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COMPARATIVE STUDY OF HERBAL AND CONVENTIONAL ANTIHISTAMINES IN THE MANAGEMENT OF ALLERGIC RHINITIS IN CHILDREN

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ABSTRACT

Background:
Allergic rhinitis (AR) is a common chronic condition in children that significantly impacts quality of life and is typically managed using antihistamines, both conventional and herbal.

Objective:
To compare the efficacy and safety of herbal versus conventional antihistamines in the management of AR in children.

Methodology:
A prospective, descriptive, comparative observational study was conducted at the University of Lahore in collaboration with the Pediatric Outpatient Department of Mayo Hospital, Lahore, over 12 months (April 2022–March 2023). A total of 130 children aged 6–12 years clinically diagnosed with AR were enrolled and divided into two groups: herbal antihistamine group (n=65) receiving Nigella sativa and Perilla frutescens, and conventional antihistamine group (n=65) receiving cetirizine or loratadine. Efficacy was assessed using

the Total Nasal Symptom Score (TNSS) at baseline, weeks 2, 4, 8, and 12, along with adverse effects, recurrence rates, and parental satisfaction.

Results:

Both groups showed significant symptom reduction over 12 weeks ($p<0.001$). At week 12, TNSS was reduced to 2.49 ± 0.87 in the herbal group and 2.10 ± 0.84 in the conventional group ($p=0.012$). Fewer adverse effects were reported in the herbal group, with 81.54% (n=53) experiencing none, compared to 58.46% (n=38) in the conventional group ($p=0.004$). Recurrence of symptoms was lower in the herbal group (15.38%) than in the conventional group (24.62%). Parental satisfaction was slightly higher in the herbal group (60%) versus the conventional group (50.77%).

Conclusion:

Herbal antihistamines offer a well-tolerated alternative to conventional therapy with comparable long-term efficacy in managing pediatric AR.

INTRODUCTION

Allergic rhinitis (AR) is a prevalent chronic condition in children, characterized by nasal congestion, sneezing, rhinorrhea, and itching, often triggered by exposure to environmental allergens such as pollen, dust mites, and pet dander [1,2]. It significantly affects the quality of life, leading to sleep disturbances, impaired school performance, and increased healthcare utilization [3]. As the prevalence of AR continues to rise globally, particularly in urban populations, its management has become a growing concern in pediatric healthcare [4].

Conventional antihistamines, particularly second-generation agents like loratadine and cetirizine, are widely prescribed for symptom relief due to their non-sedative properties and proven efficacy [5]. However, long-term use in children raises concerns about potential side effects, including drowsiness, dry mouth, headache, and, in rare cases, behavioral changes [6]. These concerns have prompted many caregivers and healthcare professionals to explore alternative therapies that offer symptom control with minimal adverse effects [7].

Herbal medicine has gained increasing attention as a complementary or alternative approach in managing allergic diseases, including AR [8]. Herbal formulations derived from natural sources such as *Nigella sativa* (black seed), *Butterbur*, and *Perilla frutescens* have demonstrated anti-inflammatory, immunomodulatory, and antihistaminic properties in various studies [9]. These remedies are often perceived as safer and more tolerable, particularly for pediatric use, given their historical usage in traditional medicine systems like Ayurveda, Unani, and Traditional Chinese Medicine [10].

Despite anecdotal evidence and small-scale studies supporting the efficacy of herbal antihistamines, there remains limited high-quality, comparative research evaluating their performance against conventional pharmacological agents in the pediatric population. A thorough, evidence-based evaluation of both treatment modalities is essential to inform clinical decision-making and parental choice, especially in regions

where herbal medicine is culturally accepted and widely used.

Research Objective

To compare the efficacy and safety of herbal antihistamines with conventional antihistamines in the management of AR in children.

METHODOLOGY

Study Design and Setting

This study was designed as a descriptive, prospective, comparative observational study aimed at evaluating the efficacy and safety of herbal versus conventional antihistamines in the management of AR in children. The research was conducted at the University of Lahore, in collaboration with the Pediatric Outpatient Department of Mayo Hospital, Lahore. The data collection period spanned 12 months, from April 2022 to March 2023.

Inclusion and Exclusion Criteria

The study population comprised children aged 6 to 12 years who were clinically diagnosed with AR based on standard diagnostic criteria. Inclusion required the presence of at least two cardinal symptoms—such as nasal congestion, sneezing, rhinorrhea, or nasal itching. Children with coexisting asthma, other chronic respiratory illnesses, known allergies to the medications under observation, recent use (within four weeks) of systemic corticosteroids or immunotherapy, or those with chronic systemic diseases were excluded. Informed written consent was obtained from parents or legal guardians of all participants prior to enrollment.

Sample Size and Sampling Technique

A total of 130 children meeting the inclusion criteria were enrolled through convenience sampling. After obtaining informed consent, participants were categorized into two observational groups based on the type of antihistamine they were already receiving—either herbal (n=65) or conventional (n=65). Group assignment was not randomized, and no experimental intervention was introduced; instead, treatment decisions were made under existing clinical guidelines by attending physicians or based on parental preference. To reduce potential selection bias, efforts were made to ensure comparable baseline characteristics between the groups during data analysis. The study retained its observational nature, with investigators collecting data passively without altering or assigning treatments.

Treatment Groups

Children in the herbal group were using a standardized herbal formulation containing *Nigella sativa* (40 mg/kg/day) and *Perilla frutescens* (25 mg/kg/day), divided into two daily doses. The formulation was prepared by a licensed herbal pharmaceutical company under Good Manufacturing Practices (GMP), and use was based on physician guidance or traditional medicine prescriptions.

Children in the conventional group were administered FDA-approved second-generation antihistamines as prescribed by their pediatricians. These included cetirizine at a dose of 5 mg once daily and loratadine at a dose of 10 mg once daily, both recommended for children aged 6 to 12 years. The specific choice of antihistamine was based on individual clinical judgment. Information regarding the type of medication, prescribed dosage, and treatment adherence was documented through a combination of medical prescriptions and parent-maintained diaries throughout the study period.

Data Collection

Demographic data (age, gender, socioeconomic background) and clinical history were collected at baseline using a structured questionnaire specifically designed by the research team in consultation with pediatric allergists and pharmacology experts to ensure clinical relevance and content validity. The severity of AR symptoms was assessed using the Total Nasal Symptom

Score (TNSS) at baseline and then at weeks 2, 4, 8, and 12. Data on side effects, recurrence of symptoms, and parental satisfaction with the treatment were gathered through follow-up interviews and clinical records. All assessments were conducted by trained clinicians using standardized tools to ensure consistency and minimize observer bias.

Outcome Measures

The primary outcome was the change in TNSS from baseline to 12 weeks.

Secondary outcomes included the frequency and severity of adverse effects, relapse of symptoms during the follow-up period, and parental satisfaction with the respective treatment approaches**.**

Statistical Analysis

Data were analyzed using SPSS version 25. Descriptive statistics such as mean, standard deviation, and frequency distribution were used to describe the baseline characteristics and outcome variables. Group comparisons were conducted using independent t-tests for continuous variables and chi-square tests for categorical variables. Repeated measures ANOVA was used to assess changes in TNSS scores over time within and between the two groups. A p-value of less than 0.05 was considered statistically significant.

Ethical Considerations

The study was approved by the Institutional Review Board of the University of Lahore. Written informed consent was obtained from the parents or guardians of all participants prior to data collection. All procedures were conducted in accordance with the ethical principles outlined in the Declaration of Helsinki, ensuring participant confidentiality, voluntary participation, and the right to withdraw at any stage without penalty.

RESULTS

The baseline demographic and clinical characteristics of the 130 participants (65 in each group) showed no significant differences between the herbal and conventional treatment groups (table 1). The mean age was 8.12 ± 1.78 years in the herbal group and 8.09 ± 1.84 years in the conventional group (p = 0.88). Males made up 36 patients (55.38%) in the herbal group and 34 patients (52.31%) in the conventional group. Socioeconomic status distribution was similar across groups: low (22 vs. 24), middle (30 vs. 28 patients), and high (13 patients in both groups), with p = 0.63. Family history of allergy was reported in 27 patients (41.54%) herbal and 29 patients (44.62%) conventional patients (p = 0.73). The duration of AR was comparable (10.32 ± 4.21 months vs. 10.54 ± 4.38 months; p = 0.78).

Table 1: Baseline Demographic and Clinical Characteristics of Study Participants (N = 130)

Characteristic	Category	Herbal Group (n;%)	Conventional Group (n;%)	p-value
Age (years)	Mean ± SD	8.12 ± 1.78	8.09 ± 1.84	0.88
Gender	Male	36 (55.38)	34 (52.31)	0.72
	Female	29 (44.62)	31 (47.69)	
Socioeconomic Status	Low	22 (33.85)	24 (36.92)	0.63
	Middle	30 (46.15)	28 (43.08)	
	High	13 (20.00)	13 (20.00)	
Family History of Allergy	Yes	27 (41.54)	29 (44.62)	0.73
	No	38 (58.46)	36 (55.38)	
Duration of AR (months)	Mean ± SD	10.32 ± 4.21	10.54 ± 4.38	0.78

The mean TNSS improved over time in both groups, with statistically significant differences emerging from week 4 onward (table 2). At baseline, scores were comparable: 8.32 ± 1.17 (herbal) vs. 8.40 ± 1.12 (conventional), p = 0.62. By week 4, TNSS had reduced to 4.72 ± 1.02 in the herbal group and 3.96 ± 0.98 in the conventional group (p = 0.001). At week 12, the herbal group had a score of 2.49 ± 0.87 compared to 2.10 ± 0.84 in the conventional group (p = 0.012). Within-group reductions were highly significant (p < 0.001), indicating both treatments were effective.

Table 2: Mean TNSS at Each Time Point

Time Point	Herbal Group (Mean ± SD)	Conventional Group (Mean ± SD)	p-value
Baseline	8.32 ± 1.17	8.40 ± 1.12	0.62
Week 2	6.19 ± 1.15	5.88 ± 1.08	0.08
Week 4	4.72 ± 1.02	3.96 ± 0.98	0.001
Week 8	3.24 ± 0.95	2.61 ± 0.91	0.003
Week 12	2.49 ± 0.87	2.10 ± 0.84	0.012
Within-group p value	<0.001	<0.001	—

Adverse effects were generally mild and less frequent in the herbal group (table 3). Drowsiness occurred in 3 patients (4.62%) herbal vs. 11 patients (16.92%) conventional patients (p = 0.025), while dry mouth was reported in 2 patients (3.08%) vs. 7 patients (10.77%), respectively (p = 0.081). Headaches were similar (5 vs. 6 patients), and nausea was low in both groups (2 vs. 3 patients). Notably, 53 (81.54%) of herbal group patients reported no side effects, compared to 38 (58.46%) in the conventional group (p = 0.004), favoring the herbal treatment in terms of tolerability.

Table 3: Adverse Effects Reported During the Study Period

Adverse Effect	Herbal Group (n;%)	Conventional Group (n;%)	p-value
Drowsiness	3 (4.62)	11 (16.92)	0.025
Dry Mouth	2 (3.08)	7 (10.77)	0.081
Headache	5 (7.69)	6 (9.23)	0.75
Nausea	2 (3.08)	3 (4.62)	0.65
No Adverse Effects	53 (81.54)	38 (58.46)	0.004

Within 4 weeks after treatment completion, recurrence of symptoms was slightly lower in the herbal group (table 4). No recurrence was noted in 55 patients (84.62%) herbal and 49 patients (75.38%) conventional patients. Mild recurrence occurred in 8 patients (12.31%) and 12 patients (18.46%) patients, respectively, while moderate to severe recurrence was reported by 2 patients (3.08%) in the herbal group and 4 patients (6.15%) in the conventional group. Although not statistically significant (p = 0.17), the trend suggests a marginally lower relapse rate with the herbal therapy.

Table 4: Recurrence of Symptoms Within 4 Weeks After Treatment Completion

Recurrence Status	Herbal Group (n;%)	Conventional Group (n;%)	p-value
No Recurrence	55 (84.62)	49 (75.38)	0.17
Mild Recurrence	8 (12.31)	12 (18.46)	
Moderate to Severe	2 (3.08)	4 (6.15)	

Parental satisfaction at week 12 was slightly higher in the herbal group (table 5). A total of 39 patients (60.00%) parents of herbal group patients were very satisfied compared to 33 patients (50.77%) in the conventional group (p = 0.29). Somewhat satisfied responses were reported by 22 patients (33.85%) in the herbal and 26 patients (40.00%) in the conventional group. Dissatisfaction was low overall, noted in 4 patients (6.15%) herbal and 6 patients (9.23%) conventional group parents, indicating favorable perception for both treatments with a mild preference toward the herbal option

Table 5: Parental Satisfaction with Treatment at Week 12

Satisfaction Level	Herbal Group (n;%)	Conventional Group (n;%)	p-value
Very Satisfied	39 (60.00)	33 (50.77)	0.29
Somewhat Satisfied	22 (33.85)	26 (40.00)	
Not Satisfied	4 (6.15)	6 (9.23)	

DISCUSSION

The present study aimed to evaluate and compare the efficacy and safety of herbal and conventional antihistamines in managing AR in children. The findings indicate that both treatment modalities significantly reduced the TNSS over 12 weeks; however, conventional antihistamines showed a slightly more rapid improvement. At week 4, the mean TNSS was 4.72 ± 1.02 in the herbal group and 3.96 ± 0.98 in the conventional group ($p = 0.001$), while by week 12, scores further decreased to 2.49 ± 0.87 and 2.10 ± 0.84, respectively ($p = 0.012$). These results are consistent with the previous findings, who demonstrated that second-generation antihistamines like cetirizine provided rapid symptom relief in pediatric AR [11,12]. However, our results also confirm that the herbal formulation was effective, albeit with a slower onset, aligning with the previous study, which reported significant symptom improvement with Nigella sativa in AR over an 8-week period [13,14].

In terms of safety and tolerability, the herbal group experienced fewer adverse effects. Drowsiness was reported in only 3 patients (4.62%) in the herbal group compared to 11 patients (16.92%) in the conventional group ($p = 0.025$), while 81.54% of herbal users reported no side effects versus 58.46% in the conventional group ($p = 0.004$). These findings support previous studies indicating that herbal therapies such as *Perilla frutescens* and *Nigella sativa* have fewer sedative and anticholinergic effects [15].

Recurrence of symptoms within four weeks' post-treatment was slightly lower in the herbal group (15.38%) than in the conventional group (24.62%), although this difference was not statistically significant ($p = 0.17$). This trend might suggest a more sustained anti-inflammatory effect of herbal compounds, as reported in a research study by Bival et al., [16], where *Perilla frutescens* extract maintained symptom control beyond the active treatment phase. Such sustained immunomodulatory activity may contribute to prolonged symptom suppression compared to conventional antihistamines, which primarily block histamine receptors without affecting the underlying inflammatory cascade.

Parental satisfaction also favored the herbal group, with 60.00% expressing high satisfaction versus 50.77% in the conventional group. While both groups showed general approval, the higher satisfaction rate among herbal users may reflect the perceived safety and minimal side effects observed, echoing findings from other pediatric complementary medicine studies [17]. Overall, these findings suggest herbal antihistamines as a viable and well-tolerated alternative, especially in settings where natural treatments are culturally accepted and preferred.

Study Strengths and Limitations

A key strength of this study is its prospective design and direct comparison of herbal and conventional antihistamines in a real-world pediatric population over a 12-week period, which enhances the clinical relevance and generalizability of the findings. The use of standardized symptom scoring (TNSS), consistent follow-up intervals, and inclusion of both efficacy and safety outcomes provide a comprehensive assessment of treatment performance. Moreover, the study addressed an important knowledge gap by evaluating culturally accepted herbal formulations using

structured clinical methods. However, limitations include the non-randomized design and convenience sampling, which may introduce selection bias. Additionally, treatment assignment was based on existing prescriptions or parental choice rather than random allocation, possibly affecting internal validity. The sample size, although adequate for preliminary comparison, may limit the power to detect smaller differences in recurrence or satisfaction rates. Lastly, reliance on parent-reported adherence and side effects may be subject to reporting bias.

CONCLUSION

This study demonstrates that both herbal and conventional antihistamines are effective in reducing AR symptoms in children, with conventional agents showing faster symptom relief and herbal options offering better tolerability and fewer side effects. While conventional antihistamines like cetirizine and loratadine provided slightly superior short-term efficacy, the Nigella sativa and Perilla frutescens formulation showed comparable long-term benefits with a lower incidence of adverse effects and higher parental satisfaction. These findings support the integration of evidence-based herbal alternatives into pediatric allergy management, particularly in populations with strong cultural acceptance of traditional medicine.

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