EVALUATION OF BOWEL CLEANSING EFFICACY IN HOSPITALIZED PATIENT POPULATION USING THE PURE-VU® SYSTEM - THE REDUCE STUDY

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INTRODUCTION

Good colon preparation is critical for ensuring high quality, successful optical colonoscopy (OC). Hospitalization status poses a significant risk to a successful bowel preparation due to comorbidities, medication use, age and debilitated status. Inadequate bowel cleansing typically leads to delayed, aborted and rescheduled procedures resulting in prolonged hospitalizations and increased costs.[1] The Pure-Vu® System is a novel device intended to fit over existing colonoscopes to facilitate intraprocedural cleansing of poorly prepped colons by simultaneously irrigating and evacuating bowel content.

STUDY DESIGN

This multicenter, prospective, single-arm study (sponsored by Motus[GI]) enrolled 95 hospitalized patients to evaluate the Pure-Vu® System following standard bowel preparation. Upon consenting, patients were enrolled regardless of the bowel preparation condition and the procedure was performed with the Pure-Vu® System. The primary endpoint was improvement of colon cleansing from baseline to post procedure as assessed by the improvement in Boston Bowel Preparation Scale (BBPS) following cleansing with Pure-Vu® System. Secondary endpoints were rate of patients with successful colonoscopy for the intended indication in the first attempt and safety.

RESULTS

The procedure was performed on 95 hospitalized patients. One patient was excluded due to the discovery of ulcerative colitis during procedure which was a study exclusion. Ninety four hospitalized patients (41% females/59% males), mean age 62 years and mean BMI of 28.1 kg/m^2 were included in the final analysis. The predominate indication for OC was GI bleeding (68%) (Table 1).

In 79 (84%) patients, the physician was able to successfully diagnosis/rule out GI bleed in the colon per the patients' colonoscopy indication using only Pure-Vu®. The analysis showed statistically significant improvement in each colon segment after Pure-Vu® use (Table 2). In only two (2%) cases, diagnosis could not be reached due to inadequate prep. In 10 (10.6%) cases another scope was used to successfully complete the procedure; (1) Enteroscope and (9) naked slim PCF scope. It is important to note in 5 of the cases that a naked PCF was used when Pure-Vu® Slim Oversleeve was unavailable. In the remaining three cases diagnosis was not reached due to: (1) severe diverticulosis, (1) diagnosis reached with EGD procedure and (1) cecum was reached but the terminal ileum was not intubated. In the 84 (89.4%) patients that received Pure-Vu® adequate preparation improved from 38% (95% CI 28, 49) to 96% (95%CI 90, 99) in segments evaluated. There was one procedure related perforation which required surgical repair, the patient was discharged 48 hours post operatively and fully recovered.

DISCUSSION

Bowel preparation for hospitalized patients remain a significant challenge resulting in delayed, cancelled and aborted procedures, missed pathology and increased costs of care.[2] This first U.S. and EU multicenter study investigates a population that poses the most challenging medical circumstances.

The Pure-Vu® System cleanses the colon intraprocedurally and may improve the efficacy and prevent a delayed or repeat OC procedure. The analysis demonstrates a significant increase in the BBPS score following the use of the Pure-Vu® System, but more importantly, it demonstrates an increase in colon cleansing adequacy to reach successful diagnosis.

CONCLUSION

The Pure-Vu® System has shown to be safe and effective in colonic cleansing in hospitalized patients regardless of the indications for the colonoscopy procedure.

REFERENCES:
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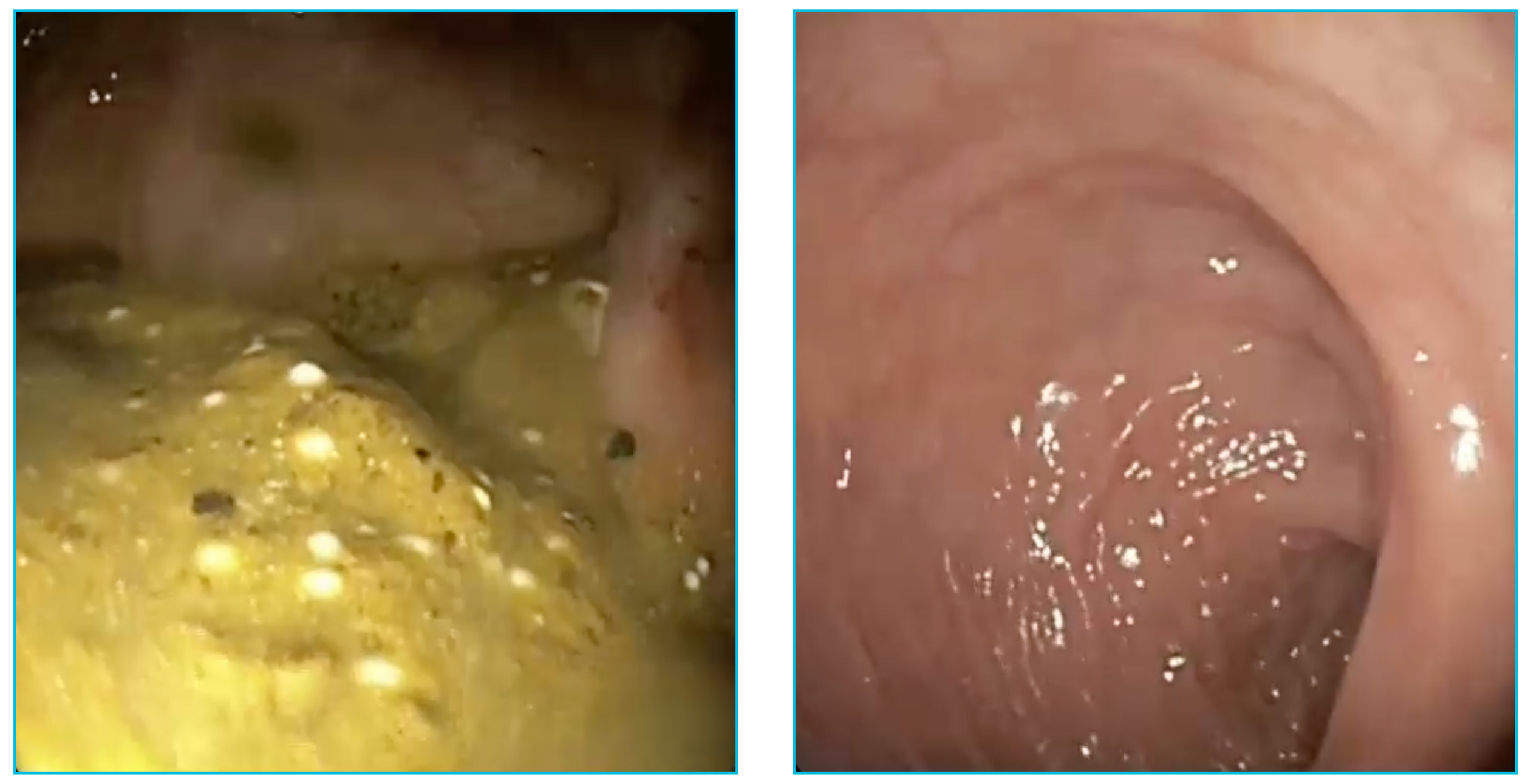

Pre- and Post- Pure-Vu® Cleansing Images

Picture 1: Pure-Vu® System Components:

Pure-Vu® Oversleeve Distal Tip

Workstation Controller

The Pure-Vu® System fits over most standard and pediatric colonoscopes, allowing physicians to cleans the colon in a safe and effective mannerto gain clear visualization of the colonic mucosa.

Table 1: Demographics and Indications for Procedure

Number of cases	95
Age (mean ± SD)	62.3±13.33
BMI (mean ± SD)	28.1±7.31
Male (%)	59%
Indications for Procedure (%)	
GI Bleeding	65 (68%)
Iron Deficiency Anemia	27 (28%)
Suspected Neoplasia/Colorectal Cancer	12 (13%)
Abdominal Pain/Diarrhea	10 (11%)
Suspected Lesion in the Colon	8 (8%)
Evaluation for Transplantation	7 (7%)

**patient could have more than one indication for colonoscopy*

Table 2: Mean Boston Bowel Prep Scores Per Colon Segment

Mean BBPS	Pre Pure-Vu® Use	Post Pure-Vu® Use	P.VALUE < 0.001
Descending Colon, Sigmoid and Rectum	1.74	2.89	< 0.001
Transverse Colon	1.74	2.91	< 0.001
Ascending and Cecum	1.50	2.86	< 0.001

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