Vol 12|Issue 1| 2022 |6-10.

ISSN 2249 - 7641
Print ISSN 2249 - 765X

International Journal of Pharmacology Research

www.ijprjournal.org

COMPARISON OF THE EFFICACY AND SAFETY OF CO-AMOXICLAV AND CEFUROXIME AXETIL IN THE TREATMENT OF ACUTE SINUSITIS IN A TERTIARY CARE HOSPITAL

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ABSTRACT

Acute sinusitis is a frequent upper respiratory illness that can become quite serious if treated incorrectly. The focus of this research was to compare & evaluate the effectiveness of cefuroxime & co-amoxiclav in treating acute sinusitis in a tertiary care hospital. In 2009, researchers conducted a randomized clinical study to compare the efficacy of 2 oral antibiotics, cefuroxime and co-amoxiclav, in treating acute sinusitis.The research included a total of 120 participants. The conjunction of suborbital discomfort, purulent rhinorrhea, & purulent discharge on the middle nasal meatus led to the clinical diagnosis of acute sinusitis. All of the patients were also radiographically checked to corroborate their findings. Patients were randomly randomised to receive either cefuroxime axetil 250 mg BD daily for 10 days (n=72) or Co-amoxiclav 500/125 mg BD daily for 10 days (n=48). Patients' reactions to therapy were evaluated both during & after therapy. Patients treated with cefuroxime or co-amoxiclav had a favorable clinical result (cure or improvement of symptoms) in 86.11 percent (62/72) and 72.91 percent (35/48) of the clinically evaluable patients, respectively (p >0.05). Cefuroxime (BD daily) appears to be equally beneficial as co-amoxiclav (BD daily) in the treatment of acute sinusitis, according to the findings of this study..

Keywords: Acute sinusitis, Cefuroxime axetil , Co-amoxiclav, Rhinorrhoea, Streptococcus pneumoniae.

INTRODUCTION

Sinusitis is a common upper respiratory illness that affects people all over the world. Fever, headache, facial discomfort, rhinitis, coughing, & purulent nasal discharges are some of the early signs of acute sinusitis. Acute sinusitis is defined by symptoms that last less than 4 week, & chronic sinusitis is defined by symptoms that last longer.[1, 2] Bacterial respiratory infections are prevalent, either as a main cause of serious sinusitis or as a side effect of upper respiratory virus infections including allergic rhinitis. [1, 2] In regular clinical practice, acute sinusitis is identified & treated. Antibiotics are recommended because the signs & symptoms of acute bacterial sinusitis might be difficult to distinguish from those of a viral upper respiratory tract infection or allergies. Antibiotics were shown to be more successful than placebo in obtaining a clinically treatment in a recent meta-analysis of the outcomes of randomized clinical trials evaluating the effectiveness of antibiotics against placebo in acute sinusitis. [1, 3] Nevertheless, when strict diagnostic criteria (such as sinus aspiration for detection of pathogens and/or sinus radiography) was employed to diagnosis acute sinusitis, antibiotics were found to be more effective. Because obtaining bacteriologic proof of the causal pathogen is generally impossible in general practice, empiric antibiotic therapy is typically administered for acute bacterial sinusitis. The most frequent organisms seen in acute bacterial sinusitis, such as Streptococcus pneumoniae, Haemophilus influenzae, & Moraxella catarrhalis, Beta-lactamase is produced

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by nearly all M. catarrhalis isolates & up to 40 percent of total of H. influenzae isolates, which may result in reduced sensitivity to several beta-lactam medicines. [5, 6] Chlamydia pneumoniae & Legionella pneumophila, for example, were infrequent cause of severe sinusitis. [1, 7] For efficient therapy of acute bacterial sinusitis, broad-spectrum antibiotics with action against beta-lactamase-producing organisms are required. [1, 7] Cefuroxime is an 2nd generation oral cephalosporin with a significant level of sinus region penetration &betalactamase stability. [8] It has in vitro action against a wide range of gram-positive & gram-negative organisms (beta-lactamase-producing & non-beta-lactamase-producing), including bacteria that cause acute sinusitis. [9, 10] In vitro, the combination of amoxicillin with clavulanate potassium, a beta-lactamase inhibitor, is equally effective against both beta-lactamase-producing & non-beta-lactamase-producing isolates of prevalent respiratory illnesses. In the management of acute bacterial sinusitis, cefuroxime & co-amoxiclav are the antimicrobials of preference.The goal of this study was to examine the effectiveness of 10-day regimens of Co-amoxiclav 500/125 mg BD & Cefuroxime axetil 250 mg BD in cases of acute bacterial sinusitis in an tertiary care hospital.

MATERIAL AND METHODS:

In 2019, a randomized single-blind research was done at the Civil Hospital in Palanpur, Gujarat, utilizing a random sampling method approach. Prior participating in the trial, all individuals signed the document informed permission form. The research enrolled 120 participants between the ages of 18 and 60 who had been diagnosed with acute sinusitis. Patients have to have two of the following symptoms to be eligible: 2 of the following signs and symptoms; nasal congestion, rhinorrhoea, cough, other symptoms not essential for enrollment are fever, postnasal drip, headache, sore throat, toothache, earache, malaise, sinus fullness. In addition, radiographic evidence of opacification, 24-mm membrane thickening, and/or airfluid level in one or both maxillary sinuses was required. Patients were excluded if they had a diagnosis or history of chronic sinusitis, required sinus surgery, post sinus surgery, received treatment with systemic antibiotics in the previous seven days, needed to initiate steroid therapy, hypersensitive to penicillin, cephalosporin, pregnant and lactating women. Patients were randomized to receive either cefuroxime (250 mh BD) (n=72) or Co-amoxiclav (500/125 mg BD) (n=48) for 10 days. Patients were assessed during treatment (6-8 days after the start of treatment) and post-treatment (2 to 5 days after cessation of treatment). At each visit, the investigator assessed whether the following signs and symptoms were reduced: rhinorrhoea, headache, toothache, nasal congestion, cough, fever, sore throat, earache, tenderness, postnasal drip, malaise, cervical lymphadenopathy. Clinical response to treatment was classified as cure (signs and symptoms improved or resolved), failure (drug withdraw due to hypersensitivity). The 2- test was used to assess baseline demographics & other patient characteristics, as well as clinical cure percentages for cefuroxime or co-amoxiclav in clinically evaluable patients at post-treatment. Individuals who satisfied the eligibility requirements & obtained the intended dosage of study medicine, had the test-of-cure evaluation, & had not taken any other antibiotic for an illness other than sinusitis throughout the trial and before the test-of-cure appointment were considered medically evaluable. The analyses have been carried out using the Statistical Package for the Social Sciences (SPSS).

RESULT AND DISCUSSION:

A total of 120 individuals with acute sinusitis were included in the study. Cefuroxime axetil was given to 72 people (60%) & Co-amoxiclav was given to 48 people (40%) in this study. The demographic features of the participants in both research groups (Table 1) were similar. In age, gender, & medical manifestation pattern, no statistically significant differences were observed between the groups.

Signs and symptoms of patients receiving cefuroxime and co-amoxiclav were found as follows: In Cefuroxime group nasal discharge was absent in 61.11%, postnasal drip were present in 100% of population, cough was present in 87.5%, sinus pain was present in 83.33%, fever was present in half of the study population, toothache was absent in 86.11% and headache was absent in 80.55% people. In Co-amoxiclav group nasal discharge was absent in 66.66%, postnasal drip were present in 100% of population, cough was present in 90.27%, sinus pain was present in 73.61%, fever was present in 66.66 of the study population, toothache was absent in 79.16% and headache was absent in 70.83% people. (Table 2)

Patients treated with cefuroxime and co-amoxiclav had a favorable clinical result (cure or improvement of symptoms) in 86.11 percent (62/72) and 72.91 percent (35/48) of the clinically evaluable patients, respectively (p value < 0.05). (Table 3)

Table 1: Demographic profile

		Cefuroxime	Co-amoxiclav
Gender	Male	30	18
	Female	40	32
Age	18-38	38	28
	39-60	34	20

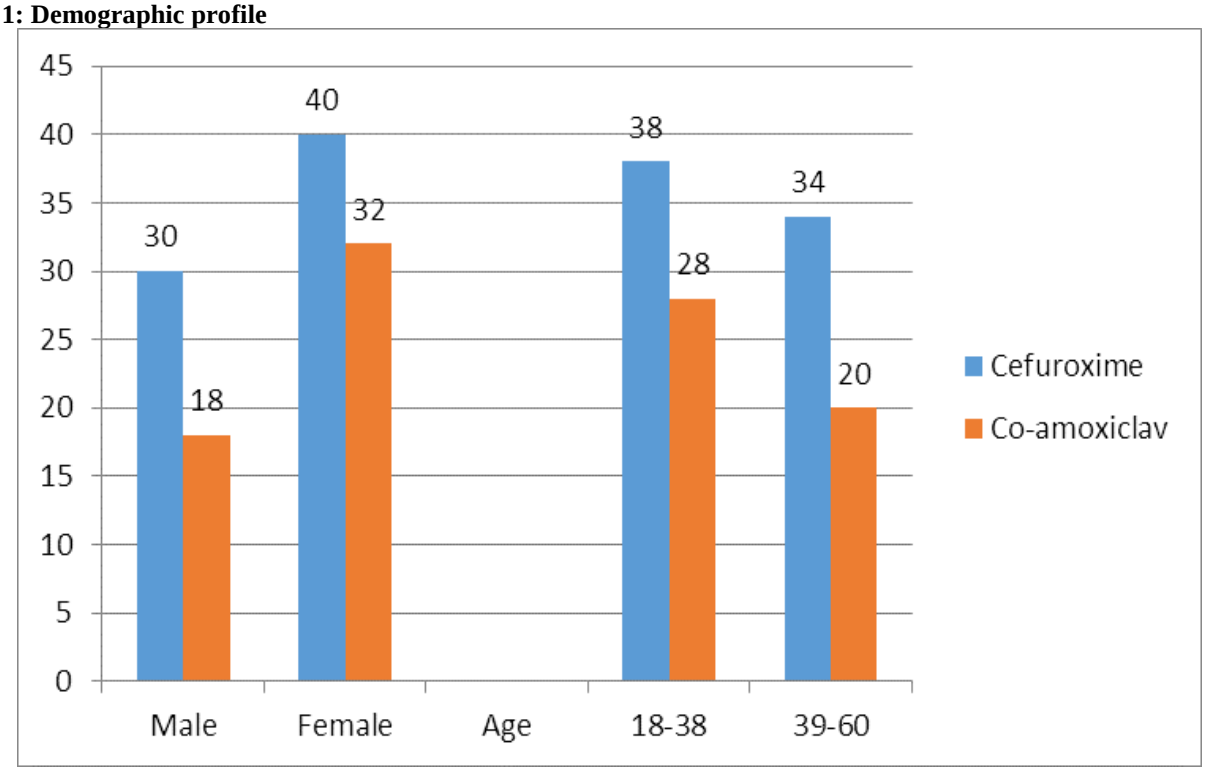
Table 2: signs and symptoms of patients receiving cefuroxime and co-amoxiclav

Signs & symptoms	Cefuroxime (n=72)	Co-amoxiclav (n=48)
Nasal discharge		
Absent	44 (61.11%)	32 (66.66%)
Present	28 (38.8%)	16 (33.33%)
Postnasal drip		
Absent	0	0
Present	72 (100%)	48 (100%)
Cough		
Absent	7 (9.72%)	6 (12.5%)
Present	65 (90.27%)	42 (87.5)
Sinus pain		
Absent	19 (26.38%)	8 (16.66%)
Present	53 (73.61)	40 (83.33%)
Fever		
Absent	36 (50%)	16 (33.33%)
Present	36 (50%)	32 (66.66%)
Toothache		
Absent	62 (86.11%)	38 (79.16%)
Present	10 (13.88%)	10 (20.83%)
Headache		
Absent	58 (80.55%)	34 (70.83%)
Present	14 (19.44%)	14 (29.16%)

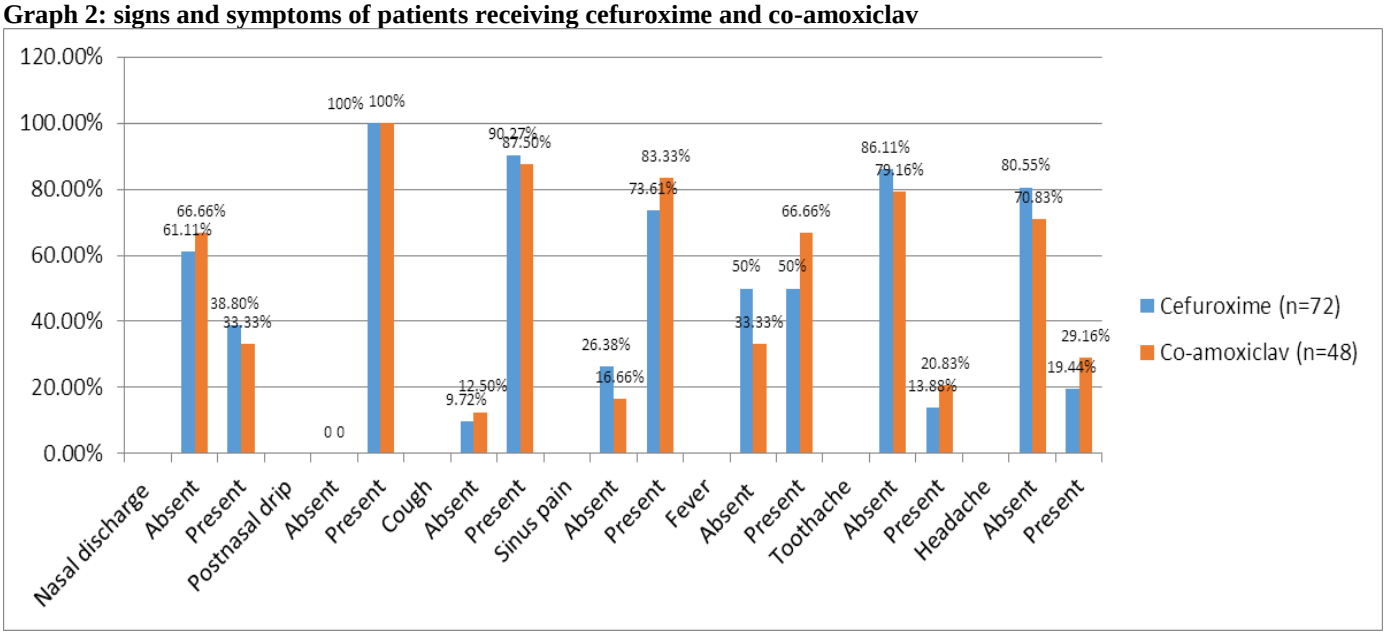
Table 3: Improvement in symptoms with the treatment

Improvement	Cefuroxime axetil	Co-amoxiclav	P- Value
	86.11 % (62/72)	72.91% (35/48)	< 0.05

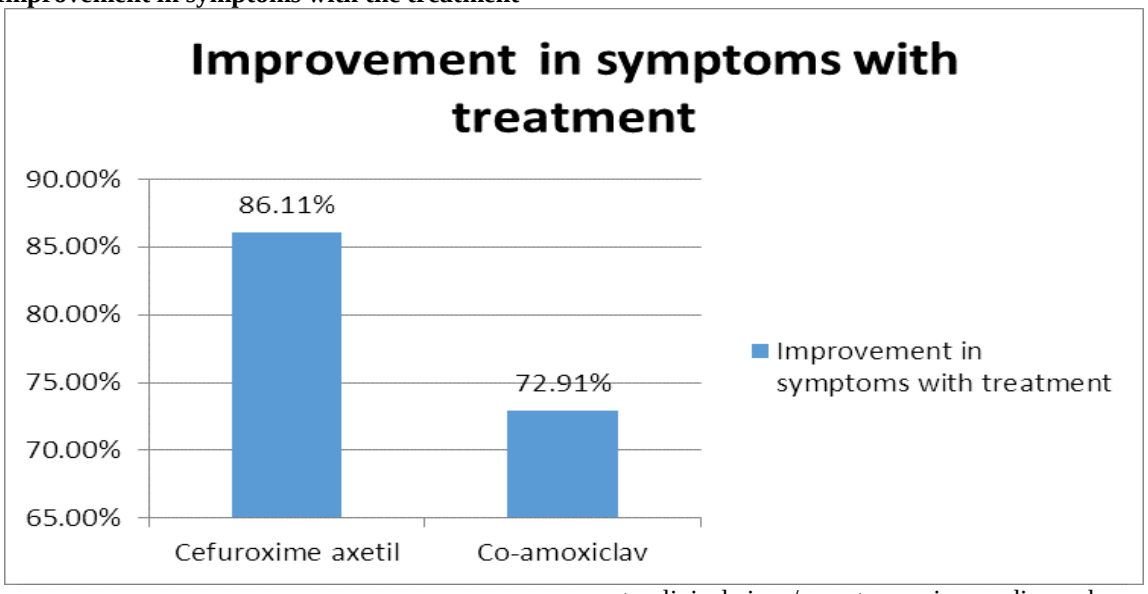
Graph 1: Demographic profile



Graph 2: signs and symptoms of patients receiving cefuroxime and co-amoxiclav



Graph 3: Improvement in symptoms with the treatment



If a patient with acute sinusitis did not react to therapy with co-amoxiclav before to the introduction of cefuroxime, physicians frequently explored a third-generation cephalosporin as an option. This might have resulted in an outbreak of antibiotic resistance. Because the effectiveness of cefuroxime and co-amoxiclav was shown to be equal, the findings of this study are particularly relevant in economically developing nation like India. It's also worth noting that utilizing cefuroxime twice a day instead of co-amoxiclav 3 times a day might be more efficient. Clinical cure & improvement rates for both treatment regimens were slightly greater in this research than in previous investigations.[1, 6, 11] This might be because, in addition to clinical signs/symptoms, sinus radiography was included in the criteria used to evaluate response rate in previous trials. We feel that the fact that we did not include sinus radiography as a parameter in our research may well have resulted in a greater cure rate than in previous research. It's worth noting that in individuals with acute bacterial infections accompanied by persistent sinus irritation or membrane thickness (chronic sinusitis), MRI may continue reveal aberrations following therapy. Based on radiologic clearance, this might be viewed as a therapeutic failure. In fact, in the lack of clinical manifestations of illness, radiographic sinus anomalies may reflect prolonged inflammation or poor secretory clearing instead of a resolved serious infection.[1, 6, 11] Antimicrobial

medication was shown to be much more effective than placebo in treating acute sinusitis in a recent meta-analysis, although the individuals who benefitted the most were those who had both clinical & radiographic signs of sinusitis.[3] In most primary care settings, clinicians consider the patient's well-being as well as the remission or improvement of symptoms over time when defining effective therapy, and follow-up radiography is not practicable or recommended. This is one of the report's shortcomings, according to the authors.Other clinical investigations [1, 12-16] have found that cefuroxime is as effective as co-amoxiclav. Cefuroxime is an excellent therapy for acute sinusitis, according to this study. Cefuroxime is a good therapeutic choice in the treatment of acute bacterial sinusitis because of its broad range antibacterial action, which includes great activity against the principal pathogenic bacterial pathogens in acute sinusitis and strong beta-lactamase stability. Furthermore, because cefuroxime is prescribed BD vs co-amoxiclav BD , patient compliance is higher with cefuroxime than with co-amoxiclav. It's worth mentioning that cefuroxime is an ancient antibiotic that has been "generic" for some years in economically developed countries. Furthermore, antibiotic resistance is a big & developing problem, which has been related to excessive antibiotic use & a lack of a drug - resistant surveillance network. As previously stated, a greater likelihood of patient satisfaction with cefuroxime (compared to co-amoxiclav) may help to reduce the risk of resistant pathogens in this context.

CONCLUSION:

In our context, a higher likelihood of patient compliance with cefuroxime (compared to co-amoxiclav) should help to reduce the risk of antimicrobial resistance. In the treatment of acute sinusitis, the findings of this trial showed that 10 days of cefuroxime 250 mg BID is as clinically efficacious as 10 days of co-amoxiclav 500/125 mg BD.

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