Virtual Colonoscopy Poised To Gain Wide Acceptance

BY KATE JOHNSON
Montreal Bureau

BOSTON — The debut of virtual colonoscopy as a mainstream option for colorectal cancer screening may be just months away, experts said at an international symposium on virtual colonoscopy sponsored by Boston University.

The much-anticipated results of the American College of Radiology Imaging Network’s (ACRIN) national trial, are expected to be announced by late March 2007. The results are expected to show virtual colonoscopy (VC) is at least as effective as conventional optical colonoscopy (OC), said one of the investigators, Dr. Judy Yee of the University of California, San Francisco.

The American Cancer Society expects to announce its updated colorectal cancer screening guidelines at about the same time, said Robert Smith, Ph.D., the society’s director of cancer screening.

To date, the ACRIN trial has enrolled 2,468 of the 2,607 subjects needed to complete its comparison of both screening modalities, and the trial is scheduled to conclude in late November, said Dr. Yee.

“Where will the results fall?” she asked. In terms of the three most important endpoints—trials comparing VC and OC, the excellent performance of VC in the landmark Pickhardt trial (New Engl J Med. 2001;345:231-23200) was not replicated in the two more recent trials (JAMA 2004;291:1731-19, and Lancet 2005;365:305-11), Dr. Yee said.

“I don’t think I am going out on a limb by saying the ACRIN results will fall right between,” she said. “I don’t think the ACRIN trial will be able to achieve the 92% sensitivity (for VC) seen in the Pickhardt trial, but taking an educated guess I would say that sensitivity will fall maybe somewhere between 80% and 90%.

“Results that would launch VC into the mainstream, predicted Dr. Joseph Ferrucci of Boston University. “We hope they will be the data that will be the final tipping point for the American Cancer Society to amend its guidelines to include VC,” he said in an interview.

Dr. Smith agreed that the ACRIN trial results will be important, but he would not comment on how they would influence the American Cancer Society’s guidelines.

“I can’t tell you whether we are going to wait (for the ACRIN results) or not,” he said in an interview. “We know the ACRIN timetable, and we are working on our guidelines now. If we are not done by the time the ACRIN results are out, we will most certainly want to see them at the earliest opportunity. We live in an electronic age, which means our guidelines process is always active. The potential is always there to adjust the guidelines in very short order if necessary.

Recognizing by the American Cancer Society of VC’s strength as a colorectal cancer screening tool would likely carry it over the threshold toward full public and medical acceptance, said Dr. Perry Pickhardt of the University of Wisconsin, Madison, principal investigator of the 2003 landmark trial.

“VC is an exciting time for us as we move from validation into implementation,” said Dr. Pickhardt, adding that the next step needs to be acceptance by third-party payers. “We are treading water now waiting for widespread reimbursement,” he said.

Dr. Smith agreed that the reaction of the American Cancer Society to the ACRIN results will be important. If VC is added to the society’s guidelines, it is reasonable to expect a resulting improvement in competence among those who perform the test, greater overall investment in the approach, and greater public awareness, he said.

The end result will hopefully be better patient compliance with screening, Dr. Pickhardt said. “Currently, more than 40 million adults over the age of 50 are not being screened.”

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Low-Tech Options for Inflammatory Bowel Disease Promising

BY SHERRY BOSCHERT
San Francisco Bureau

MONTEREY, CALIF. — Development of new treatments for Crohn’s disease or ulcerative colitis has generally focused on immunomodulators, cytokine therapy, and other biotechnology, but lower-tech options are being tried as well, Dr. Joshua K. Korzenik said.

Probiotics, paracites, and fecal transplants each have shown some positive results, although none are ready for prime time, Dr. Korzenik said at an update in gastroenterology and hepatology sponsored by the University of California, Davis.

► Probiotics. Most study findings on the use of beneficial bacteria to treat inflammatory bowel disease have not supported this strategy, but one study of treating pouchitis produced positive results.

The study included 40 patients who were treated for ulcerative colitis with cobeytoly and an ileal anastomosis (or J-pouch) operation and who subsequently developed pouchitis. A problem occurring in about 15% of J-pouches. Antibiotics can control the pouchitis, but long-term they are not ideal.

The researchers brought the patients’ pouchitis into remission with antibiotics, then discontinued the antibiotic therapy and randomized 20 patients to a potent probiotic called VSL#3 and assigned another 20 patients to placebo. The pouchitis returned in all of the patients on placebo by 5 months later, but 17 patients in the probiotic group remained in remission 9 months after starting therapy (Gastroenterology 2000;119:105).

Typical probiotics found in health foods contain between 1 and 2 billion bacteria per gram. VSL#3, which is sold over the Internet, contains about 1.6 trillion bacteria per gram, and patients in the study took three capsules a day. “You’re still talking about relatively small poofettes,” compared with the 10 billion to 1 trillion bacteria in each gram of stool, said Dr. Korzenik, codirector of the Crohn’s and Colitis Center at Massachusetts General Hospital, Boston.

The VSL#3 treatment regimen costs about $12.5 per day and is not covered by insurance.

► Parasites. Some researchers have spec- fied that the modern seal for cleanliness is a eliminated helminth ova (infectious para- site eggs) from humans, and that this con- tributes to the development of Crohn’s disease and ulcerative colitis. Reintroduc- ing these to the body might help treat these diseases, Dr. Korzenik.

In one open-label study, 29 patients with active Crohn’s disease took 2,500 Trichurs (the nematode worm) ova every week for 24 weeks ( Gut 2005;54:87-90). The disease responded to the treatment in 79% of the patients, and 72% of them achieved re-

Virtual Screening May Reduce Polypectomies

BY KATE JOHNSON
Montreal Bureau

BOSTON — With virtual colonoscopy expected to soon take center stage along with other colorectal screening tools, the management of colorectal polyps is poised for a major shift, according to several experts.

Virtual colonoscopy’s main attraction—it’s minimally invasive quality—is also its main weakness. A problematic lesion that is found on virtual colonoscopy (VC) cannot be immediately removed, as it can during conventional optical colonoscopy (OC), although same-day OC with polypctomy following VC is often an option.

“Dr. Smith responded to the treatment in 79% of the patients, and 72% of them achieved re-

mission. ‘The results are almost too good to be true, but it’s promising,’ he said.

A separate placebo-controlled trial in patients with ulcerative colitis showed marginal benefit.

The ova are sold from Europe over the Internet as an expensive product called TSO. “I suggested it be called Ova the Counter,” he joked. The Food and Drug Administration is considering whether sales should be regulated.

► Fecal transplants. This treatment, also called “human probiotics” because the implanted bacteria come from donor stool, is modeled after fecal enemas used to treat some cases of antibiotic Clostridium difficile infection to reestablish normal flora.

In an open-label study of six patients with Crohn’s disease who received daily infusions for 1 week, all had improvement in symptoms (J Clin Gastroenterol. 2003;37:42-7).