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aga American Gastroenterological Association

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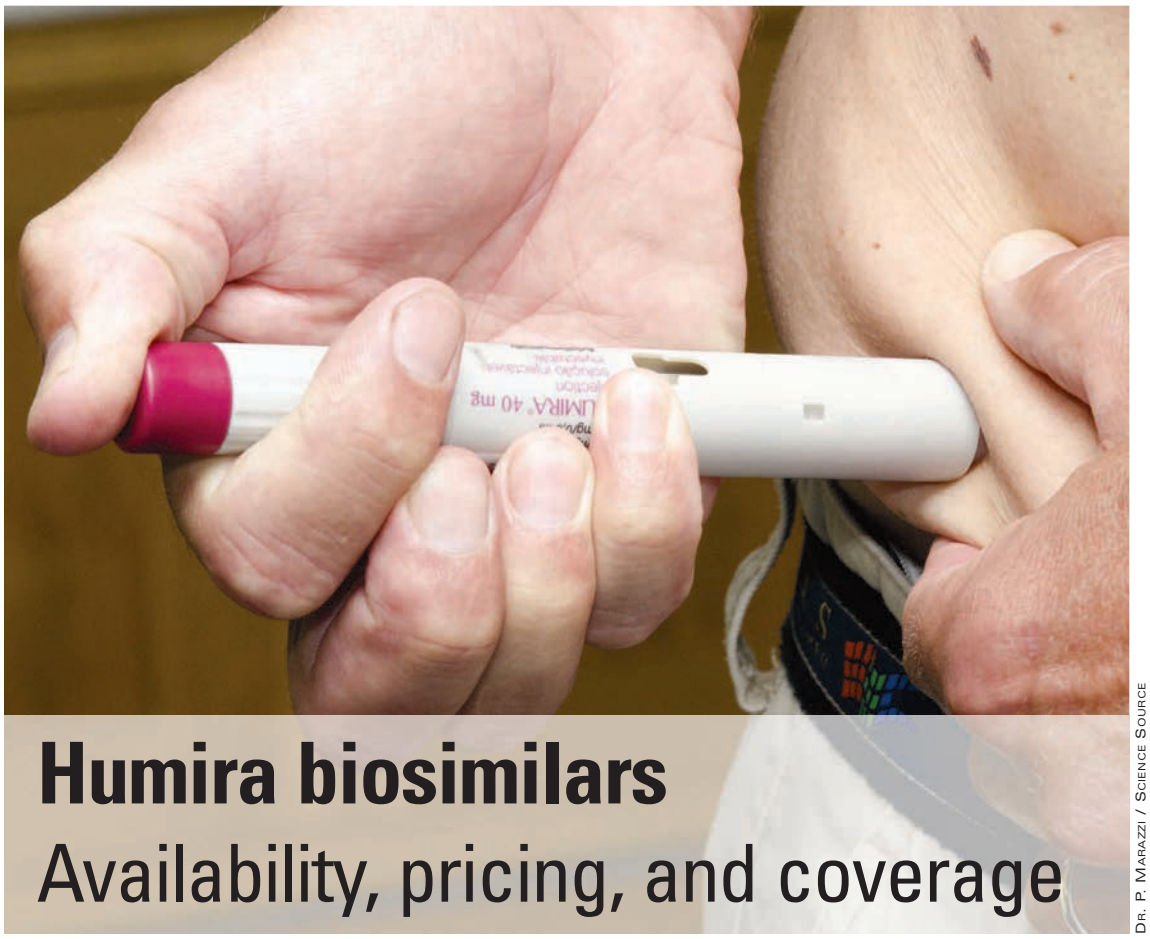
September 2023 Volume 17 / Number 9



Dr. P. Marazzi / Science Source

Humira biosimilars
Availability, pricing, and coverage

BY LUCY HICKS

The best-selling drug Humira (adalimumab) now faces competition in the United States after a 20-year monopoly. The first adalimumab biosimilar, Amjevita, launched in the United States on Jan. 31, and in July, seven additional biosimilars became available. These drugs have the potential to lower prescription drug prices, but when and by how much remains to be seen.

Here's what you need to know about adalimumab biosimilars.

What Humira biosimilars are now available?

Eight different biosimilars have launched in 2023 with discounts as large at 85% from Humira's list price of $6,922. A few companies also offer two price points.

Three of these biosimilars – Hadlima, Hyrimoz, and Yuflyma – are available in high concentration formulations. This high concentration formulation makes up 85% of Humira prescriptions, according to a report from Goodroot, a collection of companies focused on lowering health care costs.

See **Biosimilars** · *page 9*

AGA reaffirms CRC screening should begin at 45 years

ACP opposes majority opinion, opts for screening to start at age 50

BY THOMAS R. COLLINS

MDedge News

In the wake of newly issued guidance by the American College of Physicians, the American Gastroenterological Association is advising clinicians to follow the 2021 clinical practice guidelines of the U.S. Multi-Society Task Force (USMSTF) on Colorectal Cancer which recommends average-risk individuals be screened beginning at age 45.

The ACP, in a new guidance, says that "clinicians should consider not screening asymptomatic average-risk adults between the ages of 45-49 years. Clinicians should discuss the uncertainty around benefits and harms of screening in this population."

The ACP guidance is at odds with those of the USMSTF which recommend people ages 45 and up receive CRC screening. The USMSTF includes the AGA, the American College of Gastroenterology, the American Society for Gastrointestinal Endoscopy, and the American Cancer Society.

"We're disappointed that the ACP has suggested to not screen average-risk individuals between the ages of 45 to 49," said Swati Patel, MD, MS, a member of the USMSTF, the lead author on the recent USMSTF guidance, and associate professor of medicine-gastroenterology at the University of Colorado at Denver, Aurora. "This guidance essentially contradicts these other organizations, and I think from the patient perspective, likely raises a lot of confusion."

Barbara Jung, MD, AGAF, president of the AGA said

See **Screening** · *page 10*

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LETTER FROM THE EDITOR

Introducing the 'Ethics Corner'

One of the most rewarding things about serving as editor of GI & Hepatology News is to consider new content that will further engage and bring value to our readership. In addition to reporting on scientific advances from our GI journals that can inform frontline clinical care of patients with gastrointestinal conditions, we have launched several new columns over the past year, including our monthly Member Spotlight and quarterly Health Policy and Advocacy columns, to diversify our content.

In our September 2023 issue, in addition to debuting a new cover design, we are pleased to introduce yet another new offering: the "Ethics Corner" column. It is intended to highlight important ethical considerations and challenges arising in GI practice and offer practical guidance on how to navigate them. In our inaugural Ethics Corner column, AGA Ethics Committee members Dr. Sheldon Sloan and Dr. David Drew discuss the "good, the bad, and the ugly" of direct-to-consumer advertising (DTCA). They highlight the pros and cons of DTCA from an ethical perspective, illustrate how DTCA can impact everyday clinical interactions with patients, and provide insight into how to navigate these challenging conversations. We hope you enjoy this new addition to the newspaper and welcome your ideas for future Ethics Corner columns and other content.

Also in this month's issue, we update you on AGA's response to the American College of Physicians' recent decision to recommend against initiating colon cancer screening at age 45, contrary to the recommendation of the GI community. We also present a story on Humira biosimilars and how they are likely to impact clinical practice. Finally, our September Member Spotlight features GI dietitian Renee Euler, MS, RD, LD, who discusses the intersection between diet and GI disorders, the importance of a team approach to GI care, and her work as a liaison between the AGA and Academy of Nutrition and Dietetics.

Dr. Adams

"In our inaugural Ethics Corner column, AGA Ethics Committee members Dr. Sheldon Sloan and Dr. David Drew discuss the "good, the bad, and the ugly" of direct-to-consumer advertising."

We hope you enjoy these, and all the stories featured in our September issue. ■

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

CDC alerts clinicians to signs of alpha-gal syndrome

BY MARCIA FRELLICK
MDedge News

The Centers for Disease Control and Prevention has issued a report alerting clinicians to emerging cases of alpha-gal syndrome (AGS) linked with tick bites. AGS causes patients to become allergic to meat, and in some cases the reaction can be life-threatening. Symptoms typically start 2-6 hours after eating the meat.

The American Gastroenterological Association published a Clinical Practice Update (doi: 10.1016/j.cgh.2022.12.035) in February notifying gastroenterologists that a subset of AGS patients are presenting with abdominal pain, nausea, diarrhea, or vomiting, without skin changes or anaphylaxis. If alpha-gal is suspected, serum tests for immunoglobulin E (IgE) antibodies should be performed.

"It is important for gastroenterologists to be aware of this condition and to be capable of diagnosing and treating it in a timely manner," wrote authors of the clinical practice update in Clinical Gastroenterology and Hepatology. A Morbidity and Mortality Weekly Report (2023 Jul 28;72(30):809-14) demonstrates that health care provider knowledge is low surrounding AGS. Almost half of the 1,500 health care providers surveyed (42%) had never heard of the

Continued on following page

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Biosimilars are priced differently

Biosimilars *from page 1*

Cyltezo is currently the only adalimumab biosimilar with an interchangeability designation, meaning that a pharmacist can substitute the biosimilar for an equivalent Humira prescription without the intervention of a clinician. A total of 47 states allow for these substitutions without prior approval from a clinician, according to Goodroot, and the clinician must be notified of the switch within a certain time frame. A total of 40 states require that patients be notified of the switch before substitution.

However, it's not clear if this interchangeability designation will prove an advantage for Cyltezo, as it is interchangeable with the lower concentration version of Humira that makes up just 15% of prescriptions.

Most of the companies behind these biosimilars are pursuing interchangeability designations for their drugs, except for Fresenius Kabi (Idacio) and Coherus (Yusimry).

A ninth biosimilar, Pfizer's adalimumab-afzb (Abrilada), is not yet on the market and is currently awaiting an approval decision from the Food and Drug Administration to add an interchangeability designation to its prior approval for a low-concentration formulation.

Why are they priced differently?

The two price points offer different deals to payers. Pharmacy benefit managers make confidential agreements with drug manufacturers to get a discount – called a rebate – to get the drug on the PBM's formulary. The PBM keeps a portion of that rebate, and the rest is passed on to the insurance company and patients. Biosimilars at a higher price point will likely offer larger rebates. Biosimilars offered at lower price points incorporate this discount up front in their list pricing and likely will not offer large rebates.

Humira biosimilars available as of July 2023

Biosimilar	Company	Discount from Humira	2023 Launch Date
Amjevita (adalimumab-atto)	Amgen	5%; 55%	January 31
Cyltezo (adalimumab-adbm)	Boehringer Ingelheim	5%-7%	July 1
Hadlima (adalimumab-bwwd)	Organon/Samsung Bioepis	85%	July 1
Hulio (adalimumab-fkjp)	Biocon	5%; 85% (unbranded)	July 3
Hyrimoz (adalimumab-adaz)	Sandoz	5%; 81% (unbranded)	July 1
Idacio (adalimumab-aacf)	Fresenius Kabi	5%	July 3
Yuflyma (adalimumab-aaty)	Celltrion	5%	July 2
Yusimry (adalimumab-aqvh)	Coherus	84%-85%	July 3

MDedge News

Will biosimilars be covered by payers?

Currently, biosimilars are being offered on formularies at parity with Humira, meaning they are on the same tier. The PBM companies OptumRx and Cigna Group's Express Scripts will offer Amjevita (at both price points), Cyltezo, and Hyrimoz (at both price points).

"This decision allows our clients flexibility to provide access to the lower list price, so members in high-deductible plans and benefit designs with coinsurance can experience lower out-of-pocket costs," said OptumRx spokesperson Isaac Sorensen in an email.

Mark Cuban Cost Plus Drug Company, which uses a direct-to-consumer model, will offer Yusimry for $567.27 on its website. SmithRx, a PBM based in San Francisco, announced it would partner with Cost Plus Drugs to offer Yusimry, adding that SmithRx members can use their insurance benefits to further reduce out-of-pocket costs. RxPreferred, another PBM, will also offer Yusimry through its partnership with Cuban's company.

The news website Formulary Watch previously reported that CVS Caremark, another of the biggest PBMs, will be offering Amjevita, but as a nonpreferred brand, while Humira remains the preferred brand. CVS Caremark did not respond to a request for comment.

Will patients pay less?

Biosimilars have been touted as a potential solution to lower spending on biologic drugs, but it's unknown if patients will ultimately benefit with lower out-of-pocket costs. It's "impossible to predict" if the discount that third-party payers pay will be passed on to consumers, said Mark Fendrick, MD, who directs the University of Michigan Center for Value-Based Insurance Design in Ann Arbor.

Generally, a consumer's copay is a percentage of a drug's list price, so it stands to reason that a low drug price would result in lower out-of-pocket payments. While this is mostly true, Humira has a successful copay assistance program to lower prescription costs for consumers. According to a 2022 IQVIA report, 82% of commercial prescriptions cost patients less than $10 for Humira because of this program.

To appeal to patients, biosimilar companies will need to offer similar savings, Dr. Fendrick added. "There will be some discontent if patients are actually asked to pay more out-of-pocket for a less expensive drug," he said.

All eight companies behind these biosimilars are offering or will be launching copay saving programs, many which advertise copays as low as $0 per month for eligible patients.

How will Humira respond?

Marta Wosińska, PhD, a health care economist at the Brookings Institute, Washington, predicts payers will use these lower biosimilar prices to negotiate better deals with AbbVie, Humira's manufacturer. "We have a lot of players coming into [the market] right now, so the competition is really fierce," she said. In response, AbbVie will need to increase rebates on Humira and/or lower its price to compete with these biosimilars.

"The ball is in AbbVie's court," she said. "If [the company] is not willing to drop price sufficiently, then payers will start switching to biosimilars."

Dr. Fendrick reported past financial relationships and consulting arrangements with AbbVie, Amgen, Arnold Ventures, Bayer, CareFirst, BlueCross BlueShield, and many other companies. Dr. Wosińska has received funding from Arnold Ventures and serves as an expert witness on antitrust cases involving generic medication. ■

Continued from previous page

syndrome and another 35% were not confident in diagnosing or managing affected patients. The low knowledge is concerning because the range of the lone star tick, which is the species primarily associated with this syndrome, is expanding. The knowledge gaps may lead to delayed or overlooked diagnoses, wrote report authors, led by Ann Carpenter, DVM, with the CDC.

A Morbidity and Mortality Weekly Report, with lead author Johanna S. Salzer, DVM, PhD, of the CDC, issued July 28 notes that specific symptoms and severity of AGS vary and no cure or treatment is currently available. From 2010 to 2018, there were more than 34,000 suspected cases of AGS in the United States, but current knowledge of where the cases have occurred is limited, the study authors write.

The suspected AGS cases were concentrated in areas where the lone star tick is known to be found, particularly throughout Arkansas, Kentucky, Missouri, and Suffolk County, N.Y.

"During 2017-2021, there was an annual increase in positive test results for AGS in the United States. More than 90,000 suspected AGS cases were identified during the study period, and the number of new suspected cases increased by approximately 15,000 each year during the study," authors wrote.

An AGS diagnosis "can be made with GI distress and increased serum alpha-gal IgE antibodies whose symptoms are relieved adequately on an alpha-gal avoidance diet that eliminates pork, beef, and mammalian-derived products," the practice update says. Patients whose symptoms also include facial swelling, urticaria, and trouble breathing should be referred to allergists, the AGA update states. Patients should also be counseled to avoid further tick bites because additional bites can worsen the allergy.

Authors declared no relevant financial relationships. ■

CRC screening saves lives

Screening *from page 1*

in a written statement: "Studies show that colorectal cancer is increasing in younger patients and we have data backing screening for average-risk patients at 45. The bottom line: It saves lives. To release contradictory guidance is reckless."

"Generally speaking, patients seek our advice and seek our expertise to synthesize all of this complex data, to provide a recommendation that is driven by those data points."
— Swati Patel, MD, MS

Timothy Wilt, MD, MPH, professor of medicine at the University of Minnesota, Minneapolis, and past chair of the guidelines committee at the ACP, said that a key consideration for the ACP was what they considered an "incredibly small" increase in CRC incidence in people under 50 from 2000 to 2019 – from 6.0 per 100,000 to 8.7 per 100,000.

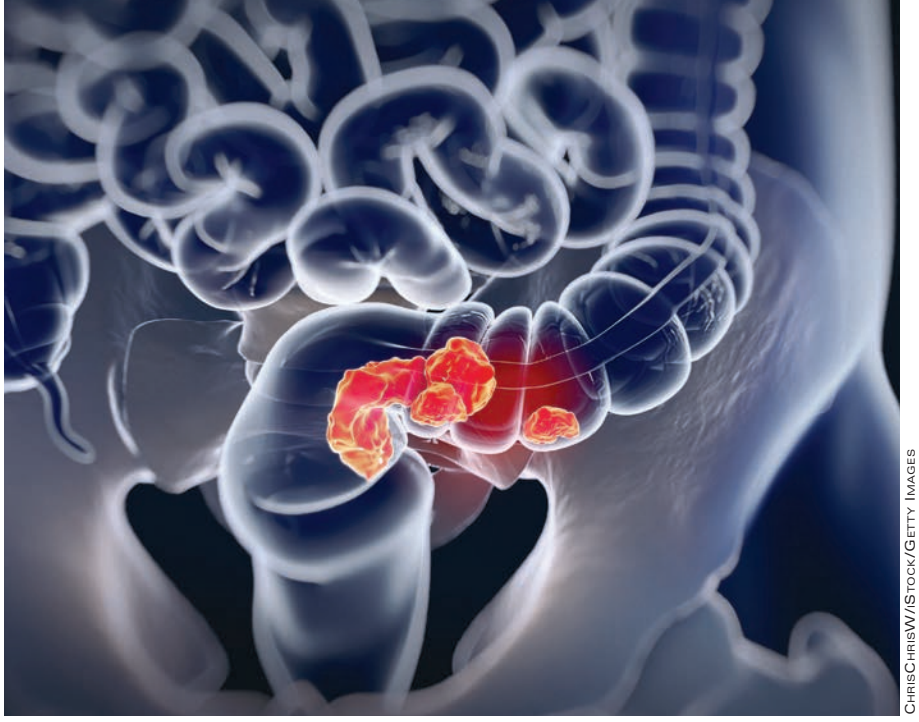
"If I would tell my patients, your chance of colorectal cancer is 6 per 100,000 and now it's really 9 per 100,000, they would say, 'No thanks,' " he said. "I have trouble getting my patients to take a statin for heart disease when their risk of heart disease in the future is 25%."

Dr. Patel said incidence numbers don't capture the magnitude of the CRC health burden, because screening historically hadn't been performed on those under 50. A 2020 study that broke incidence down in single-year increments found a 46% jump from age 49 to age 50.

"We only diagnose a cancer once we check for it," she said. The dramatic jump in CRC incidence at age 50 isn't a sign of new cancer, she said. Rather, these cancers have "been there for years and are cancers that would have been detected between 45 and 49. We just didn't know about them because patients didn't get the colonoscopy."

Data show that 16% of all rectal cancer now occur in patients under 50. "That is a substantial proportion of all rectal cancers. If these trends continue without us doing something about it, that suggests that colon cancer and rectal cancer will be the leading cause of cancer-related death in individuals under the age of 50 by 2030. That's not that far away," Dr. Patel said.

When the ACP says in its guidance that "the small estimated benefits and harms roughly balance each other out," it overestimates the risk of CRC screening, she said. The first step, which includes noninvasive options such as a stool-based screen, is no-risk and needs to be followed by a colonoscopy only in a small percentage of cases, she noted. And in recent randomized controlled trials, out of more than 28,000 colonoscopies, there were 2 perforations, 30 bleeding events, and no deaths. "I think the ACP statement very much overinflates the risks of screening," she said.



ChrisChrisW/iStock/Getty Images

Dr. Wilt suggested flatly recommending that screening start at age 45 is an overly blunt strategy, not accounting for lower CRC rates among women and varying risk for different races and ethnicities – information that patients should be given in order to make decisions.

"What I would say is, talk to your physicians, ask about the information, make a clinical decision that's right for you. ... It's your health," he said. "We believe our guidance statements are incredibly patient-centered."

Dr. Patel said that such an approach is not necessarily what patients look for from their physicians. "I think in theory it's great to have quote-unquote shared decision-making, and empower the patient to make a decision," she said. "But generally speaking, patients seek our advice and seek our expertise to synthesize all of this complex data, to provide a recommendation that is driven by those data points."

The ACP guidance also suggests that "opportunity costs and resources need to be weighed" and that expanding the screening population will take resources away from other medical services. "We are the frontline docs who have to engage in these conversations," Dr. Wilt said. "We value our GI and specialty consultants [but] they are not the ones who are there at the front line having to have these discussions."

Dr. Patel agreed that, with expanded screening, primary care physicians need more support and that "we have a long way to go in providing those support resources." But, "my perspective is that we have to look agnostically at the data." The data cited by the AGA are peer-reviewed, epidemiological data, not society-generated data, she said.

"I don't agree with the approach of, even though it's an additional burden, because we don't have the resources and time now, to just not proceed. I think our hope would be that practicing physicians – either within the ACP or outside – just have a clear message to patients, that colon cancer is a big deal, it's increasing in young patients, starting at age 45 you should be screened, and you should use the test that you're most likely to get done," she said. ■

AGA president Barbara Jung asks UHC to cease advance notification

On Aug. 1, AGA president Barbara H. Jung, MD, AGAF, wrote to UnitedHealthcare's chief medical officer, Rhonda Randall, DO, to express continued concern about the company's Advance Notification Program for gastrointestinal endoscopy procedures (which took effect June 1) and UnitedHealthcare's proposed "Gold Card" prior authorization program planned for 2024.

Dr. Jung made three requests:

1) A request for UnitedHealthcare's deidentified aggregate data on which the Advance Notification program is based.

2) Clarification regarding whether gastroenterologists who opt not to participate in the advance notification program will be automatically subject to prior authorization when UHC implements the 2024 Gold Card Program.

3) Clarification on how information gathered through the advance notification program will shape the GI Gold Card prior authorization program.

Dr. Jung asked for a written response to each of these three issues and a meeting to discuss concerns and questions. She stated that the Advance Notification Program was launched without adequate communication to gastroenterologists, plus the AGA, the American College of Gastroenterology, and the American Society of Gastrointestinal Endoscopy have had questions and concerns that haven't yet been addressed.

"Despite multiple requests, you have not shared any UnitedHealthcare-specific overuse or variation data on a code-by-code basis that would warrant such a burdensome process. Please share the deidentified aggregate data. Absent data, there is no rationale for such a policy. The Advance Notification program directly contradicts UnitedHealthcare's publicly stated goals of reducing administrative burden and streamlining access to care – goals we support and encourage you to work toward in the gastroenterological specialty. In contrast, Advance Notification is imposing significant administrative burdens on physician practices, which will negatively impact patient access to timely, medically necessary care," she wrote.


Dr. Jung

Practice burden

"The chaotic rollout of the new data reporting requirements led to widespread confusion throughout the gastroenterological community and has since forced physicians and staff to spend multiple hours every day completing reporting requirements for data that UnitedHealthcare already has through claims forms. This is a serious drain on gastroenterology practices' time, staff, and resources – which should be entirely focused on patient care, not reams of paperwork," Dr. Jung wrote.

AGA members have said most local UHC representatives are unaware of the Advance Notification Program for GI endoscopy program and are unable to advise them regarding concerns or problems.

And, they report that local UHC representatives have no information about the Gold Card program and how it might operate.

Practices have reported they have not received a follow-up from UHC requesting additional records via the Advance Notification Program.

Some large GI practices report it takes their staff 5-7 minutes per patient to enter the required data. Others quantify the additional work of participating in the advance notification program as 25%-35% more work than before the program was implemented.

Practices with large UHC volume report having to divert multiple staff to work full-time on UHC accounts.

"Given these challenges, many practices are not participating" in the advance notification program, Dr. Jung said. "AGA is troubled by the serious lack of specific details about the Gold Card prior authorization program to date. With less than 6 months until 2024, UnitedHealthcare has not issued any details about eligibility criteria, participation, or what new prior authorization requirements may be implemented for practices that do not qualify for a Gold Card. We resolutely oppose the implementation of any type of preauthorization requirements for colonoscopies and endoscopies. We are medical practitioners who have years of training and experience treating patients. Our medical decisions are evidence-based, which no prior authorization policy can claim."

The additional paperwork is disruptive and endangers patients' health, she said. "This is particularly true when it comes to performing colonoscopies and endoscopies, which are vital for detecting and monitoring diseases such as inflammatory bowel disease and colorectal cancer, the second deadliest form of cancer in the United States."

AGA is prepared to partner with UnitedHealthcare on educational initiatives to promote the appropriate use of endoscopy procedures. "However, we reiterate our call for UnitedHealthcare to halt the confusing and burdensome Advance Notification Program – and scrap plans to implement a Gold Card prior authorization program as planned in 2024. Instead, we invite UnitedHealthcare to work collaboratively with us to develop programs that improve quality of care without creating barriers to treatment for patients and unnecessary and inappropriate administrative burdens for physicians. We urge you to stop the Advance Notification and any prior authorization programs impacting GI endoscopy and directly engage with AGA to ensure patients' continued access to high-value, patient-centered endoscopy care."

Dr. Jung closed the letter urging UHC to engage in dialogue with AGA about these ongoing issues. ■

To read Dr. Jung's letter in full, see https://shorturl.at/dhjyH.

For updates on the AGA campaign to stop UHC's prior authorization plans, visit www.gastro.org/StopUHC.

AGA invests in virtual care clinic Oshi Health

The American Gastroenterological Association announced in June that it has invested in Oshi Health, a virtual care integrative health care clinic specializing in treating patients with gastrointestinal disorders. The company was named a recipient of funding through the AGA Center for GI Innovation & Technology's GI Opportunity Fund. It is AGA's fifth investment through the fund.

Launched in 2020, Oshi Health works with employers, health insurance partners, health systems, and community GI practices to scale access to multidisciplinary care, reduce health care costs, and help improve outcomes for patients.

Research shows that a whole-person, multidisciplinary GI care model – which, for Oshi, includes nutrition and diet support, health coaching, behavioral and mental health services – is effective in mitigating symptoms. For example, a 2020 literature review published in the Journal of the Canadian Association of Gastroenterology documented far more advantages with integrated care models, as compared with the traditional GI specialist model of care. The study found that integrated care teams were better equipped to meet the needs of patients with inflammatory bowel disease, patient outcomes and satisfaction were better, overall direct and indirect costs were lower, and psychological health needs were better addressed.

The member-backed GI Opportunity Fund invests in fast-growing, early-stage companies in the GI space to speed innovations from concept to clinic for the benefit of patients with digestive disease. For more information about Oshi Health, visit https://oshihealth.com. ■

Member SPOTLIGHT

Bridging the gap between GI disorders and nutrition

BY JENNIFER LUBELL

MDedge News

The gluten-free section in the grocery store didn't exist when Renee Euler, MS, RD, LD, was diagnosed with celiac disease 30 years ago. A physician handed her a fax about the gluten-free diet from a national support group and said: "Here, read this."

There was no Google to inform decisions. Patients had to rely on fact sheets or books.

"I didn't realize how much nutrition was going to change my world," said Ms. Euler, who worked as a landscape architect for 15 years before deciding to train as a dietitian.

Volunteering as a support group leader and volunteering with the University of Chicago Celiac Disease Center guided this important career change. Ms. Euler discovered she enjoyed teaching people how to live a gluten-free life and that they could enjoy travel and social functions while adhering to dietary restrictions.

Navigating celiac disease isn't easy. It can be socially isolating. Dietitians can help bridge the gap between diagnosis and important lifestyle changes, she emphasized.

Ms. Euler has made it her life's work to navigate GI disorders with physicians and patients.

She runs her own business, Nutrition Redefined, in Albuquerque and is the chair of the National Celiac Association Celiac/Gluten Intolerance Support Group in Albuquerque. Previously, she chaired the Dietitians in Medical Nutrition Therapy Dietetic Practice Group, a part of the Academy of Nutrition and Dietetics.

In an interview, she talked about the unique dietary struggles people with celiac and other gastrointestinal conditions face, and the strategies she uses to help these patients overcome hurdles and live a more normal life.

Q: What fears did you have to push past to get to where you are in your career?
Ms. Euler: Leaving a successful career as a landscape architect and going back to school was definitely a huge hurdle. When I started my practice in 2017, in my area there were no outpatient GI dietitians providing specialized care for adults with conditions like celiac disease, irritable bowel syndrome [IBS], and inflammatory bowel disease. I was starting out with no real support.

Realizing that I was going to start a private practice of my own to help the people I wanted to help, was another big fear. "Am I going to succeed? Am I going to fail? What's going to happen?" But over the years, my practice has grown as I learned to bill insurance and started receiving referrals from a large local GI practice, both of which have been the keys to my success. I have also limited my practice to GI clients so that I can focus my attention on this specialized area of nutrition and stay up to date on the latest developments.

Courtesy Erin Smith

Renee Euler, MS, RD, LD

Q: What interests you about the intersection between diet and GI disorders?
Ms. Euler: It's not just about diet. We're learning so much about how the gut microbiome can have a potential impact [on other parts of our health]. It's interesting in terms of how we respond to certain foods, for instance, could affect our mental health. This especially applies to IBS and how the microbiome might be connected to these conditions.

Q: You serve as a liaison between the American Gastroenterological Association and the Academy of Nutrition and Dietetics. As a nutritionist with a focus on GI, how do you work with gastroenterologists to manage GI disorders?
Ms. Euler: Some of the dietary therapies that GI doctors recommend don't provide sufficient guidance. They hand out that two-page fact sheet about diet and send the patient on their way. A lot of these diets have more nuance than what can be expressed in a two-page handout.

Many times, the physician doesn't know the nuance, or they don't have time to go over it. That's where we can really help.

Patients often want diet to be the answer. They want to be told: "You need to eat this and only this, and everything will be fine, and diet's going to change your world, and you won't have to take medication."

What they often don't realize and understand is a lot of these dietary therapies are not black and white. Celiac disease means a gluten-free diet for life. But a lot of these dietary therapies that get thrown out to patients as a possibility, like low FODMAPs [fermentable oligosaccharides, disaccharides, monosaccharides, and polyols] are not lifetime diets. They're tools for us to use to find out what the offending foods are for this person, and what can we do to get their symptoms under control.

Q: What is the biggest practice-related challenge in getting patients to alter their diet to improve their symptoms?
Ms. Euler: A lot of patients that come to me already have over-restricted diets. They're trying to solve things themselves. Rightfully so, a lot of them have a lot of food fears because they have been living with very uncomfortable symptoms for years, and they're trying to find answers. One of my biggest challenges with those clients is working through that process of building their confidence to broaden their diets and add foods back in, without causing their symptoms to flare up. The goal is to get them back on track to having a nutritious diet while trying to manage symptoms.

I had a patient who had been listening to wellness gurus. She was overrestricted to the point of eating just 10 different foods due to allergic and GI symptoms. Patients like this are definitely a challenge because you have to reorient them to the fact that what they're doing isn't necessarily working. My initial assessments are 90 minutes so I have time to sit with a patient and hear their story and understand their background. In this case, I said to the patient, "Why don't we try adding these foods back in, but eliminating these other types of foods and see whether that would help?" 48 hours later she sent me an email saying I hit the nail on the head. She was focusing on the wrong foods which were causing problems. Those are always great messages to get from patients." ∎

Lightning round

Do you prefer texting or talking?
Talking in person

What's your favorite breakfast?
Greek yogurt with fiber, flax seeds, and berries

What's your favorite junk food?
Ice cream

What's your favorite fruit?
Garden-grown strawberries

What's your favorite holiday?
Thanksgiving

What's your favorite type of music?
Jazz

What's your back-up career choice?
Probably a landscape architect

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Coping with burnout and repetitive injuries

Dear colleagues,

We are all part of one of the most exciting and varied fields of medicine and hope to have long and productive careers. In this month's Perspectives, we explore two different impediments to longevity as gastroenterologists: work-related disability and burnout. Physician burnout has reached almost epidemic levels and is best approached in a multimodal manner, incorporating both institutional and individual changes. Dr. Sumeet Tewani discusses ways in which groups and institutions can foster physician wellness to reduce burnout. He explores how flexibility in work schedules, among other initiatives, can improve workplace morale.

In an accompanying perspective, Dr. Anna Lipowska and Dr. Amandeep Shergill explore how to incorporate ergonomics in endoscopy to prevent injury. Endoscopic practice, with its repetitive tasks and physical demands, can predispose us to injury at all levels of training and experience. Ergonomics is thus a critical topic that is unfortunately covered too little, if at all, in our endoscopy training. We hope these essays will help your medical practice. We welcome your thoughts on these important issues at @AGA_GIHN.


Dr. Ketwaroo

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Fostering physician wellness to prevent burnout

BY SUMEET TEWANI, MD

Gastroenterology can be a challenging field, both professionally and personally, as it requires providers to have high clinical knowledge, expertise, and emotional intelligence. Burnout is a state of emotional, physical, and mental exhaustion, depersonalization, and a reduced sense of personal accomplishment, caused by prolonged or excessive stress. Burnout can be a serious and progressive chronic condition that negatively impacts the provider and patient experience, with serious consequences on the provider's health, job performance, patient satisfaction, and personal relationships.


Dr. Tewani

Adopting strategies to combat burnout are of vital importance to promoting provider wellness, a healthy work environment, and positive interactions with colleagues, staff, and patients. This also positively impacts providers' out-of-work experiences and relationships. Here I discuss factors that affect burnout, and methods our practice has adopted to combat burnout on an institutional level and on an individual level.

Multiple factors affecting burnout have been identified, including individual factors, work volume, professional risk and responsibility, resources, and relationships with colleagues and patients. Practicing gastroenterology frequently requires long and irregular work hours, heavy workloads, large panels of complex patients, invasive procedures, and high amounts of stress. Additional stressors may include an inefficient work environment, inadequate support, and loss of value and meaning in work. Nearly 50% of physicians meet criteria for burnout, citing such reasons as excessive bureaucratic tasks, lack of control, flexibility and autonomy, lack of peer respect, increasing computerization of practice, and lack of respect from patients.

Preventing burnout

When coping with burnout, many providers choose positive mechanisms such as exercising, listening to music, meditating, and talking with family and friends. Others become more isolated, eat junk food or binge eat, or turn to drug or alcohol abuse. Our primary approach to preventing burnout at an individual level is to ensure providers have access to self-care techniques such as stress management and mindfulness, and to encourage wellness with regular exercise and healthy habits. Promoting a culture of work-life balance requires providing adequate time for personal activities and hobbies, rest, relaxation, and engagement with family and friends. Allowing providers to personally shape their career paths aligns their personal

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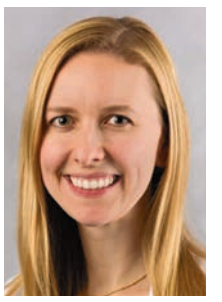
The hazards of endoscopy: Ergonomics guide the way

BY ANNA LIPOWSKA, MD, AND AMANDEEP SHERGILL, MD, MS


Dr. Lipowska


Dr. Shergill

Preventing disability and promoting a long and successful endoscopic career involves proactive measures to support well-being, and ergonomics plays a key role. Ergonomics is the science of fitting a job to the worker, with a primary goal of working smarter and safer. When hazards are identified, mitigation measures, guided by a hierarchy of controls, must be implemented that improve the fit of the tool, task, and job to the worker in order to reduce the risk of endoscopy-related injury (ERI). As more women enter the field and as the overall GI physician population ages, ensuring that endoscopy is designed to be safely performed within the capacity of a diverse group of workers will be critical to creating an inclusive and equitable work environment.

Ergonomic education is foundational

Awareness of ERI risk factors allows endoscopists to identify hazards and advocate for effective control solutions. Ergonomic education materials are available through all of the major GI societies. A road map for implementing an endoscopy ergonomics program has been previously published and provides guidance on risk assessment and mitigation measures.

Respect pain

Overuse injuries occur when the physical demands of a job are greater than tissue tolerances, leading to cumulative microtrauma. The first sign of microtraumatic injury is discomfort and pain. Studies have demonstrated that an estimated three-quarters of gastroenterologists experience ERI, with 20% requiring time off work and 12% requiring surgery. Gastroenterology trainees are also at risk, with 20% of surveyed fellows endorsing overuse injury, some even requiring work-related leaves of absence. In the early stages of ERI, aching and tiredness occur during the work shift only. In the intermediate stage, aching and tiredness occur early in the work shift and persist at night, and may be associated with a reduced capacity for repetitive work. In the late stages, aching, fatigue, and weakness persist at rest and may be associated with inability to sleep and to perform light duties. Pain is an important signal indicating mitigation measures are required to control exposures.

Utilize the hierarchy of controls

The adoption of ergonomically friendly practices lies with the

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and professional goals, leading to greater satisfaction. To this end, providers may become involved in clinical research, medical education, and clinical and administrative committees through the practice, local medical school and hospitals, and local and national societies. We provide ample vacation time and CME opportunities for our providers. Vacation time is flexible and can be taken in half-day or full-day increments, or on an hourly basis for personal time as necessary. This allows for enhanced flexibility with scheduling time off from work.

On an institutional level, leadership plays a prime role in creating a healthy work environment. Having good leaders influences the well-being and satisfaction of everyone within the organization. Leaders can have a positive impact by aligning values and work culture, using incentives in a productive manner, and promoting strategies to reduce burnout. Involving physician partners in leadership on a rotating basis allows them to better understand the roles of the leaders in the organization and empowers them to have a voice in changing policies to reduce administrative burdens and foster wellness.

We promote the concept of working together as a team for the success of the practice. All partners have an equal say in the management of the group. We eliminated the stress of competition within the group, equalizing pay across all physician partners, while maintaining equal exposure to work and equal time off from work. This levels the playing field between physicians who have varied interests and expertise, so that everyone is working toward the success of the practice and not individual compensation. To that end, our providers do not have individual offices, but work out of a "bullpen" with an open concept where we have individual workspaces and interact with each other continuously throughout the day. This promotes cohesion and teamwork between the providers for all our patients and promotes professional relationships and peer support. Efforts to promote workplace morale include access to a fully stocked deli and a newly installed espresso machine.

The concept of teamwork

The concept of teamwork also needs to pervade through the entire organization. To manage the demands of a busy workday, we have directly trained advanced practice nurses in the clinic and inpatient settings, allowing our physicians to increase throughput and procedures while maintaining a high level of patient care, satisfaction, and efficiency. Providers report excessive administrative tasks and frustration with the electronic health record as major factors contributing to burnout. Delegating tasks to staff, commensurate with their training and scope of practice, alleviates some of this burden. Each of the providers in our practice has a triage nurse who functions in a key capacity to ensure the appropriate clinical and administrative tasks are complete. Medical scribes, medical assistants, nurses, and physician assistants can be utilized for data entry and other tasks. We have developed templates within the electronic health record that can be standardized across the practice. Promoting teamwork with staff also means respecting the staff and understanding their needs. A highly functioning health care team can provide comprehensive care proactively and efficiently, with improved professional satisfaction.

In summary, I identify several ways to promote physician wellness. Every GI practice should strive to implement local approaches to prevent physician burnout and help maintain a happy and productive workforce. ■

Dr. Tewani is a gastroenterologist with Rockford (Il.) Gastroenterology Associates. He has no relevant disclosures.

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physician and institutional and industry-level support. Advancements at the industry level by eliminating or substituting hazards, or designing engineering controls to reduce exposure, will be most effective at preventing distal upper-extremity ERI. The next most effective controls are at the institutional level, with endoscopy units ensuring access to engineering controls and implementing effective administrative controls.

Adjust the endoscopy suite to achieve a comfortable position before every procedure

Neutral body posture is our position of greatest comfort and maximum strength, and any deviation from neutral posture decreases the amount of force the muscles can produce and causes the muscles to fatigue sooner. The most important factor affecting the endoscopists' overall posture is the monitor position and height. Monitors must be adjustable. Place the monitor directly in front of you, with the center of the screen 15-25 degrees below eye height for a neutral neck position and resting eye position. Procedure bed height should be adjusted 0-10 cm below elbow height to allow for neutral elbow postures and relaxed shoulders. Antifatigue mats and shoes with supportive insoles can reduce fatigue. Two-piece lead aprons distribute a portion of the static load to the hips and decrease back strain. Incorporate a pre-procedure ergonomic time-out, to assess proper room set-up, body mechanics, equipment, and team preparedness.

Give yourself a break

Breaks should be built into the endoscopy schedule, especially for a full day of endoscopy. At a minimum, incorporate microbreaks during procedures, which have been found to alleviate pain and improve performance. Exercising and stretching can be incorporated between cases, including routines designed specifically for endoscopists.

Getting older isn't for the weak

Fifty percent of our gastroenterologists are over 55 years old. The aging process leads to a distinct muscle mass and strength loss. Women are already at a disadvantage because, on average, they have less muscle mass than men in all age groups. We lose on average 8% of our muscle mass every decade which accelerates at a faster rate after age 60. Both resistance and aerobic exercise can be useful to counteract sarcopenia and maintain strength. Given the physical demands of endoscopy, exercise can help safeguard career longevity and maintain overall wellness.

Optimize all of your workstations

Prolonged computer use and desk work is also a significant part of a gastroenterologist's profession. If using a sitting desk, chair height should allow for 90-degree flexion at the hips and knees and for feet to rest flatly on the floor. The chair should provide adequate back support for a relaxed upright position. Similar to endoscopy, place the monitor directly in front with the center of the screen slightly below eye level. For mouse and keyboard placement, aim to have the elbows at or slightly below 90 degrees and one's wrists and fingers in neutral position.

Endoscopy can be hazardous to the endoscopists' health. Incorporating ergonomic principles creates a safer and more efficient work environment. At the individual level, ergonomically optimized postures during endoscopy as well as during computer-related tasks, room set-up, inclusion of microbreaks, and protective exercises can help decrease the risk of repetitive strain injury and prevent disability. Importantly, change at the industry and institutional level has the greatest potential for positive impact. Adoption of ergonomic practices promotes career longevity and ensures that gastroenterologists can continue successful and long careers and provide quality care to their patients without compromising their own health. ■

Dr. Lipowska is an assistant professor in the division of gastroenterology and hepatology, University of Illinois at Chicago. She disclosed no conflicts. Dr. Shergill is professor of clinical medicine, University of California, San Francisco; and, chief of the division of gastroenterology for the San Francisco VA Health Care System. She disclosed consulting work for Boston Scientific and Neptune Medical, honoraria for visiting professorship with Intuitive Surgical, and a research gift from Pentax. See GI&Hepatology News online for references.

Advances that help guide achalasia management

BY THOMAS R. COLLINS

MDedge News

Advancements in tools for assessing the function of the esophagus have led to important refinements in the diagnosis of achalasia and achalasia-like conditions, at a pace that has left the line-tracing technology considered to have debatable merit just 15 years ago "now as obsolete as a typewriter," experts said recently in a review in Gastro Hep Advances (2023 Feb 8. doi: 10.1016/j.gastha.2023.02.001).

"We have come to conceptualize esophageal motility disorders by specific aspects of physiological dysfunction," wrote a trio of experts – Peter Kahrilas, MD, professor of medicine; Dustin Carlson, MD, MS, assistant professor of medicine; and John Pandolfino, MD, chief of gastroenterology and hepatology, all at Northwestern University, Chicago. "A major implication of this approach is a shift in management strategy toward rendering treatment in a phenotype-specific manner."

High-resolution manometry (HRM) was trail-blazing, they said, as it replaced line-tracing manometry in evaluating the motility of the esophagus. HRM led to the subtyping of achalasia based on the three patterns of pressurization in the esophagus that are associated with obstruction at the esophagogastric junction. But the field has continued to advance.

"It has since become clear that obstructive physiology also occurs in syndromes besides achalasia involving the esophagogastric junction and/or distal esophagus," Dr. Kahrilas, Dr. Carlson, and Dr. Pandolfino said. "In fact, obstructive physiology is increasingly recognized as the fundamental abnormality leading to the perception of dysphagia with esophageal motility disorders. This concept of obstructive physiology as the fundamental abnormality has substantially morphed the clinical management of esophageal motility disorders."

HRM, has many limitations, but in cases of an uncertain achalasia diagnosis, functional luminal imaging probe technology can help, they said. FLIP can also help surgeons tailor myotomy procedures.

In FLIP, a probe is carefully filled with fluid, causing distension of the esophagus. In the test, the distensibility of the esophagogastric junction is measured. The procedure allows a more refined assessment of the movement of the esophagus, and the subtypes of achalasia.

Identifying the achalasia subtype is crucial to choosing the right treatment, data suggest. There have been no randomized controlled trials on achalasia management that prospectively consider achalasia subtype, but retrospective analysis of RCT data suggest that "achalasia subtypes are of great relevance in forecasting treatment effectiveness," they said.

In one trial, pneumatic dilation was effective in 100% of type II achalasia, which involves panesophageal pressurization, significantly better than laparoscopic Heller myotomy. But it was much less effective than LHM in type III achalasia, the spastic form, although a significance couldn't be established because of the number of cases. Data from a meta-analysis showed that peroral endoscopic myotomy, which allows for a longer myotomy if needed, was better than LHM for classic achalasia and spastic achalasia and was most efficacious overall.

The writers said that the diagnostic classifications for achalasia are likely to continue to evolve, pointing to the dynamic nature of the Chicago Classification for the disorder.

"The fact that it has now gone through four iterations since 2008 emphasizes that this is a work in progress and that no classification scheme of esophageal motility disorders based on a single test will ever be perfect," they said. "After all, there are no biomarkers of esophageal motility disorders and, in the absence of a biomarker, there can be no 'gold standard' for diagnosis."

Dr. Pandolfino, Dr. Kahrilas, and Northwestern University hold shared intellectual property rights and ownership surrounding FLIP Panometry systems, methods, and apparatus with Medtronic. Dr. Kahrilas reported consulting with Ironwood, Reckitt, and Phathom. Dr. Carlson reported conflicts of interest with Medtronic and Phathom. Dr. Pandolfino reported conflicts of interest with Sandhill Scientific/Diversatek, Takeda, AstraZeneca, Medtronic, Torax, and Ironwood. ■

16% of the U.S. population experience dysphagia, only half of whom seek medical care and the others manage their symptoms by modifying diet.

X-ray barium swallow and endoscopy with biopsy to exclude eosinophilic esophagitis are the initial tests for dysphagia diagnosis. If the above are normal, a high-resolution esophageal manometry impedance (HRMZ) is recommended to diagnose primary and secondary esophageal motility disorder.

Dr. Mittal

Studies before and after the advent of HRM show that the primary esophageal motility disorders, such as achalasia, diffuse esophageal spasm, and nutcracker esophagus/jackhammer esophagus, when combined together, are seen in only about 20% of patients presenting with dysphagia symptom. Esophagogastric junction outflow obstruction (EGJOO), another primary esophageal motility disorder characterized by impaired lower esophageal sphincter relaxation (integrated relaxation pressure > 15) in the presence of normal peristalsis is seen in 5%-24% of patients with dysphagia.

However, only in a minority of these patients is it likely to cause dysphagia because uncontrolled studies show that therapeutic strategies to address EGJOO (botox, dilation, and myotomy) relieve dysphagia symptoms in a minority of patients. Hence, in significant number of patients the cause of dysphagia symptoms remains obscure. It might be that our testing is inadequate, or possibly, patients have functional dysphagia (sensory dysfunction of the esophagus). My opinion is that it is the former.

The esophagus has only one simple function, that is, to transfer the pharyngeal pump driver, that is, swallowed contents to the stomach, for which its luminal cross-sectional area must be larger than that of the swallowed bolus and contraction (measured by manometry) behind the bolus must be of adequate strength. The latter is likely less relevant because humans eat in the upright position and gravity provides propulsion for the bolus. Stated simply, as long as esophagus can distend well and there is no resistance to the outflow at the EGJ, esophagus can achieve its goal. However, until recently, there was no single test to determine the distension and contraction, the two essential elements of primary esophageal peristalsis.

Endoscopy and x-ray barium swallow are tests to determine the luminal diameter but have limitations. Endoflip measures the opening function of the EGJ and is useful when the HRM is normal. However, pressures that are currently being used to measure the EGJ distensibility by Endoflip are not physiological. Furthermore, esophageal body motor function assessed by a bag that distends a long segment of the esophagus under high pressure is unphysiological. The distension-contraction plots, which determine the luminal CSA and contraction simultaneously during primary peristalsis is ideally suited to study the pathophysiology of esophageal motility disorders. Several studies from my laboratory show that, in patients with nutcracker esophagus, EGJOO and normal HRM, the esophagus distends significantly less than that of normal subjects during primary peristalsis. I suspect that an esophageal contraction pushing bolus through a narrow lumen esophagus is the cause of dysphagia sensation in many patients that have been labeled as functional dysphagia (Gastroenterology. 2021;160[5]:1847-9).

The last 2 decades have seen significant progress in the diagnosis of esophageal motility disorders using HRM, Endoflip, and distension-contraction plots of peristalsis. Furthermore, endoscopic treatment of achalasia and "achalasia-like syndromes" is revolutionary. What is desperately needed is an understanding of the pathogenesis of esophageal motor disorders, pharmacotherapy of esophageal symptoms, such as chest pain, proton pump inhibitor–resistant heartburn, and others because dysfunctional esophagus is a huge burden on health care expenditures worldwide.

Ravinder K. Mittal, MD, is a professor of medicine and gastroenterologist with UC San Diego Health. He has patent application pending on the computer software Dplots.

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The good, bad, and ugly of direct-to-consumer advertising

BY SHELDON SLOAN, MD, AND DAVID A. DREW, PHD


Dr. Sloan


Dr. Drew

These cases may sound familiar to a practicing gastroenterologist. The platform driving all 3 of these clinical encounters, direct-to-consumer advertising (DTCA), is a legal mechanism by which a commercial entity can communicate directly with the consumer about a medicine or device, bypassing a health care professional.

In the 1960s, the U.S. Congress granted the Food and Drug Administration (FDA) regulatory authority over prescription drug labeling and advertising. This included ensuring that ads were not false or misleading, they presented a "fair balance" of drug risks and benefits, they included facts about a drug's advertised uses, and they included a "brief summary" of all risks described in the drug's labeling.

Direct-to-consumer advertising increased dramatically in the late 1990s after the FDA eased regulations around risk information by requiring ads to include only "major risks" and provide resources directing consumers to full risk information.

In 2022, the top 10 pharmaceutical ad spenders combined for a total of ~$1.7 billion in TV ad spend, with the 2 top categories being inflammation and diabetes.

The role of the FDA in regulating DTCA of at-home tests is still evolving and largely depends on the intended use of the test results and the health claims used to market the test (i.e., whether the test is designed to simply return general information, as in case 3 where DTCA regulations may not apply, or is marketed with specific medical claims or diagnostic interpretations, as in case 2 with clear applications for DTCA regulations).

Direct-to-consumer advertising has transformed clinical interactions between patients and health care providers since its inception. It has both potential benefits and potential risks. DTCA can serve to increase disease awareness, such as the need for colon cancer screening. It may also prompt patients, who might otherwise disregard "red-flag" signs and symptoms such as rectal bleeding, to seek medical evaluation. DTCA can also alert health care providers to new treatment options for diseases within their scope of practice and encourage them to expand their armamentarium.

In bioethics terms, DTCA can be beneficial in facilitating patient autonomy and promoting justice. For example, DTCA can even the playing field by ensuring that patients have equitable access to information about available treatments regardless of their socioeconomic status. In doing so, it can empower patients and allow them to have more meaningful discussions with their health care providers and make more informed decisions.

In addition, patients may be introduced to alternative testing modalities such as stool-based colorectal cancer screening that, while not necessarily the best screening modality given individual risk as in case 2, may offer benefit with greater acceptance compared to inaction.

The idea of direct-to-consumer "omics" profiling has empowered patients as citizen scientists and has led to patients taking treatments into their own hands. In doing so, it has challenged the previous bounds of patient autonomy in health care by broadening the types of personal health data available to individuals, even when the clinical utility of this data may not yet be clear.

On the flip side, it is undeniable that DTCA of medical products is driven by commercial interests. Branded drugs are primarily, if not exclusively, promoted in DTCA, but these drugs may not always align with standard of care treatment recommendations. A study published in February in JAMA (doi:10.1001/jama.2022.23968) found that drugs with lower added clinical benefit and higher total sales were associated with higher DTCA spending.

With patients entering medical encounters with preconceived notions of what drugs they want to be prescribed based on media exposure, the ability of health care providers to provide sound medical advice regarding treatment may be circumvented. A patient's preferred therapy based on exposure to DTCA may sharply contrast with their provider's recommendation based on their experience and expertise and knowledge of the patient's unique clinical history.

Case 1: A 48-year-old female with a 10-year history of left-sided ulcerative colitis (UC) has been well controlled on an injectable biologic for 5 years. Her last colonoscopy one year ago was normal without erythema or friability. She presents for an interim visit due to an increase in stool frequency from 2 to 4 bowel movements a day. She denies urgency, nocturnal bowel movements, or blood in her stool. She is concerned about a disease flare and wonders if she is on the right medication. She just saw a TV ad for a new oral UC medication and wants to switch because she prefers an oral medication to an injectable one. Physical exam was normal and in-office flexible sigmoidoscopy demonstrates no change in her colon appearance. You advise her to stay on the biologic because she is still considered well-controlled. She insists on being switched to the new oral medicine. When you probe her more, she says that the TV ad she saw shows people getting the medicine leading normal lives, which has enormous appeal to her.

Case 2: A 52-year-old healthy male is referred for colonoscopy evaluation. He reports no change in bowel habits with rare blood in his stool and thinks his uncle had colon cancer at age 48. He is anxious and not very receptive to having a procedure. He recently saw a TV advertisement promoting non-colonoscopy-based colon cancer screening. You recommend a colonoscopy based on his family history, but he insists on stool-based screening.

Case 3: A 32-year-old female with moderately to well-controlled inflammatory bowel disease (IBD) asks you to review a new "multiomic" profile of her gut microbiome that she saw advertised on social media. The test report she provides contains a snapshot of her microbiome including abundances of single species and predicted functions for these bacteria from a single stool sample collected and submitted 6 months ago. You counsel her on the role of the gut microbiome in IBD and explain that currently there is not enough knowledge or technology to incorporate these test results into clinical care yet. The patient is frustrated and wants to know why you're "behind the times."

Unreasonable expectations

DTCA can instill unreasonable patient expectations. While DTCA is required to be fair and balanced in reporting benefits and risks, it is difficult to meaningfully address nuanced clinical risks in a brief TV ad and patients may come away with a skewed view of the risk-benefit equation. Furthermore, social media advertising and associated formats may not provide the same level of digestible information as other forms of media and are targeted to individuals likely to identify with the product.

Only branded products are advertised. They are generally more costly, and where less expensive and equally effective therapies may exist, societal costs need to be considered. This can lead to inequities in allocation of resources. The more the health care market is driven toward higher costs in one segment, the less resources are available in another.

Shared decision-making

In case 1, the patient's awareness of new treatment options has prompted a shared decision-making discussion. She has a renewed interest in exploring a different route of medication administration because of DTCA. The patient appears to have well-controlled inflammatory bowel disease (IBD) with minor fluctuations in symptoms, but she sees this as a reason to change her treatment – based on her impression from the DTCA.

In case 2, disease awareness and CRC screening acceptance is itself a positive outcome. Although commercially driven, the outcome/benefit to society leads to a decrease in disease burden and is a ready alternative with established benefits compared to no screening.

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More cuts to physician payments ahead

BY PATRICIA GARCIA, MD, AND SHIVAN J. MEHTA, MD, MBA, MSHP

In July, the Centers for Medicare & Medicaid Services (CMS) released the 2024 Physician Fee Schedule (PFS) proposed rule on proposed policy changes for Medicare payments. The proposed rule contains 2,883 pages of proposals for physician, hospital outpatient department, and ambulatory surgery center (ASC) payments for calendar year 2024. For gastroenterologists, there was good news and bad news.

CMS proposed to decrease the relative value unit (RVU) conversion factor from $33.8872 in 2023 to $32.7476 in 2024, which would result in a 3.36% cut to physician payment. Medicare physician payments have been cut each year for the better part of a decade, with additional cuts proposed for 2024.

According to the American Medical Association (AMA), Medicare physician payment has already declined 26% in the last 22 years when adjusted for inflation, and that's before factoring in the proposed cuts for 2024. Physicians are one of the only health care providers without an automatic inflationary increase, the AMA reports.

AGA opposes additional cuts to physician payments and will continue to advocate to stop them. AGA and many other specialty societies support H.R. 2474, the Strengthening Medicare for Patients and Providers Act. This bill would provide a permanent, annual update equal to the increase in the Medicare Economic Index, which is how the government measures inflation in medical practice. We will continue to advocate for permanent positive annual inflation updates which would allow physicians to invest in their practices and implement new strategies to provide high-value care.

But some positive news from the 2024 Medicare PFS, the Hospital Outpatient Prospective Payment System (OPPS) and the ASC proposed rules include increased hospital outpatient departments and ASC payments, continued telemedicine reimbursement and coverage through 2024, and a second 1-year delay in changes to rules governing split/shared visits. Specifically:

OPPS Conversion Factor: The proposed calendar year 2024 Medicare conversion factor for outpatient hospital departments is $87.488, an increase of 2.8%, for hospitals that meet applicable quality reporting requirements.

ASC Conversion Factor: The proposed calendar year 2024 ASC conversion factor is $53.397, an increase of 2.8%, for ASCs that meet applicable quality reporting requirements. The AGA and our sister societies continue to urge CMS to reduce this gap in the ASC facility fees when compared to the outpatient hospital facility rates, which are estimated to be a roughly 48% differential in CY 2024.

Telehealth: CMS proposes to continue reimbursing telehealth services at current levels through 2024. Payment for audio-only evaluation and management (E/M) codes will continue at parity with follow-up in-person visits as it has throughout the pandemic. Additionally, CMS is implementing telehealth flexibilities that were included in the Consolidated Appropriations Act 2023 by allowing telehealth visits to originate at any site in the United States. This will allow patients throughout the country to maintain access to needed telehealth services without facing the logistical and safety challenges that can surround in-person visits. CMS is proposing to pay telehealth services at the non facility payment rate, which is the same rate as in-person office visits, lift the frequency limits on telehealth visits for subsequent hospital and skilled nursing facility visits, and allow direct supervision to be provided virtually.

Split (or shared) visits: CMS has proposed a second 1-year delay to its proposed split/shared visits policy. The original proposal required that the billing provider in split/shared visits be whoever spent more than half of the total time with the patient (making time the only way to define "substantive portion"). CMS plans to delay that through at least Dec. 31, 2024. In the interim, practices can continue to use one of the three key components (history, exam, or medical decision-making) or more than half of the total time spent to determine who can bill for the visit. The GI societies will continue to advocate for appropriate reimbursement to align with new team-based models of care delivery.

Notably, the split (or shared) visits policy was also delayed in 2023 due to widespread concerns and feedback that the policy would disrupt team-based care and care delivery in the hospital setting. The AMA CPT editorial panel, the body responsible for creating and maintaining CPT codes, has approved revisions to E/M guidelines that may help address some of CMS' concerns.

For more information on the 2024 Medicare PFS and OPPS/ASC proposed rules, visit https://gastro.org/news/cuts-in-store-2024-proposed-medicare-payments. ■

Dr. Garcia is an advisor to the AGA AMA Relative Value Update Committee, clinical associate professor of medicine at Stanford University, and director of the neurogastroenterology and motility laboratory in the division of gastroenterology and hepatology. Dr. Mehta is an alternate advisor to the AGA AMA Relative Value Update Committee, associate chief innovation officer, Penn Medicine, and, associate professor of medicine and health policy, University of Pennsylvania.. Neither author has relevant conflicts of interest.

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In case 3, despite the patient's disappointment with the DCTA-promoted test's limited clinical utility, the patient may be communicating a general openness to novel approaches to treating IBD and to advancing her understanding of her disease.

As you navigate day-to-day patient interactions, keep in mind that your first obligation is to your patients and their best medical interests. Having a well-informed and engaged patient is a positive effect of DTCA despite the challenging discussions you may need to have with patients. In many cases, patients are more self-aware of and engaged in their health because of the information they obtain through DTCA platforms.

Clinicians have an ethical obligation to educate their patients and manage expectations. Although certain products may be trendy or promoted on a popular science basis, the underlying technology and clinical data are likely not well understood by the average patient who may struggle to understand why a particular treatment or test may not be their best option.

Despite potentially awkward clinician-patient dynamic precipitated by DTCA, these moments offer an opportunity for clinicians to improve rapport with patients. Take the time to talk with them about alternative treatment plans and risk factors. This can lead to a better understanding of what factors the patient prioritizes, such as quality of life or symptom management.

Ultimately, shared interest in individualized health decisions, at least partially informed by DTCA, can be a positive outcome. ■

PhotoTalk/Getty Images

Sheldon Sloan, MD, M Bioethics, is a chief medical officer at Abivax. David Drew, Ph.D., is assistant professor of medicine, Harvard Medical School, Boston, director of Biobanking for the Clinical & Translational Epidemiology Unit, and an investigator within the division of gastroenterology, Massachusetts General Hospital, Boston. Both are members of the AGA Ethics Committee.

Crohn's link seen for ultraprocessed foods

BY JENNIE SMITH

MDedge News

High consumption of ultraprocessed foods increases the risk of developing Crohn's disease, according to results from a large meta-analysis, but not ulcerative colitis.

Ultraprocessed foods contain large amounts of artificial flavors, stabilizers, emulsifiers, sweeteners, or preservatives. Studies have linked higher consumption of them to cardiovascular disease, diabetes, obesity, and cancers.

For their research, published in Clinical Gastroenterology and Hepatology (2023 Jan 29. doi: 10.1016/j.cgh.2023.01.012), Neeraj Nerula, MD, of McMaster University, Hamilton, Ont., and colleagues pooled data from five recent cohort studies to assess whether their consumption was also linked to inflammatory bowel disease (IBD).

The included cohort studies together enrolled more than 1 million participants (mean age, 43-56; 55%-85% female). Of these, 916 developed Crohn's disease (CD), and 1,934 developed ulcerative colitis, during follow-up. None of the participants had IBD at baseline, and all were followed up at least 1 year. All the studies used the same food classification system, called NOVA, to assess foods eaten, and all were conducted between 2020 and 2022.

People who consumed more ultraprocessed foods saw higher CD risk, compared with those classed as consuming lower amounts of these foods (hazard ratio, 1.71; 95% confidence interval, 1.37-2.14). Also, lower risk of CD was observed among participants who consumed more unprocessed or minimally processed foods, such as vegetables, chicken, milk, and eggs (HR, 0.71; 95% CI, 0.53-0.94). The same associations were not seen for ulcerative colitis.

"Our findings support the hypothesis that consumption of [ultraprocessed foods] and low consumption of unprocessed/minimally processed foods may increase the risk for CD," Dr. Nerula and colleagues wrote. The lack of association seen with ulcerative colitis might be explained by differences in the pathogenesis of each disease.

Ultraprocessed foods might contribute to CD by disrupting gut microbiota, the authors wrote. "For instance, emulsifiers have been shown to increase epithelial permeability, disruption of the intestinal barrier, and gut dysbiosis in mice. Carboxymethyl cellulose has been shown to facilitate bacterial adherence to gut epithelium, possibly leading to bacterial overgrowth and invasion of bacteria in between the intestinal villi. Furthermore, additives such as carrageenan, titanium dioxide, and maltodextrin have been shown to promote intestinal inflammation."

Dr. Nerula and colleagues described as strengths of their study its large size, the low heterogenicity of the included studies, and the use of validated, standardized questionnaires to measure dietary intake in each study. Nonetheless, they cautioned, the results might not apply to younger age groups, and the majority of participants were White North Americans and Europeans, making it difficult to generalize results.

"Advancements in food processing and associated changes in dietary patterns could explain the rise of IBD incidence during the 20th and 21st centuries," Dr. Narula and colleagues concluded. "Further investigations are needed to identify the specific potential culprits among processed foods that could account for the increased risk of CD observed."

The study authors did not report outside funding. Dr. Narula disclosed receiving fees from pharmaceutical manufacturers including Janssen, AbbVie, Takeda, Pfizer, Merck, and others. Two of coauthors also disclosed receiving funds from industry, and five additional coauthors had no conflicts. ■

100WORDS/DREAMSTIME

The causes of inflammatory bowel disease (IBD) are thought to be multifactorial and include genetic predisposition, dysregulated immune responses, imbalances in the intestinal microbiota, and environmental exposures.

Dr. Ungaro

Incidence and prevalence of IBD has increased over time, including in developing countries, and appear to parallel industrialization and "Westernization" of societies. One of the potential contributors to IBD risk is diet. Dietary changes associated with more modern or "Westernized" diets, including increases in processed foods, are some of the factors hypothesized to contribute to rising rates of IBD.

There is accumulating data that certain diets, such as the Mediterranean diet, may have beneficial effects in established Crohn's disease (CD) and ulcerative colitis (UC).

In the meta-analysis by Narula and colleagues, the authors observed a significant increase in the risk of CD, but not UC, in individuals who consumed significantly higher amounts of ultraprocessed foods (that is, frozen or long shelf life foods, products with thickeners/emulsifiers, etc.). Although there are limitations to the studies included in the meta-analysis, the association is intriguing and could point to potential lifestyle modifications that could form the basis of preventative interventions for individuals at higher risk for IBD, such as first-degree relatives.

More immediately, prospective research is needed to understand if restricting ultraprocessed foods (or increasing less-processed foods) can decrease disease activity or prevent flares in patients with IBD.

Understanding factors that predispose to or trigger IBD, such as specific dietary components, will lead to improved management strategies and ultimately preventative interventions.

Ryan Ungaro, MD, MS, is an associate professor of medicine in the division of gastroenterology at the Icahn School of Medicine at Mount Sinai, New York. He is director of the Comprehensive Care for the Recently Diagnosed IBD Patient (COMPASS-IBD). He has served as an advisory board member or consultant for AbbVie, Bristol-Myers Squibb, Celltrion, Lilly, Janssen, Pfizer, Roivant, and Takeda, and has received research support from AbbVie, Boehringer Ingelheim, Bristol-Myers Squibb, Lily, and Pfizer.

AGA Plenary

Two historical events that changed gastroenterology

BY JOEL D. HOWELL, MD, PHD

During the 2023 DDW Presidential Plenary Session held in May at the annual Digestive Disease Week®, attendees heard about two major historical events that helped shape the field of gastroenterology.

The first event took place in 1822 at Fort Mackinac (better known today as Mackinac Island, an island on Lake Huron in Michigan). Alexis St. Martin, a French-Canadian fur trapper, was standing outside of the general store when a shotgun blast accidentally struck him in the stomach. Ordinarily, this would have been a fatal wound, but St. Martin miraculously survived–however, with a gastric fistula that permanently exposed the interior of his stomach.

William Beaumont, the post surgeon at Fort Mackinac, engaged in a series of experiments–purportedly 238–to study human digestion. In one experiment, Dr. Beaumont would pull food in and out of the stomach to study digestion. In another, he would withdraw fluid from the stomach to observe digestion outside of the body. The experiments caused St. Martin considerable discomfort. He eventually returned to Canada, but returned later when the U.S. Army agreed to compensate him for some of his expenses.


Dr. Howell

Today, the experiments would be called into question as having crossed ethical boundaries. Dr. Beaumont published the results from his experiments in a book which established the fundamental basics of our current beliefs about digestion. The experiments arguably mark the first example of gastrointestinal research in the United States.

The second historical event, which was the invention of the fiber-optic endoscope, also occurred in Michigan. At the University of Michigan, Basil Hirschowitz, MD, invented a flexible, fiber-optic instrument that could be used to look into the stomach, and perhaps even the duodenum. He first tried the invention on himself, and in 1957, he demonstrated it at the national meeting of the American Gastroscopic Society by reading a telephone directory through the new device.

The instrument was soon adopted for clinical use by physicians. Whether the fiber-optic machine was superior for visualizing the stomach was hotly debated, but what was very clear was that the fiber-optic tool was more comfortable for patients. By the mid-1960s, the fiber-optic invention had become the instrument of choice for gastrointestinal endoscopy. Many advances have since been made to the original instrument. ■

Dr. Howell is the Elizabeth Farrand Professor and a professor of internal medicine, history, and health management and policy at the University of Michigan, Ann Arbor. He has no financial disclosures.

AGA Postgraduate Course

Noteworthy advances in treatment and management of IBD

BY MARIA T. ABREU, MD, AGAF; JESSICA R. ALLEGRETTI, MD, MPH, FACG, AGAF; EDWARD V. LOFTUS JR., MD, FACG, FACP, AGAF; RYAN C. UNGARO, MD, MS

At this year's AGA Postgraduate Course that was held in May during the annual Digestive Disease Week®, we reviewed the latest updates in inflammatory bowel disease (IBD).

Although it had been thought that incidence rates of IBD were plateauing in high-incidence areas, a Danish study found a steady increase in incidence of Crohn's disease and ulcerative colitis (UC).[1] The highest increase in rates occurred in children and young adults, which will have repercussions as people get older and contribute to higher compounding prevalence. We need to get better at dealing with other health conditions as patients get older. A very large prospective Spanish study found that 42% of IBD patients scanned consecutively had MAFLD (metabolic-associated fatty liver disease)–even if they didn't have a high body mass index (BMI) and type 2 diabetes, suggesting that systemic inflammation in IBD contributes to the development of metabolic liver disease.[2]

The AGA recently published guidelines for using biomarkers in the management of UC. Patients with very low fecal calprotectin (FCP) are unlikely to have active disease whereas FCP over 150 with significant symptoms may warrant empiric changes in treatment.[3]

Intestinal ultrasound is gaining wider acceptance as a noninvasive way to monitor IBD.[4] In a UC study, improvement in bowel wall thickness following tofacitinib treatment correlated well with endoscopic activity.[5]

There has been a lot of excitement about JAK inhibitors for IBD. Upadacitinib has recently been approved for both UC and Crohn's disease.

The majority of the presentation focused on the explosion of Food and Drug Administration–approved medications for IBD in recent years. S1P receptor agonists, such as ozanimod and etrasimod, may work by trapping specific T-cell subsets in peripheral lymph nodes, preventing migration to intestinal tissues. Ozanimod is approved for UC. Etrasimod showed efficacy in UC with clinical remission rates of about 27% at week 12 and 32% at week 52.[6,7]


Dr. Abreu


Dr. Allegretti


Dr. Loftus


Dr. Ungaro

There has been a lot of excitement about JAK inhibitors for IBD. Upadacitinib has recently been approved for both UC and Crohn's disease. Response rates of 73% and remission rates of 26% were seen in UC patients who had been largely biologic exposed.[8] Similar results were seen in a biologic-exposed Crohn's disease population treated with upadacitinib including in endoscopy.[9] Upadacitinib was effective in maintaining remission at both 15-mg and 30-mg doses; but the higher dose had a greater effect on endoscopic endpoints.[10]

For Crohn's disease, we now have risankizumab, an anti-p19/IL-23 inhibitor. Risankizumab was efficacious at inducing and maintain remission in the pivotal phase 3 studies, even with 75% of patients being biologic exposed. These studies used combined endpoints of clinical remission as well as endoscopic response.[11] Guselkumab (anti-p19/IL-23) is also being studied for Crohn's disease and early trials has appears to be efficacious.[12]

A head-to-head study of naive Crohn's disease patients treated with ustekinumab or adalimumab (SEAVUE) showed comparable rates of clinical remission. At 52 weeks, the rates of clinical remission were quite high: >60% and endoscopic remission >30% with either therapy.[13]

We now have phase 3 data showing that a biologic is efficacious in patients with chronic pouchitis. The EARNEST trial demonstrated that vedolizumab has efficacy in treating pouchitis with improved clinical symptoms and endoscopy.[14] Future treatment strategies may involve combinations of biologic therapies. The VEGA study showed that

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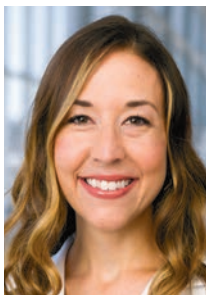
AGA Postgraduate Course

What is new in hepatology in 2023?

BY LISA B. VANWAGNER, MD, MSC; MARINA SERPER, MD, MS; DAVID S. GOLDBERG, MD, MSCE; AND ELIZABETH C. VERNA, MD, MSC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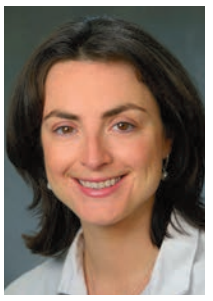
Dr. Serper


Dr. Goldberg


Dr. Verna

It has been a busy year for hepatology with major developments in the detection, management, and prevention of chronic liver disease. Two landmark phase 2 trials of the glucagon-like peptide 1 (GLP-1) receptor agonist, semaglutide, Food and Drug Administration–approved for type 2 diabetes or obesity, demonstrated improvements in nonalcoholic steatohepatitis (NASH) activity and resolution in stage 2 or 3 fibrosis (F2/F3), but not F4 fibrosis.[1,2] The first randomized trial to compare the efficacy and safety of bariatric surgery with lifestyle intervention plus best medical care for histologically confirmed NASH demonstrated the superiority of bariatric surgery.[3]

There has been a paradigm shift in risk stratification of cirrhosis and targets for prevention and treatment of decompensation. A newer term, advanced chronic liver disease (ACLD), represents a shift away from needing a histologic or radiologic diagnosis of cirrhosis while reduction in portal pressure is a therapeutic goal. Evidence supports noninvasive liver stiffness measurement (LSM) using transient elastography to identify those with clinically significant portal hypertension (CSPH) (e.g., hepatic venous pressure gradient ≥ 10 mm Hg) who may benefit from therapy to lower portal pressure. Accordingly, based on landmark studies, the American Association for the Study of Liver Diseases (AASLD) recommends early utilization of nonselective beta-blocker therapy, with carvedilol as a preferred agent, in CSPH to decrease the risk of decompensation and mortality.[4]

The definition of hepatorenal syndrome has also substantially evolved.[5] Terminology now acknowledges significant renal impairment at lower creatinine levels than previously used and recognizes the contribution of chronic kidney disease. The FDA approved terlipressin, a potent vasoconstrictor, for the treatment of hepatorenal syndrome with acute kidney injury (HRS-AKI, formerly HRS-Type I).

The AASLD published updates in advanced management of variceal bleeding highlighting intravascular interventions for esophageal, gastric, and ectopic varices. Data support early transjugular intrahepatic portosystemic shunt (TIPS) creation in patients with Child-Turcotte-Pugh (CTP) B or CTP C (< 14 points) within 72 hours of initial bleeding. However, hepatic encephalopathy remains a common complication. A randomized controlled trial demonstrated that rifaximin started 14 days prior to elective TIPS may reduce post-TIPS hepatic encephalopathy by 52%.[6]

Surveillance and treatment approaches for hepatocellular carcinoma (HCC) continue to evolve as reflected in new AASLD guidance in June 2023. Screening among high-risk patients should include ultrasound and serum alpha-fetoprotein

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combining an anti-TNF, golimumab, with an anti-IL-23, guselkumab, was superior than either alone with respect to clinical remission and endoscopic improvement in UC.[15] We will see more studies combining therapies with diverse mechanisms of action.

In summary, there have been many noteworthy advances in treatment and management of IBD in the past year. ■

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every 6 months and novel screening approaches including imaging and blood-based biomarkers are on the horizon. There also have been significant advances in systemic therapies for HCC. First-line therapy for advanced HCC with CTP A cirrhosis now includes either atezolizumab /bevacizumab or durvalumab/ tremelimumab. There is an evolving role for systemic therapy in the adjuvant setting as well, with emerging data supporting checkpoint inhibitors after resection or ablation among patients at high risk of recurrence.

Allocation policies continue to evolve for liver transplantation as waitlist prioritization transitions to MELD 3.0. The new score improves predictive accuracy for short-term mortality and addresses sex disparity in waitlist outcomes by lowering the prioritization of creatinine (and its threshold) and adding albumin to the current MELD-Na formula. MELD 3.0 will be adopted by the United Network for Organ Sharing in July 2023.

It has been a whirlwind 2023 for the liver community and we are excited and hopeful for new breakthroughs to come. ■

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