Capsule endoscopy and bowel preparation with oral sodium phosphate: a prospective randomized controlled trial

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Background: Capsule endoscopy (CE) is the first procedure to explore the small bowel in obscure GI bleeding (OGB).

Objective: To evaluate the role of bowel preparation with oral sodium phosphate (NaP) in this indication.

Design: A prospective multicenter, controlled, randomized, blind study.

Methods: A total of 129 patients with the diagnosis of OGB were included and were randomized into 2 groups (group A [n = 64] and group B [n = 63]). In group A, a CE was performed after an 8-hour fasting period. In group B, patients were asked to drink 2 doses of 45 mL NaP before swallowing the capsule. The quality of the images was assessed at 5 different locations of the small bowel. Bowel cleanliness and visibility were evaluated by using 2 scoring systems, which included assessing the presence of bubbles, liquid, and the rate of visibility.

Results: A total of 127 patients (53 men; mean age 56.9 years, range 19-90 years) were analyzed for the preparation and detection of lesions (2 patients were not able to swallow the capsule). No difference was observed for cleanliness and visibility between the 2 groups at any of the small-bowel segments; no difference was found for gastric transit time (39.8 minutes vs 35.7 minutes, $P = .63$), small-bowel transit time (257.5 minutes vs 248.6 minutes, $P = .59$), and the detection of lesions (35.9% vs 42.8%, $P = .54$).

Limitations: The evaluation of bowel cleanliness was based on subjective features.

Conclusions: The results of the present study, despite a significant number of limitations, did not support that small-bowel preparation with oral NaP can be recommended for CE exploration in patients with OGB. (Gastrointest Endosc 2008;67:1091-6.)

In 2001, the U.S. Food and Drug Administration approved capsule endoscopy (CE) for diagnosing disease and disorders of the small intestine for adults. Several studies have reported that CE has a higher diagnostic yield (55%-68%) than push enteroscopy to investigate obscure GI bleeding (OGB),[1-4] and CE is now the first examination to perform after an EGD and a colonoscopy for this indication. However, the diagnostic yield may be reduced when visibility of the mucosa is impaired because of the intestinal content or slow capsule progression. Enhanced visibility could be obtained by different means, including bowel preparations, prokinetics, and postural maneuvers, eventually in combination. Only a few well-designed and large prospective comparative studies were reported in this field; most of these studies evaluated prokinetics or preparation. Therefore, at the 4th and 5th International Conference on Capsule Endoscopy, only a limited consensus could be reached on the fact that preparations/prokinetics probably improve the quality of small-bowel cleanliness.[5] It was noted that the best type of preparation, dose, and time of administration remained to be determined. Nevertheless, intestinal preparation as a standard before a CE is

Abbreviations: BTT, bowel transit time; CE, capsule endoscopy; GET, gastric emptying time; NaP, oral sodium phosphate; NS, not significant; OGB, obscure GI bleeding; PEG, polyethylene glycol; SBTT, small-bowel transit time.

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currently not recommended, and an overnight fast only is proposed by the manufacturer. The aim of this prospective, multicenter, controlled, randomized, blind study was to compare the bowel preparation with oral sodium phosphate (NaP) versus none, without prokinetic.

Capsule Summary

What is already known on this topic

- The diagnostic yield of a capsule endoscopy may be reduced when mucosal visibility is impaired because of poor bowel preparation or slow capsule progression.

What this study adds to our knowledge

- In a randomized trial of 127 patients with obscure GI bleeding who were undergoing capsule endoscopy, there was no difference in the quality of bowel preparation between patients who used oral sodium phosphate and those who simply fasted for 8 hours.
- Likewise, no differences were found in gastric transit time, small-bowel transit time, or detection of lesions.

PATIENTS AND METHODS

Patients

All patients from December 2004 to February 2006 who were referred for a CE because of OGB were eligible to enter the study and were randomly allocated into 2 groups by using sealed envelopes. Exclusion criteria were the following: known or suspected GI obstruction or stricture, chronic renal or cardiac failure, pregnancy, or age less than 18 years. Diabetic subjects were not excluded from the study. The study was approved by the Lyon B, France, ethics committee. Informed consent was obtained from all patients.

Study design

The patients were randomized into 2 groups. In group A, the patients were instructed to consume only clear liquids during the evening before the procedure, followed by an 8-hour fast. In group B, the patients were asked to drink 45 mL oral NaP (FLEET Phospho Soda, Ferring, Gentilly, France) with a glass of water the evening before and the morning of the procedure by using at least 2 L of clear liquid until midnight (ie, 2 × 45 mL NaP). A 3-hour fast was indicated before the procedure. After swallowing the capsule, the patients were not to drink for 2 hours and not to eat for 4 hours. Iron supplements and vegetal charcoal were stopped 8 days before CE examination to avoid black residue stool. No added prokinetic drug was used.

Immediately before each procedure, a nurse questioned, by using a standardized questionnaire, each patient about the acceptability of the bowel preparation. The patients were asked about compliance (2 questions), bowel preparation acceptability (one question), and bowel preparation tolerance (one question with 9 predefined symptoms).

CE reading

A CE was performed by using the PillCam SB capsule (Given Imaging, Yoqneam, Israel). Details of the capsule were described previously.[6] Sixteen experienced investigators (in 8 centers) independently evaluated the CE images. They were blinded to which group each patient was randomized. Gastric emptying time (GET) (ie, the time from the first gastric image to the time of the first duodenal image), small-bowel transit time (SBTT) (ie, the time from the first duodenal image to the time of the first cecal image), and whether or not the cecum was reached were recorded for each patient.

Because a universally accepted scale for grading bowel cleanliness is lacking, we developed our own scores. The preparation was assessed at 5 different segments (each 5 minutes long): duodenum (T0), jejunum (T1), middle small bowel (T2), ileum (T3), and distal ileum (T4). To determine these 5 segments, we arbitrarily cut the SBTT into 5 points: the first segment started at 5 minutes after passage of the capsule through the pylorus, and the last segment began at 5 minutes before passage through the ileocecal valve. Other segments started at one fourth, one half, and three fourths of the transit time. Intestinal preparation was evaluated with 2 different blinded investigators for every examination. Bowel cleanliness and visibility were defined by 2 scoring systems. The quality of preparation (score 1-4) was defined as the following: 1, no liquid and no bubbles (excellent); 2, clear liquid (good); 3, dark liquid and/or air bubbles (fair); and 4, food residue (poor). A score was given for mucosal visibility (score 1-4), which reflected the percentage of visible surface: 1, $\geq$75% of the mucosa visualized; 2, 50% to 74% of the mucosa visualized; 3, 25% to 49% of the mucosal visualized; and 4, $\leq$24% of the mucosa visualized.

The score was determined as the predominant score (according to time) for the overall interval. For example, if 10 seconds of a reading interval was a T score of 4 and the remainder of the interval was a 1, then the score would be 1 for that interval. The final score of quality reported for each patient was the mean of the 2 values provided by the 2 blinded investigators at each center.

Small-bowel lesions detected by the CE were classified as defined by Saurin et al[4] (a potentially bleeding lesion was classified as either highly relevant [P2], of uncertain relevant [P1], or of low relevant [P0]).

Statistical analysis

The primary end point was the quality of cleansing of the small bowel. We estimated that the number of patients required for the study was 130. On the basis of our previous experience, we expected that the preparation with NaP would improve the rate of good visibility of the ileum