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Special Edition Virtual Grand Rounds
June 7, 2022 8:00 pm – 9:00 pm EDT

Alcohol Associated Liver Disease

David Bernstein, MD, FACP
Jorge Herrera, MD, FACP
Suthat Liangpunsakul, MD, MPH

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Director, Dietary and Nutrition Services, GI OnDEMAND

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Abstract Categories:
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- Colon
- Colorectal Cancer Prevention
- Endoscopy Video Forum
- Esophagus
- Functional Bowel Disease
- General Endoscopy
- GI Bleeding
- IBD
- Interventional Endoscopy
- Liver
- Obesity
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- Stomach
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All attendees will be muted and will remain in Listen Only Mode.

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.
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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, 2022 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, 2023 for this activity.

MOC QUESTION
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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There will be NO Virtual Grand Rounds on May 19

Week 21
Management of Disorders of the J-Pouch: A Practical Guide
Laura Raffals, MD, MS, FACG
May 26, 2022 at Noon Eastern and 8pm Eastern!

Week 22
ACG Clinical Guideline for the Diagnosis and Management of Gastroesophageal Reflux Disease
Philip O. Katz, MD, MACG
June 2, 2022 at Noon Eastern and 8pm Eastern!

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- Stomach
- Clinical Vignettes/Case Reports

Visit acgmeetings.gi.org to Submit!
An updated approach to Idiopathic Acute Pancreatitis in 2022

Dhiraj Yadav MD, MPH
Professor of Medicine
Associate Chief, Clinical Research and Academic Development
Co-director, EMERGE Program
Division of Gastroenterology, Hepatology and Nutrition
University of Pittsburgh Medical Center, Pittsburgh, PA
Acute Pancreatitis (AP)

• Diagnosis (2 out of 3 findings)
  • Abdominal pain
  • Elevation of serum pancreas enzymes (3 or more times normal)
  • Imaging evidence

• Disease severity
  • Mild, Moderate, Severe
  • Interstitial; Necrotizing

• Identifying etiology is key to preventing future attacks

Gut 2013;62:102-11

First episode AP – work-up

• Good history
• Liver function tests
  – Elevation suggests biliary etiology: PPV of serum ALT of ≥3x is over 90%
    (Am J Gastro 1994;89:1863-9)
• Abdominal Ultrasound
• Serum TG
  – Check soon as possible after presentation
• Calcium
• CECT scan

Pancreatology 2013;13:e1-15
First episode AP – etiology

- Gallstones (40-60%)
- Alcohol (20-30%)
- Hypertriglyceridemia (5-7%; much higher in reports from China)
- Medications
  - Post-ERCP
  - Hypercalcemia
  - Trauma
  - Post-surgical

Clinical scenarios where we encounter HTG-AP

Secondary factors
- Poorly controlled Diabetes
- Alcoholic AP
- Medications (certain)
- Pregnancy (third trimester)
- Familial chylomicronemia

Potential model for HTG-related AP

Severe/Very Severe HTG + Other Factors (TBD) → Pancreatitis

Familial:
- Combined Hyperlipidemia
- HTG
- Dysbetalipoproteinemia
- Polygenic HTG

Secondary factors:
- Diabetes
- Alcohol abuse
- Obesity
- Medications
- Pregnancy

*Previously considered as monogenic, now suggested to also have Polygenic inheritance

J Clin Gastroenterol 2014;48:195-203
HTG increases the severity of AP

- **APPRENTICE study (n=1347)**
- TG measured in 764 (57%)
  - Normal TG: 55%
  - Mild HTG: 16%
  - Moderate HTG: 23%
  - Severe/Very Severe HTG: 6%

<table>
<thead>
<tr>
<th>TG level</th>
<th>Odds Ratio (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal (reference)</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Mild HTG</td>
<td>2.3 (1.3, 4.0)</td>
<td>0.004</td>
</tr>
<tr>
<td>Moderate HTG</td>
<td>3.0 (1.9, 5.0)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Severe/Very Severe HTG</td>
<td>9.6 (1.8, 52.6)</td>
<td>0.009</td>
</tr>
</tbody>
</table>

Covariates: age, sex, race, BMI, alcohol use, biliary etiology

Digestion 2021;102:809-13

Pancreatic cancer can present as AP
Celiac disease increases the risk of pancreatitis

- Population-based study – Sweden
- Celiac disease cases (28,908; 1969-2008)
- Matched controls (143,746)
- Hazard Ratio
  - Any pancreatitis – 2.85 (95% CI 2.53-3.21)
  - Gallstone AP – 1.59 (95% CI 1.06-2.40)
  - Non-gallstone AP – 1.86 (95% CI 1.52-2.25)
  - Chronic pancreatitis – 3.33 (95% CI 2.33-4.76)

AP can be an uncommon presentation of AIP
First episode AP – work-up

- Good history
- Liver function tests
- Abdominal Ultrasound
- Serum TG
- CECT scan
- Celiac panel
- Serum IgG4
- PETH levels

First episode AP – etiology

- Gallstones (40-60%)
- Alcohol (20-30%)
- Hypertriglyceridemia
- Medications
  - Post-ERCP
  - Trauma
  - Hypercalcemia
  - Post-surgical
- Other: Pancreatic cancer, celiac disease, AIP
- Idiopathic
Alcohol cessation decreases the risk of recurrence and progression after first episode of alcoholic AP

**Randomized Controlled Trial:** Finland, enrollment 2001-2005

**Groups:** Initial counseling (n=61) vs. repeated intervention (n=59)

**Duration of observation:** 2 years

**Improved outcomes:** AP recurrences; Hospital days; Abdominal pain episodes

<table>
<thead>
<tr>
<th></th>
<th>Complete abstinence (n=18)</th>
<th>Normal (%)</th>
<th>Only acute (%)</th>
<th>Acute and chronic (%)</th>
<th>Only chronic (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Follow up</td>
<td>5.5 (1.82-9.13)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recurrence</td>
<td>None</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exocrine Insufficiency</td>
<td>Admission – 7/15 (46%)</td>
<td>32</td>
<td>39</td>
<td>14</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td>Improved: 6/7</td>
<td>55</td>
<td>0</td>
<td>7*</td>
<td>40</td>
</tr>
<tr>
<td>Endocrine Insufficiency</td>
<td>Before/during: 3/18</td>
<td>55</td>
<td>0</td>
<td>0</td>
<td>47</td>
</tr>
<tr>
<td></td>
<td>Follow up: 5/15</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*One patient had a recurrent attack and another had liver disease at this time point
Clinical CP: 11%

*Insulin insufficiency/glucose intolerance
Recurrence with partial abstinence (n=100): 34%

Gastroenterology 2009; Alcohol Alcoholism 2013; J Gastrointest Surg 2013
Early CCY after mild gallstone-related AP prevents recurrences

- PONCHO trial (12/2010-8/2013)
- 266 patients
- 28 Dutch hospitals
- Same admission vs. Interval CCY
- Primary outcome
  - Composite for mortality vs. gallstone-related complications

<table>
<thead>
<tr>
<th>Primary endpoint</th>
<th>Interval cholecystectomy (n=136)</th>
<th>Same-admission cholecystectomy (n=128)</th>
<th>Risk ratio (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality or readmission for gallstone-related complications</td>
<td>33 (25%)</td>
<td>6 (5%)</td>
<td>0.38 (0.12-0.66)</td>
<td>0.002</td>
</tr>
</tbody>
</table>

Secondary endpoints

- Readmission for gallstone-related complications:
  - Recurrent pancreatitis: 12 (9%) vs. 3 (2%) 0.22 (0.08-0.92) 0.03
  - Cholecystitis: 2 (2%) vs. 0 0.50
  - Cholelithiasis needing ERCP: 2 (2%) vs. 1 (1%) 0.53 (0.05-5.79) 1.00
  - Gallstone colic: 7 (5%) vs. 2 (2%) 0.30 (0.06-2.42) 0.27
  - Mortality: 0 vs. 1 (1%) 0.46
  - Patients reporting colics during waiting period: 62 (51%) vs. 3 (3%) 0.06 (0.02-0.21) <0.0001

Lancet 2015;386;1261-8

RAP after CCY for AP in Olmsted County, MN 1990-2005 (n=239)

- A (elevated liver enzymes and gallstones/sludge)
- B (elevated liver enzymes only)
- C (gallstones/sludge only)
- D (neither liver enzymes elevation or gallstones/sludge)

| Idiopathic RAP after CCY with ≥ 2 prior attacks |
|-----------------------------------------------|--------|
| Patient group                                | N (%)  |
| All 4 groups                                 | 9/21 (43) |
| Group A (biliary)                            | 1/5 (20) |
| Group C (probable idiopathic)                | 0/5 (0)  |
| Group D (idiopathic)                         | 7/8 (88) |

Surgery 2012;151:199-205
Tight control of TG reduces AP recurrences

- AP w TG >=500 mg/dl
- Post discharge TG (n=151):
  - Stratified as <200; 200-<500; >=500 mg/dl
- Assessed risk of recurrences during F/U based on TG control

Dig Dis Sci 2019;64:890-7

Second (or subsequent) episode(s) of AP – work-up

- Good history
- Labs – LFTs, TG, calcium, celiac panel, PETH test, IgG4
- CECT scan
- EUS
- sMRCP

Pancreatology 2013;13:e1-15
Role of EUS

- Other: ampullary/periampullary, pancreatic head lesion

MRCP – normal anatomy
Normal sMRCP

Baseline (pre-secretin) 3 minutes post secretin 10 minutes post secretin

MRCP – Pancreas divisum
Other ductal abnormalities to remember

- Abnormal PBJ with choledochal cyst
- Annular Pancreas
- Santorinicele
- Wirsungocele

Main Duct IPMN
Genetic testing

- PRSS1
- SPINK1
- CFTR
- CTRC
- Other genes

PD stricture after AP

Ac pancreatitis with focal necrosis in head

MRCP 1 yr later shows stricture in the pancreas head with upstream dilation
Second (or subsequent) episode(s) of AP – etiology

- Same d/d as first attack
- Pancreatic ductal abnormalities
- Genetic causes
- SOD
- Complications from prior episode of AP
- Chronic Pancreatitis
- Other
  - Diabetes, Autoimmune diseases, Renal failure, etc.
- Idiopathic RAP

Yield of work up for Presumed Idiopathic AP

- Post-hoc analysis of prospective registry at 19 Dutch hospitals
- 2008-2015; median follow up 4 years
- Idiopathic AP 12% patients (191 of 1632)
- 176 of 191 underwent further work up
- Etiology established in 36% (64/176)
  - Biliary 39/64, neoplasm 13/64
- Recurrences
  - 15% if etiology revealed
  - 43% if no etiology revealed

<table>
<thead>
<tr>
<th>Test</th>
<th>Number performed</th>
<th>Diagnostic yield</th>
</tr>
</thead>
<tbody>
<tr>
<td>CT</td>
<td>124</td>
<td>8%</td>
</tr>
<tr>
<td>EUS</td>
<td>62</td>
<td>36%</td>
</tr>
<tr>
<td>MRI/MRCP</td>
<td>50</td>
<td>33%</td>
</tr>
<tr>
<td>Repeat TUS</td>
<td>97</td>
<td>21%</td>
</tr>
<tr>
<td>Serum IgG4</td>
<td>54</td>
<td>9%</td>
</tr>
<tr>
<td>ERCP</td>
<td>15</td>
<td>47%</td>
</tr>
</tbody>
</table>

UEG 2020;8:340-50
• Single center study (Univ of Alabama) 2003-2013

- Single, n (%)  
  - Microthiasis/choledochitis: 12 (15) 8 (6.6)
  - Pancreatic divisum: 13 (16.3) 30 (24.8)
  - SOD: 2 (2.5) 49 (40.5)
  - Idiopathic: 43 (53.8) 17 (14.1)
  - CP: 9 (11.3) 13 (10.7)
  - Others: 1 (1.3) 4 (3.3)

Survival probability

Time to recurrence (months)

Am J Gastro 2016;111:1339-48

• Single center study
• iRAP with pancreatic SOD
  - Biliary ES (n=33)
  - Dual ES (n=36)
• iRAP with normal pressures
  - Biliary ES (n=11)
  - Sham (n=9)
• Outcomes of interest
  - Primary – Incidence of RAP
  - Secondary – RAP within 12 mo., CP, recurrent or persistent SOD on repeat ERCP
• Follow-up – Median 78 mo. (IQR 35-108)

Gastro 2012;143:1502-9
CONFERENCE REPORT

Recurrent Acute Pancreatitis

International State-of-the-Science Conference With Recommendations

Nalini M. Guda, MD,* Venkata Muddana, MD,* David C. Whitcomb, MD, PhD,† Philippe Levy, MD,‡ Pramod Garg, MD,§ Gregory Cote, MD,∥ Aliye Uc, MD,¶ Shyam Virudhagiris, MD,∥ Santini S. Vege, MD,**

Suresh T. Chari, MD,** Chris E. Forssmark, MD,†† Dhiri Raj Yadav, MD, MPH,† D. Nagashwar Reddy, MD,‡‡

Scott Tenner, MD,‴ Colin D. Johnson, MChir, FRCS,|||| Faith Akisik, MD,‴ Ashok K. Saluja, PhD,##

Markus M. Lerch, MD,*** J. Shawn Mallery, MD,††† and Martin L. Freeman, MD,‡‡‡

Pancreas 2018;47:653-66

Summary

• *Idiopathic* AP term is used in the absence of an identifiable etiology

• Identification of an etiology provides the best opportunity to address and prevent future recurrences of AP

• The extent of work up for AP etiology depends on several factors e.g. first vs. recurrent attacks, demographic factors, clinical presentation, prior work up, etc.

• The role of ES in iRAP with normal anatomy is unclear

• Future research should explore strategies that can prevent recurrences in patients with idiopathic RAP
Pancreas divisum: A prototype for obstructive acute pancreatitis?

Gregory A. Cote, MD, MS
Professor of Medicine and Division Head
Oregon Health & Science University

The value of ERCP is predicated on the "obstruction" assumption

- How could sphincterotomy attenuate acute pancreatitis?
  - Intermittent or sustained ↑ intraductal pressure
- Duct obstruction/spasm causes AP in animals
- Gallstone pancreatitis exists
- ERCP
  - Causes pancreatitis
  - PD stenting decreases risk
  - Over-injection increases risk
- Opioid/eluxadoline-induced acute pancreatitis

Eluxadoline (Viberzi)-associated pancreatitis

Potent, mu-opioid receptor agonist (smooth muscle contraction)

- Indicated for diarrhea predominant IBS

119 post-marketing cases of acute pancreatitis

- 55/67 (82%) of cases were in those with prior cholecystectomy
- 47/83 cases with reported timing developed pancreatitis within the first two doses

Harinstein L, Wu E, Brinker A, Aliment Pharmcol Therap 2018

Treatments for acute pancreatitis are limited by its complex pathophysiology

- Risk modifying mutations are more common with pancreas divisum
  - Particularly those associated with secretory dysfunction (e.g., CFTR)
- Interaction between smoking, alcohol, genetics and anatomy remains unclear

Acute pancreatitis
MANY cohort studies, most favor “treating” pancreas divisum

Limitations
1. No natural history group!
2. How many had “real” ARP at baseline?
3. Variable definitions of success
4. Inconsistent treatments (serial stents, sphincterotomy, or combination)
5. Inconsistent follow-up
6. Lack of blinded assessments of outcome


40 years of practice:
One 19-patient, open label randomized trial

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Stent</th>
<th>No stent</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominal pain</td>
<td>0/10</td>
<td>7/9</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td>Acute pancreatitis</td>
<td>1/10</td>
<td>6/9</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td>Improvement &gt;50%</td>
<td>9/10</td>
<td>1/9</td>
<td>&lt; 0.05</td>
</tr>
</tbody>
</table>

- Unblinded
- Mean follow-up 29 months (stent) and 32 months (no stent)
  - Range not provided

Lans et al., GIE 1992
The hazards of endoscopic therapy mandate careful, longitudinal follow-up

- The natural history is poorly understood but undoubtedly sporadic – many patients won’t have another episode
- ERCP, particularly with pancreatic sphincterotomy, is still a high-risk procedure
  - Post-ERCP pancreatitis
  - Stent-induced injuries to the pancreatic duct

---

Endoscopic sphincterotomy is more attractive than pharmacologic interventions for iRAP

**Pros**
- Promising preliminary data, particularly for pancreas divisum
- One-and-done intervention
  - Chronic utilization of a pharmacological agent is unattractive for a sporadic disease
- Relatively low long-term risk
- Can be studied in a sham-controlled trial
- Patients with RAP are at-risk for chronic pancreatitis; most patients with CP present with overt fibrosis

**Cons**
- Short-term risk of ERCP and pancreatic sphx
  - Small possibility of severe post-ERCP pancreatitis
- Sphincter re-stenosis (poorly studied)
- Potential for negative effect on natural history
- Lack of objective data confirming that a sphincterotomy improves pancreatic juice outflow (particularly in a small PD)
Minor papillotomy

SpHincterotomy for Acute Recurrent Pancreatitis (SHARP) trial

- Randomized, sham-controlled trial of ERCP with minor papillotomy for patients with iRAP and pancreas divisum
  - Single blind (patient) with blinded outcome assessors
- Longitudinal follow-up for 6 – 48 months
- Time dependent outcome measure (next episode of acute pancreatitis)
- Referral centers in the U.S., Netherlands, and Canada
- Anticipated sample size of 234 randomized subjects

Research supported by
NIDDK U01DK116743
Multiple PI (Cote, Durkalski, Yadav)
SpHincterotomy for Acute Recurrent Pancreatitis (SHARP) trial hypothesis

• Obstruction at the level of minor papilla is one cause of RAP in pancreas divisum
• Minor papilla endoscopic sphincterotomy (miES) will relieve the obstruction, thereby reducing the risk of a recurrent attack of acute pancreatitis by 33%.

Study Definitions

• Acute pancreatitis definition (for enrollment AND outcome)
  • Atlanta criteria (2 of 3 – pain, serum enzymes >3x ULN, imaging)
  • For enrollment and follow-up (outcome)
• Acute recurrent pancreatitis
  • Two or more discrete episodes of acute pancreatitis that occur >30 days apart
  • Complete recovery from the first before commencement of the second episode
Enrollment schema for the SHARP trial

Randomization Plan (web based):
- 1:1
- Site
- Duct diameter (during EUS)
- # of attacks in the past 24 months

Why bother with blinding? Its acute pancreatitis!

- How will you manage an enrolled subject calling with upper abdominal pain?
  - No ERCP → go to the ED right away!
  - ERCP → stay on liquids for a few days, let’s see if it subsides...

- How will a patient react to their abdominal pain
  - No ERCP → “they didn’t fix my divisum (congenital anomaly)!”
  - ERCP → “well, they opened up the duct, maybe I just have a GI bug…”
Key enrollment criteria

**Inclusion**
- Two or more episodes of acute pancreatitis, one in the last two years
- MRCP consistent with pancreas divisum variant
- No definite etiology per physician (e.g., heavy alcohol use)

**Exclusion**
- Chronic calcific pancreatitis
- Main pancreatic duct stricture
- Complication of acute pancreatitis requiring ERCP (e.g., pancreatic duct leak)

Outcomes of interest in SHARP

01 Reduce the risk of acute pancreatitis during follow-up (33% risk reduction)
02 Reduce acute pancreatitis episode frequency
03 Decrease the incidence of chronic pancreatitis
04 Improve patient-centered outcomes, such as quality of life
Challenges

• Recruitment!
  • Bias in favor of intervention (patients and U.S. providers)
  • Rare disease
  • Prior minor papillotomy is an exclusion
• Equipoise
  • Interventions can be offered during follow-up → ideally after acute pancreatitis
  • Long-term follow-up supported by study, including a “free” MRI/MRCP 18 months after randomization

89 randomizations to date!

Summary

• Pancreas divisum may not be a “clean” and modifiable risk factor for acute pancreatitis
• We need a national effort among gastroenterologists to enroll in SHARP and answer the question:

Does minor papillotomy reduce the risk of acute pancreatitis?

www.pancreasdivisum.com
Sphincterotomy in Acute Recurrent Pancreatitis with pancreas divisum

Pis: Gregory Cote (OHSU), Valerie Durkalski-Mauldin (MUSC), Dhiraj Yadav (UPMC)

Participating sites (Pis)
1. MUSC (Joe Elmunzer)
2. UPMC (Dhiraj Yadav)
3. Indiana University (Evan Fogel)
4. Minnesota (Martin Freeman)
5. UVA (Andrew Wang)
6. Ohio State University (Luis Lara)
7. Dartmouth-Hitchcock (Timothy Gardner)
8. Northwestern University (Rajesh Keswani)
9. University of Arkansas (Sumant Inamdar)
10. Methodist Dallas Hospital (Prashant Kedia)
11. U. Southern California (James Buxbaum)
12. Virginia Mason University (Andrew Ross)
13. UMKC (Sreeni Jonnalagadda)
14. UCSF (Sun-Chuan Dai)
15. Yale (Priya Jamidar)
16. U. of Manitoba, Canada (Dana Moffatt)
17. Radboud University, Netherlands (Erwin van Geenen)
18. OHSU (Gregory Cote)
19. University of Rochester (Truptesh Kothari)
20. Cedars Sinai (Sri Gaddam)
21. Beth Israel (Doug Pleskow)
22. Emory (Field Willingham)

This trial is now enrolling patients
ClinicalTrials.gov: NCT03609944

Please consider referring patients to a SHARP site near you

www.pancreasdivisum.com

Research supported by

American College of Gastroenterology

Questions?

Gregory Coté, MD, MS

Dhiraj Yadav, MD, MPH

Truptesh H. Kothari MD, MS, FACP

5/10/2022