Improving the Effectiveness of Fecal Occult Blood Screening for Colorectal Cancer

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The Medicare claims analysis by Lurie and Welch (1) in this issue of the Journal suggests that only a minority of patients have an appropriate diagnostic work-up after a positive screening fecal occult blood test (FOBT). Their analysis requires several unproven assumptions and, therefore, may reflect only an approximation of actual clinical practice. Nevertheless, the magnitude of the deviation from colorectal cancer screening guideline recommendations identifies a problem that must be addressed if FOBT screening is to be both effective and cost-effective.

Some, but not all, of the limitations of this database analysis are addressed by the authors. Lurie and Welch (1) acknowledge that 1) they do not know if the FOBTs identified in 1995 were performed for screening, 2) they do not know if patients who underwent gastrointestinal (GI) diagnostic examinations actually had a positive FOBT, and 3) they do not know if some patients with a positive FOBT had no GI evaluation whatsoever. Limitations that they do not address include the facts that 1) Medicare did not start reimbursing for colorectal cancer screening until January 1, 1998; 2) two of the five long-term, controlled studies of FOBT screening did not report endpoint mortality results until 1996; and 3) the evidence-based guidelines developed separately by the U.S. Preventive Services Task Force, a consortium of digestive disease societies, the American Cancer Society, and the American College of Physicians were not introduced and promulgated until after their 1995 study period (2–7).

These potential shortcomings notwithstanding, it appears that in 1995—and undoubtedly still in 1999—considerable educational effort is needed to ensure that the clinical effectiveness of FOBT screening approximates the impressive efficacy of this method that has been demonstrated in scientific studies. As the authors point out, even if they have overestimated the FOBT positivity rate in their analysis by over twofold, only 75% of “screened” Medicare patients would have undergone an appropriate diagnostic work-up for colorectal neoplasia as a consequence of a positive screening test.

Clearly, the most important point made by Lurie and Welch (1) is that the “screening FOBT offers little benefit without proper follow-up testing and treatment.” The FOBT is a classic example of an indirect screening test. It is a relatively simple, inexpensive method that identifies a subgroup of the average-risk, asymptomatic population sufficiently likely to have a clinically important colorectal neoplasm to justify more expensive, invasive diagnostic tests (i.e., colonoscopy). However, the screening test by itself is unable either to rule in or rule out important pathology in a given patient.

FOBT screening has been extensively studied in five long-term, controlled trials involving more than 320,000 subjects (2,3,8–10). These studies show that annual FOBT screening detects cancers at an early stage, and mortality due to colorectal cancer is reduced by up to 30%–40%. When FOBTs are used that have a high sensitivity for detecting blood, most cancers are detected by a program of repeated annual screening (11). The main limitation of FOBT screening is its low sensitivity for detecting smaller polyps, and, since the test is not specific for cancer, there are many false-positive results. Evidence-based guidelines recommend combining annual FOBT screening with screening flexible sigmoidoscopy every 5 years (5,6). This combination largely corrects most of the limitations of screening with either test alone. Flexible sigmoidoscopy accurately detects cancers and polyps in the high-risk left colon, but it fails to diagnose right-sided neoplasia. The FOBT appears to be less accurate for detecting distal cancers, but it is highly sensitive for detecting cancers located above the reach of flexible sigmoidoscopy.

Current guidelines further recommend that a positive screening FOBT should be followed by colonoscopy. Both of the clinical trials that were funded by the National Cancer Institute (NCI) in the United States employed colonoscopy for evaluating subjects with positive screening results (5,6). These studies, performed in Minnesota and New York, respectively, reported the greatest reduction in cancer mortality of the five controlled trials. Double-contrast barium enema plus flexible sigmoidoscopy is a reasonable alternative if colonoscopy is not available, acceptable, or complete. Colonoscopy is preferred because it is more accurate for detecting cancers and polyps and it allows for immediate biopsy or polypectomy, all at a single sitting with a single bowel-cleansing preparation (12). A negative colonoscopy is not entirely without value because it reassures the patient that there is little risk for colorectal cancer in the near future, obviating the need for further screening for up to 10 years. Studies that call for routine upper GI endoscopy in all patients with positive screening FOBTs and negative colonoscopy are not convincing. Little clinically important benign upper GI disease requiring treatment is found in asymptomatic patients. Curable gastric carcinoma rarely is found in screened patients in the United States who do not have either symptoms of upper tract disease or iron-deficiency anemia (5).

Screening the entire average-risk population for colorectal cancer will be very expensive. However, it is important for clinicians, health care payers, and the public to realize that the
cost of missing a curable cancer or of failing to prevent cancer by resecting premalignant polyps may be greater. Largely using data from the Minnesota FOBT trial, health economists from the NCI and from the Office of Technology Assessment of the U.S. Congress estimated that the cost of FOBT screening was less than $15,000 per year of quality life gained (13). This is substantially less than the cost of many well-accepted preventive medical interventions. They concluded that screening for colorectal cancer is highly cost-effective and represents a good investment for U.S. society. In a similar mathematical modeling analysis, Lieberman (14) concluded that, of five screening strategies, annual FOBT screening alone was the most cost-effective. Adding flexible sigmoidoscopy every 5 years to annual FOBT screening increased cancer prevention 2.2-fold. Lieberman concluded that, as the cost of cancer care rises and the cost of colonoscopy decreases, screening may soon not only become cost-effective but also could become cost-saving. Largely because of these cost-benefit considerations, the U.S. Congress for the first time provided colorectal cancer screening benefits for all Medicare patients beginning January 1, 1998.

The Medicare claims analysis conducted by Lurie and Welch (1) identifies one of several barriers to effective screening that must be addressed by carefully designed educational programs. A Gallup Poll conducted in August 1998 by the National Colorectal Cancer Roundtable, a consortium of concerned societies and health organizations that are promoting colorectal cancer screening in the United States, indicates that only about half of all people older than age 50 years have had any type of screening in the United States, indicates that only about half of all people older than age 50 years have had any type of screening. The rate of screening was higher in men than in women and higher in whites than in nonwhites. One of the most alarming findings from this survey was that most of those who had not been screened reported that no medical professional had ever recommended screening to them. Clearly, a great deal of work remains to be done to educate the public about the impact of colorectal cancer and the value of screening. Primary care clinicians need to learn more about how to screen their patients according to current guideline recommendations and how to ensure that a proper diagnostic evaluation always follows a positive screening test. Accumulating clinical experience and the results of scientific studies indicate that widespread compliance with screening recommendations could reduce by over half the death rate from colorectal cancer, the second most common cancer killer of Americans (16).

REFERENCES

(15) Bond JH. Primary care clinicians are urged to screen their patients for colorectal cancer. Pract Gastroenterology 1999;23:15–8.