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A prospective cohort study on the association between ear drop use and otomycosis: prevalence, treatment outcomes, and recurrence

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ABSTRACT

This study investigates the incidence of otomycosis associated with ear drop usage and evaluates treatment outcomes and recurrence rates in Iraqi patients with and without a recent history of ear drop application. Conducted at the ENT Clinic of Almahawil Hospital (Iraq) from April 1, 2022, to March 31, 2024, the study involved 280 patients diagnosed with otomycosis. Participants were divided into two groups: group 1 (N=72) comprised individuals who had used ear drops within 1–2 weeks prior to diagnosis, while group 2 (N=208) comprised individuals who had not recently used ear drops. Our findings revealed that 26% of otomycosis cases were linked to recent ear drop use, with ciprofloxacin being the most commonly used agent (61.1%). Both groups demonstrated high rates of symptom resolution following treatment; however, the recurrence rate was notably higher among ear drop users (11.1%) compared to non-users (7.8%). These results suggest that ear drop usage may elevate the risk of developing otomycosis and increase the likelihood of recurrence, thereby highlighting the need for judicious prescribing practices.

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1. Introduction

Otomycosis, commonly referred to as fungal otitis externa, is a superficial fungal infection affecting the external auditory canal. It is typically characterized by symptoms such as itching, pain, otorrhea, and hearing impairment. The primary causative agents are species of *Aspergillus* and *Candida*, with the infection being particularly prevalent in tropical and subtropical climates, where warm and humid conditions promote fungal proliferation[1,2]. Several risk factors have been identified in relation to otomycosis, notably the use of topical ear drops, which can

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disrupt the normal microbial flora and create an environment conducive to fungal growth[3,4]. In particular, the application of antibiotic ear drops has been associated with an increased risk of otomycosis, as these agents may disturb the natural microbial balance and facilitate fungal overgrowth[5].

This prospective cohort study has investigated the prevalence of ear drop-induced otomycosis, treatment outcomes, and recurrence rates among Iraqi patients with and without recent ear drop use. Conducted at the ENT Clinic of Almahawil Hospital, Iraq, from April 1, 2022, to March 31, 2024, this study aimed at enhancing our understanding of the clinical implications of ear drop usage in relation to otomycosis in Iraqi patients.

2. Methodology

This prospective cohort study was conducted at the ENT Clinic of Almahawil Hospital in the Babylon Governorate of Iraq, from April 1, 2022, to March 31, 2024. The study protocol was approved by the Ethics Committee of the Almahawil Hospital (approval number: AHEC-2022-045) on March 15, 2022. Written informed consent was obtained from all participants prior to their inclusion in the study.

A total of 280 patients diagnosed with otomycosis were enrolled, comprising 188 men and 92 women. Upon enrolment, patients were divided into two groups based on their history of ear drop usage. Group 1 included patients who reported using ear drops within 1–2 weeks prior to their clinic visit. Group 2 included patients who denied any ear drop use within the same timeframe. For group 1, the type of ear drops used was documented, and the duration of use prior to the clinic visit was recorded as either less than one week or more than one week. All patients underwent standard clinical management and assessments, including otoscopy and mycological testing, in order to verify treatment outcomes. Treatment responses were categorized as complete resolution of symptoms (absence of itching, pain, otorrhea, and hearing loss), partial improvement, or treatment failure. Recurrence of otomycosis was monitored, and recurrence rates were compared between group 1 and group 2.

Data were analysed using appropriate statistical methods in order to estimate the prevalence of ear drop-induced otomycosis. In order to assess the significance of differences in treatment outcomes and recurrence rates, a *p*-value lower than 0.05 was considered statistically significant. All statistical analyses were performed using SPSS version 25.0 (IBM Corp., Armonk, NY, USA).

3. Results and Discussion

The study included a total of 280 patients diagnosed with otomycosis, comprising 188 men (67.1%) and 92 women (32.9%). The age range for male patients was 19 to 74 years, with a mean age of 35 years, while the age range for female patients was 20 to 58 years, with a mean age of 34 years. Seventy-two patients (26%) reported using ear drops within 1–2 weeks prior to their clinic visit for otomycosis (group 1), while 208 patients (74%) denied recent ear drop usage (group 2). This indicates that over a quarter of the diagnosed otomycosis cases were potentially associated with recent ear drop use. Among the 72 patients in group 1, 44 (61.1%) had used ciprofloxacin ear drops, 4 (5.6%) gentamicin ear drops, 13 (18.1%) dewaxing solutions, 5 (6.9%) betamethasone ear drops, and 6 (8.3%) other / unidentified ear drops (Figure 1). The duration of ear drop use prior to the clinic visit varied, with 62 patients (86.1%) reporting use for less than 1 week and 10 patients (13.9%) for more than 1 week.

Following standard management and clinical assessments (i.e., otoscopy and mycological testing), a complete resolution of symptoms was observed in 65 patients (90.3%) of group 1 and 190 patients (91.3%) of group 2. Partial improvement was noted in 7 patients (9.7%) of group 1 and 18 patients (8.7%) of group 2. There were no cases of treatment failure in either of the studied groups. The recurrence rates of otomycosis were 11.1% (8 patients) in group 1 and 7.8% (12 patients) in group 2.

The finding that 26% of patients diagnosed with otomycosis had recently used ear drops suggests that certain formulations may predispose individu-

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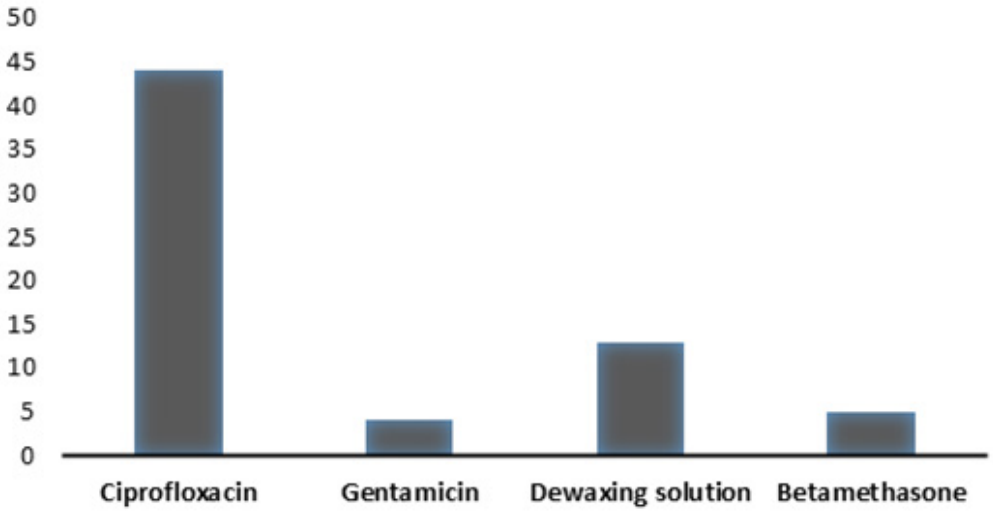

Figure 1. *Substances in the ear drops that were used by the study participants belonging to group 1. Note: the y axis denotes the number of the participants, while six participants in this group (not shown) have reported using other / unidentified ear drops.*

als to fungal infections of the ear. The predominance of ciprofloxacin use among these patients (61.1%) aligns with previous research indicating that antibiotic ear drops can disrupt the natural microbial balance of the ear, creating an environment conducive to fungal proliferation[5,6].

Notably, the high rate of complete symptom resolution in both groups (90.3% in group 1 and 91.3% in group 2) suggests that standard clinical management is generally effective in treating otomycosis, regardless of recent ear drop use. However, the slightly higher recurrence rate in the ear drop user group (11.1%) compared to the non-user group (7.8%) indicates a potential association between ear drop usage and recurrent otomycosis.

Several studies have examined the factors contributing to the development and recurrence of otomycosis. Ho *et al.*[5] have identified the use of ototopical antibiotics as a significant risk factor due to their suppression of bacterial flora, which normally inhibit fungal colonization. Similarly, Munguia and Daniel[3] have noted that inappropriate or prolonged use of ear drops may promote fungal growth.

Finally, the demographic data from this study, showing a higher prevalence of otomycosis in males, may reflect occupational or behavioural factors that increase exposure to fungal pathogens. The mean age of patients (35 years for men and 34 years for women) suggests that otomycosis primarily affects middle-aged adults, consistent with findings from other epidemiological studies[7,8]. Further research is warranted in order to explore alternative treatments and preventive strategies aimed at reducing the incidence and recurrence of otomycosis in patients using ear drops.

4. Conclusion

This study highlights a notable association between recent ear drop usage and the occurrence of otomycosis, with ciprofloxacin identified as the most frequently implicated agent. Although both ear drop users and non-users demonstrated favourable treatment outcomes, the recurrence rate was higher among those with recent ear drop use. These findings underscore the need for heightened clinical awareness regarding the potential risk of otomycosis associated with topical ear drop application.

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Conflicts of interest

None exist.

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