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Frequency Of Otitis Media with Effusion Among Preschool Children and Its Effect On Both Children And Their Parents: A Cross-sectional Study

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ORIGINAL ARTICLE**Frequency Of Otitis Media with Effusion Among Preschool Children and Its Effect On Both Children And Their Parents: A Cross-sectional Study****Khaled Abd EL-Shakor Mohammed¹, Amany Mohammed Abdallah², Mona Ahmed Mohammed EL-Didamony^{3*}**¹ ENT Department, Faculty of Medicine, Zagazig University, Sharkia Egypt.² Family Medicine Department, Faculty of Medicine, Zagazig University, Sharkia Egypt.³ Resident of Family Medicine, South Sinai, Ministry of health, Egypt.***Corresponding Author:**Mona Ahmed Mohammed
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ABSTRACT**Background and aim:**The impact of otitis media with effusion (OME) on quality of life (QoL) may be substantial. The aim of this study is to determine the magnitude of OME among children and its determinate effects on both them and their parents.**Method:**A cross-sectional study was conducted on 98 apparently healthy preschool children attending the otolaryngology clinic at Zagazig University hospital. The studied children underwent socioeconomic data assessment and clinical examination. Diagnosis of OME was established using otoscope and tympanometry. QoL in children and also level of parents stress were measured.**Results:** Mean age of the studied children was 3.27 ± 1.53 years. Of them, 22 (22.4%) had OME. There is a statistically significant difference between presence of OME and crowding index, mother education, parent smoking and type of feeding. Regression analysis showed that only four factors were found significant in this analysis: crowding index >2 /room (odds ratio (OR) = 9.36), parent smoking in the household (OR= 3.72), mother education less than secondary school education (OR=9.02) and recurrent acute otitis media (AOM) (OR=7.27). There is a significant difference between the studied children with and without OME regarding emotional functioning, school performance, and total QoL domains. There is a significant difference between the studied children regarding parents' stress**Conclusion:**

Having recurrent AOM, parent smoking in the household were strong predictors of the occurrence of OME. Children with OME reported significantly poorer quality of life and their parents had higher perceived stress.

Keywords: Otitis media; Children; Quality of life**1. INTRODUCTION**

The definition of otitis media and its consequences has changed over the years. Otitis media with effusion (OME) is an accumulation of fluid in the middle ear in the absence of signs of acute inflammation. It is the most common cause of acquired hearing loss in childhood. It has a bimodal age distribution. It is common in children between the ages of one

to three years, especially in the winter season.¹ Otitis media with effusion is common in more than two-thirds of young children because their Eustachian tube (ET) anatomy and function do not provide adequate ventilation and drainage of natural mucus during a cold. Even with the widespread use of pneumococcal conjugate vaccines, acute otitis media (AOM) following

an upper respiratory tract infection (URTI) remains common in childhood.²

The cumulative incidence to the age of four years is 80%, and at age seven, the prevalence is still 3% to 8%.³ Otitis media with effusion may be associated with otalgia, infection and/or hearing loss. Hearing loss may be significant (20 dB to 30 dB), specifically when it is bilateral and has lasted for more than a month.⁴ However, some children have nearly normal hearing despite the presence of fluid within the middle ear. The hearing loss and discomfort may have linguistic, developmental, behavioral, and other social consequences, especially if the effusion is bilateral and of long duration.⁵ Otitis media is related to difficulties in speech, delayed response to auditory input, and disturbances in attention. It may also be associated with less task oriented and less capable of independent colleagues.

Observational studies measuring caregiver reports showed that school performance might improve after OME has been identified and treated.⁶ The impact of OME on disease-specific quality of life (QOL) and functional health status may be substantial, affecting children and caregivers.

According to the parental report, 76% of children with OME suffer from otalgia, 49% from behavioral problems, 64% from sleep disruption, 35% to 62% from speech and hearing concerns, and 15% from balance symptoms. Also, child and parent interaction may be poorer than in healthy children, and caregiver concerns are high. OME has an impact on child QOL. OME may result in sequelae that include tympanic membrane atelectasis, cholesteatoma formation, ossicular erosion, and tympanic membrane perforation.⁷ Due to the lack of data about the effects of otitis media with effusion on preschool children and their parents, the objective of this study was to determine the magnitude and risk factors of otitis media with effusion among preschool children attending Zagazig university otolaryngology clinic and its determinate effects on their quality of life and their parents

2. PATIENT AND METHODS

We followed Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement guidelines when reporting this manuscript. The present study was approved by the ethical committee of Zagazig University, through the period of September 2018 to February 2019. Written informed consent was obtained from all participants' patients. The work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

2.1. Study Design, Study Setting, and Study Participants

We conducted an epidemiological cross-sectional study in the otolaryngology clinic at Zagazig University. The children were selected via systematic random sampling technique. We included apparently healthy children with less than six years old. Exclusion criteria were; children above six years old, children with chronic health problems, and patients who refused to participate in this study. The children will be selected by simple random technique. Every third child attending the audiology unit was included in the study.

2.2. Sample size

Sample size calculation was measured using Epi info-7 to be 98 cases with confidence level 95% and power of 80% after assuming that the prevalence of otitis media with effusion in Egypt is 16%. We used a systematic random method to select the patients.

2.3. Diagnostic criteria and tools of OME

In the diagnosis of OME, pneumatic otoscopy remains to be the gold standard. The use of other diagnostic tools in addition to pneumatic otoscopy, such as impedance audiometry and tympanocentesis, further improve the diagnostic accuracy.

2.4. Study Assessments and Data Collection

For each eligible patient, we reported the following data:

a) Socio-demographic information of the study:

A structured questionnaire was developed to collect socio-demographic information of the

study participants (age, sex, residence, education, etc.)

b) Pediatric Quality Of Life Inventory (Peds QL):

Health-related quality of life in children under trial using Pediatric Quality Of Life Inventory version 4 (Peds QL-4). Peds QL is a modular instrument for measuring health-related quality of life in children and adolescents ages 2 to 18. The Peds QL 4.0 generic core scales are multidimensional child self-report as the generic core measure to be integrated with the Peds QL disease-specific modules. The Peds QL 4.0 generic core scales which consist of 23 items. The 4 Peds QL 4.0 generic core scales are; Physical Functioning (8 items), Social Functioning (5 items), Emotional Functioning (5 items), and School functioning (5 items). The following scores were used: 0 if it is never a problem, 1 if it is almost a problem, 2 if it is sometimes a problem, 3 if it is often a problem, and 4 if it is almost always a problem. If the if the parents were illiterate, we read the questions to the parents⁸.

c) Perceived stress scale

The questionnaire forms included personal and familial items. The Perceived Stress Scale (PSS) is a classic stress assessment instrument. The tool remains a popular choice for helping us understand how different situations affect our feelings and our perceived stress. The questions in this scale ask about your feelings and thoughts during the last month. In each case, you will be asked to indicate how often you felt or thought a certain way. Although some of the questions are similar, there are differences between them and you should treat each one as a separate question. For each question choose from the following alternatives: 0 – never, 1 - almost never, 2 – sometimes, 3 - fairly often, and 4 - very often. We determined the PSS score by following these directions: First, reverse the scores for questions 4, 5, 7, and 8. On these 4 questions, change the scores like this: 0 = 4, 1 = 3, 2 = 2, 3 = 1, 4 = 0. Individual scores on the PSS can range from 0 to 40 with higher scores indicating higher perceived stress. Scores ranging from 0-

13 would be considered low stress. Scores ranging from 14-26 would be considered moderate stress. Scores ranging from 27-40 would be considered high perceived stress.⁹

2.5. Pilot study

A pilot study was carried out on 10% of the sample attending Zagazig university otolaryngology clinic to test the validity of the used questionnaire. It also helped to estimate the time needed for data collection. The patients included in the pilot study were excluded from the main sample.

2.6. Study Process.

All subjects included in this study were interviewed, and their parents were asked each of them. The parents were asked to fill in the PedsQL questionnaire. Time taken to fill the questionnaire was about 15 minutes. In addition, each child underwent complete ENT evaluation with an assessment of OME by otoscopy by the ENT specialist.

2.7. Statistical Analysis

All data were analyzed using SPSS 25.0 for Windows (SPSS Inc., Chicago, Illinois, USA). MedCalc Statistical Software version 14.8.1 (MedCalc Software bvba, Ostend, Belgium; <http://www.medcalc.org>; 2014). Continuous variables were expressed as mean \pm SD, median and range while the categorical variables were expressed as a number (percentage). Continuous variables were checked for normality by using Shapiro wilk test. Independent Student t (t) test (for normally distributed data) and Mann Whitney test (for normally distributed data) were used to compare means of two groups. Percent of categorical variables were compared using the Chi-square (χ^2) test. The multivariate logistic regression analysis model was done using any predictor with $p < 0.05$ in the univariate analysis. $P < 0.05$ was considered statistically significant, $p \leq 0.005$ was considered highly statistically significant, and $p \geq 0.05$ was considered not statistically significant.

3. Results

The present study included 98 patients with a mean age of 3.27 ± 1.53 years. The largest percentage of the studied patients were male

(63.3%), half of them came from rural origin, with about 45% of them were on low social class. The baseline characteristics were reported in **Table 1**. Out of the 98 included children, 22 (22.4%) were suffering from OME, and 67 (77.6%) without OME.

There is a statistically significant difference between the studied groups regarding crowding index (odds ratio of index more than 2 per room in developing OME was 5.84), mother education (odds ratio of lower education was 3), and parent smoking (odds ratio for a positive history of smoking 2.68). On the other hand, no significant difference was present between both groups regarding age, gender (OR of female 1.26), residence (OR of rural 1.27), and social class (OR of low 1.03). In addition, there is a statistically significant difference between the studied participants without and with OME regarding the type of feeding (odds ratio of bottle feeding 3.69). there is also significant difference between them and history of AOM and snoring with (OR of AOM =6.55 (95% CI;2.27 – 18.92), (OR of snoring =2.6 (95% CI; 0.987 – 6.85) respectively **Table 2**.

Results of univariate analysis of factors with statistical significance < 0.05 were reviewed using multivariate backward regression analysis model. Only four factors were found significant in this analysis: crowding index >2 /room (OR= 9.36, 95% CI: 1.782–118.633), parent smoking in the household (OR= 3.728, 95% CI: 1.178–11.8), low mother education (OR=9.021, 95% CI: 1.907–9.021) and recurrent AOM (OR=7.27, 95% CI: 2.197–24.071), **Table 3**.

There is statistically significant difference between the studied patients (with and without OME) regarding emotional functioning (57.27 ± 17.51 versus 69.21 ± 17.11 , $p=0.003$), school performance (51.36 ± 19.83 versus 69.87 ± 27.64 , $p=0.002$) and total quality of life (47.52 ± 7.67 versus 54.45 ± 9.13 , $p=0.002$) domains. All domains were significantly lower among patients with OME, as seen in **Figure 1 and Table 4**. There is a statistically significant difference between the studied groups regarding parents' perceived stress (All parents of patients with OME had moderate to high stress, $P<0.001$, **Figure 2 and Table 5**).

Tables

Table 1: Distribution of the studied patients according to demographic characteristics.

	Mean \pm SD	Range
Age	3.27 \pm 1.53	1 - 6
	N (98)	%
Gender:		
Male	62	63.3
Female	36	36.7
Residence:		
Rural	49	50
Urban	49	50
Social class:		
Low	44	44.9
Middle	40	40.8
High	14	14.3
Parent smoking:		
No	62	63.3
Yes	36	36.7
SD; Standerd deviation		

Table 2: Comparison between the studied patients with and without OME regarding demographic characteristics and their past history:

	With OME	Without OME	Z	p	OR for OME (95% CI)
	Mean ± SD	Mean ± SD			
Age (years)	3.55 ± 1.49	3.2 ± 1.55	-1	0.317	
	N=22 (%)	N=76 (%)	X²	P	
Gender:					
Male	13 (59.1)	49 (64.5)	0.213	0.645	1.26 (0.48 – 3.32)
Female	9 (40.9)	27 (35.5)			
Residence:					
Rural	10 (45.5)	39 (51.3)	0.234	0.628	1.27 (0.49 – 3.28)
Urban	12 (54.5)	37 (48.7)			
Social class:					
Low	10 (45.5)	34 (44.7)	0.760	0.684	1.03 (0.4 – 2.67)
Middle	9 (40.9)	31 (40.8)			
High	3 (13.6)	11 (14.5)			
Crowding index:					
≤2/room	9 (40.9)	55 (72.4)	4.267	0.039*	5.84 (0.91 – 37.49)
>2/room	13 (59.1)	21 (27.6)			
Mother education:					
Low	14 (63.6)	28 (36.8)	5	0.025*	3 (1.12 – 8.04)
High	8 (36.4)	48 (63.2)			
Parent smoking:					
No	8 (36.4)	46 (60.5)	4.026	0.045*	2.68 (1 – 7.17)
Yes	14 (63.6)	30 (39.5)			
Type of delivery:					
Vaginal	9 (40.9)	40 (52.6)	0.928	0.333	1.61 (0.613 – 4.2)
CS	13 (59.1)	36 (47.4)			
Feeding:			6.766	0.034*	3.69 (1.33 – 10.24)
Breast	3 (13.6)	17 (22.4)			
Artificial	10 (45.5)	14 (18.4)			
Mixed	9 (40.9)	45 (59.2)			
Pacifier use:			0.739	0.39	1.52 (0.58 – 3.98)
No	9 (40.9)	39 (51.3)			
Yes	13 (59.1)	37 (48.7)			
Recurrent AOM:					
No	6 (27.3)	54 (71.1)	13.775	<0.001**	6.55 (2.27 – 18.92)
Yes	16 (72.7)	22 (28.9)			
Snoring:					
No	10 (45.5)	52 (68.4)	3.872	0.049*	2.6 (0.987 – 6.85)
Yes	12 (54.5)	24 (31.6)			

**p < 0.05 is statistically significant **p ≤ 0.001 is statistically highly significant*
OME, otitis media with effusion; AOM, acute otitis media, SD, Standard deviation; OR, odds ratio; CI confidence interval. Z Mann Whitney test

Table 3: Multivariate logistic regression of variables independently predict the occurrence of OME among the studied patients:

Variables	OR	95% CI		P
		Lower	Upper	
Crowding index (>2/room)	9.36	1.782	118.633	0.022*
Parent smoking (yes)	3.728	1.178	11.8	0.025*
Recurrent AOM	7.27	2.197	24.071	0.001**
Low maternal education [‡]	2.86	1.907	9.021	0.023*

* $p < 0.05$ is statistically significant ** $p \leq 0.001$ is statistically highly significant

[‡] Low maternal education includes illiterate, Read and write, Basic education
 AOM, Acute otitis media; OR, odds ratio; CI confidence interval.

Table 4: Comparison between the studied groups regarding the quality of life domains:

	With OME	Without OME	p
	Mean \pm SD	Mean \pm SD	
Physical functioning domain	58.81 \pm 20.29	55.35 \pm 20.66	0.51
Emotional functioning domain	57.27 \pm 17.51	69.21 \pm 17.11	0.003*
Social functioning domain	22.63 \pm 16.3	23.37 \pm 23.21	0.6
School performance domain	51.36 \pm 19.83	69.87 \pm 27.64	0.002*
Total QoL domain	47.52 \pm 7.67	54.45 \pm 9.13	0.002*

* $p < 0.05$ is statistically significant

OME, otitis media with effusion; SD, Standard deviation; QoL, Quality of life.

Table 52: Comparison between the studied patients with and without OME regarding parents' perceived stress:

	With OME	Without OME	X ²	p
	N (%)	N (%)		
Perceived stress:				
Low	0 (0)	8 (10.6)	18.86	<0.001**
Moderate	15 (68.2)	66 (86.8)		
High	7 (31.8)	2 (2.6)		

* $p < 0.05$ is statistically significant

OME, otitis media with effusion

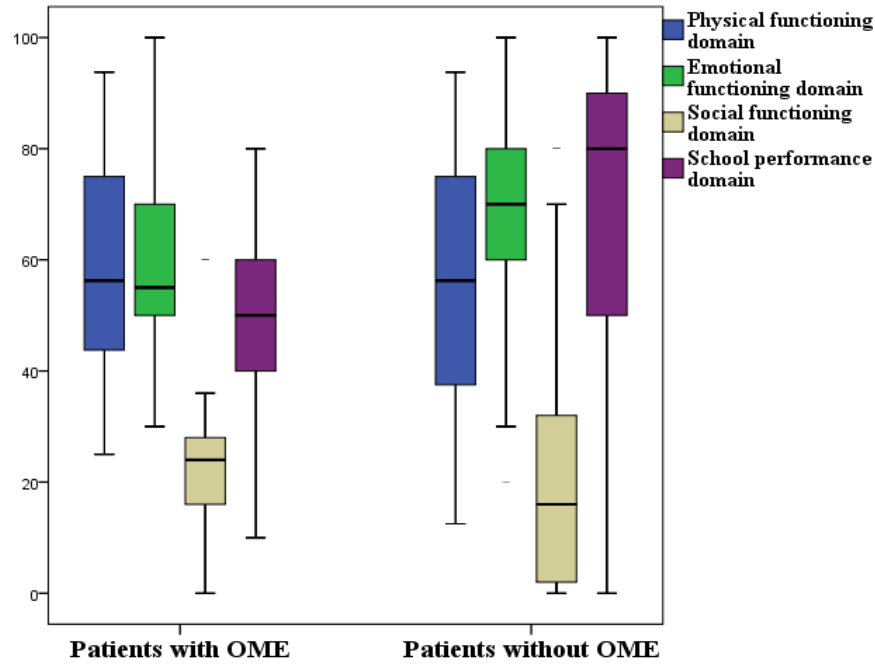


Figure 1. Boxplot graph showing the distribution of the studied groups according to QoL domains *OME, otitis media with effusion*

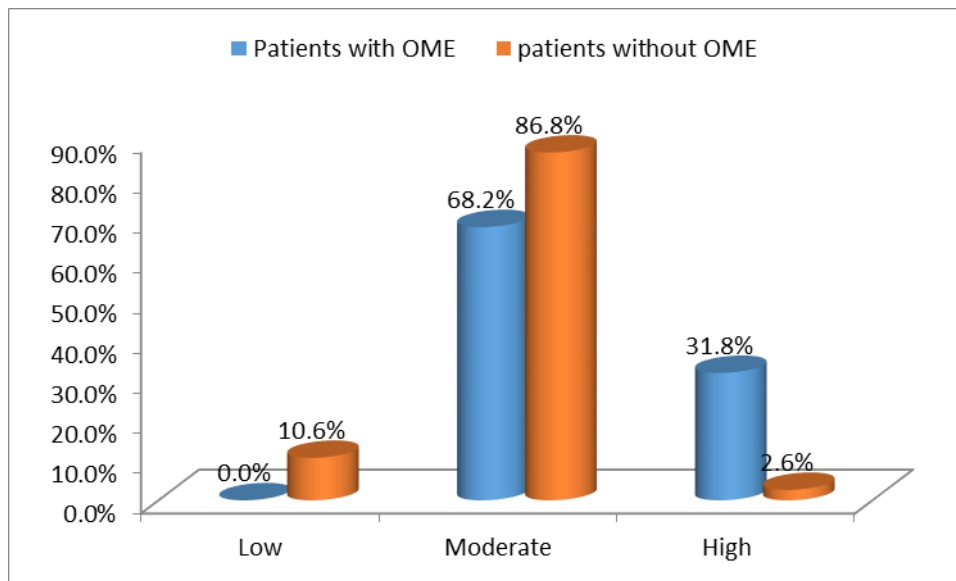


Figure 2: combined bar chart showing distribution of Parents of the studied groups according to perceived stress.

OME, otitis media with effusion

4. DISCUSSION

In this study, the frequency of patients with OME was 22 (22.4%) out of the total children that visited the otolaryngology clinic at Zagazig University. In addition, boys were more affected with OME than girls (59.1 vs. 40.9%). This is in agreement with previous studies, who

reported that boys are more likely to have OME than girls.¹⁰ This finding may be associated with a difference in geography and season of studied patients¹¹. The data from the world pediatric practice showed that most of the clinicians follow the clinical practice guidelines worldwide. For

example, only 10% to 35% of pediatricians use pneumatic otoscopy for diagnosis, and 30% obtain an age-appropriate hearing test when the OME persists. Moreover, 33% treat OME inappropriately with antibiotics, which results in unnecessary adverse events and bacterial resistance¹¹.

It has been reported that children with hearing problems aged 1.5 -19 years have difficulties with: attention, behavior, communication, conduct, relationships, emotions, and social behavior. It assumed that children with severe hearing problems might have poor outcomes, but it has been reported that children with mild hearing problems actually exhibit the worst psychosocial health-related quality of life¹².

The mean age of the studied patients was 3.27 ± 1.53 . The largest percentage of the studied patients were males (63.3%), half of them came from rural origin, and 45% of them were low social class. Most of our patients were of low socioeconomic status, as seen in many recent studies. In India, reported that only 4% of OME cases belong to the upper class and 96% belong to middle and lower classes.¹³

Furthermore, we found no association between sex and OME. There are some studies that discussed the higher prevalence in males, but most of the publications have not shown an effect of sex on OME¹⁴. In addition, neither male nor female gender was identified as strong predictor of OME in school children¹⁵. The largest percentage of patient's parents (63.3%) were nonsmokers, and there was a significant difference between patients with and without OME and a significantly elevated odds ratios (OR=2.68) for a positive history of smoking was detected smoking. Smoking is one of the most studied risk factors of OME.

In a review study, they reported that there is insufficient data to indicate a relationship between passive smoking and middle ear disease. In literature, there are studies that deny any association between parental smoking and OME¹⁶.

However, many other studies demonstrate a clear relationship between them. It was noted that clearance of glue was statistically less

frequent where the child's mother or where both parents smoked¹⁴.

The largest percentage of the studied patients had a history of mixed breast and bottle feeding 55.1% and pacifier use 51%. Also, there was a significant difference between the studied groups (with and without OME) regarding the type of feeding (OR = 3.69, P<0.05) but no significant difference regarding type of delivery and pacifier use. This contradicted the finding of previous studies which stated that the type of infant feeding during the first two years of life did not have a significant effect on the prevalence of OME. Besides, another study found that the occurrence of otitis media was associated with pacifier use considering it as one of the modifiable risk factors for otitis media¹⁷.

Moreover, there was a statistically significant difference between the studied groups regarding crowding index (OR=5.84, 95% CI: 0.91 – 37.49). On the other hand, no significant difference was present between both groups regarding age, gender, residence, and social class. Our results are similar to those reported by previous studies. They found that the probability of disease increases with each additional brother or sister¹⁵.

There is a positive correlation between socioeconomic status and OME. Children of lower socioeconomic status are more susceptible to OME as reported by earlier studies¹⁸. In a screening study comparing families with low and high socioeconomic status in Brazil, the incidence of OME was found to be higher among children of families with low socioeconomic status and resolution of the condition was observed to be reduced¹⁹. Another study reported that the higher the socioeconomic status, higher prevalence the otitis media. They found that about 43% of patients with OME belong to the upper lower class²⁰. However, in our study, no significant difference was present between both groups regarding social level.

In our study, low mother education was found to be a risk factor for OME. In the multivariate regression model, low mother education was

found to be an independent predictor of OME ($P < 0.05$; OR=3, 95% CI: 1.12–8.04). Similarly, ²¹, reported a higher prevalence of OME in families with less parental education. Also, other studies found that lower levels of maternal education were associated with poorer knowledge regarding otitis media ¹⁵.

The largest percentage of the studied patients with OME had history of recurrent AOM (72.7%) or snoring (54.5%). In univariate analysis, children with recurrent AOM were more likely to have recurrently OME [OR=6.55; 95% CI 2.27 – 18.92] (table 2) in contradict with a previous study²² Reported that some of the children continue to have middle ear problem secondary to Eustachian tube dysfunction and large adenoid, particularly in first or second grade. Also, in the multivariate regression model, we found recurrent AOM to be a strong predictor of OME. Previous studies similarly found that children with a history of recurrent AOM are more likely to have OME ^{23,24}.

Other study had investigated the psychosocial health-related quality of life outcomes of children with OM and predominantly report lower psychosocial issues. It has been reported that children with hearing problems are showed to be 3.6 times more likely to have psychological difficulties and three times more likely to have moderate to severe mental health problems than hearing children ²⁵.

Our findings showed a statistically significant difference between the studied groups regarding parents' perceived stress and all parents of patients with OME had moderate to high stress.

This might be because parents initially believe that otitis media is a short-term illness, and when the disease is prolonged or reoccurs, they become anxious and weary in coping with managing the disease and treatment ²⁶.

On the other hand, this study has some limitations. Due to the nature of the study as a cross-sectional study, the relation between risk factors and outcome cannot be proved. The sample size was relatively small. No

audiological tests were done. Only tympanometry was used.

We concluded that the frequency of OME among children attending the otolaryngology clinic at Zagazig University was about 22%. Low mother education was found to be a risk factor for OME. Children with recurrent AOM were more likely to have recurrent OME. We also found that parent smoking in the household and recurrent AOM were strong predictors of the occurrence of OME among the studied children. Interestingly, children with OME reported significantly poorer quality of life than their peers without OME regarding emotional functioning, school performance, and total QoL. These findings demonstrate that a true difference in QoL likely exists between children with and without OME. Parents of children with OME had higher perceived stress making OME a serious problem threatening the whole family. Large scale prospective study should be done to prove relation between suggested risk factors and development of OME. Parents education programs are recommended to prevent and early diagnose OME. Also, surveillance of OME should be routine procedure especially in this golden age (preschool children). Formal evaluation of hearing with correlating its degree with QoL is strongly recommended.

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