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CLINICAL SPECTRUM AND OUTCOME OF COVID-19 ASSOCIATED RHINO-ORBITAL-CEREBRAL MUCORMYCOSIS: A CROSS-SECTIONAL STUDY

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Abstract

Background. *Rhino-orbital-cerebral mucormycosis, a severe and often fatal fungal infection, has seen a notable rise in incidence among COVID-19 patients, particularly in regions such as Iran.*

Methods. *This cross-sectional study aimed to characterize the clinical spectrum, outcomes, and prognostic factors of ROCM in COVID-19 patients at a tertiary care hospital in southwestern Iran. Conducted from June 2021 to November 2022, the study included 48 consecutive patients with confirmed ROCM and COVID-19.*

Results. *The mean age of participants was 54.79 ± 14.22 years, with the majority (85.4%) having diabetes mellitus. Common clinical presentations included periorbital/orbital edema (60.4%), ptosis (62.5%), and chemosis (45.8%), while headaches were uncommon. Treatment modalities primarily included sinus endoscopy (93.8%), antifungal therapy (95.8%), and jaw debridement (43.8%). The study revealed significant morbidity, with 35.4% of patients experiencing unilateral blindness, 31.3% jaw deformity, and a mortality rate of 22.9%. Statistical analysis identified diabetes and sinus endoscopy as inversely correlated with mortality, while facial palsy showed a direct correlation. Age was significantly associated with periorbital edema, and hospital stay duration was correlated with sinus endoscopy, facial palsy, and nasal congestion.*

Conclusion. *These findings underscore the severe impact of Rhino-Orbital-Cerebral-Mucormycosis in COVID-19 patients, emphasizing the need for early diagnosis, aggressive management, and further research to improve outcomes in this high-risk population.*

Keywords: COVID-19, Rhino-Orbital-Cerebral-Mucormycosis, mortality rate.

Introduction

The order Mucorales and Entomophthorales are responsible for the fungal infection known as mucormycosis [*Kwon-Chung K J, 2012*]. Infections caused by this pathogen may arise from ingesting contaminated food, inhaling spores, or through wounds or skin breaches [*Benedict K, et al., 2016*]. In industrialized countries, zygomycosis mainly occurs in immunocompromised patients, whereas in other regions, a significant number of cases of mucormycosis occur in patients with uncontrolled

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diabetes mellitus or those who have sustained trauma [*Sannathimmappa M B, et al., 2022; Sharma A., Goel A, 2022*].

However, a recent review of 851 cases over a 7-year period, concluded that the disease burden is lower in Asia than in Europe, as they reported 31% in Asia, followed by Europe (34%) and Africa (3%), Australia (3%) and South America (28%) [*Kottarathil M, et al., 2023*]. Definitive diagnosis of the infection is made through histopathology, fungal culture of surgical samples, and direct microscopy [*Guarner J, Brandt M E, 2011*]. The rhino-orbital-cerebral mucormycosis (ROCM), the most prevalent type, is associated with different symptoms of orbital pain, swelling around the eyes, facial numbness and pain, vision loss to sightlessness, and cerebral complications such as cavernous sinus thrombosis [*Dubey S, et al., 2021*]. It is interesting to note that recently, there has been a sudden increase in cases of mucormycosis, including ROCM, observed among patients who have recently or previously tested positive for SARS-CoV2 [*Alshahawey M G, et al., 2022*]. ROCM is the prevailing clinical manifestation of the illness in patients, and it is associated with a high mortality rate [*Polo Martinez M A, et al., 2022*].

Even though ROCM is a significant concern in the context of COVID-19, to date, not many large-scale studies have investigated the clinical picture, mycology, risk factors, and treatment in Iran. Thus, we undertook a prospective study to characterize the clinical spectrum and outcome at a hospital in southwestern Iran.

Materials and Methods

This study was written in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (**STROBE**) Statement [*von Elm E, et al., 2007*].

Study design and Setting: This analytical, cross-sectional study examined the clinical spectrum and outcomes of ROCM patients with COVID-19. Conducted at Imam Khomeini Hospital, Ahvaz, Iran - a tertiary care training center affiliated with Ahvaz University of Medical Sciences (AJUMS) - the study was carried out from June 2021 to November 2022. This hospital serves as a major referral center for complex medical conditions in southwestern Iran. The study protocol received ethics approval from the AJUMS' Ethics Committee (ID: IR.AJUMS.REC.1401.513), ensuring compliance with national and international standards.

Participants: The study population comprised consecutive patients diagnosed with ROCM and COVID-19, confirmed through laboratory tests and imaging studies. Inclusion criteria consisted of a confirmed diagnosis, age 18 or older, and complete availability of medical records. Patients under 18 or with incomplete records were excluded. The aim of this study was to provide insights into clinical characteristics, treatment outcomes, and prognostic factors, informing healthcare strategies and improving patient care.

Variables: This study examined various variables related to ROCM patients with COVID-19. The independent variables included demographic characteristics (age, sex, and comorbidities) and clinical features (symptoms, duration, and severity). The dependent variables comprised clinical outcomes (mortality rate, and hospital stay duration), irreversible side effects, and treatment outcomes (response to antifungal therapy, surgical intervention need, and complications). Potential confounding variables considered were diabetes mellitus, and hospitalization period. Covariates included age and sex, which may influence the relationship between independent and dependent variables.

Data sources/measurement: The primary data sources for this study were patient medical records and clinical examination reports. Secondary data sources included hospital databases, electronic health records, and literature reviews. Data extraction was performed using a predetermined checklist and standardized questionnaires for demographic and clinical information.

Bias: This analytical cross-sectional study may be susceptible to several biases. Selection bias could result from the consecutive sampling method and limitations in the inclusion/exclusion criteria. Information bias might arise due to data extraction errors, inaccurate medical records, and recall bias. Confounding bias is possible due to uncontrolled variables such as comorbidities, immunosuppression, diagnosis and treatment delays, and COVID-19 severity. Measurement bias may stem from instrument bias and observer bias. Analyti-

cal bias could occur due to statistical analysis errors and data interpretation bias. To mitigate these biases, data validation and verification procedures were implemented, confounding variables were controlled, standardized data collection tools were used, and blinded data analysis were employed – all to ensure reliability and validity of the findings.

Study size: The sample size was determined based on the number of eligible patients who presented to the hospital during the study period.

Quantitative variables: This study assessed various quantitative variables related to ROCM patients with COVID-19. These included age, hospital stay duration, ICU stay duration, symptom duration, and treatment outcomes.

Statistical methods: This study employed descriptive and inferential statistics to analyze data. Descriptive statistics included means and standard deviations for continuous variables (age, hospital stay duration, symptom duration), medians and interquartile ranges for skewed data, and frequencies and percentages for categorical variables (sex, comorbidities). Inferential statistics included t-tests to compare means between groups (patients with/without comorbidities), chi-squared tests to examine associations between categorical variables, and Pearson's correlation to identify predictors of outcomes. Data analysis was conducted using SPSS version 27 (SPSS Inc., Chicago, IL, USA) and R software, with a significance level of $P < 0.05$.

Results

A total of 48 patients with mucormycosis were included in this study. The mean age of the patients was 54.79 ± 14.22 years, ranging from 27 to 88 years. The majority of patients (85.4%) had diabetes, and 39.6% were female. The mean hospitalization period was 35.4 ± 17.95 days, ranging from 5 to 93 days. The most common treatment types included sinus endoscopy (93.8%), antifungal treatment (95.8%), and jaw debridement (43.8%). The study population experienced significant morbidity and mortality, with 35.4% of patients experiencing blindness in one eye, 31.3% experiencing deformity of the jaw, and 22.9% resulting in death (**Table 1**).

In examining the symptoms of the patients, the majority (41 out of 48) did not experience headaches. However, 29 patients (60.4%) presented with periorbital/orbital edema. A small percentage of patients (16.7%) exhibited facial paralysis. More than 50% of patients (30 out of 48) had ptosis. Conversely, 26 patients did not have proptosis. A significant proportion of patients (31 out of 48, 64.6%) did not experience pain. Chemosis was present in 22 patients (45.8%). Additionally, 9 patients had restricted eye movements, and 4 experienced nasal congestion (Table 2).

Table 1.

Descriptive Characteristics of the Study Population (N = 48)

Variable	Value
Age (years), mean ± SD (range)	54.79 ± 14.22 (27–88)
Hospitalization period (days), mean ± SD (range)	35.4 ± 17.95 (5–93)
Sex (female), n (%)	19 (39.6%)
Diabetes, n (%)	41 (85.4%)
Treatment type, n (%)	
Sinus endoscopy	45 (93.8%)
Maxillectomy	15 (31.3%)
Jaw debridement	21 (43.8%)
Antifungal treatment	46 (95.8%)
Enucleation	1 (2.1%)
Abscess drainage	1 (2.1%)
Blindness in one eye, n (%)	17 (35.4%)
Jaw deformity, n (%)	15 (31.3%)
Decreased visual acuity, n (%)	21 (43.8%)
Death, n (%)	11 (22.9%)

Based on Pearson's correlation analysis, diabetes ($r=-0.288$, $P=0.047$) and sinus endoscopy ($r=-0.474$, $P<0.001$) showed a significant inverse correlation with mortality. However, facial palsy was positively correlated with mortality ($r=0.288$, $P=0.047$). In brief, age was significantly correlated with edema ($r=-0.29$, $P=0.046$). Furthermore,

Table 2.

Clinical Symptoms of Patients (N = 48)

Clinical Symptom	n (%)
Headache	7 (14.6%)
Periorbital/orbital edema	29 (60.4%)
Facial palsy	8 (16.7%)
Ptosis	30 (62.5%)
Proptosis	22 (45.8%)
Pain	17 (35.4%)
Chemosis	22 (45.8%)
Limitation of eye movements	9 (18.8%)
Nasal congestion	4 (8.3%)

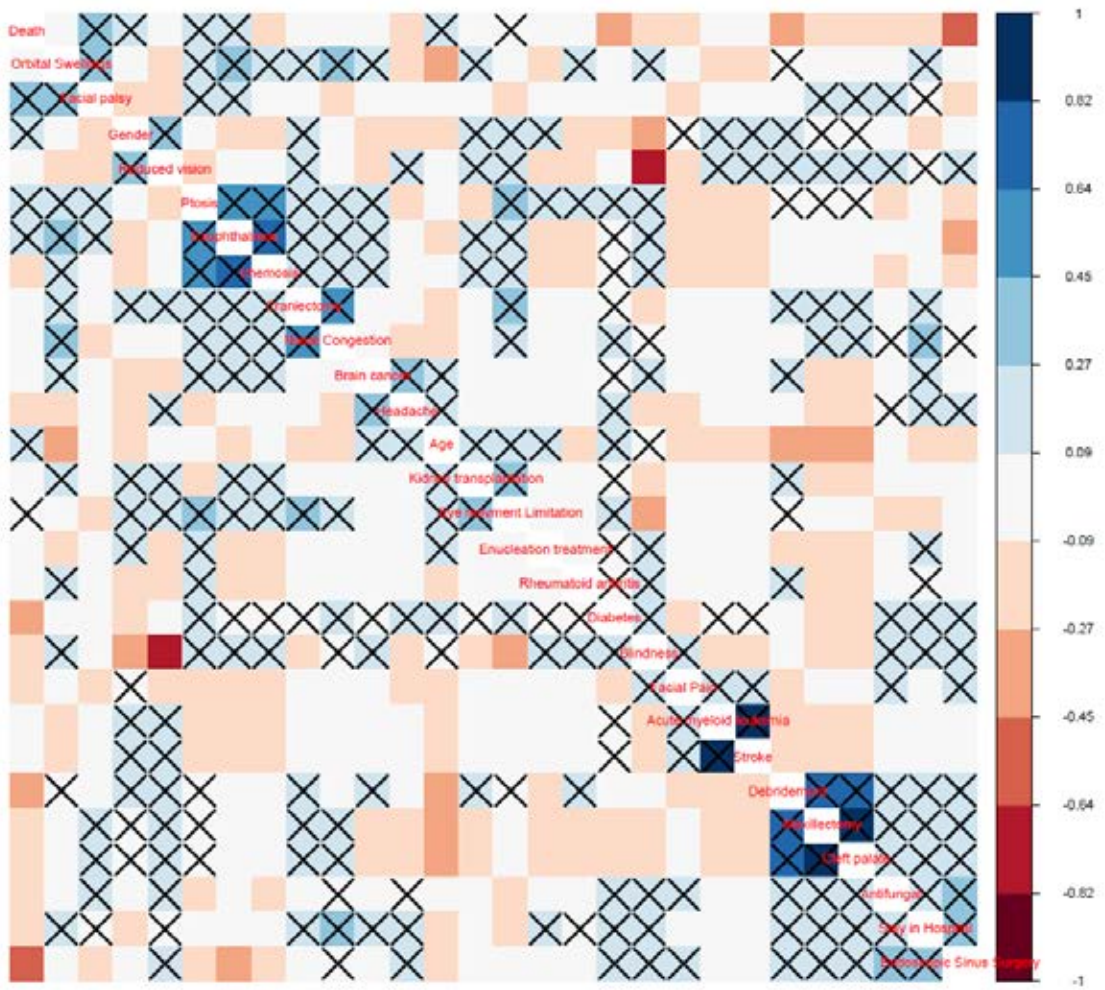

Figure 1. *Heat map showing the correlation between clinical and treatment-related variables.*
Note! Darker shades indicate stronger correlations

length of hospital stay was significantly associated with sinus endoscopy (r=0.384, P=0.007), facial palsy (r=-0.333, P=0.021), and nasal congestion (r=0.384, P=0.007) (Fig. 1).

Discussion

The results of this study provide valuable insights into the clinical manifestations and treatment outcomes of ROCM patients with COVID-19. The clinical manifestations of ROCM in this study were consistent with previous reports, with periorbital/orbital edema (60.4%), ptosis (62.5%), and chemosis (45.8%) being the most common symptoms. Notably, the majority of patients (85.4%) had diabetes, a well-established risk factor for mucormycosis. The high prevalence of diabetes in this study underscores the importance of vigilant monitoring and management of diabetes in patients with COVID-19. Treatment outcomes of ROCM in this study were poor, with a mortality rate of 22.9%, which aligns with prior studies indicating the fight fatality of ROCM. The results of this study also showed that facial palsy, diabetes, and sinus endoscopy were significantly correlated with mortality. The correlation between facial palsy and mortality is consistent with previous reports, which have shown that facial palsy is a negative prognostic factor in patients with ROCM. Similarly, the correlation between diabetes and increased mortality risk reinforces existing evidence. The inverse correlation between sinus endoscopy and mortality is remarkable and warrants further investigation.

Sinus endoscopy is a common treatment modality for ROCM, and it is possible that the procedure may have a positive impact on mortality. The results of this study also showed that the length of hospital stay was significantly correlated with

sinus endoscopy, facial palsy, and nasal congestion. This suggests that patients who undergo sinus endoscopy, have facial palsy, or experience nasal congestion may require longer hospital stays.

Clinical manifestations of ROCM include headache, tooth decay, necrosis of the internal nasal turbinates, facial pain, facial paralysis, periorbital or facial edema, skin stiffness, and black discoloration [*Metwally M I, et al., 2022*]. Symptoms associated with of invasion of the nasal and oral cavity include deformation of the palate, bloody nasal discharge, and epistaxis. Further progression can lead to damage of the ophthalmic artery and optic nerve, resulting in blindness, eyelid ptosis, proptosis, and visual disturbances.

In a large retrospective study from India, 536 (19%) patients with Coronavirus Disease-Associated Mucormycosis presented with vision loss [*Sen M, et al., 2021*]. Involvement of the cavernous sinus occurs due to the expansion beyond the orbit and appears as diplopia and ophthalmoplegia [*Talmi Y P, et al., 2002*]. A systematic review by Watanabe *et al*. (2022) reported common manifestations in 2312 patients, including headache (54%), swelling/pain around the eyes (53%), facial swelling/pain (43%), ophthalmoplegia (42%), proptosis (41%), and nasal discharge/congestion (36%). In the present study, the majority of patients (41 out of 48) did not experience headaches. However, 29 (60.4%) patients had periorbital/orbital edema, 16.7% had facial paralysis, and more than 50% of patients (30 out of 48) had ptosis. Twenty-six patients did not have proptosis (41%). Thirty-one patients (64.6%) did not experience pain. Chemosis was present in 22 patients (45.8%). Nine patients had restricted eye movements, and four had nasal congestion. Ansari *et al*. investigated the risk factors of mucormycosis in a study involving 50 patients, 78% of whom were infected with COVID-19. Diabetes mellitus was the primary risk factor for malignancy in COVID-19 patients (84%). Mucormycosis was more prevalent in men (58%) aged 40 years and older (80%) [*Ashraf GA, Haider-Mehdi, 2022*]. The findings regarding age and gender in that study are highly consistent with ours. Diabetes is also the most common comorbidity in mucormycosis. Patel *et al*. conducted a study in a private tertiary care center in western India [*Patel A K, et al., 2022*]. The distribution of age and sex in the case and control groups was similar, with 69.9% of men in both groups. Diabetes, along with corticosteroid use and home isolation, are major risk factors for COVID-19-associated mucormycosis. Another study showed a higher likelihood of developing ROCM (odds ratio: 7.55, P = 0.001) in diabetic patients [*Bala K, et al., 2015*]. Previous studies have also examined the medical records of patients and the use of corticosteroids [*Kumari A, et al., 2021*], which were not investigated in the present study.

Currently, corticosteroids are the main treatment for severe COVID-19 patients [*Nehara H. R, et al., 2021*]. Sterne et al. mentioned that corticosteroids increase survival and reduce mortality in COVID-19 patients [*WHO, 2020*]. However, the use of corticosteroids can impair the ability of white blood cells to phagocytose, predisposing patients to fungal infections and even death [*Ahmed N, et al., 2022*]. In our study, more than 95% of patients received antifungal therapy, and 11 patients died during the course of the disease (22.9%). Corzo *et al*. reported the mortality rate in 100 patients [*Corzo-Leon D E, et al., 2018*]. Various reports from Iran [*Avatef Fazeli M, et al., 2021*] and other countries [*Choksi T, et al., 2022*] have also been published. The reported severity of the co-occurrence of mucormycosis and COVID-19 differs between studies, even within the same country. A future study is needed to investigate the severity and outcomes of mucormycosis-COVID-19 co-infection. In one study, 20 patients were examined, of whom 35% had active COVID-19 disease. Diabetes was found in 80% of patients. All patients received amphotericin and underwent endoscopic debridement. Additionally, 20% of patients underwent orbital decompression, and 5% of patients underwent maxillectomy [*Kumari A, et al., 2021*].

In the present study, 15 patients underwent maxillectomy (31.3%). Only 21 patients underwent jaw debridement, while 27 patients did not. Eye and abscess drainage were performed in only one patient. The difference in the maxillectomy rate between the present study and similar studies may be attributed to geographic factors, patient conditions, and treatment protocols. To address these disciplines, future research should include multicenter or multinational studies, or a systemic review. Based on previous findings, an arrangement of antifungal therapy,

surgical debridement, removal of predisposing factors, and surgical debridement is typically required [*Mengji A K, et al., 2016*].

The present study has some limitations. The sample size was relatively small, and the study was conducted in a single center. Furthermore, the use of corticosteroids—a potential risk factor for mucormycosis—was not investigated.

Conclusion

In conclusion, this study provides valuable insights into the clinical manifestations and treatment outcomes of ROCM in patients with COVID-19. The results of this study underscore the importance of early recognition and treatment of ROCM, as well as the need for careful monitoring and management of diabetes in patients with COVID-19. The high mortality rate and significant morbidity associated with ROCM in this study emphasize the necessity of prompt and aggressive treatment. Further studies are needed to investigate the optimal treatment strategies for ROCM and to explore the relationship between ROCM and COVID-19. Additionally, larger-scale studies are required to validate the findings of this study and provide more comprehensive insights into the clinical manifestations and treatment outcomes of ROCM in patients with COVID-19.

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