DISSERTATION

TITLE OF STUDY

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

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A dissertation submitted in part fulfillment of the requirement of the University of the Nairobi, for the Award of the Degree of Masters of Medicine in ENT, Head and Neck Surgery.

2013

DECLARATION

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

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Definitions of terms

1. **Otitis media with effusion** (OME) is a condition where 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.
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.

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**1. ABSTRACT**

**Introduction**

Otitis media with effusion is a multifactorial disease process involving immunological, infectious, anatomic, socioeconomic and genetic causes among other factors. Otitis media with effusion is a clinical entity defined as the presence of fluid in the middle ear behind an intact tympanic membrane without active inflammation. Its peak prevalence varies between 1.3% -31.3% according to different countries and this has been reported to be strongly associated with the presence of risk factors. 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 subjects were diagnosed by the principal researcher by using otoscopic examination as per OME study definition. 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. Man-Whitney distribution test was used to calculate p-values and Spearman Chi-square test was used to calculate the Odd ratio.

**Results:** This study has helped to determine the risk factors associated with the occurrence of OME in 57 children aged of 7 years and less. The risk factors found significant were respectively age, gender, day-care center, parental smoking, presence of positive history of upper respiratory tract infection, adenoid hypertrophy and presence of acute otitis media in the last 3 months.

**Conclusion:** The above results have contributed to the occurrence of OME in children who were tested positive. These findings were noted potential to play an important role in the pathogenesis of the disease. Parents and caregivers must be informed about these highly
modifiable risk factors. By this way, the development or delayed diagnosis of OME can be prevented.

2. 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.

### 2.1 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 Children

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. 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. 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. 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.

2.2 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.
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. 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.

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. 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. The mTVP has its insertion in the lateral portion of the ET and a suitable contraction is needed to effectively expand the tube lumen. 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. 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.

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. There is, therefore, a significant risk of transmission in this group. Allergic rhinitis (AR) is one of the conditions which predisposes children to OME. This represents an inflammatory condition of the nasal mucosa as a result of an exaggerated immunoglobulin E (IgE)-mediated immune response to inhalant allergens. 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. 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 hypersecretion by seromucous glands.

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. 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. A possible explanation for the relation between ETS exposure and OME is a direct effect of cigarette smoke on host defenses. 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. 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. 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.
3. 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.\textsuperscript{18}

In the United States, approximately 2.2 million episodes of OME are diagnosed annually.\textsuperscript{17} OME is extremely common, affecting approximately 90% of the population at least once before they reach their third birthday.\textsuperscript{18} Two peaks are seen in the distribution, the first at around 2 years and the second at 5 years.\textsuperscript{19} A decrease in frequency is observed at around 7yrs when the ET matures.\textsuperscript{19} However, about 30% to 40% of subpopulation continues to suffer from OME after the age of 5 and/or suffer from recurrent episodes.\textsuperscript{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.\textsuperscript{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.\textsuperscript{1}

The frequency of allergic disease in pediatric OME patients was first reported to be high in 1983.\textsuperscript{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%.\textsuperscript{21} In fact, a predominance of bilateral OME with higher hearing impairment was found in atopic children.\textsuperscript{21}
Wilhelm Meyer, Danish Otolaryngologist published his work in the 18th century, about the association between hypertrophic adenoids and OME. 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. 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.

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. 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.

There is also an increased prevalence of OME associated to the human immunodeficiency virus (HIV) infection. 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. The other risk such as exposure to smoking, day care center attendance, breastfeeding, allergy, gender, race and sex were not statistically significant.

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. 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.

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.
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 Odd 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.²⁹

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

RESEARCH QUESTION

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

HYPOTHESES

Null Hypothesis

The risk factors for Otitis media with effusion in children at Kenyatta National Hospital are not different from those found elsewhere.

The null hypothesis is $H_0: p_0 = p_1$
Alternative Hypothesis

The alternative hypothesis $H_1: \ p_0 \neq p_1$

The risk factors for Otitis media with effusion in children at Kenyatta National Hospital are different from those found elsewhere.

OBJECTIVES

Broad Objective

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

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

METHODS AND MATERIAL

8.1. Study design

A cross-sectional descriptive study

8.2. Study location

Ear Nose and Throat Outpatient clinic at Kenyatta National Hospital

8.3. Study period

May- September 2014
8.4. 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.

8.5. Inclusion and Exclusion criteria:

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

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)

8.6 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) \(^{30}\)

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

\[ N = 1.96^2 \times 0.183 \times 0.817 \div (0.1)^2 \]

N = 57 patients,

The estimated sample size of 57

9. 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. Otoscopic 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.

10. Data analysis

Data recorded in the preformatted data sheets was analyzed using the statistical package for social sciences (SPSS) 21.0. Means and Percentages were calculated. Student’s t-test was used to calculate the statistical significance. Data presentation done in form of tables and bar graphs. Measure of association: odds ratio, with 95% CI.

11. 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.

Results

Risk Factors

a. Socio-Demographic Characteristics
In this study to determine the risk factors associated with the occurrence of otitis media with effusion (OME) in children at Kenyatta National Hospital, a sample of 57 children who tested positive for was used. The sample comprised of 38(66.7%) males and 19(33.3%) females sampled purposively implying that males were 67% prone to develop OME as compared to females.

<table>
<thead>
<tr>
<th>Variable, N=57</th>
<th>Categories</th>
<th>n</th>
<th>%</th>
<th>Distribution of occurrence</th>
<th>T-test</th>
<th>OR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (months)</td>
<td>&lt;12 months</td>
<td>1</td>
<td>1.75</td>
<td>Chi-square Test p-value=0.002</td>
<td>0.000</td>
<td>0.4</td>
</tr>
<tr>
<td></td>
<td>12-35 months</td>
<td>6</td>
<td>10.53</td>
<td></td>
<td>0.000</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>36-47 months</td>
<td>7</td>
<td>12.28</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>48-63 months</td>
<td>27</td>
<td>47.37</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>64 months and above</td>
<td>16</td>
<td>28.07</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td>Male</td>
<td>38</td>
<td>66.67</td>
<td>Binomial Test p-value=0.017</td>
<td>0.000</td>
<td>0.6</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>19</td>
<td>33.33</td>
<td></td>
<td></td>
<td>7</td>
</tr>
</tbody>
</table>

Table 1

![Demographic characteristics](image)

Figure 1

b. Environmental risk factors

Day-care centers (p=0.000 and parental smoking (p= 0.002) were assessed as risk factors and found to be significant. Presence and absence of smoking house hold members and location during the day either home, school or day care center did not occur with equal probabilities.
### Table 2

<table>
<thead>
<tr>
<th>Risk</th>
<th>Category</th>
<th>n</th>
<th>%</th>
<th>Distribution of occurrence</th>
<th>T-test</th>
<th>OR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smoking of tobacco by household member</td>
<td>Absent</td>
<td>47</td>
<td>82.5</td>
<td>Binomial Test p-value=0.000</td>
<td>0.002</td>
<td>0.161</td>
</tr>
<tr>
<td></td>
<td>Present</td>
<td>10</td>
<td>17.5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Location during the day</td>
<td>Home</td>
<td>42</td>
<td>73.7</td>
<td>Chi-square Test p-value=0.000</td>
<td>0.000</td>
<td>0.737</td>
</tr>
<tr>
<td></td>
<td>School</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Day care center</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Figure 2

![Bar chart showing distribution of smoking and location during the day](chart.png)

### c. Others Risk factors

1. **Mode of feeding**

Breastfeeding, age child stopped breastfeeding and child being via bottle, cup and spoon were assessed as variables for risk factors and found to be significant (p-values=0.000) each.
### Table 3

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th>Distribution of occurrence</th>
<th>T-test</th>
<th>OR</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Infections</strong></td>
<td>Category</td>
<td>n</td>
<td>%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Allergic Rhinitis (AR)</td>
<td>Yes</td>
<td>54</td>
<td>94.74</td>
<td>Binomial Test p-value=0.000</td>
<td></td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>54</td>
<td>94.74</td>
<td>Chi-square Test p-value=0.000</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0-6 months</td>
<td>2</td>
<td>3.51</td>
<td>0.000</td>
<td>0.544</td>
</tr>
<tr>
<td>Age child stopped breastfeeding</td>
<td>7-12 months</td>
<td>13</td>
<td>22.81</td>
<td>0.000</td>
<td>0.544</td>
</tr>
<tr>
<td></td>
<td>13-24 months</td>
<td>31</td>
<td>54.39</td>
<td>0.000</td>
<td>0.544</td>
</tr>
<tr>
<td></td>
<td>&gt;24 months</td>
<td>11</td>
<td>19.3</td>
<td>0.000</td>
<td>0.544</td>
</tr>
<tr>
<td>Child being fed by bottle</td>
<td>Yes</td>
<td>21</td>
<td>36.84</td>
<td>Binomial Test p-value=0.064</td>
<td></td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>36</td>
<td>63.16</td>
<td>0.000</td>
<td>0.368</td>
</tr>
<tr>
<td>Child being fed by a cup with spoon</td>
<td>Yes</td>
<td>53</td>
<td>92.98</td>
<td>Binomial Test p-value=0.000</td>
<td></td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>4</td>
<td>7.02</td>
<td>0.000</td>
<td>0.930</td>
</tr>
</tbody>
</table>

### Figure 3

2. Other conditions considered risk factors

2.1 Allergic rhinitis (AR), Upper respiratory tract infection (URTI) and Adenoid hypertrophy (AH)

Allergic Rhinitis, URTI and Adenoid Infection (AH) were assessed as probable risk factors for OME. Allergic Rhinitis (p-value=1.000) was not considered significant as compared to URTI (0.017) and Adenoid (p-value=0.003). Exposure to URTI and Adenoid Infection increased the probability of contracting OME by 66.7%.
2.2. Acute Otitis media (AOM) and Recurrent Acute Otitis Media (RAOM)

Recurrent AOM and presence of AOM were assessed as risk factors. The distribution of recurrent AOM was not significant (0.427) whereas distribution of AOM symptoms was significant (p: 0.001) which implied that AOM was a risk factor that increased the probability of contracting OME by 73.7%.
2.3. Cleft palate, Cerebral Palsy and Down Syndrome

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.
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. The sample comprised 38(66.7%) males and 19(33.3%) females (in Table1).The mean age of children was 54.6 (±17.2) months within the range of 6 to 84 months. Majority 27(47.4%) were aged 48-63 months and 16(28.1%) were aged 64 months and above which implied that those aged 48-63 months were 47% more prone to OME and 67% prone to develop OME (Figure 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 than females in our study could be considered a confounding factor due to the fact that several literatures considered gender as controversial risk factor. Some authors advocated that males were more prone to OME than girls and others reported the converse.
Among the environmental risk factors (table 2), day-care center and parental smoking were assessed as risk factors and were found to be significant with respective (p= 0.000) and (p=0.002). Presence and absence of smoking household members and location during the day either home, school or day care center did not occur with equal probabilities (p=0.000). Absence of smoking member in households reduced the occurrence of OME 16.1% (figure2). Being at home during the day was considered to reduce odds of contracting OME by 0.737. Martines et al. in their case-control study reported similar findings where smoking exposure was significant at (p< 0.0001).

Other risk factors found to be significant in our study were bottle feeding. Moderate proportions of children were fed by bottle. However, majority of children were fed by use of cup and spoon, this reduced the probability of contracting OME by 93% (Table 3). Only 3(5.3%) children were found to be breastfeeding as at time of study. Current status of breastfeeding had minimal effect to the status of OME considering odds ratio of 0.053.

Age child stopped breastfeeding had significant (p=0.000) effect on the prevalence of OME whereby breastfeeding for periods above 13 months reduced the probability of occurrence of OME by 54.4%. Moderate proportion of children was fed by bottle which had no effect on OME. However use of cup and spoon reduced probability of contracting OME by 93.0% (Figure 3).

Other conditions like Allergic rhinitis, Upper respiratory tract infection (URTI) and Adenoid hypertrophy (AH) were assessed as risk factors. Only URTI and AH considered significant as compared to Allergic rhinitis. Exposure to URTI and AH increased the probability of contracting OME by 66.7% (Table 4). This coincides also with Martines's study where from his multivariate analysis, reported positive history of URTI as significant risk factor at p value of 0.0001. Allergic Rhinitis (p-value=1.000) was not considered significant as compared to URTI (0.017) and Adenoid hypertrophy (p-value=0.003). Exposure to URTI and Adenoid Infection increased the probability of contracting OME by 66.7% (Figure 4).

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 distribution of recurrent AOM was not significant (0.427) whereas distribution of AOM symptoms was significant (p:
which implied that AOM was a risk factor that increased the probability of contracting OME by 73.7%. Only the presence of an episode of acute otitis media (AOM) was significant as compared to the presence of recurrences of AOM for the last 6 months from the time of diagnosis (figure 5). 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.30

Overall risk factors found significant in this study were age, gender, day care center, parental smoking, episode of acute otitis media in the last 3 months, a positive history of upper respiratory tract infection and presence of adenoid hypertrophy.

Cleft palate, Cerebral palsy and Down syndrome were not considered for analysis in this study because of insufficient numbers in the study sample.

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, gender, day-care center, parental smoking, presence of positive history of upper respiratory tract infection, adenoid hypertrophy 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.
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.
APPENDICES

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

APPENDIX/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. Ningekusihi 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 itakayopo kukuwa na manufaa na inaweza kusaidia kuboresha matibabu ya watoto wenye wanayo shida.

Je kuna hatari ya kushiriki au kutoshiriki?
1. Hakuna hatari yoyote itakayopo kukuwa kushiriki au kutoshiriki na
2. Kujiondoa wakati wowote au kupinga sehemu ya utafiti hutaathiri matibabu au ubora wa huduma ya afya mtoto atakayopo kukuwa.
3. Habari itakayotokea na utafiti huu pengine haitakufaidi binafsi lakini itatupa maarifa ambayo itaboresha utibabu wa ugonjwa huu siku zijazo.
4. Kuna uwezakano wa kuchapishwa kwa matokeo ya utafiti huu katika majorida 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. Ukihitaji kujadiliana na familia au rafiki una uhuru wa kufanya hivyo na niko tayari kujibu maswali yoyote. Ukihitaji kujadiliana na familia au rafiki una uhuru wa kufanya hivyo na niko tayari kujibu maswali yoyote. Ukihitaji kujadiliana na familia au rafiki una uhuru wa kufanya hivyo na niko tayari kujibu maswali yoyote.
**Kukubali Kwa mgonjwa:**

Mimi……………………kutoka……………………ninakubali……………………………………

Kushirikisha katika utafiti hu.

Nimeelezewa na daktari………………

Tarehe:……………………sahihi………………

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

Researcher: Dr MUGWANEZA ALICE, Resident in ENT Head & Neck-Surgery,

Cell phone: 0720212260. P.O. Box: 135-00202; E-mail: alicemgw09@gmail.com

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

Email: uonknh_erc@uonbi.ac.ke

**APPENDIX II: QUESTIONNAIRE**
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)

<table>
<thead>
<tr>
<th>Allergic Rhinitis Symptoms</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rhinorrhea</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nasal congestion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sneezing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Itching of the nose or eyes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Atopy</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

AR : Yes    No

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

<table>
<thead>
<tr>
<th>URTI Symptoms</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cough</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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)?

<table>
<thead>
<tr>
<th>AH Symptoms</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nasal congestion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Snoring</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mouth breathing</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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?

<table>
<thead>
<tr>
<th>Recurrent AOM</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 episodes of AOM in 6 months</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

RAOM: Yes  No

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

<table>
<thead>
<tr>
<th>Symptoms of AOM</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Otalgia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Otorrhea</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fever</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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?
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:
  o Day-care centers
  o Parental smoking

- Mode of feeding:
  o breastfeeding
  o bottle
  o both

- Infections:
  o URTI

- Other Risk factors:
  - Cleft Palate
  - Cerebral Palsy
  - Down Syndrome

- Other conditions:
  o Acute otitis media (AOM)
  o Recurrent Acute otitis media (rAOM)

REFERENCES


19. Williamson IG, Dunleavey J, Bain J. The natural history of otitis media with effusion—a three-year study of the incidence and prevalence of abnormal tympanograms in four


