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ORIGINAL ARTICLE

Outcome of Various Treatments for Functional Constipation in Children at a Tertiary Care Hospital: A Randomized Clinical Trial

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ABSTRACT

Objective: To compare the efficacy of saline enema, polyethylene glycol (PEG), and their combination in children with functional constipation over an eight-week period.

Study Design: Randomized clinical trial.

Place and Duration of Study: Department of Pediatric Surgery Unit-II, The Children's Hospital, Lahore from October 2023 to July 2024.

Material and Methods: Ninety children diagnosed with functional constipation were randomly assigned to one of three groups: saline enema (Group 1), PEG (Group 2), and combined therapy (Group 3). Evaluations were conducted at baseline, and at the 2nd, 4th, and 8th weeks. Outcome measures included pain during defecation, number of bowel movements, fecal soiling, stool consistency and complications. Data were analyzed using SPSS version 25.

Results: Significant improvement in functional constipation were observed in the PEG and combined therapy groups compared to the saline enema group. Pain during defecation was eliminated in 100% of patients in the PEG and combined groups, whereas 33.3% of patients in the saline enema group continued to experience pain. Number of bowel movements increased notably in the PEG and combined groups, with most patients achieving 4 to 7 bowel movements per week. Fecal soiling was entirely resolved in the PEG and combined groups but persisted in 36.7% of the saline enema group. Stool consistency improved in the PEG and combined groups, with most patients achieving normal stool form (Bristol Stool Chart scores of 3 or 4).

Conclusion: PEG as sole or in combination with saline enema significantly more effective than saline enema in managing pediatric functional constipation.

Key Words: *Functional constipation, Pediatric, Polyethylene glycol, Saline, Bowel movements, Fecal soiling, Stool consistency*.

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INTRODUCTION

Functional constipation is a prevalent condition in children impacting their quality of life. It is characterized by infrequent, difficult, or painful defecation, which can result in fecal soiling, abdominal pain, and reduced appetite. The

etiology of functional constipation is multifactorial, involving dietary habits, behavioral factors, and sometimes underlying medical conditions.[1,2]

Management strategies for functional constipation vary widely, ranging from dietary modifications and behavioral interventions to pharmacological treatments. Polyethylene glycol (PEG) has been widely studied and is recommended as a first-line treatment due to its efficacy and safety profile.[3] Comparatively, lactulose and other laxatives have also been used but often present with more side effects and lower efficacy.[4] Various types of enemas are also used in the management of children with functional constipation.[5]

Despite these treatment options, a significant proportion of children with functional constipation remain refractory to initial management and require referral to tertiary care for more specialized interventions.[6]

This underscores the importance of effective management strategies that not only address the gastrointestinal symptoms but also improve overall well-being and quality of life. In our study, we aimed to evaluate and compare the efficacy of three different treatment regimens — saline enema, PEG, and a combined therapy — in managing functional constipation in children. We also sought to assess the impact of these treatments on key outcome measures such as pain during defecation, frequency of bowel movements, fecal soiling, and stool consistency, using standardized scales like the Bristol Stool Chart.[7]

MATERIAL AND METHODS

Study Design: This study is a randomized clinical trial conducted at the Department of Surgery Unit-II, The Children's Hospital, Lahore between October 2023 to July 2024.

Inclusion Criteria: All patients between 1 year to 12 years with functional constipation were include in the study. Patients who had delayed passage of meconium, anorectal malformations, whose parents/guardian refused to participate and those who were lost the follow up were excluded.

Ethical Considerations*:* Approval from the institutional review board of the hospital was obtained (letter number:839/CH-UCHS). The legal guardians of the patients gave consent for participation in the study.

Data Collection Procedure: All patients presenting in the surgical outpatient department and diagnosed with functional constipation, meeting the inclusion criteria, were registered. Informed consent was obtained from the parents or guardians for using the patients' data in this research. Information such as name, age, gender, and address were recorded. Data were collected through clinical history and physical examination, guided by the Rome IV criteria for diagnosing functional constipation.[8]

Patients were randomly assigned into three groups:

Group 1: Saline enema (10 ml/kg/enema twice a day, administered per rectally);

Group 2: Polyethylene glycol (PEG) (0.4 g/kg/day diluted in water or juices and administered per orally in two divided portions);

Group 3: Combined approach (PEG + saline enema); (in the dosages as described above)

The management of functional constipation was based on four pillars:

1. Education: Patients and guardians about the physical dynamics of defecation, contributing factors, social issues, and the importance of compliance and dietary modifications were educated.

2. Fecal Disimpaction: Achieved using oral laxatives, enemas, or a combination of both to empty the colon and rectum of hardened fecal masses.

3. Maintenance Therapy/Prevention of Reaccumulation*:* Fecal reaccumulation was prevented using pharmacological agents (PEG, lactulose) and non-pharmacological methods (fiber and water intake, pelvic floor physiotherapy, toilet training, abdominal massage).

4. Follow-Up: Follow-ups were conducted at the 2nd, 4th, and 8th weeks to monitor treatment outcomes.

Outcome Measures

Outcome variable were: 1. Pain during defecation; 2. number of bowel movements per

week; 3. episodes of fecal soiling per week; 4. grades of stool consistency (using the Bristol Stool Chart); 5. any complications related to the therapy

Data analysis: The collected data were entered and analyzed using SPSS version 25. Qualitative variables (gender, type of treatment, complications of treatment) were analyzed using percentages and frequencies. While mean and standard deviation were calculated for quantitative variables (age, weight, duration of constipation). Variables (age, duration of constipation, number of stools per week, grades of stool consistency) were analyzed using ANOVA and post-hoc comparisons while (pain during defecation, fecal soiling) were analyzed using Chi-square test and the level of significance was accepted as <0.05 in all statistical analyses.

RESULTS

Age, gender, weight and duration of constipation

This study included a total of 90 patients, with 30 participants assigned to each group. There were 51 males and 39 females. The distribution and significance of these patients in each group as to age, weight, gender and duration of constipation is given in table 1.

TABLE 1: Demographic Data

Variables	Group 1 (Saline Enema)	Group 2 (peg)	Group 3 (Combined)	p value
Age (Mean ± SD)	47.57(± 37.94)	54.23(± 41.69)	63.57(± 40.17)	0.302
Gender (Male/Female)	18/12	19/11	14/16	0.395
Weight (Mean ± SD)	12.87 ± 5.96	15.93 ± 7.31	16.40 ± 6.51	0.087
Duration of constipation (Mean ± SD)	17.80±16.25	18.83±16.46	16.80±12.96	0.132

Inferential analysis:

Pain during defecation: The combined treatment of PEG and saline enema, as well as PEG alone, tend to be more effective in reducing pain during defecation compared to saline enema alone, particularly notable at 4- and 8-weeks post-treatment. The differences became statistically significant over time, with PEG and combined treatments showed a higher rate of pain resolution compared to saline enema. Table -2 shows frequency of patients in each group and the p-values are less than 0.05, indicating a significant difference in pain during defecation among the treatment groups at 4 and 8 weeks.

TABLE 2: Pain during defecation over 8 weeks

Pain during defecation	Saline enema (%)	PEG (%)	Combined (PEG+ Saline Enema) {%}	p value
Pain during defecation at presentation	23(30.3)	26(36.2)	27(35.5)	0.333
Pain during defecation after 2weeks	20(42.6)	14(29.8)	13(27.7)	0.147
Pain during defecation after 4 weeks	15(68.2)	5(22.7)	2(9.1)	0.000
Pain during defecation after 8 weeks	10(100.0)	0(0.0)	0(0.0)	0.000

Fecal soiling per week: While there are no significant differences in fecal soiling among the treatments at baseline and 2 weeks, significant differences emerge at 4 and 8 weeks. PEG and combined treatments generally lead to less fecal soiling compared to saline enema, particularly evident at the 4 and 8-week marks. Table -3 shows frequency of patients in each group and the p-values are less than 0.05, indicating a significant difference in pain during defecation among the treatment groups at 4 and 8 weeks.

TABLE 3: Fecal soiling per week over 8 weeks

Fecal soiling per week	Saline enema (%)	PEG (%)	Combined (PEG+ Saline Enema) {%}	p value
Fecal soiling per week at presentation	22(31.9)	22(31.9)	25(36.2)	0.572
Fecal soiling per week after 2 weeks	21(38.9)	18(33.3)	15(27.8)	0.287
Fecal soiling per week after 4 weeks	19(59.4)	8(25.0)	5(15.6)	0.000
Fecal soiling per week after 8 weeks	11(100.0)	0(0.0)	0(0.0)	0.000

Number of stools per week*:* The ANOVA results and subsequent post-hoc tests reveal that at 2, 4, and 8 weeks, there are significant differences in the number of bowel movements among the treatment groups. Post-hoc analysis shows that PEG and the combined treatment (PEG + saline enema) tend to differ significantly from saline enema, often demonstrating better outcomes.

In short, PEG and combined treatments resulted in a higher number of bowel movements compared to saline enema, with these differences becoming more pronounced over time.

TABLE 4: Number of stools per week over 8 weeks

Number of stools per week	Saline enema	PEG	Combined (PEG+ Saline Enema)	p value
Number of stools at presentation	1.80	1.70	1.83	0.715
Number of stools after 2 weeks	1.90	3.83	5.17	0.000
Number of stools after 4 weeks	3.07	6.07	10.30	0.000
Number of stools after 8 weeks	3.80	8.97	13.10	0.000

Grades of Stool consistency: The ANOVA results and subsequent post-hoc tests reveal that significant differences in grade of stool consistency can be observed at 2, 4 and 8 weeks. Post-hoc analysis shows that PEG is better than saline enema, and combined therapy is also better than Saline enema but similar to PEG. Overall, PEG tends to show the most consistent and favorable results in stool consistency at 2, 4, and 8 weeks compared to Saline enema. Combined treatment shows intermediate results, with no significant difference from PEG but better than Saline enema.

TABLE 5- Grades of Stool consistency over 8 weeks

Grades of Stool consistency	Saline enema	PEG	Combined (PEG+ Saline Enema)	p value
Grades of Stool consistency at presentation	1.57	1.43	1.50	0.595
Grades of Stool consistency after 2 weeks	1.77	2.60	2.83	0.000
Grades of Stool consistency after 4 weeks	2.40	3.87	4.17	0.000
Grades of Stool consistency after 8 weeks	2.97	5.17	5.10	0.000

Complications of treatment: PEG is mostly associated with diarrhea 8(26.7%) patents, which may be a common side effect of osmotic laxatives. Saline enema shows higher occurrences of bleeding and pain 5(16.7%) and 7(23.3%) patients respectively, which may be related to the mechanical and irritative nature of enemas. Combined treatment has minimal complications, with some pain reported 2(6.7%) patients, but no bleeding or diarrhea table 6.

TABLE 6: Complications related to each treatment group

Outcomes	Group 1 (Saline enema) {%}	Group 2 (peg) {%}	Group 3 (Combined) {%}
Complications			
Diarrhea		8(26.7)	
Painful Enema	7(23.3)		2(6.7)
Bleeding with Enema	5(16.7)		
None	18(60.0)	22(73.3)	28(93.3)

Summary: At the 8th week follow-up, the combination therapy (Group 3) and PEG therapy (Group 2) showed superior outcomes compared to the saline enema group (Group 1) in all assessed parameters. Pain during defecation was completely eliminated in Groups 2 and 3, while it persisted in 33.3% of patients in Group 1. Fecal soiling was also absent in Groups 2 and 3 but remained prevalent in Group 1. Stool consistency improved significantly in Groups 2 and 3 compared to Group 1. Additionally, complications were more frequent in Group 1, with a high incidence of pain with enema. The success rate was 100% in Groups 2 and 3, indicating that PEG and combined therapy are highly effective in managing the condition, whereas the saline

enema group had a lower success rate with some patients partially or not managed.

DISCUSSION

The management of functional constipation in children is challenging due to the multifaceted nature of the condition, which involves both physical and psychological components [9-11] Our study aimed to evaluate and compare the efficacy of saline enema, polyethylene glycol (PEG), and combined therapy over an eight-week period, focusing on pain during defecation, frequency of bowel movements, fecal soiling, and stool consistency.

By the end of the eighth week, significant improvements were noted in the PEG and combined therapy groups, with 100% of patients in both groups reporting no pain during defecation. In contrast, 33.3% of patients in the saline enema group still experienced pain. These findings align with previous research that highlights the superior efficacy of PEG over other treatments for alleviating pain during defecation.[2,3,8] PEG's mechanism, which increases stool water content and facilitates easier defecation, likely contributes to these outcomes.[9] Functional constipation is commonly managed with various laxatives, including Sodium picosulfate**,** lactulose, Senna**,** and Bisacodyl**.** Sodium picosulfate improves motility and stool consistency, often used in mild cases.[12]Lactulose works by drawing water into the colon, softening stools, and is effective for chronic constipation.[13] Senna**,** a stimulant laxative, promotes bowel motility but is recommended for short-term use due to risks of dependence.[14] Bisacodyl**,** another stimulant laxative, provides rapid relief for acute constipation but should be used cautiously to avoid long-term dependence.[15]

The number of bowel movements also improved markedly in the PEG and combined therapy groups. By week eight, the majority of patients in the PEG and combined groups had bowel movements ranging from 4 to 7 times per week, which is considered within the normal range for children.[1] The saline enema group, however, exhibited more variability and fewer weekly bowel movements, indicating less effective treatment. Although studies directly comparing PEG with saline enema are not found on literature search; Mansour et al. documented that the PEG is more effective than lactulose in increasing bowel movement frequency due to its osmotically active properties.[4]

A significant reduction in fecal soiling was observed in the PEG and combined therapy groups, with no patients reporting soiling at the end of the study period. In contrast, 36.7% of patients in the saline enema group continued to experience this issue. These results are consistent with the findings of de Campos et al., who reported that children with refractory functional constipation often exhibit reduced fecal soiling when treated with PEG. The ability of PEG to ensure regular bowel movements likely helps prevent fecal impaction and subsequent soiling.[6]

Stool consistency, assessed using the Bristol Stool Chart, showed notable improvements in the PEG and combined therapy groups. Most patients achieved a consistency score of 3 or 4, which indicates normal stool form. In the saline enema group, a higher prevalence of harder stools (score of 2) was observed. These findings resonate with the research by Heaton et al., which suggests that PEG helps maintain optimal stool consistency, thereby facilitating smoother and less painful bowel movements.[7]

Our study also evaluated the incidence of complications and overall success rates. Diarrhea was the most common complication in the PEG group (26.7%), aligning with previous reports that PEG can sometimes cause loose stools.[9] However, the overall success rate was highest in the PEG (100%) and combined therapy groups (100%), indicating full management of constipation symptoms. These outcomes support the conclusions of Mathew et al., who found PEG to be highly effective in treating pediatric constipation with minimal severe adverse effects.[3]

When treating functional constipation with saline enemas and polyethylene glycol (PEG), gradual tapering is essential to avoid dependency and restore normal bowel function. For saline enemas, the frequency should be reduced progressively, starting from daily use to every other day, then to twice a week, and eventually discontinued. PEG, typically used for chronic constipation, should be tapered by reducing the daily dose by 10-20% each week, while monitoring bowel function.[16]

Alongside tapering, patients should be encouraged to adopt dietary changes such as increased fiber and fluid intake to support natural bowel motility.[14]

The study has several limitations, including its single-center design and the relatively small sample size. However, it also has notable strengths. Specifically, our research compared the efficacy of saline enemas to polyethylene glycol (PEG) therapy in the management of functional constipation. While saline enemas are commonly used in local practice, there is a lack of published research on their effectiveness. This study addresses that gap by providing valuable insights into the efficacy of saline enemas for managing functional constipation.

CONCLUSION

In conclusion, our study reinforces the efficacy of PEG alone or in combination with saline enema over saline enema alone in managing functional constipation in children. PEG, due to its superior ability to alleviate pain during defecation, increase bowel movement frequency, reduce fecal soiling, and improve stool consistency, should be considered a first-line treatment. These findings contribute to the growing body of evidence supporting the use of PEG in pediatric functional constipation and highlight the importance of individualized treatment approaches for optimal patient outcomes.

Conflict of interest: None

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