COVID-19 pandemic and inflammatory bowel disease from patients’ perspective: A survey from COVID epicenter in India

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Abstract

Background and Aim: The COVID pandemic and countrywide lockdown has had significant impact on patients with inflammatory bowel disease (IBD), with delay in diagnosis, difficulty in access to healthcare and unavailability of drugs. We conducted a telephonic survey to assess this impact.

Methods: Out of 350, 302 participated in the survey. Demographic data, disease severity at the time of survey, extent of disease, details of therapy, and adherence were noted. A validated questionnaire addressing information source, perception of COVID-19 situation, contact with healthcare, and adherence to standard precautions was administered telephonically.

Results: Out of 350 contacted patients, 302 (86.28%) patients participated in the survey. Median age of cohort was 39 years. Ulcerative colitis (UC) constituted 79%, 16% Crohn’s disease (CD), and 5% IBD-unclassified. At the time of survey, 86.98% patients with UC were in clinical remission and 75.75% of CD patients were generally well. A total of 115 (38%) cases were nonadherent to therapy due to unavailability of medicines (66.38%), financial constraints (25.21%) and inability to reach healthcare facility (3.6%). Disease flare was seen in 14.2% and correlated well with non-adherence. Existing drug therapy was switched to alternative drug in 70 (23.17%) cases due to unavailability (74%). Social media (52.3%) and television (40.4%) were the common sources of information about the pandemic. Telemedicine platforms (WhatsApp and telephone) were used by 180 (59.6%) patients for consultation with good acceptance (81.6%). 87 (28.8%) patients failed to contact healthcare. Apprehension regarding severe COVID infection was noted in 80% while 29% thought that IBD therapy could increase infection risk. Adherence to wearing mask, hand washing, and social distancing was 100%.

Conclusion: Pandemic resulted in disruption of healthcare visits and medication supply. Majority were concerned about increased risk of COVID-19 infection and adhered to standard precautions. Mobile phone-based formats for patient care may be an alternative due to patient acceptance and convenience.

Introduction

The coronavirus disease (COVID-19), a new form of severe acute respiratory syndrome (SARS), is caused by the novel coronavirus SARS CoV-2 following its outbreak in China in December 2019. SARS CoV-2 was announced as a global pandemic by the World Health Organization (WHO). Severity of
COVID-19 infection ranges from asymptomatic infections, mild infection characterized by fever, malaise, cough, diarrhea, loss of taste sensations to severe disease characterized by cytokine storm, respiratory distress syndrome, multiorgan failure, and has high mortality. It has been noted that patients with older age and immunocompromising conditions are at increased risk of severe infection. Inflammatory bowel disease (IBD) is chronic inflammatory relapsing–remitting disease affecting gastrointestinal tract requiring immunosuppressive or immunomodulator therapies for induction and maintenance of remission. Initially, there were doubts regarding increased susceptibility of IBD patients either due to disease itself or due to immunosuppressive therapies to COVID-19 infection. However, a systemic review revealed that IBD patients are not at increased risk of COVID-19. Adherence to standard therapies should be continued and high dose steroids to be avoided. Neither IBD nor its therapies increase the risk of COVID-19 infection. IBD patients require repeated hospital visits for follow-up, injectable therapies, investigations and surveillance endoscopies which can increase exposure to COVID-19 infection. Most of the countries including India underwent countrywide lock down to prevent spread of COVID-19 infection which included strict travel restrictions. Essential services like healthcare were excluded from lockdown. Most of the hospitals catering IBD-related health services were directed to cater increasing load of COVID-19 cases. All these changes definitely had significant impact on IBD patients’ lives. Most of the hospitals started telemedicine services to provide consultations for patients who were unable to reach out to hospitals. There is scarcity of data assessing patients’ point of view and acceptability of IBD patients to telemedicine platforms. A study from Germany showed that patients with IBD had more fear of infection and reported less leaving house as compared to their peers. Although 96% patients were adherent to their therapy, patients with immunosuppressive therapies were more worried about interaction of immunosuppressants with medications used to prevent and treat COVID-19 infection. To assess the impact of COVID-19 pandemic and countrywide lockdown on the lives of the IBD patients, we decided to conduct a telephonic survey.

Methods

Patients who were >18 years, with a confirmed diagnosis of IBD (UC or CD), registered at the IBD clinic at a tertiary care referral center were selected for telephonic survey. The survey was conducted after approval from the Institutional Ethics Committee (Letter Reference no-IEC [II]/OUT/21/2020). Verbal telephonic consent was administered to the patients which was recorded on recorder available on mobile phone. Those patients willing to participate in study were enrolled in the study. Patients with age <18 years, indeterminate colitis, unclassified IBD (IBD-U), alternative diagnosis, pregnant patients, and those refusing to participate were excluded. Demographic data in the form of name, age, sex, diagnosis (UC or CD), duration of disease, baseline disease extent, severity, and steroid use was noted from records in IBD clinic. Current severity of disease, current medications with dosage and frequency were noted. Medication possession rate was defined as number of days patient received full dose of drug as advised by physician × 100/total number of days of therapy. Adherence to therapy was defined by medication possession rate >80%. If therapy was discontinued or switched to other therapy it was recorded along with reasons for the same. Disease severity for UC was noted based on frequency of bloody stools/day. Clinical remission was defined as less than 3 stools per day and no blood, mild disease 3 stools/day, moderate disease 4 to 6 stools per day, severe disease ≥7 per day. Disease severity for CD was assessed by generalized wellbeing score (a part of CD activity index). Score of 0—generally well, 1—slightly below par, 2—poor, 3—very poor, 4—terrible. Set of 40 questions addressing source of information and perception of COVID-19 pandemic, contact with health care and adherence to COVID appropriate behavior, were made. These questions were given to 10 experts and 10 subjects (patients with IBD) to assess clarity, relevance, ambiguity, and simplicity. These factors were rated from 1 to 4 using Likert Scale (1 being poor, 4 being optimal). Questions with total score of ≥8 were considered for final inclusion into the questionnaire. After calculation of Cohen’s Kappa index, 15 questions with index >0.6 s/o substantial agreement between observers were selected for final inclusion into the questionnaire. Questionnaire was administered telephonically by investigators and responses were noted. Data were analyzed using SPSS version 24 (IBM corporation, Armonk, NY, USA). Quantitative variables were represented using mean, median, and standard deviation. Qualitative variables in proportions were compared using Chi square test or Fisher Exact test. P value of <0.05 was considered as significant.

Results

Demography and disease severity. Out of 590 patients registered at the IBD clinic, 350 (59.32%) were contactable over the phone. Out of 350, 302 (86.3%) consented for participation into the study. Mean age of cohort was 39.35 years (IQR 29–49 years) with male preponderance (58.6%). Out 302 patients, 149 (49.33%) were graduates. Two hundred and fifty-four (84%) had UC and 48 (16%) were Crohn’s disease (CD). At the time of diagnosis, 22 (8.7%) had mild UC, 175 (69.44%) moderate, and 55 (21.82%) severe UC. Injectable or oral corticosteroids were used for 230 patients at baseline for moderate or severe disease to induce remission. Pancolitis was noted in 89 (35.13%), left sided colitis in 128 (50.79%) and proctitis in 35 (13.88%) patients. At the time of diagnosis, 10 (20.83%) patients with CD were in very poor general condition and 38 (79.16%) were in moderately poor condition. At the time of survey, 234 (86.98%) patients with UC were in clinical remission, 20 (7.43%) had mild symptoms, 12 (4.4%) moderate, and 3 (1.11%) had severe symptoms. Out of 48 patients with CD 36 (75.75%) were generally well, 9 (18.18%) felt below par, 3 (6%) were in poor general health. Table 1 shows demography and disease severity at the time of survey.

Compliance to IBD therapy. At the beginning of March 2020, 143 patients were on 5-aminosalicylates, 124 patients were on Azathioprine, 33 patients were on biologics, 10 patients were on oral steroids. Out of 302 patients 193 (63.90%) patients continued prescribed medications from the start of the lockdown till the time of survey (March 2020–December 2020). Mean medication possession rate was 75.15% (IQR: 55.4–100%). Non-adherence to therapy was noted in 109 (36.10%) of cases. Non-availability of medicines was the most common reason in 69 (66.38%) cases. Inability to purchase medications due to
Inflammatory bowel disease-COVID survey

Table 1 Shows demography and disease severity at the time of survey

| No                          | Frequency (%) |
|-----------------------------|---------------|
| 1. Mean age                 | 39.35 years (IQR 29–49 years) |
| 2. Sex                      | Male: 176 (58.6%); Female: 126 (41.4%) |
| 3. Educational status       | Less than graduation: 153 (50.7%); More than graduation: 149 (49.3%) |
| 4. UC disease status at time of survey | Clinical remission: 234 (86.98%); Mild symptoms: 20 (7.43%); Moderate: 12 (4.4%); Severe: 3 (1.11%) |
| 5. CD disease status at time of survey | Generally well: 25 (75.75%); Felt below par: 6 (18.18%); Poor general health: 2 (6%) |

financial constraints was noted in 30 (25.21%) cases. Out of these, 10 patients lost their job during lockdown, and due to financial constraints they were unable to purchase medications. Self-discontinuation of therapy due to disease in clinical remission was noted in 10 (8.4%) cases. Drug therapy was switched to other drug in 70 (23.17%) cases. Most common reason was non-availability of previously prescribed drug in 50 (71.2%) patients. Due to lockdown during COVID-19 pandemic 10 (14.28%) patients on Infliximab were unable to reach hospital for scheduled dosing and hence it was changed to steroid and Azathioprine which was available to the patients at their native place. At the time of survey, 20 patients with moderate or severe symptoms of UC and 4 patients of CD with health status lower than ‘Generally well’ were found not adherent to therapy and had completely stopped taking medicines (20 vs 0, \( P = <0.05 \); 4 vs 0, \( P = <0.05 \)). Adherence to biologics was 78.78% (26/33). Adherence to Azathioprine was 64.51% (80/124). Adherence to 5-ASA was 55.59% (144/259). There was no difference in adherence between patients on immunosuppressive or immunomodulators and those who are not (99 vs 80, \( P = 0.135 \)). Table 2 shows compliance to medications, discontinuation, and switch to other drugs.

Sources of information. Majority of the patients (158, 52.3%) received information regarding COVID-19 pandemic from social media. Television was the source of information in 122 (40.4%) cases. Very few patients (11, 3.6%) contacted treating physician for information regarding COVID-19.

COVID-19 pandemic situation from IBD patients’ perspective. Almost 242 (80%) patients thought that IBD increases the risk of acquiring COVID-19 infection. There was no significant difference in perception of this risk in patients with educational level above graduation and below graduation (127 vs 116; \( P = 0.25 \)). Eighty-six (28.5%) patients thought that medicines used to treat IBD increase risk of acquiring COVID-19 infection. There was no difference in perception of risk of acquiring COVID-19 infection in patients on immunosuppressive and immunomodulator drugs compared to those who are not (32 vs 27, \( P = 0.4 \)). Majority of patients (245, 81.1%) thought that COVID-19 infection will not increase IBD symptoms if they acquire it.

Contact with healthcare services. Ninety-five (31.5%) patients contacted healthcare facility on telephone or mobile phone, 85 (28.1%) on WhatsApp. 35 (11.6%) visited hospital personally, 87 (28.8%) were unable to contact healthcare provider by any means. Out of 180 patients who contacted healthcare services on telephone and WhatsApp, 147 (81.66%) patients were satisfied with this form of consultation. One fifty-five (51.3%) patients stayed within 11–50 km radius from the hospital, 60 (19.9%) beyond 100 km, 53 (17.5%) stayed in 51–100 km distance. Minority (34, 11.3%) stayed within 10 km. Out of 188 patients staying within 50-km radius from the hospital 25 (13.29%) visited hospital, while only 9 patients out of 114 (7.8%) staying beyond 50-km radius visited the hospital. However, this difference was not statistically significant (25 vs 9, \( P = 0.15 \)). Only 75 (25%) were worried about getting admission to hospital which can manage IBD during this pandemic.

Table 2 Shows compliance to medications, discontinuation, and switch to other drugs

| No                          | Frequency (%) |
|-----------------------------|---------------|
| 1. Self-discontinuation of medication | 119 (40%) |
| Nonavailability of drug     | 79 (66.38%) |
| Financial constraints       | 30 (25.21%) |
| Feeling of wellbeing        | 10 (8.4%) |
| 2. Switch to other drugs    | 70 (23.17%) |
| Drug nonavailability        | 50 (71.2%) |
| COVID-19 pandemic           | 10 (14.28%) |
| Drug toxicities (Switched by treating physician) | 3 (4.28%) |
| Nonresponse to index drug   | 2 (8.5%) |
| Financial constraints       | 5 (7.14%) |
| 3. Previous and changed drugs | 40 |
| Azathioprine changed to Prednisolone | 40 |
| 5-ASA changed to prednisolone 20 mg/day | 20 |
| Biologics changed to Steroids + Azathioprine | 10 |

Adherence to standard practices during COVID-19 pandemic. All patients with IBD used face mask and washed hands frequently. Government of India started a mobile phone-based application called Arogya Setu application so as to educate, help and guide people regarding COVID-19 infection, testing and management. It was downloaded and used by 121 (40%) patients. Significantly more patients with education graduation and above downloaded and used this application as compared to education status below graduation (73 vs. 48; \( P = 0.002 \)). Several medications were used as prophylaxis against COVID-19 infection such as Hydroxychloroquine and Arsenic album (a Homeopathic medicine). In our study,
43 patients took Arsenic album and 27 took Hydroxychloroquine, however, no patients reported increase in symptoms of IBD due to consumption of these medications. None of the 70 patients who took these medications suffered from symptomatic COVID-19 infection. There was no significant difference in patients with graduation and above educational status and below graduation in use of preventive medicines for COVID-19 (40 vs. 30; P = 0.1). Table 3 shows responses to questionnaires.

### Outcomes of COVID-19-infected patients.

Only four patients (1.3%) were infected with SARS CoV-2, of which one had severe infection with adult respiratory distress syndrome (ARDS) and died due to disease. Three had mild disease and recovered. Ten (3.3%) patients had contact with a case of COVID-19 but they did not acquire symptomatic infection. Increase in IBD-related symptoms were reported by 43 (6.6%) cases.

### Discussion

Our study, from the coronavirus epicenter in western India, throws light on perception of COVID-19 pandemic situation by IBD patients, their adherence to standard precautions, and IBD therapy, difficulties faced by the patients due to lock down and changing mode of healthcare contact. In this telephonic survey of 302 patients with IBD, we found that 234 (86.98%) patients with UC and 36 (75.75%) patients with CD maintained clinical remission. Twenty (7.43%) patients with UC had mild symptoms, 12 (4.4%) moderate and 3 (1.11%) had severe symptoms. Nine (18.18%) patients with CD felt below par and 3 (6%) were in poor general health. As compared to a previous study by Grunert et al., majority of our patients were in clinical remission.1 Spagnuolo et al. reported 91% (131/144) patients were in clinical remission and 9% patient had active disease6 findings similar to our study.

**Compliance to IBD therapy.** Our survey shows that out of 302 patients, 193 (63.90%) continued prescribed medications from the start of the lockdown till the time of survey (March 2020–December 2020). Rodrigo et al. in their study found that 9% of the patients discontinued treatment, with the majority of those self-discontinuing (70%), and 22% modified the therapy.7 They also reported that patients with immunomodulator or immunosuppressive therapies less frequently discontinued therapy. In our study, no significant difference in adherence to therapy was noted between patients on immunomodulator or immunosuppressive therapies and those who are not (99 vs. 80, P = 0.135). Jena et al. in their systematic review found that the pooled rate of failure to adhere to overall IBD medications was 10.12 (CI, 7.12–14.18, \(I^2 = 97\%\)) per 100 patients. The pooled rates of failure to adhere to overall IBD medication were 3.76 (1.49–9.18, \(I^2 = 97\%\)) in European studies, 20.26 (14.23–28.02, \(I^2 = 93\%\)) in Asia and 21.13 (12.31–33.84, \(I^2 = 87\%\)) in North America suggesting geographic variation in the nonadherence.8 Barnes et al. in their study noted that 5% patients reported self-initiated missed doses or dose reduction of IBD medications directly attributed to the COVID-19 pandemic.9 In our study self-discontinuation of therapy due to disease in clinical remission was noted in 8.4% cases which is more or less consistent with findings by Rodrigo et al.7 and Barnes et al.9 As compared to nonadherence rates for Asian patients as mentioned in systematic review by Jena et al., nonadherence rate in our study was higher (36.10% in our study and 21.13% in Asian studies).8 Nonavailability of medicines due to lockdown was the most common reason in 66.38% and inability to purchase medications due to financial constraints was noted in 25.21% cases. This may explain higher rates of nonadherence in our study. Khan et al. in their study found that adherence to infusible biologics was 73.6% which is consistent with our study (78.78%).10

**Source of information.** In our study, majority of the patients (52.53%) received information regarding COVID-19 patients on social media for example Facebook, WhatsApp etc. Television was the source of information in 40.4% cases. Less than 5% patients contacted treating physician to obtain information regarding the COVID-19 pandemic. In a survey conducted by Spagnuolo et al. 86% patients obtained information regarding COVID-19 on mobile phone. A total of 59% of patients contacted their treating gastroenterologist and received educational material.8 Television and internet media sites (62.7%) were commonest source of information regarding COVID-19 pandemic in a study conducted by Grunert et al.1 Easy access and availability appear to be the reasons for more use of social media and television as source of information. This also brings forward the unmet need of formation of IBD support groups involving gastroenterologists, nurses, and social workers to reach out to IBD patients, educate them, and provide authentic information during pandemic situation.
Perception of COVID-19 infection risk by IBD patients. In our study, 242 (80%) patients thought that IBD increases the risk of acquiring COVID-19 infection. Eighty-six (28.5%) patients thought that medicines used to treat IBD increase risk of acquiring COVID-19 infection. Spagnuolo et al. in their study reported that 51% of patients had a perception that IBD will increase the risk of COVID-19 infection and 40% were of the opinion that medications for IBD increase risk of COVID-19 infection. Grunert et al. noted that 67.3% IBD patients were anxious about acquiring COVID-19 infection compared to controls ($P = 0.0009$) and few (26.7%) had fear that IBD therapy can worsen COVID-19 infection findings more or less consistent with our series. Currently majority of the evidence state that there is no increase in risk of infection compared to non-IBD patients. Apart from corticosteroids and 5-aminosalicylates, other drugs do not appear to be associated with adverse outcomes of COVID-19 infection. In our study, majority of patients (245, 81.1%) thought that COVID-19 infection will not increase IBD symptoms if they acquire it. However, Axelrad et al. in their study reported that out of 83 patients with IBD and COVID-19 infection, one third (30%) had new onset or worsening diarrhea.

Contact with healthcare. In our study 95 (31.5%) patients contacted healthcare facility on telephone or mobile phone, 85 (28.1%) on WhatsApp, 35 (11.6%) visited hospital in person, and 87 (28.8%) were unable to contact healthcare provider by any means. Qui et al. in their study from Hubie, China reported significant reduction in face to face consultations from 59.1% pre-COVID to 12.1% during COVID pandemic while telemedicine (based on WeChat platform) use was increased from 15.1 to 38.9%. International survey on management practices on COVID-19 showed significant reduction in in-person consultations in countries like Nepal, New Zealand, Philippines, Puerto Rico, and UK. In our study, out of 180 patients who contacted healthcare services on telephone and WhatsApp, 147 (81.66%) patients were satisfied with their consultation. George et al. in their survey involving patients undergoing telehealth visits; 83% reported that using the system was not complicated, nearly 90% reported that all of their health concerns were addressed during the visit. Costantino et al. in their survey noted that 95% patients trusted telemedicine platform (Google meet/Microsoft teams) and 90% thought that telemedicine will solve their all problems. In our study patients with android based mobile phones commonly used WhatsApp, the application with which most of the patients were well versed and those who do not have android based mobile phones used phone call to seek help. In our study, 28.8% of the patients were unable to contact healthcare provider by any means, exposing some gaps in outreach healthcare facilities which need address.

Adherence to standard practices during COVID-19 pandemic. In our study, adherence to use of face mask, hand hygiene, and social distancing with was 100% among study participants indicating excellent awareness among IBD patients regarding COVID-19 infection preventive measures. Spagnuolo et al. reported similar findings with >90% adherence to hand washing, use of mask and social distancing. Paradoxically Grunert et al. report the use of mask 38.6% of the patient but hand hygiene was followed by 91% patients. Government of India launched Arogya Setu mobile phone-based application to guide to educate, help and guide people regarding COVID-19 infection, testing and management. It was downloaded and used by 121 (40%) patients. Significantly more patients with education graduation and above downloaded and used this application as compared to education status below graduation (73 vs. 48; $P = 0.002$). This was a novel finding and denotes the impact of level of education on healthcare utilization. In our study, 43 patients took Arsenic album and 27 took Hydroxychloroquine however, none had increased symptoms of IBD due to these medications. None of these 70 patients suffered from COVID-19 infection. Barnes et al. reported that 43% respondents reported complementary and alternative medication for prevention of COVID-19 infection.

Outcomes of COVID-19 infection in IBD patients. In our study, 4 (1.3%) patients were infected with SARS-CoV-2 virus of which one patient with UC in severe flare had severe COVID-19 infection with ARDS and died due to respiratory failure. Three patients with UC in clinical remission had mild disease and recovered. Findings from Italian IBD study (IG-IBD study) clearly showed that active IBD, old age, and comorbidities were associated with negative COVID-19 outcomes. Study from New York, USA showed that out of 83 patients, 5 (6%) patients required hospitalization and one died.

This is the first study in our knowledge from India to have studied the impact of the COVID pandemic on patients with IBD. Our study has the limitation of using telephone interview as the method of survey, which limits the number of questions which can be asked in the span of 15–20 min affecting detailed coverage of various issues. Use of email may have circumvented these issues, but most likely at the expense of fewer responses. Also, only 24% of patients registered at our IBD clinic used E-mail services. Majority of the patients were not familiar with telemedicine-based platforms like Google meet and Microsoft teams. Hence, these could not be used for the survey. There is also some selection bias as few contacted patients did not participate in the survey. It is likely that patients who were more interested in IBD and COVID-19 pandemic must have responded to the survey while those who were not interested did not.

Bridging the gaps. After the survey, all patients were provided with mobile phone number specially started by our IBD unit as a part of outreach services so that it was possible for patients to establish contact with doctors in tertiary care center and patients’ problems can be addressed. An attempt was also made to involve family physicians in the patient care as a part of outreach services of our IBD unit. This helped patients to obtain initial care at the nearest place during COVID pandemic. Family physicians were in direct contact with our IBD unit using mobile phone and WhatsApp thus helping exchange of clinical information and laboratory investigations. Family physicians were also trained to diagnose flare of IBD symptoms and complications at early stage so that patients can be timely referred to IBD care centers. As we write and complete this manuscript, this process of training and incorporating family physicians is still ongoing. This will enable us to form a network of doctors who can provide immediate care to patient, identify disease flares, drug toxicities so that timely referral is arranged. They can administer injectable
medicines to the patients (e.g. Infliximab, Adalimumab) at nearby place and give us the feedback regarding patients’ health using simple mobile phone-based applications. This will help patients reduce the travel and continue IBD therapy at nearest place under supervision of local physician and IBD care unit.

To conclude, COVID-19 pandemic had significant impact of lives of IBD patients. This was mainly in the form of disruption of regular healthcare visits, medication supply, and availability. Financial losses sustained during nationwide lockdown compounded by high cost of healthcare required to keep IBD under control caused significant financial strain on patients. Lack of access to healthcare and inadequate outreach facilities from referral centers made it difficult for patients to manage IBD. Adherence to mask use, hand washing, and social distancing was high among IBD patients. COVID-19 infection rate in IBD patients appears low. Use of mobile phone (Telephone/WhatsApp)-based formats for patient care are novel and increasingly used with good patient acceptance.

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