

# RANDOMIZED CLINICAL TRIAL COMPARING SODIUM PICOSULFATE WITH MANNITOL IN THE PREPARATION FOR COLONOSCOPY IN HOSPITALIZED PATIENTS

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**ABSTRACT – Background** - The cleansing of the colon for a colonoscopy exam must be complete so as to allow the visualization and inspection of the intestinal lumen. The ideal cleansing agent should be easily administered, have a low cost, and minimum collateral effects. Sodium picosulfate together with the magnesium citrate is a cathartic stimulant and mannitol is an osmotic laxative, both usually used for this purpose. **Aims** - Assess the colon cleanliness comparing the use of mannitol and sodium picosulfate as well as evaluate the level of patient satisfaction, the presence of foam, pain, and abdominal distension in hospitalized patients undergoing colonoscopy. **Methods** - A prospective, randomized, single-blind study with 80 patients that compared two groups: mannitol (40) and sodium picosulfate (40). Both groups received the same dietary orientation. The study was approved by the hospital's Ethics and Research Committee. The endoscopist was blind to the type of preparation. Outcomes evaluated: level of the colon's cleanliness, patient's satisfaction, the presence of foam, abdominal pain and distension, and the duration of the exam. The data was analyzed by means of the chi-squared test for proportions and Mann-Whitney for independent samples. **Results** - There were no statistically significant differences between the groups in relation to the level of the colon's cleanliness, patient's satisfaction, the presence of foam, abdominal pain, and the duration of the exam. Fifteen percent of the exams of the mannitol group were interrupted while from the sodium picosulfate group it was 5%. The presence of foam was similar for both groups. The average duration for carrying out the exam was 28.44 minutes for the mannitol group and 35.59 minutes for the sodium picosulfate group. Abdominal distension was more frequent in the mannitol group. If they would have to do the same exam, the answer was that 80% said yes from the mannitol group and 92.5% from the sodium picosulfate group. **Conclusions** - The quality of the colon preparation, foam formation, exam duration, and the collateral effects (nauseas, vomiting, and abdominal pain) were similar in both kinds of preparations. Abdominal distension was greater in the mannitol group. Both methods of preparation were well accepted by the hospitalized patients.

**HEADINGS** – Colonoscopy. Mannitol. Picolines. Inpatients.

## INTRODUCTION

The objective of the preparation of the colon for colonoscopic procedures is to completely clean out the intestinal lumen so as to allow visualization and minute inspection of the organ in its entirety. This process should conform to the needs and possibilities of the patient<sup>(12)</sup>. Colonoscopists have not reached an agreement on the best method for cleaning the colon.

The ideal cleaning agent should be well tolerated by the patient, produce adequate cleaning without the formation of explosive gases<sup>(1)</sup>, as well as be easily administered and have a low cost<sup>(5)</sup>. Some preparations require the oral ingestion of great quantities (between 2 to 4 L) in a short time, which is the case with hyperosmotic electrolytic solutions (phospho-soda),

isosmotic solutions (Golytely, Klean-prep), and a polyethylene glycol (PEG) solution<sup>(2, 12)</sup>.

Mannitol is an osmotic laxative, derivative of mannose that when administered orally in a hypertonic solution (10% to 20%) is not absorbed by the gastrointestinal tract<sup>(10)</sup>. It has a sweet taste to it and a half a litre to 1 litre must be ingested in 1 hour. Mannitol and PEG are the most common to be used and are equally effective and safe to clean the colon. However, 5%-15% of the patients experience difficulty in ingesting the volume needed, resulting in inadequate preparation<sup>(6)</sup>. Some authors have also expressed their concern due the possible increase in fermentation after the oral ingestion of the mannitol, which could be responsible for the production of mixtures of potentially explosive gases<sup>(8, 9)</sup>.

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Sodium picosulfate is a cathartic stimulant that needs activation by colonic bacteria<sup>(4, 7)</sup> and acts mainly in the left colon. Magnesium citrate is an osmotic purgative and cleans the proximal colon<sup>(15)</sup>.

The efficacy of the colon preparation with sodium picosulfate is well documented and has good results in 85% of the patients. Some authors recommend<sup>(6, 10)</sup> a dietetic restriction to help in the preparation.

Failures in adequate preparation of the colon for the colonoscopy may result in not being able to detect the pathological lesions, cancelling, or interrupting the procedure. The cost of the inadequate preparation of the colon both for the health system and for the patient's satisfaction is substantial<sup>(6)</sup>. For a hospitalized patient, this can bring an increase in the hospital stay and delays in diagnoses.

The experience of our unit is that a significant number of patients are not able to conclude the exam due to the lack of a clean colon when oral solutions with mannitol 15% was used. The cost related to this suspension along with the fact that the patients have already been sedated and their exams are not satisfactorily carried out, must also be taken into account. Considering that, we decided to compare the preparation of the colon using the routine service prescription (mannitol 20% 750 mL with 250 mL of artificial orange juice, making a solution of mannitol 15%) with sodium picosulfate since it can be ingested with a lower solution volume. The hypothesis tested was that considering both variables, tolerability and general patient's satisfaction, sodium picosulfate would be preferred by the patients when compared to mannitol, associated with an adequate cleaning of the colon.

## METHODS

The exams were carried out at the Ambulatory Surgical Floor of the "Hospital de Clínicas de Porto Alegre", RS, Brazil. One of the following colonoscopes were used: Pentax EC 380ILAO12345, Pentax EC 3800TL B012501 or Olympus CF 100L 2355833.

### Sample

The sample group was made up of patients hospitalized at "Hospital de Clínicas de Porto Alegre" when scheduled by the medical staff. All patients were included that were older than 18, capable of understanding the orientations, and accepted to participate in the study from August 2002 to August 2004. A great number of patients could not be included in the study because they were in the exclusions criterias and the great number of colonoscopy in our service is of outpatients.

Patients were excluded from the study if there was a possibility of intestinal sub-occlusion, emergency colonoscopy, patients that had received barium or ferrous sulphate in the last 7 days, and that do not accepted to participate of the study. The patients were included in the study only one time. The sample was of 80 patients divided into two groups:

- mannitol group, prepared with a 15% mannitol solution;
- sodium picosulfate group, which used a sodium picosulfate solution.

## METHOD

Both groups received the same dietary orientation. They received a no residue liquid diet 24 hours before the procedure.

The patients that were prepared with mannitol, 8 hours before the exam were given 750 mL of 20% mannitol with 250 mL of orange-flavoured juice to be consumed within 1 hour.

The patients that were prepared with sodium picosulfate received an envelope diluted in one cup of water at 8 hour intervals before the exam, a total of three doses. In both cases the patients could drink liquid ad libitum up to 3 hours before the exam. No antiemetic drug was routinely prescribed for the patients in both groups. All patients signed an informed consent. The study was approved by the Research Ethics Committee of the "Hospital de Clínicas in Porto Alegre".

The endoscopist used the scale of CHILTON et al.<sup>(2)</sup> adapted by the authors to evaluate the preparation of the colon according to the quantity of residues as shown below:

- exam interrupted or suspended due to inadequate preparation, not allowing the colon to be examined;
- poor - solid residues beyond the cecum and ascending colon;
- intermediate - large quantity of liquid residue and/or a small quantity of solid residues, limited to the cecum and ascending colon;
- good - colon partially clean with a moderate quantity of liquid residue that can be easily cleaned by aspiration;
- excellent - clean colon, with very little liquid residue.

The evaluation of the patient concerning the solution ingested was done by means of a Visual Analog Scale of 100 mm where zero meant not feeling any discomfort of the symptom in question and 100 being the worst possible for the symptom. The following aspects were evaluated: perception of the cleanliness of the colon, nausea, vomiting, abdominal pain and distension, duration of the medical exam, and patient acceptance.

### Randomization process

Forty envelopes with the word mannitol and 40 envelopes with the word sodium picosulfate were sealed. They were shuffled and the patient was asked to pick one. The unit nurse responsible for the patient was oriented as to the type of preparation and means of administration. Three bags of sodium picosulfate were provided by the interviewer for the nurse responsible for the patient.

The endoscopist was unaware of which preparation the patient had been submitted. See Figure 1.

### Collecting the data

The cleanliness of the colon was recorded by the endoscopist based on Chilton's scale. He also recorded the presence of foam and exam duration.

On the day of the exam, the patient answered a structured questionnaire about the difficulties presented during the preparation. The self-assessment questionnaire was given and the researcher simply provided it and oriented the patient. This questionnaire was given by the different nurses in the recovery room of the ambulatory surgical floor, who were instructed by one of the authors (SM).

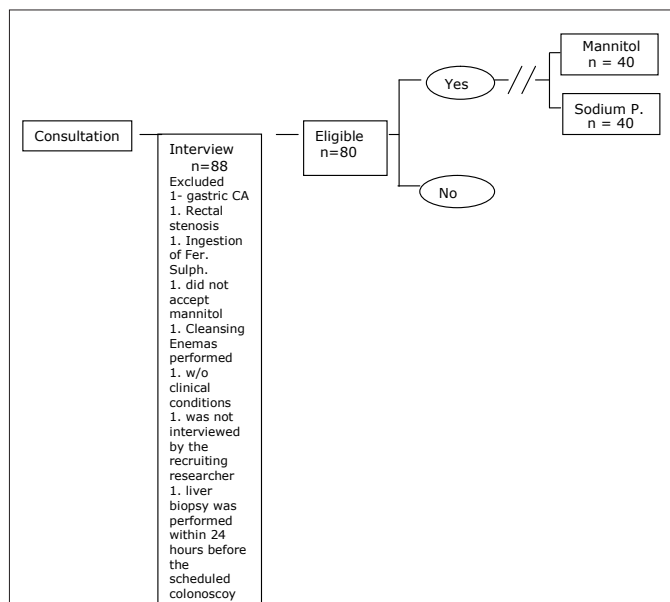


FIGURE 1. Flow of the randomization process

### Statistical analysis

Chi-square tests were carried out using the SPSS 10.0 version program in order to compare proportions along with the Mann-Whitney tests for independent samples.

### Sample size

Based on the results of a pilot study made in our service, where a group of 20 patients were prepared with mannitol, 20% (n = 4) of the examinations were interrupted because the poor preparation. It was estimated that a difference absolute of 20%, in other words, 0.01% of interruption in the patients who receive sodium picosulfate would be clinically relevant. Considering a power of 80% and a significant level of 5%, would be necessary 80 patients, 40 for each group.

## RESULTS

A total of 80 patients were included in the study. Forty patients received mannitol 15% and 40 received sodium picosulfate. Demographic data is shown in Table 1. Eight patients were excluded from the study: one diagnosed with gastric carcinoma, one with stenosis at 10 cm of the anal verge, one had used ferrous sulphate, one did not accept taking mannitol, one the nursing team carried out cleansing enemas because they saw that the colon had residues, one was without clinical conditions, one was not interviewed, and one received instructions of bed rest from the assistant doctor.

The colonoscopist's assessment of the colon's cleanliness according to Chilton's scale comparing both groups is shown in Table 2.

Of the interrupted exams whose solution was with sodium picosulfate, one patient was constipated for over 5 days and one presented solid feces at the beginning of the exam. The

TABLE 1. Demographic data of the patients

	Mannitol		Sodium picosulfate		Total
	Men	Women	Men	Women	
n	23	17	21	19	80
Average age/SD	62.38 ± 16.19		60.6 ± 16.6		

SD = standard deviation

TABLE 2. Assessment of the colonoscopist for the preparation of the colon

Result	Group		
	Mannitol	Sodium picosulfate	Total
Interrupted	6 15%	2 5.0%	8 10%
Poor	2 5.0%	2 5.0%	4 5.0%
Intermediate	6 15%	5 12.5%	11 13.8%
Good	11 27.5%	19 47.5%	30 37.5%
Excellent	15 37.5%	12 30%	27 33.8%
Total	40 100%	40 100%	80 100%

Test  $\chi^2$  P = 0.336

patients of the mannitol group whose exam was interrupted, one vomited the mannitol and two presented solid feces at the beginning of the exam, and one of them was a 92-year-old severely constipated patient.

The cecum was not reached in three patients: one patient of the mannitol group whose exam was limited to the left colon by stenosed neoplasia presented an assessment of **excellent** cleanliness by the colonoscopist. Two patients of the sodium picosulfate group presented partial intestinal obstruction due to probable malign neoplasia, resulting in one assessment of **poor** and one with **good** for the level of colon preparation.

As for the exams carried out completely, the presence of foam was similar for both the groups as shows Table 3.

The average duration for carrying out the exam was 38.44 minutes for the mannitol group and 35.59 minutes for the sodium picosulfate group. One patient of the mannitol group underwent a left hemicolectomy (10 minute exam) and one from the sodium picosulfate group had had a subtotal colectomy with ileorectal anastomosis (5 minute exam) (P = 0.56 Mann-Whitney U Test).

The quantification of the nausea symptom was 3 to 4 for 17.5% of the mannitol group and 7.5% of the sodium picosulfate group.

TABLE 3. Presence of foam

	Group		
	Mannitol	Sodium picosulfate	Total
Yes	10 28.4%	10 26.3%	20 27.4%
No	24 70.58%	28 73.7%	53 72.6%
Total	34 100%	38 100%	73 100%

Test  $\chi^2$  P = 0.829

The ratings of 9 and 10 were 2.5% for the mannitol group and 5% for the sodium picosulfate group ( $P = 0.16$  Mann-Whitney U Test). One of the patients from the sodium picosulfate group already came to the hospital with nausea (rate 3).

When assessing vomiting, the distribution was similar between the two groups ( $P = 0.45$ ).

The abdominal distension was more frequently referred by the patients in the mannitol group (Table 4).

**TABLE 4.** Assessment of the patients for abdominal distension (Visual Analogue Scale - VAS)

Rate	Mannitol	Sodium picosulfate	Total
	n %	n %	
0	22 55%	33 82.5%	55
1-2	4 10%	1 2.5%	5
3-4	1 2.5%	4 10%	5
5-6	1 2.5%	2 5.0%	3
7-8	8 20%	0	8
9-10	4 10%	0	4
Total	40 100%	40 100%	80

Mann-Whitney test  $P=0.003$

As for abdominal pain, the distribution was also very similar between the groups. The percentages that did not present pain were 65% of the mannitol group and 67.5% of the sodium picosulfate group. Both of the groups presented 25% of the ratings of 1 to 6. The ratings of 7 to 10 were 15% of the mannitol group and 25% for the sodium picosulfate group ( $P = 0.727$  Mann-Whitney U Test).

When asked if they would do the same preparation if they had to repeat the exam, 80% answered yes for the mannitol group and 92.5% for the sodium picosulfate group (Test  $\chi^2 P = 0.105$ ).

Ten patients had already undergone a colonoscopy before and when they compared it with the preparation they underwent this time, the result was the following: six from the sodium picosulfate thought that the current preparation was better than the previous one (mannitol and enemas) and one from the mannitol group thought that it was better than the enemas. Two patients (one from the mannitol group and one from the sodium picosulfate group) thought that the preparation was worse than the other one (mannitol and enemas). No one had undergone a sodium picosulfate preparation before. One patient thought that the preparation was the same as the other one (enemas).

## DISCUSSION

It is our observation at "Hospital de Clínicas" in Porto Alegre that the cancelling and interruption of the colonoscopies of hospitalized patients occurs with greater frequency than ambulatory patients. In a non-controlled assessment with 20

hospitalized patients, we noticed that 20% of the exams were suspended, interrupted, or cancelled due to a poorly prepared colon. Two factors were identified as cause for inadequate preparation: 1. the volume of mannitol to be taken, 750 mL within a short space of time along with its excessively sweet taste caused nausea and vomiting, making it difficult for the patient to accept; 2. the lack of persistence on the part of the patient to take the liquid within the time period allotted especially elderly patients that were not accompanied by family members. NESS et al.<sup>(12)</sup> observed in their study that one of the factors considered predictive of poor colon preparation was the hospitalized patient.

Colon cleansing for colonoscopy exams and in preparation for surgeries has been widely studied comparing both mannitol as well as sodium picosulfate with other medications<sup>(1, 2, 5, 6, 10, 12, 13, 15)</sup>. With the development of new medications, mannitol has currently been used less. It is still a preparation used in various centres in Brazil due to its low cost and effectiveness. It is a practice that has proven to be effective in our hospital for approximately 15 years where mannitol took the place of cleansing enemas for the preparation of the colon. It has also shown to be safe since the number of colonoscopies done is around 1200 per year, being that 300 of those are polypectomies without any complications resulting from explosive gases due to precautions taken such as continuous aspiration-insufflations with ambient air and because the exam is only done when the colon is clean. Due to the volume needed to cleanse the colon, an average of 750 mL, this makes it more difficult for the patient to accept this solution.

We carried out the evaluation of the colon preparation of hospitalized patients who were given 750 mL of mannitol 20% with 250 mL of juice (making a solution of mannitol 15%), coming to a total of 1 L of liquid to be ingested in 1 hour compared with sodium picosulfate in one cup of water (150 mL) with the powder every 8 hours.

What stands out in our study is the fact that there were no statistically significant difference between the two groups as to nausea and vomiting, colon cleanliness, patient acceptance, exam duration, and abdominal pain. The incidence of light to moderate nausea was greater in the mannitol group.

These negative findings most likely are not caused by a  $\beta$ -type error due to the fact that the sample calculation had been observed and the statistical tests did not show a tendency toward significance. One possibility that can be considered is that the people responsible for administering the preparation were concerned in following the prescription more carefully since they knew it was part of a research study (Hawthorne effect).

Other studies showed that patients in the sodium picosulfate group presented less nausea when compared with phospho-soda<sup>(2, 11)</sup> did not differ in others or were even inferior<sup>(16)</sup>.

HABR-GAMA et al.<sup>(6)</sup> compared the use of mannitol 750 mL with phospho-soda (two doses of 90 mL) where similar results were seen with an incidence of 18% of vomiting in both of the groups. In their study the patients of the mannitol group received metoclopramide intramuscularly, a fact that could have alleviated the symptom. However the incidence of vomiting in this series was still high.

In our study, the cleanliness of the colon evaluated by the colonoscopist showed to be statistically similar in both preparations ( $P = 0.336$ ). Both the solutions obtained excellent or good results in 65% of the mannitol group and 77.5% in the sodium picosulfate group. The same was seen in other researches where the sodium picosulfate was compared with phospho-soda<sup>(11, 14)</sup>.

Abdominal distension is another collateral effect generally observed in the different preparations and mentioned by the patients. In our study, the abdominal distension showed to be greater in the mannitol group. The score of zero (no distension) was of 55% in the patients of the mannitol group and 82.5% in the sodium picosulfate group. On the other hand, high distension scores (from 7 to 10) were 30% in the mannitol group and 0% in the sodium picosulfate group.

SCHIMIDT et al.<sup>(14)</sup> found that patients who received sodium picosulfate presented less abdominal pain ( $P = 0.0005$ ) when compared with sodium phosphate. This fact was not confirmed by DAKKAK et al.<sup>(3)</sup> who compared the use of polyethyl glycol with sodium picosulfate and did not notice a significant difference for abdominal pain between the groups. The same occurred with YOSHIOKA et al.<sup>(16)</sup> who did not observe a statistical significance when he compared the colon preparation for colonoscopy or surgery with sodium picosulfate and phospho-soda. Our results do not show a difference as to the pain variable with both preparations.

Patient acceptance for the ingested solution was similar in both groups with 80% for the mannitol group and 92.5% for the sodium picosulfate group. Both of the groups answered

that they would repeat the same preparation for the exam if they had to do it over again. MACLEOD et al.<sup>(11)</sup> found that the acceptance of the sodium picosulfate was better due to the ease of ingestions, better taste, and that it caused less nausea when compared with phospho-soda, though the results were not statistically significant.

## CONCLUSIONS

The quality of the colon preparation, foam formation, exam duration, and the collateral effects (nauseas, vomiting, and abdominal pain) were similar in both kinds of preparations. Abdominal distension was more frequent in the mannitol group. Both methods of preparation were well accepted by the hospitalized patients.

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**RESUMO – Racional** - A limpeza do cólon para o exame de colonoscopia deve ser completa de modo a permitir a visualização e inspeção do lúmen intestinal. O agente de limpeza ideal deveria ser de fácil administração, com baixo custo e com o mínimo de efeitos colaterais. O picosulfato de sódio juntamente com o citrato de magnésio é um estimulante catártico e o manitol é um laxativo osmótico, ambos geralmente utilizados para este propósito. **Objetivos** - Verificar a limpeza do cólon comparando o uso de manitol e picosulfato de sódio assim como avaliar o nível de satisfação do paciente, presença de espuma, dor e distensão abdominal em pacientes hospitalizados submetidos a colonoscopia. **Métodos** - Estudo prospectivo, randomizado, simples-cego com 80 pacientes que comparou dois grupos: manitol (40) e picosulfato de sódio (40). Ambos os grupos receberam a mesma orientação dietética. O estudo foi aprovado pelo Comitê de Ética do hospital e pelo Comitê de Pesquisa. O endoscopista foi cego para o tipo de preparo. Desfechos avaliados: nível de limpeza do cólon, satisfação do paciente, presença de espuma, dor e distensão abdominal e tempo de duração do exame. Os dados foram analisados pelas médias de testes qui-quadrado para proporções e Mann-Whitney para amostras independentes. **Resultados** - Não houve diferença significativa entre os grupos em relação ao nível de limpeza do cólon, satisfação do paciente, presença de espuma, dor abdominal e tempo de exame. Quinze por cento dos exames do grupo manitol foram interrompidos enquanto que grupo picosulfato de sódio foi de 5%. A presença de espuma foi similar em ambos os grupos. A média de duração do exame foi de 28h 44min para o grupo manitol e 35h 59min para o grupo picosulfato de sódio. A distensão abdominal foi mais freqüente no grupo manitol. Se eles tivessem que repetir o exame, a resposta foi de 80% disse sim do grupo manitol e 92,5% do grupo picosulfato de sódio. **Conclusões** - A qualidade do preparo de cólon, formação de espuma, tempo de exame, efeitos colaterais (náuseas, vômitos e dor abdominal) foi similar em ambos os tipos de preparo. A distensão abdominal foi maior no grupo manitol. Ambos os métodos de preparo foram bem aceitos pelos pacientes hospitalizados.

**DESCRITORES** – Colonoscopia. Manitol. Picolinas. Pacientes internados.

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