

Health Quality Ontario

The provincial advisor on the quality of health care in Ontario

Transcatheter Aortic Valve Implantation for Treatment of Aortic Valve Stenosis: OHTAC Recommendation

ONTARIO HEALTH TECHNOLOGY ADVISORY COMMITTEE RECOMMENDATIONS

- The Ontario Health Technology Advisory Committee recommends that transcatheter aortic valve implantation be publicly funded in patients with severe symptomatic degenerative aortic valve stenosis:
 - Who are not candidates for surgical aortic valve replacement *or*
 - Who have an estimated risk of mortality of 8% or greater within 30 days of surgery, as determined by a multidisciplinary cardiac team after evaluating the patient's Society of Thoracic Surgeons risk assessment score and other patient characteristics
- The Ontario Health Technology Advisory Committee recommends that transcatheter aortic valve implantation be offered only in selected hospitals, as determined by the Cardiac Care Network of Ontario

RATIONALE FOR THE RECOMMENDATION

There was consensus among Ontario Health Technology Advisory Committee (OHTAC) members that the mortality rate in patients receiving transcatheter aortic valve implantation (TAVI) was not higher than that in patients receiving surgical aortic valve replacement. Given that both methods also led to improvements in patients' quality of life during the first year,¹ OHTAC was in favour of publicly funding TAVI in high-risk surgical patients because of the less invasive nature of TAVI compared with surgical aortic valve replacement. As well, OHTAC felt that TAVI provided reasonable value for money, and that TAVI should be performed in specific centres by an appropriate specialty team with expertise in the procedure.

Public Comment: Held on August 11, 2016, to September 1, 2016

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Decision Determinants for Transcatheter Aortic Valve Implantation for Treatment of Aortic Valve Stenosis

Decision Criteria	Subcriteria	Decision Determinants Considerations
Overall clinical benefit How likely is the health technology/intervention to result in high, moderate, or low overall benefit?	Effectiveness How effective is the health technology/intervention likely to be (taking into account any variability)?	<ul style="list-style-type: none"> • Rates of cardiovascular and all-cause mortality were similar for TAVI and SAVR in all studies except one, where all-cause mortality was lower in the TAVI group • For patients who were not candidates for SAVR, cardiovascular and all-cause mortality were both significantly lower with TAVI than with balloon aortic valvuloplasty • Transapical TAVI had higher rates of mortality and stroke than transfemoral TAVI • TAVI was associated with higher risk of stroke, major vascular complications, paravalvular aortic regurgitation, and the need for a permanent pacemaker • The occurrence of adverse events after TAVI gives rise to uncertainty about the risks and benefits of this intervention in patients at intermediate or low risk for surgery. Additional studies are needed before extending to these lower-risk groups • In 2015, 643 TAVI procedures were conducted in Ontario • A large number of patients with severe degenerative aortic valve stenosis are at low risk for surgery (about 75%), while about 15% are at intermediate risk and about 10% are at high or extreme risk. At present, SAVR is preferred for low-risk patients
	Safety How safe is the health technology/intervention likely to be?	
	Burden of illness What is the likely size of the burden of illness pertaining to this health technology/intervention?	
	Need How large is the need for this health technology/intervention?	
Consistency with expected societal and ethical values^a How likely is adoption of the health technology/intervention to be congruent with societal and ethical values?	Societal values How likely is the adoption of the health technology/intervention to be congruent with expected societal values?	<ul style="list-style-type: none"> • Patients may prefer to undergo a less invasive procedure that has similar effectiveness • Will cardiac or noncardiac adverse events affect patients' long-term quality of life? Many patients may not prefer survival over long-term morbidity, but data for quality of life were available for only 1 year, with considerable missing data in all trials
	Ethical values How likely is the adoption of the health technology/intervention to be congruent with expected ethical values?	
Value for money How efficient is the health technology/intervention likely to be?	Economic evaluation How efficient is the health technology/intervention likely to be?	<ul style="list-style-type: none"> • The ICER was \$51,988 per QALY
Economic feasibility		<ul style="list-style-type: none"> • At 61 TAVI procedures per 1 million population, the budget impact of funding TAVI

Decision Criteria	Subcriteria	Decision Determinants Considerations
<p>Feasibility of adoption into health system</p> <p>How feasible is it to adopt the health technology/intervention into the Ontario health care system?</p>	<p>How economically feasible is the health technology/intervention?</p> <p>Organizational feasibility</p> <p>How organizationally feasible is it to implement the health technology/intervention?</p>	<p>for the next 5 years would be \$7.6 to \$8.3 million per year</p> <ul style="list-style-type: none"> • There are 10 TAVI programs in 10 cardiac centres in Ontario: 6 in Toronto, 1 in Ottawa, 1 in London, 1 in Kingston, and 1 in Sudbury • Due to its high-risk nature, TAVI must be performed by an experienced multidisciplinary team in a specialized centre with multimodality imaging, cardiac catheterization facilities, an operating room equipped with a cardiopulmonary bypass machine, and an anesthesiologist. Intensive-care management has been recommended for patients who undergo TAVI to manage potential complications from the procedure • Suitability for TAVI is largely determined by a multidisciplinary, collaborative cardiac team consisting of cardiac surgeons, interventional cardiologists, and other health professionals involved in the patient's care

Abbreviations: ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life-year; SAVR, surgical aortic valve replacement; TAVI, transcatheter aortic valve implantation.

^aThe anticipated or assumed common ethical and societal values held in regard to the target condition, target population, and/or treatment options. Unless there is evidence from scientific sources to corroborate the true nature of the ethical and societal values, the expected values are considered.

REFERENCES

- (1) Health Quality Ontario. Transcatheter aortic valve implantation for treatment of aortic valve stenosis: a health technology assessment. Ont Health Technol Assess Ser [Internet]. 2016 November;16(19):1-94. Available from: <http://www.hqontario.ca/evidence-to-improve-care/journal-ontario-health-technology-assessment-series>

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