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COVID-19 EXPERIENCE: AN OBSERVATIONAL CASE SERIES FROM A SINGLE TERTIARY CARE RURAL CENTRE IN NORTHERN INDIA

Clinical Research

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ABSTRACT

Introduction & Aim: COVID19 has been declared a pandemic by World Health Organization(WHO) on March, 2020. We hereby aim to identify the epidemiologic factors, comorbidities, clinical and laboratory features from a tertiary care hospital in Haryana, for better management of future cases. **Methods:** Data of 106 consecutive patients admitted with Covid19 admitted at our facility was analyzed retrospectively. Laboratory data included complete blood count, differential blood count, liver and renal function tests. The outcome was noted as discharged- after at least two consecutive nasal or nasopharyngeal swab specimens turn negative, taken at a gap of 24 hours, or patient developed respiratory failure and shifted to Intensive Care Unit (ICU). **Results:** Median age was 37+/-10.0 years. Male: Female ratio 16.67:1 Most of the patients of this cohort were asymptomatic (77.35%). The commonest symptom was fever (13.20 %), Mean saturation was 96%, no patient was hypoxic, no patient was in shock. Hydroxychloroquine(HCQ) alone was given to 92 (88.09%) of patients and in combination with Azithromycin to 10 (11.90%). No one developed severe disease or needed oxygen or ventilatory support. No adverse side effects were observed. **Conclusion:** All patients were stable and discharged after swab conversion. All these patients had a mild disease with minimum multi-organ derangements. Hydroxychloroquine alone or in combination with azithromycin can be safely administered to COVID19 patients. Further investigations are needed to formulate a specific treatment protocol.

KEYWORDS

COVID19; Clinical data, India

INTRODUCTION

Severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) is the novel Coronavirus first detected in Wuhan, China, that causes Coronavirus disease 2019 (Covid-19).1 On December 2019, cases reported, all linked to the Huanan Seafood Market, were identified by local hospitals. The identified pathogen is described as a novel enveloped RNA betacoronavirus2 that has currently been named Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (as is similar to SARS-CoV.3).

The World Health Organization (WHO) has recently declared coronavirus disease 2019 (COVID-19) a pandemic.

On 30th Jan 2020 first case of COVID-19 was identified in Kerala in India. As per ICMR (Indian Council of Medical Research), we are between stage 2 and 3- signifying localized spots of local transmission, relative early phase of pandemic.

Shahid Hasan Khan Mewati Government Medical College, Nuh with 600 bed strength is one of the nine dedicated exclusive COVID-19 hospitals of the state.

We hereby aim to identify the epidemiologic factors, comorbidities, clinical and laboratory features from a tertiary care hospital in Haryana, the centre with the largest number of COVID-19 patients in the state, for better management of future cases.

METHODOLOGY

This study is a single center, retrospective observational case series of COVID-19 positive patients who presented in our Centre, Shaheed Hasan Khan Mewati Government Medical College, Nalhar, Haryana between March 25th to April 30, 2020. Initially they were admitted in isolation ward as COVID-19 suspects-defined as per MoHFW (Ministry of health and family welfare, India)- as, symptomatic patient [defined as per WHO criteria for ILI (Influenza Like Illness) as- an acute respiratory infection with-

1. measured fever of more than 38 degree centigrade
2. cough
3. with onset within the last 10days
4. SARI- In addition to the above requiring hospitalization.

with travel history to countries with COVID-19 patients over the previous 14 days, or who exposed themselves to a COVID-19 positive patient in the community or health care workers involved in close contact with COVID-19 patients.

COVID-19 positive patient was defined as per the WHO 1 as a positive result on real-time quantitative reverse-transcriptase–polymerase-chain-reaction (RT-PCR) 1 assay of nasal and pharyngeal swab specimens sent to laboratories recognized by Government of India.

We defined the degree of severity of COVID-19 (as per guidelines of MoHFW) at the time of admission as:

1. Uncomplicated cases
2. Mild pneumonia
3. Severe pneumonia
4. Acute respiratory distress syndrome
5. Sepsis
6. Septic shock

DATA COLLECTION

These subjects were enrolled in this study. A structured proforma was prepared to capture relevant epidemiological, demographic, clinical, laboratory, management, and outcome data. Patients' medical records and data from Medical Records Department (MRD) were also reviewed. All data was checked by two physicians. Researchers also directly communicated with patients to ascertain epidemiological and symptom data.

Laboratory data included complete blood count, differential blood count, liver and renal function tests.

Patient privacy and confidentiality was specially taken care.

MANAGEMENT

Supportive treatment was started as needed, saturation percentage measured by pulse oximeter was noted.

Patients with fever were started on tablet azithromycin (500mg) once a day for five days, in addition to tablet hydroxychloroquine (400mg) twice a day for first day, followed by once a day for at least five days can be extended up to ten days. Patients without fever were given only tablet hydroxychloroquine.

The outcome was noted as discharged- after at least two consecutive nasal or nasopharyngeal swab specimens turn negative, taken at a gap of 24 hours, or patient developed respiratory failure and shifted to ICU. We sent nasal and nasopharyngeal swabs for quantitative RT-PCR of healthcare workers on the 5th and 14 day of assumed exposure to COVID-19 positive patient.

STATISTICS

The data were coded and analysed using SPSS, version 22. Frequencies and proportions were used to present the data.

RESULTS

DEMOGRAPHIC RESULTS

During the study period spanning from 25th March to 25th April, 2020, we had 106 COVID-19 positive patients. There was a male predominance, with 100 (94.33%) patients and only 6 female patients. The median age of patients were 37±10.0 years, the youngest and oldest patient in the cohort being 15 and 80 years respectively.

Out of these patients, 12 (11.32%) were foreigners- 6 from Sri Lanka,3 from Bangladesh, 1 from Thailand, 1 from Indonesia, 1 from Cote d Ivory. Amongst the Indian patients a total of 54 patients belonged to different states across India.

Out of these patients, 83 patients (78.30%) had travel history to New Delhi at a congregation - coming from various countries and Indian states. However, no patient had any history of travel from China. Three patients (2.03%) were known hypertensive, 2 were diabetics and 1 patient was a known patient of bronchial asthma. 60% of these patients were also known smokers.(refer to supplement).

CLINICAL FEATURES

Most of the patients of this cohort were asymptomatic (77.35%). The commonest symptom was fever (13.20 %), followed by cough- mainly dry in 9.4 %, 2.8% patients had headache and generalized malaise and sore throat respectively. Diarrhea was present in 1.8 % patients, while 0.94 % patients had shortness of breath (see table1).

On auscultation, the chest was clear in most patients. Two patients, one of whom was a known asthmatic had rhonchi on auscultation. Mean saturation was 96%, no patient was hypoxic, no patient was in shock.

LABORATORY FEATURES

The average hemoglobin was 12.89gm/dl, average total leucocyte count (TLC) was found to be 12,300/cumm. Lymphopenia as defined by absolute lymphocyte count of less than 1000/cumm, was found in 4.7% of patients. 7.5% of patients had thrombocytopenia (platelets less than 1.5* 109 /cumm),while the mean value of platelets count was 2.64* 109/cumm).The mean creatinine was calculated to be 0.95 mg/dl, none of the patients had deranged creatinine. On analysis of transaminases, transaminitis (as defined by elevation of transaminases by at least 3 times the cut-off value) was found in 1 patient. All patients had normal chest radiograph. CT Scan was not done.

TREATMENT

Fourteen patients had fever, these patients were started with azithromycin in addition to hydroxychloroquine. Two patients developed gastritis and nausea but was managed with addition of pantoprazole and domperidone to the regimen. None of the patients developed any chest pain or palpitation, even though due to shortage of PPE kits we could not monitor such patients as per the protocol.

All health care workers, involved in duties in the isolation ward, were started on hydroxychloroquinine 800mg on first day, followed by 400mg once a week, for seven weeks (as per ICMR protocol).

OUTCOME

All the patients were clinically stable and no patient required any supplemental oxygenation or ICU care.

Till date, ALL 106 patients have been discharged- as their nasal and pharyngeal swabs show negative result for COVID-19 RT-PCR for at least two consecutive times, taken 24 hours apart. No death has been reported till date in our cohort.

The mean time for swab conversion was 8.5 days. 46 patients (43.4%) showed conversion of sputum in the second sample (taken at least 5 days after diagnosis). 30 patients (28.3%) showed swab conversion after second sample. The same number of patents showed swab conversion after third sampling.

Swabs performed on 50 health care workers involved in management of such patents tested negative. Out of them, Male to female ratio in this subgroup was 4:1. Out of them, 30 are nursing staff, 15 doctors and 5 cleaning attendants. The median age of this subgroup was 36+/- 4 years. The median time period of prophylaxis is 4.5+/ 2.0 week. Till date all of them are continuing HCQ. None developed any nausea, vomiting or palpitation. ECG was not done. No major adverse side effects were noted due to HCQ amongst healthcare providers

DISCUSSION

Similar to studies described3[4,8,9,10], 78.3% of patients had some contact with foreigners travelling from high burden countries.

The median age was 37± 10.0 years, in contrast to studies across the world, where the mean age reported varied between 47 years to 56 years [3,8,9,10,11]

In our study, more than 77.85% of patients were asymptomatic, may be related to a relatively young population. This is the main issue in transmission of patients across India. Arons et al1reported such an outbreak of COVID-19 in a nursing facility in Washington State. 63% had positive results on swab but 56% were asymptomatic but had viral shedding up to 6 days before development of symptoms. Thus, symptom based screening alone would fail to diagnose cases and thus transmission of the disease. A new strategy thus described by ICMR has been adopted- rapid antibody card test in addition to swab testing for patients coming from hotspots, health care workers, irrespective of symptoms.[6,7],.

In our cohort, the commonest symptom was fever and cough, as evidence worldwide also shows similar findings. On analysis of the laboratory features, overall total leucocyte count and platelets, renal and liver function tests were found to be normal in most patients. Thus, we couldn't define any laboratory anomaly pathognomonic of COVID-19 patients. Only 4.7% of patients had lymphopenia which is predicted in 83.2% in studies by Guan etal,4 39% in the study by Young etal9. This discrepancy might be explained in lines of a less severe disease causing less impairment of hematologic and biochemical parameters.

All patients were started on tablet hydroxychloroquine for at least five days, extendable up to ten days, in febrile patients, tablet azithromycin was also added. All these patients had subsequent swab conversion and discharge. Unfortunately, across the world, no specific treatment protocol could be formulated till date. Studies across China and Europe showed improvement in viral shedding post treatment with hydroxychloroquine as compared to controls without any treatment. Adding azithromycin to hydroxychloroquine was synergistic.12,13 Recently, a trial in United States also showed significant improvement with Remdesivir, a nucleoside analogue prodrug, has shown promising results, may also get FDA approval. However, further studies are needed to refute this drug regimen.

As per the guidelines of ICMR, hydroxychloroquine and azithromycin were advised in severe cases.5,6 We treated all cases with hydroxychloquine with or without azithromycin. These were during the early stages of the pandemic, we wanted to ensure there is no community spread. Most of these patients also had history of travel and exposure to a congregation, hence contact tracing was difficult. At that stage we also had limited number of ICU beds and ventilators, we wanted minimum complications related to COVID-19. These being orally administered medicines were also logistically easier to provide. Colson et al12 showed similar efficacy of hydroxychloroquine in mild cases of COVID-[19].

All patients had swab conversion and were subsequently discharged during the length of study. No death was reported in the cohort. The average swab conversion was 8.5 days. Even as per the recent data of MoHFW, only 80 of 21,632 patients were on ventilators, approximately 0.3%, in agreement with different studies from Singapore and South Korea.[8,9]

One cause for this may be the strict usage of Personal Protective Equipment (PPE) kit for all involved in duties in isolation wards (in line with the MoHFW2). All these workers were also started on hydroxychloroquine prophylaxis as per ICMR guidelines, till date none have discontinued. However more research is needed to study the role of prophylactic hydroxychloroquine.

India is still it seems, on the steep part of the COVID-19 curve, but its heartening to see a recovery rate of almost 30%. Moreover, with the strict implementation of the lockdown, social distancing and hand hygiene measures, hopefully with time we will also be able to formulate a specific treatment protocol and an effective vaccine.

LIMITATIONS

We continued tablet azithromycin and hydroxychloroquine in 14 patients with fever (13.20 %), even though drug interaction with subsequent QT prolongation in ECG is a known complication, it could not be performed. Owing to limited availability of Personal Protective Equipment (PPE) kits we could not perform ECG monitoring as per standard protocols. However all these patients showed improvement of symptoms and subsequent discharge with the above medicines.

We did not have a control arm to analyse the efficacy of the drugs.

We did not measure the viral shedding. Conclusions regarding community transmission and drug efficacy could be best reached on assaying the above. Owing to financial and infrastructural constraints we could not do the same.

CONCLUSION

This is a single center observational study of the demographic and clinical characteristics of first consecutive 106 COVID-19 patients in our hospital. All the patients were classified in uncomplicated illness category, mostly being asymptomatic, others presenting with mild symptoms of fever, cough, headache and myalgia and diarrhea. None of them developed any complication. Unfortunately no specific drug or vaccine therapy could be formulated till now. But in our experience, hydroxychloroquine with or wihout azithromycin prevented further complications. At present, containment of the pandemic, by strict lockdown implementation and social distancing added up with increased screening tests including the asymptomatic and health care workers seem to be the current modus-operandi. However with the increasing numbers of recovery and milder disease there seems to be some light at the end of the tunnel.

RESULTS

Table 1: Demographic Characteristics (n=106)

Characteristic	Number (%)
Age (Years)	
• <20	6 (5.6)
• 20-40	52(49.05)
• 40-60	36(33.96)
• >60	12(11.32)
Average age of admitted patients	39.75
Sex	
• Male	100(94.33)
• Female	6 (5.67)
Residence	
• Rural	86(81.11)
• Urban	20(18.87)
Total number of family members	
• <5	30(28.30)
• 6-10	57(53.77)
• >10	19(17.92)
Average number family members	8
History of	
• International travel	12(11.32)
• Close contact with case	106(100)
• Exposure to Delhi congregation	83(78.30)
• Travel to or from high burden states in India	92(86.79)

Table 2: Clinical profile of admitted COVID-19 patients (n=106)

Parameters	Number (%)
Presentation to health facility	
• Self	25(23.58)
• Brought by health workers	81(76.41)
Presenting Symptoms	
• Fever	14(13.2)
• Cough	10(9.4)
• Shortness of breath	1(0.94)
• Headache and Myalgia	3(2.8)
• Diarrhea	2(1.8)
Total duration of hospital stay	
• <7 days	19(17.42)
• 7-14 days	54(50.94)
• >14 days	33(31.13)
Outcome	
• Recovered	106(100)
• Died	0

Table 3: Laboratory features of admitted COVID-19 patients (n=106)

Laboratory parameter	Number (%)
Reduced hemoglobin level (<12g/dl)	13(12.26)
Average Hemoglobin level	12.89
Lymphopenia	5(4.7)
Elevated alanine aminotransferase	1(0.94)
Elevated aspartate aminotransferase	1(0.94)

Figure1: Distribution of patients as per age

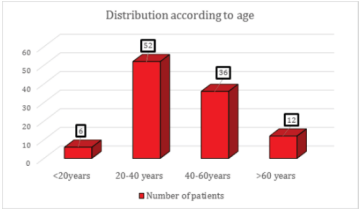


Figure 2: Presenting symptoms of the patients

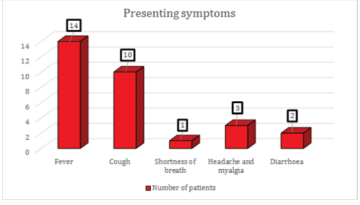
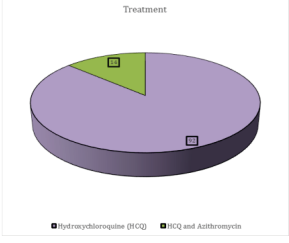


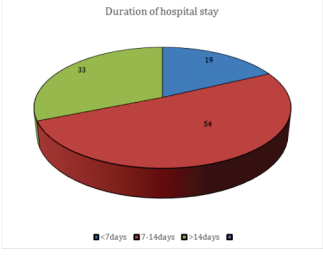
Figure 3: Treatment received



Treatment received: a febrile patients received, Tab. Hydroxychloroquine for 5 days, extendable upto 10 days

Febrile patients received Tab. Hydroxychloroquine and Tab. Azithromycin.

Figure 4: Duration of hospital stay



Duration of hospital stay: all patients got discharged by the end of study.

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