

Effect of Local Dexamethasone on Prevention of Myringosclerosis after Tympanostomy Tube insertion

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ABSTRACT

Background: Otitis media with effusion, a typical condition characterized by fluid in the middle ear area, has a significant negative influence on both the health and economy of the entire world. In children, hearing loss brought on by otitis media with effusion can hinder the development of language and conduct. **This study aimed** to assess how local dexamethasone affects human tympanic membranes' ability to resist myringosclerosis brought on by ventilation tubes. **Patients and Methods:** This prospective case-control study was conducted at Benha University Hospital, on 50 patients of both sexes and different ages complained of hearing loss due to persistent otitis media with effusion that has been resistant to therapy for nearly three months. The patients were subdivided into two equal groups: 25 patients were participants in group (A), which underwent myringotomy with breathing tube insertion only. 25 patients were participants in group (B), who had myringotomy, breathing tube insertion, and local dexamethasone instillation. **Results:** As far as myringosclerosis was concerned, there was no statistically significant variation between the two groups (P-value > 0.05). As determined by the quadrants under otomicroscopic examination, there was a significant variation between the two groups (P-value < 0.01) in relation to myringosclerosis findings. The histopathological assessment of myringosclerosis revealed a significant variation between the two groups with regard to the condition's symptoms (P-value < 0.01).

Conclusion: Topical dexamethasone use may be helpful in avoiding the development of myringosclerosis. Dexamethasone's anti-inflammatory and immunosuppressive properties may be responsible for this impact.

Keywords: Local Dexamethasone; Myringosclerosis; Ventilation Tube; Human Tympanic Membranes.

INTRODUCTION

Otitis medium with effusion, a frequent condition characterized by fluid in the middle ear area, has a significant negative influence on both the world health and economy ^[1]. Children who have otitis media with effusion may develop verbal and behavioral problems due to hearing loss ^[2].

Antibiotics, decongestants, and nasal steroids should not be used as they do not hasten the elimination of middle ear fluid. Children should be referred to an otolaryngologist if there is evidence of anatomical damage, hearing loss, or language delay in them ^[3].

In children, OME is a very common condition, and most cases will go away on their own. In cases with persistent symptoms, surgery to insert grommets, either with or without adenoidectomy, is the most successful course of action ^[4]. The most common surgical treatment done on children is myringotomy with breathing tube placement ^[5]. When properly positioned, tympanostomy tubes can restore normal hearing, stop OME from returning, and do so while remaining patent ^[6].

When treating otitis media with effusion, myringosclerosis frequently develops as a persistent side effect following the removal of the ventilation tube ^[7]. Myringosclerosis may develop after the insertion of a ventilation tube in people who are older, have a serous effusion type 2 ventilation tube, have a post-ventilation tube perforation, and frequently insert ventilation tubes; depending on how long the effusion lasts and how often

ventilation tubes are inserted, the severity of myringosclerosis may change ^[8].

Tympanosclerosis subjects without ear drainage had a higher likelihood of having a permanent ossicular chain ^[9]. The middle ear lamina propria inflammation or damage eventually progresses to myringosclerosis, which begins with excessive collagen formation in the middle ear mucosa. Hyalinization and calcification then follow, and finally, bone or cartilage metaplasia takes place ^[10].

When tympanosclerosis exclusively affects the tympanic membrane, it is known as myringosclerosis. Other areas of the body affected by tympanosclerosis include the middle ear cavity, ossicles, and occasionally the mastoid bone ^[11].

The surgical management of tympanosclerosis continues to be debatable. The use of endoscopic surgery to treat tympanosclerosis appears to be a safe procedure ^[12]. In contrast to the ears of control groups, rats' ears exposed to topical oxygen free radical or steroids had a lower probability of developing myringosclerosis ^[13].

This investigation looked at how local dexamethasone affected human tympanic membranes' resistance to myringosclerosis brought on by ventilation tubes.

PATIENTS AND METHODS

Patients of all sexes and varied ages complained of hearing loss caused by chronic otitis media with effusion,

which was recalcitrant to medical therapy for around 3 months, were included during this prospective case-control research at Benha University Hospital. All patients were chosen between January 2021 and January 2022 from the otolaryngology clinic at Benha University Hospital.

The patients were subdivided into two equal groups: 25 patients in group (A), which underwent myringotomy with breathing tube insertion only. Group (B): Consisted of 25 patients who had myringotomy, breathing tube insertion, and local dexamethasone instillation.

Inclusion criteria were patients reported having persistent otitis media with effusion for three months despite receiving medical care.

Exclusion criteria were patients who had previously undergone breathing tube insertion, those who had myringosclerosis, and those who experienced significant bleeding during surgery.

All patients were subjected to complete history taking, clinical examination, radiological investigations as follows:

- 1) History taking: With asking patient about: Difficulty of hearing (blocked ear), Loss of attention, Blocked or stuffy nose, Snoring, and difficulty of breathing.
- 2) Clinical examination: Detailed otolaryngologic examination by otoscope or microscope was done to show otitis media with effusion or signs of retraction of tympanic membrane.
- 3) Radiological investigations: Plain X-ray of the nasopharynx lateral view soft tissue shadow with opening of the mouth: to show the degree of adenoid size that encroach nasopharyngeal airway. CT scan: to show nasopharyngeal mass or any abnormality in nose.
- 4) Tympanometry: to test middle ear pressure and compliance of tympano-ossicular chain to detect middle ear effusion.

Patients underwent myringotomy and VT insertion. All patients were operated upon under general anesthesia.

Follow up:

Otoscopic and microscopic examinations were scheduled as part of routine follow-up 2, 4, and 6 months after the operation. The observer who carried out the postoperative examination (otoscopic and microscopic) was unaware of which group the case investigated in this study belonged to. When a white plaque was seen by otomicroscopy in the tympanic membrane, myringosclerosis has formed. Myringosclerosis was expressed in the results as either present or absent. All information and findings were gathered and statistically examined.

Ethical Consideration

An informed written consent was obtained from the patient. All patients were chosen and study was done after approval from the Ethical Committee of Benha University Hospital (Approval code: MS 5-1-2021). This work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Statistical analysis

The statistical program SPSS version 24 was employed to examine the data. Data in the quantitative realm were presented as mean ± SD and range, and were compared by independent t- test. In qualitative data, frequency and percentage were used as units of measurement and they were compared by chi-square test. P-value below 0.05 were deemed significant.

RESULTS

Concerning age or sex, there were insignificant differences between the two groups (**Table 1**).

Table 1: Comparison between the studied groups as regard demographic data.

	Group A (n=25)	Group B (n=25)	Test	P
Age (Years)			T= 0.18	0.86
Mean ± SD	33.12±3.54	33.3±3.51		
Sex			$\chi^2=0.08$	0.78
Male	12	13		
Female	13	12		

T: Two-sample independent t test, χ^2 : Chi-square test.

There was insignificant variation between both groups in light of myringosclerosis (**Table 2 and figure 1**).

Table 2: Comparison between the studied groups as regard side of myringosclerosis.

	Group A (n=25)	Group B (n=25)	Test	P
Right ear	3	1	$\chi^2=2.14$	0.54
Left ear	2	4		
Bilateral	7	5		
No	13	15		

χ^2 : Chi-square test

According to the quadrants under otomicroscopic assessment, there were no significant variations between the two groups in relation to myringosclerosis findings (P= 0.09). (**Table 3**).

Table 3: Comparison between the studied groups as regard myringosclerosis findings according to the quadrants under otomicroscopic assessment.

	Group A (n=25)	Group B (n=25)	Test	P
Antro-inferior Q	3	2	$\chi^2=9.514$	0.09
Post-inf Q	3	1		
Both	4	0		
Antro-superior Q	1	0		
Postro-superior Q	1	0		
NO	13	22		

χ^2 : Chi-square test, Q: quadrants.

Regarding findings of myringosclerosis based on histological testing, there were significant variations between the two groups in relation to myringosclerosis findings ($P= <0.001^*$) (Table 4).

Table 4: Comparison between the studied groups as regard findings of myringosclerosis based on histological assessment.

	Group A (n=25)	Group B (n=25)	Test	P
Not existing	0	5	$\chi^2=25.72$	<0.001*
Mild myringosclerosis	3	14		
Moderate myringosclerosis	9	6		
Severe myringosclerosis	13	0		

χ^2 : Chi-square test, *: Statistically significant

There were no significant differences regarding congestion of tympanic membrane between both groups. (Table 5).

Table (5): Comparison between the studied groups regarding congestion of tympanic membrane

	Group A (n=25)	Group B (n=25)	Test	P
Congestion of tympanic membrane				
No	10 (40%)	15 (60%)	$\chi^2=2.000$	0.157
Yes	15 (60%)	10 (40%)		

χ^2 : Chi-square test

There were no significant differences regarding extrusion of tympanostomy tube and time of tympanostomy tube extrusion between both groups. (Table 6).

Table (6): Comparison between the studied groups regarding extrusion of tympanostomy tube

	Group A (n=25)	Group B (n=25)	Test	P
Extrusion of tympanostomy tube				
No	7 (28%)	5 (20%)	$\chi^2=0.439$	0.508
Yes	18 (72%)	20 (80%)		
Time of tympanostomy tube extrusion (months)				
Mean \pm SD	4.78 \pm 1.31	4.4 \pm 1.1	t=1.111	0.272
Range	3 - 6	3 - 6		

χ^2 : Chi-square test, t: Two-sample independent t test

DISCUSSION

The most widely applied treatment for effusion-associated otitis media also serves as a preventative measure against recurrent otitis media.

It involves myringotomy along with the installation of a breathing tube. As a result of myringotomy with ventilation tube therapy, tympanosclerosis is the most frequent side effect. Tympanosclerosis is a condition in which the lamina propria develops considerable amounts of collagenic fibrosis tissue that encompasses the ossicles, the tympanic cavity walls, and the tympanic membrane's medial layer [14].

According to this study, there was no discernible difference in either group's age or sexual orientation.

In a study, the avoidance of myringosclerosis brought on by ventilation tubes in human tympanic membranes was compared to the effects of local dexamethasone and vitamin E. Three groups of 90 kids undergoing myringotomy with breathing tube insertion were included: Group I consisted of 30 kids who had myringotomies with ventilation tubes inserted only; Group II consisted of 30 kids who had myringotomies with ventilation tubes inserted along with the use of local vitamin E; Group III consisted of 30 kids who had myringotomies with ventilation tubes inserted along with the use of local dexamethasone. In line with our findings, there was no discernible difference in the groups' ages or sexes [15].

In a different study, the goal was to look into the role of topical dexamethasone in preventing myringosclerosis, which is brought on by myringotomy, in rat tympanic membranes using otomicroscopic and histologic investigations. 21 healthy male Sprague Dawley rats weighing 300–400 g was included in this study. They were 3–4 months old and in good health [16]. According to this research, there was no discernible variation in myringosclerosis between the two groups.

A study that contradicted our findings revealed a substantial difference in myringosclerosis between the two groups. In group I, twenty-one of the patients had bilateral myringosclerosis (42 ears); ten myringosclerotic patches were found (16.7%); six of these patches were

found in the right ear (10%); none of the patients' left ears had any myringosclerotic patches found [15].

According to some researchers, when the myringotomy sites were closed and investigated, the tympanic membranes in 11 (91.6%) of the 12 study participants (myringotomy plus dexamethasone), 10 (83.3%) of the 12 control participants (myringotomy + 0.9 % NaCl), and 9 (90%) of the 10 participants (only myringotomy) were all intact. Regarding the closure of myringotomy sites on day 10 ($p=0.595$), there was no statistically significant variation found between the groups [16].

Concerning the quadrants under otomicroscopic examination, this study showed a substantial variation between the two groups regarding myringosclerosis findings. In line with our findings, a study demonstrated a substantial variation between the two groups in relation to the myringosclerosis findings according to the quadrants evaluated by otomicroscopy. In group I, 8 myringosclerotic patches were present that only affected the anterior inferior quadrant (13.3%), 6 myringosclerotic patches that only affected the posterior inferior quadrant (10%), 5 myringosclerotic patches that only affected the anterior and posterior inferior quadrants (8.3%), one myringosclerotic patch that only affected the anterior and posterior superior quadrants (1.7%), and one myringosclerotic patch that only affected the anterior inferior quadrant (1.7 %). In group II, neither the anterior nor posterior superior quadrants were impacted by any myringosclerotic patches but there were four myringosclerotic patches that only affected the anterior inferior quadrant (6.7 %), and there were two that only affected the posterior inferior quadrant (3.3 %) [15].

According to a study, the rats' tympanic membranes in the research group had less developed myringosclerosis than the rats in the other two groups when the distribution of the disease was studied under otomicroscopy. Otomicroscopic examination revealed that myringosclerosis developed and spread in locations other than those where myringotomies were performed, with the majority of cases occurring in the malleus and in the anterior tympanic membrane [16].

This study showed that there was notable variation between the two groups in terms of myringosclerosis results as determined by histological examination.

A study that showed that 9 hours after myringotomy, the tympanic membrane will exhibit sclerotic changes, and 12 to 24 hours later, a severe histological inflammatory response will take place. This indicates that 40 percent of cases with otomicroscopy will exhibit histological tympanosclerosis, which may be observed in 80 percent of cases with myringotomy. This demonstrates that when tympanosclerosis is detected by otomicroscopy, there is in fact twice as much of it (at the tissue level) [17].

Another investigation revealed that on day 10, 28 tympanic membranes from all groups had developed

myringosclerosis, membrane thickness, and inflammation for histological testing. Histological examination of the tympanic membranes in each group of rats revealed that eight of the ten study group ears (80%), all ten control group ears (100%), and all eight experimental surgery group ears (100%), had inflammation [16]. Additionally, they demonstrated that myringosclerosis was found in 8 (80%) of the 10 ears in the research group, 9 (90%) of the ten ears in the control group, and in all 8 (100%) of the rats' ears in the experimental surgery group when the histological assessment of the rats' tympanic membranes in connection to the onset of myringosclerosis was performed [16].

Those who received alpha-tocopherol in order to avoid experimentally produced myringosclerosis had a lower incidence of myringosclerotic plaques, according to a study [18].

When the otomicroscopic results of one investigation were compared to the study group that had received topical dexamethasone, the development of myringosclerosis was found to be considerably greater in the control and experimental surgical groups. The study group of rats also had less myringosclerosis in the tympanic membrane quadrants than the control group. [19]

A study found that following myringotomy, immunological stimulation caused a rise in inflammatory reactive oxygen species, which was countered by vitamin E [20].

Inflammation of the rat tympanic membranes was much lower in the topical dexamethasone-treated study group as opposed to the experimental surgery group and control groups when the histological results of the investigation were analyzed. In comparison to the other two groups, the study group's average tympanic membrane thickness was less. The study group was also notable for having a low incidence of myringosclerosis and a milder type of it. There were no statistically significant inflammations in the dexamethasone+ciprofloxacin group in research looking at the impact of the combination on the closure of myringotomy sites following experimentally induced OME, while there were inflammations in 71.4 % of cases in control group. These findings supported the notion that early inflammation might be reversed during myringotomy with a dexamethasone+ciprofloxacin therapy [21]. Corticosteroids that eliminate the initial histological manifestations of inflammation—including capillary dilatation, deposition of vascular wall fibrin, serodiapedesis, and local edema—reduce the risk of tympanosclerosis induced by corticosteroid therapy subsequent to myringotomy in OME [16].

A long-term study is required to determine the positive benefits of corticosteroids on tympanosclerosis, although they also prevent fibrosis, capillary proliferation, collagen buildup, and scarification, which are late histological markers of inflammation [16].

CONCLUSION

It can be inferred from the otomicroscopic and histological results of our investigation that topical dexamethasone therapy would be beneficial in avoiding the development of myringosclerosis. The anti-inflammatory and immunosuppressive properties of dexamethasone may be responsible for this impact.

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