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Horizon Scanning Technology

Prioritising Summary

Narrow band imaging for the improved detection of pre-cancerous lesions during colonoscopy

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PRIORITISING SUMMARY

REGISTER ID: **000414**

NAME OF TECHNOLOGY: **NARROW BAND IMAGING**

PURPOSE AND TARGET GROUP: **IMAGING MODALITY FOR THE IMPROVED DETECTION OF PRECANCEROUS LESIONS DURING COLONOSCOPY**

STAGE OF DEVELOPMENT (IN AUSTRALIA):

- ☐ Yet to emerge
- ☐ 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 — ARTG number
- ☐ No
- ☒ Not applicable

INTERNATIONAL UTILISATION:

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

IMPACT SUMMARY:

Companies that produce standard imaging equipment such as Olympus provide high resolution endoscopes capable of performing narrow band imaging. Although narrow band imaging is a relatively new imaging modality, it has been in use in Australia, mainly for patients with Barrett's oesophagus. This prioritising summary examines the use of narrow band imaging for the new indication of the detection of precancerous gastric and colorectal lesions. The technology would be made available through specialist hospitals for patients undergoing a conventional bronchoscopy or endoscopy.

BACKGROUND

Narrow band imaging (NBI) is an imaging technique that exploits the specific transmissibility and absorption characteristics of specific wavelengths of light. Longer

wavelengths of light penetrate further into tissue and different wavelengths are absorbed differently by structures within the tissue. Specifically, blue light (415nm) allows the visualisation of the superficial capillary network as it does not penetrate the tissue to a great extent. Green light (540nm) penetrates further into the tissue allowing the visualisation of deeper structures such as sub-epithelial vessels. When images form the two light sources are combined a high contrast image of the tissue surface is generated.

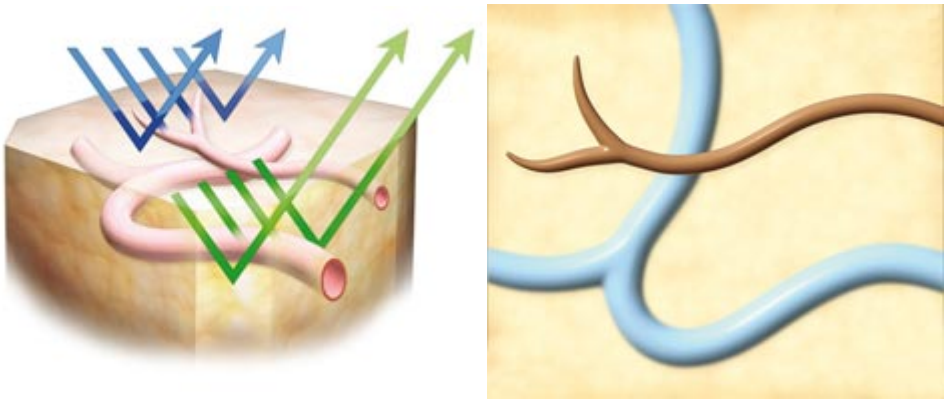

Figure 1 NBI image acquisition.
Blue light only penetrates the near surface, whereas green light penetrates to deeper structures (left). The combined image shows the capillaries in brown and the underlying veins in blue (right).

Lesions visualised with NBI can be categorised using two different techniques. One method involves the analysis of microvasculature, with neoplastic lesions displaying increased or abnormal microvessel density. A second method developed by Kudo et al (1994) involves analysis of the "pit pattern" of a lesion which results from the surface structures and superficial mucosal capillaries. The Kudo pit pattern allows the lesion to be graded on a scale from nonadenomatous to adenomatous[1]. These methods are applicable to a variety of tissue types, including the colon.

CLINICAL NEED AND BURDEN OF DISEASE

In 2004 there were 12,977 new cases of colorectal cancer diagnosed within Australia. According to the AIHW there are no national prevalence data available for colorectal cancer (AIHW 2007). In 2006-07 there were a total of 230,911 separations for colonoscopy as recorded under 4 categories (G43Z Complex Colonoscopy, G44A Other Colonoscopy W Catastrophic or Severe CC, G44B Other Colonoscopy W/O Catastrophic or Severe CC, G44C Other Colonoscopy Sameday) (AIHW 2008). It is not clear how many of these separations are related to colorectal cancer diagnosis.

[1] Adenomatous lesions are not necessarily cancerous but have the risk of progression to malignancy.

DIFFUSION

While NBI is currently in use in Australia for Barrett's oesophagus, no evidence was found indicating NBI is used during colonoscopy for colorectal cancer diagnosis. However, a recent demonstration (August 2008) of the technique was conducted at the Royal Brisbane and Women's Hospital, by Dr Omori, a gastrointestinal surgeon from Kawasaki Hospital, Japan.

COMPARATORS

Colonoscopy is the gold standard for diagnosis of potentially cancerous polyps. Being the gold standard, it is difficult to assess the accuracy of colonoscopy. As newer techniques emerge it is evident that colonoscopy is lacking in some areas such as amount of surface area of the colon able to be visualised (East et al. 2007), the difficulty of detecting flat lesions with conventional colonoscopy (Dekker and Fockens 2005), and the estimated polyp miss rate of 10-20 per cent (Bensen et al. 1999; Robertson et al. 2005).

SAFETY AND EFFECTIVENESS ISSUES

Several studies have investigated the diagnostic ability of NBI for colorectal lesions compared to conventional white light colonoscopy and histology. Adler investigated NBI in a trial where patients presenting for routine colonoscopy diagnosis were randomly assigned to either conventional or NBI colonoscopy. The study involved 401 eligible patients (200 NBI, 201 conventional colonoscopy) and found that the detection rate of adenomas was higher in the NBI group (23%) than the conventional group (17%), although this did not reach significance (p= 0.129). There was an apparent training effect involving the conventional method, where the first 100 patients showed a 26.5 per cent adenoma detection rate for NBI and eight per cent for conventional colonoscopy, however the last 100 patients had an adenoma detection rate of 25.5 and 26.5 per cent for NBI and conventional colonoscopy, respectively. The authors speculated that the improved polyp detection using NBI may increase the ability of the clinicians to recognise polyps using conventional colonoscopy (Adler et al 2008) (Level III-2 diagnostic evidence).

A second study randomised 276 patients presenting for routine colonoscopy to NBI or conventional colonoscopy. After either NBI or conventional colonoscopy was carried out a subsequent examination with conventional colonoscopy was performed as the reference standard. The neoplasm miss rate was calculated against the reference standard and was similar for both techniques (NBI = 17/135 (12.6%) vs conventional colonoscopy = 17/141 (12.1%). The miss rate for *advanced adenomas* was less than one per cent (Kaltenbach et al 2008) (Level III-2 diagnostic evidence).

Inoue et al investigated NBI versus conventional colonoscopy in a prospectively recruited population of 243 patients who were randomly assigned to either NBI or conventional colonoscopy. The procedure times for either NBI or conventional

colonoscopy were not significantly different. The NBI procedure (127 polyps, 62%) detected significantly more polyps versus conventional colonoscopy (78 polyps, 38%) ($p=0.014$). When the polyps were analysed by histology, 169 of 205 were found to be neoplastic. The NBI group had 103 neoplasms (60.9%) and the conventional colonoscopy group had 66 neoplasms (39.1%). The NBI technique detected more small adenomas compared to conventional colonoscopy ($p<0.05$). There were no significant adverse effects for either procedure reported at a two week follow up (Inoue et al. 2008) (Level III-2 diagnostic evidence).

A comparison of conventional colonoscopy and NBI was performed in 302 prospectively recruited patients. The patients were analysed in a sequential manner with polyps found by conventional colonoscopy re-analysed by NBI. The polyp's histology grades were predicted with both techniques and this was compared to the actual histology determined at a later date. The diagnostic accuracy of conventional colonoscopy and NBI versus histology were not different (77% versus 80%, $p=0.35$). However, there was an apparent learning curve associated with the NBI technique as its accuracy improved from 74 per cent to 87 per cent over the course of the trial. The sequential design only allowed the testing of the diagnostic accuracy of polyps known by conventional colonoscopy and did not allow for the potential for different rates of polyp detection with NBI that may have occurred if it was used in isolation (Rogart et al 2008) (Level III-2 diagnostic evidence).

Sikka et al compared NBI versus conventional colonoscopy with regard to correct prediction of histology status as determined later. The population consisted of 63 patients and these were analysed with both techniques sequentially. NBI showed a sensitivity of 95 per cent (correctly identified 93/98 neoplastic polyps) and a specificity of 90 per cent (correctly identified 56/62 non-neoplastic polyps). Conventional colonoscopy had a sensitivity of 59 per cent (correctly identified 58/98 neoplastic polyps) and a specificity of 76 per cent (correctly identified 47/62 non-neoplastic polyps). The overall diagnostic accuracy of NBI was 93 per cent and for conventional colonoscopy was 66 per cent ($p<0.0001$) (Sikka et al. 2008) (Level III-2 diagnostic evidence).

Most studies find that NBI performs at least equal to or better than conventional colonoscopy for the detection and prediction of the status of discovered polyps. Issues such as study design and learning curves were significant factors in some study outcomes.

COST IMPACT

No studies reported on the relative costs of NBI versus conventional colonoscopy. Olympus, manufacturer of the CF-Q180 AL colonoscope used in several studies in this prioritising summary, was contacted regarding the cost of a NBI capable colonoscope system but at the time of publication no reply was forthcoming.

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified/raised in the sources examined.

OTHER ISSUES

No issues were identified/raised in the sources examined.

SUMMARY OF FINDINGS

Based on the medium quality evidence presented in this prioritising summary, NBI seems to be an improvement over conventional colonoscopy. Evidence has been rapidly accumulating in recent times and a clear picture of the effectiveness of NBI may soon emerge.

HEALTHPACT ACTION:

The majority of colonoscopes manufactured have the capability of performing either conventional colonoscopy or narrow band imaging. There may be a learning curve involved in the use of narrow band imaging which may see the slow introduction of this technique. If the polyp detection rate is higher using narrow band imaging compared to conventional colonoscopy, then further investment in this technique would be warranted. Therefore HealthPACT have recommended that this technology be monitored in 12-months time for further information.

NUMBER OF INCLUDED STUDIES

Total number of studies	
Level III-2 diagnostic evidence	5

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Rogart, J. N., Jain, D. et al (2008). 'Narrow-band imaging without high magnification to differentiate polyps during real-time colonoscopy: improvement with experience', *Gastrointest Endosc*.

Sikka, S., Ringold, D. A. et al (2008). 'Comparison of white light and narrow band high definition images in predicting colon polyp histology, using standard colonoscopes without optical magnification', *Endoscopy*.

SEARCH CRITERIA TO BE USED:

Colonic Polyps/*pathology
Colonoscopes
Colonoscopy/*methods
Diagnosis, Differential
Diagnostic Imaging/*instrumentation
Adenocarcinoma
Colorectal Neoplasms/*diagnosis/etiology
Colonic Neoplasms/diagnosis
Endoscopy, Gastrointestinal/*methods
Gastrointestinal Neoplasms/*diagnosis
Precancerous Conditions/diagnosis
Stomach Neoplasms/diagnosis