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| RESEARCH ARTICLE

Is Mometasone Effective in Treating Otitis Media with Effusion?

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| ABSTRACT

Otitis media with effusion (OME) is the long-term deposition of mucus in the middle ear cleft. It is the leading cause of childhood hearing loss and a common childhood infection. It can impair communication and life quality. OME's direct and indirect costs are also crucial. Improving OME care is crucial. This study examines intranasal mometasone's efficacy in treating otitis media with effusion. A clinical trial study was conducted during a period from January 2021 to June 2022. It included 80 patients suffering from otitis media with effusion bilaterally (160 ears) who had an intact tympanic membrane and tympanometry type B. These patients were included only if they had a hearing change or loss noted by the parents or by the patient if he or she could complain for three months or more. These patients were split into two groups. Group A had 80 ears (40 patients) who got one puff of mometasone furoate nasal spray in each nostril every day for three months, and Group B had 80 ears (40 patients) who got one puff of seawater nasal spray in each nostril every day for the same period. On the first visit, otoscopic findings were recorded, and all patients had pure-tone audiometry and tympanometry performed. All of the above-mentioned measures were repeated and compared to the records from the first visit at the end of the three months of treatment. After treatment, 75% of ears in Group A changed from type B to type A tympanometry. This was significantly higher than in Group B, where only 15% of ears changed from type B to type A tympanometry. Regarding retraction, 75% of ears in Group A showed no retraction after treatment with mometasone furoate, while in Group B, it was 40%. The average pure-tone audiometry score in Group A improved after therapy. Corticosteroids are effective in the treatment of otitis media with effusion and safer when used as topical intranasal steroids than systemic preparations.

| KEYWORDS

Otitis media effusion, steroid, mometasone, tympanometry, Pure-tone Audiometry.

| ARTICLE INFORMATION

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1. Introduction

Otitis media with effusion (OME) is the chronic, persistent accumulation of mucus within the middle ear cleft for three months or longer (Vanneste, 2019). It is one of the most prevalent infectious conditions in children and the main contributor to childhood hearing loss (Coleman,2019). With the maximum occurrence occurring between the ages of 2 and 5 when the Eustachian tube is more horizontal in younger children and lengthens and angles caudally as the child grows into an adult, almost 80% of the children had this illness by the age of 10 (Nemade, 2018). OME displays a non-purulent middle ear effusion without the acute infection that would be present with acute otitis media, including fever and otalgia (Korona-Glowniak, 2020). The highest frequency of OME occurs during a crucial time for the development of linguistic skills, despite the fact that symptoms are not severe. After that, regular hearing exams are necessary to maintain hearing in OME patients (Rosenfeld, 2016). Adenoid hypertrophy-related blockage is the most frequent cause of OME. Middle ear fluid buildup can be brought on by submucosal cleft palate, allergies, upper respiratory infections, tumors, sinusitis, acute otitis media, radiotherapy, and Eustachian tube obstruction (Sohrabpour, 2021). It is a frequent cause of paediatric hearing loss and can significantly affect communication and quality of life. The expenditures associated with OME and its problems, both direct and indirect, are also important from an economic perspective. Thus, efforts to improve the quality of care for children with OME have a big and far-reaching impact (Wang, 2017). Different treatment methods,

including medicinal and surgical treatments, are documented for OME (Rahmati, 2017). Since conventional treatment methods fall short of providing adequate and long-lasting relief from otologic symptoms, the matter is still up for debate (Mohamed, 2018). Steroids, either topically or orally, have been used to treat OME. Oral steroid use is linked to altered behavior, increased hunger, weight gain, adrenal suppression, and femoral head vascular necrosis. Due to their low systemic absorption, topical steroids have fewer side effects (Waldron, 2016). Because the steroids are quickly converted in the mucosa of the nose to less active metabolites, and any unmodified absorbed medication is metabolised by the liver, intranasal steroids can be safer than systemic formulations. Consequently, systemic adverse effects are less probable, but the targeted anti-inflammatory effects may be comparable (Daley-Yates, 2021). Children older than two years old can use mometasone furoate, a topical glucocorticosteroid nasal spray, to treat allergic rhinitis symptoms, including nasal obstruction, rhinorrhea, itching, and sneezing. Additionally, it contributes to the alleviation of symptoms in kids with adenoid hypertrophy (Penagos, 2008; Chohan, 2015). The aim of this study is to investigate the efficacy of intranasal mometasone in the treatment of OME.

2. Patients and methods

This clinical trial study was conducted at a private clinic over an 18-month period from January 2021 to June 2022. All procedures included in this study were in accordance with the Helsinki Declaration and its later amendments for human research. After thoroughly explaining the nature and goals of the study, each patient's guardian consented to participate in the study.

The study included 80 patients suffering from OME bilaterally (160 ears) who had an intact tympanic membrane (TM) and tympanometry type B. These patients were only included if they had hearing loss noted by the parents or the patient if he or she could complain for three months or more and if pure tone audiometry (PTA) revealed no sensorineural hearing loss, as well as no adenoid enlargement judged by symptoms, an x-ray of the postnasal space, and/or an endoscope; no previous ear or adenoid surgeries; no history of ear trauma; no symptoms of acute otitis media during the last two months at the time of examination; and no ear or craniofacial anomaly. All patients received 10 days of amoxicillin. The patients were split into two groups:

- **Group A:** With 40 patients (80 ears) who were given mometasone furoate nasal spray once a day, one puff in each nostril, for three months.
- **Group B:** With 40 patients (80 ears) who received daily seawater nasal spray, one puff in each nostril, for the same period.

At the 1st visit, a full history and examination were done, otoscopic findings were recorded (position, fluid or bubbles behind the tympanic membrane, loss of luster, cone of light, color, transparency, and mobility), and PTA and tympanometry were done for all patients. At the end of the three months of treatment, all of the above steps were done again, and the records from the first visit were looked at.

3. Results

In this study, there were no statistically significant differences between study groups ($P \geq 0.05$) in age and gender, as shown in table (1).

Table 1: Distribution of study patients by general characteristics

Variable	Study group		P - Value
	A (%) n= 40	B (%) n= 40	
Gender			
Male	25 (62.5)	21 (52.5)	**0.365**
Female	15 (37.5)	19 (47.5)	
	Mean ± SD	**Mean ± SD**	
Age (Year)	8.12 ± 2.1	8.61 ± 3.2	**0.421**

In group A, 75% of ears changed from type B to type A tympanometry after treatment, which was significantly higher than that in group B (P= 0.001), where only 15% of ears changed from type B to type A tympanometry after treatment. Regarding retraction, no retraction was seen in 75% of ears in group A, which was significantly higher (P= 0.001) than that in group B (40%), as shown in table (2).

Table 2: Tympanometry types and retraction after treatment in study groups

Tympanometry Type and retraction after treatment	Study group		P - Value
	A (%) n= 80	B (%) n= 80	
Tympanometry Type			
Type A	60 (75.0)	12 (15.0)	**0.001**
Type B	4 (5.0)	52 (65.0)	
Type C	16 (20.0)	16 (20.0)	
Retraction			
Retraction	20 (25.0)	48 (60.0)	**0.001**
No retraction	60 (75.0)	32 (40.0)	

As shown in table (3), mean PTA was significantly lower in group A after treatment compared to that before treatment (21.6 versus 33.34 dB, P= 0.001), while in group B, no significant change in PTA after treatment (P= 0.427).

Table 3: Comparison of the mean of PTA before and after treatment in both study groups

PTA (dB)	Time		P - Value
	Before treatment Mean ± SD	After treatment Mean ± SD	
Group A	33.34 ± 5.3	21.6 ± 4.1	**0.001**
Group B	29.46 ± 5.1	27.42 ± 4.5	**0.427**

Otoscopic findings in group A showed that the TM was pale grey in 82% of ears, transparent in 80%, with a normal cone of light in 77.5%, mobile in 95%, and fluid behind it in 92.5% (Table 4).

Table 4: Otoscopic findings in Group A before and after treatment

Otoscopic findings in Group A	Time	
	Before treatment (%) n= 80	After treatment (%) n= 80
Color		
Pale grey	0 (0)	66 (82.5)
Amber	80 (100.0)	12 (15.0)
Blue	0 (0)	2 (2.5)
Transparency		
Dull	80 (100.0)	16 (20.0)
Transparent	0 (0)	64 (80.0)
Cone of light		
Distorted	80 (100.0)	18 (22.5)
Normal	0 (0)	62 (77.5)
TM mobility		
Mobile	0 (0)	76 (95.0)
Immobile	80 (100.0)	4 (5.0)
Fluid behind TM		
Yes	0 (0)	74 (92.5)
No	80 (100.0)	6 (7.5)

Otoscopic findings in group B showed that the TM was amber in 60% of ears, transparent in 100%, distorted cone of light in 75%, mobile in 70%, and fluid behind it in 92.5% (Table 5).

Table 5: Otoscopic findings in Group B before and after treatment

Otoscopic findings in Group B	Time	
	Before treatment (%) n= 80	After treatment (%) n= 80
Color		
Pale grey	0 (0)	28 (35.0)
Amber	64 (80.0)	48 (60.0)
Blue	16 (20.0)	4 (5.0)
Transparency		
Dull	80 (100.0)	80 (100.0)
Transparent	0 (0)	0 (0)
Cone of light		
Distorted	80 (100.0)	60 (75.0)
Normal	0 (0)	20 (25.0)
TM mobility		
Mobile	0 (0)	56 (70.0)
Immobile	80 (100.0)	24 (30.0)
Fluid behind TM		
Yes	0 (0)	74 (92.5)
No	80 (100.0)	6 (7.5)

4. Discussion

Eustachian tube (ET) dysfunction has been found to be a risk factor for otitis media with effusion, a disease that has many different causes. A diagnosis of OME is made in roughly 80% of children by the time they are ten years old, typically when they are three years old (El-Anwar, 2015). We found a significant improvement in tympanometry after treatment from type B to type A (P= 0.001). In terms of retraction, 75% of the studies in group A had no retraction post-treatment, which was significantly higher than in group B (P = 0.001). In the same accord, the Salmen et al. study revealed a significant improvement in tympanometry from type B to type A, although the difference wasn't significant (P> 0.05), and the TM retraction improved significantly (P<0.05) (Salmen, 2021). Similarly, the Ahmed et al. study found that 60% had a tympanogram type A curve and 10% had a type B curve, which was statistically significant (P= 0.006) after nasal mometasone treatment (Ahmed, 2022). The "B" curve was found to be 81.81% in the Menon et al. study, of which 36% became significantly "A" after treatment (*P*=0.0004) (Menon, 2013). El-Anwar et al. found that steroid treatment improved retraction and type B tympanometry, with a significant difference between study groups (P 0.001) (El-Anwar, 2015).

In this study, the mean of PTA was significantly lower in group A after treatment than before treatment (P= 0.001), while in group B, there was no significant change in PTA after treatment (P= 0.427). In the same vein, the Menon et al. study reported a significant improvement in the PTA (*P*= 0.029) (Menon, 2013). In the Ahmed et al. study, no significant association was found between the mometasone group and the placebo group in terms of the mean of PTA (P > 0.05) (Ahmed, 2022). In the Abdel Galil et al. study, different results were published, including an improvement in hearing threshold assessed by PTA in the steroid group compared with the control group, in which the small difference was insignificant (P=0.301) (Abdel Galil, 2019). The differences reported among studies can be related to different sample sizes and/or study designs. Add to that disease duration, severity, age of the patients, steroid formulation, duration of steroid treatment, dosage, and route of administration.

Tympanogram type and PTA thresholds significantly improved following the use of corticosteroid therapy, demonstrating their potent therapeutic role that may be explained by their combined antiallergic and anti-inflammatory mechanisms (El-Anwar, 2015). According to studies, steroids help resolve OME by either reducing the viscosity of the middle ear effusion or shrinking edoema and tissues surrounding the Eustachian tube (Rosenfeld, 2004). In addition, steroids reduce allergies, increase transepithelial sodium transfer in ME epithelium, and lower the viscosity of ME fluids, all of which encourage the evacuation of middle ear fluid (Menon, 2013).

After treatment, the TM in group A was pale grey at 82.5%, transparent at 80%, normal cone of light at 77.5%, mobile TM at 95%, and fluid behind it at 92.5%, while group B was amber at 60%, transparent in 100%, distorted cone of light in 75%, mobile membrane in 70%, and fluid behind it in 92.5%. In the Salmen et al. study, tympanic findings showed the best improvement after

mometasone treatment nasally: fluid level behind the TM (11.1% in mometasone versus 66.6% in normal saline), loss of lustre (20% vs. 50%) and normal TM (41.5% vs. 15.3%) (Salmen, 2021). In the El-Anwar et al. study, fluid level behind TM in patients receiving mometasone was found at 2.5%, with loss of lustre in 25%, and normal TM in 70%, while in the saline group, fluid level, loss of luster, and normal TM were found in 5%, 75%, and 25%, respectively (El-Anwar, 2015). In fact, the mometasone nasal spray is well-tolerated and secure. Its first pass metabolism is intensive after intranasal delivery. The systemic quantities are consequently below measurable limits, indicating a very low chance of adverse consequences (Ratner, 2009). Mometasone furoate was chosen above the other steroid nasal sprays because it has no negative effects on patients' nasal mucosal tissue, has no impact on children's growth, and has no impact on the hypothalamic-pituitary-adrenal axis (Menon, 2013).

5. Conclusion

This study aims to investigate the effectiveness of mometasone nasal spray in the treatment of otitis media with effusion, which was found useful according to the results and discussion. Therefore, topical nasal steroids are a viable alternative to surgical treatment for OME. Many patients who were initially enrolled in the study but did not finish the follow-up period were excluded, resulting in a smaller sample size. A comprehensive follow-up is required to assess if the effects are permanent or temporary.

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