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Patient Tolerability of Bowel Preparation is Associated with Polyp Detection Rate During Colonoscopy

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ABSTRACT

Background & Aims: A number of factors have been identified that influence the yield of screening colonoscopy. The perceived tolerability of bowel preparation has not been studied as a predictor of quality outcomes in colonoscopy. We aimed to characterize the association between patient-perceived tolerability of bowel preparation and polyp detection during colonoscopy.

Methods: We performed a cross-sectional cohort study of 413 consecutive adult patients presenting for outpatient colonoscopy at two outpatient endoscopy centers at our institution. We developed a standardized questionnaire to assess the patient's experience with bowel preparation. Bowel preparation quality was measured using the validated Ottawa scale and colonoscopic findings were recorded for each patient. The primary outcome was polyp detection and the secondary outcome was the quality of bowel preparation.

Results: Patient-reported clarity of effluent during bowel preparation correlated poorly with Ottawa score during colonoscopy, κ=0.15. Female gender was an independent risk factor for a poorly tolerated bowel prep (OR 3.93, 95% CI 2.30 – 6.72, p<0.001). Report of a poorly tolerated bowel prep was independently associated with the primary outcome, polyp detection (OR 0.39, 95% CI 0.18 – 0.84, p=0.02) and also with the secondary outcome, lower quality bowel preparation (OR 2.39, 95% CI 1.17 – 4.9, p=0.02).

Conclusions: A patient-perceived negative experience with bowel preparation independently predicted both a lower quality bowel preparation and a lower rate of polyp of detection. Assessment of the tolerability of bowel preparation before colonoscopy may be a clinically useful predictor of quality outcomes during colonoscopy.

Key words: bowel preparation – colonoscopy – polyp – patient perception.

INTRODUCTION

Colorectal cancer (CRC) remains the second leading cause of cancer death in the United States, but recent studies have shown a decrease in CRC mortality that is attributable to screening colonoscopy with polypectomy [1-3]. A patient's risk of polyp detection during colonoscopy is influenced by age, gender and family history of polyps or CRC, but also by the quality of bowel preparation [4-7]. Factors that affect the quality of bowel preparation may also influence the polyp detection rate (PDR) and thus may play a role in further reducing CRC mortality.

Patient assessment of bowel preparation has been shown to correlate poorly with physician assessment of bowel preparation during colonoscopy [8-9]. Tolerability of bowel preparation, including physical side effects, taste and overall acceptability, has been reported as an outcome in studies measuring the effectiveness of bowel preparation [10]. Tolerability of bowel preparation has not been considered as an independent predictor of quality outcomes in colonoscopy, including prep quality and PDR. The aim of this study was to determine whether patient-reported tolerability of bowel preparation plays a predictive role in the achievement of these outcome measures.

MATERIAL AND METHODS

Subject Selection

After obtaining approval from our center's institutional review board, we conducted a cross-sectional survey at two outpatient endoscopy centers affiliated with California Pacific Medical Center in San Francisco, CA. Between March and

August 2011, consecutive patients referred for outpatient colonoscopy were offered participation in the study on the day of colonoscopy by nursing staff not directly involved in the procedure. Patients who agreed to participate in the study provided informed consent prior to enrollment. Neither the referring physician nor the patient was aware of the study until after the bowel preparation was completed.

Colonoscopy

All patients were given verbal and written instructions to consume only clear liquids the day before colonoscopy, to drink half of the bowel preparation the night before colonoscopy and to complete the remainder of the preparation the morning of the procedure, aiming to finish 4 hours before the procedure was scheduled to begin. An oral sulfate solution (SUPREP®, Braintree Laboratories) was used by 92.9% of patients. Three gastroenterologists, each of whom had performed more than 10,000 colonoscopies, performed 54% (MV), 42% (RS) and 4% (KB) of the procedures. Colonoscopies performed by endoscopists MV and RS were preceded by administration of conscious sedation with a combination of midazolam and either fentanyl or meperidine. Diphenhydramine was administered as a 1-time dose of 50 mg for patient discomfort at the discretion of the endoscopist. All 18 procedures performed by endoscopist KB were performed using anesthesiologist-administered propofol. All procedures were performed using CF-160AL or CFH-180AL colonoscopes (Olympus Corporation). Biopsy specimens were submitted to our center's central processing unit and interpreted by one of the 9 staff pathologists.

Data Collection

We used an 18-item questionnaire designed specifically for this study to collect data about the type and timing of bowel preparation, patient perception of bowel preparation and other information related to each patient's history (Supplementary Table I). The endoscopists were aware of each patient's participation in the study but were blinded to the responses recorded in the questionnaire. Endoscopists were trained to use the Ottawa bowel preparation scale and report their assessment on a standardized form (Supplementary Table II) (http:www.jgld.ro/2014/2/supplementary-table-holt.doc). The Ottawa scale, which facilitates independent assessment of each colonic segment, has been extensively validated and is frequently used in bowel preparation studies (Table I) [11-13]

Prior to the beginning of the study, each endoscopist completed a pre-test (6 images of the colon with varying-quality bowel preparation representing 2 sample colonoscopies), a training module (21 independent colonoscopic images) and a post-test (18 images representing 6 sample colonoscopies). Endoscopists were asked to assign an Ottawa score to each colonoscopic image. Inter-observer and intra-observer correlation for the participating endoscopists' scoring of post-test images was high (interclass correlation coefficient 0.94, $p<0.0001$; Cronbach's alpha 0.94, $p=0.01$). For all polyps, the colonic segment of origin, size, morphology and total number were recorded in the procedure report. All procedure reports and pathology reports were reviewed retrospectively by 2 of the investigators (EH and HM) and recorded in the study database. Polyp detection rate was defined as the total number of patients with a polyp divided by the total number of patients in the designated group. An "excellent" or "good" bowel prep was defined by an Ottawa score ≤4.

Table I. The Ottawa scale for assessment of bowel preparation quality

Quality of Bowel Preparation	Score
Segmental Score (right, mid and rectogsigmoid segments evaluated separately)	
Perfect; >95% of mucosa visible without suctioning	0
Small amount of clear liquid; no suctioning	1
Small amount of semi-solid; requires suctioning	2
Semi-solid; requires washing and suctioning	3
Inadequate exam; requires re-prep	4
Fluid Score (all colonic segments considered together)	
Minimal; no suctioning	0
Moderate; some suctioning	1
Large: significant suctioning	2

Total score (0-14) is obtained by adding the scores for each of 3 colonic segments with fluid score.

Statistical Analysis

The primary outcome was polyp detection and the secondary outcome was quality of bowel preparation. For each outcome the tolerability of bowel preparation was evaluated as an independent variable. Comparisons between groups were performed in univariate analysis using analysis of variance (ANOVA), Fisher's exact test or Student's *t*- test. Separate logistic regression analyses were performed to determine which independent variables predicted the primary outcome, polyp detection, and the secondary outcome, quality of bowel preparation. Odds ratios were mutually adjusted for all variables reported in each analysis. Statistical significance was defined as $p<0.05$. All analyses were performed using SPSS (version 19; IBM, Armonk, NY) or STATA SE (version 12; StatCorp, College Station, TX).

RESULTS

Patients

Four hundred thirteen participants completed all parts of the questionnaire. Seventeen additional patients agreed to participate but did not complete the questionnaire and were not included in the analysis. The mean age was 60 ± 10 years, the mean BMI 26.0 ± 5.9 kg/m^2 and 49.2% of the patients were male; 66.8% of patients self-identified as Caucasian, 19.9% as Asian, 5.4% as Hispanic and 5.3% as African American; 75.5% of patients had a colonoscopy for screening or surveillance for polyps or cancer and 62.5% had previously had a colonoscopy. Additional clinical and demographic characteristics of patients are listed in Table II.

Tolerability of Bowel Preparation

21.1% of patients rated their experience with bowel preparation as good, 54.7% as tolerable, 20.3% as unpleasant and 3.9% as intolerable. A good or tolerable rating was associated with a lower rate of self-reported noncompliance

Table II. Characteristics of patients in the study, divided into those who perceived bowel preparation as more tolerable vs. less tolerable

Variable	All Patients (n=413)	Prep "Good" or "Tolerable (n=313)	Prep "Unpleasant" or "Intolerable" (n=100)	p-value[1]
Age	60.0 ± 10	60.5 ± 10	59.8 ± 11	0.55
Female gender	209 (50.6%)	134 (42.8%)	75 (75%)	<0.001
BMI	26.0 ± 5.9	26.1 ± 5	25.8 ± 6	0.69
Diabetes	30 (7.3%)	23 (7.3%)	7 (7.0%)	0.91
History of abdominal surgery	119 (28.8%)	83 (26.5%)	36 (36.0%)	0.046
Prior colonoscopy <10 years	209 (50.6%)	160 (52.8%)	49 (50.1%)	0.76
Prior colonoscopy <5 years	65 (15.7%)	49 (16.2%)	16 (16.7%)	0.91
Indication for colonoscopy				0.39
Screening	215 (52.1%)	159 (50.8%)	56 (56.0%)	
History of adenoma	118 (28.6%)	94 (30.0%)	24 (24.0%)	
Rectal bleeding	44 (10.7%)	31 (9.9%)	13 (13.0%)	
Other[2]	36 (8.5%)	29 (9.3%)	7 (7.0%)	
Split bowel preparation	406 (98.3%)	309 (98.7%)	97 (97.0%)	0.25
Prep end-colonoscopy start, hours	4.5 ± 1.5	4.6 ± 1.5	4.4 ± 1.4	0.17
Morning start time (vs. afternoon)	239 (57.9%)	185 (59.4%)	54 (54.0 %)	0.34
1st in queue (vs. all other positions)	104 (25.2%)	76 (24.3%)	28 (28.0%)	0.46
Withdrawal time, minutes[3]	11.27 ± 8	11.4 ± 8	10.9 ± 8	0.59
Use of diphenydramine	11 (2.7%)	5 (1.6%)	6 (6.1%)	0.03
Insertion time, minutes	6 ± 3	6 ± 3	7 ± 4	0.04
Ottawa score, total	2.4 ± 1.9	2.22 ± 1.69	2.95 ± 2.46	0.001
Ottawa score, right colon	0.56 ± 0.76	0.5 ± 0.69	0.75 ± 0.95	0.004
Ottawa score, mid colon	0.48 ± 0.65	0.41 ± 0.57	0.68 ± 0.82	0.0003
Ottawa score, rectosigmoid	0.52 ± 0.68	0.48 ± 0.63	0.64 ± 0.82	0.04
Ottawa fluid score	0.84 ± 0.49	0.83 ± 0.47	0.88 ± 0.54	0.35
Cecal intubation	409 (99.0%)	311 (99.6%)	98 (98%)	0.99
Polyp detection rate	233 (56.4%)	187 (59.7%)	46 (46%)	0.01
Polyp detection, right colon	121 (29.3%)	101 (32.2%)	20 (20%)	0.03
Polyp detection, mid colon	76 (18.2\4%)	65 (20.8%)	11 (11%)	0.04
Polyp detection, rectosigmoid	143 (34.6%)	117 (37.4%)	26 (26%)	0.0498
Adenoma detection rate	179 (43.3%)	144 (46.0%)	35 (35.0%)	0.05

Data are expressed as means ± SD or total number (percentage). [1]P-values characterize differences between "good" or "tolerable" and "unpleasant" or "intolerable"; [2]Other reasons for colonoscopy included abdominal pain, anemia, inflammatory bowel disease, diarrhea and removal of previously marked large polyp; [3]Withdrawal time includes time spent performing polypectomy.

(consumption of <95% of the prep) compared to an unpleasant or intolerable rating, 2.9% vs. 17%, p<0.001. A more tolerable prep rating was not associated with a lower rate of self-reported solid material in the effluent compared to a less favorable rating, 2.6% vs. 6%, p=0.11.

A patient-reported unpleasant or intolerable experience with bowel preparation was significantly associated with female gender, prior abdominal surgery, longer colonoscopic insertion time, use of diphenhydramine during colonoscopy, lower quality bowel prep and lower polyp detection rate (Table II). In a multivariate analysis, female gender independently increased the risk of an unpleasant or intolerable experience with bowel preparation by a factor of 3.93 (95% CI 2.30 – 6.72, p<0.001).

Primary Outcome: Polyp Detection

56.4% of patients had at least one polyp, 29.3% had at least one right-sided polyp and 42.6% had at least one adenoma. The PDR was higher in males than in females (65.2% vs. 48.1%, p<0.001). Polyp morphology was more frequently flat (vs. sessile or pedunculated) in the right colon compared to the rectosigmoid: 16.5% vs. 6.4%, p=0.007. Polyp histology was more frequently adenomatous (including those with villous or serrated features) in the right colon compared to the rectosigmoid: 91% vs. 77.5%, p=0.02.

Polyp detection was significantly lower in patients who reported a less tolerable experience with bowel preparation (Table II). Among those who rated the bowel preparation good or tolerable the PDR was 59.7%, including and 32.3% in the right colon, 20.8% in the mid colon and 37.4% in the rectosigmoid. Among those who rated the bowel preparation unpleasant or intolerable the PDR was 46%, including 20% in the right colon, 11% in the mid colon and 26% in the rectosigmoid (p<0.05 for each segmental comparison).

In a multivariate analysis age, gender, Ottawa score, duration of colonoscopy, withdrawal time and patient perception of the tolerability of bowel preparation were independently associated with detection of polyps (Table III).

Table III. Variables independently associated with the detection of polyps during colonoscopy

	OR	95% CI	p-value
Age >65 years	2.97	1.46 – 6.07	0.003
Male gender	1.81	1.09 – 3	0.02
Ottawa score >4	0.33	0.16 – 0.7	0.004
*Duration of colonoscopy >20 minutes	4.99	1.99 – 12.54	0.001
*Longer withdrawal time	1.11	1.01 – 1.23	0.03
Prep "unpleasant/intolerable" vs. "good/pleasant"	0.39	0.18 – 0.84	0.02

*Not adjusted for time taken for polypectomy.
Variables included in the analysis: age, gender, history of prior colonoscopy, type of bowel prep, Ottawa score, race, BMI, diabetes, duration of colonoscopy, duration of bowel prep, morning vs. afternoon colonoscopy, interval between end of prep and beginning of colonoscopy, indication for colonoscopy (screening vs. other), withdrawal time, queue position, patient-reported tolerability. Odds ratios were mutually adjusted for all variables reported in each analysis.

Patient-reported perception of bowel preparation as unpleasant or intolerable vs. good or tolerable was independently and inversely associated with polyp detection (OR 0.39, 95% CI 0.18 – 0.84, p=0.017).

Secondary Outcome: Quality of Bowel Preparation

The mean endoscopist-reported Ottawa score was 2.4 ± 1.9 and 87.4% of patients had an excellent or good prep (Ottawa score ≤4). 96.6% of patients self-reported clear or yellow/brown effluent without any solid particles at the end of bowel preparation. However, in a correlation analysis, agreement between patient-reported clarity of effluent and endoscopist-reported Ottawa score was poor, with Cohen's kappa (κ) = 0.15 (p=0.001).

In a multivariate analysis, independent predictors of lower quality bowel preparation at colonoscopy (Ottawa score >4) included an interval between the beginning of the prep and the first bowel movement of >2 hours, an interval between the end of bowel prep and the start of colonoscopy of >6 hours, self-reported effluent containing any solid material and self-reported unpleasant or intolerable experience with bowel preparation (Table IV). Patient-reported perception of bowel preparation as unpleasant or intolerable vs. good or tolerable was independently associated with a lower quality bowel preparation (OR 2.39, 95% CI 1.17 – 4.9, p=0.017).

Table IV. Variables independently associated with lower quality bowel preparation (Ottawa score >4) at colonoscopy

	OR	95% CI	p-value
>2 hour interval from beginning of prep to first BM	3.8	1.58 – 9.13	0.003
>6 hour interval from end of prep to beginning of colonoscopy	2.8	1.25 – 6.27	0.01
Self-reported solid material in effluent at the end of bowel prep	6.29	1.79 – 22.13	0.004
Prep "unpleasant/intolerable" vs. "good/pleasant"	2.39	1.17 – 4.9	0.02

Variables included in the analysis: age, gender, obesity (BMI >30 kg/m^2), interval from start of bowel prep to first bowel movement, interval from end of bowel prep to beginning of colonoscopy, morning vs. afternoon colonoscopy, patient-reported adherence (completeness) of bowel prep, patient reported clarity of effluent, patient-reported tolerability of bowel prep, history of polyps or cancer. Odds ratios were mutually adjusted for all variables reported in each analysis.

DISCUSSION

In this cross-sectional cohort study we addressed a novel clinical question, namely whether a patient's perception of the tolerability of bowel preparation is associated with quality measures in colonoscopy. We found that a less tolerable experience with bowel preparation was inversely associated with both polyp detection and with bowel prep quality, measured by the validated Ottawa bowel preparation score. We also determined that female gender is an independent risk factor for a poorly tolerated prep.

This is the first study we are aware of that separates tolerability from other patient-reported ratings of bowel preparation, and is also the first to demonstrate its predictive role. Previous studies have evaluated the relationship between patient-rated quality of bowel preparation and endoscopist-rated prep quality. In a cohort of 474 outpatients, Harewood et al found that patient-reported clarity of bowel preparation correlated poorly with endoscopist assessment, reporting a correlation coefficient of r=0.08 [8]. Fatima et al found a similarly poor correlation between patient and endoscopist rating of bowel preparation in a cohort of 429 outpatients, with Cohen's κ=0.067 [9]. In our similar-sized cohort, we replicated this poor correlation between patient and endoscopist rating of bowel prep, reporting a Cohen's κ=0.15. Unlike prior studies, however, we hypothesized that other measures of the patient's experience with bowel preparation may better identify those at risk for low-quality bowel prep, and that this risk might also apply to PDR.

Because patients do not have training or experience in evaluating the clarity of effluent after bowel preparation, it is not surprising that they are poor predictors of the quality of their own prep. However, there is no standard against which to measure a patient's perception of the bowel preparation experience. The importance of the patient's experience with bowel preparation has been recognized in prior studies. In a recent systematic review, McLachlan et al reported that laxative bowel preparation remains the biggest barrier to screening colonoscopy, often causing more discomfort than the procedure itself [14]. In another cross-sectional survey of patients undergoing outpatient colonoscopy, Sint Nicolaas et al found that female gender, age <50 years and 4L (vs. 2L) preparation were associated with a more burdensome experience [15]. In the present study we have replicated the finding that women are more likely to perceive bowel preparation as "unpleasant" or "intolerable" than men.

Female gender could act as a confounder between lower PDR and discomfort during bowel preparation because compared to men, women have lower rates of polyp detection and CRC mortality but higher rates of irritable bowel syndrome

(IBS) [16-18]. Chey et al reported lower PDR in patients with IBS, even after adjusting for age and gender, though the study was not designed to detect a difference in polyp or adenoma yield and – unlike our study – did not account for differences in indications for colonoscopy or a history of prior colonoscopy [19]. Others have reported an association between IBS and colonoscopic outcomes. Oh et al reported an association between IBS and colonoscopic insertion time, even if only female gender persisted as a risk factor for longer insertion time in a multivariate analysis [20]. We, too, examined insertion time and found it to be significantly longer in patients who reported a less tolerable experience with bowel preparation (Table II).

We used PDR as our primary outcome rather than the more traditional quality measure, adenoma detection rate (ADR). From a biologic standpoint, ADR is more closely associated with risk of CRC than PDR. However, estimation of the PDR can be done with endoscopic data alone – independently of polyp histology – and can be calculated and tracked more easily by endoscopists. There is a growing body of evidence that PDR is a valid quality measure for colonoscopy. In a large retrospective cohort, Williams et al showed a high correlation between polyp detection and adenoma detection (r=0.91) [21]. The same correlation was reproduced in a more recent study by Gohel et al (r=0.8), who found that the association was strongest for male patients and for polyps in the proximal colon [22]. Therefore, we feel that the association between patient tolerability of bowel prep and PDR maintains important clinical implications for all gastroenterologists who perform colonoscopy.

Our novel findings are strengthened by the reproduction of previously well-known associations. Male gender, older age and quality of bowel preparation were strong predictors of polyp detection in our study. The interval between bowel prep and colonoscopy, a more recently-established predictor of bowel prep quality, was independently associated with Ottawa score [13]. Prior abdominal surgery and insertion time have also been reported as variables affecting quality outcomes in colonoscopy, as they were in our study [23, 24]. An additional variable that merits further investigation is the interval between initiation of bowel preparation and first bowel movement, which we found to be an independent predictor of bowel prep quality. As is now the case with many of these variables, if the predictive capability of prep tolerability is replicated it would become an important clinical indicator. Patients who perceive the prep as intolerable may present a technical challenge to endoscopists and may be at risk for both low quality bowel preparation and for missed polyps.

Our study has several limitations. Our patient questionnaire, developed for this study, has not been validated. The Ottawa scores in our study were lower than in other studies that have used this scale, though this did not prevent us from identifying independent predictors of bowel prep quality [12, 13]. We did not collect certain elements of medical history, sociodemographic history or biologic data that would have given insight into a potential mechanism behind our findings. Additionally, the potential clinical benefit of alerting the colonoscopist about a poorly tolerated prep was not tested and thus remains theoretical. While we feel that PDR is a valid measure of quality outcomes in colonoscopy, our study was underpowered to demonstrate that patient tolerability of bowel preparation also predicted ADR. Lastly, we reported odds ratios for our logistic regression analyses even though the high frequency of polyp detection does not meet the 'rare disease assumption', which could have exaggerated the relative risk of our primary and secondary outcomes. Despite this possibility we feel our results are clinically significant, particularly in light of the fact that other known predictors of quality outcomes in colonoscopy were reproduced in this study (Table III).

There are a number of reasons a patient may tolerate a bowel preparation poorly, including taste, inconvenience, compliance and physical discomfort. We chose to study the patient tolerability of bowel preparation because there is a general paucity of research on patient-related variables in colonoscopic research. Our findings are broad but strongly suggest a relationship between how the patient perceives the bowel preparation and what occurs during colonoscopy. Our results merit further investigation in larger, prospective studies. Such studies should identify more specifically what the patient found intolerable and propose changes to the bowel prep that might improve prep quality. Ideally, future studies would also identify procedural modifications that could improve the yield of colonoscopy in these patients, such as the use of more sedation or a deliberately slower insertion time.

CONCLUSIONS

We found that patient-perceived tolerability of bowel preparation is independently associated with polyp detection and with the quality of bowel preparation. We also found that female gender is an independent risk factor for a poorly tolerated prep. We propose that a poorly tolerated bowel prep may foreshadow both a lower quality bowel preparation and a technically difficult colonoscopy, marked by a longer insertion time, need for additional sedation and a higher risk for missed polyps. We emphasize the hypothetical nature of this proposal, and hope that future studies will elucidate the mechanism linking tolerability of bowel preparation to quality outcomes. Such work would facilitate the development of focused interventions, improve the yield of screening colonoscopy and further strengthen our ability to prevent colorectal cancer.

Disclosure statement. Drs. Sundberg and Verhille are partial owners of the outpatient endoscopy center where a majority of the colonoscopies were performed. No other authors have any relevant financial relationships to disclose. No financial assistance of any kind was used in the conduction of this research or in the preparation of this manuscript.

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