Original Article

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Polyethylene Glycol versus Paraffin for the Treatment of Childhood Functional Constipation

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Abstract

Objective: Chronic constipation is a common elimination dysfunction in children. It can be treated with several drugs of different efficacy in different age groups. This study assessed the efficacy of Polyethylene glycol (PEG) and oral liquid paraffin in treatment of childhood chronic functional constipation.

Methods: A total of 126 functional constipated children aged 1 to 15 years were divided into two therapeutic groups using systematic and random sampling technique. In addition, children were divided into three age groups of 12 to 23 months, 24 to 59 months and over 60 months old. They were scored based on five main criteria as follow: stool frequency per week, painful defecation, blood-stained stools, stool consistency and number of encopresis incidents per month. At the end of one therapeutic month, the scores obtained by drugs were compared with each other. Data were analyzed by using SPSS software, McNamara test, sign test, independent t test, and paired t-test.

Findings: The scoring in PEG group was increased from 13.13 (±2.18) to 17.20 (±2.07) while in paraffin group, it increased from 13.48 (±1.90) to 16.78 (±2.51). Comparison of the mean scores showed a significant difference of the two groups after one month (*P*=0.02).

Conclusion: Our results have shown that PEG is more effective than oral liquid paraffin for treatment of childhood functional constipation. Therapeutic response to the drugs varied among the different age groups.

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Key Words: Polyethylene glycol; Paraffin; Childhood functional constipation; Stool frequency; Chronic constipation

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Introduction

Constipation is a common elimination dysfunction in children, and entails more than 3% of visits to a pediatrician and 10 to 25% of visits to pediatric gastroentero-logist[1,2,3]. Constipation is classified as functional and organic[4]. Chronic functional constipation (CFC) is defined as a delay in defecation (fewer than three times per week) which is present for more than two weeks and is associated with stool withholding behavior. It is also associated with painful defecation, without underlying anatomic or medical etiologies. For this reason, CFC is also called idiopathic [1,2,5].

Treatment includes primary stool evacuation, education regarding correct defecation method, high fiber diet and prolonged laxative administration[2]. Current drugs used include mineral oil, lactulose, Milk of Magnesia (MOM), sorbitol, less common bisacodyl, senna which is prescribed per case, depending on patients. Polyethylene glycol (PEG) is a tasteless, odorless and non-addictive powder that is utilized as a new laxative agent for treatment of constipation [6]. Physical dependency is not reported with PEG consumption [3]. In addition, PEG has no systemic and toxic effects, because it is neither degraded by gastrointestinal bacteria nor readily absorbed. Nausea, abdominal cramping and diarrhea may occur [1,2,5]. There are several studies on safe and efficient use of PEG for the treatment of chronic constipation in children [7,8].

PEG is available in different concentrations; its rate of consumption can be decreased as far as possible to make it easier for the patient to take [8]. Furthermore, there is no risk of pulmonary aspiration by using PEG.

Because there is few data available regarding efficacy of PEG and oral liquid paraffin for treatment of constipation in infants and older children in Iran, this study compared the efficacy of PEG and paraffin for treatment of functional constipation in pediatric age groups.

Subjects and Methods

This study is a single-blind clinical trial of 126 functional constipated children aged 1-15 years, referred to pediatric gastroenterology department at Boo-Ali Sina Hospital in Sari, Iran, in 2007. After receiving informed consent from the parents, children were divided by a systematic and random sampling into two therapeutic groups: group 1 (PEG) and group 2 (paraffin). To assess the age-related therapeutic responses of the two drugs, the patients were divided into three age groups: group a (12 to 23 month-olds), group b (24 to 59 month-olds) and group c (older than 60 months).

Inclusion criteria encompassed: Stool frequency less than 2 times per week with fecal hard consistency, encopresis two or more than two times per month, palpable fecal impaction in abdomen or rectum.

Patients with organic constipation, anorectal abnormalities, history of anorectal surgery were excluded.

In all cases, fecal impactions were evacuated, dietary advice given and toilet training discussed face-to-face and in pamphlets. Fissure was repaired if present.

PEG (40% solution without electrolytes) was initiated with an average dose of 1cc/kg/d twice a day (PEG powder without electrolytes, manufactured by Kimia Tous Co, Iran, solved in deionized distilled water until the volume of solution reached 300cc, with a dosage of 1cc/kg equal to 0.8 gr/kg). Oral liquid paraffin (average dose 1cc/kg) was given twice daily. Patients were followed up regularly every week for one month, thereafter monthly for 2 to 4 months. Each patient received two data forms. A copy of the forms was saved in patent's chart. Form 1 contained demographic information (age, gender, age at onset of constipation, developmental status, surgical history, family history for constipation and findings in physical examination). Form 2 included data on stool frequency per week, painful defecation, blood-stained stools, stool consistency and number of encopresis

Table 1: Scoring system of functional constipation criteria

Variables	1	2	3	4	5	6	7	8
Painful defecation	Pos	Neg	Neg	Neg	Neg	Neg	Neg	Neg
Blood with defecation	Pos	Neg	Neg	Neg	Neg	*Neg*	Neg	Neg
Stool frequency per week	-	<3	-	3-5	-	6-8	-	>8
Encopresis per month	> 8	5-8	3-5	<3	-	-	-	-
Stool consistency	Hard	consistent	soft	loose	watery	-	-	-

Pos: present
Neg: Not present

occurrences per month. These Forms were completed in all visits, altogether four to eight times. The main criteria of defecation were scored according to table 1.

Therapeutic response was scored as follows: poor (6-10), moderate (11-15) and good (16-21).

Data were analyzed by using SPSS and statistical sign test (for multivariate quality variables such as stool frequency), independent t test (comparison between the groups), paired t-test (inter groups comparison) and Mc Nemar (bivariate quality variable such as painful defecation). All study protocols were approved by medical ethical committee of the Mazandaran Medical University.

Findings

Of 126 enrolled patients consisting of 50 (48.5%) girls and 53 (51.5%) boys, 103 were followed. Forty-eight were in PEG group and 55 in paraffin group. Mean age was 48.1 (± 27.5) months (range 12 to 123 months). Mean duration of constipation was 27.5 (±23.8) months (range 2 weeks to 104 months). The mean duration of constipation with PEG and paraffin was 30.7 (±26.2) and 24.7 (±21.3) months respectively, which indicates that there was no significant difference between the two groups (P=0.2). Of 39 (37.9%) patients with positive family history, 17 (43.6%) were in PEG group and 22 (56.4%) in paraffin group with no significant differences (P=0.6).

Table 2: Comparison of therapeutic response of the two groups after one therapeutic month

Variable	Polyethylene glycol Group			Paraffin Group		
	Increase No (%)	Decrease No (%)	No change No (%)	Increase No (%)	Decrease No (%)	No change No (%)
Stool frequency/wk*	34 (70.8)	2 (4.1)	12 (25.0)	29 (53.7)	(8.3) 4	21 (38.8)
Encopresis/m‡	3 (6.2)	26 (54.1)	19(39.5)	3 (5.5)	24 (4.4)	27 (50.0)
Painful defecation	2 (4.2)	22 (45.8)	22 (45.8)	3 (5.4)	21 (38.2)	28 (50.9)
Blood with defecation	2 (4.2)	5 (31.2)	15 (64.6)	2 (3.6)	20 (36.4)	33 (9.0)
Stool consistency	5(10.4)	2 (66.7)	11 (22.9)	5 (9.0)	28 (50.9)	21 (38.2)

* wk: week; ‡m: month

Table 3: Comparison of five elimination criteria before and after treatment with Polyethylene glycol

Variable	Before PEG† therapy Mean (SD)	After PEG therapy Mean (SD)	P value
Stool frequency/wk*	2.7 (±1.4)	4.7 (±1.8)	0.001
Stool consistency	4.2 (±0.4)	4.7 (±0.4)	0.001
Painful defecation	1.4 (±0.5)	1.9 (±0.3)	0.001
Blood with defecation	1.6 (±0.5)	1.9 (±0.3)	0.001
Encopresis/m‡	3.2 (±0.8)	3.9 (±0.3)	0.001
Total	13.1 (±2.1)	17.2 (±2.1)	0.001

* wk: week; ‡m: month; † PEG: Polyethylene glycol

Comparing the results of the five main criteria after one-month treatment is depicted in table 2.

Assessment regarding pretreatment scores in group one was 13.1 (±2.1) and in group two 13.5 (±1.9), without a significant difference (*P*=0.2). Mean score was increased to 17.2 (± 2.1) in group 1 and to 16.74 (±2.5) in group 2 after one month treatment. Although a therapeutic response was significant in both groups (*P*<0.001) and was better in PEG, however, there was no significant difference between the two groups (*P*=0.3). Scores of five elimination criteria before and after treatment with PEG and paraffin are demonstrated in tables 3 and 4.

Maximum on effects was found within the age group b (24 to 59 month olds) in both groups. Maximal therapeutic response belonged to age group a (75%) and c (76%), and minimal therapeutic response belonged to age groups c (61%) and b (38%) in both PEG and paraffin groups (Table 5). The efficacy rates of the drugs in these three age groups are shown in table 5.

Discussion

In this study, PEG and paraffin were most effective on stool frequency, this being more significant with PEG. According to the achieved scores, therapeutic response to both drugs increased from moderate to good.

In 2003, Dupont et al studied the PEG effectiveness in 75 functional constipated

Table 4: Comparison of five elimination criteria before and after treatment with paraffin

Variable	Before paraffin therapy Mean (SD)	After paraffin therapy Mean (SD)	P value
Stool frequency/ wk*	3.0 (±1.5)	4.5 (±1.9)	0.001
Stool consistency	4.2 (±0.4)	4.5 (±0.6)	0.001
Painful defecation	1.3 (±0.5)	1.7 (±0.5)	0.001
Blood with defecation	1.6 (±0.5)	1.9 (±0.3)	001/0
Encopresis/ m‡	3.4 (±0.6)	3.9 (±0.3)	0.001
Total	13.5 (±1.9)	16.7 (±2.1)	0.001

* wk: week; ‡m: month

Table 5: Comparison of change of scoring after treatment in both groups according to age

Group		Increase %	Decrease %	No change %	P value
Group 1	a	75	0	25	0.03
	b	68	0	32	<0.001
	c	61	5.5	33.3	0.006
Group 2	a	50	0	50	0.1
	b	38	5.9	56.1	0.007
	c	76	7.6	15.3	0.01

patients 1 to 24 years of age. At the end of the study period, constipation was relieved in 85% with short-term (less than 4 months) and in 91% with long-term (less than 6 months) utilizing PEG therapy. Pain and blood with defecation were decreased significantly. Meanwhile, serious side effects were not seen with PEG therapy[5]. In our study, PEG was effective in improving the stool frequency in 70.8% of patients one month after beginning of the therapy. Painful defecation and blood in the stool, decreased from 45.83% to 31.25%. Dipalama et al in 2007 compared the efficacy of PEG versus placebo in treatment of constipation. They reported that 52% of patients in PEG group and 11% in placebo groupwere successfully treated [9]. There were no significant differences in laboratory findings or side effects with PEG compared to placebo. Because mega rectum due to stool withholding behavior requires several weeks of treatment, it was acceptable that therapeutic response was better in short term duration of chronic constipation or in younger patients[20]. This is very similar to the result of our study, in which the best therapeutic response was achieved in age group a (1 to 2 year olds) with PEG and in age group c (>5 year olds) in paraffin group. In a study by Baucke et al, PEG and MOM were compared. They reported a significant improvement in bowel movement, relief of abdominal pain and encopresis frequency in both groups, after 12 months especially in PEG, while, the efficacy of PEG was 62% and that of paraffin 42%. In addition, PEG acceptance by patients was more than 30% [10]. In our study, assessment of the therapeutic effect was initiated one month after treatment, which indicates early efficacy of PEG without any reported side effects. Some studies showed that infants under the age of 1 year should not receive liquid paraffin because gastroesophageal reflux and increased incoordination of swallowing are more common in infants, thereby posing a greater risk of aspiration and development of lipoid pneumonia[4,11].

Seven qualifying studies, involving 594 children were identified. Five were comparisons of PEG with lactulose, one with milk of magnesia and one with placebo. Study duration ranged from 2 weeks to 12 months. PEG was significantly more effective than placebo and either equivalent (2 studies) to or superior (4 studies) to active comparator[5,11-16].

Several studies have reported 30%-40% positive family history of constipation. It was 37.9% in our study. Influence on delayed colonic transit and low amplitude peristaltic contractions may have familial background. If stool frequency is the only evaluating criterion for therapeutic response, assessment of therapeutic response in these patients will be difficult [3,17-19].

There is no fundamental study based on gender of the patients. In this study, comparing of girls and boys to a therapeutic response was impossible due to the gender bias within the groups. For further studies, we recommend equal gender groups, in order to gain a better therapeutic response. Stool

frequency per week is considered to be the most important therapeutic response; therefore, we have given the highest score to this criterion. Moreover, we recommend further studies in different age groups, applying a steady scoring system and comparing the effect of more drugs that are laxative as well as their side effects in patients less than 1 year old.

Conclusion

In our study, the mean score variation changed from 13.1 to 17.2 in the PEG group, while it was changed from 13.5 to 16.7 in the paraffin group. The score of stool frequency in the PEG group increased from 2.6 to 4.7 and in paraffin group from 3.0 to 4.5, which indicates that PEG was clearly more effective than paraffin for treatment of childhood functional constipation. Therapeutic response to the drugs varied among the different age groups; the best response to PEGl and oral liquid paraffin was seen in age groups of 12 to 23 months, and more than 60 months.

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