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**Consequences and management of COVID-19 on the care activity of an Inflammatory Bowel Disease Unit**

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**ABSTRACT**

**Introduction:** COVID-19 has altered the usual practice of medicine and the state of emergency declared in Spain on March 14<sup>th</sup> has considerably changed the activity of inflammatory bowel disease (IBD) units. The aim of this study was to evaluate the

consequences of COVID-19 on the IBD Unit's activity and provide information on restructuring with available resources.

**Methods:** an observational study was performed in a referral hospital in Madrid (Spain). Type of appointment, loss of follow-up, hospital admission, treatment changes, endoscopic activity, surgeries and blood tests were evaluated between March 15<sup>th</sup> and May 15<sup>th</sup>, 2020. This data was compared with the usual activity a year before.

**Results:** among the 510 patients included, 476 (93.33 %) received had a remote consultation, representing an increase of 92.38 % compared with the previous year (0.95 %). There was a loss of follow-up in 26 patients (5.1 %) vs 15 (3.58 %) the previous year. A total of 60 (35.09 %) blood tests, 64 (76.19 %) endoscopies and all scheduled surgeries were suspended. Besides, 484 (94.9 %) patients remained adherent vs 417/419 (99.5 %) in the pre-pandemic period and 48 (9.41 %) reported symptoms of an IBD flare. Thirty-nine (7.6 %) patients developed symptoms suggestive of COVID-19.

**Conclusion:** a large number of tests and on-site outpatient visit consultations were suspended. However, a rapid adaptation to telemedicine allowed these patients to be closely followed up. Although it was possible to maintain therapeutic compliance, with a loss to follow-up slightly higher than the previous year, suspensions and delays of tests could have significant negative consequences in the long term.

**Keywords:** COVID-19. Pandemic. Inflammatory bowel disease. Procedures. Impact.

## INTRODUCTION

The new severe acute respiratory syndrome caused by coronavirus type 2 virus (SARS-CoV-2), also called COVID-19, has caused a pandemic that has rapidly spread to many countries around the world and has generated major public health problems. In Spain, the first case was detected on January 31<sup>st</sup>, 2020 and the state of emergency was declared on March 14<sup>th</sup>, 2020. Movement was limited and social distancing introduced in order to deal with the health emergency, with a total of 5,723 confirmed cases at that time in the country (1).

COVID-19 has altered the usual practice of medicine, and the huge need for health system resources mean that other healthcare areas received very limited attention. Inflammatory bowel disease (IBD) patients are supposed to be at high risk, especially those receiving immunosuppressants. On the other hand, these patients require close follow-up with blood and fecal tests, imaging procedures and a multidisciplinary management, including gastroenterologists, surgeons, nurses and psychologists, among others. The cancellation of outpatient visits, blood sampling and endoscopic or radiologic procedures was frequent in IBD units across the country during the peak of the pandemic and while the “state of emergency” was officially activated.

So far, the consequences of the COVID-19 pandemic on the care activity of IBD units and how to deal with them have not yet been studied in Spain. This study aimed to describe how COVID-19 has affected scheduled activity, patients and resources in an IBD Unit care. Therefore, the kind of appointment, treatment changes, withdrawal of treatment and endoscopies, surgeries and blood tests which were suspended or delayed because of the COVID-19 pandemic were studied. This data was compared with the same period in the previous year.

The secondary objective of the study was to provide updated information on the restructuring and reorganization of the health service, describing how our Inflammatory Bowel Disease Unit adapted to the safety protocols established during the pandemic, with the limited means and resources available.

## **METHODS**

### **Patients and methods**

This was an observational retrospective study performed in the IBD Unit of Hospital Universitario Puerta de Hierro Majadahonda, which is a referral center. This included those IBD patients who had scheduled visits at the outpatient clinic, the endoscopy suite or blood sampling in the period when confinement was declared due to SARS-CoV2 pandemic in Madrid.

Our IBD Unit is a dedicated multidisciplinary service composed of five specialist physicians and two specialist nurses. There are seven medical consultations spread over two days a week and three days of endoscopic services per week, exclusively for

these patients. One nurse is available to manage the IBD Unit's daily e-mail. The Day Hospital also played an important role in treatment administration and monitoring activity via blood and fecal analyses.

Data were collected on demographics, IBD type, smoking status, comorbidities and medication. The consequences of COVID-19 on the unit were evaluated based on the type of appointment, loss to follow-up, hospital admission, treatment changes, withdrawal of treatment, endoscopic activity, surgery, blood tests, healthcare worker relocation and COVID-19 infection. COVID-19 infection was considered in those patients who had a compatible symptomatology or a positive PCR in nasopharyngeal exudate. A comparison was made between IBD type, sex, immunomodulators, biologic treatment and corticosteroids. Data was obtained from electronic medical records, which included information about the unit's telephone consultation and e-mail, in which patients were asked about COVID-19 symptoms, IBD flares and medication compliance. In the case of biologic treatment, medication compliance was also obtained from the electronic data of drugs for hospital use. We also revised information recorded by the Primary Care physician, especially about the development of symptoms suggestive of COVID-19. The SARS-CoV-2 PCR test was ordered by the Primary Care provider and data were analyzed during the period from March 15<sup>th</sup> to May 15<sup>th</sup>, 2020. Pre-pandemic data were obtained for the period March 15<sup>th</sup> to May 15<sup>th</sup> of the previous year using the same information source: data from electronic medical records, telephone consultation and unit e-mail.

A safety protocol was set up for each patient at the infusion center with temperature tests, asking patients about symptoms and implementing social distancing measures. Furthermore, the possibility of a home delivery of subcutaneous treatment (adalimumab, golimumab, ustekinumab and tofacitinib) or pick-up at the hospital entrance was also offered. Disease activity was assessed by the Harvey-Bradshaw index (HB) in Crohn's disease (CD) and partial Mayo score (PMS) in ulcerative colitis (UC). This was considered as inactive if the HB index was  $\leq 4$  points and PMS  $\leq 2$  points.

### **Statistical analysis**

In the descriptive analysis, absolute and relative frequencies were calculated for categorical variables and the median with 25 and 75 percentiles for quantitative variables. Categorical variables and proportions were compared using the Chi-squared test. The statistical significance level was set at 0.05 and the statistical package Stata v 15.1 was used for analysis. The study complied with the Declaration of Helsinki.

## **RESULTS**

### **Patient characteristics**

During this period, there were 510 scheduled visits at the outpatient clinic. The baseline characteristics of patients are shown in table 1. With regard to disease activity during this period, there were 436 inactive patients (85.49 %), 48 patients (9.41 %) reported symptoms suggestive of an IBD flare and 26 (5.10 %) were unknown because they were lost to follow-up. An IBD flare was detected in 26 UC and 22 CD (PMS: 4.15 [2-7]; the Harvey-Bradshaw mean was 5.91 [1-13]). In order to aid with interpretation, from March 15<sup>th</sup>, 2019 to May 15<sup>th</sup>, 2019 there were 374/418 inactive patients (89.5 %), 29/418 (6.9 %) patients reported symptoms suggestive of an IBD flare and 15/418 (3.6 %) were unknown because they were lost to follow-up. An IBD flare was detected in 17 UC and 12 CD (PMS: 4.94 [2-8]; the Harvey-Bradshaw mean was 7.58 [4-12]). Twelve hospital admissions were recorded during this period (2.35 % of the patients), four were due to an IBD flare (0.78 %), three due to COVID-19 (0.59 %) and five (0.98 %) for other reasons not associated with IBD or COVID-19.

### **Outpatient planning**

Regarding the kind of patient visit model, 476 of the 510 patients (93.33 %) had a telephone consultation, eight (1.57 %) had a face-to-face consultation and 26 patients (5.1 %) were classified as lost to follow-up. There were 419 scheduled visits during the same period one year earlier. The most frequent type of patient visit model was face-to-face consultation with 400 patients (95.47 %) and four patients (0.95 %) had a telephone consultation. Fifteen patients (3.58 %) were classified as lost to follow-up. In addition, support was provided via e-mail and 1,783 e-mails were received and answered during the study period. A total of 951 e-mails were received before the



pandemic (from March 15<sup>th</sup> to May 15<sup>th</sup>, 2019).

With regard to the blood sampling scheduled in this period, 111 (64.91 %) were performed and a total of 60 (35.09 %) were suspended or postponed. From March 15<sup>th</sup> to April 15<sup>th</sup>, patients undergoing endoscopic evaluation did not have nasopharyngeal swabs due to limited resources. From April 15<sup>th</sup> to May 15<sup>th</sup>, patients had nasopharyngeal swabs taken three days before their endoscopy. A total of 20 endoscopies were performed (23.80 %), while 64 (76.19 %) were suspended or postponed. A total of 17 colonoscopies and three gastroscopies were performed. The reasons for the gastroscopies were two due to upper gastrointestinal bleeding and one due to persistent vomiting. The reasons for the colonoscopies were an IBD flare in ten cases, four to evaluate postsurgical recurrence and three due to lower gastrointestinal bleeding. In the same period one year earlier, 111 endoscopies (106 colonoscopies and five gastroscopies) were performed. All non-urgent scheduled surgeries were also suspended. A definitive ileostomy was performed in a patient with severe refractory CD, with no complications.

### **Treatment**

Patients received intravenous biologic drugs at the hospital infusion center or collected the medication at the hospital pharmacy. During this period, 110 (42.15 %) IBD patients receiving biologic therapy or tofacitinib needed an IV infusion (80 received infliximab and 30 received vedolizumab) and 151 (57.85 %) collected subcutaneous biologic drugs or tofacitinib from the hospital pharmacy (96 adalimumab, 43 ustekinumab, seven golimumab, five tofacitinib) (Table 2).

Drug infusion was received in 95 of 110 scheduled patients (86.36 %) during this period and 142 of 151 patients (94.03 %) obtained drugs from the hospital pharmacy. In these cases, the reason for non-adherence was due to patient decision in 19 cases and suspension of physician visits due to COVID-19 confirmed by PCR in five patients. With regard to immunosuppressants, two out of 160 patients (1.25 %) stopped treatment on the advice of their doctor due to a PCR-confirmed COVID-19 infection.

A total of 18 of 151 patients on subcutaneous biologic drugs opted for home delivery, following the available safety protocol. Concerning treatment changes, corticosteroid

treatment was initiated in five patients (0.98 %) and the corticosteroid dose was increased in three (0.59 %). Anti-TNF, ustekinumab and vedolizumab were intensified in 16 (3.13 %), two (0.39 %) and one (0.19 %) cases, respectively. Furthermore, anti-TNF was initiated in eight (1.57 %), vedolizumab in one (0.19 %) and the 5-asa dose was initiated in five (0.98 %) and increased in four (0.78 %) patients.

In the same period one year earlier, biologic treatment was initiated in 22 (5.25 %) cases, intensified in eleven (2.63 %) and suspended in three cases (0.72 %) due to infectious diseases and following the patient's own decision in two cases (0.47 %). Immunosuppressants were initiated in four patients (0.95 %) and corticosteroid treatment was suspended in six patients (1.43 %).

### **COVID-19 prevalence and characteristics**

Thirty-nine patients developed symptoms suggestive of COVID-19 (7.6 % of total patients) and a diagnosis was only made in 12 patients (seven by PCR in nasopharyngeal exudate and five by Ig M and Ig G serology). Diagnosis and follow-up were performed by Primary Care with a remote consultation. The most frequently referred symptoms were fever (59 %), cough (66.7 %), asthenia (43.6 %), dyspnea (28 %), headache (20 %), diarrhea (18 %) and nausea and vomiting (5 %). None of the cases with symptoms consistent with COVID-19 or COVID-19 confirmed by PCR had an IBD flare. Three patients were admitted due to COVID-19 and none died or needed to be admitted to the Intensive Care Unit (ICU).

Regarding treatment changes, none of the patients who initiated or increased corticosteroid treatment developed symptoms suggestive of COVID-19. In the case of biologic treatment, anti-TNF was initiated or intensified in 16 patient, while one patient had infliximab intensification and symptoms suggestive of COVID-19. No significant association was found between COVID-19 infection (including clinical and PCR diagnosis) and IBD type (UC 41 % vs Crohn 59 %;  $p = 0.65$ ), sex (male 9.52 % vs female 5.81 %;  $p = 0.11$ ), immunomodulators (8.13 % vs 7.4 %;  $p = 0.78$ ), biologic treatment (8.59 % vs 6.69 %;  $p = 0.65$ ) or corticosteroids (3.85 % vs 7.85 %;  $p = 0.67$ ).

### **Staffing**



Regarding the medical staff dedicated to inflammatory bowel disease, four of the five doctors were relocated to COVID hospitalization wards. As a result, four of the five planned consultations could not be performed on the scheduled date or time. Nevertheless, as these consultations were mainly performed remotely, the vast majority finally took place with an average delay of less than a week. Similarly, consultations managed by a doctor who was not relocated to COVID areas went ahead at all times in order to assess urgent patients or those who needed a face-to-face consultation. No medical staff have so far developed symptoms or tested positive for SARS-CoV-2. However, one of the two nurses in the unit caught COVID-19 and his partner assumed the patient overload.

## **DISCUSSION**

By May 15<sup>th</sup>, 2020, the pandemic triggered by SARS-CoV-2 had caused as many as 230,183 PCR confirmed cases in Spain and 124,571 patients were admitted to hospital. Therefore, Spain was the third country in terms of frequency in Europe and the eighth worldwide at this time (1,2). This situation led to a drastic change in the management of non-COVID-19 patients due to the declaration of the state of emergency, confinement and the fact that practically all hospital resources were taken up by COVID-19 patients.

The management of IBD patients during the pandemic is not well established. More units are reporting their experience with IBD patients during the pandemic (3-9) but most of them have focused on the management and evolution of COVID-19 in patients with IBD or with treatment adherence. The largest IBD unit that has reported data is the IBD Unit in Hull (United Kingdom), which describes the operational changes in IBD management to ensure a safe and effective care for IBD patients (3).

However, changes made in the IBD units due to the COVID-19 pandemic, as well as their impact on the different areas, have not been determined and this was the main objective of this study. Medical care was provided remotely in almost all cases, which was also proposed by other groups with significant experience in this model (3,4,10) and also as a result of the survey of different units in Spain (11). There has been an important change compared with the previous year, with an increase in the remote

delivery of healthcare services via telephone consultation in 476/510 (93.33 %) vs 4/419 (0.95 %) and 1,783 vs 951 e-mails. By shifting to remote delivery, we have been able to adequately evaluate the patient's clinical and analytical situation and therapeutic adhesion, whilst modifying the necessary treatments and promoting therapeutic compliance. Furthermore, the loss to follow-up was only slightly higher than the previous year (5.1 vs 3.58 %), probably due to the promotion of telephone consultation and e-mail support.

We demonstrated a loss of adhesion of 5.1 %, largely due to patient choice (73.08 %) and with respect to hospital administered drugs, which resulted in a lack of adherence in this case of 10.6 %. During the previous year, there were just two patients who chose not to receive hospital administered drugs. Therefore, during the pandemic, there was increase in treatment discontinuation. Especially in those patients receiving biologic treatment, 19/510 (3.73 %) vs 2/419 (0.48 %). This can probably be explained by the patient's fear of going to the hospital and contracting COVID-19. In the case of oral medication, it was possible to achieve complete adherence. In other studies, the lack of adherence was over 20 % (8,9). The IBD Hull Unit implemented similar measures to ours (3) as a safety protocol, with temperature taking, social distancing and the possibility of receiving treatment outside the hospital. There was only one patient receiving biologic treatment (553) who suspended treatment. Only a small proportion of our IBD patients experienced an IBD flare during the pandemic and most cases were mild-moderate, which is consistent with previously reported data (4-7).

Although urgent procedures are regularly performed in many hospitals, non-urgent and follow-up tests have been reduced or even suspended. In our unit, 35.9 % of blood tests and 76.19 % of endoscopies were delayed as a consequence of trying to limit hospital based procedures that were not strictly necessary. Due to the scarcity of resources, endoscopies performed in the first month were undertaken without nasopharyngeal swabs. However, the use of nasopharyngeal swabs was implemented the following month, reducing the risk of infection in healthcare workers, as recommended by scientific societies (12,13). This strategy is also implemented in other centers, such as the Hull Inflammatory Bowel Disease Unit. Procedure suspensions and test delays could have a negative long-term impact on these patients, since they

require close monitoring and we do not know when the pandemic will end. Furthermore, it will certainly lead to a large overload of rescheduled procedures, which will be difficult to manage once the pandemic is over.

With regard to COVID-19 infections, most cases were not confirmed by nasopharyngeal PCR, due to the lack of resources in our region. Most patients remained at home during infection with close control of their evolution. Only three patients had to be admitted to hospital due to test confirmed COVID infection. These patients successfully recovered with no need for intensive supportive care at the ICU, with results similar to those reported in other series (6,14). Our study included very few patients with COVID, but our data are not consistent with previous evidence that found a higher incidence among patients taking glucocorticoids than in patients on biologic drugs (14). However, this was not the aim of this study and the difficult situation of the pandemic in Madrid and the diagnostic test shortage have conditioned the heterogeneous and clinically-based diagnosis of COVID-19 of IBD in the majority of cases.

## **CONCLUSION**

The state of emergency triggered by COVID-19 has negatively impacted on care, tests and procedures for IBD patients. There was an increase in the remote management of IBD patients during the pandemic, which has enabled close contact to be maintained with patients. Thus, ensuring an adequate standard of care and a favorable outcome in most cases with therapeutic compliance and a loss to follow-up slightly higher than the previous year. However, the overall consequences of the suspension and delay of procedures and tests could have severe consequences and must be evaluated in the long term.

## **STROBE Statement**

The authors have read the STROBE Statement-checklist of items, and the manuscript was prepared and revised according to the STROBE Statement-checklist of items.

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**Table 1. Baseline characteristics**

	<i>n</i> = 510
Sex, male ( <i>n</i> , %)	252 (49.41 %)
Age ( $\bar{x}$ , IQR)	50 (40-60)
Disease ( <i>n</i> , %)	
Crohn's disease	303 (59.41 %)
Ulcerative colitis	199 (39.02 %)
Indeterminate colitis	8 (1.57 %)
Localization Montreal ( <i>n</i> , %)	
L1: Ileal	137 (45.21 %)
L2: Colonic	46 (15.18 %)
L3: Ileocolonic	120 (39.6 %)
L4: Upper GI involvement	16 (5.28 %)
E1: Proctitis	33 (16.58 %)
E2: Left-sided colitis	67 (33.66 %)
E3: Extensive colitis	100 (50.25 %)
Behavior Montreal ( <i>n</i> , %)	
B1: Inflammatory	177 (58.42 %)
B2: Stricturing	83 (27.39 %)
B3: Penetrating	49 (16.17 %)
Perianal disease ( <i>n</i> , %)	51 (16.83 %)
Smoking ( <i>n</i> , %)	68 (13.33 %)
Ex-smoking ( <i>n</i> , %)	91 (17.84 %)
Comorbidity ( <i>n</i> , %)	
Hypertension	67 (13.13 %)
Chronic liver disease	37 (7.25 %)
Current malignancy	34 (6.66 %)
Cardiovascular disease	26 (5.1 %)
Diabetes	19 (3.73 %)
Obstructive pulmonary disease	20 (3.92 %)
Chronic kidney disease	2 (0.39 %)



Medication ( <i>n</i> , %)	
5-ASA	152 (29.8 %)
Immunomodulators (thiopurines or metotrexate)	160 (31.37 %)
Oral corticosteroids	26 (5.09 %)
Vedolizumab	30 (5.88 %)
Ustekinumab	43 (8.43 %)
Tofacitinib	5 (0.98 %)
Anti-TNF $\alpha$	183 (35.8 %)
Infliximab	80 (16.69 %)
Adalimumab	96 (18.82 %)
Golimumab	7 (1.37 %)

**Table 2. Consequences of COVID-19 on IBD Unit care activity**

	<i>n</i> = 510
Active disease ( <i>n</i> , %)	48 (9.41 %)
Hospital admission	12 (2.35 %)
Kind of appointment	
Telematic consultation	476 (93.33 %)
On-site outpatient visits	8 (1.57 %)
Loss of follow-up	26 (5.1 %)
E-mail consultation	1,783
Withdrawal of treatment	26 (5.1 %)
Own decision	19/26 (73.08 %)
PCR COVID +	7/26 (26.92 %)
Treatment suspension on own decision	19 (3.7 %)
Crohn's disease	8/19 (4.2 %)
Ulcerative colitis	11/19 (5.8 %)
Intravenous biologic treatment	7/19 (36.8 %)
Intravenous biologic treatment + immunosuppressant	5/19 (26.3 %)
Subcutaneous biologic treatment	3/19 (15.8 %)
Subcutaneous biologic treatment + immunosuppressant	4/19 (21.1 %)
Biologic treatment	261 (51.18 %)
Day hospital	110/261 (42.15 %)
Hospital pharmacy	151/261 (57.85 %)
Treatment changes	64 (12.55 %)
Initiate or increase 5-ASA	9/64 (7.81 %)
Initiate or increase corticosteroids	8/64 (12.5 %)
Corticosteroids suspension	3/64 (4.69 %)
Initiate anti-TNF	8/64 (12.5 %)
Initiate vedolizumab	1/64 (1.56 %)
Biological intensification	19/64 (29.69 %)
Immunomodulators suspension	7/64 (10.94 %)

Biological suspension	5/64 (7.81 %)
Other	4/64 (6.25 %)
Appointed analysis	171 (33.53 %)
On time	111/171 (64.91 %)
Cancelled	60/171 (35.09 %)
Appointed endoscopy	84 (3.14 %)
On time	20/84 (23.81 %)
Cancelled	64/84 (76.19 %)
IBD flare	48 (9.41 %)
Symptomatology COVID-19	39 (7.6 %)
Hospital admission	12 (2.35 %)