Probiotics for the Management of Infantile Colic in Breastfed Infants

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CONTEXT

Infantile colic is a common pediatric condition, which causes significant parental distress.[1] Despite 40 years of research, the etiology of infantile colic remains elusive. The current literature suggests several causative mechanisms such as behavioral, food allergy and hypersensitivity, immaturity of gut function and dysmotility.[2]

Objectives

The study by Szajewska *et al.*, aimed to compare the effectiveness of *Lactobacillus reuteri* DSM 17938 with placebo in the treatment of breastfed infants with infantile colic.

MATERIALS AND METHODS

A Randomized, Double-Blind, Placebo-Controlled Trial at Family primary care practice in Warsaw, Poland from January 2010 to December 2011.

Population

Inclusion

Full term infants aged <5 months with infantile colic (defined as crying episodes lasting 3 or more hours/day and occurring at least 3 days/week within 7 days prior to enrollment), who were exclusively or predominantly (>50%) breastfed.

Exclusion

Acute or chronic illness, gastrointestinal disorders, or use of any antibiotics and/or probiotic pharmaceutical products within 7 days prior to the study.

Allocation

Computers were utilized to generate independent allocation sequences and a randomization list. Randomization was performed in blocks of 6 subjects. An independent person prepared the randomization schedule and oversaw the packaging and labeling of the study products.

Blinding

All study personnel, parents, and guardians were unaware of the group assignments.

Follow-up

Primary outcome was done in 97.6% of infants.

Intervention

L. reuteri (DSM 17938) (10^8 colony-forming units) 5 drops, orally, once a day for 21 days.

Control

Placebo was manufactured and supplied by BioGaia AB (Lund, Sweden) as a fluid in identical bottle and kept refrigerated until use.

Outcomes

Primary

The treatment success (the percentage of children achieving a reduction in the daily average crying time more than 50%) and the duration of crying (min/day) at 7, 14, 21, and 28 days after randomization.

Secondary

A reduction in the daily average crying time, from baseline until the end of the treatment period (day 21), to <3 h/day, persistence of infantile colic after the intervention, parental perceptions of colic severity, and parental/family quality of life. Adverse effects (i.e., vomiting, constipation, and other symptoms spontaneously reported) were recorded by the caregivers.

RESULTS

The rate of responders to treatment was significantly higher in the probiotic group compared with the placebo group at day 7 (P=0.026), day 14 (relative risk (RR) 4.3, 95% CI 2.3-8.7), day 21 (RR 2.7, 95% CI 1.85-4.1), and day 28 (RR 2.5, 95% CI 1.8-3.75). In addition, the median crying time was significantly reduced in the probiotic group compared with the control group. There was a significant reduction in the parental perception of colic severity for parents of infants and improved parental/family quality of life in the probiotic group compared with the placebo group. No adverse events associated with the probiotic therapy were reported [Table 1].

COMMENTARY

This study confirm the results of previous recent studies[3,4] that administration of *L. reuteri* at a dose of 10^8 colony-forming units to predominantly breastfed infants is associated with the treatment success and reduced crying times with no adverse events. A similar positive effect to a lesser extent was noted in the control group, which could be explained, by the natural history of infantile colic or a placebo effect. It also shows improvement in parental perception of colic severity and quality of life. It is also noted that treatment effect requires 7 days to be clinically significant and increases with time till it plateaus at 3 weeks beyond initiation of therapy. This lag in treatment effect might raise the question of whether probiotics could be utilized as a prophylactic therapy after birth. A large well designed clinical trial is required to confirm the results shown above and to test probiotics prophylactic effect in infantile colic.

SUMMARY

In summary, the use of *L. reuteri* for infantile colic is evidence based. Future studies are needed to find out the best dose, combination of strains, and long-term safety.

Abstracted from

Szajewska H, Gyrczuk E, Horvath A, *Lactobacillus reuteri* DSM 17938 for the Management of Infantile Colic in Breastfed Infants: A Randomized, Double-Blind, Placebo-Controlled Trial. J Pediatr Published Online

Table 1: Main results

Outcome	Probiotic group (n=40)	Control group (n=40)	RR (95% CI)
Treatment success (reduction in the daily average crying time >50%)			
Day 7	6	0	–
Day 14	30	7	4.3 (2.3-8.7)
Day 21	39	15	2.6 (1.8-4.0)
Day 28	40	25	1.6 (1.3-2.1)
Duration of crying (min/d) (median, IQR) baseline	240 (210-270)	240 (203-278)	0.0 (−30-30)
Day 7	180 (149-180)	180 (150-210)	0.0 (−60-0)
Day 14	105 (101-120)	150 (120-180)	−45 (−75-−30)
Day 21	75 (60-90)	128 (116-150)	−53 (−83-−45)
Day 28	52 (45-75)	120 (90-128)	−68 (−75-−60)

RR – Relative risk; IQR – Interquartile range; CI – Confidence interval

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