Cost-Effectiveness of Self-Expandable Transcatheter Aortic Valves in Intermediate-Risk Patients

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Background. **A recent clinical trial showed that self-expandable transcatheter aortic valve replacement (TAVR) was non-inferior to surgical aortic valve replacement (SAVR). However, the cost-effectiveness of self-expandable TAVR in the intermediate-risk population remains unknown.**

Methods. **A cost-utility analysis from the Canadian health care system payer's perspective was undertaken to compare self-expandable TAVR with SAVR. A fully probabilistic Markov model over the patient's lifetime was constructed to estimate differences in costs (2016 Canadian dollars) and effectiveness (quality-adjusted life-years [QALYs]), discounted at 1.5% per annum. Incremental cost-effectiveness ratios (ICERs) were calculated. Efficacy inputs were obtained from the Surgical Replacement and Transcatheter Aortic Valve Implantation trial, and costs were primarily obtained from the Canadian Institute of Health Information. Probabilistic analysis (PA) and one-way deterministic sensitivity analyses were conducted around key point estimates to address uncertainty.**

Results. **In the base case analysis, with discounting, the total lifetime costs (mean ± standard deviation) in the TAVR and SAVR arms were $44,299 ± $7,260 and $32,994 ± $13,434, respectively, whereas total effectiveness values were 6.42 ± 1.33 QALYs and 6.28 ± 1.32 QALYs, respectively. This yielded an incremental cost of $11,305 and incremental effectiveness of 0.15 QALYs when TAVR was compared with SAVR for an ICER of $76,736/QALY. In the PA, there was moderate uncertainty, with 52.8% and 57.2% of simulations less than willingness-to-pay thresholds of $50,000 and $100,000, respectively. In the sensitivity analysis, when the cost of TAVR valve system was priced at $17,397 (base case $22,000 Canadian dollars), TAVR was found to be cost-effective at a willingness-to-pay threshold of $50,000/QALY.**

Conclusions. **Self-expandable TAVR was found to be cost-effective; however, there was moderate uncertainty, reflecting the non-inferiority nature of the data.**

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Transcatheter aortic valve replacement (TAVR) has been shown to be non-inferior to surgical aortic valve replacement (SAVR) in the intermediate surgical risk population (The Society of Thoracic Surgeons [STS] Predicted Risk of Mortality at 30 days, 4% to 8%) in two recent large non-inferiority randomized clinical trials (RCTs) [1, 2]. These findings were used to support changes in the American College of Cardiology (ACC) and American Heart Association (AHA) guidelines such that TAVR is now a class IIA recommendation for the intermediate-risk population [3]. Although the intermediate-risk population already represents one of the largest patient populations who undergo TAVR in the United States, little is known about the cost-effectiveness of this intervention in this group [4]. Recently, a cost-utility analysis published by our group showed that TAVR with a balloon-expandable valve system may be cost-effective compared with SAVR, using Canadian cost data and clinical efficacy data from the Placement of AoRTic TraNscathER valve (PARTNER 2) trial [5].

The Supplemental Tables and Figure can be viewed in the online version of this article [https://doi.org/10.1016/j.athoracsur.2018.03.069] on http://www.annalsthoracicsurgery.org.

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Abbreviations and Acronyms

ACC = American College of Cardiology
AHA = American Heart Association
CAD = Canadian dollar
CADTH = Canadian Agency for Drugs and Technologies in Health
EQ-5D = EuroQoL
ICER = incremental cost-effectiveness ratio
ICU = intensive care unit
LOS = length of stay
PA = probabilistic analysis
PARTNER = Placement of Aortic Transcatheter Valve
QALY = quality-adjusted life years
QoL = quality of life
RCT = randomized clinical trial
SA = sensitivity analysis
SAVR = surgical aortic valve replacement
STS = The Society of Thoracic Surgeons
SURTAVI = Surgical Replacement and Transcatheter Aortic Valve Implantation
TAVR = transcatheter aortic valve replacement
WTP = willingness-to-pay

However, it is uncertain whether the cost-effectiveness results from a study that examined balloon-expandable TAVR can be generalized to that of self-expandable TAVR. Findings from the literature show that complication rates between balloon and self-expandable TAVR differ; in particular, the rate of permanent pacemaker insertion is more than twofold higher with self-expandable TAVR [6]. Thus, it is prudent to evaluate the cost-effectiveness of self-expandable TAVR compared with SAVR by using the latest findings from the Surgical Replacement and Transcatheter Aortic Valve Implantation (SURTAVI) trial [1].

Patients and Methods

Study Overview

We constructed a fully probabilistic Markov model with cycle lengths of 30 days to estimate the cost and benefits of TAVR compared with SAVR over the lifetime horizon. The primary cost outcome was total lifetime costs, measured in 2016 Canadian dollars (CADs), and the primary effectiveness outcome was quality-adjusted life years (QALYs). The perspective was that of the single third-party payer, the Ontario Ministry of Health and Long-Term Care. Ontario is Canada's largest province, with more than 13 million residents, all of whom receive universal health coverage from the Ministry of Health and Long-Term Care. QALYs were obtained by multiplying time spent in a particular health state with the quality of life (QoL) weight for that respective health state. We calculated an incremental cost-effectiveness ratio (ICER) by taking the differences in lifetime costs between TAVR and SAVR (ie, incremental costs) and dividing by the differences in lifetime benefits (ie, incremental effectiveness measured in QALYs). On the basis of guidelines from the ACC/AHA, an ICER less than $50,000/QALY gained is considered high value, whereas an ICER more than $150,000/QALY gained would be considered low value [7]. In accordance with Canadian Agency for Drugs and Technologies in Health guidelines, all costs and outcomes were discounted at 1.5% per annum.

Model Structure

All patients entered the model in the procedural state (TAVR or SAVR) and were at risk of clinically relevant short-term complications (major bleeding, acute kidney injury, vascular injury, atrial fibrillation, non-disabling stroke, cardiogenic shock, rehospitalization) and long-term complications (death, permanent pacemaker, and disabling stroke). After the procedural state, all patients transitioned into one of three long-term states (alive and well, disabling stroke, or death). Repeat hospitalization was a temporary state for which a patient would remain for a portion of 1-cycle length. Patients transitioned between these long-term states based on efficacy data from SURTAVI for the first 2 years. After 2 years, we made the conservative assumption that the rates of complications were assumed to be equivalent between the two arms. Furthermore, after 2 years, mortality rates were based on 2010 to 2012 age- and sex-specific Canadian life tables, given the absence of follow-up beyond 2 years in the SURTAVI trial. Transition probabilities were preferentially obtained from SURTAVI and the published literature for those not found in SURTAVI. A state transition diagram that summarizes the model structure is shown in Figure 1.

Clinical Efficacy Inputs

TRIAL OVERVIEW. The SURTAVI trial was a multicentered RCT of 87 Canadian, European, and American sites that randomly assigned 1,746 patients 1:1 to either self-expandable TAVR (CoreValve and Evolut R, Minneapolis, MN) or SAVR for the treatment of severe symptomatic aortic stenosis. The study allowed for both transfemoral and non-transfemoral (subclavian or direct aortic) approaches. In the trial, 879 patients underwent TAVR and 867 patients underwent SAVR. Only 4% and 2% underwent direct aortic and subclavian access, respectively, whereas the remaining 94% of patients underwent transfemoral TAVR. Only 16% underwent TAVR with the second-generation Evolut R system. The mean age of TAVR and SAVR patients was 79.9 $\pm$ 6.2 years and 79.8 $\pm$ 6.0 years, respectively. The mean STS score was 4.4 $\pm$ 1.5 and 4.5 $\pm$ 1.6 for TAVR and SAVR, respectively.

EFFICACY END POINTS. The 30-day clinical end points were obtained from the intention-to-treat cohort of the SURTAVI trial and included death from any cause and key complication rates (Supplemental Table 1). After 30 days, transition probabilities were obtained from the 1- and 2-year end points from SURTAVI, calculated as a conditional probability from months 2 to 24. We estimated the

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