessed the validity of our base case ICER results with univariate sensitivity analyses (see Table 3) and a Monte Carlo PSA (shown in Table 4 and Figure 2A & B & Figure 3A & B).

The results of our univariate sensitivity analysis showed the model was highly sensitive to small changes in survival probabilities after ECS and costs, as expected when comparing two interventions with minor differences in base case

Table 2. Assumptions for Monte Carlo probability sensitivity analysis of transcatheter aortic valve replacement staffing decision tree model.

	Mean chance node probabilities [†]	Standard deviation	PSA distribution	Mean terminal node costs [‡]	Standard deviation	PSA distribution	Mean terminal node life years [§]	Standard deviation	PSA distribution	Mean terminal node QALYs [§]	Standard deviation	PSA distribution
Resource-intensive approach												
ECS conversion	1.18%	0.33%	Beta									
ECS survive >30 days	38.55%			US\$55,337	US\$22,587	Gamma	0.82	0.08	Normal	0.61	0.06	Normal
ECS survive <30 days	61.45%	10.40%	Beta	US\$55,337	US\$22,587	Gamma	0.08	0.01	Normal	0.00	0.00	Normal
Uncomplicated	98.82%											
Uncomplicated survive >30 days	97.41%			US\$55,337	US\$22,587	Gamma	0.86	0.09	Normal	0.63	0.06	Normal
Uncomplicated survive <30 days	2.59%	2.00%	Beta	US\$55,337	US\$22,587	Gamma	0.08	0.01	Normal	0.00	0.00	Normal
Minimally invasive strategy												
ECS conversion	1.18%	0.33%	Beta									
ECS survive >30 days	0.00%			US\$45,485	US\$14,397	Gamma	0.82	0.08	Normal	0.61	0.06	Normal
ECS survive <30 days	100.00%			US\$45,485	US\$14,397	Gamma	0.08	0.01	Normal	0.00	0.00	Normal
Uncomplicated	98.82%											
Uncomplicated survive >30 days	97.41%			US\$45,485	US\$14,397	Gamma	0.86	0.09	Normal	0.63	0.06	Normal
Uncomplicated survive <30 days	2.59%	2.00%	Beta	US\$45,485	US\$14,397	Gamma	0.08	0.01	Normal	0.00	0.00	Normal

[†]Means and standard deviations for chance node probabilities calculated in Table 1.

[‡]Means and standard deviations for terminal node costs from Babaliaros et al. 2017 [12].

[§]Means and standard deviations for terminal node life years and QALYs from Reynolds et al. 2012.

ECS: Emergent cardiac surgery; PSA: Probability sensitivity analysis; QALY: Quality-adjusted life year.

Table 3. Univariate incremental cost–effectiveness ratio sensitivity analysis[†].

ICER sensitivity to changes in 30-day mortality rates (survival <30 days) for ECS conversion with RIA	Base case -20%	Base case -10%	Base case	Base case +10%	Base case +20%
30-day mortality rates for patients undergoing ECS with RIA	41.45%	51.45%	61.45%	71.45%	81.45%
ICER (QALYs)	US\$2,345,997	US\$2,829,191	US\$3,563,057	US\$4,810,981	US\$7,404,240
ICER sensitivity to changes in 30-day mortality rates (survival <30 days) for ECS conversion with MIS	Base case -20%	Base case -15%	Base case -10%	Base case -5%	Base case
30-day mortality rates for patients undergoing ECS with MIS	80%	85%	90%	95%	100%
ICER (QALYs)	US\$7,404,240	US\$5,832,340	US\$4,810,981	US\$4,094,034	US\$3,563,057
ICER sensitivity to cost difference between MIS vs RIA staffing models	Base case -50%	Base case -25%	Base case	Base case +25%	Base case +50%
Absolute cost difference between RIA and MIS staffing approaches	US\$4852	US\$7352	US\$9852	US\$12,352	US\$14,852
ICER (QALYs)	US\$1,754,766	US\$2,658,911	US\$3,563,057	US\$4,467,203	US\$5,371,348

[†] Base case values in third column in sections i and iii and in fifth column in section ii.
ECS: Emergent cardiac surgery; ICER: Incremental cost–effectiveness ratio; MIS: Minimally invasive strategy; QALY: Quality-adjusted life year; RIA: Resource-intensive approach.

Table 4. Monte Carlo probability sensitivity analysis simulation summary.

Statistical distribution	ICER (QALYs)	ICER (LYs)
N = Number of samples	5000	5000
n = Sample interval	3173	2601
μ = Mean	US\$4,229,831	US\$3,495,513
σ = Std Dev	US\$1,983,398	US\$1,625,385
$\mu + 4 \sigma$	US\$12,163,423	US\$9,997,053
$\mu - 4 \sigma$	-US\$3,703,760	-US\$3,006,026
Percentile 25%	US\$2,866,757	US\$2,376,189
Percentile 75%	US\$5,024,980	US\$4,195,629
Min	US\$1,008,187	US\$898,165
Max	US\$21,460,842	US\$15,411,721
Range	US\$20,452,655	US\$14,513,556
No. of bins for graph	100	100
Bin interval	US\$204,527	US\$145,136
Cost–effectiveness acceptability threshold	US\$50,000/QALY	US\$50,000/LY

ICER: Incremental cost–effectiveness ratio; LY: Life year; QALY: Quality-adjusted life year.

costs and outcomes (see Table 3). Because procedural costs and short-term (<30 days) survival probabilities after ECS are likely easier to change than long-term (>30 days) post-procedural mortality and health-related quality of life (HRQOL) outcomes (i.e. QALYs), we examined our model's sensitivity to cost and short-term (<30 days) survival probabilities after ECS in greater detail. Altering the cost difference between the RIA and MIS-TAVR procedures by +/- US\$5000, or roughly 50% from the base case, resulted in an ICER range of US\$1,754,766–\$5,371,348 per QALY (see Table 3.iii). Changing the 30-day mortality rate (survival <30 days) for ECS Conversion with the RIA by an absolute value of +/-20% from the base case resulted in an ICER range of US\$2,345,997–\$7,404,240 per QALY (see Table 3.i). Finally, reducing assumed mortality for patients undergoing ECS with the MIS from 100% to 90% and 80% resulted in ICERs of US\$4,810,981 per QALY and US\$7,404,240 per QALY, respectively (see Table 3.ii).

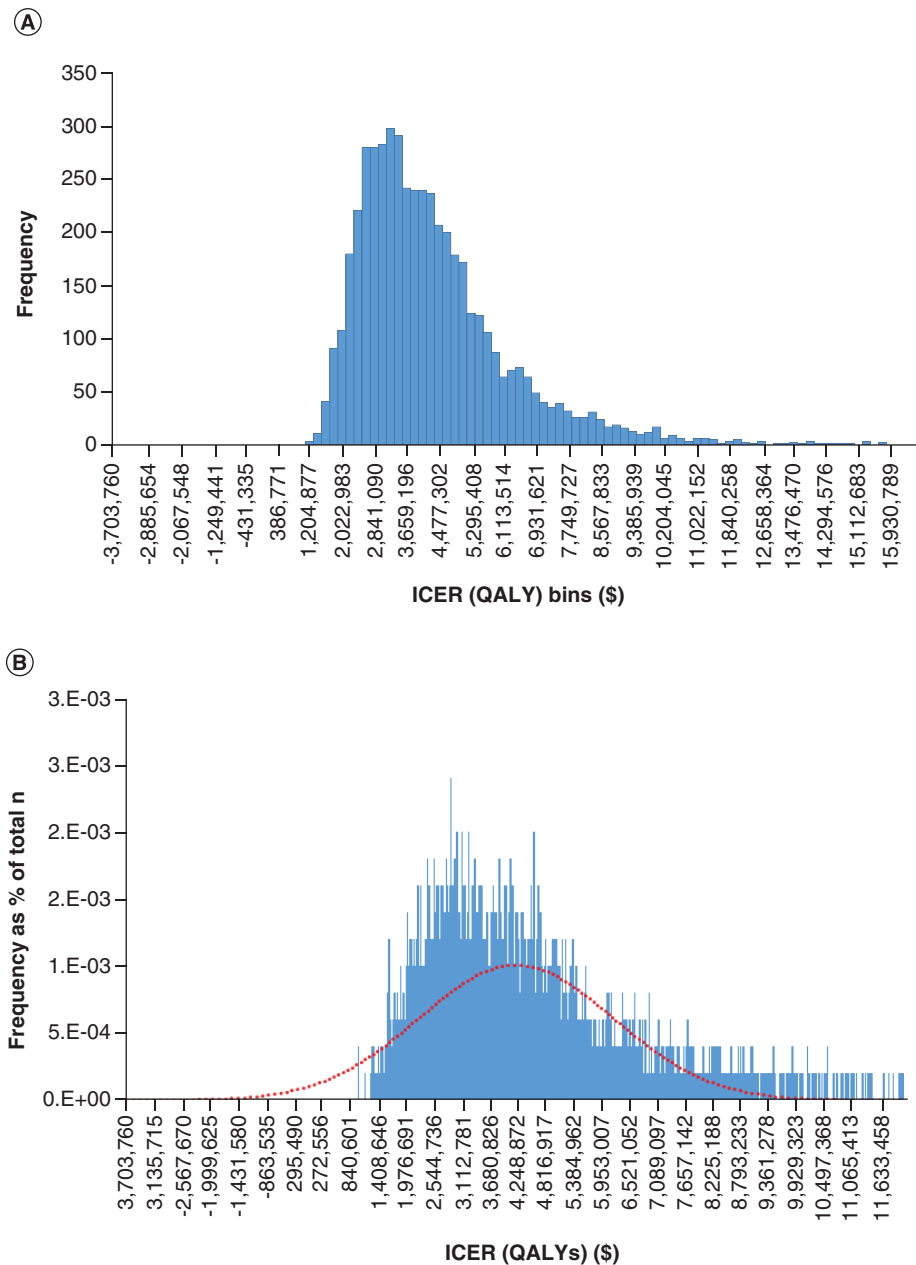


Figure 2. Incremental cost-effectiveness ratio (quality-adjusted life years). (A) Frequency distribution (n = 5000 samples). (B) Frequency distribution as percentage of simulations (n = 5000 samples).
ICER: Incremental cost-effectiveness ratio; QALY: Quality-adjusted life year.

Our Monte Carlo PSA simulation produced a mean ICER of US\$4,229,831 per QALY [IQR US\$2,866,757–\$5,024,980] while the ICER frequency distribution ranged from a minimum of US\$1,008,187 per QALY to a maximum of US\$21,460,842 per QALY (see Table 4 for Monte Carlo PSA simulation statistical summary). All ICER values were significantly above the generally accepted thresholds of US\$50,000–\$100,000 per QALY [26].

Summary

Based upon our case scenario and sensitivity analyses, it is not cost-effective to perform TAVR using a resource-intensive approach for high-risk aortic stenosis patients. These results of our ICER modeling are not surprising given the following model parameters: the low rate of ECS conversion during TAVR (~1.2%); the high 30-day mortality rate for ECS cases (~61.4%); and the small incremental difference in quality of life outcomes for those

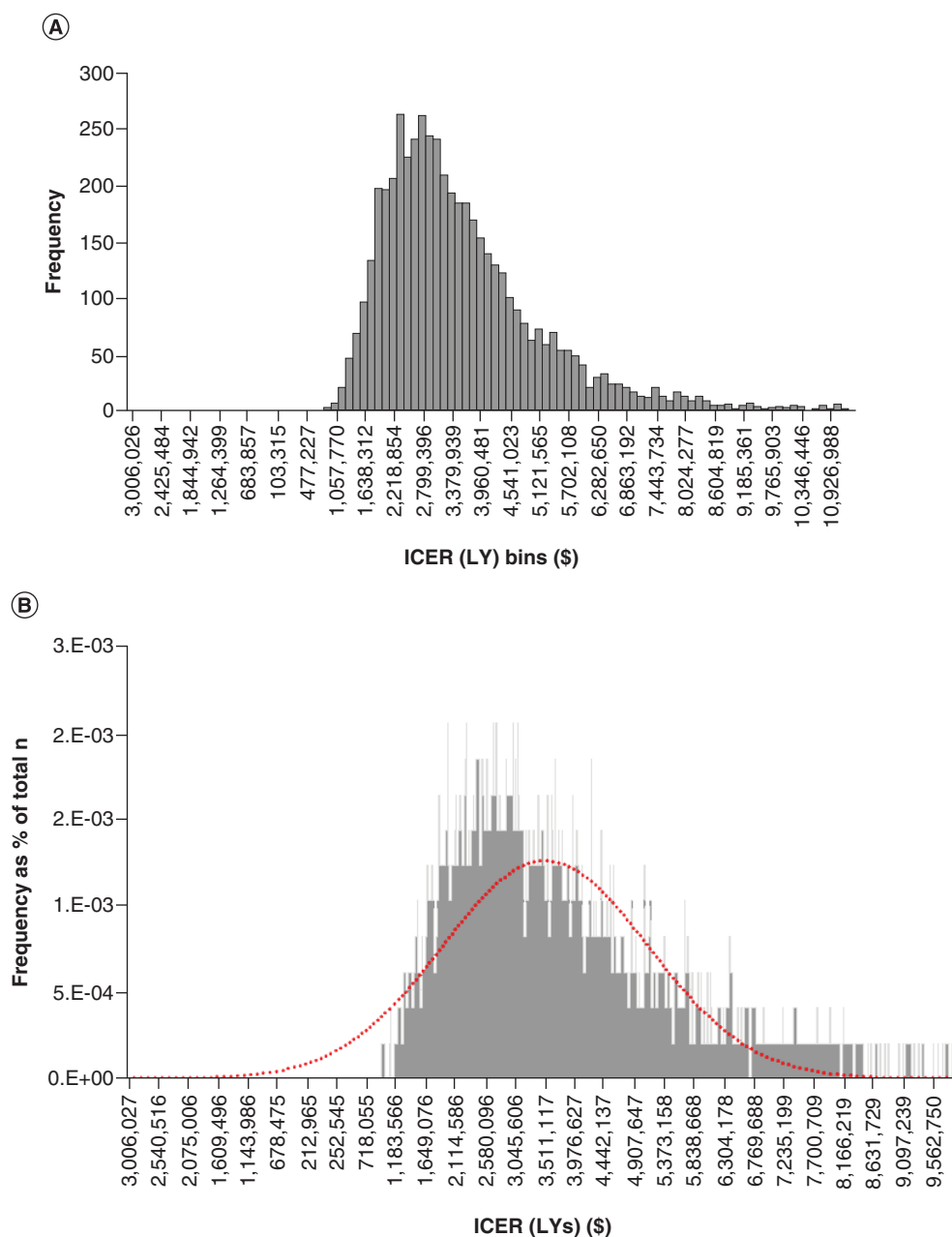


Figure 3. Incremental cost-effectiveness ratio (life years). (A) Frequency distribution (n = 5000 samples). (B) Frequency distribution as percentage of simulations (n = 5000 samples).
ICER: Incremental cost-effectiveness ratio; LY: Life year.

who survive an uncomplicated TAVR procedure compared with SAVR (0.027 QALYs). The sensitivity of our model to minor variations in cost illustrates the importance of accurate and transparent accounting practices when providers are calculating costs of procedural care [27].

Considering incidents necessitating ECS/CT back-up and anesthesiology are rare (1%) and associated with high mortality, our model assumes only incremental morbidity and mortality benefit with RIA (presence of both CT surgery back-up and cardiac anesthesiologist). Conceptually, the MIS does not preclude the possibility of converting to emergent surgery. This would require mobilization of a surgical team on an emergency basis similar to current percutaneous coronary intervention models. However, Eggebrecht *et al.* found no statistical difference in procedural outcomes (in-hospital complications and mortality) between institutions with and without on-site CT surgery departments [28]. A small randomized-controlled trial with and without an anesthesiologist found no

difference in procedural or 30-day mortality, yet only 3 of 324 cases required ECS. Clearly, if future research confirms the results of Eggebrecht and Babaliaros then MIS-TAVR will be the preferred approach [29]. In the absence of a clear consensus on whether immediate CT back-up and type of anesthesia translate into different patient outcomes, many institutions will continue to assume that RIA-TAVR is clinically superior to MIS-TAVR, albeit at a higher cost.

There is historical precedent for the adoption of a MIS strategy for TAVR. During early percutaneous coronary interventions (PCI), the procedural risks of abrupt vessel closure and bleeding necessitated cardiac surgery standby protocols and multi-day hospitalizations. With the development of 2nd generation drug eluting stents and radial artery access techniques, these adverse events now occur in less than 1% of patients. Thus, instead of prolonged procedures, hospitalizations and resource utilization, PCI can now be performed more cost effectively as a same day procedure without the necessity of anesthesia or cardiac surgery resource requirements. In the future, the delivery of MIS-TAVR may follow in the step-wise progression in similar free standing environments [30].

With regards to MIS versus RIA-TAVR, further data could be analyzed regarding the incidence and outcomes of conversion from sedation to general anesthesia. Sedation is increasingly being used for TAVR, yet with decreasing conversion rates, ranging from 3.4 to 20% [31]. It is estimated that half of conversion to GA was being attributed to patient compliance and the remainder being attributed to more serious procedural complications [32]. However, conversion to GA from sedation is poorly characterized in much of the literature. Additional data regarding these indications and outcomes would further elucidate cost-benefit findings and predictions with regards to the presence or absence of an anesthesiologist and cardiac surgery backup.

There are several limitations to these analyses. First, our study extracted model parameter data (i.e. probabilities, health utilities and costs) from multiple different sources. We attempted to mitigate the effects of single source bias on our probability parameters by calculating weighted average probabilities from multiple published studies. However, in the case of costs and health utilities there were only single studies available to provide us with data for each parameter. Second, differences in study designs, patient populations and lack of availability of procedural details may have impacted the results of our model. Third, we assumed ECS to be defined as any periprocedural event requiring CT intervention. Because there is no uniform definition of ECS, some studies contributing data to our model defined the timeframe for ECS as periprocedural and up to 24 hours post procedure. Nevertheless, a decrease in ECS rates would only increase the ICER and further support the results of our model. Lastly, the costs associated with the conversion from MIS to ECS were not included in our model, but would likely align with those associated with RIA.

Conclusion

Cost-effectiveness analysis offers an objective approach to quantifying the incremental costs of adopting a more expensive, superior intervention over a less costly, inferior treatment modality. Healthcare policymakers and clinicians must continue to contribute to this field and critically evaluate the literature to ensure the optimal balance of patient care and expenditure of healthcare resources.

Future perspective

We believe our analysis is a starting point for discussion when hospitals or healthcare systems are considering the optimal approach to TAVR staffing. Individual institutions should continue to consider unique patient characteristics, available hospital resources and annual TAVR volumes when determining TAVR staffing models [13]. TAVR will be increasingly utilized as newer generations of valves, small delivery devices, increased surgical familiarization, and outcomes continue to improve. However, considering the increased price above SAVR, costs must be justified. A recent systematic review found both SAVR and TAVR to be cost-effective or 'highly' cost effective in all studies when compared with medical management, TAVR in inoperable or high-risk surgical candidates and SAVR in operable patients. When comparing TAVR to SAVR for high-risk operable patients, the outcomes were far more mixed with a trend toward SAVR providing higher QALYs at lower costs [33]. For patients suitable for SAVR, deemed low to moderate surgical risk, ICER with TAVR becomes increasingly less favorable [34,35].

This review assesses the resource utilization and cost effectiveness between RIA versus MIS across a wide spectrum of TAVR patients. While the current methodology was not powered for subgroup analysis, a larger multi-center design might further elucidate the relative impact of these strategies according to important subgroups (e.g., low, intermediate, high or extreme risk patients). Similarly, the most recent ACC-AHA valvular heart disease guidelines no longer recommend using risk strata to choose between TAVR versus SAVR. Instead, they have recommended

risk stratification according to patient age. Accordingly, future studies should aim to analyze the cost effectiveness of the MIS stratified by age groups [36].

For TAVR to gain widespread adoption outside of high-income countries, the index procedural costs will need to decrease while outcomes and QALYs continue to improve. As we wait for a reduction in cost of the TAVR valve and delivery devices, hospitals should consider the adoption of MIS-TAVR when possible.

Summary points

- Transcatheter aortic valve replacement (TAVR) was previously an intervention reserved for high-risk individuals with severe, symptomatic aortic stenosis.
- Recent studies have demonstrated superior TAVR outcomes with regards to 30-day mortality, stroke rate, new onset atrial fibrillation, and hospital length of stay even in low-risk patients.
- As TAVR is increasingly offered to a broader range of surgical patients, it will become important to assess the cost-effectiveness of the procedure across discretely defined risk groups, as device costs make a TAVR procedure ~US\$5,000 more expensive than a surgical approach.
- Traditionally, centers have employed a resource-intensive approach (RIA) involving general anesthesia, invasive hemodynamic monitoring, trans-esophageal echocardiography and cardiothoracic surgical back-up.
- More recently, a leaner, minimally invasive strategy (MIS), involving local anesthesia, minimal conscious sedation, and transthoracic echocardiography, has been utilized to decrease resource utilization, procedural costs and hospital length of stay, with outcomes consistent with the RIA approach.
- In this cost-effectiveness study, we employed a decision tree model with Monte Carlo probability sensitivity analysis to determine the incremental cost (in US\$) per quality-adjusted life year and life year of performing the TAVR procedure using the RIA and MIS in high-risk surgical patients.
- Our base case scenario and sensitivity analyses show it is not cost-effective to perform TAVR using a resource-intensive approach.
- With TAVRs being increasingly utilized in a broader population, and considering the development of newer generations of valves and delivery devices, this analysis is offered as a starting point for analyzing the optimal approach to TAVR staffing.

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The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

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