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Effectiveness and tolerability of three types of colonoscopy preparation products

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Abstract

Objective: To establish the differences between three types of colonoscopy preparation products in terms of effectiveness and tolerability. **Materials and methods:** An analytical, prospective, blind, cross-sectional study of the Boston Bowel Preparation Scale was carried out. Adult patients over 18 years of age with a requirement for colonoscopy and completion of the survey on the type of preparation carried out for colon cleansing were included. **Results:** Three groups of products (polyethylene glycol, picosulfates, and sulfate salts) were evaluated in 907 patients. Total and segment Boston Bowel Preparation Scale was applied, without finding statistically significant differences between them (OR 1.10; 95%CI: 0.6-1.8; p = 0.728). 60% of the population were women and the average age was 52 years. Compliance with the diet was observed in 99% of the participants. Split-dose bowel preparation performed best on the Boston scale (OR 5.06; 95%CI; 3.2-8.01; p= 0.001). Picosulfates had greater acceptability (OR 15.8; 95%CI: 8.83-28.3; p= 0.001) and fewer side effects such as abdominal distension (OR 0.59; 95%CI: 0.3-0.9; p= 0.033) and vomiting (OR 0.25; 95%CI: 0.07-0.82; p= 0.015). The best result was observed when the test was performed within 6 hours of completion of preparation (OR 6.38; 95%CI: 3.84-10.6; p = 0.001). **Conclusions:** The products evaluated did not show differences between them regarding their effectiveness. Picosulfates had fewer side effects and better acceptability. Split-dose and testing up to 6 hours after preparation resulted in better bowel preparation.

Keywords

Colonoscopy; Laxatives; Side effects.

INTRODUCTION

Visualization of the mucosa is essential in detecting lesions during a colonoscopy and good or excellent colon cleansing is required for this purpose [1,2]. The effectiveness of cleaning was evaluated using the Boston scale (**Table 1**), which has been internationally validated and is widely used in gastroenterology [2-4]. The scale represents the sum of the score from 0 to 3, in the 3 colon segments [4], and a score ≥ 2 in each segment [5] is considered satisfactory. Lower scores do not reflect good visualization and thus reduce the detection of adenomas and cecal intubation [6,7].

To achieve good preparation, diets low in fiber and waste have been recommended, in addition to a liquid diet [8-10], but they are still considered insufficient measures. Consequently, various types of cathartics and laxatives are used [8], and the most recommended are osmotic laxatives based on polyethylene glycol (PEG), sulfate salts and pico-

Table 1. Boston Bowel Preparation Scale (by colon segment) [3]

	Description	Other Features of the Scale
0	Unprepared colon segment with mucosa not visible due to solid stools that cannot be removed.	Total score range (obtained by adding scores for each segment):
1	Visibility of a portion of the mucosa of the colon segment, but other areas of the segment not visible due to staining, residual stool or opaque liquid.	Minimum 0 (very poor) to maximum 9 (excellent). Score obtained after washing or vacuuming. Separately classified segments: right colon (including cecum and ascending colon), transverse (includes hepatic and splenic angles) and left colon (descending and sigmoid colon and rectum). The optimal threshold is a total score of ≥ 6 and ≥ 2 per segment.
2	Minimum amount of residual staining, small fragments of stool or opaque fluid, but good visibility of the mucosa of the colon segment.	
3	Good visibility of the entire mucosa of the colon segment, no residual staining, small fragments of stool or opaque liquid.	

Taken from: Kastenberg D et al. World J Gastroenterology. 2018;24(26):2833-2843.

sulfate [9,12], all recognized for their results for the preparation of the colon, but with differences among them in terms of use, tolerability and safety recommendations [13,14].

The aim of the study is to establish the differences among three types of colonoscopy preparation products in terms of effectiveness and tolerability. The impact of products at the level of hydroelectrolytic changes [9,15] requires an additional approach, which is not part of the scope envisaged in this study.

MATERIALS AND METHODS

Cross-sectional study, blind for the evaluator of the Boston scale. All adult outpatients[16,17] treated at a gastroenterology institution in Medellin, Colombia, who underwent complete colonoscopy between February and July 2020 were included. A database was built in Excel format, in which the following data were collected from each patient for analysis: age, sex, complied with the diet the day before, product used for the preparation, performed the preparation split into two parts, time of completion of the product, time of examination and how the taste of the product was for them. Subsequently, the total and by segment results of the Boston scale were added to the database, as described in the colonoscopy report.

At the time of colonoscopy appointment assignment, three formats were provided with the different preparation instructions institutionally protocolized, so that the patient could select the product of their choice (PEG, picosulfate, sulfate salts). The recommendation for everyone was a diet without seeds, husks, and legumes, two days before the exam and until the time of starting preparation. The group of patients prepared with PEG took 4 sachets diluted in 1 liter of water each; the picosulfate group took 2 sachets diluted in 250 mL of water each and additionally 1.5 liters of clear liquids; and the group of sulfate salts took two vials diluted in 500 mL of water each and additionally 1.5 liters of clear liquids. All patients were advised to perform the preparation split into two parts: the first one, at 6:00 p.m. the day before the exam and the second, 5 hours before the test scheduled time, having completed it at least 3 hours before the procedure. The presence of side effects related to the intake of the preparation was inquired, such as bloating, headache and vomiting. Patients categorized their perception of the taste of the ingested product into pleasant, indifferent or unpleasant.

The database was filled out by an assistant trained for this purpose at the time of admission of the patient for the procedure; recording subjective information not detailed in the clinical record: compliance of the diet, product used, preparation split into two parts or taken continuously, time of completion of the product and perception of the taste of the product.

The effectiveness of colon cleansing was classified using the Boston scale, which assesses the presence of bowel movements and visibility of the colonic mucosa in its three segments: right, transverse and left (0 to 3 points), and total (0 to 9 points). Inadequate preparation was considered when in some segment the score was 0 or 1, or the total score was less than 6. This evaluation was carried out by the group of gastroenterologists who participated in the performance of colonoscopies, which is composed of 7 specialists, and this evaluation was recorded in the examination report. The time elapsed between the end of the intake of the product and the examination was quantified in order to determine the effect on the preparation of the colon and its consequent visibility of the mucosa.

The objectives of the study were to determine the differences in the preparation of the colon with the different

products according to the Boston scale, the difference between taking the preparation in continuous or split form related to colon cleansing and, in turn, to establish results in terms of side effects, acceptability of the product and elapsed time for the examination after intake completion related to the state of colon cleansing.

The products evaluated are part of the group of osmotic laxatives used conventionally for this type of procedure; therefore, it is not an experimental intervention. There was no randomization of patients or induced demand for the preparation procedure or products. All patients have informed consent for the procedure. The performance of the study is considered to be of minimal risk and contemplates the fundamental principles of research ethics in accordance with the Declaration of Helsinki 2013 version[18] and Resolution 008430 of 1993 of the Colombian Ministry of Health[19]. The protocol was previously endorsed by the institution's Ethics Committee and the confidentiality of the information collected was safeguarded.

STATISTICAL ANALYSIS

The data was analyzed using Excel, 2019 version, and Jamovi 1.2.25. version. Univariate analysis was performed in which absolute and relative frequencies were determined for qualitative variables. For quantitative variables, mean and standard deviation (SD) or median and interquartile range (IQR) were used, after verification of the assumption of normality.

Quantitative variables were dichotomized for comparison of proportions. The chi-square association test was used for independent samples and the *Odds Ratio (OR)* was estimated with its respective 95% confidence interval (CI). A statistically significant *p-value* was considered to be < 0.05.

RESULTS

A total of 907 eligible patients were identified out of 1000 patients who underwent colonoscopy between February and July 2020. Patients who did not have a complete examination of all segments of the colon due to anatomical difficulties (angulations, adhesions or obstructive tumors), scope of study (surgical history with proximal colon resection) or indication for partial examination (left colonoscopy) were excluded from the database. Likewise, those who carried out the preparation with other types of products not protocolized by the institution and those in which the evaluation of the Boston scale was not recorded by the specialist in the examination report were excluded.

60% percent of the population was female. The average age was 52 years-old (SD: 14) (**Table 2**). 99% of patients followed the low-residue diet. The preparation of the colon was evaluated using the Boston scale, which ranges from 0 to 9 points (total colon assessment) and 0 to 3 points (segment assessment).

Table 2. Demographics

Variable	Patients (n = 907)
Average age	52.6 (DE 14.7)
Median	55
Female sex	546 (60.2 %)
Male sex	361 (39.8 %)
Ratio by sex female: male)	1.5:1

Source: own

Protocolized products for the preparation of the colon and which were subjected to comparison with each other are PEG, picosulfate and sulfate salts. No significant differences were found among the products in terms of results on the total Boston scale or by segment (OR: 1.10; 95% CI: 0,6-1,8; $p = 0,72$) (**Table 3**).

Table 3. Effectiveness and tolerability according to colon preparation products

Variables	Patients evaluated	Boston scale (good or excellent)	Acceptability (pleasant or indifferent)	Abdominal bloating	Headache	Vomit
	n	%	%	%	%	%
Picosulfate	196	90.3	93.4	11.2	16.3	1.5
PEG	524	89.1	47.9	17.4	13.2	6.1
Sulfate salts	187	90.4	44.9	18.2	10.7	4.8

Source: own

The indication for ingesting the preparation split into two doses was followed by 66% of patients and had better results in colon cleansing than those who took it continuously (OR: 5.06; 95% CI: 3.2-8.01; $p = 0,001$) (**Table 4**).

The scale for evaluating the taste of the product had three answer options: pleasant, unpleasant or indifferent. Positive (pleasant) and neutral (indifferent) responses were treated as acceptability. The picosulfate group obtained greater acceptability (pleasant: 77%, indifferent: 16%) compared to the other groups (OR: 15.8; 95% CI: 8,8-28,3; $p = 0,001$). Also, fewer side effects took place such as bloating (OR: 0.59; 95% CI: 0.3-0.9; $P = 0,03$) and vomit (OR: 0.25; 95%

CI: 0,07-0,82; p = 0,015). Regarding headache, no significant differences were found among the products evaluated.

The time elapsed between the completion of the preparation product and the start of the examination was analyzed by segmenting the variable into 3 time ranges (0 to 6 hours, 6 to 12 hours, greater than 12 hours), with the aim of identifying differences in the outcome of colon preparation. It was obtained that the range with the best result on the Boston scale was 0 to 6 hours (OR: 6.38; 95% CI: 3,84-10,6; p = 0,001). Of the patients with constipation (n = 69), 90% had good preparation.

Table 4. Results of the Boston scale according to the form of intake of the preparation product and time between the preparation and the exam.

Variables	Patients evaluated	Boston scale (good or excellent)
	n	%
Split-dose	602	95
Continuous preparation	305	79
End of preparation/exam range < 6 h	544	96.1
End of preparation/exam range < 6 h	358	79.6

Source: own

DISCUSSION

A prospective study was conducted with the aim of comparing the effectiveness and tolerability of three types of colon cleansing products in colonoscopy [20]. The incidence of inadequate preparation was 10% in the patients evaluated, unlike what was estimated in other studies, about 20% -40% [21,22]. This difference may be due to the individualized education offered to patients during the appointment assignment and two days prior to the procedure [23.24]. Patients with poor preparation were mainly women (59%) and people under 60 (68%), which controverted some recently predictive factors of poor preparation [21,25,26].

The effectiveness of the preparation is influenced by the tolerability of the product. Ideally, the colonoscopy cleanser should be safe, effective and well tolerated [27,28]. The effectiveness of the three types of products did not differ significantly from each other. Similar results were found when comparing picosulfate and PEG [29-31]. It should be noted that the effect of the products on intestinal inflammation was not inquired [32].

Better tolerability was obtained in patients who were prepared with picosulfate, with a lower incidence of bloating and vomiting [11,31,33,34]. The taste may influence the intake of the entire preparation and indirectly on the results of the Boston scale; in this regard, most patients reported perceiving the taste of picosulfate as pleasant or indifferent. Both PEG and sulfate salts had low taste acceptability [9,11].

Dietary restrictions are part of the preparation of the colon, and many patients often do not follow these recommendations properly [35]. However, patients in the study agreed to follow the recommended low-residue diet [36], in 99% of cases. Adequate hydration is also included in all preparation protocols in order to avoid adverse physiological effects related to dehydration such as hypotension or hydroelectrolytic disorders [37,38].

The use of the split-dose was significantly better compared to continuous intake [39.40], regardless of the type of product used. The result is improved mucosal cleansing and visibility in all segments of the colon [41,42].

Several studies suggest that there is a time window after completion of preparation and before the colon cleansing begins to deteriorate. The result obtained was a time limit of 6 hours [10.43]. Additionally, at the end of taking the laxative at least 3 hours before the procedure, the risk of pulmonary aspiration associated with high residual gastric volumes is reduced[44]. It should be noted that the split-dose also influences the good results of the preparation because the time interval between the last intake of the product and the colonoscopy becomes shorter [40.45].

It is important to inquire about the independent risk factors that affect colonoscopy preparation, such as constipation, diabetes, dementia, colorectal surgery, overweight, age, among others, both in outpatients and the inpatients [21,25,46]. In terms of safety, any of the products can have adverse effects. Particular care should be taken in patients with heart, liver and kidney involvement [47,48]. This is how knowledge of the advantages and disadvantages of all products will allow a better selection for each patient [49].

For patients with constipation, the percentage of good preparation was similar to that found in the study population. No stratified analysis was performed according to comorbidities or drug use related to the effectiveness of the preparation. It is recommended that future investigations address these variables for analysis.

CONCLUSIONS

The products evaluated did not show differences among them regarding their effectiveness. Picosulfate had fewer side effects and better acceptability. Split-dose and testing up to 6 hours after preparation resulted in better bowel preparation.

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