

ORIGINAL RESEARCH

To compare the effectiveness of Amoxiclav and Levofloxacin in the treatment of acute sinusitis

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ABSTRACT

Aim: The aim of this study is to compare the effectiveness of Amoxiclav and Levofloxacin in the treatment of acute sinusitis. **Materials and Methods:** Patient's aged more than 18 years presenting with signs and symptoms of acute maxillary sinusitis were included in the study. 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 7 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. **Results:** In this study a total of 220 participants were included. Group I consisted of 110 participants who received amoxiclav, whereas Group II consisted of participants who were given levofloxacin. The majority of participants in both groups fell within the age range of 35-45 years. In Group I, 40.91% of individuals belonged to this age group, whereas in Group II, the percentage was 45.45%. The therapy's clinical result revealed that 53.64% of patients in Group I and 50.91% of cases in Group II achieved full cure. Group I had a 31.82% increase in cases, whereas Group II had a 26.36% increase in cases. In Group I, there was no improvement seen in 14.55% of instances, whereas in Group II, no improvement was recorded in 22.73% of cases. **Conclusion:** The current investigation found that Amoxiclav was more effective than levofloxacin in treating the cases. The efficacy of amoxiclav was also enhanced in the improved patients. The incidence of unsuccessful outcomes was higher with levofloxacin. This demonstrates that the clinical result achieved with amoxiclav was superior to that achieved with levofloxacin.

Keywords: Amoxiclav, Levofloxacin, Acute sinusitis

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INTRODUCTION

Acute rhinosinusitis is a condition characterised by the inflammation of the mucosa of the nose and paranasal sinuses, caused by either a viral or bacterial infection [1]. The majority of cases are caused by viruses, while some instances are also of bacterial origin. The majority of patients tend to recover without the need for antibiotics. However, in cases of protracted or severe illness, it is advisable to consider the use of antibiotics. Around 40% of the patients have spontaneous recovery without requiring any kind of treatment. There are three categories of this condition based on the length of symptoms. If the symptoms last for less than 12 weeks, it is classified as acute. If the symptoms persist for a longer period, it is categorised as chronic. In situations where there are more than three acute episodes in one year, it is called

recurrent [2]. Therapeutic therapy is necessary to alleviate symptoms, expedite the healing process, enhance the clinical condition, and avoid the progression to a chronic state [2]. Rhinosinusitis is characterised by many signs and symptoms, including nasal obstruction, post nasal drip, headache, loss of sense of smell, and face pain. The clinical presentation of rhinosinusitis involves red nasal turbinate and drainage from the meatus [1-3]. Antimicrobial medicines, either alone or in combination with topical corticosteroids, have been used in many randomised controlled studies to treat acute rhinosinusitis [3-5]. The preferred treatment for mild cases of sinusitis includes amoxicillin-clavulanate or cefadroxil. For moderate to severe cases in patients who have previously received antibiotics, levofloxacin or moxifloxacin are the

recommended options. In severe forms of sinusitis, third-generation cephalosporins such as cefotaxime, ceftriaxone, or cefixime are used [6-8]. Multiple clinical trials have shown that the efficacy rate of amoxicillin/clavulanate is 96.7% [9]. The research found that levofloxacin had a success rate of 88.4% in treating rhinosinusitis [10]. The objective of the research was to assess the effectiveness of oral amoxicillin-clavulanate compared to levofloxacin in treating acute maxillary sinusitis.

MATERIALS AND METHODS

The present prospective study was conducted to compare the amoxiclav and levofloxacin in managing acute sinusitis in Department of Pharmacology. 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 7 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 recorded data was compiled, and data analysis was done using SPSS Version 25.0 (SPSS Inc., Chicago, Illinois, USA). P-value less than 0.05 was considered statistically significant.

RESULTS

In this study a total of 220 participants were included. Group I consisted of 110 participants who received amoxiclav, whereas Group II consisted of participants who were given levofloxacin. The majority of participants in both groups fell within the age range of 35-45 years. In Group I, 40.91% of individuals belonged to this age group, whereas in Group II, the percentage was 45.45%. The therapy's clinical result revealed that 53.64% of patients in Group I and 50.91% of cases in Group II achieved full cure. Group I had a 31.82% increase in cases, whereas Group II had a 26.36% increase in cases. In Group I, there was no improvement seen in 14.55% of instances, whereas in Group II, no improvement was recorded in 22.73% of cases.

Table 1 Gender distribution of the patients

Gender	Group I =110		Group II =110	
	Number	Percentage	Number	Percentage
Male	64	58.18	61	55.45
Female	46	41.82	49	44.55

Table 2: Age distribution of the patients

Age (yrs)	Group I =110		Group II =110	
	Number	Percentage	Number	Percentage
Below 25	24	21.82	23	20.91
25-35	37	33.64	35	31.82
35-45	45	40.91	50	45.45
45-55	4	3.64	2	1.82

Table 3: Clinical outcome of two groups

Clinical outcome	Groups	Number	Percentage
Cured	Group I	59	53.64
	Group II	56	50.91
failed	Group I	16	14.55
	Group II	25	22.73
Improved	Group I	35	31.82
	Group II	29	26.36

DISCUSSION

Several studies have been carried out to assess the effectiveness of amoxicillin, cephalosporins, and macrolides in treating acute sinusitis. However, no substantial difference was seen among these medications. Fluoroquinolones, which have increased effectiveness against *S. pneumoniae*, are often used in clinical practice and are recommended for treating

acute bacterial sinusitis. Currently, there are three fluoroquinolones that are used for the treatment of acute bacterial sinusitis. These fluoroquinolones are moxifloxacin, gatifloxacin, and levofloxacin. Antibiotics are often used for the treatment of acute sinusitis, despite little evidence of their effectiveness according to most studies. The Infectious Disease Society of America (IDSA) advises clinicians to

follow strict criteria for diagnosing acute bacterial sinusitis and to prescribe amoxicillin/clavulanate at the standard dose (SD) of 875/125 mg bid for 7 days as the initial treatment, unless the patient has a penicillin allergy. This approach is recommended in the IDSA's 2012 guidelines [11,12] to maximize treatment effectiveness. The recommendation is to use the high dosage (HD) of 2000 /125 mg bid if the prevalence of penicillin-resistant *Streptococcus pneumoniae* in the community exceeds 10%. The HD tablet is a pharmacokinetically-enhanced extended-release (ER) tablet containing amoxicillin and clavulanate. Its purpose is to maintain therapeutic levels of amoxicillin for a longer period of time by combining ER amoxicillin with immediate release (IR) clavulanate [13]. In this trial, a total of 220 participants were included. Group I consisted of 110 participants who received amoxiclav, whereas Group II consisted of participants who were given levofloxacin. The majority of participants in both groups fell within the age range of 35-45 years. In Group I, 40.91% of individuals belonged to this age group, whereas in Group II, the percentage was 45.45%. The clinical results of the treatment indicated that 53.64% of patients in Group I and 50.91% of cases in Group II achieved full cure. In Group I, there was a 31.82% increase in cases, whereas in Group II, there was a 26.36% increase in cases. There was no improvement seen in 14.55% of patients in Group I and 22.73% of cases in Group II. The study done by Raza et al found no statistically significant difference in the number of patients who had full clearance of signs and symptoms between those who received amoxicillin-clavulanate and those who received levofloxacin. As a result, the researchers concluded that the two medications were equally effective. A pharmacokinetically improved version of amoxicillin/clavulanate 2000/125 mg was produced and tested at the Department of Otolaryngology, University of Pittsburgh. The experiment demonstrated that this enhanced version was effective against both prevalent Acute sinusitis infections and several strains that are resistant to traditional treatments [14,15]. In a study conducted by Adel glass 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 [16-18].

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 [19]. 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 [20]. 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 [21]. A comprehensive analysis conducted by Cochrane revealed that the use of delayed prescriptions for acute upper respiratory tract infections did not cause any damage to patients and also led to a reduction in the usage of antibiotics. A clinical experiment was conducted to evaluate the effectiveness of postponing antibiotic prescription for acute sinusitis. The results showed that delaying the prescription did not have any impact on the outcomes.

CONCLUSION

The current investigation found that Amoxiclav was more effective than levofloxacin in treating the cases. The efficacy of amoxiclav was also enhanced in the improved patients. The incidence of unsuccessful outcomes was higher with levofloxacin. This demonstrates that the clinical result achieved with amoxiclav was superior to that achieved with levofloxacin.

REFERENCES

1. Kumar S, Kumari A. A comparative study between amoxicillin + clavulanic acid and levofloxacin in the management of acute maxillary sinusitis at RIMS, Ranchi. *Int J Otorhinolaryngology Head Neck Surg.* 2018;4(1):185-8. doi: 10.18203/issn.2454-5929.ijohns20175622.
2. Kumawat P, Purohit VS. Comparative study to evaluate role of Amoxiclav and levofloxacin in managing acute sinusitis: an institutional based study. *International Journal of Health and Clinical Research.* 2021;4(7):96-8.
3. Lund VJ. Therapeutic targets in rhinosinusitis: infection or inflammation? *Medscape J Med.* 2008; 29:101-5.
4. Ryan D. Management of acute rhinosinusitis in primary care: changing paradigms and the emerging role of intranasal corticosteroids. *Prim Care Respir J.* 2008;17(3):148-55. doi: 10.3132/pcrj.2008.00050, PMID 18695848.
5. Small CB, Bachert C, Lund VJ, Moscatello A, Nayak AS, Berger WE. Judicious antibiotic use and intranasal corticosteroids in acute rhinosinusitis. *Am J Med.* 2007;120(4):289-94. doi: 10.1016/j.amjmed.2006.08.035, PMID 17398218.
6. Hadley JA. The efficacy of cefdinir in acute bacterial rhinosinusitis. *Expert Opin Pharmacother.* 2006;7(8):1075-83. doi: 10.1517/14656566.7.8.1075, PMID 16722817.
7. Rosenfeld RM, Andes D, Bhattacharyya N, Cheung D, Eisenberg S. Clinical practice guideline: adult sinusitis. *Otolaryngol Head Neck Surg.* 2007;137;Suppl:1-31.
8. Leo G, Mori F, Incorvaia C, Barni S, Novembre E. Diagnosis and management of acute rhinosinusitis in children. *Curr Allergy Asthma Rep.* 2009;9(3):232-7. doi: 10.1007/s11882-009-0034-1, PMID 19348724.

9. Jose RA, Alejandro S, Eulalia S, Ximena F. Moxifloxacin vs amoxicillin/clavulanate in the treatment of acute sinusitis. *Am J Otolaryngol*. 2007;2878-82.
10. Adelglass J, DeAbate CA, McElvaine P, Fowler CL, LoCocco J, Campbell T. Comparison of the effectiveness of levofloxacin and amoxicillin/clavulanate for the treatment of acute sinusitis in adults. *Otolaryngol Head Neck Surg*. 1999;120(3):320-7. doi: 10.1016/S0194-5998(99)70269-X, PMID 10064632.
11. Lemiengre MB, van Driel ML, Merenstein D, Young J, De Sutter AIM. Antibiotics for clinically diagnosed acute rhinosinusitis in adults. *Cochrane Database Syst Rev*. 2012;10:CD006089. doi: 10.1002/14651858.CD006089.pub4, PMID 23076918.
12. Chow AW, Benninger MS, Brook I, Brozek JL, Goldstein EJC, Hicks LA et al. IDSA clinical practice guideline for acute bacterial rhinosinusitis in children and adults. *Clin Infect Dis*. 2012;54(8):e72-e112. doi: 10.1093/cid/cir1043, PMID 22438350.
13. File TM Jr, Lode H, Kurz H, Kozak R, Xie H, Berkowitz E. 600 study group. Double-blind, randomized study of the efficacy and safety of oral pharmacokinetically enhanced amoxicillin-clavulanate (2,000/125 milligrams) versus those of amoxicillin-clavulanate (875/125 milligrams), both given twice daily for 7 days, in treatment of bacterial community-acquired pneumonia in adults. *Antimicrob Agents Chemother*. 2004;48(9):3323-31.
14. Raza M, Zaman A, Khan AR, Khan Z. Comparison of efficacy of amoxicillin clavulanate and levofloxacin in treatment of acute bacterial sinusitis. *Cell*. 2015;333:9153721.
15. Anon JB, Berkowitz E, Breton J, Twynholm M. Efficacy of Amoxicillin/clavulanate in adults with bacterial rhinosinusitis. *Am J Otolaryngol*. 2006;27:248-54.
16. Adelglass J, Jones TM, Ruoff G, Kahn JB, Wiesinger BA, Rielly-Gauvin K et al. A multicenter, investigator blinded randomized comparison of oral levofloxacin and oral clarithromycin in the treatment of acute bacterial sinusitis. *Pharmacotherapy*. 1998;18(6):1255-63. doi: 10.1002/j.1875-9114.1998.tb03145.x, PMID 9855324.
17. Baz MN, Jannetti W, Villanueva C. The efficacy and tolerability of moxifloxacin compared to trovafloxacin in the treatment of acute sinusitis. *Today's Ther Trends*. 1999;17:303-17.
18. Adelglass J, DeAbate CA, McElvaine P, Fowler CL, LoCocco J, Campbell T. Comparison of the effectiveness of levofloxacin and amoxicillin/clavulanate for the treatment of acute sinusitis in adults. *Otolaryngol Head Neck Surg*. 1999;120(3):320-7. doi: 10.1016/S0194-5998(99)70269-X, PMID 10064632.
19. Wald ER, Chiponis D, Ledesma-Medina J. Comparative effectiveness of amoxicillin and amoxicillin-clavulanate potassium in acute paranasal sinus infections in children: a double-blind, placebo-controlled trial. *Pediatrics*. 1986;77(6):795-800. doi: 10.1542/peds.77.6.795, PMID 3520469.
20. Garbutt JM, Goldstein M, Gellman E, Shannon W, Littenberg B. A randomized, placebo controlled trial of antimicrobial treatment for children with clinically diagnosed acute sinusitis. *Pediatrics*. 2001;107(4):619-25. doi: 10.1542/peds.107.4.619, PMID 11335733.
21. Van Buchem FL, Knottnerus JA, Schrijnemaekers VJ, Peeters MF. Primary care based randomized placebo controlled trial of antibiotic treatment in acute sinusitis. *Lancet*. 1997;349(9053):683-7. doi: 10.1016/s0140-6736(96)07585-x, PMID 9078199.
22. Spurling GK, Del Mar CB, Dooley L, Foxlee R. Delayed antibiotics for respiratory infections. *Cochrane Database Syst Rev*. 2007;4:CD004417.