International Journal of Contemporary Pediatrics
Jose S et al. Int J Contemp Pediatr. 2018 Jan;5(1):46-49
http://www.ijpediatrics.com
pISSN 2349-3283 | eISSN 2349-3291

DOI: http://dx.doi.org/10.18203/2349-3291.ijcp20175506

Original Research Article

Effect of probiotics on constipation in children

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Received: 20 October 2017
Accepted: 20 November 2017

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ABSTRACT

Background: Constipation in children is a common problem. A constipated child has infrequent bowel movements or hard, dry stools. This is a randomized controlled trial to find the relationship between probiotics and constipation in children.
Methods: This study was a randomized, controlled blinded trial conducted in Department of Paediatric. This was done during a period of January 2014 to January 2016 conducted in 50 patients. The patients were divided into two groups randomly namely group A who received lactulose plus protexin daily and group B who received lactulose plus placebo alone.
Results: Males were 15 (60%) and females were 10 (40%) in group A and in group B, males were 10 (40%) and females were 15 (60%). Faecal incontinence was in 13 (52%) in group A and in 10 (40%) in group B. Abdominal pain was in 16 (64%) in group A and was in 14 (56%) in group B. The stool frequency and consistency improved significantly. There was a significant improvement in fecal incontinence and abdominal pain in the Group A, and at the end of the fourth week, this difference was not significant and there was improvement significantly in weight gain. Side effects were not seen in the during the treatment.
Conclusions: This study shows that there was a positive effect of probiotics on constipation in children.

Keywords: *Bifidobacterium, Lactobacillus acidophilus, Lactobacillus fermentum*

INTRODUCTION

Constipation in children is a common problem. A constipated child has infrequent bowel movements or hard, dry stools. Common causes include early toilet training and changes in diet.[1] Fortunately, most cases of constipation in children are temporary. Encouraging your child to make simple dietary changes such as eating more fiber-rich fruits and vegetables and drinking more fluids can go a long way toward alleviating constipation.[2] If your child's doctor approves, it may be possible to treat a child's constipation with laxatives.[3] Signs and symptoms of constipation in children may include less than three bowel movements a week, bowel movements that are hard, dry and difficult to pass, large-diameter stools that may obstruct the toilet, pain while having a bowel movement, abdominal pain, traces of liquid or clay-like stool in your child's underwear a sign that stool is backed up in the rectum and blood on the surface of hard stool. Although constipation in children can be uncomfortable, it usually isn't serious.[4] If constipation becomes chronic, however, complications may include painful breaks in the skin around the anus (anal fissures), rectal prolapse, when the rectum comes out of the anus, stool withholding and avoiding bowel movements because of pain, which causes impacted stool to collect in the colon and rectum and leak out (encopresis).[5] There is some preliminary evidence that probiotics, or beneficial bacteria, are useful in cases of childhood constipation. It makes sense. After all, bacteria constitute about 30 percent or more of the typical stool weight.[6] In addition, these beneficial bacteria enhance overall digestive health. Rather than using a

single strain of probiotic bacteria, it's best to use a multi-strain formula composed of highly viable and compatible strains such as *Bifidobacterium bifidum*, *Bifidobacterium breve*, *Bifidobacterium infantis*, *Lactobacillus acidophilus*, *Lactobacillus lactis*, *Lactobacillus fermentum* or *Lactobacillus rhamnosus*. There are multiple strains of bacteria in our bodies, so it's important to supplement with a multi-strain formula. A good probiotic supplement will list the strains it includes on the label. Keep in mind that much of the scientific research on probiotics involves the analysis of single strains because it's easier to evaluate the effectiveness of one strain versus multiple strains. One of the most commonly studied strains of bacteria is *Bifidobacterium breve*. "Probiotics are indeed also given in the Netherlands and elsewhere by caregivers because constipation is in the majority of patients difficult to treat and a long-lasting problem," Tabbers tells WebMD via email. Approximately 50% of all children followed for six to 12 months are found to recover and were successfully taken off laxatives. This is a randomized controlled trial to find the relationship between probiotics and constipation in children.

METHODS

This study was a randomized, controlled blinded trial conducted in Department of Paediatric. This was done during a period of January 2014 to January 2016 conducted in 50 patients.

Inclusion criteria

Children less than or equal to 18 years with constipation, that was identified by clinical symptoms, or Rome III criteria for chronic constipation. Culture or stain or dose or therapy regimen of any kind of probiotics was included.

Exclusion criteria

- Children who had hospital admission history, or any gastro-intestinal or nutritional problems,
- Children who had acquired congenital immune deficiency, or chronic illness, any underlying diseases.

This study was approved by ethical committee and informed consent was taken from all the patients who were undergoing this study. The patients were divided into two groups randomly namely Group A who received lactulose plus protexin daily and Group B who received lactulose plus placebo alone.

The first questionnaire was done by the researcher which included demographic data, drug history, medical history, constipation symptoms, physical examination.

After first and fourth weeks, a second questionnaire was done for constipation symptoms, which included defecation frequency, stool consistency, abdominal pain, fecal inconstinence, and side effects in both the groups.

RESULTS

A total of 60 patients were enrolled in the study. 5 patients from Group A were excluded from the study as 3 patients refused to complete the study in the first week and 2 patients refused to complete the study in the fourth week, 5 patients from Group B were excluded from the study as 2 patients did not show up for follow up and 3 patients did not complete the Rome III questionnaire. Hence, at last each group had 25 patients.

Table 1: Sex distribution.

Sex	Group A	Group B
Males	15 (60%)	10 (40%)
Females	10 (40%)	15 (60%)
Total	25	25

Table 1 shows that males were 15 (60%) and females were 10 (40%) in group A and in group B, males were 10 (40%) and females were 15 (60%).

Table 2: Fecal incontinence and abdominal pain.

Sex	Group A	Group B
Faecal incontinence	13(52%)	10(40%)
Abdominal pain	16(64%)	14(56%)

Table 2 shows that faecal incontinence was in 13 (52%) in group A and in 10 (40%) in group B. Abdominal pain was in 16 (64%) in group A and was in 14 (56%) in group B.

Table 3: Symptoms comparison between the beginning and end of the 1st and 4th week.

Variables	Time	Group A	Group B
Stool frequency	Beginning of 1st week	1.76±0.26	0.74±0.63
	Beginning of 4th week	2.01±0.55	1.50±0.87
	1st to 4th week	0.89±0.69	0.71±0.62
Stool consistency	Beginning of 1st week	0.40±0.55	0.25±0.49
	Beginning of 4th week	0.80±0.49	0.60±0.55
	1st to 4th week	0.42±0.54	0.38±0.56

Table 3 shows that the stool frequency and consistency improved significantly.

Table 4 shows that there was a significant improvement in fecal incontinence and abdominal pain in the Group A, and at the end of the fourth week, this difference was not significant and there was improvement significantly in

weight gain. Side effects were not seen in the during the treatment.

Table 4: Changes in symptoms at the end of the 1st week.

Symptom	Group A	Group B
With faecal incontinence	5	8
Without faecal incontinence	10	1
Total	15	9
With abdominal pain	6	11
Without abdominal pain	9	3
Total	15	14
With weight gain	11	2
Without weight gain	14	23
Total	25	25

DISCUSSION

In the present study, a total of 60 patients were enrolled in the study. 5 patients from Group A were excluded from the study as 3 patients refused to complete the study in the first week and 2 patients refused to complete the study in the fourth week, 5 patients from Group B were excluded from the study as 2 patients did not show up for follow up and 3 patients did not complete the Rome III questionnaire. Hence, at last each group had 25 patients. Males were 15 (60%) and females were 10 (40%) in group A and in group B, males were 10 (40%) and females were 15 (60%).

Faecal incontinence was in 13 (52%) in group A and in 10 (40%) in group B. Abdominal pain was in 16 (64%) in group A and was in 14 (56%) in group B. The stool frequency and consistency improved significantly. There was a significant improvement in fecal incontinence and abdominal pain in the Group A, and at the end of the fourth week, this difference was not significant and there was improvement significantly in weight gain. Side effects were not seen in the during the treatment, Sadeghzadeh M et al.[7] Inconsistent data exist about the role of probiotics in the treatment of constipated children. The aim of this study was to investigate the effectiveness of probiotics in childhood constipation. In this placebo controlled trial, fifty-six children aged 4-12 years with constipation received randomly lactulose plus Protexin or lactulose plus placebo daily for four weeks. Stool frequency and consistency, abdominal pain, fecal incontinence, and weight gain were studied at the beginning, after the first week, and at the end of the 4th week in both groups. Forty-eight patients completed the study. At the end of the fourth week, the frequency and consistency of defecation improved significantly (P = 0.042 and P = 0.049, respectively). At the end of the first week, fecal incontinence and abdominal pain improved significantly in intervention group (P = 0.030 and P = 0.017, respectively) but, at the end of the fourth week, this difference was not significant (P = 0.125 and P = 0.161, respectively). A significant weight gain was observed at the end of the 1st week in the treatment group. This study showed that probiotics had a positive role in increasing the frequency and improving the consistency at the end of 4th week, de Moraes JG et al.[8]

Many factors explain dysbiosis in chronic constipation (CC), such as a low-fiber diet. The objective of this study was to compare the fecal microbiota of constipated and non-constipated children and their intake frequencies of food. This observational study included 79 children (M/F 43/36) aged six to 36 months divided into two groups: cases (39 constipated children) and controls (40 non-constipated children). We used a structured form to collect demographic variables, conducted anthropometric assessment, and collected food intake frequency data. The fecal microbiota of the stool samples was analyzed by real-time polymerase chain reaction (PCR) using the fluorophore SYBR Green. Constipated children had a smaller concentration of *Lactobacillus* per milligram of stool (p = 0.015) than non-constipated children, but the concentration of *Bifidobacterium* per milligram of stool (p = 0.323) and the intake of fruits, vegetables (p = 0.563), and junk food (p = 0.093) of the two groups did not differ. Constipated children consumed more dairy products (0.45±0.8; p >0.001), were more frequently delivered via caesarean section (69.2%), were weaned earlier (median: 120; 60Q1-240Q3), and had a family history of constipation (71.8%). Children with CC have a smaller concentration of *Lactobacillus* in their stools and consume more dairy products. Saneain H et al have conducted a controlled trial was conducted on 60 children (2 to 14 years old) with functional constipation (Rome III criteria).[9] Children were allocated to receive the synbiotic (Lactol®, composed of *Lactobacillus Sporogenes*, 1 Tab/20 kg/d) plus mineral oil (Paraffin 1 ml/kg/d) or the mineral oil alone for two months. Symptoms of constipation including defecation frequency, stool form, strain and pain at defecation, incomplete evacuation and soiling were assessed and compared before and after the intervention. After the treatment period, the two groups were also compared with regards to subjective global assessment of improvement. After the treatment, stool frequency increased in both groups (P <0.001), with greater increase in synbiotic + mineral oil group (P = 0.001). Frequency of hard/very hard stool and frequency of painful defecation decreased similarly in both groups (P <0.001). Straining at defecation, incomplete evacuation, and soiling decreased in both groups (P <0.001), but more decrease was seen in the synbiotic + mineral oil group (P <0.05). Finally, there was a better global improvement in the synbiotic + mineral oil group (P <0.05). No severe side-effects were observed in any group. Adding the synbiotic Lactol® (containing *Lactobacillus Sporogenes*) to mineral oil can increase the improvement in the constipation symptoms of children without specific side-effects, Mugie SM et al.[10] Constipation in children is an often-long-lasting pediatric functional gastrointestinal disorder with a worldwide prevalence varying between 0.7% and 29.6%, and estimated health-care costs of US$3.9 billion per year in

the USA alone. The pathophysiology of childhood constipation is multifactorial and remains incompletely understood; however, withholding of stools, starting after an experience of a hard, painful, or frightening bowel movement is the most common cause found in children. A thorough medical history and physical examination, including a rectal examination in combination with a bowel diary, is sufficient in the majority of cases to diagnose constipation. The current standard treatment consists of education, toilet training, disimpaction, maintenance therapy and long-term follow-up. In the past decade, well-designed treatment trials in the pediatric population have emerged and long-term outcome studies have been completed. This Review summarizes the current knowledge of the clinical aspects of childhood constipation, including pathogenesis, diagnosis and treatment, with particular emphasis on the latest available data. Chmielewska A et al conducted a study to systematically evaluate and update evidence on the efficacy and safety of probiotic supplementation for the treatment of constipation.[11] The MEDLINE, EMBASE, CINAHL, and Cochrane Library databases were searched in May 2009 for randomized controlled trials (RCTs) performed in paediatric or adult populations related to the study aim. We included five RCTs with a total of 377 subjects (194 in the experimental group and 183 in the control group). The participants were adults (three RCTs, n = 266) and children (two RCTs, n = 111) with constipation. In adults, data suggests a favorable effect of treatment with B*ifidobacterium lactis* DN-173 010, *Lactobacillus casei Shirota*, and *Escherichia coli Nissle* 1917 on defecation frequency and stool consistency. In children, *L. casei rhamnosus* Lcr35, but not *L. rhamnosus GG*, showed a beneficial effect. Until more data are available, we believe the use of probiotics for the treatment of constipation condition should be considered investigational.

CONCLUSION

This study shows that there was a positive effect of probiotics on constipation in children.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Jose S, Ismael MK. Effect of probiotics on constipation in children. Int J Contemp Pediatr 2018;5:46-9.