Lack of benefit of active preparation compared with a clear fluid–only diet in small-bowel visualization for video capsule endoscopy: results of a randomized, blinded, controlled trial

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Background and Aims: Controversy remains regarding the type and amount of precapsule bowel cleansing required for small-bowel video capsule endoscopy (VCE). This study aims to assess the efficacy and tolerance of 2 active preparations and a control group of clear fluids only.

Methods: Patients with clinical indications for VCE were randomized to (1) clear fluids only the evening before VCE, (2) 2 sachets of sodium picosulfate plus magnesium sulfate (P/MC) the evening before, or (3) 2 L of polyethylene glycol (PEG) the evening before. Diet instructions were the same for all 3 groups. Small-bowel cleansing was assessed in 3 ways: a 5-point ordinal scale (primary outcome), the percentage of time the small-bowel view was clear, and a validated computerized assessment of cleansing.

Results: In total, 198 patients were randomized and 175 patients completed the trial with a mean age of 49.2 years. There was no clear benefit of active preparation with either P/MC or PEG over clear fluids only in the overall 5-point rating scale or in the distal fourth of each examination. There was no difference in diagnostic yield between groups. Significant differences were seen concerning tolerance of the preparations, with a higher proportion rating it as easy or very easy in the clear fluids–only group (93%) and the P/MC group (67%) than in the PEG group (13%) ($P < .0001$).

Conclusions: Small-bowel cleansing for VCE remains a controversial topic. This randomized control trial demonstrates no benefit in overall or distal small-bowel visualization with active preparation using either PEG or P/MC compared with clear fluids only. (Clinical trial registration number: NCT00677794.) (Gastrointest Endosc 2017;85:187-93.)

Small-bowel video capsule endoscopy (VCE) changed clinical practice when introduced in 2000.[1] It has the advantage of being able to visualize the entire small bowel and detect lesions not seen with other techniques while remaining minimally invasive. Indications for this investigation continue to be refined, but the primary indication driving its development was the evaluation of obscure GI bleeding in adults.[2] However, the use of VCE has expanded to include diagnosis and assessment of small-bowel Crohn's disease, diagnosis of small-bowel tumors, nonsteroidal anti-inflammatory drug–related injury, and evaluation of abdominal pain and possibly celiac

Abbreviations: CAC, computed assessment of cleansing; PEG, polyethylene glycol; P/MC, sodium picosulfate plus magnesium citrate; VCE, video capsule endoscopy.

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disease.[3-8] Deep balloon-assisted enteroscopy has evolved as a complement to VCE because lesions identified on the less-invasive VCE can sometimes be treated with this technique.

Although the evidence for diagnostic yield and clinical effectiveness of capsule endoscopy has grown, there is still controversy regarding the type and amount of preexamination bowel cleansing required.[9,10] Turbid fluid and food residue overlying the mucosa can make visualization difficult and lead to missed diagnoses or the need for repeat studies.[11-14] Several studies have evaluated different preparations with results varying from modest to no effect.[15-18] Comparing and/or combining these studies is hampered by the lack of a consensus assessment tool for small-bowel cleanliness. Nonetheless, 2 meta-analyses have been published suggesting preparation is better than no preparation,[13,19] but it is unclear what medications or dosing should be used. The main potential for benefit may lie in the distal small bowel.[14,20-22] Contributing to the uncertainty regarding preparation, a major manufacturer of VCE capsules, Given Imaging (Minneapolis, Minn, USA), does not recommend preparation beyond an overnight fast. Given this uncertainty, the current study was undertaken to compare the efficacy of 2 established colon cleansing agents with clear fluids only in term of adequate preparation of the small bowel in advance of VCE.

METHODS

This was a prospective, randomized, controlled trial of small-bowel cleansing. Ethics approval was obtained from the Queen's University Health Sciences Research Ethics Board.

Consecutive male and female patients, 18 years of age or older, undergoing outpatient capsule endoscopy for any indication were considered for the study. Exclusion criteria included bowel obstruction or ileus, known intestinal stricture or fistula, previous small-bowel surgery, severe gastroparesis or motility disorder, renal impairment (serum creatinine over normal range within 3 months of study), congestive heart failure, decompensated cirrhosis, implanted cardiac pacemaker or defibrillator or other electromedical device, and pregnancy.

Patient selection and randomization

Patients were recruited from outpatient gastroenterology clinics at Hotel Dieu Hospital, Kingston, Ontario. This unit orders 60 to 70 VCE examinations per year. Once the attending physician requested a VCE, a clinical research assistant met with each subject, explained the goals of the study, and requested consent.

Subjects were then randomized to 1 of 3 treatment groups via consecutively numbered opaque envelopes, which contained assignment to clear fluids only, polyethylene glycol (PEG), or sodium picosulfate plus magnesium citrate (P/MC). The contents of the envelopes were determined using random computer-generated numbers prepared by an independent biostatistician (A.G.D.) and were allocated in randomly ordered permuted blocks of sizes 3, 6, and 9 without stratification.

Interventions

The research assistant provided detailed verbal and written instructions for preparation immediately after randomization. A portion of the instructions was common across all 3 groups: Iron supplements were stopped 5 days before the examination, all patients were instructed to have a light breakfast and lunch and then have clear fluids until midnight, and all were encouraged to consume at least eight 8-oz glasses of clear liquids over the day. After an overnight fast, the capsule was ingested in the morning between 8:00 and 8:30 am. Clear fluids could be consumed 2 hours after capsule ingestion and solid food after 4 hours. All patients were given 80 mg of oral simethicone 10 minutes before ingestion of the capsule.[23]

Patients in the clear fluids group were asked to avoid solid food after lunch the day before the study and to take nothing by mouth after midnight (ie, no further preparation modification). Patients in all groups followed these same dietary instructions.

Patients assigned to the PEG group were instructed to take 2 L of the solution starting at 6:00 pm the evening before the capsule study, consumed over 2 hours. Patients assigned to the P/MC group were instructed to take 2 sachets the day before the capsule study, mixed in water, with the first dose at 4:00 pm and a second at 9:00 pm.

Outcomes

The primary outcome of this clinical trial was quality of overall small-bowel preparation as assessed by a 5-point ordinal cleanliness scale. The points on the scale were as follows: 0 = inadequate visualization for interpretation; 1 = poor: view partially obscured by solid material, which significantly limited interpretation of mucosal detail in >25% of the study; 2 = fair: view partially obscured by solid and/or liquid material, which significantly limited interpretation of mucosal detail in <25% but >10% of the study; 3 = good: no solid food material, minimal obscured view by turbid liquid <10% of the study; and 4 = excellent: no obscured view by food or turbid liquid. This scale has been used in prior trials.[24,25] The cleansing scale was assessed in a prior reliability study by 3 independent reviewers, each a clinical gastroenterologist with experience in reading VCE. The 3 reviewers initially met and reviewed several studies together in an effort to achieve adequate agreement, in addition to independently reading 20 studies each and conducting a reliability exercise.[26]

A secondary outcome was the percentage of time during which the small-bowel view was clear, defined as not obscured more than 50% of the screen view, as assessed by the 3 reviewers. The time clear was calculated by