Journal of Coloproctology

www.jcol.org.br

Original Article

Efficacy of low residue enteral formula versus clear liquid diet during bowel preparation for colonoscopy: a randomised controlled pilot trial

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ARTICLE INFO

Article history:
Received 1 June 2018
Accepted 8 October 2018
Available online 2 November 2018

Keywords:
Colonoscopy
Bowel preparation
Quality
Low residue
Enteral formula

ABSTRACT

Objectives: Conventional bowel preparation for colonoscopy confines patient to clear liquid diet the day before and such non-nutritive dietary regimen often caused discomfort and hunger. The purpose of this study is to determine the feasibility of feeding patient with low-residue, lactose-free semi-elemental enteral formula (PEPTAMEN®) compare to conventional clear liquid diet during bowel preparation before colonoscopy.

Methods: This was a randomised, endoscopist-blinded study. Patients were randomised into two groups, those receiving oral PEPTAMEN® and mechanical bowel preparation (A) and those receiving clear liquid while undergoing mechanical bowel preparation (B). Documentation was made with regard to the type of bowel cleansing agents used, completeness of the colonoscopy, cleanliness quality score, and hunger score.

Results: A total of 97 patients were included in the study, A = 48 and B = 49. Eight patients, who were not compliant to the bowel-cleansing agent or had an incomplete colonoscopic examination, were excluded from the study. In terms of the overall cleanliness score, no statistical significant difference was seen ($p = 0.25$) between the two groups, A (fair or poor 37.5%, good or excellent 62.5%) and B (fair or poor 49%, good or excellent 51%) whereas the hunger score showed a significant difference ($p = 0.016$), A (no hunger 41.7%, slight hunger 12.5%, hungry 12.5%) and B (no hunger 24.5%, slight hunger 38.8%, hungry 36.7%).

Conclusions: These data suggest that the addition of oral PEPTAMEN® as part of the bowel preparation regimen did not significantly alter the luminal cleanliness score during colonoscopy while alleviating hunger.

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https://doi.org/10.1016/j.jcol.2018.10.003

Eficácia da fórmula enteral pobre em resíduo *versus* dieta líquida clara durante o preparo intestinal para colonoscopia: um estudo piloto controlado e randomizado

Palavras-chave:
Colonoscopia
Preparo intestinal
Qualidade
Pobre em resíduo
Fórmula enteral

RESUMO

Objetivo: A preparação intestinal convencional para a colonoscopia confina o paciente à dieta líquida clara no dia anterior; esse regime dietético não nutritivo frequentemente causa desconforto e fome. O presente estudo teve como objetivo determinar a viabilidade de alimentar o paciente com fórmula enteral semielementar sem lactose e pobre em resíduos (PEPTAMEN®) em comparação com a dieta líquida clara convencional no preparo intestinal para colonoscopia.

Métodos: Este foi um estudo randomizado no qual o endoscopista foi cego quanto ao tipo de preparo. Os pacientes foram randomizados em dois grupos: aqueles que receberam PEPTAMEN® oral e preparo intestinal mecânico (A) e aqueles que receberam dieta líquida clara e preparo intestinal mecânico (B). Os pacientes foram avaliados quanto ao tipo de agente de limpeza intestinal utilizado, a completude da colonoscopia, o escore de qualidade de limpeza e o escore de fome.

Resultados: Um total de 97 pacientes foram incluídos no estudo, 48 no grupo A e 49 no grupo B. Oito pacientes foram excluídos por não aderirem ao agente de limpeza intestinal ou apresentarem um exame incompleto de colonoscopia. Quanto ao escore geral de limpeza, não se observou diferença estatisticamente significativa (p = 0,25) entre os grupos A (resultado regular ou ruim, 37,5%; bom ou excelente, 62,5%) e B (resultado regular ou ruim, 49%; bom ou excelente, 51%). Por outro lado, o escore de fome apresentou diferença significativa (p = 0,016) entre os grupos A (sem fome, 41,7%; fome leve, 12,5%; fome, 12,5%) e B (sem fome, 24,5%; fome leve, 38,8%; fome, 36,7%).

Conclusões: Os dados sugerem que a adição de PEPTAMEN® oral como parte do regime de preparo intestinal não altera significativamente o escore de limpeza luminal durante a colonoscopia, mas alivia a fome.

Introduction

Colonoscopy is an indispensable diagnostic and therapeutic tool in the management of colorectal disorders. An adequately prepared bowel is essential during colonoscopy to ensure that small or inconspicuous lesions are not missed. It is reported that up to 20%–25% of colonoscopies have inadequate bowel cleansing.[1] Ideally, the bowel should be emptied of all faecal matter to identify lesions >5 mm without causing too much discomfort to the patient.[2] Conventional bowel preparation involves 1–4 days of a low residue diet regimen followed by clear liquids and intake of a bowel cleansing agent, typically polyethylene glycol solution or a sodium phosphate preparation, a day before the procedure.[3,4] Compliance with the polyethylene glycol is low while the sodium phosphate and sodium picosulfate with magnesium citrate offer better compliance but less optimal bowel cleansing.[5] This combination of an extended period without solid food or nutritive liquids plus the intake of the laxatives makes the bowel preparation procedure a difficult and unpleasant experience for the vast majority of patients.

Materials and methods

A sample size was calculated using PS program with Power of Study 80% with a significant level of 5%. With the assumption that percentage of patients in a hungry condition when given oral PEPTAMEN® was 10% and in patients given clear liquid diet was 40%, at least 32 patients per group were expected to be recruited into the study. A total of 105 patients were recruited over a 2 month period. The patients aged between 16 and 73 years and had undergone colonoscopy in a tertiary referral hospital performed by senior endoscopists blinded to the study preparation group. The indications for the colonoscopy included symptoms of altered bowel habits, rectal bleeding, anaemia, unexplained loss of appetite and weight, and surveillance for colorectal disorders. The patients were given standard instructions for the bowel preparation and a bowel-cleansing agent prescribed. The patients were randomised into two Groups A and B; those receiving oral PEPTAMEN® and mechanical bowel preparation (A) and those receiving clear liquid diet while undergoing mechanical bowel preparation (B).

Table 1 – The modified Aronchick bowel preparation quality scale.

Score	Description
1: Excellent	Small volume of clear liquid, or greater than 95% of surface seen
2: Good	Large volume of clear liquid covering 5%–25% of the surface but greater than 90% of surface seen
3: Fair	Presence of some semi-solid stool that could be suctioned or washed away but greater than 90% of surface seen
4: Poor	Semi-solid stool that could not be suctioned or washed away and less than 90% of surface seen

Table 2 – Hunger score.

Score	Description
1	No hunger
2	Slight hunger
3	Hungry

Group A patients received three servings of full strength PEPTAMEN® (Table 1) given in the morning, afternoon and at night one day before colonoscopy in between intake of the bowel cleansing agent. Group B patients were prepared conventionally with the bowel cleansing agent and unlimited amounts of clear liquids. Patients were instructed to adopt a low residue diet 2 days before the procedure. The osmotic laxative, sodium phosphate, is the preferred cleansing agent used due to its lower volume content (90 mL in total) and the absence of the unpleasant salty taste. Polyethylene glycol (PEG, 3 L in total) is used instead where sodium phosphate is contraindicated.

Documentation was generated with regard to the type of bowel cleansing agents used, completeness of the colonoscopy, a validated bowel preparation quality scale, and a simple subjective hunger score (Table 2). The Aronchick scale is a validated tool to assess the bowel preparation quality by looking at the colonic content or the visibility of the mucosal lining during colonoscopy following administration of the mechanical bowel preparation agent.[6]

Informed written consents are taken from all patients for the endoscopic procedure while verbal consents were acquired from all patients in Group A (Test arm) about the intake of PEPTAMEN® as part of the bowel preparation.

Results

A total of 97 patients (46 females and 51 males) were included in the study (A = 48, B = 49). Eight patients (3 from Group A and 5 from Group B), who were not compliant to the bowel cleansing agent or had an incomplete colonoscopic examination, were excluded from the study. The generated cleanliness score for Group A and Group B is summarised in Table 3. There

Table 3 – Bowel cleanliness score between Groups A and B.

	1: Excellent	2: Good	3: Fair	4: Poor
Group A	3 (6.3%)	27 (56.3%)	8 (16.7%)	10 (20.8%)
Group B	4 (8.2%)	21 (42.9%)	12 (24.5%)	12 (24.5%)

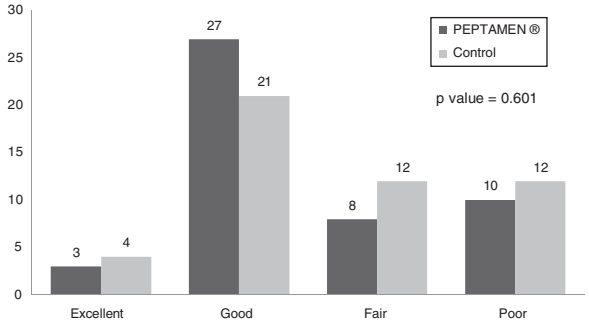

Fig. 1 – Bowel cleanliness score between PEPTAMEN® group and control group, showing no statistical difference between the two groups (*p*-value = 0.601).

is no statistical difference between the two groups regarding cleanliness (*p*-value = 0.601), but there is a clinically significant difference in the "good" score (A = 27 patients vs. B = 21 patients) as shown in Fig. 1.

Ten patients (37%) who scored "good" and 4 patients (50%) who scored "fair" for bowel cleanliness in the PEPTAMEN® group were found to have possible "milk residue" or semi-solid faeces seen during the procedure. The "milk residue" was documented as a watery whitish liquid or whitish curd-like substance in the colon. However, these milk residue or semi-solid faeces were easily aspirated and did not compromise the visibility during the procedure.

Hunger was observed to be significantly reduced in Group A patients, summarised in Fig. 2. Twenty patients did not experience hunger in the PEPTAMEN® group compared to only 4 patients in the control group. Conversely, 6 patients in the PEPTAMEN® group experienced hunger as compared to 12 patients in the control group.

Sodium phosphate was the predominant laxative used in both test and control groups (A = 93.8%, B = 89.8%) with no significant difference (*p* = 0.48). PEG (Polyethylene Glycol) was employed in patients whom sodium phosphate was

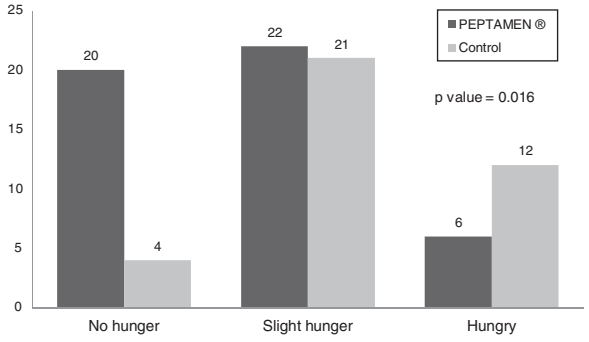

Fig. 2 – Hunger scores between the two groups with a significant improvement in hunger score (*p*-value = 0.016).

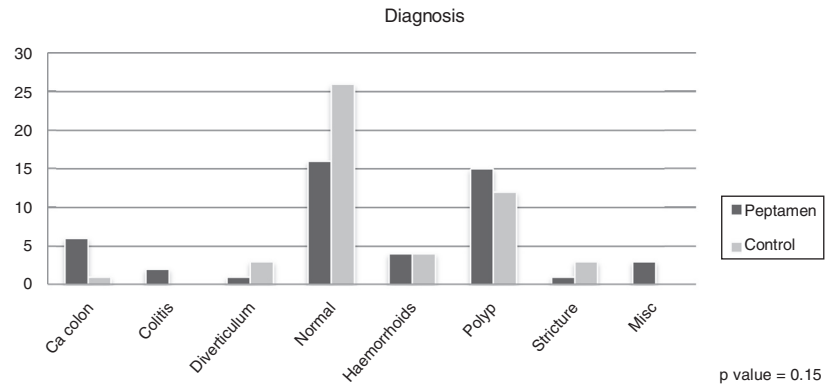

Fig. 3 – Bar chart showing the similar types of endoscopic diagnosis of both groups, with no significant difference (*p*-value = 0.15).

contra-indicated. With regard to the diagnosis of the patients, both test and control groups contained similar types of cases ($p = 0.15$) as summarised in Fig. 3.

Discussion

Colonoscopy remains the gold standard for diagnosing colonic pathologies. Hence, a visibly clean colon is essential to facilitate this procedure. This is achieved through mechanical bowel preparation with cleansing agents as well as dietary modifications before the procedure.[7] These diet regimens and the preferred cathartic differ from centre to centre. Most diet regimens require the patient to adopt a low residue diet at least 2 days before the procedure followed by a clear liquid diet one day before that particular procedure.[8] Subsequently, cathartics, in the form of either Polyethylene Glycol (PEG) or Sodium Phosphate (NaP) are prescribed for the purpose of bowel cleansing. Several randomised trials have shown no differences in tolerance and acceptance of either type of bowel preparation. However, compliant rates were higher, and the cost was lower in the Sodium Phosphate (NaP) group compared to the PEG group. Hunger was reportedly less in the PEG group compared to the NaP group.[2,8]

This preparation often leaves the patient hungry and uncomfortable which in turn often leads to non-completion of the bowel cleansing agents.[9] To counter these adverse effects and discomfort of bowel preparation, different modifications and recommendations have been advocated including pre-packaged diet regimens, allowing a low residue lunch one day before the procedure or bowel preparation with a liquid diet alone.[10–12] While these dietary modifications offer an alternative to the conventional clear liquid diet during mechanical bowel preparation, they are not practiced routinely due to the high cost of the pre-packaged diet regimens[11] or possibly due to the fear of poor understanding and compliance of the patients that might lead to an unacceptable bowel preparation.

Prolonged periods of fasting experienced by patients for different procedures and investigations like endoscopy and CT scans, often results in accumulative deficits in calories and protein. This is made worse in patients who are already at “nutrition risk” or malnourished. Also, hunger due to prolonged fasting or clear liquid diet may lead to non-compliance with the bowel preparation regimen. Clear fluids alone do not alleviate hunger nor do they contribute any nutritional value apart from hydration. It has been shown in experimental studies that the presence of lipids and free fatty acids in the duodenum is associated with the release of Cholecystokinin (CCK) which in turn is associated with satiety.[13]

Hence adding PEPTAMEN® to the patient’s diet in between the intake of the bowel cleansing agents appears to be a better alternative than a clear liquid diet. It alleviates hunger experienced during bowel preparation and helps to minimise protein energy deficit in patients with poor nutritional status. Unlike milk or other dairy products which leave visible residues on the colonic mucosa, PEPTAMEN® is a semi-elemental enteral formula containing peptides from hydrolysed whey proteins, a 70:30 ratio of Medium Chain Triglycerides (MCT) to Long-Chain Triglycerides (LCT), soy oil, maltodextrin, corn starch and micronutrients. It is easily absorbed, well tolerated, may increase the rate of gastric emptying time[14] and most importantly, it is a low residue formula.[15]

As demonstrated in this study, there is no significant difference between the experimental and control groups with regard to bowel cleanliness ($p = 0.601$) (Fig. 1). However, there is a clinically significant difference seen in the enteral formula group in terms of “good” bowel preparation; 27 patients (56.3%) in the test group compared to 21 patients (42.9%) in the control group. Furthermore, hunger scores were significantly less in the enteral formula group ($p = 0.016$) (Fig. 2). In conclusion, tolerability and bowel cleanliness with the addition of enteral formula during mechanical bowel preparation were comparable to patients who were solely given clear fluids. Hence, PEPTAMEN® can be safely prescribed routinely to all patients undergoing bowel preparation. The number of patients recruited in this pilot study is small, and a clinical trial is already being undertaken to include a larger sample size.

Conflicts of interest

The authors declare no conflicts of interest.

Acknowledgements

The bio-statistical data was analysed by Mr. Mohd Faizal, an independent statistician from the Department of Medical Research of the National Heart Institute, Kuala Lumpur.

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