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Differential Outcomes in Colorectal Cancer Detection

A Comparative Study of Swedish Nationwide Screening and Fast-Track Diagnostic Pathways

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Background: In 2021, a nation-wide screening program for colorectal cancer (CRC) was step-wise implemented in Region Örebro County (RÖC) for patients aged 60 to 74 years, utilizing the fecal immunochemical test (FIT) to refer patients for colonoscopy. Concurrently, the standardized care course for colorectal cancer (SCC-CRC), initiated in 2016, employs a fast-track pathway for patients with alarm symptoms to undergo colonoscopy. This study compares CRC screening colonoscopies with SCC-CRC colonoscopies in RÖC among patients aged 60 to 67 years.

Methods: An initial analysis of the Swedish colorectal screening cohort was combined with a retrospective cohort study, analyzing data from 307 CRC screening patients and 441 age-matched SCC-CRC patients in RÖC. Data included demographics, colonoscopy participation rates, and pathology findings. Statistical analyses compared outcomes between the 2 groups.

Results: Among the screening group, 2% tested positive for FIT, with an 86% colonoscopy participation rate (N = 9296). In RÖC, 266 screening patients underwent colonoscopy, with 10% diagnosed with CRC, compared with 20% in the SCC-CRC group. In addition, 39% of the screening group in RÖC were diagnosed with advanced adenomas, versus 15% in the SCC-CRC group

Conclusions: Screening participation was high, with effectiveness aligning with international counterparts. The SCC-CRC pathway excels in diagnosing CRC among symptomatic patients, while the nationwide screening program is effective in early detection of CRC and advanced adenomas. underscoring the importance of integrating and optimizing both approaches within the Swedish health care system to optimize CRC prevention and management.

Key Words: colorectal cancer, screening, colonoscopy, fast-track, FIT, adenoma, polyps, adenoma detection rate

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The authors declare that they have nothing to disclose.

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Colorectal cancer (CRC) ranks as the third most prevalent cancer globally and the second leading cause of cancer-related deaths.[1–5] CRC often originates from adenomas, which, like CRC, are detectable through colonoscopy. Occult intestinal bleeding, a potential early indicator of both adenomas and CRC, may occur before any other symptoms are noted.[1,5] This type of bleeding can be identified through fecal blood tests, such as the guaiac fecal occult blood test (gFOBT) and the more effective quantitative fecal immunochemical test (qFIT),[1,6] with the latter showing superior performance.[7] These testing methods are integral components of CRC screening, with colonoscopy serving as the gold standard for diagnosis.[3,5] In addition to routine colonoscopies, there are 2 alternative pathways for detecting colorectal cancer (CRC). The first is the fast-track pathway known as the Swedish Standardized Course of Care for colorectal cancer (SCC-CRC), where patients displaying potential cancer symptoms undergo a colonoscopy within 2 weeks. Previous findings indicate that the cancer detection rate in this group is 16.4%.[8] The second pathway is a nationwide screening program, adopted by many countries, which relies exclusively on a positive fecal immunochemical test (FIT). In Sweden, the FIT cutoff levels are gender specific: 40 μg hemoglobin (Hb)/g feces for women and 80 μg Hb/g feces for men.[9] The determination of these levels considers factors such as gender, age, and health care resources. The primary goal of screening is early detection of CRC and identification and removal of precancerous lesions during colonoscopy, thereby reducing both the incidence and mortality rates of CRC.[1] Evidence supports the effectiveness and cost-efficiency of CRC screening.[3,4,10]

In Sweden, the nationwide CRC screening program was gradually implemented from 2019 to 2022, with a specific launch in Region Örebro County (RÖC) in August 2021. This program biennially invites individuals aged 60 to 74 to participate in CRC screening, utilizing FIT as the primary screening method.[9,11,12]

The CRC screening process initiates with the distribution of testing kits through post to eligible individuals, accompanied by detailed instructions on how to use the test. Participants are required to collect a single stool sample and mail it back to the designated laboratory. If the test result is positive, the participant is referred for a colonoscopy. Conversely, if the test result is negative, they will remain in the screening program and receive a new FIT kit after 2 years. Should the time taken for the stool sample to reach the laboratory exceed 7 days, or if the date of the stool

sample collection is unrecorded and the test result is negative, the participant will be asked to retake the test.[13] During the colonoscopy, any detected adenomas are removed. If colorectal cancer is identified, the patient is referred to a colorectal surgeon for further treatment.[14] All data from this nationwide CRC screening are systematically compiled in a national database, SveReKKs.[15]

Implemented in 2016, the Swedish SCC-CRC aims to to shorten the time from symptoms of possible CRC to diagnosis and treatment initiation. The entry criteria for SCC-CRC colonoscopies, revised in 2019 and again in 2022, are designed to streamline access for health care professionals across both primary care centers and hospitals. These criteria include an abnormal rectal examination conducted via proctoscopy/rectoscopy or manual rectal palpation, unexplained iron deficiency anemia, visible blood in the stool without a clear source, persistent blood in the stool for more than 4 weeks despite treatment of a likely cause (typically hemorrhoids), altered bowel habits persisting for more than 4 weeks in patients over 40 years old in conjunction with a positive FIT test, and concerning radiologic findings. Following an SCC-CRC referral, a colonoscopy is mandated to be performed within 10 days.[16] The rationale for comparing these 2 pathways lies in their differing methodologies and target populations. The nationwide screening program is aimed at early detection of CRC in asymptomatic individuals, primarily using FIT to identify candidates for colonoscopy. In contrast, the SCC-CRC pathway focuses on symptomatic individuals, utilizing a combination of clinical indicators such as anemia and abnormal rectal examination results to prioritize diagnostic colonoscopies. Understanding the strengths and limitations of each approach can help in refining screening strategies and improving patient outcomes.

AIMS

To conduct an initial analysis of the Swedish CRC screening cohort and compare the efficacy and outcomes of a subgroup of 307 screening patients in Region Örebro County (RÖC) with age-matched and sex-matched patients in the fast-track SCC-CRC pathway in RÖC, to elucidate differences in cancer detection rates, polyp detection, and overall effectiveness.

METHODS

SveReKKs

SveReKKS is a comprehensive database that collects data from all Swedish health care providers involved in the organized CRC screening program. Its primary purpose is to serve as a robust source of information for patients, health care professionals, researchers, and policymakers about Swedish care practices. SveReKKS boasts a 100% coverage rate and includes complete data on participation rates, fecal testing within the organized screening program, and endoscopic outcomes. Data were collected for the period from April 1, 2019 to December 31, 2022. The latest update of the SveReKKS database was made on November 28, 2023. The collected data comprises of the number of subjects invited to participate in the nationwide screening, the participation rate in FIT testing, the proportion of positive FIT results, the number of colonoscopy referrals, the proportion of colonoscopies actually performed, and the outcomes of these colonoscopies.

Screening in RÖC

We conducted a comprehensive and detailed retrospective cohort study of all subjects referred for colonoscopy according to the nationwide CRC screening program from the hospitals in RÖC (Örebro and Karlskoga). The study period spanned from the inception of the screening program in RÖC in August 2021 through to the final data collection in October 2023. During this period, a total of 307 subjects aged 60 to 67 years who tested positive on the FIT were invited to undergo a colonoscopy (CRC-screening group).

SCC-CRC in RÖC

We compared data from the CRC-screening group with that from all subjects referred according to the SCC-CRC within RÖC from September 2016 to December 2020. This latter cohort comprised 2539 subjects, including 441 age-matched individuals (SCC-CRC group).

Colonoscopies for both groups were conducted by experienced endoscopists at the endoscopy units in RÖC, ensuring consistent and high-quality examinations. The endoscopists who performed the screening colonoscopies were also involved in the SCC-CRC colonoscopies.

Data Collection RÖC Patients

For subjects in the CRC-screening group in RÖC, detailed data were manually extracted from medical records. This information included demographics, symptoms (when available), laboratory values (when available), and colonoscopy outcomes. High-risk adenomas were classified as: high-grade dysplasia, ≥ 10 mm in size, villous histology, multiple adenomas of ≥ 5 in quantity (an increase from the previous threshold of ≥ 3, with criteria updated in 2023), or serrated polyps with dysplasia or ≥ 10 mm in size. The cutoff period for considering laboratory values was 1 month before the date of the investigation, with the most recent date being used. For the SCC-CRC group, detailed data were collected from an existing database used in our previous study.[8] This data set included all variables that were collected for the CRC-screening group, with the exception of polyps without dysplasia. Symptoms for this group were derived from information in the referrals. The definition of high-risk adenomas in this group was based on the criteria at the time the database was established, where the threshold for multiple adenomas was ≥ 3.

The study received approval from the Regional Ethical Review Board in Uppsala (Dnr 2023-03776-02 and Clinical Trials ID: NCT04585516).

Statistical Analysis

Statistical analysis was conducted using IBM SPSS software. For nominal data, the Pearson χ^2 test was used, with results presented as absolute numbers and percentages to show incidence rates. For numerical data, we used the unpaired t test for normally distributed variables and the Mann-Whitney U test for non-normally distributed variables. Results for non-normally distributed data are presented as medians and interquartile ranges (IQR), while normally distributed data are presented using means and SD. A threshold for statistical significance was established at $P < 0.05$.

RESULTS

SveReKKs

In total, 695,572 subjects were invited to participate in the nationwide screening. Out of these, 67.3% completed and returned the FIT kit. From the returned kits, 2% tested positive. Consequently, 10,790 subjects were referred for a colonoscopy, and 9296 subjects (86%) underwent a colonoscopy.

Further details on the outcomes of the screening colonoscopies are detailed in Table 1.

CRC Screening in RÖC

Within RÖC, 307 subjects were initially referred for colonoscopy as part of the CRC screening program (screening-CRC group). Of these, 41 subjects (13%) were excluded; reasons for exclusion included opting out of participation or already being scheduled for follow-up colonoscopies. Specifically, 25 subjects declined participation or were no-shows, 11 subjects had previously undergone colonoscopy, and 5 subjects were in the process of being referred for colonoscopy through the SCC-CRC pathway and were therefore excluded. The inclusion process is depicted in Figure 1, while Table 2 delineates the baseline characteristics of the included subjects.

Colonoscopy Outcomes

Outcomes from the colonoscopies are summarized in Table 3. The detection rate for colorectal cancer (CRC) was 10% in the CRC screening group in RÖC, and 20% in the SCC-CRC group, a difference that was statistically significant ($P < 0.001$). Furthermore, a significantly larger proportion of females were diagnosed with CRC in the SCC-CRC group (11%) as compared with the CRC-screening group in RÖC (3%), ($P < 0.001$). In addition, the incidence of high-risk adenomas was notably more frequent in the CRC-screening group in RÖC ($P < 0.001$).

Sex Differences in the CRC Screening Group in RÖC According to Type of Pathology

The colonoscopy findings revealed a significant disparity in the diagnosis of colorectal pathologies between sexes. A higher incidence of colorectal cancer (CRC), various polyp types, and high-risk adenomas were observed in males compared with females ($P < 0.001$). These differences are illustrated in Figure 2.

DISCUSSION

This study marks the first report on the outcomes of Sweden's national colorectal cancer (CRC) screening program. The observed FIT testing participation rate of 67.3% is commendable and compares favorably with other nations that share similar demographics and lifestyle characteristics, and have established CRC screening programs. For instance, the Netherlands reported a first-time screening participation rate of 57.7% in 2022 among a population aged 55 to 75 years (https://www.rivm.nl/en/colorectal-cancer-screening-programme). It is noteworthy that only 2% of FIT tests in Sweden yielded positive results, a figure that could be influenced by differences in the age range targeted for screening and the FIT cutoff value of 47 μg/g for both sexes utilized in the Netherlands. Moreover, the adherence rate to colonoscopy after a positive FIT test stands at 86%, mirroring the rate seen in the Dutch program.

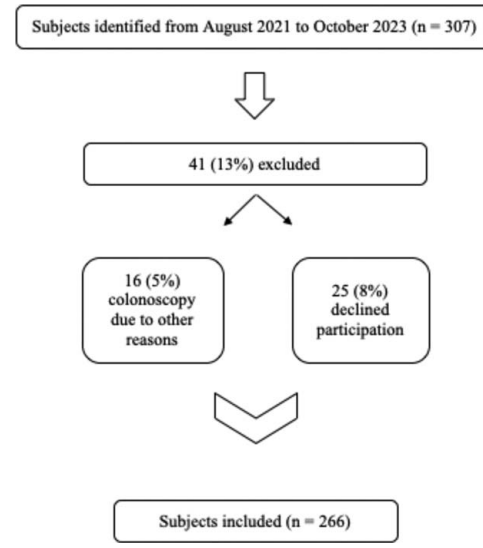

FIGURE 1. Flowchart of the inclusion and exclusion process for subjects in the CRC-screening group in RÖC.

The discrepancy in cancer detection rates across sexes can be attributed to the different FIT thresholds used for men and women in the screening program. In Sweden, the FIT threshold is set at 40 μg Hb/g feces for women and 80 μg Hb/g feces for men. These thresholds account for physiological differences but may contribute to the observed discrepancies in cancer detection rates. The difference in the detection of proximal cancers between the CRC screening and SCC-CRC pathways can be attributed to the use of FIT in the screening population. FIT is more sensitive to bleeding associated with distal cancers, while anemia, used in the symptomatic population, may better indicate proximal cancers.

TABLE 1. Data From Screening Colonoscopy

Variable	Total screening colonoscopy (N = 9296) (%)	Males (N = 4302)(%)	Females (N = 4994) (%)
Proportion (M/F)		45.7	54.3
Age (mean) (y)	63.6	63.6	63.6
Cecal intubation rate	97	97	96
Polyp detection rate	68	75	62
Adenoma detection rate	44	51	37
Advanced adenoma	20	26	16
Cancer	6	7	5

Advanced adenoma is defined as: at least 1 adenoma ≥ 10 mm, or at least 1 polyp where the pathology report shows any of the following: tubular adenoma with high-grade dysplasia or a villous/tubulovillous adenoma with high-grade dysplasia.

TABLE 2. Baseline Characteristics of the Study Populations

Variables	CRC-screening group in RÖC (N = 266)	SCC-CRC group (N = 441)	*P*
Sex, N (%)	Males: 128 (48) Females: 138 (52)	Males: 205 (46) Females: 236 (54)	0.673*
Age, mean years (SD)	62.7 (1.8)	63.8 (2.2)	< 0.001†
Hb (g/l), median (IQR)	138 (20.5)	132 (28)	0.195‡
Altered bowel habits, N (%)	35 (13)	228 (52)	< 0.001*
Rectal bleeding, N (%)	29 (11)	105 (24)	< 0.001*

*Analyzed with Pearson χ^2 test.
†Analyzed with unpaired *t* test.
‡Analyzed with Mann-Whitney *U* - test.
IQR indicates interquartile range; SCC-CRC, standardized course of care for colorectal cancer.

However, there are nuances in the outcomes of the colonoscopies: the Netherlands identified CRC in 4% of cases and advanced adenomas in 25%, whereas the corresponding figures for Sweden are 6% and 20%, respectively. The substantial detection rate of adenomas and the high cecal intubation rate in Sweden underscore the high quality of the screening colonoscopies being performed. Upon detailed examination of the CRC-screening group in RÖC, the proportion of detected cancers was 10%, which contrasts with a 20% detection rate within the age-matched SCC-CRC group. While both the nationwide CRC screening program and the SCC-CRC pathway aim to detect colorectal cancer, they target different populations and utilize distinct methodologies. The nationwide screening program focuses on asymptomatic individuals using FIT, whereas the SCC-CRC pathway prioritizes symptomatic patients based on clinical indicators. These differences should be considered when interpreting the comparative results of this study to ensure that conclusions drawn are contextually appropriate and supported by the data. Other clinical indicators factored into the SCC-CRC criteria, such as anemia, abnormal rectal examination results, and suspect radiologic findings, also possess predictive validity for CRC, although to a substantially lesser extent than a positive FIT result.[8]

TABLE 3. Colonoscopy Outcomes of the Study Populations

Variables	CRC-screening group in RÖC (N = 266), N (%)	SCC-CRC group (N = 441), N (%)	*P*
Colorectal cancer	26 (10)	87 (20)	< 0.001
Males	19 (7)	38 (9)	0.624
Females	7 (3)	49 (11)	< 0.001
Polyp (low-grade dysplasia)	160 (60)	146 (33)	< 0.001
Males	98 (37)	76 (17)	< 0.001
Females	62 (23)	70 (16)	< 0.001
High-risk adenoma	104 (39)	67 (15)	< 0.001
Males	70 (26)	38 (9)	< 0.001
Females	34 (13)	29 (7)	< 0.001
Diverticulosis	108 (41)	158 (36)	0.34
Unspecific inflammation	7 (3)	13 (3)	0.72
Suspected IBD	3 (1)	10 (2)	0.41
Hemorrhoids	39 (15)	196 (44)	< 0.001
Angiodysplasia	4 (2)	7 (2)	0.74
Microscopic colitis	1 (0)	9 (2)	0.14
Diverticulitis	0	3 (1)	0.30
Infectious colitis	0	0	0.44
Synchronic CRC	1 (0)	0	0.20
No finding	32 (12)	79 (18)	0.08

High-risk adenoma defined as high-grade dysplasia, adenomas ≥ 10 mm in size, villous histology, multiple adenomas ≥ 5 (≥ 3 in SCC-CRC group), number of serrated polyps with dysplasia or ≥ 10 mm in size.
P-values analyzed by the Pearson χ^2 test.
CRC indicates colorectal cancer; IBD, inflammatory bowel disease; SCC-CRC, standardized course of care for colorectal cancer.

The observed differences in cancer prevalence between the SCC-CRC pathway and the nationwide CRC screening program can partly be explained by the nature of the populations being studied. Patients in the SCC-CRC pathway are symptomatic, which inherently results in a higher prevalence of detected cancers compared with the asymptomatic population in the CRC screening program. In addition, lead time bias can influence cancer prevalence in screening programs. Lead time bias occurs when screening detects cancers earlier than they would be clinically diagnosed in the absence of screening, thus temporarily inflating prevalence rates due to the earlier detection. However, in this study, the higher prevalence of cancer in the SCC-CRC pathway is more likely due to the symptomatic nature of the patients rather than lead time bias.

While we do not have exact data on cecal intubation rates and adenoma detection rates specifically for the SCC-CRC group, it is reasonable to assume that these metrics do not significantly differ from the CRC screening group in RÖC, based on the large overlap of endoscopists who performed the colonoscopies for both groups, ensuring consistent quality across the procedures.

The 10% cancer yield identified within the CRC-screening group in RÖC is marginally higher than the 6% cancer yield in the nationwide screening program. The factors contributing to this variance remain indeterminate but may include the smaller participant pool in RÖC, regional variations in CRC incidence, or potential selection bias due to the exclusive analysis of the 60 to 67-year age demographic in RÖC. Cancer staging is a crucial component of evaluating screening effectiveness. At this point, we have insufficient data to perform reliable analyses but the nationwide screenings program aims to demonstrate the effectiveness of FIT in identifying cancers at a treatable stage, as supported by a long-term study from the United States, which reported a significant decrease in CRC mortality over a 30-year follow-up period postscreening, compared with no screening (relative risk: 0.78; 95% CI: 0.65-0.93).[17] In addition, Canadian research indicates that screening facilitates the early detection of CRC and decreases mortality rates associated with the disease.[18] Complementary findings from another US study revealed a 33% reduction in CRC mortality over a 13-year period following screening.[19] The benefits of screening are further

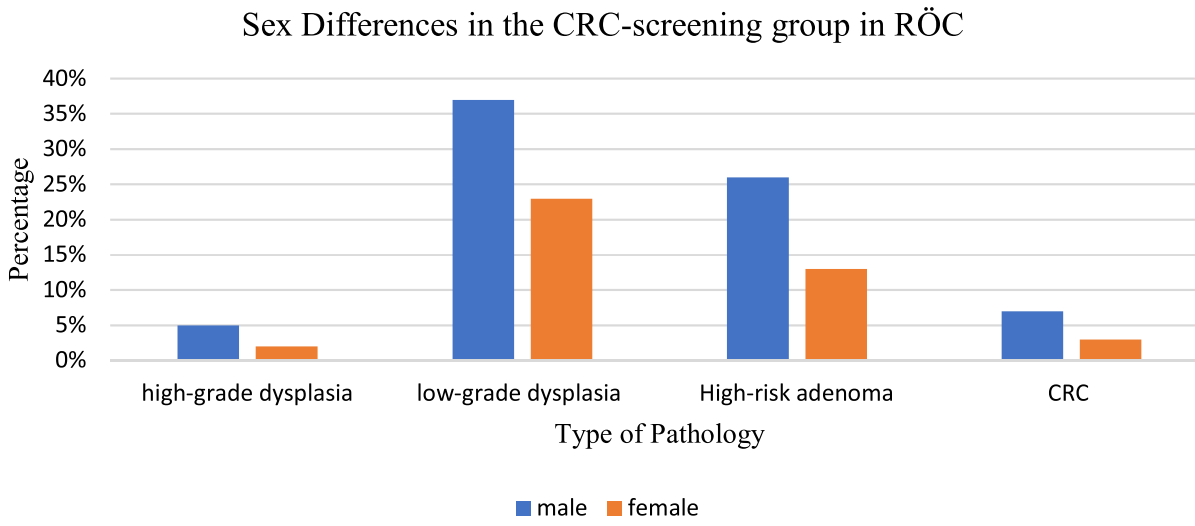

FIGURE 2. Presentation of sex differences in the CRC-screening group in RÖC indicating a higher prevalence of all analyzed pathologies among men compared with women. We observed statistically significant differences ($P < 0.001$) for all pathologies within the figure. CRC indicates colorectal cancer.

confirmed in a systematic review which showed a reduced relative risk of death (0.72) from CRC,[5] and a study with a 10-year follow-up period that documented a mortality ratio of 0.82.[20] In addition, a study from the Netherlands highlighted an interval cancer rate of 7.2% in screened individuals, predominantly in the proximal colon, underscoring the critical role of high-quality colonoscopies and thorough bowel preparation in effective CRC screening.[21]

Polyps and precancerous lesions, including those with low-grade dysplasia, high-grade dysplasia, and high-risk adenomas, were commonly observed, with a significantly higher prevalence found in the CRC-screening group. This underscores the critical role of screening not only in detecting these lesions but also in facilitating their removal, which directly contributes to reducing both the incidence and mortality of CRC.

In a prior Swedish study that analyzed colonoscopy outcomes following a positive FIT, it was observed that FIT positivity, compared with a negative result, was significantly associated with the detection of high-grade dysplasia (78% vs. 22%, respectively) and high-risk adenoma (20% vs. 8.5%, respectively).[6] In addition, a study comparing different screening methods demonstrated a reduction in CRC incidence (relative risk 0.76) and related mortality (relative risk 0.74) over a 15-year follow-up period compared with no screening.[1] Furthermore, research from the USA showed a significant decrease in CRC incidence from screening over an 18-year follow-up.[22] Another comparative study highlighted a 31% reduction in distal CRC incidence as well as decreased mortality associated with both proximal (relative risk 0.47) and distal CRC (relative risk 0.18),[23] emphasizing the effectiveness of screening in reducing CRC-related mortality.

This study has some limitations that could impact the results, including the lack of detailed quality information for index colonoscopies such as the adenoma detection rates of the endoscopists and bowel preparation quality. Future studies should incorporate these metrics to provide a more comprehensive analysis of colonoscopy quality and its impact on CRC detection rates. Notably, there are no data on lifestyle factors such as smoking, obesity, hereditary predispositions, or alcohol consumption, all of which are known to influence the incidence of CRC. The absence of this information means that these variables could serve as potential confounders. In addition, the study is geographically limited to the population of RÖC, which may not accurately represent the broader Swedish population. The age range of the participants is also restricted to 60 to 67 years, reflecting only those who have entered the screening program in RÖC to date. Future expansions of the study to include other age groups is of importance, particularly to explore age as a risk factor for CRC.

Despite these limitations, this study is the first to present data from the Swedish nationwide CRC screening program and to compare outcomes between SCC-CRC colonoscopy and screening colonoscopy. The detailed individual analysis of outcomes in both the screening and SCC-CRC groups, with age-matched participants, enhances the study's robustness. This research lays a foundation for future studies aimed at assessing the efficacy of CRC screening in Sweden.

CONCLUSIONS

The initial results from the Swedish nationwide CRC screening indicate a CRC yield of 6%, alongside a high polyp detection rate and cecal intubation rate, which are indicative of high-quality colonoscopies. These results align closely with data from the Netherlands, illustrating comparable screening effectiveness. However, the long-term effects of the screening on CRC incidence and the rate of interval cancers are yet to be determined.

In addition, the SCC-CRC group demonstrated a significantly higher prevalence of CRC at 20%, compared with 10% in the CRC-screening group. This disparity highlights the effectiveness of both the fast-track pathway and the structured screening program in terms of cancer detection and polyp identification. These findings underscore the importance of integrating and optimizing both approaches within the Swedish health care system to optimize CRC management and prevention. Future studies should focus on optimal FIT cutoff values and the effect of screening and SCC-CRC on cancer staging.

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