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Alimentary Tract

The optimal bowel preparation intervals before colonoscopy: A randomized study comparing polyethylene glycol and low-volume solutions

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ABSTRACT

Background & aims: The optimal duration of bowel preparation has only been assessed for polyethylene glycol (PEG). The aim of the study was to determine the intervals for achieving a satisfactory quality/tolerability of the preparation using PEG/ascorbic acid (PEGA) and sodium picosulphate/magnesium citrate (SPMC), and to compare them with 4L of PEG.
Methods: A randomized, endoscopist-blinded, multicentre study. The 612 outpatients referred to a colonoscopy, were prepared using PEG, SPMC, PEGA. The quality, tolerability, duration of the preparation, and the interval from the end of the preparation to the colonoscopy was assessed.
Results: Optimum duration of the preparation was similar for both PEG and SPMC (≥7.3 vs. ≥8.8 h, overall ≥8.4 h). Optimum interval to the colonoscopy was ≤11.8 h and did not differ between preparations (PEG, PEGA ≤ 11.8, SPMC ≤ 13.3 h). These times were the only predictors for a satisfactory preparation. The tolerability depends on the product type (SPMC) only. Timing of the preparation or the other factors had no impact on tolerability.
Conclusion: The optimum intervals for bowel preparation are identical for all preparations. Satisfactory preparation is achived at the preparation length ≥8.4 h and the time to colonoscopy ≤11.8 h.

1. Introduction

The quality of bowel preparation has a significant impact on the success rate of the colonoscopy and detection of any potential pathology [1]. There are multiple factors affecting bowel cleansing. Some of them cannot be influenced, e.g. diabetes, constipation [2]. Others, such as bowel preparation, can be modified. The type of laxative used is usually considered to be the most important factor. It has been shown that the time regimen used seems to be of at least the same importance. At present, the split regimen is a standard, whereby the recommended time from completing the last dose should not exceed 2–6 h [3,4]. It is questionable though; to what extent this recommendation applies universally. It is based on preparation using four litres of conventional polyethylene glycol (PEG) [5]. Currently available products contain laxatives, which differ from PEG. It is not known, if these products do not require different preparation timing.

The aim of the present study was to determine the time needed for bowel preparation using sodium picosulphate/magnesium citrate (SPMC) and PEG + ascorbic acid (PEGA) to achieve a satisfactory quality and tolerability of the preparation, and compare them with standard 4L PEG.

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2. Materials and methods

2.1. Study design

This was a prospective, randomized, endoscopist-blinded, multicentre study. The study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki (6th revision, 2008). The study was approved by the Institutional Review Board of the Bata Regional Hospital in Zlin. All study participants had provided informed written consent prior to study enrolment. The study is registered at https://clinicaltrials.gov (NCT02908919).

Outpatients aged ≥18 years, referred to a colonoscopy in the endoscopy departments of University Hospital in Brno, Prague and Bata Regional Hospital in Zlin from September to December 2016, were enrolled in the study.

Exclusion criteria included: ileus, known or suspected bowel obstruction, active bowel inflammation, active gastrointestinal bleeding, pregnancy, any presence of serious medical conditions, such as severe cardiac, renal, liver diseases, history of prior bowel surgery, and failure to obtain valid data from a subject.

2.2. Outcome measurement

The primary outcome was to assess the length of preparation-time form the start of the preparation the end of the preparation (PrepTime) and the time from the end of the preparation to the colonoscopy (TimeToCol) required for a satisfactory quality (Aronchick score 1 + 2) of the preparation and tolerability (score 1 + 2).

The secondary outcome measures included the impact of additional factors (type of product, age, sex, constipation, ingested preparation volume, BMI, diabetes) on the quality of preparation and tolerability.

2.3. Bowel preparation

The subjects received commercially available preparations in approved doses and regimens. One sachet of PEG (Fortrans™ plv. sol., Ipsen Pharma, Boulogne-Billancourt) contains 64 g of PEG 4000, 5.7 g Na_2SO_4, 1.7 g $NaHCO_3$, 2.2 g NaCl/KCl. One sachet of SPMC (Picoprep™ plv. sol., Ferring Pharmaceuticals, Kiel) contains 10 mg of sodium picosulphate, 3.5 g MgO, 12.0 g citric acid and one dose of PEGA (Moviprep™ plv. sol, Norgine Ltd., Harefield,) 100 g of PEG 3350, 7.5 g Na_2SO_4, 3.7 g NaCl/KCl, 10.6 g ascorbic acid/Na ascorbate.

All patients were instructed to start the preparation at 4:00 PM and for split preparation to take the second dose between 5–6:00 AM at the least 2 h before the procedure and to be on a low-fibre diet three days before the colonoscopy.

PEG-based preparation started in the afternoon before the colonoscopy (4 sachets + 4 L of water or 3 sachets + 3 L of water in the afternoon and 1 sachet + 1 L of water in the morning before the colonoscopy, at a rate of 1 L/h). PEGA-prepared patients used PEGA in 2 sachets dissolved in 2 L of water in the afternoon before the colonoscopy within 2 h followed by 1 L of a clear-water based drink, or 1 L of the solution in the afternoon, followed by 0.5 L of a drink, and the same dose in the morning, each dose within 1 h. SPMC group was prepared using 2 SPMC sachets (each with 150 mL of water) followed by 2 L of a clear water-based drink in the afternoon before the colonoscopy within 2–3 h, or 1 sachet + 1 L of a drink in the afternoon, and the same dose in the morning, within 1–2 h.

2.4. Bowel cleansing assessment and data collection

Prior to the colonoscopy, each patient had received an anonymous questionnaire to fill in data on his/her weight, height, age, gender, the presence of diabetes, frequency of bowel movements during one week before the colonoscopy, the amount of fluid intake during the preparation, and the time he/she started and finished drinking the solution. The preparation tolerability was assessed using a 5-point visual analogue scale (1—excellent, 5—very poor). The quality of the bowel preparation was assessed blindly by 8 experienced endoscopists using the modified Aronchick scale [6] Table 1. The modified Aronchick bowel preparation scale. The Arochick scale has been used to provide the least subjective variability of assessment, because the the centers participating in the study have been using it for a long time, and thus are well acquanted with it.

The time of starting the colonoscopy was recorded. The study subjects were randomised and allocated in each center by non-endoscoping physician using the on-line database. Data collection was performed by endoscopy nurses. The patients were asked not to disclose their bowel preparation methods to the colonoscopist.

2.5. Sample size calculation and statistical analysis

Based on our previous experience, we anticipated satisfactory preparation in 80% of the cases. For test power 0.8, α of 0.05 and AUC 0.5, the sample size for each group was estimated to be 170 subjects. The investigators anticipated a 20% drop-out rate, and planned to enrol 204 patients in each branch. The patients were randomized prospectively using a software generated random table (a method of blocks of 12). Both single and split-dose preparations for each laxative were used (ratio 1:1) in order to cover sufficient time interval. Continuous variables were described using mean (SD) and median (25th and 75th percentile), and significance of differences was tested by the Kruskal–Wallis test with the Bonferroni correction. The association between categorical variables was assessed using the Fisher exact test. Dependence of quality and tolerability on timing parameters was analysed using ROC analysis. An univariate and multivariate logistic regression model was applied to measure the association of the baseline characteristics with achievement of good quality or tolerability. The level of statistical significance was 0.05 in all analyses.

Table 1
The modified Aronchick bowel preparation scale.

Rating	Description
1	Small amount of clear liquid with clear mucosa seen; more than 95% mucosa seen
2	Small amount of turbid fluid without feces not interfering with examination; more than 90% mucosa seen
3	Moderate amount of stool that can be cleared with suctioning permitting adequate evaluation of entire colonic mucosa; more than 90% mucosa seen
4	Inadequate but examination completed; enough feces or turbid fluid to prevent a reliable examination; less than 90% mucosa seen
5	Re-preparation required; large amount of fecal residue precludes a complete examination

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