Risk of Perforation After Colonoscopy and Sigmoidoscopy: A Population-Based Study

Nicolle M. Gatto, Harold Frucht, Vijaya Sundararajan, Judith S. Jacobson, Victor R. Grann, Alfred I. Neugut

Background: **Although the risk of bowel perforation is often cited as a major factor in the choice between colonoscopy and sigmoidoscopy for colorectal screening, good estimates of the absolute and relative risks of perforation are lacking.** ***Methods:*** **We used a large population-based cohort that consisted of a random sample of 5% of Medicare beneficiaries living in regions of the United States covered by the Surveillance, Epidemiology, and End Results (SEER) Program registries to determine rates of perforation in people aged 65 years and older. We identified individuals who were cancer-free and had undergone colonoscopy or sigmoidoscopy between 1991 and 1998, calculated both the incidence and risk of perforation within 7 days of the procedure, and explored the impact on incidence and risk of perforation of age, race/ethnicity, sex, comorbidities, and indication for the procedure. We also estimated the risk of death after perforation. Risks were calculated with odds ratios (ORs) and 95% confidence intervals (CIs). All statistical tests were two-sided.** ***Results:*** **There were 77 perforations after 39 286 colonoscopies (incidence = 1.96/1000 procedures) and 31 perforations after 35 298 sigmoidoscopies (incidence = 0.88/1000 procedures). After adjustment, the OR for perforation from colonoscopy relative to perforation from sigmoidoscopy was 1.8 (95% CI = 1.2 to 2.8). Risk of perforation from either procedure increased in association with increasing age (P_{trend}<.001 for both procedures) and the presence of two or more comorbidities (P_{trend}<.001 for colonoscopy and P_{trend} = .03 for sigmoidoscopy). Compared with those who were endoscopied and did not have a perforation, the risk of death was statistically significantly increased for those who had a perforation after either colonoscopy (OR = 9.0, 95% CI = 3.0 to 27.3) or sigmoidoscopy (OR = 8.8, 95% CI = 1.6 to 48.5). The risk of perforation after colonoscopy, especially for screening procedures, declined during the 8-year study period.** ***Conclusions:*** **The risk of perforation after colonoscopy is approximately double that after sigmoidoscopy, but this difference appears to be decreasing. These observations should be useful to clinicians making screening and diagnostic decisions for individual patients and to policy officials setting guidelines for colorectal cancer screening programs.** **[J Natl Cancer Inst 2003;95:230–6]**

Guidelines for colorectal cancer screening have been in flux over the past two decades. Randomized controlled trials have demonstrated the efficacy of fecal occult blood testing (FOBT) in reducing colorectal cancer mortality *(1–4),* but the poor sensitivity and specificity of this screening tool continue to be problematic *(5).* Observational studies have demonstrated that sigmoidoscopy screening programs can dramatically reduce mortality from left-sided or distal colorectal cancer, although they have little or no impact on more proximal disease *(6–8).* Two randomized trials, one in the United States and one in the United Kingdom, are in progress to confirm these findings *(9–11).* For adults aged 50 years or older with no symptoms of colorectal cancer and at average risk for the disease, the Gastrointestinal Consortium and the American Cancer Society recommend screening consisting of annual FOBT and sigmoidoscopy every 5 years, annual FOBT and double-contrast barium enema every 5–10 years, or colonoscopy alone every 10 years *(12).*

Colonoscopy has been widely used since the 1970s as the primary diagnostic tool to follow up on positive findings from FOBT and on abnormalities found during sigmoidoscopy. In addition, colonoscopy has been recommended as the initial screening tool for individuals at high risk for colorectal cancer *(13,14).* Although no controlled trials have assessed the efficacy of colonoscopy in reducing colorectal cancer mortality, its similarity to flexible sigmoidoscopy in sensitivity, specificity, and the ability to biopsy or resect adenomas, and its ability to visualize the entire colon suggest that it may be preferable to sigmoidoscopy for screening asymptomatic individuals with average risk of developing colorectal cancer *(13–16).* Furthermore, many believe that the improved survival associated with screening by FOBT and sigmoidoscopy is actually a result of the colonoscopy that is done because of abnormal findings.

In the absence of a randomized controlled trial to compare these two screening strategies, the relative merits of each have been estimated by cost–benefit analysis and other modeling tools *(17–19).* A major deterrent to the widespread use of colonoscopy has been the fear of perforating the intestinal wall; at least one group has referred to perforation of the colon as "the most dreaded complication of colonoscopy" *(20).* Most previous studies of colon perforation have been limited to a single endoscopy practice or center or had small sample sizes *(21–29).* The observed perforation rates have ranged from 1 in 200 to 1 in 5000 *(21–29).* Perforation rates for sigmoidoscopy are believed to be markedly lower but have not been explored extensively.

In this study, we used a large population-based database to

Affiliations of authors: N. M. Gatto, J. S. Jacobson, Department of Epidemiology, Joseph L. Mailman School of Public Health, Columbia University, New York, NY; H. Frucht, Department of Medicine and Herbert Irving Comprehensive Cancer Center, College of Physicians and Surgeons, Columbia University: V. Sundararajan, Department of Epidemiology and Preventive Medicine, Monash Medical School, Melbourne, Australia; V. R. Grann, A. I. Neugut, Department of Epidemiology, Joseph L. Mailman School of Public Health, and Department of Medicine and Herbert Irving Comprehensive Cancer Center, College of Physicians and Surgeons, Columbia University.

Correspondence to: Alfred I. Neugut, M.D., Ph.D., Division of Medical Oncology, New York-Presbyterian Hospital, 630 West 168th St., PH 18-127, New York, NY 10032 (e-mail: ain1@columbia.edu).

See "Notes" following "References."

Journal of the National Cancer Institute, Vol. 95, No. 3,

compare the incidence of perforation associated with both of these flexible endoscopic procedures and to investigate what factors predict the occurrence of this complication. A better understanding of the relative risk of perforation associated with colonoscopy and sigmoidoscopy will facilitate an evidence-based choice between these two strategies, both for patients and for individuals who make population screening recommendations.

Patients and Methods

Data Source

For this study, we used the summarized denominator file (SUMDENOM), a random 5% sample of Medicare beneficiaries without cancer who resided within the Surveillance, Epidemiology, and End Results Program (SEER)[1] population areas *(30)*. We excluded individuals with any cancer because of a concern that we would not be able to distinguish perforations secondary to the procedure from perforations due to the disease. SEER collects data from tumor registries covering approximately 14% of the U.S. population *(30,31)*. Through an identifier, the SEER and SUMDENOM data files have been linked to outpatient and inpatient Medicare claims files for those aged 65 years or older *(30)*. This linked SEER–Medicare database was developed jointly by the National Cancer Institute, the Centers for Medicare and Medicaid Services, and the SEER registries.

Sample Selection

All subjects were selected from the Medicare physician/supplier National Claims History (NCH) database. Subjects were aged 65 years or older and had undergone at least one colonoscopy or sigmoidoscopy billed on NCH from 1991 through 1998 (N = 39 286 for colonoscopy and N = 35 298 for sigmoidoscopy). Colonoscopic procedures were identified from the records as colonoscopy with or without biopsy, polypectomy, control of bleeding, or removal of a foreign body (Healthcare Common Procedure Coding System [HCPCS]/the American Medical Association's Common Procedure Terminology [CPT-4] codes 45378, 45379, 45380, 45382, 45383, 45384, and 45385). Sigmoidoscopies were identified from the records as flexible sigmoidoscopy with or without biopsy, polypectomy, control of bleeding, decompression of volvulus, or removal of a foreign body (HCPCS/CPT-4 codes 45330, 45331, 45332, 45333, 45334, 45337, 45338, and 45339).

Outcomes of Interest

Perforations were identified using the International Classification of Diseases 9th revision (ICD-9) codes for perforation of intestine and accidental puncture or laceration during a procedure (ICD-9 codes 569.83 and 998.2). Diagnosis of a perforation and verified date of death were obtained from the linked NCH and Medicare Analysis and Procedure (MEDPAR) databases. To be included in the study, the perforation had to occur within 7 days of the procedure, which was measured as the difference between the date of the procedure and the date of the perforation. Similarly, mortality after a perforation was measured within 14 days and 30 days of a procedure and was determined as the difference between the date of the procedure and the date of death.

Sociodemographic Variables and Comorbidity

Data on age, race/ethnicity, and sex were obtained from the linked NCH and MEDPAR databases. The presence of comorbidity was assessed using the Klabunde adaptation of the Deyo–Charlson comorbidity index, which incorporates Medicare physician claims (part B) and hospital claims (part A) *(32–34)*. Subjects were coded as having one or more comorbidities if the relevant ICD-9 codes were identified from their records in the 365 days before the date of the procedure or in the 120 days after the date of the procedure.

Indications for the Procedure

The indications for the endoscopic procedure were obtained from the linked NCH and MEDPAR databases. The indications included hemorrhage, anemia, abdominal pain, diverticulosis, weight loss, obstruction, inflammatory bowel disease, and/or diarrhea occurring 0–30 days before the procedure. The complete list of ICD-9 codes for these indications is available at the Journal's Web site http://jncicancerspectrum.oupjournals.org/jnci/content/vol95/issue3/index.shtml. Where none of the aforementioned indications was identified, the procedure was coded as "screening/other" (N = 20 163 for colonoscopy; N = 25 951 for sigmoidoscopy).

Statistical Analysis

Incidence of perforation from a colonoscopy or sigmoidoscopy was defined as the number of perforations per 1000 procedures. Analogously, the incidence of death after a colonoscopy- or sigmoidoscopy-associated perforation was defined as the number of deaths within 7 days per 1000 perforations.

All crude and adjusted odds ratios (ORs), and 95% Wald confidence intervals (CIs) were obtained by using the LOGISTIC procedure in SAS version 8.12 (SAS Institute, Cary, NC). For both colonoscopy and sigmoidoscopy, the crude association between perforation and each of the demographic and clinical characteristics was estimated by using logistic regression. Multivariate logistic regression analyses, which controlled for the effects of all covariates, were used to obtain the adjusted association between the risk of perforation and each of the demographic and clinical variables. Because the univariate and multivariate results were similar, only the multivariate results are reported.

The crude and adjusted relative risks of death (as estimated with ORs) after a colonoscopic or sigmoidoscopic perforation were obtained by modeling death within 14 days and 30 days of a procedure as a function of perforation. The adjusted association controlled for age at the time of the procedure, year of the procedure, sex, race/ethnicity, comorbid conditions, and indication for the procedure.

Multiple logistic regression modeling was also used to compare the risk of perforation as a function of colonoscopy versus sigmoidoscopy, with age at the time of the procedure, year of the procedure, sex, race/ethnicity, comorbid conditions, and indication for the procedure as covariates. All statistical tests were two-sided.

Results

Baseline Descriptive Statistics

From 1991 through 1998, a total of 39 286 colonoscopies and 35 298 sigmoidoscopies were performed. During this time pe-

riod, the number of sigmoidoscopies per year decreased and the number of colonoscopies per year increased; 1994 was the first year when more colonoscopies than sigmoidoscopies were performed (Fig. 1).

Subjects who had a colonoscopy were demographically similar to those who had a sigmoidoscopy. The mean age of subjects in our Medicare sample who had a colonoscopy or sigmoidoscopy was 74 years. However, 21% of those who had a colonoscopy and 18% of those who had a sigmoidoscopy were aged 80 years or older. The majority of subjects who had a colonoscopy or sigmoidoscopy were women (57% and 56%, respectively) (Table 1). Non-Hispanic whites made up 84% and 87% of the subjects who had a colonoscopy or a sigmoidoscopy, respectively. Among all subjects, 4% of those who had a colonoscopy and 3% of those who had a sigmoidoscopy had one or more comorbidities.

On the basis of the preprocedure indications, approximately 51% of the colonoscopy cohort and 74% of the sigmoidoscopy cohort were classified as screening/other. For the remainder of the groups, the most common indications were abdominal pain (20%), hemorrhage (18%), anemia (13%), diverticulosis (10%), and inflammatory bowel disease (8%) for the colonoscopy cohort and abdominal pain (12%), hemorrhage (5%), anemia (5%), diverticulosis (5%), and inflammatory bowel disease (5%) for the sigmoidoscopy cohort (Table 1).

Perforation After Colonoscopy

We identified 77 subjects with an intestinal perforation within 0–7 days after a colonoscopy, corresponding to an incidence of 1.96 per 1000 procedures. Subjects aged 75 years or older had nearly four times the risk of a perforation (OR = 3.7, 95% CI = 1.7 to 8.2 for those aged 75–79 years and OR = 3.5, 95% CI = 1.5 to 7.8 for those aged 80 years or older) than those aged 65–69 years (Table 2). In univariate analyses, the risk of perforation was positively associated with increasing age (P_{trend}<.001) and number of comorbidities (P_{trend}<.001) (Table 1). Neither sex nor race/ethnicity was related to the risk of perforation after a colonoscopy. Compared with subjects who had a screening colonoscopy, an increased risk of perforation was associated with two indications: diverticulosis (OR = 2.3, 95% CI = 1.3 to 4.0) and obstruction (OR = 2.9, 95% CI = 1.3 to 6.7) (Table 2). No other indications were statistically significantly associated with an increased risk of perforation.

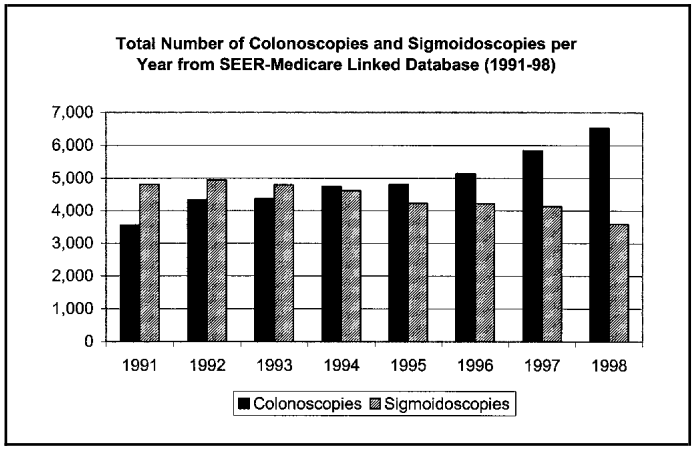

Fig. 1. Total number of colonoscopy and sigmoidoscopy procedures per year from the SEER–Medicare linked database (1991–1998).

Perforation After Sigmoidoscopy

We identified 31 subjects with an intestinal perforation within 0–7 days after a sigmoidoscopy, corresponding to an incidence of perforation of 0.88 per 1000 procedures. In multivariate analyses, the risk of perforation among patients aged 80 years and older was nearly three times that among those aged 65–69 years (OR = 2.9, 95% CI = 1.1 to 7.9) (Table 2). The risk of perforation was positively associated with increasing age (P_{trend}<.001) and number of comorbidities (P_{trend} = .03), but not to sex, race/ethnicity, or year of the procedure (Table 1). Compared with subjects who had a screening sigmoidoscopy, an increased risk of perforation was associated with two indications: diverticulosis (OR = 5.4, 95% CI = 2.4 to 12.4) and abdominal pain (OR = 2.4, 95% CI = 1.1 to 5.4) (Table 2).

Incidence of Death After a Perforation From a Colonoscopy or Sigmoidoscopy

The incidence of death subsequent to a perforation within 14 days of a procedure was 51.9 per 1000 colonoscopic perforations and 64.5 per 1000 sigmoidoscopic perforations. After adjustment for covariates, mortality among those who had a perforation compared with those who did not was nearly ninefold higher in both the colonoscopy group (OR = 9.0, 95% CI = 3.0 to 27.3) and the sigmoidoscopy group (OR = 8.8, 95% CI = 1.6 to 48.5) (Table 3). The results were similar up to 30 days following the procedure (OR = 7.1, 95% CI = 2.8 to 17.7 for colonoscopy; OR = 6.0, 95% CI = 1.5 to 24.2 for sigmoidoscopy).

Comparison Between Colonoscopy and Sigmoidoscopy

The crude OR for perforation from colonoscopy compared with that from sigmoidoscopy was 2.2 (95% CI = 1.5 to 3.4). After adjusting for covariates, the risk of perforation from colonoscopy was still nearly double the risk of perforation from sigmoidoscopy (OR = 1.8, 95% CI = 1.2 to 2.8). During the study period, the risk of perforation from colonoscopy statistically significantly declined (P_{trend} = .002), while that from sigmoidoscopy did not. In 1998, the last year of the study period, the incidence of perforation from colonoscopy was 1.84 per 1000 and from sigmoidoscopy was 1.67 per 1000 (Table 1). Since 1995, the incidence of perforation after colonoscopy in the screening/other group has been less than one per 1000 (Fig. 2).

Validity of Perforation Coding

Nearly 30% of the perforations from colonoscopy and sigmoidoscopy were coded with ICD-9 code 998.2, which is defined as "an accidental puncture or laceration during a procedure." Using only this ICD-9 code, we found that the crude and adjusted ORs between perforation from colonoscopy compared with perforation from sigmoidoscopy were 2.0 (95% CI = 0.9 to 4.4) and 1.4 (95% CI = 0.6 to 3.3), respectively.

Discussion

In this large, population-based study, we found that the incidence of perforation from colonoscopy was 1.96 per 1000 procedures (0.19%) and from sigmoidoscopy was 0.88 per 1000 procedures (0.09%). After adjustment for confounding factors, the relative risk of perforation from colonoscopy was about 1.8 times that from sigmoidoscopy. We also found a dramatically

Table 1. Incidence of perforations from colonoscopy and sigmoidoscopy procedures according to demographic and clinical characteristics

	Colonoscopy			Sigmoidoscopy		
		Perforations			Perforations	
	No. (%)	No.	Incidence*	No. (%)	No.	Incidence*
Total	39 286 (100)	77	1.96	35 298 (100)	31	0.88
Age, y						
65–69	10 608 (27)	8	0.75	10 651 (30)	6	0.56
70–74	11 420 (29)	18	1.58	10 545 (30)	2	0.19
75–79	9120 (23)	27	2.96	7785 (22)	9	1.16
⩾80	8138 (21)	24	2.95	6317 (18)	14	2.22
			P_{trend}<.001			P_{trend}<.001
Year of procedure						
1991	3560 (9)	12	3.37	4800 (14)	5	1.04
1992	4326 (11)	18	4.16	4941 (14)	3	0.61
1993	4365 (11)	8	1.83	4786 (14)	3	0.63
1994	4732 (12)	9	1.90	4609 (13)	2	0.43
1995	4800 (12)	6	1.25	4228 (12)	3	0.71
1996	5140 (13)	3	0.58	4214 (12)	5	1.19
1997	5839 (15)	9	1.54	4129 (12)	4	0.97
1998	6524 (17)	12	1.84	3591 (10)	6	1.67
			P_{trend} = .002			P_{trend} = .21
Sex						
Male	17 060 (43)	34	1.99	15 370 (44)	16	1.04
Female	22 226 (57)	43	1.93	19 928 (56)	15	0.75
Race/ethnicity						
Non-Hispanic white	33 133 (84)	65	1.96	30 669 (87)	28	0.91
Non-Hispanic black	2554 (7)	3	1.17	1759 (5)	1	0.57
Other†	3599 (9)	9	2.50	2870 (8)	2	0.70
No. of comorbidities						
0	36 748 (94)	62	1.69	33 652 (95)	27	0.80
1	782 (2)	4	5.12	511 (1)	1	1.96
⩾2	1756 (4)	11	6.26	1135 (3)	3	2.64
			P_{trend}<.001			P_{trend} = .03
Indications‡						
Screening/other	20 163 (51)	27	1.34	25 951 (74)	14	0.54
Abdominal pain	7799 (20)	16	2.05	4292 (12)	11	2.56
Anemia	5230 (13)	14	2.68	1766 (5)	3	1.70
Diarrhea	683 (2)	0	0	314 (1)	1	3.18
Diverticulosis	3829 (10)	18	4.70	1783 (5)	10	5.61
Hemorrhage	7178 (18)	22	3.06	1806 (5)	5	2.77
Inflammatory bowel disease	3095 (8)	10	3.23	1694 (5)	2	1.18
Obstruction	922 (2)	7	7.59	480 (1)	3	6.25
Weight loss	1083 (3)	1	0.92	465 (1)	1	2.15

*Number of perforations per 1000 procedures.

†Other race/ethnicity includes Hispanic, Asian, Native American, other, and unknown.

‡Indications add up to more than 100% because (except for screening/other) they are not mutually exclusive.

increased risk of death associated with perforation after either a colonoscopy or a sigmoidoscopy.

Previous studies *(22–24,27–29,35)* have found similar perforation rates but have been limited by several features. Most studies had small sample sizes, were conducted in a single medical center, were based on data from either a single endoscopist or a small number of endoscopists, or included only colonoscopies *(22–24,27–29,35).* However, several previous studies deserve special mention because of their large sample sizes. Sieg et al. *(25)* noted that 94 of 160 invited German gastroenterologists participated in a survey of colonoscopy-associated complications. They reported four perforations among 82 416 diagnostic colonoscopies (.05 per 1000 or one in 20 000 procedures) and nine perforations among 14 249 polypectomies (almost one per 200). This is the lowest reported rate of perforation, probably because the study included only perforations that required surgical intervention and because it depended on physician-reported perforations. In a study by Tran et al. *(29),* investigators reviewed the results of a series of 16 948 diagnostic colonoscopies and 9214 "therapeutic colonoscopies" from one U.S. center. In this study, only those perforations that required surgery were counted, and 11 perforations among the diagnostic colonoscopies (0.6 per 1000 procedures) and 10 perforations among the therapeutic colonoscopies (1.1 per 1000 procedures) were found. In 1979, Fruhmorgen and Demling *(21)* surveyed 27 hospitals in Germany and found 1.4 perforations per 1000 diagnostic colonoscopies and 3.4 per 1000 colonoscopies with polypectomy. None of these three studies, however, investigated sigmoidoscopy-associated perforation.

One recent study, Anderson et al. *(26)* explored the risks of perforation after either sigmoidoscopy or colonoscopy. They reported an incidence of 1.9 perforations per 1000 colonoscopies and 0.4 perforations per 1000 sigmoidoscopies. The study compared 10 486 colonoscopies with 49 501 sigmoidoscopies done over 10 years (1987 through 1996) at the Mayo Clinic. The authors found two deaths secondary to perforation (N = 20) from colonoscopy, corresponding to an overall mortality rate after a colonoscopy of 0.02% and an incidence of death after a

Table 2. Association between perforations from colonoscopy and sigmoidoscopy procedures and demographic and clinical characteristics

Factors	Colonoscopy		Sigmoidoscopy	
	n	Adjusted odds ratio (95% CI)*	n	Adjusted odds ratio (95% CI)*
Total	39 286	—	35 298	—
Age, y				
65–69	10 608	1.0 (referent)	10 651	1.0 (referent)
70–74	11 420	2.1 (0.9 to 4.8)	10 545	0.3 (0.1 to 1.6)
75–79	9120	3.7 (1.7 to 8.2)	7785	1.8 (0.6 to 5.1)
⩾80	8138	3.5 (1.5 to 7.8)	6317	2.9 (1.1 to 7.9)
Year of procedure				
1991	3560	1.0 (referent)	4800	1.0 (referent)
1992	4326	1.2 (0.6 to 2.5)	4941	—
1993	4365	0.5 (0.2 to 1.3)	4786	0.6 (0.1 to 2.4)
1994	4732	0.5 (0.2 to 1.3)	4609	0.4 (0.1 to 2.0)
1995	4800	0.3 (0.1 to 0.9)	4228	0.7 (0.2 to 2.7)
1996	5140	0.2 (0.0 to 0.6)	4214	1.1 (0.3 to 3.8)
1997	5839	0.4 (0.2 to 1.0)	4129	0.7 (0.2 to 2.8)
1998	6524	0.5 (0.2 to 1.2)	3591	1.2 (0.4 to 4.2)
Sex				
Male	17 060	1.0 (referent)	15 370	1.0 (referent)
Female	22 226	0.9 (0.6 to 1.5)	19 928	0.6 (0.3 to 1.2)
Race/ethnicity				
Non-Hispanic white	33 133	1.0 (referent)	30 669	1.0 (referent)
Non-Hispanic black	2554	0.6 (0.2 to 1.8)	1759	0.6 (0.1 to 4.5)
Other†	3599	1.4 (0.7 to 2.8)	2870	0.9 (0.2 to 3.8)
No. of comorbidities				
0	36 748	1.0 (referent)	33 652	1.0 (referent)
1	782	2.6 (0.9 to 7.2)	511	1.4 (0.2 to 10.9)
⩾2	1756	3.2 (1.6 to 6.1)	1135	2.2 (0.7 to 7.5)
Indications‡				
Screening/other	20 163	1.0 (referent)	25 951	1.0 (referent)
Abdominal pain	7799	0.8 (0.5 to 1.5)	4292	2.4 (1.1 to 5.4)
Anemia	5230	1.0 (0.5 to 1.8)	1766	0.8 (0.2 to 2.8)
Diarrhea	683	§	314	1.2 (0.2 to 10.0)
Diverticulosis	3829	2.3 (1.3 to 4.0)	1783	5.4 (2.4 to 12.4)
Hemorrhage	7178	1.5 (0.9 to 2.5)	1806	2.1 (0.7 to 5.9)
Inflammatory bowel disease	3095	1.8 (0.9 to 3.5)	1694	0.8 (0.2 to 3.4)
Obstruction	922	2.9 (1.3 to 6.7)	480	2.3 (0.6 to 8.5)
Weight loss	1083	0.4 (0.1 to 3.0)	465	1.4 (0.2 to 10.8)

*Odds ratios adjusted for all other covariates.

†Other race/ethnicity includes Hispanic, Asian, Native American, other, and unknown.

‡Indications are not mutually exclusive (other than screening/other).

§Odds ratio could not be calculated.

Table 3. No. of deaths after a perforation within 14 days of a colonoscopy or sigmoidoscopy procedure

Procedure	No. of perforations	No. of deaths	Crude OR*	Adjusted OR (95% CI)
Colonoscopy	77	4	15.5	9.0 (3.0 to 27.3)
Sigmoidoscopy	31	2	30.3	8.8 (1.6 to 48.5)

*OR = odds ratio; CI = confidence interval. OR is adjusted for age, year, sex, race/ethnicity, cormorbidity, and indications.

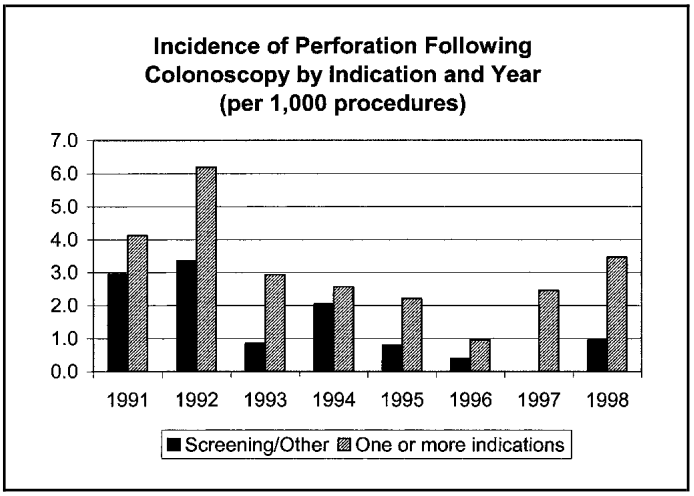

Fig. 2. Incidence (per 1000 procedures) of perforation after colonoscopy by indication and year.

perforation of 10%, which was higher than the incidence of death after a perforation from colonoscopy in our study (5.2%). The Mayo study *(26)* was the only other large study to directly compare colonoscopy with sigmoidoscopy. Although it was similar to our study in sample size, it included only patients from a single institution.

Using a Medicare sample, we have conducted the largest study to date of major complications from colonoscopy and sigmoidoscopy. The study was also population-based, with the procedures performed in major academic and specialized centers, community hospitals, clinics, and private offices. However, the databases we used have several limitations. Findings based on Medicare data may not be directly generalizable to people younger than 65 years. Moreover, a 1997 study by Nattinger et al. *(36),* found that the counties included in the SEER registry

had somewhat higher socioeconomic status and were less rural than most counties in the United States. Although the SEER counties were similar to other counties in the density of physician resources, SEER county hospitals had more beds and were more likely to have approval from the Joint Commission on the Accreditation of Hospitals. Consequently, our findings may slightly underestimate the risk of these complications in the overall U.S. population.

Still another possible limitation is that the accuracy of our identification of comorbidity, indications for colonoscopy and sigmoidoscopy, and the diagnosis of perforation itself are dependent on the precision of the diagnostic coding in the Medicare claims data. However, agreement between claims data and medical record abstracts has been found to be greater than 85% for most of the comorbidities in our index *(37).* An improvement in such agreement was demonstrated between 1977 and 1985 *(37),* and this may have improved further in the 1990s.

We were unable to determine with 100% validity whether the perforations were a direct consequence of the procedure. Therefore, we restricted the follow-up time to 7 days after the procedure, because we believe that the vast majority of such complications will be recognized within this time frame. Further follow-up would be more likely to include perforations related to the underlying colorectal pathology or other comorbidities. Moreover, when the analysis was restricted to perforations that were coded as accidental punctures or lacerations during a procedure, we found that the relative risk of perforation from colonoscopy compared with that of perforation from sigmoidoscopy did not differ from the full analysis, which also included those perforations coded as perforation of intestine. Thus, if a small number of the perforations detected within 7 days after colonoscopy or sigmoidoscopy were attributable to causes other than the procedure itself, this difference did not depend on the type of procedure.

The risk of perforation after colonoscopy was statistically significantly increased among patients with diverticulosis and obstruction, whereas the risk of perforation after sigmoidoscopy was increased among patients with diverticulosis and abdominal pain. Because patients with diverticuli and circular muscle hypertrophy have distorted colons, intubation may be more difficult. The consequence of difficult intubation may be an increase in perforation, which may also account for perforations in patients with obstruction. The reasons why there was an increased risk of perforation for patients undergoing sigmoidoscopy for the evaluation of abdominal pain are not apparent.

Overall, we found a perforation incidence of nearly two per 1000 colonoscopies, slightly more than twice the perforation incidence from sigmoidoscopy. Perforation incidence declined over the study period for colonoscopy but not for sigmoidoscopy, with the two procedures being much more similar in overall risk at the end of the study period than they had been at the beginning (Fig. 2). The decrease in the perforation incidence from colonoscopy over time may be a result of improvements in technology and in the training of endoscopists. The lack of a similar decrease in perforation incidence from sigmoidoscopy may reflect billing for a colonoscopy as a sigmoidoscopy when the procedure is aborted because of a complication, or it may reflect a trend toward having less skilled endoscopists perform this less demanding procedure.

Although current consensus guidelines suggest that asymptomatic individuals who are at average risk for colorectal cancer should undergo a yearly FOBT and flexible sigmoidoscopy every 5 years or a colonoscopy every 10 years, these guidelines are being debated *(13,38).* Observational studies and randomized trials have demonstrated that FOBT and sigmoidoscopy reduce mortality after a diagnosis of colorectal cancer *(1–4,6–8).* However, many believe that mortality may be reduced more by colonoscopy than by sigmoidoscopy *(16).* Indeed, in this study, we observed a gradual increase over time in the number of colonoscopies performed, with a concomitant decline in the annual number of sigmoidoscopies, partially supporting this belief.

Our findings are population-based, from a large and relatively unselected series of colonoscopies and sigmoidoscopies, and permit a direct comparison of the two procedures for perforation incidence. These results should be useful to clinicians making screening and diagnostic decisions for individual patients and to public health and policy officials setting guidelines for colorectal cancer screening programs.

REFERENCES

(1) Hardcastle JD, Armitage NC, Chamberlain J, Amar SS, James PD, Balfour TW. Fecal occult blood screening for colorectal cancer in the general population. Results of a controlled trial. Cancer 1986;58:397–403.

(2) Kronborg O, Fenger C, Worm J, Pedersen SA, Hem J, Bertelsen K, et al. Causes of death during the first 5 years of a randomized trial of mass screening for colorectal cancer with fecal occult blood test. Scand J Gastroenterol 1992;27:47–52.

(3) Mandel JS, Bond JH, Church TR, Snover DC, Bradley GM, Schuman LM, et al. Reducing mortality from colorectal cancer by screening for fecal occult blood. Minnesota Colon Cancer Control Study. N Engl J Med 1993; 328:1365–71.

(4) Winawer SJ, Flehinger BJ, Schottenfeld D, Miller DG. Screening for colorectal cancer with fecal occult blood testing and sigmoidoscopy. J Natl Cancer Inst 1993;85:1311–8.

(5) Lieberman DA, Weiss DG. One-time screening for colorectal cancer with combined fecal occult-blood testing and examination of the distal colon. N Engl J Med 2001;345:555–60.

(6) Selby JV, Friedman GD, Quesenberry CP Jr, Weiss NS. A case-control study of screening sigmoidoscopy and mortality from colorectal cancer. N Engl J Med 1992;326:653–7.

(7) Newcomb PA, Norfleet RG, Storer BE, Surawicz TS, Marcus PM. Screening sigmoidoscopy and colorectal cancer mortality. J Natl Cancer Inst 1992;84:1572–5.

(8) Muller AD, Sonnenberg A. Protection by endoscopy against death from colorectal cancer. A case-control study among veterans. Arch Intern Med 1995;155:1741–8.

(9) Gohagan JK, Prorok PC, Hayes RB, Kramer BS. The Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial of the National Cancer Institute: history, organization, and status. Control Clin Trials 2000; 21:251S–72S.

(10) Prorok PC, Andriole GL, Bresalier RS, Buys SS, Chia D, Crawford ED, et al. Design of the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial. Control Clin Trials 2000;21(6 Suppl):273S–309S.

(11) Sutton S, Wardle J, Taylor T, McCaffery K, Williamson S, Edwards R, et al. Predictors of attendance in the United Kingdom flexible sigmoidoscopy screening trial. J Med Screen 2000;7:99–104.

(12) Levin B, Smith RA, Feldman GE, Colditz GA, Fletcher RH, Nadel M, et al. Promoting early detection tests for colorectal carcinoma and adenomatous polyps. Cancer 2002;95:1618–28.

(13) Winawer SJ, Fletcher RH, Miller L, Godlee F, Stolar MH, Mulrow CD, et al. Colorectal cancer screening: clinical guidelines and rationale. Gastroenterology 1997;112:594–642.

(14) Markowitz AJ, Winawer SJ. Screening and surveillance for colorectal carcinoma. Hematol Oncol Clin North Am 1997;11:579–608.

(15) Neugut AI, Forde KA. Screening colonoscopy: has the time come? Am J Gastroenterol 1988;83:295–7.

(16) Detsky AS. Screening for colon cancer–can we afford colonoscopy? N Engl J Med 2001;345:607–8.

(17) Wagner JL, Herdman RC, Wadhwa S. Cost effectiveness of colorectal cancer screening in the elderly. Ann Intern Med 1991;115:807–17.
(18) Sonnenberg A, Delco F, Inadomi JM. Cost-effectiveness of colonoscopy in screening for colorectal cancer. Ann Intern Med 2000;133:573–84.
(19) Khullar SK, DiSario JA. Colon cancer screening. Sigmoidoscopy or colonoscopy. Gastrointest Endosc Clin N Am 1997;7:365–86.
(20) Waye JD, Kahn O, Auerbach ME. Complications of colonoscopy and flexible sigmoidoscopy. Gastrointest Endosc Clin N Am 1996;6:343–77.
(21) Fruhmorgen P, Demling L. Complications of diagnostic and therapeutic colonoscopy in the Federal Republic of Germany. Results of an inquiry. Endoscopy 1979;11:146–50.
(22) Nivatvongs S. Complications in colonoscopic polypectomy: lessons to learn from an experience with 1576 polyps. Am Surg 1988;54:61–3.
(23) Reiertsen O, Skjoto J, Jacobsen CD, Rosseland AR. Complications of fiberoptic gastrointestinal endoscopy—five years' experience in a central hospital. Endoscopy 1987;19:1–6.
(24) Jentschura D, Raute M, Winter J, Henkel T, Kraus M, Manegold BC. Complications in endoscopy of the lower gastrointestinal tract. Therapy and prognosis. Surg Endosc 1994;8:672–6.
(25) Sieg A, Hachmoeller-Eisenbach U, Eisenbach T. Prospective evaluation of complications in outpatient GI endoscopy: a survey among German gastroenterologists. Gastrointest Endosc 2001;53:620–7.
(26) Anderson ML, Pasha TM, Leighton JA. Endoscopic perforation of the colon: lessons from a 10-year study. Am J Gastroenterol 2000;95:3418–22.
(27) Eckardt VF, Kanzler G, Schmitt T, Eckardt AJ, Bernhard G. Complications and adverse effects of colonoscopy with selective sedation. Gastrointest Endosc 1999;49:560–5.
(28) Waye JD, Lewis BS, Yessayan S. Colonoscopy: a prospective report of complications. J Clin Gastroenterol 1992;15:347–51.
(29) Tran DQ, Rosen L, Kim R, Riether RD, Stasik JJ, Khubchandani IT. Actual colonoscopy: what are the risks of perforation? Am Surg 2001;67:845–7; discussion 7–8.
(30) Warren JL, Klabunde CN, Schrag D, Bach PB, Riley GF. Overview of the SEER-Medicare data: content, research applications, and generalizability to the United States elderly population. Med Care 2002;40(8 Suppl):IV-3–18.
(31) Potosky AL, Riley GF, Lubitz JD, Mentnech RM, Kessler LG. Potential for cancer related health services research using a linked Medicare-tumor registry database. Med Care 1993;31:732–48.
(32) Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. J Chronic Dis 1987;40:373–83.
(33) Deyo RA, Cherkin DC, Ciol MA. Adapting a clinical comorbidity index for use with ICD-9-CM administrative databases. J Clin Epidemiol 1992;45:613–9.
(34) Klabunde CN, Potosky AL, Legler JM, Warren JL. Development of a comorbidity index using physician claims data. J Clin Epidemiol 2000;53:1258–67.
(35) Nelson DB, McQuaid KR, Bond JH, Lieberman DA, Weiss DG, Johnston TK. Procedural success and complications of large-scale screening colonoscopy. Gastrointest Endosc 2002;55:307–14.
(36) Nattinger AB, McAuliffe TL, Schapira MM. Generalizability of the surveillance, epidemiology, and end results registry population: factors relevant to epidemiologic and health care research. J Clin Epidemiol 1997;50:939–45.
(37) Fisher ES, Whaley FS, Krushat WM, Malenka DJ, Fleming C, Baron JA, et al. The accuracy of Medicare's hospital claims data: progress has been made, but problems remain. Am J Public Health 1992;82:243–8.
(38) Smith RA, Mettlin CJ, Davis KJ, Eyre H. American Cancer Society guidelines for the early detection of cancer. CA Cancer J Clin 2000;50:34–49.

NOTES

[1]*Editor's note:* SEER is a set of geographically defined, population-based, central cancer registries in the United States, operated by local nonprofit organizations under contract to the National Cancer Institute (NCI). Registry data are submitted electronically without personal identifiers to the NCI on a biannual basis, and the NCI makes the data available to the public for scientific research.

Supported in part by American Cancer Society grant RSGHP-01-024-01-CCE and Public Health Service grant CA70335 from the National Cancer Institute (NCI), National Institutes of Health, Department of Health and Human Services. N. M. Gatto is supported by a T32 predoctoral fellowship (CA09529), and A. I. Neugut is supported in part by a K05 Senior Scientist Award (CA89155) from the NCI.

We acknowledge the efforts of the Applied Research Branch, Division of Cancer Prevention and Population Science, NCI; the Office of Information Services and the Office of Strategic Planning, Health Care Financing Administration; Information Management Services, Inc.; and the SEER Program tumor registries in the creation of the SEER–Medicare database.

Manuscript received July 9, 2002; revised November 18, 2002; accepted December 2, 2002.