

# Water exchange technique improves colonoscopy in patients with spinal cord injury: Results of a matched cohort study



## Authors

Thorsten Brechmann<sup>1,2</sup>, Mirko Aach<sup>3</sup>, Thomas A. Schildhauer<sup>3</sup>, Dennis Grasmücke<sup>3</sup>

## Institutions

- 1 Department of Gastroenterology and Hepatology, Berufsgenossenschaftliches Universitätsklinikum Bergmannsheil GmbH Ruhr-University Bochum, Bochum, Germany
- 2 Internal Medicine, Gastroenterology and Hematooncology, Knappschaftskrankenhaus Bottrop GmbH, Bottrop, Germany
- 3 Department of General and Trauma Surgery, Spinal Cord Injury Unit, Berufsgenossenschaftliches Universitätsklinikum Bergmannsheil GmbH Ruhr-University Bochum, Bochum, Germany

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## Corresponding author

Dr. Thorsten Brechmann, Berufsgenossenschaftliches Universitätsklinikum Bergmannsheil GmbH Ruhr-University Bochum, Department of Gastroenterology and Hepatology, Bürkle-de-la-Camp-Platz 1, 44789 Bochum, Germany  
[thorsten.brechmann@rub.de](mailto:thorsten.brechmann@rub.de)

## ABSTRACT

**Background and study aims** Colonoscopies in patients with spinal cord injury (SCI) frequently remain incomplete. This study aimed to evaluate the feasibility and impact of water exchange colonoscopy (WE) in patients with SCI.

**Patients and methods** Three matched groups, each of 31 patients (WE in SCI patients [WE-SCI]) and in the general population (WE-GP), carbon dioxide-based colonoscopy in SCI patients (CO<sub>2</sub>-SCI) were analyzed retrospectively.

**Results** Intubation of the cecum and the terminal ileum was achieved in every case in both WE groups. The intubations among the CO<sub>2</sub>-SCI patients succeeded in 29 cases (93.5 %, ns) and 20 cases (64.5 %,  $P < 0.001$ ), respectively. The cecal insertion time (23:17 ± 10:17 min vs. 22:12 ± 16:48 min) and bowel preparation during cecal insertion did not differ between WE-SCI groups. Insertion in the general population was faster (13:38 ± 07:00 min,  $P < .001$ ) and cleanliness was better. Both WE-SCI groups showed significantly better cleansing results during drawback; the improvement in cleanliness was highest in the WE-SCI (based on the five-step scale 1.4 ± 0.8 vs. 0.8 ± 0.8,  $P = 0.001$ ).

**Conclusions** The WE in SCI patients is feasible and safe and has the potential to improve the quality of colonoscopies substantially.

## Introduction

Patients with spinal cord injury (SCI) suffer from neurogenic bowel alterations characterized by impaired colonic motility, leading to decreased large bowel transport, constipation, megacolon, diarrhea, and defecation difficulties [1, 2]. If a colo-

noscopy is indicated, these neurogenic alterations hamper the entire endoscopic procedure. Despite individualized, intensified, and extended protocols for bowel preparation, the quality of cleansing remains inferior compared with the general population, leading to more aborted or re-colonoscopies after additional cleansing maneuvers [3, 4, 5, 6, 7]. The colonoscopy con-

sumes more time, presumably due to both additional bowel cleansing and a technically challenging advance with augmented looping [3].

All available data are restricted to standard colonoscopy based on insufflation of room air or carbon dioxide (CO<sub>2</sub>). Water exchange colonoscopy (WE) in the general population represents an efficacious option supported by some expert endoscopists. This technique is premised on suctioning all the gas from the lumen and instilling water instead [8]. This procedure improves patient acceptance [9, 10] and facilitates insertion in technically challenging examinations [11, 12] when a patient is not sedated, improves cleanliness [13] and, last but not least, improves the adenoma detection rate (ADR) [14, 15, 16, 17, 18, 19]. In addition, the resulting water column reduces loop formation during sigma passage [20] so that WE succeeds more easily in previously incomplete examinations [21].

On the other hand, residual feces impede insertion during endoscopy [22] and the frequently insufficient bowel cleansing of SCI patients might also lead to lower success rates, impaired quality, and even more adverse events (AEs). Because no data have been reported on outcomes of WE in SCI patients, we retrospectively compared completeness and other quality parameters in consecutive SCI patients who had undergone WE with a group of CO<sub>2</sub>-based colonoscopies in SCI patients, on the one hand, and WE in non-injured patients, on the other hand.

## Patients and methods

### Study population

Consecutive patients with chronic SCI ( $\geq 6$  months) who had undergone elective WE between February 2021 and March 2022 were included in a retrospective cohort study. All SCI subjects were treated as inpatients in a specialized SCI unit and referred to the associated endoscopy unit (University Hospital Bergmannsheil, Bochum, Germany). Non-SCI patients with WE in the same time period and SCI patients who had a CO<sub>2</sub>-based colonoscopy between January 2016 and December 2020 served as controls. Emergency examinations and patients with previous resecting large bowel surgery were excluded.

### Clinical data acquisition

Clinical data, such as demographic characteristics, previous bowel surgery, comorbidities, medication, laboratory and sedation parameters, and indication and results of the colonoscopy, and histological assessment were collected from the electronic database. All parameters were studied at the time of endoscopy. The severity of SCI was classified according to the International Standards for Neurological Classification of Spinal Cord Injury of the American Society of Spinal Cord Injury (ASIA) including the ASIA Impairment Scale (AIS) [23]. The Charlson Comorbidity Index was calculated according to Charlson and colleagues [24].

### Objectives

The primary objective was to evaluate the completeness of WEs in SCI patients as defined by intubation of the terminal ileum and/or cecum. Secondary objectives included duration of the

entire endoscopy, insertion and drawback time, cleansing level during cecum insertion and drawback, polyp detection rate (PDR), ADR, and occurrence of AEs such as bleeding, perforation, and death related to the endoscopy.

### Colonoscopy procedure

All colonoscopies were performed at the university hospital Berufsgenossenschaftliches Universitätsklinikum Bergmannsheil gGmbH, Department of Gastroenterology and Hepatology, Ruhr University Bochum, Germany, by one very experienced endoscopist (TB, > 5000 gas-based colonoscopies), who started WE in October 2020 with colonoscopes Olympus CF-180L and CF-190L; the first of the consecutive WEs that was included for analysis was number 33. Bowel cleansing was performed as previously described [3]. Flexible recto-sigmoidoscopies or sigmoidoscopies were excluded if they were initially intended to remain incomplete. Primarily intended complete but abandoned colonoscopies were included. Complete colonoscopy was defined by intubation of the cecum and/or terminal ileum. A scope guide or fluoroscopy was never used. A lack of cecum insertion was defined as the inability to push the colonoscope tip forward during insertion despite manual maneuvers. Carbon dioxide insufflation was used routinely for air-driven standard colonoscopy. WE was performed according to Cadoni and Ishaq [8]. In summary, all colonic air was suctioned from the colon and replaced by sterile distilled water (AQUA B. Braun, Melsungen, Germany). If vision was blurred by feces, the liquid stool was removed and replaced with fresh water until sufficient visibility was achieved.

A propofol mono sedation was administered on demand as non-anesthesiologist-administered sedation, according to national and international guidelines [25, 26, 27]. A person who had patient sedation as their sole task monitored the patient. The effect of bowel cleansing was determined by means of a five-step scale (excellent, good, fair, poor, very poor) during both insertion and drawback considering the entire colon; the evaluation was realized resembling the Harefield Cleansing Scale (**Supplementary Fig. S1**) [28]. Any AEs associated with the colonoscopy or sedation were recorded.

### Histological assessment

All polyps detected were removed during colonoscopy. Histological assessments were performed by an expert gastrointestinal pathologist according to current guidelines [29]. Polyps were divided into adenomatous and non-adenomatous polyps [30]. High-grade adenomas, villous history, or size  $\geq 10$  mm were regarded as advanced adenomas [31].

### Matching procedure

Consecutive WE-SCI patients who were included, as described above, provided the base for the matching process. The investigators identified matching subjects from the database in a 1:1:1 ratio based on age ( $\pm 5$  years) and gender. The first group consisted of consecutive SCI patients who had undergone elective CO<sub>2</sub>-based colonoscopy. The second group comprised non-injured patients who had undergone elective WE; these pa-

tients were also matched according to the time of performance ( $\pm 3$  months) to avoid effects from a potential learning curve.

## Statistics

Statistical analysis was performed using SPSS, version 27.0 (SPSS Inc, United States). Categorical and nominal data were indicated as absolute values and relative frequencies. The arithmetic mean with standard deviation was used for metric variables; the Charlson comorbidity index was given as the median. Interference statistics were realized using analysis of variance, Pearson's Chi-squared test and paired *t*-test were used, as appropriate.  $P < 0.05$  was regarded as significant.

## Ethical concerns

The study protocol was approved by the institutional review board of the Ruhr University Bochum [registry number 22-7450-BR] based on the ethical guidelines of the Declaration of Helsinki and its later revisions. Informed consent was obtained from all patients before colonoscopy. Informed consent for this study was exempted by the institutional review board.

## Results

Thirty-one of 33 SCI patients who had undergone WE were eligible for inclusion (► **Fig. 1**). The remaining two cases were excluded due to prior bowel resection. As intended, there were no differences regarding the matching parameters gender and age (► **Table 1**).

## Demographic characteristics

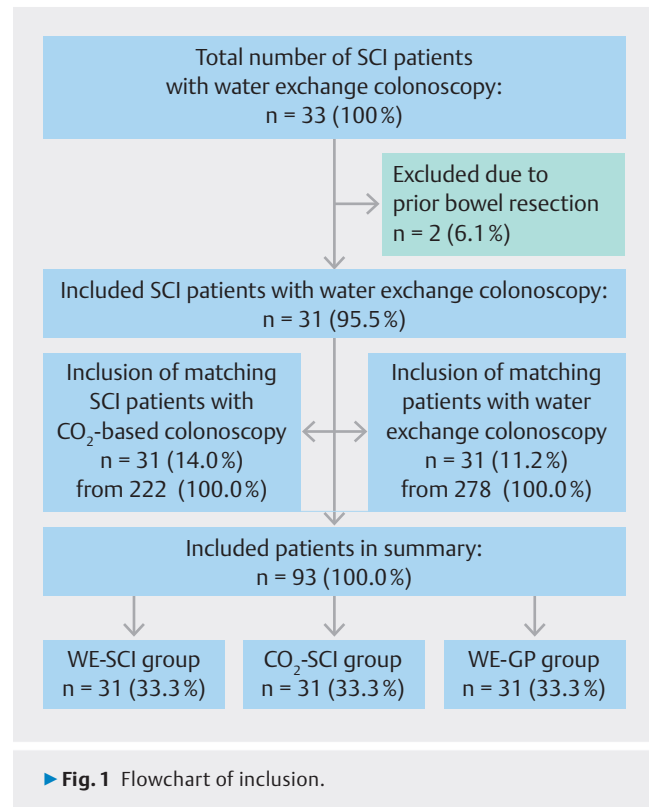
The mean age of the whole cohort was  $61.2 \pm 12.5$  years. The vast majority of the patients were male ( $n = 75$ , 80.6%). There were slight differences regarding comorbidities and medication in the WE-GP group compared with both SCI groups (► **Table 1**, **Supplementary Table S1** and **Supplementary Table S2**). The mean hemoglobin value averaged  $12.9 \pm 2.2$  g/dL (minimum 6.8 g/dL, maximum 17.6 g/dL), the white blood cell count measured  $7.3 \pm 3.0$  per nL (3.2–26.5/nL), and the platelets,  $236 \pm 85$ /nL (70–603/nL). The mean international normalized ratio was  $1.1 \pm 0.4$  (0.9–4.8) and the partial thromboplastin time  $31 \pm 6$  seconds (24–68 seconds). The average value for C-reactive protein was  $2.6 \pm 3.5$  mg/dL (0.1–19.0 mg/dL).

## Characterization of SCI injury patterns

The mean duration of SCI was  $266 \pm 180$  months. A total of 19.4% of patients ( $n = 18$ ) suffered from an injury at the cervical level, 40.9% ( $n = 38$ ) from thoracic and 6% ( $n = 6.5$ ) from lumbar injury. The AIS score consisted of grade A in 46 (49.5%), grade B in two (2.2%), grade C in 12 (12.9%) and grade D in two cases (2.2%). Data were comparable in both SCI groups (► **Table 2**).

## Indications and procedure outcomes

Only a minority of colonoscopies were performed for screening purposes (9.7%), with slight but significant differences between the groups (**Supplementary Table S3**). There were no screening cases in the CO<sub>2</sub>-SCI group, whereas the SCI patients in the WE group represented the highest rate; the general pop-



ulation lay exactly between the SCI groups. Most endoscopies were indicated by at least one symptom. The symptoms were, in decreasing order, anemia and overt or occult bleeding (29.3%), constipation (25.3%), abdominal pain (20.2%), follow-up (13.1%), weight loss (7.1%), diarrhea (6.1%) and miscellaneous, covering perioperative setting, intended polypectomy, quest for malignancy, and vegetative dysregulation, i. e. sweating, hypertension, tachycardia, elevated body temperature, and anal secretion (9.1%). Constipation, which was more common among both SCI groups (30.3% vs. 36.4% vs. 9.1%, Chi-squared test  $P = 0.028$ ), represented the only significant difference.

A total of 24 colonoscopies (24.2%) resulted in a normal finding (**Supplementary Table S4**). The pathologies included, in decreasing order, polyps (51.5%), any kind of inflammation (17.2%), diverticula (21.2%), anal prolapse (15.2%), angiodysplasia (1.0%), carcinoma (1.0%) and miscellaneous (3.0%), covering anal fissure and pseudomelanosis coli. All features were equally distributed among the groups except for anal prolapse, which occurred equally often in both groups of SCI patients but not in the WE-GP group (24.2% and 21.2% vs. 0.0%, Chi-squared test  $P = 0.011$ ).

The WE-GP group required propofol sedation more often (93.5% vs. 71.0% vs. 64.5%,  $P < 0.05$ ), and needed higher doses than the WE-SCI and CO<sub>2</sub>-SCI groups ( $0.151 \pm 0.077$  mg/minute vs.  $0.151 \pm 0.051$  mg/minute vs.  $0.209 \pm 0.090$  mg/minute,  $P < 0.05$ ). No sedation-associated AEs occurred.

Intubation of the cecum and the terminal ileum was achieved in every case in both WE groups (100.0%, ► **Table 1**), whereas the respective intubation was possible in 29 (93.5%,

► **Table 1** Basic demographic characteristics.

	WE-SCI n = 31 (%)	CO <sub>2</sub> -SCI n = 31 (%)	WE-GP n = 31 (%)	P value
<b>Age (years, mean ± SD)<sup>†</sup></b>	61.1 ± 12.9	60.8 ± 12.2	61.6 ± 12.8	0.963
<b>Gender (male)<sup>†</sup></b>	25 (80.6)	25 (80.6)	25 (80.6)	1.000
<b>ASA (mean ± SD)</b>	2.4 ± 0.9	2.6 ± 0.9	2.3 ± 0.9	0.667
<b>ASA scoring</b>				0.420
1	4 (12.9)	4 (12.9)	6 (19.4)	
2	13 (41.9)	9 (29.0)	11 (35.5)	
3	11 (35.5)	13 (41.9)	12 (38.7)	
4	3 (9.7)	5 (16.1)	2 (6.5)	
<b>Laboratory parameters</b>				
Hemoglobin (g/dL)	12.6 ± 2.1	13.0 ± 2.2	13.1 ± 2.3	0.789
WBC (/nL)	7.5 ± 4.2	7.5 ± 2.5	6.9 ± 1.9	0.531
Platelets (/nL)	239 ± 86	226 ± 59	246 ± 107	0.537
CRP (mg/dL)	2.8 ± 3.2	2.9 ± 4.2	1.7 ± 2.5	0.529
INR	1.1 ± 0.1	1.2 ± 0.7	1.1 ± 0.2	0.748
PTT (sec)	31 ± 4	33 ± 8	29 ± 6	0.060
<b>CCI</b>	1	1	1	0.702

<sup>†</sup> Matching criteria.

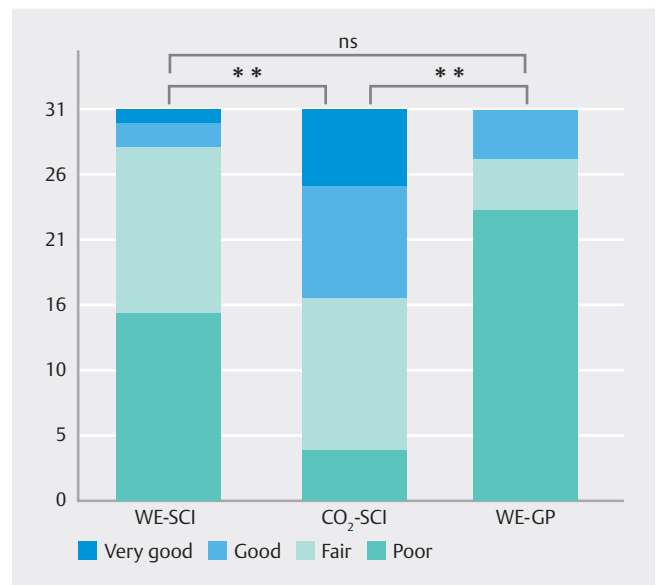
SCI, spinal cord injury; SD, standard deviation; WBC, white blood cell count; CRP, C-reactive protein; INR, international normalized ratio; PTT, partial thromboplastin time; CCI, Charlson Comorbidity Index.

Statistics were analyzed with ANOVA, Chi-squared test or *t*-test as appropriate.

ns) and 20 cases (64.5%,  $P < 0.001$ ) in the CO<sub>2</sub>-SCI group. The duration of the insertion and the entire colonoscopy did not differ between the SCI groups, whereas both the insertion and total procedure times were shorter in the WE-GP group than in the SCI groups. The low impact of the experience with water exchange technique is displayed in **Supplementary Fig. S3**; only the first 20 WEs consumed more time than the later examinations. The drawback time was comparable among the three groups.

Similarly, the cleansing level during cecum insertion did not differ between the SCI groups, whereas the WE-GP group had significantly better bowel preparation. Both WE groups had significantly better cleansing results during drawback than the CO<sub>2</sub>-SCI group (► **Fig. 2**). Based on the five-step scale, the improvement in cleansing was significantly higher in the WE-SCI group compared with the CO<sub>2</sub>-SCI and WE-GP groups ( $1.4 \pm 0.8$  vs.  $0.8 \pm 0.8$  vs.  $0.6 \pm 0.6$ ,  $P = .001$ ). Regarding both WE groups, the time needed for insertion increased from an excellent to a very poor cleansing level (analysis of variance,  $P < 0.001$ ; **Supplementary Fig. S2**).

Several endoscopic interventions were applied in 42 cases (42.4%), including polypectomy, piecemeal mucosectomy, argon plasma coagulation, and full-thickness resection. Any AEs were very rare; only one case of bleeding occurred in the WE-SCI group several days after a piecemeal mucosectomy of a laterally spreading adenoma of the rectum.



► **Fig. 2** Cleansing level during drawback. Statistics were analyzed by Chi-squared test (\*\* Significant with  $P < 0.01$ ).

► **Table 2** Spinal cord injury characteristics.

	WE-SCI n (%)	CO <sub>2</sub> -SCI n (%)	P value
<b>Duration since SCI [months]</b>	261 ± 167	216 ± 159	0.396*
<b>Etiology of SCI</b>			0.478†
Trauma	17 (38.6)	21 (47.7)	
Infection	0 (0)	1 (2.3)	
Neoplasia	0 (0)	0 (0)	
Other‡	2 (4.5)	3 (6.8)	
<b>AIS classification</b>			0.875†
Grade A	14 (31.8)	19 (43.2)	
Grade B	1 (2.3)	0 (0)	
Grade C	4 (9.1)	5 (11.4)	
Grade D	0 (0)	1 (2.3)	
<b>Level of injury</b>			0.104†
Cervical	8 (18.2)	8 (18.2)	
Thoracic	10 (22.7)	16 (36.4)	
Lumbar	1 (2.3)	1 (2.3)	

SCI, spinal cord injury; AIS, ASIA impairment scale.

\*Statistics were analyzed by paired t-test.

†Statistics were analyzed by ANOVA.

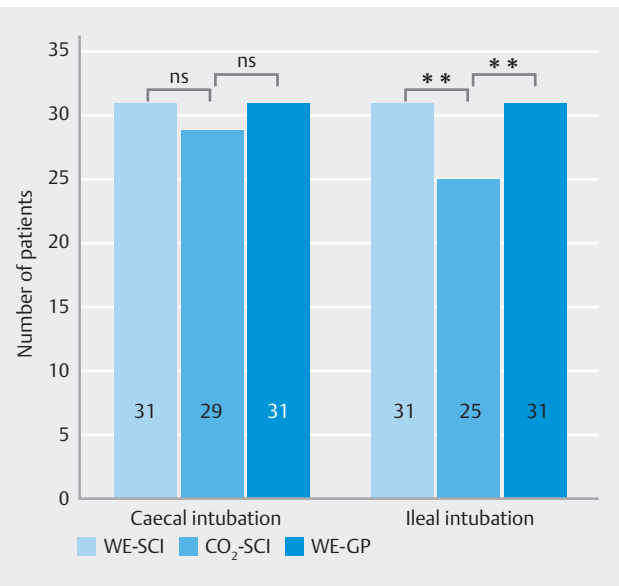
‡Including multiple sclerosis and spina bifida.

## Polyp and adenoma detection

The size of the polyps ranged from 2 to 25 mm. The PDR varied between 42% and 61%, but did not differ significantly between the groups (► **Table 3**). Given the fact that in one case, two polyps could not be retrieved, and they were regarded as non-adenomatous polyp, the ADR (46% vs. 33% vs. 33%, ns) and the average number of adenomas resected ( $1.2 \pm 1.8$  vs.  $0.9 \pm 1.7$  vs.  $0.9 \pm 1.7$ , ns) were numerically, but not significantly highest in the WE-SCI group. Some of these cases comprised adenomas with high-grade dysplasia and sessile serrated adenomas.

## Discussion

This thoroughly matched retrospective cohort study indicates that the water exchange technique offers the potential to substantially improve the quality and outcome of colonoscopy in patients with SCI. First, water exchange resulted in exclusively complete colonoscopies even in SCI patients; the cecum and the terminal ileum were intubated in all cases and exceeded the results from CO<sub>2</sub>-based colonoscopies. Of note, in this study, even the CO<sub>2</sub>-SCI group achieved better results than had been described previously [3,4,5,6,7]; in this particular setting of SCI patients, the current literature reports a high proportion of abandoned colonoscopies that are claimed to remain incomplete in up to one-quarter of cases [6]. This discrepancy in the literature might have contributed to the fact that intuba-



► **Fig. 3** Frequency of intubation of the terminal ileum and the cecum. Statistics were analyzed by Chi-squared test (\*\*Significant with  $P < 0.01$ ). Further data are detailed in ► **Table 3**.

tion of the terminal ileum, but not that of the cecum, achieved statistical significance. We assume that the extensive training and experience of the endoscopist, and all the staff in the endoscopy unit, with SCI patient colonoscopies was responsible for the high rates of caecal intubation in the CO<sub>2</sub>-SCI group. Furthermore, the whole team that was involved in patient bowel preparation has gained special insights and knowledge over time, so that patients in the study achieved better cleansing results before they were referred to endoscopy for the first time.

Second, the cleansing level during drawback was significantly better in both WE groups compared with the CO<sub>2</sub> group (► **Fig. 3**). Because there were no differences in bowel preparation during insertion, the remarkable cleansing results in the WE-SCI group can be attributed to the water exchange technique. As expected from previous studies [3,6], bowel preparation was significantly better in the WE-GP group. Although colonoscopy is the most sensitive means for detection of colorectal cancer and precursor lesions in the general population and has been proposed for screening in several guidelines [32,33], it is associated with particular limitations in patients with SCI, such as more intense but less effective bowel preparation [5] and frequently incomplete examinations [6]. None of the data refer to the consequences of poorer bowel preparation and technically challenging colonoscopy in SCI patients, but lower preparation quality may result in an increased risk of missing neoplasia [34] and the need for repeated colonoscopy after prior incomplete examination [35].

In the current study, insertion time was comparable between both SCI groups and was lower in cases with excellent or good bowel preparation. In the few cases with an excellent grade of preparation, WE was associated with the shortest insertion time (**Supplementary Table S5**). This effect was no longer detectable when the cleansing level declined. Therefore,

► **Table 3** General outcome and results of colonoscopies.

	<b>WE-SCI n = 31 (%)</b>	<b>CO<sub>2</sub>-SCI n = 31 (%)</b>	<b>WE-GP n = 31 (%)</b>	<b>P value</b>
<b>Cecal intubation</b>	31 (100.0)	29 (93.5)	31 (100.0)	0.132
<b>Ileal intubation</b>	31 (100.0)	23 (69.7)**	31 (100.0)	<0.001
<b>Duration of examination (minutes)</b>				
Insertion	23:17 ± 10:17	22:12 ± 16:48	13:38 ± 07:00**	0.005
Drawback	20:17 ± 18:18	17:46 ± 09:41	15:35 ± 08:03	0.356
Total	43:35 ± 21:39	39:58 ± 19:31	29:14 ± 11:10**	0.007
<b>Cleansing Level during insertion**</b>				
1	2 (6.5)	3 (9.7)	14 (45.2)	
2	6 (19.4)	3 (9.7)	8 (25.8)	
3	13 (41.9)	11 (35.5)	5 (16.1)	
4	7 (22.6)	11 (35.5)	3 (9.7)	
5	3 (9.7)	3 (9.7)	1 (3.2)	
<b>Cleansing Level during drawback**</b>				
1	15 (48.4)	4 (12.9)	23 (74.2)	
2	13 (41.9)	12 (38.7)	4 (12.9)	
3	2 (6.5)	9 (29.0)	4 (12.9)	
4	1 (3.2)	6 (19.4)	0 (0)	
5	0 (0)	0 (0)	0 (0)	
<b>Improvement of bowel cleansing**</b>	1.4 ± 0.8	0.8 ± 0.8	0.6 ± 0.6	<0.001
<b>Polyp and adenoma characteristics</b>				
PPP	1.7 ± 1.9	1.2 ± 1.5	1.3 ± 2.0	0.736
PDR	0.61	0.55	0.42	0.306
APP	1.2 ± 1.8	0.9 ± 1.7	0.9 ± 1.7	0.605
ADR	15 (45.5)	11 (33.3)	11 (33.3)	0.394
High-grade dysplasia	2 (6.1)	1 (3.0)	0 (0.0)	0.468
SSA	2 (6.1)	2 (6.1)	3 (4.1)	0.530
Smallest polyp (mm)	2 (in 9.1%)	2 (in 12.1%)	2 (in 9.1%)	0.678
Largest polyp (mm)	20	8	25	0.680
<b>Endoscopic intervention</b>	15 (45.5)	15 (45.5)	12 (36.4)	0.742
<b>Adverse events</b>	1 (3.2)	0 (0)	0 (0)	0.372
Perforation	0 (0)	0 (0)	0 (0)	n/a
Bleeding	1 (3.2)	0 (0)	0 (0)	0.372
Sedation	0 (0)	0 (0)	0 (0)	n/a
Other	0 (0)	0 (0)	0 (0)	n/a
<b>NAAS</b>	22 (71.0)	20 (64.5)	29 (93.5)*	0.018
<b>Propofol dose (mg/minute)</b>	0.151 ± 0.077	0.151 ± 0.051	0.209 ± 0.090*	0.011

SD, standard deviation; PPP, polyps per participant; PDR, polyp detection rate; ADR, adenoma detection rate; APP, adenomas per participant; SSA, sessile serrated adenoma; NAAS, non-anesthesiologist-administered sedation.

Statistics were analyzed with ANOVA, Chi-squared test or t-test as appropriate

\*Significant with  $P < 0.05$ .; \*\*Significant with  $P < 0.01$ .

we hypothesize that significant time is spent in order to clean the bowel from residual feces. Nevertheless, the additional cleansing maneuvers seem to be more effective in WE-SCI. Although these maneuvers may consume more time, the resulting water column in the colon may facilitate insertion.

Unfortunately, we did not measure the amount of instilled and retrieved water. In the current study, the cleansing level was given as an integrated five-step scale estimation over the entire colon, both for insertion and drawback. Despite this loss of complexity, the scoring during insertion was associated with what was probably the most relevant outcome parameter for this study, i.e. the time spent for insertion (**Supplementary Fig. S2** and **Supplementary Fig. S3**). A similar effect was seen during drawback, where an equal scoring system derived from the Harefield Cleansing Scale was applied [28].

The fact that all colonoscopies were performed by a single operator with particular experience in endoscopy of SCI patients limits the interpretation and generalizability of the data. On the other hand, experience with WE was limited, although a relevant learning curve was not detectable (**Supplementary Fig. S3**). Our matching protocol took into consideration the time of performance to compensate for potential effects associated with the learning curve. Hence, a homogenous and comparable WE control group resulted. The CO<sub>2</sub>-SCI group consisted of historic SCI colonoscopies. Matching afforded the inclusion of patients for whom data had been collected over nearly 5 years. In fact, neither the bowel preparation protocols, endoscopy nor reporting standards have changed, so that both SCI groups are largely comparable. The limited sample size hampered deeper analysis and referred to quality parameters. Because this cohort study, as the first to address WE in SCI patients, was intended as a proof-of-concept study, the promising results encourage us to investigate the effect on ADR in future studies.

## Conclusions

In this retrospective proof-of-concept study with a limited sample size, WE compensated for differences in quality measures of colonoscopies between SCI patients and the general population without increasing the risk of AEs. Hence, a prospective randomized trial is not only feasible but even mandatory in order to confirm the results in detail. Until then, we encourage endoscopists in specialized centers to use WE as the standard technique in patients with SCI.

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## Conflict of Interest

The authors declare that they have no conflict of interest.

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