VILNIUS UNIVERSITY

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COMPARATIVE ANALYSIS OF CT COLONOGRAPHY DATA AND THEIR ASSESSMENT IN THE EXAMINATION OF TUMOUR FORMATIONS

Summary of Doctoral Dissertation

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Dileta Rutkauskaitė

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ABBREVIATIONS

CRC	colon cancer
CS	colonoscopy
CT	computed tomography
CTC	computed tomography colonography
C-RADS	Colonography-Reporting and Data System
FOBT	faecal occult blood test
BMI	body mass index
2D	two dimension
3D	three dimension
PPV	positive predictive value
NPV	negative predictive value

INTRODUCTION

Relevance of the study

About half of million deaths caused by colorectal cancer (CRC) have been reported worldwide every year. Mortality associated with CRC in Lithuania has remained constantly high during the recent decade: 1354 cases were reported in 2001, 1491 cases – in 2005 and even 1629 cases were reported in 2011. Early diagnostic programmes for CRC serve to reduce mortality rates of this disease, when a cancer is detected earlier giving an opportunity for less complex curative treatment as well as for detection and resection of adenomas – precursors of CRC – leading to the potential prevention of cancer development. Screening programme for CRC involving people aged 50 to 74 in Vilnius and Kaunas districts has been initiated in 2009. The National Health Insurance Fund allocated surely big amount of financial resources – 12.636 million Litas – to finance this programme for the period 2009-2012, however only 85.4 % of these means were used. As in a majority of countries, the screening programme for CRC in Lithuania is based on the use of faecal occult blood test (FOBT). It has been proved that this test is

associated with reduced risks of colorectal cancer mortality. Faeces occult blood tests (FOBT) (based both on guaiac acid (gFOBT) or immunochemical (FIT) assay techniques) are widely used, accepted for screening purposes and cost-effective. If positive results of FOBT are received, the patients are referred for colonoscopy (CS), and cancer diagnosis is often confirmed during this procedure; endoscopic excision of smaller adenomas and malignant tumours is also possible. Still and all, colonoscopy can be carried out incompletely; it can be contraindicated or refused by a patient. This means that patients exposed to a risk of malignant disease remain not diagnosed and untreated. Based on the data of State Sick Fund, a positive FOBT result was obtained in 7.2% of the patients participating in the programme during the first three years of its implementation, whereas only 52.4% of these patients had CS examination. However, according to the European guidelines for quality assurance in colorectal cancer screening and diagnosis acceptable level of this index is > 85%, and a target value should be 90%. In addition, a complete CS with examination of the entire bowel cannot be carried out in the case of every patient (57-99.4 %).

Alternative CS study is required aiming to increase a number of diagnosed CRC cases. One of the options is a computed tomography colonography (CTC). CTC (also known as virtual colonoscopy) is a computed tomography examination designed for visualisation of polyps and masses in the colon, previously inflated with air, applying an assessment of two-dimensional (2D) and three-dimensional (3D) images.

CTC is recommended when CS examination is contraindicated or was carried out incompletely. This recommendation is substantiated by meta-analyses and randomised studies.

In our opinion CTC could be carried out for the patients with positive FOBT result, who agree to participate in the CRC screening programme, but refuse to undergo CS examination. A number of subsequent CS examinations would increase if CTC were offered as an alternative to endoscopic examination in tracking lesions. Data of available meta-analyses and randomised studies can be used to substantiate the use of CTC for the screening of CRC. However, considering an extensive application CTC examination for FOBT positive patients, one has to take into consideration the exact sensitivity and

specificity of this method in diagnostics of cancer and adenomas, when applied for the patients of namely this group. Since FOBT positive patients have been diagnosed with malignant bowel disease more often, a very sensitive examination method with as high as possible negative prognostic value (NPV) is required for diagnostic purposes.

Therefore we conducted a study aiming to establish a diagnostic value of CTC for the diagnostics of neoplastic alterations in FOBT positive patients.

The aim of the study

To establish a diagnostic value of CTC examination and the factors affecting the quality of examination in FOBT positive patients, involved in the programme for early diagnostics of CRC.

Objectives

1. To determine the sensitivity and specificity, as well as positive and negative prognostic values of CTC; to compare them with CS, for the diagnostics of lesions ≥ 6mm of size in FOBT positive patients.
2. To determine the sensitivity and specificity, as well as positive and negative prognostic values of CTC; to compare them with CS, for the diagnostics of middle sized (6-9 mm) and large (≥ 10 mm) polypus in FOBT positive patients.
3. To determine the sensitivity and positive prognostic value of CTC, to compare them with CS, for the diagnostics of neoplastic adenomas and CRC in FOBT positive patients.
4. To assess frequency and importance of extra-colonic findings reported during CTC examination.
5. To assess the level of tolerance of CTC examination as well as the correlation between the quality of examination and tolerance with the length of colon in the cases of analyzed patients.

Scientific novelty and practical significance

Non-invasive examination method – CTC – is available for the diagnosis of neoplasms in the colon for the patients with increased risk of malignant colorectal disease. CTC examination for such patients can be carried out after unsuccessful CS or with contraindications for this examination, as well as for the patients refusing to undergo CS. In such situation a routine application of CTC examination for the high-risk group patients would allow to reach better diagnostic indicators for CRC. Availability of an alternative method for colon examination would allow to improve the examination of FOBT patients, who fail to show up for the recommended CS examination.

There have been only few publications presenting the detailed and accurate analysis of CTC examination for FOBT positive patients involved in a colorectal cancer screening programme. We have failed to identify publications assessing the correlation between the quality of CTC examination and toleration by the patients with the anatomical peculiarities of the colon, i.e. length of the intestine. This is the first research analysing CTC examination in Lithuania.

Principal statements for defence

1. CTC is considered as an accurate examination technique for the diagnosis of colorectal lesions ≥ 6 mm of size in FOBT positive patients.
2. CTC is a sensitive examination technique for the diagnosis of neoplastic adenomas and colorectal cancer in FOBT positive patients.
3. A lot of clinically significant extra-colonic findings have been detected during CTC examination.
4. The tolerance of CTC examination and its quality depend on the anatomical peculiarities of colon, i.e., length of intestine.

MATERIALS AND METHODS

Patients

The regional Vilnius bioethics committee has issued the approval to conduct this prospective study (Nr. 158200-07-366-93). The study material was collected during the period of June 2011 to May 2013 in the 3rd department of Centre of Radiology and Nuclear Medicine of Vilnius University Hospital Santariškių Klinikos.

Inclusion criteria:

1. Subjects 50-74 year old, involved in the programme for early diagnostics of CRC.

2. A subject is conscious, is able to execute commands and to withhold breathing.

3. A subject signed Informed Consent Form.

Exclusion criteria:

1. Subjects not involved in the programme for early diagnostics of CRC.

2. A patient is unstable, unconscious, and not able to execute the commands and to withhold breathing.

3. A person refuses participating in the study and did not sign the Inform Consent Form.

4. Allergy to iodine containing contrast substance.

6. A subject with known renal impairment.

102 study subjects with positive FOBT result were enrolled into the study; they were examined carrying out CTC and CS examinations. A complete CS examination was carried out for 101 studysubject out of 102, thus only 101 study subjects were included in the further data analysis.

Demographic data – age, gender, height and weight – of the subject were collected and body mass index (BMI) was calculated using the equation: BMI = Body mass (kg) / height (m x m). Referral values: BMI < 18.5 – too-small weight; 18.5–24.9 – normal weight; 25–29.9 – overweight; > 30 – obesity.

CTC protocol

To prepare bowels for examinations the study subjects followed a low fibre diet for several days before a colon examination and received medicines to clean bowels the day before examination (Fortrans 3-4 litres or Cololyt 3 litres). An oral contrast preparation for faeces and fluid tagging was not applied during bowel cleaning period.

CTC examinations were carried out using 16-slices computer tomography scanner (GE LightSpeed Pro (General Electric Healthcare, Milwaukee, WI, USA)). Before the start of scanning procedure the bowels of the patient, lying on a table of CT scanner, were manually inflated with an air (within the patient's tolerance limits, ~700-900 cm^3) via disposable tip through the anus inserted into the rectum. After a CT scout was performed, the amount of air in the colon was re-assessed for the patient lying prone, and if inflation was insufficient, a few additional air blows were made. The patient underwent scanning in two positions – firstly – lying prone, and then – lying supine.

The parameters of computed tomography colonography: duration of a single rotation of a X-ray tube 0,7 s, slice thickness 1,25 mm, X-ray tube voltage 120 kV, 48 effective mAs for a patient's prone position, for a patient in supine position - 200/240 effective mAs. Intravenous contrasting with non-ionic contrast material was applied during scanning in supine position; the contrast material was injected into a peripheral subcutaneous vein of elbow fossa via automatic syringe (Ulrich Ohio tandem; Ulrich GmbH & Co, Ulm, Germany), injection rate was 3 ml/s, and dose was calculated according to body mass – 1-1.5 ml/kg body weight. The start of scan was set with 60 seconds delay.

CTC post-processing analysis

CT images were sent to the radiology Advanced Workstation 4.2 (GE Milwaukee, WI, USA), the processing and assessment of the images was performed with the Advanced CTC software. Using the above-mentioned software the CTC images were

assessed as axial images, multiplanar reconstruction and three-dimensional (3D) images. All CTC analyses were performed only by a one scholar.

CTC colonic findings

Colonography-Reporting and Data System (C-RADS) was used to describe the lesions discovered in a colon, which is used according to general agreement made in 2005 by Working Group on Virtual Colonoscopy. Analysis included lesions sized 6 mm and more, the biggest measurement of a polypus or formation (> 3 cm) was measures (except a peduncle, if applicable). CTC images were assessed as axial images, multiplanar reconstruction and three-dimensional (3D) images.

Polyps of the colon were measured and were assigned to three groups based on the size of tumour mass: group 1 – all lesions sized ≥ 6 mm; group 2 – lesions sized 6-9 mm; and group 3 – lesions sized ≥ 10 mm. Group 1 covered lesions assigned to groups 2 and 3. The findings in a colon of each study participant based on the above mentioned characteristics were classified to a separate categories according to the scale proposed by C-RADS. The morphology of polyp was classified as follows: sessile – a polyp with a large base, its width is larger that a vertical measurement; pedunculated – a polyp with individual peduncle; flat – a polyp with its vertical measurement less than 3 mm above the surrounding mucosa of a colon. A location of lesion was divided into six segments of a colon: caecum, ascending, transverse, descending, sigmoid and rectum. Only lesions of soft tissues density were included into the study data. The findings in a colon of each study participant based on the above mentioned characteristics were classified to separate categories according to the scale proposed by C-RADS (C0-C4). C-RADS was also applied to assess extracolonic findings as well as to assign a patient to a specific category based on these findings (E0-E4).

CTC study quality assessment

Colon distention evaluation

Colon distension was evaluated according to adapted de Haano et al. methodology, following which every segment of the colon was evaluated for the patient lying on his (her) back and a stomach in 2D CT images – caecum, ascending, transversal, descending, sigmoid and rectum.

Distension of the colon in each individual segment was assessed applying 0-3 points scale (the part of lowest distension was assessed) – 0 points – <25 % of gut lumen was distended, 1 point- 25–50 %, 2 points – 50–75 %, and 3 points – > 75 %. Individual segments of the colon were assessed applying this scale for a patient lying on his (her) back and a stomach, in the location in which higher distension score was reported. Qualitative assessment of general distension of the entire colon was carried out applying the above mentioned score system, summing up all scores of the distension of individual segments (poor – 0-11 points, or at least one segment of a colon was assessed by 0 points, satisfactory – 12-15 points, good – 16 points, very good – 17 points and excellent – 18 points).

Colon cleaning quality evaluation

Residuals of bowel content were assessed (yes / no) in each individual segment of a colon (caecum, ascending, transversal, descending, sigmoid and rectum) and colon cleaning quality ws assessed applying a qualitative scale – very poor (residuals of bowel content were found in all six or five segment) to excellent (residuals of bowel content were absent).

Colon length evaluation

The length of colon was measured applying CTC workstation software *(GE Advanced Workstation 4.2 06 Advanced CTC)*, which enables to make 3D reconstructions of a colon establishing and marking the central line in the colon lumen. This delineated central line can be used to measure the length of colon; the point of reference was an area of anorectal commissure and the lowest point of the bottom of caecum.

Patient acceptability of CTC evaluation

A questionnaire was presented for the study subjects after the completion of CTC examination. The study subjects were asked to describe their condition during the examination using 6 point scale (very bad – 1, bad – 2, satisfactory – 3, good – 4, very good – 5, excellent – 6). The part 2 of this questionnaire was designed for a study subject to specify subjective sensations experienced during CTC examination – pain (yes / no), abdomen tension (yes / no), abdominal colic (yes / no), no discomfort (yes / no).

The comparison of CTC and CS findings

The CS results were considered as a gold standard. All CS procedures were performed in the Endoscopic Diagnosis and Minimally Invasive Surgery Department of Vilnius University Hospital Santariškių Klinikos by the endoscopy professionals (abdominal surgeons and gastroenterologists). All CS examinations were carried out the same day as CTC procedure, applying a standard procedure technique with intravenous sedation, using a standard videocolonoscope CF-Q165L (Olympus, Germany). All CS procedures were performed as a standart methodology, following which every segment of the colon was evaluated. Professional endoscopists were aware about CTC findings for being able to compare them with CS findings. Only patients who underwent a complete CS examination, i.e., the entire colon was examined, were enrolled into the study.

The results of CS and CTC examinations were directly compared for each finding – a polyp sized ≥6 mm and a mass (sized ≥ 3 cm). The size of removed lesion discovered during CS, was assessed with the millimeter ruler if the sample was taken. If the biopsy was performed, the size of the lesion was visually compared with the size of colonoscope instrument.

However, the lesion discovered during CTC examination not found during CS were considered as false positive, and those detected during CS examination but not visible during CTC – false negative. If comparison of these two examinations revealed a lesion in the same segment characterised by the same morphological characteristics and of similar size (with a deviation of 1 mm), it was considered as the same polyp or mass and

a true positive result was reported. If the lesions in the same bowel segment were not detected during CTC and CS examination a true negative result was reported.

The results of histological examination of biopsy samples taken during CS were classified in the database as non-neoplastic polyps (hyperplastic, inflammatory), adenoma (serrated tubular, tubulovillous or villous) and carcinoma (non-invasive and invasive). Adenomas were classified as non-neoplastic (serrated) and neoplastic (tubular, tubulovillous or villous). If histological examination did not reveal any abnormalities, the samples were considered as normal.

Statistical analysis

To perform statistical calculations, we used SPSS Statistics 17.0 statistical set. In assessing the ability of CTC to detect lesions in patients comparing this method with the CS method, the sensitivity, specificity, positive and PPV were calculated for different sizes of lesions (≥ 6 mm, ≥ 10 mm, etc.). In assessing the detection of lesions (detection or non-detection of a specific lesion), the sensitivity and PPV were calculated. 95% confidence intervals are provided. Averages and standard deviations for the variables or the medians and quartiles (Q1; Q3), if the indicators are not normally distributed, are calculated for the persistent variables. Category indicators are presented in percentages. Non-parametric Mann-Whitney test is used to compare the groups. The two-sided p values are provided throughout the paper. The significance level is 0.05.

RESULTS

101 patients were enrolled into the study; the age median was 64 years. The biggest proportion of the examined patients were those aged 70 years old and above, i.e. 26.7 %; the majority of patients were those above 60 year old (69.3% of all study subjects). Female study subjects made 62.4% (n = 63) of the study population, i.e., slightly higher number than males. Only one third of participated patients had normal body weight (N = 33; 32.7 %). More than one third of the patients (36.6 %) had overweight, and almost one third of the patients were with adiposity (26,8 %). This means that more than half of the patients (n = 64; 63.4 %) had weight-related problems.

A little bit more than half of all findings (50.5%) in the colon were of C1 category, i.e., any visible malignant lesions or polyps sized ≥ 6 mm were discovered in a colon or other visible lesions were not malignant (such as diverticula, lipoma).

Per patient sensitivity, specificity, PPV and NPV of CTC compared to colonoscopy for ≥ 6 mm lesions was 95.7 % (95 % CI: 85.2 % - 99.5 %), 94.5 % (95 % CI: 84.9 % - 98.9 %), 93.6 % (95 % CI: 82.5 % - 98.7 %) and 96.3 % (95 % CI: 87.3 %- 99.5 %), respectively.

Per patient sensitivity, specificity, PPV and NPV of CTC compared to colonoscopy for ≥ 10 mm lesions was 100 % (95 % CI: 83.3%-100 %), 95.8 % (95 % CI: 88.1%-99.1 %), 90.9 % (95 % CI: 75.7%-98.1 %) and 100 % (95 % PI: 92.2%-100 %) respectively.

Per patient sensitivity, specificity, PPV and NPV of CTC compared to colonoscopy for 6–9 mm lesions was 90.9 % (95 % CI: 70.8 % - 98.9 %), 100 % (95 % CI: 93.2 % - 100 %), 100 % (95 % CI: 76.2 % -100 %) and 97.5 % (95 % CI: 91.4 %- 99.7 %), respectively.

The highest sensitivity and NVP of CTC examination per patient was reached for lesions sized ≥ 10mm, a little bit less – for the lesions sized 6-9 mm. Figure 1.

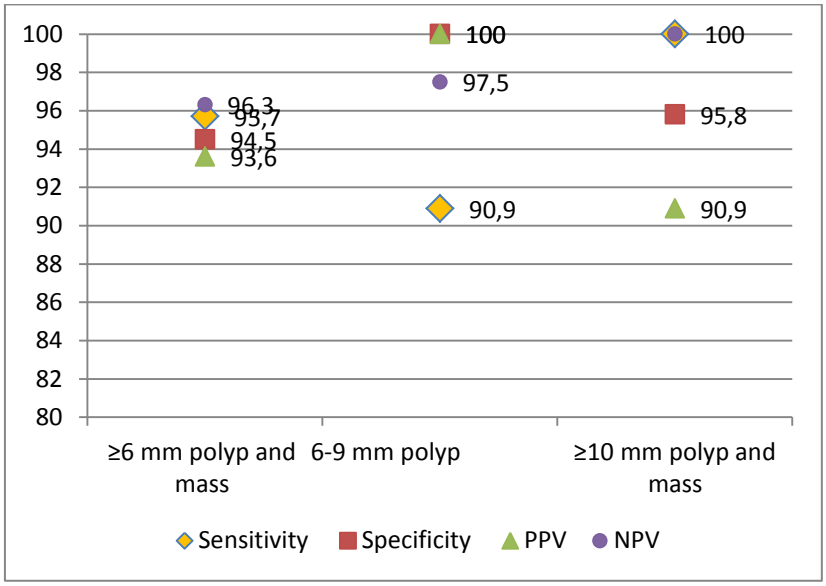

Figure 1. Per patient CTC sensitivity, specificity, PPV and NPV according three different lesion cut-off value.

Per polyp sensitivity, PPV of CTC compared to colonoscopy for ≥ 6 mm lesions was 93 % (95 % CI: 83 %- 98 %) and 89.8 % (95 % CI: 79.2 % - 96.2 %) respectively. Per polyp sensitivity, PPV of CTC compared to colonoscopy for ≥ 10 mm lesions was 96.8 % (95 % CI: 83.3 % - 99.9 %) and 83.3 % (95 CI: 67.2 %- 93.6 %) respectively. Per polyp sensitivity, PPV of CTC compared to colonoscopy for 6–9 mm lesions was 88 % (95 % CI: 68.8 % – 97.5 %) and 95.7 % (95 % CI: 78.1 %- 99.9 %), respectively. Sensitivity, PPV of CTC compared to colonoscopy for neoplastic adenoma and carcinoma was 95.3 % (95 % CI: 84.2 % -99.4 %) and 100 % (95% CI: 87.4 % – 100 %), respectively.

In total two polyps ≥ 6 mm of size were diagnosed in two patients during CS that were not detected during CTC examinations (the number of false negative test results). Both polyps were located at the sigmoid part of a bowel and were assigned to 6-9 mm size range group. Classification according to morphological type – one polyp was flat, another one appeared sessile. In case of both lesions these polyps were villous and tubulovillous adenomas based on the results of biopsy examination. In case of both lesions the amount of air in the colon was excellent, while sesile in sigmoid was detected despite the satisfactory preparation of the bowels.

Before the start of scanning procedure the bowels of the patient, lying on a table of CT scanner, were manually inflated with an air (within the patient's tolerance limits, ~700-900 cm^3) via disposable tip through the anus inserted into the rectum. After a CT scout was performed, the amount of air in the colon was re-assessed for the patient lying prone, and if inflation was insufficient, a few additional air blows were made. The patient underwent scanning in two positions – firstly – lying prone, and then – lying supine.

All lesions sized ≥ 10 mm discovered during colonoscopy were visible during CTC examination also. In total 4 lesions were discovered during CTC examination in three patients, however they were not confirmed during CS examination. All these false positive lesions were ≥ 10 mm of size. Three lesions were located in a caecum and one of them was in a rectum. Two lesions were sessile, one was pedunculated and another one appeared flat. In this case cleaning of the patients' bowels was assessed as very good

or good, and colon distension was excellent, very good or good. Two lesions detected in a caecum were the stumps of appendix (Figure 4), one lesion was associated with Crohn's disease, and one lesion in a rectum was a haemorrhoid node.

Neoplastic lesions, i.e. neoplastic adenoma and (or) carcinoma, were detected in 37 (36.6%) patients out of 101 study subjects. Carcinoma of rectum was diagnosed during CS in 8 patients (7.9%). Histological examination of all available biopsy samples of tissues revealed 9 cases of rectal carcinoma (non-invasive and invasive) and 34 cases of neoplastic adenoma. Out of 34 neoplastic adenomas 23 were tubular adenomas, 10 – tubulovillous adenomas and 1 – villous adenoma. The most common localisation of neoplastic adenoma and carcinoma was a sigmoid 23.1% and 76.9% of cases, respectively.

Certain extracolonic lesions were discovered in the majority (76.3%) of study subjects. Almost one-fourth part of study subjects, i.e. 23.8 % (n = 24) had clinically significant extracolonic lesions. Extracolonic findings classified as belonging to E2 category were discovered in 42.6% (n=43), i.e. almost half of the patients have had clinically insignificant lesions.

Colon cleaning quality was assessed positively (good – very good – excellent) for 90.1 % of patients, and negatively (very poor – poor – satisfactory) – for 9.9 % of the patients. The calculated length of the colon was 159.8 cm.

Statistically significant difference was not reported between the patients' groups with positively and negatively assessed colon cleaning quality (median [Q1; Q3]: 160 [140; 187] and 158 [142.5; 174.5], p = 0.964).

Assessment of colon distension revealed that adequate colon distension for image evaluation (good / very good / excellent distension) was reached for 93.1 % of the patients.

Assessment of tolerability of CTC examination among the patients based on the data individually presented in a questionnaire the following calculations were obtained: 93.1% of study subjects experienced at least some sensations, pain sensation was specified by 44.6% of the subjects, tension – by 65.3%, inflation – by 80.2% and

abdominal colic – by 54.5% of the patients. Even 62.4% of all study subjects the tolerability of this examination assessed positively (good, very good, excellent).

Statistically significant difference of colon length between the patients positively (good, very good and excellent) and negatively (satisfactorily, poorly, very poorly) tolerating the examination was not reported (median {Q1; Q3]: 150 [140; 175] and 158 [148; 174], p = 0.283).

The difference of age in the examination tolerability groups was not statistically significant (median [Q1; Q3]: 63 [57,5; 69] and 63 [56; 71], p=0,817).

The average effective dose during a computed tomography colonography examination in the group of study subjects was 21,4 ± 9,3 (max 44,7 - min 8,6) mSv. Effective dose was calculated, as follows: Effective dose = DLP (dose length product; measured in mGyxcm units) x k, where k = 0.015 mSv/(mGyxcm).

Our study has several limitations. The first of which is its single-centre nature. Second, our study patient exposure is quite high, as we use intravenous contrast medium and attach more value to the detection of extracolonic findings.

Conclusions

1. CTC had high diagnostic value in detection the lesions of the colon sized ≥ 6 mm in FOBT positive patients.
2. CTC was characterised by very high diagnostic value in detection of large (≥ 10 mm) polyps and somewhat lower diagnostic value in detection of middle (6-9 mm) polyps of the colon in FOBT positive patients.
3. CTC examination is a sensitive technique for diagnostics of colorectal neoplastic adenomas and cancer; however, sensitivity of CS has not reached.
4. Clinical significant extra-colonic findings have been detected in almost one fourth part of all FOBT positive patients (23.8 %) when CTC examination was carried out with intravenous contrasting.

5. The length of colon had no influence on how patients tolerated this examination and on patients well-being during CTC procedure, and colon cleaning quality before CTC procedure was not associated with the anatomical peculiarities of colon, such as length of a gut.

PRACTICAL RECOMMENDATIONS

1. Considering the results of the conducted study we recommend for FOBT positive patients to replace CS examination with CTC examination, when complete CS examination cannot be carried out or a patient refuses to undergo this examination.

2. As neoplasm pathology is commonly diagnosed in FOBT positive patients and due to still remaining likelihood of underdiagnosis of clinically significant adenomas, we do not recommend CTC examination as a first choice examination method.

3. The special attention during CTC examination should be addressed to a caecum, as the stumps after appendectomy have been found in this location, which can be misinterpreted as polyps.

4. FOBT positive patients have high likelihood of colon lesions and extracolonic lesions are often found in this group of population – thus, CTC examination using intravenous contrast substance is a useful option in this group of patients.

5. We recommend this diagnostic algorithm for colon lesions for FOBT positive patients:

For the patients with positive FOBT findings → Referred for CS examination

↓ ↓

For the patients after incomplete CS examination | For the patients refusing to undergo CS examination

↓ ↓

When CTC examination is required

↓

Polyps or tumour masses ≥ 6 mm of size have been diagnosed by CTC

↓

Patient was referred for repeated CS examination or surgery

LIST OF PUBLICATIONS

PUBLICATIONS BY DISSERTATION

1. **Dileta Rutkauskaitė**, Saulius Mikalauskas, Bernardas Rimkus, Algirdas Edvardas Tamošiūnas, Kęstutis Strupas. Storosios žarnos vėžio atrankinės patikros metodai: kompiuterinės tomografijos kolonografija, palyginti su kolonoskopija, pacientams su teigiamu slapto kraujo išmatose testu. Pirmieji palyginamieji rezultatai VUL Santariškių klinikose. *Medicinos teorija ir praktika* 09/2013; 19(3.1):33-38.
2. **Dileta Rutkauskaite**, Kestutis Strupas, Algirdas Edvardas Tamošiūnas. Computed Tomography Colonography – The Procedure in our Days. Literature Review. *Medicinos teorija ir praktika* 04/2013; 19(2):195-201.
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Dileta Rutkauskaitė was born in Tauragė, Lithuania, on September 16, 1978.

1996–2002 - medicine studies at the Faculty of Medicine, Vilnius University.

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REZIUMĖ

Santrumpos

SŽV storosios žarnos vėžys
FOBT išmatų slapto kraujavimo tyrimas
KTK kompiuterinės tomografijos kolonografija
KS kolonoskopija
C-RADS kolonografijos aprašymo ir duomenų sistema
KMI kūno masės indeksas
KT kompiuterinė tomografija
2D dvimatis
3D trimatis
TPV teigiama prognostinė vertė
NPV neigiama prognostinė vertė

Įvadas

Pasaulyje kasmet nuo storosios žarnos vėžio (SŽV) miršta apie pusė milijono žmonių. O Lietuvoje SŽV sergamumas per pastarąjį dešimtmetį pastoviai išlieka didelis – 2001 m. susirgo 1354, 2005 m. – 1491 ir 2011 m. – 1629 žmonės. SŽV ankstyvosios diagnostikos programos sumažina mirtingumą nuo šios ligos, nes vėžys yra aptinkamas anksčiau ir galima jį lengviau išgydyti; kelias vėžio vystymuisi taip pat gali būti užkertamas nustačius ir pašalinus adenomas – SŽV pirmtakus. Lietuvoje SŽV ankstyvosios diagnostikos programa 50–74 m. žmonėms Vilniaus ir Kauno apskrityse pradėta vykdyti tik 2009 m. Valstybinė ligonių kasa 2009–2012 m. šiai programai skyrė tikrai didelę sumą – 12,636 mln. litų, o šių lėšų panaudota 85,4 proc. Kaip daugumoje valstybių, taip ir Lietuvoje SŽV ankstyvosios diagnostikos programa yra paremta slapto kraujo išmatose nustatymo testu. Yra patvirtinta, kad šio testo taikymas mažina mirtingumą nuo SŽV. Išmatų slapto kraujo tyrimai (FOBT) (ar tai būtų brantmedžio rūgšties (gFOBT) ar imunochemine (FIT) reakcijomis paremti tyrimai) yra plačiai paplitę, priimtini atrankai ir ekonomiški. Po teigiamo FOBT atsakymo pacientai yra nukreipiami kolonoskopijai (KS), jos metu dažnai yra patvirtinami storosios žarnos

adenomos ir vėžys, šios procedūros metu galima mažesnių adenomų ir vėžio endoskopinė ekscizija. Tačiau KS gali būti nepilnai atlikta, kontraindikuotina ar nepageidaujama paciento. Tai reiškia, kad didelės rizikos pacientams bus nediagnozuojamas navikinis susirgimas ir jie nebus gydomi. Valstybinės ligonių kasos duomenimis per pirmuosius trejus metus iš pacientų, dalyvavusių programoje, 7,2 proc. pacientų FOBT buvo teigiamas, iš jų tik 52,4 proc. pacientų atlikta KS, o pagal Europos storosios žarnos vėžio atrankinės patikros ir diagnostikos kokybės užtikrinimo gaires, priimtinas rodiklis yra >85 proc., siektinas >90 proc. Be to atlikti KS pilnai apžiūrint visą storąją žarną pavyksta ne visiems pacientams (57–99,4 proc.).

Norint dažniau diagnozuoti SŽV, reikalingas alternatyvus KS tyrimas. Viena iš galimybių yra kompiuterinės tomografijos kolonografija (KTK). KTK (sin. virtuali kolonoskopija) – tai kompiuterinės tomografijos tyrimas storosios žarnos polipams ir tumoro masėms vizualizuoti, prieš tai ją išpūtus oru ir naudojant dvimačių (2D) ir trimačių (3D) vaizdų vertinimus.

KTK rekomenduojama tada, kai KS yra negalima ar nepilnai atlikta. Ši rekomendacija yra pagrįsta metaanalizėmis ir randomizuotais tyrimais.

Mūsų nuomone, KTK galėtų būti atliekama pacientams, kurie dalyvauja SŽV antrankos programoje ir esant teigiamam FOBT rezultatui neatvyksta į KS tyrimą. Pasiūlę alternatyvą endoskopiniam tyrimui ir radę pakitimus KTK metu, taip padidintume KS skaičių. KTK pritaikymas SŽV atrankinėje patikroje, – mes galėtume remtis jau atliktų metaanalizių ir randomizuotų tyrimų duomenimis. Bet jei galvojame apie KTK platų pritaikymą pacientams su teigiamu FOBT rezultatu, turi būti labai tiksliai žinomas šio tyrimo jautrumas ir specifiškumas nustatant vėžį ir adenomas būtent šios grupės pacientams. Pacientams su teigiamu FOBT dažniau diagnozuojamas piktybinis žarnos susirgimas, todėl diagnostikai reikalingas labai jautrus ir turintis kuo didesnę neigiamą prognostinė vertę (NPV) tyrimas.

Todėl mes atlikome tyrimą, kuriuo norėjome išsiaiškinti KTK tyrimo diagnostinę vertę nustatant neoplastinius pakitimus pacientams su teigiamu FOBT.

Tyrimo tikslas

Nustatyti KTK tyrimo diagnostinę vertę bei tyrimo kokybei darančius įtaką faktorius pacientams su teigiamu FOBT, dalyvaujantiems SŽV ankstyvos diagnostikos programoje.

Tyrimo uždaviniai

1. Nustatyti KTK tyrimo jautrumą, specifiškumą, teigiamą ir neigiamą prognostines vertes lyginant su KS diagnozuojant ≥6mm pakitimus pacientams su teigiamu FOBT.
2. Nustatyti KTK tyrimo jautrumą, specifiškumą, teigiamą ir neigiamą prognostines vertes lyginant su KS diagnozuojant vidutinius (6-9mm) ir didelius (≥10mm) polipus pacientams su teigiamu FOBT.
3. Nustatyti KTK tyrimo jautrumą ir teigiamą prognostinę vertę lyginant su KS diagnozuojant neoplastines adenomas ir SŽV pacientams su teigiamu FOBT.
4. Išsiaiškinti KTK metu rastų už storosios žarnos esančių radinių dažnumą ir svarbą.
5. Išsiaiškinti pacientų toleranciją KTK tyrimui bei tyrimo kokybės ir tolerancijos priklausomybę nuo storosios žarnos ilgio.

Darbo naujumas ir praktinė reikšmė

Pacientams, kuriems būdinga didesnė rizika sirgti storosios žarnos piktybiniu susirgimu, galima neinvaziniu tyrimo metodu – KTK – nustatyti darinius storojoje žarnoje. Tokiems pacientams KTK galima atlikti po nepavykusios KS ar esant kontraindikacijoms, taip pat pacientams, atsisakantiems šio tyrimo. Tokioje situacijoje padidintos rizikos pacientų grupei rutiniškai pritaikius KTK tyrimą, padidėtų SŽV diagnostiniai rodikliai. Turint kasdieninėje praktikoje alternatyvų tyrimą storajai žarnai

ištirti, pagerėtų pacientų su teigiamu FOBT rezultatu, kurie neatvyksta į jiems rekomenduojamą KS tyrimą, ištyrimas.

Literatūroje publikuoti tik pavieniai darbai, plačiau nagrinėjantys KTK tyrimo tikslumą pacientams, dalyvaujantiems storosios žarnos vėžio atrankos programoje ir turintiems teigiamą FOBT atsakymą. Neradome publikuotų darbų, tiriančių KTK tyrimo kokybės bei pacientų tolerancijos tyrimui priklausomybę nuo anatominių storosios žarnos ypatumų, t.y. nuo žarnos ilgio. Tai pirmas tiriamasis darbas Lietuvoje, nagrinėjantis KTK tyrimą.

Ginamieji teiginiai

1. KTK tyrimas yra tikslus nustatant ≥6 mm pakitimus storojoje žarnoje pacientams su teigiamu FOBT.
2. KTK tyrimas yra jautrus nustatant neoplastines adenomas ir vėžį storojoje žarnoje pacientams su teigiamu FOBT.
3. KTK metu nustatoma daug kliniškai svarbių pakitimų už storosios žarnos.
4. Pacientų tolerancija KTK tyrimui ir jo kokybė priklauso nuo anatominių storosios žarnos savybių, t.y. žarnos ilgio.

Tyrimo medžiaga ir metodai

Vilniaus regioninis bioetikos komitetas išdavė leidimą atlikti šią studiją (Nr. 158200-07-366-93). Tiriamoji medžiaga rinkta nuo 2011 metų birželio mėn. iki 2013 metų gegužės mėn. VšĮ Vilniaus Universiteto ligoninės Santariškių klinikos Radiologijos ir branduolinės medicinos centro III-iame Radiologijos skyriuje. Į tyrimą įtraukti 50–74 metų asmenys, kurie dalyvavo SŽV ankstyvos diagnostikos programoje, asmenys turėjo būti sąmoningi ir vykdantys paliepimus, sulaikantys kvėpavimą, pasirašęs informuoto asmens sutikimo formą. Neįtraukimo į tyrimą kriterijai: asmenys, kurie nedalyvavo SŽV ankstyvos diagnostikos programoje, nestabilūs, nesąmoningi, nevykdantys paliepimų, negalintys sulaikyti kvėpavimo, nesutinkantys dalyvauti tyrime ir nepasirašę informuoto asmens sutikimo formos, alergiški jodo kontrastiniam preparatui bei su žinomu inkstų funkcijos sutrikimu. Tyrime dalyvavo 102 tiriamieji su teigiamu FOBT atsakymu ir

dalyvaujantieji SŽV ankstyvos diagnostikos programoje, kuriems buvo atlikti KTK ir KS tyrimai. KS tyrimas iš 102 dalyvavusiųjų tyrime pilnai atliktas 101 tiriamąjam, kurie ir dalyvavo tolimesnėje duomenų analizėje.

REZULTATAI

Statistinius skaičiavimus atlikome naudodami *SPSS Statistics 17.0* statistinį paketą. Vertinant KTK gebėjimą aptikti darinių buvimą pacientams, lyginant šį tyrimo metodą su KS metodu, įvairiems darinių dydžiams (≥ 6 mm, ≥10 mm ir t.t.) apskaičiuotas jautrumas, specifiškumas, teigiama ir neigiama prognostinės vertės. Vertinant darinių aptikimą (konkretaus darinio aptikimas arba neaptikimas), apskaičiuotas jautrumas ir teigiama prognostinė vertė. Pateikiami 95 proc. pasikliovimo intervalai. Tolydiems kintamiesiems yra apskaičiuoti vidurkiai ir standartiniai nuokrypiai arba medianos ir kvartiliai (Q1; Q3), jei rodikliai nėra normaliai pasiskirstę. Kategoriniams rodikliams pateikiami procentai. Grupėms palyginti naudotas neparametrinis Mann-Whitney kriterijus. Visur pateikiamos dvipusės p reikšmės. Reikšmingumo lygmuo – 0,05.

Tyrime dalyvavo 101 pacientas, kurių amžiaus mediana buvo 64 metai. Daugiausia ištirta pacientų, kuriems 70 ir daugiau metų, t.y. 26,7 procentų. Pagrindinį tiriamųjų srautą sudarė pacientai, kuriems virš 60 metų (69,3 proc. visų dalyvavusių). Moterų dalyvavo 62,4 proc. (n=63), t.y. kiek daugiau nei vyrų. Normalaus kūno svorio pacientų buvo tik trečdalis dalyvavusiųjų (N=33; 32,7%). Daugiau nei trečdalis (36,6 proc.) pacientų turėjo antsvorį, o beveik trečdalis buvo nutukę (26,8 proc.). Tai yra daugiau nei pusė pacientų (n=64; 63,4 proc.) turėjo su svoriu susijusių problemų.

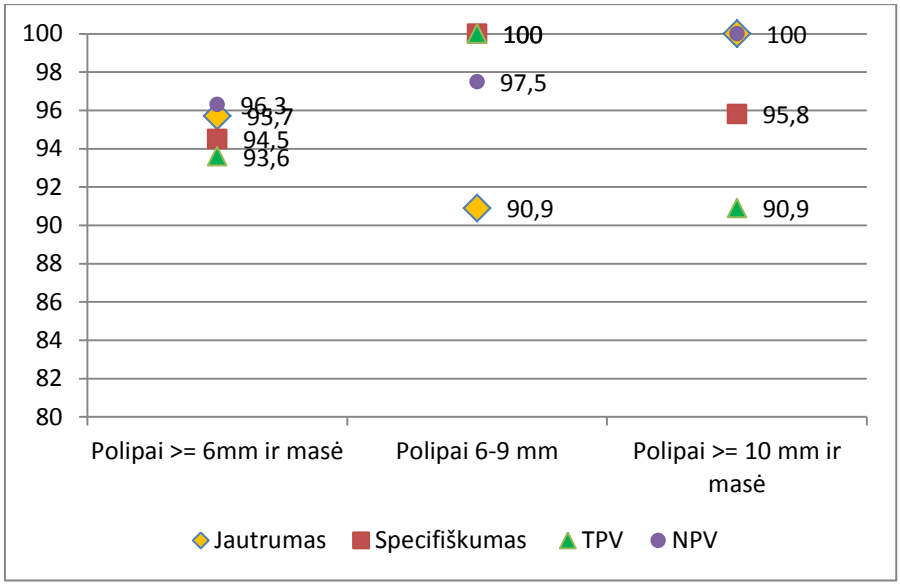
Kiek daugiau nei pusė radinių (50,5 proc.) storojoje žarnoje buvo C1 kategorijos – t.y. storojoje žarnoje iš viso nebuvo matomų pakitimų, nebuvo ≥6 mm dydžio polipų arba matomi pakitimai buvo nepiktybiniai (pvz.: divertikulai, lipoma).

KTK tyrimo jautrumas, specifiškumas, TPV ir NPV lyginant su KS ≥6 mm pakitimams (polipams ir masėms) vienam pacientui atitinkamai yra 95,7 proc. (95 proc. PI: 85,2 - 99,5), 94,5 proc. (95 proc. PI: 84,9 - 98,9), 93,6 proc. (95 proc.: 82,5 - 98,7), 96,3 proc. (95 proc. PI: 87,3 - 99,5).

KTK tyrimo jautrumas, specifiškumas, TPV ir NPV lyginant su kolonoskopija ≥10 mm pakitimams (polipams ir masėms) vienam pacientui atitinkamai yra 100 proc. (95 proc. PI: 83,3 – 100), 95,8 proc. (95 proc. PI: 88,1 - 99,1), 90,9 proc. (95 proc. PI: 75,7 - 98,1), 100 proc. (95 proc. PI: 92,2 – 100).

KTK tyrimo jautrumas, specifiškumas, TPV ir NPV lyginant su KS 6–9 mm pakitimams (polipams) vienam pacientui atitinkamai yra 90,9 proc. (95 proc. PI: 70,8 - 98,9), 100 proc. (95 proc. PI: 93,2 – 100), 100 proc. (76,2 – 100), 97,5 proc. (95 proc. PI: 91,4 - 99,7).

Pateikiamas grafikas su trims storosios žarnos pakitimų dydžių grupėms paskaičiuotais KTK tyrimo tikslumo parametrais (1 paveikslas).



1 paveikslas. Bendras KTK tyrimo vienam pacientui jautrumo, specifiškumo, TPV ir NPV reikšmių grafikas storosios žarnos pakitimams trijose dydžių grupėse *(angl. cut-off)*.

Apskaičiuoti KTK jautrumas ir TPV vienam storosios žarnos pakitimui pagal KS metu rastus pakitimus: KTK jautrumas ir TPV ≥6 mm dydžio pakitimams yra 93 proc. (95 proc. PI: 83 proc. – 98proc.) ir 89,8 proc. (95 proc. PI: 79,2 proc. – 96,2 proc.) atitinkamai. KTK jautrumas ir TPV ≥ 10 mm dydžio pakitimams yra 96,8 proc. (95 proc. PI: 83,3 proc. – 9,9 proc.) ir 83,3 proc. (95 PI:67,2 proc. – 93,6 proc.) atitinkamai. KTK jautrumas ir TPV 6–9 mm dydžio pakitimams yra 88 proc. (95 proc.PI: 68,8 proc. – 97,5

proc.) ir 95,7 proc. (95 proc. PI: 78,1 proc. – 99,9 proc.) atitinkamai. KTK jautrumas ir TPV neoplastinei adenomai ir karcinomai yra 95,3 proc. (95 proc. PI: 84,2proc. – 99,4proc.) ir 100 proc. (95 PI: 87,4 proc. – 100 proc.) atitinkamai.

Iš viso dviems pacientams KS nustatyti du polipai ≥6 mm dydžio**,** kurie nebuvo rasti KTK (klaidingai neigiamų rezultatų skaičius). Abu polipai buvo riestinėje žarnoje ir priklausė 6–9 mm dydžio grupei. Pagal morfologinį tipą – vienas polipas buvo plokščias, o kitas – iškilus. Abiem pakitimų atvejais tai buvo viliozinė ir tubulioviliozinė adenomos, nustatytos biopsijos rezultatais. Abiem atvejais storosios žarnos išsipūtimas tyrimo metu buvo puikus, iškilaus polipo atveju riestinėje žarnoje – žarnyno pasiruošimas buvo patenkinamas. Visi ≥ 10 mm dydžio pakitimai, kurie rasti KS metu, buvo rasti ir KTK metu. Trims pacientams iš viso buvo 4 pakitimai, kurie rasti KTK metu, bet nepasitvirtino KS metu. Visi šie klaidingai teigiami pakitimai priklausė ≥10 mm dydžio grupei. Trys pakitimai buvo aklojoje žarnoje, vienas – tiesiojoje. Du pakitimai iškilūs ir po vieną – su kojyte ir plokščią. Pacientų žarnynas šiuo atveju buvo išvalytas labai gerai arba gerai, o žarnos išpūtimas puikus, labai geras arba geras. Aklojoje žarnoje du pakitimai buvo kirmėlinės ataugos bigės, vienas pakitimas susijęs su Krono liga, tiesiojoje žarnoje – vienas pakitimas – hemorojinis mazgas.

Iš viso 37 (36,6 proc.) pacientams iš 101 tirtųjų nustatyti 43 neoplastiniai pakitimai – t.y. neoplastinė adenoma arba /ir karcinoma. Storosios žarnos karcinoma KS metu nustatyta 8 pacientams (7,9 proc.). Iš esamų pakitimų turimos biopsinės medžiagos, 9 pakitimų atvejais po histologinio ištyrimo nustatyta storosios žarnos karcinoma (neinvazinė ir invazinė), 34 – neoplastinės adenomos. Iš 34 neoplastinių adenomų – 23 tubulinės adenomos, 10 – tubuliovilozinių adenomų, 1 – viliozinė adenoma. Neoplastinės adenomos ir karcinomos pagal lokalizaciją dažniausiai nustatytos riestinėje žarnoje.

Daugumai tiriamųjų (76,3 proc.) rasti pakitimai už storosios žarnos. Beveik ketvirtadaliui tiriamųjų, t.y. 23,8 proc. (n=24), rasti kliniškai reikšmingi pakitimai už storosios žarnos. 42,6 proc. (n=43) visų tiriamųjų nustyti E2 kategorijos ekstrakoloniniai pakitimai, t.y. beveik pusei pacientų rasti kliniškai nereikšmingi radiniai.

Žarnyno išsivalymo kokybė teigiamai įvertinta (gerai – labai gerai – puikiai) – 90,1 proc. pacientų, neigiamai įvertinta (labai blobai – blogai – patenkinamai) – 9,9 proc. pacientų. Apskaičiuotas vidutinis storosios žarnos ilgis – 159,8 cm.

Žarnos ilgis statistiškai reikšmingai nesiskyrė tarp teigiamai ir neigiamai įvertintų pacientų grupių pagal išsivalymo kokybę (mediana [Q1; Q3]: 160 [140; 187] ir 158 [142,5; 174,5], p=0,964).

Vertinant storosios žarnos išsipūtimą, gauta, kad adekvatus storosios žarnos išpūtimas vaizdų vertinimui (išpūsta gerai / labai gerai / puikiai) pasiektas – 93,1 proc. pacientų.

Vertinant toleranciją KTK tyrimui pagal anketinius paciento duomenis apskaičiuota, kad bet kokius pojūčius tyrimo metu turėjo – 93,1 proc. tiriamųjų, iš jų skausmą jautė – 44,6 proc., tempimą – 65,3 proc., pūtimą – 80,2 proc., raižymą – 54,5 proc. pacientų.

Vertinant toleranciją tyrimui, teigiamai tyrimą vertino (gerai, labai gerai ir puikiai) 62,4 proc. tirtųjų.

Statistiškai storosios žarnos ilgis nesiskyrė ir tarp teigiamai (gerai, labai gerai, puikiai) ir neigiamai (patenkinamai, blogai, labai blogai) toleruojančių tyrimą pacientų (mediana [Q1; Q3]: 150 [140; 175] ir 158 [148; 174], p=0,283). Šiose dviejose tyrimo toleravimo grupėse pacientų amžius taip pat statistiškai reikšmingai nesiskyrė (mediana [Q1; Q3]: 63 [57,5; 69] ir 63 [56; 71], p=0,817).

Kompiuterinės tomografijos kolonografijos metu pacientui gauta vidutinė efektinė dozė buvo 21,4 ± 9,3 (max 44,7 - min 8,6) mSv. Efektinė dozė suskaičiuota pagal formulę: Efektinė dozė = DPL (angl. *dose length product;* matuojama vienetais *mGyxcm*) x *k*, kur *k*=0.015 mSv/(mGyxcm).

Išvados

1. KTK pasižymi didele diagnostine verte nustatant ≥6 mm dydžio pakitimus storojoje žarnoje pacientams, kurių teigiamas FOBT rezultatas.

2. KTK pasižymi labai didele diagnostine verte nustatant didelius (≥10 mm) polipus, bet kiek mažesne diagnostine verte nustatant vidutinius (6–9 mm) polipus storojoje žarnoje pacientams, kurių teigiamas FOBT rezultatas.

3. KTK tyrimas yra jautrus nustatant storosios žarnos neoplastines adenomas ir vėžį, bet nesiekia KS tyrimo jautrumo.

4. Atliekant KTK su intraveniniu kontrastavimu, beveik ketvirtadaliui pacientų (23,8 proc.), kurių teigiamas FOBT rezultatas, yra nustatomi kliniškai reikšmingi pakitimai už storosios žarnos.

5. Storosios žarnos ilgis neturi įtakos tyrimo tolerancijai ir paciento savijautai KTK metu, o žarnos išsivalymo kokybė prieš KTK tyrimą nepriklauso nuo anatominių storosios žarnos savybių – tokių, kaip ilgis.

PRAKTINĖS REKOMENDACIJOS

1. Atsižvelgdami į atlikto darbo rezultatus, rekomenduojame pacientams, kurių yra teigiamas FOBT rezultatas, o KS tyrimas negali būti atliktas, rinktis KTK.

2. Dėl pakankamai dažnai pasitaikančios storosios žarnos navikinės patologijos pacientams, kurių teigiamas FOBT rezultatas, bet nesant tokiam pačiam KTK tyrimo jautrumui kaip KS, KTK taikyti kaip pirmo pasirinkimo tyrimo metodą šios grupės pacientams nerekomenduojame.

3. Ypatingas dėmesys KTK metu turėtų būti kreipiamas į akląją žarną, nes ten pasitaiko apendektominės bigės, kurios gali būti klaidingai interpretuotos kaip polipai.

4. Pacientams, kurių teigiamas FOBT rezultatas, yra didelė pakitimų storojoje žarnoje tikimybė ir dažnai pasitaiko pokyčiai už storosios žarnos, todėl KTK tyrimas rekomenduojamas su intravenine kontrastine medžiaga.

5. Mes rekomenduojame tokį storosios žarnos pakitimų diagnostinį algoritmą pacientams, kurių teigiamas FOBT rezultatas: