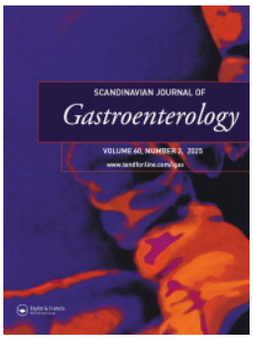

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RESEARCH ARTICLE

First local results of the Finnish FIT-based colorectal cancer screening program - high yield, low complications

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ABSTRACT

Background: The aim of screening for colorectal cancer (CRC) is to find the cancer in its early stages, thereby improving the prognosis of cancer patients by preventing cancer-related deaths. In Finland, the national CRC screening program was initiated in 2022, with fecal immunochemical test (FIT) being the primary screening test. The FIT-threshold used was 25 µg hemoglobin/g feces. The aim of this retrospective study was to evaluate the results of the first screening round that was implemented by the wellbeing services county of Southwest Finland.

Materials and methods: Participants were screened for CRC between March 1st, 2022 and April 14th, 2023. Participants aged 60–70 years had their health records scrutinized retrospectively.

Results: Out of 36 397 FIT-invitees 23 388 (64%) returned a FIT-sample. 1407 (6%) subjects gave a FIT-positive stool sample of which 1118 (79%) attended the recommended screening colonoscopy. A total of 63 (6%) CRCs were found. 31 (49%) CRCs were classified as early stage I tumors, 12 (19%) of which were solely suitable for endoscopic treatment. Endoscopically removable adenomas were detected in 709 (63%) of the colonoscopies, which resulted in a recommendation of a 3-year follow-up colonoscopy for 427 (38%) cases. There were 3 (0.27%) acute polypectomy related complications and 5 (0.45%) late post-colonoscopy complications.

Conclusions: This is the first study to show the prevalence of CRC amongst participants of the newly implemented Finnish national CRC-screening program. Nearly half of the patients with CRC were diagnosed in the early stage. The adenoma detection rate was high.

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Colorectal cancer; endoscopy; FIT; screening; polypectomy

Introduction

Colorectal cancer (CRC) is the third most common cancer in the world and the second leading cause of cancer-related deaths. CRC can have severe effects on mortality and quality of life [1]. In the early stages, CRC often lacks symptoms that would typically result in diagnosis. Consequently, CRC is often diagnosed only when the cancer has already spread. Prognosis for earlier stage CRC is better than for more advanced CRC [1]. Screening could improve CRC prognosis by reducing incidence and associated mortality [2].

The European Union recommends regular CRC screening for individuals between 50 to 74 years old. The recommended primary screening test to detect CRC is the fecal immunochemical test (FIT) with referral to colonoscopy if positive [3]. Previously (2004–2016) Finland had a gFOBT-based CRC screening in place that covered nearly half of the target population. Half of the 60 to 69 years old subjects received an invitation to the screening and half remained as a control group. No significant difference for mortality was found between the two study populations [4]. Later (2019–2021), FIT-based CRC screening in Finland was piloted by volunteer municipalities. National countrywide FIT-based CRC screening in Finland was implemented in 2022. At the time of this study, the CRC screening in Finland covered individuals between 60 to 70 years old. The goal of the screening by 2031 will be to cover all individuals aged 56–74 by 2031. The age range is currently increasing by two years every second year until the upper limit reaches 74 years by 2027. After that, the lower age limit will decrease by two years every second year, until it reaches 56 years by 2031. The subjects of the target group are invited to the screening every two years. Those who decide to participate in the screening, take a stool sample (FIT) at home and send it to the screening center. If the sample contains more than 25 µg hemoglobin/g feces, the person will be invited to colonoscopy.

The aim of this retrospective study was to evaluate the results of the first CRC screening round of the wellbeing services county of Southwest Finland, with a special focus on the precancerous and cancerous findings of the screening colonoscopies.

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Materials and methods

Screening laboratories sent an invitation to CRC screening that includes a formal invitation, instructions for FIT-test, container for FIT-sample, a prepaid return envelope and a pre-admission form. FIT-brand used for CRC-screening was OC-Sensor Pledia, Eiken Chemical Co. Ltd, Japan. Individuals with inflammatory bowel disease (IBD), persons with total colectomy and those already in follow-up protocol for CRC were excluded from the CRC screening. If the invitee had not returned the sample within six weeks of the original mailing, an automated reminder letter was sent. If the invitee had not returned the sample within six weeks from the first reminder, a second automated reminder letter was sent. If needed the invitee could order a new FIT-test kit with the help of the instructions provided in the reminder letter. In Finland three laboratories (Fimlab Laboratoriot OY Ltd in the area of wellbeing services county of Southwest Finland) analyzed the FIT-samples and sent the result of the first FIT-test to the invitee by letter. The screening nurses informed the FIT-positive invitees about the test result and organized the screening colonoscopy.

All screening colonoscopies in the area of wellbeing services county of Southwest Finland were performed in the Turku University Hospital abdominal center, which consists of 4 units. There is a colonoscopy quality program for screening endoscopists. All endoscopists must meet the following criteria: at least 3 years of colonoscopy experience after graduation, perform a yearly quantity of 200 or more colonoscopies, performed 500 or more colonoscopies, minimum amount of 50 polypectomies yearly and cecum intubation rate of 90% or more. The endoscopist must be qualified to give treatment and follow-up instructions.

Subjects living in the catchment area of the wellbeing services county of Southwest Finland who participated in CRC screening during March 1st, 2022 to April 14th, 2023 were retrospectively collected for the study. Health records were scrutinized retrospectively and maintained using the REDcap electronic data capture tool, which was hosted at the University of Turku, Finland. Patient documents were reviewed for admission to hospital within 30 days of colonoscopy. Turku University Hospital is the tertiary center for the area of wellbeing services county of Southwest Finland and all the units in the area use the same database to acquire complication data. Permission for data collection was obtained from the study center of wellbeing services of Southwest Finland (T216/2022-1).

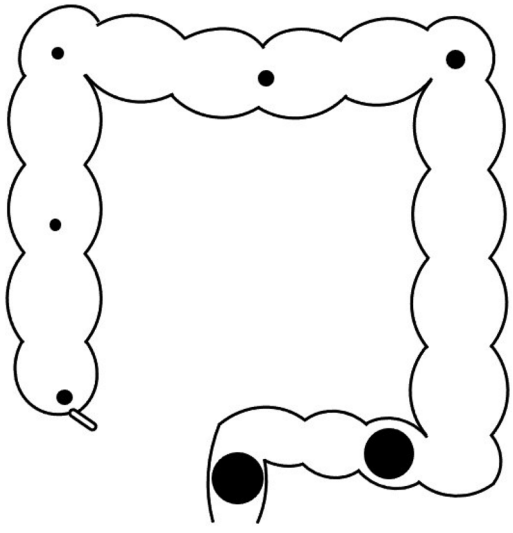

Figure 1. CRC location distribution.
Size of the circles resemble the relative quantities of CRC found in anatomical locations

The following data were obtained and recorded for each subject: age, gender, information related to colonoscopy (limiting factors, findings, polypectomies), medication affecting blood coagulation (dosage used and the length of the break in medication before colonoscopy), time of recommended post-polypectomy follow-up colonoscopy (time from primary screening colonoscopy to post-polypectomy follow-up colonoscopy), acute and late complications. Acute complications were defined as acute colonoscopy complications that resulted in either lengthening of the hospital stay, unscheduled additional endoscopic procedure or an emergency intervention, including blood transfusion or surgery. Symptoms and signs that occurred within 30 days of the colonoscopy (abdominal pain, bleeding, fever, anemia, perforation) that were attributed to the colonoscopy, were counted as late complications. When the patient had to be hospitalized, the duration of hospitalization was recorded.

Colonoscopy withdrawal time (time it takes to remove the endoscope from the colon) was documented and it included therapeutic procedures. Cecum intubation rate (the proportion of colonoscopies in which the cecum is reached) and Boston bowel preparation scale score (an assessment tool used to evaluate the quality of bowel preparation) were also recorded. All polypectomies performed were done using snare resection. The screening endoscopies in our study were performed by experienced endoscopists who used optical diagnostics in the distal sigmoid colon and in the rectum to identify hyperplastic polyps as these do not require removal.

Special attention was paid to the endoscopic and histological findings of the polyps and any cancerous changes. The size of the largest removed polyp was recorded and categorized as one of the following: 0–5 mm, 5–10 mm, 10–20 mm or more than 20 mm. The number of polyps removed were recorded as: 1–3, 4–10 or more than 10 polyps. If 1–3 polyps were removed, histological finding was recorded for 1–3 polyps. If 4–10 or more than 10 polyps were removed, histological finding was recorded for a maximum of five polyps. All specimens were examined by GI-pathologists. The most severe histological findings were documented. Polyp detection rate (PDR), adenoma detection rate (ADR) and polyp larger than 5 mm (PDR-5mm) were calculated. Hyperplastic polyps in the rectum were not included in the PDR and PDR-5mm as they did not require removal in colonoscopy. Details of the location, stage, type of treatment and treatment complications for each diagnosed cancer patient were also obtained. The splenic flexure was determined as the dividing border between right and left colon. Polyps in the splenic flexure were counted as left-sided. All the patients on direct oral anticoagulant (DOAC) were instructed to pause the medication for 24 h before the endoscopy. If polyps in

excess of 15 mm were found upon screening endoscopy, a new colonoscopy with a 48-hour DOAC pause was scheduled for polypectomy.

The criteria for referral to post-polypectomy follow-up colonoscopy were based on ESGE (2020) guidelines [5]. If CRC was found, a referral to metastatic spread examinations and to gastrosurgeon's appointment were made during the screening colonoscopy.

Statistics

Categorical variables are summarized using counts and percentages, continuous variables are expressed as mean and median. Range is also summarized for age. The statistical reporting for this paper was generated using SAS software, Version 9.4 of the SAS System for Windows (SAS Institute Inc., Cary, NC, USA).

Results

A total of 36 397 people were sent an invitation to participate in the national CRC screening of which 23 388 (64%) people returned a FIT-sample within the specified time. There were 1407 (6.0%) persons with a positive FIT and 1118 (80%) of these had a colonoscopy. Mean time between FIT-positivity and screening colonoscopy was 1.8 months in our study. Patient and endoscopy quality characteristics are shown in Table 1. Of the 199 patients taking anticoagulants 179 (90%) were instructed to take an anticoagulation break prior to colonoscopy and the mean duration of the break was 0.68 days.

A vast majority of the colonoscopies revealed polyps that were removed by a polypectomy ($n = 889$, 80%) (Table 2). Most of the detected polyps were small, i.e., they had a mean polyp diameter of 13 mm. In our patient cohort PDR-5mm was 61% and ADR was 63%. Follow-up colonoscopy due to polypectomy was recommended for 427 (38%) participants after a median interval of three years. Overall, 2550 biopsies or polyps were sent to the pathologist. The most common finding was tubular adenoma with low-grade dysplasia ($n = 1181$, 46%) (Table 2).

Table 1. Study population of FIT-positive participants who had colonoscopy and quality measures.

	N	Percent
Patients (n)	1118	100
Male	681	61
Female	437	39
Age mean (SD)	64.5 (2.9)	
Anticoagulation	198	18
Sedation	201	18
Cecum intubation	1089	97
Retroflexion	873	78
Withdrawal time (SD)	16 min (12)	
BBPS ≥8	927	83
Complications	8	0.72
Colonoscopy	3	0.27
Late complications	5	0.45

SD: Standard deviation; Retroflexion: Maneuver in colonoscopy used to examine distal rectum; Withdrawal time: Time it takes to remove the endoscope from the colon; BBPS ≥8: Boston bowel preparation scale.

Complications

In total, 3 (0.27%) acute complications occurred, all of which were related to polypectomy. Two patients suffered small perforations that were clipped during the screening colonoscopy. Neither of these patients suffered from long-term complications. The third patient had rectal arterial bleeding that was clipped during the screening colonoscopy and was monitored overnight in a GI-ward.

Post-colonoscopy complications within 30 days of colonoscopy occurred in 5 instances (0.45%). One patient went to the emergency care unit (ECU) after an episode of rectal bleeding within 30 days of colonoscopy. No active bleeding was found. In total three patients had fever within 30 days of colonoscopy and were examined in the ECU. All five patients were discharged within their respective day of presentation. An abdominal computed tomography (CT) due to abdominal pain in one patient revealed edema of the sigmoid colon that required no further measures. One patient suffered from multiple strokes within 30 days of colonoscopy and had internal carotid artery endarterectomy. The patient had already been scheduled for a head CT prior to the colonoscopy due to right arm weakness and it is unclear whether the exacerbation of symptoms was influenced by the screening colonoscopy.

There were no bleedings that required blood transfusion. Instructed anticoagulation medication breaks did not result in cardiovascular complications.

Cancer

Of the 1118 FIT-positive participants screened, 63 (6%) had cancers (Table 3 and Table 4). The CRC prevalence within the population that participated in the screening was thus 0.27%. One CRC was diagnosed in CT, and 62 in colonoscopy. A majority of the carcinomas (90%) were located in the left colon ($n = 29$, 46%) and the rectum ($n = 28$, 44%) (Figure 1). In addition, the screening revealed one squamous cell carcinoma in the anus, two neuroendocrine tumors with one being located in the appendix and the other in the rectum. For all CRC patients, the median time between colonoscopy and gastrosurgeon's appointment was 17 days, whereas the median time between colonoscopy and surgery was 43 days.

Most of the carcinomas (48, 76%) were treated with surgical bowel resection. Neoadjuvant radiotherapy or chemoradiotherapy was given to five (18%) rectal cancer patients prior to surgery. Furthermore, 14 (50%) rectal cancer patients had a colostomy, of which 2 (14%) were permanent. Three patients were inoperable, due to widely spread metastatic

Table 2. Colonoscopy finding rates.

	N	Percent
Participants with at least one polyp	889	100
1–3 polyps	548	62
4–10 polyps	291	33
>10 polyps	50	6
Participants with at least one polyp with diameter >5 mm	679	61
Participants with at least one adenoma	709	63

Percentages may not add up to 100 due to rounding.

Table 3. Colonoscopy findings per polypectomy.

	N	Percent
Histopathological diagnosis	2550	
Tubular adenoma low grade dysplasia	1181	46
Tubulovillous adenoma low grade dysplasia	261	10
High grade dysplasia	68	3
Sessile serrated lesion	250	10
Not available*	245	10
Other**	482	19
Carcinoma	63	2
Polypectomies with anatomical location	1913	100
Left-sided	1031	54
Male	718	70
Female	313	30
Right-sided	882	46
Male	589	67
Female	293	33

*Removed polyp was not collected for further histopathological diagnosis evaluation.
**includes: polypectomies with a non-diagnostic result, normal tissue, hyperplastic polyp, one squamous cell carcinoma of the anus.
Percentages may not add up to 100 due to rounding.
Anatomical location is documented of 1913 polypectomies.

Table 4. Characteristics and treatment of the detected carcinomas.

	N	Percent
Carcinoma*	63	6
Adenocarcinoma*	49	4
Carcinoma in polyp*	14	1
Location		
Right colon**	6	10
Left colon**	29	46
Rectum**	28	44
Stage		
I**	31	49
II**	11	17
III**	18	29
IV**	2	3
Undefined**	1	2
Treatment		
Endoscopy**	12	19
Colon**	5	8
Rectum**	7	11
Surgery**	48	76
Colon**	28	44
Rectum**	20	32
Radiation/Chemoradiation**	5	8

*Percentage of screening colonoscopy participants.
**Percentage of screen detected CRCs.

cancer and patient frailty. The single anal squamous cell carcinoma (SCC) was treated with radical chemoradiation.

Altogether seventeen (27%) of the carcinomas were T1-cancers, which were superficial or polyp carcinomas that invaded only the submucosa. Twelve polyp cancers were resected by polypectomy during the screening colonoscopy. Two of the T1-cancers were resected by endoscopic submucosal dissection (ESD) and three were treated primarily with surgery. A completion surgery with bowel resection was performed for two patients due to inadequate resection margin in snare polypectomy specimen or heightened risk of local lymph node metastases. None of the five patients who underwent primary or completion surgery for T1-cancer had lymph node metastases.

In total two patients had major surgical complications: one post-operative bleeding required embolization by an interventional radiologist and the second patient had a prolapsed protective colostomy surgically corrected.

Stage distribution of the detected CRCs is presented in Table 3. Nearly half were stage 1 tumors ($n = 31$, 49%). Lymph node metastases were found in 18 CRCs (28%) and these patients received adjuvant chemotherapy postoperatively.

Discussion

This study of the recently implemented national Finnish CRC-screening program showed for the first time a CRC detection rate of 0.27% among subjects who had participated in screening in South-West Finland. In a previous Finnish FIT based screening pilot study, the CRC detection rate was lower (0.17%) [6]. This difference may be due to the higher cut-off level (70 µg hemoglobin/g feces) for hemoglobin for males used in the pilot study, which thus detected fewer cancers. In that same study the cut-off level (25 µg hemoglobin/g feces) for hemoglobin for females used was the same as in our study. Based on the pilot study and later modelling, the cut-off was set to 25 µg hemoglobin/g feces for both sexes in the national screening program and used in this study. Our study showed a 6.0% FIT-positivity and 5.6% cancer detection rate in colonoscopy. Large European screening studies using the same cut-off value for hemoglobin reported similar FIT-positivity and cancer detection rates [7–9]. In those studies, FIT positivity varied between 6.2–7.3% and CRC was diagnosed in 5.6–6.2% of colonoscopy participants.

As a quality measure, 97% of colonoscopies in our study reached the cecum. This compares well with a Norwegian study that included 6945 screening colonoscopies after FIT and had an almost identical cecum intubation rate of 98% [10]. Our 63% adenoma detection rate (ADR) is high. For example, a Danish FIT-based CRC screening study that included 6749 colonoscopies, had a lower ADR that varied between 47–53% [11]. Desai et al. showed that adenoma detection rate increased when the withdrawal time increased from 6 min up to 13 min [12]. The rather long withdrawal time of 16 min in our study included therapy and therefore is not suitable as a quality indicator. The high ADR will hopefully contribute to a low number of interval cancers and a lowering of the CRC incidence in the future.

CRCs found in our study were left-sided in 90% of the cases. Similar findings have been observed in a Belgian study in which 78% of screening detected CRCs were left-sided [8]. A Norwegian pilot study for CRC screening revealed 74% left-sided FIT-screened CRCs [10]. Both the Belgian and the Norwegian studies used a FIT-threshold value of 15 µg hemoglobin/g feces. The endoscopy quality indicators were similar in our study but the lower FIT-threshold used may have contributed to a higher proportion of right-sided CRC. Lesions located in the splenic flexure were counted as distal in our study, whereas they were counted as proximal in the Belgian and Norwegian studies mentioned above. This may have an effect on the rate of left-sided lesions in our study. An Italian study consisting of six separate FIT rounds found that the detection rates for advanced adenomas and for CRC steadily decreased between first and sixth FIT rounds in the distal colon (from 1.65–0.17) and the rectum (0.82–0.17) but not so

in the proximal colon [13]. Another Belgian study found that FIT interval CRC was associated with a higher proportion of right-sided location in comparison to screening detected CRC [14]. Future screening rounds will show CRC anatomical distribution and adenoma detection rate trends amongst those who were previously FIT negative in the Finnish screening program.

The stage distribution of the detected CRCs in this study was skewed towards the earlier stages with a better prognosis compared to colonoscopies performed for symptoms. The proportion of stage I–II cancer (67%) was clearly higher than in an earlier population-based study performed in 2001–2012 in the same geographical region [15], where the percentage of stage I–II disease was 53%. Although patients with lymph node metastases were found with a similar frequency as the earlier study (25–29%), the proportion of patients with distant metastases (stage IV) was much lower (3% vs 11–20%) in this screening study. Our current stage distribution is similar to a Belgian study [16] that showed that 67% of screening detected CRCs were either stage I or II. In that same study, the ratio of stage IV CRC among FIT-interval CRC increased when comparing to screening-detected CRC (26.6% vs 6.6%). It remains to be seen whether higher stages amongst FIT-interval CRC patients become more prevalent in the Finnish screening program.

Acute complications ($n=3$, 0.27%) in our study were in line with the rate of complications in screening colonoscopy ($n=12$, 0.23%) reported in a recent German cohort study [17]. Late complications that occurred within 30 days of colonoscopy and which required a doctor's visit were slightly more frequent in our institution when compared to the same German cohort (0.45% vs 0.15%). None of our patients with anticoagulant continuation or cessation suffered a gastrointestinal bleed that required transfusion or had a cardiovascular event. A systematic review concluded that aspirin or non-steroidal anti-inflammatory drug (NSAID) therapy continuation did not present a significant risk for post polypectomy bleed. However, clopidogrel and warfarin therapy did present a risk and thus temporary cessation of clopidogrel and warfarin therapy was recommended [18]. Our results support the feasibility of this recommendation regarding aspirin and NSAID therapy. Another systematic review found no significant difference for post polypectomy bleed between warfarin and direct oral anticoagulants [19].

Major surgical complications occurred in 4% of surgically managed CRC patients in our study. A Dutch cohort study reported a higher postoperative complication rate. That same study also concluded that surgical postoperative complications were less prevalent amongst CRCs that were detected during screening (colon 12.0%, rectum 20.4%) vs non screening detected CRC (colon 17.0%, rectum 23.1%) [20]. A Swedish study observed postoperative surgical complications classified as Clavien-Dindo III or higher in 24 (15%) cases [21].

The strengths of this study are that all the colonoscopies were performed by experienced gastroenterologists with at least 6 years of experience on polypectomies. However, we acknowledge this study also has certain limitations. There is currently no Finnish national screening program data from other wellbeing services counties to compare with our findings. Screening non-responders may differ from responders in terms of FIT positivity, ADR, and CRC detection rate. We collected the patients participating in colonoscopy from March 1st, 2022 to April 14th, 2023. If the patient returned their FIT sample after the study period, they were not included in our study, which reduces the number of participants. The actual number of people who returned the FIT test was higher. In addition, small number of the patients had their colonoscopy done in private facilities. Since there was a small number of cancer cases, the stage distribution may be skewed, and the number of procedural complications can be significantly affected by chance.

Conclusions

This Finnish CRC screening population study showed for the first time the CRC prevalence of 0.27% among screening participants in South-West Finland. ADR and CIR were high, indicating high colonoscopy quality in our study. Complications were uncommon.

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