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QUANTIFICATION OF ADEQUATE BOWEL PREPARATION FOR SCREENING OR SURVEILLANCE COLONOSCOPY IN MEN

Brian T. Clark, M.D.[1], **Petr Protiva, M.D.**[1,2], **Anil Nagar, M.D.**[1,2], **Avlin Imaeda, M.D.**[1,2], **Maria M. Ciarleglio, Ph.D.**[3], **Yanhong Deng, M.P.H.**[3], and **Loren Laine, M.D.**[1,2]

[1]Yale School of Medicine, New Haven, CT

[2]VA Connecticut Healthcare System, West Haven, CT

[3]Yale Center for Analytical Sciences, Yale School of Public Health, New Haven, CT, USA

Abstract

Background & Aims—Bowel preparation is defined as adequate if it is sufficient for identification of polyps >5mm. However, adequate preparation has not been quantified. We performed a prospective observational study to provide an objective definition of adequate preparation, based on the Boston Bowel Prep Scale (BBPS, 0–3 points for each of 3 colon segments).

Methods—We collected data from 438 men who underwent screening or surveillance colonoscopies and then repeat colonoscopy examinations within 60 days by a different blinded endoscopist (1161 colon segments total) at the West Haven Veterans Affairs Medical Center from January, 2014 to February, 2015. Missed polyps were defined as those detected on the second examination of patients with the best possible bowel preparation (colon segment BBPS score of 3) on the second examination. The primary outcome was proportion of colon segments with adenomas >5mm that were missed in the first examination. We postulated that the miss rate was non-inferior for segments with BBPS scores of 2 vs those with BBPS scores of 3 (non-inferiority margin, <5%). Our secondary hypotheses were that miss rates were higher in segments with BBPS scores of 1 vs those with scores of 3 or of 2.

Results—The adjusted proportion with missed adenomas >5mm was non-inferior for segments with BBPS scores of 2 (5.2%) vs those with BBPS scores of 3 (5.6%) (a difference of −0.4%; 95%

Correspondence: Loren Laine, MD, Section of Digestive Diseases P.O. Box 208019, New Haven, CT 06520-8019, loren.laine@yale.edu.

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confidence interval [CI], −2.9% to 2.2%). Of study subjects, 347 (79.2%) had BBPS scores ≥2 in all segments on initial examination. A higher proportion of segments with BBPS scores of 1 had missed adenomas >5mm (15.9%) than segments with BBPS scores of 3 (5.6%) (a difference of 10.3%; 95% CI, 2.7%–17.9%) or 2 (5.2%) (a difference of 10.7%; 95% CI, 3.2–18.1%). Screening and surveillance intervals based solely on the findings at the first examination would have been incorrect for 16.3% of patients with BBPS scores of 3 in all segments, for 15.3% with BBPS scores of 2 or 3 in all segments, and 43.5% of patients with a BBPS score of 1 in 1 or more segments.

Conclusions—Patients with BBPS scores of 2 or 3 for all colon segments have adequate bowel preparation for detection of adenomas >5 mm and should return for screening or surveillance colonoscopy at standard guideline-recommended intervals. Colon segments with a BBPS score of 1 have a significantly higher rate of missed adenomas >5mm than segments with scores of 2 or 3. This finding supports a recommendation for early repeat colonoscopic evaluation in patients with a BBPS score of 0 or 1 in any colon segment.

Keywords

colorectal neoplasms; endoscopy; polyp; colon cancer

INTRODUCTION

Colonoscopy is an important tool for colorectal cancer screening and surveillance, markedly reducing colorectal cancer incidence and mortality.[1–4] Furthermore, colonoscopic screening and surveillance occupies the largest proportion of most gastroenterologists' workload, with estimates of more than 7.7 million lower endoscopic screening or surveillance procedures performed annually in the U.S. at a cost of nearly 13 billion dollars.[5] After performance of screening or surveillance colonoscopy, an important responsibility of the endoscopist is to recommend the time interval at which repeat colonoscopy should be done. Adherence to guideline-recommended time intervals is now considered a practice quality indicator[6], important in ensuring optimal care. Current and past guidelines state that determination of the appropriate interval for repeat colonoscopy assumes "adequate" bowel preparation. If bowel preparation is not adequate, guidelines recommend early repeat colonoscopy to adequately examine the colon and determine the appropriate interval for repeat colonoscopy.

Guidelines define adequate bowel preparation as the ability of the endoscopist to identify polyps greater than 5mm.[7, 8] However, no study has determined a quantifiable measure of the level of bowel prep quality at which visualization of polyps >5mm is unacceptably decreased.[9, 10] Lack of information on what truly defines "adequacy" is a major flaw in the current practice of colonoscopic screening and surveillance: it results in significant uncertainty and variability in practice among gastroenterologists[9, 11] and may have important clinical and economic implications due to overutilization (unnecessarily shortened intervals resulting in increased cost and risk of complications) and underutilization (inappropriately long intervals resulting in increased cancer risk).[11–16]

The aim of our study was to use a quantitative, validated and reproducible score (the Boston Bowel Preparation Scale[10, 17] (BBPS)) to define a level of prep quality at which missing

neoplastic polyps >5mm was not unacceptably increased and therefore allow for appropriate determination of which patients need early repeat colonoscopy and which patients do not.

Our primary hypothesis was that a BBPS colon-segment score of 2 (on scale of 0–3) was non-inferior to a score of 3 for the primary outcome measure of missing adenomas >5mm. Our secondary hypotheses were that a BBPS segment score of 1 was inferior to scores of both 2 and 3 for the same primary endpoint. We also aimed to describe the impact of bowel prep quality on rates of other missed lesions, such as advanced adenomas, diminutive adenomas, and sessile-serrated polyps, and on intervals for repeat screening/surveillance colonoscopy.

Because randomization of patients to different levels of bowel prep quality is not possible, we performed a prospective, observational study using a repeat examination performed by a second blinded endosocopist to determine the adenoma miss rates for different levels of bowel prep quality. The miss rate was defined by the presence of additional lesions identified on the second exam when the second exam had the best possible prep score (BBPS colon-segment score=3). Furthermore, because a control was needed to account for lesions that are missed even with the best prep quality, we used colon segments with the best possible prep score on both the first and second exam as a control group.

MATERIALS AND METHODS

Study Population

All men, age 50–75 years, undergoing colonoscopy for an indication of screening or surveillance at the West Haven Veterans Affairs Medical Center were invited to participate. Exclusion criteria included the following: prior resection of any portion of the colon or rectum, active anti-thrombotic therapy preventing polypectomy, American Society of Anesthesiologists Class 3 or higher (excluded due to significantly higher risk of serious adverse events and the small proportion of screening/surveillance colonoscopies performed in this group[18]), familial polyposis syndrome, inflammatory bowel disease, inability to achieve cecal intubation, a total BBPS of 0 (solid stool covering all segments of colon), or inability to completely remove a polyp (e.g., polyp too large). Eligible patients were recruited before their scheduled procedure and informed consent was obtained.

This study was approved by the institutional review board of the West Haven Veterans Affairs Medical Center in November 2013 with continuing review approval in November 2014.

Study Design

Eligible patients who consented to participation underwent their planned colonoscopy by one of the four study endoscopists (attending gastroenterologists on the faculty at an academic institution) assigned to perform procedures that day per normal standard of care. Fellow participation was allowed, with direct supervision by the attending study endoscopist throughout the entire procedure. In these cases, determination of all outcomes (e.g., prep quality, polyp size) was made solely by the attending study endoscopist. The colonoscope was passed to the cecum, the colonoscope was withdrawn with washing and aspiration of

colonic contents as needed to optimize visualization of colonic mucosa, the mucosa was carefully examined, and all polyps that were identified were removed, as would be done for any other screening or surveillance examination. Tiny polyps (≤3 mm) in the rectum and distal sigmoid colon determined to have characteristics of hyperplastic polyps could be left at the discretion of the endoscopist.[19] All procedures were performed using Olympus (Tokyo, Japan) EVIS Exera II high-definition colonoscopes. Narrow band imaging could be used at the discretion of the endoscopist. Each polyp was submitted for histological assessment per usual standard of care.

After completing the colonoscopy the endoscopist rated the adequacy of bowel preparation using the BBPS[10, 17], scoring left colon, transverse colon, and right colon segments as 0 (mucosa not seen due to solid stool or thick liquid stool that cannot be cleared), 1 (areas of the colon segment not well seen due to staining, residual stool and/or opaque liquid), 2 (minor amount of residual staining, small fragments of stool and/or opaque liquid but mucosa seen well), or 3 (entire mucosa of the colon segment seen well). Right colon was defined as cecum to ascending colon, transverse as hepatic flexure to splenic flexure, and left as descending colon to rectum per BBPS definitions.[17] The endoscopist also recorded whether they would recommend early repeat colonoscopy or colonoscopy at the standard recommended screening/surveillance interval based on polyp size, number, and histology. All four study endoscopists underwent formal training in assessment of bowel preparation adequacy using the BBPS prior to participating in the trial, and both their competency and inter-rater reliability were assessed prior to study commencement. The formal training for all study endoscopists included the following: watching the 8-minute instructional video at www.cori.org/bbps, completing and passing the knowledge assessment from the same training website, and completing a 12-question colonoscopic video quiz created with clips of known BBPS score from the www.cori.org website. Following the video quiz, a group educational session to review BBPS and each endoscopists' answers to this quiz was held. In the 2 months prior to the study BBPS was used routinely by the study endoscopists and BBPS replaced Aronchick as the required scale to document bowel prep quality for all colonoscopy reports.

If a patient had a total BBPS score of 8–9 (segment scores of 3/3/3 or 3/3/2), then the colonoscope was not removed and a different study endoscopist, who was blinded to the polyp findings and prep scores from the first examination, immediately performed a second examination of the colon. In order to minimize the burden on the endoscopy center, we limited enrollment of same-day repeat examinations to no more than two in one day. All other patients had repeat colonoscopy by a different study endoscopist, who was blinded to the findings from the first examination, either the next day or at a later date. The endoscopist performing the second examination was not randomly assigned but was determined by availability on the day of the procedure to ensure no delay; two or three study endoscopists were assigned to perform endoscopies each day. In order to be included in the study, patients requiring repeat colonoscopy on a later date had to call for their appointment within one month and complete their repeat examination within two months after the first colonoscopy.

Because patients were invited to participate on the day they presented for their colonoscopy, a specific study-mandated bowel-preparation regimen was not employed. The prep regimens

prescribed in our unit consisted of a total of 4 liters of PEG-electrolyte solution (GoLYTELY, Braintree Laboratories, Braintree, MA) or of a total of 255g of PEG3350 (Breckenridge Pharmaceutical, Berlin, CT) in 3 liters plus adjunctive magnesium citrate (296 ml) at 4 p.m. on the afternoon before the procedure. Split-dose regimens were used, with half of the PEG-electrolyte solution or two-thirds of the PEG3350 solution prescribed to be taken the evening before the procedure and half of the PEG-electrolyte solution or one-third of the PEG3350 solution prescribed to be taken 4–6 hours before the scheduled procedure. Whether the prep was taken uniformly in such fashion is not known. Patients returning for repeat exam the following day were instructed to continue on a clear liquid diet and repeat the bowel preparation once again. Patients who returned for repeat exam at a later date were prescribed a more extended regimen (e.g., 2-day preparation consisting of 2 consecutive days of one of the split-dose regimens described above). In addition, patients were instructed to be on a clear liquid diet beginning the morning of the day their bowel preparation began.

Data collection

The following characteristics of all polyps detected on the first and second examination were prospectively recorded: location (right, transverse, or left colon), size (using visual comparison with forceps of known dimension and/or visualization after retrieval), morphology (pedunculated, sessile), method of removal (forceps, cold snare, snare cautery), and histological characteristics. Other data prospectively collected included age, indication (screening, surveillance), endoscopist, and withdrawal time. Withdrawal time was the total time for withdrawal from cecum to anus and included all interventions or other delays, including irrigation, aspiration, biopsies, and polypectomies.

Outcome Definitions

Segments were only included in the analysis if a BBPS score of 3 was achieved on the second examination. Polyps detected on this second examination were defined as missed polyps. The primary outcome measure was the proportion of colon segments with an adenoma >5mm missed. Secondary outcome measures included the proportion of colon segments with the following missed lesions: all polyps >5mm, adenomas ≤5 mm (diminutive), advanced adenomas, and sessile-serrated polyps. An advanced adenoma was defined by any of the following features: size ≥1cm, high-grade dysplasia, villous architecture, or carcinoma. For the primary analysis, the miss rates were defined within each polyp category as the number of segments with at least one lesion identified on second examination divided by the total number of segments. We also evaluated the per-patient miss rates for patients who had all 3 colon-segment scores of 3 (total BBPS=9) on their second examination, defined as the number of patients with missed lesions (identified on the second colonoscopy) divided by the total number of patients with BBPS=9 on the second examination. Finally, using current guideline recommendations[8] for timing of repeat colonoscopy in a patient with adequate prep (based on number, size, and histology of polyps identified), we determined the recommended interval based on findings at the first exam and the recommended interval based on the findings of the combined exams.

Statistical analyses

Inter-rater reliability among study endosopists was assessed by measuring joint probability of agreement as well as the Cohen's kappa statistic for each BBPS segment score, using endoscopists' answers from a quiz using 12 colonoscopic video clips of known BBPS score (https://www.cori.org/bbps).

Miss rates for each of the outcome measures were calculated for each level of prep quality at the initial examination as measured by the BBPS colon-segment scores (1, 2, and 3). Colon segments were excluded from analysis if BBPS score on the second examination was <3. Per-patient miss rates were also stratified by the initial examination prep scores, using the total (entire colon) BBPS scores (categories of 1–4, 5, 6, 7–8 and 9) and using a dichotomous exposure of having all three colon segments with a BBPS score of 2 or 3 vs. having at least one colon segment BBPS=1. The categories of total BBPS score were chosen based on the relative frequency of the different levels of preparation in patients undergoing colonoscopy (with more patients in the intermediate scores)[17] and the likely importance of evaluating the intermediate scores with greater precision than the very poor and very good ends of the preparation spectrum. We also determined the proportion of patients who would have a change in screening/surveillance interval based on the findings of the combined exams vs. the findings of the initial exam for the different BBPS scores and the difference in these proportions for the prep quality strata described above.

Because no literature was available to provide estimates of miss rates specifically related to the bowel preparation categories being used in our study, we performed an interim analysis from our first 300 patients to more accurately adjust our initial assumptions regarding appropriate sample size calculations. Based on our interim analysis results, we assumed a miss rate of 5.2% for BBPS segment scores of 3, and we assumed a miss rate of 20% worse for BBPS=2. We defined our non-inferiority margin as 50% of the lower limit of the 95% CI of the difference in miss rates of adenomas >5mm between a BBPS segment score of 3 and the worst possible prep (the latter defined as the >5mm adenoma detection rate (ADR) for segments with BBPS score of 3 with the assumption all of these adenomas would be missed with the worse possible prep). This non-inferiority margin was calculated to be 5%. Eight clinical gastroenterologists who perform colonoscopy were then asked if they would consider one bowel prep quality score non-inferior to (not unacceptably worse than) another bowel prep quality score for detecting adenomas >5mm if the difference in miss rate was ≤5%; all accepted this margin. Documenting that a BBPS segment score of 2 has a miss rate that is non-inferior to the BBPS segment score of 3 with a non-inferiority margin of 5%, a one-sided alpha of 0.05, and a power of 80% required 441 colonic segments per study group. We planned an outcome-driven enrollment to provide 450 colonic segments with BBPS score of 2 and 450 colonic segments with BBPS of 3 at initial exam.

To account for the correlation among the three colon segments within same subject, adjusted analyses were performed using a generalized estimating equations model, adjusting for age, colonoscopy indication, colon segment, total number of polyps removed during first examination, and endoscopist performing the procedure. The interaction of segments by group was entered to assess the heterogeneity effect of group difference among the three different colon segments. Per-patient analyses were performed by using a generalized linear

model, adjusting for age, indication, total number of polyps removed during first colonoscopy, and endoscopist. Adjustment through multivariate modeling is particularly important in this non-randomized setting to control for commonly known confounders. The resulting adjusted estimate of the difference in the miss rates between BBPS segment scores was used to test the primary hypothesis of non-inferiority between BBPS scores of 2 and 3 and the secondary hypotheses of superiority for BBPS scores of 3 vs. 1 and 2 vs. 1. For other data (e.g. changes in screening/surveillance intervals), differences in proportions are presented with 95% CIs of the difference.

RESULTS

From January 2014 to February 2015, 815 patients were recruited to participate in this study. 438 patients completed both colonoscopic examinations within the specified time-frame, ultimately allowing for inclusion of 1161 colon segments for analysis (Figure 1). Of these 1161 segments, 593 had an initial BBPS of 3, 462 had an initial BBPS of 2, and 106 had an initial BBPS of 1. Selected characteristics are shown in Table 1.

Participating Endoscopists

For the competency examination two endoscopists scored 12 out of 12 correct and two endoscopists scored 11 of 12 correct. The joint probability of agreement for each of the BBPS scores were 100% (BBPS = 0), 91.2% (BBPS = 1), 93.8% (BBPS = 2) and 100% (BBPS = 3). The Cohen's kappa statistics were good to excellent: 1.0 for BBPS 0 and BBPS 3, 0.81 for BBPS 2, and 0.80 for BBPS 1. The 4 endoscopists performed between 148 (16.9%) and 262 (29.9%) of the 876 total combined examinations, (76 (17.4%) to 147 (33.6%) of the initial examinations and 72 (16.4%) to 136 (31.1%) of the second examinations) in the 438 included patients. Fellows participated, with direct attending supervision throughout the entire procedure, in 347 (39.6%) of the colonoscopic exams; 231 (66.6%) were third-year fellows.

Primary Outcome: Miss Rates of Adenomas >5mm

Table 2 shows the miss rates for each segment score. Adjusted proportions of missed adenoma >5mm were 5.6% for BBPS segment scores of 3, 5.2% for scores of 2, and 15.9% for scores of 1. A BBPS segment score of 2 was associated with a 0.4% absolute reduction in missing adenomas >5mm compared to a BBPS segment score of 3, with a 95% CI of the difference ranging from −2.9% to 2.2%. Thus, a BBPS segment score of 2 was non-inferior to a BBPS segment score of 3 for the primary endpoint. On the other hand, a BBPS segment score of 1 was inferior to BBPS segment scores of 3 and of 2, resulting in an absolute increase in missing adenomas >5mm of 10.3% (2.7% to 17.9%) and 10.7% (3.2% to 18.1%), respectively.

Testing for interaction to asses for heterogeneity among the three different colon segments (right, transverse, and left) demonstrated no significant difference in the primary outcome measure (p=0.16).

Secondary outcomes

Similar to the primary outcome measure, a BBPS segment score of 2 was non-inferior to a score of 3 for the outcome of missed polyps >5mm, with an absolute reduction of 0.3% (−3.3% to 2.8%) (Table 2). A BBPS segment score of 1 demonstrated a large absolute increase in the proportion of segments with polyps >5mm missed of 16.4% (7.6% to 25.2%) and 16.7% (8.0% to 25.3%) compared to segment scores of BBPS 3 and BBPS 2, respectively.

A BBPS segment score of 2 demonstrated an absolute increase in the proportion of segments with a diminutive adenoma missed of 7.9% (3.5% to 12.2%) compared to a segment score of 3, while a BBPS segment score of 1 showed a higher rate of missing diminutive adenomas when compared to BBPS segment scores of 3 or of 2, with differences of 23.8% (20.7% to 27.0%) and 15.6% (12.6% to 18.5%), respectively.

A BBPS segment score of 2 demonstrated a similar rate of missed advanced adenomas compared to a score of 3 (difference=−0.1%, −1.6% to 1.1%). A BBPS segment score of 1 had an absolute increase in missed advanced adenomas of 4.4% (−0.5 to 9.9%) compared to a BBPS segment score of 3 and 4.3% (−0.7 to 9.7%) compared to a score of 2. The rates of missed sessile serrated polyps were low for all BBPS segment scores, ranging from 2.5% with BBPS of 1 to 1.5% with a score of 3. Given low event rates for advanced adenomas and sessile serrated polyps, adjustment with some covariates could not be performed (Tables 2 and 3).

Per-patient analyses

Of the 438 patients that completed both a first and second examination, 340 patients achieved a total BBPS of 9 on the second examination, allowing for analysis of per-patient outcomes. The proportion of patients with an adenoma >5mm missed ranged from 10.5% for a total BBPS=9 to 38.9% for total BBPS= 1–4 (Table 3). In patients with all segments BBPS=2 or 3, 15.1% had an adenoma >5mm missed compared to 28.8% of patients with at least one segment BBPS=1 (difference=13.7%, 0.8% to 26.6%). The proportion of patients with a missed advanced adenoma ranged from 2.2% in patients with BBPS=9 to 9.7% in patients with BBPS=1–4. Compared to patients with all segments BBPS=2–3, patients with at least one segment BBPS=1 demonstrated a 2.7% (−4.9% to 10.3%) absolute increase in missed advanced adenomas and a 6.5% (−2.8% to 15.8%) absolute increase in missed sessile serrated polyps.

Change in surveillance intervals based on second examination with optimal prep score

Table 4 shows how the screening/surveillance interval based on the findings at the first examination changed when the findings from a second examination with the very best prep score (total BBPS=9) were also considered. The proportion with a change in surveillance interval for patients with the very best prep (total BBPS=9) at initial examination was 16.3%, similar to the proportions with a change in interval with total BBPS scores of 6 and 7–8 at initial examination (16.3% and 14.8% respectively). Importantly, when patients had all colonic segments with BBPS=2–3, only 15.3% had a change in surveillance interval, while 43.5% of patients with at least one segment of BBPS=1 had a change in interval

(difference=28.2%, 13.3 to 43.1%). Nearly 30% of patients with at least one segment of BBPS=1 would have been incorrectly placed in the “low-risk adenoma” surveillance category (5–10-year follow-up) rather than the “high-risk adenoma” group (3-year follow-up) as compared to 7.2% of patients with all segments of BBPS=2–3 and 9.3% of those with all segments of BBPS=3.

DISCUSSION

The effectiveness of screening and surveillance colonoscopy hinges upon adequate visualization and removal of neoplastic polyps, which is greatly dependent on the quality of bowel preparation. Our study defines the level of bowel prep quality at which an endoscopist’s ability to visualize adenomas >5mm is not unacceptably decreased, using a quantitative, reproducible and valid scoring system, and therefore defines what level of prep quality should be considered adequate. Based on the results of this study, one should consider a colon segment with a BBPS score 2 or greater adequate for screening purposes.

Patients with any colon segment score <2 should return for an early repeat colonoscopy while those with all segment scores ≥2 can return at standard, guideline-recommended intervals. The results of this study have the potential to improve the value of colorectal cancer screening and surveillance by standardizing the definition of adequate bowel prep.

Determining whether a patient’s prep quality is “adequate” is one of the most common and important decisions made by a gastroenterologists each day. More than two-thirds of all colonoscopies performed annually in the U.S. are done for the indication of either screening or surveillance.[5] Studies suggest that between 25–30% of these procedures are being performed on patients at inappropriately shortened intervals and that uncertainty in what constitutes “adequate” visualization is a major factor influencing the use of shortened intervals by practicing endosocopists.[9, 11, 13–15] Therefore defining “adequate” visualization in a practical way could yield not only reductions in cost of up to 3–4 billion dollars annually, but also reductions in complications by minimizing the overuse of unnecessary procedures. Additional benefits can be obtained by accurately identifying patients with truly “inadequate” prep who would benefit from early repeat colonoscopy and potentially reduce interval colorectal cancer rates.

It is obvious that patients with completely unprepped colons and solid stool throughout the colon do not allow for adequate visualization. Likewise, patients with the most optimally-prepped colons, completely cleared of all stool and debris, allow for adequate visualization and do not require early repeat colonoscopic examination. However bowel prep quality is a spectrum, and uncertainty abounds among practicing gastroenterologists as to what to do with the many patients who fall somewhere in the middle. This uncertainty has resulted in significant variability in practice. In a survey-based study, recommended surveillance intervals were relatively uniform for patients with “impeccable” prep quality, while surveillance intervals were shortened and variability increased for the patients with “intermediate-quality” prep.[9] In a study of 2516 average-risk screening colonoscopies with no polyps found, variability in screening interval recommendations was common for those with intermediate-subpotimal scores of total BBPS=3–5.[20] Another study demonstrated that

in clinical practice, 75% of patients with “fair” prep were given surveillance recommendations inconsistent with guidelines, 18 times more often than patients with excellent/good prep, highlighting the discordance between guidelines and practice created by this uncertainty.[11]

Although research has been done to develop standardized, quantitative, reproducible measures of bowel preparation quality,[10, 17, 21, 22] current literature regarding what should be considered “adequate” prep quality is limited.[7, 20] Calderwood et al demonstrated that total BBPS scores correlated with endoscopists’ perception of bowel prep adequacy for visualizing polyps >5mm.[10] But endoscopists in this study did not know if they missed a polyp >5mm or not--assessments of adequacy were based on opinion alone. A systematic review of studies using tandem colonoscopy, in which the colonoscope is re-inserted for a second examination immediately after completion of the first colonoscopy, did reveal substantial miss rates even when physicians consider the prep to be “adequate”: 26% for polyps <5mm, 13% for polyps 5–9mm, and 2% for polyps ≥1cm.[23] One repeat colonoscopy study demonstrated that poor/inadequate prep was associated with a higher likelihood of missing adenomas and advanced adenomas, but was not adequately powered to address the most relevant group–those with fair prep–and did not evaluate missed lesions >5mm, the current definition of “adequate.”[24] While other observational studies have also demonstrated that inadequate or poor prep is associated with a decrease in ADR or polyp detection rate,[25–31] none have identified a threshold level of prep quality at which the ability of the endoscopist to visualize neoplastic polyps >5mm is hindered.

Our study demonstrates that a BBPS segment score of 2 had miss rates not higher than the best prep score (BBPS=3) for adenomas >5mm, polyps>5mm and advanced adenomas. A BBPS segment score of 2 was however associated with a higher rate of missing diminutive (≤5mm) adenomas compared to a segment score of 3 (18.2 vs. 10.4%). Nevertheless, even when accounting for all missed adenomas, the proportion of patients with a change in surveillance interval was similar in patients with the very best prep (all segments BBPS=3) and those with intermediate levels of prep (all segments BBPS=2 or 3): 16.3% vs. 15.3%. Taken together our findings suggest that while a BBPS segment score of 2 may result in a higher rate of missing diminutive polyps, this prep quality is associated with comparable visualization of clinically significant polyps--including adenomas >5mm and advanced adenomas--and is therefore adequate for screening/surveillance purposes.

Our study also demonstrates that a BBPS segment score of 1 is inferior to BBPS segment scores of 2 or 3. Nearly 1 in 6 colon segments with a BBPS score of 1 had an adenoma >5mm missed on initial examination compared to 1 in 20 segments with scores of either 2 or 3. A BBPS segment score of 1 had consistently higher rates of missed lesions across our primary and secondary outcomes as compared to scores of 2–3. Furthermore, over 40% of patients with at least one BBPS segment score of 1 had a change in their recommended surveillance interval based on polyps missed, a rate nearly 3-times that of patients with all segments of BBPS=2 or 3. Of these patients, 10.9% had a drastic change from 10-year interval to 3-year interval recommended, compared to just 1.4% of patients with all segments BBPS=2 or 3. Thus, our findings support the classification of a BBPS segment score of 1 as inadequate and requiring early repeat colonoscopic examination.

Our study has several inherent limitations. The study population consisted of male veterans, which may limit generalizability. Given the significantly different prevalence of adenomas between men and women, adenoma miss rates must be evaluated separately in men and women (just as threshold ADRs are different for men and women). The low proportion of women among the veteran population undergoing screening and surveillance colonoscopy made achieving the necessary sample size to properly assess this question in women impractical. However, no data to our knowledge indicate that the impact of prep quality on visualization differs between men and women. Also, while colon segments are explicitly defined for the BBPS, the variability among endoscopists in reliably identifying the boundaries of these segments is unknown and potentially could have led to misclassification. In addition, specific bowel regimens given to patients were not recorded as part of this study since the purpose was to assess the impact of prep quality on adenoma detection. The efficacy of different bowel preps was not a study objective and no inferences about efficacy of different bowel preps may be ascertained from this study.

The endoscopists participating in this study were four university faculty attending gastroenterologists. Their withdrawal times were longer than typical in standard clinical practice, potentially limiting generalizability to the practice of many endoscopists. The longer withdrawal times were presumably at least in part due to the greater time spent in washing and examining patients in a study setting and fellow involvement in some cases. In addition, our withdrawal times included time for all interventions and delays. The high incidence of polyps in our population, leading to extra time frequently spent performing polypectomies, also contributed to the longer withdrawal times. The ADRs were higher in our population than would be expected in some other populations, probably due to the high adenoma prevalence in male veterans as well as our longer withdrawal times. Consequently the absolute differences in adenoma miss rates and in screening/surveillance intervals between bowel prep quality categories seen in our population likely would be smaller in a population that has a lower adenoma prevalence.

In conclusion, patients in whom all colon-segment BBPS scores are 2 or 3 have adequate bowel preparation quality for detection of adenomas >5 mm and should return for screening or surveillance colonoscopy at standard guideline-recommended intervals. In contrast, colon segments with a BBPS score of 1 have a significantly higher rate of missed adenomas >5mm than segments with scores of 2 or 3. This finding supports a recommendation for early repeat colonoscopic evaluation in patients with a BBPS score of 0 or 1 in any colon segment. Implementation of these recommendations may help optimize the value-based delivery of colonoscopy for colorectal cancer screening and surveillance and assist in standardizing practice among gastroenterologists.

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Abbreviations

BBPS	Boston Bowel Preparation Scale

ADR Adenoma detection rate

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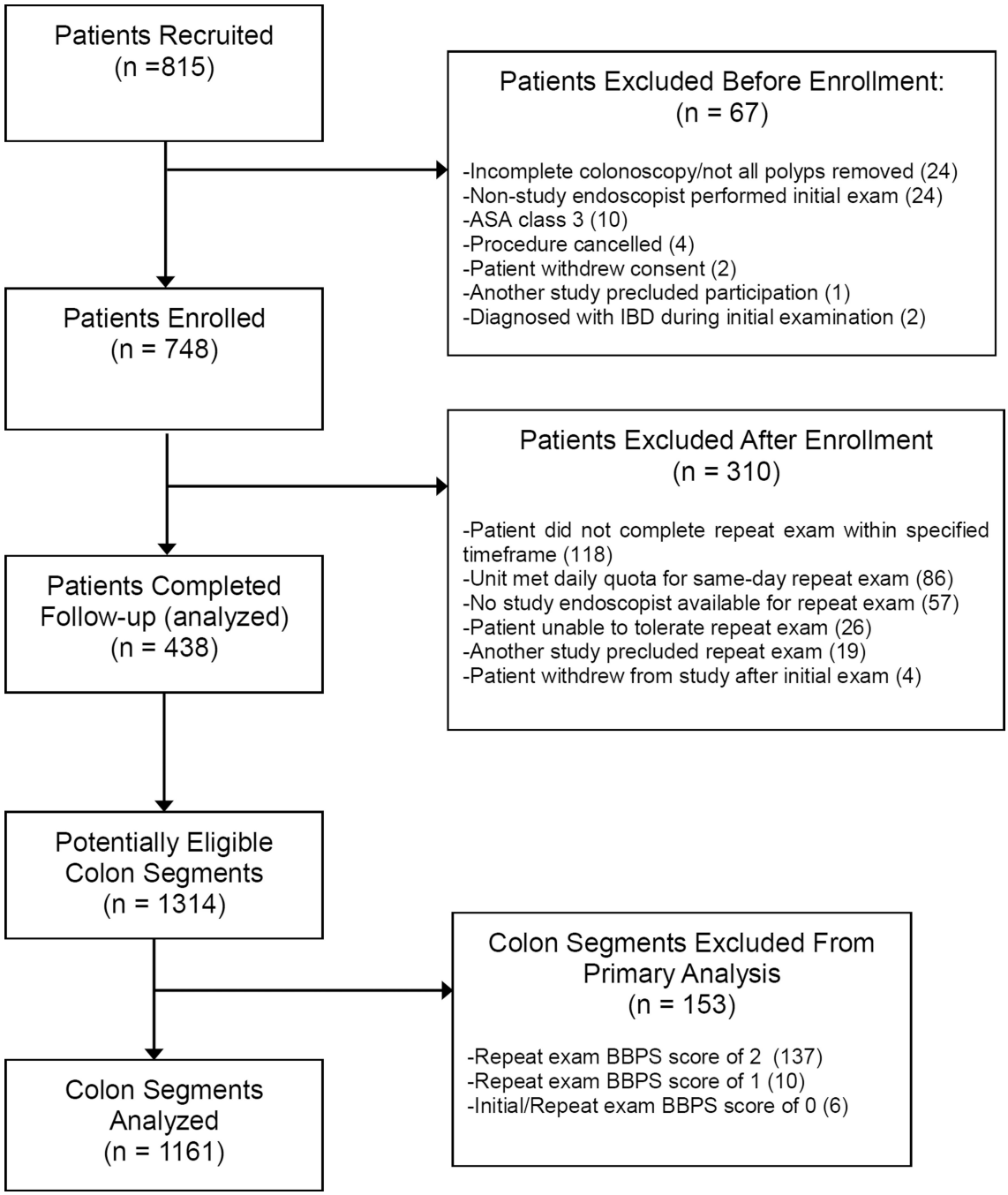

Figure 1.

Study Flow.

ASA, American Society of Anesthesiologists; IBD, inflammatory bowel disease; BBPS, Boston Bowel Preparation Scale.

Table 1

Selected characteristics

No. of Patients	438
Age mean (IQR)	63 (58–67) yrs
Indication	
Screening	229 (52.3%)
Surveillance	209 (47.7%)
Adenoma detection rate, mean ± S.E.	68.9 ± 2.2%
Withdrawal time, min. mean ± S.E.	23.8 ± 0.5 min
Early repeat colonoscopy recommended	126 (28.8%)
Total Boston Bowel Preparation Scale on initial exam	
1 to 4	55 (12.6%)
5	35 (8.0%)
6	66 (15.1%)
7 to 8	238 (54.3%)
9	44 (10.0%)
All colon segments BBPS 2 or 3	347 (79.2%)
Individual endoscopist adenoma detection rate	
Endoscopist A	57/76 (75.0%)
Endoscopist B	65/95 (68.4%)
Endoscopist C	81/120 (67.5%)
Endoscopist D	99/147 (67.3%)

Table 2

Miss Rates and Differences in Miss Rates for Different Levels of Prep Quality Based on BBPS Segment Scores

	Raw data	Adjusted analyses		Adjusted analyses
Segment score	**Miss rate**	**Miss rate**	**Comparisons of segment scores**	**Difference in miss rates (95% CI)**
Adenoma > 5 mm (Primary Outcome Measure)				
BBPS=1	16/106 (15.1%)	15.9%	BBPS 2 vs. 3	−0.4% (−2.9, 2.2%)
BBPS=2	24/462 (5.2%)	5.2%	BBPS 1 vs. 3	10.3% (2.7, 17.9%)
BBPS=3	34/593 (5.7%)	5.6%	BBPS 1 vs. 2	10.7% (3.2, 18.1%)
Polyp > 5 mm				
BBPS=1	25/106 (23.6%)	23.5%	BBPS 2 vs. 3	−0.3% (−3.3, 2.8%)
BBPS=2	32/462 (6.9%)	6.8%	BBPS 1 vs. 3	16.4% (7.6, 25.2%)
BBPS=3	42/593 (7.1%)	7.1%	BBPS 1 vs. 2	16.7% (8.0, 25.3%)
Diminutive Adenoma (≤ 5 mm)				
BBPS=1	36/106 (34.0%)	34.2%	BBPS 2 vs. 3	7.9% (3.5, 12.2%)
BBPS=2	85/462 (18.4%)	18.2%	BBPS 1 vs. 3	23.8% (14.8, 32.8%)
BBPS=3	60/593 (10.1%)	10.4%	BBPS 1 vs. 2	15.9% (6.9, 24.9%)
Advanced Adenoma				
BBPS=1	6/106 (5.7%)	6.0%	BBPS 2 vs. 3	−0.1% (−1.6, 1.1%)*
BBPS=2	6/462 (1.3%)	1.2%	BBPS 1 vs. 3	4.3% (−0.7, 9.7%)*
BBPS=3	8/593 (1.3%)	1.5%	BBPS 1 vs. 2	4.4% (−0.4, 9.9%)*
Sessile Serrated Polyp				
BBPS=1	3/106 (2.8%)	2.5%	BBPS 2 vs. 3	0.4% (−0.8, 1.5%)*
BBPS=2	9/462 (1.9%)	1.9%	BBPS 1 vs. 3	1.0% (−2.1, 4.1%)*
BBPS=3	8/593 (1.3%)	1.5%	BBPS 1 vs. 2	0.6% (−2.6, 3.8%)*

BBPS=Boston Bowel Preparation Scale

*Due to small event rates, unable to adjust for any covariates in advanced adenoma group and able to adjust only for segment in sessile serrated polyp group

Table 3

Per-Patient Miss Rates and Differences in Miss Rates for Different Levels of Prep Quality Based on Total BBPS Scores

	Raw data	Adjusted analyses		Adjusted analyses
Total BBPS Score	**Miss rate**	**Miss rate**	**Comparisons of scores**	**Difference in miss rates (95% CI)**
Adenoma > 5 mm (Primary Outcome Measure)				
BBPS=9	5/43 (11.6%)	10.5%		
BBPS=7–8	29/203 (14.3%)	14.6%	BBPS 7–8 vs. 9	4.0% (−6.3, 14.4%)
BBPS=6	11/49 (22.5%)	21.9%	BBPS 6 vs. 9	11.4% (−3.1, 25.8%)
BBPS=5	5/23 (21.7%)	20.3%	BBPS 5 vs. 9	9.8% (−8.0, 27.7%)
BBPS=1–4	8/22 (36.4%)	38.9%	BBPS 1–4 vs. 9	28.4% (6.6, 50.1%)
All segments BBPS=2–3	45/294 (15.3%)	15.1%	Any segment BBPS=1 vs. all segments BBPS=2–3	13.7% (0.8, 26.6%)
Any segment BBPS=1	13/46 (28.3%)	28.8%		
Polyp > 5 mm				
BBPS=9	5/43 (11.6%)	11.5%		
BBPS=7–8	36/203 (17.7%)	18.1%	BBPS 7–8 vs. 9	6.5% (−3.9, 17.0%)
BBPS=6	13/49 (26.5%)	24.4%	BBPS 6 vs. 9	12.8% (−2.9, 28.6%)
BBPS=5	7/23 (30.4%)	28.9%	BBPS 5 vs. 9	17.4% (−3.3, 38.1%)
BBPS=1–4	10/22 (45.5%)	46.4%	BBPS 1–4 vs. 9	34.8% (12.9, 56.7%)
All segments BBPS=2–3	54/294 (18.4%)	17.7%	Any segment BBPS=1 vs. all segments BBPS=2–3	18.4% (5.1, 31.7%)
Any segment BBPS=1	17/46 (37.0%)	36.1%		
Diminutive Adenoma (≤ 5 mm)				
BBPS=9	13/43 (30.2%)	34.2%		
BBPS=7–8	57/203 (28.1%)	27.2%	BBPS 7–8 vs. 9	−7.1% (−2.1, 6.7%)
BBPS=6	28/49 (57.1%)	55.5%	BBPS 6 vs. 9	21.3% (2.7, 40.0%)
BBPS=5	11/23 (47.8%)	44.7%	BBPS 5 vs. 9	10.5% (−13.0, 34.0%)
BBPS=1–4	17/22 (77.3%)	75.0%	BBPS 1–4 vs. 9	40.8% (20.5, 61.1%)
All segments BBPS=2–3	98/294 (33.3%)	32.7%	Any segment BBPS=1 vs. all segments BBPS=2–3	25.3% (11.6, 38.9%)
Any segment BBPS=1	28/46 (60.9%)	58.0%		
Advanced Adenoma				
BBPS=9	1/43 (2.3%)	2.2%		
BBPS=7–8	8/203 (3.9%)	4.1%	BBPS 7–8 vs. 9	1.9% (−3.6, 7.4%)*
BBPS=6	3/49 (6.1%)	5.7%	BBPS 6 vs. 9	3.5% (−4.7, 11.7%)*
BBPS=5	1/23 (4.4%)	4.0%	BBPS 5 vs. 9	1.8% (−7.7, 11.4%)*
BBPS=1–4	2/22 (9.1%)	9.7%	BBPS 1–4 vs. 9	7.5% (−5.7, 20.7%)*

	Raw data	Adjusted analyses		Adjusted analyses
Total BBPS Score	**Miss rate**	**Miss rate**	**Comparisons of scores**	**Difference in miss rates (95% CI)**
All segments BBPS=2–3	12/294 (4.1%)	4.0%	Any segment BBPS=1 vs. all segments BBPS=2–3	2.7% (−4.9, 10.3%)*
Any segment BBPS=1	3/46 (6.5%)	6.7%		
Sessile Serrated Polyp				
BBPS=9	3/43 (7.0%)	7.3%		
BBPS=7–8	9/203 (4.4%)	4.6%	BBPS 7–8 vs. 9	−2.7% (−10.8, 5.3%)*
BBPS=6	1/49 (2.0%)	1.1%	BBPS 6 vs. 9	−6.2% (−16.6, 4.2%)*
BBPS=5	1/23 (4.4%)	4.0%	BBPS 5 vs. 9	−3.3% (−15.1, 8.4%)*
BBPS=1–4	4/22 (18.2%)	18.2%	BBPS 1–4 vs. 9	10.9% (−7.0, 28.8%)*
All segments BBPS=2–3	13/294 (4.4%)	4.4%	Any segment BBPS=1 vs. all segments BBPS=2–3	6.5% (−2.8, 15.8%)*
Any segment BBPS=1	5/46 (10.9%)	10.9%		

BBPS=Boston Bowel Preparation Scale

*Due to small event rates, only able to adjust for age in advanced adenoma and sessile serrated polyp groups

Table. 4

Patients with a Change in the Screening/Surveillance Interval Based on Findings of the First Exam Only to the Interval Based on Findings of the First and Second Exams Combined (Including Only Patients with BBPS of 9 on Second Exam)

Total BBPS score	Proportion with a change in interval	Difference in proportion of patients with change in interval (95% CI)	Proportion with specific changes in interval			
			10 to 5 years	10 to 3 years	5 to 3 years	3 to 1* year
BBPS=9	7/43 (16.3%)	Ref	3/43 (7.0%)	1/43 (2.3%)	3/43 (7.0%)	0/43 (0.0%)
BBPS=7–8	0/203 (14.8%)	−1.5% (−13.6%, 10.6%)	15/203 (7.4%)	2/203 (1.0%)	9/203 (4.4%)	4/203 (2.0%)
BBPS=6	8/49 (16.3%)	0.1% (−15.1%, 15.2%)	1/49 (2.0%)	1/49 (2.0%)	5/49 (10.2%)	1/49 (2.0%)
BBPS=5	9/23 (39.1%)	22.9% (0.1%, 45.6%)	2/23 (8.7%)	2/23 (8.7%)	3/23 (13.0%)	2/23 (8.7%)
BBPS=1–4	11/22 (50.0%)	33.7% (10.0%, 57.3%)	3/22 (13.6%)	3/22 (13.6%)	5/22 (22.7%)	0/22 (0.0%)
All segments BBPS=2–3	45/294 (15.3%)	Ref	19/294 (6.5%)	4/294 (1.4%)	17/294 (5.8%)	5/294 (1.7%)
Any segment BBPS=1	20/46 (43.5%)	28.2% (13.3%, 43.1%)	5/46 (10.9%)	5/46 (10.9%)	8/46 (17.4%)	2/46 (4.3%)

BBPS=Boston Bowel Preparation Scale

*1-year interval recommended if >10 adenomas