Original Article

Comparison of Effect of Levocetirizine or Montelukast Alone and in Combination on Symptoms of Allergic Rhinitis

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Abstract

Objective. To determine the effect of levocetirizine, montelukast and the combination of both the drugs on symptoms of allergic rhinitis.

Methods. Seventy-five patients with allergic rhinitis were randomly studied prospectively for a period of two weeks divided into three groups receiving either levocetrizine or montelukast or combination of both. The outcomes were measured by a visual analogue score for nasal and eye symptom during day-time and night-time.

Results. All the three regimens were equally effective in improving the day-time symptoms, like sneezing and rhinorrhea. There was also no difference in the control of night-time and eye symptoms among the regimens.

Conclusions. Montelukast, levocetirizine and their combination is equally effective in controlling symptoms, of allergic rhinitis. Thus, use of montelukast alone would be cost-effective and do avoid adverse effects of levocetirizine in combination therapy. **[Indian J Chest Dis Allied Sci 2016;58:103-105]**

Key words: Allergic rhinitis, Montelukast, Levocetirizine.

Introduction

Allergic rhinitis is the most common atopic disorder affecting 18% to 40% of adults worldwide, and is diagnosed by history, physical examination and objective testing.[1] It exacts a toll on a patient's quality of life (QoL), cognitive and learning functions, decision-making and self-perception and if left untreated, can contribute to co-morbidities, including asthma, sinusitis and otitis media with effusion or the development of nasal polyps.

It is well known that antihistamines reduce the symptoms of sneezing, itching and rhinorrhea by antagonising the H1 receptors present in the nasal mucosa, thereby arresting the effects of early allergic reaction. Similarly, anti-leukotrienes antagonise the effects of cysteinyl leukotrienes, thus, arresting late reaction and reducing the nasal inflammation and congestion. Further, a combination therapy with antihistamine (levocetirizine) and anti-leukotriene (montelukast) could provide enhancing and complementary effect. A significant improvement has been reported in few studies with the use of such a combination in patients with allergic rhinitis.[1-3]

There are not many studies have compared the efficacy of these single agent or in combination in controlling the various symptoms of allergic rhinitis. Hence, this study was planned.

Material and Methods

Seventy-five (37 males and 38 females) presents with allergic rhinitis in the age group of 15-75 years were randomly studied prospectively for a period of two weeks in the ENT out-patinet department of Goa Medical College. The diagnosis of allergic rhinitis was made by clinical history of rhinorrhea (excess nasal secretion), itching, episodic sneezing and nasal congestion or obstruction.[4] On examination, patients had conjunctival swelling and erythema, eyelid swelling, lower eyelid venous stasis (rings under the eyes known as "allergic shiners"), swollen nasal turbinates, with or without middle ear effusion.[5] These patients had perennial allergic rhinitis on the basis of Allergic Rhinitis and its Impact on Asthma (ARIA) classification.[6] Thirty percent of the study group had positive family history of allergic rhinitis. The patients did not have any prior history of treatment for the same. Twenty-five patients (Group I) received a combination of montelukast and levocetirizine, 28 patients (Group II) received only montelukast and 22 patients (Group III) received only levocetirizine. Montelukast and levocetrizine irrespective of whether used alone or in combination were given in a dosage of 10mg and 5mg, respectively for two weeks at bed-time. Patients with asthma were excluded. The outcome was measured by a visual

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analogue score (VAS) for nasal and eye symptoms during the day-time and night-time. The day-time symptoms were nasal blockage, nasal itching, nasal discharge and sneezing. Night-time symptoms included post-nasal discharge accumulated in the oropharynx in the early morning, mouth breathing and sleep disturbance like snoring and night-time awakening were monitored based on the history obtained from the patient's relative and history of impairment of daily activities, sports, leisure, impact on attention at work and school the next day. The eye symptoms included redness and irritation of the eyes. The symptoms before and after treatment were compaired using student 't' test. A p value <0.05 was considered significant.

Results

All the three groups were equally effective in improving day-time symptoms, like sneezing, rhinorrhea, nasal blockade and nasal discharge (Table). However, four patients reported side effects of headache, dizziness and dry mouth with the combination therapy. Also, there was no difference observed in the efficacy among the three groups in controlling the night-time symptoms and the eye symptoms (Table).

Discussion

Montelukast, a leukotriene receptor antagonist, has been studied quite extensively for the treatment of allergic rhinitis over the past few years as monotherapy, combined with a second generation antihistamines, and with or without intra-nasal corticosteroids. There has been a significant reduction in the night-time symptoms with montelukast monotherapy. Combination of montelukast with antihistamines is well tolerated and has shown equivocal results. A combination therapy with antihistamine (levocetirizine) and antileukotriene (montelukast) could provide enhancing and complementary effect. A significant improvement has been reported in few studies with the use of such a combination in patients with allergic rhinitis.[1-3] In an Indian study[1] conducted in Punjab by 102 patients were randomly assigned to receive montelukast and levocetirizine (treatment group) or levocetirizine alone (control group). There was a significant decrease in total day-time, night-time and eye symptoms and composite symptoms score in both the groups as compared to baseline. However, patients treated with montelukast and levocetirizine had faster response.

Ciebiada *et al*[2] conducted a study to assess the QoL in patients with persistent allergic rhinitis treated with montelukast alone or in combination with levocetrizine or desloreatidine and it was found that they significantly improved their QoL. Addition of montelukast gave additional benefits in comparison with each agent alone and could be considered for patients whose QoL was impaired by persistent allergic rhinitis.

Kurowski *et al*[3] in their study to assess the effect of 6-week pre-treatment on seasonal allergic rhinitis with cetirizine and montelukast alone and in combination concluded that a combination therapy was more effective in preventing allergic rhinitis symptoms.

The current study shows that as a mono-therapy, montelukast alone is equally effective in controlling almost all the symptoms of allergic rhinitis, as is the combination of montelukast with levocetirizine. In 2007, Philip *et al*[7] conducted a double-blind, randomised, controlled trial on 1261 patients between

Table. Visual analogue score (mean±SD) for day-time, night-time and eye symptoms before and after the treatment in all three groups

	Day-time Symptoms							
	Nasal blockage		Nasal irritation		Nasal discharge		Sneezing	
	BT	AT	BT	AT	BT	AT	BT	AT
Group I	6.3±3.5	1.6±1.9*	5.4±3.4*	1.4±1.9	7.1±2.5	1.8±1.9*	6.9±2.8	1.3±1.9*
Group II	5.5±2.7	2.0±2.3*	3.9±3.5*	1.5±2.2	6.7±2.5	2.1±2.6*	6.0±2.3	1.9±2.1*
Group III	6.2±2.7	3.9±2.5*	4.3±3.6*	2.1±2.2	7.2±2.4	4.1±2.9*	6.5±2.3	2.9±2.7*
	Night-time Symptoms						Eye Symptoms	
	Mouth breathing		Post-nasal drip		Sleep disturbance		Redness and itching	
	BT	AT	BT	AT	BT	AT	BT	AT
Group I	4.9±3.2	1.4±2.3*	4.0±3.5	1.3±2.3*	4.0±3.7	0.9±2.0*	3.8±3.2	1.5±2.0*
Group II	4.4±2.7	1.5±2.0*	2.8±2.5	1.1±1.7*	2.8±3.2	1.0±1.8*	2.4±2.2	0.8±2.0*
Group III	4.8±3.0	2.1±3.0*	3.6±3.7	1.4±2.2*	4.6±3.3	2.7±3.0*	3.6±3.4	1.7±1.9*

*=P<0.05

Definitions of abbreviations: BT=Before treatment; AT=After treatment.

the age group of 15 to 85 years in which they were randomly allocated montelukast or placebo or cetirizine for six weeks. Over four weeks montelukast showed a numerical improvement over placebo in day-time nasal symptom score and QoL. However, when averaged over six weeks, neither active treatment was significantly different from placebo.

van Adelsberg *et al*[8] in 2003 conducted a randomised controlled trial on 1191 patients. They were randomly divided into three groups and received montelukast 10/ loratidine 10/ placebo for two weeks. The conclusion was that montelukast and loratidine had better symptom scores and improvement of QoL.

In conclusion, it would be more cost-effective to use montelukast alone in treating allergic rhinitis. Also with the monotherapy, the unnecessary side effects of levocetirizine, like headache, dizziness and dry mouth would be avoided which would otherwise arise with the combination therapy.

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