

Capsule Endoscopy in the Assessment of Obscure Gastrointestinal Bleeding: OHTAC Recommendation

Ontario Health Technology Advisory Committee

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Conflict of Interest Statement

All authors in the Evidence Development and Standards branch at Health Quality Ontario are impartial. There are no competing interests or conflicts of interest to declare.

About Health Quality Ontario

Health Quality Ontario (HQO) is an arms-length agency of the Ontario government. It is a partner and leader in transforming Ontario's health care system so that it can deliver a better experience of care, better outcomes for Ontarians, and better value for money.

Health Quality Ontario strives to promote health care that is supported by the best available scientific evidence. The Evidence Development and Standards branch works with advisory panels, clinical experts, developers of health technologies, scientific collaborators, and field evaluation partners to provide evidence about the effectiveness and cost-effectiveness of health interventions in Ontario.

To conduct its systematic reviews of health interventions, the Evidence Development and Standards branch examines the available scientific literature, making every effort to consider all relevant national and international research. If there is insufficient evidence on the safety, effectiveness, and/or cost-effectiveness of a health intervention, HQO may request that its scientific collaborators conduct economic evaluations and field evaluations related to the reviews. Field evaluation partners are research institutes focused on multicentred clinical trials and economic evaluation, as well as institutes engaged in evaluating the safety and usability of health technologies.

About the Ontario Health Technology Advisory Committee

The Ontario Health Technology Advisory Committee (OHTAC) is a standing advisory subcommittee of the Board of Directors of Health Quality Ontario. Based on the evidence provided by Evidence Development and Standards and its partners, OHTAC makes recommendations about the uptake, diffusion, distribution, or removal of health interventions within the provincial health system. When making its recommendations, OHTAC applies a unique decision-determinants framework that takes into account overall clinical benefit, value for money, societal and ethical considerations, and the economic and organizational feasibility of the health care intervention in Ontario.

Publishing Health Quality Ontario Research

When the evidence development process is nearly completed, draft reviews, reports, and OHTAC recommendations are posted on HQO's website for 21 days for public and professional comment. For more information, please visit: <http://www.hqontario.ca/evidence/evidence-process/evidence-review-process/professional-and-public-engagement-and-consultation>.

Once finalized and approved by the Board of Directors of Health Quality Ontario, the research is published as part of the *Ontario Health Technology Assessment Series*, which is indexed in MEDLINE/PubMed, Excerpta Medica/Embase, and the Centre for Reviews and Dissemination database. Corresponding OHTAC recommendations and associated reports are also published on the HQO website. Visit <http://www.hqontario.ca> for more information.

When sufficient data are available, OHTAC tracks the ongoing use of select interventions it has previously reviewed, compiling data by time period and region. The results are published in the Ontario Health Technology Maps Project Report.

Disclaimer

This report was prepared by the Evidence Development and Standards branch at Health Quality Ontario or one of its research partners for the Ontario Health Technology Advisory Committee and was developed from analysis, interpretation, and comparison of scientific research. It also incorporates, when available, Ontario data and information provided by experts and applicants to HQO. The analysis may not have captured every relevant publication and relevant scientific findings may have been reported since the development of this recommendation. This report may be superseded by an updated publication on the same topic. Please check the Health Quality Ontario website for a list of all publications: <http://www.hqontario.ca/evidence/publications-and-ohtac-recommendations>.

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Background

The Evidence Development and Standards branch at Health Quality Ontario (HQO) conducted an evidence-based analysis (1) to answer the following research question:

- What are the diagnostic accuracy, safety, and impact on health outcomes of capsule endoscopy (CE) for the diagnosis of obscure gastrointestinal bleeding compared with other diagnostic modalities?

In addition, HQO commissioned the Programs for Assessment of Technology in Health (PATH) Research Institute to evaluate the budget impact of varying levels of CE use to complement findings from push enteroscopy (PE) in patients with rebleeding post-PE. (2)

Conclusions

In determining the etiology of obscure gastrointestinal bleeding, CE:

- has a higher sensitivity than magnetic resonance enteroclysis, computed tomography, or PE (Grading of Recommendations Assessment, Development, and Evaluation [GRADE]: very low);
- has a lower specificity than magnetic resonance enteroclysis, computed tomography, or PE (GRADE: very low);
- has a good safety profile with few adverse events (GRADE: very low), although there is a risk of capsule retention and comparative safety data with other diagnostic modalities are limited;
- is perceived by patients to be more tolerable and less burdensome than PE, double-balloon enteroscopy, or magnetic resonance enteroclysis (GRADE: very low);
- is associated with no difference in patient health-related outcomes such as rebleeding or follow-up treatment compared with PE, small-bowel follow-through, or angiography (GRADE: low); and
- would result in an additional expenditure of about \$763,000 CAD to complement PE procedures in eligible patients, an estimated 50% of those undergoing PE, according to expert opinion.

Decision Determinants

OHTAC has developed a decision-making framework that consists of 7 guiding principles for decision making and a decision determinants tool. When making a decision, OHTAC considers 4 explicit main criteria: overall clinical benefit, consistency with expected societal and ethical values, value for money, and feasibility of adoption into the health system. For more information on the decision-making framework, please refer to the *Decision Determinants Guidance* document available at: <http://www.hqontario.ca/evidence/evidence-process/evidence-review-process/decision-making-framework>.

Appendix 1 provides a summary of the decision determinants for this recommendation.

Based on the decision determinants criteria, OHTAC considered the uncertainty around the diagnostic accuracy data given their low quality. OHTAC also considered societal and ethical considerations, specifically the preference of patients in favour of small-bowel CE compared with more invasive diagnostic procedures. OHTAC acknowledged the low rates of capsule retention, as well as the potential need for further surgical or endoscopic interventions for capsule retrieval.

OHTAC Recommendations

- OHTAC recommends that small-bowel capsule endoscopy¹ continues to be used as a diagnostic procedure in determining the etiology of obscure gastrointestinal bleeding in patients with negative upper and lower endoscopic evaluations.
- Given the severity of the risk of capsule retention, OHTAC recommends discussion between patients and physicians with respect to this potential risk.

¹OHTAC's recommendation is based on a systematic review of capsule devices that have the following features: 140°–170° angle of view; a frame rate of 2–3 images per second; and software for analyzing detected lesions.

Appendices

Appendix 1: Decision Determinants

Table A1: Decision Determinants for Small-Bowel Capsule Endoscopy for Obscure Gastrointestinal Bleeding

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)?	In patients with OGIB, CE: <ul style="list-style-type: none"> has a higher sensitivity than magnetic resonance enteroclysis, computed tomography, or PE (GRADE: very low); has a lower specificity than magnetic resonance enteroclysis, computed tomography, or PE (GRADE: very low); and is associated with no difference in patient health-related outcomes such as rebleeding or follow-up treatment compared with PE, small-bowel follow-through, or angiography (GRADE: low).
	Safety How safe is the health technology/intervention likely to be?	In patients with OGIB, CE has a good safety profile with few adverse events (GRADE: very low), although there is a risk of capsule retention and comparative safety data with other diagnostic modalities are limited.
	Burden of illness What is the likely size of the burden of illness pertaining to this health technology/intervention?	The incidence of GI bleeding is about 100 per 100,000 population, suggesting that there are about 13,500 people in Ontario (2013 population = 13.5 million) with GI bleeding problems in any given year. With 5% of those GI bleeding cases estimated to be in the small bowel, the burden of OGIB is low (estimated at about 675 individuals).
	Need How large is the need for this health technology/intervention?	There is a need to visualize the entire small bowel in patients with OGIB.
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?	The use of small-bowel CE is congruent with societal values associated with access to care and timeliness of care. There is some very low quality evidence that patients find CE significantly less painful and less burdensome than other diagnostic modalities.
	Ethical values How likely is the adoption of the health technology/intervention to be congruent with expected ethical values?	Unknown.

Decision Criteria	Subcriteria	Decision Determinants Considerations
Value for money How efficient is the health technology likely to be?	Economic evaluation How efficient is the health technology/intervention likely to be?	No relevant cost-effectiveness analyses were identified in the published literature; however, generally the cost-effectiveness of small-bowel CE for investigation of OGIB is favourable. Expert opinion also sees the benefit of the capsule as an add-on diagnostic tool for patients post-PE.
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? Organizational feasibility How organizationally feasible is it to implement the health technology/intervention?	Small-bowel CE has been funded by the province since 2008, with 491 procedures performed in 2012. With usage expanded to all likely potential candidates for small-bowel CE, an additional 734 procedures would need to be performed within the province.

Abbreviations: CE, capsule endoscopy; GI, gastrointestinal; GRADE, Grading of Recommendations Assessment, Development, and Evaluation; OGIB, obscure gastrointestinal bleeding; PE, push enteroscopy.

^aThe 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. Capsule endoscopy in the assessment of obscure gastrointestinal bleeding: an evidence-based analysis. *Ont Health Technol Assess Ser* [Internet]. 2015 February;15(1):1–55. Available from: <http://www.hqontario.ca/evidence/publications-and-ohtac-recommendations/ontario-health-technology-assessment-series/capsule-endoscopy-gi-bleeding>.
- (2) Palimaka S, Blackhouse G, Goeree R. Capsule endoscopy in the assessment of obscure gastrointestinal bleeding: an economic analysis. *Ont Health Technol Assess Ser* [Internet]. 2015 February;15(1):1–55. Available from: <http://www.hqontario.ca/evidence/publications-and-ohtac-recommendations/ontario-health-technology-assessment-series/econ-capsule-endoscopy-gi-bleeding>.

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