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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.

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1 A Single-Center Experience with an Intraprocedural Cleansing System to Improve
2 Inadequate Bowel Preparation During Colonoscopy

3

4 **Introduction**

5 Adequate bowel preparation is essential during colonoscopy for optimal
6 visualization, diagnosis, and treatment. However, inadequate bowel preparation (IBP) is
7 common, predicted to be >25%.[1, 2] Prior research highlights the complexities of
8 predicting which patients will have IBP, identifying contributing risk factors including
9 male gender, older age, medical comorbidities, medications, socioeconomic status, and
10 adherence to bowel preparation, among others.[2-6] Studies have also evaluated
11 various preprocedural interventions to improve the quality of bowel preparation such as
12 diet, patient education, timing, and dosing of bowel preparation with variable success.[7-
13 10] Thus, there is a potential for technology to improve bowel preparation at the time of
14 colonoscopy.

15 The Pure-Vu EVS System (Motus GI, Israel) is an FDA-cleared, single-use, over-
16 the-scope-based intraprocedural cleansing device. This system uses high-intensity
17 water and air directed through five irrigation jets to cleanse the bowel and large-caliber
18 suction to remove fecal matter during colonoscopy and leaves the colonoscope working
19 channel free to perform endoscopic interventions. Use of the third generation of the
20 device has not previously been reported. However, prior generations of this device have
21 been studied with good clinical success based on significantly improved Boston Bowel
22 Preparation Score (BBPS) and rates of adequate bowel preparation to $\geq 95\%$.[11-14]
23 Subsequent generations and in particular this newest third generation have focused on

24 improving endoscopist usability and device setup. The third generation of this device is
25 distinctively easier to load, allowing for an on-demand use after a poor preparation is
26 endoscopically visualized.

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

32 **Methods**

33 *Study Background*

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

40 *Device Information*

41 The intraprocedural cleansing device, Pure-Vu EVS System (Motus GI, Tirat
42 Carmel, Israel), is an over-the-colonoscopy-based device including five irrigation jets
43 and a large caliber suction channel that does inhibit the use of the colonoscopy's
44 working channel. The device also has its own workstation console and foot pedals, from
45 which the endoscopist controls the cleanse, suction, and purge functions (*Figure 1*). The
46 device connects to any manufacturer's standard or pediatric colonoscopy with a length

47 of 1630-1710 mm and an outer diameter range of 11.7-13.7 mm. There are no
48 specialized training certifications required to utilize the device. The Minneapolis VA
49 Medical Center purchased the device prior to the inception of the study.

50

51 *Patient Population*

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

63

64 *Procedure*

65 Patients underwent standard bowel preparation with split-dosed polyethylene
66 glycol-based regimens and either bisacodyl or magnesium citrate. Patients were
67 sedated either using moderate sedation (typically midazolam and fentanyl) or under
68 monitored anesthesia care (MAC). Sedation plans were not altered by the use or
69 potential use of the device but rather a product of standard scheduling practices. All

70 procedures were performed with an Olympus CF-HQ190L Video Colonoscope
71 (Olympus America, Center Valley, PA).

72 In patients with a prior history of IBP or concern for IBP based on their last
73 effluent, the device was pre-emptively loaded onto the colonoscope prior to the start of
74 the procedure. In patients found to have endoscopic evidence of IBP initial insertion of
75 the standard colonoscope, the colonoscope was withdrawn and the device was loaded
76 prior to re-insertion. The quality of bowel preparation was measured by the Boston
77 Bowel Preparation Score (BBPS).[15] Baseline scores of each segment were recorded
78 prior to cleansing with the device, and then scores were re-evaluated after device
79 cleansing occurred.

81 *Study Outcomes*

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

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

92

93 *Statistical Analysis*

94 Data on the BBPS score before and after using the intraprocedural cleansing
95 system was collected and analyzed for the mean and standard deviation values. Median
96 and range of the colonoscopy procedure times were determined.

97

98 *Institutional Review Board Statement*

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

101

102 **Results**

103 *Patient and Procedure Background Information*

104 Forty-six consecutive patients were included. The baseline characteristics of the
105 patient and their procedures are included in *Table 1*. 71.6% (35/46) of patients
106 completed 90-100% of the bowel preparation regimen by the time of the colonoscopy.
107 84.8% (39/46) of procedures used moderate sedation, comprised of fentanyl and
108 midazolam \pm diphenhydramine. The device was used pre-emptively for patients with
109 concern for IBP in 26 patients (56.5%) and as a rescue method after IBP was
110 endoscopically visualized in 20 patients (43.5%). One endoscopist performed 40/46
111 procedures, with the other four endoscopists performing 1-2 procedures each.
112 Interventions performed with the device in place include cold snare polypectomy (25
113 cases for a total of 83 cold snare polypectomies), hot snare polypectomy (2 cases for a
114 total of 2 hot snare polypectomies), cold forceps biopsies (6 cases for a total of 8 cold

115 forceps biopsies), and hemostatic clip placement (3 cases for a total of 3 hemostatic clip
116 placement).

117

118 *Technical Success*

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

128

129 *Quality of Bowel Preparation*

130 The baseline average BBPS in all cases was 4.4 (SD 1.97). The BBPS improved
131 to 7.9 (SD 2.08) after using the device. When removing the 10 unsuccessful cases,
132 largely related to patient intolerance or anatomic constraints, the mean BBPS improved
133 from 4.7 (SD 1.65) to 8.7 (SD 0.55) (*Figure 2*). Examples before and after
134 intraprocedural cleansing using the device are shown in *Figure 3*.

135

136 *Recommended Surveillance Intervals*

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

145 146 *Average Procedure Duration Over Time*

147 The median procedure time was 46 minutes in all cases (range 11:59 – 2:27:00).
148 When used pre-emptively in successful cases (i.e., the device was loaded on the
149 colonoscope prior to the start of the procedure), the median procedure time was 39
150 minutes (range 11:50 – 1:04:06). In successful cases where the device was used as a
151 rescue therapy after IBP was visualized and thus required extra time to load the device,
152 the median procedure time was 46 minutes (range 25:53 – 1:16:02) (*Table 2*). This is
153 compared to the median procedure time in all comers of 29 minutes in the six months
154 preceding the use of the device at our institution. Overall, procedure duration when
155 using the device tended to get shorter over time (*Figure 4*).

156 157 *Safety*

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

161

162 **Discussion**

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

169

170 *Clinical Efficacy*

171 We found the use of the device to be effective in improving endoscopic
172 visualization at the time of colonoscopy, as demonstrated by the increase in average
173 BBPS from 4.4 to 7.9. These results are in line with what has been seen in previous
174 studies using earlier generations of the device. One of the largest studies involving a
175 prior generation of this device, the REDUCE study, evaluated the efficacy of the device
176 in 94 inpatients and found that the rate of adequate bowel preparation increased from
177 38% to 96%, with adequate bowel preparation being defined by a BBPS ≥ 2 in all
178 segments of the colon.[14] Another study of 50 patients found an improvement in
179 median BBPS of 5 to 9.[11] In another study of similar size there was a noted an
180 improvement in mean BBPS of 3.1 to 8.5.[13]

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

185

186 *Technical Success and Feasibility*

187 Our technical success, as measured by procedural success rate, was 78.3%
188 (36/46 cases). Failed cases were not felt to be secondary to the device, but rather
189 patient-related factors with challenging anatomy and difficulty tolerating the procedure
190 under moderate sedation (9/10 failed cases) or poor patient selection where the device
191 could not clear solid stool in a patient (which the device is not intended to be able to
192 accomplish). While the cecal intubation rate in our cohort appears low, we must take
193 into account that the cecal intubation rate in the poor bowel preparation population is
194 lower.[18, 19] Additionally, patients with poor bowel preparation are less likely to
195 tolerate a colonoscopy compared to those with adequate bowel preparation with longer
196 exams and a higher risk of complications.[17] Therefore, while the goal is to have a
197 cecal intubation rate of greater than 90% in overall colonoscopies and 95% in screening
198 colonoscopies per the United States Multi-Society Task Force on Colorectal Cancer[20],
199 it is not easily achievable in the poor bowel preparation population.

200 In terms of assessing feasibility, the device did not inhibit our ability to perform a
201 range of therapeutic procedures in this study, including cold and hot snare
202 polypectomies, cold forceps biopsies, and hemostatic clip placement. Additionally, while

203 this case was not part of this cohort, hemostatic spray was used with ease while the
204 device was in place.[21]

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

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

219 *Safety*

220 The device was safe to use with only two of the patients in this study sustaining
221 mild mucosal injuries. Other studies using previous generations of the device
222 corroborate the low adverse event rate. A study by Tran *et al* reported two minor
223 mucosal injuries seen among 40 patients who underwent colonoscopy.[13] Jimenez *et*
224 *al* had two minor adverse events: one patient with self-limited mucosal bleeding and
225 another patient with irritable bowel syndrome who had mild post-procedural abdominal

226 pain.[11] Neumann *et al* reported three mild adverse events of fever, abdominal pain,
227 and a hemoglobin drop that were all felt to be unrelated to the device. However, this
228 study noted one case of rectal perforation sustained during rectal retroflexion. Surgical
229 repair was required, and the patient fully recovered.[14]

230

231 *Device Versus Other Options for Intraprocedural Cleansing*

232 This device provides potential cost savings. Standard lavage can be
233 cumbersome, time-consuming, and costly. Rex *et al* previously studied the cost and
234 efficiency of IBP, and found that suctioning fluid and washing took up to ~10% of the
235 total examination time and also led to up to a 12-22% increase in costs, taking into
236 account the cost of short-interval repeat colonoscopies due to IBP.[17] It is possible that
237 using this device will allow for more robust cleansing and mitigate the need for short
238 interval repeat colonoscopy reducing costs. However, this requires further study.

239

240 *Study Limitations*

241 There are some limitations of this study. First, the retrospective cohort design of
242 our study does not allow for a traditional control group. Rather, patients serve as their
243 own controls comparing their bowel preparation before and after using the device.
244 Further, BBPS is traditionally measured only after bowel cleansing is completed. Our
245 use of BBPS in this study is imperfect but it is consistent with the literature and BBPS is
246 an objective validated measure of bowel preparation. Another potential limitation is that
247 most of the procedures (40/46) were completed by one endoscopist, although this
248 arguably could have helped serve as a control. Lastly, more patients should be included

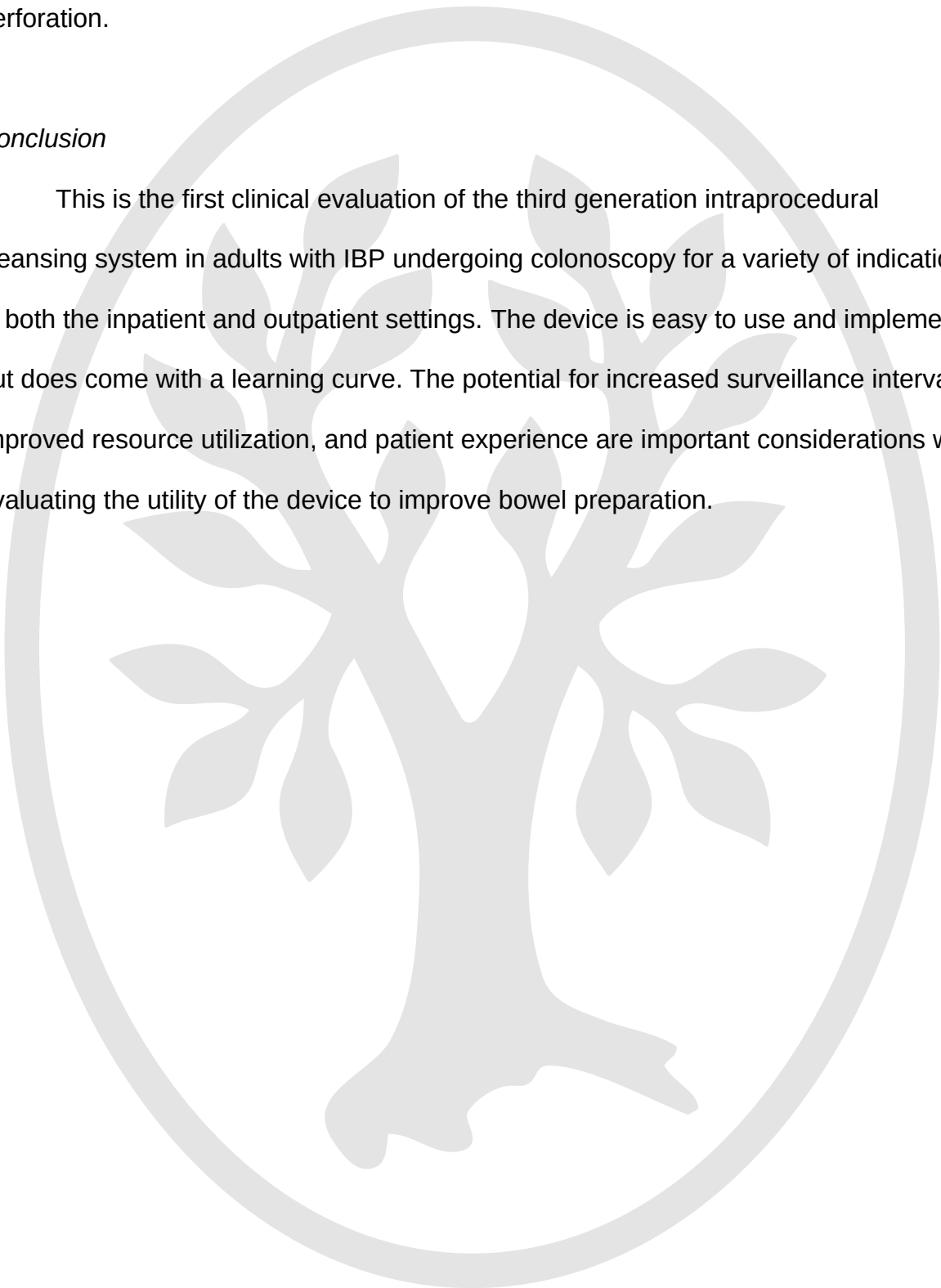
249 in future studies to provide more data on the risk of adverse outcomes such as
250 perforation.

251

252 *Conclusion*

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

259



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- 323

324

325 **Figure Legends**

<p>Figure 1</p>	<p>The intraprocedural cleansing system: The device is a single-use, oversleeve-based intraprocedural cleansing system (A). The five water jets and suction channel on the oversleeve do not obstruct the native colonoscope's working channel (B).</p>
<p>Table 1</p>	<p>Demographic Information: Table 1 reviews the demographic information for the 46 patients included in this study. Generally, this was elderly, male population undergoing outpatient colonoscopies most often for surveillance exams.</p>
<p>Figure 2</p>	<p>Average BBPS scores before (<i>green</i>) and after (<i>blue</i>) use of the intraprocedural cleansing devices for all patients: The left 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 using the device (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.</p>
<p>Figure 3</p>	<p>Endoscopic images before (a) and after (b) use of the intraprocedural cleansing system in the 1) sigmoid colon, 2) cecum, 3) transverse colon.</p>
<p>Table 2</p>	<p>Procedure Duration: The median, range, and interquartile ranges of procedure duration based upon the subset of cases: all successful cases, all cases, successful cases where the device was preemptively used for presumed IBP, and successful cases where</p>

	<p>the device was used as rescue therapy for IBP. There was a substantially shorter procedure duration for cases where the device was used pre-emptively versus as a rescue therapy. All times are listed in MM:SS or HH:MM:SS, as applicable.</p>
Figure 4	<p>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 the final removal of the device. The cases in red are the unsuccessful cases.</p>

326

327

328 **Table 1: Demographic Information**

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%)
Indications for Colonoscopy	<ul style="list-style-type: none"> • Surveillance (N=26) • Screening (N=1) • GI symptoms (N=10) <ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Poor adherence to bowel preparation regimen • Neurologic/cognitive disorders • Diabetes mellitus • Chronic constipation • Many without an identifiable reason

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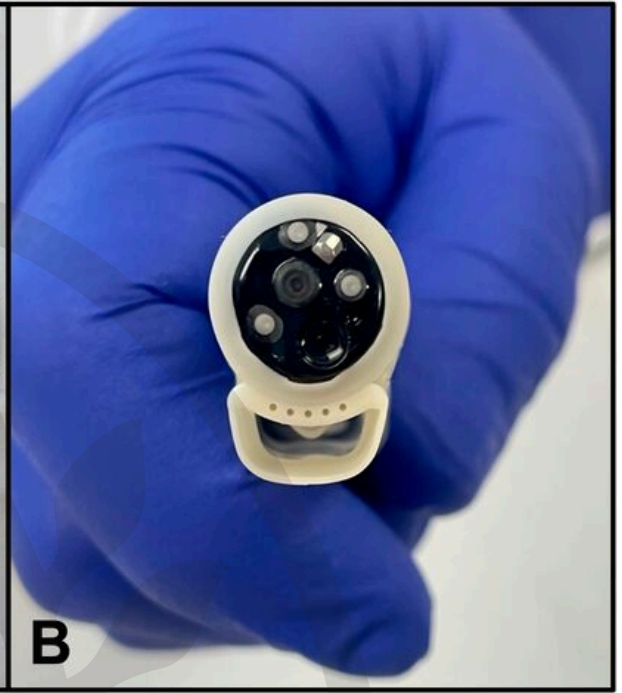
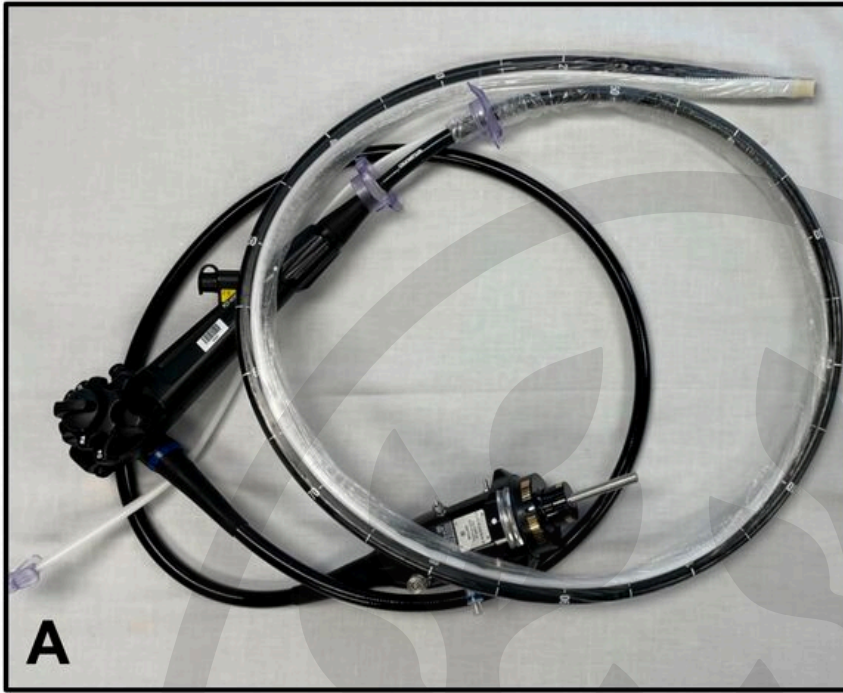
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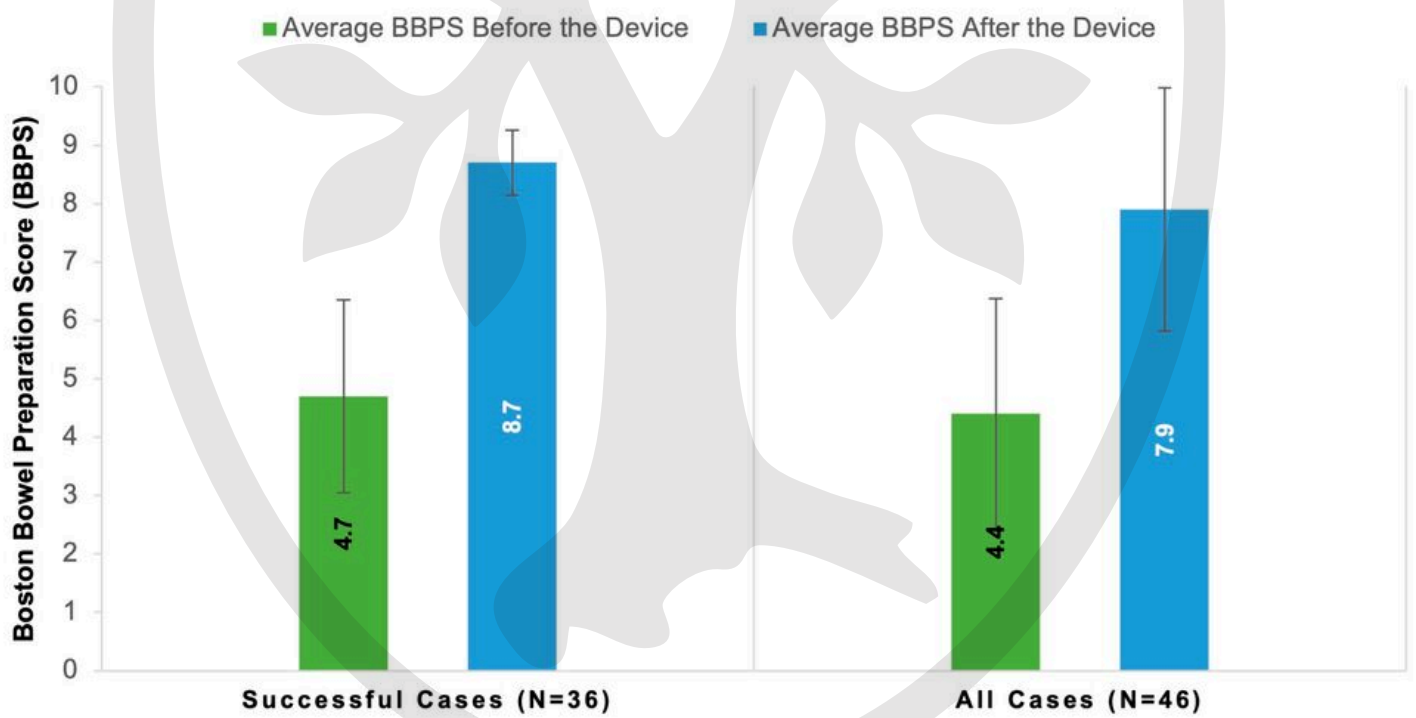
333 **Table 2: Procedure Duration**

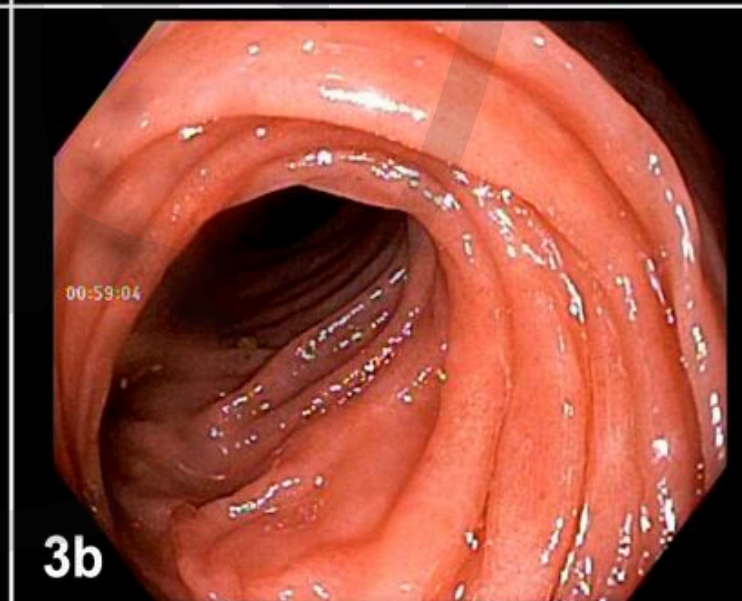
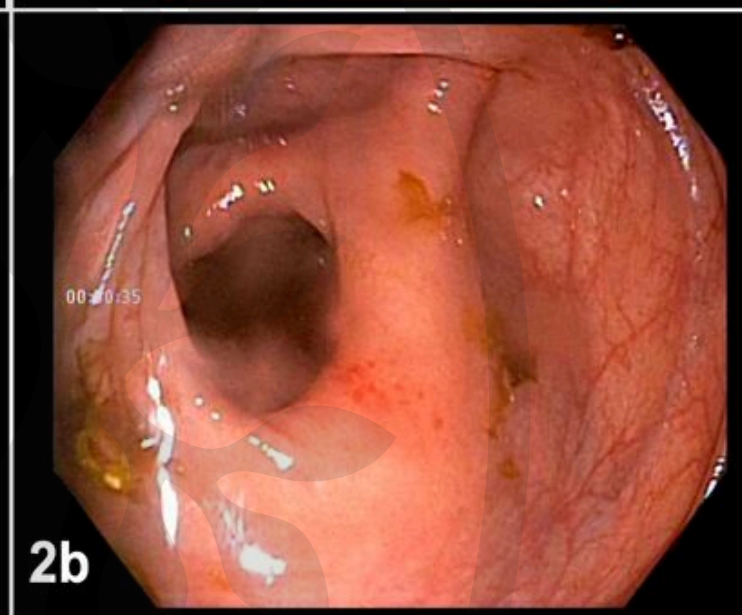
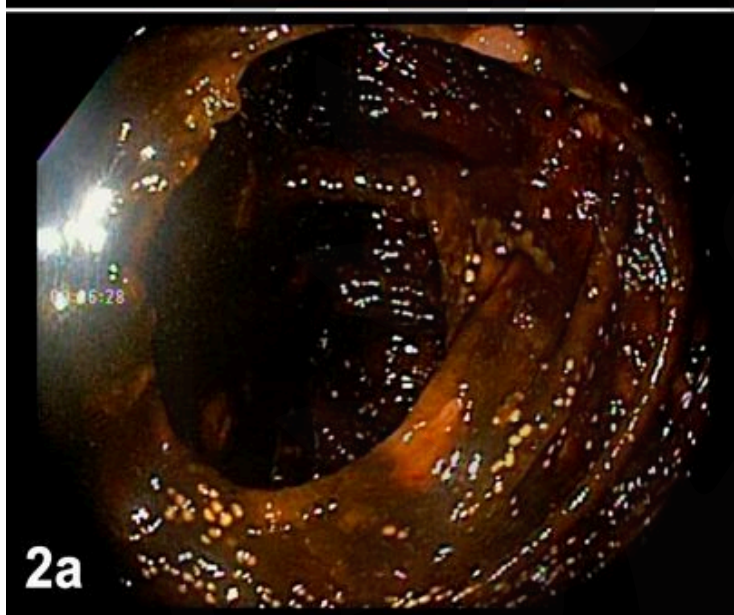
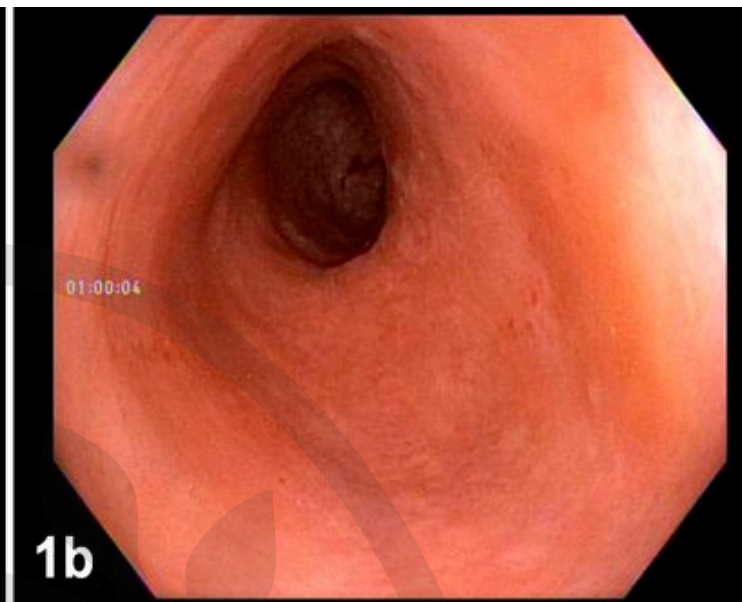
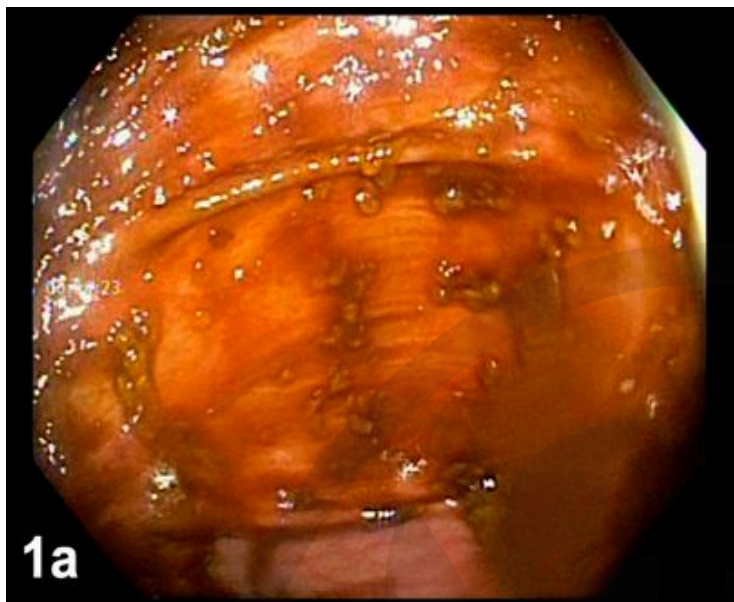
Cases of Interest	Median Procedure Duration	Range	Interquartile Range
All cases (N=46)	46:18	11:50 - 2:27:00	32:49 - 59:51
All successful cases (N=36)	39:22	11:50 - 1:16:02	30:45 - 53:54
Successful cases where device was used pre- emptively for presumed IBP	36:27	11:50 - 1:04:06	27:35 - 51:57
Successful cases where the device was used as a rescue therapy	46:18	28:53 - 1:16:02	36:53 - 1:02:18

334 Procedure Duration: The median, range, and interquartile ranges of procedure duration
 335 based upon the subset of cases: all successful cases, all cases, successful cases
 336 where the device was preemptively used for presumed IBP, and successful cases
 337 where the device was used as rescue therapy for IBP. There was a substantially
 338 shorter procedure duration for cases where the device was used pre-emptively versus
 339 as a rescue therapy. All times are listed in MM:SS or HH:MM:SS, as applicable.



Average BBPS Before and After Device Use





Colonoscopy Duration Using the Device Over Time (All Endoscopists, N=46)

