

Absence of COVID-19 Infection in Patients Accessing IBD Unit at Humanitas, Milan: Implications for Postlockdown Measures

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INTRODUCTION: The risk of coronavirus disease-19 infection for healthcare professionals and patients in hospitals remains unclear.

METHODS: We investigated whether precautions adopted in our inflammatory bowel disease (IBD) unit have minimized the risks of infection for all patients accessing our facilities in a 1-month period by assessing the rate of coronavirus disease-19 infection in the follow-up period.

RESULTS: Three hundred-twenty patients with IBD were included. None were infected from severe acute respiratory syndrome-coronavirus 2 in the follow-up period. None of the IBD team members were infected.

DISCUSSION: Neither pharmacological immunosuppression nor access to the hospital seem to be risk factors for infection in patients with IBD.

Am J Gastroenterol 2020;00:1–3. <https://doi.org/10.14309/ajg.0000000000000829>

INTRODUCTION

The coronavirus disease-19 (COVID-19) pandemic represents a great challenge for healthcare professionals (HCPs) and patients. The overcrowding of COVID-19 patients in hospitals and clinics is believed to increase the risk of infections for those who access these places for any reason. A recent survey in over 3,800 patients with inflammatory bowel disease (IBD) in Northern Italy showed that more than 80% are afraid of severe acute respiratory syndrome-coronavirus 2 (SARS-CoV2) infection and a similar proportion feared attending their referral IBD center for visits or therapies (1).

Since the beginning of the outbreak in Lombardy, Italy (first case on February 20, 2020), the Humanitas IBD Center in Milan has adopted several safety measures to protect over 4000 patients with IBD in the follow-up period and their HCPs from SARS-CoV2 infection while continuing to deliver the same quality of care and avoiding the discontinuation or initiation of any biological treatment as suggested by the International Organization for the Study of Inflammatory Bowel Diseases (2,3).

We aimed to investigate whether preventive measures adopted in our IBD unit (listed in Table 1) have been effective in minimizing the risks of infection for all patients with IBD accessing our facilities during a 1-month period (March 9 to April 8, 2020) and the implications that these measures might have for the period after lockdown, in which coping with COVID-19 infection and maintaining a COVID-free clinic is a key objective.

METHODS

Since February 22, our IBD unit has been restructured to minimize the risk of infection for patients, as previously described (4), and to maintain a minimum quality standard of care for all patients with IBD followed-up in our center (more than 4,000 patients, 75% living outside the region) (5). On March 9, national lockdown was imposed, with several restrictions on work activities and travel.

To assess the efficacy of our preventive measures, we assessed the rate of infection from COVID-19 in all patients who accessed our IBD unit from March 9 to April 8. This period was chosen to minimize the risk of bias deriving from the risk of infection outside the hospital before the national lockdown and to have a minimum follow-up of 21 days (range 21–51 days) for each patient to observe any symptom onset. Patients were checked for signs and symptoms suggesting of COVID-19 and body temperature the day they accessed the unit, and then, during the last week of April 2020, they were contacted by the research nurse to check for any diagnosis occurred during the period after the last access to our unit. Every new COVID case diagnosed in this time period (either by positive pharyngeal swab OR by chest imaging OR presence of at least 3 COVID-19 symptoms and recent close contact with any positive patient) eventually communicated by any patient was included in the analysis investigating any access in the 28 days before visiting our IBD unit.

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Received May 6, 2020; accepted July 3, 2020; published online XXXX

Table 1. Preventive measures implemented at Humanitas, Milan

Level of intervention	Preventive measure	Details
Hospital	Checkpoint at main entrance of each building	<ul style="list-style-type: none"> • Aimed at patients and HCPs • Check for COVID-19 signs and symptoms • Body temperature measurement (body scanner and second check with a tympanic device if first value > 37.5 °C) • Use of hand-sanitizing gel • Provision of surgical masks • Caregivers allowed inside only for patients who are not self-sufficient
IBD center	Rescheduling procedures	<ul style="list-style-type: none"> • Only nondeferrable procedures confirmed • Reduction in the number of concomitant patients (to avoid overcrowding) • Adequate distance (>1 m) between patients in the waiting room
	Preventive interview	<ul style="list-style-type: none"> • Phone call some days before the visit, followed by an e-mail to check for symptoms • Questions on symptoms and contacts covering the past 2 weeks: <ul style="list-style-type: none"> ◦ presence of fever, cough, muscular and articular pain, anosmia and/or ageusia, and sore throat ◦ Contact with someone with direct contact with the abovementioned symptoms • Educational activities regarding the use of personal protective equipment (PPE), according to the documents provided by the National Ministry of Health and Italian Patient's Association.
	At outpatient clinic	<ul style="list-style-type: none"> • PPE for all HCPs and patients (surgical mask, gloves, and single-use gown) • Body temperature measurement, each patient received a hand-sanitizing gel dose before any procedure, and every infusion chair sanitized after each patient • Body temperature check every 2 hours for all patients spending much time at the hospital (e.g., for clinical trial procedures) • Adequate distance between infusion chairs
	Follow-up	<ul style="list-style-type: none"> • Patients educated to immediately inform the IBD center <i>via</i> a helpline about any health problem arising. Phone calls and e-mails from the nurse were also used for active monitoring

HCP, healthcare professional; IBD, inflammatory bowel disease.

RESULTS

Table 2 shows the reasons of access to our IBD unit in the defined time period. Three hundred twenty patients (n = 155 [48.4%] with Crohn's disease and n = 165 [51.6%] with ulcerative colitis) had at least one access to our IBD unit, with a visit duration ranging from 15 minutes to 7 hours (median time = 80 minutes). The median age was 41 years (range 17–85), 52 patients (16.2%) had at least one comorbidity, 32 (10%) were on concomitant oral corticosteroids, and 76 (23.75%) had active IBD. Among these patients, 310 patients (97%) developed no symptoms or signs from COVID-19 in the follow-up period (at least 21 days). Of the 320 patients accessing the IBD unit, 3 (0.9%) were not admitted to the infusion room because they had a measured body temperature >37.5 °C. One patient (0.3%) was not admitted because he declared cough in the days before the visit, and 1 (0.3%) did not receive injection of an investigational drug because she had a temperature of 38.3 °C at the third measurement (3 hours later than the first check). These patients were remotely followed until resolution of symptoms and none were found to be infected from SARS-COV2.

Seven patients (2.2%) reported at least one symptom within 4 weeks after hospital access. They were remotely followed with a phone call every week. All of them had negative swab for SARS-COV2. None of the 11 members of the IBD team working at the clinic in the same period, and who had contacts with these patients, developed any sign and symptoms of COVID-19.

DISCUSSION

The risk of infection from SARS-COV2 for HCPs and patients attending hospitals and clinic is a major worry (6–8). Patients with IBD also are afraid that concomitant immunosuppressive therapies, especially corticosteroids (9), might increase their risk of being infected by SARS-COV2 (8). An et al. reported no cases of COVID-19 in Wuhan, China, because of strict preventive measures, including withdrawal of immunosuppressive therapies (10). In our cohort of 320 patients, we continued all therapies unchanged, including infusion therapies that require the patient to access the hospital, with no cases of COVID-19 in the follow-up period. In other reports, concomitant corticosteroids, old age, and comorbidities increased the risk of COVID-19 negative outcomes. In our global cohort of more than 4,000 patients with IBD, we recorded 20 cases of COVID-19: 15 of them had no access to our hospital, 3 of them had access to our unit before February 20, and 2 of them accessed the unit before the national lockdown, both of them living or working in high-risk situations for contagion.

Our findings suggest that strict preventive measures, including access restrictions, use of personal protective equipment, interpersonal distance, checks for early symptoms and signs of COVID-19, and patient education are effective in minimizing the risk of infections. About 15% of our patients had concomitant corticosteroid, comorbidities, or age older than 60 years, but despite these detrimental risk factors, none of them developed COVID-19. Our procedures could miss potentially asymptomatic patients or

Table 2. Number of patients accessing the Humanitas inflammatory bowel disease unit (period March 9 to April 8)

	N
Total number of accesses (any reason)	320
Vedolizumab infusion	113 (35%)
Infliximab infusion	152 (48%)
Ustekinumab infusion/injection	17 (5%)
Clinical trial procedures	38 (12%)
Procedures	
Only infusion	103 (32%)
Visit + infusion	82 (25%)
Visit + infusion + other procedures	43 (13%)
Visit + other procedures	31 (10%)
Only visit	17 (5%)
Infusion + other procedures	13 (4%)
Only endoscopy	12 (3%)
Visit + bowel ultrasound	8 (2%)
Visit + infusion + bowel ultrasound	7 (2%)
Visit + infusion + endoscopy + other procedures	2 (0.6%)
Visit + endoscopy + other procedures	1 (0.3%)
Only other procedures	1 (0.3%)

those patients with atypical symptoms of COVID-19; however, no patients in our study population had COVID-19 at the last follow-up, and no HCPs contracted COVID-19 from our patients. By following these rules, patients can safely access IBD units for therapy administration. Although these procedures were time consuming and required high level of coordination between HCPs and even patients, the routine activities of our center were not significantly affected in the numbers of patients accessing the unit and the quality of care (2). We also demonstrated that continuing effective therapies for maintenance of IBD control does not expose patients with IBD to any further risk of contracting SARS-COV2. Neither pharmacological immunosuppression nor access to the hospital seem to be risk factors for infection in patients with IBD. These findings are crucial for the next phase that every IBD center will face at the end of lockdown, when the goal will be maintaining a COVID-free clinic while awaiting an effective anti-COVID-19 treatment or vaccine.

CONFLICTS OF INTEREST

Guarantor of the article: Silvio Danese, MD.

Specific author contributions: G.F. and S.D. initiated the study; D.G., S.R., F.F., and M.A. collected the data; D.G. and G.F. analyzed the data; D.G. and G.F. drafted the manuscript; S.D. critically revised the manuscript.

Financial support: None to report.

Potential competing interests: G.F. received consultancy fees from Ferring, MSD, AbbVie, Takeda, Janssen, Amgen, Sandoz, Samsung Bioepis, Celltrion; M.A. received consulting fees from Nikkiso Europe and lecture fees from Janssen, AbbVie and Pfizer; S.D. has served as a speaker, consultant, and advisory board member for Schering-Plough, Abbott (AbbVie) Laboratories, Merck and Co, UCB Pharma, Ferring, Cellerix, Millenium Takeda, Nycomed, Pharmacosmos, Actelion, Alfa Wasserman, Genentech, Grunenthal, Pfizer, Astra Zeneca, Novo Nordisk, Cosmo Pharmaceuticals, Vifor, and Johnson and Johnson; the remaining authors have no conflicts to disclose.

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