

Is Topical Nasal Steroid Useful for Treatment of Otitis Media with Effusion in Children?

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ABSTRACT

Background: Otitis media with effusion is a common and important pediatric clinical problem; it is the leading cause of hearing impairment in children. Medical treatment remains controversial.

Aim: To evaluate the usefulness of using topical nasal steroids in the treatment of otitis media with effusion.

Patients and Methods: Between November 2019 and October 2022, a prospective controlled clinical study was carried out in the department of otolaryngology at Al-Jerrahat Teaching Hospital in Medical City, Baghdad, Iraq. This study comprised 40 patients with bilateral otitis media with effusion (23 males, 17 females). Two groups were created for the patients. Patients in group A (20 patients) were treated with mometasone furoate nasal spray; 1 puff (50 µg) in each nostril daily for 2 weeks, while the 20 patients in group B were treated with saline nasal spray; 1 puff in each nostril daily for 2 weeks. At the end of the first and second weeks of treatment, otoscopic examination was used to monitor the patients. At the end of the second post-treatment week, pure tone audiometry and tympanometry were performed again. Normal otoscopic results, a type A tympanogram, and enhanced pure tone hearing threshold average to be ≤ 20 dB HL within 0, 5, 1, and 4 KHz were used to characterize resolution of OME. The association between two means was determined using an independent sample t-test, while the association between categorical variables was determined using an X²-test.

Results: At the end of 2nd post-treatment week, there was no significant difference regarding improvement of otitis media with effusion regarding otoscopic, audiometric, and tympanometric results in both groups (P-value >0.05).

Conclusion: Topical nasal steroid is unuseful for the treatment of otitis media with effusion in the short-term.

Keywords: Otitis media with effusion, Topical nasal steroid, Audiometry, Tympanometry.

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Paper submitted on April 03, 2023; and Accepted on May 09, 2023

INTRODUCTION

Otitis Media with Effusion (OME) is defined as a condition characterized by the presence of middle ear fluid with the absence of signs of acute infection¹. Passive smoking, atopy, bottle feeding, day- care nursery are recognizable risk factors for OME². Enlarged adenoid and upper respiratory tract infection can lead to OME³. The incidence of OME is more common in children than adults due to the more horizontal position of the Eustachian tube, as well as the position of the head in children⁴. Children with developmental anomalies including decreased palatal muscle tone, or bone developmental variations are at higher risk of OME development, e.g. cleft palate, down syndrome⁵. Furthermore, in children with Down syndrome there is impaired mucociliary function that increases the risk for OME development⁶.

By the age of 10 years, about 80% of children have had one or more episodes of OME⁷. Hearing impairment is the most common complaint in patients with OME. Other complaints may include communication difficulties, lack of attention, impaired speech development, and sensation of aural fullness. Signs of OME include tympanic membrane opacification, loss of light reflex, and retracted tympanic membrane with impaired mobility⁸.

Patients with OME can be evaluated by using age-appropriate audiometry and tympanometry. Type B tympanogram will support the diagnosis of OME⁹.

Generally, OME resolves spontaneously with watchful waiting. In persistent OME, myringotomy with the insertion of a tympanostomy tube is considered an effective treatment¹⁰. However, there is no general agreement about the medical treatment of OME, e.g. steroids, and antibiotics. Therefore, this study was conducted to evaluate the usefulness of using topical nasal steroids (mometasone furoate nasal spray) in the treatment of OME.

PATIENTS AND METHODS

The Helsinki Declaration was followed to gain ethical concerns. After describing the purpose of the study to the parents, formal informed consent was acquired. The health ethics committee of the college of medicine at the University of Baghdad granted the ethics committee's permission.

40 patients with bilateral OME (Figure 1) attended the department of otolaryngology at Al-jerहत Teaching Hospital in Medical City, Baghdad, Iraq; during the period from November 2019 to October 2022 who met the inclusion criteria were included in the current prospective controlled clinical study.

The patients were subjected to routine otolaryngological examination including otoscopic examination, fiber optic nasal endoscopy, pure tone audiometry, tympanometry, and plain x-ray of postnasal space (Figure 2).

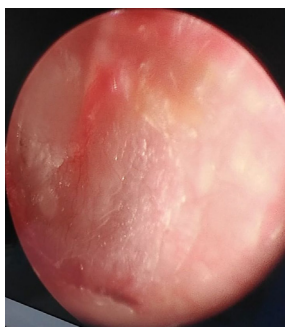


Figure 1: 8 years old boy with otitis media with effusion (retracted tympanic membrane).



Figure 2: X-ray of post-nasal space (lateral view) of 10 years old girl with asymptomatic adenoid enlargement.

The inclusion criteria were:

1. Age 6-10 years.
2. Bilateral OME for at least 3 months.

Average pure tone hearing threshold of more than 20 dB HL within frequencies 0.5, 1, 2, and 4 KHz.

Type B tympanogram.

The exclusion criteria were:

1. Symptomatic adenoid enlargement.
2. A history of steroid use in the prior three months.
3. Adenoidectomy and/or myringotomy history, with or without insertion of a tympanostomy tube.
4. A current ear infection or upper respiratory illness.
5. Cleft palate, down syndrome, Kartagener syndrome, or Young syndrome.
6. Immunocompromised diseases e.g., diabetes mellitus.

The patients who met the entry criteria were given code numbers. Group A patients, including 20 children, were given odd numbers, while the 20 patients in group B were given double numbers. Patients in group A were treated with mometasone furoate nasal spray; one puff in each nostril (100 µg/day), while patients in group B received saline nasal spray; one puff in each nostril/day. The duration of treatment was 2 weeks in both groups.

At the end of the first and second weeks of treatment, otoscopic examination was used to monitor the patients.

At the end of the second post-treatment week, pure tone audiometry and tympanometry were performed again. Normal otoscopic results, a type A tympanogram, and enhanced pure tone hearing threshold average to be ≤ 20 dB HL within 0, 5, 1, and 4 KHz were used to characterize resolution of OME. The tympanometry results were classified into types A, B, and C according to Modified Jerger Classification.

Statistical Analysis

1. The statistical software for social sciences version 23 was used to analyze the data.
2. The association between two means was defined using independent samples t-test.
3. The association between the category variables was determined using the X2-test.
4. A 5% error margin was accepted and a 95% confidence level was assigned.
5. P-value ≤ 0.05 was considered significant.

RESULTS

The total number of patients enrolled in this study was 40 patients (80 ears) with ages ranging from 6 to 10 years (mean=7.45 years ± SD 1.32). 23 patients (57.5%) were male and 17 patients (42.5%) were female, male: female ratio=1.4:1. There was no significant difference between both groups regarding age and gender (P-value >0.05) as shown in Tables 1 and 2 respectively.

There was no significant difference between group A and group B regarding pre-treatment otoscopic findings and pure tone hearing threshold average within 0.5, 1,

Table 1: Age distribution.

Age (years)	Group A		Group B		Total		Mean difference	Std. Error difference	t-test	P-value
	Number	%	Number	%	Number	%				
6	6	15	7	17.5	13	32.5				
7	5	12.5	4	10	9	22.5				
8	3	7.5	5	12.5	8	20	0.8	0.524	1.524	1.36
9	4	10	3	7.5	7	17.5				
10	2	5	1	2.5	3	7.5				
Total	20	50	20	50	40	100				

Table 2: Gender distribution.

Sex	Group A		Group B		Total		X2	P-value
	Number	%	Number	%	Number	%		
Male	11	27.5	12	30	23	57.5		
Female	9	22.5	8	20	17	42.5	0.1	>0.05
Total	20	50	20	50	40	100		

Table 3: Pre-treatment otoscopic examination.

Otoscopic Findings	Group A Number of Ears (40) & %	Group B Number of Ears (40) & %	X2	P-value
Retracted tympanic membrane	40 (100%)	40 (100%)		
Opaque tympanic membrane	35 (87.5%)	37 (92.5%)	0.66	>0.05
Air fluid level	4 (10%)	2 (5%)		
Air bubbles	2 (5%)	2 (5%)		

2, and 4 KHz as shown in Tables 3 and 4 respectively. Tympanograms were flat (type B) in all patients included in the study.

The pre-treatment pure tone audiogram and tympanogram of two patients included in the study are shown in Figures

3 and 4 respectively. Statistical analysis had shown that there was no significant difference between group A and group B patients at the end of 2nd post-treatment week regarding otoscopic, tympanometric, and audiometric results as shown in Tables 5, 6, and 7 respectively.

Table 4: Means of pre-treatment pure tone hearing threshold average within 0.5, 1, 2, and 4 KHz.

Pure tone hearing threshold means \pm SD		Independent samples t-test	P-value
Group A	Group B		
26.85 \pm 0.489	26.6 \pm 0.502	1.594	0.119

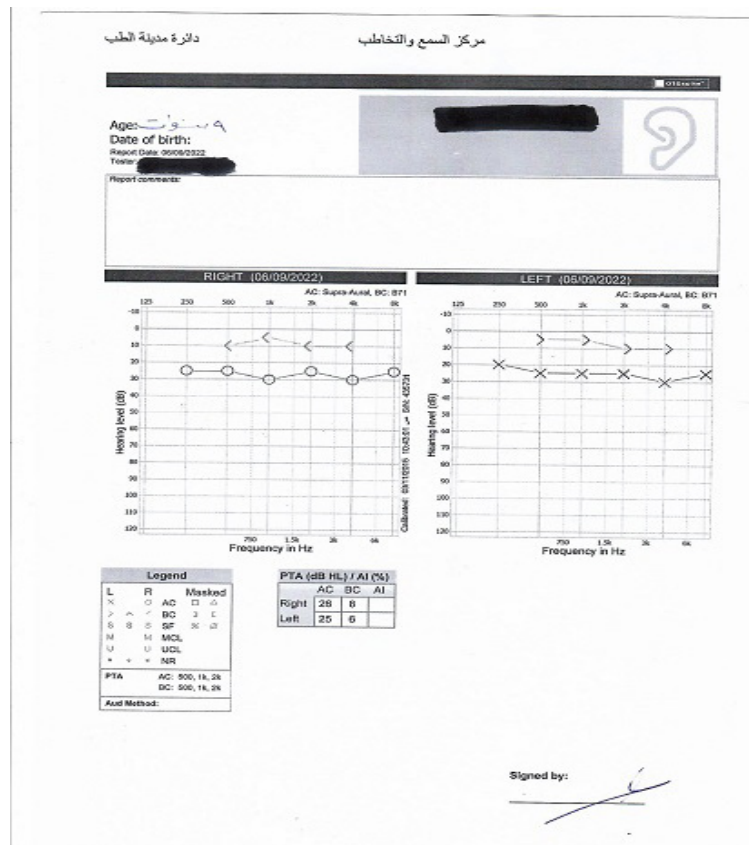


Figure 3: 9 year old patient with bilateral otitis media with effusion (conductive deafness).

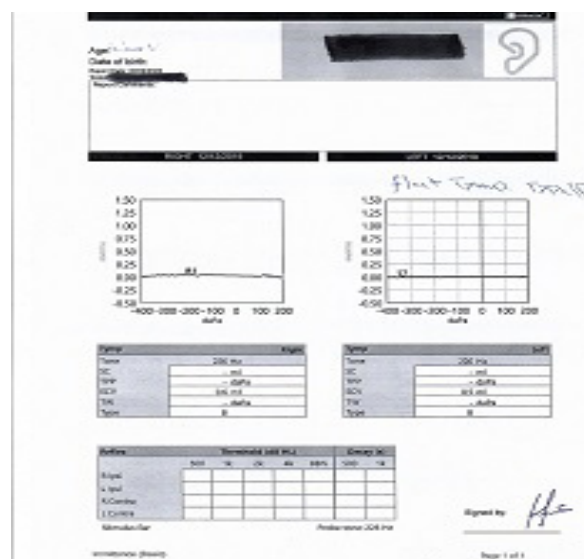


Figure 4: 7 year old patient with bilateral otitis media with effusion (type B tympanogram).

Table 5: Otoscope examination at the end of 2nd post-treatment week.

Otoscope Findings	Group A Number of Ears (40) & %	Group B Number of Ears (40) & %	X2	P-value
Retracted tympanic membrane	32 (80%)	34 (85%)		
Opaque tympanic membrane	30 (75%)	33 (82.5%)	1.28	>0.05
Air fluid level	3 (7.5%)	2 (5%)		
Air bubbles	2 (5%)	2 (5%)		

Table 6: Tympanometric results at the end of 2nd post-treatment week.

Tympanogram Type	Group A Number of Ears (40) & %	Group B Number of Ears (40) & %	X2	P-value
A	6	4		
C	8	4	2,352	>0.05
B	26	32		

Table 7: Pure tone hearing threshold average within 0, 5, 1, 2, and 4 KHz means at the end of 2nd post-treatment week.

Pure tone hearing threshold means ± SD		Independent samples t-test	P-value
Group A	Group B		
23.1 ± 1.41	23.85 ± 1.84	1.445	0.157

DISCUSSION

OME is a very common disease in children, and it is the leading cause of acquired hearing impairment during childhood. OME can occur as a result of Eustachian tube dysfunction. Adenoid hypertrophy, upper respiratory tract infection, allergy, and anatomical anomalies involving the palate and skull base are considered as causes of OME. Till now, there is controversy about the effectiveness of medical treatment, e.g. steroids, antibiotics, antihistamines, etc. in OME. Furthermore, the use of drugs is not free of side effects and cost issues. Therefore, the present study has addressed the efficacy of topical nasal steroid (mometasone) in the treatment of OME.

The current study has shown that there was no significant advantage of using mometasone nasal spray for the treatment of children with OME in comparison to saline nasal spray (P value >0.05). Perhaps, this result can be explained by the basis that intranasal steroids would not be expected to reach the middle ear.

William, in his study, found that intranasal steroid is unlikely to be of benefit in the treatment of children with OME¹¹. Nunes-Batalla et al. concluded that Topical corticoids are not advised for the treatment of OME patients since they have not been shown to have a substantial impact on the outcomes of OME¹². Williamson et al. assessed the clinical efficacy of intranasal steroids in treating children with OME in general practice and concluded that these drugs are not likely to be clinically helpful¹³. In Vanneste et al. study, they stated that while some drugs, such as intranasal steroids, can be used to treat OME, these drugs are rarely consistently successful and rarely offer long-term relief¹⁴. "However, the preponderance of data suggests that intranasal steroids do not improve the long-term clearance of isolated OME and are therefore not

recommended"¹⁵. In a systematic review done by Butler and Van der Voort et al., the authors found; in short-term follow-up studies, that oral or intranasal steroids, alone or in combination with antibiotics, can hasten the resolution of OME, but there is no evidence of a long-term benefit. Therefore, these drugs are not recommended for the treatment of OME¹⁶.

On the other hand, in a study conducted by Cengle and Akyol, they found that intranasal mometasone furoate monohydrate is a useful alternative to surgery, at least in the short-term, for the treatment of OME¹⁷. A similar result was obtained by Kadah et al., and El-Anwar et al., who mentioned that topical nasal steroids are effective in the treatment of OME in the short term^{18, 19}.

However, the international recommendation against using steroids to treat OME is because of the side effects, cost issues, and no convincing evidence of long-term effectiveness²⁰. The Cochrane review update on oral and intranasal steroids for the treatment of OME found no significant benefit of intranasal steroids²¹.

CONCLUSION

In conclusion, topical nasal steroid, in form of mometasone furoate, has no significant benefit in the treatment of children with OME in short-term follow-up. Further studies for longer duration are recommended to evaluate the usefulness of long-term intranasal steroids for the treatment of OME.

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