

# Procedural success and complications of large-scale screening colonoscopy

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**Background:** Indirect evidence and modeling analyses suggest that colonoscopy may be the most cost-effective way to screen the average-risk population for colorectal neoplasia. However, the success and safety of primary colonoscopic screening has not been prospectively evaluated in a multicenter trial.

**Methods:** Asymptomatic subjects age 50 to 75 years who had not undergone examination of the colon within 10 years were recruited from the general medicine clinics of 13 Department of Veterans Affairs Medical Centers. Eligible patients underwent colonoscopy by study coinvestigators, at which time all polyps were measured, photographed, and removed. Patients were contacted at 24 hours and 1 week to track procedure-related complications.

**Results:** Primary screening colonoscopy was performed in a cohort of 3196 asymptomatic subjects. A "good" preparation was reported in 81% of patients, and colonoscopy to the cecum was successful in 97.2% of cases. Mean insertion time to the cecum and total procedure times were 10.5 (8.7) and 30.6 (19.1) minutes, respectively. No preprocedural patient characteristics were identified that were predictive of an incomplete procedure. At least one polyp was resected in 1672 patients. There was no perforation and no death attributed to colonoscopy. Major morbidity considered to be definitely related to colonoscopy occurred in 9 of 3196 procedures (0.3%): lower GI bleeding requiring intervention (6), myocardial infarction and/or cerebrovascular accident (2), and thrombophlebitis (1). In subjects undergoing only diagnostic procedures, the major complication rate was 0.1%.

**Conclusions:** Screening colonoscopy can be performed in multiple centers with a high degree of success and safety in large numbers of asymptomatic, average-risk men. (*Gastrointest Endosc* 2002;55:307-14.)

Colorectal cancer (CRC) is the second leading cause of cancer mortality in the United States, resulting in over 55,000 deaths each year.<sup>1</sup> There is now strong evidence that CRC mortality is reduced

by screening average-risk, asymptomatic subjects with fecal occult blood tests (FOBT) or sigmoidoscopy.<sup>2-6</sup> Hence, the U.S. Preventative Services Task Force now recommends screening all average-risk, asymptomatic individuals over age 50 with either or both of these tests.<sup>7</sup> Colonoscopy is widely used for the evaluation and treatment of patients with symptoms, a positive FOBT, or abnormalities detected by sigmoidoscopy or barium enema. However, until recently its use as a screening modality in asymptomatic patients has been mainly limited to those with increased risk factors for CRC.

An expert, multidisciplinary panel recently recommended that colonoscopy be considered among the primary options for CRC screening in asymptomatic, average-risk subjects,<sup>8</sup> and one professional gastroenterology society has endorsed colonoscopy as the preferred screening strategy.<sup>9</sup> However, before colonoscopy can be recommended as a primary screening modality, the feasibility, efficacy, and

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**Table 1. Patient/procedure characteristics**

	N = 3196
Mean age (SD)	63.0 (7.1)
Gender (% male)	96.8
Race (% white)	83.5
Major comorbid conditions	
Coronary heart disease (%)	21.1
CVA/TIA (%)	8.2
Diabetes (%)	20.8
COPD (%)	8.5
Medications (% patients receiving)	
Meperidine	70.7
Fentanyl	19.1
Midazolam	71.4
Diazepam	8.5
Atropine	13.3
Glucagon	0.7

CVA/TIA, Cerebrovascular accident/transient ischemic attack; COPD, chronic obstructive pulmonary disease.

safety of this procedure should be rigorously assessed in average-risk, asymptomatic subjects. The Department of Veterans Affairs Cooperative Studies Program Study No. 380 is a multicenter study designed to assess risk factors for neoplastic lesions of 10 mm or greater diameter in asymptomatic adults between the ages of 50 and 75 years. Preliminary outcomes of this study have been reported.<sup>10</sup> The present report describes the rates of procedural success and complications of screening colonoscopy in a large asymptomatic cohort. The identification of predictive variables for procedural success and complications will enable the development of rational, evidence-based guidelines for the appropriate use of colonoscopy as a screening modality in the general population.

#### PATIENTS AND METHODS

The study protocol was approved by a central Human Rights Committee (CSPCC Perry Point, MD Department of Veterans Affairs Medical Center), and by the institutional review board of each participating center. Asymptomatic subjects age 50 to 75 years who had not undergone examination of the colon within 10 years were recruited between February 1994 and January 1997 from 13 Department of Veterans Affairs Medical Centers (VAMC) across the country. They were recruited in 1 of 3 ways: random selection from the VAMC clinic list based on age; referral for asymptomatic screening sigmoidoscopy; and advertisement for patients with a positive family history of CRC. Patients were excluded if they reported symptoms of lower GI tract disease including rectal bleeding on more than one occasion in the prior 6 months, significant change in bowel habits, or lower abdominal pain that would normally require evaluation. Other exclusion criteria included prior colonic disease (colitis, polyps, cancer, surgery); prior colon examination within 10 years (including sigmoidoscopy, colonoscopy or barium enema);

significant medical problems that could increase the risk of colonoscopy (active cardiac or pulmonary disease, or other serious disease) or a medical condition that would preclude benefit from screening (cancer, terminal illness); need for special precautions for colonoscopy (including anticoagulation and prophylactic administration of antibiotics); and women with childbearing potential.

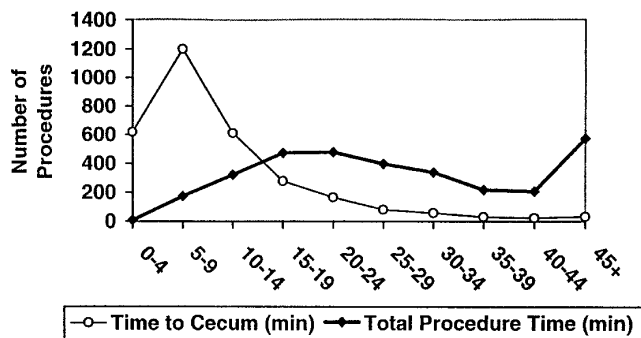
#### Study procedures

Study subjects provided informed consent before the colonoscopy. The use of nonsteroidal anti-inflammatory agents (NSAIDs) was discontinued and coagulation studies were routinely obtained before the colonoscopy in this asymptomatic cohort. Patients ingested a polyethylene glycol-based electrolyte solution for bowel preparation. All examinations were performed solely by study investigators, all of whom were staff gastroenterologists. The mean investigator experience at the start of the study was 8.4 years (range 1-23 years), and the mean yearly colonoscopy volume of the investigators was 407 procedures per year (range 100-750).

During the procedure, the use of medications for conscious sedation and/or the use of anticholinergic or antimotility agents were at the discretion of the endoscopist. The location and size of all polypoid lesions were recorded by study personnel. Investigators were required to provide photo-documentation of cecal landmarks, as well as polyps and other significant pathology. Immediately after the procedure, the endoscopist graded the adequacy of the bowel preparation as "good" (mucosa well seen throughout), "fair" (liquid contents; examination adequate), or "poor" (solid contents, examination compromised). Procedure success was defined as confirmation of cecal intubation.

All patients were instructed to contact the investigator or study coordinator if a complication occurred, and all patients were contacted by a study coordinator at 24 hours and 1 week to assess for adverse events. Complications were considered major if they required a blood transfusion, hospitalization, surgery, or if they resulted in death. Data on all complications within 30 days were collected. At the time complications occurred, investigators were asked to classify whether the complication was "definitely," "possibly," or "unlikely" to be related to the procedure. A summary of the event was written by the investigator and reported to each institution's institutional review board. The summary and copies of pertinent medical records were also forwarded to the study chairman, which were then sent to a Data Monitoring Board established for the study by the VA Cooperative Studies Program. The final adjudication of each complication for the purposes of the manuscript was made by a committee of the investigators after review of the medical record in each case.

For the purpose of analysis, doses of opioid drugs administered were converted to an equivalent dose of meperidine, with 100 µg fentanyl equivalent to 75 mg meperidine.<sup>11</sup> Similarly, benzodiazepines were converted to equivalent doses of midazolam by using a conversion of 4 mg diazepam being equal to 1 mg of midazolam.<sup>12</sup>



**Figure 1.** Distribution of procedure according to interval in minutes from colonoscope insertion to confirmation of cecal intubation (time to cecum), and total procedure duration.

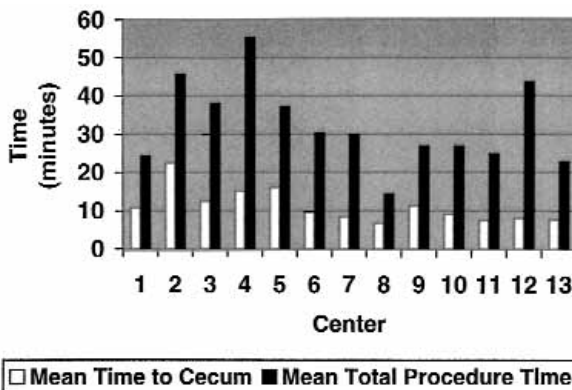
**Statistical analysis**

Study database management and all statistical analyses were performed with the Statistical Analysis System (SAS) (SAS Institute Inc., Cary, N.C.). Descriptive analysis included the calculation of rates and proportions for count data and means and standard deviations for continuous data; statistical comparisons for count data were based on chi-square procedures; comparisons for continuous data were based on *t* tests.

**RESULTS**

Selected demographics of the subjects who underwent screening colonoscopy are presented in Table 1. Colonoscopy with cecal intubation was successful on the first attempt in 3107 of 3196 (97.2%) of cases. This includes 69 cases in which the quality of the preparation was felt to be inadequate to visualize the entire colonic mucosa. In 1672 of 3107 (53.8%) of these subjects, resection of at least 1 polyp was performed. Mean insertion time to the cecum was 10.5 (8.7) minutes (median 8 minutes), and mean total procedure time was 30.6 (19.1) minutes (median 26 minutes). By using a polyethylene glycol-based electrolyte solution, the bowel preparation was described as good in 81.4%, fair in 15.8%, and poor in 2.7% of patients. The distribution of cecal intubation times and total procedure times are depicted in Figure 1. Figure 2 demonstrates the variation in procedure times between centers.

Major complications categorized as definitely or possibly related to the procedure are presented in Table 2. There were too few major complications to permit meaningful statistical analysis of predictors. There were no perforations in the 3196 colonoscopies performed. Lower GI bleeding requiring transfusion, hospitalization, or surgery occurred in 7 subjects, or 0.22% of procedures, and in all cases was associated with polypectomy. The interval between the polypectomy and the onset of clinically apparent hemorrhage ranged from 1 to 16 days and was not associated with bleeding noted at the time



**Figure 2.** Distribution of mean time to cecum and mean total procedure time by center.

**Table 2. Adverse events “definitely” or “possibly” related to 3196 screening colonoscopic procedures**

	No. of patients	%
<b>Major complications</b>		
Perforation	0	0
GI bleeding with hospitalization	7	0.22
New arrhythmia	1	0.03
MI/CVA	4*	0.12
Death within 30 days	1	0.03
Other	4	0.12
Total major complications	18	0.56
<b>Minor complications</b>		
Vasovagal events	188	5.4
Transient oxygen desaturation requiring supplemental oxygen	141	4.4
Minor GI bleeding	6	0.22
Abdominal pain lasting >2 h	24	0.8
Abdominal pain resulting in termination of procedure	29	0.9
Other	125	3.9

MI/CVA, myocardial infarction/cerebrovascular accident.  
\*One patient experienced both an MI and a CVA.

of polypectomy. This includes one case in which the subject presented with melena and hematochezia 1 week after the colonoscopy. Although an upper endoscopy showed an actively bleeding duodenal ulcer that was sclerosed with ethanol, a tagged red cell study demonstrated a bleeding site in the cecum. At surgery there were no obvious bleeding sites, and no bleeding sources (or polypectomy sites) were identified in the colectomy specimen. Five days after the procedure the patient experienced recurrent hematochezia that was treated conservatively with red cell transfusions, and approximately 1 month later, after experiencing recurrent melena, the patient was again found to have duodenal ulcers (classified as “possible”).

Major cardiovascular complications were similarly rare. One patient was hospitalized 24 hours after the procedure with new onset atrial fibrillation

**Table 3. Preprocedural predictors of incomplete colonoscopy**

	Patients (%)	Failure rate (%)	p Value
Age (y)			0.15
50-54	18.7	1.7	
55-59	14.6	3.0	
60-64	25.0	2.9	
65-69	22.5	3.1	
≥70	19.2	3.3	
Race			0.70
Minority	16.5	3.0	
White	83.5	2.7	
Gender			0.50
Male	96.8	2.8	
Female	3.3	3.9	
Body mass index (kg/m <sup>2</sup> )			0.89
<22	4.6	4.1	
22-24.9	12.7	3.5	
25-29	42.9	2.5	
≥30	39.8	2.8	
History of diverticulosis			0.14
Yes	3.0	5.2	
No	97.0	2.7	
Diabetes			0.69
Yes	20.8	3.0	
No	79.2	2.7	
Comorbid conditions			0.95
None	9.5	3.3	
1	22.1	2.7	
2	25.5	2.6	
3	21.6	2.5	
4+	21.4	3.2	
Prior abdominal surgery			0.75
Yes	6.4	2.4	
No	93.6	2.8	

(“possible”). The patient’s arrhythmia resolved without specific intervention. Myocardial infarction, stroke, or both occurred in 4 subjects, or 0.12% of procedures. An inferior wall myocardial infarction associated with a vasovagal event occurred in 1 subject immediately after an uneventful diagnostic procedure. Although the subject had no antecedent history of angina and before the procedure reported 20 minutes of daily aerobic exercise, cardiac catheterization demonstrated a complete occlusion of the right coronary artery. During the course of his hospitalization for the myocardial infarction, the patient had a cerebrovascular accident (CVA) (“definite”). Another subject had a myocardial infarction 3 days after the procedure (“possible”). A third patient had a CVA immediately after the procedure in the recovery area (“definite”), while another patient had a CVA 9 days after the procedure (“possible”).

The death of 1 subject occurred 2 days after the procedure. The subject was asymptomatic after the colonoscopy. Two days later he had a witnessed cardiac arrest in his primary care physician’s office. The primary care physician concluded that this

event was not related to the procedure, and no autopsy was performed. However, because of the temporal relationship, this was considered to be “possibly” related to the procedure. Two other deaths occurred 9 and 21 days after the procedure; local coroners attributed death to “natural causes” in the former and to electrolyte imbalance/dehydration resulting from alcohol abuse in the latter (“unlikely”).

“Other” complications included a thrombosed carotid-subclavian bypass in 1 subject attributed to the cessation of aspirin before the procedure (“possible”); one case of Fournier’s gangrene of the perineum occurring 2 days after the procedure (“possible”); 1 case of thrombophlebitis at the intravenous injection site requiring hospitalization and intravenous administration of antibiotics (“definite”); and 1 hospitalization for abdominal pain that resolved within 24 hours (“possible”). The overall major complication rate for the study was 0.56%. Given the strict criteria for a procedure-related complication, this likely overestimates the actual incidence of complications associated with screening colonoscopy, and represents a “worst-case” situation. When considering only those complications that were classified as “definitely” related to the procedure, the overall major complication rate was 9 of 3196, or 0.3%. The majority of these complications were due to bleeding after polypectomy. Furthermore, only 2 of the definite complications occurred in the 1435 patients undergoing purely diagnostic procedures (no polyps resected) for an overall major complication rate of 0.1% for diagnostic procedures.

Lower GI bleeding not requiring transfusion or hospitalization occurred in 6 subjects, or 0.2% of procedures. Hypotension or vasovagal episodes requiring intervention but without adverse sequelae occurred in 15 subjects, or 0.5% of procedures. Vasovagal events not requiring intervention and without adverse sequelae occurred in 173 subjects, or 5.4% of procedures (for a total of 188 vasovagal events). Oxygen desaturation requiring supplemental oxygen occurred in 141 subjects (4.4%). Twenty-four subjects had abdominal pain that lasted 2 hours or more after the procedure, and in 29 subjects abdominal pain resulted in termination of the procedure.

Univariate analysis of preprocedural factors that might predict procedure failure is presented in Table 3. Age, ethnicity, gender, or body mass index (BMI) were not associated with a higher likelihood of procedural failure. Pre-existing medical conditions that have been considered to impact on procedure success, including diabetes, a history of diverticulosis, or prior abdominal surgery, were also not significant predictors of procedural failure.

Univariate analysis of various procedural characteristics and the likelihood of procedure failure are shown in Table 4. Several procedural variables related to procedure duration or sedation showed suggestive but weak associations with procedure failure. However, adjusting significance levels for multiplicity of variables, only 1 was statistically significant: a poor quality colonoscopy preparation was associated with a higher rate of procedural failure. Surprisingly, longer procedure duration was not associated with an increased risk of procedure failure. In 29 cases, the procedure was terminated because of pain.

Procedural failure rates between centers ranged from 0.7% to 6.7%. Although there were significant differences in failure rates between centers ( $p = 0.001$ ), there was no linear trend between the number of patients entered into the trial by each center and their respective failure rates.

**DISCUSSION**

Indirect evidence and modeling analyses suggest that colonoscopy may be the most cost-effective way to screen the average-risk population for colorectal neoplasia.<sup>13-15</sup> Support for colonoscopy as a primary screening modality comes from 3 lines of indirect evidence. First, the majority of colorectal cancers arise from slowly growing precancerous adenomas that occur throughout the colon. Colonoscopy is highly accurate at detecting adenomas, and their removal by colonoscopic polypectomy has been shown to reduce the subsequent incidence of CRC by 76% to 90%.<sup>16</sup> Second, case-control studies of proctosigmoidoscopy indicate that this procedure reduces mortality from CRC of the distal colon by 60% to 80%. Colonoscopy accurately examines the entire colon in most patients and has been shown to detect most early stage cancers and at least two times as many polyps as does screening flexible sigmoidoscopy.<sup>17</sup> Third, colonoscopy was the definitive intervention in trials of FOBT screening that demonstrated a significant reduction in both CRC mortality and incidence.<sup>2-4,18</sup> The FOBT selects asymptomatic, average-risk people who are more likely to have advanced colonic neoplasia, but colonoscopy is required to detect early stage cancers and to detect and resect precancerous adenomas. Recent mathematical modeling analyses suggest that colonoscopy may not only be the most effective screening method for preventing cancers and reducing CRC mortality, but it may also be the most cost-effective strategy.<sup>13-15,19</sup>

However, before colonoscopy can be recommended as a primary screening modality, the feasibility, efficacy, and safety of this procedure for average-risk,

**Table 4. Procedural predictors of incomplete colonoscopy**

	Patients (%)	Failure rate (%)	p Value
Quality of preparation			0.001
Good	81.5	2.2	
Fair	15.8	2.8	
Poor	2.7	19.3	
Opioid and benzodiazepine sedation			0.05
Yes	71.2	2.4	
No	28.8	3.7	
Procedure duration (min)			0.14
0-15	19.5	4.0	
16-30	42.7	1.3	
31-45	21.5	2.9	
≥46	16.3	4.8	
Use of atropine or glucagon			0.17
Yes	14.0	1.8	
No	86.0	3.0	
Sedative agent(s) used			0.12
Yes	98.6	2.7	
No	1.4	6.5	
Benzodiazepine dose (mg midazolam or equivalent)			0.16
<1.5	40.5	3.1	
1.5-2.9	35.1	1.9	
3.0-4.9	21.0	3.1	
5.0+	3.5	6.4	
Opioid dose (mg meperidine or equivalent)			0.48
0-24	10.2	5.8	
25-49	6.5	2.9	
50-74	31.7	1.2	
75-99	35.5	2.2	
≥100	16.2	3.7	

asymptomatic subjects needs to be carefully established. The present study is the largest prospective multicenter study of the feasibility and complications of colonoscopy in asymptomatic subjects to date, and the results indicate that screening colonoscopy can be performed with a high degree of success and safety in large numbers of patients, meeting several of the criteria for a good screening method.

Colonoscopy to the cecum was successful on the first attempt in 97.2% of cases by 22 endoscopists at the 13 participating centers. In 3 retrospective and 2 prospective studies comprising 6632 patients referred for colonoscopy (presumably for the evaluation of symptoms, an abnormal screening test, or follow-up of colorectal pathology), the success rate of complete colonoscopy ranged from 91% to 97%. When patients with strictures, obstruction, or poor prep are excluded, success rates as high as 99% are reported.<sup>20-24</sup> Six previous studies evaluating screening colonoscopy comprising 1654 asymptomatic individuals reported success rates ranging from 93% to 100%.<sup>25-30</sup> All of these studies were limited to a single center. The rate of complete colonoscopy in the present study compares favorably with the rate in these series, but several factors differentiate the present study from previous investigations.

It is the largest single study of screening colonoscopy of asymptomatic subjects reported to date. The colonoscopies were performed by 22 staff gastroenterologists of varying levels of experience at 13 medical centers encompassing a wide geographic distribution. Given the wide variation in procedure times between centers (Fig. 2), the present study may be more generalizable to colonoscopy as practiced in the gastroenterology community.

Risks associated with colonoscopy include bleeding, perforation, and adverse cardiopulmonary events.<sup>31</sup> Previous estimates of risk derive from studies largely comprised of symptomatic patients undergoing colonoscopy. In these studies, significant bleeding occurred in 0.2% to 1.0% and perforation in 0.0% to 0.2% of patients.<sup>20,32-36</sup> However, these results may not be applicable to an asymptomatic screening population. It might be expected that the low complication rates in the present study were due to a lower frequency of therapeutic procedures (i.e., polypectomy) in an asymptomatic study population compared with those performed in patients with symptoms. Surprisingly, approximately 54% of the patients in the present study had at least 1 polyp removed during the procedure (although not necessarily an adenoma), compared with approximately 40% in the 3 largest earlier series.<sup>20,32,36</sup> When solely diagnostic procedures are considered, the present study had an overall complication rate of only 0.1%, which is similar to that noted in previous retrospective studies.

Although the overall success rate for colonoscopy was remarkably high and the complications extremely low, the identification of patient characteristics associated with complications or procedural failure might allow selection of individuals who should be screened with a less invasive method. However, major complications were such a rare event that meaningful statistical analysis of this outcome was precluded.

Procedural failure was uncommon in the present study, but because of the extremely large subject population there were sufficient failure events to ensure adequate statistical power to evaluate predictive factors for procedure incompleteness. No preprocedural demographic factors associated with a significantly greater chance of procedural failure could be identified. Two previous studies have found that advanced age is associated with increased procedure duration.<sup>24,37</sup> No such association was found for either mean procedure duration (data not presented) or, more importantly, for procedure success.

Although female gender was not significantly associated with procedure failure, the relative paucity of women in the present trial limits the generaliz-

ability of this observation. Several studies have concluded that female gender is associated with a lower procedural success rate, although the absolute magnitude of the difference in success rates between men and women ranged only from 2 to 6 percentage points.<sup>20,22,23,38</sup> Another study found no overall difference in procedure completion rates between men and women; however, when stratified by BMI, important differences emerged. As BMI decreased in women (but not men), the frequency of procedural failure increased significantly, with a BMI of less than 22 associated with a 49% failure rate.<sup>38</sup> If this finding is confirmed, it could have major ramifications for any proposed screening plan. No relationship could be found between BMI and procedural success in this largely male population.

No association could be demonstrated between prior abdominal surgery and a greater likelihood of procedural failure. The results of previous studies are conflicting on this issue. Two concluded that a history of abdominal surgery in women was associated with a lower completion rate,<sup>22,23</sup> whereas two other studies found no difference.<sup>20,38</sup>

Once the procedure had been started, the two factors that had the largest effect on procedural success were the presence of severe abdominal pain and a poor bowel preparation. Twenty-nine procedures were terminated because of pain reported by the patient, and in 17 cases the cecum was not reached because of a poor bowel preparation.

As has been discussed, the preponderance of men in the present study limits the applicability of these findings to women in general or to specific subgroups of women that may be at higher risk of procedural complications or failure. Another possible limitation is the timing of the follow-up telephone contact. One study demonstrated that a scheduled 30-day telephone follow-up captured more complications than were reported by the physician at a weekly morbidity and mortality conference.<sup>35</sup> It is possible that the 24-hour and 7-day follow-up contacts might have missed a delayed complication, although this seems unlikely for several reasons. Unlike other tertiary referral centers at which patient follow-up or emergency department visits are likely to occur at other hospitals, patients within the VA system have a strong financial incentive to seek care at the same hospital. Furthermore, because this is a longitudinal study, most patients had multiple subsequent contacts with study personnel at which point further complications could be identified.

Proven feasibility and safety are essential components of any proposed new population-based screening strategy. This study provides valuable information on the success and complication rates of

colonoscopy in a well-defined cohort of average-risk, asymptomatic individuals. It also evaluated preprocedural patient characteristics that would limit the applicability of colonoscopy as a screening modality to specific patient groups, and none could be identified. Screening colonoscopy can be performed with a high degree of success and safety in large numbers of asymptomatic, average-risk men.

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