ACG Virtual Grand Rounds

Join us for upcoming Virtual Grand Rounds!

Week 5: Refractory GERD: New Options for Treatment 2020
Philip O. Katz, MD, MACG
April 23, 2020 at Noon EDT

Week 6: Celiac Disease: 10 Things Every Clinician Should Know
Amy S. Oxentenko, MD, FACC
April 30, 2020 at Noon EDT

Visit gi.org/ACGVGR to Register

Participating in the Webinar

All attendees will be muted and will remain in Listen Only Mode.

Listen using your computer audio. A headset is recommended but not required.

Type your questions here so that the moderator can see them. Not all questions will be answered but we will get to as many as possible.
How to Receive CME and ABIM MOC Points

LIVE VIRTUAL GRAND ROUNDS WEBINAR

ACG will send a link to a CME & ABIM 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.

MOC QUESTION

If you plan to claim ABIM 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.
Disclosures:

Moderators:
Mark B. Pochapin, MD, FACP
David A. Greenwald, MD, FACP

Speakers:
Brian P. Bosworth, MD, FACP
Vivek Murthy, MD, FCCP
Katherine Hochman, MD, FHM
Ritu Agarwal, MD
Ira M. Jacobson, MD, FACP
Mark B. Pochapin, MD, FACP
David A. Greenwald, MD, FACP

According to ACCME guidance, because there are no current preventive or specific treatments for coronavirus infection, there are no relevant conflicts of interest for any speakers or moderators.
Our Panel of Experts

Brian P. Bosworth, MD, FACG
NYU Langone Medical Center
Gastroenterologist
Hospital Systems Gearing up for a Surge

Vivek Murthy, MD, FCCP
Montefiore Medical Center
Pulmonologist
Pulmonary Manifestations of COVID-19 and Treatment Considerations

Katherine Hochman, MD, FHM
NYU Langone Health
Internist / Hospitalist
Being and Internist and a Hospitalist for Patients with COVID-19

Ritu Agarwal, MD
Mount Sinai
Hepatologist
Liver Manifestations of COVID-19 for the Gastroenterologist

Ira M. Jacobson MD, FACG
NYU Langone Medical Center
Hepatologist
Clinical Trials for Managing COVID-19—In Use Now!

The Artist: Josef Lee
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The Tsunami Has Arrived

It Could Have Been Much Worse

Projected Needs for Hospital and ICU Beds in New York State - March 2020

https://profiles.health.ny.gov/hospital/bed_type/Total+Beds
New York City COVID-19
Gearing Up for the Surge

Brian P. Bosworth, MD, FACG
ACG Governor, Manhattan
Chief of Medicine, NYU Langone Health Tisch Hospital
Professor of Medicine, NYU Grossman School of Medicine
Brian.Bosworth@nyulangone.org

Timeline of the current international outbreak

Mid-January, 2020: First case outside China (Thailand); family clusters reported. Airport screenings in U.S.

Late January, 2020: First cases in S. Korea, US. Reports of HCW infections in China. WHO decides against emergency declaration. Multiple cases in US, France, Canada.


January 31, 2020: CDC quarantines flight from China, declares public health emergency.


Early February, 2020: China with >20,000 cases.


Mid-February, 2020: Retrospective case finding -> total cases >60,000 in China. Cruise ship quarantines in place.

Late February, 2020: Marked increase in infections in S. Korea, Iran, Italy. Estimated case-fatality rate 2-3%. Additional countries affected. Shortage of testing capacity in US. Social distancing encouraged.
Timeline of the current outbreak


March 10, 2020: >10,000 in Italy. New Rochelle, NY “containment zone”.


March 14, 2020: France closes most businesses. Travel restrictions in Germany, Spain. South Africa declares national state of disaster.


American College of Gastroenterology
COVID-19 in NYC

US data: 629,264
New York State: 213,779
NYU Langone: Pre-COVID Stacking Plan

NYU Langone: 3/6/20 Open First COVID Floor
Guideline-Directed Management of Pulmonary Complications of COVID-19

Vivek Murthy, MD, FCCP
Assistant Professor of Medicine
Associate Director of Interventional Pulmonology and Bronchoscopy
Montefiore Medical Center, Albert Einstein College of Medicine
Respiratory Pathogenesis of SARS-CoV2 Infection

- The respiratory tract is a primary target of coronaviruses with type II pneumocytes as a focus
- ACE2 receptor, highly expressed on type II pneumocytes, site of viral entry
- Close proximity to rich capillary bed may enable rapid transmission
- Normal functions of type II pneumocytes are generation of surfactant and alveolar repair

Pathologic findings reported with SARS-CoV2 and MERS
- Diffuse alveolar damage
- Denuded bronchiolar epithelium
- Extensive hyaline membrane formation
- Type 2 pneumocyte hyperplasia
- Edematous alveolar septa with lymphocytic infiltrate
- ARDS
Respiratory Pathogenesis of SARS-CoV2 Infection

- Risk factors for hypoxic respiratory failure (19%)
  - Age >60 years
  - Male gender
  - +DM, malignancy, immunocompromised status
- Progression may be rapid, within 12-24 hours of onset
- Median time to developing ARDS 8-12 days
- Median time to mechanical ventilation 10.5-14.5 days
- Median time to VAP after intubation was 8 days

Huang, et al. Lancet. 2020

Progression of Respiratory Failure in SARS-CoV2

Support of Oxygenation/Ventilation in the Setting of SARS-CoV2 Infection

Recommendations:
23. In adults with COVID-19, we suggest starting supplemental oxygen if the peripheral oxygen saturation (SpO2) is < 92% (weak recommendation, low quality evidence), and recommend starting supplemental oxygen if SpO2 is < 90% (strong recommendation, moderate quality evidence).
24. In adults with COVID-19 and acute hypoxic respiratory failure on oxygen, we recommend that SpO2 be maintained no higher than 96% (strong recommendation, moderate quality evidence).

- Titrate SpO2 to a range between 92-96%
  - Chu et al in a 2018 meta-analysis of 25 RCTs in 16,000 critically ill pts requiring supplemental O2, higher target SpO2 >96% associated with increased mortality without improvement in other outcomes
  - In the LOCO2 trial ARDS pts randomized to conservative (88-92%) vs liberal (≥96%) O2 arms—stopped early due to deaths in the conservative arm

Alhazzani, Møller, Arabi, Loeb, Gong, et al. CCM. 2020
Barrot, et al. NEJM. 2020
Support of Oxygenation/Ventilation in the Setting of SARS-CoV2 Infection


The Role of High Flow Nasal Cannula

Recommendation:
25. For adults with COVID-19 and acute hypoxemic respiratory failure despite conventional oxygen therapy, we suggest using HFNC over conventional oxygen therapy (weak recommendation, low quality evidence).

- HFNC: May reduce # of intubations, probably doesn’t reduce mortality or hospital LOS, probably doesn’t increase risk of transmitting SARS-CoV2 significantly.
  - Rochwerg et al in a meta-analysis of 9 RCTs (2093 pts) found in patients randomized to HFNC vs NC:
    - RR for intubation was 0.85 (95% CI 0.74-0.99)
    - RR for mortality was 0.94 (95% CI 0.67-1.31)
  - In an analysis of HCW transmission in the 2003 Toronto SARS-CoV outbreak, HFNC was not noted to be associated with increased risk of transmission, however NIPPV and other activities were

Alhazzani, Möller, Arabi, Loeb, Gong, et al. CCM. 2020
Rochwerg et al, ICM. 2019
The Role of Non-Invasive Positive Pressure Ventilation ("CPAP" or "BiPap")

- NIPPV: Avoid BiPap as much as possible unless the patient’s underlying comorbidities (e.g., COPD) strongly favor its use
  - Extrapolating from data on 302 critically-ill MERS pts, 92% of patients initiated on NIPPV ultimately required endotracheal intubation with no difference in mortality or ICU LOS
  - In a meta-analysis of 1084 patients in 8 RCTs looking at HFNC vs NC or NIPPV prior to consideration of mechanical ventilation, both were inferior to HFNC
    - OR for requiring intubation 0.48 for HFNC vs NIPPV (CI 0.31-0.73, p=0.0006)
    - OR for ICU mortality 0.36 for HFNC vs NIPPV (CI 0.2-0.63, p=0.0004)

Alhazzani, Møller, Arabi, Loeb, Gong, et al. CCM. 2020
Alraddadi, et al. Jinf Oth Resp Vir. 2019

The Role of Non-Invasive Positive Pressure Ventilation ("CPAP" or "BiPap")

- Significant concern regarding risk of aerosolization of SARS-CoV2 with NIPPV compared to other modalities
- Odds ratio for “super-spreading” nosocomial infection events in the 2003 SARS-CoV outbreak (case-control study of 86 SARS wards at 21 hospitals in China):
  - NIPPV, OR 11.8 (95% CI 1.92-70.8, p=0.007)
  - Minimum distance between beds <1 meter, OR 6.98 (95% CI 1.68-28.75, p=0.008)
  - Performing CPR, OR 3.81 (95% CI 1.04-13.87, p=0.04)

Management Schematic for Respiratory Failure in COVID-19 Infection

Management Schematic for Respiratory Failure in COVID-19 Infection
Modalities of Oxygen Therapy

- **Nasal cannula:** 24-44% FiO₂
  - Each “liter” is ~4% above 20% (1L is 24%, 2L 28%, 3L 32%, 4L 36%, 5L 40%)
  - Use cautiously in patients with hypercapnia as it can mask/worsen hypoventilation
  - Wean aggressively as long as SpO₂ >92%
- **Venturi mask:** 35-50% FiO₂
- **Non-rebreather:** 100% FiO₂
- **High flow nasal cannula:** 30-100% FiO₂
- **Continuous positive airway pressure (CPAP)**
- **Bi-level positive airway pressure (BiPap)**
- **Mechanical ventilation**
Modalities of Oxygen Therapy

- Nasal cannula: 24-44% FiO2
- Venturi mask: 35-50% FiO2
- Non-rebreather: 100% FiO2
  - Mask of last resort; many patients with SARS-CoV2 tolerate this and can be weaned prior to requiring intubation, but usually use of a non-rebreather on a ward patient is a sign they are failing
  - Set the wall flow rate to >12LPM; if the reservoir is empty, can’t guarantee FiO2 is 100%
- High flow nasal cannula: 30-100% FiO2
- Continuous positive airway pressure (CPAP)
- Bi-level positive airway pressure (BiPap)
- Mechanical ventilation

High flow nasal cannula: 30-100% FiO2
- You set a flow rate (20-60LPM) and an FiO2 (30-100%)
- Delivers warmed, humidified air (try to avoid humidification w/SARS-CoV2, but HFNC is caustic without)
- Provides a small but helpful amount of PEEP
- Supports ventilation to a very limited degree (↓ CO2 in the anatomic dead space)
- Continuous positive airway pressure (CPAP)
- Bi-level positive airway pressure (BiPap)
- Mechanical ventilation
Modalities of Oxygen Therapy

- Nasal cannula: 24-44% FiO₂
- Venturi mask: 35-50% FiO₂
- Non-rebreather: 100% FiO₂
- High flow nasal cannula: 30-100% FiO₂
- **Continuous positive airway pressure (CPAP)**
  - You set a single continuous pressure, FiO₂
  - Ideal for patients with OSA (pneumatic stenting of the upper airway) without severe baseline hypercapnia or
  - Patients with cardiogenic pulmonary edema (preload and afterload reduction, Δ hydrostatic pressure)
- Bi-level positive airway pressure (BiPap)
- Mechanical ventilation

**Bi-level positive airway pressure (BiPap or “S/T Mode”)**

- You set a PEEP, an inspiratory pressure (not additive), rate, FiO₂, and can be given by nasal or full face masks
- Ideal for hypercapnic respiratory failure (acute or chronic)
- For acute indications requires close titration by blood gas (if not very hypoxic, VBG is fine)
- The difference between iPAP and ePAP is the gradient for ventilatory support; a bigger gradient means more
  - iPAP should range 5-30, ePAP 5-15; 10/5 and 30% is a good place to start
- Be cautious using CPAP or BiPap in a patients with very impaired mental status as the risk of aspiration is high
- Mechanical ventilation
Medical Therapies for COVID-19 Infection

There are no definite effective therapies for SARS-CoV2 infection, but several classes of medication are being investigated:

- **Antiviral agents** (remdesivir, lopinavir+ritonavir)
- **Hydroxychloroquine/chloroquine**
- **Immunomodulators**
  - Anti-IL-6 (sarilumab, tocilizumab)
  - Anti-IL-1 (anakinra)
- **Corticosteroids**
- **Anticoagulation**
- **Antibiotics** (secondary bacterial infection)
- **Convalescent plasma**

Basic Approach to the Hypoxic SARS-CoV2 Patient

- On arrival, check a chest x-ray, EKG, ABG; **avoid CT Chest** if possible unless another dx is suspected
- Consider secondary bacterial pneumonia if worsening and start empiric antibiotics
- Maintain on minimum supplemental O2 to maintain SpO2 92-96%
- Escalate to HFNC if possible before using a non-rebreather (reasonable to touch base with Pulm/CC at this point); avoid CPAP/BiPAP unless there is a very specific indication
- If underlying COPD/Asthma, use metered dose inhalers rather than nebulizer therapy
- If in distress on oxygen therapy (lethargic/tachypneic), check an ABG and consider PE
- If on mechanical ventilation, consider daily ABG to aid in titration, though if tidal volume/rate are stable and the patient is overall improving, could also just wean FiO2/PEEP by SpO2
To access a PDF of the SCCM Guidelines Statement for managing COVID-19, please use the QR code above.

A HOSPITALIST’S APPROACH TO A COVID-19 PATIENT

Katherine Hochman, MD
April 17, 2020
The Roadmap

• Getting Started
• The NYC Experience
• Who gets hospitalized? Who gets intubated?
• Follow ACE2
• Clinical Findings
  • Renal
  • Cardiac
  • Hematologic
  • Neurologic
• Summary Recommendations

Getting Started

• Practice donning and doffing your PPE
• Get FIT tested (shave your beard!)
• Know how to mine your EMR
• Eat a big breakfast
• Your phone is contaminated! Use a plastic bag.
• Put N95 on tight but not too tight (avoid a HAPI)
• Get to know your team, especially the respiratory therapists (as proning in now standard), physical therapists
• Practice self-kindness ... it's going to be tough
A Snapshot of the NYC Experience

4,109 COVID (+) patients ➔ 2,110/4,109 (51.3%) – not hospitalized

1,999/4,109 (48.7%) hospitalized ➔
- 932/1,999 (46.6%) – discharged
- 417/1,999 (20.8%) – still hospitalized

650/1,999 (32.5%) critically ill (ICU/ventilation/death/hospice) ➔
- 116/650 (17.8%) - died/hospice without ICU or mechanical ventilation

455/650 (70%) received mechanical ventilation ➔
- 162/445 (36.4%) died/hospice
- 245/445 (55.1%) still ventilated
- 16/445 (3.6%) discharged
- 22/445 (4.9%) extubated, still hospitalized

Christopher Petrelli et al “Factors Associated with Hospitalization and Critical Illness Among 4,103 patients with COVID-19 in NYC” – pre print
Who gets hospitalized? Who gets intubated?

STRONGEST HOSPITALIZATION RISKS:
- Age
  - >75 years (OR = 66.8)
  - 65-74 years (OR = 10.9)
- Obesity
  - BMI > 40 (OR = 6.2)

STRONGEST CRITICAL ILLNESS RISKS:
- Admission O2 sat < 88% (OR = 6.9)
- First d-Dimer > 2500 (OR = 6.9)
- First Ferritin > 2500 (OR = 6.9)
- First CRP > 200 (OR = 5.78)

Decision Tree Analysis for Hospitalization:
- Age > 65 years
- Obesity

Decision Tree Analysis for Critical Illness:
- Admission O2 sat < 88%
- Procalcitonin > 0.5
- Troponin < 0.1 (protective)
- Age > 65 years
- CRP > 200

Christopher Petrilli et al. “Factors Associated with Hospitalization and Critical Illness Among 4,103 patients with COVID-19 in NYC” – pre print
Follow ACE2

- SARS-CoV2 gains entry via ACE2
- ACE2 present in:
  - Lung
  - Kidneys
  - Heart
  - Vascular epithelium
  - Brain
  - Gut/ liver


COVID-19 COURSE OF INFECTION

Course of COVID-19 Infection

https://www.ccjm.org/content/covid-19-curbside-consults
COVID and the Kidneys

NORMAL

Angiotensinogen

Renin

Angiotensin I

ACE

Angiotensin II

ACE2

Aldosterone

COVID

Angiotensinogen

Renin

Angiotensin I

ACE

Angiotensin II

ACE2

Aldosterone

(K+ wasting)

PREVALENCE

• AKI: 15-27% (independent RF in mortality)
• PROTEINURIA: 44%
• HEMATURIA: 27%
• HYPOKALEMIA: 62%

CLINICAL PEARLS

• AGGRESSIVE POTASSIUM REPLETION
  (up to 3 grams/day for severe hypokalemia)
• END of URINARY K+ LOSS PORTENDS GOOD PROGNOSIS
• ACC/ AHA RECOMMEND CONTINUATION of ACEi and ARB therapy
• CRRT is a supportive measure


Dong Chen Jr., et al Hypokalemia and Clinical Implications in Patients with Coronavirus Disease 2019 (medRxiv 2020.02.27.20028530; doi: https://doi.org/10.1101/2020.02.27.20028530)
COVID and the Heart

PREVALENCE
- 7-28% troponinemia
- 22% of ICU patients showed cardiac injury
- Mortality = 51% cardiac injury vs 4.5% without cardiac injury

CLINICAL PEARLS
- 2 patterns of cardiac injury:
  - Non-cardiac symptoms: troponin tracks with inflammatory markers in cytokine storm
  - Cardiac symptoms (palpitations/chest pain): viral myocarditis/arrhythmias, ST elevations, low EF
- EKG on admission (useful for QTC interval)
- Mild troponin elevation – no cardiac imaging
- Standard heart failure, arrhythmia therapy
- No change in ACEi/ARB management

COVID and the Blood

PRESENTATION
- WBC 4.7
- ALC < 1.5 (83% of patients lymphopenic)
- ALC < 700 patients in ICU
- NLR (neutrophil-lymphocyte ratio)
  - >3.13 = 50% severe
  - <3.13 = 9% severe disease

CLINICAL PEARLS
- Patients are very hypercoaguable and should be anticoagulated
- Not classic DIC picture (high d-dimers and fibrinogen but mild thrombocytopenia).
COVID and the Blood

Anticoagulation in the setting of COVID-19 – an interim guidance April 2020

Step 1: Confirm if there is an underlying reason to be on therapeutic anticoagulation

- These include but are not limited to: VTE (DVT/PE), AFib, mechanical valve, LA/LV thrombus, thrombophilia, other
- If on home anticoagulant – continue while admitted for COVID unless contraindication (i.e. bleeding/procedure)

*Note may consider switching anticoagulant to enoxaparin while admitted, if feasible, following NYUH guidelines on transition

Step 2: If no prior known indication for anticoagulant, review D-dimer and rate of rise (Δ > x baseline) by monitoring D-dimer every 48 hrs (acknowledge limitations of one value at predicting incidence of VTE)

<table>
<thead>
<tr>
<th>D-dimer &lt;500</th>
<th>Prophylactic Anticoagulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enoxaparin subq preferred</td>
<td></td>
</tr>
<tr>
<td>Dose w/CrCl ≥ 30 mL/min</td>
<td></td>
</tr>
<tr>
<td>&lt;150 kg: 30 mg daily or 30 mg q12h</td>
<td></td>
</tr>
<tr>
<td>150 kg-40 kg: 40 mg q12h</td>
<td></td>
</tr>
<tr>
<td>BMI &gt; 50: 60 mg q12h</td>
<td></td>
</tr>
<tr>
<td>D-dimer &lt;500</td>
<td></td>
</tr>
</tbody>
</table>

| D-dimer 500-2000 |
| Equipoise |
| Consider RCT: PROTECT-COVID-19 Prophylaxis vs. therapeutic AC Refer to Study Protocol |
| Prophylactic AC as reflected in D-dimer <500 box |
| vs. Therapeutic AC |
| Enoxaparin 1 mg/kg q12h |
| IV Heparin at 10 u/kg/hr titrate to antiXa 0.3-0.5 U/mL |

If not in trial, use Prophylactic Anticoagulation as reflected in D-dimer <500 box |
Therapeutic AC may be considered if HIGH suspicion for DVT/PE

| D-dimer >1,000 & <1,000 |
| Consider Therapeutic AC |
| Enoxaparin subq preferred |
| Dose w/CrCl ≥ 30 mL/min |
| <150 kg: 1 mg/kg q12h |
| BMI > 40: 0.75 mg/kg q12h – consider anticoagulation |
| D-dimer >1,000 |
| D-dimer >10,000 |
| Therapeutic AC Preferred |
| Enoxaparin subq preferred |
| Dose w/CrCl ≥ 30 mL/min |
| <150 kg: 1 mg/kg q12h |
| BMI > 40: 0.75 mg/kg q12h – consider anticoagulation |

If enoxaparin contraindicated:
| IV Heparin at 10 units/kg/hr titrate to antiXa 0.3-0.5 U/mL – avoid bolus dose |
| Alternatively |
| Consider RCT: PROTECT-COVID-19 Prophylaxis vs. therapeutic AC |

COVID and the Nervous System

PREVALENCE

- 36.4% neurological symptoms
  - CNS (dizziness - 17%, headache – 13%, AMS – 7%, stroke – 6%)
  - PNS (taste impairment - 6%, smell impairment – 5%)
  - Skeletal muscle injury/ muscle pain and CPK >200 – 10%
  - Severe COVID patients are more likely to have neurologic symptoms (45.5% vs. 32.5%)

CLINICAL PEARLS

- Covid patients with neurologic symptoms often lack typical cough and fever
- Many patients come in with syncope as a presenting symptom
  ?autonomic instability

SUMMARY RECOMMENDATIONS

• THE CARE OF THE COVID PATIENT IS LARGELY SUPPORTIVE

• SILENT HYPOXIA IS REAL (patients don’t realize that they are hypoxic)

• PATIENTS CAN DECLINE VERY RAPIDLY WITH NO WARNING

• Get a health care proxy signed on admission/involve palliative care early

• Prone whenever possible

• Don’t forget about patient’s diet order (or your diet!)

• Patients are terrified and lonely

• Make sure to speak with families

Evaluation of Abnormal Liver Enzymes in COVID-19 Patients

Ritu Agarwal, MD
Assistant Professor of Medicine
Director, Liver Fellows’ Practice
Division of Liver Diseases
Icahn School of Medicine at Mount Sinai
Background

• ACE-2 is a molecular target for SARS-COV-2
• ACE-2 receptors occur on liver and biliary epithelial cells
• Elevated liver enzymes are fairly common in hospitalized COVID-19 patients: 14-53%
• Liver injury in mild COVID-19 patients is typically transient and resolves with supportive care
• Seldom have liver failure
• Liver injury is more common in severe than in mild COVID-19 patients

Explanation of Liver Injury

Remains Unclear

• Indication of underlying pre-existing liver disease
• Direct Virus Induced Effect
• Immune Inflammatory Response to the Virus
• Could DILI be present as well
Evaluation of Elevated Liver Enzymes in COVID-19

Mostly Hepatocellular Injury
- mild-moderate elevated AST, ALT, elevated LDH, ferritin
- mildly elevated or normal bilirubin
- elevated AST>ALT common sources outside liver (e.g. myositis)
- Low serum albumin is a marker of COVID severity

Might be reflective of:
• Drug Induced Liver Injury
• Cytokine Release
• Ischemia and Congestion
• Myositis

AASLD Clinical Insights for Hepatology and Liver Transplant Providers. April 7, 2020

Liver Pathology

• Limited Reports
• Nonspecific
• Microvesicular steatosis
• Mixed mild lobular and portal activity

Evaluation of Elevated Liver Enzymes in COVID-19

History
- Alcohol- How many drinks per day and last drink? History of withdrawal?
- Medications
  - Home medications
  - Specific to COVID:
    - Acetaminophen use at home (Dose and Duration)
    - Herbal medications at home
    - Antibiotics (Azithromycin, Augmentin, Cephalosphorins)
    - Vitamins

Speak to family and household members

Workup Recommendation

Follow Daily:
Hepatic Function Panel including Total and Direct Bilirubin INR

Limit Ultrasound and MRI:
Unless high suspicion of biliary obstruction OR thrombus

COVID-19 patient with elevated liver enzymes

AST and ALT < xSULN (200 IU/L)
Viral Hepatitis Screening:
HAV IgM
Hep B sAG
Hep B core IgM
Hep B core IgG
Hep B surface Ab
Hep C Ab

AST and ALT > xSULN (200 IU/L)
Viral Hepatitis Screening:
HAV IgM
Hep B sAG
Hep B core IgM
Hep B core IgG
Hep B surface Ab
Hep C Ab
AND
Phosphatidylethanol (Peth)
Acetaminophen
CK, BNP
INR, Fibrinogen
Quantitative IgG
Treatment-Drug Induced Liver Injury

<table>
<thead>
<tr>
<th>Medication</th>
<th>Function</th>
<th>Liver Injury</th>
<th>Trials Exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydroxychloroquine</td>
<td>Aminoquinoline Anti-malarial</td>
<td>Low Likelihood in Chronic Use in Rheumatologic Diseases (Likelihood Score C: Probable Rare cause of acute hepatotoxicity)</td>
<td></td>
</tr>
<tr>
<td>Azithromycin</td>
<td>Macrolide Antibiotic</td>
<td>Hepatocellular and/or Cholestatic (Likelihood A-well known cause of liver injury)</td>
<td></td>
</tr>
<tr>
<td>Cephalosporins</td>
<td>Bactericidal Antibiotic</td>
<td>Cholestatic Hepatitis 1-3 weeks after starting treatment</td>
<td></td>
</tr>
<tr>
<td>Remdesivir</td>
<td>Nucleotide analogue</td>
<td>Hepatocellular</td>
<td>Exclusion if Baseline ALT, AST &gt;5x ULN</td>
</tr>
<tr>
<td>Tocilizumab</td>
<td>IL-6 inhibitor</td>
<td>Mild hepatocellular. Rare severe injury with jaundice. Consider risk for HBV reactivation.</td>
<td>Exclusion if Baseline ALT, AST &gt;5x ULN</td>
</tr>
<tr>
<td>Sarilumab</td>
<td>IL-6 inhibitor</td>
<td>Mild hepatocellular</td>
<td>Exclusion if Baseline ALT, AST &gt;5x ULN</td>
</tr>
<tr>
<td>Statins</td>
<td>HMG-CoA reductase inhibitor</td>
<td>Mild-Moderate hepatocellular. Occasional cases of autoimmune features</td>
<td></td>
</tr>
</tbody>
</table>

Livertox [https://www.ncbi.nlm.nih.gov/books/NBK547852/]

COVID-19 in Patients with Chronic Liver Disease

- No evidence that patients with stable chronic HBV, HCV, PBC, PSC, NAFLD have increased susceptibility to SARS-CoV-2
- NAFLD/NASH patients have comorbidities (DM, HTN, Obesity) increased risk of severe COVID-19
- Continue treatment for hepatitis B or C
- Continue surveillance for HCC (cirrhosis and HBV) as close to intervals as possible.
  - Arbitrary 2 month delay reasonable. Review reason for delay with patient.
- Emphasize immunization for Streptococcus pneumoniae and Influenza

AASLD Clinical Insights for Hepatology and Liver Transplant Providers. April 7, 2020
HCV-Medication Interactions

COVID-19 Immunosuppression

• Effects of immunosuppression remain unclear
• Immunosuppression possibly protective from the reactive immune response
• Age and metabolic comorbidities (Obesity, HTN, DM) in post transplant patients might be associated with increased risk of severe COVID-19 disease

Patients with Chronic Liver Disease and COVID-19

Imunosuppression

- In immunosuppressed patients without COVID-19
  - Do not make anticipatory adjustments to immunosuppression

- In immunosuppressed liver patients with COVID-19
  - Consider minimizing high dose prednisone
  - Consider reducing azathioprine or mycophenolate or calcineurin inhibitor doses
  - Individual decision based on severity of COVID-19, graft history, timing post transplant
  - Consult transplant hepatology colleagues

- Initiate immunosuppression in patients with or without COVID-19 who have strong indications for treatment (autoimmune hepatitis, graft rejection)

- In patients with COVID-19 use prednisone or immunosuppression cautiously when benefit might be outweighed by risks (alcohol hepatitis)

AASLD Clinical Insights for Hepatology and Liver Transplant Providers. April 7, 2020

Imunosuppressant- COVID-19 Therapies

Please check www.covid19-druginteractions.org for updates.

Please note that if a drug is not listed it cannot automatically be assumed it is safe to co-administer. No recommendation to use experimental therapy for COVID-19 is made.

Drug interaction data for many agents are limited or absent; therefore, risk/benefit assessment for any individual patient rests with prescribers.

<table>
<thead>
<tr>
<th>Immunosuppressants</th>
<th>ATV</th>
<th>LPV/r</th>
<th>RDV</th>
<th>FAZI</th>
<th>CLQ</th>
<th>HCQ</th>
<th>RBV</th>
<th>TCZ</th>
<th>IFN-β</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adalimumab</td>
<td>✶✶</td>
<td>✶✶</td>
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<td>✶✶</td>
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<tr>
<td>Anti-thymocyte globulin</td>
<td>✶✶</td>
<td>✶✶</td>
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<tr>
<td>Azathioprine</td>
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<td>✶✶</td>
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<tr>
<td>Basiliximab</td>
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<tr>
<td>Belatacept</td>
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<tr>
<td>Ciclosporine</td>
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<tr>
<td>Mycophenolate</td>
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<tr>
<td>Pirfenidone</td>
<td>✶✶</td>
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<tr>
<td>Sirolimus</td>
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<tr>
<td>Tocilizumab</td>
<td>✶✶</td>
<td>✶✶</td>
<td>✶✶</td>
<td>✶✶</td>
<td>✶✶</td>
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<td>✶✶</td>
<td>✶✶</td>
<td>✶✶</td>
</tr>
</tbody>
</table>

Text Legend:
- ✶: Potential increased exposure of the comependium
- ✶✶: Potential decreased exposure of the comependium
- ✶✶✶: Potential increased exposure of COVID drug
- ✶✶✶✶: Potential decreased exposure of COVID drug
- ✶✶✶✶✶: No significant effect

Numbers refer to increase or decrease in AUC as observed in drug-drug interaction studies.

∗ These drugs have been identified by www.crediblemeds.org as having a known or possible QT or TdP risk. The risk may be concentration- or dose-related and/or additive if two or more such drugs are combined. Note, please check product labels for any additional cardiac warnings.
Management Conclusion

• Limit acetaminophen < 2 grams daily
• Careful history from patient and family for alcohol and home medications
• COVID-19 liver injury is typically hepatocellular, transient and mild
• Mechanism of injury unclear
• Consider Drug Induced Liver Injury and extra hepatic sources of injury
• Continue immunosuppression when appropriate but consider dose reduction in patients with severe COVID-19

Investigational Agents for COVID-19

Ira M. Jacobson, MD, FACG
Professor of Medicine
Director of Hepatology

NYU Langone Health
SARS-Cov2

The Virus and its Receptor

https://www.google.com/search?q=remdesivir+suppression+of+SARS+virus+in+vitro&tbm=isch&ved=2ahUKEwi7l6_1m8roAhVnFt8KHUATcDgQ2-cCegQIABAA&oq=remdesivir+suppression+of+SARS+virus+in+vitro&gs_lcp=CgNpbWcQAzoECAAQQzoCCAA6BAgAEBhQ_MADWO-cCegQIACAAQGQIABAA&client=img&ei=ShqGXrvKIOes_AbApqRY&bih=954&biw=1904&hl=en#imgrc=X6Yy8aiSHtnaHM
SARS-CoV-2 Life Cycle

Hijack
How SARS-CoV-2 replicates itself in the cells of those infected

1. Spike protein on the virion binds to ACE2, a cell-surface protein.TMPRSS2, an enzyme, helps the virion enter 2. The virion releases its RNA 3. Some RNA is translated into proteins by the cell's machinery 4. Some of these proteins form a replication complex to make more RNA. 5. Proteins and RNA are assembled into a new virion in the Golgi and 6. released.

Sources: Song et al., Viruses, 2019; Jang et al., Emerging Microbes and Infections, 2012; The Economist

Potential Therapeutic Targets in COVID-19


Miura DP et al, Rheumatology 2020, April 10
Remdesivir: A Nucleotide Prodrug
Adenosine Analog

Single phosphate group

ATP
Triphosphate

Cleavate and addition of 2 phosphate groups

RDV-TP
Triphosphate

https://www.asbmb.org/asbmb-today/science/022720/study-sheds-light-on-how-a-drug-being-tested-in

Background on Remdesivir

• Inhibits RNA-dependent RNA polymerase activity among a diverse group of RNA viruses including filoviruses (e.g. Ebola, Sudan, Marburg), paramyxoviruses (e.g. RSV, Nipah, Hendra) and pathogenic coronaviruses

• Nonhuman primates: therapeutic efficacy of remdesivir against Ebola virus but survival inferior to monoclonal antibodies in PALM study (NEJM 2019)

• Activity against SARS-CoV and/or MERS-CoV in mouse infection models, non-human primates, and human airway epithelial cell assays

• Cell culture studies show potent SARS-CoV-2 suppression at micromolar level

Adapted from NIAID Protocol March 1, 2020
Antiviral activities of Test Drugs Against 2019-nCoV in Vitro

Chloroquine looks good, too

Micromolar potency for remdesivir

Wang M et al, Cell Research 2020

Compassionate Use of Remdesivir for COVID-19

- 61 patients, 53 with analyzable data
- 30/53 (57%) on mechanical ventilation
- 4/53 (8%) receiving ECMO
- Median follow-up 18 days
  - 36/53 (68%) had improvement in oxygen-support class
  - 17/30 (57%) receiving mechanical ventilation were extubated
  - 25/53 (47%) were discharged
  - 7/53 (13%) deaths
    - 6/34 (18%) receiving invasive ventilation died vs 1/19 (5%)

Grein J et al, N Engl J Med 2020; published April 10 at NEJM.org
Cumulative incidence of clinical improvement:

- Overall
- Baseline oxygen support
- Age

Authors pointed out:

- 28 day mortality 22% in lopinavir/ritonavir trial: only 1/199 were on ventilation
- 66% mortality in 44/67 on mechanical ventilation in Wuhan, China
- Need randomized trials acknowledged: large studies in progress

Grein J et al, N Engl J Med 2020; published April 10 at NEJM.org

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An “Early Peek” at Remdesivir Data From a Compassionate Use (Uncontrolled) Study From a US University Center

- 113 “severe” patients given remdesivir
  - “Most discharged”
  - “2 deaths”
  - Patient quoted: “It was a miracle”

- Critical to get data from ongoing randomized trials
- If effective: Optimal timing of drug remains to be defined, as does potential drug supply, to determine range of patients who should be treated


American College of Gastroenterology
## Clinical Trials With Hydroxychloroquine

<table>
<thead>
<tr>
<th>Study</th>
<th>Type of Study</th>
<th>N</th>
<th>Finding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gautret et al (1)</td>
<td>Consecutive series</td>
<td>20 vs 16 &quot;controls&quot;</td>
<td>• 100% vs 12.5% viral clearance at day 6</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• 6 who got AZI cleared faster</td>
</tr>
<tr>
<td>Chen et al (2)</td>
<td>Randomized</td>
<td>62</td>
<td>• Decreased time to normal temperature (2.3 vs 3.2 days)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Decreased time to cough remission (2.0 vs 3.1 days)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Improvement in pneumonia by CT: (81% vs 55%)(p&lt;0.057)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• 4 progressed to severe course, all AZI</td>
</tr>
<tr>
<td>Chen et al (3)</td>
<td>Randomized</td>
<td>30</td>
<td>• No difference in viral clearance at day 13; no effect on clinical measures</td>
</tr>
<tr>
<td>Molina et al (4)</td>
<td>Uncontrolled series</td>
<td>11</td>
<td>• &quot;No evidence of strong anirial activity/clinical benefit&quot;</td>
</tr>
<tr>
<td>Mahevas et al (5)</td>
<td>Comparative observational study (not RCT)</td>
<td>84 HCQ, 97 no HCQ</td>
<td>• ICU or death 20% vs 22%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Death 3.8% vs 4.6% (NS)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• ARDS 27% vs 24% (NS)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• QT prolong. (d/c) 8% vs 0%</td>
</tr>
</tbody>
</table>

2. Chen et al, medRxiv 2020.03.22.20040758. doi:10.1101/2020.03.22.20040758
5. Mahevas et al. medRxiv 2020

---

## A Trial of Lopinavir–Ritonavir in Adults Hospitalized with Severe Covid-19

*Bin Cao, M.D., Yeming Wang, M.D., Danning Wen, M.D., Wen Liu, M.S., Jingli Wang, M.D., Guohui Fan, M.S., Liangkuo Ruan, M.D., Bin Song, M.D., Yanping Cai, M.D., Ming Wei, M.D., Xingwang Li, M.D., Jian Xia, M.D., et al.*

**N=199 randomized patients**

**Article**

**Figures/Media**

**Metrics**

**Day**

**Cumulative Improvement Rate**

**No. at Risk**

**Lopinavir–Ritonavir**

**Control**

**Cao B et al. 2020 Mar 18. doi: 10.1056/NEJMoa2001282. [Epub ahead of print]**
IL-6R or IL-6 Monoclonal Antibodies in US Trials

IL-6 Receptor Antibody

Tocilizumab
Sarilumab

Favorable case series in China
Approved in China
Several approvals in US

IL-6 Antibody

Clazakinumab

Approved for RA in US


Convalescent Plasma for COVID-19: Early Study

• 5 patients with ARDS and continuously high viral load
• SARS-Cov-2 binding titer > 1:1000 and neutralization titer > 40: all on mechanical ventilation
• Body temperature resolved within 3 days in 4
• Viral load negative 12 days after transfusion in all
• ARDS resolved by 12 days in 4
• 3 weaned off ventilator by end of week 2
• 3 discharged (>50 days) and 2 stable

Chen C et al, JAMA 2020
Investigative Agents for COVID-19 (Not All-Inclusive)

<table>
<thead>
<tr>
<th>Drug</th>
<th>Company</th>
<th>Mechanism</th>
<th>Approved uses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remdesivir</td>
<td>Gilead</td>
<td>Nucleotide inhibitor (Antiviral)</td>
<td>None (studied for Ebola)</td>
</tr>
<tr>
<td>Hydroxychloroquine + Azithromycin</td>
<td>Sanofi-Aventis and others (generic)</td>
<td>(?) (antiviral, receptor antagonism, acidification of cytoplasm)</td>
<td>RA, SLE</td>
</tr>
<tr>
<td>Tocilizumab</td>
<td>Roche</td>
<td>IL-6R inhibitor (mAb)</td>
<td>RA, GCA, Juvenile arthritis, CRS w/CAR-T</td>
</tr>
<tr>
<td>Sarilumab</td>
<td>Regeneron</td>
<td>IL-6R inhibitor (mAb)</td>
<td>RA</td>
</tr>
<tr>
<td>Clazakinumab</td>
<td>Vitaeris</td>
<td>IL-6 inhibitor (mAb)</td>
<td>None</td>
</tr>
<tr>
<td>TAK-888</td>
<td>Takeda</td>
<td>Polyclonal IG</td>
<td>None</td>
</tr>
<tr>
<td>RNAi vs several genes</td>
<td>Alnylam/Vir</td>
<td>RNA interference</td>
<td>None</td>
</tr>
<tr>
<td>Baricitinib</td>
<td>Lilly</td>
<td>JAK 1/2 inhibitor</td>
<td>None</td>
</tr>
<tr>
<td>LY 3127804</td>
<td>Lilly</td>
<td>mAb vs angiopoietin 2</td>
<td>None</td>
</tr>
<tr>
<td>Gimsilumab</td>
<td>Roivant</td>
<td>Anti-GM-CSF</td>
<td>None</td>
</tr>
<tr>
<td>Tradpitant</td>
<td>Vanda</td>
<td>Neurokinin-1-receptor antagonist (blocks substance P)</td>
<td>None</td>
</tr>
</tbody>
</table>

HCV

- RNA virus (flavivirus)
- Non-zoonotic
- Parenteral transmission
- Chronicity common
- Genotypes: clinical differentiator
- End stage disease takes years
- Slow evolution from nonspecific to specifically targeted direct-acting antiviral agents (DAA)
- Trials took a long time to endpoints
- Virologic clearance was pivotal goal
- Resistance mattered until 2nd gen drugs
- No vaccine after 30 years

SARS-Cov2

- RNA virus (coronavirus)
- Zoonotic (“jump” from animals to humans)
- Respiratory droplet (airborne?), highly transmissible
- Does chronicity exist (?)
- Genotypic variation: any clinical implications?
- End stage disease takes days
- Controversy about whether nonspecific Rx will work: immunomodulatory or antiviral or both?
- Trials endpoints achieved quickly
- Success will be measured by clinical outcomes
- Resistance may not matter: short course, nucleotide (?), viral suppression may be enough
- Vaccine desperately needed
Preparation

• Encourage your hospital or lab to scale up COVID-19 testing now
• Conserve PPE
• If possible, obtain N95s or equivalent
• Break down all procedures into elective, semi-elective, urgent
Procedure Classification

<table>
<thead>
<tr>
<th>Elective (Delay):</th>
<th>Semi-Elective (Perform)</th>
<th>Urgent (Perform)</th>
</tr>
</thead>
<tbody>
<tr>
<td>-Screening or surveillance colonoscopy</td>
<td>-Severe iron deficiency anemia and suspected GI source (new onset and felt that endoscopy will change management)</td>
<td>-Upper and Lower GI bleeding</td>
</tr>
<tr>
<td>-Screening or surveillance EGD in a patient with asymptomatic upper GI disease</td>
<td>-Significant weight loss -PEG Placement -EUS/staging for malignancy -Prosthesis removal (luminal, pancreaticobiliary) where waiting would cause potential harm to patient -Any significant upper/lower GI symptom that will aid in diagnosis/management of suspected disease that the patient and physician believe cannot wait 3 months to evaluate.</td>
<td>-Dysphagia impacting oral intake</td>
</tr>
<tr>
<td>-Evaluation of non-urgent symptoms (e.g. EGD for non-alarm symptoms, such as vague abdominal pain, nausea, GERD, or -Non-urgent endoscopic procedures - EUS for pancreatic cyst or small submucosal lesion).</td>
<td></td>
<td>-Cholangitis</td>
</tr>
<tr>
<td>-All motility procedures (esophageal/anorectal manometry, pH studies)</td>
<td></td>
<td>-Symptomatic pancreaticobiliary disease</td>
</tr>
</tbody>
</table>

Waves of Deployment

<table>
<thead>
<tr>
<th>Wave 1 ICU</th>
<th>Critical care trained physicians currently not practicing in ICUs and non-medical ICU intensivists (Pulmonologists trained in critical care, Anesthesia trained in critical care, Cardiologists who cover the CCU, Surgeons who cover the surgical ICU)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wave 2 ICU</td>
<td>Young physicians and volunteer senior fellows who receive additional training in ICU procedures and ventilator management. These physicians are board certified in Internal medicine and just a few years our from their ICU experience as residents.</td>
</tr>
<tr>
<td>Wave 3 ICU</td>
<td>Hospitalists who received additional ICU training</td>
</tr>
<tr>
<td>Wave 4 Medical Floors</td>
<td>Internists and subspecialists (gastroenterologists) who will act as medical attendings to backfill the vacant hospitalist positions.</td>
</tr>
</tbody>
</table>
Two Tiers of the COVID Army

• Medical Attending
  • Acting as a hospitalist
  • Interns, resident, APPs
  • Responsible for overall medical management and clinical decisions
  • 12-15 patients
  • Internal medicine trained (often subspecialist)

• Supplemental medical attendings (Super Residents)
  • Part of a team of other supplemental medical attendings and housestaff
  • Overseen by a hospitalist
  • Average of 5 patients
  • Surgeons, Ophthalmologists, Dermatologists, OB/GYN

Other COVID-19 Tips:

• Uniform communication messaging wherever possible with staff and patients
• Plan for limited reopening of ASCs/Offices once the number of new cases begins to decline (May/June?)
  • Bring in the Semi-urgent patients first
• Self-monitoring for symptoms—test or retest for ANY symptoms
  • Test all doctors, nurses and other staff who are planning on working with patients
• Recognizing stress/anxiety for patients, staff, and MDs
  • Exacerbation of underlying anxiety and mental illness—all ramped up by severe limitations on “usual” activities
  • Uncertainty how long this will last
  • It is a marathon without knowing where the finish line is
Visit ACG's COVID-19 Resource Page

www.gi.org/COVID19

The Artist: Josef Lee
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Instagram: https://www.instagram.com/joseflee.stories/
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LIVE VIRTUAL GRAND ROUNDS WEBINAR

ACG will send a link to a CME & ABIM 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.
ABIM MOC QUESTION

If you plan to claim ABIM 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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Core COVID-19 Calculators

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DEADLINE: AUGUST 1, 2020

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