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The Effect of Paraffin Added to Polyethylene Glycol on Reducing Painful Defecation in Children with Functional Constipation

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Abstract

Background: Pediatric functional constipation is a common issue that imposes significant personal and societal burdens. While managing painful defecation is essential in controlling the vicious cycle of stool withholding and altered rectal physiology, current approaches have addressed stool consistency rather than focusing on this critical outcome.

Aim: We aim to assess if adding paraffin to polyethylene glycol (PEG) affects painful defecation and other constipation outcomes in children with chronic functional constipation. Paraffin, with its lubricating mechanism, is hypothesized to improve stool passage and reduce pain during defecation.

Methods: We randomized 148 children with chronic functional constipation to receive either PEG plus paraffin or PEG alone for three months. We assessed painful defecation, number of defecations per week, and stool consistency as primary outcomes at baseline and after the intervention. Secondary outcomes included nausea and vomiting, diarrhea, abdominal pain, and incontinence. We used the t-test, one-way analysis of variance (ANOVA), and repeated measures analysis to compare means in our data, and we used the chi-squared test to compare categorical data between groups. We utilized IBM SPSS Statistics 21 software for data analysis, and a p-value of 0.05 or lower was considered statistically significant. We also calculated effect sizes as mean difference and numbers needed to treat (NNT) in addition to their 95% confidence interval using MedCalc.

Results: Our study indicates that adding paraffin to PEG significantly improves painful defecation in children with chronic functional constipation. In contrast, it did not considerably impact stool consistency or the number of defecations.

Conclusion: Our findings suggest that paraffin can be a valuable adjunct to PEG in managing painful defecation, a crucial aspect of constipation treatment.

Key Words: Chronic constipation, Childhood, Functional constipation, Painful defecation, Paraffin, Polyethylene glycol, Treatment, Randomized controlled trial.

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1- INTRODUCTION

In the U.S., functional constipation accounts for about 3 percent of visits to general pediatricians. This number can rise to 25 percent when specialized pediatric gastroenterologists see patients. The worldwide occurrence of pediatric functional constipation (PFC) varies widely according to research, ranging from 0.3 percent to 29.6 percent, without substantial gender differences (1-4). Severity levels span from moderate and transient to severe and persistent, with roughly 25 percent of cases persisting into adulthood. Despite existing treatments, the standard of care remains constrained due to a need for more guidelines for managing this disorder, an ambiguous definition of its nature, and deficient evidence regarding pharmacological interventions (5).

A combination of nondrug approaches and medications is applied to address childhood constipation. These non-pharmaceutical strategies encompass educational efforts, dispelling misconceptions, nutritional adjustments, potty training, behavior modification techniques, biofeedback, and pelvic floor exercises. On the other hand, pharmacological therapies, including osmotic laxatives like polyethylene glycol (PEG), lactulose, and milk of magnesia (MOM), are commonly used to manage functional constipation in children. These laxatives are not readily absorbed in the small intestine, causing them to retain water in the colon, thereby softening stools. Alleviating pain during defecation is vital to prevent long-term complications associated with untreated or undertreated functional constipation. However, the evidence for this important outcome needs to be more extensive (6).

Managing pain during episodes of constipation in children with functional constipation (FC) is crucial because it helps interrupt the vicious cycle of stool withholding, painful defecation, and altered rectal physiology. Stool withholding, often triggered by improper toilet training and painful bowel movements, leads to the accumulation of dry, hard fecal masses in the rectum. These masses cause pain during elimination, encouraging continued withholding. This cycle can lead to megarectal dysfunction, characterized by an enlarged rectal capacity and reduced ability to expel stool, further reinforcing stool withholding and painful defecation. Untreated or poorly managed FC can result in significant complications, highlighting the importance of addressing pain management strategies to improve outcomes for children suffering from constipation (5,7-9).

Current treatments for painful defecation focus on addressing the underlying causes, such as constipation or anal fissures. Liquid paraffin, or paraffin, can help alleviate painful defecation by lubricating the stool and facilitating its passage by reducing friction. Pathophysiologically, paraffin softens the stool, making it easier to pass without straining, which can reduce pain during defecation. Liquid paraffin is a first-line therapy for constipation in North America and Australia, supported by established efficacy and long-term safety. The North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN) classifies it as a primary treatment for pediatric constipation, owing to its titratable dosing, favorable tolerability, and durable therapeutic effect in chronic cases (10-12). Its use is contraindicated in infants under one year of age due to the risks of aspiration and lipoid pneumonia (12). However, there has been no empirical testing of its additional effectiveness in reducing pain among children with functional constipation.

In this study, we aimed to evaluate the efficacy of adding paraffin to PEG in reducing pain and the severity of

constipation in children with chronic functional constipation.

2- METHODS

2-1. Design and Participants

This single-center randomized controlled trial utilized a parallel design with a 1:1 allocation ratio. It was conducted independently, without any influence from commercial entities, at Amirkabir Hospital in Arak, Iran, from September 2022 to January 2023. One hundred forty-eight participants were randomly assigned to either the intervention or comparison groups. The interventions consisted of either 0.7 g/kg/day PEG plus 0.7 ml/kg/day oral paraffin or 0.7 g/kg/day PEG alone for three months, the most common dosage in previous trials (13).

The study included children aged 2-18 who had been diagnosed with functional constipation for at least three months, which was as this age range encompasses a broad spectrum of pediatric patients. The diagnosis of functional constipation was based on the Rome IV Criteria (Figure 1).

Exclusion criteria included patients with organic causes of constipation, allergies to study medications, or current use of other constipation treatments. Children with metabolic disorders (e.g., hypothyroidism), anatomical abnormalities (e.g., Hirschsprung disease), neurological conditions, developmental delays, or mental health issues affecting bowel function were also excluded. To rule out organic causes, a thorough clinical evaluation was performed, including a detailed medical history, physical examination, relevant laboratory tests (e.g., thyroid function), and abdominal X-rays when necessary.

Written informed consent was obtained from the parents of the patients, and the study protocol was approved by the ethics committee at Arak University of Medical Sciences (IR.ARAKMU.REC.1401.109). The study was registered at the Iranian Registry of Clinical Trials (www.irct.ir) with registration number ID: IRCT20141209020258N179.

2-2. Sample Size and Randomization

The sample size was calculated using the following formula:

$$n = \frac{\left(z_{\left(1-\frac{\alpha}{2}\right)} + z_{(1-\beta)}\right)^2 (\delta_1^2 + \delta_2^2)}{\left(\mu_{1-\mu_2}\right)^2}$$

- Confidence Level: 95%
- Power(β): 80%
- Effect size($\mu_{1-\mu_2}$): 0.4
- δ_1^2: 1.49
- δ_2^2: 0.64

Based on this formula and previous studies, the sample size of each group was calculated as 74. We utilized Research Randomizer, a free online tool, and blocked randomization with a block size of 4 to randomly assign the included patients. Medications were prepared in identical packages and numbered consecutively according to the random sequence. The person who enrolled the participants was unaware of the randomization sequence.

2-3. Blinding

Our trial was initially planned to have a single-blind design, but this proved unfeasible due to the different forms of interventions: PEG alone versus PEG combined with liquid paraffin. Because the treatments differed visibly, blinding participants was impractical. We chose to forgo blinding in order to ensure proper treatment administration and a clear understanding of the participants. This decision was carefully considered and did not compromise the study's validity, allowing for a clearer assessment of each treatment outcome. Although blinding is important, the intervention differences necessitated this protocol adjustment.

2-4. Outcome Assessment

The primary outcome measures were stool consistency, frequency, and painful defecation. The secondary outcome measures included adverse events such as encopresis, abdominal pain, nausea and vomiting, and diarrhea. Data were recorded in standardized forms for each patient at baseline and on day 120 of the study.

Patients in both groups underwent scheduled assessments at baseline (day 0) and on day 120 after enrollment. On day 120, patients were also asked about adverse events during medication use. The person assessing the outcomes was unaware of the patients' assignments, although the patients themselves were not blinded.

2-5. Statistical Analysis

If the data were normally distributed, the mean and standard deviation were used to present continuous variables. We utilized a t-test, one-way analysis of variance (ANOVA), and repeated measures analysis to compare means in our data. For categorical data, we used numbers and percentages to present data and the chi-squared test to compare groups IBM SPSS Statistics 21 software was used for data analysis, with a p-value of 0.05 or lower considered statistically significant.

We used MedCalc to calculate the mean difference and 95% confidence intervals as the effect size for the continuous outcomes based on the group's mean, standard deviation, and sample size.

We calculated numbers needed to treat (NNT) and its confidence interval for categorical outcomes using an online calculator based on the rate of patients who responded to the treatment in each group (14).

Following criteria should be present for at least 3 months with symptom onset at least 6 months prior to diagnosis

1	Presence of ≥2 of the following symptoms: • Lumpy or hard stools (Bristol Stool Form Scale 1–2) in >25% of defecations • Straining during >25% of defecations • Sensation of incomplete evacuation for >25% of defecations • Sensation of anorectal obstruction/blockage for >25% of defecations • Manual maneuvers to facilitate >25% of defecations (digital manipulations, pelvic floor support) • <3 spontaneous bowel movements per week
2	Loose stools rarely present without the use of laxatives
3	Insufficient criteria for irritable bowel syndrome

Though a 2-week bowel diary is recommended, in Rome IV criteria, it has been suggested that as an alternative for clinical and epidemiological purpose, sub-typing can be done based on patients' reported pattern of stool types during the periods with abnormal bowel movement without laxative

Figure-1: Rome IV Criteria.

3- RESULTS

At the start of the study, 160 patients were evaluated for eligibility. A total of 12 patients were excluded; 2 declined to participate, 5 did not meet the inclusion criteria, and 5 did not participate for other reasons. Eligible participants were then enrolled and randomly assigned to either the PEG plus Paraffin or PEG treatment groups. Throughout the study, these 148 participants were consistently monitored for treatment compliance, adverse effects, and any changes in their conditions. Importantly, no participants were lost to follow-up. Figure 2 provides a flow chart detailing the selection of patients for analysis.

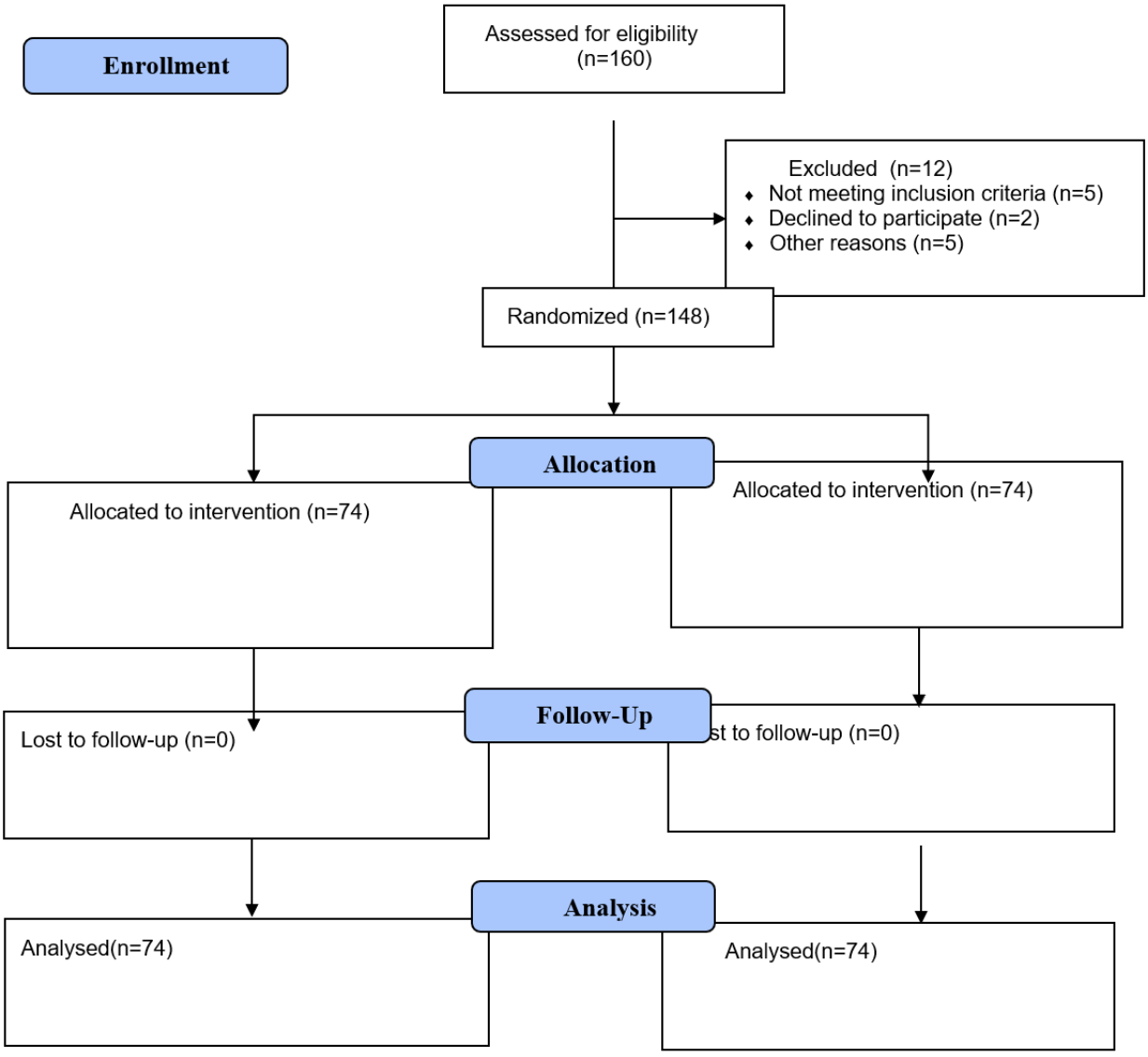

Figure-2: Consort participants' flow diagram.

Table-1: Participants' baseline characteristics.

		PEG + paraffin mean ± standard deviation	PEG mean ± standard deviation
Age (years)		6.29 ± 3.65	6.66 ± 3.3
Gender	**Male**	30 (40.5%)	38 (51.4%)
	female	44 (59.5%)	36 (48.6%)
Weight(kilograms)		23.41 ± 13.82	26.6 ± 13.52
Height(centimeters)		111.5 ± 18.95	118.5 ± 20.31
Duration of constipation (months)		14.73 ± 22.1	16.82 ± 22.07
Numbers of defecation (per week)		2.78 ± 2.22	2.77 ± 1.74
Painful defecation	**yes**	66 (89.2%)	58 (78.4%)
	no	8 (10.8%)	16 (21.6%)
Stool consistency	**Hard and lumpy**	72 (97.3%)	73 (98.6%)
	Smooth	2 (2.7%)	1 (1.4%)
	loose	0	0
incontinency	**yes**	9 (12.2%)	10 (13.5%)
	no	65 (87.8%)	64 (86.5%)
Abdominal pain	**yes**	67 (90.5%)	59 (79.7%)
	no	7 (9.5%)	15 (20.3%)
History of laxative intake	**yes**	12 (16.2%)	14 (18.9%)
	no	62 (83.8%)	60 (81.1%)

The demographic and clinical characteristics of the two groups were similar. The PEG plus Paraffin group was slightly younger, with a mean age of 6.29 ± 3.65, compared to the PEG group, with a mean age of 6.66 ± 3.3. However this difference was not statistically significant. The proportion of female and male participants was nearly equal. Additionally, the average weight and height of both groups showed comparable values (Table 1).

Table-2: Results for primary outcomes.

		PEG + paraffin mean ± standard deviation	PEG mean ± standard deviation	P value
Numbers of Defecation (per week)		7.43 ± 3.31	7.09 ± 3.69	0.55
Painful defecation	**yes**	1 (1.4%)	5 (6.8%)	0.02
	no	73 (98.6%)	69 (93.2%)	
Stool consistency	**Hard And lumpy**	3 (4.1%)	15 (20.3%)	0.001
	smooth	41 (55.4%)	46 (62.2%)	
	loose	30 (40.5%)	13 (17.6%)	

The addition of paraffin had a significant effect on decreasing the number of patients with painful defecations (NNT= 1.09, 95%CI: 1 to 1.2). Also, the rate of hard and lumpy stool consistency decreased significantly in the PEG+paraffin group (NNT= 6.17, 95%CI: 3.8 to 16.6). However, the number of defecation per week did not differ between the PEG + Paraffin and the PEG group at the end of the study (mean difference= 0.34 , 95%CI: -0.7989 to 1.4789) (Table 2).

We also assessed adverse events during the study period. The rate of adverse events, including stool incontinence, abdominal pain, nausea and vomiting, and diarrhea, did not significantly differ between groups (Table 3).

Table-3: Results for secondary outcomes

		PEG + paraffin mean	PEG mean	P value
Stool incontinence	**yes**	1 (1.4%)	1 (1.4%)	1
	no	73 (98.6%)	73 (98.6%)	
Abdominal pain	**yes**	5 (6.8%)	10 (13.5%)	0.17
	no	69 (93.2%)	64 (86.5%)	
History of Laxative intake	**yes**	12 (16.2%)	14 (18.9%)	0.66
	no	62 (83.8%)	60 (81.1%)	
Nausea And vomiting	**yes**	1 (1.4%)	1 (1.4%)	1
	no	73 (98.6%)	73 (98.6%)	
Diarrhea	**yes**	4 (5.4%)	2 (2.7)	0.4
	no	70 (94.6%)	72 (97.3)	

4- DISCUSSION

We found that adding paraffin to PEG substantially decreased the rate of painful defecation compared to PEG alone in children with functional constipation. Adding paraffin to PEG also improved stool consistency compared to PEG alone. However, we did not find any additional benefit of adding paraffin to PEG on the number of defecations in children with constipation. Regarding safety, no difference in the rate of adverse events was observed between the paraffin+PEG and PEG-alone groups.hese findings show that adding paraffin can have a significant effect on the rate of painful defecation and can improve stool consistency without causing any additional adverse events.

We did not find any studies that were identical to our study. However, the most relevant study by Moslemi Nia et al. randomly assigned children to two groups: one received polyethylene glycol-senna-paraffin (experimental), and the other polyethylene glycol-senna (control). Both treatments reduced abdominal and rectal pain, anal discomfort, and stool diameter, but adding paraffin shortened the treatment duration for functional constipation in children (15). In contrast with this study's findings, we found that adding paraffin reduced the rate of painful defecation. However, we did not assess the time required for the treatment response. This difference may be due to the addition of Senna to treatment in both groups in Moslemi Nia’s study, which may reduce

painful defecation to an optimal level and make adding paraffin redundant.

Xiong et al. (2023) demonstrated the benefit of adding castor oil as a lubricant to PEG for its potential to promote bowel evacuation. The results of this study indicated that PEG combined with castor oil is an effective and safe regimen for bowel cleansing and is relatively affordable, making it suitable for wider use. The study also found that the combination of these two drugs resulted in a decrease in PEG consumption. This study's findings align with our findings in that adding a lubricant facilitated bowel evacuation (16).

The clinical trial conducted by Rafati et al. (2011) compared the efficacy of PEG 3350 and liquid paraffin and showed no difference in treating chronic functional constipation in children. Both medications were found to be safe and effective in this age group (11). In contrast with this study, another study comparing the effects of paraffin and PEG on pediatric bowel function showed a significant superiority of PEG in the number of bowel movements per week, encopresis, and rectal pain reduction. The study indicates that PEG is more effective than oral liquid paraffin for pediatric constipation. These studies compared the efficacy of PEG and paraffin. However, in our study, PEG was considered the baseline treatment in both groups, focusing on the benefit of combining PEG and paraffin (11). In contrast, another study that compared the efficacy of paraffin and PEG for functional constipation demonstrated that paraffin had a better therapeutic effect in children younger than three years.

Our randomized controlled trial on the efficacy of adding paraffin to PEG for functional constipation in children is valuable due to its practical significance in evaluating pain as an essential outcome in children's functional constipation. This trial is the first to focus on pain as a primary outcome and the first to assess the effect of the combination of PEG and paraffin compared to PEG alone. As a pediatric laxative, liquid paraffin has been widely accepted for managing childhood constipation. The drug acts primarily as a stool lubricant, reducing the pain caused by certain conditions such as piles (hemorrhoids), making it an ideal treatment for chronic childhood constipation and encopresis when large doses or long-term usage is necessary.

Although our trial did not reveal any adverse events, addressing safety concerns associated with paraffin is crucial. Liquid paraffin can pose significant risks for certain patients, particularly those with a history of aspiration or respiratory issues, as inhalation may lead to lipid pneumonia. Additionally, prolonged use of liquid paraffin can result in dependency and disrupt normal bowel function. Paraffin is often considered equivalent to mineral oil in terms of dosing and administration; both substances act as lubricants to facilitate stool passage. While mineral oil is commonly used in the United States, paraffin is more frequently utilized in other regions. The typical dosage for mineral oil is between 1 to 3 teaspoons (approximately 5 to 15 ml) for children, depending on their age and specific needs. In contrast, paraffin can be dosed at approximately 0.5 to 1 ml/kg/day. Therefore, while paraffin can be a valuable adjunct in managing painful defecation, clinicians must carefully weigh these safety considerations against its benefits when formulating treatment plans for pediatric patients (17).

The study's limitations include the lack of long-term follow-up and blinding, which may underestimate the effects of adding paraffin or introduce reporting bias. Given the differential impacts of laxatives in different age groups, the study would have benefited from subgroup analyses for age groups if the sample size had sufficed. Also, outcome assessment at different time

intervals from the intervention would have provided useful information on the onset and durability of the effects of paraffin and PEG on different study outcomes. Future researchers may implement these points in the trial designs.

5- CONCLUSION

This study showed that adding paraffin to PEG safely and significantly reduced painful defecation and improved stool consistency among children with chronic functional constipation. However, there was no additional benefit in reducing the severity of constipation.

6- ABBREVIATIONS

PEG: Polyethylene Glycol; **ANOVA:** Analysis of Variance; **NNT:** Numbers Needed to Treat; **FC:** Functional Constipation; **MOM:** Milk of Magnesia; **IR:** Iranian Registry; **IRCT:** Iranian Registry of Clinical Trials; **PFC:** Pediatric Functional Constipation.

7- DECLARATIONS

7-1. Ethics Approval and Consent to Participate

Written informed consent was obtained from the patient's parents, who provided written informed consent. The study protocol was approved by Arak Medical University's ethics committee (IR.ARAKMU.REC.1401.109).

We confirm that all methods employed in this study were conducted in accordance with the relevant guidelines and regulations. Specifically, all procedures involving human participants adhered to the ethical standards set forth by the institutional and national research committees, as well as the principles outlined in the 1964 Helsinki Declaration and its subsequent amendments. Additionally, informed consent was obtained from all individual participants involved in the study, ensuring that their rights and welfare were prioritized throughout the research process.

7-2. Consent for Publication

All authors read and approved the final manuscript.

7-3. Availability of Data and Materials

The data supporting the findings of the study titled "Polyethylene glycol plus paraffin vs. Polyethylene glycol alone: Which is more effective in treating pediatric functional constipation? A Randomized controlled clinical trial" are available upon reasonable request from the corresponding author, Nooshin Sajjadei (nooshin1sadjadei@gmail.com).

The original data generated during this research, including participant demographics and outcomes related to painful defecation and stool consistency, will be provided in a de-identified format to protect participant privacy.

7-4. Competing Interests

The authors declare that they have no competing interests.

8- FUNDING

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