

Impact of the COVID-19 pandemic on patients with systemic lupus erythematosus: Observations from an Indian inception cohort

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Abstract

Introduction: The ongoing pandemic of COVID-19 has led to severe disruption of healthcare services worldwide. We conducted this study to assess the impact of COVID-19 pandemic on the management of Systemic Lupus Erythematosus (SLE) patients who were enrolled in the nation-wide inception cohort.

Methods: A questionnaire was administered to the SLE patients enrolled in the inception cohort. Questions related to the effect on disease activity, preventive measures adopted against COVID-19, the incidence of COVID-19, hardships faced in getting access to health care professionals and availability of medicines, adherence, fear of COVID-19 and the potential benefits of being part of the registry.

Results: A total of 1040 (90% females) patients completed the questionnaire. The mean age was 27.5 ± 19.1 years and the mean disease duration was 1.25 years. Twenty-Four (2.3%) patients had developed fever (>1 day) during this period, including one patient with additional symptoms of diarrhoea and anosmia, however, none of the patients developed COVID-19 infection. 262 patients (25.2%) reported financial difficulty during this period and patients reported an average excess expenditure of at least 2255.45 INR (\$30) per month. 378 patients (36%) reported problems in getting their prescribed medicines due to lockdown. Of these, 167 (40%) patients needed to change their medication schedule due to this non-availability. Almost 54% of patients missed their scheduled follow up visits during the lockdown period and 37% of patients were unable to get their investigations done due to closure of laboratories and hospitals. 266 patients (25.5%) reported worsening of various symptoms of SLE during this period. Almost 61% patients felt confident that being associated with the inception cohort had helped them in managing their disease better during this period of lockdown as they received help in the form of timely and frequent telephonic consults, assistance in making the medicines available, and regular counselling resulting in abatement of their fears and anxieties.

Conclusion: The current COVID-19 pandemic has made a huge impact on our SLE patients. Patients faced difficulty in the availability of medicines, missed the doses of medicines, had financial constraints, and spent more money on health during the pandemic.

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Introduction

The new severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) disease which was first reported in December 2019 from the Wuhan city of China, which is referred to as COVID-19.^{1,2} Subsequently, the infection spread all over the world and was declared as a global pandemic by the World Health Organisation on the 11th of March 2020.³ Many parts of the world adopted lockdown to curb the person to person transmission. The non-COVID patients were unable to report to the hospital and subsequently resorted to tele-consultations facilities provided by their hospitals and physicians.

India also announced a total and complete nationwide lockdown on 24th March 2020.⁴ This complete lockdown affected public and private transportation, access to healthcare facilities, and availability of medicines and consumables as well as out-patient and in-patient services. The problem of non-COVID patients is more intricate in developing countries like India where most patients are dependent on government hospitals and public transport. Anxiety and reluctance to come to hospital managing COVID-19 patients make the situation worse.

During this pandemic, patients with autoimmune rheumatic diseases are under the focus of researchers worldwide for various reasons. Though immunosuppressed patients are at increased risk for developing infections, the data on the incidence and risk of COVID-19 infection in patients with immunosuppression is not clear.⁵ While some studies suggest that underlying immunosuppressed state may be beneficial in that the subject does not mount an intense immune response resulting in less severe manifestations of the disease,^{6,7} while others have reported a similar incidence if not more in patients with immunosuppressed state compared with patients without immunosuppression.^{8,9} Covid-19 Global rheumatology alliance reported one of the largest series of 600 Covid-19 patients with various underlying rheumatological disorders from 40 countries.¹⁰ Although the study did not report on the incidence of Covid-19 in these patients, a glucocorticoid dose of ≥ 10 mg/day was associated with higher odds of hospitalisation.

In patients with active systemic lupus erythematosus (SLE), intense immunosuppression may not allow an effective anti-viral immune response in case of exposure to COVID-19 resulting in progression to severe respiratory phase.⁸ Another important fact is that almost all the patients of SLE are on long term Hydroxychloroquine (HCQ) to prevent the relapse of disease. HCQ is an immunomodulator and has been shown to reduce viral activity *in vitro* in SARS-CoV-2 infected Vero cells.^{11,12} Besides, hydroxychloroquine has been shown to significantly reduce viral load in nasopharyngeal swabs in 20 French patients with COVID-19.¹³ So, hydroxychloroquine has both direct anti-viral effects and anti-inflammatory effects.¹⁴ Various multi-centric clinical trials are being conducted to study the effect of this drug on prophylaxis as well as treatment of COVID-19. However, the evidence at present is not definitive regarding the role of HCQ. It is also essential that disease activity remains under control else a dysregulated immune system may predispose these patients to flare, major organ involvement, damage, and increased risk to infection.¹⁵

Similarly, lockdown may itself affect the disease activity of SLE due to direct restriction of outdoor activity and exposure to sunlight as well as indirectly by making the availability of drugs and health facilities difficult and even costlier at times. Because of the channelization of the existing stocks of HCQ for the care of COVID-19 patients and prophylaxis of healthcare workers, patients of SLE faced acute shortage and difficulties in procuring the medicine.

While the pandemic was ongoing, a study was conducted on the recruited patients of the Indian SLE Inception cohort for research (INSPIRE) nation-wide registry. The aim was to study the various health-related aspects that could have got affected directly or indirectly during the pandemic and the lockdown with major emphasis being on the effect on disease activity, preventive measures adopted against COVID-19, the incidence of COVID-19, hardships faced in getting access to health care professionals, or in the availability of medicines, adherence to the drugs, fear of COVID-19 and perceived benefits, if any, of being associated with the registry.

Methods

Indian SLE Inception Cohort for Research (INSPIRE) is a Department of Biotechnology, Government of India supported the multi-institutional network programme on SLE to understand its diversity in Indian patients. A total of ten centres from different parts of the country are participants of this registry. In this registry, SLE patients fulfilling 2012 SLICC criteria¹⁶ seen at recruiting institutions for the first time after August 31, 2018, and having disease duration of fewer than three years were eligible to be enrolled. Patients with overlap syndrome were excluded from the registry. One of the aims of the multicentric cohort is to address the relationship between the clinical phenotype and autoantibody profile of SLE patients and the generation of a biorepository to assess biomarkers. All patients enrolled in the registry are followed up at a six-monthly interval. The socio-economic class classification was done using Kuppuswamy scale modified in 2018.¹⁷ Kuppuswamy scale is based on educational classification scored from 1–7, occupation from 1–10 and income from 1–12 of the head of the family. The total of all the three components is calculated and the different classes are as follows: 26–29 Upper class, 16–25 upper middle, 11–15 lower middle, 5–10 upper lower class and <5 lower class.

For the present study, all the enrolled patients were contacted telephonically and asked for their consent to participate.

A questionnaire was developed comprising of a total of 30 questions in English (supplementary file). This was administered by a medical officer for two months from April–May 2020. The medical officer established contact with the patient enrolled in the respective centres via phone call, WhatsApp, e-mail, text message, or any other media platform available with the patient. The medical officer explained the question along with all the options to the patient in English or their vernacular language and the feedback was collected. The patient global assessment was done using the PGA scale from 0 to 10 where zero meant feeling worst and 10 meant very good. The data was entered in the excel sheet and analysed.

Results

A telephonic call was made to a total of 1049 patients enrolled in the INSPIRE registry. Of these, 4 patients could not be contacted due to either change in the phone number or network issues, while 5 patients had expired since their last follow-up. Thus, a total of 1040 patients completed the questionnaire. The female to

male ratio of the participants was 9:1 with a mean age of 27.5 ± 19.1 years and the mean disease duration was 1.25 years.

SLE and COVID-19

Three patients (0.28%) reported having had contact with a person who was experiencing flu-like symptoms or were COVID-19 suspect/positive or had met someone who had recently travelled back to India from a foreign country. The majority of patients affirmed that they were following one or more measures of precaution in the form of physical distancing, hand hygiene, self-isolation, wearing masks, and avoid going out even for purchasing grocery/other essentials, etc. Almost one-third of the patients reported that they were following all the five above-mentioned precautions to prevent exposure to nCoV-2.

A total of 24 (2.3%) patients had developed fever lasting more than one day during this period, including one patient with additional symptoms of diarrhoea and anosmia, which may be suggestive of nCoV-2 infection. None of the patient-reported associated cough or breathlessness. Ten patients had been tested for SARS COV-2 infection by reverse-transcriptase polymerase chain reaction (RT-PCR) of the nasopharyngeal or oropharyngeal swab. However, none of the patients had tested positive for SARS COV-2 infection.

Difficulties faced by SLE patients due to lockdown

Two hundred and sixty-two patients (25.2%) reported financial difficulty during this period and patients reported an average excess expenditure of at least 2255.45 INR (\$30) per month either directly or indirectly on healthcare during this period. The average Kuppuswamy score was 17 in our patients (range 3–26). The different classes were as follows: Lower class 4%, Upper-lower class 49%, lower-middle 31%, upper-middle 15% and upper class 1%.

Three hundred and seventy-eight patients (36%) reported problems in getting their prescribed medicines due to lockdown. Of these, 167 (40%) patients needed to change their medication schedule due to this non-availability, while remaining patients were able to arrange their medicines with the help of either online pharmacy (2.1%), or by contacting either their doctors (7.4%) or pharmaceutical representatives (4.5%). Around 10 (01%) patients had missed their scheduled cyclophosphamide dose due to either non-availability of drug or facility to provide intravenous infusion. A specific question was asked about the availability of hydroxychloroquine, and 190 patients (21.9%) responded that they had faced difficulty in the

availability of the drug, and 69 patients (6.6%) had been forced to miss several doses.

Almost 54% of patients also missed their scheduled follow up visits during this lockdown period and 37% of patients reported that they were unable to get their investigations done due to closure of laboratories and hospitals.

Disease-related features

Two hundred and sixty-six patients (25.5%) reported worsening of the symptoms of SLE like joint pain, malar rash, or oral ulcers during this period, while 333 patients (32.1%) reported improvement in their symptoms. Other problems reported by the patients during this period of lockdown included insomnia, fearfulness, headache, and stress of losing their work. The average Patient's Global Assessment score during these two months was 6.69 ± 1.26 .

Sense of vulnerability and impact of enrolment in the registry on the management of disease

One hundred and fifty-two patients (14.6%) felt that they were more vulnerable to COVID-19 during this period and 133 patients (12.8%) were concerned that their disease is more likely to flare up due to COVID-19 pandemic, while 15.67% patients were worried that they were more likely to get COVID-19 infection either because of their underlying disease or the drugs they were taking.

Almost 61% of patients felt confident that being associated with the INSPIRE registry had helped them in managing their disease better during this period of lockdown. All the registry patients were contacted actively by the medical team personnel of the registry during this lockdown by the means of either telephone call or WhatsApp messages for their follow up.

They also reported that being associated with the registry provided them easy access to medical service almost anytime and to share their concerns and worries. Being associated with registry also helped them in getting their follow up prescription and assistance in arranging for their medicines. They also reported that they were being provided with appropriate information about the pandemic and advice on the precautions to be taken. Patients reported that being associated with the registry provided them a 'good feeling' and they were less stressed about their disease and the infection.

Discussion

The present study analyzes the impact of COVID-19 pandemic on the SLE patients enrolled in a nationwide INSPIRE registry. The key themes that emerge are a disruption in management due to the non-availability of medications, perception of new risks due to unavailable or less approachable healthcare, psychological or emotional stress due to the COVID-19 pandemic. Besides, it also highlights that being associated with the registry staff has positive gains in the form of psychological support, awareness about COVID-19 precautions, timely counselling, and help in getting drugs.

None of the patients enrolled in our registry had been tested positive or had COVID-19 infection, though three patients had a history of contacts with suspect or proven COVID-19 patients. A study from Italy on 916 patients with various rheumatological disorders had 397 patients of SLE. In the study, only 2 patients tested positive for COVID-19. However, none of these two patients had underlying SLE as a basic disease.⁸ Another multicentric survey from our country included 845 patients of SLE and reported only two cases of COVID-19.¹⁸ The COVID-19 Global Rheumatology Alliance had reported 600 cases of COVID-19 in patients with underlying rheumatological disorders. Of these 600 patients, 85 (14%) had underlying SLE.¹⁰

The low incidence of COVID-19 in our study could be the result of a pro-active attitude of the patients to follow preventive measures as well as the effect of chronic HCQ therapy. Also, almost all our patients had a feeling of self-realization of the comorbid condition and thus actively practiced protective measures such as social distancing, cancellation of all non-essential travel, reducing contact with others, and application of frequent hand hygiene practices. A study from Hongkong also reported that universal use of masking has resulted in no case of SLE being reported with COVID 19.⁶ However, this low incidence of COVID-19 in our study may also be due to the timing of our study. Our study was conducted in the initial part when the pandemic was not so widespread in our country and there was lockdown in force. This may have prevented the development of infection in our patient group. It may be possible that if studied now with a more widespread pandemic, the incidence of COVID-19 may be higher in our patients.

The protective effect of HCQ cannot be verified with certainty. All our patients were on treatment with HCQ. In-vitro studies have suggested that HCQ inhibits the replication of SARS-CoV-2.^{11,12} HCQ has many other mechanisms including change in lysosomal pH leading to reduced TLR signalling, decrease in pro-inflammatory cytokine release, induction of apoptosis,

and inhibition of autophagy.¹⁴ However, the clinical studies are conflicting in terms of the protective role of HCQ in the prevention of COVID-19. It has been shown that after high-risk or moderate-risk exposure to COVID-19, HCQ did not prevent illness when used as post-exposure prophylaxis.¹⁹ It has been suggested that too much reliance on HCQ in the prevention of COVID-19 should be avoided due to a lack of sufficient data.¹⁵ However, the contentious use of HCQ is still being debated and is being used in many parts of the world including the Indian sub-continent leading to its acute shortage.²⁰ Even in India, all asymptomatic healthcare workers involved in containment and treatment of COVID-19 including asymptomatic healthcare workers, surveillance workers deployed in containment zones, and paramilitary/police personnel involved in COVID-19 related activities are prescribed HCQ.²¹

A notable finding of this study is problems in getting the prescribed drugs. Thirty-six percent of the patients reported that they had faced problems in getting the prescribed medicines due to lockdown and 40% of the patients were forced to change their medication schedule due to the non-availability of medicines. The availability of HCQs was especially an issue for our patients with 22% of patients facing difficulty in getting the drug and 6% being forced to miss the doses. The effect of antimalarials in COVID-19 has contributed to the massive emergence of the interest of media, health care professionals, and the general population in this drug.²² Another contributing factor is that there is a lack of other therapy with such low cost and better safety profile as HCQ in treatment against COVID-19. This has led the Indian government to re-categorized HCQ as a scheduled H1 drug. More concern has risen about decreasing perturbation amongst patients already taking HCQ and making it more accessible to SLE patients and keeping them on HCQs.²⁰

Another important issue highlighted by this study was financial constraints reported by patients during the pandemic. Our patients spent of an excess amount of 2255.45 INR per month either directly or indirectly on healthcare during this period. The added expenditure was spent on medicines and lab investigations. Also, patients reported a loss of income during this period. People throughout the world have faced unemployment issues and fiscal emergencies amid this COVID-19 pandemic.^{23,24} and Indian sub-continent is no different. The pecuniary predicament of the lupus patients was also noted in the study. The impact is likely more in lower socioeconomic strata as they are more likely to be affected by this crisis due to loss of wages, migration to home, and lack of job opportunities near home. This economic loss and loss of employment can take a serious toll on the management of these patients and steps need to be taken to reduce

the economic distress in already weaker sections of society.

It was interesting to learn that more patients showed improvement than worsening. This could be partly due to better follow up of these cohort patients over telemedicine though we don't have non cohort patients to compare. Furthermore, this could be partly related to limited exposure to sun and robust family support. COVID-19 has also affected the mental health of patients. In a study performed during the first two weeks following the outbreak conducted by Wang et al, females were reported to experience a higher degree of the psychological impact of the outbreak, stress, anxiety, and depression.²⁵ Lupus patients can also develop a feeling of being more vulnerable and fragile amid pandemic either due to ongoing immunosuppression or due to unavailability of medications, insufficient essential commodities, inaccessible healthcare, loss of jobs, and perception of increased risk of contracting COVID-19 infection. Stress is also a well-recognised trigger for precipitation of lupus flare and thus becomes an added risk in the management of SLE patients. The sense of vulnerability, anxiety, and stress was curtailed to some extent in our patients by effective patient education on precautions against COVID-19 infection and supportive patient management and by using telemedicine as a multipurpose tool in patients participating in the INSPIRE registry.

Telemedicine and enrolment in the INSPIRE registry have been proven to be a boon covering multiple health-related aspects amid the COVID-19 pandemic. It provided the man-power to be able to reach out to more than 1000 lupus patients during a time of unprecedented resource crunch in the health care sector. Besides a different patient behaviour driven by the COVID-19 infection fear, the lockdown regulations themselves were although successful in general to halt the pandemic, our observation states that the telephonic call is the most chosen form of media out of all available channels of communication media. Hearing from a healthcare professional once in a fortnight made the patients feel better and helped in extending moral support. It also helped in instilling confidence in otherwise anxious patients. With our observation, provision of a 24*7 helpline needs to be set up for patients; to minimize the disease flare related risk and it could prove to be one of the most promising possibilities. The extension of the application of telephonic consult or telemedicine in SLE patients must be further investigated in studies.

Conclusion

The current COVID-19 pandemic has made a huge impact on our SLE patients. Though none of our

patients developed the nCOV-2 infection, they faced difficulty in the availability of medicines, missing the doses of medicines, particularly hydroxychloroquine, financial constraints and spending more money on health during the pandemic. Being part of the registry; patients received help in the form of counselling by timely and frequent telephonic consults, assistance in making the medicines available, and ultimately allaying their anxieties.






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Supplemental material

Supplemental material for this article is available online.

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