

Technology Is Revolutionizing Colon Imaging

BY DOUG BRUNK
San Diego Bureau

SAN DIEGO — Colonoscopy remains the standard for imaging the colon, but the future may rest in nonoptical techniques such as virtual colonography and colonic visualization devices such as the PillCam, Dr. P. Jay Pasricha said at a meeting jointly sponsored by the AGA Institute and the Japanese Society of Gastroenterology.

"For a long time, colonoscopy was con-

sidered a done deal in terms of technology," said Dr. Pasricha, chief of the division of gastroenterology and hepatology at the University of Texas, Galveston. "But it's interesting to see in the last 3-4 years that there has been a virtual revolution in the way we're thinking about colonoscopy."

One force that has led to innovations is patients themselves, who are increasingly concerned about safety and "hassle" factors such as inconveniences related to sedation.

"They also want standardization of qual-

ity," Dr. Pasricha said. "They don't want to go to one endoscopist and have one outcome and go to another endoscopist and have another outcome. They think of this as a standardized test; they don't view colonoscopy as a variable. It should be done the same way with the same results every time. The patients expect that."

Another force driving new technologies is physicians who are concerned about the limitations of colonoscopy. The "miss rate" of conventional colonoscopy

for adenomas greater than 1 cm is 12%-17%, Dr. Pasricha said. Reasons why adenomas are missed include anatomical factors, such as lesions hiding behind folds, and variability in examiner skills. Detection rates can vary 4- to 10-fold among clinicians in the same practice, he noted.

"Some of it is skill, some of it is the interpretation, and some of it is just how long you take," he said. "The pressure of time has become very important in today's practice. Longer withdrawal times improve detection rates."

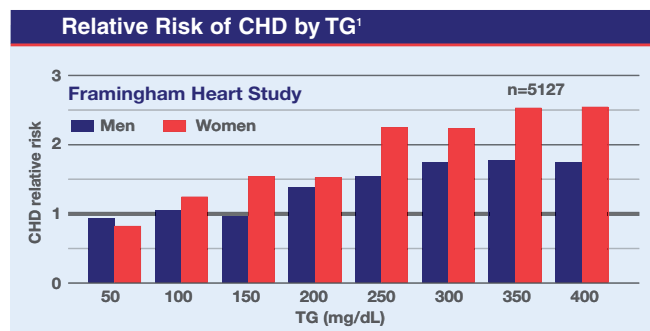
He added that colonoscopy as it is currently practiced—as opposed to the large national trials, such as the National Polyp Study—"may not consistently protect against colorectal cancer or prevent mortality. However, this is the implicit promise that we have offered to our patients. Are we really delivering on that promise? We need to be sure."

Last year, a joint task force of the American College of Gastroenterology and the American Society for Gastrointestinal Endoscopy recommended that the withdrawal time for examining the mucosa should be at least 6 minutes. As a measure

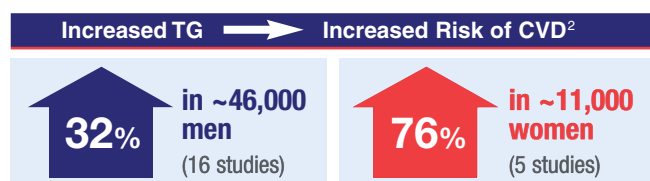


Elevated Triglycerides Make a Difference in Women's Risk of CHD

While great attention and clinical efforts have been directed toward LDL-C-lowering, the Framingham Heart Study 30-year follow-up clearly showed that elevated triglycerides (TG) are also associated with an increased relative risk of coronary heart disease (CHD)—especially in women.¹



In addition, meta-analyses demonstrated that every 1 mmol/L (89 mg/dL) increase in TG increased cardiovascular disease (CVD) risk by:²



CHD is the #1 Killer of Women

The effect of elevated TG in women is important to keep in mind in view of the fact that CHD is the single leading cause of death among American women, claiming nearly 500,000 lives each year.³

Menopausal women are particularly at risk, with CHD rates 2 to 3 times those of women the same age who are premenopausal.³

CHD Risks With Diabetes or Metabolic Syndrome* in Women: Role of TG and HDL-C

Of the estimated 16 million Americans with diabetes, more than half are women.⁴ In women, diabetes is a powerful risk factor for CHD, increasing CHD risk 3-fold to 7-fold compared to a 2-fold to 3-fold increase in men.⁵ It has also been shown that metabolic syndrome is associated with a 2-fold risk of CHD mortality in women.⁶ **It is important to note that the most common pattern of dyslipidemia in patients with type 2 diabetes is elevated TG levels and decreased HDL-C levels.⁷**

*At least 3 of the 5 criteria: abdominal obesity with waist circumference >102 cm in men and >88 cm in women; triglycerides ≥150 mg/dL; HDL-C <40 mg/dL in men and <50 mg/dL in women; blood pressure ≥130/85 mmHg; fasting glucose ≥110 mg/dL.⁸

More Aggressive Guidelines for TG and HDL-C

While LDL-C lowering is recognized as the primary lipid target to reduce CHD morbidity and mortality, it does not remove all risk.⁹ Recent data has shed more light on the role of increased TG and decreased HDL-C in CHD risk. It is critical that these lipid abnormalities be considered and managed, in addition to LDL-C. In fact, the current National Cholesterol Education Program (NCEP) guidelines recommend more aggressive TG and HDL-C target goals.⁸ The American Heart Association (AHA) and American Diabetes Association (ADA) recommend similar aggressive goals for TG (<150 mg/dL) and HDL-C (>50 mg/dL) in CVD prevention for women.^{10,11}

You Can Help Make a Difference

A majority of women are still not aware of the substantial CHD risks posed by abnormal lipid levels.¹² As a physician, you can help make a difference by raising your female patients' awareness of these issues, and by helping them achieve optimal lipid levels, as recommended by the NCEP, the AHA and the ADA.



'Colonoscopy is still the gold standard, but ... this emerging technology [will] catch up in about 3-5 years.'

DR. PASRICHA

of efficacy, clinicians should be able to document that 25% of male patients and 15% of female patients older than age 50 years had one or more adenomas.

Even if you follow the best-practice guidelines, clinicians "still have this problem of excessive demand [for colonoscopies] and the pressure to do more," Dr. Pasricha said.

"You are going to have to spend more time per colonoscopy if you adhere to these guidelines. You're going to get less well paid for the time you spend if current trends in reimbursement continue; there are going to be increases in liability and probably increases in patient dissatisfaction as our performance, in terms of missed rates, gets publicity. That's going to lead to increasing oversight by regulatory agencies," Dr. Pasricha said.

The good news, he noted, is that almost all of these problems are amenable to technologic solutions. One solution is to use nonoptical techniques such as virtual colonography and improved biomarkers.

Virtual colonography is a high-resolution CT scan with a software program that allows you to recreate or simulate the colon. "Some researchers have suggested that the sensitivity is not as good, but there are a lot of new developments in this area that are probably going to make this a reality," he said. "It's going to be along the lines of computer-aided diagnosis, which is really going to shorten the time frame for interpretation of images."

"Prepless" CT colonography, which
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eliminates the need to cleanse the colon, is another promising approach. "Once that becomes a reality, probably in the next 2-3 years, you will see a lot of patients embrace this," he said.

Combining CT colonography with colonoscopy also shows promise. One study suggests that if you stratify patients into low-risk and high-risk categories, with the former undergoing colonoscopy directly while the latter undergo CT colonography as the initial test, you can detect 89% of advanced neoplasia, with far fewer colonoscopies being performed, compared with a rate of 94% when universal colonoscopy was performed (Gastroenterology 2006;131:1011-9).

Other promising alternatives to colonoscopy include non-physician-based colonic visualization devices such as the Aer-O-Scope and the PillCam. The Aer-O-Scope, an investigational device made by G.I. View Ltd., is a disposable, self-pro-

PELLING visualization device that travels from the rectum to the cecum. It has two balloons: The distal balloon contains an optical scanning component, whereas the proximal balloon seals off the rectum.

Proof of concept was achieved in 12 human cases (Gastroenterology 2006; 130:672-7). The device reached the cecum in 10 patients in an average of 14 minutes. Only two patients required sedation, and no major mucosal damage was observed.

In two patients, the device stopped at the hepatic flexure, "so it's not perfect," Dr. Pasricha said. The device "still requires insertion of a blunt instrument into the rectum. Some patients would object to that."

The PillCam, a device made by Given Imaging Ltd., is a variation of the capsule endoscopy devices currently on the market. Its dual cameras cover twice as much area as most of the small bowel capsules do.

A pilot study of 91 patients found that the sensitivity of the PillCam was 56%-76%, and the specificity was 69%-100% (Endoscopy 2006;38:963-70). "We have a way to go with this technology," Dr. Pasricha said. "But given its simplicity and the rate of innovation, this may well be the so-called magic bullet in the future."

The PillCam is not currently approved for use in the United States.

Other solutions include products that

decrease the duration without compromising the quality of care. These include NeoGuide Systems Inc.'s Navigator Endoscopy System, the ShapeLock endoscopic guide (USGI Medical), and the SoftScope (SoftScope Medical Technologies Inc.).

Devices that address the problem of missed polyps include the Third-Eye Retroscope (Avantis Medical Systems Inc.), cap-assisted colonoscopy, wide-angle colonoscopy, and bioendoscopic techniques such as chromoendoscopy.

"Clearly, at this point colonoscopy is still the gold standard, but I think this emerging technology is going to catch up in about 3-5 years," Dr. Pasricha said. ■

Esophageal Erosion in GERD Worse in Men

BERLIN — Women with gastroesophageal reflux disease had a lower prevalence of severe esophageal erosion than did men in an analysis of more than 6,000 patients.

"The lower prevalence of severe erosive changes in women suggests they respond differently to reflux, which may reflect genetically determined differences in visceral sensitivity," Dr. Hubert Mönnikes and his associates said in a poster presented at the 14th United European Gastroenterology Week.

The researchers used data that had been collected on 3,398 women and 3,412 men with gastroesophageal reflux disease (GERD) who had been enrolled in any of 14 studies that tested various treatments for GERD during 2001-2004. The extent of esophageal erosion in each patient was determined by endoscopy, and was graded using the Los Angeles classification.

In the total group, about 14% of patients had nonerosive reflux disease, and the remaining 86% had some degree of erosive esophagitis. The extent of erosion was limited, grade A in about 34%, grade B in 41%, grade C in 9%, and the most extensive erosion, grade D, in about 2% of patients, reported Dr. Mönnikes, a gastroenterologist at Charité Hospital, Berlin.

Of the 964 patients with nonerosive GERD, 61% were women; there were nearly 60% more women with no esophageal erosion, compared with men.

Among the other patients who had some degree of erosion, women tended to have milder disease and men more severe disease. Among the approximately 2,300 patients with the most limited grade A erosions were 44% of all women with erosions and 35% of the men, the researchers said.

The 800 patients with the most extensive grade C or D lesions included 17% of the men and 9% of the women. More severe erosions occurred about 60% more often in men than in women.

—Mitchel L. Zoler

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Relief is defined as ≥ 3 SBMs per week.

Please see Brief Summary of Prescribing Information on adjacent page.

*Spontaneous bowel movements.

¹In 4-week clinical studies. Placebo: 44%-53%.

References: 1. Data on file, Sucampo Pharmaceuticals, Inc. 2. AMITIZA [package insert]. Bethesda, Md: Sucampo Pharmaceuticals, Inc.; 2006.

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