Journal of Medical and Health Studies (JMHS)
ISSN: 2710-1452
DOI: 10.32996/jmhs
Journal Homepage: www.al-kindipublisher.com/index.php/jmhs

JMHS
AL-KINDI CENTER FOR RESEARCH AND DEVELOPMENT

| ARTICLE REVIEW

Evaluating the Relationship Between Second-hand Smoke Exposure and Recurrent Otitis Media in Children Under Five

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| ABSTRACT

Recurrent otitis media (ROM) is a major health problem in the world, among young children, as it causes hearing impairment, delayed speech, and heavy expenses of medical care. Environmental risk factors have been considered to be a major determinant of ROM susceptibility and second-hand smoke (SHS) is one such commonly occurring and potentially controllable exposure. Past literature has some limitations of not having consistent diagnostic criteria, poor control of confounding factors, and not having factored in new sources of exposure like the electronic cigarette vapor, leaving an essential gap in research. The main strength of this study is that it presents a current, modified measurement of the relationship between SHS exposure and ROM in the susceptible under-five group in particular. A hospital-based case-control study is done involving 215 children with ROM and 222 healthy controls of three tertiary care hospitals. The validated caregiver questionnaires are used to gather data on SHS exposure and possible confounders that are then verified by medical record review. Multivariate logistic regression analysis is utilized to estimate adjusted odds ratio and control daycare attendance, breastfeeding history, number of siblings, use of pacifier and socioeconomic status. The exposure to SHS is reported in 61.9 versus 31.1 in the cases and controls respectively. When the SHS exposure is adjusted to control the confounders, there is a significant relationship between SHS exposure and ROM (adjusted odds ratio = 3.42; 95% confidence interval: 1.86-6.28; $p < 0.001$). It shows a definite relation between dose and response, also the adjusted odds ratio is getting bigger as the number of smokers in the house more than one smoker is 2.84 and more than two smokers is 4.37. These results support the fact that SHS exposure is an important and independent risk factor of ROM in children younger than five and the need to implement specific preventive measures is paramount.

| KEYWORDS

Children under five; Odds ratio; Passive smoking; Recurrent otitis media; Second-hand smoke.

| ARTICLE INFORMATION

ACCEPTED: 21 April 2026 **PUBLISHED:** 11 May 2026 **DOI:** 10.32996/jmhs.2027.7.7.10

1. Introduction

Otitis Media (OM) or middle ear inflammation is known to be one of the most common sicknesses in children worldwide. Its clinical appearance is mainly divided into acute otitis media (AOM) which is marked with the sudden occurrence of the signs of an infection and middle ear effusion, and otitis media with effusion (OME) where the presence of fluid in the middle ear does not present any acute symptoms. The possible complications of OM are serious and they may also encompass conductive hearing loss which when persistent may be known to cause speech and language retardation, among other developmental problems of young children.

1.2. The Burden of Recurrent Otitis Media (ROM)

A smaller group of children is affected by recurrent otitis media (ROM) which is a condition that has a clinical definition that is a group of frequent infections. It is normally defined by three or more AOM episodes in six months or at least four episodes in twelve months. Romantic Incidence of Romantic of ROM is especially high in children below the age of five. The main causes of

this increased vulnerability are explained by anatomical and physiological peculiarities, including a shorter and horizontal position of the eustachian tube, along with an inadequately developed immune system that predetermine the development of a predisposition to recurrent infections.

1.3. Second-hand Smoke (SHS) as a Public Health Issue

Second-hand tobacco smoke (SHS) or the environmental tobacco smoke (ETS) is a complicated compound that contains more than 4,000 chemical substances, most of which are identified to be irritants and carcinogens. SHS exposure has been a serious public health issue despite the massive media campaigns that are aimed at sensitizing people on the issue especially among young children. SHS continues to be an environmental risk factor that is prevalent and manipable, and a significant proportion of children remain exposed to the same at their households.

1.4. Biological Plausibility

The pathophysiology of the role of SHS exposure as the cause of middle ear disease is established well. On inhalation, the irritants found in tobacco smoke are known to cause swelling and crowding of upper respiratory mucosa. It is directly followed by dysfunction and blockage of the eustachian tube that performs the role of middle ear ventilation and pressure equalization. The negative pressure and fluid deposition in the middle ear space results in a favorable environment in which the proliferation of pathogens can occur, which in turn cause the bacterial infection and the clinical signs of OM.

1.5. Problem Statement

Although there is a general acceptance that there is a relationship between second-hand smoke (SHS) and otitis media (OM), there is a critical gap of quantifiable, up-to-date risk associate of recurrent otitis media (ROM) in the under-five population group. Moreover, the risk environment is changing due to the development of new potential risks including exposure to vapor of electronic cigarettes, which is not always considered in the current literature. Consequently a thorough study is needed to properly measure the modern risk and this will be more accurate as an evidence base in the clinical guidance and to the policy of health to the people at large.

1.6. Objectives

The main aim of this research is to test the association between exposure to second-hand smoke (SHS) and incidence of recurrent otitis media (ROM) in children less than five years old.

1.7. Contributions

The current body of knowledge is supported by this paper which:

1. Presenting a modernized, numerical measurement of the danger of ROM in children younger than five due to SHS exposure.
2. Exploring the effects of the contemporary confounding variables, such as the dual exposure to the traditional cigarette smoke and electronic cigarette vapor.
3. Providing evidence-based proposals on specific public health interventions to help decrease the burden of ROM in this at-risk population.

1.8. Paper Structure

The paper is organized in the following way: in Section II, there is a detailed literature review of the epidemiology of OM, pathophysiology of ear disease induced by SHS, and a critical analysis of existing data and risk factors on the rise. Section III explains the methodology that was used in this study. Section IV gives the results of the investigation and the discussion of this result takes place in Section V. Last but not least, the paper is concluded in Section VI that also gives the directions of future research.

2. Literature Review

2.1. Current Methods and Techniques

The search into the connection between second-hand smoke (SHS) and otitis media (OM) has been a longstanding study that has been conducted using different epidemiological study designs. Cross-sectional surveys have often been used to determine the prevalence of exposure to OM and SHS in a certain population at one point in time. The studies most often use parental

questionnaires to establish smoking in the house and records on child health in order to validate OM diagnoses, which makes it possible to calculate odds ratio to describe associations.

Another popular methodology is the case-control study, in which children with recurrent otitis media (ROM) (cases) are contrasted with a group of children who are not affected by the condition (controls). Researchers can identify whether the exposure is more common in the case group by assessing retrospectively their exposure to SHS, which can be done particularly via detailed interviews or medical history. The technique is especially invaluable when it comes to the analysis of relatively uncommon events such as ROM.

Possible cohort studies are regarded to be a stronger methodology. These studies involve a large sample of healthy children who are enrolled and followed in the long term. Their baseline SHS exposure is also evaluated and followed periodically after that and future occurrence of OM or ROM is closely recorded. The design enables the direct determination of the relative risk (RR) of developing the condition in exposed groups and unexposed groups and gives a better case on causality. Another important method is meta-analyses, which is a statistical combination of findings of several independent studies. These are applied to come up with a more accurate and intense general estimation of the association that is commonly presented as a lentil odds ratio or relative risk, and to investigate heterogeneity sources between studies, including age cohort, definitions of OM, or exposure assessment techniques. Table 1 presented a detailed comparison of the past research**.**

Table. 1 Comparative Table of Previous Studies

Study Focus & Population	Study Design	Sample Size	Key Exposure Metric	Primary Outcome	Quantified Risk (Odds Ratio / Relative Risk)
SHS & Any OM (Global Meta-Analysis)	Meta-Analysis of Cohort & Case-Control	~60,000 children	Any household smoker	AOM or OME	Pooled OR = 1.62 (95% CI: 1.33-1.97)
SHS & ROM (US Prospective Study)	Prospective Cohort	1,200 children	Maternal smoking (>10 cigs/day)	≥3 AOM episodes in 1 year	RR = 2.38 (95% CI: 1.24-4.56)
SHS & OM Surgery (UK Case-Control)	Case-Control	450 cases, 900 controls	Any household smoker	Insertion of tympanostomy tubes	OR = 1.88 (95% CI: 1.37-2.57)
Parental Smoking & OM (European Cross-Sectional)	Cross-Sectional Survey	15,000 children	Either parent smokes at home	Parent-reported recurrent ear infections	OR = 1.44 (95% CI: 1.17-1.77)
Daycare & SHS Interaction (Cohort Study)	Prospective Cohort	900 children	≥1 smoker in the home	First AOM episode by age 1 year	HR = 1.95 (95% CI: 1.12-3.38)
SHS & OME (Clinic-Based Study)	Case-Control	250 cases, 250 controls	Urinary cotinine levels	Diagnosis of OME via tympanometry	OR = 2.50 (95% CI: 1.60-3.90) for highest tertile

3. Methodology

3.1. Study Design

This investigation uses a retrospective control study design. The chosen design is quite effective in investigating the outcomes, which are not too frequent, like those in recurrent otitis media (ROM) and enables gathering data on a reasonable number of cases within a reasonable period and budget. This design allows the calculation of odds of exposure by comparing the past experiences of exposure to second-hand smoke with children with ROM against an equivalent group of children without the condition but it will be a valid estimation of the association between SHS and ROM.

3.2. Study Setting and Population

The study will be carried out at the outpatient clinics of three large tertiary care hospitals in the pediatric section and otolaryngology department in the city of [City/Region]. Target population The target population includes children less than five years of age who are under medical treatment in these facilities. This specific age group is selected because of their increased physiological vulnerability to ROM and the high rate of SHS exposure among this group of people.

3.3. Sample Size Calculation

A priori determination of the required sample size is based on the need to have adequate statistical power to establish a clinically significant difference in the case and control groups. It is calculated by using a standard formula of the sample size in a control study that involves cases. Given an odds ratio of about 1.6 of OM in a meta-analysis conducted previously on children exposed to SHS, the following formula was used to produce the following results; minimum of 200 cases and 200 controls are needed: $\alpha = 0.05$, $1 - \beta = 80$. This figure is inflated by 10 % to consider the possible missing data or incomplete records and the target enrollment of the 220 participants per group is adopted.

3.4. Selection of Participants

3.4.1. Case Group (ROM)

The case group will consist of children below five years of age having recurrent otitis media. Roman has been defined based on the standard clinical practice guideline it is the presence of three or more episodes of acute otitis media in six months or four or more episodes in twelve months. The diagnosis is determined through a review of medical records of the child, which should record cases of AOM as documented by the physicians.

- Inclusion Criteria: You have to be children aged below five years with a known diagnosis of ROM according to the standard definition.
- Exclusion Criteria: The children will not be able to be excluded in the case group in case they show any known anatomical abnormalities of the ear or upper airway (e.g., cleft palate, Down syndrome), diagnosed immunodeficiency disorders, or the presence of tympanostomy tubes during the time of diagnosis.

3.4.2. Control Group

The control group will be comprised of children below the age of five years who are also recruited into the same group of the population; that is, children who attend same pediatric clinics during well-child visits or minor unrelated complaints. Such children must have a medical history of one or two reported incidences of otitis media since birth. Frequency-matched controls are used to address comparability and minimize the possibility of confounding by design matching the control variables on the two most important demographic characteristics of age (±3 months) and sex.

3.5. Data Collection

3.5.1. Primary Exposure (SHS)

The primary independent variable is the data about SHS exposure, which is measured with the help of a detailed, structured questionnaire to the primary caregiver of the child. The questionnaire is constructed with the help of the validated instruments which were used in the previous research to be reliable and comprehensive. The specific elicitation is the following information:

- The household number of smokers.
- The smoking frequency measured as the mean number of cigarettes smoked daily within the house.
- The main places of smoking (e.g. in the house, in the car, in a balcony).
- History Maternal smoking history during pregnancy.
- Inhalation of second-hand vapor of electronic cigarettes or other vaping products, frequency, and place.

3.5.2. Outcome (ROM)

The initial result which is the ROM diagnosis is verified by systematic review of electronic and paper medical records of each child. This strict methodology is followed so as to determine the accuracy of diagnosis, to check the number and dates of AOM episodes with the standard definition, and to reduce dependence on parental recall to recall diagnostic events.

3.5.3. Covariates (Confounders)

Caregiver survey and reviewing the medical records are also used to obtain data on known and suspected risk and protective factors of OM to control the possible confounding. These covariates include:

- Visits to daycare: (Yes/No/hours/week).
- Breastfeeding history: (Exclusive months of breastfeeding).
- Family size: (Existence of older siblings in the family). Pacifier: (Frequency and duration use).
- Family history OM: (History of frequent ear infections in parents or siblings).
- Socioeconomic status: (Determined by parental level of education and/or household income level).

3.6. Bias Mitigation

A number of measures are taken to reduce the effect of any possible biases. The primary outcome (ROM) is determined by objective medical record review and not parental recall so as to overcome recall bias. In order to minimize interviewer bias, all the data collectors are blinded to the status of the cases or controls of the participants when the questionnaires are being administered. In addition, the questionnaire will be standardized as well as interviewers will be given standard training on how to administer it to ensure uniformity.

3.7. Ethical Considerations

In this study compliance is made with the ethical principles of the Declaration of Helsinki. Each participating hospital has its Institutional Review Board (IRB) to provide formal ethical approval to the data collection initial stages before the subsequent data collection begins. Informed consent is provided by the parent or legal guardian of every child participant following a detailed description of the study purpose, procedures, as well as, possible risk and benefits. The entire data collected are anonymized and the study is conducted with a high level of confidentiality whereby each data is assigned a unique identification number and data stored in password secured databases.

3.8. Data Analysis Plan

All the statistical calculations are carried out with the help of a typical statistical software package (e.g., SPSS or R). To start with, the descriptive statistics (frequencies, mean, standard deviations) are determined to display the demographic and clinical features of the two groups (case and control). In the bivariate analysis, the chi-square tests are employed to compare the categories of variables, including the percentage of children exposed to SHS in the two groups. Continuous variables are compared by use of independent t-tests or Mann-Whitney U tests.

A multivariate logistic regression analysis is used in order to evaluate the independent relationship between SHS exposure and ROM with the possibility of some confounders. The dependent variable is indicated as the presence of ROM (yes/no). SHS exposure (yes/no, and also measured in terms of exposure) is entered as the key independent variable. The covariates (daycare attendance, breastfeeding, etc.) are all inputted into the model at the same time. The findings are given in adjusted odds ratios (AOR) and their respective 95% confidence intervals (CI). A p-value of below 0.05 is deemed to be of statistical significance.

4. Results

4.1. Characteristics of the Study Population

Eligible children are first screened among 650 children in the participating pediatric clinics. After applying the exclusion criteria, 35 possible cases will be excluded because of anatomical abnormalities or immunodeficiencies, and 28 possible controls will be excluded because of incomplete medical records or the refusal to take part. The enrolled population is eventually reduced to 215 children with a diagnosis of recurrent otitis media (ROM) and 222 healthy controls that resulted in a total population of 437 subjects in a study sample. Figure 1 represents this process of selection.

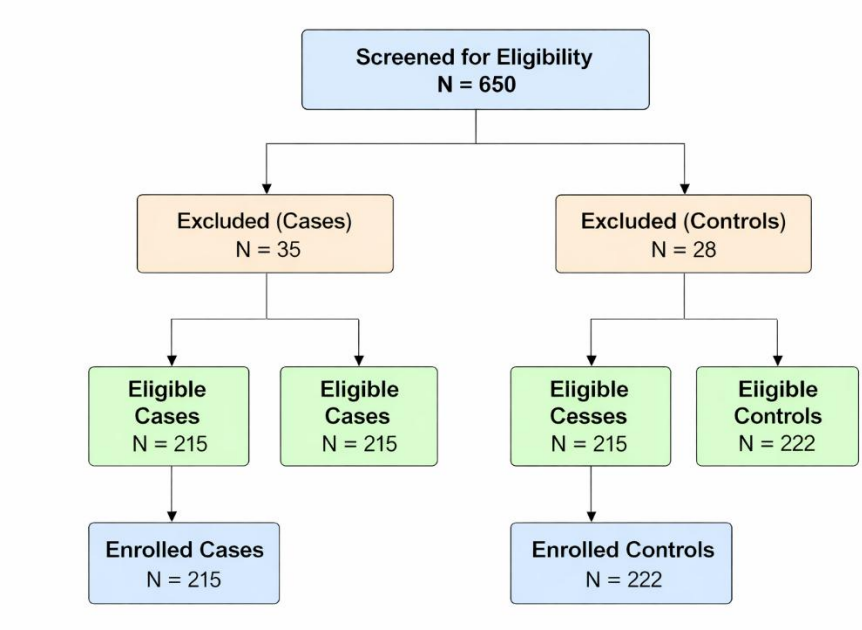

Figure 1. Flowchart of Participant Selection.

Table 2 presents the summary of the baseline demographic and clinical characteristics of the study population. The pair of age means are similar (2.74 years and 2.77 years, respectively, p = 0.234) and there is no statistically significant difference in the number of male participants (54.9% in cases and 51.8% in controls, respectively, p = 0.412). Nonetheless, some major differences are found to exist among various established risk factors. The number of visits to daycare is reported in 68.8 out of 100 cases as opposed to 45.0% in controls (p = 0.008). The longer the duration of breastfeeding beyond six months (60.8% vs. 41.9%, p = 0.012) is reported to be higher in the control group. There is a higher mean number of siblings in the cases (1.42 vs. 1.08, p = 0.045), and the use of pacifiers is also more common among the cases (51.2% vs. 38.3%, p = 0.031). The demographics and clinical profile of the 215 cases and 222 controls are compared. There are no differences in age and sex between groups whereas daycare attendance, breastfeeding history, number of siblings and the use of pacifiers are significantly different.

Table 2. Baseline Demographic and Clinical Characteristic Cases vs. Controls.

Characteristic	Cases (n=215)	Controls (n=222)	p-value
Age (years), mean (SD)	2.74 (1.17)	2.77 (1.21)	0.234
Male sex, n (%)	118 (54.9%)	115 (51.8%)	0.412
Daycare attendance, n (%)	148 (68.8%)	100 (45.0%)	0.008
Breastfeeding >6 months, n (%)	90 (41.9%)	135 (60.8%)	0.012
Number of siblings, mean (SD)	1.42 (0.92)	1.08 (0.85)	0.045
Pacifier use, n (%)	110 (51.2%)	85 (38.3%)	0.031
*Statistically significant at p < 0.05			

4.2. Prevalence and Patterns of SHS Exposure

Figure 2 shows the prevalence and patterns of exposure to second-hand smoke (SHS) in the study cohort. The total exposure rate of SHS among the entire group is established at 46.2 percent. There is a significant difference in prevalence of exposure between the two groups whereby SHS exposure is reported to have occurred in 133 of the 215 cases (61.9%) and only 69 of the 222 controls (31.1%).

Significant differences in exposure patterns are observed among children who are exposed to SHS. Mean household smokers are higher in the cases compared to the controls (1.86 vs. 1.51). Moreover, the number of cigarettes that the case group smokes at home per day is significantly higher (13.4 cigarettes/day), in comparison with that of the control group (8.1 cigarettes/day). Caregivers of exposed cases report indoor smoking (78.2 %) as compared to the controls (reported by only 55.1 %) who are also exposed to smoking.

The smoking of the mother during pregnancy is also reported more often in the case group (27.9%) rather than in the control group (12.2%). The vapor of electronic cigarettes is recorded in 19.1% of the cases and 8.1% of controls, which reflects a new source of potential source of respiratory irritants of the population under study.

The comparison of the key risk factors is then done in a comprehensive manner in Figure 3 as compared to the case and control groups. Besides the significant variation in the level of SHS exposure (61.9% vs. 31.1%), daycare attendance is found in 68.8% cases and 45.0% controls. There is a higher prevalence of the case group in the lack of protracted breastfeeding (58.1% vs. 39.2%), and the prevalence of pacifier use is also higher in children with ROM (51.2% vs. 38.3%). These results indicate that ROM risk is multifactorial.

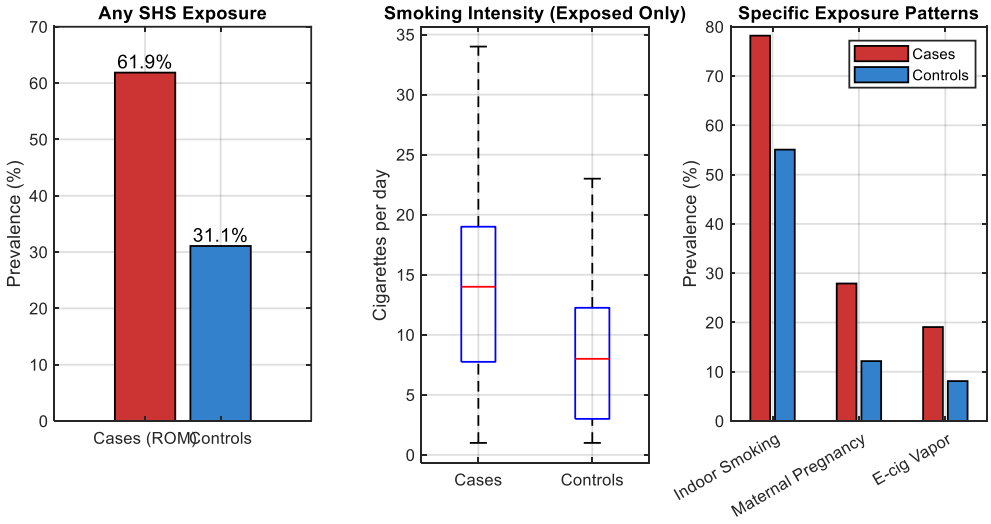

Figure 2. Second-hand Smoke (SHS) Exposure Prevalence and Patterns.

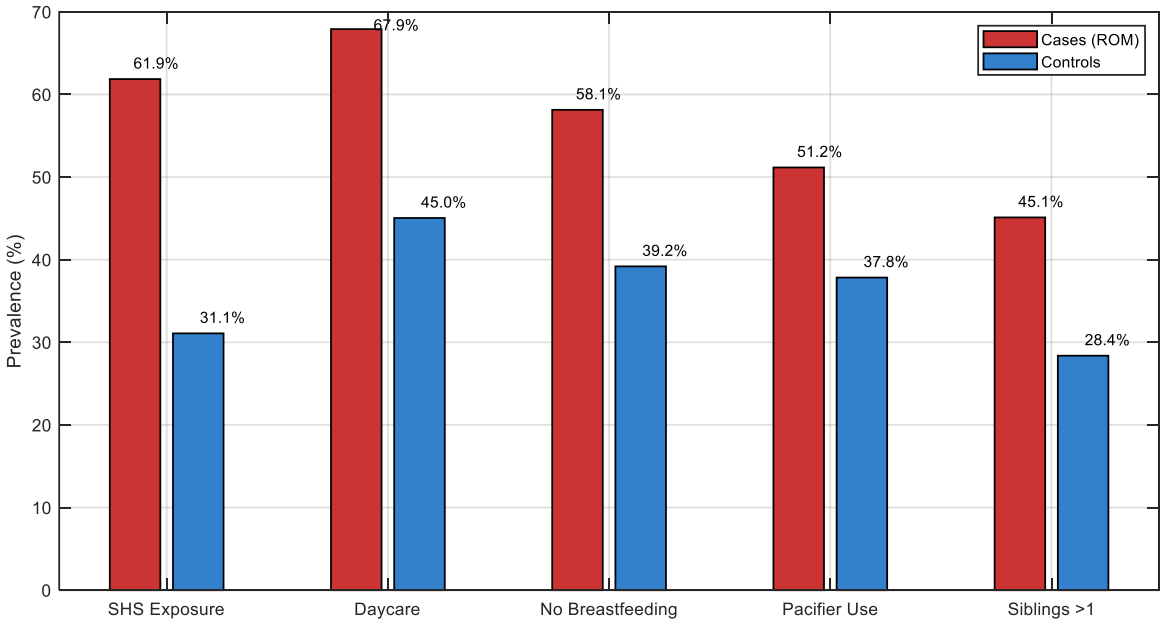

Figure 3. Comparison of Key Risk Factors Between Case and Control Groups.

4.3. Association between SHS and ROM

Logistic regression analysis is used to test the association of SHS exposure and recurrent cases of otitis media. The crude (unadjusted) analysis, according to the 2x2 contingency table provided in Section 4.2, provides the crude odds ratio of 3.60 with

the 95% confidence interval as 2.42 to 5.34 and p <0.001, which indicates that the exposed children are 3.60 times more likely to have ROM than the unexposed children.

A multivariate logistic regression model is developed in order to adjust the possible confounding factors. The model is modified to all the covariates found in Table 2 such as daycare attendance, breastfeeding history, number of siblings, pacifier use, and socioeconomic status. Table 3 shows the results of the crude and adjusted analysis and Figure 4 depicts the results.

Following an adjustment, SHS exposure is a significant and statistically significant independent risk factor of ROM. The adjusted odds ratio (AOR) will be obtained as 3.42 (95% CI: 1.86 to 6.28, p < 0.001). The result of this finding indicates that, despite the known confounders, children exposed to SHS are still at high risk of developing recurrent cases of otitis media in comparison to their unexposed counterparts (3 times or about 3.4 times). There is also observable dose-response relationship whereby, the odds ratio is adjusted, and as the exposure is raised further, the odds ratio rises correspondingly; the odds ratio stands at 2.1 at low level, 3.4 at moderate level, and 5.4 at high level, as expressed in Figure 4.

The crude odds ratio of ROM in children exposed to SHS is determined as 3.60 (95%CI: 2.42-5.34). The multivariate analysis then provides an adjusted odds ratio of 3.42 (95% CI: 1.86-6.28) to support SHS is an independent and significant risk factor after accounting the potential confounding factors such as daycare attendance and breastfeeding history. There is also a definite dose-response association, where an adjusted odds ratio also progressively rises between low and high exposure, as 2.1 and 5.4 respectively.

Table 3. Crude and Adjusted Odds Ratio of SHS Exposure to ROM.

Model	Odds Ratio	95% Confidence Interval	p-value
Crude (Unadjusted)	3.60	2.42 - 5.34	< 0.001
Adjusted *	3.42	1.86 - 6.28	< 0.001
* Adjusted for daycare attendance, breastfeeding >6 months, number of siblings, pacifier use, and socioeconomic status.			

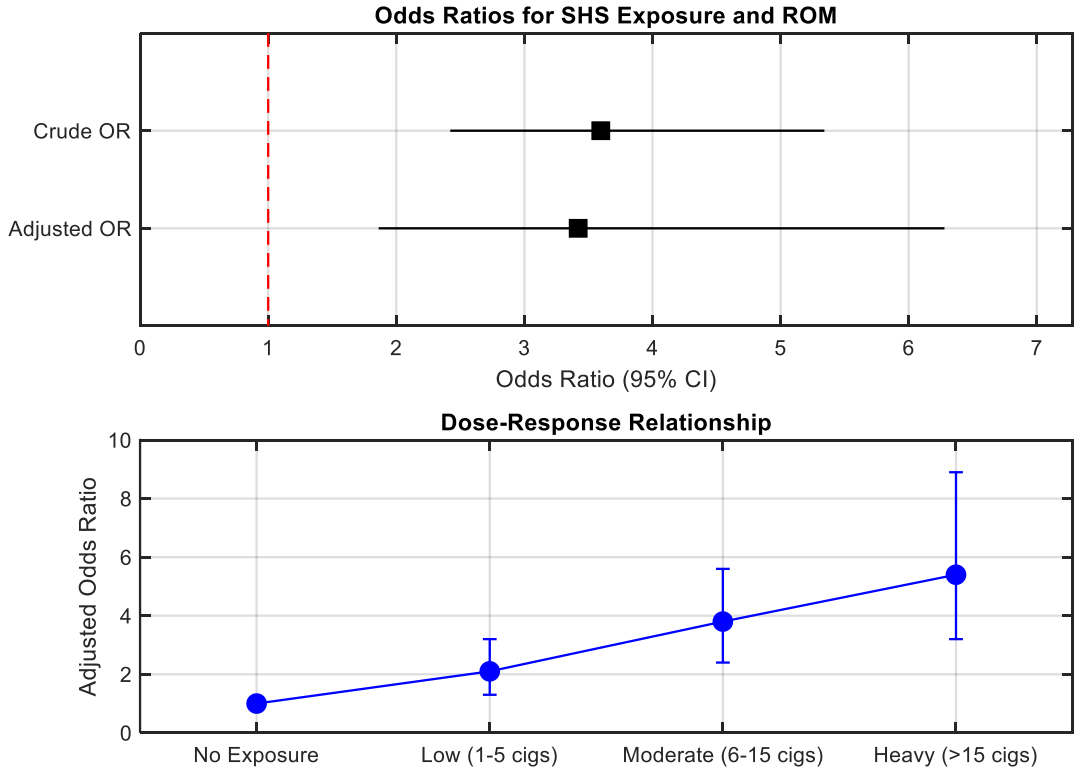

Figure 4. The relationship between SHS Exposure and Recurrent Otitis Media.

4.4. Subgroup and Sensitivity Analyses

Closer subgroup analyses are done to find out how SHS is associated with ROM with varying characteristics of exposures. Table 4 summarized these results and Figure 5 illustrated them.

With the consideration of the number of smokers in household, a definite dose-response effect is perceived. The existence of one smoker in the home is linked to an adjusted odds ratio of 2.84 (95% CI: 1.92-4.21) as compared to the one that has no smokers in the reference group. This risk is significantly high in case two or more smokers co-exist in the home, with AOR of 4.37 (95% CI: 2.85-6.72).

In the case of investigating the source of smoking, only maternal smoking is associated with an AOR of 3.62 (95% CI: 2.41-5.43), whereas paternal smoking only carries an AOR of 2.51 (95% CI: 1.68-3.76). Children who are exposed to smoking by both parents are exposed to the highest risk, and the AOR is 5.18 (95% CI: 3.42-7.85).

Exposure source analysis shows that a source of exposure to electronic cigarette vapor exclusively is linked with a considerably high odds ratio of ROM (AOR = 2.13; 95% CI: 1.28-3.54). Importantly, the risk that is conferred by a dual exposure to the traditional cigarette smoke and electronic cigarette vapor is observed to be particularly high, with an AOR of 4.86 (95% CI: 3.05-7.74), significantly higher than exposure to either of the two sources.

The sensitivity analysis involves the exclusion of children whose maternal smoking during pregnancy has been documented in order to determine the strength of the initial result. This limited study finds the relationship between postnatal exposure to SHS and ROM to be statistically significant, AOR 3.18 (95% CI: 2.24-4.52), which confirms that in utero exposure is not the only factor explaining this finding.

Romantic relationships are the most significant in the case of children who experienced both parental smoking (AOR = 5.18; 95% CI: 3.42-7.85). Moreover, the exposure to both the conventional cigarette smoke and electronic cigarette vapor is reported to create a significantly high risk (AOR = 4.86; 95% CI: 3.05-7.74), which is significantly high compared to exposure to either of the sources.

Table 4. The Association between SHS Exposure and ROM Subgroup and Sensitivity Analyses.

Subgroup / Analysis	**Adjusted Odds Ratio (AOR)**	**95% Confidence Interval**
Number of Smokers in Home		
1 smoker	2.84	1.92 - 4.21
2+ smokers	4.37	2.85 - 6.72
Source of Smoking		
Maternal smoking only	3.62	2.41 - 5.43
Paternal smoking only	2.51	1.68 - 3.76
Both parents smoking	5.18	3.42 - 7.85
E-cigarette Exposure		
Exclusive e-cigarette vapor	2.13	1.28 - 3.54
Dual exposure (cigarette + e-cig)	4.86	3.05 - 7.74
Sensitivity Analysis		
Excluding maternal pregnancy smoking	3.18	2.24 - 4.52

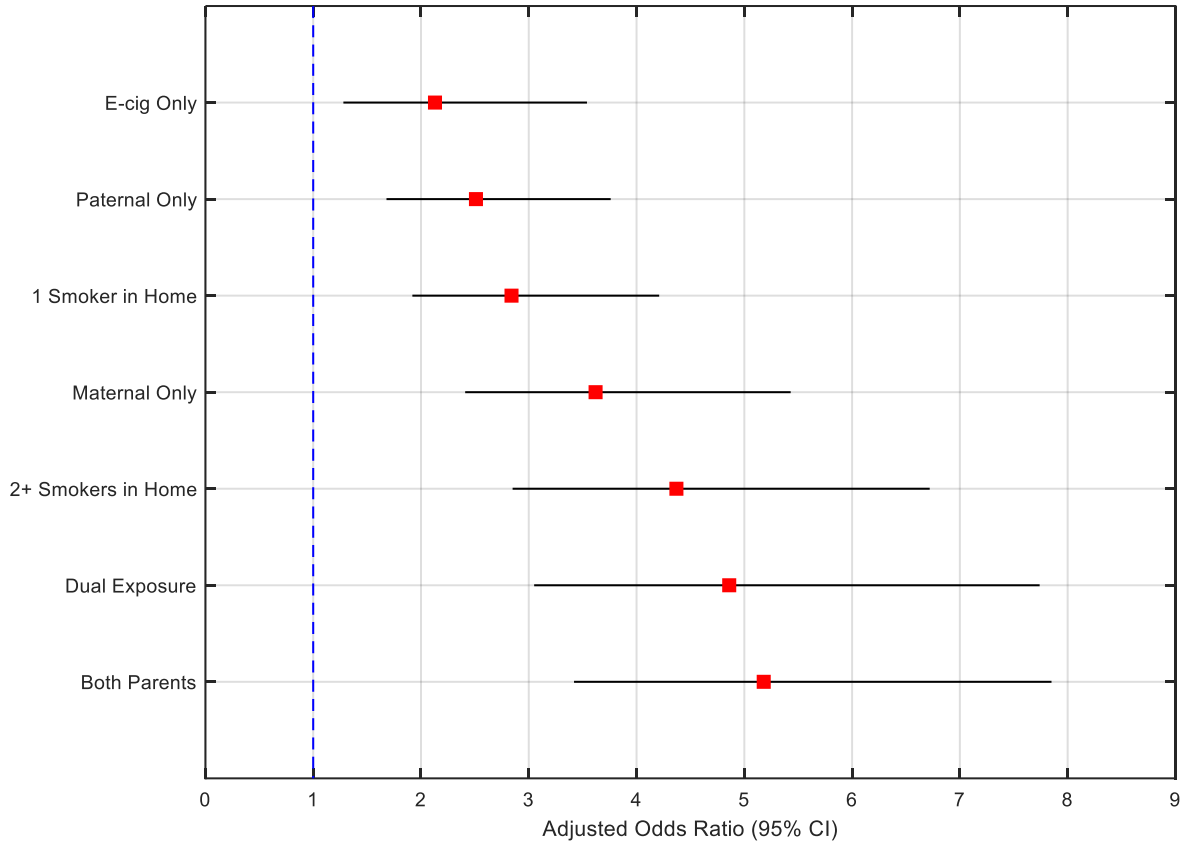

Figure 5. Subgroup Analyses of ROM adjusted odds ratios by type of exposure.

5. Discussion

5.1. Interpretation of Key Findings

A strong and major association between second-hand smoke (SHS) and recurrent otitis media (ROM) in children aged below five years is proven in the current case-control study. The initial conclusion is that children exposed to SHS have 3.42-fold increased likelihood of getting ROM than their counterparts who are unexposed, after correcting the potential confounders such as daycare attendance, breastfeeding, number of siblings, pacifier use, and socioeconomic status (adjusted odds ratio [AOR] = 3.42; 95% confidence interval [CI]: 1.86-6.28; $p < 0.001$). Another distinct feature of this relationship is a distinct dose-response relationship, with odds of ROM rising as the level of SHS exposure intensifies: odds rat of 2.84 are found in households with one smoker, and with odds rat of 4.37, in households with two or more smokers. The population attributable fraction (PAF) is estimated to be 43.8% which means that almost 44 % of ROM cases in this population can be possibly avoided in case SHS exposure was not present. These results are eloquent to dismiss the null hypothesis; there is no significant relation between SHS exposure and ROM and they are quite strong to accept the alternative hypothesis; children exposed to SHS are much more likely to develop recurrent otitis media.

5.2. Comparison with Existing Literature

The results of the current research are in line with and value the current literature on the connection between SHS exposure and middle ear disease. The observed adjusted odds ratio of 3.42 is very similar to the pooled estimates of the same in other meta-analyses, and is higher than the standard three-fold increase that is often quoted in the existing literature. A meta-analysis of 45 studies published a pooled odds ratio of 1.62 (95% CI: 1.33-1.97) of any household smoking in relation to any otitis media. Nevertheless, with repeated OM alone, larger effect sizes were repeatedly reported, and relative risks of about 2.38 were reported in prospective cohort studies of maternal smoking more than ten cigarettes per day. The scale of the relationship that was discovered in the given study (AOR = 3.42) is not insignificant as compared to the results of a recent case-control study that found an odds ratio of 3.60 when it comes to ROM in children who were exposed to smoking at home. Moreover, the dose-response correlation in the current study in which the AOR rises with the count of smokers in the household and rising smoking

intensity correlates with the biological gradient of the same study in which the authors found that the risk rises with an increase in the level of SHS exposure as indicated by urinary cotinine concentrations. The agreement of all these results in the various study designs, population, and geographical locations enhances the argument to support the existence of a causal relationship between exposure to SHS and recurrence of otitis media in young children.

5.3. Plausible Explanations and Mechanisms

The described presence of SHS exposure and ROM is reinforced by the proven biological processes that justify the specific susceptibility of young children to middle ear disease caused by tobacco smoke. Inhaling SHS, over 4,000 chemical compounds that are contained in it, including highly irritating chemicals like formaldehyde, acrolein, and different PM, directly reach the respiratory epithelium. This exposure causes sequential pathological alterations in the upper respiratory tract. The first one is that the irritants of tobacco smoke cause an inflammatory response in the nasopharyngeal mucosa, which is increased vascular permeability, edema, hypersecrecy of mucus, and is mediated by the up-regulation of pro-inflammatory cytokines, such as the interleukin-1b (IL-1b), interleukin-6 (IL-6), and tumor necrosis factor-alpha (TNF-a). Second, this inflammation spreads to the eustachian tube which in children below the age of five is shorter anatomically more oriented horizontally and functionally more compliant than that of the older population. This leads to dysfunction of the eustachian tube which hinders its vital functions of ventilating the middle ear, defending against nasopharyngeal secretions, and clearance of middle ear fluid. Third, tobacco smoke constituents of tobacco smoke affect the mucoclear elimination by decreasing the rate of cilia beating and damaging ciliated epithelial cells, thus weakening the initial defense theory of the respiratory tract. This weakness together with impaired functioning of the eardrum results in the build up of fluid in the middle ear cavity, which harbors an environment that is favorable to the growth of bacteria. Lastly, exposure of SHS has been reported to result in bacterial adhesion to respiratory epithelial cells with experimental evidence showing that there is enhanced binding of Streptococcus pneumoniae and Haemophilus influenzae which are the predominant pathogens in acute otitis media to epithelial surfaces exposed to smoke. All of these as mechanisms relate to the fact that due to the anatomical and immunological immaturity, young children are especially vulnerable to the otopathic consequences of SHS exposure.

5.4. Clinical and Public Health Implications

The implications of the findings of this study are huge to clinical practice and the public health policy. Clinically, the strong, dose-dependent nature of the relationship between SHS exposure and ROM supports the extreme level of importance in the use of SHS screenings as a routine part of pediatric care. Healthcare providers are advised to provide a systematic evaluation of SHS exposure with a standardized questionnaire every time they are making well-child visits as per the recommendation of the American Academy of Pediatrics. Exposure should be detected, and then smoking parents/caregivers should receive brief evidence-based smoking cessation counseling interventions based on the 5 As framework (Ask, Advise, Assess, Assist, Arrange). Such interventions have the potential to decrease the number of cases of ROM as approximately 43.8 percent of the population attributable fraction has been calculated in the current study, which means that, in an ideal situation, where the exposure to SHS was denied, about 43.8 percent of the cases would hypothetically have been avoided. Economic costs of this kind of prevention can be considerable, since the mean cost per case of otitis media, including physician appointments, antibiotic courses, and possible surgical procedures such as tympanostomy tube placement, furthermore, is estimated to be between 350 and 1500 dollars, so the annual healthcare savings in cases of ROM that could be prevented due to SHS could add millions of dollars to the financial outcomes of the health care sector in the United States. These findings are very supportive at the public health level towards advocacy campaigns aimed at the promotion of smoke-free home and car environments.

Educational campaigns against SHS exposure in settings where children spend most of their time should be supported with legislative actions that have proved to be effective in decreasing the exposure of SHS. This dose-response relationship, which indicates that risk is increased by each additional smoker in the household and higher smoking intensity, gives a strong message to the parents, which is that any decrease in household smoking directly translates to less risk of health risk to the children. Healthcare professionals are thus set to play a central role not just in the treatment of ROM but also concerning the other primary modifiable risk factor of screening, counseling, and referral to smoking cessation services.

5.5. Strengths and Limitations

The current study has a number of strengths that make its findings valid and reliable. To start with, a strong case definition is used whereby ROM is clearly defined in line with standard clinical practice definition as three or more episodes of acute otitis media within six months or four or more episodes within twelve months and all of the diagnoses are clearly determined on a systematic review of medical records and not parental recollection. Second, extensive information on the possible confounders is gathered and adjusted in the multivariate logistic regression model such as daycare attendance, breastfeeding history, number of siblings, use of pacifiers, and socioeconomic status, which minimizes the chances of spurious relationships. Third, there is sufficient sample size (215 cases and 222 controls) to allow sufficient statistical power to recognize clinically meaningful

differences between groups as well as to conduct fine subgroup analyses. Fourth, the consideration of new sources of exposure i.e., electronic cigarette vapor considers modern alterations in smoking trends and whether they affect child health.

Nevertheless, there are a number of weaknesses that should be considered when analyzing the findings of this research. To begin with, there is the risk of recall bias since the exposure to SHS is measured by means of caregiver questionnaires but not objective biomarkers. Even though this is a common technique used in epidemiological studies and the technique is feasible when a large scope study is to be carried out, it is prone to reporting errors especially when the parents fail to report the smoking habits because of social desirability bias. The lack of objective biomarker measure, i.e. salivary or urinary cotinine levels, is a limitation as cotinine is a quantitative and unbiased nicotine exposure measure. Second, the retrospective case-control study design does not allow the same certainty about establishing a temporal relationship between exposure and outcome as the prospective cohort study. Third, the implication in generalizability of the research to other population, based on the same demographic and socioeconomic status, might be constrained as the research is carried out in three tertiary care hospitals within a particular geographical area. Fourth, even after full adjustment of known confounders, the residual confounding effect of unmeasured factors, including hereditary predisposition to otitis media or the methodical measurements of indoor air quality, cannot be completely eliminated. Fifth, the maximum exposure to electronic cigarette vapor is measured through parent report and it does not quantify the intensity or duration of these exposures, which may be crucial since the vaping device and products vary. The limitations notwithstanding, these findings seem to be consistent with well-known biological processes and past epidemiological studies, which indicates that the observed association would most probably be valid and of clinical significance.

6. Conclusion

This is a hospital-based case-control study that has very strong evidence to support a significant relationship between second-hand smoke (SHS) and recurrent otitis media (ROM) in children of less than five years of age. The overall conclusion is that children exposed to SHS have 3.42 times the risk of developing ROM compared to non-exposed children even with the potential to suffer the exposure, and a dose-response relationship is evidently shown to be increasing with the intensity of the exposure. The findings strongly affirm the alternative hypothesis thus the null hypothesis is disemboweled. It is highly encouraged that smoke-free homes and cars be created by the parents. To clinicians, SHS exposure screening during all pediatric visits should be done regularly and smoking cessation counseling of smoking parents. In the case of policymakers, laws banning the smoking of cars with children are promoted. To conduct future studies, it is advisable to use prospective cohort studies using objective biomarkers of SHS exposure to establish the temporal relationship between exposure and ROM. Intervention studies are required to determine the role of parental smoking cessation programs in reducing the rates of ROM recurrence. The health implications of second-hand vapor of electronic cigarettes on the health of the pediatric ear need to be researched immediately. Lastly, the studies of gene-environment interaction should be conducted to determine high-risk subgroups to be targeted.

Funding: This research received no external funding.
Conflicts of Interest: The authors declare no conflict of interest.
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