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**Permalink** https://escholarship.org/uc/item/10h4p63m

**Journal** Gastrointestinal Endoscopy, 37(4)

**ISSN** 0016-5107

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**Publication Date** 

1991-07-01

## DOI

10.1016/s0016-5107(91)70777-3

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# Per-rectal pulsed irrigation versus per-oral colonic lavage for colonoscopy preparation: a randomized, controlled trial

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The aim of this study was to compare the efficacy and patient tolerance of a new pulsed irrigation system to colonic lavage for colonoscopic preparation. Thirty-four prospective patients scheduled for routine colonoscopy were randomized to one of two preparations: a per-rectal pulsed irrigation device (18 patients) versus per-oral colonic lavage (15 patients). Colonoscopic preparation was assessed on a 0 to 4 plus scale by region and overall. This was done live and by video tape by two independent endoscopists who were blinded to the patient's preparation. There was no significant difference with respect to cleanliness of the colon with pulsed irrigation patients having an average overall preparation score of  $3.00 \pm 0.19$  (SEM) versus colonic lavage patients with a score of  $3.14 \pm 0.19$ . There was also no statistically significant difference between the two groups with respect to demographics, time to reach the cecum, time for entire procedure, volume of aspiration or wash, or sedation given. We conclude that the new pulsed irrigation device provides an alternative to the standard per-oral lavage solution for colonoscopic preparation. (Gastrointest Endosc 1991;37:444–448)

The most common method of preparation for colonoscopy is the use of an oral lavage solution containing polyethylene glycol (PEG) as a non-absorbable osmotic agent. Clinical studies have confirmed its efficacy in cleansing the colon in preparation for colonoscopy,<sup>1-5</sup> barium enema,<sup>6, 7</sup> and colonic surgery.<sup>8, 9</sup> However, in many patients, especially the elderly, this preparation may not be well tolerated.<sup>10, 11</sup> and there is potential for increased ventricular ectopy.<sup>12</sup> Prior to per-oral lavage, methods for preparing the colon for diagnostic tests or surgery included per-rectal methods such as enemas and cathartics. Recently, a new perrectal method of colonic lavage has been developed using a pulsed irrigation system. This pulsed irrigation system has been used for bowel disimpaction, regulation of bowel movements in spinal cord injury pa-

Received November 15, 1990. For revision December 31, 1990. Accepted April 16, 1991.

From the Department of Medicine, Department of Veterans Affairs Medical Center, Long Beach, California; and the University of California, Irvine, California. Reprint requests: Kenneth Chang, MD, Gastroenterology Section (111G), Department of Veterans Affairs Medical Center, 5901 East Seventh Street, Long Beach, California 90822. tients, and preparation for sigmoidoscopy and colonoscopy. However, to date, there has been no comparative trial of the use of this technique to per-oral lavage for colonoscopic preparation. In this study, we compared the effectiveness of pulsed irrigation plus magnesium citrate with the standard per-oral colonic lavage preparation in a randomized, single-blind, controlled trial.

#### METHODS

This study was carried out at the Veterans Affairs Medical Center, Long Beach, California and approved by the Human Subjects Subcommittee. All patients prospectively scheduled for colonoscopy for one endoscopist (K. C.) from July 10, 1990 to August 30, 1990 were considered for enrollment. The only exclusion criteria for participation were those patients who had previous bowel resection or who had known constricting lesions in the colon. Only one patient did not consent to participate in the study from among those who were eligible. Following the standard practice for colonoscopy in our institution, all patients were admitted the afternoon before the procedure. After obtaining informed consent, the patients were randomized to either colonic lavage preparation or pulsed irrigation. Following the assigning of the preparation procedure, the exact details of the procedure were explained to the patient by a trained gastroenterology nurse (T. C. or C. M.).

Pulsed irrigation was performed using the Avitar 2000 Bowel Evacuation System (Aegis Medical, Inc., Denver, Colo.). This device works by infusion of short pulses of warm (93 to 103°F) tap water into the rectum through a rectal tube (Fig. 1). These pulses last a few seconds, alternating with a draining period, allowing water and stool to flow by gravity into a sealed plastic bag. Approximately 25 ml were introduced into the rectum/second, with a total volume of 5 gallons of water used through the entire procedure. In our preliminary testing with this device, magnesium citrate, given the night prior to pulsed irrigation, was found to be necessary to adequately clean the right colon.

The protocol for pulsed irrigation was as follows:

1. Clear liquid dinner, nothing by mouth thereafter except for medications.

2. At 7:00 p.m. the patient drank 296 ml (10 ounces) of magnesium citrate (Citroma<sup>®</sup>, Swan, Inc., Smyrna, Tenn.).

3. The next morning an intravenous heparin-lock was started in the right arm.

4. Approximately 30 min before the colonoscopy, the patient was brought to the Gastroenterology Laboratory and had the pulsed irrigation tube inserted into the rectum by a gastroenterology nurse (T. C. or C. M.) while lying on the left side in a bed. After 5 min, they were sequentially turned onto the right side for 5 min, supine for 5 min, and back onto the left side for the remaining 2 to 5 min of the procedure. Patients were then allowed to sit on a commode to evacuate any remaining fluid. The overall time of the preparation was approximately 20 to 30 min.

5. The patient was then interviewed and psychological questionnaires were filled out.

6. Colonoscopy was performed.

The per-oral colonic lavage used in this study was Colyte® (Reed and Carnrick Pharmaceuticals, Piscataway, N. J.), a polyethylene glycol non-absorbable osmotic solution that essentially flushes the colon clean. The protocol for colonic lavage was as follows:

1. Clear liquid dinner, nothing by mouth thereafter except for medications.

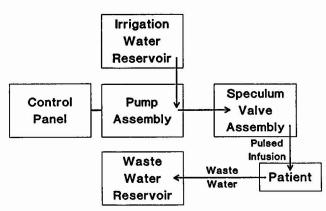


Figure 1. Diagrammatic representation of the pulsed irrigation for enhanced evacuation system (PIEE).

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2. At 7:00 p.m. the patient began drinking 4 liters of Colyte<sup>®</sup>. This was to be consumed over a period of 2 hours.

3. The next morning an intravenous heparin-lock was started in the right arm.

4. The patient was interviewed and psychological questionnaires filled out.

5. Colonoscopy was performed.

All interviews were conducted by a member of the Behavioral Medicine Research Laboratory of the Veterans Affairs Medical Center, Long Beach, California. In addition to providing demographic information, patients completed a Patient Perception of Treatment Questionnaire and a Self-Analysis Questionnaire.13

All colonoscopies were performed by one endoscopist (K. C.) who was blinded to the preparation received. Colonoscopy was performed using the Pentax Video EC 3800 F Colonoscope with video tape recording each procedure. All videotapes were reviewed by a second endoscopist (R. E.), who was also blinded to the preparation received. Both the live examination and the video recording were scored for cleanliness of the colon on a scale of zero to four plus for each anatomic segment of the colon as well as an overall rating (Table 1). The scores of the two endoscopists were then averaged together.

The amount of time to reach the cecum and for the entire examination was noted, as well as the volume of aspiration and wash.

Statistical analysis of the preparation was carried out using a one-way analysis of variance. Statistical analysis of the psychological evaluation was performed using the BMDP P2D, P3D t test, and P4F chi-square software programs.14

#### RESULTS

A total of 34 patients consented to the study out of 35 eligible patients. One patient was later excluded (from the per-oral colonic lavage group) as he disclosed he had prepared himself at home prior to admission with a clear liquid diet and enemas. Additionally, one patient in the per-oral colonic lavage group had only the rectosigmoid examined because of inability to pass the colonoscope through an adhesed sigmoid colon. Another patient in this group had a constricting lesion in the ascending colon that prevented assessment of the cecum.

#### Table 1. Rating scale for quality of colonic preparation

	Totally inadequate for examination of colon	
0	Totally inadequate for examination of colon section	
1+	Much solid/liquid fecal material making less than adequate examination of area	
2+	Moderate solid/liquid fecal material allow- ing for an adequate examination of the area	
3+	Some liquid fecal material, allowing for complete examination of the area	
4+	Perfectly clean area with no solid or liquid material after suction/lavage	

### PIEE SYSTEM

A total of 18 patients were randomized to pulsed irrigation and 15 patients to per-oral lavage. There were no statistically significant differences between the two groups with respect to sex, age, education level, marital status, and employment status. The two groups were also similar with respect to indications for the procedure and findings on colonoscopy (Table 2).

There was a very slight difference in favor of peroral preparation in the quality of bowel preparation in all areas of the colon, which did not reach statistical significance, and this was not clinically important as colonoscopy was successfully achieved in all patients with no difference in time to reach the cecum or time for total examination, or ability to complete polypectomy (Fig. 2). In the assessment of regional differences, there was no statistical difference between the rectosigmoid, descending, transverse, ascending colon or cecum.

Two patients receiving pulsed irrigation were obviously inadequately prepared as assessed by the nurse performing the preparation. One patient went on to have colonoscopy, which confirmed an inadequate preparation, and the other patient received a second cycle of pulsed irrigation prior to colonoscopy. After the second cycle, the colon was adequately prepped.

Variables that may have been dependent on the quality of the preparation were also quantified. There was no statistical significance between the two groups with respect to time to reach the cecum, time for entire procedure, volume of aspiration or wash, or sedation given (Table 3).

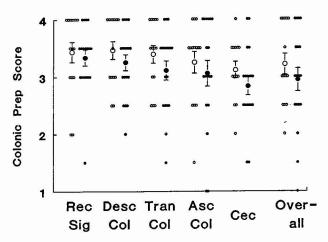
There were no statistical differences between the two groups with respect to psychological perception of the preparation method used.

#### DISCUSSION

The most frequently used form of preparation for colonoscopy is per-oral lavage solution containing polyethylene glycol. Clinical trials have shown its efficacy in cleansing the colon for colonoscopy as well as barium enemas and pre-operative preparation of the

Table 2.			
Indications	for	colonoscopy	

	Indications		Findings	
	Pulsed irrigation	Per-oral lavage	Pulsed irrigation	Per-oral lavage
Polyps	15 (83%)	13 (87%)	13 (72%)	11 (73%)
Hematochezia/occult blood in stool	1 (6%)	2 (15%)	NA	NA
Inflammatory bowel disease	1 (6%)	1 (7%)	1 (6%)	0 (0%)
Iron-deficiency anemia	0 (0%)	2 (14%)	NA	NA
Malignancy	1 (6%)	1 (7%)	1 (6%)	1 (7%)



**Figure 2.** Colonoscopic preparation score (see Table 1) with per-rectal versus per-oral colonic lavage. These scores are the average of two independent endoscopists' assessment of regional and overall adequacy of preparation. Open circles represent the average preparation score (0 to 4+) for each segment of the colon (Rec Sig, rectosigmoid; Desc Col, descending colon; Tran Col, transverse colon; Asc Col, ascending colon; Cec, cecum) for each patient prepared by per-oral colonic lavage. The closed circles represent each patient prepared by per-rectal colonic irrigation. The average score at each anatomical level is shown by the large circles  $\pm$  SEM.

#### Table 3.

Variables measured during colonoscopy (all data are shown  $\pm$  SEM)

Variable	Pulsed irrigation	Per-oral lavage	
Time to reach the cecum (min)	$9.11 \pm 0.99$	$9.07 \pm 1.47$	
Total time for colonoscopy (min)	$33.28 \pm 4.0$	$30.21 \pm 2.63$	
Volume of water flushed in (ml)	457.33 ± 83.08	$301.57 \pm 80.48$	
Volume of fluid suctioned (ml)	$468.06 \pm 71.92$	386.79 ± 83.39	
Dosage of midazolam given (mg)	$1.94 \pm 0.33$	$1.75 \pm 0.25$	
Dosage of meperidine given (mg)	$49.72 \pm 4.09$	$53.21 \pm 7.74$	

colon. Although an excellent form of preparation, PEG has its drawbacks. It is occasionally not tolerated by patients, especially the elderly, with possible side effects of nausea, vomiting, and shivering. It is also inconvenient for patients who have numerous bowel movements throughout the night prior to colonoscopy, especially for those who are unable to ambulate. There have also been complaints about the taste of the solution.<sup>11</sup> A number of alternative methods have been tried in attempt to avoid these side effects. These have included using sulfate-free polyethylene glycol,<sup>11</sup> fractional cleansing with oral lavage,<sup>15</sup> oral sodium phosphate,<sup>16</sup> or other combinations of laxatives and enemas.<sup>17-19</sup> However, until the current trial there has not been a study using pulsed irrigation evacuation as a means of colonoscopic preparation.

In this study, we have shown that the pulsed irrigation bowel evacuation system (Avitar 2000) in combination with one bottle of magnesium citrate was as effective and well tolerated as per-oral colonic lavage.

The pulsed irrigation system has some technical advantages over per-oral colonic lavage. One is its ability to prepare the colon in a relatively short amount of time. Patients can take 296 ml of magnesium citrate the night prior to the procedure, which is usually well-tolerated, and have the colon prepared in 30 min just prior to the procedure. The magnesium citrate was found in our preliminary study to be necessary to move the content of the right colon more distally where it could be removed by per-rectal lavage. This amount of magnesium citrate usually did not cause more than a few loose bowel movements for patients.

For patients who have been unable to tolerate oral lavage preparation or are not able to ambulate to a commode, pulsed irrigation would also be advantageous. Theoretically, it could also be used for barium enema preparation or colonic surgery preparation. However, since it cleans from below, there is the possibility that small intestinal content may eventually enter the colon during radiologic study or operation. However, we did not observe unusual amounts of small intestinal content moving into the cecum during colonoscopy in our patients. Further studies are necessary to assess possible application in preparation for barium enema or surgery.

The main disadvantage is the greater amount of nursing staff time necessary to perform the preparation and the additional space required for patient preparation. There is also still a need to give 296 ml of magnesium citrate as part of the preparation in order to adequately clean the right colon. Additionally, in 2 of the 18 patients receiving pulsed irrigation, the colon was obviously inadequately prepared for colonoscopy, and at the end of the first irrigation cycle a second cycle was necessary. This means that in approximately 10% of patients using pulsed irrigation according to our protocol, there will be a need for two cycles. The necessity for an additional cycle of perrectal lavage was easily assessed by observing the effluent coming from the patient. The patients would not need to be moved from the preparation room or have a colonoscopy to decide that an additional preparation cycle was needed.

There may be better protocols for administration of antegrade colonoscopic preparation than that used in this study. For example, some institutions use a stimulant cathartic the night before the procedure and have the patient drink their antegrade preparation solution just a few hours before the colonoscopy. Such regimens need to be compared to per-rectal lavage in separate trials.

The costs of this method of colonoscopy preparation should also be considered. Although exact cost comparisons are institution-dependent, we estimate that the above per-rectal lavage technique is considerably more expensive than the per-oral lavage. In addition to the initial cost of the Avitar unit, we estimate that the average cost of a per-rectal preparation would be about \$50.00. This includes \$25 for the disposable perrectal lavage unit, \$2 for magnesium citrate, and \$13 for 30 min of nursing time. In comparison, the cost of 1 gallon of an antegrade lavage solution such as Colyte<sup>®</sup> is approximately \$17.

In summary, the per-rectal pulsed irrigation method for cleansing the colon is as effective as per-oral colonic lavage for colonoscopic preparation. This technique offers an alternative form of colonoscopic preparation.

#### ACKNOWLEDGMENT

This work was supported in part by a grant from Aegis Medical, Inc. Denver, Colorado.

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