A 9-Year Follow-up Study of Participants and Nonparticipants in Sigmoidoscopy Screening: Importance of Self-Selection

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Abstract

Background: **Self-selection may compromise cost-effectiveness of screening programs. We hypothesized that nonparticipants have generally higher morbidity and mortality than participants.**

Methods: **A Swedish population-based random sample of 1,986 subjects ages 59 to 61 years was invited to sigmoidoscopy screening and followed up for 9 years by means of multiple record linkages to health and population registers. Gender-adjusted cancer incidence rate ratio (IRR) and overall and disease group-specific and mortality rate ratio (MRR) with 95% confidence intervals (95% CI) were estimated for nonparticipants relative to participants. Cancer and mortality rates were also estimated relative to the age-matched, gender-matched, and calendar period-matched Swedish population using standardized incidence ratios and standardized mortality ratios.**

Results: **Thirty-nine percent participated. The incidence of colorectal cancer (IRR, 2.2; 95% CI, 0.8-5.9), other gastrointestinal cancer (IRR, 2.7; 95% CI, 0.6-12.8), lung cancer (IRR, 2.2; 95% CI, 0.8-5.9), and smoking-related cancer overall (IRR, 1.4; 95% CI, 0.7-2.5) tended to be increased among nonparticipants relative to participants. Standardized incidence ratios for most of the studied cancers tended to be >1.0 among nonparticipants and <1.0 among participants. Mortality from all causes (MRR, 2.4; 95% CI, 1.7-3.4), neoplastic diseases (MRR, 1.9; 95% CI, 1.1-3.5), gastrointestinal cancer (MRR, 4.7; 95% CI, 1.1-20.7), and circulatory diseases (MRR, 2.3; 95% CI, 1.2-4.2) was significantly higher among nonparticipants than among participants. Standardized mortality ratio for the studied outcomes tended to be increased among nonparticipants and was generally decreased among participants.**

Conclusion: **Individuals who might benefit most from screening are overrepresented among nonparticipants. This self-selection may attenuate the cost-effectiveness of screening programs on a population level.** (Cancer Epidemiol Biomarkers Prev 2008;17(5):1163–8)

Introduction

A potential threat to the cost-effectiveness of colorectal cancer screening is selective uptake in the population. Nonparticipants have been shown to have an ''unhealthy'' lifestyle (1, 2). Thus, they might be at greater risk of developing cancer and might potentially benefit more from screening than those who actually participate. The latter category has been shown to have a healthier lifestyle (3) and might have lower cancer and mortality risks. Insights about cancer morbidity and mortality among nonparticipants may guide efforts to increase participation of individuals belonging to population categories with particularly high prevalence of precancerous or cancerous lesions.

In this follow-up study, we compared cancer incidence and mortality among participants and nonparticipants in a population-based pilot study of colorectal cancer screening with sigmoidoscopy. We also made comparisons with the age-matched, gender-matched, and calendar period-matched general population of Sweden. The study was approved by the Regional Research Ethics Committees at Karolinska Institutet and at Uppsala University and Lund University.

Materials and Methods

The screening study has been described previously (4, 5). Briefly, from the population register, we randomly selected 2,000 men and women ages 59 to 61 years residing in two areas in central (Uppsala) and southern (Lund) Sweden. The selected individuals were invited to screening sigmoidoscopy in 1996/1997. Thirteen of the subjects selected were excluded because they had moved out of the study areas and one because of an erroneous National Registration Number. No other exclusion criteria were used. Of the remaining 1,986 individuals,

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1,001 (50.4%) were men and 985 (49.6%) were women. The mailed invitation letter included information about colorectal cancer, screening in general, and the sigmoidoscopic examination. Half of the subjects were randomly assigned to receive a version of the invitation letter where they were asked to call a specific phone number to make an appointment. The other half of the invitees were not told to make an appointment themselves but were called up by a nurse, who made the arrangements. Compliance did not differ significantly between these two modes of invitation (4). All sigmoidoscopies were free of charge for the invitees and performed on an outpatient basis at two hospitals, one in each area. In case of a positive finding, the participants were subsequently scheduled for a colonoscopy.

A computer file with the invitees' National Registration Numbers (unique personal identifiers assigned to all Swedish residents and used in the registers used for this study) and information about participation status was sent to the Swedish Cancer Register (6) to obtain information on all occurrences of cancer after the invitation according to the *International Classification of Diseases* (ICD-7). Information was also extracted about cancer occurrences between start of cancer registration in Sweden in 1958 and time of invitation. We grouped neoplastic outcomes into all forms of cancer (ICD-7 140-209), colorectal cancer (ICD-7 153, 154), other gastrointestinal cancer (ICD-7 150-152, 155-159), lung cancer (ICD-7 162, 163), and overall smoking-related cancers [ICD-7 140-148 (lip-pharynx), 150-151 (esophagus-stomach), 157 (pancreas), 161-162 (larynx-bronchus/lung), 171 (cervix uteri), 180-181 (kidney-bladder/other urinary organs); ref. 7].

Dates and underlying causes of death were obtained from the Causes of Death Register (8). The causes of mortality are classified according to ICD-10. We obtained information on all-cause mortality, mortality from all neoplastic diseases (ICD-10 C00-D48), gastrointestinal cancer specifically (ICD-10 C15-C26, C48), and mortality from diseases of the circulatory system (ICD-10 I00-I99). We also studied accident-related (ICD-10 V01-Y98), alcohol-related, and drug-related mortality (ICD-10 F10-F19).

As the Death Register lacked information about the causes of deaths that had occurred after December 31, 2003, follow-up for specific causes of deaths was terminated 2 years earlier than the follow-up for all-cause mortality. To ensure correct censoring, we also requested information from Statistics Sweden about dates of emigration for cohort members who left Sweden during follow-up. After these record linkages, the data set was de-identified through removal of the National Registration Numbers before it was delivered to the investigators.

Statistical Analyses. The cohort members were followed from the date of start of invitations, that is, May 3, 1996 in Uppsala and November 1, 1996 in Lund, until the date of studied outcome, emigration, or death, whichever occurred first. End of follow-up varied with outcome: December 31, 2004 for cancer incidence, December 31, 2003 for cause-specific mortality, and December 31, 2005 for all-cause mortality. There was no censoring for cancer incidence in the mortality analyses.

To assess associations between participation status and incidence of the studied cancer and mortality outcomes mentioned in the foregoing, Poisson regression modeling was used with adjustment for gender, yielding estimates of incidence rate ratio (IRR) for cancer incidence and mortality rate ratio (MRR) for mortality. Further, observed numbers of cancers and deaths among participants and nonparticipants were compared with the expected numbers based on the rates in the matching general population. This yielded standardized incidence ratio (SIR) and standardized mortality ratio (SMR) as measures of age-adjusted, gender-adjusted, and calendar year-adjusted relative risk with the general population as reference. The expected numbers were calculated by multiplying the accumulated person-time decomposed into 5-year age, gender, and 1-year calendar strata in the studied subcohorts times the incidence and mortality rates in the corresponding strata in the general Swedish population (6, 8). Although we had 2 extra years of follow-up for all-cause mortality (see above), the corresponding SMR values were based on data up until December 31, 2003 because we did not have access to population rates beyond this date. All 95% confidence intervals (95% CI) were calculated based on the assumption that the observed number of outcomes followed a Poisson distribution.

Results

In total, 1,215 (61%) of the invited subjects (616 men and 599 women) chose not to participate, whereas 771 (39%; 385 men and 386 women) participated. In Uppsala, the

Table 1. Cancer incidence (per 1,000 person-years) among 1,215 nonparticipants relative to 771 participants in screening sigmoidoscopy

Outcome (ICD-7)	Nonparticipants		Participants		IRR* (95% CI)
	Observed no.	Incidence†	Observed no.	Incidence	
All-site cancer (140-209)	115	13.4	75	13.1	1.02 (0.8-1.4)
Colorectal cancer (153, 154)	16	1.7	5	0.8	2.2 (0.8-5.9)
Other gastrointestinal cancer (150-152, 155-159)	8	0.9	2	0.3	2.7 (0.6-12.8)
Lung cancer (162, 163)	16	1.7	5	0.8	2.2 (0.8-5.9)
Smoking-related cancer‡	32	3.5	16	2.6	1.4 (0.7-2.5)

NOTE: Relative risks are expressed as gender-adjusted IRR with 95% CI.
*Gender adjusted.
†Incidence rate per 1,000 person-years.
‡ICD-7 140-148, 150-151, 157, 161-162, 171, 180-181.

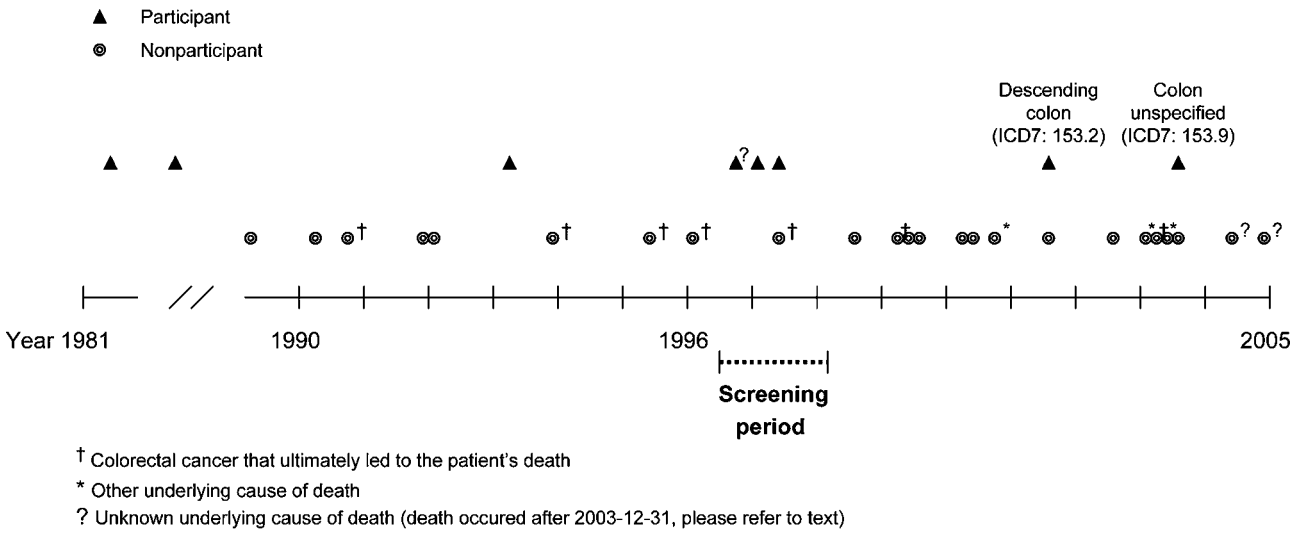

Figure 1. Time of diagnosis in 32 colorectal cancers among 1,986 randomly selected Swedish residents ages 59 to 61 y zinvited to sigmoidoscopy in 1996/1997 and localization in colorectal cancers among participants not diagnosed at screening.

last screening sigmoidoscopy was done on October 10, 1997; in Lund, the last screening sigmoidoscopy was done on March 3, 1998. The median (25th percentile, 75th percentile) time from invitation to screening sigmoidoscopy was 64 days (44, 88) with minimum and maximum of 8 and 252 days, respectively.

Cancer Incidence. Nonparticipants did not differ significantly from participants with regard to overall cancer incidence, but nonsignificant incidence elevations were noted among the former for all of the specific cancers under study (Table 1): colorectal cancer IRR was 2.2 (95% CI, 0.8-5.9), other gastrointestinal cancer IRR was 2.7 (95% CI, 0.6-12.8), lung cancer IRR was 2.2 (95% CI, 0.8-5.9), and smoking-related cancer IRR was 1.4 (95% CI, 0.7-2.5).

The colorectal cancer incidence among nonparticipants was evenly distributed over the follow-up period; for participants, the incidence was concentrated to the screening period. During this period, 3 of 5 colorectal cancers were diagnosed among the participants compared with 1 of 16 among the nonparticipants (Fig. 1).

Relative to the matching general population, there was no increased risk of cancer overall among nonparticipants (Table 2). For the specific cancers under study, however, the risks tended to be increased among nonparticipants, except for other gastrointestinal cancer (SIR, 0.9; 95% CI, 0.4-1.9). Among participants, the risks of the specific cancers studied tended to be low (e.g., a 40% decreased risk of colorectal cancer; SIR, 0.6; 95% CI, 0.2-1.4). Due to the small number of cancers observed, the 95% CIs were wide.

Mortality. Overall, mortality differed statistically significantly between nonparticipants and participants (Table 3): all-cause MRR was 2.4 (95% CI, 1.7-3.4), neoplastic diseases MRR was 1.9 (95% CI, 1.1-3.5), gastrointestinal cancer (including colorectal cancer) MRR was 4.7 (95% CI, 1.1-20.7), and circulatory diseases MRR was 2.3 (95% CI, 1.2-4.2). There were only 5 and 2 observations, among nonparticipants and participants, respectively, where deaths were attributed to accidents, alcohol, or drugs.

As a sizeable proportion of all cancer deaths in the relatively short follow-up period may be attributable to disease that was already known at the time of invitation, and because the presence of a prevalent cancer may have affected the decision to abstain from participation, we

Table 2. SIR with 95% CI for all-site and selected cancers among 1,215 nonparticipants and 771 participants in sigmoidoscopy screening

Outcome (ICD-7)	Nonparticipants		Participants	
	Expected no.	SIR* (95% CI)	Expected no.	SIR (95% CI)
All-site cancer (140-209)	108.3	1.1 (0.9-1.3)	72.3	1.0 (0.8-1.3)
Colorectal cancer (153, 154)	12.7	1.3 (0.7-2.1)	8.6	0.6 (0.2-1.4)
Other gastrointestinal cancer (150-152, 155-159)	8.5	0.9 (0.4-1.9)	5.8	0.3 (0.0-1.3)
Lung cancer (162, 163)	10.0	1.6 (0.9-2.6)	6.8	0.7 (0.2-1.7)
Smoking-related cancer †	26.9	1.2 (0.8-1.7)	18.3	0.9 (0.5-1.4)

NOTE: For observed number of cancers, please refer to Table 1.
*Incidence relative to the age-matched, gender-matched, and calendar period-matched Swedish population.
†ICD-7 140-148, 150-151, 157, 161-162, 171, 180-181.

Table 3. Mortality (per 1,000 person-years) among 1,215 nonparticipants relative to 771 participants in screening sigmoidoscopy

Cause of death (ICD-10)	Nonparticipants		Participants		MRR* (95% CI)
	Observed no.	Mortality †	Observed no.	Mortality	
All-cause	151	14.6	42	6.0	2.4 (1.7-3.4)
Neoplastic diseases (C00-D48)	43	5.2	15	2.7	1.9 (1.1-3.5)
Gastrointestinal cancer (C15-C26, C48)	14	1.7	2	0.4	4.7 (1.1-20.7)
Circulatory diseases (I00-I99)	44	5.3	13	2.3	2.3 (1.2-4.2)
Accident-, alcohol-, and drug-related deaths ‡	5	0.6	2	0.4	1.7 (0.3-8.6)

NOTE: Relative risks are expressed as gender-adjusted MRR with 95% CI.
*Gender adjusted.
†Mortality rate per 1,000 person-years.
‡ICD-10 V01-Y98, F10-F19.

repeated the analyses after excluding 61 cohort members (45 in the nonparticipating category and 16 in the participating category) with a current cancer at the time of the screening (cancer diagnosed within 5 years before invitation). However, the excess cancer mortality among nonparticipants remained; MRR for total cancer was 2.5 (95% CI, 1.8-3.6) and MRR for gastrointestinal cancer was 4.3 (95% CI, 0.97-19.1).

Among nonparticipants, there was a clear pattern of an increased risk of mortality from all causes (SMR, 1.2; 95% CI, 0.99-1.5), mortality from gastrointestinal cancer (including colorectal cancer; SMR, 3.1; 95% CI, 1.7-5.3), and mortality from circulatory diseases (SMR, 1.4; 95% CI, 0.99-1.8) relative to the matching general population (Table 4). Among the participants, there was a statistically significantly decreased risk by 50% (SMR, 0.5; 95% CI, 0.3-0.7) for all-cause mortality, by 40% for mortality from cancer (SMR, 0.6; 95% CI, 0.3-0.97), and by a borderline significant 40% for mortality from circulatory diseases (SMR, 0.6; 95% CI, 0.3-1.02).

Discussion

We found a pattern suggestive of a higher incidence of cancer of the colorectum, other parts of the gastrointestinal tract, lung, and overall cancer related to smoking along with statistically significantly higher all-cause mortality and cancer-specific mortality among nonparticipants relative to participants in a population-based pilot study of sigmoidoscopy screening. Moreover, relative to the matching Swedish population, there was a pattern indicating an increased risk of cancer and mortality among nonparticipants and a corresponding decreased cancer risk among participants. Participants had a statistically significant 50% decrease in all-cause SMR and a 40% decrease in total cancer SMR.

The major strength of our study is the population-based setting and the essentially complete 9-year follow-up of both participants and nonparticipants. The invited subjects, representative of the two target populations in central and southern Sweden, had an average risk of colorectal cancer that was close to that expected in the age-matched, gender-matched, and calendar period-matched population of entire Sweden (SIR, 0.99; 95% CI, 0.6-1.5). Neither before nor after our pilot study has colorectal cancer screening in the average-risk population been a public health policy in Sweden.

The completeness of the follow-up in both participants and nonparticipants leaves only a small probability of ascertainment bias that would then occur due to differential misclassification of type of cancer or cause of death. Nondifferential misclassification would bias the results toward the null. The nationwide Cancer Register is deemed to be >98% complete (9-11) and ~99% of all cancers are cytologically or histologically verified (6). In the Causes of Death Register, only 14% of death certificates were based on autopsies in 2003 (8). Hence, the validity of the reported causes of death could be questioned when they are based on a clinical assessment only. However, most discrepancies between death certificates and the corresponding hospital discharge

Table 4. SMR with 95% CI for all-cause and selected cause-specific deaths among 1,215 nonparticipants and 771 participants in sigmoidoscopy screening

Cause of death (ICD-10)	Nonparticipants		Participants	
	Expected no.	SMR* (95% CI)	Expected no.	SMR (95% CI)
All-cause	91.7 †	1.2 (0.99-1.5)	61.7	0.5 (0.3-0.7)
Neoplastic diseases (C00-D48)	37.9	1.1 (0.8-1.5)	25.5	0.6 (0.3-0.97)
Gastrointestinal cancer (C15-C26, C48)	4.5	3.1 (1.7-5.3)	3.0	0.7 (0.1-2.4)
Circulatory diseases (I00-I99)	32.3	1.4 (0.99-1.8)	21.7	0.6 (0.3-1.02)
Accident-, alcohol-, and drug-related deaths ‡	5.4	0.9 (0.3-2.2)	3.6	0.6 (0.1-2.0)

NOTE: For observed number of deaths, please refer to Table 3.
*Mortality relative to the age-matched, gender-matched, and calendar period-matched Swedish population.
†Because follow-up for all-cause mortality in Table 3 was 2 y longer than in this table (see Materials and Methods), the observed number of deaths cannot be derived from Table 3. The observed numbers were 110 and 31 among nonparticipants and participants, respectively.
‡ICD-10 V01-Y98, F10-F19.

records seem to be explained by differences in coding (12). Because screening is expected to increase incidence somewhat among participants due to the detection of some indolent cancers that would otherwise have remained silent throughout life, the difference between nonparticipants and participants in occurrence of clinically relevant colorectal cancer may even be underestimated.

We did not intend to explain the variation in morbidity and mortality in terms of background risk factors but to quantify the net difference in baseline risk between participants and nonparticipants — a difference that may importantly affect the effectiveness of a screening program. In a separate article, we have evaluated the effect of some sociodemographic characteristics, hospital contacts, distance to the screening center, and cancer in the family on nonparticipation (13). Having male gender, being unmarried or divorced, and having a low income were associated with low participation, whereas a family history of colorectal cancer was linked with increased participation (13).

Our interpretation is that the main driving force behind the observed differences in cancer morbidity and mortality among nonparticipants and participants is not the effect of screening per se but rather the self-selection. The higher incidence of smoking-related cancers, albeit statistically nonsignificant, and a significantly higher mortality from circulatory diseases among nonparticipants, relative to participants, supports the hypothesis of an ''unhealthy'' lifestyle among the nonparticipants and is consistent with the results of other colorectal cancer screening studies (1, 2, 14-16).

Self-selection may to a large extent be determined by comorbidity. However, in our study of risk indicators for nonparticipation (13), neither the hospitalization rate in the 5-year period preceding invitation nor previous cancer history differed significantly between nonparticipants and participants. Moreover, removing invitees with a *current* cancer (diagnosed within 5 years before the invitation) from our analyses did not substantially change the overall picture. Another possibility is that the self-selection is determined by the socioeconomic status of the invitees, known to be linked to morbidity and mortality (17-19). Our invitees in the lowest tertile of income, according to the Register of Income and Wealth (20), were significantly less prone to participate compared with the invitees in the highest tertile (13). Earlier studies have indicated that socioeconomically underprivileged people are less motivated to participate in screening (21-24). Poorly motivated nonparticipants may be less aware of colorectal cancer as a health problem and of the possible benefits of screening for the disease (25, 26).

We cannot completely rule out the possibility that the screening sigmoidoscopy had some effect on morbidity and mortality in addition to the effects of self-selection. However, even if removal of adenomatous polyps has a documented effect against colorectal cancer development (27-29), only 6% of participants had adenomas diagnosed (4), and it is unlikely that the difference in colorectal cancer incidence in our study is due to adenoma removal. However, some participants may have changed to an even healthier lifestyle with effect on overall mortality.

Our study has limitations. First, as we only had information about previous in-hospital care, we cannot exclude the possibility that some nonparticipants had conditions or treatments that rendered them noneligible for average-risk sigmoidoscopy screening (e.g., inflammatory bowel disease, colonoscopy in the previous 2-5 years, or high risk for hereditary cancer) but were only noted in outpatient records. Second, we did not have direct individual information about several important determinants of future health, such as smoking, diet, and physical activity. Third, the numbers in most outcome categories were small, and our incidence rates and relative risk estimates had low precision.

In conclusion, our results are suggestive of reversed targeting (30); on average, the screening participants seemed to have a *decreased* risk of colorectal cancer compared with both nonparticipating individuals and the average in the matching population. If people with low risk of colorectal cancer are overrepresented among the participants, the positive predictive value and the effectiveness on the population level of screening will be low (31). Therefore, one of the challenges in colorectal cancer screening is to increase participation among less motivated, high-risk individuals.

Disclosure of Potential Conflicts of Interest

No potential conflicts of interest were disclosed.

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