

For Immediate Release
August 5, 2010



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STUDY SHOWS THAT SPLITTING BOWEL PREPARATION DOSAGE IS MOST EFFECTIVE CLEANSING METHOD BEFORE COLONOSCOPY

OAK BROOK, Ill. – August 5, 2010 – A new study from researchers in Italy has found that a split-dosage schedule of bowel (colon) preparation is the most effective method for bowel cleansing before colonoscopy. Colonoscopies performed within six to eight hours of the end of preparation were associated with significantly better cleansing than those performed more than eight hours after the end of preparation. Two different types of bowel cleansing products were also assessed and researchers found that low-volume polyethylene glycol (PEG) plus ascorbic acid was as effective as high-volume PEG-electrolyte solution, but has superior palatability (or taste). This is the first study to demonstrate that the advantage of split-dosage intake is also true for low-volume bowel cleansing solutions. The study appears in the August issue of *GIE: Gastrointestinal Endoscopy*, the monthly peer-reviewed scientific journal of the American Society for Gastrointestinal Endoscopy (ASGE).

Diagnostic accuracy and therapeutic safety of colonoscopy depend on the quality of colon cleansing (the large intestine is referred to as the colon or large bowel). Inadequate bowel preparation can result in missed lesions, aborted procedures, and increased discomfort as well as a potential increase in complication rates. A standard bowel cleansing product is polyethylene glycol (PEG) taken in a large single dose (four liters), which is required for effective bowel cleansing. When taken in divided doses, a standard four-liter PEG dosage was demonstrated to be as effective as, and better tolerated than, the single dose given one day before the procedure. A new cleansing solution consisting of high molecular weight PEG plus ascorbic acid has been developed which reduces the volume patients have to drink without compromising efficacy or safety.

“The aims of this study were to evaluate the degree of colon cleansing in patients undergoing colonoscopy, comparing split-dosage versus non-split-dosage of two different volumes of PEG solution, low-volume PEG plus ascorbic acid versus standard-volume PEG, and to identify predictors of poor bowel cleansing,” said study lead author Riccardo Marmo, MD, Hospital “L. Curto,” Polla, Sant’ Arsenio, Italy. “We demonstrated that a split-dosage regimen provides the best colon cleansing independent of the volume of PEG and that the optimal timing of colonoscopy is within eight hours of the last fluid intake. The study also found that male patients were at higher risk of poor bowel cleansing and that procedures might be better scheduled late-morning or in the afternoon to allow for split dosing, especially for male patients.”

Patients and Methods

This was a single-blind, active control, prospective, randomized study of adult (18 years of age or over) patients undergoing routine elective colonoscopy. A total of 868 randomized patients were analyzed: 435 patients in the split-dosage group and 433 in the non-split-dosage group. Two cleansing products were used in the study: PEG 4000 plus electrolytes (standard PEG solution) taken diluted into four liters of

plain water (high-volume) and the low-volume solution composed of macrogol 3350 plus electrolytes and 4.700 grams ascorbic acid taken diluted into two liters of plain water. Patients were randomly allocated to receive one of the four different bowel preparation regimens (split-dosage vs. non-split-dosage, low- vs. high-volume). The preparations were dispensed by a nurse endoscopist who carefully explained how they should be taken, emphasizing the importance of complete intake of the solution to ensure a safe and effective procedure. Dietary advice was also given to patients and all patients were instructed to take nothing by mouth from midnight on before the procedure.

Bowel cleansing was assessed by colonoscopists who were unaware of the preparation method. For each anatomical segment of the colon, the degree of bowel cleansing was rated on a segmental scoring scale of one to four (four-excellent, three-good, two-fair and one-poor, see study for a more detailed description of the scale). On the morning of the colonoscopy, immediately before the procedure, a nurse questioned each patient about his or her experience regarding compliance with preparation instructions, tolerance, additional fluid intake, acceptability and willingness to repeat the same type of bowel preparation if necessary. Colonoscopies were performed by experienced colonoscopists unaware of the treatment allocation.

Results

Researchers found that study compliance in both groups was excellent, independent of the intake schedule: complete preparation (drinking the full amount of fluid indicated) was accomplished by 96.3 percent of the low-volume group patients and 95.8 percent of the high-volume group patients in the non-split dosage group, and 97.2 percent and 98.6 percent for both volumes respectively in the split-dosage group.

The split-dosage regimen produced markedly superior cleansing results over the non-split dosage regimen. Overall, a good/excellent degree of bowel cleansing was recorded in 75.2 percent of patients in the split-dosage group versus 43 percent of patients in the non-split-dosage group. The superiority of the split-dosage intake schedule was independent of the volume of PEG solutions. Both low-volume and high-volume PEG solutions produced the same degree of cleansing: 77 percent versus 73.4 percent respectively in the split-dosage group and 41.7 percent versus 44.3 percent, respectively, in the non-split-dosage group. The time elapsed between the last fluid intake and the colonoscopy was an important factor affecting the degree of bowel cleansing. The cleansing score decreased significantly after six to eight hours from the last fluid intake.

Both preparations were well-tolerated; patients reported no side effects. Overall, complete colonoscopy (intubation to the cecum) was achieved in 94.6 percent of cases, confirming a strong association with the degree of bowel cleansing. Incomplete colonoscopy was rare (5.4 percent), but significantly more frequent in patients with fair/poor bowel cleansing. Colorectal polyps were detected in 23.1 percent of patients. The polyp detection rate was significantly higher in patients with bowel cleansing rated as fair/good or good/excellent. A logistic regression analysis showed that independent predictors of poor bowel cleansing were male sex and the non-split-dosage schedule. Researchers concluded that low-volume polyethylene glycol (PEG) plus ascorbic acid was as effective as high-volume PEG-electrolyte solution, but has superior palatability; a split-dosage schedule provides the most effective bowel cleansing; and that colonoscopies should be performed within eight hours of the last fluid intake.

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About the American Society for Gastrointestinal Endoscopy

Since its founding in 1941, the American Society for Gastrointestinal Endoscopy (ASGE) has been dedicated to advancing patient care and digestive health by promoting excellence in gastrointestinal endoscopy. ASGE, with more than 11,000 members worldwide, promotes the highest standards for endoscopic training and practice, fosters endoscopic research, recognizes distinguished contributions to endoscopy, and is the foremost resource for endoscopic education. Visit www.asge.org and www.screen4coloncancer.org for more information and to find a qualified doctor in your area.

About Endoscopy

Endoscopy is performed by specially-trained physicians called endoscopists using the most current technology to diagnose and treat diseases of the gastrointestinal tract. Using flexible, thin tubes called endoscopes, endoscopists are able to access the human digestive tract without incisions via natural orifices. Endoscopes are designed with high-intensity lighting and fitted with precision devices that allow viewing and treatment of the gastrointestinal system.