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A novel device for intracolonoscopy cleansing of inadequately prepared colonoscopy patients: a feasibility study

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Appendix e1
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ABSTRACT

Background The importance of high quality preprocedural bowel preparation is widely acknowledged, but suboptimal bowel cleansing still occurs in up to 20 % of all colonoscopy patients. The aim of this study was to evaluate the performance of a novel intraprocedural cleaning device for cleaning poorly prepared colons.

Methods This multicenter feasibility study included patients aged 18 – 75 years who were referred for colonoscopy. Intraprocedural cleaning was performed in patients after a limited preprocedural bowel preparation regimen (2 days of dietary restrictions and 2 × 10 mg bisacodyl). The primary outcome was the proportion of adequately prepared patients (Boston Bowel Preparation scale [BBPS] ≥ 2 in each segment) before and after segmental washing with the new device. Secondary outcomes included: cecal intubation rate, procedure time, system usability, patient satisfaction, and safety.

Results 47 patients (42.6 % male), with a median age of 61 years (interquartile range [IQR] 46 – 67 years), were included at three clinical sites. Cecal intubation was achieved in 46/47 patients (97.9 %). The cleaning device significantly improved the proportion of patients with adequate bowel cleansing (from 19.1 % to 97.9 %; $P < 0.001$) and median BBPS score (from 3.0 [IQR 0.0 – 5.0] to 9.0 [IQR 8.0 – 9.0]). Median cecal intubation time and total procedure time were 16.5 minutes (IQR 9.0–28.3) and 34.0 minutes (IQR 25.0 – 42.8), respectively. Physicians were satisfied with the ease of use of the device and it was well tolerated by patients. No severe adverse events occurred during the study period.

Conclusions This feasibility study suggests that the intraprocedural cleaning device appears to be safe and effective in cleaning poorly prepared colons to an adequate level, allowing a thorough colorectal examination.

Clinical.Trials.gov
NCT03026075
TRIAL REGISTRATION: Single-arm, international, multicenter study NCT03026075 at clinicaltrials.gov

Introduction

Colonoscopy is an endoscopic procedure for the detection and treatment of colon disorders, and is currently the gold standard for screening and surveillance of colorectal cancer [1]. It is widely acknowledged that the efficacy of colonoscopy depends on the quality of preprocedural bowel preparation [2]. Suboptimal bowel preparation limits visualization within the colon and is associated with missed (pre-) cancerous lesions, lower cecal intubation rates, longer procedure times, and shorter surveillance intervals [3 – 7]. Furthermore, insufficient bowel preparation increases the need for repeat examinations, which ultimately increases healthcare costs and patient burden in terms of (pre-) procedural-related risks and disruption of daily routines [8 – 10]. Despite the variety of bowel cleansing agents available, suboptimal bowel preparation still occurs in up to 20 % of all colonoscopy procedures [11 – 15].

The quality of colon preparation is affected by multiple patient-related (compliance, comorbidities, socio-economic status) and center-related (scheduling, quality of instructions, type of purgative) factors [16]. Some of these variables can be modified whereas others cannot. Patient adherence to the bowel preparation instructions is considered the most important determinant of bowel cleansing quality, but compliance is difficult to improve because of the unpleasant taste and significant side effects produced by the large volumes of purgative that patients are required to take. In addition, some patient-related factors associated with suboptimal bowel cleansing cannot be controlled, such as older age, diabetes, chronic obstipation, poor general physical condition, polypharmacy, and previous intra-abdominal or pelvic surgery [13 – 18]. Negative colonoscopy outcomes and patient burden associated with repeat examinations emphasize the need for a new method to clean the colon that can overcome poor therapy adherence and uncontrollable patient-related factors.

A novel device, the Pure-Vu System (Motus GI, Tirat Carmel, Israel), which has been developed to facilitate intraprocedural bowel cleaning in poorly prepared colons, has recently been introduced. Pure-Vu could potentially improve overall colonoscopy outcomes and might reduce the need for rigorous preprocedural bowel preparation. The aim of this multicenter feasibility study was to evaluate the performance of the Pure-Vu in cleaning poorly prepared colons.

Methods

Study design

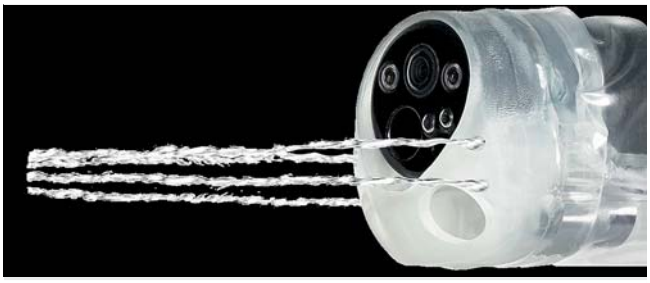
We performed a single-arm, international, multicenter study to evaluate the performance and safety of the Pure-Vu system. The study protocol was approved by the local ethics committees of all centers. An independent monitor was assigned to review all trial data, and an independent data and safety monitoring board reviewed all adverse events. The study was performed in compliance with the Declaration of Helsinki and registered at ClinicalTrials.gov (NCT03026075).

Study population

Study patients aged 18 – 75 years who had been referred for screening, diagnostic or surveillance colonoscopy were recruited from three tertiary care endoscopy departments (Erasmus University Medical Center, Rotterdam, the Netherlands; Radboud University Medical Center, Nijmegen, the Netherlands; University Hospital of Mainz, Mainz, Germany). Exclusion criteria were as follows: inflammatory bowel disease, diverticulitis or prior incomplete colonoscopy due to diverticular disease, previous colorectal surgery, colonic obstruction, toxic mega colon, coagulopathy, lower gastrointestinal bleeding with hemodynamic instability, renal insufficiency (creatinine ≥ 1.5 mg/dL), abnormal liver enzymes (alanine aminotransferase/aspartate aminotransferase ≥ 2 times upper limit of normal), American Society of Anesthesiologists classification score > 3, body mass index < 18.5 or > 35, pregnancy or lactating, and inability to provide informed consent. Written, informed consent was obtained from all study patients before study commencement.

Pure-Vu System

The Pure-Vu System is a US Food and Drug Administration-approved device designed to improve visualization in an inadequately prepared colon by facilitating intraprocedural bowel cleaning (▶ **Fig. 1**) [19]. The Pure-Vu System consists of a disposable over-sleeve and a workstation controller. The disposable over-sleeve fits over conventional colonoscopes (maximum outer diameter of 21.2 mm). The workstation controls an irrigation technology that creates a pulsed mixture of saline (0.9 % sodium chloride or water) and air via four jets to wash the colon, and an evacuation mechanism that is active during the cleansing but can also be used independently to evacuate all stool and fluids. The maximal air and water pressure during bowel cleansing with the Pure-Vu is 1.55 Bar (23 PSI) with flows up to 1350 mL/min and 3.5 Bar (52 PSI) with flows up to 650 mL/min, respectively. In addition, the evacuation system has an auto purge function to prevent clogging of the system. Foot pedals are used to switch between cleaning and evacuation modes. Cleaning with the Pure-Vu can be conducted by the endoscopist without the need for additional assistance, and the external attachment allows for simultaneous use of diagnostic/therapeutic devices via the working channel. For more information about the Pure-Vu System, see Gross et al. [19].



▶ **Fig. 1** Head of the Pure-Vu System (Motus GI, Tirat Carmel, Israel). Source: Motus GI

Study procedures

Bowel preparation

Instructions regarding bowel preparation were provided by a research assistant and all study patients received a paper copy of all study instructions. Bowel preparation was limited to a low-residue diet starting 2 days before the procedure (no dried fruits, seeds, nuts or vegetables), a clear liquid diet 24 hours prior to the procedure, and a split dose of 2 × 10 mg bisacodyl. More details about the bowel preparation instructions received by patients are shown in ▶ **Appendix e1** (available online).

Endoscopists

At each study site, one experienced endoscopist performed all study procedures (H.N., M.C.W.S, P.D.S). Each of the participating endoscopists had previous experience with the Pure-Vu System in porcine models [19]. Additional training regarding the use of the Pure-Vu System and application of the Boston Bowel Preparation Scale (BBPS) was provided before study commencement [20].

Endoscopic procedure

Anesthesia providers administered deep sedation with propofol in all study patients. Study procedures were performed with either a Pentax EC38-i10L (Pentax Medical, Tokyo, Japan) or Olympus CF HQ190L (Olympus Corp., Tokyo, Jaoan) colonoscope with the Pure-Vu device attached. Simultaneous use of advanced imaging techniques was allowed. Time to reach the cecum was recorded as the cecal intubation time. The success of cecal intubation was verified by identification of the usual anatomic landmarks: the appendiceal orifice and ileocecal valve. Endoscopists evaluated the level of bowel cleansing before and after segmental washing with the Pure-Vu using the BBPS scoring system [20]. Washing was performed during insertion and/or withdrawal depending on the preference of the endoscopist. Location, size, and morphologic appearance of all colon lesions were documented, and all polyps detected and removed were sent for histologic examination [21]. Diagnostic and therapeutic interventions were performed with the Pure-Vu attached. All study procedures were video recorded, and procedure times were measured using a stopwatch. The time required for diagnostic/therapeutic interventions (e.g. biopsies/polypectomies) was subtracted from the total procedure time.

Follow-up

Telephone follow-up of patients was performed by a research assistant at 48 hours and 14 days after the procedure to evaluate possible delayed adverse events.

Outcomes

The primary outcome was the proportion of adequately prepared colonoscopy patients before and after segmental washing using the Pure-Vu System. Adequate bowel cleansing was defined as a BBPS score ≥ 2 in all three colon segments and was assessed by the performing endoscopist [20]. Secondary outcome measures included: cecal intubation rate, procedure times, Pure-Vu System usability, patient satisfaction, and adverse events. Usability of the Pure-Vu System and patient satisfaction were evaluated by self-constructed questionnaires after each study procedure. Endoscopists were asked to grade the usability of the Pure-Vu System on a 5-point scale: 1 = unacceptable, 2 = difficult, 3 = acceptable, 4 = good (as good as conventional colonoscopy), and 5 = excellent. Procedure times did not include time required for assembling the device, sedation or interventions.

Statistical methods

Data on demographic and baseline characteristics were summarized for continuous variables by mean and SD (normal distribution) or by median and interquartile range (IQR; non-normal distribution). Counts and percentages were calculated for categorical variables and outcomes. Intention-to-treat analyses were performed for all study outcomes. The McNemar test was used to compare proportions of adequate bowel cleansing before and after cleaning with the Pure-Vu. In secondary analysis, the learning curve of the Pure-Vu was assessed by excluding the first three study patients of each endoscopist and compared using a Mann–Whitney *U* test. All statistical analyses were performed with IBM SPSS 22 (IBM Corp., Armonk, New York, USA).

Estimated sample size

Based on previous studies using the same bowel cleansing preparation regimen, we expected adequate bowel cleansing in 36 % of the study patients at baseline and in 96 % of the study patients after cleaning with the Pure-Vu (Unpublished data). To determine whether the paired discordant proportions would differ significantly with an 80 % power and a significance level of 0.05 (McNemar test), 11 patients were required per study site. Three additional patients per physician were included to compensate for the system operation learning curve and a 10 % dropout rate, which resulted in a total sample size of 47 patients (three sites, one endoscopist per site).

Results

Patient characteristics

A total of 47 study patients were enrolled (15–16 per site) between 1 December 2016 and 31 May 2017. The median age of patients was 61 years (IQR 46 – 67 years), 42.6 % were male, and the median body mass index was 25.5 kg/m^2 (IQR 23.1–28.6 kg/m^2) (▶ **Table 1**). Most patients were referred for polyp surveillance (76.6 %). No study patients were lost to follow-up.

Primary outcome

The proportion of study patients with adequate bowel cleansing differed significantly before and after segmental washing with the Pure-Vu System, either when considering the whole colon (19.1 % vs. 97.9 %; $P < 0.001$) or individual colon segments (right colon 23.4 % vs. 100 %, $P < 0.001$; transverse colon 29.8 % vs. 100 %, $P < 0.001$; left colon 29.8 % vs. 97.9 %, $P < 0.001$). In one patient, the Pure-Vu could not pass the sigmoid colon because the diameter of the colonoscope with the Pure-Vu attached was too wide, but adequate bowel cleansing could be

achieved with conventional flushing and suctioning using the working channel of a pediatric colonoscope. The median BBPS score at baseline was 3.0 (IQR 0.0–5.0); this increased to 9.0 (IQR 8.0–9.0) after cleaning with the Pure-Vu ($P<0.001$) (▶ **Table 2**, ▶ **Fig. 2**, and ▶ **Video 1**).

Secondary outcomes

Cecal intubation

The cecum was reached in 46/47 study patients (97.9%) using a standard colonoscope with the Pure-Vu attached, and in one patient with a pediatric colonoscope without the Pure-Vu (▶ **Table 3**).

Procedure times

Median cecal intubation time and total procedure time were 16.5 minutes (IQR 9.0–28.3 minutes) and 34.0 minutes (IQR 25.0–42.8 minutes), respectively. Secondary analysis, excluding the first three cases of each endoscopist, did not show any significant differences regarding procedure times (▶ **Table 3**).

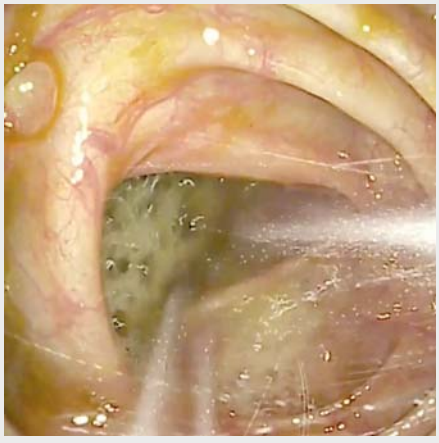
▶ **Table 1** Patient characteristics.

Number of patients, n	47
Male, n (%)	20 (42.6)
Age, median (IQR), years	61 (46–67)
BMI, median (IQR), kg/m²	25.5 (23.1–28.6)
Colonoscopy indication, n (%)	
▪ Screening	6 (12.8)
▪ Surveillance	36 (76.6)
▪ Diagnostic	5 (10.6)

BMI, body mass index; IQR, interquartile range.

Usability of the Pure-Vu System

Physicians were satisfied with the general ease of use of the device, with a median score of 4.0 (as good as conventional colonoscopy; IQR 3.0–5.0) (▶ **Fig. 3**). In most cases, insertion to the rectum (91.5%), advancement (95.7%), and angulation (87.2%) with the Pure-Vu were found to be acceptable, good or excellent. The external attachment of the Pure-Vu increased device stiffness and holding forces in 36.2% and 44.7% of our study patients compared with conventional colonoscopy, but this was only considered a problem in a small portion of patients (4.3% and 2.1%, respectively). As mentioned above, in one patient the Pure-Vu could not pass the sigmoid and therefore all Pure-Vu characteristics, except for insertion to rectum, were

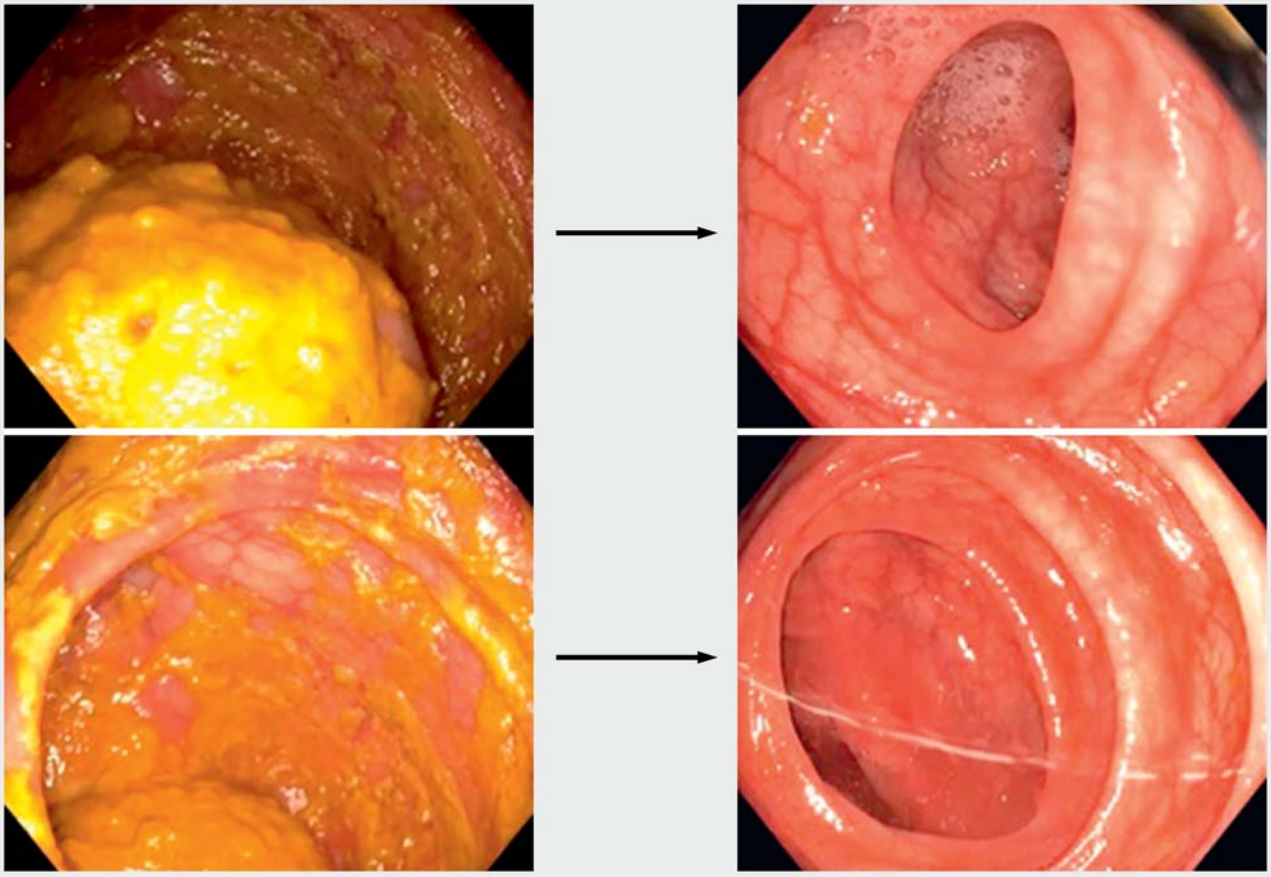


Video 1 Intracolonoscopy cleansing of inadequately prepared colons using the Pure-Vu System (Motus GI, Tirat Carmel, Israel). Online content viewable at: https://doi.org/10.1055/a-0632-1927

▶ **Table 2** Primary outcome.

	Before cleaning with Pure-Vu (n=47)	After cleaning with Pure-Vu (n=47)	*P* value
BBPS ≥ 2 in all colon segments, n (%)	9 (19.1)	46 (97.9)[1]	<0.001
BBPS ≥ 2 per colon segment, n (%)			
▪ Right colon[2]	11 (23.4)	47 (100)	<0.001
▪ Transverse colon[3]	14 (29.8)	47 (100)	<0.001
▪ Left colon[4]	14 (29.8)	46 (97.9)	<0.001
BBPS, median (IQR)	3 (0–5)	9 (8–9)	<0.001

BBPS, Boston Bowel Preparation Scale; IQR, interquartile range.
[1] In one patient the Pure-Vu could not pass the sigmoid colon.
[2] Right colon: cecum and ascending colon.
[3] Transverse colon: transverse colon and both flexures.
[4] Left colon: descending colon, sigmoid colon, and rectum.



▶ **Fig. 2** Illustrations of the cleaning abilities of the Pure-Vu System (Motus GI, Tirat Carmel, Israel). Left images are before and right images are after cleaning with the Pure-Vu.

▶ **Table 3** Secondary outcomes.

	Primary analysis[1]	Secondary analysis[2]	*P* value
Cecal intubation rate, n/N (%)	46/47 (97.9)	38/38 (100)	
Cecal intubation time, median (IQR), minutes	16.5 (9.0 – 28.3)	16.5 (8.8 – 28.0)	0.79
Total procedure time, median (IQR), minutes	34.0 (25.0 – 42.8)	33.0 (25.0 – 41.3)	0.76

IQR, interquartile range.
[1] Procedure times do not include time for diagnostic/therapeutic procedures.
[2] Secondary analysis: the first three patients of each participating endoscopist were excluded in order to assess system operator learning curve.

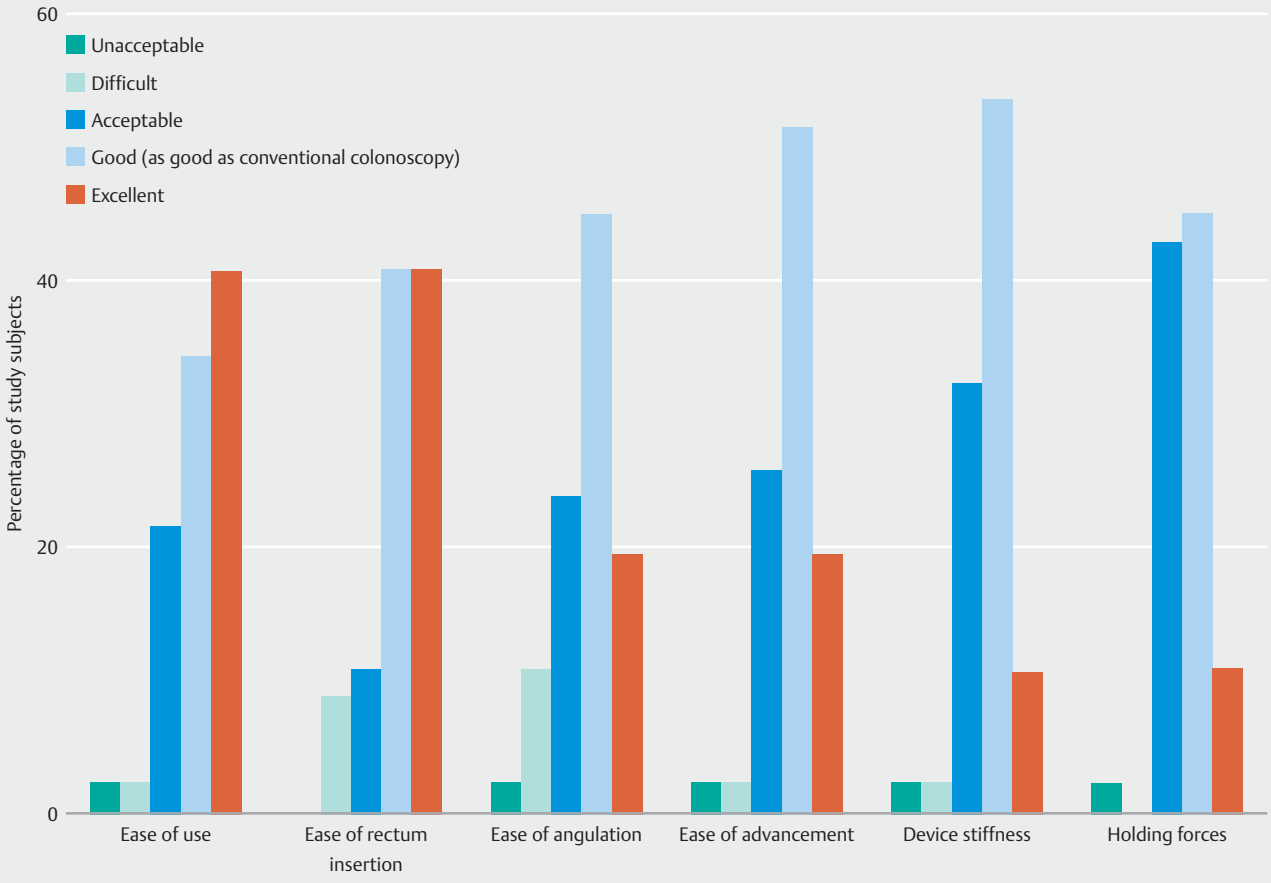
considered unacceptable. Retroflection with the Pure-Vu was performed in 15/46 patients.

Patient satisfaction

Overall, 86.0 % of the study patients with previous colonoscopy experience preferred the reduced bowel preparation over their previous bowel preparation, and 91.7 % reported the overall experience with Pure-Vu to be similar (27.8 %) or better (63.9 %) compared with their last colonoscopy experience. Furthermore, 93.0 % of all study patients would recommend the Pure-Vu to family and friends.

Adverse events

No severe adverse events related to the procedure occurred within 14 days after the procedure. All minor adverse events (n = 7) were transient and resolved without the need for extra measures (i. e. mild abdominal discomfort [n = 1], mild mucosal trauma [n = 1], mild anal pain [n = 1], mild stomach pain [n = 2], and bloating [n = 2]).



▶ **Fig. 3** System usability of the Pure-Vu System (Motus GI, Tirat Carmel, Israel). Physicians graded the usability of the Pure-Vu after each study procedure on a self-constructed questionnaire using a 5-point scale, ranging from unacceptable to excellent.

Clinical findings

The overall prevalence of colorectal polyps was 44 in 18 patients: 17 tubular adenomas, 1 tubulovillous adenoma, 4 sessile serrated adenomas, 16 hyperplastic polyps, and 4 others. Two polyps were not retrieved for histologic examination. The adenoma detection rate was 25.5 %. No major difficulties relating to diagnostic or therapeutic interventions were reported.

Discussion

In this multicenter feasibility study the performance and safety of the Pure-Vu System was evaluated in study patients after a reduced bowel preparation regimen (2 days of dietary restrictions and a split-dose of 2 × 10 mg bisacodyl). Intraprocedural bowel cleaning with the Pure-Vu significantly improved the proportion of study patients with adequate bowel cleansing (BBPS ≥ 2 in each segment) from 19.1 % at baseline to 97.9 % after cleaning with the Pure-Vu (P < 0.001). Furthermore, the median BBPS score improved from 3.0 (IQR 0.0 – 5.0) to 9.0 (8.0 – 9.0; P < 0.001), and the Pure-Vu appeared to be safe with no unanticipated adverse events or severe adverse events occurring during the study period.

The European Society of Gastrointestinal Endoscopy recommends adequate bowel cleansing in at least 90 % of all colonoscopy patients, with a target standard of ≥ 95 % [22]. In daily practice, adequate bowel preparation is only achieved in approximately 80 % of all colonoscopy patients, despite the numerous bowel cleansing agents available [11 – 15].

Poor bowel preparation adherence and “one-size-fits-all” bowel preparation schemes contribute to the persisting high rates of suboptimal bowel cleansing. An intraprocedural bowel cleaning device such as the Pure-Vu could potentially ensure high quality bowel cleaning in all patients. In this study with the Pure-Vu, adequate bowel cleansing was achieved in 97.9 % of all study patients, which is in line with the 100 % adequate bowel cleansing rate of a previously published study with the Pure-Vu in porcine models [19].

Negative colonoscopy outcomes associated with suboptimal bowel cleansing and high patient burden associated with repeat procedures has prompted the development of several intraprocedural bowel cleaning devices. Some devices use the working channel of the colonoscope to clean the colon (the MedJet system and the Jetprep system (MedJet Ltd. Tel Aviv, Israel) [23 – 26], whereas others are attached externally to the

colonoscope, similarly to the Pure-Vu (the Clearpath system [Easy-Glide, Kefar Truman, Israel]) [27 – 29].

Externally attached devices have some potential advantages over devices that use the working channel: 1) bowel cleaning can be performed by the endoscopist without the need for additional assistance; 2) the working channel remains free, which allows for the simultaneous use of diagnostic/therapeutic devices; 3) externally attached devices have separate jets to facilitate effective bowel cleaning; and 4) externally attached devices have an additional evacuation system to facilitate fast evacuation of all residual stool and fluids. An additional advantage of the Pure-Vu System is the auto purge function, which is designed to prevent clogging of the evacuation system, whereas clogging of the working channel needs to be resolved manually. It can be speculated that these advantages of the Pure-Vu could make intraprocedural bowel cleaning more effective and less time-consuming compared with other cleaning devices.

Nonetheless, externally attached devices also have some potential disadvantages, as the device needs to be preloaded onto the colonoscope, the external attachment increases the outer diameter of the colonoscope, and the external attachment could influence maneuverability of the colonoscope. Although adequate training will start to address these issues, these disadvantages could potentially increase the technical difficulty of colonoscopy procedures, especially in narrow and stenotic parts of the colorectum. In addition, retroflexion in the rectum and intubation of the ileocecal valve may be more difficult with the Pure-Vu attached. Unfortunately, it is not possible to compare efficacy of different intraprocedural cleaning devices because study designs differ and only pilot studies have been conducted to date.

The most important limitation of all intraprocedural bowel cleaning devices is likely to be the additional time required for bowel cleaning. In this study, the median procedure time was 34.0 minutes (IQR 25.0 – 42.8 minutes) whereas conventional colonoscopy rarely takes more than 20 minutes. However, caution should be exercised when trying to interpret these results, because this study was not designed nor powered to draw any conclusion with regard to procedure times, and because multiple variables could have influenced the procedure times. First, the participating endoscopists stated that they were extra prudent in order not to cause harm to the patient (unpublished results). Second, endoscopists had little previous experience with the Pure-Vu and only in porcine models. Third, study patients had poor bowel preparation at baseline, with a median BBPS of 3.0; this was improved to a median BBPS score of 9.0 after Pure-Vu use, which might suggest that physicians spent extra time trying to achieve excellent cleansing levels rather than adequate bowel cleansing. It should be recognized that the latter could also have resulted in more technically challenging procedures. Furthermore, procedure time may further increase in patients with unexpected poor cleansing, as they will require withdrawal of the colonoscope and reinsertion with the Pure-Vu attached. Nevertheless, as long as the additional procedure time does not exceed the time required for a repeat colonoscopy procedure, the use of a cleaning device could potentially be justified.

Physicians were satisfied with the general ease of use of the Pure-Vu, with a median score of 4.0 (IQR 3.0 – 5.0), meaning as good as colonoscopy. The external attachment of the Pure-Vu resulted in a noticeable increase in device stiffness and holding forces in 36.2 % and 44.7 % of the study patients, but this was only considered a problem in a small portion of patients (4.3 % and 2.1 %, respectively). Furthermore, insertion into the rectum, advancement, and angulation with the Pure-Vu were considered unacceptably difficult in only 8.5 %, 4.3 %, and 12.8 % of study patients, respectively, and in one patient the cecum could not be reached with the Pure-Vu attached owing to a narrowed sigmoid. Nevertheless, the ability of the Pure-Vu to achieve adequate bowel cleansing might outweigh a slightly more technically challenging examination.

From a patient perspective, bowel preparation is often considered the most burdensome part of colonoscopy, and might even influence colonoscopy uptake. The reduced preprocedural bowel preparation regimen used in this study was very well tolerated, and study patients were satisfied with the overall experience with the Pure-Vu. However, it should be noted that all study procedures were performed under sedation with propofol, which is not routine practice in all countries.

The primary indication for the Pure-Vu will most likely be for patients with suboptimal bowel preparation despite the use of routine preprocedural bowel preparation, and might even be a solution for patients who do not tolerate conventional bowel preparation (e. g. severe nausea/vomiting requiring bowel preparation via a nasogastric tube). Pure-Vu could also potentially be used in patients with acute lower gastrointestinal hemorrhage, for water-assisted colonoscopy (due to its ability to instill large volumes of water), or it may be of additional value when combined with new imaging techniques, as these techniques rely on rigorous bowel cleansing.

This uncontrolled feasibility study has some limitations. The pilot study had a small sample size (n = 47) and therefore no robust conclusions regarding efficacy or safety of the Pure-Vu can be drawn. Moreover, the next step is to assess the effectiveness of the device in cases where bowel preparation was inadequate following a standard preparation regimen. All study procedures were performed by experienced endoscopists and only patients with expected uncomplicated procedures were included in order to minimize the number of adverse (device-related) events. Furthermore, observer-related bias might have occurred with regard to system usability scores and BBPS scores because they were not (re-)assessed by an independent observer. Thus, the outcome data from this study need further confirmation in a larger population.

In conclusion, this feasibility study suggests that the Pure-Vu appears to be safe and effective in cleaning inadequately prepared colons to an adequate level for a thorough colonoscopic examination. Future studies should assess the efficacy and safety of the Pure-Vu, but also evaluate whether intraprocedural bowel cleaning with the Pure-Vu could improve overall colonoscopy outcomes.

Competing interests

The study was sponsored by Motus GI. The sponsor did not have a role in data collection, data analysis or interpretation, writing of the manuscript or decision to submit for publication.

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