ACG AWARDS

Nominate a Colleague by April 15th!

2022 Award Categories:

- New! NP/PA Award for Clinical Excellence
- Berk/Fise Clinical Achievement Award
- Community Service Award
- Distinguished Mentorship & Teaching Award
- Diversity, Equity & Inclusion Award
- International Leadership Award
- Master of the American College of Gastroenterology
- Samuel S. Weiss Award

Nominations for these awards will be presented at the College’s Annual Scientific Meeting in Charlotte, NC on October 22, 2022.

gi.org/about/awards

Special Edition ACG VRG April 11, 2022 8pm - 9pm EDT
ASSESSING HEREDITARY GI CANCER RISK EARLIER:
INSIGHTS FROM A GI PRACTICE

Register Now for April 11th Webinar

giod.co/Care0411
Participating in the Webinar

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.

How to Receive CME and MOC Points

LIVE VIRTUAL GRAND ROUNDS WEBINAR
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.

ACG Virtual Grand Rounds
Join us for upcoming Virtual Grand Rounds!

Week 14
CAM and Psychological Therapies for Functional and Inflammatory Bowel Disease
Jill K. Deutsch, MD and Laurie A. Keefer, PhD
April 7, 2022 at Noon Eastern and **NEW!** 8pm Eastern!

Week 15
There will be No ACG Virtual Grand Rounds on April 14th due to Passover and Easter

Week 16
Practical Patient Education Tips and Strategies
Connie Arnold, PhD; Terry Davis, PhD; and James D. Morris, MD, FACG
April 21, 2022 at Noon Eastern and **NEW!** 8pm Eastern!

Visit [gi.org/ACGVGR](http://gi.org/ACGVGR) to Register
ACG SPECIAL Grand Rounds
Join us for upcoming Virtual Grand Rounds!

Special Edition ACG VRG April 11, 2022 8pm - 9pm EDT
THE POTENTIAL FOR EARLIER HEREDITARY GI CANCER DETECTION WITH INSIGHT FROM A GI PRACTICE

Visit gi.org/ACGVGR to Register

Disclosures:

Vivek Kaul, MD, FACG: Ambu: Consultant, Cook Medical: Consultant, ECAN: Board of Directors, endo-cdx: Advisory Board, Microtech: Consultant, MOTUS GI: Advisory Board, STERIS CORP/CSA MEDICAL: Consultant, UpToDate: Royalties

Jason R. Taylor, MD, FACG: AbbVie: Speakers Bureau

Adam J. Kichler, DO: has no relevant financial relationship(s) with ineligible companies to disclose.

Marta L. Davila, MD, FACG: has no relevant financial relationship(s) with ineligible companies to disclose.

Sarah M. Enslin, PA-C: has no relevant financial relationship(s) with ineligible companies to disclose.

M. Anthony Sofia, MD: Prometheus Biosciences: Advisory Board

Adam Buckholz, MD: has no relevant financial relationship(s) with ineligible companies to disclose.

Daniel Castaneda, MD: has no relevant financial relationship(s) with ineligible companies to disclose.

Amer AliSamman, MD: has no relevant financial relationship(s) with ineligible companies to disclose.


Samir A. Shah, MD, FACG: has no relevant financial relationship(s) with ineligible companies to disclose.

*All of the relevant financial relationships listed for these individuals have been mitigated
Best of ACG 2021: Endoscopy and Pancreas

Jason R. Taylor, MD, FACG
Associate Professor of Medicine
Saint Louis University
Endoscopy and Pancreas Abstracts

- **Endoscopy**
  - **Trivedi et al:** Retrospective comparison of cold snare vs. hot snare polypectomy for non-ampullary duodenal adenomas

- **Pancreas**
  - **Sharma et al:** Locally advanced pancreatic cancer and EUS FNI of paclitaxel

---

**Endoscopy:**

Cold snare vs. hot snare polypectomy for non-ampullary duodenal adenomas (Trivedi et al)

**Overview:**

- Retrospective study comparing safety and efficacy of cold vs. hot snare polypectomy for non-ampullary duodenal polyps

- 110 patients, 120 duodenal polyps
  - 69 patients (63%) underwent hot snare polypectomy (HSP)
  - 41 patients (37%) underwent cold snare polypectomy (CSP)
Endoscopy: Cold snare vs. hot snare polypectomy for non-ampullary duodenal adenomas (Trivedi et al)

Demographics:
- Age, sex, polyp size, and antiplatelet/anticoagulant use similar in both groups

Results:
- 7 patients in hot snare group had complications
  - 6 bleeding, 1 perforation
- No patients in cold snare group had complications
  - (p=0.04)
- Submucosal lift and clips used more frequently in HSP group compared to CSP (p <0.01 for both)
**Endoscopy:**
Cold snare vs. hot snare polypectomy for non-ampullary duodenal adenomas (Trivedi et al)

**Results:**
- **Predictors of polyp recurrence** from multivariate analysis
  - Larger polyp size (per mm, OR 1.02, 95% CI 1.01-1.03, P<0.01)
  - Increasing number of polyps resected per session (OR 0.78, 95% CI 0.62-0.98, p=0.02)
- **Decreased risk of recurrence**
  - Use of Argon Plasma Coagulation (APC)
- **NO CHANGE**
  - Use of HSP or CSP was not a predictor of polyp recurrence

**Summary:**
1) Use of hot snare polypectomy vs. cold snare polypectomy was not a predictor of polyp recurrence in resection of non-ampullary duodenal adenomas.
2) Cold snare polypectomy is potentially safer than hot snare polypectomy for resection of non-ampullary duodenal polyps

**Reference:** The American Journal of Gastroenterology 116:S249, October 2021
**Pancreas:**
Locally advanced pancreatic cancer and EUS FNI of paclitaxel (Sharma et al)

**Overview:**
- Prospective study for patients with locally advanced pancreatic cancer (LAPC)

- Received large surface area microparticle paclitaxel (LSAM pac, NanOlogy, Inc) via EUS-FNI into the tumor

**Methods:**
- 2 phases. Dose escalation phase and then second phase
  - 15mg/mL LSAM pac were administered 1 month apart
Pancreas:
Locally advanced pancreatic cancer and EUS FNI of paclitaxel (Sharma et al)

Results:
• 13/22 subjects enrolled in the second phase of the trial
  • 7 of 13 patients (54%) were restaged becoming eligible for surgery following LSAM pac injections
  • 5 of 6 surgical patients had successful R0 resections, the 6th resulted in R1 resection

Complications:
• None
  – No increasing toxicities associated with systemic chemotherapy
Pancreas:
Locally advanced pancreatic cancer and EUS FNI of paclitaxel
(Sharma et al)

Summary:
• EUS-guided delivery of nanoparticles is a novel approach to the treatment of advanced pancreatic adenocarcinoma with the goal of downsizing pancreatic tumors to meet criteria for surgical resection

Reference: The American Journal of Gastroenterology. 116:S1-S2, October 2021

Discussion and Questions
Endoscopy and Pancreas
Virtual Grand Rounds
Best of ACG 2021: Outstanding Science, Expert Discussions

Best of ACG 2021:
Innovation in Artificial Intelligence

Adam J. Kichler, DO
Allegheny Health Network
Division of Gastroenterology, Hepatology & Nutrition

Innovation in Artificial Intelligence

Artificial Intelligence and Digital Single-operator Cholangioscopy (D-SOC):
Automatic Identification of Tumor Vessels in Patients with Indeterminate Biliary Stenosis


Artificial Intelligence for Automatic Diagnosis of Mucinous Pancreatic Cystic Lesions (PCL) in Endoscopic Ultrasound: A Pilot Study

Artificial Intelligence and Digital Single-operator Cholangioscopy (D-SOC): Automatic Identification of Tumor Vessels in Patients with Indeterminate Biliary Stenosis

• Develop and validate a convolutional neural network to aid in the detection of malignant biliary strictures
  • Deep learning algorithm created
  • Trained to detect tumor vessels (dilated, irregular, and tortuous)
  • 6,475 images from 85 patients obtained during D-SOC
  • Malignancy diagnosis was histologically confirmed


Artificial Intelligence and Digital Single-operator Cholangioscopy (D-SOC): Automatic Identification of Tumor Vessels in Patients with Indeterminate Biliary Stenosis

• Accuracy: 99.3%
• Sensitivity: 99.3%
• Specificity: 99.4%
• PPV: 99.6%
• NPV: 98.7%

Artificial Intelligence for Automatic Diagnosis of Mucinous Pancreatic Cystic Lesions (PCL) in Endoscopic Ultrasound: A Pilot Study

- Aimed to develop a convolutional neural network model to assist in the diagnosis and differentiation of mucinous PCLs.
  - 10,700 images from 34 patients

- EUS images labeled with corresponding pancreatic lesion
  - Mucinous (7,420 images): IPMN or MCN
  - Non-Mucinous (3,230 images): Serous Cystadenoma or Pseudocyst

- Diagnosis of mucinous PCL previously confirmed by
  - CEA > 192 ng/mL
  - Glucose < 50 mg/dL
  - Histopathologic analysis


Artificial Intelligence for Automatic Diagnosis of Mucinous Pancreatic Cystic Lesions (PCL) in Endoscopic Ultrasound: A Pilot Study

- Accuracy: 99.8%
- Sensitivity: 99.7%
- Specificity: 100%
- PPV: 100%
- NPV: 99.2%
- AUC: 1.00

Discussion and Questions
Innovation in Artificial Intelligence

Best of ACG 2021:
General GI / Esophagus

Marta L. Davila, MD, FACG
Professor of Medicine
Department of Gastroenterology, Hepatology and Nutrition
The University of Texas MD Anderson Cancer Center
Long-Term (> 5 Year) Outcomes of Endoscopic Resection for T1 Esophageal Adenocarcinoma: A Multicenter Cohort Study

Kevin Song, Allon Kahn, Shivani Thanawala, Siddharth Agarwal, Nicholas McDonald, Joel Gabre, Gary Falk, Gregory Ginsberg, Herbert Wolfsen, Francisco Ramirez, Kenneth Wang, Prasad Iyer

Mayo Clinic, Scottsdale, AZ
University of Pennsylvania, Philadelphia, PA
Mayo Clinic, Rochester, MN
University of Minnesota Medical Center, Minneapolis, MN
Mayo Clinic, Jacksonville, FL

Aim

- To assess the outcomes of endoscopic eradication therapy (EET) for T1 esophageal adenocarcinoma (EAC) with follow up beyond 5 years

Patients and Methods

- Patients with T1 EAC undergoing endoscopic mucosal resection (EMR) from 1995-2016 with at least 5 years follow up were identified from prospectively maintained institutional databases
- Demographic and clinical data were collected by chart review
Definitions

- Complete remission of intestinal metaplasia (CRIM) was defined as one post-treatment surveillance endoscopy with negative biopsies from the tubular esophagus and the gastroesophageal junction
- EAC recurrence was defined as early if within 2 years of endoscopic therapy

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Study Population (N=98)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (SD) age at diagnosis</td>
<td>68(±)10</td>
</tr>
<tr>
<td>Male sex, N (%)</td>
<td>88 (89.8%)</td>
</tr>
<tr>
<td>T1 stage</td>
<td></td>
</tr>
<tr>
<td>T1a</td>
<td>80 (81.6%)</td>
</tr>
<tr>
<td>T1b</td>
<td>18 (18.4%)</td>
</tr>
<tr>
<td>Grade of differentiation</td>
<td></td>
</tr>
<tr>
<td>Well differentiated</td>
<td>12 (12.2%)</td>
</tr>
<tr>
<td>Moderately differentiated</td>
<td>16 (16.3%)</td>
</tr>
<tr>
<td>Poorly differentiated</td>
<td>18 (18.4%)</td>
</tr>
<tr>
<td>Unknown</td>
<td>52 (53.1%)</td>
</tr>
<tr>
<td>Lymphovascular invasion</td>
<td>3/31 (9.7%)</td>
</tr>
<tr>
<td>Endoscopic ablation techniques</td>
<td></td>
</tr>
<tr>
<td>Argon plasma coagulation</td>
<td>14/84 (16.7%)</td>
</tr>
<tr>
<td>Cryotherapy</td>
<td>1/84 (1.2%)</td>
</tr>
<tr>
<td>Photodynamic therapy</td>
<td>20/84 (23.8%)</td>
</tr>
<tr>
<td>Radiofrequency ablation</td>
<td>28/84 (33.3%)</td>
</tr>
</tbody>
</table>
Results

Median Follow up
8.76 years
Interquartile range:
6.51-11.28

Study population
N=98

EAC remission
93 (95%)

No remission
5

CRIM
82 (84%)

Complete remission of
Dysplasia (CRD)
5 (5%)

Persistent dysplasia
6 (6%)

Patient outcomes

Study population
98

CRIM
82

EAC remission, No CRIM
11

No remission
5

Recurrence
9

No recurrence
73

Early
4

Late
5

Recurrence
5

No recurrence
6

Early
4

Late
1
### Outcomes

<table>
<thead>
<tr>
<th>Dysplastic recurrence</th>
<th>7/93 (7.5%)</th>
<th>4/93 (4.3%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low grade dysplasia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>High grade dysplasia</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>EAC recurrence</th>
<th>9/93 (9.7%)</th>
<th>2/93 (2.2%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>T1a</td>
<td>2/93 (2.2%)</td>
<td></td>
</tr>
<tr>
<td>T1b</td>
<td>1/93 (1.1%)</td>
<td></td>
</tr>
<tr>
<td>T2</td>
<td>2/93 (2.2%)</td>
<td></td>
</tr>
<tr>
<td>Lymph node metastases</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Results – EAC recurrence

<table>
<thead>
<tr>
<th></th>
<th>Incidence (95% CI)</th>
<th>Median (IQR)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Overall</strong></td>
<td>2.67 per 100 patient-years (95% CI: 1.46-4.47)</td>
<td>1.29 years (IQR 0.74-7.0)</td>
</tr>
<tr>
<td><strong>EAC remission and CRIM</strong></td>
<td>1.95 per 100 patient-years (95% CI: 0.89-3.70)</td>
<td>5.20 years (IQR: 0.75-8.58)</td>
</tr>
<tr>
<td><strong>EAC remission, No CRIM</strong></td>
<td>7.86 per 100 patient-years (95% CI: 2.55-18.33)</td>
<td>0.81 years (IQR: 0.43-2.35)</td>
</tr>
</tbody>
</table>
Results

- EAC recurrence was significantly higher in patients without CRIM compared to those who achieved CRIM (p=0.01), with OR: 6.55 (95% CI 1.71-26.71)
- 5/93 (5.38%) patients recurred >5 years
- EAC related mortality rate: 6.45%

Conclusions

- EET for T1 EAC achieves a high rate of cancer remission
- Surveillance is important even when early recurrence is not observed
- CRIM should be considered the most significant clinical endpoint for EET of T1 EAC
Rapid Prediction of *H. pylori* Antibiotic Resistance Using Next Generation Sequencing of Stool Samples Compared to Gastric Biopsies

Steven F. Moss*, Amporn Atsawarungruangkit*, Long P. Dang^, David Chua #, Yi Zhou@, Zhao Z. Chong@, Hongjun Zhang@, David Y. Graham +

*Brown University, Providence, RI  
^Fountain Valley Hospital, Fountain Valley CA  
#Summit Digestive, Chicago, IL  
@American Molecular Laboratories, Vernon Hills, IL  
+Baylor College of Medicine, Houston, TX

Background

- *H. pylori* culture-based susceptibility testing requires endoscopy, gastric biopsies, and a complex sample processing that makes it difficult for universal implementation
- Molecular resistance testing of *gastric biopsies* using next generation sequencing (NGS) has become available recently, yielding results that are similar to those of culture-based methods
- Whether reliable resistance testing by NGS is possible from *stool samples* remains unclear
Aim

- To compare the results of *H. pylori* antibiotic resistance testing by NGS using stool versus gastric biopsy specimens in the same patients

Methods

- Patients underwent EGD with biopsies. Two gastric biopsies were obtained for NGS
- A spontaneously passed stool specimen was also obtained within two weeks from endoscopy

Methods

- Gastric biopsies and Stool specimens
  - *H. pylori* presence was evaluated by PCR
  - Positive cases were then subjected to NGS to identify mutations associated with *H. pylori* resistance
    - Amoxicillin (*pbp1*), clarithromycin (*23S rRNA*), metronidazole (*rdxA*), tetracycline (*16S rRNA*), levofloxacin (*gyrA*), rifabutin (*rpoB*)
  - Agreement between tests was expressed as a kappa coefficient
Results

262 patients

73 (29%) *H pylori* positive by both stool and gastric PCR
Age: 18-83 yr (mean 61)
32 M, 41 F

• 71 cases with matched gastric and stool specimens analyzed by NGS
• 2 had only stool samples analyzed by NGS

Results

• Identical profiles for stool and biopsy samples in 65/71 patients (92%)
• In 6 cases there was mismatch between gastric and stool results
  • In 4 cases this was due to 1 antibiotic-associated mutation difference
  • In 1 case: 2 mutations in gastric sample, none in stool
  • In 1 case: 3 mutations in gastric sample, only 1 of these in stool
Virtual Grand Rounds
Best of ACG 2021: Outstanding Science, Expert Discussions

<table>
<thead>
<tr>
<th>Antibiotic</th>
<th>Gene evaluated</th>
<th>Resistance Associated Mutations (N, %)</th>
<th>Agreement between tests (k)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Gastric (N=71)</td>
<td>Stool (N=71)</td>
</tr>
<tr>
<td>Clarithromycin</td>
<td>23S rRNA</td>
<td>39 (54.9%)</td>
<td>39 (54.9%)</td>
</tr>
<tr>
<td>Levofloxacin</td>
<td>gyr A</td>
<td>23 (32.4%)</td>
<td>20 (28.2%)</td>
</tr>
<tr>
<td>Metronidazole</td>
<td>rdxA</td>
<td>23 (32.4%)</td>
<td>21 (29.6%)</td>
</tr>
<tr>
<td>Tetracycline</td>
<td>16s rRNA</td>
<td>7 (9.9%)</td>
<td>7 (9.9%)</td>
</tr>
<tr>
<td>Amoxicillin</td>
<td>pbp1</td>
<td>4 (6%)</td>
<td>4 (6%)</td>
</tr>
<tr>
<td>Rifabutin</td>
<td>rpoB</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>

Conclusions

- Profiling *H. pylori* antibiotic resistance by NGS from stool samples provides rapid results highly comparable to those obtained from gastric biopsies
- It is possible to rapidly obtain susceptibility data without the need for endoscopy and gastric biopsies
Discussion and Questions
General GI / Esophagus

Best of ACG 2021: Liver Abstracts

Sarah M. Enslin, PA-C
University of Rochester Medical Center
APP Manager, Department of Medicine
Lead APP, Division of Gastroenterology & Hepatology
Plenary Session 2B - Liver

30 - Effect of Fecal Microbiota Transplant on Hepatic Encephalopathy Varies by Donor and Recipient Factors

Patricia P. Bloom, MD, John Donlan, Mariam Torres Soto, BA, MA, Michael Daidone, BA, Elizabeth Hohmann, MD, Raymond Chung, MD

➢ Background:
  • Fecal microbiota transplant (FMT) may reduce admissions in HE
  • Appropriate patients and donors are not yet delineated

➢ Aim:
  • Assess the safety and efficacy of FMT in patients with prior overt HE while comparing 5 FMT donors

Effect of Fecal Microbiota Transplant on Hepatic Encephalopathy Varies by Donor and Recipient Factors

• N=10 patients with prior overt HE on lactulose and rifaximin
• Pts received 15 oral FMT capsules 5 times over 21 days (days 1, 2, 7, 14, 21)
• Primary outcomes: change in psychometric HE score (PHES) and SAEs

• Results:
  • 3 SAEs (2 unrelated to FMT)
  • 1 transmission of ESBL E. coli to patient
Ammonia levels did not change after 5 doses of FMT (73 µmol/L vs. 75 µmol/L, \( P=0.73 \))

Significant Heterogeneity Based on Donor and Recipient Factors!

- Possibly mediated by *Bifidobacterium* abundance
  - Produces short chain fatty acid

- 2 FMT responders lost rpoB gene (resistance to rifaximin) over time

- Additional research needed to further describe the appropriate donor and recipient factors for FMT in patients with HE
Background:

- Tenofovir disoproxil fumarate (TDF) is a nucleotide reverse transcriptase inhibitor
- TDF is associated with risk of nephrotoxicity

Tenofovir Alafenamide (TAF): Background

- Tenofovir alafenamide (TAF) is a novel tenofovir prodrug
  - Enhanced hepatic delivery of active drug
  - Lower circulating levels of tenofovir vs TDF

- Prior study of pts with mod-severe kidney disease at 24 wks:
  - Persistent viral suppression
  - Stable or improved bone and renal function
Phase 2 Open-Label Study: 48 weeks

- **Aim:** Evaluate the safety/efficacy of switching from TDR to TAF after 48 weeks

- **N=93 pts (89% retention at Week 48)**
  - Cohort 1: moderate-severe renal insufficiency (eGFR$_{CG}$ 15 to < 60 mL/min); n=78
  - Cohort 2: end-stage renal disease (eGFR$_{CG}$ < 15mL/min); n=15

### Results

<table>
<thead>
<tr>
<th></th>
<th>Moderate-Severe RI</th>
<th>ESRD on HD</th>
</tr>
</thead>
<tbody>
<tr>
<td>HBV DNA &lt; 20 IU/mL</td>
<td>72/78 (92%)</td>
<td>14/15 (93%)</td>
</tr>
<tr>
<td>ALT normal</td>
<td>68/78 (87%)</td>
<td>12/15 (80%)</td>
</tr>
<tr>
<td>Hip BMD, % change</td>
<td>+0.27 (-0.67, 1.40)</td>
<td>-1.74 (-3.85, 1.17)</td>
</tr>
<tr>
<td>Spine BMD, % change</td>
<td>+1.06 (-0.83, 3.28)</td>
<td>-0.04 (-1.76, 3.63)</td>
</tr>
<tr>
<td>CTX, % change, (ng/mL)</td>
<td>-20.5 (-38.5, 0.0)</td>
<td>-14.2 (-47.6, 11.4)</td>
</tr>
<tr>
<td>P1NP, % change (ng/mL)</td>
<td>-15.25 (031.82, -0.76)</td>
<td>-20.55 (-35.62, 15.32)</td>
</tr>
<tr>
<td>Serum creatinine, change mg/dL</td>
<td>+0.03 (-0.07, 0.08)</td>
<td>n/a</td>
</tr>
<tr>
<td>Serum phosphorus, change mg/dL</td>
<td>0.0 (-0.1, 0.4)</td>
<td>n/a</td>
</tr>
<tr>
<td>eGFR$_{CG}$, change mL/min</td>
<td>-15.25 (031.82, -0.76)</td>
<td>-20.55 (-35.62, 15.32)</td>
</tr>
<tr>
<td>RBP/Cr, % change, ug/g</td>
<td>-42.4 (-67.4, -1.4)</td>
<td>n/a</td>
</tr>
<tr>
<td>B2MG/Cr, % change, ug/g</td>
<td>-50.9 (-81.1, 51.8)</td>
<td>n/a</td>
</tr>
</tbody>
</table>

**Conclusion:** TAF may be a safe and effective option for patients with CKD and hepatitis B infection
Discussion and Questions
Liver

Best of ACG 2021:
Inflammatory Bowel Disease

M. Anthony Sofia, MD
Assistant Professor of Medicine
Division of Gastroenterology and Hepatology
Oregon Health and Science University
S702: Evaluation of a Novel Pharmacy Program for Reducing Variation in Prescribing Biologics for Inflammatory Bowel Disease

Jennifer T. Chan, MD, Abhik Roy, MD, Navendu Samant, PhD, Fernando Velayos, MD, MPH

Methods:
- Four specialist IBD pharmacists supporting 143 gastroenterologists within an integrated healthcare organization (2016-2019)
- Referral to IBD pharmacist was at the discretion of the gastroenterologist
- Pharmacists followed an approved protocol
- IBD Pharmacist Biologic Protocol
  - Before initiation:
    - TB, Hepatitis B screening
  - After initiation:
    - Regular symptom assessment via email or phone
    - CRP, FCP, TDM after induction
    - Follow up with MD via EMR with results
Conclusions:

- Practice patterns differ between a pharmacist-gastroenterologist co-management model as compared to a traditional gastroenterologist-only model with regards to pre-biologic laboratory testing and laboratory monitoring following biologic initiation.

- An IBD pharmacist-gastroenterologist partnership model can be conducted across a large region through virtual communication, and does not require co-location of the pharmacist and gastroenterologist.
S902: Intestinal Ultrasound Response and Transmural Remission After 48 Weeks of Treatment With Ustekinumab in Crohn’s Disease: STARDUST Trial Substudy Results by Line of Treatment and by Location

Torsten Kucharzik, MD, PhD, Rune Wilkens, MD, PhD, Maria Antonietta D’Agostino, MD, PhD, Giovanni Maconi, MD, Manuela Le Bars, MD, Marjolein Lahaye, MSc, Ivana Bravatà, MD, Maciej Nazar, MD, PhD, Lioudmila Ni, MD, Elena Ercole, MD, Mariangela Allocca, MD, PhD, Nadezda Machkova, MD, Floris E. de Voogd, MD, PhD, Carolina Palmela, MD, Rose Vaughan, MD, Christian Maaser, MD

PRESIDENTIAL POSTER AWARD

Methods:
• Sub-study of STARDUST (phase 3b, RCT, compared T2T versus SoC protocols for ustekinumab in moderate to severe Crohn’s disease)
• IUS performed at baseline, W4, 8, 16, 48 in 88 patients from both groups with central reader
• Bowel wall thickness (BWT) change from baseline (mm)
• IUS response: ≥25% reduction in BWT from baseline
• Normalization of:
  • BWT predefined (≤ 2.0mm ileum; ≤ 3.0mm colon) and new (≤ 3.0mm overall)
  • Bowel wall echostratification (BWS)
  • Vascularization (Color Doppler imaging signal ≤ 1)
  • Absence of inflammatory mesenteric fat (i-Fat)
• Transmural remission (TMREM):
  • Normalization of BWT, BWS, vascularization and i-Fat
Figure 2. Mean change from baseline in BWT over time for all patients in IUS substudy

- Overall BWT decreased.
- Biologic naïve subjects had greater reduction in BWT.
- Colon wall thickness changed more than ileal wall thickness.

Figure 3A. Percentage of patients with IUS response or TMREM (using two definitions) at Week 48 for all patients in the IUS substudy – overall and by most affected bowel segment

- IUS response and TMREM were numerically more common in colon predominant inflammation
- BWT normalization and absence of inflammatory fat were also somewhat more likely in colon predominant inflammation.
- Normalization of BWS and vascularization were similar between locations of inflammation.
Conclusions:

- This is the first interventional, multicenter study using IUS with central reading in patients with Crohn’s disease

- BWT decreases in response to ustekinumab with colon BWT more responsive than ileal

- A numerically higher transmural remission with ustekinumab was noted in colon compared to ileum, increasing progressively over time up to week 48.

Discussion and Questions

Inflammatory Bowel Disease
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