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Colon Irrigation Bowel Preparation Supports Multiple Clinical Benefits in Over 8,000 Patients

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ABSTRACT

This retrospective clinical study evaluates an FDA-cleared high-volume colon irrigation bowel prep (BP) for colonoscopy, performed under standard operating procedures with Austin Gastroenterology (AG, Austin, TX). Patient related outcomes in 8,364 procedures, prescribed by 33 physicians in 4.5 years, demonstrated no serious adverse events and excellent satisfaction rates. The high level of adequacy using this BP far exceeds national benchmarking thresholds for adequate colon preparations. Adequacy rates remain high even when considering poor BP risk factors and patient noncompliance with ancillary pre-preparation regimens. Our analysis demonstrates that this colon irrigation BP has excellent Boston bowel preparation scores (BBPS), associated with high-level adenoma detection rates (ADR) and sessile serrated polyp (SSP) detection rates. ADR and SSP are inversely related to the patient's post-colonoscopy interval colorectal cancer (CRC) risk, and are similarly related to an inadequate BP. Both modeling data and performance characteristics strongly suggest that this colon irrigation BP is highly safe, effective, and will reduce the costs and risks related to inadequate BP. This, accordingly, leads to significantly improved quality outcomes, savings to the healthcare systems, and a reduction of the patient's burden.

Keywords: colonoscopy; colon preparation; colonoscopy quality; ADR; SSP; CRC

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Introduction

Gastroenterologists use colonoscopies as the tool of choice for colorectal cancer (CRC) prevention and screening, as it allows for both visualization and polyp removal in the lower gastrointestinal tract [1,2]. CRC is the third most common cancer in the United States [3]. An updated survey from the American Cancer Society (ACS) projects that in 2020, almost 150,000 new cases will be diagnosed, and over 53,000 will die from the disease [4]. Overall, both CRC incidence and mortality have significantly decreased over the past two decades due to the expansion of colonoscopy screening coverage by Medicare and other commercial insurance carriers and health maintenance groups (HMOs) [5]. According to the Centers for Disease Control and Prevention (CDC), almost 70% of adults aged 50-75 undergo colonoscopies at the recommended frequency. However, up to 20% of colonoscopies are reported to have inadequate bowel preparation (BP), resulting in lower detection rates, lengthier procedures, early repeat procedures, and increased costs [6–12]. Incremental colonoscopy related health system cost estimates, as a result of an inadequate BP, have been reported to be 12% and 22% for university and public hospitals, respectively [13]. For these reasons, BP regiments have increasingly become standardized, with multiple publications of international guidelines and suggested quality scales for assessing adequacy [12,14–16]. The standardized and clinically validated Boston bowel preparation score (BBPS) scores the cleanliness of each of the three bowel segments (ascending, transverse, and descending) on a scale of 0-3, during withdrawal and after washing [14]. The BBPS scores are highly correlated to adequate BP for colonoscopy [17], defined as a total score of over 6 [18]. More recent data have suggested that segmental scores of <2 correlate with missed high-risk adenomas [19].

A key measure of colonoscopy quality is the adenoma detection rate (ADR), the percentage of patients aged ≥50 years with an adenoma detected and removed during their first-time screening colonoscopy [18]. It is widely accepted that the ADR is a significant parameter for colonoscopy quality and is inversely correlated to interval cancer risk [20]. However, it appears that adenomas account for only 70% of CRCs, and approximately 30% arise through the serrated pathway, which is also a disproportionate contributor to interval CRC [21]. Notably, the pathway for sessile serrated polyps (SSP), found in approximately 5-7% of screening colonoscopies, is often detected in the proximal colon, thus hindering detection. Missed lesions, or incomplete removal of precancerous polyps, often due to inadequate BP, are estimated to account for up to 80% of interval cancers [22]. Thus, high-quality BP is crucial for both the identification and removal of colorectal lesions.

The current standard of care (SOC) BP protocol is a split dose administration of an oral purgative. Recognizably, this often causes severe disruption to daily routines and sleep loss [23]. It is also associated with low patient satisfaction [24], which inevitably reduces compliance with screening guidelines and surveillance recommendations. Noncompliance with pre-prep instructions accounts for over 20% of inadequate BP cases [10,25–28]. Oral purgative BPs are generally considered safe and well-tolerated with common side-effects that include nausea, vomiting, and electrolyte disturbances [12]. Although the split oral dose is the current SOC, results demonstrate that up to 20% of outpatient and up to 60% of inpatient colonoscopies [12] can result in incomplete or

low-quality colonoscopies due to inadequate BP [29]. The probability of inadequate BP is correlated with patient-specific factors, including age, male gender, medications, and several comorbidities [30–33]. These comorbidities include chronic constipation, diabetes, gastrointestinal surgery, cirrhosis, obesity, stroke, and irritable bowel disease (IBD) [12,25,33,34]. Following inadequate BP, patients often require a repeat procedure, leading to an increased burden on the healthcare system and the patients [34,35].

A novel method has been developed to decrease inadequate BP rates and increase patient satisfaction and compliance. This FDA-cleared open-system is based on purging the colon by low pressure (gravity directed) high-volume irrigation on the day of the colonoscopy. The system, operating in dedicated centers under stringent standard operating procedures (SOPs) and located in proximation to endoscopy centers, is well-tolerated and highly effective [36–39]. This retrospective review reports real-world evidence (RWE) of clinical outcomes derived from this high-volume colon irrigation BP by analyzing 8,364 procedures prescribed to 7,988 patients in 4.5 years.

Methods

Collection and statistical analysis of demographic and clinical information –

This retrospective database analysis is based on de-identified clinical and demographic data of patients who received high-volume colon irrigation BP. Data was collected at the Austin Gastro-Hygieacare center (AG-Hygieacare, Austin,TX) between August 2015 and December 2019. During this time, 8,364 procedures, performed on 7,988 patients, were prescribed by 33 physicians. The demographic and self-reported clinical data were collected via patient questionnaires. The center's staff documented adverse events (nausea, vomiting, dizziness, and abdominal cramping) occurring during and immediately after the high-volume colon irrigation BP. The Boston bowel preparation score (BBPS), a 10-point scale (0-9) assessing BP, was completed by the endoscopist after all cleansing protocols and was used to assess bowel cleanliness levels. BBPS data were recorded for 7,624 patients between November 2015 and December 2019. The analysis is presented as an average score per year, including a statistical analysis to assess significant changes between the years. The analysis of the distribution of procedures' BBPS scores is presented as a percentage of the total cohort (Figure 1). For a subset of these patients (n=2,652), BBPS was also recorded as individual scores per segment (0-3), ascending, transverse, and descending, segment scores. An analysis of these segments' scores is also presented by year. Statistical analysis to assess significant improvement from the previous year was done using one-way ANOVA with a Tukey HSD post-hoc test (* $p<0.05$, ** $p<0.005$). Since this is a retrospective descriptive review of a standard FDA-cleared and unchanged approved procedure, de-identified and with patient consent, no IRB was required.

Analysis of high-volume colon irrigation BP sensitivity to predictors for poor BP

To check for a correlation between predictors for inadequate BP factors (male gender, advanced age, and comorbidities) and poor BP, we analyzed all database entries with recorded clinical outcomes (adequacy reported) and documented age and/or gender. We found 6,316 procedures with reported age and adequacy (Figure 3). Patients were divided into eight age groups (under 35, 36-45, 46-55, 56-65, 66-75, 76-85, and over 86). The statistical difference between BP adequacy across the different age

groups was compared using a nonparametric Kruskal-Wallis test ($p<0.05$, R software). Patient self-reported comorbidities were recorded over 13 months, September 2016-September 2017. The comorbidities include chronic constipation, diabetes, irritable bowel disease (IBD), irritable bowel syndrome (IBS), carcinoma of the rectum, cirrhosis, colon surgery, abdominal surgery, rectal surgery, intestinal obstruction, stricture, abdominal hernia, heart conditions, and intestinal perforation. This analysis is presented for 2,240 consecutive indexed procedures. The specific comorbidities are reported as a percentage of adequate procedures from all documented procedures where a particular comorbidity was recorded.

Data collection for the sensitivity of the high-volume colon irrigation BP to different pre-prep regimes-

To allow for improved clinical outcomes, physicians prescribed pre-colonoscopy BP instructions to patients, regardless of the chosen method. These include a clear liquid or a low residue diet with laxatives, such as bisacodyl and Magnesium hydroxide, given in various combinations and doses. The effectiveness of the high-volume colon irrigation BP, relative to other pre-prep regimes, was determined in those cases where these specifics were reported. A correlation of pre-prep regimes to BBPS scores, overall and for each colon segment, was tested for a subset of 297 patients for which this information was available. Compliance with the physician's pre-prep instructions was defined as four tablets of 5 mg bisacodyl (2 tablets twice a day for one day) and 10 tbsp of Magnesium hydroxide (2 tbsp for 5 nights). The total BBPS score and BBPS per intestinal segment were compared between the compliant and non-compliant groups using a two-tailed T-test ($p<0.05$, R software).

Adenoma and sessile serrated polyps detection rates

The adenoma detection rates (ADR) and detection rates of sessile serrated polyps (SSP) are routinely collected by Austin Gastroenterology (Austin, TX) as part of the endoscopy center routine colonoscopy for quality metrics. Patients who chose the high-volume colon irrigation BP and met the analysis criteria were included in the analysis (October 1, 2018 to June 31, 2019). The criteria were as follows: patients must be asymptomatic; age > 45 and African American or > 50 (all other ethnicities); and must be undergoing their initial screening colonoscopy. The search yielded 112 eligible patients examined by 18 physicians. This analysis was performed retrospectively on a de-identified dataset.

Patient satisfaction analysis and willingness to repeat the colonic irrigation procedure-

To estimate patient satisfaction with the high-volume colonic irrigation BP procedure, all patients were asked to fill out a standard post-procedure satisfaction survey. The survey included four questions relating to their experience with the BP. Answers were ranked on a 4-point scale from definitely agree to definitely disagree. Two additional questions evaluated the patients' willingness to choose this BP for their next procedure, and the patients' willingness to recommend this BP to a friend. Patient responses were analyzed by counting responses in each bracket, and results are presented as a percentage of the total maximum response. Additionally, we report on patients that have chosen the high-volume colon irrigation BP more than once over the reported time period, August 2015 to December 2019.

Results

Clinical outcome, BP adequacy, and demographic information

Between August 2015 and December 2019, the high-volume colon irrigation BP for colonoscopy was performed 8,364 times in 7,988 patients, as prescribed by 33 gastroenterologists from Austin Gastroenterology (AG, Austin, TX). Patients' age ranged from 18-96 (average=62±11), 61% of the procedures with assigned gender were performed on females and 39% on males. Out of the 8,364 procedures performed during this time, 7,624 had reported outcomes. The BBPS score was 8.20±1.38 for all reported procedures, and 80% of all procedures had a total BBPS of 8 or 9 (Table 1, Figure 1). The BP adequacy scores, defined herein as BBPS≥6, improved throughout the years. The BBPS significantly increased between 2015 (n=149) and 2016 (n=1,909) and between 2016 and 2017 (n=2,181) (ANOVA with a Tukey HSD post-hoc test, $p<0.005$, Figure 2). Between January 2017 and December 2019, over 96% of the patients, including patients with underlying diseases, were reported to have BBPS≥6, with an average of 8.28±1.36 (n=5,566).

Statistical analysis of the BBPS per segment (ascending, transverse, and descending, n=2,652) revealed significant progressive improvements in segmental BBPS scores throughout the years (Table 2), probably due to increased staff experience. For the ascending colon, a statistically significant improvement was detected between 2015 and 2016 (ANOVA with a Tukey HSD post-hoc test, $p<0.005$) as well as between 2017 and 2018 ($p<0.05$), reaching BBPS of 2.70±0.53 and 96% patients with segmental BBPS≥2. The transverse colon segmental BBPS also showed statistically significant increased cleanliness between the years, it averaged 2.87±0.36 in 2018 (n=278), and 99% of the patients recorded segmental BBPS≥2. The descending colon BBPS score constantly improved, however, not significantly. In 2018, the descending colon BBPS score was 2.89±0.35. Overall, our results show that since 2017, reported outcomes reveal that 96% of the ascending colon, 98%-99% of the transverse colon, and 98-99%of the descending colon have a BBPS ≥2 (Table 2).

No serious adverse events (SAE) were recorded in the 8,364 procedures. Minor adverse events (AE) were reported in 13% of the procedures (n=1,098). Nausea, vomiting, dizziness, and abdominal cramping were reported for 8% (n=662), 1.3% (n=107), 3% (n=266), and 6% (n=492) of the procedures, respectively. Of the 1,031 procedures for which both AE and clinical outcomes were recorded, 97.6% (n=1,007) reported an adequate outcome. Demographics and key results are presented in Table 1.

High-volume colon irrigation BP sensitivity to predictors for poor BP

There are three main predictors for inadequate BP: male gender, age, and a variety of comorbidities [40]. Our database included 4,312 high-volume colon irrigation procedures with disclosed gender and reported clinical outcome. Of these, 61% (n=2,642) were performed on females and 39% (n=1,670) on males. BP adequacy for colonoscopy of these patients was 98%, regardless of reported gender. An additional 3,129 procedures with reported clinical adequacy, but no assigned gender, had 96% adequacy. The database had 6,316 indexed procedures with detailed age and reported clinical outcomes. The age range was 18-96, with an average of 62±11, and 43% were over 66 years of age. Patients ages 18 to 75 demonstrate over 97% adequacy (n=5,726), while patients over 76 (n=590) present 95%

adequacy (Figure 3). We then performed statistical analysis to determine whether there were differences in the adequacy between age groups and found no significant difference between the groups (K-W test, $p<0.05$). For all age groups, the adequacy of the high colon irrigation BP was over 95%.

Table 1 Key demographics and summary of key results. All patients underwent high-volume colon irrigation bowel preparation for colonoscopy as prescribed by physicians affiliated with Austin Gastroenterology (Austin, TX), between August 2015 and December 2019.

Parameter	Summary of demographic data and key results
Procedures performed in the center	8,364
Number of patients	7,998
Number of referring physicians	33
Overall Boston bowel prep score (BBPS)	8.20±1.38 (n=7,624)
BBPS by segment	Ascending - 2.5±0.65 Transverse - 2.74±0.52 Descending- 2.81±0.46 (n=2,652)
Age of patients	min -18; max - 96; average- 62±11 (n=6,316)
Gender of patients	Male – 2,642 (39%) Female – 1,670 (61%) (n=4,321)
Serious adverse events	0
Other adverse events	13% (n=1098) reported some adverse events (nausea, vomiting, dizziness and/or abdominal cramping)
Patients that have had multiple procedures	343

Table 2 Boston bowel prep score (BBPS) per segment divided according to available data from 2015-2018. Asterisks indicate statistically significant improvements from the previous year (* $p<0.05$, ** $p<0.005$).

Colon segment		2015 (n=149)	2016 (n=1,905)	2017 (n=320)	2018 (n=278)
Ascending	***score***	2.32±0.71	2.49±0.66**	2.56±0.58	2.70±0.53*
BBPS	**≥2**	88%	93%	96%	96%
Transverse	***score***	2.60±0.60	2.74±0.52**	2.82±0.43*	2.87±0.36
BBPS	**≥2**	95%	97%	98%	99%
Descending	***score***	2.72±0.56	2.80±0.46	2.86±0.39	2.89±0.35
BBPS	**≥2**	96%	98%	98%	99%

Comorbidities, as self-reported by the patients, were recorded for 2,233 consecutive procedures performed on 2,190 patients and prescribed by 27 physicians between September 2016 and September 2017. Of these procedures, 2,075 had reported clinical outcomes with 97%

adequacy for colonoscopy (n=2,014). Comorbidities were reported in 24% of the performed procedures (n=537, prescribed by 26 physicians). The procedures' comorbidities and clinical outcomes are reported in Table 3 and include constipation, diabetes, IBS, IBD, other gastrointestinal conditions, renal disease, and cardiac conditions (n=2-195 per comorbidity). BP adequacy was >92% among all comorbidities listed, except one. Out of 7 patients with cirrhosis that underwent the high-volume colon irrigation BP during the reported period, 6 had an adequate BP, accounting for 86% adequacy.

Sensitivity to pre-prep regimes

To examine whether pre-BP affects adequacy, we checked for differences in BBPS in a sub-cohort of 281 patients for whom we had self-reporting on their pre-prep compliance. We compared patients that were compliant with physician's pre-prep instructions to patients who did not. Compliance was defined as 2x5 mg bisacodyl (2 tablets twice a day for one day) and 10 tbsp of Magnesium hydroxide (2 tbsp for 5 days). There were no statistical differences (two-tailed T-test, $P<0.05$) between the groups in overall BBPS and BBPS scores per colon segment (Table 4).

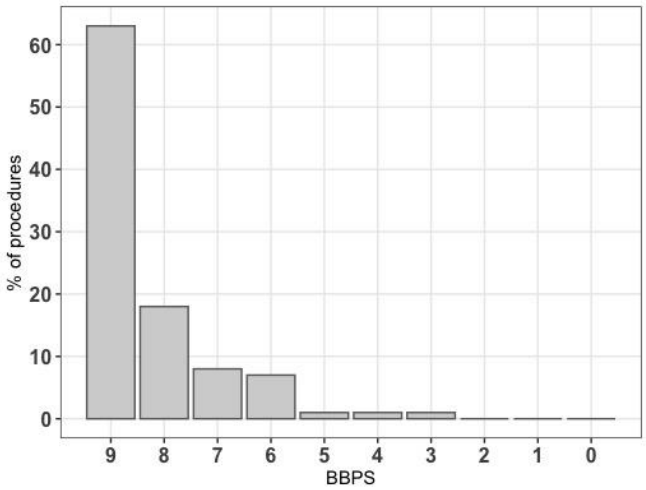


Figure 1 Percent of all procedures performed between 2015 and 2019 according to total Boston bowel prep score (BBPS) (n=7,624).

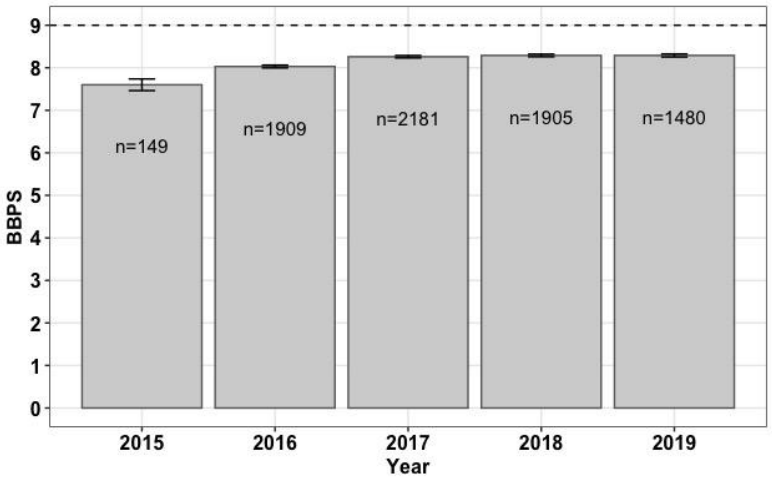
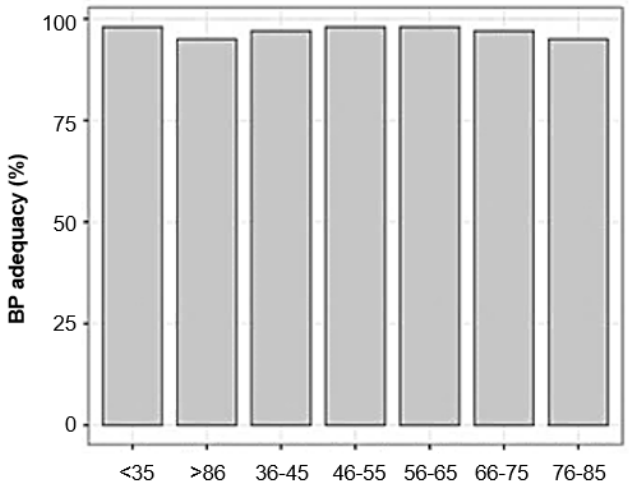


Figure 2 Annual Boston bowel prep score (BBPS) average for 2015-2019 (n=7,624). Bars represent ± SEM (standard error of the mean), the number of high-volume water colon irrigation procedures from each year is noted in the bars. Dashed line at BBPS=9 represents the maximum possible BBPS. Asterisks represent significant difference between annual average BBPS scores (*** $p<0.005$).

a



b

Adequce	100%	97%	98%	97%	97%	94%	97%
% of population	1.3%	4.7%	21.4%	29.6%	33.7%	8.8%	0.6%

Figure 3 Bowel prep adequacy of high-volume water colon irrigation procedures performed between August 2015 and December 2019 divided by age group (for procedures with disclosed age). Adequacy is defined as Boston bowel prep score (BBPS) ≧6, n=6316. a. Represented as a bar graph of adequacy versus age group. b. Represented as a table with all number of patients and adequacy information.

Adenoma and sessile serrated polyps detection rates

A sub-population of 112 average-risk patients, 43% male, 57% female, were analyzed for ADR and SSP detection rates. All patients were scheduled for their first colonoscopy and chose the high-volume colon irrigation for BP, as prescribed by 18 physicians. The physicians in this study prescribed 1-14 procedures, with an average of 6.2±4.7 procedures per physician. All procedures were recorded at 99% adequacy for BP (111 of 112 patients), with an average BBPS of 8.3±1.3. The ADR was 46% on average, 60% in males and 34% in females. The SSP detection rate after high-volume colon irrigation BP was 12.5% (Table 5).

Patient satisfaction

Following their colon irrigation BP, patients were asked to assess their experience and willingness to repeat the procedure for their next colonoscopy. In over 4,500 patients, 99% reported positive responses to all survey questions (Table 6). The average percentage for “definitely agree” for the four post-BP questions was 92.3%. In addition, 3,494 patients responded to the question “For my next colonoscopy, I would choose this BP again”. Of these, 97.3% marked that they “definitely agree” (n=2,888) and “agree” (n=512) to use the high-volume colon irrigation BP for their next colonoscopy. The patients were also asked to rank their willingness to recommend this BP to a friend from 0 to 10, where 10 is the most willing and 0 is not at all willing to recommend (n=2,223 responses). Ranking of 7-to-10 was chosen by 95% of the patients, 4% of the responders ranked the question as 4-to-6, and 1% marked 0-to-3.

Between August 2015 and December 2019, 343 patients who initially chose the high-volume colon irrigation BP selected this BP again for their follow-up colonoscopies (prescribed per medical needs). Approximately 18% of these patients had taken a traditional oral prep prior to past colonoscopies (n=63), before choosing the

high-volume colon irrigation BP. Within the reported period, 90% of the 343 returning patients had done two of these procedures, and 9% had three colonoscopies. One patient had four procedures. Overall, the 343 patients underwent 719 high-volume colon irrigation BPs, of which 343 were naive, and 376 were repeating procedures.

Table 3 Bowel prep adequacy after high-volume colon irrigation procedure in patients with various comorbidities. Adequacy is defined as Boston bowel prep score (BBPS)≧6 .

Comorbidity	Total number of performed procedures	Adequate procedures (% of performed procedures)
Constipation	195	185 (95%)
Diabetes	100	97 (97%)
Irritable bowel syndrome (IBS)	100	98 (98%)
Irritable bowel disease (IBD)/ Crohn's disease / Ulcerative colitis	62	60 (97%)
Other indications	62	57 (97%)
Bladder or pelvic mesh	56	54 (92%)
Severe hemorrhoids	50	48 (96%)
Fissures or rectal fistula	29	29 (100%)
Diarrhea	23	22 (96%)
Intestinal obstruction/stricture	14	14 (100%)
Stroke	13	13 (100%)
Congestive heart failure	10	10 (100%)
Clostridium difficile	10	10 (100%)
Celiac disease	8	8 (100%)
Cirrhosis	7	6 (86%)
Renal insufficiency including dialysis	5	5 (100%)
Carcinoma of the rectum	5	5 (100%)
Intestinal perforation	2	2 (100%)

Table 4 Boston bowel prep score (BBPS) according to pre-prep regime as self-reported by consecutive patients, during July and August 2018 (n=281). The Austin Gastro instructions for colonoscopy patients were to take 2 tablespoons of Magnesium hydroxide for five days and 2X2 5 mg bisacodyl before their colonoscopy. Differences between the compliant and non-compliant groups were measured using a two-tailed T-test, $p<0.05$.

	BBPS all	BBPS left	BBPS transverse	BBPS right
Compliant (n=88)	8.29±1.58	2.82±0.53	2.81±0.51	2.82±0.53
Not compliant (n=193)	8.36±1.50	2.87±0.43	2.87±0.41	2.71±0.54
P (T-test)	0.88	0.56	0.74	0.30

Table 5 Adenomas detection rates (ADR) and detection rates of sessile serrated polyps (SSP) following traditional oral prep or high-volume colon irrigation bowel preparation procedure.

	ADR average	ADR males	ADR females	SSP detection rate
High-volume colon irrigation bowel prep	46%	60%	34%	12.5%
Traditional oral prep	25%	30%	20%	5-7%

Table 6 Analysis of the patient's quality of service survey following the high-volume colon irrigation bowel prep procedure. Results are presented as the percentage of responses. The number of total responses to all four questions was n=4,545.

Patients satisfaction survey questions	**Definitely agree**	**Agree**	**Disagree**	**Definitely disagree**
	Definitely agree + Agree		**Definitely disagree + disagree**	
Check-in was welcoming and efficient	90%	9%	0%	1%
	99%		1%	
Explanation received from my tech about what to expect was clear and to the point	92%	7%	0%	1%
	99%		1%	
Techs were available as needed; adequate privacy was kept	94%	5%	0%	1%
	99%		1%	
Prep room and system were clean to my satisfaction	94%	5%	0%	1%
	99%		1%	

Discussion

In this retrospective clinical study performed on Austin Gastroenterology patients (AG, Austin, TX), we showed that a high-volume colon irrigation BP for colonoscopy is safe and effective. We recorded excellent patient-reported satisfaction rates and no serious adverse events in 8,364 procedures performed on 7,998 patients. Minor AE were reported in 13% of the performed procedures. This number is significantly lower than those reported for high volume polyethylene glycol (PEG) oral prep (adverse events in 90% of patients), low volume PEG plus ascorbate (80%), low volume PEG plus bisacodyl tablet (66%) [41], and sodium phosphate (75%) [42]. The high level of BP adequacy (overall BBPS≥6, 96%) following high-volume colon irrigation BP far exceeds national benchmarking thresholds for quality [15,43]. Adequacy rates remain high even when considering poor BP risk factors, including male gender, advanced age, and underlying health conditions (Figure 3, Table 2). We conclude that the high-volume colon irrigation BP is superior to traditional oral purgative BP that have much lower adequacy rates, reported at ~75% for high volume PEG [44] and ~70% for sodium phosphate [45]. Our results also show that the high-volume colon irrigation BP is agnostic to the patient's age, gender, and comorbidities.

An additional important factor that does not affect the high-volume colonic irrigation efficiency is the ancillary pre-prep regime (Table 4). Before performing the BP, patients are often

prescribed laxatives or stool softeners for a better colon cleansing. Although optimal BP requires patients to adhere to written instructions, patients often do not fully follow these instructions [46]. There is a significant association between compliance with pre-BP instructions and level of education, health literacy, functional status, income, and medication burden. Suboptimal colonic preparation is a significant problem, accounting for a reduced yield of screening colonoscopies and increased healthcare costs because of longer procedure times and aborted procedures. Since the high-volume colon irrigation BP is agnostic to pre-prep regiments (Table 4), we predict that it will reduce the costs and risks related to inadequate BP and ease patient burden.

The ADR is inversely related to the patient's post-colonoscopy CRC risk. SSP are particularly sensitive to inadequate BP due to their subtle morphology and flat appearance, making them difficult to visualize [21]. Improved methods and techniques to increase ADR and SSP detection rates will improve patient care and outcomes [47,48]. The FDA-cleared high-volume colon irrigation BP has excellent BBPS, ADR, and SSP detection rates (Table 5), exceeding the national benchmarks [49]. Thus, using the high-volume colon irrigation BP as an SOC is expected to improve patient care by increasing the detection of neoplastic polyps and reducing the risk for interval CRC.

Our RWE presented here reports on the safety and efficacy of 8,364 high-volume colon irrigation BP. Providing a BP that patients accept and reducing their burden can increase the likelihood that these patients will return for scheduled recommended subsequent colonoscopies [47]. In our data, the patients' responses to the satisfaction survey questions revealed that 99% of 4,545 patients responded positively to the questions, and 97% said that they would choose this BP for their next colonoscopy. Moreover, while the technology has been available to patients for less than five years, 343 Austin Gastroenterology patients chose this BP more than once (and up to four times, for a medically indicated follow-up colonoscopy) despite the out-of-pocket expenses. The out-of-pocket expense by patients was up to $245 per BP. A Monte Carlo simulation previously predicted lifetime savings to the healthcare system of $150M for a cohort of 100,000 average-risk patients over 50 when using the high-volume colon irrigation BP, compared to a traditional oral BP [39]. The model predicted that the high-volume colon irrigation BP is economically preferred when costs are kept under $975, proven safe, and adopted by a large cohort of physicians and patients. Another variable to which the model showed sensitivity was the willingness to pay repeatedly for the prep. The patient's willingness to repeat is demonstrated by the patients' post-procedure questionnaires responses and the 343 patients who already chose this BP method more than once. The predicted high BP tolerance is also expected to reduce the number of canceled colonoscopies [36]. These results have clear direct and indirect cost effects. Our RWE corroborates the Monte Carlo model assumptions and strengthens its prediction that the high-volume BP can lead to significant savings to the healthcare system and that high-volume colon irrigation BP is a dominant BP strategy.

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