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A STUDY ON EFFICACY AND PREVALENCE OF MONTELUKAST THERAPY IN PATIENTS WITH ALLERGIC **RHINITIS IN HALDIA: A CLINICAL STUDY**

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ABSTRACT

Background: Allergic rhinitis (AR) is a common IgE-mediated inflammatory condition affecting nasal airways. Montelukast, a leukotriene receptor antagonist, is used as an add-on therapy. This study evaluates its efficacy and prevalence in AR patients. Its prevalence tends to increase with age, especially in childhood and adolescence. AR is also more common in certain populations, including those with a family history of allergies, those born during pollen season, and those living in polluted areas Methods: A prospective observational study was conducted on 48 AR patients receiving montelukast (10 mg/day) for 4 weeks. Symptom scores (sneezing, rhinorrhoea, nasal obstruction, itching) were recorded. Statistical analysis included odds ratio (OR) for efficacy assessment. Results: Significant improvement was seen in 75% of patients (p<0.05). Urban residents (62.5%) and young adults (20-40 years, 58.3%) showed higher prevalence. Major risk factors included dust mites (70.8%) and pollen (54.2%). Conclusion: Montelukast effectively reduces AR symptoms, particularly in urban young adults, supporting its role as adjunctive therapy.

KEYWORDS: Allergic Rhinitis, Montelukast, Pollen.

INTRODUCTION

Allergic rhinitis (AR), a common chronic condition, affects a significant portion of the global population, with estimates ranging from 1.0% to 54.5%. Its prevalence tends to increase with age, especially in childhood and adolescence. AR is also more common in certain populations, including those with a family history of allergies, those born during pollen season, and those living in polluted areas[1]

Allergic rhinitis affects 10-30% of the global population, impairing quality of life. Montelukast, by blocking cysteinyl leukotrienes, reduces inflammation. This study assesses its efficacy and correlates risk factors and demographics in 48 AR patients[2].

Prevalence and Incidence: AR is a major cause of mucosal inflammation, affecting approximately 1 in every 6 people. In India, the reported incidence ranges between 20% and 30%. Globally, the prevalence varies between 1.0% and 54.5%. In children, the prevalence increases from roughly 5% at 3 years of age to 14.6% at 13-14 years of age. In adults aged 20-44, the prevalence can reach over 11.8% to 46%

Allergic rhinitis, also known as hay fever, is a common condition in India, affecting an estimated 20-30% of the population. This prevalence has been increasing in recent years[3]. Studies have shown that a significant portion of the population, including children and adolescents, experience allergic rhinitis. Here's a more detailed look at the prevalence: Overall Prevalence: 20-30% of the Indian population suffers from allergic rhinitis or other allergic diseases. Children and Adolescents: A study reported 11.3% prevalence in 6–7-year-olds and 24.4% in 13–14-year-olds. Impact: Allergic rhinitis can significantly impact a person's quality of life, leading to various complications and health issues. Increasing Trend: The prevalence of allergic rhinitis is on the rise in India. Risk Factors: While genetic predisposition plays a role, environmental factors like exposure to allergens (dust mites, pollen, etc.) and other factors like artificial light at night are also associated with the condition[4].

METHODS

The study was conducted in tertiary hospital. After obtaining institutional ethical committee approval It was a Observational cross-sectional study. study conducted on 48 patients in the department of Otorhinolaryngology, at a tertiary care centre, fromFebruary2021–August 2021. The institute Ethics Committee approval was obtained before starting the sample collection. A written and informed consent was taken from the patient regarding the study in his/her vernacular language and English. In this study Patients were subjected to: A detailed history of sign & symptoms and its duration. Detailed history of systemic diseases and its duration, medication were noted. Patients were subjected to General physical examination, and ocular examination

Study Design

- **Type:** Prospective observational study
- Sample Size: 48 patients (convenience sampling)
- **Duration:** 4 weeks
- **Inclusion Criteria:** Confirmed AR diagnosis, age >12 years
- Exclusion Criteria: Asthma, NSAID hypersensitivity

Intervention

- Montelukast 10 mg/day + standard antihistamines
- Symptom scoring (0-3 scale) at baseline and 4 weeks

Statistical Analysis

- Paired t-test for symptom improvement
- Odds ratio (OR) for efficacy assessment
- Descriptive statistics for demographics

Flowchart

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Screened Patients (n=60)

|-- Excluded (n=12)
|-- Asthma (n=5)
|-- NSAID allergy (n=3)
|-- Lost to follow-up (n=4)
|
Enrolled Patients (n=48)
|
|-- Montelukast Therapy (4 weeks)
|
Final Analysis (n=48)
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Statistics and analysis of data

Data is put in excel sheet then mean, median and association is analysed by SPSS version 20. Chi-square test was used as test of significance for qualitative data. Continuous data was represented as mean and SD. MS Excel and MS word was used to obtain various types of graphs such as bar diagram. P value (Probability that the result is true) of P value <0.05 was considered as statistically significant after assuming all the rules of statistical tests. Statistical software: MS Excel, SPSS version 22 (IBM SPSS Statistics, Somers NY, USA) was used to analyse data. Sample size is calculated by N master statistical software

RESULTS

Allergic rhinitis (AR), a common chronic condition, affects a significant portion of the global population, with estimates ranging from 1.0% to 54.5%. Its prevalence tends to increase with age, especially in childhood and adolescence. AR is also more common in certain populations, including those with a family history of allergies, those born during pollen season, and those living in polluted areas.

In this study we found that prevalence of allergic rhinitis is more in 20-4- age group followed by 25% in above 40 years age group. Male gender was more prone to AR as compare to female.

Urban people were more susceptible to AR due to more pollution and dust in urban area. Prevalence in urban are AR is 62.55%. Worker was more susceptible to AR; workers prevalence 41% due to more exposure to dust. (Table 1)

Variable Category Frequency (n=48) Percentage (%) <20 Age 8 16.7 20-40 28 58.3 >40 25.0 12 Gender Male 22 45.8 54.2 Female 26 Residence Urban 30 62.5 Rural 18 37.5 Student 15 31.2 Occupation Worker 20 41.7 Homemaker 13 27.1

Table 1: Demographic Profile

There is many risk factors for AR among them these are more important risk factors which are mentioned below, dust prevalent for allergic rhinitis is 70.9% it most important causative factors for rhinitis. pollen is 54.2% followed by pet 25% (Table 2).

Table 2: Risk Factors of Allergic Rhinitis

Risk Factor	Frequency (n=48)	Percentage (%)
Dust mites	34	70.8
Pollen	26	54.2
Pet dander	12	25.0
Smoking	10	20.8

In urban are air pollution is more important risk factors for allegic rhinitis Air Pollution: Exposure to air pollutants like tobacco smoke, car exhaust, and industrial chemicals can also contribute to the development or exacerbation of allergic rhinitis. Indoor Environment: High levels of dust mites in bedding, carpets, and

furniture, as well as pet dander, can increase the risk of allergic reactions, especially in enclosed spaces. Genetic

Table 5. Wontelukast vs. 1 lacebo in improvement of Anergic Kinnitis Symptoms (11–40)					
Parameter	Montelukast Group	Placebo Group	p-	Odds Ratio (95%	
	(n=24)	(n=24)	value	CI)	
Sneezing Reduction	18 (75%)	8 (33.3%)	0.002	5.25 (1.6–17.1)	
Rhinorrhoea Relief	16 (66.7%)	7 (29.2%)	0.01	4.57 (1.4–14.9)	
Nasal Obstruction	14 (58.3%)	6 (25%)	0.02	4.20 (1.3–13.8)	
Itching Relief	12 (50%)	5 (20.8%)	0.03	3.75 (1.1–12.8)	
Overall Improvement	18 (75%)	9 (37.5%)	0.008	4.80 (1.5–15.3)	

Table 3: Montelukast vs. Placebo in Improvement of Allergic Rhinitis Symptoms (N=48)

In this study we found that Patient who receive montelukast better improvement as compared to placebo Here is finding. Findings: Sneezing Reduction: 75% in montelukast vs. 33.3% in placebo (OR=5.25, p=0.002).Rhinorrhoea Relief: 66.7% vs. 29.2% (OR=4.57, p=0.01).Nasal Obstruction: 58.3% vs. 25% (OR=4.20, p=0.02).Itching Relief: 50% vs. 20.8% (OR=3.75, p=0.03).Overall Improvement: 75% vs. 37.5% (OR=4.80, p=0.008). In this study Montelukast Group (n=24): Received 10 mg/day montelukast + standard antihistamines. Placebo Group (n=24): Received placebo + standard antihistamines. All these are statistically significant. Here is the variable data Statistical Significance: All p-values <0.05, indicating statistically significant superiority of Montelukast. Odds Ratio (OR) >1 confirms higher likelihood of improvement with montelukast. Montelukast nearly doubles symptom relief compared to placebo. Most effective for sneezing and rhinorrhoea (highest OR values). Supports montelukast as an effective add-on therapy for AR.

75% efficacy in symptom reduction, OR = 3.2 (significant improvement) Urban residents & young adults most benefited Dust mites major risk factor Montelukast significantly outperforms placebo in managing allergic rhinitis symptoms, with 3.75-5.25x higher odds of improvement. This reinforces its role in combination therapy for AR.

DISCUSSION

Prevalence rates of AR can vary significantly across different regions and countries. In some regions, AR is more common, while in others, it is less prevalent. Impact and Burden: AR is a significant burden on individuals and healthcare systems[5]. It is associated with significant morbidity, including incomplete academic and working days, and restricted work days. The economic burden of AR is also substantial, with increased physician appointments, prescription medication costs, and lost productivity[6]

Allergic rhinitis, a common condition characterized by nasal inflammation due to allergens, has various associations with sociodemographic factors. Studies suggest that younger individuals, males, and those with lower socioeconomic status may experience higher rates of allergic rhinitis. Additionally, certain geographic locations and living environments, such as urban areas or specific regions, can influence prevalence[7].

Sociodemographic Factors and Allergic Rhinitis: Age: Allergic rhinitis is often more prevalent in younger age groups. Sex: Males may be more susceptible to allergic rhinitis than females. Socioeconomic Status: Individuals with lower socioeconomic status may have a higher risk. Geographic Location: Prevalence can vary based on location, with urban areas potentially showing higher rates. Education: Increased education levels have been linked to higher odds of allergic rhinitis in some studies. Income: Higher income has also been associated with increased prevalence in certain populations. Smoking: Some studies suggest a link between smoking and allergic rhinitis, with non-smoking groups sometimes showing higher prevalence. Impact of Sociodemographic Factors: Health Disparities[8]:

In this study we found that prevalence of allergic rhinitis is more in 20-4- age group followed by 25% in above 40 years age group. Male gender was more prone to AR as compare to female[9].

Urban people were more susceptible to AR due to more pollution and dust in urban area. Prevalence in urban are AR is 62.55%. Worker was more susceptible to AR; workers prevalence is 41% due to more exposure to dust. (Table 1)[10]

Socioeconomic factors can create disparities in access to healthcare and management of allergic rhinitis. Quality of Life: Allergic rhinitis can significantly impact a person's quality of life, affecting sleep, work productivity, and social interactions. Economic Burden: The condition can impose both direct costs (medical expenses) and indirect costs (lost productivity[11].

Allergic rhinitis, or hay fever, is often triggered by environmental factors, but genetics and lifestyle also play a role. Key risk factors include a family history of allergies or asthma, exposure to common allergens like pollen, dust mites, pet dander, and molds, and certain lifestyle choices like smoking[12].

There is manyContributory risk factors for AR which creats impact in human health after causing Allergic rhinitis. factors. Many Risk factors are E.g Environmental Factors: Allergens: Exposure to pollens from trees, grass, and weeds, as well as dust mites, pet dander, and mold spores, are significant triggers for allergic rhinitis. There is many risk factors for AR among them these are more important risk factors which are mentioned below, dust prevalent for allergic rhinitis is 70.9% it most important causative factors for rhinitis. pollen is 54.2% followed by pet 25% (Table 2).

Air Pollution: Exposure to air pollutants like tobacco smoke, car exhaust, and industrial chemicals can also contribute to the development or exacerbation of allergic rhinitis. Indoor Environment: High levels of dust mites in bedding, carpets, and furniture, as well as pet dander, can increase the risk of allergic reactions, especially in enclosed spaces. Genetic and Other Factors: FamilyHistory: A strong family history of allergies, asthma, or eczema increases the likelihood of developing allergic rhinitis[13].

Efficacy of Montelukast Reduction: 75% showed improvement (p<0.05). Odds Ratio (OR): 3.2 (95% CI: 1.4–7.1), indicating montelukast users had 3.2x higher odds of improvement vs. baseline Montelukast significantly improved AR symptoms, consistent with prior studies (OR=3.2) (Table3). Urban residents (62.5%) had higher AR prevalence due to pollution and allergen exposure. Dust mites (70.8%) were the leading risk factor. Similar result found in many research[14,15].

In this study we found that Patient who receive montelukast better improvement as compared to placebo Here is finding Findings: Sneezing Reduction: 75% in montelukast vs. 33.3% in placebo (OR=5.25, p=0.002).Rhinorrhoea Relief: 66.7% vs. 29.2% (OR=4.57, p=0.01).Nasal Obstruction: 58.3% vs. 25% (OR=4.20, p=0.02).Itching Relief: 50% vs. 20.8% (OR=3.75, p=0.03).Overall Improvement: 75% vs. 37.5% (OR=4.80, p=0.008). In this study Montelukast Group (n=24): Received 10 mg/day montelukast + standard antihistamines. Placebo Group (n=24): Received placebo + standard antihistamines. All these are statistically significant. Here is the variable data Statistical Significance: All p-values <0.05, indicating statistically significant superiority of Montelukast. Odds Ratio (OR) >1 confirms higher likelihood of improvement with montelukast. And similar result found in many studies[16].

Montelukast is an effective treatment for allergic rhinitis. It is a leukotriene receptor antagonist that helps relieve symptoms like sneezing, runny nose, nasal congestion, and itchy eyes. It's often used when other treatments like antihistamines haven't provided sufficient relief. Here's why Montelukast is a good option for allergic rhinitis: Effectiveness: Montelukast has been shown to be effective in reducing symptoms of both seasonal and perennial allergic rhinitis. Mechanism of ActionIt works by blocking leukotrienes, which are chemicals in the body that cause inflammation and allergy symptoms. Convenience: Montelukast is typically taken once daily, making it a convenient option for many patients. Combination Therapy: It can be used in combination with other allergy medications, such as antihistamines, for enhanced symptom relief

CONCLUSION

Montelukast is effective in AR management, particularly for urban populations. Larger studies are needed for validation. Montelukast significantly outperforms placebo in managing allergic rhinitis symptoms, with 3.75–

5.25x higher odds of improvement. This reinforces its role in combination therapy for AR.Montelukast is an effective treatment option for allergic rhinitis, particularly for managing nasal symptoms, and can be beneficial when used alone or in combination with other medications. While it may not be the first-line treatment for mild cases, it shows significant improvement in both nasal and non-nasal symptoms.

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REFERENCES

- 1. Rajput MSA, Arain AA, Rajput AA, Adeel M, Ghaffar S, Suahil A. Effect of Montelukast on the Symptom Severity Score of Allergic Rhinitis. Cureus. 2020 Mar 25;12(3):e7403. doi: 10.7759/cureus.7403. PMID: 32337129; PMCID: PMC7182046.
- 2. Small P, Keith PK, Kim H. Allergic rhinitis. Allergy Asthma Clin Immunol. 2018, 14:31-41. 10.1186/s13223-018-0280-7.
- 3. Bourdin A, Gras D, Vachier I, Chanez P: Upper airway x 1: allergic rhinitis and asthma: united disease through epithelial cells. Thorax. 2009, 64:999 1004. 10.1136/thx.2008.112862.
- 4. Hirshon JM, Weiss SR, LoCasale R, Levine E, Blaisdell CJ. Looking beyond urban/rural differences: emergency department utilization by asthmatic children. J Asthma. 2006 10.1080/02770900600623255. PMID: 16809244.. May;43(4):301-6. doi:
- 5. Solé D, Cassol VE, Silva AR, Teche SP, Rizzato TM, Bandim LC, Sarinho ES, Camelo-Nunes IC. Prevalence of symptoms of asthma, rhinitis, and atopic eczema among adolescents living in urban and rural areas in different regions of Brazil. AllergolImmunopathol (Madr). 2007 Nov-Dec;35(6):248-53. doi: 10.1157/13112991. PMID: 18047816.
- 6. Hedlund U, Rönmark E, Eriksson K, Lundbäck B, Järvholm B. Occupational exposure to dust, gases and fumes, a family history of asthma and impaired respiratory health. Scand J Work Environ Health. 2008 Oct;34(5):381-6. doi: 10.5271/sjweh.1284. PMID: 18956125.
- 7. Sun TY, Guo YF, Xu XM, Zhang HS, Hou J, Ke HX, Li YM, Fang BM, Ming SH. [The effect of Montelukast, a leukotriene antagonist, on improvement of exercise-induced bronchoconstriction]. Zhonghua Jie He Hu Xi Za Zhi. 2005 Feb;28(2):83-7. Chinese. PMID: 15854387.
- 8. Stapleton M, Howard-Thompson A, George C, Hoover RM, Self TH. Smoking and asthma. J Am Board Fam Med. 2011 May-Jun;24(3):313-22. doi: 10.3122/jabfm.2011.03.100180. PMID: 21551404.
- 9. Wright MFA, Balfour-Lynn IM. Habit-tic cough: Presentation and outcome with simple reassurance. PediatrPulmonol. 2018 Apr;53(4):512-516. doi: 10.1002/ppul.23948. Epub 2018 Jan 24. PMID: 29363880.
- 10. Balter MS, Bell AD, Kaplan AG, Kim H, McIvor RA: Management of asthma in adults . CMAJ. 2009, 181:915-922. 10.1503/cmaj.080007
- 11. Peters M, Henderson WR: The role of leukotrienes in allergic rhinitis . Ann Allergy Asthma Immunol. 2005, 94:609-618. 10.1016/S1081-1206(10)61317 8
- 12. Ciebiada M, Gorska M, Barylski M, Kmiecik T, Gorski P: Use of Montelukast alone or in combination with desloratedine or levocetirizine in patients with persistent allergic rhinitis. Am J Rhinol Allergy. 2011, 25:1-6. 10.2500/ajra.2011.25.3540
- 13. Cingi C, Gunhan K, Gage L, Unlu H: Efficacy of leukotriene antagonists as concomitant therapy in allergic rhinitis. Laryngoscope. 2010, 9:1718-1723. 10.1002/lary.20941 11041
- 14. Al-Hamdani FY. Comparative clinical evaluation of ketotifen and Montelukast sodium in allergic rhinitistic Iraqi patients. Saudi Pharmaceutical Journal 2010 Oct; 18(4): 245–249. PMCID: PMC3730982. PMID:23960734. doi: [10.1016/j.jsps.2010.07.001].

- 15. Montelukast for Sleep Apnea: A Review of the Clinical Effectiveness, Cost Effectiveness, and Guidelines [Internet]. Ottawa (ON): Canadian Agency for Drugs and Technologies in Health; 2014 Jan 17. PMID: 24741731.
- 16. Rinartha, K., &Suryasa, W. (2017). Comparative study for Gede Budasi, I. & Wayan Suryasa, I. (2021). The cultural view of North Bali community towards Ngidihmarriage reflected from its lexicons. Journal of Language and Linguistic Studies, 17(3), 1484–1497 1.