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Annals of Clinical and Analytical Medicine
Original Research

Assessment of demographic characteristics and their response to treatment of infants between 0-6 months diagnosed with lactose intolerance

Lactase intolerance in infants aged 0-6 months

Ekin Say[1] Özlem Üzüm[2] Tolga İnce[2] Belgin Ünal[3] Adem Aydın[2]

[1]Clinic of Pediatrics, Dr Behcet Uz Children Hospital, İzmir, Türkiye.
[2]Department of Pediatrics, Faculty of Medicine, Dokuz Eylül University, İzmir, Türkiye.
[3]Department of Public Health, Faculty of Medicine, Dokuz Eylül University, İzmir, Türkiye.

Abstract

Aim: Lactose intolerance is a clinical condition that affects both the infant and the family physically and mentally, and can also be seen in infants, adults, and children. Diagnosis is more difficult in infants than in children and adults. In this study, we aimed to assess 113 infants, aged 0-6 months, who respond to treatment, have lactose intolerance symptoms, and have received oral lactase treatment.

Methods: 113 infants aged 0-6 months with lactose intolerance, clinical symptoms, and positive stool-reducing substances who had started receiving oral lactase treatment were included in the study. The patients' demographic characteristics, symptoms, and lactase enzyme use were recorded and compared using appropriate statistical methods.

Results: It has been determined that 86.7% of infants utilize the lactase enzyme. No differences have been observed in birth weight, birth week, or gender in the utilization of the lactase enzyme. It has been observed that the longer the lactase enzyme utilization period, the greater the benefit (P = .01). No significant difference has been observed when the stool-reducing substance and stool pH level are compared to the utilization of the lactase enzyme.

Conclusion: The lactase utilization of infants with lactose intolerance who have clinical symptoms, positive stool-reducing substances, and who use lactase does not vary by gender, birth weight, or birth week. The utilization increases as the treatment period extends.

Keywords

colic, infant, lactase, lactose intolerance

DOI: 10.4328/ACAM.23027 Ann Clin Anal Med 2026;17(10):1005-1010
Received: 26.12.2025 Accepted: 09.03.2026 Published Online: 01.06.2026 Printed: 01.10.2026
Corresponding Author: Özlem Üzüm, Department of Pediatrics, Faculty of Medicine, Dokuz Eylül University, İzmir, Türkiye.
Email: baspinarozlemm@hotmail.com **P.:** +90 507 785 96 37
Corresponding Author ORCID: https://orcid.org/0000-0003-3297-7476
Other Authors ORCID: Ekin Say, https://orcid.org/0000-0001-7303-4074 • Özlem Üzüm, https://orcid.org/0000-0003-3297-7476 • Tolga İnce, https://orcid.org/0000-0001-6686-5208 • Belgin Ünal, https://orcid.org/0000-0002-4354-8266 • Adem Aydın, https://orcid.org/0000-0002-8480-2857

Introduction

Lactose intolerance is defined as the occurrence of one or more symptoms such as abdominal pain, diarrhea, nausea, gas, and bloating after the ingestion of lactose or lactose-containing foods.[1] These symptoms primarily result from impaired lactase–phlorizin hydrolase activity, leading to an enzyme deficiency that prevents lactose absorption in the small intestine. The unabsorbed lactose increases the intraluminal osmotic load, thereby increasing intestinal volume and fluidity, and is subsequently fermented in the colon, producing excessive gas.[1,2] In some patients, decreased intestinal motility leads to constipation rather than diarrhea.[2] Additional systemic manifestations such as headache, dizziness, impaired concentration, short-term memory difficulties, severe fatigue, musculoskeletal pain, allergic reactions, cardiac arrhythmias, oral ulcers, sore throat, and increased urinary frequency may also occur.[2]

Symptoms of lactose intolerance typically emerge 30 minutes to 1–2 hours following the ingestion of lactose-containing food products.[3,4] The amount of lactose required to induce symptoms varies widely among individuals. It is influenced by the quantity of lactose consumed, the degree of lactase deficiency, and the form in which lactose is ingested.[1,2] Diagnostic methods for lactose intolerance include hydrogen breath testing, low stool pH, the presence of stool-reducing substances, and small intestinal biopsy.[1,2] In exclusively breastfed infants with clinical suspicion and laboratory findings supporting lactose intolerance, treatment should prioritize continuation of breastfeeding while considering oral lactase replacement therapy.[1,5] In infants, lactase therapy is effective only when added to expressed breast milk or infant formula several hours before feeding.[1,6] A study conducted in premature infants demonstrated clinical benefit from lactose-reduced formulas and lactase-supplemented formulas.[7] The role of prebiotics and probiotics in lactose intolerance has shown inconsistent results across studies, and direct probiotic consumption has not demonstrated a clear therapeutic benefit.[8,9]

In this study, we aimed to evaluate the demographic characteristics and response to oral lactase therapy in infants aged 0–6 months who presented to our outpatient clinic with clinical findings suggestive of lactose intolerance and demonstrated positive stool-reducing substances.

Materials and Methods

Between January 2018 and September 2021, a total of 195 infants aged 0–6 months who presented to the Division of Social Pediatrics with clinical features suggestive of lactose intolerance and demonstrated positive stool-reducing substances were screened for study eligibility. Caregivers (parents or legal guardians) were contacted via phone or online platforms. Infants were excluded if caregivers could not be reached using the hospital registry contact information, if they declined to participate in the survey, or if they rejected or discontinued oral lactase therapy. After exclusions, data from 113 infants were included in the final analysis.

For each infant, sex, gestational age, birth weight, age at symptom onset, frequency of gastrointestinal symptoms, their relationship with breastfeeding, stool characteristics, age at initiation of lactase supplementation, duration of treatment, presence of additional symptoms (e.g., rash, erythema), and therapeutic response to lactase were recorded.

To confirm the presence of lactose intolerance in infants, fresh stool samples (evaluated no later than 1 hour after collection) were analyzed at the Tanyalçın Private Laboratory. Two milliliters of Benedict's solution were added to the samples and heated until a color change occurred. Samples were centrifuged for 5 minutes following boiling. A green–brown supernatant was interpreted as a positive test result. Stool acidity was assessed using pH indicator paper.

Ethical Approval

This study was approved by the non-interventional clinical research Ethics Committee of Dokuz Eylül University School of Medicine (Date: 03.11.2021, Decision No: 2021/31-19).

Statistical Analysis

Statistical analyses were performed using IBM SPSS Statistics version 24. Continuous variables were compared using the Mann–Whitney U test. Paired categorical variables (e.g., diarrhea/constipation, irritability) before and after treatment were evaluated using the McNemar chi-square test. A P value < 0.05 was considered statistically significant.

Reporting Guidelines

This retrospective observational study was reported in accordance with the STROBE guidelines.

Results

A total of 195 infants who presented with symptoms of lactose intolerance and demonstrated positive stool-reducing substances were initially planned for inclusion. However, 82 infants were excluded because caregivers declined participation, provided incomplete information, or refused/discontinued oral lactase therapy. Consequently, data from 113 infants were analyzed.

Table 1. Demographic Characteristics Of The Cases And Lactase Enzyme Treatment Data

Characteristics	*n* (%)	
Sex		
Girl	57 (50.4)	
Boy	56 (49.6)	
Comorbidities		
None	105 (92.0)	
Multiple food allergy	2 (1.8)	
Atopic dermatitis	1 (0.9)	
Pollen allergy	1 (0.9)	
Pulmonary stenosis	1 (0.9)	
Beta-thalassemia carrier	1 (0.9)	
Osteogenesis imperfecta	1 (0.9)	
Visual impairment	1 (0.9)	
Additional symptoms		
None	95 (84.1)	
Atopic dermatitis	5 (4.4.2.7)	
Facial erythema	3 (8.8)	
Rash	10	
Therapeutic benefit from lactase enzyme		
Benefited	98 (86.7)	
Not benefited	15 (13.3)	
	Mean ± SD	**Min–max**
Gestational age, we	37.91 ± 0.774	33–41
Birth weight, g	3026.05 ± 241.648	1500–4100
Age at initiation of lactase therapy, d	52.58 ± 32.992	8–179
Duration of lactase therapy, d	137.60 ± 95.200	30–450

Table 2. Gastrointestinal Symptom Profiles Of Infants

Variable	*n* (%)
Age at onset of gastrointestinal symptoms	
From birth	22 (19.5)
After 2–3 weeks of age	42 (37.2)
Between 1–3 months	41 (36.3)
Between 3–6 months	6 (5.3)
Unknown	2 (1.8)
Days per week symptoms occurred	
<3 days/week	15 (13.3)
>3 days/week	88 (77.9)
Duration of symptoms per day	
<3 hours/day	27 (23.9)
>3 hours/day	64 (56.6)
Initial stool characteristics at onset	
Watery, without blood	34 (30.1)
Loose–semi-solid, without blood	64 (56.6)
Initial stool frequency at onset	
<3/day	29 (25.7)
>3/day	58 (51.3)
Every 2–3 days	9 (8.0)
Once weekly	6 (5.3)
Unknown	11 (9.7)
Onset of symptoms after breastfeeding	
Within first hour	45 (39.8)
After 1 hour	29 (25.7)
Relationship between feeding amount and symptoms	
Symptoms increased	50 (44.2)
Symptoms decreased	35 (31.0)

The sociodemographic characteristics of the infants are summarized in Table 1. Of the participants, 50.4% were female, the mean gestational age was 37.91 ± 0.774 weeks, and the mean birth weight was 3026.05 ± 241.648 grams. While 92% of infants had no known medical history, 1.8% had multiple food allergies.

Regarding gastrointestinal symptoms, 37.2% of infants developed symptoms after 2–3 weeks of age, and the most common presentation was abdominal distension accompanied by irritability (58.4%). Gastrointestinal complaints occurred at any time of the day in 49.6% of cases and occurred more than three days per week in 77.9% of infants. Symptoms lasted longer than 3 hours per day in 56.6% of infants, and vomiting was reported in 31.9%.

Assessment of stool characteristics revealed that 56.6% of infants had stool consistency ranging from soft to loose, with no visible blood. Stool frequency exceeded three times per day in 51.3% of infants. Gastrointestinal symptoms began within the first hour after breastfeeding in 39.8% of infants, while 44.2% reported increased symptoms associated with breastfeeding. During this period, 84% of infants exhibited no additional symptoms, whereas atopic dermatitis was the most common accompanying finding (Table 2).

Stool-reducing substance positivity was ≤ 2 in 69.0% (*n* = 78) and ≥ 3 in 30.1% (*n* = 34) of infants; testing could not be performed in one infant. The stool pH was < 7 in 74.3% (*n* = 84) and ≥ 7 in 23.9% (*n* = 27); two infants lacked pH evaluation (Table 2, Supplementary Table 1).

The age of initiation of lactase therapy ranged from 8 to 179 days, with a mean initiation age of 52.58 ± 32.992 days. The duration of enzyme use ranged from 30 to 450 days, with a mean of 137.60 ± 95.20 days. Lactase supplementation was beneficial in 86.7% of infants, while 13.3% experienced no change in symptoms (Table 1).

When infants were grouped according to therapeutic response (benefited vs. not benefited), no statistically significant differences were found regarding gestational age, birth weight, sex, age at symptom onset, simultaneous presence of abdominal distension and irritability, weekly symptom frequency, stool frequency or consistency, relationship between breastfeeding and symptoms, presence of additional symptoms, timing of lactase initiation, or stool test parameters. However, infants who experienced symptoms throughout the day were more likely to benefit from lactase therapy than those whose symptoms appeared later in the day (*P* = .043). The duration of lactase use was significantly longer in the group that benefited from therapy (*P* = .001) (Table 3, Supplementary Table 2).

Discussion

Multiple factors have been investigated regarding the etiology of lactose intolerance. Studies have demonstrated that lactose intolerance is more frequently observed in infants born at or before 37 weeks of gestation. These findings have been attributed to the progressive maturation of intestinal structure and microbiota over

Table 3. Demographic Findings And Symptom Characteristics Of Patients Who Benefited And Did Not Benefit From Lactase Enzyme Therapy

Variable	Benefited (%)	Not benefited (%)	P value
Gender			**.810**
Female	49 (86)	8 (14)	
Male	49 (87.5)	7 (12.5)	
Age at symptom onset			**.782**
<1 month	56 (87.5)	8 (12.5)	
≥1 month	42 (85)	7 (15)	
Abdominal distension + irritability			**.322**
Single symptom	59 (89.3)	7 (10.7)	
Both present	39 (83)	8 (17)	
Time of most intense symptoms			**.043**
Throughout the day	52 (92.8)	4 (6.2)	
Later in the day	43 (79.6)	11 (20.4)	
Duration of lactase therapy, d	**148.33 ± 97.43**	**68.57 ± 29.83**	**.001**

time, which enhances lactose absorption as infants grow older. Previous studies have also shown no significant differences in the prevalence of lactose intolerance between sexes.[10,11] Since only infants who had already been diagnosed were included in the present study, prevalence could not be evaluated. Nevertheless, despite literature suggesting associations between gestational age and sex and disease frequency, our findings indicate that these factors were not associated with therapeutic response to lactase enzyme supplementation.

In a study by Liebman and colleagues involving 56 infants with prominent colic symptoms, no correlation was found between clinical symptoms and stool pH or stool-reducing substance positivity.[1,12] In contrast, in our cohort, stool-reducing substance results ranged from 1+ to 5+, and the overall response rate to lactase therapy was 86.7%. This remarkably high proportion suggests that, when accompanied by clinical symptoms, positive stool-reducing substance findings support lactose intolerance in infants. Regarding stool acidity, pH values among our patients ranged from 5 to 8. When stool-reducing substance positivity and stool pH were evaluated individually for their association with treatment response, no statistically significant differences were detected. This finding indicates that the effectiveness of lactase supplementation is not dependent on stool-reducing substance levels or stool pH.[3]

Lactose intolerance clinically resembles infantile colic. According to Wessel's definition, infantile colic is a symptomatic disorder characterized by irritability, agitation, or prolonged crying episodes lasting more than 3 hours per day, occurring more than 3 days per week for at least 3 weeks in an otherwise healthy infant. Based on these criteria, infants classified as having colic due to gastrointestinal symptoms that persist more than 3 days per week should be reevaluated for lactose intolerance.[12,13] In our cohort, 49.6% of infants experienced symptoms throughout the day, and no significant difference in lactase benefit was observed between those who experienced symptoms continuously and those who experienced symptoms later in the day. Gastrointestinal complaints persisted more than 3 days per week in 77.9% of infants, and therapeutic response was similar across symptom frequency groups. Overall, the predominance of symptoms that persist throughout the day, last more than 3 days per week, and exceed 3 hours per day strongly supports lactose intolerance as the underlying condition.

Furthermore, the literature reports that among infants with a diagnosis of colic who received lactase therapy, 26% showed improvement, accompanied by a significant reduction in crying duration. These findings suggest that infantile colic may have multiple etiologies and that lactose intolerance may play a significant role in this group. Therefore, the use of lactose-free formulas or lactase supplementation in breastfed infants may provide meaningful symptomatic improvement in selected cases.[14,15]

Another gastrointestinal disorder, cow's milk protein allergy (CMPA), most commonly seen during the first six months of life, also clinically resembles lactose intolerance. Although both intolerance and allergy are considered unexpected reactions to food, their mechanisms differ. Lactose intolerance results from enzyme deficiency and/or absence, whereas CMPA arises from an immune-mediated hypersensitivity response to milk protein.[6] Both conditions may present with gas, chronic diarrhea, and abdominal pain; however, CMPA more frequently presents with rectal bleeding, growth delay, atopy, or anaphylaxis, while lactose intolerance may be accompanied by perianal rash. Accordingly, CMPA requires elimination of cow's milk protein, whereas lactose intolerance is managed by dietary lactose restriction and/or lactase supplementation.[3,16,17]

In our cohort, 15.9% of infants exhibited atopic features such as erythema or rash. However, therapeutic benefit was similar in infants with and without additional symptoms, and caregivers did not report worsening of concomitant symptoms. This finding suggests that although lactose intolerance and CMPA may coexist, the presence of clinical improvement following lactase supplementation indicates that lactose intolerance is likely the dominant etiology in infants presenting with overlapping symptoms.[16]

Several explanations have been proposed regarding the decrease in lactose intolerance symptoms with advancing age. For instance, a study by Briet et al. involving 46 adult patients diagnosed with lactose intolerance reported that continuous lactose exposure reduced hydrogen production and the severity of gastrointestinal symptoms. The authors stated that this effect may not always reflect increased lactase activity but instead may represent an adaptive response driven by intestinal microbial composition and alterations in colonic function.[18]

Similarly, lactase activity in the intestine is known to mature particularly between the 24th and 40th gestational weeks. Therefore, lactase activity is used as a marker of intestinal maturation in infants born before 40 weeks of gestation. In an experimental study by Lebenthal and colleagues conducted in mice, lactase activity increased as breastfeeding duration increased.[19] Based on these findings, it may be hypothesized that increasing intestinal maturation after birth or prolonged breastfeeding may enhance lactase activity, thereby increasing the benefit of lactase supplementation. Alternatively, it may be suggested that parents extend lactase use because they observe clinical improvement.

Another proposed explanation is that lactase levels are naturally very low in neonates, and that breast milk production—stimulated by infant suckling—leads to a gradual increase in lactose synthesis, which may induce a parallel increase in intestinal lactase enzyme activity.[20] Consistent with this, our study demonstrated that the therapeutic benefit increased with longer lactase use. Although no strict standards exist regarding treatment duration, previous studies have advocated the necessity of at least 14 days of therapy.[20] These findings suggest that regular, consistent lactase supplementation improves clinical effectiveness, and this benefit may be partially attributable to intestinal adaptation, as supported by the literature.

Among current therapeutic approaches for lactose intolerance, lactose-free formulas are frequently utilized, and studies report improvement or resolution of symptoms in infants fed with such products. However, no long-term studies exist evaluating potential growth impairment in these infants.[21] In exclusively breastfed infants, treatment should prioritize continuing breastfeeding, and oral lactase supplementation may be more beneficial than discontinuing breast milk, which remains the most valuable nutritional source.[1] In our study, 86.7% of infants benefited from lactase therapy. In the literature, studies conducted in adults diagnosed with lactose intolerance have demonstrated favorable clinical responses to oral lactase supplementation.[22,23] One study further reported that 94% of physicians preferred lactase enzyme therapy, and 34.5% advocated prophylactic lactase supplementation in symptomatic and/or high-risk newborns, even without diagnostic confirmation.[20]

Studies on infants and children remain limited, largely due to diagnostic challenges in infancy and difficulties with treatment adherence. In studies of premature infants, lactase supplementation was associated with significant improvements in clinical symptoms, stool-reducing substances, and stool pH.[24] Consistent with these findings, our study also demonstrated a high rate of therapeutic benefit, and continuation of breastfeeding was successfully maintained.

In conclusion, although the demographic profiles of exclusively breastfed infants presenting with lactose intolerance symptoms share clinical similarities with other conditions, the persistent nature of symptoms throughout the day, the low frequency of accompanying findings, and the significant benefit observed with regular and prolonged lactase supplementation support the use of oral lactase therapy in such cases, independent of gestational age, birth weight, sex, age at symptom onset, and symptom combinations.

Limitations

Lactose intolerance is often confused with many infant diseases due to clinical similarities. This leads to diagnosis in infants during the later stages of symptoms. In this study, because patients were examined retrospectively using clinical follow-up, interpretations were based on information recalled by parents. This is considered the most limiting aspect of our study.

Conclusion

Although many factors influence the clinical presentation of lactose intolerance, the absence of any association between clinical benefit and demographic or symptom-related variables—other than treatment duration—suggests that oral lactase supplementation should be supported in clinically suspected and laboratory-confirmed cases. The persistence of symptoms throughout the day, the low frequency of accompanying findings, and the significant benefit observed with regular and prolonged lactase use indicate that oral lactase therapy can be considered in exclusively breastfed infants presenting with symptoms of lactose intolerance, regardless of gestational age, birth weight, sex, age at symptom onset, or symptom combinations.

Declarations

Animal and Human Rights Statement

All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Declaration of Helsinki and its later amendments, or comparable ethical standards.

Informed Consent

Due to the retrospective design of the study, the requirement for informed consent was waived by the ethics committee.

Data Availability

The datasets used and/or analyzed during the current study are not publicly available due to patient privacy reasons but are available from the corresponding author on reasonable request.

Conflict of Interest

The authors declare no conflict of interest.

Funding

None.

Author Contributions (CRediT Taxonomy)

Conceptualization: E.S., Ö.Ö., A.A.
Methodology: E.S., T.İ., B.Ü.
Software: E.S., T.İ.
Validation: Ö.Ö., A.A.
Formal analysis: E.S., Ö.Ö.
Investigation: E.S., Ö.Ö.
Resources: E.S., T.İ.
Data curation: T.İ., B.Ü., A.A.
Writing – original draft: E.S., Ö.Ö.
Writing – review & editing: E.S., B.Ü., A.A.
Visualization: T.İ., A.A.
Supervision: Ö.Ö., T.İ., A.A.
Project administration: E.S., B.Ü.
Funding acquisition: E.S., B.Ü.

AI Usage Disclosure

The authors declare that no AI-assisted technologies were used.

Abbreviations

CMPA: Cow's milk protein allergy
STROBE: Strengthening the reporting of observational studies in epidemiology

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How to Cite

Ekin Say, Özlem Üzüm, Tolga İnce, Belgin Ünal, Adem Aydın. Assessment of demographic characteristics and their response to treatment of infants between 0-6 months diagnosed with lactose intolerance. Ann Clin Anal Med 2026;17(10):1005-1010. doi:10.4328/ACAM.23027