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# Systematic literature review and meta-analysis on therapeutic management of faecal impaction in the paediatric population

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## ABSTRACT.

**Background** To date, there is no universally accepted or standardised protocol for management of faecal impaction (FI) in paediatric population. If left untreated, it can lead to serious consequences for the health and well-being of the child. We set out to determine the effectiveness and safety of existing therapeutic interventions for FI in children and identify any gaps occurring in current research.

**Methods** We have performed a systematic literature review on treatment of FI in paediatric population in accordance with Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines. We have included randomised controlled trials (RCTs) on all interventions for children (0–18 years old) with FI on background of functional constipation and excluded children with organic causes of FI. Our primary outcomes were treatment success, defecation frequency and withdrawals due to adverse events. We have performed a meta-analysis of the data.

**Results** Out of 13 341 records identified, only eight RCTs met our inclusion criteria with a total of 513 participants randomised. The diagnosis of functional constipation was mainly made using ROME III criteria. The diagnosis of FI varied from study to study. We identified several intervention groups based on our search. Our analysis has shown that there is no difference probably between PEG (Polyethylene Glycol).
and PEG with sodium picosulphate, and there may be no difference between PEG and rectal enema for treatment success, but enema may lead to greater stool frequency. No other studies produced anything other than very low certainty evidence.

**Conclusions** No therapeutic approach was superior to others, with evidence limited by significant clinical heterogeneity related to varying patient and clinical factors, different outcome measures and limited study numbers. More high-quality research is needed to determine effective strategies for FI. Moreover, a consensus should be reached regarding the definition and diagnosis of FI as based on that a standardised approach to patient's care can be determined.

### WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Faecal impaction is a problem that can have detrimental consequences. It can be a consequence of functional constipation. To date, there is no widely accepted treatment strategy, and management consists of various pharmacological and non-pharmacological options.

### WHAT THIS STUDY ADDS

⇒ There is some evidence suggesting no difference between PEG (Polyethylene Glycol) and rectal enemas or PEG with sodium picosulphate. The rest of the evidence base is limited and no further conclusions can be made.

### HOW THIS STUDY MAY AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This meta-analysis could inspire future research by identifying gaps in the current literature. It can also guide researchers towards a more targeted approach in children with faecal impaction.

## INTRODUCTION

To date, there is no widely accepted definition of faecal impaction (FI). In general, it is referred to as a large mass of compacted stool in the rectum and/or colon that cannot be spontaneously evacuated.[1] FI can be identified by physical examination, including rectal examination, or with the help of imaging techniques (abdominal radiograph, ultrasound).[1] Lack of definition could reflect the understanding of FI as a symptom of wider constipation, rather than a standalone condition. However, it is a common reason for acute presentation in constipated children.[2] Prompt attention to FI is vital to minimise the risk of complications and avoid inappropriate or prolonged treatment. There is also no universally accepted or standardised protocol for the management of FI. Currently, various therapeutic strategies exist including pharmacological (laxatives, lubricants, prucalopride, lubiprostone, linaclotide, enemas/ rectal irrigation), or surgical (ACE procedure).

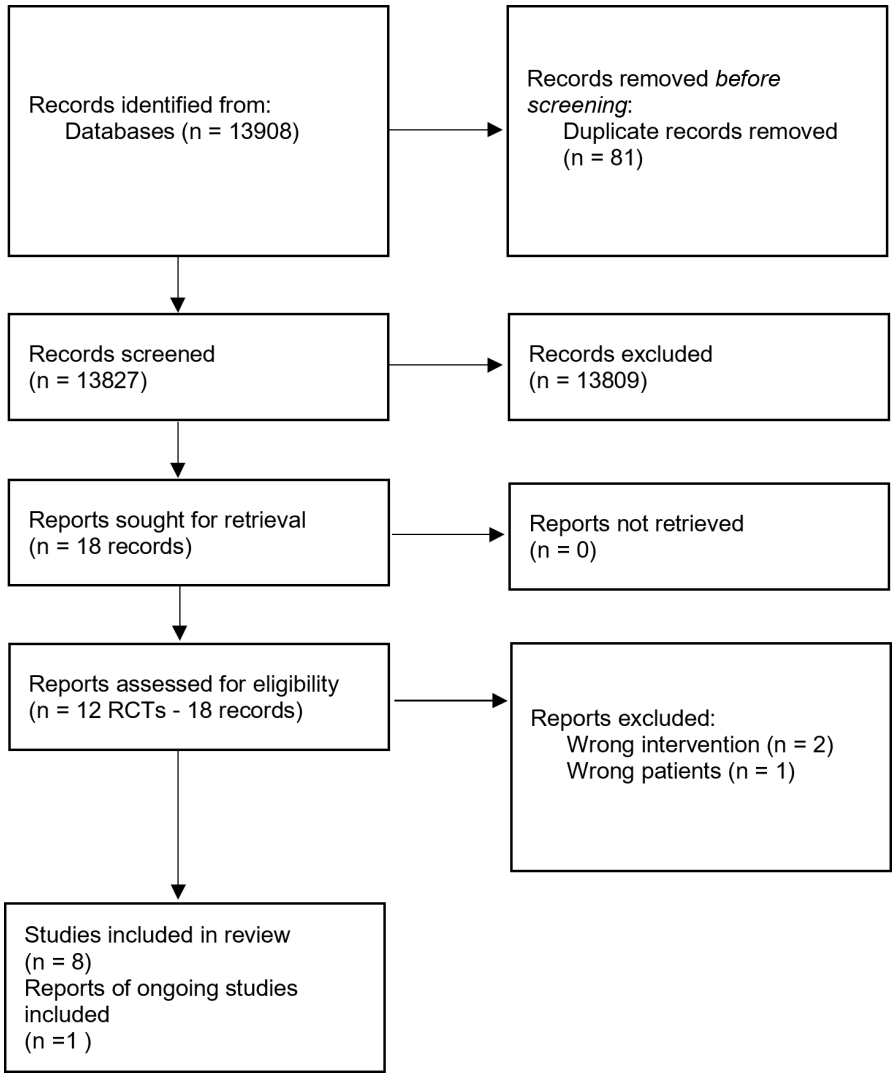


**Figure 1** PRISMA flow diagram. PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

FI may form as a result of certain conditions (neurological, endocrine), however, in this systematic literature review, we are focusing on FI that developed as a result of functional constipation (FC). FC is one of the most common disorders of gut–brain interaction in children with prevalence ranging between 0.7% and 29.6%.[2] It is diagnosed according to ROME IV criteria.[3] Children with FC are found to have lower health-related quality of life compared with healthy controls,[4] more behavioural problems and emotional symptoms.[5] Often FC is accompanied by FI. One study found that out of 169 children who were diagnosed with FC, 76 (45%) had FI.[6] Another study reported FI in 66% of children who qualified for an FC diagnosis.[7] Hereby, identification and treatment of FI are paramount in establishing the well-being of a child.

Due to varied definitions for FI as well as varied treatment options, it can be difficult for a caregiver to decide on the best treatment strategy for children presenting with FI. Some of the treatment options are invasive, and not the preferred first choice for the management of FI in children. In this review, we aimed to assess the efficacy and safety of pharmacological and non-pharmacological treatment options for faecal disimpaction in children with FC (0–18 years). We also aim to propose a stepwise approach for treatment escalation, therefore suggesting a guide for caregivers to use when managing FI. Finally, this meta-analysis serves as a template to identify gaps in the current literature and guide researchers towards the areas that need development.

## METHODS

We included all published, unpublished and ongoing randomised controlled trials (RCT) on the management of FI in children. We considered studies published as full text or abstract, we also considered unpublished data. This systematic review was registered at Prospero.[8] Patient and public were not involved in this work as it was secondary synthesis and not primary research.

On 6 November 2023 (with a further update search on 1 February 2025), the relevant trials were identified by searching PubMed, MEDLINE, EMBASE, PsycINFO, Cochrane Library (from inception to present). Detailed search strategy is available in online supplemental material.

To identify unpublished or ongoing studies, we searched the following websites: the ClinicalTrials.gov register, the WHO International Clinical Trials Registry Platform Search Portal, the Current Controlled Trials meta-Register of Controlled Trials—active registers. We have also contacted the experts in the field. To identify relevant articles and reviews missed by the search strategies, we have searched the reference lists from reviewed articles. No language restrictions were applied.

We have included all RCTs on pharmacological and/or non-pharmacological interventions for children aged 0–18 diagnosed with FC and FI as defined by authors of the study. We have excluded studies where there was no definition of FC, intractable constipation or FI provided, studies including children with organic causes for constipation or previous bowel surgery, studies describing faecal incontinence without the presence of constipation.

We considered all pharmacological (osmotic and/or stimulant laxatives, enemas, suppositories, lubricants, prucalopride, lubiprostone, linaclotide, rectal irrigation) and non-pharmacological (manual disimpaction, ACE procedure) treatment options. We considered both dichotomous and continuous outcomes. If both were available for the same outcomes, we analysed and reported them separately.

Our primary outcomes were treatment success defined by primary studies, defecation frequency at every follow-up point, and withdrawals due to adverse events. Our secondary outcomes were based on the developed core outcome set for children with FC 0–18 years and included painful defecation, stool consistency, quality of life of parents and patients measured using any validated defined measurement tool, faecal incontinence (if age appropriate), abdominal pain (if age appropriate), school attendance (if age appropriate), serious adverse events, total adverse events, tolerability (or defined as acceptability or compliance).

### Data collection and analysis

We carried out data collection and analysis according to recommendations in the Cochrane Handbook for Systematic Reviews of Interventions.[9]

Four review authors (SL, AA, MG and AB) independently screened the titles and abstracts identified during the literature search using Covidence. We obtained the full report of studies that appeared to meet our inclusion criteria, or for which there was insufficient information to make a final decision. Two review authors (VS and AA) independently assessed the full reports to establish whether the studies met the inclusion criteria. Same studies with multiple reports were linked together. We resolved disagreements by discussion and consulted with a third review author (MG) if resolution was not possible. We documented all excluded studies with their reason for exclusion. In case of an abstract or a letter report, or a study with insufficient information, the authors were contacted for full details. If no response was received within 2 weeks, the study was excluded. Three review authors (SL, AA, AB) independently performed data extraction using a predesigned data extraction form. Inter-researcher disagreements were resolved by a fourth investigator (MG, VS).

### Risk of bias assessment

Two review authors (SL and VS) independently assessed all studies that met the inclusion criteria for their risk of bias (ROB), using the original Cochrane ROB tool.[10] We judged the studies to be at low, high or unclear ROB for each domain assessed. Any discrepancies were resolved by the third author (MG).

Two review authors (VS and MG) independently assessed the overall quality of evidence using the GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach and graded them as follows: high quality, moderate quality, low quality, very low quality.[11]

### Measure of treatment effect

When interventions, patient groups and outcomes (primary and secondary outcomes as listed above) were deemed to be sufficiently similar (determined by consensus), data from individual trials were combined for meta-analysis. Dichotomous outcomes were analysed as relative risks (RRs) along with 95% CIs. Continuous outcomes were reported as mean differences (MDs) with 95% CIs. Heterogeneity was quantified by using $\chi^2$ tests and the $I^2$ statistics. We used a random effects model. For all outcomes in all studies, we carried out analyses as far as possible on an intention-to-treat basis. We conducted analyses for continuous outcomes based on participants completing the trial, in line with available case analysis; this was assumed that data were missing at random.

## RESULTS

The results of the search are demonstrated in the study flow diagram (figure 1). One study[12] comparing efficacy and tolerability of PEG 4000 and PEG 3350+ electrolytes has been included as ongoing—only clinical trial registration is available for review.

### Included studies characteristics

Summary of characteristics of included eight studies is found in table 1 and more information per study in online supplemental table 1. Details about excluded studies are in online supplemental table 2.

Seven out of eight studies defined FC according to Rome III criteria.[13 14] There was no consistent definition and diagnosis of FI. The main diagnostic techniques included abdominal examination, digital rectal examination and the use of abdominal X-rays. The duration of FI was not reported in five studies, and in those reported varied between 5 and 18 months.

### Risk of bias

A summary of the risk of bias of the included studies is seen in figure 2, and details per study in online supplemental table 3. Six out of eight studies scored low for random sequence generation, with two having uncertain ROB.

Table 1 Summary of characteristics of included studies

| Study ID | FI diagnosis | Intervention | Concurrent therapy | Treatment success definition | Study duration |
|---|---|---|---|---|---|
| Acharyya 2021[17] | FC diagnosed by Rome III criteria. FI was decided on abdominal examination or abdominal X-ray | PEG3350+E solution vs PEG3350+E with sodium picosulphate | Lactulose, PEG, Homeopathic, Ayurvedic preparations, Sitz-bath | Not stated very clearly. We have used the outcome of 'no need for enema' as a successful disimpaction | Inpatient for 2 days, outpatient thereafter (18 months) |
| Bekkali 2009[15] | Presence of rectal FI on digital rectal examination (DRE) defined as large amount of hard stool in rectum (faecaloma). Rome III criteria for FC | Rectal enemas (dioctylsulfosuccinate sodium, Klyx) OD for 6 days vs oral PEG3350 with electrolytes, Movicol 1.5 g/kg/d for 6 days | Prior use of enemas | Absence of faecaloma on DRE. If children were scared to undergo the second DRE—AXR was performed | 6 days followed by maintenance treatment for 2 weeks |
| Farahmand 2010[18] | Rome III for FC with DRE to confirm FI | 3 mL/kg/day liquid paraffin oil per oral route in two divided doses VS (same dosage) rectal route | Dietary fibre | Not reported | 3 days |
| Miller 2012[16] | FC defined according to Rome III criteria. FI: lower quadrant mass or dilated rectum with hard stool | Milk and molasses enema vs oral high-dose PEG 3350 (1.5 g/kg/d, max dose of 100 g/d) | Sodium biphosphate/sodium phosphate enema treatment | Treatment success=opposite of treatment failure. Treatment failure: participant who received an enema at home, returned to the ED for evaluation, or was later admitted to an inpatient service for treatment of FI. | 3 days in emergency department |
| Shatnawi 2019[19] | FC according to Rome III criteria with evidence of FI. FI is the presence of faecal mass (faecaloma) that can be assessed radiologically or by rectal exam | Lactulose 4–6 mL/kg/day divided into two doses (maximum 120 mL/day) vs PEG (macrogol 4000) 1.5 g/kg/day divided into two doses (max 30 g/day) | Not reported | Not reported | Treatment until resolution or for 6 days. |
| Tolia 1993[20] | On physical examination, assessment for palpable faecal masses in the abdomen, bloating, tenderness or distention of the abdomen was done. On rectal examination, anal sphincter tone, presence of fissures, perineal soiling, consistency and approximate amount of stool in the rectal ampulla and presence of occult blood in the stool was determined | 2–8 tablespoons (30 mL/10 kg body weight) of mineral oil in two divided doses vs oral lavage solution 20 mL/kg/h for 4 hour once daily | Metoclopramide | No palpable abdominal masses | 2 days |
| Vadlapudi 2022[13] | FC according to Rome III. FI was identified based on palpable faecalith per abdomen, hard stool palpable per rectum or X-ray showing a loaded colon as per Barr scoring criteria | Hospital-based: PEG-3350 with electrolytes at a rate of 20 mL/kg/hour till they passed clear watery stools vs home-based: PEG-3350 at a dose of 1–1.5 g/kg/day for 6 days | Not reported | Passage of clear watery stools | Hospital-based—until treatment success, home-based for 6 days |

Continued

**Table 1** Continued

| Study ID | FI diagnosis | Intervention | Concurrent therapy | Treatment success definition | Study duration |
|---|---|---|---|---|---|
| Youssef 2002[14] | FC diagnosed with Rome criteria. FI: palpable mass in the left lower abdomen and/or a dilated rectum filled with a large amount of hard stool | PEG 3350 in 1 of 4 doses, 0.25 g/kg per day (group I), 0.5 g/kg per day (group II), 1 g/kg per day (group III), or 1.5 g/kg per day (group IV) | None | Clearance of FI determined by abdominal and rectal examination: rectal vault that was either empty or had a small amount of soft stools; resolution of the left lower quadrant mass | 3 days (home treatment) |

ED, Emergency Department; FC, functional constipation; FI, faecal impaction; PEG, Polyethylene Glycol.

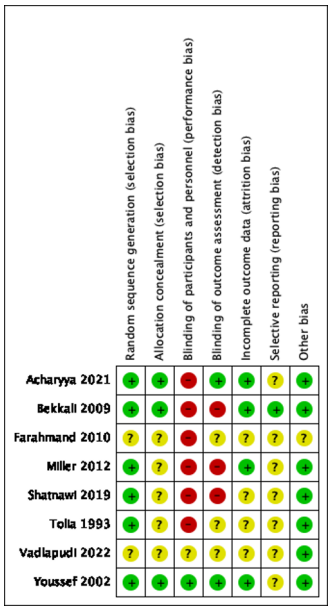


**Figure 2** Risk of bias within included studies.

Five out of eight studies had uncertain ROB for allocation concealment with three scoring low. Six out of eight studies scored as high for blinding of participants and personnel, one scored low and one had uncertainty. Three out of eight studies had high ROB for blinding of outcome assessors, three uncertain ROB and two low. Four out of eight studies had low ROB for incomplete outcome data, with four having uncertainty. Seven out of eight studies had uncertainty for selective reporting, with one being low. Seven out of eight studies scored low for other bias, with one having uncertainty.

### Primary outcomes

The eight included studies made seven different comparisons of interventions with a total of 513 participants randomised. The extracted data for all outcomes can be found in online supplemental table 1), and summary of findings table with per study information in table 2 and online supplemental table 4.

Forest plots are in the main text (figure 3,(figure 4,(figure 5) and those that are not included in the main text are available in supplementary materials as online supplemental figures 1-8.

### Rectal enema versus oral PEG

This comparison included two studies.[15 16]

For treatment success, defined by one study as absence of faecaloma, and by another study as the opposite of treatment failure, there may be no difference between oral PEG (64/83) and rectal enema (75/87). The certainty of the evidence is low (RR 0.92, 95% CI 0.81 to 1.04).

For defecation frequency at 2 weeks, defined as the mean number of stools per week, there may be a difference between oral PEG (mean 8.8 SD 8.5) and rectal enema (mean 5.8 SD 3.6) towards the rectal enema

**Table 2** Summary of findings table—rectal enema versus PEG

**Rectal enema compared with oral PEG for faecal impaction.**

**Patient or population: children with faecal impaction**
**Settings: outpatient department in single Amsterdam tertiary hospital and emergency department in single USA hospital**
**Intervention: oral PEG**
**Comparison: rectal enema**

| Outcomes | Illustrative comparative risks* (95% CI) | | Relative effect (95% CI) | Number of participants (studies) | Quality of the evidence (GRADE) | Comments |
|---|---|---|---|---|---|---|
| | Assumed risk | Corresponding risk | | | | |
| | With rectal enema | With oral PEG | | | | |
| Treatment success Day 5 and Day 28 | 862 per 1000 | 793 per 1000 (698–896) | RR 0.92 (0.81–1.04) | 170 (2 studies) | ⊕⊕⊖⊖ **low** | 1 level downgraded for serious concerns with ROB. 1 level downgraded for serious concerns with imprecision. |
| Defecation frequency at 2 weeks Times per week Day 14 | | The mean defecation frequency in the intervention groups was 3.00 **lower** (0.28 lower to 5.72 higher) | The mean score in the control group was 8.8 defecations per week | 90 (1 study) | ⊕⊕⊖⊖ **low** | 1 level downgraded for serious concerns with ROB. 1 level downgraded for serious concerns with imprecision. |
| All withdrawals. Day 5 and Day 28 | 161 per 1000 | 246 per 1000 (135–449) | RR 1.53 (0.84–2.79) | 170 (2 studies) | ⊕⊖⊖⊖ **very low** | 1 level downgraded for serious concerns with ROB. 2 levels downgraded for very serious concerns with imprecision. |
| Stool consistency: watery stools. Day 28 | 217 per 1000 | 636 per 1000 (352–1000) | RR 2.93 (1.62–5.29) | 90 (1 study) | ⊕⊕⊖⊖ **low** | 1 level downgraded for serious concerns with ROB. 1 level downgraded for serious concerns with imprecision. |
| Stool consistency 'ideal' on day 5 Day 5 | 634 per 1000 | 437 per 1000 (285–666) | RR 0.69 (0.45–1.05) | 80 (1 study) | ⊕⊖⊖⊖ **very low** | 1 level downgraded for serious concerns with ROB. 2 levels downgraded for very serious concerns with imprecision. |
| Faecal incontinence. Frequency times per week Day 28 | | The mean faecal incontinence in the intervention groups was 10.20 **lower** (6.28 lower to 14.12 higher) | The mean score in the control group was 3.4 faecal incontinence episodes per week | 90 (1 study) | ⊕⊕⊕⊖ **moderate** | 1 level downgraded for serious concerns with ROB. |

Continued

**Table 2** Continued

| Rectal enema compared with oral PEG for faecal impaction. | | | | | | |
|---|---|---|---|---|---|---|
| **Patient or population: children with faecal impaction**<br>**Settings: outpatient department in single Amsterdam tertiary hospital and emergency department in single USA hospital**<br>**Intervention: oral PEG**<br>**Comparison: rectal enema** | | | | | | |
| | **Illustrative comparative risks* (95% CI)** | | | | | |
| | **Assumed risk** | **Corresponding risk** | | | | |
| **Outcomes** | **With rectal enema** | **With oral PEG** | **Relative effect (95% CI)** | **Number of participants (studies)** | **Quality of the evidence (GRADE)** | **Comments** |
| Abdominal pain. Day 5 and Day 28 | 264 per 1000 | 541 per 1000 (271–1000) | RR 2.05 (1.03–4.08) | 170 (2 studies) | ⊕⊖⊖⊖ **very low** | 1 level downgraded for serious concerns with ROB. 1 level downgraded for serious concerns with imprecision. 1 level down for serious concerns with inconsistency. |
| Accessibility: struggle to administer. Day 28 | 522 per 1000 | 386 per 1000 (245–616) | RR 0.74 (0.47–1.18) | 90 (1 study) | ⊕⊖⊖⊖ **very low** | 1 level downgraded for serious concerns with ROB. 2 levels downgraded for very serious concerns with imprecision. |
| Tolerability: more anxious during disimpaction. Day 28 | 783 per 1000 | 572 per 1000 (423–767) | RR 0.73 (0.54–0.98) | 90 (1 study) | ⊕⊖⊖⊖ **very low** | 1 level downgraded for serious concerns with ROB. 2 levels downgraded for very serious concerns with imprecision. |
| Adverse events: abdominal pain after treatment Day 28 | 816 per 1000 | 514 per 1000 (359–751) | RR 0.63 (0.44–0.92) | 90 (1 study) | ⊕⊖⊖⊖ **very low** | 1 level downgraded for serious concerns with ROB. 2 levels downgraded for very serious concerns with imprecision. |
| Painful defecation, day 5. Day 5 | 146 per 1000 | 128 per 1000 (42–385) | RR 0.88 (0.29–2.64) | 80 (1 study) | ⊕⊖⊖⊖ **very low** | 1 level downgraded for serious concerns with ROB. 2 levels downgraded for very serious concerns with imprecision. |
| Tolerability: 'somewhat upset' Day 5 | 463 per 1000 | 14 per 1000 (0–199) | RR 0.03 (0.00–0.43) | 80 (1 study) | ⊕⊖⊖⊖ **very low** | 1 level downgraded for serious concerns with ROB. 2 levels downgraded for very serious concerns with imprecision. |

GRADE Working Group grades of evidence. **High quality:** Further research is very unlikely to change our confidence in the estimate of effect. **Moderate quality:** further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate. **Low quality:** further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate. **Very low quality:** we are very uncertain about the estimate.
*The basis for the **assumed risk** (eg, the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% CI) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
ROB, risk of bias; RR, risk ratio.

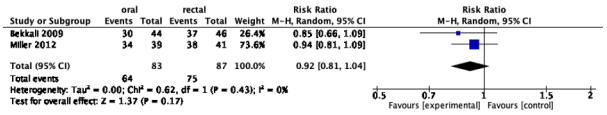


**Figure 3** Forest plot of treatment success PEG versus rectal enemas.

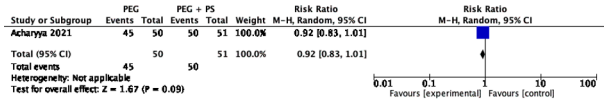


**Figure 5** Forest plot of treatment success PEG versus PEG and sodium piscosulphate.

group. The certainty of the evidence is low (MD 3.00 95% CI 0.28 to 5.72).

There were no withdrawals due to adverse events reported by the studies.

### PEG versus PEG with sodium picosulphate

This comparison included one study.[17]

For treatment success, defined as no need for enema, there is probably no difference between PEG (45/50) and PEG with sodium picosulphate (50/51). The certainty of evidence is moderate (RR 0.92 95% CI 0.83 to 1.01).

For mean stool frequency at week 1, defined as number of stools per week, when PEG (mean 3.5 SD 0.84) was compared with PEG+PS (mean 7.1 SD 1.2), no conclusions can be drawn due to the very low certainty of the evidence (MD −3.60 95% CI −4.00 to −3.20). For mean stool frequency at week 4, when PEG (mean 7.3 SD 1.5) was compared with PEG+PS (mean 14.4 SD 2.1), no conclusions can be drawn due to the very low certainty of the evidence (MD −7.10 95% CI −7.81 to −6.39).

Withdrawals due to adverse events were not reported by the authors.

### Oral paraffin oil versus rectal paraffin oil

This comparison included one study.[18]

For treatment success, definition of which was not reported by the study, when oral paraffin oil (37/40) was compared with rectal paraffin oil (33/40), no conclusions can be drawn due to the very low certainty of the evidence (RR 1.12 95% CI 0.95 to 1.33).

Defecation frequency was not reported by the study.

There were no withdrawals occurring.

### Lactulose versus PEG

This comparison included one study.[19]

For treatment success, the definition of which was not reported by the authors, when lactulose (21/33) was compared with PEG (28/32), no conclusions can be drawn due to the very low certainty of the evidence (RR 0.73 95% CI 0.54 to 0.97).

Defecation frequency was not reported by the authors. There were no withdrawals occurring due to adverse events.

### Mineral oil versus oral lavage solution

This comparison included one study.[20]

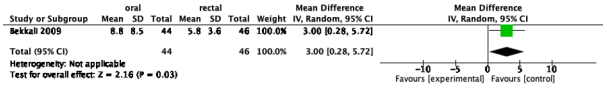


**Figure 4** Forest plot of defecation frequency PEG versus rectal enemas.

For treatment success, defined as no palpable abdominal masses, when mineral oil (10/24) was compared with oral lavage solution (17/24), no conclusions can be drawn due to the very low certainty of the evidence (RR 0.59 95% CI 0.34 to 1.01).

For defecation frequency, defined as number of bowel motions after the treatment (>5 bowel motions), when mineral oil (2/24) was compared with oral lavage solution (9/24), no conclusions can be drawn due to the very low certainty of the evidence (RR 0.22 95% CI 0.05 to 0.92). For defecation frequency (1–5 bowel motions), when mineral oil (10/24) was compared with oral lavage solution (8/24), no conclusions can be drawn due to the very low certainty of the evidence (RR 1.25 95% CI 0.60 to 2.61).

This study reports no withdrawals.

### Hospital-based care with PEG versus home-based care with PEG

This comparison included one study.[13]

For treatment success, defined as the passage of clear watery stools, when hospital-based care with PEG (21/21) was compared with home-based care with PEG (20/21), no conclusions can be drawn due to the very low certainty of the evidence (RR 1.05 95% CI 0.92 to 1.19).

Defecation frequency and withdrawals due to adverse events were not reported by the study.

### PEG 3350 0.25 g/kg/day versus PEG 3350 0.5 g/kg/day versus PEG 3350 1 g/kg/day versus PEG 3350 1.5 g/kg/day

This comparison included one study.[14] No meta-analysis could be performed because there was no per group outcome data for any of the outcomes.

### Secondary outcomes

Summary of secondary outcomes is found in online supplemental table 5. Detailed data extraction is found in online supplemental table 1. Summary of findings is found in online supplemental table 4. Individual study forest plots are found in online supplemental figures 9–31.

Overall, most of the secondary outcomes were of very low certainty, thereby, conclusions could not be drawn.

## DISCUSSION

This review has set out to identify the safety and efficacy of treatments for FI in childhood. There were no clear findings of superiority considering any of the therapies under the study, with low certainty evidence of no difference between rectal enemas versus PEG and moderate certainty evidence of no difference between

PEG versus PEG combined with sodium picosulphate. The remaining comparisons were of very low certainty, so conclusions cannot be drawn. Throughout the studies, most safety outcomes were of very low certainty, also limiting the drawing of any conclusions. However, no specific serious adverse events or cases of mortality were reported.

The primary evidence included in this review suffers with key methodological flaws. The risk of bias is pervasively unclear or of high risk. In the context of blinding, this is less impactful given the difficulties in blinding such studies. The range of outcomes used and, more precisely, the specific measures for each outcome are very diverse and this limits the clinical utility of potential meta-analysis in the future. Given the limited scope for meta-analysis at present, further consideration of imprecision or heterogeneity is not possible.

This review has highlighted far more in terms of the completeness, or lack thereof, of the evidence base. First, there is a lack of a consistent definition of the condition itself. This is a wider problem in the field but significantly impacts the scope for this type of analysis as the patients are very clinically diverse and as such the outcome measures are similarly heterogeneous. Second, there are many diverse treatments, and this has left the evidence base very uncertain, with no single therapy reaching a threshold of high certainty evidence of either a difference or no difference. Finally, in terms of outcomes, the focus of the studies is on outcomes of clinical efficacy. While efficacy is key, given that these are studies of two active comparators, it could be argued that other outcomes are of more importance. Perhaps the most important are acceptability and tolerability, both of which were rarely and heterogeneously reported. These outcomes may be the ones that show difference where efficacy is similar and given the remitting nature of the condition and the likely need for multiple rounds of disimpaction therapy in childhood, ensuring these outcomes are positive is important. This is especially relevant in the context of therapies that can be used for both disimpaction and onward care, such as PEG.

When considering the review itself, one of the potential limitations is related to the lack of definitions for FI. We chose to use the studies reporting of this as the key criteria for considering the patients, rather than considering the full range of childhood constipation literature. There may be an overlap with some studies offering therapy for impaction as part of a constipation protocol and essentially in combination with long-term therapy, but we have not included these. It is also important to note that the nature of the interventions in this review is such that many do not support viable blinding. This leads to difficult decisions within GRADE and is a source of potential subjectivity. Finally, the reporting within the primary studies was limited in a number of ways that hampered the review. Despite best efforts to use methods that minimised the impact, such as contacting primary authors.[21]

Currently, there are no clear implications for practice from this review and this is a reflection of the many issues we have raised in this discussion. This does not mean therapies should not be used, but rather that no high-quality evidence exists to guide choices or a specific therapy in this context. This is despite how common this clinical paradigm presents and how often these therapies are used in the clinical setting.[6]

There are substantial implications for research. A consensus definition on FI is vital. It is possible that this chooses to view the condition as standalone or as a symptom of constipation but defining how long symptoms need to occur and how to diagnose is vital to support research. Once a definition exists, key outcomes of interest can also be agreed. This is contentious and a source of heterogeneity in this review and needs a consensus to support future investigation. The combination of clear definitions and critical outcomes will then support further research. Issues with risk of bias must be addressed. We would also suggest the choice of interventions for study should be made with formal consultation with stakeholders, including patients, in line with other approaches in the field. This will not only ensure relevance of studies but that a focus on key interventions will allow a high certainty outcome to be achieved with good precision.

## CONCLUSIONS

No clear difference in efficacy or safety was found between PEG and Rectal Enemas or PEG combined with sodium picosulphate. Further high-quality research is needed to determine effective strategies for FI. Moreover, a consensus should be reached regarding the definition and diagnosis of FI as based on that a standardised approach to patient's care can be determined.

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## REFERENCES

1 Benninga M, Candy DCA, Catto-Smith AG, *et al*. The Paris Consensus on Childhood Constipation Terminology (PACCT) Group. *J Pediatr Gastroenterol Nutr* 2005;40:273–5.
2 van den Berg MM, Benninga MA, Di Lorenzo C. Epidemiology of childhood constipation: a systematic review. *Am J Gastroenterol* 2006;101:2401–9.
3 The ROME foundation. Rome IV Criteria, Available: https://theromefoundation.org/rome-iv/rome-iv-criteria
4 Vriesman MH, Rajindrajith S, Koppen IJN, *et al*. Quality of Life in Children with Functional Constipation: A Systematic Review and Meta-Analysis. *J Pediatr* 2019;214:141–50.
5 Dos Santos IR, de Abreu GE, Dourado ER, *et al*. Emotional and behavioural problems in children and adolescents: The role of constipation. *J Paediatr Child Health* 2021;57:1003–8.
6 Pradhan S, Jagadisan B. Yield and Examiner Dependence of Digital Rectal Examination in Detecting Impaction in Pediatric Functional Constipation. *J Pediatr Gastroenterol Nutr* 2018;67:570–5.
7 Modin L, Walsted AM, Jakobsen MS. Identifying faecal impaction is important for ensuring the timely diagnosis of childhood functional constipation. *Acta Paediatr* 2015;104:838–42.
8 Benninga M, Tabbers M, Gordon M, *et al*. Fecal disimpaction in children with functional constipation (0-18 years): a systematic review on the effectiveness and safety of pharmacological treatment options. *BMJ Paediatr Open* 2025;9:e003085.
9 Higgins J, Thomas J, Chandler J, *et al*. Cochrane Handbook for Systematic Reviews of Interventions.2023. Available: www.training.cochrane.org/handbook
10 Higgins JP, Savović J, Page MJ, *et al*. Assessing Risk of Bias in a Randomized Trial. Cochrane Handbook for Systematic Reviews of Interventions.2019:205–28.
11 Guyatt GH, Oxman AD, Schünemann HJ, *et al*. GRADE guidelines: a new series of articles in the Journal of Clinical Epidemiology. *J Clin Epidemiol* 2011;64:380–2.
12 Panda K. Institute of Medical Sciences and SUM Hospital (India), 2024. Available: https://clinicaltrials.gov/study/NCT06349031
13 Vadlapudi S, Poddar U, Srivastava A, *et al*. Home-based disimpaction with polyethylene glycol (PEG) in children with functional constipation: is it the way forward? A randomised control trial. *J Pediatr Gastroenterol Nutr* 2022;2:464–5.
14 Youssef NN, Peters JM, Henderson W, *et al*. Dose response of PEG 3350 for the treatment of childhood fecal impaction. *J Pediatr* 2002;141:410–4.
15 Bekkali N-L-H, van den Berg M-M, Dijkgraaf MGW, *et al*. Rectal fecal impaction treatment in childhood constipation: enemas versus high doses oral PEG. *Pediatrics* 2009;124:e1108–15.
16 Miller MK, Dowd MD, Friesen CA, *et al*. A randomized trial of enema versus polyethylene glycol 3350 for fecal disimpaction in children presenting to an emergency department. *Pediatr Emerg Care* 2012;28:115–9.
17 Acharyya BC, Bhattacharyya C, Mukhopadhyay M, *et al*. Polyethylene Glycol Plus Electrolytes with Stimulant Laxative in Paediatric Faecal Disimpaction: A Randomised Controlled Study. *Pediatr Gastroenterol Hepatol Nutr* 2021;24:230–7.
18 Farahmand F, Eftekhari K, Modarresi V, *et al*. Comparing Oral Route Paraffin Oil versus Rectal Route for Disimpaction in Children with Chronic Constipation; a Randomized Control Trial. *Iran J Pediatr* 2010;20:291–6.
19 Shatnawi MS, Alrwalah MM, Ghanma AM, *et al*. Lactulose versus polyethylene glycol for disimpaction therapy in constipated children, a randomized controlled study. *Sudan J Paediatr* 2019;19:31–6.
20 Tolia V, Lin CH, Elitsur Y. A prospective randomized study with mineral oil and oral lavage solution for treatment of faecal impaction in children. *Aliment Pharmacol Ther* 1993;7:523–9.
21 Sinopoulou V, Shah E, Gordon M, *et al*. Primary author contact for systematic reviews of randomized controlled trials: A systematic review. *World J Methodol* 2025;15:95559.