

# AZYTHROMICIN VERSUS AMOXICILLIN- CLAVULANATE IN THE TREATMENT OF ACUTE SINUSITIS IN CHILDREN

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## ABSTRACT

In this prospective study we compared the efficiency of azithromycin and amoxicillin-clavulanate in treatment of acute sinusitis in children. Seventy patients were included in the age between 5 and 15 years. Beside ENT and pediatricians examination, nasal and throat smear on culture and antibiogram is taken from all the patients, as well as, X-ray of paranasal sinuses and laboratory findings, followed by check-up of nasal and throat smear and X-ray of paranasal sinuses. Azithromycin in single daily dose of 10 mg/kg during three days showed same efficiency as amoxicillin-clavulanate given three times per day in dose of 45 mg/kg during ten days.

KEY WORDS: acute sinusitis, children, azithromycin, amoxicillin-clavulanate

## INTRODUCTION

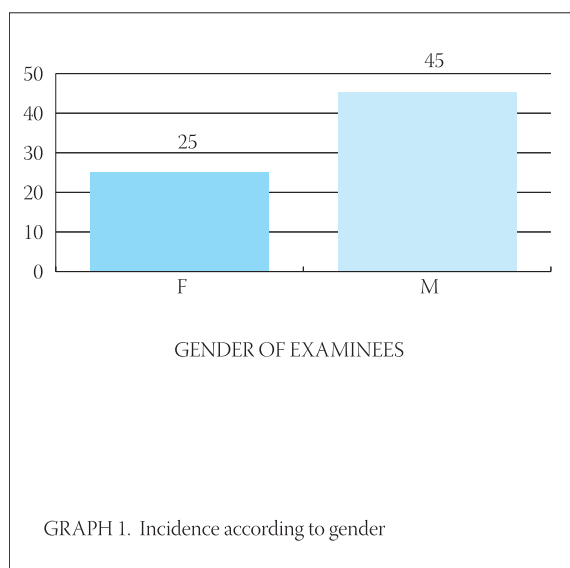
The treatment of acute sinusitis in childhood is, in most cases, based on antibiotic treatment (1). Even minimally invasive sinus surgery with aim to widen natural ostium doesn't have a lot of supporters in our country (2,3). Since the swelling of paranasal sinuses mucosa is very often in children and combined with the infection of upper respiratory tract, we conducted this study with goal to compare the efficiency of azithromycin and amoxicillin-clavulanate in the treatment of acute sinusitis (4,5).

## PATIENTS AND METHODS

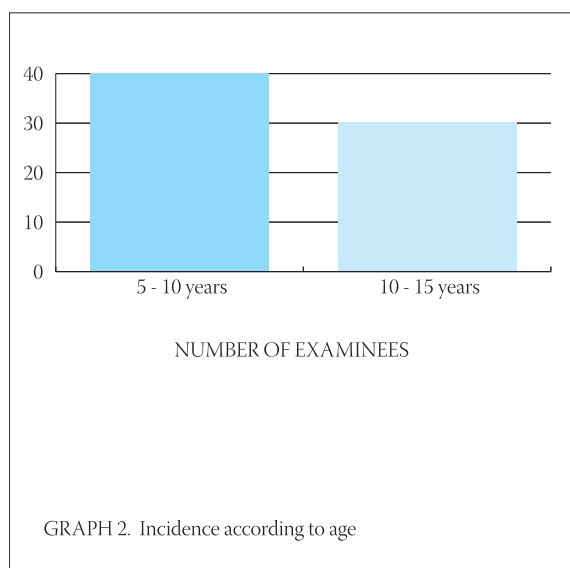
This research made in concordance of recommends from Good Clinical Practice guidelines (GCP) involving human subjects and material derived from human subjects complied with ethical principles outlined in World Medical Association Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects. The children treated in outpatient department were included in this prospective clinical study. Total number of children is 70, 45 male and 25 female in the

	Azithromycin	Amoxicillin/ clavulanate
Included in study	45	32
Full dosis applied	40	30
Didn't show up on follow-up examination	5	2

TABLE 1. Observed group of examinees



GRAPH 1. Incidence according to gender

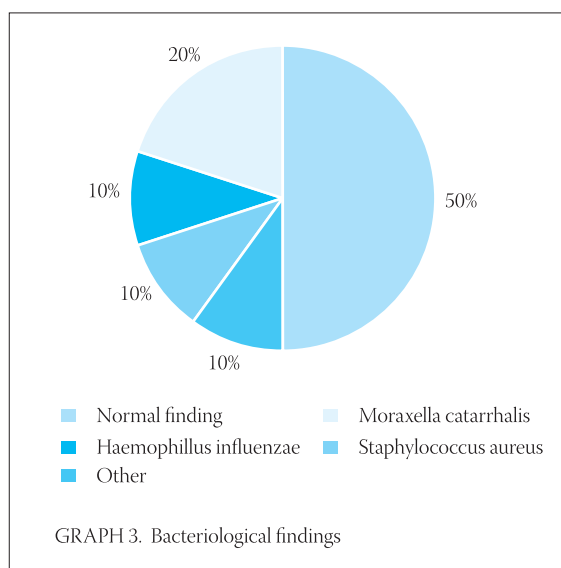


GRAPH 2. Incidence according to age

age between 5 and 15 years. Beside ENT and pediatricians examination, nasal and throat smear on culture and antibiogram is taken from all the patients, as well as, X-ray of paranasal sinuses and laboratory findings. In the patients where positive bacteriological finding in the nose and X-ray obvious sinusitis (maxillary sinus was predominant site of inflammation) were encountered, we applied azithromycin in single daily dose of 10 mg/kg during three days or amoxicillin-clavulanate given three times per day in dose of 45 mg/kg during ten days with ephedrin hydrochloride nasal decongestive solution twice a day. 10-15 days following treatment we did check-up nasal and throat smear and X-ray of paranasal sinuses.

## RESULTS

Observed groups of examinees included 45 patients, treated with azithromycin and 32 with amoxicillin/clavulanate, among them 40 patients received full dosage of azithromycin and 30 od amoxicillin clavulanate. Seven patients did not show up on follow up examination (Table 1). Total number of observed children was 70, 45 male and 25 female (Graph 1). Age distribution was: 40 between 5-10 years, 30 between 10-15 years. In all observed groups we took nasal and throat smear, culture and antibiogram which showed normal finding in 50%, Moraxella catarrhalis was isolated in 20%, Haemophilus influenzae in 10%, Staphylococcus aureus in 10%, other bacteria were isolated in 10% of patients. We analyzed X ray findings at the first examination, as well as tenth day of treatment. According to sinus location, maxillary sinus prevailed (Table 2). There was good response on azithromycin therapy in maxillary sinus infection as evident on X rays (10th day of treatment). In some cases therapy effect was evident after 20 days.



GRAPH 3. Bacteriological findings

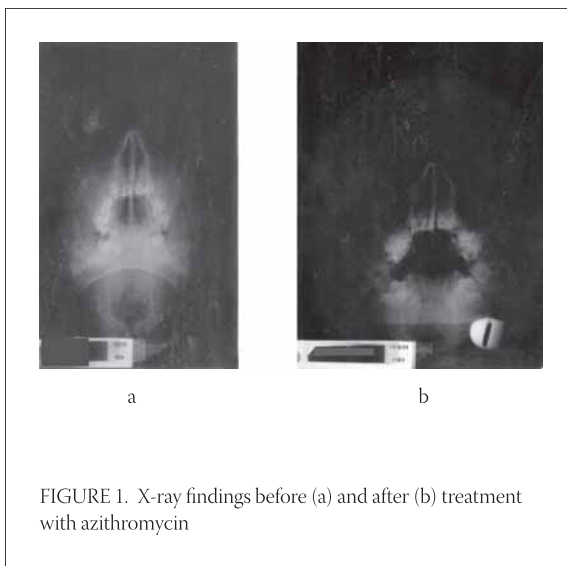


FIGURE 1. X-ray findings before (a) and after (b) treatment with azithromycin

Location	N°. of patient treated	After treatment	
		Improvement	Recovery
Maxillary sinus	54	10	44
Frontal sinus	6	-	6
Ethmoid sinus	10	2	8

TABLE 2. X-ray findings

## DISCUSSION

Both antibiotics were well tolerated. The incidence of adverse events was low in both treatment groups; there were no significant differences between azithromycin and amoxicillin/ clavulanate. There also were no severe adverse reactions attributable to either agent. Treatment with azithromycin in a single dose of 10 mg/kg during three days showed same efficiency as amoxicillin/ clavulanate which has been applied three times per day during ten days in a dose of 45 mg/ kg. Since all the patients had follow up check 10-15 days after treatment we couldn't make a conclusion regarding when, actually, the improvement occurred. Bacteriological eradication at the end of treatment was similar comparing both groups. X-ray verified improvement or recovery was similar in both groups, too.

## CONCLUSION

Azithromycin in a single day dose during three days has the same efficiency as amoxicillin/ clavulanate applied three times per day during ten days in the treatment of acute sinusitis.

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