Flexible Sigmoidoscopy: A Complete Clinical Guide
Jerome Waye, M.D.
Zephyr Medical, 2002, Encino, CA, www.zephyrmical.com; $150.00

My first impression after viewing this DVD was, “How long ago was this DVD made?” I found parts of this DVD to be quite outdated such as the use of fiberoptic scopes, the cleansing techniques, and the old light sources. Were those latex gloves being used?

In the section on training I was concerned to see the statement that a person can do these exams after only 10-20 sessions. I was further concerned with Dr. Waye’s listing of persons who could become qualified to perform this procedure. I was wondering what the difference was between an “adequately trained nurse” and a “nurse endoscopist.” Who are the other “assistants who could be trained for flex sigs?” Are these medical assistants, physician assistants or some other group? I was unclear who these trained nurses or assistants were, what training they would require, and what their titles would be.

Another area of concern was when it was stated that all adenomas require a colonoscopy and that it would take 3–5 years for an adenoma to grow to 1.0 cm. Although the literature is conflicting there are some papers that suggest colonoscopy is not required if a single small adenoma is found on flex sig.

One of the things I was surprised to see was that during one of the exams, an 88 year-old lady was found to have a polyp at approximately 25 cm (this was addressed by the physician) but the polyp was not removed.

On a positive note: the sections on Techniques, Anatomy and Diagnosis, The Exam, Complications, and Pathology Atlas were very beneficial. The section on polyp variations and cancer/adenomas was especially well done. The pictures and explanations would be superb to the trainee just entering this field.

In conclusion: The sections on introduction, preparation, equipment, endoscopy assistants, cleaning, and disinfection could be updated. The other sections are of great benefit to anyone wanting to learn flexible sigmoidoscopy.

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Quest Diagnostics Offers Insure™ Colorectal Cancer Screening Test to Help Physicians Identify Cancer at an Early Stage

Test is Easy for Patients to Use, Non-Invasive, Sensitive and Specific

Quest Diagnostics Incorporated has begun to market InSure™, an FDA-cleared fecal immunochemical test to detect the presence of blood in stool samples. The test is intended to help physicians screen for colorectal cancer at an early stage in patients who are at average risk. Earlier this year, Quest Diagnostics and Enterix Inc., a privately held colorectal cancer screening company, announced that they had entered into an agreement for Quest Diagnostics to offer InSure.

“InSure meets the critical need for a broad-based colorectal cancer screening test,” said Joyce Schwartz, M.D., Vice President and Chief Laboratory Officer of Quest Diagnostics, “it is sensitive, specific and easy for patients to use.”

“Increasing compliance with screening guidelines is the key to reducing the number of cases of colorectal cancer, which is a preventable disease,” noted Jack Mandel, Ph.D., M.P.H., Chairman of the Department of Epidemiology at the Emory University Rollins School of Public Health and lead investigator for the definitive clinical trial of guaiac-based fecal occult blood tests. “InSure offers physicians a screening tool that has been shown to have greater compliance than guaiac-based fecal occult blood tests.”

InSure is specifically designed to detect human hemoglobin only from lower gastrointestinal bleeding, from sources such as the colon and rectum, without requiring the patient to observe dietary and medicinal restrictions. In addition, studies indicate that InSure provides 87% sensitivity (1) for colorectal cancer detection and 97.8% specificity.

The American Cancer Society’s 2003 guidelines for colorectal cancer screening cite immunochemical tests’ advantages over guaiac-based fecal occult blood tests. Based on a recent review (2) of various colorectal cancer screening technologies by The American Cancer Society’s (ACS) Colorectal Cancer Screening Advisory Group, the ACS’s Recommendations for Screening and Surveillance for the Early Detection of Adenomatous Polyps and Col (continued on page 72)
orectal Cancer for 2003 now include the statement: “In comparison with guaiac-based tests for the detection of occult blood, immunochemical tests are more-patient friendly, and are likely to be equal or better in sensitivity and specificity.” The Group also noted that “...recent studies of InSure combined with previously published reports on the performance of immunochemical tests for stool occult blood provide a persuasive argument that these tests offer enhanced specificity in colorectal cancer screening compared with guaiac-based testing.”

The new InSure technology provides uncomplicated specimen collection that is easy for patients to use at home. InSure is non-invasive and it requires no handling of fecal matter. To date, guaiac-based fecal occult blood testing has been the cornerstone of early colorectal cancer screening.

The current rate of patient adherence with recommended colorectal cancer screening guidelines—using any method—is lower than for screening tests for breast, cervical or prostate cancers. It is estimated that only 33% of Americans over the age of 50 have been screened for colorectal cancer by fecal occult blood testing within the past two years (3)—versus 84% of American women over the age of 45 who have been screened for cervical cancer by Pap testing within the past three years (4). For the 80 million people over the age of 50 who are of average risk, the American Cancer Society recommends annual colorectal cancer screenings. If detected and treated at an early stage, the 5-year relative survival rate for colorectal cancer is 90%.

“We are confident that InSure will overcome the current challenge of patient non-compliance associated with traditional testing methods and improve the chances of detecting colorectal cancer in more patients at an early and treatable stage,” said Dr. Schwartz.

Physicians and patients who are interested in learning more about InSure may call 800-531-3681, ext. 10, or may visit the InSure website at www.insurefobt.com.

INSURE Fact Sheet

- The InSure T fecal immunochemical test (FIT) is an immunoassay test designed for annual colorectal cancer screening in asymptomatic patients 50 years of age and older.
- InSure selectively detects blood leaking into the lower gastrointestinal tract, which is where cancer and precancerous polyps develop.

References/Footnotes

1. The sensitivity of InSure Fecal Occult Blood Test was assessed in a study of a high-risk population.

Helicobacter pylori (H. pylori) Infection, A Major Cause Of Upper Gastrointestinal Conditions, Often Underdiagnosed And Undertreated

Innovative BreathTek™ test provides convenient, accurate, non-invasive diagnosis of this prevalent, serious, but curable infection

Many physicians may currently underdiagnose and undertreat an infection caused by a serious bacterium called Helicobacter pylori (H. pylori) in patients who suffer from persistent gastrointestinal (GI) complaints. Discovered in 1983, H. pylori has been determined to be the major cause of many serious GI conditions including gastritis, inflammation of the stomach lining and peptic ulcer disease. It is estimated that approximately one in three Americans has H. pylori (1). While many physicians are aware about the serious effects of H. pylori, a majority continue to treat the symptoms rather than properly diagnosing and curing the infection. Left untreated, H. pylori can have serious long-term effects, including gastric cancer. However, when diagnosed and treated appropriately, the infection is curable. The BreathTek™ test now offers an innovative, accurate and non-invasive means to test for active H. pylori infection and can ultimately help physicians alleviate their patient’s GI discomfort and disease.

“Testing for H. pylori must be included in the first-line diagnostic assessment for any and all patients who have a history of GI discomfort,” said David Y. Graham, M.D., Chief, Digestive Disease Division, Department of Medicine, Baylor College of Medicine, Houston, Texas. “Early diagnosis and treatment of H. pylori may mean less discomfort and medication in the long term for the patient and may diminish the possibility of other more serious conditions, such as ulcers and gastric cancer.”

According to a recent 12-month retrospective study of more than 14,000 patients with new-onset GI disor-
ders, only 26 percent of patients received an \textit{H. pylori} diagnostic test at any time during their care. Of the patients who received an \textit{H. pylori} diagnostic test, only 46 percent received it on the same day as their initial diagnosis. Interestingly, almost 50 percent of the patients who did not receive an \textit{H. pylori} test at their first diagnosis had a changed diagnosis when they were eventually tested (within 30 days of their initial visit) (2). The study, authorized by Meretek Diagnostics, Inc., evaluated treatment patterns of specific GI disorders and intervention strategies. Early detection and proper treatment of \textit{H. pylori} is paramount to curing the infection. Left untreated, \textit{H. pylori} infection can often lead to duodenal and gastric ulcers. In fact, studies have shown that \textit{H. pylori} causes nearly 95 percent of duodenal ulcers and approximately 75 percent of gastric ulcers in the United States (1). This bacterium has also been strongly linked to gastric cancers. In fact, the World Health Organization (WHO) has declared \textit{H. pylori} a group I carcinogen (3).

\textbf{Proper Treatment of \textit{H. pylori}}

Each year in the U.S., there are between 500,000 and 850,000 new cases of peptic ulcer disease and more than one million ulcer-related hospitalizations (5). The majority of these cases are the result of \textit{H. pylori} infection. Though most physicians are well informed about the role of \textit{H. pylori} in ulcers and other serious GI conditions, early testing, diagnosis and appropriate treatment of this serious infection remains low.

In 1994, the National Institutes of Health (NIH) published recommendations that stressed the need for antibiotics to cure \textit{H. pylori} (6). According to the Centers for Disease Control and Prevention (CDC), national surveys of primary care physicians (PCPs) and gastroenterologists conducted in years following these recommendations indicate that 90 percent of these physicians correctly identified \textit{H. pylori} as the primary cause of ulcers (6). However, PCPs surveyed still reported treating more than 50 percent of first-time ulcer patients with acid-reducing medications, such as proton pump inhibitors (PPIs), rather than the recommended antibiotic based regimens (6). In addition, gastroenterologists reported treating more than 30 percent of first-time ulcer patients with acid-reducing medications only (6). Unfortunately, while these therapies can be effective in relieving GI discomfort and healing ulcers, these drugs may merely mask \textit{H. pylori} symptoms which can result in a recurrence of pain and serious ulceration.

Once an \textit{H. pylori}-related ulcer is diagnosed, proper eradication treatment usually involves a course of triple therapy, which includes two antibiotics to kill the bacteria and either an acid suppressor, such as a PPI, or a stomach-lining shield. Results are encouraging for this method of treatment. According to the National Digestive Diseases Information Clearinghouse (NDDIC), this course of therapy reduces ulcer symptoms, kills the bacteria, and prevents the recurrence of ulcers in 60 to 90 percent of patients (7,8).

“Twenty years after its discovery, \textit{H. pylori} continues to be underdiagnosed and undertreated, leaving a considerable number of the infected population at risk for serious and long-term gastrointestinal problems,” said Dr. Graham. “We need to decrease the effects of \textit{H. pylori} by increasing diagnostic testing and improving cure rates among the general population. BreathTek is an accurate, non-invasive tool that will help us achieve this goal and improve diagnosis and treatment of \textit{H. pylori.”}

The use of BreathTek to test for \textit{H. pylori} detection now provides a quicker, more accurate means to early treatment and cure for the infection. In addition, treating active \textit{H. pylori} infection after a positive diagnosis with BreathTek, rather than merely masking symptoms of the infection, may also minimize the utilization of healthcare resources and reduce healthcare costs.

\textbf{References}


**PPI Effects on Gastric Mucosa**

Two identically designed randomized placebo-controlled trials of Esomeprazole 40 mg, 20 mg or 14 mg daily for up to 6 months, as well as a noncomparative, multicentered trial of Esomeprazole 40 mg daily for up to 12 months were conducted in 1,326 patients with healed erosive esophagitis. 1,294 were negative for *H. pylori*. Gastric biopsy samples were obtained before treatment and on completion of, or discontinuation from the trials. Samples were evaluated for the presence of *H. pylori*, characteristics of acute or atrophic gastritis and enterochromaffin-like cell pathology. During treatment, the number of patients with an improvement in gastric histologic scores was typically greater than or equal to the number who worsened. The worsening occurred in less than 6.2 percent of patients. Histologic scores on Esomeprazole and placebo were similar throughout the six month trial. Only one of the treated patients had evidence of treatment-emergent atrophic gastritis.

On final biopsy, 5 to 12 percent had abnormal enterochromaffin-like cell scores, including simple, linear or micronodular hyperplasia with no instances of cell dysplasia, carcinoids or neoplasia.

It was concluded that patients receiving Esomeprazole for up to 12 months had minor fluctuations in gastric histologic scores, similar to those experienced in untreated populations. No safety concerns were raised with respect to development of atrophic gastritis or cause clinically significant changes in enterochromaffin-like cells. (Genta RM, Rindi G, Fiocca R, et al. “Effects of 6 to 12 Months of Esomeprazole Treatment on the Gastric Mucosa.” *American Journal of Gastroenterology.* 2003; Vol, 98, pp. 1257-1265.)

**Infusion Reactions to Infliximab**

A total of 165 consecutive patients who received 479 Infliximab infusions from July, 1998 to January, 2001 were evaluated. Specific treatment protocols for initial and subsequent infusion reactions were followed and the outcomes were documented. The overall incidence of infusion reactions was 6.1 percent (29 of 479 infusions). It affected 9.7 percent (16 of 165 patients).

Use of treatment protocols resulted in rapid resolution of all acute reactions. With the prophylaxis protocol, all patients who experienced an initial mild to moderate acute reaction were able to receive additional infusions. Four patients experienced a total of five severe acute reactions. Three patients were retreated, two patients had no further problems, whereas one patient had a second severe acute reaction that rapidly resolved with treatment.

It was suggested that acute infusion reaction are not type I hypersensitivity reactions. In 11 patients who experienced 14 acute infusion reactions, serum tryptase levels were normal. Delayed infusion reactions occurred in 0.6 percent (3 of 479) of infusions.

It was concluded that Infliximab infusions were accompanied by acute reactions in approximately 5 percent of infusions, and that these reactions did not seem to be true IgG-mediated, type I hypersensitivity events. Utilizing appropriate treatment protocols, these reactions were effectively treated and prevented upon retreatment in nearly all patients. Delayed reactions were rare, occurring in less than one percent of infusions. (Scheifetz A, Smedley M, Martin S, et al. “The Incidence and Management of Infusion Reactions to Infliximab: A Large Center Experience.” *American Journal of Gastroenterology.* 2003; Vol, 98, pp. 1315-1324.)

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