

STUDY OF SHORT USE OF PREDNISONE IN THE TREATMENT OF MIDDLE EAR EFFUSION

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Abstract

It is well known that otitis media with effusion is one of the most common diseases in Otolaryngology. The role of oral steroids is controversial in the conservative treatment of such disease. A double blind randomized study was performed to evaluate the efficacy of oral steroids in combination with amoxicillin for the treatment of otitis media with effusion. Four hundred and eight children age group 3.5 to 7 years with otitis media with effusion during 1999 - 2001 in a double – blind , randomized prospective study to evaluate the efficacy of oral steroids in the department of Otolaryngology at Imam Khomeini Hospital were treated. Results obtained in this study showed complete recovery from otitis media with effusion in the group treated by a combination of oral steroid with amoxicillin , compared with amoxicillin or placebo treated group. The findings of our study imply that a combined course of amoxicillin with oral steroids deserves its place as a routine conservative trial before surgery.

Key words:

Otitis, effusion, amoxicillin, oral steroid,

Introduction

Otitis media with effusion is one of the most common diseases in otolaryngological practice and if not treated in time can cause a wide range of complication (1). The administration of steroids in the form of either a topical nasal spray or a systemic preparation has been advocated for treatment of otitis media with effusion for the last three decades (2).

In 1995, approximately 25 million office visits were related to otitis media in the United States (1). Most children by the age of 7 years at least have experience of acute otitis media and about one third have recurrent of acute Otitis media (3). In the conservative treatment of otitis media with effusion, the role of oral corticosteroids is controversial (4).

Heisse reported excellent results with depomethyl prednisolone in 30 allergic

patients who had otitis media with effusion (5). Oppenheimer recommended a short – term trial of corticosteroids in children (6). Savic also reported success in treating allergic children who had middle ear effusions a 4 day course of prednisolone (7).

Schwartz and colleagues in 1988 reported 70 percent success in treating 41 children with a 7 days course of prednisolone in a double – blind, placebo – controlled , cross – over study (8). The steroid appeared to be equally effective in those children who had and in those who did not have a history of allergy (1).

Other studies challenged the good results of steroids in the conservative treatment of otitis media with effusion. Thus Macklin and Jones found no difference between dexamethasone and placebo, and Lambert reported that the combination of prednisolone and amoxicillin was no more

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effective than placebo or amoxicillin alone in double-blind study of 60 children with otitis media with effusion of at least 2 months duration (9) . We decided to perform a double-blind, strictly randomized study to evaluate the efficacy of oral steroids in the treatment of persistent otitis media with effusion.

Patients and methods

From December 1999 to December of 2001 a total of 408 children with otitis media with effusion of at least 3 months duration entered this study. They were seen in Otolaryngology department of Emam Khomeini Hospital of Ahwaz Jundishapur Medical Sciences University. Patients were referred to us by otolaryngologists and resident associated with otolaryngology department. They were treated randomly under our supervision and followed up in the outpatient clinics. The children so treated were sent up for a final evaluation 6 weeks after the beginning of treatment.

The diagnosis of hypertrophic adenoids was made by lateral neck X-Ray. The adenoid – nasopharyngeal ratio was measured as described by Fujioka et al (10). Children with an adenoidal nasopharyngeal ratio greater than 0.73, which was indicative of pathologic enlargement of the adenoids, were also excluded from this study.

The diagnosis of otitis media with effusion was made by pneumo- otoscopy, audiometry and tympanometry. If otitis media with effusion was diagnosed by pneumo –otoscopy and tympanogram was flat (Type B) , the child was included in the study. The children who met these criteria were randomly divided into three groups. The first group of 157 children mean age,

6.5 years received amoxicillin 50mg/kg and placebo for 10 days. The second group of 150 children means age 7.1 years received amoxicillin 50 mg/kg and prednisolone (1mg/kg) for 10 days. The dosage of prednisolone reduced by 5 mg every two days. The third group consisted of 101 children (mean age of 6.1 years) which were treated by placebo alone.

After 6 weeks, a clinical and audiologic reevaluation was performed. The criteria for success were a normal eardrum, a closure of the air-bone gap and a normal tympanogram (type A). The presence of tympanic retraction, some conductive hearing loss or a type C tympanogram was considered as partial improvement which required further therapy. No improvement at all was the third possibility.

The results of otoscopy and tympanometry were statistically evaluated using the X^2 test for contingency tables.

Results

The age and sex distribution of the different treatment groups is presented in table 1, which indicate that there is much similarity between three groups. The post treatment change is summarized in table 2. The results of the differences between the three treated groups are summarized in Table 3.

According to table 1. males have a higher incidence of otitis media with effusion than females. According to table 2. Children treated with a combination of prednisolone and amoxicillin achieved good results than other children. As the number of patients were 157, the obtained results were statistically significant (Table 2,3) .

Table 1: Age and sex distribution

Treatment group	No. of subjects	Age range (years)	Mean age (years)	Sex	
				M	F
1	157	4 - 7.5	6.5	87	70
2	150	3.5 - 7	7.1	77	73
3	101	4 - 7	6.1	55	46

Table 2: Improvement rate of air-bone gap and tympanogram of the different groups

Groups	Complete Improvement		Partial Improvement		No Improvement	
	Audiometry	Tympanometry	Audiometry	Tympanometry	Audiometry	tympanometry
1	66 (40%)	65 (30%)	31 (20%)	25 (10%)	60 (40%)	57 (60%)
2	60 (40%)	66 (40%)	75 (50%)	66 (40%)	15 (10%)	30 (20%)
3	0 (0%)	0 (0%)	53 (57%)	25 (15%)	48 (43%)	76 (85%)

Table 3: Statistic results of otoscopic, tympanometric pre treatment and post treatment

Group	Otoscopy severity		Tympanometry severity	
	X ²	P.value	X ²	P.value
1 and 2	21.0	0.001	15.8	0.000
1 and 3	5.4	<0.27	5.6	<0.052
2 and 3	30.8	<0.000	32.2	<0.000

Discussion

Abnormal function of the eustachian tube appears to be the most important factor in the pathophysiology of middle ear effusion (9,11). Sade tends to blame the mucociliary drainage system dysfunction as the major factor responsible for otitis media with effusion (12). The logic of using a combined antimicrobial and steroid treatment in otitis media with effusion is to facilitate the surfactant production, thereby decreasing the viscosity of middle ear fluid, reducing the edema around the torus, and destroying the bacteria in the nasopharynx and the potential pathogens in the fluid itself (5). Persico and coworkers postulated that the drug altered surface tension forces within the lumen of the eustachian tube (4). Schwartz and colleagues suggested that steroids may shrink the lymphoid tissue around the eustachian tube, acting on mucoproteins to decrease the viscosity of the middle ear effusion by reducing tubal edema or reversing metaplasia of the middle ear mucosa (8).

Niederman et al., reported good results in treating 22 children with otitis media with effusion with dexamethazone, but because of the small number of patients, the results

were not statistically significant (13). Lambert conducted a double blind, prospective, randomized, cross over study and found no difference between the group treated with amoxicillin and placebo and the group treated with amoxicillin and prednisolone (14).

Our study, which was also double-blind and randomized, showed that the group treated with amoxicillin and steroids had a much better response than the group treated with placebo or amoxicillin alone. As the number of patients are sufficient, these results are statistically significant. (Table 2) We think that the main differences between Lambert's results and ours can be explained by the age of the patients and the size of adenoids. In Lambert's study the age was 2 and 15 years but in our study was 3.5-7 years. Children younger than 3 years are prone to suffer from recurrent otitis media which are not good candidates for oral steroid therapy. The size of adenoids may be a factor in the differences between his and our results too.

Based on the results of our study, it seems to us that short term treatment with a combination of steroids and

antibiotics should have a place in the final stages of the conservative therapy before a surgical procedure is initiated.

Conclusion

The most common pathophysiologic factor of otitis media with effusion is some degree of eustachian tube dysfunction leading to hypoventilation and deficient drainage of the middle ear. One of the causes of this dysfunction could be the lack of surfactant; steroids can play a beneficial role in facilitating tubal surfactant production, thereby enhancing the return of normal tubal function. More investigations are required to find out the optimal time for initiation of therapy and the optimal dose of steroids. Meanwhile, we believe that our proposed combined treatment of steroids and antibiotics deserves its place as a routine conservative trial before surgery.

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