Authors have nothing to disclose with regard to commercial support.

AORTIC VALVE IMPLANTATION OR REPLACEMENT: WHICH PROCEDURE IS MORE COST-EFFECTIVE?

To the Editor:

Cost-effectiveness analysis of a procedure is always difficult because of the many factors involved and the quantification of costs to achieve the desired outcome. In particular, the new devices for transcatheter aortic valve implantation (TAVI) are increasingly compared with traditional prostheses, not only in terms of clinical outcome but also in terms of costs, because of the more expensive technology required.¹

Although this minimally invasive procedure has been reported to reduce length of hospital stay, transfusions, and hence total costs, the higher price of TAVI prostheses makes this procedure less cost-effective than traditional surgery.¹ Additionally, in countries where a reimbursement system for TAVI procedures is established, this treatment is almost always disadvantageous for the facility performing this procedure under the cost reimbursement plan.

Recently, in an analysis Tam and colleagues² concluded that TAVI procedures would be more cost-effective than traditional surgery in intermediate-risk patients. However, also considering previous analyses, these results are still open to debate.

First, a comment should be made on the selection of patients: the results are derived from the Placement of Aortic Transcatheter Valves (PARTNER) 2 trial, whereas, for cost-effectiveness analyses, data should be obtained as much as possible from “real-life” settings rather than from randomized clinical trials. Second, the effect of paravalvular leak is completely neglected, which is an independent predictor of mortality, as also shown in the PARTNER trial. If paravalvular leak had been considered by the authors, no positive delta for quality-adjusted

life-years or life years in favor of TAVI could be found, and the Kaplan–Meier estimates at 2 years would have been very different for the TAVI arm. The same information on costs deserves better understanding: in the report of Tam and colleagues, the costs are \$24,000 and \$6000 for TAVI and surgery, respectively, but these were previously presented at the Transcatheter Cardiovascular Therapeutics conference 2017 as \$32,500 and \$5000, respectively. A difference of almost \$10,000 is not negligible! Moreover, other costs should be taken into consideration for TAVI, which is the cost of the on-call cardiac team not included by the authors, and the specific analyses for patient preparation (eg, computed tomography scan, angiography) calculated at \$119, which seems somewhat underestimated. In summary, the cost-effectiveness of surgical procedures versus TAVI is still an open issue and, at present, the only certainties seem to be the significantly higher cost of TAVI prostheses and the dependence of cost-effectiveness on the health system within which the procedure is performed.

Giuseppe Santarpino, MD^{a,b}

Luigi Specchia, MD^b

Luigi Lombardi, MD^b

^aParacelsus Medical University

Nuremberg, Germany

^bCittà di Lecce Hospital–GVM Care & Research

Lecce, Italy

References

1. Santarpino G, Pfeiffer S, Jessl J, Dell'Aquila A, Vogt F, von Wardenburg C, et al. Clinical outcome and cost analysis of sutureless versus transcatheter aortic valve implantation with propensity score matching analysis. *Am J Cardiol*. 2015;116:1737–43.
2. Tam DY, Hughes A, Fremes SE, Youn S, Hancock-Howard RL, Coyte PC, et al. A cost-utility analysis of transcatheter versus surgical aortic valve replacement for the treatment of aortic stenosis in the population with intermediate surgical risk. *J Thorac Cardiovasc Surg*. 2018;155:1978–88.

<https://doi.org/10.1016/j.jtcvs.2018.05.031>

Cost-savings
Sustainability
Efficiency
Cost
Cost-effectiveness
Cost-benefit

COST AND EFFECTIVENESS: CAN'T HAVE ONE WITHOUT THE OTHER

Reply to the Editor:

We thank Dr Santarpino and colleagues¹ for their interest in our cost-utility analysis comparing the cost-effectiveness of transcatheter aortic valve implantation (TAVI) with surgical aortic valve replacement (SAVR) in intermediate surgical risk patients.² By adapting randomized clinical trial (RCT) data from the Placement of Transcatheter Aortic Valves (PARTNER) 2 study, we showed that TAVI might be cost-effective compared with SAVR at commonly used willingness-to-pay thresholds.³

The Editor welcomes submissions for possible publication in the Letters to the Editor section that consist of commentary on an article published in the Journal or other relevant issues. Authors should: • Include no more than 500 words of text, three authors, and five references. • Type with double-spacing. • See <http://jtcvs.ctsnetjournals.org/misc/fora.shtml> for detailed submission instructions. • Submit the letter electronically via jtcvs.editorialmanager.com. Letters commenting on an article published in the JTCVS will be considered if they are received within 6 weeks of the time the article was published. Authors of the article being commented on will be given an opportunity to offer a timely response (2 weeks) to the letter. Authors of letters will be notified that the letter has been received. Unpublished letters cannot be returned.

Dr Wijeyesundera has received research funding from Edwards Life Sciences, and Medtronic Inc. All other authors have nothing to disclose with regard to commercial support.

The term “cost-effectiveness” might take on a different meaning depending on the context and the perspective of the individual or organization. Santarpino and colleagues have previously studied the overall costs associated with TAVI and SAVR with a sutureless valve system in 102 propensity-score matched pairs of high surgical risk patients and showed that overall hospitalization costs were lower with SAVR than transcatheter aortic valve replacement (TAVR).⁴ On the basis of their findings, they suggest that TAVR is not cost-effective in their letter to the Editor.¹ However, although in their analysis they measured relevant early outcomes, a formal conclusion regarding the comparative effectiveness of the 2 treatment strategies was not made. Hence, their study can only suggest that SAVR is less costly than TAVR in a highly selected group of patients treated at a center of excellence—conclusions cannot be drawn about the cost-effectiveness of one treatment strategy over another. In contrast, in our study, we compared overall and lifetime projected costs along with differences in quality-adjusted life years (QALYs) between the 2 treatment groups in a multicentered large RCT. This allowed for a comparison of costs and effectiveness. The use of QALYs as the primary outcome is supported by multiple health technology assessment regulatory bodies.⁵ QALYs makes up the denominator of the incremental cost-effectiveness ratio (ICER) and allows for comparisons against other medical interventions. Strictly reporting costs does not provide evidence on cost-effectiveness because only the numerator of the ICER is examined. Finally, the use of RCT data to inform economic models remains a valid means of conducting cost-utility analyses and is supported by best practice guidelines.⁶

We agree with the authors that paravalvular leak (PVL) is an important outcome and one that we did not include as a specific health state in our model. As the authors correctly pointed out, some studies suggest that PVL is associated with increased mortality at up to 2 years.⁷ In cost-effectiveness modeling, there is always a balance between incorporating all of the relevant health states while being parsimonious. We expect that any hazards associated with PVL will be reflected in the overall 2-year mortality rate observed in PARTNER 2.⁸ Because PARTNER 2 was a noninferiority trial—TAVR outcomes were similar to SAVR at 30 days and 2 years, leading to uncertainty in the overall effectiveness between the 2 strategies (ie, the denominator of the ICER), which we addressed by conducting

our base-case analysis as a fully probabilistic Markov model.

Finally, Santarpino¹ points out that our cost input for TAVI and surgical valves was different from the work presented by Cohen and colleagues⁹ at the Transcatheter Cardiovascular Therapeutics Conference. In our model, we used the Canadian list price of the valves (provided by Edwards LifeSciences Canada). A survey of the literature suggests that the price of valves do vary significantly between countries—despite adjustment for purchasing power parity.¹⁰ This price disparity reflects the complex nature of medical device procurement that varies between countries and even within countries.¹¹

Michael Porter has defined value in health care as cost per outcome achieved.¹² The use of cost-effectiveness analyses is a tool to allow policy and decision-makers to evaluate the overall costs and effectiveness of multiple treatment strategies to ensure that the adoption of any new technology provides value. Nonetheless, cost-effectiveness analysis is an imperfect tool, subject to constraints on available data, and is jurisdiction- and context-dependent and must be interpreted accordingly.

Derrick Y. Tam, MD^{a,b}

Avery Hughes^b

Harindra C. Wijeyesundera, MD, PhD^{b,c}

Stephen E. Fremes, MD, MSc^{a,b}

^aDivision of Cardiac Surgery

Department of Surgery

^cDivision of Cardiology

Department of Medicine

Schulich Heart Centre

Sunnybrook Health Sciences Centre

^bInstitute of Health Policy

Management and Evaluation

University of Toronto

Toronto, Ontario, Canada

Dr Tam is supported by the Ontario Ministry of Health Clinician Investigator's Program (Toronto, Ontario). Dr Wijeyesundera is supported by a Distinguished Clinician Scientist Award for the Heart and Stroke Foundation of Canada (Ottawa, Canada). Avery Hughes is supported by the SickKids-University of Toronto Ontario Student Opportunity Trust Fund (RestraComp) Award (Toronto, Ontario). Dr Fremes is supported by the Bernard S. Goldman Chair in Cardiovascular Surgery (Toronto, Ontario).

References

1. Santarpino G, Specchia L, Lombardi L. Aortic valve implantation or replacement: which procedure is more cost-effective? *J Thorac Cardiovasc Surg*. 2018;156:1851.
2. Tam DY, Hughes A, Fremes SE, Youn S, Hancock-Howard RL, Coyte PC, et al. A cost-utility analysis of transcatheter versus surgical aortic valve replacement for

the treatment of aortic stenosis in the population with intermediate surgical risk. *J Thorac Cardiovasc Surg.* 2018;155:1978-88.e1.

3. Anderson JL, Heidenreich PA, Barnett PG, Creager MA, Fonarow GC, Gibbons RJ, et al. ACC/AHA statement on cost/value methodology in clinical practice guidelines and performance measures: a report of the American College of Cardiology/American Heart Association task force on performance measures and task force on practice guidelines. *Circulation.* 2014;129:2329-45.
4. Santarpino G, Pfeiffer S, Jessl J, Dell'Aquila A, Vogt F, Von Wardenburg C, et al. Clinical outcome and cost analysis of sutureless versus transcatheter aortic valve implantation with propensity score matching analysis. *Am J Cardiol.* 2015;116:1737-43.
5. Mathes T, Jacobs E, Morfeld JC, Pieper D. Methods of international health technology assessment agencies for economic evaluations- a comparative analysis. *BMC Health Serv Res.* 2013;13:256.
6. Ramsey SD, Willke RJ, Glick H, Reed SD, Augustovski F, Jonsson B, et al. Cost-effectiveness analysis alongside clinical trials II-an ISPOR good research practices task force report. *Value Health.* 2015;18:161-72.
7. Tam DY, Chu MW. Paravalvular leak after transcatheter aortic valve implantation: trading one disease for another? *Expert Rev Cardiovasc Ther.* 2014;12:407-11.
8. Leon MB, Smith CR, Mack MJ, Makkar RR, Svensson LG, Kodali SK, et al. Transcatheter or surgical aortic-valve replacement in intermediate-risk patients. *N Engl J Med.* 2016;374:1609-20.
9. Cohen DJ. Health status benefits of transcatheter vs surgical aortic valve replacement in patients with severe aortic stenosis at intermediate surgical risk. Presented at: TCT 2016; November 1, 2016; Washington, DC. Available at: https://www.acc.org/e/media/Clinical/PDF-Files/Approved-PDFs/2016/10/25/07/TCT16_Nov01/950amET%20PARTNER%20II%20QUALITY%20OF%20LIFE.pdf. Accessed February 6, 2018.
10. Sud M, Tam DY, Wijesundera HC. The economics of transcatheter valve interventions. *Can J Cardiol.* 2017;33:1091-8.
11. Pauly MV, Burns LR. Price transparency for medical devices. *Health Aff (Millwood).* 2008;27:1544-53.
12. Porter ME. What is value in health care? *N Engl J Med.* 2010;363:2477-81.

<https://doi.org/10.1016/j.jtcvs.2018.05.027>

**NOT PERFECT,
BUT...**

Reply to the Editor:

Santarpino and colleagues¹ correctly highlight some of the weakness of the cost-utility analysis of transcatheter versus surgical aortic

valve replacement recently published by Tam and associates in *The Journal of Thoracic and Cardiovascular Surgery*.² Most of these limitations have been acknowledged

Author has nothing to disclose with regard to commercial support.

by Tam and colleagues in the text of their excellent report. It is obvious that aggregate data analysis are far from perfect in terms of representing patient-level heterogeneity, patient selection decision-making, and the granularity of the data set. However, compared with individual studies, aggregated data drastically increases the sample size and, thus, the precision of the analysis. For example, the study quoted by Santarpino and associates³ on the comparison between transcatheter and sutureless surgical valve replacement is a single-center experience on the basis of 102 propensity score-matched patient pairs and has obvious limitations in term of generalizability and power.

In summary, individual patients' data and aggregate data analysis have weaknesses and strengths. With this in mind, the report by Tam and others² is a very important step in the right direction in evaluating transcatheter aortic valve replacement using complex cost-utility analysis.

Mario Gaudino, MD

Department of Cardiothoracic Surgery

Weill Cornell Medicine

New York, NY

References

1. Santarpino G, Specchia L, Lombardi L. Aortic valve implantation or replacement: which procedure is more cost-effective? *J Thorac Cardiovasc Surg.* 2018;156:1851.
2. Tam DY, Hughes A, Fremes SE, Youn S, Hancock-Howard RL, Coyte PC, et al. A cost-utility analysis of transcatheter versus surgical aortic valve replacement for the treatment of aortic stenosis in the population with intermediate surgical risk. *J Thorac Cardiovasc Surg.* 2018;155:1978-88.
3. Santarpino G, Pfeiffer S, Jessl J, Dell'Aquila A, Vogt F, von Wardenburg C, et al. Clinical outcome and cost analysis of sutureless versus transcatheter aortic valve implantation with propensity score matching analysis. *Am J Cardiol.* 2015;116:1737-43.

<https://doi.org/10.1016/j.jtcvs.2018.05.028>