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Original Article

Evaluation Of Efficacy Of Ciprofloxacin And Amoxycillin/Clavulanic Acid In Treating Patients With Chronic Sinusitis: A Comparative Study

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ABSTRACT
Background: Chronic inflammation of the sinus/nasal passage existing for a time period of more than 3 months in a single time is known as chronic sinusitis. When such episodes occur for more than four times a year, it is known as recurrent sinusitis. We planned the present study to assess the efficacy of ciprofloxacin and amoxycillin/clavulanic acid in treating patients with chronic sinusitis. **Materials & methods:** The present study included assessment of efficacy of ciprofloxacin and amoxycillin/clavulanic acid in treating patients with chronic sinusitis. A total of 40 patients with diagnosis of chronic sinusitis were enrolled in the present study and were broadly divided into two study groups with 20 patients in each group as follows: Group 1: subjects, who were given 500 mg of ciprofloxacin twice daily, Group 2: subjects, who were given 500 mg of amoxycillin/clavulanic acid thrice daily. Microbiological culture examination was done for assessment of bacterial eradication rates and cure rates. **Results:** After 9 days of treatment, nasal discharge ended in 13 patients and 11 patients of group 1 and group 2 respectively. Clinical cure completely occurred in 11 and 10 patients of group 1 and group 2 respectively. Complete bacteriological cure occurred in 17 and 18 patients of group 1 and group 2 respectively. Statistically non-significant results were obtained while comparing the clinical efficacy of both the study groups. **Conclusion:** For treating the chronic sinusitis patients, both the drug can be used with equal efficacy.

Key words: Chronic sinusitis, Clinical efficacy, Microbiological

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INTRODUCTION

Chronic inflammation of the sinus/nasal passage existing for a time period of more than 3 months in a single time is known as chronic sinusitis. When such episodes occur for more than four times a year, it is known as recurrent sinusitis. The evaluation and management of acute and chronic sinusitis are similar.[1-3] Chronic sinusitis is diagnosed when at least two of the following four symptoms are present and occur for more than 12 weeks: (1) purulent drainage, (2) facial and/or dental pain, (3) nasal obstruction, (4) hyposmia). The Infectious Disease Society of America (IDSA) defines sinusitis as two of the following major clinical symptoms: purulent nasal discharge, nasal congestion or obstruction, facial congestion or fullness, facial pain or pressure, hyposmia, anosmia.[4-6] Alternatively, ISDA defines sinusitis as one of the aforementioned major symptoms plus two or more minor criteria such as a headache, ear pain, pressure, or fullness, halitosis or bad breath, dental pain, cough, or fatigue. There is no consensus on an approach to the management of chronic sinusitis. The treatment should focus on modulating triggers, reducing inflammation, and eradicating the infection.[7, 8] Hence; we planned the present study to assess the efficacy of ciprofloxacin and amoxycillin/clavulanic acid in treating patients with chronic sinusitis.

MATERIALS & METHODS

The present study was conducted in the department of ENT and it included assessment of efficacy of ciprofloxacin and amoxycillin/clavulanic acid in treating patients with chronic sinusitis. Written consent was obtained from all the subjects enrolled in the present study. A total of 40 patients with diagnosis of chronic sinusitis were enrolled in the present study and were broadly divided into two study groups with 20 patients in each group as follows:Group 1: subjects, who were given 500 mg of ciprofloxacin twice daily, Group 2: subjects, who were given 500 mg of amoxycillin/clavulanic acid thrice daily

Inclusion criteria for the present study included:

- Subjects with persistence of clinical signs and symptoms of sinusitis for more than 3 months

- Subjects with negative history of any other nasal pathology,
- Subjects with negative history of any known drug allergy
- Subjects with presence of rhinorrhoea

All the subjects were given antibiotic therapies according to the desired groups. Detailed demographic details of all the patients were obtained. Complete follow-up assessment of all the patients was done. Disappearance of nasal discharge was taken as one of the parameter for assessment of clinical efficacy of both the antibiotic regimes. Microbiological culture examination was done for assessment of bacterial eradication rates and cure rates. All the results were summarized and assessed by SPSS software. Chi-square test was used for assessment of level of significance. P-value of less than 0.05 was taken as significant.

RESULTS

Total of 40 patients with diagnosis of chronic sinusitis were included in the present study and were broadly divided into two study groups; group 1 and group 2. Mean age of the subject of the group 1 and group 2 was 29.4 years and 31.7 years respectively. There were 10 males and 10 females in the group 1 and there were 12 males and 8 females in the group 2. Mean duration of sinusitis among subjects of group 1 was 3.2 months while mean duration of sinusitis among subjects of group 2 was 3.4 months respectively. After 9 days of treatment, nasal discharge ended in 13 patients and 11 patients of group 1 and group 2 respectively. Clinical cure completely occurred in 11 and 10 patients of group 1 and group 2 respectively. Complete bacteriological cure occurred in 17 and 18 patients of group 1 and group 2 respectively. Statistically non-significant results were obtained while comparing the clinical efficacy of both the study groups.

Graph 1: Comparison of demographic and clinical details

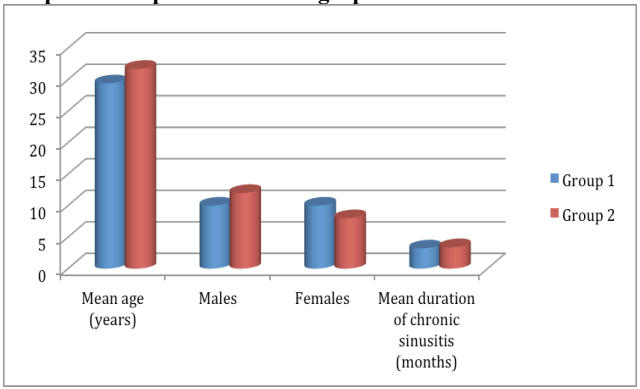
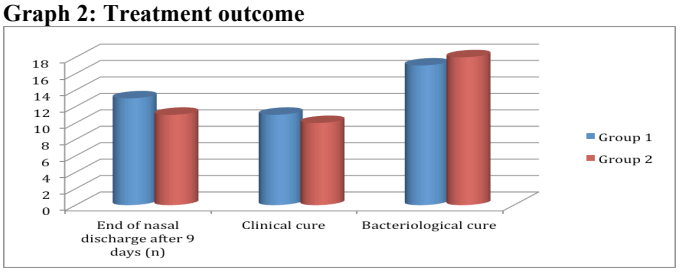


Table 1: Comparison of treatment outcome

Parameter	Group 1	Group 2	p- value
End of nasal discharge after 9 days (n)	13	11	0.58
Clinical cure	11	10	0.80
Bacteriological cure	17	18	0.34

Graph 2: Treatment outcome



DISCUSSION

In the present study, after 9 days of treatment, nasal discharge ended in 13 patients and 11 patients of group 1 and group 2 respectively. Clinical cure completely occurred in 11 and 10 patients of group 1 and group 2 respectively. Complete bacteriological cure occurred in 17 and 18 patients of group 1 and group 2 respectively. Statistically non-significant results were obtained while comparing the clinical efficacy of both the study groups. Camacho AE et al compared the clinical and bacteriologic efficacy of two oral antibiotics, cefuroxime axetil and amoxicillin/clavulanate, in the treatment of acute bacterial maxillary sinusitis. Three hundred seventeen patients with clinical and radiographic evidence of acute maxillary sinusitis were enrolled at nine centers and were randomly assigned to receive 10 days of treatment with cefuroxime axetil 250 mg twice daily or amoxicillin/clavulanate 500 mg three times daily. With respect to the eradication of the bacterial pathogens, a satisfactory outcome (cure or presumed cure) was obtained in 84% and 87% of bacteriologically evaluable patients treated with cefuroxime axetil or amoxicillin/clavulanate, respectively. Treatment with amoxicillin/clavulanate was associated with a significantly higher incidence of drug-related adverse events, particularly diarrhea. Two patients in the cefuroxime axetil group and three patients in the amoxicillin/clavulanate group withdrew from the study due to adverse events. Their results indicated that cefuroxime axetil twice a day is as effective as amoxicillin/clavulanate three times a day in the treatment of acute bacterial maxillary sinusitis but produces fewer adverse effects.[9]

Legent F et al compared the efficacy of ciprofloxacin (500 mg twice daily) was compared with that of amoxycillin/clavulanic acid (500 mg three times daily) in 76 patients with acute exacerbations of chronic non-cholesteatomatous suppurative otitis media enrolled in this open randomized multicentre trial. A total of 40 ciprofloxacin-treated patients and 35 amoxycillin/clavulanic acid-treated patients were evaluable for clinical efficacy following the 9-day treatment period. Pseudomonas aeruginosa was the main pathogen isolated prior to treatment. At the end of treatment, otorrhoea had disappeared in 57.5% of the ciprofloxacin group and 37.1% of the amoxycillin/clavulanic acid group (p = 0.04). Bacterial eradication rate was also significantly greater with ciprofloxacin (69.7%) than with amoxycillin/clavulanic acid (27.3%). Both treatments were well tolerated. Ciprofloxacin appears to be an effective treatment of chronic otitis media, and superior to amoxycillin/clavulanic acid.[10] Legnani D et al evaluated the clinical and microbiological efficacy of amoxycillin-clavulanic acid and ciprofloxacin in outpatients observed within the previous year who were affected by acute purulent

exacerbations of chronic bronchitis. Of the 95 patients included in the trial, 50 received amoxycillin 875 mg-clavulanic acid 125 mg 8-hourly for 10 days and 45 received ciprofloxacin 500 mg 12-hourly before meals for 10 days. Of the amoxycillin-clavulanic acid-treated patients, 90% showed clear clinical improvement and in 10% treatment failed. In the ciprofloxacin group, 75.5% of patients showed improvement and in 24.5% treatment failed. All pathogens isolated prior to therapy were susceptible to the antibiotic used for therapy. At the end of treatment, in the amoxycillin-clavulanic acid-treated group, 84% of strains were eradicated and 8% persisted; others were superinfections. In the ciprofloxacin group, 57.7% of strains were eradicated, 26.6% persisted and 15.5% were superinfections. No clinically significant side effects were observed in either group. Overall, amoxycillin-clavulanic acid demonstrated superior clinical and microbiological efficacy to ciprofloxacin, although this might be attributable to the higher proportion of aerobic Gram-negative pathogens in the ciprofloxacin group.[11]

CONCLUSION

Under the light of above obtained data, the authors conclude that for treating the chronic sinusitis patients, both the drug can be used with equal efficacy. However; further studies are recommended.

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