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# PEDIATRICS®

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## **Rectal Fecal Impaction Treatment in Childhood Constipation: Enemas Versus High Doses Oral PEG**

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# Rectal Fecal Impaction Treatment in Childhood Constipation: Enemas Versus High Doses Oral PEG



**WHAT'S KNOWN ON THIS SUBJECT:** Despite a lack of scientific data, rectal enemas have long been advocated as the best first-line treatment for RFI. Two studies showed that oral PEG treatment yielded 95% successful disimpaction. However, no studies have compared enemas with oral PEG treatment.



**WHAT THIS STUDY ADDS:** This is the first prospective, randomized, controlled trial evaluating disimpaction with either rectal enemas or orally administered laxatives for children with severe RFI attributable to constipation.

## abstract

**OBJECTIVE:** We hypothesized that enemas and polyethylene glycol (PEG) would be equally effective in treating rectal fecal impaction (RFI) but enemas would be less well tolerated and colonic transit time (CTT) would improve during disimpaction.

**METHODS:** Children (4–16 years) with functional constipation and RFI participated. One week before disimpaction, a rectal examination was performed, symptoms of constipation were recorded, and the first CTT measurement was started. If RFI was determined, then patients were assigned randomly to receive enemas once daily or PEG (1.5 g/kg per day) for 6 consecutive days. During this period, the second CTT measurement was started and a child's behavior questionnaire was administered. Successful rectal disimpaction, defecation and fecal incontinence frequencies, occurrence of abdominal pain and watery stools, CTTs (before and after disimpaction), and behavior scores were assessed.

**RESULTS:** Ninety-five patients were eligible, of whom 90 participated (male,  $n = 60$ ; mean age:  $7.5 \pm 2.8$  years). Forty-six patients received enemas and 44 PEG, with 5 dropouts in each group. Successful disimpaction was achieved with enemas (80%) and PEG (68%;  $P = .28$ ). Fecal incontinence and watery stools were reported more frequently with PEG ( $P < .01$ ), but defecation frequency ( $P = .64$ ), abdominal pain ( $P = .33$ ), and behavior scores were comparable between groups. CTT normalized equally ( $P = .85$ ) in the 2 groups.

**CONCLUSION:** Enemas and PEG were equally effective in treating RFI in children. Compared with enemas, PEG caused more fecal incontinence, with comparable behavior scores. The treatments should be considered equally as first-line therapy for RFI. *Pediatrics* 2009;124:e1108–e1115

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### KEY WORDS

randomized trial, rectal fecal impaction, enemas, polyethylene glycol, childhood constipation

### ABBREVIATIONS

CTT—colonic transit time  
PEG—polyethylene glycol  
RFI—rectal fecal impaction

This trial has been registered at [www.trialregister.nl](http://www.trialregister.nl) (identifier NTR602).

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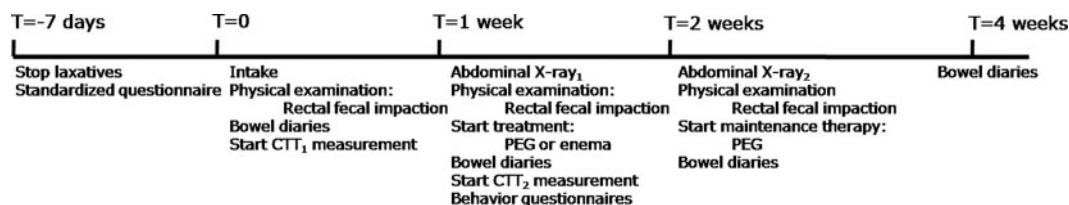
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**FIGURE 1**  
Protocol design.

Functional constipation is a common condition in childhood, with a worldwide prevalence of 7% to 30%.<sup>1</sup> Approximately 30% to 75% of children with long-standing functional constipation have abdominal fecal impaction and/or rectal fecal impaction (RFI) on physical examination, which results in severe fecal incontinence in 90% of the patients.<sup>2-4</sup> Fecal impaction has been defined as a large fecal mass, noted through either abdominal palpation or rectal examination, which is unlikely to be passed on demand.<sup>5</sup> It is important to assess the presence of RFI in children with constipation, because disimpaction should be achieved before initiation of maintenance therapy.<sup>6,7</sup> If initial disimpaction is omitted, then oral laxative treatment may result paradoxically in an increase of fecal incontinence attributable to overflow diarrhea.

Despite the lack of scientific data, enemas have long been advocated as the best first-line treatment for severe RFI. It often is assumed, however, that children strongly dislike enema administration.<sup>3,8</sup> Manual evacuation of feces under general anesthesia may decrease the stress for the child; however, one study described the risk of structural injury to the anal sphincter after manual disimpaction in constipated adults.<sup>9</sup> Manual disimpaction not only contributes to sphincter weakness in some patients but also is an expensive procedure.<sup>9</sup> Two studies showed that oral administration of a high dose of polyethylene glycol (PEG) for 3 to 6 consecutive days was effective

in clearing RFI for many as 95% of patients.<sup>3,10</sup> Youssef et al<sup>3</sup> performed an uncontrolled trial in which possible adverse events (eg, fecal incontinence) were not documented, however, and Candy et al<sup>10</sup> applied an unclear definition for fecal impaction.

We hypothesized that enemas and orally administered laxatives would be equally effective in removing a fecal mass from the rectum but enemas would be less well tolerated and colonic transit time (CTT) would improve during disimpaction. Therefore, the aim of our study was to evaluate the efficacy and tolerability of enemas versus high doses of orally administered PEG for disimpaction in children with functional constipation and RFI. Furthermore, we aimed to evaluate the effect of disimpaction on bowel habits and CTT.<sup>11-13</sup>

## METHODS

### Study Setting and Design

Between February 2005 and July 2008, a randomized, controlled trial was conducted at a tertiary hospital (Emma Children's Hospital, Amsterdam, Netherlands). The hospital's medical ethics committee approved the research protocol. All parents and children >12 years of age provided written consent.

### Subjects

Patients were eligible if they were between 4 and 16 years of age and demonstrated evidence of RFI on rectal examination. Furthermore, they needed

to fulfill  $\geq 1$  of the other Rome III criteria for functional constipation present for  $\geq 8$  weeks, that is, (1) defecation frequency of  $< 3$  times per week, (2)  $\geq 1$  fecal incontinence episode per week, (3) history of retentive posturing or excessive volitional stool retention, (4) history of painful or hard defecation, and (5) history of large-diameter stools that may obstruct the toilet.<sup>14</sup> Patients with a history of colorectal surgery or an organic cause for constipation were excluded.

### Protocol

The protocol design is depicted in Fig 1.

### Definition of RFI and Successful Disimpaction

Before study entry, the presence of RFI was evaluated by the physician performing a rectal digital examination. RFI was defined as a large amount of hard stool in the rectum (fecaloma). Successful disimpaction was defined as the absence of fecaloma on rectal examination. If patients were too frightened to undergo a second rectal examination, then abdominal radiography was performed for assessment of RFI.

### Standardized Questionnaire and Bowel Diary

The standardized questionnaire at intake included questions regarding medical history, age at onset of defecation problems, current bowel habits, and laxative use. The standardized bowel diary recorded defecation and

fecal incontinence frequency, consistency of stools, and abdominal pain.

### CTT Assessments

Whole and segmental CTTs were determined by using the method described by Arhan et al.<sup>11</sup> Radiograph localization of markers was based on the identification of bony landmarks and gaseous outlines, as described by Arhan et al.<sup>11</sup> Patients ingested 1 capsule with 10 radioopaque markers (Sitzmarks [Bipharma, Weesp, Netherlands]) for 6 consecutive days. Subsequently, an abdominal radiograph was obtained on day 7 for counting of the markers present in the colon and rectosigmoid bowel segment. The number of markers multiplied by 2.4 determined the total CTT (in hours). A total CTT of >62 hours, an ascending colon CTT of >18 hours, a descending colon CTT of >20 hours, and a rectosigmoid segment CTT of >34 hours were considered delayed.<sup>11</sup>

### Disimpaction and Maintenance Treatment

One group received rectal enemas (dioctylsulfosuccinate sodium; Klyx [Pharmachemie, Haarlem, the Netherlands]) once daily for 6 consecutive days (60 mL for children <6 years of age and 120 mL for children ≥6 years of age). The other group received orally administered PEG 3350 with electrolytes (Movicolon [Norgine, Amsterdam, the Netherlands], 1.5 g/kg per day) for 6 consecutive days. Maintenance treatment was started after 6 days of disimpaction treatment and consisted of orally administered PEG 3350 with electrolytes (Movicolon, 0.5 g/kg per day) for ≥2 weeks (follow-up period).

### Behavior Score Assessments

A child's behavior questionnaire containing 7 questions evaluating the association between behavior and laxative treatment was completed by all

parents at the end of the disimpaction week.

### Outcome Measurements

The primary outcome was successful disimpaction. Secondary outcome measures of defecation and fecal incontinence frequency, abdominal pain, watery stools, CTT values, and child's behavior scores were calculated for children who completed the study protocol.

### Adequacy of Sample

A total sample size of 90 was required to achieve 80% power, at a significance level of .05, to detect a 20% difference in proportions of successful disimpaction between treatment groups with a 2-sided  $\chi^2$  test, with the assumption that 75% of children who received oral laxative treatment would be treated successfully.

### Data Analysis and Interpretation

Patients' characteristics were documented descriptively. Data for all patients, including those who did not complete the 2 study periods according to the protocol, were analyzed according to an intention-to-treat approach, to describe the primary outcome variable. Comparison of the proportions of successful disimpaction between the 2 groups was performed by using the  $\chi^2$  test. Differences in defecation and fecal incontinence frequency were analyzed by using Student's *t* test. For CTT analysis, differences in CTT values within groups, before disimpaction versus after 6 days of disimpaction, were assessed with a paired-sample *t* test; differences between the groups after 6 days of disimpaction were assessed through analysis of covariance, to adjust for scores at baseline. Segmental CTTs (delayed or not delayed) were evaluated by using  $\chi^2$  statistics. Differences in the presence (yes or no) of abdominal pain or watery stools were

tested by using Yates' continuity-corrected  $\chi^2$  statistics or Fisher's exact test, depending on cell frequencies. Statistical significance was defined as  $P < .05$ . All analyses were performed by using the statistical software package SPSS 14.0 (SPSS Inc, Chicago, IL).

## RESULTS

### Baseline Findings

Between February 2005 and July 2008, 627 patients with constipation visited our outpatient clinic (Fig 2), of whom 90 participated. Forty-six and 44 patients were assigned randomly to receive enemas and PEG, respectively. As depicted in Table 1, baseline > characteristics were balanced between the 2 treatment groups. Before study enrollment, 39% ( $n = 18$ ) of the enema group and 36% ( $n = 16$ ) of the PEG group had a history of enema use ( $P = .83$ ). A total of 10 patients dropped out (Fig 2). In the enema group, dropout was attributable to receipt of 5 enemas instead of 6 ( $n = 1$ ), hospitalization during the study ( $n = 1$ ), noncompliance in recording bowel diaries ( $n = 1$ ), or missed appointments at the outpatient clinic ( $n = 2$ ). The patient who was hospitalized during the study required clinical oral lavage with Klean-prep (Norgine, Amsterdam, the Netherlands; 1.5 L/day = 88.5 g of PEG) for 7 consecutive days and therefore was excluded from analysis. In the PEG group, dropout was attributable to administration of a low PEG dose (0.5 g/kg per day instead of 1.5 g/kg per day) ( $n = 3$ ), noncompliance in recording bowel diaries ( $n = 1$ ), and failure to return for follow-up evaluation ( $n = 1$ ).

### Enemas Versus Oral PEG Treatment

Successful disimpaction was achieved for 37 patients (80%) from the enema group and 30 patients (68%) from the

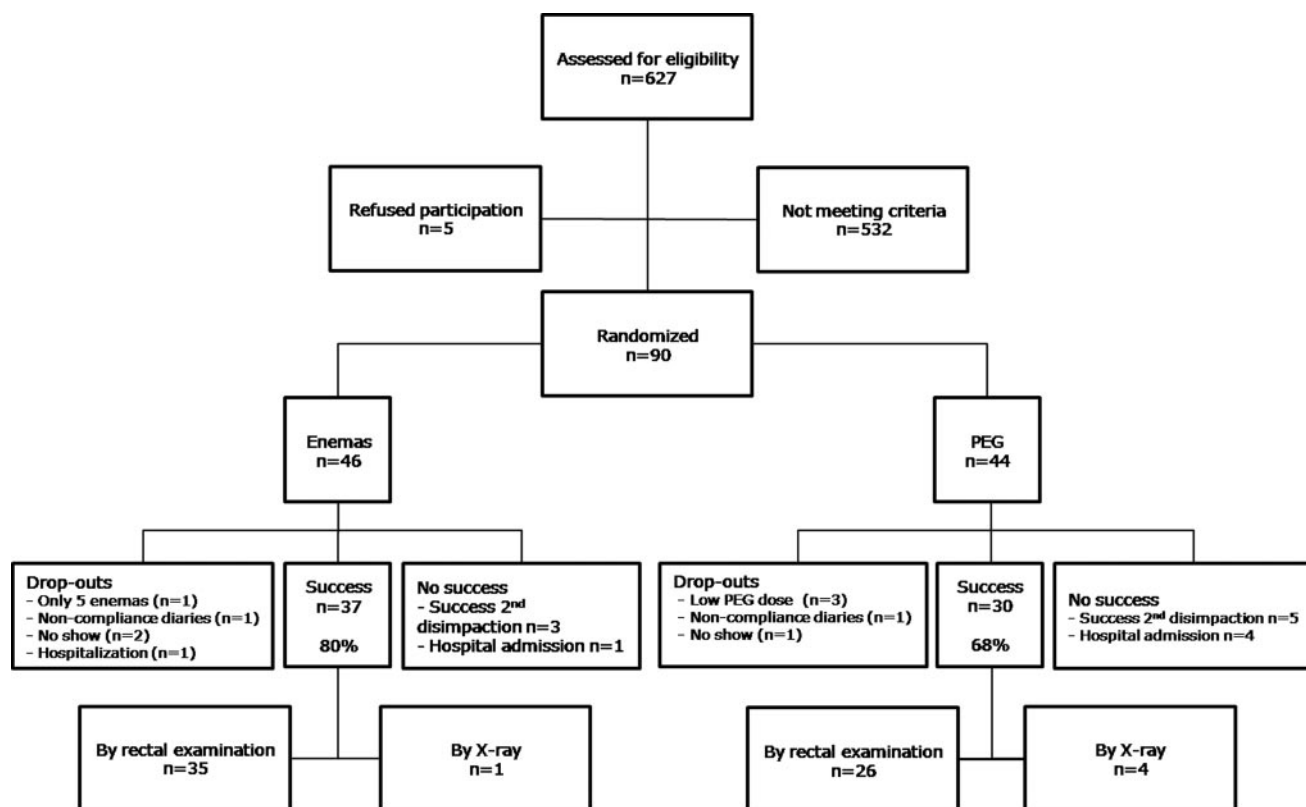


FIGURE 2

Consolidated Standards of Reporting Trials diagram.

PEG group ( $P = .28$ ) (Fig 2). Three patients from the enema group with unsuccessful initial disimpaction achieved successful disimpaction after extension of the rectal treatment with 1 enema for 1 day in combination

with PEG maintenance treatment. Patients who initially experienced failure of oral disimpaction treatment ( $n = 9$ ) achieved successful disimpaction with addition of 1 enema daily for a total of 3 days in 4 cases. Patients who experi-

enced failure of a second intensive oral or rectal disimpaction regimen were admitted to the clinic for colonic lavage (Fig 2).

### Bowel Habits and Symptoms

As shown in Tables 1 and 2, a significant increase in defecation frequency was achieved in both groups after the disimpaction week. The frequency of fecal incontinence was significantly lower in the enema group ( $P < .001$ ) during disimpaction but not at the follow-up evaluation ( $P = .58$ ). Watery stools were reported more frequently in the PEG group during disimpaction (10 vs 28 patients;  $P < .001$ ) and at the follow-up evaluation (4 vs 13 patients;  $P = .03$ ).

### CTT Results

Two patients in the enema group and 6 patients in the PEG group were not able to ingest the radioopaque mark-

TABLE 1 Baseline Characteristics With Inclusion and Exclusion of Dropouts

	Total Patients			Patients With Follow-up Data		
	Enema	PEG	<i>P</i>	Enema	PEG	<i>P</i>
<i>N</i>	46	44		41	39	
Male, <i>n</i>	29	31		27	27	
Age, mean $\pm$ SD, y	7.9 $\pm$ 2.9	7.2 $\pm$ 2.6		7.9 $\pm$ 2.9	7.2 $\pm$ 2.6	
Defecation frequency, mean $\pm$ SD, times per wk	1.9 $\pm$ 2.4	1.5 $\pm$ 1.8	.46	2.1 $\pm$ 2.5	1.4 $\pm$ 1.7	.18
Symptom duration, mean $\pm$ SD, mo	5.2 $\pm$ 3.3	4.7 $\pm$ 2.8	.29	5.4 $\pm$ 3.3	4.8 $\pm$ 2.9	.42
Presence of abdominal fecal mass, <i>n</i>	17	29	.01	15	27	.003
Daytime fecal incontinence frequency, mean $\pm$ SD, times per wk	15.7 $\pm$ 13.1	16.6 $\pm$ 12.4	.13	14.9 $\pm$ 14.0	12.0 $\pm$ 10.7	.30
Nighttime fecal incontinence frequency, mean $\pm$ SD, times per wk	1.2 $\pm$ 2.4	1.0 $\pm$ 2.4	.70	1.0 $\pm$ 2.1	1.1 $\pm$ 2.6	.85
Abdominal pain, <i>n</i>	22	28	.37	21	27	.34
Watery stools, <i>n</i>	2	4	.18	1	4	.12

**TABLE 2** Bowel Habits and Gastrointestinal Symptoms After 6 Days of Disimpaction and at Follow-up Evaluation (2 Weeks After Disimpaction)

	Disimpaction			Follow-up Evaluation		
	Enema (N = 46)	PEG (N = 44)	P	Enema (N = 41)	PEG (N = 39)	P
Defecation frequency, mean ± SD, times per wk	5.8 ± 3.6	8.8 ± 8.5	.64	7.7 ± 5.3	8.7 ± 6.4	.48
Fecal incontinence frequency, mean ± SD, times per wk	3.4 ± 4.3	13.6 ± 12.6	<.001	4.9 ± 5.4	5.7 ± 5.9	.58
Abdominal pain, n	21	17	.33	23	17	.24
Watery stools, n	10	28	<.001	4	13	.03

ers. Before disimpaction, delayed CTT was found for 42 patients (95%) in the enema group and 37 patients (97%) in the PEG group; delayed rectosigmoid segment CTT was found for 33 patients (75%) and 33 patients (87%), respectively (Table 3). As shown in Table 3, a significant decrease in CTT was found between intake and disimpaction in all colonic segments ( $P < .001$ ). No significant differences in CTT between the 2 groups were found at any time point.

### Behavior Scores

A total of 38 patients (93%) in the enema group and 31 patients (79%) in the PEG group completed the questionnaires (Table 4). Struggles to administer medication, actions necessary to enable treatment, and levels of anxiety were reported equally in the 2 groups. Abdominal pain directly after administration of the laxative was reported more frequently in the enema group

( $n = 31$ ) than in the PEG group ( $n = 16$ ;  $P = .008$ ). Abdominal pain that occurred immediately after enema use resolved within 30 minutes for 23 (77%) of 30 patients.

### DISCUSSION

This is the first prospective, randomized, controlled study demonstrating that enemas and high-dose PEG (1.5 g/kg) are equally effective in treating RFI in children with constipation. Children who received enemas reported fewer episodes of fecal incontinence and watery stools but more abdominal pain directly after enema administration. Defecation frequency increased in both groups, and the occurrence of abdominal pain during the day, as reported in the bowel diaries, was not different between the groups. Surprisingly, extra effort to administer medication, as well as tricks necessary

to enable treatment, was reported equally in the 2 groups.

The dosage (PEG at 1.5 g/kg per day) and duration (6 days) of oral and rectal disimpaction were based on previous studies that showed mean disimpaction times of 3 to 7 days.<sup>3,10,15,16</sup> With this regimen, successful disimpaction was achieved with enemas and PEG for 80% and 68%, respectively, of the children in our study. These results are in accordance with other studies in which success with high doses of orally administered PEG was reached in 92% to 97% of cases.<sup>3,10,15</sup> In a retrospective chart review of clinical outcomes in 5 hospitals in England and Wales, it was found that enemas were successful for 73% of children with fecal impaction, compared with 97% for PEG.<sup>15</sup> It is not possible to compare our results with the latter study, however, because a definition of fecal impaction was lacking. Furthermore, it is not clear how the investigators confirmed disimpaction in their study. The strength of this study was that only children were included and reevaluation after therapy was performed through either rectal examination or abdominal radiography.

As expected, a high dosage of PEG resulted in an increase in fecal incontinence frequency during the disimpac-

**TABLE 3** Total and Segmental CTT Values

	CTT				P	
	Enema		PEG		Intake	Disimpaction
	Intake (N = 44)	Disimpaction (N = 41)	Intake (N = 38)	Disimpaction (N = 39)		
Ascending colon						
Median (IQR), h	14.4 (7.2–43.2)	7.2 (2.4–21.6)	21.6 (9.0–50.4)	12.0 (7.2–24.0)	.24	.47
Delayed >18 h, %	46	33	59	44		
Descending colon						
Median (IQR), h	21.6 (9.6–50.4)	9.6 (2.4–19.2)	24.0 (12.0–39.0)	7.2 (4.2–21.6)	.69	.48
Delayed >20 h, %	51	23	56	32		
Rectosigmoid segment						
Median (IQR), h	57.6 (38.4–79.2)	24.0 (8.4–42.0)	61.2 (43.2–79.8)	20.4 (11.4–24.6)	.57	.07
Delayed >34 h, %	75	29	87	13		
Total colon						
Median (IQR), h	117.6 (86.4–136.4)	37.2 (24.6–67.8)	120.0 (98.4–141.6)	43.2 (27.6–67.2)	.89	.78
Delayed >62 h, %	95	72	97	75		

Segmental and total CTTs decreased significantly after disimpaction in both groups ( $P < .001$ ). IQR indicates interquartile range.

**TABLE 4** Behavior Scores at End of Disimpaction Week

	Enema (N = 38)	PEG (N = 31)	P
Struggle to administer oral or rectal treatment			
Yes	24	17	.18
No	14	14	
Actions necessary to enable treatment (eg, distraction)			
Yes	21	18	.25
No	17	13	
More anxious during disimpaction			
Yes	36	25	.13
No	2	6	
Abdominal pain soon after treatment			
Yes	31	16	.008
No	7	15	
If abdominal pain, how long did pain last?			
<5 min	6	5	
5–15 min	10	3	
15–30 min	7	2	
30–60 min	2	1	
>1 h	5	2	
Not applicable or not recorded	8	18	
Who administered enema to child?			
Father	5	0	
Mother	22	0	
Both	9	0	
Someone else	2	0	
Not applicable	0	31	
After how much time did defecation occur?			
<5 min	5	0	
5–15 min	25	0	
15–30 min	6	0	
30–60 min	1	0	
Not applicable	1	31	

tion period. PEG is a soluble inert polymer that acts by hydrogen-bonding water molecules to expand the volume in the large intestine, resulting in softer and more-watery stools.<sup>17–19</sup> Until the fecaloma has been cleared, soft stool leaks along the fecal mass in the rectum. An increase in episodes of fecal incontinence also was found in a randomized, controlled trial evaluating the efficacy of PEG 3350.<sup>20</sup> In contrast, rectal enemas (dioctylsulfosuccinate) are hypertonic and stimulate direct contraction of the colon. Direct contraction stimulates the rectum to empty the fecal mass, which explains why episodes of fecal incontinence were less common with enemas. As expected, however, abdominal pain directly after treatment was reported more frequently in the enema group, because of the contractile effect. The increase in peristalsis might

be experienced as cramping and thus abdominal pain. The majority of patients (77%) experienced abdominal pain relief within 30 minutes, and overall abdominal pain, as reported in the bowel diaries, did not differ between the treatment groups. Probably parents and children qualified the abdominal pain directly after enemas differently.

Fecal incontinence is associated with lower quality of life with respect to both physical and psychosocial functioning, as reported by parents and by children with constipation.<sup>21–23</sup> Therefore, it is important to inform children and parents that disimpaction with oral PEG treatment is likely to cause more episodes of fecal incontinence, compared with disimpaction with enemas. In accordance with an earlier study,<sup>7</sup> we observed a significant de-

crease in fecal incontinence episodes after the intensive disimpaction period in the current study.

This is the first study to compare changes in behavior in children with constipation, by using a questionnaire, between treatment with enemas and treatment with oral laxative therapy. In accordance with the general opinion regarding enema use in children, we found that 95% of children receiving enemas exhibited fearful behavior. However, we also found fearful behavior for 81% of children receiving oral laxative treatment. Given the comparable behavior in the 2 groups, disimpaction with enemas should not necessarily be withheld to prevent anxiety. We did not find more fearful behavior in the enema group, which might be explained by the administration of enemas by parents at home instead of by nurses in an unfamiliar environment (hospital), which is more common in practice. In adults, retrograde colonic irrigation, which is performed by the patients themselves, improved both quality of life and bowel habits.<sup>24</sup>

Rectal examinations to confirm the diagnosis of constipation are controversial. Many pediatricians advocate avoidance of rectal examinations and invasive treatments, such as rectal enemas, to prevent uncomfortable, painful, and/or embarrassing situations. However, the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition guidelines for constipation in infants and children recommend  $\geq 1$  digital examination of the anorectum, to evaluate the amount and consistency of stool and its location within the rectum and to identify organic disorders.<sup>6</sup> In our center, rectal examinations are performed routinely for children presenting with constipation. If fecal impaction is present, then rectal disimpaction is performed with enemas. This treatment regimen is based on a small study that sug-



gested that rectal disimpaction shortly after the onset of symptoms was more effective than less-aggressive means of therapy.<sup>7</sup> Because this study shows that enemas are not superior to oral laxative treatment, we question the need for a rectal examination as a prerequisite for the choice of oral or rectal treatment. We suggest performing rectal examinations only for children for whom the diagnosis of constipation is uncertain, when they exhibit only 1 symptom of the Rome III criteria for constipation. Furthermore, a rectal examination should be performed when symptoms of constipation persist after initial oral or rectal disimpaction. Although anatomic problems are rare, a rectal examination may be necessary for such children.

In this study, CTT measurements were used as a noninvasive tool to localize delay of colonic transit and to verify the effect of disimpaction. In contrast to previous observations for children with constipation,<sup>25</sup> both total and rectosigmoid segment CTTs were more delayed in our study. In our study, however, only children with a

large, palpable, rectal mass were included. Such children have significantly longer CTTs than children with symptoms of constipation without RFI.<sup>26</sup> The latter phenomenon, outlet obstruction (ie, delay of transit at the level of the rectum), is found in both children and adults with constipation.<sup>4,27</sup> Indeed, in our study, we found delays in rectosigmoid segment CTT for 75% to 87% of patients. We also demonstrated that both CTT and rectosigmoid segment CTT improved while defecation frequency increased during both oral and rectal disimpaction. This is in accord with the suggestion that a distended rectum, with feces, slows down the motor activity of the colon, through an inhibitory rectocolonic feedback mechanism.<sup>28</sup> It was remarkable, however, that 72% to 75% of patients still had delayed CTT after disimpaction. This proportion is larger than that in earlier studies with a comparable group of children with constipation with RFI (ie, 30%–36%).<sup>25,29</sup> It is likely that, in our current study, we included children with more-severe motility disorders, given the impacted

rectum in all of these children and the presence of a palpable abdominal fecal mass in 37% to 66% of them.

This study has limitations. Because we included children with a history of enema use, as well as those without such a history, the findings regarding fearful behavior might be confounded. However, it is unclear whether children with a history of enema use would be more or less anxious regarding enemas. The latter could not be extracted from the behavior questionnaires we used in our study. A second limitation is the assessment of behavior scores only after the start of disimpaction. However, the questions were formulated in a way to detect changes in behavior, rather than general behavior at a single point in time.

## CONCLUSIONS

We demonstrated that enemas and orally administered laxatives were equally effective in treating RFI in functional childhood constipation. Therefore, rectal enema treatment and oral laxative treatment should be considered equally as first-line therapy.

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