

Continuous quality improvement of colorectal cancer screening

Mariusz Madalinski

Mariusz Madalinski, Gastroenterology Department, The Pennine Acute Hospitals NHS Trust, Manchester, Lancashire BURY BL9 7TD, United Kingdom

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Correspondence to: Dr. Mariusz Madalinski, Gastroenterology Department, The Pennine Acute Hospitals NHS Trust, Fairfield General Hospital, Rochdale Old Road, Manchester, Lancashire BURY BL9 7TD,
United Kingdom. m.h.madalinski@pro.onet.pl

Telephone: +44-161-7782642 Fax: +44-161-7782642

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Abstract

Quality assurance is a key issue in colorectal cancer screening, because effective screening is able to improve primary prevention of the cancer. The quality measure may be described in terms: how well the screening test tells who truly has a disease (sensitivity) and who truly does not have a disease (specificity). This paper raises concerns about identification of the optimal screening test for colorectal cancer. Colonoscopy vs flexible sigmoidoscopy in colorectal cancer screening has been a source of ongoing debate. A multicentre randomised controlled trial comparing flexible sigmoidoscopy with usual care showed that flexible sigmoidoscopy screening is able to diminish the incidence of distal and proximal colorectal cancer, and also mortality related to the distal colorectal cancer. However, colonoscopy provides a more complete examination and remains the more sensitive exam than flexible sigmoidoscopy. Moreover, colonoscopy with polypectomy significantly reduces colorectal cancer incidence and colorectal cancer-related mortality in the general population. The article considers the relative merits of both methods and stresses an ethical aspect of patient's involvement in decision-making. Patients should be informed not only about tests tolerability

and risk of endoscopy complications, but also that different screening tests for bowel cancer have different strength to exclude colonic cancer and polyps. The authorities calculate effectiveness and costs of the screening tests, but patients may not be interested in statistics regarding flexible sigmoidoscopy screening and from an ethical point of view, they have the right to chose colonoscopy, which is able to exclude a cancer and precancerous lesions in the whole large bowel.

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Key words: Colorectal cancer; Cancer screening; Sigmoidoscopy; Colonoscopy; Standard of care; Ethical aspects; Clinical competence

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COMMENTARY ON HOT TOPICS

Colorectal cancer (CC) is a common cause of morbidity and mortality in which early detection is vital. From the United States comes a multicentre randomized study of colorectal screening with flexible sigmoidoscopy (FS)^[1]. The results of this study raise a number of important questions regarding the assessment of quality in screening tests and ethical issues.

A total of 77 445 participants of Schoen *et al*^[1] were randomly assigned to be screened for CC, and 77 455 to usual care (from 1993 to 2001). Participants in the intervention group were offered FS at baseline and at 3 or at 5 years. They were referred to their primary care physicians for decisions regarding diagnostic follow-up. A screening-detected cancer was defined as a CC diagnosed within 1 year after a positive FS and was considered to be posi-

tive, if a polyp or mass was detected. Cancers located in the rectum through the splenic flexure were defined as distal, and those in the transverse colon through the caecum were defined as proximal. Death from CC was the primary end point. Secondary end points included CC incidence, cancer stage, survival, harms of screening, and all-cause mortality. Participants in the control group only received endoscopy (FS or colonoscopy), if they asked for it, or if their physician recommended it.

A total of 86.6% of participants (67 071) underwent at least one FS screening, and 50.9% (39 440) underwent two screenings; at least one screening was positive for a polyp or mass in 28.5% of participants (22 083)^[1].

The study showed a reduction in the incidence of distal CC in the intervention group for each cancer stage, ranging from 19.8% for stage I cancers (50 fewer cases diagnosed) to 61.7% for stage IV cancers (66 fewer cases diagnosed). Mortality related to distal CC was also reduced for each stage, by 21.4% for stage I cancers (3 fewer deaths) to 60.7% for stage IV cancers (51 fewer deaths)^[1]. The number needed to screen with FS to prevent 1 death from CC was 871 and to invite to FS screening to prevent 1 CC was 282^[1].

Also the incidence of proximal CC was reduced by 14.4% to 20.7% in the intervention group for stages I, II, and III cancers (22, 34, and 25 fewer cases, respectively), but by only 2.0% (2 fewer cases) for stage IV disease^[1].

The study described by Schoen *et al*^[1] showed a reduction in the incidence of proximal CC, but FS was not success in identifying and removing all precursor lesions destined to develop into cancer in the whole colon and the authors did not show a reduction in mortality related to proximal CC^[1]. Although the study revealed that FS as compared with usual care may result in overall CC mortality, but much of the benefit in reducing CC in mortality from screening derived from its reduction in stage IV the disease, which has a much higher mortality than lower stages^[1].

Using colonoscopy as the screening method, Schoen *et al*^[1] calculated that they could increase the number of screening-detected cancers by approximately 16 percentage points (from < 25% to approximately 40% of CC diagnosed in participants assigned to FS). There is also evidence that colonoscopy with adenomas removal reduces incidence of CC^[2]. Moreover, it has an impact on the reduction of mortality from CC^[3-6], and in the first 10 years after polypectomy, reduces the risk to a level similar to that in a control group of patients with no adenomas^[3].

In the Schoen *et al*^[1] study, 28.5% of participants (22 083) underwent at least one positive endoscopy screening test for a polyp or mass. However, the authors did not mention, whether the second FS revealed only polyps? If this was the case and the second FS revealed a CC or large polyps then it is possible that the endoscopists' skills or bowel preparation may have an impact on the study results.

A high-quality examination ensures the detection of "all" neoplastic lesions - it may be related to an endosco-

pist's speciality^[5-7]. Patients who underwent colonoscopy performed by a gastroenterologist had the greatest reduction in risk for CC mortality^[5,6]. Also a reduction in death from proximal CC may be probably related to colonoscopy performed by a gastroenterologist^[5,6].

It could be argued that colonoscopy screening is more expensive than FS, but 50.9% participants (39 440) of the Schoen *et al*^[1] study, underwent two screenings FS (in 3-5 years). Moreover, there are no studies directly assessing the optimal interval for FS screening^[8], but there is a strongly and significantly lower risk of CC within 10 year after negative colonoscopy^[9]. Although, the ratio of the cost of FS screening to colonoscopy screening is unknown^[10], but diagnostic colonoscopy and diagnostic FS may cost £555 and £441 respectively (figures derive from the Trust's Service Line Reporting information April-September 2012 in The Pennine Acute Hospitals NHS Trust, United Kingdom). I think therefore a model-based economic analysis may easily find colonoscopy screening as less costly than FS screening.

Although colonoscopy has a slightly higher incidence of perforation than FS^[11], but the most common site of perforation during colonoscopy used to be the left colon^[11,12]. Schoen *et al*^[1] reported 0.0028% perforation for screening with FS (2.8 per 100 000 examinations), and nearly 40 times more perforations on repeat screening 0.1075% (107.5 per 100 000 examinations). The incidence of colonoscopic perforation could be very low 0.004% in diagnostic colonoscopy and could be as high as 0.02% in therapeutic colonoscopies, with individual series rates ranging from 0% to 0.86%^[13]. The national colonoscopy audit performed in the United Kingdom, reported rate 0.04% perforations (1:2511 procedures)^[14]. Nonetheless, the audited adult patients who underwent diagnostic or therapeutic colonoscopy could have an even higher risk of complications than screening individuals, because they were symptomatic patients (two perforations occurred in patients with inflammatory bowel disease)^[14].

Colorectal cancer is the third most common in incidence and the fourth most common cause of cancer death worldwide^[15]. An effective screening programme plays a key role to cope with the growing problem of CC. So far, the United Kingdom study has been the only study to show a significant 31% reduction in CC mortality from one-time screening with FS^[16]. It also found a significant reduction in the CC incidence (by 23%)^[16]. Another study performed in Italy showed an 18% reduction in incidence of CC, but FS in this study did not cause significant reduction in mortality^[17]. In Schoen's study comparing FS with usual care, after an average of nearly 12 years, participants in the screening group had a 21% reduction in the incidence of CC and a 26% lower rate of CC mortality than participants in the usual care group. Also a reduction of mortality by 50% and incidence by 29% related to distal CC was noticed.

Despite this great result, the doctors and health authorities are in an ethical dilemma over the optimal screening for CC. Colonoscopy provides a more complete examina-

tion than FS and a patient may not be interested in statistics regarding FS, and ask, if it is better for him to have FS or a complete colonoscopy.

When the patients will be totally informed about the limitations and benefits of FS and colonoscopy, they may be interested to make a decision themselves and choose a more sensitive endoscopy test which is able to exclude a cancer and precancerous lesions in the whole large bowel. Very experienced doctors do not need much more time to complete colonoscopy in most cases, when the top of the endoscope is in the area of splenic flexure. Furthermore, colonoscopy without sedation is common in many European countries and Asia^[18,19]. Therefore the cost of colonoscopy and FS may not differ widely, if endoscopists offer really good skills. In the future, every individual may be involved in the decision-making, and the doctors should be interested in the patient's preference regarding the screening test, because patients have the right to make their own choice^[20].

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