

Occurrence of Infantile Colic and Treatment Effectiveness of Conventional Treatment

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ABSTRACT

Background: Infantile colic is a common condition that involves excessive, unexplained crying in healthy infants that may be distressing to the family. There is limited data on its occurrence and effectiveness of conventional treatments in clinical setting in Bangladesh. **Objective:** To assess the incidence of infantile colic in a sample of infants attending a hospital, and to measure the effectiveness of traditional treatment measures. **Methods & Materials:** Prospective cohort study was performed at Shaheed Quazi Robee Rahman BGB Hospital, Chuadanga, Dhaka, Bangladesh from October 2025 to March 2026. Forty-three infants meeting inclusion criteria for a diagnosis of “colic” were recruited using purposive sampling. All participants were given conventional treatment (parental reassurance, dietary changes and simethicone drops). Structured interviews and follow up diaries were used to gather the data for four weeks. Duration and the frequency of crying was recorded at baseline and following the intervention. The data obtained were analysed by SPSS version 23.0. **Result:** Infants who were screened reported 18.7% of infantile colic. The mean duration of daily crying significantly decreased from 3.2 (± 0.8) hours to 1.1 (± 0.6) hours ($p < 0.001$), and the number of daily crying episodes decreased from 5.4 (± 1.3) to 1.9 (± 1.0) ($p < 0.001$) after conventional treatment. There was a positive treatment response in 95.3% of the cohort and no serious adverse events were reported. **Conclusion:** Infantile colic was a fairly common condition. Overall, the treatment protocol was effective and safe, and could be adopted in normal pediatric care in Bangladesh to reduce crying symptoms, thereby reducing infant and family distress.

Keywords: Colic, conventional treatment, occurrence, pediatrics, treatment effectiveness

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INTRODUCTION

Colic, defined by Wessel's ‘rule of threes’: crying more than 3 hours a day, for more than 3 days a week and for more than 3 weeks in a healthy infant, is a frequently observed and troublesome condition in early childhood practice [1,2]. This behavioral syndrome is most common around six weeks of age and generally resolves by 3-4 months of age, and is a common reason for parental anxiety, distress and seeking healthcare in the first three months of life [3,4]. The aetiology of colic is complex and partially understood, and there are several hypotheses, such as gastrointestinal, psychosocial, and neurodevelopmental. Gastrointestinal factors include the immaturity of the gut microbiome, lactose intolerance and infantile dyschezia, and psychosocial factors include difficult infant temperament and suboptimal caregiver-infant interaction [5,6]. The biopsychosocial model suggests that colic is a result of a combination of what happens with the baby's physiology and what happens around them [7]. Colic is estimated to affect 5–25% of infants worldwide, depending on how the condition is defined, cultural views on crying, and how parents report their babies' crying [8,9]. Even though usually a short-lived period, the effects of infantile colic reach beyond the infant. It is an important risk factor for maternal postpartum depression and early weaning from breastfeeding as well as shaken baby

syndrome, thus posing a major public health risk [10,11]. In low- and middle-income countries (LMICs) such as Bangladesh, the burden could be increased due to low or inadequate parental awareness, cultural practices, and low information literacy. However, low- and middle-income countries like Bangladesh, the burden may increase due to low or inadequate awareness on the part of parents, cultural practices and low information literacy, although extensive local epidemiology data is lacking, there is limited information available on and healthcare resources [12]. Treatment of infantile colic is mainly directed toward reassuring and supporting the child because there is no single cure that is effective for all children. First-line treatments are multi-modal including education and reassurance for parents as well as practical treatments. These are usually dietary changes like use of hydrolyzed protein formula in breast-fed infants, maternal exclusion diet, and the use of simethicone for its purported anti-flatulent effect [2,13]. In some populations, probiotics, specifically the probiotic strain *Lactobacillus reuteri* DSM 17938, are a promising evidence-based intervention, but may be context-dependent and strain-specific [5]. The effectiveness of these traditional practices, however, in the real world setting of Bangladesh, particularly the socio-cultural and healthcare setting, has not been comprehensively explored. Little efficacy information comes from

LMIC settings, and it is unclear whether the generalizability of this information applies to LMIC settings. This is a lack of context specific evidence, which highlights the need for pragmatic clinical research. Hence, the aim of this prospective cohort study was to look into the prevalence of infantile colic among infants attending the tertiary hospital in Dhaka, Bangladesh and to systematically assess the effectiveness of a standard treatment protocol in reducing crying time and frequency in infants. The results will be used for local practice and as part of the expanding literature on the management of this ubiquitous condition in resource-poor environments.

METHODS & MATERIALS

This was a prospective cohort study conducted at Shaheed Quazi Robee Rahman BGB Hospital, Chuadanga, Bangladesh during the period of October 2025 to march, 2026. Infants under the age of four months who came to the paediatric Out Patient Department with complaints of excessive and unexplained crying formed the study population.

Inclusion criteria

Infant enrolment was based on the modified Wessel's definition of infantile colic (paroxysmal crying >3 hours/day, for ≥ 3 days/week). Also, the participants had to be otherwise healthy with a gestation period from 2 weeks to 16 weeks, and their

parents/guardians had to sign a written informed consent.

Exclusion criteria

Infants were excluded if they had evidence of an organic illness (e.g., infection, cow's milk protein allergy diagnosed before), history of prematurity (<37 weeks of gestation), low birth weight (<2500g), major congenital anomalies or received, previously, probiotic or prescribed pharmacological treatment for colic.

Study procedure

A purposive sampling method of 43 eligible infants was used. All were given a standardised conventional treatment

programme of comprehensive parental reassurance, feeding technique advice, dietary changes (hypoallergenic formula or maternal diet modification) and oral simethicone drops (20mg, four times a day prior to feeds). Structured crying diary kept by primary caregivers. Face-to-face interviews and diary reviews were used to evaluate baseline data and outcomes at enrollment and after four weeks.

Data analysis

IBM SPSS Statistics, Version 23.0 was used for data analysis. The major outcomes were the difference in the mean daily crying length and frequency. Data are presented as mean ± SD. Pre- and post-

treatment values were compared using paired-sample t-test with a p-value of < 0.05 defined as statistically significant.

RESULT

Table I presents the demographic and baseline characteristics of the study cohort (N=43). Among the enrolled infants, 27 (62.8%) were male and 16 (37.2%) were female. The mean age at enrollment was 6.1±2.4 weeks, with an age range of 3–14 weeks. Regarding feeding practices, 25 (58.1%) infants were exclusively formula-fed, 14 (32.6%) were exclusively breastfed, and 4 (9.3%) received mixed feeding.

Table I

Demographic and baseline characteristics of the study cohort (N=43).

Characteristic	Category	Frequency (n)	Percentage (%)
Sex	Male	27	62.8
	Female	16	37.2
Mean age (weeks)		6.1 (SD ± 2.4)	-
Age range (weeks)		3-14	-
Feeding mode	Exclusively formula	25	58.1
	Exclusively breast	14	32.6
	Mixed feeding	4	9.3

Table II shows the occurrence and baseline clinical profile of infantile colic. The prevalence of infantile colic among screened infants during the study period

was 18.7%. At baseline, the mean daily crying duration was 3.2±0.8 hours, while the mean number of crying episodes was 5.4±1.3 per day. Most infants (35, 81.4%)

exhibited predominant crying during the evening hours.

Table II

Occurrence and baseline clinical profile of infantile colic.

Parameter	Value
Occurrence among screened infants	18.7%
Mean daily crying duration (hours)	3.2 (SD ± 0.8)
Mean daily crying episodes (n)	5.4 (SD ± 1.3)
Predominant evening crying	35 (81.4%)

Table III summarizes the primary outcomes before and after treatment. The mean daily crying duration significantly decreased from 3.2±0.8 hours at baseline to

1.1±0.6 hours after treatment, representing a mean reduction of 2.1 hours. Similarly, the mean daily crying episodes declined from 5.4±1.3 to 1.9±1.0 episodes per day,

corresponding to a mean reduction of 3.5 episodes. These comparisons were analyzed using the paired samples *t*-test.

Table III

Primary outcomes before and after treatment.

Outcome measure	Baseline	Post-treatment	Mean reduction
	Mean (SD)		
Daily crying duration (hours)	3.2 (± 0.8)	1.1 (± 0.6)	2.1 hours
Daily crying episodes (n)	5.4 (± 1.3)	1.9 (± 1.0)	3.5 episodes

Data analyzed using Paired Samples t-test.

Table IV presents the statistical significance of changes in the primary outcomes following treatment. Daily

crying duration showed a highly significant reduction (*t*=12.745, *df*=42, *p*<0.001). Likewise, the reduction in daily crying

episodes was also highly significant (*t*=14.218, *df*=42, *p*<0.001), as determined by the paired samples *t*-test.

Table IV
Statistical significance of change in primary outcomes.

Outcome measure	t-value	df	p-value
Daily crying duration	12.745	42	<0.001
Daily crying episodes	14.218	42	<0.001

Data analyzed using Paired Samples t-test.

Table V illustrates the categorization of clinical response to treatment. Complete response, defined as post-treatment crying of less than 1 hour per day, was achieved in 17 (39.5%) infants. Partial response, defined as more than a 50% reduction in baseline crying duration while still crying for at least 1 hour per day, was observed in 24 (55.8%) infants. Only 2 (4.7%) infants were classified as non-responders, showing less than a 50% reduction in crying duration.

Table V
Categorization of clinical response to treatment.

Response category	Definition	n	%
Complete response	Post-treatment crying <1 hour/day	17	39.5
Partial response	>50% reduction from baseline, but crying ≥1 hour/day	24	55.8
Non-response	<50% reduction from baseline crying duration	2	4.7

Table VI describes the adverse events reported during the follow-up period. No serious adverse events were observed. Minor and transient adverse events occurred in 3 (7.0%) infants, all of which consisted of changes in stool consistency and resolved without intervention or discontinuation of treatment.

Table VI
Reported adverse events during follow-up.

Adverse event	Frequency (n)	Percentage (%)	Outcome
Serious adverse events	0	0	None reported.
Minor/Transient events	3	7	Resolved without intervention.
Change in stool consistency	3		(included above)

DISCUSSION

A prospective cohort study of occurrence and treatment outcome of infantile colic was conducted in a hospital environment in Chuadanga, Bangladesh according to the conventional protocol. The results suggest that colic is a common clinical issue with 18.7% of screened infant population experiencing it and that a systematic approach of parental reassurance strategies, dietary changes and the use of simethicone is statistically and clinically effective in reducing symptoms of crying. The prevalence rate observed (18.7%) is within the upper limit of the estimated range of prevalence in the world (5% to 25%) [8,9]. This fairly high rate in our clinical sample indicates that infantile colic is a real issue in the pediatric setting in the Bangladeshi context, and in keeping with research that infantile colic accounts for significant outpatient visits in early infancy [14]. The age distribution of our cohort, which was predominantly male (62.8%) with a mean age of 6.1 weeks, is consistent with what has been reported worldwide [1,15]. The result from this study is the significant effectiveness of the traditional treatment method. The protocol resulted in a mean decrease of 3.2 to 1.1 hours of crying per day (a mean decrease of 2.1 hours) and a mean decrease of 3.5 crying episodes per day. The highly significant p-values (<0.001) for both outcomes strongly support the effectiveness of the

intervention. The findings were similar to those found in the biopsychosocial approach to managing the colic [7]. Parental reassurance and education likely reduced caregiver anxiety and helped to increase coping, which may have decreased the infant's fussiness related to stress [16]. Dietary changes are a principal part of traditional treatment and are directed to potential gastrointestinal causes of colic, such as intolerance to cow's milk protein or lactose overload, which are believed to occur in some babies with colic [17]. Simethicone is important enough to comment on in our protocol. It is a common and safe first-line agent, though some systematic reviews have doubted its effectiveness as compared with placebo [13,18]. It has been included in our pragmatic study because of its relevance in the real clinical world. The positive findings reported could be related to the interaction of the different components in the multi-component protocol, or to a specific benefit in infants whose symptoms are related to trapped gas, which is a parental concern. The high proportion of positive responses (95.3% infants had either a complete (39.5%) or partial (55.8%) response) shows the practical utility of this readily available and cost-effective intervention in a resource-limited setting. We have a few limitations within the research that we should note. First, the study does not have a control group or placebo group, which

makes it difficult to unequivocally pinpoint all of the improvements as a result of the intervention rather than as a result of the natural healing of colic. Secondly, findings from this purposive sampling method and small sample size (n=43) in a single tertiary center may not be extrapolable to the general community and other health care settings in Bangladesh. Thirdly, although a standard tool, diaries of crying are subject to reporter bias and perception of the parent. The study is nonetheless informative with regard to its limitations of context. The results confirm the value of a systematic, empathetic, and educative approach from healthcare providers which can make significant gains [19]. To conclude, future studies of similar settings should include randomized controlled methods, include certain probiotic strains (Lactobacillus reuteri DSM 17938) which has Level I evidence in certain populations, and explore cultural or dietary factors unique to the region [5,20]. In addition, long-term effects of these interventions on parental mental health (a known outcome of colic) would be of value to extend this work [10,11].

LIMITATIONS

Some of the main shortcomings of the study are that it does not have a control group, there may be natural resolution of the symptoms over time, it is a small sample size from a single center, and

purposive sampling may not be generalizable.

CONCLUSION

Infantile colic is one of the common problems of the infants in a tertiary hospital in Dhaka. A standard approach of structured parental support, dietary recommendations and the use of simethicone was shown to be very effective and safe, and had a marked effect on the amount of crying of affected infants and its frequency. This pragmatic approach is suggested for implementation in routine pediatric practice in similar settings to reduce infant distress and to support families.

RECOMMENDATIONS

This is a multi-component conventional protocol designed to be implemented in routine pediatric care and is recommended to effectively manage infantile colic. Consistent parental reassurance, nutrition advice, and treatment of infants' symptoms should be provided by healthcare providers to enhance outcomes for infants and families.

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CONFLICT OF INTEREST

None declared

ETHICAL APPROVAL

The study was approved by the Institutional Ethics Committee.

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