

Comparative Study to Evaluate Role of Amoxclav and Levofloxacin in Managing Acute Sinusitis: An Institutional Based Study

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Abstract

Background: Acute rhinosinusitis is defined pathologically by transient inflammation of the mucosal lining of the paranasal sinuses lasting less than 4 weeks. 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. The present study was conducted to compare the amoxclav and levofloxacin in managing acute sinusitis. **Materials and Methods:** The present prospective study was conducted to compare the amoxclav and levofloxacin in managing acute sinusitis. The patients were divided into two groups, in Group I patient's amoxicillin-clavulanate was given and in Group II levofloxacin was given. Patient's complete demographic details were recorded. Assessment of all the patients was done and data was collected. The recorded data was compiled, and data analysis was done using SPSS Version 20.0 (SPSS Inc., Chicago, Illinois, USA). P-value less than 0.05 was considered statistically significant. **Results:** In the present study, a total of 240 subjects were enrolled, 120 subjects belonged to Group I in which amoxclav was given and in patients of Group II, levofloxacin was given. In both the groups, majority of the subjects were between 40-50 years of age. There were 40.83% in Group I and 45.83% in Group II who belonged to this age group. The clinical outcome of the therapy showed that there were 53.33% cases in Group I and 49.16% cases in Group II who were completely cured. 28.33% Improved cases were seen in Group I and 25.83% cases of Group II. No improvement was seen in 18.33% cases of Group I and 25% cases of Group II. **Conclusion:** The present study concluded that Amoxclav completely more cases than levofloxacin. Improved cases were also more with amoxclav. Failed cases were more with levofloxacin. this shows that clinical outcome with amoxclav was better than levofloxacin.

Keywords: Amoxclav, Levofloxacin, Clinical Outcome.

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Introduction

Sinusitis is one of the most common conditions treated by primary care providers[1-3]. Like other upper respiratory infections (URI), sinusitis is usually a viral infection[4,5]. The American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) classifies rhinosinusitis into subtypes based on symptom duration. Acute rhinosinusitis refers to symptoms lasting less than four weeks; subacute, four to 12 weeks[6]; and chronic, more than 12 weeks[7,8]. Approximately 0.5% of all upper respiratory tract infections are complicated by sinusitis; the incidence of acute sinusitis ranges from 15 to 40 episodes per 1000 patients per year, depending on the setting [9,10]. It is much more common in adults than it is in children, whose sinuses are not fully developed. Acute sinusitis is the second most common infectious disease[11-13]. Symptoms of acute rhinosinusitis manifest when the mucosal lining in the paranasal sinuses and nasal cavity becomes inflamed. Because the nasal mucosa is contiguous with mucosa of the paranasal sinuses, inflammation of the sinuses rarely occurs without inflammation of the nasal mucosa. Although this process is commonly called sinusitis, rhinosinusitis is the more accurate term[7]. 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[13-15]. The present study was conducted to compare the amoxclav and levofloxacin in managing acute sinusitis.

Materials and Methods

The present prospective study was conducted to compare the amoxclav and levofloxacin in managing acute sinusitis in Department of Pharmacology, PDU Medical College, Churu, Rajasthan, India. Written consent was taken from the patients after explaining the study. Patient's aged more than 18 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, 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 pre-designed performa. The recorded data was compiled, and data analysis was done using SPSS Version 20.0 (SPSS Inc., Chicago, Illinois, USA). P-value less than 0.05 was considered statistically significant.

Results

In the present study, a total of 240 subjects were enrolled, 120 subjects belonged to Group I in which amoxclav was given and in patients of Group II, levofloxacin was given. In both the groups, majority of the subjects were between 40-50 years of age. There were

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40.83% in Group I and 45.83% in Group II who belonged to this age group. The clinical outcome of the therapy showed that there were 53.33% cases in Group I and 49.16% cases in Group II who were

completely cured. 28.33% Improved cases were seen in Group I and 25.83% cases of Group II. No improvement was seen in 18.33% cases of Group I and 25% cases of Group II.

Table 1: Distribution of patients according to age

Age (yrs)	Group I n (%)	Group II n (%)
18-30	28(23.33%)	26(21.66%)
31-40	43(35.83%)	39(32.54%)
40-50	49(40.83%)	55(45.83%)

Table 2: Clinical outcome of two groups

Clinical outcome	Groups	N(%)
Cured	Group I	64(53.33%)
	Group II	59(49.16%)
failed	Group I	22(18.33%)
	Group II	30(25%)
Improved	Group I	34(28.33%)
	Group II	31(25.83%)

Discussion

Acute sinusitis is typically treated with antibiotics even though most studies have shown little benefit. To maximize the benefit of treatment, the Infectious Disease Society of America (IDSA) recommends in its 2012 guidelines [16,17] that clinicians use strict criteria to diagnose acute bacterial sinusitis and prescribe amoxicillin/ clavulanate at the standard dose (SD) of 875 /125 mg bid for 7 days as first-line treatment (unless the patient is allergic to penicillin). It recommends using the high dose (HD) of 2000 /125 mg bid if the rate of penicillin-resistant *Streptococcus pneumoniae* in the community is greater than 10%. The available HD is a pharmacokinetically- enhanced extended-release (ER) tablet of amoxicillin/ clavulanate that aims to achieve a longer duration of therapeutic amoxicillin concentrations by providing ER amoxicillin along with immediate-release (IR) clavulanate.¹⁸In the present study, a total of 240 subjects were enrolled, 120 subjects belonged to Group I in which amoxclav was given and in patients of Group II, levofloxacin was given. In both the groups, majority of the subjects were between 40-50 years of age. There were 40.83% in Group I and 45.83% in Group II who belonged to this age group. The clinical outcome of the therapy showed that there were 53.33% cases in Group I and 49.16% cases in Group II who were completely cured. 28.33% Improved cases were seen in Group I and 25.83% cases of Group II. No improvement was seen in 18.33% cases of Group I and 25% cases of Group II. 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. 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 [19,20]. A review suggests that if an antibiotic is used the best one in primary care is probably a cheap broad-spectrum one such as amoxicillin, [9] and that a 5-day course is probably as effective as a 10-day course [21]. A Cochrane systematic review [25] found that, for acute upper respiratory tract infections, use of delayed prescriptions did not result in patient harm and it reduced antibiotic use. One of the trials reviewed was for acute sinusitis; delaying the antibiotic prescription made no difference to outcomes [22].

Conclusion

The present study concluded that Amoxclav completely more cases than levofloxacin. Improved cases were also more with amoxclav. Failed cases were more with levofloxacin. This shows that clinical outcome with amoxclav was better than levofloxacin.

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