Comparative Effectiveness of Water vs. Air Methods in Minimal Sedation Colonoscopy Performed by Supervised Trainees in the US - Randomized Controlled Trial

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Abstract

Concern over the complexity of the water method of colonoscopy insertion has dampened enthusiasm for its adoption. To compare the water method vs. air method in the hands of supervised trainees, a randomized, controlled trial was performed. Screening and surveillance colonoscopy patients consented to randomization. They all received minimal sedation for premedication. Colonoscopy was performed by supervised trainees. The primary outcome was pain during colonoscopy. During insertion the following parameters were significantly lower with the water method: pain scores and total doses or increments (fentanyl and midazolam) of medications. The above were accomplished without compromising unassisted or total cecal intubation rates, patient satisfaction scores at discharge and at 24 hours, patient willingness to repeat colonoscopy, or yield of adenomas. Predominance of male veterans was the main limitation. Supervised trainees replicated the superior performance of the water method reported for the attending staff confirming the water method is not difficult to learn.

Introduction

In the US, training in sedated colonoscopy involves insertion of the colonoscope aided by air insufflations (air method).[1-4a,4b] Overseas variations of a water method have been described[5-7] to facilitate insertion in unsedated patients. There is a current push towards deep sedation for colonoscopy based on practice efficiency and economics in the US.[8,9] Publications by US clinicians[10] and investigators[11] documenting the use of water infusion in enhancing colonoscopy performance[10] and reduced patient discomfort[11] received relatively minor attention until recently. In the past seven years we found ourselves in a unique position to provide scheduled, unsedated colonoscopy in the US.[12-14] The search for a more comfortable approach[15] resulted in the description of a water infusion in lieu of air insufflation technique (water method) to aid colonoscope insertion in the unsedated patients in the US.[16-18] Concern over the complexity of the method requiring the acquisition of an entirely new set of skills dampened enthusiasm for its adoption by other investigators (personal communications). Recently, we reported an

observational[19] as well as a randomized controlled trial (RCT)[20] by attending endoscopists showing that the water method was superior to the air method – producing less discomfort and engendering a reduced need for sedation medications. In the current RCT, we assessed the comparative effectiveness of the water vs. air methods in the hands of supervised trainees. We tested the hypothesis that the water method can be learned by supervised trainees who can replicate the superior impact of the water method in minimally sedated patients.[20]

Methods

This study, approved by the Institutional Review Board of Sacramento VA Medical Center, is registered with ClinicalTrials.gov (NCT00841282). Patients received instructions in a class setting. Those who reside at a distance were contacted by telephone and given a comparable narrative description. The research consent form was given to the patient during class or sent to the patient by mail. Patients received written instructions for standard bowel preparation.[20] Those who signed the research consent form on the day of colonoscopy were randomized. Consecutive screening or surveillance colonoscopy patients examined by the participating trainees were enrolled in the study. There were no exclusion criteria.

Patients were placed in the left lateral position. For pre-medication each patient received minimal sedation consisting of intravenous fentanyl (25 µg or 0.5 increment) and midazolam (1 mg or 0.5 increment) plus a single dose of 50 mg diphenhydramine,[20] a routine adjunct since 2006.[21] Blood pressure, pulse, EKG, and oximetry were monitored. A sealed envelope was opened to reveal the method (air vs. water). Five supervised second- or third-year gastroenterology trainees participated. First-year trainees were not included because none rotated at the VA during the study period. Each trainee had experience in ~400 cases of supervised sedated colonoscopy using the air method. All the trainees were instructed on the water method in ~20 cases each before commencement of the trial. They were shown how to recognize and avoid diverticular openings (Figure 1A), infusion of water to produce local distension to permit advancement of the colonoscope (Figure 1B), the slit-like appearance of the collapsed lumen (Figure 1C), simultaneous suction of dirty water due to residual fecal matter, and infusion of clean water to clear the sub-optimally prepared colon (Figure 1D) and appearance of the appendix opening under water (published in references 18 and 20). Application of abdominal compression and change in position were employed when repeated attempts to advance the colonoscope failed. The usual sites, e.g., sigmoid or transverse colon, were used for application of abdominal compression in both methods. Unassisted cecal intubation was defined as no hands-on involvement by the attending. The trainees were supervised by experienced endoscopists (JWL and SKM). Verbal instructions were allowed for both methods.

Figure 1: All the trainees were instructed on the water method in ~20 cases each before commencement of the trial.

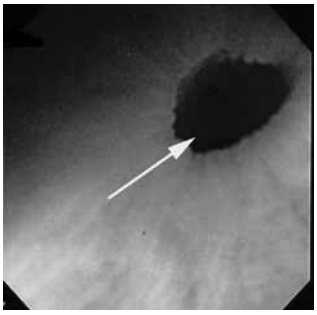


Figure 1A

Figure 1B

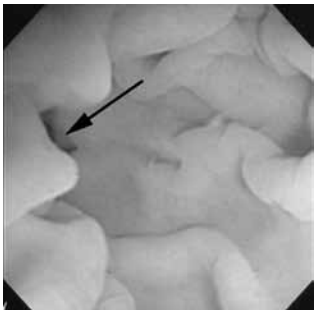


Figure 1C

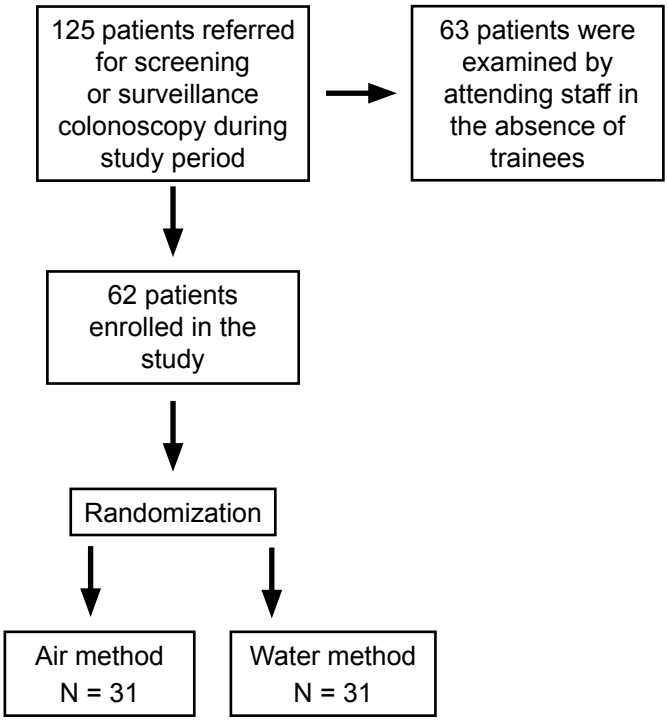
Figure 1D

Trainees were shown how to recognize diverticular opening to be avoided (A), infusion of water to produce local distension to permit advancement of the colonoscope (B), the slit-like appearance of the collapsed lumen (C), simultaneous suction of dirty water due to residual fecal matter and infusion of clean water to clear the sub-optimally prepared colon (D).

With the air method, air was used during insertion, and water at room temperature administered by a 20 ml syringe was used for washing. With the water method, the air pump on the light source generator (CLV 180, Olympus, Tokyo, Japan) was turned off before scope insertion. Water in one liter bottles (maintained at 37°C using a water bath [Cardinal Health, McGraw Park, IL]) was infused intermittently using a peristaltic pump (Endolav EL-100C, Cooper Surgical, Trumbull, CT) with a blunt needle adaptor through the biopsy channel. If turbid water (due to residual fecal matter) obscured the view, the dirty water was suctioned and clean water was infused to improve the view and to facilitate advancement or visualization of the appendix opening.[16-20]

Prior to insertion, the nurse provided guidance regarding reporting of pain score, i.e., pain or discomfort experienced in the abdomen exclusive of other painful conditions, such as hemorrhoids, back pain, or joint pain. At regular intervals of two to three minutes, the minimally sedated patients were asked to report their pain score (0=none, 10=most severe). For pain score ≥2, maneuvers to minimize pain (e.g., suction of colonic content, shortening of the length of the colonoscope inside the patient) were implemented in the same manner for both methods. To eliminate bias by the endoscopists,[22] nurses assessed the pain score as described above and offered additional medications, which the patients could either accept or decline. Since control of pain was the primary indication for additional medications, fentanyl (25 µg) was given first, then alternating with midazolam (1 mg).[20]

Figure 2: CONSORT flow chart



To blind the patient to the method, a towel was used to cover the patient's eyes. If the trainee failed to achieve cecal intubation, the attending would continue with the same method to complete cecal intubation. Upon confirmation of cecal intubation by visualization of the ileocecal valve, the appendix opening and touching the cecal floor, the towel was removed. The patient could observe the withdrawal phase and engage in dialogue with the endoscopist or nurse if they were not too sedated.

For both methods, residual colonic content was suctioned and sufficient air was insufflated to distend the lumen for inspection on withdrawal; biopsy and polypectomy were performed. The amount of water used and time taken for insertion and withdrawal (inclusive of time for biopsy and polypectomy) were recorded. Upon completion of withdrawal the patient was asked by the endoscopy nurse (not blinded to colonoscopy method) regarding pain before transfer to recovery. When vital signs returned to baseline at 30 minutes from the last dose of medication, the patient would be fit for discharge. The time spent in recovery was documented. The recovery nurse (blinded to colonoscopy method) queried the patient about willingness to repeat future colonoscopy (0=no, 1=yes) and satisfaction with the experience (0=not satisfied, 10=very satisfied) at the time of discharge. At a telephone follow-up call after 24 hours, the question regarding satisfaction score was repeated.

Statistics

In a study involving attending endoscopists,[20] the maximum pain scores during insertion were 1.3 (1.8) (water method) and 4.1 (3.4) (air method). The mean difference of 2.9 in pain score in SD units was 1.61 using SD of 1.8 or 0.85 using SD of 3.4. In order to replicate such a magnitude of reduction in pain score, with a power of 90% and an alpha of 0.05 (two-sided), a sample size of 36 participants was needed, or 18 in each group.[23] With five trainee-endoscopists performing procedures, the cluster design to account for possible variation in skills was adopted. Based on the cluster design, calculations with intra-class correlation of 0.05 suggested by preliminary data, the sample size had to be inflated by a factor of 1.7 giving a total of 62 subjects to be enrolled in the study. Pain scores, willingness to repeat future colonoscopy, satisfaction scores, total procedure time, and recovery time were compared using two-sample t test. The mean doses of fentanyl and midazolam and medication increments were analyzed by the Wilcoxon rank-sum test. Cecal intubation rate was compared using the χ^2 test. All tests were two-sided with $p<0.05$ considered significant. Data analysis was performed using Stata version 10 (College Station, Texas).

Results

From 11/05/2008 to 02/09/2009, 125 patients underwent screening or surveillance colonoscopy. Sixty-three were examined by attending staff in the absence of trainees. Sixty-two consented to be randomized (figure 2). The mean age (years) 61 (7.9) and 61 (7.8); the male to female ratio 31:0 and 30:1; the ratio of screening to surveillance colonoscopy 23:8 and 21:10 and the ratio of colonoscopy class attendance to non-attendance 23:8 and 22:9, for the air and water method group, respectively, were comparable.

Tables 1 and 2 tabulate data comparable to the published data of the attending staff (20). Table 1 shows the trainees reproduced

Table 1: Medication requirement and pain scores

		Supervised Trainee Performance		
Medication increments		Water (n=31)	Air (n=31)	P*
To cecum		2.4 (1.7)	3.3 (1.5)	<0.05
During withdrawal		0.1(0.4)	0.1 (0.3)	NS
Total		2.5 (1.9)	3.4 (1.6)	<0.05
Pain score before procedure		0.1 (0.4)	0.6 (1.3)	NS
Pain score (0 = none; 10 = max)	Ascending colon	3.1 (2.9)	4.8 (3.3)	<0.05
	Cecum	1.9 (2.4)	2.1 (2.9)	NS
Pain score at discharge		0.4 (0.8)	1.1 (1.6)	<0.05

*Data are expressed as mean (SD). *One increment is equivalent to 25 μg of fentanyl or 1 mg of midazolam; **Wilcoxon rank-sum test; NS, not significant.*

Table 2: Procedure characteristics

		Supervised Trainee Performance		
		Water (n=31)	Air (n=31)	P
Unassisted intubation rate		94%	94%	NS
Cecal intubation rate		100%	100%	-
Cecal time (min)		11 (7.3)	10 (5.5)	NS
Total procedure time (min)		21 (8.5)	24 (11.6)	NS
Compression/position change		No 22, yes 9	No 12, yes 19	<0.05*
Water used (ml)		1006 (429)	3 (18)	<0.05**
Total recovery (from last meds) (min)		34 (8.8)	37 (10.4)	NS
In recovery room time (min)		18 (8.3)	21 (6.5)	NS
Cardiopulmonary unplanned events		0/31	1/31	NS
Willingness to repeat (same method)		29/31	25/31	NS
Satisfaction (0 = not satisfied, 10 = very satisfied)	After exam	9.0 (1.7)	9.4 (1.3)	NS
	1 day later	8.7 (2.2)	9.3 (1.3)	NS

*Data are expressed as mean (SD). *Fisher's exact test; ** t test*

the lower pain score in the ascending colon but not in the cecum; but the patients did have less pain at the time of discharge with the water method. Expressed as increments of medications used during insertion, significantly fewer increments [2.4 (1.7) vs. 3.3 (1.5), p<0.05] were needed for the water method, again reproducing the findings of the attending staff. Table 2 shows data similar to the attending, less abdominal compression/position change was required with the water method. Unassisted (94%) and total (100%) cecal intubation rates were similar for both methods. By design, the volume of water used was significantly larger in the water than the air method. The insertion and withdrawal times were also comparable. One subject in the air group had a transient episode of bradycardia. At the time of completion of the colonoscopy, more patients in the water group were willing to repeat 29 of 31 vs. 25 of 31, but the difference was not significant. Satisfaction scores were comparable between the two methods at the time of discharge and at 24 hours after colonoscopy. Unlike the attending data, more medications were administered to both groups resulting in no shortening of the time spent in the recovery room. Table 3 shows there was no difference in the yield of adenomas.

Discussion

This RCT shows that, during insertion, the pain scores and the medication requirements were significantly lower with the water method (Table 1). Not surprisingly, compared with the data generated by the attending endoscopists,[20] both the maximum pain scores and medication requirement were higher in the current study performed by the supervised trainees (Table 1), attesting to the fact that experience does impact performance. Unassisted and total cecal intubation rates, willingness to repeat, and satisfaction scores were comparable between the air and water groups in this trainee study (Table 2). The current results support the hypothesis that, compared with the air method, patients examined by supervised trainees using the water method have diminished discomfort and require less sedation medications, without compromising cecal intubation rate and patient satisfaction scores.

Cecal intubation rate of supervised trainees was enhanced by the addition of sedation,[24] but sedation in the hands of supervised trainees had also been associated with more frequent sedation-related complications.[25] The techniques of minimal air insufflation, loop reduction and abdominal compression are well-described adjuncts to reduce colonoscopy discomfort and

Table 3: Number of patients with at least one adenoma (ADR) and number of patients whose adenomas are in the proximal colon

Number of patients with at least one adenoma (ADR)			Number of patients whose adenomas are in the proximal colon		
Water (n=31)	Air (n=31)	P	Water (n=9)	Air (n=10)	P*
9 (29%)	10 (32%)	NS	7 (78%)	8 (80%)	NS

**Fisher's exact tes*

to enhance cecal intubation with the air method.[1-4] However, lengthening of the colon by air insufflation has been well-documented by one study comparing computerized tomographic colonography with optical colonoscopy measurements.[26] Lengthening of the colon increases difficulty in reaching the cecum. Initial findings of the water method to aid insertion permitted 52% of patients accepting on-demand sedation to complete without medications.[16] The water method significantly increased cecal intubation from 76% to 97% in patients accepting scheduled, unsedated colonoscopy.[18] Both reports suggested that the water method increased tolerance for colonoscopy without sedation in US patients. These observations are particularly important in the context of sedation being the usual practice in the US because of the widely held viewpoint that colonoscopy is a painful experience.[27-29]

The volume of water used was dependent on the quantity of residual fecal matter, which, when suspended by the infused water, decreased visibility in the lumen. The discolored water was removed by suction followed by infusion of clean water in order for the lumen to be visualized again to allow further insertion. While the exchange was developed initially to facilitate passage of the colonoscope, the net result was additional cleansing of the lumen. Suction removal of the dirty water also meant that most of the water was collected in the suction bottle even during insertion. When the bowel preparation was excellent, only a small amount of water was necessary to produce local distension of the colonic lumen to provide the clear view for advancement. When the patient is in the left lateral position, the water in the left colon weighs that segment down to straighten the sigmoid colon[5,6,30] minimizing the need for sigmoid compression,[16,18-20] which was confirmed by the data in the present study.

The need to improve cecal intubation in the scheduled, unsedated patients[31] prompted us to review methods for reducing discomfort during colonoscopy.[15] In contrast to reports of water as an adjunct to air insufflation found on review of Medline-indexed literature,[5,7,10,11,30] we described the method of water infusion in lieu of air insufflation during insertion.[16,17] We added the feature of turning off the air pump until the cecum is reached,[16,18-20] in anticipation of involvement of trainees who might "accidentally" trigger air insufflations causing elongation of the colon. Subsequently in 2008, we discovered similar methods described in the Japanese literature[32,33] and in journals not indexed in MEDLINE.[6] In retrospect, it is remarkable to observe that independent clinicians came to the recognition that a paradigm shift, namely, exclusion of air and inclusion of water only, is critical to enhance success of cecal intubation,[18] minimize patient discomfort,[20] and facilitate trainee education.[6] Table 3 shows that adenomas detection was not affected. Taken together, these features of the water method should reassure even experienced colonoscopists that the acquisition of the novel skill set may be worthwhile.

Limitations include the recruitment of predominant male patients at a single VA site. We did not determine whether the patients were able to guess more correctly than by chance what method was used to ascertain adequacy of blinding. Reported unassisted cecal intubation rates using the air method for trainees who have performed at least 100 supervised colonoscopies range from 62%-84%[34-36] in the sedated patients and 81% in unsedated patients.[31] The unassisted cecal intubation rate of 94% in this study reflected the considerable experience of the participant trainees.

We concur with the calls to assess efficacy of the water method by RCT.[37,38] This study reveals the water method to be simple and relatively easy to learn. Successful transfer of skills to trainees will expand the pool of colonoscopists needed to address questions that require large number of patients and varied practice settings, e.g., impact on sedation-related complications, cost-effectiveness, and applicability of the method to non-VA settings, female and younger patients, and those with prior abdominal surgery, as these are factors associated with difficult colonoscopy.[39] Finally, the impact of the water method on less experienced supervised trainees also deserves to be assessed.

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