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Original Article

Evaluation of efficacy of topical and systemic antihistaminic drugs in children with allergic rhinitis

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ABSTRACT

Objective: To evaluate the efficacy of topical and systemic antihistaminic drugs in children with allergic rhinitis (AR). **Methods:** This prospective, hospital-based study was conducted on children aged 6-18 years attending pediatric and ENT OPD. The children with a clinical diagnosis of AR were selected for study and were divided into two groups randomly. Group A children received oral second generation antihistamine levocetrizine and Group B children received intranasal antihistaminic drug azelastine. Both groups received medications for 4 weeks. A post therapy response was recorded in the form of symptomatic and histopathological response. **Results:** There was better symptomatic response for sneezing and rhinorrhea with levocetrizine than azelastine but better response for nasal blockage with azelastine. There was no significant difference in histopathological response of both groups. **Conclusion:** Levocetrizine was showing better symptomatic response as topical azelastine and also showing better acceptability.

Key words: *Allergic rhinitis, Azelastine, Levocetrizine*

Allergic rhinitis (AR) has a major effect on the quality of life. It also affects work performance, sleep, and school attendance [1]. AR is a common in children and is one of the most frequent health problems. It is a highly prevalent disease in many countries, affecting about 10-20% of the general population [2,3]. AR is characterized by paroxysms of sneezing, rhinorrhea, and nasal obstruction, often accompanied by itching of the eyes, nose, and palate. Cough, postnasal drip, irritability are other common symptoms [4,5]. According to the time of exposure, it can be subdivided into perennial, seasonal, and occupational disease. An occupational AR is rare in children. Perennial AR is mostly caused by dust mites and animal dander while seasonal AR is mainly related to a variety of pollen allergens. It can be also categorized as mild intermittent, moderate to severe intermittent, mild persistent, and moderate to severe persistent AR as per ARIA classification [6].

There are many modes of the treatment. Among all the methods of treatment, every method has its own limitations and degree of success. Topical as well as oral antihistamines both are recommended as the first-line therapy in the treatment of AR [4,7]. Second-generation antihistaminic agents are usually preferred because they are causing lesser sedation, performance impairment, and other side effects in children [8]. Topical antihistamines mainly target nasal symptoms, whereas oral antihistamines primarily target symptoms associated with histamine release such as sneezing, rhinorrhea, itchiness, watering, redness of eyes, and simultaneously oral antihistamines have some effect on nasal congestion too but less than intranasal agents.

Oral antihistamines are approved for use in young children. Desloratadine and cetirizine are approved for use in children above 6 months of age. Loratadine and fexofenadine are used in children above 2 years of age and levocetrizine above 6 years. Although not as fast as topical histaminic, oral antihistamines have also a relatively rapid onset of action [9]. Levocetrizine works by blocking histamine receptors. It is a non-sedating antihistamine, worked by preventing the action of histamines. Considering above facts the present study was done with an objective of to evaluate the efficacy in the form of symptomatic relief, histopathological response and safety of topical and systemic antihistaminic drugs in children with AR.

MATERIALS AND METHODS

The study was a prospective study and carried out in the Department of Pediatrics, ENT with active collaboration of Department of Pathology at a Tertiary Care Teaching Hospital of North India. The duration of study was from August 2014 to July 2015. Ethical clearance was taken from Institutional

Ethics Committee. Children from Pediatric and ENT OPD aged 6 to 18 years with clinical diagnosis of AR were selected for study. An informed consent was obtained from parent before recruitment in the study. AR was diagnosed clinically by the presence of any 2 or more of the following 4 clinical features-nasal blockage, rhinorrhea, sneezing, and itching for more than 1 h every day for more than 2 weeks duration [10]. Children, who received systemic or topical steroids within 4 weeks, or antihistaminic, decongestant drugs within past 7 days, were excluded from study. Children with gross anatomical abnormality like polyp, chronic sinusitis, deviated nasal septum, throat abnormality, and children less than 6 years were also excluded from the study. Children with any other systemic diseases were also excluded from study.

Selected children were divided into two groups randomly using computer generated random number tables. Detailed history and clinical examination were done for every child. Routine investigations - such as complete blood count, absolute eosinophil count, and X-ray paranasal sinuses - were done in every case. Group A children received oral second generation antihistamine levocetrizine in dose of 5 mg once at night if age above 12 years and 2.5 mg at night if age less than 12 years. Group B children received intranasal antihistaminic azelastine nasal spray one puff in each nostril twice daily. Both group received medications for 4 weeks. Specimen from nasal mucosa was taken under local anesthesia in all the children after completing 4 weeks of treatment.

The post-therapy symptomatic responses were divided into three categories, i.e. (1) Good response - complete absence of symptoms, (2) Fair response - some relief in symptoms, and (3) Poor response - no improvement. Histopathological responses were also divided into three categories: (1) Good response - normal histopathology, (2) Fair response - some improvement, and (3) Poor response - no improvement. Various symptomatic and histopathological responses were recorded in a three-point Likert scale (poor response, fair response, good response). Subsequently, these were tabulated and comparisons were made for a difference in the two responses at 95% confidence interval using Mann–Whitney test.

RESULTS

A total of 84 children with clinical AR were enrolled in the study divided into two groups randomly as shown in Fig. 1. Out of 84 children, only 76 children completed the study leaving 38 children in each group. There was no statistically significant difference in baseline characteristics of recruited subjects like age, sex, weight, socio-economic status, and severity of symptoms between two groups. The Group A children received oral levocetrizine and Group B children azelastine nasal spray. There were 24 males and 14 females in Group A and 23 males and 15 females in Group B.

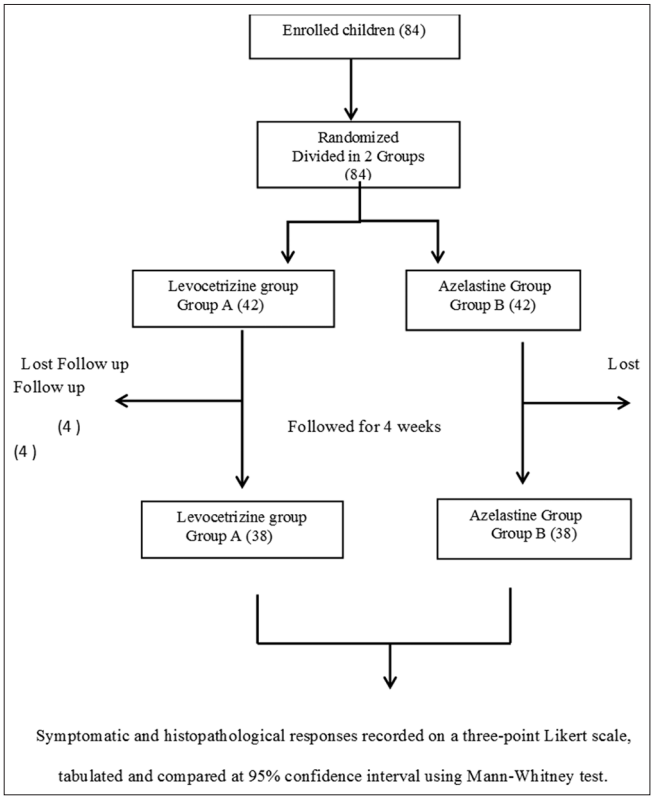

Figure 1: Flow chart of study

Table 1 shows that better symptomatic response in sneezing and rhinorrhea was observed in the Group A (levocetrizine group) in comparison to Group B (azelastine group) children. This difference was statistically significant (p=0.009 and p=0.023 respectively). However, a better response in "nasal obstruction" was observed with the azelastine (Group B) than levocetrizine (Group A). The difference was statistically significant (p=0.002). An more number of subjects reported good response to itching of the nose in the levocetrizine group, while more number of subjects in azelastine group reported fair response to nasal itching; this difference was, however, not statistically significant (p=0.124).

Table 2 shows the difference in histopathological response between two groups. Most of the children in both groups showed fair histopathological response (p>0.992) indicating no significant difference in histopathological response in both the groups. Side effects - such as dryness of mouth and nose, altered taste, nasal burning, sleepiness, headache, and visual problems - were monitored and none of the patients from both groups showed any serious effect that warrant termination of the treatment.

DISCUSSION

In this study, male predominance may be due to the fact that most of the children were from rural background and belonged to low socio-economic status and low education level or illiterate families who were giving more care to male than the female

Table 1: Degree of improvement from main symptoms following levocetrizine and azelastine therapy

Symptoms	Response	Group A (Levoctrizine) (%)	Group B (Azelastine) (%)	p value
Sneezing (n=38 in each group)	Good response	7 (18.4)	2 (5.3)	0.076
	Fair response	25 (65.8)	19 (50.0)	0.163
	Poor response	6 (15.8)	17 (44.7)	0.006
Rhinorrhea (n=38 in each group)	Good response	6 (15.8)	3 (7.9)	0.287
	Fair response	23 (60.5)	15 (39.5)	0.066
	Poor response	9 (23.7)	20 (52.6)	0.009
Nasal obstruction (n=32 in each group)	Good response	4 (12.5)	15 (46.9)	0.003
	Fair response	15 (46.9)	13 (40.6)	0.614
	Poor response	13 (40.6)	4 (12.5)	0.011
Nasal itching (n=22 in each group)	Good response	13 (59.1)	7 (31.8)	0.069
	Fair response	6 (27.3)	10 (45.5)	0.210
	Poor response	3 (13.6)	5 (22.7)	0.434

Table 2: Post-therapy histopathology with levocetrizine and azelastine therapy

Group	Histopathological response (%)			p value
	Good response	Fair response	Poor response	
Group A (Levoctrizine)	11 (28.9)	17 (44.7)	10 (26.3)	p=0.992
Group B (Azelastine)	9 (23.7)	21 (55.3)	8 (21.1)	

children. Another probable cause for male predominance may be increased outdoor exposures and hence, allergens in males than females especially in adolescents. Chanda et al. [11] also reported male predominance in their study.

In our study, there was better response of levocetrizine for sneezing and rhinorrhea as compared to local azelastine but poor response for nasal blockage by levocetrizine in comparison to azelastine. Srivastava et al. [12] reported that azelastine is showing better result than levocetrizine in all the symptoms (sneezing, nasal obstruction and rhinorrhea) in adults probably because of better compliance of topical medications in adults than in children.

In our study, histopathalogical improvement after completing 4 weeks of treatment with systemic levocetrizine and topical azelastine were similar and statistically no significant difference were found. Shrivastava et al. [12] also reported similar findings in their study.

Our children were complaining irritability with azelastine and were more comfortable with systemic levocetrizine. The response on nasal itching was almost similar in both the groups and having no statistical significant difference in both levocetrizine and azelastine groups.

Sastre and Mosges [13] did their study to know the safety of local and systemic medications in adults and found that local medications were having better safety than systemic medications with similar efficacy. We also found almost similar efficacy of local and systemic medications for symptomatic response, but systemic medications were having more acceptability than local intranasal medications especially in children. Study limitations were short duration of study, small sample size, difficulty to do biopsy in children.

CONCLUSION

Allergic rhinitis is children are more common in adolescent age group with male predominance. The common symptoms were sneezing and rhinorrhea. Levoctrizine showed better symptomatic response as compared to topical azelastine for sneezing and rhinorrhea and inferior response for nasal obstruction in children. Histopathological responses were similar in both levocetrizine and azelastine groups.

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