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ORIGINAL ARTICLE

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Role of anal dilatation in treatment of idiopathic constipation in children: long-term follow-up of a double-blind randomized controlled study

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Abstract Constipation in childhood is a common symptom, with an estimated incidence between 0.3% and 8%. Most of the evidence for the current management of constipation and fecal soiling in children is based on reports of nonrandomized retrospective trials. Anal dilatation has had an established role in the management of idiopathic constipation but has never been evaluated by a randomized study. A double-blind randomized controlled trial was done of children who failed to respond to medical treatment and were admitted for investigation and treatment of idiopathic constipation to Guy's Hospital, London, between April 2001 and April 2003. All children had intestinal transit study on admission. They were randomized, using a computer-generated allocation in sealed envelopes, to receive no anal dilatation (control group) or anal dilatation (anal dilatation group). Anorectal manometry and endosonography were done under ketamine anesthesia followed by anal dilatation if necessary under the same anesthesia. Disimpaction of feces from the rectum was done at the end of the procedure under general anesthesia using propofol muscle relaxant to minimize stretching of anal sphincter muscles in the control group. All children had intensification of medical treatment, toilet training, and monitoring of their response to treatment during their hospital stay, which ranged from 3 to 5 days. Outcome was measured using a parent's questionnaire of symptom severity at 3 and 12 months of follow-up by one of the authors, who was blinded to randomization. The symptom severity score ranged between 0 and 65 and consisted of scores for the following: delay in defecation (score range 0–10), difficulty and pain with passing stool (0–5), soiling problem (0–10), intensity of laxative treatment (0–10), child's general health (0–5), behavior related to the bowel problem (0–5), overall improvement of symptoms (0–12,) and assessment of megarectum on abdominal examination (0–8). Of 60 neurologically normal children, 31 (19 males) were randomized in the control group and 29 (18 males) in the anal dilatation group. All children had findings consistent with idiopathic constipation and positive anorectal reflex on manometry, no anal sphincter damage on endosonography, and no anal fissure on examination under anesthesia. The median age for control and anal dilatation groups was 7.97 (range 4.1–14.25) years and 7.78 (4–13.25) years, respectively. Both groups were also comparable with regard to median of duration of laxative treatment (32 months vs. 31.5 months), internal anal sphincter thickness on endosonography (0.90 mm vs. 0.80 mm), resting anal sphincter pressure on manometry (51 mmHg vs. 51 mmHg), total rectal capacity on manometry (260 mmHg vs. 260 mmHg), and total symptom severity score before admission (33 vs. 29), respectively. At 12-month follow-up, the median pre-admission symptom severity score had improved significantly, from 33 (range 12–49) in the control group and 29 (16–51) in the dilatation group to 15 (0–51, $p < 0.0001$) and 19 (1–46, $p < 0.0001$), respectively. There was no significant difference between the two groups with regard to symptom severity score improvement at 12-month follow-up ($p < 0.92$). We found a significant correlation between total rectal capacity measured on manometry and symptom severity score before admission and at 12-month follow-up ($r = 0.30$, $p < 0.01$ and $r = 0.25$, $p < 0.05$, respectively). Our results indicate that

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anal dilatation does not contribute to the management of school-aged children with idiopathic constipation. Admission to hospital for clarification of diagnosis and intensification of medical treatment with disimpaction of stool from the rectum is beneficial.

Keywords Idiopathic constipation · Children · Anal dilatation · Anorectal manometry · Endosonography

Introduction

Constipation is a common problem in childhood, and when it becomes chronic and relapsing, the child and family face very distressing problems. In the United Kingdom it accounts for 20% of pediatric gastroenterological complaints presenting to pediatricians [1]. In the United States, the estimated prevalence of constipation has varied from 0.3% to as high as 8% of children, accounting for 3% of visits to the pediatric outpatient clinic at the University of Iowa Hospital and to a large gastroenterology clinic in Boston [9, 11]. Most evidence for the current management of constipation and fecal soiling in children is based on reports of nonrandomized retrospective trials and studies in the adult population.

Anal dilatation (AD) has had an established role in the management of idiopathic constipation (IC) not responding to medical treatment [3, 6, 21], but it has never been evaluated by a randomized study. The aim of this study was to assess the benefit of anal dilatation in school-aged children with IC not responding to medical treatment.

Materials and methods

We conducted a double-blind randomized controlled trial of children who failed to respond to medical treatment and were admitted for investigation and treatment of IC at Guy's Hospital, London, between April 2001 and April 2003. The ethics committee of Guy's and St Thomas' Hospital approved this research project. Written informed consent was given by all parents and children. A full history was taken, including details of the symptoms, gender, age of onset, and duration and type of laxative treatment and enemata. Children aged between 4 and 16 years were included in the study if symptomatic with constipation and/or fecal soiling despite at least 1 month of conventional treatment under our care. At least two of the following four criteria were required: stool frequency of less than three per week, two or more episodes of soiling and/or encopresis per week, periodic passage of large amounts of stool at least once every 7–30 days, and a palpable abdominal or rectal mass [12, 18]. Patients were excluded from the study if they had an underlying anorectal anomaly or endocrine abnormality, neuropathic bowel, learning difficulties, or evidence of sphincter damage or low anal sphincter pressure on anorectal manometry.

Investigations included intestinal transit study on admission followed by anorectal manometry and endosonography under ketamine anesthesia. The transit study was done in all children by having them ingest 10 radio-opaque markers of different shapes for each of three days and taking a plain x-ray film of the abdomen on day 5 [17] of hospital admission. We performed anorectal manometry by using a 14-cm-long probe with an air-filled rectal balloon tied on the flexible end, which lay in the rectum approximately 7 cm from the anal verge. The rectal balloon was used to record rectal pressure and also to distend the rectum. There were four water-filled microballoons on the stalk of the probe, located at 1-cm intervals for simultaneous measurement of pressure changes in the rectum and anal canal, as described previously [3, 8]. The chamber giving the highest anal sphincter pressure reading was used for analysis. The anal canal chambers and rectal balloon were connected to a Statham-type pressure transducer by stainless steel and nylon tubes and via amplifiers to a personal computer that converted the pressure recordings to digital information in millimeters of mercury (mmHg). The rectal balloon was inflated with increments of air at an initial volume of 10 ml followed by 50 ml until the anal sphincter was completely inhibited or until the balloon was inflated to a maximum volume of 310 ml, which represented the total rectal capacity. The total rectal capacity in those children who needed manual evacuation of stool was calculated by adding the weight of stool in grams to the maximum rectal balloon volume in milliliters of air.

We used the Bruer and Kjaer ultrasound system (B&K Medical, Gentofte, Denmark) for endosonography with axial endosonic probe type 1850 and 10-MHz rotating transducer covered by a sonolucent cone 17 mm in diameter. The assembled unit was filled with degassed water for acoustic coupling, and the plastic cone was covered with a lubricated condom. Internal anal sphincter IAS thickness was measured in the mid-anal canal by using the callipers on the ultrasound machine at 3, 6, and 9 o'clock positions, and the mean value of the three measurements in millimeters was used for analysis. We performed anorectal manometry and endosonography under ketamine anesthetic without using muscle relaxants, and the patient was lying in the left lateral position during the studies.

On admission, children were randomized, using computer-generated allocation in sealed envelopes, to receive AD (anal dilatation group) or no AD (control group). Anorectal manometry and endosonography were done under ketamine anesthesia followed by evacuation of feces if necessary at the end of the procedure under general anesthesia with muscle relaxant to minimize stretching of anal sphincters in the control group. AD was carried out by progressive dilatation of the anus up to four fingers to the ischial tuberosities for 30 s. Manual evacuation of feces was done when nec-

essary under the profound muscle relaxation produced by propofol.

During their hospital stay, which ranged from 3 to 5 days, all children had intensification of medical treatment, in-hospital toilet training, and assessment by a pediatrician, pediatric surgeon, and specialist nurse practitioner. The investigation findings were explained to parents and children, who were encouraged to become engaged in the management and ownership of their problems. The children were motivated to establish a regular pattern of bowel habits and laxative intake, including methylcellulose, with high fluid intake as a stool softener and senna as a bowel stimulant. Sodium picosulphate and Movicol were given if the child did not stool for 3 days.

Outcome was measured using a parent's questionnaire of symptom severity (SS) scoring routinely used in our unit. The score correlates with anatomical and physiological features of longstanding constipation described previously [8]. We devised our own severity score because existing scoring systems were not suitable for this age group and focused on either fecal incontinence or difficulty with defecation. The items in the parent-completed questionnaires were refined from earlier versions that we had piloted in our clinics. We assessed the value of each item and the weighting by correlating the severity score with an intensity-of-management score (where discharge was 1 and plan to admit was 12, and scores in between were inversely proportional to the planned follow-up interval). The effect on the correlation coefficient by excluding questions or modifying their weighting led us to use the current parent questionnaire SS score system. The sum of SS scores ranged between 0 and 65 and consisted of scores for the following: delay in defecation (score range 0–10), difficulty and pain with passing stool (0–5), soiling problem (0–10), intensity of laxative treatment (0–10), child's general health (0–5), behavior related to the bowel problem (0–5), overall improvement of symptoms (0–12), and assessment of megarectum on abdominal examination (0–8). Follow-up was done at 3 and 12 months by one of the authors (GSC), who was blinded to whether the child had an anal dilatation or no dilatation.

The patient data were recorded in Microsoft Access database, and statistical analysis was done by SPSS package version 12 and Microsoft Excel spreadsheet. Matched-paired related observation was analyzed by the Wilcoxon rank sum test, and unrelated observation was analyzed by the Mann–Whitney *U*-test, and a *p* value of less than 0.05 was considered significant. Correlation coefficient was analyzed by Spearman's rho two-tailed test, and results were expressed as median and range.

Results

There were 95 neurologically normal children eligible for the research study who were admitted for investigation and treatment of their chronic IC. Parents of 27 children did not consent to the trial, and 68 children participated in the study, of whom eight were lost to follow-up. The remaining 60 children form the basis of this report (Fig. 1). There were 31 children (19 males) randomized in the control group and 29 (18 males) in the AD group. Six children in the control group and seven in the AD group required evacuation of stool under general anesthesia. Both groups were comparable with regard to age, gender, duration of symptoms and laxative treatments, SS score before admission and at 3- and 12-month follow-ups, thickness of IAS on endosonography, and resting anal sphincter pressure on manometry, as shown in Table 1. All children had findings consistent with IC, the presence of anorectal reflex on manometry, absence of sphincter damage on endosonography, and no anal fissure on examination under anesthesia. The transit study showed delayed intestinal transit time mainly in the rectosigmoid region in most of the children.

The median pre-admission total SS score was 33 (range 12–49) in the control group and 29 (16–51) in the AD group. At 3-month follow-up, the total SS score had improved significantly in 27 children in the control group and in 22 children in the AD group, to 14 (0–40) and 17 (2–39), respectively ($p < 0.001$; Table 1). At 12-month follow-up, the improvement in the total SS score was maintained in 23 (74%) children in the control group, with an SS score of 15 (0–51, $p < 0.0001$), and in 25 (86%) children in the AD group, with an SS score of 19 (1–46, $p < 0.0001$) (Fig. 2). The components of SS score before admission and at 12 months follow-up in control and anal dilatation groups are summarized in tables 2 and 3. The improvements in total SS score at 3- and 12-month follow-up were not significantly different between the control and AD groups, $p < 0.43$ and $p < 0.92$, respectively (Table 1). There was a significant

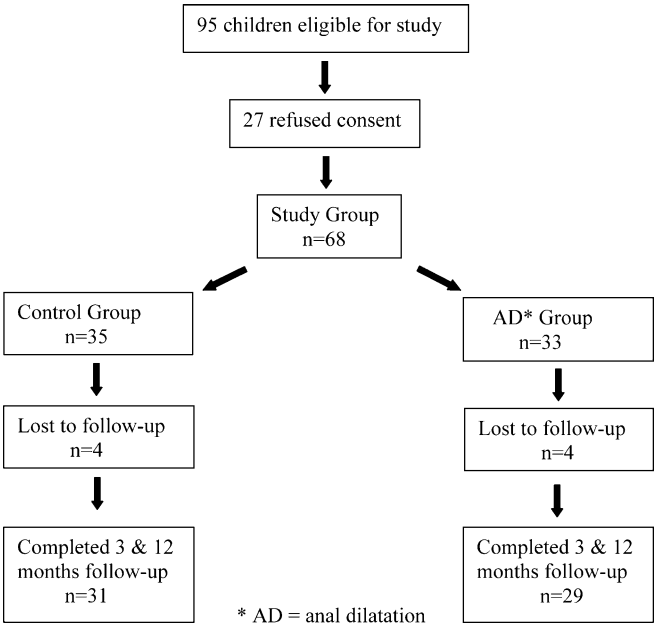

Fig. 1 Flow diagram of study design

Table 1 Comparison of demographic and anorectal manometry and endosonography data in 60 children studied

	Control ($n=31$)	Anal dilatation ($n=29$)	p (MWU)[c]
	Median (range)	Median (range)	
Age (years)	7.97 (4.1–14.25)	7.78 (4–13.25)	0.89
Duration of symptoms (months)	36 (4–114)	33 (2–110)	0.77
Duration of laxatives (months)	32 (4–102)	31.5 (2–100)	0.90
Internal anal sphincter thickness on endosonography (mm)	0.90 (0.33–1.77)	0.80 (0.33–1.97)	0.47
Resting anal sphincter pressure on manometry (mmHg)	51 (19–83)	51 (25–107)	0.90
Total rectal capacity on manometry (ml)	260 (60–623)	260 (135–757)	0.69
Total SS score[a] before admission	33 (12–49)	29 (16–51)	0.53
Total SS score at 3-month follow-up	14 (0–40)[b]	17 (2–39)[b]	0.43
Total SS score at 12-month follow-up	15 (0–51)[b]	19 (1–46)[b]	0.92

[a] Symptom severity score

[b] Wilcoxon rank sum test $p<0.0001$, SS score before admission against the score at 3- and 12-month follow-up in the same group

[c] Mann–Whitney U-test, p values not significant, comparison of data between the control and anal dilatation groups

correlation between the total rectal capacity measured on manometry and the total SS score before admission and at 12-month follow-up—$r=0.30$, $p<0.01$ and $r=0.25$, $p<0.05$, respectively (Fig. 3). That is, children with larger-size rectums had higher SS scores before hospital admission and after treatment at follow-up assessments.

Discussion

Constipation in childhood is common, with an estimated incidence between 0.3% and 8% [10, 12]. Most of the evidence for the current management of constipation and fecal soiling in children is based on nonrandomized retrospective studies and reports in the adult population [3, 6, 11, 14, 21]. The conventional treatment of constipation includes careful explanation of the physiology of defecation and how constipation arises; dietary modification, including high intake of fluids and fiber; use of laxatives and suppositories or enemas; toilet training; and psychological therapy and biofeedback training [3, 5, 11, 18]. When there is no response to conventional treatment, surgical intervention is indicated. This includes manual disimpaction of hard stool from the rectum under general anesthetic and treatment of hypertonic internal sphincter by anal stretching or internal anal sphincter myectomy [3–6] or intrasphincteric injection of botulinum toxin [7]. Manual dilatation of the anus was first described by Recamier in 1829 for managing anal fissures and was popularized by Lord for third-degree hemorrhoids [13]. However, anal dilatation was adopted for children with chronic constipation because it produces temporary relief in ultra-short-segment Hirschsprung disease by reducing internal anal sphincter hyperactivity [4].

In a series of 106 children, 25 of 64 patients (39%) responded significantly to a single vigorous anal dilatation and were taken off stimulant laxatives 1–2 months postoperatively [3]. The symptoms improved in 31 chil-

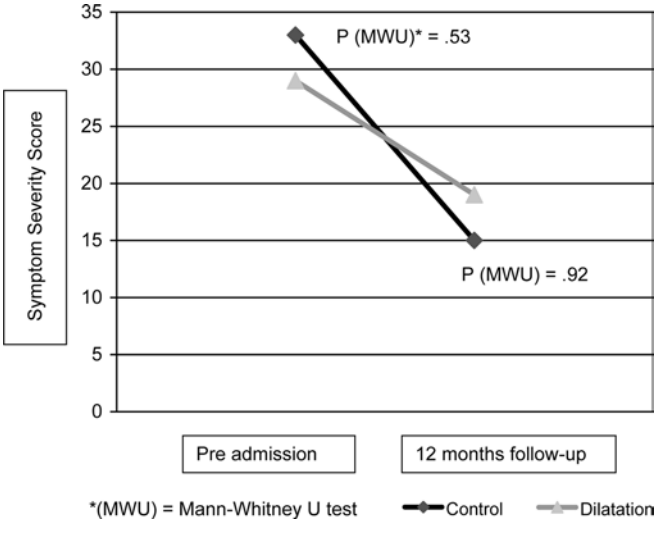

Fig. 2 Comparison of median symptom severity score between control and AD groups before admission and at 12-month follow-up

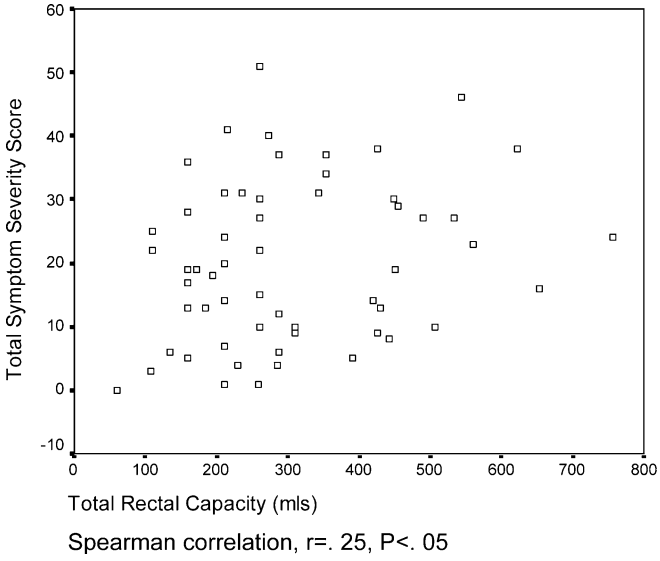

Fig. 3 Correlation between total rectal capacity measured on manometry and symptom severity score at 12-month follow-up

Table 2 Symptom severity score before admission and at 12 months follow-up in 31 children of control group

	Soiling	Delay defecation	Pain in defecation	Laxatives	General Health	Behaviour	Overall improvement	Megarectum	Total SS score[a]
Median (pre admission)	8	5	2	4	2	2	8	2	33
Range (pre admission)	(0–10)	(0–10)	(0–5)	(0–10)	(0–4)	(0–5)	(4–12)	(0–8)	(12–49)
Median 12 months	2	2	1	2	0	0	4	1	15
Range 12 months	(0–10)	(0–8)	(0–5)	(0–10)	(0–4)	(0–5)	(0–12)	(0–5)	(0–51)
Negative rank	19	20	18	8	13	17	16	16	23
Positive rank	5	3	4	7	6	4	3	5	8
Ties	7	8	9	16	12	10	12	10	0
P[b]	0.001	0.001	0.003	0.6	0.079	0.009	0.003	0.015	0.0001

[a] Symptom severity score
[b] P = Wilcoxon rank sum test

Table 3 Symptom severity score before admission and at 12 months follow-up in 29 children of anal dilatation group

	Soiling	Delay defecation	Pain in defecation	Laxatives	General Health	Behaviour	Overall improvement	Megarectum	Total SS score[a]
Median (pre admission)	8	5	2	2	2	2	8	2	29
Range (pre admission)	(0–10)	(0–10)	(0–5)	(0–10)	(0–4)	(0–5)	(1–12)	(0–5)	(16–51)
Median 12 months	2	1	1	2	2	0	4	1	19
Range 12 months	(0–10)	(0–10)	(0–5)	(0–8)	(0–5)	(0–5)	(0–12)	(0–5)	(1–46)
Negative rank	19	15	18	14	6	10	16	19	25
Positive rank	2	5	7	6	1	3	3	2	3
Ties	8	9	4	9	22	16	10	8	1
P[b]	0.001	0.003	0.027	0.14	0.17	0.008	0.006	0.001	0.0001

[a] Symptom severity score
[b] P = Wilcoxon rank sum test

dren, who required reduced doses of laxatives. Repeat anal dilatation was needed in 25 children, of whom eight had persistent symptoms and 17 (26%) had relapse symptoms. At 3–12 months of follow-up, 11 of 18 children who had initial improvement of their symptoms underwent sphincterotomy because of relapse. There was no control group in this series. In 79 children, anorectal manometry was suggestive of functional obstruction by showing prominent rhythmical waves in the internal anal sphincter and hypertrophic rectal waves in megarectum. We have shown active rectal contraction waves and high-amplitude internal anal sphincter activities, particularly in children with megarectum and fecal impaction [8]. But we could not confirm the obstructive nature of anal sphincters in these children because the average resting sphincter pressure was 51 mmHg, which was comparable with the reports of healthy children [2, 10]. We did find a weak significant positive correlation between the total rectal capacity and the SS score before admission and during follow-up. This is probably secondary to chronic retention of stool in the megarectum with incomplete rectal emptying on defecation and consequent fecal retention and overflow soiling contributing to a high total SS score before hospital admission. Interestingly, this correlation existed at 1-year follow-up, as children with larger-size rectums had higher SS scores despite symptom improvement. In a prospective study of 144 children, we reported a positive correlation between the size of megarectum on the one hand and duration of symptoms and laxative treatment, total SS score on admission, and thickness of internal anal sphincter on the other hand [8]. These factors support the use of measures to treat the megarectum rather than to weaken the anal sphincters by dilatation, particularly if a risk of long-term damage exists.

In a retrospective review of 61 children, forceful anal dilatation and anorectal myectomy as described by Bentley was reported for treating intractable constipation [6]. It was found that 14 of 16 (87.5%) children who had anorectal myectomy benefited from the procedure. Of 33 children who had anal dilatation, the symptoms improved in 22 (67%), and five patients required further myectomy with good results. Symptom improvement was attributed to shortening and widening of the functioning anal canal after anal stretcing and myectomy, thereby allowing stool to be expelled easily. Although this study does not indicate if and how these patients were selected for the various treatment groups, it is interesting that there were no reports of fecal incontinence. In our present series, we found no difference in outcome between the control and AD groups at 3 and 12 months of follow-up. Symptoms had improved in the control and AD groups at 3-month follow-up, and this improvement was maintained in 74% and 86% of children, respectively, at the 12-month follow-up. The symptoms of soiling, delay and painful defecation; and size of megarectum improved in many children in both groups. This is probably because of effective emptying of the rectum and maintenance laxative treatment required

during the long period of follow-up. Our results show the beneficial effect of hospital admission for clarification of diagnosis, toilet training, intensification of medical treatment, and evacuation of stool if necessary in children with intractable constipation with or without megarectum.

There are no long-term reports of anal dilatation in children, but the literature regarding adults has extensively reported complications including fecal incontinence and anal stenosis following manual dilatation of the anus for anal fissures, hemorrhoids, or stricture [14, 19]. In a group of 100 consecutive adults undergoing manual dilatation of the anus for anal fissures, stenosis, and hemorrhoids, 27 of 55 patients (49%) who returned a questionnaire developed fecal incontinence, with major soiling in 13%. Fecal incontinence was reported early in the first week in 18% of patients and late in 4% [15].

In 1991 anal endosonography demonstrated for the first time the nature of structural injuries in 12 adult men with fecal incontinence following anal dilatation [20]. Eleven men had a disrupted internal anal sphincter, which was extensively fragmented in 10, three of whom also had defects of the external anal sphincter. In one recent review, endosonography follow-up showed mainly an internal anal sphincteric defect in 13 of 20 (65%) patients 2–6 years after anal dilatation for fissure [16]. However, only two (10%) had symptoms of fecal incontinence. Analysis of these reports should be done with caution because of the retrospective design of the studies and inadequate information about the technique of anal dilatation used. We have performed prospective analysis of endosonography in 44 children who had previous anal dilatation for chronic constipation and subsequently underwent botulinum toxin injection or myectomy of internal anal sphincter because of symptom relapse. These children are subjects of another report and are not included in the present series. We found no sphincter damage following previous anal dilatation in any of these children who had progressive stretching of anal sphincters using up to four fingers for 30 s until the ischial tuberosities were felt.

In summary, our results show that anal dilatation does not contribute to the management of school-aged children with chronic idiopathic constipation. Most of these children require long-term follow-up, and they respond to intensification of medical treatment, toilet training, disimpaction of stool, and explanation of underlying functional abnormality. However, there might be a role for anal dilatation in younger children who have pelvic floor dyssynergia secondary to fear of defecation and withholding. But injection of botulinum toxin into the external anal sphincter may be a better alternative because the effect of toxin is temporary and does not risk permanent sphincter damage, which may occur following anal dilatation in children.

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