Indocyanine Green Fluorescence Imaging for Colorectal Surgery

Recommendation

MONTH 2025

Ontario Health

Draft Recommendation

Ontario Health, based on guidance from the Ontario Health Technology Advisory Committee, recommends publicly funding indocyanine green fluorescence imaging for perfusion assessment during colorectal surgery.

Rationale for the Recommendation

The Ontario Health Technology Advisory Committee made the above recommendation after considering the clinical, economic, and patient preferences and values evidence reported in the health technology assessment.[1]

Ontario Health Technology Advisory Committee members noted the clinical evidence showed that compared with visual assessment alone, adding indocyanine green fluorescence imaging (ICGFI) to assess perfusion during colorectal resection surgeries involving the creation of an anastomosis (colorectal surgery) reduces anastomotic leaks and reoperations. The economic evidence showed that ICGFI was more effective and less costly compared with visual assessment alone. ICGFI could help prevent major anastomotic leaks, which have negative short- and long-term impacts to patients' functional status and quality of life, as well as increased hospital costs due to the need for reoperation. Publicly funding ICGFI to assess anastomotic perfusion in colorectal surgery would lead to cost savings of $19.03 million over 5 years; these savings represent a reduction in health care resource use, specifically hospital resources.

The committee took into account that anastomotic leak is a potentially catastrophic complication for patients and their families and that taking measures to reduce this risk is valued highly by both patients and surgeons. Committee members emphasized the importance of ICGFI being available at all centres that perform colorectal resection surgery with anastomosis. Committee members remarked that ICGFI for perfusion assessment is supported by clinical practice guidelines.

Decision Determinants for Indocyanine Green Fluorescence Imaging for Colorectal Surgery

Overall Clinical Benefit

Effectiveness

How effective is the health technology/intervention likely to be (taking into account any variability)?

Compared with visual assessment alone, adding ICGFI for the assessment of anastomotic perfusion during colorectal surgery reduces anastomotic leaks (GRADE: Low) and reoperations (GRADE: Low). It also slightly reduces sepsis, but the evidence is very uncertain (GRADE: Very low to Low). ICGFI appears to have little to no effect on hospital readmissions (GRADE: Low) or length of stay (GRADE: Low to Moderate), and its effect on mortality is very uncertain (GRADE: Very low).

Safety

How safe is the health technology/intervention likely to be?

Intraoperative ICGFI perfusion assessment involves no ionizing radiation, and the ICG dye has a very short half-life. Contraindications for the use of ICG dye include iodine allergy and liver dysfunction given that the dye is hepatically cleared.

Burden of Illness

What is the likely size of the burden of illness pertaining to this health technology/intervention?

In Ontario, colorectal cancer is the fourth most common cancer, and the prevalence is projected to increase from 77,097 in 2019 to 115,460 in 2034.[2] Diverticulosis is estimated to affect 30% to 50% of older adults in industrialized countries, of which an estimated 5% progress to diverticulitis. The prevalence of inflammatory bowel disease (Crohn's disease and ulcerative colitis) in Canada is estimated to be among the highest worldwide and is projected to increase from 0.82% of the general population (322,600 people) in 2023 to 1.08% (470,000 people) in 2035.[3] Other less common benign conditions that may require colorectal surgery include acute bowel obstruction and genetic conditions that increase the risk of colorectal cancers, such as familial adenomatous polyposis (estimated prevalence: 1 in in 100,000)[4] and Lynch syndrome (estimated prevalence: 1 in 279).[5] The budget impact analysis estimated that around 7,650 colorectal resections with anastomosis are done per year in Ontario for benign and malignant conditions.

Need

How large is the need for this health technology/intervention?

One of the most severe complications after colorectal surgery is anastomotic leak. This occurs when the contents of the bowel leak from the newly created anastomosis into the abdominal space, causing peritonitis, an infection of the abdominal lining that can spread quickly, resulting in sepsis, which is

associated with a high risk of morbidity and mortality. The estimated incidence of anastomotic leak ranges from 1.6% to 14.3% for ileocolic, 0.5% to 18% for colorectal, and 5% to 19% for coloanal anastomoses, with an overall associated mortality of 12%.[6] Risk factors for anastomotic leak include poor blood flow at the surgical site, smoking and alcohol consumption, obesity, preoperative use of steroids, male sex, and the presence of comorbidities.

Patient Preferences and Privacy

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?

A previously published rapid review evaluating the experiences of patients who had undergone colorectal cancer surgery found no qualitative literature on the patient experience of ICGFI; however, qualitative studies identified anastomotic leak and quality of life as core outcomes.[7]

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?

A previously published rapid review evaluating the experiences of patients who had undergone colorectal cancer surgery found no qualitative literature on the patient experience of ICGFI. However, in the included studies, patients often reported not receiving enough information about surgical outcomes, which can make it difficult for them to make fully informed decisions about their care.[3]

Equity and 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?

Colorectal surgery is performed widely across Ontario, but there are currently only a limited number of hospitals in Ontario that use ICGFI to assess perfusion in colorectal surgery. The technology is used at a number of centres in Ontario for other surgical and minimally invasive procedures.

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?

By reducing the risk of anastomotic leaks and reoperations, ICGFI contributes to improved patient outcomes.

Cost-Effectiveness

Economic Evaluation

How efficient is the health technology/intervention likely to be?

Compared with visual assessment alone, the addition of ICGFI generated 0.07 additional QALYs per patient, prevented 22 major anastomotic leaks per 1,000 patients, and was on average less costly by $1,424 per patient. With ICGFI, the number needed to treat to prevent an additional major anastomotic leak was 45. Our probabilistic analysis found that ICGFI was highly likely to be the dominant strategy (i.e., more effective and less costly) compared with visual assessment alone.

Feasibility of Adoption Into Health System

Economic Feasibility

How economically feasible is the health technology/intervention?

Publicly funding the use of ICGFI to assess perfusion in colorectal surgery in Ontario would lead to an annual budget impact ranging from a cost savings of $0.81 million in year 1 to a cost savings of $8.13 million in year 5, for a total budget impact of $19.03 million in cost savings over the next 5 years. These savings represent a reduction in health care resource use (specifically hospital resources) rather than net savings to the Ministry of Health's overall budget. As such, these savings would accrue to hospitals rather than to the Ministry of Health, as they are an estimate of the savings associated with a release of hospital resources. If only ICGFI costs were considered, publicly funding ICGFI to assess perfusion in colorectal surgery would increase the total 5-year budget impact by $5.85 million.

Organizational Feasibility

How organizationally feasible is it to implement the health technology/intervention?

The use of ICGFI to assess perfusion during colorectal surgery has been expanding across Ontario in hospitals that have access to upgraded imaging systems with near-infrared visualization capabilities and using ICGFI for various surgical indications.

References

1) TBD
2) Ontario Health (Cancer Care Ontario). Ontario cancer statistics 2022 [Internet]. Toronto (ON): Ontario Health; 2022 [cited 2023 Dec]. Available from: https://www.cancercareontario.ca/en/data-research/view-data/statistical-reports/ontario-cancer-statistics-2022
3) Coward S, Benchimol EI, Kuenzig ME, Windsor JW, Bernstein CN, Bitton A, et al. The 2023 impact of inflammatory bowel disease in Canada: epidemiology of IBD. J Can Assoc Gastroenterol. 2023;6(Suppl 2):S9-15.
4) Kanth P, Grimmett J, Champine M, Burt R, Samadder NJ. Hereditary colorectal polyposis and cancer syndromes: a primer on diagnosis and management. Am J Gastroenterol. 2017;112(10):1509-25.
5) Colorectal Cancer Canada. Lynch syndrome, explained [Internet]. Westmount (QC): Colorectal Cancer Canada; n.d. [cited 2023 Dec]. Available from: https://www.colorectalcancercanada.com/blog/lynch-syndrome-explained/
6) Ellis CT, Maykel JA. Defining anastomotic leak and the clinical relevance of leaks. Clin Colon Rectal Surg. 2021;34(6):359-65.
7) Canadian Agency for Drugs and Technologies in Health. Patient perspectives and experiences regarding colorectal surgery and indocyanine green angiography: a review of patient perspectives. Ottawa (ON): The Agency; 2016 Dec 20. Report No.: RC0834.

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