



# Laxatives in children? New study confirms effectiveness and tolerability of long-term bisacodyl

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A retrospective study investigated the efficacy and tolerability of long-term and regular use of bisacodyl in children. Even when taken over a long period (mean duration of treatment: 14 months), bisacodyl was effective, safe and well-tolerated in children. Concerns about the development of dependence proved to be unwarranted; in most patients bisacodyl could be gradually withdrawn without any change in stool frequency.

Not only adults, but also children often suffer from chronic constipation. However, previously only limited data were available concerning the long-term regular use of bisacodyl in paediatric patients. A new study from the New Haven Children's Hospital (USA) has now filled this gap and provided up-to-date data on the effectiveness and tolerability of long-term treatment. The conclusion: Bisacodyl is effective, safe and well-tolerated in children – even with long-term use. Concerns about dependence are unwarranted.

Constipation is a frequent occurrence in children. If the symptoms are chronic, functional constipation is usually present. This term refers to the irregular and often also painful passage of hard stools without anatomical causes or an underlying disease.

Standard treatment includes a fibre-rich diet, osmotic laxatives and enemas as well as the additional use of stimulant laxatives such as bisacodyl if the effect of the other measures was inadequate. Although a majority of patients respond to this therapeutic concept, a remaining subgroup (known as refractory cases) benefits only a little – if at all – from this

approach. In these patients in particular, more intensive use of bisacodyl can be helpful.

In order to expand the limited data on the long-term, regular administration of bisacodyl – particularly in children – a study was conducted on the effectiveness and tolerability of bisacodyl in paediatric patients [1].

## Retrospective study in children and adolescents

Children with refractory functional constipation, who had been referred to the New Haven Children's Hospital (USA) between 2007 and 2014 for evaluation and treatment of their chronic constipation, were included in the retrospective study.

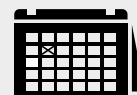
The children had shown a stool frequency of two – or fewer – bowel movements per week under baseline treatment with osmotic laxatives. Bisacodyl was then added to their treatment for a period of at least four weeks. Demographic data such as age and sex, dose of bisacodyl, duration of treatment, number of bowel movements per week before and after treatment with bisacodyl, side effects and length of follow-up, were recorded.



**Number of participants**  
n = 164  
(girls: 52 %)



**Median age:**  
9.5 years  
(0.9 – 21 years)



**Median duration of treatment:**  
14 months  
(1 – 77 months)



Median weekly stool frequency under baseline therapy – **without** regular bisacodyl treatment



Median weekly stool frequency (baseline therapy) – **with** regular bisacodyl treatment ( $p < 0.001$ )

A total of 164 patients were included in the study. The median age was 9.5 years (0.9–21 years) and 52% of children were girls. The median dose of bisacodyl was 5 mg (1 to 20 mg), the median duration of treatment was 14 months (1 to 77 months) and 90% of patients took the medication for less than 36 months.

### Number of weekly bowel movements doubled

The results of the study showed that the median stool frequency on regular administration of bisacodyl (added to the existing therapy with osmotic laxatives) increased significantly from two to four bowel movements per week ( $p < 0.001$ ).

Furthermore, 57% of patients (94 of 164) had a stool frequency of  $\geq 3$  bowel movements per week.

### No dependence under long-term bisacodyl treatment

The authors also investigated whether patients could gradually be weaned off the bisacodyl treatment while maintaining a constant stool frequency of  $\geq 3$  bowel movements per week. Relevant data from 71 children were available for analysis.

In 55% of patients, the symptoms could be kept under control so well that bisacodyl could be successfully stopped (through a gradual reduction in dosage and/or decrease in frequency of administration). 45% of patients continued to be reliant on bisacodyl treatment.

The authors found that the ability or inability to discontinue treatment was not influenced by the duration of treatment, dosage or the age or sex of the patient. Many patients could be weaned off bisacodyl – and this was irrespective of treatment duration and dosage.

Side effects were observed in only 8% of patients (13 of 164) and principally consisted of transient abdominal pain and diarrhoea. These side effects disappeared in most cases after dose adjustment and led to treatment being ended in only five patients.

### Bisacodyl: effective and safe for long-term use

The retrospective study showed that the weekly stool frequency in children with refractory chronic constipation could be doubled by bisacodyl.

The drug was well-tolerated throughout the median 14-month treatment period; side effects occurred in only 8% of children and generally vanished when dose adjustments were made. Concerns about dependence on bisacodyl were allayed by the authors – long-term treatment was not associated with dependence or with other complications.

In summary, the study confirmed the efficacy and safety of bisacodyl in children, especially with regard to long-term use.

### Literature

1. Bonilla S et al. Long Term Use of Bisacodyl in Pediatric Functional Constipation Refractory to Conventional Therapy. *Journal of Pediatric Gastroenterology and Nutrition* 2020, published ahead of print, doi: 10.1097/MPG.0000000000002795.

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