

Prevalence and Severity of Gastroesophageal Reflux Disease in Indian Children Presenting with Symptoms of Acid Reflux: A Real-world Evidence Study

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Gastroesophageal reflux (GER) refers to the backward flow of stomach contents into the esophagus, which may or may not involve regurgitation or vomiting. This condition is typically physiological and frequently diagnosed in infants and early childhood. Approximately 50% of infants under 2 months of age experience GER, with peak incidence at 3–4 months (60–70%). The incidence of GER reduces to 5% by the age of 1 year. Most GER episodes are brief, infrequent, and asymptomatic, thus not leading to complications.¹ Conversely, gastroesophageal reflux disease (GERD) presents as symptoms or complications associated with pathological GER. Gastroesophageal reflux disease affects only 5–9% of infants with GER but gradually increases in prevalence, reaching 20% by adolescence, comparable to prevalence rates in adults.² Differentiating GERD from GER in children is challenging due to the lack of a definitive diagnostic test.³ Large-scale assessment is easier through symptom evaluation rather than the use of tedious and expensive diagnostic tests. The most common approach for assessing GERD is based on the reported symptoms.⁴ Younger children present with primary symptoms of GERD like vomiting along with poor weight gain or other symptoms like feeding refusal, generalized irritability, excessive crying, poor sleep, etc., due to pain associated with esophagitis. Hence, to diagnose true cases of GERD, it is imperative to distinguish pathological causes of acid reflux from physiological GER.² Infant Gastroesophageal Reflux Questionnaire Revised (I-GERQ-R) is a validated 12-item multiple-choice questionnaire used to assess GER symptoms, with a score of ≥ 16 suggestive of GERD.⁵ The I-GERQ-R may not only be used for diagnosing GERD but also helps differentiate cases from those without sufficient symptoms for the confirmed diagnosis and also to monitor treatment outcomes.⁶ Currently, acid suppressants like Histamine type 2-receptor antagonists (H2RAs, e.g., Ranitidine, Famotidine, etc.) and proton pump inhibitors (PPIs, e.g., Lansoprazole, Omeprazole, Esomeprazole, etc.) are widely used for the management of GERD even in pediatric patients.⁷ Thus, I-GERQ-R would be a suitable tool to also prevent the unnecessary prescription of potent acid suppressants like PPIs in otherwise symptomatic patients who could be misdiagnosed as having GERD. The primary objective of this study was to determine true cases of GERD with the help of I-GERQ-R in pediatric patients presenting with symptoms of acid reflux (SAR) in the outpatient department (OPD) in India and to grade the severity of the disease ranging from mild-to-severe categories Table 1.

Hence, with great interest, we conducted a study to investigate the prevalence and severity of GERD in 1987 children aged 1–24 months who presented with SAR in OPD from August 2023 to March 2024. Children presenting with typical symptoms of GERD were eligible for the study. This study, spanning 643 centers across India, employed the I-GERQ-R. Parents or caregivers of children presenting with SAR were approached during their regular check-ups, and those who expressed their interest, the I-GERQ-R was surveyed. Parents or primary

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Table 1. Percentage Prevalence of Gastroesophageal Reflux Disease and Subgroups Based on Severity in Pediatric Patients (age-group wise (months)) Depending on Infant Gastroesophageal Reflux Questionnaire Revised Scores

Groups	Age Group (months) (%)			
	1- 6	7-12	13-18	19-24
GERD	37.78	36.93	30.95	19.50
<i>Subgroup Based on Severity</i>				
Mild to moderate	49.73	59.63	65.02	66.67
Moderate to severe	21.93	20.50	12.81	14.10
Severe	28.34	19.88	22.17	19.23

GERD, gastroesophageal reflux disease.

caregivers filled out the I-GERQ-R, and scores ≥ 16 were considered indicative of GERD. Severity was evaluated by physicians based on I-GERQ-R scores, with higher scores indicating more severe GERD symptoms.

Our findings revealed that GERD prevalence among children with SAR in OPD was 31.66%, with most cases being mild to moderate in severity. The prevalence of GERD was highest in infants below 1 year of age and reduced to approximately 20% by 2 years of age (Table 1). On the contrary, 68.34% of patients were symptomatic with possibly no GERD and presented with reflux-like symptoms. The authors concluded that the prevalence of GERD in Indian children aged between 1 and 24 months who frequently present with SAR in OPD is low, with mild-to-moderate symptoms occurring in more than 50% of patients.

The I-GERQ-R serves as a reliable screening tool, supplementing clinicians' assessment of true cases of GERD and their severity from those presenting with SAR in resource-limited countries like India. This screening tool would also help prevent the unnecessary prescription of acid suppressants in pediatric patients by clinicians. The 2020 API-ISG guidelines for managing GERD in India recommend treating mild/infrequent GER symptoms with H2RAs and/or antacids (Level I Grade A) and avoiding long-term PPI use due to potential adverse effects, including increased risk of infections, fractures, kidney disorders, and nutrient deficiencies.⁸ This recommendation is corroborated by a recent study conducted on 250 Indian children, where 86.2% of children were routinely co-prescribed PPIs inappropriately with steroids or NSAIDs. Alarming, 58.4% of children who had been prescribed a PPI did not have a diagnosis that could possibly warrant a PPI, suggesting that several physicians added PPIs to their prescriptions in a blanket manner.⁹ A guidance document highlighted higher incidences of GI and non-GI side effects with long-term PPI use compared to H2RAs like Ranitidine or Famotidine. The expert panel recommended H2RAs for acid suppression due to fewer side effects compared to PPIs (Level I Grade A strong). Additionally, the recommendations of the Pediatric Gastroenterology Chapter of the Indian Academy of Pediatrics and the Indian Society of Pediatric Gastroenterology, Hepatology and Nutrition (ISPGHAN) also suggest the use of H2RAs like Ranitidine, in contrast to PPIs, for on-demand use due to their rapid onset of action, providing immediate relief of symptoms in otherwise symptomatic children.¹⁰ Hence, efforts should be made to promote the judicious use of PPIs in children, only in confirmed cases of GERD and erosive esophagitis and to avoid unnecessary use during acute

episodes of nausea and vomiting in cases unrelated to acid peptic disorders.^{7,11,12}

Limitations of our study include—first, oesophageal 24-hour pH/impedance reflux monitoring and upper endoscopy were not performed, which have the highest sensitivity and specificity. However, the use of such diagnostic tests routinely in such a large population-based cohort study in resource-limited settings poses a practical challenge. Second, we only analyzed using I-GERQ-R, while there are several other questionnaires for GERD diagnosis. However, using all of them together may lead to high heterogeneity, and I-GERQ-R is a validated questionnaire commonly used for infants and younger children. Thus, we had to choose only 1 questionnaire for the study.

In conclusion, diagnosing GERD in pediatric patients is often challenging. Our study found a low prevalence of GERD among children with SAR in Indian OPDs, with mild-to-moderate symptoms being most common. These findings and the best available evidence may lead to changes in diagnosing and treating pediatric GERD in India. Further research is needed to assess GERD prevalence in older children using similar validated tools.

Data Availability Statement: The data that support the findings of this study are available on request from the corresponding author.

Informed Consent: Written informed consent was obtained from the primary caregivers before starting the I-GERQ-R data collection.

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