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Research Article

Comparison of efficacy of amoxicillin-clavulanateand levofloxacin in the treatment of acute bacterial rhinosinusitis

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ABSTRACT

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

Materials & Methods: This comparative study was conducted at Department of Otorhinolaryngology, Head & Neck SurgeryDera Ghazi Khan Medical College, D.G. Khanfrom September 2017 to March 2018. Total 300 patients with acute bacterial rhinosinusitis were selected and randomly divided into two groups A & B. Group A was managed with Levofloxicinand group B was managed with Amoxicillin-Clavulanate and efficacy of treatment was compared between the both groups.

Results: Mean age of patients in group A was 40.57 ± 12.37 years and in group B was 40.13 ± 12.41 years. Treatment was found effective in 140 (93.33%) patients of study group A while in 125 (83.33%) patients of study group B. Significantly higher efficacy rate was found in treatment group A as compared to treatment group B with p value 0.007. Among the male patients, efficacy of treatment was noted in 66 (92.06%) patients of group A while in 34 (79.07%) patients of group B and the difference was statistically significant with p value 0.029. Among the female patients, treatment was found effective in 74 (93.67%) patient of group A and in 91 (85.05%) patients of group B and the difference was not significant with p value 0.066.

Conclusion: Results of present study 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

By definition, acute rhinosinusitis is an acute viral or bacterial in which there is inflammation of the mucosa of the nose and paranasal sinuses.[1] Majority of the cases are viral in origin but some of the cases also have bacterial basis. A vast majority of patients have the tendency to recover without the use of antibiotics but in patients with prolonged or severe disease, the use of antibiotics

should be given consideration. Approximately 40% of the patients recover without any treatment. 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.[2] 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.[1-3] Various antimicrobial agents alone or in combination with topical corticosteroids have been used in various randomised controlled trials for the management of acute rhinosinusitis.[3-5] 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.[6-8] Various clinical studies have shown the success rate of amoxicillin/clavulanate to be 96.7%.[9] The success rate of levofloxacin as a treatment modality for rhinosinusitis was 88.4% in one study.[10]

The rationale of this study was to compare clinical efficacy of two commonly used medications for treatment of acute rhinosinusitis in a sample of Pakistani population. Levofloxacin has the potential to be a cost effective alternative for amoxicillin/clavulanate in the treatment of acute bacterial rhinosinusitis in our 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:

Complete Resolution of clinical signs and symptoms.

MATERIALS & METHODS

This randomized controlled trial was conducted at Department of Otorhinolaryngology, Head & Neck Surgery D.G Khan Hospital, DG Khan from July 2017 to December 2017 over the period of six months. Total 300 patients with acute bacterial rhinosinusitis having age between 15-55 years wither male or female were selected. Patients already on some other antibiotics, patients who fail to complete the duration and prescribed dosage of the treatment, with complications like Pneumonia, any history of allergy to Amoxicillin-clavulanate or Levofloxicin, patient with previous sinus/conventional nasal surgery, patients with history of diabetes mellitus and patients with history of Pregnancy and actively lactating mothers were excluded from the study. Approval was taken from institutional review committee and written informed consent was taken from every patient. Selected patients was divided into two groups by lottery method.

Group A (Levofloxicin Group) received oral Amoxicillin-clavulanate 1 g every 12 hours for 10 days. Group B (Amoxicillin-clavulanate Group)

received Oral Levofloxicin250 mg every 12 hours for 10 days. All the patients were kept under strict surveillance and side effects if any, were noted. Follow up was ensured by taking telephone contacts. All the patients were assessed for signs and symptoms resolution. Symptoms and signs were recorded at visit one before the start of antibiotics and at day 11 after completion of treatment. Data was collected using proforma.

All the collected was analyzed by using SPSS version 18. Mean and standard deviation was calculated for age and duration of sign and symptoms. Frequency and percentage was calculated for gender and efficacy. Chi-Square test was used to determine the difference in efficacy in two groups. Potential effect modifiers like sex, age and duration of rhinosinusitis at presentation were controlled through stratification and post-stratification chi square was applied to see their effect on efficacy. P- value ≤0.05 was taken as significant.

RESULTS

In present study mean age of the patients was 40.35 ± 12.37 years. Mean age of patients in group A was 40.57 ± 12.37 years and in group B was 40.13 ± 12.41 years.

As shown in table 1, treatment was found effective in 140 (93.33%) patients of study group A while in 125 (83.33%) patients of study group B. Significantly higher efficacy rate was found in treatment group A as compared to treatment group B with p value 0.007. (Table 1)

Age range in this study was 20-60 years. Patients were divided into two age groups, age group 20-40 years and age group 41-60 years. In age group 20-40 years, out of 74 (49.33%) patients of group A, treatment was fond effective in 69 (93.24%) patients. Among the 77 (51.33%) of group B, efficacy of treatment was noted in 68 (88.31%) patients. Difference of efficacy between the both groups was not statistically significant with p value 0.296. In age group 41-60 years, there were total 76 (50.67%) patients in group A while 73 (48.67%) patients in group B. Treatment was found effective in 71 (93.42%) patients of group A and in 57 (78.08%) patients of group B. Difference of efficacy between the both groups was statistically significant with p value 0.007. (Table 2)

Total 71 (47.33%) and 43 (28.67%) patient of group A and B were male. Efficacy of treatment was noted in 66 (92.06%) patients of group A while in 34 (79.07%) patients of group B and the difference was statistically significant with p value 0.029. Among the 79 (52.67%) female patients of group A and 107 (71.33%) female patients of group B, treatment was found effective in 74 (93.67%) patient of group A and in 91 (85.05%) patients of group B and the difference was not significant with p value 0.066. (Table 3)

Patients were divided into two groups according to duration of symptoms i.e. ≤4 weeks group and > 4 weeks group. In ≤4 weeks group, efficacy of treatment was noted in 131 (97.04%) patients of group A and in 124 (93.04%) patients of group B but the difference was not statistically significant with p value 0.2514. In >4 weeks group, efficacy was noted in 9 (60%) and 1 (5.56%) patients of group A and B respectively. Difference of efficacy between both groups was statistically significant with p value 0.0015. (Table 4)

Table 1: Comparison of efficacy between both groups

Group	Efficacy		Total	P value
	Yes	No		
A (Levofloxacin)	140 (93.33)	10 (6.67)	150	0.007
B(Amoxicillin-clavulanate)	125 (83.33)	25 (16.67)	150	

Table 2: Comparison of efficacy between both groups for age

Group	Efficacy		Total	P value
	Yes	No		
Age group 20-40 Years				0.296
A	69 (93.24)	5 (6.76)	74 (49.33)	

B	68 (88.31)	9 (11.69)	77 (51.33)	
Age group 41-60 Years				
A	71 (93.42)	**4** (6.587.89)	76 (50.67)	0.007
B	57 (78.08)	16 (21.92)	73 (48.67)	

Table 3: Comparison of efficacy between both groups for gender

Group	**Efficacy**		**Total**	**P value**
	Yes	**No**		
Male patients				
A	66 (92.96)	5 (7.04)	71 (47.33)	0.029
B	34 (79.07)	9 (20.93)	43 (28.67)	
Female patients				
A	74 (93.67)	5 (6.33)	79 (52.67)	0.066
B	91 (85.05)	16 (14.95)	107 (71.33)	

Table 4: Comparison of efficacy between both groups for duration of symptoms.

Group	**Efficacy**		**Total**	**P value**
	Yes	**No**		
≤4 weeks				
A	131 (97.04)	4(2.96)	135 (90)	0.2514
B	124 (93.94)	8 (6.06)	132 (88)	
>4 weeks				
A	9 (60)	6 (40)	15 (10)	0.0015
B	1 (5.56)	17 (94.44)	18 (12)	

DISCUSSION

The objective of present study was to compare the efficacy of Amoxicillin-Clavulanate and Levofloxacin for the management of acute bacterial rhinosinusitis.

Various studies have been conducted to compare the efficacy of the amoxicillin, the cephalosporins and macrolides for the management of acute sinusitis but no significant difference was noted between them. Drugs like fluoroquinolones which have enhanced activity against S. pneumoniae are being widely used in clinical practice and are indicated for the management of acute bacterial sinusitis. Presently, there are three fluoroquinolones that are used against acute bacterial sinusitis, they are moxifloxacin, gatifloxacin, and levofloxacin. In a study conducted by Adelglass et al, Baz et al and Bate et al, to compare the efficacy of levofloxacin 500 mg once a day with either clarithromycin 500 mg BD or amoxicillin-clavulanate 500/125 mg tds in managing cases of sinusitis. They concluded that 88 to 95% subjects on levofloxacin achieved complete clinical cure or there was significant improvement. Clarithromycin and amoxicillin-clavulanate also showed similar results.[11-13]In a study conducted by Wald et al to compare amoxicillin and amoxicillin-clavulanate with placebo amongst 93 children in a 10 day trial. They found that the cure rate amongst children who received antibiotics was 67%, whereas only 43% of those receiving placebo showed resolution.[14] This was contrary to a study conducted by Gurbutt et al, who did not show any significant difference in clinical cure on comparing placebo and amoxicillin or amoxicillin-clavulanic acid in treatment of acute sinusitis.[15] In another randomized controlled trial, there were 83% of patients who received amoxicillin had improvement in signs and symptoms of sinusitis compared with 77% of patients who were on placebo.[16] In a trial at Department of Otolaryngology, University of Pittsburgh, amoxicillin/clavulanate 2000/125 mg

which was pharmacokinectically enhanced was developed and found to be effective against the common Acute sinusitis pathogens and even many resistant strains.[17]

CONCLUSION

Results of present study 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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