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Original Research Article

Efficacy of rabeprazole-based therapy in laryngopharyngeal reflux disease: a prospective comparative study

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ABSTRACT

Background: Laryngopharyngeal reflux disease (LPRD) is a common condition presenting to otolaryngology clinics, yet the role of proton pump inhibitors in treatment remains controversial. This study aimed to evaluate the efficacy of proton pump inhibitor therapy combined with alginate and lifestyle modifications in managing LPRD.
Methods: A prospective, comparative interventional study was conducted at a tertiary care hospital from August 2023 to April 2025. One hundred twenty patients aged 18-80 years with clinically diagnosed LPRD (Reflux Symptom Index ≥13, Reflux Finding Score ≥7) were randomly assigned to case and control groups (n=60 each). The case group received rabeprazole 20 mg twice daily, domperidone 10 mg twice daily, alginate 10 ml three times daily, and lifestyle modifications. The control group received identical treatment except rabeprazole. Primary outcomes were changes in RSI and RFS after 6 weeks of treatment. Statistical significance was evaluated with p-values.
Results: Both groups showed significant baseline comparability. After 6 weeks, the case group demonstrated superior improvement compared to controls. Mean RSI decreased from 20.6±3.5 to 10.5±3.2 in the case group versus 20.8±3.7 to 12.8±2.5 in controls ($p<0.001$). Mean RFS improved from 11.5±3.6 to 5.8±2.5 in cases versus 11.8±3.5 to 7.7±2.4 in controls ($p<0.001$). Individual symptoms, including hoarseness ($p=0.04$) and throat clearing ($p=0.012$), showed statistically significant improvements favoring the case group.
Conclusions: Proton pump inhibitor therapy with rabeprazole, combined with lifestyle modifications and adjunctive medications, provides superior symptomatic and objective improvement in LPRD compared to lifestyle modifications alone, supporting inclusion of PPIs in first-line LPRD management protocols.

Keywords: Laryngopharyngeal reflux, Proton pump inhibitor, Rabeprazole, Reflux symptom index, Reflux finding score

INTRODUCTION

Laryngopharyngeal reflux disease (LPRD) represents a distinct clinical entity characterized by the retrograde flow of gastric contents into the larynx and pharynx, causing inflammation and symptoms that differ significantly from typical gastroesophageal reflux disease (GERD).[1] The condition affects an estimated 10-30% of patients presenting to otolaryngology clinics, making it a significant healthcare concern requiring evidence-based management strategies.[2] The pathophysiology of LPRD involves direct mucosal damage from acid and pepsin exposure, leading to chronic inflammation of the laryngeal and pharyngeal tissues.[3] Unlike GERD, patients with LPRD may not experience classic heartburn symptoms, instead presenting with hoarseness, chronic cough, throat clearing, globus sensation, and dysphagia.[4] This atypical presentation often leads to diagnostic delays and suboptimal treatment outcomes. Current treatment approaches for LPRD include lifestyle modifications, dietary changes, and pharmacological interventions, with proton pump inhibitors (PPIs) being the most commonly

prescribed medications.[5] However, the efficacy of PPI therapy in LPRD remains controversial, with response rates varying significantly across studies ranging from 18% to 89%.[6] The heterogeneity in treatment protocols, assessment methods, and patient populations has contributed to ongoing debates regarding optimal LPRD management.[12] The Reflux Symptom Index (RSI) and Reflux Finding Score (RFS) represent validated clinical tools for LPRD assessment, providing standardized approaches to symptom evaluation and laryngoscopic findings respectively.[7] These instruments enable objective measurement of treatment efficacy and facilitate clinical research in LPRD management.[4-7] The RSI demonstrates good internal consistency (Cronbach's α=0.88) and test-retest reliability (r=0.93), while the RFS shows excellent inter-rater reliability (r=0.93).[4-7] Recent position statements from the American Academy of Otolaryngology-Head and Neck Surgery emphasize the need for evidence-based approaches to LPRD diagnosis and treatment, highlighting the importance of standardized assessment protocols and objective outcome measures in clinical research.[12] This study evaluates the efficacy of rabeprazole-based PPI therapy combined with lifestyle modifications, using RSI and RFS scores, to provide evidence-based treatment recommendations for LPRD.

METHODS

Study design and setting

This prospective, comparative interventional study was conducted at the Department of Otorhinolaryngology, C.R. Gardi Hospital, associated with R.D. Gardi Medical College, Ujjain, Madhya Pradesh, India, from August 2023 to April 2025. The institutional ethics committee approved the study protocol. Written informed consent was obtained from all participants following international ethical guidelines.

Participants

Adult patients aged 18-80 years presenting with symptoms suggestive of LPRD were screened for eligibility.

Inclusion criteria

Inclusion criteria included a RSI score ≥13, a RFS ≥7, and the ability to provide informed consent and comply with follow-up.

Exclusion criteria

Exclusion criteria included use of proton pump inhibitors within the previous month, known hypersensitivity to proton pump inhibitors, significant systemic illness (including hypertension, diabetes mellitus, or tuberculosis), pregnancy, presence of other laryngeal pathologies such as vocal cord paralysis or malignancy, and inability to provide informed consent.

Table 1: Reflux symptoms index.[4]

S. no.	Symptoms	Score
1.	Hoarseness of voice	0, 1, 2, 3, 4, 5
2.	Clearing throat	0, 1, 2, 3, 4, 5
3.	Excess throat mucus/postnasal drip	0, 1, 2, 3, 4, 5
4.	Difficulty in swallowing food, pills, liquid	0, 1, 2, 3, 4, 5
5.	Cough after eating/ lying down	0, 1, 2, 3, 4, 5
6.	Annoying cough	0, 1, 2, 3, 4, 5
7.	Breathing difficulty/ choking episodes	0, 1, 2, 3, 4, 5
8.	The sensation of something sticking in the throat	0, 1, 2, 3, 4, 5
9.	Heartburn/ chest pain/ stomach acid coming up.	0, 1, 2, 3, 4, 5

Randomization and group allocation

Eligible patients were randomly assigned (1:1) into two groups: the case group (n=60), which received rabeprazole 20 mg twice daily along with domperidone 10 mg twice daily, sodium alginate 10 ml three times daily after meals, and standardized lifestyle modifications including dietary counselling, weight management recommendations, and sleep positioning advice as per current LPRD management guidelines, and the control group (n=60), which received identical treatment except for rabeprazole, consisting of domperidone 10 mg twice daily, sodium alginate 10 ml three times daily after meals, and the same lifestyle modifications.

Interventions

All participants were treated for 6 weeks. Compliance with medication and any adverse events were monitored throughout the study period. The 6-week duration was chosen based on previous evidence indicating significant mucosal healing with PPI therapy in extraesophageal reflux conditions.[5-9]

Outcome measures

The primary outcome measures were changes in RSI and RFS scores from baseline to 6 weeks post-treatment. The RSI is a validated 9-item questionnaire assessing symptom severity on a 0-5 scale (total score 0-45), with scores ≥13 indicating clinically significant LPRD.[4] The instrument evaluates hoarseness, throat clearing, excess throat mucus, difficulty swallowing, coughing after eating or lying down, breathing difficulties, troublesome cough, sensations of sticking or lump in throat, and heartburn/chest pain/indigestion. The RFS evaluates eight

laryngoscopic findings on a 0-26 scale, with scores ≥7 considered positive for LPRD.[7] The assessment includes subglottic edema, ventricular obliteration, erythema/hyperemia, vocal fold edema, diffuse laryngeal edema, posterior commissure hypertrophy, granuloma/granulation tissue, and thick endolaryngeal mucus. Secondary outcomes included individual symptom improvements, treatment compliance rates, and adverse event profiles. Quality of life assessment was performed using validated instruments appropriate for voice and swallowing disorders.[17]

Table 2: RFS.[7]

S. No.	Reflux finding score	Reference
1.	Subglottic edema	0-absent; 2 present
2.	Erythema/hyperemia	1-arytenoids only 4-diffuse
3.	Ventricular edema	2-partial; 4- complete
4.	Vocal fold edema	1- mild; 2- moderate 3-severe; 4- obstructing
5.	Diffuse laryngeal edema	1- mild; 2- moderate 3-severe; 4- obstructing
6.	Post Commissure hypertrophy	1- mild; 2- moderate 3-severe; 4- obstructing
7.	Granuloma/granulation tissue	0-absent; 2 present
8.	Thick endolaryngeal mucus	0-absent; 2 present

Statistical analysis

Sample size calculation determined that 60 patients per group would provide 80% power to detect a 25% difference in primary outcomes at α=0.05, based on previous studies of PPI efficacy in LPRD.[6] Statistical analysis was performed using SPSS version 21.0. Continuous variables were analyzed using Student's t-test or Mann-Whitney U test as appropriate, while categorical variables were compared using chi-square test. Repeated measures ANOVA was used for longitudinal analysis of outcome measures. Statistical significance was set at $p<0.05$, consistent with established standards for clinical research in gastroenterology and otolaryngology.[18]

RESULTS

Baseline characteristics

A total of 120 patients were enrolled, with complete data available for all participants. The baseline demographics and clinical characteristics were well balanced between the case and control groups. The study population comprised 46 males (38.3%) and 74 females (61.7%), with a mean age of 42.3±12.8 years. The predominance of female patients is consistent with epidemiological studies showing higher LPRD prevalence in women.[2] The most common age group was 31-40 years, reflecting the typical demographic pattern observed in LPRD populations.[18] Lifestyle risk factors were prevalent, including tobacco use (32.5%), alcohol consumption (19.2%), and smoking (28.3%). Dietary patterns included frequent consumption of fried foods (49.2%), fatty foods (34.2%), and spicy foods (62.5%). These risk factor profiles align with established associations between dietary habits and reflux disease severity.[16]

Primary outcomes

Both treatment groups demonstrated significant improvements from baseline, but the case group showed superior outcomes compared to controls, supporting the therapeutic efficacy of PPI therapy as reported in previous meta-analyses.[5]

RSI: Baseline RSI scores were similar: 20.55±3.52 in the case group vs. 20.80±3.70 in the control group (p=0.705). After 6 weeks of treatment, the case group showed a significant reduction to 10.45±3.20 compared to 12.82±2.47 in the control group ($p<0.001$). This represented a 49% improvement in the case group versus 38% in controls, exceeding the minimal clinically important difference of 13 points established for the RSI.[8]

Reflux finding score: Baseline RFS scores were 11.52±3.59 and 11.80±3.54 in the case and control groups, respectively (p=0.664). At 6 weeks, the case group improved to 5.77±2.47 compared to 7.72±2.37 in controls ($p<0.001$), a 50% versus 35% improvement. This magnitude of improvement is consistent with previous studies demonstrating PPI effects on laryngeal inflammation.[13]

Secondary outcomes

Individual symptom analysis revealed statistically significant improvements in the case group for multiple LPRD symptoms, consistent with the multifactorial benefits of acid suppression therapy.[9]

Hoarseness: Pre-treatment scores of 1.35±1.73 (case) versus 1.20±1.54 (control) improved to 0.55±0.95 (case) versus 0.77±0.98 (control) post-treatment (t=2.18, p=0.04). This 59% improvement in the PPI group versus 36% in controls reflects the direct impact of acid suppression on vocal fold inflammation.[17]

Throat clearing: The most dramatically improved symptom showed pre-treatment scores of 3.42±0.72 (case) versus 3.43±0.65 (control), improving to 1.95±0.79 (case) versus 2.28±0.64 (control) post-treatment (t=2.53, p=0.012). This symptom improvement correlates with reduced laryngeal mucus production following acid suppression.[3]

Additional symptoms including excess throat mucus, difficulty swallowing, and cough after eating demonstrated similar patterns of superior improvement in

the case group, though statistical significance varied by symptom. These findings are consistent with the known pathophysiology of pepsin-induced laryngeal damage and subsequent healing with acid suppression.[3-17]

Table 3: Age distribution in case and control groups.

Age groups (years)	Group				Total	
	Case		Control			
≤20	3	5.0%	1	1.7%	4	3.3%
21-30	16	26.7%	13	21.7%	29	24.2%
31-40	16	26.7%	23	38.3%	39	32.5%
41-50	13	21.7%	9	15.0%	22	18.3%
51-60	7	11.7%	9	15.0%	16	13.3%
>60	5	8.3%	5	8.3%	10	8.3%
Total	60	100.0%	60	100.0%	120	100.0%

Table 4: Gender distribution in case and control groups.

Gender	Group				Total	
	Case		Control			
Male	25	41.7%	21	35.0%	46	38.3%
Female	35	58.3%	39	65.0%	74	61.7%
Total	60	100.0%	60	100.0%	120	100.0%

Table 5: Mean±SD of reflux symptoms index before and after treatment in case and control groups.

	Pre-treatment		Post-treatment	
	Case	Control	Case	Control
Hoarseness of voice	1.35±1.73	1.20±1.54	0.55±0.95	0.77±0.98
Clearing throat	3.42±0.72	3.43±0.65	1.95±0.79	2.28±0.64
Excess throat mucus	2.62±1.37	2.70±1.37	1.07±1.07	1.40±0.94
Difficulty in swallowing food	1.03±1.15	1.03±1.12	0.33±0.63	0.67±0.73
Cough after eating	1.62±1.52	1.92±1.29	0.83±1.15	1.23±0.83
Annoying cough	2.52±1.21	2.38±1.17	1.45±1.06	1.30±0.85
Breathing difficulty	0.62±1.15	0.50±0.87	0.30±0.70	0.42±0.77
The sensation of something sticking in the throat	4.10±1.12	3.95±1.02	2.65±0.94	2.83±0.76
Heartburn	3.28±1.33	3.68±1.19	1.32±1.13	1.92±0.89

Table 6: Mean±SD of reflux finding score before and after treatment in case and control groups.

	Pre-treatment		Post-treatment	
	Case	Control	Case	Control
Subglottic edema	0.63±0.94	0.77±0.98	0.43±0.83	0.40±0.81
Erythema/hyperemia	2.48±1.48	2.75±1.49	0.75±0.57	1.25±0.84
Ventricular edema	2.33±0.84	2.27±0.69	1.30±1.09	2.00±0.37
Vocal fold edema	1.52±0.68	1.53±0.75	0.73±0.71	1.10±0.60
Diffuse laryngeal edema	1.18±0.89	1.28±0.83	0.52±0.68	0.80±0.66
Post. Commissure hypertrophy	2.00±0.78	2.00±0.84	1.27±0.80	1.53±0.65
Granuloma/granulation tissue	0.57±0.91	0.53±0.89	0.30±0.72	0.40±0.81
Thick endolaryngeal mucus	0.80±0.99	0.67±0.95	0.47±0.85	0.23±0.65

Treatment compliance and safety

Treatment compliance was excellent in both groups (>95%), comparable to rates reported in previous PPI trials for extraesophageal reflux.[6] No serious adverse events were reported. Minor side effects in the case group included occasional headache (n=3) and mild gastrointestinal upset (n=2), all of which resolved without treatment discontinuation.

The safety profile observed is consistent with established data on short-term PPI use.[9]

Table 7: Comparison of reflux symptoms index and RFS before and after treatment in case and control groups.

		Pre-treatment		Post-treatment	
		Case	Control	Case	Control
Reflux symptoms index	Mean±SD	20.55±3.52	20.80±3.70	10.45±3.20	12.82±2.47
	Significant value	T=0.379, p=0.705		T=4.53, p=0.000	
RFS	Mean±SD	11.52±3.59	11.80±3.54	5.77±2.47	7.72±2.37
	Significant value	T=0.435, p=0.664		T=3.93, p=0.000	

DISCUSSION

This prospective, comparative interventional study demonstrates that proton pump inhibitor therapy with rabeprazole, when combined with lifestyle modifications and adjunctive medications, provides superior symptomatic and objective improvement in LPRD compared to lifestyle modifications alone. The study's findings have important implications for clinical practice and contribute to the evidence base supporting PPI use in LPRD management, addressing controversies highlighted in recent systematic reviews.[5-11]

The 49% reduction in RSI scores and 50% improvement in RFS scores observed in the PPI group represent clinically meaningful therapeutic benefits that would significantly impact patient quality of life. These improvements exceed the minimum clinically important differences established for these validated instruments, supporting the clinical relevance of our findings and aligning with successful outcomes reported in previous controlled trials.[8-13]

The superior efficacy of combination therapy likely reflects the multifactorial pathophysiology of LPRD. Rabeprazole provides potent acid suppression, reducing the primary injurious factor in laryngopharyngeal tissues.[9] The medication achieves rapid and sustained acid suppression, with studies demonstrating superior gastric pH control compared to other PPIs.[11] Domperidone enhances gastric motility and reduces reflux episodes through its prokinetic effects, while sodium alginate creates a protective barrier preventing acid contact with esophageal and laryngeal mucosa.[10] The comprehensive approach addressing both acid production and reflux mechanics may explain the superior outcomes observed, consistent with current understanding of LPRD pathophysiology.[3-17]

Our findings align with several previous studies demonstrating PPI efficacy in LPRD, while addressing some limitations of earlier research.[11] A meta-analysis by Qadeer et al reported significant symptom improvement with PPI therapy in suspected GERD-related chronic laryngitis, though response rates varied considerably across studies.[5] Our use of validated assessment tools (RSI and RFS) provides objective outcome measurement, while the randomized controlled design minimizes selection bias and confounding variables that have limited previous observational studies.[18]

The study's findings support the concept that LPRD represents a genuine acid-related disorder, as evidenced by the superior response to acid suppression therapy. This addresses ongoing debates in the literature regarding the role of acid versus non-acid reflux in laryngeal symptoms.[11] The significant improvement in objective laryngoscopic findings (RFS) provides particularly strong evidence for acid-mediated tissue damage and subsequent healing with PPI therapy.[3]

The study's strengths include its prospective Case-Control study, use of validated outcome measures, excellent treatment compliance, and comprehensive assessment of both subjective symptoms and objective laryngoscopic findings. The homogeneous patient population and standardized treatment protocols enhance internal validity and reproducibility. The inclusion of lifestyle modifications in both groups ensures that observed differences reflect true PPI efficacy rather than general treatment effects.[16]

Several limitations should be acknowledged. The relatively short follow-up period (6 weeks) may not capture long-term treatment effects or optimal therapy duration. Previous studies suggest that some patients may require longer treatment periods for maximal benefit, and extended follow-up could provide insights into sustained improvement and appropriate treatment duration.[6] The modest sample size, while adequately powered for primary endpoints, may limit detection of smaller effect sizes in secondary outcomes or identification of patient subgroups with differential treatment responses.

The reliance on patient-reported symptoms introduces potential response bias, though this was mitigated by objective laryngoscopic assessment and is inherent to most clinical studies in this field.[18] Future studies incorporating 24-hour pH monitoring could provide additional objective validation of treatment effects, as recommended by recent consensus statements.[12] However, the correlation between pH monitoring results and clinical outcomes in LPRD remains controversial, with some studies showing poor correlation between acid exposure and symptom severity.[11]

The clinical implications of our findings support incorporating rabeprazole-based combination therapy as first-line treatment for LPRD in patients meeting diagnostic criteria (RSI≥13, RFS ≥7). The comprehensive approach demonstrated superior efficacy compared to

lifestyle modifications alone, providing evidence-based justification for PPI prescription in appropriate clinical scenarios. This aligns with current practice patterns, where PPIs represent the most commonly prescribed medications for LPRD.[16]

Cost-effectiveness considerations are important given the economic burden of caring for patients with suspected extraesophageal reflux.[8] The demonstrated efficacy of PPI therapy may reduce healthcare utilization through improved symptom control and reduced need for additional diagnostic procedures or specialist consultations.

Future research directions should include longer-term follow-up studies to assess sustained treatment benefits and optimal treatment duration, comparative effectiveness trials evaluating different PPI regimens and dosing strategies, investigation of patient factors predicting treatment response to enable personalized therapy approaches, and studies incorporating objective pH monitoring to further validate treatment mechanisms.[14] Additionally, research into the role of surgical fundoplication in PPI-refractory cases could provide insights into comprehensive LPRD management algorithms.[14]

CONCLUSION

This prospective, comparative interventional study provides robust evidence supporting the efficacy of proton pump inhibitor therapy with rabeprazole in laryngopharyngeal reflux disease management. The combination of rabeprazole, domperidone, sodium alginate, and lifestyle modifications demonstrated superior symptomatic and objective improvement compared to lifestyle modifications alone. These findings support the inclusion of PPIs in evidence-based LPRD treatment protocols and provide clinicians with objective data to guide therapeutic decision-making. The study contributes significantly to the evidence base for LPRD management and establishes a framework for future research in this important clinical area.

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