IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)
e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 14, Issue 1 Ver. VIII (Jan. 2015), PP 15-20
www.iosrjournals.org

Comparative Study of Efficacies of Oral Levocetrizine and Fluticasone Nasal Spray in Allergic Rhinitis Patients

Dr. Y. Lakshmi[1], MD., Dr. B.Vasundara Devi[2], MD
[1(]*Assistant Profesor, Department of Pharmacology, S.V. Medical Collage, Tirupati, NTRUHS,A.P., India.)*
[2] *(Professor & HOD, Department of Pharmacology, S.V. Medical Collage, Tirupati, , NTRUHS,A.P., India.)*

Abstract:
Background: *Allergic Rhinitis(A.R.) is an Ig E mediated hypersensitivity disease of the mucous membranes of the nasal airways characterized by Sneezing, Itching, watery nasal discharge, nasal congestion, sensation of nasal obstruction for > 1 hr on most days either seasonally or throughout the year. Drugs used for this condition are oral antihistamines, topical corticosteroids, oral corticosteroids, topical anticholinergics and immunotherapy (Desensitization).*
Aim/Objective: *To compare the efficacy of Fluticasone Nasal Steroidal Spray(F.N.S.S.) and Oral Levocetrizine in Allergic Rhinitis Patients.*
Materials & Methods: *60 Patients with A.R. received Fluticasone NSS and 60 patients (Group B) received oral Levocetrizine for 15 days.*
Results: *With Fluticasone marked improvement of all symptoms observed on 2nd day which was statistically significant, with Levocetrizine it has taken more than 1 week for relief of all symptoms which was statistically not significant.,*
Conclusion: *Fluticasone is better choice than Levocetrizine.*
Keywords: *A.R. Fluticasone, nasal spray, Levocetrizine.*

I. Introduction

Allergic Rhinitis(A.R.) is more common disease and a common cause of morbidity, social embarrassment and impaired performance at school/work place. Prevalence of the disease varies from 10% to 20% with more distribution in young adulthood.

Allergic Rhinitis commonly occurs in atopic individuals who are exposed to common aeroallergens. Paranasal sinus mucosa may be involved. Associated allergic conjunctivitis and bronchial asthma may occur. Commonly due to house dust mites[11], Pollution like traffic vehicles fume, tobacco smoke etc., pet animals occupational (flourmill workers, Chilly powder, etc.) or food allergens (some spices of Fish, Prawns etc.). Exposure to cold atmosphere[5] washing hands and legs with cool water, drinking cool water in cold seasons. ACE Inhibitors etc., may increase A.R.

Allergic Rhinitis has clinical symptoms[15] of sneezes, nasal congestion/obstruction, watery nasal discharges.

Pathophysiology

Immunoglobulin Ig E binds reversibly to mast cells and basophils. The interaction between allergen & Ig E initiates secretion of active mediators like histamine, leukotrien and prostaglandins that cause clinical manifestations of A.R. Ig E antibodies are produced by human B-Lymphocytes in response to antigenic stimulation by aeroallergens.. Mast Cells & Eosinophils number is increased[15] in A.R. patients. Activated mast cells secrete mediators by direct physical damage. Histamine[12] binds to site of action. Local accumulation of inflammatory cells including T-lymphocyltes, mast cells[9], eosinophils, basophils and neutrophils occurs – characteristic feature of A.R.

Treatment:

Topical corticosteriods[10] are effective in controlling nasal symptoms of A.R. they control sneezing, rhinorrhoe nasal congestion/pruritus. Corticosteriods[4,17] like Mometasone Beclomethasone, Budesonide and Fluticesone available as Aqueous nasal sprays, better tolerated, have better local distribution with in the nasal cavity. Side effects are minimal. Local irritation settles down when the underlying inflammation responds to treatment. Topical corticosteroids are preferred anti inflammatory therapy for persistent A.R[12]. Fluticasone propionate is very effective[20] and better than other steroids[14] no systemic effects for nasal corticosteroids with usual recommended therapeutic doses. FNSS improves sleep in patients with A.R. without change in the apnoea/hypoapnoea index[6]. It has greater immunologic improvement than other intranasal steroidal

preparations[19]. It is better than leukotrien receptor antagonist in managing night times symptoms of A.R[16]. It is good treatment for A.R. in 2-4 years old children[8]. It has no negative effect on lower leg growth velocity[21]. It provide relief of seasonal A.R. symptoms regardless of disease severity[13].

Mechanism of Antiinflammatory and anti allergic actions

Corticosteriods[3] Suppress all types of hypersensitization and allergic phenomena. Inhibition of Ig E mediated release of histamine and leukotrine-C_4 (LT-C_4) from basophils. Reduced production of endothelial leulcocyte adhesine molecule ($ELAM_1$) of intracellular adhesion molecule 1-(ICAM-1). Decreased production of acute phase reactants from macrophages and endothelial cells.

Antihistamins[4,17]

These are the most commonly used drugs in the treatment of A.R. effective of relieve the symptoms of sneezing, itching watery rhinorrhoea. Histomine actagonists act by reversible competitive antagonism at the H_1 receptor, effectively block histamine[2] binding to its site of action. 2nd generation antihistamins are used for the treatment of the A.R. Sedation anti muscarinic actions are the common adverse effects of H_1 anti histamines.

II. Materials And Methods

A prospective parallel and open clinical trail was conducted on 120 patients (both male & female). (Levocitrizen given for 60 and Fluticasone for 60) at the department of pharmacology in collaboration with department of ENT Sri Venkateswara Ram Narayan Reuea Government Hospital. Patient population with A.R. were recruited by using inclusion criteria sneezing, watery nasal discharge/itching, nasal blockade, watering of eyes & post nasal discharge were included at least for 1 month (to rule out common cold or other minor upper respiratory tract infections).

Exclusion criteria:

Respiratory Tract Infections with purulent, foul smelling discharge and fever. Patients using anti-histamines for past 48 hours or topical steroids for past 2 weeks or systemic steroid in the past 4 weeks as above drugs can alter the clinical picture. Diabetic, Hypertensive, Tuberculosis patients, pregnant/lactating women, patients undergoing desensitization are excluded.

Investigations-Complete blood picture i.e.,–HB% TC, DC, Nasal cyctology for eosinophil Count (before and after the treatment in both groups.) absolute eosinophil count, Serum Bilrubin, Serum creatinine, LFT–SGOT & SGPT are done.

Follow up: This includes recording of improvement in symptoms and signs after the treatment of 1st day, 2nd day, 8th day and 15th day, recording of any adverse effects and repetition of all investigations in all visits to see the effect of the given drug on the investigative parameters.

Total No. of visits 4: 1st visit on 1st day; 2nd visit on 2nd day; 3rd visit on 8th day; 4th visit on 15th day.

III. Results

120 patients who were diagnosed for allergic rhinitis were studied for a period of 15 days for each patient (data collection period is 6 months).

60 patients were treated with Fluticasone nasal steroidal spray under group-I.

60 patients were treated with Levocetrizine under group-II. The results of both groups were recorded.

In this study of 120 cases, all the patients (100%) with allergic rhinitis had sneezing. Watery nasal discharge was present in 118 patients (98.3%). Itching of nose/eyes was presented by 111 patients (92.5%), nasal congestion by 119 patients (99.2%), watering of eyes in 98 patients (8l.7%). Post nasal discharge in 90 patients (75%)

Improvement Of Clinical Symptoms

On second day there is marked improvement of all clinical symptoms in patients who are receiving Fluticasone nasal steroidal spray ($P<0.001$;s) than those receiving Levocetrizine On eighth day there is marked improvement of all clinical symptoms in patients who are receiving Fluticasone nasal steroidal spray ($P<0.001$;s) than those receiving Levocetrizine

On fifteenth day there were no significant differences observed among the patients in two treatment groups with regard to clinical symptoms, "No statistical significance"

Table 1: Fluticasone * Levocetrizine Groups Compared – 8th Day Therapy)

Sl.No.	Parameter	Fluticasone group (Mean±SD)		Levocetrizine group (Mean±SD)		*Statistical Significance	
		8 day	15 day	8 day	15 day	8 day	15 day
1.	Nasal cytology	1.55±1.61	0.00±0.00	9.85±4.89	9.83±4.74	P<0.001;S	P<0.001;S

Chart 1:

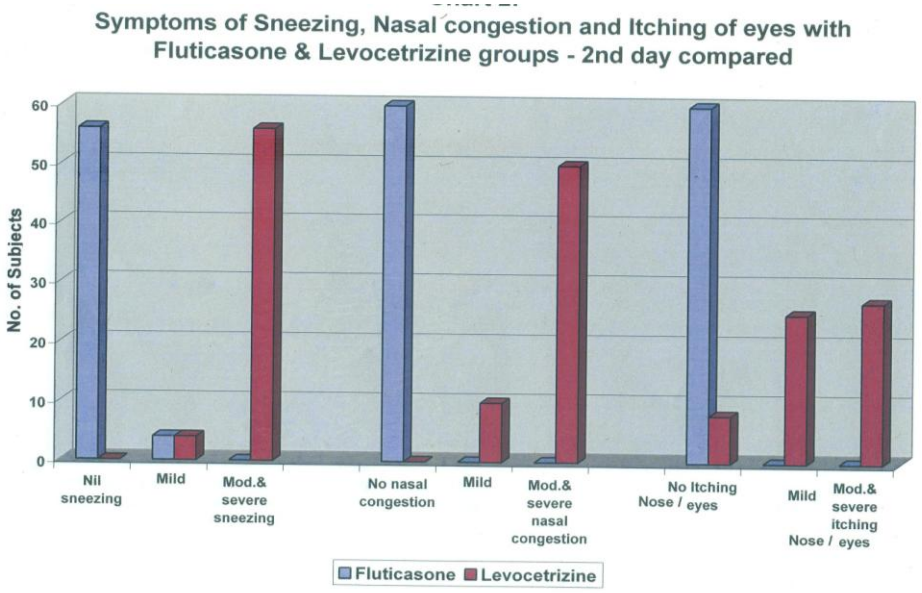


Table –2 Fluticasone – Summary Of Symptiom Profile (N=60)

Sl. No.	Symptom & Severity	Number of patients reporting symptoms				*Statistical Significance
		1st day	2nd day	8th day	15th day	
1.	Sneezing					
	Nil	0	56	60	60	P<0.001;S
	Mild	4	4	0	0	
	Moderate	4	0	0	0	
	Severe	52	0	0	0	
2.	Nasal congestion					
	Nil	0	60	60	60	P<0.001;S
	Mild	11	0	0	0	
	Moderate	20	0	0	0	
	Severe	29	0	0	0	
3.	Itching nose/eyes					
	Nil	6	60	60	60	P<0.001;S
	Mild	45	0	0	0	
	Moderate	5	0	0	0	
	Severe	4	0	0	0	
4.	Postnasal discharge					
	Nil	12	60	60	60	P<0.001;S
	Mild	42	0	0	0	
	Moderate	4	0	0	0	
	Severe	2	0	0	0	
5.	Watery nasal discharge					
	Nil	0	56	60	60	P<0.001;S
	Mild	15	0	0	0	
	Moderate	3	4	0	0	
	Severe	42	0	0	0	
6.	Watering eyes					
	Nil	10	60	60	60	P<0.001;S
	Mild	37	0	0	0	
	Moderate	7	0	0	0	
	Severe	6	0	0	0	
7.	Drowsiness					
	Yes	0	0	0	0	P<0.001;S
	No	60	60	60	60	

8.	Dryness of mouth (mild)					
	Yes	0	0	0	0	P<0.001;S
	No	60	60	60	60	

*Based on Chi-square test for differences in proportions

Table –3 Levocetrizine – Summary Of Symptiom Profile (N=60)

Sl. No.	Symptom & Severity	Number of patients reporting symptoms				*Statistical Significance
		1st day	2nd day	8th day	15th day	
1.	Sneezing					
	Nil	0	0	17	60	P<0.001;S
	Mild	0	4	43	0	
	Moderate	5	43	0	0	
	Severe	55	13	0	0	
2.	Nasal congestion					
	Nil	0	0	21	60	P<0.001;S
	Mild	0	10	39	0	
	Moderate	15	49	0	0	
	Severe	45	1	0	0	
3.	Itching nose/eyes					
	Nil	0	8	31	60	P<0.001;S
	Mild	24	25	29	0	
	Moderate	14	25	0	0	
	Severe	22	2	0	0	
4.	Postnasal discharge					
	Nil	17	17	54	60	P<0.001;S
	Mild	26	23	6	0	
	Moderate	1	17	0	0	
	Severe	16	3	0	0	
5.	Watery nasal discharge					
	Nil	0	8	13	60	P<0.001;S
	Mild	7	38	47	0	
	Moderate	22	23	0	0	
	Severe	31	4	0	0	
6.	Watering eyes					
	Nil	0	8	60	60	P<0.001;S
	Mild	29	38	0	0	
	Moderate	24	13	0	0	
	Severe	7	1	0	0	
7.	Drowsiness					
	Yes	0	60	60	60	P<0.001;S
	No	60	0	0	0	
8.	Dryness of mouth (mild)					
	Yes	0	0	60	60	P<0.001;S
	No	60	60	0	0	

*Based on Chi-square test for differences in proportions..

Chart 2:

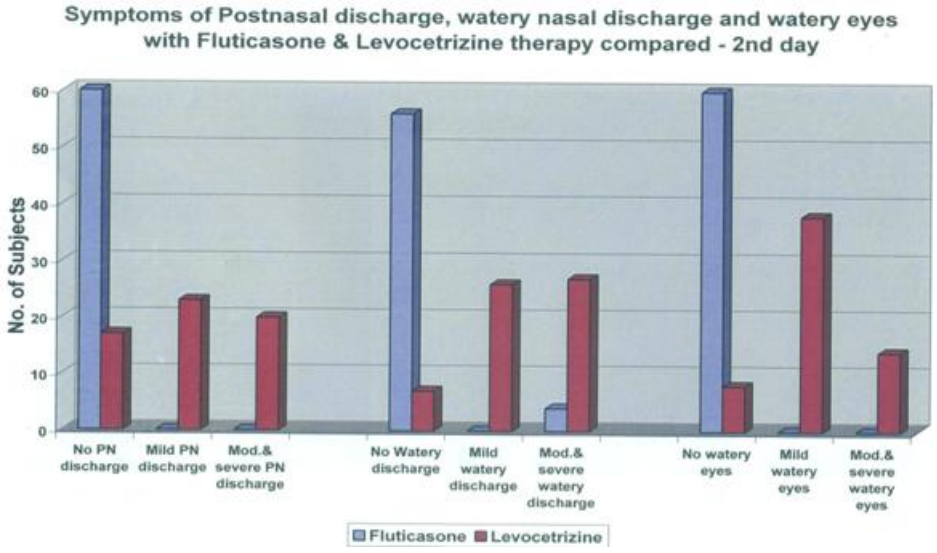


Chart 3

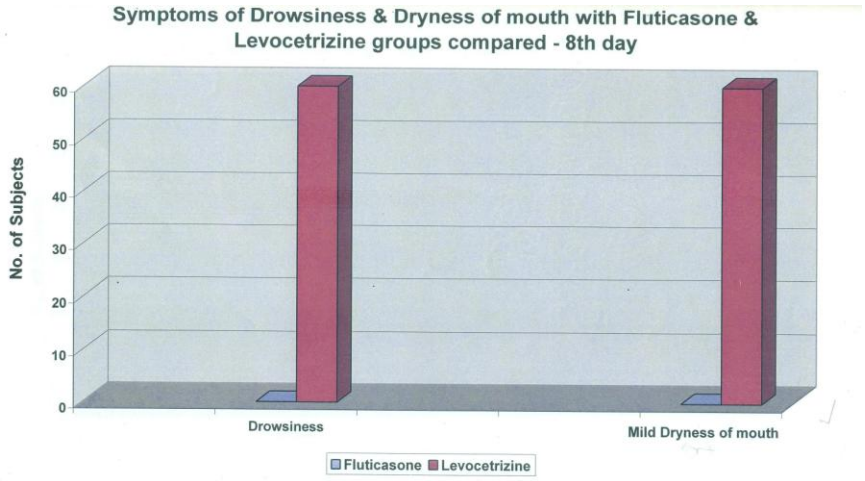
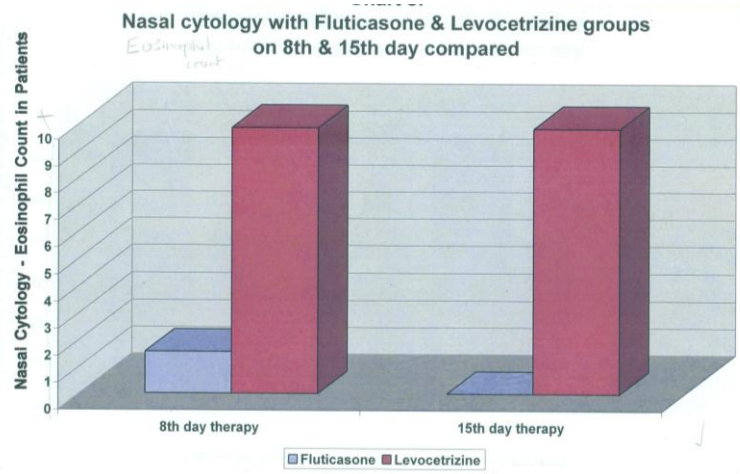


Chart 4



There are no significant differences observed among the patients in two treatment groups with regard to CBP, Eosinophil count, SGOT, SGPT, Serum bilirubin, Serum Creatinine. 'P' value not significant

Nasal Cytology:

There is marked decrease in Eosinophils (basophils & monocytes) in nasal smear among the patients receiving Fluticasone nasal steroidal spray (P<O.OO I ;S) than those receiving Levocetrizine (Chart-4).

Adverse Drug Reactions

Adverse drug reactions were NIL in Fluticasone nasal steroidal spray group.(Table2, chart3)

In Levocetrizine group all 60 patients had adverse effects like drowsiness and mild dryness of mouth (Table-3, Chart-3)

IV. Discussion

This study consisted of a total of 120 cases of allergic rhinitis selected at the E.N.T. OP. of the Sri Venkateswara Ramnarayan Reua Government General Hospital (S.V.R.R.G.G.H), Tirupati.

1. Patients are divided into two groups of 60 patients each treated by the two drugs 1. Fluticasone Nasal Steroidal spray 2. Levocetrizine
2. Patients having the typical features of allergic rhinitis using inclusion & exclusion criteria were taken.

History taking was followed by General, Systemic and ENT examination of the patient. After examining the patients investigations were done. Then the patients were divided into two groups. Patients in Group-I received Fluticasone Nasal Steroidal spray twice daily for 15 days. Patients in Group-II received 15 tablets of Levocetrzine l tablet daily for 15 days. Patients in Group-I & II were told to come to the ENT OP on 2nd day, 8th day and 15th day to assess the clinical improvement and also to note down any adverse effects reported by

the patients. The results were obtained after treatment. Symptomatic improvement was similar with both drugs at the end of 15 days. But symptoms improved very well within 2 days with Fluticasone Nasal Steroidal Spray and there were no side effects reported with Fluticasone spray. Adverse effects like drowsiness and mild dryness of mouth were observed with Levocetrizine and these adverse effects subsided by themselves with discontinuation of treatment.

V. Conclusion

In conclusion the two drugs were found to have similar level of efficacy in controlling the symptoms at the end of 15 days. But symptoms subsided to the maximum within two days with Fluticasone nasal steroidal spray.

FLUTICASONE NASAL STEROIDAL SPRAY was found to be more effective in suppressing the symptoms with in short period without side effects. Fluticasone nasal steroidal spray has significant effect on Nasal cytology- eosinophil count. Levocetrizine has no significant effect on Nasal cytology- eosinophil count Adverse effects were found be more with levocetrizine. Considering this factor Fluticasone nasal steroidal spray appears to be a better choice in the treatment of allergic rhinitis in those patients who cannot tolerate the adverse effects of Levocetrizine.

Acknowledgement

We thank Dr.Indira, Professor of Pharmacology, Gandhi medical college, Hyderabad and Dr.Harinadh, Retired Professor & H.O.D of Department of E.N.T and Dr.G.Srinivas, Assistant Professor of Department of E.N.T, S.V.R.R.G Hospital, Tirupati.

References

[1]. Baroody (FM-Cheng CC. moyla). Arch otolaryangol head neck surg. 2001, Feb; 193-9 absence of nasal mucosal atrophy and increased mucosal thickness with fluiticasone aqueous nasal spray.
[2]. Bennet P.N. Brown M.J. Laurence, clinical pharmacology, 9th edition, Respiratory System, Chapter 27, P.554. Histamine H_1 and H_2 – Receptor Antagonists.
[3]. Bernard P. Schimmer and Keith L. Parket. Adrenocorticotophic hormone; Adrenocortical Steroids of their synthetic Analogues. Chapter 59 Goodman and Gillman's the pharmacological basis of therapeutics 11th edition 2006, page no.1587 to 1610.
[4]. Bertram G. Katzung M.D., Ph.D Histamine, Serotonin and the Ergot Alkaloids section IV Chapter 16. Basic & Clinical pharmacology, 9th edition, 2004 P-263-268.
[5]. C. Hablet E.R. Chievers P.A. Corris. Diseases of the nasopharynx, Davidson's principles and practice of medicine year 2002, page 566.
[6]. Craig TH. Allergy Asthma Proc. 2003 Jan-Feb; 24(1) :53-8. The effect of topical nasal fluticasone on objective sleep testing and the symptoms of rhinitis, sleep and day time somnolence in perennial allergic rhinitis.
[7]. Elio Meltzer, Cytology (Nasal); Chapter 8: Allergic & Non allergic rhinitis clinical aspects edited by Niels Mygind – 1997, Page No.70-71.
[8]. Fokkens-Pediatr Allergy Immunol, 2004 June; 15 (3); 261-6 comment in; Pediatr Allergy Immunol, 2005 March; 26 (2); 1845-5 F.N.S.S. controls symptoms A.R. in Childen.
[9]. H.P. Rang, M.M. Dale, J. M. Ritter, P.K. Moore Local hormones inflammation and immune reactions, Chapter – 15, Text book of Pharmacology, 5th edition, 2003, P.220.
[10]. Jeffrey L. Kishiyama, M.D. & Daniel C. Adelman, MD. Allergic and Immunologic Disorders. CMDT – Current Medical Diagnosis and Treatment – 2005 P-764.
[11]. K. Frank Austen, Disorders of Immune system part XIII Allergies, Anaphylaxis, Harrisons Principles of Internal Medicine Volume II, 16th edition, P.298.
[12]. K. Howarth PH-Allergy 2000; 55 suppl 62:6-11 A comparison of the anti-inflammatory properties of intranasal corticosteroids and antihistanmines in allergic rhinitis.
[13]. Kaiser HB, Allergy Asthama Proc. 2004 Nov-Dec; 25(6); 423-8. Triameinolone acetonide and fluticasone propionate nasal sprays provide comparable relief of seasonal allergic rhinitis symptoms regardless of disease severity.
[14]. Kivisaari E. Clin Exp Allergy, 2001 Jun; 31 (6); 855-63. F.N.S.S. is more efficacious.
[15]. Michael Kaliner in Allergic Rhinities; Chapter 18; Allergic and Non allergic Rhinitis clinical aspects edited by Niels Mygind, Robert M. Naclerio-1997, P.156.
[16]. Nathan RA.J. Allergy clin Imunol, 2005 Aug; 116 (2); 463-4. F.N.S.S. better than Leukotriene antagonists.
[17]. Randal A. Skidgel and Ervin G. Erodos, Histamine, Bradykinin and their Antagonists. Chapter 24, Goodman Gillman's. The pharmacological basis therapeutics 11th edition 2006, P-269 to 649.
[18]. S.R. Durham mechanism of treatment of allergic rhinitis. Scott Brown's otolaryngology (volume 4 Rhinology 6th edition eyar d1997, P. 4/6/1 to 4/6/8.
[19]. Tai CJ. Obtolaryngol head Neck Surg. 2003 Nov; 129(5); 518-25. F.N.S.S. and Immunologic improvement.
[20]. Webb DR; Ann Allergy Asthma Immunol, 2002 Apr; 88(4); 385-90. Intranasal fluticasone propionate is effective for perennial non allergic rhinitis with or without eosinophilia.
[21]. W.S. Kover D.P. Ann Allergy Asthma Immunol, 2003. Jan;90(1); 56-62. Fluticasone nasal steroidal spray had no negative effect on lower leg growth velocity.