

Many New Colonoscopic Devices Are in Pipeline

BY JANE NEFF ROLLINS
Contributing Writer

LOS ANGELES — New methods and devices for diagnostic colonoscopy improve the physician's ability to image the entire colon and to identify so-called hidden polyps, which are often missed by current techniques, Dr. Jacques Van Dam said at the annual Digestive Disease Week.

With these new techniques, patients may be more willing to be screened as well, said Dr. Van Dam of Stanford (Calif.) University. He reviewed six studies with 465 patients who underwent two colonoscopies on the same day. The results showed that physicians missed 2.1% of polyps 10 mm in diameter or larger, 13% of polyps measuring 5-10 mm, and 26% of adenomas less than 5 mm in diameter (Am. J. Gastroenterol. 2006;101:343-50).

Colorectal cancer screening has become increasingly important in gastroenterology. In a 2005 study, 5%-20% of all colonoscopies failed to reach the cecum (Endoscopy 2005;38:209-13). Current colonoscopic de-

vices are prone to looping on insertion, leading to incomplete procedures and the need for sedation and analgesia. These devices require force against the colon wall to advance them to the cecum. Physicians using the devices require rigorous training.

Several investigational colonoscopy devices may increase the rate of successful colonoscopies and lessen patient discomfort, he said.

The CathCam is a disposable multilumen, wire-guided catheter. An outer segment 11 mm in diameter contains a 3-mm-diameter camera with six light-emitting diodes. The guide wire is placed via colonoscopy. In 14 volunteers with a current or previous failure of complete colonoscopy, 12 procedures reached the cecum, one was blocked by a stricture, and one patient dropped out. All patients were sedated with 2-5 mg of midazolam. The average time to reach the cecum was 24

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minutes. In nine cases, the new device helped to identify important findings that had been missed with previously failed colonoscopies (Endoscopy 2005;38:209-13).

The Aer-O-Scope, a self-propelling, self-navigating disposable device, allows successful imaging of the colon independent of the clinician's skill. In a test that included standard colonoscopy, the device reached the cecum in 10 of 12 healthy volunteers, in a mean time of about 14 minutes (Gastroenterology 2006;130:672-7).

A computer-assisted colonoscope made by NeoGuide Systems is propelled with the aid of a follow-the-leader algorithm, eliminating the force applied in standard colonoscopies. A prospective, nonrandomized, unblinded feasibility study was done with five physicians of various levels of experience. In all 10 consecutive patients (6 men and 4 women, age range 19-80) in

the study, the device reached the cecum and enabled identification of diverticular disease in two cases and multiple colonic polyps in two cases. Polyps were removed using standard endoscopic techniques.

The Third Eye Retroscope (Avantis Medical Systems) is a disposable device used in conjunction with colonoscopy. When tested using tandem colonoscopy on latex models configured with polyps located on both sides of folds, the Third Eye identified 12% of distal side and 81% of proximal side polyps.

The PillCam Colon, a new design of the PillCam capsule that is not yet approved for U.S. use, measures 11 mm by 32 mm. The device, which is swallowed, requires no sedation or intubation. A specially developed procedure combines laxatives and prokinetic agents. The Given Diagnostic Imaging System is used for image acquisition, processing, and interpretation.

Dr. Van Dam revealed that he receives research support from, is a consultant to, and owns stock in NeoGuide Systems Inc. and Avantis Medical Systems Inc. ■

Optical Colonoscopy Referrals: Polyp Size Really Does Matter

BY JANE NEFF ROLLINS
Contributing Writer

LOS ANGELES — Referral of patients with adenomas 6-9 mm in diameter for optical colonoscopy remains an area of contention, Dr. David A. Lieberman said at the annual Digestive Disease Week.

Computed tomography colonoscopy (CTC) may miss 40% of lesions of that size, and 7%-20% of the lesions will be at an advanced stage when eventually identified with optical colonoscopy (OC), said Dr. Lieberman, chief of gastroenterology at the Veterans Affairs Medical Center in Portland, Ore.

CTC and OC have comparable rates of identification of adenomas larger than 9 mm in diameter. Using CTC in tandem with OC, some investigators have shown that CTC can identify adenomas measuring 6-9 mm with a sensitivity of 94% and specificity of 96%. Other researchers using CTC, however, have found similar sensitivities, but specificities in the 55%-60% range. The differences may be accounted for by interobserver variability and the difficulty of detecting flat adenomas.

Dr. Lieberman reviewed the natural history of adenomas, 70% of which are tubular and less than 1 cm in diameter when found at screening. There is some epidemiologic evidence that patients with one or two tubular adenomas have a lower risk of progressing to cancer than patients with more adenomas. Polyps less than 9 mm in diameter that are left in place remain stable in 25% of cases, regress in 35% of cases, but progress in 40% of cases, particularly if they are smaller than 5 mm. Polyps 3-9 mm in diameter grow approximately 0.58 mm/year, and the average polyp grows from 6.4 mm to 7.3 mm within 2 years

(Am. J. Gastroenterol. 1997;92:1117-20).

Little is known of the natural history of diminutive polyps (those less than 5 mm in diameter), and the availability of CTC offers researchers a chance to study them. On the basis of recent research, diminutive polyps will develop high-grade dysplasia in up to 2.3% of cases and become cancerous in up to 1.5% of cases. Given this prevalence, Dr. Lieberman asked meeting attendees to consider whether it is justifiable to ignore diminutive polyps and to defer colonoscopy when patients are known to have 6- to 9-mm polyps.

Because the risk of conversion into high-grade dysplasia is directly associated with polyp size, many physicians and patients demand colonoscopy for polyps larger than 5 mm in diameter. The clinician's dilemma is whether to suggest immediate OC to patients with diminutive polyps or to repeat CTC—and, if the latter, at what interval. Cost issues for clinicians providing CTC on demand include establishing a threshold for what constitutes a positive test, who gets referred for OC, and how to handle the expense of evaluating extracolonic findings.

If a large proportion of CTC-evaluated patients get referrals to optical colonoscopy, CTC will not be cost-effective. "We in the GI community are going to have to wrestle with the issue of who gets colonoscopy," Dr. Lieberman told meeting attendees.

The management of diminutive polyps is controversial because the risk of advanced neoplasia is low, and the guidelines developed by the U.S. Multi-Society Task Force on Colorectal Cancer and the American Cancer Society recommend ignoring diminutive polyps. However, "the strategy of not reporting adenomas smaller than 6 mm may lead to medicolegal problems," Dr. Lieberman said. ■

Colon Exams Follow Abnormal Stool Tests Only Half the Time

BY JANE SALODOF MACNEIL
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ATLANTA — Only about half the people who screen positive for blood in the stool during routine physical examinations are thoroughly checked for colorectal cancer, according to a Centers for Disease Control and Prevention study presented at the annual meeting of the American Society of Clinical Oncology.

Complete colon examinations were reported by 71 (53.1%) of 136 participants who said they had an abnormal fecal occult blood test (FOBT) that was not done because of a specific problem or as a follow-up to an earlier test.

A total of 22 people said they had no colon evaluation at all. Another 16 people reported that their doctors ordered a repeat of the FOBT. Eight had sigmoidoscopy, and three had a barium enema. Twelve patients went on to surgery, and four patients did not know what, if anything, was done as a result of their abnormal FOBT.

"The follow-up to screening seems to be a black box," Dr. Lisa C. Richardson said in an interview at the poster session where she presented the data.

Dr. Richardson, a medical officer in the CDC's Division of Cancer Prevention and Control, reviewed the responses of 4,908 people who participated in the 2000 National Health Interview Survey Cancer Control Sup-

plement, a nationally representative sample of households. A total of 80% said they had had the FOBT screen for colorectal cancer, she said.

She and CDC coinvestigator Zahava Berkowitz determined that 287 respondents reported they had an abnormal FOBT result. Of these, 151 were excluded from the sample because their tests were prompted by a specific problem or were done to follow-up on an earlier exam. The other 136 patients screened positive during routine FOBT.

Analysis of demographic factors showed that people were more likely to receive a complete colon examination if they were older than 65, reported excellent or very good health status, or had a college education.

Complete colon examination is the only screening method that has been shown to reduce the incidence of and mortality from colorectal cancer in randomized trials, according to the investigators.

Dr. Richardson noted that the patient-reported data correspond to previous studies of FOBT follow-up and to physicians surveys in which only 50%-60% of respondents said they recommend total colon examination after an abnormal FOBT.

"Some doctors don't trust the fecal occult blood test results. They don't think a whole colon examination is necessary," she said. ■



'The follow-up to [positive fecal occult blood test] screening seems to be a black box.'

DR. RICHARDSON