Original Articles

Covid-19-associated rhino-orbito-cerebral mucormycosis (CAROM) in Delhi: Demographics and risk factors in a single-centre consecutive cohort of 200 inpatients

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ABSTRACT

Background. There was a dramatic rise in the incidence of rhino-orbito-cerebral mucormycosis associated with the 2021 Covid-19 wave in India. We aim to document the demographic characteristics and risk factors of a consecutive cohort of inpatients with Covid-19-associated rhino-orbito-cerebral mucormycosis (CAROM) during the surge of April–June 2021.

Methods. We included all patients of CAROM treated at our tertiary referral facility from 1 April to 14 June 2021. We prospectively gathered details with regard to Covid-19 illness and treatment, CAROM presentation, comorbid conditions and risk factors.

Results. Our prospective cohort consisted of 200 consecutive patients, of which 146 (73%) patients tested positive on the Covid-19 RT-PCR test at presentation. CAROM occurred concurrent with the Covid-19 infection in 86%, and delayed CAROM after seeming recovery from Covid-19 was seen in 14%. Covid-19 was classified as mild, moderate and severe in 54%, 33% and 13%. The surge of CAROM followed the population peak of Covid-19 infections by about 3 weeks. Advanced disease at presentation was frequent with ocular involvement in 56.6% (111/196) and central nervous system involvement in 20% (40/199). One or more comorbid conditions were identified in 191/200 (95.5%) patients. The dominant associations were with diabetes (189/200; 94.5%) and uncontrolled hyperglycaemia (122/133; 91.7%), recent steroid use (114/200; 57%), which was often considered as inappropriate in dosage or duration, lymphopenia (142/176; 80.7%), and increased ferritin levels (140/160; 87.5%). No evidence supported the role of previous oxygen therapy or previous nasal swab testing as risk factors for CAROM.

Conclusion. The inpatient volumes of CAROM were noted to parallel the Covid-19 incidence curve by about 3 weeks. Covid-19 infection may directly predispose to CAROM by way of lymphopenia and increased ferritin levels. Uncontrolled hyperglycaemia is identified as a near-invariable association. Recent steroid use is noted as very frequent and was often received in excess of treatment advisories.

Natl Med J India 2022;35:132–7

INTRODUCTION

The ongoing Covid-19 pandemic has so far affected over 17.3 crore individuals with over 37 lakh deaths worldwide. India suffered the second Covid-19 wave in the early part of 2021 caused by SARS-CoV-2 delta variant, and till 31 May 2021, a total of 28.8 million (2.88 crore) individuals have been infected.[1] The epidemic was additionally impacted by an unprecedented surge of rhino-orbito-cerebral mucormycosis (ROCM), which is out of proportion to previous estimates. ROCM, an opportunistic infection associated with immunosuppression, had been noted previously with the SARS/MERS epidemics and was also noted to increase with the onset of Covid-19.[2–5] Previous estimates from India of the occurrence of ROCM complicating Covid-19 were 0.25%–0.27%.[4,6] The exact incidence of CAROM for the current epidemic is, however, not yet clear.

Mucormycosis progresses rapidly and may turn lethal if not diagnosed and treated timely with appropriate antifungals and surgical debridement. The mortality rate is higher with cerebral

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[**To cite:** Singh A, Sikka K, Goel G, Kanodia A, Chandran A, Konkimalla A, *et al.* Covid-19-associated rhino-orbito-cerebral mucormycosis (CAROM) in Delhi: Demographics and risk factors in a single-centre consecutive cohort of 200 inpatients. *Natl Med J India* 2022;**35**: 132–7.]

extension or disseminated illness. A mortality rate of 31%–49% has been reported in Indian patients suffering from ROCM,[7] and a similar figure of 40% has been reported globally.[8]

The exact factors predisposing to the dramatically increased incidence are not yet fully understood. This report on 200 consecutive patients gives the time course of the epidemic and documents an initial evaluation of the associated comorbid conditions and risk factors which contribute to the illness.

METHODS

This prospective cohort included consecutive patients admitted with ROCM at the All India Institute of Medical Sciences, New Delhi, from 1 April to 14 June 2021. This period relates to an abrupt rise in the number of cases of Covid-19 in New Delhi and neighbouring areas ('second Covid wave').[9] Institutional ethics committee's approval was obtained. The initial diagnosis was made on clinical grounds and confirmed by microbiological and pathological examination of nasal swabs or tissue that showed aseptate broad irregularly branching hyphae typical of mucormycosis.

The admitted patients were enquired about a past history of Covid-19 and evaluated for current Covid infection using nasal and throat swabs for reverse transcription polymerase chain reaction test (RT-PCR). A thorough history eliciting underlying diabetes, other comorbid conditions, or immunosuppressive state was obtained. In patients who had recovered from Covid-19, the severity of Covid-19 and dosage and duration of steroid intake were enquired. Based on the treatment guidelines for mild disease,[10] use of steroids was judged as appropriate or not.

In addition to the complete blood counts, serum biochemistry, blood sugar levels, and serum HbA1c levels, the serum levels of ferritin were documented. To map the extent of mucormycosis, a computed tomography (CT) or magnetic resonance imaging (MRI) was obtained. Antifungal treatment was started on the day of admission, and debridement was carried out using an endoscopic or external approach. Antifungals (liposomal amphotericin, or tablet posaconazole if the patient did not tolerate the former) were continued in the postoperative period for a few weeks with ongoing clinico-radiological assessment of the patient for disease resolution. Patients were staged as per the staging system proposed by Talmi *et al*.[11]

The collected data were tabulated using Microsoft® Excel 2020 (Version 16.36) for Mac. Continuous variables were summarized as mean (standard deviation; range) or median (interquartile range) depending on the type of data distribution, and categorical variables as absolute numbers and percentages.

RESULTS

The study group included 200 inpatients with sinonasal mucormycosis confirmed by microbiological or pathological demonstration of broad aseptate hyphae. Nearly all the patients (185 [92.5%]) had had a positive test confirming Covid-19 either in the recent past or at the current admission, while 15 had had a Covid-like illness but a negative test or were not tested. Two-thirds of the patients were men and the mean age was 50.6 years (range 17–76 years; Table I).

The majority of patients were Covid-positive (146/200) and needed admission in a Covid-19 care facility. Concomitant Covid-19 and mucormycosis infection was predominant (159/200), and a delayed mucormycosis infection post-recovery from Covid-19 was less frequent (26/200). The onset of symptoms of mucormycosis ranged from 38 days before the diagnosis of Covid-19 to 115 days after the diagnosis (Fig. 1). In the group where mucormycosis preceded or occurred within 10 days of Covid-19, an RT-PCR test was almost invariably positive (Fig. 1). In patients with onset of mucormycosis 10 days from the onset of Covid-19 too, RT-PCR tests were frequently positive, suggesting ongoing disease activity (Fig. 1).

The number of patients admitted to our facility on a per-day basis and the daily cases of Covid-19 in Delhi are shown in Fig. 2. The two curves are parallel to each other with the mucormycosis curve showing a lag of about 3 weeks to the Covid-19 curve.

Data regarding the severity of Covid-19 was available in 178 patients and the majority of them (96/178; 54%) had mild disease. Around 40% of the patients had received treatment at home.

The majority of patients had diabetes or impaired glucose tolerance (189/200; 94.5%; known to have diabetes or impaired random sugar levels or HbA1c values at admission) with mean (SD) HbA1c levels (data available for 135 patients of which 133 were people with diabetes) of 10.1 (2.2%) at the time of admission. Seventy-seven of the 189 patients had been recently detected to have diabetes (40.7%). Of these 77 patients, only 2 had HbA1c values <6.5%. In addition, of 133 patients for whom HbA1c data were available, 122 patients had poor control of diabetes (HbA1c >7% at the time of admission). Only 11 patients had a normal value of HbA1c (<6.5%). The other comorbid illnesses are detailed in Table I. Only 9 patients (9/200; 4.5%) had no detected or reported premorbid illness.

A definite history of steroid use was present in 114 patients. In 19 patients, this aspect could not be identified (data not available or unclear history). Sixty-seven patients did not receive steroids. Details of dose and duration could be ascertained for 92 of 114 patients (Table II). The median duration of steroid use was 10 days (IQR 7–14 days). The daily median dose of steroid (methylprednisolone equivalent) was 42.53 mg (IQR 32–80 mg), while the median total dose per patient received in the last month was 338.5 mg (IQR 182.5–739 mg). A large proportion of patients with mild Covid-19 had received systemic steroids (52/96; 54.2%) with the majority of such steroid use in the home-care setting (33/52; 63.5%). Such use of steroids was judged as inappropriate.

Oxygen supplementation for Covid-19 was received by 81 (41.8%) of 194 patients. Sixty-nine patients received it in the hospital setting, 12 patients received at home, while 8 patients used oxygen in both home and hospital setting. Of the 20 patients (20/81; 24.7%) who received oxygen at home, 10 patients used it for mild Covid-19 illness. Three patients used oxygen concentrators, 9 used home oxygen cylinders, while 1 patient used both. Home filtered water was used for humidification in 9 patients who used oxygen cylinders at home (details were not available for the tenth patient).

Approximately one-third of the patients (71/199; 35.7%) presented with advanced stage-4 disease (Table III and Fig. 3).

Clinical ocular involvement was a common finding with 43 (43/196; 21.9%) patients presenting with reduced visual acuity and 62 patients (62/196; 31.6%) presenting with blindness. On examination, 63 patients (63/196; 32.1%) had a frozen globe at the time of presentation, while another 39 (19.9%) had restricted ocular motility. Eighty-five patients (43.4%) had normal visual acuity and ocular motility.

Laboratory evaluations revealed lymphocytopenia in 80.7% of the patients tested (142/176). The median proportion of

TABLE I. Demographic and clinico-radiological details of the rhino-orbito-cerebral mucormycosis (ROCM) patients (*n*=200)

Clinico-epidemiological parameter	*n* (%)
Mean (SD) age	50.6 (12.3) years
Gender distribution (men:women)	136:64
Covid-19 test status	
Positive test at current illness	146 (73)
Positive test previously	39 (19.5)
Covid-like illness but negative test/not tested	15 (7.5)
Covid-ROCM chronology	
Concurrent mucormycosis and Covid-19	159* (85.9)
Delayed mucormycosis after Covid-19 recovery	26 (14.1)
Covid-19 disease severity† (*n*=178)	
Mild	96 (53.9)
Moderate	58 (32.6)
Severe	24 (13.5)
Comorbid conditions‡ (*n*=199)	
Diabetes mellitus	189 (94.5)
Known	102
Newly diagnosed	77
Duration not known	10
No diabetes	10
Blood sugar levels at presentation (*n*=165)	Median 236; IQR 166–342.5
HbA1c (*n*=135)	10.1(2.2)%†
Hypertension	64
Coronary artery disease/cardiac illness	12
Hypothyroidism	11
Chronic kidney disease	10
Post-renal transplant	2
Asthma	5
Obesity, stroke, haematological disorder	3 each
Tuberculosis (present or past)	2
Solid organ malignancy, ventriculoperitoneal shunt, decompensated chronic liver disease	1 each
No comorbid conditions	9
Data not available	1
First symptom experienced by the patient (*n*=193)	
Naso-facial (*n*=110)	
Nasal pain, nasal discharge, nasal bleed	4 each
Nasal blockage/congestion	6
Frontal headache	27
Facial pain	35
Facial swelling	8
Facial numbness	10
Tooth/palatal pain	12
Ocular (*n*=79)	
Periorbital pain	47
Periorbital swelling	11
Periorbital numbness	1
Ptosis	5
Watery eyes	9
Decreased vision	6
Neurological (n=4)	
Altered sensorium	2
Headache	1
Facial weakness with hemiparesis	1

Laboratory parameter	*Observed values (median and IQR)*	*Normative values*
TLC‡ ($\times 10^3$)/ml	10.5 (7.95–15)	4–11
Lymphocyte¶ (% of TLC)	10 (7–17)%	20%–40%
Serum ferritin§ (ng/ml)	968.6 (583.8–1500)	30–400

Covid-19 treatment setting (*n*=179)	
Home	70 (39.1)
Hospital	109 (60.9)
Oxygen requirement (*n*=194)	
No	113 (58.2)
Yes	81 (41.8)
In hospital	69
At home	12
At home+in hospital	8
History of steroid intake (*n*=200)	
Yes	114 (57)
No	67 (33.5)
Unclear history/data not available	19 (9.5)

IQR interquartile range TLC total leucocyte count NA not available * Three patients had symptoms of mucormycosis onset antedating (by 10, 8, and 4 days; respectively) Covid positive test ** Covid-19 severity index is detailed in methodology section # Some of the patients had more than one associated premorbid conditions † HbA1c values (available in 135 patients) were >6.5% in majority of the patients (125/135; 92.6%) with ROCM ‡ *n*=177 ¶ *n*=176 § *n*=160

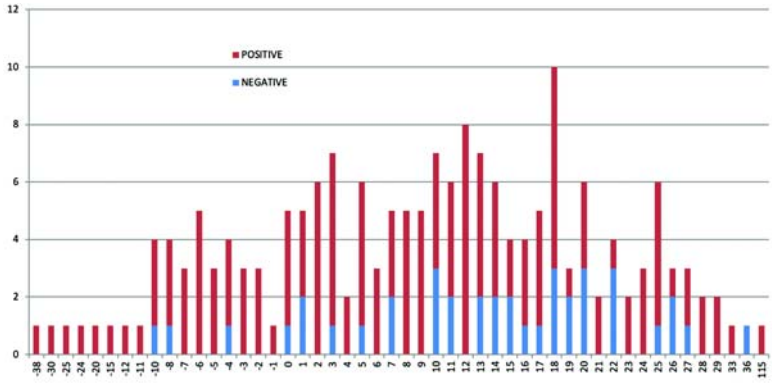

FIG 1. Patient distribution with respect to Covid-rhino-orbito-cerebral mucormycosis interval and Covid-19 reverse transcription-polymerase chain reaction test (RT-PCR) status at the time of admission. The shaded part on the right side of the curve shows Covid-19 status (RT-PCR) in patients presenting with mucormycosis >10 days after being previously diagnosed Covid-19. As can be seen, most of the patients continued to be Covid-19-positive >10 days after the first diagnosis of Covid-19

TABLE II. Details of steroid use in patients with rhino-orbito-cerebral mucormycosis during the Covid-19 pandemic (*n*=92)*

Steroid use-related parameter	Median	IQR	Range
Days of steroid use	10	7–14	1–36†
MPS equivalent maximum daily dosage	42.53	32–80	4–1000
MPS equivalent dosage in one week	260	160–560	4–3125
MPS equivalent dosage in one month	338.5	182.5–739	4–3125

IQR interquartile range MPS methylprednisolone * patients with history of steroid intake †3 patients were receiving steroids for >8 months for non-Covid indications

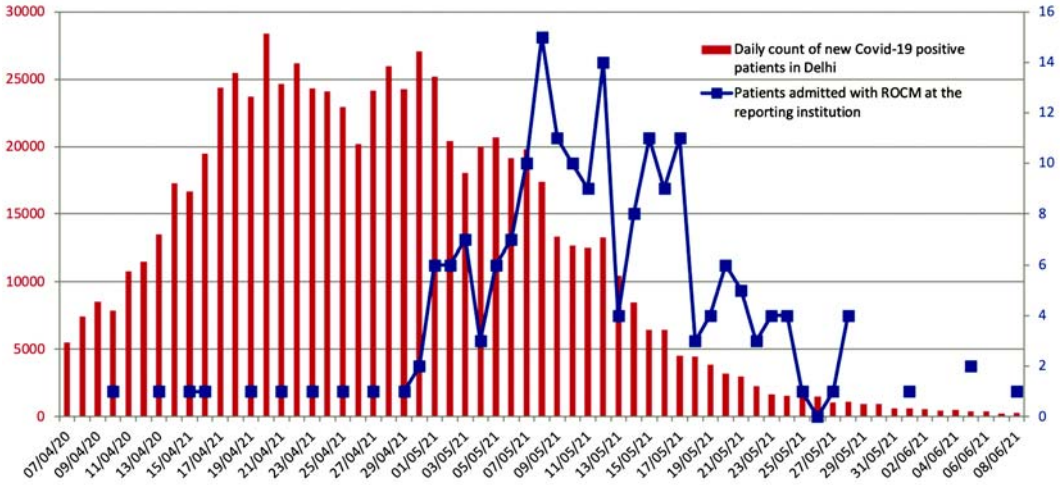

FIG 2. Delhi Covid-19 peak versus rhino-orbito-cerebral mucormycosis (ROCM) load at our institute

TABLE III. Stage-wise distribution of rhino-orbito-cerebral mucormycosis in the patients (*n*=199) at presentation*

Stage	Description	*n* (%)
1	Limited to nose with limited invasion	6 (3.0)
2	Limited to nose, sinus and orbit†	108 (54.3)
3	Involvement of intracranial structures‡ with unimpaired or limited impairment of cognition	14 (7.0)
4	Total¶	71 (35.7)
	Intracranial involvement with unconsciousness or hemiplegia‡	26
	Bilateral disease	22
	Skin necrosis	13
	Palate involvement	57

* staging system adopted from Talmi *et al*.[11] †this stage includes nose and sinus involvement with or without orbital involvement. Orbital involvement is not synonymous with reduced visual acuity or ocular motility. Orbital involvement with reduced visual acuity or restricted extraocular movement or both, was present in 56.6% (111/196) of patients ‡ central nervous system involvement was present in a total of 40 patients (14 patients with stage-3 and 26 patients with stage-4 disease) ¶ some patients with involvement of more than one subsites needed to be categorized as stage 4

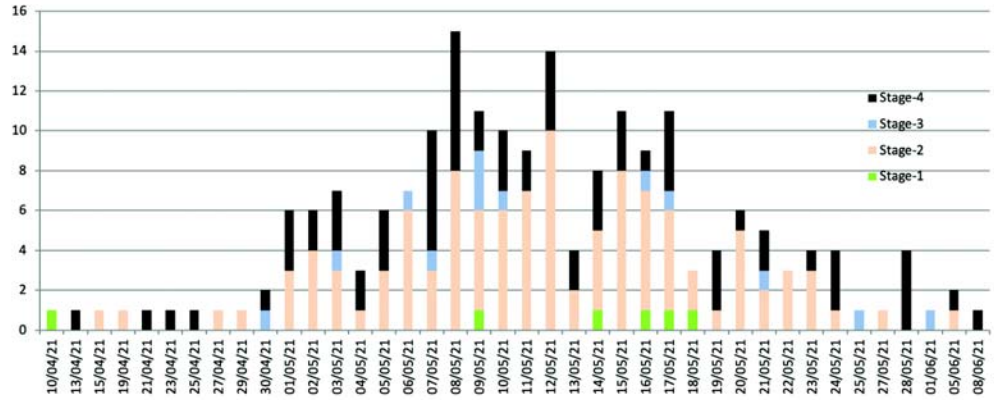

FIG 3. Timeline showing daily rhino-orbito-cerebral mucormycosis (ROCM) patient load with the mucormycosis stage at presentation

lymphocytes (in terms of % of total leucocyte count) was 10% (IQR 7%–17%; normal range 20%–40%). Ferritin levels were above the normal range in 87.5% of the patients tested (140/160), and the median value noted as being considerably raised at 968.6 ng/ml (IQR 583.8–1500; normal range 30–400 ng/ml). Persistent Covid-19 RT-PCR positivity beyond 10 days of initial RT-PCR positivity was very frequent (Fig. 1).

DISCUSSION

The epidemic of ROCM accompanying the second wave of Covid-19 in India imposed an overwhelming challenge for the healthcare system already pressed with the burden of Covid-19. This report details demographics and risk factors of 200 consecutive patients admitted with Covid-19-associated ROCM (CAROM) during April–June 2021. It is the largest single-centre experience published to date on CAROM. It confirms the previous impressions of the host immunosuppression being predominantly driven by uncontrolled hyperglycaemia (94.5%), by steroid use and overuse (57%), and a probable Covid-19-related immunosuppression (lymphopenia 80.7%). The majority of patients were RT-PCR-positive at admission (73%), even in situations with >10 days from disease onset, indicating to a more protracted clinical course of Covid-19 in these patients.

The previous SARS epidemic of 2004 as well as the Covid-19 pandemic too were noted to be associated with invasive fungal infections.[2,4,6] However, the March–May 2021 wave of Covid-19 in India has been particularly devastating in this regard. Experiences with regard to CAM in 2020 have been contradictory with regard to the temporal relationship between Covid-19 and mucormycosis. Patel *et al*.[6] in a retrospective multicentric study noted the majority of patients with CAROM (158/187) present late (>8 days from onset of Covid-19 infection). However, this was not our experience even in the first Covid-19 wave-associated CAM[4] wherein concurrent presentation was usual and delayed CAM only noted in 12.5%. This particular experience too notes of concurrent presentation of mucormycosis and Covid-19 being predominant (Table I, Fig. 1). The subset of patients wherein mucor symptoms have predated Covid-19 symptoms or diagnosis perhaps indicates to Covid-19 being asymptomatic or mild in its initial presentation, and to being detected only on RT-PCR testing at presentation with mucor. As shown in Fig. 2, however, the peak of the admitted patients with ROCM followed the peak of Covid-19 patients in Delhi during the second wave by about 3 weeks. This temporal relationship of the ROCM and Covid-19 peaks further supports the previous observation that mucormycosis is consequent to the effect of Covid-19 and its treatment.

Some limitations to this analysis relate to data gaps on some aspects. This was primarily as detailed history taking was not possible with patients suffering from multiple neurological and pulmonary issues and requiring oxygen or ventilatory support. Cultural practices in India wherein medicines can be procured without medical consultation and prescriptions, additionally compounded our inability to deeply investigate previous treatments. Further, a degree of reticence on the part of patients to admit to a diagnosis of Covid-19 and to treatments undertaken without prescription hampered complete data acquisition.

Time trends (Fig. 2) indicate to an initial rapid incline and subsequent decline in the number of cases presenting with CAROM. The decline in incidence of CAROM is probably related to the overall decline of Covid-19 itself. It is also probable that the efforts towards education and public awareness in the initial phase decreased the inappropriate use of steroids. The time trends also indicate a trend to earlier presentation in the naso-maxillary stage as the epidemic progressed (Fig. 1), and this too may be consequent to the education and awareness among the general public and physicians of the early manifestations of the illness.

This experience also validates previous publications[12,13] with regard to early sentinel signs of the infection. Naso-facial symptoms (facial pain, swelling, and paraesthesia) were the predominant initial symptoms experienced by our cohort. Nasal obstruction and discharge were present as primary symptoms in only 5 patients. Ocular symptoms as presenting complaints were seen in a large majority, but many of these were in the form of periorbital pain and swelling, which may be considered as facial symptoms. Visual symptom as initial presenting symptom in the form of blurring of vision, ptosis, or epiphora was present in only 20 patients. Only 3 patients presented with altered sensorium/hemiparesis.

Immune compromising comorbid illnesses were almost invariable (191/200), with many patients having multiple comorbid conditions (Table I). Diabetes was noted in 189/200 (94.5%) and 77 of these were newly diagnosed at this illness. Previous reports from India with regard to Covid-19 unrelated mucormycosis too have reported diabetes as the predominant comorbid illness,[3,7,13,14] and the unmasking of an underlying undetected diabetes is noted in as many as 24%–43% of patients presenting with mucormycosis.[7,13,14] Diabetes leads to impaired macrophage and neutrophilic phagocytic action, and hyperglycaemia and diabetic ketoacidosis lead to increased availability of free iron in the serum, thus promoting mucormycosis growth and pathogenicity. Indian adults have a very high prevalence of diabetes (8.9%).[15] Moreover, Covid-19 itself is pro-diabetogenic by causing direct damage to the pancreatic islet β-cells and creating a state of insulin resistance caused by the massive cytokine storm characteristic of the illness.[16–18] However, this particular experience indicates to new-onset diabetes being a rare phenomenon, as only 2 of the 77 patients with newly detected diabetes had HbA1c values <6.5, indicating that the vast majority of these were patients with undiagnosed pre-existing and poorly controlled diabetes rather than new-onset diabetes.

The other major factor noticed in a majority of our patients was usage of steroids for Covid-19 infection. A clear history of steroids intake (oral or systemic) was present in 57% of the patients, while 33.5% did not receive steroids. The median duration of steroid use was 10 days (median total dosage of methyl prednisolone (MPS) equivalent 338.5 mg). The use of steroids, especially for prolonged periods, results in immunosuppression and also glycaemic derangement, and is a well-documented risk factor for invasive fungal infections including ROCM.[7,8] Recently reported experiences in smaller cohorts of Covid-ROCM by Sharma *et al*.[3] and Moorthy *et al*.[13] have noted steroid use in 100% and 89%, respectively.

Since we were not privy to the patient's clinical situation which necessitated such steroid use, it would be inappropriate to judge whether such steroid use was appropriate in individual patients. However, some patients have received excessively high doses (Table III), and also a fair proportion of patients classified as mild Covid-19 have received steroids (52/96; 54.2%). Often, patients with mild Covid-19 have received steroids in the home-care setting (33/52; 63.5%). Since guidelines do not recommend steroid prescriptions for mild Covid-19 illness, this

does make apparent that the number of patients receiving steroids far exceeds the number of patients wherein it would have been indicated as per guidelines.[10]

Covid-19 infection itself, too, seems predisposing to derangement of immune function and susceptibility to mucormycosis. Support for the hypothesis is lent in this report by the associated findings of persistent RT-PCR positivity beyond 10 days of the illness in a majority of these patients (Fig. 1), and laboratory evaluations indicating frequent lymphopenia and elevated ferritin levels (Table I). The clinical course of ROCM is known to be exacerbated by the availability of iron, and high ferritin levels are known to lead to increased iron availability. High ferritin levels are a known risk factor for the development of mucormycosis and to its increased disease severity and progression.[19]

There have been widespread speculations in the media regarding the role of dietary factors and nutritional supplements and if a specific variant of the virus predisposes to CAROM. These questions are not addressed in this report.

There is also speculation concerning mucormycosis being caused by mucorales spores inhalation with oxygen therapy, particularly with oxygen delivered without medical supervision. It is also speculated that nasal mucosal trauma caused by testing for Covid-19 is leading to epithelial breach and implantation of mucormycosis into the tissues. In this particular experience though, most patients did not receive any oxygen, and only 18 patients received oxygen outside of a hospital setting. Similarly, only a minority of patients had had a recent Covid-19 test before the diagnosis of mucormycosis (Table I). The observations in this dataset indicate that the majority of our patients did not have exposure to these factors and therefore do not support the above speculations.

Conclusion

The triad of poor glycaemic control, steroid therapy for Covid-19, and Covid-induced immunosuppression is proposed as underlying the recent epidemic of CAROM.

Uncontrolled hyperglycaemia is identified as a near-invariable association with CAROM. Recent steroid use is noted as very frequent, and on occasion not in keeping with advisories and guidelines. Immune compromise is suggested by persistent Covid positivity on the RT-PCR test and frequent lymphopenia.

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