Biological and Clinical Sciences Research Journal
eISSN: 2708-2261; pISSN: 2958-4728
www.bcsrj.com
DOI: https://doi.org/10.54112/bcsrj.v6i6.1730
*Biol. Clin. Sci. Res. J., Volume 6(6), **2025**: 1730*
Original Research Article

Effectiveness of Polyethylene Glycol vs Lactulose in the Management of Functional Constipation in Children

Faiza Qayyum[1*], Nighat Haider[2], Sara Ambreen[1], Maryam Naseer[1], Sana Ejaz[3], Tehmina Zahid[1]

[1]Department of Peads Medicine, Pakistan Institute of Medical Sciences, Islamabad, Pakistan
[2]Department of Paeds Infections Disease, Pakistan Institute of Medical Sciences, Islamabad, Pakistan
[3]Department of Paeds, Sindh Institute of Urology and Transplantation, Karachi, Pakistan
**Corresponding author`s email address:* faizaqayyum30@yahoo.com

(Received, 05th June2025, Accepted 25th June 2025, Published 30th June 2025)

Abstract: *Functional constipation is a prevalent gastrointestinal disorder in children, often leading to discomfort and reduced quality of life. Effective management is essential for timely symptom resolution and improved patient outcomes. Among the various therapeutic agents, polyethylene glycol (PEG) and lactulose are commonly used, yet comparative data on their efficacy remain limited in pediatric populations.* ***Objectives:*** *To compare the effectiveness of polyethylene glycol versus lactulose in the management of functional constipation in children.* ***Methods:*** *This quasi-experimental study was conducted at Pediatrics department of Pakistan Institute of Medical Sciences, Islamabad, Pakistan from January 2025 to May 2025. A total of 118 children with functional constipation were included, who were divided into Group-P (polyethylene glycol) and Group-L (lactulose), each containing 59 children. Diagnosis of the functional constipation in children was based on the well-validated tool named the Rome IV criteria along with the decreased number of stools (two or fewer) in a week being set as the essential criteria for making a diagnosis. Baseline characteristic including age, gender, duration of constipation, and number of stools passed each week were documented and compared between groups. Therapy was continued for a period of twelve weeks and the final assessment for the effectiveness was made after twelve weeks of therapy. The effectiveness of both these drugs was assessed based on the achievement of therapeutic success at 12-weeks and the comparison was performed between groups using the Chi-square test. Analysis of data was performed through the Statistical Package for Social Sciences (SPSS) software version 22.* ***Results:*** *Median age was 7.00 (5.00) years. There were 75 (63.60%) male and 43 (36.40%) female patients. Median weight was 22.00 (10.00) kg. Median duration of constipation was 2.00 (1.00) weeks. Median number of stools per week was 1.00 (1.00). Frequency of achievement of therapeutic success in Group-P (n = 59) at twelve weeks follow up was 54 (91.53%) while in Group-L (n = 59), it was 31 (52.54%), (p < 0.001).* ***Conclusion:*** *Polyethylene glycol is a better therapeutic option for the management of functional constipation in children as compared to lactulose.*

Keywords: Constipation, Effectiveness, Lactulose, Polyethylene Glycol

[***How to Cite:*** 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): 42-45. doi: https://doi.org/10.54112/bcsrj.v6i6.1730

Introduction

Constipation in children is a prevalent condition that can significantly impact quality of life and overall health, defined as a decrease in the frequency of bowel movements or the presence of hard, difficult-to-pass stools over an extended period leading to discomfort, abdominal pain, and distress for both the child and their caregivers. (1, 2) In general, the prevalence of functional constipation in the pediatric age group is quite high and has been reported to affect around 14.4% of the children globally. (3) Similarly, in Pakistani children, a study found that amongst all the functional gastrointestinal diseases, constipation constituted 14% of these cases. (4)

In children, constipation is often functional, meaning that it is not typically associated with an underlying organic disease but rather with certain factors of behavioral, dietary, or developmental nature. Some of these factors include poor dietary habits, certain factor related to data to today's lifestyle, emotional stressors, and in a small number of cases, underlying physiological or anatomical issues. (5, 6) Based on such etiopathology, effective management of functional constipation in children includes increasing dietary fiber intake by incorporating more fruits, vegetables, whole grains, and legumes into the child's diet, encouraging physical activity and use of certain medications. (7)

In this instance, a variety of medications are commercially available that are utilized for managing the children with this prevalent condition related to gastrointestinal tract including osmotic laxatives (lactulose, magnesium hydroxide and polyethylene glycol), stimulant laxatives (bisacodyl and senna), mixed action laxative (like sodium picosulfate), lubricants (like paraffin and mineral oils) and rectal laxatives (including sodium phosphate, sodium docusate, bisacodyl and sodium lauryl sulfoacetate). (8) Amongst these, two of the most commonly known and used formulations are the lactulose and polyethylene glycol, however, when it comes to the choice of the best laxative amongst these two, no conclusive evidence exists in the pediatric population. This creates a potential research gap regarding the effective management option for pediatric functional constipation. Therefore, in order to address this important research question that which amongst these two laxatives is a better therapeutic option for effectively managing pediatric functional constipation present study was conducted.

Methodology

This quasi-experimental study was conducted at Pediatrics department of Pakistan Institute of Medical Sciences, Islamabad, Pakistan, from January 2025 to May 2025 after getting approval from institutional ethical committee (Ref No: F.1-1/2015/ERB/SZABMU/1354). Sample size

$$n = \frac{\left\{ z_{1-\alpha/2}\sqrt{2\bar{P}(1-\bar{P})} + z_{1-\beta}\sqrt{P_1(1-P_1)+P_2(1-P_2)} \right\}^2}{\left(P_1 - P_2\right)^2}$$

calculation was performed using WHO sample size calculator using the following formula:

Sample size calculation was performed by using level of significance 5%, a power of 80% and anticipated frequency of achievement of therapeutic success with polyethylene glycol and lactulose of 95% and 77.3%, respectively. (9) This gave a sample size of 118 (59 in each group).

Study sample was selected by using a non-probability consecutive sampling technique. Male and female patients, aged 2-14 years who presented with functional constipation for four weeks or less were included. Patients with a history of hypothyroidism, celiac disease, hirschprung disease, structural deformity of the gut, neuromuscular disorder and those with prior history of gut surgery were excluded. Before inclusion in the study, informed written consent was obtained from every parent of the patients, and the risk and benefits of each type of intervention were explained to the parents of the patients. After that baseline characteristics including age, gender, weight, duration of constipation, and number of stools per week were documented. Diagnosis of functional constipation was made using Rome IV criteria with a must have criteria of two stools or less being passed in a week by the child.

Group allocation was performed based on the medical registration (MR) number of the patients, and patients were kept blinded to the drug being prescribed. Patients with their MR number ending at an even number were allocated in Group-P, in which patients were prescribed polyethylene glycol (PEG) 3350 at a dose of 0.8g/kg/day to be given twelve hourly for a period of twelve weeks. Patients who had their MR number ending at an odd number were allocated in Group-L, in which they were prescribed lactulose at a dose of 2ml/kg/day to be given twelve hourly for a period of twelve weeks. At the time of prescription, mothers were asked to keep a diary of the stool passage routine of their child. In patients of both the groups, follow up visits were set at four weekly intervals. At each follow-up visit, patients were assessed for the number of stool per week by reviewing the diary of stool passage frequency kept by the mother. At the last follow up visit scheduled at twelve weeks, children were assessed for achievement of therapeutic success which was defined by the passage of three or more stools in a week for two consecutive weeks.

Process of patient selection and group allocation till outcome assessment is demonstrated below in the form of a CONSORT patient flow diagram in Figure 1:

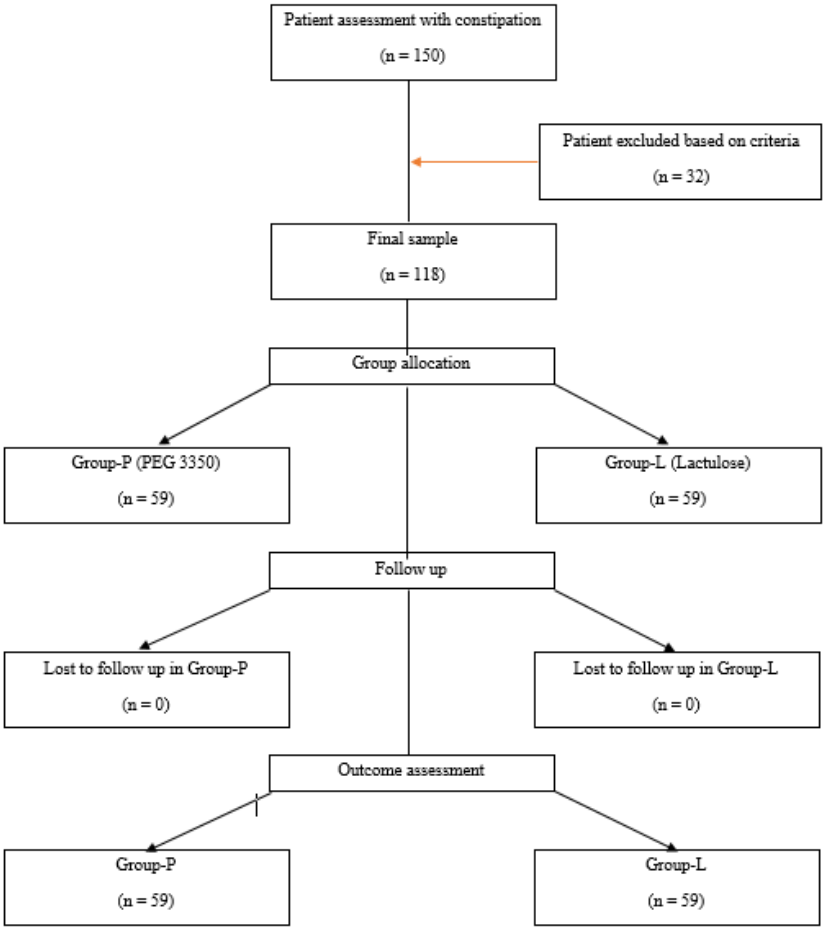

Figure-1: CONSORT patient flow diagram

Data was analyzed using Statistical Package for Social Sciences (SPSS) version 22. Quantitative variables normality was checked by Shapiro-Wilk test, which showed that age, weight, duration of constipation and number of stools per week were not normally distributed and were thus presented as median interquartile range (IQR). Age, weight, duration of constipation and number of stools per week were compared between groups by using Mann Whittney U-test. Qualitative variables (gender and achievement of therapeutic success) were presented as frequency and percentages. Gender and achievement of therapeutic success were compared between groups using Chi-square test. A p-value of ≤ 0.05 was considered as statistically significant.

Results

In this study, 118 patients were included. Median age was 7.00 (5.00) years. There were 75 (63.60%) male and 43 (36.40%) female patients. Median weight was 22.00 (10.00) kg. Median duration of constipation was 2.00 (1.00) weeks. Median number of stools per week was 1.00

(1.00). Pre-treatment patient demographics are compared between groups in Table-I:

Table-I: Comparison of pre- injection patient characteristics between groups (n = 118)

Parameter	Group-P (n = 59)	Group-L (n = 59)	p-value
Median age	6.00 (4.00) years	8.00 (4.00) years	0.047
Age groups			
1-7 years	38 (64.41%)	28 (47.46%)	0.07
8-14 years	21 (35.59%)	31 (52.54%)	
Gender			
Male	37 (62.71%)	38 (64.41%)	0.85
Female	22 (37.29%)	21 (35.59%)	
Median weight	21.00 (10.00) kg	24.00 (9.00) kg	0.049
Median duration of constipation	2.00 (1.00) weeks	3.00 (1.00) weeks	0.19
Median number of stools per week	1.00 (1.00)	1.00 (1.00)	0.38

Frequency of achievement of therapeutic success in Group-P (n = 59) at twelve weeks follow-up was 54 (91.53%) while in Group-L (n = 59), it was 31 (52.54%), ($p < 0.001$). This comparison of achievement of therapeutic success between groups is given in Table-II:

Table II: Comparison of achievement of therapeutic success between groups (n = 118)

Achievement of therapeutic success	Group-P (n = 59)	Group-L (n = 59)	p-value	Chi-square value
Yes	54 (91.53%)	31 (52.54%)	< 0.001	22.254
No	5 (8.47%)	28 (47.46%)		

Discussion

One of the most common pathophysiological mechanism that leads to constipation in children is begins with the alteration in dietary habits of the children which usually lacks the content of fiber in it leading to formation of hardened stool (10), pain while passage of this hardened stool causing fear to pass feces (11), retention of stool in the gut leading to excessive water reabsorption and finally ending in constipation. (12) Based on this, osmotic laxatives are considered to be a highly useful therapeutic intervention for managing children with this common gut problem. (3, 13) Present study focused on the effectiveness of two of these osmotic laxatives, including the PEG and lactulose.

In present study, average age of the children with functional constipation was seven years, with the majority of the patients aged between one and seven years. Compared to this, a study was conducted to assess the clinical characteristics of the children who presented with functional constipation in which they found that the average age of such children was approximately seven to eight years, with majority belonging to the younger age group, which was quite similar to present study. (14) Similarly, in another study it was found that most children who presented to a healthcare center for being treated for functional constipation were aged between two and five years, which was comparable to the age distribution trend being found in current study. (15) In terms of gender distribution, male children were found to have a slight predominance in terms of the burden of functional constipation constituting 63.6% of the patients. This finding was somewhat opposite to the general trend being reported in some previous studies conducted by Isa et al. (16) and Benzamin et al. (17) in which they found that instead of male predominance, there was rather a female predominance about the burden of functional constipation in children of different genders.

In order to make the diagnosis of functional constipation in children, Rome IV criteria was utilized. This criteria is a well-validated tool that is globally accepted by physicians in order to make diagnosis of this common gut condition. (18, 19) Upon comparative analysis of the effectiveness of the osmotic laxatives in terms of achievement of therapeutic success it was observed that PEG was significantly more effective, with a success rate of 91.53%, as compared to lactulose therapy in which the success rate was only 52.54% ($p < 0.001$). In comparison to this, a study was conducted by Mansour et al. (9) with the similar aim of comparing the effectiveness of these two famously used osmotic laxatives and the reported that, similar to current study findings, success rate while managing pediatric functional constipation was significantly higher with the use of PEG rather than the lactulose, ($p = 0.03$). In another study conducted by Rao et al. (20) it was found that when the comparative analysis of effectiveness of lactulose and PEG was performed while managing pediatric cases of functional constipation, it was observed that PEG, which has been used for a long time as a preferred laxative for treating this gut problem, was significantly more effective than the lactulose, ($p = 0.038$). In one study which was conducted by Talakesh et al. (21) to find out which amongst these two medications was more effective to treat children with constipation and they found that although the frequency of stools being passed was much higher among patients treated with PEG but when it came to resolution of symptoms related to this gut condition in children, there was no significant difference between these two agents. In another meta-analysis, it was found that there was no difference in the effectiveness of these laxatives in treating function constipation among children and they concluded that both of these can be used without any preference. (22)

Based on the results of present study, it is evident that PEG is significantly more effective compared to lactulose and thus should be used as a preferred therapeutic medication for managing children with functional constipation.

Conclusion

In conclusion, polyethylene glycol is a better therapeutic option for management of functional constipation in children as 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-F.1-1/2015/ERB/SZABMU/1354)

Consent for publication

Approved

Funding

Not applicable

Conflict of interest

The authors declared the absence of a conflict of interest.

Author Contribution

FQ (Post Graduate Resident)
Manuscript drafting, Study Design,
NH (Associate Professor)
Review of Literature, Data entry, Data analysis, and drafting articles.
SA (Post Graduate Resident)
Conception of Study, Development of Research Methodology Design,
MN (Medical Officer)
Study Design, manuscript review, critical input.
SE (Fellow),
Manuscript drafting, Study Design,
TZ (Medical Officer)
Conception of Study, Development of Research Methodology Design,

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

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