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Original Research Article

The multifaceted use of *Lactobacillus reuteri* DSM 17938 in a pediatric clinic: a retrospective observational study

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ABSTRACT

Background: *Lactobacillus reuteri* DSM 17938 is a well-studied probiotic which colonizes many mammals. In humans, *L. reuteri* is found in various body sites including the gastrointestinal tract, urinary tract, skin and breast milk. It fulfills all the prerequisites of being a good probiotic as described by the world gastroenterology organization.

Methods: This was a retrospective observational study, where a nutritional supplement *L. reuteri* DSM 17938 was given to 197 children, aged 0-16 years, along with normal diet. The participants were having complains of diarrhea, stomach pain and frequent hospitalization. Various parameters were recorded such as sex, age, anthropometry-weight and height (every visit), diagnosis, reason for outpatient visits and various demography including but not limited to-birthplace, current location, year in school, reason for hospital admission (if any). Paired t test was used to find difference in weight and height between each visit.

Results: A total of 118 subjects were included in the analysis. Five drops of nutritional supplement *L. reuteri* DSM 17938 was given. Supplementation of *L. reuteri* reduced the need for hospital admissions. 96% children did not require hospital admission. It improved the overall health of the children. There was a statistical significance in the height and weight between first and second visits (p<0.001). A 7.65% weight increase was noted in between first and second visit. A 2.32% height increase was seen between first and second visit.

Conclusions: *L. reuteri* DSM 17938 given as a nutritional supplement improved the health of the children and reduced the need for hospital admissions.

Keywords: Nutritional supplements, Height, Weight, Children, L. reuteri DSM17938, Probiotic

INTRODUCTION

Malnutrition in children may directly correlate with stunted growth, impaired cognitive development and reduced academic performance. It causes the impairment of cell-mediated immunity through its impact on phagocytic and cytokine activities. Fermented foods or probiotics have been known to modulate the gut microflora stimulating an immune response. Probiotics are defined as live organisms, which when administered in adequate dosages help to incur a health benefit for the host.

Probiotics improve the child's growth by preventing infections and micronutrient deficiencies by increasing the absorption of certain nutrients such as calcium, zinc and vitamin B12.^{3,4} By improving gut health, probiotics also reduce the incidence of diarrhea.^{3,4} Overall, the benefits of probiotics in children with specific disease conditions such as acute infectious diarrhea, antibiotic-associated diarrhea, necrotizing enterocolitis in very low birth weight infants, childhood atopy, *Helicobacter pylori* infection and infantile colic have been established.⁵⁻⁸

L. reuteri was first isolated in 1962 and has been characterized as a heterofermentative species that grows in oxygen-limited atmospheres.⁹ It confers desired probiotic properties as it colonizes the gastrointestinal (GI) tract of humans and animals.9 L. reuteri can withstand a wide variety of pH environments by employing multiple mechanisms that allow it to successfully inhibit pathogenic microorganisms. By reducing antimicrobial intermediaries, L. reuteri has also been found to reduce the incidence of infections in children.^{9,10} Pertaining to these benefits, the use of L. reuteri as a nutritional supplement in infants and children has been supported by several guidelines including European Food Safety Agency (EFSA) and European Society Paediatric of Gastroenterology Hepatology Nutrition and (ESPGHAN). 11,12 Previous research on Lactobacillus strains have shown that they help in the prevention and treatment of numerous GI tract disorders including enteric infections, antibiotic-associated diarrhea, necrotizing enterocolitis in preterm neonates, inflammatory bowel disease, colorectal cancer and irritable bowel syndrome. 10 Current available medical evidence supports it in the prevention/management of multiple pathological conditions in children.

Since the indigenous environment of the human GI tract is suitable for its growth, *L. reuteri* has shown several generalized health benefits like reduction of infections, improvement in feed tolerance, enhancement of nutrient absorption, modulation of host immune responses, promotion of gut mucosal integrity, reduction of bacterial translocation and overall health promotion.¹³ Due to its ability to survive in low pH and enzyme-enriched environments, it survives in the proximal end of the digestive tract where it adheres to the epithelium for host-probiotic interaction, competing with pathogenic microorganisms.¹⁴ This is another mechanism through which, the administration of *L. reuteri* helped in reducing the incidence of infections in pediatric hosts.¹³

An increased use of probiotics over the last few decades has primarily been because of its role in the management of acute diarrheal disease. However, probiotics offer serve several other benefits in infants and children including an improvement in anthropometry (height and weight parameters). While the role of *L. reuteri* in reducing diarrhea has been widely studied, this study aimed to analyze the overall health benefits of probiotics in children with a focus on the use of *L. reuteri*.

The manuscript aimed to determine the effect of *L. reuteri* on improvements in the GI diseases, its effects on the need for hospitalization and the effect on height and weight of the children, in order to determine its direct benefit with respect to growth and development in children.

METHODS

Participants

For this retrospective observational analysis, data was collected from 197 children who visited our clinic, SS

childcare, Chennai, India. The participants were within the age group of 0-16 years and having complains of diarrhea, stomach pain and frequent hospitalizations.

Intervention

All participants of this study had been prescribed with *L. reuteri* DSM 17938 to study its impact on reduction in the events of hospitalization as well as change in height and weight parameters. All the participants of the study were treated equally and data retrospectively analyzed for one year. There were no treatment/control groups for the purpose of comparison and no randomization sequence was followed.

The use of *L. reuteri* as a nutritional supplement had been formulated for Indian children as per the ICMR guidelines. Its use was indicated as a probiotic food supplement containing the patented lactic acid bacterium, *L. reuteri* DSM 17938.

For our study, this nutritional supplement was administered to all the participants as OD (once daily)/BD (twice daily) formulations depending on their independent clinical profile. Five drops orally each were administered with the help of a plastic dropper along with promotion of intake of a normal diet. No lifestyle changes were recommended to the participants. They were followed up at regular intervals to determine any change in their symptoms.

Data collection

Demographic parameters such as their sex, age and educational status were recorded along with necessary anthropometric data including the weight and height (in kgs and cms) at every visit. Their primary diagnosis, reason for outpatient visits, reason for hospital admission as well reasons and frequency of second visits were recorded along with their overall symptoms during visits.

Statistical analysis

Following data collection, SPSS software was used for statistical analysis. Paired t test was used to analyze the difference between height and weight between the visits. The p value <0.05 was considered statistically significant. Paired t test and Wilcoxon signed rank test were used to find the difference between the weights between the visits.

Ethical considerations

Since the participants were below 18 years of age, parents/guardians provided written informed consent before entering the study. The participants of the study were not followed up for their consent and only those agreeing to the purpose of the study were included based on their written permissions.

RESULTS

Demographic results

A total of 197 children were initially selected on the basis of our retrospective analysis, but 79 dropped out. Thus, data from 118 children was considered. The mean age of the participants was 2.89±3.3 years and the gender distribution included 64 boys and 54 girls. Most of the participants of the study were currently residing in Chennai 111 (94%) and were Indian. The study included data from a diverse group of children from different socioeconomic strata. 100% children received 5 oral drops of the nutritional supplement, 98% received it once a day (OD) and only 1.7% got it twice a day (BD). Mode of delivery at parturition was normal vaginal delivery for 37 (31.4%) children and lower (uterine) segment caesarean section (LSCS) for 81 (68.6%) children (Table 1). Data regarding their gestational age at delivery was not recorded. All the participants of the study had vaccinations up to date according to the Indian academy of pediatrics recommendation.

Primary diagnosis of the participants

Mean age of children on the date of commencement of the nutritional supplement was 2.44±3.03 years. After the primary diagnosis, 21 (17.8%) children were diagnosed

with functional abdominal pain, 23 (19.5%) for prophylaxis of infections, 12 (10.2%) had recurrent infections, 14 (11.9%) with recurrent URTI, 11 (9.3%) with functional constipation, 1 (0.8%) child for each was diagnosed with infantile regurgitation, exaggerated gastrocolic reflex, infantile dyschezia and small intestinal bacterial overgrowth (Figure 1 and 2).

Relationship between L. reuteri and symptom reduction in the participants

After a follow up period of 12 weeks, it was observed that one (0.8%) child was diagnosed for each pathological conditions including aerophagia, antibiotic associated diarrhea, functional abdominal pain, functional constipation and functional constipation, functional diarrhea, GERD, infantile dyschezia. However, 61 (51.7%) out of 118 children were well (Figure 3).

Impact of L. reuteri on the rate of hospital admission

Administration of *L. reuteri* helped in reducing the need for hospital admissions. With respect to hospital admissions, it was observed that after the first visit by 118 participants, 64 participants (54.2%) did not visit again (no visit). 16 participants (13.6%) came for a second hospital visit owing to their clinical symptoms after *L. reuteri* administration. Only one (0.8%) child came for a third visit (Figure 4).

Parameters	Values
Age (mean±SD) (in years)	2.89±3.3 years (range 0-16)
Gender	
Male	64
Female	54
Mode of delivery	
Normal (N, %)	37 (31.4)
LSCS (N, %)	81 (68.6)
Dosing	
5 drops (%)	100
OD dose (%)	98.3
BD dose (%)	1.7

Table 1: Demographic data.

Table 2: Mean and standard deviation of weight during 1st and 2nd hospital visits.

Pair 1	Mean	N	Standard deviation	Standard error mean
1st visit weight	12.252	118	7.6813	.7071
2nd visit weight	13.190	118	8.1072	.7463

Table 3: Mean and standard deviation of height during 1st and 2nd hospital visits.

Pair 1	Mean	N	Standard deviation	Standard error mean
1st visit height	84.43	118	26.802	2.467
2nd visit height diagnosis	86.39	118	26.523	2.442

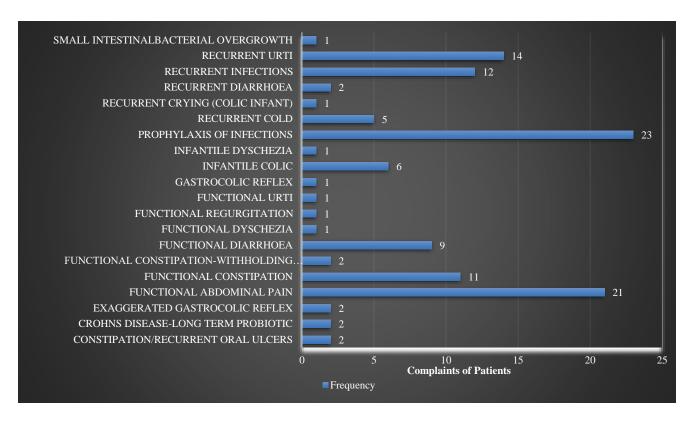


Figure 1: Frequency of primary complaints of the patient at the first hospital visit (prior to the *L. reuteri* administration).

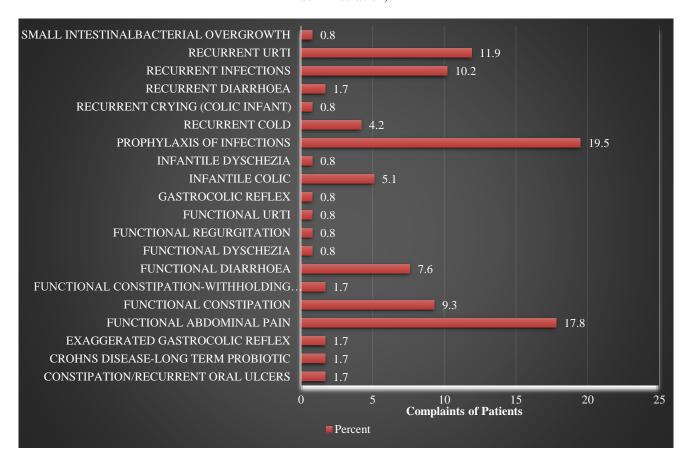


Figure 2: Percentage of primary complaints of the patient at the first hospital visit (prior to the *L. reuteri* administration).

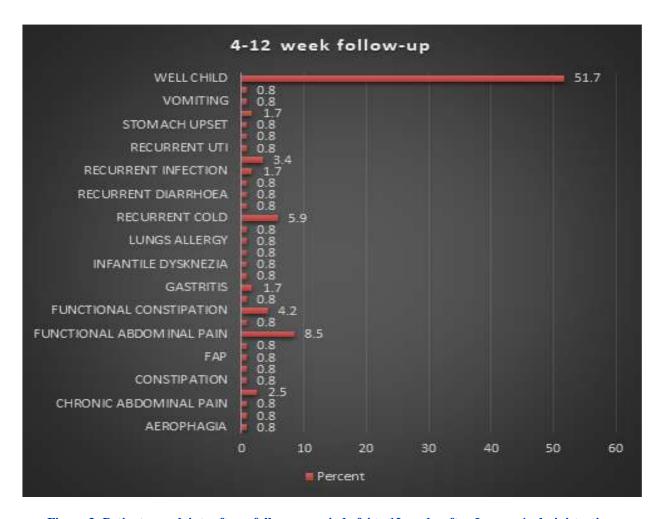


Figure 3: Patient complaints after a follow up period of 4 to 12 weeks after L. reuteri administration.

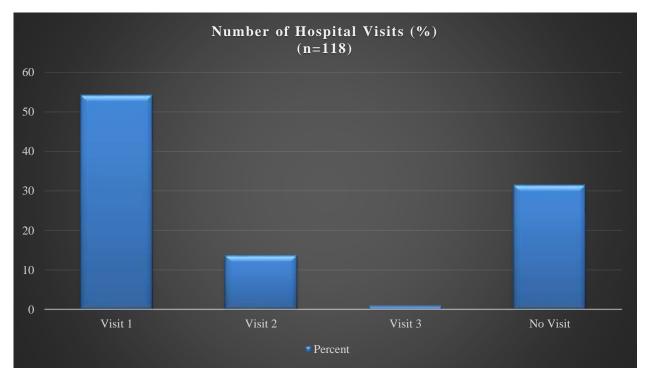


Figure 4: Number of hospital visits of the participants (first visit by 118 participants was the initial visit before the administration of *L. reuteri*).

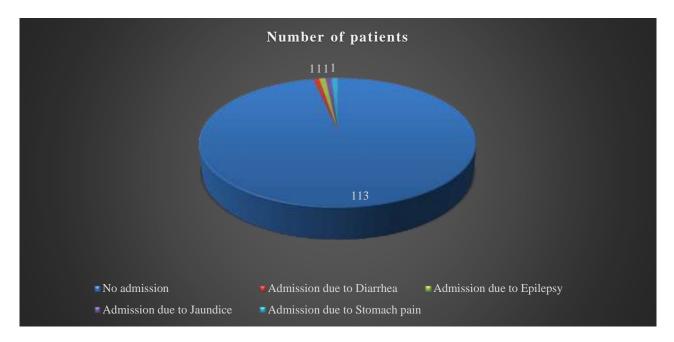


Figure 5: Reason of hospital admission of the participants.

Among participants reporting for the second time, 45 participants (38.1%) were well at the time of their presentation to the clinic. 28 participants (23.7%) reported due to URTI, 14 participants (11.9%) came for a general visit and nine participants (7.6%) came for routine vaccination.

113 out of 118 participants (95.8%) did not require hospital admission during our study (Figure 5). Of the five children who required inpatient admission, abdominal pain, diarrhea, seizures, sepsis and jaundice were the respective diagnosis, which were observed owing to their individual clinical profile and were not considered as side effects of *L. reuteri* administration.

Impact of L. reuteri administration on height, weight and growth parameters of the participants

The intake of *L. reuteri* significantly improved the anthropometric parameters of the participants. The mean weight during first visit was 12.252 ± 7.6 kg and during second visit was 13.19 ± 8.1 kg (p<0.001) (Table 2). 7.65% increase in weight was observed at the second visit. Statistical differences in the height of the participants were observed at the second visit (p<0.001). The mean height during first visit was 84.43 ± 26.8 cm and during second visit was 86.39 ± 26.5 cm (Table 3).

DISCUSSION

The results of the study indicated that administration of *L. reuteri* improved patient symptoms and their overall status of health, which was reflected by reduced need for hospital admissions and significantly improved the anthropometric development of children, after a follow up of 12 weeks.

Improvement in clinical symptoms similar to our study had also been highlighted in the literature. A multi-center RCT (randomized controlled trials) (N=127) depicted that the use of *L. reuteri* alongside the standard treatment protocol of the patient helped in reducing the duration of hospital stay because of improvement of GI symptoms. ¹⁶ Its use also helped in improving major symptoms of the patient at day one itself as indicated by a meta-analysis report of three RCTs. ¹⁷ Thus, the administration of *L. reuteri* in children helped in reducing diarrheal symptoms and prevented their recurrence.

In a 2012 RCT of 74 children, the use of *L. reuteri* significantly reduced the duration of diarrhea when compared with placebo.¹⁸ Along with this, it also reduced the risk of recurrence of symptoms and worsening of symptoms in the form of watery diarrhea.¹⁸ Further, *L. reuteri* supplementation also reduced the incidence of infectious diarrhea as indicated by a 2015 trial by Dinleyici et al (N=64).¹⁹

A majority of patients in our study presented with functional abdominal pain (21.7%). Thus, overall reduction in hospitalization visits in our study also suggested that *L. reuteri* supplementation favored a reduction functional abdominal pain. This was similar to the findings of a 2010 trial of 60 pediatric patients where *L. reuteri* supplementation over a four week follow up period was shown to reduce pain intensity in patients with functional abdominal pain. ²⁰ The improvement in patient symptoms as presented in Figure 2, following the use of *L. reuteri* can be attributed to the anti-inflammatory and antimicrobial actions of *L. reuteri*. Supplementation of *L. reuteri* decreased the microbial translocation from the gut lumen to the tissues impeding the initiation of

inflammation and facilitating the amelioration of inflammatory conditions.9 An RCT study of 117 infants supported the safe use of L. reuteri in infants with colic disease including those with neutropenia. In these infants, resolution of symptoms was noted within a period of three weeks. 21 Literature evidence also pointed out that L. reuteri can help in reducing the incidence of diarrhea while having a suitable efficacy for the treatment of functional constipation.²² Similar study supported the use of L. reuteri as a nutrient supplement added to cow's milk.²² This was also helpful in reducing the incidence of diarrhea in malnourished children.²³ In preterm infants, on the other hand, the use of L. reuteri had evidenced a reduction in food intolerances as supported by a double blinded RCT of 94 neonates.²⁴ Since L. reuteri facilitated reduction in most common primary diagnosis of the participants enrolled in our study, 51.7% of participants of our study were symptom free at the time of their subsequent hospital visit. Thus, L. reuteri also helped in managing diarrhea, functional inflammatory conditions, neutropenia, abdominal pain and functional constipation.

In this study, administration of *L. reuteri* had positive impact on height and weight. The average increase in height was 1.96 cm during the study period while the average increase in weight was 0.938 kg (p<0.001). Similar results have been found in the literature, which emphasized the role of *L. reuteri* in improving height and weight status of children. In six months RCT study of 494 participants within the age group of one to six years, it was found that *L. reuteri* caused significantly higher weight gain and more favorable growth velocities.²³ In this study, *L. reuteri* was found to be more beneficial than *L. casei*, which only improved weight and not height.²³ Systematic reviews and meta-analysis conducted in developing countries have also supported that probiotic supplementation helped in reducing growth status in undernourished children.¹⁵

Based on our observations, we recommend the use of *L. reuteri* as a nutritional supplement in children in the age group of 0 to 16 years to enhance their overall growth and development and five drops of once daily formulations can be safely prescribed in children who frequently present to the hospital with GI symptoms alongside their normal meal. Its use in healthy term infants had been supported by an RCT pediatric participants conducted in South East Asia, which concluded that its use helped in achieving WHO growth parameters.²⁵

Since our study only included participants with clinical complaints who presented to our hospital, the evidence was insufficient to support the routine use of *L. reuteri* in infants and children. Although no side effects were associated with the use of *L. reuteri* in our study or in the literature, in children with severe symptoms, close follow up was recommended along with continuation of their medical management since a direct impact of *L. reuteri* in the improvement of existing medical conditions had not yet been concluded.^{22,26} In critically ill children and children

with immunocompromised patients, cautionary use was recommended.²⁷

Limitations

One of the primary limitations of our study was the small sample size of the research and the use of a retrospective research design. Further, our study was a single-centre study and there was no comparison between the intervention and control arms.

CONCLUSION

The findings of our retrospective analysis of 118 children (mean age 2.89±3.3 years) convincingly concludes that the use of L. reuteri as a probiotic or a nutrient supplement helps in reducing the rate of hospital admissions and overall hospital visits among children as observed in this COHORT. This is because it causes an improvement in patient symptoms, which can be attributed to its nutritional and immunomodulative effects. It also facilitates significant improvement in height and weight parameters. Throughout the course of our study, no major side effects pertaining to the use of L. reuteri were reported. Thus, it can be safely recommended in both infants and children who frequently report to the outpatients because of gastrointestinal symptoms like diarrhea or functional abdominal pain. The administration of L. reuteri has been found to be particularly beneficial in reducing the risk of recurrence of diarrheal symptoms and pain reduction in cases of functional abdominal pain or functional constipation. For healthy preterm infants, its use has been associated with an improvement in food tolerance. Since most of the included studies for our evaluation had a small sample size and were single-centre studies, it is recommended that the routine prescription of L. reuteri in infants/children as well as in critically ill patient be determined based on a large, multi-centre randomized clinical trial.

Recommendations

Although our research provided useful insights into the role of *L. reuteri* in the growth and development of children, t test could not be run for symptom improvement and hospital admission, so, their statistical significance could not be determined. Thus, future research must be conducted in the form of a multi-centre randomized controlled trial where successful t-tests are conducted for each result so that the drawbacks of the present research can be met. This research must also include healthy participants so that insights into regular supplementation of *L. reuteri* in the pediatric population can be obtained.

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