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In the News

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Improving Effectiveness of Screening Colonoscopy Remains a Challenge More Frequent Exams Not a Substitute for Thoroughness

by Monica J. Smith

New York City—Screening colonoscopy may be the most powerful strategy available for the prevention of colorectal cancer, but as is true for other cancer screening methods, its effectiveness is being challenged.

Part of meeting that challenge will be assuring screening quality and adherence to national guidelines for surveillance, said Sidney J. Winawer, MD, Paul Sherlock Chair



in Medicine, Memorial-Sloan Kettering Cancer Center, New York City, at the New York Society for Gastrointestinal Endoscopy (NYSGE)'s annual course held in December.

Quality Over Quantity

A consensus guideline for surveillance colonoscopy, which comprises 25% to 65% of current colonoscopy volume, was published in 2006 by the U.S. Multi-society Task Force on Colorectal Cancer and the American Cancer Society (Rex DK et al. *Gastroenterology* 2006;130:1865-1871). A three-year follow-up is recommended for high-risk patients (those with three to 10 adenomas, an advanced adenoma or a dysplastic serrated polyp). A follow-up of less than three years is recommended for those with more than 10 adenomas and those suspected of having a hereditary syndrome, as well as for people with multiple dysplastic serrated polyps. Intervals of three to six months are recommended for patients with piecemeal polyp resection or large sessile polyps.

The majority of people who have had a polypectomy—70%—fall into a lower-risk category: A follow-up of five to 10 years is recommended for those with one or two small adenomas and low-grade dysplasia, and a follow-up of 10 years or more is recommended for those with only distal hyperplastic polyps.

It appears, however, that many endoscopists do not adhere to these guidelines, which has the dual effect of increasing health care costs and restricting screening resources.

"The best studies demonstrated that adherence [to guidelines] was not very good," Dr. Winawer told attendees of the NYSGE meeting [Schoen RE et al. Gastroenterology 2010;138:73-81]. "With no adenomas, 25% [of patients] had a follow-up of less than five years; [with] small adenomas, low-grade dysplasia, 40% had a repeat colonoscopy in less than five years; and interestingly enough, in patients with high-risk adenomas, 40% did not have a colonoscopy in three years.

"The important message here is that careful examination is very important to reduce the rate of interval cancers," Dr. Winawer said. "The miss rate is related to the baseline colonoscopy. Doing another colonoscopy a year or two earlier than the guidelines recommend usually will not make up for an examination at baseline that is not of the highest quality."

Although studies have shown that colonoscopy does reduce the incidence of and mortality from colon cancer, the famous Baxter study suggested that the procedure still misses many proximal cancers (<u>Baxter NN et al. *Ann Intern Med* 2009;150:1-8</u>). Criticisms of the study have piled up. Opponents say the study was based mainly on administrative claims data; 70% of the procedures were performed by non-gastroenterologists; the procedures included a mixture of screening and diagnostic colonoscopy; bowel preparation method was unknown; and so forth. Nevertheless, the results made clear the difference in colonoscopy's effectiveness between the left and right colon.

"They got it right in terms of concept: There was a difference between proximal and distal effect of colonoscopy. But they got it wrong in terms of magnitude," Dr. Winawer said.

Subsequent studies showed that colonoscopy is effective at detecting proximal cancers on the right side—just not *as* effective as it is on the left side. A recent case-control study of 1,688 subjects showed colonoscopy to have an overall effectiveness of 77%—84% in the left side, and 56% in the right (Brenner H et al. *Ann Intern Med* 2011;154:22-30).

"I think a number of studies have well established the concept of difficulty in the right colon," Dr. Winawer said.

Reasons for this include poorer proximal bowel preparation, and incomplete examinations and polypectomy. But the major factor may be that the proximal colon has a higher prevalence of flat and serrated polyps, which are more difficult to identify. Furthermore, the biology of serrated polyps appears to be different; they may give rise to fast-growing tumors with microsatellite instability and CpG island methylator phenotype. Updated surveillance guidelines, which will be published later this year, will include data on the serrated polyp pathway and recommendations for following patients with those polyps. "So, it's not all based on operator dependence," Dr. Winawer said. "There are some new cancers on a 'fast track' that probably have a different molecular pathway than 'garden variety' colorectal cancers, and that's a new concept. We don't know enough about that yet and how to identify people who might have it."

Until it becomes possible to recognize people at risk for fast-moving cancers, the burden still falls to the endoscopist to provide an exam of the highest possible quality.

"Can we reduce the rate of interval cancers with a higher-quality colonoscopy? Of course, the answer to that is yes," Dr. Winawer said. "The most important point is to do a careful exam, and everyone knows what a careful exam is."

Although some quality indicators, such as endoscope withdrawal time, are controversial, others, such as adenoma detection rate (ADR) and cecal intubation rate, are hallmarks of a quality colonoscopy. For example, one study showed that an ADR of less than 20% was significantly associated with a risk for interval cancers (Kaminski MF et al. N Engl J Med 2010:362:1795-1803).

Colonoscopy Quality Initiative

With this in mind, New York City's Citywide Colon Cancer Control Coalition (C5) and the New York City Department of Health and Mental Hygiene (DOHMH), which have made great strides toward raising colorectal cancer screening rates and eradicating disparities in New York City, are focusing their attention on examination quality.

"We have not taken our eye off the ball in terms of increasing colorectal cancer screening rates in New York City, but parallel to that, we need to focus on exam quality, which is inextricably linked with the effectiveness of screening colonoscopy," said Josephine Tsai, MD, MPH, program manager for the New York City Colonoscopy Quality Initiative.

The New York City Colonoscopy Quality Initiative is a partnership between C5, the DOHMH and the NYSGE, with David Greenwald, MD, of Montefiore Medical Center, representing the latter as the society's director of medical education. The program gained momentum in October 2011 under the direction of Dr. Tsai and Mari Carlesimo, director of the Cancer Program at the DOHMH, although plans for the initiative had been in the works for years under the leadership of Marian S. Krauskopf, MS, former director of Cancer Prevention and Control, DOHMH, who retired last year. The program is supported by grants from the Centers for Disease Control and Prevention and the New York State Department of Health.

"The goals of the initiative are twofold: to ensure and improve the effectiveness of colorectal cancer screening in New York City through benchmarking colonoscopy quality citywide, and to identify and address any disparities in colonoscopy screening quality," Dr. Tsai said.

At this point, the program is inviting all sites in the city where colonoscopies are performed hospitals as well as ambulatory surgery centers—to join the initiative and become members of the New York City Colonoscopy Benchmarking Group. To do so, sites need to register with the national <u>GI Quality Improvement Consortium</u> registry, established by the American College of Gastroenterology (ACG) and the American Society for Gastrointestinal Endoscopy (ASGE; see <u>"Nationwide Benchmarking Pilot Program Drives Participants To</u> Improve Quality." by Monica Smith. *Gastroenterology & Endoscopy News*. October 2009:60 [10]:18-20).

They also need to agree to let the DOHMH be a super data manager.

"As a super data manager, the DOHMH will have access through the GI registry to deidentified data," Dr. Tsai explained. "So we don't know the patients, and we don't know the physicians. This initiative is for public health objectives; we're not here to regulate the quality of the physicians, but to assist them in their quality improvement initiative."

The data submitted by participants in the benchmarking group are analyzed and compiled into benchmarking reports, which are essentially report cards that allow sites to compare themselves with other sites. Participants will not see the names of the participating sites because that data will be aggregated as New York City.

As the initiative evolves, the program will be able to standardize quality indicators, establish mean ADR rates for New York City and set specific targets.

"For example, the literature indicates the ADR should be 15% for women and 25% for men, but we don't know what New York City's average is," Dr. Tsai said. "There's no data out there, so it's really important that we are creating this citywide database on colonoscopy quality indicators."

In addition to possibly improving the quality of screening colonoscopy—quality that gets measured tends to improve over time—participating physicians may benefit financially, eventually, through such pay-for-reporting programs as the Center for Medicare & Medicaid Services' Physician Quality Reporting Systems.

To receive reimbursement for Physician Quality Reporting, physicians need to report three quality indicators. At this point, only two such indicators have been specifically identified for colonoscopy screening, so gastroenterologists have not yet been able to fully capitalize on this incentive. But the ACG and the ASGE have submitted several colonoscopy screening quality indicators for consideration to the National Quality Forum, so it may be only a matter of time before that body endorses another indicator, allowing gastroenterologists to receive reimbursement on their Medicare part B physician fee schedule claims for colonoscopy screening.

"We are excited that the New York City C5 program, which increased screening rates and eliminated racial disparities in screening colonoscopy over a six-year period, has now moved to a new level that we hope will help assure the highest quality for this procedure for New Yorkers," Dr. Winawer said. "This has been an excellent urban model for other large cities, and the many professional participants are to be congratulated," he said.

Drs. Winawer and Tsai reported no conflicts of interest.

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