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Horizon scanning prioritising summary

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**ScopeGuide™ : Magnetic endoscopic
imaging of the colon for patients requiring
colonoscopy.**

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Assessment*

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PRIORITISING SUMMARY

REGISTER ID: 000096

NAME OF TECHNOLOGY: SCOPEGUIDE™

PURPOSE AND TARGET GROUP: MAGNETIC ENDOSCOPIC IMAGING OF THE COLON FOR PATIENTS REQUIRING COLONOSCOPY

STAGE OF DEVELOPMENT (IN AUSTRALIA AND/OR NEW ZEALAND):

- | | |
|---|---|
| <input type="checkbox"/> Yet to emerge | <input type="checkbox"/> Established |
| <input type="checkbox"/> Experimental | <input type="checkbox"/> Established <i>but</i> changed indication or modification of technique |
| <input checked="" type="checkbox"/> Investigational | <input type="checkbox"/> Should be taken out of use |
| <input type="checkbox"/> Nearly established | |

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- | | |
|--|---|
| <input type="checkbox"/> Yes | ARTG number |
| <input checked="" type="checkbox"/> No | <input type="checkbox"/> Not applicable |

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
United Kingdom	✓		
Germany	✓		

IMPACT SUMMARY:

Olympus Corporation, Tokyo, Japan has developed a new system the ScopeGuide™ for the diagnosis of colorectal cancer. The ScopeGuide™ has been available in Australia for less than two years. The University of Western Australia, in conjunction with St John of God Hospital, has purchased the ScopeGuide™ as an educational, training and teaching tool. In addition, the Royal Adelaide Hospital in South Australia trialled the ScopeGuide™ but has since returned the equipment to the manufacturer. The manufacturer released a demonstration model of the ScopeGuide™ for individual hospitals to borrow (personal communication, Olympus Australia Pty Ltd Customer Service).

BACKGROUND

The ScopeGuide™ uses magnetic endoscopic imaging to display in real time the three-dimensional configuration and position of the colonoscope during a colonoscopy procedure (Shah et al 2000). The ScopeGuide™ probe incorporates built-in 12 source coils that generate magnetic fields. These magnetic fields are detected by ScopeGuide™'s built-in antenna and are processed to generate a composite display of the scope's shape on the monitor: this allows the operator to view the scope's location at all times.

The ScopeGuide™ is the first insertion tube system that enables physicians to view the shape of the scope from the outside during an endoscopic examination without the risk of x-ray exposure (Olympus America 2004). The ScopeGuide™ provides a constant 3D display of the scope's position.

CLINICAL NEED AND BURDEN OF DISEASE

In both males and females, the combination of cancers of the colon and rectum (12,405 new cases), often referred to as bowel or colorectal cancer, was the most common registrable cancer in Australia in 2000, and the second most common cause of cancer death (AIHW 2003, p10). The number of new cases of colon cancer (excluding cancers originating in the rectum) in 2000 was 7,971, a rate of 41.6 per 100,000 (AIHW 2004a). The number of deaths from colorectal cancer in 2000 was 2,149 (20.2 per 100,000) and 2,569 (31.0 per 100,000) in females and males, respectively – representing 13% of all cancer deaths (AIHW 2003, p10).

DIFFUSION

Studies with the ScopeGuide™ suggest that it is an “appealing” tool for training endoscopists as it allows the user to view the location of the colonoscope instead of having to rely on feel alone and for use in technically difficult cases such as detecting and straightening loops during colonoscopy. There may be potential for the device to be used in major centres as an adjunct to conventional colonoscopy.

COMPARATORS

The difficulty in achieving complete colonoscopy (to the caecum) is in straightening the colonoscope once a loop is formed (Shah et al 2000). Although fluoroscopic systems can help with finding and straightening the loops, these systems are not generally used as they expose patients to high doses of radiation, are expensive and do not provide high quality views.

Fibreoptic colonoscopy is the current gold standard for diagnosing 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 examines the left side of the colon. Risks associated with colonoscopy include perforation, bleeding, side effects from sedation and discomfort. Although the technique is well established, success rates in achieving complete colonoscopy (to the caecum) vary considerably, depending on the expertise of the endoscopist (Shah et al 2000). The total time required, from the patient’s perspective, 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 2004b).

COST IMPACT

The Olympus Corporation provided the following list of prices for the ScopeGuide™ system components (personal communication):

ScopeGuide Unit - US\$48,990 (in Australia \$78,500)

Colonoscope, CF-Q160DL -US\$27,900 (in Australia \$40,000)

Probe, MAJ-1300 - US\$3495 (in Australia \$6,600)

EFFECTIVENESS AND SAFETY ISSUES

Several studies have demonstrated that the ScopeGuide™ improved endoscopy times.

113 consecutive patients were examined, in one group, by two endoscopist trainees randomised to undertake the examination either with (58) or without (55) the ScopeGuide™. A second group of 183 consecutive patients were viewed by two expert endoscopists randomised to undertake patient examinations either with (92) or without the ScopeGuide™ (91) (Shah et al. 2000).

The study (level II evidence) reports that the ScopeGuide™ improves colonoscopy for both trainees and experienced endoscopists. In both groups, endoscopy times with the ScopeGuide™ were shorter (*Group 1* - median 11.8 min vs 15.3 min; *Group 2* - 8.0 min vs 9.3 min) and the number of attempts at straightening the colonoscope were fewer (*Group 1* - median 5 vs 12; *Group 2* - 7 vs 10). In group 1, colonoscopy completion rates were also higher (100% vs 89%) and duration of looping was reduced (median 3 min vs 5.4 min) when the imager view could be seen. Abdominal hand pressure was also more effective when the endoscopist and endoscopy assistant could see the imager view.

There have been several studies by the same author indicating that the ScopeGuide™ accurately determines the anatomical position of the endoscope during endoscopy (Shah et al 2002b and Shah et al 2002c).

A study of 133 consecutive patients (level IV evidence) reported on detection of loops, the location of the endoscope tip at defined positions, the insertion time and pre-medication rate by the prototype ScopeGuide™ (Wehrmann 2002). This study validated the accuracy of the ScopeGuide™ in detection and observation of loops during colonoscopic examination.

In a randomised, controlled study (level II evidence) of 122 consecutive patients undergoing routine colonoscopy by a single experienced endoscopist, patients were randomised to have the procedure performed either with the endoscopist viewing the ScopeGuide™ imager display, or without the imager view (Shah et al 2002a). The study aimed to assess patient tolerance and sedation requirements during colonoscopy. Procedures began with administration of hyoscine-N-butylbromide alone, and sedative medications (midazolam and meperidine) were self-administered by the patient with a patient-controlled analgesia pump. Cardio-respiratory parameters were recorded and patient pain was assessed with a 100-mm visual analogue scale. The study reported the number of attempts at straightening the colonoscope was fewer (median 8 vs. 15 attempts, $p = 0.0076$) and the duration of looping less (median 4.5 min vs. 6.4 min), when the endoscopist used the ScopeGuide™. The total number of patient demands (by patient-controlled analgesia) for medication (median 1 vs. 2.5) and total doses of midazolam (median 0.44 mg vs. 0.88 mg) and meperidine (median 16.75 mg vs. 32.5 mg) administered did not significantly differ between patients examined with or without the ScopeGuide™. Patient pain scores between the two groups were similar thus it was not possible to demonstrate that the ScopeGuide™ reduced pain.

It is important to note, however, that although these studies affirm the ScopeGuide™ is reliable in detecting anatomical position and may improve endoscopists' technique, the impact on rates of colon cancer detection has yet to be measured.

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified/raised in the sources examined.

CONCLUSION:

Although there is a lack of evidence for the ScopeGuide™ demonstrating improved outcomes for colonoscopy patients, ScopeGuide™ may be used as an adjunctive technology when there is a colon loop present.

HEALTHPACT ACTION:

Therefore it is recommended that this technology be monitored in six months time.

SOURCES OF FURTHER INFORMATION:

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Wehrmann, K. & Fruhmorgen, P. (2002). 'Evaluation of a new three-dimensional magnetic imaging system for use during colonoscopy', *Endoscopy*, 34 (11), 905-908.

SEARCH CRITERIA TO BE USED:

Colonic Neoplasms/ diagnosis

Colonoscopy/ methods

Fluoroscopy