


High-Volume Colonic Lavage Is a Safe and Preferred Colonoscopy Preparation for Patients With Inflammatory Bowel Disease

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Background: Colonoscopies provide a crucial diagnostic and surveillance tool for inflammatory bowel disease (IBD). Accordingly, IBD patients undergo repeated and frequent colonoscopies. The oral purgative bowel prep (BP) is often burdensome on patients, resulting in delayed or missed colonoscopies due to patient noncompliance. Additionally, oral BP has been noted to possibly induce colon mucosal inflammatory changes in some patients, which may be misleading when assessing actual disease activity.

Methods: In this retrospective clinical study, we evaluated the use of an FDA cleared, defecation-inducing high-volume colon irrigation (>40 L) BP to prepare IBD patients for colonoscopy. Data were collected at 4 US Hygieacare centers from September 2016 to March 2021. The IBD patient population consisted of 314 patients that underwent 343 BPs. The BPs were prescribed by 65 physicians and performed by 16 nurses and technicians.

Results: Patient ages were 20–85 years old, 76% females, 24% males, and 97% of the patients were adequately prepared for their colonoscopy ($n = 309$). Patient satisfaction with the BP was very high, as reflected in postprocedure surveys and open-ended responses text analyses, and there were no serious adverse events.

Conclusions: We present data supporting that the defecation-inducing high-volume colon irrigation BP for colonoscopy is safe, effective, and preferred for IBD patients. Using this BP for IBD patients can allow earlier interventions, significantly impacting disease management and future outcomes.

Lay Summary

Patients with inflammatory bowel disease (IBD) now have an alternative to traditional methods for colonoscopy preparation. The HygiPrep is safe, effective, and highly rated by patients. This allows for a more potentially accurate and effective assessment and, thereby, management of IBD.

Key Words: IBD, colonoscopy, bowel prep

Introduction

Colonoscopies provide a crucial diagnostic tool for inflammatory bowel disorder (IBD) since they deliver clear, detailed views of the gastrointestinal tract. The term IBD usually includes ulcerative colitis (UC) and Crohn's disease (CD). Patients with IBD are at increased risk of developing colorectal cancer (CRC), the third most common malignancy globally and the second most common cause of cancer deaths in the United States.¹ Recognizably, IBD increases CRC risk by 2- to 5-fold, accounting for 10%–15% of IBD deaths.^{2–8} The American Gastroenterologist Association (AGA), the American College of Gastroenterology (ACG), and other international gastroenterology associations have recommended that IBD patients, starting from 10 years

after diagnosis, undergo surveillance colonoscopies every 1–3 years.^{9–11} Patient adherence to the recommended surveillance frequency is directly linked to their probability of developing CRC,^{5,12} yet compliance is estimated to be only 50%–75%.^{13,14}

High-quality bowel preparation (BP) is crucial for both clear colonic mucosa visualization and the diagnosis and surveillance of IBD progression and flares. However, 20%–60% of colonoscopies are associated with inadequate BPs, accounting for 20%–70% of incomplete procedures.^{15,16} Inadequate BP for colonoscopy is associated with increased adverse outcomes,^{17,18} thereby significantly affecting IBD patients.¹⁹ Colonoscopies are also used as surveillance for mucosal healing to assess long- and short-term therapeutic

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efficacy, postoperative follow-up, and neoplasia identification.²⁰ When evaluating the root causes for colonoscopy noncompliance among IBD patients, the most common was difficulties with BP.¹⁴

An FDA-cleared open-system technology to purge the colon by controlled gravity-fed water infusion provides an alternative to overcome the well-established issues with the oral purgative colonoscopy BP. This BP is prescription based and performed by highly trained personnel operating under stringent standard operating procedures (SOPs). The method has proved safe, effective, and well tolerated in patients, with a 97% adequacy in over 12 000 colonoscopy preparations.^{21–25} Clinical adequacy remains high even in patients with poor BP predictors such as age, male sex, and various comorbidities.²¹ Furthermore, the procedure has high patient satisfaction rates and fewer side effects than the standard oral purgative prep for colonoscopy.²¹ Here, we present a retrospective analysis of 343 BPs performed in 319 patients with IBD.

Methods

High-Volume Colon Irrigation BP

The high-volume water irrigation BP is used to purge the colon by gravity-fed water infusion before colonoscopy.^{22,26} This BP is FDA cleared and intended for use when medically indicated, such as before radiological or endoscopic examination. It is performed by trained personnel and under stringent SOPs. During the BP, the patients are seated on a disinfected basin, and a sterile, disposable nozzle is inserted about 1 inch into their rectum. Gravity-directed water (37–39 °C) flows into the bowel, loosening stool and allowing the patient to evacuate their colon. Water continues to flow and clean the colon until the patient is notified that the BP is completed. The BP takes approximately 1 hour and is automatically stopped if the water temperature exceeds the safe range of 37–39 °C. As a pre-BP regiment, patients were asked to follow a clear liquid diet the day before and the day of their colonoscopy (similar to instructions given for oral purgative-based BP). They were also instructed to take a stimulant laxative (bisacodyl, 2 × 5 mg) twice on the day before the BP (noon and evening) and once on the morning of their high-volume colon irrigation BP and colonoscopy. Some physicians also instructed the patients to take magnesium hydroxide (gentle laxative and antacid) 1–5 days before their BP.

Collection of Clinical Data and Demographic Information

Clinical and demographic data were collected from IBD patients at 4 centers: GI Associates (GIA)—Hygieacare Center in Jackson, MS, Ohio Gastroenterology and Liver Institute (OGI)—Hygieacare Center in Cincinnati, OH, Austin Gastro (AG)—Hygieacare Center in Austin, TX, and Hygieacare Center in Norfolk, VA, between September 2016 and March 2021. Procedures were prescribed by 65 physicians. The demographic and self-reported clinical data were collected via the patients' responses to questionnaires. Since this is a retrospective descriptive study, in a standard FDA and unchanged cleared procedure, deidentified and with patient consent, no IRB was required. The examining physicians provided the BP's adequacy for the colonoscopies,

and the data were directly fed into the database by an endoscopy center employee.

Recording and Analysis of Adverse Events

All adverse events (AEs) that occurred during and immediately after the high-volume gravity-fed colonic lavage with induced defecation BP procedures were documented by the center's staff. The AEs recorded included nausea, vomiting, dizziness, and abdominal cramping.

Patients' Satisfaction Report and Free-Text Analysis

To estimate patients' satisfaction, all patients were provided with a post-BP satisfaction survey that included 4 questions referring to the gravity-fed colonic lavage with induced defecation quality: (1) "Was the check-in welcoming and efficient?"; (2) "Were the explanations received from the staff about what to expect clear and to the point?"; (3) "Were the techs available as needed and adequate privacy kept?"; (4) "Were the prep room and system clean to their satisfaction?" The survey included an additional question regarding the patients' preference when choosing between the colonic lavage BP and an oral purgative BP in the future. The answers to the survey questions were ranked on a scale of 0–3: definitely agree, agree, disagree, or definitely disagree. The survey responses were analyzed by counting responses in each category for each of the centers, and the results are presented per rating and satisfaction percentages.

In addition, the patients were given two open-ended questions to express their opinion on the colonic lavage BP and past oral purgative BP, if applicable. Patient open-text feedback was available for 104 HygiPrep procedures and 100 past oral prep responses, gathered from all 4 sites. The patient responses were analyzed for word abundance and presented as a word cloud analysis, where the size of the words represents their relative abundance in the patients' responses.

Results

Between September 2016 and March 2021, the gravity-fed colonic lavage with induced defecation BP for colonoscopy was performed 342 times in 318 patients suffering from IBD, as prescribed by 65 gastroenterologists. Patients' age ranged from 20 to 85 (average = 57 ± 14), 76% of the procedures with assigned gender were performed on females and 24% on males (Table 1). Of these patients, 58% were diagnosed with UC, 33% with CD, 3% with both UC and CD, and 6% with unspecified IBD (Table 2). Out of the 342 procedures performed during this time, 309 had reported outcomes, of which 301 were deemed adequate (97%). Demographics and key results are presented in Table 1.

The BP adequacy remained high (>90%) even when patients reported comorbidities considered as predictors of poor BP, such as constipation and diabetes (Table 3). The only exception was severe hemorrhoids that reduced adequacy to 89% (17/19). Prior clinical procedures, including abdominal hernia, bariatric, and GI tract surgeries, did not affect adequacy, which remained >94% (Table 4, *n* = 229). No severe AEs were recorded. Other AEs, defined as a patient rating of "quite a bit" or "a lot" (Table 5) included: nausea (*n* = 23, 7%), vomiting (*n* = 13, 4%), diarrhea (*n* = 5, 1%), and abdominal pain/cramping (*n* = 15, 4%).

Table 1. Demographics and summary of key results.

Parameter	Summary of demographic data and key results
Procedures performed	342
Number of patients	Overall—318; patients with 1 procedure—297; patients that have had 2-to-3 procedures—21 patients (45 procedures)
Number of referring physicians	65
Adequacy	97% (301/309)
Age of patients	min—20; max—85; average—57.5 ± 14 (n = 328)
Gender of patients	Male—61 (24%) Female—192 (76%) (n = 253)
Serious adverse events	0

All patients underwent gravity-fed colonic lavage with induced defecation BP between January 2017 and March 2021. Abbreviation: BP, bowel preparation.

Table 2. Breakdown of IBD diagnosis of 314 patients that underwent the gravity-fed colonic lavage with induced defecation BP.

IBD indication	
Ulcerative colitis (UC)	182 (58%)
Crohn's disease (CD)	104 (33%)
UC and CD	10 (3%)
Unspecified IBD	18 (6%)

Abbreviations: BP, bowel preparation; IBD, inflammatory bowel disease.

Table 3. Comorbidities diagnosed in 343 gravity-fed colonic lavage procedures with induced defecation BP procedures and their effect on BP adequacy.

Comorbidity	Total number of performed procedures	Adequate BPs (% of performed BPs)
Constipation	56	52 (93%)
Diabetes	37	34 (92%)
Bladder or pelvic mesh	18	17 (94%)
Severe hemorrhoids	19	17 (89%)
Fissures or rectal fistula	15	15 (100%)
Diarrhea	10	9 (90%)
Intestinal obstruction/stricture	12	12 (100%)
<i>Clostridium difficile</i> (C. Diff)	17	16 (94%)

Abbreviation: BP, bowel preparation.

Patients were given questionnaires to assess how satisfied they were with the treatment center and the procedure itself. Patient satisfaction (on a scale of 0–3) was 2.94 for “efficient check-in” and “clear explanation regarding the procedure,” 2.96 for technician availability and room cleanliness, and 2.73 for preferring the gravity-fed colonic lavage with induced defecation technique over the traditional BP (Table 6). Analysis of the free-text analysis from the postprocedure

Table 4. The occurrence of prior surgeries in 343 gravity-fed colonic lavage procedures with induced defecation BP procedures and the effect on BP adequacy.

Prior procedures	Total number of performed procedures	Adequate BPs (% of performed BP)
Abdominal hernia	18	17 (94%)
Bariatric surgery	115	110 (96%)
Colon, rectal or abdominal surgery, etc.	97	93 (96%)

Abbreviation: BP, bowel preparation.

Table 5. Analysis of adverse events as experienced and reported by patients before and after the gravity-fed colonic lavage with induced defecation BP.

	Very little	Some	Quite a bit	A lot	None
Nausea	22 (6%)	32 (9%)	6 (2%)	17 (5%)	266 (78%)
Vomiting	8 (2%)	15 (4%)	10 (3%)	3 (1%)	307 (89%)
Dizziness	7 (2%)	5 (1%)	3 (1%)	2 (1%)	326 (95%)
Abdominal pain/cramping	6 (2%)	19 (5%)	5 (1%)	10 (3%)	303 (88%)

Abbreviation: BP, bowel preparation.

Table 6. Analysis of patient's quality of service survey following gravity-fed colonic lavage with induced defecation BP.

Satisfaction parameter	Score (0–3)
Efficient check-in	2.94 ± 0.3 (n = 248)
Clear explanation	2.94 ± 0.3 (n = 248)
Technician availability	2.96 ± 0.3 (n = 249)
Room cleanliness	2.96 ± 0.3 (n = 249)
Gravity-fed colonic lavage with induced defecation over traditional oral prep	2.73 ± 0.6 (n = 240)

Patients were asked to rate parameters on a 0–3 scale where 0 = definitely disagree, 1 = disagree, 2 = agree, 3 = definitely agree. Abbreviation: BP, bowel preparation.

survey provided the patients' opinions and sentiments on the defecation-inducing colonic lavage BP (n = 104) and 100 responses on the patients' experience with past oral purgative preps. For the colonic lavage BP, the most abundant words were “staff,” “great,” “prep,” and “experience,” all with 12–70 occurrences in 104 responses. These were followed up with the words “excellent,” “helpful,” “friendly,” “care,” “feel,” “made,” and “professional,” with 8 and 9 occurrences (Figure 1). The responses regarding past oral preps were characterized with words of different sentiment, where “vomit,” “nausea,” “drink,” and “make” were the most common words with 15–30 occurrences in 100 responses, followed by “prep,” “sick,” and “pain” with 8 and 9 occurrences (Figure 1).

Discussion

In this multicenter retrospective clinical study, high-volume gravity-fed colonic lavage with induced defecation (HygiPrep)

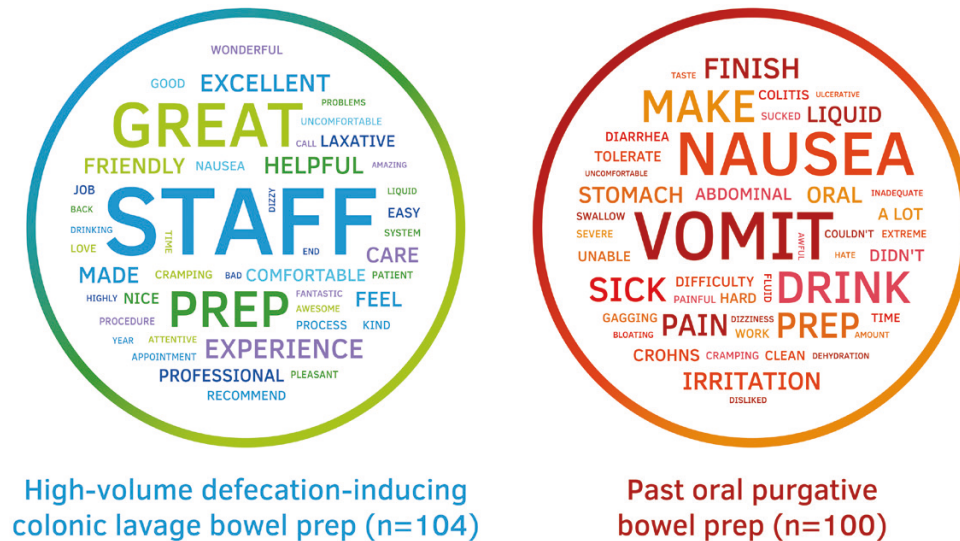


Figure 1. Word cloud analysis of free-text open-ended responses of the reported IBD population. On the left—responses from patients asked about their past experience with oral preps. On the right—responses from patients asked about their experience with the high-volume colon irrigation bowel prep. Abbreviation: IBD, inflammatory bowel disease.

was shown to be a well-tolerated, safe, and effective therapeutic treatment for 318 patients suffering from inflammatory bowel disease (IBD) (Table 1). In this study, 318 patients underwent 342 procedures with no severe AEs and minimal other AEs (Table 5). In addition, patients reported high levels of satisfaction (Table 4) that could translate into increased patient compliance. Physician acceptance was demonstrated by the number of physicians ($n = 65$) located in 4 independent endoscopy centers that referred patients (1–3 times over 4.5 years) to this prescription-only BP.

Routine colonoscopies are especially crucial for monitoring IBD patients since they are at increased risk of developing CRC.^{2–8} Although international guidelines recommend that IBD patients undergo colonoscopies every 1–3 years,^{9–11} patient adherence is estimated at only 50%–75%.^{13,14} Increasing compliance is crucial for improving patient quality of life and decreasing CRC occurrence and burden on the health-care system. One factor known to reduce compliance is the burden of the pre-prep regime on patients.¹⁴ The high-volume gravity-directed colonic lavage with induced defecation presented here has shown to be safe, well tolerated, and with high patient satisfaction in 12 000 patients.^{25,27} Furthermore, the technology is comorbidities agnostic BP with high adequacy (97%),²⁷ which is crucial for both IBD surveillance²⁰ and CRC detection.^{17,18}

It is well known that IBD is characterized by chronic inflammation of the bowel manifested by episodic or continuous intestinal symptoms such as diarrhea, abdominal pain and endoscopically by mucosal damage. Altering the natural history of the disease requires mucosal healing, and the achievement of endoscopic remission (ER) has been consistently associated with improvements in short- and long-term disease outcomes.²⁸ ER has progressively become integrated as a primary treatment target in IBD patients, and colonoscopies are used for IBD diagnosis, assessing disease severity, disease surveillance, and adjusting treatment. Since the accurate diagnosis of IBD depends upon mucosa visualization, any procedure that can potentially disrupt the gut mucosa layer can skew diagnosis and surveillance results. Previously, it has been

shown that several oral purgative-based preps, especially those containing sodium phosphate, can injure the mucosa, even to the point that it mimics CD.^{29,30} The HygiPrep is a gravity-fed and defecation-inducing colonic lavage that does not use any chemicals that might affect the mucosa. The prep induced peristalsis as the water gently flows in the gut lumen and naturally loosens the colon content, including that of the ascending (right) colon.^{26,27} Therefore, this prep is likely to be less disruptive for the bowels of IBD patients and circumvents the disruptive nature of the oral purgative prep while providing a more accurate assessment of disease activity.

The high-volume gravity-fed colonic lavage with induced defecation (HygiPrep) BP holds both clinical and patients facing advantages and increases patients' compliance with clinical guidelines for managing the disease. In addition, from a research perspective, studying the colon effluent, mucosa layer, and gut epithelial from a gut that was not prepped using a chemical agent can hold a myriad of benefits, from accurate biomarkers detection to microbiome research for personalized medicine. We suggest that the presented consistent BP adequacy and high patient satisfaction make this defecation-inducing colonic lavage a favorable strategy for colonoscopy preparation in IBD patients and can be a powerful tool in improving disease management and treatment for this population.

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The data for this retrospective study were mined using the Hygiecare Inc. database. There was no external funding for this study.

Conflicts of Interest

Amit Gajera, Christopher South, Kevin M. Cronley, John J. Ziebert, and Cynthia H. Wright declare that they have no conflict of interest. Orly Levitan and Dawn B. Bursleson: Employees of Hygiecare Inc. David A. Johnson: consultant for Johnson and Johnson, Hygiecare Inc., and ISOThrive Inc.

Data Availability

Not publicly available.

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