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"A COMPARATIVE STUDY ON EFFICACY OF VARIOUS TOPICAL DRUGS IN ALLERGIC RHINITIS."

Otorhinolaryngology

Dr. Varsha Rathi Postgraduate Department Of ENT M.G.M. Medical College And M.Y.H. Hospital, Indore M.P.

Dr Yamini Gupta Professor And HOD Department Of ENT M.G.M. Medical College And M.Y.H. Hospital, Indore M.P.

Dr Jagram Verma Associate Professor Department Of ENT M.G.M. Medical College And M.Y.H. Hospital, Indore M.P.

Dr. Nirmala Kumari Postgraduate Department Of ENT M.G.M. Medical College And M.Y.H. Hospital, Indore M.P.

Dr. Prem Prakash Dhurwey* Postgraduate Department Of ENT M.G.M. Medical College And M.Y.H. Hospital, Indore M.P. *Corresponding Author

ABSTRACT

Introduction: - This study highlights the multifaceted approach to managing allergic rhinitis, emphasizing the effectiveness of various topical treatments. Rhinitis, marked by nasal irritation and inflammation, manifests as nasal congestion, runny nose, sneezing, and post-nasal drip, often triggered by viruses, bacteria, irritants, or allergens. The study confirms that the combination of Xylometazoline, Fluticasone Furoate, and Azelastine is particularly effective in alleviating symptoms compared to single-agent therapies. Xylometazoline and oxymetazoline, as nasal decongestants, reduce mucosal edema through vasoconstriction, while topical nasal steroids like Fluticasone Furoate offer superior long-term relief by targeting the underlying inflammation. Azelastine, a second-generation antihistamine with additional anti-inflammatory and mast cell-stabilizing effects, demonstrates rapid and sustained symptom relief. **Methods:** - A Prospective comparative study was conducted on 120 patients who reported symptoms of allergic rhinitis were categorised randomly in 4 groups with equal members who were treated with different combinations of topical agents. **Results:** - The study shows that allergic rhinitis primarily presents with varied signs and symptoms. Among the treatment provided, the combination of Xylometazoline, Fluticasone Furoate, and Azelastine was the most effective, significantly reducing nasal discharge from 80% to 8.3% over two months. Xylometazoline and Fluticasone Furoate also provided substantial relief, while Azelastine was less effective on its own. **Conclusion:** -. The study evaluated various treatments, finding that the combination of Xylometazoline, Fluticasone Furoate, and Azelastine was the most effective in reducing nasal discharge and related symptoms. This combination therapy demonstrated superior results in alleviating symptoms and improving patient outcomes compared to single-agent treatments.

KEYWORDS

Allergic Rhinitis, Xylometazoline, Fluticasone, Azelastine.

INTRODUCTION

Rhinitis, often accompanied by coryza, refers to the irritation and inflammation of the nasal passages. Typical symptoms include a blocked and runny nose, frequent sneezing, and post-nasal drip. This inflammation can be triggered by viruses, bacteria, irritants, or allergens.[1]

The key pathological changes observed include nasal airway epithelial metaplasia, where goblet cells take the place of ciliated columnar epithelial cells in the nasal mucosa. This leads to an overproduction of mucus by the goblet cells and a reduction in mucociliary function. Consequently, nasal secretions are not effectively cleared, resulting in symptoms such as nasal congestion, sinus pressure, post-nasal drip, and headaches.[1]

Allergic diseases arise from a complex interaction of genetic and environmental factors. Over the last 30 to 40 years, high-income countries have experienced a surge in allergies, with nearly 25% of children now diagnosed with conditions such as allergic rhinitis, asthma, or eczema. The phase 3 International Study of Asthma and Allergy in Children (ISAAC) found that 7% of Indian children aged 6–7 years and 13–14 years' experience current wheeze, with some regions reporting prevalence rates as high as 10–20%.[2]

Allergic rhinitis (AR) is categorized into two types: seasonal and perennial. Seasonal Allergic Rhinitis (SAR) is triggered by exposure to pollen from trees, grass, weeds, or seasonal mold spores. On the other hand, Perennial Allergic Rhinitis (PR) is linked to environmental allergens that are present throughout the year, such as house dust, animal dander, and insect droppings. The "Allergic Rhinitis and its Impact on Asthma (ARIA) guidelines" offer an alternative classification, dividing allergic rhinitis into intermittent and persistent types based on the frequency and duration of symptoms. Symptoms of SAR often include nasal congestion, a runny nose, itching in the nasal and nasopharyngeal areas, ear discomfort, sneezing, and ocular symptoms such as itchy and watery eyes.[2]

Xylometazoline and oxymetazoline are imidazole derivatives with sympathomimetic properties. These medications target α-adrenergic receptors directly, and through their agonistic action on α1 and α2-adrenergic receptors located on the nasal mucosal endothelial cells, they help alleviate nasal congestion by decreasing mucosal edema. When used topically as nasal sprays, they induce vasoconstriction, which reduces congestion, exudate, and swelling in the nasopharyngeal mucosa, thereby relieving inflammation. This action enhances sinus drainage and makes nasal breathing easier. Other commonly used nasal sprays include phenylephrine and pseudoephedrine.[3]

For the maintenance treatment of allergic rhinitis, the most effective and well-tolerated option is topical nasal steroid sprays. Available formulations include beclomethasone, fluticasone furoate, fluticasone propionate, and mometasone. Intranasal glucocorticoids are classified into two generations: first-generation and second-generation. While both generations offer comparable efficacy, second-generation agents have the advantage of being less readily absorbed into the systemic circulation. This reduced absorption leads to a lower incidence of systemic side effects. First-generation agents, such as beclomethasone, triamcinolone, and budesonide, are older formulations, whereas the second-generation agents include fluticasone furoate, fluticasone propionate, and mometasone.[4]

Intranasal steroids are more effective than antihistamines for alleviating symptoms such as nasal congestion, rhinorrhea, nasal itching, and postnasal discharge. Generally, these steroids start to work within 1 to 2 hours of administration. They exert a comprehensive inhibitory effect on the nasal inflammatory pathway. This occurs as corticosteroids bind to intracellular steroid receptors on immune cells, leading to inhibition of inflammation. Upon binding, the receptor undergoes a conformational change and moves to the nucleus. Inside the nucleus, the receptor attaches to glucocorticoid response elements within anti-inflammatory DNA regions. This interaction triggers the transcription of mRNA, which codes for proteins that counteract the

inflammatory response. Concurrently, the bound steroid receptors inhibit the transcription of genes responsible for pro-inflammatory cytokines and chemokines.[5]

Azelastine nasal spray is a second-generation antihistamine applied topically, selectively targeting the H1-receptor and being about ten times more potent than chlorpheniramine. It has one of the quickest onsets of action among current rhinitis treatments, with effects beginning within 15 minutes when used as a nasal spray and as quickly as 3 minutes with eye drops. The effects of azelastine last for at least 12 hours, which supports a dosing regimen of once or twice daily.[6]

Azelastine offers more than just antihistamine activity; it has a rapid and long-lasting effect due to its triple mode of action, which includes anti-inflammatory and mast cell stabilizing properties. In addition to its anti-allergic effects, azelastine inhibits the activation of mast cells and the release of key inflammatory mediators such as interleukin (IL)-6, tryptase, and histamine. It also decreases levels of leukotrienes, which are involved in the late-phase allergic response, by reducing their production and inhibiting enzymes like phospholipase A2 and LTC4 synthase. Leukotrienes contribute to nasal congestion, mucus production, and the recruitment of inflammatory cells through their effects on vessel dilation, increased vascular permeability, and edema. Furthermore, azelastine lowers concentrations of substance P and bradykinin, which are formed during inflammation and contribute to the inflammatory process.[6][7][8]

Topical treatments offer several advantages over systemic treatments. Firstly, nasal sprays deliver medication directly to the site of allergic inflammation, which can enhance efficacy. Secondly, topical administration achieves higher concentrations of antihistamines in the nasal mucosa compared to oral administration, potentially increasing both anti-allergic and anti-inflammatory effects. Thirdly, a 0.28 mg dose administered intranasally provides a faster onset of action than a 2.2 mg oral dose. Finally, topical administration reduces the risk of drug interactions with other medications and minimizes the potential for systemic side effects.[9][10].

MATERIALS AND METHOD

A Prospective comparative study was conducted on 120 patients who reported in the Department of ENT from 01 March 2022 to 28 February 2024.

Inclusion Criteria:

1. Patients of age above 12 years who presented to the Department of ENT with symptoms suggestive of allergic rhinitis (like runny nose, nasal obstruction, itchy eyes, pharyngeal itch, otitis media with effusion, etc.).
2. Patients giving consent for Diagnostic Nasal Endoscopy were included.

Exclusion Criteria:

1. Patients who did not give consent for Diagnostic Nasal Endoscopy.
2. Patients having atrophic rhinitis, benign and malignant lesions of the nasal cavity.
3. Patients of developed Antrochoanal polyp.
4. Patients of mucormycosis operated for FESS before the study.
5. Patients with the immunocompromised state due to Chemotherapeutic drugs, cancer or HIV were excluded from this study.

- All the patients who presented to the Department of ENT with symptoms suggestive of allergic rhinitis (like runny nose, nasal obstruction, itchy eyes, pharyngeal itch, otitis media with effusion, etc.), were included in this study after a thorough history taking and clinical examination.
- All patients underwent Diagnostic Nasal Endoscopy to look for signs of allergic rhinitis.
- The patients were divided randomly in 4 groups.
- **Group A:** Treated with nasal drops Xylometazoline.
- **Group B:** Treated with nasal spray fluticasone furoate.
- **Group C:** Treated with nasal spray Azelastine.
- **Group D:** Treated with combination of Xylometazoline, fluticasone furoate and azelastine.

DISCUSSION

In this study there is a peak in the age group between 12 to 20 years followed by 21 to 30 years. From the study we can derive that the number of patients decreased with increasing age. This study shows that allergic rhinitis was overall most common in males as compared to females. In most of the age groups male predominance is seen.

Deviation of the nasal septum towards one of the cavities with the resultant decrease in space is one of the causes of nasal obstruction. In this study DNS right was seen in 62% of the patients and DNS left was seen in 44% of the patients. 14% patients had a central septum.

Allergic rhinitis is associated with watery nasal discharge, which was seen in 97% of the patients, 17% patients had mucoid discharge and only 6% had mucopurulent discharge. Allergic rhinitis is associated with inferior turbinate hypertrophy or it's Mulberry appearance which is seen in 82% of the patients.

On posterior rhinoscopy, the postnasal drip was seen in 6% of the patients. On early evaluation polypoidal changes in the mucosa of turbinates were found in 54% of the patients.

Watery nasal discharge is the most common presenting complaint with allergic rhinitis In Group A 83.3% of the patients presented with the complaint of nasal discharge. Out of these when the patients were treated with xylometazoline in appropriate dosage 40% of the patient's got relief from the symptoms in 3 weeks and at 2 months follow up only 32% patients had complaints of nasal discharge.

In Group B as treated with fluticasone furoate, initially 86.6% of the patients presented with complaints of nasal discharge and out of these 50% of the patients got relief of the symptoms in first three weeks and after two months follow up only 23% patients still had the complainer nasal discharge.

The patients in Group C who were treated with azelastine alone 80% of the patients presented with complaints of nasal discharge, 75% of them still had the complaint of nasal discharge at the end of three weeks and when followed up at 2 months 50% of the patients still had the complaint

The last group consisted of treatment with a combination of xylometazoline, fluticasone furoate and azelastine, this group showed the most prominent results at three weeks of follow up. Among the 80% of the patients who had the complaint initially only 33.3% still had the complaint, which further dropped down to 8.3% at the end of two months

In Group A the complaints of recurrent episodes of sneezing were found in only 38% of the patients presenting with the complaint while In Group B 20% of the patients had persisting complaint at the end of two months In Group C&D the problem load was 22% add 7% respectively at the end of two months.

The headache associated with the nasal complaints decreased to 46.1% 25% 53.3% and 0% In Group A, B, C&D respectively.

On diagnostic nasal endoscopic visualization for nasal discharge similar results were seen as in the clinical examination.

Polypoidal mucosal changes were seen in 43% of patients in Group A, 40% patients in Group B, 50% patients in Group C and 46.6% patients in Group D. When they were followed up at 3 weeks and two months respectively with the above-mentioned treatment Group A showed the decrease of the disease burden as 33.33% and 20% respectively. While the data for group B, C&D is 50% and 25% respectively for Group B, 66% and 33.3% for Group C, and 42% and 14% for Group D.

CONCLUSION

In this study, allergic rhinitis was most common among males and peaked in the 12 to 20-year age group, with a decrease in prevalence as age increased. Deviated nasal septum (DNS) was frequently observed, contributing to nasal obstruction. Watery nasal discharge was the primary symptom. The study evaluated various treatments, finding that the combination of Xylometazoline, Fluticasone Furoate, and Azelastine was the most effective in reducing nasal discharge and related symptoms. This combination therapy demonstrated superior results in alleviating symptoms and improving patient outcomes compared to single-agent treatments.

Tables

Table 1: Distribution Of Patients According To Age And Sex

AGE (YRS)	NO OF PATIENTS	MALE	FEMALE
12-20	58	36	22
21-30	32	25	7
31-40	16	4	12
41-50	8	5	3
>50	6	2	4
TOTAL	120	72	48

Table 2: Clinical Findinds

CLINICAL FINDINGS		FREQUENCY	PERCENTAGE
DNS	RIGHT	62	62
	LEFT	44	44
NASAL DISCHARGE	WATERY	97	97
	MUCOID	17	17
	MUCOPURULENT	6	6
INFERIOR TURBINATE HYPERTROPHY		82	82
POSTERIOR RHINOSCOPY-PND		6	6
POYLPOIDAL MUCOSAL CHANGES		54	54

Table 3: Comparison On The Basis Of Clinical Symptoms

CLINICAL FINDING	PRE TREATMENT PHASE				FOLLOW UP AT 3 WEEKS				FOLLOW UP AT 2 MONTHS			
	A	B	C	D	A	B	C	D	A	B	C	D
NASAL OBSTRUCTION	18	20	17	19	12	13	10	8	7	8	8	5
NASAL DISCHARGE	25	26	24	24	15	13	18	8	8	6	12	2
SNEEZING	26	24	27	26	18	13	16	12	10	5	6	2
HEADACHE	13	12	15	14	10	7	10	6	6	3	8	0
ITCHING IN EYES	18	20	17	19	12	13	10	8	7	8	8	5
FACIAL CONGESTION / FULLNESS	8	6	7	5	6	3	5	2	2	1	4	0
HYPOSMIA/ ANOSMIA	3	4	2	3	3	3	2	1	3	3	2	1
DISCOLOURED PND	2	1	1	2	1	0	1	0	0	0	1	0
AURAL FULLNESS	26	24	24	22	12	14	12	8	8	6	10	2
EAR DISCHARGE	4	3	4	5	2	2	3	2	0	0	2	0

Table 4: Endoscopic Findings:

ENDOSCOPIC FINDING	PRE TREATMENT PHASE				FOLLOW UP AT 3 WEEKS				FOLLOW UP AT 2 MONTHS			
	A	B	C	D	A	B	C	D	A	B	C	D
NASAL DISCHARGE	25	26	24	24	15	13	18	8	8	6	12	2
INFERIOR TURBINATE HYPERTROPHY	22	18	22	20	18	12	16	9	12	7	12	4
MUCOSAL OEDEMAA	26	24	24	22	12	14	12	8	8	6	10	2
POLYPOIDAL MUCOSAL CHANGES	13	12	15	14	10	6	10	6	6	3	5	2

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Informed consent is taken wherever necessary.

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