The Effect of Anorectal Manometry on the Outcome of Treatment in Severe Childhood Constipation: A Randomized, Controlled Trial

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ABSTRACT. Objective. Approximately 50% of constipated children contract rather than relax the external sphincter complex during a defecation attempt. Although biofeedback training (BF) is able to change this defecation behavior, there is no additional effect of BF to conventional treatment (CT) on clinical outcome compared with CT alone. It has been postulated that the absence of a significant difference between these 2 treatment options might be because of a therapeutic, "demystifying" effect of performing anorectal manometry in conventionally treated children, necessary to obtain basal manometric data. The objective of this prospective, controlled, randomized study was to evaluate the effect of CT with 2 anorectal manometry sessions compared with CT alone (dietary advice, diary, toilet training, oral laxatives, and enemas) on clinical outcome.

Methods. A total of 212 constipated children (143 boys) who were visiting a referral pediatric gastroenterologic practice were randomized prospectively to CT alone (115 patients) or to CT combined with 2 manometry sessions (CTM; 97 patients). Patients were included in the study when they fulfilled at least 2 of the 4 following criteria: stool frequency fewer than 3 per week, 2 or more soiling and/or encopresis episodes per week, periodic passage of very large amounts of stool every 7 to 30 days, or a palpable rectal or abdominal fecal mass. CT comprises dietary advice, a daily diary, toilet training, and oral laxative treatment preceded by rectal disimpaction with enemas on 3 consecutive days. During both manometries, the child and the parent could watch the tracing on the computer screen. No explanation was given to either the child or the parents during the procedure. When the procedure was finished, the tracings were clarified. Successful treatment was defined as a defecation frequency of 3 or more per week and fewer than 1 soiling/encopresis episode per 2 weeks and no use of laxatives.

Results. Only 4 and 2 children from the CT and CTM groups showed no soiling and/or encopresis, whereas 76% and 65%, respectively, reported the periodic passage of large stools. In 26% and 30% of the patients, a rectal scybbum was found on physical examination. The success rates at 6, 26, 52, and 104 weeks’ follow-up were 4%, 24%, 32%, and 43% and 7%, 22%, 30%, and 35% in the CT and CTM group, respectively. No significant difference in success percentage was observed between the 2 groups at any time of follow-up with relative risks (CT/CTM) and 95% confidence intervals, respectively, of 0.55 (0.16–1.89), 1.13 (0.67–1.89), 1.07 (0.69–1.65), and 1.23 (0.81–1.85). A significant increase in defecation frequency was observed between the first (intake) and second visits, which was sustained at all subsequent visits and stages of follow-up in both groups (not significant). Also in relation to the first visit, a significant decrease in encopresis episodes was shown and a further slow but significant decrease at 52 weeks of follow-up in both groups. The manometric data obtained from the CTM group showed a low percentage of children with normal defecation dynamics, namely 28%, which (significantly) increased to 38% at the last manometry.

Conclusions. Anorectal manometry combined with CT compared with CT alone did not result in higher success rates in chronically constipated children. Therefore, anorectal manometry has no additional demystifying or educational effect on clinical outcome in chronically constipated children. This observation together with the observation in the current and previous studies that no correlation was found between (achievement of) normal defecation dynamics and success and that no relation was observed between volume of urge or critical volume and success leaves no diagnostic or therapeutic role for anorectal manometry in chronic constipated children, except its use as a diagnostic test to exclude Hirschsprung’s disease. A simple CT is successful in 30% of severely constipated children who are referred to a tertiary hospital, underscoring the importance of long-lasting and adequate laxative treatment. Pediatrics 2001; 108(1). URL: http://www.pediatrics.org/cgi/content/full/108/1/e9; childhood constipation, anorectal manometry, biofeedback training, laxatives.

ABBREVIATIONS. BF, biofeedback training; CT, conventional therapy; CTM, conventional therapy and 2 anorectal manometries.

Constipation is a common disorder in children, accounting for ~3% of consultations in an average pediatric practice. Despite the high prevalence of this problem, the exact cause remains unknown. It causes distress to the child and to the family and can result in severe emotional disturbance and family discord. Many treatments have been used, such as dietary advice (increasing fiber and fluid intake), toilet training, oral laxatives, enemas, and behavioral therapy. Despite these treatment regimens, long-term follow-up studies have demonstrated that ~50% of these children continue to require therapy for long periods of time.
In the past 2 decades, manometric evaluation of anorectal function showed paradoxic contraction of the anal sphincter during defection in 35% to 63% of constipated children. This phenomenon may be caused by attempts to avoid defection because of fears and pains experienced during defection of hard stools early in life. Biofeedback training (BF), a habit training that is based on reinforcement, is able to teach these children how to normalize these abnormal defection dynamics. However, a large randomized controlled study showed no additional clinical effect of BF, despite a significant improvement of abnormal defection dynamics, compared with conventional treatment alone. A high cure rate of 50% was found in the conventionally treated group compared with other studies that evaluated conventional treatment protocols in childhood constipation of comparable severity reaching 16% to 43% success. This high success percentage of 50% in the CT group might be caused by the performance of 2 anorectal manometry sessions at the start and at the end of the intensive conventional treatment period. These 2 manometric sessions were performed to compare the manometric values with the BF program. During these sessions, patients watched the manometric tracings on the computer screen. Visualization of anorectal function by the performance of anorectal manometry in these children might have had a “de-mystifying” therapeutic effect, reducing the expected difference in success between the BF and conventionally treated children. Therefore, the purpose of this controlled, randomized study was to evaluate the additional effect of 2 anorectal manometry sessions compared with conventional treatment alone on clinical outcome.

METHODS
A 2-group, parallel, randomized, controlled trial was conducted in children who had chronic constipation and were referred by general practitioners, school doctors, pediatricians, and psychiatrists to the Academic Medical Center of Amsterdam. The medical ethics committee of the hospital approved the study protocol. All patients and/or parents gave written, informed consent.

Design
A consecutive number of patients were individually electronically randomized at the intake visit, when they seemed to fulfill the inclusion criteria. They were randomized to conventional treatment alone (CT) or to conventional treatment plus 2 manometry sessions (CTM). The study was not blinded. The investigator who was performing the manometries also attended to the patients at the outpatient clinics.

Patients
Patients with pediatric constipation as previously defined were eligible. In short, they had to fulfill at least 2 of the 4 following criteria: 1) stool frequency fewer than 3 per week, 2) or more soiling and/or encopresis episodes per week, 3) periodic passage of very large amounts of stool every 7 to 30 days, or 4) a palpable abdominal or rectal fecal mass.

Soiling is defined as the loss of loose stool in the underwear. Encopresis is defined as the voluntary or involuntary passage of a quantitatively normal bowel movement in the underwear in children older than 4 years and occurring on a regular basis without any organic cause. A large amount of stool was estimated to be twice the standard shown in a clay model. A fecal mass was defined as a large, hard or soft stool in the rectum that completely filled the rectal vault. Patients were considered to have day/nighttime enuresis when they had ≥1 enuresis episode per week at day or at night.

Children needed to be at least 5 years of age to understand the manometric procedure and instructions. All patients had to be treated with adequate doses of laxatives (at least 5 g of lactulose per 10 kg body weight per day) for a minimum period of 2 months in the period between the start of symptoms and inclusion in the study.

Patients with pathologic causes of constipation, such as previous Hirschsprung’s disease, spina bifida occulta, hypothyroidism, or immune metabolic or renal abnormalities, or with mental retardation and children who were using drugs that influenced gastrointestinal function other than laxatives were excluded.

Intervention
The intervention period lasted only 6 weeks with a visit at intake and at 3 and 6 weeks after intake. At the beginning and the end of the 6-week intervention period, each patient had a detailed medical history and abdominal and rectal examination. The child and the parents were asked about bowel function, frequency of defection, soiling and/or encopresis, consistency and size of stool, pain during defection, and associated symptoms such as abdominal pain, appetite, and enuresis. The abdominal examination assessed abdominal distension and fecal masses. The rectal examination included inspection of the anus for fissures and/or hemorrhoids. Digital rectal examination was performed to assess anal tone and the presence and character of a rectal fecal mass. Patients who were randomized to CT had visits lasting 30 minutes during which laxative treatment and information from the diary containing defection frequency and encopresis and/or soiling episodes were discussed. During this first visit, the child and the parents were educated about the different aspects of childhood constipation and the associated encopresis, with an explicit effort to alleviate guilt and to be nonaccusatory. In week 3 (visit 2), the diary card was discussed shortly, and if necessary, the dose of the laxatives and the number of enemas were adapted. A rectal examination was repeated when there was little or no production of feces.

Patients were instructed to try to defecate on the toilet for 5 minutes after each meal. A high-fiber diet was advised, but additional fiber supplements were not prescribed. During the first 3 days of CT, all patients were instructed to use daily enemas (Klyx: sodiumdiocthylsulfosuccinate/sorbitol; 120 mL) at home. If on day 3 the enemas still resulted in large amounts of stool, enemas were continued for a maximum of 7 days. After the initial 3-day enema treatment, patients started oral laxatives with lactulose (5 g/10 kg body weight divided into 2 doses) during the 6-week intervention period and a variable period during follow-up. The laxatives were reduced and ultimately stopped, when patients had fewer than 2 encopresis episodes per month and a defection frequency of 3 or more bowel movements per week. Enemas were given whenever spontaneous defection was delayed for >3 days. Praise and small gifts enhanced motivation.

The other group received in addition to the same CT 2 anorectal manometry sessions, at intake and at 6 weeks after intake (CTM). Follow-up was conducted at 6, 26, 52, and 104 weeks after the last visit of the 6-week intervention period. Follow-up was performed either during a clinical visit or by telephone, using a standard questionnaire.

Anorectal Manometry
Anorectal manometry was performed with bowel preparation, when needed, using an open, perfused catheter. The catheter (4.8 mm outside and 0.8 mm inside diameter with 2 side holes 3 cm apart) was perfused with distilled, degassed water at a rate of 0.6 mL/min by a pneumohydraulic perfusion pump. When inserted into the anus, the proximal side hole was placed in the rectum and the distal side hole in the mid-anal canal. Pressures were measured by transducers in the perfusion line and connected to PC Polygraph HR preamplifiers (Synectics Medical, Alphen aan de Rijn, The Netherlands). Signals from the preamplifier were converted to digital values and transmitted to a computer. Rectal distension was produced with a highly compliant 7-cm-long distended rectal balloon, tied at the end of the catheter. The proximal end of the balloon was located 13.5 cm from the distal side hole. Anal sphincter resting pressure was measured at the end of the manometric procedure and was calculated as the mean of a
3-minute period. Maximal squeeze pressure was determined by asking the child to squeeze the sphincter complex as tight as possible (5 times). The maximum squeeze pressure was measured as the highest pressure during these efforts. The threshold for urge was defined as the smallest reproducible distension of the rectal balloon that was noticed as urge by the child. Critical volume was defined as the minimal volume required to produce a sensation of persistent urge to defecate or if abdominal pain was sensed for at least 1 minute by filling the rectal balloon with increments of 30 mL of air per 30 seconds with a maximum of 300 mL. The anorectal inhibitory reflex was tested by distending the rectal balloon (5–50 mL). The reflex was defined to be normal (excluding Hirschsprung’s disease) when rectal distension produced a relaxation of the anal sphincter pressure of at least 5 mm Hg. Defecation dynamics were considered to be normal when the pressure in the anal sphincter complex decreased during bearing down in at least 2 of the 5 defecation attempts.

During both manometries, the child and the parents could watch the tracing on the computer screen. No explanation was given to either the child or the parents during the procedure. When the procedure was finished, the tracings were clarified to the child and the parents. The main instructions were to increase the abdominal pressure by the abdominal wall muscles and to relax the pelvic floor during a defecation attempt. Moreover, children were stimulated to perform these defecation exercises at home at the slightest urge to defecate.

Outcome Measures

Treatment was considered to be successful when patients achieved 3 or more bowel movements per week and fewer than 1 soiling and/or encopresis episodes per 2 weeks while not receiving laxatives.

Statistics

Descriptive statistical measures were calculated for baseline characteristics of patients in both arms of the trial. Manometric values at intake and 6 weeks after intake were compared with the use of the Wilcoxon rank sum test. Defecation dynamics were compared with the use of McNemar’s test. We calculated relative risks and 95% confidence intervals to compare the success rate in both groups. In addition, we did a multivariate logistic regression analysis to examine the presence of confounding as a result of an imbalance of prognostic factors despite randomization. Success at 1 year was the outcome variable in this analysis. We compared the unadjusted odds ratio of treatment with the odds ratio of treatment after adjusting for several prognostic factors, to determine whether a meaningful change occurred. The following (potential) prognostic factors were included in the model: gender, age at intake, total period of treatment before intake, and total period of symptoms.

All analyses of outcomes between groups were conducted on an intention-to-treat basis, using 2-tailed tests or 95% confidence intervals. It was estimated that a total sample size of 212 patients would be adequate to show a difference of at least 70% success at 6 months using CTM compared with 45% success using CT alone with a 2-tailed α level of 0.05 with a power of 90%.

RESULTS

Patient Characteristics

Between February 1995 and August 1999, 212 consecutive children (5–17 years) with chronic constipation were enrolled in the study. The CT and CTM groups consisted of 115 and 97 patients, respectively. During the initial phase of the intervention period, 4 patients in the CT group and 6 patients in the CTM group were lost for analysis and follow-up. In the CT group, 3 patients refused therapy and the parents of 1 patient demanded anorectal manometry. In the CTM group, 5 patients refused manometry because of anxiety, and 1 child developed severe psychological problems during the intervention period (Fig 1). No other patients were lost for follow-up. Respectively, 17 and 55 patients did not yet reach the follow-up time of 52 and 104 weeks when we analyzed the results of this study.

Despite randomization, more boys were included in the CTM group. All other baseline characteristics (Table 1) were comparable for both groups. More than 65% of all patients were boys. Nighttime soiling
TABLE 1. Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>CT Group (n = 111)</th>
<th>CTM Group (n = 91)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boys</td>
<td>55 (49%)</td>
<td>82 (89%)</td>
</tr>
<tr>
<td>Age (y) [median (range)]</td>
<td>7.7 (5–16)</td>
<td>7.5 (5–17)</td>
</tr>
<tr>
<td>Defecation frequency (per wk)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>2.5</td>
<td>2.0</td>
</tr>
<tr>
<td>Range</td>
<td>0–25</td>
<td>0–17</td>
</tr>
<tr>
<td>P25–P75</td>
<td>1.0–5.0</td>
<td>1.0–6.0</td>
</tr>
<tr>
<td>Soiling frequency [median (range)]</td>
<td>2.8 (0–50)</td>
<td>3.0 (0–40)</td>
</tr>
<tr>
<td>Nighttime soiling/wk [median (range)]</td>
<td>0.0 (0–7)</td>
<td>0.0 (0–14)</td>
</tr>
<tr>
<td>Encopresis frequency/wk [median (range)]</td>
<td>3.0 (0–47)</td>
<td>4.0 (0–31)</td>
</tr>
<tr>
<td>Production of large amount of stool</td>
<td>85 (76%)</td>
<td>60 (65%)</td>
</tr>
<tr>
<td>Abdominal scybala</td>
<td>20 (18%)</td>
<td>18 (20%)</td>
</tr>
<tr>
<td>Rectal scybala</td>
<td>29 (26%)</td>
<td>28 (30%)</td>
</tr>
<tr>
<td>Total period of symptoms (y) [median (range)]</td>
<td>5.6 (1–3)</td>
<td>5.7 (0.3–16.1)</td>
</tr>
<tr>
<td>Presence of daytime enuresis</td>
<td>41 (37%)</td>
<td>40 (43%)</td>
</tr>
<tr>
<td>Presence of nighttime enuresis</td>
<td>47 (42%)</td>
<td>41 (45%)</td>
</tr>
</tbody>
</table>

Anorectal Manometry

A significant increase in maximum squeeze pressure (Table 2) was found at the second anorectal manometry. No difference in anorectal sensation was found between the first and second manometry sessions. At the first manometry session, only 28% of the CTM group had normal defecation dynamics. This increased to 38% (P = .05) at the end of the intervention period. No relation was shown between (the achievement of) normal defecation dynamics and successful outcome. Furthermore, no relation was found between volume of urge or critical volume at intake and success.

Success Rates

No significant difference was observed in the percentage of children who were treated successfully in the CTM group compared with the CT group at any time of follow-up. Only a minority of patients were treated successfully at the end of the intervention period and at 6 weeks’ follow-up in both groups (Table 3). At 1 year of follow-up, the success percentage increased in the CT group to 32% compared with 30% in the CTM group. Using multivariate techniques, correcting for the skewed distribution of gender between the 2 study groups, including gender, age at intake, total period of symptoms before intake, and total period of treatment before intake, did not show any difference (odds ratio: 0.99 [0.48–2.03]) compared with univariate analysis (odds ratio 1.09 [0.58–2.05]).

Criteria of Success

Given the combined nature of the criteria of successful treatment (defecation frequency of 3 or more per week, encopresis episodes fewer than 1 per 2 weeks, no use of laxatives), it is important to analyze these 3 variables separately. Figure 2 shows normalization of defecation frequency in 81% and 77% of the children in the CT and CTM groups, respectively at 1 year of follow-up. The percentage of children with fewer than 1 encopresis episode per 2 weeks decreased to 53% and 49% in the CT and CTM groups, respectively. The percentage of children who were not using laxatives was 66% and 62% for the CT and CTM groups, respectively, at that time. Figure 3 shows the distribution of the defeation and encopresis frequency at intake compared with that at 1 year of follow-up for the CT and CTM groups, showing a marked improvement in encopresis episodes in both study groups compared with intake, although only approximately 50% reached the threshold of ≤1 episode per 2 weeks.

Subgroups

No relation was found between achievement of success and gender, age of onset of symptoms, defecation frequency and encopresis frequency at intake, abdominal/rectal scybala on physical examination at intake, the total period of symptoms before intake, and the total period of treatment before intake. Patients who had ever experienced a symptom-free period of at least 4 weeks, at baseline assessment, had a higher success percentage compared with children with no symptom-free episode (P = .08). The total period of treatment before intake was

TABLE 2. Results of Anorectal Manometry [Median (Range)]

<table>
<thead>
<tr>
<th></th>
<th>First Manometry (n = 91)</th>
<th>Last Manometry (n = 91)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anal sphincter resting pressure (mm Hg)</td>
<td>50 (24–86)</td>
<td>53 (25–103)</td>
</tr>
<tr>
<td>Maximum squeeze pressure (mm Hg)</td>
<td>150 (42–370)</td>
<td>163 (65–411)*</td>
</tr>
<tr>
<td>Threshold for urge (mL)</td>
<td>50 (5–300)</td>
<td>40 (5–300)</td>
</tr>
<tr>
<td>Critical volume (mL)</td>
<td>150 (60–360)</td>
<td>150 (20–300)</td>
</tr>
<tr>
<td>Defecation dynamics</td>
<td>28%</td>
<td>38%†</td>
</tr>
</tbody>
</table>

* P < .01; between first and last manometry; Wilcoxon rank sum test.
† P = .05; between first and last manometry; McNemar’s test.

occurred in 27 (24%) and 26 (28%) of the CT and CTM patients, respectively. Only 6 children showed no soiling and/or encopresis at intake. At intake, 53% of the children were not using laxatives. These children failed earlier laxative therapy given for at least 2 months and therefore often on their own initiative stopped oral laxatives. In 104 of the 202 patients, a combination of soiling and encopresis was shown. Therefore, we decided to add the soiling episodes to the encopresis episodes, calling them together encopresis episodes.
in the successful treated children and in the unsuccessful treated children respectively 10 months (range: 1–48 months) and 12 months (range: 1–104 months; \( P = .98 \)).

**Defecation Frequency and Encopresis Episodes**
Whereas no differences in defecation frequency and encopresis episodes were observed between the CT and CTM groups at the different stages of follow-up, the results as presented in Fig 4 are the combination of the patients of the CT and CTM groups. A significant increase in defecation frequency was observed between the first (intake) and second visits \( (P < .05; \text{Fig 4}) \). This result was sustained at all subsequent visits and stages of follow-up. Children with a normal defecation frequency at intake showed an increase in defecation frequency from 7 (range: 3–25) to 8 (range: 1–24; not significant) at the second visit. In patients with an abnormal defecation frequency at intake, a significant increase was observed at the second visit, from 1 (range: 0–2.5) to 5 (range: 0–26; \( P < .05 \)). No difference in increase in defecation frequency was observed between children who were on laxatives at intake (47%) and those who were not. A significant decrease in encopresis episodes was found between the first and second visits in both groups \( (P < .01) \). Moreover, an additional slow but significant decrease \( (P < .01) \) was observed at 52 weeks of follow-up compared with the end of the intervention period (Fig 4).

**Enuresis**
Daytime and nighttime enuresis decreased from 39% and 43% at intake to 16% and 23%, respectively, at 52 weeks of follow-up in both groups.

**DISCUSSION**
This study was performed to investigate whether the performance of 2 anorectal manometry sessions in combination with laxative treatment (CTM) had an additional effect on clinical outcome compared with CT alone in children with severe chronic constipation. We observed no difference in success rate between the 2 study groups at any stage of follow-up.

In our previous study, no difference in clinical outcome was shown in the BF group compared with the CT group of children. It was suggested that the expected difference could have been blunted by an educational and demystifying effect of manometry in the CT children, representing a short intervention comparable to BF.\(^4\) This demystifying effect was thought to result from the visualization and explanation of anorectal sensation and sphincter function on the computer screen, awakening in these children the ability to influence their anorectal function. However, the success rate in the CTM group of the current study is not higher compared with the CT group, indicating that there is no educational or demystifying effect of performing anorectal manometry in constipated children.

### TABLE 3. Overall Success for Both Treatment Groups at the Different Follow-up Periods

<table>
<thead>
<tr>
<th>Follow-up</th>
<th>CT Group ((n = 111))</th>
<th>CTM Group ((n = 91))</th>
<th>RR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 wk</td>
<td>4/111 (4%)</td>
<td>6/91 (7%)</td>
<td>0.55 (0.16–1.89)</td>
</tr>
<tr>
<td>26 wk</td>
<td>26/111 (24%)</td>
<td>19/91 (22%)</td>
<td>1.13 (0.67–1.89)</td>
</tr>
<tr>
<td>52 wk</td>
<td>32/101 (32%)</td>
<td>25/84 (30%)</td>
<td>1.07 (0.69–1.65)</td>
</tr>
<tr>
<td>104 wk</td>
<td>36/83 (43%)</td>
<td>23/65 (35%)</td>
<td>1.23 (0.81–1.85)</td>
</tr>
</tbody>
</table>

RR indicates relative risk; CI, confidence interval.

![Fig 2. Percentage of children from the CT and CTM groups who fulfilled the 3 criteria for success at 1 year of follow-up. The criteria of success are defecation frequency \( \geq 3 \) per week, encopresis frequency of \( \leq 1 \) per 2 weeks, and no use of laxatives.](http://www.pediatrics.org/cgi/content/full/108/1/e5)
Compared with previous studies in children with constipation, an unexplained high percentage of patients showed abnormal defecation dynamics during the 2 manometry sessions. A significant but small number of patients showed normalization of the defecation dynamics at the second manometry session. Nevertheless, the improvement in defecation dynamics was significantly lower compared with constipated children who were treated with BF in previous studies. This difference might be due to the 2 instead of the usual 5 manometry sessions during BF and to the explanation of the manometric tracings after and not during the session. Similarly to previous findings, no correlation was found between successful outcome and the achievement of normal defecation dynamics. This suggests once more that there is no causal relation between abnormal defecation dynamics and the pathophysiology of constipation in children.

There was no relation between volume of urge or critical volume at intake and successful outcome. This finding is in accordance with a study by Borowitz et al., which showed no association between diminished ability to sense rectal distension and frequency of spontaneous bowel movements. This observation together with the absence of a therapeutic effect of BF or the performance of anorectal manometry as well as the absence of a correlation between defecation dynamics and achievement of success leaves no diagnostic or therapeutic role for the performance of anorectal manometry in children with chronic constipation, except its use as a diagnostic test to exclude Hirschsprung’s disease.

The success rate of this study is comparable to the 16% to 51% success rates reported in other studies that used laxatives in chronically constipated children. Those studies with success rates in the higher range, however, excluded severely constipated children or included markedly improved children in their success rates. Compared with our previous study in chronically constipated children who also received CT and 2 additional manometry sessions, a smaller number of patients were cured in the present study (respectively, approximately 50% and 30%). In the current study, patients were seen once every 3 weeks during the intervention period, whereas the patients from our previous study visited the outpatient clinic 5 times in 6 weeks. This suggests that intensive patient contact at the start of the treatment period might be of influence on clinical outcome in children with severe and longstanding constipation. Furthermore, the referral of more severe cases since the start of our specialized outpatient clinic might have resulted in lower success rates compared with our first large randomized trial. This is illustrated by the high percentage of children with nighttime soiling, abnormal defecation dynamics, and day- and nighttime urinary incontinence.

Fig 3. Defecation frequencies and encopresis frequencies at intake (A and B) and at 1 year of follow-up (C and D) for the CT and CTM groups.
Interesting is that only a symptom-free period for at least 4 weeks was a prognostic factor related to success, whereas any other finding during history taking could not be related to success. Also, the total period of symptoms before intake as well as the total treatment period before intake did not relate with successful outcome. In contrast, Staiano et al. found a significant correlation between age of onset and success at 5-year follow-up.

It is noteworthy that a significant increase in defecation frequency and a significant decrease in encopresis episodes were observed after the first visit. This suggests that an adequate laxative regimen in combination with toilet training is able to improve symptoms dramatically. This regimen is aimed at complete disimpaction of the rectosigmoid by the initial daily use of enemas, thus enhancing the effect of the oral laxatives. This decrease in symptoms further enhances motivation and toilet training. In addition, other factors such as traveling to a tertiary center with high expectancies of cure and the time and attention abundantly given to the children and their parents during the outpatient visits might have an influence on improvement of symptoms.

The majority of children achieved a normal defecation frequency of 3 times or more per week. However, normalization of the defecation frequency was not related to the disappearance of encopresis in the group of unsuccessfully treated patients. This may suggest that the phenomenon of encopresis in constipated children is not due only to fecal retention in the rectum. Other pathophysiologic mechanisms such as an involuntary transient relaxation of the anal sphincter as has been documented in the esophagus or psychologic factors, eg, habit forming, need to be investigated. It might also indicate that an increase in defecation frequency is not identical to an increase in the total amount of stool.

The decrease in encopresis episodes parallels the decrease in enuresis episodes. This might suggest a behavioral or psychologic maturation disturbance in these children.

**CONCLUSION**

Anorectal manometry in combination with CT compared with CT alone has no additional educational or demystifying effect on clinical outcome in chronically constipated children. Large randomized trials already showed that the role of BF in the treatment of constipation is limited. The treatment of severely and chronically constipated children is difficult and often long-lasting and demands a lot of patience of patients, parents, and caregivers. CT, including education of constipation, intensive patient contact, enhancing motivation by small gifts, toilet training, daily diary cards, and oral laxatives preceded by the cleaning of the rectosigmoid by the use of enemas, forms the cornerstone in the treatment of these patients.

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