



CCOHTA

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PRE-ASSESSMENT *Virtual Colonoscopy*

Before CCOHTA decides to undertake a health technology assessment, a pre-assessment of the literature is performed. Pre-assessments are based on a limited literature search; they are not extensive, systematic reviews of the literature. They are provided here as a quick guide to important, current assessment information on this topic. Readers are cautioned that the pre-assessments have not been externally peer reviewed.

Introduction

In Canada, colorectal cancer is the fourth most commonly diagnosed cancer and the second most common cause of cancer-related mortality. An estimated 18,000 new cases and 8,300 deaths from colorectal cancer occurred in Canada in 2003.¹ The prognosis and survival of those with colorectal cancer are related to the stage of the cancer at the time of diagnosis. This disease is treatable and often curable if the cancer is localized. Early detection of colorectal cancer through screening (secondary prevention) can reduce the mortality and morbidity associated with this disease.²

Several approaches to screening are available, ranging from the least expensive and least invasive (fecal occult blood testing) to the more costly and invasive procedures (flexible sigmoidoscopy, barium enema and colonoscopy). Each of these tests has inherent strengths and weaknesses related to cost, risk, sensitivity, specificity and availability.^{2,3} Colonoscopy, which is considered to be the gold standard, is an invasive test that must be performed by an experienced specialist. It carries risks of bleeding, the required sedatives cause side effects and there are other associated complications. Some patients complain that the bowel-cleansing preparation is worse than the procedure itself.³

Virtual colonoscopy (VC) was first described in 1994 as a non-invasive test for the examination of the colonic lumen for cancers and polyps.^{2,3} The term VC is used interchangeably with computed tomographic colonography (CTC) and magnetic resonance colonography. The latter technique uses magnetic resonance imaging, but thus far, CTC has been studied and used more extensively.⁴

CTC requires the same bowel-cleansing preparation as colonoscopy. The insertion of a rectal tube and the insufflation of air or carbon dioxide are required to distend the colon.² Sedation is unnecessary. The time required for the procedure is approximately five to 15 minutes, plus an additional 15 to 40 minutes for interpretation.² Typically, two-dimensional computed tomographic (CT) images can be processed with the use of commercially available software programs to render a three-dimensional display of the colonic lumen. Virtual images of the entire colon can be examined segment by segment, much as they are during colonoscopy.³

The Canadian Coordinating Office for Health Technology Assessment (CCOHTA) published a pre-assessment of CTC in October 2002 concluding that: "Several other HTA agencies have recently assessed virtual colonoscopy and others have work underway. At this point, CCOHTA will not duplicate these efforts and will wait until further evidence becomes available."⁴ This topic was subsequently forwarded by a

consumer through CCOHTA's web site, for consideration as an assessment, to CCOHTA's Devices and Systems Advisory Committee (DSAC) in September 2003. The DSAC selected this topic for assessment as an update to the October 2002 pre-assessment.

Research Question

How does CTC compare with conventional technologies that image the colon?

Assessment Process

PubMed was searched using controlled vocabulary and key words for "virtual colonoscopy" and "controlled trials" or "comparative studies." Retrieval was limited to the human population (this limit was not applied to publisher-supplied or in-process citations). The Cochrane Library 2004 issue 1 was also searched. Grey literature was obtained through searching the web sites of health technology assessment and related agencies; and their associated databases. Google™ was used to search for additional web-based information. Correspondence was initiated with the Medical Advisory Secretariat of the Ministry of Health and Long-Term Care in Ontario to determine the status of its ongoing evaluation. A draft of the Ontario report dated October 2003 was given to CCOHTA.

Summary of Findings

Reviews or Meta-analysis

Two reviews published since the October 2002 pre-assessment were identified: the draft Ontario report (October 2003) and a meta-analysis on CT of colorectal polyps published in the *American Journal of Radiology* in December 2003⁵ (Table 1).

Table 1: Summary of findings

Title (Author, Year)	Objective(s)	Methods	Results	Conclusions
Computed tomographic colonography (virtual colonoscopy) (Medical Advisory Secretariat, Ontario, draft, October 2003)	To compare effectiveness and safety of CTC as a screening method for detection of colon cancer and pre-cancerous polyps with	Literature search on MEDLINE and EMBASE for English language studies from 2000 to May 2003	18 studies of 2,017 patients, of whom 126 (6%) were asymptomatic. Performance of CTC depends on size of lesions. Sensitivity ranges for multi-slice versus single-slice scanning: 86% to 100% versus	With limited sensitivity and specificity of CTC relative to colonoscopy; and lack of therapeutic intervention, CTC may result in inconvenience, cost and complications.



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	reference standard of conventional colonoscopy		67% to 100% for cancer detection; 80% to 100% versus 57% to 100% for polyps >10 mm; 33% to 86% versus 0% to 80% for polyps 6 mm to 9 mm; 3% to 70% versus 10% to 68% for polyps ≤5 mm. Diagnostic performance of CTC depends on methods of bowel preparation, adequate bowel distension and scanning techniques.	Based on current evidence, CTC cannot be proposed for routine population-based screening for polyps or cancer. Patients with colonic symptoms or history of polyps will benefit more if they undergo colonoscopy including excision of premalignant polyps. CTC can be the examination of choice for preoperative evaluation of patients with colorectal carcinomas, given its possibility of assessing entire colon, extracolonic structures and tumour staging. CTC can be considered for diagnostic purposes when colonoscopy is clinically contraindicated or when patients had incomplete colonoscopy because of stenosis or obstruction of colon. MRI-based VC that excludes risk of ionizing radiation may be of more benefit than CTC in the future.
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<p>CT Colonography of Colorectal Cancer: A Meta-analysis (Sosna, December 2003)⁵</p>	<p>To assess reported accuracy of CTC compared to conventional colonoscopy for detecting colorectal polyps</p>	<p>Literature search on PubMed and MEDLINE for English language studies from 1994 to July 2002</p>	<p>14 studies of 1,324 patients (1,411 polyps).² Pooled per-patient sensitivity (95% CI): 88% (0.84 to 0.93) for polyps >10 mm; 84% (0.80 to 0.89) for 6 mm to 9 mm; 65% (0.57 to 0.73) for polyps ≤5 mm. Sensitivity for detection of polyps increased as polyp size increased (p<0.0001). Pooled specificity for polyps >10 mm was 0.95 (0.94 to 0.97).</p>	<p>Specificity and sensitivity of CTC are high for polyps >10 mm.</p>
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¹ Two additional studies published since original literature search are being incorporated in Ontario report.

² All nine studies published in 2000 to 2002 were included in Ontario report.

Primary studies

In comparison to the studies included in the two reviews above, the literature search identified an additional eight diagnostic accuracy studies,⁶⁻¹³ two studies on cost or cost-effectiveness^{14,15} and five studies on patients' acceptance of CTC.¹⁶⁻²⁰

a) Diagnostic studies

Two of the largest diagnostic studies^{7,11} identified for this pre-assessment are being incorporated in the Ontario report. Pickhardt *et al.* report the largest prospective evaluation to date of CTC as a colorectal screening test. The study involved 1,233 asymptomatic adults who underwent CTC and same-day conventional colonoscopy.¹¹ More than 97% of the subjects were at average risk for colorectal cancer. The sensitivity of CTC was 92% for polyps of ≥10 mm, 93% for polyps of ≥8 mm and 86% for polyps of ≥6 mm, as compared with 88%, 89.5% and 90% respectively for colonoscopy performed by colonoscopists who were blinded to the CTC test results.¹¹ The negative predictive value of normal findings on CTC was >99% for polyps of ≥8 mm. If a threshold polyp size of 10 mm had been used, for example, 7.5% of patients who underwent CTC would have required referral for polypectomy. The average time spent by patients undergoing CTC was 14 minutes (approximately half that required for colonoscopy) and the average time required for the interpretation of CTC studies was <20 minutes.¹¹ Several factors may explain these impressive results by Pickhardt *et al.* They used a different technique from that used in previous studies. It enabled the imaging software to digitally remove all opaque fluid and stool from the image

by a process known as electronic cleansing. They used multi-detector CT scanners, which permitted faster higher-resolution imaging than single-detector scanners that had been used previously. The calculation of CTC sensitivity was based only on adenomas with the exclusion of non-adenomatous polyps as false positive results.

The second largest study being incorporated in the Ontario report is by Johnson *et al.* This study consists of 703 asymptomatic patients reporting on polyp detection rates at CTC being below those at colonoscopy with high inter-observer variability of CTC test results among three experienced readers.⁷ The remaining six studies reporting on conflicting findings include a small sample size (range of 23 to 205 subjects) and consist of symptomatic and asymptomatic patients.^{6,8-10,12,13}

b) Cost and cost-effectiveness studies

Two studies examined the cost or cost-effectiveness of CTC in comparison to colonoscopy screening. McGrath, using a decision analytic model based on Ontario cost data, reported on the cost of finding an advanced adenoma in patients undergoing flexible sigmoidoscopy, colonoscopy and CTC.¹⁴ Colonoscopy was less costly and detected more cases of advanced adenomas in comparison with the other two screening strategies.¹⁴ Sonnenberg, using computer models based on a Markov process, found screening by colonoscopy to remain more cost-effective even if the sensitivity and specificity of CTC both rose to 100%. To become cost-effective, CT or magnetic resonance colonography would have to be offered at a low price or result in compliance rates that are better than those associated with colonoscopy.¹⁵

c) Patient acceptance for CTC

Five studies reported on patients' acceptance and preferences for CTC. Four studies reported an overall preference by patients for CTC in comparison with colonoscopy for follow-up examinations.¹⁷⁻²⁰ Patients in the study by Akerkar, despite tolerating both CTC and colonoscopy, reported more pain, discomfort and less respect undergoing CTC.¹⁶

Conclusion

As a review is being undertaken by the Ministry of Health and Long-Term Care in Ontario, CCOHTA will not undertake an assessment on CTC at this time.

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