International Journal of Research in Medical Sciences
Ramakrishnan SR et al. Int J Res Med Sci. 2026 Apr;14(4):1518-1525
www.msjonline.org
pISSN 2320-6071 | eISSN 2320-6012
DOI: https://dx.doi.org/10.18203/2320-6012.ijrms20260962

Original Research Article

A multicenter and post-marketing surveillance study to evaluate the safety and effectiveness of a sodium alginate-based raft-forming antacid oral suspension in Indian patients with heartburn and indigestion

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Received: 21 January 2026
Revised: 17 February 2026
Accepted: 23 February 2026

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ABSTRACT

Background: This study evaluated the safety and effectiveness of a sodium alginate-based raft-forming antacid oral suspension in Indian patients with heartburn and indigestion.
Methods: This multicenter post-marketing surveillance study, conducted across five centers in India, included adult patients with heartburn and indigestion prescribed a sodium alginate-based antacid suspension (10-20 ml after meals and at bedtime) for 7 days. Patients were evaluated on day 8 (±2). Effectiveness was assessed by adequate symptom relief, improvement in RDQ frequency and severity scores, reduction in symptom duration, and improvement in night-time symptoms. Safety was evaluated based on reported adverse drug reactions and global tolerability assessments by patients and investigators.
Results: Of 319 enrolled patients, 297 completed the study. After 7 days, adequate relief was reported by 95.6% for heartburn and 96.6% for indigestion. RDQ frequency and severity scores significantly improved (both ~74-76% reduction; $p<0.0001$), with marked reductions in daily symptom duration and nighttime episodes. Only one non-serious, unrelated ADR was reported, and tolerability was rated "good" by ~90% of patients and investigators.
Conclusions: The sodium alginate-based raft-forming antacid oral suspension provided effective relief of heartburn and indigestion, reflected by greater than 95% adequate relief rates, over 74% reductions in RDQ scores and marked decreases in symptom duration, with an acceptable safety and tolerability profile during the course of the study.

Keywords: Alginate-based antacid, Dyspepsia, Gastric acid, Gastric regurgitation, Heartburn

INTRODUCTION

Heartburn and Indigestion are typical symptoms of Reflux disorders.[1] Consistent with the central role of gastric acid in the genesis of reflux symptoms, the inhibition of gastric acid secretion with proton pump inhibitors (PPIs) has been the mainstay of the medical management of reflux disorders.[2] However, symptoms persist in up to 45% of patients despite PPI therapy.[3] In non-erosive reflux disease, 50% to 65% of patients do not respond to PPI therapy.[4] Therefore, other therapeutic agents are needed for adequate relief of heartburn and indigestion in patients with refractory symptoms.

The World Gastroenterology Organisation (WGO) recommends antacids, alginates, and acid suppression therapy, apart from adherence to family practitioners' advice and lifestyle management for the relief of breakthrough symptoms of heartburn.[5]

Alginate-based antacids displace or eliminate the postprandial acid pocket.[6] Alginate forms a rigid raft of alginic acid in the stomach reducing gastric reflux. Sodium bicarbonate reacts with gastric acid, producing carbon dioxide, which is retained in the alginate gel and allows the raft to rise to the surface of the gastric contents and creates a relative pH-neutral barrier.[7] Calcium ions from calcium carbonate link the alginic acid molecules and strengthen the raft.[8,9] Alginates prevent gastric reflux, inhibit pepsin and bile acids, and protect the esophageal mucosa.[10] Alginate-based formulations act more rapidly than PPIs and H2 antagonists and provide longer-lasting relief from symptoms like heartburn and indigestion than conventional antacids.[9,10]

The sodium alginate-based antacid oral suspension contains a combination of sodium alginate 250 mg, sodium bicarbonate 133.5 mg, and calcium carbonate 80 mg per 5 ml oral suspension. This oral suspension is approved for the treatment of heartburn and indigestion in India.[11] However, there are no post-marketing safety and effectiveness data, especially in the Indian population. We conducted this post-marketing surveillance study to show the safety, tolerability, and effectiveness of this sodium alginate-based antacid oral suspension in Indian adult patients with heartburn and indigestion.

METHODS

Study design

This was a prospective, post-marketing surveillance study conducted at five sites across India from July 2021 to March 2022. The study was approved by the independent ethics committee at each site and conducted in compliance with International Committee on Harmonization of Good Clinical Practice and local regulatory requirements to assure that the rights, safety, and well-being of the participants were protected, consistent with the ethical principles that have their origin in the Declaration of Helsinki. This study was registered in the Clinical Trials Registry- India with the registration number CTRI/2021/04/033028 on 22 April 2021.

Participants

Male and female patients aged 18 to 60 years (inclusive), with heartburn and indigestion who were prescribed the sodium alginate-based antacid oral suspension as per the approved label in accordance with the clinical practice, and who signed the patient authorization form were included in the study. Patients on highly restricted salt/sodium diet; patients with hypercalcemia, nephrocalcinosis, or recurrent calcium-containing renal calculi; patients with known or suspected hypersensitivity to the active substance or any of the excipients; or patients with any other conditions or diseases that an investigator considered inappropriate for enrolment were excluded from the study. Patients taking any medications with a potential to interfere with the action of the study treatment prior to the start of the study, female patients who were pregnant or nursing, and patients who were determined to be at risk for COVID-19 were also excluded from the study.

Study endpoints

The primary endpoints of the study were: 1) proportion of patients with treatment-emergent adverse drug reactions (ADRs) and/or other pharmacovigilance-relevant information (OPRI), 2) proportion of patients who discontinued study treatment due to ADRs and/or OPRI, and 3) global tolerability assessment by patients and investigators after 7 days of treatment.

The secondary endpoints were: 1) percentage of patients achieving adequate heartburn and indigestion relief after 7 days of treatment, 2) change in reflux disease questionnaire (RDQ) total score from baseline to 7 days after treatment, 3) change in total duration of heartburn and indigestion from baseline to 7 days after treatment, and 4) percentage of patients who experienced night-time heartburn and indigestion in the preceding night from baseline to 7 days after treatment.

Treatment and study assessments

The study involved clinical assessments of patients at baseline visit (day 1, visit 1) and after 7 days of treatment (day 8+2, visit 2). The sodium alginate-based antacid oral suspension was prescribed by the investigator as a part of routine clinical practice, independent of the decision to include the patient in the study.

Patients were prescribed the sodium alginate-based antacid oral suspension, Digeraft™ (10-20 ml after meals and at bedtime) for 7 days as per the approved label. A diary was provided to each patient to record their clinical symptoms. If the clinical symptoms did not improve after 7 days, the patient's clinical situation was reviewed by the investigator. Patients were advised to consider a time interval of 2 hours between the administration of the study treatment and other medicinal products.

All ADRs were collected throughout the study period and coded using medical dictionary for regulatory activities version 23 or higher. A treatment-emergent ADR was defined as a noxious and unintended response to the study treatment that was absent before exposure to the investigational product or any pre-existing event that worsened following exposure to the investigational product. Other pharmacovigilance-relevant information (OPRI) was also collected throughout the study period. This included product overdose, abuse, misuse, off-label use, occupational exposure, medication errors, lack of

therapeutic efficacy, suspected transmission of an infectious agent, and unexpected therapeutic or clinical benefit from use of the product.

Global tolerability assessment to study medication was done independently by the patients and by investigators for all patients on day 8 (+2 days) on a 3-point scale where 0 = good tolerability (side effects mild or not observed), 1 = moderate tolerability (side effects of moderate intensity), or 2 = poor tolerability (side effects severe or leading to discontinuation).

Adequate relief from heartburn and indigestion was defined as no more than 1 day of mild heartburn and indigestion episodes (based on the 4-point severity scale) during the 7 days after the baseline visit. Mild heartburn and indigestion was defined as presence of symptoms that were easily tolerated with minimal discomfort and not affecting any normal activities. Patients were asked to record the severity of heartburn and indigestion during the 7 days after the baseline visit. The severity of heartburn and indigestion was rated on a 4-point scale where score 0 = no symptoms, 1 = mild symptoms (easily tolerated, with minimal discomfort and not affecting normal activities), 2 = moderate symptoms (sufficient to affect normal activities), or 3 = severe symptoms (markedly affecting normal activities).

Patients were asked to report the frequency and severity of their upper gastrointestinal symptoms consisting of heartburn, regurgitation, and dyspepsia using the 12-item RDQ.[18] Response options were graded on a 6-point Likert scale with scores ranging from 0 to 5 for frequency ("did not have" to "daily") and severity ("did not have" to "severe"). The RDQ scores range from 0 to 30. Each patient's score was calculated as the mean of item responses, with higher scores indicating more severe or frequent symptoms.

No additional tests or interventions were suggested; however, investigations done as a part of routine clinical check-up per the investigator's routine medical practice were captured.

Statistical analyses

Sample size was calculated based on the rate of treatment-emergent adverse events (TEAEs). The maximum TEAE rate for sodium alginate is 5.5%, i.e., 5.5% of the enrolled patients were expected to have one or more TEAEs.[19,20] Considering the same rate with 2.5% precision at 95% confidence, the required sample size was 320. The sample size calculation was performed using two-sided binomial distribution.

The enrolled population set included all patients who met the eligibility criteria and were enrolled in the study. The full analysis set (FAS) included all enrolled patients who received at least one dose of the study treatment and had one post-baseline data for at least one efficacy parameter. The safety analysis set included all enrolled patients who received at least 1 dose of the study treatment. The per protocol set (PPS) included all enrolled patients who completed the study as per the protocol.

All the primary endpoints were summarized using the safety analysis set. Descriptive summaries were provided for analysis of treatment-emergent ADRs and OPRI, ADRs and/or OPRI leading to discontinuation of the study treatment, and global tolerability assessment. All categorical variables were summarized as frequency and percentages.

Secondary endpoints were summarized using FAS and PPS. Paired t-test was used to evaluate the difference in RDQ total score at baseline and after 7 days of treatment, and the difference between total duration of heartburn and indigestion at baseline and at 7 days post-treatment. Statistical testing was two-sided and was performed using a significance (alpha) level of 0.05. Analysis of patients achieving adequate relief from heartburn and indigestion after 7 days of treatment and patients who experienced night-time heartburn and indigestion in the night preceding baseline and 7 days after treatment was performed using descriptive statistics as frequency and percentages.

Continuous variables were summarized descriptively as the number of patients, mean, and standard deviation (SD).

Statistical analyses were performed using SAS (version 9.4 or higher) software (SAS Institute Inc., USA).

RESULTS

Patient disposition and baseline characteristics

A total of 320 patients were screened and 319 patients were enrolled in the study. Only 297 patients took the sodium alginate-based antacid oral suspension as prescribed by the investigator (Figure 1). These patients also maintained records in the diary dispensed on the day of enrolment. The FAS, safety analysis set, and PPS used for statistical analyses had 297 patients. All protocol deviations in the study were considered to be minor; hence, FAS and PPS included the same number of patients.

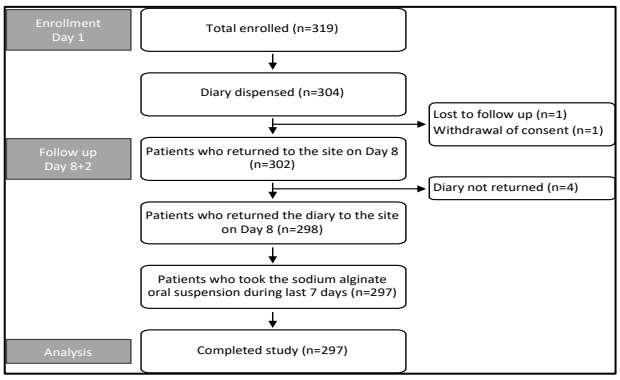

Figure 1: Patient disposition.

Table 1: Patient demographics and baseline characteristics (n=319).

Demographics,	N (%)
Gender	
Female	125 (39.18)
Male	194 (60.82)
Race	
Asian	319 (100)
Characteristics, mean (SD)	
Age (years)	38.29 (10.93)
BMI (kg/m^2)	24.29 (3.26)
Medical history	
System organ class/preferred term	
Patients with any medical history	23 (7.21)
Endocrine disorders	1 (0.31)
Hypothyroidism	1 (0.31)
Gastrointestinal disorders	2 (0.63)
Dyspepsia	1 (0.31)
Constipation	1 (0.31)
Injury, poisoning and procedural complications	1 (0.31)
Joint injury	1 (0.31)
Metabolism and nutrition disorders	8 (2.51)
Diabetes mellitus	6 (1.88)
Dyslipidemia	1 (0.31)
Hyperlipidemia	1 (0.31)
Musculoskeletal and connective tissue disorders	3 (0.94)
Arthralgia	1 (0.31)
Back pain	1 (0.31)
Osteoarthritis	1 (0.31)
Nervous system disorders	1 (0.31)
Diabetic neuropathy	1 (0.31)
Respiratory, thoracic and mediastinal disorders	1 (0.31)
Oropharyngeal pain	1 (0.31)
Surgical and medical procedures	1 (0.31)
Female sterilization	1 (0.31)
Vascular disorders	5 (1.57)
Hypertension	5 (1.57)

BMI- body mass index; n- number of patients in the enrolled population set; N- number pf patients; SD- standard deviation.

Table 1 gives the patient demographics and baseline characteristics. The proportion of males was higher than females (60.82% males and 39.18% females), and the mean (SD) age for the enrolled population was 38.29 years (10.93). In the enrolled population set, 23 (7.21%) patients had a medical or surgical history. The most prevalent diagnoses were metabolic and nutritional disorders in eight (2.51%) patients, and vascular disorders in five (1.57%) patients.

Effectiveness of the sodium alginate-based antacid oral suspension

All the 297 patients from the FAS were also included in the PPS; hence, results were identical for the two analysis sets.

Adequate heartburn and indigestion relief

By day 8, 95.62% patients (284/297) achieved adequate relief from heartburn, and 96.63% (287/297) achieved relief from indigestion.

Change in RDQ (frequency and severity) total score

Mean RDQ frequency and severity scores decreased by 76.3 % and 74.0 %, respectively, versus baseline (Figures 2 and 3; p<0.0001 each).

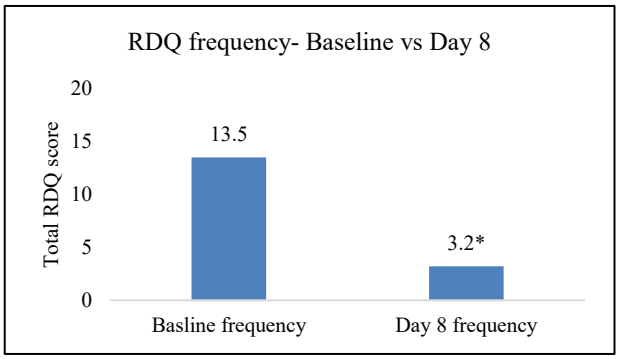

Figure 2: Mean RDQ frequency at baseline and on day 8 visit (full analysis set/per protocol set).

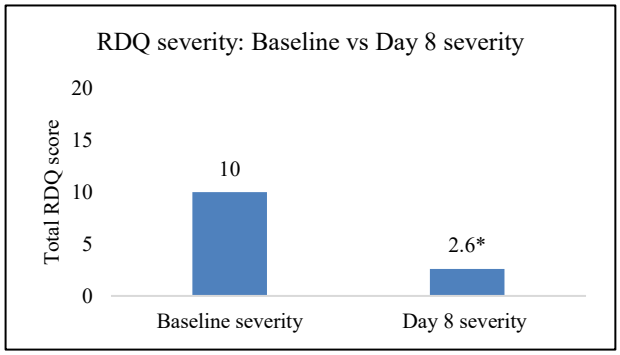

Figure 3: Mean RDQ severity at baseline and on day 8 visit (full analysis set/per protocol set).

Data are presented as mean (bar). A two-sided paired t-test was used for statistical analysis. RDQ: reflux disease questionnaire; * p<0.0001 versus baseline.

Change in total daily duration of heartburn and indigestion

At day 8, the mean (±SD) total daily heartburn duration decreased from 2.5±1.70 hours at baseline to 0.9±0.88 hours, representing an absolute reduction of 1.6±1.78

hours and a 64.0 % relative decrease (p<0.0001). The corresponding mean total daily indigestion duration decreased from 2.3±1.73 hours to 1.1±1.18 hours, an absolute reduction of 1.2±1.61 hours and a 52.2% relative decrease (p<0.0001). These findings are illustrated in Figures 4 and 5, and night-time symptom data are summarised in Table 2.

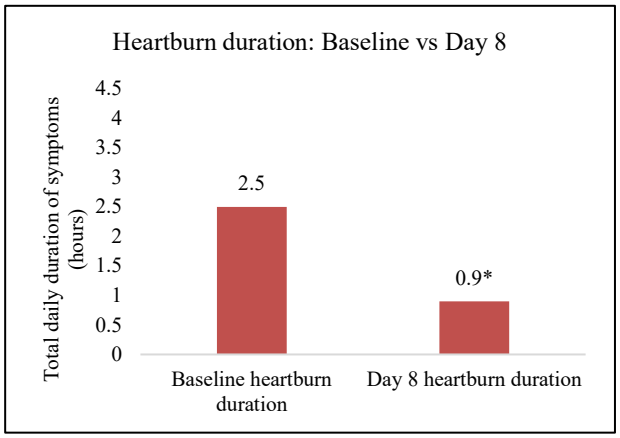

Figure 4: Total duration of heartburn at baseline and on day 8 visit (full analysis set/per protocol set).

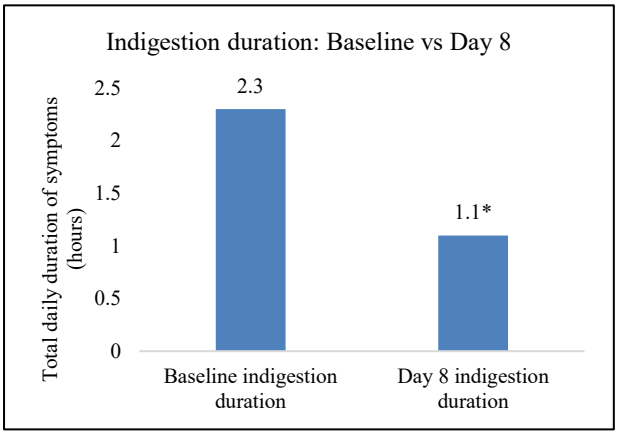

Figure 5: Total duration of indigestion at baseline and on day 8 visit (full analysis set/per protocol set).

Data are presented as mean (bar). A two-sided paired t-test was used for statistical analysis. *P<0.0001 versus baseline.

Night-time heartburn and indigestion

Table 2 gives the proportion of patients who experienced night-time heartburn and indigestion in the preceding night at baseline and 7 days after treatment, and the duration of heartburn and indigestion for the same. At baseline, the majority of patients experienced heartburn (88.2%) and indigestion (81.8%) in the preceding night. At the day 8 visit, fewer patients experienced heartburn (13.8%) and indigestion (12.1%) in the preceding night. The mean (SD) duration of symptoms also decreased from baseline to day 8.

Table 2: Night-time symptoms of heartburn and indigestion in the night preceding baseline and day 8 visit.

Preceding night parameters	Baseline (n=297)	Day 8 visit* (n=297)
Proportion of patients experiencing heartburn, N (%)	262 (88.2)	41 (13.8)
Duration of heartburn (hours), mean (SD)	1.9 (1.22)	1.1 (1.05)
Proportion of patients experiencing indigestion, N (%)	243 (81.8)	36 (12.1)
Duration of indigestion (hours), mean (SD)	1.9 (1.44)	1.3 (1.34)

n= total number of patients in the full analysis set or the per protocol set; N= number of patients; SD= standard deviation
*Data from 3 patients were missing for the Day 8 visit.

Safety and tolerability of the sodium alginate-based antacid oral suspension

The safety analysis set of 297 patients was used for analyses of primary endpoints. Only one (0.34%) patient experienced a treatment-emergent ADR of pyrexia, which was not serious and unrelated to the study drug. Among OPRI, one (0.34%) patient experienced lack of therapeutic efficacy (worsening of acid peptic disease), which was determined as per the investigator's discretion. None of the patients discontinued the treatment due to ADRs or OPRI.

In the global tolerability assessment after 7 days of treatment, 266 (89.56%) patients rated "good tolerability" of the study treatment, while investigators rated "good tolerability" for 267 (89.90%) patients (Figure 6). None of the patients or investigators reported poor tolerability.

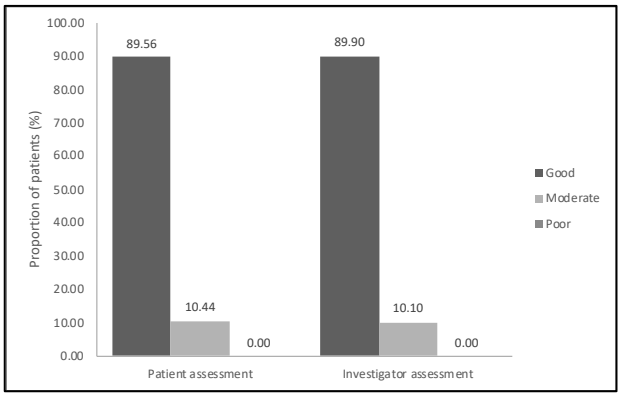

Figure 6: Global tolerability assessment by patients and investigators after 7 days of treatment (full analysis set/per protocol set).

None of the patients showed clinically significant differences in vital signs, physical examination, and other observations on day 8 when compared to baseline.

DISCUSSION

This study investigated the safety and effectiveness of the sodium alginate-based antacid oral suspension in Indian adults with heartburn and indigestion. Most patients (95.6% for heartburn and 96.6% for indigestion) achieved adequate relief from symptoms after 7 days of treatment. The treatment significantly reduced the frequency and severity of symptoms as observed by the total RDQ scores from baseline to the day 8 visit. The duration of heartburn and indigestion also significantly reduced after the 7-day treatment.

Clinical evidence supports the use of alginate-based antacids for the treatment of symptoms such as heartburn and indigestion.[2] Alginates are not associated with severe or significant ADRs, and this study also shows that the combination of sodium alginate 250 mg, sodium bicarbonate 133.5 mg, and calcium carbonate 80 mg per 5 mL oral suspension has a good safety profile.[12] Previous studies have reported TEAEs with up to 5.50% with alginates.[13,14] However, the incidence of treatment-emergent ADRs in this study was very low (0.34%).

In this study, most of the patients did not experience more than 1 day of mild heartburn and indigestion episodes- episodes that do not cause discomfort or affect daily activities- during the 7 days of treatment. This agrees with previous clinical studies where the majority of patients show global improvement in symptoms.[5] Alginate-based antacid formulations improve night-time reflux symptoms, and this study corroborates this finding as well.[5]

Compared to traditional antacid formulations, alginate-based antacid formulations show superior efficacy.[2,13] A study comparing sodium alginate with magaldrate showed that sodium alginate relieved reflux symptoms faster with a prolonged duration of action and provided complete symptom relief in a higher proportion of patients.[15] A similar formulation significantly reduced distal esophageal acid exposure when compared to a traditional antacid.[8] In patients with non-erosive reflux, an alginate-antacid combination was more effective than an antacid for the treatment of heartburn, regurgitation, vomiting, and belching.[16] Thus, the alginate-based antacid formulation in this study could be considered more clinically beneficial than traditional antacids for the treatment of heartburn and indigestion.

Compared to PPIs or H2 antagonists, alginates are equally efficacious.[12,13] In a randomized clinical trial, sodium alginate 20 ml thrice daily was non-inferior to omeprazole 20 mg once daily for symptomatic relief in patients with NERD.[16] Moreover, alginate-based antacid formulations provide faster relief than PPIs or H2 antagonists.[12,13]

Compared to alginate-based antacid formulations with lower alginate content or containing aluminium- or magnesium-based antacids, this sodium alginate-based antacid oral suspension has better acid neutralization properties and forms stronger and more resilient rafts.[17] Moreover, calcium-based antacids have calcium ions that strengthen the alginate raft.[13,14] Thus, this oral suspension may provide better symptom relief than other alginate-based antacid formulations.

This study did not enrol pregnant women. However, alginate-based antacids have been shown to be well tolerated and efficacious in the treatment of heartburn and regurgitation in pregnant women.[18] An Indian study conducted in pregnant women concluded that alginates should be used for rapid symptom relief in patients with acute symptoms as an induction agent, and PPIs should be used for longer duration of action as maintenance therapy.[19]

This study assessed safety as a primary study endpoint in the real-world setting post approval of this sodium alginate-based antacid oral suspension in Indian adults with heartburn and indigestion. Due to the prospective design of the study, we could capture the incidence and duration of symptoms for the statistical analyses. We utilized RDQ- a symptom-focused 12-item questionnaire- to quantify treatment response and differentiate levels of patient-assessed symptom severity. RDQ has four items each on frequency and severity of symptoms thus, it accurately translates symptom severity and response to treatment for clinical studies.[15] Another strength is the inclusion of patients from five different sites across India thereby allowing generalization of the study results.

A limitation of the study is that we enrolled patients with symptoms of heartburn and indigestion without classifying the underlying disease responsible for the symptoms. These patients may have these manifestations due to gastroesophageal reflux disease (GERD), non-erosive gastroesophageal reflux disease (NERD), or functional dyspepsia.[1,11,20] Understanding the patient profiles may help with the placement of the study treatment in the management of symptoms. However, since the product is indicated for treatment of heartburn and indigestion, this limitation does not affect the study results.[14] It also lacks information on the placement of this alginate-based antacid formulation with respect to PPI therapy. Additionally, the inherent bias of single-arm studies must be considered while interpreting the study results.

However, the prospective design of the study is an advantage as it allowed measurement of the frequency, severity, and duration of symptoms, and helped conclude effectiveness based on statistical significance.

Alginate formulations have been available for the treatment of heartburn and regurgitation for over 50 years.[10] While their efficacy and safety in relieving heartburn and indigestion are well-established globally, this is the first Indian study reporting the safety and effectiveness of an oral suspension of sodium alginate-based antacid.

CONCLUSION

This study, being the first Indian investigation evaluating a sodium-alginate based raft-forming antacid oral suspension, demonstrated both the effectiveness and safety of this formulation in patients with heartburn and indigestion. The results showed greater than 95% adequate relief rates, over 74% reductions in RDQ scores and marked decreases in symptom duration. These outcomes are consistent with global evidence supporting alginate-based therapies, and confirm their applicability in the Indian population. Importantly, the formulation had an acceptable safety and tolerability profile during the course of the study, underscoring its value as an effective treatment option for patients with heartburn and indigestion.

ACKNOWLEDGEMENTS

Authors thank Actu-Real Inc. and Shital Sarah Ahaley for providing manuscript writing and editorial support.

Funding: The study was funded by Abbott India Ltd
Conflict of interest: The study was funded by Abbott India Ltd Dr. Jejoe Karankumar and Dr. Shivani Acharya are employees of Abbott India Ltd
Ethical approval: The study was approved by the Institutional Ethics Committee CTRI/2021/04/033028

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Cite this article as: Ramakrishnan SR, Anand J, Basu I, Kalita PP, Karankumar J, Acharya S, et al. A multicenter and post-marketing surveillance study to evaluate the safety and effectiveness of a sodium alginate-based raft-forming antacid oral suspension in Indian patients with heartburn and indigestion. Int J Res Med Sci 2026;14:1518-25.