

Research

Mometasone Furoate Nasal Spray as Adjunctive Treatment for Otitis Media with Effusion in Young Children

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Abstract

Background

Otitis media with effusion (OME) is a major cause of conductive hearing loss in the pediatric population. Steroids, through their anti-inflammatory effect on middle ear mucosa, Eustachian tube function and adenoid size may lead to quicker resolution of this condition.

Aim of the study

To assess the efficacy of nasal Mometasonefuroateas adjunctive treatment to oral antibiotics in OME in young children.

Methods

84 children in the age range 4-7 years; diagnosed clinically and with tympanometry as unilateral or bilateral OME were randomly divided into two equal groups: 1st group (n=42) received Mometasonefuroate aqueous nasal spray in combination with oral Amoxicillin-Clavulanate for 4 weeks. The 2nd group (n=42) received Amoxicillin-Clavulanate only for same period.

Results

After 2 weeks of treatment, 25 ears (40%) of the first group had normal type A tympanogram while in 2nd group only 8 ears (14%) had normal type A tympanogram (p=.002). After 1 month of treatment, 34 ears (55 %) of the 1st group had normal type A tympanogram while in 2nd group only 8 ears (14%) had type A tympanogram (p=.0001).

Conclusion

Mometasonefuroate nasal spray is useful when used as adjunctive therapy in management of OME in young children. Adjusting the

dose and duration of treatment is needed to maximize the benefit of this mode of treatment and to have a sustained response.

Key Words: Otitis Media; Mometasone; Topical; Tympanometry; Effusion

Introduction

Otitis media with effusion (OME), which is defined as accumulation of non-purulent fluid behind the intact eardrum is considered a major cause of conductive hearing loss in the pediatric population[1].

Hearing loss is generally mild and is often detected only with an audiogram. No pain or fever characterizes this condition although aural fullness may be reported by older children. The latter may be due to rapid decrease in middle ear pressure relative to the atmospheric pressure[2].

Pathophysiologic theory of this inflammatory condition is related to Eustachian tube. Equilibration of pressure between the middle and external ears, clearance of middle ear secretions and protection of the middle ear are the three function of this tube. Its dysfunction can be

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Sub Date: July 1st, 2019, **Acc Date:** July 7th, 2019, **Pub Date:** July 9th, 2019

Citation: Ahmed MR, EL Hennawi DM, Abou-Halawa AS, Naeem Gad Allah (2019) Mometasone Furoate Nasal Spray as Adjunctive Treatment for Otitis Media with Effusion in Young Children. Annl Otolarinl 3: 015.

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caused by anatomic blockage e.g. large adenoids and/or inflammatory blockage e.g. infection or allergy[3].

Oral steroids alone or combined with an antibiotic lead to a quicker resolution of OME in the short-term; by their anti-inflammatory effect. Other potential mechanisms of action include directly shrinking tissue around Eustachian tube, improving Eustachian tube surfactant secretion, and reducing viscosity of middle ear fluid[4].

Although short-term use of systemic steroids has no clinically noticeable side effects, their long-term use is fraught with severe side effects.

Nasal steroids have been used in young children without systemic side effects[5]. Mometasone furoate is a glucocorticoid that could be used in children more than 2 years of age to control the symptoms of allergic rhinitis and to improve nasal breathing in children with adenoid hypertrophy[6,7].

The aim of the present study is to assess the efficacy of mometasone furoate nasal steroid as adjunctive therapy in young children who have OME.

Materials and Methods

This is a prospective study conducted in the Otolaryngology Department, Suez Canal University Hospital (Ismailia, Egypt) from September 2016 to March 2017. The study protocol was approved by the local ethics committee and a written informed consent was obtained from parents. Eighty-four children aged 4-7 years with unilateral or bilateral OME were included. Children with adenoid hypertrophy grade 2 and grade 3 (Mary K et al, 2005 classification) were excluded from our study[8]. Also, children with craniofacial anomalies such as cleft palate were also excluded. To avoid any confounding effect of the nasal status and to study the direct effect of Mometasone on the middle ear, we excluded children with allergic rhinitis based on clinical ground i.e. those with persistent nasal stuffiness, discharge and irritation and those who were already on anti-allergic treatment.

Study Design

All patients were subjected to complete head and neck evaluation, including otoscopic examination. OME was diagnosed clinically i.e. retraction of tympanic membrane, loss of luster, fluid level or air bubbles in middle ear and confirmed with tympanometry[9]. Type B tympanogram or flat curve is used as indicative of middle ear effusion.

Nasal endoscopy with flexible scope was used to assess the grade of the adenoid tissue depending on the degree of choanal obstruction as follows: Grade 1: <50% of choanal space occupied, Grade 2: 50-75% of choanal space occupied and Grade 3: >75% of choanal space occupied[8].

Patients were divided into two equal groups: 1st group received Mometasone furoate aqueous nasal spray (Nasonex® Schering Plough Corporation) 100mcg/day in form of nasal spray (50 mcg/puff) one puff per each nostril once daily for 1 month in addition to Amoxicillin-Clavulanate 90mg/kg/day for the same period[4-11]. The 2nd group received Amoxicillin-Clavulanate 90mg/kg/day for 1 month.

Parents were instructed how to use this nasal spray in the clinic. Follow up of both groups was done clinically and with tympanometry after 2 weeks and 1 month of treatment.

Statistical Analysis

Data collected were processed using SPSS version 15 (SPSS Inc., Chicago, IL, USA). Wilcoxon two-sample test was used to analyse the tympanometric results and level of significance was set at .05.

Ethical Consideration

Parents of children included in the study have been informed before the study and written informed consent was obtained from them. The local ethics committee approved the study.

Results

The mean age in 1st group was 5.7 ± 1.4 years while the mean age in 2nd group was 5.8 ± 1.3 years. Forty-three percent were boys and 57% girls in the 1st and 40% boys and 60% girls in the 2nd group without statistically significant difference ($p > .05$).

In the 1st group, 20 children (48%) had bilateral OME and 22 children (52%) had unilateral OME while in 2nd group, 22 children (52%) had bilateral OME and 20 patients (48%) had unilateral OME without statistically significant difference between the two groups. Overall we had 62 ears with OME in 1st group and 64 ears with OME in the 2nd group.

After 2 weeks of treatment, tympanometric results were as follows (Table 1): in 1st group: 25 ears (40%) had normal type A tympanogram, 13 ears (22%) with type C and 24 ears (38%) had type B tympanogram (flat curve) indicating persistent middle ear effusion. In 2nd group only 8 ears (12%) had normal type A tympanogram, 9 ears (14%) with type C and 47 ears (74%) had type B tympanogram. The difference between the two groups was highly statistically significant ($p = 0.002$).

After 1 month of treatment tympanometric results were as follows (Table 2): in the 1st group 34 ears (55%) had normal type A tympanogram, 17 ears (28%) with type C and 11 ears (17%) had type B tympanogram (flat curve) indicating middle ear effusion. In the

Table 1: Tympanometry results after 2weeks of treatment

	Study group		Control group		p-value
	N= 62 ears		N= 64 ears		
Type A	25	40%	8	12%	0.002* ^c
Type C	13	22%	9	14 %	
Type B	24	38%	47	74%	

^c: Wilcoxon 2 sample test *: statistically significant difference

Table 2: Tympanometry results after 1 month

	Study group		Control group		p-value
	N= 62 ears		N= 64 ears		
Type A	34	55 %	8	14 %	0.0001 ^c *
Type C	17	28 %	28	43%	
Type B	11	17 %	28	43%	

^c: Wilcoxon 2 sample test *: statistically significant difference

2nd group only 8 ears (14%) had normal type A tympanogram, 28 ears (43%) with type C and 28 ears (43%) with type B tympanogram. The difference between the two group was highly statistically significant (p= 0.0001).

Discussion

Eighty percent of all children had an episode of OME by the age of 10 years, mostly by the age of 3 years [12]. However, OME may be present without significant hearing loss and the positive predictive value of abnormal tympanogram for hearing loss of > 25 dB was estimated by Kazanas and Maw to be as low as 49% [13].

In a prospective randomized double blind study comparing nasal momtasonefuroate with placebo in children s with adenoid hypertrophy and bilateral OME. Rahul and Arunabha had significantly more resolution of the disease in study group compared control group (p= 0.0004). Moreover, significant improvement in hearing loss and other symptoms was seen in the study group (p < 0.04) [14].

Another comparative study was carried by El-Anwar MW et al., on 60 patients with OME divided into three groups: 20 patients received momtasonefuroate spray, one puff in each nostril daily, for 3 months; 20 patients received oral prednisolone, 5mg three times per day for 3 weeks; and 20 patients received nasal saline spray, one puff in each nostril daily for 3 months. Tympanometry 3 and 6 months after treatment showed a highly significant difference between steroid therapy either systemic or nasal and saline nasal spray (p < 0.001), while the difference between systemic and topical steroid was non-

significant (p > 0.05) [15].

In another double blind randomized placebo controlled trial in 217 children aged (4-11 years) who had tympanometrically confirmed bilateral OME, Williamson, et al. gave either mometasone nasal spray one puff /nostril (n=105) or placebo nasal spray (n=112), for three months. They concluded contrary to the previous study and our study that intranasal corticosteroids were not likely to be an effective means of treating children with bilateral OME, a disease that has a particularly high natural resolution rates occurring after as little as one month of follow-up [16].

In another prospective, controlled, randomized study, Cengel and Akyol divided 122 children (3-15year-old) who were on the waiting list for an adenoidectomy and/or ventilation tube placement into two groups: 67 patients with adenoid hypertrophy, 34 of them with OME received intranasal momtasonefuroate monohydrate 100 mcg/day, and 55 patients with adenoid hyper trophy, 29 of them with OME received saline nasal spray. After 6 weeks, resolution of OME in Mometasone group (42.2%) was significantly higher than that in the control group (14.5%) (P < 0.001). Forty-five patients (67.2%) with adenoid hypertrophy in Mometasone group showed a significant decrease in adenoid size compared to the control group (p < 0.001) [5].

Tracy et al., studied the efficacy of intranasal beclomethasone as an adjunct to treatment of chronic ME effusion and found 15-16% difference in tympanometry outcomes after one month but smaller effect of 7-8% on symptomatic outcomes [17]. Mandel et al., found that trials of oral corticosteroids alone and in combination with an antibacterial agent had short-term efficacy and recurrence of OME was common [18].

There is some heterogeneity among different studies involving topical steroids in OME with or without antibiotics. This could be explained by differences in pharmaceutical formulation, duration of steroid treatment and concomitant antibiotic.

We also admit that even if we had statistically significant improvement of OME in the 1st group using momtasone nasal spray with oral antibiotic compared to the 2nd group using antibiotic only, a placebo group using normal saline spray would have added power to the study. We plan to do this in a future study with larger sample size and longer follow up period.

Conclusion

Mometasonefuroate nasal spray is useful as adjunctive therapy in management of OME in young children. Adjusting the dose and duration of treatment is needed to maximize the benefit of this mode of treatment and to have sustained response.

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