ORIGINAL ARTICLE

Quality Indicators for Colonoscopy and the Risk of Interval Cancer

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ABSTRACT

BACKGROUND

Although rates of detection of adenomatous lesions (tumors or polyps) and cecal intubation are recommended for use as quality indicators for screening colonoscopy, these measurements have not been validated, and their importance remains uncertain.

METHODS

We used a multivariate Cox proportional-hazards regression model to evaluate the influence of quality indicators for colonoscopy on the risk of interval cancer. Data were collected from 186 endoscopists who were involved in a colonoscopy-based colorectal-cancer screening program involving 45,026 subjects. Interval cancer was defined as colorectal adenocarcinoma that was diagnosed between the time of screening colonoscopy and the scheduled time of surveillance colonoscopy. We derived data on quality indicators for colonoscopy from the screening program's database and data on interval cancers from cancer registries. The primary aim of the study was to assess the association between quality indicators for colonoscopy and the risk of interval cancer.

RESULTS

A total of 42 interval colorectal cancers were identified during a period of 188,788 person-years. The endoscopist's rate of detection of adenomas was significantly associated with the risk of interval colorectal cancer (P=0.008), whereas the rate of cecal intubation was not significantly associated with this risk (P=0.50). The hazard ratios for adenoma detection rates of less than 11.0%, 11.0 to 14.9%, and 15.0 to 19.9%, as compared with a rate of 20.0% or higher, were 10.94 (95% confidence interval [CI], 1.37 to 87.01), 10.75 (95% CI, 1.36 to 85.06), and 12.50 (95% CI, 1.51 to 103.43), respectively (P=0.02 for all comparisons).

CONCLUSIONS

The adenoma detection rate is an independent predictor of the risk of interval colorectal cancer after screening colonoscopy.

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Although colonoscopy is widely used for colorectal-cancer screening,[1-3] its miss rate for cancers and adenomatous polyps (benign premalignant tumors or adenomas), which is low but not negligible, remains a concern.[4-6] It has been suggested that a high-quality examination that ensures the detection and removal of all neoplastic lesions is key for screening efficacy.[6-8] In response, professional societies have proposed the use of various quality-assessment indicators. Of such indicators, the rates of adenoma detection and cecal intubation are the most commonly used.[7-10] However, these measurements have never been validated, and it is not known whether an improvement in quality indicators translates into improved screening efficacy. For example, there are scant data on whether these measurements have an effect on the subsequent risk of interval cancer (defined as cancer diagnosed between screening and post-screening surveillance examinations), which is thought to arise mainly from lesions that were overlooked at screening.[5,6] To address this question, we identified independent risk factors for interval cancer in colonoscopy-screened subjects by analyzing rates of adenoma detection and cecal intubation for individual endoscopists involved in a large colonoscopy-based program of colorectal-cancer screening.

METHODS

STUDY DESIGN

We analyzed the database records for 50,148 subjects from the National Colorectal Cancer Screening Program in Poland for the period from October 2000 through December 2004. Details of this colonoscopy-based screening program involving subjects between the ages of 40 and 66 years who were at average risk for colorectal cancer have been described previously.[11]

We used the screening program's database to obtain data on quality indicators for colonoscopy, including rates of adenoma detection and cecal intubation. We also used the database to select a predefined group of subjects who were subsequently assessed for interval colorectal cancer with the use of national and regional cancer registries. This group included subjects who had undergone screening colonoscopy after adequate bowel preparation (classified as either very good or good and sufficient on the basis of the Aronchick scale),[12] with removal of all detected polyps (clearing colonoscopy) and no detection of colorectal cancer. We excluded subjects who had undergone colonoscopy performed by an endoscopist who had performed fewer than 30 colonoscopies during the study period, as well as subjects whose inclusion in the screening program was subsequently shown to have violated the program's inclusion criteria (e.g., a personal history of colorectal cancer that was not reported at the time of entry in the screening program).

We then used the personal-identification data of the included subjects to search the national and regional cancer registries for the diagnosis of interval colorectal cancer. Interval cancer was defined as colorectal adenocarcinoma that was diagnosed between the time of screening colonoscopy and the scheduled time of surveillance colonoscopy, according to the recommendations of the U.S. Multisociety Task Force on Colorectal Cancer and the American Cancer Society[13] (Fig. 1). For the purpose of this study, cancer was considered interval only when the involved bowel segment was visualized at the screening colonoscopy and bowel preparation was adequate. Observation was initiated at the time of the screening colonoscopy. Observation was completed when interval cancer was diagnosed or censored at the time of the scheduled surveillance colonoscopy. The data-collection period ended 5 years after the screening colonoscopy or at the most recent date available in the cancer registry, whichever occurred first. Using colorectal-cancer codes, we searched national and regional cancer registries from January 1, 2000, to the most recent date for which data were available (December 31, 2007, or December 31, 2008, depending on the registry).

QUALITY INDICATORS

We determined quality indicators for colonoscopy — rates of adenoma detection and rates of cecal intubation — for each endoscopist in the program who had performed at least 30 screening examinations within the study period. The adenoma detection rate was defined as the proportion of screened subjects in whom at least one adenomatous lesion was identified.[8] Cecal intubation was defined as the passage of the colonoscope tip to a point proximal to the ileocecal valve and visualization of the entire cecum. The rate of cecal intubation was defined as the proportion of complete examinations, adjusted for incomplete examinations owing to very poor bowel preparation or

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a stricture caused by a tumor.[9] The examination was considered to be complete when identification of cecal landmarks or intubation of the terminal ileum was recorded by the endoscopist in the colonoscopy report. Photographic documentation was not required.

STUDY OVERSIGHT

The research proposal was reviewed by the ethics committee at each of the authors' institutions and was judged to be exempt from oversight. Written informed consent was obtained from all subjects entering the National Colorectal Cancer Screening Program.

STATISTICAL ANALYSIS

We used a multivariate Cox proportional-hazards regression model to assess the influence of the quality measurements for each endoscopist on the risk of interval cancer. Model assumptions were tested on the basis of Schoenfeld residuals.[14] The following variables were included in the model: adenoma detection rate (<11.0%, 11.0 to 14.9%, 15.0 to 19.9%, or ≥20.0%), cecal intubation rate (<85.0%, 85.0 to 89.9%, 90.0 to 92.9%, 93.0 to 94.9%, or ≥95.0%), sex of patient, age of patient (40 to 49, 50 to 54, 55 to 59, or 60 to 66 years), family history of colorectal cancer (none, two first-degree relatives with colorectal cancer, one first-degree relative <60 years of age with colorectal cancer, or one first-degree relative ≥60 years of age with colorectal cancer), sex of the endoscopist, age of the endoscopist (≤39, 40 to 49, or ≥50 years), and specialty of the endoscopist (gastroenterology, internal medicine or no specialty, or surgery of any kind). The likelihood-ratio test was used to determine whether there was a significant association between a particular predictor and the risk of interval colorectal cancer. When the association was significant, a hazard ratio and 95% confidence interval were reported for each of the predefined categories.

The predefined categories of quality indicators were chosen arbitrarily; however, they also included the calculated median rates of adenoma detection and cecal intubation for the entire set of 50,148 screening examinations. The same model was used for the secondary analysis, in which the examinations of subjects with inadequate bowel preparation were included and interval cancers were redefined to include cancers occurring in bowel segments that were not evaluated during the screening colonoscopy. No model reduction was performed to allow for adjustment of the effect of quality measurements for the effect of possible clinical predictors. Cumulative hazard rates were calculated with the use of the Nelson–Aalen estimator.[15,16] A P value of less than 0.05 was considered to indicate statistical significance. All reported P values are two-sided and have not been adjusted for multiple testing. The analyses were performed with the use of Stata statistical software, version 9.

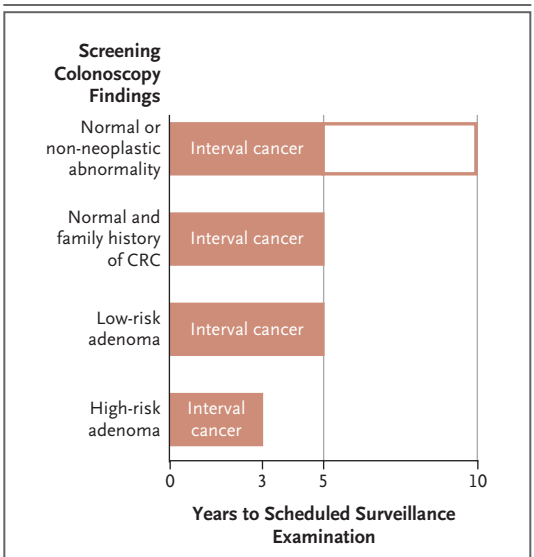

Figure 1. Intervals between Screening Colonoscopy and Scheduled Surveillance Examination, as Recommended by the U.S. Multisociety Task Force on Colorectal Cancer and the American Cancer Society.

Subjects are classified as having high-risk adenomas if they have 3 to 10 adenomas or an adenoma that is 10 mm or more in diameter, high-grade dysplasia, or an adenoma with villous or tubulovillous histologic characteristics. Subjects are classified as having low-risk adenomas if they have one or two tubular adenomas with low-grade dysplasia that are under 10 mm in diameter. CRC denotes colorectal cancer.

RESULTS

SUBJECTS

Of the 50,148 subjects enrolled in the 2000–2004 colorectal-cancer screening program,[11] 5122 (10.2%) were excluded for the following reasons: inadequate bowel preparation in 3932 subjects (7.8%), the detection of colorectal cancer on screening in 416 subjects (0.8%), the lack of a clearing colonoscopy in 94 subjects (0.2%), a screening

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Table 1. Characteristics of the 45,026 Subjects.*

Characteristic	Value
Age — yr	
Mean ±SD	55.1±5.8
Range	40–66
Age group — no. (%)	
40–49 yr	6,479 (14.4)
50–54 yr	14,390 (32.0)
55–59 yr	12,626 (28.0)
60–66 yr	11,531 (25.6)
Male sex — no. (%)	16,065 (35.7)
Family history of colorectal cancer — no. (%)	
None	35,627 (79.1)
Two first-degree relatives	397 (0.9)
One first-degree relative	
<60 yr at diagnosis	2,417 (5.4)
≥60 yr at diagnosis	6,585 (14.6)
Total colonoscopy — no. (%)	41,552 (92.3)
Adequate bowel preparation — no. (%)†	45,026 (100.0)
Intravenous sedation — no. (%)	13,628 (30.3)
Follow-up for subjects without interval colorectal cancer	
Subjects — no. (%)	44,984 (99.9)
Duration of follow-up — mo	
Median (interquartile range)	52.1 (41.3–60.0)
Range	0.1–60.0
Follow-up for subjects with interval colorectal cancer	
Subjects — no. (%)	42 (0.1)
Duration of follow-up — mo	
Median (interquartile range)	29.9 (17.7–39.9)
Range	5.5–57.7

* Because of rounding, percentages may not total 100.
† Bowel preparation was assessed by the endoscopists.

colonoscopy performed by an endoscopist who registered fewer than 30 examinations with the screening program in 657 subjects (1.3%), and an inadvertent violation of inclusion criteria for the screening program that was detected after the fact in 23 subjects (<0.1%). The remaining 45,026 subjects were followed in cancer registries for a median of 52.1 months (interquartile range, 41.3 to 60.0) for the occurrence of interval cancer. The characteristics of this group are summarized in Table 1.

INTERVAL COLORECTAL CANCERS

During the follow-up period of 188,788 person-years, we identified a total of 42 interval colorectal cancers. Of these cancers, 35 (83.3%) occurred in subjects with no family history of colorectal cancer, and 39 (92.9%) occurred in subjects in whom no adenomas had been identified at the screening examination. In only one subject (2.4%) could the interval cancer be attributed to an ineffective polypectomy: the adenoma was located in the same bowel segment, and the completeness of the polypectomy was undetermined. The characteristics of the identified interval colorectal cancers and affected subjects are shown in Table 1 in the Supplementary Appendix, available with the full text of this article at NEJM.org.[17] The 42 cases of interval cancer were identified in subjects examined by 32 endoscopists; the number of cases that were linked to individual endoscopists was 0 for 154 endoscopists (who performed a total of 25,874 examinations), 1 for 25 endoscopists (10,658 examinations), 2 for 4 endoscopists (5189 examinations), and 3 for 3 endoscopists (3035 examinations).

Table 2 shows the characteristics of the participating endoscopists, according to categories for the adenoma detection rate. Altogether, 186 endoscopists contributed cases to the program database, with a median of 145 colonoscopies (interquartile range, 80 to 262) each. The median adenoma detection rate was 12.2% (interquartile range, 8.4 to 16.6), and the median cecal intubation rate was 93.8% (interquartile range, 88.5 to 96.4). Figure 2 shows the estimated cumulative hazard rates for interval colorectal cancer during the follow-up period on the basis of the endoscopist's rate of adenoma detection, according to the following categories: less than 11.0%, 11.0 to 14.9%, 15.0 to 19.9%, and 20.0% or more.

In the Cox proportional-hazards regression model, we identified two independent risk factors for interval colorectal cancer: the endoscopist's rate of adenoma detection (P=0.008) and the subject's age (P=0.005) (Table 3). The rate of cecal intubation was not significantly associated with the risk of interval colorectal cancer (P=0.50). An individual rate of adenoma detection below 20.0% was significantly associated with an increased risk of interval colorectal cancer, as compared with a detection rate of 20.0% or more, with increased hazard ratios for a rate below 11% (hazard ratio, 10.94; 95% confidence interval [CI], 1.37 to 87.01), 11.0 to 14.9% (hazard ratio, 10.75; 95% CI, 1.36 to 85.06), and 15.0 to 19.9% (hazard ratio, 12.50; 95% CI, 1.51 to 103.43) (P=0.02 for all comparisons). The results of the secondary analysis are

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Table 2. Characteristics of 186 Endoscopists, According to the Adenoma Detection Rate.*

Characteristic	Adenoma Detection Rate				
	<11.0%	11.0 to 14.9%	15.0 to 19.9%	≥20.0%	Total
Colonoscopists — no. (%)	80 (43.0)	46 (24.7)	34 (18.3)	26 (14.0)	186 (100.0)
No. of colonoscopies included in study					
Median (interquartile range)	130 (54–230)	161 (98–304)	125 (98–194)	178 (112–654)	145 (80–262)
Range	30–1824	34–1848	35–1589	32–1737	30–1848
Person-years of follow-up — no.	65,528	54,339	27,490	41,431	188,788
Mean age in 2000 (±SD) — yr	43.8±7.6	41.0±6.0	40.8±5.9	40.3±5.0	42.1±6.7
Male sex — no. (%)	65 (81.2)	38 (82.6)	27 (79.4)	19 (73.1)	149 (80.1)
Screening centers — no.†	35	28	18	12	45
Rate of cecal intubation — %					
Median (interquartile range)	91 (84–95)	94 (88–96)	94 (91–96)	95 (92–98)	94 (88–96)
Range	55–100	52–100	60–98	85–100	52–100
Complete colonoscopies — no./total no. (%)	14,273/15,883 (89.9)	12,129/13,281 (91.3)	6,249/6,607 (94.6)	8,901/9,255 (96.2)	41,552/45,026 (92.3)
Colonoscopic experience — no. (%)‡					
<5 yr	18 (22.5)	13 (28.3)	16 (47.1)	12 (46.2)	59 (31.7)
5–10 yr	20 (25.0)	17 (37.0)	7 (20.6)	6 (23.1)	50 (26.9)
>10 yr	30 (37.5)	14 (30.4)	8 (23.5)	5 (19.2)	57 (30.6)
Unknown	12 (15.0)	2 (4.3)	3 (8.8)	3 (11.5)	20 (10.8)
Specialty — no. (%)					
Gastroenterology	22 (27.5)	17 (37.0)	14 (41.2)	14 (53.8)	67 (36.0)
Internal medicine or no specialty	24 (30.0)	14 (30.4)	8 (23.5)	6 (23.1)	52 (28.0)
Surgery	34 (42.5)	15 (32.6)	12 (35.3)	6 (23.1)	67 (36.0)
No. of interval cancers/100,000 person-yr of follow-up	33.6	22.1	25.5	2.4	22.3

* Plus–minus values are means ±SD. Because of rounding, percentages may not total 100.
† The numbers of centers do not total 45 because endoscopists at each center had multiple rates of adenoma detection.
‡ The years of colonoscopic experience for endoscopists were not included in the multivariate analysis because of the lack of prospectively collected complete data.

presented in Table 2 in the Supplementary Appendix.

DISCUSSION

In our study, a widely recommended quality indicator for screening colonoscopy (the endoscopist's rate of adenoma detection) was significantly associated with the risk of interval cancer among 45,026 subjects who underwent such screening. The risk was significantly higher among subjects who underwent colonoscopies that were performed by endoscopists with an adenoma detection rate of less than 20% than among subjects examined by endoscopists with a detection rate of 20% or more. A second widely recommended quality indicator, the cecal intubation rate, was not associated with the risk of interval cancer. These results, obtained in a large cohort, underscore the crucial role of meticulous inspection of the colorectal mucosa at the baseline examination and indicate that such inspection is a very important factor in the efficacy of screening.[18,19]

Other factors — such as an ineffective polypectomy, alternative pathways to colorectal cancer (e.g., the *BRAF*–CpG island methylation pathway), and biologic aggressiveness of selected tumors — may also be associated with the risk of interval colorectal cancer. However, in our study, only one interval cancer (2.4%) was attributed to an ineffective polypectomy. Although two previous studies have suggested that ineffective poly-

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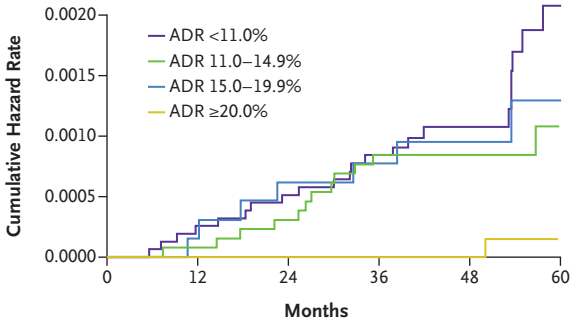

No. at Risk						
ADR <11.0%	15,883	15,805	15,744	15,669	9355	4717
ADR 11.0–14.9%	13,281	13,223	13,182	13,120	7571	4003
ADR 15.0–19.9%	6,607	6,582	6,562	6,539	4022	2529
ADR ≥20.0%	9,255	9,235	9,202	9,166	7155	5548

Figure 2. Cumulative Hazard Rates for Interval Colorectal Cancer, According to the Endoscopist's Adenoma Detection Rate (ADR).

The graph shows cumulative hazard rates for interval colorectal cancer among subjects who underwent screening colonoscopy that was performed by an endoscopist with an ADR in one of the following categories: less than 11.0%, 11.0 to 14.9%, 15.0 to 19.9%, and 20.0% or more.

pectomy may account for 25% of interval cancers,[5,20] these studies were limited in terms of assessing both the quality of the baseline colonoscopy and the adequacy of efforts to clear all neoplasia. Similarly, there is a lack of firm evidence for an increased proportion of poorly differentiated tumors among interval cancers, as compared with noninterval cancers.[21,22] However, in one study, there was an increased likelihood that such tumors were associated with mismatch-repair gene dysfunction.[22] There are no data linking the occurrence of interval cancers to serrated-pathway colorectal cancer. Unfortunately, we could not assess the biologic aggressiveness and genetic characteristics of interval cancers from the data available in the cancer registries.

On the basis of the prevalence of adenomas and cecal intubation rates in studies of screening colonoscopy in the United States, threshold values for rates of adenoma detection (15% among women and 25% among men ≥50 years old) and cecal intubation (95% for both sexes) have been proposed.[7-9] There is no proof that these values apply to large-scale screening programs involving a high proportion of nonexpert centers, located in countries with different epidemiologic features of colorectal cancer and lower adenoma detection rates. Although our study was not designed to determine the threshold for the adenoma detection rate, the 20% value that emerged from the analysis (for both sexes combined) is close to these recommendations. Nonetheless, it may not be possible to establish a universal threshold for the rate of adenoma detection because of geographic differences in the epidemiology of colorectal cancer and its precursors.[11,18,23,24]

Surprisingly, our study showed that the cecal intubation rate, when used as a quality measurement, was not associated with the risk of interval cancer. One can speculate that the rate of adenoma detection is a risk factor for interval cancer in the entire colon, whereas the importance of the cecal intubation rate is limited to the right colon; thus, it is difficult to evaluate the importance of cecal intubation because of the small number of interval cancers in the right colon. Our findings do not argue against the need for a complete examination but rather highlight the primary role of the adenoma detection rate. We did not find a significant association between individual characteristics of endoscopists (including age, sex, and specialty) and the risk of interval cancer. (In one previous study, the endoscopist's specialty was associated with the rate of detection of new or missed colorectal cancers.[25])

In our study, another factor that was independently associated with the risk of interval colorectal cancer was the subject's age. The risk was particularly high for subjects who were 60 years of age or older, a finding that is consistent with the results of previous studies.[5,25,26]

Our study has several notable features. The incidence of colorectal cancer and the rate of death are the most appropriate end points for validating quality indicators for screening colonoscopy. However, the use of these end points requires a long-term observation period and a large number of subjects to achieve adequate statistical power. For that reason, we chose the occurrence of interval cancer as a surrogate end point, since it is closely related to the incidence of colorectal cancer and has been used previously in case–control studies to estimate a reduction in incidence.[1,5,27] Furthermore, in screening programs for breast cancer, interval cancers have been inversely associated with a reduction in mortality, and surveillance for interval cancers is widely used to monitor the performance of such programs.[28,29]

In addition, there is no universally accepted definition of interval cancer. In colonoscopy stud-

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Table 3. Risk Factors for Interval Colorectal Cancer.

Variable	No. of Subjects	No. of Interval Cancers	P Value (Likelihood-Ratio Test)*	Hazard Ratio (95% CI)	P Value
Subjects					
Age			0.005		
40–49 yr	6,479	1		1.00	
50–54 yr	14,390	12		6.54 (0.81–52.84)	0.08
55–59 yr	12,626	10		6.41 (0.78–52.85)	0.08
60–66 yr	11,531	19		13.35 (1.69–105.65)	0.01
Family history of colorectal cancer			0.70		
No family history	35,627	35			
Two first-degree relatives	397	1			
One first-degree relative					
<60 yr at diagnosis	2,417	2			
≥60 yr at diagnosis	6,585	4			
Sex			0.54		
Female	28,961	25			
Male	16,065	17			
Endoscopists					
Cecal intubation rate†			0.50		
<85.0%	6,800	8			
85.0–89.9%	6,582	11			
90.0–92.9%	6,891	6			
93.0–94.9%	4,064	2			
95.0–100.0%	20,689	15			
Adenoma detection rate			0.008		
≥20.0%	9,255	1		1.00	
15.0–19.9%	6,607	7		10.94 (1.37–87.01)	0.02
11.0–14.9%	13,281	12		10.75 (1.36–85.06)	0.02
<11.0%	15,883	22		12.50 (1.51–103.43)	0.02
Age			0.10		
≤39 yr	17,757	12			
40–49 yr	22,647	20			
≥50 yr	4,622	10			
Sex			0.22		
Female	7,286	9			
Male	37,740	33			
Specialty			0.56		
Gastroenterology	17,069	15			
Internal medicine or no specialty	12,753	11			
Surgery	15,204	16			

* The values were calculated with the likelihood-ratio test for models with and those without the specified covariate.
† The rate of cecal intubation was adjusted for incomplete examinations owing to very poor bowel preparation or a stricture caused by a tumor.

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ies, a cancer is considered to be an interval cancer if it occurs within a defined time period after a screening colonoscopy (e.g., 3 or 5 years), depending on the study.[6,20,22,25] On the other hand, breast-cancer screening programs define interval cancer as cancer diagnosed between screening examinations.[28,29] In our study, we adopted the breast-cancer screening definition but modified the definition to reflect the variable time points for recommended surveillance examinations, which for colonoscopy screening (but not breast-cancer screening) depend on findings from the index examination.

We excluded subjects who had inadequate bowel preparation for two reasons. First, bowel preparation cannot be controlled by endoscopists, but inadequate preparation impairs detection of both small and large adenomas.[20,30] Second, subjects with inadequate preparation may have undergone an additional examination by another endoscopist before long-term surveillance.

We also excluded endoscopists who had contributed a very low number of colonoscopy results to the screening program in order to eliminate any bias that might have been introduced by including their individual quality indicators. We arbitrarily chose a threshold of 30 colonoscopies that had been performed within the framework of the Cancer Screening Program in order to minimize the rate of endoscopist exclusion. For the same reason, examinations that were performed by individual endoscopists in male and female subjects were not analyzed separately.

Our study has several limitations. First, the data on interval cancers were derived from cancer registries, which are known to be incomplete, with a marked delay in submission of data. The estimated average completeness of cancer registration in Poland is 89%.[24] To minimize bias due to incomplete data, we searched regional cancer registries in addition to the national registry. Nevertheless, some interval cancers might have been missed. Although the completeness of the registry data is questionable, this should have had a rather minor effect on the results of the final analysis, since the same imperfect data source was used for the entire study population, regardless of whether subjects had undergone colonoscopies performed by endoscopists with low-quality indicators or by those with high-quality indicators. However, considering the under-registration and missing data on asymptomatic, undetected cancers, the prevalence of interval cancers in the study population should be interpreted with caution. Second, the models that we used for analyses included age, sex, and family history but not other potential confounding factors, such as smoking status, body-mass index, and presence or absence of diabetes.[31,32] Third, the extent of the endoscopic examination was reported by the endoscopists, with no photographic documentation of the cecal landmarks in the majority of cases. Fourth, the amount of time spent examining the colon during withdrawal of the colonoscope (withdrawal time) was not measured. This measurement has emerged as a quality indicator that is potentially associated with a low rate of adenoma detection.[18,19] However, it has also been shown that institution-wide policies to keep the colonoscopic withdrawal time within the recommended limits has no effect on the rate of polyp detection.[33]

In summary, our findings indicate that the endoscopist's rate of adenoma detection is an independent predictor of the risk of interval cancer after screening colonoscopy with clearing of all visualized lesions in the large bowel. Our findings support the primary role of this measurement in continuous quality-improvement programs for colorectal-cancer screening.

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