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RESEARCH ARTICLE

A Cross-sectional Survey on the Perception of Pediatricians about Constipation in Indian Pediatric Patients (CROSCIP)

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ABSTRACT

Background: Constipation accounts for more than 50% of the workload in pediatric outpatient clinics, with functional constipation being the most frequently diagnosed condition. Pediatricians have varied perceptions about constipation and its management.

Objective: A national prospective questioner based cross-sectional survey was conducted to understand the perceptions and practices of Indian pediatricians on the current management of pediatric constipation.

Methods: A 14-item questionnaire with open and closed-ended questions was developed with a focus on understanding the prevalence of constipation in the pediatric setting, common clinical presentations, management approaches, treatment choices, and patient compliance. Pediatricians PanIndia, among varied practice backgrounds, were invited to participate in the survey.

Results: A total of 1150 pediatricians were invited, of which 1042 completed the survey. The majority of the responding pediatricians were based in the outpatient clinic setting. The most common age group of children presenting with functional constipation was 2-4 years. The most commonly reported symptoms were painful passage of hard and dry stools with a frequency of fewer than two stools per week. Polyethylene glycol (PEG) 4000 was the preferred choice for fecal disimpaction and maintenance by the majority of pediatricians. Most pediatricians prescribe laxatives for 1-3 months. The major challenge with PEG 3350 was the volume to be consumed and poor palatability. The survey results showed poor compliance and a high relapse rate in children with functional constipation.

Conclusion: Functional constipation is prevalent in toddlers with growing incidence and is managed by pediatricians in outpatient clinics. We found that Indian pediatricians prefer PEG 4000 for fecal disimpaction and maintenance therapy.

Keywords: Children, Fecal disimpaction, Functional constipation, Laxatives, Maintenance therapy, PEG 4000

INTRODUCTION

Constipation is a common gastrointestinal condition frequently encountered in pediatric practice. Functional constipation (FC) is the predominant form and the commonest cause of constipation in Indian children.¹ A systematic review and meta-analysis reported nearly 10% of pooled prevalence of FC in children worldwide.² The most recent Indian study conducted by Musali and Damireddy, utilizing the Rome IV criteria for diagnosis, revealed a 17.1% prevalence of FC among children. They further reported that FC is more common in toddlers with a slight female preponderance and more in urban resident children and children belonging to the low socioeconomic group.³ Another study by Makhwana et al., applying the Rome IV diagnosis criteria, reported a prevalence of 5.6% of FC in Indian children.⁴ Another Indian study by Kondapalli and Gullapalli reported a higher prevalence of 30.8%; however, this study applied ROME III criteria for the diagnosis of FC.⁵ In the majority of Indian children, FC is also associated with fecal impaction, with a study reporting the presence of fecal impaction in nearly 60% of the children with FC.⁶

The Rome IV criteria define FC for infants and toddlers as the presence of any two symptoms for at least one month, which includes two or fewer defecations per week, history of excessive stool retention, history of painful or hard bowel movements, history of large diameter stools, and presence of a large fecal mass in the rectum. Two additional criteria may be used in toilet-trained children: incontinence at least once a week and a history of large-diameter stools that may block the toilet.^{1,7} For children of developmental age (≥ 4 years), Rome IV criteria define FC as the presence of two or more criteria for at least one month. These criteria include two or fewer defecations per week in the toilet; at least one episode of fecal incontinence per week; retentive behavior; painful or hard bowel movements; detection of large fecal mass in the rectum; and stools of large diameter that may obstruct the toilet.^{1,7}

Early diagnosis and management of FC in children with good symptom control are key factors for long-term prognosis. A delay between the onset of symptoms and the first presentation at pediatricians is negatively related to recovery.^{8,9} The pharmacological management of FC involves three step approach comprising disimpaction, maintenance therapy, and gradual weaning off medications. Polyethylene glycol (PEG) is the osmotic laxative of the first choice for both disimpaction and maintenance treatment. Lactulose is recommended as an osmotic laxative if PEG is not available or is poorly tolerated due to palatability.

Stimulant laxatives like sodium picosulfate and senna, and/or lubricants may be considered as second-line or additional treatment if treatment with osmotic laxatives is insufficient.¹⁰

Despite the development of effective and safe treatment options, many challenges persist in managing constipation in children.¹¹ Studies have reported that acceptability, adherence, and tolerance to FC treatment are still challenging.¹¹ Pediatricians have varying perceptions of the condition and its treatment. There is limited research on pediatricians' perceptions of managing pediatric constipation in India. A national cross-sectional survey was conducted across India to address this knowledge gap and understand the existing clinical practice. This is the largest Indian survey with the objective to understand the perceptions and current practices in the management of pediatric constipation, including therapeutic choices and the challenges faced by practicing pediatricians.

METHODS

Study design, demographics, and survey development & distribution

This study was a CROss-sectional Survey conducted among pediatricians to understand about Constipation in Indian Pediatric patients (CROSCIP). A 14-item questionnaire with open and closed-ended questions was developed by a team of healthcare experts with lead inputs from a subject matter expert in pediatric gastroenterology. The respondents were asked to complete the survey through an online Google form distributed through email. The survey remained open between November 2022 to March 2023.

The survey focused on understanding the prevalence of constipation in real-world clinical settings, common clinical presentations, management approaches, and treatment adherence. The opinions of general pediatricians and specialists were gathered on the choice of fecal disimpaction in children, including preferences between PEG 3350 and PEG 4000.

A nationally representative sample of practicing pediatricians responded to this survey. A total of 1150 pediatricians and pediatric gastroenterologists from Pan India were invited to participate in the survey to avoid region-specific responses and bias. The survey was also conducted at different practice settings, including clinics and hospitals, to ensure that the outcomes represent and reflect the current practices.

Ethical Considerations

Approval from the ethical committee was not required as the survey was conducted among pediatricians and did not involve the direct

participation, contact, personal data collection, or intervention of any patient. Participation in the survey was voluntary. The respondents and their responses were assured confidentiality. Pediatricians provided their consent for the use of collected data for research purposes. No patient-identifiable data was used.

Data Analysis

Only fully (i.e., all 14 questions) completed survey forms were considered for analysis. Descriptive statistics were applied to analyze the data collected through this survey. The outcomes were calculated and presented in the form of percentages and frequencies.

RESULTS

A total of 1042 out of 1150 invited pediatricians completed the survey. Most clinicians who participated in the survey were practicing in the clinic (outpatient) setting (64.2%), and the remaining 35.8% were based in the hospital setting. General pediatricians (95.2%) were the most common specialization among the respondents, followed by general practitioners (2.11%), and pediatric gastroenterologists (2.11%). Nearly half of the pediatricians (47.9%) reported that they are presented with less than five cases of FC in their daily practice, while 40.4% of the respondents reported 5-10 cases per day. The most common age group of children presenting with FC was 2-4 years, as responded by 65.3% of the pediatricians (Figure 1). FC was reported most commonly in children younger than two years by

17.3% of pediatricians and in children aged 4-8 years by 16% of pediatricians. Children above eight years less frequently presented with FC in clinical practice of 1.4% of responding pediatricians.

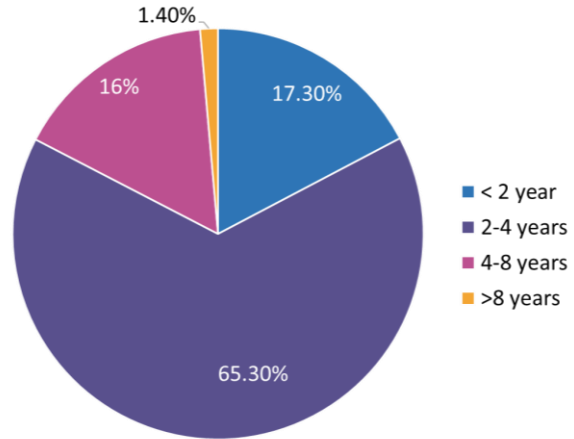


Figure 1: Common age group of children presenting with FC

The most common symptoms reported in children with FC were passing hard and dry stools (77%), complaining of pain while passing stools (62.9%), and having less than two stools per week (54.8%). Withholding behavior and frequently soiling underpants were reported by 31.4% and 25.7% of pediatricians, respectively. The presence of anal fissures was also reported by 17.6% of pediatricians (Figure 2).

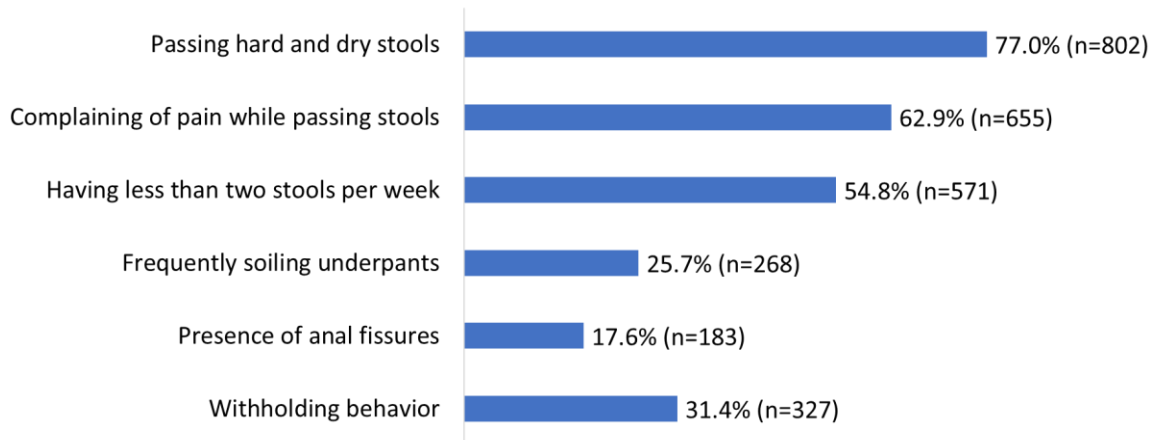


Figure 2: Common symptoms of FC presented in children (pediatricians were allowed to choose more than one option)

PEG 4000 was the preferred choice for fecal disimpaction by most pediatricians (44.2%). Nearly half of the pediatricians (52.2%) also preferred PEG 4000 as maintenance therapy (Figure 3). The

second most common choice for both fecal disimpaction (25%) and maintenance therapy (25.2%) was PEG 3350 (with or without electrolytes).

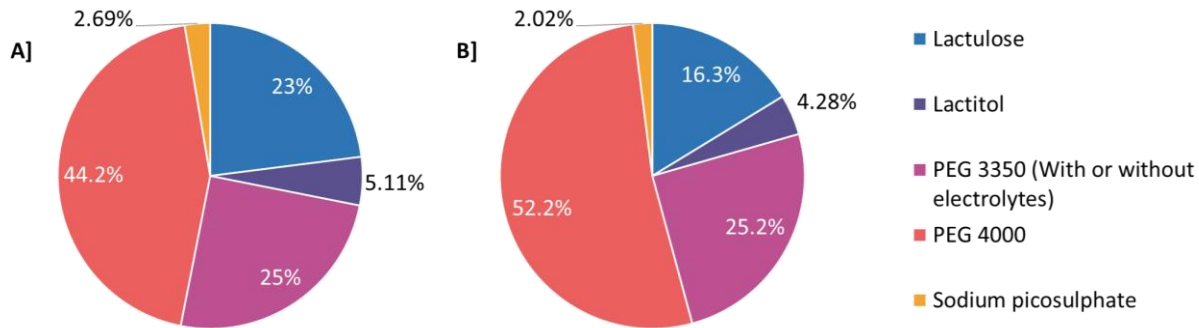


Figure 3: Preferred choice for Fecal disimpaction [A] and Maintenance therapy [B] in children with FC

Other treatment choices for fecal disimpaction and maintenance therapy were lactulose (by 23% and 16.3% of pediatricians, respectively) and lactitol (by 5.1% and 4.3% of pediatricians, respectively). Sodium picosulphate was preferred by very few pediatricians for both indications.

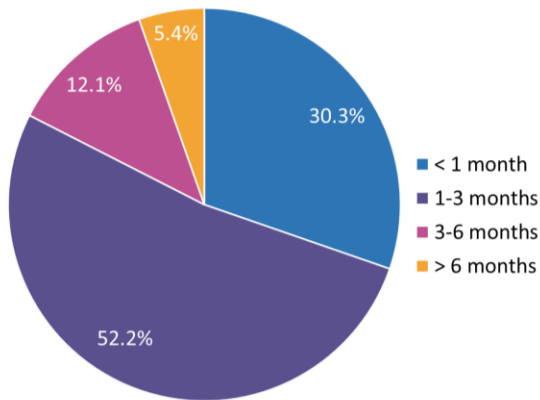


Figure 4: Duration of laxative therapy in children with FC

Most pediatricians (52.2%) reported prescribing laxatives for 1-3 months in pediatric patients with FC (Figure 4). A significant proportion (30.3%) of pediatricians said they prescribe laxatives for less

than one month in these patients. The remaining 12.1% of pediatricians reported prescribing laxatives for 3-6 months, and 5.4% reported prescribing them for more than six months.

Most pediatricians responding to this survey said they know the physical and pharmacological differences between PEG 3350 and PEG 4000. When asked about the challenges in ensuring patient compliance using PEG 3350 in routine clinical practice, most pediatricians (69.8%) reported a large administration volume as the main challenge (Figure 5). Other significant challenges were poor palatability (reported by 44% of pediatricians) and poor compatibility with daily consumable liquids (reported by 43.2% of pediatricians). Duration of therapy and compliance to treatment were also reported as barriers to prescribe PEG 3350 by 32.1% and 34.5% of pediatricians, respectively.

A large proportion of pediatricians (69.7%) reported having prescribed PEG 4000 oral liquid in their pediatric practice. Pediatricians enlisted different advantages of PEG 4000 over PEG 3350, including small volume, ease of administration, quick action, better palatability, and better compliance.

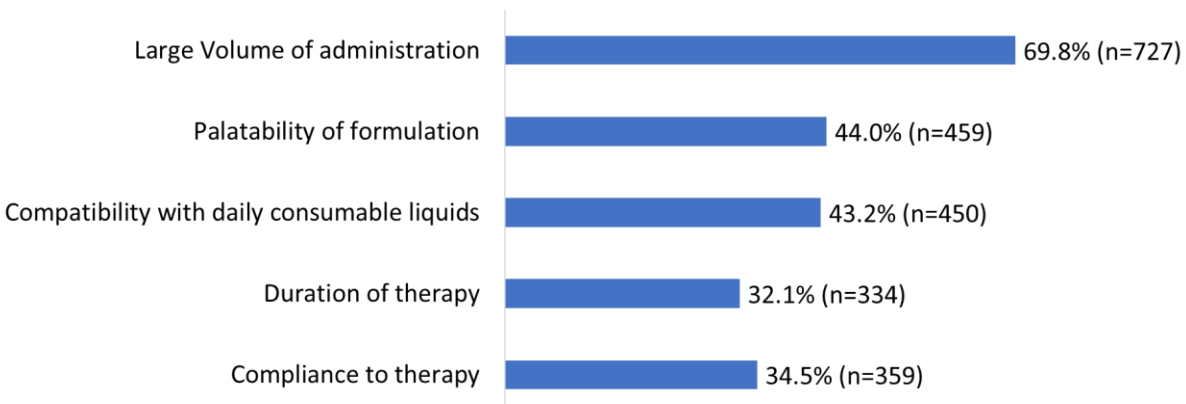


Figure 5: Challenges in ensuring patient compliance in the usage of PEG 3350 (Pediatricians were allowed to choose more than one option)

Most pediatricians spent 2-5 minutes (53.2%) counseling parents about non-pharmacological therapy, diet, toilet training, and the importance of adhering to the duration of medical treatment for FC. Nearly one-fourth (26.1%) of the pediatricians said they counsel the parents for 5 to 10 minutes, and 5.2% were involved in counseling for 10 to 15 minutes. There were also 15.5% of pediatricians who spent less than 2 minutes on counseling.

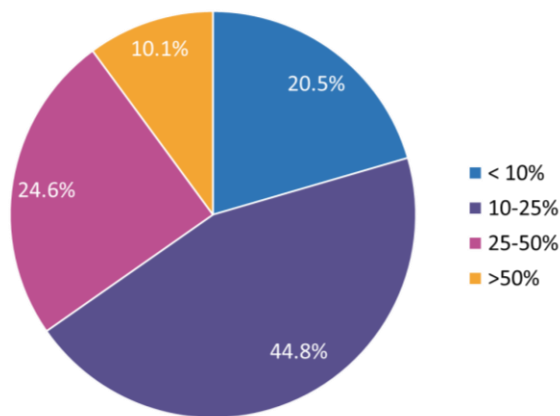


Figure 6: Rate of patient adherence to maintenance therapy

In this survey, 44.8% of pediatricians reported that the rate of patient adherence to the complete course of recommended maintenance therapy is 10 to 25%. An adherence rate of less than 10% was reported by 20.5% of pediatricians. The remaining 24.6% of pediatricians reported 25-50% adherence, and only 10.1% reported an adherence rate of more than 50% (Figure 6). Half of the pediatricians (50.28%) reported observing recurrence/relapse in some children with FC even after adherence to the completed therapy recommendation.

DISCUSSION

Literature from different countries has documented a large variation in practice patterns among pediatric care providers in terms of treating childhood constipation.¹² Current national survey, conducted among pediatricians from various specialties and settings, provides insight into the clinical practice patterns of pediatricians in the management of pediatric constipation in India. It has been reported that different variables, including pediatricians working in various settings and status, may affect the perception and practice of managing children with constipation.¹³ Based on this survey, it becomes clear that pediatricians are the primary care providers for children with constipation, with a majority of respondents practicing in a clinic (outpatient) setting in India. The

joint guideline (2014) from the North American and the European Societies for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN and ESPGHAN, respectively), recommends that children with intractable constipation unresponsive to first-line optimal therapy should be referred to a specialized pediatric gastroenterologist and evaluated for underlying medical conditions.¹⁴ Indian Academy of Pediatrics (IAP) guidelines also recommend that children with constipation who do not respond to the sustained optimal treatment should be referred for expert opinion.¹⁵ Despite the high prevalence of refractory FC at the primary care pediatrician level in India,¹⁶ the current survey suggests that only 2.1% of pediatric gastroenterologists manage FC in children, which reflects that there is a need to encourage referral to specialization in case of intractable constipation in children.

Previous Indian studies have reported a high prevalence of pediatric constipation in toddlers/pre-school children.⁴⁻⁶ Our findings are consistent with literature that has reported the common age of presentation of FC in children as 2-4 years. However, it is alarming that a significant proportion of pediatricians also reported FC in children younger than two years, as this is an unusual age for the presentation of FC. The typical characteristics of FC are infrequent defecation, hard and/or large stools, painful defecation, and fecal incontinence, which is often accompanied by abdominal pain.¹⁷ Withholding behavior, frequently occurring after a negative experience, hard, painful, and/or frightening bowel movement is also one important etiological factor of FC that can lead to fecal impaction. Furthermore, fecal impaction often causes overflow fecal incontinence.¹⁰ The survey outcomes were in agreement with the typical characteristics of the FC and published literature.

The first goal of treatment of FC is establishing regular bowel movements, and the second goal is to prevent relapses by preventing the re-accumulation of feces.¹⁸ Typical management of FC in children involves four important phases, including education, fecal disimpaction, maintenance, and follow-up.¹⁸ Education is the first essential step in the non-pharmacological treatment of FC, which is majorly overlooked. It involves counseling parents and children on defecation dynamics tailored to the child's developmental age, emphasizing diet, fluid intake, and toilet training. Parents should also be informed about the negative effects of painful bowel movements and the role of withholding behavior and overflow incontinence in FC.¹⁹ The current survey showed that a majority of

respondents spend 2-5 minutes counseling parents on non-pharmacological approaches for managing pediatric constipation. However, there are also pediatricians spending less than 2 minutes on counseling which may be insufficient to achieve the goal.

Unsuccessful non-pharmacological interventions in pediatric FC are followed by pharmacological treatment, which involves disimpaction, maintenance, and weaning.^{10,19} Any potential fecal impaction needs to be evacuated before initiation of maintenance treatment to increase treatment success.^{10,19} Rectally administered sodium docusate enemas or temporary high-dose oral PEG can be used for a successful disimpaction.²⁰ However, being less invasive and acceptable, PEG is recommended as the first choice for

disimpaction.^{14,19} After disimpaction, maintenance therapy is important to prevent fecal re-accumulation. The preferred laxative for maintenance therapy is PEG. If there is no response or intolerance to PEG, lactulose/lactitol can be tried as a second-line treatment. Stimulant laxatives, like sodium picosulphate and senna, are often used for short periods of time but are associated with more side effects.²¹ Weaning can be considered when symptoms are stable for at least one month under maintenance treatment when children have a defecation frequency of ≥ 3 times per week and do not fulfill any other Rome IV criteria. It is recommended that abrupt cessation of maintenance therapy should be avoided, as it may induce a relapse.¹⁹

Table 1: Comparative guideline recommendations for the use of PEG for constipation in children

Guidelines	Recommendations for first-line therapy	
	For fecal disimpaction	For maintenance therapy
ESPGHAN/ NASPGHAN ¹⁴	PEG with or without electrolytes at the dose of 1 to 1.5 g/kg/day orally for 3 to 6 days	PEG with or without electrolytes at starting dose of 0.4 g/kg/day, to be adjusted according to the clinical response
NICE ²²	PEG with electrolytes using an escalating dose regimen	PEG with electrolytes with dose adjustment according to symptoms and response
ISPGHAN ²³	PEG is preferred agent for disimpaction at 1.5-2 g/kg/day in two divided doses for 3-6 days for home-based disimpaction	PEG is first line of maintenance treatment at 0.5-1 g/kg/day for children >12 months of age
IAP ¹⁵	PEG is preferred agent for fecal disimpaction at the dose of 1.5-2 g/kg/day as two divided doses for 3-6 days as a home-based disimpaction regimen	PEG is preferred first choice in the maintenance phase at the dose of 0.5-1 g/kg/day

[ESPGHAN: European Societies for Pediatric Gastroenterology, Hepatology, and Nutrition; IAP: Indian Academy of Pediatrics; ISPGHAN: Indian Society of Pediatric Gastroenterology, Hepatology, and Nutrition; NASPGHAN: North American Societies for Pediatric Gastroenterology, Hepatology, and Nutrition]

Based on the current evidence, the joint guideline from ESPGHAN and NASPGHAN for evaluation and treatment of FC in infants and children,¹⁴ NICE guidelines for constipation in children and young people²² and Indian Academy of Pediatrics (IAP) standard treatment guidelines on constipation in children¹⁵ recommend PEG as the first-line therapy for both fecal disimpaction and maintenance treatment in children with FC (Table 1). Indian Society of Pediatric Gastroenterology, Hepatology and Nutrition (ISPGHAN) and Pediatric Gastroenterology Chapter of the Indian Academy of Pediatrics guidelines also recommends PEG as first-line maintenance therapy for FC in children.²³ Findings of our survey are in line with the current

international and national guidelines. Most physicians in our study reported prescribing PEG as a preferred laxative for managing pediatric FC. Lactulose and lactitol were also reported as treatment options by some physicians. However, the survey showed that the stimulant laxative sodium picosulphate is rarely used in Indian settings for constipation in children.

Being biologically inert and non-absorbable osmotic laxatives, PEG exhibits a reliable and consistent response at a steady dose regimen. It is well-tolerated, causing less bloating and flatulence than lactulose.²⁴ Pharmacokinetic studies showed that PEGs are minimally absorbed after oral administration, with almost complete excretion in the

faeces within 4 to 6 hours and around 93% of a single dose excreted.^{24,25} Currently, two types of PEG formulations are available for clinical use as laxatives for constipation, which include PEG 3350 and PEG 4000.²⁶ For treating FC, PEG 4000 is preferred over PEG 3350 as it doesn't cause significant electrolyte imbalances and can be used without electrolytes. Studies show that children prefer the taste of PEG 4000 without electrolytes, which can affect their acceptance and adherence to treatment.²⁴ In our survey, PEG 4000 was the most preferred choice for fecal disimpaction and maintenance therapy over PEG 3350. Pediatricians responding to this survey said that palatability and better compliance are the key advantages of PEG 4000. Pediatricians also reported concerns about ensuring compliance with PEG 3350 therapy, which may further impact treatment outcomes. A large volume of administration, poor palatability, and compatibility with daily consumable liquids were enlisted as significant barriers to adherence to PEG 3350.

The current evidence and guidelines suggest that maintenance treatment for FC should be continued for at least two months, and symptoms should be resolved for at least one month before gradual weaning of the medication.^{10,21} Guidelines by ISPGHAN advise that the child should remain asymptomatic while on maintenance therapy for at least six months before considering gradual tapering of the laxatives over a period of 3 months.²³ However, it is worth noting that a significant proportion of pediatricians in this survey reported prescribing laxatives for less than one month, which may not be sufficient for the effective management of constipation and the high proportion of patients with recurrence.

Regular follow-ups with ongoing support are important to ensure treatment adherence and prevent relapse in FC children. Guidelines by ISPGHAN recommend the first follow-up at 14 days to assess therapy compliance and subsequent follow-ups every 1-2 months until normal bowel habit is achieved or a 'successful outcome' is attained.²³ Symptoms should also be re-evaluated two months after treatment cessation to prevent or detect relapses.¹⁰ Very low patient adherence and high relapse rates are reported in earlier studies assessing the treatment outcomes in children with constipation.^{27,28} Our survey also showed low patient adherence to maintenance therapy and frequent relapse in children with FC. The outcomes of this survey imply that there is a need to identify barriers to adherence and develop better

strategies for ongoing monitoring and addressing underlying causes of constipation. As per the survey outcomes, relapse is also observed in children complying with the suggested treatment. Identifying and addressing underlying causes of constipation, such as dietary factors or anatomical abnormalities, is important in these patients. Referral to pediatric gastroenterologists can also be considered in these patients. Further research is needed to find out the reasons behind the high recurrence rate and low adherence to therapy in children with FC.

Overall, there is considerable variation in clinical practice, with differences in approaches to managing FC in children, despite the availability of evidence-based guidelines. This variation may result in suboptimal patient outcomes as well as unnecessary healthcare costs. The survey highlighted the need to improve the consistency and quality of care with reduced variations in practice. There is a need to address the knowledge gap with increased physician education and training, including the latest guidelines and best practices for diagnosis and management.

The present study has limitations intrinsic to cross-sectional surveys. One of the limitations of this study is that the outcomes depend on self-reported data from physicians, which may be subject to reporting bias. Additionally, as the survey was conducted among those who agreed to participate, our sample may not represent all physicians in India.

CONCLUSION

Functional constipation is a prevalent condition in toddlers, mainly managed by pediatricians in the outpatient setting. We conclude, as per the survey, that PEG 4000 is the preferred choice of osmotic laxative for fecal disimpaction and maintenance therapy in children with FC. Although most pediatricians manage children with FC based on clinical evidence and guideline recommendations, there is variation in the perception and practice of pediatricians across India in the management of FC in children. Further research and sensitization of clinicians are essential to address the issues of low adherence to treatment and high relapse of FC.

Conflicts of interest statement

Dr. Dhanasekhar Kesavelu is a speaker for several pharmaceutical companies. Ms. Shreya Savla, Dr. Jay Savai & Dr. Kapil Dev Mehta are employees of JB Pharmaceuticals Ltd. This Survey was conducted autonomously and had no influence of any pharmaceutical company.

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