A pilot study to assess feasibility of the water method to aid colonoscope insertion in community settings in the United States

Donald J. Portocarrero¹, Kendrick Che¹, Snorri Olafsson¹, Michael H. Walter¹, Christian S. Jackson², Felix W. Leung³, Ariel Malamud⁴

¹Gastroenterology, Loma Linda University Medical Center, Loma Linda, CA, United States; ²Gastroenterology, Loma Linda VA Health Care System, Loma Linda, CA, United States; ³Research and Medical Services, Sepulveda Ambulatory Care Center, Veterans Affairs Greater Los Angeles Healthcare System, David Geffen School of Medicine at UCLA, Los Angeles, CA, United States; ⁴Gastroenterology, White Memorial Medical Center, Los Angeles, CA, United States

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Abbreviations: ADR, adenoma detection rate; VA, Veteran Affairs; WMMC, White Memorial Medical Center; LLUMC, Loma Linda University Medical Center

Background: The water method decreases patient discomfort and sedation requirement. Applicability in non-veteran community settings in the United States (U.S.) has not been reported.

Aims: Our aim is to perform a pilot study to establish feasibility of use the water method at 2 community sites. We tested the hypothesis that compared with air insufflation patients examined with the water method would require less sedation without adverse impact on outcomes.

Methods: Two performance improvement projects were carried out. Consecutive patients who consented to respond to a questionnaire after colonoscopy were enrolled. Project 1: The design was single-blinded (patient only); quasi-randomized – odd days (water), even days (air). Colonoscopy was performed by a staff attending. Project 2: A supervised trainee performed the reported procedures. In both, patient demographics (age, gender and body mass index), amount of sedation required during colonoscopy and procedure-related variables were recorded. The patients completed a questionnaire that enquired about discomfort during colonoscopy and willingness to repeat the procedure within 24 hours after the procedure.

Results: Project 1: Significantly lower doses of fentanyl and midazolam were used and a higher adenoma detection rate (ADR) was demonstrated in the water group. Project 2: 100% cecal intubation rate was achieved by the supervised trainee.

Conclusion: This is the first pilot report in the U.S. documenting feasibility of the water method as the principal modality to aid colonoscope insertion in both male and female community patients. In a head-to-head comparison, significant reduction of sedation requirement is confirmed as hypothesized. No adverse impact on outcomes was noted.

Introduction

The water method decreased patient discomfort and sedation requirement in predominantly male Veteran Affairs (VA) settings^{1,2}. Applicability in non-VA settings in the United States (U.S.) has not been reported. Our aim is to perform a pilot study to establish feasibility of water method use at two non-VA community sites and to compare the water method with air insufflation at one. We tested the hypothesis that compared with air insufflation, patients examined with the water method would require less sedation without adverse impact on outcomes.

Methods

Performance improvement projects were carried out at 2 sites. The goal was to minimize patient sedation burden. Experienced colonoscopists at these 2 sites were coached by one of the authors with experience in the water method (FWL) in 6 colonoscopies each using the water method. These attendings then taught one of the GI fellows in training. All subjects at both study sites undergoing elective outpatient screening colonoscopies had medical insurance. Patients were initially given fentanyl 25 mcg and midazolam 1 mg IV, which is half of our usual sedation dose. Dosage was increased if they showed common clinical signs of increased discomfort (e.g. verbalized pain sensation, grimaced due to pain in the abdomen, change in vital signs deemed to be due to pain by the colonoscopist).

Project 1: At the White Memorial Medical Center (WMMC), a community-based teaching hospital, a single endoscopist

*Correspondence to: Donald Portocarrero; Email: dportocarrero@llu.edu
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Table 1. Pilot data of Project 1 and Project 2

Method	Project 1 WMMC		Project 2 LLUMC
	Water	Air	Water
Number of patients	11	12	17
Age (years)	69 (10)	67 (15)	62 (7)
Male/Female	4/7	3/9	5/12
BMI	29 (7)	28 (6)	28 (4)
Midazolam (mg)	1.4 (0.5)*	3.8 (0.9)	2.7 (1.5)
Fentanyl (mg)	59 (20) [‡]	79 (26)	56 (31)
Cecal intubation rate	100%	100%	100%
Total procedure time (min)	14 (3)	16 (7)	27 (7)
Discomfort during colonoscopy	1.8 (1.0)	1.8 (0.8)	1.4 (0.7)
Willing to repeat	11 (100%)	11 (92%)	17 (100%)
No. of patients with at least 1 polyp	9 (82%) [‡]	5 (42%)	9 (53%)
No. of patients with at least 1 adenoma (ADR)	6 (55%) ^{††}	2 (17%)	6 (35%)

Data are mean (SD) or frequency count (%).

ADR, adenoma detection rate; BMI, body mass index; LLUMC, Loma Linda University Medical Center; WMMC, White Memorial Medical Center.

Discomfort score (1=least, 5=most severe).

*vs. air, $p < 0.0001$, [‡]vs. air, $p = 0.04$; Wilcoxon test. [†]vs. air, $p = 0.049$, ^{††}vs. air, $p = 0.057$; Pearson chi square test..

(AM) performed all reported procedures (Fujinon EC-450HL5 standard colonoscope). The design was single-blinded (patient only); quasi-randomized – odd days (water method), even days (air insufflation).

Project 2: At the Loma Linda University Medical Center (LLUMC), a university-affiliated teaching hospital, a supervised trainee (KC) who had performed 300 prior colonoscopies performed the reported procedures (Olympus CF-Q180AL with variable stiffener)

For implementation of the water method, upon insertion of the colonoscope into the rectum, all air was suctioned out and a peristaltic pump for infusion of sterile water at room temperature, through the water channel in lieu of air insufflation, combined with suction of residual air to minimize angulations at flexures and water exchange to clear residual feces for luminal viewing, was used to navigate through the colon.

In both projects, patient demographics (age, gender and body mass index), amount of sedation required during colonoscopy and procedure-related variables were recorded. The patients completed a questionnaire within four hours after the procedure that inquired about discomfort during colonoscopy (on a scale 1 to 5 with 1= lowest pain and 5= severe pain) and willingness to repeat the procedure (yes/no). The data were prospectively monitored. Permission was obtained from the WMMC Institution Review Board to report the data.

Results

In Project water infusion was compared with air insufflation. In Project 2 all colonoscopies were done using water infusion. **Table 1** shows the data collected for each of the projects. Project 1: Significantly lower doses of fentanyl and midazolam were used and a higher adenoma detection rate (ADR) was demonstrated in the water group. Project 2: Low doses of sedation were given, the patients experienced little discomfort, and 100% cecal intubation

rate was achieved by the supervised trainee.

Discussion

In a review of water infusion as an adjunct to air insufflation, water infusion has been well-documented to facilitate insertion through difficult segments affected by diverticulosis, speed insertion to the cecum and decrease pain.³ The need to complete examination to the cecum using the unconventional option of unsedated colonoscopy in the U.S. led to the recognition that air insufflation, which lengthens the colon, is the major contributor limiting success⁴⁻⁶, an experience probably not dissimilar from those of the early colonoscopists who resorted to sedation. Incremental steps were taken to confirm that cecal intubation could be accomplished using water in lieu of air during insertion at various levels of sedation, most notably being the unsedated patients.^{1,2,7-11}

In one RCT, combined with the option of sedation on-demand, the water method permitted a significantly higher proportion of patients to complete unsedated colonoscopy (78% vs. 54%). The median maximum pain score during colonoscopy was significantly lower in the water group. The water group spent significantly less time in recovery on site and at home. In the water group, the dose of fentanyl was significantly lower and the lower dose of midazolam approached significance¹⁰. In another RCT comparing air vs. water in unsedated patients¹, the median maximum pain score during colonoscopy was significantly lower in the water group (3 vs. 6). The median overall pain score (0=none; 10=most severe) after colonoscopy (2 vs. 3) was lower in the water group and the difference approached significance. The proportion with severe overall pain score of ≥ 5 after colonoscopy was significantly lower in the water group (12% vs. 33%). The cecal intubation rate (98% vs. 78%) and willingness to repeat unsedated colonoscopy (93% vs. 78%) were both significantly higher in the water group. The findings in these two RCT are being confirmed by others¹²⁻¹⁴.

Despite the confirmatory studies from overseas, there is a paucity of reports in the U.S. addressing the feasibility of the water method in non-veteran community settings. The current report is the first report in the U.S. documenting feasibility of the water method as the principal modality to aid colonoscope insertion in both male and female community patients. In a head-to-head comparison at one site, significant reduction of sedation requirement is confirmed as hypothesized. Patient-centered (discomfort, willingness to repeat) and procedure-related (examination duration, adenoma detection) outcomes were not compromised. The higher ADR in the water group, albeit non-definitive due to the small sample size, is nonetheless consistent with earlier reports of a favorable impact of the water method on ADR^{15,16}. Furthermore, the current data do not substantiate the concern over the water method prolonging total procedure time previously reported in a proof-of-concept study in the VA setting.

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