

Comparison of Paraffin versus Polyethylene Glycol (PEG) in Children with Chronic Functional Constipation

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Abstract

Background

Constipation is one of the most common disorders in children. The purpose of this study was to compare paraffin and polyethylene glycol (PEG) in the treatment of children with chronic constipation.

Materials and Methods

This study is a double-blind randomized trial. Total 160 children aged 2-12 years old with chronic constipation attending the pediatric clinic of Mousavi Hospital in Zanjan (Iran) were examined by the same pediatric gastroenterologist. They randomly received PEG solution (1cc/kg/day divided in two doses) or paraffin at the same dose. Patients were assessed regularly once a week up to one month and then monthly until 6 months. Data were analyzed by SPSS version 16 software.

Results

From children enrolled in the study, 43.1% were boys with mean age 5.27 ± 1.3 years. The male to female ratio in Paraffin and PEG groups was similar (35/45 vs. 34/46; respectively, P -value= 1.27). The mean age of the participants in paraffin group and PEG group were 5.28 ± 1.4 and 5.24 ± 1.9 years, respectively. The good and intermediate response to PEG in comparison to paraffin were 11.3% and 38.8% vs. 23.8% and 35%; respectively ($P=0.111$). In children lower than 3 years old, the improvement after receiving paraffin was significantly higher ($P=0.048$). The frequency of adverse effects was similar and didn't differ significantly between the two groups.

Conclusion

There was no significant difference between two groups (PEG and Paraffin groups) in terms of gender and adverse effects of drugs. However paraffin had better therapeutic effect among children less than 3 years of age.

Key Words: Children, Chronic Functional Constipation, Paraffin, Polyethylene Glycol (PEG).

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1- INTRODUCTION

Constipation is one of the most common disorders in children. It may impact normal activity and quality of life. More than 3% of patients referred to pediatricians and 10-25% of these referred to pediatric gastroenterologists suffer from this disorder (1-3). Constipation is defined as a problem in defecation for two or more weeks enough to cause discomfort for the patients (4, 5). Childhood constipation can be divided into two types: functional and organic. According to Rome III criteria, chronic constipation must contain at least two of the following criteria: less than two bowel movements per week, more than one episode of fecal incontinence (soiling) per week, history of voluntary stool retention or withholding, history of painful or stiff defecation, presence of a huge mass of stool in the rectum or history of toilet block due to the large stool (6). Fecal incontinence or soiling is common in chronic functional constipation. The alarm signs of organic cause of chronic constipation include: growth retardation and weight loss, abdominal pain, vomiting, persistent anal fistula or fissure (7, 8).

The current treatment of chronic functional constipation consists of: parental education about suitable diet (use of high-fiber foods), toilet training, medical treatment with polyethylene glycol, Lactulose, paraffin, magnesium hydroxide, sorbitol and rarely bisacodyl and senna. Maintenance therapy is continued until the defecation is normal and the pain resolves (9-20). Polyethylene glycol is another current treatment for constipation. Some clinical studies have reported its benefits with very little side effects (9-12). The solution of polyethylene glycol (PEG) 3350 is an osmotic laxative without electrolytes and odor. Therefore there is no risk of electrolyte imbalance. PEG is available in powder form and could be a solution after mixing with water or juice. Little amounts of it are absorbed from the

gastrointestinal tract (20, 21). The recommended therapeutic dose is 0.4-1.4 g/kg/day, which is well tolerated. The drug has mild and minor side effects such as abdominal distension (bloating, flatulence), abdominal pain and loose stools (21). Paraffin is a mineral oil which is used as a lubricant laxative for treatment of children with chronic constipation and can lead to slippery stools, reduce intestinal water absorption and facilitate bowel movements (22). To date, few studies have been done to compare the effects of PEG with other medication such as paraffin. The aim of this study was to compare the effect of oral paraffin and PEG (polyethylene glycol) for treatment of children with chronic functional constipation in order to achieve the most effective results.

2- MATERIALS AND METHODS

2-1. Study design and population

This study is a double-blind randomized clinical trial. The population consisted of children aged 2-12 years old attending the pediatric gastroenterology clinic of Ayatollah Mousavi Hospital in Zanjan from April 2014 to June 2015 who had chronic functional constipation for at least 6 months and without improvement after given suitable diet and toilet training.

2-2. Methods

Based on the calculated sample size, 160 eligible children were randomized to either intervention. The patients selected at the pediatric gastroenterology clinic of Ayatollah Mousavi Hospital in Zanjan (Iran). After completing the questionnaires, the children run into study and randomly were received PEG solution with dose of 1cc/kg/day divided in two doses or liquid paraffin at the same dose. The study was conducted in a double-blind fashion. The polyethylene glycol (PEG) without electrolyte is a powder manufactured by Sepidajh Company in

Iran (Named Pidrolax). Initially it must be brought as a solution, which 1 cc of solution containing 0.8 gr of PEG. The solution is packaged in the same as paraffin. The oral paraffin is liquid and manufactured by Sepehr Kimia Darou Company in Iran. All patients were instructed about proper diet (including dietary fibres) and the appropriate bowel movements routine (sitting on the toilet for 5 minutes after each meal). Patients were assessed regularly once a week up to one month and then monthly until 6 months and at this time, the frequency of defecation per week, stool consistency, rectal bleeding, painful defecation, fecal incontinence (encopresis) and abdominal pain were measured. Success was defined as 3 or more defecations per week with soft or normal consistency and painless defecation during follow-up (21).

Finally, the response to treatment was classified into three categories: good, intermediate and bad. Good response was considered when there were more than five bowel movements per week, with soft stool, without difficulty, no bloody feces and no soiling or incontinence. A poor response consisted in less than three bowel movements per week, or painful defecation, or stony and bloody stools, or daily soiling and incontinence. The intermediate response include: status of response to treatment between good and bad response (23). The sample size was calculated as 160 patients according to following formula:

$$n = \frac{(z_{1-\frac{\alpha}{2}} + z_{1-\beta})^2 (p_1q_1 + p_2q_2)}{d (p_1 - p_2)^2} = 160$$

2-3. Measuring tools and measurement

All parents were given enough information about the study and taken consent for participation in the project. Then the questionnaires were completed with the cooperation of parents, which included demographic information (age, gender,

developmental status, age at onset of constipation, history of surgery and positive findings in physical examination), and bowel movement information (frequency of defecation per week, painful defecation, bloody stool, consistency of stool and number of fecal incontinence per month).

2-4. Ethical consideration

The study was approved by the ethical committee of Zanjan University of Medical Sciences and registered in Iranian Clinical Trial Registry and its Code number is: IRCT. 2014091618971N2

2-5. Inclusion criteria included

All children aged 2 to 12 years with chronic functional constipation according to Rome III diagnostic criteria including children with fecal excretion of less than 2 times per week, firm consistency of stool, pain on defecation, fecal incontinence 2 or more than 2 times per month and palpable fecal mass in the abdomen or rectum (6).

2-6. Exclusion criteria include

- Having organic causes of constipation such as Hirschsprung's disease, hypothyroidism, cardiac, renal and neurological disorders.
- Having a failure to thrive (FTT) or weight loss more than 5% of body weight.
- Having a history of gastrointestinal surgery.
- Having a history of drug use in the past 3 months (including antidepressants or anticonvulsant, and sedative).
- Incorrect use of medication by children.
- Inadequate follow up.
- Occurrence of adverse drug reactions during treatment.

2-7. Data analysis

The Data were analyzed with SPSS software (version 16.0). To describe the study population were used descriptive statistics such as absolute and relative frequencies, mean and median. The t-test and non-parametric tests were used to compare quantitative variables and Chi-square test was used for qualitative variables between the two groups. P-value of less than 0.05 was considered statistically significant.

3- RESULTS

One hundred and sixty children with chronic functional constipation were selected and completed the study. Of these patients, 69 (43.13%) were male, and 91(56.87%) female, mean age 5.27 ± 1.3 years; 68 (42.5%) patients were under 3 years, 70 (43.75%) between 3 to 7 years and 22 (13.75%) over 7 years of age. The patients were equally divided in two groups treated with paraffin or PEG. The male to female ratio in Paraffin and PEG groups was similar (35/45 versus 34/46; respectively, P-value=1.27). The mean age of the participants in paraffin group and

PEG group were 5.28 ± 1.4 and 5.24 ± 1.9 years, respectively, which didn't also differ significantly. Nineteen (23.8%) and 9 (11.3%) patients had good response to treatment with paraffin and PEG; respectively. However the difference was not statistically significant (P-value =0.111). (**Table.1**). There wasn't a statistically significant difference in response to treatment with respect to participants' sex (**Table.2**).

On the other hand, age had a significant effect on response to treatment; the patients under 3 years of ages had significantly better response to paraffin (**Table.3**). Most patients didn't report any complications (77.5% in paraffin and 75% in PEG group). Thirty eight (23.75%) of patients did not finish the treatment course, because of side effects; including abdominal pain (32 patients), emesis (4 patients) and encopresis (2 patients).

The frequency of adverse effects was similar and didn't differ significantly between the two groups (**Table.4**). However new patients were replaced instead of these patients.

Table-1: Comparison of response to treatment in both groups (Paraffin and PEG)

Group	Response			P-value
	Poor	Intermediate	Good	
Paraffin	33 (41.3%)	28 (35%)	19 (23.8%)	0.111
PEG	40 (50%)	31 (38.8%)	9 (11.3%)	

PEG: Polyethylene Glycol.

Table-2: Comparison of response to therapy in both groups (Paraffin and PEG) according to gender

Gender	Group	Number	Response			P-value
			Poor	Intermediate	Good	
Boys	Paraffin	35	15 (42.9%)	10 (28.6%)	10 (28.6%)	0.346
	PEG	34	19 (55.9%)	10 (28.6%)	5 (14.7%)	
Girls	Paraffin	45	18 (40%)	18 (40%)	9 (20%)	0.305
	PEG	46	21 (45.7%)	21 (45.7%)	4 (8.7%)	

PEG: Polyethylene Glycol.

Table-3: Comparison of response to treatment in both groups (Paraffin and PEG), according to age

Age	Group	Number	Response			P-value
			Poor	Intermediate	Good	
Under 3 years	Paraffin	39	15 (38.5%)	14 (35.9%)	10 (25.6%)	0.048
	PEG	29	15 (51.7%)	13 (44.8%)	1 (3.4%)	
3 to 7 years	Paraffin	33	12 (36.4%)	13 (39.4%)	8 (24.2%)	0.541
	PEG	37	19 (51.4%)	11 (29.7%)	7 (18.9%)	
Above 7 years	Paraffin	8	6 (75%)	1 (12.5%)	1 (12.5%)	0.213
	PEG	14	6 (42.9%)	7 (50%)	1 (7.1%)	

PEG: Polyethylene Glycol.

Table-4: Comparison side effects of treatment in the both groups

Group	No complication	Abdominal Pain	No tolerance	Soiling	P-value
Paraffin	60 (75%)	15 (18.8%)	3 (3.8%)	2 (2.5%)	0.368
PEG	62 (77.5%)	17 (21.3%)	1 (1.3%)	0 (0%)	

PEG: Polyethylene Glycol.

4- DISCUSSION

The purpose of our trial was to compare the efficacy and safety of paraffin and PEG in children with functional constipation. The results of this study showed that both drugs have similar efficacy. There was no statistically significant difference between the two groups (both among boys and among girls), in terms of response to treatment. Only children under three years showed significantly better response to treatment with paraffin. In 2004, Loening-Baucke et al. studied the effect of PEG in 75 children with functional constipation aged 1 to 24 months (mean 17 months, with a median duration of 10 months). In their study, constipation resolved by using PEG, in 85% of cases within the first 4 months and at 91% within 6 months of initiation of treatment without serious side effects (24). Llerena and coworkers showed more than 70% hard stool reduction in two groups of children receiving PEG or PEG with electrolyte after 6 and 12 weeks treatment (25). Whereas in our study about 50% of children showed good response to PEG

after 6 months. The explanation for this difference can be explained by the high mean age of our patients. The best response was observed in the short time chronic constipation and in younger patients. We did not enroll children under 1 year, due to limitations of paraffin use in these children. In 2007, Dipalma and colleagues compared the effect of PEG versus placebo in the treatment of constipation. They reported that 52% of patients in the PEG group and 11% in the placebo group had a successful response (26). Their results were similar to our study. Other similar study by Rafati et al. that conducted on 160 children aged 2-12 years with chronic constipation, showed that treatment with PEG and paraffin significantly increased the number of bowel movements per week and reduce the number of encopresis episodes in both groups. It showed that PEG is as effective as paraffin in treatment of chronic functional constipation on children (27). In contrast, their side effects with PEG were less than with paraffin whereas in our study, the side effects of paraffin were slightly fewer than with PEG (22.5% vs.

25%). Karami et al. showed that both drugs (PEG and Paraffin) have a good effect on improving constipation, but PEG significantly had a stronger effect than paraffin. In this study it was observed that PEG is effective in improving bowel movements in 70.8% of patients one month after initiation of therapy. With the treatment the number of painful bowel movements and bloody stools were reduced from 45.83% to 31.25% (28). In our study the therapeutic effect of PEG was not better than paraffin. We also found the better response to treatment with paraffin, especially in younger children. The possible reason for the difference might be related to study design or the duration of treatment.

Loening-Baucke V et al demonstrated the effectiveness of PEG in comparison with Milk of Magnesia (MOM) in bowel movements, abdominal pain and frequency of encopresis during 12 months and found significantly better response to PEG. The effect of PEG and MOM were 62% 42% respectively. There was no rejection of polyethylene glycol, but 33% of children rejected milk of magnesia (29). In our study, only 3.8% of the patients refused the use of PEG and 1.3% of paraffin users showed intolerance. Based on the results of this study, both drugs (Paraffin and PEG) had almost equal effect on treatment and none of them had serious side effects; moreover, considering the low price and acceptability of paraffin, it could be recommended as the first step of treatment among children with constipation.

5- CONCLUSION

The results of this study showed that the paraffin and polyethylene glycol have similar therapeutic effects in the treatment of functional constipation in children. Paraffin had a better therapeutic effect than polyethylene glycol only in children less than three years. The side effects of both drugs were insignificant and not serious.

About half of the children did not show any improvement after treatment, thus investigating other therapeutic approaches could be beneficial.

6- CONFLICT OF INTEREST

The Authors had no conflict of interest.

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