Water immersion sigmoidoscopy versus standard insufflation for colorectal cancer screening: A cohort study

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Abstract Background: Although the efficacy of water-assisted colonoscopy is well established, the role of water immersion sigmoidoscopy (WIS) remains unclear. We compared WIS with carbon dioxide insufflation sigmoidoscopy (CO₂S) on patient outcomes.

Methods: We conducted an analysis of prospectively collected data from a single-center quality improvement program about patients undergoing unsedated screening sigmoidoscopy (WIS and CO₂S) between May 2019 and January 2020. Outcomes studied included the following: Rates of severe pain <17% (score of \geq 7 on a numeric rating scale of 0–10, and on a Likert scale), willingness to repeat the procedure without sedation, adequate bowel cleanliness >75% (proportion of Boston Bowel Preparation Scale score: 2–3) and adenoma detection rate (ADR).

Results: In total, 234 patients (111 WIS; 123 CO_2S) were included. All patients were aged 58 years and 58.9% were female; baseline characteristics were comparable between groups. There were no significant differences in rates of severe pain (WIS: 16.5%, CO_2S : 13.8%; P = 0.586), willingness to repeat the unsedated procedure (WIS: 82.3%, CO_2S : 84.5%; P = 0.713), adequate bowel cleanliness (WIS: 78.4%, CO_2S : 78%, P = 0.999) or ADR (WIS: 25.2%, CO_2S : 16.3%; P = 0.106) between groups. However, average procedure times were longer with WIS (9.06 min) compared to CO_2S (6.45 min; P < 0.001). Overall, 29.6% of women reported that they would repeat sigmoidoscopy only if sedated.

Conclusions: WIS does not ameliorate tolerance to and quality of sigmoidoscopy screening measured by several scores. When offered a choice, the women's willingness to repeat WIS or CO₂S without sedation was poor and raises concern on the opportunity of screening sigmoidoscopy without sedation in these subjects.

Keywords: Adenoma detection rate, colon cleanliness, procedural pain

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INTRODUCTION

Sigmoidoscopy screening reduces mortality from colorectal cancer (CRC) and has been adopted as a screening strategy

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in the UK,^[1] Canada,^[2] Italy,^[3] the USA,^[4,5] and Norway.^[6] Procedures are usually conducted in a day care setting without sedation and with enema preparation, leading to procedural

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discomfort and limited mucosal views, respectively. Carbon dioxide insufflation (CO₂) instead of room air insufflation decreases post-procedural discomfort and is routinely used in some countries during colonoscopy.^[7-9]

Over the last two decades, there has been increasing evidence in support of the role of water-assisted colonoscopy (WAC). This entails the use of water instead of gas (room air or CO_2) insufflation to distend the lumen to allow instrument progression during sigmoidoscopy and/or colonoscopy.^[10-12] Infused water is removed predominantly during the withdrawal (water immersion, WI) or during the insertion phase (water exchange, WE).^[12,13] WAC shortens and straightens the sigmoid colon facilitating passage into the descending segment and decreases discomfort.^[10,12,13]

Considering that sigmoidoscopy is a part of a complete colonoscopic examination, it seems reasonable to extend to it the benefits shown by WAC.^[10] However, few studies have evaluated the role of water immersion sigmoidoscopy (WIS) in the screening population.

In this study, we analyzed prospectively the data collected from a quality improvement program aimed to compare WIS with CO₂ sigmoidoscopy (CO₂S) on patient outcomes and to compare them with available quality standards in sigmoidoscopy.^[14-16]

PATIENTS AND METHODS

Study design

We conducted a prospective analysis of the data collected from a single-center quality improvement program aimed to monitor and improve quality parameters using WIS and CO₂S in patients undergoing primary unsedated CRC screening sigmoidoscopy. In accordance with our regional screening protocol (Piedmont, Italy), all 58-year-olds were invited for primary CRC sigmoidoscopy screening. Exclusion criteria included a personal history of CRC, colorectal adenomas or inflammatory bowel disease, colorectal endoscopy done within the previous 2 years, having two or more first-degree relatives with CRC, and having a medical condition that would preclude a benefit from screening.^[17] Between May 2019 and January 2020, participating patients at the Gastroenterology Unit of the S.S. Trinità Borgomanero Hospital (ASL Novara, Piedmont Region, Italy) were included in the quality improvement program. This program was exempted from approval of the local Ethics Committee, which was notified that the anonymized and aggregated data would be analyzed and used for publication. Signed informed consent was obtained from the patients before the procedure.

Outcomes

In the absence of standardized performance measures specifically developed for monitoring quality in sigmoidoscopy, we chose to ascertain if compared with literature data, severe pain would be <17% of the procedures,^[14] adequate bowel cleanliness >75%, and adenoma detection rate (ADR, proportion of patients with at least one adenoma removed) >10%.^[15,16]

The primary outcomes of the quality improvement program were severe pain during the procedure in <17% of cases [assessed through the use of a numerical rating scale (NRS) with 0 = no pain to 10 = maximum pain and a simplified Likert scale (no pain, mild pain, severe pain)],^[18] and patients' willingness to repeat the procedure in the future without sedation.

Secondary outcomes were adequate bowel cleanliness in >75% of the procedures [measured according to the validated Boston Bowel Preparation Scale (BBPS) relative to the distal colon segment explored and defined as BBPS score ≥ 2];^[19] ADR and polyp detection rate (PDR; the proportion of patients with at least one polyp removed), and bloating during the procedure (NRS with 0 = none, 10 = full bloating).

Before starting the procedure, a questionnaire recording the demographic data, previous abdominal surgery, comorbidities, and current medications was administered by the endoscopist (CC), that also explained the scoring systems (NRS and Likert scale) to the patients, who were also asked if they expected the procedure to be painless, slightly painful or very painful.

At the end of the examination, the colonoscopist that did all the procedures (CC) recorded patients' pain during the procedure on the NRS and bloating. At discharge (approximately 5 minutes after the examination), the colonoscopist recorded recalled pain using the Likert scale and made a note of patients' willingness to repeat the procedure in the future without sedation.

Pathology records were reviewed to evaluate ADR, to which contributed adenomas resected at sigmoidoscopy, and those found during this procedure and subsequently relocated and removed at a successive colonoscopy.

Procedures

No dietetic regimen was suggested to patients; bowel cleansing was obtained only by a self-administered 133-ml phosphate enema 2 hours before the procedure. WIS was performed on odd days and usual CO_2S on even days. The endoscopist (CC) had experience in

more than 14,000 colonoscopies and routinely used WI colonoscopy and WIS in clinical practice since 2017 (about 400 WI and WIS accrued at the beginning of the study). All examinations were carried out using high-definition adult colonoscopes (Olympus CF-HQ190, Olympus Europa SE and Co., Hamburg, Germany), an Olympus UCR CO_2 insufflation unit, and an Olympus OFP-2 water pump.

Sigmoidoscopy began with the patients in the left lateral position, without premedication. With the $\rm CO_2$ insufflation pump turned off, WIS entailed infusion of water to distend the lumen to allow instrument insertion without restriction of the overall volume of water infused.^[12] Murky water and/or feces were removed when necessary to safely allow colonoscope progression but without maximizing cleanliness; however, infused water was removed predominantly during withdrawal.^[12,13] Residual gas pockets were not always aspirated but could also be used to bypass dirty colon content.^[12] CO₂S was performed with the minimal insufflation required to distend the lumen, allowing for washing as needed to clear the view. In all procedures, withdrawal was carried out using CO₂ insufflation, and washing as necessary to obtain a clear view of the mucosa.

A stopwatch was used to time the procedures. Procedure time is defined as the time from instrument insertion to the anus up at least to the distal descending colon (where the examination was considered to be complete as per study protocol) or to the reach of the scope, and withdrawal from the anus. Loop reduction, position change, and abdominal compression were applied as needed during insertion in both groups. Polyps were resected either during insertion or withdrawal; lesions $\leq 3 \text{ mm}$ were removed with biopsy forceps, larger lesions were resected using a cold snare, if appropriate. Patients with large lesions needing hot polypectomy were scheduled for a successive colonoscopy. As the CRC sigmoidoscopy screening protocol did not allow the use of on-demand sedation, if the patient asked to stop the procedure due to pain, the examination was interrupted, considered incomplete, and the patient was scheduled for a sedated colonoscopy.

In case of incomplete procedures due to poor bowel preparation, patients were rescheduled to another sigmoidoscopy, preceded by three days of low-fiber diet and bowel preparation with two self-administered enemas 2 hours before the procedure. Data of these examinations are not part of our analyses.

Statistical analysis

Intention-to-treat analyses were conducted using IBM SPSS Statistics version 23.0 (IBM Corp, Armonk, NY, USA). De-identified data are summarized with mean and standard deviation (SD), and/or median and inter-quartile range for continuous variables; or n and % for categorical variables. Categorical variables were compared by the Chi-square test. Continuous variables were assessed by *t*-test or nonparametric Mann–Whitney U test, as appropriate. P < 0.05 was considered significant.

RESULTS

In total, 234 patients were enrolled, of whom 111 underwent WIS and 123 CO_2S [Figure 1]. All patients were aged 58 years and 58.9% were female. Some demographic and/or procedural data relative to 20 cases were lost from analyses. There were no significant differences in demographic profiles [Table 1], rates of previous abdominal surgery, and the presence of diverticulosis between the WIS and CO_2S groups, attesting that the two groups were similar cohorts.

Based on the primary outcome [Table 2 and Figure 2], procedures with severe pain on the NRS (score: \geq 7) were met in 16.5% in the WIS group and 13.8% in the CO₂S group (P = 0.586). When measured on the Likert scale, rates of severe pain were comparable between groups (WIS: 11.7%, CO₂S: 9.8%; P = 0.526). This did not vary in the subgroup analysis of female patients for pain scores measured on the NRS (WIS: 33.3% vs. CO₂S: 26.1% on the NRS; P = 0.497) and on the Likert scale (WIS: 26.7% vs. CO₂S: 19.6%; P = 0.454). Mean maximum pain score (SD) during the procedure was comparable between groups: WIS 3.6 (2.4) vs. CO₂S 3.5 (2.4); as well as recalled pain score recorded on the Likert scale. Overall, with comparable patients' expectations about the level of pain associated with the examination, the majority were willing to repeat the





	Table 1:	Demo	graphics	details
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	Water immersion sigmoidoscopy (WIS) <i>n</i> =111	CO ₂ insufflation sigmoidoscopy (CO ₂ S) <i>n</i> =123	Р
Sex n (%)			
Female	45 (40.5)	46 (37.4)	0.688ª
Male	66 (59.5)	77 (62.6)	
Age, mean (SD), years	58 (0)	58 (0)	NA
BMI, mean (SD), kg/m ²	25.2 (3.7)	25.8 (4.3)	0.167⁵
	n=101/111	n=118/123	
Previous abdominal surgery, n (%)	34 (34.0)	35 (29.9)	0.560ª
	n=100/111	n = 117/123	
Diverticulosis, n (%)	37 (33.3)	35 (28.5)	0.479ª
· · · ·	<i>n</i> =100/111	<i>n</i> =117/123	

SD, Standard deviation; "Fisher exact test; "t-Test; NA, not allowed

procedure in future without sedation (WIS: 82.3%, CO₂S: 84.5%, P = 0.713). However, in the WIS and CO₂S groups, 33.3% and 27.3% of females, respectively, were willing to repeat the procedure only with sedation (P = 0.485).

Also, all other procedural outcomes were comparable [Table 2], with the exception of procedure time (with and without polypectomy), which was significantly longer (P < 0.001) using WIS: Mean minutes (SD) WIS: 9.06 (3.4), CO₂S: 6.45 (2.9); WIS: 8.27 (3.2), CO₂S: 5.76 (2.4), respectively.

Adequate cleanliness (BBPS: 2–3) was achieved in 78.4% of cases in the WIS group and 78.0% in the CO₂S group; WIS showed higher, but comparable ADR (25.2%) than CO₂S 16.3% (P = 0.106).

Due to inadequate lumen visualization for instrument progression, in one case the insertion technique was changed from WIS to CO₂S; no changes occurred in the CO₂S group.

DISCUSSION

To the best of our knowledge, this is the first study to assess the impact of WIS and CO₂S on Italian patients undergoing



Figure 2: Proportion of severe pain by gender and insertion technique, recorded just after the examination (score of ≥ 7 on NRS) and at discharge (Likert scale). CO₂S: carbon dioxide insufflation sigmoidoscopy; NRS: Numerical rating scale; WIS: water immersion sigmoidoscopy

primary unsedated CRC screening sigmoidoscopy. In our study, the outcomes selected for the quality improvement study were comparable between WIS and CO_2S and all were above the suggested sigmoidoscopy quality standards. WIS was not superior to CO_2S in decreasing procedure pain, particularly in female patients that reported severe pain more frequently than males, and in increasing BBPS, PDR, and ADR (WIS increased the latter, but not significantly).

Colonoscopy is the main examination method for CRC screening around the world.^[20] However, some countries have included sigmoidoscopy as an available option in their CRC screening programs,^[1-6] exploiting the opportunity to offer alternate tests when patients decline colonoscopy.^[21] To date, four randomized controlled trials (RCT) have demonstrated that a single flexible sigmoidoscopy examination at around age 60 years reduces CRC incidence by 18%–23% and mortality by 22%–33%,^[1,3,4,22] providing substantial protection from CRC diagnosis and death, lasting up to 17 years.^[23]

Sigmoidoscopy is a fast and safe procedure. Its advantages include lower cost and risk compared with colonoscopy and a more limited bowel preparation. Its disadvantages include a lower protection against right-sided colon cancer, and in case of unsedated procedures, as is usually planned in population-based screening programs,^[1-6,24] a low satisfaction experience for patients, as our study confirmed.

Tolerance of sigmoidoscopy and willingness to repeat the procedure are critical points.^[14,24-27] In our quality improvement program, we assessed patients' experience with sigmoidoscopy, an important quality domain,^[28] by the proxy of willingness to repeat it in the future, a comprehensive item for assessing tolerance encompassing social and examination-related issues.^[25] Unfortunately, 29.6% of females were willing to repeat sigmoidoscopy only with sedation (WIS: 33.3%; Co₂S: 27.3%). This raises concerns about the opportunity of using unsedated sigmoidoscopy for CRC screening in this cohort of

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Table 2: Procedural data

	Water immersion sigmoidoscopy (WIS) <i>n</i> =111	CO_2 insufflation sigmoidoscopy (CO_S) <i>n</i> =123	Р
Severe pain, NRS score ≥7, d (%)			
Overall	16.5	13.8	0.586ª
	<i>n</i> =109/111		
Women	33.3	26.1	0.497ª
Men	4.7	6.5	0.728ª
Dein seers during the presedure of mean (CD) (median OF% CI)	n=64/66		
Overall	36(21)	35(21)	0 830
Overall	[3 0 3 1 - 4 0]	[3 0 3 1-3 9]	0.830
	n = 109 / 111	[0:0, 0:1 0:7]	0.027
Women	5.0 (2.4)	4.2 (2.6)	0.153 ^b
	[5.0, 4.3–5.7]	[4.0, 3.5–5.0]	0.132°
Men	2.6 (1.8)	3.1 (2.1)	0.136 ^b
	[2.0, 2.2–3.0]	[3.0, 2.6–3.6]	0.174°
	n=64/66		
Recalled pain score, ^e n (%)			
No pain			
Overall	32 (28.8)	35 (28.5)	0.884ª
	<i>n</i> =96/111	n=115/123	
Women	8 (17.8)	9 (19.6)	>0.999ª
	<i>n</i> =41/45	n=43/46	
Men	24 (36.4)	26 (33.8)	0.464ª
	<i>n</i> =55/66	n=72/77	
Mild pain			
Overall	51 (45.9)	68 (55.3)	0.405ª
	n=96/111	n=115/123	
Women	21 (46.7)	25 (54.3)	0.517ª
	n=43/45	n=43/46	
Men	30 (45.5)	43 (55.8)	0.591ª
	n=55/66	n=72/77	
Severe pain	10 (11 7)	10 (0, 0)	0.50(0
Overall	13 (11.7)	12 (9.8)	0.526ª
14/	n=96/111	n=115/123	0 45 49
women	12 (20.7)	9 (19.6)	0.454°
Maria	n=41/45	n=43/40	0 (0 0 %
Men	I (I.3)	3 (3.9)	0.033
Willingness to repeat the precedure only with the addition of codation	//=55/00 17 (17 7)	19 (15 5)	0 712a
with gress to repeat the procedure only with the addition of sedation, $p_{(0)}(x) = p_{(0)}(x)$	1/(1/.7)	10(13.3)	0.7 13*
Willingness to repeat the precedure only with the addition of sodation	15 (22 2)	12 (27.2)	0 1958
with gress to repeat the procedure only with the addition of sedation, n (%) females	15(33.3)	12(27.3)	0.465*
Adaguate prop (BBPS score 2 or 2), $p(\%)$	87 (78 /)	06 (78 0)	>0 000b
BBPS score mean (SD)	21(11)	2 1 (1 1)	>0.000b
Adenoma detection rate n (%)	28 (25.2)	20 (16.3)	0.106ª
Polyn detection rate n (%)	41 (36.9)	35 (28.5)	0.208ª
Examinations completed (reached at least the distal descending colon)	100 (90 1)	107 (87 0)	0.541ª
Incomplete procedures	100 (701)	107 (07.0)	0.011
Intolerance, n (%)	6 (5.4)	4 (3.3)	0.524ª
Poor prep. n (%)	4 (3.6)	12 (9.8)	0.073ª
Adhesions or bends, n (%)	1 (0.9)	0	N ^A
Procedure time, mean minutes (SD)	9.06 (3.4)	6.45 (2.9)	<0.001 ^b
Procedure time, cases without polypectomy, mean minutes (SD)	8.27 (3.2)	5.76 (2.4)	<0.001 ^b
Bloating during the procedure, ^f mean (SD)	3.5 (2.2)	3.9 (2.2)	0.200 ^b
Do you think that the procedure will be ^g	· · /	. /	
Overall Painless, n (%)	29 (29.9)	33 (28.9)	>0.999ª
· · · ·	<i>n</i> =97/111	n=114/123	
Overall Slightly painful, n (%)	29 (29.9)	36 (31.6)	0.881ª
	<i>n</i> =97/111	n=114/123	
Overall Very painful, n (%)	9 (9.3)	7 (6.1)	0.441ª
		n=114/123	
Overall Doesn't know, n (%)	30 (30.9)	38 (33.3)	0.768ª
	n=97/111	n = 114 / 123	

SD, Standard deviation; BBPS, Boston Bowel Preparation Scale. ^aFisher exact test; ^bt-test; ^cMann-Whitney *U* test; ^dMeasured at the end of procedure on a Numerical Rating Scale (NRS): 0=no pain, 10=maximum pain; ^cModified Likert scale: No pain, mild pain, severe pain; ^fMeasured at the end of procedure on an NRS: 0=no bloating, 10=full bloating; ^gData recorded before the procedure patients. Finding ways to substantially decrease the pain score in this subset of patients has important clinical implications and should be a research priority.^[25,28]

We selected the easy-to-use WI technique to facilitate the progression of the instrument through the sigmoid colon.^[10] Unfortunately, bowel preparation with one enema 2 hours before the procedure left residual solid feces and debris; this hampered infusing and aspirating water keeping lumen distention to a minimum to safely insert the instrument. In addition, sometimes, water infusion promoted the transit of feces from the descending to the sigmoid colon, further hindering the WI technique. This suboptimal way to perform WI might explain its lack of impact on decreasing the pain score.

Moreover, WI is not the least painful colonoscopy technique for the examination of the lower gastrointestinal tract,^[12,13] and with only one exception,^[29] compared with CO₂ insufflation, WI did not improve colon cleanliness and in all published RCTs did not increase ADR.^[13]

On the contrary, WE (gasless insertion in clear water, maximizing cleanliness with minimal lumen distension) is the least painful insertion technique and has been associated with an increase in both colon cleanliness and ADR.^[13,30] However, we could not perform WE because the bowel preparation used would have hindered its application even more than WI.

A single enema 2 hours before sigmoidoscopy is a good option that cleans the distal bowel and facilitates tolerance by patients.^[15,31,32] Future studies should investigate if a different preparation could give the opportunity to use WE, e.g. one additional enema 1 hour before the examination, as suggested by our CRC screening sigmoidoscopy protocol in the case of rescheduled procedures due to poor cleanliness. WE frequently allows an extended view beyond the splenic flexure (and in the best scenario, an entire complete colon examination) without the costs and potential side-effects of a sedated colonoscopy.^[11]

Our observations seem to support in part the results of a recent multicenter CRC screening sigmoidoscopy trial conducted within the English Bowel Scope Screening^[24] However, in our study, we found some differences that deserve consideration. Our data show that BBPS was comparable between groups, this notwithstanding lesion detection [Table 2] was higher (even if comparable) in the WIS group than in the CO₂S group. In the WASH trial, ADR and PDR using WIS or CO₂ insufflation were 8% and 12%, and 26% and 26%, respectively; in the current study, they were 25.2% and 16.3%, and 36.9% and 28.5%, respectively. A possible explanation could be the

difference in colonoscopists' expertise: In our study experience in about 400 WI procedures, in the WASH study, only 20 procedures were required to attest expertise in WIS.

ADR is also a function of time spent searching for lesions.[33,34] The difference in overall procedure time between the two arms of the WASH trial was 43 s (WIS: 8.83 min; CO₂ insufflation: 8.12 min); this small difference can possibly explain the lower ADR achieved by WIS. Indeed, in our study [Table 2], the difference in total procedure time between WIS and CO₂S was 2.21 min (all procedures) and 1.51 min (procedures without polypectomy). Unfortunately, we did not keep a separate record of insertion time. However, considering that withdrawal was done similarly in both groups striving to search for lesions, in our study, the difference in procedure times can be reasonably accounted for by the time spent infusing and also aspirating water when necessary. Anecdotally (we did not record in which phase of the examination lesions were resected), during insertion, WIS provided increased visualization of polyps floating into the lumen that were resected during this phase or relocated and removed during withdrawal.

We acknowledge some limitations. First, ours is a not randomized study and there was some loss of data. Second, procedures and data recording were performed by a single, unblinded colonoscopist. Our study also has strengths. Patients—although not randomized—were casually allocated to WIS or CO_2S , and the use of both techniques reflects actual clinical practice. Pain score was not affected by the use of sedation. We assessed patients' experience, an important quality domain, by the proxy of willingness to repeat in the future "only if sedated" or "without sedation"; and we used a validated scale to measure bowel cleanliness.^[19] Finally, the colonoscopist had expertise in both WI and WIS.

In conclusion, in our study both WIS and CO₂S met and improved selected sigmoidoscopy quality standards, but WIS was not superior to CO₂S in decreasing pain score; increased BBPS, PDR, and ADR; and required a significantly longer procedure time.

When a choice was offered, women's willingness to repeat WIS or CO_2S without sedation was poor. This result raises concern on the opportunity of screening sigmoidoscopy without sedation in females. Future studies should assess the impact of different bowel preparation and water-assisted sigmoidoscopy technique on these quality indicators, and their impact on the pain score in female patients.

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Conflicts of interest

There are no conflicts of interest.

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