The Egyptian Journal of Hospital Medicine (January 2024) Vol. 94, Page 826-831

Intratympanic Steroid Treatment in Otitis Media with Effusion Resistant to Conventional Therapy in Children

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ABSTRACT

Background: Children's hearing impairment is primarily caused by otitis media with effusion (OME). OME may be linked to developmental delays, thus early and appropriate therapy of OME avoids hearing and speech impairment in children. Treatment is still a contentious topic, though.

Objectives: We aimed to assess the efficacy of Intratympanic (IT) steroids for the management of OME resistant to traditional medical Therapy.

Patients and methods: The study was conducted on 40 patients who had complaints of hearing loss and bilateral OME that resisted medical treatment lasting at least three months. Under general anesthesia, we performed myringotomy and ventilation tube (VT) was inserted bilaterally on each patient Then we injected steroid (.5 ml methylprednisolone 40 mg/mL) into the right middle ear. During the operation and in follow-up visits, once a week for three weeks in a row.

Results: Resolved OME was 32 (80%) ears with ventilation tube (VT) alone and 38 (95%) ears with ventilation tube (VT) and steroid injection. This difference was significant (p = 0.043). As regard postoperative complication, tympanosclerosis was noted in 6 (15%) non-injected ears and one injected ear (2.5%) and the difference was statistically significant (p<0.05). Also, permanent perforation occurred in two (5%) non-injected ears and one (2.5%) injected ears, with statistically non-significant difference (p =1.000). While Otorrhea occurred in 4 (10%) non-injected ears and 5 (12.5%) injected ears, with statistically non-significant difference (p =1.000).

Conclusion: IT steroid injections have been shown to be effective in treating OME resistant to pharmaceutical and surgical interventions, with a little risk of recurrence and surgical side effects. The best well-known therapeutic method combines IT steroid injection with ventilation tubes.

Keywords: OME, Glue ear, Secretory otitis media, Tympanometry, VT, IT steroids.

INTRODUCTION

Considering how much hearing influences our capacity for communication, hearing may be the most important sense for humans. After all, what sets humans apart from other animals is this amazing ability to communicate. According to reports, hearing impairment is becoming the most frequent sensory deficiency in humans and is rising quickly on a global scale [1]. The most common ear condition in children and the main factor contributing to hearing loss at this time is OME. By the time they are ten years old, around 80% of kids have had at least one OME episode. The malfunction of the Eustachian tube is essential to the development of OME [2].

OME is the main cause of childhood hearing impairment. Because OME may be linked to developmental delays, early and appropriate care of OME avoids hearing and speech damage in children. OME therapy is still a contentious topic, though [3]. Oral antibiotics, nasal or oral corticosteroids, antihistamines, decongestants, and mucolytics do not enhance medium- or long-term hearing and have minimal effect on retrotympanic effusion [4].

Since the healing of myringotomy usually takes only one or two days, myringotomy and fluid aspiration alone have shown to be ineffectual [5,6]. However, the ventilation tube has a somewhat lengthy 4-to 6-month lifespan [6,7].

Additionally, it is frequently associated with a high incidence of otorrhea and postoperative middle ear infections, which may not respond well to medicinal or local therapy [7,8].

It is known that systemic steroids can improve hearing in people with inner ear illnesses, Menière's disease, and SSNHL. Higher steroid concentrations in the inner ear may be achieved by IT steroid injection, all the while preventing systemic adverse effects [9,10].

We aimed to assess the efficacy of IT steroids for the management of OME resistant to traditional medical therapy.

PATIENTS AND METHODS

The study was conducted on forty patients aged 5 to 15 years presented in the outpatient clinic of Benha University Hospitals during the period of October 2022 and October 2023. The individuals who were part of the study had to have complained of bilateral OME and hearing loss, which required medical attention for a minimum of three months. We excluded patients with mixed hearing loss, familial muco-ciliary diseases (like Kartagener's syndrome), craniofacial anomalies, and patients with chronic medical diseases (DM).

Tympanometry was used to verify OME, and pure tone audiometry was used to ascertain the hearing threshold. Preoperatively, the kids had this process done over the course of one to four days.

The surgeon performed a myringotomy on the anteroinferior quadrant of the tympanic membrane (TM) while the patient was under general anaesthesia using a sickle knife. After aspirating the middle ear

Received: 01/11/2023
Accepted: 31/12/2023

fluid, each patient had a bilateral ventilation tube placed. Subsequently, the physician readied the right middle ear to receive an injection of steroids. Adenoidectomy was also performed on the individuals. With their heads rotated thirty degrees away from the surgeon, the patients were put in a supine position. The surgeon directly observed the right tympanic cavity under an operating microscope while they administered 0.4–0.6 ml of methylprednisolone 40 mg/mL through the grommet tube using a syringe attached to a 22- or 25-gauge spinal needle. To guarantee that the steroid made contact with the middle ear mucosa, the patient remained in the prescribed posture for thirty minutes after the injection. Following surgery, patients were given oral prophylactic antibiotics postoperatively and were released from the hospital on the same day.

For three weeks, there were once-weekly follow-up exams; after that, there were monthly exams for nine months. Steroids (0.5 mL methylprednisolone 40 mg/mL) were administered as ear drops during the follow-up session. Five drops were placed into the ear that had received the prior injection once a week for three weeks. Diagnostic evaluations were conducted.

All patients had audiometry air conduction pure tone averages (AC-PTA) recorded at speech frequencies (0.5, 1, 2, and 4 KHz) at the beginning and six months later. The difference between the first week and the third month's hearing gain was computed, compared, and statistically analysed. Tympanometry and TM inspection of the two groups' data were performed. The duration of tube extrusion and its consequences, such as tympanosclerosis, otorrhea, and chronic TM perforation, were also evaluated in the patients.

Ethical approval:

The Research Ethics Committee at Benha University has awarded full ethical approval. Patient relatives provided voluntary, written, informed consent. The Helsinki Declaration was adhered to at every stage of the investigation.

Statistical analysis

IBM SPSS Version 20.0 was used for the computer's analysis once the data were entered. Numerical and percentage descriptive statistics were used to characterise the qualitative data. Furthermore, the distribution's normality was evaluated by the application of the Shapiro-Wilk test. The mean and standard deviation were used to describe quantitative data. When the p-value was equal to or less than 0.05, it was deemed significant.

RESULTS

Out of the 40 patients (80 ears), 23 (57.5%) were males and 17 (42.5%) were females. They were five to fifteen years old (Table 1). Hearing impairment and aural fullness was the main complaint from all patients (100%). Tinnitus (20%) and intermittent earache (10%) were other associated complaints. And all of them have type B tympanogram for both ears (100%).

Table (1): The demographic characteristics (Age and gender) of the study participants.

Variables		No.	Percentage (%)
Gender	**Male**	23	57.5%
	Female	17	42.5%
Age	**Min. - Max.**	5 – 15	
	Mean ± SD	7.6 ± 2.6	
	Median	7	

Postoperative hearing improvement was statistically significant in both ears. Considering that there were non-significant variations in the preoperative mean hearing levels of both ears, but the mean postoperative hearing level with IT steroid administration was considerably greater than VT alone (Table 2).

Table (2): Pre- and postoperative hearing loss threshold in ears with and without intratympanic steroid.

	VT Insertion only	**VT Insertion + IT Steroid**	**t**	**P-value**
Pre-treatment (dB HL)	32.5±2.8	32.7±2.5	0.337	0.737
Post-treatment (dB HL)	13.7±4.4	10±3.8	3.974*	<0.001*
P-value	<0.001*	<0.001*		

*: Statistically significant

In terms of postoperative complications, tympanosclerosis was observed in 6 (15%) non-injected ears and 1 injected ear (2.5%), with a statistically significant difference. A statistically insignificant difference was found between both groups regarding the number of permanent perforations and the incidence of otorrhea. Conservative therapy was administered to all patients who presented with otorrhea; this included 10 days of oral antibiotics, topical antibiotic drops guided by culture, and repeated suction.

There was significant difference between the two groups as regard the total number of recurring OME and unilateral recurrent OME. The patients with recurrent OME in their injected ear also had recurrent OME in the non-injected ear. There was also a significant difference between both groups as regard the number of ears with VT alone and VT with steroid injection with resolved OME (Table 3).

Table (3): Differences between VT insertion only and VT insertion combined with IT steroid administration.

	VT insertion only		VT Insertion + IT Steroid		Test of Significance	FEP-Value
	Number of ears	Percent	Number of ears	Percent		
Tympanosclerosis	6	15.0%	1	2.5%	χ^2= 3.914	<0.05*
Otorrhea	4	10%	5	12.5%	χ^2= 0.125	1.000
Permanent perforation	2	5%	1	2.5%	χ^2= 0.346	1.000
Recurrence OME	8	20.0%	2	5%	χ^2= 4.114	0.043*
Unilateral recurrence	6	15.0%	0	0%	χ^2= 6.486*	0.026*
Resolution of effusion	32	80%	38	95%	χ^2= 4.114	0.043*
Mean time of tube extrusion	6 ±1.3	4-8 months	6.7 ±1.2	5-9 months	t= 2.502	0.014*

*: Statistically significant

Tympanogram was done postoperatively at 6-month follow-up, and it showed that there was a significant difference between the two groups as regards to types of tympanograms (Table 4).

Table (4): Postoperative tympanogram in the different groups.

		VT Insertion only		VT Insertion + IT Steroid		Total		χ^2	MCP-Value
		No.	%	No.	%	No.	%		
Postoperative tympanogram	Type A	32	80%	38	95.0%	70	87.5%	5.79	<0.025*
	Type B	6	15%	1	2.5%	7	8.75%		
	Type C	2	5.0%	1	2.5%	3	3.75%		
	Total	40	100.0%	40	100.0%	80	100.0%		

*: Statistically significant.

DISCUSSION

OME is quite prevalent, especially in young people. It is distinguished by fluid accumulation in the middle ear, which happens in the absence of symptoms and indicators of an acute infection. OME can develop as a follow-up to acute otitis media or as a separate main illness [11]. According to **Tos *et al.*** [12]**,** secretory otitis media frequently improves on its own. Improvement was seen in 78% to 88% of OME cases with type B tympanometry. Conversely, at six months and a year, the OME resolution rate is just 26% and 33%, respectively, suggesting that there is little opportunity for greater resolution rates. extended waiting times raise the possibility of potential complications.

OME management is still an open problem. Watchful waiting has become increasingly popular, however in developing nations where medicinal and surgical therapies are employed more quickly, it might not be appropriate.

Options for treatment include myringotomy alone or in conjunction with the implantation of a tympanostomy tube (grommet), To maintain the middle ear aerated for an extended period of time and to stop fluid from re-accumulating. The incision heals in two to three days if a tympanostomy tube is not implanted, but there is a possibility that the condition will continue or return [13].

The use of intratympanic delivery of medicine as a therapeutic modality for a variety of otologic conditions has been improving. Barany treated tinnitus with intratympanic lidocaine in 1935. Schuknecht was one of the first to treat Meniere's illness with intratympanic streptomycin. Intratympanic steroid administration has been investigated as a potential therapy for SSNHL in more recent times. IT steroid treatment offers a high local concentration of steroids but limited systemic absorption [14-17].

In our present study, we evaluated the effectiveness of IT steroids for treating OME in children.

Due to the difficulty in tolerating or accepting local anesthesia, as well as maintaining the IT position, which is nearly impossible, and most cases necessitate

adenoidectomy. Thus, in this study, general anaesthesia was employed, enabling us to maintain the patient in the required posture following IT steroid injection. Moreover, the use of VT in this trial made it feasible for drops to be administered once a week.

Our study included 40 patients (80 ears), there were 23 (57.5%) males and 17 (42.5%) females. Their age ranged from 5 to 15 years with mean age 7.6±2.6 years. This coincides with **Saleh *et al.*** [18] study in which mean age of studied participants was 6.77 ± 2.71 years, (76.9%, n=10) of cases were males and (23.1%, n=3) of cases were females. This is also congruent with the findings of **James *et al.*** [19], who said that male gender was a constant risk factor for OME. They also found that male children had a greater frequency of childhood infections as compared to female children, male children are more likely to be exposed to allergenic and infectious agents. However, according to **Erdivanli *et al.*** [20], the incidence of OME did not differ between the sexes.

OME may result in varying degrees of conductive hearing loss according on the kind of effusion—serious or mucoid [15]. The range of hearing loss is 15–40 dB. Children with OME typically have hearing thresholds of 27.8 dB [16]. This observation aligns with our study's findings, which showed that the group treated with VT insertion alone experienced a mean preoperative hearing loss of 32.5±2.8 dB, while the group treated with VT insertion and IT steroid experienced a mean hearing loss of 32.7±2.5 dB with non-significant differences between the two groups.

The two groups' postoperative hearing gains were compared in order to determine which procedure produces superior hearing outcomes. Both methods considerably enhanced hearing in our investigation. The mean preoperative and postoperative hearing loss in the VT insertion alone group was 32.5±2.8 dB and 13.7±4.4 dB, respectively. The mean preoperative and postoperative hearing loss in the group treated with VT insertion and IT steroids was 32.7±2.5 dB and 10±3.8 dB, respectively. As a result, both ears' postoperative hearing improved considerably, and the benefit of IT steroid administration over VT alone without injection was noticeably greater.

The results also unequivocally showed that, in comparison to VT insertion alone, the administration of IT steroids after VT insertion dramatically decreased the recurrence of OME. 32 (80%) ears with VT alone and 38 (95%) ears with VT and steroid injection had resolved OME. This supports the assertion made by Chinese academics **Han *et al.*** [21] that treating OME with an intratympanic dexamethasone injection is a viable option. It was observed that oral administration and intratympanic injection of glucocorticoids are both effective treatments for OME in their research of 84 individuals with OME lasting no more than two months.

Furthermore, **Paksoy *et al.*** [22] demonstrated that treating OME or chronic Eustachian tube dysfunction with an intratympanic dexamethasone injection is both safe and efficacious. Compared to the control group, which had undergone a different course of medical therapy, they saw more improvement in the study group's patients who had been receiving 0.5 ml dexamethasone once weekly for four weeks. **Reda *et al.*** [23] observed that there was only a slight improvement right after the injection, but they clarified that this might be because to a tiny quantity of glue that during the injection leaves the middle ear and enters the external auditory canal. However, no patient's hearing or aural fullness had improved noticeably at the conclusion of the follow-up period. Furthermore, none of the patients' tympanometry or pure tone audiometry results indicated any discernible improvement. Four local intratympanic injections of dexamethasone were administered to each of the 14 patients (24 ears) in their study who had either declined surgical therapy or had recurrences after failing medicinal treatment. Every time, around 0.5 ml of dexamethasone was administered.

According to **Flynn *et al.*** [24], complications following tube insertion include purulent otorrhea (10-26%), myringosclerosis (39-65%), segmental atrophy (16-75%), atrophic scars and pars flaccida retraction pockets (21-28%), or a combination of these. Granulation tissue (5%–40%), TM perforation (3%; up to 24% with T-tubes) and cholesteatoma (1%–4%) are also present. **Rosenfeld *et al.*** [25] also noted that it is not unusual for the TM to have possible adverse effects following the insertion of a grommet, which is consistent with our observations. **Khan *et al.*** [26] found that myringotomy with tube insertion is a widely accepted and safe treatment, with few complications such as perforation, scarring, infection, and premature or prolonged tube removal.

In terms of postoperative complications, our study found that tympanosclerosis occurred in 6 (15%) of the non-injected instances, although it was substantially less common; in one case (2.5%) of injected ears. This explains the notable decrease in tympanosclerosis following steroid injection and lends credence to the autoimmune hypothesis of OME. The study found that the incidence of post-VT otorrhea was higher in instances with IT steroid usage (5 cases, or 12.5%) and in non-injected ears (4 cases, or 10%). However, the results were not statistically significant, suggesting that otorrhea was connected to patient variables, VT factors, or the administration of aural drops. In comparison to injected ears, non-injected ears experienced greater permanent perforation. Two cases (5%): One case (2.5%) had a difference that was not statistically significant. This contradicts the findings of **Silverstein *et al.*** [27], who found that the rate of persistent perforation in their research (36.4%) was higher than that of other MicroWick applications (gentamicin perfusion of the inner ear, for example). The steroid solution most likely causes atrophy around the tympanotomy rim, which prevents TM from

healing. The surgical results at the time of the myringoplasty they performed for those cases confirmed this theory. It was discovered that the membranes were delicate and avascular.

In all, there were eight (20%) ears with VT alone and two (5%) ears with VT with steroid injection in our study of reported recurrent OME. Something was noticeably different. To clarify, the number of unilaterally reported recurrent OME in non-injected ears was 6, whereas in injected ears, it was 0. Both of these individuals who had recurrent OME in the injected ear, also had recurrent OME was seen in the non-injected ear.

All mentioned postoperative results coincide with **Amer *et al.*** [28] results, in their study on 42 children (84 ears), nine (21.4%) ears had recurrent OME following VT alone, whereas two (4.76%) ears had it after VT with steroid treatment. Following surgery, they observed tympanosclerosis in one of the injected ears (2.3%) and six non-injected ears (12.9%). Eight (19%) ears with VT alone and three (7.1%) ears with injections had otorrhea.

To assess the histological alterations in the middle ear mucosa following IT steroid injection in paediatric OME patients, more research is required. Further research is required to determine a way to shorten the time that a patient remains in a posture following an IT injection, which extends the duration of general anaesthesia.

CONCLUSION

Steroid injections IT have been shown to be effective in treating otitis media with effusion resistant to pharmaceutical and surgical interventions, with a little risk of recurrence and surgical side effects. The best well-known therapeutic method combines IT steroid injection with ventilation tubes. To determine the most effective treatment methods for chronic OME, more research is required.

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