Webinar Moderator

Elizabeth C. Verna, MD, MS

Associate Professor of Medicine
Center for Liver Disease and Transplantation and Division of Digestive and Liver Diseases

Columbia University
A. Sidney Barritt IV, MD, MSCR
Associate Professor, Liver Center
Transplant Hepatology Fellowship
Program Director

University of North Carolina
Chapel Hill
Olivia Kates, MD
Developer and lead investigator
UW COVID-SOT Registry project
University of Washington
Who is the AST?

Mission Statement:
The American Society of Transplantation is dedicated to advancing the field of transplantation and improving patient care by promoting research, education, advocacy, organ donation, and service to the community.
AST Resources for Patients & Professionals

• The AST continually creates and updates COVID-19 resources for both medical professionals and the transplant community.
• Transplant Community: https://www.myast.org/covid-19
• Professionals: https://www.myast.org/covid-19-information

• General Information About the AST: https://www.myast.org/
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AASLD Calendar of Events

Speakers A. Sidney Barratt IV, MD, MScR, Olivia Yates, MD, and moderators Elizabeth C. Verna, MD, MS and Emily Blumberg, MD. FAST will discuss how COVID-19 has had a profound impact on liver transplantation and patients with advanced chronic liver disease, and then take questions during a live Q&A.

Thursday, 5:00pm ET - Thursday, 6:00pm ET
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TRANSPLANT HEPATOLOGY BOARD REVIEW COURSE
This course helps prepare physicians for American Board of Internal Medicine and American Board of Pediatrics certification and maintenance of certification exams in transplant hepatology and pediatric transplant hepatology, led by hepatology and transplant medicine experts.

Saturday, 8:00am ET - Wednesday, 8:00pm ET
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COVID-19 & Liver Disease

View the Latest issue of CLD, AASLD’s multimedia journal: COVID-19 & Liver Disease

cldlearning.com
AASLD-AST COVID-19 and the Liver: Chronic Liver Disease and Transplant

June 25, 2020
5:00pm – 6:00pm EDT

Moderated by:
Elizabeth C. Verna, MD, MS, FAST
Emily Blumberg, MD, FAST

Presenters:
A. Sidney Barritt IV, MD, MSCR
Olivia Kates, MD
Webinar Q&A

Submit your questions in the Q&A box at the top or bottom of your screen.

Questions will be answered at the end of the presentation.
Webinar Moderator

Elizabeth C. Verna, MD, MS

Associate Professor of Medicine
Center for Liver Disease and Transplantation and Division of Digestive and Liver Diseases

Columbia University
Webinar Moderator

Emily Blumberg, MD, FAST
Director of the Transplant Infectious Diseases Program and the Infectious Diseases Fellowship
University of Pennsylvania
A. Sidney Barritt IV, MD, MSCR

Associate Professor, Liver Center
Transplant Hepatology Fellowship Program Director

University of North Carolina
Chapel Hill
Webinar Presenter

Olivia Kates, MD
Developer and lead investigator
UW COVID-SOT Registry project
University of Washington
Webinar Panelist

• Michael L. Schilsky, MD, FAASLD, Yale New-Haven Hospital
• Michael Ison, MD, MS, Northwestern University Feinberg School of Medicine
• John C. Bucuvalas, MD, FAASLD, Icahn School of Medicine at Mount Sinai (ISMMS)
• Jean C. Emond, MD, FAASLD, Columbia University
Clinical Oversight Subcommittee

- Co-chair, Oren K. Fix, MD, MSc, FAASLD, Swedish Medical Center (Washington)
- Co-chair, Elizabeth C. Verna, MD, MS, Columbia University (New York)
- Kimberly Brown, MD, Henry Ford Health System (Michigan)
- Jaime Chu, MD, Icahn School of Medicine at Mount Sinai (New York)
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- Norah Terrault, MD, MPH, FAASLD, Keck Medicine of USC (California)
- Andrew Reynolds, (Patient Advocate)
- Raymond Chung and K. Rajender Reddy (ex-officio)

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Webinar Agenda

❖ Housekeeping Items – Dr. Elizabeth Verna
❖ Presenter Introductions – Dr. Elizabeth Verna
❖ Webinar Contributors
❖ Webinar Introduction – Dr. Elizabeth Verna
❖ Expert Panel Consensus Document Update – Dr. Oren Fix
❖ Emerging data on the impact of COVID-19 in advanced liver disease – Dr. A. Sidney Barritt IV
❖ COVID-19 in Liver Transplant Recipients – Dr. Olivia Kates
❖ Panel Discussion / Q&A
Globally, as of 10:37am CEST, 25 June 2020, there have been 9,277,214 confirmed cases of COVID-19, including 478,691 deaths, reported to WHO.
COVID-19 in Transplant: New York State

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<td>20</td>
<td>17</td>
<td>10</td>
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</tbody>
</table>

Source: 13/14 Transplant Hospitals reporting
Data is cumulative through June 24, 2020
Impact of COVID-19 on LT Rates

Agopian, Verna and Goldberg, Liver Transpl 2020

https://unos.org/covid/
COVID-19: Increasing Cases in the US

CDC COVID Data Tracker, accessed June 25, 2020

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Expert Panel Consensus Statement

- First published online March 23rd
- New update posted today: www.aasld.org/covid19
Expert Panel Consensus Statement

Major Changes Since June 4, 2020

• Changes reflecting the ramping up of routine and in-person clinical care, procedures, and clinical research
• Clearly identified preprint articles that have not been peer-reviewed
Expert Panel Consensus Statement

Cirrhosis + COVID-19 = Bad

• Retrospective Italian study showing a high mortality rate (35%) in hospitalized patients with cirrhosis and COVID-19

Iavarone M et al. J Hepatol 2020
Expert Panel Consensus Statement

But Cirrhosis – COVID-19 = Also Bad

• Accumulating evidence that patients with cirrhosis and COVID-19 have a higher risk of death compared to patients with COVID-19 alone

• Inpatient mortality in patients with cirrhosis and COVID-19 may be similar to the mortality of patients with cirrhosis alone without COVID-19

Expert Panel Consensus Statement

Immunosupp + COVID-19 = Not Bad?

• Retrospective Italian report of 10 patients with AIH on immunosuppression and with COVID-19 suggests the course of COVID-19 may be similar to non-immunosuppressed patients
• The authors suggest that pre-emptive reduction in immunosuppression during COVID-19 can be potentially harmful
• Single-center and registry data of liver transplant recipients with COVID-19

Gerussi A et al. Hepatology Communications 2020
Bhoori S et al. Lancet Gastroenterol Hepatol 2020
Webb GJ et al. Lancet Gastroenterol Hepatol 2020
Belli LS et al. Lancet Gastroenterol Hepatol 2020
Expert Panel Consensus Statement

Dexamethasone = Good(?)

- RECOVERY trial demonstrated a significant mortality benefit from dexamethasone in patients receiving invasive mechanical ventilation or oxygen without invasive mechanical ventilation (RR 0.83, 95% CI 0.74-0.92, P<.001)
- There was no benefit (and possible harm) from dexamethasone in patients who did not require respiratory support (RR 1.22, 95% CI 0.93-1.61, P=.14)

Expert Panel Consensus Statement

Hydroxychloroquine = Not Good

• The FDA revoked the Emergency Use Authorization for chloroquine and hydroxychloroquine after determining they are unlikely to be effective in treating COVID-19

Emerging data on the impact of COVID-19 in advanced liver disease

A. Sidney Barritt IV, M.D., M.S.C.R.
Medical Director of Liver Transplantation
UNC Liver Center
University of North Carolina
29 April 2020
Disclosures

• No relevant conflicts
Roadmap

• Direct and indirect effects of COVID-19 on the liver

• Impact of COVID-19 on patients with chronic liver disease

• Where do we go from here?
Direct effects of coronavirus on the liver

• Liver damage common with previous coronavirus infections SARS-CoV and MERS-CoV
• SARS-CoV-2 binds to cells through angiotensin-converting enzyme 2 (ACE2)
  • As ACE2 occurs on liver and biliary epithelial cells, the liver is a target for infection
• Data regarding SARS CoV2 (COVID-19) suggest that liver damage might be mediated by a direct cytopathogenic effect or due to an immune-mediated inflammatory response
  • Summary of 12 reports of COVID-19 describe abnormal LFTs in 10-58% with mixed impact on outcomes
COVID-19 infections lead to elevated liver enzymes in up to ½ of patients.

60 consecutive patients admitted to MGH follow during hospitalization.

- Cholestatic enzyme elevations were rare.
- AST predominance was common.
  - Not correlated with CK levels/muscle injury.
  - Appears to reflect true hepatic injury.
  - No clear demographic or comorbidities associated with injury.

Indirect coronavirus impact on the liver

- There may be confounding in regard to abnormal liver enzymes among patients with COVID-19
  - Many critically ill
  - Prevalent chronic liver disease (CLD)?
    - Maybe not – prevalence of CLD lower than expected in most reports of COVID-19 infections
- How does this impact clinical trials for COVID therapies?

- Drug Induced Liver Injury?

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Xu L et al, Liver Int 2020
Impact of COVID-19 on patients with liver disease

Patients with chronic liver disease (CLD)
• Limited information available
• Prevalence of CLD in data reported thus far is lower than expected
  • Only 7/12 studies in literature review from China report prevalence of CLD and range is low (2-11%)
  • 5700 COVID-19 patients in NYC, only 19 (0.4%) with cirrhosis
    • Obesity and diabetes common but not designated as NAFLD
  • Patients with CLD/cirrhosis sheltering in place?
  • Misclassification of current data?

Xu L et al, Liver Int 2020
Richardson et al, jamanetwork 2020

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Registry data

• Secure Cirrhosis and COVID-HEP
  • Combined international registry for patients with laboratory confirmed COVID-19 infection and chronic liver disease, cirrhosis and liver transplantation
  • 915 submissions from 34 countries
    • NASH (38%) is the most common etiology

Participating Countries

USA (25%), UK (25%), China (18%) submitted greatest number of cases
Ten countries with ≥10 submissions
Impact of COVID-19 on patients with liver disease

Patients with Cirrhosis
- SECURE-Cirrhosis and COVID-HEP registries’ multivariable analysis shows increase in OR of mortality with CTP class
  - CLD w/o cirrhosis [ref]
  - CTP A 1.14, p=0.8
  - CTP B 4.82, p=0.027
  - CTP C 23.6, p<0.001
- Other independent risk factors for mortality include age and obesity
  - Consistent with general population
- Trend consistent with potentially significant risk even for CTP A patients in larger cohort of 750+ patients

Moon, et al, J Hep 2020
Unpublished data courtesy of Secure Cirrhosis and COVID-HEP
Hepatic decompensation events

- Decompensation events are common when patients with cirrhosis suffer COVID-19 infections
- Frequency of events increases with severity of cirrhosis as measured by CTP class
- GI symptoms common as a presenting symptom in this population

Unpublished data courtesy of Secure Cirrhosis and COVID-HEP
COVID-19 infection can trigger ACLF

- Acute on chronic liver failure is deadly and frequently triggered by infection
- COVID-19 case fatality associated with rising ACLF score

Unpublished data courtesy of Secure Cirrhosis and COVID-HEP

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Care for patients with chronic liver disease

- Abnormal liver enzymes need evaluation
  - HBV or AIH flare? ETOH consumption? COVID-19?
- No need to reduce immunosuppression for asymptomatic/COVID-19 negative patients
- Social distancing, handwashing etc.
- Telephone/video visits
- Do not need to update labs solely for UNOS listing

- Need more data, greater numbers and better sense of the denominator of patients with COVID-19 to determine risk factors and role of immunosuppression in disease course
Where do we go from here?

- COVID-19 will have a heterogeneous impact on hepatology practices
  - Geography
  - Population density
  - Second wave?
- Need to acknowledge the limitations of data thus far:
  - Registries subject to selection bias
  - Single center data may not be generalizable
  - Expert opinion
- Practices will evolve over time with more experience and better data
Where do we go from here?

- Cannot forget impact of COVID-19 on patients without infection
  - Resource limitations for acute care needs
  - Disruption in chronic care practices
  - Will there be a “4th wave” of post pandemic trauma that has implications for hepatologists?
    - Alcohol/Substance abuse/Mental health
- Economic impact on liver care
  - Impact on liver related public health initiatives
  - Viral hepatitis and alcohol
Acknowledgements

Andrew Moon (UNC)
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Patricia Jones (University of Miami)
Feng Su (University of Washington)
Xiaolong Qi (Lanzhou University, China)

Endorsing Organizations

@SecureCirrhosis
URL: www.covidcirrhosis.org

@CovidHep
URL: www.covid-hep.net

Tom Marjot (Oxford, UK)
Gwilym Webb (Oxford, UK)
Ellie Barnes (Oxford, UK)
Tamsin Cargill (Oxford, UK)
Thank you!

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COVID-19 in Liver Transplant Recipients

Outcomes and management

Olivia Kates, MD
Second-Year Fellow
Division of Allergy and Infectious Diseases
University of Washington
Disclosures

- No financial disclosures
- UW COVID-SOT registry results presented today are preliminary
UW COVID-SOT Registry

- 73 Liver transplant recipients
- 16 (22%) liver/kidney
UW COVID-SOT Registry

Race/Ethnicity of cases reported to the UW COVID-SOT Registry compared to liver transplant recipients in U.S. and New York

- Asian or Pacific Islander
- Black
- Hispanic
- Non-Hispanic White

Bar chart showing the percentage distribution of various ethnicities in UW COVID-SOT, UNOS, and UNOS (New York State).
UW COVID-SOT Registry

- Median time post-transplant: 5 years (2-11)
  - 8 (11%) transplanted since January 1, 2020
- Maintenance immunosuppression
  - Triple IS (CNI + antimetabolite + steroid): 23 (32%)
  - Two-drug IS (CNI + antimetabolite OR steroid): 21 (28%)
  - mToRi-containing IS: 3 (4.1%)
UW COVID-SOT Registry

- Comorbidities are common
  - Hypertension: 39 (53%)
  - Diabetes: 34 (47%)
  - Obesity: 23 (32%)
  - CKD: 24 (33%)
  - Coronary artery disease: 15 (21%)
  - CHF: 2 (2.7%)
  - Chronic lung disease: 5 (6.8%)
UW COVID-SOT Registry

- Symptoms at presentation are similar to general population
  - Fever: 34 (47%)
  - Cough: 50 (69%)
  - Dyspnea: 40 (55%)
  - URI Symptoms: 24 (33%)
  - GI Symptoms: 29 (40%)
UW COVID-SOT Registry

- Admitted for COVID-19 related illness: 47 (64%)
  - Inpatient for another indication at diagnosis: 8 (11%)
- ICU: 23 (33%)
- Mechanical ventilation: 20 (27%)
- Vasopressors: 15 (21%)
UW COVID-SOT Registry

- 28-day all-cause mortality (all patients): 15 (21%)
  - Mortality in pts admitted for COVID-19: 12 (26%)
  - Mortality in pts already inpatient for another indication: 2 (25%)
- Still hospitalized as of day 28: 6 (8.2%)
UW COVID-SOT Registry

- Mortality in SOT pts admitted for COVID-19: 12 (26%)
- Inpatient case fatality in the general population?
  - 33% (Buckner, Washington State)
  - 16% (Gold, Georgia)
  - 15% (Imam, Michigan)
  - 21% (Richardson, New York)
  - 23% (Ciceri, Northern Italy)
UW COVID-SOT Registry

- AKI: 24 (33%)
  - Newly required renal replacement therapy: 5 (6.8%)
- Liver injury: 6 (8.2%)
  - Median peak transaminases: ~200
- Thrombosis: 2 (2.7%)  

- AKI in general population with COVID-19: 37%
UW COVID-SOT Registry

• Bacterial pneumonia
  • Microbiologic diagnosis: 4 (5.5%)
    • *Pseudomonas aeruginosa*, MSSA, *Enterobacter*, *Klebsiella*, *H. influenzae*
  • Presumptive: 14 (19%)
• Rhinovirus/enterovirus: 2 (2.7%)
• Invasive fungal infection: 1

• Bacterial PNA among general population with COVID-19: 5-17%
UW COVID-SOT Registry

- Bloodstream infection: 5 (6.8% or 4.1% excluding CoNS)
  - 2 coagulase negative staphylococci (possible contaminant)
  - 1 MRSA
  - 1 polymicrobial with *S. aureus*, *Citrobacter*, *Serratia*
  - 1 polymicrobial with *E. coli* (ESBL), *Pseudomonas* (XDR), VRE

- BSI among general population with COVID-19: 1.6%
UW COVID-SOT Registry

- Positive test
- Negative test

- Day of last positive: 18.5
- Day of first negative: 24
- Maximum duration: 52 days
- General population: ~20 days
Other Registries

- ELITA Registry (100), reported by Belli et al. in *Lancet GI*
  - Admit rate similar to UW COVID-SOT but less ICU and intubation
  - Mortality 16% of all patients at 18 days, 24% of hospitalized patients
  - Older age predictive of mortality
- SECURE & COVID-Hep (39), reported by Webb et al. in *Lancet GI*
  - Mortality 23%
  - No factors predictive of mortality
Unanswered questions

- What are **risk factors** for mortality?
  - Evidence to support age & comorbidities
  - To date no evidence to support transplant-related factors
- What are unique **mediators** of mortality?
  - Complications? Renal failure? Secondary infections?
- What is an optimal management strategy?
# UW COVID-SOT Registry

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Immunosuppression management

- Calcineurin inhibitors
  - Inhibits replication of coronaviruses *in vitro*
  - Associated with delayed recurrence of HCV *in vivo*
  - Rodriguez-Cubillo et al. studied change to cyclosporine as a management strategy in 29 kidney transplant patients with COVID-19
    - 23- change tacrolimus to cyclosporine, no reduction in immunosuppression
    - 6- reduce immunosuppression (typically hold MMF, reduce CNI)
    - Lower mortality in the cyclosporine group
Immunosuppression management

• Steroids
  • RECOVERY press release: Dexamethasone reduces mortality
  • In patients with inflammatory bowel disease and COVID-19:
    • Baseline steroid use associated with increased risk of infection
    • Baseline steroid use associated with increased mortality (aOR 11.6, CI 2.1 – 64.7)
Treatments in SOT patients

• Remdesivir (ACTT-1)
  • No safety data in CKD, ESRD, or baseline transaminases >5xULN
  • Liver toxicity, although not common
• Dexamethasone (RECOVERY, press release)
  • Drug-drug interactions with CNIs
  • Fluid retention, neuropsychiatric side effects
  • Increased hypokalemia in combination with loop diuretics
Treatments in SOT patients

- Tocilizumab (observational data)
  - Safety concerns in patients with hepatic impairment
  - Liver toxicity, infectious complications
- Convalescent plasma (observational data)
  - Theoretical risk of anti-HLA antibodies should be minimized by screening/collection procedures
A way forward?

- SOT patients with COVID-19 are similar to general population patients with regard to known risk factors for infection/mortality, clinical presentation, some complications
- Infectious complications, often with high-concern pathogens, may have more serious implications for SOT patients
- Still unclear what (if anything!) to do about immunosuppression either prior to infection or after diagnosis
- Likely reasonable to extrapolate some treatment data to SOT, but certain toxicities may be more important.
A way forward?

- Continual release of new morbidity and mortality data should motivate continual reassessment of transplantation practices.
Thank you!

Ajit Limaye MD  Cynthia Fisher MD  Erika Lease MD  Robert Rakita MD

Catherine Liu MD  Steve Pergam MD  Gina Campelia PhD  Michael Boeckh MD, PhD

>80 unique contributors to the University of Washington COVID-SOT Case Report Registry

University of Washington Department of Medicine & Department of Surgery Transplant Faculty

University of Washington Institute of Translational Health Science (IThS)

The American Society of Transplantation (AST)

IDCOP, WHCOP, and Outstanding Questions in Transplantation Community Message Board

American Transplant Society (ATS), International Society for Heart and Lung Transplantation (ISHLT), American Association for the Study of Liver Diseases (AASLD)
Panel Discussion Q&A

Please submit any remaining questions to the Q&A Chat at this time!
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COVID-19 Resources Webpage & Clinical Insights
Document: aasld.org/covid19

COVID-19 & the Liver Webinar Page:
aasld.org/COVIDwebinars

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