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A Randomized, Controlled Trial to Assess a Novel Colorectal Cancer Screening Strategy: The Conversion Strategy

A Comparison of Sequential Sigmoidoscopy and Colonoscopy With Immediate Conversion From Sigmoidoscopy to Colonoscopy in Patients With an Abnormal Screening Sigmoidoscopy

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OBJECTIVE: Our study was a randomized, controlled trial to assess a novel strategy that provides comprehensive colorectal cancer screening in a single visit *versus* traditional sigmoidoscopy and, where appropriate, colonoscopy on a subsequent day.

METHODS: Consecutive patients referred for screening were randomized to control or so-called "conversion" groups. Patients in the control group were prepared for sigmoidoscopy with oral phospho-soda. Those with an abnormal sigmoidoscopy were scheduled for colonoscopy on a future day after oral polyethylene glycol preparation. In the conversion group, patients were prepared with oral phospho-soda. Patients with a polyp >5 mm or multiple diminutive polyps were converted from sigmoidoscopy to colonoscopy, allowing comprehensive screening in a single visit. Clinical outcomes were assessed by postprocedure physician and patient questionnaires.

RESULTS: Two hundred thirty-five patients were randomized (control = 121, conversion = 114). In the control group, 28% had an indication for colonoscopy. Three of 33 (9%) with an abnormal sigmoidoscopy did not return for colonoscopy. At colonoscopy, 27% had a proximal adenoma. In the conversion group, 28% had an abnormal sigmoidoscopy and underwent conversion to colonoscopy. Forty-one percent undergoing colonoscopy in the conversion group had a proximal adenoma. Physicians reported no differences in preparation or procedure difficulty, whereas patients reported no differences in the level of comfort or overall satisfaction between groups. When queried regarding preferences for future screening, 96% chose the conversion strategy.

CONCLUSIONS: The conversion strategy led to similar outcomes compared to traditional screening while improving compliance with colonoscopy in patients with an abnormal sigmoidoscopy. (Am J Gastroenterol 2000;95:2074–2079. © 2000 by Am. Coll. of Gastroenterology)

INTRODUCTION

Colon cancer is the third-leading cause of cancer mortality in men and the third-leading cause of cancer mortality in women within the U.S., but the second leading cause of death nationally (1). It has been estimated that the cumulative lifetime risk of developing colon cancer is approximately 5% (1).

Screening for colon cancer with annual fecal occult blood testing and/or flexible sigmoidoscopy leads to the detection of earlier stage tumors and decreases colon cancer mortality (2, 3). Colon cancer screening has recently been endorsed by a consortium of medical societies including the American Cancer Society and the American Gastroenterological Association (2). Although this consortium supported five different screening strategies, randomized, controlled trial data exist for only annual fecal occult blood testing (4–9). Case control studies suggest that flexible sigmoidoscopy every 5 years may also reduce colon cancer mortality (10). As the guideline supported five different strategies, it is clear that the optimal means of screening for colorectal cancer has yet to be determined.

At the Ann Arbor Veterans Affairs Medical Center, all patients referred for screening flexible sigmoidoscopy are prepared with a buffered oral phosphate solution. The quality of preparation achieved by this method is similar to that of the more traditional colonoscopy preparation with polyethylene glycol (PEG) (11) and, in our anecdotal experience, superior to enema preparation. In addition, all sigmoidoscopies are performed with a colonoscope. We have

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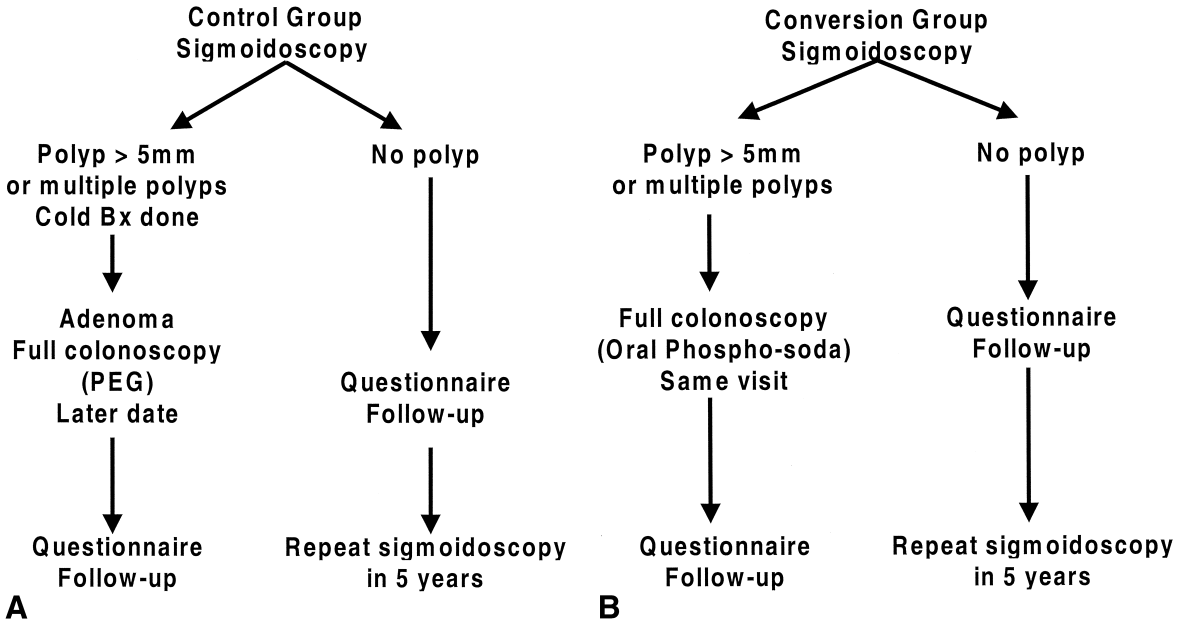

Figure 1. Management flow diagram of patients randomized to the control (*A*) or conversion (*B*) groups.

recently reported the feasibility of converting screening sigmoidoscopy to full colonoscopy in selected patients (12). This so-called "conversion" strategy allows comprehensive colorectal cancer screening in a single visit.

We performed a randomized, controlled trial to assess the feasibility as well as technical and clinical outcomes of converting sigmoidoscopy to colonoscopy in selected patients in a single visit *versus* traditional screening with sigmoidoscopy and, where appropriate, colonoscopy on a subsequent day.

MATERIALS AND METHODS

Patient Population

From November 1997 until June 1998, consecutive average-risk patients referred from the General Medicine and Gastroenterology outpatient clinics for colorectal cancer screening with sigmoidoscopy were recruited from the Department of Veteran's Affairs Medical Center (VAMC) in Ann Arbor, Michigan. This protocol was approved by the Ann Arbor VAMC ethics committee. All patients were >50 yr of age and able to understand and provide written informed consent. Patients with indications for immediate colonoscopy including gastrointestinal bleeding, weight loss, inflammatory bowel disease, family history of familial adenomatous polyposis, or colon cancer were not eligible. In addition, patients taking warfarin for any reason were not enrolled. Because we used preparation with oral phosphate solution, patients with a creatinine >3 mg/dl or a history of congestive heart failure were not eligible for the protocol.

Study Protocol

At the time sigmoidoscopy was ordered, patients were offered participation and randomized by calendar day to one of two arms, as described below. Both study arms underwent flexible sigmoidoscopy using a colonoscope. All procedures were performed by or under the supervision of a faculty member in the Division of Gastroenterology at the University of Michigan Medical Center using state-of-the-art videoendoscopy equipment (Olympus Corporation, Melville, NY). A schematic of the study protocol is outlined in Figure 1*A*, *B*.

CONTROL GROUP. The control group underwent traditional colon cancer screening with flexible sigmoidoscopy. Sigmoidoscopy preparation at the Ann Arbor VAMC consists of two doses of oral Fleets phospho-soda buffered saline laxative (CB Fleet Co, Inc, Lynchburg, VA). Patients were instructed to mix 1.5 oz of Fleets phospho-soda with 4 oz of water to be taken at 4 pm and again at 8 pm on the day before the procedure. At least three 8-oz portions of clear liquids were taken after each dose. Small amounts of clear liquids were allowed until 2 h before the procedure.

On the day of the procedure, patients underwent sigmoidoscopy to 60 cm or the level of the splenic flexure. Patients with a normal examination were told to arrange for a repeat sigmoidoscopy in 5 yr. Any polyp >5 mm in diameter or multiple diminutive polyps were cold biopsied. For both arms of the study, polyp size was assessed relative to an open standard biopsy forcep. If examination of the polyp demonstrated hyperplastic or normal histology, the patient was told to arrange for a repeat flexible sigmoidoscopy in 5 yr. If histopathological examination revealed the polyp or polyps to be adenomatous, arrangements were made for full colonoscopy at a later date. Patients were notified of the need for colonoscopy by phone and in writing. Colonoscopy was scheduled within 30 days of the sigmoidoscopy. The

number of patients who ultimately did not return for colonoscopy was recorded.

Preparation for colonoscopy consisted of oral PEG (Golytely, Braintree Laboratories, Inc, Braintree, MA), which was taken starting at 2 pm on the day before the procedure. Eight-ounce aliquots of PEG were taken every 30 min until the fecal effluent was clear or until a total of 4 L was consumed. Small amounts of clear liquids were allowed thereafter until 2 h before colonoscopy.

CONVERSION GROUP. Patients were prepared for the procedure with two doses of oral Fleets phospho-soda buffered saline laxative as described above. Before their procedure, patients provided informed consent for the conversion strategy. This informed consent included a full description of the possible need for colonoscopy. If examination to 60 cm or the splenic flexure was normal, the procedure was discontinued and the patient was instructed to schedule a follow-up sigmoidoscopy in 5 yr. If a polyp of >5 mm in diameter or multiple diminutive polyps were seen, full colonoscopy was performed during the same visit. Intravenous access (IV) was established at the time the decision was made to proceed with colonoscopy. IV sedation with diazepam and meperidine were administered as necessary to facilitate a complete examination of the colon. Any polyps identified were hot biopsied (Endostat II, Microvasive, Natick, MA) and separated into those obtained in the distal 60 cm of the colon and those taken more proximally. Polyps were evaluated by a VAMC pathologist blinded to the study.

PHYSICIAN ASSESSMENTS. After each procedure, physicians filled out a questionnaire that assessed the extent of the procedure, number and size of any polyps identified, quality of the preparation, and difficulty of the procedure. Quality of preparation was assessed using a 4-point Likert scale and difficulty of procedure was assessed using a 3-point Likert scale.

PATIENT ASSESSMENTS. After completing each endoscopic procedure, patients evaluated their experience with a questionnaire that assessed comfort and overall satisfaction. These outcomes were assessed using a 4-point Likert scale. Patients in the control group who underwent both sigmoidoscopy with the Fleets phospho-soda preparation and colonoscopy with the PEG preparation were questioned regarding which preparation they preferred. Patients' preferences were also determined for a hypothetical situation describing colorectal cancer screening as performed in the control *versus* conversion groups (Appendix 1).

Statistics

Physician and patient assessments between groups were compared using the Z-test for proportions with Yates correction for continuity. A p value of <0.05 defined a statistically significant difference between the control and conversion groups.

Table 1. Control and Conversion Group Results

	Control	Conversion	p Value
Randomized	121	114	NS
Completed study	117	105	NS
Adenomas by FS	33 (28%)*	29 (28%)	NS
Proximal adenomas by colonoscopy	8 (27%)	12 (41%)	NS
Physician assessments			
Preparation (good or excellent)	21/30 (70%)	20/29 (69%)	NS
Procedure difficulty (difficult)	2/30 (6%)	3/29 (10%)	NS
Patient assessments			
Comfort (good or excellent)	22/30 (73%)	19/29 (66%)	NS
Overall satisfaction (good or excellent)	26/30 (86%)	23/29 (79%)	NS

* Three patients in the control group did not return for colonoscopy
NS = not significant; FS = flexible sigmoidoscopy.

RESULTS

Two hundred thirty-five patients (227 men, 8 women) were randomized to the control (n = 121) or conversion (n = 114) groups. The control and conversion groups were comparable with regard to gender distribution, age, and ethnic composition. Seventy-one percent of patients were referred from the General Medicine clinic and 29% from the Gastroenterology clinic. Clinical outcomes, and physician and patient assessments are provided in Table 1.

Control Group

One patient (1%) in the control group refused to participate. During sigmoidoscopy, 33/120 (28%) in the control group had an indication for colonoscopy (Table 1). Five of 120 (4%) patients had only hyperplastic polyps during sigmoidoscopy. Of the 33 patients with at least one adenomatous polyp by sigmoidoscopy, three (9%) patients did not return for colonoscopy. Of the patients who returned for colonoscopy, 100% achieved intubation of the cecum. Eight of 30 (27%) patients who underwent colonoscopy were found to have proximal adenomatous polyps. No colonic malignancies were identified in the control group.

Conversion Group

Nine of 114 patients (8%) randomized to the conversion group did not complete the study. One patient refused enrollment after being informed of the protocol. Six patients did not bring a driver to their appointment. Two patients randomized to the conversion arm were disqualified from the study when the endoscopist on duty mistakenly performed routine screening with sigmoidoscopy alone rather than the conversion strategy. Both patients had adenomatous polyps on sigmoidoscopy, which were managed with colonoscopy on a different day.

Twenty-nine of 105 (28%) patients in the conversion group had an indication for colonoscopy (Table 1). All patients who were converted to colonoscopy achieved suc-

cessful intubation of the cecum. Twelve of 29 (41%) patients who underwent conversion to colonoscopy were found to have more proximal adenomas. Four patients (14%) in the conversion group underwent colonoscopy based upon left colon polyp/polyps ultimately found to be hyperplastic by histology. Of these four patients, two were found to have a more proximal adenomatous polyp, including one tubulovillous adenoma, by colonoscopy. No carcinomas were found in the conversion group.

Physician Assessments

The quality of colonoscopy preparation was assessed for those receiving PEG in the control group and oral Fleets phospho-soda in the conversion group. Preparation was rated as good or excellent in 21/30 (70%) of the control group *versus* 20/29 (69%) of the conversion group (NS). Two patients in each group were believed to have an inadequate preparation during colonoscopy. All four patients eventually underwent successful colonoscopy at a later date. We acknowledge that the design of our protocol made it difficult to blind endoscopists to the method of preparation used for colonoscopy. Physicians assessed difficulty of the procedure as difficult in 2/30 (6%) in the control group *versus* 3/29 (10%) in the conversion group (NS).

Patient Assessments

Patient assessments of comfort during colonoscopy between the study groups were comparable. Twenty-two of 30 (73%) patients in the control group and 19/29 (66%) in the conversion group rated their comfort level as good or excellent (NS). Overall satisfaction with the screening process was rated as good or excellent in 26/30 (86%) patients in the control group and 23/29 (79%) patients in the conversion group (NS).

Patients in the control group who were prepared for sigmoidoscopy with oral Fleets phospho-soda and colonoscopy with PEG overwhelmingly preferred the oral Fleets phospho-soda preparation (n = 30, 73% *vs* 14%, $p = 0.01$).

After their screening procedure, all patients in the control and conversion groups were asked which screening program they would prefer in the future: traditional screening with sigmoidoscopy and, where appropriate, colonoscopy on a separate day, or the conversion strategy in a single visit (Appendix 1). Despite being told that all participants would need a driver and that there was only a 1/3 chance that conversion to colonoscopy would be necessary, 96% preferred the conversion strategy (n = 222, $p = 0.001$). It is noteworthy that 40% of patients in the control group brought a driver or companion to their appointment for sigmoidoscopy.

DISCUSSION

Screening for colorectal cancer by means of fecal occult blood testing and/or sigmoidoscopy is achieving widespread acceptance. Unfortunately, fecal occult blood testing is neither sensitive nor specific for colorectal neoplasia (13). Flexible sigmoidoscopy is more specific but does not detect all patients with adenomatous polyps or malignancy (2). Of the five proposed screening strategies, four require an additional visit for colonoscopy if an abnormality is identified during the first phase of the screening process. Associated with a second visit are the need for another preparation, loss of time from work, the small but definable associated risk, and the monetary cost of an additional procedure.

Of the five recommended screening strategies, only colonoscopy every 10 yr allows for comprehensive diagnostic and therapeutic intervention in a single visit. Although few would disagree that colonoscopy is the optimal means by which to screen for colon cancer, this strategy is arguably the least commonly implemented in clinical practice. Issues delaying the widespread acceptance of screening colonoscopy include high up-front costs, limited accessibility, inadequate manpower, the lack of clinical trials to support the cost-effectiveness of such a strategy, and a lack of familiarity by primary care physicians with this strategy as a screening option.

Recognizing the limitations of the currently available methods of screening for colorectal cancer, we evaluated a novel strategy consisting of converting sigmoidoscopy to colonoscopy in those with a single polyp >5 mm in diameter or multiple diminutive polyps. Our criteria for converting sigmoidoscopy to colonoscopy were based upon several observations from the literature. The size of an adenomatous polyp has been found to be an independent risk factor for the presence of colonic malignancy. Polyps <5 mm in diameter have a $<1\%$ likelihood of containing high-grade dysplasia. In contrast, polyps >1 cm have a 21% chance of containing high-grade dysplasia (14). The size of an adenoma also predicts the likelihood of having additional adenomas or malignancy elsewhere in the colon (15). Other factors associated with colonic malignancy include villous histology and the presence of multiple polyps (14–16). Several recent studies have supported performing colonoscopy in patients found to have even diminutive distal colonic adenomas (17, 18).

By preparing patients scheduled for sigmoidoscopy with oral Fleets phospho-soda and performing screening procedures with a colonoscope, the conversion strategy proved technically feasible. The technical and clinical outcomes measured between the study groups were similar. All patients with an indication for colonoscopy underwent successful intubation of the cecum. As others have previously reported (11), we found that the quality of preparation for colonoscopy with Fleets phospho-soda was comparable to PEG. Two patients in each group were believed to be inadequately prepared for their procedure and required a follow-up colonoscopy. Although the quality of preparation was equivalent, patients who received both preparations preferred oral Fleets phospho-soda over PEG. We did not formally evaluate patient preferences for sigmoidoscopy preparation with enemas *versus* oral Fleets phospho-soda in this study. However, we did informally survey preferences of study patients who had prepared for a previous sigmoidoscopy with enemas. Overwhelmingly, patients preferred

the oral Fleets phospho-soda over enemas. In addition, patients reported no significant difference in the level of discomfort or overall satisfaction between the two study arms.

We believe that the conversion strategy improves upon traditional screening with fecal occult blood testing and/or sigmoidoscopy by providing comprehensive evaluation and intervention in a single visit. In our study, 3/33 (9%) patients in the control group with an adenoma by sigmoidoscopy did not return for colonoscopy. Other studies have reported that as many as 25% of patients with a positive fecal occult blood test or abnormal sigmoidoscopy do not comply with colonoscopy (5, 19). If a patient with an abnormal screening test fails to undergo colonoscopy and develops a colorectal cancer, the effort and resources committed to the screening enterprise will have been wasted. In addition, the conversion strategy limits colonoscopy to only those with an abnormal sigmoidoscopy. As such, it is conceivable that this strategy could limit the number of colonoscopies performed in patients with no colonic neoplasia, a point worthy of consideration in this age of limited health care resources.

There are several potential limitations associated with the widespread adoption of the conversion strategy. As the endoscopist does not know whether a patient will require sigmoidoscopy or colonoscopy before the procedure, scheduling conflicts are likely to arise with the conversion strategy. After discussions between the investigators and participating endoscopists, we have estimated that converting to colonoscopy takes approximately 15–20 min longer than a standard sigmoidoscopy alone. We acknowledge that this is only our best estimate as no formal evaluation in this regard was performed. This incremental increase in procedure time is accounted for by placement of an IV catheter for conscious sedation and the additional time required to evaluate the transverse and ascending colon. It is worth noting that a small number of patients did not require placement of an IV catheter for sedation. The feasibility of unsedated colonoscopy has recently been reported by several groups (20, 21). Certainly, for a high-volume endoscopy practice, this increase in procedure time could prove problematic. However, if an endoscopist schedules two to three sigmoidoscopies per day and approximately one-third require conversion from sigmoidoscopy to colonoscopy, the incremental increase in time should prove to be minimal. In addition, endoscopists will ultimately save time using the conversion strategy, as patients with a polyp will require one rather than two procedures. By streamlining the screening process, the conversion strategy may provide a means of dealing with the growing number of sigmoidoscopies ordered by primary care physicians.

In addition, the conversion strategy does lead to colonoscopy in a percentage of patients with only hyperplastic polyps by sigmoidoscopy. The literature would suggest that patients with distal hyperplastic polyps should not undergo colonoscopy given their minimal risk of harboring more proximal neoplastic lesions (2). In our study, 4/29 (14%) patients who underwent conversion of sigmoidoscopy to colonoscopy were ultimately found to have only hyperplastic polyps in the left colon. Interestingly, 2/4 patients were found to have at least one adenoma (including a tubulovillous adenoma) in the proximal colon.

We wondered whether the conversion strategy would be acceptable from a patient's perspective, as only one-third would receive conscious sedation yet all would require a driver for their procedure. In addition to the associated inconvenience, this could lead to indirect expenses associated with lost time from work for the driver. This proved to be a relevant concern, as 6/114 (5%) patients in the conversion arm did not bring a driver and had to be disqualified from the study. These patients were managed with sigmoidoscopy and, when indicated, colonoscopy on a different day. An interesting observation from our study was that 40% of patients in the control group brought a driver or companion to their appointment for sigmoidoscopy despite being told that this would not be necessary. When patients in both groups were asked which screening program they would prefer in the future (traditional screening with sigmoidoscopy and, where appropriate, colonoscopy on a separate day or the conversion strategy in a single visit), 96% preferred the conversion strategy ($p = 0.001$). We acknowledge that surveys such as this are subject to bias based upon the manner in which it is written and prior patient experiences. Because of these concerns, we purposely excluded any mention of the preparation for traditional screening or the conversion strategy from this survey in the hopes of limiting bias based upon a particular patient's previous experiences. In addition, only 30 control group patients found to have a polyp by sigmoidoscopy received oral phospho-soda for sigmoidoscopy and PEG preparation for colonoscopy. Eighty-five percent of the patients surveyed received only oral phospho-soda before their procedure, further limiting the chance of bias associated with the preparation.

The most difficult issue to deal with regarding the conversion strategy is that of reimbursement. This was not an issue in the VA patient population utilized for this study. However, this is certainly an issue that will need to be considered and reconciled before implementation of the conversion strategy in a non-VA patient population. In our opinion, it would be reasonable to bill for a sigmoidoscopy when procedures are not converted to colonoscopy. In cases requiring conversion of sigmoidoscopy to colonoscopy, billing for colonoscopy would seem appropriate. From a payor's perspective, the conversion strategy should be quite attractive given the significant savings associated with the elimination of charges for sigmoidoscopy in as many as one-third of patients.

In conclusion, we have shown that the conversion strategy is technically feasible and leads to similar clinical outcomes compared to traditional screening with sigmoidoscopy. From the patient's perspective, comprehensive colorectal cancer screening can be achieved in a single visit. From the physician's perspective, the conversion strategy leads to improved compliance with colonoscopy in patients

with an abnormal sigmoidoscopy. From the payor's perspective, this strategy should decrease overall costs associated with colorectal cancer screening by eliminating charges associated with sigmoidoscopy in as many as one-third of patients. For a number of practical reasons, the conversion strategy will not be appropriate for all patients to be screened for colorectal cancer. However, the conversion strategy should be considered as another viable colorectal screening option. Studies to confirm the applicability of the conversion strategy to a community-based setting are currently in progress.

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APPENDIX 1

Choices for Colon Cancer Screening

Which of the following choices of colon cancer screening would you prefer:

A. Sigmoidoscopy, which consists of passing a tube which we can view through, only a short distance into the colon without medication to sedate you. As no sedation is given, you will not need a driver for the sigmoidoscopy. If an abnormal growth is seen, it will be biopsied at the time of this procedure. If the biopsy shows a precancerous growth (1/3 chance), you will require a full examination of the colon on a *different day*. Medications to make you comfortable will be given for the full examination of the colon. Because of this, you will need a driver for your second appointment.

B. Sigmoidoscopy is performed as outlined above. If a polyp or abnormal growth is identified, an intravenous catheter will be placed and medications will be given to make you comfortable. A full examination of the colon will then be performed during the *same visit*. This will require that you bring a driver to your appointment. There is a greater chance that a full examination of the colon will be performed using this strategy.