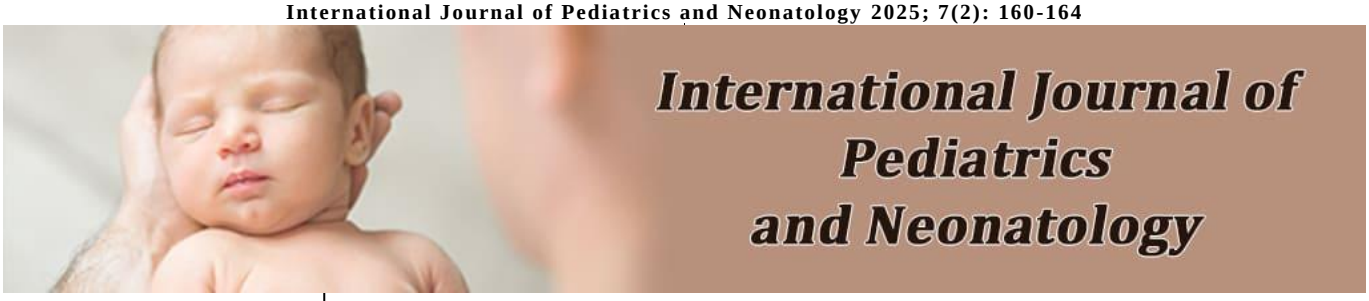

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Medication adherence and treatment satisfaction with PEG 4000 in Indian pediatric patients with functional constipation: PIPPS study

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Abstract
Background: Polyethylene glycol (PEG) 4000 is widely used for FC management; however, real-world data on medication adherence and treatment satisfaction with its ready-to-use liquid formulation in Indian pediatric patients remain limited. The PIPPS study assessed medication adherence and treatment satisfaction in children receiving PEG 4000 liquid for functional constipation.
Methods: A prospective, cross-sectional survey was conducted across 44 centers in Pan India between June 2023 and February 2024. Parents of pediatric patients (1-18 years) diagnosed with FC, based on Rome IV criteria, were invited for the survey. Medication adherence was evaluated using the Medication Adherence Report Scale (MARS-5). Treatment satisfaction was assessed using the Treatment Satisfaction Questionnaire for Medication (TSQM). Parental perspectives on ease of administration and overall satisfaction were also recorded.
Results: A total of 498 pediatric patients participated (median age: 7.4 years; 60.6% male). Adherence to PEG 4000 liquid (MARS-5 score ≥23) was observed in 57.83% of patients, with younger children (1–11 years) showing higher adherence (60.65%) compared to adolescents (50.42%). The mean TSQM score was 60.68, indicating high treatment satisfaction. Most parents reported the formulation as easy (66.2%) and convenient (63.2%) to administer, with 69.6% believing its benefits outweighed any side effects. Adherence and satisfaction rates were higher in urban patients compared to semi-urban and rural counterparts.
Conclusion: PEG 4000 liquid formulation demonstrated moderate adherence and high treatment satisfaction in Indian pediatric patients with FC.

Keywords: Functional constipation, MARS-5, medication adherence, polyethylene glycol 4000, pediatric gastroenterology, parental perception, treatment satisfaction, TSQM

Introduction

Functional constipation (FC) is a prevalent condition among pediatric populations worldwide, significantly impacting the quality of life for children and their families. In India, studies have reported varying prevalence of FC. A study found that FC accounted for 5.56% of pediatric hospital visits, with the majority of children aged between 2 and 6 years [1]. While another study reported a prevalence of 30.8% in children aged 2 to 4 years, with a higher incidence in females [2].

Pediatric FC is managed through dietary changes, behavioral interventions, and laxatives like lactulose, milk of magnesia, mineral oil, bisacodyl, and senna. However, these treatments have limitations, including variable efficacy, taste aversion, and side effects affecting adherence [3].

Polyethylene glycol (PEG) 4000 has emerged as a preferred treatment for FC due to its favorable efficacy and safety profile. A cross-sectional survey has also indicated that Indian pediatricians favor PEG 4000 for both fecal disimpaction and maintenance therapy in children with functional constipation [4]. The liquid formulation of PEG 4000 offers additional advantages, including ease of administration and improved palatability, which may enhance medication adherence in the pediatric population [4].

Despite its widespread use, there is a paucity of data on medication adherence and treatment satisfaction associated with PEG 4000 liquid formulation in Indian pediatric patients. Hence, we conducted this PIPPS (PEG 4000 liquid in Indian Pediatric PatientS) study to assess medication adherence and treatment satisfaction among Indian children receiving PEG 4000 liquid for functional constipation. Secondary objectives include identifying factors influencing adherence and satisfaction and evaluating parental perceptions of convenience and acceptability of liquid PEG 4000 formulation.

Methods

Study design and ethical considerations

This was a prospective cross-sectional survey conducted in Pan India in 44 centers between June 2023 and February 2024. The study protocol was approved by the Institutional Ethics Committee (IEC) for Biomedical Research of Apollo Hospital, Chennai (Approval number: ACH-C-S-003/03-23, dated 28th March 2023). Written informed consent was obtained from all parents or legal guardians before participation in the study.

Study Population and Eligibility Criteria

Parents of pediatric patients aged 1-18 years diagnosed with functional constipation, as per the Rome IV criteria, were invited to participate in the survey. Eligible patients had not received any treatment for constipation in the six months preceding enrollment and were prescribed PEG 4000 liquid formulation for a minimum of two months at a daily dosage of 0.4–1 g/kg/day. Patients who required additional laxatives or bowel preparation regimens during the study period were excluded. Parents willing to provide written informed consent and share relevant data were eligible to participate.

Outcome Measures

Medication adherence

Medication adherence was assessed using the Medication Adherence Report Scale (MARS-5). The total score ranges from 5 to 25, with higher scores indicating greater adherence. A score of ≥23 was considered indicative of adherence.

Treatment satisfaction

Treatment satisfaction was evaluated using the Treatment Satisfaction Questionnaire for Medication (TSQM) across four domains, including effectiveness, side effects, convenience, and global satisfaction. This 14-item questionnaire uses a seven-point Likert scale, with total scores in each domain converted to a scale of 0 to 100, where higher scores represent greater satisfaction.

Qualitative feedback

Qualitative feedback from parents was collected to assess parental perspectives on the use of PEG 4000 in children. The questionnaire included items assessing ease of administration, convenience, confidence in the medication, perceived benefit versus side effects, and overall satisfaction. Responses were rated on a Likert scale ranging from "Extremely Dissatisfied" to "Extremely Satisfied.

Data collection and management: Data were collected electronically using an eCRF (Electronic Case Report Form) platform. The survey was available in both English and Hindi to accommodate linguistic diversity among participants. Data confidentiality and security were ensured through anonymization and restricted access.

Statistical analysis

Descriptive statistics were used to summarize baseline characteristics and outcome measures. Adherence rates were reported as percentages, while TSQM domain scores were presented as mean values with standard deviations. Subgroup analyses were conducted to assess variations in adherence and satisfaction across demographic groups. Statistical analyses were performed using SPSS version 27.0 (IBM Corp., Armonk, NY, USA).

Results

Baseline Characteristics

Parents of a total of 498 pediatric patients took this survey. Among these, 349 (70.1%) patients were 1-11 years old, while 149 (29.9%) patients were 11-18 years old. The median age of the patients was 7.4 years (range: 1-18 years); among them, 302 (60.6%) were male. Patients were predominantly from urban areas (309,62.05%), followed by semi-urban (115, 23.09%) and rural areas (74, 14.86%).

Adherence rates

Among the 498 pediatric patients, 288 (57.83%) demonstrated adherence to PEG 4000 liquid with a MARS-5 score of ≥23 (Table 1). Adherence rates were higher in younger children (1-10 years), with 60.65% of them having MARS-5 scores of ≥23 compared to adolescents (11-18 years, 50.42%). It is to be noted that a MARS-5 score of ≥20 was reported in 352 (70.68%) of the patients who participated.

Table 1: Medication adherence rate

Subgroups	Adherence Rate (%)
Overall	57.83
Age Group (years)	
1–10	60.65
11–18	50.42
Geographic location	
Urban	59.85
Semi-Urban	56.10
Rural	52.09

Treatment satisfaction

The mean TSQM score was 60.68 (±9.45), indicating high overall treatment satisfaction with the PEG 4000 liquid formulation (Table 2). The majority of participants (92.96%) reported TSQM scores between 40 and 69, reflecting moderate to high satisfaction. Analysis of individual TSQM domain scores also showed higher satisfaction across the subdomains, demonstrating consistent satisfaction across various aspects of treatment evaluation.

Table 2: Treatment Satisfaction Scores

Subgroups	Mean TSMQ score (± SD)
Overall TSQM	60.68 (± 9.45)
TSMQ scores by domains	
Effectiveness	63.20 (± 8.50)
Convenience	65.80 (± 7.90)
Global Satisfaction	58.50 (± 9.20)
TSMQ scores by geographic location	
Urban	62.10 (± 8.00)
Semi-Urban	59.20 (± 9.10)
Rural	57.28 (± 10.20)

Data presented as Mean (± SD)

Parental Feedback

The majority of parents expressed high satisfaction with PEG4000, with over two-thirds reporting the medication was easy (66.2%) and convenient (63.2%) to administer. Confidence in the benefits of medication was high, with 63.4% of parents believing it was effective in their child. Furthermore, 69.6% felt that the benefits outweighed any side effects, contributing to an overall satisfaction rate of 66.4%.

Subgroup analysis

In subgroup analysis, adherence rates were highest among urban patients, with 59.85% of them having a MARS-5 score of ≥23, followed by semi-urban and rural patients. Similarly, comparatively higher treatment satisfaction was reported in urban patients (TSMQ: 62.10 ± 8.00) than in semi-urban and rural patients.

Discussion

PEG 4000 is an osmotic laxative widely used in pediatric patients to manage FC. Its efficacy and safety have been demonstrated in several studies. These studies indicated that PEG 4000 significantly increased stool frequency and improved stool consistency and ease of passage compared to lactulose, which is associated with higher clinical remission rates without significant adverse effects [5,6]. Our study assessed adherence and treatment satisfaction with the ready-to-use PEG 4000 liquid formulation in Indian pediatric patients with FC, addressing a gap in real-world adherence data. Our findings indicate that 57.83% of participants demonstrated good adherence (MARS-5 score ≥23), with a high overall treatment satisfaction score (TSQM: 60.68). Notably, younger children (1-10 years) showed higher adherence rates compared to adolescents, suggesting that ease of administration plays a pivotal role in maintaining treatment continuity. Additionally, parental feedback highlighted the convenience and acceptability of the liquid formulation, reinforcing its potential to improve adherence compared to conventional laxative treatments. These results highlight the importance of formulation characteristics in optimizing treatment adherence and patient outcomes in pediatric functional constipation.

Nonadherence to treatment is a widely recognized challenge in managing chronic diseases in pediatric patients [7]. Medication adherence is a key determinant of treatment success in pediatric FC, impacting both symptom resolution and long-term disease management. Additionally, poor treatment adherence can lead to increased healthcare costs due to frequent hospital visits, admissions for symptomatic relapses, and wasted medication [8]. Factors such as treatment inconvenience and dissatisfaction with therapy may contribute to poor adherence in these patients, while convenience of treatment and higher treatment satisfaction are found to be associated with greater adherence [8]. A study by Steiner *et al*. reported low adherence to constipation treatment in children, highlighting the need for strategies to improve compliance, prevent complications, and reduce costs [7]. Approaches such as patient and caregiver education, simplified treatment regimens, and addressing barriers to adherence are essential [7]. Comparatively higher adherence has been reported with PEG in children with chronic FC compared to other laxatives [7]. However, adherence to PEG 3350 remains low, likely due to the large volume required and its poor palatability, which negatively affects compliance [4]. Our study reported a moderate adherence rate with PEG 4000 liquid suggesting potential benefits of this formulation in terms of enhanced compliance and further prevention of complications associated with FC.

Although there are no extensive studies on differences in adherence rates among younger children and adolescents, earlier studies have indicated that later have lower adherence to constipation treatment than younger ones [9]. A systematic review and meta-analysis also found that younger children are more likely to follow medication regimens [10]. These differences may be due to adolescents' desire for independence, self-esteem struggles, or lower executive function skills, including organization, planning, and self-monitoring, which affect their ability to adhere to treatment [11]. In our study, which was also consistent with earlier reports, younger children demonstrated better adherence to PEG 4000 liquid compared to older children.

Assessing treatment adherence in children using laxatives is challenging. In our study, we evaluated medication adherence using the MARS-5, a validated self-reported questionnaire consisting of five items rated on a five-point Likert scale [8]. While MARS-5 is commonly used in adults, its application in children is limited, with only one previous study in functional constipation defining adherence as a MARS-5 score ≥23 [8]. Based on this study, we adopted the same threshold for defining adherence in our population. However, there is no established consensus on the optimal MARS-5 cut-off for children, as studies in adults also have used thresholds ranging from 20 to 25 [8]. Given that adherence in children was assessed via proxy reporting by parents rather than direct self-reporting, we explored a lower cut-off. When defining adherence as a MARS-5 score ≥20, we found that 70.68% of children met the new adherence criteria, demonstrating a higher adherence rate.

Treatment satisfaction is highly important in pediatric treatment adherence because the willingness of patients to follow a treatment plan is significantly influenced by their positive experience with the treatment. Studies consistently show a strong correlation between patient satisfaction and

adherence, with satisfied patients more likely to continue treatment. In pediatric care, parental involvement plays a crucial role. When parents are satisfied with the outcomes, they are more likely to actively support their children's adherence to the prescribed treatment [12]. Higher treatment satisfaction has been associated with better compliance and persistence in treatment [13]. The positive treatment satisfaction observed in our study aligns with the earlier findings that PEG-based treatments are generally well-received in the pediatric population [14]. Our study found that PEG 4000 liquid is perceived as effective and convenient by most parents, with a higher TSQM score indicating its effectiveness and convenience. These outcomes indicate that PEG 4000 liquid is generally well-accepted by parents of pediatric patients. The higher satisfaction level reported may also have contributed to better adherence, supporting PEG 4000 as a preferred treatment for pediatric functional constipation.

Parental perceptions play a key role in treatment adherence in children with FC. Research indicates that parents who find a treatment convenient and effective are more likely to ensure their child follows the prescribed regimen [8]. Given that parental input is often considered in clinical decision-making, assessing their satisfaction and identifying barriers, such as difficulties in medication administration, could help improve adherence rates [15]. In a study by Koppen *et al*., parents who perceived medication administration as convenient reported higher adherence rates to PEG formulations. This association was observed for both intentional and unintentional adherence [8]. In our study, qualitative feedback from parents highlighted the convenience of the liquid formulation as a major factor in adherence. Parents appreciated the ready-to-use nature of the PEG 4000 formulation, reporting that it eliminated the need for preparation and reduced the likelihood of missed doses. These positive parental perspectives further reinforced the favorable safety and efficacy profile of PEG 4000, supporting its continued use in pediatric patients with constipation.

Rural-urban disparities in healthcare access and quality are well-documented globally, including in India, and these disparities may influence treatment adherence and satisfaction among pediatric populations. While specific studies on rural-urban differences in adherence to treatment for functional constipation in Indian children are limited, a broader perspective suggests potential variations [16]. Adherence to treatment protocols is influenced by several factors, including parental knowledge and perceptions. Barriers such as limited health literacy, cultural beliefs, and inadequate provider communication can affect treatment adherence, particularly in rural settings [16]. In our study, the subgroup analyses also revealed higher adherence and satisfaction rates among patients from urban areas compared to semi-urban and rural regions. This disparity may be attributed to differences in healthcare access, educational resources, and socioeconomic factors. Targeted interventions addressing these disparities could be beneficial in improving adherence and satisfaction with PEG 4000 liquid across diverse geographies.

The high adherence and satisfaction rates observed with PEG 4000 liquid formulation suggest that ease of administration and improved palatability can significantly enhance compliance in pediatric patients. Given that nonadherence to laxative therapy can lead to symptom recurrence and increased healthcare utilization, PEG 4000 liquid offers a practical option for sustained symptom control. Furthermore, our findings highlight the need for clinicians to consider parental perspectives on treatment convenience when prescribing laxatives. Addressing barriers to adherence, particularly among adolescents and rural populations, through patient education and tailored interventions may further improve treatment outcomes.

While this study provides valuable real-world insights, certain limitations should be acknowledged. First, the cross-sectional design assessed the outcomes at a single time point, limiting the ability to assess long-term treatment adherence. Second, reliance on self-reported measures, including the MARS-5 and TSQM, introduces the potential for recall and response bias. Parental proxy reporting, rather than direct patient feedback, may also affect the accuracy of adherence assessment, particularly in older children and adolescents. Future longitudinal and randomized controlled studies with objective adherence measures are warranted to validate and expand upon these findings.

Conclusions

In conclusion, PEG 4000 liquid formulation is associated with moderate adherence and high treatment satisfaction among Indian pediatric patients with functional constipation. Parental feedback further reinforced the convenience and acceptability of PEG 4000 liquid, suggesting its potential to improve long-term compliance compared to conventional laxative treatments.

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