Magnesium alginate in patients with laryngopharyngeal reflux

G. Ciprandi[1], V. Damiani[2], F.M. Passali[3], A. Crisanti[4], G. Motta[5], D. Passali[6]

[1]Consultant allergist, Casa di Cura Villa Montallegro, Genoa, Italy; [2]Medical Department, D.M.G. Italia, Pomezia, Italy; [3]Department of Clinical Sciences and Translational Medicine univ Tor Vergata, Rome, Italy; [4]Clinical Medicine Department, Regina Apostolorum Hospital, Albano Laziale, Rome, Italy; [5]ENT Clinic, University Vanvitelli, Naples, Italy; [6]International Federation ORL Societies (IFOS) Executive Board members Rome Italy

Laryngopharyngeal reflux (LPR) is a common disease caused by the leaking beck of gastric material out of the esophagus. The main symptoms are dysphonia, dysphagia, and cough. There is an established use of proton pump inhibitors (PPI) in patients with suspected LPR in common practice. This habit is translated by the standard strategy to use PPI in treating patients with gastroesophageal reflux. However, PPI can not wholly inhibit all types of reflux and are burden by adverse effects. Alginate, a derivative from algae, is devoid of side effects and effectively counteracts gastric material reflux forming a foaming gel in the stomach. The current study enrolled 100 outpatients with LPR. Alginate treatment was administered for two months. Patients underwent four visits (at baseline and 15, 30, and 60 days after treatment). A visual analog scale assessed the perception of dysphonia, dysphagia, and cough. Alginate significantly ($p<0.0001$) reduced all parameters. Therefore, the current study demonstrated that magnesium alginate was effective and safe in LPR treatment.

Laryngopharyngeal reflux (LPR) is an extra-esophageal manifestation of gastroesophageal reflux (1). The gastroesophageal reflux frequently becomes a disease (GERD) (2,3). Many patients experience unusual sensations in the laryngopharynx (4,5). Consequently, LPR has a relevant impact on otolaryngologist practice, namely, up to 50 % of patients referring to dysphonia have LPR (6). Moreover, LPR is associated with different diseases, including reflux laryngitis and reflux cough. LPR's main symptoms are hoarseness, throat clearing, choking sensation, dysphagia, dysphonia, laryngeal globus, sore throat, and laryngospasm (7).

The LPR diagnostic work-up is pragmatically based on history, clinical examination, and laryngoscopy. Moreover, a protonic pump inhibitor (PPI) test, such as an empiric course of this medication, is very popular in the clinic setting (8). Altman suggested that empirical PPI therapy for 1–2 months is a reasonable initial approach in patients with LPR symptoms (9). Therefore, LPR diagnosis usually results from history, fiberoptic endoscopic outcomes, and empiric trial (10). So, patient-reported outcome measures are currently a primary method of diagnosing LPR and monitoring prescribed treatments' effectiveness. In this regard, the symptom perception measurement fruitfully relies on the visual analog scale (VAS). VAS may reasonably reflect the symptom severity and is a reproducible measure over time.

Keywords: laryngopharyngeal reflux, magnesium alginate, dysphagia, dysphonia, cough

Corresponding Author:
Giorgio Ciprandi
Via P. Boselli 5, 16146 Genoa, Italy
e-mail: gio.cip@libero.it

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From a therapeutic perspective, PPIs are overprescribed, expensive, and there are some safety concerns. On the contrary, alginate is an anionic polysaccharide occurring naturally in brown algae and has a unique property in gastric reflux treatment. The alginate-antacid formulation can reduce postprandial symptoms by neutralizing the acidity of gastric contents. In addition to neutralizing gastric acidity, alginate and bicarbonate, usually contained in an alginate-based formulation, form a foamy gel-like raft floating on gastric contents' surface interacting with gastric acid. This barrier-like gel displaces the acid pocket from the oesophageal-gastric junction and protects both the oesophageal and the upper respiratory mucosa from the acid and non-acid reflux by gel coating (11-14). Like an antacid, an alginate-based formulation demonstrates an immediate onset of effect within one h of administration, which is faster than a PPI and antagonist of the histamine-2 receptor (15). Compared with antacids, an alginate-based formulation is more effective than an antacid in controlling postprandial oesophageal acid exposure and quickly relieving reflux symptoms, including heartburn, regurgitation, vomiting, and belching, with longer duration (16-18). Alginate-based formulations are also non-inferior to omeprazole in achieving a heartburn-free period in moderate episodic heartburn (19). Therefore, alginate has the unique properties of protection of the oesophageal and upper respiratory mucosa from acid and non-acid reflux and displacement of the acid pocket away from the esophagus (20).

Based on this background, the current study aimed at investigating the efficacy and safety of a medical device containing magnesium alginate, simethicone, Dex-panthenol, zinc hydroxide, and sodium bicarbonate (Gastrotuss®) in patients with LPR.

MATERIALS AND METHODS

This study included 100 outpatients (52 males, mean age 54.4 ± 12.5 years) with LPR. Inclusion criteria were adulthood, both sexes, and documented LPR diagnosis. Exclusion criteria were comorbidities and concomitant treatments able to interfere with the interpretation of the results. All patients signed informed consent. The local Review Board approved the procedure. The perception of dysphagia, dysphonia, and cough severity was measured by VAS, where 0 was no symptom, ten was very bothersome symptoms. Each outpatient took magnesium alginate-simethicone (20 mL/three times a day) for two months. Patients underwent a medical examination at baseline and after 15, 30, and 60 days after treatment. Safety was also considered by reported side effects. The statistical analysis was performed using the Wilcoxon test.

RESULTS

All patients completed the study. The active treatment was tolerated, and no clinically relevant adverse event was reported. Table I shows the mean VAS scores for dysphonia, dysphagia and cough in patients with LPR treated with alginate-simethicone at baseline and after 15, 30 and 60 days after treatment. Active treatment significantly ($p<0.0001$) diminished the VAS values over time.

Table I. Mean VAS scores for dysphonia, dysphagia and cough in patients with LPR treated with alginate-simethicone at baseline and after 15, 30 and 60 days after treatment.

MEAN VAS SCORES					
	Baseline	Day 15	Day 30	Day 60	Willcoxon
dysphonia	6.2	4.65	3.79	3.23	P<0.0001
dysphagia	6.35	4.52	3.64	3.22	P<0.0001
cough	6.71	3.82	2.85	2.24	P<0.0001

DISCUSSION

The current study demonstrated that a 2-month magnesium alginate-simethicone course significantly reduced the perception of dysphonia, dysphagia, and cough in patients with LPR. The treatment was also safe and well-tolerated. Interestingly, this study is the first report concerning the efficacy and safety of this medical device in treating patients with LPR.

The obtained outcomes depend on the mechanisms of action of the various components of the medical device. Magnesium alginate is well-known alginate that is effective in counteracting gastric reflux. Simethicone is an inert silicone type substance and reduces the effects of excessive gas in the digestive tract. The Dex-panthenol and zinc hydroxide repair mucous wounds due to aggressive refluxate. Sodium bicarbonate is a buffer system for acid material.

The present study has some limitations, including the open design, the lack of objective assessment, and sample size calculation. However, the study was conducted in a real-world setting, such as an outpatient clinic. Thus, the outcomes can mirror what occurs in clinical practice. Moreover, the halving of symptom severity is an optimal outcome for a medical device, such as a product that does not require a medical prescription, so it is easily available.

In conclusion, the current study demonstrated that magnesium alginate was effective and safe in LPR treatment.

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