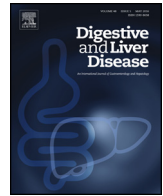




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Insertion water exchange increases right colon adenoma and hyperplastic polyp detection rates during withdrawal



Sergio Cadoni^{a,*}, Přemysl Falt^b, Stefano Sanna^c, Mariangela Argiolas^c, Viviana Fanari^c, Paolo Gallittu^a, Mauro Liggi^a, Donatella Mura^a, Maria L. Porcedda^c, Vit Smajstrla^b, Matteo Erriu^d, Felix W. Leung^{e,f}

^a Digestive Endoscopy Unit, St. Barbara Hospital, Iglesias, CI, Italy

^b Digestive Diseases Center, Vitkovice Hospital, Ostrava, Czech Republic

^c Digestive Endoscopy Unit, N. S. di Bonaria Hospital, San Gavino Monreale, VS, Italy

^d Department of Surgical Sciences, University of Cagliari, Cagliari, CA, Italy

^e Sepulveda Ambulatory Care Center, Veterans Affairs Greater Los Angeles Healthcare System, North Hills, CA, USA

^f David Geffen School of Medicine at University of California at Los Angeles, Los Angeles, CA, USA

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ABSTRACT

Background: Single site studies in male Veterans in the U.S. reported increased detection of presumptive cancer precursors (adenomas, hyperplastic polyps) in the proximal colon (cecum-splenic flexure) by water exchange.

Aims: Assess the reproducibility of the observation.

Methods: Analysis of secondary outcomes collected prospectively in 3 similarly designed randomized controlled trials using water exchange, water immersion and insufflation (air or carbon dioxide). Main outcome: detection rates of adenomas and hyperplastic polyps in proximal, transverse and right colon (cecum-ascending).

Results: 704 males (173 screening) were evaluated. In the proximal colon, WE showed increased detection of small adenomas ($p=0.009$) and adenomas plus hyperplastic polyps ($p=0.015$) (vs insufflation); increased detection of adenomas plus hyperplastic polyps of any size ($p=0.045$) and of small size ($p=0.04$) (vs water immersion). In the right colon water exchange increased detection of small adenomas (19% vs 12.1%, $p=0.04$) (vs insufflation); small adenomas (19% vs 12%, $p=0.038$), adenomas plus hyperplastic polyps of any size (25% vs 16.7%, $p=0.028$) and of small size (23.7% vs 14.6%, $p=0.012$) (vs water immersion). Water exchange significantly improved bowel cleanliness. Sedation had no impact on lesion detection.

Conclusions: Water exchange is a superior insertion technique for detection of adenomas and hyperplastic polyps primarily in the right colon, especially those of small size.

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1. Introduction

Effectiveness of colonoscopy depends on the detection and removal of cancer precursors and early detection of colorectal cancers (CRC) [1]. Cancers found within the time interval preceding the next recommended examination after screening or surveillance colonoscopy are defined as interval CRC [2].

Interval CRCs are more likely to be found in the right colon (cecum and ascending) or in the proximal colon (cecum to splenic flexure included), and are partly due to missed lesions [3,4]. Jass has provided evidence that hyperplastic polyps (HPs) in the proximal colon might serve as precursors of colon cancers through DNA methylation and deficient DNA mismatch repair [5]. They have also been the focus of a growing body of clinical literature [6].

Water-aided colonoscopy entails infusion of water to distend the lumen to advance the instrument during the insertion phase of colonoscopy. It can be subdivided broadly into water immersion (WI) and water exchange (WE) [7,8]. WI is characterized by water infusion as an adjunct to insufflation, and by suction removal of the infused water predominantly during withdrawal to minimize insertion time. WE is characterized by insertion devoid of

* Corresponding author at: St. Barbara Hospital, Digestive Endoscopy Unit, Via S. Leonardo, 1, 09016 Iglesias, CI, Italy. Tel.: +39 0781 3922858; fax: +39 0781 3922323.

E-mail address: cadonisergio@gmail.com (S. Cadoni).

insufflation, and suction of residual air pockets, feces and infused water predominantly during colonoscopy insertion to the cecum, decreasing insertion pain by minimizing distension and maximizing cleanliness.

Some studies conducted in U.S. male Veterans reported that WE enhanced detection of adenomas [9–12], and of adenomas and hyperplastic lesions [11] in the proximal colon.

We evaluated secondary outcome data recorded in three randomized controlled trials (RCTs) to determine the reproducibility of these findings in a mixed European male population. We focused the analysis on adenoma detection rate (ADR, proportion of patients with at least one adenoma) and HP detection rate (HPDR, proportion of patients with at least one HP) in the proximal and right colon. We tested the hypotheses that WE would produce the highest ADR, and combined ADR and HPDR, in the proximal and right colon.

2. Materials and methods

Data were recorded prospectively in three similarly designed RCTs focused on colonoscopy pain conducted at two Italian and one Czech Republic community hospital endoscopy centers [8,13]. From March 2013 through June 2014, both 18–85 year-old patients for clinical indications (ClinicalTrials.gov NCT01781650, NCT01954862) and 50–70 year-old screening patients (NCT01780818) were randomized to WE, WI and air or carbon dioxide (CO₂) insufflation (AICD) at each site. Study protocols conformed to the Declaration of Helsinki and were approved by Local Ethics Committee. Written informed consent was obtained at enrollment.

2.1. Study procedures

All patients were provided with detailed written instructions for colonoscopy preparation [14]. Each ingested a split-dose bowel cleansing solution [14]. The second dose was started about 4–6 h prior to the time of the scheduled examination [14].

Procedures were performed by 10 board-certified endoscopists experienced in all the colonoscopy techniques: 2000–10,000 AICD, 90–800 WI and 90–260 WE. Demographics and indications for colonoscopy were recorded before starting the examination.

High-definition wide-angle adult video colonoscopes (Olympus HD 180–190 series; Olympus Corp, Hamburg, Germany) were used. Patients, but not endoscopists and assisting nurses, were blinded to the insertion method. Investigators were not aware of the gas used for insufflation.

Colonoscopies started with the patients in the left lateral position and without medication. On-demand sedation to minimize pain was available at patients' request.

In the WI and WE arms insufflation was turned off before colonoscopy insertion. After reaching the rectosigmoid junction, the colon was irrigated with water at 37 °C using flushing pumps [8,13].

WI entailed infusion of water to help insertion to the cecum without attempting to clear the colon contents [8,13]. If visualization of the lumen could not be achieved, three insufflations (of no more than ten seconds each) were allowed to advance the instrument [8,13]. Infused water was removed predominantly during withdrawal.

WE involved airless insertion, and infusion-suction of water to distend the lumen to the minimum required to reach the cecum. Residual feces and opaque water were removed predominantly during insertion, maximizing colon cleanliness [8,13].

In the AICD group colonoscopy was performed as usual, using air or CO₂ insufflation as required [8,13]. Cleaning was done predominantly during withdrawal, although some could also be carried out during insertion at the discretion of the endoscopists. Cecal

intubation was defined as insertion beyond the ileocecal valve with adequate visualization of the cecum. During withdrawal (which lasted at least 6 min) air or CO₂ insufflation were used in all arms to distend the lumen for exploration [8,13]. Polyps were resected during withdrawal; size and histology were based on pathology records.

2.2. Pain assessment and sedation

Pain was assessed using a numeric rating scale (NRS) with a score 0 = absence of pain, 1–2 = simply “discomfort”, 10 = the worst possible pain. Before the procedure, the NRS was explained to the patients. During the procedure, at the discretion of the assisting nurse and at irregular intervals, patients were asked about discomfort or pain several times to assess the need and dosage of sedation. On-demand sedation was offered at a NRS score ≥ 2 (discomfort). If patients accepted, it was started with an intravenous dose of 2 mg of midazolam, with step-ups of 1 mg (up to 5 mg) if the patients continued to report pain. Medication was administered based on patients' request, and not at the discretion of the endoscopist. No other analgesic or sedative medications were used [8,13].

2.3. Study endpoints

The primary outcomes of the current study were adenoma and HP detection rates in the proximal and right colon. Serrated lesions were counted as adenomas; non-adenomatous polyps were classified as hyperplastic.

Secondary outcomes were: proportions of patients with at least one slightly elevated or flat adenoma and/or HP in the proximal colon segments (morphology was assessed according to the Paris classification) [15], colon cleanliness using the Boston Bowel Preparation Scale (BBPS) [16], use of sedation and its impact on adenoma detection. The amount of water infused and aspirated during insertion was recorded to confirm the correct application of WI and WE [8,13].

2.4. Statistical analysis

Analyses were performed based on assigned method using Minitab® 16.1.1 software (Minitab Inc., State College, Pennsylvania, USA). Descriptive statistics were used to summarize patient demographic data, clinical factors, counts and percentages. Categorical data were compared by using Fisher's exact test or Chi-squared test (both two tailed) as appropriate; continuous variables were compared by using the *t* test (two tailed). *p* values <0.05 were considered statistically significant.

A post hoc power calculation was performed, based on the significant data of lesion detection in the proximal colon. The WI and AICD groups were comparable. 232 patients per arm would be required to detect at least a 11% difference in ADR and ADR & HPDR in the proximal colon among the WE and the WI and AICD groups with a 80% power at a α value of 0.05.

3. Results

The database stored information relative to 704 male patients randomly allocated to WE (*n* = 232), WI (*n* = 233) or AICD (*n* = 239); 173 patients were screening cases (WE *n* = 53, WI *n* = 60, AICD *n* = 60). Demographics and indications were comparable (Table 1), as well as cecal intubation rates and procedure times (Table 2), except for a longer insertion time of WE vs AICD, *p* = 0.013.

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