Colon Capsule Endoscopy for the Detection of Colorectal Polyps: OHTAC Recommendation

HEALTH QUALITY ONTARIO

ONTARIO HEALTH TECHNOLOGY ADVISORY COMMITTEE RECOMMENDATION

- OHTAC recommends against the public funding of colon capsule endoscopy.

BACKGROUND

Colorectal cancer is a leading cause of mortality and morbidity in Ontario. Many cases of colorectal cancer can likely be prevented through early diagnosis and removal of precancerous polyps. Colon capsule endoscopy is a relatively new, non-invasive test for detecting colorectal polyps. Colon capsule endoscopy involves a capsule designed to be swallowed by patients that takes images of the colon as it passes through the gastrointestinal tract.

Health Quality Ontario conducted an evidence-based analysis (1) to answer the research questions presented below. In addition, HQO commissioned the Programs for Assessment of Technology in Health (PATH) Research Institute to evaluate the cost-effectiveness of colon capsule endoscopy as an alternative to computed tomographic (CT) colonography, using estimates of diagnostic accuracy from the clinical evidence, for patients with a prior incomplete colonoscopy. The costs of both procedures and resultant budget impact were also estimated. (2)

REVIEW OF THE EVIDENCE

Research Questions

- What are the sensitivity and specificity of colon capsule endoscopy, using the PillCam COLON 2 device (PCC2), for the detection of colorectal polyps among adult patients either with signs or symptoms of colorectal cancer or with increased risk of colorectal cancer?
- What are the sensitivity and specificity of colon capsule endoscopy, using PCC2, compared with computed tomographic colonography for the detection of colorectal polyps among adult patients either with signs or symptoms of colorectal cancer or with increased risk of colorectal cancer?
- What are the adverse events associated with the use of PCC2?
- What is the cost-effectiveness and 1-year budgetary impact of colon capsule endoscopy for the detection of colorectal polyps and cancer?

Main Findings

Colon capsule endoscopy allows for the visualization of the entire colon. However, the technology is limited by its lack of biopsy or therapeutic capabilities. In patients with signs or

symptoms of colorectal cancer or who are at increased risk of colorectal cancer, colon capsule endoscopy, using PCC2, had a pooled sensitivity and specificity of 87% (95% confidence interval [CI] 77%–93%) and 76% (95% CI 60%–87%), respectively, for the detection of a colorectal polyp at least 6 mm in size (GRADE: very low). PCC2 had a pooled sensitivity and specificity of 89% (95% CI 77%–95%) and 91% (95% CI 86%–95%), respectively, for the detection of a colorectal polyp at least 10 mm in size (GRADE: low). There was no statistically significant difference in the sensitivity or specificity of colon capsule endoscopy compared with CT colonography (GRADE: low). Few adverse events were reported with PCC2, with 3.9% (95% CI 2.4%–6.5%) experiencing adverse effects related to bowel preparation. Capsule retention, which may require surgery or colonoscopy to remove the capsule, was the most serious adverse event and occurred in 0.8% (95% CI 0.2%–2.4%) of patients.

The cost-effectiveness of colon capsule endoscopy may be favourable compared with CT colonography, although substantial uncertainty remains due to the lack of significant difference in the underlying diagnostic accuracy data for the two procedures. The additional cost of unnecessary colonoscopies for patients with false-positive results and additional cost and life-years lost for patients with false-negative results were used to estimate a cost-effectiveness of approximately $26,750 per life-year gained for colon capsule endoscopy versus CT colonography. This estimate is highly sensitive to changes in diagnostic sensitivity of either colon capsule endoscopy or CT colonography and should be interpreted with caution.

The budgetary impact of implementing colon capsule endoscopy would be an additional $2.72 million to replace all CT colonography procedures with colon capsule endoscopy, or $740,000 more to replace only those CT colonography procedures for patients with an incomplete colonoscopy within 1 year prior to referral.

OHTAC DELIBERATIONS

HQO has developed a decision-making framework to help guide deliberation and support the development of OHTAC recommendations regarding the uptake, diffusion, distribution, or removal of health interventions in Ontario. Appendix 1 provides a summary of the decision determinants for this recommendation.

After considering the decision determinants, OHTAC recommended against public funding of colon capsule endoscopy primarily for the following reasons.

A key concern for OHTAC was whether the colon capsule would be used for screening in average-risk individuals. Computed tomographic colonography has a natural barrier to diffusion, given the need for a CT scanner. An analogous barrier does not exist for colon capsule endoscopy. OHTAC did not believe that the available evidence justifies the use of the colon capsule for screening in average-risk individuals.

As the clinical evidence does not show that colon capsule endoscopy is more accurate than CT colonography, OHTAC also considered the relative costs of colon capsule endoscopy and CT colonography. Currently, colon capsule endoscopy appears to be more expensive than CT colonography.

OHTAC also noted that there are other alternatives for examining the colon.

APPENDICES

Appendix 1: Decision Determinants

Table A1: Decision Determinants for Colon Capsule Endoscopy in the Detection of Colorectal Polyps

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)?	Detect a colorectal polyp at least 6 mm in diameter: • Sensitivity: 87% (GRADE: Very low) • Specificity: 76% (GRADE: Very low) Detect a colorectal polyp at least 10 mm in diameter: • Sensitivity: 89% (GRADE: Low) • Specificity: 91% (GRADE: Low) No statistically significant difference in sensitivity or specificity between CCE and CTC (GRADE: low).
	Safety How safe is the health technology/intervention likely to be?	Colon capsule endoscopy is generally a safe procedure, with capsule retention the most serious adverse event. • Adverse events related to bowel preparation: 3.9% • Difficulties in swallowing the capsule: 1.1% • Capsule retention: 0.8% Technical failure: 1.4%
	Burden of illness What is the likely size of the burden of illness pertaining to this health technology/intervention?	About 40% of average-risk individuals have colorectal polyps of any size and 7% have advanced polyps. (3) In 2013, 8,700 people were estimated to have colorectal cancer in Ontario and 3,350 died from it. (4)
	Need How large is the need for this health technology/intervention?	Early detection and removal of colorectal polyps is highly effective in preventing subsequent development of CRC.
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?	Colon capsule endoscopy is minimally invasive and has low rates of reported adverse events. No radiation exposure has been reported for colon capsule endoscopy. Providing CCE as an additional option to patients and explaining the benefits and potential risks may enhance patients' engagement and adherence with colonic examination.
	Ethical values How likely is the adoption of the health technology/intervention to be congruent with expected ethical values?	Uncertain.
Value for money How efficient is the health technology likely to be?	**Economic evaluation** How efficient is the health technology/intervention likely to be?	Cost-effectiveness point estimate of $26,750 (uncertainty due to non-significant difference in diagnostic accuracy from head-to-head clinical study). Additional expenditure of $2.72 million for replacing all CTC procedures with CCE and $740,000 for replacing CTC procedures in patients with prior incomplete colonoscopy.

Decision Criteria	Subcriteria	Decision Determinants Considerations
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?	Likely feasible as it is currently used in clinical trials in Canada. Small-bowel capsule endoscopy is already diffused in Ontario.

Abbreviations: CCE, colon capsule endoscopy; CRC, colorectal cancer; CTC: computed tomographic colonography
[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

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(4) Betes IM, Munoz-Navas MA, Duque JM, Angos R, Macias E, Subtil JC, et al. Diagnostic value of distal colonic polyps for prediction of advanced proximal neoplasia in an average-risk population undergoing screening colonoscopy. Gastrointest Endosc. 2004;59(6):634-41.

DISCLAIMER

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.

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About OHTAC

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