



Parental Perception and Experience in Infants with Colic Symptoms Receiving Probiotic Supplementation

Probiotik Takviyesi Kullanan Kolik Semptomlu Bebeklerde Ebeveyn Algısı ve Deneyimi

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ABSTRACT

Aim: We aimed to evaluate the effects of probiotic drops containing the microbial strains *Bifidobacterium breve* BR03 and *Bifidobacterium breve* B632 on symptoms and quality-of-life indicators in infants aged 0–12 months under real-life conditions, particularly in subgroups such as colic, cesarean delivery, prematurity, hospitalization, and antibiotic exposure.

Material and Method: This four-center, multicenter study was conducted in the pediatric clinics of Prof. Dr. Cemil Taşcıoğlu City Hospital, Yalova Training and Research Hospital, Esenyurt State Hospital, and Sancaktepe Prof. Dr. İlhan Varank Training and Research Hospital. Symptoms of a total of 150 infants aged 0–12 months were compared before and after probiotic use using a parental questionnaire. The Wilcoxon signed-rank test was used for continuous/ordinal variables, and the McNemar test was used for binary variables (statistical significance set at $p < 0.05$).

Results: The median age of the infants was 4.5 months (25th–75th percentile: 2–8), and 56% of the cases were male. The reasons for initiating probiotic use were irritability (42.7%), colic (26.7%), gas (22.7%), and recommendation (8.0%). The median duration of use was 90 days, and the median daily dose was 5 drops. After probiotic use, a marked improvement was observed in crying-related parameters: median crying duration decreased from 1 hour/day (25th–75th percentile: 1–3) to 0 hours/day (25th–75th percentile: 0–1), median crying frequency decreased from 2 (25th–75th percentile: 2–3) to 1 (25th–75th percentile: 1–1), and the median number of daily crying episodes decreased from 10 (25th–75th percentile: 8–10) to 2 (25th–75th percentile: 2–4). In parallel, significant reductions were observed in the severity scores of gasses, abdominal distension, and irritability, along with increases in maternal and paternal sleep duration and a decrease in maternal depressive mood score (all comparisons $p < 0.001$). In binary symptom assessment, the presence of gas decreased from 63.3% to 7.3%, irritability from 47.3% to 11.3%, and abdominal distension from 63.3% to 22.7%, while the proportion of infants reported to have nighttime sleep increased from 32.0% to 68.0% (all $p < 0.001$).

Conclusion: The use of probiotic drops containing the microbial strains *Bifidobacterium breve* BR03 and *Bifidobacterium breve* B632 was found to be associated with clinically meaningful improvement in gastrointestinal complaints and parent-related sleep and mood parameters, as well as good tolerability, in infants aged 0–12 months.

Keywords: Probiotic, *Bifidobacterium breve*, infantile colic, gas, sleep

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ÖZ

Amaç: *Bifidobacterium breve* BR03 ile *Bifidobacterium breve* B632 mikrobiyal suşlarını içeren probiyotik damla kullanımının 0–12 ay arası bebeklerde gerçek yaşam koşullarında (özellikle kolik, sezaryen doğum, prematürite, hastane yatışı ve antibiyotik maruziyeti gibi alt gruplarda) semptomları ebeveyn algısı ve antibiyotik maruziyeti üzerindeki etkisini değerlendirmeyi amaçladık.

Gereç ve Yöntem: Bu çalışma, Prof. Dr. Cemil Taşcıoğlu Şehir Hastanesi, Yalova Eğitim ve Araştırma Hastanesi, Esenyurt Devlet Hastanesi ve Sancaktepe Prof. Dr. İlhan Varank Eğitim ve Araştırma Hastanesi'nin çocuk kliniklerinde yürütülen, dört merkezli ve multisentrik bir araştırmadır. Toplam 0-12 ay aralığındaki 150 bebeğin probiyotik kullanım öncesi ve sonrası semptomları ebeveyn anketiyle karşılaştırıldı. Sürekli/ordinal değişkenlerde Wilcoxon işaretli sıralar, ikili değişkenlerde McNemar testi kullanıldı (anlamlılık $p < 0,05$).

Bulgular: Bebeklerin medyan yaşı 4,5 ay (25.–75. persentil: 2–8) olup, olguların %56'sı erkekti. Probiyotik başlama nedenleri huzursuzluk (%42,7), kolik (%26,7), gaz (%22,7) ve tavsiye (%8,0) idi. Kullanım süresi medyan 90 gün, günlük doz medyan 5 damla olarak kaydedildi. Probiyotik kullanımı sonrasında ağlama göstergelerinde belirgin düzelleme saptandı; ağlama süresi medyan 1 saat/gün (25.–75. persentil: 1–3) iken 0 saat/gün'e (25.–75. persentil: 0–1) geriledi, ağlama sıklığı medyan 2'den (25.–75. persentil: 2–3) 1'e (25.–75. persentil: 1–1) düştü ve günlük ağlama sayısı medyan 10'dan (25.–75. persentil: 8–10) 2'ye (25.–75. persentil: 2–4) azaldı. Buna paralel olarak gaz, karın şişliği ve huzursuzluk şiddet skorlarında anlamlı azalma; anne ve baba uyku sürelerinde artış ve anne depresif ruh hali skorunda azalma izlendi (tüm karşılaştırmalar için $p < 0,001$). İkili semptom değerlendirmesinde gaz varlığı %63,3'ten %7,3'e, huzursuzluk varlığı %47,3'ten %11,3'e ve karın şişliği varlığı %63,3'ten %22,7'ye gerilerken; gece uykusunun 'var' olarak bildirilme oranı %32,0'den %68,0'e yükseldi (tümü $p < 0,001$).

Sonuç: *Bifidobacterium breve* BR03 ile *Bifidobacterium breve* B632 mikrobiyal suşlarını içeren probiyotik damla kullanımı, 0-12 ay arası bebeklerde gastrointestinal şikayetler ile ilişkili ebeveyn uyku/mood parametrelerinde klinik olarak anlamlı düzelleme ve iyi tolerabilite ile ilişkili bulunmuştur.

Anahtar Kelimeler: Probiyotik, *Bifidobacterium breve*, infantil kolik, gaz, uyku

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INTRODUCTION

Infantile colic and early-life gastrointestinal complaints (gas, abdominal distension, irregular bowel movements, irritability/crying) are among the most common reasons for visits to pediatric outpatient clinics during the first year of life and significantly negatively affect both infant comfort and family quality of life (1–3). Although these symptoms are benign and self-limiting in most cases, they may lead to recurrent healthcare visits, increased parental anxiety, sleep disturbances, and a greater caregiving burden (2,3). In recent years, it has been reported that processes such as gut microbiota composition, maturation of the intestinal barrier, and low-grade inflammation play a role in the emergence and persistence of these symptoms; therefore, probiotics may represent a targeted therapeutic approach (4–6). *Bifidobacterium breve* strains are among the dominant species in the microbiota of breastfed infants and are considered candidate agents of the “therapeutic microbiology” approach in early life (7). The aim of this study is to evaluate, using a before–after comparative design, the effects of probiotic drop supplementation containing *Bifidobacterium breve* BR03 and *Bifidobacterium breve* B632 on gastrointestinal complaints and parental sleep/mood parameters in infants aged 0–12 months. The study is noteworthy in that it presents multicenter real-life data.

MATERIAL AND METHOD

This study is a four-center, multicenter investigation conducted in the pediatric clinics of Prof. Dr. Cemil Taşcıoğlu City Hospital, Yalova Training and Research Hospital, Esenyurt State Hospital, and Sancaktepe Prof. Dr. İlhan Varank Training and Research Hospital. Symptoms of a total of 150 infants aged 0–12 months were recorded before and after probiotic use using a parental questionnaire. A total of 150 cases were included in the study. Infants were recommended to use probiotic drops containing *Bifidobacterium breve* BR03 and *Bifidobacterium breve* B632 at a dose of 1×5 drops/day for 90 days.

In the questionnaire data, crying duration (hours/day), crying frequency, number of crying episodes (times/day), severity of gas/irritability/abdominal distension (1–3), defecation frequency (times/day), stool consistency (1–3), maternal and paternal sleep duration (hours/night), and maternal depressive mood score (1–10) were compared before and after probiotic use. In addition, the presence of gas, irritability, abdominal distension, nighttime sleep, and bowel regularity were evaluated as binary variables.

The study was observational in nature, and analyses were conducted while preserving patient confidentiality.

Statistical Analysis

Data analysis was performed using SPSS or similar statistical software packages. Continuous variables were presented as mean ± standard deviation or median [interquartile range] according to distribution characteristics, and categorical variables were presented as n (%). In this analysis, variables measured before and after probiotic use had a paired structure. Continuous variables were summarized as median [IQR], and before–after comparisons were performed using the Wilcoxon signed-rank test. Ordinal variables (e.g., mild–moderate–severe) were converted into numerical scores and evaluated using the Wilcoxon test. For binary categorical variables (Yes/No, Present/Absent, Regular/Irregular), the McNemar exact test was applied; proportions were reported with 95% confidence intervals using the Wilson method. Effect size was reported as rank-biserial correlation for Wilcoxon tests and as the discordant pair odds ratio (b/c) for McNemar analyses. For multiple comparisons, Benjamini–Hochberg false discovery rate (FDR) correction was applied, and q-values were calculated; q<0.05 was considered statistically significant. All tests were two-sided, and α was set at 0.05.

RESULTS

A total of 150 cases were evaluated. The median age of the infants was 4.50 (0–12) months, and 84 (56.0%) were male. Distribution according to gestational age was as follows: term 113 (75.3%), preterm 27 (18.0%), and post term 10 (6.7%). The mode of delivery was cesarean section in 64 cases (42.7%). The median birth weight was 3500 [3050–3800] grams. Feeding type was breast milk in 44 infants (29.3%), formula in 27 (18.0%), and mixed feeding in 79 (52.7%). The history of neonatal intensive care unit admission was present in 47 infants (31.3%), history of hospitalization during the neonatal period in 47 (31.3%), and history of hospitalization outside the neonatal period in 40 (26.7%). The history of jaundice was recorded in 64 infants (42.7%), phototherapy in 20 (13.3%), neonatal antibiotic use in 37 (24.7%), and antibiotic use within the first year of life in 65 (43.3%). The reasons for initiating probiotic use were irritability in 64 infants (42.7%), colic in 40 (26.7%), gas in 34 (22.7%), and recommendation in 12 (8.0%). Regular use was reported in 119 cases (79.3%). No adverse effects were reported (n=150, 100% “No”) (Table 1).

In the comparison before and after probiotic use, a marked reduction was observed in crying-related parameters after probiotic supplementation: crying duration decreased from 1 [1–3] hours/day to 0 [0–1] hours/day; crying frequency decreased from 2 [2–3] to 1 [1–1]; and the number of crying episodes decreased from 10 [8–10] to 2 [2–4] (all p<0.001). Gastrointestinal symptom severity scores also decreased: gas severity



decreased from 2 [1–3] to 1 [1–1], irritability severity from 2 [1–3] to 1 [1–1], and abdominal distension severity from 2 [1–2] to 1 [1–1] (all $p < 0.001$). Defecation frequency decreased from 5 [4–7] to 4 [3–4], and stool consistency improved from 3 [3–3] to 2 [2–3] ($p < 0.001$). Regarding family-related parameters, maternal sleep duration increased from 6 [4–6] to 8 [8–10], paternal sleep duration increased from 8 [6.50–8] to 10 [8–10], and maternal depressive mood score decreased from 8 [6–10] to 3 [2–6] (all $p < 0.001$) (Figure 1, Figure 2, Table 2).

Variable	Value
Age (months), median [IQR]	4.50 [2–8]
Sex (Male), n (%)	84 (56.0)
Mode of delivery (Cesarean section), n (%)	64 (42.7)
Gestational age, n (%)	Term 113 (75.3); Preterm 27 (18.0); Postterm 10 (6.7)
Birth weight (g), median [IQR]	3500 [3050–3800]
Feeding type, n (%)	Breast milk 44 (29.3); Formula 27 (18.0); Mixed 79 (52.7)
History of NICU admission, n (%)	47 (31.3)
History of hospitalization during the neonatal period, n (%)	47 (31.3)
History of hospitalization outside the neonatal period, n (%)	40 (26.7)
History of jaundice, n (%)	64 (42.7)
Phototherapy, n (%)	20 (13.3)
Neonatal antibiotic use, n (%)	37 (24.7)
Antibiotic use within the first year of life, n (%)	65 (43.3)
Reason for probiotic initiation, n (%)	Colic 40 (26.7); Gas 34 (22.7); Irritability 64 (42.7); Recommendation 12 (8.0)
Duration of use (days), median	90
Daily dose (drops), median	5
Regular use, n (%)	119 (79.3)
Adverse events, n (%)	0 (0)

Abbreviations; IQR: interquartile range; NICU: neonatal intensive care unit.

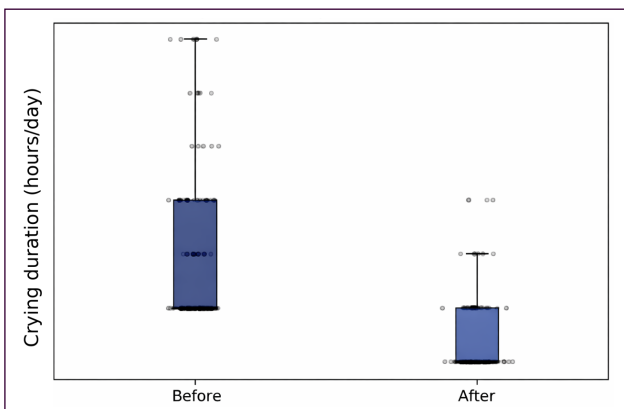


Figure 1. Distribution of crying duration before and after probiotic use
 Note: The median crying duration decreased from 1 [1–3] hours/day to 0 [0–1] hours/day ($p < 0.001$).

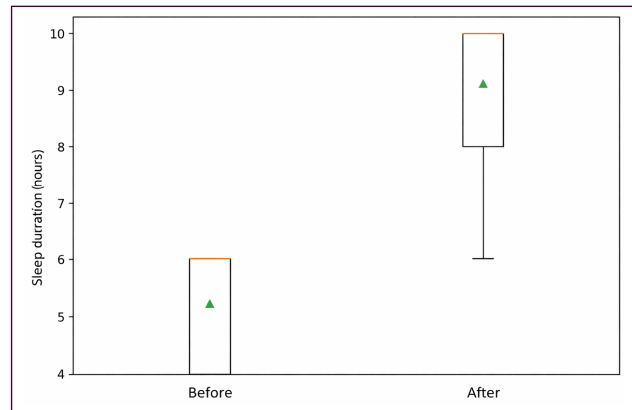


Figure 2. Maternal sleep duration in the colic subgroup: before–after comparison

Outcome	Before	After	Change	p value
Crying duration (hours/day)	1 [1–3]	0 [0–1]	–1	<0.001
Crying frequency (1=Rare, 2=Moderate, 3=Frequent)	2 [2–3]	1 [1–1]	–1	<0.001
Number of crying episodes (times/day)	10 [8–10]	2 [2–4]	–8	<0.001
Gas severity (1–3)	2 [1–3]	1 [1–1]	–1	<0.001
Irritability severity (1–3)	2 [1–3]	1 [1–1]	–1	<0.001
Abdominal distension severity (1–3)	2 [1–2]	1 [1–1]	–1	<0.001
Defecation frequency (times/day)	5 [4–7]	4 [3–4]	–1	<0.001
Stool consistency (1=Hard, 2=Normal, 3=Watery)	3 [3–3]	2 [2–3]	–1	<0.001
Maternal sleep duration (hours/night)	6 [4–6]	8 [8–10]	+2	<0.001
Paternal sleep duration (hours/night)	8 [6.50–8]	10 [8–10]	+2	<0.001
Maternal depressive mood (1=good–10=poor)	8 [6–10]	3 [2–6]	–5	<0.001
Gas (presence)	63.3%	7.3%	–56.0 pp	<0.001
Irritability (presence)	47.3%	11.3%	–36.0 pp	<0.001
Abdominal distension (presence)	63.3%	22.7%	–40.7 pp	<0.001
Nighttime sleep (presence)	32.0%	68.0%	+36.0 pp	<0.001
Bowel regularity (regular) (presence)	30.7%	76.0%	+45.3 pp	<0.001

Note: Continuous/ordinal variables are presented as median [IQR], and binary variables are presented as percentages. The change column represents “After–Before.” For symptom-related parameters, negative values indicate a reduction, whereas for parameters such as sleep duration, positive values indicate an increase.

A marked improvement was also observed in binary symptoms: the presence of gas decreased from 63.3% to 7.3%, irritability from 47.3% to 11.3%, and abdominal distension from 63.3% to 22.7% (all $p < 0.001$). The presence of nighttime sleep increased from 32.0% to 68.0%, and the proportion of infants reported to have regular bowel habits increased from 30.7% to 76.0% (all $p < 0.001$) (Figure 3).

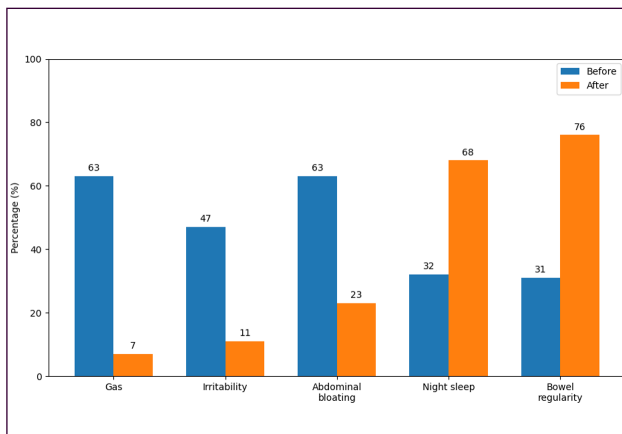


Figure 3. Rates of binary symptoms before and after probiotic use

Note: While the rates of gas, irritability, and abdominal distension decreased significantly, the rates of reported nighttime sleep and regular bowel habits increased significantly (all $p < 0.001$).

In the case-based evaluation, symptom improvement was reported in 124 cases (82.7%) (Figure 4). The median time to improvement was 30 [5–60] days. Overall satisfaction was reported as satisfied in 138 cases (92.0%), undecided in 9 cases (6.0%), and not satisfied in 3 cases (2.0).

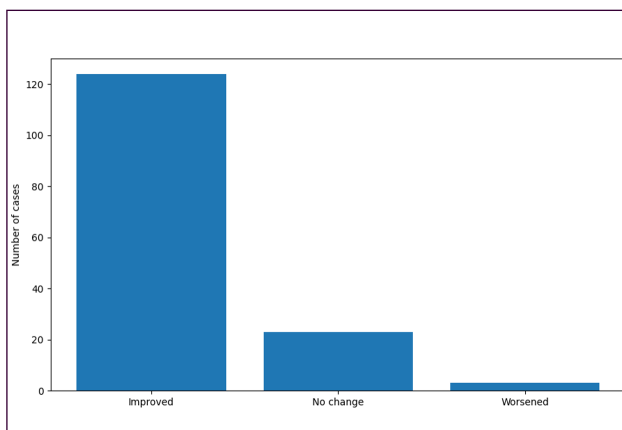


Figure 4. Distribution of symptom change ($n=150$)

When change scores were compared in subgroup analyses, improvement in certain parameters, particularly crying frequency and abdominal distension—was found to be more pronounced in infants delivered by cesarean section ($p < 0.001$). In preterm infants, the change in crying frequency was greater compared with the term/post term group ($p=0.007$). Among cases in whom probiotics were initiated with an indication of colic, the change in crying duration was observed to be more pronounced compared with non-colic cases ($p=0.006$) (Figure 5).

Overall, although a trend toward reduction in complaints and improvement in sleep/well-being after probiotic use was observed in cases with a history of jaundice/phototherapy, no significant differentiation was observed in other primary outcomes.

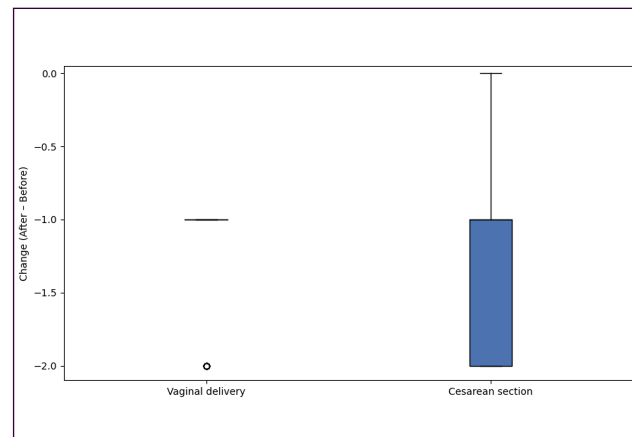


Figure 5. Comparison of change in crying frequency according to mode of delivery

Note: The reduction in crying frequency was more pronounced in the cesarean section group (subgroup comparison $p < 0.001$).

DISCUSSION

In our multicenter study, following the use of probiotic drops containing the microbial strains *Bifidobacterium breve* BR03 and *Bifidobacterium breve* B632 in infants aged 0–12 months, statistically and clinically significant improvements were observed both in infant gastrointestinal symptoms and in family-related sleep and mood indicators. When the reductions in crying duration, frequency, and number are evaluated together with the decreases in gas and abdominal distension severity scores, it can be considered that probiotic use containing *Bifidobacterium breve* BR03 and *Bifidobacterium breve* B632 may provide potential benefit in the management of functional gastrointestinal complaints, particularly during the early years of life.

In the literature, there are systematic reviews and randomized studies evaluating the effects of probiotics on infantile colic and related symptoms (4–7). The fact that the *Bifidobacterium* genus constitutes one of the dominant taxa in early-life microbiota, along with its potential effects on intestinal barrier function and immune responses, represents biological mechanisms that may explain the observed clinical improvement (5,6).

In subgroup analyses, it is noteworthy that certain symptom changes were more pronounced in infants delivered by cesarean section and in preterm infants. This finding is consistent with the hypothesis that early-life microbiota may differ according to mode of delivery and gestational age, and that probiotic response may vary within this context (5,6).

Following probiotic use containing the microbial strains *Bifidobacterium breve* BR03 and *Bifidobacterium breve* B632, symptom improvement and high satisfaction rates were observed in most cases. In the colic subgroup, statistically robust improvement was detected not only in crying duration, number, and



frequency but also in accompanying symptoms such as gas, irritability, and abdominal distension. These findings are consistent with the results of studies reporting a protective and/or therapeutic effect of the BR03+B632 combination on colic (8).

In the literature, a randomized controlled study evaluating the administration of two *Bifidobacterium breve* strains at a dose of 5 drops/day for 90 days reported reductions in functional gastrointestinal symptoms, decreased frequency of regurgitation and vomiting, and improvement in stool consistency, with no adverse events observed (9,10). These data support the safety profile observed in our study.

The efficacy of probiotics in infantile colic is strain-specific; nevertheless, systematic reviews and meta-analyses have demonstrated that probiotic use may be associated with a reduction in crying duration. In the systematic review by Schreck Bird et al., infants receiving probiotics were reported to have a higher likelihood of “response” (defined as at least a 50% reduction in crying/fussing duration) compared with controls (11). A meta-analysis of randomized controlled trials indicated that probiotics may increase the overall response/effectiveness rate in the management of colic and reduce crying duration (12). A more recent systematic review and meta-analysis similarly suggested that probiotics may be associated with clinical improvement (13). These data suggest that the improvement observed in the colic subgroup in our study may be consistent with the existing literature.

Systematic reviews and meta-analyses examining the effect of probiotics on colic have emphasized that crying duration may decrease particularly within the first four weeks of use, while also highlighting that strain-specific efficacy is critical. Our study, conducted using the combined administration of *B. breve* strains such as BR03 and B632, is noteworthy in that it demonstrated a substantial reduction in crying duration with this dual-strain combination, a finding that is consistent with the literature (12).

One of the most important messages regarding probiotic use in clinical practice is that evidence varies according to “strain and indication.” The ESPGHAN position paper on the use of probiotics in pediatric gastrointestinal disorders emphasizes that recommendations should be based on strain-specific evidence, that routine use of strains with insufficient evidence should not be encouraged, and that clinical studies should be methodologically standardized (14). In line with this approach, although the real-life data from our study support symptom improvement associated with a product containing BR03+B632, a strain-based approach tailored to patient profile and supported by traceable outcomes should be preferred in clinical practice rather than a generalized “probiotic” approach.

The results of our study are consistent with the hypothesis that factors such as cesarean delivery and early antibiotic exposure may alter the microbiota and that specific probiotic strains may be associated with a more meaningful clinical response in this context (15–22).

CONCLUSION

The use of probiotics containing the microbial strains *Bifidobacterium breve* BR03 and *Bifidobacterium breve* B632 in infants aged 0–12 months was found to be associated with a high rate of symptom improvement and good tolerability. Following probiotic use, statistically significant changes were observed in crying-related measures, symptoms such as gas, abdominal distension, and irritability, as well as sleep and defecation parameters. In the colic subgroup, clinically meaningful improvement was observed in crying parameters and accompanying gastrointestinal symptoms. Improvement was also observed in clinical subgroups such as prematurity, cesarean delivery, hospitalization, and antibiotic exposure.

The observed clinical improvements suggest that the combined use of *Bifidobacterium breve* BR03 and B632 may be associated with beneficial effects on functional gastrointestinal symptoms.

Our study is noteworthy in that it presents multicenter real-life data.

ETHICAL DECLARATIONS

Ethics Committee Approval: The study protocol was approved by the Istanbul Prof. Dr. Cemil Taşcıoğlu City Hospital Non-Interventional Clinical Research Ethics Committee (Decision No: 255, Date: 11.08.2025).

Informed Consent: Written informed consent was obtained from the parents of all cases included in the study.

Referee Evaluation Process: Externally peer-reviewed.

Conflict of Interest Statement: The authors have no conflicts of interest to declare.

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Author Contributions: All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

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