

A head-to-head comparison of the water vs. air method in patients undergoing screening colonoscopy

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Key words: colonoscopy, adenoma detection, water method, air method

Abbreviations: ADR, adenoma detection rate; AN, advanced neoplasia; BMI, body mass index; CORI, Clinical Outcomes Research Initiative; ITT, intent-to-treat; n.s., not significant; VAMC, Veterans Affairs Medical Center; RCT, randomized controlled trial, SEM, standard error of mean; SSN, social security number

Background: The water method facilitates colonoscope insertion in unsedated patients.

Objective: To compare quality indicators in sedated veterans.

Design: Performance improvement.

Setting: VA endoscopy unit.

Patients: 368 consecutive screening patients.

Intervention: Air or water method assignment (high definition colonoscope) was based on the last digit of social security number.

Measurements: Adenoma detection rate (ADR), cecal intubation rate; intubation and withdrawal times; sedation requirements and external pressure used.

Results: ADR was higher with the water method (57.1% vs. 46.1%, $p=0.04$). After controlling for age, body mass index, smoking, alcohol, withdrawal time and quality of bowel preparation, the odds of detecting an adenoma was 81% higher with the water method (OR 1.81; 95% CI: 1.12–2.90). In the proximal colon ADR was higher with the water method (45.8% vs. 34.6%, $p=0.03$), including adenomas <10 mm in size (41.8% vs. 31.4%, $p=0.04$). The water method showed significantly longer cecal intubation time (6.9 ± 0.3 vs. 5.3 ± 0.3 min, $p=0.0001$); less external pressure used (11.9% vs. 28.3%, $p=0.0001$); lower need for additional sedation (17.5% vs. 27.2%, $p<0.03$).

Limitations: Predominance of males, single unblinded endoscopist with high ADR.

Conclusions: The water method is an independent factor associated with significantly higher ADR. Replication by blinded colonoscopist(s) is indicated.

Introduction

The water method developed to minimize colonoscopy discomfort¹⁻⁷ yielded numerically higher adenoma detection rate (ADR) in unsedated veterans in one observational study³ and one small RCT⁶ and significantly higher ADR in one retrospective data base review⁸ in sedated veterans. In predominantly unsedated veterans the impact was more pronounced on the diminutive adenomas in the proximal colon.⁹ In the current performance improvement project we assessed quality indicators in patients

undergoing sedated screening colonoscopy in a head-to-head comparison of the water and air methods. We tested the hypothesis that the water method yields superior quality indicator data.

Methods

Study Design

A performance improvement project evaluating the utility of the water method was carried out by a single unblinded colonoscopist (FCR) at the Carl T. Hayden VAMC in Phoenix, Arizona. Data were collected prospectively to monitor performance. Approval was obtained from the local IRB to report the observations. Informed consent waiver was granted since data were de-identified.

Patients

368 consecutive screening colonoscopy patients (9/2009–8/2010) were scheduled by staff without knowledge of the assignments. A standard bowel preparation of clear liquid diet, bisacodyl 20 mg

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and four liters of polyethylene glycol (PEG) on the day before procedure was used. Those with diabetes, chronic constipation or on chronic narcotics received an additional two liters of PEG the day prior to the standard preparation.

Assignment

Patients were assigned at the time of endoscopy, using quasi-randomization allocation to treatment¹⁰ based on the last digit of the patient's social security number (SSN) - air (odd number) or water (even number). Patients were excluded if any fellow in training was involved in the procedure.

Assessment of Outcomes

All colonoscopies were performed using adult, high-definition equipment (Olympus CFH-180). Pre-medications included fentanyl and midazolam. Blood pressure, pulse, electrocardiogram and pulse oximetry were monitored. Colonoscopy began with the patient in the left lateral decubitus position. Tolerability was assessed by the colonoscopist. Additional sedation administered was patient-driven depending on the level of discomfort reported. Patient age, gender, body mass index (BMI), current smoking and alcohol consumption were recorded.

Interventions

Air method

Air insufflation, shortening maneuvers, abdominal compression and change of patient position were used as needed to facilitate the proximal advancement of the colonoscope.

Water method^{11,12}

The air pump was turned off and water (room temperature) was infused by a pedal pump connected to the base of the colonoscope. Removal of angulations by suction of residual air was implemented. The tip of the colonoscope was oriented towards and abutted the "slit-like lumen" ahead and the infused water opened the lumen if the orientation was correct. The colonoscope was advanced by a series of to and fro, back and forth, or repeated insertion and withdrawal motions of the shaft of the colonoscope with a torque in the direction of the expected lumen, and intermittent water infusion. Suspended residual feces obscuring the view had to be suctioned and replaced by clean water until the colonic lumen was visualized again. The turbulence produced by the simultaneous infusion and suction of water in the collapsed lumen dislodged the residual feces from the surrounding mucosa in close proximity to the tip of the colonoscope. Most of the infused water was aspirated into the suction bottle instead of remaining in the colon. Over-distension was obviated. If advancement failed, the assistant provided abdominal compression followed by the patient changing position if necessary. When the cecum was thought to be reached, the air feature was turned on to confirm the location. If the cecum had not been reached, failed intubation was recorded based on intent-to-treat (ITT) but colonoscopy was continued.

Both methods during insertion and withdrawal

Cecal intubation was defined as passage of the colonoscope tip to a point proximal to the ileocecal valve so that the entire cecal caput, including the medial wall of the cecum between the ileocecal valve and appendix orifice were visible. Cleaning of mucosal surface with water and suction of residual water were implemented. Air

insufflation was used to distend the colon for inspection, biopsy and polypectomy.

Primary endpoint

The primary outcome was ADR (proportion of patients with at least one adenoma of any size).

Secondary endpoints

Colon cleanliness was documented using the Clinical Outcomes Research Initiative (CORI) drop box (**Table 1**) as an overall (non-segmental) assessment at the end of each procedure. Success of cecal intubation (ITT and final), intubation and withdrawal time (stopwatch was started at the time of introduction of the colonoscope into the rectum and stopped at the time of its removal from the patient; intubation time was calculated as the time elapsed from insertion to cecal intubation whereas withdrawal time was calculated as: total procedure time – cecal intubation time), use of external compression, patient position change, additional sedation medication during colonoscopy, and polyp and adenoma detection rates (total, proximal and distal) were recorded. Adverse events were registered.

Statistical analysis

For sample size calculation, an ADR of 46% in the air group based on historical data¹³ was adopted. An 11% increase in ADR was considered to be clinically significant.^{3,8} To show a significant difference with 80% power and an alpha of 0.05, 354 subjects or 177 per group were needed. All outcomes were analyzed using ITT. Data are frequency count (%) and mean±SEM (standard error of mean). Student's t-test, Fisher's exact test and logistic regression analysis calculated using SPSS 16.0 software (SPSS, Chicago, Illinois). A p value <0.05 was considered significant.

Results

In the time needed to recruit 177 subjects in the water group, 191 were examined in the air group (see **Figure 1**: Flow Chart). The mean age was 60.0±0.5 and 59.3±0.5 years, with seven and six women in the water and air group, respectively. The proportion of current smokers was significantly higher in the air group; the proportion of current³ "occasional" alcohol drinkers was similar in the two groups. Seventeen patients underwent colonoscopy without any sedation (8 in the water, and 9 in the air group). Patients in the water group received significantly lower doses of both fentanyl (68.8±1.4 vs. 76.5±1.7 mg; p=0.0006) and midazolam (2.8±0.1 vs. 3.1±0.1 mg; p=0.0007) (**Table 2**).

Primary endpoint

The ADR was significantly higher in the water (57.1%) than the air group (46.1%) (p=0.04). After controlling for age, BMI, current smoking and alcohol consumption, withdrawal time and quality of bowel preparation, the odds of detecting an adenoma was 81% higher in the water than the air group (OR 1.81; 95%CI: 1.12-2.90). Patients with at least one proximal adenoma were significantly more likely to be in the water than the air group (45.8% vs. 34.6%; p=0.03) and this was true for adenomas <10

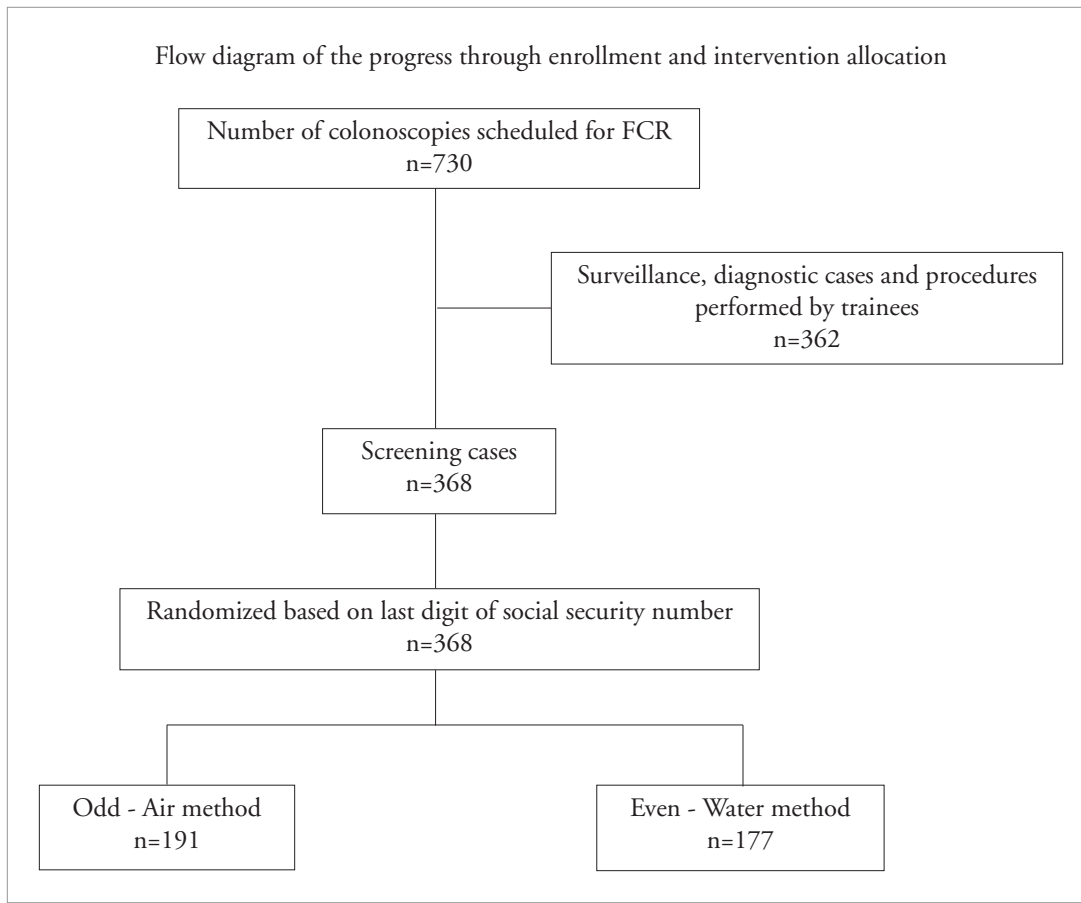


Figure 1. Flow diagram

Table 1. Colon cleanliness was recorded using the Clinical Outcomes Research Initiative (CORI) drop box

Excellent	No more than small bits of adherent fecal material
Good	Small amounts of feces or fluid not interfering with the examination
Fair-adequate	Between good and fair-compromised
Fair-compromised	Enough feces or fluid to prevent a completely reliable examination
Poor	Large amounts of fecal residue with additional cleansing required

mm in size (41.8% vs. 31.4%; $p=0.04$) (**Table 3**).

Secondary endpoints

Cecal intubation was achieved in 99.4% in the water, and 100% in the air group. ITT cecal intubation was 92% in the water, and 100% in the air group, respectively. Fourteen (8%) patients who were assigned to the water group crossed over to the air group (“failed” cecal intubation using water method only). Although the total procedure and withdrawal times were similar, the water group had a significantly longer cecal intubation time (6.9 ± 0.3 vs. 5.3 ± 0.3 min; $p<0.0001$) (**Table 2**).

Compared with the air method, significantly fewer patients in the water method required external pressure (11.9% vs. 28.3%; $p<0.0001$). The need for change in patient position was lower (but not statistically significant) in the water group (7.9% vs. 11.5%). Colon preparation and patient’s tolerance were rated good to excellent similarly in both groups. Additional intra-

procedure sedation was required significantly less often with the water (17.5%) than the air method (27.2%) ($p=0.03$) (**Table 2**).

The water and air groups had similar number of polyps and polyps/patient (375, 2.1 ± 0.2 vs. 364, 1.9 ± 0.2); adenomas and adenomas/patient (211; 1.2 ± 0.1 vs. 213; 1.1 ± 0.1). The water method group had significantly more patients (79.1%) with at least one polyp, than the air method group (63.8%) ($p=0.001$).

Supplementary analyses

In patients rated to have a good to excellent bowel preparation the ADR in the water group was significantly higher 58.4% vs. 45.1% ($p=0.02$).

Five (1.34%) cancers were found, one in the water, and four in the air group. Excluding those with cancer, advanced neoplasia (AN) (defined by size ≥ 10 mm, villous histology or high grade dysplasia) rates were similar (27 patients (15.3%) vs. 39 patients (20%) in the water and air groups, respectively). In addition, ≥ 3

Table 2. Head-to-head comparison of water vs. air method in screening colonoscopy patients

	Air (n=191)	Water (n=177)	p*
Age (years)	59.3±0.5	60.0±0.5	n.s.
Gender (male/female)	184/7	171/6	n.s.
BMI	29.9±0.4	30.1±0.4	n.s.
Current smokers	68 of 191 (35.6%)	44 of 174 (25.3%)	0.03
Proportion of current smokers with adenomas	33 of 68 (48.5%)	24 of 44 (54.5%)	0.56
Current ³ occasional alcohol drinkers	73 of 191 (38.2%)	78 of 177 (44.1%)	0.289
Proportion of current ³ occasional alcohol drinkers with adenomas	34 of 73 (46.6%)	45 of 78 (57.7%)	0.19
ITT cecal intubation	100%	92%	n.s.
Final cecal intubation	100%	99.4%	n.s.
Time to cecum (min)	5.3±0.3	6.9±0.3	<0.0001
Withdrawal time (min)	13.7±0.5	12.9±0.4	n.s.
Total time (min)	18.9±0.6	19.9±0.5	n.s.
External pressure; n (%)	54 (28.3%)	21 (11.9 %)	<0.0001
Change in position	22 (11.5 %)	14 (7.9 %)	n.s.
Fair-adequate or fair-compromised prep	41 (21.5%)	28 (15.8%)	n.s.
Good or Excellent prep	150 (78.5%)	149 (84.2%)	n.s.
Fair- adequate or fair-compromised tolerance	14 (7.3%)	12 (6.8%)	n.s.
Good or Excellent tolerance	177 (92.7%)	165 (93.2%)	n.s.
Fentanyl dose (mg)	76.5±1.7	68.8±1.4	0.0006
Midazolam dose (mg)	3.1±0.1	2.8±0.1	0.0007
Added sedation	52 (27.2%)	31 (17.5%)	0.03

Data are mean ± SEM and frequency count (%). *Student's t test or Fisher's exact test.

Table 3. Adenoma detection rate (ADR), advanced neoplasia (AN) and anatomical distribution (proximal = proximal to splenic flexure; distal = splenic flexure and below)

	Air Method (n=191)	Water Method (n=177)	p*
Screening	100%	100%	
Total number polyps	364	375	
Polyps/patient	1.9±0.2	2.1±0.2	n.s.
Total number adenomas	213	211	
Adenomas/patient	1.1±0.1	1.2±0.1	
Number of proximal adenomas	134 (62.9%)	142 (67.3%)	n.s.
Number of distal adenomas	79 (37.1%)	69(32.7 %)	n.s.
Patients with AN, n (%)	39 (20%)	27 (15.3%)	n.s.
Patients with ≥ 3 adenomas (without AN features)	7 (3.6%)	10 (5.6%)	n.s.
Patients with cancer	4 (1 Proximal)	1 (Proximal)	
Adenoma detection rate; n (%)	88 (46.1%)	101 (57.1%)	0.04
At least one proximal adenoma; n (%)	66 (34.6%)	81 (45.8%)	0.03
<10 mm	60 (31.4%)	74 (41.8%)	0.04
≥10 mm	19 (9.9%)	15 (8.5%)	n.s.
At least 1 distal adenoma; n (%)	54 (28.3%)	52 (29.4%)	n.s.
<10 mm	35 (18.3%)	41 (23.2%)	n.s.
≥10 mm	31 (16.2%)	18 (10.2%)	n.s.

AN, advanced neoplasm. Data are mean ± SEM and frequency count (%). *Student's t test or Fisher's exact test.

adenomas (without AN features) were found in 17 patients: seven in the water, and ten in the air group (**Table 3**). There was no significant difference in the proportion of subjects with combined advanced neoplasms and cancers (air, 43 of 191, water 28 of 177).

Adverse events

There was one (0.3%) post-polypectomy bleeding requiring endoscopic therapy and hospitalization, and one vasovagal

reaction requiring atropine among the 368 patients studied.

Discussion

The already reported beneficial effects of the water method¹⁻⁷ are further enhanced by the results of this study where the water method group revealed a significantly higher ADR than the conventional colonoscopy. Earlier precursors in the form

of water-related techniques as adjuncts to air insufflation have been described¹⁴⁻¹⁸ and recently reviewed.^{18,19} With the patient in the left lateral position, the water infused opens a passage¹⁴ and weighs down the left colon straightening the sigmoid segment thus facilitating the advancement of the colonoscope^{15,16} whereas suction of residual air in the colonic lumen minimizes angulations at the flexures.¹⁷ The turbulence set up by the simultaneous suction of dirty water and infusion of clean water in the collapsed colonic lumen facilitates suspension of the residual feces for removal by suction^{11,12} providing serendipitously salvage bowel cleansing in patients with suboptimal bowel preparation.¹⁻⁷ This salvage cleansing in part could have accounted for the significantly increased ADR previously observed with the water method.^{8,9}

In the current head-to-head comparative study we found although the cecal intubation time was significantly longer (albeit only 1.6 minutes) in the water group, the method had significantly less frequent assistant involvement to provide external pressure, lower fentanyl and midazolam doses and less intra-procedure added sedation than the air group. These findings may have implications not only from the patient's (safety) but also the assistant's (external pressure application) and nursing staff's (recovery time) perspective.

Even though withdrawal times were equivalent (water, 12.9±0.4 vs. air, 13.7±0.5 min), ADR was significantly higher in the water (57.1%) than the air (46.1%) group. The water group ADR compares favorably to recently reported ADR with high definition white light equipment (48.8%) or high definition chromocolonoscopy (55.5%) in average risk screening patients.²⁰ Compared to the air method, the effect of the water method was more pronounced in the proximal than in the distal colon particularly for those adenomas <10 mm in size (41.8% vs. 31.4%; p=0.04). The number of polyps and adenomas per patient, the number of patients with non-neoplastic lesions being similar in both groups and, finding an ADR of 46.1% in the air group being similar to a prior baseline period,¹³ argue against an effect of heightened attention to identify polyps and adenomas only in the water group. The ADR (57.1%) with the water method compares more favorably to ADR reported in screening colonoscopy by others.²⁰⁻²² The explanations for the higher ADR in the water than the air method group remain to be determined.

Although our study did not show any difference in the rate of patients with advanced neoplasia or, three or more adenoma between the two methods, the combined rates (24% and 21% for the air and water methods, respectively) were above those reported in the literature (3.2% to 13%).²⁰⁻²² The cancer detection rate in our study is similar to those reported in other screening colonoscopy studies.²⁰⁻²²

Our results differ from those of Radaelli et al.²⁷ who reported a significantly lower ADR in the water than the air group (25% vs. 40%) and might be related to fundamental methodological differences^{16,28}. They permitted the use of air insufflation at the beginning of colonoscopy and whenever difficulty was encountered during colonoscopy; water exchange during insertion was not mentioned. Others have pointed out that one limitation of infusing water into the colonic lumen during insertion is a possible decrease in the ability to detect subtle mucosal disease because of excessive residual water in the colon.¹⁶ Although residue

could be suctioned while infusing more water to clean the colon, if there is too much residue it is very difficult to see clearly enough to insert the colonoscope properly.²⁸ Whether the salvage cleansing during insertion with the water exchange component of the water method^{3,6,7,11,12} might have accounted for the improvement remains to be further evaluated.

The strengths of this head-to-head comparison include a homogenous population (screening colonoscopy only), the use of high definition equipment in all patients and the absence of ADR variability introduced by multiple endoscopists. The limitations include: the absence of blinding for both endoscopist and nurse injects the potential for bias that could not be avoided; a single endoscopist experience is akin to a case series and the high ADR in the air method group undercut the generalizability of the results; the quasi rather than true randomization design; and the evaluation of predominantly male veterans. Future studies taking these issues into account deserve to be supported.

In conclusion, the data confirm findings that compared to the air method, the water method is associated with significantly higher ADR⁸ especially in the proximal colon.⁹ The novelty rests with the enhancement being independent of age, BMI, current smoking and alcohol consumption, withdrawal time and quality of bowel preparation. Applicability in non-veteran settings should be assessed.

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