

Oral versus rectal laxatives for functional constipation in children

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Abstract

Background Functional constipation is a common childhood condition. Benefits of oral and rectal laxatives in terms of recovery and recurrence in children with functional constipation are still controversial.

Objective To compare the effectiveness of oral and rectal laxatives in terms of recovery and recurrence in children with functional constipation.

Methods Children aged 8 to 17 years who met the Rome III criteria for functional constipation were enrolled in this open randomised trial. Data was collected through questionnaires, interviews, and physical examinations. The participants were randomly assigned to receive stimulant laxatives (5 mg bisacodyl) either orally for three consecutive days or rectally in a single dose. Subjects kept daily defecation records for 7 days, and were followed up on days 14, 21, 28, 35, and 42. Comparisons of defecation patterns and recurrence of constipation between groups were assessed using Chi-square test.

Results Of 99 subjects, 46 children (5 boys, 41 girls) received oral laxatives (group I) and 45 children (8 boys, 37 girls) received rectal laxatives (group II). Four children in each group dropped out. Baseline characteristics are comparable between the groups. Rate of recovery in the first 7 days was higher in the oral compared to rectal groups [84.8% versus 73.3%, respectively, but this was not statistically significant ($P=0.278$)]. In the second week, the recurrence of constipation was significantly higher in the rectal (57.5%) than in the oral laxative group (42.5%) ($P=0.026$).

Conclusion Although recovery tends to occur more with oral compared to rectal laxative agents, the difference was not statistically significant. Higher recurrence in the second week after treatment occurred with rectal laxative agent. [Paediatr Indones. 2016;56:162-6].

Keywords: stimulant laxative, functional constipation, children

Constipation is a common problem in children, occurring in 16 to 37% of school-aged children and in about 4% of preschool-aged children. As many as 90 to 95% of functional constipation cases are in children over 1 year of age. Only 5 to 10% of constipation cases are caused by organic or pathological disorders.^{1,2} Constipation is not a clinical diagnosis, but causes of functional constipation include holding a bowel movement deliberately, bathroom phobias, or a history of pain from recent defecation.³ Functional constipation in children can persist to adulthood. A cross-sectional study found that 24% of children with constipation have chronic constipation as adults. Persistent constipation can affect the quality of life.⁴

Treatment of functional constipation includes evacuation of feces, maintenance with drug therapy, behavior modification, and dietary intervention. Early treatment increases the likelihood of resolving

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the constipation symptoms. Feces evacuation can be done with oral laxative, suppository, or enema.^{1,2,5} A randomized clinical trial of 100 people aged 8 to 18 years showed that the addition of rectal laxatives on oral laxatives and behavior therapy resulted in higher frequency of normalized defecation, but not in the overall success rate.⁶

Rectal disimpaction may be performed before maintenance therapy is administered. A study showed the effectiveness of rectal disimpaction using oral, rectal, or both types of laxatives. Although there have been few studies showing the effectiveness of laxatives such as bisacodyl for initial disimpaction, this therapy may be effective as an initial therapy only, not for maintenance.^{5,7} Furthermore, so far there has been no randomised study comparing oral and rectal laxatives only for children with chronic constipation. The aim of our study was to determine the effectiveness of oral compared to rectal laxatives in terms of recovery and recurrence in children with functional constipation.

Methods

An open, randomized, controlled trial was conducted from May to June 2010 at Mandailing Natal Regency, North Sumatera Province. We included primary and secondary school students aged 8 to 17 years diagnosed with functional constipation according to the ROME III criteria. The criteria were as follows: defecation ≤ 2 times in 1 week, history of excessive stool retention, history of painful or difficult defecation, large palpable fecal mass in the rectum, and/or history of stool size large enough to block the toilet. We excluded those who refused to take medications, as well as those with bloody stool, vomiting, chronic diarrhea, fever of unknown origin, abnormal stool, organ enlargement, or gastrointestinal disorders such as appendicitis and peritonitis.

Subjects were randomized by a random table method into two groups. The first group received 5 mg of oral bisacodyl once daily for three consecutive days. The second group received a single dose of 5 mg of rectal bisacodyl. Subjects were followed up daily for the first seven days, and on days 14, 21, 28, 35, and 42 to assess recurrence of constipation and frequency of defecation. Recovery was defined to be an increase in defecation to more than 3 times/week. Recurrence

was defined to be defecation frequency returning to less than two times/week after a period of recovery. Subjects' parents provided informed consent. This study was approved by the Ethics Committee of the University of Sumatera Utara Medical School.

We used SPSS version 17.0 software for data processing. The primary analysis involved all patients who were randomly assigned (intention-to-treat analysis). Recovery rate and recurrence were compared between the two groups using Chi-square test. Statistical significance was accepted to be $P < 0.05$.

Results

Between May and June 2010, of the 109 children screened, 99 children were enrolled into the study. They were randomized into two groups: 50 children in the oral laxative group, and 49 children in the rectal laxative group (Figure 1).

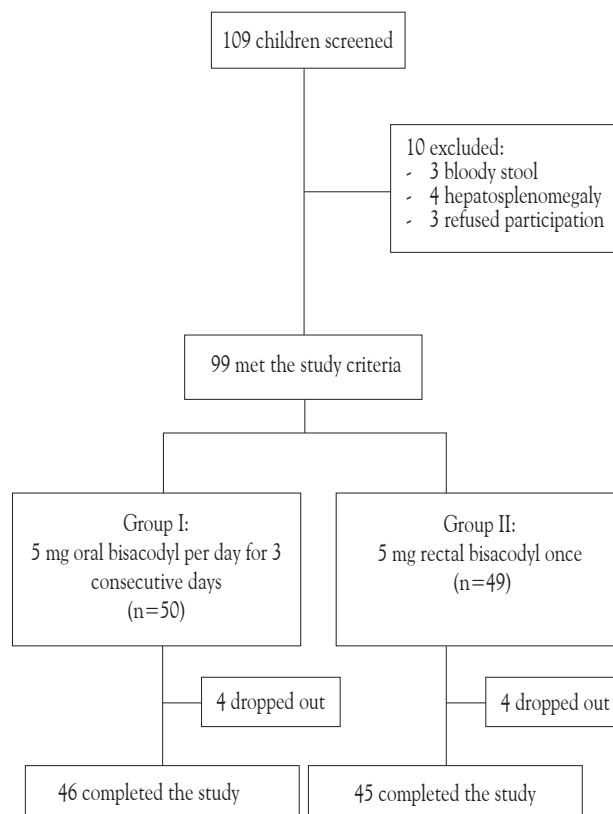


Figure 1. Study profile

As seen in Table 1, the two treatment groups were similar in terms of baseline characteristics.

Table 2 shows the recovery rates of each group. Successful disimpaction was achieved for 39 children (85%) in the oral laxative group and 33 children (73%) in the rectal laxative group, however the difference were not statistically significant ($P = 0.278$).

Table 3 shows the recurrence of constipation in each group. At the second week, the rectal laxative group had significantly more recurrence than the oral laxative group ($P=0.026$). However, at the third, fourth, fifth, and sixth weeks of observation, there were no significant differences in recurrence between the two groups.

Table 1. Baseline characteristics

Characteristics	Laxative groups	
	Oral Group I (n=46)	Rectal Group II (n=45)
Mean age (SD), years	15.0 (1.41)	15.1 (1.36)
Gender, n (%)		
Males	5 (11)	(18)
Females	41 (89)	37 (82)
Mean body weight (SD), kg	48.6 (8.11)	45.6 (7.80)
Mean body height (SD), cm	149.9 (6.79)	146.5 (6.90)
Mean BMI (SD), kg/m ²	21.6 (2.77)	21.1(2.66)

Table 2. Recovery rate of the oral and rectal laxative groups

	Recovered n (%)	No recovery n (%)	P value
Oral (Group I)	39 (85)	7 (15)	0.278
Rectal (Group II)	33 (73)	12 (27)	

Table 3. Recurrence of constipation by week after treatment

	Recurrence		P value
	Oral Group I	Rectal Group II	
2 nd week, n (%)	17 (42.5)	23 (57.5)	0.026
3 rd week, n (%)	11 (37.9)	18 (62.1)	0.110
4 th week, n (%)	6 (30.0)	14 (70.0)	0.111
5 th week, n (%)	4 (50.0)	4 (50.0)	0.659
6 th week, n (%)	2 (50.0)	2 (50.0)	0.965

Discussion

Our study found that there was no statistically significant difference in constipation recovery between oral and rectal laxatives although there was a trend

that oral laxatives resulted in higher recovery rate. Recurrence in the second week after treatment occurred more frequently with rectal than oral laxatives. Given relatively small sample size, findings need to be confirmed in a larger study.

Constipation is common in children, but only 3% of constipated children are brought by their parents to the doctor, and only 10 to 25% visit the pediatric gastroenterology clinic.^{1,8} The prevalence of constipation in children aged 4 to 17 years was reported to be 22.6%, while that for under 4-year-olds was 16%.⁹ Another study reported that 18% of children aged 9 to 11 years suffered constipation.¹⁰

In our study, the mean ages for children who suffered functional constipation were not significantly different: 15 years for the oral laxative group and 15.1 years for the rectal laxative group. This study included 8 to 17-year-old children as subjects because there is a high prevalence of functional constipation in this age group. Moreover, constipation caused by organic or pathologic disorders is less likely in this age group.

Early intervention may improve the chances for complete resolution of functional constipation.¹¹ Disimpaction is necessary before initiation of maintenance therapy. It may be accomplished with either oral or rectal laxatives. The oral approach is non-invasive and gives a sense of power to the child, but adherence to the treatment regimen may be a problem. The rectal approach is faster, but is invasive.⁵ Enemas and polyethylene glycol (PEG) were found to be equally effective in treating constipation and fecal impaction in children aged 4 to 16 years.¹²

Stimulant laxatives such as bisacodyl are widely prescribed and many can be purchased without a prescription. Only a small amount of bisacodyl can be absorbed in the small intestine after oral administration, as well as in the large intestine after rectal administration.¹³ Bisacodyl works locally to increase motility and decrease colonic transit time of the stool, as well as to increase the fluid in the stool.¹⁴

Functional constipation is difficult to treat and the recurrence rate is high. In one study, 52% of children with constipation and encopresis still had symptoms after 5 years of treatment.¹⁵ Another study found that 30% of children who had been

medically treated for constipation for a mean of 6.8 years continued to have intermittent constipation.¹⁶ In addition, a study of 418 constipated patients older than 5 years found that in the group of children who were successfully treated, 50% experienced at least one period of recurrence.¹⁷

In our study, there was no significant difference between the recurrence of constipation in the third to sixth weeks, between the oral and rectal laxative groups of the students with complete recovery. However, greater recurrence of constipation occurred in the rectal laxative group at the second week after administration.

There were several limitations in this study. The recovery was judged only on the improvement of defecation to more than 3 times/week, without long-term follow-up and without assessing for rectal stool retention, recurrent history of pain or difficult defecation, and abdominal palpation for fecal mass. In addition, the factors affecting the recovery of functional constipation such as physical activity, nutritional intake of fiber, and the availability of appropriate facilities, especially bathrooms, were not assessed. A more extensive study on the efficacy of oral and rectal laxatives as initial therapy and maintenance therapy, as well as factors that affect the recovery and recurrence rates of constipation need to be undertaken.

In conclusion, although higher recovery tends to occur with oral compared to rectal laxative agents, the difference is not statistically significant and therefore findings need to be replicated in a larger study. Higher recurrence of constipation in the second week after treatment occurs with rectal laxatives.

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