AASLD COVID-19 Clinical Oversight & Publications Subcommittee Presents

COVID-19 and the Liver: Reentry and Return to a Pre-Pandemic State

May 14, 2020
4-5 pm ET

Presenters:
Patricia Harren, DNP, DCC
David C. Mulligan, MD, FAASLD
Bilal Hameed, MD

Moderator:
Kimberly Ann Brown, MD, FAASLD
Webinar Moderator
Kimberly Ann Brown, MD, FAAASLD
Chief, Division of Gastroenterology & Hepatology

Henry Ford Health System
Webinar Presenter
Patricia Harren, DNP, DCC
Clinical Director of the Center for Liver Disease & Transplantation / Clinical Director for Pediatric Transplantation & Adult Abdominal Organ Transplantation

Columbia University
Webinar Presenter

David C. Mulligan, MD, FAASLD
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Yale University / Yale New Haven Health System
Webinar Presenter
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Associate Professor of Medicine and the Hepatology Clinic Chief
University of California, San Francisco
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AASLD-ALEH COVID-19 & the Liver in the Americas

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COVID-19 and the Liver: Reentry and Return to a Pre-Pandemic State
Webinar Agenda

- Webinar Contributors
  - Presenter Introductions – Dr. Kimberly Brown
  - Housekeeping Items
    - OpenSAFELY Study – Dr. Kimberly Brown
  - Expert Consensus Panel Update – Dr. Oren Fix
    - Outpatient – Dr. Bilal Hameed
    - Inpatient – Dr. Patricia Harren
    - Transplant – Dr. David Mulligan
  - Panel Discussion / Q&A
Clinical Oversight & Publications Subcommittee

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- Co-chair, Elizabeth C. Verna, MD, MS, Columbia University (New York)
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- Norah Terrault, MD, MPH, FAASLD, Keck Medical Center of USC (California)
- Andrew Reynolds, (Patient Advocate)
- Raymond Chung and K. Rajender Reddy (ex-officio)
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 Presenter
Bilal Hameed, MD
Associate Professor of Medicine
and the Hepatology Clinic Chief
University of California,
San Francisco
Webinar Presenter
Patricia Harren, DNP, DCC
Clinical Director of the Center for Liver Disease & Transplantation / Clinical Director for Pediatric Transplantation & Adult Abdominal Organ Transplantation

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- Elizabeth C. Verna, MD, MS, Columbia University (New York)
- Jaime Chu, MD, Icahn School of Medicine at Mount Sinai (New York)
- Karen Hoyt, BA, Patient Advocate
- Guadalupe Garcia-Tsao, MD, FAASLD, Yale University (Connecticut)
- Ryutaro Hirose, MD, University of California, San Francisco (California)
- K. Gautham Reddy, MD, FAASLD, University of Chicago Medical Center (Illinois)
OpenSAFELY: Factors associated with COVID-19-related hospital deaths in the linked electronic health records of 17 million adult NHS patients

- 17,425,445 adults
- Feb 1, 2020 to April 25, 2020
- Primary outcome death in hospital in patients with confirmed COVID-19 (5683 deaths)

https://doi.org/10.1101/2020.05.06.20092999
HR adjusted for all other factors listed other than ethnicity
Largest cohort study to date evaluating a variety of clinical factors for death from COVID-19

Asians and blacks appear to be at increased risk of in-hospital death with only partial attribution to pre-existing clinical risk factors or deprivation

Patients with pre-existing liver disease, transplantation or on immunosuppression appear to have increased risk of in-hospital death when adjusted for age/sex alone or fully adjusted

Strengths
- Largest cohort study to date representing 40% English population
- Inclusion of variables including liver disease, transplant for analysis

Weaknesses
- Deaths related to patients with false-negative tests or died without testing would be missed
- Censoring patients at date of death from other causes or outside the hospital stopped 9 days short of study end
- Cohort limited to those practices using the EHR software SystmOne Some variable were assumed absent if missing
- Characterization of “liver disease” is general and not complete

Further characterization of liver disease and potential risks due to etiology, MELD, etc will be helpful in future studies

https://doi.org/10.1101/2020.05.06.20092999
Expert Panel Consensus Statement

- First published online March 23rd
- New update posted today: www.aasld.org/covid19
- Spanish and Portuguese translations available online
- *Hepatology* manuscript published online
May 14th Update: Major Changes

- Acknowledgement of possible link between COVID-19 and Kawasaki-like pediatric multisystem inflammatory syndrome
- Italian autopsy series describing involvement of hepatic vasculature including acute portal and sinusoidal thrombosis
- Introduction of SARS-CoV-2 antigen testing in addition to increasing availability of antibody testing

Sonzogni et al Preprints 2020
May 14th Update: Major Changes

- OpenSAFELY study from the UK: chronic liver disease is a risk factor for in-hospital death from COVID-19
- Large US study also showed that chronic liver disease and cirrhosis are associated with higher COVID-19 mortality
May 14th Update: Major Changes

- Clarification that treatment of hepatitis B is not contraindicated in patients with or without COVID-19
- Recommendations regarding use of masks for patients and caregivers as well as providers in the clinic or hospital setting
May 14th Update: Major Changes

- Evolving data on hydroxychloroquine suggesting it should no longer be used outside RCTs
- New data on triple therapy with lopinavir-ritonavir, ribavirin and interferon-beta-1b showing more rapid viral clearance compared to lopinavir-ritonavir (phase 2 RCT)
- Reentry

Geleris et al N Eng J Med 2020
Hung et al Lancet 2020
Impact of COVID-19 on Liver Disease: Safe Outpatient Re-Entry Process

Bilal Hameed, MD
Associate Professor of Medicine
Clinic Chief, Hepatology
University of California, San Francisco
Outline

- The COVID-19 effects on liver care
- Recommendations for re-entry and re-opening facilities
- Ambulatory re-entry and recovery challenges and plan at UCSF
- Gradual re-entry of liver patients in the ambulatory setting
The Untold Toll — The Pandemic’s Effects on Patients without COVID-19

The Washington Post

Patients with heart attacks, strokes and even appendicitis vanish from hospitals

The Pandemic’s Effects on Patients without COVID-19

38% reduction in STEMI activations in the US during COVID-19 pandemic

Decrease in routine pediatric vaccination during COVID-19


https://www.cdc.gov/mmwr/volumes/69/wr
Unexpected Consequences of the Pandemic

- To expand capacity for COVID-19 patients, on March 18th CMS recommended limiting non-essential care and procedures
  - 8 week pause in usual care activities
  - Fear of returning to care
  - Change in patient’s perception of risk/benefit
- Areas with low/stable incidence of COVID-19, CMS allowing non-emergent, non-COVID-19 healthcare

COVID-19 Pandemic: Impact on the Cirrhosis Care

Delayed: LDLT, selected DDLT elective procedures, imaging, routine patient follow-up

Increased: Emergent decompensations, transplant waitlist dropout, backlog of deferred visits/tests

Prioritized: high-acuity care

Loss to follow-up: missed diagnoses, incomplete cancer screening, progressive disease

Loss of insurance

COVID-19 Pandemic - First wave

Physical distancing policies

Third wave
## Outpatient Impact of COVID-19 Pandemic: UCSF Experience

Maximizing Appropriate Use of Video Visits during Re-entry

<table>
<thead>
<tr>
<th>Prior State</th>
<th>Current State</th>
<th>Future State</th>
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<tbody>
<tr>
<td>~20% of total visits were video visits</td>
<td>~95% of total visits are video visits</td>
<td>Appropriate mix of telehealth visits ~50%</td>
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<tr>
<td>Continue expanding to:</td>
<td></td>
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<tr>
<td>- Patients that live far away</td>
<td>- Free up clinic space</td>
<td>- Post-ops &amp; post-discharge follow-up</td>
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<tr>
<td>- Chronic disease management (NAFLD/HBV/HCV etc)</td>
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February: 2% of all visits
2nd largest video visit program in the country among AMCs, largest in California

End of March: 60% of visits
End of April: Double March volume
Hepatology Video Visits by Month at UCSF

Able to see the same number of patients even during pandemic
CMS Phase I Recommendations: Re-opening Facilities for Non-emergent Non-COVID-19 Healthcare

- In coordination with State and local public health officials, evaluate the incidence and trends for COVID-19 in the area
- Prioritize surgical/procedural care and high-complexity chronic disease management and select preventive services
- Consider establishing Non-COVID Care (NCC) zones that would screen all patients for symptoms of COVID-19
- Sufficient resources should be available across phases of care, including PPE, healthy workforce, testing capacity etc, and without jeopardizing surge capacity

https://www.whitehouse.gov/openingamerica/#criteria
San Francisco COVID-19 Numbers

1,977 Total Cases
35 Total Deaths

https://data.sfgov.org/stories/s/dak2-gvuj
Ambulatory Re-entry and Recovery – Cascaded Principles

Strategies to limit unnecessary exposure while continuing to provide high-quality care for our liver patients

- Ensure morbidity and mortality do not increase due to liver related illness and provide care in a safe manner
- Continue to prioritize the health and safety of workforce
- Prioritize urgent patients
- Communicate consistently and transparently
- Invest appropriately in services and improvement efforts
Ambulatory Recovery Challenges and Plan
Providing Best Care While Living with COVID-19

- COVID symptoms check protocol
- Social distancing in clinic
- Masking and safety policies
- Waiting rooms changes
- Visitor policies

- Optimization and flexibility of schedules (hours/weekend?)
- Utilization of clinic space
- Sustain telehealth
- Digital technology for symptoms monitoring
- Staff redeployment

- Prioritize urgent patients
- Back log data and referrals
- Pre-clinic communication
- In clinic flow (Echeck in, rooming and check out policies)

- Patient communication is the key
- Staff anxiety and stress reduction
- Focus on vulnerable population
- Physician burn out and health needs
- Trainees re-entry and education

- Staff and Patient Safety
- Clinic Work Flows
- Resource Utilization
- Support and Education
Physical Distancing & Safety Guidelines
Innovation and Improving Operations

Conversa Employee Screening

Mychart Screener

Apex texting for patients in nearby waiting areas
Gradual Re-entry of Liver Patients in the Ambulatory Setting
LIVER TRANSPLANT EVALUATION DURING COVID-19 WORKFLOW

MELD >24 or HCC/Exception? or MELD 20-24 and any of the complications below:
1). Hospitalization within the previous 3 months for any complication – HE, volume overload, SBP, GI bleeding or AKI.
2). Severe fluid retention requiring LVP or thoracentesis.
3). Records or referral indicating a potential living donor.

Patient will be scheduled for **ON-SITE evaluation** (One care-giver allowed)

Day of evaluation:
Patient up for onsite video visits in clinic room.

RN Education via on site video visits
Hepatologist visit via onsite Zoom or in-person
Surgeon visit via onsite Zoom or in-person (surgeon on campus)
Labs and US on site at UCSF
Social work and Nutrition visit via onsite Zoom
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Remainder of evaluation will be onsite when restrictions are lifted.

1. Pre-clinic/arrival COVID screening for patients/caregiver
2. Universal masking
Re-entry of Liver Patients in Clinic: June 2020

- All new liver transplant evaluations and HCC diagnosis
- New decompensation or worsening symptoms
- Listed patients for transplant with decompensated cirrhosis
- Acute hepatitis or liver injury
- Early post transplant
- Patients with difficulty with telehealth
Re-entry of Liver Patients: HCC Surveillance

- HCC surveillance should continue as close to schedule (an arbitrary delay of 2 months were acceptable)
- Working on list of all delayed imaging and prioritizing them by risk categories
  - Known HCC, surveillance for treatment response, elevated AFP
- Key is working with Radiology (Options of imaging locally)
- Communication with patients and documentation is important
- No delay in HCC treatment (risk/benefits discussion)

https://www.aasld.org/sites/default/files/2020-05/AASLD-COVID19-ClinicalInsights-May42020
Liver Biopsies

- Rule out rejection or autoimmune hepatitis diagnosis
- Going over the back log and prioritizing biopsies (June 2020)
- Updating radiology protocols
- No COVID testing for outpatient biopsies (standard PPE)

Re-entry of Liver Patients: Procedures

Liver Biopsies

- Rule out rejection or autoimmune hepatitis diagnosis
- Going over the back log and prioritizing biopsies (June 2020)
- Updating radiology protocols
- No COVID testing for outpatient biopsies (standard PPE)

Fibroscan

- Not urgent but planning to start June-July 2020
- Huge back log
- Using radiology US protocol for PPE (mask/googles and gown)
- Flexible schedules based on safety guidelines

NURSES
MAKE A DIFFERENCE EVERY DAY!
Reentry and Return to a Pre-Pandemic State

Inpatient Setting

Patricia Harren, DNP, DCC
Clinical Director of Transplant Services
Columbia University Medical Center
Institutions are under major financial constraints due to the lack of operative and ambulatory services.

- Increased cost of supplies and overtime staffing
- Increase need for expensive equipment: Beds/ventilators
- Increase in laboratory expenses for testing
Over Capacity Struggles:

- Emergency Department
- ICU (NYP 422 to 970 beds in 19 days)
  - OR suites still needed for ICU patients
  - Entire units still a mix of ICU and Step down patients
  - COVID Free ICU needed
- Dialysis both CVVH and HD staffing and supply issues.
- Beds
  - Still high volume of COVID patients admitted
  - Step down need for trached patients
  - Increased need for rehab beds
  - “Field Hospital” patients need disposition
PPE improving but still shortages

- NYS Governor “suggestion/mandate”:
  Institutions need a stockpile of 90 supply of all PPE equal to the amount used at PEAK:

  Masks: 100,000/day = 9,000,000 in reserve PLUS current needs met.

*This is compounded by increased prices and low availability.
Transplant Cases 2019-2020
OR Schedule Restart:

- OR suites converted back from ICU to OR
- COVID Free ICU and Units
- Rapid COVID testing needed for aerosolized procedures
- Operational Radiology Department
- Operational Interventional Radiology
- Operational Cardiac Catherization Lab
COVID Testing

• Currently COVID negative needed within 48 hours
• Rapid PCR Test (2 hours) prior to procedures regardless of if aerosolized
• Consider Rapid testing for all elective admissions and transfers (hold in ED until testing results)

• Broader testing in the coming weeks to months needed to monitor for outbreaks
Staffing:

- Many redeployed employees from outpatient areas staffing units due to increased acuity still needed.
- Increase number of travel staff
- Units no longer specialized
- Employee PCR & Antibody testing. When and how often?
Visitation Policy

- Current State: No visitors permitted unless on Palliative Care unit for end of life visit.
  - Patients hesitating to come to ED or Admission
  - Struggles with staff contacting families
  - Discharge coordination sometimes difficult
Lessons Learned:

• Start with more restrictions and more protection and reduce as data indicates
  • Limited Visitors
  • More testing of staff
  • More testing not just with symptoms
  • Testing non COVID inpatients periodically especially prior to procedures
• Secure your valuable PPE
• Increase of Telemedicine is valuable and needed
Doctors worry the coronavirus is keeping patients away from US hospitals as ER visits drop: ‘Heart attacks don’t stop’

Published: May 4, 2020

Is it safe to go to the hospital during COVID-19 pandemic? Doctors say yes

By American Heart Association News
How to make patients feel safe to return?

• Project confidence
• People respond to tangibles:
  • Screening at entrances
  • Wearing masks - every one all the time.
  • Doing testing pre admission/pre procedures
  • Observing good hand hygiene
  • Being consistent
Impact of COVID-19 on Liver Transplantation: Creating Safe Plans For Re-Entry

David C. Mulligan, MD, FACS, FAASLD, FAST
Professor and Chair, Transplantation and Immunology
Yale University/Yale New Haven Health System
Impact of COVID-19 on Transplant

2020 Transplants in Tongji Hospital

All the staffs in hospital must be screened for PCR and Abs before returning to work

Courtesy of Lan Zhu, MD, Tongji Hospital of Tongji Medical College
D&T ACTIVITIES IN SPAIN 2020

Donors: 7.2/day
Transplants: 16/day

Transplant and deceased donation activity

Donors: 1.4/day
Transplants: 2.9/day

National Alarm State
De-escalation

...an excellent thermometer of what happens in the hospital

Courtesy of Beatriz Dominguez-Gil, Organizacion Nacional de Trasplantes
Impact of COVID-19 on Organ Donation
Deceased Donors Recovered by Week
Deceased Donor Transplants by Week, Geography, and Organ Type
Living Donor Transplants by Week, Geography, and Organ Type
Variable Liver Transplant Activity

- Not all transplant centers decreased liver transplants.
- Centers in COVID spared geographies and those with resources to minimize exposure to patients continued to transplant.

Changes in liver transplant center practice in response to COVID-19: Unmasking dramatic center-level variability

Vatche Agopian, Elizabeth Verna, David Goldberg

First published: 05 May 2020 | https://doi.org/10.1002/lt.25789
Impact of COVID-19 on Transplant in Ontario, Canada

- Ontario is Canada’s most populous province, with 38.3 percent of the country’s population
- 8 transplant programs: adult, pediatric, heart, lung, liver, pancreas, kidney and small bowel
- COVID Management System: Daily calls supported by OPO (TGLN)
- All programs participated, incl crit care, ID, TGLN leadership
- Mar 15: unanimous decision to limit transplant activity
  - High status: heart, liver, lung
  - cPRA 99/100, medically urgent

Courtesy of Darin Treleaven, MD, MSc, McMaster University
Liver Transplant C-19 Triage

Emergent
- Acute liver Failure
- MELD >35 or CTP score C
- CTP B or MELD >30 with recurrent hospitalisations

Urgent
- CTP score B or C
- Recurrent admissions with liver decompensation
- Pulmonary hypertension/ HPS/HRS (extrahepatic organ failure
- Advanced HCC on Milan criteria
- Underserved by MELD

Semi-urgent
All listed patients with features liver decompensation or HCC

Elective
Some Living Donor Liver Transplants

1. Speeding up is harder than slowing down
2. Implementation requires multi-level (local and provincial) coordination of surgical services
3. Local hospital and dialysis unit outbreaks have moved programs between stages already
4. It has helped immensely to have guiding principles and key considerations from other jurisdictions
5. Monitoring: COVID, WL deaths, WL impact

Courtesy of Darin Treleaven, MD, MSc, McMaster University
Liver Transplant Covid-19 (C-19) Pathway

1. Liver accepted
   - Admit to ER
     - COVID test
       - negative: Admit to South pavilion 3 preop for Liver transplant
       - positive: Blood-bank status
         - CT-ICU/SICU bed status
           - unavailable: HOME
           - available: check

2. Preop
   - Admission for Liver transplant (h&p, consent, labs, ekg, cxr etc.)

3. OR
   - Liver Transplant *(minimized personnel)*

4. SICU
   - Co-manage by SICU and Transplant Sx (Co-primary)

5. Txp Floor
   - Minimized personnel *(to conserve PPE and reduce transmission)*
   - Identify patient needs to plan Convalescence *(rehab, enteral nutrition)*
   - Early discharge plan with appropriate caregiver support

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Additional Considerations

Recipient testing strategies

• Immediately prior to transplant
• Upon discharge?
• Need for direct vs. Telehealth visits postop
• Testing of caregiver(s) and quarantine?

Timing to restart living donation

• Testing of donor with quarantine prior to surgery
• Testing at discharge and quarantine for 2 weeks
Conclusions:

- Re-Entry is complex and difficult
- Effort to determine correct timing depending on:
  - COVID-19 prevalence
  - Hospital staff, space, supplies
  - Blood product supplies
  - Adequate pre- and post- testing
- Ability to be flexible on rebound to minimize COVID exposure
Panel Discussion

Please submit your questions to the Q&A Chat now.
AASLD’s COVID-19 Resources

Follow/Share: COVID-19 Resources
Webpage: www.aasld.org/covid19

Join/Engage: COVID-19 Care Community on AASLD’s online community, Engage. Open to all members. Log in to Engage with your AASLD user name and password: engage.aasld.org/covid19

Submit: Hepatology, Liver Transplantation, Hep Commun all accepting and fast tracking review of COVID-19 original articles, case reports