Biological and Clinical Sciences Research Journal
eISSN: 2708-2261; pISSN: 2958-4728
www.bcsrj.com
DOI: https://doi.org/10.54112/bcsrj.v6i6.1993
*Biol. Clin. Sci. Res. J., Volume 6(6), **2025**: 1993*
Original Research Article

Comparison of Polyethylene Glycol 3350 and Lactulose for Treatment of Chronic Constipation in Children

Zunaira Azam[1]*, Nida Zarqoon[1], Sundas Shafique[1], Mehak Fatima[2], Haris Ali[3], Chaudhary Muhammad Awais[1], Mudassar Fiaz Gondal[1]

[1]Department of Pediatric Surgery, Holy Family Hospital, Rawalpindi Medical University, Rawalpindi, Pakistan
[2]CDA Hospital, Islamabad, Pakistan
[3]RHC, Dina, Pakistan
**Corresponding author`s email address:* aazamzunaira@gmail.com

(Received, 24th April 2025, Accepted 22nd June 2025, Published 30th June 2025)

Abstract: *Chronic functional constipation (CFC) is a prevalent gastrointestinal disorder characterized by persistent constipation without an identifiable organic cause. The pathophysiology of chronic functional constipation in children involves a complex interaction of behavioral, physiological, and dietary factors. Toilet training is crucial in helping to address functional constipation. The mainstay of pharmacological treatment of chronic functional constipation in adults and the pediatric population includes the use of laxatives.* ***Objective:*** *To compare the efficacy of Polyethylene Glycol 3350 and lactulose in the treatment of chronic constipation in children.* ***Methodology:*** *This study was a quasi-experimental study conducted from September 2024 to March 2025. After obtaining approval from the Ethical Review Board of Rawalpindi Medical University, the sample size of 86 patients was calculated using the Clincalc calculator, with a 95% confidence interval and 80% power, based on statistical literature. Simple non-random consecutive sampling was done. The study sample was divided into two groups, i.e., Group A and Group B. Each group included 43 patients. Patients were divided into two groups by lottery method. Group A included patients receiving PEG 3350, whereas Group B included patients receiving lactulose.* ***Results:*** *Eighty-six patients were selected for the study, fulfilling the sample selection criteria. The mean age of the study population was 5.20 +/-2.39 years. Fifty-three patients were males, i.e., 61.16% of the study population. The post-treatment frequency of stool per week was 3.74 ± 1.13 in group A and 3.30 ± 1.35 in group B, respectively. There was a significant improvement in stool frequency after 2 weeks of treatment in both groups. The treatment success, measured as the percentage of patients achieving success with the treatment in each group, was 72.1% in group A compared to 37.2% in group B. There was a statistically significant difference between the two groups in terms of treatment success, with a p-value of 0.009.* ***Conclusion:*** *The efficacy of Polyethylene Glycol 3350 formulation is significantly greater than that of the lactulose formulation in the treatment of chronic functional constipation in children. The treatment with PEG 3350 is associated with fewer adverse effects compared to lactulose.*

Keywords: chronic constipation, Polyethylene Glycol 3350, lactulose, encopresis

[***How to Cite:*** Azam Z, Zarqoon N, Shafique S, Fatima M, Ali H, Awais CM. Gondal MF. Comparison of polyethylene glycol 3350 and lactulose for treatment of chronic constipation in children. *Biol. Clin. Sci. Res. J.*, **2025;** 6(6): 468-471. doi: https://doi.org/10.54112/bcsrj.v6i6.1993

Introduction

Chronic functional constipation (CFC) is a prevalent gastrointestinal disorder characterized by persistent constipation without an identifiable organic cause (1). According to the Rome IV criteria, the global prevalence of chronic functional constipation is reported to be 14.4% of the general population (1). Common clinical manifestations include dry stools, low stool volume, difficulty defecating, poor defecation, and decreased frequency of defecation. Its symptoms might be persistent or recurrent (2).

A low-fiber diet, sedentary lifestyles, and changes in the gut microbiota may result in constipation (3). Stool withholding is the primary pathophysiological mechanism, while other significant roles are played by impaired rectal function, anal sphincter, pelvic floor, and colonic dysfunction (3). The incidence of chronic constipation in children is widely reported between 5 to 30% (4).

The pathophysiology of chronic functional constipation in children involves a complex interaction of behavioral, physiological, and dietary factors. A key component is voluntary stool withholding, often triggered by a previous painful defecation experience. This leads to prolonged stool retention, causing the colon to absorb excessive water from the feces, making it harder and more difficult to pass (5). Over time, the rectum becomes stretched and less sensitive to the urge to defecate, further worsening stool retention (5). This cycle can result in large, impacted stools and overflow incontinence. Additionally, inadequate fiber and fluid intake, along with a sedentary lifestyle, contribute to reduced colonic motility. Psychological stressors and toilet training difficulties also play a role. Importantly, no anatomical or biochemical abnormalities are present, distinguishing it from organic causes (6).

Diagnosis is typically clinical, based on history and physical examination (6). Functional constipation in children is clinically diagnosed using the Rome IV criteria, which include symptoms such as infrequent bowel movements, painful defecation, large or hard stools, and stool delaying behavior (7). A comprehensive medical history and physical examination are usually required to rule out organic causes of constipation. Typically, no particular imaging or laboratory tests are needed. Management involves education, dietary changes, behavioral strategies, and, in some cases, the use of laxatives. Early intervention is crucial for preventing complications and promoting healthy bowel habits, thereby improving the child's overall quality of life and development (7).

The management of chronic functional constipation can be classified as pharmacological and nonpharmacological treatment (8). The nonpharmacological treatment involves lifestyle changes and adjustments on behalf of children's parents. Toilet training is crucial in addressing functional constipation (9). Toilet training should ideally be initiated between 18 and 24 months and reinforced with parental support, as per recent published literature (10). The mainstay of pharmacological treatment of chronic functional constipation in adults and the pediatric population includes the use of laxatives (11). According to recently published data, lactulose and PEG 3350, combined with electrolytes, can both be used for the treatment of chronic functional constipation (11).

Lactulose is the most commonly used laxative for treating functional constipation in children (12). However, recent studies indicate that the effectiveness of PEG 3350 plus electrolytes is superior to that of lactulose in treating constipation. According to a recently conducted study, the frequency of patients with painful defecation after treatment with PEG 3350 was found to be 43.8% whereas it was 73.3% in patients who received lactulose (13). The dosage recommendation of lactulose as per the literature is a 6g/ day dosage of lactulose in children < 6 years of age and a 12g/ day dosage for children > 6 years of age. The recommended dose of PEG 3350 for children less than 6 years of age is 2-3g/day and 4-6g/day for children more than 6 years of age (14).

According to a recently conducted study in Syria, clinical outcomes after 12 weeks of treatment with lactulose and Polyethylene glycol 3350 formulation were significantly better for PEG 3350, with a 95% increase in defecation frequency in the PEG group compared to 77% in the lactulose group, with significantly fewer side effects (15). This study was conducted to compare the effectiveness and adverse effects of PEG 3350 and lactulose in the treatment of chronic functional constipation in children.

Methodology

The quasi-experimental study was conducted from September 2024 to March 2025. After obtaining approval from the Ethical Review Board of Rawalpindi Medical University, the study was conducted in the Department of Pediatric Surgery at Holy Family Hospital. A sample size of 86 patients was calculated using the Clincalc calculator, with a 95% confidence interval and 80% power, based on statistics from previous literature. Simple non-random consecutive sampling was done. Inclusion criteria for sample selection included children belonging to both genders, aged 1-13 years, presenting with chronic functional constipation with stool frequency < 3/ week and encopresis frequency >1/week. Exclusion criteria included children with a history of gastrointestinal surgery and those with diagnosed organic causes of constipation, such as Hirschsprung disease and anorectal malformations. A self-made, structured pro forma was used for data collection. Proper written informed consent was taken from the parents of all the patients included in the study. The study sample was divided into two groups using a lottery method, namely Group A and Group B. Each group included 43 patients. Literature was searched and reviewed for optimal safe and effective doses of PEG 3350 and lactulose for treatment of chronic functional constipation. Group A patients received Polyethylene Glycol PEG 3350 formulation in the form of a commercially available sachet MOVICOL (13g of PEG 3350). One sachet of MOVICOL was dissolved in 50 ml of distilled water, and children <6 years of age received a 5 ml twice-daily dose for 2 weeks, i.e., 2.6g of PEG 3350 daily divided into two doses. Children over 6 years received a 10 ml twice-daily dose of PEG 3350 preparation, i.e., 5.2g of PEG 3350 divided into two doses. Group B patients received a lactulose formulation in the form of commercially available Duphalac syrup (3.35g/5 mL lactulose). Children < 6 years of age received a 5 ml twice daily dose of lactulose, i.e., 6.7g daily dose of lactulose, whereas children > 6 years of age received a 10 ml twice daily dose of Duphalac, i.e., 13.4g daily dose of lactulose. Each patient included in the study was followed for a duration of 6 weeks. During the first two weeks of pretreatment, the frequency of stool and the frequency of encopresis were monitored in patients. The next 2 weeks included the treatment period. At the end of treatment, each patient was followed for the next 2 weeks, and post-treatment stool frequency and encopresis frequency were noted. Prior to treatment, each patient was administered an enema, specifically MICRONEMA, 30-50 ml, to remove any impacted stool. The data collected included quantitative variables such as age, frequency of stool prior to treatment, frequency of encopresis prior to treatment, frequency of stool after treatment, and frequency of encopresis after treatment. The efficacy of treatment was determined by the frequency of stools per week after treatment and the frequency of encopresis per week after treatment. Treatment success was defined as stool frequency >= 4 = 4/week post-treatment and encopresis frequency < 1/week for 2 weeks after treatment. Patients with successful treatment were noted for each group. Adverse effects of treatment were also noted for each treatment group and included abdominal pain, nausea, vomiting, and diarrhea. The primary outcome variable was treatment success, whereas the secondary outcome variable included the frequency of adverse events. Data was analyzed using the Statistical Package for the Social Sciences SPSS v 23.0. Means with standard deviations were used to represent continuous variables, such as age, frequency of stool before treatment, frequency of encopresis before treatment, frequency of stool after treatment, and frequency of encopresis after treatment. Frequencies with percentages were used to represent qualitative variables, such as gender, treatment success, and adverse effects. Both groups were compared for the primary and secondary outcome variables using the chi-square test. P-value < 0.05 was considered statistically significant. The outcome variable was stratified for effect modifiers, such as age and gender, using the chi-square test. P-value <0.05 was considered statistically significant.

Results

Eighty-six patients were selected for the study, fulfilling the sample selection criteria. The mean age of the study population was 5.20 +/-2.39 years. Fifty-three patients were males, accounting for 61.16%, whereas 33 females comprised 38.4% of the study population. The mean frequency of stools per week prior to treatment was 1.54 ± 0.50, and the mean frequency of encopresis prior to treatment was 1.62 ± 0.63. The mean frequency of stools per week in group A was 1.60 ± 0.49, compared to 1.48 ± 0.50 in group B. Compared to this, the frequency of stools per week was significantly increased in both groups after treatment with the respective agents.

The post-treatment frequency of stool per week was 3.74+/-1.13 in group A and 3.30+/-1.35 in group B, respectively. The pretreatment and posttreatment stool frequency and encopresis frequency were compared between the two groups using an independent sample t-test. There was an improvement in stool frequency after 2 weeks of treatment in both groups. There was a significant difference in posttreatment stool frequency between the two groups, with a p-value of 0.05. The demographic variables, along with quantitative variables, have been shown (Table 1).

The treatment success, measured as the percentage of patients achieving success with the treatment in each group, was 72.1% in group A compared to 37.2% in group B. There was a statistically significant difference between the two groups when comparing treatment success, with a p-value of 0.009. The secondary outcome, measured as the percentage of adverse events, was 11.6% in group A compared to 18.6% in group B. However, there was no statistically significant difference between the two groups when compared for adverse events, with a p-value of 0.274. Comparison of primary and secondary outcome variables between the two groups has been depicted (Table 2, 3).

The data were stratified for effect modifiers, such as age and gender, for the primary outcome variable, and a chi-square test was applied. There was no significant difference in age and gender between the two treatment groups, as shown (Table 4, 5).

Table 1- Comparison of demographic variables and study variables between the two groups.

	Frequency		
Study Variable	Group A	Group B	**P-value**
Age	5.05+/-2.40	5.34+/-2.39	-
Gender			-

Male Female	31 12	22 21	
Pretreatment frequency of stools per week	1.60+/-0.49	1.48+/-0.50	0.17
Posttreatment frequency of stools per week	3.74+/-1.13	3.30+/-1.35	0.05
Pretreatment encopresis frequency	1.67+/-0.60	1.58+/-0.66	0.49
Posttreatment encopresis frequency	0.51+/-0.073	0.767+/-0.06	0.09

Table 2 - Comparison of the Primary outcome variable between the study groups

Study Group	Treatment Success		p-value
	Yes	No	
Group A	28	15	0.009
Group B	16	27	
Total	44	42	86

Table 3 - Comparison of secondary outcome variables between the study groups

Study Group	Adverse Events		p-value
	Yes	No	
Group A	5	38	0.27
Group B	8	35	
Total	13	73	86

Table 4 - Stratification of treatment success between the two study groups with respect to age

Study Group	Age	Treatment Success		p-value
		Yes	No	
Group A	<6 years	12	17	0.10
	≥6 years	4	10	
Group B	<6 years	19	12	0.32
	≥6 years	9	3	

Table 5 - Stratification of treatment success between the two study groups with respect to gender

Study Group		Treatment Success		p-value
	Gender	Yes	No	
Group A	Male	19	12	0.318
	Female	9	3	
Group B	Male	10	12	0.204
	Female	6	15	

Discussion

The results of this study indicate that the Polyethylene Glycol 3350 formulation is more effective in treating chronic functional constipation in children compared to the lactulose formulation. This finding is consistent with recently published data on the efficacy of PEG 3350 in treating chronic constipation compared to lactulose (13). Similarly, a recently conducted study in Pakistan established the superior efficacy of PEG 3350 over lactulose, with 91% treatment success in the PEG 3350 group compared with 50% in the lactulose group (16).

Comparing the adverse events following treatment with PEG 3350 and lactulose, no statistically significant difference was found in this study. According to recently published data, PEG 3350 is associated with fewer adverse events, such as vomiting and nausea (17). Similarly, Hassan et al state that the frequency of adverse events following treatment with PEG 3350 was 4.3% compared to 10.6% in the case of treatment with lactulose. This difference, however, was not found to be statistically significant, with a p-value of 0.221 (18). There is a paucity of data when comparing the adverse effects of either of the two treatment regimens. Some studies suggest a lower frequency of adverse events with Polyethylene Glycol 3350 compared to lactulose; however, statistically significant differences could not be established in recently published data (18, 19, 20). The results of this study are also consistent with the trend of adverse events published in international data. The adverse events in treatment were encountered less frequently in the PEG 3350 group as compared to the lactulose group, i.e., 11.6% versus 18.6%. However, this difference was not statistically significant.

The post-treatment stool frequency was significantly greater than the pretreatment frequency for both groups, i.e., the PEG and lactulose groups. However, the efficacy of PEG was found to be significantly greater with nearly comparable adverse events. The post-treatment encopresis frequency was significantly lower compared to the pretreatment frequency in both treatment groups. According to Bareera et al., post-treatment defecation frequency with PEG 3350 was found to be 4-7/ week.[21] This is consistent with the results of this study, where the mean post-treatment defecation frequency in the PEG 3350 group was 3.74+/-1.13. While the results of treatment with PEG 3350 for chronic constipation are promising, the tolerability of PEG 3350 is also well established in the pediatric population (21).

Upon stratification analysis, no significant impact of age could be established on the treatment success of either of the two drugs. Jorge Lopez et al. evaluated the efficacy of PEG 3350 in treating chronic functional constipation in children (22). It was concluded that PEG 3350 is more effective in treating children under 2 years old, with 79.5% of children below 2 years responding well to the treatment (22). The results of this study indicate a significant effect of age on treatment success. This implies that PEG 3350 can be used in the pediatric population, irrespective of age, with equal efficacy. However, more targeted studies are needed to advocate this implication.

Conclusion

The efficacy of the Polyethylene Glycol 3350 formulation is significantly greater than that of the lactulose formulation in the treatment of chronic functional constipation in children. The treatment with PEG 3350 is associated with fewer adverse effects compared to lactulose.

Declarations

Data Availability statement

All data generated or analysed during the study are included in the manuscript.

Ethics approval and consent to participate

Approved by the department concerned. (IRBEC-24)

Consent for publication

Approved

Funding

Not applicable

Conflict of interest

The authors declared the absence of a conflict of interest.

Author Contribution

ZA (Postgraduate Trainee)
Manuscript drafting, Study Design,
NZ (Postgraduate Trainee)
Review of Literature, Data entry, Data analysis, and drafting an article.
SS (Postgraduate Trainee) **& MF**
Conception of Study, Development of Research Methodology Design,
HA (Medical Officer)
Review of Literature, Data entry, Data analysis, and drafting an article.
CMA (PGT)
Conception of Study, Development of Research Methodology Design,
MFG (Associate Professor)
Supervised the study, provided expert guidance, critically reviewed the manuscript, and approved the final version

All authors reviewed the results and approved the final version of the manuscript. They are also accountable for the integrity of the study.

References

1. Classen M, Enck P, Katzer L, Reppin K, Keller F, Hillemacher T. Constipation in children and adolescents. Dtsch Ärztebl Int. 2022 Oct;119(41):697–708. https://doi.org/10.3238/arztebl.m2022.0309
2. Kilgore A, Khlevner J. Functional constipation: pathophysiology, evaluation, and management. Aliment Pharmacol Ther. 2024 Jul;60(S1):S20–S29. https://doi.org/10.1111/apt.17852
3. Kumar K, Srivastava A, Yachha SK, Poddar U, Singh H. Functional constipation: a common and often overlooked cause for abdominal pain in children. Indian J Gastroenterol. 2023 Apr;42(2):274–278. https://doi.org/10.1007/s12664-022-01329-1
4. Rajindrajith S, Devanarayana NM, Crispus Perera B, Benninga MA. Childhood constipation: current status, challenges, and future perspectives. World J Clin Pediatr. 2022 Sep;11(5):385–404. https://doi.org/10.5409/wjcp.v11.i5.385
5. Todhunter-Brown A, Dretzke J, Fraser C, Hounsome J, Hui A, Harker R, et al. Strategies used for childhood chronic functional constipation: the SUCCESS evidence synthesis. Health Technol Assess. 2024 Jan;28(5):1–266. https://doi.org/10.3310/PLTR9622
6. Tran DL, Sintusek P. Functional constipation in children: what physicians should know? World J Gastroenterol. 2023 Feb;29(8):1261–1288. https://doi.org/10.3748/wjg.v29.i8.1261
7. Khayat A, Algethami G, Baik S, Alhajori M, Banjar D. The effect of using Rome IV criteria on the prevalence of functional abdominal pain disorders and functional constipation among children of the Western Region of Saudi Arabia. Glob Pediatr Health. 2021 May;8:2333794X211022265. https://doi.org/10.1177/2333794X211022265
8. de Geus A, Haitsma M, Tabbers MM. An update of pharmacological management in children with functional constipation. Pediatr Drugs. 2023 May;25(3):343–358. https://doi.org/10.1007/s40272-023-00565-9
9. Fedele F, Pallotta N, Tabbers MM, Staiano A. The ten "hard" questions in pediatric functional constipation. Ital J Pediatr. 2024 Apr;50(1):64. https://doi.org/10.1186/s13052-024-01623-y
10. Pan Y, Jiao FY. Addressing functional constipation in children: a call for comprehensive and collaborative management. World J Gastroenterol. 2025 Feb;31(7). https://doi.org/10.3748/wjg.v31.i7.98889
11. Dheivamani N, Prasad N, Venkatesan M, Srinivasan R. Efficacy of polyethylene glycol 3350 as compared to lactulose in treatment of ROME IV criteria–defined pediatric functional constipation: a randomized controlled trial. Indian J Gastroenterol. 2021 Apr;40(2):227–233. https://doi.org/10.1007/s12664-021-01148-w
12. Isa HM, Alkharsi FA, Salman FA, Ali MS, Abdulnabibi ZK, Mohamed AM. Assessing indicators and clinical differences between functional and organic childhood constipation: a retrospective study in pediatric gastroenterology clinics. Clin Exp Pediatr. 2023 Jul;66(7):296–303. https://doi.org/10.3345/cep.2022.01298
13. Vriesman MH, Koppen IJN, Camilleri M, Di Lorenzo C, Benninga MA. Management of functional constipation in children and adults. Nat Rev Gastroenterol Hepatol. 2020 Jan;17(1):21–39. https://doi.org/10.1038/s41575-019-0222-y
14. Voskuijl W, de Lorijn F, Verwijs W, Hogeman P, Heijmans J, Makel W, et al. PEG 3350 (Transipeg) versus lactulose in the treatment of childhood functional constipation: a double blind, randomised, controlled, multicentre trial. Gut. 2004 Nov;53(11):1590–1594. https://doi.org/10.1136/gut.2004.043620
15. Ahmed HM, Raza S, Tariq A. Effectiveness of polyethylene glycol 3350 versus lactulose in management of functional constipation in children. Int J Pediatr Res. 2022 Mar;8(1). https://doi.org/10.23937/2469-5769/1510089
16. Qayyum F, Haider N, Ambreen S, Naseer M, Ejaz S, Zahid T. Effectiveness of polyethylene glycol vs lactulose in the management of functional constipation in children. Biol Clin Sci Res J. 2025;6(6):1730. https://doi.org/10.54112/bcsrj.v6i6.1730
17. Rao H, Mandot S, Goyal D, Vyas A. Comparison of polyethylene glycol (PEG 3350) and lactulose in functional constipation in children (1–4 years): a double-blinded randomised controlled trial. Int J Toxicol Pharmacol Res. 2023;14(1):142–146. [No DOI assigned].
18. Talakesh H, Alinejad S, Zandian K, Mehrpour O, Shafiee A. Polyethylene glycol versus lactulose in the treatment of chronic functional constipation in children: a randomized clinical trial. J Shahrekord Univ Med Sci. 2024 Dec;26(4):140–145. https://doi.org/10.34172/jsums.892
19. Owais M, Akhtar T, Shaikh S, Waqar S. To determine the efficacy of polyethylene glycol in the treatment of pediatric constipation. Med Forum Mon. 2024 Dec;35(12). [No DOI assigned].
20. Worona-Dibner L, López-Alarcón M, Villasís-Keever MA, Muñoz-Hernández O, Fernández-Barriales M, Valverde-Delgado J. Efficacy, safety, and acceptability of polyethylene glycol 3350 without electrolytes vs magnesium hydroxide in functional constipation in children from six months to eighteen years of age: a controlled clinical trial. Rev Gastroenterol Mex (Engl Ed). 2023 Apr;88(2):107–117. https://doi.org/10.1016/j.rgmx.2021.05.007
21. Walia R, Steffen R, Feinberg L, Worley S, Mahajan L. Tolerability, safety, and efficacy of PEG 3350 as a 1-day bowel preparation in children. J Pediatr Gastroenterol Nutr. 2013 Feb;56(2):225–228. https://doi.org/10.1097/MPG.0b013e3182758c69
22. López J, Barba MG, Fernández SN, Solana MJ, Urbano J, Sánchez C, López-Herce J. Protocol for treatment of constipation with polyethylene glycol 3350 plus electrolytes in critically ill children. An Pediatr (Engl Ed). 2023 Sep;99(3):176–184. https://doi.org/10.1016/j.anpede.2023.05.009
23.