Purpose: Rhino-orbital mucormycosis in times of ongoing COVID-19 pandemic. Aims: The aim of the study was to document cases of rhino-orbital mucormycosis seen at our Regional Institute of Ophthalmology during COVID-19 (coronavirus disease 2019) times. Methods: The study is a retrospective, institutional cohort, interventional study. It was carried out at our Regional Institute of Ophthalmology from September 2020 to mid-March 2021. All patients of biopsy-proven mucormycosis were enrolled in the study. The patients were subjected to complete history taking, ophthalmological examination, and imaging studies. The patients were treated via a multidisciplinary approach with intravenous liposomal amphotericin B and debridement of local necrotic tissue. Exenteration was done when indicated. A minimum 75-day follow-up period was accorded to all study patients. Statistical analysis was done using Chi-square test. A P value ≤0.05 was taken as significant. Results: Thirty-one patients were seen, with a mean age of 56.3 years. The major risk factors included uncontrolled diabetes (96.7%) and COVID-19 positivity (61.2%), with concomitant steroid use in 61.2% patients. The most common presentation was diminution of vision (<6/60 in 80.64% patients) and ophthalmoplegia (77.4%). The most common imaging findings were orbital cellulitis (61.29%) and pansinusitis (77.4%). Intravenous liposomal amphotericin B was given to all patients for an average 18.93 days. Exenteration was required in (n = 4) 12.9% of cases. Twenty-eight patients recovered and were alive on follow-up. Mortality was seen in three patients. The presence of cerebral involvement and a HbA1c value of ≥8 were found to be significant in the prediction of survival of patients with mucormycosis. Conclusion: We present the largest institutional cohort of rhino-orbital mucormycosis patients during the ongoing COVID-19 pandemic era from our unique perspective.

Key words: COVID-19, rhino-orbital mucormycosis, pandemic

The tale goes in ancient Greek mythology that the phoenix (a long-lived bird) is born again by rising from the ashes of its predecessor. Such is the tale of the pathogen, which in recent times has risen like the phoenix from the ashes. Rhino-orbital mucormycosis is a fungal infection of the orbital tissues by the fungus Mucor of the class Phycomycetes (order Mucorales). It has been described classically as an aggressive opportunistic infection occurring in the immune-compromised patients.[10] The pathogen is ubiquitous, occurring naturally in the environment, the body surface, and orifices. The spores inoculate the parasanal sinuses and the nasopharynx with subsequent spread to the orbit and intracranial cavity in persons with decreased cellular and humoral defenses. The pathogen invades the vascular lamina propounding the inflammation with infarction and necrosis. Early diagnosis with the institution of appropriate antimicrobial therapy saves both sight and life. The present COVID-19 pandemic has witnessed a resurgence of cases of rhino-orbital mucormycosis. This study documents these cases and their management from a unique perspective.

Methods

The study was carried out at our Regional Institute of Ophthalmology from September 2020 to mid-March 2021. It is a retrospective, interventional institutional cohort study. All patients with biopsy-proven mucormycosis were enrolled in the study. Enrollment was carried out till the first day of January 2021. Thereafter, a minimum management/follow-up period of 2.5 months (75 days) till mid-March was taken. Informed consent was obtained from the participants. Approval of the local ethics committee was obtained. All the patients with rhino-orbital mucormycosis had been subjected to a nasal endoscopic debridement with subsequent microbiology and histopathology. The reports showed a positive fungal element, that is, large nonseptate branching hyphae, mycelia with surrounding tissue involvement, and/or a positive fungal culture report suggestive of Mucor. Each patient was subjected to a complete history taking, including ocular complaints. A complete history of concomitant systemic illnesses with their treatment was elicited. Patients reporting a history of COVID-19 were confirmed positive by reverse transcription-polymerase chain reaction (RT-PCR) of...
nasopharyngeal swab. High-resolution computed tomography thorax and COVID-19 reporting and data system (CORAD) score were additionally used. The COVID-19 facility in our hospital gave intravenous dexamethasone in a dose of 0.1 to 0.2 mg/kg body weight for the mild to moderate cases of COVID-19 as per the clinical severity and hematology. Severe COVID-19 patients were given intravenous dexamethasone in a dose of 0.4 mg/kg body weight. The duration of steroid use was 7 to 14 days with necessary tapering. A complete ophthalmic examination, including visual acuity, extraocular movements, slit-lamp biomicroscopy, and fundus examination, was done. Imaging studies included magnetic resonance imaging (MRI) or computed tomography scan of both the orbits, brain, and paranasal sinuses with or without contrast. Hematology included complete hemogram, blood sugar, and renal function tests. The disease was classified as mild-to-moderate and severe for the sake of management. Mild-to-moderate disease was defined as ophthalmoplegia, diminution of vision, and sinus involvement. Severe disease was defined as the presence of any of the following: obvious necrosis of orbital tissue, facial tissue necrosis, and cerebral extension.

The patients were managed via a multidisciplinary approach in coordination with Medicine and Otorhinolaryngology alias Ear, Nose, Throat (ENT) departments. Patients with uncontrolled diabetes were given insulin and/or oral antidiabetic drugs as per the physician’s advice. Patients with hypertension and other concurrent systemic illnesses were managed accordingly. Intravenous liposomal amphotericin B was given to all patients under the physician’s guidance in a dose of 3 to 5 mg/kg body weight/day. Intravenous liposomal amphotericin B was given only after a confirmed microbiological or histopathological diagnosis of mucormycosis. The drug was not used empirically because of systemic side effects and high cost. The drug was continued until 4 to 7 days after resolution of the disease. Oral posaconazole was added in a dose of 5 mg/kg body weight/day at the time of resolution. The combination therapy of liposomal amphotericin B and oral posaconazole was given for 4 to 7 days after resolution to allow for the onset of action of posaconazole. Sinus debridement was done on the ENT side. Debridement of orbital necrotic tissue was done on our (ophthalmic) side. Exenteration was considered in patients with the absence of light perception, total ophthalmoplegia, obvious necrosis of orbital tissues, and worsening despite the above concurrent systemic management. The patient was subjected to serial imaging studies and/or nasal endoscopy to know the disease resolution or worsening. Repeat sinus and/or local tissue debridement was done on worsening. The resolution was evident on clinical improvement, hematology, and radiology. The resolution was confirmed by a negative sinus biopsy and normal metabolic parameters. Thereafter, the patient was discharged with continued medical management of comorbidities. Syrup posaconazole was continued orally after discharge for a minimum of 8 weeks as a protocol. The patients were followed up during the duration of the study, and the outcome was noted. A minimum follow-up period of 75 days was given to all patients.

Statistical analysis: Statistical analysis was done using Chi-square test. A P value ≤ 0.05 was taken as significant.

Results

The results are tabulated in the accompanying tables [Tables 1-5]. Figs. 1-3 show the images of some of the patients. In our present study, most of the patients were in the fifth, sixth, and seventh decades of their life. The mean age was 56.3 years [Table 1]. The major risk factors included diabetes (96.7%) and COVID-19 positivity (61.2%) with concurrent steroid use (61.2%) [Table 2]. The duration from COVID-19 positivity to presentation of mucormycosis was on an average of 2 months. Concurrent ongoing COVID-19 with rhino-orbital mucormycosis was

| Number (%) |
|---|
| Age (years) |
| 20-30 | 2 (6.45) |
| 31-40 | 1 (3.22) |
| 41-50 | 6 (19.35) |
| 51-60 | 10 (32.2) |
| 60-70 | 9 (29.0) |
| 71-80 | 3 (9.67) |

| Number (%)
|---|
| Gender |
| Male | 20 (64.5) |
| Female | 11 (35.5) |

| Number (%)
|---|
| Laterality |
| OD only | 19 (61.29) |
| OS only | 10 (32.2) |
| OU | 2 (6.45) |

| Number (%)
|---|
| Diabetes mellitus |
| 30 (96.7) |
| COVID-19 | 19 (61.2) |
| Intravenous Methylprednisolone | 19 (61.2) |
| Hypertension | 17 (54.8) |
| Ischemic Heart Disease | 1 (3.22) |
| Kidney Disease | 2 (6.45) |

| Number (%)
|---|
| Visual acuity |
| >3/60 to PL+ | 2 (6.45) |
| <6/18 to 3/60 | 2 (6.45) |
| <6/60 to 6/60 | 4 (12.9) |
| PL to 3/60 | 13 (41.9) |
| No PL | 8 (25.8) |
| Ophthalmoplegia | 24 (77.4) |
| Proptosis | 8 (25.8) |
| Keratitis | 2 (6.45) |
| Chemosis | 6 (19.35) |
| Necrosis | 1 (3.22) |
| Eyelid swelling | 9 (29.0) |
| Significant Fundus findings |
| CRAO | 2 (6.45) |
| Vitritis | 1 (3.22) |
| Disc Edema | 1 (3.22) |
| Disc Pallor | 2 (6.45) |
| PDR with VH | 1 (3.22) |

PL=Perception of light, CRAO=Central retinal artery occlusion, PDR=Proliferative diabetic retinopathy, VH=Vitreous hemorrhage
not seen in our study. Twenty-nine patients had uncontrolled type II diabetes mellitus (93.54%), and one patient had uncontrolled type I diabetes mellitus. Six patients had newly diagnosed diabetes mellitus at the time of presentation of mucormycosis. Twenty-four patients had an average duration of 4.4 years of diabetes. The average value of HbA1c of these patients was 7.57 mmol/mol. The most common clinical presentation was diminution of vision (<6/60 in 80.64% of patients) and ophthalmoplegia (77.4%) [Table 3]. The most common imaging findings were orbital cellulitis (61.29%) and pansinusitis (77.41%) [Table 4]. Intracranial extension in the form of cerebral involvement was seen in seven (22.58%) cases, internal carotid artery thrombosis in two (6.45%) cases, and cavernous sinus thrombosis in one (3.22%) case. Intravenous liposomal amphotericin B was given to all patients. The average duration of intravenous amphotericin B was 18.93 days. Exenteration was required in four (12.9%) cases [Table 5]. Twenty-eight patients (90.32%) recovered and were alive on the last follow-up during the study period. Mortality occurred in three patients. The first patient was a 25-year-old female with uncontrolled type I diabetes mellitus. She did not have a history of COVID-19 and steroid use. She presented with rhino-orbital cerebral mucormycosis. She was managed by the physician as per their protocol. Mucormycosis was treated by intravenous amphotericin B for 21 days with sinus debridement. Death occurred due to diabetic ketoacidosis with multiple organ failure. The second patient was a 60-year-old female diabetic and hypertensive with

### Table 4: Imaging findings

| Finding                                | Number (percentage) |
|----------------------------------------|---------------------|
| Orbital cellulitis (soft tissue inflammation) | 19 (61.29)         |
| Extraocular muscle involvement         | 6 (19.35)           |
| Optic neuritis                         | 3 (9.67)            |
| Bony orbital wall erosion              | 2 (6.45)            |
| Pansinusitis                           | 24 (77.41)          |
| Ethmoid and Sphenoid                   | 2 (6.45)            |
| Maxillary                              | 1 (3.22)            |
| Cavernous Sinus Thrombosis             | 1 (3.22)            |
| Cerebral Involvement                   | 7 (22.58)           |
| Internal Carotid artery thrombosis     | 2 (6.45)            |

### Table 5: Treatment of mucormycosis

| Treatment                                      | Number (percentage) |
|------------------------------------------------|---------------------|
| IV Amphotericin B (liposomal)                  | 31 (100)            |
| Sinus debridement                              | 31 (100)            |
| Exenteration                                   | 4 (12.9)            |

IV=Intravenous
negative COVID-19 history. She had rhino-orbital mucormycosis and was managed with intravenous amphotericin B. Death occurred early within 72 hours due to cardiopulmonary arrest. The third patient was a 71-year-old diabetic male with positive COVID-19 history and steroid use having rhino-orbital cerebral mucormycosis. He was managed with intravenous amphotericin B for 21 days with extensive sinus debridement and exenteration along with physician management. Death occurred due to diabetic ketoacidosis with multiple organ failure. Table 6 shows the factors associated with survival. Age, gender, COVID-19 positivity, presence of multiple systemic comorbidities, and management modality were not found to be significant. Presence of cerebral involvement and a HbA1c value of ≥8 were found to be significant in prediction of 75-day mortality with a P value significance of ≤0.05. There were no recurrences during the follow-up period in the surviving patients.

Discussion
Rhino-orbital mucormycosis is an aggressive fungal opportunistic infection of the immune-compromised, debilitated patients. The ubiquitous, naturally occurring fungus presents as a rhino-orbital cerebral infection in those with weak innate immunity to fight the external invading pathogen. Classically, the clinical presentation has been described as an orbital cellulitis with proptosis, visual loss, and apical neuropathies.[1] An early diagnosis with a prompt, well-coordinated, multidisciplinary approach has been vital to save both the life and sight of the patient. Microbiological diagnosis, control of the underlying systemic condition, and antimicrobial therapy with debridement of necrotic tissue have remained the mainstay of management of rhino-orbital mucormycosis over the years. Exenteration may not be absolutely necessary if well managed.[5] In our study, a large institutional cohort of rhino-orbital mucormycosis in the present COVID-19 ongoing pandemic was seen. The demographic profile of the patients was similar to those reported in the world literature.[2-4] The mean age of presentation was 56.3 years with a skew deviation toward the male gender (64.5%) vis-à-vis females (35.5%). The most common systemic risk factor was uncontrolled diabetes (66.7%). COVID-19 positivity and concurrent steroid use further decreased the immunity in 61.2% of patients. This correlation has been reported in studies of the COVID-19 era cited below.[2,3] Still a substantial proportion of our patients had uncontrolled diabetes without a history of COVID-19 and steroid use (32.25%). A single patient had no history of diabetes but had a history of COVID-19 with steroid use. The clinical presentation, imaging studies, and management of patients in our study were in keeping with the current COVID-19-era studies. We report the factors associated with survival. Age, gender, COVID-19 positivity, duration of diabetes, presence of multiple systemic comorbidities, and management modality were not found to be significant. The presence of cerebral involvement and a HbA1c value of ≥8 were found to be significant in prediction of 75-day mortality at a P value significance of ≤0.05.

Song et al.[5] reported fungal coinfections associated with the global COVID-19 pandemic based on a retrospective analysis. They presented epidemiology of fungal coinfections in COVID-19 patients based on a World Wide Web search. They also suggested the possibility of neglected fungal coinfections in COVID-19 patients by suggestive ideas from SARS (severe acute respiratory syndrome) and influenza worldwide data. They additionally provided a diagnostic and therapeutic pathway for invasive fungal coinfections. They reported that COVID-19 accompanied with immune-compromised state such as long-standing diabetes, HIV (human immunodeficiency virus), tumor, severe prolonged neutropenia, and so on were
more likely to develop fungal coinfection. Sen et al.\cite{10} reported six cases of rhino-orbital mucormycosis with a mean age of 60.5 years. The major risk factors were uncontrolled type 2 diabetes with systemic corticosteroids for COVID-19 in all patients. The patients presented with pain, redness, and periocular swelling. This was followed by acute progressive ptosis, ophthalmoplegia, and visual loss. These findings were similar to our study. Mehta and Pandey,\cite{5} Mekonnen et al.,\cite{6} and Werthman-Ehrenreich\cite{7} each presented with a case of concurrent COVID-19 infection with invasive rhino-orbital mucormycosis. In our study, concurrent COVID-19 with rhino-orbital mucormycosis has not been documented.

As per the present literature, we report a large institutional cohort of patients with rhino-orbital mucormycosis during the ongoing COVID-19 pandemic. Although only 61.2% patients had a positive documented history of COVID-19 infection in the recent past, the large cohort of rhino-orbital mucormycosis seen is a far cry from the very few patients seen in pre-COVID-19 era. The average pre-COVID-19 era annual incidence of mucormycosis in the past 5 years (2015–2019) at our institute was 2.8 per year. It has been well recognized in the clinical circles that the concurrent COVID-19 infection with subsequent systemic steroid use in patients with immune-compromised status as uncontrolled diabetes is the reason for the rise in mucormycosis cases. Our study also has a number of cases without COVID-19 infection positivity. A total of 38.70% (n = 12) patients in our study had no positive history of COVID-19 and steroid use.

Patel et al.\cite{8} reported a prospective multicenter study from January 1, 2016, to September 30, 2017, conducted at 12 tertiary-care centers across India. In the study, they reported rhino-orbital mucormycosis as the most common presentation (315/465, 67.7%) of mucormycosis. Diabetes mellitus was the most common predisposing factor (73.5%). Amphotericin B was the primary therapy (81.9%), and posaconazole was used as a combination therapy in 11.4% individuals. Surgical treatment was performed in 62.2% of the participants. The 90-day mortality rate was 52%. They reported that disseminated and rhino-orbital (with cerebral extension) mucormycosis, shorter duration of symptoms, shorter duration of antifungal therapy, and treatment with amphotericin B deoxycholate (vs. liposomal) were independent risk factors for mortality. A combined medical and surgical management was associated with better survival. This study was done over a long duration of 1 year and 9 months and conducted at 12 centers. Our study is a single-center study with short study period of 6.5 months. The previous study was of the non-COVID-19 era, whereas ours is of the COVID-19 era.

Brunet and Rammaert\cite{9} have recommended liposomal amphotericin B as the first-line therapy for the treatment of mucormycosis along with surgery whenever possible.

Nithyanandam et al.\cite{9} in their study on the clinical features and treatment outcomes of rhino-orbital cerebral mucormycosis have reported that debridement of sinuses is necessary in all cases of rhino-orbital cerebral mucormycosis. Diagnosis in the early stage needs a high index of suspicion. Orbit retention has a definite role to play in patients with controlled metabolic derangement and nonprogressive orbital involvement.\cite{9}

Other studies of pre-COVID-19 era have reported an increasing prevalence of mucormycosis in India due to increase in the cases of diabetes mellitus.\cite{9}

### Table 6: Factors predictive of survival of patients with mucormycosis

| Factor                                      | Survivors | NonSurvivors | P      |
|---------------------------------------------|-----------|--------------|--------|
| Age                                         |           |              |        |
| ≥45 years                                   | 25        | 2            | 0.266713|
| 45 years                                    | 3         | 1            |        |
| Gender                                      |           |              |        |
| Male                                        | 19        | 1            | 0.234929|
| Female                                      | 9         | 2            |        |
| Extent of Mucormycosis                      |           |              |        |
| Rhino-orbital                               | 23        | 1            | 0.054652|
| Rhino-orbital cerebral                      | 5         | 2            |        |
| COVID-19 history                            |           |              |        |
| Positive                                    | 18        | 1            | 0.29554 |
| Negative                                    | 10        | 2            |        |
| Mucormycosis Management                     |           |              |        |
| Medical+Debridement                         | 25        | 2            | 0.266713|
| Medical+Debridement+Exenteration            | 3         | 1            |        |
| Systemic conditions                         |           |              |        |
| Diabetes Mellitus                           | 8         | 2            | 0.196706|
| Diabetes Mellitus+Comorbidities (HTN/IHD/Kidney Disease) | 19 | 1 | |
| HbA1c values                                |           |              |        |
| ≤8.0%                                       | 24        | 1            | 0.02907 |
| >8%                                         | 4         | 2            |        |
| Duration of Diabetes                        |           |              |        |
| <5 years                                    | 16        | 1            | 0.389961|
| ≥5 years                                    | 11        | 2            |        |

HTN=Hypertension, IHD=Ischemic Heart Disease, P values obtained using Chi-square test. P value of <0.05 (rounded off to the 2nd decimal place) was taken as significant.
Notwithstanding the above, it may be speculated that Mucor infections are on the rise in the present times due to the rise in cases of uncontrolled diabetes associated with poor dietary control and medical care during the lockdown phase. Another hypothesis may be decreased natural reservoirs. Increased cases of aggressive fungal infection, especially mucormycosis, have been reported after natural disasters.[11,12] Further studies are needed to document the reasons for the unprecedented rise of rhino-orbital mucormycosis.

We present a large institutional cohort of rhino-orbital mucormycosis patients during the ongoing COVID-19 pandemic era from our unique perspective. The study was done in the ongoing COVID-19 pandemic era, which itself makes it novel. Ours is a multispecialty government hospital with a dedicated COVID-19 facility and a Regional Institute of Ophthalmology. Patients were seen as a team with Medicine, Otorhinolaryngology, Pathology, Microbiology, Radiodiagnosis, and Ophthalmology departments coordinating with each other at every level of patient management. Even at the time of sinus debridement, one Ophthalmology team member was involved and vice versa during orbital surgical intervention. All these variables together would render the institutional cohort distinctive. It goes without saying that the unique epidemiology of the geographical region renders the study exclusive.

Rhino-orbital mucormycosis is a known entity affecting the immune-compromised patients. Uncontrolled diabetes mellitus, COVID-19 infection, and steroid use are identified risk factors. Rhino-orbital mucormycosis has been reported in the world literature with the largest series in pre-COVID-19 era with 315 cases from 12 tertiary centers in India over a year and 9 months period with identifiable risk factors for 90-day mortality.[7]

The study adds probably the largest series of rhino-orbital mucormycosis in COVID-19 patients to the world literature (as per World Wide Web search). Nineteen patients had a history of COVID-19 positivity in our study from a single tertiary-care center over a short period. We reiterated the above risk factors for the infection. HbA1c ≥ 8 mmol/mol and cerebral involvement were associated with high mortality. On the other hand, age, gender, COVID-19 history, exenteration, and modality of management did not affect the final outcome. A dramatically higher prevalence at our center was seen in pre-COVID-19 versus COVID-19 era.

Where can we improve? Further studies to evaluate steroid use in COVID-19 patients with uncontrolled diabetes mellitus and safe dose of steroids to prevent subsequent rhino-orbital mucormycosis would be warranted.

Conclusion

There must be a high index of suspicion of rhino-orbital mucormycosis in COVID-19 era in all patients referred or presenting to the ophthalmologist with ophthalmoplegia and diminution of vision with or without history of concurrent uncontrolled diabetes mellitus. The numbers may represent just the tip of the iceberg. Further studies need to be done to document management modality and risk factors. Rhino-orbital cerebral mucormycosis and HbA1c ≥8 mmol/mol must be treated aggressively.

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Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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