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Research Article

Clinical Profile, Risk Factors, and Treatment Response of Malignant Otitis Externa in Diabetic Patients

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ABSTRACT

Background: Malignant otitis externa (MOE) is a potentially life-threatening invasive infection of the external auditory canal that predominantly affects patients with diabetes mellitus.

Objective: To evaluate the clinical profile, risk factors, and treatment response of malignant otitis externa in diabetic patients.

Methods: This prospective observational cohort study was conducted at ENT department Bahawal Victoria Hospital/Quaid Azam Medical College Bahawalpur from September 2024 to June 2025, and included 170 diabetic patients diagnosed with malignant otitis externa.

Results: The mean age of patients was 64.8 ± 10.9 years, and 104 (61.2%) were male. The mean duration of diabetes was 11.6 ± 6.3 years, with a mean HbA1c of 8.9 ± 1.5%. Severe otalgia (95.9%) and otorrhea (83.5%) were the most common presenting symptoms, while Pseudomonas aeruginosa was isolated in 119 (70.0%) patients. Patients with poor treatment response were significantly older (72.1 ± 11.4 vs. 63.2 ± 10.1 years; $p<0.001$) and had higher HbA1c levels (10.4 ± 1.6% vs. 8.5 ± 1.2%; $p<0.001$). Chronic kidney disease, facial nerve palsy, skull base osteomyelitis, prolonged hospitalization (16.4 ± 5.6 vs. 9.2 ± 3.8 days; $p<0.001$), and recurrence (36.7% vs. 6.4%; $p<0.001$) were significantly more common among patients with poor outcomes.

Conclusion: Malignant otitis externa in diabetic patients is associated with substantial morbidity, particularly among those with poor glycemic control and advanced disease. Early diagnosis, aggressive culture-directed antimicrobial therapy, optimal diabetic management, and close follow-up are essential to improve treatment outcomes and reduce recurrence.

Keywords: Malignant Otitis Externa, Necrotizing Otitis Externa, Diabetes Mellitus, Pseudomonas Aeruginosa, Skull Base Osteomyelitis.

INTRODUCTION

Malignant otitis externa (MOE), or necrotizing otitis externa, is a rare but potentially fatal invasive external ear canal infection which spreads to the skull base via fissures of Santorini and osseocartilaginous junctions [1]. MOE is a progressive osteomyelitis of the temporal bone and other skull base structures that result in large morbidity and, if untreated, mortality. Although there have been advances in imaging and antimicrobial therapy, MOE is still a difficult disease to treat due to its aggressive nature, delayed diagnosis and high rate of recurrence [3]. Diabetes mellitus is known to be the most significant predisposing factor for the development of malignant otitis externa and is responsible for about 80-95% of the reported cases [2]. Chronic hyperglycemia also leads to impairment of neutrophil chemotaxis, phagocytosis and ability to kill bacteria, and to microvascular insufficiency leading to reduced tissue perfusion and host immune defenses. These changes increase

susceptibility to secondary infections, especially in the external auditory canal which is vulnerable to the entry of bacteria due to minimal trauma or chronic inflammation [5]. Thus, elderly patients with diabetes, who have poor glycemic control are especially prone to MOE and its complications. The most frequently associated pathogen is Pseudomonas aeruginosa, which is responsible for most culture positive cases due to its characteristic of forming biofilms, its virulence factors and its mechanisms of antimicrobial resistance [4]. However, infections with methicillin-resistant Staphylococcus aureus, fungal pathogens like Aspergillus spp. and Candida spp., and polymicrobial pathogens have recently been reported more frequently in patients with compromised immune systems and those who previously received broad-spectrum antibiotics [7]. Correct identification of the causative organism is crucial in selecting the right antimicrobial treatment and for achieving clinical results. The clinical presentation of patients with malignant otitis externa usually includes a persistent earache and otorrhea with purulent drainage, external auditory canal swelling, granulation tissue at the bone-cartilage border and conductive hearing loss [6]. Extension to the skull base, as manifested by involvement of the cranial nerves (such as facial nerve palsy) can occur as the infection progresses, indicating a poor prognosis. In advanced disease, osteomyelitis of the skull base, multiple cranial neuropathies, intracranial extension, meningitis, venous sinus thrombosis and sepsis may occur, which highlights the need for early diagnosis and timely treatment [9].

Diagnosis is based on a combination of clinical examination, microbiological culture, inflammatory markers and radiological imaging. The computed tomography (CT) scan can help to show bony erosion, while the magnetic resonance imaging (MRI) can help to assess soft tissue involvement and intracranial extension. Treatment response monitoring and the identification of persistent infection may be aided by radionuclide imaging techniques such as technetium-99m and gallium-67 scintigraphy [8]. The timely diagnosis is important as it will have a significant impact on the risk of complications and the length of time spent in hospital if delayed. Management is currently mostly based on long-term systemic antipseudomonal antibiotic therapy, careful control of blood glucose, careful local ear care, and treatment of underlying diseases [10]. Surgery is usually reserved for those who develop an abscess, for removal of sequestrum, tissue biopsy or for those who don't respond to medical treatment. In a few cases of refractory disease, hyperbaric oxygen therapy has also been investigated as an additional treatment, but the consequences of routine use are still not clear [12]. The elevated inflammatory markers, uncontrolled diabetes, chronic kidney disease, involvement of cranial nerves, multidrug-resistant organisms, delayed presentation and osteomyelitis of the skull base are several factors associated with poor treatment response and adverse outcomes [11]. These prognostic factors should be identified to aid in risk stratification, individualized treatment planning and better long-term prognosis. While there have been significant advances in the diagnosis and management of malignant otitis externa, there are still subvariations in clinical presentation, microbiological profile, response to treatment and recurrence rates among diabetic patient populations in different parts of the world [13]. More real-world data is needed to gain deeper insight into the nature of the disease and to improve disease management.

Objective

To evaluate the clinical profile, risk factors, and treatment response of malignant otitis externa in diabetic patients.

METHODOLOGY

This prospective observational cohort study was conducted at ENT department Bahawal Victoria Hospital/Quaid Azam Medical College, Bahawalpur from September 2024 to June 2025, and included 170 diabetic patients diagnosed with malignant otitis externa (MOE) to evaluate their clinical profile, risk factors, treatment response, and clinical outcomes. Patients with a clinical, microbiological culture and radiological diagnosis of malignant otitis externa and diabetes mellitus were included, aged 18 years or older. Complete medical records, definite medical treatment and a minimum follow-up period of three months were required for eligible patients. Patients who had uncomplicated otitis externa, chronic suppurative otitis media and cholesteatoma were excluded, as were those with head and neck malignancy involving the temporal bone, those who were immunocompromised but were not diabetic, those with incomplete medical records and those who were lost to follow-up.

Data Collection

After approval from the Institutional Ethical Review Committee, the data were collected from electronic medical records, outpatient files, inpatient charts, microbiology laboratory reports, radiological investigation, operative record, follow up documentation by using a standardized data collection proforma. Baseline demographic data consisted of age, gender, body mass index (BMI), diabetes mellitus (DM) duration, glycated hemoglobin (HbA1c), smoking, hypertension, chronic kidney disease, ischemic heart disease and past history of otitis externa (OE). Clinical parameters measured were presentation symptoms (otalgia, otorrhea, hearing loss, fever, facial weakness), the duration of symptoms, external auditory canal granulation tissue, involvement of the cranial nerves, laterality, inflammatory markers (WBC, ESR, CRP), microbiological culture results, and imaging results, including a skull base osteomyelitis. Treatment-related variables included the type of antibiotic treatment (empirical or culture), the amount of time the patient was on intravenous or oral antibiotics, topical antibiotic treatments, glycemic control measures, surgery, hyperbaric oxygen therapy (when indicated), length of hospital stay and complications associated with treatment. The primary outcome was successful clinical treatment response, which was defined as complete resolution of clinical symptoms, normalization of inflammatory markers and no evidence of clinical disease progression at follow-up assessment. Secondary outcomes were: recurrence, recovery of cranial nerves, need for surgery, long hospital stay, failure to treat and death.

Statistical Analysis

The analysis of the data was done using SPSS version 26.0. Data on continuous variables were reported as the mean ± SD and data on categorical variables were reported as frequencies and percentages. Comparisons between the patients who responded well to treatment and those who responded poorly to treatment were made using either independent t-tests or Mann–Whitney Utests as appropriate for the continuous variables. Categorical variables were analyzed using chi-square or Fisher's exact test. After adjustment for age, duration of diabetes, HbA1c level, chronic kidney disease, cranial nerve involvement, skull base osteomyelitis, inflammatory markers, and microbiological findings, multivariable logistic regression analysis was used to identify independent predictors of poor treatment response. A p value of ≤ 0.05 was considered statistically significant.

RESULTS

The mean age of patients was 64.8 ± 10.9 years, with males forming the majority (104, 61.2%). The mean duration of diabetes was 11.6 ± 6.3 years, and mean HbA1c was 8.9 ± 1.5%, indicating generally poor glycemic control. Hypertension was present in 109 (64.1%), chronic kidney disease in 38 (22.4%), and skull base osteomyelitis in 27 (15.9%) patients.

Table 1: Baseline Demographic and Clinical Characteristics of Diabetic Patients with Malignant Otitis Externa (N = 170)

Variable	n (%) / Mean ± SD
Age (years)	64.8 ± 10.9
Male	104 (61.2)
Female	66 (38.8)
Duration of Diabetes (years)	11.6 ± 6.3
HbA1c (%)	8.9 ± 1.5
Hypertension	109 (64.1)
Chronic Kidney Disease	38 (22.4)
Current Smokers	42 (24.7)
Right Ear Involvement	92 (54.1)
Left Ear Involvement	74 (43.5)
Bilateral Disease	4 (2.4)
Skull Base Osteomyelitis	27 (15.9)

Severe otalgia was the most common symptom, reported in 163 (95.9%) patients, followed by otorrhea in 142 (83.5%), external auditory canal granulation tissue in 131 (77.1%), and hearing loss in 109 (64.1%). *Pseudomonas aeruginosa* was the leading organism, isolated in 119 (70.0%) cases. The mean intravenous antibiotic duration was 20.8 ± 7.1 days, while surgical debridement was required in 28 (16.5%) patients.

Table 2: Clinical Presentation, Microbiological Findings, and Treatment Modalities

Variable	n (%) / Mean ± SD
Severe Otalgia	163 (95.9)
Otorrhea	142 (83.5)
Hearing Loss	109 (64.1)
External Auditory Canal Granulation Tissue	131 (77.1)
Facial Nerve Palsy	24 (14.1)
Fever	37 (21.8)
Pseudomonas aeruginosa Isolated	119 (70.0)
MRSA Isolated	19 (11.2)
Fungal Infection	11 (6.5)
Intravenous Antibiotic Duration (days)	20.8 ± 7.1
Surgical Debridement	28 (16.5)
Hyperbaric Oxygen Therapy	12 (7.1)

Poor treatment response was associated with older age (72.1 ± 11.4 vs. 63.2 ± 10.1 years; p<0.001) and higher HbA1c levels (10.4 ± 1.6 vs. 8.5 ± 1.2%; p<0.001). Chronic kidney disease, facial nerve palsy, skull base osteomyelitis, longer hospital stay, and recurrence were all significantly more common in the poor-response group.

Table 3: Comparison between Patients with Successful and Poor Treatment Response

Variable	Successful Response (n=140)	Poor Response (n=30)	p-value
Age (years), Mean ± SD	63.2 ± 10.1	72.1 ± 11.4	<0.001
HbA1c (%), Mean ± SD	8.5 ± 1.2	10.4 ± 1.6	<0.001
Chronic Kidney Disease, n (%)	24 (17.1)	14 (46.7)	0.001
Facial Nerve Palsy, n (%)	12 (8.6)	12 (40.0)	<0.001
Skull Base Osteomyelitis, n (%)	16 (11.4)	11 (36.7)	0.001
Hospital Stay (days), Mean ± SD	9.2 ± 3.8	16.4 ± 5.6	<0.001
Recurrence	9 (6.4)	11 (36.7)	<0.001

Facial nerve palsy was the strongest predictor of poor treatment response (AOR=4.68, 95% CI: 1.89–11.60; p<0.001), followed by HbA1c >9% (AOR=3.84), skull base osteomyelitis (AOR=3.42), chronic kidney disease (AOR=2.94), age >70 years (AOR=2.76), and MRSA/fungal infection (AOR=2.51).

Table 4: Multivariable Logistic Regression Analysis of Predictors of Poor Treatment Response

Predictor	Adjusted OR	95% CI	p-value
HbA1c >9%	3.84	1.67–8.82	0.002
Age >70 Years	2.76	1.18–6.46	0.019
Chronic Kidney Disease	2.94	1.23–7.04	0.015
Facial Nerve Palsy	4.68	1.89–11.60	<0.001
Skull Base Osteomyelitis	3.42	1.43–8.17	0.006
MRSA/Fungal Infection	2.51	1.02–6.20	0.045

DISCUSSION

A prospective study of the clinical profile, risk factors, and response to therapy in 170 diabetic patients with MOE was performed. It was found that MOE mainly occurred in elderly patients, long-standing poorly controlled diabetes and was most frequently due to Pseudomonas aeruginosa. Resistant microbial infections, poor glycemic control, chronic kidney disease, facial nerve palsy, and skull base osteomyelitis were significantly associated with poor treatment response. The results highlight the need for timely diagnosis, prompt antibiotic treatment and better control of diabetes to achieve better clinical outcomes. The mean age of the study population was 64.8 ± 10.9 years, and 61.2%

of patients were males. The mean diabetes duration of 11.6 ± 6.3 years and mean HbA1c of 8.9 ± 1.5% indicated poor glycemic control in the majority of patients. The most common comorbidities were hypertension, which was present in more than half of the patients, and chronic kidney disease, which was present in more than one-fifth of patients. The same previous studies have also suggested that the onset of the condition of otitis externa in the human body is related with the rise in age of the patient, diabetes mellitus and poor glycemic control, with the first two main risk factors, and prolonged duration of diabetes being a significant predisposing factor [14]. As far as clinical manifestations was concerned, severe otalgia was the most common symptom, present in 95.9% of the patients, followed by otorrhea, granulation tissue of the external auditory meatus, and hearing loss. In 14.1% of patients, facial nerve palsy was present, which means that the disease was advanced. Pseudomonas aeruginosa continued to be the most common pathogen isolated - 70.0% of positive cultures compared to MRSA and fungal infections, which were much less common. The clinical features and microbiological characteristics have been consistently reported in the past with Pseudomonas aeruginosa as the main cause and the emergence of resistant bacterial and fungal infections, especially Pseudomonas species. Patients had to have long-term antibiotic treatment, with a mean of 20.8 ± 7.1 days; 16.5% of patients needed to have surgical debridement. A small number of patients with refractory disease were treated with hyperbaric oxygen therapy. Previous studies have also demonstrated prolonged culture directed antimicrobial therapy is effective in most patients while surgery is indicated when there is an abscess formation, necrotic tissue, or failure of conservative management [16].

Not all patients responded to treatment and the number of patients who responded was dependent on the severity of the disease and the patient's characteristics. Patients who were poorly responsive to treatment were significantly older (72.1 ± 11.4 vs. 63.2 ± 10.1 years) and had significantly worse glycemic control (HbA1c 10.4 ± 1.6% vs. 8.5 ± 1.2%). These patients were significantly more likely to have chronic kidney disease, facial nerve palsy and skull base osteomyelitis. They also had a longer hospital stay (16.4 + 5.6 days vs. 9.2 + 3.8 days) and had a significantly higher recurrence rate (36.7% vs. 6.4%). Similarly, uncontrolled diabetes, renal impairment and advanced skull base involvement were found to be strongly associated with the prolonged treatment, the recurrence and poor clinical outcome in previous studies [17][18]. One of the most significant indicators of severe disease was facial nerve palsy. The treatment response was significantly worse in patients with cranial nerve involvement compared with those without neurological deficits. Facial nerve palsy has been consistently shown to be a sign that the infection has spread beyond the external auditory meatus into the skull base, and is correlated with length of treatment and morbidity rate [19]. Facial nerve palsy was the most powerful independent predictor of poor response to treatment, with a nearly fivefold increased risk, in a multivariable logistic regression. Additionally, poor glycemic control (HbA1c >9%), skull base osteomyelitis, chronic renal failure, advanced age and MRSA or fungal infection were all independently associated with treatment failure. Previous studies have also found that sub-optimal control of blood sugar decreases ability to fight infection and heal tissues, and resistant organisms and skull base involvement significantly decrease the likelihood of a cure [20].

Limitations

This study has several limitations. First, its prospective design may have introduced selection and information bias because the analysis relied on previously documented medical records. Second, the study was conducted at a single tertiary care center, which may limit the generalizability of the findings to other populations and healthcare settings. Variations in antimicrobial regimens, timing of diagnosis, glycemic control strategies, and clinician preferences could not be completely standardized. Although microbiological culture results and imaging findings were evaluated, factors such as antimicrobial resistance patterns over time, patient adherence to prolonged antibiotic therapy, nutritional status, and socioeconomic factors were not consistently available for analysis. Furthermore, long-term outcomes including hearing recovery, quality of life, and recurrence beyond the follow-up period were not assessed.

CONCLUSION

Malignant otitis externa predominantly affects elderly patients with long-standing, poorly controlled diabetes mellitus and remains an

aggressive infection associated with significant morbidity. *Pseudomonas aeruginosa* was the most frequently isolated pathogen, while prolonged intravenous antibiotic therapy constituted the mainstay of treatment. Advanced age, poor glycemic control, chronic kidney disease, facial nerve palsy, skull base osteomyelitis, and resistant microbial infections were independently associated with poor treatment response. Patients with unfavorable outcomes experienced longer hospitalization and higher recurrence rates.

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