Interim report of a randomized cross-over study comparing clinical performance of novice trainee endoscopists using conventional air insufflation versus warm water infusion colonoscopy

Catherine Ngo¹, Joseph W. Leung^{2,3}, Surinder K. Mann³, Cecilia Terrado³, Christopher Bowlus³, Drew Ingram³, Felix W. Leung^{4,5}

¹University of California Davis, USA; ²Division of Gastroenterology, Sacramento VA Medical Center, Mather, CA; ³Division of Gastroenterology, UC Davis Medical Center, Sacramento, CA; ⁴Division of Gastroenterology, Sepulveda Ambulatory Care Center, VAGLAHS, North Hills, CA; ⁵David Geffen School of Medicine at UCLA, Los Angeles, CA

Key words: water method, trainee, novice, education

Abbreviations: BMI, body mass index

Background: The applicability of water method colonoscopy in trainee education is not known.

Aim: To compare the water method vs. usual air method in teaching novice trainee colonoscopy.

Method: An IRB approved prospective randomized cross-over study (NCT01482546) in a university setting with diverse patient population.

Design: Three first year GI fellows consented to participate in the study. Trainees were randomized to learn with either usual air method or the water method in performing colonoscopy with a dedicated endoscopy attending during their weekly outpatient endoscopy clinics for the initial six months of training and then cross-over to the other method for the remaining six months.

Patients: Patients undergoing screening, surveillance or diagnostic colonoscopy.

Results: The interim data revealed no significant difference in age, gender, and body mass index (BMI). Trainees rated the water method colonoscopy as significantly easier to learn compared to the air method ($p=0.007$).

Conclusions: The interim data demonstrate positive effects of using the water method in training novice endoscopists who reported a significant ease of learning colonoscopy using this method. Training programs could consider joining us in evaluating the use of warm water infusion in colonoscopy education.

Introduction

Initial maneuvers made by an endoscopist during insertion can determine the success of a colonoscopy.¹ Most colonoscopies taught & performed in the US are done with air insufflation.^{2,3} Procedural problem arise due to introduction of loops and over distension resulting in patient discomfort.⁴ In the US there is a growing trend for deeper sedation to manage patient discomfort and facilitate completion.⁵ Increased use of medications carries an inherent albeit small risk of cardiopulmonary complications, 1.3% in trainees compared to 0.8% in experienced endoscopists.⁶ The idea of using water came about as the result of a need to develop new techniques to facilitate endoscopic insertion⁷ and relieve patient pain.⁸ Infusion of water is able to straighten the ordinarily twisty sigmoid colon facilitating smooth passage^{9,10} including faster passage through the left colon,¹¹ decreased cecal intubation time,^{9,10,12,13} and increased success of cecal intubation

and completion rate of colonoscopy.^{10,12-15} Warm water infusion minimizes colonic spasms, decreases patient discomfort resulting in reduction of sedation requirement.^{9,10,12-16} In this study we evaluate the hypothesis that novice trainees who begin training with water colonoscopy will achieve a significantly higher unassisted cecal intubation rate when compared to those who begin with the air method. The primary outcome is unassisted successful cecal intubation. The study is in progress and recruitment has not reached the projected sample size to evaluate the primary outcome. This interim report focuses on trainee assessment of learning the two methods.

Method

This is a prospective randomized cross-over study (**Fig. 1**). Trainees randomized to either use of conventional air insufflation or warm water infusion method will be performing colonoscopies with a dedicated endoscopy attending during their half-day weekly outpatient endoscopy clinics (for which main indications for colonoscopy will be screening or surveillance) for each 6-month study period. Three faculty gastroenterologists will be participating as dedicated research personnel.

*Correspondence to: Catherine Ngo; Email: catherine.b.ngo@gmail.com
Submitted: May/11/2012; Revised: May/31/2012; Accepted: May/31/2012
Previously published online: www.landesbioscience.com/journals/jig/
DOI: 10.4161/jig.23736

Patients will be monitored in a standard fashion (including regular nursing assessments of vital signs and discomfort). The sedation nurse will administer medications during the procedure according to patient pain levels (0=none to 10=most severe) assessed every 3-5 minute intervals or at any time the patient appears to be in discomfort. Standard incremental doses of medications (using either meperidine 25 mg or fentanyl 25 mcg and midazolam 1mg) will be offered to the patient when the pain level is ≥ 2 .^{10,15,17,18} The nurse will record procedural times (start time, cecal intubation time, and end time in minutes), medications administered (for pre-procedural sedation, from procedure start to cecal intubation, and during withdrawal period from cecum to across anus), and attending involvement (hands-on assistance or take-over).

An attending dedicated to colonoscopy training will be present for the entire duration of the procedure. Cecum is considered reached by the attending if clear-cut cecal landmarks are identified (appendiceal orifice, ileocecal valve, or intubation of the terminal ileum). In concordance with prior studies, attending endoscopists will allow trainees 20 minutes to reach the cecum, provided the examination is progressing in a safe manner and the patient is comfortable.^{1,19,20} If advancement does not occur within 3 to 5 minutes, an assistant will provide abdominal compression, followed by changing the patient's position to facilitate passage of the colonoscope. If the trainee has not reached the cecum by 20 minutes, the instructor will take over until the cecum is reached. The instructor will take over sooner than this if the trainee cannot advance the colonoscope for 5 minutes at the same site, or if it is judged that patient tolerance is becoming a factor. For both the air and water methods, unlimited verbal instruction will be allowed so that the instructor may guide the trainee with descriptions of maneuvers as if he/she were performing the procedure. The

instructor will not provide hands-on assistance until either the trainee stated that he or she had reached the cecum, 20 minutes had passed, or it was necessary for the instructor to take over sooner than 20 minutes for one of the reasons stated above.

After each colonoscopy, the instructor will fill out a questionnaire regarding any prior colonic surgery, presence of abnormal anatomy or masses, polyp detection and removal, quality of preparation using the Boston Bowel Preparation Scale,²¹ and difficulty of the procedure (1=very easy to 5=very difficult). Overall assessment of the trainee's colonoscopy skills will be assessed by the instructor after each procedure (1=poor to 5=excellent). The instructor will also indicate whether the cecum was intubated and the colonoscopy completed independently by the trainee, if there was hands-on assistance, or if attending had to take-over the procedure. The trainee will be assessed for ease of learned technique (1=very easy to 5=very difficult) and self-assessment of clinical confidence (1=not at all confident to 5=extremely confident).

Data analysis

Summary data were tabulated as frequency counts and means (SD). Chi Square analysis and Student t tests were used to evaluate the data. Analysis was done by intention-to-treat.

Results

Table 1 shows the data revealed by the interim analysis. Baseline patient characteristics including age, gender distribution, BMI, and ASA health status were similar. Trainee perception of ease of learning the two techniques was better with the water compared to air method ($p=0.043$). Trainee procedure related outcomes were not statistically significant, but demonstrated trends that

Figure 1. Study flow chart

should be considered of clinical significance. Time to cecum was shorter with water 16 minutes vs. air 21 minutes ($p=0.2$). Total procedure time was shorter with water 32 minutes vs. air 40 minutes ($p=0.2$). Unassisted cecal intubation rate was higher with water 83.3% vs. air 55.5% ($p=0.35$). Polyp detection rate was higher with water 66.7% vs. air 44.4% ($p=0.43$). Adenoma detection rate was higher with water 50% vs. air 11% ($p=0.17$). Patient satisfaction scores were similar. The number of cases for analysis in this interim report was small as they included only screening and surveillance colonoscopies. Type II errors may well be the explanation for the absence of significance in the differences at this stage of evaluation.

Discussion

For certification of trainee procedural competence ACGME guidelines require at least 140 supervised colonoscopies. Recent studies have pushed for more objective measures of clinical competence, e.g. cecal intubation rate >90%, cecal intubation time <15 to 20 minutes. Several studies have reported cecal intubation rates for experienced trainees, average of 72.4% (range 37 to 96.1%) with air method, 94.7% (range 94 to 95.4%) with water method (Table 2).^{1,9,10,15,19,20,22-26} However, few studies have evaluated colonoscopies in novice trainees. The calculated average cecal intubation rate of first year trainees with air based on prior studies is 42.3% (range 37 to 71.5%).^{1,19,20,22} Of these reports, only two are from the US. The calculated average cecal intubation rate for US first year trainees with air is 35.7%.^{1,19} No data is currently available for the cecal intubation rate of first year trainees with water method.

The few studies available comparing the air and water methods in experienced trainee endoscopists revealed data in

favor of the water method. They demonstrated a significant decrease in cecal intubation and total procedural times, decreased degree of procedural difficulty with decreased need for external compression or positional changes, decreased patient pain scores and medication requirements without compromising detection of colorectal disease (including neoplasm prevalence and adenoma detection rates) or patients' willingness to repeat the procedure.^{9,10,12,15}

Several reports have addressed the issue of colonoscopy learning curves amongst trainees with the use of the traditional air method. In a prospective multicenter trial, Lee et al. pooled the resources of 15 tertiary care academic medical centers in Korea.²⁰ Over an 8 month observation period, the investigators prospectively evaluated the procedures of 24 first year GI fellows in these tertiary care academic medical centers. A total of 4351 colonoscopies were assessed prospectively with variable clinical factors. The main outcome measure was acquisition of competence (success rate) was evaluated for colonoscopic training on the basis of 2 objective criteria (1) adjusted completion rate (>90%) and (2) cecal intubation time <20 minutes. The results showed that overall success rate was 83.5%. Mean cecal intubation time 9.2 ± 4.6 minutes. Success rate significantly improved and reached requisite standard of competence after 150 procedures (71.5%, 82.6%, 94.4%, 98.4%, and 98.7%, respectively, for every 50 consecutive blocks). The polyp detection rate did not improve significantly. Mean time to cecal intubation decreased significantly from 11.2 to 8.4 minutes after 150 procedures. These investigators concluded that competence in technically efficient screening and diagnostic colonoscopy generally requires experience with more than 150 cases. In another study, Chung et al. determined the colonoscopy learning curves and factors associated with difficult procedures at a single center.²² A total of

Table 1. Patient demographics and procedure-related outcomes (interim analysis)

	Air fellow	Water fellow	P-value
Number of cases	9	10	
Average age (years)	57	63	0.08
Gender (M/F)	4/5	7/3	NS
BMI (kg/m ²)	30	28	NS
Cecal time (minutes)	21	16	0.2**
Total procedural time (minutes)	40	32	0.2**
Trainee ease of technique	3.7	2.7	0.043*
Trainee cecum unassisted (%)	55.5	83.3	0.35**
Trainee withdrawal unassisted (%)	77.7	83.3	NS
Polyp detection rate (%)	44.4	66.7	0.43**
Adenoma detection rate (%)	11.1	50.0	0.17**
Instructor trainee score	2.6	2.7	NS
Patient post-procedural pain score	0.8	0.1	NS
Patient experience score	1.4	1.4	NS
Patient satisfaction score	9.6	8.3	NS

Trainee ease of learning scale: 1=very easy to 5=very difficult.

Instructor assessment of trainee: 1=poor (technical failure, poor scope control, lost position, failed coordination, trainer take over) to 5=excellent (confident, careful and complete execution, good control, 1-2 attempts, successful).

Patient experience score: 1=Much better than I expected to 5=Much worse than I expected

Patient satisfaction score by Visual Analog Scale: 1=Not satisfied to 10=Very satisfied

*P-value<0.05, ** Though not statistically significant due to small sample size, there is a trend to suggest clinical significance.

Table 2. Current trainee colonoscopy cecal intubation and success rates

Reference	Number of trainees	Year in training	Prior number of endoscopies	Method	Cecal intubation rate	Colonoscopy success rate	Number of colons per fellow	Comments
Parry et al. 1991	1	Unknown	Unknown	Air	67%	90%	100	
					88%		200	
					95%		300	
Cass et al. 1993	12	Unknown	Unknown	Air	84%	n/a	100	Gastroenterology&surgery residents
Marshall et al. 1995	13	7 FYT	FYT=avg 149 colons by end of first year	Air	FYT 53.7%	n/a	~17 (123 all FYT)	Observations made in the last 7 months of first & second year training
		6 SYT	SYT=avg 328 colons by end of second year		SYT 85.8%		~18 (106 all SYT)	
Chak et al. 1996	12	5 FYT	FYT=no prior endo experience	Air	FYT 7.7%	63.7% SYT	~16 (79 all FYT)	Observations made in the first 4 academic months of training year
		7 SYT	SYT=avg 123 colon		SYT 84%		~15 (102 all SYT)	
Church et al. 2002	18	FYT	Unknown	Air	n/a	43.1%	25	Study period of 5 years. Looking at performance of trainees during their first 100-125 cases.
						52.6%	50	
						49.3%	75	
						61.8%	100	
						75.1%	125	
Hamamoto et al. 2002	3	Experienced	Unknown	Air (N=130)	96.1%	n/a	~43	Observed over 14 months
				Water (N=129)	95.4%		~43	
Lee et al. 2008	24	All FYT	Experience with EGD/sig & observed 50 colons	Air	71.5%	n/a	50	Observed over 8 months, cecal intubation in <20 mins
					82.6%		100	
					91.3%		150	
					94.4%		200	
					98.4%		250	
					98.7%		300	
Spier et al. 2009	18	9 FYT	FYT=avg 119 colon	Air	n/a	63%	~41 (369 all FYT)	Observed over 18 months, colon completion rate
		4 SYT	SYT=avg 318 colon			84%	~40 (158 all SYT)	
		5 TYT	TYT=avg 566 colon			92%	~49 (243 all TYT)	
Park et al. 2010	3	Experienced	100 colons	Air (N=39)	n/a	89.7%	~39 (117 all trainees)	Observed over 5 months
				Water (N=41)		95.1%		
				Oil (N=37)		83.8%		
Chung et al. 2010	12	FYT	Experience with EGD/sig & observed 20 colons	Air	37%	n/a	50	Study period of 22 months
					64%		100	
					77%		150	
					85%		200	
					94%		250	
					95%		300	
					94%		350	
Leung et al. 2010	n/a	n/a	Unknown	Air	n/a	16%	n/a	Study looking at successful minimal sedation colonoscopy
				Water		34%		
Ransibrahmanakul et al. 2010	5	2 SYT	~400 air colons & 20	Air (N=31)	94%	n/a	~6	Study period of 3 months (11/2009 to 2/2009)
		3 TYT	water colons	Water (N=31)	94%		~6	

FYT= first year trainee; SYT= second year trainee; TYT=third year trainee; avg=average.

3243 colonoscopies were performed by 12 first year GI fellows, and various clinical factors were assessed prospectively for 22 months. Acquisition of competence (success rate) was evaluated based on two objective criteria (1) the adjusted completion rate >90% and (2) cecal intubation time <20 minutes. The results showed that the overall success rate in reaching the cecum in <20 minutes was 72.8%. The cecal intubation time was 9.3±4.1

minutes. Trainee's skill at performing cecal intubation in <20 minutes reached the requisite standard of competence after 200 procedures. Cecal intubation time decreased significantly from 11.3 to 9.4 minutes after 100 procedures and improved continuously thereafter. One US retrospective database analysis at a VA GI fellowship program included consecutive patients who underwent colonoscopy primarily for symptoms, previous

polyps, or family history of cancer (a minority were performed for screening only) from April 2007 to September 2008.²³ This study involved 11 GI fellows who performed 770 colonoscopies during 18 individual month long rotations. The main outcome measure was determining when $\geq 90\%$ independence in colonoscopy performance was reached. The results showed that independent completion was achieved in $\geq 90\%$ for all fellows after 500 colonoscopies, whereas no fellow reached a $\geq 90\%$ rate after 140 colons.

Previous studies report clinical competence as measured by $\geq 90\%$ completion rate with the air method was only achieved after 150 to 500 colonoscopies. As greater emphasis is made to ensure trainee competence, the warm water method has been shown to be a simple, safe, and feasible method to aid the colonoscopy trainee in inserting the scope with ease, increasing the likelihood of independent successful completion of the procedure. Studies have demonstrated higher cecal intubation rates and procedure completion rates with the water method compared to traditional air insufflation. With this in mind, it is plausible that training endoscopists earlier on with the water method may improve learning curves with trainees reaching clinical competence with less number of procedures.

In this interim analysis, we demonstrate the positive effects of using warm water infusion as an initial method to colonoscopy training in novice endoscopists. Trainees perceive the water method to be an easier technique to learning colonoscopy. Objective procedural competence parameters revealed trends in favor of the water method in our group of novice trainees and are consistent with prior studies comparing the method in experienced trainees. Training programs could consider joining us in evaluating the use of warm water infusion in colonoscopy education.

Acknowledgement

Presented at the Third Colorectal Cancer Screening Symposium, Sacramento VAMC, Mather, CA on March 17, 2012.

References

1. Chak A, Cooper GS, Blades EW, Canto M, Sivak MV Jr. Prospective assessment of colonoscopic intubation skills in trainees. *Gastrointest Endosc* 1996; 44(1):54-7.
2. Rex DK. Colonoscopy. *Gastrointest Endosc Clin N Am* 2000; 10:135-60.
3. Waye J, Rex DK, Williams CB. Insertion Techniques. *Colonoscopy Principles and Practice*. 2003:318-38.
4. Rex DK, Kkhalafan HK. Sedation and the technical performance of colonoscopy. *Gastrointest Endosc Clin N Am* 2005; 15:661-72.
5. Chokshi RV, Hovis CE, Hollander T, Early DS, Wang JS. Practice efficiency and economics: the case for rapid recovery sedation agents for colonoscopy in a screening population. *J Clin Gastroenterol* 2007; 41:591-8.
6. Sharma VK, Nguyen CC, Crowell MD, Lieberman DA, de Garmo P, Fleischer DE. A national study of cardiopulmonary unplanned events after GI endoscopy. *Gastrointest Endosc* 2007; 66:27-34.
7. Falchuk ZM, Friffin PH. A technique to facilitate colonoscopy in areas of severe diverticular disease [letter]. *N Engl J Med* 1984; 310:598.
8. Leung FW. Water-related techniques for performance of colonoscopy. *Dig Dis Sci* 2008; 53:2847-50.
9. Hamamoto N, Nakanishi Y, Morimoto N, Inoue H, Tatukawa M, Nakata S, et al. A new water instillation method for colonoscopy without sedation as performed by endoscopists-in-training. *Gastrointest Endosc* 2002; 56:825-8.
10. Leung CW, Kaltenbach T, Soetikno R, Wu KK, Leung FW, Friedland S. Water immersion versus standard colonoscopy insertion technique: randomized trial shows promise for minimal sedation. *Endoscopy* 2010; 42:557-63.
11. Baumann UA. Water intubation of the sigmoid colon: water instillation speeds up left-sided colonoscopy. *Endoscopy* 1999; 31:314-7.
12. Park SC, Keum B, Kim ES, Jung ES, Lee SD, Park S, et al. Usefulness of warm water and oil assistance in colonoscopy by trainees. *Dig Dis Sci* 2010; 55:2940-4.
13. Brocchi E, Pezzilli R, Tomassetti P, Campana D, Morselli-Labate AM, Corinaldesi R. Warm water or oil-assisted colonoscopy: toward simpler examinations? *Am J Gastroenterol* 2008; 103:581-7.
14. Leung FW, Harker JO, Jackson G, Okamoto KE, Behbahani OM, Jamgotchian NJ, et al. A proof-of-principle, prospective, randomized, controlled trial demonstrating improved outcomes in scheduled unsedated colonoscopy by the water method. *Gastrointest Endosc* 2010; 72:693-700.
15. Ransibrahmanakul K, Leung JW, Mann SK, Siao-Salera R, Lim BS, Hasyagar C, et al. Comparative effectiveness of water vs. air methods in minimal sedation colonoscopy performed by supervised trainees in the US-a RCT. *Am J Clin Med* 2010; 7:113-8.
16. Radaelli F, Paggi S, Amato A, Terruzzi V. Warm water infusion versus air insufflation for unsedated colonoscopy: a randomized, controlled trial. *Gastrointest Endosc* 2010; 72:701-9.
17. Leung JW, Salera R, Toomsen L, Mann S, Leung FW. Pilot feasibility study of the method of water infusion without air insufflation in sedated colonoscopy. *Dig Dis Sci* 2009; 54:1997-2001.
18. Leung JW, Mann S, Leung FW. Options for screening colonoscopy without sedation: a pilot study in United States veterans. *Aliment Pharmacol Ther* 2007; 26:627-31.
19. Marshall JB. Technical proficiency of trainees performing colonoscopy: a learning curve. *Gastrointest Endosc* 1995; 42:287-91.
20. Lee SH, Chung IK, Kim SJ, Kim JO, Ko BM, Hwangbo Y, et al. An adequate level of training for technical competence in screening and diagnostic colonoscopy: a prospective multicenter evaluation of the learning curve. *Gastrointest Endosc* 2008; 67:683-9.
21. Calderwood AH, Jacobson BC. Comprehensive validation of the Boston Bowel Preparation Scale. *Gastrointest Endosc* 2010; 72:686-92.
22. Chung JI, Kim N, Um MS, Kang KP, Lee D, Na JC, et al. Learning curves for colonoscopy: a prospective evaluation of gastroenterology fellows at a single center. *Gut Liver* 2010; 4:31-5.
23. Spier BJ, Benson M, Pfau PR, Nelligan G, Lucey MR, Gaumnitz EA. Colonoscopy training in gastroenterology fellowships: determining competence. *Gastrointest Endosc* 2010; 71:319-24.
24. Church J, Oakley J, Milsom J, Strong S, Hull T. Colonoscopy training: the need for patience (patients). *ANZ J Surg* 2002; 72:89-91.
25. Cass OW, Freeman ML, Peine CJ, Zera RT, Onstad GR. Objective evaluation of endoscopy skills during training. *Ann Intern Med* 1993; 118:40-4.
26. Parry BR, Williams SM. Competency and the colonoscopists: a learning curve. *Aust N Z J Surg* 1991; 61:419-22.