LEADING ARTICLE

Care of inflammatory bowel disease patients during coronavirus disease-19 pandemic using digital health-care technology

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Key words

azathioprine, biological, COVID-19, Crohn's disease, teleconsultation, telemedicine, ulcerative colitis.

Accepted for publication 9 January 2021.

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Declaration of conflict of interest: None. Author contributions: Uday C Ghoshal: Conceptualizing the study and the web-based platform, patient care and education, data analysis, manuscript writing. Shikha Sahu: Patient appointment, online data collection, and help in data management. Sugata Biswas, Prashant Singh, Moni Chaudhary: Help in the online clinic including patient appointment. Ujjala Ghoshal: SARS-CoV-2 RNA testing of patients and the controls. Priyanka Tiwari: Technical support for web-based consultation system development. Sushmita Rai: Management of online data. Saroj K Mishra: Supervision of the work and providing telemedicine support and infrastructure.

Abstract

Background and Aim: Although telemedicine is an option for the care of inflammatory bowel disease (IBD) patients during the Coronavirus Disease (COVID)-19 pandemic, its feasibility and acceptability data are scant. Data on the frequency of COVID-19 among patients with IBD, quality of life (QOL), access to health care, psychological stress, and anxiety during the COVID-19 pandemic are scant.

Methods: Video/audio consultation for IBD patients was undertaken after a webbased appointment, and data on acceptability, IBD control, Hospital Anxiety Depression Scale (HADS), and World Health Organization Quality of Life questionnaire (WHOQOL-Bref) were obtained electronically. IBD patients were assessed for COVID-19 symptoms or contact history and tested using reverse transcriptase polymerase chain reaction (RT-PCR) on naso- oro-pharyngeal swabs, and data were compared with 16,317 non-IBD controls.

Results: Teleconsultation was feasible and acceptable. IBD patients had COVID-19 as frequently as non-IBD controls despite immunosuppressive therapy, possibly due to their awareness and preventive practices. Although the physical, psychological, and social QOL scores during the COVID-19 pandemic were comparable to the prepandemic period, the environmental scores were worse. Psychological tension and interference with work due to pain were lower during the pandemic, which might be influenced by the control of the disease.

Conclusions: Teleconsultation is a feasible and acceptable alternative for IBD patients. They had COVID-19 as frequently as non-IBD controls despite a high frequency of immunosuppressive treatment, possibly due to their awareness of the disease and preventive practices. The QOL scores (except the environmental domains) and psychological issues were quite comparable or even better during the COVID-19 pandemic than earlier.

Introduction

Severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) infection causing the coronavirus disease-19 (COVID-19) pandemic has led to difficulties in providing health-care services throughout the world, including India.¹ The disease originated in Wuhan city, China, in December 2019 and spread throughout the whole world.² The first case of COVID-19 was reported in India from Kerala on 30th January 2020.³ Subsequently, the disease has spread in most parts of India. The number of patients reported is 6 143 019, of whom 96 351 (1.56%) died (as on 29th September 2020); the numbers are rising day by day. Repeated lockdowns have been imposed from time to time to control the epidemic in the country, which further resulted in disruptions of routine health-care services. In fact, in a pan-Indian survey, we found that gastrointestinal (GI) endoscopic services were so disrupted that only 10% of the routine endoscopies were being

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performed in the country during the last week of April 2020.⁴ Outpatient services for GI diseases have also been disrupted drastically.

Moreover, to reduce the risk of transmission among health-care professionals, a policy of having a negative test result for SARS-CoV-2 ribonucleic acid (RNA) before visiting a health-care facility has been recommended in many parts of India. Several hospitals have been provided with a rapid chipbased real time polymerase chain reaction (TruNat test, Molbio Diagnostics Pvt. Ltd., Tirupati, India) that gives results within 1–2 h in addition to the existing reverse transcriptase polymerase chain reaction (RT-PCR) test in India.⁵ However, this imposes a logistic and economic burden on the health-care systems. We recently undertook a multinational review to suggest ways to provide health care, including GI care, cost-effectively during and after this COVID-19 pandemic.¹

Digital methods of communication have advanced day by day in the world, including in India. Telemedicine is quite developed in India, and around 231 government medical colleges are connected through networks of 100 megabytes per second under the National Medical College Network project. Moreover, telemedicine is also being practiced in nongovernment organizations to provide health care. Recently, during the COVID-19 pandemic, the government of India legalized teleconsultation. Accordingly, we thought it worthwhile to use digital and telephonic remote consultation technology to follow-up patients with inflammatory bowel disease (IBD).

Recently, international guidelines have been published for the care of IBD patients during the COVID-19 pandemic.^{6–8} These guidelines suggest, albeit without much scientific evidence, the safety of different drugs to maintain remission of IBD.⁶ To summarize, while some medications are considered safe (e.g. 5-aminosalicylate, biologicals), others are deemed unsafe (e.g. azathioprine, corticosteroids).⁶ However, it is important to mention here that most of these guidelines are based on opinions as high-quality scientific data are scant till date. For example, the recently published SECURE-IBD data showed that even sulfasalazine or 5-aminosalicylate use was associated with the development of severe COVID-19 (adjusted odds ratio 3.1: 95% confidence interval 1.3–7.7).⁹ The same study demonstrated that antitumor necrosis factors may be safe and may even combat the early cytokine storm.9 Although some studies suggested that corticosteroids such as intravenous methylprednisolone and dexamethasone might be useful in severe COVID-19.^{10,11} glucocorticoids were not found to be safe when used for IBD in the SECURE-IBD study.9 Although azathioprine was not found to be so unsafe in patients with other chronic conditions such as rheumatic diseases^{12,13} and may not delay viral clearance,¹⁴ it is not recommended for use in IBD treatment according to the above-mentioned guidelines. Moreover, the availability of drugs might be limited during the lockdown. As stress and anxiety during the COVID-19 pandemic may influence control of IBD and the quality of life (QOL) of these patients, it is worthwhile to study these aspects. Accordingly, we aimed to evaluate (i) the feasibility, acceptability, and limitations of teleconsultation in the follow-up of patients with IBD during the COVID-19 pandemic; (ii) the frequency of COVID-19 among patients with IBD compared to controls in relation to the preventive practices against the infection; (iii) how the epidemic influenced OOL, drug and investigative test availability, and psychological stress and anxiety among IBD patients; and (iv) real-life situations of applicability of international IBD practice guidelines during the COVID-19 pandemic in the care of IBD patients in India.

Methods

During a 1.5-month period (28th May to 16th July 2020), 50 patients with IBD were seen, supported by a web-based



Figure 1 A photograph showing the teleconsultation clinic.

536 JGH Open: An open access journal of gastroenterology and hepatology 5 (2021) 535–541 © 2021 The Authors. JGH Open: An open access journal of gastroenterology and hepatology published by Journal of Gastroenterology and Hepatology Foundation and John Wiley & Sons Australia, Ltd. platform hosted at www.spreadhealth.in (Fig. 1). These were follow-up patients of the Luminal Gastroenterology Clinic in the Department of Gastroenterology in a multilevel public sector teaching institute in northern India who would not be able to physically travel for follow-up due to travel restriction and lockdown. All of them were given the option to consult remotely, and they agreed. These patients could request an online rescheduling of their appointment using this platform on their preferred date. Subsequently, the treating physician could confirm their appointments on the same platform. On the day of consultation, the patients were seen preferably using a video consultation via a mobile app or through telephonic consultation for patients who were unfamiliar with the video-calling technique or did not have the required bandwidth of the network. Before requesting an appointment, all the patients were asked to fill in a digital form, which stated that they consented to consult the physician not in person but digitally due to the constraints related to the COVID-19 epidemic and travel restrictions. The physician's advice was written in the same digital platform (www. spreadhealth.in), which extracted the data filled in by the patients when requesting an appointment and then autogenerated a prescription. A standard predesigned questionnaire was used to capture the data from the patients digitally, which included parameters related to the state of the IBD (Truelove Witt's score and clinical activity index for ulcerative colitis [UC] used earlier in a study on cyclosporine in acute attack of UC refractory to corticosteroids^{15,16} and Harvey-Bradshaw simple index for Crohn's disease [CD]),¹⁷ current drug treatment, dosages, and availability of the drug and investigative tests during COVID-19 pandemic. In addition, data on the hospital anxiety and depression scale (HADS), quality of life (World Health Organization Quality of Life questionnaire [WHOQOL-Bref]),¹⁸ satisfaction with the digital consultation, whether the patient would like the next consultation to be digital or physical, the distance the patient had to travel in case of physical consultation, the quality of video transmission, the voice quality, and need for converting the video consultation to telephonic consultation due to low video quality were all recorded. The subjective parameters were assessed using a Likert scale.19

The data on risk factors for COVID-19 to which patients were exposed, such as outdoor movement, degree of exposure to outside visitors, and use of mask while going out, were also recorded. Regular Group Awareness for Patients (GAP) sessions were scheduled and popularized on a web-based platform (www. biomedinfo.net), and video conferences were organized to educate the patients about COVID-19. The patients were also counseled during these online sessions to allay their anxiety, depression, and fear about IBD and COVID-19. Patients were allowed to ask questions to the physicians during these sessions. All the patients were asked about the presence of symptoms or contact with any patients with COVID-19; if present, the patients were tested for SARS-CoV-2 RNA using naso- oropharyngeal swabs. Hospital admission, if needed, was organized through telemedicine. Admission was offered only after a negative SARS-CoV-2 RNA result of the patient and one of his or her attendants. As per our hospital policy, patients with SARS-CoV-2 infection with other chronic diseases requiring admission are admitted in a building about 3 km away from the main hospital building to prevent the spread of infection. The number of IBD patients who developed COVID-19 was also recorded. The study protocol was approved by the Ethics Committee of the institute (No. 2020-276-IP-EXP-31).

Statistical analysis. The data were analyzed using the Statistical Package for the Social Sciences (SPSS) version 15 (SPSS, Inc., Chicago, Illinois, USA), R epicalc and R studio software (Vienna, Austria), and MedCalc version 14 (Warandeberg 3, 1000 Brussels, Belgium). Qualitative data were analyzed using a Chi-squared test with Yates correction, as applicable. The parametric and nonparametric quantitative data were analyzed using the *t*-test and Mann–Whitney *U* test, respectively. *P* values less than 0.05 were considered significant.

Results

Overall, 50 patients (median age 23 years, range 23-66; 28 [56%] male) with IBD (34 [68%] UC, 16 [32%] CD) were seen using video (n = 40, 80%) and telephonic media (n = 10, 30%)20%) during the 1.5-month period. Of them, 29 (58%) were from urban and 21 (42%) from rural areas. Of the 10 patients who consulted using a telephone, 5 changed from video call to audio call (4 from rural area) due to poor network connectivity. If these 50 patients had to visit us for a physical consultation, the median distance to be traveled would have been 174.5 km (range 5-700); the travel distance was comparable among patients hailing from urban and rural areas (90 km, range 5-600 vs 280 km, range 62–700, respectively; P = 0.3). Network connectivity was rated as good during the consultation with 35 (70%) patients, average for 9 patients (18%), and poor for 6 patients (12%). Good connectivity could be achieved more often during consultation with patients from urban compared to rural areas (25/29, 86% vs 10/21, 47.6%, respectively; P = 0.008).

Satisfaction with the teleconsultation: Of the patients, 16 (32%), 32 (64%), and 2 (4%) reported being "very satisfied," "satisfied," and "neither satisfied nor dissatisfied" with the consultation using digital technology, respectively. None was "dissatisfied" with the teleconsultation. Of the 50 patients, 23 (46%) even rated remote consultation using digital technology to be superior to physical consultation. Interestingly, people from urban areas tended to rate digital consultation as better than physical consultation compared to those from the rural areas (17/29 [74%] vs 6/21 [26%]; P = 0.06) even though the latter group of patients might have to travel a longer distance for physical consultation than the former group (307.2 ± 186.3 vs 158.8154.0; P < 0.05).

Frequency of COVID-19 among IBD patients: Of 50 patients with IBD, 1 (2%) developed COVID-19. This 52-year-old male with CD had comorbid conditions that included morbid obesity (BMI 35 kg/m²), diabetes mellitus and non-alcoholic fatty liver disease, and tobacco addiction, and he was on azathioprine and 5-aminosalicylic acid (5-ASA). He had a mild course, was quarantined at home, and recovered. One other patient with UC, however, had fever and dysgeusia, but her SARS-CoV-2 RNA test was negative. In comparison, 252 (1.5%) of the 16,317 non-IBD controls were positive for SARS-CoV-2 RNA based on their naso- oropharyngeal samples (P = NS).²⁰ Most of them reported being healthy (32; 0.196% reported having comorbidity).

JGH Open: An open access journal of gastroenterology and hepatology 5 (2021) 535–541

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Parameters of infection control measures against COVID-19 among IBD patients: Median number of outdoor visits in a week was reported to be 1 (range 0–7) in response to the question "How many times do you go out of home in a week?" The median number of outsiders met during the last week before the index consultation was 3 (range 0–600). The patients washed their hands regularly (8 times/day [range 4–30]). All except two patients (4%) reported using a mask every time (n = 43, 86%) and most of the time (5, 10%) when went out or met outsiders. Forty-seven (94%) reported following social-distancing practices. On a Likert scale, the fear of COVID-19 was said to be high by most of the respondents (median 7, range 0–10).

Drug therapy and availability of medicines and investigative tests during the pandemic: Fifty patients have been receiving a variable combination of azathioprine (n = 26, 52%), methotrexate (n = 2, 4%), budesonide (n = 5, 10%), tacrolimus (n = 4, 10%)8%), prednisolone (n = 9, 18%), infliximab (n = 1, 2%), and 5-ASA (n = 35, 70%) at the time of digital consultation. Patients reported difficulty regarding the availability of immunomodulators (azathioprine, tacrolimus, methotrexate, and biological) more often than the first-line drugs for the treatment of IBD such as 5-ASA, prednisolone, or budesonide (easy availability of firstline drugs 15/33, 45.5% vs 3/17, 18%; P = 0.06). The availability of the drugs was, however, comparable among patients from urban compared to the rural areas (21/29 [63.6%] vs 12/21 [36.4%], P = ns). Of 50 patients, 36 (72%) reported that they could not undergo the investigations (e.g. total leukocyte and platelet counts and fecal calprotectin) as advised during the previous consultation due to lockdown.

Status of control of IBD before and during index teleconsultation visit: As shown in Table 1, a larger proportion of patients with UC was controlled during index teleconsultation than during the previous consultation. Of the seven patients with moderate to severe UC, three were admitted to the hospital during index consultation (after a negative SARS-CoV-2 RNA test); two were controlled using a biological (infliximab biosimilar in one and vedolizumab in the other due to the previous history of tuberculosis activation following infliximab biosimilar administration). The other patient with UC with a history of variceal bleeding was admitted for workup for possible primary biliary cholangitis and underwent transjugular liver biopsy and adjustment of the dose of tacrolimus.

Psychological status and QOL before and during the COVID-19 pandemic: Figures 2 and 3 show that, although

physical, psychological, and social QOL scores during the prior consultation before the COVID-19 pandemic were comparable to the current consultation, the environmental scores were worse during the current than the initial consultation. Table 2 shows the parameters of HADS during the previous and current consultations; interestingly, psychological tension and interference with work due to pain was lower during the COVID-19 pandemic than previously. It is important to reiterate that IBD was more often in remission during the current than the prior consultation (Table 1), which might have influenced the psychological scores.

Discussion

The current study showed that (i) teleconsultation is feasible and acceptable among IBD patients; (ii) patients with IBD have a comparable frequency of occurrence of COVID-19 despite immunosuppressive therapy, which may be related to their awareness and preventive practices; (iii) although the first-line drugs used in the treatment of IBD were available both in rural and urban areas during the lockdown, the immunomodulators and biologicals were challenging to obtain; (iv) although physical, psychological, and social QOL scores during the current consultation were comparable to those during the previous consultation, the environmental scores were worse during the recent compared to the last consultation; and (v) psychological tension and interference with work due to pain was lower during the COVID-19 pandemic, although this might also be influenced by the fact that IBD was more often under control currently than earlier.

Teleconsultation is an alternative to face-to-face consultation in the care of patients with chronic diseases; although its potential role has been suggested,^{21,22} its feasibility and acceptability among patients with IBD with varying sociocultural background need evaluation. The current COVID-19 pandemic has necessitated physical distancing measures during doctor–patient consultation. Considering the number of patients the doctors have to see in their outpatient clinics in Asia compared to the West, maintaining physical distancing is impossible to achieve. Although telemedicine is likely to be an effective alternative, its value has not been evaluated earlier in the care of IBD patients in Asia. A Spanish study showed that telephone consultation was quite acceptable to the patients.²³ We used video consultation rather than a telephone call and used a web-based platform for appointment rescheduling and prescription writing, making it a

Table 1 Status of control of inflammatory bowel disease before and during index teleconsultation visit

Type of IBD ($n = 50$)	Parameters	Previous consultation	Index consultation	P value
Ulcerative colitis (<i>n</i> = 35)	Number of patients under control	18	28 [†]	0.02
	Truelove Witt's score			0.02
	Mild	0	0	
	Moderate	14	5	
	Severe	3	2	
	Clinical activity index	7 (2–16)	5 (1–16)	
Crohn's disease ($n = 15$)	Number of patients under control	10	11	NS
	Harvey-Bradshaw Index (median, range)	3 (1–7)	2 (0–8)	NS

[†]Two UC patients underwent colectomy.

IBD, inflammatory bowel disease; NS, not significant.

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Figure 2 Health-related quality of life (QOL) data of patients with inflammatory bowel disease during the current teleconsultation at the time of coronavirus disease (COVID)-19 pandemic and earlier before the pandemic. (a) World Health Organization Quality of Life (WHOQOL)-100 physical domain score, (b) WHOQOL-100 physical domain score, (c) WHOQOL-100 social relationship domain score, and (d) WHOQOL-100 environmental domain score. Higher scores indicate better QOL.



Figure 3 World Health Organization Quality of Life questionnaire (WHOQOL-Bref) parameters presented as categorical data during the coronavirus disease-19 pandemic compared to previous consultation.

superior technology. As the period during which the current COVID-19 pandemic would persist is uncertain, teleconsultation may become the new normal for outpatient clinic services, as suggested earlier.¹ Hence, technological improvement is expected to have significant clinical implications.

In the current study, the frequency of COVID-19 among patients with IBD was comparable to a large number of non-IBD controls. The low frequency of COVID-19 has been reported earlier in multiple uncontrolled studies from Spain,²⁴ Hong Kong,²⁵ Taiwan,²⁵ and Italy.²⁶ A systemic review also showed the same result.²⁷ However, our study also compared these data with a large number of non-IBD controls. Patients with IBD are at higher risk of SARS-CoV-2 infection as they are on multiple immunosuppressive medications and need to go to health-care

Table 2 Psychological status before and during the coronavirus disease-19 pandemic (n = 50)

Hospital anxiety and	Previous	Current				
depression scale questions	consultation	consultation	P value			
Tension in last week						
Most of the time	3	4				
A lot of the times	9	4	0.003			
Occasionally	25	14				
Not at all	10	28				
Felt downhearted in last week						
Most of the time	2	2				
A lot of the times	7	3				
Occasionally	19	11	NS			
Not at all	19	34				
Tried hurting or killing yourself	÷					
Often	0	0				
Occasionally	2	2	NS			
Not at all	45	48				
Body pain severity in last 1 month						
Very severe	1	0				
Severe	3	4				
Moderate	17	8	NS			
Mild	11	18				
None	15	20				
Interference in work due to pain						
Extremely	2	1				
Quite a bit	6	4				
Moderate	9	1	0.038			
A little bit	11	13				
Not at all	19	31				
Felt will never get better						
Always	2	0				
Sometimes	15	10	NS			
Never	30	40				
Emotionally, physically or sexually victimized						
Yes	7	2	NS			
No	40	48				

facilities repeatedly, and chronically inflamed gut mucosa has been shown to have an increased abundance of SARS-CoV-2-binding receptors, such as angiotensin converting enzyme-2 (ACE-2).²⁸⁻³⁰ The virus enters into the host cells, binding the ACE-2 and host cellular transmembrane serine protease 2 (TMPRSS2).³¹ However, the low frequency of COVID-19 among patients with IBD possibly relates to greater awareness among these patients (further raised by regular patient education sessions) and adherence to preventive practices. The experience of the IBD center in Wuhan with 318 patients showed the benefit of such an approach.³²

Interestingly, most of the domains of QOL and psychological issues were either comparable or better during the current pandemic compared to the prepandemic period. This might be related to the fact that, in the prepandemic period, more patients had active disease than during the pandemic, suggesting that the activity of IBD is a significant contributor to psychological disturbances and impairment in the QOL than the pandemic itself. However, environmental domains of the QOL, which included financial resources, freedom, physical safety and security,

accessibility and quality of health and social care, home environment, opportunities for acquiring new information and skills, participation in and opportunities for recreation/leisure activities, physical environment (e.g. traffic), and transport were significantly worse during the pandemic than earlier. The current data also suggest that optimal drug treatment for IBD is more critical to control the disease than suboptimal pharmacotherapy in fear of COVID-19. Most of our patients were on immunomodulators, yet the frequency of COVID-19 was comparable to that in the general population, possibly due to a high level of awareness and adequate preventive practices, reiterating the importance of these strategies. Moreover, our data may also raise concern regarding the recent guidelines on pharmacotherapy for IBD during the COVID-19 pandemic, particularly in the Indian context, which suggested cheaper immunomodulators such as azathioprine and 6-mercaptopurine to be unsafe in the absence of rigorous, controlled, scientifically valid data.⁶ Some studies even suggested that patients with IBD on treatment may have less severe COVID-19.²⁷ Although there is not enough data regarding the safety or adverse event profile with thiopurines in patients with IBD in the context of COVID-19 in the literature, our studydue to its small sample size and observational design-does not support the use of these agents in the context of SARS-CoV-2 infection either.

Our study showed that the availability of immunomodulators (azathioprine, tacrolimus, methotrexate, and biological) was lower than the first-line drugs, such as 5-ASA, prednisolone, or budesonide, for the treatment of IBD both in rural and urban areas. This is quite expected. In a large country like India, privately owned medicine shops dispense prescribed medicines both in the rural and urban areas. Because the medicines stocked by these shops depend upon the prescription pattern of the local physicians, the less-prescribed medicines such as azathioprine, tacrolimus, methotrexate, and biologicals might not be available in rural places.

Our study, however, is not without limitations. A small number of patients with IBD is a limitation. Although we are continuing to see more patients with IBD during the COVID-19 pandemic using telemedicine, we wanted our initial results to be published rapidly for the benefit of the patients and health-care workers during this global emergency. Data on outdoor movement and degree of exposure to outside visitors are subject to self-reporting bias. Severity assessment for IBD, such as Harvey-Bradshaw Index and Truelove Witt's score, would require systemic and abdominal examination, which could not be performed during teleconsultation. As all these patients already had an appointment scheduled prior to the COVID-19 epidemic, and none declined to participate, selection bias is quite unlikely.

In conclusion, we found that teleconsultation is a feasible and acceptable alternative for the follow-up of patients with IBD. In this controlled study, IBD patients were found to have a comparable frequency of COVID-19 to the non-IBD controls despite a high frequency of immunosuppressive treatment among them; this might have resulted from the fact that awareness about COVID-19 and preventive practices were quite prevalent among the IBD patients. The QOL scores (except the environmental domains) and psychological issues were quite comparable or even better during the COVID-19 pandemic than earlier. This might be related to the fact that the IBD was quite controlled during the current consultation than earlier, which might have resulted from an optimal immunosuppressive treatment. It is important to reiterate that, in spite of the immunosuppression, the frequency of COVID-19 was not greater among IBD patients, raising concern about the contrary opinion expressed in the international guidelines.⁶

Acknowledgment

The authors acknowledge Shanti Public Educational and Development Society for support of this work.

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