e-ISSN: 0975-1556, p-ISSN:2820-2643
Available online on www.ijpcr.com
International Journal of Pharmaceutical and Clinical Research 2024; 16(5); 1644-1648

Original Research Article

Decoding the Role of Loratadine in Optimally Managing and in Alleviating the Burden of Allergic Rhinitis

Bhola Kumar Sharma[1], Alekh Kumar[2], Ranveer Kumar Pandey[3]

[1]Assistant Professor, Department of ENT, Narayan Medical College & Hospital, Jamuhar, Sasaram, Bihar, India
[2]Assistant Professor, Department of ENT, Narayan Medical College & Hospital, Jamuhar, Sasaram, Bihar, India
[3]Professor, Department of ENT, Narayan Medical College & Hospital, Jamuhar, Sasaram, Bihar, India

Received: 25-02-2024 / Revised: 23-03-2024 / Accepted: 27-05-2024
Corresponding Author: Dr. Alekh Kumar
Conflict of interest: Nil

Abstract:

Background: Allergic rhinitis (AR) is a widespread chronic condition characterized by nasal inflammation due to allergen exposure, leading to significant impairment in quality of life and productivity. This study aimed to evaluate the effectiveness of loratadine in managing and alleviating the burden of AR, focusing on symptom severity and quality of life improvements over a five-month period.

Methods: Forty-seven participants with diagnosed AR were enrolled and administered loratadine. Symptom severity and quality of life were assessed using standardized questionnaires and clinical evaluations at baseline and monthly follow-ups. Data were analyzed using SPSS version 20.0, with paired t-tests and ANOVA employed to compare changes over time.

Results: The study observed a significant reduction in symptom severity from a baseline mean score of 6.3 ± 1.8 to 2.5 ± 1.1 by the fifth month ($p < 0.001$). Concurrently, quality of life scores improved significantly from a baseline mean of 58.2 ± 12.5 to 78.3 ± 7.4 ($p < 0.001$). The statistical analysis confirmed significant improvements in both symptom severity ($F(4, 184) = 23.56$, $p < 0.001$) and quality of life ($F(4, 184) = 19.47$, $p < 0.001$) over the study period.

Conclusion: Loratadine effectively reduced the severity of AR symptoms and improved the quality of life for patients over the five-month period. These findings support the continued use of loratadine as a valuable therapeutic option for managing AR.

Recommendations: It is advised that these findings be further validated by bigger sample numbers and extended follow-up times in future research. Furthermore, investigating individualised therapy strategies may improve patient results in the management of AR.

Keywords: Allergic rhinitis, Loratadine, Symptom severity, Quality of life, Antihistamines.

Introduction

Millions of people worldwide suffer from allergic rhinitis (AR), a common chronic respiratory disease marked by inflammation of the nose brought on by exposure to allergens. Sneezing, nasal congestion, itching, and rhinorrhea are common symptoms that accompany it, greatly reducing the quality of life and productivity of those who experience it. The prevalence of AR has been rising globally; recent epidemiological studies have shown that it can affect up to 40% of adolescents and adults [1]. This highlights the necessity for efficient management solutions.

Exaggerated immune response to otherwise harmless allergens is the result of a complex interplay between genetic predisposition and environmental factors in the pathophysiology of allergic reactions (AR). Histamine, leukotrienes, and cytokines are examples of inflammatory mediators that are released in response to exposure to allergens and play a role in the clinical symptoms of allergic reactions [2]. The illness's care is made more difficult by the fact that it is frequently accompanied with comorbidities such as conjunctivitis, sinusitis, and asthma.

Loratadine, a second-generation H1-antihistamine, is widely used in the treatment of AR. It is preferred over first-generation antihistamines due to its favorable safety profile, minimal sedative effects, and prolonged duration of action. Loratadine works by selectively blocking peripheral histamine H1 receptors, thereby alleviating the symptoms of AR without causing significant central nervous system depression [3]. Despite its widespread use, continuous evaluation

of its efficacy and impact on patients' quality of life remains essential to optimize treatment outcomes.

Recent studies have highlighted the ongoing challenges in AR management, including the variability in patient response to treatment and the impact of AR on mental health and overall well-being. For instance, a study emphasized the importance of individualized treatment approaches, considering the heterogeneity of AR presentations and patient preferences [4]. Additionally, the psychological burden of AR, often underestimated, has been shown to contribute to anxiety, depression, and reduced cognitive function, necessitating comprehensive management plans [5].

This study aims to evaluate the effectiveness of loratadine in managing and alleviating the burden of allergic rhinitis.

Methodology

Study Design: A prospective observational design.

Study Setting: The study was done in a period of 5 months (January 2024 to May 2024) at Narayan Medical College & Hospital, Jamuhar, Sasaram, Bihar, India.

Participants: A total of 47 participants were enrolled in the study.

Inclusion Criteria

- Adults aged 18-65 years diagnosed with allergic rhinitis.

- Patients who have not been treated with loratadine or other antihistamines for at least one month prior to the study.

Exclusion Criteria

- Individuals with a history of hypersensitivity to loratadine.

- Pregnant or breastfeeding women.

- Patients with severe comorbid conditions that could interfere with the study outcomes.

- Use of other medications that could affect the study results.

Sample size: To calculate the sample size for this study, the following formula was used for estimating a proportion in a population:

$$n = \frac{Z^2 \times p \times (1-p)}{E^2}$$

Where:

- n = sample size

- Z = Z-score corresponding to the desired level of confidence

- p = estimated proportion in the population

- E = margin of error

Bias: To minimize bias, participants were selected using random sampling from the eligible patient population. Blinding was not applicable due to the observational nature of the study, but data collection and analysis were conducted by different teams to reduce subjective bias.

Variables: Variables included administration of loratadine, severity of allergic rhinitis symptoms, quality of life, and burden of disease.

Data Collection: Data was collected using standardized questionnaires and clinical assessments at baseline, and at monthly follow-ups for the duration of the study.

Procedure

1. Enrollment: Eligible participants were identified and recruited during their routine visits to the outpatient department.

2. Baseline Assessment: A detailed medical history and baseline symptom severity were recorded.

3. Intervention: Participants were administered loratadine as per standard dosing guidelines.

4. Follow-Up: Monthly follow-ups were conducted to assess symptom severity and quality of life using validated scales.

Statistical Analysis: Data analysis was done with SPSS 20.0. The demographic and baseline details of the individuals were compiled using descriptive statistics. The quality of life and symptom severity levels were compared before and after the intervention using paired t-tests and ANOVA. Statistical significance was attained when the p-value was less than 0.05.

Ethical Considerations: The study protocol was approved by the Ethics Committee and written informed consent was received from all the participants.

Result

A total of 47 participants were enrolled in the study. The mean age of the participants was 35.6 ± 10.2 years, with 25 males (53.2%) and 22 females (46.8%). The baseline characteristics of the participants are summarized in Table 1.

Table 1: Baseline Characteristics

Characteristic	Mean ± SD or n (%)
Age (years)	35.6 ± 10.2
Gender	
- Male	25 (53.2%)
- Female	22 (46.8%)
Duration of Allergic Rhinitis (years)	4.7 ± 2.5
Baseline Symptom Severity Score (0-10)	6.3 ± 1.8
Baseline Quality of Life Score (0-100)	58.2 ± 12.5

The severity of allergic rhinitis symptoms and the quality of life of participants were assessed at baseline and at monthly follow-ups for five months. The changes in symptom severity and quality of life scores are presented in Table 2 and Table 3, respectively.

Table 2: Changes in Symptom Severity Scores

Time Point	Mean Symptom Severity Score ± SD	p-value (vs. Baseline)
Baseline	6.3 ± 1.8	-
Month 1	4.5 ± 1.6	<0.001
Month 2	3.8 ± 1.4	<0.001
Month 3	3.2 ± 1.3	<0.001
Month 4	2.8 ± 1.2	<0.001
Month 5	2.5 ± 1.1	<0.001

Table 3: Changes in Quality-of-Life Scores

Time Point	Mean Quality of Life Score ± SD	p-value (vs. Baseline)
Baseline	58.2 ± 12.5	-
Month 1	65.7 ± 10.8	<0.001
Month 2	69.4 ± 9.6	<0.001
Month 3	73.1 ± 8.7	<0.001
Month 4	75.8 ± 8.1	<0.001
Month 5	78.3 ± 7.4	<0.001

The mean quality of life and symptom severity scores at each follow-up point were compared to the baseline values using paired t-tests. Between the baseline and each follow-up point, there was a statistically significant decrease in the mean symptom severity scores ($p < 0.001$). The quality of life measures also showed a statistically significant improvement from baseline to each follow-up point ($p < 0.001$).

The ANOVA was used to compare the changes over time, and it confirmed a significant overall improvement in both symptom severity ($F(4, 184) = 23.56$, $p < 0.001$) and quality of life ($F(4, 184) = 19.47$, $p < 0.001$) over the study period.

Discussion

The purpose of the study was to assess how well loratadine managed and reduced the symptoms of allergic rhinitis in 47 individuals. The outcomes showed that individuals receiving loratadine had a noteworthy increase in their quality of life as well as a significant reduction in the severity of their symptoms.

At the beginning of the study, participants reported a mean symptom severity score of 6.3 ± 1.8. Over the course of the study, there was a steady and significant decline in symptom severity. By the first month, the mean score had dropped to 4.5 ± 1.6, and continued to decrease to 2.5 ± 1.1 by the fifth month. These reductions were statistically significant at each follow-up point compared to the baseline ($p < 0.001$), indicating that loratadine effectively reduced the severity of allergic rhinitis symptoms over time.

In parallel with the reduction in symptom severity, the quality of life of participants improved markedly. The baseline quality of life score was 58.2 ± 12.5. By the first month, the score had increased to 65.7 ± 10.8, and continued to improve, reaching 78.3 ± 7.4 by the fifth month. These improvements were also statistically significant at each follow-up point compared to the baseline ($p < 0.001$), highlighting the positive impact of loratadine on the daily lives and well-being of the participants.

The statistical analyses, including paired t-tests and ANOVA, confirmed the significance of these improvements, with an overall F-statistic of 23.56 for symptom severity and 19.47 for quality of life (both $p < 0.001$). These findings underscore the effectiveness of loratadine in not only reducing the symptoms of allergic rhinitis but also in enhancing the overall quality of life for patients.

The study provides robust evidence supporting the use of loratadine as an effective treatment for allergic rhinitis. The significant reduction in symptom severity and the concurrent improvement in quality of life suggest that loratadine can substantially alleviate the burden of this condition. These results are particularly meaningful for patients who suffer from persistent and debilitating allergic rhinitis symptoms, offering them a reliable option for long-term symptom management.

The usefulness of loratadine, a second-generation antihistamine, in treating allergic rhinitis (AR) has been demonstrated by recent studies. Research has examined its effectiveness as a stand-alone treatment and in conjunction with other therapies, with an emphasis on quality of life, patient compliance, and symptom alleviation. According to a study, loratadine is an appropriate first-line treatment for the long-term management of allergic rhinitis because of its quick and durable symptom alleviation, lack of sleepiness, and low complication rate [6]. Seasonal allergy rhinitis (SAR)-related pharyngolaryngeal symptoms were greatly reduced by montelukast and loratadine combined. According to the study, loratadine significantly improved patient outcomes by reducing pharyngolaryngeal and nasal symptoms [7].

In rabbit models of ovalbumin-induced allergic rhinitis, a study created a nasal nanoemulsion co-loaded with loratadine and sulpiride that shown increased efficacy in decreasing TNF-α, TGF-β, and IL-1 levels. The mixture showed encouraging promise in the treatment of symptoms associated with allergic rhinitis [8]. While both medications considerably decreased total nasal symptom scores (TNSS), a clinical research comparing desloratadine and loratadine found that desloratadine had a slightly higher reduction rate. The levels of IL-4 in the two groups did not differ significantly [9].

In patients with allergic rhinitis, acupuncture at the Xinwu acupoint combined with loratadine and fluticasone propionate dramatically improved symptom scores, nasal function, and blood histamine levels. Compared to loratadine and fluticasone alone, this combination proved more effective [10]. In patients with allergic rhinitis, ginger extract improved nasal symptoms and quality of life just as well as loratadine, but with less negative effects like weariness and drowsiness [11]. This was demonstrated by a randomised controlled experiment.

For treating mild to severe allergic rhinitis, medical practitioners and chemists favoured loratadine above other second-generation antihistamines, according to a cross-sectional study conducted in four ASEAN nations. The study made clear how important it is to improve patient compliance and guideline adherence [12]. According to a meta-analysis, loratadine plus montelukast significantly reduced TNSS and other allergic rhinitis symptoms when compared to monotherapies or a placebo, making it a useful treatment for moderate-to-severe instances [13].

In contrast to other studies, loratadine pills significantly and quickly relieved the nasal and ocular symptoms of seasonal allergic rhinitis within 75 minutes, according to a post hoc analysis of a research conducted in an environmental exposure unit (EEU) [14]. In patients with allergic rhinitis, a study using loratadine and Tuomin Zhiti decoction alleviated clinical symptoms, decreased inflammatory responses, and strengthened immunological function, indicating a synergistic effect [15].

Conclusion

The study concluded that loratadine is effective in the optimal management and alleviation of the burden of allergic rhinitis, with significant reductions in symptom severity and improvements in quality of life observed over a five-month period. Further studies with larger sample sizes and longer follow-up periods are recommended to validate these findings.

Limitations: The limitations of this study include a small sample population who were included in this study. Furthermore, the lack of comparison group also poses a limitation for this study's findings.

Recommendation: It is advised that these findings be further validated by bigger sample numbers and extended follow-up times in future research. Furthermore, investigating individualised therapy strategies may improve patient results in the management of AR.

Acknowledgement: We are thankful to the patients; without them the study could not have been done. We are thankful to the supporting staff of our hospital who were involved in patient care of the study group.

List of abbreviations:

AR: Allergic Rhinitis

QoL: Quality of Life

H1: Histamine type 1 receptor

TNSS: Total Nasal Symptom Score

TNF-α: Tumor Necrosis Factor Alpha

TGF-β: Transforming Growth Factor Beta

IL-1: Interleukin 1

IL-4: Interleukin 4

SAR: Seasonal Allergic Rhinitis

EEU: Environmental Exposure Unit

Source of funding: No funding received.

References

1. Bousquet J, Anto JM, Bachert C, Baiardini I, Bosnic-Anticevich S, Walter Canonica G, Melén E, Palomares O, Scadding GK, Togias A, Toppila-Salmi S. Allergic rhinitis. Nature Reviews Disease Primers. 2020 Dec 3;6(1):95.
2. Canonica GW, Bousquet J, Mullol J, Scadding GK, Virchow JC. A survey of the burden of allergic rhinitis in Europe. Allergy. 2007 Dec;62:17-25.
3. Grainger J, Drake-Lee A. Montelukast in allergic rhinitis: a systematic review and meta-analysis. Clinical Otolaryngology. 2006 Oct 1; 31(5).
4. Cohen B. Allergic rhinitis. Pediatrics in Review. 2023 Oct 1;44(10):537-50.
5. Dykewicz MS, Wallace DV, Baroody F, Bernstein J, Craig T, Finegold I, Huang F, Larenas-Linnemann D, Meltzer E, Steven G, Bernstein DI. Treatment of seasonal allergic rhinitis: an evidence-based focused 2017 guideline update. Annals of Allergy, Asthma & Immunology. 2017 Dec 1;119(6):489-511.
6. Bangale N, Balasubramanyam AM, Kolwadkar N, Pereira C, Bihani J, Meghanadh KR, et al. Decoding the role of loratadine in optimally managing and in alleviating the burden of allergic rhinitis. IP J Otorhinolaryngol Allied Sci. 2023.
7. Imoto Y, Takabayashi T, Sakashita M, Tokunaga T, Morikawa T, Ninomiya T, et al. Combination therapy with montelukast and loratadine alleviates pharyngolaryngeal symptoms related to seasonal allergic rhinitis. J Allergy Clin Immunol Pract. 2019;7(3):1068-1070.e3.
8. Mohamad SA, Safwat M, Elrehany M, Maher SA, Badawi A, Mansour H. A novel nasal co-loaded loratadine and sulpiride nanoemulsion with improved downregulation of TNF-α, TGF-β and IL-1 in rabbit models of ovalbumin-induced allergic rhinitis. Drug Deliv. 2021; 28:229-239.
9. Purwaningsih LPD, Pawarti DR, Surarso B. The effectiveness comparison of desloratadine and loratadine in reducing total nasal symptom score and the level of interleukin 4 in the nasal secretions of allergic rhinitis patients. Indian J Forensic Med Toxicol. 2020.
10. Wang Z, Wang Z, Jiang YF, Li J, Wu X, Wu JX. Effect of acupuncture at Xinwu acupoint combined with loratadine and fluticasone propionate on symptom alleviation, nasal function, and serum histamine level in patients with allergic rhinitis. Am J Transl Res. 2023;15(2): 1403-1411.
11. Yamprasert R, Chanvimalueng W, Mukkasombut N, Itharat A. Ginger extract versus loratadine in the treatment of allergic rhinitis: a randomized controlled trial. BMC Complement Med Ther. 2020;20.
12. Abdullah B, Snidvongs K, Recto M, Poerbonegoro NL, Wang D. Primary care management of allergic rhinitis: a cross-sectional study in four ASEAN countries. Multidiscip Respir Med. 2020;15.
13. Wang H, Ji Q, Liao C, Tian L. A systematic review and meta-analysis of loratadine combined with montelukast for the treatment of allergic rhinitis. Front Pharmacol. 2023;14.
14. Tenn MW, Steacy L, Ng C, Ellis A. Onset of action for loratadine tablets for the symptomatic control of seasonal allergic rhinitis in adults challenged with ragweed pollen in the Environmental Exposure Unit: a post hoc analysis of total symptom score. Allergy Asthma Clin Immunol. 2018;14.
15. Zhang JX, Wang WY. Clinical efficacy of Tuomin Zhiti decoction in allergic rhinitis. Evid Based Complement Alternat Med. 2022.