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RESEARCH CORRESPONDENCE

Maintaining the Quality Standards of Care for Inflammatory Bowel Disease Patients During the COVID-19 Pandemic

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See editorial on page 1688; also see related article on page 1744.

Since February 20, 2020, the SARS-COV2 infection has spread in Lombardy, and in the rest of the Italian regions, forcing our government to impose a national lockdown.[1] Hospitals have been forced to adapt and to restructure their units to cope with this urgent new critical situation.[2] Alternative solutions have been found to manage patients with inflammatory bowel disease (IBD), including remote monitoring, drug home delivery, limitations for infusion units, and patient education on measures to prevent infection,[3] to maintain high-quality care.[4]

Our IBD team at Humanitas Clinical and Research Center (Rozzano, Milan, Italy) includes 7 gastroenterologists, 3 IBD nurses, 6 trial coordinators, and 10 biologists. More than 4000 patients (75% from outside Lombardy) are in better active follow-up. Seven hundred patients are treated with biological therapy and 118 are enrolled in 25 clinical trials. Our weekly activity includes the following: 5 full days for outpatient clinics, endoscopy, and bowel ultrasound, multidisciplinary team discussions with the patient and other specialists, 2 dedicated time slots for patients with ileoanal pouch every week, and dedicated time slots on demand for patients who have been discharged from the hospital for a severe flare or surgical resection. Finally, the helpline allows us to manage approximately 80 contacts every day. As previously reported,[3] the restrictions imposed by the government have forced us to adapt our structure and processes to face the COVID-19 emergency.

Methods

The aim of this study was to report the outcomes of restructuring our IBD referral center (Humanitas Clinical and Research Centre). Specifically, we assessed how many patients received the standards of care after restructuring our clinical operations. Importantly, we analyzed the number of patients who missed/postponed monitoring visits and examinations because of the IBD unit readjustment, based on the European Crohn's and Colitis Organisation's recommended standards of care.[4]

Results

Inflammatory Bowel Disease Unit

Three clinicians (42%) and 1 (33%) nurse were assigned to the COVID-19 units, 4 trial coordinators (66%) and all biologists and laboratory technicians (100%) were allowed to work from home. The reduction of the IBD personnel was balanced by the closure of clinics and procedures for nonurgent patients.

Assessment and Treatment

Outpatient visits planned for new patients were canceled to comply with local regulations and were not replaced by virtual consultations. Outpatient follow-up clinics were replaced by virtual clinics, allowing timely follow-up evaluation of 55.5% (20 of 36) of patients. The multidisciplinary discussions were managed online through virtual clinics, resulting in 11 of 13 planned (84.6%) discussions. Seven hundred patients were scheduled for monoclonal antibody infusions and/or subcutaneous drug delivery during this time period. An additional 25 patients had a scheduled consultation to start biological therapy. Among these, 98.7% received their biological therapy timely, 84% started a biological therapy as planned (n = 21), 12% (n = 3) were postponed but closely monitored through regular telephone calls, and 4% (n = 2) were lost to follow-up evaluation. Among the 174 visits planned for interventional clinical trials, 162 visits were performed (93.1%), and only 12 (6.8%) were postponed. However, no patient was

Abbreviation used in this paper: IBD, inflammatory bowel disease.

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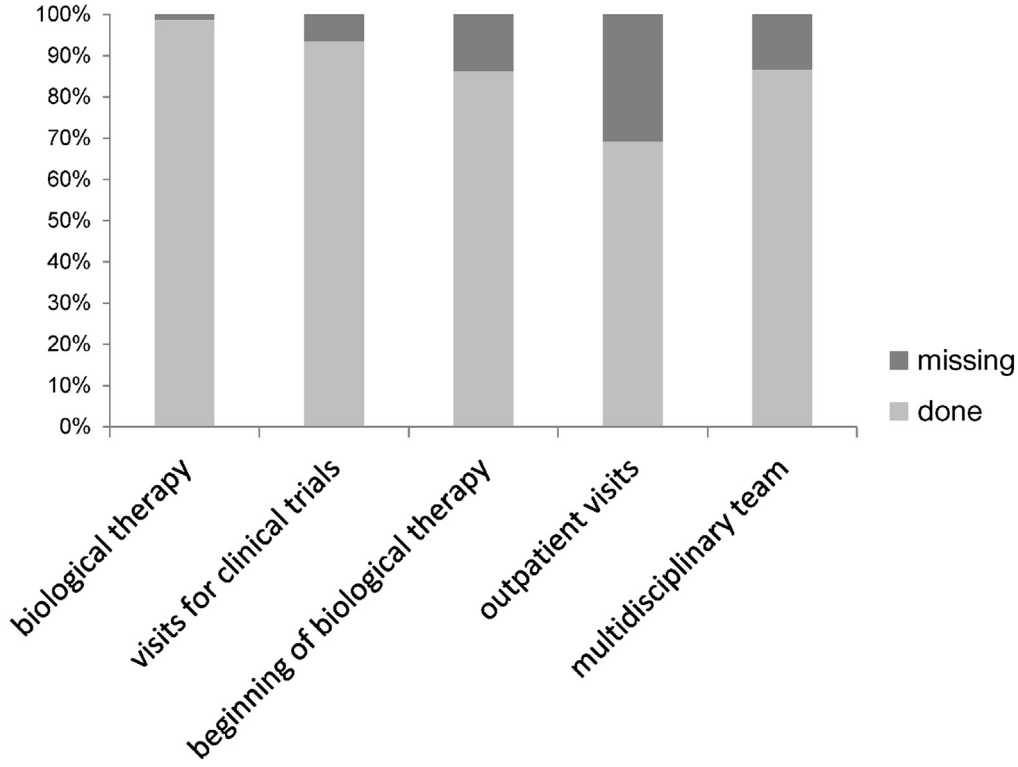

Figure 1. Graphic representation of done and missed activities in the inflammatory bowel disease unit during the COVID-19 outbreak.

withdrawn from the clinical trial after randomization, although 8 screening procedures were canceled (4 patients were shifted to another therapy and 4 procedures were postponed) (Figure 1). All urgent endoscopic and imaging procedures were performed (100%), whereas all elective procedures were canceled as a result of the local restrictions.

Patient Education

At the beginning of the Italian outbreak, our helpline received 280 contacts (+350%) per day by email/telephone to ask for information about dealing with the COVID-19 situation. Our patients were given all relevant information and were invited to find educational material on the national IBD society (IG-IBD) and the national Patients' Association websites, as well as on our hospital weekly newsletter. After the first week, the number of contacts returned to the usual number before the outbreak. We measured on average the same increase (approximately +350%) of contacts after every change in the restriction rules announced by the Prime Minister, mainly asking how to deal with travel restrictions, preventive measures, and drug delivery.

Discussion

This article reports on the outcomes of restructuring an IBD unit during the COVID-19 pandemic. Implementation of virtual clinics, drug home delivery, and IBD networking were able to maintain acceptable standards of care for our IBD patients. Whether the IBD unit restructuring achieves the same outcomes in other local and national contexts remains to be investigated.

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Conflicts of interest
The authors disclose the following: Mariangela Allocca has received consulting fees from Nikkiso Europe and lecture fees from Janssen, AbbVie, and Pfizer; Federica Furfaro has received consulting fees form Amgen and AbbVie, and lecture fees from Janssen and Pfizer; Gionata Fiorino is a consultant and a member of Advisory Boards for MSD, Takeda Pharmaceuticals, AbbVie, Pfizer, Celltrion, Amgen, Sandoz, Samsung, and Janssen Pharmaceuticals. Laurent Peyrin-Biroulet has received personal fees from Merck, AbbVie, Janssen, Genentech, Mitsubishi, Ferring, Norgine, Tillots, Vifor, Hospira/Pfizer, Celltrion, Takeda, Biogaran, Boerhinger-Ingelheim, Lilly, HAC-Pharma, Index Pharmaceuticals, Amgen, Sandoz, Forward Pharma GmbH, Celgene, Biogen, Lycera, and Samsung Biosepsis; and Silvio Danese has received personal fees from AbbVie, Ferring, Hospira, Johnson & Johnson, Merck, Millennium Takeda, Mundipharma, Pfizer, Tigenix, UCB Pharma, and Vifor. The remaining authors disclose no conflicts.