

The managed health care study for screening and early detection of colorectal cancer in Lodz urban population

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Abstract

The quality improvement initiative was undertaken in parallel with prospective studies on the incidence and frequency of colorectal cancer (CRC) in urban population of Lodz, Poland. The study was conducted in four primary care providers with the support of academic medical institutions. The study population included the citizens of Lodz, both genders, aged 45 to 65. The study was divided in two stages; each conducted consecutively in 2003 and 2004. This prospective, two stage study included 3152 patients. After positive serial guaiac-based fecal occult blood tests, high CRC odds ratio based on per rectum examination and the standardized questionnaire data 47.8% out of 1648 and 18.9% out of 1504 initially enrolled patients were enrolled into the extended diagnostic stage of the study within the consecutive years, respectively. CRC was found in 0.9% and 0.54% patients, respectively and the diagnosis of CRC was confirmed with histopathological tests. Colorectal diseases other than CRC were found in 23.1% and 11.2% of the study subjects, respectively. It is crucial to design and implement follow-up studies for those among our study subjects at high risk of CRC who finished the current study even without an unfavourable diagnosis or risk rating.

Key words: colorectal cancer, screening.

Introduction

Most relevant guidelines for CRC screening identify subjects aged 50 or more, with an average risk, as those who should undergo either annual fecal occult blood testing, flexible sigmoidoscopy and fecal occult blood testing every five years, double contrast barium enema every five years or colonoscopy every ten years [1, 2]. However, based on further recommendations, the combination of fecal occult blood testing and an invasive diagnostic procedure remarkably increases specificity and sensitivity of the screening procedure in this time frame. The subjects with an increased or high risk of CRC should be screened with the same tests in more frequent schedule. Every three or six years, colonoscopy should be performed in persons with a single adenoma of the diameter less than 1 cm, whereas

within three years in patients after initial excision of a large, more than 1 cm diameter, adenoma, multiple adenomas or adenomas with high-grade dysplasia or villous type [1]. The increased or high risk of CRC is commonly associated with a family history consisting of one or two close relatives with cancer (15-20%) hereditary non-polyposis colorectal cancer (5%); inflammatory bowel disease; familial adenomatous polyposis (1%) (as a predisposing factor in CRC cases yearly, respectively) [3]. According to American Cancer Society (ACS) Guidelines and Surveillance for the Early Detection of Cancer, persons with family history of CRC or adenomatous polyps in first degree relatives before age of 60 or two or more first degree relatives regardless of age are at the increased risk. This group is recommended to undergo colonoscopy as early as at the age of 40 or ten years before the earliest CRC case in the intermediate relative [1]. About 25% of CRC cases represent patients with a familial risk of this cancer. The prevalence of polypoid lesions, adenomas and high risk adenomas (above 10 mm diameter and/or of villous type) in proximal sigmoid colon were found approximately increased twice in 40 to 50 years old relative of CRC patients. Therefore, a screening colonoscopy may be necessary as early as between 40 and 50 years in persons with the familial risk [4]. The development of early detection markers as a non-invasive option to colonoscopy is still being pursued. According to the most recent updates, it includes fecal occult blood, globulin protein, stool mucins, mutated DNA along with serum biomarkers including protein panels identified with transitional studies, DNA aberrations and nuclear matrix proteins of undetermined sensitivity, specificity and costs [5]. Even though there is a remarkable progress in diagnostic and screening options in CRC patients, fecal occult blood testing, with its low sensitivity, is still a proven screening method for the reduction of CRC related death risk [6-8]. Endoscopic, invasive screening is currently the most favourable detection method of CRC. As such, this invasive diagnostic procedure faces poor participation rates. Apparently, this is related with patients concerns before the procedure. This limitation accelerates the studies aimed to develop less invasive and still, sensitive and reliable methods of CRC detection. Still, the regular screening for CRC is still remarkably infrequent [9].

Therefore, the quality improvement initiative was undertaken designed as prospective studies on the incidence of colorectal cancer in urban population of Lodz, Poland. The study was conducted in four primary care providers with the support of academic medical institutions.

Materials and methods

Patients' population

The study population included the citizens of Lodz, both genders, aged 45 to 65. The study was conducted in four sites including primary care providers at NZOZ Salve, Military Medical Academy Memorial Clinical Hospital of Medical University of Lodz, Saint John Memorial Clinical Hospital and Pirogow Clinical Hospital. The study was divided in two stages; each conducted consecutively in 2003 and 2004. Descriptive epidemiological data of the colorectal cancer regarding frequency, crude incidence, age distribution, age standardized incidence rates, tumour-stage, number of the senior surgeons involved, number of colonoscopies, number of rectoscopies, mortality rates were studied.

The initial diagnostic stage of the study

At the initial diagnostic stage, the study participants were recruited among patients during routine primary care visits. Before the study enrolment patients completed demographic and epidemiological questionnaires to identify the relevant risk factors. After the evaluation of the risk odds and the medical interview, the patients at risk were directed for further evaluation, including serial guaiac-based fecal occult blood testing. In case of the positive results of serial guaiac-based fecal occult blood testing, the study participants were referred for surgical or proctologist consultation in order to qualify for the extended diagnostic stage of the study. All study participants received the information and educational leaflets on the prophylaxis of colorectal cancer.

The extended diagnostic stage of the study

The extended diagnostic stage of the study included the patients referred from the initial diagnostic stage. The study participants were invited for either screening colonoscopy or rectoscopy based on per rectum examination, questionnaire and fecal occult blood test results by the consultants. In case of the diagnosis of malignancy or any other colorectal diseases, the study subjects were included into the standard therapeutical procedure as the beneficiaries of nationwide health care system and they received the directions and information for the primary care physician at the original place of referral. All patients diagnosed with colorectal cancer were included into the regional cancer registry.

Serial guaiac-based fecal occult blood testing

Serial guaiac-based fecal occult blood testing was performed with Hemocult II (Beckman Coulter, former SmithKline Diagnostics).

Endoscopic screening

Endoscopic screening was performed with standardized procedure of flexible sigmoidoscopy. The program directives ensured appropriate qualifications of endoscopists performing flexible sigmoidoscopy. The sigmoidoscopy results were carefully documented. There were no colonoscopic perforations in the study subjects. The technical procedure was performed according to recommendations and was in compliance with the most current international recommendations regarding procedure, timing, antibiotic prophylaxis and bowel preparation [10]. Histopathological examination was performed in every single case of excised polyp during colonoscopy and their architecture was classified either as tubular adenomas (1 cm in diameter or larger); villous architecture or high-grade dysplasia or invasive cancer.

Results

The pooled data from 2003 to 2004 are depicted in Table I. The current, prospective study involved 3152 patients over two years' time between 2003 and 2004. The study program included 47.8% out of 1648 and 18.9% out of 1504 initially enrolled patients into the extended diagnostic stage of the study in 2003 and 2004, respectively (see Table I). Among those, colorectal cancer was found in 0.9% and 0.54% patients, respectively. The diagnosis of colorectal cancer was confirmed with histopathological tests. Other diseases of the colon and rectum were found in 23.1% and 11.2% of the study subjects in 2003 and 2004, respectively.

The subjects at high risk of CRC, including persons with inflammatory bowel disease, Crohn's disease, chronic ulcerative colitis constituted 4% of the study population and were managed with standard medical therapy appropriate in each case. There were

no subjects with family history of hereditary non-polyposis colon cancer or familial adenomatous polyposis found in this study. The subject at the increased of CRC, according to ACS Guidelines and Surveillance for the Early Detection of Cancer, represented 7% of the study population.

Discussion

The incidence of colorectal cancer in general population in Poland is estimated at 3.5% in males and 2.5% in females annually and it is known to increase with advanced age. The data from our study is coherent with these numbers. If they were to be compared with the data in another Polish urban population, the incidence of CRC in Gdansk area was 0.23% in 2001 and 0.32% in 2002. Also in this urban area, the other diseases of colon and rectum were found in strikingly close number of the study subjects 30.3% and 16.3% if compared with our study in the respective years [11].

The early detection and prevention of CRC is still a management and therapeutical challenge related with its insidious biology and scarce clinical symptoms preceding malignant transformation. Since there is no relation between CRC symptomatic period and the stage or prognosis [12], efficient invasive and non-invasive screening is of utmost importance. Other screening studies commonly demonstrate that CRC screening is more efficient in case of elder patients, patient regularly undergoing medical examinations and those under the supervision in integrated medical care facilities. Potential variation in technical quality may have a profound impact on the effectiveness of flexible sigmoidoscopy on the early detection and prevention of CRC [10]. Also, even in the most well funded medical care systems, the quality assurance

Table I. The study recruitment, diagnostic stages and medical management

Study participants at respective diagnostic workup	Number of study subjects	
	2003	2004
1. Patients included into the initial diagnostic stage	1648	1504
number of serial fecal occult blood tests	1479	1384
number of surgical/proctologist referrals	788	866
2. Number of patients who underwent		
rectoscopy	304	284
colonoscopy	270	
3. Number the abnormalities found, including:	394	176
confirmed colorectal cancer	14	8
other diseases	380	168
4. Number of referrals for conservative treatment	267	152
5. Number of referrals for surgical treatment	43	24

interventions, specifically the modifications of health system structures, reportedly did not lead to the increased rate of CRC screening [9, 13]. Technically speaking and apparently without cost considerations, not only standard colonoscopy but also computed tomographic colonography (CTC) are beginning to be considered a viable screening method in large populations [14]. Further, the colonoscopic follow-up of positive stool test screening results was recently found efficient in early CRC detection [15]. Patients managed on the out-patient basis, especially those with advanced age, commonly require more persuading and information to understand the objectives and the benefit of CRC screening than those hospitalized, who, on the contrary, more readily accept invasive diagnostic workup [16]. In case of our patients, inclusion criteria allowed for the study participation for those aged less than 65, that to a certain extent might improve patient cooperation and compliance.

The relevance and the role of information, including diet and lifestyle modification, the study subject received during outpatient visit cannot be underestimated. It is noteworthy that a recent study on supplemental and dietary calcium intakes of nearly four thousand patients with histologically verified adenoma found that high supplemental calcium reduced the risk of colorectal adenoma of descending, sigmoid colon and rectum [17]. Although a proven screening method for the reduction of CRC related death risk, fecal occult blood testing has the low sensitivity [6-8]. Fecal occult blood testing can detect only approximately 10% of advanced cases of neoplasia and even DNA testing in CRC screening trails has only a minor advantage (approx. 18%) over fecal occult blood tests in this particular setting [18]. Therefore, it seems that the effectiveness of the managed health care screening programs is related with their continuation throughout several years and emphasizes the need for regular screening in any given subject. The current two-year program is more of an observational study whose results confirm that several CRC related deaths might be prevented in the large urban area annually.

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