Controversy

Population-based fecal occult blood screening for colon cancer: Will the benefits outweigh the harm?

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? Articles under the Controversy flag appear in the form of a debate. Dr. Marshall was asked to respond to Drs. Winawer and Zauber's article (page 543). Rebuttals follow on page 547.

Cancer Care Ontario, the cancer control agency for Ontario, has recommended that population-based fecal occult blood screening for colon cancer be instituted in the province. Under this recommendation and at a cost of $20–$30 million per year, all adults in Ontario over 50 years would have the opportunity of submitting stools for occult blood screening and, should the test result be positive, would undergo barium enema or full colonoscopy within 3 weeks. An integral part of the program would be educational interventions for physicians and the public.[1]

The rationale for such a screening program is that 3 long-term randomized trials, from Minnesota,[2,3] Great Britain[4] and Denmark,[5] have all shown a decrease in colon cancer mortality with fecal occult blood screening. The initial Minnesota report indicated that, among people who submitted 3 stool samples annually over a mean of 8 years, colon cancer mortality was reduced by 33% at 13 years. Overall mortality was not reduced. The 33% is a relative reduction rate and gives no inkling of the actual numbers of people who benefit. A more clinically meaningful way of reporting these data is in terms of the number needed to be screened to prevent a specific number of deaths from colon cancer.[6] In the Minnesota trial 1000 people had to be screened over a 13-year period to prevent 3 deaths from colon cancer.[2] A second arm of that trial involved screening every second year: after 13 years mortality did not decrease,[2] but after 18 years a decrease in colon cancer mortality (not overall mortality) was noted; it took 3200 stool samples to save 1 life.[3] In the British study, screening every second year resulted in a relative reduction rate of 15% in colon cancer mortality after 8 years (screening 1000 people over 8 years prevented 1 death),[4] and in the Danish study screening every second year resulted in a relative reduction rate of 18% in colon cancer mortality after 10 years (screening 1000 people over 10 years prevented 2 deaths).[5]

Fecal occult blood screening has been clearly shown to prevent death from colon cancer, but the number of lives saved is small. According to a systematic review by Towler and associates,[7] 1000 people would have to be screened for about 10 years to prevent 1 death from colon cancer.

All screening programs cause harm, and this may affect either the individuals participating in the program or society as a whole.[8] The harm to society comes not only from diverting funds (in this case $25–$30 million annually) from other projects but, even more important, by fostering a distortion of our communal value system. Over 2 decades ago Thomas[9] talked about our "unhealthy obsession with health." Recently Goodwin[10] spoke of the "medicalization of everyday life," and Meador[11] suggested that the search for disease eliminates wellness. Fecal occult blood testing is no worse than any other screening program in this respect, but the cumulative effect of promoting ever-increasing numbers of screening programs (the latest being for diabetes mellitus and colon cancer) is oppressive.

The harm to individuals occurs in various ways, 2 important ones being psychological and physical.[8] Both anxiety and physical harm escalate when a positive result is received. In the Minnesota study one-third of the people screened annually had positive results and had to undergo full colonoscopy;[12] in the British[4] and Danish trials,[5] only about 4% underwent colonoscopy. (The higher rate in the Minnesota study is explained by the use of rehydrated Hemoccult slides; hydrated slides increase sensitivity but decrease specificity.) Harm is also induced by false reassurance: 50% of colon cancers are not detected through fecal occult blood testing.[2,4,5]

Most people with a positive result of fecal occult blood testing do not have cancer (low positive predictive value). In the Minnesota trial the positive predictive value for cancer was 2%, and in the British and Danish trials, depending on whether initial or subsequent screenings were analysed, it was between 9% and 17%.[3,4] In all 3 trials the positive predictive value for the combination of adenomatous polyps and cancer was about 30%.[2,3,5] However, because adenomas rarely bleed, most of the adenomas reported in people who undergo occult blood testing are likely detected by chance during colonoscopy.[13]

People participating in a fecal occult blood screening program deserve to know the complication rates of colonoscopy, since many will be subject to this investigation. In 1996 Waye and associates[14] analysed the combined complication rates reported in the few prospective studies of complications from colonoscopy published between 1987 and 1994. The perforation rate was 1 per 2222, the rate of significant hemorrhage 1 per 81 if a polypectomy had been performed and 1 per 1352 if it had not, and the mortality rate was 1 per 16 745. The authors cautioned that these figures were from centres with extensive experience in endoscopy and may not

reflect the experience of the broader medical community, since it is well documented that complication rates are higher with inexperienced than with experienced operators.

Cardiopulmonary complications secondary to colonic preparation with laxatives or sedation given during colonoscopy are reported in up to 20% of patients undergoing the procedure.[15] Although most such complications are minor, cardiac death has occurred on rare occasions and is the leading cause of death related to colonoscopy.[13]

Another cause of morbidity and mortality in patients screened for colon cancer is associated with surgical resection of identified adenomas that cannot be removed endoscopically. Reported operative mortality rates range from 1% to 7%.[13] Because the progression of adenomas to cancer takes many years, numerous elderly patients achieve no benefit from adenoma resection yet still are exposed to the risks associated with such an intervention.[13]

Transmission of infection during colonoscopy is well documented.[16,17] Although this problem should be prevented if established guidelines for cleaning colonoscopes are followed,[18] surveys indicate that inadequate cleaning and disinfection is common in clinical practice.[16,17] One microbiology study found that 24% of "patient-ready" endoscopes were contaminated.[17] In 1997, 2 cases of hepatitis C transmitted during colonoscopy were reported from France;[19] other cases have probably been transmitted this way and have gone undiagnosed because of the long incubation period and the frequent absence of clinical symptoms.[20]

The introduction of a province-wide fecal occult blood screening program in Ontario is almost certain to result in higher morbidity and mortality rates than those reported in randomized controlled trials. The reason is that many of the endoscopists who will be investigating patients with positive screening results will, understandably, be relatively inexperienced and at the bottom of the learning curve. The importance of the learning curve has been clearly shown for flexible sigmoidoscopy. Robinson and associates,[21] in a survey of gastroenterologists in the United Kingdom, reported a perforation rate of 1 per 16 810 procedures. In contrast, Kewenter and Brevinge[22] reported that the rate in their centre was 1 per 716; they explained that they had just started a program and were at the bottom of the learning curve.

Fecal occult blood screening is not innocuous. It can lead to psychological, social and physical morbidity, and in some instances death. Because the quantitative decrease in colon cancer mortality from such screening programs is small, even a slight increase in the number of deaths from colonoscopy or operative removal of detected lesions could counterbalance any benefits achieved. These factors alone are sufficient reasons to reject a province-wide fecal occult blood screening program. When costs are added to the equation, adopting such a program becomes absurd. For Ontario alone, the estimated cost is $20–$30 million annually, and an estimate from the United States is $20 billion within the next decade.[23] If we are really concerned about our health, we would be far better off to direct our financial and emotional resources into potentially remediable social problems that have a far higher impact on mortality, such as smoking,[24] sedentary lifestyle,[24] alcoholism[24] and poverty.[25]

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