Ontario Health
Quality

Transcatheter Aortic Valve Implantation in Patients With Severe Aortic Valve Stenosis at Low Surgical Risk: Recommendation

Draft Recommendation

- The Quality business unit at Ontario Health, based on guidance from the Ontario Health Technology Advisory Committee, recommends publicly funding transcatheter aortic valve implantation in patients with severe aortic valve stenosis who are at low surgical risk

Rationale for the Recommendation

The Ontario Health Technology Advisory Committee has reviewed and accepted the findings of the health technology assessment.[1]

Committee members agreed that, given the evidence regarding short-term quality of life, stroke, and mortality, and given the lived experience of patients with aortic stenosis and their caregivers, most older adults with severe aortic valve stenosis who are at low surgical risk would likely choose transcatheter aortic valve implantation (TAVI) over surgical aortic valve replacement (SAVR; the conventional treatment in this patient population).

Committee members did express some concern about uncertainty with respect to the long-term durability of TAVI valves in the low-risk patient population. Members also expressed concern about the cost-effectiveness of TAVI, given the cost of the device. They suggested that the overall costs of TAVI might be reduced through negotiating reductions in device price and by encouraging shorter stays in hospital.

Public Comment: TBA

Decision Determinants for Transcatheter Aortic Valve Implantation in Patients With Severe Aortic Valve Stenosis at Low Surgical Risk

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)?	Both TAVI and SAVR improved symptoms and quality of life at 1 y after these procedures. TAVI is a less invasive procedure that results in greater symptom improvement and quality of life (GRADE: High), and in a slight decrease in mortality and disabling stroke (GRADE: Moderate) compared with SAVR at 30 d after surgery
		Mortality was similar between groups (1 y) (GRADE: Low); there was possibly a slightly lower risk of disabling stroke (1–2 y) (GRADE: Moderate and Low, respectively) with TAVI
	Safety How safe is the health technology/intervention likely to be?	TAVI had a lower risk of life-threatening or disabling bleeding, acute kidney injury, and atrial fibrillation (GRADE: High) vs. SAVR. A study that used a self-expanding TAVI valve showed TAVI had a higher risk of pacemaker implantation (GRADE: High), moderate-to-severe paravalvular regurgitation (GRADE: Moderate), and left bundle branch block (GRADE: High). The long-term clinical implications of these events are currently unknown
	Burden of illness What is the likely size of the burden of illness pertaining to this health technology/ intervention?	About 2% of people > 65 y present with severe aortic valve stenosis, 80% of which are at low surgical risk
	Need How large is the need for this health technology/intervention?	SAVR is the conventional treatment in this patient population. TAVI is a less invasive alternative to SAVR

Decision Criteria	Subcriteria	Decision Determinants Considerations
Patient preferences and values How likely is adoption of the health technology/intervention to be congruent with patient preferences and values and with ethical or legal standards?	**Patient preferences and values** Do patients have specific preferences, values, or needs related to the health condition, health technology/intervention, or life impact that are relevant to this assessment? (Note: The preferences and values of family members and informal caregivers are to be considered as appropriate.)	We did not find any quantitative or qualitative evidence on patient preferences and values specific to the low-risk surgical group. Among a mixed or generally high-risk population, people preferred the less invasive nature and the faster recovery time of TAVI compared with SAVR.
	Autonomy, privacy, confidentiality, and/or other relevant ethical principles as applicable Are there concerns regarding accepted ethical or legal standards related to patient autonomy, privacy, confidentiality, or other ethical principles that are relevant to this assessment? (Note: The preferences and values of the public are to be considered as appropriate.)	Providing the choice between TAVI or SAVR allows for greater autonomy for patients.
Equity and patient care How could the health technology/ intervention affect equity of access and coordination of patient care?	**Equity of access or outcomes** Are there disadvantaged populations or populations in need whose access to care or health outcomes might be improved or worsened that are relevant to this assessment?	Patients reported financial and access barriers for both TAVI and SAVR, particularly in northern/remote Ontario. Shorter hospital stay for TAVI reduces financial and access burden
	Patient care Are there challenges in the coordination of care for patients or other system-level aspects of patient care (e.g., timeliness of care, care setting) that might be improved or worsened that are relevant to this assessment?	Receiving TAVI can improve health outcomes for patients in the short term (30 d after surgery). Receiving less-invasive TAVI can result in a shorter hospital stay and quicker return home

Decision Criteria	Subcriteria	Decision Determinants Considerations
Cost-effectiveness How efficient is the health technology/ intervention likely to be?	**Economic evaluation** How efficient is the health technology/intervention likely to be?	We identified one cost-effectiveness analysis conducted in Ontario that had minor limitations and was directly applicable to our research question. Based on this study, compared with SAVR, ICERs were $27,196/QALY and $59,641/QALY for balloon expandable and self expanding TAVI, respectively. There was considerable uncertainty in these results.
Feasibility of adoption into health system How feasible is it to adopt the health technology/intervention into the Ontario health care system?	**Economic feasibility** How economically feasible is the health technology/intervention?	The cost of a TAVI valve is approximately $25,000. In addition, costs related to the initial procedure and complications are expected to be incurred over time. We estimated that the annual budget impact of publicly funding TAVI in people with severe aortic valve stenosis at low surgical risk would range from about an additional $5 to $8 million over the next 5 y.
	Organizational feasibility How organizationally feasible is it to implement the health technology/intervention?	Currently 11 centres provide TAVI in Ontario. There is sufficient infrastructure to provide TAVI to people at low surgical risk.

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

Reference

(1) TBD

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About the Ontario Health Technology Advisory Committee

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