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Gl&Hepatology News

July 2025 Volume 19 / Number 7



BY MARCIA FRELLICK

MDedge News

he "Shark Tank" winning innovation at the American Gastroenterological Association (AGA) Tech Summit in Chicago this April has "life-altering" potential for ostomy patients, according to one of the judges, and eliminates the need for constant pouch wear.

The innovation is called Twistomy, and it is designed to replace current ostomy-pouch systems that can cause leaks, odor, skin irritation, embarrassment, and social and emotional distress. The AGA Committee for GI

Innovation and Technology (CGIT) organizes the annual Tech Summit.

Twistomy's winning design includes a flexible ring and sleeve, which are inserted into the stoma and secured on the outside with a set of rings that make up the housing unit attached to a standard wafer. The housing unit twists the sleeve closed, allowing the user to control fecal output. For evacuation, the user attaches a pouch, untwists the sleeve, evacuates cleanly and effectively, and then discards the pouch.

Twistomy cofounders Devon Horton, BS, senior bioengineer, and Lily Williams, BS,

See Innovation \cdot page 20

BOSS Trial: No Survival Difference Between Regular and At-Need Surveillance

BY KATHLEEN DOHENY

FROM DDW 2025

SAN DIEGO—Gastroenterologists have debated the best course of action for patients with Barrett's esophagus for decades. Which is better for detecting early malignancy and preventing progression to esophageal adenocarcinoma (EAC) — surveillance endoscopy at regular intervals or only when symptoms occur? Does one offer a better chance of survival than the other?

Now, researchers who conducted what they believe is the first randomized clinical trial comparing the two approaches say they have the answer.

Surveillance endoscopy every 2 years offers no benefit in terms of overall or cancer-specific survival, said Oliver Old, MD, a consultant upper-GI surgeon at Gloucestershire Royal Hospital, England, who presented the findings at Digestive Disease Week® (DDW) 2025 following their online publication in *Gastroenterology* (2025 Apr. doi: 10.1053/j. gastro.2025.03.021).

At-need endoscopy may be a safe alternative for low-risk patients, the research team concluded.

The BOSS Trial

The Barrett's Oesophagus Surveillance Versus Endoscopy At Need Study (BOSS) ran from 2009 to 2024 at 109 centers in the United Kingdom, and 3452 patients with Barrett's esophagus of 1 cm circumferential or a 2 cm noncircumferential tongue or island were followed for a minimum of 10 years.

Researchers randomly assigned patients to undergo

See BOSS Trial · page 17



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LETTER FROM THE EDITOR

Vital Partners in GI Care

emand for specialized GI care has skyrocketed in recent years, eclipsing the supply of gastroenterologists and impairing patient access to high-quality GI care, particularly in rural and other underserved areas. In this environment, advanced practice providers (APPs), including nurse practitioners (NPs) and physician assistants (PAs), have become increasingly vital clinical partners to gastroenterologists in optimizing patient access, improving health outcomes, and ensuring continuity of

Across specialties, APPs are estimated to constitute roughly a third of the US clinical workforce, and demand is only growing. A June 2024 MGMA Stat poll found that 63% of medical groups planned to add new APP roles in the next year. As the GI APP workforce grows, so too will

demand for advanced training tailored to the APP role.

AGA has invested heavily in professional development opportunities for NPs and PAs in recognition of their vital role in providing high-quality GI care. The newly formed AGA NPPA Task Force, co-chaired by Abigail Meyers (who we featured in GIHN's April issue) and Kimberly Kearns, works closely with the Education



Dr. Adams

'AGA has invested heavily in professional development opportunities for NPs and PAs in recognition of their vital role in providing high-quality GI care.'

and Training Committee to develop education programs to meet the specific needs of NPs and PAs, and advocate for more APP involvement in AGA programming. One example of this is AGA's 2025 Principles of GI for the NP and PA course, which will be held in Chicago in early August — I encourage you to spread the word and support

your APP colleagues in getting involved in these important initiatives as our vital partners in GI care delivery.

In this month's issue of GIHN, we present the exciting results of the BOSS trial, showing no survival difference between regular and at-need surveillance for Barrett's esophagus, suggesting that at-need endoscopy may be a safe alternative for low-risk patients. Continuing our coverage of potentially practice-changing research from DDW, we highlight another recent study challenging the use of papillary sphincterotomy as a treatment for pancreas divisum.

In our July Member Spotlight, Dr. Eric Shah, (University of Michigan), a past AGA Research Scholar Award recipient, highlights how this critical research support aided him in his journey to develop a now Food and Drug Admininstra-

tion-approved point-of-care

screening tool used to evaluate patients with chronic constipation for pelvic floor dysfunction during a routine clinic visit. In our quarterly Perspectives column, a GI hospitalist and an interventional radiologist discuss best practices in management of lower GI bleeding. We hope you have a restful summer!■

Megan A. Adams, MD, JD, MSc Editor in Chief



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CADe Not Ready for Prime Time: AGA Clinical Practice Guideline

BY DIANA SWIFT

FROM GASTROENTEROLOGY

n American Gastroenterological Association (AGA) multidisciplinary panel has reached the conclusion that no recommendation can be made for or against the use of computer-aided detection (CADe)-assisted colonoscopy for colorectal cancer (CRC), the third most common cause of cancer mortality in the United States.

The systematic data review is a

other endoscopy outcomes to CRC incidence and CRC death relied on the modeling study, which included a lot of assumptions, which also contributed to our overall lower certainty."

The systematic and meta-analysis included 41 randomized controlled trials with more than 32,108 participants who underwent CADe-assisted colonoscopy. This technology was associated with a higher polyp detection rate than standard colonoscopy: 56.1% vs 47.9% (relative

but not involved in its formulation, Larry S. Kim, MD, MBA, AGAF, a gastroenterologist at South Denver Gastroenterology in Colorado, and current AGA president, said his practice group has used the GI Genius AI system in its affiliated hospitals but has so far chosen not to implement the technology at its endoscopy centers. "At the hospital, our physicians have the ability to utilize the system for select patients or not at all," he told GI & Hepatolo-



We need better intermediate- and long-term data on the impact of adenoma detection on interval cancers and CRC incidence [and] to understand at the population or health system level what the impact is on resources, cost, and access.'

collaboration between AGA and *The* BMJ's MAGIC Rapid Recommendations. The BMJ (2025 Mar. doi: 10.1136/bmj-2024-082656)issued a separate recommendation against CADe shortly after the AGA guideline was published.

Dr. Sultan

Led by Shahnaz S. Sultan, MD, MHSc, AGAF, of the division of gastroenterology, hepatology, and nutrition at University of Minnesota, Minneapolis, and recently published in *Gastroenterology* (2025 Mar. doi: 10.1053/j.gastro.2025.01.002), the review found only very low certainty of GRADEbased evidence for several critical long-term outcomes, both desirable and undesirable. These included the following: 11 fewer CRCs per 10,000 individuals and two fewer CRC deaths per 10,000 individuals. an increased burden of more intensive surveillance colonoscopies (635 more per 10,000 individuals), and cost and resource implications.

This technology did, however, yield an 8% (95% CI, 6%-10%) absolute increase in the adenoma detection rate (ADR) and a 2% (95% CI, 0%-4%) increase in the detection rate of advanced adenomas and/or sessile serrated lesions. "How this translates into a reduction in CRC incidence or death is where we were uncertain," Sultan said. "Our best effort at trying to translate the ADR and risk [RR], 1.22, 95% CI, 1.15-1.28). It also had a higher ADR: 44.8% vs 37.4% (RR, 1.22; 95% CI, 1.16-1.29).

But although CADe-assisted colonoscopy may increase ADR, it carries a risk for overdiagnosis, as most polyps detected during colonoscopy are diminutive (< 5 mm) and of low malignant potential, the panel noted. Approximately 25% of lesions are missed at colonoscopy. More than 15 million colonoscopies are performed annually in the United States, but studies have demonstrated variable quality of colonoscopies across key quality indicators.

"Artificial intelligence [AI] is revolutionizing medicine and healthcare in the field of GI [gastroenterology], and CADe in colonoscopy has been brought to commercialization," Sultan told GI & Hepatology News. "Unlike many areas of endoscopic research where we often have a finite number of clinical trial data, CADe-assisted colonoscopy intervention has been studied in over 44 randomized controlled trials and numerous nonrandomized, real-world studies. The question of whether or not to adopt this intervention at a health system or practice level is an important question that was prioritized to be addressed as guidance was needed."

Commenting on the guideline

When evidence for benefit is uncertain, underlying values are critical. ... With different priorities, other bodies could reasonably decide to recommend either for or against CADe.'

The fact that The BMJ reached a different conclusion based on the same data, evidence-grading system, and microsimulation, Kim added, "highlights the point that when evidence for benefit is uncertain, underlying values are critical." In declining to make a recommendation, the AGA panel balanced the benefit of improved detection of potentially precancerous adenomas vs increased resource utilization in the face of unclear benefit. "With different priorities, other bodies could reasonably decide to recommend either for or against CADe."

The Future

According to Sultan, gastroenterologists need a better understanding

of patient values and preferences and the value placed on increased adenoma detection, which may also lead to more lifetime colonoscopies without reducing the risk for CRC. "We need better intermediate- and long-term data on the impact of adenoma detection on interval cancers and CRC incidence." she said. "We need data on detection of polyps that are more

clinically significant such as those 6-10 mm in size, as well as serrated sessile lesions. We also need to understand at the population or health system level what the impact is on resources, cost, and access."

Ultimately, the living guideline underscores the trade-off between desirable and undesirable effects and the limitations of current evidence to support a recommendation, but CADe has to improve as an iterative AI application with further validation and better training.

With the anticipated improvement in software accuracy as AI machine learning reads increasing numbers of images, Sultan added, "the next version of the software may perform better, especially for polyps that are more clinically significant or for flat sessile serrated polyps, which are harder to detect. We plan to revisit the question in the next year or two and potentially revise the guideline."

These guidelines were fully funded by the AGA Institute with no funding from any outside agency or industry.

Sultan is supported by the US Food and Drug Administration. Three coauthors are supported by grants from the National Institute of Diabetes and Digestive and Kidnev Diseases. One coauthor is supported by the Permanente Medical Group Delivery Science and Applied Research Program. One coauthor is a consultant for Fujifilm and Olympus. One coauthor reported doing research work for Freenome and advisory board work for Guardant Health and Natera.

Kim disclosed no competing interests relevant to his comments.



Colorectal Cancer Screening Choices: Is Compliance Key?

BY NANCY A. MELVILLE

FROM DDW 2025

SAN DIEGO — In the ever-expanding options for colorectal cancer (CRC) screening, blood tests using precision medicine are becoming more advanced and convenient than ever; however, caveats abound, and when it comes to potentially life-saving screening measures, picking the optimal screening tool is critical.

Regarding tests, "perfect is not possible," said William M. Grady, MD, AGAF, of the Fred Hutchinson

rates seen among those racial and ethnic groups, with lower rates for conventional colonoscopy, he noted.

Importantly, in terms of performance in detecting CRC, bloodbased tests stand up to other modalities, as demonstrated in a real-world study conducted by Grady and his colleagues showing a sensitivity of 83% for the cf-DNA test, 74% for the fecal immunochemical test (FIT) stool test, and 92% for a multitarget stool DNA test compared with 95% for colonoscopy (Chung et al. Diges-



Dr. Grady

'What we can see is that the sensitivity of blood-based tests looks favorable and comparable to other tests. ... The bottom line is that these tests decrease CRC mortality and incidence, and we know there's a potential to improve compliance with [CRC] screening if we offer blood-based tests for average-risk people who refuse colonoscopy.'

Cancer Center, University of Washington School of Medicine in Seattle, who took part in a debate on the pros and cons of key screening options at Digestive Disease Week® (DDW) 2025.

"We have to remember that that's the reality of colorectal cancer screening, and we need to meet our patients where they live," said Grady, who argued on behalf of blood-based tests, including cell-free (cf) DNA (Shield, Guardant Health) and cfDNA plus protein biomarkers (Freenome).

A big point in their favor is their convenience and higher patient compliance — better tests that don't get done do not work, he stressed.

He cited data that showed suboptimal compliance rates with standard colonoscopy: Rates range from about 70% among non-Hispanic White individuals to 67% among Black individuals, 51% among Hispanic individuals, and the low rate of just 26% among patients aged between 45 and 50 years.

With troubling increases in CRC incidence among younger patients, "that's a group we're particularly concerned about," Grady said.

Meanwhile, studies show compliance rates with blood-based tests are ≥ 80%, with similar

tive Diseases Week 2023. Abstract #913e).

"What we can see is that the sensitivity of blood-based tests looks favorable and comparable to other tests," he said.

Among the four options, cfDNA had a highest patient adherence rate (85%-86%) compared with colonoscopy (28%-42%), FIT (43%-65%), and multitarget stool DNA (48%-60%).

"The bottom line is that these tests decrease CRC mortality and incidence, and we know there's a potential to improve compliance with colorectal cancer screening if we offer blood-based tests for average-risk people who refuse colonoscopy," Grady said.

Blood-Based Tests: Caveats, Harms?

Arguing against blood-based tests in the debate, Robert E. Schoen, MD, MPH, professor of medicine and epidemiology, division of gastroenterology, hepatology and nutrition, at the University of Pittsburgh in Pennsylvania, checked off some of the key caveats.

While the overall sensitivity of blood-based tests may look favorable, these tests don't detect early CRC well," said Schoen. The sensitivity rates for stage 1 CRC are 64.7% with Guardant Health and 57.1% with Freenome.

Furthermore, their rates of detecting advanced adenomas are very low; the rate with Guardant Health is only about 13%, and with Freenome is even lower at 12.5%, he reported.

These rates are "similar to the false-positive rate, with poor discrimination and accuracy for advanced adenomas," Schoen said. "Without substantial detection of advanced adenomas, bloodbased testing is inferior [to other options]."

Importantly, the low advanced adenoma rate translates to a lack of CRC prevention, which is key to reducing CRC mortality, he noted.

Essential to success with bloodbased biopsies, as well as with stool tests, is the need for a follow-up colonoscopy if results are positive, but Schoen pointed out that this may or may not happen.

He cited research from FIT data showing that among 33,000 patients with abnormal stool tests, the rate of follow-up colonoscopy within a year, despite the concerning results, was a dismal 56% (JAMA Netw Open. 2023 Jan. doi: 10.1001/jamanetworkopen.2022.51384).

"We have a long way to go to make sure that people who get pos-

would be 79% and 81%, respectively, followed by annual FIT, at 72% and 76%; multitarget DNA every 3 years, at 68% and 73%; and cfDNA (Shield), at 45% and 55%.

Based on those rates, if patients originally opting for FIT were to shift to blood-based tests, "the rate of CRC deaths would increase," Schoen noted.

The findings underscore that "blood testing is unfavorable as a 'substitution test,'" he added. "In fact, widespread adoption of blood testing could increase CRC morbidity."

"Is it better than nothing?" he asked. "Yes, but only if performance of a colonoscopy after a positive test is accomplished."

What About FIT?

Arguing that stool-based testing, or FIT, is the ideal choice as a first-line CRC test, Jill Tinmouth, MD, PhD, a professor at the University of Toronto, Ontario, Canada, pointed to its prominent role in organized screening programs, including regions where resources may limit the widespread utilization of routine first-line colonoscopy screening. In addition, it narrows colonoscopies to those that are already prescreened as being at risk.

Data from one such program,



Dr. Tinmouth

This study shows that in the context of organized screening, the benefits of FIT are the same as colonoscopy in the most important outcome of CRC — mortality. ... FIT has clear and compelling advantages over colonoscopy. It is less costly and also better for the environment [by using fewer resources].'

itive noninvasive tests get followed up," he said.

In terms of the argument that blood-based screening is better than no screening at all, Schoen cited recent research that projected reductions in the risk for CRC incidence and mortality among 100,000 patients with each of the screening modalities (Ann Intern Med. 2024 Oct. doi: 10.7326/ANNALS-24-00910).

With standard colonoscopy performed every 10 years, the reductions in incidence and mortality reported by Kaiser Permanente of Northern California, showed that participation in CRC screening doubled from 40% to 80% over 10 years after initiating FIT screening. CRC mortality over the same period decreased by 50% from baseline, and incidence fell by as much as 75%

In follow-up colonoscopies, Tinmouth noted that collective research from studies reflecting real-world participation and adherence to FIT in populations in the United Kingdom, the



Netherlands, Taiwan, and California show follow-up colonoscopy rates of 88%, 85%, 70%, and 78%, respectively.

Meanwhile, a recent large comparison of biennial FIT (n = 26,719) vs one-time colonoscopy (n = 26,332) screening, the first study to directly compare the two (Lancet. 2025 Mar. doi: 10.1016/S0140-6736[25]00145-X), showed noninferiority, with nearly identical rates of CRC mortality at 10 years (0.22% colonoscopy vs 0.24% FIT) as well as CRC incidence (1.13% vs 1.22%, respectively).

"This study shows that in the context of organized screening, the benefits of FIT are the same as colonoscopy in the most important outcome of CRC — mortality," Tinmouth said.

Furthermore, as noted with blood-based screening, the higher participation with FIT shows a much more even racial/ethnic participation than that observed with colonoscopy.

"FIT has clear and compelling advantages over colonoscopy," she said. As well as better compliance among all groups, "it is less costly and also better for the environment [by using fewer resources]," she added.

Colonoscopy: 'Best for First-Line Screening'

Making the case that standard colonoscopy should in fact be the first-line test, Swati G. Patel, MD, director of the Gastrointestinal Cancer Risk and Prevention Center at the University of Colorado Anschutz Medical Center, Aurora, emphasized the robust, large

population studies showing its benefits. Among them is a landmark national policy study showing a significant reduction in CRC incidence and mortality associated with first-line colonoscopy and adenoma removal (CA A Cancer J Clin. 2020 Mar. doi: 10.3322/caac.21601).

A multitude of other studies in different settings have also shown similar benefits across large populations, Patel added.

In terms of its key advantages over FIT, the once-a-decade screening requirement for average-risk patients is seen as highly favorable by many, as evidenced in clinical



Dr Patel

'Colonoscopy had a substantial and impressive long-term protective benefit both in terms of developing colon cancer and dying from colon cancer. [The collective findings underscore that] 'colonoscopy as a standalone test is uniquely cost-effective.'

trial data showing that individuals highly value tests that are accurate and do not need to be completed frequently, she said (Prev Med Rep. 2022 Nov. doi: 10.1016/j. pmedr.2022.102047). Research from various other trials of organized screening programs further showed patients crossing over from FIT to colonoscopy, including one study of more than 3500 patients comparing colonoscopy and FIT, which had approximately 40% adherence with FIT vs nearly 90% with colonoscopy (Gastroenterology. 2023 Mar. doi: 10.1053/j. gastro.2023.03.206).

Notably, as many as 25% of the patients in the FIT arm in that study crossed over to colonoscopy, presumably because of preference for the once-a-decade regimen, Patel said.

"Colonoscopy had a substantial and impressive long-term protective benefit both in terms of developing colon cancer and dying from colon cancer," she said.

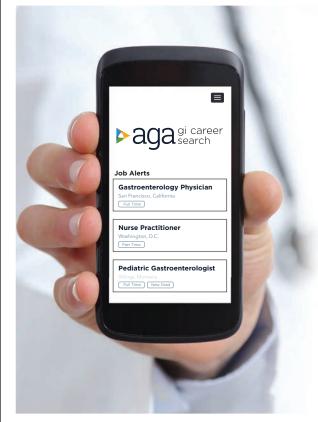
Regarding the head-to-head FIT and colonoscopy comparison that Tinmouth described, Patel noted

that a supplemental table in the study's appendix of patients who completed screening does reveal increasing separation between the two approaches, favoring colonoscopy, in terms of longer-term CRC incidence and mortality.

The collective findings underscore that "colonoscopy as a standalone test is uniquely cost-effective," in the face of costs related to colon cancer treatment.

Instead of relying on biennial tests with FIT, colonoscopy allows clinicians to immediately risk-stratify those individuals who can benefit from closer surveillance and really relax surveillance for those who are determined to be low risk, she said.

Grady had been on the scientific advisory boards for Guardant Health and Freenome and had consulted for Karius. Shoen reported relationships with Guardant Health and grant/research support from Exact Sciences, Freenome, and Immunovia. Tinmouth had no disclosures to report. Patel disclosed relationships with Olympus America and Exact Sciences.



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Member Michigan Gl Designs a Simple SPOTLIGHT Tool for a Common Problem

BY JENNIFER LUBELL

MDedge News

atients sometimes drive hundreds of miles to see their gastroenterology (GI) physicians for problems that never seem to resolve. Constipation is one of those ailments that can affect quality of life.

The advice is, "Try this diet or laxative. Get a colonoscopy. Often, that's not getting at the root problem," said Eric Dinesh Shah, MD, MBA, a gastroenterologist at the University of Michigan, Ann Arbor.

Such methods aren't equipped to test the pelvic floor, said Dr. Shah, who worked with clinical experts to develop a simple point-of-care device called RED (Rectal Expulsion Device) that makes it easier to diagnose and predict treatment options for constipation.

The device uses a foam-filled balloon to evaluate pelvic floor problems related to constipation, after a digital rectal exam during an office visit. Because the procedure can be performed during a patient's initial office visit, it can eliminate the need for referrals to far-away specialists for many patients.

In 2019, Dr. Shah received the AGA-Shire Research Scholar Award in Functional GI and Motility Disorders from the AGA Research Foundation for developing RED, and the device was recently cleared by the Food and Drug Administration.

GI doctors don't always have the answers, he acknowledged in an interview, but this creates the opportunity for new advancements such as RED. It's important for GI trainees to test out ideas early in their career, Dr. Shah said, utilizing local and regional workshops as well as national conferences to meet like-minded people at similar career stages, and to look for funding opportunities to explore those ideas.

What is the most challenging case you've encountered?

Dr. Shah: The most challenging cases to me have been the ones where I wish we could have helped people years ago. It's not that anyone did anything wrong or was poorly intentioned. It's quite the opposite: There sometimes is no real avenue to offer testing locally with current technology, even though the local clinical teams completely understand what should be done in a perfect world. That creates challenges where patients go hours out of their way to see specialists, just to find an answer that might have been 1 mile down the road all along.

What has been your solution to help these patients?

Dr. Shah: My work has been about helping patients who drive a hundred miles or routinely go hours out of their way for their care. Usually that's a sign that things just aren't working locally. Patients have lost trust in their ability to get care with the teams they have. Or the teams themselves just need help. I think a major part of the job is to reinforce the bond between the patient and their local team by



Dr. Eric Dinesh Shah developed RED for point-of-care use.

giving them the tools and expertise so that the patients can get that care locally.

There's been this trend toward this "hub and spoke" model in care where all the patients are filtering into these large hospital-owned mega practices. I wonder about the sustainability of that model because it takes away the ability of patients to see doctors who are invested in their local community. What we need to be doing is trying to flip that.

I'd love to discuss the RED device and how was this device conceived?

Dr. Shah: I partnered with experts, including William Chey, MD, AGAF, at the University of Michigan, who dedicate their entire careers toward creating robust science in large academic medical centers. In understanding the best ways to care for patients today, I could focus my own career on how to translate that level of care for the patients of tomorrow. I would encourage GI trainees to find senior and peer mentors who share perspective on this approach as an anchor to shared success.

For the RED device, the problem in constipation is that patients see their gastroenterologist over and over and over. It's "try this diet, try this laxative, try this drug, try this other treatment," and we're not getting at the root problem. Patients might go through a series of colonoscopies to reassure them but also to reassure their doctor that they're not missing something. What we haven't had is a way to test and evaluate the pelvic floor locally because those technologies are high tech and live in these big academic medical centers.

What are plans for its distribution and use in the consumer space?

Dr. Shah: The device is now available in the United States [https://www.red4constipation.com].

As an AGA Research Scholar Award winner, how might AGA play a role in supporting GI doctors?

Dr. Shah: The AGA Research Scholar Award enabled

me to learn how RED predicted outcomes for patients seeing general gastroenterologists who then see pelvic floor physical therapy in the community to treat constipation. The availability of pelvic floor physical therapy and the field at large, has exploded in recent years across the country [https:// www.pelvicrehab.com], making it easier for patients to get the local care they need.

In looking at what this award did for my own career and those of others in my cohort, I think the AGA Research Scholar Award mechanism serves as an example of what other GI trainees can do across the many areas of GI that are ripe for transformation.

What other AGA workshops are useful to GI doctors?

Dr. Shah: The AGA Tech Summit and Innovation Fellows programs give access to a positive learning environment to network with people across career stages who are seeking to advance the field in this way. These programs are particularly successful because they focus on helping GI trainees find peer success and professional satisfaction in the shared journey, rather than focusing on the accolades. I would strongly encourage GI trainees who have an

Continued on following page

Lightning round

Do you prefer texting or talking? **Texting**

Do you prefer coffee or tea?

Are you an early bird or night owl? Early bird

What's your go-to comfort food? Tex Mex

If you could travel anywhere, where would you go?

Antarctica

What's your favorite TV show? **Below Deck**

What's one hobby you'd like to pick up?

What's your favorite way to spend a weekend? A lazy weekend

If you could have dinner with any historical figure, who would it be?

Winston Churchill

What's your go-to karaoke song?

Our endoscopy nurses give no choice other than Taylor Swift, Green Day, and the Backstreet Boys

Targeted CRC Outreach Doubles Screening Rates, Cuts Deaths by Half

BY MEGAN BROOKS

FROM DDW 2025

SAN DIEGO — A 20-year initiative by Kaiser Permanente Northern California that assessed colorectal cancer (CRC) screening status and offered flexible options for screening has made a huge difference in CRC incidence, deaths, and racial disparities, an analysis showed.

"The program promptly doubled the proportion of people up to date with screening," reported lead investigator Douglas A. Corley, MD, PhD, AGAF, a research scientist with Kaiser's Division of Research, at a press briefing held on April 24, ahead of a presentation at the Digestive Disease Week (DDW)® 2025.

Additionally, within about 10 years, cancer rates were cut by a third, deaths were halved for the second most common cause of cancer deaths in the United States, and the differences that had previously been seen by race or ethnicity were largely eliminated, he said.

"Ten years ago, there were big gaps in cancer risk and death, especially among our Black patients. Now, those differences are nearly gone," Corley said.

Closing the Gap

A systematic CRC screening program was implemented across Kaiser Permanente Northern California. The program included proactive outreach to members who were overdue for screening and mailing them fecal immunochemical test (FIT) kits for at-home use.

Corley and colleagues tracked screening status and CRC incidence

Continued from previous page interest but don't know where to start to apply for these programs.

What do you think is the biggest misconception about your specialty?

Dr. Shah: That gastroenterologists have all the answers with current technology. There's a lot we still don't know. What gives me reassurance is the momentum around new ways of thinking that GI trainees and early-stage gastroenterologists continually bring forward to improve how we care for patients.

and mortality annually from 2000 to 2019 among about 1.1 million members aged 50-75 years across 22 medical centers of the integrated healthcare system. The cohort included American Indian or Alaska Native, Asian, Black, Hispanic, Na-



Dr. Corley

tive Hawaiian or Pacific Islander, and White members.

Screening rates via FIT, colonoscopy, or sigmoidoscopy more than doubled after starting the program, from about 37%

in the early years to about 80% within a few years, and it stayed that high through 2019, Corley reported.

"Importantly, these large increases occurred across the whole population with only small differences," he said.

For example, about 76% of Hispanic members, 77% of Black members, 82% of White members, and 83% of Asian members were up to date in the later years and through 2019.

"This shows that systematic, comparable outreach can provide a level playing field for completion of preventive care," Corley said. After an expected early uptick in CRC incidence due to early detection, incidence later declined and by 2019 had dropped approximately 30% across the groups.

Disparities Erased

CRC deaths also fell by about 50% across all groups, with the largest decline among Black members, Corley noted.

Racial and ethnic disparities in both CRC incidence and mortality have long existed, with Black patients in particular experiencing higher risks and worse outcomes, likely from a mixture of risk factors and healthcare utilization, Corley said.

Offering outreach and equal access to screening in the Kaiser program erased those long-standing disparities.

"It's remarkable that some of these large differences in mortality by race and ethnicity that we saw two decades ago, and which are found throughout the United States, are now similar to small chance variation in the population," Corley said.

Flexibility was key to getting more people screened, he noted. "It's about reaching people at their homes and offering a choice to patients. It's an astonishingly simple concept."

It's important to note that these findings stem from a large,

integrated healthcare system, which may differ from other settings, although similar outreach strategies have succeeded in safety net clinics and smaller practices, Corley added.

By boosting screening rates to 80%, the health system reached the level that's essentially been defined in the past as our goal of screening programs, said Loren Laine, MD,



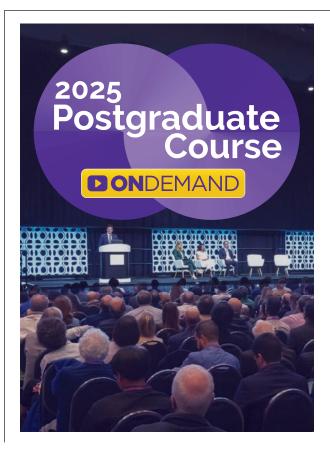
Dr. Laine

AGAF, professor of medicine (digestive diseases) at Yale School of Medicine, New Haven, Connecticut, and chair of this year's DDW.

"It shows that if health systems insti-

tute programmatic screening for all their covered individuals, they could markedly increase screening," said Laine. "Most importantly, of course, [screening] was associated with a reduction in colorectal cancer incidence and deaths."

The study had no commercial funding. Corley reported no relevant conflicts of interest. Laine's disclosures included consulting and/or relationships with Medtronic, Phathom Pharmaceuticals, Biohaven, Celgene, Intercept, Merck, and Pfizer. ■



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The New Gastroenterologist

Improving Care for Patients From Historically Minoritized and Marginalized Communities With Disorders of Gut-Brain Interaction

BY ROSA L. YU, MD; JENNIFER DIMINO, MD; CHRISTOPHER VÉLEZ, MD

Introduction: Cases

Patient 1: A 57-year-old man with post-prandial distress variant functional dyspepsia (FD) was recommended to start nortriptyline. He previously established primary care with a physician he met at a barbershop health fair in Harlem, who referred him for specialty evaluation. Today, he presents for follow-up and reports he did not take this medication because he heard it is an antidepressant. How would you counsel him?

Patient 2: A 61-year-old woman was previously diagnosed with mixed variant irritable bowel syndrome (IBS-M). Her symptoms have not significantly changed. Her prior workup has been reassuring and consistent with IBS-M. Despite this, the patient pushes to repeat a colonoscopy, fearful that something is being missed or that she is not being offered care because of her undocumented status. How do you respond?

Patient 3: A 36-year-old man is followed for the management of generalized anxiety disorder and functional heartburn. He was started on low-dose amitriptyline with some benefit, but follow-up has been sporadic. On further discussion, he reports financial stressors, time barriers, and difficulty scheduling a







Dr. Vélez

meeting with his union representative for work accommodations as he lives in a rural community. How do

you reply?

Dr. Yu

Patient 4: A 74-year-old man with Parkinson's disease who uses a wheelchair has functional constipation that is well controlled on his current regimen. He has never undergone colon cancer screening. He occasionally notices blood in his stool, so a colonoscopy was recommended to confirm that his hematochezia reflects functional constipation complicated by hemorrhoids. He is concerned about the bowel preparation required for a colonoscopy given his limited mobility, as his insurance does not cover assistance at home. He does not have family members to help him. How can you assist him?

Social Determinants of Health, Health Disparities, and DGBIs Social determinants of health affect all aspects of patient care, with an increasing body of published work looking at potential disparities in organ-based and structural diseases.¹⁻⁴ However, little has been done to explore their influence on disorders of gut-brain interaction or DGBIs.

From a pathophysiologic perspective, the impact of biopsychosocial stressors is particularly relevant in patients with DGBIs.5 As DGBIs cannot be diagnosed with a single laboratory or endoscopic test, the patient history is of the utmost importance and physician-patient rapport is paramount in their treatment. Such rapport may be more difficult to establish in patients coming from historically marginalized and minoritized communities who may be distrustful of healthcare as an institution of (discriminatory) power.

Potential DGBI Management Pitfalls in Historically Marginalized or Minoritized Communities

For racial and ethnic minorities in the United States, disparities in healthcare take on many forms. People from racial and ethnic minority communities are less likely to receive a gastroenterology (GI) consultation and those with IBS are more likely to

undergo procedures as compared to White patients with IBS.⁶ Implicit bias may lead to fewer specialist referrals, and specialty care may be limited or unavailable in some areas. Patients may prefer seeing providers in their own community, with whom they share racial or ethnic identities, which could lead to fewer referrals to specialists outside of the community.

Historical discrimination contributes to a lack of trust in healthcare professionals, which may lead patients to favor more objective diagnostics such as endoscopy or to view being counseled against invasive procedures as having necessary care denied. Because of a broader cultural stigma surrounding mental illness, patients may be more hesitant to utilize neuromodulators, which have historically been used for psychiatric diagnoses, as it may lead them to conflate their GI illness with mental illness.^{7,8}

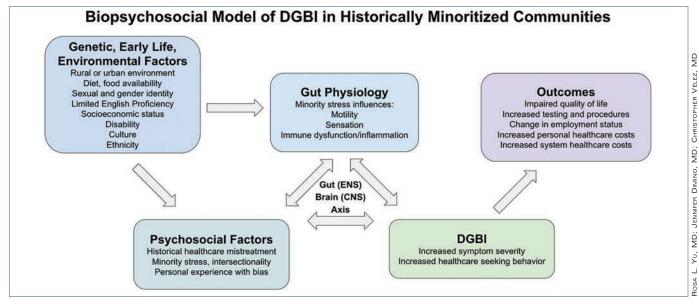
Since DGBIs cannot be diagnosed with a single test or managed with a single treatment modality, providing excellent care for patients with DGBIs requires clear communication. For patients with limited English proficiency (LEP), access to high-quality language assistance is the foundation of comprehensive care. Interpreter use (or lack thereof) may limit the ability to obtain a complete and accurate clinical history, which can lead to fewer referrals to specialists and increased reliance on endoscopic evaluations that may not be clinically indicated.

These language barriers affect patients on many levels — in their ability to understand instructions for medication administration, preparation for procedures, and

Clinical Highlights & Tips

Provider & Care	Form Accessibility	Language Accessibility	Physical Accessibility
Team Accessibility			
Multicultural staff. Implicit bias and sensitivity training for staff. Shared decision-making (with family involvement if desired). Acknowledgment intersectional identities. Community health engagement: Host community health fairs, integrate community health workers, invest in patient navigators.	Forms in multiple languages and with visuals aids suitable for patients of all education levels. Appropriate name, pronoun, and gender options.	Interpreter services should always be used or offered, even when family members may be present to translate. Multilingual staff.	Accessible route for entry into the clinic. Examination rooms: • Door with adequate width • Enough clearance to maneuver • Assistive devices & hardware eg, patient lifts Availability of support staff to facilitate patient transfers.

Source: Rosa L. Yu, MD; Jennifer Dimino, MD; Christopher Vélez, MD



From a pathophysiologic perspective, the impact of biopsychosocial stressors is particularly relevant in patients with DGBIs.

return precautions — which may ultimately lead to poorer responses to therapy or delays in care. LEP alone is broadly associated with fewer referrals for outpatient follow-up, adverse health outcomes and complications, and longer hospital stays. These disparities can be mitigated by investing in high-quality interpreter services, providing instructions and forms in multiple languages, and engaging the patient's family and social supports according to their preferences.

People experiencing poverty (urban and rural) face challenges across multiple domains including access to healthcare, health insurance, stable housing and employment, and more. Many patients seek care at federally qualified health centers, which may face greater difficulties coordinating care with external gastroenterologists.¹⁰

Insurance barriers limit access to essential medications, tests, and procedures, and create delays in establishing care with specialists. Significant psychological stress and higher rates of comorbid anxiety and depression contribute to increased IBS severity.¹¹ Financial limitations may limit dietary choices, which can further exacerbate DGBI symptoms. Long work hours with limited flexibility may prohibit them from presenting for regular follow-ups and establishing advanced DGBI care such as with a dietitian or psychologist.

Patients with disabilities face many of the health inequities previously discussed, as well as additional challenges with physical accessibility, transportation, exclusion from education and employment, discrimination, and stigma. Higher prevalence of comorbid mental illness and higher rates of intimate partner violence and interpersonal violence all contribute to DGBI severity and

challenges with access to care. ^{12,13} Patients with disabilities may struggle to arrive at appointments, maneuver through the building or exam room, and ultimately follow recommended care plans.

How to Approach DGBIs in Historically Marginalized and Minoritized Communities

Returning to the patients from the introduction, how would you counsel each of them?

Patient 1: We can discuss with the patient how nortriptyline and other typical antidepressants can and often are used for indications other than depression. These medications modify centrally mediated pain signaling and many patients with functional dyspepsia experience a significant benefit. It is critical to build on the rapport that was established at the community health outreach event and to explore the patient's concerns thoroughly. Patient 2: We would begin by inquiring about her underlying fears associated with her symptoms and seek to understand her goals for repeat intervention. We can review the risks of endoscopy and shift the focus to improving her symptoms. If we can improve her bowel habits or her pain, her desire for further interventions may lessen. **Patient 3:** It will be important to

Patient 3: It will be important to work within the realistic time and monetary constraints in this patient's life. We can validate him and the challenges he is facing, provide positive reinforcement for the progress he has made so far, and avoid disparaging him for the aspects of the treatment plan he has been unable to follow through with. As he reported a benefit from amitriptyline, we can consider increasing his dose as a feasible next step.

Patient 4: We can encourage the patient to discuss with his primary

care physician how they may be able to coordinate an inpatient admission for colonoscopy preparation. Given his co-morbidities, this avenue will provide him dedicated support to help him adequately prep to ensure a higher quality examination and limit the need for repeat procedures.

DGBI Care in Historically Marginalized and Minoritized Communities: A Call to Action

Understanding cultural differences and existing disparities in care is essential to improving care for patients from historically minoritized communities with DGBIs. Motivational interviewing and shared decision-making, with acknowledgment of social and cultural differences, allow us to work together with patients and their support systems to set and achieve feasible goals.¹⁴

To address known health disparities, offices can take steps to ensure the accessibility of language, forms, physical space, providers, and care teams. Providing culturally sensitive care and lowering barriers to care are the first steps to effecting meaningful change for patients with DGBIs from historically minoritized communities.

Dr. Yu is based at division of gastroenterology and hepatology, Boston Medical Center and Boston University. Dr. Dimino and Dr. Vélez are based at the division of gastroenterology, Massachusetts General Hospital and Harvard Medical School, both in Boston. Dr. Yu, Dr. Dimino, and Dr. Vélez do not have any conflicts of interest for this article.

Additional Online Resources Provider & Care Team Accessibility

 Cultivating Cultural Competency in Gastroenterology Practices (https://doi.org/10.1016/j. cgh.2022.12.022)

Form Accessibility

- Intake Form Guidance for Providers (www.queeringmedicine. com/resources/intake-form-guidance-for-providers)
- Making Your Clinic Welcoming to LGBTQ Patients (http://unmfm.pbworks.com/w/file/fetch/110464234/Making Your Clinic Welcoming to LGBTQ Patients.pdf)
- Transgender Data Collection in the Electronic Health Record: Current concepts and issues (https:// doi.org/10.1093/jamia/ocab136)

Language Accessibility

 Overcoming the Challenges of Providing Care to Limited English Proficient Patients (https://tinyurl.com/4xb745td)

Physical Accessibility

- Access to Medical Care for Individuals With Mobility Disabilities (www.ada.gov/resources/medical-care-mobility/#top)
- Making Your Medical Office Accessible (www.friendlylikeme.com/access-spotlight/making-your-medical-office-accessible)

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Papilla Sphincterotomy Shows No Risk Reduction in Pancreas Divisum

BY NANCY A. MELVILLE

FROM DDW 2025

SAN DIEGO — In treating pancreas divisum, the common use of endoscopic retrograde cholangiopancreatography (ERCP) with minor papilla endoscopic sphincterotomy showed no significant benefit over a sham procedure, suggesting that patients can be spared the intervention, which can carry risks of its

"This is a topic that has been debated for decades," said first author Gregory A. Coté, MD, AGAF, division head, professor of medicine, division of gastroenterology & hepatology, Oregon Health & Science University, Portland.

"Many doctors believe the procedure helps and offer it because we have limited options to help our patients, whereas others believe the procedure is harmful and doesn't help," he explained in a press briefing for the late-breaking study, presented at Digestive Disease Week (DDW)® 2025.

The study's findings supported the latter argument.

"Patients who underwent ERCP with sphincterotomy were just as likely as those who did not have



Dr. Coté

this procedure to develop acute pancreatitis again," Coté reported.

While clinical guidelines currently recommend ERCP as treatment for pancreas divisum, "these

guidelines are likely to change based on this study," he said.

Pancreas divisum, occurring in about 7%-10% of people, is an anatomic variation that can represent an obstructive risk factor for acute recurrent pancreatitis.

The common use of ERCP with minor papilla endoscopic sphincterotomy to treat the condition is based on prior retrospective studies showing that in patients who did develop acute pancreatitis, up to 70% with the treatment never developed acute pancreatitis again. However, there have been no studies comparing the use of the treatment with a control group.

Coté and colleagues conducted the multicenter SHARP trial, in which 148 patients with pancreas divisum were enrolled between September 2018 and August 2024 and randomized to receive either ERCP with minor papilla endoscopic sphincterotomy (n = 75) or a sham treatment (n = 73).

The patients, who had a median age of 51 years, had a median of three acute pancreatitis episodes prior to randomization.

With a median follow-up of 33.5 months (range, 6-48 months), 34.7% of patients in the ERCP arm experienced an acute pancreatitis incident compared with 43.8% in the sham arm, for a hazard ratio of 0.83 after adjusting for duct size and the number of episodes, which was not a statistically significant difference (P = .27).

A subgroup analysis further showed no indication of a

treatment effect based on factors including age, diabetes status, sex, alcohol or tobacco use, or other factors.

"Compared with a sham ERCP group, we found that minor papillotomy did not reduce the risk of acute pancreatitis, incident chronic pancreatitis, endocrine pancreatic insufficiency or diabetes, or pancreas-related pain events," Coté said.

The findings are particularly important because the treatment itself is associated with some risks, he added.

"Ironically, the problem with this procedure is that it can cause acute pancreatitis in 10%-20% of patients and may instigate other issues later," such as the development of scarring of the pancreas related to incisions in the procedure.

"No one wants to offer an expensive procedure that has its own risks if it doesn't help," Coté said.

Based on the findings, "pancreas divisum anatomy should no longer be considered an indication for ERCP, even for idiopathic acute pancreatitis," he concluded.

Hepatic Encephalopathy: Improve Diagnosis, Management, and Care

epatic encephalopathy (HE) is no longer a rare complication — it's an urgent clinical reality that's a leading cause of hospitalization in patients with cirrhosis. HE can be deceptively subtle or profoundly severe, presenting with a wide clinical spectrum — from mild cognitive slowing to life-threatening coma. Without clear disease biomarkers, HE remains a diagnosis of exclusion, making it critical for clinicians to remain vigilant, especially in patients with chronic liver disease (CLD).

The incidence of CLD is climbing, fueled by rising rates of alcohol-associated liver disease, metabolic dysfunction—associated steatotic liver disease (MASLD), and hepatitis C, which is often undiagnosed. For example:

- More than 2 million Americans had alcohol-associated cirrhosis as of 2017.²
- Currently, 38% of all adults and 7%-14% of children and adolescents have MASLD. By 2040, the MASLD prevalence rate for adults is projected to increase to more than 55%.³
- The economic burden is staggering from \$1 billion⁴ in 2003 to over \$7 billion⁵ in hospital costs for cirrhosis-related admissions today.

These figures aren't just statistics — they represent a growing population of patients who are at risk of developing HE, sometimes without ever

receiving a proper diagnosis or follow-up care.

Because HE mimics many other forms of neurological dysfunction — delirium, alcohol intoxication, diabetes-related confusion — it can be easy to miss or misdiagnose. But differentiating HE from other causes of altered mental status is critical, especially for patients who may ulti-

The incidence of CLD is climbing, fueled by rising rates of alcohol-associated liver disease, metabolic dysfunction—associated steatotic liver disease, and hepatitis C, which is often undiagnosed.

mately require liver transplantation.^{6,7}

Moreover, patients frequently leave the hospital without adequate education or maintenance medication for episodic overt HE. Without coordinated follow-up between primary care, hepatology, and caregivers, these patients are at risk for recurrence.

To close these practice gaps, education is key. AGA's course, "Missing the Mark: Hepatic Encephalopathy," provides clinicians with up-todate guidance on:

• The changing epidemiology of cirrhosis and

- undiagnosed cirrhosis for patients with liver disease.
- Assessment guidelines and best practices for HE diagnosis and management.
 How to develop transition-of-care plans with
- patients, caretakers, and specialty providers. Take the course today: https://tinyurl.com/3muwhmj5.

Don't wait until HE is an emergency. Equip yourself with the tools to recognize it earlier, treat it effectively, and coordinate better care.

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Don't Overlook Processed Meat as Colorectal Cancer Risk Factor

BY JOHN WATSON

ven though older adults are more likely to be diagnosed with colorectal cancer (CRC), there is a concerning rise in diagnoses among younger adults, making it essential for healthcare providers to educate adult patients of all ages about the lifestyle-related risk factors associated with the disease.

Many are familiar with the modifiable risk factors of obesity, smoking, and alcohol consumption, but the impact of processed meat — a common element of the Western diet —often remains underappreciated.

But the data are clear: Processed meat, defined as meat that has been altered through methods such as salting, curing, fermenting, or smoking to enhance flavor or preservation, has been linked to an increased risk for CRC.

The International Agency for Research on Cancer, part of the World Health Organization, analyzed over 800 global studies and classified processed meats as carcinogenic to humans, whereas red meat was deemed "probably" carcinogenic. Their findings were later published in *The Lancet Oncology* (2015 Dec. doi:10.1016/S1470-2045[15]00444-1), confirming that the strongest epidemiological evidence linked processed meat consumption to CRC.

"While I routinely counsel my patients about lifestyle and dietary risk factors for CRC, including processed meat, I'm not sure how often this is specifically mentioned by physicians in practice," Peter S. Liang, MD, MPH, an assistant professor and researcher focused on CRC prevention at NYU Langone Health in New York City, and an American Gastroenterological Association (AGA) spokesperson, told *GI & Hepatology News*.

David A. Johnson, MD, chief of gastroenterology at Eastern Virginia Medical School and Old Dominion University, both in Norfolk, Virginia, concurred. Many healthcare providers may not fully recognize the risks posed by processed meat in relation to CRC to counsel their patients, Johnson said. "In my experience, there is not a widespread awareness."

Understanding the Carcinogenic Risks

The excess risk for CRC per gram

of intake is higher for processed meat than for red meat. However, the threshold for harmful consumption varies among studies, and many group red and processed meat together in their analyses.

For example, a 2020 prospective analysis of UK Biobank data (Int J Epidemiol. doi: 10.1093/ije/dyaa142) reported that a 70 g/d higher intake of red and processed meat was associated with a 32% and 40% greater risk for CRC and colon cancer, respectively.

More recently, a 2025 prospective study (Nat Commun. doi: 10.1038/ s41467-024-55219-5) examined the associations between CRC and 97 dietary factors in 542,778 wom-



Dr. Liang

'While I routinely counsel my patients about lifestyle and dietary risk factors for CRC, including processed meat, I'm not sure how often this is specifically mentioned by physicians in practice.'

en. Investigators found that, aside from alcohol, red and processed meat were the only other dietary factors positively associated with CRC, with a 30-g/d intake increasing the risk for CRC by 8%.

Although the World Cancer Research Fund (WCRF) and the American Institute for Cancer Research (AICR) recommend limiting red meat consumption to no more than three portions a week, their guidance on processed meat is simpler and more restrictive: Consume very little, if any.

The risk for CRC associated with processed meats is likely due to a naturally occurring element in the meat and carcinogenic compounds that are added or created during its preparation, Johnson said.

Large bodies of evidence support the association between certain compounds in processed meat and cancer, added Ulrike Peters, PhD, MPH, professor and associate director of the public health sciences division at the Fred Hutchinson Cancer Center in Seattle.

These compounds include:

 Heterocyclic amines: Prevalent in charred and well-done meat, these chemicals are created from the reaction at high temperatures between creatine/creatinine, amino acids, and sugars.

- Nitrates/nitrites: Widely used in the curing of meat (eg, sausages, ham, bacon) to give products their pink coloring and savory flavor, these inorganic compounds bind with amines to produce N-nitrosamines, among the most potent genotoxic carcinogens.
- Polycyclic aromatic hydrocarbons: Generated during high-temperature cooking and smoking, these compounds can induce DNA damage in the colon.
- Heme iron: This type of iron, abundant in red and processed meats, promotes formation of

carcinogenic N-nitroso compounds and oxidative damage to intestinal tissue.

Peters said that the compounds may work synergistically to increase the risk for CRC

through various mechanisms, including DNA damage, inflammation, and altered gut microbiota.

While it would be useful to study whether the different meat-processing methods — for example, smoking vs salting — affect CRC risk differently, "practically, this is difficult because there's so much overlap," Liang noted.

Risk Mitigation: Lifestyle Factors

Lifestyle factors likely play a crucial role in the risk for CRC. For example, a study of European migrants to Australia found that those from countries with lower CRC incidences tended to develop a higher risk for CRC the longer they resided in Australia because of the dietary change.

Understanding how to mitigate these risk factors is becoming increasingly important with the rates of early-onset CRC projected to double by 2030 in the United States, a trend that is also being observed globally.

"With early-onset CRC, it's becoming quite clear that there's no single risk factor that's driving this increase," Liang said. "We need to look at the risk factors that we know cause CRC in older adults and see which have become more common over time."

The consumption of processed meats is one such factor that's been implicated, particularly for early-onset CRC. The average global consumption of all types of meat per capita has increased significantly over the last 50 years. A 2022 report estimated that global mean processed meat consumption was 17 g/d, with significantly higher rates in high-income regions. This number is expected to rise, with the global processed meat market projected to grow from \$318 billion in 2023 to \$429 billion by 2029. Given this, the importance of counseling patients to reduce their meat intake is further underscored.

Another strategy for mitigating the risks around processed meat is specifically identifying those patients who may be most vulnerable.

In 2024, Peters and colleagues published findings (Cancer Epidemiol Biomarkers Prev. doi: 10.1158/1055-9965.EPI-23-0717) from their genomewide gene-environment interaction analysis comparing a large population with CRC and healthy control individuals. The research identified two novel biomarkers that support the role of red and processed meat with an increased risk for CRC and may explain the higher risk in certain population subgroups.

Their research team is working on genetic risk prediction models that will incorporate these genetic markers, but must first ensure robust validation through larger studies.

"This approach aligns with precision medicine principles, allowing for more personalized prevention strategies, though we're not quite there yet in terms of clinical application," Peters said.

Another knowledge gap that future research efforts could address is how dietary factors influence survival outcomes after a diagnosis of CRC.

"The existing guidelines primarily focus on cancer prevention, with strong evidence linking processed meat consumption to increased CRC

Continued on following page

Simple Score Predicts Advanced Colorectal Neoplasia in Young Adults

BY MEGAN BROOKS

esearchers have developed and internally validated a simple score using clinical factors that can help estimate the likelihood of advanced colorectal neoplasia in adults younger than age 45 years.

While colorectal cancer (CRC) incidence has declined overall because of screening, early-onset CRC is on the rise, particularly in individuals younger than 45 years — an age group not currently recommended for CRC screening.

Studies have shown that the risk for early-onset advanced neoplasia varies based on several factors, including sex, race, family history of CRC, smoking, alcohol consumption, diabetes, hyperlipidemia, obesity, and diet.

A score that incorporates some of these factors to identify which younger adults are at higher risk for advanced neoplasia, a precursor to CRC, could support earlier, more targeted screening interventions.

The simple clinical score can be easily calculated by primary care providers in the office, Carole Macaron, MD, lead author of the study and a gastroenterologist at Cleveland Clinic, told *GI & Hepatology News*. "Patients with a high risk score would be referred for colorectal cancer screening."

The study was published in *Digestive Diseases and Sciences* (2025 Feb 13. doi: 10.3322/caac.21772).

To develop and validate their risk score, Macaron and colleagues did a retrospective cross-sectional analysis of 9446 individuals aged 18-44 years (mean age, 36.8 years; 61%

women) who underwent colonoscopy at their center.

Advanced neoplasia was defined as a tubular adenoma ≥ 10 mm or any adenoma with villous features or high-grade dysplasia, sessile serrated polyp ≥ 10 mm, sessile serrated polyp with dysplasia, traditional serrated adenoma, or invasive adenocarcinoma.

The 346 (3.7%) individuals

found to have advanced neoplasia served as the case group, and the remainder with normal colonoscopy or non-advanced neoplasia served as controls.



Dr. Itzkowitz

A multivariate logistic regression model identified three independent risk factors significantly associated with advanced neoplasia: higher body mass index (P = .0157), former and current tobacco use (P = .0009 and P = .0015, respectively), and a first-degree relative with CRC < 60 years (P < .0001) or other family history of CRC (P = .0117).

The researchers used these risk factors to develop a risk prediction score to estimate the likelihood of detecting advanced neoplasia, which ranged from a risk of 1.8% for patients with a score of 1 to 22.2% for those with a score of 12. Individuals with a score of ≥ 9 had a 14% or higher risk for advanced neoplasia.

Based on the risk model, the likelihood of detecting advanced neoplasia in an asymptomatic

32-year-old overweight individual, with a history of previous tobacco use and a first-degree relative younger than age 60 with CRC would be 20.3%, Macaron and colleagues noted.

The model demonstrated "moderate" discriminatory power in the validation set (C-statistic: 0.645), indicating that it can effectively differentiate between individuals at a

'If these lesions can be predicted, it would enable these young individuals to undergo screening colonoscopy, which could detect and remove these lesions, thereby preventing [CRC].'

higher and lower risk for advanced neoplasia.

Additionally, the authors are exploring ways to improve the discriminatory power of the score, possibly by including additional risk factors.

Given the score is calculated using easily obtainable risk factors for individuals younger than 45 who are at risk for early-onset colorectal neoplasia, it could help guide individualized screening decisions for those in whom screening is not currently offered, Macaron said. It could also serve as a tool for risk communication and shared decision-making.

Integration into electronic health records or online calculators may enhance its accessibility and clinical utility.

The authors noted that this

retrospective study was conducted at a single center caring mainly for White non-Hispanic adults, limiting generalizability to the general population and to other races and ethnicities.

Validation in Real-World Setting Needed

"There are no currently accepted advanced colorectal neoplasia risk scores that are used in general practice," said Steven H. Itzkowitz, MD, AGAF, professor of medicine, oncological sciences, and medical education, Icahn School of Medicine at Mount Sinai in New York City. "If these lesions can be predicted, it would enable these young individuals to undergo screening colonoscopy, which could detect and remove these lesions, thereby preventing colorectal cancer."

Many of the known risk factors (such as family history, high body mass index, or smoking) for CRC development at any age are incorporated within this tool, so it should be feasible to collect these data," said Itzkowitz, who was not involved with the study.

But he cautioned that accurate and adequate family histories are not always performed. Clinicians also may not have considered combining these factors into an actionable risk score.

"If this score can be externally validated in a real-world setting, it could be a useful addition in our efforts to lower CRC rates among young individuals," Itzkowitz told *GI* & Hepatology News.

The study did not receive any funding. Macaron and Itzkowitz reported no competing interests. ■

Continued from previous page

risk. However, the impact of dietary choices on survival after CRC diagnosis remains poorly understood," Peters said. "This distinction between prevention and survival is crucial, as biological mechanisms and optimal dietary interventions may differ significantly between these two contexts."

Well-designed studies investigating the relationship between dietary patterns and CRC survival outcomes would enable the development of evidence-based nutritional recommendations specifically tailored for CRC survivors, Peters said. In addition, she called for well-designed studies that compare levels of processed meat consumption between cohorts of patients with early-onset CRC and healthy counterparts.

"This would help establish whether there's a true causal relationship rather than just correlation," Peters explained.

Simple Strategies to Dietary Changes

With a 2024 study finding that greater adherence to WCRF/AICR

Cancer Prevention Recommendations, including reducing processed meat consumption, was linked to a 14% reduction in CRC risk (Cancer Epidemiol Biomarkers Prev. doi: 10.1158/1055-9965.EPI-23-0923), physicians should emphasize the benefits of adopting dietary and lifestyle recommendations to their patients.

Johnson advised simple discussion strategies physicians can use to encourage patients to incorporate any needed dietary changes.

"Tell them to pay attention to what you eat, proportions, and

variation of meal menus. Those are good starter points," he told *GI & Hepatology News*. "None of these recommendations related to meats should be absolute, but reduction can be the target."

Liang stressed the importance of repeated, nonjudgmental discussions.

"Research shows that physician recommendation is one of the strongest motivators in preventive health, so even if it doesn't work the first few times, we have to continue delivering the message that can improve our patients' health."

'At-need' vs. Surveillance

BOSS Trial from page 1

upper gastrointestinal endoscopy with biopsy every 2 years (the standard of care when the trial was set up) or endoscopy "at-need" when symptoms developed. Patients in the latter group were counseled about risk and were offered endoscopy for a range of alarm symptoms.

The study found no statistically significant difference in all-cause mortality risk between the two groups. Over the study period, 333 of 1733 patients (19.2%) in the surveillance group died, as did 356 of 1719 patients (20.7%) in the at-need group.

Similarly, no statistically significant between-group difference was found in the risk for cancer-specific mortality. About 6.2% of patients died from cancer in both groups — 108 in the regular surveillance group and 106 in the at-need group.

Nor was there a statistically significant difference in diagnosis of EAC, with 40 regular surveillance patients (2.3%) and 31 at-need patients (1.8%) receiving the diagnosis over median follow-up of 12.8 years. Cancer stage at diagnosis did not differ significantly between groups.

"The really low rate of progression to esophageal adenocarcinoma" was a key finding, Old said. The rate of progression to EAC was 0.23% per patient per year, he said.

Low- or high-grade dysplasia was detected in 10% of patients in the regular surveillance group, compared with 4% in the at-need group.

The mean interval between endoscopies was 22.9 months for the regular surveillance group and 31.5 months for the at-need group, and the median interval was 24.8 months and 25.7 months, respectively. The mean number of endoscopies was 3.5 in the regular surveillance group and 1.4 in the at-need group.

Eight patients in the regular surveillance group (0.46%) and seven in the at-need group (0.41%) reported serious adverse events.

Will BOSS Change Minds?

Current surveillance practices "are based on pure observational data, and the question of whether surveillance EGD [esophagogastroduo-



Dr. Zhou

'This study does not end the debate and will not change my practice of doing surveillance endoscopy on NDBE [nondysplastic Barrett's esophagus], which I typically perform every 3-5 years.'



Dr. Rubenstein

lated mortality, which would be an important outcome to be able to assess whether surveillance EGD has an impact," she said.

randomly assigned to regular

surveillance, at a median inter-

val of about 2 years, Zhou noted.

Therefore, she said, "It's difficult to

veillance endoscopy has no impact."

Additionally, the study was un-

derpowered to detect a difference

in all-cause mortality and assumed

Barrett's esophagus that is higher

Zhou said. "It also did not address

the important question of EAC-re-

than the current understanding,

a progression rate for nondysplastic

conclude from this study that sur-

Joel H. Rubenstein, MD, MSc, AGAF, director of the Barrett's esophagus program and professor in the division of gastroenterology at the University of Michigan Medical School, Ann Arbor, agreed that the study doesn't answer the pressing question of whether regular surveillance works.

While Rubenstein said he would not tell colleagues or patients to stop routine surveillance in patients with Barrett's esophagus on the basis of these results, "it is a reminder that we should be circumspect in who we label as having Barrett's esophagus, and we should be more proactive in discussing discontinuation of surveillance in

'It is a reminder that we should be circumspect in who we label as having Barrett's esophagus, and we should be more proactive in discussing discontinuation of surveillance in patients.'

patients based on advancing age and comorbidities."

The study was funded by the UK's National Institute for Health and Care Research. Zhou is a consultant for CapsoVision and Neptune Medical. Rubenstein has received research funding from Lucid Diagnostics. Old reported no disclosures.

denoscopy] impacts EAC diagnosis and mortality has been ongoing," said Margaret Zhou, MD, MS, clinical assistant professor at Stanford University School of Medicine, California. A randomized clinical trial on the subject has been needed for years, she added.

However, Zhou said, "In my opinion, this study does not end the debate and will not change my practice of doing surveillance endoscopy on NDBE [nondysplastic Barrett's esophagus], which I typically perform every 3-5 years, based on current guidelines."

The AGA clinical practice guideline, issued in June 2024 (Gastroenterology. doi: 10.1053/j. gastro.2024.03.019), addresses surveillance and focuses on a patient-centered approach when deciding on treatment or surveillance.

Patients in the at-need endoscopy arm underwent endoscopy almost as frequently as the patients



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OM24-04

Lower Gastrointestinal Bleeding: Two Viewpoints

Dear colleagues,

Lower gastrointestinal bleeding (LGIB) remains a frequent and sometimes perplexing clinical challenge. Despite advancements in endoscopic and radiologic tools, questions persist: What is the role and optimal timing of colonoscopy? How can we best utilize radiologic studies like CT angiography or tagged RBC scans? How should we manage patients with recurrent or intermittent bleeding that defies localization?

In this issue of Perspectives, Dr. David Wan, Dr. Fredella Lee, and Dr. Zeyad Metwalli offer their

expert insights on these difficult questions. Dr. Wan, drawing on over 15 years of experience as a GI hospitalist, shares — along with his coauthor Dr. Lee — apragmatic approach to LGIB based on clinical patterns, evolving data, and multidisciplinary collaboration. Dr. Metwalli provides the interventional radiologist's perspective, highlighting how angiographic techniques can complement GI management and introducing novel interventional radiology strategies for patients with



Dr. Ketwaroo

recurrent or elusive bleeding.

We hope their perspectives will offer valuable guidance for your practice. Join the conversation on X at @ AGA GIHN.

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

Management of Lower Gastrointestinal Bleeds: A GI Perspective

BY FREDELLA LEE, MD; DAVID WAN, MD

cute lower gastrointestinal bleeding (LGIB) presents unique challenges, many of which stem from the natural history of diverticular bleeding, the most common etiology of LGIB.

First, while bleeding can be severe, most will spontaneously stop. Second, despite our best efforts with imaging or colonoscopy, finding an intervenable lesion is rare.



Dr. Lee

Third, LGIB has significant rates of rebleeding that are unpredictable.

While serving as a GI hospitalist for 15 years and after managing over 300 cases of LGIB, I often find myself frustrated and colonoscopy feels futile. So how can we rationally approach these patients? We will focus on three clinical questions to develop a framework for LGIB management.

- What is the role and timing for a colonoscopy?
- · How do we best utilize radiologic
- · How can we prevent recurrent

The Role of Colonoscopy

Traditionally, colonoscopy within 24 hours of presentation was recommended. This was based on retrospective cohort data showing higher endoscopic intervention rates and better clinical outcomes. However, this protocol requires patients to drink a significant volume of bowel preparation over a few hours (often requiring a nasogastric tube [NGT]) to achieve clear rectal effluent. Moreover, one needs to mobilize a



Dr. Wan

team (ie, nurse, technician, anesthesiologist, and gastroenterologist), and find an appropriate location to scope (ie, ED, ICU, or OR), Understandably, this is challenging, especially over-

night. When the therapeutic yield is relatively low, this approach quickly loses enthusiasm.

Importantly, meta-analyses of the randomized controlled trials have shown that urgent colonoscopies (< 24 hours upon presentation), compared to elective colonoscopies (> 24 hours upon presentation), do not improve clinical outcomes such as re-bleeding rates, transfusion requirements, mortality, or length of stay. In these studies, the endoscopic intervention rates were

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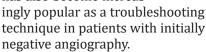
Lower Gastrointestinal Bleeding: An Interventional Radiologist's Perspective

Dr. Metwalli

BY ZEYAD METWALLI, MD, FSIR

hen colonoscopy fails to localize and/or stop lower gastrointestinal bleeding (LGIB), catheter angiography has been commonly employed as a tool for both diagnosis and treatment of bleeding with emboliza-

tion. Nuclear medicine or CT imaging studies can serve as useful adjuncts for confirming active bleeding and localizing the site of bleeding prior to angiography, particularly if this information is not provided by colonoscopy. Provocative mesenteric angiography has also become increas-



Localization of LGIB

Radionuclide technetium-99m-lableled red blood cell scintigraphy (RBCS), also known as tagged RBCS, has been in use since the early 1980s for investigation of acute GI bleeding. RBCS has a high sensitivity for detection of active bleeding with a theoretical ability to detect bleeding at rates as low as 0.04-0.2 mL/min.

Imaging protocols vary but should include dynamic images. which may aid in localization of bleeding. The relatively long halflife of the tracer used for imaging allows for delayed imaging 12-24 hours after injection. This can be useful to confirm active bleeding, particularly when bleeding is inter-

> mittent and is not visible on initial images.

With the advent of computed tomography angiography (CTA), which continues to increase in speed, imaging quality and availability, the use of RBCS for evaluation of LGIB has declined. CTA is quicker to perform than RBCS and allows for de-

tection of bleeding as well as accurate anatomic localization, which can guide interventions.

CTA provides a more comprehensive anatomic evaluation, which can aid in the diagnosis of a wide variety of intra-abdominal issues. Conversely, CTA may be less sensitive than RBCS for detection of slower acute bleeding, detecting bleeding at rates of 0.1-1 mL/min. In addition, intermittent bleeding which has temporarily stopped at the time of CTA may evade detection.

Lastly, CTA may not be appropriate in patients with impaired renal function because of risk of contrast-induced nephropathy, particularly in patients with acute kidney injury, which commonly afflicts hospitalized patients with LGIB.

RADIOLOGIST continued on following page



Please find full-length versions of these debates online at MDedge.com/gihepnews/perspectives.

GI continued from previous page 17%-34%; however, observational data show rates of only 8%. In our practice, we will use a clear cap attachment device and water jet irrigation to increase the odds of detecting an active source of bleeding. Colonoscopy has a diagnostic yield of 95% — despite its low therapeutic yield; and while diverticular bleeds constitute up to 64% of cases, one does not want to miss colorectal cancer or other diagnoses. Regardless, there is generally no urgency to perform a colonoscopy. To quote a colleague, Elizabeth Ross, MD, "there is no such thing as door-to-butt time."

The Role of Radiology

Given the limits of colonoscopy, can radiographic tests such as computed tomography angiography (CTA) or tagged red blood cell (RBC) scan be helpful? Multiple studies have suggested using CTA as the initial diagnostic test. The advantages of CTAs are:

- Fast, readily available, and does not require a bowel preparation
- If negative, portend a good prognosis and make it highly unlikely to detect active extravasation on visceral angiography
- If positive, can localize the source of bleed and increase the success of intervention

Whether a positive CTA should be followed with a colonoscopy or visceral angiography remains unclear. Studies show that positive CTAs increase the detection rate of stigmata of recent hemorrhage on colonoscopy. Positive CTAs can also identify a target for embolization by interventional radiology (IR). Though an important caveat is that the success rate of embolization is highest when performed within 90 minutes of a positive CTA. This highlights that if you have IR availability, it is critical to have clear communication, a well-defined protocol, and collaboration among disciplines (ie, ED, medical team, GI, and IR).

Our institution has implemented a CTA-guided protocol for severe LGIB. Those with positive CTAs are referred immediately to IR for embolization. If the embolization is unsuccessful or CTA is negative, the patient will be planned for a non-urgent inpatient colonoscopy. However, our unpublished data and other studies have shown that the overall CTA positivity rates are only 16%-22%. Moreover, one randomized controlled trial comparing CTA versus colonoscopy as an initial test did not show any

meaningful difference in clinical outcomes. Thus, the benefit of CTA and the best approach to positive CTAs remains in question.

Lastly, people often ask about the utility of RBC nuclear scans. While they can detect bleeds at a slower rate (as low as 0.1 mL/min) compared to CTA (at least 0.4 mL/min), there are many limitations. RBC scans take time, are not available 24-7, and cannot precisely localize the site of bleeding. Therefore, we rarely recommend them for LGIB.

Approach to Recurrent Bleeding

Unfortunately, diverticular bleeding recurs in the hospital 14% of the time and up to 25% at 5 years. When it occurs, is it worthwhile to repeat a colonoscopy or CTA?

Given the lack of clear data, we have adopted a shared decision-making framework with patients. Oftentimes, these patients are older and have significant co-morbidities, and undergoing bowel preparation, anesthesia, and colonoscopy is not trivial. If the patient is stable and prior workup has excluded pertinent alternative diagnoses other than diverticular bleeding, then we tell patients the chance of finding an intervenable lesion is low and opt for conservative management. Meanwhile, if the patient has persistent, hemodynamically significant bleeding, we recommend a CTA based on the rationale discussed previously.

The most important clinical decision may not be about scoping or obtaining a CTA — it is medication management. If they are taking NSAIDs, they should be discontinued. If antiplatelet or anticoagulation agents were held, they should be restarted promptly in individuals with significant thrombotic risk given studies showing that while rebleeding rates may increase, overall mortality decreases.

In summary, managing LGIB and altering its natural history with either endoscopic or radiographic means is challenging. More studies are needed to guide the optimal approach. Reassuringly, most bleeding self-resolves and patients have good clinical outcomes.

Dr. Lee is a resident physician at New York Presbyterian Weill Cornell Medical Center, New York City. Dr. Wan is associate professor of clinical medicine at Weill Cornell Medicine, New York City. They declare no conflicts of interest. RADIOLOGIST continued from previous page Prophylaxis with normal saline hydration should be employed aggressively in patients with impaired renal function, particularly when estimated glomerular filtration rate is less than 30 mL/min. Iodinated contrast should be used judiciously in these patients.

In clinical practice, CTA and RBCS have a similar ability to confirm the presence or absence of clinically significant active gastrointestinal bleeding. Given the greater ability to rapidly localize the bleeding site with CTA, this is generally preferred over RBCS unless there is a contraindication to performing CTA, such as severe contrast allergy or high risk for development of contrast-induced nephropathy.

Angiography and Embolization

Mesenteric angiography is a well-established technique for both detection and treatment of LGIB. Hemodynamic instability and need for packed RBC transfusion increases the likelihood of positive angiography. Limitations include reduced sensitivity for detection of bleeding slower than 0.5-1 mL/min as well as the intermittent nature of LGIB, which will often resolve spontaneously. Angiography is variably successful in the literature with a diagnostic yield of 40%-80%, which encompasses the rate of success in my own practice.

Once bleeding is identified, microcatheter placement within the feeding vessel as close as possible to the site of bleeding is important to ensure treatment efficacy and to limit risk of complications such as non-target embolization and bowel ischemia. Once the feeding vessel is selected with a microcatheter, embolization can be accomplished with a wide variety of tools including metallic coils, liquid embolic agents, and particles. In the treatment of LGIB, liquid embolic agents and particles should be used judiciously as distal penetration increases the risk of bowel ischemia and procedure-related morbidity. For this reason, metallic coils are often preferred.

Although the source of bleeding is variable and may include diverticulosis, recent polypectomy, ulcer, tumor, or angiodysplasia, the techniques employed are similar. Accurate and distal microcatheter selection is a key driver for successful embolization and minimizing the risk of bowel ischemia. Smallintestinal bleeds can be challenging to treat because of the redundant supply of the arterial arcades supplying small bowel and may require

occlusion of several branches to achieve hemostasis. This approach must be balanced with the risk of developing ischemia after embolization. Angiodysplasia, a less frequently encountered culprit of LGIB, may also be managed with selective embolization with many reports of successful treatment with liquid embolic agents.

Provocative Angiography

When initial angiography in a patient with suspected active LGIB is negative, provocative angiography can be considered to uncover an intermittent bleed. This may be particularly helpful in a patient where active bleeding is confirmed on a prior diagnostic test.

The approach to provocative mesenteric angiography varies by center, and a variety of agents have been used to provoke bleeding including heparin, vasodilators, and thrombolytics, often in combination. Thrombolytics can be administered directly into the territory of interest (ie, superior mesenteric or inferior mesenteric artery) while heparin may be administered systemically or directly into the catheterized artery. Reported success rates for provoking angiographically visible bleeding vary, but most larger series report a 40%-50% success rate. The newly detected bleeding can then be treated with either embolization or surgery. A surgeon should be involved and available when provocative angiography is planned.

In summary, when colonoscopy fails to identify or control LGIB, imaging techniques such as RBCS and CTA play a crucial role in localizing active bleeding. While RBCS is highly sensitive, especially for intermittent or slow bleeding, CTA offers faster, more detailed anatomical information and is typically preferred unless contraindicated by renal issues or contrast allergies. Catheter-based mesenteric angiography is a well-established method for both diagnosing and treating LGIB, often using metallic coils to minimize complications like bowel ischemia. In cases where initial angiography is negative, provocative $angiography--using\ agents\ like$ heparin or thrombolytics — may help unmask intermittent bleeding, allowing for targeted embolization or surgical intervention.

Dr. Metwalli is associate professor in the department of interventional radiology, The University of Texas MD Anderson Cancer Center, Houston. He declares no conflicts of interest.

'Life-Altering' Potential

Innovation from page 1

biomedical researcher and engineer, both work for the department of surgery at University of Colorado, Denver.

Horton said in an interview that when he was approached with the idea to create a better ostomy solution for a senior-year capstone project he was intrigued because the traditional ostomy system "has not changed in more than 70 years. It was crazy that no one had done anything to change that."

The Twistomy team also won the Grand Prize this spring at the Emerging Medical Innovation Valuation Competition at the Design of Medical Devices Conference held at the University of Minnesota, Minneapolis.

Witnessing the Struggle

Horton also works as a certified nursing assistant at an inpatient unit at University of Colorado Hospital and the ostomy patients he sees there every shift help drive his passion to find a better solution.

He hears the emotional stories of people who manage their ostomy daily.

"Many express feelings of depression and anxiety, feeling isolated with their severe inability to go out and do things because of the fear of the noise the stoma makes, or the crinkling of the plastic bag in a yoga class," he said. "We want to help them regain that control of quality of life."

They also hope to cut down on the ostomy management time. "Ini-

They combined smart engineering with deep understanding of patient need, which is restoring control, dignity, and quality of life for ostomy users while also reducing healthcare costs.'

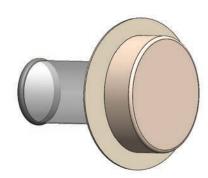
tial user testing [for Twistomy] was less than 75 seconds to insert and assemble," he said. "I did an interview with a patient yesterday who said they probably spend an hour a day managing their ostomy," including cleaning and replacing.

Horton and Williams have a patent on the device and currently use three-dimensional printing for the prototypes.

Williams said they are now conducting consumer discovery studies

through the National Science Foundation and are interviewing 30 stakeholders — "anyone who has a relationship with an ostomy," whether a colorectal surgeon, a gastrointestinal nurse, ostomy patients, or insurers.

Those interviews will help in refining the device so they can start



Twistomy is a low-profile continent ostomy device. The external housing unit depicted here twists the internal sleeve closed until the user decides to untwist it for excretion.

consulting with manufacturers and work toward approval as a Class II medical device from the US Food and Drug Administration (FDA), Williams said.

Saving Healthcare Costs

Another potential benefit for Twistomy is its ability to cut healthcare costs, Horton said. Traditional ostomies are prone to leakage, which can lead to peristomal skin complications.

He pointed to a National Institutes of Health analysis that found that on average peristomal skin complications caused upwards of \$80,000 more per ostomy patient in increased healthcare costs over a 3-month period than for those without the complications (J Wound Ostomy Continence Nurs. 2017 Jun. doi: 10.1097/WON.000000000000000339).

"With Twistomy, we are reducing leakage most likely to zero," Horton said. "We set out to say if we could reduce [infections] by half or a little less than half, we can cut out those tens of thousands of dollars that insurance companies and payers are spending."

Permanent and Temporary Ostomy Markets

He pointed out that not all ostomies are permanent ostomies, adding that the reversal rate "is about 65%." Often those reversal surgeries cannot take place until peristomal skin

complications have been healed.

"We're not only hoping to market to the permanent stoma patients, but the patients with temporary stomas as well," he said.

The team estimates it will need \$4 million-\$6 million in funding for manufacturing and consultation costs as well as costs involved in seeking FDA approval.

Horton and Williams project the housing unit cost will be \$399 based on known out-of-pocket ex-



The Twistomy device is composed of a soft flexible sleeve and internal ring that sit within the stoma channeling waste. The external housing unit twists the sleeve closed to prevent leakage and odor.

penses for patients with ostomy care products and the unit would be replaced annually. Disposable elements would be an additional cost.

Assuming insurance acceptance of the product, he said, "With about an 80/20 insurance coverage, typical for many patients, it would be about \$100 in out-of-pocket expenses per month to use our device, which is around the lower end of what a lot of patients are spending out of pocket."

One of the Tech Summit judges, Somaya Albhaisi, MD, a gastroenterology/hepatology fellow at University of Southern California, Los Angeles, said in an interview that the Shark Tank results were unanimous among the five judges and Twistomy also took the fan favorite vote.

She said the teams were judged on quality of pitch, potential clinical impact, and feasibility of business plan. Teams got 5-7 minutes to pitch and answered questions afterward.

"Deep Understanding of Patient Need"

"They combined smart engineering with deep understanding of patient need, which is restoring control, dignity, and quality of life for ostomy users while also reducing healthcare costs. It is rare to see a solution this scalable and impactful. It was a deeply empathetic solution overall." She noted that nearly 1 million people in the United States

currently use an ostomy.

Ostomy users' quality of life is compromised, and they often have mental health challenges, Albhaisi said. This innovation appears to offer easy use, more dignity and control.

The other four Shark Tank finalists were:

- Al Lumen, which developed a retroview camera system that attaches to the colonoscope and enhances imaging to detect hidden polyps that may evade conventional endoscopes.
- Amplified Sciences, which developed an ultrasensitive diagnostic platform that detects biomarker activities in minute volumes of fluid from pancreatic cystic lesions, helping to stratify patients into low risk or potential malignancy, reducing unneeded surgeries, costs, and comorbidities.
- KITE Endoscopic Innovations, which designed the Dynaflex TruCut needle to offer a simpler endoscopic ultrasound–guided biopsy procedure with fewer needle passes, deeper insights into tumor pathology, and more tissue for geonomic analysis.
- MicroSteer, which designed a device to facilitate semiautomated endoscopic submucosal dissection by decoupling the dissecting knife from the endoscope, enhancing safety and effectiveness during the procedure.

The Twistomy Team "Surprised Everyone"

The competitors' scores were "very close," one of the judges, Kevin Berliner, said in an interview. "The Twistomy team surprised everyone — the judges and the crowd — with their succinct, informative, and impactful pitch. That presentation disparity was the tiebreaker for me," said Berliner, who works for Medtronic, a sponsor of the competition, in Chicago.

He said Horton and Williams were the youngest presenters and had the earliest stage pitch they judged, but they "outpresented other competitors in clarity, simplification, and storytelling."

Also impressive was their description of their "commercially viable path to success" and their plan for the challenges ahead, he said.

Those challenges to get Twistomy to market center "on the ongoing changing climate we have with research funds lately," Horton said. "We're giving it an estimate of 3-5 years."

Horton, Williams, Albhaisi, and Berliner reported no relevant financial relationships. ■

Intensive Nutrition Therapy Improves Outcomes in Alcohol-Related ACLF

BY MEGAN BROOKS

FROM CLINICAL GASTROENTEROLOGY
AND HEPATOLOGY

recent study supports the importance of intensive nutrition therapy in managing patients with alcohol-related acute-on-chronic liver failure (ACLF).

In a randomized controlled trial, compared with standard care, dietitian-supported, intensive nutritional therapy improved survival, reduced frailty, and lowered hospitalization rates in men with alcohol-related ACLF.

The study, performed by a team from the Postgraduate Institute of Medical Education and Research, Chandigarh, India, was published in *Clinical Gastroenterology and Hepatology* (2024 Oct. doi: 10.1016/j.cgh.2024.09.021).

ACLF related to alcohol use is associated with poor outcomes due to poor nutritional intake and frailty. Frail patients with ACLF face higher morbidity, mortality, and hospitalization rates than their nonfrail counterparts. However, research on the role of structured nutritional interventions in improving these outcomes is limited.

Patal Giri, MBBS, MD, and colleagues enrolled 70 men with alcohol-related ACLF and frailty (liver frailty index [LFI] > 4.5) in a single-center, open-label study. Half were randomly allocated to an intervention group receiving outpatient intensive nutrition therapy (OINT) plus standard medical treatment (SMT) and half to a control group receiving SMT alone for 3 months.

The intervention group received a monitored high-calorie, high-protein, and salt-restricted diet as prescribed by a dedicated senior liver dietitian. The control group received regular nutritional recommendations and were managed for the ACLF-associated complications, without intervention or guidance by the study team.

After 3 months follow-up, overall survival (the primary outcome) was significantly improved in the OINT group compared with the control group (91.4% vs 57.1%), "suggesting that the improvement in nutrition status is associated with better survival," the study team noted. Three patients died in the OINT group vs 15 in the SMT group.

OINT also led to a significant improvement in frailty, with LFI scores decreasing by an average of 0.93 in the intervention group vs 0.33 in the control group; 97% of patients improved from frail to prefrail status in the OINT group, whereas only 20% of patients improved in the SMT group.

The mean change in LFI of 0.93 with OINT is "well above the substantially clinically important difference" (change of 0.8) established in a previous study, the authors noted.

Significant improvements in weight and body mass index were also observed in the OINT group relative to the control group.

Liver disease severity, including model for end-stage liver disease (MELD) scores, showed greater improvement in the OINT group than in the control group (-8.7 vs -6.3 points from baseline to 3 months).

During the follow-up period, fewer patients in the intervention group than in the control group required a hospital stay (17% vs 45.7%).

Limitations of the study include the single-center design and the short follow-up period of 3 months, which limits long-term outcome assessment. Further, the study included only patients meeting Asia Pacific Association for Study of Liver criteria for ACLF, which does not include the patients with organ failure as defined by European Association for the Study of the Liver-Chronic Liver Failure Consortium criteria. Patients with ACLF who had more severe disease

'If a dietitian works in the same clinic as the hepatologist and patients can be referred and seen the same day, this is ideal. ... [P]rotein/calorie intake can be more closely monitored and encouraged by a multi-disciplinary team.'

(MELD score > 30 or AARC > 10) were also not included.

Despite these limitations, the authors said the study showed that "dietician-monitored goal-directed nutrition therapy is very important in the management of patients with alcohol-related ACLF."

Confirmatory Data

Reached for comment, Katherine Patton, MEd, RD, a registered dietitian with the Center for Human Nutrition at Cleveland Clinic, said it's well known that the ACLF patient population has a "very high rate of morbidity and mortality and their

quality of life tends to be poor due to their frailty. It is also fairly wellknown that proper nutrition therapy can improve outcomes; however, barriers to adequate nutrition include decreased appetite, nausea, pain, altered taste, and early satiety from ascites.

"Hepatologists are likely stressing the importance of adequate protein energy intake and doctors may refer patients to an outpatient dietitian, but it is up to the patient to make that appointment and act on the recommendations," Patton told *GI & Hepatology News*.

"If a dietitian works in the same clinic as the hepatologist and patients can be referred and seen the same day, this is ideal. During a hospital admission, protein/calorie intake can be more closely monitored and encouraged by a multi-disciplinary team," Patton said.

She cautioned that "the average patient is not familiar with how to apply general calorie and protein goals to their everyday eating habits. This study amplifies the role of a dietitian and what consistent education and resources can do to improve a patient's quality of life and survival."

The study had no specific funding. The authors and Patton declared no relevant conflicts of interest. ■



MASH Driving Epidemic of Primary Liver Cancer

BY DIANA SWIFT

MDedge News

FROM CLINICAL GASTROENTEROLOGY
AND HEPATOLOGY

etabolic dysfunction—associated steatotic liver disease (MASLD) and metabolic dysfunction—associated steatohepatitis (MASH), the leading causes of liver disease, are now emerging as the main risk factors globally for primary liver cancer (PLC). Although the incidence of PLC from most etiologies is declining, MASH and alcohol-related liver disease (ALD) are exceptions.

A recent analysis in *Clinical Gastroenterology and Hepatology* (2024 Dec. doi: 10.1016/j. cgh.2024.10.026) found a near doubling of cases from 2000 to 2021 in data from the 2024 Global Burden of Disease (GBD) study.

The analysis assessed age-standardized incidence, mortality, and disability-adjusted life-years (DALYs) from MASH-associated PLC, stratified by geographical region, sociodemographic index, age, and sex.

The burden of MASH-associated PLC is rising rapidly while, thanks to effective suppressive treatments, the incidence of PLC from viral hepatitis is declining.

"Given the shifting epidemiology and limited global data, this analysis was timely to provide updated, comprehensive estimates using the GBD 2021 database," lead authors Ju Dong Yang, MD, MS, and Karn Wijarnpreecha, MD, MPH, told GI & Hepatology News in a joint email. Yang is an associate professor and medical director of the liver cancer program at Cedars-Sinai Medical Center in Los Angeles, and Wijarnpreecha is a transplant hepatologist in the of division of gastroenterology at University of Arizona College of Medicine in

Phoenix. "Our study helps identify regions, populations, and sex-specific trends that are most affected and informs global policy response."

Interestingly,the United States ranks among the top three countries worldwide in terms of MASH-associated PLC burden, with nearly 3400 newly diagnosed cases reported in 2021 alone. The Americas in general experienced the highest increase in age-standardized incidence rate (annual percent change [APC], 2.09%, 95% CI, 2.02–2.16), age-standardized death rate (APC, 1.96%; 95% CI, 1.69–2.23),



Dr. Wijarnpreecha

and age-standardized DALYs (APC, 1.96%; 95% CI, 1.63–2.30) from MASH-associated PLC.

Globally, there were 42,290 incident cases, 40,920 deaths, and 995,470

DALYs from PLC. Global incidence (+98%), death (+93%), and DALYs (+76%) from MASH-associated PLC increased steeply over the study period.

Among different etiologies, the global study found that only MASH-associated PLC had increased mortality rates, for an APC of +0.46 (95% CI [CI], 0.33%-0.59%). Africa and low-sociodemographic index countries exhibited the highest age-standardized incidence, death, and DALYs from MASH-associated PLC.

MASH promotes PLC through chronic liver inflammation, oxidative stress, lipotoxicity, and fibrosis, which together create a procarcinogenic environment even in the absence of cirrhosis. "This distinct pathway makes MASH-associated PLC harder

eviewing this study for *GI* & *Hepatology News*, but not involved in it, Scott L. Friedman, MD, AGAF, chief emeritus of

the division of liver diseases at Mount Sinai Health System in New York City and director of the newly established multidisciplinary Mount Sinai Institute for Liver Research, said the increase in primary liver cancer (PLC) burden revealed by the

research has been recognized for several years, especially among liver specialists, and is worsening, particularly in America.

Dr. Friedman

"This is most evident in the changing composition of liver transplant waiting lists, which include a diminishing number of patients with chronic viral hepatitis, and a growing fraction of patients with steatotic liver disease, either from MASH [metabolic dysfunction—associated steatohepatitis] alone or with concurrent alcohol-associated liver disease," Friedman said. He noted that apart from the brain, the liver is the body's least understood organ.

Friedman said that an urgent need exists for increased awareness of and screening for steatotic liver disease in primary care and general medicine practices — especially in patients with type 2 diabetes, about 70% of whom typically have steatosis — as well as

those with features of the metabolic syndrome, with obesity, type 2 diabetes, lipid abnormalities, and hypertension. "Awareness of metabolic-associated liver disease and MASH among patients and providers is still inadequate," he said. "However, now that there's a newly approved drug, Rezdiffra

[resmetirom] — and more likely in the coming years — early detection and treatment of MASH will become essential to prevent its progression to cirrhosis and PLC through specific medications."

Once patients with MASH have more advanced fibrosis, Friedman noted, regular screening for PLC is essential to detect early cancers that are still curable either by liver resection, liver transplant, or direct ablation of small tumors. "Unfortunately, it is not unusual for patients to present with an incurable PLC without realizing they had any underlying liver disease, since MASH is not associated with specific liver symptoms."

Friedman disclosed no competing interests relevant to his comments.

to detect early, especially when cirrhosis is not yet evident," Yang and Wijarnpreecha said.

By gender, DALYs increased in females (APC, 0.24%, 95% CI, 0.06-0.42) but remained stable in males. "Males have higher absolute rates of MASH-associated PLC in terms of incidence and DALYs. However, our study found that the rate of increase in MASH-associated PLC-related disability is steeper in females. This suggests a growing burden among women, possibly related to aging, hormonal changes, and cumulative metabolic risk," the authors said. In terms of age, "while our study did not assess age at onset, separate analyses have shown that both MASH-associated and alcohol-associated liver cancer are rising among younger individuals."

Yang and Wijarnpreecha emphasized the need for a multi-pronged remedial strategy, including broad public health policies targeting obesity and metabolic syndrome and better risk stratification tools such as no-invasive biomarkers and genetic profiling. They called for investment in liver cancer surveillance, especially in populations at risk, and special attention to sex disparities and health equity across regions.

"We're entering a new era of liver cancer epidemiology, where MASLD is taking center stage. Clinicians must recognize that MASH can progress to liver cancer even without cirrhosis," they said. "Early diagnosis and metabolic intervention may be the best tools to curb this trend, and sex-based approaches to risk stratification and treatment may be essential moving forward."

Yang's research is supported by the National Institutes of Health. He consults for AstraZeneca, Eisai, Exact Sciences, and FujiFilm Medical Sciences. ■

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Video Capsule Endoscopy Aids Crohn's Treatment

BY DIANA SWIFT

MDedge News

FROM GASTROENTEROLOGY

treat-to target (T2T) strategy based on video capsule endoscopy (VCE) identified Crohn's disease (CD) patients in clinical remission but with smallbowel inflammation, resulting in fewer clinical flares versus a treatby-symptoms standard approach.

"A VCE-guided treat-to-target strategy for patients with CD in remission confers superior clinical outcomes compared with continued standard care," investigators led by Shomron Ben-Horin, MD, director of gastroenterology at Sheba Medical Center in Ramat-Gan, Israel.

Published in Gastroenterology (2025 Mar. doi: 10.1053/j.gastro.2025.02.031), the CURE-CD (Comprehensive Individualized Proactive Therapy of Crohn's Disease), a prospective, temporally blinded, randomized controled trial, looked at 60 adult patients with quiescent CD involving the small bowel (either L1 or L3 of the terminal ileum and upper colon).

The researchers defined quiescent disease as corticosteroid-free clinical remission with a Crohn's Disease Activity Index (CDAI) of < 50 for the past 3 months on a stable regimen.

Patients ingested a VCE at baseline and those with a Lewis inflammatory score (LS) of \geq 350 were designated high risk (n = 40) and randomized to either T2T optimization (n = 20) or continuing standard care (n = 20).

T2T was optimized with repeat VCE results every 6 months. Patients with LS < 350 ("low risk") continued standard care. The primary outcome was the rate of disease exacerbation, demonstrated by a CDAI increase of > 70 points and a score > 150, or hospitalization/ surgery, in high-risk standard care vs T2T groups at 24 months.

Treatment intensification in the high-risk group allocated to a proactive strategy comprised escalating biologic dose (n = 11 of 20), starting a biologic (n = 8 of 20), or swapping biologics (n = 1 of 20).

The primary outcome, clinical flare by 24 months, occurred in 5 of 20 (25%) of high-risk T2T patients vs 14 of 20 (70%) of the high-risk standard-care group (odds ratio [OR], 0.14; 95% confidence interval [CI], 0.04-0.57; P = .006).

s treat-to-target (T2T) strategies continue to redefine inflammatory bowel disease (IBD) care, this randomized controlled

trial by Ben-Horin et al highlights the value of proactive video capsule endoscopy (VCE) monitoring in patients with quiescent small-bowel Crohn's disease (CD). The study demon-

strated that scheduled VCE every 6 months, used to guide treatment adjustments, significantly reduced clinical flares over 24 months compared to symptom-based standard care. While differences in mucosal healing between groups were less pronounced, the results underscore that monitoring objective inflammation, even in asymptomatic patients, can improve clinical



Dr. Allocca

patients do not undergo objective disease assessment within a year of starting biologics.

In clinical practice, symp-

tom-driven management remains

common, often because of limited

hesitancy toward inva-

sive procedures. VCE

offers a noninvasive,

well-tolerated alterna-

tive that may improve

patient adherence to dis-

ease monitoring, partic-

ularly in small-bowel CD.

This approach addresses

a significant gap in care,

as nearly half of IBD

Clinicians should consider integrating VCE into individualized T2T strategies, especially in settings where endoscopic access is constrained. Furthermore, adjunctive noninvasive tools such as intestinal ultrasound (IUS) with biomarkers could further support a noninvasive, patient-centered monitoring approach. As the definition of remission evolves toward more ambitious targets like transmural healing, the integration of cross-sectional imaging modalities such as IUS into routine monitoring protocols may become essential. Aligning monitoring techniques with evolving therapeutic targets and patient preferences will be key to optimizing long-term disease control in CD.

Mariangela Allocca, MD, PhD, is head of the IBD Center at IRCCS Hospital San Raffaele, and professor of gastroenterology at Vita-Salute San Raffaele University, both in Milan, Italy. Silvio Danese, MD, PhD, is professor of gastroenterology at Vita-Salute San Raffaele University and IRCCS Hospital San Raffaele. Both authors report consulting and/or speaking fees from multiple drug and device companies.

Mucosal healing was significantly more common in the T2T group when determined by a cutoff LS < 350 (OR, 4.5; 95% CI, 1.7-17.4; nominal P value = .03), but not by the combined scores of total LS < 450 and highest-segment LS < 350.

outcomes.

Among all patients continuing standard care (n = 40), baseline LS was numerically higher among relapsers vs nonrelapsers (450, 225-900 vs 225, 135-600, respectively; P = .07). As to safety, of 221 VCEs ingested, there was a single (0.4%) temporary retention, which spontaneously resolved.

The authors cautioned that since the focus was the small bowel, the findings are not necessarily generalizable to patients with Crohn's colitis.

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