

A COMPARATIVE STUDY ON TOLERABILITY AND EFFICACY OF COMBINATION THERAPY MONTILUKAST/CETIRIZINE AND MONOTHERAPY CETIRIZINE IN ADULT PATIENTS WITH ALLERGIC RHINITIS

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Abstract

Allergic Rhinitis occurs due to exposure to airborne allergen that tends to escalate a cascade contributing to release of mediators that presents overall picture of inflammatory response. Interleukins, Cytokines take active part in this inflammatory cascade while subsequent release of Eosinophils, Basophils and IgE strengthens this chain. Retarding the release of Histamine and Cysteinyl leukotriene helps in improving the overall symptoms of Allergic Rhinitis and thus Anti Histamines and Leukotriene receptor antagonists are the mainstay in its treatment which improves the associated symptoms of nasal congestion and Rhinorrhoea. Two groups were employed treatment regimens i.e, Group A was treated with Cetirizine (CT) 10mg/day and Montelukast (MTL) 10mg/day and Group B was only given CT 10mg/day. Results were evaluated statistically using Severity of symptoms and Visual Analogue Scale (VAS) and showed significant and promising result in case of Group A. Thus such treatment model can be helpful in managing Allergic rhinitis while it still provides the space for new and novel approaches to compete Allergic Rhinitis in more specific and optimistic way.

INTRODUCTION

Allergic rhinitis (AR) is caused by exposure to an airborne allergen in a predisposed individual

(Matricardi et al., 2000). Activation of both humoral (B-Cell) and cytotoxic (T-Cell) immune responses with subsequent release of allergen

specific IgE antibody that leads to the release of inflammatory mediators such as interleukins and cytokines. The response is increased as antigen is passed to regional lymph nodes for greater T-Cell activation.(Bousquet et al., 2008). Interleukin and cytokine release causes specific activation of mast cells, eosinophils, plasma cells, basophils and other T-Cells, many of these circulating cells then migrate into the nasal and ocular epithelium where they contribute directly to symptoms through pro-inflammatory mediators including histamine, prostaglandins, cysteinyl leukotrienes and kinnins.(Akdis et al., 1998; Siddiq et al., 2026). Seasonal AR is most commonly caused by pollens and spores. Flowering shrub and tree pollens are most common in the spring, flowering plants and grasses in the summer, and ragweed and molds in the fall. Dust household mites, air pollution and pet dander may produce year round symptoms termed as perennial rhinitis. Symptoms of AR are characterized by clear rhinorrhoea, nasal congestion, sneezing, tearing, eye irritation and eye pruritis. Associated symptoms include cough, bronchospasm, and eczematous dermatitis. Nasal symptoms are oftenly accompanied with eye irritation, pruritis, conjuntival erythema and excessive tearing.

In the Allergic Rhinitis and its Impact on Asthma (ARIA) guidelines, the classification of AR is based upon both quality of life and symptom severity and duration(Bousquet et al., 2008; Pirzada et al., 2025). In this regard, nasal obstruction constitutes the most bothersome symptom and has been proposed as the key symptom in AR. Nasal obstruction may be evaluated subjectively by the perception of air passage through the nose, and objectively by measuring nasal airflow resistance through rhinomanometry. However, the objective assessment of nasal obstruction, even though simple to perform, needs the use of rhinomanometry, which is rarely present in the doctor's office. Recently, the visual analog scales (VAS) have been proposed as a useful parameter in assessing allergic rhinitis.(Ciprandi et al., 2009). A VAS ranging from 0 (nasal symptoms,

not at all bothersome) to 10 cm (nasal symptoms, extremely bothersome) was used to assess the severity of combined nasal symptoms.(Bousquet et al., 2007; Shahab et al.)

Eosinophil-derived mediators such as major basic protein, eosinophil cationic protein, and leukotrienes have been shown to damage the epithelium, leading ultimately to the clinical and histologic pictures of chronic allergic rhinitis.(Khan et al., 2026; Skoner, 2001)

The literature supports the use of anti leukotriene medications such as Montelukast 10mg/day orally alone (Abdulla, 2012; Abrar et al., 2026) or with cetirizine 10mg/day or loratadine 10mg/day orally which improves AR symptoms including nasal rhinorrhoea, sneezing and nasal congestion.(Ciprandi et al., 1997; Ghufraan et al., 2023)

Montelukast is a selective and orally active leukotriene receptor antagonist that especially inhibits the cysteinyl leukotriene receptor (Cys LTR). It is rapidly absorbed following oral administration of 10mg ,the mean peak plasma concentration (C_{max}) is achieved in 3 hours (T_{max}) in adults, the mean oral bioavailability is 64%. It is used for the prophylaxis of Asthma and seasonal allergies.(Bunnag et al., 2009; Ghufraan et al., 2023)

Cetirizine is a third generation sedative anti histamine. Plasma concentration of 10mg of cetirizine is approximately 300µg/dl and is achieved within 1.0 ± 0.5hour. Terminal half life is app 10hours. It is used in AR, hay fever, urticaria.(Sheffer & Samuels, 1990)

Materials and Methods

A randomized trial study was conducted and 88 patients were enrolled. The study was carried out over a period of 5-3-2016 to 01-04-2016. The enrolled patients were followed up to one month. They were categorized into two groups A & B. In group A number of adult patients (M=20 Mean 35.55 and SD 14.24 /F=18 Mean 31.83 and SD 12.18) were 38, and those patients were prescribed Montelukast 10mg and Cetirizine 10mg daily for two weeks and in group B 50

adult patients (M=27 Mean 38.33 and SD 14.57/F=23 Mean 37.57 and SD 11.96) were enrolled they were prescribed Cetirizine 10mg daily for two weeks. Ages of males were between 14 to 66years and females were 13 to 65years. All the patients were initially screened for suggested symptoms of AR including VAS, presenting

symptoms, history, laboratory values pertaining to Basophils, and Eosinophils were recorded.

Patients with history of nasal surgeries, nasal polyps with AR, Perennial rhinitis, Vasomotor rhinitis, Viral rhinitis, those with history of immunotherapy and who have taken treatment before were excluded from the study.

The Criterion for AR symptoms was set as follows

Numbering	Severity	Symptoms
1	Minor	Nasal itching, eye pruritis
2	Mild	Sneezing 3-5/d, nasal itching
3	Moderate	Sneezing 5-10/d, nasal itching, eye pruritis and tearing
4	Severe	Rhinorrhoea, Tearing, Sneezing >10/d with associated coughing

A VAS ranging from 0 (nasal symptoms, not at all bothersome) to 10 cm (nasal symptoms, extremely bothersome) was used to assess the severity of combined nasal symptoms. Patients were asked to keep pen over the length of 10cm from 0 to 10 and subsequently symptoms were gauged accordingly.

Results

In Group A 38 patients were treated and each patient was followed up to 10 days of short

treatment. They were well improved from nasal congestion and Rhinorrhoea (AR). VAS also showed significant decrease. They were complaining of dryness of mouth as a side effect. In Group B 50 patients were treated and followed up to 10 days of short treatment. They showed a little bit of improvement from nasal congestion and Rhinorrhoea (AR). VAS showed no significant decrease. They were complaining of vertigo and drowsiness.

Severity of AR symptoms

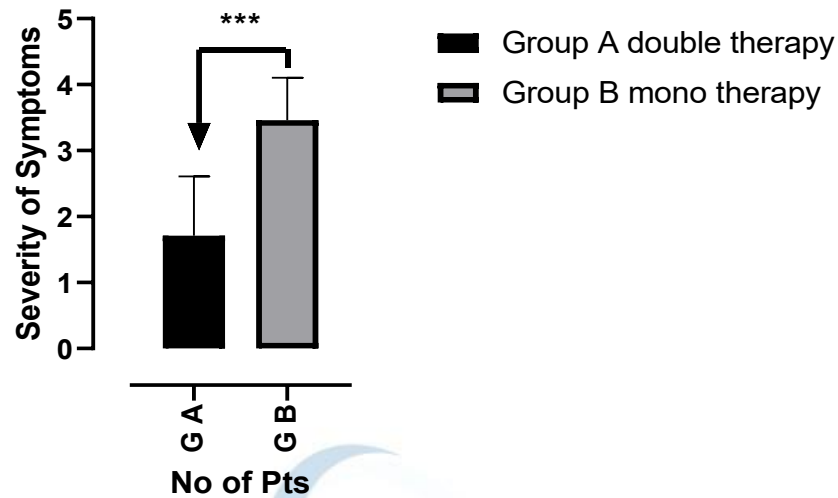


Fig1.1: It shows comparison of Group A (Cetirizine 10mg and Montilukast 10mg/day) with Group B only Cetirizine 10mg/day. Unpaired t-test showed (***) significance with p value <0.0001 for Severity of symptoms.

Visual Analogue Scale

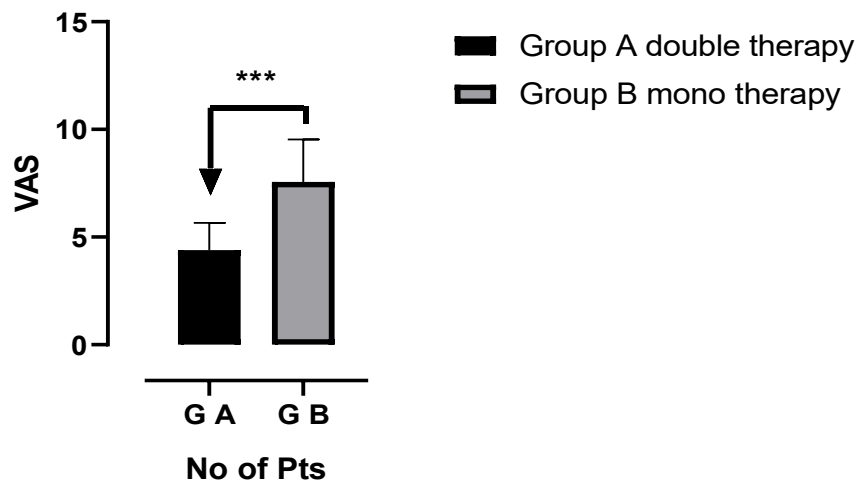


Fig 1.2: It shows comparison of Group A (Cetirizine 10mg and Montilukast 10mg/day) with Group B only Cetirizine 10mg/day. Unpaired t-test showed (***) significance with p value <0.0001 for VAS.

The results were evaluated statistically using GraphPad Prism 8.0.2. It revealed that there was statistically significant (***) improvement of nasal congestion and Rhinorrhoea in Group A with combined therapy as compared to Group B with monotherapy. VAS also showed significant decrease (p value <0.0001,) for Group A in terms of decrease in symptoms that were bothersome.

Conclusion

Results of the study suggest that the combination therapy of Montelukast 10mg and Cetirizine 10mg once daily gives better improvement of patients with AR then monotherapy with Cetirizine 10mg once daily. But further study is warranted to assure more multifaceted approach to the treatment of Allergic Rhinitis

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