J Pediatr (Rio J). 2015;91(6):567–573

Jornal de Pediatria
www.jped.com.br

ORIGINAL ARTICLE

Effect of 4′galactooligosaccharide on constipation symptoms☆,☆☆,☆☆☆

Célia A.V. Beleli[a], Maria A.R.G.M. Antonio[a], Rosângela dos Santos[b], Gláucia M. Pastore[b], Elizete A. Lomazi[a,*]

[a] *School of Medical Sciences, Universidade Estadual de Campinas (UNICAMP), Campinas, SP, Brazil*
[b] *Faculty of Food Engineering, Universidade Estadual de Campinas (UNICAMP), Campinas, SP, Brazil*

Received 29 September 2014; accepted 23 January 2015
Available online 30 July 2015

KEYWORDS
Child;
Constipation;
Functional food;
Therapy

Abstract
Objective: Fructooligosacharides and galactooligosacharides soften fecal bolus and increase frequency of depositions when added to infant formula. This study aimed to determine the effects of galactooligosaccharide in pediatric patients with chronic constipation.
Methods: From 2010 to 2012, 20 constipated patients (4–16 years of age) attended to at a primary healthcare unit were enrolled in a double-blinded, placebo-controlled crossover trial. Eleven children ingested galactooligosaccharide (1.7 g) for 30 days, followed by a 15-day washout period, and a 30-day period of placebo (maltodextrin). Nine patients ingested maltodextrin for 30 days, followed by 15-day washout period, and galactooligosaccharide (1.7 g) for 30 days. Constipation symptoms were considered as primary outcomes: bowel movements/week, straining during defecation, and stool consistency. Outcome symptoms were ranked according to a numerical scale elaborated for this study. Data were recorded at baseline, and on days 15 and 30 of each 30-day crossover period. Repeated-measures analysis of variance (ANOVA) was used to analyze symptoms along time.
Results: At baseline, there was no significant difference in symptoms severity between groups ($p = 0.45$). Galactooligosaccharide ingestion was related to increase of the bowel movement frequency, $p < 0.0001$; relief of defecation straining, $p < 0.0001$; and decrease in stool consistency, $p = 0.0014$, compared to placebo ingestion. Patients reported no side effects from galactooligosaccharide.

☆ Please cite this article as: Beleli CA, Antonio MA, dos Santos R, Pastore GM, Lomazi EA. Effect of 4′galactooligosaccharide on constipation symptoms. J Pediatr (Rio J). 2015;91:567–73.
☆☆ Study linked to School of Medical Sciences and Faculty of Food Engineering, Universidade Estadual de Campinas (UNICAMP), Campinas, SP, Brasil.
☆☆☆ Study conducted at Basic Health Unit in the outskirts of Campinas, coordinated by a team of pediatricians of the Department of Pediatrics, School of Medical Sciences, Universidade Estadual de Campinas (UNICAMP), Campinas, SP, Brasil.

* Corresponding author.
E-mail: elizete.apl@gmail.com (E.A. Lomazi).

http://dx.doi.org/10.1016/j.jped.2015.01.010

Conclusion: Galactooligosaccharide was effective at improving clinical symptoms in this group of constipated children.

PALAVRAS-CHAVE
Criança;
Constipação intestinal;
Alimento funcional;
Tratamento

Efeito do galactooligosacarídeo sobre os sintomas de constipação

Resumo
Objetivo: A adição de frutooligosacarídeos e galactooligosacarídeos a fórmulas infantis pode diminuir a consistência fecal e aumentar a frequência das evacuações. O objetivo do presente estudo foi determinar o efeito do galactooligosacarídeo em crianças com constipação crônica.
Métodos: Entre 2010 e 2012, 20 pacientes constipados (4-16 anos), atendidos numa unidade básica de saúde, completaram ensaio clínico duplo cego, placebo-controlado e de delineamento *crossover*. Onze pacientes receberam galactooligosacarídeo (1,7 g) por 30 dias, seguidos por 15 dias de *washout*, e, após, placebo (maltodextrina) por 30 dias; outros nove pacientes receberam placebo 30 dias, seguidos de 15 dias de *washout* e 30 dias de galactooligosacarídeo (1,7 g). Os desfechos primários foram frequência semanal de evacuações, esforço evacuatório e consistência fecal, classificada por escala numérica elaborada para esse estudo e compilada no primeiro, 15º e 30º dias de cada período de crossover. Análise estatística foi feita por método de análise de variância (ANOVA) para medidas repetidas.
Resultados: Intensidade dos sintomas nos grupos foi semelhante no início do estudo ($p = 0,45$). Durante a ingestão de galactooligosacarídeo constatou-se maior frequência de evacuações, $p < 0,0001$, menor dificuldade evacuatória, $p < 0,0001$ e diminuição da consistência fecal, $p = 0,0014$. Efeitos colaterais não foram referidos durante a ingestão do prebiótico.
Conclusão: Durante a ingestão de galactooligosacarídeo os sintomas clínicos da constipação em crianças e adolescentes foram significantemente aliviados.

Introduction

Data from the last decades have indicated childhood constipation as a common problem worldwide. Its reported prevalence has varied from 0.7% to 30%; in addition, in recent years, the number of patients has grown significantly in western world.[1,2] Different therapeutics have been recommended for constipation management, including stool lubricants, dietary fiber supplementation, laxatives, prokinetics, and functional foods. Osmotic laxatives and dietary fibers are the most widely used therapeutic tools; however, there are very few evidence-based studies to support any treatment recommendations for constipation in pediatric patients.[3,4]

Functional foods containing probiotics or prebiotics have been identified as useful for regulating bowel habits in children.[5] A multicenter controlled trial showed that consumption of fermented dairy products containing *Bifidobacterium lactis* was associated to increase in stool frequency in children with constipation and stool frequency <3 times/week.[6]

Concerning the effects of prebiotics on laxation, studies conducted in pediatric patients have included predominantly infants fed exclusively on milk formulas. Ingestion of prebiotics was proposed to be effective for treating constipation, since consumption of fructooligosaccharides and galactooligosaccharides added to infant formula has been shown to increase fecal bolus and the frequency of depositions.[7–10]

The rationale of prebiotics' therapeutic effects on constipation is based on the fact that 4′galactooligosaccharide (GOS) affects the host health by stimulating the growth and/or activity of colonic bifidobacteria.[11] Bifidobacteria, mainly *Lactobacillus acidophillus* or *Bifidobacterium bifidum*, act by fermenting carbohydrates, producing short chain fatty acids (SCFAs), the major anion on the large intestine; SCFAs are able to increase colonic blood flow and muscular activity, enhancing fecal wet weight and thus promoting laxation.[12,13]

The current study was aimed at evaluating the effectiveness of the prebiotic GOS in the treatment of constipation in children and adolescents.

Methods

Design: An interventional, non-randomized, double-blinded, placebo-controlled, crossover assignment study was conducted from June 8, 2010 to March 25, 2012.

Setting: A primary healthcare unit managed by medical school staff.

Patients: Subjects aged 4–16 years old who spontaneously sought medical care and, when eligible after initial examination, were invited to participate in the study.