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Gastrointestinal Manifestations of COVID-19

Latest Data on Symptoms, Stool Testing, and Clinical Outcomes

MONDAY, MAY 18, 2020 Webinar
8:00 to 9:30 pm Eastern Daylight Time

Presenters
- Brennan M. R. Spiegel, MD, MSHS, FACG
- Paul Y. Kwo, MD, FACG
- Millie D. Long, MD, MPH, FACG
- Jordan E. Axelrad, MD, MPH

Moderators
- Mark B. Pochapin, MD, FACG
- David A. Greenwald, MD, FACG

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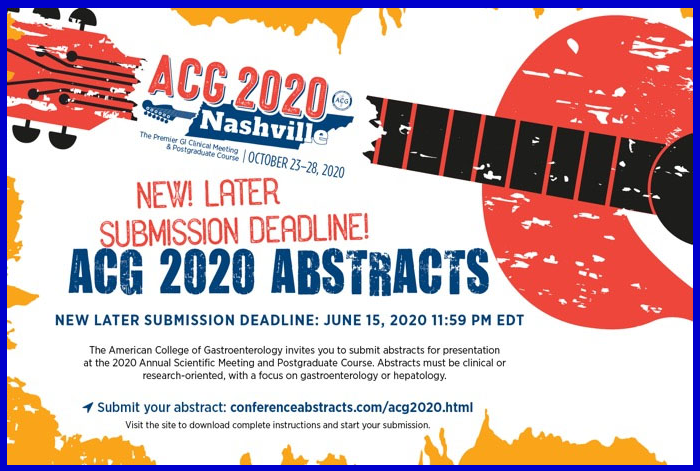
NEW!!

ACG 2020 ABSTRACT SUBMISSION DEADLINE

EXTENDED 2 WEEKS!



NEW!! DEADLINE: JUNE 15, 2020 11:59pm Eastern

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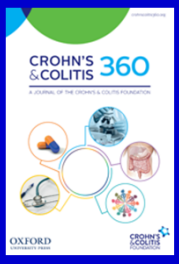
Foundation Peer-Reviewed Journals

- *Inflammatory Bowel Diseases* publishes high-quality, original papers and is a top-rated GI journal.
- Foundation professional members receive a subscription. **Learn more at:**
- www.ibdjournal.org



Crohn's & Colitis 360 - an online-only, open access journal - publishes content that engages, informs, and catalyzes dialogue on state-of-the-art comprehensive care for patients with IBD. Readers can access full articles for all content.

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www.crohnscolitis360.org

Publications Include Current Articles on the Novel Coronavirus

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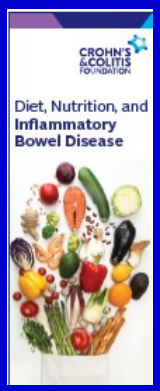
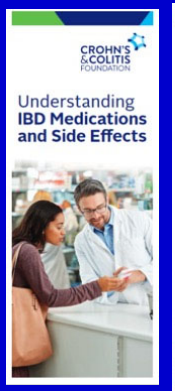
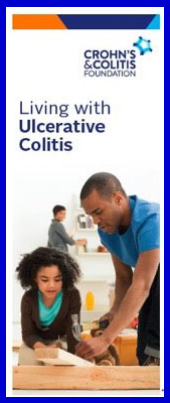
ASK US ABOUT EDUCATION AND SUPPORT MATERIALS FOR YOUR PATIENTS

- Print on Demand Resources
- Educational Brochures
- New Patient Packets
- Support Groups
- COVID-19 Patient Resources







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Resources

- IBD Circle: https://ibd-circle.within3.com/public/sign_in
  - Posts of previous questions and answers
  - Can post your questions for the faculty
- ACG website: gi.org

  https://gi.org/media/covid-19-and-gi/

  Education Universe : http://universe.gi.org/
- Crohn's & Colitis Foundation

  https://www.crohnscolitisfoundation.org/coronavirus/professional-resources

  https://www.crohnscolitisfoundation.org/coronavirus/what-ibd-patients-should-know

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Resources

- https://covidibd.org
  - Open access data
  - Can report your patients easily

- International Organization of IBD: https://www.ioibd.org
  - https://www.gastrojournal.org/article/S0016-5085(20)30465-0/fulltext
  - IOIBD Recommendations (dd 17 April 2020) Infusion Center guidance (PDF)
  - IOIBD Recommendations (dd 19 April 2020) endoscopy (PDF)
- PDFs to be sent to all registrants

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Friendly Reminders

- Your audio will be muted.
- We will be taking questions during the webinar via the "question" functionality of our webinar tool – which is located in the right-side panel of Go-to-Webinar. If you would like to ask a question via the "question" feature, type your question directly in to the space provided.
- Please contact technical support (855) 352-9002 during this event if you have any questions or need assistance with the webinar tool.
- This call is being recorded and will be available on the IBD Circle. All IBD Circle members will receive a link to access the recording in an upcoming IBD Circle digest.

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Accreditation, CME & MOC Information

The American College of Gastroenterology is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

The American College of Gastroenterology designates this live activity for a maximum of 1.5 *AMA PRA Category 1 Credits*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Successful completion of this CME activity, which includes participation in the evaluation component, enables the participant to earn up to 1.5 MOC points in the American Board of Internal Medicine's (ABIM) Maintenance of Certification (MOC) program. Participants will earn MOC points equivalent to the amount of CME credits claimed for the activity. It is the CME activity provider's responsibility to submit participant completion information to ACCME for the purpose of granting ABIM MOC credit.

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How to Receive CME and MOC Points

ACG will send a link to a CME & MOC evaluation to all attendees on the live webinar.

ABIM Board Certified physicians need to complete their MOC activities by December 31, 2020 in order for the MOC points to count toward any MOC requirements that are due by the end of the year. No MOC credit may be awarded after March 1, 2021 for this activity.

ACG will submit MOC points on the first of each month. Please allow 3-5 business days for your MOC credit to appear on your ABIM account.

If you plan to claim MOC Points for this activity, you will be asked to: Please list specific changes you will make in your practice as a result of the information you received from this activity.

Include specific strategies or changes that you plan to implement.
THESE ANSWERS WILL BE REVIEWED

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Disclosures:

Moderators:

Samir A. Shah, MD, FACG
- Dr. Shah has indicated no relevant financial disclosures.

Jean-Paul Achkar, MD, FACG
- Dr. Achkar has indicated no relevant financial disclosures.

Faculty:

David T. Rubin, MD, FACG
- Advisory Committee/Board Member: CCFA, Janssen
- Consultant: AbbVie Pharmaceuticals, Abgenomics, Allergan, Biomica, Boehringer Ingelheim, Bristol-Myers Squibb, Celgene, Check-cap, Dizal Pharmaceuticals, Galen Pharma/Atlantica, Genentech, Gilead Sciences, Ichnos Sciences S.A. (formerly Glenmark Pharmaceuticals), GSK, Janssen, Lilly, Narrow River Mgmt., Pfizer, Prometheus, Reistone, Shire, Takeda, Techlab, Inc.
- Grant/Research Support: AbbVie Pharmaceuticals, Genentech, Janssen, Prometheus Laboratories, Shire, Takeda
- Co-Founder: Cornerstones Health Inc. (non-profit medical education company), GoDuRn LLC (no financial support received)
- Royalties: Slack Publications

Erica Brenner, MD
- Dr. Brenner has indicated no relevant financial disclosures.

Ryan C. Ungaro, MD
- Grant Support: NIH K23 Career Development Award (K23KD111995-01A1).
- Advisory board member or consultant for Eli Lilly, Janssen, Pfizer, and Takeda.
- Research support from AbbVie, Boehringer Ingelheim, and Pfizer.

David P. Hudesman, MD
- Research support - Pfizer
- Consulting - AbbVie, BMS, Janssen, Pfizer, Takeda

Sunanda V. Kane, MD, MSPH, FACG
- Consultant: Gilead, Samsung Bioepis

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ACG and the Crohn's & Colitis Foundation IBD Circle May 12th, 2020 Webinar

IBD in the COVID-19 Era: Update for the Busy Clinician

- Review knowledge on risk of COVID-19 in IBD patients and how COVID-19 affects medical management of immunomodulators and biologics in IBD
- Discuss data gathered from a large research registry: SECURE-IBD
- Review the real-life clinical experience with COVID-19 from a highly impacted area (NYC)

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Agenda

- 8:00-8:05 pm Welcome and Overview of IBD-COVID resources. Dr. Samir A. Shah
- 8:05-8:25 pm Management of the IBD patient in the COVID-19 era. Dr. David Rubin
- 8:25-8:40 pm What are we learning from the SECURE-IBD registry? Drs. Ryan Ungaro and Erica Brenner
- 8:40-8:50 pm What have we learned from the NYC experience? Dr. David Hudesman
- 8:50-9:30 pm Panel discussion with faculty: Drs. Sunanda Kane, David Rubin, Ryan Ungaro, Erica Brenner, and David Hudesman

Moderators: Drs. Samir A. Shah and Jean-Paul Achkar

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Dr. Rubin Dr. Kane Dr. Brenner Dr. Ungaro Dr. Hudesman

IBD IN THE COVID-19 ERA: UPDATE FOR THE BUSY CLINICIAN
Tuesday, May 12, 2020 at 8 pm EDT

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Management of the IBD Patient in the COVID-19 Era

David T. Rubin, MD, FACG
Joseph B. Kirsner Professor of Medicine
Chief, Section of Gastroenterology, Hepatology and Nutrition
University of Chicago

@IBDMD
RubinLab.uchicago.edu

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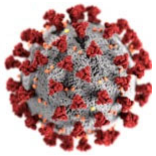
Coronavirus



- **Enveloped, single-stranded RNA viruses**
- **Endemic coronaviruses ae frequent causes of respiratory infections globally**
- **New human coronaviruses include severe acute respiratory syndrome (SARS, 2002) and Middle East Respiratory Syndrome (MERS, 2012)**
- **Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is the most recently identified human coronavirus**

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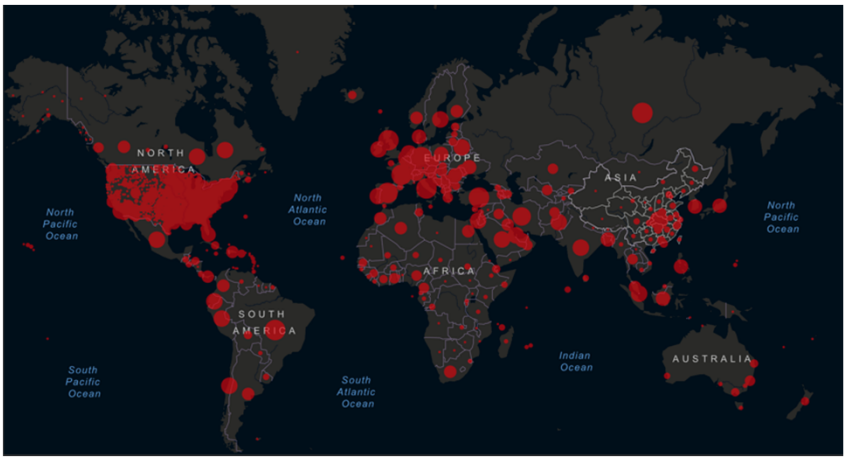
Current World Numbers



Total Confirmed
3,910,738
Total Deaths
272,778
187
countries/regions

COVID-19 Global Cases by Johns Hopkins CSSE.
https://www.arcgis.com/apps/opsdashboard/index.html#/85320e2ea5424dfaaa75ae62e5c06e61. Accessed May 8, 2020.

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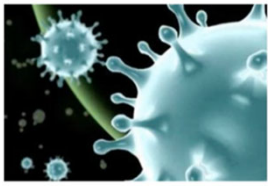
Incubation Period

- **Incubation period:** 1-14 days with an average of 5 days
- **Infectiousness:** around 12 hours prior to symptoms onset to 5-6 days after
- Symptomatic individuals are 50% more infectious than asymptomatic ones
- Two-thirds of infected individuals are symptomatic (many mild)



Long incubation period without any obvious symptoms

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Ferguson NM, et al. Imperial College COVID-19 Response Team. 2020

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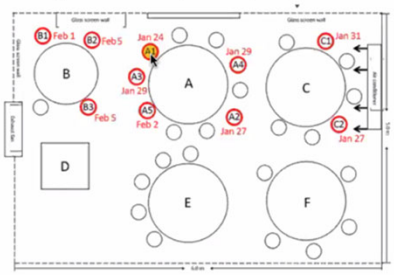
Outbreaks in shared spaces

Diners in a restaurant, Guangzhou: One or two index patients infect individuals at adjacent tables, determined by airflow, over 53-73 min.



Lu et al., *EID*, 2020

Workers in a call center, South Korea: 43% attack rate in 216-person call center; 16% SAR at home; limited by aggressive contact tracing & quarantine

Park et al., *EID*, 2020

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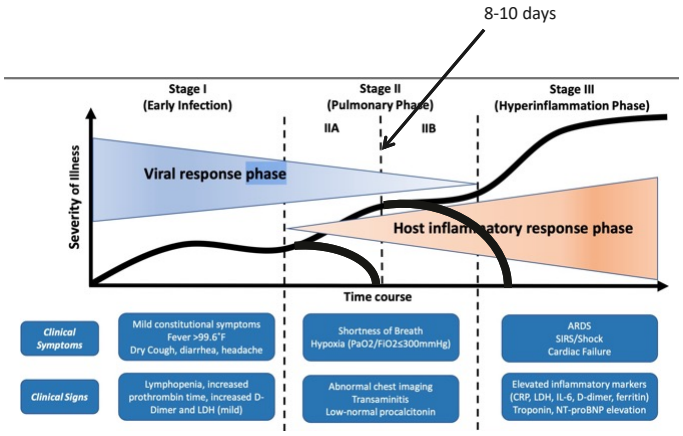
Possible Disease Course



Siddiqi HK, Mehra MR. *J Heart Lung Transpl*. March 2020. [Epub ahead of print].

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When to Suspect COVID-19

- Cough
- Shortness of breath or difficulty breathing

Or at least two of these symptoms:

- Fever
- Chills
- Repeated shaking with chills
- Muscle pain
- Headache
- Sore throat
- New loss of taste or smell

- Known exposure to infected person
- Abnormal chest imaging
- Lymphopenia (low wbc)
- Elevated CRP (blood test)

What about GI symptoms?

CDC. Coronavirus Disease 2019 (COVID-19) – Symptoms. Centers for Disease Control and Prevention. https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html. Published April 27, 2020. Accessed April 28, 2020.

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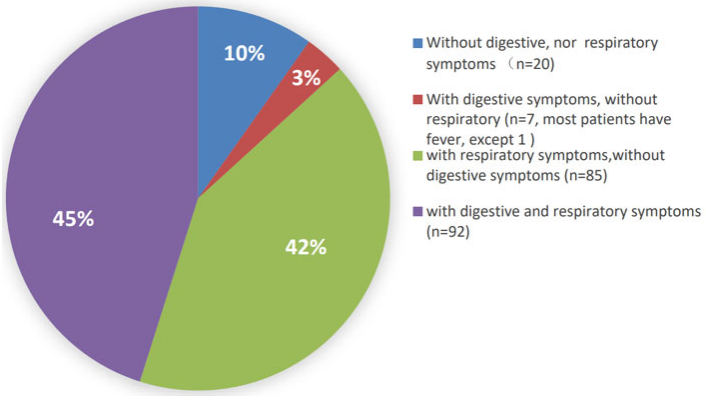
Frequency of COVID-19 Hospitalized Patients with or without Digestive Symptoms



Pan L, et al. *Am J Gastroenterology*. 2020.

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What We Know So Far About GI Symptoms and Viral Detection in Stool

Author	Journal	Year Published	N of Patients	Findings
Jin X, et al	Gut	2020	651	- 11.45% with one GI symptom (nausea, vomiting, diarrhea) - Identified novel methylation site in S protein that changed from SARS to Wuhan and some differences to the strain in Zhenjiang Province → may account for change in frequency of GI symptoms
Xiao F, et al	Gastro-enterology	2020	73	- 39 (53%) had positive stool RNA - Stool remained positive in 17 patients (23.29%) after respiratory samples were negative
Wu Y, et al	Lancet Gastroenterol Hepatol	2020	74	- 41 (55%) had positive stool samples - Fecal samples were positive for a mean of 27.9 days (vs. respiratory samples – mean 16.7 days)
Wolfel R, et al	Nature	2020	9	- Viral RNA detected in sputum and stool samples - Live virus was not isolated from stool samples - Virus in stool is not thought to be infectious

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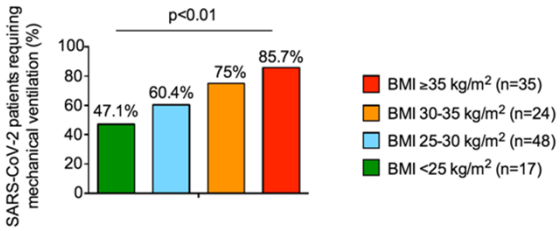
Risk Factors for Poor Outcomes

Table 4. Bivariate Cox Regression of Factors Associated With ARDS Development or Progression From ARDS to Death

Patient characteristics and findings	ARDS		Death	
	HR (95% CI)	*P* value	HR (95% CI)	*P* value
Clinical characteristics				
Age (≥65 vs <65), y	3.26 (2.08-5.11)	<.001	6.17 (3.26-11.67)	<.001
Gender (male vs female)	1.47 (0.92-2.36)	.11	0.56 (0.30-1.05)	.07
Highest patient temperature (≥39 °C vs <39 °C)	1.77 (1.11-2.84)	.02	0.41 (0.21-0.82)	.01
Comorbidities				
Hypertension (yes vs no)	1.82 (1.13-2.95)	.01	1.70 (0.92-3.14)	.09
Diabetes (yes vs no)	2.34 (1.35-4.05)	.002	1.58 (0.80-3.13)	.19



[1]Wu C. et al. *JAMA Internal Medicine*. 2020.
[2]Simonnet A, et al. Obesity (Silver Spring). 2020. [Epub ahead of print]

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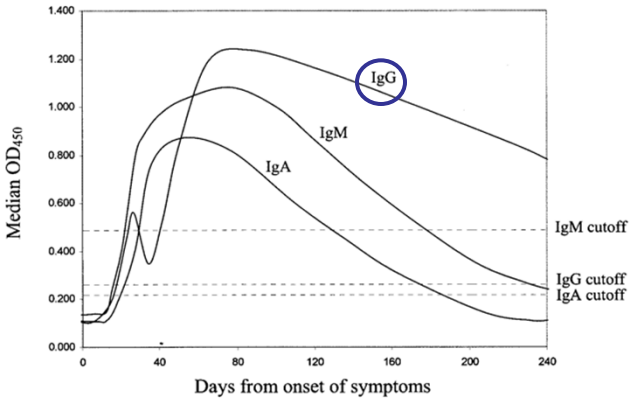
Profile of Antibodies in Patients with Pneumonia Due to SARS-CoV



Woo PCY, et al. *Clin Diagn Lab Immunol.* 2004;11(4):665-668.

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Are IBD Patients at Unique Risk?

- Management of IBD often involves immunosuppressive or immune modifying therapies
- Known increased risk of some viral infections with IBD therapies (influenza, VZV, CMV…)
- Exposures:
  - Patients with IBD may be receiving infusions in infusion centers
  - Patients with IBD require routine and diagnostic endoscopic procedures
- Pathophysiology (in theory): bowel expresses ACE2 receptor

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Questions of Concern Related to IBD and COVID-19

- **What is the risk of infection with SARS-CoV-2?**
- **Does bowel inflammation increase risk of infection with SARS-CoV-2?**
- **What is the risk of COVID-19?**
- **Do patients with IBD have different outcomes with COVID-19?**
- **Do IBD therapies increase risk of infection or COVID-19?**
- **Are any IBD therapies protective against COVID-19?**
- **Should patients with IBD modify their therapies during the pandemic?**

Rubin DT, et al. *Gastroenterology*. 2020. [Epub ahead of print].

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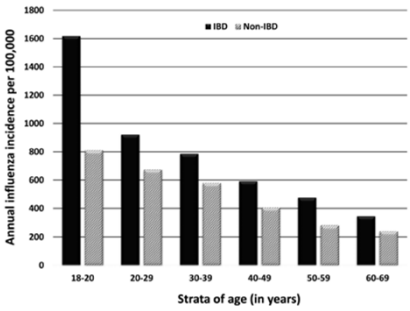
Viral Infections and IBD Therapies

- Increased risk of varicella zoster infection with tofacitinib[1]
- Reactivation of hepatitis B with anti-TNF therapy[2]
- Cases of viral warts associated with thiopurines[3]
- IBD patients have an increased influenza risk compared with those without IBD[4]
- Systemic corticosteroids were found to be independently associated with influenza (Table)[4]



Medications Used for IBD Treatment	OR [95%CI]
5-ASA	0.96 [0.88-1.05]
Thiopurine	0.95 [0.84-1.06]
Anti-TNF	1.06 [0.88-1.27]
Corticosteroids	**1.22 [1.08-1.38]**

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[1]Winthrop KL, et al. *Inflamm Bowel Dis*. 2018;24(10):2258-2265.
[2]Pauly MP, et al. *Clin Gastroenterol Hepatol*. 2018;16:1964–1973.
[3]Timmer MR and Ooteghem N. *Ann Gastroenterol*. 2013;26(2):173-174.
[4]Tinsley A, et al. *Inflamm Bowel Dis*. 2019;25(2):369-376.

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Task Forces

- Clinical trials task force
- Endoscopy task force
- Hospitalization task force
- Research task force
  - Epidemiology
  - Etiology
  - Prognosis and natural history
  - Prevention
  - Outcomes and quality of life
  - Clinical Practice
- Telemedicine task force

Publications

- Management of IBD Patients during COVID-19 Pandemic[1]
- Recommendations for Surgery in IBD Patients during COVID-19 Pandemic[2]

[1]Rubin DT, et al. *Gastroenterology*. 2020. [Epub ahead of print].
[2]Remzi FH, et al. *Dis Colon Rectum*. 2020. [in press].
Covid-19 | IOIBD. Accessed May 5, 2020.
https://www.ioibd.org/ioibd-update-on-covid19-for-patients-with-crohns-disease-and-ulcerative-colitis.

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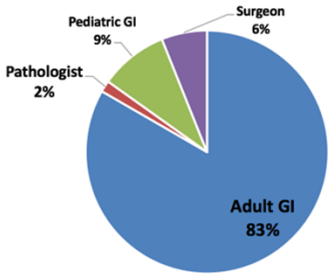
Management of Patients with Crohn's Disease and Ulcerative Colitis During the COVID-19 Pandemic: Results of an International Meeting

David T. Rubin*, Maria T. Abreu, Victoria Rai, Corey A. Siegel on behalf of the International Organization for the Study of Inflammatory Bowel Disease

PlumX Metrics

DOI: https://doi.org/10.1053/j.gastro.2020.04.002

Demographics of Participants by Specialty (N=66)



Acknowledgements:
The authors thank all the participants of the RAND panel.
IOIBD Members:
Vineet Ahuja, Matthieu Allez, Ashwin N. Ananthakrishnan, Charles N. Bernstein, Jonathan G. Braun, Yehuda Chowers, Jean-Frederic Colombel, Silvio Danese, Geert D'Haens, Andre D'Hoore, Axel Dignass, Iris Dotan, Marla C. Dubinsky, Anders Ekbom, Phillip R. Fleshner, Miquel A. Gassull, Richard B. Gearry, Subrata Ghosh, Anne M. Griffiths, Jonas Halfvarson, Stephen B. Hanauer, Noam Harpaz, Ailsa Hart, Michael A. Kamm, Gil G. Kaplan, Ioannis Koutroubakis, Peter L. Lakatos, Arie Levine, James D. Lewis, James O. Lindsay, Edward V. Loftus Jr., Edouard Louis, Milan Lukas, Fernando Magro, Uma Mahadevan, Gerasimos J. Mantzaris, Dermot P. McGovern, Bjørn A. Moum, Pia Munkholm, Markus F. Neurath, Siew C. Ng, Colm O'Morain, Remo Panaccione, Julian Panes, Laurent Peyrin-Biroulet, Cosimo Prantera, Zhihua Ran, Walter Reinisch, Feza H. Remzi, David B. Sachar, William J. Sandborn, R. Balfour Sartor, Jürgen Schölmerich, Stefan Schreiber, Britta Siegmund, Mark S. Silverberg, Johan D. Söderholm, Eduard F. Stange, Flavio Steinwurz, Dan Turner, Morten H. Vatn, and Severine Vermeire.
Additional invited participants:
Erica J. Brenner, Britt Christensen, Ferdinando D'Amico, Chris M. Griffiths, Peter D. Higgins, Michael D. Kappelman, Charlie Lees, Miguel D. Regueiro, Joel R. Rosh, Ryan Ungaro

The authors wish to acknowledge Cindy Traboulsi, Amarachi I. Erondu and Seth R. Shaffer for their assistance in data management and Raymond Kulig and Marischka Konings for invaluable help in logistical coordination.

Rubin DT, et al. *Gastroenterology*. 2020. [*Epub ahead of print*].

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IOIBD RAND Panel

to Develop Guidance for IBD Patients During COVID-19

Statements developed by steering committee → Survey sent to participants → Webinar → Statements modified → Participants re-surveyed

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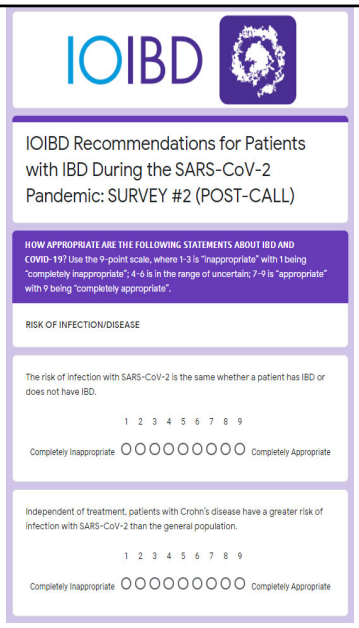

IOIBD

IOIBD Recommendations for Patients with IBD During the SARS-CoV-2 Pandemic: SURVEY #2 (POST-CALL)

HOW APPROPRIATE ARE THE FOLLOWING STATEMENTS ABOUT IBD AND COVID-19? Use the 9-point scale, where 1-3 is "inappropriate" with 1 being "completely inappropriate"; 4-6 is in the range of uncertain; 7-9 is "appropriate" with 9 being "completely appropriate".

RISK OF INFECTION/DISEASE

The risk of infection with SARS-CoV-2 is the same whether a patient has IBD or does not have IBD.

1 2 3 4 5 6 7 8 9

Completely Inappropriate ○○○○○○○○○ Completely Appropriate

Independent of treatment, patients with Crohn's disease have a greater risk of infection with SARS-CoV-2 than the general population.

1 2 3 4 5 6 7 8 9

Completely Inappropriate ○○○○○○○○○ Completely Appropriate

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Survey Results

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1	2	3	4	5	6	7	8	9
Inappropriate Statement			Uncertain Statement			Appropriate Statement		

	Pre-Survey (N=64) 69 Statements	Post-Survey (N=66) 76 Statements	Agreement (based on post-survey)	Disagreement (based on post-survey)
Appropriate Statement	16	26	18	8
Uncertain Statement	24	19	15	4
Inappropriate Statement	29	31	31	0
		Total Statements:	64	12

$$Disagreement\ Index(DI) = \frac{66\ \%ile\ -\ 33\ \%ile}{2.35 + \left(1.5 * \left(5 - \frac{66\ \%ile + 33\%ile}{2}\right)\right)}$$

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Are IBD Patients at a Higher Risk?

Results of an International Consensus Meeting

- The risk of infection with SARS-CoV-2 is the same whether a patient has IBD or does not have IBD.
- Independent of treatment, patients with CD or UC do not have a greater risk of infection with SARS-CoV-2 than the general population.
- It is uncertain if active inflammation from IBD increases the risk of getting SARS-CoV-2.
- Patients with an ostomy are not at increased risk for COVID-19.
- Patients with a J pouch are not at increased risk for COVID-19.

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What about Special Situations?

Results of an International Consensus Meeting

- Elective surgeries and endoscopies should be postponed at this time.
- It is uncertain if healthcare workers with IBD on immune modifying medications working in an environment with known or suspected COVID-19 patients should continue working in that same environment.
- Patients with IBD on immune modifying medications should discontinue any non-essential travel.
- It is safe to continue infusions in an infusion center, assuming the infusion center has a screening protocol in place.

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What About IBD Therapy?

	5-ASA	BUD	PRED (≥20mg /d)	AZA/ 6MP	MTX	Anti-TNF	VEDO	UST	TOFA
To **prevent** SARS-CoV-2 infection.									
If **infected** with SARS-CoV-2 **but don't have COVID-19**.									
Confirmed COVID-19.									

Continue Therapy Unsure Hold/Delay/Stop Therapy

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Treatment of IBD After SARS-CoV-2 Infection

Results of an International Consensus Meeting

- In an IBD patient who tests positive for SARS-CoV-2 and whose IBD meds have been stopped because of this, IBD meds can be restarted:
  - –after 14 days (provided they have not developed COVID-19).
  - –after COVID-19 symptoms resolve.
  - –after 2 nasopharyngeal PCR tests are negative.

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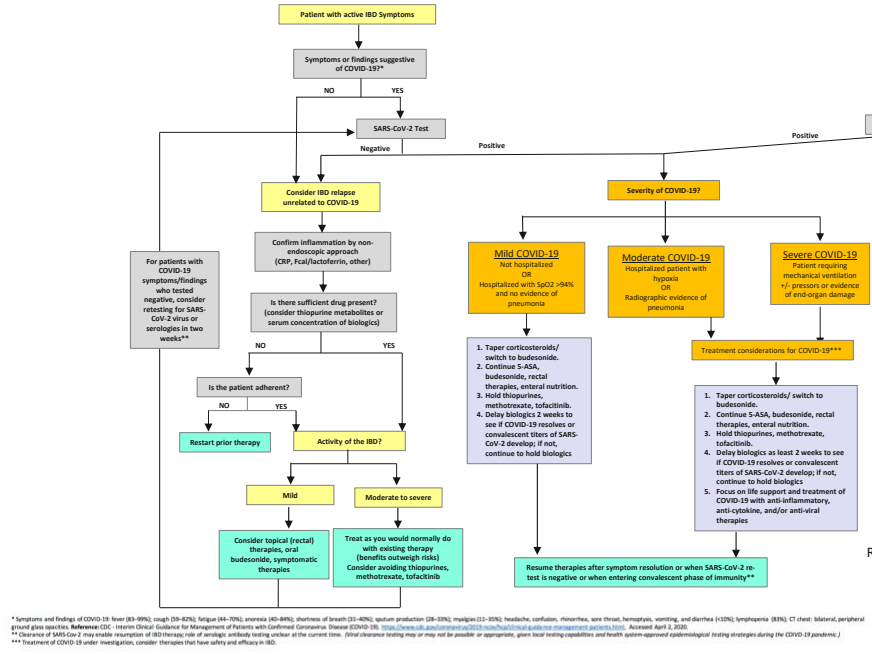
Management of IBD Patients During COVID-19



Rubin DT, et al. *Gastroenterology*. 2020. [Epub ahead of print].

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When Do You Restart Therapy?

- **Unclear**
- **Options:**
  - **When patient is asymptomatic**
  - **When patient is asymptomatic for more than 3 days (?)**
  - **When patient has PCR test for SARS-CoV-2 negative (once or twice?) (maybe not[1])**
  - **When patient is in convalescent phase of illness (IgG positive, IgM negative)**

1. Wajnberg A, et al. Humoral immune response and prolonged PCR positivity in a cohort of 1343 SARS-CoV 2 patients in the New York City region. Preprint in medRxiv, accessed May 5, 2020.

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Limitations to Our Current Approach

- **Limited data.**
- **Long half life of many drugs makes holding them of questionable benefit.**
- **Unclear denominator of infected IBD patients.**
- **No distinction between infectious and inflammatory phases of COVID-19.**

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Outcomes of COVID-19 in 79 patients with IBD in Italy

Risk Factor	COVID-19 related pneumonia		COVID-19 related death	
	OR [95%CI]	P-value	OR [95%CI]	P-value
Age > 65	5.87 [1.15, 29.66]	0.03	19.6 [2.95, 130.6]	0.002
CCI* score > 1	2.91 [1.06, 9.21]	0.04	16.66 [1.8, 153.9]	0.01
UC diagnosis	2.72 [1.06, 6.99]	0.03	2.95 [0.31, 27.73]	0.34
Active IBD	10.25 [2.11, 49.73]	0.003	8.45 [1.26, 56.56]	0.02
Corticosteroids	4.94 [0.95, 25.55]	0.05	6.28 [0.89, 44.24]	0.064
Thiopurines	1.21 [0.22, 6.40]	0.82	-	-
Anti-TNF	1.18 [0.47, 2.97]	0.71	0.4 [0.04, 3.78]	0.42
Vedolizumab	0.53 [0.16, 1.73]	0.29	-	-

*Charlson Comorbidity Index

Bezzio C, et al. *Gut*. 2020. [Epub ahead of print].

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COVID-19 in Immune-Mediated Diseases

Case Series from New York (NYU)

- **N = 86**
- **RA, IBD, psoriatic arthritis, ankylosing spondylitis, psoriasis…**
- **59 PCR confirmed COVID-19**
- **HTN, DM, COPD were associated with higher hospitalization**

Medication	Total (n=59)	Ambulatory (n=45)	Hospitalized (n=14)	Adjusted OR [95%CI]
Hydroxychloroquine	7 (11.9)	4 (8.9)	3 (21.4)	1.43 [1.04, 1.97]
MTX	14 (23.7)	8 (17.8)	6 (42.9)	1.37 [1.06, 1.78]
Steroids	7 (11.9)	3 (6.7)	4 (28.6)	1.40 [1.01,1.93]

Haberman R, et al. *N Engl J Med*. 2020. [Epub ahead of print].

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Case Reports of IBD and COVID-19

Author	Journal, year	Patient Characteristics	Presentation	Management/Outcome
Rosen MH, Axelrad J, Hudesman D, Rubin DT, Chang S	Inflamm Bowel Dis, 2020 [in press]	- 26 year old woman with a history of UC pancolitis - Received 3 doses of infliximab in the past and went into clinical remission - self-discontinued medications 6 years ago	- Abdominal pain, diarrhea, hematochezia, and urgency for 6 weeks -> hospitalized for UC flare -> treated with methylprednisolone and discharged - 2 days later, worsening bloody diarrhea and abdominal pain, no respiratory symptoms	- **B-hcg positive, confirmed intrauterine pregnancy** - **Tested positive for SARS-CoV-2** - Started on iv methylprednisolone, was unable to transition to oral, so was given iv cyclosporine - Developed pleuritic chest pain, ruled out PE and was started on **hydroxychloroquine + azithromycin** - **Experienced a spontaneous abortion on day 9**
Wolf DC, Wolf CH, Rubin DT	Am J Gastroenterol, 2020 [submitted]	- 85 year old man with CD on no therapy for his disease - Takes loperamide PRN	- 4 liquid stools per day, anorexia, fatigue, 13-pound weight loss in 10 days - Persistent non-productive cough despite azithromycin	- Telehealth management, **started on bismuth subsalicylate (BSS) 525 mg PO 2-4x a day while waiting for labs** - **Tested positive for SARS-COV-2** - Diarrhea improved within 6 hours, 80% improvement of all other symptoms by day 6, **near resolution by day 10** - **Patient remained only on BSS throughout course of illness**
Jacobs J, Clark-Snustad K, Lee S	Inflamm Bowel Dis, 2020 [Epub ahead of print]	- 33 year old woman with a 13 year history of UC - Started tofacitinib 10 mg BID in June 2019 - Achieved clinical remission after 5 months of therapy	- Fever, chills, cough, myalgia, sore throat, fatigue, and night sweats - No GI symptoms	- **Tested positive for SARS-COV-2** - **Tofacitinib 10 mg BID was continued.** - Respiratory sx resolved after 5 days - **Remained well with no symptoms after 2 weeks**

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Vitamin D Supplementation Can Reduce the Clinical Effects of COVID-19

- **Vitamin D deficiency can be implicated in ARDS, heart failure and sepsis**
- **These can all be manifestations of critically ill COVID-19 patients**
- **To reduce the risk of infection, it is recommended that people at risk of influenza and/or COVID-19 consider taking vitamin D_3.**
- **Randomized controlled trials and large population studies should be conducted to evaluate these recommendations.**

Clinical Characteristics	Findings from Vitamin D Supplementation Trials
Treatment of CAP with vitamin D	Did not significantly result in complete resolution. Baseline 25(OH)D was 20 ng/mL. Achieved 25(OH)D in the treatment arm was 40 ng/mL.
Increased production of pro-inflammatory cytokines such as IL-6	Reduces concentration of IL-6
Increased CRP	Reduces CRP in diabetic patients
Increased risk of sepsis	No reduction in mortality rate found for adults with sepsis supplemented with vitamin D. Most trials included participants with 25(OH)D <20 ng/mL; vitamin D_3 doses between 250 and 600 thousand IU.
Risk of ARDS	Vitamin D deficiency contributes to development of ARDS

Grant WB, et al. *Nutrients*. 2020;12(4):E988.

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Reliable References to Stay Updated

- who.int/health-topics/coronavirus
- cdc.gov/coronavirus/2019-ncov
- coronavirusupdates.uchicago.edu
- crohnscolitisfoundation.org/coronavirus
- covidibd.org
- ioibd.org
- clinicaltrials.gov
- rubinlab.uchicago.edu/blog
- twitter.com/IBDMD

World Health Organization

CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

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NIH U.S. National Library of Medicine
ClinicalTrials.gov

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Update on Impact of COVID-19 in Inflammatory Bowel Disease Patients

Erica Brenner, MD (University of North Carolina at Chapel Hill)
Ryan Ungaro, MD MS (Icahn School of Medicine at Mount Sinai, New York)
Jean-Frederic Colombel, MD (Icahn School of Medicine at Mount Sinai, New York)
Michael Kappelman MD, MPH (University of North Carolina at Chapel Hill)

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Background

- Coronavirus disease 2019 (COVID-19) has rapidly spread throughout the world and is now an international pandemic
- Almost 80% of patients with severe COVID-19 (requiring intensive care) have at least one underlying comorbidity[1]
- Inflammatory bowel disease (IBD) patients are frequently on immunosuppressive treatments that increase the risk of infection
- To date, there are limited data on the disease course of COVID-19 in IBD patients including impact of clinical characteristics and medications

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1. MMWR Morb Mortal Wkly Rep 2020;69:382-386

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Aim

- To define the impact of COVID-19 on patients with IBD
- To evaluate associations between age, co-morbidities, IBD characteristics, and IBD treatments and COVID-19 outcomes

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Methods

- Surveillance Epidemiology of Coronavirus Under Research Exclusion for Inflammatory Bowel Disease (SECURE-IBD) is an international registry of IBD patients who have had COVID-19
- Health care providers invited to report cases on a web-based platform
- Cases reported after a minimum of 7 days from symptom onset and sufficient time has passed to observe the disease course through resolution of acute illness or death
- Data collected include patient demographics, IBD type, co-morbidities, disease activity (by physician global assessment), BMI, smoking, and IBD medications at time of COVID-19 infection
- COVID-19 outcomes: hospitalization, need for intensive care unit (ICU), need for ventilator, and death

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Methods

- Descriptive statistics reported on cohort characteristics and outcomes
- Age-standardized mortality ratios (SMRs) calculated using reference populations from China, Italy, and the United States[1-3]
- Primary outcome was severe COVID-19, defined as a composite of ICU admission, ventilator use, and/or death, consistent with existing COVID-19 literature
- Multivariable logistic regression estimated the independent effects of age, sex, disease (CD vs UC/IBD-U), disease activity, smoking, BMI ≥30, number of comorbidities (0, 1, ≥2), systemic corticosteroids, TNF antagonists, and mesalamines (5-ASA) / sulfasalazine on the primary outcome

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1. Onder G et al. JAMA 2020
2. Zhonghua Liu Xing Bing Xue Za Zhi 2020
3. Centers for Disease Control and Prevention 2020

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Results: Cohort Characteristics

- Analysis based on first 525 cases
- 33 different countries
- Median age 41 years
- 53% men, 84% white
- 59.4% Crohn's disease
- IBD disease activity at time of infection
  - 60% Remission
  - 18% Mild
  - 19% Moderate/Severe
  - 1% Unknown
- Outcomes
  - 30.7% Hospitalized
  - 4.6% ICU
  - 4% Ventilator
  - 3% Death
  - 7% Severe COVID-19 (composite)

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Results: Age-Standardized Mortality Ratios

Reference Country Population	SMR (95% CI)
China	1.76 (0.90-2.62)
Italy	1.45 (0.74-2.16)
United States	1.66 (0.85-2.47)

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Outcomes by Age

Characteristic	Total N	Outpatient only, n (%)	Hospitalized, n (%)	Death, n (%)	ICU/Ventilator/ Death, n (%)
Overall	525	363 (69)	161 (31)	16 (3)	37 (7)
Age Group					
0-9 years	3	3 (100)	0 (0)	0 (0)	0 (0)
10-19 years	26	23 (88)	3 (12)	0 (0)	0 (0)
20-29 years	116	93 (80)	23 (20)	0 (0)	2 (2)
30-39 years	108	87 (81)	20 (19)	1 (1)	4 (4)
40-49 years	95	64 (67)	31 (33)	2 (2)	5 (5)
50-59 years	74	45 (61)	29 (39)	2 (3)	6 (8)
60-69 years	54	30 (56)	24 (44)	3 (6)	11 (20)
70-79 years	24	7 (29)	17 (71)	2 (8)	3 (13)
>=80 years	23	9 (39)	14 (61)	6 (26)	6 (26)

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Outcomes by Medication Class

Characteristic	Total N	Outpatient only, n (%)	Hospitalized, n (%)	Death, n (%)	ICU/Ventilator/Death, n (%)
Sulfasalazine/ mesalamine	117	60 (51)	57 (49)	9 (8)	20 (17)
Budesonide	18	9 (50)	9 (50)	1 (6)	3 (17)
Oral/parenteral steroids	37	11 (30)	26 (70)	4 (11)	9 (24)
6MP/azathioprine monotherapy	53	29 (55)	24 (45)	1 (2)	3 (6)
Methotrexate monotherapy	5	2 (40)	3 (60)	0 (0)	0 (0)
Anti-TNF without 6MP/AZA/MTX	176	150 (85)	25 (14)	1 (1)	4 (2)
Anti-TNF + 6MP/AZA/MTX	52	32 (62)	20 (38)	2 (4)	5 (10)
Anti-integrin	50	34 (68)	16 (32)	0 (0)	3 (6)
IL-12/23 inhibitor	55	51 (93)	4 (7)	0 (0)	1 (2)
JAK inhibitor	8	7 (88)	1 (13)	1 (13)	1 (13)

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Multivariable Analysis

Variable (Referent group)	ICU/Vent/Death Odds Ratio (95% CI) (n = 517)	p
Age	1.04 (1.01-1.06)	0.002
Male (Female)	1.20 (0.55-2.60)	0.65
Diagnosis Crohn's disease (ulcerative colitis/IBD unspecified)	0.76 (0.31-1.85)	0.54
Disease severity (remission) Active disease	1.14 (0.49-2.66)	0.76
Systemic corticosteroid (none)	6.87 (2.30-20.51)	<0.001
TNF antagonist (none)	0.90 (0.37-2.17)	0.81
Current smoker	0.55 (0.06-4.94)	0.59
BMI ≥ 30	2.00 (0.72-5.51)	0.18
Comorbidities (none) 1 ≥2	 1.22 (0.45-3.26) 2.87 (1.05-7.85)	 0.70 0.04
5-ASA/sulfasalazine (none)	3.14 (1.28-7.71)	0.01

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Recent updates (5/12/2020)

- 1,074 cases reported from 42 different countries

Characteristic	Total N	Hospitalized (n, %)		Death (n, %)		ICU/Ventilator/Death (n, %)	
Sulfasalazine/mesalamine	294	145	49%	22	7%	49	17%
Budesonide	27	13	48%	2	7%	4	15%
Oral/parenteral steroids	85	56	66%	10	12%	22	26%
6MP/azathioprine monotherapy	104	38	37%	2	2%	10	10%
Methotrexate monotherapy	8	4	50%	1	13%	1	13%
Anti-TNF without 6MP/AZA/MTX	314	60	19%	3	1%	8	3%
Anti-TNF + 6MP/AZA/MTX	106	38	36%	3	3%	12	11%
Anti-integrin	107	31	29%	4	4%	9	8%
IL 12/23 inhibitor	102	13	13%	0	0%	2	2%
JAK inhibitor	17	5	29%	1	6%	2	12%
Other IBD medication	40	17	43%	1	3%	3	8%

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Strengths

- Robust, worldwide collaboration
- Large, geographically diverse sample of pediatric and adult IBD patients
- Reporting directly by physicians and trained staff

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Limitations

- Convenience sample
- Only includes confirmed cases
- Risk of reporting bias
  - May over-represent severe cases and areas with readily available testing
  - May under-represent severely ill patients hospitalized at an outside hospital or die without physician's awareness

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Summary

- Increasing age, comorbidities, and corticosteroids are associated with severe COVID-19 outcomes
- TNF antagonist medications do not appear to be associated with severe COVID-19 outcomes
- More data needed to further understand signals in other drug classes (5-ASA, TNF antagonist combination therapy)

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Thank you!

All reporting providers and our partners:

Crohn's & Colitis Foundation
NASPGHAN North American Society for Pediatric Gastroenterology, Hepatology and Nutrition
IOIBD International Organization for the Study of Inflammatory Bowel Disease
ECCO European Crohn's and Colitis Organisation
Asian Organization for Crohn's & Colitis
UNC School of Medicine North Carolina Translational and Clinical Sciences Institute
The Leona M. and Harry B. Helmsley Charitable Trust
Pan American Crohn's and Colitis Organisation
SECURE-IBD DATABASE
Surveillance Epidemiology of Coronavirus (COVID-19) Under Research Exclusion

And many more organizations listed at https://covidibd.org/our-partners/

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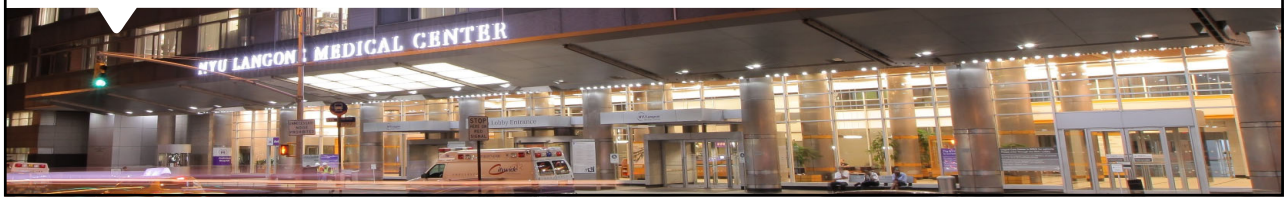
NYU Langone Health

Inflammatory Bowel Disease Center
Division of Gastroenterology

WHAT HAVE WE LEARNED FROM THE NYC EXPERIENCE?

David Hudesman, MD
Co-Director, IBD Center at NYULMC
Associate Professor of Medicine, NYU



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COVID-19 in Immune-Mediate Inflammatory Diseases

- Prospective case of 86 patients from NYU Langone Health with known (59) or highly suspected (27) COVID-19
  - Inflammatory Bowel Disease
  - Psoriatic Arthritis
  - Psoriasis
  - Rheumatoid Arthritis
  - Ankylosing Spondylitis
- Median age = 46, 49% Female
- 72% on a biologic or JAK inhibitor
- 16% (14/86) were hospitalized

Haberman et al., N Engl J Med. 2020 Apr 29

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COVID-19 in Immune-Mediate Inflammatory Diseases

- Hospitalized patients were older and were more likely to have comorbidities
- Use of biologics or JAK inhibitors
  - 76% (55/72 patients) not hospitalized
  - 50% (7/14) hospitalized
- Multivariate analysis (adjusting for age, sex, and comorbidities)
  - **Prednisone use: 29% hospitalized vs 6% ambulatory**
  - Hydroxychloroquine use: 21% hospitalized vs 7% ambulatory
  - Methotrexate use: 43% hospitalized vs 15% ambulatory

Haberman et al., N Engl J Med. 2020 Apr 29

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Updated NYU IBD/COVID-19 Experience

- 72 patients with known or suspected COVID-19
- 6 hospitalizations
  - 3 patients home within 24-48 hours, never required oxygen (one male patient with moderate disease, 2 female patients in remission)
  - 1 patient hospitalized for severe UC flare during first trimester of pregnancy
  - 1 patient intubated in ICU: 73 year old male with UC on mesalamine with HTN and prostate cancer (IBD in remission)
  - 1 patient died: 80 year old male on adalimumab with Parkinsons (IBD in remission)

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Managing an IBD Practice in the COVID era

- IBD patient with COVID-19
  - Personalized approach
- IBD patient who is in a presumed flare
  - Telehealth vs Office visit
  - Labs and stool studies
  - Change in medication
  - Colonoscopy
- IBD patient who is stable
  - Disease monitoring
  - Medication compliance
- Provider and staff concerns and well being

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THANK YOU

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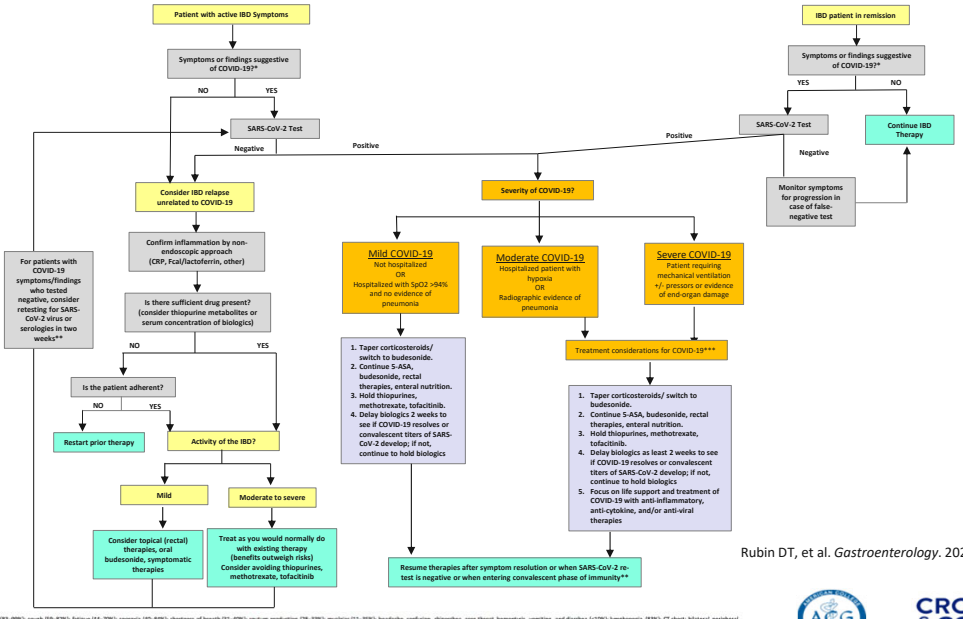
Management of IBD Patients During COVID-19



Rubin DT, et al. *Gastroenterology*. 2020. [Epub ahead of print].

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A Partnership of the American College of Gastroenterology and the Crohn's & Colitis Foundation

Member-Only Online Community

A member-only online resource, the IBD Circle is a trusted source for professional advice, collaboration, support, and practice resources to help you deliver quality patient care. Join as a professional member to access.

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