ORIGINAL RESEARCH

Amoxicillin/potassium clavulanate is effective treatment for acute bacterial sinusitis in children

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ABSTRACT
Background: The study was conducted to evaluate that Amoxicillin/potassium clavulanate is effective treatment for acute bacterial sinusitis in children. **Material and methods:** This research was a cross-sectional study involving 20 children aged between 1 and 10 years. The participants received either Amoxicillin (90 mg/kg) combined with potassium clavulanate (6.4 mg/kg) or a placebo. Symptom assessments were conducted on days 0, 1, 2, 3, 5, 7, 10, 20, and 30. A clinical evaluation of the patients took place on day 14. The children's health outcomes were classified as cured, improved, or failed based on established scoring criteria. Statistical analysis was conducted using SPSS software. **Results:** In this study, the symptoms persisted in 6 subjects and non-persistence was seen in 14 subjects.Mild illness was seen in 4 subjects, moderate illness was seen in 9 cases and severe illness was seen in 7 subjects. Out of 20 subjects, 17 cases got cured, 2 cases were improved and 1 case showed failure. **Conclusion:** Most of the cases got cured with the treatment, a few cases showed improvement while only 1 case showed failure. This concluded that amoxicillin was effective in treating bacterial sinusitis in children.
Keywords: Amoxicillin, Potassium clavulanate, bacterial sinusitis.

INTRODUCTION

Sinusitis, characterized by the inflammation of the mucosal lining of one or more paranasal sinuses, can be categorized based on the duration of clinical symptoms into three types: acute (lasting less than 30 days), subacute (30 to 90 days), and chronic (exceeding 90 days). Acute sinusitis may arise from viral, bacterial, or fungal infections, as well as from environmental irritants and allergies. Acute bacterial sinusitis (ABS) typically occurs as a secondary bacterial infection of the sinus. Research indicates that around 7.5% of upper respiratory tract infections (URI) in children are complicated by ABS.[1,2]

Despite its common occurrence, ABS is frequently overlooked in young children due to the non-specific nature of its clinical manifestations and the prevailing belief that bacterial sinusitis is uncommon in this demographic.[3]If left untreated, ABS can progress to subacute or chronic sinusitis and may lead to severe or life-threatening complications. Consequently, ABS presents a diagnostic and therapeutic challenge for primary care pediatricians who may lack familiarity with this condition.[1-3]

This study was conducted to evaluate that Amoxicillin/potassium clavulanate is effective treatment for acute bacterial sinusitis in children

MATERIAL AND METHODS

This research was a cross-sectional study involving 20 children aged between 1 and 10 years. The participants received either Amoxicillin (90 mg/kg) combined with potassium clavulanate (6.4 mg/kg) or a placebo. Symptom assessments were conducted on days 0, 1, 2, 3, 5, 7, 10, 20, and 30. A clinical evaluation of the patients took place on day 14. The children's health outcomes were classified as cured, improved, or failed based on established scoring criteria. Statistical analysis was conducted using SPSS software.

RESULTS

Table 1: Persistence of symptoms

Variable	Number of cases	Percentage
Persistence	06	30
Non-persistence	14	70

In this study, the symptoms persisted in 6 subjects and non-persistence was seen in 14 subjects.

Table 2: Degree of illness

Degree of illness	Number of cases	Percentage
Mild	04	20
Moderate	09	45
Severe	07	35

Mild illness was seen in 4 subjects, moderate illness was seen in 9 cases and severe illness was seen in 7 subjects.

Table 3: Treatment outcome

Outcome	Number of cases	Percentage
Cured	17	85
Improved	02	10
Failure	01	05

Out of 20 subjects, 17 cases got cured, 2 cases were improved and 1 case showed failure.

DISCUSSION

The paranasal sinuses, which include the maxillary, ethmoidal, sphenoidal, and frontal sinuses, are bilateral structures that arise as extensions of the mucous membranes found in the nasal meatuses.[4,5]

These air-filled cavities are lined with ciliated, pseudostratified columnar epithelium. The maxillary and ethmoidal sinuses begin to form during the third to fourth month of gestation and, despite their small size, are typically present at birth. In contrast, the sphenoidal and frontal sinuses generally do not develop until the ages of 2 to 3 years and remain underdeveloped until approximately 5 to 6 years of age.[6] Complete pneumatization of the maxillary and ethmoidal sinuses is usually reached by around 12 years of age, while the frontal and sphenoidal sinuses may not fully mature until the age of 20.

The drainage pathways for the maxillary, frontal, and anterior ethmoidal sinuses lead to the middle meatus, whereas the sphenoidal and posterior ethmoidal sinuses drain into the superior meatus located beneath the superior turbinate.[6]

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The purpose of this study conducted by Wald ER et al[7] was to determine the effectiveness of high-dose amoxicillin/potassium clavulanate in the treatment of children diagnosed with ABS. This was a randomized, double-blind, placebo-controlled study. Children 1 to 10 years of age with a clinical presentation compatible with ABS were eligible for participation. Patients were stratified according to age (<6 or >or=6 years) and clinical severity and randomly assigned to receive either amoxicillin (90 mg/kg) with potassium clavulanate (6.4 mg/kg) or placebo. A symptom survey was performed on days 0, 1, 2, 3, 5, 7, 10, 20, and 30. Patients were examined on day 14. Children's conditions were rated as cured, improved, or failed according to scoring rules. Two thousand one hundred thirty-five children with respiratory complaints were screened for enrollment; 139 (6.5%) had ABS. Fifty-eight patients were enrolled, and 56 were randomly assigned. The mean age was 66 +/- 30 months. Fifty (89%) patients presented with persistent symptoms, and 6 (11%) presented with nonpersistent symptoms. In 24 (43%) children, the illness was classified as mild, whereas in the remaining 32 (57%) children it was severe. Of the 28 children who received the antibiotic, 14 (50%) were cured, 4 (14%) were improved, 4 (14%) experienced treatment failure, and 6 (21%) withdrew. Of the 28 children who received placebo, 4 (14%) were cured, 5 (18%) improved, and 19 (68%) experienced treatment failure. Children receiving the antibiotic were more likely to be cured (50% vs 14%) and less likely to have treatment failure (14% vs 68%) than children receiving the placebo. ABS is a common complication of viral upper respiratory infections. Amoxicillin/potassium clavulanate results in significantly more cures and fewer failures than placebo, according to parental report of time to resolution of clinical symptoms.

Poachanukoon O et al.[8]This study compared the clinical efficacy and tolerability of cefditorenpivoxil and amoxicillin/clavulanate in children with uncomplicated acute bacterial rhinosinusitis.This was a randomized, investigator-blinded, controlled study in pediatric patients (age 1-15 years) with clinical and radiographic signs and symptoms of acute rhinosinusitis. Patients were allocated to receive either

cefditoren (8-12 mg/kg daily) or amoxicillin/clavulanate (80-90 mg/kg amoxicillin daily) for 14 days. Changes in sinus symptoms were assessed daily by patients or their parents using a quantitative symptom score (the S5 score). Rates of improvement, the primary efficacy measure, were also evaluated by the study investigators 7 and 14 days after the initial visit. Secondary outcome measures included time to improvement, adverse effects, and rates of relapse (assessed at days 21 and 28) and recurrence (assessed at day 60) of sinus symptoms. Relapse was defined as a subjective rating of lack of improvement at day 21 or 28 in a patient rated as improved on day 14, and recurrence was defined as sinus symptoms lasting for >or=10 days during the second month of follow-up in a patient rated as improved on day 28. Time to improvement was defined as the number of days between the initial visit and the time at which caregivers noted an improvement in patients' symptoms. Adverse events were monitored by parents/caregivers using a self-administered questionnaire and were also elicited by telephone contact.The study enrolled 142 pediatric patients: 70 in the cefditoren group (42 males, 28 females; median age, 7.15 years) and 72 in the amoxicillin/clavulanate group (37 males, 35 females; median age, 6.60 years). Four patients in the cefditoren group were excluded from the study analyses (2 who were noncompliant [used <80% of the assigned medication] and 2 who developed infection at other sites). There were no significant differences in baseline medical history or signs and symptoms between the 2 groups. Rates of improvement at day 14 in the cefditoren and amoxicillin/clavulanate groups were 78.8% (52/66) and 84.7% (61/72), respectively (P = NS). There was no significant difference in the change in S5 scores between groups at day 14. The median time to improvement was 3.0 days in both groups. There were no significant differences between groups in rates of relapse (9.1% and 11.1%) or recurrence (3.0% and 5.6%) of sinus symptoms. The most common adverse event in both groups was diarrhea, occurring in 4.5% of the cefditoren group and 18.1 % of the amoxicillin/clavulanate group. In these children with acute bacterial rhinosinusitis, there were no significant differences between cefditoren and amoxicillin/clavulanate, the currently recommended treatment, in terms of rates of response, relapse, or recurrence.

CONCLUSION

Most of the cases got cured with the treatment, a few cases showed improvement while only 1 case showed failure. This concluded that amoxicillin was effective in treating bacterial sinusitis in children.

REFERENCES

1. American Academy of Pediatrics, Subcommittee on Management of Sinusitis and Committee on Quality Improvement. Clinical practice guideline: management of sinusitis. Pediatrics. 2001;108(3):798–808.
2. Leung AKC, Kellner JD. Acute sinusitis in children: diagnosis and management. J Pediatr Health Care. 2004;18(2):72–76.
3. Zacharisen M, Casper R. Pediatric sinusitis. Immunol Allergy Clin North Am. 2005;25(2):313–332. vii.
4. American Academy of Pediatrics, Subcommittee on Management of Sinusitis and Committee on Quality Improvement. Clinical practice guideline: management of sinusitis. Pediatrics. 2001;108(3):798–808.
5. Leung AKC, Kellner JD. Acute sinusitis in children: diagnosis and management. J Pediatr Health Care. 2004;18(2):72–76.
6. Zacharisen M, Casper R. Pediatric sinusitis. Immunol Allergy Clin North Am. 2005;25(2):313–332. vii.
7. Wald ER, Nash D, Eickhoff J. Effectiveness of amoxicillin/clavulanate potassium in the treatment of acute bacterial sinusitis in children. Pediatrics. 2009 Jul;124(1):9-15.
8. Poachanukoon O, Kitcharoensakkul M. Efficacy of cefditorenpivoxil and amoxicillin/clavulanate in the treatment of pediatric patients with acute bacterial rhinosinusitis in Thailand: a randomized, investigator-blinded, controlled trial. Clin Ther. 2008 Oct;30(10):1870-9.