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A PROSPECTIVE STUDY TO COMPARE THE EFFICACY OF CETIRIZINE AND BEPOTASTINE IN ALLERGIC RHINITIS

Otorhinolaryngology

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ABSTRACT

Introduction: Allergic rhinitis is a type 1 allergic disease of nasal mucosa. The symptoms of Allergic rhinitis are sneezing, watery nasal discharge, nasal congestion. The prevalence of Allergic rhinitis worldwide is 25%. Cetirizine is a second-generation antihistamine. It acts by antagonistic effect on H1 receptor. Bepotastine is a second-generation antihistamine, which is non sedative. It also stabilizes Mast cell function and has inhibitory action on leukotrienes. **Objectives:** To compare the efficacy of Cetirizine and Bepotastine in Allergic rhinitis. To assess the Total Nasal Symptom Score at baseline and at the end of 2 weeks of completion of treatment for all the participants as an efficacy indicator. **Methodology:** Patients presenting with signs and symptoms of allergic rhinitis, who fulfil all inclusion criteria and exclusion criteria and are willing to participate in this study was selected. History, nasal examination and allergic skin prick testing were done. Patients were grouped in to group A and B each consisting of 30 patients. Tab cetirizine 10 mg and Tab bepotastine 10 mg were given at once daily dose to Group A and Group B patients respectively for a period of 2 weeks. Total Nasal symptom score is assessed at start of treatment and also at the end of treatment at 2 weeks. **Results:** In the present study, 60 patients presenting with signs and symptoms of allergic rhinitis were allocated into two groups. They underwent clinical examination, and allergic skin prick testing. From the study, it demonstrated that majority of patients were within 21-30 years of age with majority being females. The most common presenting symptom being the nasal congestion and nasal discharge. It was also observed that majority of patients were sensitive to house dust mite, followed by pollens. The total nasal symptom score was reduced significantly among patients treated with bepotastine compared to cetirizine. Before treatment, the mean TNSS was 8.93±0.63 in Group A and 9.10±0.66 in Group B, indicating no significant difference in baseline symptom severity. Posttreatment, the TNSS scores significantly reduced in both groups, with Group A showing a mean of 2.90±0.66 and Group B showing a lower mean of 2.0±0.45. The mean difference at posttreatment was 0.90, and the comparison between groups was statistically significant (t=6.139, p=0.001*). Bepotastine was also associated with less adverse effects. **Conclusions:** Effectiveness of Bepotastine was more than cetirizine with respect to symptom control, which was interpreted based on total nasal symptom score. Bepotastine was associated with fewer adverse effects compared to bepotastine in our study.

KEYWORDS

Allergic rhinitis; Allergic skin prick testing; Cetirizine; Bepotastine.

INTRODUCTION

Allergic rhinitis is a type 1 allergic disease of nasal mucosa. The symptoms of Allergic rhinitis are sneezing, watery nasal discharge, blockage of nose. The prevalence of Allergic rhinitis worldwide is 25%. Around 20-30% Indian population suffers from allergic rhinitis.[1] The Allergic rhinitis incidence has increased over the decades. Due to high occurrence, impact on quality of life, and also loss of productivity, it represents a worldwide health concern.

Allergy results in approximately 50% of all cases of rhinitis. The symptoms are mainly due to immunoglobulin E mediated immune response to a specific type of allergen. These allergens includes dust mites, pollens, animal dander, and molds. The immunological response triggers release of mediators of inflammation and recruitment of activated cells into the nasal mucosa.[2]

Cetirizine is a second-generation antihistamine. It acts by antagonistic effect on H1 receptor. It has been effective in Allergic rhinitis. There is evidence which shows that cetirizine is efficacious, fast acting, well tolerated, and hence useful in the management of paediatric, adolescent and adult patients with Allergic rhinitis.[3]

Bepotastine is a second-generation antihistamine, which is non sedative. It also stabilizes Mast cell function and has inhibitory action on leukotrienes. It has got minimal adverse effects, has quick onset of action. It's a good drug for treatment of allergic rhinitis, urticaria, pruritis associated with skin disorders.[4]

The need for this study is to add More information to the present knowledge about the efficacy of Bepotastine and cetirizine in the treatment of Allergic rhinitis.

MATERIALS AND METHODS

Patients presenting with signs and symptoms of allergic rhinitis, who fulfil all inclusion criteria and exclusion criteria and are willing to participate in this study was selected, informed and written consent was taken from all patients.

During study, 60 patients with Allergic rhinitis was selected. A detailed history, clinical examination, Allergic skin prick test, Differential blood count, Absolute eosinophil count are done and Total Nasal symptom Score was calculated for all patients. The patients were then categorized into two groups –

- Group A: will consist of 30 patients receiving Tab. Cetirizine 10 mg oral once daily; and
- Group B: will consist of 30 patients receiving Tab. Bepotastine 10 mg Oral once daily.

Both groups will have 30 patients each. History of presenting illness, local and clinical examination, nasal examination, and the details of drugs given were recorded at the start of treatment. Total Nasal symptom score is assessed at start of treatment and also at the end of treatment at 2 weeks.

The patients had a follow up at the end of 2 weeks And Total nasal symptom score is assessed.

The following investigations will be done in the selected patients.

- Allergic skin prick test - It is an investigation routinely done in patients suspected with allergies.

Statistical Analysis

The statistical analyses were conducted using IBM SPSS Statistics for Windows, Version 25.0 (IBM Corp., Armonk, NY). Categorical variables were expressed as frequencies and percentages, while continuous variables were summarized as means and standard deviations. Chi-square and Fisher's exact tests were used to compare categorical variables, while Independent t-tests were applied to compare continuous variables between the two study groups. Additionally, paired t-tests were utilized to assess pre- and post-treatment differences within each group. A p-value < 0.05 was considered statistically significant.

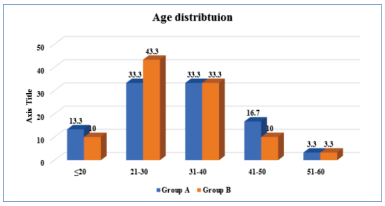
Results:

Table 1: Age Distribution (Years)

Age	Group A N (%)	Group B N (%)	t value; p-value
≤20	4(13.3)	3(10)	0.767; 0.446
21-30	10(33.3)	13(43.3)	

31-40	10(33.3)	10(33.3)	
41-50	5(16.7)	3(10)	
51-60	1(3.3)	1(3.3)	
Total	30(100)	30(100)	
Range	19-58	19-51	
Mean±SD	32.66±9.93	30.80±8.89	

Chi-square test



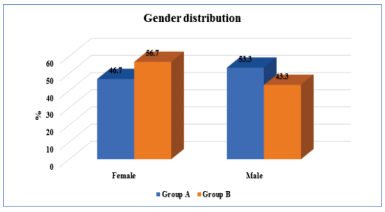
Graph 1: Age Distribution (Years)

The age distribution of participants in Group A and Group B was analyzed. In Group A, 13.3% of the participants were aged ≤20 years, whereas 10% in Group B belonged to this age group. The majority of the participants fell within the 21-30 years and 31-40 years age brackets. In Group A, 33.3% were in the 21-30 years category, and an equal proportion (33.3%) was in the 31-40 years group. Similarly, Group B had 43.3% of participants in the 21-30 years group and 33.3% in the 31-40 years category.

Table 2: Gender Distribution

Gender	Group A N (%)	Group B N (%)	Chi-square value; p-value
Female	14(46.7)	17(56.7)	0.601; 0.606
Male	16(53.3)	13(43.3)	
Total	30(100)	30(100)	

Chi-square test



Graph 2: Gender Distribution

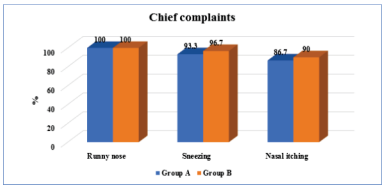
Inference

Gender distribution was examined between the two groups. In Group A, 46.7% of the participants were female, while in Group B, a slightly higher percentage (56.7%) were female. Conversely, male participants comprised 53.3% in Group A and 43.3% in Group B. The statistical analysis (Chi-square value = 0.601, p = 0.606) suggests that there was no significant difference in gender distribution between the two groups, indicating a relatively balanced distribution of male and female participants.

Table 3: Chief Complaints

Gender	Group A N (%)	Group B N (%)	Chi-square value; p-value
Runny nose	30(100)	30(100)	0.01; 0.995
Sneezing	28(93.3)	29(96.7)	
Nasal itching	26(86.7)	27(90)	

*Statistically significant (p<0.05), Chi-square test



Graph 3: Chief Complaints

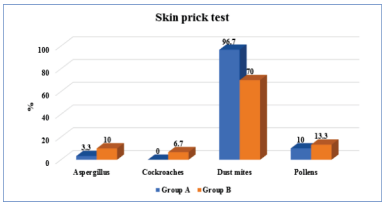
Inference

The primary symptoms reported by participants were assessed across the two groups. All participants in both Group A and Group B (100%) reported experiencing nasal congestion and runny nose. Sneezing was another common complaint, with 93.3% of Group A and 96.7% of Group B reporting this symptom. Nasal itching was observed in 86.7% of Group A and 90% of Group B participants. The statistical comparison (Chi-square value = 0.01, p = 0.995) demonstrated no significant difference in chief complaints between the two groups, suggesting that the participants had comparable baseline symptomatology.

Table 4: Skin Prick Test

Skin prick test	Group A N (%)	Group B N (%)	Chi-square value; p-value
Aspergillus	1(3.3)	3(10)	4.29; 0.231
Cockroaches	0	2(6.7)	
Dust mites	29(96.7)	21(70)	
Pollens	3(10)	4(13.3)	

Chi-square test



Graph 4: Skin Prick Test

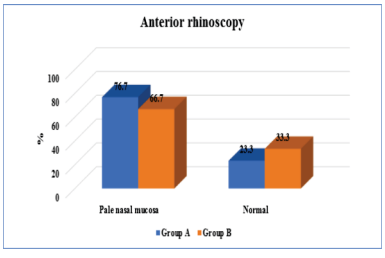
Inference

The skin prick test results indicated varying sensitivities to different allergens between the two groups. Sensitivity to Aspergillus was observed in 3.3% of Group A and 10% of Group B participants. A small proportion (6.7%) of Group B exhibited sensitivity to cockroaches, while none of the participants in Group A reacted to this allergen. Dust mite sensitivity was prominent in both groups, with 96.7% in Group A and 70% in Group B showing a reaction. Sensitivity to pollens was relatively low, with 10% in Group A and 13.3% in Group B reacting positively. The statistical analysis (Chi-square value = 4.29, p = 0.231) did not reveal significant differences between the groups in terms of allergen sensitivity.

Table 5: Anterior Rhinoscopy

Anterior rhinoscopy	Group A N (%)	Group B N (%)	Chi-square value; p-value
Pale nasal mucosa	23(76.7)	20(66.7)	0.739; 0.567
Normal	7(23.3)	10(33.3)	
Total	30(100)	30(100)	

Chi-square test



Graph 5: Anterior Rhinoscopy

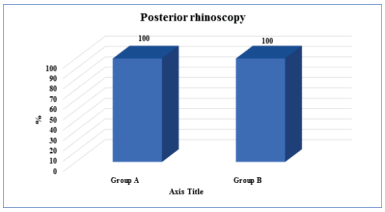
Inference

The anterior rhinoscopy findings were compared between the two groups. A majority of the participants in both groups exhibited pale nasal mucosa, with 76.7% in Group A and 66.7% in Group B presenting this feature. A smaller proportion of participants had normal nasal mucosa, accounting for 23.3% in Group A and 33.3% in Group B. The statistical comparison (Chi-square value = 0.739, p = 0.567) showed no significant difference between the groups, indicating similar anterior rhinoscopic findings among participants.

Table 6: Posterior Rhinoscopy

Posterior rhinoscopy	Group A N (%)	Group B N (%)	Chi-square value; p-value
Normal	30(100)	30(100)	1.00
Total	30(100)	30(100)	

Chi-square test



Graph 6: Posterior Rhinoscopy

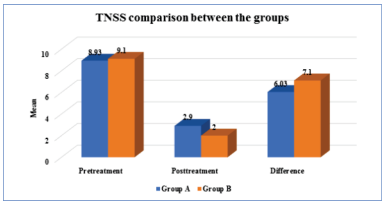
Inference

All participants in both Group A and Group B had normal findings in posterior rhinoscopy. Since there was no variation in the observations, the statistical analysis resulted in a p-value of 1.00, confirming no difference between the groups regarding posterior rhinoscopic findings.

Table 7: Comparison of TNSS Between the Groups

TNSS	Group A (Mean±SD)	Group B (Mean±SD)	Mean difference	t value; p-value
Pretreatment	8.93±0.63	9.10±0.66	-0.167	-0.992; 0.325
Posttreatment	2.90±0.66	2.0±0.45	0.90	6.139; 0.001*
Difference	6.03±0.93	7.10±0.88	-1.06	-4.557; 0.001*

*Statistically significant (p<0.05), Independent t-test



Graph 7: Comparison of TNSS Between the Groups

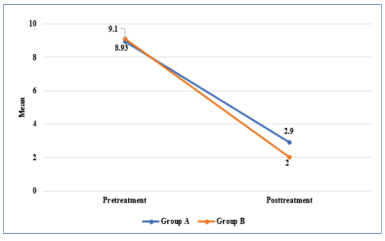
Inference

The Total Nasal Symptom Score (TNSS) was compared between the groups at the pretreatment and posttreatment stages. Before treatment, the mean TNSS was 8.93±0.63 in Group A and 9.10±0.66 in Group B, showing a negligible mean difference of -0.167 (t=-0.992, p=0.325), indicating no significant difference in baseline symptom severity. Posttreatment, the TNSS scores significantly reduced in both groups, with Group A showing a mean of 2.90±0.66 and Group B showing a lower mean of 2.0±0.45. The mean difference at posttreatment was 0.90, and the comparison between groups was statistically significant (t=6.139, p=0.001*). The difference in symptom improvement was also compared, revealing a mean TNSS reduction of 6.03±0.93 in Group A and 7.10±0.88 in Group B. This resulted in a mean difference of -1.06 (t=-4.557, p=0.001*), indicating a significantly more significant improvement in Group B.

Table 8: Pre and Post-comparison of TNSS within a Group

TNSS	Group A (Mean±SD)	Group B (Mean±SD)
Pretreatment	8.93±0.63	9.10±0.66
Posttreatment	2.90±0.66	2.0±0.45
t value; p-value	35.61; 0.001*	43.95; 0.001*

*Statistically significant (p<0.05), Paired t-test



Graph 8: Pre and Post-comparison of TNSS within a Group

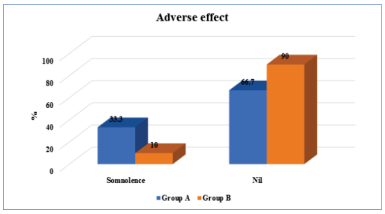
Inference

The within-group comparison of TNSS before and after treatment demonstrated a substantial reduction in symptom severity for both groups. In Group A, the mean TNSS decreased from 8.93±0.63 to 2.90±0.66, with a statistically significant t-value of 35.61 (p=0.001*). Similarly, in Group B, the mean TNSS reduced from 9.10±0.66 to 2.0±0.45, yielding a t-value of 43.95 (p=0.001*), which was also statistically significant. This indicates that both groups experienced significant improvement in nasal symptoms after treatment, with Group B showing a more significant reduction.

Table 9: Adverse Effect

Adverse effect	Group A N (%)	Group B N (%)	Chi-square value; p-value
Somnolence	10(33.3)	3(10)	4.812; 0.028
Nil	20(66.7)	27(90)	
Total	30(100)	30(100)	

Chi-square test



Graph 9: Adverse Effect

Inference

The occurrence of adverse effects was compared between the two groups. Somnolence was reported in 33.3% of participants in Group A, whereas only 10% of Group B experienced this side effect. The remaining participants in each group reported no adverse effects, accounting for 66.7% in Group A and 90% in Group B. The statistical analysis (Chi-square value = 4.812, p = 0.028) indicated a significant difference, suggesting that somnolence was more prevalent in Group A.

DISCUSSION

Allergic rhinitis (AR) is a common condition. Studies shows a prevalence of 20 to 30% in adults and up to 40% in children's. The symptoms of AR can have significant impact on the quality of life, sleep and performance at school and work. It is necessary to distinguish AR from non-AR[5].

All participants in both Group A and Group B (100%) reported experiencing a runny nose. Sneezing was another common complaint, with 93.3% of Group A and 96.7% of Group B reporting this symptom. Nasal itching was observed in 86.7% of Group A and 90% of Group B participants.

Pale nasal mucosa was observed in 43 patients and the other 17 patients had normal healthy mucosa on anterior rhinoscopy examination. Posterior rhinsocopy showed normal findings.

In a study done by Mahir serbes, included 874 patients. The median age of AR patients was 8.3 (5.1-12.2) years, and 54.7% were male. The most common presenting complaints were nasal obstruction (86.3%) and nasal discharge (84.3%). The most frequent comorbidities were rhinosinusitis, conjunctivitis, asthma and atopic dermatitis. Their study revealed that 42.2% of AR patients presented with the moderate-to-severe persistent disease in the pediatric population. Rhinosinusitis and conjunctivitis were the most common comorbid conditions.[6]

In our present study 60 patients who presented with signs and symptoms of allergic rhinitis and fulfilled all inclusion criteria were selected, informed and written consent were taken.

In the present study, considering the age, majority of the participants fell within the 21-30 years category, and an equal proportion was in the 31-40 years category.

In the present study in Group A, 46.7% of the participants were female, while in Group B, a slightly higher percentage (56.7%) were female. Conversely, male participants comprised 53.3% in Group A and 43.3% in Group B.

In a study conducted by Hideyuki et al, described that antihistamines targeting the H1 receptors have an important role in improving and maintaining the quality of life of patients with AR. For first line therapy, they should not have central depressant or sedative activities.[7]

A study conducted by Donald W Aaronson mentions that cetirizine significantly reduces severity of symptoms of rhinitis such as nasal

itching, nasal congestion, and watery eyes and asthma. It also helped in resolution of other symptoms such as post nasal drip, cough and sputum production.[8]

Study done by E.N. Charlesworth et al., to determine the effect of cetirizine on inflammatory mediators during the cutaneous late-phase response showed that prostaglandin D2 production was reduced by cetirizine treatment. It also had the most significant effect on the reduction of inflammatory cell migration. So they concluded that cetirizine has a significant effect on reduction of both cellular infiltration and prostaglandin D2 production.[9]

In a study conducted by Katherine et al., they stated that twice-daily bepotastine is very effective and generally well tolerated second-generation antihistamine in the treatment of patients with allergic rhinitis, chronic urticaria and associated allergic diseases. Bepotastine 20 mg/day was significantly more effective than terfenadine 120 mg/day in patients with perennial allergic rhinitis.[10]

Bepotastine besilate is effective and well-tolerated in the treatment of allergic rhinitis. It has less side effects in patients with AR who do not have kidney or liver disease. Clinical trial experience with oral bepotastine has confirmed its safety. It can be useful as a therapeutic option in patients with AR as an alternative to the currently available once-daily oral H1-antihistamines. The studies determined that the optimal dosage of bepotastine was 20 mg/day (administered 10 mg bid) and that 4 weeks of treatment was effective in PAR.[11]

Priyanka AT, et al.,[12] studied on 60 patients with allergic rhinitis wherein 30 patients received tab cetirizine 10mg OD, and 30 patients received tab. Bepotastine 10mg OD for 2 weeks. Total symptom score (TSS) assessed at the end of 2 weeks of treatment showed statistically significant results. Mean TSS was reduced from 12.36 ± 2.12 to 4.2 ±1.66 in cetirizine group and from 13.33 ± 3.039 to 3.033 ± 1.40 in bepotastine group. In this study, mild adverse effects were noted in both groups, the most common being the sedation and was associated with cetirizine. So, bepotastine is more efficacious compared to cetirizine in allergic rhinitis with respect to mean change in Total symptom score at end of treatment.

Fujikura et al.,[13] studied on 24 subjects with perennial allergic rhinitis. All the subjects were associated with a dust mite allergy. They compared bepotastine besilate versus olopatadine hydrochloride in PAR. They were given medication twice daily for a period of 10 to 14 days and symptoms were assessed. The mean sneezing count before the study was 1.43 ± 0.45 for bepotastine group and 2.64 ± 1.00 for olopatadine group. In group B, the mean sneezing count was reduced on day 3, 7, 10, and 13. A significant change in nasal congestion score and peak nasal inspiratory flow was also observed after treatment with bepotastine and olopatadine. This had a significant impact on quality of life of the patients.

Godse K, et al.,[4] They explored currently available literature on bepotastine besilate to find out its pharmacokinetics and pharmacodynamics and Described that Bepotastine besilate is a very promising drug in the management of allergic rhinitis, urticaria and pruritis and is non sedative. It inhibits IL-5 action or production which has a role in eosinophil-mediated inflammation. At a dose of 2.5-40mg/day, it didn't produce any significant changes in blood pressure, body temperature and electrocardiography. It has quick onset of action, that is helpful in bothersome allergic conditions. Bepotastine was found to be tolerated well in paediatric and elderly population

In the present study of distribution of study characteristics by SPT, SPT positive for pollen were seen in 7 patients. SPT positive for cockroaches was seen in 2 patients. SPT positive for Aspergillus was seen in 4 patients, SPT positive for dust mites was seen in 50 patients.

A study done by Rasool R, in all SPT-positive patients, 54% having asthma, 48% having allergic rhinitis and 2.5% having urticaria, were sensitive to one or more species of pollens. The reason could be inhabitants are living in close proximity of farmlands, meadows and forest areas. The surroundings in our part of the world are highly enriched with natural flora. The patterns of aeroallergens in the environment differ widely in different localities and seasonal changes (particularly when they affect pollen) are important.[14]

In the present study The Total Nasal Symptom Score (TNSS) was compared between the groups at the pretreatment and posttreatment stages. The mean TNSS was 8.93±0.63 in Group A and 9.10±0.66 in Group B. Posttreatment, the TNSS scores significantly reduced in both groups, with Group A showing a mean of 2.90±0.66 and Group B showing a lower mean of 2.0±0.45.

CONCLUSION

Effectiveness of Bepotastine was more than cetirizine with respect to symptom control, which was interpreted based on total nasal symptom score. Bepotastine was associated with fewer adverse effects compared to cetirizine in our study.

Declarations:

- Funding: The authors have no relevant financial or non-financial interests to disclose.
- Conflict of Interest: The Authors declare that there is no conflict of interest.
- Data Availability: The data used in this study was not used or published in any other publications.
- Code Availability: The data was compiled and analyzed using IBM SPSS STATISTICS version 28 for Windows.

Ethics Approval: The study was conducted after obtaining approval from the Institutional Ethics Committee of JJM Medical College, Davangere, Karnataka, India, in accordance with the ethical standards of the institutional and/or national research committee.

Consent to Participate: Written informed consent was taken from all the patient attenders(parents).

Consent for Publication: All authors have reviewed and approved the manuscript for publication.

Authors Contribution: All authors contributed to the study conception and design. Dr.Mudduswamy. A.C performed material preparation, data collection and analysis and wrote the first draft of the manuscript. All authors reviewed and approved subsequent versions.

REFERENCES

1. Varshney J, Varshney H. Allergic rhinitis: an overview. Indian J Otolaryngol Head Neck Surg 2015;67(2):143-9
2. Broide DH. Allergic rhinitis: pathophysiology. In: Allergy & Asthma Proceedings. 2010 Sep 1; 31(5).
3. Zhang L, Cheng L, Hong J. The clinical use of cetirizine in the treatment of allergic rhinitis. Pharmacology. 2013 Jul 18;92(1-2):14-25.
4. Godse K, Kumari N. Bepotastine besilate: A novel anti-histamine. Indian Journal of Drugs in Dermatology. 2017 Jul 1;3(2):64-8.
5. Hoyte FCL, Nelson HS. Recent advances in allergic rhinitis. F1000Res. 2018 Aug 23;7:F1000 Faculty Rev-1333. doi: 10.12688/f1000research.15367.1. PMID: 30210782; PMCID: PMC6107993.
6. Serbes M. Clinical characteristics and comorbid diseases of pediatric patients with allergic rhinitis in SIVAS. In KBB - Forum: Elektronik Kulak Burun Boğaz ve Baş Boyun Cerrahisi Dergisi 2023 Mar 28;22(1).
7. Kawauchi H, Yanai K, Wang DY, Itahashi K, Okubo K. Antihistamines for allergic rhinitis treatment from the viewpoint of nonsedative properties. International Journal of Molecular Sciences. 2019 Jan 8;20(1):213.
8. Aaronson DW. Evaluation of cetirizine in patients with allergic rhinitis and perennial asthma. Annals of Allergy, Asthma & Immunology. 1996 May 1;76(5):440-6.
9. Charlesworth EN, Kagey-Sobotka A, Norman PS, Lichtenstein LM. Effect of cetirizine on mast cell-mediator release and cellular traffic during the cutaneous late-phase reaction. Journal of allergy and clinical immunology. 1989 May 1;83(5):905-12.
10. Lyseng-Williamson KA. Oral bepotastine: in allergic disorders. Drugs. 2010 Aug 20;70(12):1579-91.
11. Ismael Carrillo-Martina, Alexei Gonzalez-Estradab and Ves Dimovc. Bepotastine besilate for the treatment of perennial allergic rhinitis.
12. Priyanka AT, Mamatha KR, Puttamadaiah GM. A comparative study to assess the efficacy and safety of bepotastine and cetirizine in allergic rhinitis. International Journal of Basic & Clinical Pharmacology 2019;8(10):2304–2308
13. Fujikura T, and Okubo K. Effectiveness of Second-Generation Antihistamine for the Treatment of Morning Symptoms Observed in Patients with Perennial Allergic Rhinitis: Comparison Study of Bepotastine Besilate versus Olopatadine Hydrochloride. Otolaryngol (Sunnyvale) 2015;5: 185.
14. Rasool R, Shera IA, Nissar S, Shah ZA, Nayak N, Siddiqi MA, Sameer AS. Role of skin prick test in allergic disorders: a prospective study in Kashmiri population in light of review. Indian J Dermatol. 2013 Jan;58(1):1