Water Immersion and Polyp Detection: A Randomized Controlled Trial

Edited April 23rd 2019

NCT03231917

Introduction

Although water can be used to facilitate colonoscope insertion[1-13], the use of two techniques employing water have been evaluated for their effects on adenoma detection as compared to standard insertion methods which employ air or CO2[14, 15]. These techniques are called water exchange (WE) and water immersion (WI). In WI, water is used to distend the colon during insertion and is removed largely during withdrawal. WI utilizes enough water during insertion to identify the luminal direction but dirty water is removed primarily during withdrawal. WE is a slower insertion technique in which the air valve is turned off and clean water is infused and dirty water is suctioned during insertion and the instrument is not advanced until the lumen is clean. WE also involves aspiration of retained gas pockets during insertion. Both WE and WI use air or CO_2 rather than water to distend the lumen during withdrawal, and therefore it is not known whether visualization of the mucosa using water as a medium, as opposed to air or CO_2, increases adenoma detection[16]. In contrast to the other methods, TUC involves water exchange (WE) during insertion followed by continuous water infusion (rather than gas) on withdrawal in order to distend the lumen for total underwater mucosal visualization.

The use of water during colonoscopy may improve adenoma detection through several possible mechanisms[17]. It may help to further clear the bowel of any residual stool. In addition, since water may allow for mucosal inspection without fully distending the lumen like air does, water techniques might increase the yield for flat lesions. Very flat lesions may be less visible with full distention of the lumen. Finally, water has a magnifying effect, which may also increase detection. Thus, TUC, in which the entire procedure including withdrawal is performed underwater, could potentially improve polyp detection compared to gas insufflation.

The goal of our study was to use TUC in tandem with standard CO_2 insufflation to determine if water is a better medium than CO_2 for visualizing and detecting polyps and adenomas. Our goal was to randomize patients to tandem colonoscopy performed first with either TUC or CO_2 followed by the other medium in order to compare miss rates for

polyps and adenomas. Our hypothesis was that TUC was associated with a lower adenoma and polyp miss rate for tandem performance of colonoscopy than CO_2.

Methods

We conducted a randomized trial of tandem colonoscopies comparing TUC to CO_2 insufflation. Our study was approved by the Institutional Review Boards at the White River Junction Veterans Affairs Medical Center and Indiana University. All patients were consented with written consent prior to the colonoscopies. In one group, TUC was employed as the first method for mucosal inspection while in a second group, CO_2 insufflation was used first.

Study Population

Eligible subjects were adults 50-80 years who presented for colonoscopy at White River Junction VAMC, Indianapolis VAMC, and Indiana University. Exclusion criteria included a co-morbid status of American Society of Anesthesiologists physical status classification system ASA of III (severe systemic disease) or higher, Inflammatory Bowel Disease (IBD), surgical resection of the large bowel, as well as the use of non-aspirin anticoagulants. Finally, potential subjects who did not report a clear effluent in the most recent bowel movement at time of colonoscopy were excluded from the study.

Randomization

The participants were randomized using a random number generator, stratified by endoscopist/site. The results of the randomization were opened prior to the initial insertion of the colonoscope, informing the endoscopist which method was first, CO_2 or TUC.

Colonoscopy

Consenting adults were randomized to undergo colonoscopy with either TUC or CO2 insufflation for the first colonoscopy followed by an examination using the other technique. All examinations were performed by one of three experienced endoscopists (JCA, CJK, DKR). Participants were sedated using propofol or moderate sedation with midazolam/fentanyl and diphenhydramine. All colonoscopies were performed with high definition colonoscopes. (Olympus CF-HQ190L; Olympus (Tokyo, Japan))

The randomization envelope was opened prior to the initial insertion. An assistant measured the inspection time with a stopwatch from insertion of scope into the rectum until the cecum was reached, stopping the watch during insertion for polyp resection in both techniques or for time spent washing or suctioning (in CO_2 arm only). For the arm where CO_2 insufflation was used first, the lumen was distended with the gas during insertion. When the TUC technique was used first, the air valve was shut off and water was infused and any residual stool or air was suctioned out during insertion. After the cecum was intubated, the endoscopist attempted to intubate the terminal ileum. The mucosal inspection was then initiated during withdrawal when the distention with water or CO2 was adequate for visualization. Measurement of withdrawal and inspection times was initiated at this point. Inspection time was the withdrawal time minus the time for biopsy or polypectomy or for time spent washing or suctioning (in CO_2 arm only). The assistant with a stopwatch announced the withdrawal time periodically with the goal to equalize inspection times.

When the withdrawal of the colonoscope reached the rectum and after the retro-flexion was performed, the endoscopist re-inserted the colonoscope using the other technique. For the exams with TUC as the first method, water was suctioned out of the lumen as CO_2 was introduced into the lumen during the second insertion. Upon withdrawal, the remaining water was aspirated and CO_2 was used to distend the lumen to allow for adequate inspection of the mucosa. In the group in which CO_2 is used first, CO_2 was suctioned out during the second colonoscopy as the scope was inserted with water infusion. As the scope was withdrawn, water was infused with the air valve turned off. Inspection was not started until after cecal intubation and the lumen was filled with water allowing for adequate visualization of the mucosa through the infused water. Inspection time was measured as outlined above.

Outcomes

The primary outcome measure and study endpoint was the miss rate for polyps and adenomas in the two study groups [18]. Miss rates were also calculated for participant level for each technique. Adenoma-level miss rates were calculated as the number of additional adenomas detected during the second examination (for both insertion and withdrawal) divided by the total number of adenomas detected during insertion and

withdrawal for both examinations. These miss rates were reported for the technique used for the first examination. Participant-level miss rates were calculated as the number of participants with one or more adenomas detected during the second examination, divided by the total number of participants with at least one adenoma in either examination. We also examined proximal (cecum, ascending colon, transverse colon and splenic flexure) adenoma miss rates as a secondary outcome, which were calculated as above. Finally, we also calculated serrated polyp (hyperplastic, sessile serrated polyp and traditional serrated adenoma)

For each polyp, we estimated size by open forceps, and noted location, method of removal, whether polyps were detected by insertion or withdrawal and whether CO_2 or TUC was used for mucosal inspection.

We used the Boston Bowel preparation score to assess the quality of the preparation. We also used a scale of good (3), fair (2) and poor (1) to assess the clarity or turbidity of the water during TUC for 3 segments, right, transverse and left colons.

Co-variates

Data collected included participant age and sex, exam indication, personal history of colorectal neoplasia, family history of CRC, time (total procedure, insertion and inspection), volume of water infused during insertion and withdrawal, quality of bowel preparation as measured by the Boston Bowel Preparation Score and medications provided during the procedure.

Statistical considerations

In calculating a sample size required to detect a clinically important difference in miss rates between TUC and CO2 we used the following assumptions: a 30% adenoma miss rate for regular colonoscopy[19, 20]; a 10% adenoma miss rate with TUC; 50% of participants would have at least one adenoma, and participants with adenomas would have an average of two adenomas. We based this in part on a tandem study using cap since the cap had similar reported increase in adenoma detection to water exchange[18]. For the study to have 80% power to detect a 3-fold reduction in adenoma miss rates, by using a chi-square test with a 5% significance level, the study needed 60 adenomas per group. We assumed that each participant would have on average two polyps and planned to enroll at least 120 participants (60 at each site).

Participants who underwent initial colonoscopy with TUC were compared with participants who underwent colonoscopy with CO_2 first for differences in age and propofol dose by using 2-sample t-tests, for differences in sex and indication by using chi square tests, and for a difference in quality of bowel preparation by using a Mantel-Haenszel test for ordered categories. Logistic regression was used to compare the miss rates between participants who underwent TUC first and participants who underwent CO_2 first. The model was adjusted for participant age, sex, family history of CRC, exam indication, time for inspection, insertion time and volume of water infused/aspirated. A generalized estimating equation was used to control for the effect of the endoscopist.

1. Leung FW, Amato A, Ell C, et al. Water-aided colonoscopy: a systematic review. Gastrointestinal endoscopy 2012;76:657-66.
2. Ramirez FC, Leung FW. The water method for aiding colonoscope insertion: the learning curve of an experienced colonoscopist. J Interv Gastroenterol 2011;1:97-101.
3. Ramirez FC, Leung FW. A head-to-head comparison of the water vs. air method in patients undergoing screening colonoscopy. Journal of interventional gastroenterology 2011;1:130-135.
4. Pohl J, Messer I, Behrens A, et al. Water infusion for cecal intubation increases patient tolerance, but does not improve intubation of unsedated colonoscopies. Clinical gastroenterology and hepatology : the official clinical practice journal of the American Gastroenterological Association 2011;9:1039-43 e1.
5. Leung J, Mann S, Siao-Salera R, et al. A randomized, controlled trial to confirm the beneficial effects of the water method on U.S. veterans undergoing colonoscopy with the option of on-demand sedation. Gastrointestinal endoscopy 2011;73:103-10.
6. Leung FW. Water exchange may be superior to water immersion for colonoscopy. Clinical gastroenterology and hepatology : the official clinical practice journal of the American Gastroenterological Association 2011;9:1012-4.
7. Hsieh YH, Tseng KC, Hsieh JJ, et al. Feasibility of colonoscopy with water infusion in minimally sedated patients in an Asian Community Setting. Journal of interventional gastroenterology 2011;1:185-190.
8. Hsieh YH, Lin HJ, Tseng KC. Limited water infusion decreases pain during minimally sedated colonoscopy. World journal of gastroenterology : WJG 2011;17:2236-40.
9. Radaelli F, Paggi S, Amato A, et al. Warm water infusion versus air insufflation for unsedated colonoscopy: a randomized, controlled trial. Gastrointestinal endoscopy 2010;72:701-9.
10. Leung FW, Harker JO, Jackson G, et al. A proof-of-principle, prospective, randomized, controlled trial demonstrating improved outcomes in scheduled

unsedated colonoscopy by the water method. Gastrointestinal endoscopy 2010;72:693-700.
11. Leung CW, Kaltenbach T, Soetikno R, et al. Water immersion versus standard colonoscopy insertion technique: randomized trial shows promise for minimal sedation. Endoscopy 2010;42:557-63.
12. Leung FW, Aharonian HS, Leung JW, et al. Impact of a novel water method on scheduled unsedated colonoscopy in U.S. veterans. Gastrointestinal endoscopy 2009;69:546-50.
13. Rex DK, Chen SC, Overhiser AJ. Colonoscopy technique in consecutive patients referred for prior incomplete colonoscopy. Clinical gastroenterology and hepatology : the official clinical practice journal of the American Gastroenterological Association 2007;5:879-83.
14. Hsieh YH, Tseng CW, Hu CT, et al. Prospective multicenter randomized controlled trial comparing adenoma detection rate in colonoscopy using water exchange, water immersion, and air insufflation. Gastrointest Endosc 2017;86:192-201.
15. Cadoni S, Falt P, Rondonotti E, et al. Water exchange for screening colonoscopy increases adenoma detection rate: a multicenter, double-blinded, randomized controlled trial. Endoscopy 2017;49:456-467.
16. Rex DK. Reply. Clin Gastroenterol Hepatol 2016;14:323-4.
17. Rex DK. Editorial: Water Exchange vs. Water Immersion During Colonoscope Insertion. The American journal of gastroenterology 2014;109:1401-3.
18. Hewett DG, Rex DK. Cap-fitted colonoscopy: a randomized, tandem colonoscopy study of adenoma miss rates. Gastrointestinal endoscopy 2010;72:775-81.
19. Rex DK, Cutler CS, Lemmel GT, et al. Colonoscopic miss rates of adenomas determined by back-to-back colonoscopies. Gastroenterology 1997;112:24-8.
20. van Rijn JC, Reitsma JB, Stoker J, et al. Polyp miss rate determined by tandem colonoscopy: a systematic review. Am J Gastroenterol 2006;101:343-50.