Cost-effectiveness of the Edwards SAPIEN transcatheter heart valve compared with standard management and surgical aortic valve replacement in patients with severe symptomatic aortic stenosis: A Canadian perspective

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Objectives: The primary analysis estimated the cost-effectiveness of transfemoral transcatheter aortic valve implantation (Edwards SAPIEN heart valve; Edwards Lifesciences LLC, Irvine, Calif) compared with standard management in inoperable patients with severe, symptomatic aortic stenosis. The secondary analysis estimated the cost-effectiveness of transcatheter aortic valve implantation (transfemoral or transapical approaches) (SAPIEN heart valve) compared with surgical aortic valve replacement in operable patients with severe, symptomatic aortic stenosis.

Methods: A combined decision tree and Markov model was developed to compare costs, life-years, and quality-adjusted life-years over a 20-year time horizon from the Canadian health-care payer perspective. The Placement of Aortic Transcatheter Valves trial provided rates of postoperative complications and mortality. Costs were derived from the Ontario Case Costing Initiative. Comprehensive sensitivity analyses were used to explore the impact of uncertainty on the cost-effective estimates.

Results: In the primary analysis, comparing transfemoral transcatheter aortic valve implantation and standard management resulted in incremental cost-effectiveness ratios of $36,458/life-year and $51,324/quality-adjusted life-year. In the secondary analysis, transcatheter aortic valve implantation (transfemoral or transapical) and surgical aortic valve replacement were compared, resulting in an incremental cost-effectiveness ratio of $870,143/life-year and transcatheter aortic valve implantation being dominated by surgical aortic valve replacement when comparing quality-adjusted life-years. Deterministic sensitivity analysis for the primary analysis identified the procedural costs and 1-year mortality rates of both transfemoral transcatheter aortic valve implantation and standard management to be the most sensitive parameters in the model, whereas results from the secondary analysis were largely unchanged. Removal of long-term complications in both analyses led to more favorable incremental cost-effectiveness ratios for transcatheter aortic valve implantation.

Conclusions: This economic evaluation suggested that transfemoral transcatheter aortic valve implantation was a cost-effective option compared with standard management for inoperable patients with severe, symptomatic aortic stenosis, but it might not be a cost-effective treatment compared with surgical aortic valve replacement for operable patients. (J Thorac Cardiovasc Surg 2013;146:52-60)

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Aortic stenosis (AS) is a common valvular heart disease characterized by the narrowing or constriction of the aortic valve.[1] Approximately 300,000 patients have severe AS in the United States, with approximately 60,000 of these patients undergoing aortic valve replacement each year.[2] As the population continues to age, these numbers are expected to increase.

Patients managed with only medical therapy or percutaneous aortic balloon valvuloplasty have a poor prognosis, and therefore this treatment is now used only as a bridge to more invasive therapy or for palliative care.[2]

Abbreviations and Acronyms

AKI = acute kidney injury
AS = aortic stenosis
CI = confidence interval
DSA = deterministic sensitivity analysis
ICER = incremental cost-effectiveness ratio
LY = life-year
MI = myocardial infarction
NYHA = New York Heart Association
OCCI = Ontario Case Costing Initiative
PARTNER = Placement of Aortic Transcatheter Valves
PSA = probabilistic sensitivity analysis
QALY = quality-adjusted life-year
SAVR = surgical aortic valve replacement
SM = standard management
SSAS = severe symptomatic aortic stenosis
TA = transapical
TAVI = transcatheter aortic valve implantation
TF = transfemoral
WTP = willingness to pay

The standard of care for patients with severe AS is an invasive procedure known as ''surgical aortic valve replacement'' (SAVR). Operative mortality in octogenarians and high-risk patients was high, ranging from 5% to 11%,[3,4] and because of the invasiveness of the procedure many potential candidates refused surgery or were denied surgery.[5] These patients were usually considered at an increased surgical risk because of 1 or a combination of the following characteristics: age greater than 75 years, significant comorbidities, European System for Cardiac Operative Risk Evaluation greater than 20%, or Society of Thoracic Surgeons risk score greater than 10%.[5] This has led to the development of less-invasive approaches, such as transcatheter aortic valve implantation (TAVI), to provide high-risk patients with a suitable alternative to open surgery.

TAVI is preformed mainly via 2 different approaches: the ''retrograde'' (transfemoral [TF]) approach and a more invasive approach known as ''transapical'' (TA), which is used in patients with poor vascular access.[6]

The results of the Placement of Aortic Transcatheter Valves (PARTNER US, cohorts A and B) randomized clinical trial have recently been published.[5,7] Cohort B randomized patients who were unable to undergo SAVR to TF-TAVI or standard management (SM) and showed TF-TAVI to have a significant impact on mortality ($P < .001$).[5] Cohort A randomized patients with a high operative risk to TAVI (TF or TA) or SAVR and showed TAVI to be noninferior in terms of mortality ($P < .001$).[7] Despite the promising clinical evidence collected in the PARTNER trial, estimates of cost-effectiveness from the Canadian perspective are not currently available.

The primary objective of the present study was to estimate the cost-effectiveness of TF-TAVI compared with SM in inoperable patients with severe symptomatic aortic stenosis (SSAS). A secondary analysis was conducted to estimate the cost-effectiveness of TAVI (TF or TA) compared with SAVR in operable patients with SSAS.

MATERIALS AND METHODS

Overview

From a third-party Canadian payer's perspective, an economic model was developed to estimate the expected costs and outcomes measured using life-years (LYs) and quality-adjusted life-years (QALYs) associated with 4 treatment options (ie, TF-TAVI, SM, TAVI [TF or TA], and SAVR) for patients with SSAS over a 20-year time horizon.

Model Structure

The model is composed of a decision tree for a 30-day postoperative phase and a Markov model for a long-term phase (ie, day 31 to 20 years). The structures of the short-term and long-term models are shown in Figure 1, *A* and *B*, respectively. During the 30-day postoperative phase, patients were at risk of operative death and postoperative complications, including other acute complications (eg, endocarditis, major vascular complications, paravalvular leaks, pacemaker implantation, major bleeding, and atrial fibrillation), stroke, myocardial infarction (MI), acute kidney injury (AKI), or reoperation. In addition, patients receiving TAVI or SM might require a SAVR. The 30-day model estimated the expected costs of the index hospitalization along with expected LYs and QALYs over 30 days for the 4 treatments.

The long-term costs and effects beyond 30 days after the surgery were estimated using a Markov model. Patients surviving a postoperative complication in the short-term model entered the long-term model in their respective post-event health state. Patients surviving other acute complications or experiencing no complications in the short-term model entered the ''alive without complications'' health state in the long-term model. Three postoperative complications, including stroke, MI, and AKI, were included in the long-term model. The model estimates were on a yearly basis (so termed a ''yearly Markov cycle'') on which the costs and effects were calculated at the end of each year. Then patients transitioned among these health states according to their characteristics, and the calculations were started over again. Because of the unavailability of the long-term data, it was assumed that patients with stroke or MI, or receiving dialysis will stay in these post-events health states until they died.

Clinical Parameters

Overview. The clinical data used for the economic model primarily came from cohorts A and B of the PARTNER randomized controlled trial[5,7] and were supplemented by a targeted literature search that identified any relevant studies on TAVI, SM, and SAVR. Important data and sources for the models are listed in Tables 1 and E1 and briefly summarized next.

Mortality. Cumulative 30-day postoperative mortality was derived from PARTNER cohorts B and A for the primary and secondary analyses, respectively.[5,7] The 1-year mortality for all 4 treatments was based on the respective cumulative mortality reported in the PARTNER cohorts at 1 year; however, to avoid double counting, the number of patients dying at 30 days was subtracted from both the numerator and the denominator of the cumulative rate. Because of a lack of relevant long-term mortality data for both inoperable and operable patient populations, the mortality

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