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### **ORIGINAL ARTICLE**

# Otitis Media With Effusion and its Relation to Vitamin D Deficiency

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### Abstract

*Background*: Otitis media with effusion (OME) refers to inflammation in the middle ear (ME) that does not present with typical acute ear infection symptoms. It has been estimated that 90% of children will experience it by the time they turn four. Several factors contribute to OME, however, eustachian tube dysfunction (ETD) is a major contributor. Several reports have shown an association between lack of vitamine D (vit D) and upper respiratory tract infections.

*Aim and objectives*: To assess the clinical function of vit D in OME prognosis by examining the correlation among vit D levels and the severity of OME in children.

Patients and methods: This randomized, single-blind, case-control research was done on 100 children at Al-Hussien Hospital of Al-Azhar University from the period of February 2022 to February 2023.

*Results*: There was statistically significant variance among Cases group and Control group concerning 1st vit D level. There was highly statistically significant variance among Cases group and Control group concerning first ear examination. There was highly statistically significant variance among COME group and complete recovery OME group concerning first vit D level and second vit D level. There was no statistically significant variance among COME Group and Complete recovery OME group concerning first Tympanogram and second Tympanogram.

Conclusion: It appears from our findings that vit D deficiency contributes to OME. Serum 25 (OH) D levels should be studied in these children for this reason.

Keywords: Effusion, Otitis, Vitamin D deficiency

### 1. Introduction

**T** he presence of middle ear effusion (MEE) behind an intact tympanic membrane (TM) without signs or symptoms of acute infection defines Otitis media with effusion (OME). The effusion may be mucoid, serous, purulent, or a mix of these.<sup>1</sup>

OME has a complex set of causes, but the immaturity of the immune system and the ETD are major contributors. In addition to food allergy, factors such as upper respiratory tract infections (URI), viral and bacterial ME infections, nasal inflammation after allergic rhinitis, adenoid hypertrophy leading to mechanical Obstruction in the nasopharynx, and craniofacial abnormalities may contribute to the development of OME in children. It has been hypothesized that autoimmunity contributes to the development of effusion in OME.<sup>2</sup>

Myringotomy and the insertion of a ventilation tube are the traditional surgical treatments for chronic and persistent cases of OME. Surgical care of OME should be confined to these cases. In cases of chronic bilateral OME, the use of ventilation tubes has been advised as a standard therapy. Hearing difficulty that has persisted for more than three months, starting either from the date of commencement (if known) or from the date of diagnosis (if unknown).<sup>3</sup>

Their purpose is to take the position of the Eustachian tube and to reduce the severity of OME.<sup>4</sup>

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https://doi.org/10.58675/2682-339X.2343 2682-339X/© 2024 The author. Published by Al-Azhar University, Faculty of Medicine. This is an open access article under the CC BY-SA 4.0 license (https://creativecommons.org/licenses/by-sa/4.0/). Nevertheless, the usage of ventilation tubes might lead to postoperative problems such as otorrhoea, progressive myringosclerosis, local atrophy, retraction pocket, and chronic perforation if they are not used properly.<sup>5</sup>

This research aims to assess the clinical function of vitamin D (vit D) in OME prognosis by examining the correlation among vit D levels and the severity of OME in children.

### 2. Patients and methods

This randomized, single-blind, case—control research was done on 100 children at Al-Hussien Hospital of Al-Azhar University from the period of February 2022 to February 2023.

### 2.1. Patients were allocated into two groups

Group 1 (n = 50): Vit D level detection in Children diagnosed with OME clinically and laboratory and group 2 (n = 50): Vit D level detection in normal children.

### 2.2. Ethical considerations

This study was conducted according to the standards approved by the Al-Azhar University's Research Ethics Committee. All participants signed the informed consent after full explanation of the study details.

### 2.3. Randomization

A control group was comprised of children whose ENT examinations revealed that they do not exhibit symptoms of OME. Simple randomization using computer-generated numbers for randomizing the selected subjects was done.

### 2.4. Inclusion criteria

Children who were diagnosed with bilateral OME & healthy controls.

### 2.5. Exclusion criteria

Age below 1 year, Children with craniofacial abnormalities, patients with chronic diseases, Patients with congenital or acquired immunodeficiency and patients with acute URI.

### 2.6. Sampling

5 ml of venous blood are withdrawn from all study population; the samples were left to clot for 20 min

then centrifuged and serum was separated and stored frozen at -20 °C till assay for vit D level at laboratories of Clinical Pathology Department at Al-Hussien Hospital of Al-Azhar University.

### 2.7. Methods

#### 2.7.1. All cases were subjected to the following

Written consent, detailed history taking and E.N.T examination.

# 2.7.2. Screening for patients with OME was diagnosed on the basis of

Loss of light reflex on the TM, Retraction of the TM, Type B or C tympanogram, and Glue in the ME (Fig. 1).

Without therapy, all OME cases were monitored for at least 3 months. Cases that were not resolved following 3 months of follow-up and were deemed to have persistent or chronic OME had general anesthesia for ventilation tube placement (Fig. 2).

Application. Blood tests for general anesthesia, including those looking for vit D, were performed on all patients who had surgery to apply VT.

Patients who had fully recovered by the conclusion of the follow-up period had their vit D levels checked as well.

### 2.8. Assay of vitamin D level

### 2.8.1. Principle of assay

The electrochemiluminescence immunoassay is designed to be utilized on immunoassay analyzers such as the elecsys and the cobas e (Fig. 3).

A control group was comprised of children whose ENT examinations ruled out the presence of OME.

#### 2.9. Statistical analysis

After collecting, reviewing, and coding the data, it was put into the Statistical Package for Social Science International Business Machines (IBM) Armonk, New York, United States (IBM SPSS) version 20. The quantitative data were given as the mean, standard deviations, and ranges when their distribution was determined to be parametric. The qualitative data were provided as a number and a percentage of the total.

In order to do a comparison among two groups that only had qualitative data, the  $\chi^2$  test was utilized. However, the Fisher exact test was utilized in place of the  $\chi^2$  test if the anticipated count in any cell was determined to be less than 5.





Fig. 1. Bilateral type B tympanogram.

Independent *t*-test was utilized to do the comparison among two separate groups utilizing quantitative data and parametric distribution.

It was decided that a margin of error of 5% would be acceptable, and the confidence interval would be set at 95%. In light of this, the following thresholds for significance were applied to the *P* value: *P* greater than 0.05 = not significant (NS), *P* less than or equal to 0.05 = significant (S), and *P* less than 0.001 = highly significant (HS).

### 3. Results

Table 1.



Fig. 2. Ventilation tube (grommet tube) in chronic OME case.

This table revealed that there were 52 cases were male and 48 were female and their ages varied from 2 to 15 years (mean 5.74 years) (Table 2).

This table showed that the average first vit D level in case group were;  $42.12 \pm 18.94$ , while the average first vit D level in control group were  $48.00 \pm 21.16$ and the average second vit D level in case group were;  $40.40 \pm 17.53$ .

There was statistically significant variance among cases group and control group concerning first vit D level (Table 3).

This table showed that during the first examination in case group, 34.0% of them were TM retraction in ear examination, 30.0% were loss of light reflex in ear examination, 16.0% were Glue in M ear in ear examination and 20.0% were combined signs in ear Examination while the control group, all cases were normal ear examination.

During the second examination 31cases out of 50 were improved after 3 months in case group, 8.0% of them were TM retraction in ear examination, 6.0% were loss of light reflex in ear examination, 10.0% were Glue in M ear in ear xamination,14.0% were combined signs in ear examination and 62.0% were normal ear examination,.



Fig. 3. Rosch diagnostic GmbH sandhofer strasse116, D-68305 Mannheime.

Table 1. Distribution of the examined cases concerning demographic data.

	All cases number = 100 [n (%)]
Sex	
Female	48 (48.0)
Male	52 (52.0)
Age	
Mean $\pm$ SD	$5.74 \pm 3.18$
Range	2–15

There was a highly statistically significant variance among the cases group and control group regarding first ear examination (Table 4).

This table showed that in COME group; 68.4% of them were Cow's milk exposure before 12 months

and 63.2% were Breastfeeding at least 6 months only, while in the complete recovery OME group, 45.2% were Cow's milk exposure beforehand 12 months and 74.2% were Breastfeeding at least 6 months only.

There was no statistically significant variance among COME group & Complete recovery OME Group concerning Cow's milk exposure beforehand 12 months and Breastfeeding at least 6 months only (Table 5).

This table showed that the average first vit D level in COME group were;  $51.53 \pm 11.81$ , while average first vit D level in complete recovery OME group were  $36.35 \pm 20.30$  and the average second vit D level in COME group were;  $50.62 \pm 11.80$ , while average second vit D level in complete recovery OME Group were  $34.35 \pm 17.85$ .

There was a highly statistically significant variance among COME group and complete recovery OME Group concerning first vit D level and second vit D level (Table 6).

This table showed that in COME group, 0.0% of them were tympanogram A, 73.7% were tympanogram B and 26.3% were Tympano C, while the complete recovery OME group; 0.0% of them were tympanogram A, 67.7% were tympanogram B and 32.3% were Tympanogram C.

During the second tympanogram in COME group, 0.0% of them were tympanogram A, 73.7% were tympanogram B and 26.3% were tympanogram C,

Table 2. Comparison among case group (no. = 50) and control group (no. = 50) concerning first vitamin D level and second vitamin D level.

	Case group no. = 50	Control group no. = 50	Test value	P value	Significance
First vitamin D level (	(ng/ml)				
Mean $\pm$ SD	42.12 ± 18.94	$48.00 \pm 21.16$	1.464•	0.042	S
Range	10-70	11-80			
Second vitamin D lev	el (ng/ml) (after 3 montl	ns)			
Mean $\pm$ SD	$40.40 \pm 17.53$	—	_	—	_
Range	11-63	_			

Ta	ble	3.	Com	varison	between	ı case	group	(no.	= 50	) and	control	group	(no.	= 50	) regardi	ing f	irst	ear	examination	and	l second	ear	examination.
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	Case group no. = 50 [n (%)]	Control group no. = 50 [n (%)]	Test value	<i>P</i> value	Significance
First ear examination					
TM retraction	17 (34.0%)	0	100.000	0.000	HS
Loss of light reflex	15 (30.0)	0			
Glue in M ear	8 (16.0)	0			
Combined signs	10 (20.0)				
Normal	0	50 (100.0)			
Second ear examination (af	iter 3 months)				
TM retraction	4 (8.0)	_	_	_	_
Loss of light reflex	3 (6.0%)	_			
Glue in M ear	5 (10.0)	_			
Combined signs	7 (14.0)				
Normal	31 (62.0)	-			

Table 4. Comparison between COME (no. = 19) and complete recovery OME (no. = 31) regarding Cow's milk exposure before 12 months and breastfeeding at least 6 months only.

	COME Number (%)	Complete recovery OME Number (%)	Test value*	P value	Significance
Cow's milk	exposure before 12 mon	ths			
No	6 (31.6)	17 (54.8)	2.566	0.109	NS
Yes	13 (68.4)	14 (45.2)			
Breastfeedi	ng for at least 6 months	only			
No	7 (36.8)	8 (25.8)	0.683	0.409	NS
Yes	12 (63.2)	23 (74.2)			

Table 5. Comparison between COME (no. = 19) and complete recovery OME (no. = 31) regarding 1st Vit D level and 2nd Vit D level.

	COME No. = 19	Complete recovery OME No. $= 31$	Test value	P value	Significance
First vit D level (ng	/ml)				
Mean ± SD	$51.53 \pm 11.81$	$36.35 \pm 20.30$	2.599	0.005	HS
Range	10-62	10-70			
Second vit D level	(ng/ml) (after 3 months	s)			
Mean $\pm$ SD	$50.62 \pm 11.80$	$34.35 \pm 17.85$	3.443	0.001	HS
Range	14-63	13-60			

Table 6. Comparison between COME (no. = 19) and complete recovery OME (no. = 31) regarding first tympanogram and second Tympanogram.

	COME Number = 19 [n (%)]	Complete recovery OME Numbert = 31 [n (%)	Test value	P value	Significance
First tymp	anogram				
A	0	0	0.110	0.308	NS
В	14 (73.7)	21 (67.7)			
С	5 (26.3)	10 (32.3)			
Second typ	mpanogram (after 3 months)				
A	0	31 (100.0)	0.190	0.373	NS
В	14 (73.7)	0			
С	5 (26.3)	0			

while the complete recovery OME group, 100% of them were tympanogram A, 0% were tympanogram B and 0% were tympanogram C.

There was no statistically significant variance among COME group and complete recovery OME group concerning first tympanogram and second tympanogram.

### 4. Discussion

OME is an inflammation of the ME described by the presence of fluid in the ME cleft in the absence of clinical symptoms or evidence of acute infection. It is the most prevalent infectious condition in children and the major contributor to conductive hearing loss in children.<sup>6</sup>

In the current study, the average age in case group were  $6.20 \pm 3.83$ , while average age in control group were  $5.28 \pm 2.31$ . In case group, 58.0% of them were males and 42.0% were females, while in the control group; 46.0% were males and 54.0% were females. There was no statistically significant variance among the cases group and control group concerning age and sex.

This is not in line with Ahmed et al. who stated that blood 25-hydroxyvitamin D levels were measured in 100 Cairo, Egypt-based children between the ages of 2 and 8 (split evenly into two groups of 50). The first group in this research involved children who had both OME and ATH. These children were subjected to a wait-and-see approach for more than 3 months. After this waiting period, they underwent a audiological evaluation, comprehensive which involved serial tympanometry that demonstrated a flat type (B) pattern. The mean age of these children was  $53.4 \pm 9.2$  months. They subsequently underwent adenotonsillectomy and ventilation tube insertion. The second group, which served as the control group, comprised children who did not have any medical or surgical conditions. These children visited our outpatient clinics for routine hearing checkups. They had normal otoscopy findings, normal results on the audiological evaluation, and exhibited a type (A) tympanometry pattern. The mean age of this control group was  $65.0 \pm 13.2$ months. There were 29 boys and 21 girls in the OME group (or 58 and 42%, respectively), while there were

27 boys and 23 girls in the control group (46 and 54%, respectively, P = 0.689).<sup>7</sup>

The mean ages of the case and control participants were 7.65 and 6.10 years, respectively, according to the research by Mandour *et al.* In their research, the age of these cases elevated significantly (P = 0.002).<sup>8</sup>

Both the cases and control groups had their levels of first vit D decline significantly in this research.

Patients with recurrent otitis media had lower levels of vit D than controls in a case–control investigation done by Cayir *et al.* There was also a reduction in the recurrence of otitis media once vit D therapy was added.<sup>9</sup>

A decreased rate of OME was observed in children with greater blood vit D levels, according to research by Walker *et al.*, although the study was criticized for including children from varied racial and ethnic backgrounds, which might have influenced the results.<sup>10</sup>

Our study showed that in the case group, 38.0% of them were COME and 62.0% were complete recovery OME.

Supplementation with vitamin D, vitamin E, vitamin C, and immune-stimulating molecules in the form of an oral pill led to fewer bouts of URI and OME in children, according to a randomized controlled experiment conducted by Della Volpe *et al.*<sup>11</sup>

Also, Ahmed *et al.* found that although the control group had a blood vit D3 average of  $15.7 \pm 5.3$  ng/ml, the OME group had a mean of  $16 \pm 6.1$  ng/ml. Despite the fact that Cairo, Egypt is a sunny city for the majority of the year, the findings of this research demonstrated that the mean level of vit D was below normal in both groups (16 and 15.7 ng/ml in groups A and B, respectively); nevertheless, there was no statistically significant distinction in the mean serum level of vit D among the two groups.<sup>7</sup>

In the current study, through the first tympano in case group, 66.0% of them were tympano B and 34.0% were tympano C, while in the control group, all cases were Tympano A. Through the second tympano in case group; 54.0% of them were Tympano A, 40.0% were tympano B and 6.0% were tympano C. There was highly statistically significant variance among cases group and control group concerning first tympano.

Akcan *et al.* reported that individuals were examined in accordance with the type of tympanogram they had only 8 cases had a type C tympanogram, and all of these cases were in the OME group for complete recovery. The variance in mean vit D levels among the type B and Type C groups was not statistically significant (P = 0.475), coming in at 19.10  $\pm$  10.78 ng/ml for the Type B and 16.35  $\pm$  5.32 ng/ml for the Type C group.<sup>12</sup> In the current study, the average first vit D in COME group were  $39.63 \pm 18.09$ , while average first vit D in complete recovery OME group were  $36.35 \pm 20.30$  and the average second vit D in COME group were  $38.53 \pm 16.96$ , while average second vit D in complete recovery OME group were  $34.35 \pm 17.85$ . There was no statistically significant variance among COME group and complete recovery OME group concerning first vit D and second vit D.

Akcan *et al.* reported that, Thirty-three of 66 cases (50.0%) in the chronic OME group and thirty-five of 108 cases (32.4%) in the full recovery OME group had vitamin D insufficiency (P = 0.021). There was a significant variance in the prevalence of 25(OH) Vit D insufficiency between the chronic OME and the recovery chronic OME groups (P = 0.006), with the prevalence in the control group being 25%. Vitamin D's influences in OME are shown. Follow-up outcomes of OME are significantly associated with 25(OH) D insufficiency.<sup>12</sup>

Li *et al.* concluded that Plasma vit D level had no significant influence in cases with chronic OM.<sup>13</sup>

### 4.1. Conclusion

The findings of our study indicate that low vitamin D levels are correlated with OME. Therefore, in these children, assessing serum 25 (OH) D levels ought to be examined.

### Authorship

All authors have a substantial contribution to the article.

### Funding

The study is self-funded, no grants or external funders.

### Ethics

The ethical committee of faculty of medicine-Al Azhar university. approved the study protocol and observe the work of the study including the patient consents and participation.

### **Conflicts of interest**

The authors declared that there were no conflicts of interest.

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Disclosure: the authors have no financial interest to declare in relation to the content of this article.

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