Development and Validation of a Novel Patient Educational Booklet to Enhance Colonoscopy Preparation

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OBJECTIVES: The success of colonoscopy depends on high-quality bowel preparation by patients; yet inadequate preparation is common. We developed and tested an educational booklet to improve bowel preparation quality.

METHODS: We conducted patient cognitive interviews to identify knowledge and belief barriers to colonoscopy preparation. We used these interviews to create an educational booklet to enhance preparatory behaviors. We then prospectively randomized patients scheduled for outpatient colonoscopy at a VA Medical Center to receive usual instructions vs. the booklet before colonoscopy. Patients in both groups received standard pharmacy instructions for single-dose bowel preparation; the protocol did not specify which purgatives to prescribe. The primary outcome was preparation quality based on blinded ratings using the validated Ottawa score. We performed bivariate analyses to compare mean scores between groups using a t-test, and logistic regression to measure the booklet effect on preparation quality, adjusting for potential confounders.

RESULTS: A total of 436 patients were randomized between arms. In an intention-to-treat analysis of the primary outcome, mean Ottawa scores were superior in patients allocated to booklet vs. controls (P=0.03). An intention-to-treat analysis of the secondary outcome revealed a “good” preparation in 68 vs. 46% of booklet and control patients, respectively (P=0.054). In a per-protocol analysis limited to patients who actually received the booklet, preparation was good in 76 vs. 46% patients, respectively (P<0.00001). Regression analysis revealed that booklet receipt increased the odds of good preparation by 3.7 times (95% confidence interval = 2.3 – 5.8).

CONCLUSIONS: Provision of a novel educational booklet considerably improves preparation quality in patients receiving single-dose purgatives. The effect of the booklet on split-dose purgatives remains untested and will be evaluated in future research.

SUPPLEMENTARY MATERIAL is linked to the online version of the paper at http://www.nature.com/ajg

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INTRODUCTION

Although there are several approaches to colorectal cancer screening, colonoscopy is the only test that allows for identification and removal of polyps from the entire colon (1). Case–control studies have revealed that polypectomy is associated with a 50–90% reduction in colorectal cancer mortality vs. no polypectomy (2,3).

Successful colonoscopy requires that patients effectively evacuate their bowels through proper use of purgatives and adherence to strict dietary restrictions (4–6). However, as most recipients of...
coloscopy can attest, preparing for the procedure is often more demanding than the procedure itself. Patients must sustain a clear liquid diet for 1–2 days, consume a purgative that induces large-volume diarrhea, and often experience abdominal discomfort, bloating, and nausea. For many patients, the preparatory experience is difficult, unpleasant, and disruptive of daily routines. Thus, it is not surprising that inadequate bowel preparation is common; up to one-quarter of patients presenting for colonoscopy have an inadequate preparation, although rates vary considerably among patient populations and centers (4,5).

Inadequate bowel preparation is important because it is linked to poor outcomes and high costs. Rex et al. (7) found that patients with inadequate preparation had 45% fewer polyps detected and 5% more incomplete or aborted procedures than did those with adequate preparation. The authors further demonstrated that patients with inadequate preparation cost 22% more on average—an incremental expense largely driven by repeated procedures. In short, compared with adequately prepared patients, those with inadequate bowel preparation have more incomplete examinations, fewer polyps found, more repeat colonoscopies, and higher cost of care.

Although preparation quality is partly determined by the prescribed purgative and by the timing of administration (e.g., single dose vs. split dose), purgatives generally require that patients follow similar dietary guidelines. The effectiveness of a bowel preparation is closely linked to patient compliance with both pharmacy and dietary instructions. The reliance on patient compliance may explain why randomized trials reveal only minimal differences in efficacy between competing single-dose purgatives (8). Although there have been extensive attempts to study competing preparations (8,9), with recent emphasis on the use of split-dose preparations (10–12), relatively less attention has been paid to understanding non-pharmacological factors that may optimize bowel preparation quality. It is likely that even the most effective bowel regimens can be further enhanced through efforts to maximize patient compliance during the preparatory period.

In this study, we present the development and validation of a novel educational booklet (see Supplementary Booklet online) aimed at addressing patient knowledge, attitude, and belief barriers to colonoscopy preparation. We hypothesized that patients receiving the booklet in a randomized controlled trial of single-dose purgatives would achieve better bowel preparation quality vs. controls independent of the specific purgative prescribed.

METHODS
Study overview
This is a two-phase study conducted in patients referred for colonoscopy at the West Los Angeles VA Medical Center—a large, demographically diverse, urban, university-affiliated health-care facility. In phase I, we established the content validity of an educational booklet for colonoscopy preparation. In phase II, we conducted a randomized controlled trial to compare bowel preparation quality between outpatients receiving the booklet vs. no booklet. We obtained approval from the West Los Angeles VA Institutional Review Board for each phase of the study. The phase II trial was registered with http://ClinicalTrials.gov (# NCT00975247).

Phase I: booklet development
Content development. We conducted cognitive interviews to identify patient knowledge, attitude, and belief deficits hypothesized to drive inadequate colonoscopy preparation in a sample of 15 patients presenting for outpatient colonoscopy at the West Los Angeles VA Gastrointestinal Procedures Unit. Interviews were conducted on the day of colonoscopy before the procedure itself. This allowed us to speak with patients who had just experienced the bowel preparation process, and were informed to recall and discuss barriers and facilitators to preparation success. We prepared a standard introductory script for the interviews developed in concert with the research team and a psychometrician (R.B.). After introduction, each interview began with an open-ended probe using the “think-aloud” technique of cognitive interviewing (13,14). The interviewer then focused the respondent with a series of direct scripted probes (13). The interviews assessed patient perceptions regarding facilitators and barriers to colonoscopy, their experiences during preparation, and their knowledge, attitudes, and beliefs regarding bowel preparation and colorectal cancer screening. This process identified major domains and associated minor domains of knowledge and belief barriers to effective colonoscopy preparation.

We repeated these methods in separate interviews with providers. We interviewed 10 gastroenterologists and 5 experienced ancillary staff members, including 3 endoscopy nurses, 2 endoscopy technicians, and 1 gastroenterology physician assistant. For these interviews, we prepared a provider-specific introductory script for the interviews, along with a list of “think-aloud” probes.

Booklet construction. We developed a draft version of an educational booklet for patients preparing for colonoscopy. The booklet was designed to meet the following four criteria: (i) address the knowledge and belief barriers identified in the phase I cognitive interviews; (ii) feature high-quality visual elements to assist patients in preparing for colonoscopy; (iii) ensure that frequently asked questions are explicitly addressed; and (iv) ensure the language did not exceed a sixth grade level using the SMOG (Simple Measure of Gobbledygook) readability formula (15), as calculated by the SMOG readability calculator (16).

The booklet was based on the principles of the Health Belief Model by Rosenstock et al. (17), which describes factors contributing to a patient’s decision of whether to follow recommended health behaviors—in this instance, proper preparations for colonoscopy. The technical Appendix (online) describes in detail how the educational booklet was designed to address each component of the Health Belief Model.

Pilot testing for comprehensiveness, comprehensibility, and helpfulness. We performed a pilot study to establish patient receipt, understanding, and acceptance of the educational booklet in 60 consecutive patients scheduled for outpatient colonoscopy at the West Los Angeles VA Medical Center. Patients with dementia or
other forms of cognitive impairment were excluded. All patients received the booklet by mail 1 week before their scheduled colonoscopy. We interviewed patients in person on the morning of their procedure and transcribed responses onto a data collection form. We asked patients about their experiences with the booklet, including whether they received and read the booklet, whether they believed the booklet was clear and understandable, and whether they found the booklet interesting, informative, and helpful. Patients also completed closed-ended scoring sheets to rate each section of the draft booklet across three domains: (i) clarity and understandability, (ii) interest, and (iii) helpfulness. Assessments were rendered on a 5-point Likert scale (e.g., 1 = not helpful, 5 = extremely helpful). We calculated mean scores for each section and planned to remove any sections that achieved a mean score of 3 (somewhat helpful) or less. On the basis of qualitative and quantitative feedback, coupled with reviews from our consulting physicians and ancillary staff, we iteratively revised the booklet to its final form.

Phase II: randomized controlled study

Study procedures. In phase II, we prospectively randomized patients scheduled for outpatient colonoscopy in a 1:1 ratio to either receive usual care instructions or receive the booklet by mail 1 week before their scheduled colonoscopy. Patients were included if they had been scheduled for an outpatient, non-urgent, screening, surveillance, or diagnostic colonoscopy, were > 18 years of age, and did not have dementia or other forms of cognitive impairment. Although we did not place any restrictions on language, virtually all patients in our VA speak English at a sixth grade minimum level, as required to read the booklet. Patients in both arms received standard pharmacy directions for bowel preparation consisting of written dietary and purgative instructions. In addition, patients in both arms were scheduled for a pre-procedural colonoscopy class, which included a 10-min instructional video and a question-and-answer session with a trained health educator. All patients received a telephone number to speak with a trained nurse to answer preparation-related questions. The study did not specify which purgatives to prescribe. Physicians selected between one of three preparations according to usual institutional practices, including: (i) sodium phosphate (Fleet Phosphosoda, C.B. Fleet Company, Inc., Lynchburg, VA), (ii) magnesium citrate (3,450 ml bottles split between two doses the evening before the procedure), or (iii) 21 oral lavage of polyethylene glycol the evening before the procedure (MoviPrep, Salix Pharmaceuticals, Inc., Morrisville, NC). Patients were instructed to take their regimens the night before colonoscopy; split dosing was not used in the unit during the course of this study. The study was conducted from September through December of 2009. During the study period, there were 8 gastroenterology fellows and 11 faculty members who performed colonoscopies in the unit. Allocation was determined by a random number generator. All patients, physicians, endoscopists, nurses, and technicians were blinded to group allocations.

Study outcome measures. The primary outcome was bowel preparation quality at the time of colonoscopy. Endoscopists photographed and labeled representative segments of the right (cecum/ascending), mid (transverse/descending), and rectosigmoid colon, and research coordinators abstracted data on the volume of water infused and fluid aspirated (measured in cubic centimeters) during the procedure. These data were uploaded onto an electronic interface, programmed specifically for this study, which displayed images and fluid volumes on a standardized template. To ensure blinding of the rater, the template did not reveal any patient identification and the program accessed subjects in a random order. Two blinded rater (N.A. and B.S.) used the standardized Ottawa scoring system (18) using a point-and-click template function to measure the preparation quality in each bowel segment based on photodocumentation and data regarding amount of aspiration required during the procedure. Before the Ottawa scale yields a composite score reflecting overall fluid (0 = small, 1 = moderate, 2 = large) and cleanliness in the right, mid, and rectosigmoid colon, each rated between 0 and 4 (0 = “excellent,” 1 = “good,” 2 = “fair,” 3 = “poor,” and 4 = “inadequate”). The total score is calculated by adding the three segmental scores and the overall fluid score (range = 0–14; lower is better).

We enacted quality-control measures to maximize accuracy and minimize bias in applying the Ottawa score. Before starting assessments, the raters reviewed test cases outside the context of the study and discussed application of the Ottawa scale. The raters then jointly graded a test set of 30 cases, and achieved a correlation coefficient of 0.92 between raters. The reviewers divided the abstractions in equal halves. Within each half, there were both cases and controls. The computerized scoring interface, described above, ensured that the reviewers were unaware of who the patient was, and whether the patient was a case or a control. Thus, even if there were systematic differences between the reviewers, those differences would be equally distributed between arms.

Our secondary outcome was bowel preparation quality as measured by the principal endoscopist for each procedure using a standard global 6-point Likert scale (1 = inadequate, 2 = poor, 3 = adequate, 4 = fair, 5 = good, and 6 = excellent). The scores were entered into an electronic form immediately after the procedure using a drop-down menu interface (endoPRO operating system, Pentax Medical, Montvale, NJ). In a previous audit of 932 patients receiving colonoscopy in our institution, we found a linear and statistically significant relationship between bowel preparation quality and the number of polyps found than did patients with lower preparation quality using the Likert scale (1.6 vs. 1.1 polyps; \( P = 0.0006 \)) (19).

Sample size calculation. Although both the Ottawa and the Likert scales are widely used measures of bowel preparation quality, there are no data measuring the minimally clinically important difference on these scales. Therefore, we powered our study to achieve a half s.d. difference in mean scale scores between the groups—i.e., an effect size of 0.5. This effect size is considered to be clinically meaningful using the rules of Cohen (20). Assuming a two-tailed 5% significance level with a power of 80%, we required a mini-
Table 1. Description of patients in phase I content validation studies

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Content development cohort (n=15)</th>
<th>Content pilot testing cohort (n=60)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in years, mean±s.d.</td>
<td>63.3±9.6</td>
<td>64±7.6</td>
</tr>
<tr>
<td>Gender, % male</td>
<td>87%</td>
<td>93%</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>40%</td>
<td>51%</td>
</tr>
<tr>
<td>Black</td>
<td>27%</td>
<td>22%</td>
</tr>
<tr>
<td>Other</td>
<td>33%</td>
<td>27%</td>
</tr>
<tr>
<td>Personal history of colorectal cancer</td>
<td>7%</td>
<td>3%</td>
</tr>
<tr>
<td>Personal history of polyps</td>
<td>53%</td>
<td>44%</td>
</tr>
<tr>
<td>Prior colonoscopy</td>
<td>67%</td>
<td>68%</td>
</tr>
<tr>
<td>Family history of colorectal cancer</td>
<td>20%</td>
<td>18%</td>
</tr>
<tr>
<td>American Society of Anesthesiologists comorbidity score, mean±s.d.</td>
<td>2.0±2.8</td>
<td>2.2±2.1</td>
</tr>
<tr>
<td>Purgative received</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Magnesium citrate</td>
<td>66%</td>
<td>71%</td>
</tr>
<tr>
<td>Sodium phosphate</td>
<td>7%</td>
<td>5%</td>
</tr>
<tr>
<td>Polyethylene glycol lavage</td>
<td>17%</td>
<td>24%</td>
</tr>
<tr>
<td>Colonoscopy indication</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colorectal cancer screening</td>
<td>40%</td>
<td>34%</td>
</tr>
<tr>
<td>Colorectal cancer surveillance</td>
<td>40%</td>
<td>44%</td>
</tr>
<tr>
<td>Diagnostic indication*</td>
<td>20%</td>
<td>22%</td>
</tr>
</tbody>
</table>

*Other indications include abdominal pain, abnormal imaging, anemia, diarrhea, constipation, hematochezia, and inflammatory bowel disease.

Results

Phase I results

Content development. The technical Appendix provides a summary of qualitative feedback regarding knowledge and belief barriers for colonoscopy. The Supplementary Appendix categorized patient-reported barriers into major and minor domains using the framework of the Health Belief Model, and presents them along with patient-proposed solutions to overcome perceived barriers. Table 1 provides descriptive data of the content validation cohorts, including the content development and content pilot testing cohorts.

Booklet construction. On the basis of feedback from cognitive interviews, we created an initial draft of the educational booklet, entitled Getting Ready for Your Colonoscopy, with the subtitle One and Done: Let’s to This Once and Do it Right! Figures 1 and 2 provide sample pages from the booklet, which is printed onto double-sided glossy paper that is folded and stapled along its spine. The full booklet is provided in the Appendix. The booklet includes various sections based on the needs expressed by patients outlined in the technical Appendix, including:

- An overview that emphasizes the importance of patient participation to ensure a successful procedure, provides information about risk and consequences of colon cancer, and highlights the risk reduction afforded by screening colonoscopy.
- The use of a visual analogy, based on feedback from provider interviews, to highlight the importance of proper bowel preparation.
- Daily preparatory instructions including the sequence of steps to follow on each day preceding the colonoscopy.
- Pictures of allowable and prohibited foods, including large, clear, color photographs of foods that can and cannot be consumed during preparation for colonoscopy.
- Description of clear liquids, including instructions on how to distinguish a “clear liquid” from other liquids. The booklet introduces the “newsprent test,” suggested by nurses in our interviews, by which a clear liquid is defined by the ability to read newsprint through the liquid.
- A “guide to stool effluent” based on feedback from patients who did not know how to interpret their stool effluent—i.e., how to know when they “were done.” We created a simple visual color scale for interpreting graded effluent color and transparency; the scale is analogous to the Bristol Scale for...
Why is it Important To Get Cleaned Inside?

Your doctor must be able to see in order to do the test right. If it is dirty on the inside, your doctor may not be able to see important things, like polyps or cancer, and may even have to do the test again. That would mean you would have to start over, and nobody wants that. So help us help you make this “one and done.”

Imagine This

Think of it this way: a clean colon is like driving on a country road on a sunny day. A dirty colon is like driving in a snowstorm.

When your colon is clean, doing the colonoscopy is like driving on a country road on a sunny day. It is easy to see and to drive.

When your colon is dirty, doing the colonoscopy is like driving on a winter road in a snowstorm. It is hard to see and hard to drive.

Is My Prep Working?

How do I know when my bowel prep is complete?

The stool coming out should look like the stuff you are eating and drinking — clear, without many particles. You know you’re done when the stool coming out is yellow, light, liquid, and clear — like urine. Below is a guide to help.

<table>
<thead>
<tr>
<th>Color Description</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dark and murky</td>
<td>NOT OK</td>
</tr>
<tr>
<td>Brown and murky</td>
<td>NOT OK</td>
</tr>
<tr>
<td>Dark orange and semi-clear</td>
<td>NOT OK</td>
</tr>
<tr>
<td>Light orange and mostly clear</td>
<td>ALMOST THERE!</td>
</tr>
<tr>
<td>Yellow and clear, like urine</td>
<td>YOU'RE READY!</td>
</tr>
</tbody>
</table>

Why is it Important To Get Cleaned Inside?

Imagine This

Think of it this way: a clean colon is like driving on a country road on a sunny day. A dirty colon is like driving in a snowstorm.

When your colon is clean, doing the colonoscopy is like driving on a country road on a sunny day. It is easy to see and to drive.

When your colon is dirty, doing the colonoscopy is like driving on a winter road in a snowstorm. It is hard to see and hard to drive.

What Is a “Clear Liquid?”

As you get ready for your colonoscopy, you must only drink clear liquids. A liquid is considered “clear” if you can read something through it. Use this simple test to figure out what you can drink, and what you cannot drink.

This is pineapple juice. It’s also not clear. Don’t drink this.

This is orange juice. Orange juice is not clear because you can’t read the newspaper through it. Don’t drink this.

This is apple juice. Apple juice is clear because you can read newspaper print through it. You can drink this.

What Drinks are OK?

- Soda pop, ginger ale, and club soda
- Water and mineral water
- Black coffee (No Cream or Milk)
- CLEAR sports drink with electrolytes
- Apple juice
- Tea

Figure 1. Sample pages from booklet addressing importance of bowel preparation quality. a Provides imagery to inform patients why a complete preparation is important. b Provides instructions for how to interpret stool effluent to help ensure high-quality preparation.

Figure 2. Sample pages from booklet addressing dietary preparation for colonoscopy. a Provides a litmus test to help distinguish a “clear liquid” from other liquids. b Provides photographs of acceptable drinks.
objectively judging stool form as a clinical diagnostic aid (21); yet in this instance, the scale is designed for interpreting stool output to judge preparation quality.

- Answers to frequently asked questions identified by patients during content development.
- An interactive colonoscopy checklist of sequential steps to follow while preparing for colonoscopy.

In the content validation cohort, all sections of the draft booklet achieved helpfulness scores of 4 (quite a bit helpful) or higher for each assessment; no sections were dropped.

**Phase II results**

**Figure 3** provides the CONSORT (developed by the Consolidated Standards of Reporting Trials) diagram of patients enrolled into the randomized controlled trial. Table 2 lists the sample characteristics of patients in the control ($N=220$) and booklet ($N=216$) groups. There were no significant differences in characteristics between groups. Overall, 78% of evaluable patients randomized to the intervention arm reported receiving the booklet. The intention-to-treat analysis included all analyzable patients, including 132 in the booklet arm and 134 in the control arm. The per-protocol analyses limited the study to the 103 patients in the booklet arm who actually received the booklet.

In the intention-to-treat analysis of the primary outcome including all patients, blindly rated Ottawa scores were superior in patients allocated to the booklet arm vs. controls (4.4±2.3 vs. 5.1±2.9 (lower score = higher quality); difference = 0.7; 95% CI for difference = 0.06–1.25; $P=0.03$). When excluding subjects who never received the booklet intervention (and therefore could not benefit from its content in the first place), patients receiving the booklet had significantly improved bowel preparation quality vs. controls in per-protocol analysis (4.2±2.2 vs. 5.1±2.9; difference = 0.9; 95% CI = 0.27–1.53; $P=0.005$).

In the intention-to-treat analysis of the secondary outcome, mean bowel preparation Likert scores were higher in patients allocated to booklet vs. controls (4.0±1.0 vs. 3.8±1.3; rank-sum $P=0.04$). Preparation was rated as “good” or better in 68% of patients allocated to the booklet arm compared with 46% of controls (difference = 22%; 95% CI = 14–31%; $P=0.054$). Therefore, for every 4.5 booklets sent out, there was 1 additional “good” or better prep vs. controls. When limiting the secondary analyses to patients who received a booklet, mean bowel preparation Likert scores were higher in patients receiving the booklet compared with controls (4.2±1.1 vs. 3.8±1.3; rank-sum $P=0.006$). Preparation was rated as “good” or better in 76% of patients who received the booklet compared with 46% of controls (difference = 30%; 95% CI = 20–40%; $P<0.00001$). Therefore, for every 3.3 booklets sent out and received, there was 1 additional “good” preparation vs. controls. In multivariable regression analysis adjusting for type of purgative received, age, sex, race, and body mass index, booklet receipt increased the odds of a “good” preparation by 3.7 times (95% CI = 2.3–5.8).
DISCUSSION

Successful colonoscopy requires that patients effectively evacuate their bowels through proper use of purgatives and careful adherence to dietary restrictions (4,7). As inadequate bowel preparation is common, we created and tested an educational booklet to address patient knowledge and belief barriers to quality colonoscopy preparation. We found that addressing patient perceptions with an inexpensive and simple booklet based on the Health Belief Model (17) improved preparation quality independent of the single-dose purgative received.

This finding may help bolster efforts to effectively screen for colorectal cancer with colonoscopy. Health-care systems in the United States and abroad have committed extensive resources to colorectal cancer screening, including the development of reimbursement policies by major insurance carriers to cover screening colonoscopy, use of report cards to audit rates of colonoscopic screening, provision of patient navigator programs to enhance completion of screening colonoscopy (22), creation of provider educational workshops to raise awareness about colorectal cancer screening (23), and home mailings to combat “no shows” for scheduled procedures (24), among other strategies. Yet despite efforts to raise awareness about screening and improve access to colonoscopy, relatively less attention has been paid to the quality of colonoscopies themselves outside the context of clinical trials or formal quality-improvement initiatives. Poor quality preparations undermine the benefits of colonoscopy and erode the cost-effectiveness of policies designed to enhance access to colonoscopic screening. The booklet tested in this study may help, in a small way, to bridge this gap by improving bowel preparation quality and by maximizing the yield of colonoscopy.

Our study is limited because we do not yet know the impact of the booklet on colonoscopy quality indicators, resource utilization, or outcomes. Future research will measure the booklet’s impact on indicators, such as cecal intubation rates, polyp detection rates, insertion time, and withdrawal times. We will also evaluate whether the upfront printing cost of the booklet (roughly $3.00 per unit for printing costs) is offset by downstream savings engendered by a lower need for repeated colonoscopies or missed lesions. It is also unknown whether the booklet can improve cancer detection and related mortality.

The study is further limited by its unique population of overwhelmingly male, English-speaking, US Veterans; the booklet should also be studied in other populations, and should be evaluated in non-English languages. Nonetheless, as the booklet was efficacious in our older and comorbid population with an inordinately high prevalence of poor preparation quality (only 46% achieved a “good” or better preparation in the control arm), it may also be efficacious in younger and less morbid groups. However, populations with very high rates of excellent preparation may derive less benefit from the booklet because of diminishing returns.

Another study limitation is that split-dose preparations (i.e., half night before, high morning of procedure) were not used in our study. Data indicate that split-dose preparations improve bowel preparation quality compared with standard single-dose preparations (10–12). However, split dosing is not always feasible in our population as many patients must travel long distances to receive colonoscopy and are unable to continue bowel preparation the morning of a procedure. Moreover, despite its proven efficacy, split-dose preparation inevitably leaves some patients with less-than-perfect prep quality; it is likely that the booklet might also enhance split-dosing regimens just as it seems to enhance standard dosing. However, future research should evaluate the impact of the booklet on split-dose regimens, and should further evaluate how the booklet affects right- vs. left-sided preparation quality. In the meantime, we have prepared an updated version of the booklet for patients prescribed a split-dose preparation (Appendix), and are planning to test the efficacy of the modified booklet in patients receiving split-dose instructions.

Our study has several strengths. First, we conducted a series of cognitive interviews to maximize content coverage in lieu of relying on preconceived ideas. Second, we iteratively pilot tested the booklet with a second cohort of 60 patients before finalizing the content. Third, we worked with a psychometrician and health

Table 2. Description of patients in the phase II randomized controlled trial

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Phase II: randomized controlled trial</th>
<th>Control group (n=220)</th>
<th>Booklet group (n=216)</th>
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<tbody>
<tr>
<td>Age in years, mean±s.d.</td>
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<td>60.0±12.3</td>
<td>60.0±10.7</td>
</tr>
<tr>
<td>Gender, % male</td>
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<td>98%</td>
<td>96%</td>
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<tr>
<td>Race</td>
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<tr>
<td>White</td>
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<td>38%</td>
<td>42%</td>
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<td>Black</td>
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<td>34%</td>
<td>28%</td>
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<tr>
<td>Other</td>
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<td>28%</td>
<td>30%</td>
</tr>
<tr>
<td>Body mass index, mean±s.d.</td>
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<td>29.3±6.8</td>
<td>28.8±6.4</td>
</tr>
<tr>
<td>Prior abdominal surgery</td>
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<td>18%</td>
<td>16%</td>
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<tr>
<td>Personal history of colorectal cancer</td>
<td></td>
<td>5%</td>
<td>2%</td>
</tr>
<tr>
<td>Personal history of polyps</td>
<td></td>
<td>28%</td>
<td>25%</td>
</tr>
<tr>
<td>Previous colonoscopy</td>
<td></td>
<td>37%</td>
<td>38%</td>
</tr>
<tr>
<td>American Society of Anesthesiologists comorbidity score, mean±s.d.</td>
<td></td>
<td>2.3±2.1</td>
<td>2.3±2.4</td>
</tr>
<tr>
<td>Family history of colorectal cancer</td>
<td></td>
<td>6%</td>
<td>7%</td>
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<td>Purgative received</td>
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<tr>
<td>Magnesium citrate</td>
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<td>73%</td>
<td>76%</td>
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<tr>
<td>Sodium phosphate</td>
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<td>2%</td>
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<tr>
<td>Polylethylene glycol lavage</td>
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<td>25%</td>
<td>22%</td>
</tr>
<tr>
<td>Colorectal cancer screening</td>
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<td>23%</td>
<td>26%</td>
</tr>
<tr>
<td>Colorectal cancer surveillance</td>
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<td>14%</td>
<td>11%</td>
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<tr>
<td>Diagnostic indication*</td>
<td></td>
<td>63%</td>
<td>63%</td>
</tr>
</tbody>
</table>

*Other indications include abdominal pain, abnormal imaging, anemia, diarrhea, constipation, hematochezia, and inflammatory bowel disease.
literacy expert to optimize the visual appeal and comprehensibility of the booklet. Finally, we included a blinded and objective assessment of bowel preparation quality in our randomized trial.

In conclusion, provision of a novel educational booklet improves blindly rated bowel preparation quality in patients undergoing colonoscopy following traditional single-dose purgatives. The impact of the booklet on colonoscopy outcomes and resource utilization remains unknown. However, because bowel preparation quality is a predictor of polyp yield, it is possible that the booklet may ultimately improve polyp detection and reduce cancer incidence through improving preparation quality. Future research will measure the impact of the booklet on polyp yield, cancer incidence, and attendant resource utilization, and will further evaluate its potential benefits in patients receiving split-dose preparations.

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CONFLICT OF INTEREST
Guarantor of the article: Brennan M.R. Spiegel, MD, MSHS.
Specific author contributions: Study design, study implementation, data collection, data analysis, data interpretation, manuscript preparation, and manuscript approval: Brennan M.R. Spiegel; study implementation and data collection: Jennifer Talley; study design, data interpretation, and manuscript approval: Paul Shekelle; study implementation, data collection, data interpretation, and manuscript approval: Nikhil Agarwal; data collection and manuscript approval: Bradley Snyder; study design, data analysis, and manuscript approval: Roger Bolus; study implementation and data collection: Nicole Kurzbard; study design, data interpretation, and manuscript approval: Michael Chan; study implementation, data collection, and manuscript approval: Andrew Ho; study implementation, data collection, and manuscript approval: Marc Kaneshiro; study design, data analysis, and manuscript approval: Kristina Cordasco; study design, study implementation, data interpretation, and manuscript approval: Hartley Cohen.
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Disclaimer
The opinions and assertions contained herein are the sole views of the authors and are not to be construed as official or as reflecting the views of the Department of Veteran Affairs. Clinical Trial Registration: http://Clinicaltrials.gov (# NCT00975247).

Study Highlights

**WHAT IS CURRENT KNOWLEDGE**
- The success of colonoscopy depends on high-quality bowel preparation by patients; yet inadequate preparation is common.
- Although there have been extensive attempts to study competing bowel preparation regimens, relatively less attention has been paid to understanding non-pharmacological factors that may optimize bowel preparation quality.
- It is likely that even the most effective bowel regimens can be further enhanced through efforts to maximize patient compliance during the preparatory period.

**WHAT IS NEW HERE**
- In this study, we present the development and validation of a novel educational booklet aimed at addressing patient knowledge, attitude, and belief barriers to colonoscopy preparation.
- We found that patients receiving the booklet in a randomized controlled trial of single-dose purgatives achieved better bowel preparation quality vs. controls independent of the specific purgative prescribed.
- The effect of the booklet on split-dose purgatives remains untested and will be evaluated in future research.

REFERENCES


