

Assessment of Grommet Tube Insertion versus Myringotomy with Intratympanic Steroid Injection in Treatment of Otitis Media with Effusion

Ahmed Suliman Mohammed Saleh*, Ahmed Hassan Sweed, Ahmed Mohamed Anany, Ezzat Ahmed Merwad

Department of Oto-Rhino-Laryngology, Faculty of Medicine, Zagazig University, Egypt

*Corresponding author: Ahmed Suliman Mohammed Saleh, Mobile: (+20)01150905292, E-Mail: aleh8084@gmail.com

ABSTRACT

Background: Due to the short duration of effect, simple myringotomy and aspiration of fluid do not yield significant therapeutic outcomes.

Objective: To compare the efficacy of myringotomy with intratympanic dexamethasone injection versus grommet tube insertion in treatment of Otitis Media with effusion (OME).

Subjects and Methods: At Oto-Rhino-Laryngology, Department of Zagazig University Hospital, during the period from 2021 to 2022 on 13 patients (26 ears) with persistent OME. Ears were divided into two groups: Group (A) included right ears that underwent the radial grommet tube. Group (B) included left ears that underwent the circumferential myringotomy with intratympanic dexamethasone

Results: There was statistically no significant difference as regards tympanosclerosis and persistent discharge between both right and left ears. At right ears, 15.4% of cases showed both persistent discharge and tympanosclerosis while 38.5% of left ears showed tympanosclerosis and no residual discharge. There was a statistically significant difference in the rate of recurrence between the right and left ears 6 months after surgery, with 23.1% of left ears reporting recurrence while 100% of right ears showed no recurrence.

Conclusion: Myringotomy with grommet tube insertion with or without adenoidectomy is a classical method in treatment of chronic OME with potential complications especially otorrhea with less significant low recurrence rate. On other hand, circumferential myringotomy with ITD an effective method in treatment of chronic OME with less postoperative complications –equivalent postoperative hearing threshold, but with higher recurrence rate.

Keywords: Grommet tube insertion, Myringotomy, Intratympanic steroid injection, Otitis Media with effusion.

INTRODUCTION

Multiple factors contribute to the development of otitis media with effusion (OME). When middle ear effusion lasts for less than three weeks, the condition is classified as acute OME. Between three weeks and three months, it is classified as subacute, and longer than three months, it is classified as chronic. The pathogenesis of chronic OME cannot be reduced to a single factor. It's likely the result of a complex combination between inherited susceptibility and environmental factors like infection and allergies⁽¹⁾.

Secretory change of the epithelium lining the middle ear cavity, sub-epithelial edoema, and infiltration of phagocytes and lymphocytes are hallmarks of OME. The fluid in the middle ear might be the product of transudation, exudation, or active secretion by the epithelial cells that line the cavity⁽²⁾. In children, otitis media with effusion is the most common cause of hearing loss. When OME is treated early, it can prevent permanent hearing loss and language delays in children. While OME treatment has been debated, many questions remain⁽³⁾.

Since the effects of a simple myringotomy and aspiration of effusion only last for a few days, they cannot be considered therapeutically effective. However, there are risks associated with putting in a ventilation tube (VT), and one of the most common is tube otorrhea, which has an incidence rate of 29%. As a result, otologic symptoms are not always effectively treated with standard methods⁽⁴⁾.

In addition to antibiotic therapy, steroid injections using a tympanostomy tube or intratympanic dexamethasone (ITD) were found to be more successful

in the decrease of granulation tissue⁽²⁾. This research purpose was to compare the efficacy of myringotomy with intratympanic dexamethasone injection versus grommet tube insertion in treatment of OME.

SUBJECTS AND METHODS

Subjects:

At Oto-Rhino-Laryngology, and Head and Neck Surgery Departments, Zagazig University Hospital, 13 patients (26 ears) with persistent OME and scheduled for surgery after being diagnosed clinically and investigated by audiometry and tympanogram. The ears were divided into two groups: Group (A) included right ears underwent radial myringotomy with grommet tube insertion and group (B) that included left ears underwent the circumferential myringotomy with intratympanic steroid (dexamethasone) injection.

Inclusion criteria: Patients with persistent OME and scheduled for surgery after being diagnosed clinically and investigated by audiometry and tympanogram.

Exclusion criteria: Patients with mucocilliary disorders, previous surgery OME, recurrent OME, syndromic disorder (Down syndrome), and patient refusal.

This is what all of the participants in this research had to go through:

1. A thorough review of the patient's medical history. The main complaint can be taken from parents of the child or from patient himself, like otalgia, hearing loss, tinnitus and fullness in ear
2. For exclusion of any systemic diseases or syndromes associated with otitis media with effusion

3. Otolological examination:

- Otoscopy

The signs of OME in otoscopic examination were:

- Dull opaque appearance of the ear drum with loss of translucent and glistening appearance.
- Air bubbles and fluid level.
- TM retraction.
- Restriction of TM mobility.
- Prominence of anterior and posterior malleolar folds and lateral process of malleus.

Audiological assessment:

Tympanometry: confirm diagnosis showing type B tympanogram.

Pure tone audiometry:

The average air-bone gap and hearing loss were reported, speech reception threshold (SRT) was assessed.

4. Radiological examination: Digital X-ray to show adenoid hypertrophy.

5. Hematological evaluation:

Routine preoperative as:

- Complete blood count (CBC), Bleeding time and prothrombin time.
- Every procedure had been performed while the patients were under general anesthesia. A radial myringotomy was made in the anterior-inferior quadrant of the right ear, and the surgeon drained the fluid with a grommet tube implanted.

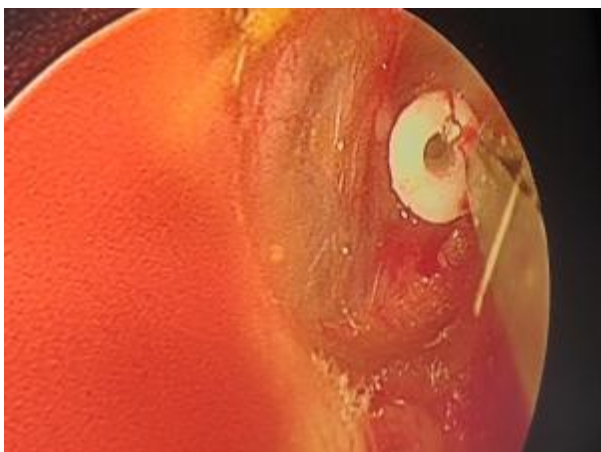


Figure (1): Radial myringotomy with grommet tube

The left ears did circumferential myringotomy in antero-inferior quadrant with suction of all fluid while ITD injected into another entry either antero-superior or postero-inferior. Injection was done till fluid came over myringotomy, gel foam was applied over TM soaked with dexamethasone (less than 1ml).

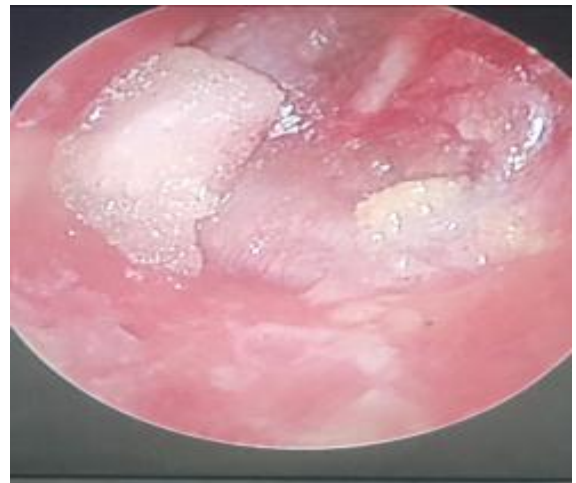


Figure (2): Circumferential myringotomy with intratympanic dexamethasone.



Figure (3): Covered myringotomy with gel foam soaked with dexamethasone.

The patient consented to an adenotonsillectomy or adenoidectomy when necessary.

Postoperatively:

1. All patients received systemic antibiotic with steroid for 2 weeks with nasal wash saline.
2. Regular otoscopic examination to assess TM healing, tube extraction and TM complication.
3. PTA, tympanometry was done within more than 3 months postoperative period to assess speech hearing threshold (SRT).

Ethical approval:

After receiving written agreement from each participant, Zagazig University Research Ethics Board (ZU-IRB#8060/15-09-2021) approved the study. The World Medical Association's Helsinki Declaration established standards for the treatment of patients who participated in medical trials.

Statistical analysis

In order to analyze the data acquired, Statistical Package of Social Sciences version 20 was used to execute it on a computer (SPSS). In order to convey the findings, tables and graphs were employed. The

quantitative data were presented in the form of the mean, median, standard deviation, and confidence intervals. The information was presented using qualitative statistics such as frequency and percentage.

The student's t test (T) was used to assess the data while dealing with quantitative independent variables. Pearson Chi-Square and Chi-Square for Linear Trend (X²) were used to assess qualitatively independent data. The significance of a P ≤ 0.05 or less was determined.

RESULTS

The mean age of studied participants was 6.77 ± 2.71 years. More than half of cases (76.9%, n=10) were males and the other (23.1%, n=3) cases were females (Table 1).

Table (1): Demographic data of the studied group (n=13)

Items	Categories	Study group (n=13)	
		N	%
Gender	Male	10	76.9
	Female	3	23.1
Age	Mean ± SD	6.77 ± 2.71	
	Range	4-12	

As shown After 6 months, there was no statistically significant difference in SRT between the two groups, despite their being a statistically significant difference between pre- and post-op SRT assessments in each group (Table 2).

Table (2): SRT speech reception threshold within the studied group (n=26)

Items	Categories	Right ear (n=13)	Left ear (n=13)	Test	P - value
SRT baseline pre-operative	Mean ± SD	35.38 ± 5.58	31.54 ± 7.74	1.45 4	0.159
SRT 6 month postoperative	Mean ± SD	18.08 ± 5.60	17.31 ± 8.07	0.28 2	0.780
Paired Samples Test	Test	11.078	6.124	-----	
	P value	<0.001*	<0.001*		

Tympanometry results were significantly different between the right and left ears at the 6-months follow-up, with 76% of left ear cases being type A and 23% of cases being type B, whereas 15% of right ear cases were type A and most cases were still type B (Table 3).

Table (3): Tympanometry of right and left ears within the studied groups (n=13)

Items	Categories	Right ear (n=13)		Left ear (n=13)		test	P- value
		N	%	N	%		
Baseline pre-operative after 6 months	B	13	100	13	100	----	-----
	A	2	15.4	10	76.9	9.9 05	0.002 *
	B	11	84.6	3	23.1		

Table (4) showed that, the mean healing duration in the left side was 12.54 ± 4.7 days ranging from 7 to 21 days. Also, early TM healing is more in left ears than in right ears (Table 4).

Table (4): Healing characteristics of the studied group (n=13)

Items	Categories	Study group (n=13)	
		N	%
Healing of TM within right ear	Tube in place	11	84.6
	Yes (after 3 months)	2	15.4
Healing duration of Lt ear (days)	Mean ± SD Range	12.54 ± 4.7 7-21	

At right ears, 23.1% of cases showed both persistent discharge and tympanosclerosis, while at left ears, 38.5% showed tympanosclerosis and no persist discharge. TM perforation cannot be assessed due to shorting of study (Table 5).

Table (5): Side effects within the studied group (n=13)

Items		Right ear (n=13)		Left ear (n=13)		test	P value
		N	%	N	%		
Tympanosclerosis	No	11	84.6	8	61.5	1.7 59	0.185
	Yes	2	15.4	5	38.5		
Persistent discharge	No	10	76.9	13	100	19. 333	<0.001
	Yes	3	23.1	0	0		

There was a statistically significant difference in the occurrence of recurrence between the two ears, with 23.1% of left ears reported recurrence while 100% of right ears showed no recurrence (Table 6).

Table (6): Recurrence within 6 months

Variable	Right ear (n=13)		Left ear (n=13)		Test	P value
	Yes	No	Yes	No		
Recurrence	0	100%	3	23.1%	19.333	<0.001*
	13		10	76.9%		

DISCUSSION

The medical term for middle ear fluid accumulation without infection is otitis media with effusion (OME) ⁽⁵⁾. Middle ear effusion is defined by fluid accumulation under negative pressure in the middle ear cleft, indicating a dysfunction of the mucociliary system ⁽⁶⁾. Acute middle ear infections and conductive hearing loss are the most prevalent consequences of middle ear fluid. Several options were available for managing OME, including as auto inflation and medical treatment with antibiotics and corticosteroids. In cases where the effusion did not cure on its own or where medical treatment had failed after 3 months, surgery was recommended. Surgery was performed to restore middle ear ventilation by relieving negative intratympanic pressure, which resulted in normalization of the mucosa, an increase in the number of ciliated cells, and a decrease in the secretion potential ⁽⁷⁾.

Most cases of OME are treated surgically, and myringotomy with breathing tube installation is the method of choice ⁽⁸⁾. Since the effects of a simple myringotomy and aspiration of effusion only last for a few days, they cannot be considered therapeutically effective. Contrarily, there have been reports of adverse consequences, such as tube otorrhea, following VT implantation, with an incidence rate ranging from 29% to 64% ⁽⁹⁾.

As reported by **Han et al.** ⁽¹⁰⁾, it has been suggested by Chinese authors that a dexamethasone injection into the tympanic membrane may be effective in treating OME. Treating OME or chronic Eustachian tube dysfunction with an intratympanic injection of dexamethasone is a safe and effective option. Patients who had previously tried medicinal or surgical treatment without success were included in their research.

A total of 75 ears from 64 individuals, ranging in age from 12 to 60 years old, were used for the study. Middle ear effusion was designated as a study group and ITD was received by 47 ears from 41 patients who had previously been treated with medication or surgical therapy. Twenty-three individuals were categorised as a control group and given conventional medical treatment for an additional 28 years. Dexamethasone (ITD) injections of 0.5 ml/4 mg per mm were placed in the antero-superior quadrant of the tympanic membrane. Once a week for four weeks, these injections were given. Measurements of hearing and middle ear pressure were taken at 1 and 3 months following therapy to assess efficacy. The average air-bone gap was reduced by 9.91 dB, with an increase of 15.17 dB in air conduction pure-tone averages (PTA) and a decrease of 5.25 dB in bone conduction PTAs as measured by

audiometry. The average air-bone gap, AC-PTA, and BC-PTA all improved by 3 dB in the experimental group, but only 2 dB in the control group. An increase in tympanometric threshold was seen. The study group showed a conversion from type B or C to type A in 28 ears (59.6%) without complications, while the control group showed just 3 ears (10.7%). When used to treat otitis media with effusion or chronic Eustachian tube dysfunction, ITD injections into the middle ear are well tolerated and produced desirable results. There have been no adverse effects, such as perforation of the tympanic membrane or sensorineural hearing loss ⁽¹¹⁾.

The mean age of studied participants in this study was 6.77 ± 2.71 years, more than half of cases (76.9%, n=10) were males and the other (23.1%, n=3) cases were females. This is in agreement with those of **James et al.** ⁽¹²⁾ who reported that male gender had consistently been identified as one of the risk factors for OME. Also, they reported that male children had more incidence of childhood infection as they are more exposed to allergic and infectious agents compared to female children. While, **Erdivanli et al.** ⁽¹³⁾ reported that there was no difference in OME incidence between both sexes.

As shown in this current study, there was no statistically significant difference in SRT between both right and left ears at baseline preoperative and postoperative follow up after 6 months, while at the level of each ear there was statistically significant decrease in SRT between baseline and follow up after 6 months. **Paksoy et al.** ⁽¹¹⁾ in their prospective clinical trial on 64 patients presented with OME treated with intratympanic dexamethasone (ITD) found statistically significant improvement in SRT where AC-PTA improved from 36.2 to 33.2 dB and BC-PTA improved from 10.6 to 9.2. However, **Popova et al.** ⁽¹⁴⁾ in otitis media with effusion in children aged 3-7 years in a randomised controlled trial comparing myringotomy and tympanostomy tubes with and without adenoidectomy. Patients with bilateral otitis media with effusion were shown to benefit no further from the insertion of tympanostomy tubes in conjunction with adenoidectomy compared to adenoidectomy in conjunction with myringotomy alone in terms of hearing loss. And they didn't discover any connection between the type of surgery used and the OME recurrence rate. On the other hand, **Boston et al.** ⁽¹⁵⁾ reported that 20-50% of children with tympanostomy tubes may need additional tubes inserted if the first ones extrude.

The current study showed that tube was extruded after 3 months in 15.4% of cases. The mean healing duration in the left side was 12.54 ± 4.7 days ranging

from 7 to 21 days. These results are in agreement with results of **Khan et al.** ⁽¹⁶⁾ who reported that myringotomy and ventilation tube insertion had higher healing time compared to adenoideotomy with myringotomy alone. Reportedly, if ear tubes were placed, they should fall out between 6 and 12 months and full recovery should occur within 4 weeks. **Aboulwafa et al.** ⁽⁸⁾ showed that the mean healing time was significantly longer in children who underwent myringotomy and adenoideotomy with ventilation tube (Group II) compared to patients of (Group I) myringotomy alone with adenoideotomy, (p <0.001) (28.5 vs. 2.2 weeks). **Aboulwafa et al.** ⁽⁸⁾ showed that patients in group II, who underwent myringotomy and adenoideotomy with a breathing tube, had a considerably longer mean healing time than patients in group I, who received myringotomy and adenoideotomy without the tube (p 0.001). (28.5 vs. 2.2 weeks)

Also, in agreement with those of **Popova et al.** ⁽¹⁴⁾ who found that while 40% of patients who underwent adenoideotomy with a breathing tube experienced episodes of otorrhea, none of those who underwent adenoideotomy plus myringotomy did. Twenty-four percent had experienced only one case of otorrhea, twelve percent had experienced two cases, two percent had experienced three cases, and two percent had experienced four cases or more.

Additionally, **Flynn et al.** ⁽¹⁷⁾ reported that complications associated with tube insertion, the presence of a cholesteatoma (1%), granulation tissue (5%-40%), or tympanic membrane perforation (3%; up to 24% with T-tubes), 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. Also, similar to our findings **Rosenfeld** ⁽¹⁸⁾ reported that it's not uncommon for the tympanic membrane to have potential negative effects after having a grommet inserted. **Khan et al.** ⁽¹⁶⁾ found that myringotomy with tube insertion is a popular and safe treatment with few problems as perforation, scarring, infection, and premature or prolonged tube removal. **Popova et al.** ⁽¹⁴⁾ reported that otitis media with effusion in children aged 3-7 years old in a comparison of myringotomy and tympanostomy tubes with and without adenoideotomy. In agreement with the results of this trial, they discovered that the rate of OME recurrence was greater in the adenoideotomy with myringotomy group than in the adenoideotomy with ventilation tube group.

CONCLUSION

Myringotomy with grommet tube insertion with or without adenoideotomy is a classical method in treatment of chronic OME with potential complications especially otorrhea with less significant low recurrence rate. On other hand, circumferential myringotomy with ITD is an effective method in treatment of chronic OME with less postoperative complications –equivalent

postoperative hearing threshold, but with higher recurrence rate.

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REFERENCES

1. **Danishyar A, Ashurst J (2017):** Acute otitis media. <https://www.ncbi.nlm.nih.gov/books/NBK470332/>
2. **Hembrom R, Singh M, Ghosh S et al. (2021):** A comparative study between the efficacy of intratympanic steroid injection and conventional medical treatment in resistant cases of otitis media with effusion. *Bengal Journal of Otolaryngology and Head Neck Surgery*, 29 (1): 11-16.
3. **Yousaf M, Khan F (2012):** Medical versus surgical management of otitis media with effusion in children. *J Ayub Med Coll Abbottabad*, 24 (1): 83-85.
4. **Amer H, El-Anwar M, Elfeky A (2016):**The efficacy of adjuvant intratympanic steroid treatment for otitis media with effusion in children. *International Archives of Otorhinolaryngology*, 20 (03): 244 - 247.
5. **O'Connor S, Coggins R, Gagnon L et al. (2016):** Plain language summary: otitis media with effusion. *Otolaryngology–Head and Neck Surgery*, 154 (2): 215-225.
6. **Mohammed M, Elsherief W, Osman M et al. (2016):**Role of medical management in otitis media with effusion *Journal of Current Medical Research and Practice*. *Journal of Current Medical Research and Practice*, 1 (2): 24-28.
7. **Chen K, Wu X, Jiang G et al. (2013):**Low dose macrolide administration for long term is effective for otitis media with effusion in children. *Auris Nasus Larynx.*, 40 (1): 46-50.
8. **Aboulwafa W, El Habashy H, Ibrahim M et al. (2019):** Comparative Study between Adenoideotomy with Myringotomy and Adenoideotomy with Ventilation Tube Insertion in Management of Secretory Otitis Media. *The Egyptian Journal of Hospital Medicine*, 74 (6): 1322-1329.
9. **Amer H, El-Anwar M, Elfeky A (2016):**The efficacy of adjuvant intratympanic steroid treatment for otitis media with effusion in children. *International Archives of Otorhinolaryngology*, 20 (03): 244 - 247.
10. **Han Z, Zhibin C, Dengyuan W et al. (2009):** The therapeutic effects of oral administration and intratympanic injection of glucocorticoid in the treatment of otitis media with effusion. *J Audiol Speech Pathol.*, 17 (6): 560- 2.
11. **Paksoy M, Altin G, Eken M et al. (2013):** Effectiveness of intratympanic dexamethasone in otitis media with effusion resistant to conventional therapy. *Indian Journal of Otolaryngology and Head & Neck Surgery*, 65 (3): 461-467.
12. **James F, George J, Regina M (2018):** Impact of adenotonsillectomy on hearing profile of children with chronic middle ear effusion. *Int J Contemp Pediatr.*, 5: 1377-1381.
13. **Erdivanli O, Coskun Z, Kazikdas K et al. (2012):** Prevalence of otitis media with effusion among primary school children in Eastern Black Sea, in Turkey and the effect of smoking in the development of otitis media with effusion. *Indian J Otolaryngol Head Neck Surg.*, 64 (1):17-21.
14. **Popova D, Varbanova S, Popov T (2010):** Comparison between myringotomy and tympanostomy tubes in combination with adenoideotomy in 3–7-year-old children with otitis media with effusion. *International Journal of Pediatric Otorhinolaryngology*, 74(7): 777-780.
15. **Boston M, McCook J, Burke B et al. (2003):** Incidence of and risk factors for additional tympanostomy tube insertion in children. *Arch Otolaryngol Head Neck Surg.*, 129: 293–296.
16. **Khan M, Alamgir A, Musharaf M (2018):** Comparison of outcome of myringotomy alone with myringotomy and tympanostomy tube (Grommet) in otitis media with effusion (OME). *Journal of Rawalpindi Medical College*, 22 (2): 140-143.
17. **Flynn T, Möller C, Jönsson R et al. (2009):** The high prevalence of otitis media with effusion in children with cleft lip and palate as compared to children without clefts. *Int J Pediatr Otorhinolaryngol.*, 73:1441-1446.
18. **Rosenfeld R (2003):** Natural history of untreated otitis media. *Laryngoscope*, 113 (10): 1645–1657.