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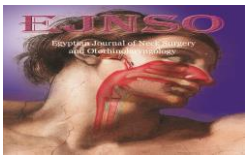

The Efficacy of Nasal Steroids in Treatment of Otitis Media with Effusion: A Comparative Study

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Abstract:

Introduction: Otitis media with effusion (OME) is defined as an effusion in the middle ear without signs and symptoms of an acute infection.

Objectives*:* To evaluate the efficacy of nasal steroids in OME in children by compared with oral steroids and with nasal saline spray.

Patients and Methods: This study included 60 children with bilateral OME. The children were divided into three equal groups; group A, 20 children received mometasone furoate nasal spray. In group B, 20 children received oral prednisolone. In group C, twenty children received hypertonic seawater nasal spray. Clinical follow-up was done once per week for four weeks, at the end of treatment, and then monthly for three months. Otoscopic examination, audiological evaluation was done before treatment for each group and repeated at 3,6 months after treatment.

Results: A highly significant difference between systemic or topical nasal steroid and hypertonic seawater nasal spray was detected regarding symptoms improvement, clinical examination, adenoids hypertrophy, and hearing condition. The difference between systemic and topical steroids was statistically insignificant.

Conclusion: Nasal steroid spray is an effective treatment for OME, similar to systemic steroid but without the hazard of corticosteroids.

Keywords: Otitis Media Effusion, Acute otitis media, Eustachian tube, mometasone furoate nasal spray, hypertonic seawater nasal spray, Secretory otitis media

Introduction

Otitis media with effusion (OME) is non-purulent fluid collection in the middle ear present more than three months without signs and symptoms of an acute infection. It is a leading cause of hearing impairment in children. Early and proper management can prevent hearing and speech impairment, which may cause developmental delay. [1-2]

Acute otitis media (AOM) is nearly universal and highly prevalent. More than 90% of children experience one or more episodes before the seventh birthday. [3] 30% of children below three years visit general practitioner with AOM each year. [2] 42% of antibiotic prescriptions in children under age 10 are for AOM.[4] After treatment of AOM,

fluid persists in the middle ear for weeks or months, leading to OME. [2]

OME is still a controversial issue, as conventional treatment approaches fail to provide satisfactory and permanent otology symptoms. [7]

The conventional treatment concludes 1.Antibiotics, 2.Intranasal steroids, 3.Systemic steroids, 4.Nasal decongestants and antihistamines 5.

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In 2016, an update of the 2004 guidelines was developed after extensive work and cooperation between the American Academy of Otolaryngology—Head and Neck Surgery Foundation, the American Academy of Pediatrics, and the American Academy of Family Physicians. After revising the strongest scientific, systematic reviews and evidence-based medical studies and reviews. The update group made strong recommendations to manage OME to clinicians (19). These recommendations were,

(1) Clinicians should document the presence of middle ear effusion with pneumatic Otoscopy when diagnosing OME in a child.
(2) Clinicians should perform pneumatic Otoscopy to assess for OME in a child with otalgia, hearing loss, or both.
(3) Clinicians should obtain tympanometry in children with suspected OME for whom the diagnosis is uncertain after performing (or attempting) pneumatic otoscopy.
(4) Clinicians should manage the child with OME who is not at risk with watchful waiting for three months from the date of effusion onset (if known) or three months from the date of diagnosis (if the onset is unknown).
(5) Clinicians should recommend against using intranasal or systemic steroids for treating OME.
(6) Clinicians should recommend against using systemic antibiotics for treating OME.
(7) Clinicians should recommend against using antihistamines, decongestants, or both for treating OME.

Patients and methods:

This study was an interventional comparative clinical study done in the outpatient clinic of the ENT department Assiut university hospital from August 2018 to October 2019 after obtaining approval from the institutional ethics committee and after obtaining consent from parents of all children sharing in this study.

The study was approved and monitored by the Medical Ethics Committee, Assiut Faculty of Medicine. IRB no: 17100366.

The investigators explained the steps and value of the research to all eligible parents of participants—those who agreed to be included in the study by fully informed verbal consent. The study had 60 children with OME.

Inclusion criteria:

1. Bilateral OME with type B tympanogram.
2. Conductive hearing loss (CHL)

Exclusion criteria:

1. Unilateral otitis media with effusion.
2. Previous surgery for OME.
3. Craniofacial anomalies and cleft palate.
4. Sensorineural hearing loss.
5. Previous history of radiotherapy.

The children were divided into three equal groups: group A, 20 children received mometasone furoate nasal spray, one puff in each nostril daily for 3months. In group B, 20 children received oral prednisolone, 5 mg three

times per day for three weeks, then gradual withdrawal over two weeks. In group C, 20 children received hypertonic seawater nasal spray, one puff in each nostril daily for three months. All sixty-child received amoxicillin (7.5mg /Kg per dose twice daily) for the first ten days. To overcome the possibility of infection.

The study included 60 children who had bilateral OME with type B tympanogram and CHL. Age range was from 4 to 12 years Children previously managed by ventilation tube and those who had a cleft palate or sensorineural hearing loss was excluded from the study.

These children were subjected to the following:

1-**Detailed history** was taken from the parents of children and from the children themselves when possible as regard aural symptoms (hearing loss, delayed language development (DLD) and earache); nasal symptoms(nasal obstruction, nasal discharge, sneezing, nasal itching, and postnasal discharge); nasopharyngeal and oropharyngeal symptoms (snoring, mouth breathing and/or sleep apnoea and sore throat). Family history of nasal allergy or bronchial asthma before and after treatment was recorded.

2-**General examination** for exclusion of any contraindication of steroid therapy.

3- **ENT examination** before and after treatment.

4-**Investigations** in the form of:

A-PTA before and after treatment was carried out to evaluate the degree of hearing loss in children older than five years old using Madsen Audiometer model Itera II (Denmark) at the audiology unit of Assiut university hospital. During a diagnostic hearing evaluation, the average pure tone is measured at different frequencies (0.5, 1, 2, and 4 kHz).

B-Tympanometry before and after treatment was done for all children included in the study. The evaluation was performed using Zodiac tympanometer model 902 (Denmark) at the audiology unit of Assiut university hospital, and its results were distinguished into four grades (type A, C1 , C2 , B) as classified by Cohen and Konak, 1985 (17)

C-Lateral view X-ray soft tissue to nasopharynx to detect adenoid hypertrophy.

Otoscope examination, Basic audiological evaluation including PTA, and immittancemetry were performed before treatment and repeated at 3, 6 months after treatment.

Follow-up clinical examinations were done once per week for 4weeks, at the end of treatment, and then monthly for three months. OME resolution was defined as normal findings on otoscope, type A tympanogram, and improved hearing.

Statistical analysis:

The data variables were described by number and percent (N, %), where continuous variables were described by the mean and standard deviation (Mean ± SD). Chi-square test and Fisher exact test used to compare between categorical variables where compare between continuous variables by t-test ANOVA. A two-tailed $p < 0.05$ was considered statistically significant. All analyses were performed with the IBM SPSS 20.0 software.

Results:

The Sixty children with bilateral OME enrolled in this study were equally distributed in the three groups (20

patients for each group). Their ages ranged from 4-12 years. Their main symptoms at presentation were hearing loss, Earache or discomfort, and DLD. The demographic data and the percentage of symptoms were shown in table (1).

As shown in table 2, there is a marked improvement of hearing in group A treated by mometasone furoate nasal (70%), and the least improvement was noticed in group C treated by hypertonic seawater solution (40%). On the contrary, improvement in earache was the best in group C treated by hypertonic seawater (66.7%) (figure1). DLD showed the best result in group B treated by oral prednisolone (66.7%).

Before treatment, all ears showed tympanic membrane retraction, loss of luster, and fluid level or air bubbles. All clinical findings showed the best improvement after steroid treatment either nasally or systemically and there was no significant difference p >.05) in the clinical findings between steroid spray and systemic steroids as shown in Table 3.

After treatment with nasal or systemic steroids, tympanometry revealed the best improvement regarding the tympanogram; the difference between them wasn't statistically significant compared to those treated with hypertonic seawater solution, as shown in table 4.

Regarding hearing improvement post-treatment, the difference between Mometasone furoate and Hypertonic seawater solution was highly significant ($p<0.001$). The difference between Oral prednisolone steroid and Hypertonic seawater solutions was highly significant ($p<0.001$). The difference between Oral prednisolone and Mometasone furoate nasal wasn't significant ($p=0.21$) as shown in table 5. (The table showed the differences of each method before and after treatment, not the differences among the three groups)

Table1: Personal characteristics of patients in the three studied groups

	Mozmetasone furoate (n=20)	Oral prednisolone (n=20)	Hypertonic sea water solution (n=20)
	No. (%)	No. (%)	No. (%)
Sex			
Male	12 (60%)	14(70%)	8(40%)
Female	8 (40%)	6(30%)	12(60%)
Age			
Mean ± SD	7.1±2.1	7.4±2.4	7.15±2.41
Main symptom at presentation			
Hearing loss	20(100%)	20(100%)	20(100%)
Earache	8(40%)	9(45%)	6(30%)
DLD	4(20%)	6(30%)	5(25%)
No. of negative smokers (Parental)	11 (55 %)	10 (50%)	8 (40 %)

Table 2: Effect on symptoms in each group before & after treatment.

			Hearing loss	Earache	DLD
Group (A) Mometasone furoate	**Before treatment**		**20(100%)**	**8(100%)**	**4(100%)**
	After treatment	**Improved**	**14(70%)**	**5(63%)**	**2(50%)**
		Not Improved	**6(30%)**	**3(37%)**	**2(50%)**
Group (B) Oral prednisolone	**Before treatment**		**20(100%)**	**9(100%)**	**6(100%)**
	After treatment	**Improved**	**12(60%)**	**5(56%)**	**4(67%)**
		Not Improved	**8(40%)**	**4(44%)**	**2(33%)**
Group (C) Hypertonic seawater solution	**Before treatment**		**20(100%)**	**6(100%)**	**5(100%)**
	After treatment	**Improved**	**8(40%)**	**4(67%)**	**2(40%)**
		Not Improved	**12(60%)**	**2(33%)**	**3(60%)**

Table 3: Results of post-treatment Clinical examination: -

Clinical observation at Otoscopy	Mometasone furoate (No, of ears)	Oral prednisolone (No, of ears)	Hypertonic seawater solution (No, of ears)	P. value
T. M retraction	**12**	**12**	**28**	**0.007****
Fluid level or air bubbles	**1**	**2**	**6**	**0.097**
Loss of luster	**8**	**12**	**20**	**0.061**
Normal	**27**	**28**	**10**	**0.009****

Table 4: Results of post-treatment tympanometry curves after three months in each group.

Tympanometry curves	Mometasone furoate spray (n=40) ears	Oral prednisolone (n=40) ears	Hypertonic seawater solution (n=40) ears	P. value
Type B	2	4	22	<0.001**
Type C1	6	4	4	0.752
Type C2	4	6	6	0.779
Type A	28	26	8	0.003**

Chi-square test,
* Statistically significant difference ($p<0.05$)
** Highly statistically significant difference ($p<0.01$).

Table 5: Comparison between before and after treatment average of hearing thresholds (improvement) and between after treatment and 6 months follow up:

	Before treatment HL (db)	Post-treatment HL (db)	6-month follow-up HL (db)	P. value
	Mean ±SD	**Mean ±SD**	**Mean ±SD**	
Mometasone furote spray	**30.9(±5.0)**	**14.6(±3.9)**	**14.4(±4.6)**	**<0.001****
Oral prednisolone	**31.8(±5.0)**	**15.6(±3.8)**	**15.9(±4.1)**	**<0.001****
Hypertonic seawater solution	**32.1(±4.7)**	**25.1(±4.3)**	**26.4(±5.4)**	**<0.001****

One-way ANOVA test,
* Statistically significant difference ($p<0.05$)
** Highly statistically significant difference ($p<0.01$).

Discussion :

OME is a common entity in children. It is a multifactorial disease, and it has long been recognized that ET dysfunction predisposes to OME. Allergic etiology has been supported in its pathogenesis by several scientific data. [9, 12] Due to the continuity of nasal mucosa with the middle ear mucosa, the changes in nasal mucosa can continue into the middle ear. Therefore, ET dysfunction is considered the underlying pathophysiological process for all chronic otitis media entities. [15-16]

Few studies have addressed the efficacy of nasal steroid spray on OME; two studies report that topical nasal steroid is beneficial either alone or with an antibiotic in treating OME at one month. However, the findings were not statistically significant [13-14], with no evidence of benefit beyond two weeks of treatment. [14]

On the other hand, an intranasal steroid for up to 6 weeks was found to be effective in patients with OME and adenoid hypertrophy. [12] In the current study, intranasal steroid for three months was found to be effective in patients with OME with and without adenoid hypertrophy.

The difference between systemic and nasal steroids was not significant. Thus, it is better to use nasal steroids as it minimizes systemic steroids' side effects, especially with mometasone furoate, which is known for its low bioavailability. It could be used for longer periods to maintain its effect for persistent relief of OME, in addition to its long-term control of the nasal allergy and the adenoid size, allowing time for the ET to recover. [12, 20] Moreover, steroids could exert their anti-inflammatory activity locally on the upper airways with limited or absent side effects. [20]

Our results agree with the results of Butler and Van Der Voort. They extracted data from the published reports and concluded that oral and topical intranasal steroids alone or in combination with an antibiotic led to a quicker resolution of OME in the short term. [11]

Hearing loss, whether detected by the child himself or by his caregiver at school or at home, was the main presenting symptom in our patients. It was present in all patients. Earache in the form of ear discomfort, short periods of pain, or rubbing the ear, especially in young children, was the next frequent complaint. It was present in one-third of patients. Delayed language and speech development were the least frequent complaint. Most studies in the literature support that OME is classically a painless condition. [21]

The duration of hearing loss in this current study varied from few weeks to more than one year. More than 80 % of studied children had hearing loss for more than six months. More than half of all patients had hearing loss for more than **nine** months. (Table2) The reason for this relatively long time of hearing loss is that we have chosen those cases with significant hearing loss where the decision of surgery has already been made. Such a significant hearing loss usually requires some time to establish.

This current study recorded the clinical effects of nasal mometasone on the ear. More than half of the patients noticed a subjective improvement of their hearing, denoting improvement in the OME. The improvement in earache was to a lesser extent, and the least improvement was in the DLD. It is well known that DLD needs a relatively long time to develop and a longer time to improve. We evaluated the patients after six weeks of treatment which is a relatively short time for delayed speech

and language to improve even with improved OME.

In addition to that, Controlled studies have failed to show any increased prevalence of an atopic history or positive skin prick tests in children with OME compared to normal children. [23] This, however, did not rule out that allergy can cause OME through its effect on ET physiology or mucociliary mechanism. [22] Some researchers have tried to link the patient's age as a determining factor that may modify the allergic effect on the middle ear mucosa. [24] It is also important here to mention the particular type of OME, which attained universal interest in the last decade and is called eosinophilic otitis media, which was proposed to be a local allergic reaction of the middle ear to a particular allergen.

Conclusion:

Nasal steroid spray is an effective treatment for OME, showing a result similar to systemic steroid but without the hazard of corticosteroid side effects.

Recommendation:

Further studies are needed to investigate its use for longer duration, larger scale and in recurrent cases.

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