Comparison between two different colon cleansing methods prior to colonoscopy

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Abstract

Introduction and objectives: A good bowel cleansing is essential, since it is directly related to the reliability of colon investigation with colonoscopy. In order to achieve optimal colon cleansing different methods are used at different endoscopy units with varying outcomes. The purpose of this prospective clinical study is to determine if Polyethylene Glycol Plus Ascorbic Acid (Movprep) is superior in regards to colon cleansing efficacy and patient acceptability in patients undergoing colonoscopy, compared to Sodium Picosulfate Plus Magnesium citrate solution (Picoprep), both given in split doses.

Method: A single center observer blinded study aimed to assess the effectiveness and patient acceptability of two purgatives in patients undergoing colonoscopy. A total of 46 patients, with equal distribution between genders, referred from either a primary care physician or hospital clinicians in Orebro region, with clinical indication for colonoscopy procedure were scheduled to attend our endoscopy unit at Örebro university hospital. Patients were randomly divided into two groups, one group received Movprep, whereas the second group obtained Picoprep as a bowel preparation before colonoscopy. Cleansing efficacy was scored using validated Ottawa preparation Scale (OPS), considering Ottawa score less than 6 points as satisfactory. Compliance and patient acceptability was documented using a questionnaire.

Results: More patients in the Picoprep group complied with the minimum fluid intake of 3 l or more compared to the Movprep group (62% compared to 30 %.). In regard to patient acceptability, a statistically significant difference (P<0,001) to the benefit of Picoprep was found. Only 10% of patients in this group scored their taste experience as bad/repulsive, in contrast 75% of Movprep group stated that they were able to ingest their preparation with great difficulties, scoring bad /repulsive more frequently. Efficacy measured using Ottawa Scores in each colon segment showed that the proportion of patients receiving less than 6 points were 81% in Picoprep and 85% in Movprep group representing equal colon cleansing achievement (P= 0,731).

The overall cleansing adequacy showed no major differences between the groups, with a total median score of 3 in Picoprep group and 1 in Movprep group. However, in segment level particularly left colon, patients given Movprep show a tendency towards better cleansing.

Conclusion: The results from this study found no significant difference between the two laxatives in regard to colon cleansing efficiency, however, a tendency towards a better cleansing was observed in left colon in patients who received Movprep. Tolerability and compliance was better in Picoprep group.

Key words: Peg based solutions, Sodium Picosulfate, colon cleansing, colonoscopy.
Abbreviations:
OPS: Ottawa preparation Scale
PEG: Polyethylene glycol
ASC: Ascorbic Acid
SMPC: Sodium Picosulfate plus Magnesium Citrate

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1. Introduction

1.2 Colonoscopy

Colorectal cancer is not only the third common cancer type in both genders in Sweden. It is also one of the most common malignant tumors diagnosed in developed countries and one of the key causes of cancer related mortality worldwide with nearly over two million new incidents and a half million associated deaths every year [1-4]. According to European Society of Gastrointestinal Endoscopy, colonoscopy is an important and preferred method of choice for colon investigation to deal with the increasing burden of colorectal cancer and other lower gastrointestinal abnormalities in elderly and other high risk patients with underlining family history of colorectal cancer [5,6].

It is well recognized that most colorectal carcinomas arise primarily from adenoma, giving colonoscopy a major therapeutic role to differentiate and remove suspected premalignant lesions, which in some cases are difficult to distinguish using radiologic methods such as CT-Colonography [7].

Colonoscopy procedure is carried out by passing high sensitive fiber optic endoscopic camera on a flexible tube through the rectum to the cecum in order to visualize the entire colon mucosa and if possible even intubate terminal ileum. This along with biopsy obtaining possibilities and removal of premalignant lesions, which can be sent for histological assessment if further investigation is needed, provides a unique opportunity that makes colorectal cancers more or less preventable [8,9].

In other words, this relatively simple procedure has transformed the management and diagnosis of lower gastrointestinal disorders and has become standard diagnostic procedure available at all major hospitals in Sweden [10].

In Örebro county, around 800 colonoscopy procedures are performed each year in Karlskoga, 500 in Lindesbergs Hospital and over 1800 colonoscopies at the endoscopy unit in Örebro University Hospital [personal communication].

This procedure is considered to be safe apart from seldom serious adverse events such as perforation, possible adverse reaction to sedative used during the process and bleeding from the site where biopsy has been taken or polyp being removed [11].

Unlike gastroscopy, colonoscopy procedure requires extensive and well planned bowel preparation with laxatives in conjunction with clear liquid diet before colonoscopy in order to achieve acceptable images of colon mucosa, ensuring that no significant pathological abnormalities have remained undetected [12].
For these reasons a typical routine procedure should be effective and reliable with a minimum discomfort for the patients, however many of the patients undergoing colonoscopy report the procedure as unpleasant and preparation as the most difficult part of the whole process [13]. This may influence patients’ acceptance to prescribed laxative resulting presence of fecal material in colon during the observation that may mask potential mucosal abnormalities as it may lengthen the examination time while suctioning leftovers in colon or even lead to termination of the whole process [14,15].

As much as 25-30 percent of colonoscopy procedures are to some extent suboptimal and does not meet the standard criteria for accurate diagnosis. This is primarily because of insufficient preparation but also many other factors related to patient comfortability, the experience of the Endoscopist, and whether sedatives were offered or not [16-18].

As expected, the diagnostic accuracy of colonoscopy is mainly related to the level of colon cleansing and any insufficient cleansing results in poorer outcome with failure to detect as much as 6 percent of adenoma larger than 1 cm [19-21].

This highlights the need of reliable laxative agents that does not only evacuate colon from all material without causing any serious side effects and electrolyte disturbances, but also tolerated regardless of age and comorbidity.

1.3 Elderly

Despite the fact of the steady increase of our aging population and the accompanying higher risk for lower gastrointestinal abnormalities that requires frequent colonoscopy assessment, our elderly is over-represented in regard to incomplete colonoscopy procedures, mostly because current laxatives seems to be less effective in this patient group [22,23].

It is not fully known why insufficient colon cleansing is more common in older patients, but data from previous studies suggest that elderly generally challenge the procedure due to bad adherence to the obtained laxative in conjunction with difficulties in maintaining cleansing timetable prior to colonoscopy [24].

Presence of one or more medical conditions that may need complex medical management and difficulties in diet modifications is believed to contribute to the poor diagnostic outcome when accurate diagnostic is mostly needed because of more frequent lower gastrointestinal disorders in elderly [25].
With increasing age, the cardiovascular system loses its ability to comply with changes in circulation, thus intake of high volume polyethylene glycol which is one of the most commonly used laxatives tends to worsen fluid accumulation since it is believed to induce increase in blood volume [26].

It is worth to note that intravascular volume excess is extremely rare. It may occur when intake is much higher volume than needed in normal colon cleansing for diagnostic assessment. However, minimum change of plasma volume in elderly combined with minimum electrolyte disturbances, especially potassium, in patients treated with diuretics or potassium manipulating agents may cause fatal problems [27].

Diabetes is a common comorbidity among elderly patients that needs careful planning of meal and medication time during the bowel preparation as the blood glucose level needs to be watched closely in order to avoid a possible hypoglycemic reaction. Diabetes is also considered in many studies as a probability indicator that anticipates inadequate bowel preparation [28]. Evidence suggest that diabetes patients show poor colon cleansing as they respond weakly to available laxatives, specially polyethylene glycol based solutions, with nearly 15 percent difference in cleansing quality when compared to healthy patients [29].

Another major age related problem in elderly is gradual decrease of renal elimination capacity although this greatly varies between individuals, and lower glomeruli filtration rate that induces a great risk for possible electrolyte disturbances, especially when phosphate rich laxatives are used which is contraindicated according to ESGE guidelines [10,30]. Meanwhile elderly have reduced kidney function with minimum ability to compensate the loss during colon cleansing, many are experiencing volume related obstacles to maintain sufficient liquid intake risking to end up in fatal dehydration and severe electrolyte shifting.

1.4 PEG-based solutions

As mentioned polyethylene glycol based solutions are considered to be safe and effective compared to other laxatives such as sodium phosphate, they also constitute the only recommended laxative in patients with severe comorbidities such as renal and heart failure. This isosmotic laxative is an electrolyte balanced solution that traps fluid in the lumen causing no potential electrolyte shifting across the gut, which makes it suitable even for patients with advanced diseases [31,32].

Despite the superiority of this laxative in safety matters, they may cause severe hypokalemic condition in patients with certain comorbidity leading to critical and life threatening situations that requires urgent care if serum electrolytes are not monitored carefully during the process [33].
As also mentioned, the isotonic PEG based solution require high volume intake, namely 4 l has to be ingested for full efficacy, as it has unpleasant taste which may lead to compliance issues and difficulties to manage the intake of required doses, resulting in unacceptable colon cleansing [34]. A lot of contribution has been made to reduce volume and taste related problems in terms of flavoring or laxative ingestion in split doses, which is believed to increase both compliance and number of successful procedures [35,36]. Picoprep is a low volume laxative containing Sodium picosulfate which is metabolized by intestinal flora into active substance and magnesium citrate yielding a dual effect by inducing peristaltic movement and an osmotic action respectively [37]. The patients still need to drink at least 3 liters of clear fluid during the preparation process, but the laxative solution is only a minor part of this (200mlx2).

A small study conducted earlier by the endoscopy unit in Örebro, has shown that Picoprep is better tolerated among patients when compared to other high volume laxatives (Laxabon®, Globance® Lavage), but major other studies have questioned this conclusion. However, volume related issues continue to be the main reason for insufficient cleansing [38-40]. To deal with this issue, a new beg based laxative(Movprep) has been launched which is similar to Laxabon, but contains a large dose of ascorbic acid, which is absorbed in low dose in the small intestine via active mechanism, but in large doses it saturates the system causing an osmotic action [41].

As a result, to this, mega doses of vitamin C combined with traditionally used PEG, the volume needed for effective colon cleansing can be reduced to 2 l without affecting its effectiveness. According to previous studies it is also considered to be more acceptable among patients [42,43]. This type of laxative is not the standard lavage in Örebro endoscopy unit, but it is widely used in Denmark and this study will examine if this could address compliance related issues given in split doses for both morning and afternoon scheduled procedures [Personal communication].

2. Objectives

A good bowel cleansing is essential for a colon investigation with colonoscopy but different methods are used at different endoscopy units in order to achieve optimal colon cleansing. The main goal of this prospective clinical study is to improve colon cleansing quality by comparing the efficiency and patient acceptability of Movprep® (Peg plus Asc) with Picoprep® (Sodium Picosulfate+Mg citrate), both given in split doses, in patients undergoing colonoscopy.
Successful investigation depends not only on the effectiveness of laxatives taken, but also patient compliance and the tolerability, therefore evaluation of which of the laxative methods is best tolerated by the patients will be performed.

If it turns out that Movprep is more effective and well tolerated by the patients than now used Picoprep, the endoscopy unit in Örebro will conduct further and larger clinical study to verify the result of this study.

2.1 Hypothesis
The main working theory of this study propose that patients who obtained Movprep, PEG based solution combined with ascorbic acid, show more effective colon cleansing compared to low volume Picoprep, Sodium picosulfate and Magnesium Citrate solution.
Similarly, we assume that patients given Movprep, show significantly better compliance if compared to patients prescribed Picoprep prior to colonoscopy.

2.2 Null hypothesis
We suggest that both above mentioned laxatives are similar and there are no measurable differences in terms of colon cleansing effectiveness and patient acceptability.

3 Method and Materials
3.1 Randomization and blinding
A prospective clinical study designed to measure the efficacy and patient compliance of two laxative methods, estimated to take place in January- May 2016 at the endoscopy unit in Orebro university hospital.
100 patients were planned to be included, 50 in each treatment arm, giving an 80% power to detect a 20% difference between groups.
Patients of both genders referred from either a primary care physician or hospital clinicians in Örebro with suspected lower gastrointestinal abnormalities requiring evaluation or diagnostic consideration of colon mucosa were enrolled to participate in the study.
Patients who are hospitalized, underage, or with suspected risk for allergic reaction to the examining substances or having severe cardiovascular, hepatic and lower gastrointestinal abnormalities were not qualified to take part in the study.
Likewise, patients with severe renal failure, defined as a creatinine above or equal to 170 µmol/L were excluded from participation in the study. The observers were blinded to avoid possible expectancy bias that may influence the outcome of the investigation.
In other words, the Endoscopist does not know and were urged to avoid discussing anything that might lead to disclose or reveal which laxative were used by the subject as a colon preparation during or prior to colonoscopy procedure.

In contrast, the participants obtained full information of type of laxatives administered and were requested to be vigilant while cleansing colon, noting the amount of liquid taken, taste experience and following the given instructions as much as possible. Furthermore, participants were requested not to reveal their preparation method to the Colonoscopist.

Flipping a coin, or so called heads or tails facilitated process, was carried out by the expeditor of our endoscopy unit whilst sending prescriptions, to allocate patients randomly into one of the treatment arms.

The first group was prescribed to 2 l Movprep, PEG- plus ascorbic acid oral solution, and was also recommended to drink one liter of extra fluid consisting of clear liquid. The second group was prescribed low volume Picoprep, containing a combination of Sodium picosulfate and magnesium citrate and extra fluid intake of 3 l were recommended.

Unlike the standard preparation method which is to prescribe split doses only for afternoon scheduled patients, we gave both drugs in split doses to all our participants, regardless of whether they were scheduled for morning or afternoon examination.

Morning scheduled participants were encouraged to take their first dose in the evening of the day before colonoscopy and the second dose in the early in the morning. In contrast, afternoon scheduled patients were told to take their first dose late in the evening, while taking the second dose in the morning but not later than two hours before the time of colonoscopy.

Patients also received written instructions regarding dietary recommendations, preparation, ingestion, dosing intervals and in case of any further information needed, they were encouraged to contact our team.

3.2 Tolerance and Efficacy evaluation

Two separate questionnaires were used, one for patients consisting of 7 questions assessing the tolerability and taste experience, the second for the Colonoscopist evaluating the effectiveness of the laxation.

When patients arrived for their scheduled examination appointment, they were individually inquired before the procedure by a nurse using the patient evaluation questionnaire, asking compliance related questions and the rate of completeness of their laxative.
Adherence was predefined as a consumption of a certain amount in which intake of full dose laxative and ingestion of clear liquid more than 3 liters was defined as excellent or complied. Subsequently, ingestion of less than above mentioned limit were considered to be poor or not complied.

Patient tolerability was also assessed by evaluating the frequency of gastrointestinal discomfort and reports of repulsive taste experience recorded immediately before the examination using the standard 10-point grading scale questionnaire.

Patients was also asked whether they were comfortable with information received by reporting if they were able to plan ahead or were fully aware of the coming steps during the preparation procedure. This was also measured as an excellent if patients were satisfied or poor if not.

The effectiveness of colon cleansing was measured by using the Ottawa Preparation Scale, which is a validated scoring system that indicates the effectiveness of the bowel cleansing [44]. The Endoscopists, who were blinded to the patients’ preparation method, evaluated the effectiveness of colon cleansing in three separate colon segments; ascending, transverse and descending/sigmoid colon.

Each colon segment was graded from zero to four in which zero stands for excellence in mucosal view obtained, while grade four represents presence of solid fecal remnants that cannot be cleared with washing/suctioning. An overall evaluation of colon cleansing was also made.

The Endoscopists were asked to complete the questionnaire as soon as they finish the examination by circling or ticking a suitable score for their findings. Then the scores given in each segment was summed up to calculate the whole colon cleansing, considering a total Ottawa score of 6 points or less as optimal or successful and anything greater than that amount as insufficient or failed.

All data regarding overall acceptability and cleansing effectiveness, which is our main variable to investigate in this study, were gathered from the results of the two above mentioned questionnaires (see appendix 1, 2).

### 3.3 Ethics

Since both laxatives are already used in clinical practice, an application to the regional ethics board for ethical approval will not be submitted. An information leaflet written in easy and understandable language was sent to our patients, informing of the type of research we are conducting, intervention being used and the overall main objectives of the study.

Patients were informed of the risks and advantages of participating this study, informed that all gathered personal data will be treated confidentially and in line with the data protection act 1988:
They were also informed that if they do agree to participate in this study, they do so on an entirely voluntary basis and will have the right to withdraw at any time during the process (see appendix 3). The participants were asked to sign a participation agreement, stating that they have accepted that both survey responses and investigation results will be analyzed by a medical student, and unidentified data, which cannot be traced to any patient will be presented (see appendix 3).

3.4 Statistical method
To summarize the distributions of age, gender and other basic characteristics of the study’s population simple descriptive statistics were applied and frequencies were displayed in percentages or in terms of Median and Min-Max for continuous variables. Since the patients’ groups were small and could not be assumed to be normally distributed, non-parametric statistics using Mann-Whitney U test for analyzing continuous variables were used. For categorical variables, differences between the two independent groups were examined using Chi Square test. All performed analyses were calculated using SPSS 23.0.

4. Results
As the study proceeded, ascendency was discovered for one of our laxatives, namely Picoprep was prescribed a bit more frequently than Movprep. This was mainly because of cancelation and administrative errors, and partly, due to lack of printed prescription papers for a short period of time.

Due to this randomization error, we had to launch another distribution schedule to make sure of an equal probability of given laxatives between the groups. A new distribution process of 1:2 was formed, meaning that whenever a subject receive one of the purgatives to be examined another two patients were prescribed to the second laxative regardless of age, sex and diagnosis.

Due to a somewhat slower inclusion rate than intended, and the approaching deadline for this study, we had to terminate the study before reaching intended number of patients (Fig 1).

4.1 Patient demographics
46 patients were included. Two of the forty-six enrolled patients were excluded in the study due to incomplete or unreadable patient questionnaires. Further, one subject was not included because of intake of all laxative regimen at once, instead of split doses as recommended.
An additional two patients were also excluded due to missing or incorrect scores recorded in the endoscopic assessment questionnaire. Thus, a total of 41 patients were included in the final analysis. 20 subjects received Movprep, whereas 21 patients received Picoprep (Fig 1).

Figure 1 Patients Flow

This figure shows the overview of all 46 participants who underwent colonoscopy, 5 of them were excluded due to missing data and did not contribute to the data collection. Type of the bowel preparation prescribed, administration manner, recommended dose and additional fluid intake for each treatment groups were also presented.
Demographic characteristics of the 41 patients who were included in the final analysis are presented in Table 1. The two groups were comparable and there was no significant difference with respect to age and gender.

The median age of the study’s all participants were 51 years, ranging from 23-74-year-old. Half (51, 2%) of the study’s population was female (Table1) and both genders were similarly represented within the two groups (P=0.879).

Nearly half (48.8%) of patients have undergone colon cleansing earlier and were to some extent familiar with the preparation procedure(Table1).

Table 1 Patient demographics and clinical characteristics

This table compares the baseline characteristics and other objective data collected from all patients enrolled in this study. Participants were randomized into Movprep (PEG+ASC) or Picoprep (SMPC) treatment groups, and all data are presented as n (%), Median and Min-Max.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Picoprep (SPMC)</th>
<th>Moviprep (Peg+Asc)</th>
<th>Total</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>21</td>
<td>20</td>
<td>41</td>
<td></td>
</tr>
<tr>
<td>Age, Yr. Median (Min-Max)</td>
<td>55(23-74)</td>
<td>50,5(23-68)</td>
<td>51</td>
<td>0.473^^</td>
</tr>
<tr>
<td>Gender</td>
<td>11(52,4)</td>
<td>10(47,6)</td>
<td>41(51,2)</td>
<td>0.879^</td>
</tr>
<tr>
<td>Previous colon cleansing? Y (%)</td>
<td>57,1%</td>
<td>40%</td>
<td>48,8%</td>
<td>0.272^</td>
</tr>
<tr>
<td>Examination scheduled more than one week(%)</td>
<td>90,5</td>
<td>90</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

P- value was calculated using Mann-Whitney U test (^^) and Chi Square (\^) for continuous and categorical variables respectively.
4.2 Compliance and tolerance

Since compliance was measured as the amount of fluid consumed in liters, this variable was grouped in the analysis into complied and not complied, considering intake of 3 l or more as a compliant (Table 2). All patients (100%), in both study groups, have stated that they were able to ingest the amount of laxative solution prescribed in split doses.

13 patients (61.9%) in the Picoprep group had ingested the minimum (>3 l) clear fluid intake required, while 8 patients (38.1%) have failed to do so. In the Moviprep group only 6 patients (30%) reported that they had consumed the entire clear liquid (> 3 l) needed to complete the preparation, while 14 patients (70%) did not complete their treatment (Table 2).

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Picoprep(SPMC)</th>
<th>Moviprep(Peg+Asc)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>21</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>Total fluid intake &gt;3 l (n %)</td>
<td>13(61,9)</td>
<td>6(30)</td>
<td>0,030*^^</td>
</tr>
<tr>
<td>Compliance: n(complied %) n,(not complied %)</td>
<td>13(61,9), 8(38,1)</td>
<td>6(30), 14(70)</td>
<td>0,041^</td>
</tr>
<tr>
<td>Patient instructions n,(excellent %) n,(good%) n,(difficult%)</td>
<td>17(81), 4(19)</td>
<td>15(75), 5(25)</td>
<td>0,555^^</td>
</tr>
<tr>
<td>Taste: n(very good), n(good), n(bad), n(repulsive)</td>
<td>17(81), 2(9,5), (0)</td>
<td>3(15), 2(10), 9(45), 6(30)</td>
<td>&lt;0,001*^^</td>
</tr>
<tr>
<td>Was it difficulty or easy to take preparation? (n,% very easy), (n, %easy) (n,% difficult) , (n,% very difficult%)</td>
<td>18(85,7), 2(9,5), (0), 1(4,8)</td>
<td>11(55%), 2(10), 5(25), 2(10)</td>
<td>0,048* ^</td>
</tr>
</tbody>
</table>

^^Mann Whitney U test
^Chi Square.
The majority of patients (95%) in the Picoprep group reported that they found it very easy/easy to swallow their preparation (Table 2), whereas (65 %) of patients in the Movprep group found it very easy /easy to ingest their preparation(P=0.048).

In regard to the taste experience, a statistically significant difference (P<0.001) to the benefit of Picoprep has been found (Table2). Only 10% of patients in this group have scored their taste experience as bad/repulsive, in contrary 75% of Movprep group stated that they were able to ingest their preparation with great difficulties, scoring bad /repulsive more frequently (Fig 2).

Figure 2 taste experience:

This figure demonstrates the overall taste experience and the frequency of unpleasant taste reported by the two treatment groups who ingested Picoprep or Movprep as a bowel preparation. The figure also shows statistically insignificant gender differences in terms of reported taste experience.
4.3 Efficacy

To measure the efficacy Ottawa Scores in each colon segment were summed up, and a score of < 6 points was considered adequate (Table 3). The proportion of patients receiving less than 6 points were 17(81%) patients in Picoprep and 17(85%) in Movprep group. The overall cleansing adequacy show no major differences between the groups (median score 3 respective 1 as shown in Table 3) but in left colon a tendency towards better cleansing was seen for the Movprep group (P=0.098).

Tabel 3: Efficacy

This table compares the efficacy of bowel cleansing in 41 patients undergoing colonoscopy who either received Movprep (n=20) or Picoprep (n=21) as a bowel preparation, using Ottawa preparation scale. Each colon segment was graded from zero to four in which zero stands for excellence in mucosal view obtained, while grade four represents presence of solid fecal remnants. Ottawa scores in different colon segments were presented as median (range)

<table>
<thead>
<tr>
<th></th>
<th>Picoprep(SPMC)</th>
<th>Movprep (Peg plus Asc)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Left Colon</td>
<td>N=21</td>
<td>N=20</td>
<td>0.098^^</td>
</tr>
<tr>
<td>Colon Transversum</td>
<td>1(0-3)</td>
<td>0(0-3)</td>
<td>0.291^^</td>
</tr>
<tr>
<td>Right Colon</td>
<td>1(0-4)</td>
<td>1(0-3)</td>
<td>0.636^^</td>
</tr>
<tr>
<td>Overall Fluid in colon</td>
<td>0(0-2)</td>
<td>0(0-2)</td>
<td>0.452^^</td>
</tr>
<tr>
<td>Total Ottawa scores</td>
<td>3(0-13)</td>
<td>1(0-11)</td>
<td>0.168^^</td>
</tr>
<tr>
<td>Adequate cleansing?</td>
<td>(81)(19)</td>
<td>(85)(15)</td>
<td>0.731 ^</td>
</tr>
<tr>
<td>Ottawa score &lt;6</td>
<td>17(81)</td>
<td>17(85)</td>
<td></td>
</tr>
</tbody>
</table>

^^Mann Whitney
^Chi-Square
5. Discussion

Although colonoscopy is widely recognized as effective procedure to examine lower gastrointestinal abnormalities, suboptimal colon cleansing remains a major clinical problem that challenges the diagnostic reliability of this examination method.

Successful procedures are mainly related to the extent in which patients act in accordance with instructions, but many patients (30%) fail to do so because of large volume intake requirements and unpleasant taste experience [45].

This has negative impact on patient acceptance of colon cleansing preparations leading to inadequate colon cleansing, termination and rescheduling procedures that may not only increase procedure related risks but also contribute to economic consequences [46].

Many clinical studies have been performed comparing different types of laxatives in conjunction with different adjuvants in order to address compliance related matters, in this study we have examined if Movprep (Peg plus ascorbic acid) compares positively with Picoprep (Sodium Picosulfate).

Based on the findings in this study, the two groups in the study have shown high rates of successful colonoscopy procedures, which indicates that the two laxative methods were largely comparable and there were no significant differences in terms of cleansing efficacy.

Recalling our proposed alternative hypothesis, the observed results in this study does not support the proposal of significant difference in cleansing quality between the two laxative methods, since no difference in Ottawa scores has been detected.

Similar observations have been made by recently published clinical trials, that have examined Peg based solution in comparison to Sodium Picosulfate with an outcome of no significant differences in terms of cleansing quality [47,48].

Although this study has failed to prove the superiority of Movprep, a tendency toward a better cleansing was found in left colon when segments were assessed separately. These findings are to some extent in line with one previous study that found not only overall better cleansing in patients who used Movprep , (compared to Picoprep) but a better cleansing in proximal colon instead of distal colon as stated in our study [49].

Adequate cleansing in proximal colon is very important since pathological lesions occur more frequently in proximal than in distal colon, however the partial inconsistency with prior
studies could be explained by the low number of patients which probably reduce the chances of detecting a real difference [50].

As mentioned, we intended to include 100 patients in total giving a power of 80% detecting a 20% difference, but since the inclusion rate was slower than expected and this study had a clear deadline less than half of the intended patients were included. Therefore, this study may lack statistical power and our results may not reflect the real difference between the groups, this means that one should be careful about drawing conclusions.

Despite an equal proportion of patients in both groups have managed intake of their laxatives, many patients reported that they found intake of Movprep more difficult and did not complete the succeeding additional fluid intake required.

However, this conclusion is questioned by a prior study that found no difference in the proportion of patients who managed to complete their preparation. This could be explained by the fact that the fluid intake requirements are completely different among the treatment groups and the limit of what is considered satisfactory fluid intake was poorly defined [48].

Another procedural concern is the survey questions used to measure the overall fluid intake, which were designed in a manner that make them prone to potential misunderstanding and the answers received may not accurately reflect the total fluid intake.

Even though volume related problems are mainly to blame for the poor patient adherence to the cleansing preparations, there are many other factors that affect patients’ acceptability such as taste and previous colon cleansing experiences.

This study’s results have shown that many patients who ingested Picoprep found it less problematic reporting that they have managed to swallow the solution with easiness, as evidenced by other previous studies [47].

The reason for these findings are probably due to the small proportion of sole laxative ingestion required for adequate cleansing and the administration manner in which both groups recommended split doses that may have increased patients’ acceptance and the likelihood of achieving adequate colon cleansing.

Unpleasant taste experiences have been reported more frequently by patients given Movprep, as many patients indicate that they found it very distressful and would not do it unless it was necessary, scoring their experience as bad or repulsive.
In regard to the gender, there were no overall differences in terms of taste experience between the groups but female patients appear to score a higher score in both groups, reporting repulsive taste experience more frequently (see fig 2).

According to the results of this study, a statistically significant differences in regard to the taste experience between the two groups have been found to the benefit of Picoprep and these patients’s showed a higher rate of completeness and better compliance.

6. Conclusion

Since the quality of colon cleansing determines the diagnostic and therapeutic outcome of any colonoscopy procedure, an effective colon cleansing is needed. This study has compared Movprep to Picoprep given in split doses.

The results from this study found no significant difference between the two laxatives in regard to colon cleansing quality, however, a tendency towards a better cleansing in left colon was observed in patients who received Movprep.

Concerning acceptability many patients found Movprep more distressing and less pleasant compared to Picoprep which seems to be better tolerated by many patients.

Currently, Picoprep is prescribed for most patients at the endoscopy unit at Örebro University Hospital, and this study supports this strategy. Before changing clinical practice further, larger, investigations are needed to truly find the optimal cleansing method prior to colonoscopy.

7. Acknowledgement

Completing this research paper was challenging but I was fortunate to have a supervisor who gave a guidance to proceed, pushed me to do better and proposed ideas that have improved the contents of this manuscript.

I hereby express my deepest gratitude to my supervisor, MD, PhD Nils-Nyhlin for the amazing support over past six months, it has been a period of intense learning and the completion of this learning process could not have been possible without his valuable suggestions.

I would also like to give my thanks to all staff working at endoscopic unit in Örebro for their contribution to this study.
8. References


37. Läkemedelsverket. Picoprep, pulver till oral lösning.


40. Anne-Kristin Gustafsson, reg nurse, Jeanette Fagrell, reg nurse, Ulla Johansson, enrolled nurse and Nils Nyhlin, MD, PhD Endoscopy Unit, Dept of Medicine, Örebro University Hospital, Sweden. What is the best bowel-cleansing method for colonoscopy?
41. Läkemedelsverket. Movprep pulver till oral lösning.


Appendix

Appendix 3

Patientinformation

Hej,

Du har i detta brev fått en tid för koloskopi (kameraundersökning av tjocktarmen) och ett recept på laxeringsmedel samt instruktioner hur du ska förbereda dig inför undersökningen. En bra rengjord tarm är viktigt för att man ska kunna påvisa eller utesluta förändringar och sjukdomstillstånd i tjocktarmen. Det finns idag flera olika typer av laxermedel på marknaden och de är alla vetenskapligt utvärderade och godkända av läkemedelsverket. Det är dock oklart om någon av varianterna är bättre än de andra vad gäller lättethet att ta och tarmrengörande effekt. Därför gör vi på endoskopinheten USÖ just nu en jämförande studie mellan de två preparat som vi uppfattar vara de bästa för att avgöra vilket vi fortsättningsvis ska förskriva inför koloskopiundersökningar. Det recept på laxermedel du fått är således ett av dessa varianter, antingen PEG-baserat (Movprep eller laxabon) eller innehållande natriumpikosulfat (Picoprep).


Dina uppgifter, enkätsvaren och endoskopiresultatet kommer att sammanställas av ansvarig student för projektet samt dess handledare. Avidentifierade uppgifter som inte går att härleda till dig som individ kommer presenteras i samband med att studentens kandidatarbete på termin 6 Läkarprogrammet Örebro redovisas.


Vi vill än en gång informera om att deltagandet i denna utvärdering är helt frivilligt. Oavsett om du tackar ja eller nej kommer detta inte att påverka ditt omhändertagande eller den vård du erbjuds i samband med besöket hos.
Nils Nyhlin
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Jag har läst patientinformationen och samtycker till att medverka i studien utvärderingen av laxermedel på endoskopienheten USÖ och att forskarna/ Region Örebro Län behandlar personuppgifter om mig som är relevanta för studiens genomförande.

........................................................................................................................................

Ort och datum

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Namnunderskrift

........................................................................................................................................

Namnförtydligande

Informerande Läkare/Sjukköterska

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Ort och datum

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Namnunderskrift

Appendix 1
Pat nr _____
Patientutvärdering av laxering inför koloskopi

Ålder........... Kön: Man □ Kvinna □

Druckit Movprep □
Druckit Picoprep □
Druckit Laxabon □

All laxering eftermiddag-kväll dagen innan □
Delad dos med första laxering på kvällen och andra på morgonen □

Blev kallad mindre än en vecka före undersökningen □
Blev kallad mer än en vecka före undersökningen □

1: Erfarenhet av laxering/tarmsköljning

1) Första gången
2) Andra gången
3) Gjort det flera gånger

2: Hur stor del av laxermedlet fick Du i dig?

1) Mindre än en fjärde del
2) ungefär hälften
3) Tre fjärdedelar
4) Allt

3: Hur många liter vätska uppskattar Du att Du druckit totalt från det att du påbörjade laxeringen tills du kom till endoskopienheten

1) Mindre än 2 liter
2) 2-3 liter
3) 3-4 liter
4) Över 4 liter
För att besvara nedanstående frågor sätter Du ett kryss på valfritt ställe på linjen

4: Hur bedömer Du patientinstruktionerna?

Utmärkta ________________________________ Undermåliga

5: Hur upplevde Du att förberedelserna inför undersökningen var?

Bra ________________________________ Outhärdlig

6: Vad tyckte Du om smaken på preparatet?

Gott ________________________________ Vedervärdigt

7: Hur lätt var det att få i sig preparatet?

Mycket lätt ________________________________ Mycket svårt

8: Övriga kommentarer:

Tack för Din medverkan!

Appendix 2
Utvärdering: Endoskopistbedömning

Pat nr_______  Endoskopist_____________________

Datum__________

Ottawa Preparation Scale (OPS)

4=Inadequate (Solid stool not cleared with washing and suctioning)
3=Poor (Necessary to wash and suction to obtain a reasonable view)
2=Fair (Necessary to suction liquid to adequately view segment)
1=Good (Minimal turbid fluid in segment)
0=Excellent (mucosal detail clearly visible)

Vänster kolon: 0 1 2 3 4 (renast-smutsigast)

Transversum: 0 1 2 3 4

Höger kolon: 0 1 2 3 4

Vätska kolon: 0=obetydligt 1=måttligt 2=mycket

Totalt antal poäng____

Anser du att laxeringen var adekvat ?  Ja  Nej