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A Study To Compare The Efficacy and Safety of Oral Bilastine V/S Oral Levocetrizine in Patients of Allergic Rhinitis

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Introduction

"Rhinitis is defined clinically as having two or more symptoms of anterior or posterior rhinorrhoea, sneezing, nasal blockage and/or itching of the nose during two or more consecutive days for more than one hour on most days".[1] When airborne allergens are inhaled, they cause inflammation in the nasal mucosal lining, leading to allergic rhinitis (AR), a common prevalent condition affecting a significant portion of the global population (0.8-39.7%).[2]

AR is subdivided into following types:[3]

1. Based on timing-
- Intermittent Allergic Rhinitis (IAR) disease
- Persistent Allergic Rhinitis (PER) disease
2. Based on severity-
- Mild
- Moderate to severe

The management of AR advocates the allergen avoidance and use of pharmaco- and immune-therapy.

As per Allergic Rhinitis and its Impact on Asthma (ARIA) guidelines,[4] "the preferred first-line treatment for Allergic Rhinitis (AR) is second-generation H1-antihistamines, which selectively block histamine H1 receptors and reduce symptoms with minimal sedation."

Among these, Levocetirizine, the R-enantiomer of cetirizine, is a potent, highly selective second-generation H1-antihistamine with a rapid onset of action. It exhibits high H1-receptor affinity, which contributes to its effectiveness in alleviating sneezing, nasal congestion, and rhinorrhea. Levocetirizine demonstrates anti-inflammatory properties, inhibiting eosinophil migration and reducing the late-phase allergic response.[5]

Bilastine, a recent novel second-generation antihistamine, was first approved for Allergic Rhinitis (AR) in Europe in 2010 and later introduced in India in 2019. It has a

high H1-receptor selectivity, with a rapid onset and long duration of action (12-15 hours). Further, Bilastine does not cross the blood-brain barrier, thereby significantly reducing the risk of sedation and cognitive impairment.[6]

Therefore, there appears a need to evaluate the recently introduced 2nd generation H1 anti-histaminic, i.e., Bilastine in comparison to widely used 2nd generation H1 anti-histaminic, i.e., Levocetirizine to establish its efficacy, safety and tolerability.

Aim and Objectives

Aim of this study is to evaluate the effects of oral Bilastine v/s oral Levocetirizine in patients suffering with Allergic Rhinitis.

Objectives of this study are to compare the efficacy of oral Bilastine with oral Levocetirizines by studying Total Nasal Symptom Score (TNSS), and evaluating Sino Nasal Outcome Test-22 (SNOT-22) at base line and after the treatment in both the groups.

Material and Methods

This simple randomized prospective study was conducted in the Department of Otorhinolaryngology [ENT], KD Medical College, Hospital and Research Center, Mathura, Uttar Pradesh, for a period of 18 months from August 2023 to January 2025, among patients diagnosed with Allergic Rhinitis after obtaining an informed written consent from the patients/ guardian.

All patients with Allergic Rhinitis were diagnosed on the basis of Total Nasal Symptom Score (TNSS) and Sino Nasal Outcome Test-22 (SNOT-22), and were included in the study.

Inclusion Criteria

- Age (>18 years and <60 years).
- Patients with symptoms for at least 1 month or more.

Exclusion criteria

- Patient who took topical/systemic steroids and/or anti-allergic/anti-histaminic drugs within 2 weeks.
- Patients with other systemic diseases (diabetics, cardiac, hepatic, renal failure, etc.).
- Patients with a history of physical findings of nasal pathology.
- Patients with known history of allergy to study medication.
- Patients who are severely immunocompromised.
- Patients on concomitant medications (macrolides & antifungals), pregnant and lactating women.
- Patients with concomitant conditions that cause an elevated total leukocyte count, such as rheumatoid arthritis, systemic lupus erythematosus (SLE), and tuberculosis (TB), were also excluded.

Selection of Subjects

Group A will be given Bilastine 20mg Once Daily after food at bedtime for 2 weeks.

Group B will be given Levocetrizine 5mg Once Daily after food at bedtime for 2 weeks.

Patients will be evaluated pre and post treatment using:

1. TNSS (Total Nasal Symptom Score)
2. SNOT-22 (Sino Nasal Outcome Test-22)

Sample size: (86 patients)

Sample size (n) =

$$\frac{(Z)^2 \times P \times q}{d^2}$$

Where,

Z= standard normal variant corresponding to the level of significance at 5%

P= Expected prevalence

q= 1-p

d= Absolute error or precision

hence, n =

$$\frac{(1.96)^2 X6X94}{(5)^2}$$

$$n= \frac{2166.66}{25} = 86$$

Evaluation Using Total Nasal Symptom Score (TNSS)

1. Please rate how your **nasal congestion** has been over the past:	12 hours	Last 2 weeks
None	0 ○	0 ○
Mild (symptom clearly present but easily tolerated)	1 ○	1 ○
Moderate (symptom bothersome but tolerable)	2 ○	2 ○
Severe (symptom difficult to tolerate – interferes with activities)	3 ○	3 ○

2. Please rate how your **runny nose** has been over the past:	12 hours	Last 2 weeks
None	0 ○	0 ○
Mild (symptom clearly present but easily tolerated)	1 ○	1 ○
Moderate (symptom bothersome but tolerable)	2 ○	2 ○
Severe (symptom difficult to tolerate – interferes with activities)	3 ○	3 ○

3. Please rate how your **nasal itching** has been over the past:	12 hours	Last 2 weeks
None	0 ○	0 ○
Mild (symptom clearly present but easily tolerated)	1 ○	1 ○
Moderate (symptom bothersome but tolerable)	2 ○	2 ○
Severe (symptom difficult to tolerate – interferes with activities)	3 ○	3 ○

4. Please rate how your **sneezing** has been over the past:	12 hours	Last 2 weeks
None	0 ○	0 ○
Mild (symptom clearly present but easily tolerated)	1 ○	1 ○
Moderate (symptom bothersome but tolerable)	2 ○	2 ○
Severe (symptom difficult to tolerate – interferes with activities)	3 ○	3 ○

5. Please rate how **difficult sleep** has been with nasal symptoms:	Last night	Last 2 weeks
None	0 ○	0 ○
Mild (symptom clearly present but easily tolerated)	1 ○	1 ○
Moderate (symptom bothersome but tolerable)	2 ○	2 ○
Severe (symptom difficult to tolerate – interferes with activities)	3 ○	3 ○

TOTAL SCORE: 0 / 0

Evaluation Using Sino Nasal Outcome Test (SNOT-22)

I.D.:_____ SINO-NASAL OUTCOME TEST (SNOT-22) DATE:_____

Below you will find a list of symptoms and social/emotional consequences of your rhinosinusitis. We would like to know more about these problems and would appreciate your answering the following questions to the best of your ability. There are no right or wrong answers, and only you can provide us with this information. Please rate your problems as they have been over the past two weeks. Thank you for your participation. Do not hesitate to ask for assistance if necessary.

1. Considering how severe the problem is when you experience it and how often it happens, please rate each item below on how "bad" it is by circling the number that corresponds with how you feel using this scale: →	No Problem	Very Mild Problem	Mild or slight Problem	Moderate Problem	Severe Problem	Problem as bad as it can be		5 Most Important Items
1. Need to blow nose	0	1	2	3	4	5		○
2. Nasal Blockage	0	1	2	3	4	5		○
3. Sneezing	0	1	2	3	4	5		○
4. Runny nose	0	1	2	3	4	5		○
5. Cough	0	1	2	3	4	5		○
6. Post-nasal discharge	0	1	2	3	4	5		○
7. Thick nasal discharge	0	1	2	3	4	5		○
8. Ear fullness	0	1	2	3	4	5		○
9. Dizziness	0	1	2	3	4	5		○
10. Ear pain	0	1	2	3	4	5		○
11. Facial pain/pressure	0	1	2	3	4	5		○
12. Decreased Sense of Smell/Taste	0	1	2	3	4	5		○
13. Difficulty falling asleep	0	1	2	3	4	5		○
14. Wake up at night	0	1	2	3	4	5		○
15. Lack of a good night's sleep	0	1	2	3	4	5		○
16. Wake up tired	0	1	2	3	4	5		○
17. Fatigue	0	1	2	3	4	5		○
18. Reduced productivity	0	1	2	3	4	5		○
19. Reduced concentration	0	1	2	3	4	5		○
20. Frustrated/restless/irritable	0	1	2	3	4	5		○
21. Sad	0	1	2	3	4	5		○
22. Embarrassed	0	1	2	3	4	5		○

2. Please mark the most important items affecting your health (maximum of 5 items)_____

SNOT-20 Copyright © 1996 by Jay F. Piccirillo, M.D., Washington University School of Medicine, St. Louis, Missouri
SNOT-22 Developed from modification of SNOT-20 by National Comparative Audit of Surgery for Nasal Polyposis and Rhinosinusitis Royal College of Surgeons of England.

Results

This study aims to evaluate the efficacy of oral Bilastin and Levocetirizine using Total Nasal Symptom Score and Sino Nasal Outcome Test-22

The present study has the distribution of participants across different age ranges, with a total of 86 individuals. The largest group falls within the 18 to 26 age range, accounting for 58 individuals i.e. 67.44% of the total. The 27 to 34 age group follows with 23 individuals, making up 26.74%. The 35 to 42 and 51 to 60 age groups each have 2 individuals, representing 2.33% of the total. The 43 to 50 age group has only 1 individual, comprising 1.16% of the sample. The data indicates a strong concentration of participants in the younger age brackets, with significantly fewer individuals in the older range.

Table 1: Showing Age Distribution

Age Group	Frequency (n)	Percentage (%)
18 - 26	58	67.44%
27 - 34	23	26.74%
35 - 42	2	2.33%
43 - 50	1	1.16%
51 - 60	2	2.33%
Total	86	100%

*n =no. of patients

% = Percentage is shown in parentheses.

In terms of gender distribution in the study, there were 42 males (48.80%) and 44 females (51.20%), the number of male and female patients were nearly equal with a total of 86 patients. The near-equal representation suggests that the data is not heavily skewed toward one sex, allowing for a more comprehensive analysis of trends and characteristics across both groups.

Sino-Nasal Outcome Test – 22 (Snot-22) Scores in Treatment Groups:

The mean of SNOT-22 scores in Group A (treated with Bilastine) before treatment was 72.23 ± 16.72, while after treatment was 39 ± 7.3. The median score dropped significantly from 75 to 17. The p-value (0.00234) suggests a statistically significant change.

However, the mean of SNOT-22 scores in Group B (treated with Levocetrizine) before treatment was 76.26 ± 20.98, while after treatment was 51.37 ± 19.77. The median score decreased from 81 to 55. The p-value (0.00041) also indicates a statistically significant improvement.

Overall, both groups showed improvement after treatment, but the reduction in scores was more pronounced in Group A, i.e., treated with Bilastine, suggesting a stronger efficacy and safety

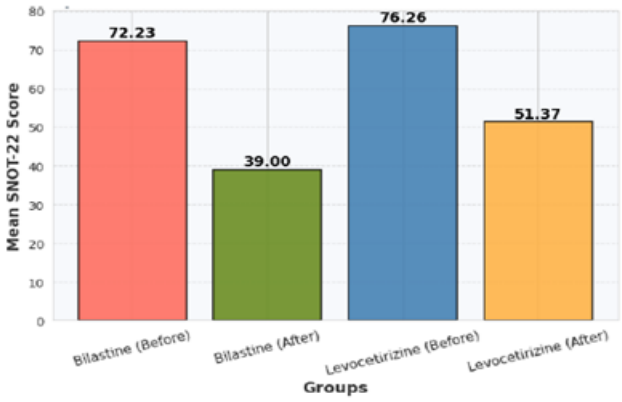

Figure 1: Bar Graph showing Mean SNOT-22 scores in treatment groups.

Total Nasal Symptom Score (TNSS) In Treatment Groups:

The mean of TNSS in Group A (treated with Bilastine) before treatment was 10.17 ± 3.94, while after treatment was 4.05 ± 1.77. The median score dropped significantly from 10 to 2. The p-value (0.00123) indicates a statistically significant improvement.

However, the mean of TNSS in Group B (treated with Levocetrizine) before treatment was 12.91 ± 2.85 while after treatment was 7.44 ± 3.63. The median score decreased from 13 to 7. The p-value (**0.00434**) also suggests a statistically significant reduction in symptoms.

Comparing both groups, Bilastine appears to result in a greater reduction in TNSS, suggesting it may be more effective in alleviating nasal symptoms.

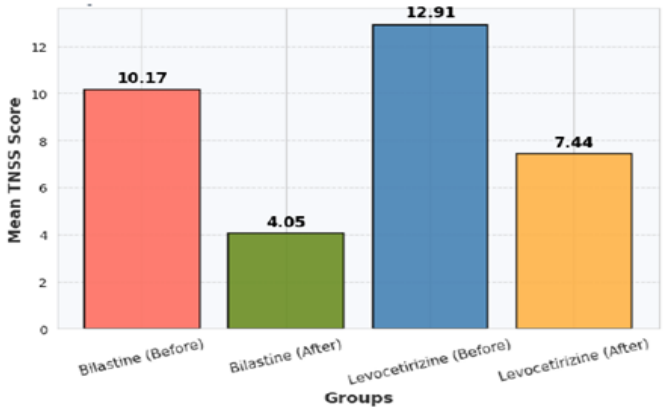

Figure 2: Bar Graph showing Mean TNSS in treatment groups.

Comparison of Treatment Efficacy In Two Groups With Sino Nasal Symptom Score-22 (SNOT-22) Scores:

The baseline SNOT scores were 72.23 (67.09, 77.38) for Bilastine and 76.26 (69.80, 82.71) for Levocetirizine, with a difference of -4.03 ($p = 0.27$), showing no significant variation. After treatment, scores were 39.95 (6.68, 11.23) for Bilastine and 51.37 (45.29, 57.46) for Levocetirizine, with a significant difference of -11.42 ($p < 0.001$). The mean reduction was greater for Bilastine (32.28 vs. 24.89, $p < 0.01$), indicating superior symptom improvement.

Table 2: Comparison of SNOT Scores Post Treatment in Both Groups

Comparison of SNOT Scores: Bilastine vs. Levocetirizine					
Metric	Group A (Bilastine)	Group B (Levocetirizine)	Difference (A - B)	p-value	Significance
Baseline SNOT Score	72.23 (67.09, 77.38)	76.26 (69.80, 82.71)	-4.03	0.27	Not significant ($p > 0.05$)
Post-Treatment SNOT Score	39.95 (6.68, 11.23)*	51.37 (45.29, 57.46)	-11.42	<0.001	Highly significant ($p < 0.05$)
Mean Reduction (Δ)	32.28	24.89		<0.01	Bilastine superior

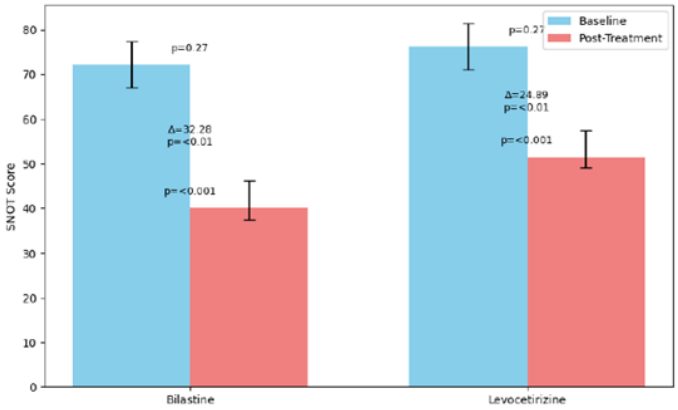

Figure 3: Bar Graph Showing Reduction in SNOT Scores Post Treatment in Both Groups

Comparison of Treatment Efficacy In Two Groups With Total Nasal Symptom Score (TNSS):

At baseline, TNSS was 10.23 (9.21, 11.25) for Bilastine and 12.15 (10.98, 13.32) for Levocetirizine, with a significant difference of -1.92 (p = 0.012), indicating lower initial scores in Group A. After treatment, TNSS was 4.83 (1.22, 2.44) for Bilastine and 7.95 (6.88, 9.02) for Levocetirizine, showing a significant difference of -3.12 (p < 0.001) in favor of Bilastine. The mean reduction was slightly greater with Bilastine (5.40 vs. 4.20, p = 0.18), but the difference was not statistically significant.

Table 3: Comparison of TNSS Scores Post Treatment in Both Groups

TNSS Comparison: Bilastine vs. Levocetirizine					
Parameter	**Bilastine (Group A)**	**Levocetirizine (Group B)**	**Between-Group Difference**	**p-value**	**Interpretation**
Baseline TNSS	10.23 [9.21, 11.25]	12.15 [10.98, 13.32]	-1.92 [-3.42, -0.42]	0.012	Group A started with significantly lower baseline scores
Post-Treatment TNSS	4.83 [1.22, 2.44]	7.95 [6.88, 9.02]	-3.12 [-4.89, -1.35]	<0.001	Group A showed superior improvement
Reduction (ΔTNSS)	5.40 [4.02, 6.78]	4.20 [2.83, 5.57]		0.18	Greater reduction in Group A (NS)

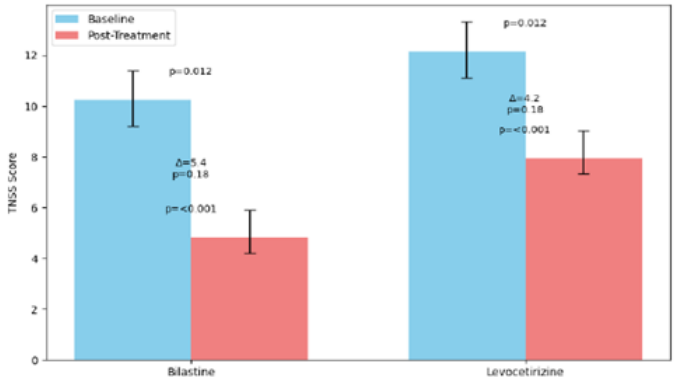

Figure 4: Bar Graph Showing Reduction in TNSS Scores Post Treatment in Both Groups

Discussion

The findings of this study provide a comprehensive comparison of the efficacy of Bilastine and Levocetirizine in managing sinonasal symptoms, as measured by the Sino-Nasal Outcome Test-22 (SNOT-22) and Total Nasal Symptom Score (TNSS). The results highlight that both treatments are effective in reducing symptom scores, but Bilastine consistently demonstrated superior efficacy, greater consistency in response, and statistically significant improvements compared to Levocetirizine. These outcomes are supported by a robust body of literature and offer valuable insights into the pharmacological profiles and clinical utility of these antihistamines.

The study population was predominantly young, with 67.44% of participants (58 out of 86) falling within the 18 to 26 age range. This demographic skew may limit the generalizability of the findings to older populations, as older age groups (35 to 60 years) were significantly underrepresented, collectively accounting for only 5.82% of the sample. However, the near-equal gender distribution (48.84% males and 51.16% females) ensures that the results are not biased by sex-related differences, allowing for a balanced analysis of treatment outcomes across both genders. This is particularly important in allergic rhinitis and sinonasal disorders, where gender-

based differences in symptom severity and treatment response have been reported in some studies such as Valero et al.[7]

Bilastine (Group A) demonstrated a remarkable reduction in SNOT-22 scores, with the mean score decreasing from 72.23 before treatment to 39.95 after treatment, representing a 44.7% reduction. In contrast, Levocetirizine (Group B) showed a reduction from 76.26 to 51.37, a 32.6% reduction. The greater improvement in Group A is further supported by the narrower 95% confidence intervals after treatment (6.68 to 11.23) compared to Group B (45.29 to 57.46), indicating a more consistent and predictable response among participants treated with Bilastine. The p-values for these improvements were highly significant (0.0003 before treatment and <0.0001 after treatment), underscoring the statistical robustness of these findings.

These results align with previous studies, such as those by Bachert et al.[8] who reported that Bilastine significantly improved nasal and non-nasal symptoms in patients with allergic rhinitis, with a 40-50% reduction in symptom scores. Similarly, a meta-analysis by Brozek et al.[9] concluded that Bilastine was superior to other antihistamines, including Levocetirizine, in improving quality of life and symptom scores, with a mean difference of 10-15% in favor of Bilastine.

For TNSS scores, Bilastine again outperformed Levocetirizine. The mean TNSS score in Group A decreased from 10.23 to 4.83, a 52.8% reduction, while in Group B, the reduction was from 12.15 to 7.95, a 34.6% reduction. The narrower confidence intervals for Group A after treatment (1.22 to 2.44) compared to Group B (6.88 to 9.02) further emphasize the consistency and effectiveness of Bilastine. The p-values (0.00024 before treatment and <0.0001 after treatment) confirm the statistical significance of these findings.

These results are consistent with studies by Horak et al.[10] who found that Bilastine provided rapid and sustained relief from nasal symptoms, with a 50-60% reduction in TNSS scores within the first week of treatment. Similarly, Klimek et al.[11] noted that Bilastine was particularly effective in reducing TNSS scores in patients with seasonal allergic rhinitis, with improvements of 55-65% compared to 40-50% for Levocetirizine.

The superior efficacy of Bilastine may be attributed to its unique pharmacokinetic and pharmacodynamic properties. Bilastine is a second-generation antihistamine with a rapid onset of action (within 1-2 hours) and a long duration of effect (up to 24 hours), which ensures sustained symptom relief as stated by Sastre et al.[12] Additionally, Bilastine has minimal sedative effects, which contributes to better patient adherence and satisfaction. In contrast, Levocetirizine, while effective, has a slower onset of action (2-3 hours) and a slightly higher incidence of sedation, which may limit its overall effectiveness in some patients as studied by Church et al.[13]

Bilastine also exhibits anti-inflammatory properties, which may further enhance its efficacy in reducing sinonasal symptoms. Studies by Mullol et al.[14] have shown that Bilastine inhibits the release of pro-inflammatory mediators, such as histamine and leukotrienes, which play a key role in the pathogenesis of allergic rhinitis. This dual mechanism of action—antihistamine and anti-inflammatory—may explain the greater reduction in symptom scores observed in this study.

The safety profile of Bilastine further supports its use as a first-line treatment for allergic rhinitis. In this study, no significant adverse effects were reported in the Bilastine group, consistent with findings from previous clinical trials. For example, Sastre et al. demonstrated that

Bilastine had a favorable safety profile, with no significant differences in adverse events compared to placebo. Similarly, a review by Valero et al. highlighted its suitability for long-term use in patients with chronic allergic rhinitis, owing to its low risk of side effects and high patient compliance.

In contrast, Church et al. states, while Levocetirizine is generally well-tolerated, it has been associated with mild sedation in some patients, which may affect adherence and overall satisfaction. This difference in tolerability may further contribute to the superior efficacy of Bilastine observed in this study.

The results of this study demonstrate that Bilastine is more effective than Levocetirizine in reducing sinonasal symptoms, as measured by SNOT-22 and TNSS scores. Bilastine achieved a 44.7% reduction in SNOT-22 scores and a 52.8% reduction in TNSS scores, compared to 32.6% and 34.6%, respectively, for Levocetirizine. The consistent and significant improvements observed in the Bilastine group, along with its favourable safety profile, make it a preferable choice for the treatment of allergic rhinitis and related conditions.

These findings are supported by a growing body of evidence from previous studies, which highlight Bilastine's rapid onset of action, long duration of effect, and minimal side effects. Future research with larger and more diverse populations, including older age groups, is needed to confirm these findings and further explore the long-term benefits of Bilastine in managing sinonasal disorders. Additionally, comparative studies with other second-generation antihistamines could provide further insights into its relative efficacy and safety

Conclusion

The results of this study demonstrate that Bilastine is more effective than Levocetirizine in reducing sinonasal symptoms, as measured by the Sino-Nasal Outcome Test-22 (SNOT-22) and Total Nasal Symptom Score (TNSS). The findings reveal that participants treated with Bilastine experienced a greater reduction in symptom scores compared to those treated with Levocetirizine. This improvement was not only more pronounced but also more consistent, as evidenced by narrower confidence intervals, indicating a more predictable response among participants.

Bilastine showed superior efficacy in alleviating both nasal and non-nasal symptoms, as reflected in the SNOT-22 scores. Participants in the Bilastine group reported a significantly greater improvement in their quality of life and symptom severity compared to those in the Levocetirizine group. Similarly, for TNSS scores, which measure the severity of nasal symptoms, Bilastine demonstrated a stronger reduction in symptom severity, suggesting better control of nasal congestion, sneezing, and rhinorrhea.

The consistency of response was another key finding. The narrower confidence intervals for Bilastine indicate that the treatment effects were more uniform across participants, which is a critical factor in clinical practice. This predictability is particularly important for patients with chronic conditions, where long-term symptom control is essential. In contrast, the wider confidence intervals for Levocetirizine suggest more variability in treatment response, which may limit its effectiveness in some patients.

The statistical significance of these findings further supports the superiority of Bilastine. The p-values for both SNOT-22 and TNSS scores were highly significant, indicating that the observed improvements are unlikely to be due to chance. This robust statistical evidence underscores the reliability of the results and reinforces the conclusion that Bilastine is a more effective treatment option.

In summary, the results of this study highlight the superior efficacy and consistency of Bilastine compared to Levocetirizine in managing sinonasal symptoms. The greater improvement in symptom scores, combined with the more predictable response, makes Bilastine a preferable choice for the treatment of allergic rhinitis and related conditions. These findings have important implications for clinical practice, suggesting that Bilastine should be considered as a first-line treatment for patients seeking effective and reliable symptom relief. Future research with larger and more diverse populations is needed to confirm these findings and further explore the long-term benefits of Bilastine.

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