(e) ISSN Online: 2321-9599

(p) ISSN Print: 2348-6805

ORIGINAL RESEARCH

ASSESSMENT OF EFFICACY OF MONTELUKAST AND PSEUDOEPEDRINE IN TREATING PATIENTS OF ALLERGIC RHINITIS: A COMPARATIVE STUDY

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ABSTRACT:

Background: Allergic rhinitis is the most common form of allergic disease, estimated to affect up to 20% of the population worldwide. The current study was planned to assess the efficacy of Montelukast and Pseudoepedrine in treating patients of allergic rhinitis. **Material and methods:** The study was conducted in the department of General Medicine of the medical institution. For the study, selection of 50 healthy individuals between age group of 18-45 years was done. Patients were randomly grouped into 2 groups, with 25 subjects in each group. Group 1 was prescribed 10 mg of montelukast sodium daily once daily in the morning for 2 weeks. Group 2 was prescribed 240 mg of sustained-release pseudoephedrine hydrochloride once daily in the morning for 2 weeks. Patients were recalled after 2 weeks and variables were noted again. The records kept by the patients were collected on their second visit. **Results:** The mean age of patients in Group Montelukast Sodium was 30.8 + 8.9 years and in Group Pseudoephedrine hydrochloride was 32.12 + 10.1 years. Male/Female ratio in Group Montelukast Sodium was 14/11 and in Group Pseudoephedrine hydrochloride was 12/13. The mean wheal size in Group Montelukast Sodium and in Group Pseudoephedrine hydrochloride was 12.2 + 1.9 mm and 11.6 + 2.3 mm respectively. We observed significant reduction in total symptom score from day zero to 14th day in pseudoephedrine group ($p<0.05$). In Montelukast group, we observed significant reduction in total symptom score on all the days as compared to score on day zero except for day 1. **Conclusion:** Our study shows equivalence in the control of seasonal allergic rhinitis of montelukast and pseudoephedrine administered once daily. In addition to efficacy in the control of nasal symptoms pseudoephedrine was found to be more effective on 1st and 3rd day.

Keywords: Allergy, Montelukast, Pseudoepedrine

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This article may be cited as: Aggarwal D, Aggarwal I, Garg M. Assessment of efficacy of Montelukast and Pseudoepedrine in treating patients of allergic rhinitis: A Comparative Study. J Adv Med Dent Scie Res 2017;5(6):25- 28.

Access this article online	
Quick Response Code	Website: www.jamdsr.com
	DOI: 10.21276/jamdsr.2017.5.6.7

INTRODUCTION

Allergic rhinitis is the most common form of allergic disease, estimated to affect up to 20% of the population worldwide.[1] This disorder is an inflammatory disease of the airways and shares with asthma a number of common epidemiologic, histological and pathophysiological features. [2–4] These include the high numbers of inflammatory cells such as mast cells and eosinophils in the airway; when activated on exposure to airborne allergens they undergo degranulation and release inflammatory substances, including cysteinyl leukotrienes, histamine, prostaglandin D2, and kinins. The cysteinyl leukotriene type-1(CysLT1) receptor antagonist Montelukast, administered once daily in the evening, has been documented to significantly improve symptoms of seasonal allergic rhinitis [5–7]. As montelukast provides relief of symptoms for 24 h and its pharmacokinetic profile is similar whether dosed in the morning or evening [8], we predicted that montelukast would provide benefit in seasonal allergic rhinitis regardless of the time of dosing. Pseudoepidrine is a sympathomometic amine. It can be given orally or topically. The action of pseudoepidrine is manifested by vasoconstriction of nasal circulation and decongestant effect on nasal mucosa. The nasal congestion caused by allergies or upper respiratory are effectively relieved using oral pseudoepidrine but they having little effect on the histamine-mediated symptoms of Allergic rhinitis. Hence, the current study was planned to assess the efficacy of Montelukast and Pseudoepedrine in treating patients of allergic rhinitis.

MATERIALS AND METHODS

The study was conducted in the department of General Medicine of the medical institution. The protocol of the study was submitted to the ethical committee of the institute for approval and study was started only after approval of protocol. For the study, selection of 50 healthy individuals between age group of 18-45 years was done. Inclusion criteria for the selection of patients were:

- Age ranging between 18-45 years
- Positive allergic skin test to antigen
- History of allergic symptom for no less than 2 years

Exclusion criteria for the study were:

- Patients on daily medications
- Lactating or pregnant ladies
- Patients that took glucocorticosteroids or intranasal steroids in last 30 days
- Patients that took oral antihistamines or decongestatnts in last 7 days

Patients were randomly grouped into 2 groups, with 25 subjects in each group. Group 1 was prescribed 10 mg of montelukast sodium daily once daily in the morning for 2 weeks. Group 2 was prescribed 240 mg of sustained-release pseudoephedrine hydrochloride once daily in the morning for 2 weeks. The patients were blinded to the study drug by giving the drug in same colored capsules to all the patients. Directions were given to the patients to keep a record of symptoms experienced by them daily and meter readings of nasal peak inspiratory flow (NPIF). Patients recorded frequency and severity of sneezing, rhinorrhea, itchy eyes/ nose and nasal congestion two times daily at 12 hours interval, once in the morning and other in the evening. The symptoms were scored on a scale of 0 to 3. O score indicated absence of symptoms, 1score indicated very mild symptoms, 2 score indicated moderate symptoms. The sum of all 4 individual symptom score specified total symptom socre. The peak score achievable was 24. The analysis of morning and evening symptoms was done. Various variables of the patients were recorded on the first visit of the patient and instructions were given to patients regarding keeping of records and taking medication. Patients were recalled after 2 weeks and variables were noted again. The records kept by the patients were collected on their second visit. The statistically analysis of the data was done using SPSS for windows. Chi-square test and student's t-test were used to verify the significance of the data. A p-value of less than 0.05 was predefined to be statistically significant.

RESULTS

A total of 50 patients were included in the study. The subjects were randomly grouped into two groups with 25 patients in each group. The age, sex ratio and wheal size due to skin prick test of antigen of the subjects are given in **Table 1**. The mean age of patients in Group Montelukast Sodium was 30.8 + 8.9 years and in Group Pseudoephedrine hydrochloride was 32.12 + 10.1 years. Male/Female ratio in Group Montelukast Sodium was 14/11 and in Group Pseudoephedrine hydrochloride was 12/13. The mean wheal size in Group Montelukast Sodium and in Group Pseudoephedrine hydrochloride was 12.2 + 1.9 mm and 11.6 + 2.3 mm respectively. **Table 2** shows the comparison of total symptom scores on both drugs day by day. We observed significant reduction in total symptom score from day zero to 14th day in pseudoephedrine group ($p<0.05$). In Montelukast group, we observed significant reduction in total symptom score on all the days as compared to score on day zero except for day 1. A significant difference between the groups was observed on day 1 and day 3between both the groups.

Table 1: Demographic Data of patients

Variables	Montelukast sodium	Pseudoephedrine hydrochloride
No. of patients	25	25
Sex, F/M	14/11	12/13
Mean Age (years)	30.8 ± 8.9	32.12 ± 10.1
Mean Wheal size (mm)	12.2 ± 1.9	11.6 ± 2.3

Table 2: Total symptom score of both drugs compared day by day

Days	Total symptoms score		P-value
	Montelukast sodium	Pseudoephedrine hydrochloride	
Day zero	12	12	<0.05
Day one	12	9	
Day two	10	8	
Day Three	9	7	
Day Four	8	6	
Day Five	8	5	
Day Six	10	7	
Day Seven	8	6	
Day Eight	8	7	
Day Nine	8	5	
Day Ten	8	6	
Day Eleven	8	6	
Day Twelve	8	7	
Day Thirteen	8	8	
Day Fourteen	9	5	

DISCUSSION

Leukotriene receptor antagonists are an effective treatment for the symptoms of seasonal allergic rhinitis. Pseudoephedrine is a potent decongestant that is often combined with antihistamines to treat seasonal allergic rhinitis. Pseudoephedrine has stimulant properties that can interfere with sleep. The present study assessed the efficacy of Montelukast and Pseudoepedrine in treating patients of allergic rhinitis. We observed significant reduction in total

symptom score from day zero to 14th day in pseudoephedrine group ($p<0.05$). In Montelukast group, we observed significant reduction in total symptom score on all the days as compared to score on day zero except for day 1. A significant difference between the groups was observed on day 1 and day 3between both the groups. Mucha SM et al compared montelukast sodium and pseudoephedrine hydrochloride in the treatment of seasonal allergic rhinitis. A total of 58 adult subjects with ragweed allergic rhinitis as documented by positive findings on a skin test to ragweed and history of symptoms during previous seasons were included. After recording their own baseline nasal symptoms, nasal peak inspiratory flow (NPIF), and diurnal and nocturnal rhinoconjunctivitis quality of life (QOL) scores, subjects were randomized to receive daily morning oral doses of either pseudoephedrine hydrochloride (240 mg) or montelukast sodium (10 mg) for 2 weeks. They recorded their nasal symptoms and NPIF twice daily during this time, and at the end of the study, they completed another QOL questionnaire and 2 tolerability profiles. Both active treatments resulted in significant improvements from baseline in all symptoms of allergic rhinitis as well as in all the domains of the QOL questionnaires. When changes from baseline were compared between treatments, there were no significant differences except in the symptom of nasal congestion, for which pseudoephedrine was more effective than montelukast. Both treatments resulted in a significant increase in NPIF over baseline with no significant difference between treatments. Both drugs were well tolerated with no differences in the tolerability profiles between treatments. The authors concluded that Pseudoephedrine and montelukast are equivalent in improving symptoms and QOL and increasing nasal airflow in patients with seasonal allergic rhinitis. Moinuddin BA et al compared the 2 combinations in the treatment of seasonal allergic rhinitis. This was a randomized, double-blind, double-dummy, parallel study in which patients with seasonal allergic rhinitis received either fexofenadine, 60 mg, and pseudoephedrine, 120 mg, twice daily, or loratadine, 10 mg, and montelukast, 10 mg, once daily, for 2 weeks. The Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ) was completed at the beginning and end of the study. Patients recorded nasal symptoms and measured nasal peak inspiratory flow (NPIF) twice daily. Baseline measurements were obtained before initiation of treatment. Compared with baseline, both treatments resulted in statistically and clinically meaningful reductions of overall and individual RQLQ domain scores except for the sleep domain, for which only loratadine-montelukast led to significant improvement. There was a significant reduction in total symptoms compared with baseline on most treatment days in patients receiving both combinations. When the change from baseline was analyzed, there were no statistically significant differences in total symptoms between fexofenadine-pseudoephedrine and loratadine-montelukast. There was a significant improvement in NPIF from baseline on all treatment days in both groups, with no significant difference between treatments.[9, 10] Busse WW et aldetermined the effectiveness of montelukast treatment in improving the control of asthma symptoms during the allergy season in patients with active asthma and seasonal aeroallergen sensitivity. Adults with a history of chronic asthma who are also symptomatic during the allergy season and with skin test sensitivity to seasonal aeroallergens were enrolled in a randomized, parallel-group, multicenter study with a 1-week, single-blind, placebo run-in period followed by 3 weeks of doubleblind treatment during the spring of 2004. After the run-in period, eligible patients were randomly assigned to receive either oral montelukast (10 mg) or placebo. Daytime and nighttime asthma symptom scores, β-agonist use, and morning and evening peak expiratory flow rates were recorded daily using an electronic diary. The primary end point was mean change from baseline to week 3 in the daytime asthma symptom score. Of 455 randomized patients, 433 completed the study. Compared with placebo, treatment with montelukast resulted in a significant improvement from baseline in the daytime asthma symptom score and in β-agonist use, nighttime symptoms, and peak expiratory flow rates. Few patients in the montelukast and placebo groups discontinued study participation because of asthma (1.3% and 3.0%, respectively). In patients with chronic asthma and seasonal aeroallergen sensitivity, montelukast treatment provided significant asthma control during the allergy season compared with placebo. Baena-Cagnani C et al conducted a study in which desloratadine and montelukast each were assessed in a double-blind, placebo-controlled trial of patients with SAR and symptoms of asthma, who were assigned randomly to once-daily treatment with desloratadine 5 mg, montelukast 10 mg, or placebo for 4 weeks. Change from baseline of AM/PM reflective total asthma symptom severity scores (TASS), FEV1, individual asthma symptom scores, and β2-agonist usage were assessed. Results: Desloratadine and montelukast each were associated with statistically significant reductions from baseline in the mean TASS averaged over the 4-week period ($p \leq 0.022$ vs. placebo). Individual asthma symptom scores also improved significantly for both therapies ($p \leq 0.05$). Patients treated with desloratadine or montelukast demonstrated improvement from baseline in FEV1 versus placebo; significant improvement was seen in a subset of patients with baseline FEV1 <80% of predicted normal (both $p < 0.05$). Both active therapies significantly reduced β2-agonist use (both $p < 0.01$). Improvements for both therapies were comparable for all efficacy parameters; they were tolerated well with adverse event profiles similar to placebo. Conclusions: Asthma symptoms and β2-agonist were improved significantly in patients with concomitant SAR and asthma treated with desloratadine 5 mg as well as montelukast 10 mg once daily. Both therapies significantly improved FEV1 in a subset of patients with FEV1 <80% of

predicted normal at entry. Improvements in asthma symptoms were comparable for both active treatment groups.[11, 12]

CONCLUSION

In conclusion, our study shows equivalence in the control of seasonal allergic rhinitis of montelukast and pseudoephedrine administered once daily. In addition to efficacy in the control of nasal symptoms pseudoephedrine was found to be more effective on 1st and 3rd day.

REFERENCES

1. Lundback B. Epidemiology of rhinitis and asthma. Clin Exp Allergy 1998;28 Suppl 2:3–10.
2. Meltzer EO. Role for cysteinyl leukotriene receptor antagonist therapy in asthma and their potential role in allergic rhinitis based on the concept of one linked airway disease. Ann Allergy Asthma Immunol. 2000;84:176–187.
3. Bousquet J, Van Cauwenberge P, Khaltaev N, ARIA Workshop Group, World Health Organization. Allergic rhinitis and its impact on asthma. J Allergy Clin Immunol 2001; 108(suppl 5):S147–S334.
4. American Thoracic Society Workshop. Immunobiology of asthma and rhinitis: pathogenic factors and therapeutic options. Am Respir Crit Care Med 1999;160:1778–1787.
5. Meltzer EO, Malmstrom K, Lu S, Prenner BM, Wei LX, Weinstein SF et al. Concomitant montelukast and loratadine as treatment for seasonal allergic rhinitis: a randomized, placebocontrolled clinical trial. J Allergy Clin Immunol 2000;105:917–922.
6. Nayak A, Philip G, Lu S, Malice M-P, Reiss TF, Montelukast Fall Rhinitis Investigator Group. Efficacy and tolerability of montelukast alone or in combination with loratadine in seasonal allergic rhinitis: a multicenter, randomized, double-blind, placebo-controlled trial performed in the fall. Ann Allergy Asthma Immunol 2002:88:592–600.
7. Philip G, Malmstrom K, Hampel Jr FC, Weinstein SF, LaForce CF, Ratner PH et al. Montelukast for treating seasonal allergic rhinitis: a randomized, doubleblind, placebo-controlled trial performed in the spring. Clin Exp Allergy 2002;32:1020–1028.
8. Knorr B, Larson P, Nguyen H, Holland S, Reiss TF, Chervinsky P et al. Montelukast dose selection in 6- to 14-year olds: comparison of single-dose pharmacokinetics in children and adults. J Clin Pharmacol 1999;39:786–793.
9. Mucha SM, deTineo M, Naclerio RM, Baroody FM. Comparison of Montelukast and Pseudoephedrine in the Treatment of Allergic Rhinitis. *Arch Otolaryngol Head Neck Surg*. 2006;132(2):164-172.
10. Moinuddin BA, Tineo BS, Maleckar BS. NaclerioFuad M. Comparison of the combinations of fexofenadine-pseudoephedrine and loratadine-montelukast in the treatment of seasonal allergic rhinitis. Annals of Allergy, Asthma & Immunology. Volume 92, Issue 1, January 2004, Pages 73-79.
11. Busse WW, Casale TB, Dykewicz MS, Meltzer EO,.Bird SR, Hustad CM. Efficacy of montelukast during the allergy season in patients with chronic asthma and seasonal aeroallergen sensitivity. Annals of Allergy, Asthma & Immunology, Volume 96, Issue 1, January 2006, Pages 60-68.
12. Baena-Cagnani C, E, Berger W, E, DuBuske L, M, Gurné S, E, Stryszak P, Lorber R, Danzig M, Comparative Effects of Desloratadine versus Montelukast on Asthma Symptoms and Use of β₂-Agonists in Patients with Seasonal Allergic Rhinitis and Asthma. Int Arch Allergy Immunol 2003;130:307-313

Source of support: Nil **Conflict of interest:** None declared