Original Article

A prospective study to compare the therapeutic effects of histaglobulin and nasal steroids in allergic rhinitis.

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Abstract:

Background: Allergic rhinitis is an allergic response to specific allergens characterized by rhinorrhea, sneezing, itching of nose, ears and throat. It is usually treated with antihistamines and nasal steroids. The present study is aimed to evaluate the efficacy of histaglobulin and nasal steroids in patients suffering from allergic rhinitis.

Aims and Objectives: To compare the therapeutic effects of histaglobulin and nasal steroids in allergic rhinitis.

Materials and Methods: This prospective study was conducted in the Department of ENT, Azeezia Institute of Medical Sciences and Research Kollam, Kerala, India between January 2022 and December 2022**.** A total of 64 patients were divided into two groups. Group-I was treated with histaglobulin and Group-II was given nasal steroids. All patients demographic, clinical and biochemical data were recorded and analyzed**.**

Results and Observations: Demographic data (age, gender) did not show any significant difference between the groups. Rhinorrhea, nasal congestion and sneezing scale showed significant difference between the groups. Significant reduction in eosinophil count and IgE antibody was noted in both groups compared to baseline. Group-I showed more significant decrease compared to Group-II.

Conclusion: Histaglobulin therapy is a safe and effective treatment for allergic rhinitis with no adverse effects. It can be easily given in OPD to patients not responding to conventional treatment modalities. Allergic rhinitis can be treated with anti-allergic drugs, anti-inflammatory agents and nasal steroids. Histaglobulin showed significant long term effect compared to nasal steroids in chronic allergic rhinitis. It can be concluded that histaglobulin can be used for long term treatment in patients with allergic rhinitis to prevent the recurrence and steroid induced adverse effects.

Key Words: Allergic disorders of nose, chronic allergic rhinitis, allergic rhinitis, steroids, allergy, nasal, histaglobulin, eosinophils, IgE antibody, nasal steroids, rhinorrhea, nasal congestion.

INTRODUCTION:

Allergic rhinitis can be defined as congestion of nasal mucous membrane accompanied by rhinorrhoea, sneezing and itching. It is an extremely common condition affecting 20-40 million people in USA and 10-30% of world's population. Two elements required for its development are an immunological sensitivity to an allergen and recurrent continuous exposure to it**.[1-5]** Allergic rhinitis (AR) is one of the allergic disorders of nose. It can develop in any age group**[6]** . AR is caused mainly due to introduction of allergen into the nose. Exposure to allergen is most commonly seen in polluted metropolitan cities. The common allergens are pets in house, plant pollen, dust particles, smoke, chemicals and drugs **[7]**. These allergens can cause allergic reactions leading to the release of IgE antibody. The released IgE trigger immune reactions which can produce inflammation, increase in nasal secretion and nasal stuffiness **[8]** .

The major symptoms of AR are rhinorrhea, sneezing and nasal congestion . These symptoms will affect the day today life because it will produce insomnia, irritation, mood changes, difficulty in breathing and cognitive effects **[9]** . In some patients AR may be associated with other disorders like otitis media, sinusitis, postnasal drip and conjunctivitis. Early diagnosis and treatment can prevent the progression of disease. In recent years various classes of drugs are used in the treatment of AR **[10]** . But each class of drug has its own uses and limitations. Most commonly used drugs are steroids, anti-histamines and anti-IgE antibody. Intra nasal steroids are usually preferred in the treatment of AR **[11]**.

They can reduce the immune reactions, inflammation and can relieve the symptoms of AR. It was observed that use of steroids have some limitations and cannot prevent the recurrence. Recently immunotherapeutic drugs are introduced in the treatment of AR. Histaglobulin is a nonspecific immunotherapeutic agent used in the treatment of AR **[12]**. But its efficacy was not studied completely in AR . The present study is aimed to compare the therapeutic efficacy of histaglobulin and nasal steroids in allergic rhinitis patients.

MATERIALS AND METHODS:

This prospective study, was conducted in the Department of ENT, Azeezia Institute of Medical Sciences and Research Kollam, Kerala, India between January 2022 and December 2022**.** A total of 64 patients were divided into two groups. Group-l was treated with histaglobulin and Group-II was given nasal steroids. All patients demographic, clinical and biochemical data were recorded and analyzed**.**

Inclusion criteria : Age between 18-50 years, Patients with runny nose, sneezing, stuffy nose for last one week , Not on any other medications. Willing to give consent.
Exclusion criteria : Asthma, Respiratory tract infection, Diabetes, Patients taking steroids, antibiotics or NSAIDs, COPD, Recent nasal surgery.

Study groups- Group-I: Histaglobulin (2 ml) subcutaneous weekly for 10 weeks followed by booster dose once a month for 3 months.
Group-II: Fluticasone (2 puffs).

In this study 64 patients were included on the basis of inclusion and exclusion criteria. They were divided into two groups each of 32 patients. All patients were explained about the study procedure and dose schedule in understandable language. Both groups patients demographic data (Age, gender and occupation), clinical data (sneezing, runny nose and stuffy nose) were recorded. Total eosinophil count (Automatic Cell counter) and IgE antibody level **[13]** (ELISA) were measured at the beginning and end of the study.

RESULTS AND OBSERVATIONS:

Group-I and II showed maximum number of patients between 31-40 years. Lowest number of patients were between 18 to 20 years (Table-1and figure 1). Males were more compared to females in both groups. Age and gender did not show any significant difference between the groups. In group-I maximum patients presented with runny nose (26) . 18 showed stuffy nose in group-I and 19 in group-II (Table-2, 3,4 and Figure, 2, 3). In both groups maximum number of patients showed severe RNS score (Group-I 23 and group-II 22).

Nasal symptoms and RNS score did not show any significant difference ($p>0.05$). Comparison between baseline and end of the study values between and within the groups showed significant difference ($p<0.05$) (Table-5,6, Figure 4,5) Baseline eosinophil and IgE levels did not show any significant difference between the groups ($p<0.05$). Significant difference ($p<0.04$) was observed in baseline and end of the treatment score with in the groups. Group-I showed significant difference compared to group-II in eosinopil count and IgE levels.

Table1. Age Distribution

Age(in years)	**Group I(n=32)**		**Group II(n=32)**	
	No. of the patients	%	No. of the patients	%
>18	2	6.3	4	12.5
20-30	5	15.6	7	21.9
31-40	16	50	15	46.9
41-50	9	28.1	6	18.8

Figure 1. Age segregation of patients.

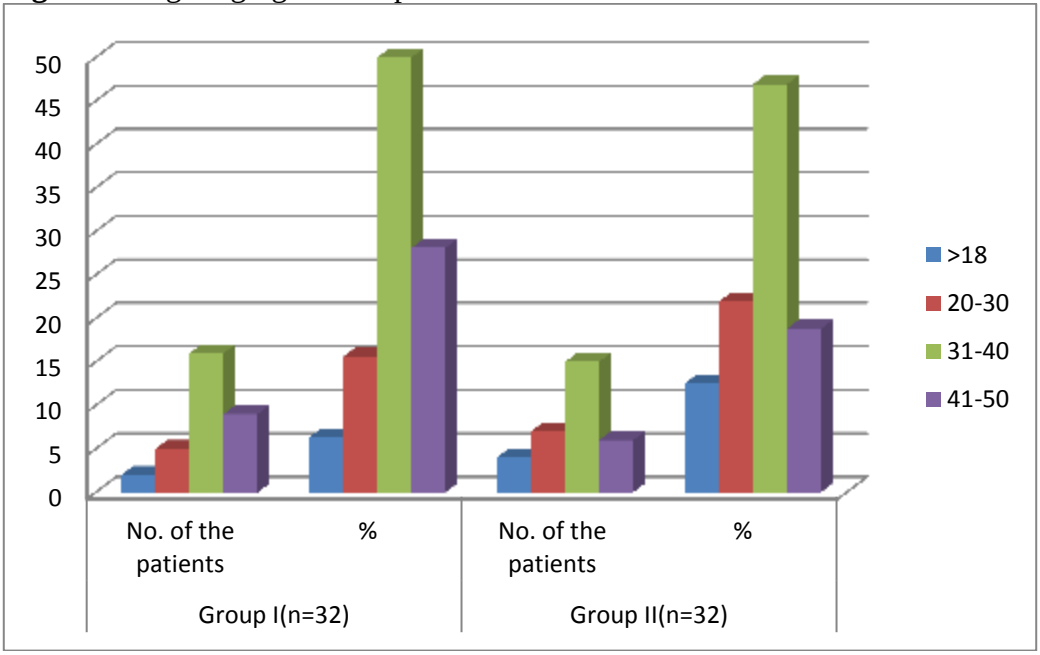

Table-2: Distribution of patents based on nasal symptoms and score.

Nasal symptoms (Base line)	**Group I(n=32)**	**Group II (n=32)**
Sneezing	16	13
Runny nose	26	22
Stuffy nose	18	19
Rhinorrhea, Nasal congestion and sneezing score		

No symptoms	0	0
Mild	4	4
Moderate	3	4
Severe	25	24

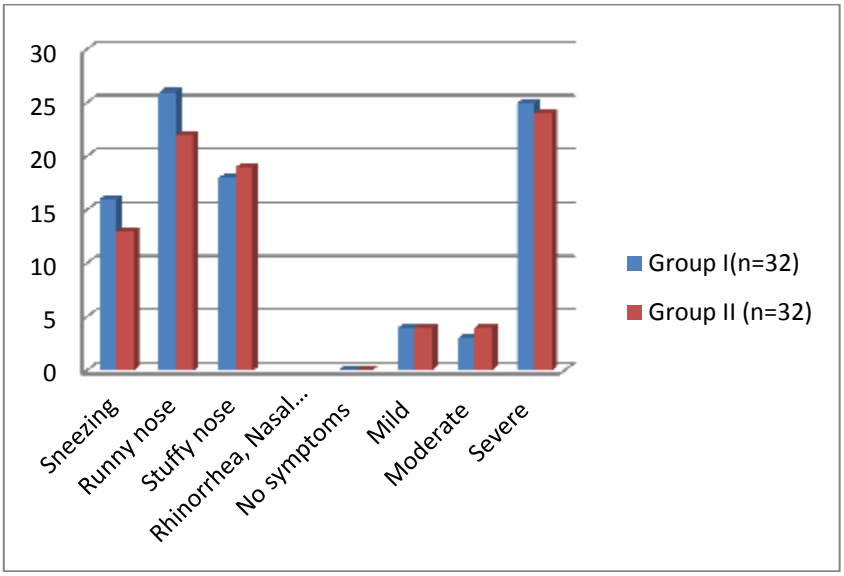

Figure 2: Patient distribution based on nasal symptoms and score.

Table-3: Comparison of number of patients baseline and end of study score between group-I and II.

Nasal symptom (Base line)	**Group-I (n=32)**		**Group-II (n=32)**	
	Baseline	End of the study	Baseline	End of the study
Sneezing	16	9	13	8
Runny nose	26	21	22	16
Stuffy nose	18	10	19	11
Rhinorrhea, Nasal congestion and sneezing score				
No symptoms	0		0	
Mild	4	8	4	6
Moderate	3	14	4	10
Severe	25	8	24	14

Table 4. Sex distribution in both the groups

Sex	**Group I**	**Group II**
Male	**15**	**13**
Female	**17**	**19**
Total	**32**	**32**

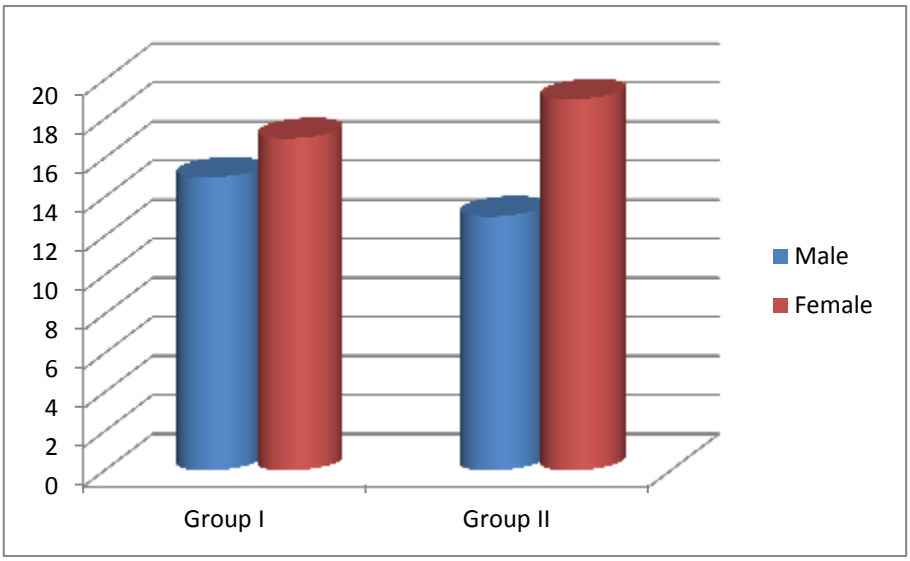

Figure 3: Sex distribution

Table 5. Comparison of total eosinophil count between Group-I and Group-II.

Eosinophil Count(cells/ml) Group-I		**Eosinophil Count(cells/ml) Group-II**	
Baseline	End of the study	Baseline	End of the study
115	55	120	85

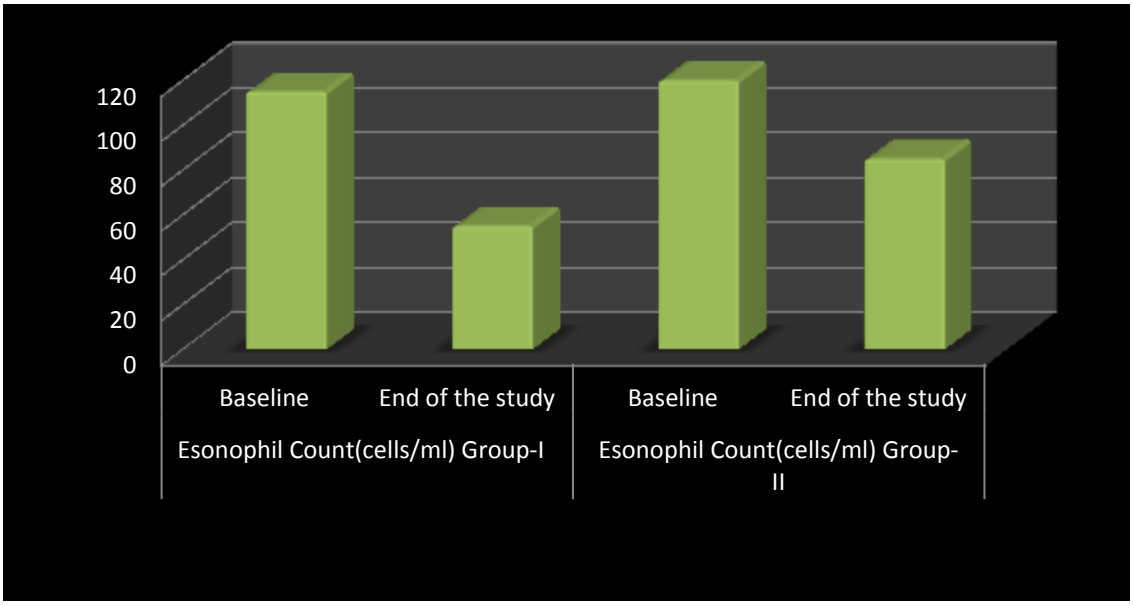

Figure 4: Eosinophil count between Group-I and Group-II

Table 6. Comparison of IgE Level between Group-I and Group-II.

IgE Level(IU/ml) in Group I		IgE Level(IU/ml) in Group II	
Baseline	End of the study	Baseline	End of the study
80	40	85	70

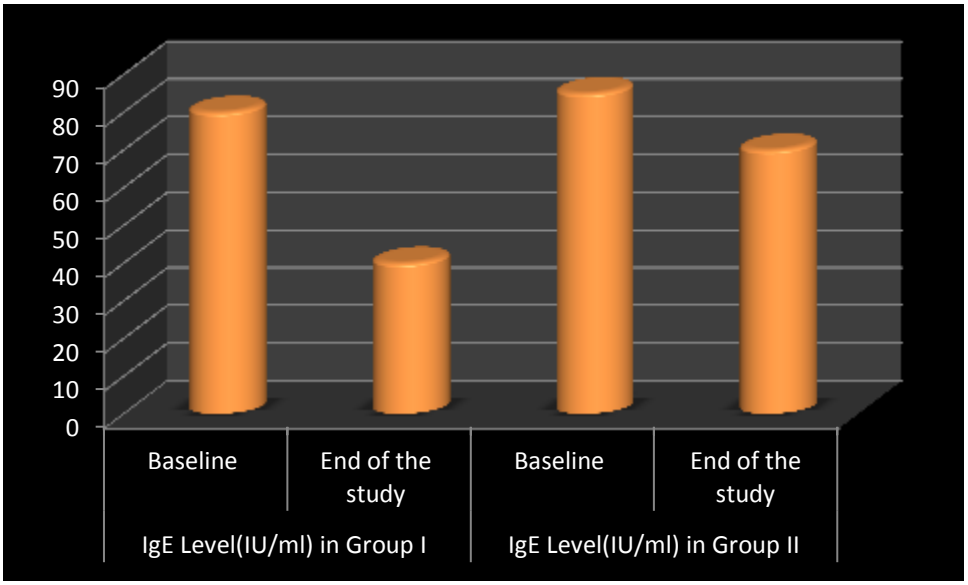

Figure 5: Comparison of IgE Level between Group-I and Group-II.

DISCUSSION:

The present study included 64 AR patients. They were divided into two groups. Group-I patients was given nasal steroids and group-II was given histaglobulin. In both groups the acute condition is treated with Montelukast and levocetrizine and Nasal spray containing Azelastine hydrochloride and Fluticasone propionate. Once the acute symptoms subsided they were put on specific treatment. Nasal steroids were used commonly in the treatment of AR. Several studies showed that use of steroids can treat the condition but cannot prevent the recurrence of disease. It was observed that intra nasal treatment is associated with some disadvantages like nasal irritation, dryness, nasal bleeding, altered taste and smell, headache and rarely septal perforation.It is not cost effective and patient's adherence to therapy and habituation is also a concern. In this study use of steroids significantly reduced the eosinophil and IgE antibody levels. Most of the patients shifted from severe RNS score to moderate. It reflects that intra nasal steroids are quite effective in the treatment of AR. Varshney J et.al., study also showed administration of intra nasal steroids significantly reduced the symptoms of AR **[14]** . Trangsrud AJ et. al., study also concluded that use of nasal steroids significantly prevent reduced the symptoms of AR **[15]**. Recently immunomodulators are introduced in the treatment of AR. These drugs have some advantages compared to the steroid therapy. Most of the limitations of steroid therapy can be overcome with the use of immunomodulators. They are quite effective than steroids especially in long term control of allergic symptoms in chronic allergic rhinitis. But response with steroids is faster compared to immunomodulators. Histaglobulin is one of the immunotherapeutic agent used widely in the treatment of AR. It has immune suppression action which reduced the IgE and other immune cell mediated allergic reactions. In the present study administration of histaglobulin significantly reduced the symptoms of AR and also reduced the levels of eosinophils, IgE antibody levels. It was observed that administration of histaglobulin showed significant results compared to intra nasal therapy. Narayana J et.al study also emphasizes the efficacy of histaglobulin on allergic rhinitis. They observed that use of histaglobulin significantly reduced the symptoms of AR **[16]** .Abhinav V et.al study concluded that histaglobulin significantly prevent the symptoms of AR compared to other drugs **[17]**. The present study also showed similar effect. This study results showed that use of histaglobulin produce better efficacy than nasal steroids in patients with AR. It mainly reduced the recurrence rate compared to steroids.

CONCLUSION:

Histaglobulin therapy is a safe and effective treatment for allergic rhinitis with no adverse effects. It can be easily given in OPD to patients not responding to conventional treatment modalities. Intranasal steroids are commonly prescribed drugs in allergic rhinitis which can cause various adverse effects on long term usage and moreover discontinuation of steroids leads to recurrence of symptoms that again lead to habituation which becomes a vicious cycle. It can be overcome with the use of Histaglobulin. From the study results it can be concluded that histaglobulin can be used for long term therapy in patients suffering from allergic rhinitis**.**

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Conflict of interest: None.

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