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EVALUATION OF A LACTOBACILLI FORMULATION IN THE MANAGEMENT OF INFANTILE COLIC IN THE REAL WORLD SETTING

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ABSTRACT

Background: Infantile colic poses a significant health concern in early infancy, often leading to considerable distress for both infants and caregivers. This study aimed to evaluate the effectiveness and safety of Lactobacilli in the management of infantile colic in the real-world setting.

Methods: This questionnaire-based study was conducted among health care professionals (HCPs), including paediatricians, gastroenterologists. A questionnaire consisting of 15 questions explored HCP preferences regarding the use of Lactobacilli for infantile colic. The questionnaire focused on last 10 patients with infantile colic.

Results: A total of 68 HCPs were included in the study. Incorrect feeding techniques, overfeeding, underfeeding, or insufficient burping (67.65%) were predominantly identified as the most common causes of colic in the patients. Crying louder than usual (60.29%) was identified as the most common symptoms in the 10 patients with infantile colic. A majority of HCPs (83.82%) reported advising the mother of the patient with infantile colic was burping the baby frequently. Most of the HCPs (69.12%) gave dietary advice to the mothers of breast-fed infants was to follow a hypoallergenic diet that eliminates dairy, eggs, nuts, wheat, and soy. Reduction in crying time (95.59%) was identified as an effect of probiotic formulation on sleep in patients with infantile colic. A majority of HCPs (94.12%) reported effect of the probiotic formulation on sleep in patients with infantile colic was improved maternal mental health. A majority of HCPs (72.06%) reported repeating the probiotic dose in patients with infantile colic. Most of the HCPs rated the efficacy (50.00%), safety (61.76%) and adherence (48.53%) of the probiotic formulation in patients with infantile colic as excellent.

Conclusion: Healthcare professionals consider Lactobacilli formulations as an effective and well-tolerated option for the management of infantile colic in breastfed infants, with significant reduction in crying time and improved maternal mental health.

KEYWORDS: Colic, probiotics, Lactobacillus reuteri, infants, healthcare professionals.

1. INTRODUCTION

Infantile colic is commonly defined as intense crying for at least three hours a day, three days a week, for three weeks. It occurs most often in the first six weeks of life and typically resolves by three months [1, 2].

Infantile colic is believed to have multiple causes, including medical factors like food hypersensitivity, gut immaturity, and dysmotility, as well as behavioural factors such as poor maternal-infant interaction, maternal anxiety, and difficult infant temperament [3]. The global prevalence of infantile colic is estimated at around 20%, although most studies have been conducted in Western populations [4].

Probiotics are live microorganisms that support health by balancing the host's gut microflora, with common strains including Lactobacillus, Bifidobacterium, and Streptococcus. Emerging evidence suggests that colic infants have different gut flora compared to healthy ones, and probiotics may help restore this balance. Their low cost and accessibility make them a promising option for preventing infantile colic [5, 6].

Lactobacillus reuteri is a probiotic found in various parts of the human body, including the gut, urinary tract, skin, and breast milk, though its presence varies among individuals. It offers several health benefits, such as producing antimicrobial compounds like organic acids, ethanol, and reuterin, which help inhibit harmful microbes and support a balanced gut microbiota [7].

Lactobacillus reuteri seems to reduce crying time in exclusively or predominantly breastfed infants with colic, but not in formula-fed infants. Early evidence also suggests possible benefits in preventing functional gastrointestinal disorders, though further research is needed. [8, 9].

Treatment options for infantile colic are limited, but altering the gut microbiome may offer some benefit. *L. reuteri* is the most extensively studied probiotic, particularly in breastfed infants [10].

This study aims to bridge this knowledge gap by evaluating the effectiveness of a probiotic formulation in a real-world clinical setting. By analysing data on colic symptom relief, sleep patterns, maternal well-being, and overall treatment adherence, this study provides valuable insights into the practical application of probiotics for infantile colic management.

This study presents a comprehensive analysis of the study findings, focusing on the impact of probiotic treatment on infant crying duration, sleep quality, maternal mental health, and the necessity for dose repetition. Additionally, the study evaluates the safety profile of probiotics and the extent of adherence among caregivers, offering a holistic perspective on their role in colic management.

2. MATERIALS AND METHODS

Study design

This questionnaire-based study was designed to evaluate the clinical effectiveness, safety, and adherence of the formulation Lactobacilli in the management of infantile colic in a real-world clinical setting. It was conducted among health care professionals (HCPs), including paediatricians, gastroenterologists. Participation in the study was entirely voluntary, and the study process, along with data analysis, ensured the confidentiality and anonymity of the HCPs. The ethical approval was obtained from the Independent Ethics Committee (ACEAS). Informed consent was obtained from patients before participating in the study.

Study questionnaire

The study questionnaire was designed based on existing literature, guidelines and expert opinions. It consisted of a total of 15 questions focused on the management of infantile colic, including the use of Lactobacilli in infantile colic. The

questionnaire also covered the impact of probiotic supplementation on crying duration, sleep patterns, maternal mental health, and overall quality of life. The questionnaire focused on the last 10 patients with infantile colic.

Inclusion and exclusion criteria

The study included paediatricians, gastroenterologists with at least 5 years of clinical experience in managing infantile colic and who had prescribed Lactobacilli in their clinical practice. Participants without a paediatric or gastroenterology specialisation, no recent Lactobacilli prescriptions, or unwilling to participate in the study were excluded.

Data collection

The HCPs participating in the study were provided with a concise overview of the study's nature and the process for completing the questionnaire.

Data analysis

The responses of HCPs were entered into Microsoft Excel and descriptive statistics, such as frequencies and percentages, were employed to present data.

3. RESULTS

A total of 68 HCPs were included in this study. According to 23.53% of the HCPs, the age of the 10 patients with infantile colic was 2 weeks old, followed by 3 weeks (25.00%), 6 weeks (22.06%), and >6 weeks old (29.41%). The majority of HCPs (67.65%) reported that the most common causes of colic in the patients were incorrect feeding techniques, overfeeding, underfeeding, or insufficient burping [Table 1].

A higher proportion of HCPs (60.29%) observed that the most common symptoms in these 10 patients with infantile colic were crying louder than usual, followed by stiffening of the arms, and drawing up of the legs (13.24%), arching of the back (11.76%), tensing of the abdomen (11.76%), red face (1.47%) and circumoral pallor (1.47%). A majority of HCPs (83.82%) reported advising the mother of the patient with infantile colic was burping the baby frequently, followed by a trial of feeding a bottle-fed baby vertically (11.76%) and using curved bottles (4.41%) [Table 1].

According to 47.06% of HCPs, the soothing technique advised to the mothers of the patients was doing a gentle abdominal massage. Most of HCPs (69.12%) gave dietary advice to the mothers of breast-fed infants was to follow a hypoallergenic diet that eliminates dairy, eggs, nuts, wheat, and soy, followed by eliminating dairy from their diet (30.88%). According to 25.00% of the HCPs, the duration of probiotic sachet prescription for relief of infantile colic was one sachet per day for 3 days, followed by one sachet per day for 7 days (73.53%), and one sachet per day only on the day the baby had colic (45.59%) [Table 1].

Additionally, 45.59% of the HCPs reported testing increased faecal calprotectin levels in patients with infantile colic. A majority of HCPs (95.59%) reported effect of probiotic formulation on sleep in patients with infantile colic was a reduction in crying time, followed by no effect on crying time (4.41%). A majority of HCPs (94.12%) reported effect of the probiotic formulation on sleep in these 10 patients with infantile colic was improved sleep, followed by no effect on sleep (5.88%). Most of HCPs (55.88%) reported effect of the probiotic formulation on sleep in these 10 patients with infantile colic was improved maternal mental health, followed by improved quality of life (44.12%) [Table 1].

Table 1: Responses of HCPs in the treatment of the 10 infantile colic patients

Options	Response of HCPs (N=68)
Age distribution of patients with infantile colic	
2 weeks old	16 (23.53)
3 weeks	17 (25.00)
6 weeks	15 (22.06)
>6 weeks old	20 (29.41)
Most common cause of colic among the patients	
Insufficient burping	12 (17.65)

Options	Response of HCPs (N=68)
Incorrect feeding techniques	7 (10.29)
Overfeeding	3 (4.41)
Underfeeding	-
All of the above	46 (67.65)
Most common symptoms observed in the infants with infantile colic	
Cry louder than usual	41 (60.29)
Stiffening of the arms, and drawing up of the legs	9 (13.24)
Arching of the back	8 (11.76)
Tensing of the abdomen	8 (11.76)
Red face	1 (1.47)
Circumoral pallor	1 (1.47)
Advice given to mothers of the infants with infantile colic	
Burping the baby frequently	57 (83.82)
A trial of feeding a bottle-fed baby vertically	8 (11.76)
Using a curved bottle	3 (4.41)
Soothing techniques advised to mothers of infants with infantile colic	
Doing a gentle abdominal massage	32 (47.06)
Gently rocking, using a swing or front carrier	15 (22.06)
Feeding the infant in a darkened room can facilitate infant sleep and reduce crying	6 (8.82)
Taking a ride in the car or stroller	5 (7.35)
Having a warm bath	3 (4.41)
Using a pacifier	2 (2.94)
Playing soft white noise in the background	2 (2.94)
Avoiding strong-smelling odors or perfumes	2 (2.94)
Reducing stimulation	1 (1.47)
Dietary advice given to the mothers of breast-fed infants	
Following a hypoallergenic diet that eliminates dairy, eggs, nuts, wheat, and soy	47 (69.12)
Eliminating dairy from their diet	21 (30.88)
Duration of probiotic sachet prescription for relief of infantile colic	
One sachet per day for 3 days	17 (25.00)
One sachet per day for 7 days	50 (73.53)
One sachet per day only on the day the baby had colic	1 (1.47)
Increased faecal calprotectin testing in infants with infantile colic	31 (45.59)
Effect of probiotic formulation on crying time in patients with Infantile Colic	
A reduction in crying time	65 (95.59)
No effect on crying time	3 (4.41)
Effect of the probiotic formulation on sleep in patients with infantile colic	
Improved sleep	64 (94.12)
No effect on sleep	4 (5.88)
Effect of the probiotic formulation maternal mental health in patients with infantile colic	
Improved maternal mental health	38 (55.88)
Improved quality of life	30 (44.12)
Repetition of probiotic dose in children with infantile colic	49 (72.06)

Data presented as n (%).
HCPs, Healthcare Professionals.

A majority of HCPs (72.06%) reported repetition of probiotic dose in patients with infantile colic. According to 50.00% of the HCPs, the rating of the efficacy of the probiotic formulation in these 10 patients with infantile colic was excellent, followed by good (42.65%), and fair (7.35%). A majority of HCPs (61.76%) rated the safety of the probiotic formulation in these 10 patients with infantile colic as excellent, good (32.35%) and fair (5.88%). Additionally, 48.53% of the HCPs rated the adherence to the probiotic formulation in the patients with infantile colic as excellent, good (47.06%), fair (4.41%) [Figure 1].

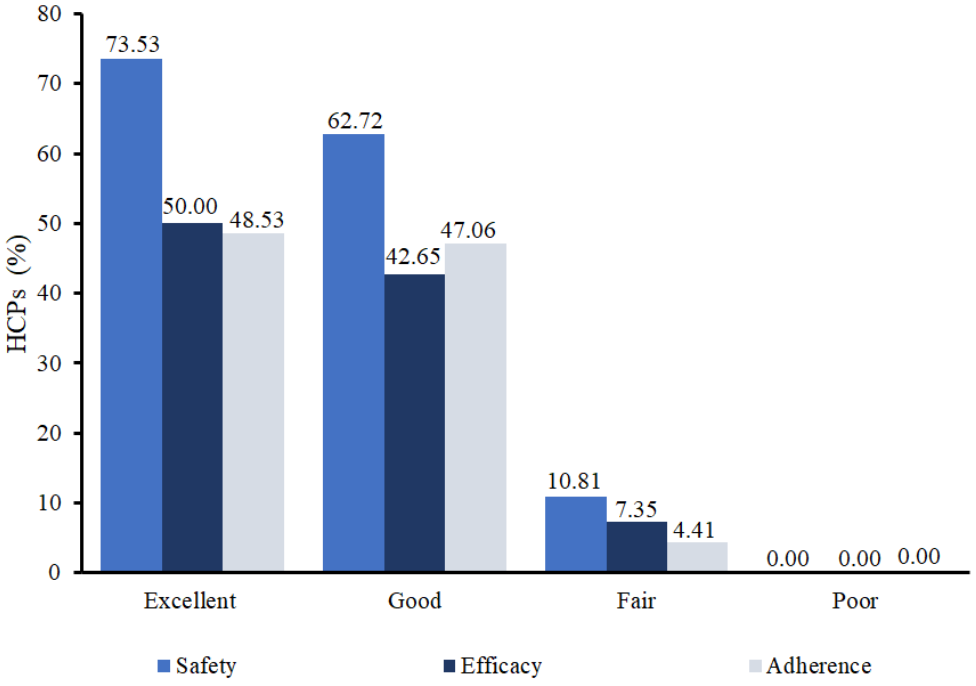

Figure 1. Rating the efficacy, safety and adherence of the probiotic formulation in patients with infantile colic

4. DISCUSSION

The present study successfully evaluated the formulation of Lactobacilli in the management of infantile colic in real-world setting.

In the present study, the majority of HCPs reported that the age of these 10 patients with infantile colic was 2 weeks old. Previous study has identified that lower gestational age increased the risk of infantile colic, highest in infants born before 32 weeks [11]. Fussing and crying are normal in the first three months, with infants averaging 2.2 hours of crying per day, peaking around six weeks and then gradually declining [12].

In the present study, the majority of the HCPs have reported that the most common causes of colic in the patients are incorrect feeding techniques, overfeeding, underfeeding, or insufficient burping. Previous studies have reported that proposed causes include changes in gut hormones, microflora, absorption, gas production, and allergies to cow's milk proteins or maternal dietary components [13, 14].

In the present study, a higher proportion of HCPs observed that the most common symptom in these 10 patients with infantile colic was crying louder than usual. This is supported by the evidence that infantile colic may involve gut dysfunction, with excessive crying as the primary symptom [15, 16].

In the present study, majority of HCPs reported advising the mother of the patient with infantile colic was burping the baby frequently. In contrast, previous studies have reported that burping did not significantly reduce colic episodes and was associated with a notable increase in regurgitation events in healthy full-term infants over a follow-up period of up to three months [17].

In the present study, the soothing technique advised to the mothers of the patients was doing a gentle abdominal massage. This is supported by the evidence that massage therapy is more effective than rocking for treating symptoms of infant colic [18]. Routine daily massage therapy for healthy breastfed infants was found to be more effective in relieving colic than massage given only during colic episodes [19].

In the present study, most of HCPs gave dietary advice to the mothers of breast-fed infants to follow a hypoallergenic diet that eliminates dairy, eggs, nuts, wheat, and soy. This is supported by the evidence that infantile colic should ideally be managed by advising caregivers to minimise stimulation and conducting a one-week trial of hypoallergenic formula milk [15]. Evidence indicates that dietary changes may help reduce colic in only a small minority of infants [20].

In the present study, according to most of the HCPs the duration of probiotic sachet prescription for relief of infantile colic was one sachet per day for 7 days.

In the present study, HCPs reported testing increased faecal calprotectin levels in patients with infantile colic. Previous studies have revealed fecal calprotectin levels were assessed in colicky and non-colicky infants using a point-of-care (PoC) test. [21]. High fecal calprotectin levels in infants with colic suggest a potential association between infantile colic and intestinal inflammation [22].

In the present study, a majority of HCPs reported effect of probiotic formulation on crying time in these 10 patients with infantile colic was reduction in crying time. This is supported by the evidence that L. reuteri may effectively treat crying in exclusively breastfed infants with colic [23]. A study suggests there is no definitive evidence that probiotics are more effective than a placebo in preventing infantile colic, although probiotic use seemed to decrease daily crying time compared to placebo [5].

In the present study, a majority of HCPs reported effect of probiotic formulation on sleep in these 10 patients with infantile colic was improved sleep. However, previous studies with *Lactobacillus reuteri* specifically did not show significant benefits on crying, sleep, or maternal mental health, suggesting that probiotic effects may vary depending on the strain used [24]. Evidence suggests there was no significant difference between probiotic receiving and placebo receiving groups in the pattern of sleep [25].

In the present study, a majority of HCPs reported effect of the probiotic formulation on maternal mental health in patients with infantile colic was improved maternal mental health. In contrast, previous studies have reported *L reuteri* treatment did not reduce crying or fussing in infants with colic, nor was it effective in improving infant sleep, maternal mental health, family or infant functioning, or quality of life [24].

In the present study, a majority of HCPs reported to repeat the probiotic dose in patients with infantile colic.

In the present study, according to most of the HCPs, the rating of the efficacy of the probiotic formulation in the patients with infantile colic was excellent. This is supported by the evidence *L. reuteri* supplementation in breastfed infants seems safe and effective for managing infantile colic [26, 25].

In the present study, a majority of HCPs rated the safety of the probiotic formulation in patients with infantile colic as excellent. Previous studies have reported probiotic L. reuteri seems safe and effective for managing infantile colic in breastfed infants [26].

In the present study, most of the HCPs rated the adherence to the probiotic formulation in the patients with infantile colic as excellent. This is supported by the evidence that a study suggests the adherence rate of the probiotic formulation was high [24].

5. LIMITATIONS

This study has a few limitations. A small sample size may limit the generalizability of findings, as the responses may not adequately represent the larger population of HCPs. The use of a self-reported questionnaire introduces the potential for response bias. The questionnaire may not cover all relevant aspects of the subject matter.

6. CONCLUSION

Healthcare professionals consider Lactobacillus-based probiotic formulations as an effective and well-tolerated option for managing infantile colic in breastfed infants, with significant reduction in crying time and improved maternal mental health. While the probiotic has potential benefits in alleviating colic symptoms, particularly in breastfed infants, its effectiveness in formula-fed infants remains uncertain and needs further studies.

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