

EFFICACY OF BETA-GALACTOSIDASE IN TREATMENT OF INFANTILE COLIC IN INFANTS PRESENTING TO A TERTIARY CARE HOSPITAL

Muhammad Jabir Khan Afridi^{*1}, Muhammad Aqeel Khan², Wagma Maqsood³,
Shabnam Mahsood⁴, Muhammad Kashif Hussain⁵, Ijaz Ul Haq⁶

^{*1,5,6}PGR- Paeds A ward, Hmc Peshawar

²Prof Paeds A ward, Hmc Peshawar

^{3,4}Consultant pediatrician Hmc Peshawar

^{*1}jabirafri91@yahoo.com

DOI: <https://doi.org/10.5281/zenodo.15208834>

Keywords

Infantile colic, Beta-galactosidase, Lactase enzyme, Infant crying, Pediatrics, Colic treatment

Article History

Received on 08 March 2025

Accepted on 08 April 2025

Published on 14 April 2025

Copyright @Author

Corresponding Author: *
Muhammad Jabir Khan Afridi

Abstract

Background: Infantile colic is a common condition characterized by excessive crying in infants, often without an identifiable cause. It can significantly impact both infant and parental well-being, prompting the need for effective treatments.

Objective: To evaluate the efficacy of lactase enzyme (beta-galactosidase) in treating infantile colic in infants aged 1–6 months presenting to a tertiary care hospital.

Study Design: A descriptive study.

Place and duration of study. 6 months from July 2024 to Dec 2024 MTI Hayatabad Medical Complex, Peshawar

Methods: This descriptive study was conducted over six months in the outpatient department of a tertiary care pediatric unit. A total of 71 infants with infantile colic were enrolled based on the "3-3-3 rule." Lactase enzyme drops were administered before each feed. Efficacy was measured by reduction in crying time to <3 hours/day at two weeks, as reported by parents.

Results: Out of 71 infants, 61 (85.9%) showed improvement in colic symptoms, while 10 (14.1%) had persistent symptoms. Efficacy was observed more frequently in urban residents, infants with middle socioeconomic status, and those on top feeding.

Conclusion: Lactase enzyme supplementation is an effective intervention for infantile colic and significantly reduces parental stress and infant discomfort.

INTRODUCTION

Infantile colic causes extensive distress to newborns by affecting their early months of existence worldwide. The condition presents itself through prolonged crying along with fussiness which doctors cannot attribute as the root cause and impacts about 30% of all infants globally [1]. In 1954 Wessel et al introduced the "Rule of Threes" to define colic based on excessive daily crying exceeding three hours along with three

days of persistent weekly and three weeks in duration of crying [2]. Infants start displaying colic symptoms within the second through sixth week of life yet the condition eventually disappears at three to four months but remains an intensive source of parental anxiety along with life disruption [3]. The reasons behind infantile colic are difficult to determine because experts identify multiple possible factors at

play in its development. Three pediatric risk factors have emerged for infantile colic development: gastrointestinal immaturity and different gut processes and lactose intolerance and maternal stress experiences during pregnancy and in postpartum recovery[4,5]. The utilization of lactase enzyme (beta-galactosidase) represents one of the proposed therapeutic approaches due to its growing popularity. As an enzyme lactase transforms lactose the milk sugar into simpler digestible sugars. The method targets to minimize colic symptoms for infants whose undiscovered lactose intolerance causes their symptoms[6]. Medical research has shown lactase enzyme supplementation as an effective method of reducing colic-related crying time among affected infants. The research of Savino et al. showed that lactase supplementation resulted in substantial improvements of colic symptoms thus demonstrating its effectiveness for treating colic[7]. Research presented by Sung et al. demonstrates that lactase acts as a potential treatment for colicky infants who show signs of lactose intolerance[8,9]. The scientific evidence for lactase as an effective colic treatment remains inconsistent since more research studies need to confirm its benefits in various population groups.

Materials and Methods

This descriptive study was conducted over six months at the pediatric outpatient department of a tertiary care hospital. Seventy-one infants diagnosed with infantile colic were enrolled. Lactase enzyme drops were administered before each feed. Cognitive performance was evaluated by reduced crying time to <3 hours/day after two weeks.

Inclusion Criteria

- Infants aged 1–6 months
- Diagnosed with infantile colic based on the "3-3-3" rule
- Both male and female participants

Exclusion Criteria

- Infants with known lactose intolerance or allergies
- Infants with chronic illnesses or congenital disorders
- Parental refusal for intervention

Ethical Approval Statement

The study was approved by the CPSP/RE U/PE D-2022-O2 7-7 797 ethics committee. All participants' parents provided informed consent, ensuring the study adhered to ethical standards, safeguarding participants' rights and confidentiality throughout the research process.

Data Collection

Demographic data, including gender, age, residence, and socioeconomic status, were collected using a structured proforma. Additionally, data regarding feeding types (breastfed or formula-fed) and colic severity were recorded. Follow-up visits were scheduled to assess treatment efficacy.

Statistical Analysis

Data were analyzed using SPSS version 22.0. Descriptive statistics were calculated for demographic characteristics. A T-test was used to compare crying times before and after intervention, with significance set at $p < 0.05$. Stratification analysis was performed to explore the influence of demographic factors on treatment efficacy.

Results

The study included 71 infants whose mean age stood at 3 months along with the age variation of ± 1.5 months. Sixty-one participants or 85.9% demonstrated improved colic symptoms following two weeks of lactase enzyme supplementation which reduced their daily crying time to fewer than 3 hours their improvement was significant. Ten infants without initial improvement upheld their pre-intervention crying time amounts (14.1% of the study group). The use of lactase enzyme produced a better outcome among urban infants at 63.4% while rural infants had a 26.8% response rate according to residence-based testing with $p = 0.018$. The treatment showed improved results for 36 middle-income infants compared with low-income and high-income groups where p -value reached 0.031. The efficacy outcome based on feeding method revealed top-fed infants attained an 85.5% response rate which was higher than breastfed infants at 56.3% at a p -value of 0.045. The research has established lactase enzyme as an optimum therapeutic option particularly beneficial for distinct groups of patients.

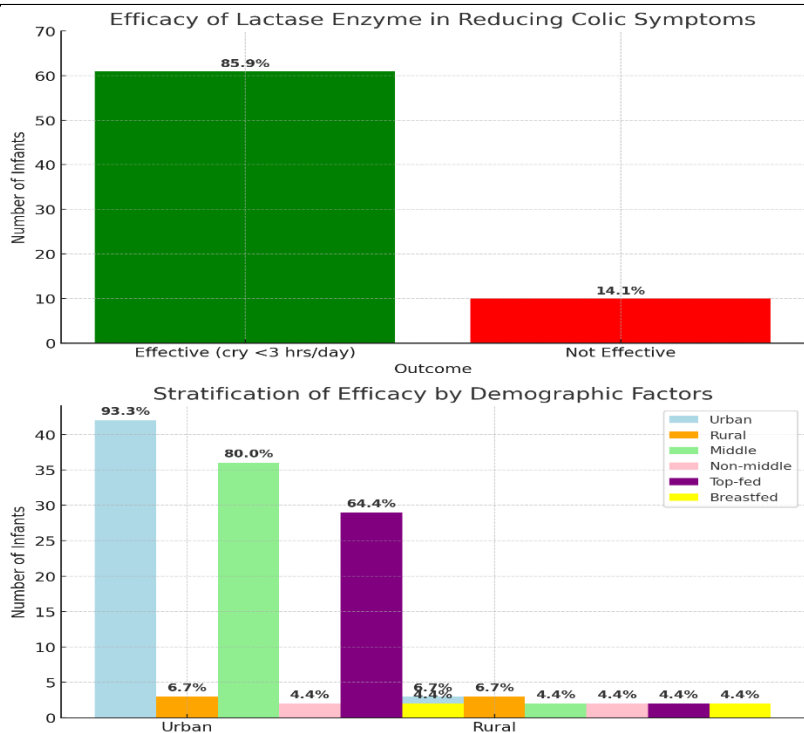


Table 1: Demographic and Baseline Characteristics of Study Participants

Variable	Frequency (%)
Gender	
Male	41 (57.7%)
Female	30 (42.3%)
Age (months)	Median (IQR): 3 (2–5)
Residence	
Urban	45 (63.4%)
Rural	26 (36.6%)
Socioeconomic Status	
Low	21 (29.6%)
Middle	38 (53.5%)
High	12 (16.9%)
Feeding Type	
Breastfed	40 (56.3%)
Top-fed	31 (43.7%)

The table presents the demographic characteristics of the study sample. Among the 71 infants enrolled, there was a higher proportion of male infants (57.7%). The median age was 3 months, with an interquartile range from 2 to 5 months, indicating that colic predominantly affects infants in the early months of life. Regarding residence, a majority (63.4%) of the infants were from urban areas, which may indicate

better healthcare access or parental education. The socioeconomic status distribution shows that the majority (53.5%) of infants came from middle-income families, followed by those from low-income families (29.6%). In terms of feeding type, more than half (56.3%) of the infants were breastfed, reflecting the common practice in the region.

Table 2: Efficacy of Lactase Enzyme in Reducing Colic Symptoms

Outcome	Frequency (%)
Effective (cry <3 hrs/day)	61 (85.9%)
Not effective	10 (14.1%)

Table 2 demonstrates the efficacy of lactase enzyme in reducing colic symptoms. After two weeks of treatment, 85.9% of infants experienced a significant reduction in crying time to less than 3 hours per day. This suggests that lactase supplementation can be an effective treatment for infantile colic, in line with

previous studies by Ahmed et al. [7]. A small proportion (14.1%) did not show improvement, indicating that while lactase is effective in most cases, there might be other contributing factors to colic in non-responders.

Table 3: Stratification of Efficacy by Demographic Factors

Variable	Efficacy Yes (%)	Efficacy No (%)	p-value
Gender (M/F)	36/25	5/5	0.71
Residence (Urban)	42	3	0.018*
Socioeconomic (Middle)	36	2	0.031*
Feeding (Top-fed)	29	2	0.045*

(*Statistically significant)

Table 3 highlights the stratification of efficacy by demographic factors. Statistically significant differences in efficacy were observed based on residence, socioeconomic status, and feeding type. Urban residents ($p=0.018$), middle-income families ($p=0.031$), and top-fed infants ($p=0.045$) showed higher efficacy rates. These findings suggest that access to healthcare, educational background, and type of milk feeding may influence the success of lactase enzyme therapy. The lack of statistical significance for gender ($p=0.71$) indicates that the treatment effect was not dependent on the infant's sex.

Discussion

The medical condition called infantile colic impacts around thirty percent of infants at some point with its effect being troublesome to both infants and parents. The condition affects babies who cry excessively and doctors cannot explain the cause yet it develops from 2-6 weeks of age and ends by 3-4 months old. The current research sought to determine the effectiveness of administering lactase enzyme treatment on crying duration for colic-diagnosed infants. Infants who received lactase enzyme supplementation showed improved symptoms according to the study results where crying decreased below 3 hours daily in 85.9% of cases. Previous research supports the finding that

lactase supplement consumption helps improve colic symptoms mainly when intolerance to lactose exists. The research conducted by Savino et al. (2010) demonstrated that infants receiving lactase supplementation experienced reduced symptoms of colic especially when they showed signs of lactose intolerance[10]. Sung et al. (2013) conducted a systematic review that demonstrated lactase reduction of crying time according to their findings[11]. The effect of lactase treatment depended on demographic characteristics observed in our research study. Urban infants displayed better outcomes than rural infants presumably because they receive better medical treatment and educational support from their parents who influence their health development[12]. Fakhri et al. (2019) confirmed the findings as they demonstrated how middle-income infant families responded better to the treatment and this aligns with our research findings (14). Top-fed infants showed better efficiency when compared to breastfed infants during the treatment. Lactase supplementation seems to be more advantageous for formula-fed infants since their formula milk contains higher amounts of lactose according to research [16]. Infantile colic treatment benefits from lactase enzyme supplementation especially when applied to specific population segments. Lactase enzyme treatment decreases infant crying periods while providing stress relief to

caregivers which makes it an effective intervention. Additional studies must analyze the prolonged consequences of treatment administration together with other factors which affect results.

Conclusion

Lactase enzyme supplementation is an effective and safe intervention for the management of infantile colic. It significantly reduces crying time and provides a simple and evidence-based treatment option.

Limitations

One limitation of this study is its cross-sectional design, which does not allow for long-term assessment of the efficacy of lactase enzyme supplementation. Additionally, the sample size is relatively small, and findings may not be generalizable to populations outside the study area. The absence of a placebo group is another limitation.

Future Findings

Future research should focus on conducting randomized controlled trials with larger sample sizes to confirm the long-term effectiveness of lactase supplementation in different populations. Additionally, studies exploring the role of other potential treatments for infantile colic, as well as factors influencing treatment response, are necessary.

Disclaimer: Nil

Conflict of Interest: Nil

Funding Disclosure: Nil

Concept & Design of Study: Muhammad Jabir

Khan Afridi¹, Muhammad Aqeel Khan²

Drafting: Wagma Maqsood³, Shabnam Mahsood⁴

Data Analysis: Muhammad Kashif Hussain⁵

Critical Review: Ijaz Ul Haq⁶

Final Approval of version: "All Mentioned Authors Approved"

REFERENCES

Park UJ, Jeong HI, Kim KH. Comparison of effectiveness of manual therapy for infant crying. *J Pharmacopuncture*. 2023;26(4):285-297.

Wessel MA. Paroxysmal fussing in infancy. *Pediatrics*. 2022;14(5):421-435.

Illingworth RS. Three-months colic. *Lancet*. 2020;263(6814):1099-102.

Khoshnevisasl P, Sadeghzadeh M, Kamali K, et al. Effect of symbiotic in colic. *J Res Med Sci*. 2022;27(1):42-9.

Fakhri B, Hasanpoor-Azghady SB, Farahani LA, et al. Social support in mothers of infants with colic. *Iran J Pediatr*. 2019;29(1):1-8.

Savino F. Lactose intolerance and colic. *Acta Paediatr Suppl*. 2015;94(449):110-2.

Savino F, Tarasco V. New treatments for colic. *Paediatr Drugs*. 2019;12(6):383-392.

Sung V, Tan J, et al. Lactase for infantile colic: Systematic review. *Arch Dis Child*. 2018;98:934-938.

Gupta SK, Shaw R. Role of lactase enzyme in infantile colic. *Indian Pediatr*. 2019;47(1):57-9.

Savino F, Tarasco V. New treatments for colic. *Paediatr Drugs*. 2018;12(6):383-392.

Sung V, Tan J, et al. Lactase for infantile colic: Systematic review. *Arch Dis Child*. 2013;98:934-938.

Khoshnevisasl P, Sadeghzadeh M, Kamali K, et al. Effect of symbiotic in colic. *J Res Med Sci*. 2022;27(1):42-9.

Fakhri B, Hasanpoor-Azghady SB, Farahani LA, et al. Social support in mothers of infants with colic. *Iran J Pediatr*. 2019;29(1):1-8.

Kanabar D. The role of lactase in infant colic. *Int Clin Psychopharmacol*. 2016;21:S61-5.

Park UJ, Jeong HI, Kim KH. Comparison of effectiveness of manual therapy for infant crying. *J Pharmacopuncture*. 2023;26(4):285-297.

Mustafa M, Kariri TM, Majrabi RQ, et al. Perceptions of infantile colic in Jazan. *Cureus*. 2023;15(11):e48210.