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Comparison the Efficacy of Polyethylene Glycol and Paraffin for the Treatment of Childhood Functional Constipation

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Abstract: Chronic constipation is a common elimination dysfunction in children. Chronic Functional Constipation (CFC) is referred to condition in which there is not underlying anatomic or medical causes. In addition to correction of defecation pattern and nutritional considerations, treatment of childhood CFC is also included case related drugs such as lactulose, paraffin and sorbitol that have different efficacy in different age groups. This study were assessed the efficacy of polyethylene Glycol (PEG) and Paraffin in treatment of childhood CFC. Material and Methods: Functional constipation is defined as a non anatomical constipation. A total of 126 functional constipated children aged 1-15 years, systematic randomly divided into two therapeutic groups: group 1 (PEG without electrolytes 40%, 1cc/kg/d, twice a day) and group 2 (Paraffin, 1cc/kg, twice daily). Children were divided into three age groups 12-23 mon, 24-59 mon and over 60 months and then the therapeutic response in each group were assessed separately. In order to evaluation of the drugs effects, we were scored to 5 following main criteria according to the severity of symptoms: stool frequency per week, pain and blood with stools, stool consistency and number of encopresis per month. At the end of one therapeutic month, the score obtained by each drug was compared with each other. Collected dada were analyzed by using SPSS software, mcNemar test, sign test, independent t test and pair-t test. At the end of first therapeutic month, increasing of stool frequency was 34 (70.8 %) in group 1 and 29 (53.7 %) in group 2 and improvement of stool consistency in group 1 and 2 were 66.6 and 50. 90 %, respectively. Pain with stool was decreased 36.36 % in group 1 and 31. 25 % in group 2. Decreasing of blood with stool in the both groups were 88. 2 and 90. 9 %, respectively and encopresis per month was decreased in 54.1 % of PEG and 44.4 % of Paraffin group. There was no significant difference between two groups. The scoring in PEG group was increased from 13.13±2.18-17. 20±2.07 and in Paraffin group increased from 13.48±1.9-16.78±2.51. Comparing of the mean scores were significant in each group after one month ($p = 0.024$). Our results have shown that PEG is more effective than Paraffin for treatment of childhood functional constipation. Therapeutic response to the drugs was varied among different age groups, as the best response to PEG and Paraffin was seen in age groups of 12-23 months and more than 60 months.

Key words: Polyethylene Glycol (PEG), Paraffin, Childhood Functional Constipation (CFC)

INTRODUCTION

Constipation is a common elimination dysfunction in children and more than 3 % of visits to pediaterist and 10-25 % of visits to pediatric gastroenterologist (Issenman *et al*., 1987; Loening-Baucke *et al*., 2004; Croffie and Fitzgerald, 2004). Constipation is classified into two groups: Functional and organic constipation (Bishop, 2006). CFC is defined as a delay in defecation (fewer than three per week) present more than two weeks that associated with stool withholding behavior and pain with defecation without underlying anatomic or medical etiologies. For this reason, CFC is also called idiopathic (Issenman *et al*., 1987; Loening-Baucke *et al*., 2004; Dupont *et al*., 2004). Treatment is included primary stool evacuation, education of correct defecation method, high

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fiber diet and prolonged laxative administration (Loening-Baucke *et al*., 2004). Current using drugs include mineral oil, lactulose, MOM, sorbitol, less common bisacodyl, Sena and laxative, that prescribed case relatively. PEG is a tasteless, odorless and non-addictive powder that is used as a new laxative agent in treatment of constipation (Erickson *et al*., 2003). Physical dependency is not reported with PEG consumption (Croffie and Fitzgerald, 2004). In addition, PEG has not systemic and toxic effect because it is not degraded by gastrointestinal bacteria and is not readily absorbed (Issenman *et al*., 1987; Loening-Baucke *et al*., 2004; Dupont *et al*., 2004). There are several studies on safe and efficient use of PEG in treatment of chronic constipation in children (Robert, 2004; Mchail *et al*., 2004). Because the prevalence of chronic constipation is high among infants less than 1 year of age, paraffin is not recommended for this age group. Therefore, that PEG can be an effective and useful therapeutic agent in the infants. Meanwhile, PEG can be available in different concentration and the rate of consumption can be decreased as far as possible that make its easy to use for the patient (Mchail *et al*., 2004). Furthermore, there is no risk of pulmonary aspiration using of PEG.

As there is few data about efficacy of PEG and Paraffin for treatment of constipation in infant and older children in Iran, this study was compared the efficacy of PEG and Paraffin for treatment of functional constipation.

MATERIALS AND METHODS

This is a 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 achieving the letter of satisfaction from parents, children divided as systematic randomly into two therapeutic groups: Group 1(PEG) and group 2 (Paraffin). To assess the age-related therapeutic response of the two drugs, the patients divided into three age groups: group a (12-23 months), group b (24-59 months) and group c(more than 60 months). Inclusion criteria were included Stool frequency less than 2 per week with fecal hard consistency, encopresis for two or more than two monthly, palpable fecal impaction in abdomen or rectum. Exclusion criteria were included present of symptoms suspected to organic constipation, anorectal abnormalities, history of anorectal surgery and not responding to the selected drugs. For all cases, fecal impactions were evacuated; face to face and pamphlet educations were performed about toilet training and dietary advice. Fissure was repaired if existed. PEG without electrolytes from 40 % solution was started at an average dose of 1cc/kg/d twice a day and Paraffin at on average dose 1cc/kg twice daily was given. Follow up was done every week until one month (regularly) and then followed monthly for 2-4 months. There were two data forms for each patient (form 1 and form 2 one copy of each form), a copy of the data forms provided for the patient and another copy for saving in patient's chart in order to fill by calling if the patients could not refer to the center. Pretreatment information of the patients was recorded in the form 1 and data about efficacy of the drugs was recorded in form 2. Form 1 including demographic information such as age, gender, age of onset of constipation, developmental status, surgical history, family history of constipation and physical exam. Form 2 was included data such as stool frequency per week, pain and blood with stools, stool consistency and number of encopresis per month that was filled four to eight times for each patient separately in all visits. Then main criteria of defecation in patients were scored according to Table 1.

Therapeutic response of the patients was scored as follow: Poor (6-10), moderate (11-15) and good (16-21). Data were analyzed by using SPSS and statistical sign test (for multivariational quality variables such as stool frequency), independent t test (comparison between the groups), pair-t test (inter groups comparison) and Mc Nemar (bivariational quality variable such as Pain with defecation).

Table 1: Scoring system of functional constipation criteria

Score variable	1	2	3	4	5	6	7	8
Pain with defecation	+	-	-	-	-	-	-	-
Blood with defecation	+	-	-	-	-	-	-	-
Stool frequency per week	-	<3	-	3-5	-	6-8	-	>8
Encopresis per month	> 8	5-8	3-5	<3		-	-	-
stool consistency	Hard stool	consistence	soft	loose	watery	-	-	-

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

	PEG			Paraffin		
Group variable	Increase Number (%)	Decrease Number (%)	Nochange Number (%)	Increase Number (%)	Decrease Number (%)	No change Number (%)
Stool frequency per week	(70.8) 34	(4.1) 2	(25) 12	(53.7) 29	(8.3) 4	(38.8) 21
Encopresis per month	(6.2) 3	(54.1) 26	(39.5) 19	(5.5) 3	(44.4) 24	(50) 27
Pain with defecation	(4.16) 2	(45.83) 22	(45.83) 22	(5.45) 3	(38.18) 21	(50.9) 28
Blood with defecation	(4.16) 2	(31.25) 5	(64.57) 15	(3.63) 2	(36.36) 20	(60) 33
Stool consistency	(10.41) 5	(66.66) 2	(11.91) 22	(9) 5	(50.90) 28	(38.18) 21

RESULTS

From 126 enrolled patients, 103 were followed, 48 were in PEG group and 55 were in Paraffin group. Fifty (48.5%) were girls and 53(51.5%) were boys. Mean age was 48.06±27.54 months (range, 12-123 months). The 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 30.67±26.25 and 24.75±21.3, respectively, that was not significant difference between two groups (p = 0.2). From 37. 9% (39) with positive family history, 43.6% (17) were in PEG group and 56.4% (22) were in Paraffin group, that there were not different significantly (p = 0.63). The results of comparing of the five main criteria after one-month treatment are seen in Table 2.

Assessment of pretreatment score in group1 (13.08±2.15) and group2 (13.51±1.9) had no significant differences (p = 0. 2). Mean score was increased to 17. 2±2.07 in group1 and increased to 16.74±2.51 in group2, one month after treatment. Although therapeutic response was significant in each group (p<0.001) and was better in PEG, there was no significant difference between the two groups according to p = 0. 28. Scores of five elimination criteria before and after treatment with PEG and paraffin are seen in Table 3 and 4.

Maximum cases were located at the age group b (24-59 months) in both studied groups. Maximum therapeutic response was belonging to age groups a (75%) and c (76%) and minimum therapeutic response was belonging to age groups c (61%) and b (38%) in both PEG and paraffin groups (Table 5). The efficacy of the drugs in three age groups is shown in Table 5.

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

Variable	Before PEG therapy	After PEG therapy	p-value
Stool frequency per week	2.66±1.38	4.70±1.77	0.001
Stool consistency	4.18±0.39	4.75±0.43	0.001
Pain with defecation	1.37±0.48	1.91±0.27	0.001
Blood with defecation	1.64±0.48	1.91±0.27	0.001
Encopresis per month	3.20±0.79	3.87±0.33	0.001
Total	13.08±2.15	17.20±2.07	0.001

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

Variable	Before paraffin therapy	After paraffin therapy	p-value
Stool frequency per week	3.01±1.53	4.54±1.86	0.001
Stool consistency	4.16±0.37	4.54±0.60	0.001
Pain with defecation	1.30±0.46	1.69±0.46	0.001
Blood with defecation	1.60±0.49	1.92±0.26	0.001
Encopresis per month	3.41±0.65	3.87±0.33	0.001
Total	13.51±1.90	16.74±2.10	0.001

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

Therapeutic response Group	Increase (%)	Decrease (%)	No change (%)	p-value
Group-1				
a	75	0	25	0.031
b	68	0	32	0.0001
c	61	5.5	33.3	0.006
Group-2				
a	50	0	50	0.125
b	38	5.88	56.12	0.007
c	76	7.6	15.3	0.012

DISCUSSION

In the present study, the most efficacies of PEG and Paraffin on main defecation criteria were on stool frequency and it was more significant with PEG. According to the achieved scores, therapeutic response with each drugs changed from moderate score to good.

Dupont *et al.* (2003) studied the PEG effectiveness in 75 functional constipated patients 1-24 years. At the end of study period, constipation was relieved in 85% with short-term (less than 4 months) and in 91% with long-term (less than 6 months) PEG therapy. Pain and blood with defecation were decreased significantly. Meanwhile, serious side effects were not seen with PEG therapy (Dupont *et al.*, 2004). In our study, PEG was effective in improving of stool frequency in 70.8% of patients one month after starting PEG therapy. Pain and blood in the stool were decreased from 45.83%-31. 25%. Dipalama *et al.*

(2007) were compared the efficacy of PEG versus placebo in treatment of constipation. They reported that 52% of patients in PEG group and 11% in placebo were successfully treated. There were no significant differences in laboratory findings or side effects with PEG compared with placebo (Dipalma *et al*., 2007). Because mega rectum due to stool withholding behavior requires several week′s treatment, it was acceptable that therapeutic response was better in short duration chronic constipation or in younger patients. This is very similar to the result of our study, in which the best therapeutic response was in age group a (1-2 years) with PEG and in age group c (more than 5 years) 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 group, after 12 months especially in PEG. While, the efficacy of PEG was 62 and paraffin was 42%. In addition, PEG acceptance by patients was more than 30% (Loening, 2002). In our study, assessment of the therapeutic effect was started one month after treatment that shows early efficacy of PEG without any report of side effect.

Several studies were reported 30-40% positive family history of constipation and it was 37. 9% in our study. Delayed colonic transit and low amplitude peristaltic contractions are influenced in family background. If stool frequency is the only evaluating criteria for therapeutic response, assessment of therapeutic response in these patients will be difficult. Considering change in scoring of main criteria, follow up of the patients will be carefully.

Our study, score variation changed from 13.08±2.15-17. 2±2.07 in the PEG group and changed from 13.51±1. 9-16.74±2.1 in the Paraffin group. The score of stool frequency in PEG group increased from 2.66±1.38-4.7±1.77 and in Paraffin group from 3.01±1.53-4.54±1.86 that the PEG effect was clearly more than the Paraffin did.

There is no fundamental study based on gender of the patients. In this study, comparing of girls and boys therapeutic response was impossible because of sex bias in the groups. For further studies, we recommend equal sex groups comparing better therapeutic response. Considering the most important therapeutic response is stool frequency per week, so that we have given the highest score to the criteria.

Moreover, we recommend further studies with different age groups, applying a steady scoring system and comparing the effect of more laxative drugs as well as their side effects in patients less than 1 year old.

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