A comparative study of the efficacy of topical nasal steroids versus systemic steroids in the treatment of otitis media with effusion in children

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Objective
To evaluate the effectiveness of using topical nasal steroids versus oral steroids in the treatment of otitis media with effusion (OME) in children.
Methods
One hundred (100) patients were included in the study, they were divided into two equal groups, group A received intranasal mometasone furoate spray once daily for 6 weeks, and group B received oral steroids in tapering doses for 6 weeks, plus systemic antibiotics, and nasal decongestants for both groups, tympanogram was done every 2 weeks for all patients.
Results
Highly significant improvement ($P < 0.01$) of OME regarding symtoms, signs, and tympanometric results, occurred in each group separately at the end of the study, with no significant difference ($P > 0.05$) in improvement between the two groups.
Conclusion
Both topical intranasal and oral steroids are effective medical therapy in the treatment of OME in children with no significant difference between the two methods.

Keywords:
otitis media with effusion, systemic steroids, topical nasal steroids

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Introduction

Otitis media with effusion (OME) or glue ear is the collection of fluid behind the tympanic membrane without inflammatory signs present for 6 weeks [1].

By the age of 4 years, ~80% of children will have had an episode of OME, most of which resolve and only 10% of episodes last for a year or more [2].

The natural history of otitis media is very favorable. Combined estimates of spontaneous resolution provide a benchmark, against which new or established interventions can be evaluated. The need for surgery in children with recurrent acute otitis media (AOM) or chronic OME should be balanced against the likelihood of timely spontaneous resolution and the potential risk for learning, language, or other adverse sequelae from persistent middle ear effusion [3].

Adenoidal hypertrophy (AH) and OME are the most frequent indications for surgery in children. The current treatment options for OME include the following: elimination of the risk factors, follow-up without treatment, use of antibiotic and/or decongestant medication, maneuvers to open the Eustachian tubes, such as with nasal balloons, prophylactic antibiotic use, and, if medical treatment fails, tympanostomy tube placement with or without adenoidectomy [4,5].

Recently, a potential role of corticosteroids in the treatment of OME has emerged. The short-term use of systemic steroids provides a temporary improvement, but long-term use of systemic steroids is not appropriate in children due to severe side effects. In contrast, topical nasal steroids without systemic side effects might be used [6].

This study aimed to compare the efficacy of the use of topical intranasal steroids with oral steroids in the treatment of OME in children.

Materials and methods

This study was conducted on 100 patients suffering from OME. Patients were selected from those attending ENT clinics of Kasr El Eini Cairo University Hospital during the period from January

2013 to September 2014. The study was approved by the scientific and ethical committee of Kasr Alaini Hospital, Faculty of Medicine, and Cairo University.

Inclusion criteria

(1) Children aged 3–10 years.
(2) Documented middle ear effusion by means of otoscopic examination and tympanometry (bilateral type B tympanogram) at the time of entry to the study.
(3) Conductive hearing loss in pure-tone audiometry, if possible, (above the age of 6 years) supporting the diagnosis of OME.

Exclusion criteria

(1) Children who have taken systemic or topical intranasal steroids in the previous 3 months.
(2) Children who previously underwent operative procedures for treatment of their OME.

All patients were subjected to the following diagnostic workup:

Full medical history including diminution of hearing, tinnitus, earache, or any associated complaint, and full clinical examination including general examination and otoscopic examination.

Basic audiological evaluation to diagnose otitis media with effusion

(1) Tympanometry: using low frequency probe tone 226 Hz for pressure applied to the external canal between +300 and −300 daPa.
(2) Pure-tone audiometry (if possible) was carried out in children older than 6 years to diagnose the degree of hearing loss.

Children meeting the inclusion criteria were divided into two equal groups:

Group A (50 children) received 50 μg (one puff) of topical intranasal mometasone furoate, once a day for 6 weeks in each nostril (total daily dose of 100 μg).

Group B (50 children) received oral prednisolone in syrup form at a dose of 1 mg/kg/day in divided doses in tapering doses for 6 weeks.

In addition, both groups received systemic antibiotic (amoxicillin) for 10 days and nasal decongestants (xylometazoline) for 5 days.

All patients were evaluated at 0, 2, 4, and 6 weeks

The assessment of each patient included history taking, otoscopic examination, a tympanogram, and a pure-tone audiogram (above the age of 6 years).

The appropriate method of using the intranasal steroid spray was demonstrated at the baseline visit to the children's parents. The parent's use of the spray was observed and assessed. This was intended to produce maximal local anti-inflammatory effects on the posterior nasal airway.

At the follow-up visits (every 2 weeks), subjective improvement in the symptoms, otoscopic examination findings, and the tympanometry evaluation were recorded.

Outcome of the study

(1) Resolution or cure of bilateral glue ear was defined as complete bilateral clearance (A tympanogram) at any stage.
(2) Partial improvement was defined by C tympanogram.
(3) No improvement was defined by persistence of B tympanogram.

Results

The present study included 100 patients (children) between 3 and 10 years of age (65% male and 35% female patients). The patients were divided into two equal groups (group A and group B) for a comparative study between the use of oral steroids and topical nasal steroids in the treatment of OME.

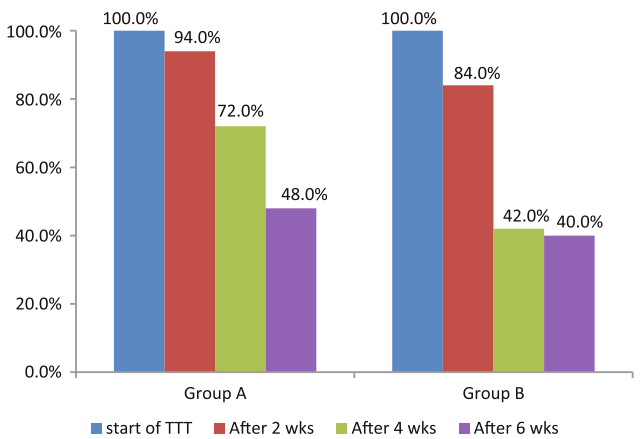
Group A received intranasal mometasone furoate monohydrate at a dose of 100 μg/day, one spray in each nostril once a day for 6 weeks. Group B received oral prednisolone in tapering doses for 6 weeks.

A highly significant improvement in OME as regards symptoms, signs, and tympanometric results occurred within each group at the end of the study, with no significant difference in improvement between the two groups.

There was no significant difference between group A and group B as regards improvement in hearing impairment at all stages of the study, but a highly significant difference between the two groups was found at stage 2 (after 4 weeks) (Table 1). A highly significant improvement in hearing occurred within each group separately at the end of the study, with no significant improvement in group A after 2 weeks and after 6 weeks in group B (Fig. 1).

As regards earache, there was no significant difference between group A and group B at all stages of the

Figure 1



Improvement in hearing impairment with time within each group separately.

Table 1 Comparison between the two groups as regards hearing impairment at different time points

Hearing impairment at	Group A [*N* (%)]	Group B [*N* (%)]	χ^2	*P* value
Start of treatment				
Positive	50 (100.0)	50 (100.0)	0	1.0
Negative	0 (0.0)	0 (0.0)		NS
After 2 weeks				
Positive	47 (94.0)	42 (84.0)	2.6	0.2
Negative	3 (6.0)	8 (16.0)		NS
After 4 weeks				
Positive	36 (72.0)	21 (42.0)	9.2	0.004
Negative	14 (28.0)	29 (58.0)		HS
After 6 weeks				
Positive	24 (48.0)	20 (40.0)	0.6	0.5
Negative	26 (52.0)	30 (60.0)		NS

HS, highly significant ($P < 0.01$); NS, nonsignificant ($P > 0.05$); S, significant ($P = 0.05$–0.01).

study. Within each group separately, there was a highly significant improvement after 2 weeks in both groups. Overall, there was a highly significant improvement within each group separately.

No significant difference was found between group A and group B as regards tympanic membrane appearance at all stages of treatment. Within each group separately, there was no significant improvement in both groups after 2 weeks and in group A after 4 weeks, but a highly significant improvement occurred in group B after 4 weeks and in both groups after 6 weeks. Overall, there was a highly significant improvement in tympanic membrane appearance within each group separately.

No significant difference was found between group A and group B as regards improvement in tympanic membrane retraction at all stages of the treatment. Within each group separately, there was no significant improvement in both groups after 2 weeks and in group A after 4 weeks, but a highly significant improvement occurred in group B after 4 weeks and in both groups after 6 weeks. Overall, there was a highly significant improvement in tympanic membrane appearance within each group separately.

As regards the tympanogram results, there was no significant difference between group A and group B at all stages of the study. Within each group separately, there was a highly significant improvement in tympanometric results in both groups at all stages of the study except at the first stage (after 2 weeks), when there was a significant improvement in group A.

Discussion

OME has been defined as the presence of fluid in the middle ear without signs or symptoms of acute ear infection [7]. Epidemiological studies of OME reveal that it affects 50–80% of children by the age of 5 [8,9]. Without effective intervention, severe OME can cause significant hearing loss, which may result in linguistic, developmental, behavioral, motor, and social impairment [10]. Although many OME cases resolve spontaneously, referral rates from primary care remain high, with ~1–5/1000 children in the general population undergoing surgery (grommets) each year [11].

OME in children is a global health problem due to its negative impact on quality of life. It is one of the most common causes of treatable conductive hearing loss. Many patients remain undiagnosed especially in developing countries, which can lead to poor performance in school and affect the overall development of the child. In recent years, the diagnosis and method of treatment of OME have emerged. Many studies have conduced however that the usefulness of steroid spray in patients with OME is debatable. The mechanism of action of steroids in this context is still unclear. Mometasone furoate has been shown to help in the recovery of transport function of ciliary epithelium helping in appreciable clinical effect [12].

A high level of expression of the human glucocorticoid receptor-a (vs. b) in the adenoids and tonsils of patients who have obstructive sleep apnea versus recurrent throat infections suggested a possible chance for these patients to respond to topical steroid therapy [13].

The current treatment options for OME include elimination of the risk factors, follow-up without treatment, use of antibiotic and/or decongestant medication, maneuvers to open the Eustachian tubes, such as with nasal balloons, prophylactic antibiotic use, and, if medical treatment fails, tympanostomy tube placement with or without adenoidectomy [4,5].

Systemic corticosteroids produce a prompt, temporary decrease in adenoid size and resolution in middle ear effusion, but significant side effects cause avoidance of its chronic use in children [14]. Compared with systemic steroids, topical nasal steroids have limited systemic effects and would be expected to exert their anti-inflammatory effects locally on the nose, nasopharynx, and Eustachian tube [15]. Although systemic steroids have been extensively studied, the topical nasal steroids as the sole treatment of OME and adenoid hypertrophy have not been adequately evaluated.

The present study included 100 patients (children) divided into two equal groups (group A and group B) in a comparative study between the use of oral steroids and topical nasal steroids in the treatment of OME within 6 weeks.

Group A received intranasal mometasone furoate at a dose of 100 μg/day, one spray in each nostril once a day for 6 weeks, and group B received oral prednisolone in tapering doses for 6 weeks. In addition, both groups received systemic antibiotic (amoxicillin) for 10 days and nasal decongestant (xylometazoline) for 5 days. A highly significant improvement ($P < 0.01$) in OME as regards symptoms, signs, and tympanometric results occurred within each group at the end of the study, with no significant difference ($P > 0.05$) in improvement between the two groups.

Cengel and Akyo conducted a prospective, controlled, randomized, clinical study on a total of 122 children (3–15-year-old) who were on the waiting list for adenoidectomy and/or ventilation tube placement; they were enrolled into the study and control groups. The study group (67 patients with AH, 34 of them with OME) received intranasal mometasone furoate monohydrate at a dose of 100 μg/day, one spray in each nostril once a day for 6 weeks. The control group (55 patients with AH, 29 of them with OME) was followed up without any treatment. No other medication was allowed during the study in either group. Resolution of OME in the study group (42.2%) was significantly higher than that in the control group (14.5%). Forty-five patients (67.2%) with adenoid hypertrophy in the study group showed significant decreases in adenoid size according to the endoscopic evaluation compared with the control group. A significant improvement in obstructive symptoms was seen in the treatment group. These results indicated that nasal mometasone furoate monohydrate treatment can significantly reduce adenoid hypertrophy and obstructive symptoms and is a useful alternative to surgery, at least in the short term, for OME [6].

Williamson and colleagues reported a randomized, placebo-controlled trial on 217 children aged 4–11 years presenting with one or more episodes of otitis media or ear-related problems in the previous 12 months and with bilateral OME who were enrolled into two groups. The study group received topical nasal steroid mometasone furoate (50 μg) in each nostril, and the placebo group received topical nasal steroid mometasone furoate once daily for 3 months. An overall 41% of the topical steroid group and 45% of the placebo group were cured in one or both ears at 1 month. At 3 months, 58% of the topical steroid group and 52% of the placebo group were cured. However, they concluded that topical steroids are unlikely to be an effective treatment for OME in general practice [16].

In our study, both topical and systemic steroids gave a highly significant improvement as regards symptoms, signs, and tympanometric results in OME at the end of the study (after 6 weeks). Thus, both topical intranasal and systemic steroid administration are considered effective treatments of OME in children; however, complications of systemic steroids can be avoided using topical steroids.

Conclusion

Both topical intranasal and oral steroids are effective adjunctive treatment for OME in children in the short term.

In our study, 100 children who fulfilled the inclusion criteria were divided into two equal groups: group A received topical intranasal steroids and group B received oral steroids. The results showed improvement in the average tympanogram results in 17 patients from group A and in 21 patients from group B after treatment. From these findings, it can be concluded that both topical intranasal and systemic steroids are effective in the treatment of OME in children, without significant difference between the two methods, and thus oral steroid complications could be avoided using local steroid spray.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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