Bowel Preparation for Capsule Endoscopy: A Prospective Randomized Multicenter Study

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Background/Aims: The ability to visualize the small bowel mucosa by capsule endoscopy is limited. Moreover, studies involving small-bowel preparation with purgative drugs have failed to establish which preparations produce better images and higher diagnostic yields. The aim of this study was to evaluate the efficacies and diagnostic yields of different bowel preparations.

Methods: A cohort of 134 patients with suspected small bowel disease was randomly assigned to 3 groups. Patients in group A (n=44) fasted for 12 h before being administered an M2A capsule (Given Imaging, Yoqneam, Israel). Patients in group B (n=45) were asked to drink two doses of 45 mL of sodium phosphate (NaP) with water during the afternoon and evening on the day before the procedure and to drink at least 2 L of water thereafter. Patients in group C (n=45) drank 2 L of a polyethylene glycol (PEG) lavage solution the evening before the procedure.

Results: Overall cleansing of the small bowel was adequate in 43% of patients in group A, 77% of those in group B, and 56% of those in group C (group A vs group B, p=0.001). Diagnoses for obscure gastrointestinal bleeding were established in 9 patients (39%) in group A, 16 patients (69%) in group B, and 14 patients (50%) in group C. No significant difference in diagnostic yield was observed between groups.

Conclusions: Bowel preparation with NaP for capsule endoscopy improved small-bowel mucosal visualization when compared to 12-h overnight fasting.

Key Words: Capsule endoscopy; Sodium phosphate

INTRODUCTION

Capsule endoscopy is a highly effective method for evaluating the entire small bowel during its normal peristalsis without inconvenience of patients. The diagnostic algorithm for small bowel disease has thus been adapted to exploit the excellent diagnostic yield of capsule endoscopy compared to that of conventional methods.1-4

Despite its diagnostic accuracy, the yield of capsule endoscopy can be limited by intestinal contents, food, and air bubbles. To obtain better mucosal images via capsule endoscopy, some clinicians have prepared the small bowel using purgative agents, such as, simethicone, polyethylene glycol (PEG), and sodium phosphate (NaP).5-9 These studies have generally shown that preparation before capsule endoscopy increases the quality of images and the diagnostic yield. However, a comparative analysis to establish the most effective preparation for capsule endoscopy is lacking.

The aim of this prospective, randomized, single-blind, multi-center study was to evaluate the quality of visualization and the diagnostic yield produced by three methods of bowel preparation.
MATERIALS AND METHODS

A total of 135 patients at 9 tertiary academic hospitals were enrolled for the evaluation of suspected small bowel disease, including obscure gastrointestinal bleeding, Crohn’s disease, chronic abdominal pain and diarrhea, and familial polyposis syndrome. All evaluations took place between October 2004 and September 2007. We excluded pregnant women, patients with suspicious gastrointestinal obstruction, patients with any implanted electromedical device (e.g., cardiac pacemaker or defibrillator), and patients less than 18 years old. When capsule endoscopy was scheduled, the patients were assigned to Group A, B, or C by using randomization lists. Group A fasted overnight before swallowing the mouth-to-anus (M2A) capsule (Given Imaging, Yoqneam, Israel) in the morning, without any supplementary bowel preparation. Group B self-administered two bottles of oral NaP, 2 bottles (45 mL each; Solin®, Korea Pharma Co., Ltd., Seoul, Korea) with water, drinking one bottle at 3:00 p.m. and the second at 7:00 p.m. the day before the procedure; Group B patients were also asked to drink at least 2 L of clear liquid before midnight on the day before the procedure. Group C ingested 2 L of a PEG/electrolyte lavage solution (Colyte®, Taejoon Pharm Co., Ltd., Seoul, Korea) 16 h before the procedure. All patients were requested to ingest a liquid diet after a regular breakfast the day before the procedure and were allowed to drink clear liquid for 2 h and have a liquid diet for 4 h after swallowing the capsule. At least two expert endoscopists, unaware of the type of bowel preparation, evaluated the capsule endoscopy findings. The gastric emptying time (GET) and the small intestinal transit time (SITT) were automatically calculated. The GET was defined as the time from the first gastric image to the first duodenal image and the SITT was defined as the time from the first duodenal image to the first cecal image.

The primary study outcome was to evaluate the effects of bowel preparation on the quality of images obtained by capsule endoscopy. Although few previous studies on bowel preparation for capsule endoscopy are available, including several studies with a small sample size reported in abstract form, we used these reports to calculate the necessary sample size for our study. The secondary study outcome was to evaluate the effect of preparation on diagnostic yield. We used the standard defined by Viazis et al.9 to evaluate the effects of bowel preparation. Obstacles such as intestinal contents, intraluminal gas, bile, and food were evaluated. The intestinal mucosa was defined as clean if, at any time, less than 25% of the mucosal surface was covered by intestinal contents, concentrated bile, intraluminal gas, and food. By using a timer, investigators recorded the exact time period during which the small intestinal mucosa was not clean. The percentage of the SITT during which the small intestinal mucosa was not clean was then calculated as an objective score. Small bowel cleansing was considered “adequate” if the objective score was less than 10% and “inadequate” if the score was 10% or greater. All investigators independently evaluated all of the digital image streams and the objective score reported for each patient was the mean of the values provided by these investigators.

A subset of patients then underwent further evaluation (double balloon enteroscopy, Meckel’s scan, Tc99 red cell scan, small bowel series, or computerized tomography) to confirm findings of capsule endoscopy. Final diagnoses were established through further evaluation or capsule endoscopy alone with a definite positive finding. In the diagnosis of Crohn’s disease, capsule endoscopy results were defined as positive if four or more obvious clear ulcers, erosions, or regions with clear exudates and mucosal hyperemia and edema were identified. The patient’s history and clinical course of the disease were considered before a diagnosis of Crohn’s disease was made. The test subjects completed a questionnaire and evaluated the difficulty and side effects of the preparatory method.

1. Ethical considerations

All of the patients provided written consent to undergo capsule endoscopy. This study was approved by the Institutional Review Board of Medical Ethics and the Human Clinical Trial Committee at each hospital.

2. Statistical analysis

Quantitative data were summarized as the mean and standard deviation (SD). Continuous measures were analyzed using analysis of variance (ANOVA). Nonparametric data were compared by the Kruskal-Wallis test and categorical measures were compared by using the chi-square test or Fisher’s exact test. p-values < 0.05 were considered statistically significant, and all statistical analyses were performed using SPSS 11.5 (SPSS Inc., Chicago, IL, USA). When each variable was compared to the other two, categorical data were analyzed using the chi-square test with Bonferroni correction. The significance level was therefore adjusted to p < 0.017.

RESULTS

1. Patient characteristics

A total of 135 patients underwent capsule endoscopy. Among the patients in Group A, one patient was ex-