



## Original Article



## Prevalence of Allergic Indicators in Patients with Chronic Otitis Media: A Case-Control Study

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## ABSTRACT

Chronic Otitis Media (COM) was a persistent inflammation of the middle ear that often leads to prolonged effusion and hearing loss. It was a significant health concern, particularly in children, due to its impact on speech development and academic performance. **Objective:** To investigate the association between allergies and Chronic Otitis Media (COM) by assessing allergy positivity, blood eosinophil levels, and skin prick test results in patients with COM compared to healthy controls. **Methods:** It was a cross-sectional, case-control study conducted at Shahida Islam Medical Complex from August 2023 to January 2024. 112 patients suffering from COM in case groups and 112 participants were taken as healthy control were selected. The positivity of allergy, increase in blood eosinophils and, skin prick test was assessed. The data analysis was conducted using the SPSS version 24.00. The p-value of less than 0.05 was considered significant. **Results:** The mean age of participants in the case group was 37.4 years  $\pm$  12.6 and control groups was 38.9 years  $\pm$  10.9. The prevalence of positive skin prick tests in the case group at 56.25%, compared to 36.61% in the control group ( $p = 0.01$ ). Blood eosinophil counts were significantly higher in the case group ( $0.39 \pm 0.15$  cells  $\times 10^{-3} \mu\text{l}$ ) than in the control group ( $0.23 \pm 0.11$  cells  $\times 10^{-3} \mu\text{l}$ ) ( $p = 0.031$ ). The positivity rate for allergies, based on clinical assessment, was significantly higher among patients in the case group (63.39%) compared to those in the control group (24.11%) ( $p = 0.04$ ). **Conclusion:** Findings of this suggests that there was strong association between allergies and chronic otitis media in patients

## INTRODUCTION

Chronic Otitis Media (COM) is a prolonged middle ear infection that leads to continuous fluid discharge behind the eardrum, potentially causing hearing loss. This condition significantly impacts young people, affecting speech and learning abilities [1]. Globally, COM in younger population has a prevalence rate of 4.1%, with higher rates observed in Africa (8%), Asia (14%) and Oceania (50%) [2]. Studies indicate a male preponderance and suggest a possible link between allergies and various forms of otitis media, though the specific pattern remains unclear [3, 4]. A vicious circle among allergic rhinitis, turbinate hypertrophy and otitis media may occur, with AR

potentially playing a role in causing otitis media [5]. The pathophysiological connection between allergies and COM includes various processes. A significant aspect of Eustachian tube dysfunction is among those that are usually seen among persons who are allergic. If the nasopharyngeal compartment has irritation caused by allergies it might bring about an abscessed Eustachian tube impeding its aerating effects on the tympanic cavity. So by forming this kind of blockage there arise a situation where a vacuum is created allowing for accumulation of fluids leading to infections hence culmination [6]. Allergens can also make more mucus since they can hinder



the cleaning of mucus within Eustachian tube and ear. Moreover, these substances may directly serve as triggers for 'attack' to produce inflammatory mediators in particular histamines and leukotrienes which worsen the middle ear mucosal inflammation and middle ear cavity [7]. Immunological responses play a crucial role in linking allergies to COM. Allergens can trigger a Type I hypersensitivity reaction, leading to the release of IgE antibodies. These antibodies bind to mast cells and basophils, causing degranulation and the release of various inflammatory mediators [8]. Besides, Th2 cytokines such as IL-4, IL-5 and IL-13 have been shown to play an important role in allergy-causing inflammation and the development of COM. They promote IgE synthesis and attract eosinophils to inflammatory foci which results in constant inflammation in the middle ear along with accumulation of effusion there [9]. The connection between allergies and COM has prominent clinical implications. It indicates that it is vital in the prevention and treatment of COM to manage allergic conditions that are underlying to it. The allergic part of COM may however be lessened as well as improving the patient's outcomes using potential therapeutic strategies such as antihistamines, intranasal corticosteroids and allergen immunotherapy. This underscores the need for a multidisciplinary approach. Comprehensive allergy testing and targeted treatments may reduce the incidence and severity of in these individuals [10]. An in-depth examination of the literature has revealed significant shortcomings. There is scarce scientific background on allergies that might evolve into COM. Most studies on the matter deal with people from more or less the same group disregarding various aspects such as age difference among others. The impact of different types of allergies (e.g., food allergies, seasonal allergies, perennial allergies) on the risk and severity of COM is not well-characterized [11]. Further research is needed for interventions that measure how well allergy management methods work (like antihistamines or allergy shots) before they can be used to stop or cure otitis media. In addition, the relationship between second-hand smoke, pollutants and allergic conditions is an area where little is known so far [12]. Addressing these gaps through comprehensive, multidisciplinary research could significantly advance this understanding of the connection between allergies and chronic otitis media, ultimately leading to more effective prevention and treatment strategies. The primary objective of this research is to find out how allergies cause COM. In doing so, find the most common allergens (like pollen, dust mites or pet dander) responsible for causing or worsening chronic otitis media. The purpose was to suggest the evidence-based criteria

for diagnosing and treating chronic otitis media in individuals whose allergies have been ascertained, with a view to enhancing quality patient care.

## METHODS

It was a cross-sectional, case-control study conducted at Shahida Islam medical complex from August 2023 to January 2024 after taking approval from the Institutional ethical review committee, SIMC/ET.C/10004/23. All the patients presented in the outdoor patient's department in the selected timeframe were screened for inclusion in this study. All the patients with aged 18 to 60 years, diagnosed with COM were included in this study. A Chronic Otitis Media (COM) was characterized by a perforated ear drum, otorrhea and other symptoms that frequently lead to acquired hearing impairment [13]. Patients with congenital ear malformations or syndromic conditions affecting the ear, immunodeficiency disorders and patients who have undergone ear surgery within the past six months were excluded from this study. Moreover, patients with history of nasal polyposis, deviated nasal septum and history of upper respiratory tract infections in past 3 months and presence of cholesteatoma were also not included in this study. Demographic data including age, gender and history of smoking was noted and informed consent was taken. Detailed history including allergy symptoms (e.g., rhinitis, asthma, eczema) and family history of allergies were noted along with comprehensive otolaryngological examination will be conducted, including otoscopy to confirm the diagnosis of COM. To measure the blood eosinophil count, the samples were run on an automated blood cell counter (Bio-Rad's TC20™), and the results were expressed in several eosinophils/ $\mu\text{L}$ . [13]. The sample size was calculated by considering 80% power added to the study, prevalence rate of 7.8%, a confidence level of 95% and a margin of error of 5%, are approximately 224 participants with 112 patients suffering from COM in case groups and 112 participants were taken as healthy control [14]. Written informed consent was obtained from each participant. The positivity of allergy was defined as presence of persistent sneezing on exposure to allergen with pale, watery nasal mucosa along with increase in blood eosinophils levels 0.04-0.36 (cells  $\times 10^{-3} \mu\text{l}$ ) for females and 0.04-0.54 (cells  $\times 10^{-3} \mu\text{l}$ ) for males. In addition to positive skin prick test to any of the 19 selected Turkish mixed respiratory allergens. Histamine hydrochloride was used as positive control and the glycerol saline was used as negative controls. The skin prick test was interpreted as positive if a wheal of 3mm larger than the negative control was observed after 15 minutes. The data analysis was conducted using the Statistical Package for Social Sciences (SPSS) version 24.0. For quantitative variables, the calculations were mean and standard deviation; for qualitative variables, the calculations were frequencies and percentages. The p-value of less than 0.05 was considered significant.

## RESULTS

In this study comparing patients with COM in a case group (n=112) and a control group (n=112), the mean age of participants in the case group was 37.4 years  $\pm$  12.6, slightly lower than the control group's mean age of 38.9 years  $\pm$  10.9, although this difference was not statistically significant ( $p = 0.06$ ). Regarding gender distribution, 60.71% of the case group were male and 39.29% female, compared to 50.89% male and 49.11% female in the control group ( $p = 0.59$  for male/female distribution and  $p = 0.07$  for overall gender comparison). Analysis of COM characteristics revealed that unilateral involvement was predominantly left-sided (33.93%) and right-sided data 27.23% cases. Bilateral COM was noted in 38.84% of the case group. The duration of illness was reported as 4.8 years  $\pm$  6.9 in the case group. Significantly, a history of smoking differed between groups, with 47.32% of cases having a history of smoking compared to 36.6% in the control group ( $p = 0.05$ ) (Table 1). This finding suggests a potential association between smoking history and the development or severity of COM in children.

**Table 1:** Demographic Characteristics of the Study Population (n=224)

Variables	Case Group Mean $\pm$ SD/N (%)	Control Group Mean $\pm$ SD/N (%)	p-Value
Age	37.4 $\pm$ 12.6	38.9 $\pm$ 10.9	0.06
<b>Gender</b>			
Male	68 (60.71%)	57 (50.89%)	0.59
Female	44 (39.29%)	55 (49.11%)	0.07
<b>Unilateral COM</b>			
Left Sided	76 (33.93%)	-	-
Right Sided	61 (27.23%)	-	-
Bilateral COM	87 (38.84%)	-	-
Duration of Illness (Years)	4.8 $\pm$ 6.9	-	-
History of Smoking	53 (47.32%)	41 (36.6%)	0.05

The prevalence of positive skin prick tests, indicative of allergic sensitization, was notably higher in the case group at 56.25%, compared to 36.61% in the control group ( $p = 0.01$ ). This finding suggests a higher prevalence of allergic sensitization among patients with COM compared to their healthy counterparts. Secondly, blood eosinophil counts, a marker often elevated in allergic conditions, were significantly higher in the case group ( $0.39 \pm 0.15$  cells  $\times 10^{-3}$   $\mu$ L) than in the control group ( $0.23 \pm 0.11$  cells  $\times 10^{-3}$   $\mu$ L) ( $p = 0.031$ ). Moreover, a striking majority in the case group (79.64%) had raised eosinophil counts, further supporting the link between allergic inflammation and COM. In contrast, only 18.75% in the control group exhibited raised eosinophil counts. The positivity rate for allergies, based on clinical assessment, was significantly higher among patients in the case group (63.39%) compared to those in the control group (24.11%) ( $p = 0.04$ ; Table 2). This indicates that patient with COM was more likely to have allergies

compared to their healthy peers, suggesting a potential role for allergic sensitization in the pathogenesis of COM.

**Table 2:** Comparison of Variables in Case and Control Group (n=224)

Variables	Case Group Mean $\pm$ SD/N (%)	Control Group Mean $\pm$ SD/N (%)	p-Value
Positive Skin Prick Test	63 (56.25%)	41 (36.61%)	0.01
Blood Eosinophils Count (Cells $\times 10^{-3}$ $\mu$ L)	0.39 $\pm$ 0.15	0.23 $\pm$ 0.11	0.03
Raised Eosinophil Count	89 (79.64%)	21 (18.75%)	0.02
Positivity of Allergy	71 (63.39%)	27 (24.11%)	0.04

## DISCUSSION

In this comparative study involving 112 patients in both a case group and a control group, several key parameters related to allergies were evaluated to discern differences between the groups. The case group, comprising patients with COM, demonstrated significant disparities in allergy-related metrics compared to the control group. The higher prevalence of positive skin prick tests, elevated blood eosinophil counts, raised eosinophil count frequency and overall allergy positivity rate in the case group underscore the need for comprehensive allergy evaluation in patients presenting with COM [15]. The findings of this study correlate with the recent literature. A randomized control trial conducted by Sharifian MR *et al.*, have also revealed higher positivity of skin prick test in patients suffering from COM than the healthier control. It highlights the strong connection exists between allergic rhinitis and COM [16]. It suggests that allergic reaction or hypersensitivity play a significant role in the pathogenesis of COM. The middle ear stays in equilibrium with outside pressure through Eustachian tubes which also remove any fluids present. Inflammation was one of the ways allergic rhinitis. When someone suffering from allergies (or hay fever) comes into contact with something that triggers an allergic reaction such as pollen or dust mites then their immune system responds by releasing antibodies on the lining of its nasal cavities which results into inflammation followed by constriction thereby leading them experiencing tightness when breathing; which further blocked their air passages thus causing discomforts like hissing sounds heard during inhalation phase among others. This process may continue into the Eustachian tubes resulting in swelling and blockage [17]. As a result, the normal function of the Eustachian tubes, including ventilation and drainage of fluids from the middle ear, was impaired. Studies have shown that eustachian tube dysfunction was significantly higher in allergic rhinitis patients (83.3% compared to 84.2% of healthy subjects) than in healthy subjects [18]. A significant number of eosinophils in the circulation are usually linked by medical professional because they believe it may answer some questions about what happens during COM disease process such as whether there was any

connection between allergy in one's body system and developing this disease condition. Additionally, the investigation discovered eosinophil counts were extremely raised among cases compared with controls (79.64% vs 18.75%); hence, this trend underlines the connection between COM occurrence and general allergy responses signified via the levels of eosinophils in the blood [19]. It was important to understand how allergies relate to COM since it impacts what doctors do and what patients do. If a patient comes with symptoms that resemble those seen in either chronic or recurring cases of otitis media, tests for hypersensitivity reactions would have to be carried out particularly among those who have had previous diagnoses of atopy or allergic rhinitis. Understanding more about this relationship facilitates more individualized interventions among different people such as really controlling allergic conditions through use of medicine such as antihistamines while avoiding foods known to cause discomforts [20]. Educating patients and caregivers about the association between allergies and COM can empower them to recognize early symptoms and seek timely medical intervention. This study had the objective of investigating the linking factor among COM and allergies although there are various limitations to this study. Consequently, in these studies which are mainly observational, it was very important though difficult to establish a temporal sequence between allergies and COM. It was very often unclear about which one comes first between allergies preceding development of COM or conversely; this situation makes causal inference problematic. The study has a limited sample size hence the generalizability of results was doubtful. The development of COM could be affected differently based on the various kinds of allergies, such as food or environmental ones. This implies that general conclusions made from such researches may not apply to particular allergy types because the research does not clearly distinguish among them. This lack of specificity necessitates further studies using better methodology such as cross-sectional design and exploration of temporal relationships.

## CONCLUSIONS

In conclusion, we would like to note that in this patient cohort, there was a very close connection exists between the presence of allergies and cases of COM. Positive skin prick tests, though, were found at a much higher rate in those patients within the research group who had either raised eosinophil counts or a frequent occurrence of such counts or an overall allergy positive rate. Consequently, it has been proposed that thorough allergy assessment be carried out among patients with COM.

## Authors Contribution

Conceptualization: AH

Methodology: AH, IA, ABM

Formal analysis: JH

Writing, review and editing: IA, THK, MA

All authors have read and agreed to the published version of the manuscript

## Conflicts of Interest

All the authors declare no conflict of interest.

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