Transcatheter Valve-in-Valve Implantation for Degenerated Mitral or Tricuspid Bioprosthetic Valves: Recommendation

Draft Recommendation

- Ontario Health, based on guidance from the Ontario Health Technology Advisory Committee, recommends publicly funding transcatheter valve-in-valve implantation for adults with degenerated mitral or tricuspid bioprosthetic valves who are considered inoperable or high-risk for surgery

Rationale for the Recommendation

The Ontario Health Technology Advisory Committee has reviewed the findings of the health technology assessment[1] and determined that transcatheter valve-in-valve implantation may improve the functional status of patients with degenerated mitral or tricuspid bioprosthetic valves who are considered inoperable or high-risk for surgery (as determined by Society of Thoracic Surgeons risk score[2] and clinical judgment).

Transcatheter valve-in-valve implantation may also reduce the rates of mortality, stroke, and myocardial infarction associated with heart failure because of degenerated mitral or tricuspid bioprosthetic valves, but the evidence for this is uncertain. The cost-effectiveness of valve-in-valve implantation for degenerated mitral or tricuspid bioprosthetic valves could not be determined because of uncertainties in the clinical evidence, but a 5-year budget impact assessment estimated an overall cost saving for the health care system if transcatheter valve-in-valve implantation were used instead of medical management (i.e., drug therapy, the current standard of care in Ontario).

In making their recommendation, Ontario Health Technology Advisory Committee members took into account the lived experience of people with heart valve failure, people's experience with minimally invasive valve replacement surgery, and the positive effect of this procedure on their quality of life. The Ontario Health Technology Advisory Committee also acknowledged that people with degenerated mitral

or tricuspid valves who are considered inoperable or high-risk for surgery currently have no treatment options other than medical management, and that even with medical management they may continue to experience severe heart failure symptoms that limit physical function.

The Ontario Health Technology Advisory Committee weighed in favour of publicly funding transcatheter valve-in-valve implantation because it may provide benefits for health outcomes that are important to patients, such as improved functional status; it is estimated to be cost-saving for the health care system compared to medical management (standard care); and people who are considered inoperable or high-risk for surgery value its minimal invasiveness and short recovery time after treatment.

Decision Determinants for Transcatheter Valve-in-Valve Implantation for Degenerated Mitral or Tricuspid Bioprosthetic Valves

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)?	No studies compared TMViV or TTViV with medical management (standard care). People with degenerated mitral or tricuspid bioprosthetic valves who are considered inoperable or high-risk for surgery may experience improved functional status after TMViV or TTViV (over approximately 3 years or 1 year of follow-up, respectively), as measured by NYHA functional classification[3] (GRADE: Low), which describes how much a patient's physical activity is limited because of their heart failure symptoms. TMViV or TTViV may reduce mortality (over approximately 4 years or 2 years of follow-up, respectively) but the evidence is uncertain (GRADE: Very low).
	Safety How safe is the health technology/intervention likely to be?	TMViV or TTViV may reduce rates of stroke, myocardial infarction, or other complications (over approximately 1 year or 6 months of follow-up, respectively) but the evidence is uncertain (GRADE: Very low).
	Burden of illness What is the likely size of the burden of illness pertaining to this health technology/ intervention?	Reoperation is the standard treatment for prosthetic valves that develop severe stenosis or regurgitation; however, repeat open-heart surgery may carry significant risks, especially in the presence of comorbidities. Medical management (e.g., diuretics, anticoagulants) does not significantly alter the course of valvular heart disease or degenerated bioprosthetic valves for people who are considered inoperable or high-risk for open-heart surgery.
	Need How large is the need for this health technology/intervention?	In Ontario, approximately 25 patients per year may be candidates for TMViV, and approximately 1 to 2 patients per year may be candidates for TTViV.
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.)	People reported that they preferred and valued the minimally invasive nature and short recovery time of transcatheter valve-in-valve implantation.

Decision criteria	Subcriteria	Decision determinants considerations
	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.)	There are no concerns about the adoption of TMViV and TTViV in Ontario with respect to patient autonomy, privacy, confidentiality, or other relevant ethical principles.
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?	The availability of TMViV and TTViV at a limited number of cardiac centres in Ontario could lead to inequitable access and therefore inequity of outcomes. People who live in rural or remote areas may incur higher travel-related costs to access TMViV or TTViV treatment if it is not available in the health facility that serves their community. People with compromised physical functioning because of heart failure may be unable to travel long distances to access TMViV or TTViV outside their community, and because of this they may not be afforded the same outcomes as those who can access such care in their community.
	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?	Challenges include accessing the care setting in a timely manner. For example, people with degenerated bioprosthetic mitral or tricuspid valves living in rural or remote areas may accrue travel-related costs and experience long travel times (all while experiencing severe heart failure symptoms) to access TMViV or TTViV.
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 no cost-effectiveness studies on TMViV or TTViV for degenerated mitral or tricuspid bioprostheses. Due to uncertainties in the clinical evidence, we did not perform a primary economic evaluation to determine the cost-effectiveness of TMViV or TTViV. Therefore, the cost-effectiveness of this treatment is unknown.
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?	We estimated that the budget impact of publicly funding TMViV and TTViV in Ontario would range from a budget increase of $0.35 million in year 1 to a cost saving of $0.19 million in year 5, for a total cost saving of $0.33 million over the next 5 years. We expect that the estimated cost saving would be attributable to improved efficiencies in health care resource utilization rather than to direct budgetary savings.

Decision criteria	Subcriteria	Decision determinants considerations
	Organizational feasibility How organizationally feasible is it to implement the health technology/intervention?	Implementation of TMViV and TTViV in Ontario would be facilitated by the low prevalence of degenerated mitral or tricuspid bioprostheses among people at high surgical risk, as well as the existing infrastructure for both procedures and the technical expertise to offer them.

Abbreviations: GRADE, Grading of Recommendations Assessment, Development and Evaluation; NYHA, New York Heart Association; TMViV, transcatheter mitral valve-in-valve implantation; TTViV, transcatheter tricuspid valve-in-valve implantation.

References

(1) TBA
(2) The Society of Thoracic Surgeons. STS short-term risk calculator [Internet]. Chicago (IL): The Society; 2018 [updated 2018 Nov 5; cited 2021 Aug 5]. Available from: https://www.sts.org/resources/risk-calculator
(3) American Heart Association. Classes of heart failure [Internet]. Dallas (TX): The Association; 2017 [updated 2017 May 31; cited 2021 Aug 5]. Available from: https://www.heart.org/en/health-topics/heart-failure/what-is-heart-failure/classes-of-heart-failure

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