2021 Fourth Annual National Conference
September 9-11, 2021
Red Rock Hotel – Las Vegas, NV

Jointly provided by the Annenberg Center for Health Sciences at Eisenhower and Gastroenterology and Hepatology Advanced Practice Providers.
Post Covid IBD

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Speakers Bureau: AbbVie, Clinical Area – IBD
Speakers Bureau: Janssen, Clinical Area – IBD
Advisory Board: Gilead, Clinical Area – IBD
Advisory Board: Bristol-Myers Squibb, Clinical Area – IBD
Advisory Board: Eli Lilly, Clinical Area – IBD
Objectives

• Discuss IBD outcomes and practical guidelines for the management of IBD patients during the COVID-19 pandemic

• Review updates from the SECURE-IBD study

• Describe how the pandemic changed the landscape of IBD monitoring and management

• Recognize the mental health needs in the IBD patient population post COVID

• Review COVID-19 resources and the recognize the need for enhanced communication
Management Goals of IBD During Pandemic

- Maintain remission by continuing IBD therapies
- Steroid free remission
- Proactive monitoring of stable patients and rapid reactive management of flaring patients.
- Minimize the need for systemic corticosteroids and hospital admission, thus decreasing the risk of SARS-CoV-2 infection and the severity of COVID-19 disease

Are IBD Patients at Greater Risk for Contracting COVID-19?

<table>
<thead>
<tr>
<th>Study, year</th>
<th>Country</th>
<th>Study period</th>
<th>Total IBD Patients, n</th>
<th>IBD With COVID-19, n</th>
<th>CD</th>
<th>UC</th>
<th>IC</th>
<th>Mean age, (SB)</th>
<th>Male Proportion, n (%)</th>
<th>Hospitalization, n (%)</th>
<th>ICU admission, n (%)</th>
<th>Mechanical Ventilation, n (%)</th>
<th>Death, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allocca, 2020</td>
<td>France, Italy</td>
<td>NR</td>
<td>6000</td>
<td>15</td>
<td>9</td>
<td>6</td>
<td>0</td>
<td>39.1 (10.1)</td>
<td>4 (26.7%)</td>
<td>5 (33.3%)</td>
<td>0 (0%)</td>
<td>NR</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Bezzio, 2020</td>
<td>Italy</td>
<td>Mar 11–Mar 29</td>
<td>NR</td>
<td>79</td>
<td>32</td>
<td>47</td>
<td>0</td>
<td>47 (17.9)</td>
<td>44 (55.7%)</td>
<td>22 (27.8%)</td>
<td>11 (13.9%)</td>
<td>11 (13.9%)</td>
<td>6 (7.6%)</td>
</tr>
<tr>
<td>Norsa, 2020</td>
<td>Italy</td>
<td>Feb 19–Mar 23</td>
<td>522</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td></td>
</tr>
<tr>
<td>Rodriguez-Lago, 2020</td>
<td>Spain</td>
<td>Feb 27–Apr 7</td>
<td>NR</td>
<td>40</td>
<td>13</td>
<td>23</td>
<td>4</td>
<td>58.5 (5.7)</td>
<td>24 (60.0%)</td>
<td>21 (52.5%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>2 (5.0%)</td>
</tr>
<tr>
<td>Taxonera, 2020</td>
<td>Spain</td>
<td>Through Apr 8</td>
<td>1918</td>
<td>12</td>
<td>7</td>
<td>5</td>
<td>0</td>
<td>52.3 (15.4)</td>
<td>3 (25.0%)</td>
<td>8 (66.7%)</td>
<td>4 (33.3%)</td>
<td>3 (25.0%)</td>
<td>2 (16.7%)</td>
</tr>
<tr>
<td>An, 2020</td>
<td>China</td>
<td>Jan 3–Mar 30</td>
<td>318</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td></td>
</tr>
<tr>
<td>Grassia, 2020</td>
<td>Italy</td>
<td>NR</td>
<td>251</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td></td>
</tr>
<tr>
<td>Gubatan, 2020</td>
<td>USA</td>
<td>Mar 4–Apr 14</td>
<td>168</td>
<td>5</td>
<td>2</td>
<td>3</td>
<td>0</td>
<td>70.6 (4.2)</td>
<td>2 (40.0%)</td>
<td>1 (20.0%)</td>
<td>1 (20.0%)</td>
<td>1 (20.0%)</td>
<td>1 (20.0%)</td>
</tr>
</tbody>
</table>

IBD patients do not appear to be at higher risk for infection with SARS-Co-V-2 or development of Covid 19

Systemic review—relatively low incidence of COVID-19 in IBD

Incidence in IBD 0.3%

Incidence in general population 0.2-4.0%

What Are the Risks in IBD Patients for Negative COVID Outcomes?

- Older age
- Obesity
- Presence of comorbidities
- Active disease
- Corticosteroid use

<table>
<thead>
<tr>
<th>Risk factor</th>
<th>Or</th>
<th>95% CI</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age &gt;65 years</td>
<td>19.6</td>
<td>2.95 to 130.6</td>
<td>0.002</td>
</tr>
<tr>
<td>CCI score &gt;1</td>
<td>16.66</td>
<td>1.80 to 153.9</td>
<td>0.01</td>
</tr>
<tr>
<td>Active IBD</td>
<td>8.45</td>
<td>1.26 to 56.56</td>
<td>0.02</td>
</tr>
<tr>
<td>UC diagnosis</td>
<td>2.95</td>
<td>0.31 to 27.73</td>
<td>0.34</td>
</tr>
<tr>
<td>Corticosteroids</td>
<td>6.28</td>
<td>0.89 to 44.24</td>
<td>0.064</td>
</tr>
<tr>
<td>Anti-TNF</td>
<td>0.40</td>
<td>0.04 to 3.78</td>
<td>0.42</td>
</tr>
</tbody>
</table>

CCI, Charlson Comorbidity Index; TNF, tumour necrosis factor.
# Outcomes by Comorbidities: SECURE IBD

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Total N</th>
<th>Hospitalized</th>
<th>(N, %)</th>
<th>Death</th>
<th>(N, %)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comorbidities</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>3,918</td>
<td>390</td>
<td>10%</td>
<td>10</td>
<td>0%</td>
</tr>
<tr>
<td>1</td>
<td>1,099</td>
<td>238</td>
<td>22%</td>
<td>27</td>
<td>2%</td>
</tr>
<tr>
<td>2</td>
<td>294</td>
<td>122</td>
<td>41%</td>
<td>18</td>
<td>6%</td>
</tr>
<tr>
<td>3+</td>
<td>193</td>
<td>119</td>
<td>62%</td>
<td>35</td>
<td>18%</td>
</tr>
</tbody>
</table>

In multivariable model, >=2 comorbidities associated with ICU/Vent/Death, aOR 2.87 (95% CI 1.05-7.85, p<0.04)

Impact of specific comorbidities in IBD patients on risk of severe COVID-19 from SECURE-IBD:

- Chronic kidney disease 3.02 (1.45-6.31)
- COPD 2.92 (1.32-6.48)

IBD Disease Activity and COVID-19

- One study of 118 IBD patients with COVID-19 showed microbiome differences however no durable impact of COVID-19 on IBD disease activity
- No significant differences between pre- and post-COVID-19 clinical, endoscopic, and laboratory values
- Another study showed disease activity was associated with greater risk for hospitalization and severe covid, increased among younger patients. They same effect was not seen with older patients

How Do We Manage COVID in IBD?

- No symptoms, no testing ➔ Continue treatment, consider de-escalate thiopurines in combination therapy

- No symptoms, +SARS-CoV-2 ➔ withhold IBD therapies for a minimum of 10 days. If no symptoms of COVID-19, resume therapy. Hold delay but continue anti-TNF or anti-IL12/23 in asymptomatic

- Positive test for SARS-CoV-2 and symptoms of COVID-19 ➔ Hold/delay but continue anti-TNF or anti-IL 12/23 in mild COVID-19

- Convalescent phase ➔ When to restart therapy: symptom-based vs test-based strategy

IOIBD COVID-19 task force. Siegal CA et al. JCC. 2020; Adapted from Ungaro, R. 2021.
When to Restart Therapy With COVID

If Symptom-based strategy:

1. At least 10 days have passed since COVID 19 symptom onset and
2. At least 3 days (72 hours) have passed since recovery- defined as resolution of fever without the use of fever-reducing medications and improvement in respiratory symptoms (ex. Cough, SOB)
3. In severe COVID-19, a greater time frame from recovery may be appropriate depending on severity of IBD and need to restart medication

If Test-based strategy is required, the above clinical parameters must be met plus two consecutive negative NP or OP COVID-19 molecular assays collected >/=24 hours apart

IOIBD COVID-19 task force. Siegal CA et al. JCC. 2020; Adapted from Ungaro, R. 2021.
Heightened Goal: Steroid Free Remission

- COVID-19 pandemic has heightened the need for our goal of steroid free remission
- Steroids at the time of the infection, prior to onset of cytokine storm, may have deleterious effect on viral clearance or immune response
- Steroids should be used at the lowest dose possible to control the underlying disease, regardless of COVID-19 exposure or infection status
- Higher rates of COVID and worsening outcomes with steroids

Corticosteroids are associated with an increased risk of severe COVID-19 and worse COVID-19 outcomes.

5ASAs, biologics, and immunomodulators show no increased risk of severe COVID-19.

Biologics are associated with a decreased risk of severe COVID-19.

There are no significant differences between biologic classes on the risk of severe COVID-19.

<table>
<thead>
<tr>
<th>Medication</th>
<th>Total N</th>
<th>Outpatient (N%)</th>
<th>Hospitalized (N%)</th>
<th>ICU (N%)</th>
<th>Ventilator</th>
<th>Death</th>
<th>ICU/Vent/Death</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulfasalazine/ mesalamine</td>
<td>1,924</td>
<td>1,494 78%</td>
<td>411 21%</td>
<td>81 4%</td>
<td>70 4%</td>
<td>53 3%</td>
<td>118 6%</td>
</tr>
<tr>
<td>Budesonide</td>
<td>175</td>
<td>133 76%</td>
<td>41 23%</td>
<td>9 5%</td>
<td>5 3%</td>
<td>6 3%</td>
<td>12 7%</td>
</tr>
<tr>
<td>Steroids</td>
<td>414</td>
<td>260 63%</td>
<td>146 35%</td>
<td>41 10%</td>
<td>29 7%</td>
<td>28 7%</td>
<td>53 13%</td>
</tr>
<tr>
<td>6MP/AZA</td>
<td>551</td>
<td>433 79%</td>
<td>114 21%</td>
<td>26 5%</td>
<td>17 3%</td>
<td>11 2%</td>
<td>33 6%</td>
</tr>
<tr>
<td>MTX</td>
<td>49</td>
<td>35 71%</td>
<td>13 27%</td>
<td>1 2%</td>
<td>1 2%</td>
<td>2 4%</td>
<td>3 6%</td>
</tr>
<tr>
<td>Anti-TNF monotherapy</td>
<td>2,082</td>
<td>1,882 90%</td>
<td>178 9%</td>
<td>24 1%</td>
<td>16 1%</td>
<td>10 0%</td>
<td>31 1%</td>
</tr>
<tr>
<td>Anti-TNF + 6MP/AZA/MTX</td>
<td>636</td>
<td>535 84%</td>
<td>91 14%</td>
<td>17 3%</td>
<td>12 2%</td>
<td>6 1%</td>
<td>21 3%</td>
</tr>
<tr>
<td>Anti-integrin</td>
<td>706</td>
<td>601 85%</td>
<td>94 13%</td>
<td>21 3%</td>
<td>11 2%</td>
<td>9 1%</td>
<td>28 4%</td>
</tr>
<tr>
<td>IL 12/23 Inhibitor</td>
<td>602</td>
<td>539 90%</td>
<td>50 8%</td>
<td>9 1%</td>
<td>8 1%</td>
<td>5 1%</td>
<td>11 2%</td>
</tr>
<tr>
<td>JAK inhibitor</td>
<td>103</td>
<td>90 87%</td>
<td>12 12%</td>
<td>4 4%</td>
<td>1 1%</td>
<td>1 1%</td>
<td>4 4%</td>
</tr>
</tbody>
</table>

### Highlighted themes of accepted statements related to SARS-CoV-2 Vaccination for patients with IBD by the International Organization for the Study of Inflammatory Bowel Disease (IOIBD)

<table>
<thead>
<tr>
<th>Statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with IBD should be vaccinated against SARS-CoV-2</td>
</tr>
<tr>
<td>The best time to administer SARS-CoV-2 vaccination in patients with IBD is at the earliest opportunity to do so</td>
</tr>
<tr>
<td>SARS-CoV-2 vaccines including messenger RNA vaccines, replication-incompetent vector vaccines, inactivated vaccines and recombinant vaccines are safe to administer to patients with IBD</td>
</tr>
<tr>
<td>SARS-CoV-2 vaccination should not be deferred because a patient with IBD is receiving immune modifying therapies</td>
</tr>
<tr>
<td>Patients with IBD vaccinated with SARS-CoV-2 should be counselled that the vaccine efficacy may be decreased when receiving systemic corticosteroids</td>
</tr>
</tbody>
</table>

IBD and Vaccination

- The risks of vaccination in IBD patients are very low
- Prednisone is associated with a lower antibody titer response
- The delta variant is highly transmissible with unvaccinated individuals
- FDA approved 3rd vaccine booster for immunocompromised

Summary of Studies of Vaccine Immunogenicity With Immunosuppressive Therapies

Seroconversion and Biologic Therapy

IBD patients receiving biologics can seroconvert with robust serological responses after complete Pfizer-BioNTech and NIH-Moderna COVID-19 vaccination according to one study on biologic monotherapy

- 48 vaccinated IBD patients, assessed anti-spike IgG post vaccine
- IBD patients had similar antibody responses to healthy controls after 2\textsuperscript{nd} vaccine dose

Wong et al. Gastroenterology. 2020. in press
Vaccine Titers and Post Vaccine Side Effects

Overall % with positive titer levels
As of 7/27/2021, a total of 2016 participants
Defined per test as >= 1

Rates of immediate post vaccine side effects

https://ibdpartners.org/preventcovid/results.
Landscape Change in IBD Management

How has the pandemic changed the landscape of IBD management?

• Remote monitoring
  – Serum markers
  – Fecal calprotectin
  – PROs
• Telemedicine
• Communication

Benefits of Telemedicine for IBD

- Improvement in patient-reported quality of life and decreased healthcare costs.
- According to one survey, most patients stated this method is convenient, time saving and increases their compliance.
- Digital technology has offers significant opportunity for growth and innovation.
- Strong desire to continue based on the results of a global telemedicine survey by the International Organization for the study of Inflammatory Bowel Disease.

Barriers to Telemedicine

- Patient and provider must have the equipment and technological skills to participate
- Unable to perform physical exams/rectal exams/vital signs
- Reverting to pre-pandemic standards: No longer having relaxation of rules allowing telemedicine across state lines and may face changes to reimbursement

Prevalence of Depression and Anxiety in IBD

Mental Health in IBD During/Post COVID-19

• COVID-19 presents relevant effects on psychological well-being. IBD health care professionals should be attentive of patients’ psychological response to this pandemic and of its possible consequences on disease expression.

• Significant amount of fear and anxiety also employment, health insurance, and system-wide changes that impact every level of their care.

• Advise patients to seek psychological support if necessary and provide resources.

Mental Health in IBD During/Post COVID

• In one Australian study, over 2/3 of the respondents with pre-existing anxiety/depression reported *worsening of their pre-existing depression/anxiety* due to the current pandemic.

• Of those without a pre-existing diagnosis of *high rates of moderate to severe depression (34.9%), anxiety (32.0%) and stress (29.7%) were noted.*

• Younger age, lack of access to an IBD nurse and lack of education on reducing infection risk were associated with significant stress, anxiety and/or depression.

Educational Resources

Crohn’s & Colitis Foundation
www.crohnscolitisfoundation.org/coronavirus-update/adults

International Organization of IBD (IOIBD) www.ioibd.org

SECURE-IBD registry www.covidibd.org

COVID-19 vaccine studies in IBD
IBD Provider-Patient Communication

• Provide clear and specific recommendations in a period of uncertainty and evolving data
  – Global survey of 4,000 IBD patients showed that 2/3 believed that immunosuppressant drugs were associated with an increased risk of developing COVID-19

• Shared decision making

• Enhanced communication:
  – Patient portal updates
  – EMR Quicktext

Take Home Points

• Maintaining remission with steroid free treatments is important in managing IBD patients through this pandemic
• The pandemic changed the landscape of IBD monitoring and management
• Telemedicine is here to stay and we will continue technology innovation to improve remote monitoring
• Provide mental health resources to IBD patients given the increased prevalence prior to COVID
• Ongoing patient education and communication is needed to help our IBD patients navigate through this pandemic