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Only 23% of patients with HCV-related hepatocellular cancer receive DAAs.



Official newspaper of the AGA Institute

mdedge.com/gihepnews

# GI & Hepatology News

January 2024

Volume 18 / Number 1

## 2024 Medicare Payment Rules *What Gastroenterologists Need to Know*



THE PHOTOGRAPHY/DREAMSTIME

### BY THE COVERAGE AND REIMBURSEMENT SUBCOMMITTEE OF THE AGA GOVERNMENT AFFAIRS COMMITTEE

The 2024 updates to the Medicare Physician Fee Schedule (MPFS) and the Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgery Center (ASC) final rules represent a mixed bag for gastroenterologists.

#### Medicare Physician Fee Schedule (MPFS) Final Rule

Cuts to physician payments continue:

The final calendar year (CY) 2024 MPFS

conversion factor will be \$32.74, a cut of approximately 3.4% from CY 2023, unless Congress acts. The reduction is the result of several factors, including the statutory base payment update of 0%, the reduction in assistance provided by the Consolidated Appropriations Act, 2023 (from 2.5% for 2023 to 1.25% for 2024), and budget neutrality adjustments of -2.18 % resulting from CMS' finalized policies.

*New add-on code for complex care:* CMS is finalizing complexity add-on code, G2211 (Visit complexity inherent to evaluation and management associated with medical care

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## Antireflux Surgery May Not Reduce Cancer Risk in Barrett's Esophagus

BY WILL PASS

MDedge News

FROM GASTROENTEROLOGY

Antireflux surgery may be no more effective than antireflux medication for reducing risk of esophageal adenocarcinoma (EAC) among patients with Barrett's esophagus, according to a Nordic retrospective study.

Risk of EAC was higher among patients who underwent surgery, and risk appeared to increase over time, suggesting that postoperative patients should continue to participate in surveillance programs, reported lead author Jesper Lagergren, MD, PhD, of the Karolinska Institutet, Stockholm, and colleagues.

"Antireflux surgery with fundoplication increases the ability of the gastroesophageal anatomic and physiological barrier to prevent reflux, and can thus prevent any carcinogenic gastric content from reaching the esophagus, including both acid and bile," the investigators wrote in *Gastroenterology* (2023 Sep 8. doi: 10.1053/j.gastro.2023.08.050), noting that surgery reduces esophageal acid exposure to a greater degree than medication. "Antireflux surgery may thus prevent esophageal adenocarcinoma better than antireflux medication."

Three meta-analyses to date, however, have failed to provide consistent support for this hypothesis.

"Most of the studies included in these meta-analyses came from single centers, were of small sample size, examined only one treatment arm, and had a short or incomplete follow-up, and ... were hampered

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## LETTER FROM THE EDITOR

# We Want to Hear From You, Our Readers

**H**appy New Year, everyone. It's hard to believe, but we are nearing the mid-point of our five-year term on the *GI & Hepatology News (GIHN)* board of editors. Our central goal over the past two-and-a-half years has been to curate thought-provoking content for *GIHN* that helps to inform clinical practice and keeps you up-to-date on emerging scientific innovations and policy changes impacting patients with digestive and liver diseases.

As we usher in 2024, we want to hear from you—our readers—to ensure we are appropriately tailoring our coverage to your needs. Your feedback is critical to ensuring the continued success of the newspaper as your go-to source for cutting-edge news relevant to our field.

To start, we welcome your thoughts on the following questions:

- What do you want to see more of in the newspaper (e.g., a particular column, topic)?
- How can we continue to serve you best as a reader?

Please email your feedback to us at [GINews@gastro.org](mailto:GINews@gastro.org). Your input is greatly appreciated by both the board and our larger editorial team and will help inform future coverage.

In this month's issue of *GIHN*, we update you on the proceedings of AGA's 2023 Innovation Conference, highlight

a new Clinical Practice Guideline focused on the role of biomarkers in Crohn's disease management, and summarize key AGA journal content.



Dr. Adams

**Your feedback is critical to ensuring the continued success of the newspaper as your go-to source for cutting-edge news relevant to our field.**

The AGA Government Affairs Committee also details 2024 updates to Medicare payment rules, including a new add-on code for complex care,

increased facility payment for POEM procedures, and continuation of expanded telehealth coverage through the end of 2024.

*GIHN* associate editor Dr. Avi Ketwaroo introduces this month's Perspectives column focused on the impact of substance use (specifically alcohol and marijuana) on liver transplant candidacy.

In our January Member Spotlight, we feature Dr. Sonali Paul, a hepatologist and co-founder of Rainbows in Gastro. She shares her passion for promoting health equity in sexual and gender minority populations.

We hope you enjoy this, and all the exciting content included in our January issue. ■

**Megan A. Adams, MD, JD, MSc**  
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# 2024 Payment Rules Detailed

Medicare from page 1

services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition), that it originally proposed in 2018 rulemaking. CMS noted that G2211 cannot be used with an office and outpatient E/M procedure reported with modifier -25. CMS further clarified that the add-on code "is not intended for use by a professional whose relationship with the patient is of a discrete, routine, or time-limited nature ..." CMS further stated, "The inherent complexity that this code (G2211) captures is not in the clinical condition itself ... but rather the cognitive load of the continued responsibility of being the focal point for all needed services for this patient." For gastroenterologists, it is reasonable to assume G2211 could be reported for care of patients with complex, chronic conditions such as inflammatory bowel disease (IBD), celiac disease, and/or chronic liver disease.

CMS to align split (or shared) visit policy with CPT rules: Originally, CMS proposed to again delay "through at least December 31, 2024" its planned implementation of defining the "substantive portion" of a split/shared visit as more than half of the total time. However, after the American Medical Association's CPT Editorial Panel, the body responsible for maintaining the CPT code set, issued new guidelines for split (or shared)

services CMS decided to finalize the following policy to align with those guidelines: "Substantive portion means more than half of the total time spent by the physician and non-physician practitioner performing the split (or shared) visit, or a substantive part of the medical decision making except as otherwise provided in this paragraph. For critical care visits, substantive portion means more than half of the total time spent by the physician and nonphysician practitioner performing the split (or shared) visit."

While the CPT guidance states, "If code selection is based on total time on the date of the encounter, the service is reported by the professional who spent the majority of the face-to-face or non-face-to-face time performing the service," this direction does not appear in the finalized CMS language.

CMS has extended Telehealth flexibility provisions through Dec. 31, 2024:

- Reporting of Home Address — CMS will continue to permit distant site practitioners to use their currently enrolled practice location instead of their home address when providing telehealth services from their home through CY 2024.
- Place of Service (POS) for Medicare Telehealth Services — Beginning in CY 2024, claims billed with POS 10 (Telehealth Provided in Patient's Home) will be paid at the non-facility rate, and claims billed with POS 02 (Telehealth Provided Other than in Patient's Home) will be paid at the facility

rate. CMS also clarified that modifier -95 should be used when the clinician is in the hospital and the patient is at home.

- Direct Supervision with Virtual Presence — CMS will continue to define direct supervision to permit the presence and "immediate availability" of the supervising practitioner through real-time audio and visual interactive telecommunications through CY 2024.
- Supervision of Residents in Teaching Settings — CMS will allow teaching physicians to have a virtual presence (to continue to include real-time audio and video observation by the teaching physician) in all teaching settings, but only in clinical instances when the service is furnished virtually, through CY 2024.
- Telephone E/M Services — CMS will continue to pay for CPT codes for telephone assessment and management services (99441-99443) through CY 2024.

## Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgery Center (ASC) Final Rule

Hospital and ASC payments will increase: Conversion factors will increase 3.1% to \$87.38 for hospitals and \$53.51 for ASCs that meet applicable quality reporting requirements.

Hospital payments for Peroral Endoscopic Myotomy (POEM) increase: The GI societies successfully advocated for a 67% increase to the facility payment for POEM. To better align with the procedure's cost, CMS will place CPT code 43497 for POEM into

a higher-level Ambulatory Payment Classification (APC) (5331 — Complex GI procedures) with a facility payment of \$5,435.83.

Cuts to hospital payments for some Level 3 upper GI procedures: CMS has finalized moving the following GI CPT codes that had previously been assigned to APC 5303 (Level 3 Upper GI Procedures — \$3,260.69) to APC 5302 (Level 2 Upper GI Procedures — \$1,814.88) without explanation and against advice from AGA and the GI societies. This will result in payment cuts of 44% to hospitals.

- 43252 (EGD, flexible transoral with optical microscopy)
- 43263 (ERCP with pressure measurement, sphincter of Oddi)
- 43275 (ERCP, remove foreign body/stent biliary/pancreatic duct)

GI Comprehensive APC complexity adjustments: Based on a cost and volume threshold, CMS sometimes makes payment adjustments for Comprehensive APCs when two procedures are performed together. In response to comments received, CMS is adding the following procedures to the list of code combinations eligible for an increased payment via the Complexity Adjustment.

- CPT 43270 (EGD, ablate tumor polyp/lesion with dilation and wire)
- CPT 43252 (EGD, flexible transoral with optical microscopy)

For more information, see 2024 the payment rules summary and payment tables at <https://gastro.org/practice-resources/reimbursement>.

The Coverage and Reimbursement Subcommittee members have no conflicts of interest. ■

# Meta-Analysis of Postcancer Use of Immunosuppressive IBD Therapies Shows No Increase in Cancer Recurrence Risk

BY CHRISTINE KILGORE

FROM CLINICAL GASTROENTEROLOGY AND HEPATOLOGY

Patients with immune-mediated diseases and a history of malignancy had similar rates of cancer recurrence whether or not they were receiving immunosuppressive treatments, shows a newly published systematic review and meta-analysis that covered approximately 24,000 patients and 86,000 person-years of follow-up.

The findings could "help guide clinical decision making," providing "reassurance that it remains safe to use conventional immunomodulators, anti-TNF [tumor necrosis factor] agents, or newer biologics in individuals with [immune-mediated diseases] with a prior malignancy consistent with recent guidelines," Akshita Gupta, MD, of Massachusetts General Hospital, Boston, and

coinvestigators wrote in *Clinical Gastroenterology and Hepatology* (2023 Aug 12. doi: 10.1016/j.cgh.2023.07.027).

And because a stratification of studies by the timing of immunosuppression therapy initiation found no increased risk when treatment was started within 5 years of a cancer diagnosis compared to later on, the meta-analysis could "potentially reduce the time to initiation of immunosuppressive treatment," the authors wrote.

Ustekinumab, a monoclonal antibody targeting interleukin-12 and IL-23, and vedolizumab, a monoclonal antibody that binds to alpha4beta7 integrin, were covered in the meta-analysis, but investigators found no studies on the use of upadacitinib or other Janus kinase (JAK) inhibitors, or the use of S1P modulators, in patients with prior malignancies.

The analysis included 31 observational

studies, 17 of which involved patients with inflammatory bowel disease (IBD).

## Similar Levels of Risk

The incidence rate of new or recurrent cancers among individuals not receiving any immunosuppressive therapy for IBD or other immune-mediated diseases after an index cancer was 35 per 1,000 patient-years (95% confidence interval, 27-43 per 1,000 patient-years; 1,627 incident cancers among 12,238 patients, 43,765 patient-years), and the rate among anti-TNF users was similar at 32 per 1,000 patient-years (95% CI, 25-38 per 1,000 patient-years; 571 cancers among 3,939 patients, 17,772 patient-years).

Among patients on conventional

Continued on following page

# Surgery vs drugs

Cancer from page 1

by heterogeneity among the included studies,” they noted.

For the present study, Dr. Lagergren and colleagues analyzed national registry data from 33,939 patients with Barrett’s esophagus in Denmark, Finland, Norway, and Sweden. Out of this group, 542 patients (1.6%) had undergone antireflux surgery, while the remainder were managed with antireflux medication.



Dr. Lagergren

In both groups, approximately two-thirds of the patients were men. The median age at enrollment was about a decade higher in the medication group (66 vs 54 years), and this group also tended to have more comorbidities.

After a follow-up period as long as 32 years, the absolute rates of EAC were 1.3% and 2.6% in the medication and surgery groups, respectively. Multivariate analysis, with adjustments for sex, age, year, comorbidities, and age, revealed that postsurgical patients had a 90% increased risk of EAC (hazard ratio, 1.9; 95% CI, 1.1-3.5), versus patients treated with antireflux medication alone.

The relatively higher risk of EAC appeared to increase over time, based on a nonsignificant hazard ratio of 1.8 during the 1- to 4-year follow-up period (HR, 1.8; 95% CI, 0.6-5.0), versus a significant, fourfold risk elevation during the 10- to 32-year follow-up period (HR, 4.4; 95% CI, 1.4-13.5).

“In this cohort of patients with Barrett’s esophagus, the risk of esophageal adenocarcinoma did not decrease after antireflux surgery compared with antireflux medication,” the investigators wrote. “Instead, the risk was increased throughout the follow-up among patients having undergone antireflux surgery.”

Dr. Lagergren and colleagues suggested that

Esophageal adenocarcinoma (EAC) has been increasing in frequency for decades. EAC’s only known precursor is Barrett’s esophagus (BE), a complication of GERD with chronic esophageal inflammation (reflux esophagitis). Chronic inflammation can predispose to cancer and re-fluxed acid itself can cause potentially carcinogenic double-strand DNA breaks in Barrett’s metaplasia. PPIs, which block secretion of the gastric acid that causes reflux esophagitis and DNA damage, are recommended to BE patients for cancer prevention. Logical as that practice may seem, meta-analyses have reached contradictory conclusions regarding the cancer-preventive benefits of PPIs. PPIs do not stop the reflux of other potential carcinogens such as bile salts, and thus it has been argued that fundoplication, which blocks the reflux of all gastric material, should be superior to PPIs for cancer prevention. Plausible as that argument sounds, meta-analyses of the generally small and heterogeneous studies on this issue have not found consistently that antireflux surgery is superior to medical therapy for cancer prevention in BE.

Now, a large, population-based cohort study by Åkerström et al. of Nordic BE patients followed for up to 32 years has found that the overall risk of EAC was higher for patients treated with fundoplication than for those

the reason for relatively higher cancer risk in the group that underwent surgery likely stems from early and prolonged acid exposure.

“[P]erforming antireflux surgery after years of GERD may be too late to enable a cancer-preventative effect, and most of the patients first diagnosed with Barrett’s esophagus reported a history of many years of GERD symptoms,” the investigators wrote, suggesting that carcinogenic processes had already been set in motion by the

was statistically significant only for vedolizumab ( $P = .03$  vs immunomodulators and  $P = .04$  vs anti-TNF agents).

Subgroup analyses for new primary cancers, recurrence of a prior cancer, and type of index cancer (skin cancer vs other cancers) similarly found no statistically significant differences between treatment arms. Results were similar in patients with IBD and RA.

## Timing of Therapy

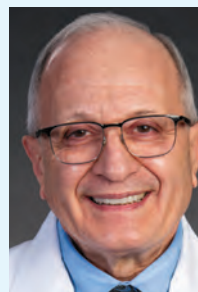
The new meta-analysis confirms and expands a previous meta-analysis published in *Gastroenterology* in 2016 (151:97-109.e4) that showed no impact of treatment – primarily IMM or anti-TNF treatment – on cancer recurrence in patients with immune-mediated diseases.

The 2016 meta-analysis reported similar cancer recurrence rates with IMM and anti-TNFs when immunosuppression was introduced before or after 6 years of cancer diagnosis. In the new meta-analysis – with twice the number of patients, a longer duration of follow-up, and the inclusion of other biologic therapies – a

treated with medication (adjusted HR, 1.9; 95% CI, 1.1-3.5). Furthermore, the EAC risk increased over time in the surgical patients. Well done as this study was, it has important limitations. The overall BE population was large ( $n=33,939$ ), but only 1.6% (542 patients) had antireflux surgery, and only 14 of those developed EAC during follow-up. Those small numbers limit statistical power. Moreover, important residual confounding cannot be excluded. The surgical patients might have had more severe GERD than medical patients, and it is difficult to make a plausible argument for why fundoplication should increase

EAC risk. Nevertheless, this study provides a good lesson on why a plausible argument needs supportive evidence before acting on it in clinical practice. While there may be some excellent reasons for recommending antireflux surgery over medication for patients with severe GERD, better esophageal cancer prevention does not appear to be one of them.

*Stuart Jon Spechler, MD, AGAF, is chief of the division of gastroenterology and codirector of the Center for Esophageal Diseases at Baylor University Medical Center, and codirector of the Center for Esophageal Research at Baylor Scott & White Research Institute, Dallas, Texas. Dr. Spechler is a consultant for Phathom Pharmaceuticals and ISOThrive, LLC.*



Dr. Spechler

time surgery was performed.

“[P]atients with Barrett’s esophagus who undergo antireflux surgery remain at an increased risk of esophageal adenocarcinoma and should continue taking part in surveillance programs,” they concluded.

The study was funded by the Swedish Cancer Society, Swedish Research Council, and Stockholm County Council. The investigators disclosed no conflicts of interest. ■

stratification of results at the median interval of therapy initiation similarly found no increased risk before 5 years, compared with after 5 years.

“Although several existing guidelines recommend avoiding immunosuppression for 5 years after the index cancer, our results indicate that it may be safe to initiate these agents earlier than 5 years, at least in some patients,” Dr. Gupta and coauthors wrote, mentioning the possible impact of selection bias and surveillance bias in the study. Assessment of the newer biologics ustekinumab and vedolizumab is limited by the low number of studies (four and five, respectively) and by limited duration of follow-up, they noted.

The study was funded in part by grants from the Crohn’s and Colitis Foundation, and the Chleck Family Foundation. Dr. Gupta disclosed no conflicts. One coauthor disclosed consulting for Abbvie, Amgen, Biogen, and other companies, and receiving grants from several companies. Another coauthor disclosed serving on the scientific advisory boards for AbbVie and other companies, and receiving research support from Pfizer. ■

Continued from previous page

immunomodulator therapy (thiopurines, methotrexate), the incidence rate was numerically higher at 46 per 1,000 patient-years (95% CI, 31-61; 1,104 incident cancers among 5,930 patients; 17,018 patient-years), but was not statistically different from anti-TNF ( $P = .92$ ), or no immunosuppression ( $P = .98$ ).

Patients on combination immunosuppression also had numerically higher rates of new or recurrent cancers at 56 per 1,000 patient-years (95% CI, 31-81; 179 incident cancers, 2,659 patient-years), but these rates were not statistically different from immunomodulator (IMM) use alone ( $P = .19$ ), anti-TNF alone ( $P = .06$ ) or no immunosuppressive therapy ( $P = .14$ ).

Patients on ustekinumab and vedolizumab similarly had numerically lower rates of cancer recurrence, compared with other treatment groups: 21 per 1,000 patient-years (95% CI, 0-44; 5 cancers among 41 patients, 213 patient-years) and 16 per 1,000 patient-years (95% CI, 5-26; 37 cancers among 281 patients, 1,951 patient-years). However, the difference

# Hepatologist Finds Purpose as Health Equity Advocate for LGBTQI+

BY JENNIFER LUBELL

MDedge News

**S**onali Paul, MD, once thought she was an anomaly in the world of medicine. “As I was going through training, I didn’t think others like me existed, a gay South Asian transplant hepatologist. I certainly didn’t have mentors that looked like me. I didn’t have anyone to look up to,” she said.

Fighting to promote health care equity in the LGBTQI+ population has been a cornerstone of her career. As cofounder and an executive

**“I’ve had medical students and residents come to me and say they were going to go into endocrine or some other field because they thought it was more gay friendly, until they saw our group and the work we’re doing.”**

board member of Rainbows in Gastro, a sexual and gender minorities affinity group that builds community among LGBTQI+ medical trainees and physicians in gastroenterology, Dr. Paul often goes into the community to promote open discussions about health equity in sexual and gender minority populations.

“Our mission is CHARM: community, healing, advocacy, research, and mentorship,” said Dr. Paul, a transplant hepatologist with the University of Chicago Medicine with a specific niche within fatty liver disease and obesity medicine. She serves as an associate program director for the Internal Medicine Residency Program specifically for diversity, equity, and inclusion.

In 2022 she received the University of



Dr. Sonali Paul

Chicago’s Department of Medicine Diversity Award.

Dr. Paul has worked to establish policies such as documenting preferred gender identity of patients in electronic medical records and using pronoun cards on ID badges to make LGBTQI+ patients more comfortable. Rainbows in Gastro has shown trainees they can be open about their sexual orientation and gender identity without fear of retribution. “I’ve had medical students and residents come to me and say they were going to go into endocrine or some other field because they thought it was more gay friendly, until they saw our group and the work we’re doing,” Dr. Paul said.

In an interview, she talks more about her two key passions: reducing disparities and promoting health equity.

**Q: You presented “Embrace the Rainbow: Creating Inclusive LGBTQ+ Spaces in Medicine” at the University of Chicago Medicine Grand Rounds. What were some of the key takeaways of that presentation?**

**Dr. Paul:** One is education. Knowing the history of the LGBT community and how marginalization and discrimination affects the individual coming into that clinic is important. Having little things like pronoun badges or a rainbow flag, having nondiscrimination policies that include sexual orientation, gender identity that are displayed in the clinics, are very small things that seem almost trivial to some people. But I can tell you for myself, it matters if I walk into a door and there’s a rainbow flag there. I feel immediately safer.

**Q: What are your hopes and aspirations for the field of GI moving forward?**

**Dr. Paul:** I didn’t learn about social determinants

of health in medical school, but more and more I think we’re starting to pivot and really look at those things. I hope GI and hepatology continues to do that.

For me, it’s looking at everything through a health disparities lens, seeing the health disparities across communities and finding solutions to mitigate them. How do we get people access to transplant for all our patients, and really examining the social determinants of health in the health care we provide?

**Q: Your clinical focus has been on nonalcoholic fatty liver disease. Can you tell me how you got interested in that area of medicine?**

**Dr. Paul:** There’s been a name change for the disease itself. It’s now metabolic dysfunction-associated steatotic liver disease (MASLD). I got interested from an obesity medicine perspective. I thought the liver pathology was interesting but I wanted to approach it from a different kind of perspective and not just focus on the liver, but also the metabolic factors.

I practice from that kind of lens: Looking at a lot of the metabolic comorbidities that happen with fatty liver disease to help patients with weight loss.

**Q: What do you think about the new weight loss drugs?**

**Dr. Paul:** I think they’re very effective. They’re obviously very popular. Weight loss is a really hard thing and I think they are really changing the

**“I’m interested in the changes in fatty liver with gender-affirming hormone therapy with estrogen and testosterone, an area that’s never been studied.”**

game. A newer one that was just approved, tirzepatide (Zepbound, Lilly) resulted in up to 20% body weight loss. I think if there’s a medicine that we can give to avoid surgery for some people, I think that’s great. I think what is quite disheartening is insurance access to the medications.

**Q: Is there any type of research you’re doing in this area right now?**

**Dr. Paul:** I’m interested in the changes in fatty liver with gender-affirming hormone therapy with estrogen and testosterone, an area that’s never been studied.

**Q: Describe how you would spend a free Saturday afternoon.**

**Dr. Paul:** With my wife, my 9-year-old son, and two dogs. One of our favorite places to go is the Lincoln Park Zoo. We go there, especially over the summer, sometimes every week just to walk around. And, my son loves animals. Or, play with our dogs. ■

## LIGHTNING ROUND

**What is your favorite junk food?**

Doritos

**What is your favorite holiday?**

Thanksgiving

**Is there a book that you reread often?**

“Interpreter of Maladies” by Jhumpa Lahiri

**What is your favorite movie genre?**

Comedy

**Are you an introvert or extrovert?**

Somewhere in the middle

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*Continued on following page*

# 2023 AGA Innovation Conference on the Advances in Endosurgery

BY UZMA SIDDIQUI, MD

WASHINGTON, DC — The American Gastroenterological Association Center for GI Innovation and Technology recently held its fifth annual Innovation Conference (formerly Consensus Conference) on the Advances in Endosurgery, November 10 – 11. It was organized and chaired by Amrita Sethi, MD, Columbia University Irving Medical Center—NYP and Sri Komanduri, MD, MS, Feinberg School of Medicine, Northwestern University, Chicago.

The conference brought together gastroenterologists (GIs), surgeons, and industry partners to explore what further collaboration and clinical adoption is needed to advance endosurgical applications. Both GIs and surgeons welcomed potential collaboration especially in developing strategies to promote education and training initiatives, including defining what procedures

and techniques are to be included in the endosurgery arena. Jeffrey Potkul, Medtronic Endoscopy, noted that this was a “great forum, format, and discussions — it will take novel approaches such as this conference and new collaboration models to ensure technology innovation in the endoluminal space can reach patients and empower improved outcomes in Gastroenterology.”

Topics discussed included third space endoscopy, endobariatric and metabolic endoscopy, and endoscopy related to transluminal access. Exciting new developments in robotic endoscopy were also highlighted with an attempt to understand the value proposition of this innovation in the endoscopy space, as well as successes and failures of past efforts to help guide success going forward. Other issues raised were methods for device development including initiating research studies, how to navigate regulatory

processes for Food and Drug Administration approval of new devices, and ongoing issues related to billing and reimbursement. There was consensus around the need for collaboration between all stakeholders to drive innovation and its adoption in the field of endosurgery. This meeting is one of the first of its kind to bring innovators across multiple disciplines together with the intention of moving the entire field of endosurgery forward and encouraging creative solutions.

We would like to thank the members of the AGA Center for GI Innovation and Technology Committee and attendees who made this year's conference a success. The conference was supported by independent grants from Boston Scientific Corporation, Cook Medical Inc., Endo Tools Therapeutics, Fujifilm Healthcare Americas Corporation, Intuitive Surgical, Olympus Corporation, and Medtronic. ■



2023 AGA Innovation Conference: Advances in Endosurgery attendees.

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Continued from previous page

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A photograph of a computer monitor on a desk. The screen shows the MDedge.com website, which features a colorful graphic of a liver and various text elements related to medical news and education.A promotional banner for the AGA Postgraduate Course. It features the AGA logo at the top left. The main title 'AGA Postgraduate Course' is in large, bold, orange letters, followed by the subtitle 'THE LATEST FROM THE GREATEST' in white. Below this are three circular portraits of speakers: Janice Jou, MD, MHS (Oregon Health and Science University), Christen K. Dilly, MD, MEHP, AGAF (Indiana University School of Medicine), and Laura E. Raffals, MD, MS (Mayo Clinic). The event details 'May 18, 2024 ■ 8 a.m.-5:30 p.m. During Digestive Disease Week® in Washington, D.C.' are listed. At the bottom, a yellow bar contains the registration information: 'Register by March 13 to take advantage of early bird pricing. Learn more at [pgcourse.gastro.org](http://pgcourse.gastro.org).' A small code 'EDU23-050' is visible in the bottom right corner of the banner.A promotional banner for Digestive Disease Week 2024 (DDW2024). The background is dark green with colorful, concentric circular patterns in shades of blue, green, and orange. The title 'IT'S ALL ABOUT YOUR PATH' is prominently displayed in white and pink. Below the title, the text reads: 'At Digestive Disease Week® (DDW) 2024, we have one mission — to provide better outcomes to people living with digestive diseases — but we don't have a one-size-fits-all approach. Our self-curated program lets you forge your own way at the world's largest gathering of digestive disease clinicians, researchers and industry, whether you attend in Washington, D.C. or online:'. A list of bullet points follows: 'Explore solutions to your challenges and advance toward your goals during lectures, hands-on workshops and other educational sessions, with opportunities to earn CME credits and MOC points.', 'Discover the latest research in the Poster Hall and spark new possibilities for your own work.', 'Connect with the brightest minds from around the globe and share your ideas and knowledge.', and 'Meet trusted industry partners in the Exhibit Hall and see how their products and technologies can meet your specific needs.' Below this, the text 'ONE PURPOSE. MANY PATHS.' is shown. A pink box contains the text: 'Discounted rates available through March 13. Register now at [ddw.org/register](http://ddw.org/register).' The DDW2024 logo is on the right, with the text 'Digestive Disease Week® MAY 18-21, 2024 | WASHINGTON, D.C. EXHIBIT DATES: MAY 19-21, 2024'.

# Exploring the Impact of Substance Use on Liver Transplant

Dear colleagues,  
In this issue of Perspectives, we explore the impact of substance use on liver transplantation (LT). With recent dramatic improvements in treating hepatitis C, alcoholic liver disease has now become the leading indication for LT. Determining candidacy for a transplanted liver is a rigorous process and there has always been concern for relapse to alcohol use and its effect on the implanted graft. But, have we been too strict in restricting access in such patients?

Drs. Mitchell Mah'moud and John Aita

explore this topic with a concise review of the current literature through an ethical lens. After alcohol, the most commonly used psychotropic drug is marijuana. Marijuana has traditionally been a barrier to candidacy for LT but, as with alcohol, should transplant centers relax this restriction, especially with ongoing legalization across the United States? Drs. Mohamed Shoreibah, Joven Tristeza, and Thomas Ruli explore this topic through a cogent review of the literature assessing the impact of marijuana



Dr. Ketwaroo

use on liver transplant outcomes. We hope these essays will help your medical practice and ongoing advocacy for your patients.

We welcome your thoughts on X at @AGA\_GIHN.

*Gyanprakash A. Ketwaroo, MD, MSc, is associate professor of medicine, Yale University, New Haven, Conn., and chief of endoscopy at West Haven VA Medical Center in Connecticut. He is an associate editor for GI & Hepatology News.*

## High Stakes: Navigating the Hazy Intersection of Marijuana and Liver Transplants

**BY JOVEN TRISTEZA, MD,  
THOMAS RULI, MD, AND  
MOHAMED SHOREIBAH, MD**

**M**arijuana remains a topic of controversy even amidst the ever-changing sociopolitical landscape, particularly in the United States.

Marijuana is currently illegal at the federal level and is listed as a schedule I substance. However, marijuana for medical and recreational use has been legalized by several states, leading to an increase in its use. This unclear and disparate status



Dr. Tristeza

the singular reason to deny a patient listing for liver transplant.

Marijuana has been studied extensively regarding its effects on the human body. The main compounds in marijuana are tetrahydrocannabinol, or THC, and cannabidiol, or CBD. These compounds exhibit many effects that we observe clinically through the endocannabinoid system. Beneficial effects related to the



Dr. Ruli



Dr. Shoreibah

gastrointestinal tract include relief from nausea and vomiting and stimulation of appetite in patients with anorexia. Other benefits outside the GI tract include alleviation of chronic pain and management of some forms of drug-resistant epilepsy. Ongoing studies are investigating the role of marijuana in other medical conditions. At least equally notable

**High Stakes** *Continued on following page*

## Liver Transplantation in the Setting of Severe Alcohol-Related Liver Disease

**BY MITCHELL MAH'MOUD, MD,  
FACG, AGAF, FAASLD, AND  
JOHN AITA, MD**

**A**lcohol-related liver disease (ALD), with its subset of severe alcohol-associated hepatitis (SAH), currently accounts for most liver transplantation (LT) recipients in the United States. Patients with SAH, particularly those with a MELD-NA of at least 35, have a 70%-75% mortality rate within 6 months. The ethics of liver transplantation in the setting of SAH are complex and still

controversial. With liver transplantation in general, there are more patients with various disorders listed for transplant than available organs. There may also be concern regarding a posttransplant return to harmful alcohol use leading to graft dysfunction or loss. Ultimately, in ethics terms, there is an inherent conflict between the values of beneficence (the obligation to

act for an individual patient's benefit) and justice (fair and equitable treatment of a society).

The past decade has yielded supportive data depicting adequate posttransplant (LT) survival in select SAH patients. Previously, 6 months of alcohol sobriety was typically mandated by LT centers. Reasons for this requirement included (a) documentation of sobriety



Dr. Mah'moud

(including enrollment in an alcohol rehabilitation program) and (b) determination of maximal recovery (such that transplant may not be indicated). Present day

information shows poor correlation between the 6-month alcohol sobriety period and reduced posttransplant alcohol use. In particular, the ACCELERATE-AH study, in which patients with severe alcoholic hepatitis underwent LT before 6 months of abstinence, demonstrated post-LT survival rates of 94% at 1 year and 84% at 3 years, similar to post-LT survival rates of other LT recipients. Although other factors may play into a transplant committee's decision to require a period of sobriety before liver transplant evaluation, these data suggest that a "one size fits all"

**Transplant** *Continued on following page*

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**High Stakes** *Continued from previous page*

are marijuana's potential adverse effects, which include tachycardia, hypertension, agitation, nausea, psychosis, and hallucinations. Marijuana may also increase the risk of heart failure, acute myocardial infarction, and stroke.

The exact effect of marijuana on the liver remains inconclusive. Receptors for endocannabinoids have been associated with steatosis and fibrosis in some studies. However, some evidence also suggests that marijuana may reduce inflammation in the liver. Small, prospective studies have not been able to link marijuana use with hepatic laboratory abnormalities, and there is currently no significant association between marijuana and liver disease, injury, or cirrhosis. Of particular relevance to liver transplant recipients is marijuana's effect on cytochrome P450 enzyme function, especially CYP3A4 which is the CYP class that metabolizes tacrolimus, a common immunosuppressant used in liver transplant patients. Marijuana inhibits CYP3A4 which could increase tacrolimus levels, potentially leading to morbidity. One strategy to mitigate this process is closer monitoring of tacrolimus levels for patients using marijuana.

The once-presumed increased risk of fungal infection — particularly *Aspergillus* — for liver transplant patients who use marijuana has been refuted. Furthermore, there have been concerns by liver transplant selection committees that marijuana use may be related to a greater risk of post-liver transplant noncompliance, infections, or even death. However, marijuana use on its own has not been associated with these concerns in the liver transplant population.

The practice of excluding marijuana users from being listed for liver transplant does not appear to be evidence based. In a 2018 study focusing on US transplant centers, 40% of centers would not accept any marijuana use, and only 28% would list those who were taking medical marijuana for transplant. Interestingly, eight states have passed legislation prohibiting withholding transplant evaluation for marijuana users if it is solely based on their marijuana use. In the 5 years since that study was published, there have been major changes in the legality of marijuana. A future study of interest could assess how these changes have affected the position of transplant centers.

The sociopolitical and transplant medicine worlds alike continue to

adapt to the legalization of marijuana. While marijuana use is associated with adverse effects, its potential for benefit for a variety of medical conditions is an evolving area that has shown promise. It is therefore logical to view marijuana as a pharmacologic agent with potential for risks and benefits, but not necessarily a sole reason to exclude patients from listing for liver transplant. The current data are reassuring in that those who use marijuana and receive liver transplantation are not at higher risk of posttransplant complications, infections, or death when

**“It is therefore logical to view marijuana as a pharmacologic agent with potential for risks and benefits, but not necessarily a sole reason to exclude patients from listing for liver transplant.”**

compared to those who do not use it. Should marijuana use exist in the context of substance use disorder or other behavioral and mental health issues, then the case warrants careful multidisciplinary evaluation prior to consideration for liver transplant. The aim of our discourse is not to encourage the use of marijuana in patients being considered for liver transplant but rather to discourage their exclusion from listing solely on the basis of marijuana use. In the pursuit of an equitable organ allocation system, our hope is that this work facilitates a more informed discussion and a change in policy in liver transplant programs that may still consider marijuana use an exclusion criterion. ■

*Dr. Tristeza and Dr. Ruli are residents in internal medicine at the University of Alabama at Birmingham; Dr. Shoreibah is a specialist in gastroenterology and hepatology at the University of Alabama at Birmingham where he also serves on the faculty of the internal medicine residency program. The authors have no conflicts of interest.*

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**Transplant** *Continued from previous page*

mandatory sobriety period prior to LT evaluation is now incongruent with normative medical practice.

One overarching principle of LT is that society provides organs to those patients with the greatest need. An inherent effect of listing select patients with SAH for liver transplant is that it potentially increases the wait time (and therefore the mortality risk) for other liver disease patients. Unfortunately, alcohol use disorder (AUD) has increased significantly in recent years among younger patients (from 2001 to 2013), and some patients may even be at greater risk of ALD (e.g., PNPLA3, TM6SF2 polymorphisms or post gastric bypass) with even mild/moderate use compared to other individuals. LT should not be considered a cure for AUD but rather a treatment for SAH that carries a high mortality rate but comparable post-LT survival to other indications for LT. Data from the ACCELERATE-AH trial revealed a cumulative incidence of any alcohol use at 1 year of approximately 25% and at 3 years of 34% for post-LT patients with SAH. This is roughly equivalent to reported disease recurrence rates of 10%-40% over 1-10 years post LT for AIH, PBC, and PSC and 7%-33% for MASLD. Despite these data, concern for reemergence of metabolic syndrome has never been an impediment when evaluating patients for LT due to end-stage liver disease from MASLD. LT centers may have a selection pathway that permits judicious transplant evaluation for SAH patients who, in the context of beneficence, are felt to greatly benefit from liver transplant in the near term (and are felt unlikely to recover without transplant) while, in the spirit of the ethical tenet of justice, also yield the best suitability for the donated organ (meaning the organ was put to good use with adequate graft survival). In this setting, a liver transplant program may use tools such as S-DAT, the PACT scoring system and TERS in identifying candidates with SAH for LT and those who are likely to relapse post LT.

The optimal role of liver transplant in SAH patients is still emerging, but recent evidence suggests that the post-LT survival rate and alcohol-relapse rate appear to be acceptable. Nonetheless, the need to prevent harmful and sustained alcohol use post LT is vital since it is considered the strongest predictor of graft loss and death. Recent observations

have also highlighted younger age and consumption of >10 drinks/day within 6 months of LT as predictors of sustained alcohol use post LT. Hence, early identification of sustained alcohol use post LT coupled with timely interventions based on abstinence-promoting behavioral and pharmacologic therapy should remain the goal of all transplant centers to avoid relapse and alcohol-related deaths. In addition, incorporating addiction treatment centers into post-LT management should be considered standard of care to provide continued therapy

**“The optimal role of liver transplant in SAH patients is still emerging, but recent evidence suggests that the post-LT survival rate and alcohol-relapse rate appear to be acceptable.”**

for AUD in all patients post LT. As in the DAA era of hepatitis C therapies, the role of LT in the setting of SAH may dwindle as emerging SAH-specific therapies evolve resulting in adequate transplant-free survival. Until then, it is beneficial to refine the guidelines periodically across all the UNOS regions on patient selection for LT in SAH, consistent with ethical principles of beneficence and justice. Finally, despite the concern about return to harmful drinking post LT, the need to destigmatize AUD and explain the purpose of LT for SAH through public education is vital. ■

*Dr. Mah'moud is a consulting professor in the division of gastroenterology at Duke University School of Medicine, Durham, N.C., and a gastroenterologist with RMG Gastroenterology in North Carolina. Dr. Aita is a gastroenterologist with Cleveland Clinic Indian River Hospital in Vero Beach, Fla. Dr. Mah'moud disclosed serving on the advisory board of CLDF, and receiving research support from Intercept Pharma and Gilead Scientific, but not in a capacity related to this article. Dr. Aita has no relevant financial conflicts.*

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# NAFLD Familial Risk Score Outperforms FIB-4 Index for Identifying Advanced Fibrosis

BY WILL PASS

MDedge News

FROM CLINICAL GASTROENTEROLOGY  
AND HEPATOLOGY

A new risk model for nonalcoholic fatty liver disease (NAFLD) could offer a simpler and more accurate way of predicting advanced fibrosis in first-degree relatives, according to investigators.

By leveraging basic clinical factors instead of more advanced diagnostic findings, the NAFLD Familial Risk Score is more scalable than existing strategies for identifying advanced fibrosis, reported lead author Rohit Loomba, MD, of the University of California San Diego, La Jolla, and colleagues.

The investigators conducted a prospective, cross-sectional, familial study that comprised 242 consecutive probands and 396 first-degree relatives. All participants underwent liver fibrosis evaluation, most with magnetic resonance elastography, the researchers wrote in *Clinical Gastroenterology and Hepatology* (2023 Jul 3. doi: 10.1016/j.cgh.2023.06.020).

Dr. Loomba and colleagues developed the risk model by analyzing data from a derivation cohort of 220 individuals, among whom 92 were first-degree relatives of probands without advanced fibrosis and 128 were first-degree relatives

of probands with NAFLD and advanced fibrosis.

They identified four risk factors for advanced fibrosis: age of 50 years or more, presence of type 2 diabetes mellitus, obesity, and family history of NAFLD with advanced fibrosis. These variables were used to construct the NAFLD Familial Risk Score, with age and diabetes each accounting for one point, and obesity and family history contributing two points each.

Within the derivation cohort, this scoring system demonstrated an area under the receiver operating characteristic curve (AUROC) of 0.85 (95% CI, 0.76-0.92), suggesting high accuracy for identifying advanced fibrosis.

When applied to a validation cohort of 176 individuals, the AUROC was higher still, at 0.94 (95% CI, 0.89-0.99). In the same group, the FIB-4 index had a significantly lower AUROC of 0.70 ( $P = .02$ ).

The score “potentially can be used by family members who are aware of the diagnosis of advanced fibrosis in the proband,” they wrote. “Information on how to calculate and interpret the score can be conveyed to first-degree relatives by the proband, or by medical staff to first-degree relatives who accompany the proband to medical appointments. First-degree relatives with a score of four points or more (corresponding to 13% risk of NAFLD with advanced fibrosis)

My patients with metabolic dysfunction–associated steatotic liver disease (MASLD) and advanced fibrosis and cirrhosis often worry about the risk of MASLD and advanced fibrosis among their relatives, especially their children and siblings. Based on my clinical experience, I tell them that their first-degree relatives should get checked for MASLD with liver enzymes and a liver ultrasound. I advise if



Dr. Chalasani

either of these tests is abnormal, they should see a gastroenterologist for further evaluation. In this paper, investigators developed and validated a NAFLD Familial Risk Score to identify advanced fibrosis in the first-degree relatives of patients with NAFLD and advanced fibrosis. This score consists of age greater than 50 years (one point), BMI greater than 30 kg/m<sup>2</sup> (two points), type 2 diabetes (one point), and a first-degree relative with NAFLD and advanced fibrosis (two points).

A score of  $\geq 4$  denotes heightened risk for NAFLD with advanced fibrosis in a first-degree relative and thus they should be directed to a health care provider for further evaluation. This observation, while it needs confirmation by other researchers, is practice changing for me. Next time, when I see a patient with MASLD and advanced fibrosis, I will not only ask for the family history of liver disease, but will attempt to estimate the risk

for MASLD and advanced fibrosis among the first-degree relatives using this scoring system. If you are caring for patients with NAFLD, this system is worth considering.

*Naga Chalasani, MD, AGAF, is a practicing hepatologist and David W. Crabb Professor of Gastroenterology and vice president for academic affairs at Indiana University School of Medicine and Indiana University Health in Indianapolis. He declared no relevant conflicts of interests.*

may consider undergoing an imaging-based fibrosis assessment.”

The National Center for Advancing Translational Sciences, the National Institute of Diabetes and Digestive

and Kidney Diseases, and others supported the study. The investigators disclosed relationships with Aardvark Therapeutics, Altimimmune, Anylam/Regeneron, and others. ■

## Acylcarnitines Could Drive IBD via Dysbiosis

BY WILL PASS

MDedge News

FROM CELLULAR AND  
MOLECULAR GASTROENTEROLOGY  
AND HEPATOLOGY

Increased levels of carnitine and acylcarnitines are associated with increased dysbiosis and disease activity in pediatric inflammatory bowel disease (IBD), according to investigators.

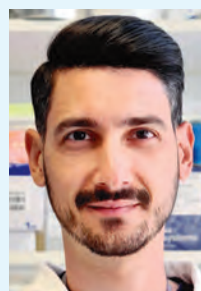
These findings improve our understanding of IBD pathogenesis and disease course, and could prove valuable in biomarker research, reported lead author Gary D. Wu, MD, of the University of Pennsylvania, Philadelphia, and colleagues.

*Continued on following page*

The description of noninvasive biomarkers for inflammatory

bowel disease (IBD) is key to better characterizing the disease pathogenesis. In this new publication, Lemons et al. describe deleterious effects of gut luminal carnitine and acylcarnitine in pediatric IBD patients, showing that these metabolites can serve as energy substrates

Dr. Corrêa



to the microbiota, especially *Enterobacteriaceae*, promoting the growth of pathobionts and contributing to the persistence of dysbiosis which, in turn, may foster the course of IBD. In fact, acylcarnitine had been highlighted as a potential

new target for IBD during dysbiosis by a previous multi-omics study of

the gut microbiome. Moreover, Dr. Wu’s team has shown that the intestinal epithelium can uptake and use acylcarnitine as an alternative source for energy production. However, epithelial mitochondrial dysfunction triggered by inflammation reduces the capacity of colonocytes to consume long-chain fatty acids, thus enhancing the fecal levels of acylcarnitine as described in IBD patients.

Distinct host- and microbiota-derived factors combinedly contribute to the elevation of luminal

acylcarnitine, which the authors then suggested to be both a symptom and a cause of IBD. Further studies will be needed to elucidate the refined balance of this relationship, which may have a potential to be used as a clinical biomarker for the diagnosis and prognosis of IBD.

*Renan Oliveira Corrêa, PhD, is a postdoctoral researcher at the Imagine Institute of Genetic Diseases in Paris. Nadine Cerf-Bensussan, MD, PhD, is a research director at the French National Institute of Health and Medical Research (INSERM), and head of the Laboratory of Intestinal Immunity at Imagine Institute in Paris and Paris University. They have no conflicts of interest.*

# Statins and the Liver: Not Harmful, Possibly Beneficial

BY PAUL MARTIN, MD, AND  
LAWRENCE S. FRIEDMAN, MD

**N**onalcoholic fatty liver disease is a manifestation of the metabolic syndrome, and effective management requires weight reduction and mitigation of other risk factors, including glucose intolerance and hyperlipidemia. A lingering concern about potential hepatotoxicity has resulted in widespread reluctance to prescribe statins to treat hyperlipidemia in patients with liver disease; however, their safety in this setting has been documented in the literature as well as in clinical practice. Therefore, statins should not be withheld in patients with liver disease when indicated — with a few caveats. Baseline liver chemistries should be obtained. After initiation of statin therapy, a modest rise in serum aminotransferase levels may occur but is

not an indication to discontinue the drug. In fact, monitoring of liver biochemical tests more frequently than is appropriate for any patient with chronic liver disease is unnecessary. The role of statins in cirrhosis may even expand, as recent reports suggest that statin use in patients with cirrhosis may slow the progression of liver disease and reduce the frequency of complications, such as hepatocellular carcinoma. These observations, however, require confirmation before statins can be suggested for any indication other than treating hyperlipidemia in patients with chronic liver disease, and statins are generally not appropriate in patients with decompensated cirrhosis. ■



Dr. Martin



Dr. Friedman

*Pearls from the Pros was published in Gastro Hep Advances (2023 Nov 11. doi: 10.1016/j.gastha.2023.08.003).*

*Dr. Friedman is the Anton R. Fried, MD, Chair of the Department of Medicine at Newton-Wellesley Hospital in Newton, Mass., and assistant chief of medicine at Massachusetts General Hospital, and a professor of medicine at Harvard Medical School and Tufts University, all in Boston. Dr. Martin is chief of the division of digestive health and liver diseases at the University of Miami, where he is the Mandel Chair of Gastroenterology. The authors disclose no conflicts.*

*Continued from previous page*

In health, carnitine and acylcarnitines aid in fatty acid transport, the investigators wrote in September in *Cellular and Molecular Gastroenterology and Hepatology* (2023. doi: 10.1016/j.jcmgh.2023.09.005). Acylcarnitines are also involved in metabolic signaling, and in the absence of sufficient short-chain fatty acids may serve as an alternative energy source for the intestinal epithelium.

“Recently, we and others have shown that fecal acylcarnitines are increased in patients with IBD, especially during dysbiosis,” they noted. “However, the mechanism(s) responsible for the increase of fecal acylcarnitines in IBD and their biological function have not been elucidated.”

The present study aimed to address this knowledge gap by characterizing both carnitine and acylcarnitines in pediatric IBD.

First, the investigators confirmed that both carnitine and acylcarnitines were elevated in fecal samples from pediatric patients with IBD.

Next, they analyzed fecal samples from subjects in the Food and Resulting Microbiota and Metabolome (FARM) study, which compared microbiota recovery after gut purge and antibiotics among participants eating an omnivorous diet, a vegan diet, or an exclusive enteral nutrition (EEN) diet lacking in fiber. After the antibiotics, levels of fecal carnitine and acylcarnitines increased significantly in all groups, suggesting that microbiota were consuming these molecules.

To clarify the relationship

between inflammation and levels of carnitine and acylcarnitines in the absence of microbiota, Dr. Wu and colleagues employed a germ-free mouse model with dextran sodium sulfate (DSS)-induced colitis. Levels of both molecule types were significantly increased in bile and plasma of mice with colitis versus those that were not exposed to DSS.

“Because the gut microbiota consumes both carnitine and acylcarnitines, these results are consistent with the notion that the increase of these metabolites in the feces of patients with IBD is driven by increased biliary delivery

of acylcarnitines to the lumen combined with the reduced number and function of mitochondria in the colonic epithelium as previously reported,” the investigators wrote.

Further experiments with plated cultures and mice revealed that various bacterial species consumed carnitine and acylcarnitines in distinct patterns. *Enterobacteriaceae* demonstrated a notable proclivity for consumption in vitro and within the murine gut.

“As a high-dimensional analytic feature, the pattern of fecal acylcarnitines, perhaps together with bacterial taxonomy, may have utility as a biomarker for the presence

or prognosis of IBD,” Dr. Wu and colleagues concluded. “In addition, based on currently available information about the impact of carnitine on the biology of *Enterobacteriaceae*, acylcarnitines also may have an important functional effect on the biology of the gut microbiota that is relevant to the pathogenesis or course of disease in patients with IBD.”

The study was supported by the Crohn’s and Colitis Foundation, the PennCHOP Microbiome Program, the Penn Center for Nutritional Science and Medicine, and others. The investigators disclosed no conflicts of interest. ■

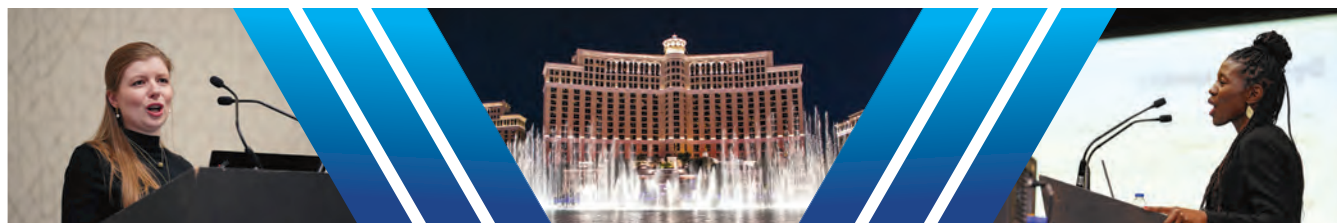
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# AGA CPU Updates Usage of Vasoactive Drugs, IV Albumin for Cirrhosis

BY WILL PASS

MDedge News

FROM GASTROENTEROLOGY

American Gastroenterological Association (AGA) has released a new Clinical Practice Update (CPU) guiding the use of vasoactive drugs and intravenous albumin in patients with cirrhosis.

The publication, authored by Vincent Wai-Sun Wong, MBChB, MD, and colleagues, includes 12 best practice advice statements concerning three common clinical scenarios: variceal hemorrhage, ascites and spontaneous bacterial peritonitis, and acute kidney injury and hepatorenal syndrome.

These complications of liver decompensation “are manifestations of portal hypertension with a [consequent] vasodilatory–hyperdynamic circulatory state, resulting in progressive decreases in effective arterial blood volume and renal perfusion,” the update authors wrote in November in *Gastroenterology* (2023. doi: 10.1053/j.gastro.2023.10.016).

“Because a potent vasoconstrictor, terlipressin, was recently approved by the United States Food and Drug Administration and because recent trials have explored use of intravenous albumin in other settings, it was considered that a best practice update would be relevant regarding the use of vasoactive drugs and intravenous albumin in these 3 specific scenarios.”

## Variceal Hemorrhage

Variceal hemorrhage comprises 70% of all upper GI hemorrhage in patients with cirrhosis and carries a 6-week mortality rate as high as 43%. Dr. Wong and colleagues advise immediate initiation of vasoactive drugs upon suspicion of variceal hemorrhage, ideally before therapeutic and/or diagnostic endoscopy.

“The goals of management of acute variceal hemorrhage include initial hemostasis, preventing early rebleeding, and reducing in-hospital and 6-week mortality,” they wrote, noting

that vasoactive drugs are effective at stopping bleeding in up to 8 out of 10 cases.

In patients with acute variceal hemorrhage undergoing endoscopic hemostasis, vasoactive agents should be continued for 2-5 days to prevent early rebleeding, according to the second best-practice-advice statement.

**The authors called albumin “the volume expander of choice in hospitalized patients with cirrhosis and ascites presenting with acute kidney injury.”**

The third statement suggests octreotide as the drug of choice for variceal hemorrhage due to its favorable safety profile.

“Nowadays, vasopressin is no longer advised in patients with acute variceal hemorrhage because of a high risk of cardiovascular adverse events,” the update authors noted.

## Ascites and Spontaneous Bacterial Peritonitis

In cases requiring large-volume (greater than 5 L) paracentesis, intravenous albumin should be administered at time of fluid removal, according to the update. In these patients, albumin reduces the risk of post-paracentesis circulatory dysfunction (defined as an increase in plasma renin activity), thereby reducing the risk of acute kidney injury.

Intravenous albumin should also be considered in patients with spontaneous bacterial peritonitis as this can overcome associated vasodilatation and decreased effective arterial blood volume, which may lead to acute kidney injury if untreated. In contrast, because of a demonstrated lack of efficacy, albumin is not advised in infections other than spontaneous bacterial peritonitis, unless associated with acute kidney injury.

Long-term albumin administration should be avoided in patients with cirrhosis and uncomplicated ascites, whether they are hospitalized or not, as evidence is lacking to support a consistent beneficial effect.

The update also advises against vasoconstrictors in patients with uncomplicated ascites, with bacterial peritonitis, and after large-volume paracentesis, again due to a lack of supporting evidence.

## Acute Kidney Injury and Hepatorenal Syndrome

In hospitalized patients with cirrhosis and ascites presenting with acute kidney injury, Dr. Wong and colleagues called albumin “the volume expander of choice in hospitalized patients with cirrhosis and ascites presenting with acute kidney injury;” however, the authors caution the dose of albumin “should be tailored to the volume status of the patient.”

The update authors suggested that terlipressin and norepinephrine are suitable options for patients with cirrhosis and the hepatorenal syndrome; however, they suggest terlipressin above the others based on available evidence and suggested concomitant albumin administration as it may further improve renal blood flow by filling the central circulation.

Terlipressin also has the advantage (over norepinephrine) of being administrable via a peripheral line without the need for intensive care unit monitoring, the update authors wrote. The agent is contraindicated in patients with hypoxia or with coronary, peripheral, or mesenteric ischemia, and it should be used with caution in patients with ACLF grade 3, according to the publication. Risks of terlipressin may also outweigh benefits in patients with a serum creatine greater than 5 mg/dL and those listed for transplant with a MELD score of 35 or higher.

The Clinical Practice Update was commissioned and supported by AGA. The authors disclosed relationships with Advanz, Boehringer Ingelheim, 89bio, and others. ■

# AGA Clinical Practice Guideline Affirms Role of Biomarkers in Crohn’s Disease Management

BY JENNIE SMITH

MDedge News

FROM GASTROENTEROLOGY

A new Clinical Practice Guideline from American Gastroenterological Association points to a stronger and better defined role for fecal and blood biomarkers in the management of Crohn’s disease, offering the most specific

evidence-based recommendations yet for the use of fecal calprotectin (FCP) and serum C-reactive protein (CRP) in assessing disease activity.

Repeated monitoring with endoscopy allows for an objective assessment of inflammation and mucosal healing compared with symptoms alone. However, relying solely on endoscopy to guide management is an approach “limited by cost and

resource utilization, invasiveness, and reduced patient acceptability,” wrote guideline authors on behalf of the AGA Clinical Guidelines Committee. The guideline was published online Nov. 17, 2023, in *Gastroenterology* (doi: 10.1053/j.gastro.2023.09.029).

“Use of biomarkers is no longer considered experimental and should be an integral part of IBD

care and monitoring,” said Ashwin Ananthakrishnan, MBBS, MPH, AGAF, a gastroenterologist with Massachusetts General Hospital in Boston and first author of the guideline. “We need further studies to define their optimal longitudinal use, but at a given time point, there is now abundant evidence that biomarkers provide significant

*Continued on following page*

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incremental benefit over symptoms alone in assessing a patient's status."

Using evidence from randomized controlled trials and observational studies, and applying it to common clinical scenarios, the authors made conditional recommendations on the use of biomarkers in patients with established, diagnosed disease who were asymptomatic, symptomatic, or in surgically induced remission. Those recommendations, laid out in a detailed Clinical Decision Support Tool (*Gastroenterology* 2023;165:1400-2), include the following:

For asymptomatic patients: Check CRP and FCP every 6-12 months. Patients with normal levels, and who have endoscopically confirmed remission within the last 3 years without any subsequent change in symptoms or treatment, do not need to undergo endoscopy and can be followed with biomarker and clinical checks alone. If CRP or FCP are elevated (defined as CRP  $\geq 5$  mg/L, FCP  $\geq 150$  mcg/g), consider repeating biomarkers and/or performing endoscopic assessment of disease activity before adjusting treatment.

For mildly symptomatic patients: Role of biomarker testing may be limited and endoscopic or radiologic assessment may be required to assess active inflammation given the higher rate of false positive and false negative results with biomarkers in this population.

For patients who have more severe symptoms: Elevated CRP or FCP can be used to guide treatment adjustment without endoscopic confirmation in certain situations. Normal levels may be false negative and should be confirmed by endoscopic assessment of disease activity.

For patients in surgically induced remission with a low likelihood of recurrence: FCP levels below 50 mcg/g can be used in lieu of routine endoscopic assessment within the first year after surgery. Higher FCP levels should prompt endoscopic assessment.

For patients who are in surgically induced remission with a high risk of recurrence: Do not rely on biomarkers. Perform endoscopic assessment.

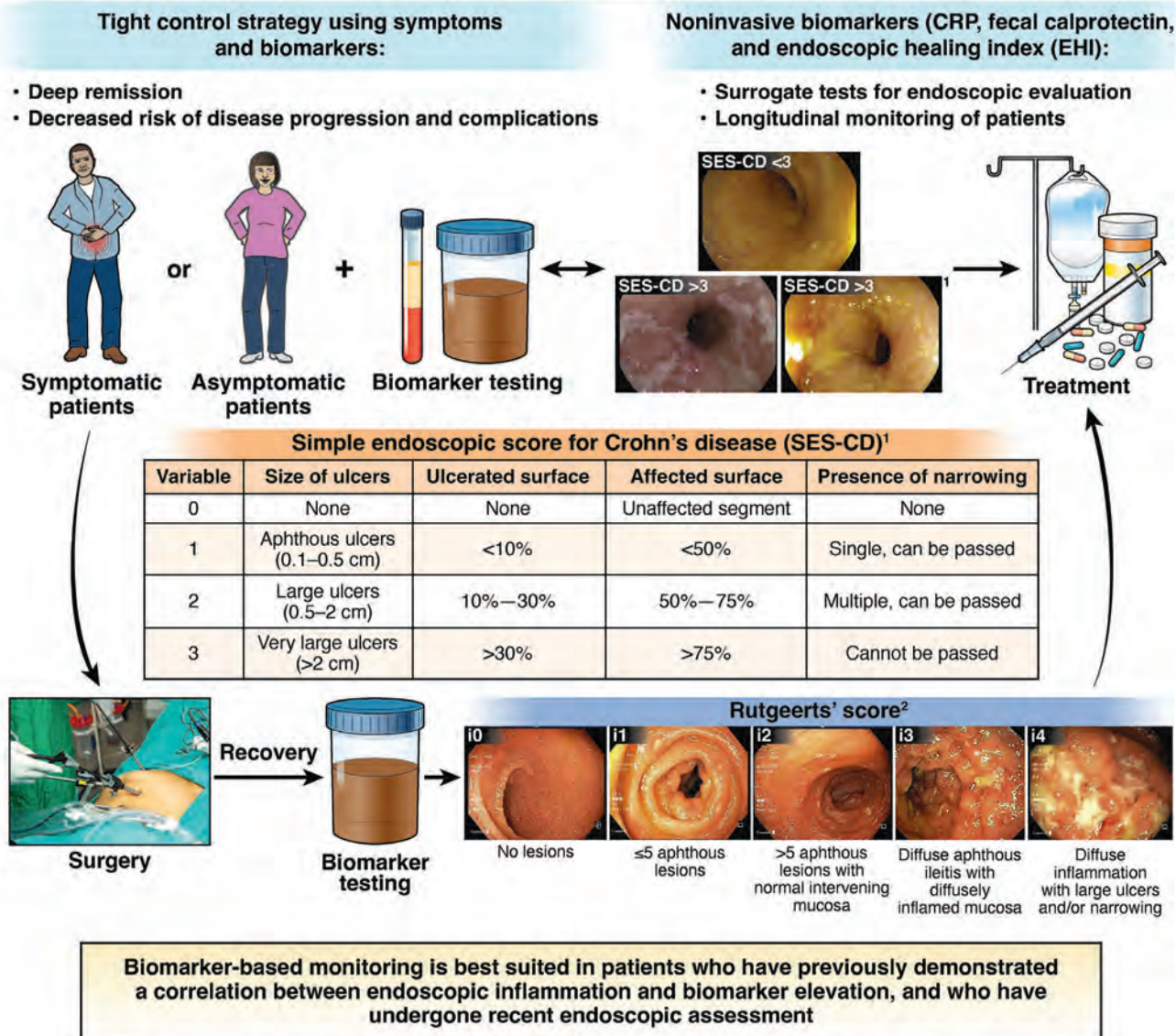
All recommendations were deemed of low to moderate certainty based on results from randomized clinical trials and observational studies that utilized these biomarkers in patients with Crohn's disease. Citing a dearth of quality evidence, the guideline authors determined

they could not make recommendations on the use of a third proprietary biomarker — the endoscopic healing index (EHI).

Recent AGA Clinical Practice Guidelines on the role of biomarkers in ulcerative colitis, published in March, also support a strong role for fecal and blood biomarkers, determining when these can be used to avoid unneeded endoscopic assessments. However, in patients with Crohn's disease, symptoms correlate less well with endoscopic activity.

As a result, "biomarker performance was acceptable only in asymptomatic individuals who had recently confirmed endoscopic remission; in those without recent endoscopic assessment, test performance was suboptimal." In addition, the weaker correlation between symptoms and endoscopic activity in Crohn's "reduced the utility of biomarker measurement to infer disease activity in those with mild symptoms."

The guidelines were fully funded by the AGA Institute. The authors disclosed a number of potential conflicts of interest, including receiving research grants, as well as consulting and speaking fees, from pharmaceutical companies. ■



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# Fewer Than One Out of Four Patients With HCV-Related Liver Cancer Receives Antivirals

BY WILL PASS

MDedge News

**F**ewer than one out of four patients with hepatitis C virus (HCV)-related hepatocellular carcinoma (HCC) receive oral interferon-free direct-acting antiviral agents (DAAs), and rates aren't much better for patients seen by specialists, based on a retrospective analysis of private insurance claims.

The study also showed that patients receiving DAAs lived significantly longer, emphasizing the importance of prescribing these medications to all eligible patients, reported principal investigator Mindie H. Nguyen, MD, AGAF, of Stanford University Medical Center, Palo Alto, California, and colleagues.

"Prior studies have shown evidence of improved survival among HCV-related HCC patients who received DAA treatment, but not much is known about the current DAA utilization among these patients in the general US population," said lead author Leslie Y. Kam, MD, a postdoctoral scholar in gastroenterology at Stanford Medicine, who presented the findings in November at the annual meeting of the American Association for the Study of Liver Diseases.

To generate real-world data, the investigators analyzed medical records from 3922 patients in Optum's Clinformatics Data Mart Database. All patients had private medical insurance and received care for HCV-related HCC between 2015 and 2021.

"Instead of using institutional

databases which tend to bias toward highly specialized tertiary care center patients, our study uses a large, national sample of HCV-HCC patients that represents real-world DAA treatment rates and survival outcomes," Dr. Kam said in a written comment.

Within this cohort, fewer than one out of four patients (23.5%) received DAA, a rate that Dr. Kam called "dismally low."

Patients with either compensated or decompensated cirrhosis

**"Culturally appropriate efforts to improve awareness of HCV must continue among the general public and health care workers as well as efforts to provide point of care accurate and rapid screening tests for HCV."**

had higher treatment rates than those without cirrhosis (24.2% or 24.5%, respectively, vs. 16.2%;  $P = .001$ ). The investigators noted that more than half of the study patients had decompensated cirrhosis, suggesting that HCV-related HCC was diagnosed late in the disease course.

Receiving care from a gastroenterologist or infectious disease physician also was associated with a higher treatment rate. Patients managed by a gastroenterologist alone had a treatment rate of 27.0%, while those who received care from a gastroenterologist or

infectious disease doctor alongside an oncologist had a treatment rate of 25.6%, versus just 9.4% for those who received care from an oncologist alone, and 12.4% among those who did not see a specialist of any kind ( $P = .005$ ).

These findings highlight "the need for a multidisciplinary approach to care in this population," Dr. Kam suggested.

As in previous research, DAAs were associated with extended survival. A significantly greater percentage of patients who received DAA were alive after 5 years, compared with patients who did not receive DAA (47.2% vs. 35.2%;  $P$  less than .001). After adjustment for comorbidities, HCC treatment, race/ethnicity, sex, and age, DAAs were associated with a 39% reduction in risk of death (adjusted hazard ratio, 0.61; 0.53-0.69;  $P$  less than .001).

"There were also racial ethnic disparities in patient survival whether patients received DAA or not, with Black patients having worse survival," Dr. Kam said. "As such, our study highlights that awareness of HCV remains low as does the use of DAA treatment. Therefore, culturally appropriate efforts to improve awareness of HCV must continue among the general public and health care workers as well as efforts to provide point of care accurate and rapid screening tests for HCV so that DAA treatment can be initiated in a timely manner for eligible patients. Continual education on the use of DAA treatment is also needed."

Robert John Fontana, MD, AGAF, professor of medicine and transplant hepatologist at the University of Michigan, Ann Arbor, described the findings as "frustrating," and "not the kind of stuff I like to hear about."

"Treatment rates are so low," Dr. Fontana said, noting that even among gastroenterologists and infectious disease doctors, who should be well-versed in DAAs, antivirals were prescribed less than 30% of the time.

In an interview, Dr. Fontana highlighted the benefits of DAAs, including their ease-of-use and effectiveness.

"Hepatitis C was the leading reason that we had to do liver transplants in the United States for years," he said. "Then once these

really amazing drugs called direct-acting antivirals came out, they changed the landscape very quickly. It really was a game changer for my whole practice, and, nationally, the practice of transplant."

Yet, this study and others suggest that these practice-altering agents are being underutilized, Dr. Fontana said. A variety of reasons could explain suboptimal usage, he suggested, including lack of awareness among medical professionals and the public, the recency of DAA approvals, low HCV testing rates, lack of symptoms in HCV-positive patients, and medication costs.

This latter barrier, at least, is dissolving, Dr. Fontana said. Some payers initially restricted which providers could prescribe DAAs, but now the economic consensus has swung in their favor, since curing patients of HCV brings significant health care savings down the line. This financial advantage—theoretically multiplied across 4-5 million Americans living with HCV—has bolstered a multi-institutional effort toward universal HCV screening, with testing recommended at least once in every person's lifetime.

"It's highly cost effective," Dr. Fontana said. "Even though the drugs are super expensive, you will reduce cost by preventing the people streaming towards liver cancer or streaming towards liver transplant. That's why all the professional societies—the USPSTF, the CDC—they all say, 'OK, screen everyone.'"

Screening may be getting easier soon, Dr. Fontana predicted, as at-home HCV testing kits are on the horizon, with development and adoption likely accelerated by the success of at-home viral testing during the COVID-19 pandemic.

Beyond broader screening, Dr. Fontana suggested that greater awareness of DAAs is needed both within and beyond the medical community.

He advised health care providers who don't yet feel comfortable diagnosing or treating HCV to refer to their local specialist. "That's the main message," Dr. Fontana said. "I'm always eternally hopeful that every little message helps."

The investigators and Dr. Fontana disclosed no relevant conflicts of interest. ■



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# Food Insecurity Increases Risk of Adolescent MASLD

BY WILL PASS

MDedge News

Adolescents facing food insecurity have a significantly increased risk of metabolic dysfunction–associated steatotic liver disease (MASLD), likely due to overconsumption of low-cost, ultra-processed, unbalanced diets, according to a recent study.

These findings suggest that more work is needed to ensure that eligible adolescents can access Supplemental Nutrition Assistance Program (SNAP) benefits and have opportunities to engage in physical activities through school-associated programs, reported principal investigator Zobair M. Younossi, MD, MPH, who is professor and chairman of the Beatty Liver and Obesity Research Program, Inova Health System, Falls Church, Virginia, and colleagues.

Dr. Younossi presented the findings in November during a press conference at the annual meeting of the American Association for the Study of Liver Diseases.

“Food insecurity among children is about 10.2% in the United States,” Dr. Younossi said. “[Food insecurity has] been shown to be a risk factor for MASLD among adults, but the data and children and adolescents are really lacking at the moment.”

To address this knowledge gap, Dr. Younossi and colleagues analyzed data from 771 adolescents aged 12-18 years in the National Health and Nutrition Examination Survey (2017-2018). Among these participants, 9.8% reported food insecurity and 10.8% had MASLD. Rates of obesity and central obesity were 22.5% and 45.4%, respectively, while 1.0% had diabetes and 20.9% had prediabetes.

Among adolescents facing food insecurity, more than half (51.5%) did not eat enough food, a vast majority (93.2%) could not access a balanced meal, and almost all (98.9%) relied upon low-cost food for daily sustenance.

The prevalence of MASLD in the food insecure group was almost twice as high as in the food secure

group (18.7% vs 9.9%), and advanced fibrosis was about 9 times more common (2.8% vs. 0.3%). Food insecure participants were also more likely to come from a low-income household (70.4% vs. 25.7%) and participate in SNAP (62.4% vs. 25.1%).

Adjusting for SNAP participation, demographic factors, and metabolic disease showed that food insecurity independently increased

risk of MASLD by more than twofold (odds ratio, 2.62; 95% CI, 1.07–6.41). The negative effect of food insecurity was almost twice as strong in participants living in a low-in-

come household (OR, 4.79; 95% CI, 1.44–15.86).

“The association between food insecurity and MASLD/NAFLD is most likely the result of not being able to eat a balanced meal and more likely having to purchase low-cost food,” Dr. Younossi said. “Together, these factors may lead to a cycle of overeating along with the overconsumption of ultra-processed foods and sugar-sweetened food and beverages.”

He went on to suggest that more work is needed to remove “systemic and structural barriers” that prevent eligible adolescents from participating in SNAP, while offering support so they can participate in “more physical activity in school and in after-school programs.”

Elliot Benjamin Tapper, MD, associate professor of medicine at the University of Michigan, Ann Arbor, recently published a similar study in the *Journal of Clinical Gastroenterology* (2023 Aug. doi: 10.1097/MCG.0000000000001741) linking food scarcity and MASLD in adults.

In an interview, Dr. Tapper praised this new study by Dr. Younossi and colleagues because it “identifies a serious unmet need” among younger individuals, who may stand to benefit most from early intervention.

“The goal [of screening] is to prevent the development of progressive disease,” Dr. Tapper said. “Our current guidelines for screening for advanced liver disease and people with risk factors focus exclusively on adults. If you waited longer, then

there’s a risk that these [younger] people [in the study] would have progressed to a later stage of disease.”

Dr. Tapper predicted increased enthusiasm for MAFLD screening among adolescents in response to these findings, but he cautioned that conventional educational intervention is unlikely to yield significant benefit.

“If you’re food insecure, you can’t go out and buy salmon and olive oil to follow the Mediterranean diet,” Dr. Tapper said. In this era, where the people who are at risk tomorrow are young and food insecure, we have to come up with a way of tailoring our interventions to the means that are available to these patients.”

To this end, health care providers need to collaborate with individuals who have personally dealt with food scarcity to implement practicable interventions.

“Referral to social work has to be paired with some kind of standard teaching,” Dr. Tapper said. “How would I use social and nutritional assistance programs to eat



CATHERINE FALLS COMMERCIAL/GETTY IMAGES

in a liver-healthy way? What can I avoid? [Educational materials] should be written by and edited by people with lived experience; i.e., people who have food insecurity or have walked a mile in those shoes.”

Dr. Younossi disclosed relationships with Merck, Abbott, AstraZeneca, and others. Dr. Tapper disclosed relationships with Take-da, Novo Nordisk, Madrigal, and others. ■

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# Low-Dose Aspirin Does Not Provoke Flares in Patients With IBD During Pregnancy

BY HEIDI SPLETE

MDedge News

Use of low-dose aspirin to manage hypertension in pregnancy caused no increased flares in patients with inflammatory bowel disease, shows new research presented in October at the annual meeting of the American College of Gastroenterology.

Low-dose aspirin is recommended for pregnant women who are at risk of hypertensive disorders, such as eclampsia, preeclampsia, and gestational diabetes, said Uma Mahadevan, MD, AGAF, a gastroenterologist and director of the University of California, San Francisco Colitis and Crohn's Disease Center, who presented the research at the meeting.

Regular nonsteroidal anti-inflammatory drug use has been associated with increased disease activity in patients with inflammatory bowel disease (IBD), but the impact of low-dose aspirin on IBD during pregnancy has not been well studied, she said.

The study, which was conducted between January 2013 and December 2022 at a single clinic, included 325 women (mean age 34 years) with IBD who had at least one pregnancy. Of these, 53% had ulcerative colitis and 47% had Crohn's disease. The primary outcome was IBD flare during pregnancy or within 6 months post partum. Flares were defined as an IBD-related hospitalization and/or surgery, new initiation of IBD therapy, elevated level of fecal calprotectin greater than 150 micrograms per milligram, or new active endoscopic disease.

A total of 95 patients (29%) used low-dose



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aspirin during pregnancy; 59 took 81 mg and 36 took 162 mg. The cumulative flare rate was similar between patients who took low-dose aspirin and those who did not (24% vs. 26%,  $P = .83$ ). However, patients who took low-dose aspirin were significantly more likely than were those who did not to experience preterm birth, younger gestational age at delivery, and cesarean delivery (22.1% vs. 6.1%, 38 weeks vs. 39 weeks, 51% vs. 27%, respectively,  $P < .01$  for all).

Overall rates of hypertensive disorders of pregnancy were similar between the low-dose aspirin and non-low-dose aspirin groups (22% vs. 19%, respectively,  $P = .59$ ), but individuals on

low-dose aspirin were more likely to experience preeclampsia than were those not on low-dose aspirin (11.6% vs 4.3%,  $P = .03$ ).

The study findings support the benefits of aspirin for pregnant women at increased risk for these conditions. "Pregnant patients with IBD should be offered low-dose aspirin without concern for increased risk of flares," Dr. Mahadevan said.

"This is a very practical study with high relevance in our everyday management of IBD patients," Shannon Chang, MD, a specialist in IBD with NYU Langone Health, said in an interview. "Having this study helps us understand the risk of increased IBD activity in the setting of aspirin use during pregnancy."

Dr. Chang was not surprised by the findings. "Since the [ACOG] guidelines changed several years ago, there have been more and more patients with IBD who have taken aspirin during their pregnancies and the results of this study seem to match what we see in clinical practice," she said. "This study will help us counsel our patients on the safety of aspirin use during pregnancy, and the findings will also be useful for discussions with our obstetrics colleagues who may seek guidance on the safety of aspirin [use] in our pregnant IBD patients."

The study received no outside funding. Dr. Mahadevan disclosed relationships with AbbVie, Boehringer Ingelheim, Bristol Myers Squibb, Celltrion, Eli Lilly, Gilead, Janssen, Pfizer, Prometheus Biosciences, Protagonist Therapeutics, Rani Therapeutics, Roivant, and Takeda. Dr. Chang disclosed serving as a consultant for Pfizer, AbbVie, and BMS. ■

## New Study Ties Ultra-Processed Foods to IBD

BY KERRY DOOLEY YOUNG

Researchers reporting in Vancouver at the annual meeting of the American College of Gastroenterology have identified a higher risk of inflammatory bowel disease (IBD) among adults who consumed a diet rich in ultra-processed foods, suggesting another field for inquiry about the potential role of industrial-produced edible food products in IBD.

The study, which was a meta-analysis of four studies, found a 47% greater risk of IBD in adults who consumed high levels of ultra-processed foods, compared with adults in reference groups.

"Our data are also consistent with other observational studies that found increased consumption of junk food, along with reduced

intakes of fresh fruit and vegetables, are associated with the development of IBD. Because Americans consume over 60% of their calories in the form of ultra-processed foods, reductions in this level of consumption could meaningfully decrease the incidence of IBD,"

**"What I tell my own patients in the clinic is to really try to clean up the diet as much as possible and in a realistic way."**

wrote authors who were led by Eric Hecht, MD, PhD, MPH, president and executive director of the nonprofit Institute of Etiological Research, Boca Raton, Florida.

The potential effect of poor diet on the gut is a critical public health question, he said. Diet may be just one possible contributor to inflammatory bowel disease. Other contributors include genetics and having a compromised immune system.

Dr. Hecht and colleagues began this study with a search on the PubMed database of published research on IBD that included details of diet. Of 10 relevant studies, 4 studies met the inclusion criteria for the analysis.

The four studies included 652,880 adults, 2,240 cases of IBD with a follow-up period ranging from 2.3 to 22.3 years. Statistically significant elevated risks for both Crohn's disease and ulcerative colitis were documented in the studies. There was a relative risk of 1.47

(95% confidence interval, 1.29-1.66) for IBD; 1.94 (95% CI, 1.45-2.58) for Crohn's disease, and 1.26 (95% CI, 1.10-1.45) for ulcerative colitis.

### Findings From the 4 Studies

Chen et al. reported, in the *Journal of Crohn's and Colitis* (2022 Oct 28. doi: 10.1093/ecco-jcc/jjac167), the results of a cross-sectional and prospective cohort study of 187,854 adults who were followed for an average of 10 years. They found that a higher intake of ultra-processed foods was associated with a higher incidence of Crohn's disease but not ulcerative colitis. It also found that people who were already diagnosed with an IBD consumed more ultra-processed

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foods than did those without a diagnosis. The authors called for further studies to address the impact of UPF intake.

Vasseur et al. documented, in *Inflammatory Bowel Diseases* (2021 Jan 1. doi: 10.1093/ibd/izaa018), research drawn from the Nutri-Net-Santé Study, a large French web-based prospective study. It did not find that ultra-processed foods were significantly associated with the risk of incident IBD.

But the authors noted that certain types of food items or dietary patterns could partly explain the increase in the incidence of IBD observed in several countries, saying that further large-scale studies would be needed to support pathophysiological assumptions made about the dietary risk factors and IBD.

In September 2020 in *Gastroenterology*, Lo et al. used data from the Nurses' Health Study (1984-2014), Nurses' Health Study II (1991-2015), and Health Professionals Follow-up Study (1986-2012). The authors reported finding dietary patterns associated with high inflammatory potential to be associated with increased risk of Crohn's disease but not ulcerative colitis (2020. doi: 10.1053/j.gastro.2020.05.011).

In October 2021 in *Gastroenterology*, Narula et al. reported finding no significant association between certain dietary patterns and risk of ulcerative colitis (2021 Jun 9. doi: 10.1053/j.gastro.2021.06.007). There was some signal for Crohn's disease, in keeping with findings from earlier research. Longer term follow-up is needed to clarify whether the observed excess risk for Crohn's disease becomes more evident as more cases accumulate.

However, in an email interview with *GI & Hepatology News*, Neeraj Narula, MD, MPH, of McMaster University, Hamilton, Ontario, cited two of his other published works that did make a connection between diet and IBD. In July 2021 in *BMJ*, he and colleagues reported findings of a prospective cohort study that found that higher intake of ultra-processed food was positively associated with risk of IBD (2021 Jul 14. doi: 10.1136/bmj.n1554). Further studies are needed to identify the contributory factors within ultra-processed foods, they wrote. He and colleagues published a meta-analysis of five cohort studies which concluded that higher ultra-processed food

and lower unprocessed/minimally processed food intakes were associated with higher risk of Crohn's disease but not ulcerative colitis (2023. doi: 10.1016/j.cgh.2023.01.012).

### Study Limitations

Aviva Musicus, ScD, the science director for the nonprofit Center for Science in the Public Interest (CSPI), said the Dr. Hecht et al. meta-analysis suggests there could be a signal in the association between higher ultra-processed food consumption and IBD, but there's also a lot of "noise" in this presentation.

It's not clear from these analyses presented what might be driving the relationship between IBD and ultra-processed food, she said. "Is it the nutrient content of these foods, given that many are high in added sugar, sodium, and saturated fat and low in dietary fiber (potential risk factors for IBD)? Is it the emulsifiers used in some of these foods, or other chemicals added during processing? Or, is it something else?" Dr. Musicus said.

She said further studies are needed on the issue of ultra-processed food and IBD.

"I wasn't convinced by the conclusion of this research abstract. It's not clear to me that general reductions in UPF (ultra-processed foods) consumption could



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meaningfully decrease the incidence of IBD, given that it may be a subset of these (somewhat heterogeneous) foods driving the associations, and people may not reduce their consumption of that specific subset upon hearing this news," Dr. Musicus said.

"However, we already know that consumers can reduce chronic disease risk by eating more vegetables, fruits, whole grains, and legumes (good sources of dietary fiber) and limiting consumption of added sugars, sodium, and saturated fat," she added.

Miguel Regueiro, MD, AGAF, who is chair of the Digestive Disease and Surgery Institute at Cleveland Clinic, agreed with the need for further study. There are limitations with the methodology used in the research from Dr. Hecht and colleagues, he said.

"Meta-analyses aren't perfect and I think we all acknowledge that," he

said, adding that the Hecht poster provides "a larger perspective on the topic."

There's widespread agreement that ultra-processed foods are not healthy, raising heart and cancer risks, he said. In counseling his patients, Dr. Regueiro said he acknowledges the challenges many people face in trying to pursue a healthier diet. Ultra-processed foods tend to be cheap and readily available, and many people need help in spotting them, such as learning to look at labels for unfamiliar terms.

"What I tell my own patients in the clinic is to really try to clean up the diet as much as possible and in a realistic way," he said.

The authors of the ACG poster did not report any financial conflicts. Dr. Hecht said he founded the Institute for Etiological Research to pursue questions about public health. Its funders include the Bertarelli Foundation. ■



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# Two Novel Choices for Resection Defect Repair Show Similar Success

BY HEIDI SPLETE

MDedge News

**T**wo novel devices are similarly effective for tissue approximation of large endoscopic resection defects, but each has advantages, shows new research presented in October at the annual meeting of the American College of Gastroenterology

“We know from previous data that defect closure is beneficial, and reduces complications such as delayed bleeding and delayed per-

dual-action tissue clip (DAT) and the TTS tack/suture device (TSD) – have not been directly compared on the basis of efficacy and cost, he said.

In the current study, Dr. Jawaid and colleagues randomized 56 adults undergoing tissue approximation and defect closure after endoscopic resection to DAT (31 patients) or TSD (25 patients). The patients were treated at a single center between August 2022 and May 2023 for closures of endoscopic resection defects including

gastric, duodenum, and colon lesions greater than 20 mm wide and greater than 30 mm long.

The primary outcomes were technical success of tissue approximation

and tissue approximation costs. Secondary outcomes were technical success of complete closure, closure costs, and speed of approximation and closure, as well as safety outcomes. Tissue approximation was defined as less than 15 mm of visible resection bed at the widest margin, and complete closure was defined as no visible resection bed.

Tissue approximation rates were not significantly different between the TSD and DAT groups (88% vs. 83.9%,  $P = .92$ ). However, approximation cost was significantly lower for DAT compared to TSD (\$673.1 vs. \$973.6;  $P = .002$ ).

Similarly, complete closure rates were not significantly different between the TSD and DAT groups

(92% vs. 93.5%,  $P = .83$ ), but closure cost/mm<sup>2</sup> was significantly lower for DAT compared to TSD (\$1.0/mm<sup>2</sup> vs. \$1.6/mm<sup>2</sup>;  $P = .002$ ).

Notably, the three DAT failures (60%) underwent successful tissue approximation with TSD, and the single TSD failure (33%) underwent successful tissue approximation using DAT.

In terms of speed, the averages for both tissue approximation time and closure speed were significantly faster in the DAT group, compared with the TSD group (12.2 minutes vs. 4

in which the study was presented.

“With different items now available for defect closure, this randomized controlled study provides guidance on which TTS approximation device should be considered, and helps determine effectiveness of defect closure,” she said.

“The results of this randomized controlled trial were very informative,” Dr. Afzali said. The data indicated that both DAT and TSD achieved similar rates of tissue approximation and complete closure, but “what was interesting was that

one TSD is equivalent to two DAT for tissue approximation. Further, tissue approximation was three times faster with DAT, and complete closure costs were lower in the DAT-treated group.”

In clinical practice, “the study was able to help identify scenarios, such as resection beds involving greater than 50% circumference or

defects located in the duodenum, where TSD is preferred over DAT for defect closure. These suggested scenarios are also important for clinical practice and device considerations,” Dr. Afzali said. “Additional studies with use of both devices, TSD and DAT simultaneously on a defect site may be needed to further assist endoscopists in defect management.”

The study was limited by the small size and use of data from a single center.

However, “based on our interim data, both devices are equally effective for tissue approximation of large endoscopic defects,” and facilitate complete defect closure, Dr. Jawaid said.

Ultimately, “both devices have a role,” with DAT being faster and likely more cost effective, while TSD is likely preferable for defects in the duodenum and those with a circumference greater than 50%, he said.

The study received no outside funding. Dr. Jawaid disclosed a consultancy with Boston Scientific, ConMed, CREO Speedboat, and DiLumen. Dr. Afzali disclosed numerous relationships with pharma including having served as an adviser/consultant for AbbVie, Bristol Myers Squibb/Celgene, Eli Lilly, and Gilead, among others. ■



Dr. Jawaid

**“Both devices have a role,” with DAT being faster and likely more cost effective, while TSD is likely preferable for defects in the duodenum and those with a circumference greater than 50%.**



Dr. Afzali

**“What was interesting was that one TSD is equivalent to two DAT for tissue approximation.”**

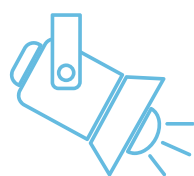
foration,” said Salmaan A. Jawaid, MD, of Baylor College of Medicine, Houston, in a presentation at the meeting.

In the past, defect closure was relatively straightforward; however, “the characteristics of these defects are evolving,” and defects are increasing in size, complexity, and number of locations, he said.

In response, management of resection defects has shifted from a one-step closure to a two-step process with approximation of the widest mucosal edges first, followed by complete resection bed closure, Dr. Jawaid said.

Two novel through the scope (TTS) tissue approximation devices used for the closure of large endoscopic resection defects – the

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### Data May Inform Device Decisions

“This was an important study conducted to evaluate the different scope devices for defect closure,” said Anita Afzali, MD, MPH, AGAF, a gastroenterologist specializing in inflammatory bowel disease and executive vice chair of internal medicine at the University of Cincinnati.

“These devices have an impact on risk for delayed bleeding and perforation,” said Dr. Afzali, who served as moderator of the session

# Cold Snare Polypectomy Underused Despite Recommendations

BY HEIDI SPLETE  
MDedge News

**J**ust over half of endoscopists use cold snare polypectomy to remove small polyps of less than 1 cm, despite recommendations from the U.S. Multisociety Task Force for its use in small lesions, shows new research presented in Vancouver at the annual meeting of the American College of Gastroenterology.

Polypectomy is a key part of colorectal cancer prevention, but endoscopists' choice of polypectomy is a major factor in quality, and the characteristics of polypectomies in clinical practice are highly variable, said Seth D. Crockett, MD, AGAF, of Oregon Health & Science University, Portland, in a presentation at the meeting.

Cold snare polypectomy is preferred for the removal of polyps less than 1 cm because of a high complete resection rate and a strong safety profile, compared to forceps and hot snares, which tend to be associated with high incomplete resection rates, inadequate histopathologic specimens, and/or complication rates. The adherence of endoscopists to the recommen-

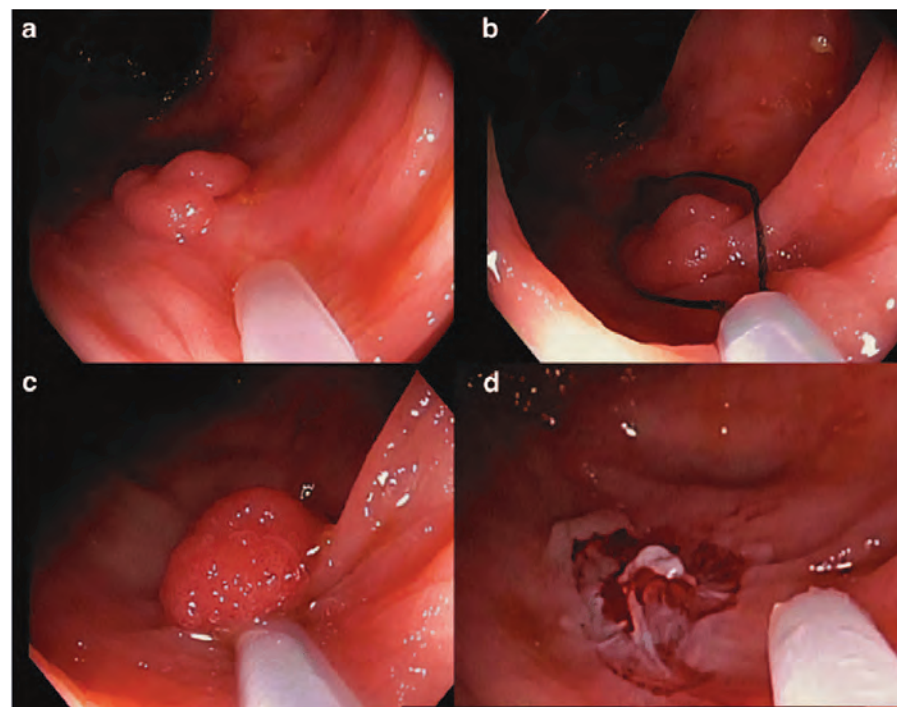
**The mean endoscopist cold snare polypectomy rate was 51.2%, which was “lower than expected based on current guideline recommendations.”**

dations was not known until now, Dr. Crockett said.

This was a cross-sectional study of 1,589,499 colonoscopies that were conducted between 2019 and 2022 in patients (aged 40-80 years) who underwent a screening or surveillance colonoscopy in which at least one small polyp of less than 1 cm was removed. The final analysis included 3,082 endoscopists. Colonoscopies in which larger polyps were detected, or there was a confirmed case of cancer, were not included.

The mean endoscopist cold snare polypectomy rate (CSPR) was 51.2%, which was “lower than expected based on current guideline recommendations,” Dr. Crockett said.

Higher cold snare polypectomy



A 7-mm polyp is removed with cold snare polypectomy (a-c); the resection site is shown after the procedure (d).

rates were more common among specialists with training in gastroenterology, and more common among those who practiced in the Midwest (69%), as compared with practitioners in the Northeast who, at 40%, had the lowest rate. Colonoscopy volume, adenoma detection rate (ADR), serrated polyp detection rate (SDR), and cecal intubation rate (CIR), were all associated with a higher CSPR.

CSPR was more than 30% higher for endoscopists with an ADR of greater than 35%, compared with those with an ADR of less than 25% (58% vs. 27%, respectively;  $P < .0001$ ). Lower usage rates among endoscopists with low ADRs could compound the problem of interval cancer if polyps are missed, Dr. Crockett said. Endoscopist serrated polyp detection rates of 7% or higher, cecal intubation rates of 95% or higher, and mean withdrawal times greater than 9 minutes were significantly associated with higher CSPR ( $P < .0001$  for all).

The findings suggest a correlation between higher cold snare usage and improved quality metrics, such as adenoma detection rate and cecal intubation rate, said Jonathan A. Leighton, MD, AGAF, of the Mayo Clinic, Scottsdale, Ariz., in an interview.

“I would agree with the authors that much of the focus on colonoscopy quality has been directed

toward polyp detection, and little on the quality of polyp resection, which can be difficult to measure,”

he said. “Their results suggest that cold snare polypectomy for removal of small polyps is currently underutilized, but as with any polypectomy, it is important that all of the dysplastic tissue is removed using good technique.”

The results were strengthened by the large sample size and high fidelity of measurements of polyp size, polypectomy tools, and quality measures. But more research is needed to determine the impact of polypectomy technique on outcomes of colonoscopy efficacy and safety. In terms of limitations, small polyps carry a relatively low risk of recurrence, and the associations between an endoscopist's polypectomy practice and polyp recurrence, interval cancer, and adverse events were not examined, Dr. Crockett said.

The study was supported by a grant from the ACG. Dr. Crockett disclosed relationships with Carelon, Exact Sciences, Freenome, and Guardant. ■



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