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## Comparison between the fate of secretory otitis media in patients with adenoids hypertrophy undergoing adenoidectomy alone or with myringotomy or with myringotomy and tympanostomy tube application

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### Abstract:

**Background:** Otitis Media with Effusion (OME) is characterized by middle ear fluid in the absence of acute infection symptoms (fever and otalgia). The adenoid tissue is crucial to the pathogenesis of OME. There were several options for managing OME, including auto inflation and medical treatment. Surgery was used primarily to reestablish middle ear aeration by removing negative intratympanic pressure when the effusion did not resolve naturally or after three months of unsuccessful medical treatment.

**Aim:** This study compares the results of OME in adenoids hypertrophy patients who underwent adenoidectomy alone, adenoidectomy plus myringotomy, or adenoidectomy with insertion of a tympanostomy tube (TT).

**Patients and methods:** A total of 150 children suffering from persistent OME brought on by enlarged adenoids were scheduled for adenoidectomy alone, myringotomy, or TT implantation were included in this study. The included children were divided randomly into three equal groups as follow Group I: 50 patients underwent adenoidectomy. Group II: 50 patients underwent adenoidectomy plus myringotomy. Group III: 50 patients underwent adenoidectomy with TT insertion (Shepard tubes).

**Results:** The results of the tympanogram after six months of healed myringotomy were significantly improved in group III relative to group I and group II. According to age class, 18 cases <4 years old, 23 cases between 4 and 8 years old, and 21 cases >8 years old were cured, and these differences were statistically significant. Regarding residence, gender and associated tonsillectomy, there were no statistically insignificant results .

**Conclusion:** Below the age of 4 years old, for children with problems specifically related to the adenoids, clinicians may do an adenoidectomy in addition to TT insertion, while above age of 4 years old, all options are available but adenoidectomy and TT insertion has the best results.

**Key words:** Otitis media with effusion, adenoid hypertrophy, adenoidectomy, myringotomy, tympanostomy tube application.

### Introduction

Middle ear fluid in the absence of acute infection symptoms (fever and otalgia) is known as otitis media with effusion (OME); its synonyms include: chronic non-purulent otitis media,

secretory otitis media, serous otitis media and glue ear.<sup>1</sup> The most common symptoms of fluid in the middle ear include conductive loss and a higher risk of acute otitis media (AOM).<sup>2</sup>

Complications from persistent OME include hearing impairment and tympanic membrane abnormalities (cholesteatoma, atrophy, and retraction pockets).<sup>3</sup> It can impair language development and lead to behavioral changes.<sup>4</sup>

There were several options for treating OME, including medical treatment (mucolytics and steroids) and surgery.<sup>5</sup> Surgery was recommended when the effusion did not go away on its own or after three months of unsuccessful medical treatment, and the surgery's main aim was to restore aeration by eliminating negative middle ear pressure in order to normalize the mucosa, increase the number of cilia, and reduce the secretion potential.<sup>6</sup>

The adenoid tissue is crucial to the pathogenesis of OME. The Eustachian tube may become mechanically blocked by adenoid enlargement.<sup>7</sup> The middle ear mucosa may become inflamed due to bacterial infection in the adenoid, which may also create an environment for the development of T lymphocytes.<sup>8</sup>

Adenoidectomy is increasingly used to treat OME when chronic adenoiditis is suggested.<sup>9</sup> Also, Children over the age of four who had previously had a Tympanostomy Tube (TT) implanted reacted favorably to adenoidectomy for otitis media.<sup>10</sup>

Ventilation tubes are minute cylinders that are applied through the tympanic membrane to ventilate the middle ear.<sup>5</sup> The most frequent surgical approach used to treat OME is myringotomy with TT implantation. Recurrent AOM, persistent Eustachian Tube Dysfunction (ETD), and OME are common indications for it.<sup>11</sup> When certain conditions and specific children subgroups were present, difficulties related to tube insertion occurred more frequently than expected, affecting 80% of the ears that had been operated on.<sup>12</sup> The most frequent complications

were tympanic membrane perforation, cholesteatoma, granulation tissue, purulent discharge, tympanosclerosis, atrophic scars and retraction pockets.<sup>13</sup>

So, this research was done to compare the effect of adenoidectomy versus adenoidectomy plus myringotomy versus adenoidectomy and tympanostomy tube implantation in the treatment of OME.

### **Patients and methods:**

This is a randomized controlled clinical trial that took place at Assiut University Hospital's ENT department between the 1st of February, 2021 and the end of October, 2022 and was approved by the Faculty of Medicine's Local Committee of Ethics (IRB no: 17101469).

The study comprised 150 patients who had persistent OME caused by adenoid hypertrophy and were scheduled for adenoidectomy alone, with myringotomy, or with TT insertion. Before participation, the purpose and scope of the research were described to parents of children. Before enrolment, a detailed consent was obtained.

Enrolled patients were randomly assigned to one of three equal groups: Group I included 50 children who had adenoidectomy. Group II included 50 children who had adenoidectomy plus myringotomy. Group III included 50 children who had adenoidectomy with TT implantation (Shepard tubes). Ages > 18 years old, history of allergic rhinitis, prior myringotomies with or without TTs, prior tonsillectomy or adenoidectomy, cholesteatoma, cleft palate, Down syndrome, congenital ear malformation, and previous ear surgery were all reasons for exclusion from the study. A thorough history was taken of every patient. The preoperative assessment was completed. Additionally, a preoperative lateral X-

ray of the nasopharynx and tympanometry for postoperative comparison were performed.

#### **Operative technique:**

Under general anesthesia, an endotracheal tube with a cuff was used to operate on each patient. A povidone-iodine solution was used to clean the outer ear canal. By using suction, cerumen was removed. Adenoidectomy with or without tonsillectomy was carried out in group I. Along with a straightforward myringotomy incision performed in the antero-inferior quadrant of the pars tensa to aspirate middle ear fluids, group II underwent the same procedures as group I. The identical procedures as in group II were carried out in group III in addition to the insertion of a tympanostomy tube.

#### **Postoperative treatment and monitoring:**

Children were refrained from allowing water entry into both ears. Extrusion of tubes, closure of myringotomies, and early postoperative problems were monitored in patients after one week and then once a month. Based on clinical and tympanometric results, patients were checked for recurrence of the effusion six months following each tube extrusion or myringotomy closure.

#### **Statistical analysis**

The software program SPSS\_22 (Illinois, Chicago, USA) was employed. Frequency and percent were used to depict categorical data. The chi-square ( $\chi^2$ ) test for categorical data was used to compare the groups. If the probability level (P value) was greater than or equal to 0.05, it was deemed non-significant.

#### **Results**

The enrolled patients were classified according to residence: 97 patients lived in rural areas; group I was represented by 33 patients, while both group II and group III were represented by 32 patients; 53 patients lived in urban areas, distributed as 17 in group I and 18 in group II and group III. According to gender, patients were categorized into 27, 30, and 28 males (85) and 23, 20, and 22 females (65), for groups I, II, and III, respectively. Patients were classified according to age into three classes:  $\leq 4$ : less than or equal to four years (43), 4-8: between four and eight years old (67) and  $>8$ : more than eight years (40). They were distributed for the three studied groups. Tonsillectomy was performed in 84 patients in whom it was indicated, and 66 patients did not undergo tonsillectomy as there was no indication for it. The tonsillectomy patients were classified into 27, 28, and 29 for groups I, II, and III, respectively. The others were 23, 22, and 21 in groups I, II, and III, respectively. All these fluctuations in numbers were statistically insignificant ( $P \geq 0.005$ ) (Table1).

The results of the tympanogram after six months of healed myringotomy were significantly improved in group III compared to group I compared to group II, as evidenced by the fact that there were 40 (80%) cases with type A tympanogram in group III compared to 13 (26%) in group I compared to 9 cases (18%) in group II. There were significant variations between groups ( $\chi^2 = 49.172$ , p value  $< 0.001$ ) (Fig. 1).

According to age class, 18 cases  $\leq 4$  years old, 23 cases between 4 and 8 years old, and 21 cases  $>8$  years old were cured, and these differences were statistically significant ( $\chi^2 = 31.418$ , p value  $< 0.001$ ) (Fig.2). Below the age of 4 years, 13 (100.0%) cases in group III

were cured relative to 3 (16.7%) cases in group I and 2 (16.7%) cases in group II, and these differences were statistically significant. ( $\chi^2 = 25.880$ , p value  $<0.001$ ) and their strength were (strength of the relation = 61, p value  $<0.001$ ). Between the ages of 4 and 8 years, 16 (66.7%) cases in group III were cured compared to 6 (30.0%) cases in group I and 1 (4.3%) case in group II, and these variations were significant ( $\chi^2 = 29.923$ , p value  $<0.001$ ) and their strength were (strength of the relation = 56, p value  $<0.001$ ). Above the age of 8 years, 11 (84.6%) cases in group III cured relative to 6 (40.0%) cases in group II and 4 (33.3%) cases in group I, and these differences were statistically insignificant ( $\chi^2 = 8.224$ , p value 0.084) (Fig.2. Table 2).

Regarding residence, 39 cases living in rural areas showed improvement on the tympanogram compared to 23 cases living in urban areas. This difference was statistically not significant ( $\chi^2 = 0.163$ , p value = 0.922). But, inside the rural areas, there were 27 (84.4%) cases in group III that showed improvement compared to 8 (24.2%) cases in group I and 4 (12.5%) in group II, and these results were significant ( $\chi^2 = 40.910$ , p value  $<0.001$ ) and their strength were (strength of the relation = 54, p value  $<0.001$ ). While, inside the urban areas, there were 13 (72.2%) cases in group III that showed improvement compared to 5 (29.5%) cases in group I and 5 (27.8%) cases in group II, and these results were significant ( $\chi^2 = 15.560$ , p value  $<0.004$ ) and their strength were (strength of the relation = 48, p value 0.004) (Table 2).

Regarding gender, 34 males and 28 females improved, but these numbers were insignificant ( $\chi^2 = 5.368$ , p value = 0.068). Among the males, 22 (78.6%) in group III improved relative to 8 (29.6%) in group I and 4 (13.3%) in group II, and these results were

significant ( $\chi^2 = 28.052$ , p value  $<0.001$ ) and their strength were (strength of the relation = 50, p value 0.004). Among the females, 18 (81.8%) in group III improved relative to 5 (25%) in group II and 5 (21.7%) in group I, and these results were significant. ( $\chi^2 = 27.914$ , p value  $<0.001$ ) and their strength were (strength of the relation = 55, p value 0.004) (Table 2).

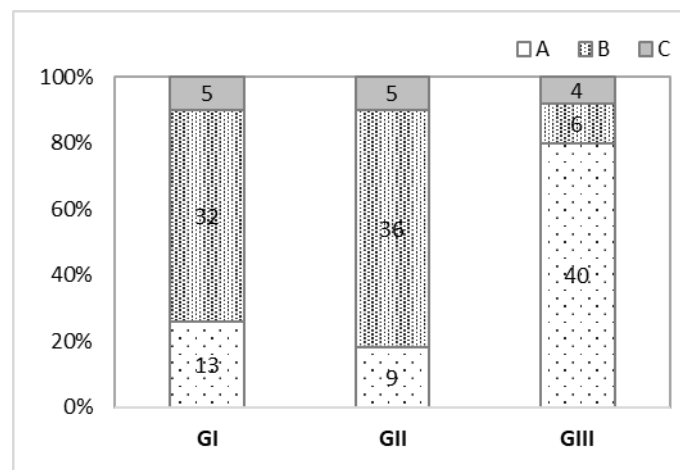
According to associated tonsillectomy or not, 35 cases underwent tonsillectomy, compared to 27 cases that did not undergo tonsillectomy, and these results were insignificant ( $\chi^2 = 1.684$ , p value 0.431). Between the cases that had tonsillectomy, 22 (75.9%) in group III were cured, compared to 8 (29.6%) in group I and 5 (17.9%) in group II, and these variations were significant. ( $\chi^2 = 24.078$ , p value  $<0.001$ ) and their strength were (strength of the relation = 47, p value  $<0.001$ ). While the in-between cases did not have tonsillectomy, 18 (85.7%) in group III were cured compared to 5 (21.7%) in group I and 4 (18.2%) in group II, and these variations were significant ( $\chi^2 = 26.649$ , p value  $<0.001$ ) and their strength were (strength of the relation = 54, p value  $<0.001$ ) (Table 2).

**Table 1.** The demographics of patients enrolled in the research according to residence, gender, age class and associated tonsillectomy or in different groups.

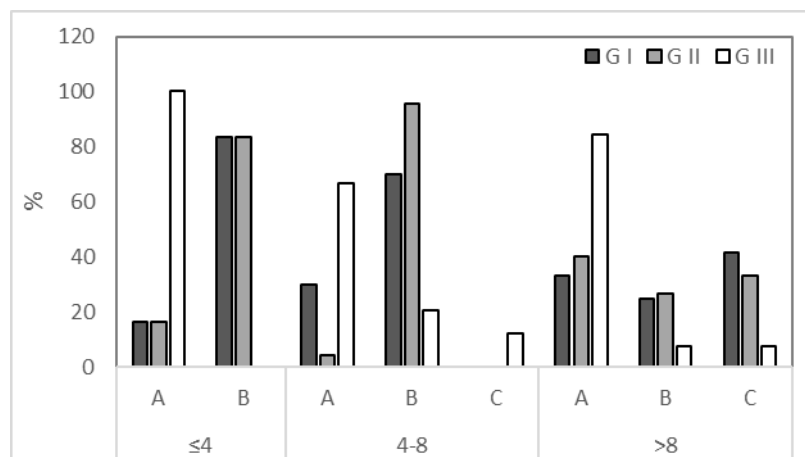
Residence	Gender	Age Class	Tonsillectomy	Groups			Total
				I	II	III	
Rural (97)	M (61)	<4 (13)	Yes	1	2	2	5
			No	2	2	4	8
		4-8 (30)	Yes	7	5	7	19
			No	1	6	4	11
		>8 (18)	Yes	7	4	3	14
			No	1	2	1	4
	F (36)	<4 (10)	Yes	1	1	1	3
			No	4	1	2	7
		4-8 (19)	Yes	3	4	6	13
			No	4	2	0	6
		>8 (7)	Yes	0	2	0	2
			No	2	1	2	5
Urban (53)	M (24)	<4 (5)	Yes	1	0	0	1
			No	3	0	1	4
		4-8 (10)	Yes	3	5	1	9
			No	0	0	1	1
		>8 (9)	Yes	1	3	3	7
			No	0	1	1	2
	F (29)	<4 (15)	Yes	0	1	1	2
			No	6	5	2	13
		4-8 (8)	Yes	2	0	4	6
			No	0	1	1	2
		>8 (6)	Yes	1	1	1	3
			No	0	1	2	3
<b>Total cases</b>				<b>50</b>	<b>50</b>	<b>50</b>	<b>150</b>

**Table 2.** The relationship between the tympanogram results after six months and different studied groups according to residence, gender, age class and associated tonsillectomy or not with their statistical results.

Tympanogram	GI		GII		GIII		$\chi^2$	p value	
	No	%	No	%	No	%			
Residence	Rural	A	8	24.2	4	12.5	27	84.4	40.910 0.004
		B	20	60.6	25	78.1	4	12.5	
		C	5	15.2	3	9.4	1	3.1	
	Urban	A	5	29.4	5	27.8	13	72.2	
		B	12	70.6	11	61.1	2	11.1	
		C	0	0.0	2	11.1	3	16.7	
Gender	M	A	8	29.6	4	13.3	22	78.6	28.052 27.914
		B	14	51.9	21	70.0	4	14.3	
		C	5	18.5	5	16.7	2	7.1	
	F	A	5	21.7	5	25.0	18	81.8	
		B	18	78.3	15	75.0	2	9.1	
		C	0	0.0	0	0.0	2	9.1	
Age class	≤4	A	3	16.7	2	16.7	13	100.0	25.880 29.923
		B	15	83.3	10	83.3	0	0.0	
	4-8	A	6	30.0	1	4.3	16	66.7	
		B	14	70.0	22	95.7	5	20.8	
		C	0	0.0	0	0.0	3	12.5	
	>8	A	4	33.3	6	40.0	11	84.6	
B		3	25.0	4	26.7	1	7.7		
C		5	41.7	5	33.3	1	7.7		
Tonsillectomy	Yes	A	8	29.6	5	17.9	22	75.9	24.078 26.649
		B	15	55.6	20	71.4	4	13.8	
		C	4	14.8	3	10.7	3	10.3	
	No	A	5	21.7	4	18.2	18	85.7	
		B	17	73.9	16	72.7	2	9.5	
		C	1	4.3	2	9.1	1	4.8	



**Figure 1.** Results of tympanogram after six months in percentage.



**Figure 2.** The percentage relationship between the tympanogram results after six months and different studied groups according to age classes.

## **Discussion:**

OME is one of the most common chronic otological illnesses in children. It hinders speech development and behaviour and produces ear fullness, conductive hearing loss, pressure shift pain, and ear pain.<sup>14</sup> The prevalence of OME has been found to range from 10% to 30%, with an overall incidence of 80%.<sup>15</sup>

The current study found insignificant variations between the analysed groups in children's age classes ( $P=0.703$ ), sex ( $P=0.827$ ), residency ( $p=0.971$ ), and tonsillectomy association ( $p=0.922$ ). This outcome is crucial for guaranteeing research group homogeneity and achieving precise outcomes from the comparison of the three procedures. These findings are consistent with those of **Khan et al.**<sup>16</sup> and **Smith and Greinwald**<sup>17</sup>, who found no significant differences in age classes, gender, residency, or tonsillectomy association between their investigated groups, which could lead to more precise outcomes from comparing operations in post-operative characteristics.

Our current findings revealed that the investigated sample had a male

predominance (85 males vs. 65 females). These findings are consistent with **James et al.**<sup>18</sup>, who noted that male children have been identified as a risk factor for OME on multiple occasions. Furthermore, it has been stated that male children have a higher prevalence of infection because they are more liable to allergy and infection.<sup>19</sup> While, **Erdivanli et al.**<sup>20</sup> discovered no variation in OME incidence across sexes.

In our study, 97 people lived in rural areas, while 53 people lived in cities. **Tong et al.**<sup>21</sup> reported that People with lower socioeconomic level are more likely to get the condition .

Young children are more likely to have OME. In children under the age of six, the frequency varied from 10% to 17%, dropping to 3%-4% in older.<sup>22, 23</sup>

Approximately 90% of children had experienced at least a single bout of OME by the age of four. Our findings revealed that the incidence of OME (cases under the age of four were 43 per 150, those between the ages of four and eight were 67 per 150, and those over the age of eight were 40 per 150 (**Table 1**), which mostly due to the anatomical characters of the eustachian tube in children, which is short and flat, has a

sharp angle to the horizontal plane, a large lumen, and a broad isthmus. All these factors predispose to OME.<sup>24, 25</sup>

In our study, we found that 84 cases associated with chronic tonsillitis, and 66 cases are not (**Table1**). Previous research indicated chronic tonsillitis to be one of the most common risk factors for OME, which is consistent with our findings.<sup>21-23</sup>

The tympanogram results after six months of healed myringotomy were significantly improved in group III compared to group I compared to group II, as evidenced by the fact that there were 40 cases (80%) with type A tympanogram in group III compared to 13 cases (26% in group I) and 9 cases (18% in group II), **Farhadi et al.**<sup>26</sup> reported that adenoidectomy plus tympanostomy tubes improved the tympanogram significantly, which was similar to our findings. Also, **Shishegar and Hobhoghi**<sup>27</sup> and **Vlastos et al.**<sup>28</sup> found that adenoidectomy plus tympanostomy tube application improved tympanogram and Pure Tone Audiometry (PTA) in children with OME.

On the other hand, **Casselbrant et al.**<sup>29</sup> reported that adenoidectomy with or without tube application showed no benefit regarding the duration of effusion in children with chronic OME when compared with tube insertion alone. They also stated that lesser tympanostomy tubes were placed in children who had adenoidectomy and myringotomy as their initial procedures, although this should be calibrated by the more intrusive procedure and the longer duration of effusion. As first-line treatment for chronic OME or recurrent AOM, many surgeons have conducted adenoidectomy plus TT insertion.

The Agency for Health Care Policy and Research released treatment guidelines for otitis media with effusion in 1994.<sup>30</sup> Adenoidectomy was not

indicated as a first-line treatment for children under the age of four with uncomplicated OME.

The recommendations in the 2004 Guidelines<sup>31</sup> were similar to those in 1994. Because of this similarity, as well as "the risk of postoperative epistaxis," the Panel concluded that adenoidectomy is not a suitable first-line treatment for simple MEE in children under the age of four, unless there is a clear indication (e.g., infection, postnasal discharge, chronic sinusitis). We found that, younger than the age of 4 years, there were 15 (83.3%) cases in group I that showed persistent OME on tympanogram compared to 3 (16.7%) cases that showed improvement, and by revision of their histories, and we found that there was a history of snoring and persistent nasal discharge.

Wallace's meta-analyses<sup>14</sup> found that adenoidectomy alone, as an adjunct to myringotomy, or combined with tubes improved OME and enhanced hearing when compared to myringotomy or wait & see. In addition, his studies revealed that tubes & adenoidectomy minimize the amount of time with OME and improve hearing in a hurry.

**Wang et al.**<sup>32</sup> discovered that adenoidectomy has a beneficial effect in reducing tympanostomy tube re-insertion when compared with tympanostomy tubes only, particularly for children older than 4 years old who need tubes initially. One possible explanation is that older children with recurrent ear infection may have a more complex ETD process that leads in recalcitrant disease, potentially benefiting more from the addition of adenoidectomy to TT. Another theory is adenoid is more active in children aged 4 to 10 years old, potentially contributing more to the pathophysiology of ETD in these children.<sup>33</sup>



Also, it is effective in elimination of middle ear effusion in children with OME. These studies support that adenoidectomy is effective.

**Popova et al.**<sup>34</sup> discovered that the risk of relapse of OME was greater in the adenoidectomy with myringotomy group than the adenoidectomy with tympanostomy tube group. Furthermore, **Farhadi et al.**<sup>26</sup> proposed that adenoidectomy is an effective surgical treatment in the management of otitis media, especially when combined with the insertion of TTs, which significantly reduces tube extrusion rate, possibly due to improved Eustachian tube function, which reduces repeated otitis media.

In addition, **Mikals and Brigger**<sup>35</sup> came to the conclusion that adenoidectomy plus initial tube placement seemed to protect against repeat surgery in children over the age of four.

**Casselbrant et al.**<sup>29</sup> examined the effects of three surgical therapy options in children suffering from chronic OME: Myringotomy and Tympanostomy Tube placement (M&T), Adenoidectomy plus M&T (A-M&T), or Adenoidectomy with Myringotomy (A-M). They discovered that children had MME in the following proportions in the period of 36 months of intervention: 18.6% in the M&T group, 20.6% in the A-M&T group, and 31.1% in the A-M group. After 36 months, there were no variations in the number of subsequent surgical procedures for ear problems required between the groups.

All these statements matched with our study as we found that, between the ages of 4 and 8 years, 16 (66.7%) cases in group III cured relative to 6 (30.0%) cases in group I and 1 (4.3%) case in group II, and these variations were significant ( $\chi^2 = 29.923$ , p value <0.001) and their strength were (strength of the relation = 56, p value

<0.001). Above the age of 8 years, 11 (84.6%) cases in group III cured relative to 6 (40.0%) cases in group II and 4 (33.3%) cases in group I, and these differences were statistically insignificant ( $\chi^2 = 8.224$ , p value 0.084) (**Fig. 2. Table 2**).

### Conclusion:

1. For children under the age of four, doctors may perform an adenoidectomy in addition to TT insertion if the condition is directly connected to the adenoids; otherwise, myringotomy and TT application are sufficient.
2. Above age of 4 years old, all options are available but adenoidectomy and TT insertion has the best results regarding improvement of middle ear aeration, eustachian tube function, hearing level and the need for tube re-application. But it has some complication as persistent perforation, tympanosclerosis and otorrhea.

### Recommendations:

- (1) Clinicians can offer adenoidectomy in addition to tympanostomy tube placement in children with adenoidal symptoms (infection or nasal obstruction) OR in children aged 4 years or older to decrease the incidence of recurrent otitis media or the necessity for repeat tube placement.
- (2) Further studies should be done on larger numbers or multicenter studies to validate the results of our study on wide scale.

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**Conflicts of interest:** No

**Reference:**

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