Otitis Media with Effusion in Children Aged 2-12 Years Attending the Paediatric Clinic at Mulago National Referral Hospital, a Ugandan Tertiary Hospital: A Cross-Sectional Study.

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Abstract

Background

Otitis media with effusion (OME) is common in children aged between 6 months to 4 years, and it is one of the causes of hearing loss (HL) in children worldwide. OME is a type of inflammation of the middle ear in which there is collection of the fluid. The later causes HL which interferes with speech and language development, communication skills, school performance, psychosocial skills, and quality of life of children.

Methods

This was a prospective cross-sectional study on 246 children aged 2 -12 years, attending Mulago National Referral Hospital (MNRH). Consecutive sampling procedure was used to reach each participant under ethical considerations until the sample size was reached. All children aged 2-12 years who meeting inclusion criteria were examined first by the Paediatrician and then by the Principal Investigator. Patients who had diagnosis of OME following the otoscopy and tympanometry findings were then proceed for audiological assessment. Prevalence of OME was summarized as a proportion and multivariate analysis was used to determine the factors associated with OME. Data was analyzed using STATA version 13.0.

Results

A total of 246 children were recruited into the study. Of the 246 children, 60% were male. The median age of the participants was 4.8 ± 2.8 years. The prevalence of OME was found to be 11%. Upper respiratory tract infections (URTI), recurrent AOM ($p= 0.005$, OR:5.14, 95% CI: 1.66-15.96), and snoring ($p= 0.000$, OR: 6.32, 95% CI: 2.32-17.26) were found to be strongly associated with OME in children aged 2-12 years attending MNRH.

Conclusions

The prevalence of OME among children 2-12 years attending MNRH was found to be 11%. There is association between OME and URTI, recurrent AOM, and snoring in children aged 2-12 years attending MNRH.

Background

Otitis media with effusion (OME) is common in children aged between 6 months to 4 years, and it is one of the causes of hearing loss (HL) in children worldwide. Otitis media with effusion is one of the most commonly occurring childhood illnesses in the United States of America (USA), with more than 2.2 million diagnosed cases each year [1].

The prevalence of OME reported from the developed countries, USA 15 to 30% in adolescents [2], 63.9% in Italy in children with lower respiratory tract infection [2].

In developing countries, India with 32.3% [3], and Africa countries, South Africa has a prevalence of 16.5% in children attending a primary healthcare clinic [4], Nigeria 25.2% in school age children [5], and Uganda 14.1% in school going children [6]. Otitis media with effusion is a type of inflammation of the middle ear in which there is collection of fluid. It is mostly due to a blockage or dysfunction of the Eustachian tube (ET), most often between the ages of 6 months and 4 years. This later causes HL which interferes with speech and language development, communication skills, school performance, psychosocial skills, and quality of life of children [7–9].

Methods

Study design, setting and population

This was a prospective cross-sectional study carried out among children aged 2 to 12 years, attending the Paediatric clinic at Mulago National Referral Hospital, Kampala, Uganda from February 2019 to April 2019. The inclusion criteria were all children aged 2-12 years, attending the Paediatric clinic at MNRH, all children whose parents or guardians consented and assented children with age more than 8 years. The exclusion criteria were children with chronic ear infections, perforation of the tympanic membrane; children who were sick and needed to be admitted, and uncooperated children.

Study procedure

Recruitment of participants was done at the Paediatric Clinic, Mulago National Referral Hospital. Consecutive sampling was used on those who satisfy the eligibility criteria until the sample size was achieved. The research assistants and/or the principal investigator comprehensively explained to the parents or caretakers of the selected participants the purpose of the study, benefits, risks and thereafter requested for their participation. The eligible patients who agreed to participate signed a consent/assent form by writing their name and signature and subsequently were assigned a study number. Participants were then interviewed after seeing the Paediatrician or Clinician. They were examined and underwent otoscopy and tympanometry by the PI assisted by an Audiologist and the Paediatrician in the consultation room of Paediatric Clinic. The diagnosis of OME was confirmed following the otoscopy findings (dull, bulging ear drum, presence of air bubble or air-fluid level) and tympanometry findings (tympanogram type B).

Otological exam

Otoscopy was performed by the PI using Welch-Allyn otoscope. This included the status of the tympanic membrane, normal, dull, bulging, presence of air bubble or air-fluid level, absence or presence of perforation with or without pus discharge, ... The children who didn't have wax, tympanic membrane perforation, ear discharge, were sent for the next test which was the tympanometry. Participants with

impacted wax were advised to use a cerumen softener for three days. After use of the softener, ear syringing was carried out then followed by audiological assessment.

Statistical data analysis

Analysis of the data collected was done using a computer statistical software EPI-DATA version 3.1 with automatic checks to avoid double entry of a questionnaire. The entered data was then exported to STATA version 13.0 for data cleaning and analysis with the help of a professional statistician. Continuous variables were analyzed using mean, standard deviations, median and interquartile ranges while categorical variables were presented using tables, bar graph, and pie-charts.

The prevalence of OME in children aged 2-12 years was determined using simple proportions, i.e., by calculating the number of children with OME 2-12 years divided by the total number of children recruited into the study. The associated factors were assessed in steps: bivariate analysis followed by multivariate analysis, with variables with a p-value<0.2 at bivariate analysis being included in the multivariate model, using logistic regression. The results were presented using odds ratios and P values whereby, the P value of 0.05 was used as the measure of statistical significance when considering 95% confidence intervals.

Ethical approval.

Permission letter to carry out the study was obtained from ENT Department, College of Health Sciences (CHS), Makerere University, School of Medicine Research and Ethics Committee (SOMREC). A written informed consent/assent was sought from parents/caretakers/children before recruitment into the study, and it included a clear explanation of the purpose of the study, the possible benefits and risks.

Results

Between February 2019 to April 2019, a total of 256 children attending Paediatric Clinic in Mulago Hospital were invited to participate in the study; 4 caretakers decline to consent, 2 were outside the required age range of 2-12years, 4 were unable to participate due to other reasons and 246 were recruited.

Demographic profile and clinical characteristics of the study participants.

Table 1 below shows the socio-demographic characteristics of the study participants (Table 1).

Among the 246 children recruited aged 2-12 years, the mean age of the participants was 4.8±2.8. Most of the participants 154/246 (63%) were aged 2-4 years while 22/246 (9%) within the age group of 8-10 years and 17/246 (7%) were within the age group of 11-12 years (Figure 1). Overall, 147/246 (60%) of the children were male. The histogram below shows the age distribution of the study participants (Figure 1).

Table 1: Shows socio-demographic characteristics of study participants

Characteristic		Frequency (n=246)	Percentage (%)
Age in years (Mean±SD)	2-4	154	63
	5-7	53	21
	8-10	22	9
	11-12	17	7
Sex of the child	Male	147	60
	Female	99	40
School attendance	Yes	173	70
	No	73	30
Breastfeeding duration	Never	1	1
	<6 months	5	2
	6-12 months	26	10
	>12 months	214	87
Breastfeeding position	Head raised	238	97
	Flat	8	3
Mothers' education	No/low education	90	37
	High/Tertiary	156	63
Family size	≤3 people	38	15
	4-6	164	67
	≥7	44	18

Prevalence of OME in children aged 2-12 years attending the Paediatric Clinic at MNRH

Among the 246 children recruited aged 2-12 years, the prevalence of OME in this study was 11% (26/246) as shown in figure 2 below (Figure 2). Children without OME were 220/246(89%). All 26 patients with OME presented bilateral OME.

Factors associated with OME among children 2-12 years attending Paediatric clinic

Using the bivariate analysis, the table below shows history of frequent AOM ($p<0.001$, OR:6.75, 95% CI:2.60-17.54); allergy ($p=0.007$, OR:3.24, 95% CI:1.38-7.61), snoring ($p<0.001$, OR:7.66, 95% CI:3.23-17.18), delayed speech ($p=0.005$, OR:3.67, 95% CI:1.48-8.93) were significantly associated with OME. Important to know also is that, all 26 children who had tympanogram type B for both ears, had history of

frequent URTI. Other factors like age, sex, school attendance, mothers’ education, family size, and exposure to smoking were not directly associated with OME as shown in a table below (Table 2):

Table 2: Shows bivariate analysis of socio demographic characteristics with OME in children aged 2-12 years attending the Paediatric clinic at MNRH.

Characteristics		Had Type "B" (n=26)	No type B (n=220)	OR (95% CI)	P-value*
	(Mean±SD)	3.3±1.6	4.9±2.9		
Age in years	2-4	24 (92)	130 (59)	0.26 (0.03 – 2.01)	0.196
	5-7	1 (4)	52 (24)	2.48 (0.15 – 41.45)	0.528
	8-10	1 (4)	21 (10)	-	-
	11-12	0 (0)	17 (9)	Ref	
Sex	Male	17 (65)	130 (59)	1.31 (0.56 – 3.06)	0.537
	Female	9 (35)	90 (41)	Ref	
School attendance	Yes	21 (81)	152 (69)	1.88 (0.68 – 5.19)	0.224
	No	5 (19)	68 (31)	Ref	
Mothers' education	No/low education	11 (42)	79 (36)	1.31 (0.57 – 2.99)	0.523
	High/Tertiary	15 (58)	141 (64)	Ref	
Family size	≤3 people	2 (8)	36 (16)	Ref	
	4-6	20 (77)	144 (66)	0.40 (0.09 – 1.79)	0.231
	≥7	4 (15)	40 (18)	0.56 (0.10 – 3.22)	0.512
Exposure to smoking	Yes	1 (4)	9 (4)	0.94 (0.11 – 7.71)	0.952
	No	25 (96)	211 (96)	Ref	
Frequent AOM	Yes	9 (35)	16 (7)	6.75 (2.60 – 17.54)	<0.001*
	No	17 (65)	204 (93)	Ref	
Allergy	Yes	17 (65)	81 (37)	3.24 (1.38 – 7.61)	0.007*
	No	9 (35)	139 (63)	Ref	
Snoring	Yes	16 (62)	38 (17)	7.66 (3.23 – 17.18)	<0.001*

	No	10 (38)	182 (83)	Ref	
Delay speech	Yes	9 (35)	28 (13)	3.67 (1.48 – 8.93)	0.005*
	No	17 (65)	192 (87)	Ref	

Considering the multivariate analysis, the prevalence in affected children was strongly associated with recurrent AOM (p=0.005, OR: 5.14, 95% CI: 1.66-15.96), snoring (p=0.000, OR: 6.32, 95% CI:2.32-17.26). Important to note all 26 children with OME had URTI, and reported snoring at night. This is possibly due to enlarged adenoids, which could affect the function of the Eustachian tube.

Sex, school attendance, exposure to smoking, allergy, and delayed speech were less associated with OME as shown in the table 3 below (Table 3):

Table 3: Shows multivariate analysis for the Factors associated with OME in children aged 2-12 years attending Paediatric Clinic at MNRH

Characteristics	odds ratio	95% CI	P-value*
Male child	2.22	0.80 – 6.20	0.127
School attendance	2.78	0.82 – 9.44	0.102
Exposure to smoking	0.22	0.01 - 3.23	0.269
Frequent AOM	5.14	1.66 – 15.96	0.005*
Allergy	1.49	0.56 – 3.99	0.429
Snoring	6.32	2.32 – 17.26	0.000*
Delayed speech	1.99	0.64 – 6.20	0.235

***Statistically significant risk factors.**

Discussion

This study set out to determine the prevalence and associated factors of otitis media with effusion among children aged 2-12 years attending Paediatric Clinic at Mulago National Referral Hospital.

Prevalence of otitis media with effusion

The prevalence of otitis media with effusion in this study was found to be 11%. All 26 children with OME had bilateral OME, there were no children with unilateral OME. This is similar to the prevalence of OME (11.9%) found in a study done by Els et al in South Africa, in 2016[10], where 109 children aged 2-12 years were recruited.

Also, a study done by Caylan R et al, in Turkey, in 2006, found the prevalence of OME was 11.1% in children aged 5-12 years. This study had the similar findings to our study, even though they didn't have in their study children younger than 5 years[11].

In another cross-sectional study done by Chibuikwe et al, in Nigeria, in 2017[5] the prevalence of OME was reported to be 25.2% in children aged 1-6 years. In this study, the prevalence of OME was higher than what we found in our study. This could be attributed to the fact that it was a community study conducted in Sub region of Nigeria, which is characterized by high rainfall and humidity. It is also known as an industrial area with high air pollution. Another reason could be they considered tympanograms types B and C as diagnosis of OME.

Aydemir G et al, in Turkey, in 2011[12], found 16% of 423 children 7-12 years enrolled had OME. This prevalence was higher as well compared to ours, the reason may be due to the fact that they considered the types B and C tympanograms as indicating of OME. In our study, the diagnosis of OME was based on type B tympanogram (flat curve).

Bisso F (unpublished data), in Uganda, in 2002[6], found the prevalence of OME was 14.1% in school going children aged 4-6 years. This prevalence was slightly similar to our study, the only difference the former was a community study and didn't include children less than 4 years and older than 6 years.

Factors associated with otitis media with effusion

We found frequent episodes of URTI, recurrent otitis media with effusion, and snoring to be factors strongly associated with otitis media with effusion, this is similar to that reported by F.Martines et al [13] where snoring ($p<0.0001$; OR=3.86, 95% CI:2.72-5.47), recurrent acute otitis media ($p<0.0015$; OR=2.54, 95% CI:1.41-4.61), frequent URTI ($p<0.0001$; OR=3.17, 95% CI:2.22-4.52) were factors associated with otitis media with effusion.

Our results were also similar to the findings of Kiris M et al [14] who found that snoring ($p<0.0001$) and URTI ($p<0.0001$) were important associated factors with otitis media with effusion. But they didn't consider recurrent acute otitis media as variable, which was included in our present study.

In a study done by Aydemir G. et al in 2011 [12], URTI ($p<0.05$), snoring ($p<0.05$), frequent episodes of acute otitis media ($p<0.05$) were reported to be predictors to otitis media with effusion, which are similar to the findings of our study.

Snoring reported in our 26 children with bilateral OME, could be due to a mechanical obstruction of the nasopharynx by enlarged adenoid, which could affect the function of the Eustachian tube.

Limitation of the study

Otitis media with effusion leads to conductive hearing loss in affected children, we would have wished to assess the degree, types and configuration of the hearing loss, using the diagnostic Auditory Brainstem

Response machine, we were not able to do it.

Conclusion

The prevalence of OME in children aged 2-12 years attending Paediatric Clinic at MNRH was found to be 11%, which is low or high to compare to other studies.

URTIs, recurrent acute otitis media, and snoring are found to be predictors to OME at Pediatric clinic at MNRH. We recommend to all Pediatricians and other medical professionals working at Pediatric unit to always give special attention to children presenting with URTI and other ENT conditions such as hearing loss, recurrent acute otitis media, snoring at night. Those who are not responding to the treatment should be referred early to ENT clinic for further management. Government should make policies on tympanometric test at Paediatric Clinic at Mulago National Referral Hospital, Kampala Uganda for early detection of hearing loss in children, which could indicate the presence of OME, thus to prevent them from sequelae that may arise.

Abbreviations

ABR
Auditory Brainstem Response
AOM
Acute Otitis Media
CHL
Conductive Hearing Loss
CHS
College of Health Sciences
dB
deci-Bel
dBHL
decibel Hearing Level
ENT
Ear
Nose and Throat
EAC
External Auditory Canal
HL
Hearing Loss
MoH
Ministry of Health
MNRH
Mulago National Referral Hospital

OME
Otitis Media with Effusion
PTA
Pure Tone Audiometry
SNHL
Sensorineural Hearing Loss
SOMREC
School Of Medicine Research and Ethics Committee
TM
Tympanic Membrane
URTI
Upper Respiratory Tract Infection.

Declarations

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Availability of data and materials

The datasets used and/or analyzed during the current study are not publicly available due to legal and ethical reasons but are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

Ethical approval was obtained on the 01st April 2019 from Makerere University College of Health Sciences, School of Medicine Research and Ethics Committee. All study methods were performed in accordance with the relevant guidelines and regulations of Declaration of Helsinki

A written informed consent/assent was obtained from participants. The results of this study were kept strictly confidential, and used only for research purposes. The name was not appearing anywhere on the coded forms with the information.

Consent for publication - Not applicable

Competing interests

The authors declared they have no competing interests.

Authors' contributions.

KB: conception and design of the study, data collection, data interpretation, drafting and review of the manuscript, JN: conception and design of the study data analysis, data interpretation, drafting and review of the manuscript, RH: conception and design of the study data analysis, data interpretation, drafting and review of the manuscript, ENS: contributed to the data collection, reviewed study data, and contributed to manuscript writing. All authors read and approved the final manuscript.

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Figures

Figure 1

Shows the age distribution of the study participants

**THE PREVALENCE OF OME IN CHILDREN AGED 2-12 YEARS
ATTENDING PAEDIATRIC CLINIC**

Figure 2

Pie-chart showing the prevalence of OME in children aged 2-12 years attending Paediatric Clinic