

# Intratympanic Injection of Dexamethasone in the Management of Otitis Media with Effusion

Haitham El-farargy<sup>1</sup>, Saad El-zayat<sup>2</sup>

<sup>1</sup> ENT Department, Alhayat National Hospital,  
Jizan, Saudi Arabia

<sup>2</sup> ENT Department, Kafr Elsheikh University,  
Kafr Elsheikh, Egypt

## Abstract

Early treatment of otitis media with effusion is essential to prevent its serious complications especially speech delay. If medical treatment failed after 3 months, surgical intervention should be put in mind. Ventilation tube insertion in tympanic membrane is the most common surgical solution, but may be followed by complications. As a trial to decrease this complications, we added intratympanic dexamethasone injection once in the same operation. Our results showed decrease the complications of ventilation tube insertion, especially recurrence and tympanosclerosis, without recorded side effects. This encourages the use of intratympanic dexamethasone injection regularly with ventilation tube insertion in the management of OME.

**Keywords:** *otitis media, ventilation tube, dexamethasone*

## 1. Introduction

Otitis media with effusion means the presence of fluid (serous or mucoid) in the middle ear cleft behind an intact tympanic membrane, without signs and symptoms of acute inflammation.<sup>3</sup> It is the most important cause of deafness among children all over the world.<sup>5</sup> The aetiology of OME may be due to Eustachian tube dysfunction (as in enlarged adenoid and rhinitis), middle ear gas composition change (which may occur in recurrent attacks of acute otitis media which causes increase middle ear vascularity) or nasopharyngeal disproportion (as in Trisomy 21).<sup>7</sup> The main complaint is hearing loss and fullness. Otoscopic examination (especially pneumatic otoscopy) is very important, it may reveals signs of OME as retracted tympanic membrane or air-fluid level.<sup>6</sup> Tympanogram is very sensitive, type B

tympanogram may indicate OME.<sup>8</sup> Early diagnosis and management of the OME is important to avoid complications of the OME especially speech delay, developmental delay, decreased language skills, atelectasis and may be cholesteatoma.<sup>11</sup> Once the diagnosis of OME is done, the patients is first given medical treatment for at least 3 months with observation. If the condition does not improve after 3 months, surgical options should be considered.<sup>1</sup> The placement of ventilation tubes after myringotomy for treatment of OME is the surgical procedure most commonly performed in children (with treatment of the underlying cause as doing adenoidectomy).<sup>12</sup> This may be followed by complications as tympanosclerosis atelectasis, residual perforations and rarely cholesteatoma formation, but still the best surgical treatment of the OME.<sup>4</sup> As a trial to decrease this complications, we did this study to improve the results of by adding intratympanic injection of dexamethasone in the same procedure without the systematic complications of corticosteroids.

## 2. Patients and methods

This prospective study was carried out in Dar El-Shafaa Hospital in Tanta city. Study population was forty consecutive cases, with age ranged from 5 to 20 years. Case enrollment started from October 2014 to October 2015. All patients that were chosen for this study had complaint from persistent middle ear effusion in both ears, which could not be solved by classic treatments for at least 3 months with chronic adenotonsillitis. All patients were suffering from aural symptoms especially hearing loss and aural fullness. we excluded cases with previous ear surgeries, cleft palate cases, previous radiotherapy, chronic suppurative otitis media, patients with chronic medical disorders as DM and patients who did not continue the proper follow up. All patients were operated by the same surgeon. Approval to

participate in this study was taken by singing an informed consent by the parents. In every patient, one ear (right) was treated by ventilation tube insertion only, and the other ear (left) was treated by ventilation tube insertion with intratympanic dexamethasone injection, so there were 2 groups with 40 ears in each group. Adenotonsillectomy operation was done for all cases. These patients were subjected to: Detailed history taking, complete general examination, complete ENT examination, otoscopic and microscopic examination of ears, tuning fork tests, audiological evaluation: tympanometry and pure tone audiometry with measurement of ABG at frequency 500,1000,2000 and routine investigations for anesthesia which were done 1 week before operation.

Under general anesthesia, adenotonsillectomy was done first. Then the patient was placed in a supine position with using a microscope, we started by the right ear, the head was tilted by 30 degree away from the surgeon. Myringotomy was done in the antero-inferior quadrant with aspiration of the middle ear fluid then insertion of the ventilation tube (grommet tube) was done. Then we changed the position to the left ear. Myringotomy was done in the antero-superior quadrant. After aspiration of the fluid of the middle ear, we injected 1 ml (4 mg) of dexamethasone through a syringe connected with a 22 gauge spindle needle passing through the opening in the tympanic membrane, finally the tube was inserted. The patient was maintained in this position for about 30 minutes allowing adequate absorption of the dexamethasone through the left middle ear mucosa. In all ears, we use the same type of ventilation tube, fibroplastic Shepards drain with wire 1.14 mm

The patients were discharged the next morning on a 7-day course of oral amoxicillin-clavulanic with local aural drops (ofloxacin+dexamethasone). Follow up of the patients was done after one week, then after 2 weeks, then every month for 6 months and 1 year after operation. During follow up, we concentrated on the improvement of the aural symptoms of OME especially aural fullness, extrusion of the tube, state of the tympanic membrane (residual perforation-tympanosclerosis) and otorrhea. Pure tone audiometry and tympanometry were done after extrusion of the tubes. Complete recovery occurred when the following criteria happened: no aural fullness- normal otoscopy of the tympanic membrane- type A tympanogram. We compared between the results of the two groups: group A (ventilation tube only) and group B (ventilation tube with intratympanic injection of the dexamethasone).

### 3.Results

The total number of patients was 40 patients. They were 20 males (50%) and 20 females (50%). The age ranged from 5 years to 20 years old with the mean age  $9.475 \pm 2.35$ . In group A; the pre-operative ABG was  $27.95 \pm 5.706$  dB and the post-operative ABG was  $9.015 \pm 4.029$ , the improvement was  $18.5 \pm 4.461$  dB which was statistically significant ( $p < 0.001$ ). In group B; the pre-operative ABG was  $28.175 \pm 5.546$  dB and the post-operative ABG was  $4.75 \pm 3.848$ , the improvement was  $23.5 \pm 4.815$  dB which was statistically significant ( $p < 0.001$ ). Comparing the improvement in the hearing (the difference between pre-operative ABG and post-operative ABG) between the 2 groups, there was a significant difference between the two groups, being higher in group B ( $p < 0.001$ ). Taking in mind comparing between the pre-operative ABG in both groups was insignificant ( $p$  value = 0.859) but post-operative ABG between the 2 groups was significant ( $p < 0.001$ ). The tube extruded in group A after  $4.85 \pm 1.388$  month, and extruded after  $4.65 \pm 1.424$  month in group B. The difference in time of extrusion between the 2 groups is statistically insignificant ( $p = 0.527$ ). Tympanosclerosis was noticed in 11 cases (27.5%) of group A, while it was noticed in 2 cases (5%) of group B, this was statistically significant ( $p = 0.023$ ). Otorrhea was noted in 5 cases (12.5%) of group A, while it was noted in 3 cases (7.5%) of group B. This was statistically insignificant ( $p = 0.456$ ), but in a lower rate in group B. In all cases of otorrhea, they were managed by conservative treatment in the form of antibiotics (oral+local) for 10 days. Residual perforation after extrusion of the tubes was noticed in 2 cases (5%) of group A, and also in 2 cases (5%) of group B, so there was no significant difference between the 2 groups in residual perforation ( $p = 1$ ). Recurrence occurred in 6 cases (15%) of group A, while it occurred only in one case (2.5%) of group B, so there was a significant difference between the 2 groups regarding recurrence of OME ( $p = 0.048$ ). The time of recurrence after extrusion of the tubes was  $4$  weeks  $\pm 1.685$  in group A, while it was after 2 months in group B.

Table 1: Audiological results

| Parameter            | Group | Mean   | SD    | P value |
|----------------------|-------|--------|-------|---------|
| Pre-op PTA-ABG (dB)  | A     | 27.95  | 5.706 | 0.859   |
|                      | B     | 28.175 | 5.546 |         |
| Post-op PTA-ABG (dB) | A     | 9.015  | 4.029 | 0.001   |
|                      | B     | 4.75   | 3,848 |         |
| ABG change (dB)      | A     | 18.5   | 4.461 | 0.001   |
|                      | B     | 23.5   | 4,815 |         |

#### 4. Discussion

Early diagnosis and management of the OME is important to avoid its complications.<sup>11</sup> Failure of the medical treatment which is continued for 3 months should be followed by surgical intervention.<sup>1</sup> The placement of ventilation tube after myringotomy for treatment of OME is the surgical procedure most commonly performed in children.<sup>12</sup> This may be followed by complications as tympanosclerosis, atelectasis, residual perforations and rarely cholesteatoma formation., but still the best surgical treatment of the OME.<sup>4</sup> Many trials have been done before to decrease this complications. One of this trials is only myringotomy and aspiration of middle ear fluids, but this is usually followed by recurrence due to early healing of the tympanic membrane without resolution of the pathology of the disease.<sup>10,13</sup> In our study we tried to improve results of the operation of ventilation tube insertion by adding intratympanic dexamethasone injection. Application of dexamethasone inhibits the production of middle ear effusion and the proliferation of leukocytes in the middle ear mucosa. Dexamethasone acts mainly as a glucocorticoid, not a mineralocorticoid, through mRNAs of glucocorticoid receptors present in the ear. It decreases formation of lipopolysaccharides and prostaglandins, the main modulators in the OME.<sup>2,9,14</sup> In our study, the total number of patients was 40 patients. They were 20 males (50%) and 20 females(50%). The age ranged from 5 years to 20 years old with the mean age  $9.475 \pm 2.35$ . They were divided into 2 groups: group A which included the ears treated by ventilation tube insertion only, and group B which included the ears treated by insertion of ventilation tube with intratympanic dexamethasone injection. Adenotonsillectomy operation was done in all cases. In group A; the pre-operative ABG was  $27.95 \pm 5.706$  dB and the post-operative ABG was  $9.015 \pm 4.029$ , the improvement

was  $18.5 \pm 4.461$  dB which was statistically significant ( $p < 0.001$ ). In group B; the pre-operative ABG was  $28.175 \pm 5.546$  dB and the post-operative ABG was  $4.75 \pm 3,848$ , the improvement was  $23.5 \pm 4.815$  dB which was statistically significant ( $p < 0.001$ ). In both groups hearing was improved and fullness which was the main complaint of the patient, disappeared Comparing the improvement in the hearing (the difference between pre-operative ABG and post-operative ABG) between the 2 groups, there was a significant difference between the two groups, being higher in group B ( $p < 0.001$ ). The tube extruded in group A after  $4.85 \pm 1.388$  month, and extruded after  $4,65 \pm 1.424$  month in group B. The difference in time of extrusion between the 2 groups is statistically insignificant ( $p = 0.527$ ). Regarding the post-operative complications which usually found after ventilation tube insertion we found that, tympanosclerosis was noticed in 11 cases (27.5%) of group A. while it was noticed in 2 cases(5%) of group B, this was statistically significant ( $p = 0.023$ ). Tympanosclerosis decreased after usage of dexamethasone making the tympanic membrane movement better. Otorrhea was noted in 5 cases (12.5%) of group A, while it was noted in 3 cases(7.5%) of group B. This was statistically insignificant ( $p = 0.456$ ) but lower in group B. In both groups otorrhea occurred after water coming into the ears as during bathing. In all cases of otorrhea, they were managed by conservative treatment in the form of antibiotics (oral+local) for 10 days. Residual perforation after extrusion of the tubes was noticed in 2 cases(5%) of group A, and also in 2 cases (5%) of group B, so there was no significant difference between the 2 groups in residual perforation ( $p = 1$ ). Recurrence occurred in 6 cases (15%) of group A after  $4 \text{ weeks} \pm 1.685$  from the time of extrusion of the tubes, while it occurred only in one case(2.5%) of group B after 2 months, so there was a significant difference between the 2 groups regarding recurrence of OME ( $p = 0.048$ ) as the effect of the dexamethasone improved the condition of the middle ear cleft mucosa especially the mucosa of the Eustachian tube making the recurrence is uncommon.. The usage of dexamethasone improved the post-operative results of the ventilation tube insertion operation in the treatment of OME

#### 5. Conclusion

Ventilation tube insertion in the tympanic membrane after myringotomy in the management of OME still the best surgical solution. Intra tympanic injection of dexamethasone improve its results and decrease its complications without recorded side effects.

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