Article published online: 2022-07-15

Bowel preparation prior to colonoscopy with a new colonic irrigation device: Results of a prospective observational study

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submitted 4.11.2021
accepted after revision 3.5.2022

Bibliography
Endosc Int Open 2022; 10: E971–E977
DOI 10.1055/a-1858-3728
ISSN 2364-3722
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ABSTRACT

Background and study aims The success of colonoscopy is mainly dependent on the effectiveness of prior bowel preparation (BP). Patients often consider BP to be the most burdensome part of colonoscopy, which might be a main barrier to the procedure. The aim of this study was to evaluate safety and effectiveness of colonic irrigation with a new colon hydrotherapy (CHT) device as an alternative to traditional oral BP.

Patients and methods A prospective, non-randomized observational study was conducted to evaluate the quality of BP. A BP was considered effective if a score of 6 or better through the Boston Bowel Preparation Scale (BBPS) could be reached. Colonoscopy was performed immediately following colonic irrigation. For safety analysis, data on adverse events (AEs) were collected. Among the secondary outcomes, the BBPS assessed in each bowel segment and cecal intubation rate were analyzed.

Results Twenty-eight consecutive patients (11 male [39.3%] and 17 [60.7%] female) undergoing screening/surveillance or diagnostic colonoscopy were enrolled. Mean age was 54 ± 12.4 years (range 19–80). The evaluated mean BBPS was 7.8 ± 1.5. Twenty-five patients (89.3%) had a BBPS score of 6 or above. Colonic irrigation was performed without any complications and no AEs were reported within 30 days. The cecal intubation rate was 100%.

Conclusions Colonic irrigation with a new CHT device is an effective and low-risk alternative to traditional oral preparation prior to colonoscopy.

Introduction

Colonoscopy is a standard method for diagnosing colon disease. According to the guidelines of the European Society of Gastrointestinal Endoscopy (ESGE), an adequate level of cleansing is critical for the efficacy of colonoscopy [1]. ESGE, therefore, proposed that at least 90% of screening examinations should be rated as having "adequate" (Boston Bowel Preparation Score [BBPS] ≥ 6) or better bowel cleansing [2]. Kastenberg et al concluded that the optimal threshold is a total BBPS ≥ 6 and all segment scores ≥ 2, thus combining overall and segmental quality of cleaning, which is regarded as an adequacy standard for 10-year follow-up [3, 4].

BP for patients is challenging, as they need to change their diet and use diarrhea-inducing agents in the day(s) before colonoscopy [1]. Patients often find oral BP unpleasant and uncomfortable due to the unpalatable taste, the large volume of drinking solution, and the side effects of catharsis including nausea, vomiting, and bloating [5], and consider it to be the most bur-

densome part of colonoscopy [6]. Furthermore, the discomfort and inconvenience of oral BP might be the main barrier to colonoscopy and may prevent patients from participating in screening programs [1, 7]. Inadequate preparation can be troublesome for patients and physicians because they must repeat and reschedule bowel cleansing and colonoscopy at another time. That results not only in increased healthcare costs but also shorter colonoscopy surveillance intervals, and may render screening colonoscopy cost-ineffective [1, 7].

Alternatives to oral BP are important, especially if BP by oral ingestion of colon cleansing preparations is not possible for various reasons, such as if patients do not tolerate the side effects of catharsis or want an alternative, because they have experienced oral BP as a burdensome process. Colonic irrigation as an alternative method has been reported and was described as safe, effective and well tolerated. In addition, bowel cleansing quality of colonic irrigation is considered comparable to oral purgative regimes but with less side effects and high patient satisfaction [8–17]. Furthermore, colonic irrigation in the form of colon hydrotherapy is described by Parekh et al. as the "future direction of bowel preparation" [18].

The advantage of colonic irrigation is that there is no unpleasant taste, it avoids the discomfort of long diarrheic episode, and there is no need to drink a large volume of unpalatable purgation fluids. In addition, the patient can undergo the scheduled colonoscopy immediately after going through the preparation by colonic irrigation.

We, therefore, performed an observational study to evaluate the use of colonic irrigation in the form of colon hydrotherapy (CHT) to assess its safety and effectiveness in clinical routine use.

Patients and methods

Setting

All consecutive patients with an indication for colonoscopy who wanted an alternative to standard oral preparation and who consented to the study were recruited from February 2, 2021 to March 24, 2021 at a gastroenterological practice located in Leipzig, Germany. Colonoscopies were performed by certified endoscopists with a minimum of 18 years (median 25.5 years) experience.

Treatment

The Colon Hydromat (manufacturer Herrmann Apparatebau GmbH, Germany), is a CE marked device marketed in Europe that is intended for colon cleansing when medically indicated, such as before colonoscopy. Colonic irrigation with the Colon Hydromat uses constant warm water lavage with a contained temperature and pressure control. The device cleanses the large bowel through a series of fill and empty cycles by hydrating the colon, stimulating peristalsis, and evacuating bowel contents without the use of further chemicals. In addition, by using a complete closed system, the method is discrete and without odor or embarrassment for the patient.

Patients followed a low-residue diet for 3 days. To enhance response to colonic irrigation, patients were instructed to take 5 mg of bisacodyl (Dulcolax, Sanofi-Aventis Deutschland GmbH) at noon and in the afternoon for stool softening [19]. Colonoscopy was performed immediately following colonic irrigation the next day.

BBPS scoring system

The cleanliness score for each bowel segment examined (right colon [RC], transverse colon [TC] and left colon [LC]) was graded by with the BBPS [20]. The BBPS was chosen, as it is the most thoroughly validated scale for assessing colon cleanliness [5, 21], and its use is also recommended by ESGE [2]. A priori, the developers of the BBPS recommended that a score <5 corresponds to inadequate BP [20]. Meanwhile, ESGE has published performance measures for adequate preparation (at least 90 % of BBPS ≥ 6) [2].

Study design

A prospective, single-center, non-randomized observational study was performed to evaluate the performance (effectiveness) and safety of colonic irrigation as a non-oral BP prior colonoscopy during routine clinical use. A total of 28 consecutive patients, seen in routine practice, were part of the study, which was described in accordance with the STROBE (Strengthening the Reporting of Observational studies in Epidemiology) guidelines [22]. The CHT device was used within its intended use.

Patients

The patients were adults who required colonoscopy due to gastrointestinal symptoms and for screening/surveillance who wanted to have an alternative BP method to traditional use of orally taken purgatives. Exclusion criteria were in compliance with the contraindications stated in the instructions for use of the CHT device. Study-specific exclusion criteria were psychiatric conditions and/or inability to provide informed consent, emergency colonoscopy, off-label use, and pregnancy and lactation. Elderly patients and those with medical risk factors for poor BP [9, 23–25] were not excluded.

Ethics

The study was conducted in accordance with the Declaration of Helsinki and the study protocol was advocated by the ethics committee of the Saxonian State Board of Physicians (Sächsische Landesärztekammer, SLAEK, Dresden, Germany; Ref. EK-BR-128/20-1, issued 26th Nov 2020). Patients gave written informed consent prior to the study protocol being implemented and all consented to data collection and publication of their anonymized data.

Outcomes

Performance (effectiveness)

The primary performance endpoint was the quality of bowel cleansing, assessed with the BBPS and rated by the responsible endoscopist.

The hypothesis tested was that colonic irrigation with CHT would achieve a mean BBPS that was comparable to preparation with oral purgatives. Therefore, a mean BBPS score of 6.8

(with a standard deviation of 2.5) was defined to demonstrate that the quality BP of CHT was as good as with oral purgatives.

The main secondary endpoints were BBPS in each bowel segment and runway time (time interval between when the patient's bowel cleaning/colonic irrigation ended and the moment the colonoscope was inserted as well as the cecal intubation rate).

Safety

For safety analysis, device and/or procedure-related adverse events (AEs) within 30 days after the procedure were collected.

Sample size calculation and statistical analysis

The sample size calculation performed was based on the hypothesis. A total of 28 patients were required to achieve statistical significance with a one-sided one-sample *t*-test with a power of 80 % at a significance level of $\alpha = 0.05$.

Data on all planned 28 patients were analyzed. Statistical analyses have been performed using R version 4.0.2. (The R Foundation for Statistical Computing; Vienna, Austria). $P < 0.05$ was considered statistically significant.

Results

Baseline characteristics

Results of all patients were analyzed without missing data. The mean age of the study population was 54 ± 12.4 years (range: 19–80, median 55); 39.3 % were male and 60.7 % were female (▶ **Table 1**). Of the patients, 64.3 % had their first colonoscopy, 28.6 % had already experienced oral BP before colonoscopy, and 7.1 % had a previous colonoscopy with colonic irrigation (CHT) as the BP procedure.

Two patients (7.1 %) had a body mass index (BMI) ≥ 30 kg/m^2. A BMI over 30 is considered obese (WHO definition). Obesity is regarded as a medical risk factor for poor BP [9, 23]. Other known risk factors for poor preparation were diabetes mellitus, irritable bowel disease (IBD), hypothyroidism, and use of tricyclic antidepressants, opioids or calcium antagonists [9, 23–25]. Twelve of patients (42.9 %) had medical risk factors for poor BP (▶ **Table 2**).

▶ **Table 1** Demographics of the study population (N = 28).

Demographic data	Variables	N = 28
Gender		
	▪ Male	11 (39.3 %)
	▪ Female	17 (60.7 %)
Age (years)		
	▪ Mean	54
	▪ SD	12.4
	▪ Min	19
	▪ Median	55
	▪ Max	80
Patients had a previous colonoscopy with oral BP	N (%)	08 (28.6 %)
Patients had a previous colonoscopy with CHT preparation	N (%)	02 (7.1 %)
Patients had their first colonoscopy	N (%)	18 (64.3 %)

SD, standard deviation; BP, bowel preparation; CHT, colon hydrotherapy

▶ **Table 2** Patients with risk factors for a poor preparation (N = 12).

Medical risk factors for a poor BP	N (%)
Diabetes mellitus	1 (3.6 %)
IBD	1 (3.6 %)
Hypothyroidism (full substituted)	5 (17.9 %)
Obesity (defined as BMI ≥ 30 kg/m^2)	2 (7.1 %)
Patient is taking one (or more) of the following drugs: tricyclic antidepressants, opioids or calcium antagonists	3 (10.7)
Patients with risk factors for a poor preparation	12 (42.9 %)

IBD, inflammatory bowel disease; BMI, body mass index.

Modalities

The duration of treatment for an individual patient was the time taken for the colonic irrigation, runway time, the colonoscopy, and corresponding follow-up subsequent to these procedures. Follow up was performed directly at the end of colonic irrigation using patient questionnaires and after colonoscopy by investigator assessment.

The mean duration of colonic irrigation was 60.2 ± 0.94 minutes, 14.8 ± 1.04 cycles and 59 ± 1.72 L of water were used for cleaning the colon.

The mean duration of subsequent colonoscopy was 21.1 ± 2.83 minutes (range: 7 to 15 minutes). Colonoscope withdrawal time from cecum to anus was 10.1 ± 2.22 minutes (range: 8 to 19 min.).

Effectiveness

The mean BBPS score among 28 patients was 7.8 ± 1.5 (minimum 4, maximum 9, median 8). The study, therefore, showed the effectiveness of colonic irrigation with the Colon Hydromat device ($t = 7.55$, $df = 27$, $P < 0.0001$; mean BBPS > 5.6) as the primary endpoint would have failed with an observed mean BBPS < 6.43.

In detail, the distribution of BBPS scores is shown in ▶ **Table 3**.

Twenty-eight colonoscopies evaluating 84 bowel segments were included in the final analysis. Mean segmental BBPS and their distribution are indicated in ▶ **Table 4**. The mean segmental BBPS for RC is 2.4 ± 0.69, for LC 2.7 ± 0.61, and for TC 2.7 ± 0.55.

▶ **Table 3** Distribution of total BBPS scores, mean and median BBPS.

BBPS	N = 28
BBPS 9	11 (39.3 %)
BBPS 8	09 (32.1 %)
BBPS 7	03 (10.7 %)
BBPS 6	02 (7.1 %)
BBPS 5	01 (3.6 %)
BBPS 4	02 (7.1 %)
BBPS ≤ 3	00 (0)
Median BBPS	08
Mean BBPS	07.8
SD	01.5

BBPS, Boston Bowel Preparation Score; SD, standard deviation.

▶ **Table 4** Segmental Boston scores, RC, TC and LC (mean) and their distribution.

Colon segment	Segmental BBPS scores (mean ± SD)	Distribution of BBPS scores (N = 28)
		BBPS 3: 20 (71.4 %)
LC	2.7 ± 0.61	BBPS 2: 7 (25.0 %)
		BBPS 1: 1 (3.6 %)
		BBPS 3: 21 (75.0 %)
TC	2.7 ± 0.55	BBPS 2: 5 (17.9 %)
		BBPS 1: 2 (7.1 %)
		BBPS 3: 14 (50.0 %)
RC	2.4 ± 0.69	BBPS 2: 11 (39.3 %)
		BBPS 1: 3 (10.7 %)

RC, right colon; TC, transverse colon; LC, left colon; BBPS, Boston Bowel Preparation Score.

According to Kastenberg et al., the threshold of an adequate BP is optimal at a total BBPS score ≥ 6 AND ≥ 2 per segment [3]. With regard to segmental BBPS assessed in the three colon regions, RC, LC and TC, adequate preparation was reached in 89.3 % in the RC, 92.9 % in the TC, and 96.4 % in the RC (▶ **Table 5**).

A total BBPS ≥ 6 and all segmental scores ≥ 2 was achieved by 24 of 28 patients (85.7 %); 20 of 24 patients (83.3 %) had "excellent" results, with BBPS ≥ 8 and all segmental scores ≥ 2.

The data also showed that the effect of cleaning was best in the LC, and only one patient (3.6 %) had a BBPS score < 2. The effect of cleaning with colonic irrigation decreased from the LC to the RC. The RC was the most difficult section to clean. Although the majority of patients had a BBPS score ≥ 2 in the RC (89.3 %), more patients than for the other colon segments had a score < 2 (10.7 %). The six inadequately prepared bowel segments were found in only three patients: one patient had a total failure of colon hydrotherapy with inadequately cleaned LC, TC, and RC; one patient had inadequately cleaned RC and TC; and one patient had inadequately cleaned RC only.

Runway time

The runway time evaluated for 28 patients was 43.8 min ± 18.24 minutes (minimum 15 minutes, maximum 80 minutes, median 45 minutes). The time between the end of preparation and colonoscopy (runway time, [18, 26]) influenced the quality of the bowel cleansing. In this study, schedule of preparation and start of colonoscopy was managed so that the time in between did not exceed 1 hour and 20 minutes.

Safety and colonoscopic findings

Colonic irrigation was performed in all 28 patients (100 %) without any complications and no AEs within 30 days after or premature terminations of the procedure were reported. No AEs associated with the colonic irrigation procedure occurred during colonoscopy. In addition, no colonoscopy procedure had to be terminated due to inadequate BP and the cecal intubation rate was 100 %.

In five patients, a total of nine polyps (4 adenomatous and five non-adenomatous) were detected by colonoscopy, which were distributed among the different bowel sections as follows: two of nine polyps were detected in the right colon, two of nine polyps (measuring < 5 mm) in the sigmoid colon, and most of the polyps (five of nine) were detected in the rectum.

▶ **Table 5** BBPS ≥ 2 in colon segments.

RC	N	TC	N	LC	N
Inadequate		**Inadequate**		**Inadequate**	
BBPS < 2	03 (10.7 %)	BBPS < 2	02 (7.1 %)	BBPS < 2	01 (3.6 %)
Adequate		**Adequate**		**Adequate**	
BBPS ≥ 2	25 (89.3 %)	BBPS ≥ 2	26 (92.9 %)	BBPS ≥ 2	27 (96.4 %)

BBPS, Boston Bowel Preparation Score; RC, right colon; TC, transverse colon; LC, left colon.

▶ **Table 6** Segmental and total BBPS scores in comparison to previous studies.

Literature	BBPS of RC	BBPS of TC	BBPS of LC	Total BBPS
Bowel preparation with colonic irrigation (as colon hydrotherapy/CHT):				
Own study data	2.4 ± 0.69	2.7 ± 0.61	2.7 ± 0.55	7.8 ± 1.5
Godell 2021 [32][1]	2.5 ± 0.65	2.74 ± 0.52	2.81 ± 0.46	8.2 ± 1.38
Sportes 2017, CHT group [13]	2.1 ± 0.6	2.6 ± 0.5[2]	2.6 ± 0.5[3]	7.3 ± 1.1
Gagneja 2016 [11]	2.47	2.71	2.78	7.96
Oral bowel preparation:				
Bor 2020[4] [27]	2.67 ± 0.54	2.73 ± 0.46	2.79 ± 0.43	8.19
Haibin 2020[5] [31]	2.04 ± 0.84	2.25 ± 0.68	2.48 ± 0.64	6.77 ± 1.88
Bisschops 2018[6] [28]	2.2 (N2 D) 2.2 (N1 D) 2.0 (2 L PEG)	Data not available	Data not available	6.7 ± 1.22 (N2 D) 6.6 ± 1.46 (N1 D) 6.3 ± 1.25 (2LPEG)
Sportes 2017, PEG group [13]	2.4 ± 0.6	2.5 ± 0.5[12]	2.5 ± 0.6[13]	7.3 ± 1.2
Manes 2014[7] [29]	2.15 ± 0.75 (split-dose) 1.78 ± 0.94 (only 1 dose)	Data not available	Data not available	7.25 ± 1.67 (split-dose) 6.33 ± 2.19 (only 1 dose)

BBPS, Boston Bowel Preparation Score; RC, right colon; TC, transverse colon; LC, left colon; CHT, colon hydrotherapy; PEG, polyethylene glycol.
[1] A retrospective analysis of patients who underwent colonoscopy (preparation with CHT; BBPS recorded for 7624 patients).
[2] Assessed in transverse/ descending colon.
[3] Assessed in sigmoid colon.
[4] Observational study using oral preparation of MCSP.
[5] A retrospective analysis of patients who underwent colonoscopy (preparation with PEG).
[6] MORA study: assessing efficacy, safety and tolerability of oral products (NER1006 (Plenvu, 1 L PEG) N2 D (spit-dose) and N1 D (morning only) versus Moviprep, standard 2 L PEG in adult patients).
[7] A multicenter, randomized, single-blind study using sodium picosulfate plus magnesium citrate (PMC) either in the standard or in split dosing.

Discussion

In this prospective observational study, we were able to show that BP with colon hydrotherapy using the Colon Hydromat device was very comparable to oral preparation procedures and to other devices for colonic irrigation (▶ **Table 6**).

Although multiple society guidelines recommend use of the BBPS [2, 26], it is difficult to compare study results with data in the literature, because often different definitions for "adequate" have been applied. Many studies, especially those conducted outside the EU, did not use the definition for "adequate," as given by ESGE guidelines, which is a BBPS ≥ 6 [2].

With regard to BBPS measurements, total and segmental, the study results are comparable with the results reported from studies using colonic irrigation as well as oral preparation (▶ **Table 6**).

The mean BBPS in our study was 7.8 ± 1.5. Total BBPS scores from other studies using CHT devices for BP vary between 7.3 and 8.2 [13]. In studies using oral BP before colonoscopy, BBPS scores varied depending on which oral agent was used, between 6.3 (2 L polyethylene glycol/Moviprep) and 6.7 ± 1.22 (1L PEG/Plenvue; split-dose) and 8.19 [27, 28], using a split-dose bowel cleansing regimen of magnesium citrate with sodium picosulfate (MCSP).

The mean segmental score for RC was 2.4 ± 0.69, for TC 2.7 ± 0.61 and for LC was 2.7 ± 0.55. In studies using colonic irrigation before colonoscopy, segmental BBPS scores vary, between 2.1 and 2.5 [13, 28–32] for the RC, between 2.6 [13] and 2.74 [32] for the TC, and between 2.6 [13] and 2.81 [32 for the LC. In studies using oral preparation before colonoscopy, segmental BBPS scores vary depending on which oral agent was used, between 2.04 [31] and 2.67 [27] for the RC, between 2.25 [31] and 2.73 [27] for the TC, and between 2.48 [31] and 2.79 [27] for the LC. A segmental BBPS score < 2 for the RC (1.78) was reported by Manes et al. [29] in patients receiving sodium picosulfate plus magnesium citrate (PMC) as standard dose (two sachets taken the day before endoscopy). To summarize, our study shows that BP results with the CHT device used in this study are comparable to results received with oral BP, as well as with colonic irrigation by other CHT devices.

With regard to the performance measures published by ESGE, that at least 90 % of screening examinations should be rated as having "adequate" (BBPS ≥ 6) or better bowel cleansing [2], 89.3 % of colonoscopies in our study were rated "adequate" according to ESGE. Our result, therefore, is in line with the ongoing data collection process of the European Colonoscopy Quality Investigation (ECQI) Group, which aims to document how the ESGE guidelines are considered in daily practice throughout Europe. Data collected between June 2, 2016 and April 30, 2018 showed that adequate BP in this analysis was achieved in 86.96 % of these procedures [30].

Regarding safety issues, there seem to be fewer side effects in patients undergoing CHT compared to oral preparation with cathartics. This is in line with the results of other studies of co-

Ionic irrigation in the form of colon hydrotherapy [8–17, 32]. No AEs were recorded during the present study. All patients (28/28) stated that they felt comfortable and would prefer this method again for their next colonoscopy.

One limitation of the present study is the relatively small number of patients. Although the sample size calculation was based on the hypothesis, more observations are necessary in everyday practice – especially to identify patients with a very good or very bad CHT performance. The CHT runway time of almost three-quarters of an hour might be too long in some endoscopy units that have limited space and personnel capacity. Furthermore, all nurses were well trained and had many years of experience in performing CHT. However, currently there is no reference for how CHT training should be performed and how many CHTs are necessary to obtain good cleaning results. In addition, BBPS was defined by the individual endoscopists but not by central reading. That might have caused performance bias and could have resulted in overestimation of our data.

Conclusions

Colonic irrigation has been shown to be a non-oral alternative to traditional oral BP procedures. Colonic irrigation is an effective and low-risk alternative to oral preparation prior to colonoscopy.

Acknowledgments

The authors are grateful to Sybille Hofmann PhD, Ceres GmbH evaluation & research, Germany for drafting the manuscript and for support in data analysis and interpretation as well as to Emil Boller, Ceres GmbH evaluation & research, Germany for statistical analysis of data. The authors thank Herrmann Apparatebau GmbH for giving the colonic irrigation device to the gastroenterological practice. We thank Ramona Dietel, local study nurse, very much for supporting data obtainment and documentation.

Competing interests

The authors received financial remuneration for all study procedures in accordance with the German tariff for doctors (GOÄ) by Herrmann Apparatebau GmbH, Germany.

Clinical trial

EU Clinical Trials Register
NCT04684082
TRIAL REGISTRATION: prospective trial at https://www.clinicaltrialsregister.eu

Funding

Herrmann Apparatebau GmbH

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