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A STUDY ON THE PHARMACOTHERAPY OF PARA NASAL SINUSITIS IN A TERTIARY CARE HOSPITAL

Dr. Anand R Kalamdani*, Dr. Pavithra Krishnan, Dr. T M Nagraj, Dr. Basavaraj Bhandare

[1]Professor, Department of Pharmacology, Rajarajeswari Medical College and Hospital, Bangalore.

[2]Post Graduate, Department of Pharmacology, Rajarajeswari Medical College and Hospital, Bangalore.

[3]Professor and Head, Department of ENT, Rajarajeswari Medical College and Hospital, Bangalore.

[4]Professor and Head, Department of Pharmacology, Rajarajeswari Medical College and Hospital, Bangalore.

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***Correspondence for Author**
Dr. Anand R Kalamdani
Professor, Department of Pharmacology, Rajarajeswari Medical College and Hospital, Bangalore.

ABSTRACT

Background: Episodes of Acute Rhinosinusitis are common among adults and are associated with a significant amount of morbidity. The symptoms of Rhinosinusitis are nasal drainage, congestion, and sinus pressure. As diagnosing bacterial sinusitis is difficult, the misuse and overuse of antibacterials for the treatment of sinusitis, has become a major problem throughout the world. **Aims and Objectives:** To analyse the Pharmacotherapy in Acute Bacterial Sinusitis and to assess the efficacy and tolerability of the Antimicrobials prescribed. **Materials and Methods**: A total of 60 patients diagnosed with Acute Bacterial Sinusitis were included in the study and their prescriptions were assessed which included Antimicrobials and adjuvant drugs used, route of administration, dose, tolerability, side effects and drug interactions were recorded. **Results**: Out of 60 patients who completed the study, 38% were males and 62% were females. Most common symptom that patients presented were nasal congestion (n=60), headache (n=50), post nasal drip (n=50). 90% of the study group received a Antimicrobial belonging to Beta Lactam group. NSAIDS like Paracetamol and Decongestants were used in all patients and Amoxicillin Claavulinic acid combination was

the most frequent antimicrobial prescribed. The subjects showed good tolerability with minimal to no side effects. **Conclusion:** In our study we found that Amoxicillin Clavulinic acid was the primary option due to its proven efficacy, safety and tolerability. The other antimicrobials (majority Beta lactam group) that were prescribed also showed good tolerability and patient compliance.

KETWORDS: Paranasal Sinus Infections, Pharmacotherapy, Antimicrobials, Acute Bacterial Rhinosinusitis.

INTRODUCTION

Rhinosinusitis refers to an inflammatory condition involving the four paired structures surrounding the nasal cavities. Although most cases of sinusitis involve more than one sinus, the maxillary sinus is most commonly involved; next, in order of frequency, are the ethmoid, frontal, and sphenoid sinuses. When the sinus ostia are obstructed, or when ciliary clearance is impaired or absent, the secretions can be retained, producing the typical signs and symptoms of sinusitis.[1] As these secretions accumulate with obstruction, they become more susceptible to infection with a variety of pathogens, including viruses, bacteria, and fungi. Sinusitis affects a tremendous proportion of the population, accounts for millions of visits to primary care physicians each year, and is the fifth leading diagnosis for which antibiotics are prescribed.[2] It typically is classified by duration of illness (acute vs. chronic); by etiology (infectious vs. noninfectious); and, when infectious, by the offending pathogen type (viral, bacterial, or fungal)Acute rhino sinusitis —defined as sinusitis of <4 weeks' duration- constitutes the vast majority of sinusitis cases.[3] Most cases are diagnosed in the ambulatory care setting and occur primarily as a consequence of a preceding viral Upper Respiratoty Tract Infection. Differentiating acute bacterial from viral sinusitis on clinical grounds is difficult. Therefore, it is perhaps not surprising that antibiotics are prescribed frequently (in 85–98% of all cases) for this condition.

Among Bacterial Rhinosinusitis, S. pneumoniae and non typable Haemophilus influenzae are the most common pathogens, accounting for 50–60% of cases. Moraxella catarrhalis causes disease in a significant percentage (20%) of children but a lesser percentage in adults.[4] Most cases of acute sinusitis present after or in conjunction with a viral Upper Respiratory Tract Infection, and it can be difficult to discriminate the clinical features of one from the other. Common presenting symptoms of sinusitis include nasal drainage and congestion, facial pain or pressure, and headache. Thick, purulent or discolored nasal discharge is often thought to

indicate bacterial sinusitis but also occurs early in viral infections such as the common cold and is not specific to bacterial infection. Other nonspecific manifestations include cough, sneezing, and fever. In acute sinusitis, sinus pain or pressure often localizes to the involved sinus (particularly the maxillary sinus) and can be worse when the patient bends over or is supine. Life-threatening complications of sinusitis include meningitis, epidural abscess, and cerebral abscess. Acute sinusitis is a common reason for prescription of antibiotics. [5]

The effectiveness of antibiotics, however, has been poorly documented. The pattern of antibiotic prescription varies with geographical location based on the strains of pathogens rampant and the availability of the anti microbial agents. There is limited data available in the Indian population and therefore this study was taken up. In this clinico- pharmacological study,the most common symptoms and signs of sinusitis, pattern of drug prescription and their efficacy and side effect profile have been studied.

MATERIALS AND METHODS

This study was a prospective observational clinical study permitted by the Institutional Ethical Committee.60 patients diagnosed with Acute bacterial sinusitis(Diagnosed based on signs and symptoms by the ENT specialist in accordance with the IDSA guidelines)[6] attending the ENT Outpatient Department from August 2013 to August 2014 at Rajarajeswari Medical College and Hospital were included in the study. Written informed consent was obtained from all the study subjects after fully explaining the study procedure to their satisfaction. Subjects fulfilling the inclusion criteria were taken in to the study. The inclusion criteria were, patients above the age of 3 years, patients willing to give consent, patients available for follow up once after antimicrobial therapy. Exclusion criteria include patients with nasal polyps, deviated nasal septum, allergic rhinitis immunocompromised patients, patients' refusal of consent and patients diagnosed with viral or fungal sinusitis based on the signs and symptoms and ENT examination and patients already on other anti-microbial therapy. Patients history, General Physical Examnation, history of any co morbid conditions, Anterior Rhinoscopy findings, Diagnostic Nasal Endoscopic findings, relevant investigations like x ray skull Waters' view, antimicrobials with the adjuvants prescribed were recorded in patient case record form .The patients were instructed to complete the drug regimen and record the side effects if any.

Statistical Analysis: The data was analysed using descriptive statistics which includes mean, median and mode, standard deviation and the results were analysed in Microsoft Excel.

RESULTS AND DISCUSSION

Out of the 60 patients 38% were male and 62% female, Table 1. Majority of the patientswere in the age group of 20-30 years and the mean age of the patients in years was 26.5±9.6 depicted in Table-2. The most common clinical symptom the patients presented with were nasal congestion (n=60), fever (n=50) and headache (n=50).Majority of the patients had multiple symptoms shown in Table 3. The mean duration of symptoms was 6.86±2.56 days. 42 patients had similar complaints (atleast one episode) in the last one year. The most common clinical signs observed were sinus tenderness and post nasal drip shown in Table 4.

On Diagnostic Anterior Rhinoscopy all 60 patients had congested nasal mucosa with serous discharge with no gross deviation of the septum.Lateral wall showed hypertrophy of the Inferior Turbinate in 52(86%) patients. Diagnostic Nasal Endoscopy was done in patients which showed edematous nasal mucosa with pus present in the middle meatus in 32(54%) patients.

Table 5 shows the investigations advised. X-Ray PNS (Water's view) was advised to all the subjects. Pus for culture sensitivity was advised to 32(53%) patients.

Table 1: **Sex distribution.**

Sex	Number of Patients (%)
Male	23 (38)
Female	37 (62)

Table 2: Age Distribution.

Age group(in years)	Number of Patients (%)
3-10	00 (0)
10-20	05(8.33)
20-30	20 (33.3)
30-40	15 (25)
40-50	12 (20)
50-60	05(8.3)
>60	03(5)

Table-3: Symptoms.

Symptoms	N (%)
Nasal congestion	60 (100)
Headache	50 (83.3)
Fever	50 (83.3)
Facial pain	50 (83.3)
Cough	25 (41.6)
Ear pain	2 (3.3)
Multiple symptoms (> 1 Symptom)	60 (100)

Table-4: Clinical Signs.

Clinical Signs	N (%)
Sinus tenderness	60 (100)
Post nasal drip	55 (91.6)
Nasal discharge	50 (83.3)
Congested pharnyx	5 (8.3)
Enlarged cerivallymphnodes	6 (10)
Multiple signs	60 (100)

Table 5: Investigations Advised.

Investigations	N (%)
X ray skull water's view	60 (100)
Pus in middle meatus for c/s	32 (53.3)
CTscan PNS	0 (0)

Table 6: DrugsPrescribed.

AntiMicrobials	Dose	Route	Frequency	Duration	N
Amoxicillin+clavulinic acid	625mg	Oral	BID	5 Days	29
Cefpodoxime+Clavulinic acid	325mg	Oral	BID	5 Days	12
Cefixime+Clavulinic acid	325mg	Oral	BID	5 Days	10
Azithromycin	500mg	Oral	BID	3Days	5
Cefuroxime axetil	250mg	Oral	BID	5 Days	4

Figure 1: Percentage distribution of various antimicrobials.

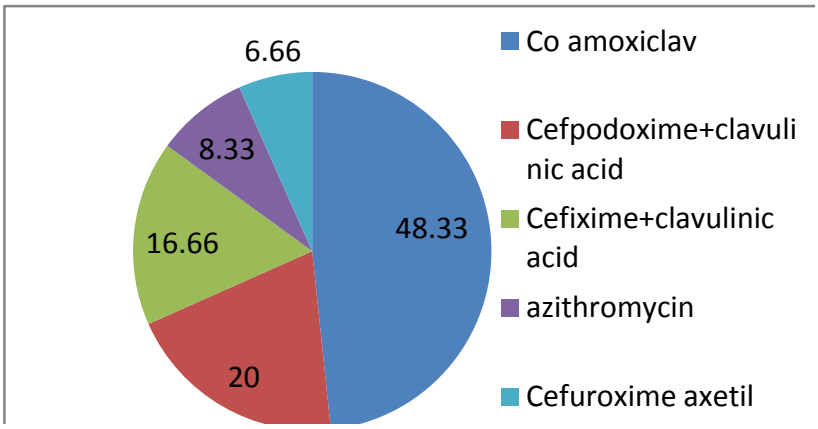

Table 7: Adjuvant Drugs Prescribed.

Drugs	N (%)
Xylometazoline nasal drops	60 (100)
Cetrizine	12 (20)
Levocitrizine	17 (28.3)
Cetrizine+Phenyleprine	8 (13.3)
Cetirizine+Phenylephrine+Paracetamol	13 (21.6)

Levocetrizine+Pseudoephidrine	10 (16.6)
Aceclofenac+Paracetamol	32 (53.3)
Diclofenac+Paracetamol	12 (20)
Paracetamol	4 (6.6)
Pantoprazole	12 (20)

In this study,the pattern of clinical signs and symptoms manifested by the patients were consistent with the observations in other studies.[6] According to the IDSA guidelines, sinus infection should be considered probably bacterial in cause and antibiotics started only if symptoms last 10 days or more and are not improving, or if symptoms are severe (high fever and purulent nasal discharge or facial pain lasting 3–4 days),or if symptoms get worse.[7]The IDSA guidelines recommend 5–7 days of antibiotics for adult bacterial sinusitis which has been adhered to, by both the prescribers and patients in this study.

Table 6 shows that 92% of the patients received the anti microbial from the Beta Lactam group and Amoxicillin+clavulinic acid was the most preferred anti-microbial of choice, which was in accordance with most guidelines that recommend Co-amoxiclav as the drug of first line therapy due to its good tolerability and cost effectiveness.[8][9]Azithromycin was prescribed to 5 subjects which was a once daily regimen and they showed similar clinical improvement.

Combination therapy containing Cephalosporins was prescribed as the second most common, next to Co-amoxiclav in this study which is consistent to other studies that show that Cephalosporin and clavulinic acid combination has better activity against H.Influenza and anaerobes. [10] Table 7 shows the most commonly prescribed adjuvant drugs were Decongestants (xylometazoline), NSAIDS (Aceclofenac+Paracetamol) and Levocetrizine. Studies show that Continued use of xylometazoline for more than 3days may result in rebound nasal congestion and Rhinitis Medicamentosa. [11] In this study 5 patients on xylometazoline nasal drops complained of rebound nasal congestion for which they were advised to stop the medication and were prescribed alternative therapy.The outcome of treatment was assessed clinically after the completion of 5 days course of Antimicrobial therapy. All the subjects showed significant clinical improvement, both subjective and objective.[12] The rate at which the symptoms resolved were similar for all Antimicrobials. In terms of the side effect profiles, all the patienrs recruited into the study completed the course of antibiotics and did not need discontinuation of the therapy and showed good tolerability.

CONCLUSION

Prescribing pattern of drugs reflects the clinical judgement of the clinicians. Our study revealed that Amoxicillin Clavulinic acid as the most sought after antimicrobial by the clinicians due to its proven efficacy, safety and tolerability which is in accordance with the various treatment guidelines.

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