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STRAIN-SPECIFIC EFFICACY OF PROBIOTICS IN MANAGEMENT OF INFANTILE COLIC – A LITERATURE REVIEW

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ABSTRACT

Introduction and purpose: Functional gastrointestinal disorders (FGIDs), such as infantile colic (IC), are conditions that occur without any identified structural or biochemical abnormalities. It is estimated that nearly 20% of infants under five months of age experience infantile colic, which is characterized by episodes of excessive crying that are difficult to soothe. The condition causes significant emotional and economic impact on families and healthcare systems. This review aims to analyse efficacy of various probiotic strains in managing symptoms of infantile colic.

Results: Probiotic strains vary in the effects on treating infantile colic. The most extensively analysed probiotic for IC is *Limosilactobacillus reuteri* DSM 17938 (formerly named *Lactobacillus*). However, its effectiveness in formula-fed infants is still questionable. Other strains, including *Bifidobacterium animalis* subsp. *lactis* BB-12, *Bifidobacterium breve* CECT7263, and combinations such as *Bifidobacterium longum* KABP042 with *Pediococcus pentosaceus* KABP041 have shown promising results, often outperforming *L. reuteri* and even pharmacological treatments for example with simethicone.

Conclusions: Probiotic therapy offers a safe and promising approach to reducing symptoms of infantile colic, especially in breastfed infants. However, its efficacy is strain-dependent and not universal. Further large-scale, high-quality randomized controlled trials are necessary to establish standardized recommendations and explore long-term outcomes. Personalized probiotic interventions targeting the infant gut microbiota may be included in the future of colic management.

KEYWORDS

Infantile Colic, Probiotics, Excessive Crying In Infants, Gut Microbiota

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Introduction

Functional gastrointestinal disorders (FGIDs) are defined by specific symptoms occurring in the absence of structural or biochemical abnormalities. When referring to infants and toddlers, these symptoms are usually age-dependent and may correspond with normal developmental processes or result from dysfunctional responses to stimuli [1].

Infantile colic (IC) is one of the FGIDs. It occurs in infants from early infancy up to 5 months of age and is characterized by sudden, prolonged crying episodes that are difficult to soothe. The traditional perspective on infantile colic is based on Wessel's criteria. They define the condition as crying or fussing for more than three hours per day, during more than three days per week for three or more weeks [2]. The more recent symptom-based criteria are the Rome IV criteria. They were established in 2016 and are commonly used as a diagnostic tool for infantile colic. These criteria state that for infantile colic to be diagnosed, the infant must be less than 5 months of age. The colic should have a defined onset and resolution, with the infant crying, fussing, or being irritable for no apparent reason, making it difficult for caregivers to control the symptoms. Additionally, physical examination and the patient's medical history assessed by a physician should be focused on key red flags, such as: fever, failure to gain weight, severe vomiting, arching of the back, Sandifer syndrome, gastrointestinal bleeding, abdominal bloating, distention, and any other symptoms that may point to potential underlying organic conditions. They must be ruled out and may suggest other causes of the arising symptoms [1, 3].

Infantile colic affects approximately 20% of infants. However, determining the exact occurrence of this issue is challenging due to variations in its definition across different studies. It is presumably one of the FGIDs with the highest prevalence [4]. The broader impact of FGIDs extends beyond clinical concerns, representing a substantial socioeconomic burden. In England, the assessed median cost of managing these conditions in 2014/2015 was minimum £72.3 million. Of this amount, £49.1 million was allocated by the National Health

Service for prescriptions, hospital services, and community care. These data underscore the considerable pressure FGIDs place on both public healthcare systems and affected families [5].

Beyond economic aspects, infantile colic also has a profound psychosocial impact on families. Some parents feel that the colic period has strained family dynamics, leading to challenges in communication and support. Caregivers typically portray the experience as unfavourable overall [6]. Moreover, high risk of maternal depression was linked to infantile colic and prolonged crying [7]. It is also possible that excessive crying in infancy has impact on a patient in the future. It has been associated with a substantially elevated risk of developing behavioural difficulties by the age of 5–6 years, including conduct problems, hyperactivity, and emotional disturbances, as reported by mothers. This early distress appears to influence child development, potentially doubling the likelihood of such adverse outcomes. Such association is partially mediated by the psychological burden placed on the mother, with maternal stress and, to a lesser extent, aggressive behaviour contributing to the child's later difficulties. Therefore, providing targeted support for mothers experiencing high caregiving stress may serve as an important preventive measure against future emotional and behavioural disorders in children [8].

In many studies a link between IC and the later development of other functional gastrointestinal disorders has been documented, likely due to shared possible etiopathogenetic factors such as environmental influences, dietary patterns, intestinal dysmotility, and visceral hypersensitivity [9].

Infantile Gut Microbiota

The human intestine houses trillions of microbial cells that are crucial for maintaining overall health. These microorganisms establish a symbiotic relationship with the host, which is unique to everyone [10].

The development of a diverse microbiota in infants is a progressive process that may start even before the moment of birth. Some data show that human amniotic fluid and placenta contain microbial communities. These microbes may serve as the initial source for gut colonization. The presence of distinct microbial populations in the placenta, amniotic fluid, and colostrum was consistent across individuals. However, these conclusions still require broader evaluation [11].

A study on 98 mothers and their full-term infants shows that infants delivered via C-section had a faecal microbiome enriched *Enterobacter hormaechei*/E. cancerogenus, *Haemophilus parainfluenzae*/H. aegyptius/H. influenzae/H. haemolyticus, *Staphylococcus saprophyticus*/S. lugdunensis/S. aureus, *Streptococcus australis*, and *Veillonella dispar*/V. parvula. This suggests that in C-section infants, the initial microbial colonizers were primarily skin and oral microbes, as well as bacteria from the surrounding environment during delivery. On the other hand, vaginally delivered newborns had gut microbiota mostly comprised of *Bacteroides*, *Bifidobacterium*, *Parabacteroides*, and *Escherichia/Shigella* species [12].

Alongside the mode of delivery, the type of infant feeding plays an important role in shaping the gut microbiota in early life. Studies in the United States have shown that exclusively breastfed infants have a different microbial composition compared to those who are exclusively formula-fed. These differences are particularly evident in infants aged 4 to 5 months [13].

With growing evidence suggesting that many different factors may influence the composition of gut microbiota, researchers have increasingly focused on probiotic therapies for managing infantile colic. The purpose of this review is to evaluate the efficacy of various probiotic strains in alleviating the symptoms of infantile colic. Particular attention is given to their impact on reducing daily crying duration, which is often used as a primary outcome measure in clinical trials assessing treatment effectiveness.

Materials and Methods

A review of scientific literature was conducted using the PubMed and Google Scholar database. The terms used for the search included "infantile colic" or "excessive crying", "probiotics", as well as "treatment". The analysis focused only on randomised clinical trials published from 2014 to 2025. The papers were reviewed to evaluate relevance of their outcomes and the source of the article. Because this work is not a meta-analysis, statistical methods were not used.

Limosilactobacillus reuteri

In 2013, an Expert Panel convened by the International Scientific Association for Probiotics and Prebiotics (ISAPP) conducted a comprehensive review of the term “probiotic.” As a result, the definition was reaffirmed as: “Live microorganisms that, when administered in adequate amounts, confer a health benefit on the host” [14]. This remains the globally accepted standard for what constitutes a probiotic.

Limosilactobacillus reuteri DSM 17938 is one of the most frequently studied probiotics in clinical trials on infantile colic. Its highest efficacy has been observed in breastfed infants. In accordance with these findings, the ESPGHAN guidelines recommend the use of *L. reuteri* DSM 17938 for managing infantile colic exclusively in breastfed infants, at a dosage of 1×10^8 colony-forming units (CFU) per day for a minimum of 21 days [15].

Savino et al. (2017) conducted a double-blind, placebo-controlled, randomized trial to investigate the effects of *L. reuteri* DSM 17938 on daily crying duration and immune response markers in infants with colic. Sixty exclusively or predominantly breastfed infants meeting the modified Wessel criteria for infantile colic were randomly assigned to receive either daily oral *L. reuteri* (1×10^8 CFU) or a placebo (maltodextrin) for one month. Crying duration was documented daily in structured diaries. After one month, 75% of infants in the probiotic group and 36.4% in the placebo group reached a minimum 50% decrease in crying time. By the end of the study, the mean daily crying time was around two times lower in the probiotic group (74.67 ± 25.04 minutes/day) compared to the placebo group (147.85 minutes/day). Although both groups experienced reductions in crying time over the study period, the probiotic group showed a significantly greater improvement.

Additionally, Savino et al. compared faecal calprotectin levels between infants with colic and healthy controls. The colic group had a notably higher median calprotectin concentration (500 $\mu\text{g/g}$ vs. 145 $\mu\text{g/g}$), suggesting that *L. reuteri* administration may contribute to a marked decrease in this clinical marker of intestinal inflammation [16].

In contrast, Sung et al. (2014) conducted a trial that included both breastfed and formula-fed infants. Of the 167 infants enrolled between August 2011 and August 2012, 127 (76%) completed the study and were included in the primary outcome analysis. Eligibility was based on a diagnosis of infantile colic using the modified Wessel criteria. Participants in clinical group received *L. reuteri* DSM 17938 (0.2×10^8 CFU per drop) in an oil suspension, administered as five drops daily for one month. Participants in the placebo group received maltodextrin in the identical oil suspension.

Although both groups showed reductions in daily crying or fussing time over the course of the study, the decrease was greater in the placebo group. Moreover, after one month the probiotic group cried or fussed an adjusted mean of 49 minutes more per day than the other group. By six months, there were no significant differences between the groups in crying or fussing duration.

Sung et al. also analysed subgroups within the sample. Among exclusively breastfed infants, there was no significant difference in crying or fussing duration between the probiotic and placebo groups after one month - an outcome differing from Savino et al.'s findings. Furthermore, formula-fed infants who received *L. reuteri* cried or fussed an adjusted mean of 78 minutes more per day compared to the placebo group. Among infants aged six weeks or younger, those in the probiotic group cried or fussed an adjusted mean of 88 minutes more per day than those in the placebo group. In both subgroups, the increase was primarily due to fussing - 63 minutes more per day in formula-fed infants and 67 minutes more per day in infants ≤ 6 weeks of age [17].

Alternative Probiotic Strains in Infantile Colic Management

Probiotic strains possess distinct biological and functional properties; therefore, results obtained from studies on one strain cannot be generalized to others. To accurately assess the potential health effects of different bacterial strains, it is essential to conduct well-designed clinical trials. Such studies are fundamental for establishing strain-specific efficacy and ensuring evidence-based recommendations for probiotic use. In line with this approach, the following sections of this article focus on a selection of the newest research exploring alternative probiotic strains beyond *L. reuteri*, highlighting their potential health benefits.

The randomized controlled trial by J. M. Moreno-Villar et al. is particularly noteworthy, as it compares the efficacy of different probiotics in the treatment of infant colic. Moreover, the participants were either exclusively breastfed or exclusively/predominantly formula-fed. The aim of the study was to compare the efficacy of a probiotic combination comprised of *Bifidobacterium longum* KABP042 and *Pediococcus pentosaceus* KABP041 (BL + PP) with *L. reuteri* DSM17938 (LR) in alleviating symptoms of infantile colic. The BL + PP suspension contained 1×10^9 CFU per 5 drops, whereas the LR suspension contained 1×10^8 CFU

per 5 drops. The primary outcomes were determined as a $\geq 50\%$ reduction in daily crying and fussing time from baseline and also total crying and fussing time. A significantly greater proportion of infants in the BL + PP group achieved the daily reduction in crying and fussing time compared to those in the LR group at day 7 and day 14. Median daily crying and fussing times were also measured, showing a decrease in both groups. However, reductions from baseline at days 7, 14, and 21 were significantly and consistently greater in the BL + PP group. On day 7, the median duration was 180.0 minutes per day in the LR group, vs. 119.0 minutes in the BL + PP group. By day 14, crying and fussing time had decreased to 120.0 minutes in the LR group and 60.0 minutes in the BL + PP group. On day 21, the median time further lowered to 67.0 minutes per day in the LR group vs. only 29.0 minutes in the BL + PP group [18].

In earlier years, a different probiotic strain was investigated during a trial conducted by Nocerino et al. (2019). In this double-blind randomised trial, eighty only breast-fed infants with IC were divided into two groups. All participants received parental reassurance and education. Infants in one group received BB-12 (*Bifidobacterium animalis* subsp. *lactis* BB-12, DSM 15954; 1×10^9 CFU per dose in an oil-maltodextrin suspension; Bifidolactis Infant, Sofar SpA), while in the second group received placebo (oil-maltodextrin suspension). Results from this trial indicated that treatment with the probiotic strain BB-12 may also be beneficial in the management of infantile colic. By the end of the second week, number of infants, who reached the primary outcome, was significantly higher in the BB-12 group compared to the placebo group. After 28 days of treatment, 80% of infants in the BB-12 group and 32.5% in the placebo group achieved the 50% improvement [19].

To examine the effectiveness of *Bifidobacterium breve* CECT7263 for infantile colic, Maldonado-Lobón et al. (2021) conducted a clinical trial. The 28-day multicentre, randomised, open-label, parallel-group controlled trial included 150 infants diagnosed with colic according to the Rome III criteria. Importantly, the participants were either exclusively breastfed or exclusively/predominantly formula-fed. All infants were randomly divided into three groups. One group was assigned to receive simethicone (20 mg, 4 times per day in drops) half an hour before meals, another received *B. breve* CECT7263 at a dose of 2×10^8 CFU/day, and the last group received a combination of *Lactobacillus fermentum* CECT5716 at a dose of 1×10^8 CFU/day and *B. breve* CECT7263 at a dose of 1×10^8 CFU/day. It is noteworthy that the two bacterial strains, *Lactobacillus fermentum* CECT5716 (Lf) and *Bifidobacterium breve* CECT7263 (Bb) are naturally present in breast milk. In all three groups, a significant reduction in daily crying time was observed by the end of the intervention compared to baseline. Results from the Bb group showed a significant decrease in crying time as early as the first week. In contrast, significant improvements in the Bb+Lf and simethicone groups were only evident from the second week onward. While overall mean daily crying times did not differ significantly between the groups, a notable exception occurred in the second week, when infants receiving the Bb+Lf combination cried significantly less than those in the Bb or simethicone groups. The percentage reduction in crying time from baseline was significantly greater in the Bb group compared to the simethicone group at every weekly assessment throughout the intervention: -40.3% vs. -27.6% at week 1, -59.2% vs. -43.2% at week 2, -64.5% vs. -53.5% at week 3, and -68.5% vs. -59.5% at week 4. The study found a significant interaction between feeding type and treatment efficacy. In breastfed and formula-fed infants, *Bifidobacterium breve* led to a greater and earlier reduction in crying time compared to simethicone and the Bb+Lf combination, especially in the first three weeks. In mixed-fed infants, the Bb+Lf group showed superior results only at weeks 2 and 3 compared to simethicone [20].

Besides the measurement of crying time reduction, parental quality of life is also an important indicator of symptom alleviation. In their study Delcourt et al. (2024) investigated the efficacy of a synbiotic (Bactecal D Liquid) in infants consulting a primary health care professional for inconsolable crying. Infants were enrolled in the trial regardless of their method of feeding. Accepted feeding types included exclusive breastfeeding, mixed feeding, and formula feeding. In this randomised, however not blinded, study, 68 participants were divided into two groups. Infants in one group received synbiotic once a day, while in the second group received it twice a day. Each dose of the synbiotic contained a total of 1.8×10^9 CFU, comprising *Lactobacillus rhamnosus* PHA-113, *L. acidophilus* PHA-121, *Bifidobacterium infantis* PHA-211, *B. lactis* PHA-222, and *Streptococcus thermophilus* PHA-311. In addition to the bacterial strains, the formulation also included fructooligosaccharides (20 mg), vitamin D (2.5 μ g), and pharmaceutical-grade sunflower oil (2 ml). Quality of life (QoL) scores improved significantly from baseline to day 28, with overall median scores increasing from 2 to 6. However, there was no significant difference in QoL between the two study groups on the last (28th) day: 6 vs 6. There was no control group, so there is only the possibility to compare two intervention groups, which may be seen as a disadvantage of this study. However, it is remarkable that symptom improvement in both groups was observed within just 7 days, which is well ahead of the typical timeline for spontaneous resolution of infant colic [21].

Conclusions

Infantile colic remains one of the most prevalent and distressing functional gastrointestinal disorders in early infancy, with a significant emotional, social, and economic impact on families and the healthcare system. While its exact aetiology is still not fully understood, growing evidence suggests that gut microbiota may play a key role in its pathogenesis, which has led to increasing interest in the use of probiotics as a therapeutic approach.

Among all probiotic strains, *Limosilactobacillus reuteri* DSM 17938 is the most extensively researched and has demonstrated significant efficacy in reducing crying duration in exclusively breastfed infants. However, its effectiveness in formula-fed infants remains inconclusive. Alternative strains such as *Bifidobacterium animalis* subsp. *lactis* BB-12, *Bifidobacterium breve* CECT7263, and combinations like *Bifidobacterium longum* KABP042 with *Pediococcus pentosaceus* KABP041 show encouraging results, often outperforming *L. reuteri* and even conventional treatments like simethicone. However, probiotic interventions do not demonstrate consistent efficacy across all clinical scenarios. Their effectiveness is strain-specific and influenced by factors such as feeding type, infant age. The lack of standardized protocols, variation in study methodologies, and limited long-term data necessitate further high-quality, large-scale clinical trials to establish robust, evidence-based recommendations.

In conclusion, probiotic supplementation, particularly with well-selected, strain-specific formulations, offers a promising, safe, and non-invasive approach for managing infantile colic. While not universally effective, it holds clear potential for improving outcomes in subgroups of infants, especially those who are breastfed. Integrating microbiota-targeted therapies into colic management may represent an important step toward more personalized and biologically grounded paediatric care.

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