

**RISK FACTORS FOR OTITIS MEDIA WITH EFFUSION IN
CHILDREN AT KENYATTA NATIONAL HOSPITAL**

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the Degree of Masters of Medicine in ENT, Head and Neck
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DECLARATION

This is my original work and has not been presented for a degree in any other university.

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Dedication

To my ever supportive and wonderful family, my best friends who have been so encouraging

Throughout my studies.

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LIST OF ACRONYMS AND ABBREVIATIONS:

AH	Adenoid Hypertrophy
AOM	Acute otitis media
AR	Allergic Rhinitis
COM	Chronic otitis media
ENT	Ear, Nose and Throat.
ET	Eustachian tube
GER	Gastro-esophageal reflux
KNH	Kenyatta National Hospital
MED	Middle ear disease
MEE	Middle ear effusion
OME	Otitis Media with effusion
SHTS	Second Hand Tobacco Smoke
SPSS	Statistical package for the social sciences
TM	Tympanic membrane
TVPM	Tensor veli palatin muscle
URTI	Upper respiratory tract infections
VT	Ventilation tube
WHO	World Health Organization

Definitions of terms

- 1. Otitis media with effusion (OME)** is a condition where by serous fluid collects in the middle ear usually in children and usually without involvement of any microbiologic agents.
- 2. Recurrent acute otitis media (rAOM):** This is a condition characterized by recurrent episodes of pain, fever, +/- otorrhea and bulging or hyperemic tympanic membrane occurring with a frequency of three or more distinct episodes within six months.
- 3. Upper respiratory tract infections (URI or URTI):** This is a group of illnesses usually caused by acute viral or less frequently bacterial infection involving nose, sinuses, pharynx or larynx. The most frequent symptoms are cough, nasal congestion, rhinorrhea, sneezing, fever (low grade) and sore throat.
- 4. Allergic rhinitis:** This is an atopic condition characterized by rhinorrhea; nasal congestion; sneezing and itching.
- 5. Adenoid hyperplasia** is defined as the presence of clinical symptoms such as nasal airway obstruction, snoring and sleeping with mouth open. Children found with above symptoms are closely followed up for a lateral soft tissue neck X-ray to rule out the diagnosis.

ABSTRACT

Introduction

Otitis media with effusion is a multifactorial disease process involving immunological, infectious, anatomic, socioeconomic and genetic causes among other factors. Its peak prevalence varies between 1.3 and 31.3 percentage in different settings. Knowledge of risk factors for otitis media with effusion may help to understand the causation, the prevention and hence the management of OME.

Study objective

The aim of this study was to determine if age, gender, day care center attendance, cigarette smoke, positive history of upper airway obstruction, adenoid hyperplasia, bottle feeding and history of recurrent acute otitis media are the risk factors associated with the occurrence of Otitis media with effusion in children at Kenyatta National Hospital

Study design:

This was a hospital based cross-sectional descriptive study

Study area

The study was carried out at Kenyatta National Hospital Ear Nose and Throat, Head and Neck Surgery Outpatient Clinic

Materials and Methods

A questionnaire was used to collect data on demographic and relevant history in 57 Children aged 7 years and less.

The case definition of OME was based on clinical syndromic diagnosis and the detection of presence of fluid in the middle ear behind an intact tympanic membrane without active inflammation. Tympanographic assessment was carried out to confirm the presence of OME. Children with type B tympanograph were recruited into the study. Clinical data were collected on a preformatted questionnaire and descriptive analysis was performed in SPSS 21 version. The analysis included calculating measures of central tendency (mean and medians), measures of spread (standard deviation and ranges) for continuous variables, and frequency distributions for categorical variables.

Results

The mean age of the children presenting with OME was 54.6 months (SD 17.2), 27 (47.4%) patients were aged between 48 and 63 and 38 (66.7%) were males. For the environmental risk factors it was determined that 11 (19.3%) children attended day care centers and 9 (16.1%) lived in the same household with an adult who smokes tobacco, with 5 adults reported to smoke within the residence. The median duration of breastfeeding was 19 months (range 6 to 36) and bottle feeding was prevalent (63.2%) in children with OME. URTI symptoms were common in OME patients: rhinorrhea 41 (73.2%), nasal congestion 42 (73.7%) and cough 40 (70.2%). AH and AR occurred in 35 (79%) and 49 (86%) patients, respectively. The prevalence of AOM was 75.4% and rAOM occurred in 25 (43.9%) patients.

Conclusion

This study has determined the prevalence of established risk factors of OME in Kenyan children aged ≤ 7 years with tympanographic assessment which confirmed OME diagnosis. These findings highlight modifiable risk factors that can be targeted in the management and prevention of the disease. Health education for parents and caregivers can help prevent the development of OME diagnosis.

1.0 INTRODUCTION

1.1 BACKGROUND

Otitis media with effusion (OME) refers to an accumulation of fluid in the middle ear cavity without any signs of infection. There is association of socio-environmental, host risk factors, anatomical and immunological factors involved in the development of OME in children. Among them, craniofacial anomalies affecting Eustachian tube (ET) function often increase the risk of OME. Children with a cleft palate or deformity of the midface, skull base, or nose/paranasal sinuses have a statistically higher incidence of OME at all ages, especially during the first 2 years of life.¹

Many other risk factors have been reported to be associated with the development of OME; which among them are environmental risk factors like exposure to second-hand smoke, day-care attendance; together with other host factors like immaturity of the immune system, method of feeding (breast or bottle); race; sex and familial predisposition. In addition, upper respiratory tract infections are reported to precede OME; atopy or allergic disease as well as adenoid tissue hypertrophy have been shown to be involved in the causation of OME.²

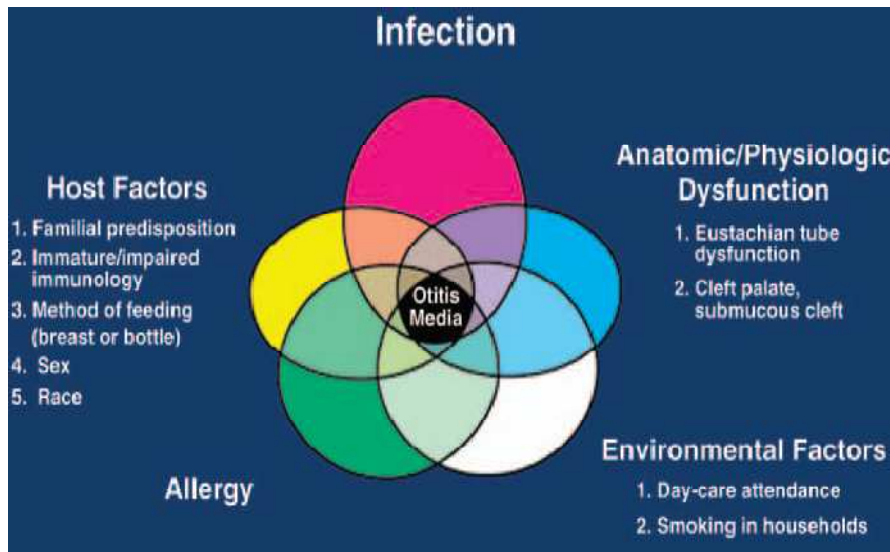
OME is a common health problem in pre-school and school-children. Its symptoms may appear insidious, therefore, creating delays in diagnosis. Such delays may raise the risks of complications of otitis media with effusion which include tympanosclerosis, retraction pockets and further persistence of middle ear effusion which may impair hearing as well as speech development.

1.2 Etiology

The etiology and pathogenesis of otitis media with effusion are multifactorial, which includes factors other than the Eustachian tube system, such as infection (usually viral and bacterial), immunologic status and socio-environmental factors. An increased incidence of otitis media with effusion in infants and young children is largely due to immaturity of their immune system and Eustachian tube. Once children are exposed to upper respiratory tract infections, otitis media with effusion is a common complication. Abnormal function of the Eustachian tube appears to be the most important factor in the pathogenesis of middle-ear disease.³

The following diagram summarizes the different risk factors considered to be involved in the occurrence of otitis media with effusion.

Risk factors causing OME in Children¹



1. Host factors
2. Infection (URTI, AOM, AH)
3. Anatomic & Physiologic Dysfunction
4. Environmental factors
5. Allergy (Allergic Rhinitis)

Otitis Media can be of acute or chronic onset; and may be associated with suppuration. Once an acute infection of the middle ear resolves, there is persistence of fluid in the middle ear due to poor pressure regulation and drainage of the middle ear. This may resolve spontaneously or may require medical intervention. This situation where there is an accumulation of fluid in the middle ear without active infection or inflammation is termed Otitis Media with Effusion.

The reasons for the accumulation of fluid without active infection are multifactorial namely the host factors: method of feeding (bottle or breast), immaturity of both Eustachian tube and immune system and the environmental risk factors among them day-care attendance, parental smoking which may be associated to the development of the Otitis Media with effusion.³ Other risk factors like recurrent upper respiratory infection and allergic rhinitis are also included.

The role of adenoidal hyperplasia in OME has also been well established.⁴ Additionally; OME is often associated with other diseases such as gastro-esophageal reflux, craniofacial deformities like cleft palate; sinonasal and nasopharyngeal disease. These may decrease the Eustachian tube function, therefore leading to ET dysfunction.

Children who have gastro-esophageal reflux develop OME due to inflammation of the Eustachian tube or middle-ear mucosa, or both when the secretions from the stomach are present in the nasopharynx by regurgitations and or aspirations, therefore entering ET.⁵ Tasker and colleagues reported that at the time of myringotomy and tympanostomy tube placement, 91% of 65 children were found with increased pepsinogen level from their aspirated middle ear fluid.⁶

1.3 Pathophysiology of development of OME

OME is primarily caused by an inflammation of the epithelium in the Eustachian tube and hypotympanum. Once the middle ear fluid has become established, the normal, flat cuboidal middle ear and mastoid mucosa is patchily replaced by thickened pseudostratified mucus-secreting epithelium with varying degrees of specialization, such as the development of cilia.³ Goblet cells are frequently present and sometimes mucus-secreting glands are formed.

A current proposed model, termed “Unified airway model,” hypothesizes that the upper and lower airways could be considered as an integrated system linked by physiologic and pathophysiologic mechanisms.⁷ This can be extended to include the middle ear cleft due to the fact that histologically, the middle ear mucosa is lined with the same pseudostratified, ciliated columnar epithelium as found in the upper and lower airways. Interference with the proper functioning of the ciliary lining leads to inefficient removal of secretions from the middle ear into the nasopharynx, which is necessary for normal working of the middle ear.

The commonest cause of improper function of the ciliary lining is inflammation which can be due to various causes. Inflammation of the ciliary lining leads to the submucosa becoming edematous, dilation and engorgement of blood vessels and an increased number of macrophages, plasma cells and lymphocytes.⁷

The active opening of the Eustachian tube which in turn regulates the middle ear pressure is primarily provided by contraction of Tensor veli palatini muscle (mTVP) during swallowing.⁸ This muscle is shown to be the most effective muscle in the opening of nasopharyngeal orifice and may be one of the causes of obstructive tubal dysfunction in children.

The initial event in the pathogenesis of otitis media consists of a persistent ET dysfunction (functional obstruction) or to an inefficient active tubal opening mechanism, or both.⁸ The mTVP has its insertion in the lateral portion of the ET and a suitable contraction is needed to effectively expand the tube lumen.⁸ Children born with cleft palate are predisposed to recurrent ear infections especially OME due to the abnormal insertion of the Tensor veli palatin muscle which prevents satisfactory emptying of middle ear secretions.⁹

Normal anatomical and physiological status of the Eustachian tube and the surrounding structures is a prerequisite for a functional middle ear.

The adenoids may cause mechanical obstruction of the nasopharynx, resulting in stasis of secretions and infection.¹⁰

Currently, there is recognition that Day care centers for very young children may serve as significant reservoirs for transmission of infectious diseases. There are factors that may contribute to the transmission. Children whose infections are in incubation period, asymptomatic carriers, or who are convalescing from illness are generally not recognized as sources of infection.¹¹ There is, therefore, a significant risk of transmission in this group.

Allergic rhinitis (AR) is one of the conditions which predisposes children to OME.¹² This represents an inflammatory condition of the nasal mucosa as a result of an exaggerated immunoglobulin E (IgE)-mediated immune response to inhalant allergens.¹³ In 1994, Bernstein highlighted the importance of immunoglobulin E-mediated hypersensitivity in the development of otitis media with effusion. The release of biologic mediator of inflammation from basophils and mast cells of rhinopharyngeal mucosa leads to Eustachian tube edema and stenosis. This chronic inflammatory response, along with viral or bacterial infections, produces middle ear effusion.¹⁴

Bernstein et al proposed three mechanisms that explain Eustachian tube obstruction due to an inflammatory process: The first one being dysfunction which may represent a retrograde spread of edema and congestion of nasal mucosa; the second one being dysfunction of the mucociliary activity which may result in the secretion covering the ostium and leading to intraluminal inflammation; and the third one being the obstructed lumen of the Eustachian tube resulting from of hypersecretion by seromucous glands.¹⁴

In children, OME is more prevalent due to the fact that their ET is more horizontal than in adults. This may explain the reason why when they are breast-fed or bottle-fed; (milk) may pass easily from nasopharynx through the ET. Another reason is that the ET is less patent more in supine position than semi-upright position. Hence its size and shape at the early age are not contributing to a favorable ventilation of the middle ear cavity.¹

In a systematic quantitative review, Strachan et al. concluded that there was probably a causal relation between parental smoking and middle ear disease in children.¹⁵ A possible explanation for the relation between ETS exposure and OME is a direct effect of cigarette smoke on host defenses.¹⁵

A suggestion that ET dysfunction may be secondary to the ambient smoke pollution from the child's close proximity to the primary caregiver and not to development effects.¹⁵

Several theories have been proposed on the mechanism through which exposure to environmental tobacco smoke(ETS) lead to development of OME. These are: first is smoke exposure may cause toxic injury of mucosal epithelium resulting in prolonged inflammation and airway congestion.¹⁶ Second, impaired mucociliary function of the Eustachian tube(ET) results in ciliostasis (ie, impaired clearance of nasopharyngeal airways). Third, ETS exposure may enhance the adherence of the microorganisms to the epithelial cell surface of the respiratory tract.

Fourth, there is a possibility that ETS may result in depressed local immune function such as Ig A production. Overall, a combination of these factors in children may predispose them to ET dysfunction.¹⁷

2.0 LITERATURE REVIEW

The prevalence of OME has varied between 1.3%-31.3% and this is associated with the existence of various risk factors in different communities.¹⁷

In the United States, approximately 2.2 million episodes of OME are diagnosed annually.¹⁸

OME is extremely common, affecting approximately 90% of the population at least once before they reach their third birthday.¹⁷ Two peaks are seen in the distribution, the first at around 2 years and the second at 5 years.¹⁹ A decrease in frequency is observed at around 7yrs when the ET matures.¹⁹ However, about 30% to 40% of subpopulation continues to suffer from OME after the age of 5 and/or suffer from recurrent episodes.¹⁹ Conductive hearing loss and its delayed effects on speech development are the most worrisome effects. This could be explained by stasis of middle ear effusion which impairs the transmission of sounds as well as the mobility of ossicles.¹⁹ The onset of OME is associated with various risk factors. Among the factors are bacterial infections, Eustachian tube dysfunction, allergic and immunologic factors, genetic factors, breast feeding, gender, and race. Environmental factors like exposure to secondhand tobacco smoking, including communal living and unhygienic habits are also seen. The anatomical and physiological factors include the cleft palate and the Eustachian tube dysfunction.¹

The frequency of allergic disease in pediatric OME patients was first reported to be high in 1983.²⁰ Many studies support the association between OME and AR. This could be explained by its high prevalence range which varies between 16 to 25%.²¹ In fact, a predominance of bilateral OME with higher hearing impairment was found in atopic children.²¹

Wilhelm Meyer, Danish Otolaryngologist published his work in the 18th century, about the association between hypertrophic adenoids and OME.²²

Orji et al. determined the degree of nasopharyngeal obstruction in adenoidal patients and normal controls by an evaluation of the adenoidal-nasopharyngeal ratio obtained from soft-tissue radiographs.²³

The risk of developing OME was higher than 7 times among the adenoidal patients and the diagnosis of OME correlated significantly with the degree of nasopharyngeal obstruction.²⁴

Environmental Tobacco Smoke (ETS) exposure or passive smoke exposure is now recognized as one of the significant contributors to the middle ear disease in communities.

In 1983, Cook et al. reported for the first time a possible link between parental smoking and the risk of developing otitis media with effusion in children.¹⁵

In a systematic review and meta-analysis performed by Jones et al., there was a relationship which has been explored providing suggestions that maternal postnatal smoking has the strongest influence on the disease than maternal prenatal or paternal smoking.²⁵

There is also an increased prevalence of OME associated to the human immunodeficiency virus (HIV) infection.¹ Tikaram et al. in a cross-sectional study done in 2012 in Malaysia found a prevalence of OME of 18.3% in children aged from 3 months to 12 years. Only, children who were having recurrent episodes of AOM were the ones who had increased risk of developing OME later on.²⁶ The other risk such as exposure to smoking, day care center attendance, breastfeeding, allergy, gender, race and sex were not statistically significant.²⁷

Recently in 2011, in Italy, Martines and colleagues did a case-control study, found a prevalence of OME of 6.8% in children aged from 5 to 14 years.²⁸ From their univariate analysis, a strong correlation associated risk factor and OME, was allergy which was described as an atopic reaction. A skin prick test for twelve allergens was performed to confirm which type of allergy was involved.

Among 321 children, 90 had allergy (28.04%). This was found increased again in children who are not breast-fed to 68.42%. Other variables with strong evidence were: presence of URTI, snoring and previous history of AOM.²⁸

In Netherlands, Engel et al. in 1999, published in a prospective study on risk factors of OME during infancy. Their findings of significant high risk factors of OME were infants with older siblings, histories of ear infection with reduced hearing, mouth breathing and common cold. Other factors such as gender, passive smoking, family history and socio-economic status did not show any significant association with the prevalence of OME.²⁹

In China, in 2006, Tong and Yue identified significant risk factors of OME among schoolchildren 6-7 years. In their univariate analysis, factors like atopy, hearing loss, nasal obstruction, rhinorrhea and previous history of AOM were found with elevated Odds ratio (OR). In multivariate analysis, the nasal obstruction, previous AOM and history of acute tonsillitis in the last 12 months were significant.

The Chinese findings were similar to the ones found by the Europeans and Americans. Studies done in different countries have shown the variation of risk factors associated with the prevalence of OME and have also contributed to the understanding of the development of OME in children.³⁰

There is a paucity of studies in sub-Saharan Africa on risk factors associated with otitis media with effusion.

3.0 JUSTIFICATION OF THE STUDY

Many children affected by Otitis media with effusion are exposed to multiple risk factors which are avoidable. This thesis hopes to contribute to the growing body of research showing risks of OME in children. Knowledge of the magnitude of risk factors in children with OME will help lead to avoidance of factors and hence a decrease the prevalence of OME. Identification of potential risk factors associated with OME is very important in our set-up and this will allow comparison with other countries where this kind of study has been done. Evidence linking association of risk factors to OME comes from studies conducted in developed countries. However, there is still need of information about presence of risk factors and its contribution to the development of OME in children at Kenyatta National Hospital. In addition, this study seeks to address the knowledge gap therefore to highlight the association of some of the risk factors for OME.

3.1 RESEARCH QUESTION

What are the risk factors contributing to the development of otitis media with effusion in children at Kenyatta National Hospital?

3.2 OBJECTIVES

3.2.1 Broad Objective

To determine the risk factors associated with the occurrence of otitis media with effusion in children at Kenyatta National Hospital

3.2.2 Specific objectives

1. Determine the socio-demographic factors in children with OME
2. Determine the environmental risk factors in children with OME
3. Determine the host risk factors for OME

4.0 METHODOLOGY AND MATERIAL

4.1 Study design

A cross-sectional descriptive study

4.2 Study location

Ear Nose and Throat Outpatient clinic at Kenyatta National Hospital

4.3. Study period

May- September 2014

4.4 Study population

The cases were children aged 7 years and less, diagnosed with OME as per study definition of OME. They were recruited from ENT clinic by purposive sampling.

4.5 Inclusion and Exclusion criteria

4.5.1 Inclusion criteria

Children who are aged 7 years and less:

- Diagnosed with Otitis media with effusion as per study definition of OME,
- Children with type B Tympanographic evidence of OME,
- Children whose parents or guardians who accepted to give consent

4.5.2 Exclusion criteria: (>7yrs) are

- Children whose parents or caregivers who declined to give consent
- Children presenting with other comorbidities (e.g.: Cor-pulmonale, renal disease, neurological disease and malnutrition)

4.6 Sample Size

Based on the 95% confidence interval, a precision (margin of error) $d = \pm 10\%$ and that the estimated population prevalence proportion is known we use $p = 0.183$ (Current Prevalence of OME study done in Malaysian population)³¹

Significance level $\alpha = 0.05$ implying $Z_{1-\alpha} = 1.96$ i.e. 95 % confidence level

The following sample size determination formula for incidence studies for unknown population proportion (Cochran, 1963)³¹ was used to estimate the proportion of population study size

$$n = \frac{[Z_{1-\alpha}^2] p(1-p)}{d^2}$$

$$N = 1.96^2 \times 0.183 \times 0.817 / (0.1)^2$$

N= 57 patients

4.7 Methodology: Procedure

57 Children aged 7 years and less, diagnosed with OME were recruited from the clinic of ENT Department. In the beginning, the procedure was explained to the parents or children's guardians. Their agreement to be enrolled in the study was approved by the informed consent.

Those who decline to participate in the study were excluded as well as those who were presenting with other comorbidities such as Cor-pulmonale, renal, neurological problems. These were referred to their specific specialist. The interview was conducted for each child; this means after having signed the consent the following part was the use of a questionnaire. Parents or guardians had to answer specific questions accordingly and this allowed us to get appropriate information about age, gender, duration of breastfeeding, itching of the nose or eyes, watery eyes, rhinorrhea, nasal congestion, snoring, sneezing, otalgia, ear discharge and cough. Data on presence of the above symptoms were collected in the questionnaire. The following conditions of Adenoid hypertrophy, Upper respiratory tract infections, Allergic rhinitis and recurrent acute otitis media were recorded according to their signs and symptoms as per definition list.

Information about tonsil infection, cleft palate, cerebral palsy, HIV status, day care center, exposure to smoking was taken. Otosopic examination was conducted by the researcher to reveal the middle ear status and assess if presence of fluid level, bubbles or hypervascularity; all suggestive of OME. After otoscopy; Tympanometry, was performed for each child by the researcher by using a machine (Impedance Audiometer AT 235). The findings were confirmed by type B tympanograph which is considered as positive screen of OME.

The findings were recorded in the questionnaire for data analysis. However, children who presented with type B tympanograph were well followed-up under medication and among

those who have not responded to treatment, these required surgical intervention of ventilation tube's insertion.

4.9 Data analysis

Data recorded in the pre-formatted data sheets was analyzed using the statistical package for social sciences (SPSS) 21.0. Descriptive analysis was performed in SPSS 21 version. The primary analysis included calculating measures of central tendency (mean and medians), measures of spread (standard deviation and ranges) for continuous variables namely, age of patients and duration of breast feeding, and determining the frequency distributions for categorical variables. The main risk factors were identified by calculating the percentage of children with OME who had each of the established risk factors classified as: environmental risk factors, host factors, infection, allergy and physiological or anatomic risk factors.

4.10 Ethical Considerations

1. The study was carried out only after approval by the KNH/UON ethics and research committee.
2. Informed consent from parent/ guardian was obtained before recruitment into the study.
3. Those that declined to participate in the study were not penalized but were offered the same management on the same principles as those who consented to the study.
4. The study results will be shared with the medical fraternity (and public if relevant) through medical conferences, seminars, lectures, medical journals and print and electronic media where relevant.

5.0 RESULTS

In this study, a sample of 57 children who tested positive for otitis media with effusion (OME) was used. They were recruited from the outpatient ENT clinic at Kenyatta National Hospital. The analysis of the socio-demographic characteristics, host and environmental risk factors showed the following.

5.1 Socio-demographic factors

The mean age of the children presenting with OME was 54.6 months (SD 17.2). The peak age of presentation with OME was between 48 and 63 months with 27 (47.4%) patients being in the modal age group (Table 1). There was a single infant (1.8%) who presented to the outpatient clinic with OME.

Table 1: Age distribution of children with OME at KNH

	Frequency*	Percent (%)*
Average age (in months)	54.6‡	17.2¶
Age group		
<12 months	1	1.8
12-35 months	6	10.5
36-47 months	7	12.3
48-63 months	27	47.4
64 months and above	16	28.1

*values are frequency and percent unless stated otherwise

‡ mean age; ¶ standard deviation

This study included 38 (66.7%) males presenting to the outpatient clinics with OME compared to 19 (33.3%) females also presenting with OME. The ratio of male-to-female patients with OME was 2:1 (Figure 1).

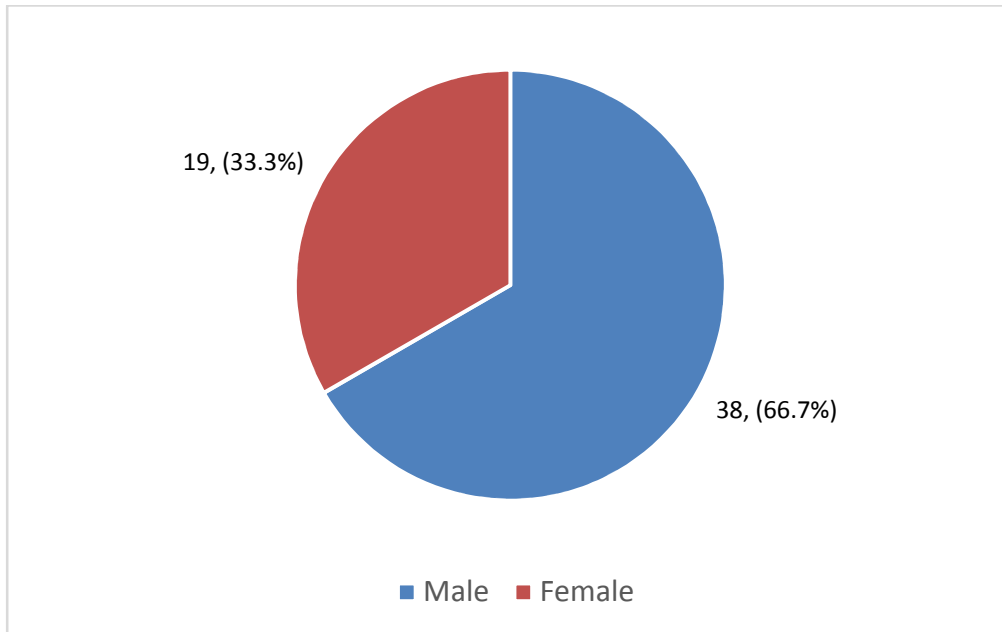


Figure 1. Gender distribution of children with OME

5.2 Environmental factors

The prevalence of the two environmental risk factors investigated in this study were: 19.3% for attendance of day care centers and 16.1% for presence of a smoker within the patient's household.

Most children 42 (73.7%) with OME were at home during daytime and 11 (19.3%) attended day care centers (Table 2). The children attending day care (n = 11) had a median age of 60 months compared to median ages of 56 months and 53.5 months for children staying at home (n = 42) and attending school (n = 4), respectively.

Out of the 57 patients with OME, 9 (16.1%) lived in the same household with an adult who smokes tobacco (Table 2). Five (55.6%) of these adult smokers were reported to smoke within the residence shared with the child presenting with OME.

Table 2: Environmental risk factors

	Frequency	Percent (%)
Child's location during the day		
Home	42	73.7
School	4	7
Day care center	11	19.3
Household member smokes tobacco		
Yes	9	16.1
No	47	83.9
Tobacco smoking within child's residence		
Outside residence	4	44.4
Inside residence	5	55.6

5.3 Other Risk factors for OME

5.3.1 Mode of feeding

The practice of bottle feeding was prevalent in children with OME with 63.2% reporting ever being fed using a bottle. Figure 2 summarizes information on breastfeeding practices in children with OME enrolled in the study. Out of the 57 patients, 54 (94.7%) had stopped breastfeeding and 3 (5.3%) were currently breastfeeding. Thirty six (63.2%) children had been fed using bottles and 4 (7%) had been fed using cup and spoon.

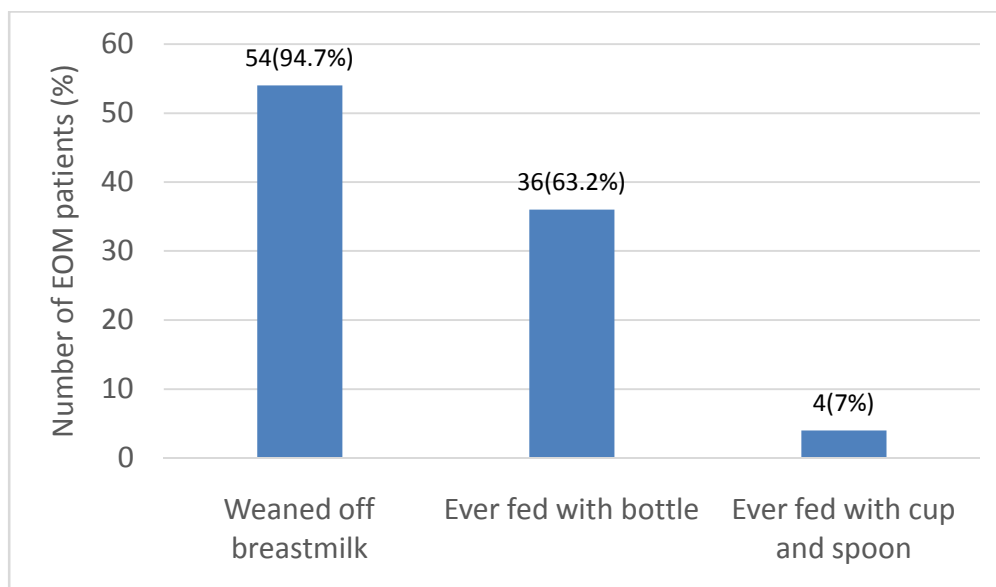


Figure 2. Mode of feeding

The median duration of breastfeeding was 19 months, with a range from 6 to 36 months and interquartile range (IQR) from 12 to 24 months (figure 2).

Figure 3 shows that there were no differences in the duration of breastfeeding in the group of children who were never fed with bottles (median duration [IQR] 18 months [12-24]) compared to children who were bottle fed (median duration [IQR] 19 months [15-24]).

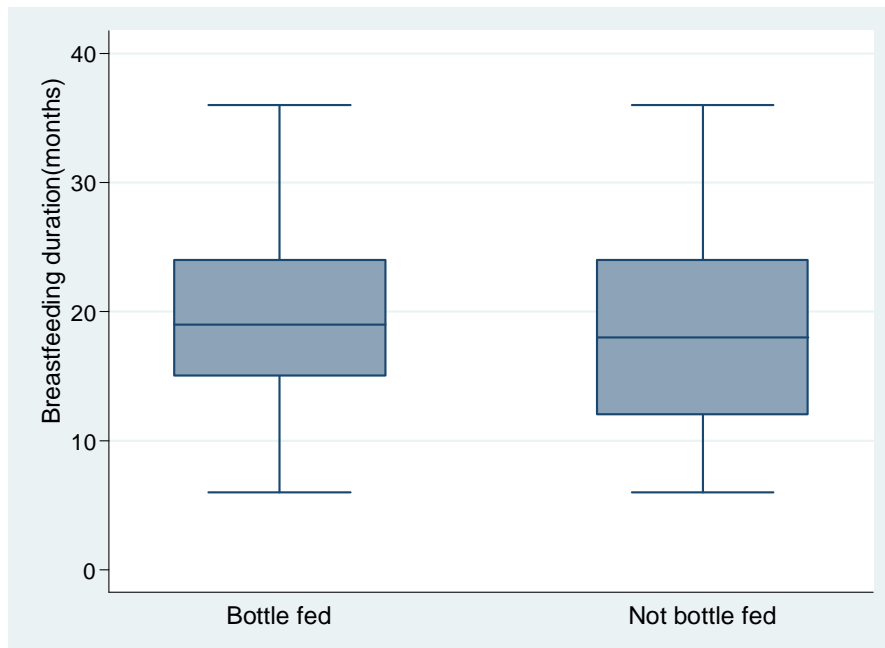


Figure 3: Breast feeding duration in bottle fed children and children who were not bottle fed

5.3.2 Other conditions considered risk factors

a. Upper Respiratory Tract infection

URTI symptoms were commonly reported among children with OME. Forty eight (84.2%) OME children reported having experienced any of the six symptoms of URTI presented in Table 3 during the three-month period prior to the infection. The median duration of URTI symptoms was 6 days (IQR 3-8). The most prevalent symptoms were rhinorrhea 41 (73.2%), nasal congestion 42 (73.7%) and cough 40 (70.2%), (table3).

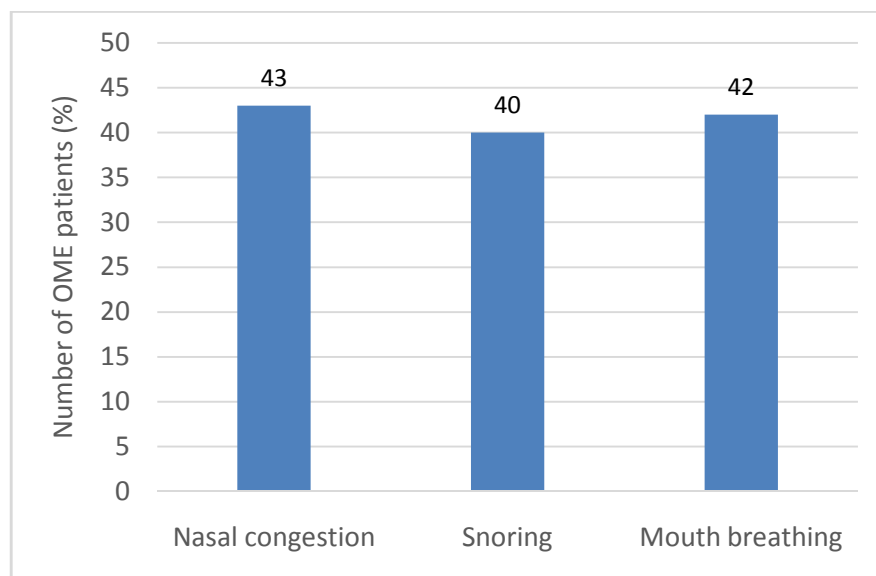
Table 3: Prevalence of URTI symptoms in children with OME

	URTI symptom	
	Present	Absent
Sore throat	22(38.6)	35(61.4)
Sneezing	27(47.4)	30(52.6)
Low grade fever	34(60.7)	22(39.3)
Cough	40(70.2)	17(29.8)
Nasal congestion	42(73.7)	15(26.3)
Rhinorrhea	41(73.2)	15(26.8)
Any symptom of URTI	48(84.2)	9(15.8)

b. Adenoid hypertrophy (AH)

The symptoms of AH were common in children with OME. Thirty-five (61.4%) children reported having had any of the three symptoms of AH investigated: nasal congestion, snoring or mouth breathing. These symptoms affected between 70.2 and 75.4% of children with OME

Figure 4: Prevalence of Adenoid hypertrophy symptoms in OME children



c. Allergic rhinitis (AR)

Forty nine (86%) patients with OME had at least one of the symptoms of AR presented in Table 4. The most prevalent AR symptoms were: rhinorrhea 48 (84.2%), nasal congestion 47 (82.5%), and sneezing 25 (43.9%).

Table 4: Allergic rhinitis symptoms in children with OME

	AR symptoms	
	Present	Absent
Atopy	6(10.5)	51(89.5)
Itching of nose or eyes	19(33.3)	38(66.7)
Sneezing	25(43.9)	32(56.1)
Nasal congestion	47(82.5)	10(17.5)
Rhinorrhea	48(84.2)	9(15.8)
Any symptom of allergic rhinitis	35(61.4)	22(38.6)

d. Acute otitis media (AOM) and Recurrent acute otitis media (rAOM)

The prevalence of symptoms of AOM was 75.4% and rAOM occurred in 25 (43.9%) patients. Fever and otalgia were the most common symptoms of otitis media affecting 40 (70.2%) and 43 (75.4%), respectively (table 5).

Table 5: Prevalence of AOM and rAOM in children with OME

	Otitis media with effusion	
	Present	Absent
Recurrent AOM (6 months)	25(43.9)	32(56.1)
AOM symptoms	43(75.4)	14(24.6)
Otalgia	43(75.4)	14(24.6)
Otorrhea	11(19.3)	46(80.7)
Fever	40(70.2)	17(29.8)

e. Cleft palate, Cerebral palsy, Down syndrome and HIV status

The patient's caretakers were asked to provide information on four additional risk factors of OME namely, HIV status, cleft palate, cerebral palsy and Down's syndrome.

Thirty five (61.4%) of caretaker's reported that the HIV status of the child was known and the remaining 22 (38.6%) were not aware of the child's HIV status. All the 35 caretakers who knew the patients' HIV status reported that the children were HIV negative. No testing for HIV status was conducted during the study.

One (1.8%) child had cerebral palsy and 1 (1.8%) child had Down syndrome. There was no child with cleft palate in this study. In this study, analysis of cleft palate, cerebral palsy and Down syndrome as probable risk factors was not done due to insufficiency of the numbers in the sample.

5.4 ENT clinical examination

Clinical examination was conducted on each patient followed by tympanometry. The findings of the otoscopic examination are presented in figure 5. The otoscopic findings commonly occurred on both ears (bilateral). The most common finding was a dull tympanic membrane with bilateral occurrence in 23 (40.4%) patients and unilateral right sided occurrence in 12 (21.1%) patients and left sided occurrence in 13 (22.8%) patients, Figure 5. Middle ear fluid occurred bilaterally in 7 (12.3%) cases and unilateral right sided and left sided occurrence in 1 (1.8%) and 6 (10.6%) patients, respectively. Hyperemic TM was not reported bilaterally and was equally likely to affect the right 5 (8.8%) or left ear 5 (8.8%).

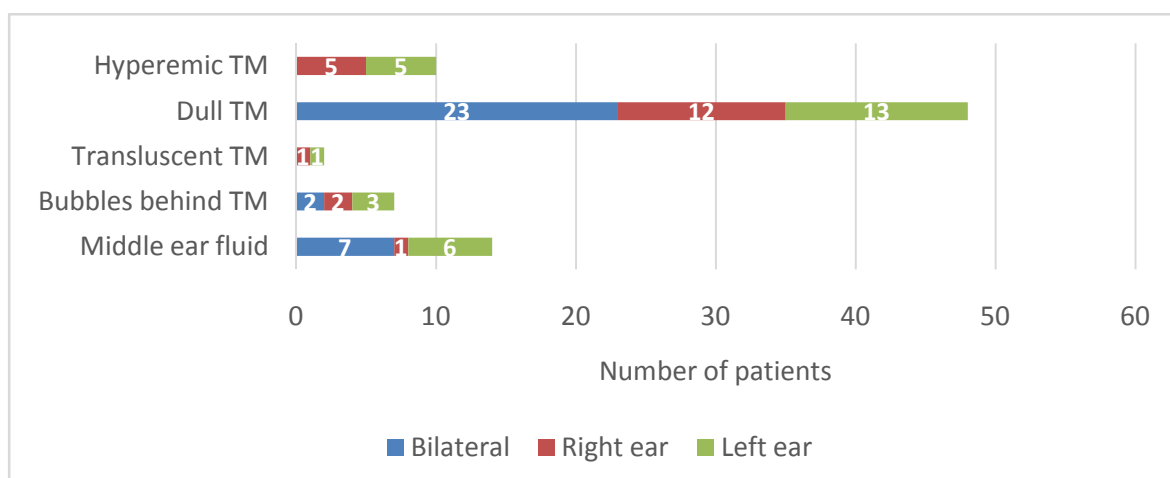


Figure 5. Otoscopic findings during clinical examination

5.5 Hearing loss

Hearing level testing was conducted in 8 (14%) patients with OME and evidence of hearing impairment. The findings of the hearing test are presented in Figure 1. All the 8 patients had varying level of conductive hearing loss with 3 (37.5%) patients presenting with bilateral hearing loss and 5 (62.5%) with unilateral hearing loss. The most common type of conductive hearing loss was mild loss occurring in 4 (50%) of patients with loss. Right-sided profound hearing loss occurred with left sided moderate hearing loss in one patient.

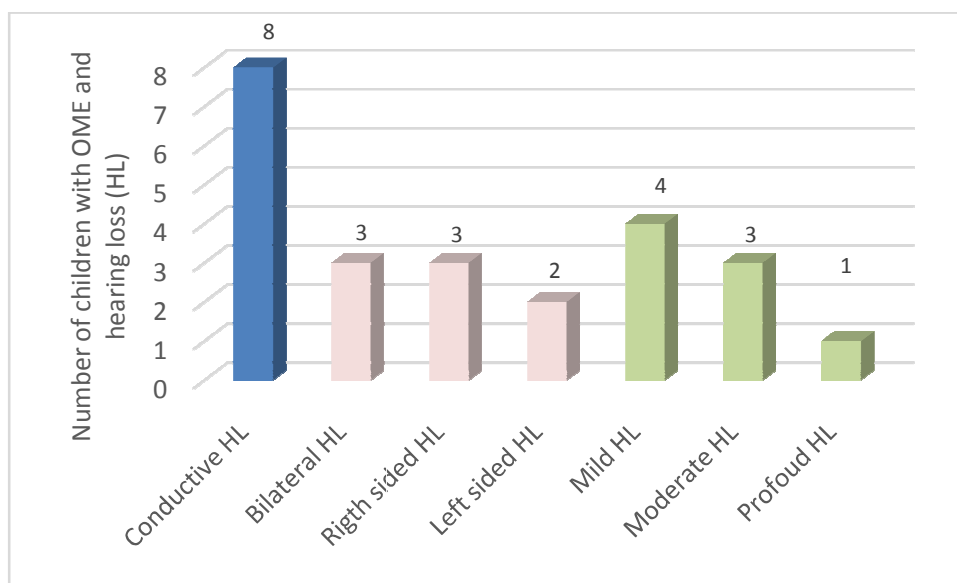


Figure 6. Distribution of hearing loss among children with OME

6.0 DISCUSSION

Otitis media with effusion is considered as a clinical entity which consists in the presence of middle ear fluid behind the tympanic membrane without an active infection. Multiple risk factors have been associated with the occurrence of otitis media with effusion (OME) and these were found to be different based to community's conditions.

A total number of 57 children aged 7 years and less were tested positive for OME and enrolled in the study. They were recruited from the outpatient ENT clinic at Kenyatta National Hospital. The sample comprised 38(66.7%) males and 19(33.3%) females. The mean age of the children presenting with OME was 54.6 months (SD 17.2). There was only one child (1.8%) who was less than one year and who presented to the outpatient clinic with OME. The frequency of children with OME was less of 10.5% and 12.3% respectively between age groups of 12-35 months and 36-47 months in this study. The peak age of presentation with OME was between 48 and 63 months with 27 (47.4%) patients being in the modal age group (Table 1). This could be explained by the occurrence of OME in the second prevalent peak which is described at the age of 5 years. However, the high number of males 38(66.7) than females 19(33.3) in our study could be considered a confounding factor due to the fact that several literatures considered gender as controversial risk factor. The ratio of male-to-female patients with OME reported was 2:1. Some authors advocated that males were more prone to OME than girls and others reported the converse. (Figure1)

The environmental risk factors analysis revealed a prevalence of two factors which were investigated in this study: 19.3% for attendance of day care centers and 16.1% for presence of a smoker within the patient's household.

Most children 42 (73.7%) with OME were at home during daytime and 11 (19.3%) attended day care centers (Table 2). The children attending day care (n = 11) had a median age of 60 months compared to median ages of 56 months and 53.5 months for children staying at home (n = 42) and attending school (n = 4), respectively.

Out of the 57 patients with OME, 9 (16.1%) lived in the same household with an adult who smokes tobacco (Table 2). Five (55.6%) of these adult smokers were reported to smoke within the residence shared with the child presenting with OME.

Other risk factors found to be significant in our study were bottle feeding. Figure 2 summarizes information on breastfeeding practices in children with OME enrolled in the

study. The practice of bottle feeding was prevalent in children with OME with 63.2% reporting ever being fed using a bottle. Out of the 57 patients, 54 (94.7%) had stopped breastfeeding and 3 (5.3%) were currently breastfeeding. Thirty six (63.2%) children had been fed using bottles and only 4 (7%) had been fed using cup and spoon.

Figure 3 is showing the duration of breastfeeding in children who were bottle fed and those who were not bottle fed. The median duration of breastfeeding was 19 months, with a range from 6 to 36 months and interquartile range (IQR) from 12 to 24 months (figure 2). It shows that there were no differences in the duration of breastfeeding in the group of children who were never fed with bottles (median duration [IQR] 18 months [12-24]) compared to children who were bottle fed (median duration [IQR] 19 months [15-24]).

Other conditions like Upper respiratory tract infection (URTI), Adenoid hypertrophy (AH) and Allergic rhinitis were assessed as risk factors.

URTI symptoms were commonly reported among children with OME. Forty eight (84.2%) OME children reported having experienced any of the six symptoms of URTI presented in Table 3 during the three-month period prior to the infection. The median duration of URTI symptoms was 6 days (IQR 3-8). The most prevalent symptoms were rhinorrhea 41 (73.2%), nasal congestion 42 (73.7%) and cough 40 (70.2%), (table3). This coincides also with Martines' study where from his multivariate analysis, reported positive history of URTI as significant risk factor at p value of 0.0001.

The symptoms of AH were common in children with OME. Thirty-five (61.4%) children reported having had any of the three symptoms of AH investigated: nasal congestion, snoring or mouth breathing. These symptoms affected between 70.2 and 75.4% of children with OME (Figure 4).

This study analyzed patients with allergic rhinitis who were diagnosed with OME and reported Forty nine (86%) patients with OME had at least one of the symptoms of AR presented in Table 4. The most prevalent AR symptoms were: rhinorrhea 48 (84.2%), nasal congestion 47 (82.5%), and sneezing 25 (43.9%).

In addition, variables like episode of acute otitis media in the last 3 months and recurrent acute otitis media (3 episodes in the last 6 months) were analyzed. Recurrent AOM and presence of AOM were assessed as risk factors. Table 5 shows the prevalence of symptoms of AOM which was 75.4% and rAOM occurred in 25 (43.9%) patients. Fever and otalgia

were the most common symptoms of otitis media affecting 40 (70.2%) and 43 (75.4%), respectively.

This could be explained by the non-recognition or lack of awareness of symptoms by the parents or the caregivers.

Tikaram et al. in his cross-sectional study done in Malaysia, confirmed the presence of acute otitis media to be highly significant, later on increasing the development of OME.²⁶

Overall, the most prevalent risk factors in this study were age (48-63 months), male gender, day care center, parental smoking, episode of acute otitis media in the last 3 months, a positive history of upper respiratory tract infection, presence of adenoid hypertrophy and allergic rhinitis.

The patient's caretakers were asked to provide information on four additional risk factors of OME namely; HIV status, cleft palate, cerebral palsy and Down's syndrome and these were less involved in this study. Thirty five (61.4%) of caretaker's reported that the HIV status of the child was known and the remaining 22 (38.6%) were not aware of the child's HIV status. All the 35 caretakers who knew the patients' HIV status reported that the children were HIV negative. No testing for HIV status was conducted during the study.

One (1.8%) child had cerebral palsy and 1 (1.8%) child had Down syndrome. There was no child with cleft palate in this study. Cleft palate, Cerebral palsy and Down syndrome were not considered for analysis in this study because of insufficient numbers in the study sample.

In this study, a clinical examination was conducted by using an otoscope on each patient and was followed by tympanometry. The findings of the otoscopic examination are presented in figure 5. The otoscopic findings commonly occurred on both ears (bilateral). The most common finding was a dull tympanic membrane with bilateral occurrence in 23 (40.4%) patients and unilateral right sided occurrence in 12 (21.1%) patients and left sided occurrence in 13 (22.8%) patients. Middle ear fluid occurred bilaterally in 7 (12.3%) cases and unilateral right sided and left sided occurrence in 1 (1.8%) and 6 (10.6%) patients, respectively. Hyperemic TM was not reported bilaterally and was equally likely to affect the right 5 (8.8%) or left ear 5 (8.8%).

On the other hand, hearing level testing was conducted in 8 (14%) patients with OME and evidence of hearing impairment (Figure 6). Although this was not the primary focus of the

study, it was important to highlight the specific type of hearing loss in order to allow further management of the patient .All the 8 patients had varying level of conductive hearing loss with 3 (37.5%) patients presenting with bilateral hearing loss and 5 (62.5%) with unilateral hearing loss. The most common type of conductive hearing loss was mild conductive hearing loss occurring in 4 (50%) of patients with loss. Right-sided profound hearing loss occurred with left sided moderate hearing loss in one patient.

7.0 CONCLUSION

Otitis media with effusion is a disease process associated with multiple risk factors different from each community.

This study has helped to bring out the risk factors associated with the occurrence of OME which were found significant and respectively were: age, male gender, day-care center, parental smoking, presence of positive history of upper respiratory tract infection, adenoid hypertrophy, allergic rhinitis and presence of acute otitis media in the last 3 months. These findings were noted potential to play an important role in the pathogenesis of the disease. Parents and caregivers must be informed about these modifiable risk factors. By this way, the development or delayed diagnosis of OME can be prevented.

8.0 RECOMMENDATIONS

1. There is need to do counsel parents and teachers to observe the children and to notice as soon as possible the symptoms related with OME to allow better management.
2. Parental counseling about harmful smoking closer to their children and to quit smoking completely.
3. A study with comparison children with OME and those without to analyze correlation between children with or without OME
4. Management of risk factors could avoid occurrence of OME if recognized and diagnosed early.

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APPENDICES

APPENDIX I

GENERAL PATIENT INFORMATION/CONSENT/EXPLANATION FORM

Title: Risk factors for Otitis media with effusion in children at Kenyatta National Hospital

Investigator: Dr MUGWANEZA Alice, Resident in ENT Head and Neck Surgery, University of Nairobi. Contact: 0720212260; email: alicemgw09@gmail.com ; P.O.Box:135-00202.

KNH/ UON-ERC: Prof. CHINDIA, Secretary, 2726300, Ext 44355.

Email: uonknh_erc@uonbi.ac.ke

Background

Otitis media with effusion refers to an accumulation of fluid in the middle ear cavity without any signs of infection. Various factors associated with the presence of Otitis media with effusion have been described in United States and European developed countries. Prevalence reported is varied according to socio-environmental factors found in different communities. There is an interest to know what is happening in our African continent, more precisely in our based Hospital Institution Kenyatta National Hospital. This thesis will help to understand the causation of Otitis media with effusion and multiple conditions which probably are avoidable. The researcher is carrying out a study on the “Risk factors for Otitis media with effusion in children at Kenyatta National Hospital. Your child has been diagnosed with Otitis media with effusion and will be enrolled in this study if you give consent. This form will provide you with information you require to make an informed consent.

Children with OME are initially seen at the ENT clinic and followed-up for adequate management. The study will determine the risk factors associated with the causation of OME. The information obtained will be used to improve the care.

General Patient Information:

I am a resident doctor in Ear Nose Throat, Head and Neck Surgical unit. I would like to seek your consent for your child to be enrolled in a study aimed at documenting the conditions and characteristics associated with the causation of Otitis media with effusion in children at Kenyatta National Hospital in ENT clinic.

How you will participate

1. I will ask you questions regarding your child's past medical history and the current complaint. I will need your accurate answer as possible.
2. I will carry out the Complete Ear Nose Throat examination on your child and will need to assess the middle ear by help of a machine, Tympanometry to be able to detect exactly if there is any abnormal findings like presence of fluid level, bubbles or TM retractions.
3. There will be no monetary benefits for participating in the study and it will be purely on a voluntary basis.
4. You will not incur any extra financial costs and the confidentiality will be maintained at all times
5. You will reserve the right to withdraw from the study at any time without any penalty.
6. You will be informed about investigations and the results.

How your participation affect your child

The study does not affect your child negatively in any way. This is to assure you that your child will get the right standard treatment and the procedure will not cause any adverse effects.

1. All the information you give will be confidential
2. The conclusions drawn from the study shall be used to improve the current management for Otitis Media with effusion.

Are there any hidden dangers in your participation or non-participation?

1. None whatsoever
2. Objecting to any part or whole of this study will not affect the quality of care you receive.

What will I do with the information I get

The information I get may not be of immediate benefit to you but it will help in the long run in management the condition better.

Like all scientific information will seek to share our findings with other people undertaking similar studies. Therefore we may publish our findings in scientific journals or present them in scientific meetings.

If you require discussing this matter with the family or friend you are free to do so and I will be ready to answer any questions. If you are satisfied with my explanation and willing to participate, then please sign the consent form below.

In any case a child is found with some other issues related to his/her health; this matter will be taken into consideration. A referral to the Doctor specialist will be given for appropriate management.

CONSENT FORM:

Patient number:.....

Consent by patient's parents/guardian:

I.....of.....hereby give consent
for

to be included in this study, on'' Risk factors for Otitis media with effusion in children
at Kenyatta National Hospital.''

The nature of the study has been explained to me by Dr.

Date..... Signed..... (parent/ guardian/other)

I Dr.....confirm that I have explained to the patient the nature of the study.

Date.....signed.....

APPENDIX II /KIAMBATISHO

KIAMBATISHO 1:

FOMU YA MAELEZO KUHUSU IDHINI YA MGONJWA

Maelezo kuu:

Mimi ni Daktari ninaye endelea na masomo ya juu kwa utengo wa ENT-HNS;yaani upasuaji wa kitengo cha masikio,mapua,koo,kichwa na shingo katika Chuo kikuu cha Nairobi.Ningependa Kuomba idhini yako ya kushiriki katika utafiti wenye lengo za sababu zinazopelekea ukosefu wa kusikia kwa watoto katika Hospitali Kuu ya Kenyatta.

Jinsi Ya Kushiriki

Nitauliza mzazi au mlezi wa mtoto maswali kuhusu historia ya hali yake ya afya na matibabu aliyopata mbeleni pamoja na malalamiko ya sasa. Ningekusihii unipe majibu ya sahihi iwezekanavyo.

1. Nitafanya uchunguzi wa kikamilifu wa masikio, pua na koo na nitatumia mashine kuchunguza uwezo na kiasi ambacho mtoto anaweza kusikia ikiwa anakasoro au ukosefu wa kusikia.
2. Utafiti huu utafanywa kwa hiari ya mgonjwa na hakutakuwepo na faida ya fedha au fidia kwa kushiriki.
3. Hakutakuwa na malipo yoyote ya ziada au gharama utakayohitajiwa kulipa na usiri wa mgonjwa utaendelezwa wakati wote.
4. Una haki ya kujiondoa kutoka utafiti huu wakati wowote bila adhabu yoyote.
5. Utapewa taarifa au habari kuhusu uchunguzi utakawofanywa na umuhimu wa matokeo

Jinsi gani Ushiriki wako unaweza kudhuru mtoto wako

Utafiti hautadhuru mtoto kwa njia yoyote kwa vile:

1. Taarifa yote kuhusu mgonjwa yatakuwa ni yasiri
2. Utambulisho wa mtoto au mzazi binafsi hautatanganzwa
3. Baada ya kuhitimisha utafiti huu maarifa itakayo patikana itakuwa na manufaa na inaweza kusaidia kuboresha matibabu ya watoto wenye wanayo shida.

Je kuna hatari ya kushiriki au kutoshiriki ?

1. Hakuna hatari yoyote itakayo jiri kwa kushiriki au kutoshiriki na
2. Kujiondoa wakati wowote au kupinga sehemu ya utafiti hautaathiri matibabu au ubora wa huduma ya afya mtoto atakayopokea.
3. Habari itakayotokea na utafiti huu pengine haitakufaidi binafsi lakini itatupa maarifa ambayo itaboresha utibabu wa ugonjwa huu siku zijazo.
4. Kuna uwezekano wa kuchapishwa kwa matokeo ya utafiti huu katika majarida ya kisayansi au kuwekwa katika mikutano ya kisayansi.
5. Ukihitaji kujadiliana na jamaa na familia au rafiki una uhuru wa kufanya hivyo na niko tayari kujibu maswali yoyote. Ukiridhika na maelezo yangu na uko tayari kushiriki, tafadhali weka sahihi yako kwenye fomu ya idhini.
6. Mtoto akipatikana shida nyingine ya afya, jambo hili litazingatiwa na utapewa mapendekezo kwa Daktari aliye mtaalamu wa shida ya aina hiyo ili afuatiliwe. Ikiwa mtoto atahitaji upasuaji wowote mzazi au mlezi ataelezewa.

Kukubali Kwa mgonjwa:

Mimi.....kutoka.....ninakubali.....

Kushirikisha katika utafiti hu.

Nimeelezwa na daktari.....

Tarehe:.....sahihi.....

Mimi daktari..... nahakikisha ya kwamba nimelezea mgonjwa juu ya utafiti huu. Tarehe..... Sahihi.....

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APPENDIX III: QUESTIONNAIRE

TITLE: RISK FACTORS FOR OTITIS MEDIA WITH EFFUSION IN CHILDREN AT KENYATTA NATIONAL HOSPITAL

Date:

Study ID.No.:

Residence:.....

Age: Years/.....Months

Sex: M/F

1. Is the child breastfeeding? Y / N
2. What was the duration of breastfeeding?
3. At what age did the child stop breastfeeding?
4. Has your child been fed by a bottle? Y / N
5. Has your child been fed by a cup with spoon? Y/ N
6. Does the child have the following symptoms of allergic rhinitis (AR)

Allergic Rhinitis Symptoms	Yes	No
Rhinorrhea		
Nasal congestion		
Sneezing		
Itching of the nose or eyes		
Atopy		

AR : Yes No

7. Has the child recently: in the last 3 months had following symptoms of upper respiratory tract infection (URTI)?

URTI Symptoms	Yes	No
Cough		
Nasal congestion		
Sneezing		
Sore throat		
Low grade fever		
Rhinorrhea		
Duration of symptoms		

URTI: Yes No

8. Has your child had following symptoms of adenoid infection (AH)?

AH Symptoms	Yes	No
Nasal congestion		
Snoring		
Mouth breathing		

AH : Yes No

9. Has your child been done a Post-nasal space X-Ray (lateral view)? Y/ N

If yes, do you have it with you? Grading of AH.

10. Has your child had episodes of recurrent acute otitis media infection (defined as otalgia, fever, bulging or hyperemic TM and +/- otorrhea) or 3 episodes within six months?

Recurrent AOM	Yes	No
3 episodes of AOM in 6 months		

RAOM : Yes No

11. Has your child had an (AOM) ear infection (pain, discharge) in the past 3 months?

Symptoms of AOM	Yes	No
Otalgia		
Otorrhea		
Fever		

Presence of Symptoms Yes No

12. Has your child had throat infection? Y / N If yes, when?

13. Was your child born with cleft palate? Y/ N

14. Was your child born with Cerebral palsy? Y / N

15. Do you know on your child's HIV status? Yes / No; If yes what is it?

16. Where does the child normally remain during the day?

Home

School

Day-care center

17. What is the duration does the child has been going on there?...

18. Does anyone in the household smoke tobacco? Y / N

19. If yes, who? The mother? Y/ N or The father? Y / N Other: Household?

20. Where do they smoke from?

What is the duration of exposure?

Complete ENT Clinical examination: (ear exam followed by Tympanometry)

EAR Exam: Right Ear Left ear

Otoscopic findings

(Screening characteristics)

Middle ear fluid

Bubbles behind TM

Translucent TM

Dull TM

Hyperemic TM

Tympanometric findings:

Type B

➤ **Nasal Examination:** If presence of enlarged Inferior Turbinates? Y/ N

➤ **Oropharyngeal Examination:** grade of tonsils : I, II, III and IV

- **Grade I:** tonsils < 25% of space between pillars
- **Grade II:** tonsils < 50% of space between pillars
- **Grade III:** tonsils < 75% of space between pillars
- **Grade IV:** tonsils > 75% of space between pillars

➤ **Summary of Risk factors for OME**

- Environmental:
 - Day-care centers
 - Parental smoking
- Mode of feeding :
 - breastfeeding
 - bottle
 - both

- Infections :
 - o URTI
 - o AH
 - o AR
- Other conditions:
 - o Acute otitis media(AOM)
 - o Recurrent Acute otitis media (rAOM)
- Other Risk factors:
 - Cleft Palate
 - Cerebral Palsy
 - Down Syndrome