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Medical Policy Manual

Topic: In Vivo Analysis of Colorectal Polyps

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Section: Medicine

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

During a colonoscopy or sigmoidoscopy as a screening test for colorectal cancer, the physician must often decide which polyp should be removed for histologic diagnosis. While hyperplastic polyps are considered benign without malignant potential, adenomatous polyps are thought to represent one of the earliest stages in the progression to a malignancy. Identification of these premalignant lesions is considered one of the cornerstones of colorectal cancer prevention. The physician must thus balance the time and potential morbidity of removing all polyps, many of which will be benign, versus removal of those polyps most likely to be adenomatous. Techniques have been developed as adjuncts to colonoscopy that are intended to distinguish between normal and precancerous tissue.

The first system developed was based on the observation that benign and malignant tissues emit different patterns and wavelengths of fluorescence after exposure to a laser light. One such device was approved by the Food and Drug Administration (FDA) in 2000, the Optical Biopsy System (SpectraScience, Minneapolis MN). This system consists of an optical fiber, emitting a laser that is directed against three different regions of the same polyp. The subsequent florescent signal is collected, measured, and analyzed by a proprietary software system, which classifies a polyp as "suspicious" (i.e., adenomatous) or "not suspicious" (i.e., hyperplastic).

Narrow band imaging (NBI) is another new technique that allows visualization of the mucosal surface and capillary vessels and thus may assist in the differentiation of abnormal from normal mucosa during colonoscopy. Two NBI systems are available. The NBI color chip system is used in the United States; in this system a single filter with a 2-band pass characteristic is used to generate central wavelengths at 415 nm (blue) and 540 nm (green and red). The NBI red-green-blue sequential illumination system uses narrow spectra of red, green, and blue light and a video endoscopic system with a frame sequential lighting method. The light source unit consists of a xenon lamp and a rotation disk with 3 optical filters. The rotation disk and monochrome charge-coupled device are synchronized and sequentially generate images in 3 optical filter bands. By use of all 3 band images, a single color endoscopic image is synthesized by the video processor. NBI has limited penetration into the mucosal surface and has enhanced visualization of capillary vessels and their fine structure on the surface layer of colonic tissue.

The FDA-labeled indication for the Optical Biopsy System reads as follows:

> "The SpectraScience™ Optical Biopsy™ System is indicated for use as an adjunct to lower gastrointestinal endoscopy. The device is intended for the evaluation of polyps less than 1 cm in diameter that the physician has not already elected to remove. The device is only to be used in deciding whether such polyps should be removed (which includes submission for histological examination)."

NBI received FDA clearance through the 510K process in 2005. This clearance (K051645) added NBI with the EVIS EXERA 160A System (Olympus Medical Systems Corp) to existing endoscopic equipment. FDA indications are for endoscopic diagnosis, treatment, and video observation.

MEDICAL POLICY CRITERIA

In vivo analysis of colorectal polyps is considered **investigational**.

SCIENTIFIC EVIDENCE

This policy was first developed in February 2002 and focused on the Optical Biopsy System and preliminary data on narrow band imaging (NBI). Since that time, literature searches have failed to find any new data on the Optical Biopsy System, while several randomized, controlled trials on narrow band imaging of colorectal polyps have been identified.

Optical Biopsy System

The FDA approval for the SpectraScience™ Optical Biopsy™ System was based on a prospective, non-randomized phase II study involving 101 subjects from five sites. The data from this trial have not been published in a peer-reviewed journal but are available as an FDA summary of safety and effectiveness.[1] Patients who participated in the study had undergone a prior lower GI endoscopic procedure with at least one polyp identified. They were then referred for an additional colonoscopy exam, in which fiberoptic analysis of the polyps was performed. At the time of the colonoscopy, the physicians documented whether or not the polyp was considered hyperplastic or adenomatous, and whether or not they would remove the polyp. The fiberoptic probe was then applied to three different portions of the polyp and a

segment of normal adjacent mucosa. The physician did not know the results of the analysis and thus the test did not affect patient treatment. The effectiveness of the analysis was then calculated as its ability to correctly identify adenomatous polyps (sensitivity) and to correctly identify hyperplastic polyps (specificity), either alone or in conjunction with the physician assessment. The sensitivity and specificity of the physician assessment alone was 82.7% and 50%, respectively, compared to a combined sensitivity and specificity of 96.3% and 33%, respectively. In other words, fiberoptic analysis identified additional adenomatous polyps that the physician had classified as hyperplastic and presumably would not have removed based on visual assessment alone. This increase in sensitivity comes at the price of a decrease in specificity, as more hyperplastic polyps will undergo biopsy. However, according to the FDA, the risk of taking biopsies of additional hyperplastic polyps is minimal.

The clinical significance of these results and their effect on patient management is difficult to interpret from the data presented. It is not clear how the physician decided to select additional polyps for fiberoptic analysis (it is not entirely clear whether all polyps were analyzed and then underwent biopsy), or whether the same results could be obtained by simply randomly taking a biopsy of a subset of polyps that were considered hyperplastic on visual assessment. While adenomatous polyps are considered premalignant lesions, the evolution to cancer is a slow process requiring 7 to 8 years, and thus the immediate removal of all adenomatous polyps is not required. In addition, the finding of an adenomatous polyp serves as a marker that the patient should undergo more frequent endoscopic exams. It is well known that the current practice of visual inspection of polyps will certainly miss some adenomatous polyps, but this lack of sensitivity is considered acceptable if at least one adenomatous polyp is identified and the patient undergoes more frequent screening.

Few data have been published on the SpectraScience Optical Biopsy System since 2002. A feasibility study of fiberoptic analysis of normal, adenomatous, and cancerous tissue in 11 patients was published in 2003.[2] No additional literature on the Optical Biopsy System was found, but a report in 2006 detailed the results of spectral scattering to different colonic lesions in a small series of 45 patients.[3]

Narrow Band Imaging (NBI)

Meta-Analysis

Sabbagh and colleagues conducted a meta-analysis of studies (regardless of indication) evaluating NBI compared to colonoscopy and did not find any significant differences in the mean number of polyps (5 RCT, 2479 participants), the mean number of adenomas (8 RCT, 3517 participants), and the rate of patients with at least one adenoma (8 RCT, 3512 participants).[4] However, individual studies included in the analysis were noted to have heterogeneous populations and indications, as well as diverse findings. Overall, the authors concluded that NBI did not improve detection of colorectal polyps when compared with conventional colonoscopy.

Randomized Controlled Trials

Several studies from both outside[4-14] and inside[15-22] the U.S. have evaluated the narrow band imaging (NBI) system. These studies are a mixture of those evaluating its overall detection rates for colonic polyps[4,5,8,9,11,15,18] and those specifically examining its ability to differentiate between neoplastic and non-neoplastic lesions.[10-12,16,17,19,20] Data from five randomized trials of NBI versus white-light colonoscopy (WLE) failed to show any advantage in total detection rate for NBI.[4,8,9,15,18] Published randomized trials differed from the conventional approach to the assessment of diagnostic tests. In these trials patients were randomized to one test or the other (i.e., they received only one test). In general,

when comparing diagnostic tests we would have each patient receive both tests and compare the test results.

- Adler and colleagues published two trials. The first trial enrolled 401 participants where the majority of the patients (89%) were enrolled for a diagnostic colonoscopy and evaluated by expert endoscopists (>500 patients per provider).[8] The second trial enrolled 1,256 participants evaluated with a screening colonoscopy in a private practice setting by six endoscopists with substantial lifetime experience (>10,000 total colonoscopies).[9] Both trials randomized participants to receive NBI or white-light colonoscopy; neither trial showed a benefit of NBI over white-light for overall polyp detection rate.
- In a similar study, with the same conclusion, Rex and colleagues enrolled 434 participants, in a population split between 60% screening colonoscopy and 40% returning for surveillance.[18] Each participant was randomized to either NBI or white-light colonoscopy. No benefit of NBI for the detection of adenomas was observed over white-light colonoscopy.
- Kaltenback and colleagues randomized 434 participants to receive both NBI and a white-light colonoscopy, or two white-light colonoscopies. Participants were screened by experienced endoscopists. With the first test, all visible polyps were removed, then the second test was performed to pick up any additional “missed” polyps; from this difference, the polyp miss rate was calculated. The major limitation with this method is that removing polyps with the first test eliminates the opportunity for the second test to “miss” any polyps which were already removed. NBI did not improve what was termed the “neoplasm miss rate” compared with white light.[15]
- Inoue and colleagues, in a randomized, controlled trial of 243 patients in Japan, presented data showing that NBI did improve overall adenoma detection rates over conventional colonoscopy, as well as improving the number of small (<5 mm) adenomas detected, while the number of patients with at least one adenoma remained the same.[5] Participants in this trial had a previous positive colonoscopy or positive fecal occult blood test; approximately 80% were undergoing polyp surveillance. All testing was performed at an endoscopy center by six experienced endoscopists. Differences in results may be attributed to different study populations and/or differences in the version of NBI system used.
- In addition to the meta-analysis of published studies noted above, Sabbagh and colleagues randomized 482 patients to NBI colonoscopy or conventional colonoscopy.[4] They reported the overall rate of polyp detection was significantly higher in the conventional group compared with the NBI group; however, no significant differences were found in the mean number of polyps and the mean number of adenomas detected. A noted limitation of this study was the lack of tandem colonoscopy in both groups.
- In a randomized controlled trial reported by Gross and colleagues, 100 patients undergoing routine screening and surveillance were randomized to receive tandem colonoscopies with standard definition white light (SDWL) and image-enhanced (HD-NBI) colonoscopy.[21] The main outcome measurement was the per-polyp false-negative ("miss") rate. Secondary outcomes were adenoma miss rate, and per-patient polyp and adenoma miss rates. Polyp and adenoma miss rates for SDWL colonoscopy were 57 % (60/105) and 49 % (19/39); those for image-enhanced colonoscopy were 31 % (22/72) and 27 % (9/33) (P = 0.005 and P = 0.036 for polyps and adenomas, respectively). Image-enhanced and SDWL approaches had similar per-patient miss rates for polyps (6/35 vs. 9/32, P = 0.27) and adenomas (4/22 vs. 8/20, P = 0.11). The authors concluded that utilization of multiple recent improvements in image-enhanced colonoscopy was associated with a reduced miss rate for all polyps and for adenomatous polyps. It is not known which individual feature or combination of image-enhancement features led to the improvement.

Two randomized trials addressed both total detection rate and differentiation of neoplastic from nonneoplastic lesions.

- Pohl and colleagues conducted a randomized multicenter trial of virtual chromoendoscopy with the "Fujinon intelligent colour enhancement" system (FICE or NBI) versus standard colonoscopy with targeted indigocarmine chromoscopy.[11] This German trial included 764 patients in the final analysis and reported that FICE/NBI was not superior to control for overall adenoma detection rates; it was comparable on the differentiation of neoplastic and non-neoplastic lesions. The sensitivity of FICE/NBI was 92.7% versus 90.4% for the control.
- Rastogi and colleagues reported on a randomized controlled trial of 630 subjects who were randomized to undergo colonoscopy with standard-definition white-light (SD-WL), high-definition white-light (HD-WL), or NBI.[22] The proportion of subjects with adenomas was 38.6% with SD-WL compared with 45.7% with HD-WL and 46.2% with NBI (P = .17 and P = .14, respectively). Adenomas detected per subject were 0.69 with SD-WL compared with 1.12 with HD-WL and 1.13 with NBI (P = .016 and P = .014, respectively). HD-WL and NBI detected more subjects with flat and right-sided adenomas compared with SD-WL (all P values <.005). NBI had a superior sensitivity (90%) and accuracy (82%) to predict adenomas compared with SD-WL and HD-WL (all P values <.005). The authors concluded there was no difference in the proportion of subjects with adenomas detected with SD-WL, HD-WL, and NBI. However, HD-WL and NBI detected significantly more adenomas per subject (>60%) compared with SD-WL. NBI had the highest accuracy in predicting adenomas in real time during colonoscopy.
- Kakol et al. evaluated the usefulness of NBI for detection of missed polyps after colonoscopy comparing white light (WL) to NBI.[23] After initial colonoscopy 253 patients were randomized to a second colonoscopy with either NBI or WL. Authors found no significant difference between missed polyps or adenomas between groups.
- East et al. reported on 214 patients who were randomized to examination with either NBI or WL in order to determine whether NBI would enhance adenoma detection in high-risk patients.[24] High risk was defined as a patient with a history of 3 or more adenomas on last colonoscopy, colon cancer, and positive fecal occult blood test. There were no significant differences observed in detection of either polyps or adenomas between groups.
- Additional data on NBI for the differentiation of neoplastic from non-neoplastic lesions comes from nonrandomized studies of various sizes where the conclusion often is that NBI may be more accurate than conventional colonoscopy for the differentiation of lesions.[10,16,17,19,20]

For example, Hirata evaluated 148 colorectal lesions and concluded that determination of pit patterns of colorectal neoplasia by NBI magnification was nearly the same as that by standard magnification with chromoendoscopy and that NBI can distinguish neoplastic and non-neoplastic lesions without chromoendoscopy.[13] Rastogi and colleagues, after evaluating 100 patients with 236 detected polyps, concluded that NBI without magnification was significantly superior to high-definition white-light colonoscopy for the real-time prediction of adenomas.[17] Van Den Broek reported sensitivity, specificity, and overall accuracy of NBI for differentiation of 90%, 70%, and 79%, respectively, and while the specificity and overall accuracy were superior to high-resolution endoscopy, endoscopic trimodal imaging and autofluorescence imaging, the test characteristics were disappointing for the diagnostic accuracy for polyp differentiation.[12] These studies only reported on the accuracy of the NBI system in the in vivo evaluation of colonic polyps. None of the studies evaluated the impact of this technology on outcomes including whether or not there would be an improvement in the selection of polyps for removal during colonoscopy.

Additional publications on NBI[25-39] continue to have significant methodological flaws and are of limited clinical utility due to one or more of the following:

- Non-comparative or retrospective design
- Use of inadequate comparator group (eg, NBI comparator group not receiving standard of care; WLE in combination with NBI compared against histopathology findings, limiting ability to compare WLE alone vs. WLE with NBI)
- Lack of diagnosis confirmation from histopathological findings
- No in vivo polyp assessment

In an editorial, Soetikno mentions the need for a user-friendly classification system for use of these devices.[40] The editorial also comments on the need for high-definition recording devices to allow further research. As noted, without these devices, the details of lesions cannot be seen beyond the fleeting moment during the procedure and patterns cannot be fully correlated with pathology. Current technology allows for images to be saved and reviewed at a later time, but development of a standardized system for the classification of the different patterns seen on NBI is needed.[41]

While other technologies are under investigation, including chromocolonoscopy,[6,7] Third Eye Retroscope,[42] and autofluorescence,[43] there is no evidence that current studies of these technologies overcome the issues referenced above. Randomized trial data, where participants receive both screening tests, and where histologic confirmation of disease is matched to screening test results for each polyp are required to evaluate this technology.

Clinical Practice Guidelines

Neither the U.S. Preventive Services Task Force nor the National Comprehensive Cancer Network (NCCN) mentions NBI in their current policy statements or screening guidelines. The American Gastroenterological Association (AGA) in 2008 published a technology assessment of image-enhanced endoscopy, which mentions optical and electronic devices potentially playing a role in colon screening in the future, but currently, more data are needed.[44] In a 2010 position statement regarding diagnosis of colorectal neoplasia in patients with inflammatory bowel disease, the AGA stated, “Additional studies are needed to evaluate the efficiency of other imaging methods, such as narrow band imaging and confocal endomicroscopy, in detecting dysplasia.”[45]

Summary

It is uncertain whether in vivo assessment of colorectal polyps using fiberoptic analysis or narrow band imaging as adjuncts to colonoscopy improves patient management. Collectively, the published data suffer from methodological limitations and fail to evaluate the impact of these technologies on health outcomes, including whether or not there would be an improvement in the selection of polyps for removal during colonoscopy. Therefore, in vivo analysis of colorectal polyps using any system is considered investigational.

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CROSS REFERENCES

None

CODES	NUMBER	DESCRIPTION
CPT	44799	Unlisted procedure, intestine

CODES	NUMBER	DESCRIPTION
	88375	Optical endomicroscopic image(s), interpretation and report, real-time or referred, each endoscopic session
HCPCS	No code	