

Comparison between pulsed irrigation enhanced evacuation and polyethylene glycol-electrolyte lavage solution for bowel preparation prior to elective colonoscopy in veterans with spinal cord injury

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Background: Poor preparation for elective colonoscopy is common in persons with spinal cord injury (SCI). This unsatisfactory outcome is likely due to long-standing difficulty with evacuation and decreased colonic motility. Our objective was to determine the most effective preparation for elective colonoscopy applying a novel and traditional approach to bowel cleansing.

Methods: Twenty-four subjects with SCI were consented and scheduled to receive one of the two possible arms: pulsed irrigation enhanced evacuation (PIEE) or polyethylene glycol-electrolyte lavage solution (PEG; CoLyte[®]). The quality of the preparation was scored during the colonoscopy by applying the Ottawa scoring system.

Results: Patients with SCI who received PIEE tended to have lower Ottawa scores and a higher percentage of acceptable preparations than did those who received PEG; however, the results were not statistically different.

Conclusion: In this preliminary study in subjects with SCI, neither PIEE nor PEG produced acceptable bowel preparation for elective colonoscopy. Future studies should confirm our findings and consider studying alternative, more efficacious approaches to bowel cleansing prior to colonoscopic procedures in patients with SCI, which should provide better outcomes.

Registration number for clinicaltrials.gov: NCT00745095.

Keywords: Polyethylene glycol, Bowel preparations, Paraplegia, Tetraplegia, Colonoscopy, Polyp detection

Background

It has been demonstrated that performing elective colonoscopies to detect and remove precancerous adenomas prevents the later development of colon rectal cancer (CRC).¹⁻⁶ Due to dramatic advances in clinical care, persons with spinal cord injury (SCI) currently have life spans that are comparable to those of able-bodied

(AB) individuals. As such, those with SCI are likely to have similar life-long risks for the development of CRC to that of the general population. However, a retrospective analysis of findings of colonoscopies noted a significantly decreased polyp detection rate in persons with SCI (22%) than that observed in the AB controls (52%).^{7,8}

Poor colonoscopic visualization of the bowel wall occurs far more frequently in persons with SCI than in AB individuals due to long-standing difficulty with evacuation and decreased intestinal peristalsis, factors

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which prolong the bowel transit time.⁹ It may be assumed that predisposition to severe and chronic constipation increases the chance of obtaining an unpredictable and inadequate response to standard colonoscopic bowel preparations. This supposition is supported by our prior work, in which the authors observed that ~75% of individuals with SCI had suboptimal bowel preparation for elective colonoscopy when being electively screened for premalignant lesions.¹⁰ Another report found that patients with SCI received fewer colonoscopies than that performed in the general population.¹¹ The unfavorable combination of a decreased rate of elective colonoscopic screening and generally poor quality of bowel preparations would be anticipated to heighten the rate of missed or delayed polyp detection, thus increasing the risk for the subsequent occurrence of CRC in individuals with SCI.

A number of standard colonoscopic preparations are routinely used in the general population. Polyethylene glycol (PEG) solutions promote bowel cleansing through the ingestion of large quantities of a non-absorbable, balanced electrolyte solution; PEG is a high-molecular weight, non-absorbable polymer that minimizes fluid exchange across the colonic membrane. While standard PEG solutions produce good quality bowel preparations in the general population,^{9,12–14} the use of a low-volume PEG preparation has not been reported to date in the SCI population. Non-pharmacological methods, such as pulsed irrigation enhanced evacuation (PIEE) devices, have been successfully used in the short- and long-term to treat impaction and to stimulate bowel movement during routine bowel care.^{15–17} While PIEE has been reported to be safe and effective for routine bowel care and the treatment of impaction, its utility as an adjunct to colonoscopy preparation has also not been reported. A single study in AB individuals reported that colonoscopy preparation with PIEEs and magnesium citrate did not differ from that of PEG alone.¹⁸

Despite evidence demonstrating the difficulty of obtaining adequate bowel cleansing regimens prior to elective colonoscopy in persons with SCI, in large part due to the lack of randomized clinical trials addressing this issue, there are currently no specific clinical guidelines for bowel preparation. In the current study, subjects with SCI received either PEG, a standard bowel preparation solution, or PIEE, a non-pharmacological method for bowel cleansing, in an effort to determine which approach will provide a more effective bowel cleansing method prior to elective colonoscopy. However, because PIEE would be unable to cleanse the entire colon, specifically, the right section of the

colon, which would result in an incomplete preparation, we hypothesized that oral lavage solutions (PEG) may produce more acceptable bowel preparations than non-pharmacological approaches (PIEE) in individuals with SCI.

Methods

An observational, single-blinded study design was performed. Subjects with SCI were defined as those veteran patients with a primary diagnosis of SCI. Subjects with SCI were scheduled to receive one of the following two preparations: PIEE or PEG (CoLyte®) solution. The study protocol was approved by the Institutional Review Board of the James J. Peter VA Medical Center, and the study was registered on the Clinical Trials.gov website (ClinicalTrials.gov Identifier: NCT00745095).

Subjects of either sex who were scheduled for elective colonoscopy were recruited to participate in this study if they were between the age 18 and 69 and had stable chronic SCI (SCI for >1 year). As a precaution against aggravating pre-existent renal insufficiency from potential electrolyte shifts that may result from the application of PIEE, all potential subjects with SCI were excluded from participation in the study if they had a glomerular filtration rate (GFR) ≤ 50 ml/minute. All colonoscopic procedures and data collection were performed at the James J. Peters Veteran Affairs Medical Center, Bronx, New York.

Subjects in the PIEE preparation group were pre-treated with a standard split-dose magnesium citrate oral preparation for 2 days prior to elective colonoscopy; after completion of the magnesium citrate oral bowel preparation, the PIEE procedure was performed on the day of colonoscopy. The subjects were placed on his/her left side on a level surface (bed) while a well-lubricated PIEE speculum was inserted into the rectum. The speculum was secured in place by inflating the balloon attached to it, which created a watertight seal. The PIEE system was then initiated using warm water (93–104°F). After 5 minutes of PIEE on the left side, the subjects were then transferred onto his/her right side and then again in a supine position for a period of 5 minutes while the PIEE procedure was repeated for each position until the discharge from the speculum was clear. Once cleared, the speculum balloon was deflated and removed; the patient was allowed to evacuate any remaining contents onto the commode.

The PEG preparations were administered according to the recommendations of the company, which was prescribed as a split-dose over 2 days. The subjects were

provided verbal instructions and told to follow the package insert directions.

The quality of the cleansing bowel preparations was scored during colonoscopy by using the Ottawa Scale for Bowel Evacuation. The Ottawa score (OS) is a semi-quantitative measure of the colonoscopic preparation with a range from 0 (a perfectly clean and dry colon) to 14 (a colon completely filled with stool and liquid).¹⁹ The right colon, mid-colon, and rectosigmoid colon were independently rated from 0 to 4, and the fluid quantity of the entire colon was captured by the addition of a score of 0–2. The total score is calculated by summing the individual rating numbers for the three colonic segments plus the rating number signifying the fluid content of the colon. The range of the scale is from 0 (perfect score) to 14 (solid stool in each colon segment and excess fluid). For purposes of this study, an acceptable total OS was defined as ≤ 3 .¹⁹ Because the level of impaction that individuals with SCI experience would require significant bowel cleansing procedures to adequately view the colon and to detect any possible colonic polyps, the threshold value for an acceptable score OS for bowel preparation was defined as ≤ 3 .¹⁹ The total time to perform the procedure was recorded. Complications to the colonoscopy procedure, such as the presence and degree of distension, discomfort, as well as a patient's willingness to repeat the bowel preparation, were recorded.

The OS was determined for each bowel preparation by one of the four board certified gastroenterologists who were blinded to the bowel cleansing procedure that had been performed prior to colonoscopy. These gastroenterologists had been previously "calibrated" to use the OS. The calibration procedure involved collectively observing colonoscopies and then individually rating the quality of each preparation. When the scores did not coincide, additional colonoscopies were performed and discussions ensued until acceptable inter-observer variability on applying the scoring system was obtained. Inter-observer reliability calibration has been reported as a component of a pilot study that was performed prior to initiating this project.¹⁹

The primary outcome for this study was the number of acceptable or unacceptable colonoscopic preparations as determined from the OS obtained for each of the colon cleansing preparation subgroups. The number of polyps detected was also recorded and compared with the quality of the preparation and the subgroup by preparation. The presence and degree of discomfort, distension, and/or other complications from the preparations were self-reported by the subjects

using a Likert scale of 0–10, and further subcategorized by ≤ 5.0 or >5.0 .

The demographic continuous variables are reported as mean \pm SD. Separate one-sample analysis of variance (ANOVA) models with Fisher *post hoc* analyses were used to determine significant differences among the preparation groups in SCI for all continuous demographic variables. OS values were treated with a parametric (one-sample ANOVA) analysis. A contingency table and Chi-square analysis was used to determine the significance of the percentage of acceptable preparation among the groups. The level of significance was set at $P < 0.05$ for all analyses.

Results

From September 2009 to February 2013, a total of 24 subjects with SCI were scheduled to receive one of the two possible preparations: PIEE ($n = 12$) or PEG ($n = 12$) (Fig. 1).

The demographic characteristics were stratified by the preparation group (Table 1). No significant differences were noted among the demographic variables for each group (Table 1). The average duration of injury for all subjects was 25 ± 14 years.

OSs were not significantly different between the groups, but OS were higher after PEG than PIEE (Table 2). No significance difference was found as to which bowel cleaning preparation afforded a greater percentage of acceptable outcomes, but the PIEE approach was noted to have a slightly higher percentage compared to PEG (50 vs. 42% $\chi^2 = 0.168_{(df,1)}$ $P = 0.682$) (Fig. 2). No significant difference were noted between PIEE and PEG preparations for the detection of polyps ($F = 0.042$, $P = 0.859$, power = 0.54) (Table 3).

None of the SCI groups, regardless of bowel preparation, experienced a serious adverse event. No significant changes were noted in renal function or serum electrolytes before or after the bowel preparation procedures (i.e. blood urea nitrogen, glomerular filtration rate, serum creatinine, serum sodium, serum potassium, serum bicarbonate, and serum chloride); for all groups, the mean values for these determinations pre- and post-colonoscopy remained within the normal reference ranges. A significant, but not clinically relevant, elevation in serum magnesium levels was found in the groups that received PIEE. In addition, one subject in the PIEE group was diagnosed with orthostatic hypotension during study participation; this adverse event was ascribed to being possibly related to study participation, and the subject remained stable and was willing and able to continue with the procedure.

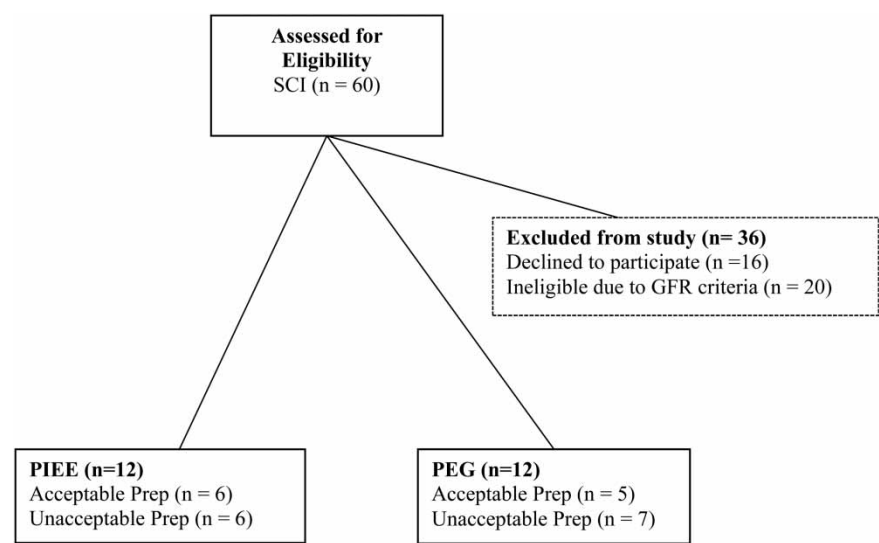


Figure 1 Study flow chart. Number of subjects assessed for eligibility: SCI, spinal cord injured; PIEE, pulsed irrigation enhanced evacuation; PEG, polyethylene glycol-electrolyte lavage. “Acceptable Prep” denotes colonoscopy preparations with an OS of ≤3.

A number of subjects in the PIEE bowel preparation group reported significant gastrointestinal (GI) discomfort from the preparation prescribed and/or indicated that they would not likely consider that particular approach to be used for bowel cleansing in preparation for a future colonoscopy (3 (25%) vs. 0 (0%), $P < 0.001$) (Table 4). There were no similar reports or adverse events reported by subjects who received the PEG preparation.

Discussion

Bowel preparation of sufficiently high quality for colonoscopic examination is crucial for optimal CRC screening and prevention. Standard bowel cleansing preparations for screening colonoscopy used in the

general population when applied to the SCI population have usually resulted in suboptimal bowel cleansing and unacceptable OSs.¹⁰ In the current study, using an OS of ≤3 as the criterion for an acceptable bowel preparation, neither PIEE nor PEG produced an acceptable bowel preparation in subjects with SCI. Each bowel cleaning approach was not significantly different from the other, and neither one provided more than half of the subjects in either group with an acceptable OS prior to elective colonoscopy.

Spinal cord injuries above the sacral level can cause either upper motor neuron or lower motor neuron lesions to the colon, resulting in “neurogenic bowel”, characterized by an impairment of defecatory reflexes and control, as well as a slowing of peristaltic activity, which results in increased whole gut transit time (WGTT) and chronic constipation/impaction. Such colonic patterns of obstruction, with associated stool retention, tend to be difficult to clear, even with aggressive bowel evacuation treatments. The efficacy of standard bowel preparations, such as PEG depends in large measure on spinal cord-mediated reflex peristalsis, which is impaired or absent in persons with SCI.

Table 1 Characteristics of study population

Demographics	SCI	
	PIEE (n = 12)	PEG (n = 12)
Age (years)	61 ± 11	57 ± 8
Height (cm)	176 ± 8	178 ± 6
Weight (kg)	86.1 ± 27.0	80.0 ± 18.0
BMI (kg/m ²)	28.0 ± 9.0	25.4 ± 6.0
DOI	30 ± 13	21 ± 14
Para, n (%)	5 (58%)	6 (50%)
Tetra, n (%)	11 (42%)	6 (50%)
Neurological injury level (range)	C5–C7; T4–T12	C4–C7; T4–T12; L1–L3
AIS impairment scale (range)	A–D	A–D

SCI, spinal cord injury; PIEE, pulsed irrigation enhanced evacuation; PEG, polyethylene glycol-electrolyte lavage; cm, centimeters; kg, kilograms; BMI, body mass index; m², meters squared; DOI, duration of injury; Para, paraplegia; Tetra, tetraplegia; C, cervical; T, thoracic; L, lumbar.

Table 2 OS results by colonoscopy preparation

	PIEE	PEG
Mean ± SD	3.6 ± 3.1	4.8 ± 2.1
(Min, max)	(0, 8)	(2, 7)
Count	12	12

SD, standard deviation; Min, minimum value; Max, maximum value; PIEE, pulsed irrigation enhanced evacuation; PEG, polyethylene glycol-electrolyte lavage. No significant differences were noted for OSs between the groups ($F = 1.2$, $P = 0.287$).

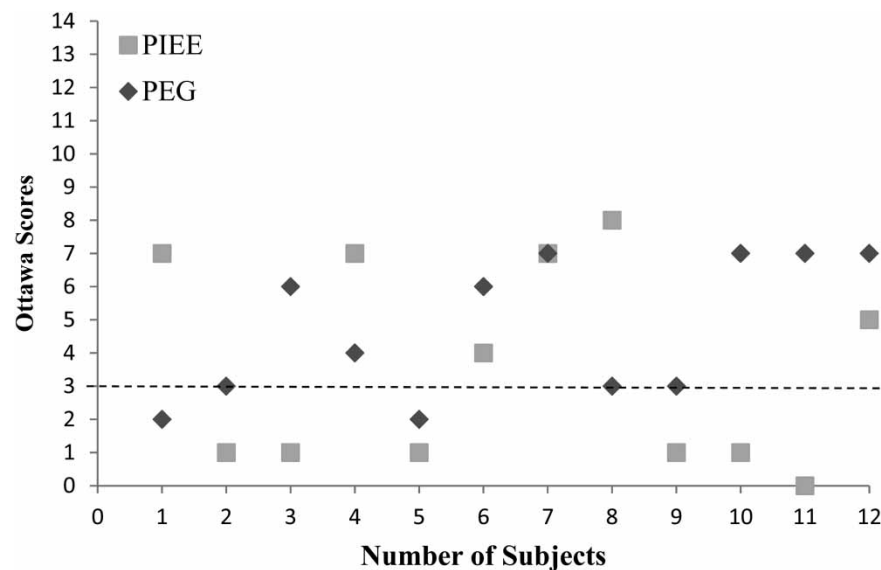


Figure 2 OSs among the colonoscopy preparations. The individual OSs for each subject by preparation is presented (PIEE, pulsed irrigation enhanced evacuation; PEG, polyethylene glycol-electrolyte lavage solution). The OS were not significantly different between the preparation groups. The broken line represents the cutoff OS for an acceptable preparation ($OS \leq 3$).

In the general population, WGT is on average, 24 hours.²⁰ Persons with SCI experience prolonged transit time, and WGT is, on average, in excess of 3 days.²¹ The majority of standard bowel preparations for elective colonoscopy are administered and completed within 48 hours. Due to the increased colonic transit time in the SCI population, 48 hours may be inadequate for full colonic emptying. Most conventional preparations available are based on the use of isosmotic solutions of large volumes (PEG-based solutions), or hyperosmotic preparations, such as magnesium citrate or hyperosmotic sodium phosphate. Whether by ingesting a large volume of isosmotic solution, or smaller quantities of hyperosmotic solution, stool is liquefied and volume increased, triggering peristalsis and, ultimately, defecation. Regardless of the exact mechanism of action, these solutions would be anticipated to be more effective in individuals who have preservation of autonomic control of their GI system because of the maintenance of adequate peristalsis, which individuals with SCI

lack. As a result, the use of PEG in SCI subjects as a method for bowel cleansing may not produce the most optimal or acceptable preparation for colonoscopy, as confirmed by the finding in this study.

In comparison, while the use of pulsed irrigation increases sensory input at the colonic wall, and as a result may also increase colonic activity, previous literature in the general population suggests that PEE with pre-treatment with magnesium citrate does not differ in efficacy for bowel preparation than PEG, which coincides with the results of this study that was performed in subjects with SCI.¹⁸ However, while there was no significant difference between the two bowel cleansing approaches, patients who had the PEE procedure reported more undesirable side effects, including those of GI bloating, distension, and discomfort, as well as producing an undesirable rise in the serum magnesium concentration due to pre-treatment with magnesium citrate. Since the PEE procedure uses a small volume of water to stimulate peristaltic activity in the

Table 3 Polyp detection by colonoscopy preparation

	PIEE	PEG
Mean \pm SD	0.4 \pm 1.2	0.5 \pm 0.8
(Min, max)	(0, 4)	(0, 2)
Count	12	12

SD, standard deviation; Min, minimum value; Max, maximum value; PEE, pulsed irrigation enhanced evacuation; PEG, polyethylene glycol-electrolyte lavage. No significant difference was noted between groups for the number of polyps detected ($F = 0.042$, $P = 0.859$).

Table 4 Safety and harms data

Adverse events	PIEE (N = 12)
Orthostatic hypotension*	1 (3.6%)
Reported GI discomfort, bloating or distention ^{†,‡}	3 (25%)
Would not be likely to consider preparation again ^{†,‡}	3 (25%)

*Possibly related to participation.

[†]Related to participation.

[‡] $P < 0.001$.

PIEE, pulsed irrigation enhanced evacuation.

colon through the rehydration of stool in the colon, we anticipated that some subjects might experience a degree of GI discomfort, bloating, and distension, and if sufficiently troubling, these individuals may opt not to repeat this bowel cleansing procedure when considering a bowel cleansing approach prior to performing future colonoscopies. Note that all subjects randomized to PIEE had upper motor neuron lesions and since we did not define our subjects based on colonic phenotype (flaccid bowel vs. spastic bowel function), we are not able to conclude whether or not PIEE would be less effective in subjects with a flaccid, lower motor neuron bowel compared to subjects with a spastic, upper motor neuron bowel.

Because neither PIEE nor PEG produced acceptable preparations for elective colonoscopy procedures, future studies should investigate additional methods or agents that will promote successful and complete evacuations in those individuals such as SCI who typically have inadequate bowel evacuations. Previous literature suggests that newer bowel preparation solutions such as magnesium citrate and low-volume PEG with ascorbic acid are more effective than standard PEG in producing adequate bowel evacuations and have been noted to be more tolerable than PEG.²² In addition, the use of prokinetic agents (e.g. neostigmine) has been shown to improve bowel care by promoting colonic activity.^{23,24} Thus, additional studies should investigate the possible use of prokinetic agents in conjunction with standard methods to determine if bowel preparations can be improved in patients with SCI.

Conclusion

In conclusion, our findings in this preliminary study suggest that neither PIEE nor the administration of standard PEG solutions produced acceptable bowel preparation in individuals with SCI prior to elective colonoscopy. Subjects who received PEG reported less unfavorable side effects than those who received PIEE. Future studies with larger patient sample sizes should confirm our findings, but the investigation of alternative bowel cleansing procedures that will promote more complete bowel evacuations should certainly be considered in individuals who typically have difficulty in achieving adequate bowel cleansing, such as those with SCI. Identifying more efficacious approaches to bowel cleansing prior to elective colonoscopy should improve the rate of polyp detection and excision, which should be associated with a reduction in the occurrence of colonic malignancy, improving general health and survival.

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Disclaimer statements

Contributors BLL, research coordinator in the National Center of Excellence for the Medical Consequences of Spinal Cord Injury (NCEMCSOI), is the guarantor of this submission and assisted in the preparation of this manuscript. MAK, Chief of Gastroenterology (GI) and Invasive GI, was primarily responsible for design of the protocol and for its implementation. AMS, the Associate Director of NCEMCSOI, assisted with the development of the protocol and its research design. AMS was responsible for statistical analysis, and assisted with the writing of this manuscript. ASR, KH, and MAK, gastroenterologists, who are on staff at the medical center, performed the colonoscopies. MR, MDG, and SDK, staff physicians on the Spinal Cord Injury Service, aided in the recruitment of subject and implementation of the study. CY, research coordinator in the NCEMCSOI, was responsible for recruitment of subjects. WAB, the Director of NCEMCSOI, was responsible for the conceptualization of this project with MAK (PI), and WAB assisted in the preparation of the protocol and of the manuscript. All authors listed on this study have read and approved the final version being submitted for consideration of publication.

Conflicts of interest None.

Ethics approval This protocol followed all ethical standards throughout the study period. The study was approved and monitored by the Institutional Review Board of the James J. Peters VA Medical Center.

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