

**Title: Hydrotherapy Compared with PEG-ES Lavage and Aqueous Sodium Phosphate as Bowel Preparation for Elective Colonoscopy: A Prospective, Randomized, Single Blinded Trial<sup>1</sup>**

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**Purpose:** Hydrotherapy is a method of colon cleansing using constant warm water lavage using a contained temperature and pressure controlled device administered by a trained technician. The aim of this study was to compare the efficacy and patient acceptance of same-day hydrotherapy (HYDRO) with polyethylene glycol-electrolyte lavage (PEG-ES) and aqueous sodium phosphate (ASP) in patients undergoing elective colonoscopy.

**Methods:** Consecutive outpatients referred for elective colonoscopy were randomly assigned to receive 4 liters (L) PEG-ES (n =55), two doses of aqueous sodium phosphate (n=52), or same day hydrotherapy (n =53), as bowel preparation. The endoscopists were blinded to the method of preparation. The overall quality of the colon cleansing was evaluated with respect to the adequacy of visualization of the right, transverse, and left colon. Patients were asked to rate the preparation with respect to ease, convenience, and comfort using structured, validated questionnaire. Results were analyzed using the chi square test.

**Results:**

Endoscopists rated the quality of colon cleansing as good for:

	ASP	PEG-ES	<b>HYDRO</b>
Right colon	62%	49%	<b>92% (p&lt;0.001)</b>
Transverse colon	80%	63%	<b>100% (p&lt;0.001)</b>
Left colon	84%	67%	<b>98% (p&lt;0.001)</b>

Patients rated the preparations as:

	ASP	PEG-ES	<b>HYDRO</b>
Easy	87%	56%	<b>96% (p&lt;0.001)</b>
Convenience	61%	79%	<b>98% (p&lt;0.001)</b>
Comfort	71%	36%	<b>94% (p&lt;0.001)</b>

**Conclusion:** The quality of colon cleansing, overall tolerance, comfort, and convenience were significantly better for HYDRO. In this study ASP was better than PEG-ES for the same parameters. Hydrotherapy should be further investigated as a viable alternative to PEG-ES and ASP for bowel preparation prior to colonoscopy.

\*Manufacturer's note: The equipment used in this study was the Toxygen Model BSC-UV, a "closed system" manufactured by Dotolo Research Corp. The Dotolo Colon Irrigation system has been cleared by the F.D.A. for the intended use as described in this study.

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# Benefits of Hydrotherapy Protocol- Colonoscopy Preparation

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*Danbury Hospital ABSTRACT RESULTS, 2006*

## **Patient Considerations:**

- Limited oral prep as compared to traditional prep alone
- No large amount of thick liquids to consume
- No missed work sitting in the restroom
- Soothing and relaxing atmosphere
- No embarrassing odors or mess
- Improved patient compliance

## **Business Considerations:**

- Additional source of revenue for your practice
- 95% of patients surveyed would come back for their next colonoscopy with this prep
- CPT codes pending

## **Doctors and Clinicians choose the ColoLAVAGE<sup>sm</sup> Prep:**

- All parts coming into contact with the patient are disposable and non-toxic
- Colon Hydrotherapy on a closed system provides the most effective bowel preparation.
- Complete Closed System; no odor, no mess, no embarrassment for the patient
- FDA Registered Equipment - intended use: (b) Classification. Class II (performance standards) when the device is intended for colon cleansing when medically indicated, such as before radiological or endoscopic examinations'

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Patients were asked if they wanted a different preparation for the next colonoscopy:

	ASP	PEG-ES	<b>HYDRO</b>
Yes	48% ASP	60% PEG-ES	<b>4%</b>

Overall satisfaction rating:

	ASP	PEG-ES	<b>HYDRO</b>
Yes	71% ASP	56% PEG-ES	<b>96% HYDRO</b>