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## Myringotomy with or without ventilation tube in management of children with otitis media with effusion: A comparative

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### Abstract:

**Introduction:** Otitis media with effusion (OME) is defined as inflammation of the middle ear (ME) space accompanied by fluid collection without signs or symptoms of acute infection.

**Aim of the work:** This study aimed to compare the functional outcome and complications of myringotomy with and without VT in management of children with OME for whom surgery was justified.

**Patients and methods:** We compared the results of treating children with bilateral OME refractory to conservative treatment by myringotomy with and without VT. Patients were followed up for six months after surgery. The primary outcome measure was hearing status at one week; three and six-month follow up visits. Secondary outcome measures were intraoperative and postoperative complications and recurrence of OME during follow-up.

**Results:** At one week after surgery, there was subjective hearing improvement in all patients. Myringotomy was found closed in 13 ears in the RT side. Ventilation tube was found blocked by blood in three ears in the LT side. Subjective hearing improvement was maintained at 3rd month follow up with no significant difference between both sides. At the 6th month follow-up however hearing was significantly better in the LT side. Complications were generally few. Intraoperative bleeding and post-operative discharge were more and recurrent effusion was less with VT insertion.

**Conclusion:** Myringotomy with ventilation tube is superior to myringotomy alone. For better hearing outcome, insertion of ventilation tube should be done in all children with OME when surgery is indicated.

**Keywords:** Myringotomy; ventilation tube; otitis media; effusion.

### Introduction:

Otitis media with effusion is defined as inflammation of the ME space associated with fluid collection without signs or symptoms of acute infection like fever, otalgia and red bulging TM.<sup>1</sup>

The etiology of OME is very diverse and includes viral and bacterial infection, Eustachian tube dysfunction

and excessive exudates-production due to allergy and chronic inflammation.<sup>2</sup>

By the age of 4 years, approximately 80% of children have suffered OME at least once. Untreated, OME may cause temporary and permanent acquired hearing loss in infants and young children with the possibility of delayed speech development and learning problems.<sup>3</sup>

The classic lines of treatment of OME used to include elimination of risk factors like smoking, maneuvers to open the Eustachian tube, watchful waiting, and use of long list of medications like steroids, antibiotics, mucolytics and decongestants.<sup>1</sup>

The recent guidelines however - recommended against using most of the previously used medications. They recommended for the policy of watchful waiting unless the hearing loss was significant or the TM starts to show structural changes. Some exceptions from long watchful waiting (when the hearing loss is associated with some co-morbidity) were also put.<sup>2, 4, 5</sup>

Surgery is indicated if hearing loss was significant, the TM starts to show structural changes like atrophy or retraction pocket formation and after short watchful waiting in children with these co-morbidities.

Surgery for OME used to include myringotomy with or without VT and adenoidectomy when there is an enlarged adenoid. Myringotomy without VT has the advantage of rapid healing of the TM, no residual perforation and less chance of ME infection and tympanosclerosis. Recurrence of OME and reappearance of symptoms are however common. Advantages of myringotomy with VT include long term improvement of hearing and proper ventilation of ME. The disadvantages of VT include higher incidence of permanent perforation of the TM, ME infection, tympanosclerosis and premature subluxation of the tube. There is also a need for proper care of the tube during pathing and swimming.<sup>6</sup>

The aim of the study is to compare the results of myringotomy with and without VT in children with OME for whom surgery was justified.

## **Patients and Methods:**

This clinical trial was carried out on 100 children with bilateral OME for whom surgical intervention was justified according to the guidelines of the American Academy of Otolaryngology Head & Neck Surgery released in 2016.<sup>2</sup>

Approval from the institutional ethics committee and consent from one parent of each participant child were obtained prior to enrollment in the study. All surgeries were done in El-Helal hospital for health insurance, Sohag city, Egypt. The study extended from April 2017-March 2019.

Diagnosis of OME was made clinically and confirmed by tympanometry. Inclusion criteria were children 2-12 years with bilateral OME, with symmetrical nature of ME aspirate (serous, mucoid or glue) and suitable size of the external auditory canal (EAC) that allows surgery.

Patients < 2 years old, patients with unilateral OME, asymmetrical nature of the effusion, atelectatic TM or adhesive OM in one or both ears were excluded. Patients with previous unilateral or bilateral ear discharge, previous unilateral or bilateral myringotomy, patients with submucosal or repaired palatal cleft, patients refused to join the study and patients lost for follow up were also excluded.

All children were subjected to detailed history and full general and ENT examination including endoscopic examination of the TM using 0-degree (2.7 or 4 mm) endoscope. The endoscope was used also to examine the nose and nasopharynx for significant adenoid enlargement. The later step was done under local surface anesthesia using a small piece of cotton soaked with equal volumes of lidocaine 10% solution (Astra Zeneca, Rueil-Malmaison, France) and epinephrine 1/200,000.

When this step was not feasible, lateral view X-ray soft tissue to the nasopharynx was obtained. Preoperative routine laboratory investigations, anesthesia fitness and recent tympanometry were obtained.

All surgeries were done under general endotracheal inhalation anesthesia. When adenoidectomy or adenotonsillectomy was indicated, it was done first followed by myringotomy.

The patient was kept supine on the table with the head turned opposite the side of the ear to be operated. The EAC was sterilized with alcohol 70%. The surgical microscope was then brought to the field and suitable ear speculum was inserted in the EAC for better visualization. Wax and alcohol were removed by suction and myringotomy was done in the anteroinferior quadrant of the TM using a suitable knife.

In the **RT ear**, a suitable suction tip was used to get the ME fluid out. The nature of the fluid was recorded.

In the **LT ear**, the same was done like the RT ear, then a Shepard ventilation tube was placed through the myringotomy incision using alligator forceps. Significant bleeding from the EAC, TM or ME mucosa was dealt with through irrigation of the EAC with epinephrine-containing saline (1/200000) for few minutes.

The EAC was packed with a small cotton ball and pack in the nasopharynx-if present- was removed. The patient was then transferred to the recovery room for some time and discharged from the hospital few hours later. Oral Amoxicillin-Clavulanic acid 90mg/ kg/day were given for 5 days. Cefdinir at a dose of 14 mg/kg/day in 2 divided doses (maximum 600mg) was used for patients with penicillin allergy or intolerance.

Patients were asked to come back for follow up at the 7th day and by the end of the 3rd and 6th months. Patients were

asked to come back for follow up any time should they experienced ear discharge, ear bleeding, diminution of hearing or persistent pain. Patients were also advised to use ear plugs during bathing to avoid water entry to the ear.

At the 7th day, patients or their parents were asked for the status of hearing, ear bleeding, discharge, itching or pain. Both ears were then checked for blood, discharge and otitis externa. The RT side was checked for closure of the myringotomy incision. The tube in the LT side was also checked for presence, position and patency.

At the 3rd month visit, patients or their parents were asked about hearing, ear bleeding, discharge, itching or pain. The RT side was checked for the presence of perforation, position of the TM, signs of recurrent OME or AOM. The LT side was also checked for presence, position and patency of the VT. Tympanometry was also done.

At the 6th month visit, the same checks of the 3rd month visit were done again.

### **Statistical analysis:**

Data obtained were analyzed using Statistical Package for Social Science (SPSS) version 25 (IBM, Chicago, IL, USA, August 2017). Pearson Chi-square test was used to compare percentages of qualitative variables. Fisher's exact test was used for non-parametric data. P-value was considered statistically significant when  $P < 0.05$ .

### **Results:**

The age of our patients ranged between 2–10 years. Ninety six patients were below eight years and only four were 8-years and above. A little more than half (57%) were boys and 27% had history of exposure to cigarette smoking at home.

The main presenting symptom was hearing impairment which was present in all patients. Other less common symptoms were ear ache (55%), chronic nasal obstruction (32%), nasal discharge (29%) and snoring (21%).

Significant adenoid enlargement (>50% choanal obstruction) was present in 63 patients while the remaining 37 patients were having small adenoids to be considered significant. The nature of ME fluid was glue in 63% and serous in 37%.

Hearing evaluation at different follow up visits is shown in Table (1)

Intraoperative and post-operative complications in both groups are shown in Table (2).

**Table (1): Hearing evaluation at different follow up visits.**

Hearing evaluation		RT ear	LT ear	P value
Subjective hearing change at 7 <sup>th</sup> day (N=100)		Improved		
Subjective hearing improvement at 3 <sup>rd</sup> month (N=66)		Sustained 52 (78.8%)	Sustained 58 (87.9%)	0.161
Subjective hearing improvement at 6 <sup>rd</sup> month (N=66)		Sustained 30 (45.5%)	Sustained 61 (92.4%)	0.001
		<b>N=98</b>	<b>N=95</b>	
Tympanogram at 3 <sup>rd</sup> month	A& leakage	70 (71.4%)	89 (93.6%)	0.001
	Type B	21 (21.4%)	3 (3.2%)	
	Type C	7 (7.1%)	3 (3.2%)	
		<b>N=100</b>	<b>N=100</b>	
Tympanogram at 6 <sup>th</sup> month	A& leakage	33	77	0.001
	Type B	56	12	
	Type C	11	11	

Chi- square test

**Table (2): Intraoperative and postoperative complications**

Complication		RT ear	LT ear	P value
Intraoperative bleeding		<b>4</b>	<b>12</b>	<b>0.037</b>
Postoperative discharge during 3 month		<b>2</b>	<b>15</b>	<b>0.001</b>
State of the TM	At 3 <sup>rd</sup> month	Healed (98 cases)	Healed(37cases)	<b>0.001</b>
	At 6 <sup>th</sup> month	Healed (99 cases)	Healed(61cases)	<b>0.3</b>
Recurrent OME	At 3 <sup>rd</sup> month	<b>21</b>	<b>3</b>	<b>0.001</b>
	At 6 <sup>th</sup> month	<b>56</b>	<b>12</b>	<b>0.001</b>
Persistent perforation at 6 <sup>th</sup> month		<b>1</b>	<b>3</b>	<b>0.614</b>
Tympanosclerosis at 6 <sup>th</sup> month		<b>2</b>	<b>5</b>	<b>0.442</b>

Chi-square test Fisher exact test

## **Discussion:**

The present study aimed to answer the question of whether myringotomy with VT is better or worse than myringotomy without VT in management of patients with OME refractory to watchful follow up, or both procedures have just similar results. For the sake of validating the comparison we choose to do the 2 operations in the same patient making the RT side for myringotomy and the LT for myringotomy with VT.

The age of our patients ranged from 2-10 years. Sixty six of them were above 5 years. This shouldn't be taken as the actual general peak-age of OME because we calculated here only the 10% of patients with OME who needed surgery. We also excluded patients with asymmetric nature of ME fluid, narrow EAC and those lost for follow up. Most studies mentioned earlier age peak for OME. The National Collaborating Centre for Women's and Children's Health (UK) in 2008 concluded the presence of a bimodal peak for the problem at 2 and 5 years.<sup>7</sup>

The presenting symptom was hearing loss in all patients, this is because we complied with the American guidelines released 2016<sup>2</sup> which gives watchful waiting the whole time to correct the problem and presents significant hearing loss and TM structural changes as the main indications for surgery. Ear ache was present at some time in one or both ears in around half of patients. Nasal symptoms such as obstruction, discharge and snoring were present in around 30 % of these patients. This reflects the association between OME and adenoid enlargement. Significant adenoid enlargement was present in 63 patients in this study. Adenoidectomy alone was and is still considered one of the surgical options for patients with OME.<sup>8-10</sup>

The nature of ME fluid aspirated was glue in about 2/3 and serous in 1/3 of cases. At the first post-operative visit (at one week) there was subjective hearing improvement in all patients relative to the preoperative status. In the 66 patients with ages above 5 years (whose age might validate a comparison between both sides) this initial hearing improvement was maintained at 3rd month follow up in a slightly larger number in the LT side. The difference between both ears however was statistically insignificant. In contrary to the subjective hearing evaluation at the 3rd month point of follow up, the tympanometric findings were significantly better in the VT side. Similar studies also found that the prevalence of OME using the tympanometric data for diagnosis was more than when using the clinical data.<sup>11</sup> Similar results were also reported by **Zakzouk et al (2002)**.<sup>12</sup>

At the 6th month follow up, the presence of VT has maintained the hearing improvement in double the number of patients compared with the side without VT. The difference was statistically highly significant. Getting a look to the tympanometric findings in both sided at 6th month, echoed the subjective hearing results at that time. The number of type A or leaking tympanogram in the LT side was more than double that of the RT side. The number of flat tympanogram (type B) in the RT side was about 5 times more than that in the LT side; Table (1).

It looks here that the premature healing of the TM in the RT ear did not give enough time for the ME to be ventilated and the mucosal changes to be reversed while in the LT side the VT did.

Popova et al (2010) in Bulgaria found no differences in hearing at one, six or 12 month-follow up in patients with or without grommet tube.<sup>13</sup> Mandel et al

(1989 and 1992) in the United States<sup>14-15</sup>, **Wallace et al** in their large systematic review published 2014<sup>8</sup>, **Caye-Thomassen et al (2008)**<sup>16</sup>, **Steel et al (2017)**<sup>9</sup>, **Khan et al (2018)**<sup>17</sup>, all concluded the superior hearing results of myringotomy with VT relative to myringotomy without VT.

In a local similar study, **Aboulwafa et al (2019)**<sup>10</sup> found that patients who had VT did better in hearing than those without VT.

Complications of both procedures were few (Table 2). Trivial intraoperative bleeding occurred in a significantly larger number of patients in the VT side. The reason here was the extra manipulations required for tube insertion especially when the EAC was narrow.

Post-operative infection and otorrhea was statistically significantly higher in the VT side (15 Vs 2). Early healing of the TM in the RT side acted as a barrier against ME infection when water enters the ear. The literature reported very variable incidences of otorrhea depending upon the length of the follow up.

The longer the follow up the higher the chance of otorrhea.<sup>3, 8, 9, 13-17</sup> The incidence of otorrhea in our study was relatively low, because of the relatively short follow up time. The routine use of Antibiotic in the first post-operative week is probably another factor.

Although the initial hearing improvement (at one week) was subjectively maintained at 3rd month, both the tympanometric findings and clinical signs of recurrence at 3rd month were significantly better in VT side compared with the no-tube side (Table 1&2). This discrepancy between the subjective and objective data might be explained by the fact early effusion is usually not associated with significant hearing impairment. That is why the recommendations of the recent

guidelines paved towards conservation unless significant hearing loss appeared or early signs of damage to the TM were noticed.<sup>11</sup>

By the end of the study, one patient had persistent perforation and two had tympanosclerosis in the no-tube side relative to 3 with perforation and 5 with tympanosclerosis in the tube side. The difference here is statistically insignificant.

### **Conclusion:**

Although myringotomy with and without VT insertion provide early hearing improvement for children with OME refractory to conservative treatment, hearing results at 6th month were much better when VT was used. Complications with VT are higher yet still infrequent and of little clinical impact.

### **Recommendation:**

Longer follow up might be required to compare the long term hearing results and complications as some complications like tympanosclerosis usually need long period to develop.

A large study comparing between both procedures using the nature of effusion and the age of the child might help decision making to or not to insert a VT based on the nature of the fluid in the ME and / or the age of the patient.

**Conflicts of interest:** None of the authors have any conflicts of interest to declare.

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