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Research Article

Comparison between amoxicillin-clavulanate and levofloxacin in the management of acute bacterial rhinosinusitis

[1]Muhammad Yousaf Saleemi, [2]Ayesha Amjad and [3]Zainab Khalid

[1]Associate Professor, Department of ENT, DHQ Teaching Hospital Sahiwal,
Cell No. 0301-6528841, Email. yousaf.saleemi@yahoo.com
[2]House Officer, Jinnah Hospital, Lahore
[3]House Officer, Jinnah Hospital, Lahore

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ABSTRACT

Objective: To compare the efficacy of Amoxicillin-Clavulanate and Levofloxacin in the management of acute bacterial rhinosinusitis

Materials & Methods: This randomized controlled trial was conducted at Department of Otorhinolaryngology, Head & Neck SurgeryDHQ Hospital, Sahiwal from March 2018 to September 2018 over the period of six months.
In this study, patients of Group A was managed with Amoxicillin-clavulanate and patients of group B was managed with Levofloxicin and efficacy of treatment was compared between the both groups.

Results: In present study mean age of the patients was 36.45 ± 8.72 years. Mean age of patients in group A was 35.73 ± 7.31 years and in group B was 35.91 ± 8.24 years. Efficacy of treatment was noted in 146 (81.11%) patients of group A while in 172 (95.56%) patients of group B. Significantly (P = 0.000) higher efficacy rate was observed in group B as compared to group A.

Conclusion: Findings of present study reveals that levofloxacin is better treatment option for the management of acute bacterial rhinosinusitis as compared to amoxicillin-clavulanate. Statistically significant difference of efficacy rate was observed in different age groups, gender and duration of disease.

Keywords: Bacterial, rhinosinusitis, levofloxacin, amoxicillin.

INTRODUCTION

Acute bacterial rhinosinusitis (ABRS) is a bacterial infection involving the paranasal sinuses and is usually preceded by a viral upper respiratory tract infection (URTI; i.e., the “common cold”) or an acute exacerbation of an allergic disorder.[1]

According to the ABRS treatment guidelines of the Sinus and Allergy Health Partnership (SAHP), a clinical diagnosis of ABRS may be made when URTI symptoms (e.g., nasal congestion, facial pressure and/orpain [especially unilateral], and postnasal drip) worsen after 5–7 days or do not improve after 10–14 days.[2] However, the identification of specific signs and symptoms at clinical examination does not appear to reliably predict bacterial infection.[3]

It is of three types depending upon the duration of symptoms, if the symptoms are present for less than 12 weeks then it is considered acute, if the time period is more than it is considered as

chronic and in recurrent cases there are more than three acute episodes in one year. Therapeutic treatment is required to provide relief from symptoms, accelerate healing, improve clinical picture and prevent the development of chronic state.[4] Nasal blockage, post nasal drip, headache, loss of perception of smell, facial pain is the various signs and symptoms associated with rhinosinusitis. The clinical picture associated with rhinosinusitis includes erythmatous nasal turbinates and discharge from meatus.[5-6] Various antimicrobial agents alone or in combination with topical corticosteroids have been used in various randomized controlled trials for the management of acute rhinosinusitis.[7-8] The treatment of choice for mild cases of sinusitis are amoxicillin-clavulanate or cefadroxil, while amongst moderate or mild patients who have been previously treated with antibiotics, levofloxacin or moxifloxacin are the treatment of choice, whilst in the severe forms, third generation cephalosporins, like cefotaxime or ceftriaxone or cefixime are used.[9] Various clinical studies have shown the success rate of amoxicillin/clavulanate to be 96.7%.[10] The success rate of levofloxacin as a treatment modality for rhinosinusitis was 88.4% in one study.[11] The aim of study was to compare the efficacy of oral amoxicillin-clavulanate with levofloxacin in the management of acute maxillary sinusitis.

MATERIALS & METHODS

This randomized controlled trial was conducted at Department of Otorhinolaryngology, Head & Neck Surgery DHQ Hospital, Sahiwalfrom March 2018 to September 2018 over the period of six months.

Total 360 patients with acute bacterial rhinosinusitis having age between 15-55 years wither male or female were selected. Patients taking antibiotics, patients with complications or any other systemic disease, patients with nasal surgery and pregnant or lactating mothers were excluded from the study.

Selected patients were randomly divided into two groups A & B. Group A was managed with oral Amoxicillin-clavulanate 1 g every 12 hours for 10 days and group B was managed with Oral Levofloxicin250 mg every 12 hours for 10 days. At day 11, all the patients were assessed for signs and symptoms resolution.Findings were noted on pre-designed performa along with demographic of the all the patients.

OPERATIONAL DEFINITIONS:

1 **Acute Bacterial rhinosinusitis:** The following clinical parameters were considered for diagnosis:
   - **a.** Patient's complaints including feeling of stuffiness or blockage in nose, discharge from nasal cavity, headache, inability to smell or feeling of bad smell (cacosmia) was recorded. The duration in hours per day and frequency of episodes per day of these complaints was recorded.
   - **b.** Physical findings include red and swollen nasal turbinates, mucopurulent nasal discharge in meatus and post nasal drip was assessed by clinical examination by an ENT specialist.

2 A diagnosis of acute bacterial rhinosinusitis requires presence of any four or more symptoms and two or more signs, persistence of symptoms for longer than 10 days or a worsening of symptoms after 7 days.

3 **Efficacy**: Efficacy was assessed by using the following parameter on day 11 in the term of:

a. Complete Resolution of clinical signs and symptoms.

4 **Amoxicillin-Clavulanate:** It is a moderate-spectrum, bacteriolytic, β-lactam antibiotic used to treat bacterialinfections caused by susceptible microorganisms. We used it in a dose of 1gm every 12 hours for 10 days in our study (Group A).

Levofloxacin: It is a synthetic chemotherapeutic antibiotic of the fluoroquinolone drug class and is used to treat

severe bacterial infections or bacterial infections that have failed to respond to other antibiotic classes. We used it in a dose of 250 mg every 12 hours for 10 days in our study (Group B).

All the collected was analyzed by using SPSS version 18. Mean and SD was calculated for numerical variables and frequencies were calculated for categorical variables. Difference of efficacy of treatment between both groups was detected by using chi-square test. P- value ≤0.05 was taken as significant.

RESULTS

In present study mean age of the patients was 36.45 ± 8.72 years. Mean age of patients in group A was 35.73 ± 7.31 years and in group B was 35.91 ± 8.24 years. Efficacy of treatment was noted in 146 (81.11%) patients of group A while in 172 (95.56%) patients of group B. Significantly (P = 0.000) higher efficacy rate was observed in group B was compared to group A. (Table 1) Patients were divided into three age groups, age group 15-30 years, age group 31-45 years and age group 46-55 years. In age group 15-30 years, treatment was found effective in 50 (98.04%) patients of group B while in 46 (86.79%) patients of group A. Difference of efficacy was significant with p value 0.031. In age group 31-45 years, treatment was found effective in 61 (92.42%) patients and 47 (74.60%) patients respectively in group B and A and the difference was statistically significant with p value 0.006. In age group 46-55 years, efficacy was noted in 61 (96.83%) patients of group B and in 53 (82.81%) patients of group A and the difference of efficacy between the both groups was statistically significant with p value 0.009. (Table 2)

Patients were divided into two group according to duration of disease which are ≤4 weeks duration of disease group and >4 weeks duration of disease group. Efficacy of treatment was observed in 107 (98.17%) patients of group B while in 93 (87.74%) patients of group A. Difference of efficacy was statistically significant with p value 0.003. In >4 weeks group, treatment was found effective in 65 (91.55%) patients of group B while in 53 (71.62%) patients of group A. Significantly (P = 0.002) higher efficacy rate was observed in group B as compared to group A. (Table 3)

Out 73 (40.56%) male patients of group B and 70 (38.89%) male patients of group A, treatment was found effective in 70 (95.89%) and 55 (78.57%) male patients of group B and group A and the difference was statistically significant with p value 0.002. Efficacy of treatment was seen in 102 (95.33%) female patients of group B while in 91 (82.73%) female patients of group A and difference of efficacy was statistically significant with p value 0.003. (Table 4)

Table 1: Comparison of efficacy between both groups

Group	Efficacy		Total	P value
	Yes	No		
A	146 (81.11%)	34 (18.89%)	180	0.000
B	172 (95.56%)	8 (4.44%)	180	

Table 2: Comparison of efficacy between both groups for age groups

Age of patients	Group B (n=180)		Total	Group A (n=180)		Total	p-value
	Efficacy			Efficacy			
	Yes	No		Yes	No		
15-30 years	50 (98.04%)	01 (1.96%)	51 (28.33%)	46 (86.79%)	07 (13.21%)	53 (29.44%)	**0.031**
31-45 years	61 (92.42%)	05 (7.58%)	66 (36.67%)	47 (74.60%)	16 (25.40%)	63 (35%)	**0.006**
46-55 years	61 (96.83%)	02 (3.17%)	63 (35%)	53 (82.81%)	11 (17.19%)	64 (35.55%)	**0.009**

Table 3: Comparison of efficacy between both groups for duration of disease

Duration of disease (weeks)	Group B (n=180)		Total	Group A (n=180)		Total	p-value
	Efficacy			Efficacy			
	Yes	No		Yes	No		
≤4 weeks	107 (98.17%)	02 (1.83%)	109 (60.56%)	93 (87.74%)	13 (12.26%)	106 (58.89%)	**0.003**
>4 weeks	65 (91.55%)	06 (8.45%)	71 (39.44%)	53 (71.62%)	21 (28.39%)	74 (41.11%)	**0.002**

Table 4: Comparison of efficacy between both groups for gender

Gender	Group B (n=180)		Total	Group A (n=180)		Total	p-value
	Efficacy			Efficacy			
	Yes	No		Yes	No		
Male	70 (95.89%)	03 (4.11%)	73 (40.56%)	55 (78.57%)	15 (21.43%)	70 (38.89%)	**0.002**
Female	102 (95.33%)	05 (4.67%)	107 (59.44%)	91 (82.73%)	19 (17.27%)	110 (61.11%)	**0.003**

DISCUSSION

Acute rhinosinusitis is a symptomatic inflammation of the paranasal sinuses and nasal cavity lasting no longer than 4 weeks.[13] Rhinosinusitis is common and accounts for up to 5% of visits to primary care physicians. Its cause may be viral, bacterial, allergic, or, less frequently, of other etiology. [14] Distinguishing acute bacterial rhinosinusitis from other types is important because of the potential benefit of antibiotic therapy.[15]Although no single, simple factor confirms the diagnosis of acute bacterial rhinosinusitis, its probability can be estimated based a number of signs and symptoms. In one study, however, a physician's overall clinical impression was better than any single symptom or sign for predicting acute bacterial rhinosinusitis.[16]Symptoms of rhinosinusitis can last well over two weeks with or without antibiotic treatment. Expensive antibiotics are often prescribed when equally effective and less expensive alternatives are available. The long duration of symptoms in some patients may result in referral for otolaryngology evaluation before an adequate trial of medical therapy.[17]

Mean age of the patients was 36.45 ± 8.72 years. Mean age of patients in group A was 35.73 ± 7.31 years and in group B was 35.91 ± 8.24 years. Efficacy of treatment was noted in 146 (81.11%) patients of Amoxicillin-clavulanate Group while in 172 (95.56%) patients of group B. Significantly (P = 0.000) higher efficacy rate was observed in group B was compared to Levofloxicin Group. In one study by Jareoncharsri eta al,[18] bacteriological eradication was noted in 78.5% patients in the Levofloxicin Group and 70.0% in the Amoxicillin-clavulanate group, which was not significantly different. In another study by et al[19] efficacy was noted in 88.4% patients in levofloxacin group and in 87.3% patients of Amoxicillin-clavulanate group. In another such study by Adelglasset al[20] compared amoxicillin- clavulanate and levofloxacin in ABRS. The success rates of treatment was 88.4% patients in levofloxacin group and 87.3% patients in Amoxicillin-Clavulanate group. In another trial, Jareoncharsriet al[21] compared the clinical efficacy and bacteriological response of levofloxacin and amoxicillin/clavulanic acid (co-amoxiclav) in sixty patients having purulent maxillary sinusitis for 14 days. This study demonstrated that levofloxacin 300 mg orally once daily was as effective and safe as amoxicillin/clavulanic acid 625 mg three times a day in the treatment of maxillary sinusitis, either acute or acute exacerbation. Both drugs showed bacteriological efficacy that was not significantly different. On the whole, it is concluded that levofloxacin has

better efficacy than amoxicillin-clavulanate in the treatment of acute bacterial rhinosinusitis in terms of signs and symptoms relief.

CONCLUSION

Findings of present study reveal that levofloxacin is better treatment option for the management of acute bacterial rhinosinusitis as compared to amoxicillin-clavulanate. Statistically significant difference of efficacy rate was observed in different age groups, gender and duration of disease.

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