Studies examine Third Eye Retroscope during colonoscopy

March 18 2010

Two new studies show an increase in polyp detection rates using the Third Eye Retroscope (TER), a retrograde viewing device, during colonoscopy. The first study found that TER added to standard colonoscopy detected 13.2 percent more polyps than colonoscopy alone, including 11 percent additional adenomas (precancerous polyps). A second study examined endoscopist experience using TER and its impact on polyp detection rates, concluding that polyp detection rates improved significantly with TER. The studies appear in the March issue of GIE: *Gastrointestinal Endoscopy*, the monthly peer-reviewed scientific journal of the American Society for Gastrointestinal Endoscopy (ASGE).

Colonoscopy is recommended as the primary screening method for colorectal cancer and is the final common pathway for all other recommended screening tests. It is considered the "gold standard" for colorectal cancer screening because of the ability to diagnose and remove polyps (growths in the colon) before they become cancer. During a colonoscopy, the endoscopist uses a thin, flexible tube (colonoscope) fitted with a miniature camera and light source. This device is connected to a video monitor that the endoscopist watches while performing the test. Various miniaturized tools can be inserted through the colonoscope to obtain samples (biopsies) of the colon and to perform maneuvers to diagnose or treat conditions.

The Third Eye Retroscope is a disposable catheter imaging device that is inserted through the instrument channel of a standard colonoscope to provide a retrograde view of the colon during the withdrawal phase of a

colonoscopy. After the colonoscope has been advanced to the cecum, the TER is inserted through the instrument channel. As it emerges from the distal tip of the colonoscope, the TER automatically bends 180 degrees to form a J shape so that its sensor and integrated light source are directed back toward the tip of the colonoscope. The device is then withdrawn together with the colonoscope, providing a continuous retrograde view to complement the forward view of the colonoscope. Previous studies showed that TER can increase detection rates for adenomas and other polyps.

"A retrograde-viewing device improves detection of adenomas in the colon: a prospective efficacy evaluation"

In this prospective, multicenter study, researchers evaluated the added benefit for polyp detection during colonoscopy using the Third Eye Retroscope. A total of 249 patients (age range 55-80 years) undergoing screening or surveillance colonoscopy were enrolled in the study at eight U.S. sites, including university medical centers, ambulatory surgery centers, a community hospital and a physicians office.

For each polyp visualized, the endoscopist indicated whether it could be seen with the normal colonoscope view or whether it could be seen with the colonoscope only after it was first detected with the TER. Therefore, polyps that were visualized simultaneously with the forward view and the TER or that were initially viewed with the TER, but then were readily apparent on the forward view with the colonoscope, were not considered additional polyp detections by the TER. Polyps detected by the TER constituted a group of polyps that, in the best judgment of the investigators, would not have been detected by the forward-viewing colonoscope. Once any polyp was detected, the TER was withdrawn from the colonoscope, the polyp was removed by using standard

techniques, and the TER was reinserted before continuing withdrawal.

The increase in detection of all polyps by using the TER was 13.2 percent and the increase in adenoma detection was 11 percent, both statistically significant. The additional detection rates of all polyps by the TER were 9.7 percent in the left side of the colon (the splenic flexure to the rectum) and 16.5 percent in the right side of the colon (the cecum through the transverse colon). The mean size of adenomas detected with the TER was 5.2 mm (range 2□□ mm) compared with 4.4 mm (range 1□□ mm) for adenomas detected with the colonoscope. Of the 15 adenomas detected with the TER, 53.3 percent were 6 mm or larger and 20 percent were 10 mm or larger. Of the 136 adenomas detected with the colonoscope, 23.5 percent were 6 mm or larger and 6.6 percent were 10 mm or larger. The TER allowed detection of 25 percent additional adenomas 6 mm or larger and 33.3 percent additional adenomas 10 mm or larger.

The authors concluded that the results suggest a potential role for a retroflexed view during colonoscopy withdrawal. Additional study of the impact of this specific device on colonoscopy is warranted.

"Impact of experience with a retrograde-viewing device on adenoma detection rates and withdrawal times during colonoscopy: the Third Eye Retroscope study group"

This study was designed to evaluate whether there is a learning curve for the TER in terms of both polyp detection and procedure time. This was an open-label, prospective, multicenter study at nine U.S. sites, involving 298 patients (men and women, mean age 56.8 years) presenting for colonoscopy, evaluating the use of the TER in combination with a

standard colonoscope. Fifteen experienced endoscopists who had no previous experience with the TER other than a training session with an anatomical model, participated in the study.

The TER was inserted through the channel, much as one would insert a polypectomy snare or biopsy forceps. During withdrawal, the forward and retrograde video images were observed simultaneously side by side on a wide-screen monitor. When a polyp was seen, the endoscopist indicated whether it could have been seen with the colonoscope alone or whether it was found only because it was detected with the TER. When a polyp was seen both with the colonoscope and the TER, the colonoscope was credited with finding it. For each polyp, the endoscopist indicated its size, its distance from the anal verge, and the segment of the colon in which it was found. When a polyp was seen during withdrawal, the TER was removed while maintaining the colonoscope in place. The polyp was then removed by using the tip of the colonoscope or the instrument (snare or biopsy forceps). Because each polyp was removed at the time that it was found, there was no possibility that a lesion could be counted twice.

The 20 subjects who were enrolled by each endoscopist were divided into quartiles, ie, the first five constituted the first quartile, the second five the second quartile, and so on. The learning curve was evaluated by comparing results among quartiles.

Overall, 182 polyps were detected with the colonoscope and 27 additional polyps with the TER, a 14.8 percent increase. A total of 100 adenomas were detected with the colonoscope and 16 more with the TER, a 16 percent increase. For procedures performed after each endoscopist had completed 15 procedures while using the TER, the mean additional detection rates with the TER were 17 percent for all polyps and 25 percent for adenomas. For lesions 6 mm or larger, the overall additional detection rates with the TER for all polyps and for

adenomas were 23.2 percent and 24.3 percent, respectively. For lesions 10 mm or larger, the overall additional detection rates with the TER for all polyps and for adenomas were 22.6 percent and 19 percent. Mean withdrawal times in the first and fourth quartiles were 10.6 minutes and 9.2 minutes, a variance that researchers concluded was not significant. (According to ASGE quality indicators, average withdrawal time should be six minutes or more.)

Experienced endoscopists new to the TER were able to detect a mean of 15.4 percent additional adenomas during their first five procedures. After completing at least 15 procedures with the device, their mean additional detection rates with the TER compared with the colonoscope alone were 17 percent for all polyps and 25 percent for adenomas of all sizes. Additional detection rates with the TER for medium-size and large adenomas were greater than those for smaller lesions. Although this increase was not statistically significant, it suggested a trend toward improvement with greater experience. The variation in the results among the endoscopists suggests that they learned the basic mechanical skills after only a few procedures, but that they required varying amounts of experience to develop optimal technique.

According to the study authors, these results suggest that, compared with routine colonoscopy, a retrograde-viewing device can increase detection rates for clinically significant adenomas without detriment to procedure time or procedure complications.

However, in an accompanying editorial regarding the TER, James S. Barthel, MD, FASGE, H. Lee Moffitt Cancer Center and Research Institute, Tampa, Fla., stated, "It appears that colonoscopists using unassisted 140° angle of view colonoscopes who are willing to spend a few more minutes withdrawing the instrument and pay a bit more attention to procedural technique, particularly tip deflection and cleansing maneuvers, can produce efficacy and efficiency results

equivalent or superior to those reported by Waye et al for colonoscopists using TER-assisted 140° to 170° angle of view colonoscopes. Therefore, the role of
retroscopy remains unclear."

Provided by American Society for Gastrointestinal Endoscopy