

Advances in
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Advances in **Otorhinolaryngology** **Indian Clinical Perspective**

KEY HIGHLIGHTS

- Chronic rhinosinusitis is characterized by mucosal inflammation of the nose and paranasal sinuses. The management includes the following: Avoidance of allergen; symptomatic treatment; treatment of the cause and maintenance therapy
- A combination of montelukast + fexofenadine is useful to control allergy and the symptoms of nasal congestion by decreasing edema and improving the drainage through the sinus ostia
- Allergic rhinitis has a contributory role in asthma; it has a pathogenic role and also exacerbates the symptoms of asthma
- Combined administration of montelukast and fexofenadine seems promising for the management of allergic rhinitis and asthma

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CASE REVIEW

A case of acute exacerbation of chronic sinusitis complicated with polypoidal changes in the nasal and sinus mucosa



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CASE PRESENTATION

- A 25-year-old male reported to the ENT clinic with chronic sinusitis which was diagnosed around 15 years back. The diagnosis of chronic sinusitis was established after nasal endoscopy and CT scan of nose and paranasal sinuses
- Since then the patient has been experiencing facial discomfort, headache (frontal), nasal obstruction/blockage, nasal discharge, post-nasal drip and dental pain from time to time
- The patient was a smoker, had irregular food habits and was allergic to pollen
- There was no similar family history.

At present, the patient visited an ENT doctor due to severe headache, nasal blockage and high grade fever since 3 days. The patient also stated that the previous symptoms have increased in severity and frequency.

EXAMINATION

General examination

- The patient was conscious, well-oriented but looked ill
- Pallor, icterus, cyanosis and edema were absent
- Temperature was 102°F
- Blood pressure was normal, pulse rate was 90/min
- Respiratory rate was normal.

Local examination

- Nose and paranasal sinuses: On palpation, there was tenderness over the frontal and maxillary sinuses. Anterior rhinoscopy with a nasal speculum showed congested and edematous nasal mucosa with purulent discharge. Polypoidal changes of the sinus (maxillary, right>left) and mucosa were also noted. There was deviated nasal

- septum (DNS) towards the right with hypertrophied inferior turbinate on the left side of the nasal cavity
- Oral cavity, larynx and pharynx: Post-nasal drip was present. Vocal cords were congested and edematous
 - Ear: External ear and tympanic membrane was normal (on both sides)
 - Nasal endoscopy showed purulent secretions within the middle meatus of left nasal cavity. It also ruled out the presence of any mass in the nasopharynx
 - Examination of central nervous system, respiratory system, cardiovascular system, gastrointestinal system was normal.

INVESTIGATIONS

- Complete blood count
 - White blood cell count: 11,500 per microliter
 - Erythrocyte sedimentation rate: 19 mm per hour
 - Random blood sugar: 90 mg/dl
 - Eosinophils: 9%
- Radiography of sinuses: X-ray of the sinuses showed opacity over the frontal and maxillary sinuses. For a detailed study, CT scan (nose and paranasal sinuses) was done. It showed gross mucosal thickening and haziness of the maxillary (right>left) and frontal sinuses with air fluid level on the right maxillary sinuses. Mild polypoidal changes of nasal and sinus (maxillary, right>left) mucosa were noted. Posterior part of the nasal septum was grossly deviated towards the right
- Chest radiography was normal
- Nasal and sinus cultures were positive for *Staphylococcus aureus*, *Streptococcus pneumoniae* and *Haemophilus influenzae***
- Allergy skin test showed moderate sensitivity for pollen.**

DIAGNOSIS

Acute exacerbation of chronic sinusitis with polypoidal changes of nasal and sinus (maxillary, right>left) mucosa.

MANAGEMENT

- The patient was immediately prescribed anti-pyretic tablets (paracetamol, 6 hourly after food) along with oral antibiotics (amoxicillin + clavulanic acid) 625 mg thrice daily for 5 days. The anti-pyretic resolved his headache too**
- To combat the symptoms of allergy and nasal congestion, a combination of montelukast + fexofenadine was prescribed once-daily for 21**

days. This combination was chosen to avoid the sedative effects of other anti-histaminics as the patient was a working professional and required to be alert and performing at work

- Topical nasal decongestant was also added, 2 drops, both nostrils, 8 hourly for 7 days
- The patient was on intranasal corticosteroid spray from time to time. But for the last two months, he was not taking any spray/medicine. He was restarted with intranasal corticosteroid spray containing fluticasone furoate, 1 puff both nostrils, twice-daily for 2 weeks. Oral corticosteroids (deflazacort) was also added to control the severity of the symptoms. Deflazacort, 6 mg was prescribed for a duration of 21 days. Dosages were: 6 hourly for the 1st seven days, 8 hourly for the next 7 days, 12 hourly for the next four days and then once-daily for the last 3 days. Before starting oral corticosteroid, his RBS was checked and found to be normal
- Proton pump inhibitors (PPIs) were also added, once-daily before breakfast for 21 days. This was given as the patient had a history of gastritis and also to reduce the side-effects of oral corticosteroids
- The patient's fever subsided after 3 days of antibiotic therapy. Anti-pyretics were discontinued after this. Significant improvement in nasal symptoms occurred after 5-6 days of montelukast and fexofenadine decongestants and steroid (fluticasone) spray. However, he was advised to complete the total dosage/duration of the prescribed medicines. The pain in the right ear also decreased significantly after 5-6 days
- On follow up after 2 weeks, the patient's symptoms were significantly reduced. The polypoidal changes in the nasal and sinus mucosa resolved. There was only mild tenderness over the maxillary sinus (right>left)
- The patient was advised to continue the nasal corticosteroid spray for 3 months. He was also advised to avoid certain allergens and to do regular follow ups. Moreover, the patient was also told about the need for surgical correction of DNS (right) which was obstructing the drainage of sinuses on the right side thereby further contributing to sinusitis.

DISCUSSION

Chronic sinusitis/rhinosinusitis: The unrecognized epidemic

Chronic rhinosinusitis (CRS) is the most common disease for which an ENT consultation is sought for.¹ CRS is characterized by mucosal inflammation of the nose and paranasal sinuses. The clinical manifestations are nasal congestion, nasal discharge, fatigue, headache, hyposmia/anosmia and facial pain.² CRS affects a significant

proportion of population with a negative impact on their daily lives. This necessitates early diagnoses and proper treatment of CRS.³ Moreover, CRS also involves significant expenditure of medical resources and global economic costs.⁴ Studies have shown a growing prevalence of CRS in the recent years and there is a significant variation in incidence of CRS depending on the geographical variation.⁵ In USA, CRS incurs 11.1 million healthcare visits, 250,000 sinus surgeries, 7.1% of all adult outpatient antibiotic prescriptions and an estimated \$8.6 billion in direct healthcare costs thereby placing CRS among the top 10 most costly conditions to U.S. employers. Further, taking indirect costs into consideration such as workdays missed, increased antibiotic resistance or antibiotic-related complications, the true costs associated with CRS may be significantly higher.⁶ In Europe and Korea, the prevalence rates were 10.9% and 7%, respectively.⁶ In India, an estimated population of 134 million suffer from chronic sinusitis.⁷

Risk factors like gastroesophageal reflux disorder (GERD) and smoking have significant role in the chronicity of symptoms. Various anatomical variations are also responsible for CRS of which DNS is the most common variation followed by concha bullosa (unilateral) and paradoxically bent middle turbinate.¹ There is also a possible association between aeroallergens and CRS. More than 50% of individuals with allergic rhinitis (AR) have clinical/radiographic evidence of CRS and 25–58% of individuals with sinusitis have sensitivity to aeroallergen. Elevated total IgE is a risk factor for the presence of severe CS/CRS.⁸

Acute exacerbation of chronic sinusitis

Acute exacerbation of chronic sinusitis (AECS) represents a sudden worsening of baseline chronic sinusitis with either worsening of or appearance of new symptoms. These acute (not chronic) symptoms usually resolve completely between the occurrences. Although triggers leading to acute exacerbations of CRS are not well characterized. Several hypotheses have been postulated suggesting a potential relationship between CRS disease activity and infection, air quality, air temperature, air humidity or indoor allergen/irritant exposure.⁹ Acute exacerbations of CRS are most likely due to infectious exacerbations secondary to viral infections. Although a causal relationship has yet to be established between bacterial infection and CRS, some studies strongly implicate bacterial infection. Usually, bacteria for acute rhinosinusitis are *Streptococcus pneumoniae*, *Haemophilus influenzae* and *Moraxella catarrhalis*. As the patient transitions to the chronic phase, a mixed bacterial infection involving aerobic and anaerobic agents such

as *Prevotella*, *Fusobacterium* and *Peptostreptococcus* species are encountered. But organisms involved in AECS are those of acute sinusitis. In CRS, the flora of the paranasal sinuses seems to be altered, with a higher prevalence of *Staphylococcus* species and anaerobes. This flora is often polymicrobial and may exhibit significant antibiotic resistance.¹⁰ AECS are more common during winter season as compared to the other seasons.⁹

Chronic sinusitis, especially due to nasal allergy might lead to disturbed function of the eustachian tube and impair the communication of the middle ear with the nasopharynx, nasal cavity, and indirectly with paranasal sinuses. This facilitates the development of serous otitis media (SOM) manifesting as decreased hearing, reduced elasticity of the tympanic membrane and/or pain.¹¹ Proper and timely management of SOM is very crucial to prevent further complications such as hearing loss or tympanic membrane rupture.

MANAGEMENT

The management in AECS include the following:

- Avoidance of allergen
- Symptomatic treatment
- Treatment of the cause
- Maintenance therapy

In the present case, since the patient had a history of allergy, he was advised to take certain precautions to avoid the concerned allergen. **Firstly, he was prescribed anti-pyretics to control the fever. Then a combination of oral decongestant + anti-histaminic (montelukast + fexofenadine) to control allergy and the symptoms of nasal congestion by decreasing edema and improving the drainage through the sinus ostia. Since the effect of nasal decongestion following oral decongestant starts within 30 min (and persists for up to 6 h), he was prescribed topical decongestant too for immediate relief.**¹² Empiric antibiotic therapy should be prescribed only in cases of acute exacerbation of chronic sinusitis and the antibiotics prescribed should aim the usual bacteria causing acute sinusitis. In case of therapy failure, antibiotics should be changed having in mind that under certain circumstances any bacteria colonizing sinus mucosa can cause acute exacerbation of chronic sinusitis.¹³ Intranasal corticosteroid spray, used as an adjunctive treatment with an oral antibiotic, has shown to be significantly more effective in reducing the symptoms of AECS than antibiotic treatment alone.¹² Oral antibiotics are the most commonly prescribed medication for AECS and remain the mainstay of treatment. The increasing prevalence of *Staphylococcus aureus* and antimicrobial resistance in CRS highlights the importance of using culture-directed antimicrobial therapy with the

goal of minimizing future resistance patterns. Severe inflammation and edema of the nasal and sinus mucosa might necessitate the need of oral corticosteroids. A course of oral corticosteroids has shown statistically significant improvement over placebo in symptoms and quality of life outcome measures.¹⁴

Gastritis/GERD has shown to exacerbate chronic sinusitis. Anti-reflux therapy (PPI) has shown improvements in sinus symptoms with corresponding improvements in reflux symptoms.¹⁵

Intranasal corticosteroid spray should be continued for a considerable duration. It usually takes a few days for the full effects of steroid sprays to be felt. Relieving symptoms for good usually means that medication needs to be taken for several months or even over a year. Nasal steroid sprays have far fewer side effects than oral steroids taken in tablet form or as an infusion. Because steroids in tablets are carried throughout the entire body, whereas topical agents like nasal sprays mainly affect only the area they are applied to.¹⁶

TO SUMMARIZE....

Chronic rhinosinusitis is a common health problem which significantly affects the quality of life. Acute exacerbations (AECS) are due to a multiple of causes but secondary bacterial infection appears to be the commonest. The management of AECS should be based not only on infection control but also on controlling the precipitating/aggravating factors. This should be followed by a maintenance therapy for a considerable duration of time. The comprehensive management strategy should be targeted to provide symptomatic control as well as to reduce the burden of the disease.

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DIAGNOSIS CORNER

Diagnosis of empty nose syndrome

Empty nose syndrome (ENS) represents a rare, late, iatrogenic complication of turbinate surgical procedure. It is usually debilitating and has substantial negative impact on the quality of life of patients. The diagnosis is often based on clinical, subjective and objective findings.^{1,2}

The identification of presenting symptomatology is critical for diagnosis. The presenting symptoms include paradoxical nasal obstruction, nasal dryness and crusting, and a persistent feeling of dyspnea, sensation of suffocation, and empty nose. Patients may also exhibit loss of concentration (nasal aprosexia), fatigue, anxiety, irritability or depression. In addition, physical examination is used to identify permeable nasal cavities enlarged by previous surgery, with turbinal structures missing or greatly reduced. The nasal mucosa is generally dry, pale and crusted. Cotton test is a simple pre-therapeutic diagnostic test used to identify ENS. For the test, a moist cotton piece is placed for 20 to 30 minutes, in the nasal cavity at proposed position of implant placement. Improvement in symptoms confirm diagnosis and need for repair surgery. Additionally, imaging is useful in detecting various non-pathognomonic signs that are not identified clinically. In this context, sinus computed tomography may show rhinosinus mucosal thickening and maxillary opacity in more than 50% of cases. **Rhinomanometry and Peak Nasal Inspiratory Flow (PNIF) corroborates with the absence of any obstacle, demonstrating normal or weak nasal resistance.**³

Medical management subsequent to diagnosis usually involves mucosal humidification, irrigations, and application of emollients. In addition, surgical therapy such as turbinate reconstruction should be reserved for non-responsive cases.¹

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FDA NEWS RELEASE

Fluoroquinolones safety labelling update: Serious side-effects outweigh benefits in respiratory infections

Recently, the Food and Drug Administration (FDA) approved the suggested labelling changes concerned with safety of fluoroquinolones. Fluoroquinolones are antibacterial agents used for management of infections.

The current changes propose revision of Boxed Warning, suggesting that serious adverse effects associated with use of fluoroquinolones may outweigh the benefits in patients with acute bacterial sinusitis, acute bacterial exacerbation of chronic bronchitis and uncomplicated urinary tract infections. It was further commented that whenever possible, fluoroquinolones should be reserved for patients with these conditions who do not have any alternative treatment options.



The use of oral and systemic fluoroquinolones may have an adverse effect on the tendons, muscles, joints, nerves and central nervous system. Therefore, FDA required and permitted labelling changes associated with use of this antibacterial agent.

Source: FDA approves safety labeling changes for fluoroquinolones. Available at: <http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm500325.htm>. Accessed on: 5.8.2016.



Comorbid allergic rhinitis and asthma: Rationale for administration of montelukast and fexofenadine

ALLERGIC RHINITIS AND ASTHMA

Allergic rhinitis presents as a spectrum of disorders, profoundly associated with comorbidities such as asthma, chronic middle ear effusion, sinusitis, sleep disorders, lymphoid hypertrophy with obstructive sleep apnea, and related behavioral and educational effects. In addition, it may adversely impact the overall health and quality of life of an affected individual. The co-existence of allergic rhinitis and asthma often presents as an intricate situation. It has a diagnostic implication; the diagnosis of asthma may be confused by symptoms of cough caused by allergic rhinitis and post-nasal drip. Nonetheless, allergic rhinitis and asthma are associated with each other.¹

COMMON LINKS IN PATHOMECHANISMS OF ALLERGIC RHINITIS AND ASTHMA

Allergic rhinitis has a contributory role in asthma; it has a pathogenic role and also exacerbates the symptoms of asthma.¹ Allergic rhinitis is an inflammatory condition of nasal mucosa that ensues immunoglobulin E mediated early phase and late phase hypersensitivity responses, mostly to the inhaled allergens, akin to the process in allergic asthma. Allergic rhinitis typically occurs before the development of asthma in adolescence or adult life. Bronchial hyperresponsiveness, elevated exhaled nitric oxide and reduced lung function have been observed in patients with allergic rhinitis.² Interestingly, inflammation has an important role in increasing the bronchial hyperresponsiveness to allergic stimuli.³

RATIONALE FOR CO-ADMINISTRATION OF MONTELUKAST AND FEXOFENADINE

Therapeutic strategies for rhinitis may influence asthma control in patients. Moreover, therapeutic regimen for rhinitis has a direct impact on lower airway inflammation.⁴ The therapy primarily acts on the inflammatory cascade by blocking the action of chemical mediators in response to allergic stimuli. Histamines are established mediators for development of allergic rhinitis, and antihistamines have shown efficacy in alleviating symptoms of this disorder. In addition, leukotrienes released in response to allergens have fundamental role in developing the symptoms of allergic rhinitis. High concentrations of leukotrienes have been observed in nasal secretion of patients with allergic rhinitis, that may explain symptomatic relief in asthma and allergic rhinitis on administration of antileukotrienes.⁵

Montelukast

Montelukast is a leukotriene receptor antagonist that exerts its actions majorly through antagonism of cysteinyl leukotrienes mediated bronchoconstriction, recruitment and activation of inflammatory cells. Besides this, cysteinyl-leukotrienes also stimulate mucus production, and mucosal edema. Montelukast enhances vascular permeability and reduces bronchial hyper-reactivity. Montelukast is effective in treatment of allergic airway inflammation in patients with allergic rhinitis without asthma, and in patients with comorbid asthma.⁶

Fexofenadine

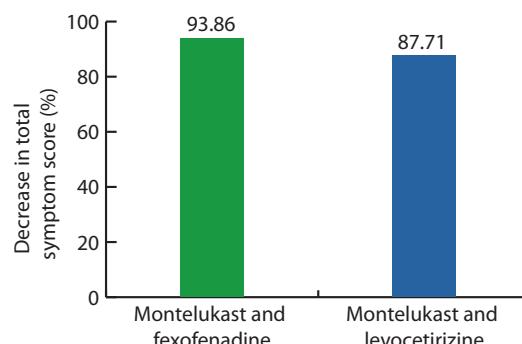
Fexofenadine is a selective histamine H1 receptor antagonist with anti-inflammatory properties. It has a rapid onset of action and long duration of action. It has been observed that fexofenadine is useful in reducing the symptoms of allergic rhinitis. Furthermore, at doses used for allergic rhinitis, it also renders benefits in allergic asthma. Remarkably, fexofenadine does not cross the blood brain barrier, thus has advantage of being devoid of sedative side-effects even at high doses, which are associated with first generation antihistamines.^{7,8} Thus, it is reasonable to assert that combined administration of these agents may be advantageous in comorbid allergic rhinitis and asthma.

A randomized, open label, prospective, two arm, comparative, multi-centric clinical trial aimed to estimate the effectiveness and tolerability of montelukast and fexofenadine (MF) combination, and montelukast and levocetirizine (ML) combination in patients with allergic rhinitis. Patients were randomized to receive ML or MF once-daily for 14 days. The main outcome assessed was variation in total symptom score and total ocular symptom score as compared to baseline. There was a decrease in total symptom score in both the groups; **however, the decrease was more in patients receiving MF (93.86%) as compared to ML (87.71%) (Figure 1).** In addition, variations in the sum of total nasal symptom score and total ocular symptom score were also significant in patients receiving MF (92.52% and 95.34%, respectively) as compared to ML group (85.58% and 92.23%, respectively). The global impression by investigator demonstrated 53.23% individuals rated excellent to very good with MF as against 36.36% individuals with ML. Global impression by subjects demonstrated excellent to very good rating for 50% individuals with MF as compared to 34.54% individuals with ML. **Thus, showing that combination of montelukast and fexofenadine was superior to montelukast and levocetirizine in attaining symptomatic control in allergic rhinitis.⁹**

CONCLUSION

Allergic rhinitis often presents with comorbidities such as asthma in adolescents and adults. There is a causal pathomechanism link between these disorders. It is believed that allergic rhinitis usually occurs before the development of asthma in adolescence or adult life. Therapeutic strategies used for controlling symptoms of allergic rhinitis may prove useful in controlling asthma.

Figure 1 Superiority of montelukast and fexofenadine over montelukast and levocetirizine in allergic rhinitis



Source: Nayak P, Srinivas CV, Jagade MV, Chandrasekharan S. A randomized, open label, prospective, comparative, multicentric study to evaluate the efficacy and safety of montelukast and fexofenadine fixed-dose combination vs montelukast and levocetirizine fixed-dose combination in allergic rhinitis. *Indian Journal of Clinical Practice.* 2013;24(3):241-246.

In this context, combined administration of montelukast and fexofenadine seems promising. Various studies have shown that combined administration of these agents is effective in reducing the symptoms of allergic rhinitis.

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