Health Quality Ontario

Left Ventricular Assist Devices for Destination Therapy: OHTAC Recommendation

ONTARIO HEALTH TECHNOLOGY ADVISORY COMMITTEE RECOMMENDATIONS

- OHTAC recommends that continuous flow left ventricular assist devices (LVAD) be publicly funded as permanent therapy (also known as destination therapy) in patients with end-stage heart failure who are ineligible for heart transplantation.
- OHTAC recommends that the Cardiac Care Network and Trillium Gift of Life Network provide guidance regarding which hospitals should offer this procedure, and which patients should be eligible.
- OHTAC further recommends that the Cardiac Care Network and/or Trillium Gift of Life Network ensures data is collected on survival and quality of life for individuals receiving continuous flow LVAD as permanent therapy, and that this data be reviewed by OHTAC in 2 years.

RATIONALE FOR THE RECOMMENDATION DECISION

After a review of the evidence (1), OHTAC felt that the clinical benefit of LVADs as permanent therapy for patients with end-stage heart failure, who are ineligible for heart transplantation, outweighed its lack of cost-effectiveness. However, because there was uncertainty about this treatment's effect on quality of life, OHTAC requested continued quality of life data collection to be reviewed by OHTAC in two years.

ABOUT OHTAS

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Ontario
Health Quality Ontario

Decision Determinants for Left Ventricular Assist Devices for Destination Therapy

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)?	A continuous flow LVAD is currently licensed by Health Canada. Pulsatile flow LVADs are not currently licensed by Health Canada. Two RCTs compared 1. pulsatile flow LVADs to optimal medical management. 2. continuous flow LVADs to pulsatile flow LVADs. No studies were identified that compared a continuous flow LVAD to optimal medical management which is the direct comparison of interest. Therefore the evidence comes from comparisons 1 and 2 above. These are considered indirect comparisons because they are not the direct comparison of interest. Continuous flow LVADs as destination therapy significantly improve survival (moderate quality evidence) and quality of life (low quality evidence) compared to optimal medical management in patients with end-stage heart failure and who are ineligible for heart transplantation.
	Safety How safe is the health technology/intervention likely to be?	In patients with end-stage heart failure and who are ineligible for heart transplantation, continuous flow LVADs have a higher rate of adverse events compared to optimal medical management (moderate quality evidence).
	Burden of illness What is the likely size of the burden of illness pertaining to this health technology/intervention?	Based on expert opinion and published literature for a budget impact analysis to the MOHLTC, it was estimated in year one, 94 LVAD implants can be achieved, increasing at a rate of 20% per year to reach 195 in year 5. Potential to increase based on INTERMACS 2014 annual report (2).
	Need How large is the need for this health technology/intervention?	The alternative for patients with end-stage heart failure and who are ineligible for heart transplantation is optimal medical therapy (i.e., taking medicine).
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?	Estimated to be congruent.
	Ethical values How likely is the adoption of the health technology/intervention to be congruent with expected ethical values?	Estimated to be congruent.
Value for money How efficient is the health technology likely to be?	**Economic evaluation** How efficient is the health technology/intervention likely to be?	LVAD is a relatively expensive intervention and the incremental cost-effectiveness associated with continuous-flow LVAD for destination therapy is relatively high, and is not cost-effective within the traditional cost-effectiveness thresholds of $50,000 and $100,000.
Feasibility of adoption into health system	**Economic feasibility** How economically feasible is the health technology/intervention?	The expected budget impact to the MOHLTC of each LVAD patient, will total an average net cost in Year 1 of implant of $153,150, and an average maintenance cost for each year of survival after Year 1 of $44,782.

Decision Criteria	Subcriteria	Decision Determinants Considerations
How feasible is it to adopt the health technology/intervention into the Ontario health care system?	**Organizational feasibility** How organizationally feasible is it to implement the health technology/intervention?	Require surgeons experienced in LVAD implantation and follow-up care.

Abbreviations: INTERMACS, Interagency Registry for Mechanically-Assisted Circulatory Support; LVAD, Left ventricular assist device; RCT, Randomized controlled trial.

[a]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.

REFERENCES

(1) Health Quality Ontario. Left Ventricular Assist Devices for Destination Therapy: A Health Technology Assessment. Ont Health Technol Assess Ser [Internet]. 2016 February;16(3):1-60. Available from: http://www.hqontario.ca/evidence/publications-and-ohtac-recommendations/ontario-health-technology-assessment-series/hta-lvad.

(2) Kirklin JK, Naftel DC, Pagani FD, Kormos RL, Stevenson LW, Blume ED, et al. Sixth INTERMACS annual report: a 10,000-patient database. J Heart Lung Transplant. 2014;33(6):555-64.

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