BACKGROUND AND INTRODUCTION

Following the first reports of cases of acute respiratory syndrome in the Chinese Wuhan municipality at the end of December 2019, Chinese authorities have identified a novel coronavirus as the main causative agent. The outbreak has rapidly evolved affecting other parts of China and outside the country. Cases have been detected in several countries in Asia, but also in Australia, Europe, Africa, North as well as South America. On February 12th 2020, the novel coronavirus was named severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) while the disease associated with it is now referred to as COVID-19. Human-to-human transmission has been confirmed but more information is needed to evaluate the full extent of this mode of transmission. The evidence from analyses of cases to date is that COVID-19 infection causes mild disease (i.e. non-pneumonia or mild pneumonia) in about 80% of cases and most cases recover, 14% have more severe disease and 6% experience critical illness. The great majority of the most severe illnesses and deaths have occurred among the elderly and those with other chronic underlying conditions (https://www.ecdc.europa.eu/en/current-risk-assessment-novel-coronavirus-situation).

The aim of the current document is to provide to health care professionals some understanding and knowledge on the best care we can offer to our patients in general and particularly those under immunosuppressive/ immunomodulatory treatment in the current situation of the COVID-19 epidemy.

Due to the urgency, ECCO has suggested to gather together a group of gastroenterologists with special interest in Opportunistic Infections and infectious disease experts, in order to provide on a regular basis guidance to the physicians of the ECCO community.

This guidance shall not replace any national recommendations from health care authorities but must be understood as an additional piece of information that will be updated when necessary based on our better understanding of this novel disease. Similarly, the following guidance is not accompanied by any ECCO recommendations.

The format below is based on an interview by gastroenterologists and experts in infectious disease from various places in Europe and reviewed by the COVID-19 Taskforce.

QUESTIONS AND ANSWERS

1. Should we use biologics / immunomodulatory agents differently in elderly IBD patients and/or in IBD patients with comorbidities at risk of COVID-19 infection? Shall we differentiate elderly IBD patients with controlled and uncontrolled IBD disease? Shall we apply additional measures in this fragile population compared to the general IBD patients?

This is an important question that we unfortunately don't have perfect answers to yet. However, we should continue to try and treat IBD patients similarly to how we were in the pre-COVID-19 world. That being said, for elderly patients, particularly those who are frail, it is likely prudent to try the best we can to use monotherapy strategies and limit use of immunomodulators out of an abundance of caution. This has been a practice pattern for many even before COVID-19 emerged due to concerns for increased risks of infection in our elderly IBD patients. Active inflammation itself may be a risk factor for infections in IBD and we also want to keep our patients away from the hospital at this time so benefit of staying on treatment likely outweighs risks of getting COVID19 at this point**.** We are still learning more about this but keeping elderly patients out of a flare (with immunosuppressives/immunomodulators if needed) will have two potential benefits in addition to helping their IBD: 1) potentially decreasing their risk of contracting COVID-19 and 2) preventing our patients from having to go to hospital where risk of COVID-

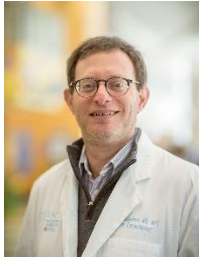
19 infection is amplified. The data currently shows that the highest case fatality rates are among patients 60 and older. This was highlighted nicely in a paper by Onder et al in JAMA[1] where case fatality rates among patients age 80 and older was as high as 20%. Therefore, elderly IBD patients, especially if on immunosuppression, should take all precautions recommended by local/national health authorities for at risk populations, including stricter social distancing (allowing someone else in household to go to stores for essential items for example).

2. Description of the SECURE-IBD initiative and first results on what we know globally about IBD patients with COVID-19

Surveillance Epidemiology of Coronavirus) Under Research Exclusion (SECURE-IBD) is an international, pediatric and adult registry to monitor and report on outcomes of COVID-19 occurring in IBD patients. SECURE-IBD (www.covidibd.org) has been developed in partnership with the Crohn's & Colitis Foundation, the International Organization for the Study of IBD (IOIBD), the European Crohn's and Colitis Organisation (ECCO), and the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN). The purpose of SECURE-IBD is to rapidly define the impact of COVID-19 on patients with IBD, including the impact of factors such as age, comorbidities, and IBD treatments on COVID outcomes. SECURE-IBD is committed to providing regular updates to the IBD community regarding number of reported cases and outcomes, including data broken down by geographic region and IBD treatment. Updates are disseminated through the project website, email, and Twitter.
The SECURE-IBD registry collects de-identified data, in accordance with HIPAA Safe Harbor De-Identification standards.[2] The UNC-Chapel Hill Office for Human Research Ethics has determined that storage and analysis of de-identified data does not constitute human subjects research and does not require IRB approval.[3]

To date, the response to the SECURE-IBD registry has been truly extraordinary. As of March 23rd, over 23,000 visitors from 120 countries have accessed the SECURE-IBD website. We have learned a lot over the past week, and are happy to share these data with you. Please also visit www.covidibd.org on a regular basis as things are changing so fast and information will be updated frequently.
A total of 41 COVID-19 cases have been reported as of 23rd March (22 CD and 19 UC). We have received reports from 13 different countries. Ten patients have been hospitalized and two patients have died including an 82 yo male from Europe with ulcerative colitis (mildly active disease), Alzheimer's disease, and cardiovascular disease on mesalamine 4,000 mg daily and a 25 yo male with ulcerative colitis (moderately active disease) on infliximab 300 mg every 8 weeks and methotrexate 15 mg weekly. More information including a breakdown of cases by age, gender, geography, disease type, and medication use is available at www.covidibd.org. See the Updates and Data tab.
We need your help! Please be sure to report all cases of confirmed COVID-19 in IBD patients, regardless of severity. Cases should be reported after a minimum of 7 days and sufficient time has passed to observe the disease course through resolution of acute illness and/or death. And, please spread the word about SECURE-IBD to all of your colleagues, locally, nationally, and internationally.
Through international cooperation, collaboration, and communication, we will be able to optimize the care of our patients during this unprecedented, worldwide health crisis. We are truly all in this together!

Interview realized on behalf of the COVID-19 ECCO Taskforce with



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Note

Since the infection is dynamic and knowledge and evidence are growing rapidly, some of this guidance will be regularly updated based on tailored recommendations for each region according to the best evidence.

Two independent projects are being set up very recently to increase our knowledge on this novel disease in our IBD patients. We encourage you to participate.

The first project is an ECCO survey to better appreciate your view and understanding of the current situation. The coronavirus pandemic is a difficult time for everyone, including physicians and IBD patients. None of us have experienced a similar emergency, which requires dealing with complex situations, of which we know little or nothing, and which evolve day by day.
For this reason, we invite you to participate in a short survey on your current management, your fears and the difficulties you are facing every day in the context of this serious global pandemic.
The survey compilation takes only a few minutes and we ask you to respond before March 30 due to the emergency setting. This project is accessible until March 30 following the link: https://survey.ecco-ibd.eu/index.php/433996?lang=en

The second project is the global initiative from the International Organization for the study of IBD (IOIBD) to record timely proven cases of COVID-19 infection in our IBD patient described above.

REFERENCES

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[3] Code of Federal Regulations. 21 CFR 56.102. 2018. https://www.govinfo.gov/app/collection/cfr