

Health Quality Ontario

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Percutaneous Ventricular Assist Devices: OHTAC Recommendations

ONTARIO HEALTH TECHNOLOGY ADVISORY COMMITTEE RECOMMENDATIONS

- The Ontario Health Technology Advisory Committee recommends that Impella percutaneous ventricular assist devices not be publicly funded for use in high-risk percutaneous coronary intervention
- The Ontario Health Technology Advisory Committee recommends that Impella percutaneous ventricular assist devices not be publicly funded for use in cardiogenic shock

RATIONALE FOR THE RECOMMENDATIONS

The Ontario Health Technology Advisory Committee (OHTAC) accepted the findings of the health technology assessment.¹

The main reasons for the recommendations were as follows.

First, there was no moderate or high quality evidence showing a difference in clinically important outcomes between patients treated with Impella devices and intra-aortic balloon pumps in high-risk percutaneous coronary intervention and in cardiogenic shock.

Second, given the price of the technology and the limited evidence of clinical benefit, Impella devices do not appear to provide good value for money.

OHTAC did acknowledge that there may be a small group of patients who would likely benefit from this intervention. However, given the current evidence, OHTAC did not believe that this group could be clearly identified for the purpose of a funding recommendation.

Decision Determinants for Percutaneous Ventricular Assist Devices

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)?	High-Risk PCI: Impella 2.5 improved hemodynamic stability when compared with IABP (GRADE Low) Cardiogenic Shock: Impella 2.5 improved hemodynamic stability when compared with IABP (GRADE Very Low)
	Safety How safe is the health technology/intervention likely to be?	High-Risk PCI: 30-day mortality and major adverse cardiac events were not significantly different between Impella 2.5 and IABP (GRADE Low) Cardiogenic Shock: 30-day mortality and major adverse cardiac events were not significantly different between Impella 2.5 and IABP, but Impella 2.5 was associated with higher rate of hemolysis (GRADE Low)
	Burden of illness What is the likely size of the burden of illness pertaining to this health technology/intervention?	In fiscal year 2015/16, the estimated prevalence of high-risk PCI and cardiogenic shock with the use of IABP or Impella in Ontario was 184 and 171, respectively (data from Cardiac Care Network of Ontario)
	Need How large is the need for this health technology/intervention?	Some clinical demand for a less invasive device with higher flow rate to provide support in high-risk PCI and cardiogenic shock
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 adoption of the health technology/intervention to be congruent with expected societal values?	Estimated to be congruent with expected societal values
	Ethical values How likely is adoption of the health technology/intervention to be congruent with expected ethical values?	Estimated to be congruent with expected ethical values
Value for money How efficient is the health technology likely to be?	Economic evaluation How efficient is the health technology/intervention likely to be?	The device is indicated in high-risk PCI patients. Impella is associated with higher costs and fewer QALYs compared with IABPs
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?	Publicly funding Impella devices could result in extra spending of \$2.9–\$11.5 million per year
	Organizational feasibility How organizationally feasible is it to implement the health technology/intervention?	Requires infrastructure and trained personnel to insert Impella devices

Abbreviations: GRADE, Grading of Recommendations Assessment, Development and Evaluation; IABP, intra-aortic balloon pump; PCI, percutaneous coronary intervention; QALY, quality-adjusted life-year.

^aAnticipated or assumed common ethical and societal values held in regard to target condition, target population, or treatments. 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. Percutaneous ventricular assist devices: a health technology assessment: a health technology assessment. Ont Health Technol Assess Ser [Internet]. 2017 Feb;17(2):1-97. Available from: <http://www.hqontario.ca/Evidence-to-Improve-Care/Journal-Ontario-Health-Technology-Assessment-Series>

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