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**2023**

**OCTOBER**  
20-25, 2023  
VANCOUVER, CANADA


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 **Virtual Grand Rounds**  
Best of ACG 2022: Outstanding Science, Expert Discussions

# Moderators

Vivek Kaul, MD, FACC

Vladimir M. Kushnir, MD

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## Participating in the Webinar

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

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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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## How to Receive CME and MOC Points

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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, 2023 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, 2024 for this activity.

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## 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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## ACG Virtual Grand Rounds

Join us for upcoming Virtual Grand Rounds!



**Week 10 – Thursday, March 9, 2023**  
 The Role of Genetic Testing in Early Colorectal Cancer Detection  
 Faculty: Jordan J. Karlitz, MD, FACG; Heather L. Hampel, MS, CGC; and Candace Peterson, MS, CGC  
 At Noon and 8pm Eastern



**Week 11 –Thursday, March 16, 2023**  
 CRC Screening: How Can We Improve?  
 Faculty: Aasma Shaukat, MD, MPH, FACG  
 At Noon and 8pm Eastern

Visit [gi.org/ACGVGR](https://gi.org/ACGVGR) to Register

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# ACG

# 2023

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## Disclosures

Vivek Kaul, MD, FCG: Castle Biosciences: Consultant; COOK Medical: Consultant; CDX Diagnostics: Consultant; Motus GI: Consultant; Steris: Consultant

Vladimir M. Kushnir, MD: Allurion Therapeutics: Research Support; Apollo Endo-Surgery: Consultant; BSCI: Consultant; Cook Medical: Consultant; Medtronic: Consultant

Sarah M. Enslin PA-C: Castle Biosciences: Consultant; Exact Sciences: Consultant; Regeneron Pharmaceuticals: Consultant


Prabhleen Chahal, MD, FCG: Medtronic: Advisory Board; BSCI: Consultant

*\*All of the relevant financial relationships listed for these individuals have been mitigated  
All other individuals have no relationships with ineligible companies.*


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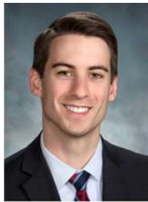
## Presenters




Sarah M. Enslin, PA-C




Daniel Castaneda, MD



Adam Buckholz, MD




Daniela Guerrero Vinsard, MD




Amer AlSamman, MD


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## Panelists




Ryan B. Perumpail, MD




Jean Chalhoub, MD



Prabhleen Chahal, MD, FACG





Aparna Repaka, MD



Brandon A. Wuerth, MD

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## Endoscopy / Pancreas

### **Sarah Enslin, PA-C**

Division of Gastroenterology & Hepatology  
University of Rochester Medical Center  
Rochester, NY, USA

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**Session: Plenary Session 2B - Endoscopy / Stomach / GI Bleeding**

## 34 - Distal Cap-Assisted Endoscopic Mucosal Resection Is a Safe and Effective Technique for Resection of Non-Lifting or Adherent Colorectal Polyps: An International, Multicenter, Retrospective Study

*Scott R. Douglas, MD, Douglas K. Rex, MD, MACG, Alessandro Repici, MD, Melissa Kelly, BSN, RN, CGRN, Wes Heinle, MPH, Matthew T. Moyer, MD, MS*

### ➤ Background:

- Non-lifting/fibrotic colon polyps can be difficult to remove
- Fibrosis may be caused by prior biopsy sampling, submucosal tattoo, prior resection attempts or invasive pathology

### ➤ Aim:

- Evaluate the safety and efficacy of distal cap-assisted endoscopic mucosal resection (EMR-DC) for the removal of non-malignant colonic lesions with submucosal fibrosis

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## DC-EMR is a Safe and Effective Technique for Resection of Non-Lifting or Adherent Colorectal Polyps

- 3 international centers, retrospective study
- N=61 patients
- Mean age 67 yr
- Anticoagulation use:
  - ASA: 36.1%
  - Antiplatelet: 4.9%
  - DOAC/Warfarin: 9.8%
- > 50% pts had previous abdominal surgery

### Lesion Characteristics

- Prior attempted polypectomy/EMR: 89%
- Prior submucosal tattoo injection: 1.6%
- Prior biopsy: 4.9%
- Prior biopsy/tattoo: 4.9%
- Lesion size: 15-95mm (average 49mm)

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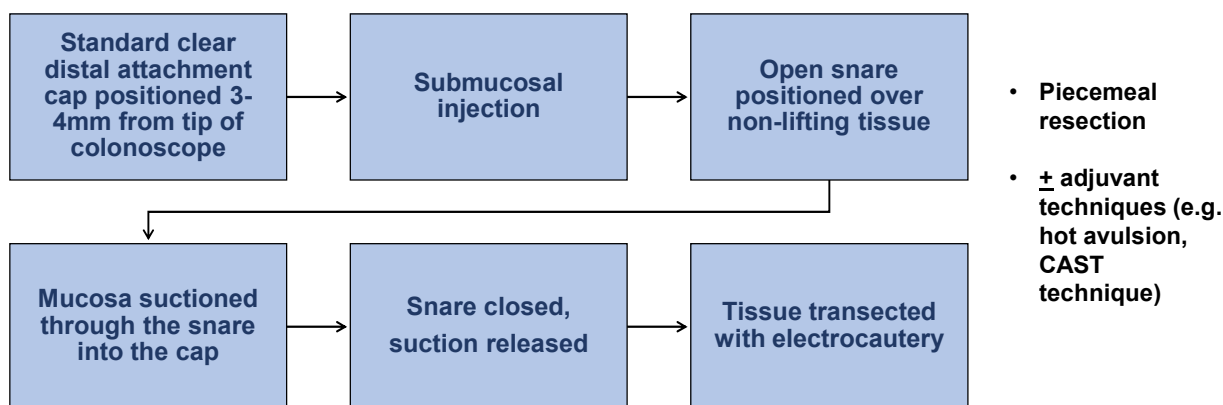




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## DC-EMR is a Safe and Effective Technique for Resection of Non-Lifting or Adherent Colorectal Polyps

### ➤ Technique:



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## DC-EMR is a Safe and Effective Technique for Resection of Non-Lifting or Adherent Colorectal Polyps

### ➤ Results:

- **Complete macroscopic resection: 100%**
- Average procedure time: 49.5 minutes
- **Residual Adenoma at 6 mo: 9.8%**
- Serious AE: 3.3% (n=2)
  - Post-procedure bleeding requiring repeat colonoscopy (n=1)
  - Post-polypectomy syndrome requiring hospitalization (n=1)

**Conclusion: DC-EMR is a safe and effective technique for removal of adherent and non-lifting colon polyps**

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Session: Presidential Plenary Session 1

## 4 - Results of First Round of Enrollment from the Screening for Pancreatic Cancer in High-Risk Individuals (Pancreas Scan Study): A Prospective Multi-Center Study

*Ishani Shah, MD, Andy Silva-Santisteban, MD, Katharine A. Germansky, MD, Rishi Pawa, MBBS, Vladimir Kushnir, MD, Arvind Trindade, MD, Jiannis Anastasiou, MD, Kara L. Raphael, MD, Girish Mishra, MD, Sumant Inamdar, MD, Benjamin Tharian, MD, Mandeep S. Sawhney, MD*

### ➤ Background:

- Early detection of pancreatic cancer is the most effective way to improve survival
- Consensus guidelines recommend screening of HRIs (high risk individuals)
- Limited data on outcomes of pancreas cancer screening

### ➤ Aim:

- Evaluate yield, harm and outcomes of pancreas cancer screening in HRIs

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## Results of First Round of Enrollment from the Screening for Pancreatic Cancer in HRI (Pancreas Scan Study)

- Prospective, multicenter study
- N=252 pts
  - EUS = 208, MRCP = 44
  - First screening exam: 97 pts (38.5%)
- Age  $\geq$  18yo

### Indication for pancreas cancer screening:

- Familial pancreatic cancer (31.7%)
- BRCA2 (29%)
- BRCA1 (7.5%)
- ATM (3.5%)
- Lynch syndrome (6.7%)
- Peutz-Jeghers (4.3%)
- FAMMM (3.5%)
- **Did not meet guideline criteria (13%)**

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## Prevalence of Pancreatic Pathology Among HRI Undergoing Screening

Pancreatic Pathology	Prevalence
<b>23.4%</b> Low-risk lesions	
Fatty pancreas	15 (5.95%)
CP-like changes	44 (17.5)
Definitive CP (Rosemont criteria)	0
<b>31.7%</b> Intermediate-risk lesions	
BD-IPMN	79 (31.3%)
Pt with multiple BD-IPMN	35 (44.3%)
Net < 1cm	1 (0.4%)
<b>0.8%</b> High-risk lesions	
MD-IPMN	0

Pancreatic cancer (n=2)  
Both pts BRCA2 mutation +

- T2N1M0 (Stage IIB): neoadjuvant therapy, surgical resection ← Compliant w/screening
- T2N1M1 (Stage IV): palliative chemotherapy ← Lost to f/u x 6 yrs

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## Results of First Round of Enrollment from the Screening for Pancreatic Cancer in HRI (Pancreas Scan Study)

### ➤ Results (continued):

- 4.8% of pts underwent further evaluation (EUS in 8pts, MRCP in 4pts) as a result of screening results
- No AEs from screening tests or further interventions

### Conclusion:

- High risk lesions detected in 0.8%
- Intermediate risk lesions in 31.7%
- Findings prompted further testing in ~5% of pts
- No low-yield surgeries were performed

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## E0009 - Radiofrequency Ablation With Stent versus Stent-Only for Biliary Tree Drainage in Patients With Malignant Biliary Strictures: A Systemic Review and Meta-Analysis

*Umar Hayat, MBBS, Cyrus Munguti, MD, Muhammad Kamal, MD, Muhammad Haseeb, MD, MSc*

### ➤ Background:

- Palliative stent placement is effective for biliary decompression of malignant obstruction from cholangiocarcinoma and adenocarcinoma
- Intraductal RFA has been shown to improve overall stent patency and survival

### ➤ Aim:

- Assess the efficacy and safety of biliary stenting with RFA vs stent alone for management of malignant biliary strictures

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## RFA + Stent vs Stent-Only for Biliary Tree Drainage in Patients with Malignant Biliary Strictures

### ➤ Systematic review and meta-analysis

### ➤ 13 studies, 1339 patients

### ➤ Results:

- Stent patency: RFA > stent alone
  - Pooled weighted mean difference 43.5 days
- Overall survival: RFA > stent alone

***Conclusion: RFA + biliary stenting is safe and associated with improved stent patency and overall survival compared to biliary stenting alone in the management of malignant biliary strictures***

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# Inflammatory Bowel Disease Abstracts



Daniel Castaneda, MD  
Consultant Gastroenterologist  
Cone Health Annie Penn Hospital, Reidsville, NC

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# Inflammatory Bowel Disease Abstracts

## *Ulcerative colitis*

- **Feagan et al:** Benefits of High versus Low Dose Upadacitinib as Maintenance Treatment in Ulcerative Colitis Patients Who Were Responders to 8-week Induction with Upadacitinib: Results From the U-ACHIEVE Phase 3 Maintenance Trial.

The American Journal of Gastroenterology.  
117(10S):e496, October 2022.

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### Methods

- Post-hoc analysis from U-ACHIEVE trial patients that had response to 8-week upadacitib (UPA) induction.
- Patients re-randomized 1:1:1 to 15 mg, 30 mg or placebo daily for 52 weeks.
- Clinical remission and severity was evaluated with Partial Adapted Mayo Score.
- Area under the curve (AUC) analysis for each group to determine number of weeks in remission.
- Sub-analysis in patients <65 years.

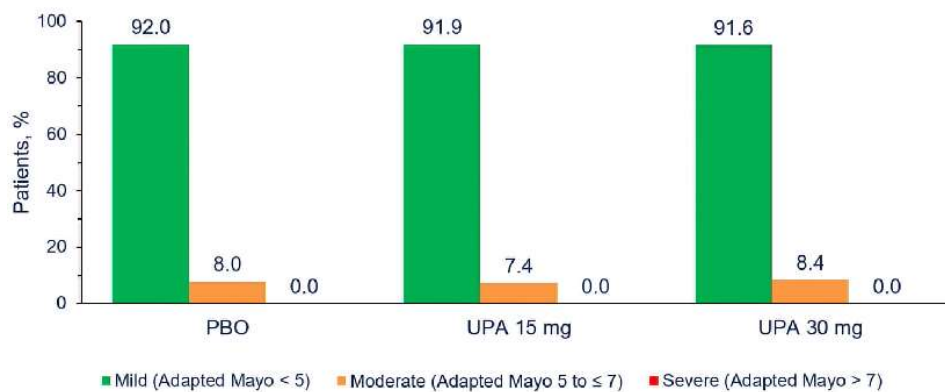
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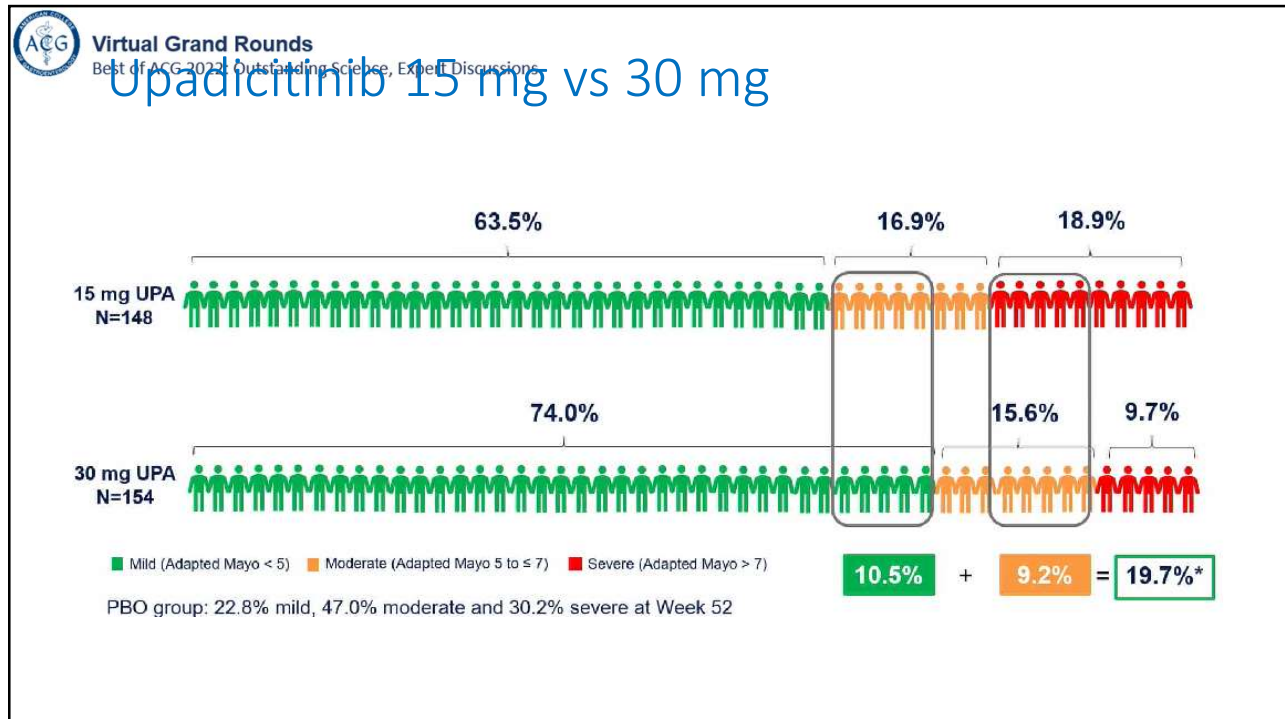
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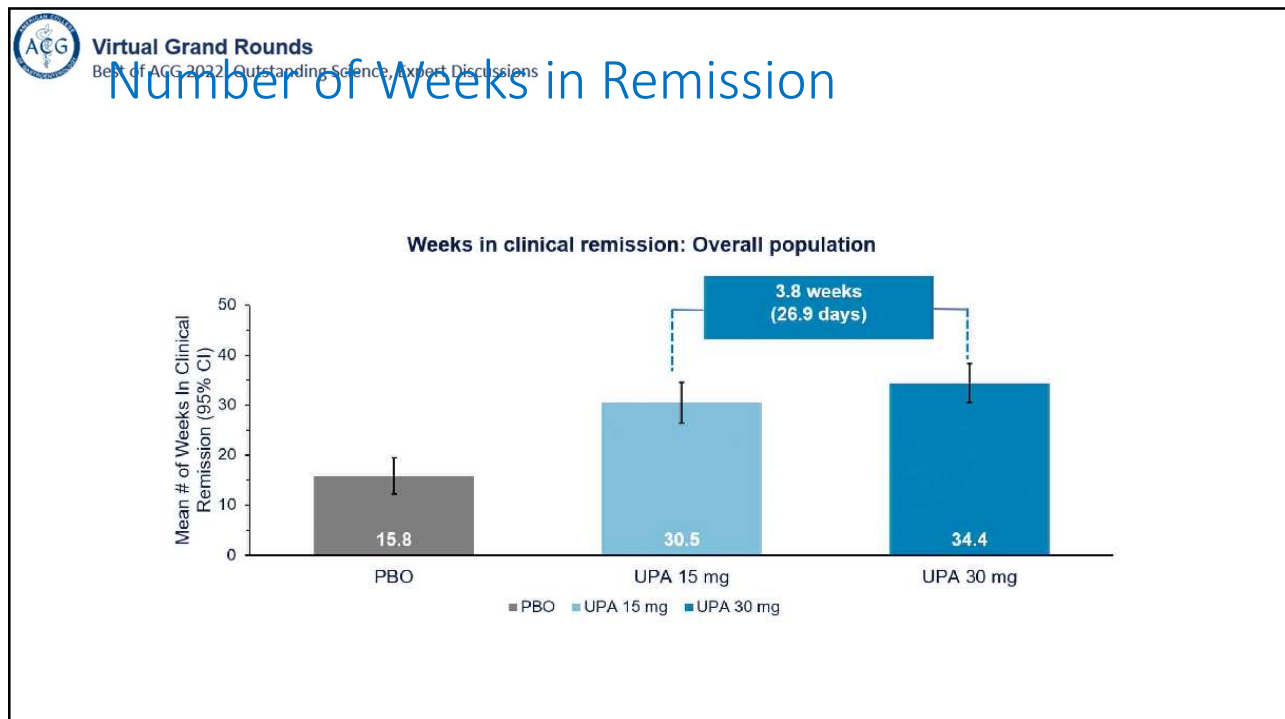
### Baseline – Groups by Severity of Disease



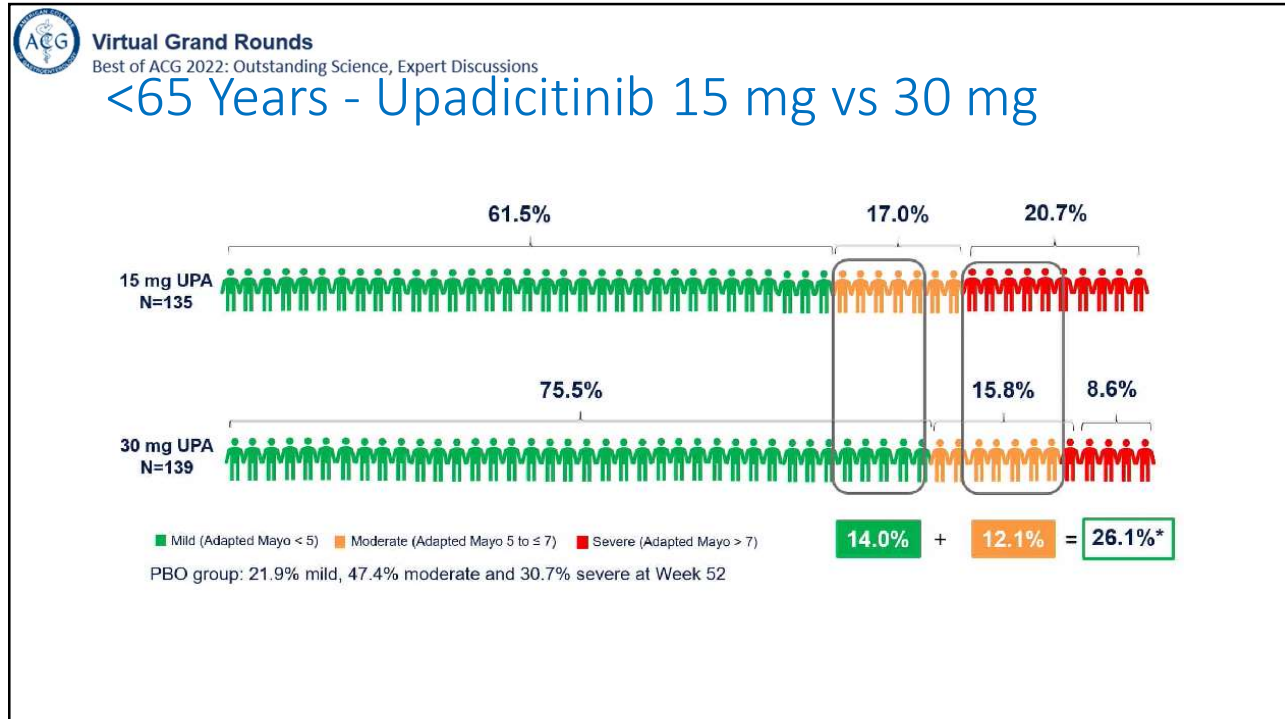
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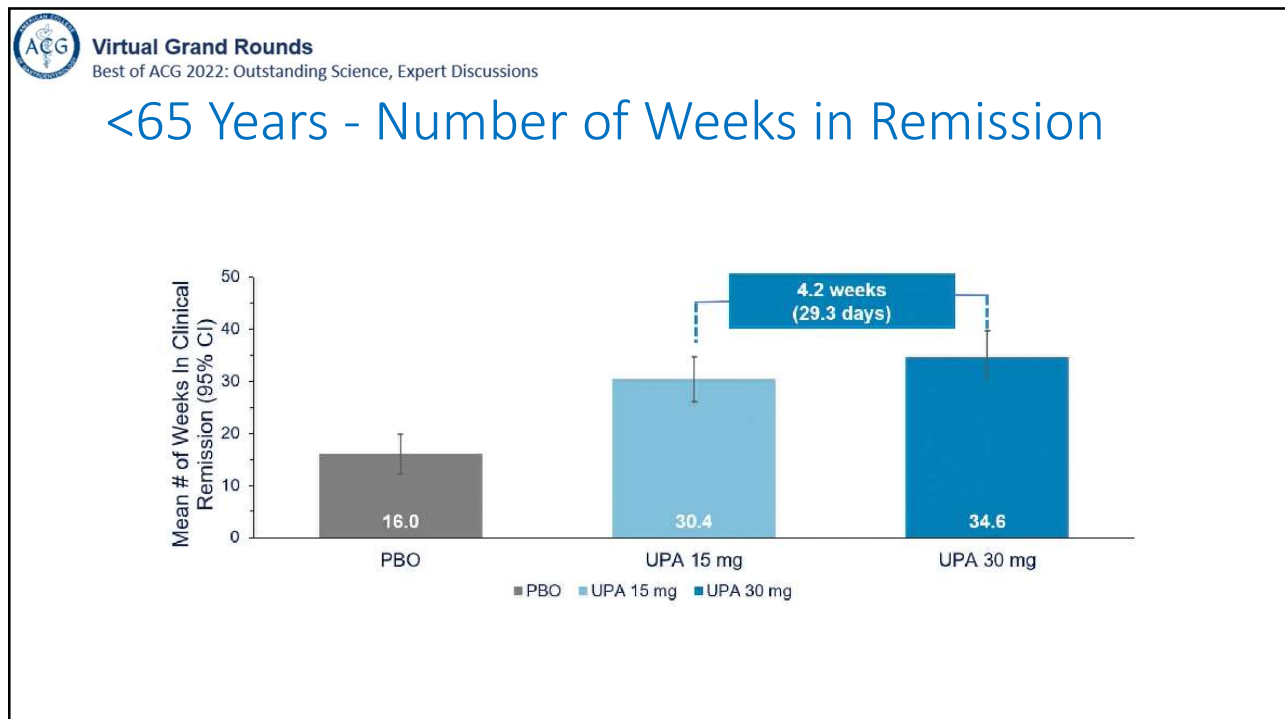
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## Conclusions

- After 52 weeks of maintenance with UPA for ulcerative colitis, patients with 30 mg daily dosing had less severe disease compared to 15 mg daily.
- There was a longer remission interval with UPA 30 mg compared to UPA 15 mg every day.
- In patients younger than 65 years, there was a presence of milder disease and longer remission interval with 30 mg dosing in patients younger than 65 years.

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## Inflammatory Bowel Disease Abstracts

### Crohn's disease

- **Ferrante et al:** Clinical and Endoscopic Improvements With Risankizumab Induction and Maintenance Dosing versus Placebo Are Observed Irrespective of Number of Prior Failed Biologics

The American Journal of Gastroenterology.  
117(10S):e496-e497, October 2022.

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## Methods

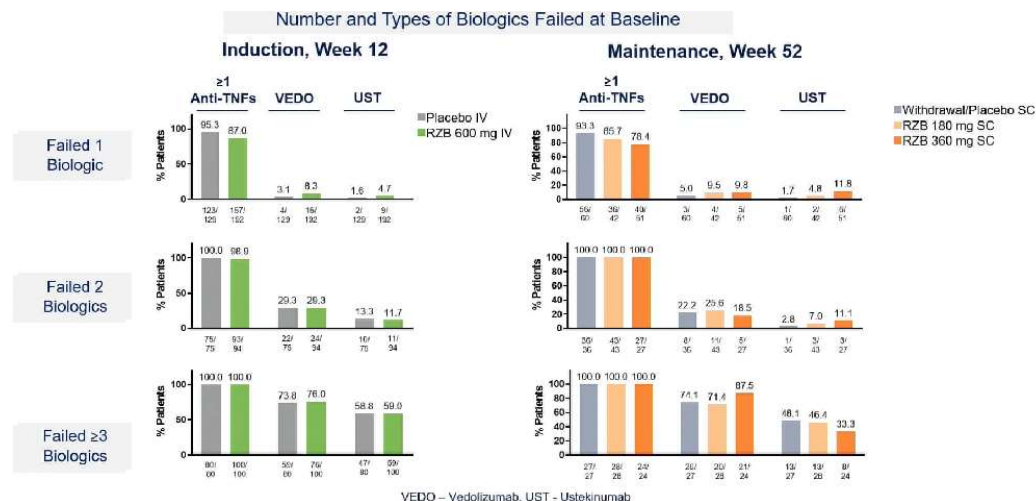
- Post-hoc analysis from 3 studies (ADVANCE, MOTIVATE and FORTIFY) evaluating the efficacy and safety of risankizumab (RZB) for moderate-severe Crohn's disease in patients who have failed other biologics.
- Patients were on placebo (PBO) or RZB 600 mg for induction – outcome at week 12.
- Maintenance: PBO, RZB 180 mg, RZB 360 mg every 8 weeks – outcome at week 52.
- Clinical - stool frequency (SF), abdominal pain score (APS), CDAI.
- Endoscopic - response, remission and ulcer-free endoscopy.
- Deep remission.

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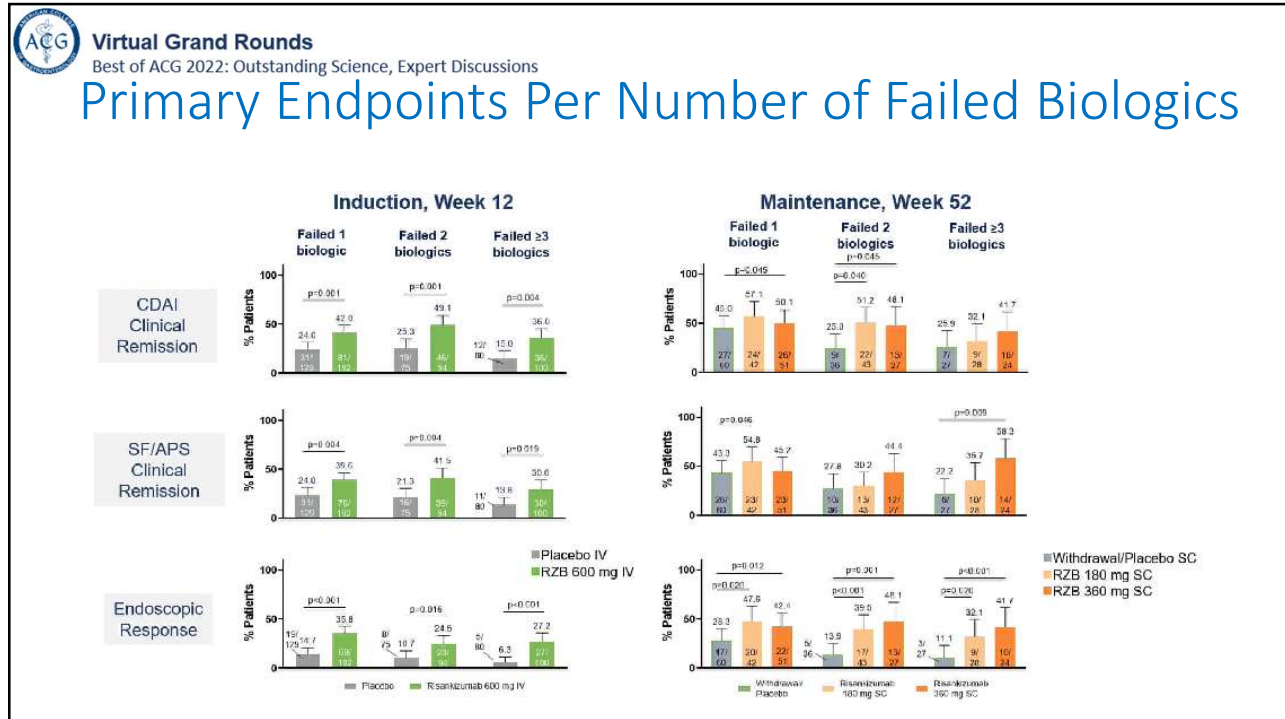


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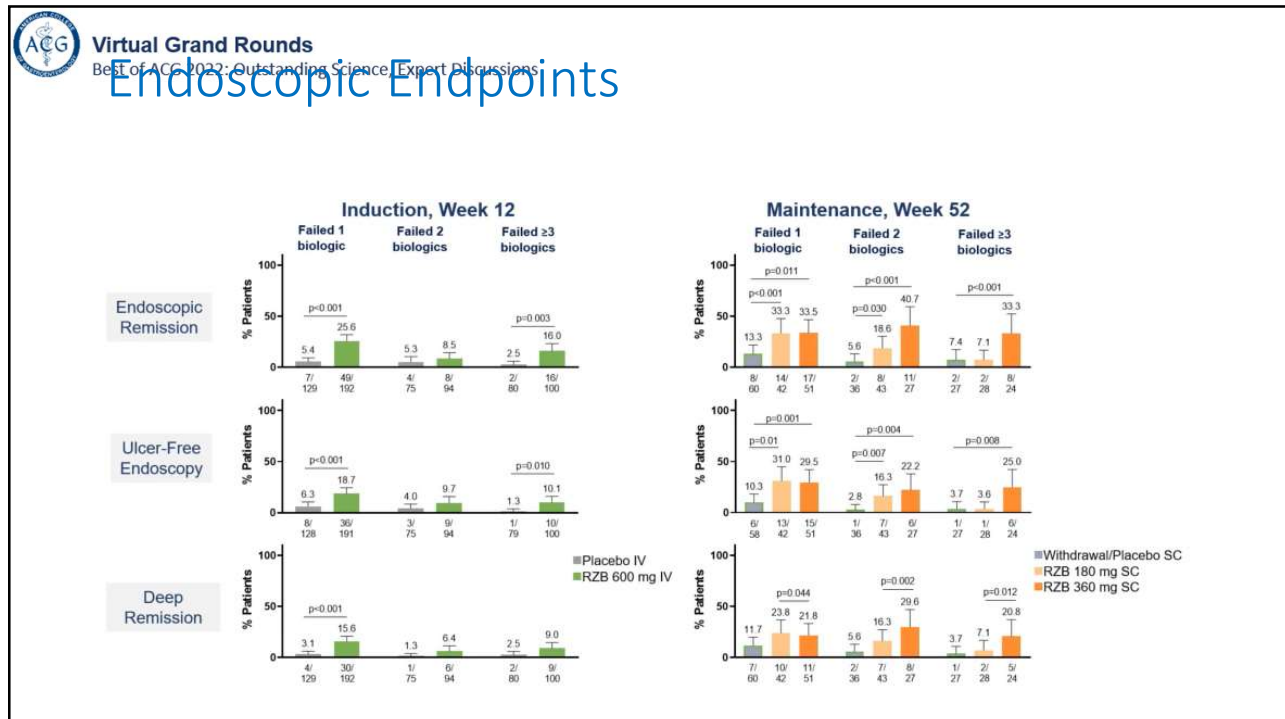
## Baseline Prior Biologic Use



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## Safety Results

- No difference in the incidence of adverse events or new safety signals based on the number of biologicals.

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## Conclusions

- Rizankizumab is an effective treatment for moderate-severe Crohn's disease, irrespective of the number of biologicals used.
- For maintenance, rizankizumab 360 mg was associated with better endoscopic and clinical outcomes compared to 180 mg dosing, specifically in patients who had failed 2 or more biologicals.
- Rizankizumab was safe, irrespective of the number of biologicals used.

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# Liver

Adam Buckholz, MD

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## Terlipressin Treatment of Patients With Hepatorenal Syndrome Type 1 Decreased the Need for Renal Replacement Therapy in Transplant Recipients: A 12-Month Follow-Up of the CONFIRM Study

Khurram Jamil, MD; Ethan Weinberg MD; Rajender Reddy MD,  
FACG

University of Pennsylvania and Mallinckrodt Pharmaceuticals

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# Background and Aims

- The CONFIRM trial demonstrated benefit of terlipressin over placebo for the reversal of HRS Type 1 (Wong et al NEJM 2021)
- However, a similar number of patients underwent subsequent transplant in both groups
- Among those who underwent transplant, did use of terlipressin alter risk of subsequent RRT or death?

Table 3. Additional Secondary End Points Assessed at Days 14, 30, 60, and 90.<sup>20</sup>

End Point	Terlipressin (N=199)	Placebo (N=101)
	<i>number of patients (percent)</i>	
Received renal-replacement therapy		
Day 14	45 (23)	35 (35)
Day 30	51 (26)	36 (36)
Day 60	56 (28)	38 (38)
Day 90	58 (29)	39 (39)
Underwent liver transplantation		
Day 14	19 (10)	15 (15)
Day 30	32 (16)	22 (22)
Day 60	43 (22)	28 (28)
Day 90	46 (23)	29 (29)

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# Methods and Patient Characteristics

- Eligible patients had HRS-1 defined as doubling of creatinine to 2.25 mg/dL or greater within 14 days, cirrhosis and ascites
  - Those with improvement with albumin challenge were excluded
- Treatment was for up to 14 days barring TIPS, RRT, etc
- 300 patients (199 terlipressin, 101 placebo) were randomized, and 75 (46 terlipressin/29 placebo) underwent LT within 90 days
- Study compared need for pre-transplant RRT, RRT at 180 days, RRT at 365 days, and overall survival at 365 days

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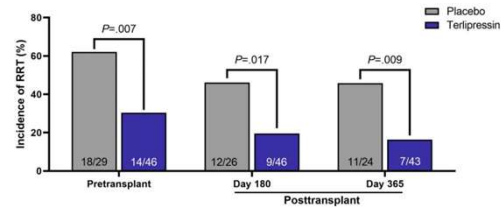


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## Results and Discussion

- At all time points, terlipressin significantly reduced the need for renal replacement therapy at  $p < 0.05$
- There was a trend towards improvement in overall survival at 12 months (94% vs 83%,  $p = 0.09$ )
- While liver transplant is considered definitive treatment in HRS-1, this study suggests that aggressive pre-transplant management, potentially with terlipressin, improves overall renal outcomes even after transplant.



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## Comparison of Baveno VI Criteria, Expanded Baveno VI Criteria, Chess Alarm Score and Other Noninvasive Scores for Predicting Esophageal Varices and Varices Needing Treatment

Nimy John MD, Yash Shah MD, Cody Timmerman MD, Fares Mashal MD, Matthew Deneke MD, Mary Rude MD, Ragesh Thandassery MD DM

University of Arkansas Little Rock

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# Background and Aims

- Screening EGD remains a mainstay for preventing morbidity from esophageal variceal hemorrhage (EVH)
- The Baveno VI criteria set standards for those at low risk for primary bleed, thus potentially avoiding unnecessary endoscopies utilizing lab and transient elastography
- This study sought to evaluate these parameters in a real world North American population and in comparison to other non-invasive markers for fibrosis severity

### *Identification of patients with cACLD who can safely avoid screening endoscopy (new)*

- Patients with a liver stiffness <20 kPa and with a platelet count >150,000 have a very low risk of having varices requiring treatment, and can avoid screening endoscopy (1b:A).
- These patients can be followed up by yearly repetition of TE and platelet count (5;D).
- If liver stiffness increases or platelet count declines, these patients should undergo screening esophagogastroduodenoscopy (5;D).

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# Methods and Evaluated Scoring Systems

- 424 patients in a single center between 2015-2021 undergoing screening EGD
  - 43% male, 73% Caucasian
  - NAFLD (55%) and HCV (33.7%) most common etiologies of cirrhosis
- 126 had EV and 32 (7.5%) had varices needing treatment
- Scores included
  - Baveno VI criteria (LSM>20 or plt<150)
  - Expanded Baveno VI criteria (LSM>25 or plt<110)
  - MELD-Na
  - CHES-ALARM score (includes age, gender, platelet count, liver stiffness)
  - APRI (AST and platelets)
  - Fib-4 score (Age, ALT, AST, platelets)

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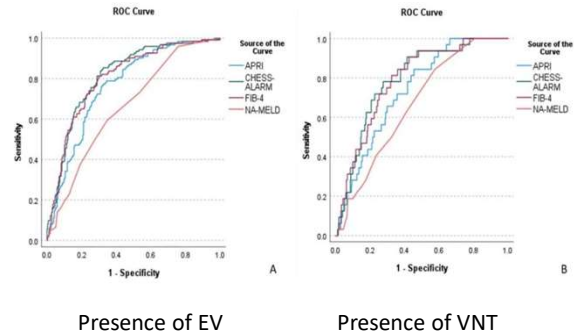


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# Results and Discussion

- Of 126 patients with EV, 87.7% met Baveno criteria and 77.4% expanded Baveno criteria
- Highest predictive accuracy (defined by AUROC) for ruling in presence of varices was Baveno VI criteria (0.931) and for varices needing treatment was expanded Baveno VI criteria (0.983)
- Fib-4 performed best of tests not requiring LSM, but all were similar and worse than Baveno
- Incorporating LSM appears to offer improved predictive value for presence of varices/high risk varices in a real life clinical cohort
  - Further studies need to prospectively evaluate clinical consequences of the “rule out”



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# INNOVATION IN ARTIFICIAL INTELLIGENCE



Daniela Guerrero Vinsard, MD  
Gastroenterology and Hepatology  
Mayo Clinic, Rochester, MN, USA

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# Innovation in Artificial Intelligence

## 1. Artificial Intelligence Identifies High Risk Patients Lost to Colon Cancer Screening Follow-Up During COVID-19 Pandemic

Feuerstein et al.

*The American Journal of Gastroenterology* 117(10S):p e221,  
October 2022.

## 2. Validation of a Deep Machine Learning Tool to Determine Intra-Procedural Screening Colonoscopy Quality Indicators in an Academic Health System

Galoosian et al.

*The American Journal of Gastroenterology* 117(10S):p e204-e205,  
October 2022.

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## Artificial Intelligence Identifies High Risk Patients Lost to Colon Cancer Screening Follow-Up During COVID-19 Pandemic

- During the SARS-COV2 pandemic, many CRC screening programs were paused, affecting patients due for screening or surveillance colonoscopy.
- Aim: To identify high risk patients who are overdue for surveillance colonoscopy using AI (Natural Language Processing) and the reasons for missed colonoscopy.

Feuerstein et al.

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## Artificial Intelligence Identifies High Risk Patients Lost to Colon Cancer Screening Follow-Up During COVID-19 Pandemic

- **The NLP system:**
  1. The NLP used OCR (optical character recognition) to convert typed text in endoscopy reports into machine-encoded text.
  2. The reports were linked with EHR data to determine the **indication** and **timing** of surveillance.
- **Human review:**
  1. Data was manually reviewed to assess reasons for missing surveillance and to assess accuracy of the NLP (96%).

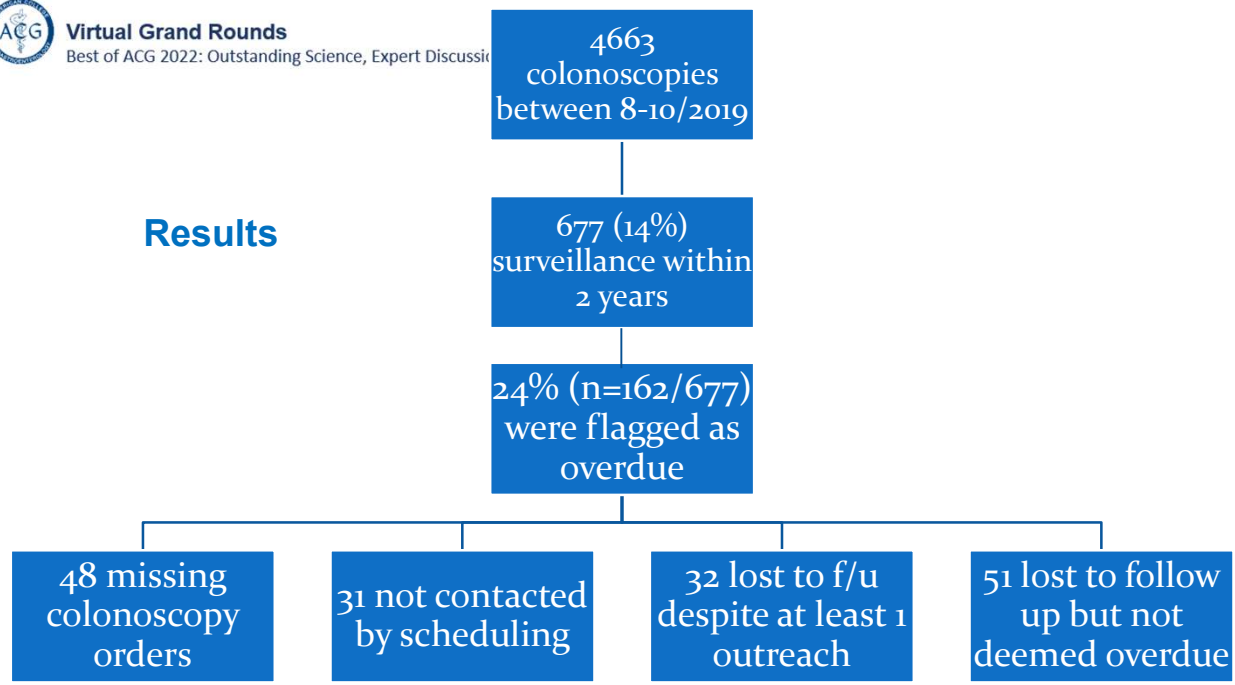
Feuerstein et al.

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### Results



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#### Strengths:

- ❑ Automated flagging of patients overdue for surveillance colonoscopy.
- ❑ Implementation of safety net in EMR system for high-risk patients.
- ❑ Optimization of systems and operations. (Exp. placing orders, automatic reminders to patients)

#### Limitations:

- ❑ Many patients (51%) flagged were not overdue: did have a colonoscopy elsewhere, passed away, etc.
- ❑ Flagged cases will still need human verification → time → effort.

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## Validation of a Deep Machine Learning Tool to Determine Intra-Procedural Screening Colonoscopy Quality Indicators in an Academic Health System

- Aim: To develop and validate an NLP (Natural Language Processing) tool to automatically measure 4 colonoscopy quality metrics:
  1. colonoscopy indication (IND)
  2. bowel preparation (BP)
  3. cecal intubation (CI)
  4. successful cecal intubation (SCI).

Galoosian et al.

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## Validation of a Deep Machine Learning Tool to Determine Intra-Procedural Screening Colonoscopy Quality Indicators in an Academic Health System

- The NLP was trained to automatically extract these QI indicators from endoscopy reports.
- The NLP performance was compared to manual chart review (gold standard) in 600 colonoscopies.
- When NLP and manual review were discordant, another physician performed manual review to resolve it.

Galoosian et al.

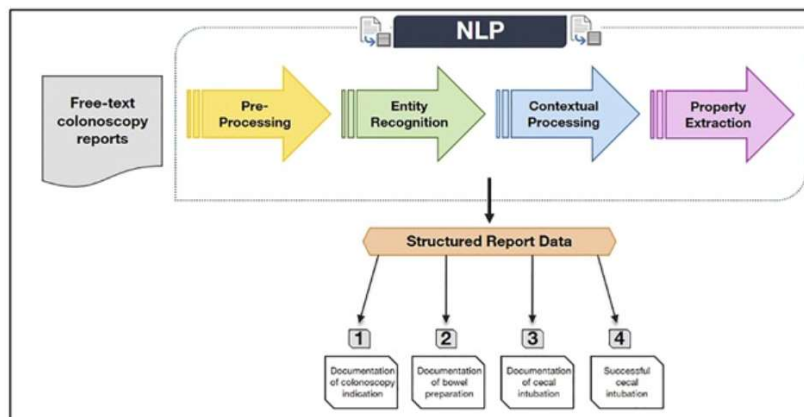
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## Results

For all metrics, the NLP sensitivity ranged from 99.3 to 100.0% and specificity ranged from 94.3 to 100.0%



- Compared to humans, NLP misclassified 15 cases (2 IND, 1 BP and 12 SCI). These were mostly due to conflicting documentation by the endoscopist in the endoscopy report.

Galoosian et al.

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#### Strengths:

- ❑ NLP automatically processes and structures data from all new daily colonoscopy reports.
- ❑ Automated extraction of QI indicators can inform where to invest resources for quality improvement in colonoscopy.

#### Limitations:

- ❑ NLP reads and codes what is documented by endoscopist (including human errors). If there is an error in documentation, NLP will misclassify this indicator.

Exp: endoscopist not mentioning the word “cecum” or documenting “terminal ileum” instead.

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## General GI and Esophagus

Amer AlSamman, MD



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## Esophagus

- Fass et al, Efficacy and Safety of On-Demand Vonoprazan versus Placebo in the Treatment of Heartburn in Symptomatic Nonerosive Reflux Disease (NERD) Patients: A Phase 2 Randomized Controlled Trial.
- Dellon et al, Dupilumab Improves Clinical, Symptomatic, Histologic, and Endoscopic Aspects of EoE up to 24 Weeks: Pooled Results From Parts A and B of Phase 3 LIBERTY-EoE-TREET

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## Efficacy and Safety of On-Demand Vonoprazan versus Placebo in the Treatment of Heartburn in Symptomatic Nonerosive Reflux Disease (NERD) Patients: A Phase 2 Randomized Controlled Trial

Fass, Ronnie MD<sup>1</sup>; Vaezi, Michael F. MD<sup>2</sup>; Sharma, Prateek MD<sup>3</sup>; Yadlapati, Rena MD, MS<sup>4</sup>; Hunt, Barbara MSc<sup>5</sup>; Harris, Tom BSc<sup>5</sup>; Smith, Neila MD<sup>5</sup>; Leifke, Eckhard MD<sup>5</sup>; Armstrong, David MA, MBBCh, FACG<sup>6</sup>

*The American Journal of Gastroenterology* [117\(10S\):p e272-e273, October 2022.](#) | DOI: 10.14309/01.ajg.0000858200.17525.4a

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## Background

- Vonoprazan, a potassium-competitive acid blocker, rapidly and profoundly suppresses gastric acid.
- Current treatment for NERD is daily acid-suppressive therapy; however, on-demand treatment is an attractive option for long-term management.
- The aim of this study was to evaluate the efficacy and safety of vonoprazan vs placebo for on-demand treatment of symptomatic NERD

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## Methods

- Phase 2, double-blind, placebo-controlled study.
- NERD patients (normal endoscopy, heartburn episodes for  $\geq 6$  months, heartburn on  $\geq 4/7$  consecutive days).
- They were enrolled into a 4-week run-in period of once-daily vonoprazan 20mg.
- Patients without heartburn in the last 7 days of the run-in period were randomized 1:1:1:1 to receive vonoprazan 10mg, 20mg, 40mg, or placebo on-demand for 6 weeks.

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## Methods

- No more than one dose of study drug for 24h after a heartburn episode.
- No rescue antacids  $\leq 3$ h after taking study drug.
- Patients recorded heartburn symptoms, drug and antacid use in an electronic diary.

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## Methods

- The primary endpoint was the % of evaluable heartburn episodes with complete and sustained relief (within 3h and with no further heartburn reported for 24h after taking study drug).
- The onset of complete and sustained relief was evaluated within 30 min and 1, 1.5, 2, and 3h after study drug.

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## Results

- 458 patients entering the run-in period, 207 (females: 125; mean age: 54y).
- In the Vonoprazan 10, 20, and 40mg groups; 56.0% (201/359), 60.6% (198/327) and 70.0% (226/323) of heartburn episodes met the criteria for complete and sustained relief, respectively, vs 27.3% (101/370) for placebo ( $P < 0.0001$  for each vonoprazan treatment vs placebo).

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Endpoint	Vonoprazan 10 mg n=52	Vonoprazan 20 mg n=52	Vonoprazan 40 mg n=51	Placebo n=52
Heartburn episodes with complete and sustained relief within 3 hours <sup>a</sup>				
n/N evaluable episodes <sup>b</sup> (%)	201/359 (56.0)	198/327 (60.6)	226/323 (70.0)	101/370 (27.3)
<i>P-value (vs placebo)</i>	< 0.0001	< 0.0001	< 0.0001	-
Timing of complete and sustained relief <sup>a</sup> , n/N evaluable episodes <sup>b</sup> (%)				
Within 30 minutes	31/359 (8.6)	17/327 (5.2)	9/323 (2.8)	21/370 (5.7)
<i>P-value (vs placebo)</i>	0.15	0.87	0.09	-
Within 1 hour	101/359 (28.1)	63/327 (19.3)	74/323 (22.9)	44/370 (11.9)
<i>P-value (vs placebo)</i>	< 0.0001	0.0083	0.0002	-
Within 1.5 hours	151/359 (42.1)	103/327 (31.5)	139/323 (43.0)	67/370 (18.1)
<i>P-value (vs placebo)</i>	< 0.0001	< 0.0001	< 0.0001	-
Within 2 hours	182/359 (50.7)	151/327 (46.2)	187/323 (57.9)	81/370 (21.9)
<i>P-value (vs placebo)</i>	< 0.0001	< 0.0001	< 0.0001	-
<sup>(a)</sup> Complete and sustained relief is defined as complete relief with no antacid taken within the indicated time frame after taking study drug and no further heartburn reported for 24 hours after taking study drug.				
<sup>(b)</sup> An evaluable heartburn episode is defined as any for which study drug was taken and for which the subject completed $\geq 1$ entry in the heartburn episode diary.				

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## Dupilumab Improves Clinical, Symptomatic, Histologic, and Endoscopic Aspects of EoE up to 24 Weeks: Pooled Results From Parts A and B of Phase 3 LIBERTY-EoE-TREET

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## Background

- Dupilumab, a fully human mAb, blocks the shared receptor component for IL-4/IL-13, key and central drivers of type 2 inflammation.
- Eosinophilic esophagitis (EoE) is a chronic, progressive, type 2 inflammatory disease of the esophagus.
- Current treatment offers suboptimal long-term disease control.

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## Methods

- Three-part, randomized, placebo-controlled phase 3 study.
- Randomized 1:1 to weekly dupilumab (N=122) or placebo (N=118).
  
- Endpoints (all at Week 24):
  - 1- Proportion of patients achieving peak eosinophil count  $\leq 6$ /high-power field (hpf).
  - 2- Absolute and % change in Dysphagia Symptom Questionnaire (DSQ) score.
  - 3- % change in peak eosinophil count.

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## Results

- Endpoints (all at Week 24):
  - 4- Absolute change in Histologic Scoring System (HSS) grade and stage scores and Endoscopic Reference Score (EREFs).
  
  - 5- proportion of patients achieving peak eosinophil count  $< 15$ /hpf.
  
- Binary endpoints were assessed using the Cochran-Mantel-Haenszel (CMH) test. Continuous endpoints were analyzed using an analysis of covariance (ANCOVA) model.

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## Methods

- Pinch biopsies were collected from 3 esophageal regions (proximal, mid, distal) at screening and Week 24 for histology.
- The Dysphagia Symptom Questionnaire is a patient-reported outcome measure that is administered daily and assesses the frequency and severity of dysphagia. The biweekly total DSQ score ranges from 0 to 84; higher scores indicate greater dysphagia-related symptom burden.

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## Methods

- Biopsies were scored for eosinophil density, basal zone hyperplasia, eosinophil abscesses, eosinophil surface layering, dilated intercellular spaces, surface epithelial alteration, dyskeratotic epithelial cells, and lamina propria fibrosis. Each region was scored separately from 0 to 1, and the 3 regions were summed for the final score which ranges from 0 to 3; 0 represents normal and 3 maximum change.
- Endoscopies were performed at screening and Week 24, and the proximal and distal esophageal regions scored for edema, rings, exudates, furrows, and strictures. The overall score ranges from 0 to 18; higher scores indicate greater severity.

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## Results

- Baseline characteristics were comparable among different groups.
- More patients treated with dupilumab versus placebo achieved peak eosinophil count  $\leq 6$ /hpf (59.0% vs 5.9%;  $P < 0.0001$ ).
- Dupilumab vs placebo had greater absolute (LS mean  $-23.2$  vs  $-12.7$ ; LS mean difference [95% CI]  $-10.5$  [ $-14.5$ ,  $-6.6$ ];  $P < 0.0001$ ) and % ( $-65.5\%$  vs  $-38.3\%$ ;  $-27.3$  [ $-38.2$ ,  $-16.2$ ];  $P < 0.0001$ ) change in DSQ.

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## Results

- Dupilumab vs placebo had a greater % change in peak eosinophil count ( $-80.1$  vs  $1.5$ ;  $-81.7$  [ $-96.2$ ,  $-67.1$ ]).
- Proportion of patients achieving  $< 15$  eos/hpf (77.0% vs 7.6%).
- Change in HSS grade ( $-0.82$  vs  $-0.1$ ;  $-0.71$  [ $-0.81$ ,  $-0.62$ ]) and stage ( $-0.79$  vs  $-0.09$ ;  $-0.70$  [ $-0.79$ ,  $-0.61$ ]) scores; and change in EREFS score ( $-3.95$  vs  $-0.41$ ;  $-3.54$  [ $-4.27$ ,  $-2.81$ ]).

All  $P < 0.0001$ .

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## Results

- Dupilumab was generally well tolerated. The most common TEAEs for dupilumab/placebo were injection-site reactions (37.5/33.3%).

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## Conclusion



Dupilumab improved clinical, symptomatic, histologic, and endoscopic aspects of EoE and was well tolerated.

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**Moderators:**

Vivek Kaul, MD, FACP   Vladimir M. Kushnir, MD






## Questions?

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