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Single-center experience with intraprocedural cleansing system to improve inadequate bowel preparation during colonoscopy

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ABSTRACT

Inadequate bowel preparation is common despite various preprocedure interventions. There is a need for an intervention at the time of colonoscopy to combat poor preparation. In this retrospective, observational study of 46 patients, we evaluated the clinical efficacy and feasibility of implementing the third generation of the Pure-Vu EVS System, a US Food and Drug Administration-cleared over-the-scope-based intraprocedural cleansing device, into our practice at the Minneapolis VA Medical Center (Minneapolis, Minnesota, United States). To study clinical efficacy, we measured bowel preparation adequacy before and after using the device, as measured by the Boston Bowel Preparation Score, and reviewed colonoscopy surveillance interval recommendations. Technical success and feasibility of using the device were measured by procedure success rates and duration. We found that BBPS scores increased from 4.4 to 7.9 when using the device. Technical success was achieved 78.3% of the time (36/46 cases). Median colonoscopy duration was 46 minutes, although there was a trend toward shorter procedures over time. This is the first clinical evaluation of the third generation of an intraprocedural cleansing device. We found the device efficacious and easy to use with low procedure failure rates, but it does come with a learning curve. We suspect that adoption of this device mutually will benefit patients and health systems with the potential to improve resource utilization.

Introduction

Adequate bowel preparation is essential during colonoscopy for optimal visualization, diagnosis, and treatment. However, inadequate bowel preparation (IBP) is common, predicted to occur in > 25% of cases [1, 2]. Prior research highlights the complexities of predicting which patients will have IBP, identifying contributing risk factors including male gender, older age, medical comorbidities, medications, socioeconomic status, and adherence to bowel preparation, among others [2, 3, 4, 5,

6]. Studies have also evaluated various preprocedural interventions to improve the quality of bowel preparation, such as diet, patient education, timing, and dosing of bowel preparation with variable success [7, 8, 9, 10]. Thus, there is a potential for technology to improve bowel preparation at the time of colonoscopy.

The Pure-Vu EVS System (Motus GI, Israel) is a US Food and Drug Administration-cleared, single-use, over-the-scope-based intraprocedural cleansing device. This system uses high-intensity water and air directed through five irrigation jets to cleanse the bowel and large-caliber suction to remove fecal matter during colonoscopy and leaves the colonoscope working channel free to perform endoscopic interventions. Use of the third generation of the device has not previously been reported. However, prior generations of this device have been studied with good clinical success based on significantly improved Boston Bowel Preparation Score (BBPS) and increase in rates of adequate bowel preparation to ≥ 95% [11, 12, 13, 14]. Subsequent device generations and in particular this newest third generation have focused on improving endoscopist usability and device setup. The third generation of this device is distinctively easier to load, allowing for on-demand use after poor preparation is endoscopically visualized.

This is the first published clinical experience using the third generation of the intraprocedural bowel cleansing device. We sought to assess the feasibility and efficacy of this device in clinical practice to improve bowel preparation at the time of colonoscopy.

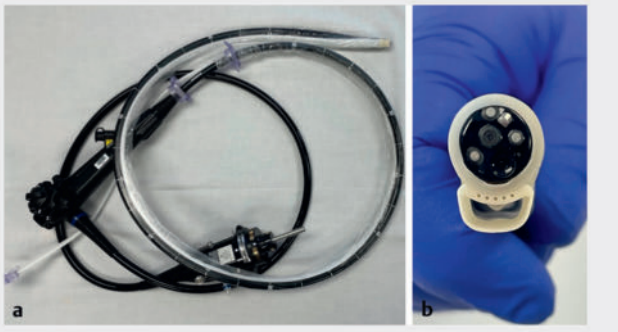
Patients and methods

Study background

We performed a retrospective, observational cohort study assessing the clinical efficacy and technical success of using the Pure-Vu EVS System, an intraprocedural cleansing device, in 46 consecutive patients among five endoscopists at the Minneapolis Veteran Affairs (VA) Medical Center (Minneapolis, Minnesota, United States) in the first 6 months of its use (April to September 2022).

Device information

The intraprocedural cleansing device, Pure-Vu EVS System (Motus GI, Tirat Carmel, Israel), is an over-the-colonoscope-based device including five irrigation jets and a large-caliber suction channel that inhibits use of the colonoscope working channel. The device also has its own workstation console and foot pedals, from which the endoscopist controls the cleanse, suction, and purge functions (▶ **Fig. 1**). The device connects to any manufacturer's standard or pediatric colonoscope with a length of 1630 to 1710 mm and an outer diameter range of 11.7 to 13.7 mm. There are no specialized training certifications required to utilize the device. The Minneapolis VA Medical Center purchased the device prior to the inception of the study.



▶ **Fig. 1** The intraprocedural cleansing system. **a** The device is a single-use, oversleeve-based intraprocedural cleansing system. **b** The five water jets and suction channel on the oversleeve do not obstruct the native colonoscope working channel.

Patient population

The study included all adult patients undergoing colonoscopy in which the intraprocedural cleansing device was used. The device was used preemptively in patients determined to be at risk for IBP or as a rescue method in patients with endoscopic evidence of IBP during their colonoscopy. Patients at risk for IBP were identified based on prior history of IBP or based on their description of their last effluent. Exclusion criteria included patients with severe colitis as per the manufacturer's recommendation. Both inpatients and outpatients were included and procedure indications included diagnostic, screening, and surveillance procedures. Basic patient demographic information and potential contributors to poor bowel preparation including age, gender, comorbidities, non-adherence to bowel preparation, medications, and body mass index were collected.

Procedure

Patients underwent standard bowel preparation with split-dose polyethylene glycol-based regimens and either bisacodyl or magnesium citrate. Patients were sedated either using moderate sedation (typically midazolam and fentanyl) or under monitored anesthesia care. Sedation plans were not altered by use or potential use of the device, but rather, were a result of standard scheduling practices. All procedures were performed with an Olympus CF-HQ190 L Video Colonoscope (Olympus America, Center Valley, Pennsylvania, United States).

In patients with a prior history of IBP or concern for IBP based on their last effluent, the device was preemptively loaded onto the colonoscope prior to the start of the procedure. In patients found to have endoscopic evidence of IBP on initial insertion of the standard colonoscope, the colonoscope was withdrawn and the device was loaded prior to reinsertion. Quality of bowel preparation was measured with the BBPS. [15] Baseline scores for each segment were recorded prior to cleansing with the device, and then scores were reevaluated after device cleansing.

Study outcomes

Clinical efficacy was measured by the quality of the bowel preparation before and after device cleansing per the BBPS, as well as the recommended colonoscopy surveillance interval per United States Multi-Society Task Force on Colorectal Cancer guidelines [16] to determine if patients required short-interval repeat colonoscopy due to IBP. IBP was defined as a total BBPS < 6.

Technical success was defined as reaching the intended anatomical extent (cecum) in addition to a post-cleansing BBPS ≥ 6. Procedure duration was also measured for the purposes of assessing feasibility, defined by the initial time of colonoscope insertion (either the standard colonoscope in rescue cases or the device-loaded colonoscope in preemptive cases) until the time of final colonoscope removal.

Statistical analysis

Data about the BBPS score before and after use of the intraprocedural cleansing system were collected and analyzed for mean and standard deviation values. Median and range of colonoscopy procedure times were determined.

Institutional Review Board statement

The study was reviewed by and approved by the Minneapolis VA IRB Committee.

Results

Patient and procedure background information

Forty-six consecutive patients were included. Baseline characteristics of the patient and their procedures are listed in ▶ **Table 1**. Of the patients, 71.6% (35/46) completed 90% to 100% of the bowel preparation regimen by the time of colonoscopy. Of the procedures, 84.8% (39/46) used moderate sedation, composed of fentanyl and midazolam ± diphenhydramine. The device was used preemptively for patients with concern for IBP in 26 patients (56.5%) and as a rescue method after IBP was endoscopically visualized in 20 patients (43.5%). One endoscopist performed 40 of 46 procedures, with the other four endoscopists performing one to two procedures each. Interventions performed with the device in place include cold snare polypectomy (25 cases for a total of 83 cold snare polypectomies), hot snare polypectomy (2 cases for a total of 2 hot snare polypectomies), cold forceps biopsies (6 cases for a total of 8 cold forceps biopsies), and hemostatic clip placement (3 cases for a total of 3 hemostatic clip placement).

▶ **Table 1** Demographic information for patients included in this study.

Patient and procedure background	
Average age	66 (median 70.5; range 29–86)
Biological sex	45/46 male (91%)
Average BMI	30.5 (median 29.6, range 18.2–45.3)
Colonoscopy setting	41/46 outpatient (89%)
Colonoscopy indications	Surveillance (N = 26) Screening (N = 1) Gastrointestinal symptoms (N = 10) ▪ Abdominal pain (N = 3) ▪ Diarrhea (N = 3) ▪ Hematochezia (N = 4) ▪ Positive FIT test (N = 2) ▪ Anemia (N = 3) ▪ Abnormal imaging (N = 4)
Predicted reasons for poor prep	Poor adherence to bowel preparation regimen Neurologic/cognitive disorders Diabetes mellitus Chronic constipation Many without an identifiable reason

Generally, this was an elderly male population undergoing outpatient colonoscopies, most often for surveillance exams.

Technical success

The overall procedure success rate, defined as achieving a BBPS ≥ 6 while reaching the intended anatomical extent, was 78.3% (36/46 cases). Procedure failures included patient intolerance of the procedure under moderate sedation (N = 2) or for anatomical reasons such as tortuous colon or tight angulation (N = 7) limiting the ability of the colonoscope to reach the cecum, with or without the device. Failures were not device-related but patient-related because the procedures failed both with and without use of the device. When excluding patients in whom the procedure failed due to intolerance or for anatomical reasons, the cecal intubation rate was 100% In only one case was failure due to inability to cleanse the colon of solid stool.

Quality of bowel preparation

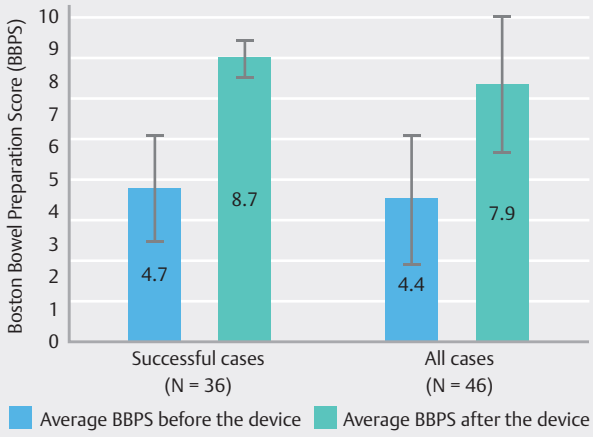
The baseline average BBPS in all cases was 4.4 (SD 1.97). The BBPS improved to 7.9 (SD 2.08) after using the device. After exclusion of the 10 unsuccessful cases, largely related to patient intolerance or anatomic constraints, the mean BBPS improved from 4.7 (SD 1.65) to 8.7 (SD 0.55) (▶ **Fig. 2**). Examples before and after intraprocedural cleansing using the device are shown in ▶ **Fig. 3**.

Recommended surveillance intervals

The improved quality of the bowel preparation afforded the maximum recommended surveillance interval for the next colonoscopy in all 22 successful surveillance exams. Unsuccessful cases required either repeat colonoscopy (4 were recommended to have repeat colonoscopy in 4 months, 2 were recommended to have repeat procedures in ≥ 1 year) or computed tomography colonography follow-up (N = 2). Two patients were not recommended to have repeat colonoscopies: one patient with a sigmoid stricture preventing a safe, successful colonoscopy and another patient who had rectal prolapse that was felt to explain his symptoms.

Average procedure duration over time

The median procedure time was 46 minutes in all cases (range 11:59 to 2:27:00). When used preemptively in successful cases (i. e., the device was loaded on the colonoscope prior to the

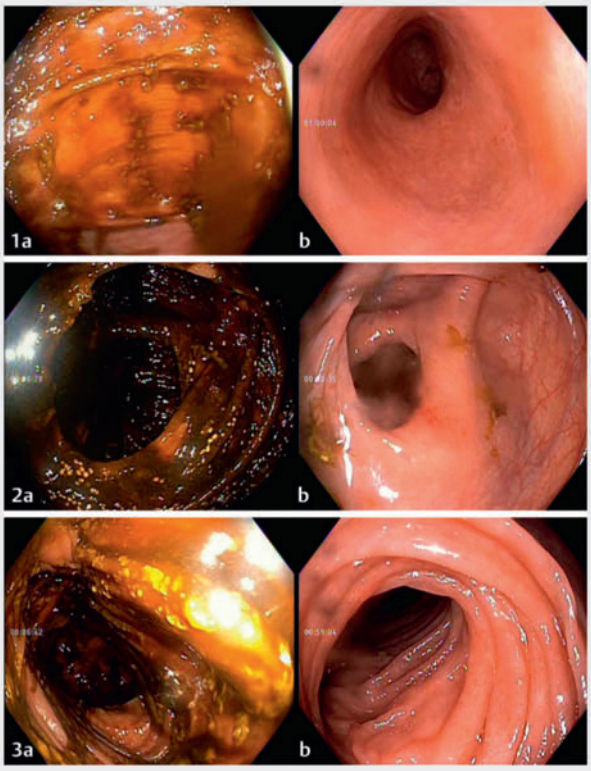


▶ **Fig. 2** Average BBPS scores before (green) and after (blue) use of the intraprocedural cleansing devices for all patients: The left panel shows the BBPS average for all successful cases using the device (N = 36), which are 4.7 (SD 1.65), and 8.7 (SD 0.55), respectively. The right panel shows all cases in which the device was used (N = 46), revealing an average BBPS of 4.4 (SD 1.97) and 7.9 (SD 2.08), respectively. Error bars indicate the standard deviation.

start of the procedure), the median procedure time was 39 minutes (range 11:50 to 1:04:06). In successful cases in which the device was used as rescue therapy after IBP was visualized and which thus required extra time to load the device, the median procedure time was 46 minutes (range 25:53 to 1:16:02) (▶ **Table 2**). This was compared with the median procedure time in all comers of 29 minutes in the 6 months preceding use of the device at our institution. Overall, procedure duration when using the device tended to get shorter over time (▶ **Fig. 4**).

Safety

Two patients sustained minor mucosal injuries during procedures using the device. The injuries did not require any intervention. No serious adverse events (AEs) occurred related to using the device in this study.



▶ **Fig. 3** Endoscopic images **a** before and **b** after use of the intraprocedural cleansing system in the 1) sigmoid colon, 2) cecum, and 3) transverse colon.

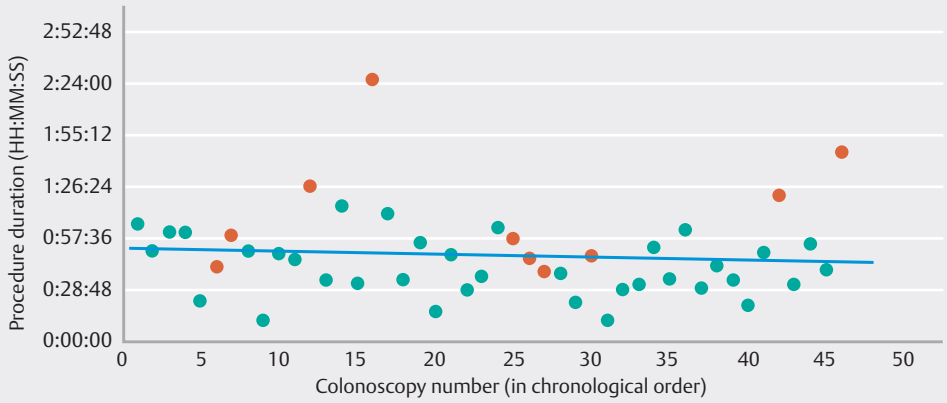
Discussion

This was the first study to evaluate clinical efficacy and technical feasibility of a third-generation intraprocedural bowel cleansing device to improve the rate of IBP. We found this device was effective at improving visualization at time of colonoscopy and feasible to incorporate into our endoscopic practice. Implementation of this device may yield significant benefits by decreasing the rate of IBP, leading to higher-quality colonoscopies with less need for short-interval follow-up procedures.

▶ **Table 2** Procedure duration.

Cases of Interest	Median procedure duration	Range	Interquartile range
All cases (N = 46)	46:18	11:50–2:27:00	32:49–59:51
All successful cases (N = 36)	39:22	11:50–1:16:02	30:45–53:54
Successful cases in which device was used preemptively for presumed IBP	36:27	11:50–1:04:06	27:35–51:57
Successful cases in which the device was used as rescue therapy	46:18	28:53–1:16:02	36:53–1:02:18

Median, range, and interquartile ranges of procedure duration based upon the subset of cases: all successful cases, all cases, successful cases in which the device was preemptively used for presumed IBP, and successful cases in which the device was used as rescue therapy for IBP. Procedure duration was substantially shorter in cases in which the device was used preemptively versus as rescue therapy. All times are listed in MM:SS or HH:MM:SS, as applicable.
IBP, inadequate bowel preparation.



▶ **Fig. 4** Colonoscopy duration using the device over time (all providers; 46 patients): There was an overall trend of decreased procedure duration over time using the intraprocedural cleansing system. Procedure duration was measured from initial insertion time (either of the loaded device or the device-free colonoscope before need for the device was determined) until final removal of the device. The cases in red are the unsuccessful cases.

Clinical efficacy

We found use of the device to be effective in improving endoscopic visualization at time of colonoscopy, as demonstrated by the increase in average BBPS from 4.4 to 7.9. These results are in line with what has been seen in previous studies using earlier generations of the device. One of the largest studies involving a prior generation of this device, the REDUCE study, evaluated device efficacy in 94 inpatients and found that the rate of adequate bowel preparation increased from 38% to 96%, with adequate bowel preparation being defined by a BBPS ≥ 2 in all segments of the colon [14]. Another study of 50 patients found an improvement in median BBPS of 5 to 9 [11]. In another study of similar size, an improvement was noted in mean BBPS of 3.1 to 8.5 [13].

Use of this device also afforded the maximum recommended colonoscopy surveillance interval for all successful screening or surveillance colonoscopies. This serves as a surrogate marker for adequate bowel preparation. The device helped to eliminate the need for a short-interval (≤ 1 year) repeat colonoscopy due to IBP.

Technical success and feasibility

Our technical success, as measured by procedure success rate, was 78.3% (36/46 cases). Failed cases were not felt to be secondary to the device, but rather, patient-related factors with challenging anatomy and difficulty tolerating the procedure under moderate sedation (9/10 failed cases) or poor patient selection in which the device could not clear solid stool in a patient (which the device is not intended to be able to accomplish). While the cecal intubation rate in our cohort appears low, we must take into account that the cecal intubation rate in the poor bowel preparation population is lower [17, 18]. In addition, patients with poor bowel preparation are less likely to tolerate a colonoscopy compared with those with adequate bowel preparation, with longer exams and a higher risk of complications [19]. Therefore, while the goal is to have a cecal intubation rate > 90% in overall colonoscopies and 95% in screening colonoscopies per the United States Multi-Society Task Force on Colorectal Cancer [20], it is not easily achievable in the poor bowel preparation population.

In terms of assessing feasibility, the device did not inhibit our ability to perform a range of therapeutic procedures in this study, including cold and hot snare polypectomies, cold forceps biopsies, and hemostatic clip placement. In addition, although this case was not part of this cohort, hemostatic spray was used with ease while the device was in place [21].

Another important aspect of device feasibility is its effect on procedure time. As can often be expected with implementation of new technology, we observed a longer procedure time when using the device. However, we did note a trend of shorter procedure times over the 6-month period. In addition, our procedures times include the total time from initial scope in to scope out. The times are also inclusive of setup time when the device was implemented after first using a device-free scope and include the time for all therapeutic interventions. Another study showed a median procedure time of 34 minutes using this device but was exclusive of therapeutic maneuvers and setup time [12]. We expect that the total procedure duration at our institution will continue to improve with increased use.

Lastly, the device was easy to implement into our practice. There were no significant technical barriers to using the device. The device requires a single person to set up (although a second person can accelerate the process) and only a few minutes to load the oversleeve system onto the colonoscope.

Safety

The device was safe to use with only two of the patients in this study sustaining mild mucosal injuries. Other studies using previous generations of the device corroborate the low AE rate. A study by Tran et al reported two minor mucosal injuries seen among 40 patients who underwent colonoscopy [13]. Jimenez et al had two minor AEs: one patient with self-limited mucosal

bleeding and another patient with irritable bowel syndrome who had mild post-procedure abdominal pain [11]. Neumann et al reported three mild AEs of fever, abdominal pain, and a hemoglobin drop that were all felt to be unrelated to the device. However, this study noted one case of rectal perforation sustained during rectal retroflexion. Surgical repair was required, and the patient fully recovered [14].

Device versus other options for intraprocedural cleansing

This device provides potential cost savings. Standard lavage can be cumbersome, time-consuming, and costly. Rex et al previously studied the cost and efficiency of IBP, and found that suctioning fluid and washing took up to ~10% of the total examination time and also led to up to a 12% to 22% increase in costs, taking into account the cost of short-interval repeat colonoscopies due to IBP [19]. It is possible that using this device will allow for more robust cleansing and mitigate the need for short-interval repeat colonoscopy, reducing costs. However, this requires further study.

Study limitations

There are some limitations of this study. First, the retrospective cohort design of our study did not allow for a traditional control group. Rather, patients served as their own controls, comparing their bowel preparation before and after using the device. Further, BBPS is traditionally measured only after bowel cleansing is completed. Our use of BBPS in this study was imperfect but it was consistent with the literature and BBPS is an objective validated measure of bowel preparation. Another potential limitation is that most of the procedures (40/46) were completed by one endoscopist, although this arguably could have helped serve as a control. Lastly, more patients should be included in future studies to provide more data about the risk of AEs such as perforation.

Conclusions

This was the first clinical evaluation of the third-generation intraprocedural cleansing system in adults with IBP undergoing colonoscopy for a variety of indications in both inpatient and outpatient settings. The device is easy to use and implement but does come with a learning curve. The potential for increased surveillance intervals, improved resource utilization, and a better patient experience are important considerations when evaluating the utility of the device for improving bowel preparation.

Conflict of Interest

Dr. Brian Hanson is a consultant for MotusGI. MotusGI did not play a role in the study design, collection, analysis/interpretation of data, or writing of the report. The remaining authors have no conflicts of interest to declare.

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