

## Transcatheter Aortic Valve Implantation in Patients With Severe, Symptomatic Aortic Valve Stenosis at Intermediate Surgical Risk: Health Quality Ontario Recommendation

### DRAFT RECOMMENDATION

- Health Quality Ontario, under the guidance of the Ontario Health Technology Advisory Committee, recommends publicly funding transcatheter aortic valve implantation (TAVI) in patients with severe, symptomatic aortic valve stenosis who are at intermediate surgical risk

### RATIONALE FOR THE RECOMMENDATION

The Ontario Health Technology Advisory Committee has reviewed the findings of the health technology assessment<sup>1</sup> and accepted the findings that the risk of mortality and disabling stroke with TAVI was similar to that with surgical aortic valve replacement (the conventional treatment for severe, symptomatic aortic valve stenosis in patients at intermediate surgical risk).

Committee members expressed some concern about uncertainty with respect to the long-term durability of TAVI and to its cost-effectiveness, given the cost of the device. They also took into account the lived experience of patients with aortic valve stenosis and their caregivers, and in particular the comments about postoperative recovery.

Based on these considerations, Health Quality Ontario decided to recommend public funding for TAVI in patients with severe, symptomatic aortic valve stenosis who are at intermediate surgical risk.

## Decision Determinants for Transcatheter Aortic Valve Implantation in Patients With Severe, Symptomatic Aortic Valve Stenosis at Intermediate Surgical Risk

Decision Criteria	Subcriteria	Decision Determinants Considerations
<b>Overall clinical benefit</b> How likely is the health technology/intervention to result in high, moderate, or low overall benefit?	<b>Effectiveness</b> How effective is the health technology/intervention likely to be (taking into account any variability)?	TAVI was similar to SAVR with respect to the composite endpoint of all-cause mortality or disabling stroke within 2 years of follow-up  Both TAVI and SAVR improved patients' quality of life compared to baseline ratings. There was a greater improvement in quality of life with TAVI vs. SAVR in the full cohort at 30 days of follow-up, but no difference between groups beyond 6 months
	<b>Safety</b> How safe is the health technology/intervention likely to be?	TAVI and SAVR had different complication patterns: <ul style="list-style-type: none"> <li>• TAVI was associated with a higher risk of moderate to severe paravalvular aortic regurgitation and major vascular complications than SAVR. One study showed a higher risk of new pacemaker implantation with TAVI compared to SAVR</li> <li>• TAVI was associated with a lower risk of acute kidney injury and atrial fibrillation than SAVR. One study showed a lower risk of life-threatening or disabling bleeding with TAVI compared to SAVR</li> </ul>
	<b>Burden of illness</b> What is the likely size of the burden of illness pertaining to this health technology/intervention?	Approximately 2% of people over 65 years of age present with severe aortic valve stenosis. Approximately 14% of patients with severe aortic valve stenosis are at intermediate surgical risk
	<b>Need</b> How large is the need for this health technology/intervention?	SAVR is the conventional treatment for patients with severe aortic valve stenosis who are at low or intermediate risk for surgery; TAVI is an alternative to SAVR
<b>Consistency with expected societal and ethical values<sup>a</sup></b> How likely is adoption of the health technology/intervention to be congruent with societal and ethical values?	<b>Societal values</b> How likely is adoption of the health technology/intervention to be congruent with expected societal values?	Patients and caregivers reported that providing TAVI to people with aortic valve stenosis would reduce pain and recovery time, improve quality of life, and increase people's ability to return to their usual activities more quickly than with SAVR
	<b>Ethical values</b> How likely is adoption of the health technology/intervention to be congruent with expected ethical values?	TAVI is highly likely to be congruent with societal and ethical values

Decision Criteria	Subcriteria	Decision Determinants Considerations
<p><b>Cost-effectiveness</b></p> <p>How efficient is the health technology/intervention likely to be?</p>	<p><b>Economic evaluation</b></p> <p>How efficient is the health technology/intervention likely to be?</p>	<p>Two previously published studies conducted from an Ontario perspective showed that TAVI may be cost-effective compared to SAVR in people at intermediate surgical risk (ICERs: \$46,083 and \$76,736). Cost-effectiveness was improved when considering TAVI using the transfemoral access route only. However, there was moderate to high uncertainty in the results: at a willingness-to-pay value of \$100,000/QALY, the probability of TAVI being cost-effective was &lt; 60%</p>
<p><b>Feasibility of adoption into health system</b></p> <p>How feasible is it to adopt the health technology/intervention into the Ontario health care system?</p>	<p><b>Economic feasibility</b></p> <p>How economically feasible is the health technology/intervention?</p> <p><b>Organizational feasibility</b></p> <p>How organizationally feasible is it to implement the health technology/intervention?</p>	<p>We estimated it would cost an additional \$3 million to \$4 million per year to publicly fund TAVI in people at intermediate surgical risk</p> <p>Given that TAVI is already publicly funded for people who cannot have surgery or have a high risk of dying if they have the surgery, experts stated that there would be no issues with organizational feasibility for TAVI in patients with severe, symptomatic aortic stenosis at intermediate surgical risk if funding is approved</p>

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

<sup>a</sup>The 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.

*Draft — do not cite. Report is a work in progress and could change following public consultation.*

## REFERENCE

(1) TBA

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