

Original Research Article

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A comparative study between amoxicillin + clavulanic acid and levofloxacin in the management of acute maxillary sinusitis at RIMS, Ranchi

Sandeep Kumar¹, Abha Kumari^{2*}

¹Department of ENT, ²Department of Pharmacology, Rajendra Institute of Medical Sciences, Ranchi, Jharkhand, India

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*Correspondence:

Dr. Abha Kumari,

E-mail: abhakumaridoc@yahoo.com

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ABSTRACT

Background: Acute rhinosinusitis is an acute viral or bacterial in which there is inflammation of the mucosa of the nose and paranasal sinuses. The aim of study was to compare the efficacy of oral amoxicillin-clavulanate with levofloxacin in the management of acute maxillary sinusitis.

Methods: The present prospective study was conducted in the Department of ENT, Rajendra Institute of Medical Sciences, Ranchi during a period of 8 months i.e. from July 2016 to June 2017. In Group I patients 1 gm of amoxicillin-clavulanate was given two times a day and in Group II, 500 mg of Levofloxacin was given once a day for a period of 10 days. Patient's complete demographic details were recorded including name, age and gender. Xylometazoline nasal spray and steam inhalations were given to all the patients.

Results: The mean age of the subjects was 36.43±6.43 years. In both the groups, majority of the subjects were between 36-45 years of age. There were 34.7% (52) in Group I and 38.7% (n=58) in Group II who belonged to this age group. Least number of subjects was those aged more than 48 years. There were 88% subjects (n=132) in group I and 86% (n=129) subjects in Group II in whom complete resolution of symptoms was seen.

Conclusions: From the above study we can conclude that both amoxicillin-clavulanic acid and levofloxacin are equally efficacious in managing cases of acute sinusitis. In this study there was no difference in the rate and duration of resolution amongst both the groups.

Keywords: Bacterial, Inflammation, Paranasal sinus, Rhinosinusitis, Maxillary sinusitis

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 erythematous 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 aim of study was to compare the efficacy of oral amoxicillin-clavulanate with levofloxacin in the management of acute maxillary sinusitis.

METHODS

The present prospective study was conducted in the Department of ENT, Rajendra Institute of Medical Sciences, Ranchi during a period of 12 months i.e. from July 2016 to June 2017. All the patients were informed about the study and a written informed consent was obtained from all the patients. Prior to initiation of the study, ethical committee clearance was obtained from the institute's ethical board. Patient's aged more than 15 years presenting with signs and symptoms of acute maxillary sinusitis were included in the study. Medically compromised patients like diabetics, hypertensives and pregnant and lactating mothers were excluded from the study. Patients already on antibiotics, allergic to levofloxacin or amoxicillin were also excluded. The patients were divided into two groups.

In Group I patients 1gm of amoxicillin-clavulanate was given two times a day and in Group II, 500 mg of levofloxacin was given once a day for a period of 10 days. Patient's complete demographic details were recorded including name, age and gender. Xylometazoline nasal spray and steam inhalations were given to all the patients. Assessment of all the patients was done for resolution of signs and symptoms. All the data was collected in a predesigned performa. The results were analysed using SPSS software. Chi square test was applied as a test of significance. Probability value of less than 0.05 was considered significant.

RESULTS

In the study, a total of 300 subjects were enrolled, 150 subjects belonged to Group I in which amoxyclav was given and in patients of Group II, levofloxacin was given. The mean age of the subjects was 36.43 ± 6.43 years.

Table 1 shows the age distribution of the subjects. In both the groups, majority of the subjects were between 36-45 years of age. There were 34.7% (52) in Group I and 38.7% (n=58) in Group II who belonged to this age group. Least number of subjects was those aged more than 48 years. In group I and Group II there were 10.7% (n=16) and 11.3% (n=17) who belonged to this age group. There were 28.7% (n=43) subjects in Group I and 26.7% (n=40) subjects in Group II who were between 15-25 years of age. There were 26% (n=39) and 23.3% (n=35) in Group I and Group II who belonged to 26-35 years age group. On applying chi square test there was no significant difference between the both groups.

Table 1: age distribution of study subjects.

Age (years)	Group I (%)	Group II (%)	P value
15-25	43 (28.7)	40 (26.7)	>0.05
26-35	39 (26)	35 (23.3)	
36-45	52 (34.7)	58 (38.7)	
>45	16 (10.7)	17 (11.3)	

Table 2: Parameters of study group that were assessed.

Varaile		Group I	Group II	P value
Gender	Male	81 (54%)	76 (50.7%)	>0.05
	female	69 (46%)	74 (49.3%)	>0.05
Resolution of symptoms (%)		132 (88%)	129 (86%)	>0.05
Time taken for resolution (days)		5.46	5.79	>0.05

Table 2 shows the various parameters that were assessed in the study. There were 54% (n=81) males and 46% (n=69) females in group I and 50.7% (n=76) males and 49.3% (n=74) females in Group II. There was no significant difference in the male to female ratio between the two groups. There were 88% subjects (n=132) in group I and 86% (n=129) subjects in Group II in whom complete resolution of symptoms was seen. The mean

time taken for resolution of symptoms was 5.46 days in Group I and 5.79 days in Group II. There was no significant difference between the two groups.

Figure 1 shows the clinical outcome of the therapy. There were 54% cases in Group I and 53.3% cases in Group II who were completely cured. Improvement from baseline results were seen in 34% cases of Group I and 32.7%

cases of Group II. No improvement was seen in 12% cases of Group I and 14% cases of Group II.

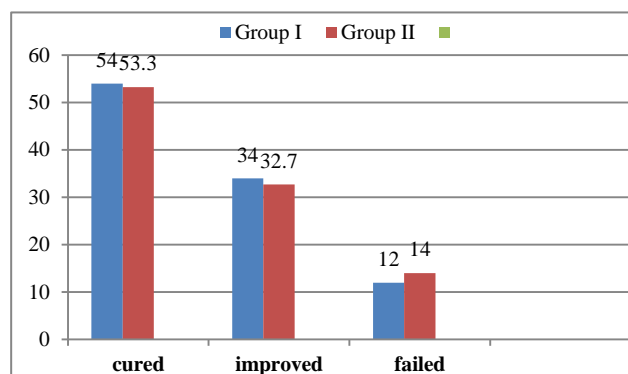


Figure 1: Clinical outcome of therapy.

DISCUSSION

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

In our study, There were 54% (n=81) males and 46% (n=69) females in group I and 50.7% (n=76) males and

49.3% (n=74) females in Group II. There was no significant difference in the male to female ratio between the two groups. There were 88% subjects (n=132) in group I and 86% (n=129) subjects in Group II in whom complete resolution of symptoms was seen. The mean time taken for resolution of symptoms was 5.46 days in Group I and 5.79 days in Group II. There was no significant difference between the two groups. In a study conducted by Gehanno et al to evaluate the efficacy and tolerance of oral levofloxacin as a treatment modality for acute bacterial sinusitis amongst 231 patients found that clinical success was observed in 94.1% patients in 7 days and 85.1% in 14 days.¹⁸ In a study conducted by Raza et al there was no significant difference in the number of patients who showed complete resolution of signs and symptoms between the amoxicillin-clavulanate and levofloxacin receiving patients; therefore they concluded that the two drugs had similar in efficacy.¹⁹

CONCLUSION

From the above study we can conclude that both amoxicillin-clavulanic acid and levofloxacin are equally efficacious in managing cases of acute maxillary sinusitis. In this study there was no difference in the rate and duration of resolution amongst both the groups. Once daily dosing of levofloxacin is more comfortable for the patients and hence should be preferred.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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