



A New Choice For Colonoscopy Preparation

DANBURY, CT – January 24, 2008 – People sometimes avoid a colon cancer screening because they fear the inconvenience of the cleansing preparation more than the colonoscopy itself.

Danbury Hospital is the first hospital in Connecticut and around the nation to offer an alternative method to cleanse the bowel to prepare for a colonoscopy -- one that is more convenient, quicker, and eliminates having to drink a gallon of liquid laxatives the night before.

"Patients now have a choice," said Joseph Fiorito, M.D., chief of the Section of Gastroenterology, a nationally recognized program at Danbury Hospital, the regional medical center and university teaching hospital.

The innovative new method is called colon hydrotherapy, a procedure that infuses warm, filtered, chemical-free water into the colon to cleanse it prior to colonoscopy, a life-saving screening that detects pre-cancerous polyps.

The infusion is done by a trained technician in a private room at the hospital, in a soothing atmosphere with little discomfort to the patients. Patients lie on a stretcher on their backs and sides for the 45-minute procedure that flushes water in and out of the colon prior to colonoscopy.

With colon hydrotherapy, patients can avoid the inconvenience and often messy preparation of drinking laxatives prior to the procedure. "Some people find the palatability of the liquid unacceptable," said Dr. Fiorito. "Many people can't tolerate drinking the gallon of liquid laxatives required the night before a colonoscopy to cleanse their colon."

"Colon hydrotherapy is also much more convenient," he added. "People don't have to worry about having to miss work, not eat for 24 hours and stay up all night because of diarrhea."

Colon cancer survivor Ethel Pancotti of Danbury is one of the people who colon hydrotherapy has greatly helped. She is among those who couldn't tolerate the laxative process and would suffer loss of electrolytes, eventually passing out and ending up in the Emergency Department.

"With hydrotherapy, there's no pain or discomfort," she said. "I was so relaxed that I fell asleep listening to music during the cleansing procedure."

This procedure is especially beneficial for the elderly, said Dr. Fiorito, who sometimes can't tolerate the volume of liquid that they need to drink, along with feeling side effects from the laxatives. They're also more prone to electrolyte abnormalities and kidney damage from the laxative cleansing process.

Doctors recommend having a colonoscopy beginning at age 50, and sooner if patients have a history of colon cancer in the family, or other risk factors. For more information, visit www.danburyhospital.org, or see your doctor.

Danbury Hospital is a 371-bed regional medical center and university teaching hospital associated with New York Medical College, the Yale University School of Medicine, the Connecticut School of Medicine and Columbia University Medical Center. It provides centers of excellence in cardiovascular services, cancer, weight-loss surgery, orthopedics, digestive disorders and radiology, with specialized programs for sleep disorders and asthma management. More than 95 percent of the medical staff are board certified in their specialties.

It is ranked in the top 5 percent of hospitals in the country for overall clinical performance by HealthGrades®, an independent health-care rating organization, for 2005 through 2007. In addition, Danbury Hospital is a recognized leader named among the nation's 100 Top Hospitals® by Solucient, a leading national source of health care business intelligence.

It is No. 1 in Connecticut for overall gastrointestinal (GI) services and only one of seven hospitals in New England to be ranked among the top 5 percent for overall GI services.

MEDICAL STUDY

This study was accepted and delivered as an oral presentation at the American College of Gastroenterology -ACG- Annual Meeting, October 2006. **(Only 1% to 2% of all studies submitted, from thousands of abstracts are selected for oral presentation. A testament to how important the ACG feels this topic and research is.)**

* Study showed Hydrotherapy was good or better than alternative preparations and patients preferred Hydrotherapy.

* 150 patients evaluated to compare Hydrotherapy to the present standard pre-colonoscopy preparation Methods of Golytely and Fleets Phosphasoda.

Who performed the Medical Study?

Blind Study - Dr. Joseph Fiorito

ACG 2006 : The American College of Gastroenterology
Annual Scientific Meeting

Abstract Number : 751814

Primary Author : Joseph Fiorito

Department / Institute : Gastroenterology, Danbury Hospital

Address : 24 Hospital Ave

City / State / Zip/ Country : Danbury, CT, 06810, United States

Phone : 203-707-7506

Fax : 203-796-7974

E-Mail : joseph.fiorito@danhosp.org

Awards : No Award Selected

Abstract Categories : 11 Endoscopy

Presentation Preference : Either oral or poster only

ACG Research Grant : No

Key Words : Colonoscopy, cathartics, colon preparation.

Title : HYDROTHERAPY COMPARED WITH PEG-ES LAVAGE AND AQUEOUS SODIUM PHOSPHATE AS BOWEL PREPARATION FOR ELECTIVE COLONOSCOPY : A PROSPECTIVE, RANDOMIZED, SINGLE BLINDED TRAIL.

Joseph J. Fiorito, MD, Joan A Culpepper-Morgan, MD, Scott G. Estabrook, MD, Patricia Scofield, LPN, Victor Usatii, MD and Jodi Cuomo, Rph2. Gastroenterology, Danbury Hospital, Danbury, CT United States.

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 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 the right : 62% ASP, 49% PEG-ES, and 92% HYDRO (p<0.001). For the transverse colon : 80% Asp, 63% PEG-ES, and 100% HYDRO (p<0.001). For the left colon: 84% ASP, 67% PEG-ES, and 98% HYDRO (p<0.001). Patients rated the preparations as easy : 87% ASP, 56% PEG-ES, 96% HYDRO (p<0.001). Patients rated convenience : 61% ASP, 79% PEG-ES, and 98% HYDRO (p<0.001). Patients rated for comfort : 71% ASP, 36% PEG-ES, and 94% HYDRO (p<0.001). Patients were asked if they wanted a different preparation for the next colonoscopy : 48% ASP, 60% PEG-ES, and 4% HYDRO (p<0.001).

Conclusion : The quality of colon cleansing, overall tolerance, comfort, and convenience were significantly better for HYDRO. In the study ASP was better than PEG-ES for the same parameters. Hydrotherapy should be further

investigates as a viable alternative to PES-Es and ASP for bowel preparation prior to colonoscopy.

** Manufacturer's note : the equipment used in the 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 FDA for the intended use as described in the st*

What are the Key Points of the Medical Study?

The current business has, as a key foundation, the benefits of a recent medical study.

The study was conducted by Joseph J. Fiorito, MD, FACP, Assistant Clinical Professor of Medicine, Albert Einstein College of Medicine, Chief – Division of Gastroenterology at Danbury Hospital, Connecticut.

The Hydrotherapy Study concluded that using colon cleansing procedures (Hydrotherapy or hydro) were both preferred by patients over chemical preparations and by the doctors who found it less likely that patients were not adequately cleansed for exams and procedures.

The Hospital has become an avid customer of the Company including expanding its use of the services and products, having now expanded its purchase from one machine to three machines, operating them regularly to our knowledge. This leads us to believe that other hospitals will potentially also start with one and expand and if correct, the figures as to financial performance may be far in excess of our estimates. Here are some key points of the study:

* 150 patients evaluated to compare Hydrotherapy to the present standard pre-colonoscopy preparation Methods of Golytely and Fleets Phosphasoda.

* Study showed Hydrotherapy was good or better than alternative preparations and patients preferred Hydrotherapy. This study was accepted and delivered as an oral presentation at the American College of Gastroenterology -ACG- Annual Meeting, October 2006.

(Only 1% to 2% of all studies submitted, from thousands of abstracts are selected for oral presentation. A testament to how important the ACG feels this topic and research is.)

The presentation generated a great deal of interest. HydroHealth is recognized as the corporation behind the research. The study was submitted for publication to the American Journal of Gastroenterology and is waiting final acceptance and publishing. Hydrotherapy appears not only cost effective, but may also contribute to revenues for gastro healthcare providers as follows:

1. Increased total numbers of screening procedures due to easier and more acceptable preparation method.
2. Eliminate failed procedures due to "poor prep."
3. Allow increased afternoon procedures due to preparation method with improved results. Hydrotherapy is now being expanded at Danbury Hospital. It is the most requested preparation method when patients are given a choice. The hospital has performed more than 200 pre-colonoscopy preparations to with excellent results and follow up studies are planned.

Efforts to obtain Medicare and insurance reimbursement codes are planned as studies are published. Nationally recognized university based endoscopy centers are considering adopting Hydrotherapy pending publication of studies. ***As proven by the study, the Hydrotherapy prep is as good as the most popular prep, Fleets phos soda. The difference proven is the patient compliance with the prep.***

Another use for the Hydrotherapy is that it can be used if a patient undergoes a colonoscopy and the endoscopist finds stool in the colon. Instead of canceling the procedure due to a poor prep, the endoscopist can order the prep to cleanse the colon. While the patient is having hydro the endoscopist can proceed with an endoscopy on another patient, keeping him/her on schedule. Once the patient is done with hydro, they can proceed with the procedure as planned. We are presently working on presenting the data to the insurance companies.

At present the hospital is charging a "room" fee for the procedure, which is paid out of pocket at the time of service. \$65.00. The hospital has used the hydro on patients not associated with colons. Therapeutic cleansing for patients with chronic constipation.