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

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Original Article

INTRODUCTION

Sigmoidoscopy screening reduces mortality from colorectal cancer (CRC) and has been adopted as a screening strategy in the UK, Canada, Italy, the USA, and Norway. Procedures are usually conducted in a day care setting without sedation and with enema preparation, leading to procedural pain. 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 ≥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 CO₂S) 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%, CO₂S: 13.8%; P = 0.586), willingness to repeat the unsedated procedure (WIS: 82.3%, CO₂S: 84.5%; P = 0.713), adequate bowel cleanliness (WIS: 78.4%, CO₂S: 78%, P = 0.999) or ADR (WIS: 25.2%, CO₂S: 16.3%; P = 0.106) between groups. However, average procedure times were longer with WIS (9.06 min) compared to CO₂S (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

Access this article online

Quick Response Code: www.saudijgastro.com
DOI: 10.4103/sjg.sjg_198_21

How to cite this article: Calcara C, Aseni P, Siau K, Gambitta P, Cadoni S. Water immersion sigmoidoscopy versus standard insufflation for colorectal cancer screening: A cohort study. Saudi J Gastroenterol 2022;28:39-45.
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 CO₂) insufflation to distend the lumen to
allow instrument progression during sigmoidoscopy and/or
colonoscopy.¹⁰–¹³ 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 CO₂S 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\textsubscript{2} insufflation unit, and an Olympus OFP-2 water pump.

Sigmoidoscopy began with the patients in the left lateral position, without premedication. With the CO\textsubscript{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.\textsuperscript{12} Murky water and/or feces were removed when necessary to safely allow colonoscopy progression but without maximizing cleanliness; however, infused water was removed predominantly during withdrawal.\textsuperscript{12,13} Residual gas pockets were not always aspirated but could also be used to bypass dirty colon content.\textsuperscript{13} CO\textsubscript{2} S 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 CO\textsubscript{2} 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 to the distal descending colon (where the examination was considered to be complete 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 ≤3 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\textsubscript{2} S [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\textsubscript{2} S 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: ≥7) were met in 16.5% in the WIS group and 13.8% in the CO\textsubscript{2} S group (\(P = 0.586\)). When measured on the Likert scale, rates of severe pain were comparable between groups (WIS: 11.7%, CO\textsubscript{2} S: 9.8%; \(P = 0.526\)). This did not vary in the subgroup analysis of female patients for pain scores measured on the NRS (WIS: 11.7%, CO\textsubscript{2} S: 9.8%; \(P = 0.497\)) and on the Likert scale (WIS: 26.7% vs. CO\textsubscript{2} S: 19.6%; \(P = 0.454\)). Mean maximum pain score (SD) during the procedure was comparable between groups: WIS 3.6 (2.4) vs. CO\textsubscript{2} S 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 procedure.

Figure 1: Study flow chart
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 primary unsedated CRC screening sigmoidoscopy. In our study, the outcomes selected for the quality improvement study were comparable between WIS and CO₂S and all were above the suggested sigmoidoscopy quality standards. WIS was not superior to CO₂S 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
Calcara, et al.: Water immersion screening sigmoidoscopy

Table 2: Procedural data

| Procedure                          | Water immersion sigmoidoscopy (WIS) n=111 | CO₂ insufflation sigmoidoscopy (CO₂ S) n=123 | P     |
|------------------------------------|------------------------------------------|---------------------------------------------|-------|
| Severe pain, NRS score ≥7, d (%)   | 16.5                                     | 13.8                                       | 0.586*|
| Overall                            | n=109/111                                |                                             |       |
| Women                              | 33.3                                     | 26.1                                       | 0.497*|
| Men                                | 4.7                                      | 6.5                                        | 0.728*|
| Pain score during the procedure, d mean (SD) [median, 95% CI] | Overall | 3.6 (2.4) [3.0, 3.1–4.0] | 3.5 (2.4) [3.0, 3.1–3.9] | 0.830* |
| Overall                            | n=109/111                                |                                             |       |
| Women                              | 5.0 (2.4) [5.0, 4.3–5.7]                 | 4.2 (2.6) [4.0, 3.5–5.0]                   | 0.153*|
| Men                                | 2.6 (1.8) [2.0, 2.2–3.0]                 | 3.1 (2.1) [3.0, 2.6–3.6]                   | 0.174*|
| Recalled pain score,* n (%)        | Overall | 32 (28.8) n=96/111 | 35 (28.5) n=115/123 | 0.884* |
| No pain                            | n=109/111                                |                                             |       |
| Women                              | 8 (17.8) n=41/45                         | 9 (19.6) n=43/46                           | >0.999*|
| Men                                | 24 (36.4) n=55/66                       | 26 (33.8) n=72/77                          | 0.464*|
| Mild pain                          | Overall | 51 (45.9) n=96/111 | 68 (55.3) n=115/123 | 0.405* |
| n=109/111                          |                                             |                                             |       |
| Women                              | 21 (46.7) n=43/45                       | 29 (54.3) n=43/46                          | 0.517*|
| Men                                | 30 (45.5) n=55/66                       | 43 (55.8) n=72/77                          | 0.591*|
| Severe pain                        | Overall | 13 (11.7) n=96/111 | 12 (9.8) n=115/123 | 0.526* |
| n=109/111                          |                                             |                                             |       |
| Women                              | 12 (26.7) n=41/45                       | 9 (19.6) n=43/46                           | 0.454*|
| Men                                | 1 (1.5) n=55/66                         | 3 (3.9) n=72/77                            | 0.633*|
| Willingness to repeat the procedure only with the addition of sedation, n (%), overall | 17 (17.7) n=96/111 | 18 (15.5) n=116/123 | 0.713*|
| n=109/111                          |                                             |                                             |       |
| Willingness to repeat the procedure only with the addition of sedation, n (%), females | 15 (33.3) n=41/45 | 12 (27.3) n=44/46 | 0.485*|
| Adequate prep (BBPS score 2 or 3), n (%) | 87 (78.4) n=96/111 | 96 (78.0) n=116/123 | >0.999*|
| BBPS score, mean (SD)              | 2.1 (1.1) n=41/45                       | 2.1 (1.1) n=44/46                          | >0.999*|
| Adenoma detection rate, n (%)      | 28 (25.2) n=41/45                       | 20 (16.3) n=44/46                          | 0.106*|
| Polyp detection rate, n (%)         | 41 (36.9) n=41/45                       | 35 (28.5) n=44/46                          | 0.208*|
| Examinations completed (reached at least the distal descending colon) | 100 (90.1) n=114/123 | 107 (87.0) n=114/123 | 0.541*|
| Incomplete procedures              | Intolerance, n (%)                       | 6 (5.4) n=29/9                              | 0.524*|
| Poor prep, n (%)                   | 4 (3.6) n=3/9                            | 12 (9.8) n=97/111                           | 0.073*|
| Adhesions or bends, n (%)          | 1 (0.9) n=0                              | 0 n=9/111                                   | N*    |
| Procedure time, mean minutes (SD)  | 9.06 (3.4) n=97/111                      | 6.45 (2.9) n=114/123                       | <0.001*|
| Procedure time, cases without polypectomy, mean minutes (SD) | 8.27 (3.2) n=97/111 | 5.76 (2.4) n=114/123 | <0.001*|
| Bloating during the procedure, mean (SD) | 3.5 (2.2) n=97/111 | 3.9 (2.2) n=114/123 | 0.209*|
| Do you think that the procedure will be* | Overall Painless, n (%) | 29 (29.9) n=97/111 | 33 (28.9) n=114/123 | >0.999*|
| Overall Slightly painful, n (%)    | 29 (29.9) n=97/111                       | 36 (31.6) n=114/123                       | 0.881*|
| Overall Very painful, n (%)        | 9 (9.3) n=9/111                          | 7 (6.1) n=114/123                          | 0.441*|
| Overall Doesn't know, n (%)        | 30 (30.9) n=97/111                       | 38 (33.3) n=114/123                       | 0.768*|
| Adequate prep                      | 15 (33.3) n=41/45                       | 12 (27.3) n=44/46                          | 0.485*|
| BBPS score, mean (SD)              | 2.1 (1.1) n=41/45                       | 2.1 (1.1) n=44/46                          | >0.999*|
| Adenoma detection rate, n (%)      | 28 (25.2) n=41/45                       | 20 (16.3) n=44/46                          | 0.106*|
| Polyp detection rate, n (%)         | 41 (36.9) n=41/45                       | 35 (28.5) n=44/46                          | 0.208*|
| Examinations completed (reached at least the distal descending colon) | 100 (90.1) n=114/123 | 107 (87.0) n=114/123 | 0.541*|

SD, Standard deviation; BBPS, Boston Bowel Preparation Scale. *Fisher exact test; t* test; ‘Mann-Whitney U test; ‘Measured at the end of procedure on a Numerical Rating Scale (NRS): 0=no pain, 10=maximum pain; ‘Modified Likert scale: No pain, mild pain, severe pain; ‘Measured at the end of procedure on an NRS: 0=no bloating, 10=full bloating; ‘Data 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.\textsuperscript{[25,28]}

We selected the easy-to-use WI technique to facilitate the progression of the instrument through the sigmoid colon.\textsuperscript{[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,\textsuperscript{[12,13]} and with only one exception,\textsuperscript{[29]} compared with CO\textsubscript{2} insufflation, WI did not improve colon cleanliness and in all published RCTs did not increase ADR.\textsuperscript{[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.\textsuperscript{[13,38]} 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.\textsuperscript{[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.\textsuperscript{[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.\textsuperscript{[33,34]} 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 CO\textsubscript{2}\textsuperscript{S} group. In the WASH trial, ADR and PDR using WIS or CO\textsubscript{2}\textsuperscript{S} 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.\textsuperscript{[33,34]} The difference in overall procedure time between the two arms of the WASH trial was 43 s (WIS: 8.83 min; CO\textsubscript{2}\textsuperscript{S} 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 CO\textsubscript{2}\textsuberscript{S} 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\textsubscript{2}\textsuperscript{S}, 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.\textsuperscript{[19]}

Finally, the colonoscopist had expertise in both WI and WIS.

In conclusion, in our study both WIS and CO\textsubscript{2}\textsuperscript{S} met and improved selected sigmoidoscopy quality standards, but WIS was not superior to CO\textsubscript{2}\textsuperscript{S} 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\textsubscript{2}\textsuperscript{S} 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.

**Financial support and sponsorship**

Nil.
Conflicts of interest
There are no conflicts of interest.

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