**Outcome of Gastroesophageal Reflux Therapy in Children with Persistent Otitis Media with Effusion**

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**Abstract**

**Introduction** Otitis media with effusion (OME) is considered one of the most common disorders that affect children during the first years of life. There are many risk factors of persistent middle ear effusion; one of these risk factors is gastroesophageal reflux. Association between persistent OME and gastroesophageal reflux diseases (GERDs) could be explained by respiratory tract infections, insufficient ciliary clearance, and poor drainage of the Eustachian tube.

**Objective** To investigate whether the control of gastroesophageal reflux plays a role in the management of persistent OME and decreases tympanostomy tube insertion

**Method** A cross-sectional study was conducted on 50 children complaining of persistent OME. Their ages ranged between 5 and 12 years old. All children were subjected to full history taking, audiological assessment and 24-hour esophageal pH monitoring. The study group was divided according to pH results into two groups: GERD positives and GERD negatives.

**Result** The prevalence of GERD in persistent OME was 58%. There were statistically significant differences in the hearing levels and middle ear condition before and after the treatment ($p < 0.05$). The percentage of improvement of children complaining of persistent OME after antireflux treatment was 52%.

**Conclusion** Gastroesophageal reflux disease should be considered in patients with persistent OME. The administration of proton pump inhibitor (PPI) can set aside superfluous surgical treatment (such as tympanostomy).

**Keywords**
- otitis media with effusion
- gastroesophageal reflux
- child
- prevalence

**Introduction**

Otitis media with effusion (OME) is considered one of the most common disorders that affect children during the early years of their life. Its true prevalence is difficult to estimate as it is a silent disorder. Moreover, according to a previous study, its prevalence in children is ~ 16.5%, and between 2.2 and 4.8% worldwide. About 90% of children have reported at least one episode of OME by the age of 4 years old. One of the most common causes of hearing loss in children is persistent middle-ear effusion, which lasts for > 3 months, with no improvement even after treatment.

Many risk factors exist for persistent middle ear effusion, one of them being gastroesophageal reflux (GER), which is the reflux of gastric content beyond the oropharynx, the larynx, and the nasopharynx. Children with GER may complain of different symptoms such as heartburn, vomiting, and regurgitation. The association between persistent OME and
gastroesophageal reflux diseases (GERDs) can be explained by respiratory tract infections, insufficient ciliary clearance, and poor drainage of the Eustachian tube.^

Two studies were conducted on rats, and in the first one, Heavner et al.\(^9\) concluded that the repeated exposure of the Eustachian tube to the main components of gastric juice (hydrochloric acid [HCL] and pepsin) may lead to Eustachian tube dysfunction, followed by OME. In the other study, the authors found that mucociliary clearance was affected in rats exposed to HCL.\(^9\)

A previous study conducted on 54 children, aged between 2 and 8 years old, who complained of glue ear, reported an increase in the level of pepsin/pepsinogen in effusion samples compared with its level in the serum, suggesting that GER may be the cause of persistent OME.\(^10\)

The presence of bothersome symptoms and complications of the reflux of gastric content can be roughly diagnosed as GERD.\(^11\) The diagnosis of GERD can be confirmed by esophageal PH monitoring with a double probe in which acid may pass the anatomical barrier of the upper esophageal sphincter and come into contact with the extraesophageal mucosa.\(^12\) Proton pump inhibitor (PPI) such as lansoprazole or omeprazole is considered the current treatment for GERD.\(^13\) This medication is safe for use in children as young as 2 years old.\(^14\) While the tympanostomy tube (TT) is considered the standard treatment for persistent OME, it is not completely safe. The hazards of TT insertion include otorrhea, perforation of the tympanic membrane; c) tympanometry: type B (flat curve tympanogram with normal external ear canal volume) with absent acoustic reflex; d) pure-tone audiometry: the conductive hearing loss diagnosed by elevated pure tone threshold with air bone gap (ABG) should be at least 10 dB and bone conduction threshold should be better than 25 dB. The exclusion criteria were: a) children with a medical history or concurrent conditions known to increase the incidence of OME, including cleft palate, neurologic delay, allergic rhinitis or Down syndrome, were excluded. b) patients with structural abnormalities of the tympanic membrane, including atelectasis, or deep retraction pockets, were also excluded.

All participants in the current study were subjected to the following

1. Full history taking including
- Personal history (age, name and gender)
- History of hearing loss, tinnitus, discharge, earache, headache
- History of GERD symptoms (heartburn, vomiting)
- Past history of systemic disease, physical trauma, acoustic trauma, ototoxic drug and operations

2. Otological examination: preauricular region, ear pinna, postauricular region, and tympanic membrane.

3. Basic audiological evaluation
   a- Pure-tone audiometry using Orbiter 922 GM (Otomatrix, Denmark): This included
   - Air conduction: (Air conduction hearing thresholds were determined by the frequency range of 0.250 and 8 KHz)
   - Bone-conduction: (bone conduction hearing thresholds were determined by the frequency range of 0.500 and 4 KHz).
   - Hearing thresholds > 25dB were considered as hearing loss (HL).

   b- Speech audiometry Speech Reception Threshold (SRT) using Arabic spondee words and the Word discrimination scores (WDS) using Arabic phonetically balanced words

   c- Immittancemetry using Amplaid 724 (Ampilfon, Italy). This included tympanometry and acoustic reflex threshold measurement.

   4- 24-hour esophageal pH monitoring.

   Children were assessed for GERD symptoms (acid regurgitation and heartburn) and all those having GERD were clinically referred to the Pediatric Gastroenterology Unit and underwent a prolonged ambulatory 24-hour esophageal pH monitoring.

   Diagnosis of GERD was based on the presence of GERD-related complaints and a decrease in esophageal pH to < 4 for at least 15 seconds. Thereafter, the patients were divided into two groups: GERD positive and GERD negative.

**Procedure**

The parents were instructed on antireflux precautions, antireflux therapy was prescribed by a pediatric Gastroenterology specialist. The antireflux precautions were avoiding...
chocolate, acidic or fruit juices, tomatoes, and fatty or greasy foods; avoiding eating before bedtime; and elevating the head of the bed. Also, the parents were instructed to avoid smoking near the child.

The GERD positive group was given the PPI lansoprazole for between 8 and 12 weeks; 2 dosages of lansoprazole were administered based on the weight of the child. Children weighing < 30 kg were given 15 mg lansoprazole per day, while children weighing > 30 kg were given 30 mg per day.³

Each month, the children returned to the clinic for a follow-up visit. At each follow-up visit, the physician completed a follow-up data sheet documenting history taking, GERD symptoms and basic audiological evaluation. After 3 months; children who did not improve were referred to an ear, nose and throat (ENT) clinic for placement of a tympanostomy tube. Improvement was defined as improvement in middle ear effusion and audiometric testing.

Statistical Analysis
The data were analyzed by IBM SPSS Statistics for Windows, version 24.0 (IBM Corp, Armonk, NY, USA). Continuous variables were presented as the mean ± standard deviation (SD) and range. Numerical variables were presented by the count and percentage. The independent-samples t-test was used to determine if a difference exists between the means of two independent groups on a continuous dependent variable. The chi-squared test of association was used to discover if there was a relationship between two categorical variables. The differences were considered significant at \( p < 0.05 \). All statistical comparisons were two-tailed.

Results

Baseline Characteristics of the Study Groups
Ages ranged between 5 and 12 years old with a mean age of 8.4 ± 1.2 years old. They were 22 females (44%) and 28 males (56%).

The Distribution of Study Group According to 24-hour Esophageal pH Monitoring
The study group was divided into two groups: GERD positives (58%) and GERD negatives (42%). The prevalence of GERD in persistent OME was 58%, as shown in Fig. 1.

Fig. 1 Percentage of gastroesophageal reflux in persistent otitis media with effusion.
The prevalence of GERD in the present study was 58%, as shown in Fig. 2. This result was in accordance with a previous study conducted by Yüksel et al. They found that the percentage of GERD in OME was 68%, as shown in Table 3. The present study was similar to a previous study conducted by McCoul et al. In that study, the children complaining of OME were submitted to ventilation tube, tonsillectomy and adenoidectomy, and then assessed pH after recovery from surgery. So, the effects of these procedures on GERD were not well established, as the best time for assessing pH must be before the surgery.

Three mechanisms could explain the increased prevalence of GERD in OME. The first and the most significant one is the harmful effect of acid contents on the mucosa, which results in mucosal swelling, hypersecretion, and ciliary dysfunction. The second mechanism is vagus nerve stimulation. The last one assumed a relation between Helicobacter pylori infection and OME. Several studies reported the presence of this bacterium in aspirates of the middle ear. The stimulation of Muc5b gene expression in the middle ear epithelium by the acidic and proteolytic effect of refluxed pepsin in the middle ear, is considered another possible explanation for the association between the two disorders.

One of the positive confirmations for the role of GERD in the pathogenesis of OME is the improvement of OME with antireflux treatment. According to the previous studies, the percentage of the improvement of the treatment was ~ between 80 and 85% of the studied patients, which resulted in a reduction in the planned surgical procedures.

In the present study, there was a statistically significant difference in audiometric and tympanometric findings before and after the intake of PPI. The percentage of the improvement of OME in the children with GERD positive were 52%, and the improvement of the hearing thresholds was 68%, as shown in Table 3.

The improvement of the middle ear condition and the hearing level of the children occurred gradually. After 1 month of treatment, the OME was improved in 5 patients and the hearing thresholds reached normal levels in 4 patients. The level of improvement increased after 2 months of treatment; 9 patients recovered from OME and 10 patients had normal hearing thresholds. At the end of the study, improvement of OME was found in 15 patients (52%) and improvement of hearing threshold was found in 17 patients (68%). The present study was similar to a previous study conducted by McCoul et al. They reported statistically significant improvements in hearing loss, tympanometry, and middle ear status after the intake of PPI; progress occurred in 28 of 37 children (76%) at the second visit and in 6 of 10 children (60%) at the third visit.

Table 3 Middle ear condition and hearing loss in the patients before and after antireflux treatment

<table>
<thead>
<tr>
<th>Number</th>
<th>Before treatment</th>
<th>After treatment</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hearing loss</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Present</td>
<td>25</td>
<td>8 (32%)</td>
<td>0.00002212*</td>
</tr>
<tr>
<td>Absent</td>
<td>4</td>
<td>21 (68%)</td>
<td></td>
</tr>
<tr>
<td>Tymanometry</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type B/C in one or both ear</td>
<td>29</td>
<td>14 (48%)</td>
<td>0.00002691*</td>
</tr>
<tr>
<td>Type A</td>
<td>0</td>
<td>15 (52%)</td>
<td></td>
</tr>
</tbody>
</table>

p ≥ 0.05: nonsignificant.
*p < 0.05: significant.
Also, Dewan et al.4 demonstrated that lansoprazole administration has a significant enhancement in the pure tone threshold (PTA) and the speech recognition threshold with 33% improvement rate of the middle ear effusion by the end of 3 months of follow-up. In addition, Rosenfeld et al.28 stated a 28% improvement rate of effusion by the end of 3 months.

Conclusions

The present study specifies that GERS could have a significant etiologic role in the pathogenesis of OME, as a result of a 28% improvement rate of effusion by the end of 3 months. In addition, Rosenfeld et al.33% improvement rate of the middle ear effusion by the end of 3 months of follow-up. In addition, Rosenfeld et al.28 stated a 28% improvement rate of effusion by the end of 3 months.

Conflict of Interests

The authors have no conflict of interests to declare.

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