Continuous quality improvement of colorectal cancer screening

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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-
positive, 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 cecum 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).

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). 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.

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

The study described by Schoen et al. showed a reduction in the incidence of proximal CC, but FS was not successful 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. 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 disease, which has a much higher mortality than lower stages.

Using colonoscopy as the screening method, Schoen et al. 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. Moreover, it has an impact on the reduction of mortality from CC, 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.

In the Schoen et al. study, 28.5% of patients (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 endoscopist's speciality. Patients who underwent colonoscopy performed by a gastroenterologist had the greatest reduction in risk for CC mortality. Also a reduction in death from proximal CC may be probably related to colonoscopy performed by a gastroenterologist.

It could be argued that colonoscopy screening is more expensive than FS, but 50.9% participants (39 440) of the Schoen et al. study, underwent two screenings FS (in 3-5 years). Moreover, there are no studies directly assessing the optimal interval for FS screening, but there is a strongly and significantly lower risk of CC within 10 year after negative colonoscopy. Although, the ratio of the cost of FS screening to colonoscopy screening is unknown, 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, but the most common site of perforation during colonoscopy used to be the left colon. Schoen et al. 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%.

The national colonoscopy audit performed in the United Kingdom, reported rate 0.04% perforations (1:2511 procedures). Nonetheless, the 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).

Colorectal cancer is the third most common in incidence and the fourth most common cause of cancer death worldwide. 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. It also found a significant reduction in the CC incidence (by 23%).

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. 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 \[19,20\]. 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\[23\].

**REFERENCES**

1. Schoen RE, Pinsky PF, Weissfield JL, Yokochi LA, Church T, Laiyemo AO, Bresalier RS, Andriole GL, Buys SS, Crawford ED, Fouad MN, Isaacs C, Johnson CC, Reding DJ, O'Brien B, Carrick DM, Wright P, Riley TL, Purdue MP, Ijmizilian G, Kramer BS, Miller AB, Golahan JK, Prorok PC, Berg CD. Prevalence of colorectal cancer by colonoscopy polyp detection. The National Polyp Study Workgroup. N Engl J Med 1993; 329: 1977-1981 [PMID: 8247072 DOI: 10.1056/NEJM199312023291001]

2. Winawer SJ, Zauber AG, Ho MN, O'Brien MJ, Gottlieb LS, Sternberg SS, Wade JD, Schapiro M, Bond JH, Panish JF. Prevention of colorectal cancer by colonoscopy polypectomy. The National Polyp Study Workgroup. N Engl J Med 1993; 329: 1977-1981 [PMID: 8247072 DOI: 10.1056/NEJM199312023291001]

3. Zauber AG, Winawer SJ, O'Brien MJ, Landsorp-Vogelaar I, van Ballegooijen M, Hankef BY, Shi W, Bond JH, Schapiro M, Panish JF, Stewart ET, Wade JD. Colonoscopy polypectomy and long-term prevention of colorectal-cancer deaths. N Engl J Med 2012; 366: 687-696 [PMID: 22356322 DOI: 10.1056/NEJMoa1100370]

4. Manners CN, Bachmann LM, Brunner J, Hunold F, Bauerfeind P, Marbet UA. Colonoscopy screening markedly reduces the occurrence of colon carcinomas and carcinoma-related death: a closed cohort study. Gastrointest Endosc 2012; 76: 110-117 [PMID: 22498179 DOI: 10.1016/j.gie.2012.02.040]

5. Baxter NN, Warren JL, Barrett MJ, Stukel TA, Doria-Rose VP. Association between colonoscopy and colorectal cancer mortality in a US cohort according to site of cancer and colonoscopy specialty. J Clin Oncol 2012; 30: 2664-2669 [PMID: 22689809 DOI: 10.1200/JCO.2011.40.4772]

6. Singh H, Nugent Z, Demers AA, Kiewer EV, Mahmud SM, Bernstein CN. The reduction in colorectal cancer mortality after colonoscopy varies by site of the cancer. Gastroenterology 2010; 139: 1128-1137 [PMID: 20600206 DOI: 10.1053/j.gastro.2010.06.052]

7. Rabeneck L, Pansat LF, Saksin R. Endoscopy specialist is associated with incident colorectal cancer after a negative colonoscopy. Clin Gastroenterol Hepatol 2010; 8: 275-279 [PMID: 19879970 DOI: 10.1016/j.cgh.2009.10.022]

8. Rogal SS, Pinsky PF, Schoen RE. Relationship between detection of adenomas by flexible sigmoidoscopy and interval distal colorectal cancer. Clin Gastroenterol Hepatol 2013; 11: 73-78 [PMID: 22902761 DOI: 10.1016/j.cgh.2012.08.002]

9. Singh H, Turner D, Yue L, Targownik LE, Bernstein CN. Risk of developing colorectal cancer following a negative colonoscopy examination: evidence for a 10-year interval between colonoscopies. JAMA 2006; 295: 2366-2373 [PMID: 16720882 DOI: 10.1001/jama.295.20.2366]

10. Whyte S, Chilcott J, Cooper K, Essat M, Stevens J, Wong R, Kalita N. Re-appraisal of the options for colorectal cancer screening. Report for the NHS Bowel Cancer Screening Programme. Sheffield, UK: School of Health and Related Research, 2011

11. Lohsiriwat V, Sujaritdanakarn S, Ajarakvitha T, Lertakamanee N, Lohsiriwat D, Kachinthorn U. What are the risk factors of colorectal perforation? BMC Gastroenterol 2009; 9: 71 [PMID: 19778446 DOI: 10.1186/1471-230X-9-71]

12. Korman LV, Overholt BF, Box T, Winker CK. Perforation during colonoscopy in endoscopic ambulatory surgical centers. Gastrointest Endosc 2003; 58: 554-557 [PMID: 14520289 DOI: 10.1016/s0016-5072(03)01890-x]

13. Church J. Complications. In: Waye JD, Rex DK, Williams ChB. Colonoscopy. Principles and practice. Oxford, United States/Hoboken, United States: Wiley-Blackwell, 2009: 705-716

14. Gavin DR, Valori RM, Anderson JT, Donnelly MT, Williams JG, Swarbrick ET. The national colonoscopy audit: a nationwide assessment of the quality and safety of colonoscopy in the UK. Gut 2013; 62: 242-249 [PMID: 22661458 DOI: 10.1136/gutjnl-2011-301848]

15. Wild C. Preface. In: Segnan N, Patnick J, von Karsa L. European Guidelines for Quality Assurance in Colorectal Cancer Screening and Diagnosis. 1st ed. World Health Organisation/International Agency for Reserch on Cancer, 2010: XVI-XVII

16. Atkin WS, Edwards R, Kralj-Hans I, Wooldrage K, Hart AR, Northover JM, Parkin DM, Wardle J, Duffy SW, Cuzick J. Once-only flexible sigmoidoscopy screening in prevention of colorectal cancer: a multicentre randomised controlled trial. Lancet 2010; 375: 1624-1633 [PMID: 20430429 DOI: 10.1016/s0140-6736(10)60551-x]

17. Segnan N, Armaroli P, Bonelli L, Riso M, Sciallero S, Zappa M, Andreoni B, Arrigoni A, Bisanti L, Casella C, Crosta C, Falcini F, Ferrero F, Giacomin A, Giuliani O, Santarelli A, Visioli CB, Zannetti R, Atkin WS, Senore C. Once-only sigmoidoscopy in colorectal cancer screening: follow-up findings of the Italian Randomized Controlled Trial–SCORE. J Natl Cancer Inst 2011; 103: 1310-1322 [PMID: 21852264 DOI: 10.1093/jnci/djr284]

18. Elliott VS. Study supports use of no-sedation colonoscopy. Amednews. January 12, 2009. Available from: URL: http://www.ama-assn.org/amednews/2009/01/12/hl102012.htm

19. Leung FW, Aljbreen AM, Brocchi E, Chang EB, Liao WC, Mizukami T, Schapiro M, Triantafyllou K. Sedation-risk-free colonoscopy for minimizing the burden of colorectal cancer screening. World J Gastrointest Endosc 2010; 2: 81-89 [PMID: 21160707 DOI: 10.4253/wjge.v2.i3.81]

20. Wollf SH. The best screening test for colorectal cancer—a personal choice. N Engl J Med 2000; 343: 1641-1643 [PMID: 11096175]

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