

RECOMMENDATIONS

Management of Childhood Functional Constipation: Consensus Practice Guidelines of Indian Society of Pediatric Gastroenterology, Hepatology and Nutrition and Pediatric Gastroenterology Chapter of Indian Academy of Pediatrics

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Justification: Management practices of functional constipation are far from satisfactory in developing countries like India; available guidelines do not comprehensively address the problems pertinent to our country.

Process: A questionnaire-based survey was conducted among selected practising pediatricians and pediatric gastroenterologists in India, and the respondents agreed on the need for an Indian guideline on the topic. A group of experts were invited to present the published literature under 12 different headings, and a consensus was developed to formulate the practice guidelines, keeping in view the needs in Indian children.

Objective: To formulate practice guidelines for the management of childhood functional constipation that are relevant to Indian children.

Recommendations: Functional constipation should be diagnosed only in the absence of red flags on history and examination. Those with impaction and/or retentive incontinence should be disimpacted with polyethylene glycol (hospital or home-based). Osmotic laxatives (polyethylene glycol more than 1 year of age and lactulose/lactitol less than 1 year of age) are the first line of maintenance therapy. Stimulant laxatives should be reserved only for rescue therapy. Combination therapies of two osmotics, two stimulants or two classes of laxatives are not recommended. Laxatives as maintenance therapy should be given for a prolonged period and should be tapered off gradually, only after a successful outcome. Essential components of therapy for a successful outcome include counselling, dietary changes, toilet-training and regular follow-up.

Keywords: Lactulose, Laxatives, Polyethylene glycol, Rescue therapy.

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Functional constipation is a common problem in children. Although some guidelines exist for management of childhood constipation, there are no such guidelines for Indian children. In order to understand the existing practices and magnitude of the problem, a questionnaire was prepared with 22 questions and circulated to practicing pediatricians and pediatric gastroenterologists in India from October to December, 2014 using Monkey Survey tool. All the respondents felt the need for an Indian guideline. To accomplish this goal, a group of pediatric gastroenterologists and surgeons searched the published literature under 12 headings. A two-day deliberation was held on 19-20 September, 2015 at Jaipur, attended by selected pediatricians, pediatric

gastroenterologists and pediatric surgeons (*Annexure 1*). Each expert presented the existing literature, which was discussed inclusive of experiences and a consensus opinion was reached on different issues.

Functional constipation constituted 30% of pediatric gastroenterology office practice, 4-5% of all referrals to pediatric gastroenterology tertiary care centers and 0.8-1% of all pediatric cases in medical colleges. At the end of the meeting, it was decided to include these recommendations as a guideline on the evaluation and management of functional constipation in children in India. A writing group was designated for the same. The draft was sent by email to all experts and their suggestions were incorporated in the final guidelines.

DEFINITIONS

Normal stool frequency: There are very few studies on normal stool frequency and consistency in Indian children. The average stool frequency of Indian children is as follows: <1 month age: 3-4 times/day; 1 month to 1 year age: 1.5-2 times/day; 1 to 2 year age: 1-2 times/day, mostly formed; older than 2 year age: 1 time/day [1,2].

Constipation: A delay or difficulty in defecation sufficient to cause significant distress to the patient is defined as constipation. When the duration of constipation is less than 4 week, it is labeled as acute constipation and when the duration is more, it is labeled as chronic constipation.

Based on the North American Society of Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) guidelines, Rome III criteria [3,4] and expert opinion, the definition recommended for application in Indian children is given in **Box 1**.

Based on normal stool frequency of >1/day in Indian children of older than 2 year, physicians should be guided more by the stool consistency and other features of functional constipation rather than stool frequency. Stool frequency of ≤2/week as defined in Western guidelines may not be necessarily applicable in Indian children and may miss a substantial number of children with constipation if this criterion is taken in isolation. Collateral manifestations in the form of irritability, decreased appetite and/or early satiety may be observed, which improve after defecation.

The terms soiling/encopresis should not be used. Instead, the term 'fecal incontinence' should be used. This is defined as passage of stools in the undergarment. Fecal incontinence is classified as: (a) Constipation-associated fecal incontinence and (b) non-retentive fecal incontinence: diagnosed only if there is no constipation

Box 1 DEFINITION OF CONSTIPATION FOR USE IN INDIAN CHILDREN

- Duration of more than 4 weeks for all ages; and
- Presence of ≥2 of the following: (a) defecation frequency ≤2 times per week, (b) fecal incontinence ≥1 times per week after the acquisition of toileting skills, (c) history of excessive stool retention, (d) history of painful or hard bowel movements, (e) presence of a large mass in the rectum or on per abdomen examination, (f) history of large-diameter stools that may obstruct the toilet (This may not be elicitable for majority of Indian children who do not use the Western type of toilet).

and normal anal sphincter tone, and symptoms last for more than 2 months in a child with a developmental age of ≥4 years.

Refractory constipation: Constipation not responding to optimal conventional treatment for at least 3 months, despite good compliance [5]. These patients should be referred to a pediatric gastroenterologist for evaluation.

HISTORY AND EXAMINATION

History and examination are relevant in making a diagnosis of constipation, differentiating functional and organic constipation, looking for precipitants of functional constipation and eliciting issues relevant to management like incontinence, impaction, past treatment, treatment compliance and response to treatment. Clinical features and their interpretation are shown in **Table I**.

Dietary history: Details of diet should be taken: intake of fruits and vegetables and refined foods (e.g., bakery products), beverages etc. in older children, nature of feeds (breast vs top feeds) and details of supplementary feeds in younger babies. Exclusive and prolonged milk intake with minimal solids in young infants is a major factor causing functional constipation in India (unanimous opinion). These children are at an increased risk of iron deficiency anemia.

Important precipitating factors of functional constipation: The following are the most common factors which initiate constipation in children [8]: (a) premature initiation of toilet training (normally toilet training should start not before 24 months in a developmentally normal child) (b) drugs (**Table I**) and inter-current illnesses, (c) quick and abrupt transition of diet e.g. liquid to solid, breastfeeding to bottle feeding and (d) change in local environment (start of schooling) and psychosocial factors.

EVALUATION

Patients should be examined thoroughly with proper growth assessment to rule out an organic etiology (**Table I**). Lower abdomen should be palpated for fecoliths (soft or hard indentable masses). In the absence of abdominal fecoliths, anal fissure or anal malformations, digital rectal examination (index finger in an older child or little finger in an infant) helps in the following: (a) presence of fecal impaction (seen in 50-70% children with functional constipation and is diagnosed in the presence of a hard mass (fecal mass) in the lower abdomen or presence of large, hard stools (fecolith) on Digital rectal examination (DRE), (b) diagnosis of Hirschprung's disease (empty rectum, gush of stools/air on withdrawal of finger), and (c) sacral mass lesion (palpable mass). DRE is not essential

TABLE I CHARACTERISTICS OF FUNCTIONAL AND ORGANIC CONSTIPATION

<i>Clinical features</i>	<i>Interpretation</i>
Age at onset of constipation and time of passage of first meconium after birth	If onset is in early infancy: organic causes more likely. Normally, meconium is passed within first 48 hours of birth (in term babies); delayed passage is seen in Hirschsprung disease and other organic causes like cystic fibrosis.
Stool characteristics <ul style="list-style-type: none"> • Consistency • Frequency • Size-large/ small • Pain during defecation • Blood with defecation: streak on surface, drops after stooling 	Pasty stool in Hirschsprung disease and large or hard stools in functional constipation. Blood with painful defecation suggests anal fissure in vast majority and in older children painless bleeding occurs due to hemorrhoids or solitary rectal ulcer syndrome.
Retentive postures: the child hides behind furniture or goes to a corner; stands on toes with legs crossed and may be red faced. parents	Such posturing suggests holding of stools, a characteristic of functional constipation. Though it is often interpreted by as if the child is straining to pass stools.
Urinary symptoms in the presence of constipation: urinary frequency, burning, crying during micturition, urinary retention/ incontinence [6]	Known to occur with impacted stools as a part of constipation. Lately described as a part of Dysfunctional elimination syndrome (DES) wherein bladder-bowel dysfunction sets in due to several reasons like bladder instability due to fecaloma pushing urinary bladder or compression over bladder neck which inhibits bladder emptying [7]
<i>Features suggestive of common organic causes</i>	
Developmental delay, open posterior fontanel in young infants; lethargy, dry skin, cold intolerance in older children	Hypothyroidism
Abdominal distention, enterocolitis (fever, diarrhea, blood in stools, failure to thrive, suggestive per rectal findings)	Hirschsprung disease
Frequent falls after 1 year of age, abnormal gait, delayed walking, spinal dimple / tuft of hair or any abnormal neurological examination (power, tone and reflexes of lower limbs, anal tone and perianal reflex)	Spinal cord abnormalities: Spinal dysraphism, tethered cord, spinal cord tumour, sacral agenesis
Developmental delay, regression of mile stones, seizures, feeding difficulties.	Cerebral palsy, Down syndrome, Neurodegenerative disorders
Meconium ileus, recurrent respiratory infections, failure to thrive	Cystic fibrosis
Abdominal pain, distension and bilious vomiting	Mechanical intestinal obstruction, post surgical intestinal adhesions (history of prior abdominal surgery), pseudo-obstruction (megaduodenum, megaureter)
Rare causes should be suspected in definite clinical settings particularly when there is a failure of response	Celiac disease in the presence of anemia and growth failure. Lead poisoning presents with pain abdomen, blue gum lines and pallor.
<i>Drugs</i>	
Drug intake	Antispasmodics for abdominal pain: dicyclomine, drotaverine Anti-diarrheal agents like loperamide Antitussives (opioid analogues) in respiratory infection: codeine, dextromethorphan Anticholinergics for bladder instability in spinal disorders (oxybutynin, tolterodine)

in all cases or at all visits. It is recommended in the following instances: (a) red flag symptoms or signs, (b) onset <6 months of age, (c) non-responders despite good compliance to therapy, and (d) patients presenting with fecal incontinence to differentiate between constipation related and non-retentive incontinence [9-11].

Red flags suggestive of organic constipation: delayed passage of meconium, onset in early infancy, ribbon or pellet stools, bilious vomiting, uniform abdominal distension, failure to thrive, recurrent lower respiratory infections, cold intolerance, neuro-developmental delay or regression, gush of stools on DRE, anal malformations,

abnormal neurological examination (paraspinal, lower limbs and anorectal reflexes). Details are given in **Table I**.

Investigations: 95% children with constipation have functional constipation and do not need any investigations. Children with red flags (as above) suggestive of organic etiology or those who are diagnosed as functional constipation but fail to respond to therapy need diagnostic evaluation. A plain erect Xray abdomen or barium enema is not required as a routine investigation in all cases. [12-14].

MANAGEMENT OF FUNCTIONAL CONSTIPATION

The following points should be addressed: patient counseling, toilet training, modifications in diet, drug management, and follow-up.

Patient Counseling

Salient pathophysiological aspects inclusive of objective of treatment should be explained to the parents. Parents should be clearly explained the cause of functional constipation, preferably with a diagram. Any precipitating factors identified should be eliminated or modified by appropriate advice (*e.g.* in a child with exclusive milk feeding, (semi) solid diet supplementation should be instituted; drugs causing constipation should be stopped; any psychosocial factor operating needs to be addressed).

Toilet-training

Toilet training should not be started before 24 months of age; however, there is a variation in recommended age of training between 3-4 years. Follow the 'Rule of 1': Toilet training to be done by one person, one routine (5 min after each major meal), one place, one word *e.g.* pooh/potty etc. In a child with constipation: (a) make the child sit in the toilet, 2-3 times a day for 5-10 minutes after meals (within 30 minutes of meal intake), (b) make the defecation painless by treating anal fissures, if present, (c) sit in squatting position in the Indian toilet or with foot rest in English toilet/potty seat to have appropriate angulation of knees and thighs to facilitate expulsion of stools, (d) reward system (positive reinforcement) helps in motivating the child and avoiding child-parent conflict.

Diet, Fiber and Water Intake

There are no well-conducted randomized controlled studies of diet and treatment of constipation. Daily fiber requirement is 0.5 gm/kg/day. Adequate intake of fiber-rich diet (cereals, whole pulses with bran, vegetables, salad and fruits) is recommended at the initial counseling. High fiber diet chart should be given to parents (as per local practice). Restrict milk and encourage intake of semi-

solids and solids in younger children. Ensure adequate intake of water. Normal activity is recommended.

Medical Therapy

It consists of initial phase of disimpaction in patients with fecal impaction and a maintenance phase with laxatives.

Disimpaction

Rationale of disimpaction: Completely clear the colon so that no residual hard fecal matter is retained. Thereafter the maintenance laxative therapy can keep the bowel moving and empty so that there is no retention. This enables rectum to achieve the normal diameter and tone for proper anorectal reflexes and pelvic floor coordination to facilitate normal stool expulsion

Options for Disimpaction: There are two ways of disimpaction (**Table II**) (a) one-time hospital based (100% success) (b) home based in split doses (68-97% success) [14,15,17]. Rarely rectal enemas can be used as supplementary therapy to clear the heavily hard loaded colorectal region. Oral route is preferred as it non-invasive, has better patient acceptability, cleans the entire colon and is equally effective as rectal disimpaction. Manual evacuation of rectum is rarely required in patients failing oral and rectal disimpaction but it should be performed under anaesthesia. Children undergoing disimpaction should be reviewed within one week of disimpaction to assess for re-impaction. Maintenance therapy should be started only after effective disimpaction.

Maintenance therapy

There are different classes of laxatives used for constipation (osmotic and stimulants).

Osmotic laxatives: These are the mainstay of maintenance therapy in children [5]. These laxatives draw water into the stool thereby making the stools softer and easy to pass. The two main osmotic laxatives are polyethylene glycol (PEG) and lactulose/lactitol (**Table III**). Based on the literature, and the experience of the group, the recommendations are: (i) PEG is the first line of therapy and is more effective as compared to lactulose/lactitol. However in children <1 year of age, the only drug recommended is lactulose/lactitol. (ii) In case of non-response or intolerance due to non-palatability to PEG, the second line of treatment is lactulose/lactitol which is safe for all ages. (iii) Two osmotic agents like PEG and lactulose/lactitol should not be given simultaneously. Combinations therapy with two classes of laxatives is not recommended for children [5].

Stimulant Laxatives: Stimulant laxatives are used only as rescue therapy No randomized controlled trials are

TABLE II DISIMPACTION

<i>Agent</i>	<i>Dosage</i>	<i>Side effect</i>	<i>Comments</i>
<i>Oral agents</i>			
Polyethylene glycol*(at home)	1.5-2 g/kg/ d in two divided doses for 3-6 d** only depending upon the clarity of rectal effluent	Loose stools, bloating/ flatulence, nausea, vomiting	–
Polyethylene glycol solution for lavage (in hospital)	25 mL/ kg/ h oral or by nasogastric tube in young children End point is clear rectal effluent Young children may require intravenous fluids to maintain hydration	Nausea, vomiting, abdominal cramps, rarely electrolyte abnormality, pulmonary aspiration	Caution: during one-time disimpaction, watch for bloating, abdominal distension or fluid overload
<i>Rectal agents</i>			
Enemas (once per day) [15]			
Saline	Neonate <1 kg: 5 mL; >1 kg: 10 mL >1y: 6 mL/kg, once or twice/day		Not usually practised except in special situations
Phosphate soda (Proctoclysis enema 100 mL)	2-18 y: 2.5 mL/kg, max 133 mL/dose	Hyperphosphatemia Hypocalcemia	

*PEG is a metabolically inert, large molecular weight soluble polymer with capacity to retain intraluminal water. PEG is available with or without electrolytes and as PEG 3350 or 4000. With the available evidence, PEG 3350 or 4000 and PEG with or without electrolytes are all equally effective in disimpaction [16]; *For one-time disimpaction there are Indian formulations where one pack (containing polyethylene glycol of 118gm) should be reconstituted in 2 litres of water; ** For maintenance or home-based disimpaction the preparation may vary from 6.5g/scoop to 17g /sachet, and needs to be confirmed before prescription.*

TABLE III OSMOTIC LAXATIVES FOR MAINTENANCE THERAPY

<i>Osmotic laxative</i>	<i>Dose</i>	<i>Side effects</i>	<i>Comment</i>
<i>Polyethylene Glycol [16]</i>	0.5-1g/kg/day >12 mo age	Bloating, Abdominal pain/cramps Vomiting Loose stools	Safe for both short and long term use
<i>Disaccharides [19]</i>			
Lactulose: non absorbable synthetic disaccharide, consists of 2 molecules of galactose and fructose	1mo-12mo: 2.5 mL BD; 1-5y: 2.5-10 mL BD; 5-18y: 5-20 mL BD	Abdominal distension Discomfort	Lactulose undergoes fermentation in the colon to yield short chain fatty acids, CO ₂ and H ₂
Lactitol (β-galactosido-sorbitol): monohydrate is a analogue of lactulose, consists of galactose and sorbitol	250 to 400 mg/kg/d (15 mL =10 g of lactitol monohydrate)		Lactitol is more palatable with better acceptability

available in children regarding their efficacy. Stimulants are usually required as rescue therapy (an acute or sudden episode of constipation while being on regular compliant maintenance therapy). These stimulants are given for a short duration of 2-3 days to tide over the acute episode of constipation, and then stopped (**Table IV**) [18].

Behavioral therapy and biofeedback; These are helpful

when constipation is associated with behavioral comorbidity or pelvic floor dysfunction in older children and adolescents. This requires referral to centers with expertise.

Follow-up: Regular follow-up is essential. At each follow-up, record the stool history, associated symptoms, compliance with diet, medications and toilet-training. It is

TABLE IV STIMULANT LAXATIVES: RESCUE THERAPY

Name	dose	Side effects	Comments
Acts by stimulating colonic motility, promoting secretion and inhibition of absorption of water and electrolytes in colon	Oral (effect in 6-8 h), single bedtime dose 3-10 y: 5 mg/d >10 y: 5-10 mg/d Should not be used in children below 3 years of age Rectal (effect within 30-60 min) 2-10 y: 5 mg/d >10 y: 5-10 mg/d	Short term usage is free from side effects. Abdominal cramps, diarrhea, hypokalemia, proctitis (rare), on prolonged use.	Contraindicated in children with proctitis or anal fissures.
<i>Sodium Picosulphate</i>			
Acts through its active metabolite that is produced by the intestinal bacteria and increases the peristalsis of gut	Given as single dose 1 mo-4 y 2.5-10 mg/d 4 to 18 y 2.5-20 mg/d Available as liquid	Abdominal pain, nausea, and diarrhea ~ 50%	Contraindicated in setting of proctitis and gaseous abdominal distension (underlying intestinal obstruction or paralytic ileus)

In view of the side effects of these agents, it is advocated for short duration as rescue therapy.

important to have a stool diary for proper follow-up. Parents should maintain a stool diary for objective assessment of response to therapy related to stool frequency and consistency. First follow-up is advised at 14 days to assess compliance. Subsequently, 1-2 monthly follow-up till normal bowel habit is attained or physician is satisfied with response as defined below as 'successful outcome'. Further, 3-monthly follow-up for a minimum period of one year. While on follow-up, the maintenance dose may be increased or decreased to achieve daily passage of stools, keeping in view the features of successful outcome.

Successful outcome of treatment should be defined as (a) stool normalcy while on laxatives for a period of at least 4 weeks of initiation of therapy, and (b) achievement of stool normalcy for a minimum period of 6 months before tapering. Normalcy of stools should be defined as daily, not hard, nor loose watery stools, with absence of pain, straining, bleeding, posturing or incontinence.

In Western countries, 50% of children with functional constipation recover and are taken off medication within 6-12 months [19, 20]. About 25% continue to experience symptoms up to adult age [21]. Data from India show that 95% respond over a mean (SD) follow-up of 15.0 (16.7) months [14]. 18.4% patients have recurrence of symptoms on follow up; 10.5% of them require rescue disimpaction after a median duration of 5.5 (1.5-17) months of the first disimpaction [14].

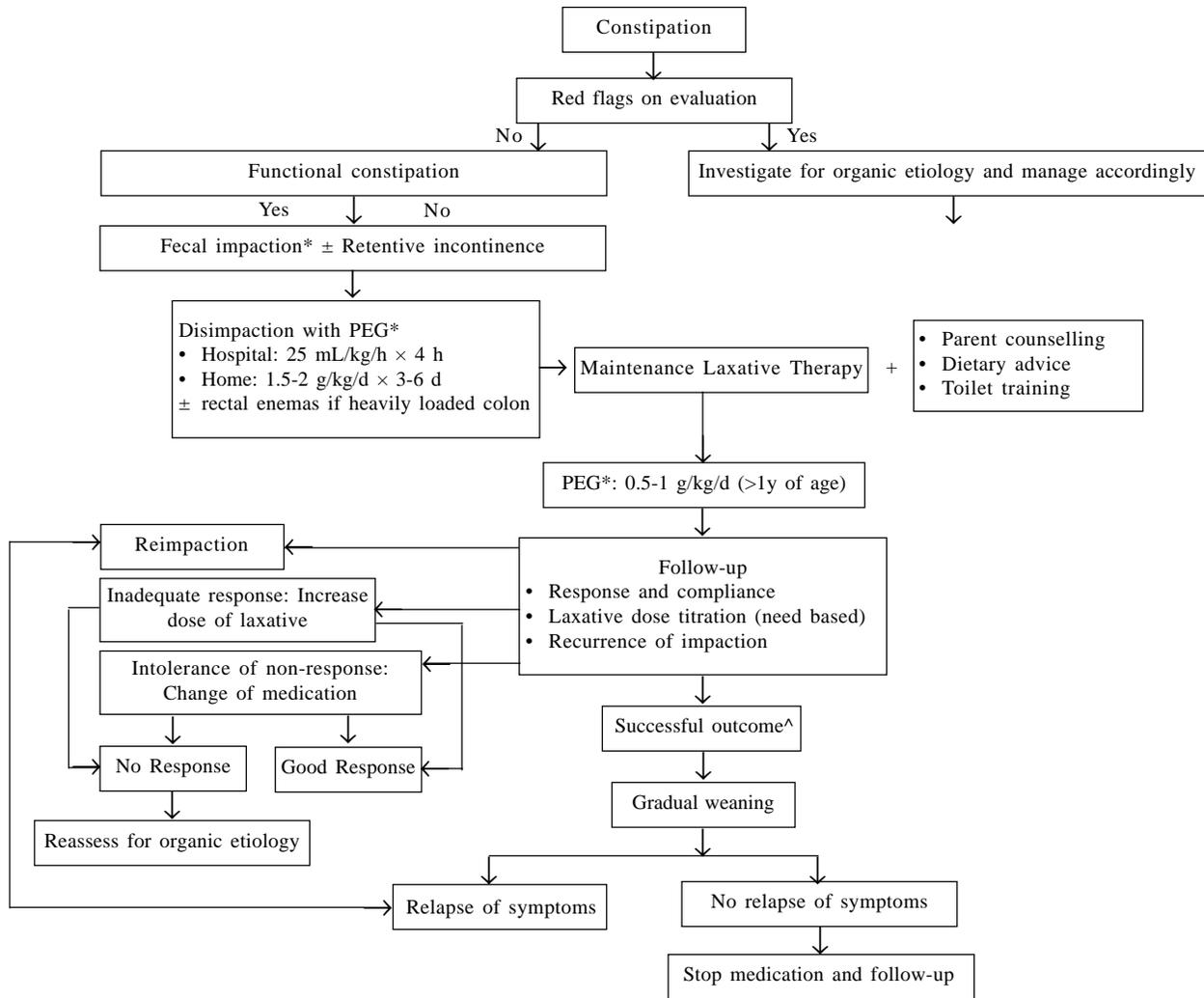
When to stop laxatives: No clear guidelines exist and only expert opinions are available. Based on the natural

history, child should have been symptom-free while on maintenance therapy for at least 6 months before attempting to taper the laxatives. It is then advisable to taper gradually over a period of 3 months. Laxatives should never be stopped abruptly. In the developmental stage of toilet training, medication should only be stopped once toilet training and establishment of a regular stooling pattern is achieved. Dietary and toilet training advice should continue even after stoppage of laxatives. Triggers and precipitating factors of functional constipation should have been adequately addressed. Parents should have the knowledge about the management and also risk of relapse of symptoms on stoppage of medication.

Refractory constipation: Those patients not responding to a sustained optimal medical management of functional constipation should be investigated for hypothyroidism, celiac disease, Hirschprung disease, Cow milk protein allergy in young children, lead poisoning and spinal abnormalities. These children also need evaluation for presence of slow colonic transit, pelvic dyssynergia and pseudo-obstruction, in centers with expertise.

CONCLUSION

Functional constipation should be diagnosed in the absence of red flags. Impacted (incontinent) and non-impacted subgroups should be identified. Management protocol should be adapted as per the algorithm shown in **Fig. 1**. Emphasis should be laid on toilet-training and importantly in counselling particularly related to long-term usage of medical therapy.



*Fecal impaction (seen in 50-70% children with functional constipation) is diagnosed in the presence of a hard mass (fecal mass) in the lower abdomen or presence of large, hard stools on DRE (fecolith); and ^Successful outcome defined as (a) stool normalcy while on laxatives for a period of at least after 4 weeks; initiation of therapy, and (b) achievement of stool normalcy for a minimum period of 6 months before tapering; PEG: polyethylene glycol (refer table 2); stimulant laxatives are not a part of the routine management of algorithm and should only be reserved for rescue therapy.

FIG. 1 Algorithm for the management of childhood functional constipation.

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ANNEXURE 1: PARTICIPANTS OF THE INDIAN SOCIETY OF PEDIATRIC GASTROENTEROLOGY, HEPATOLOGY AND NUTRITION COMMITTEE ON CHILDHOOD FUNCTIONAL CONSTIPATION, AND PEDIATRIC GASTROENTEROLOGY SUBSPECIALTY CHAPTER OF INDIAN ACADEMY OF PEDIATRICS

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