Virtual colonoscopy: Non-invasive CT scanning technique for screening patients with possible bowel disease.

December 2003
PRIORITISING SUMMARY

REGISTER ID: 0000042

NAME OF TECHNOLOGY: VIRTUAL COLONOSCOPY/ COLONOGRAPHY

PURPOSE AND TARGET GROUP: NON-INVASIVE CT SCANNING TECHNIQUE FOR SCREENING PATIENTS WITH POSSIBLE BOWEL DISEASE

STAGE OF DEVELOPMENT (IN AUSTRALIA):

- Experimental
- Investigational
- Nearly established
- Established
- Established but changed indication or modification of technique
- Should be taken out of use

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- Yes
- No
- Not applicable

INTERNATIONAL UTILISATION:

<table>
<thead>
<tr>
<th>COUNTRY</th>
<th>LEVEL OF USE</th>
<th>Trials Underway or Completed</th>
<th>Limited Use</th>
<th>Widely Diffused</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening study, colorectal neoplasia, Australia</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>RCT, polyp and colon cancer, UK</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>RCT, colon and rectal lesions, UK</td>
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<tr>
<td>RCT, colonic investigation, UK</td>
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<td>Comparative study, colorectal cancer, UK</td>
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<tr>
<td>Comparative screening study, colorectal cancer, USA</td>
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<td>Comparative study, Crohn’s Disease, Italy</td>
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<td>Comparative study, colorectal cancer, United Kingdom</td>
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<tr>
<td>Cost-effectiveness model, USA</td>
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IMPACT SUMMARY:
Virtual colonoscopy or colonography (VC) utilises computer tomography (CT) scanning to provide 3-dimensional diagnostic images for the investigation of bowel disease, including
colorectal cancer, without the need of utilising invasive colonoscopy techniques. Patients do not require sedation. However patients must undergo the same bowel cleansing preparation as conventional colonoscopy in addition to colonic insufflation with air or carbon dioxide. Two-dimensional images are examined and processed with software to produce a 3-dimensional image of the colon. The procedure takes approximately 15 minutes with an additional 15-30 minutes for interpretation of the results. The technology would be available through private and public hospitals equipped with CT scanners with advanced imaging software.

Fibreoptic colonoscopy is the current gold standard for screening for colorectal cancer in asymptomatic patients over 50 years of age. Several problems are associated with colonoscopy, including the invasive nature of the procedure and that it only screens the left side of the colon. Risks associated with colonoscopy include perforation, bleeding, side effects from sedation and discomfort. The total time estimated for conventional colonoscopy is 2 hours.

The AIHW reported the number of separations for the AR-DRG numbers G43Z, G44A, G44B and G44C (colonoscopy procedures) as 847, 5,780, 12,223 and 231,331 respectively, a total of 250,181 separations in the year 2001-02 (AIHW 2003).

The MSAC conducted a Horizon Scanning Brief on VC in 2001 and identified several randomised controlled trials that were underway. None of these studies have been published as yet. The blinded prospective, comparative study by Spinzi et al (2001) reported that VC had a sensitivity of 58%, 93% specificity and an 87% positive predictive value for detecting polyps. The prospective comparative study by Pickhardt et al (2003) in asymptomatic adults reported the sensitivity of virtual colonoscopy for adenomatous polyps at least 10mm, 8mm and 6mm in diameter as 94, 94 and 89%, respectively. The corresponding sensitivities for conventional colonoscopy were 88, 92 and 92%. The specificity of virtual colonoscopy for adenomatous polyps was respectively reported as 96, 92, 80% for polyps at least 10mm, 8mm and 6mm in diameter. The Australian screening study of asymptomatic patients, conducted by Edwards et al (2003), found that VC positively predicted colonic polyps in 73% of patients initially identified with the condition. 5.7% of VC findings were false positive.

The study by Pickhardt et al (2003) also reported that although the virtual colonoscopy procedure was more acceptable than conventional colonoscopy to almost 70% of patients, only 50% of patients chose the virtual method as their preference for future screening. The remaining patients opted for conventional colonoscopy because it allows for the removal of suspicious lesions in a single procedure.

The cost-effectiveness study conducted by Sonnenberg et al (1999) found that screening by conventional colonoscopy remained more cost-effective that virtual colonoscopy, even if the sensitivity and specificity of VC rose to 100%. However, if virtual colonoscopy resulted in increased compliance rates than conventional colonoscopy then the procedure may become cost-effective. Costing of the software package (Advantage Windows Workstation, GE Medical Systems) and hardware is approximately A$95,000. Conventional CT scanners currently installed in Australian hospitals are able to download images in the Dicom format, which is suitable for use with this software.

**CONCLUSION:**

Based on patient preferences for a less invasive mode of colonic investigation, the apparently comparable specificity and sensitivity of the procedure and the availability of CT technology in Australia, it is likely that virtual colonoscopy will diffuse rapidly into the Australian health system. It is likely that Level II and III-2 evidence would be available for this technology if further searches are conducted.
HEALTHPACT ACTION:
Therefore it is recommended that this technology be referred to MSAC for a full HTA.

SOURCES OF FURTHER INFORMATION:

SEARCH CRITERIA TO BE USED:
Adenoma/radiography
Colon Polyp/radiography
*Colonography, Computed Tomographic Colonoscopy
Colorectal Neoplasms/*radiography
Imaging, Three-Dimensional