Diyala Journal of Medicine

ORIGINAL RESEARCH
Published: 5 April 2023
Doi: 10.26505/DJM.24016971011

Lactulose vs Lactuloseand inulin in treatment of pediatric constipation

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Abstract

Background: Assess the efficacy of combining fiber and lactulose in the treatment of constipation in the pediatric age group.

Objective: To assess the efficacy of combining fiber and lactulose in the treatment of constipation in the pediatric age group.

Patients and Methods: One hundred forty-six patients with fuctionalconstipation were chosen in a non-randomized superiority trial manner as they were convenient to enroll due to their presentation to the outpatient clinic during the period from August 2019 to February 2022.Patient received either a solution of lactulose 3.3g/5ml in group A or a solution of 4.005g Inulin fiber and 4.005g lactulose per 20ml in group B.

Results: Total of 146 children were included; all, 146 patients completed the study. In the lactulose group, 19 patients were on therapy for less than 6 months, and 48 were on therapy for more than 6 months. In the lactulose + fiber group, 59 patients were on therapy for less than 6 months, and 20 were on therapy for more than 6 months. No serious adverse effects were registered but 18 (27%) of children in the lactulose group encountered side effects, while 11 (14%) of children in the lactulose + fiber group encountered side effects.

Conclusion: A solution of Lactulose + fiber is superior to a solution of Lactulose alone in terms of efficacy for the treatment of constipation in the pediatric age group. It also has a lower side effects profile.

Keywords: Abdominal pain, bloating, constipation, distension, lactulose, inulin

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Received: 11 October 2022
Accepted: 4 December 2022
Published: 5 April 2023

Introduction

Constipation is acommonly encountered pediatric problem and is generally described as having fewer than three bowel movements a week with stools that are hard and dry which are difficult or paiful to pass,They may have bowel movements less common than they used to have, for example, having a motion every other day rather than normal previous of three or four motion per day [1].

Howevermany children who have constipation do not recognized to have any underlying health problem or diseases and hencemostly have functional constipation (FC) [1].Newly released criteria define functional constipation as having two or more of the following at least once per week over the last month [2]:

1. Two or less bowel motion per week.
2. Fecal incontinence at least 1 per week.

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3. Retentive posturing and excess volitional stool retention.
4. Passing hard or painful bowel movements.
5. Large fecal mass in the rectum.
6. Large-diameter stools which mayblock the toilet.

The goals of treatment for chronic constipation is to restore bowel movement by accelerating gut motility [3].

Polyethylene glycol (PEG) is recommend by ESPGHAN/NASPGHAN guidelines as the first-line treatment for disimpaction of fecal material and maintenance treatment, Lactulose may be used as an alternative therapy [4].

Lactulose composed of synthetic disaccharide fermented by colonic bacteria leading to decrease in PH of the colonic ,increase in fecal volume with facilitating colonic transit [5].Lactulose reaches the lower part of intestine unchanged, it increases amount of water and electrolytes by its osmotic effect. Lactulose will be braked down by enteric bacteria to organic acids as lactic and acetic acids which stimulate intestinal motility [6].

Side effects most commonly reported in lactulose treatmentinclude abdominal pain , nausea, frequent bowel motion and too much flatulence [7].

Inulin regarded as nondigestible oligosaccharide found in the diet as a soluble fiber (naturally found in vegetables such as wheat, garlic, onion and asparagus). It is stable and resistant todigestion by digestive enzymes and reaches the distal bowel unchanged and further selectively fermented by colonic flora as a source of energy. they are regarded as prebiotics since they nourish and stimulate beneficial flora and provide health benefits to the body [8].

Dietary fibers intake in large amount reduces risk of developing many diseases, including chronic constipation [9]. Microbiota component accommodates promptly to dietary changes [10]. Prebiotics like inulin fructo-oligosaccharides is regarded as 'functional fibers [11].Ameta-analysis published in 2014 and 2016 respectively viewed that giving inulin has a positive effect on intestinal function in those individuals with chronic constipation and improves stool consistency in constipated 2–5-year old children [7,12,14,]. The most common side effects include gas, bloating, diarrhea, constipation, and cramps. These side effects are more severe with high doses of inulin (more than 30 grams) [7].

Patients and Methods

Children aged three months to 6.5 years were included.

The inclusion criteria were childrenwho had less than three bowel motions per week,at least 25% of the bowel motionaccompanied by straining, and at least 25% bypassing hardstool [5].

Verbal consent was obtained before starting the study.

The exclusion criteria were children who had organic causes of constipation like Hirschsprung’s disease, spinal dysraphism, abnormal thyroid function,urinary tract abnormalities, cognitive behavior and mental retardation andthose using drugs affecting intestinal motility.

Study materials

Patients received either a solution of lactulose 3.3g/5ml in group A or a solution of 4.005g Inulin Fiber and 4.005g Lactulose per

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20ml in group B according to preparations that available for treatment of pediatric constipation. The amount of fiber and Lactulose taken depended on the weight of the patient. Patients weighing 6-8 kg received X per day, 9-11 kg received X per day, 12-13 kg, and weight 14-17 kg received X per day in which X means amount of solution in both milliliter and grams per body body weight per day.

Setting and duration of the study

The study was conducted in public Hospital / outpatient clinic of a pediatrician and pediatric surgery in Erbil/Kurdistan, Iraq. Sample size and sampling method

One hundred forty-six patients were chosen in a non-randomized superiority trial manner as they were convenient to enroll due to their presentation to the outpatient clinic.

Data collection

The data was collected through a detailed history taken from the patient's parents, followed by a general physical examination and for some patients laboratory and radiologic investigation to rule out organic or other underlying causes.

Study Design

The study has a non-randomized superiority design. The period of the study composed of two phases: first, a one week baseline and then asix week intervention period. All patients were screened during their first consultation to the clinic or out patientdepartment . Detailed clinical history was taken, and a complete physical examination was done including abdominal examination. During the baseline period, frequency of defecation, frequency and number of fecal incontinence, consistency of stool, abdominal pain and discomfort , and excessive flatulence were recorded. Patients were seen two and six weeks after inclusion during the treatment period. Data were recorded daily by the parents or patient andall side effects encountered were recorded. Side effect was defined as any adverse event occurred after starting treatment plan .

Statistical Analysis

Were done using Statistical Package for the Social Sciences (SPSS-version 22) package software program has used forstatistical analysis. Descriptive statistics (numbers andpercentages)have calculated for all variables, analyticalstatistics were done to find the relations betweenvariables by using, Chi-square, and fisher exact test. Ap-value < 0.05 was considered as significant .

Results

Table (1): Difference in baseline characteristics between Group A and B

	Group A Lactulose n = 67	Group B Lactulose + fiber n = 79
Boy/Girl	42/25	46/33
Median range of age in months	16, 78	16, 78
Weight 6-8	25	44
Weight 9-11	33	27
Weight 12-13	9	7
Weight 14-17	0	1

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There was no significant differences ,18 (27%) of patients in lactulose group encountered side effects, while 11 (14%) of patients in lactulose + fiber group encountered side effects such as flatulence, abdominal pain, nausea/vomiting,diarrhea,abdominal pain, distention, headache,pruritis ani.

In the lactulose group,7 patients had abdominal distensionbefore therapy and 13 had fecal impaction and 1 had soiling. In the lactulose + fiber group, 6 patients had abdominal distensionbefore therapy and 16 had fecal impaction and 1 had soiling. In the lactulose group,19 patients were on therapy forless than 6 months, and48 were on therapy for morethan 6 months. In the lactulose+fiber group,59 patients were on therapy for less than 6 months, and 20 were on therapy for morethan 6 months. In the lactulose group, 7 patients needed further treatment with stimulant laxatives, and 3 requiredtreatments with enemas. In the lactulose+fiber group, 10 patients needed further treatment with stimulant laxatives, and 1 required treatment with enemas.

Only 1 patient needed surgical intervention and they were in the lactulose group.

Table (2): Side effects encountered during therapy in both group A and B

	Lactulose	Lactulose+ Fiber
Patients with side effect	18	11
Abdominal distension	7	6
Fecal impaction	13	16
Soiling	1	12

Table (3): Duration of treatment for both group A and B

	Lactulose	Lactulose + fiber
On therapy for less than 6 months	19	48
On therapy for more than 6 months	59	20
Further treatment with stimulant	7	10
Further treatment with an enema	3	1

Discussion

This study showed that both lactulose and lactulose + fiber were effective at treating pediatric age group patients with constipation. A solution of lactulose + fiber had lower side effects than a solution of lactulose alone as proven by the literature. This is probably due to the fact that inulin acts as a prebiotic for the normal flora of the intestine thus relieving or preventing side effects from ‘lactulose such as bloating, a solution of lactulose and fiber seems to have a synergistic effect in contrast to a solution of lactulose alone which has only laxative effect.

Patients receiving a solution of lactulose + fiber required treatment for a shorter period of time than those who only received lactulose. This is probably due to the proven effect of fiber in accelerating GI transit time and reducing stool viscosity. Lactulose reaches the large intestine unchanged and will be broken down by intestinal bacteria into short-chain fatty acids causing decrease in intraluminal pH leading to increase in peristaltic activity are absorbed together with

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water and electrolytes, leading to the reduction of amount of fecal water content. Fermentation, enhances intestinal bacterial growth , increase stool weight and volume, intestinal dilatation and eventually causes the reflex intestinal peristalsis. The fate of these fibers in this mixture is comparable to that of lactulose except for the difference in site and rate of fermentation. Several strains of bacteria and their enzymes are involved and probably may take longer time to efficiently degrade these fibers. This might explain the more prolonged softening of stool seen in the fiber group.Finding in our study is comparable to those found in a study done by Collado Yurrita *et al* in 2014 in which they found a significant overall effect of inulin on stool frequency , stool consistency , transit time and hardness of stool but pain and bloating do not improve with inulin intake [12] and also with the study done by Ricardo Closa-Monasterolo et al in 2005 in which they found that prebiotic inulin-type fructans supplementation improves stool consistency in constipated 2–5-year old children [7]. A study in 2017 done by Ting Yu et al to determine the effects of prebiotics and synbiotics on functional constipation in adults found that Galacto-oligosaccharides and synbiotics made up of fructo-oligosaccharides with probiotic combinations may improve stool frequency, consistency and some other symptoms related to constipation [13].

Intake of high amount of fiber has been encouraged as a treatment option for chronic pediatric constipation. Early reports explained a positive relationship between low fiber intake and the risk of constipation [10].

Conclusions

According to this study, we have found that a solution of Lactulose + fiber is superior to a solution of Lactulose alone in terms of efficacy for the treatment of constipation in the pediatric age group. It also has a lower side effects profile.

Recommendations

For better outcomes for patients delivered with constipation, we recommend the inclusion of fiber along with lactulose therapy for the pediatric age group.

Source of funding: The current study was funded by our charges with no any other funding sources elsewhere.

Ethical clearance: The protocol of this study was approved by the ethics committee of Hawler Medical University.

Conflict of interest: Nil

References

[1] M M Tabbers, C DiLorenzo, M Y Berger, C Faure, M W Langendam, S Nurko, et al. Evaluation and treatment of functional constipation in infants and children: evidence-based recommendations from ESPGHAN and NASPGHAN. J PediatrGastroenterolNutr 2014;58(2): 258–74.

[2]Jeffrey S Hyams, Carlo Di Lorenzo, Miguel Saps, Robert J Shulman, Annamaria Staiano, Miranda van Tilburg . Functional disorders: children and adolescents. Gastroenterology 2016;150(6):1456–68.

[3]Bleser S, Brunton S, Carmichael B, Olden K, Rasch R, Steege J. Management of chronic constipation: recommendations from the consensus panel. J Fam Pract 2005;54(8):691–8.

ORIGINAL RESEARCH
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Doi: 10.26505/DJM.24016971011

[4] Shatnawi MS, Alrwalah MM, Ghanma AM, Alqura'an ML, Zreiqat EN, Alzu'bi MM. Lactulose versus polyethylene glycol for disimpaction therapy in constipated children, a randomized controlled study. Sudan J Paediatr. 2019;19(1):31-36.

[5] Dorota Jarzebicka, Joanna Sieczkowska-Golub, Jaroslaw Kierkus, Piotr Czubkowski, Monika Kowalczuk-Kryston, Maciej Pelc, et al. PEG 3350 versus Lactulose for Treatment of Functional Constipation in Children: Journal of Pediatric Gastroenterology and Nutrition. 2019 Mar;68(3):318-324.

[6] Mugie SM, Benninga MA, Di Lorenzo C. Epidemiology of constipation in children and adults: a systematic review. Best Pract Res ClinGastroenterol 2011;25(1): 3–18.

[7]Ricardo Closa-Monasterolo,Natalia Ferré,GemmaCastillejo-DeVillasante , VeronicaLuque ,MarionaGispert-Llaurado,Marta Zaragoza-Jordana,et al. The use of inulin-type fructans improves stool consistency in constipated children. International Journal of Food Sciences and Nutrition.2016 ;pages 587-594.

[8] Micka A, Siepelmeyer A, Holz A, Theis S and Schön C: Effect of consumption of chicory inulin on bowel function in healthy subjects with constipation: A randomized, double-blind, placebo-controlled trial. Int J Food SciNutr. 2017; 68:82–89..

[9] Dahl WJ and Stewart ML: Position of the Academy of Nutrition and Dietetics: Health implications of dietary fiber. J AcadNutr Diet.2015; 115:1861–1870.

[10] David LA, Maurice CF, Carmody RN, Gootenberg DB, Button JE, Wolfe BE, et al: Diet rapidly and reproducibly alters the human gut microbiome. Nature 2014. 505:559–563.

[11]Slavin J: Fiber and prebiotics: Mechanisms and health benefits. Nutrients. 2013; 5:1417–1435.

[12] ColladoYurrita L, San Mauro Martín I, Ciudad-Cabañas MJ, Calle-Purón ME and Hernández Cabria M: Effectiveness of inulin intake on indicators of chronic constipation; a meta-analysis of controlled randomized clinical trials. Nutr Hosp. 2014; 30:244–252.

[13] Ting Yu, Yong-Ping Zheng, Jia-Cheng Tan, Wen-Jie Xiong, Yun Wang, Lin Lin. Effects of Prebiotics and Synbiotics on Functional Constipation. AM J Med Sci; . 2017 Mar; 353 (3): 282-292.

[14] Ziegler E, Vanderhoof JA, Petschow B, Mitmesser SH, Stolz SI, Harris CL, et al.Term infants fed formula supplemented with selected blends of prebiotics grow normally and have soft stools similar to those reported for breast-fed infants. J Pediatr Gastroenterol Nutr. 2007; 44:359–364.

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ORIGINAL RESEARCH
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Doi: 10.26505/DJM.24016971011

لاكتولوز مقابل لاكتولوز مع إينولين في علاج إمساك الأطفال

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الملخص

خلفية الدراسة: الإمساك مشكلة شائعة لدى الأطفال. غالبًا ما يستخدم الأطباء اللاكتولوز كعلاج من الدرجة الأولى ، ولكن هناك القليل من البيانات حول تضمين الألياف في علاج اللاكتولوز.

اهداف الدراسة: لتقييم فعالية الجمع بين الألياف مع اللاكتولوز في علاج الإمساك لدى الأطفال.

المرضى والطرائق: تم اختيار مائة وستة وأربعين مريضًا كانوا مناسبين للتسجيل بسبب عرضهم على العيادة الخارجية في فترة من اب ٢٠١٩ إلى شباط ٢٠٢٢. تلقى المريض إما محلول من اللاكتولوز ٣,٣ جم / ٥ مل في المجموعة أ أو محلول ٤,٠٠٥ جم من ألياف الإنولين و ٤,٠٠٥ جم لاكتولوز لكل ٢٠ مل في المجموعة ب.

النتائج: كان ما مجموعه ١٤٦ طفلاً مؤهلين ؛ جميعًا ، أكمل ١٤٦ طفلاً الدراسة. في مجموعة اللاكتولوز ، خضع ١٩ مريضًا للعلاج لمدة تقل عن ٦ أشهر ، و ٤٨ كانوا في العلاج لأكثر من ٦ أشهر. في مجموعة اللاكتولوز + الألياف ، كان ٥٩ مريضًا يتلقون العلاج لمدة تقل عن ٦ أشهر ، و ٢٠ كانوا في العلاج لأكثر من ٦ أشهر. لم يتم تسجيل أي آثار ضاهرة خطيرة ، حيث عانى ١٨ (٢٧٪) من المرضى في مجموعة اللاكتولوز من آثار جانبية ، بينما تعرض ١١ (١٤٪) من المرضى في مجموعة اللاكتولوز + الألياف لأعراض جانبية.

الاستنتاجات: كان يتفوق محلول اللاكتولوز + الألياف على محلول اللاكتولوز وحده من حيث الفعالية في علاج الإمساك لدى الأطفال. كما أن لها تأثيرات جانبية أقل.

الكلمات المفتاحية: آلام في البطن ، انتفاخ ، إمساك ، انتفاخ ، لاكتولوز ، ألياف ، أنولين ، فئة عمر الأطفال ، أعراض جانبية

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تاريخ استلام البحث: ١١ تشرين الاول ٢٠٢٢

تاريخ قبول البحث: ٤ كانون الاول ٢٠٢٢

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