ANALYSIS OF THE EFFICACY OF SCREENING TESTS IN COLORECTAL CANCER BY FAECAL OCCULT BLOOD TEST – OWN EXPERIENCE

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Screening of the colon cancer seems to be important to improve the results of the surgical treatment. There are different screening programs, the most common use the fecal occult blood (FOB) tests or colonoscopy.

The aim of the study was to evaluate the results of the colon cancer screening based on the FOB test and perform the algorithm improving the effectiveness of the screening.

Material and methods. 941 patients with the positive results of the FOB (immunochromatographic method) test were investigated. In all cases the rectosigmoidoscopy for the detection of the lower GI tract pathology was done. 312 patients were qualified to colonoscopy.

Results. Adenomatous polyps and adenocarcinomas were detected in 116 patients. There was no correlation between clinical symptoms and the colorectal cancer. The colorectal cancer was recognized statistically more common at the patients with previous detected neoplasia, in the colon and other organs, with hereditary nonpolyposis colorectal cancer and with inflammatory bowel diseases.

Conclusions. The colorectal cancer screening based on the FOB can be effective in the early recognition of the bowel malignancy. The previous questionnaire can eliminate from the FOB screening the patients without indications (previously done colonoscopy or barium enema) or with directly indications for colonoscopy.

Key words: colorectal cancer, mass screening, fecal occult blood test

Colorectal cancer is an increasingly more common neoplasm in both genders, occurring most often in people over 60 years of age. It is estimated that in the Polish population the colorectal cancer incidence is 22-25 per 100,000 in males and 17.6-22 per 100,000 in females, which translates into 4-7 thousand new cases in the country each year (1, 2). Colorectal cancer is in Poland the 3rd cause of death, after lung cancer and prostate cancer in males and lung cancer and breast cancer in females. A steady growth in the incidence of this neoplasm is being observed. According to the data of the Epidemiology Laboratory, Institute of Oncology in Warsaw, the increase in incidence in the analysed 5-year period in the late 1990s was approx. 35% (2).
The lack of mass-scale secondary prevention contributes to the increase in the incidence and mortality rate of this neoplasm. Unfortunately, in Poland, in approx. 60-70% cases colorectal cancer is diagnosed and treated at advancement stage 3 or 4, this is why only less than 20% of patients have a chance of being cured. The widely adopted sequence of neoplastic transformation is based on subsequent stages of cancer development in which the initial stage is the formation of polypoid adenoma. The primary objective of screening programmes aimed at reducing the colorectal cancer mortality rate and conducted in the population of healthy individuals aged 45-75 is early diagnosis and removal of colon polypoid adenoma.

Analysing the programmes and accepted practices aimed at reducing the mortality rate due to colorectal cancer, of note is the fact that they do not focus on oncological or surgical treatment alone but concern to a large extent, if not primarily, the improvement in the detection of these complaints at the early form of their clinical advancement.

Among the basic screening programmes of early detection of colorectal cancer, the predominant ones are models based on the analysis of the presence of occult blood in faeces and on endoscopy, most often flexible rectosigmoidoscopy. Both models are characterised by efficacy in detection of early forms of neoplasm and precancerous stages. Endoscopic examinations have higher sensitivity and specificity, with simultaneous significantly higher costs and weaker patient approval. The analysis of occult blood, relatively cheap and commonly accepted by patients, is a less sensitive and specific method (3). For a long time, the basic, and in practice the only, method of determining occult blood in faeces has been the performance of benzidine test. In this test, globin fragments present in the analysed faeces were analysed. This caused the possibility of significant result falsification by the presence of other, extrasytemic globin sources, such as meat, cold cuts, certain legumes or soups. Currently, the previously used benzidine test actually has a historical value. The binding programmes are based on guaiac or immunohistochemical methods. The guaiac test consists in detecting haemoglobin peroxidase in faeces. It is positive in 50% of patients in whom the blood loss with stool is 20-40 ml daily. The percentage of false negative results (e.g. in patients taking vitamin C) is estimated at 50%. False positive results may be caused by the intake of food products containing peroxidase – chicken meat, pork, goat meat, beef, rabbit meat, horse radish root, red radish, fresh turnip, cauliflower, broccoli, parsnip. The limitation of this test is the need for, similarly as in the benzidine test, banning the consumption of the above food products for 3 days prior to the test. Unfortunately, most commonly, the individuals participating in the test are not properly prepared for it. The test that does not require any dietary restrictions as is at the same time characterised by twice higher sensitivity with comparable specificity is the immunohistochemical test (4). The test detects, in a specific manner, only human haemoglobin, while the sensitivity and specificity of this analysis method is assessed as 94.1% and 87.5%, respectively (5). These tests may be positive already at the 25 ng/ml haemoglobin level in the sample, with the result accuracy not being affected by dietary factors, interfering substances or patient’s condition (6).

Screening studies based on large patient groups (such as national programmes for early detection of cancer) emphasise the role of occult blood tests as extremely effective in terms of population. Although their sensitivity and specificity is lower than in endoscopic examinations, the percentage of participants in studies based on occult blood tests is higher, which translates into higher population effectiveness (7). In the 1980s and 1990s, there were conducted in many countries population and screening studies aimed at improving the detection of early colon neoplasms. The largest ones include: the Swedish study involving individuals aged 60-64 (8), the English study involving patients of family doctors (9) the Danish controlled study on the population aged 45-75 (10,11) and the Memorial Sloan-Kettering Cancer Center-Strang Clinic (MSKCC) study completed in 1985 (12). Due to the required relatively long follow-up period for the full evaluation of efficacy of a given examination model (patient life span, long-term follow-up monitoring the course of cancer treatment) the complete clinical data are usually available many years after the performance of occult blood tests. All the above studies have been characterised by reduced mortality due to colorectal cancer. Studies conducted later confirm their effectiveness and efficacy.
Analysis of the efficacy of screening tests in colorectal cancer by faecal occult blood test

One of the latest available in literature reviews of studies, being a meta-analysis covering in total 320,000 participants, fully confirms that the occult blood test is a very good method with 16% reduction in mortality due to colorectal cancer (13). Even better results, explained by high self-discipline of the society and acceptance of endoscopic examinations, are reported by the Japanese researchers reporting a 30% reduction in mortality due to colorectal cancer in patients subject to screening tests based on faecal occult blood test (14). Similar, very good, results have been produced by the national programme for the early detection of colorectal cancer in Taiwan (15). The efficacy and effectiveness of screening tests, including those based on the detection of occult blood in faeces, is decided to a large extent by the widespread participation of individuals from a given age group (16).

The opinions on whether to use screening tests based on the analysis of occult blood or on endoscopic methods or on both the above methods used at the same time are divergent. The current European guidelines suggest that more effective is the model based on the occult blood test and colonoscopy in the case of a positive result (17). Similarly current Asian studies suggest that due to the low sensitivity and specificity of occult blood test it is more advisable to perform colonoscopy alone as a screening test (18). However, it seems that irrespectively of the adopted protocol of screening tests, each of the above models of screening tests is economically effective in terms of population (19). It is also emphasised that the conducted programmes for early detection of colorectal cancer contribute to the increase in the detection of other complaints, including neoplasms of different localization or different histological structure (20).

The aim of this study was the optimization of the manner of conducting screening tests for the early detection of colorectal cancer based on the determination of occult blood in faeces. To this end, a test qualification questionnaire was developed.

MATERIAL AND METHODS

Study group characteristics

All the patients covered by the study participated in the screening test programme “Prophylaxis and early detection of colorectal cancer – faecal occult blood tests”. The programme was conducted in the Greater Poland province in the years 2007-2009 and was financed by the Greater Poland Marshal Office and the Town Council in Poznań. The programme is directed to the residents of the Greater Poland province aged 50 and above.

The programme is based on annual determination of faecal occult blood, each participant (individuals aged 50 and above) may have done, free of charge, faecal occult blood test once a year. The executor of the programme is the Social Foundation “Ludzie dla Ludzi” [People for People], the site is Ośrodek Profilaktyki i Epidemiologii Nowotworów (OPEN) [Centre for Neoplasm Prophylaxis and Epidemiology] in Poznań. These studies were conducted in collaboration with and upon approval of Ośrodek Profilaktyki i Epidemiologii Nowotworów in Poznań.

In the analysed period, there were 5000 people reporting for examinations, of which in 1066 the result of faecal occult blood test was positive, while in the other individuals the results of faecal occult blood test was negative.

The study authors had no influence on the course and execution of the screening test programme. The colorectal cancer screening test programme is directed, as a principle, to asymptomatic individuals. However, some of the patients were included in the programme despite the presence of alarming gastrointestinal symptoms (haemorrhage, disturbed rhythm of faecal evacuation, change in the stool shape, etc.), positive history (hereditary neoplasms in the family, positive neoplasm history) or, on the other hand, previously (less than 5 years) undergone check-up colonoscopy. The procedure described by the authors further in the study was therefore a sort of “secondary verification” to the participation in screening tests. However, it should be unambiguously and firmly emphasise that the positive result of faecal occult blood test in an asymptomatic patients constitutes an absolute indication for the performance of check-up colonoscopy.

Faecal occult blood test

In all programme participants, immuno-chromatography was used for the detection of occult blood in faeces. Stool samples were collected with the use of FOB Advance kit
who were referred for check-up rectoscopy. In the course of the programme, 30 individuals were excluded from follow up due to accidental situations (other diseases, deaths, family situations, travel abroad, change of decision on participating in examinations).

The final group subject to analysis encompassed 941 individuals. Based on questionnaires, basic clinical data were collated for those individuals. The above information was collated in a database based on which further statistical analysis was performed.

Patient check-up examinations, along with endoscopic examinations, were performed pursuant to the approval of the Bioethics Committee at the Poznań University of Medical Sciences (Resolution 700/08).

Rectoscopy

The examination was performed in an outpatient setting upon a prior independent patient preparation by performing enema. The examination was performed with the use of sigmoido-proctoscopic KIT RTE (Heine, Germany) using disposable tubes of 25 cm. In the performed rectoscopy, there were evaluated potential causes of the presence of occult blood in faeces. In 3 cases, rectal cancer was diagnosed and the patients were referred for pre-operative radiation therapy and further surgical treatment. The other patients with diagnosed polyps were referred directly for colonoscopy, the patients with diagnosed non-cancerous complaints of the lower gastrointestinal tract (haemorrhoids, anal fissure, inflammation) were treated for approx. 3 weeks and referred repeat, performed twice, faecal occult blood test. In cases of another positive result and absence of symptoms indicating bleeding from haemorrhoids or their inflammations, the patients were referred for colonoscopy.

The patients with a negative result were informed about the principles of prophylaxis and the symptoms of neoplastic diseases of colon. Subsequent check-up visits were arranged depending on the diagnosis. The patients without pathological lesions, with negative results of faecal occult blood test on two occasions, were encouraged to repeat the occult blood test within a year.

The performed rectoscopy was not treated in any manner as standard verification of the
positive result of occult blood test. It was aimed at diagnosing conditions within the course of which rectal bleeding occurred (active haemorrhoids) in patients who should not with this type of symptoms participate in screening tests. Upon treating the acute conditions, each time the faecal occult blood test was repeated. Further approach consisted in, as per the standard, referring, in each case, the patient with a positive result for check-up colonoscopy.

Colonoscopy

Colonoscopy was performed at the Laboratory of gastrointestinal Endoscopy, F. Struś Municipal Hospital in Poznań. Colonoscopy was performed in 310 patients. All colonoscopy examinations were performed with anaesthesia. A definite majority of examinations (97%) was performed under general anaesthesia, while in remaining cases (3%), when there where present contraindications against general anaesthesia (cardiorespiratory failure, other conditions) or consent was not granted by the patient, under short-term analgesedation. Colonoscopy examinations were performed with the use of OLYMPUS equipment: CF 2T165L; CF-Q165L; CF-Q180AI; CF-Q180AL; CF-2T160L.

In cases of diagnosed polyps qualifying for polypectomy, the procedure was performed at the same time with the use of standard endoscopic equipment. In 14 cases, cancer was diagnosed during colonoscopy. In 8 cases, carcinoma in situ was diagnosed in the resected poly, with the polyp stalk being free of neoplastic lesions. In 6 cases, due to the advancement of neoplastic lesion, patients were qualified for surgical treatment which in all cases consisted in radical resection of the lesion with adequate intestinal margin.

In the performed colonoscopy examinations, in the studied group, there were observed 5 complications (1.6%) requiring hospitalization of 1-2 days (post-polypectomy bleeding and moderate abdominal pain). All the complications occurred in patients subject to polypectomy. None of the cases laparotomy was required.

Statistical analysis

The data concerning age, gender, patient’s clinical symptoms and incidence of malignant and benign colon lesions were presented in the form of tables with absolute numbers and percentages of the total number of patients in studied groups. The univariate analysis of incidence of individual complications post the procedure was compared with the Fisher’s exact test and with the use of $\chi^2$ test. The multivariate analysis was performed by logistic regression, there was studied correlation between patient’s clinical symptoms, history elements, gender, age, and the presence of neoplastic lesions in the colon. Statistical significance was accepted at $p < 0.05$. Statistical calculations were performed with the use of StatXact (Cytel Inc) and MedCalc (MedCalc Software) software.

RESULTS

The mean age n the studied group was 60.82 ± 7.22, with the mean age of males (59.74 ± 7.10) being significantly lower than the mean age of females (62.17 ± 7.16; $p = 0.0001$). Patient’s age was not a factor significant for the studied clinical symptoms (blood, mucus in faeces, constipation, haemorrhoids, change in the rhythm of faecal evacuation). However, age proved a statistically significant factor. With increasing patient’s age, the likelihood of the need for colonoscopy and diagnosis of pathological lesions in the form of single adenomas, multiple adenomas and malignant neoplasms in rectoscopy and colonoscopy rose.

Patient’s gender was a significant factor in qualification for colonoscopy (significantly more often in males), the presence of multiple (more than one) colon polyps diagnosed by colonoscopy and colorectal cancer diagnosed by colonoscopy (both lesions significantly more frequent in males) in males. Gender had no influence on the other analysed symptoms, risk factors and examination results.

There were also analysed subsequent elements of the clinical study, with statistical significance being determined between the occurrence of specific symptoms and positive history reported by patients and the presence of cancer diagnosed by rectoscopy or colonoscopy. It was accepted, in terms of localization, that cancers diagnosed by rectoscopy were deemed rectal cancers, while those diagnosed by colonoscopy as colon/sigmoid colon cancer. There was achieved high convergence of results for rectal and colon/sigmoid colon cancers.
In total, colonoscopy was performed in 312 individuals. The indications were pathological lesions (polyps, cancers) diagnosed by rectoscopy or another positive results of faecal occult blood test in patients in whom rectoscopy did not reveal pathological lesions. The results of performed examinations are presented in the table and on the chart.

No correlation was observed between the analysed clinical symptoms (blood in faeces, mucus in faeces, constipation, change in the rhythm of faecal evacuation, change in stool shape, pain at defecation, haemorrhoids, haemorrhoids with active bleeding) and the presence of rectal cancer and colon/sigmoid colon cancer. The use of anticoagulants did not have a statistical correlation with the diagnosis of colorectal cancer either.

The incidence of rectal cancer and colon/sigmoid colon cancer was statistically significantly higher with patients with previously diagnosed neoplasms of both colon and other organs and in patients with family history of hereditary nonpolyposis colorectal cancer. The presence of inflammatory bowel diseases had no influence on the presence of rectal cancer but was statistically significant for the occurrence of colon/sigmoid colon cancer.

There was also evaluated the correlation between the remaining clinical data and the results of performed endoscopic examinations. The analysis was performed with the use of $\chi^2$.
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Macroscopically present blood was not a significant factor for the occurrence of single adenomas in rectoscopy (p = 0.3781, ns), multiple adenomas in rectoscopy (p = 0.3814, ns), cancer in rectoscopy (p = 0.2176, ns), single adenomas in colonoscopy (p = 0.2782, ns), multiple adenomas in colonoscopy (p = 0.7904, ns), cancer in colonoscopy (p = 0.6383, ns). Mucus was not a significant factor either for the occurrence of single adenomas in rectoscopy (p = 0.8993, ns), multiple adenomas in rectoscopy (p = 0.9903, ns), cancer in rectoscopy (p = 0.6625, ns), single adenomas in colonoscopy (p = 0.9306, ns), multiple adenomas in colonoscopy (p = 0.1111, ns), cancer in colonoscopy (p = 0.1841, ns).

Macroscopic presence of blood in faeces reported by patients did not correlate with any of other analysed clinical features, such as presence of mucus in faeces, constipation, use of anticoagulants (p = 0.9226, ns) or even haemorrhoids (p = 0.4115, ns).

DISCUSSION

In the performed studies, age qualification criterion was applied of at least 50 years of age. This standard is quite commonly applied and corresponds with the standards of the majority of colon screening tests in asymptomatic population (21, 22). A significant portion of studies is based on a closed age range of participants and its upper limit is the age of 70 (23), 75 (22, 24, 25) or even 80 (26). Sometimes, this range is made even narrower, to e.g. 60-69 in Canadian studies, but this usually applies to studies conducted on a smaller sample size. The variations in the age qualification criteria may affect the results of the studies, as the prevalence of colorectal cancer increases with age.
scale and more of epidemiological nature than of national screening programmes (20). In the evaluated programme of screening tests, no upper age limit was adopted. Such an approach seems to be fully justified, Despite the open nature of examinations, only 32 individuals aged above 75 reported to it, which constitutes 3.2% of the studied group. Therefore, this had no significant impact on the costs or organisational burden of the programme, yet it was a form of reaching as broad a group of participants as possible and did not eliminate the elderly, which could constitute a factor lowering their self-esteem (“I’m too old to get examined”). Usually, the age limitation in the adopted screening test programmes stem from potential predispositions of individuals aged above 75, which might limit the indications for further endoscopic examinations or surgical approaches, which significantly lowers the programme effectiveness. In the studied group, out of 94 individuals excluded from further examinations, only in 18 the indirect cause was advanced age of the patient (other diseases, poor general condition, lack of understanding of programme premises, absence of consent to further examinations). It should also be noted that in the group of individuals aged above 75, there were found by endoscopy as many as 8 single polyps, one case of multiple polyps and one malignant neoplasm (early lesions, excised endoscopically). This is, of course, associated with the risk, cumulating with age, of lesions of benign and malignant neoplasm nature in the colon. The adoption in the assessed examinations for the detection of colorectal cancer, based on the assessment of faecal occult blood based on faecal occult blood tests, of no upper age limit seems to be definitively justified and recommended in the further part of the programme.

Screening tests for early diagnosis of colorectal cancer are by principle directed to a broad group of individuals. Most commonly, the only criterion (apart from symptoms suggesting the need for performing specific diagnostic examinations) is the abovementioned age criterion. Programmes are conducted for many years, and their effectiveness is evaluated in long, often of a dozen or so years, time ranges. An example could be one of the first screening test programmes based on the occult blood tests executed in the United States of America: “The Minnesota trial” (26). The examinations were performed in the years 1975-1982 on 46,551 participants aged 50-80, and the results were evaluated after 18 years. There was found a reduction in mortality due to colorectal cancer by 33% (26, 27). One of the largest screening studies based on faecal occult blood test was the randomized English study conducted in the years 1981-1995 in Nottingham on a group of 152,850 individuals. The results were evaluated after 14 years, finding a reduction in mortality due colorectal cancer by 12% (28). A significant portion of population (1.15% of country residents) was covered by the randomised Danish study in the Funen area conducted in the years 1985-2002 on a group of 61,933 individuals. The results of this study, evaluated after 7 years, confirmed the previous observations, indicating a reduction in mortality due to colorectal cancer by 18% (29).

The results of presented studies are of course of limited character due to the number of patients qualified for the programme. Therefore, it is not possible, based on the results of those studies, to formulate conclusions of population and epidemiological nature or to evaluate the influence of the programme on the reduction in the colorectal cancer incidence and mortality rate. However, the conducted studies allow to determine the impact of the screening examination based on faecal occult blood test on the frequency of diagnosing neoplastic lesions within colon, correlation of those lesions with clinical symptoms and positive history and the usefulness of the questionnaire used in preliminary qualification of patients for examinations.

In the analysed group, the presence of malignant neoplasm diagnosed based on colonoscopy was found in 1.5% of individuals with a positive result of faecal occult blood test, which is a figure significantly higher than the neoplasm incidence in the Greater Poland population of 34.3/100,000 individuals (30). Of course, it should be remembered that the Greater Poland rate concerns the whole population (all the residents, irrespective of age). However, even taking into account patient’s age in the conducted studies (predisposing to neoplastic lesions in the colon) and the higher percentage of males (more at risk of developing colon neoplasms), it is still evident that the frequency of diagnosing cancer in the studied group is very high. This confirms the efficacy of the programme premises, based on the qualification based on the presence of occult blood in faeces.
The evaluated clinical symptoms of colorectal cancer are non-specific and vary depending on the neoplasm advancement and localization. The most commonly listed ones include the presence of macroscopically visible blood in faeces, the visible presence of mucus in faeces, change in the rhythm of faecal evacuation, alternating diarrhoea/constipation, development of constipation in individuals who had not experienced it before, constant feeling of urgency, abdominal pain associated or not with defecation, or change in the stool shape. The presence of the above symptoms should induce the patients to report to a physician who should refer them for further examinations depending on the type of predominating clinical symptoms. The development of symptoms by definition qualifies the patient to the group of symptomatic patients who should be treated until the time of unambiguous diagnosis as suspected neoplastic diseases. It is commonly accepted that the presence of clinical symptoms, particularly blood, constitutes a symptom increasing the likelihood of colorectal cancer. The absence of such a correlation in the above studies seems to be associated with two factors. Firstly, the patients qualified for studies are patients with diagnosed presence of occult blood in faeces. Therefore, by assumption, they constitute a high-risk group, where the macroscopically visible traces of blood does not have an impact on the increase in the risk of cancer, constitutes more a visualisation of a symptom than the symptom itself. Secondly, the definite majority of patients quoting in the questionnaire the presence of macroscopically visible blood also had haemorrhoids, including bleeding haemorrhoids.

A different, interesting and still discussed issue is the influence of anticoagulants on the results of faecal occult blood test. It is often stated that anticoagulants lead to the increase in the percentage of false positive results. This statement is not correct, since the use of the abovementioned drugs might potentially increase the risk of minor, subclinical gastrointestinal bleeding and in fact lead to the occurrence of traces of blood in faeces allowing its detection with the use of faecal occult blood tests. Therefore, it is a truly positive result, yet not correlated with the presence or absence of neoplastic lesions in the intestine. It is commonly assumed that the use of the abovementioned drugs increases the risk of the positive result in the faecal occult blood test.

The patients participating in the programme often emphasised that they were recommended the discontinuation for several days of anticoagulants prior to the performance of faecal occult blood test. However, in the comparative analysis performed by us, the incidence of malignant ad benign neoplastic lesions in the colon had no correlation with the use of anticoagulants by patients. This interesting observation is confirmed by studies of other authors, analysing the intake of warfarin on the results of occult blood tests and not finding any influence of this drug on the results of faeces tests (31).

As long as the presence of the listed clinical symptoms seems to have no influence on the presence of neoplastic lesions in the colon, the risk factors concerning the positive history proved to be strongly correlated with the risk of colon adenomas. In the performed analysis of results, it was found that the incidence of rectal and colon/sigmoid colon cancer was significantly higher in patients with previously diagnosed neoplasms of both the colon and other organs, and in patients with positive family history of hereditary nonpolyposis colorectal cancer (HNPCC). The presence of inflammatory bowel diseases did not have any impact on the presence of rectal cancer, but was statistically significant for the development of colon/sigmoid colon cancer. This observation is in agreement with numerous observations of other authors (32,33). The presence of inflammatory diseases increases the risk of colorectal cancer, with this risk increasing with the disease duration, particularly after 8-10 years since the appearance of the first disease symptoms (34). The risk of cancer also increases in individuals with previously diagnosed colon polyps (35).

Particular attention should be paid to patients in whom based on the pedigree analysis and clinical features HNPCC or polyloid symptoms might be suspected. An earlier presence of mesogastric neoplasms, the presence of polyps or the presence of several persons with neoplastic disease of the colon constitute significant suggestions for diagnosing HNPCC.

In the group studied by us, there was found the presence of inflammatory lesions in 4 patients, positive history of intestinal neoplasms, including benign ones, in 32 patients, other neoplasms in 57 cases, and pedigree features of HNPCC or suspected HNPCC in 16 patients. In as many as 5 cases, coexistence of at least two of the above predispositions was found. It
is clear that those patients should not be included in the programme of screening tests prepared for the asymptomatic population, since the risk factors present in them unambiguously indicate the need for covering them with regular endoscopic monitoring, medical care, and in some cases genetic counselling.

One of the objectives of conducted studies was the evaluation of the presence of clinical symptoms in the analysed group and their correlation with the presence of benign and malignant lesions in the colon, diagnosed based on endoscopic examinations.

When evaluating the usefulness of the evaluation of symptoms and positive history on the possibility of preliminary selection of patients with increased risk of colon neoplasms, there should be emphasised the most significant role of the patient medical history. As it transpires from the presented in the results section correlation, the presence of inflammatory diseases, previous precancerous and neoplastic lesions in the intestine and other organs, and familial aggregation of colon neoplasms significantly increase the risk of intestinal polyps and cancers. This is why particular attention should be paid to the group of patients to whom the screening test programme should not be applied and who should be referred directly for check-up colonoscopy. A significant portion of patients are included in the programme of determining faecal occult blood due to the improperly functioning medical care or failure of informing them by the physician about the increased risk of colon neoplastic disease and the need for regular colonoscopy examinations. The programme also included a group of patients in whom no indications existed for determining faecal occult blood since those patients had undergone within a short period prior to the examination (maximum of 2 years) colonoscopy or imaging examination of the colon.

Thus, it seems that there exists a definite need for defining the manner of qualifying those reporting for participation in the programme of screening tests of early colorectal cancer detection. This should improve the efficacy of this programme, while at the same time lowering its costs.

The primary qualification criteria should concern at the preliminary stage only the need for examination of individuals who had undergone diagnostic examinations of the gastrointestinal tract ruling out the presence of neoplastic lesions (colonoscopy, contrast colonic enema, CT colography). The determination of occult blood in such patients is not justified and unnecessarily increases the programme costs. On the other hand, there should be selected the group of individuals in whom increased risk of colon neoplastic lesions exists and they should be referred directly for colonoscopy. Based on the observation of programme participants, such patients are well aware of the risk and in vast majority fully accept the need for colonoscopy. Some of those patients admitted that they took part in the screening examination only to “get to” colonoscopy. The fact that those patients had problems and restrictions in the performance of examination necessary for them unfortunately constitutes a reflection of still inadequately functioning system of planned and standard diagnostics, and it often is a reflection of too limited knowledge of physicians about the predispositions for colon neoplasms.

In the analysis of results of this programme, there was shown the absence of correlation between the presence of analysed, most typical, clinical symptoms and the risk of precancerous or neoplastic lesions in the colon. This is why it seems that the attempt of qualification based on the analysis of symptoms seems little appropriate. There exists large subjectivity in the evaluation of symptoms by patients, and besides this some of them might not understand the seemingly simple questions (e.g. the question about constipation for many individuals meant only the presence of hard stool irrespective of the frequency of its evacuation). Attention should also be paid to the fact that some patients, being aware that the presence of gastrointestinal clinical symptoms eliminates them from the participation in the programme, might intentionally omit such symptoms, not wanting to lose the possibility of expediting and facilitating the diagnostics.

The analysis of data collected from the survey may be performed in many ways, immediately after the questionnaire completion, at the qualifying centre, or during the meeting with the patient.

It seems that the best manner of preliminary qualification should be a questionnaire that is easy to fill and analyse, the basic premises of which are presented below.

As evidenced by observations concerning the completion of questionnaires by the patients, both in this and in many other studies
conducted previously at the Centre, the simpler the questions are formulated, the higher the percentage of complete, correctly filled-in questionnaires. An important criterion was also the number of questions, the increase in their number above the symbolic limit of "one page" often discouraged the patients or constituted an impediment, for instance for the elderly or those with impaired vision.

This is why in the case of screening tests based on the analysis of faecal occult blood it is necessary to focus on:

- excluding from further examinations the individuals in whom there are no indications for further diagnostics of the gastrointestinal tract and those declaring lack of consent to further colonoscopy examinations
- disqualification from faecal occult blood test of individuals at high risk of colon neoplasm (and direct referral of those patients for colonoscopy examination)

In the proposed questionnaire, presented below, questions 1-3 are aimed at excluding patients from the screening test programme due to the absence of indications for colon diagnostics. If within the last several years (maximum of 5) intestinal examination has been performed and has not revealed any pathologies, there are no indications for repeating such examination, similarly to a situation where the patient has already been qualified for such examination and is awaiting its performance. The answer “yes” to any of questions 1-3 causes the patient to be informed about being excluded from further studies, the reason for such a situation and when they should undergo check-up examination.

Questions 4-7 are aimed at identifying the group of patients at high risk of colon neoplastic lesions. In the case of answer “yes” to any of the questions, the patient is subject to further analysis (particularly questions 4 and 6 requiring a more detailed verification) conducted in person or by phone, depending on the adopted model, and referred directly for colonoscopy examination.

Patients answering “no” to all questions 1-7 are qualified for faecal occult blood test and further management depending on its result.

CONCLUSIONS

1. Colorectal cancer screening tests based on the determination of faecal occult blood may be effective in the early detection of malignant and benign neoplastic lesions in the colon.

2. Clinical symptoms reported by the patients with occult blood present in faeces do not correlate with the occurrence of colon neoplasms.

3. The qualifying questionnaire should eliminate from the screening test the patients without indications for its performance (previously performed colonoscopy or contrast colonic enema) or requiring, due to the positive history, a direct referral for colonoscopy.

Questionnaire for individuals interested in participating in the faecal occult blood test

Full name .................................................................
Date of questionnaire completion .................................
Date of birth ..................................................................
Address of residence ....................................................

1. Have you ever been colonoscopy performed?  YES NO
When?.........................

2. Have you ever had contrast colonic enema performed?  YES NO
When?..............

3. Do you have planned check-up colon examinations in the nearest future?  YES NO
If yes, please state what examinations and approximately when: .................................

4. Have you suffered or do you suffer from an inflammatory bowel disease (ulcerative colitis, Crohn’s disease)  YES NO
Please state what diseases and for how long ...

5. Have you been diagnosed with a colon neoplasm (tumour, polyp, cancer)?  YES NO
If yes, please state what neoplasm and when..

6. Have you been diagnosed with a neoplasm of another organ?  YES NO
If yes, please state what neoplasm and when..

7. Have neoplasms of the gastrointestinal tract been diagnosed in your family?  YES NO
If yes, please state in whom, at what age and what type of neoplasm

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Thank you for your answers
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