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ORIGINAL ARTICLE

Impact of Montelukast on Allergic Rhinitis and Asthma as Emerging New Treatment Option

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ABSTRACT

Background: AR (allergic rhinitis) is a condition that causes chronic nasal mucosal inflammation. Among the regional signs of AR are sneezing, rhinorrhea, nasal discomfort, and nasal congestion. AR places a considerable financial and social impact on both the person with AR and society. There is mounting evidence that AR may elevate inflammatory mediators throughout the body and raise the chance of developing asthma.
Aim: To determine the degree to which Montelukast altered the symptoms and signs of allergic rhinitis (AR) and asthma, as well as to estimate the proportion of participants who were adversely affected. The absolute eosinophil count and five essential asthma and allergic rhinitis symptoms were assessed before and after therapy.
Method: This was a randomized trial. This experiment at the Lahore General Hospital involved 204 participants with asthma and allergic rhinitis. Participants received either (budesonide) BD (256 mg) with (montelukast) MNT (10mg) + MNT for two weeks, or BD alone (256 mg). The data was entered and analysed in SPSS 23.
Results: However, when compared to BD alone, BD + MNT demonstrated noticeably greater improvements in nasal blockage and itching. Both treatments greatly lessened the five primary symptoms as compared to the baseline. After two weeks of treatment, absolute eosinophil counts in BD + MNT significantly surpassed BD.
Practical Implication: Asthma and allergic rhinitis are major problems nowadays. This investigation will help find better answers to this problem. BD+ MNT is a more successful treatment for this illness. **Conclusion:**BD + MNT therapy may be more efficient overall than BD monotherapy for those with asthma and allergic rhinitis, especially in lowering nasal obstruction, itching, and subclinical lower airway inflammation. The absolute eosinophil count can also be used to monitor a patient's response to treatment for allergic rhinitis. Keywords: Asthama, budesonide, montelukast, and allergic rhinitis.
Key words: Montelukast, allergic rhinitis, Asthma, Emerging New Treatment Option

INTRODUCTION

Allergic rhinitis (AR) is a condition that causes chronic nasal mucosal inflammation. Some of the regional signs of AR are sneezing, rhinorrhea, itching in the nose, and nasal congestion. AR places a considerable financial and social impact on both the person with AR and society. A growing amount of research suggests that AR may elevate inflammatory mediators in the body and raise the chance of developing asthma. Inflammatory cells such as mast cells and eosinophils, histamine, tryptase and leukotrienes have all been connected to the emergence of disease.

Currently available treatments for AR include nonpharmacological methods, medicine, and immunotherapy. The most successful topical therapy for mild-to-severe AR is intranasal corticosteroids (INSs), which are regarded as the first-line treatment in this regard. Treatment for AR should be viewed as both a chance to halt its effects and a plan to control its symptoms. AR has recently been treated using leukotriene receptor antagonists (LTRAs), which are given orally and are unaffected by steroids or antihistamines. LTRAs diminish cysteine leukotrienes, which are crucial mediators of the late-phase AR response and asthma symptoms. Since loratadine and other antihistamines' effectiveness has been shown to be comparable to that of LTRAs6, Originally prescribed to treat asthma, these medications are now more frequently used to ostensibly reduce nasal congestion.

The most common comorbidity for asthmatics is AR, which accounts for 80% of all underdiagnosed coexisting "ghost" diagnoses in asthmatics. According to a US study, 53% and 72% of asthmatics, respectively, reported having AR symptoms. These participants had no AR diagnosis. Epidemiology shows that asthma is a very frequent condition. With an AR frequency of 70% in asthmatics, around 30% of patients have AR as their primary diagnosis. According to the same data from a Japanese study of a similar nature, up to 67.3% of asthmatic sufferers carried AR[9].

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Because it interacts with Cysteinyl Leukotriene-1 and 2 receptors, the leukotriene (LT) antagonist montelukast is effective in treating asthma and AR. It is a frequently used medication that was first given US approval in 1998. With an oral dosage of 10 mg once daily for adults, it is typically recommended for the prevention and treatment of asthma, as well as the prevention of exercise-induced bronchoconstriction and AR10. Montelukast successfully improves patients' quality of life (QoL) by addressing their symptoms, in contrast to long-acting beta2 agonists (LABA) and inhaled corticosteroids (ICS). According to a 2019 study, treating the symptoms effectively significantly improves QoL when compared to a placebo group.

A patient-friendly mode of management had been needed for such a long time, and montelukast, a single-dose medication with many other benefits, delivered it. We have concentrated on classifying the data and evaluating montelukast's contribution to two of the hypersensitivity syndromes. Due to symptomatic relapses, asthma and AR fall under the category of conditions that call for lifelong therapy, which is both the root of and an explanation for noncompliance.

Given these findings, this study's goal was to estimate the proportion of patients who experienced adverse effects and to ascertain how Montelukast altered the signs and symptoms of asthma and allergic rhinitis (AR). The absolute eosinophil count and five essential asthma and allergic rhinitis symptoms were assessed before and after therapy.

METHODOLOGY

This randomised trial was conducted at Lahore General Hospital. In this study, 204 people with asthma and allergic rhinitis took part. Participants received either (budesonide) BD (256mg) with (montelukast) MNT (10mg) for two weeks or BD alone (256mg). The inclusion criteria were that the participants had gone at least seven days without taking any antibiotics or AR therapies prior to the trial. None of the participants smoked or had asthma, and none of them were pregnant[18-19].

The sample size was calculated to have 102 individuals in each group with a power of 90% and a confidence level of 95%

using the formula below. With BD and MNT, the projected mean improvement in the overall symptom score was calculated to be 5.0 + 1.1, while with BD, it was 4.5 + 1.1 (Chen et al., 2019).

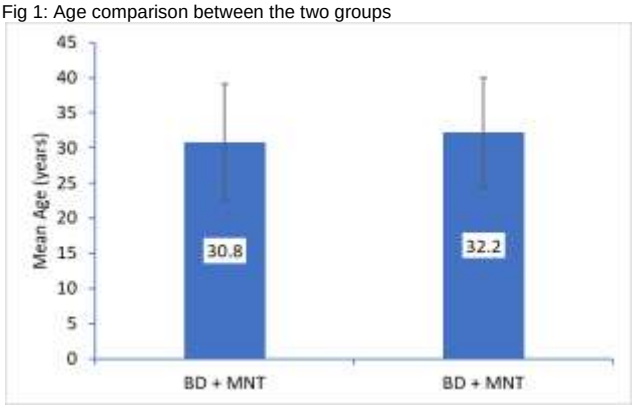
Statistical Analysis: The data was entered and analysed using SPSS 23. The absolute eosinophil count, age, and VAS symptom score were all provided as mean SD. The frequency and percentage were calculated for gender-based categorical data. Using an independent sample t-test, the age, VAS symptom score, and absolute eosinophil count were compared between the two groups. A chi-square test was used to compare the gender distribution between the two groups. Significant data was defined as a p-value of 0.05 or lower.

RESULTS

However, when compared to BD alone, BD+MNT demonstrated noticeably itching and nasal obstruction has improved more. Both treatments greatly lessened the five primary symptoms as compared to the baseline. After two weeks of treatment, the absolute eosinophil count significantly rose in BD+MNT, surpassing BD.

The average age of the patients in the BD+MNT group was 30.8 8.3 years, whereas the average age of the patients in the BD group was 32.2 7.8 years. An independent sample t test was utilized to compare the mean ages of the two groups. The p-value of 0.534 indicates that there was no significant difference in the mean age between the two groups (Fig.1).

Fig 1: Age comparison between the two groups



The BD+MNT group had 52 (51.0%) and 54 (52.9%) males, respectively. The gender distribution of neither group was different from the other, according to a chi-square analysis (p = 0.779).

Table 1: Participants' gender distribution in the study

Group	Male	Female	p-value
BD +MNT	54 (52.9%)	48 (47.1%)	0.779
BD	52 (51.0%)	50 (49.0%)	

A t test with an independent sample was used to compare the average baseline symptoms score between the two groups. The results revealed that the baseline symptom scores of the two groups did not significantly differ (Table 2).

Table 2: Comparison of the two groups' baseline symptom scores

Symptoms	BD +MNT	BD	p-value
Nasal block	7.65±2.98	7.22±2.62	0.197
Rhinorrhea	6.82±2.52	6.42±2.90	0.160
Sneezing	7.52±2.82	7.30±3.12	0.311
Nasal itching	6.30±2.71	6.52±2.84	0.639
Eye itching	5.98±2.82	6.18±2.96	0.627
Average of total symptoms	6.86±2.54	6.73±2.66	0.644
absolute eosinophil count	988.4±452.5	973.2±465.6	0.775

In contrast to BD alone, BD + MNT significantly increased improvements in nasal obstruction, sneezing, and nasal itching. Both treatments greatly lessened the five main symptoms as compared to the initial state. The average of the whole symptom score and the absolute eosinophil count both shown a significant improvement as compared to the BD alone group (Table 3).

Table 3: Comparison of symptoms score between both groups after treatment

Symptoms	BD +MNT	BD	p-value
Nasal block	1.05±0.80	1.98±1.26	< 0.001*
Rhinorrhea	1.18±1.25	1.16±1.10	0.200
Sneezing	1.02±0.98	1.13 ± 1.20	0.043*
Nasal itching	1.16±0.70	1.35±0.88	0.022*
Eye itching	1.20±0.92	1.38±1.02	0.301
Average of total symptoms	1.78±1.10	2.73±1.36	0.034*
absolute eosinophil count	240.8±101.2	260.3±123.8	0.044*

DISCUSSION

A specific immunoglobulin E (IgE) response to an inhaled allergen causes allergy rhinitis. Th2 cells, which are helper cells, mediate it. It is discovered that eosinophils are invading the mucosa and producing irritation[12]. When an allergy exists, a particular IgE with high affinity binds to an IgEreceptor, activation factors trigger mast cells, which release histamine, leukotriene, prostaglandin, and platelets. These lead to the early stages of allergy symptoms. Additionally, these mediators draw inflammatory cells that cause late-phase reactions. Lymphocytes and eosinophils invade tissues as a result of tumour necrosis factor a, which activated mast cells produce[13].

The LTRAs potency and INS in treating the signs and symptoms of SAR has been the subject of additional investigations recently, however the findings have been mixed[14]. We were able to quantify the decrease in AR symptoms, nasal patency, and lower airway inflammation in patients with mild-to-severe AR during the pollen season in order to evaluate the effectiveness of intranasal BD alone with BD + MNT in the current trial.

According to our research, nasal symptoms were considerably reduced by both BD+MNT and BD-alone treatments when compared to baseline; the benefits of BD + MNT surpassed those of BD for nasal obstruction and itching. While the other AR symptoms also improved more with BD + MNT than with BD alone, there was no statistically significant difference between the two therapy groups. These outcomes are consistent with those of Pinar and colleagues, who demonstrated that a combination of 200 g of intranasal (mometasonefuroate) MF and 10 mg of oral mometasone (MNT) considerably outperformed MF alone in lowering total nasal symptom scores in patients with AR grass-pollen sensitised to MF[15].

The most distressing symptom for AR patients is frequently nasal obstruction[16]. In the current investigation, we also carried out unbiased and quantitative evaluations of nasal patency NCV and NAR in order to remove bias and to confirm the findings for the significantly decreased nasal obstruction. These evaluations looked at changes in nasal congestion or mucosal edoema. In this regard, it was observed that after 2 weeks of therapy, both BD alone and in conjunction with MNT considerably enlarged the nasal cavity and decreased nasal resistance. Additionally, the combined medication statistically improved NCV in comparison to BD monotherapy. The fact that MNT has an extra ability to prevent the swelling of the mucosa brought on by cysteinylleukotrienes is probably what accounts for the larger improvement seen with combination therapy[17].

Limitations: Because it only included a small number of patients and was an open-label trial without a control group, this study was subject to a number of limitations. This approach was chosen in part due to the fact that, to our knowledge, no studies had been conducted on Pakistani patients with moderate-to-severe seasonal allergy rhinitis caused by the allergen to look at the effects of taking a combination of BD and MNT. Additionally, the experiment was done using outpatients. Therefore, larger patient populations and placebo-controlled individuals are needed in future well-

controlled, double-blind, randomised, placebo-controlled investigations in order to validate these findings.

CONCLUSIONS

It was concluded that combination of budesonide with montelukast therapy was more efficient overall than budesonidemonotherapy for those with asthma and allergic rhinitis, especially in lowering nasal obstruction, itching, and subclinical lower airway inflammation. Absolute eosinophil count can also be used to monitor a patient's response to treatment for allergic rhinitis thus montelukast addition can be a better option as treatment for allergic rhinitis and asthma.

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