Original Article
Mastoid antral ventilation tube; new treatment modality for recurrent otitis media with effusion and its long term results

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Received January 26, 2015; Accepted March 26, 2015; Epub April 15, 2015; Published April 30, 2015

Abstract: Objectives: To evaluate the efficiency of mastoid antral ventilation tube (MAVT) treatment in recurrent/chronic otitis media with effusion (OME). Methods: 20 OME patients who were unsuccessfully treated with ventilation tube (VT) at least twice, who consented to MAVT and who were followed up at least three years were included in the study group. Control group comprised 10 patients who had the same characteristics and refused to undergo MAVT and underwent VT placement again. Pre-operative and post-operative otomicroscopic, hearing tests, and CT findings were compared between the groups statistically. Results: MAVT was placed into 24 ears of 20 patients. In the control group, VT was placed in 13 ears of 10 patients. Postoperatively, in the study group, one tympanic membrane with adhesion and nine membranes with retraction returned to their anatomic positions after MAVT. In the control group, 2 retracted tympanic membranes returned to normal position. There was significant difference between groups in terms of mastoid aeration (P = 0.006). Post-operative pure tone threshold values and mastoid aeration findings were statistically different from preoperative conditions. Conclusion: This preliminary study demonstrates that MAVT may be effective in the surgical treatment of recurrent/chronic OME. However, further studies with larger patient series should be carried out.

Keywords: Otitis media with effusion, ventilation tube, mastoid pneumatization, mastoid antral ventilation, atelectasis, adhesive otitis media

Introduction

Otitis media with effusion (OME) is characterized by middle ear effusion without pain, redness, or bulging of the tympanic membrane. It is the most common middle ear disease of childhood, and prolonged disease may cause hearing loss, delayed speech and failed school performance. It heals quickly with medical therapy or by minor surgical procedures in most cases. Sequelae such as hearing loss, retraction pockets and adhesive otitis that lead to cholesteatoma may rarely occur. When medical treatment is unsuccessful, middle ear effusion is treated surgically with a ventilation tube (VT) in the affected ear. Although definitive resolution is obtained in the majority of patients with these tubes, some patients require a second VT placement. In a very few patients, even the second attempt is not beneficial. In these cases, a third tube insertion or mastoidectomy procedure may be warranted. The aim of our study was to evaluate the results of a newly developed mastoid antral ventilation tube (MAVT) treatment in recurrent OME patients who had previously undergone VT placement twice.

Material and methods

The present study was prospectively initiated in 2007 in Ankara Atatürk Training and Research Hospital with the approval of local ethics committee and completed in December 2013. Thirty patients in whom at least two VTs were used as treatment for recurrent OME, had find-
ings such as retraction, adhesion, atrophy and sclerosis in their tympanic membranes, whose CT findings included aeration loss in mastoid air cells, and who experienced hearing loss were included in the present study. Of these patients 20 consented to MAVT and formed the study group and the remaining 10 patients refused MAVT and consented to repeat ventilation tubes placement and formed the control group. Patients with frequent upper respiratory

Figure 1. The appearance of MAVT: figure (on the left), prototype used in the study (on the right side).

Figure 2. The appearance of MAVT placed into ear [1) mastoid air cells, 2) MAVT, 3) antrum, 4) attic, 5) tympanic membrane, 6) tympanic bone, 7-8) external canal].

tract infections, those who had congenital anomalies such as Down syndrome and cleft palate, and patients with cystic fibrosis, immotile cilia syndrome and allergy were excluded from the study. In addition, those who with sclerotic mastoiditis or pneumatized mastoid air system in CT were excluded as well.

All previous treatments, operations, and the number of the VTs placed were recorded. In physical examination, tympanic membranes were evaluated otomicroscopically. Audiometric and tympanometric measurements were made, and the temporal bone CT was taken. In the evaluation of CT findings, integrity of ossicles, aeration status of ear, and the presence of soft tissues and cholesteatoma were noted. Based upon the aeration findings in aditus, antrum and mastoid cells of the patients, each region (middle ear, aditus, antrum and mastoid cells) was scored separately by an expert radiologist for easier classification in CT. In this scoring system, each region was stratified into four categories according to the rate of aeration, i.e. 0-25%,
Surgical techniques of MAVT and VT

Surgical procedure was initiated with postauricular small incision under general anesthesia. After mastoidotomy (antrotomy) was performed, the aeration and mucosa of antrum was evaluated. After the glue (if any) was aspirated, then a prototype tube, developed just for this study, of MAVT (Figure 1) was placed into external auditory canal with one end directed to mastoid antrum and the other to external auditory canal space using an incision large enough to allow tube passage and extending from upper margin of posterior bone wall towards the skin of external auditory canal (Figure 2).

VT’s were placed into the most suitable place of tympanic membrane, taking into account, calcareous plaques, retraction pouches and pseudomembranes associated with previously placed tubes.

Postoperative care

All patients received postoperative antibiotic treatment for seven days. To test the patency of MAVT, if it needs, the tube was aspirated. Incision sutures in post-auricular region were also removed on the seventh day. Patients were seen at baseline and then invited to control visits at two, four, and eight weeks after the operation. In control visits, the patients’ hearing, the appearance of membrane and the status of MAVT were evaluated. Cerumen (if any), blocking the tube were cleaned. Taste test was carried out with MAVT before the removal of it. 0.5% 1 ml dextrose was administered to mastoid antrum from the opening of MAVT, and patients were asked to make swallowing movements. If the patient is able to taste, this means that MAVT can be removed. Then, external canal wound healing was followed. MAVT was removed at the end of 8th week postoperatively regardless of taste test.

Data analysis was performed by using SPSS for Windows, version 11.5 (SPSS Inc., Chicago, IL, United States). Whether the distributions of continuous variables were normally or not was determined by Shapiro Wilk test. Data were shown as mean ± SD or median (min-max), where applicable. While, the mean differences between groups were compared by Student’s t test, otherwise, Mann Whitney U test was applied for comparisons of the median values. Nominal data were analyzed by Fisher’s exact or Likelihood Ratio test, where applicable. Whether the differences between pre- and post-op measurements within groups were statistically significant or not was evaluated by Paired t-test or Wilcoxon Sign Ranked test, where appropriate. A p value less than 0.05 was considered statistically significant. But, for all possible multiple comparisons, the Bonferroni Correction was applied for controlling Type I error.

Results

There were 10 females and 10 males in the study group. Their age ranged from five to 17 years (mean 10.2 ± 3.38). MAVT was implanted into 24 ears, eight to the right, eight to left and four to both. The shortest period of follow up was 3 years; the longest 6 years (mean 4.2). In control group, there were 10 patients (4 males, 6 females) with a mean age of 12.3 ± 3.1.3 of these patients underwent bilateral VT. 13 ears of 10 patients were placed VT. Mean duration of follow up was 3 years.

Twenty one patients underwent two times VT procedures, five underwent three-four times procedures, and four patients underwent five or more times procedures. The number of patients who underwent mastoidotomy along with tube placement was two.

In the preoperative otomicroscopic evaluation, there were various degrees of calcifications in tympanic membranes associated with previous placement of tube, and it was determined that of 24 ears, the membrane was adhesive in seven (29.1%) and retracted in 17 (70.9%) in study group. In control group, there was adhesion in three ears along with calcareous plaques and retraction in 10 ears. In postoperative evaluation, it was observed that six (25%) membranes were adhesive, eight tympanic membranes (33.3%) retracted, and ten (41.7%) ear membranes aerated at normal anatomic level in the study group. In control group, 3 retracted tympanic membranes returned to normal position. There was no change in other ears.
Mastoid antral ventilation tube

Table 1. Aeration score and ABG levels according to evaluation

<table>
<thead>
<tr>
<th>Variables</th>
<th>Pre-op</th>
<th>Post-op</th>
<th>p-value †</th>
<th>Change</th>
<th>p-value †</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Aeration score</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Control</strong></td>
<td>9 (4-13)</td>
<td>8.5 (7-14.5)</td>
<td>0.042 †</td>
<td>1.7 (-2-5)</td>
<td></td>
</tr>
<tr>
<td><strong>Study</strong></td>
<td>7.5 (4-16)</td>
<td>12.5 (5-16)</td>
<td>0.006 †</td>
<td>2.5 (-2-12)</td>
<td></td>
</tr>
<tr>
<td><strong>ABG</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Control</strong></td>
<td>21.2 ± 12.0</td>
<td>12.5 ± 11.8</td>
<td>0.014 †</td>
<td>-8.7 ± 9.1</td>
<td></td>
</tr>
<tr>
<td><strong>Study</strong></td>
<td>21.4 ± 11.7</td>
<td>12.5 ± 10.8</td>
<td>0.009 †</td>
<td>-8.9 ± 13.7</td>
<td></td>
</tr>
</tbody>
</table>

†Comparisons between pre-ve post-op measurements within groups were analysed. According to Bonferroni correction, P<0.025 was considered statistically significant for results. ‡Comparison between groups in terms of changes between preop and post op periods was analysed. P<0.05 value was considered statistically significant. $Wilcoxon Sign Ranked test, \*Paired t-test, \$Mann Whitney U test, ‡Student’s t test.

Discussion

One of the important causes of recurrent OME could be loss of mastoid ventilation combined with the presence of mastoid glue. There are only a few studies on the topic, which was first introduced by Yung MW as “Percutaneous Mastoid Vent” [1]. Building on that research, we have developed a tube called MAVT [2] for the treatment of recurrent OME and for the conditions caused by persistent eustachian tube dysfunction. This method essentially provides a novel approach for the re-ventilation of middle ear and mastoid cells. This tube is not for the initial treatment for OME, but is rather developed for the recurrent/ chronic OME, and it should particularly be used in the presence of mastoid glue. The Yung tube is inserted externally to the antrum and thus cannot be used in patients younger than twelve years of age. In contrast, MAVT is inserted through mastoidotomy and thus is suitable for all patients with a developed antrum. Even though the surgical requirement might seem as an advantage for MAVT, it also provides a direct way of observing the antrum. Furthermore, while the Yung vent has to remain in the patient for many months, MAVT can be removed just after two months.

The most important factor in the development of OME is negative pressure in middle ear, usually caused by deficiency of eustachian tube or mastoid aeration. The resistance to negative pressure of patients with adequate mastoid aeration is much better than the patients with poor aeration [3, 4]. In the study of Cinnamon and Sade [5], it was stressed that in temporary eustachian tube dysfunction, the mastoid air system should be adequate for the prevention of effusion developed in middle ear and high negative pressure. It is evident that an obstructed anterior and posterior isthmus is not open, despite VT; mastoid air system filled with mastoid glue cannot contribute to middle ear in terms of equalization of pressure and gas exchange, facilitating the recurrence of OME. In the present study, aeration loss was observed in all the mastoid air cells including antrum in all of our patients. Except for one ear with cho-

Of 24 ears, mastoid glue was found in 17, serous fluid in two, and dry mucosa with calcareous plaque in the mastoid antrum in the remaining five. In the control group, mastoid glue was found in 3 ears. Serous fluid was found in 5 ears. MAVT was removed between 15 days and two months (means 1.7 ± 0.3 months) after insertion. In one patient, the tube was removed early due to a skin reaction which healed with the administration of topical treatment. The surgical site was epithelized and closed in all patients. Mean duration of VT was 5 (3-8) months. Preoperatively, air bone gap in study group was 21.4 ± 11.7 while that of control group was 21.2 ± 12.0 dB idi. There was no statistically significant difference between groups in terms of tympanic membrane findings, mastoid operations and air bone gap.

While there was no statistically significant change in post op mastoid aeration score compared to pre-op score according to Bonferroni correction, in the control group, (P=0.042), in the study group, statistically significant increase was observed in postop scores compared to preop scores in the study group (P=0.006) (Table 1).

In the study group, significant decrease was observed in post-op ABG levels compared to pre-op ones (P=0.009). Similarly, in the control groups also, statistically significant decrease was observed in in post op ABG levels compared top re-op levels (P=0.014). Control and study groups were found to be similar with regard to the changes in ABG levels (P=0.979).

In patients with mastoid glue, the reaeration rates with MAVT were high (Figure 3). Tympanometric findings were not evaluated statistically.
Mastoid antral ventilation tube

lesteatoma development, mastoid aeration was enabled in other ears by MAVT, and lack of OME recurrence in long term follow up indicates that mastoid aeration loss plays an important part in recurrence. Therefore, it is our recommendation that in all patients with recurrent OME, the mastoid air cells should be monitored by MRI or CT to determine whether they are patent.

Stangerup and Tos [6], and Robinson et al. [7], established that in ears in which VT was used, mastoid cell pneumatization increases. In the study of Csakanyi et al [8], mastoid volumes of healthy children and those with recurrent OME were compared, and it was demonstrated that mastoid area and volume were considerably smaller in children with recurrent OME. Therefore, it is known that in all cases of middle ear effusions involving mastoid air cells, although aeration returns in middle ear, mastoid aeration does not return in all cells. Hence, the mastoid aeration system itself becomes smaller. According to CT and surgical findings, when antrum and peripheral cells are filled with glue, calcification and sclerosis occurred in more peripheral cells, indicating that ossification of mastoid air cells extends from periphery towards antrum. In addition, Valtonen et al, tracked 281 ears of 305 patients under 17 months of age and who were administered tympanostomy tube placement due to the recurrent OME or AOM for five years. Their findings suggest that early placement of VTs may mostly reverse the loss of aeration in mastoid and enable normal aeration. With a similar reasoning, it is our recommendation that mastoid bone aeration must be controlled to prevent mastoid bone sclerosis in patients for whom VT placement for a second time is indicated. Mastoid glue detected early responds to treatment much better. In the present study, mastoid aeration improved better in 17 ears of the patients with mastoid glue in comparison to the sclerotic and hyalinized mastoids (Figure 3).

Aeration of middle ear is almost complete at birth. However, aeration of mastoid cells continues until approximately age of 15 for males and 10 for females [9, 10]. Therefore, it can be shown that mastoid pneumatization develops under the control of both hereditary and acquired factors [7, 9, 11-14]. In people who did not have obstruction in eustachian tube with middle ear infection in childhood, mastoid pneumatization develops under the influence of hereditary factors. However, in those who have eustachian tube obstruction and middle ear infection and inflammation, mastoid pneumatization develops according to acquired processes rather than hereditary factors. In the study of May et al, [14] on rats, it was suggested that only a single otitis attack prevents bone growth, slows pneumatization, and leads final volume of mastoid bone to be smaller, and those findings match those obtained in infections during early childhood. Csakanyi et al [8] compared the volume of mastoid bone between healthy children and those with recurrent OME, and demonstrated that mastoid area and volume were significantly smaller in children with recurrent OME. These findings demonstrate that mastoid system is connected to the vestibule of the middle ear with very small holes.

Figure 3. Preoperative bilateral mastoid glue (A), postoperative mastoid air cells (B) and MAVT (arrow).
called isthmus anterior and posterior, so the mastoid system and the vestibule of the middle ear are in mucosal continuity. Nevertheless, we do not have adequate information on how sclerosis in mastoid aerated cells develops. Is it due to the obstruction of connections called isthmus anterior or posterior or due to the lack of aeration in peripheral mastoid air cells as a consequence of OME? In the present study, unilateral mastoid aeration in 16 of 20 patients indicates that acquired incidents do not influence mastoid air cells symmetrically while in four patients, the impact was symmetrical.

In the study of Hasebe et al, [15] it was established that when mastoids of subjects with severe attic retraction were examined with CT, at least three months after the placement of tympanostomy tube, there was significantly more soft tissue density in the adults than children. Previous volumetric and histological observations determined that in ears with OME, effusion improves within three months after the placement of the tube, but the mastoid effusion appears in CT taken at the same time as organized inflammatory lesion [16, 17]. In the present study, it is our opinion that 1-2 months period of MAVT placement is sufficient, especially for patients with glue mastoid. Görür et al [18] reported that in the diagnosis and monitoring of irreversible mucosal changes, tympanometric examination was not adequate, and CT may be required. In some cases of chronic OME not responding to repeated VT, mastoidectomy is recommended [19, 20]. During surgical intervention of such cases, hyperplastic mucosa with dense edema, granulation tissue, polypoid tissues and thick mucoid effusion content in mastoid are observed [19]. According to Palva [21], these tissues are transformed into a cellular dense bone structure in time, which leads mastoid volume and surface area to decrease gradually and to be too small for gas exchange. In the present study, from CT findings in middle ear, aditus, antrum and mastoid cells, it could not be determined whether the partial or complete obstruction was caused by fluids or soft tissue. Mastoidectomy was neither planned nor administered for any of our patients. When mastoidectomy was carried out, glue was found in 17, serosity in two, and hyalinization-calcification and aburnation in the remaining five ears. The findings of this small series of patients suggest that mastoid air system should be monitored with MR or CT so mastoid glue can be detected early.

The results of the treatment of completely collapsed tympanic membrane with conventional methods are disappointing. It is reported that over 50% of the completely atelectatic membranes, collapse will recur [22]. However, the encouraging finding of the present study is that a new device, MAVT, can facilitate reaeration in atelectatic tympanic membranes and improve hearing. In the present study, preoperative otopscopic and microscopic examination showed that membrane was adhesive in seven ears and retracted in 17. Postoperatively, ten tympanic membranes were found to have normal membrane appearance, eight ears were retracted, and six were adhesive. The difference between preoperative and postoperative pure tone and ABG mean values were found statistically significant (P<0.009). While in the control group, no statistically significant change was seen in post op mastoid aeration score compared to pre-op one (P=0.042), in the study group, statistically significant increase was seen in post op mastoid aeration scores (P=0.006). These results indicate that in OME, monitoring mastoid aeration is as important as monitoring middle ear, and with timely and judicious interventions to mastoid bone, the process of adhesive otitis and mastoid sclerosis can be reversed. Further prospective studies with higher number of cases are required in order to elucidate this issue better.

Acknowledgements

The work was carried out at the Department of Otorhinolaryngology-Head and Neck Surgery and Radiology of Ataturk Research and Education Hospital, ANKARA, Turkey.

Disclosure of conflict of interest

None.

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Mastoid antral ventilation tube


