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GI&Hepatology News

October 2023

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More data needed on stopping GLP-1 use prior to endoscopy

Semaglutide, and other GLP-1 receptor agonists, could be problematic for patients undergoing endoscopy.

BY MEGAN BROOKS

In a new statement, five professional gastroenterology organizations caution that there are currently no data to support stopping glucagon-like peptide 1 (GLP-1) receptor agonists prior to elective endoscopy.

The medications, which include semaglutide (Ozempic, Wegovy), tirzepatide (Mounjaro), and liraglutide (Saxenda), among others, are used for the treatment of diabetes or for weight loss and may be associated with delayed gastric emptying.

Patients taking GLP-1 receptor agonists for diabetes management "need to be cautious about withholding these medications because doing so can adversely impact blood glucose control," said Octavia Pickett-Blakely, MD, a gastroenterologist with University of Pennsylvania in Philadelphia and spokesperson for the American Gastroenterological Association (AGA). "In patients undergoing endoscopic procedures, poorly controlled blood glucose could raise the risk of complications."

In commentary on Medscape, David Johnson, MD, professor of medicine and chief of gastroenterology at Eastern Virginia Medical School in Norfolk, urges clinicians to learn about the topic and inform patients when

See **GLP-1** · *page 7*

TC-325 hemostatic powder decreases GI tumor bleeding

Should it be a first-line treatment?

BY JENNIE SMITH
MDedge News

FROM GASTROENTEROLOGY

A hemostatic powder was shown superior to standard endoscopic treatment in stopping and preventing recurrence of gastrointestinal bleeding caused by malignant tumors.

The findings, published online in Gastroenterology (2023 Jun 3. doi: 10.1053/j.gastro.2023.05.042), come from the largest randomized trial to date of TC-325 (Hemospray, Cook Medical), compared with standard endoscopic hemostatic interventions for tumor bleeding.

For their research, Rapat Pittayanon, MD, of Chulalongkorn University in Bangkok and her colleagues, randomized patients (60% male, mean age 63) with active malignant upper or lower GI bleeding and low disability levels related to their cancers (ECOG score 0-2). The study was conducted at nine hospitals in Thailand.

The 106 patients who passed screening underwent either TC-325 or standard endoscopic hemostasis, which could involve use of thermal or mechanical methods or adrenaline injection, alone or combined with another modality, at the endoscopist's discretion. Crossover between treatment allocations was permitted if hemostasis was not achieved. Investigators assessed rates of immediate hemostasis and rebleeding at 30 days.

Dr. Pittayanon and colleagues found rebleeding to be significantly lower among TC-325 treated

See **Tumor bleeding** · *page 11*

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LETTER FROM THE EDITOR

Obesity in GI care

AGA has long been a powerful voice in advocating locally and nationally for issues of critical importance to our profession and patients.

While AGA's advocacy efforts related to access to colorectal cancer screening are frequently highlighted, this is one aspect of a larger advocacy agenda.

Dr. Adams

This month, I wish to highlight AGA's extensive advocacy efforts focused on expanding access to obesity treatment. More than two in five U.S. adults have obesity, and weight management has been shown to be beneficial in patients with comorbid gastrointestinal diseases, such as metabolic dysfunction–associated steatotic liver disease, gastroesophageal reflux disease, gallbladder disease, pancreatitis, and GI malignancy.

In 2022, Inside Scope, a podcast by AGA, featured a six-part series called "Obesity in GI." In July, Dr. Octavia Pickett-Blakely and Dr. Naresh Gunaratnam moderated a Gastro Bites lunch-and-learn (https://shorturl.at/fpTV5) session on "Obesity in GI Care – Embracing and Putting It Into Practice" in which they discussed models of care delivery supporting obesity management in GI practice.

In November 2022, AGA released "AGA Clinical Practice Guideline on Pharmacological Interventions for Adults With Obesity" (https://shorturl.at/bDNOV) to aid clinicians in appropriately prescribing obesity pharmacotherapy on the front lines of care.

On the policy front, in June, AGA held a Capitol Hill briefing (https://shorturl.at/frDZ2) in support of H.R.1577 - Treat and Reduce Obesity Act of 2021 (TROA) (https://shorturl.at/bjCT4), a bipartisan bill that would improve access to obesity treatment and care by expanding coverage under Medicare Part D for Food and Drug Administration-approved obesity pharmacotherapy, as well as related services such as behavioral, nutrition, and other counseling. Please check out our new obesity advocacy toolkit (https://shorturl.at/fFKO1) for more information.

This month we update you on important multi-society guidance regarding peri-endoscopic management of GLP-1 receptor agonists. We highlight new AGA Clinical Practice Updates on ostomy management and use of gastric POEM for treatment of gastroparesis, as well as a randomized controlled trial from Gastroenterology showing the effectiveness of hemostatic powder in the management of malignant GI bleeding as compared with standard care.

In our Member Spotlight, we feature gastroenterologist Sameer K. Berry, MD, MBA, who discusses his role as a physician-entrepreneur seeking to transform GI care delivery through his AGA GI Opportunity Fund–supported company, Oshi Health.

This issue includes our annual supplement, "Gastroenterology Data Trends." It features a collection of contributions on GI and climate change, long COVID and the GI tract, and the evolution of targeted therapies for *C. difficile*, among others.

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

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

Landmark obesity legislation reintroduced

The AGA Government Affairs Committee is pleased to announce the Senate and House have reintroduced the bipartisan Treat and Reduce Obesity Act (TROA) (H.R. 4818/S. 2407). This legislation is a vital first step in expanding access to obesity treatment as it would expand Medicare coverage to include screening and treatment of obesity by a diverse range of health care providers who provide obesity care. The bill also includes coverage of behavioral counseling, prescription drugs for long-term weight management, and other prevention and treatment options. The passage of TROA could lead to improved obesity care options because many private insurance companies model their covered health benefits to reflect Medicare. You can help lawmakers understand the urgent need for expanded access to affordable, effective obesity treatments and how greater access to these tools will equip you to better care for your patients.

See the new obesity advocacy toolkit (https://shorturl.at/dfluJ) for resources. ■

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‘Proceed cautiously’ expert says

GLP-1 *from page 1*

prescribing GLP-1 receptor agonists.

“These are new and changing issues. In our world as gastroenterologists, we should be considering – very strongly – mitigating strategies to protect the patients on this wonderful class of therapy,” he says. “Sometimes these drugs can have significant side effects that we need to at least be aware of. Nothing is perfect, but let us be better informed.”

“We really don’t know what the risks are yet. With endoscopy, they could be significant, but perhaps they’re not,” Jonathan Leighton, MD, a gastroenterologist with Mayo Clinic Arizona in Phoenix and president-elect of the American College of Gastroenterology (ACG), told this news organization. “There are a lot of factors that go into this, and we just want to proceed cautiously and carefully until we know more.”

“As patient safety will always be paramount, and in the absence of actionable data, we encourage our members to exercise best practices when performing endoscopy on these patients who are taking GLP-1 receptor agonists.”

The ACG, AGA, the American Association for the Study of Liver Diseases, the American Society for Gastrointestinal Endoscopy, and the North American Society for Pediatric Gastroenterology, Hepatology & Nutrition released the statement on Aug. 11.

It was issued in response to recent guidance on the preoperative management of adults and children on GLP-1 receptor agonists put forth by the American Society of Anesthesiologists.

The five gastroenterology organizations caution that “more data are needed to understand if and when these medications should be held prior to elective endoscopy.

“There is concern that this class of medication may be associated with safety issues regarding sedation and endoscopy. While there is anecdotal experience that increased gastroparesis risk may be dose dependent, or related to whether it is being used for diabetes control versus weight loss, we also acknowledge that there is little or no data related to the relative risk of complications from aspiration,” they stated.

In a separate statement, the AGA addressed unkowns associated with stopping treatment: “The impact associated with stopping these therapies prior to undergoing upper GI endoscopy or other moderate to deep sedated procedures is unknown at this time.

“As clinical gastroenterologists and hepatologists, we are very familiar with safety issues regarding the performance of endoscopy in our patients suffering from gastroparesis as well as unexplained nausea, vomiting, and epigastric pain, particularly in emergency situations. As patient safety will always be paramount, and in the absence of actionable data, we encourage our members to exercise best practices when performing endoscopy on these patients who are taking GLP-1 receptor agonists. More data are needed to understand if and when these medications should be held prior to elective endoscopy.

“Given the need for further data regarding the emerging use of these novel compounds, we encourage our anesthesiology, endocrinology, and industry partners to work collaboratively with our members to develop the necessary evidence to appropriately inform medication adjustments prior to elective endoscopy.”

ASA recommendations

The ASA Task Force on Preoperative Fasting reviewed the available literature on GLP-1 receptor agonists and associated gastrointestinal adverse effects, including the consequences of delayed gastric emptying.

The task force acknowledges the evidence to provide guidance for preoperative management of these drugs to prevent regurgitation and pulmonary aspiration of gastric contents is “sparse, limited only to several case reports.”

Nevertheless, given the concerns of GLP-1 receptor agonist–induced delayed gastric emptying and high risk for regurgitation and aspiration of gastric contents, the task force made these recommendations for elective procedures.

The day before the procedure

For patients on daily dosing, consider holding GLP-1 agonists on the day of the procedure/surgery. For patients on weekly dosing, consider holding GLP-1 agonists a week prior to the procedure/surgery.

This suggestion is irrespective of the indication (type 2 diabetes or weight loss), dose, or the type of procedure/surgery.

If GLP-1 agonists prescribed for diabetes are held for longer than the dosing schedule, consider consulting an endocrinologist for bridging the antidiabetic therapy to avoid hyperglycemia.

The day of the procedure

If GI symptoms such as severe nausea/vomiting/retching, abdominal bloating, or abdominal pain are present, consider delaying the elective procedure and discuss the concerns of potential risk of regurgitation and pulmonary aspiration of gastric contents with the proceduralist/surgeon and the patient.

If the patient has no GI symptoms and the GLP-1 agonists have been held as advised, proceed as usual.

If the patient has no GI symptoms but the GLP-1 agonists were not held as advised, proceed with “full stomach” precautions or consider evaluating gastric volume by ultrasound, if possible and if proficient with the technique. If the stomach is empty, proceed as usual. If the stomach is full or if gastric ultrasound is inconclusive or not possible, consider delaying the procedure or treat the patient as “full stomach” and manage accordingly. Discuss the concerns of potential risk of regurgitation and pulmonary aspiration of gastric contents with the proceduralist/surgeon and the patient.

There is no evidence to suggest the optimal duration of fasting for patients on GLP-1 agonists. Until we have adequate evidence, we suggest following ASA fasting guidelines.

For patients on GLP-1 receptor agonists who need urgent or emergent procedures, the ASA advises proceeding and treating the patient as “full stomach” and managing accordingly.

Dr. Leighton has financial relationships with Olympus and Pfizer. Dr. Pickett-Blakely has no relevant disclosures. Dr. Johnson is an adviser to ISOThrive and Johnson & Johnson. ■

Member SPOTLIGHT

New York GI advocates for team approach in GI care

BY JENNIFER LUBELL

MDedge News

Sameer K. Berry, MD, MBA, comes from a family of GI doctors. As a child, he used to accompany his father when he made rounds at the local county hospital.

"I was a little kid, so I wasn't helping him," but he said he learned a great deal by sitting in the hallways and listening to his father talk to patients. "I could clearly hear the human suffering on the other side."

This experience had a big impact on Dr. Berry who continues the family trade. Like his father, talking with patients about their condition is his favorite part of the job, but especially talking about the role of diet, lifestyle, and stress on GI health, said Dr. Berry, who is a gastroenterologist and clinical assistant professor of medicine at New York University's Grossman School of Medicine.

In addition to his clinical practice, Dr. Berry serves as the co-founder & chief medical officer at Oshi Health. Oshi is an integrative health care clinic that is entirely virtual and entirely and solely about GI health. The clinic works with GI clinicians and other health care providers allowing patients access to multidisciplinary care that has proven to reduce health care costs and improve patient outcomes. The company was recently named a recipient of funding through the American College of Gastroenterology and the American Gastroenterological Association's Center for GI Innovation & Technology's GI Opportunity Fund.

The Oshi model is a whole-person, multidisciplinary GI care model, which includes traditional medical care for GI conditions, but also provides access to health coaching, nutrition and diet support, and behavioral and mental health services. Research shows the approach is effective in mitigating symptoms. A 2020 randomized controlled trial published in The Lancet Gastroenterology and Hepatology demonstrated that integrated multidisciplinary care led to improvement in symptoms, quality of life, and cost of care for complex GI conditions, as compared with the traditional GI specialist care model. Numerous similar studies have found that integrated care teams were better equipped to meet the needs of patients with inflammatory bowel disease and patients with disorders of gut-brain interaction, patient outcomes and satisfaction were better, overall direct and indirect costs were lower, and psychological health needs were better addressed.

Dr. Sameer K. Berry

Q: What was the inspiration behind Oshi Health?

Dr. Berry: Gastroenterologists continue to witness unnecessary patient suffering due to antiquated care delivery models and perverse incentives in our healthcare system. Oshi's care model was designed to align incentives and provide patients with access to clinicians who are traditionally not reimbursed in fee-for-service healthcare while also helping GI practices provide this care to their patients. During my clinical training it was easy for me to order expensive and invasive testing for my patients, but very difficult for me to get them the multidisciplinary care they needed. Many of the patients I would see didn't need more MRIs, CT scans, or expensive medications. They needed access to a team of clinicians to help with all the aspects of GI care, including diet, behavioral, and medical.

Q: Why is multidisciplinary care the right approach?

Dr. Berry: GI is a very complex field with many nuances that can impact a patient's symptoms. As physicians, our role is now evolving to oversee a team of clinicians working together to maximize expertise in nutrition and the gut-brain axis. With these new multidisciplinary care models, GI practices can expand their capabilities. At Oshi Health, every single patient has access to a nurse practitioner, dietician, psychologist, and health coach — all overseen by a gastroenterologist — as a covered benefit through their health plan. Providing multidisciplinary care through a virtual-first model solves some of the scalability challenges of these intensive care models and can significantly improve access to care.

Q: What grant-funded clinical research are you doing right now?

Dr. Berry: Most of my research focuses on evaluating the impact of novel care delivery models in GI and the evaluation of digital technologies in GI and how we can incorporate those digital technologies into clinical practice. How can we determine what type of care can be done remotely via video visits? What can be done on the phone or via text messaging? How can we get these new services paid for so patients can reap the benefits of seeing their doctor more frequently?

Q: What teacher or mentor had the greatest impact on you?

Dr. Berry: John Allen, MD, MBA has had an incredible impact on my career. He's the former president of the American Gastroenterological Association, and was the chief clinical officer and a professor at the University of Michigan. He's one of the rare GI doctors that has both a strong clinical and leadership role in GI. I can't thank him enough for planting the seeds to encourage me to focus on improving the ways we deliver care to patients.

"The Oshi model is a whole-person, multidisciplinary GI care model, which includes traditional medical care for GI conditions, but also...health coaching, nutrition and diet support, and behavioral and mental health services."

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

Dr. Berry: Exploring a new neighborhood either in New York City or anywhere in the world. If I wasn't going to be a doctor, I'd probably be an anthropologist. I love observing people in their element, and exploring new neighborhoods that are off the beaten path is a great way to do that. ■

Lightning round

Do you prefer texting or talking?
Texting

What's high on your list of travel destinations?
Antarctica

Where was your most memorable vacation?
Patagonia

How many cups of coffee do you drink daily?
Four

What's your favorite holiday?
Halloween

What's your favorite junk food?
In-N-Out Burger

If you weren't a gastroenterologist, what would you be?
Anthropologist

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CMGH names new co–editors-in-chief

AGA is excited to announce the new co–editors-in-chief of Cellular and Molecular Gastroenterology and Hepatology (CMGH). Michele A. Battle, PhD, and Jonathan P. Katz, MD, will be taking over their new roles beginning July 1, 2024.


Dr. Battle


Dr. Katz

"In my role as co–editor-in-chief of CMGH, I look forward to working with Jonathan Katz to advance its longstanding mission to disseminate rigorous, reproducible, and impactful digestive biology research. I am excited to launch new initiatives including the addition of special topic editors who will cover themes relating to early-career investigators and diversity, equity, and inclusion," said Dr. Battle, who is a professor in the department of cell biology, neurobiology, and anatomy at the Medical College of Wisconsin, Milwaukee.

"I am honored to work with Michele Battle and the rest of our new CMGH board of editors. Some of our goals are to expand CMGH outreach and engagement, incorporate more programs and opportunities for junior investigators, and provide rapid advancements and technical reports that drive research in the field.

"As such, we will strive to ensure that CMGH remains the preeminent journal focused on high-impact, basic, mechanistic research in GI and hepatology," said Dr. Katz, who is an associate professor of medicine in the department of medicine gastroenterology division, director of molecular pathology and imaging care, and director of the undergraduate student scholars program at the University of Pennsylvania, Philadelphia. He is also currently an associate editor for CMGH.

Dr. Battle and Dr. Katz are former AGA Research Foundation awardees, with Dr. Battle receiving an AGA Research Scholar Award in 2009 and Dr. Katz receiving the AGA Astra Merck Advanced Research Training Award in 1998.

Over the next year, they will meet with the current editorial board and start to plan and develop new special sections and initiatives to bring to CMGH during their term.

Please join us in congratulating Dr. Battle and Dr. Katz on their new role as incoming co–editors-in chief. ■

The inaugural Gastro Journal Club is online

We are delighted to introduce the Gastro Journal Club in which an author of a study published in Gastroenterology will present their paper followed by a Q&A. The inaugural Gastro Journal Club features Loren Laine, MD, professor of medicine (digestive diseases) at Yale University, New Haven, Conn., and was hosted by the McMaster University gastroenterology division. Dr. Laine presented his article "Vonoprazan Versus Lansoprazole for Healing and Maintenance of Healing of Erosive Esophagitis: A Randomized Trial," published in the January 2023 issue of Gastroenterology.

The Gastro Journal Club is open to GI units at any institution worldwide.

If you are interested in participating, please contact mpogachar@gastro.org. ■

Watch the inaugural Gastro Journal Club at https://rb.gy/j8mqm.

Is it time to change the words we use to promote cancer screening?

Except possibly for colorectal cancer screening with sigmoidoscopy, common cancer screening tests do not extend life, according to a new study published in JAMA Internal Medicine (2023 Aug 28. doi: 10.1001/jamainternmed.2023.3798).


Dr. Kim

The study, which was a systematic review and meta-analysis of 18 long-term randomized clinical trials involving 2.1 million individuals, found that colorectal cancer screening with sigmoidoscopy prolonged lifetime by 110 days, while fecal testing and mammography screening did not prolong life. An extension of 37 days was noted for prostate cancer screening with prostate-specific antigen testing and 107 days with lung cancer screening using CT.

The study involved more than 1 decade of follow-up reporting all-cause mortality of people who had undergone mammography screening for breast cancer; colonoscopy, sigmoidoscopy, or fecal occult blood testing for colorectal cancer; CT screening for lung cancer in smokers and former smokers; or prostate-specific antigen testing for prostate cancer.

The study received a fair amount of attention in the press, but the AGA believes the premise of the study is flawed because cancer screening is not intended to increase longevity, but it can prevent premature death.

"Cancer prevention and earlier-stage diagnoses through colorectal cancer screening provides significant morbidity and cost benefits, even if all-cause mortality is not reduced," said Lawrence Kim, MD, AGAF, AGA vice president.

The authors of the study, who were led by Michael Bretthauer, MD, PhD, of the Clinical Effectiveness Research Group, University of Oslo, are not suggesting that cancer screenings be abandoned. However, they do suggest that "organizations, institutions, and policy makers who promote cancer screening tests by their effect to save lives may find other ways of encouraging screening. It might be wise to reconsider priorities and dispassionately inform interested people about the absolute benefits, harms, and burden of screening tests that they consider undertaking." ■

ZzzVuk/E+/Getty Images/WebMD

Treatment shown to be effective

Tumor bleeding *from page 1*

patients, at 2.1%, compared with 21.3% for standard care (odds ratio, 0.09; 95% CI, 0.01-0.80; *P* = .03). Rates of immediate hemostasis were 100% for TC-325–treated subjects, compared with 68.6% in the group that received conventional treatment (OR, 1.45; 95% CI, 0.93-2.29; *P* < .001).

None of the 55 patients in the TC-325 group underwent crossover treatment, but 15 patients in the standard care group were crossed over to TC-325 after their endoscopic treatment was deemed to have failed. One-fifth of patients who got TC-325 as a crossover treatment developed rebleeding at 30 days, which the investigators surmised was related to mucosal damage incurred during the endoscopic procedure.

The study was not powered to adequately assess survival outcomes. Seven patients in the TC-325 group and four in the conventional-care group died before 30 days' follow-up, and no death was directly related to recurrent tumor bleeding.

"To our knowledge, our trial is the first to show such significant findings in a randomized controlled trial setting, which now provide a long-awaited efficacious hemostatic approach where one had been lacking when managing patients with malignant GI bleeding," the investigators wrote in their analysis.

"Perhaps most importantly, this carefully controlled study also highlights the unreliable hemostatic effect of standard endoscopic modalities available for GI tumor hemostasis, with high 30-day rebleeding rates in our patient population."

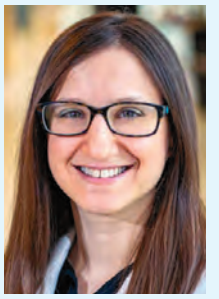
Dr. Pittayanon and colleagues noted several limitations of their study. These included the inability to blind patients to an endoscopist, which "may have influenced subsequent management decisions … including the decision to cross over."

Only in 5 of 15 cases of crossover did the treating endoscopist provide photo evidence of treatment failure as required by the trial's protocol. Also, the use of adrenaline injection alone was permitted in the study, in contrast to best practice guidelines for endoscopic hemostasis to treat peptic ulcer bleeding. Finally, the study was conducted in Thailand, potentially reducing the generalizability of the results.

The study was funded by King Chulalongkorn Memorial Hospital; the Thai Red Cross; and Chulalongkorn University. Cook Medical donated some of the TC-325 kits used in the study.

One study coauthor, Alan N. Barkun, disclosed consulting work for Medtronic and past paid work for Cook Medical. The remaining authors disclosed no conflicts of interest.

Gastrointestinal tumor bleeding is a challenging problem that can lead to prolonged hospitalization and interruption of curative or palliative oncologic interventions. Standard endoscopic hemostasis interventions, such as subepithelial epinephrine injection and mechanical and thermal treatments, can be limited because of the underlying tumor biology that alters angiogenesis, distorts the surrounding mucosa, and undermines the normal coagulation process.



Dr. Simons

This randomized trial by Pittayanon et al. demonstrated that the hemostatic powder TC-325 (Hemospray, Cook Medical) was superior to standard endoscopic intervention in achieving immediate hemostasis (100% vs. 69%) and reducing 30-day rebleeding rate (2% vs. 21%).

Hemostatic powder has been shown to be a useful tool in managing nonmalignant GI bleeds and recent studies have supported its role in GI tumor bleeding. The nonabsorbable granules adhere to the actively bleeding site and then pull water from the vessels to stimulate the normal coagulation pathway.

Its noncontact, easy-to-use application and ability to treat a wide defect area make it an appealing first-line treatment option in this setting. Several other hemostatic powders are available including Nexpowder Endoscopic Hemostasis System (UI-EW, Nextbiomedical) and Endoclot Polysaccharide Hemostatic System (Endoclot Plus Inc.).

As the use of hemostatic powder becomes more popular, we need to be mindful of its contraindications, namely fistulas, active perforation, or lesions that are high risk for perforation because the pressure generated during application can exacerbate a transmural defect, although this adverse event is rare.

As clinicians and endoscopists, our ultimate goals in treating GI tumor bleeding are to provide safe and efficient hemostasis, to decrease hospital stay, and to minimize delay and interruption of oncologic or palliative treatments.

This study advocates that TC-325 may be a better primary option than standard endoscopic treatments for GI tumor bleeding in the appropriate setting. Safety, efficacy, and feasibility studies comparing TC-325 to the other hemostatic powder products are needed.

Malorie K. Simons, MD, is an interventional endoscopist at Fox Chase Cancer Center, Temple University Health System, Philadelphia. She has no conflicts of interest.

Crohn's disease indicators manifest years before diagnosis

BY WILL PASS
MDedge News

FROM CLINICAL GASTROENTEROLOGY AND HEPATOLOGY

Changes in proteins and antibodies suggesting immune dysregulation may be detectable in serum years before clinical manifestation of complicated Crohn's disease, shows a study published in Clinical Gastroenterology and Hepatology (2023 Feb 26. doi: 10.1016/j.cgh.2023.01.033).

These preclinical signatures could one day play a role in screening for complicated Crohn's disease (CD) and in mapping underlying disease pathways, potentially opening doors to new preventive approaches, wrote study authors who were led by Joseph A. Murray, MD, of the division of gastroenterology and hepatology at Mayo Clinic, Rochester, Minn.

"Mounting evidence suggests that the diagnosis of CD is preceded by a lengthy asymptomatic preclinical period," investigators wrote. "Gaining insight into this phase may allow a better understanding of the primary events that lead to its development and offer potential strategies to predict and prevent the disease including its complications."

The study, which was a nested case-control study based on the PREDICTS study, included 201 patients with CD who had serum samples archived 2, 4, and 6 years prior to diagnosis, as well as 201 healthy controls who provided serum samples for comparison. Serum samples were analyzed with a comprehensive panel of 1,129 proteomic markers and antimicrobial antibodies. At time of diagnosis, 47 of the patients with CD (24%) had a complicated phenotype, including stricturing behavior, penetrating behavior, or need for early surgery.

"The unique availability of preclinical samples collected at multiple time points allowed us to examine the sequence of immunological changes and protein biomarkers that occurred before diagnosis," the investigators wrote. "We also evaluated a wide array of protein biomarkers, utilizing a novel proteomic platform, and applied novel rigorous statistical approaches, which allowed us to discover the potential biomarkers and biologic pathways for the complicated phenotypes even before diagnosis."

As early as 6 years before diagnosis, patients with complicated CD had significantly higher levels of antimicrobial antibodies than patients with noncomplicated CD, as well as elevations in 22 protein biomarkers indicating immune dysregulation. Complicated CD was preceded by elevated anti–*Saccharomyces cerevisiae* antibodies (ASCA) IgA/IgG, anti-Flagellin antibodies, and other proteins linked with fibrosis, adaptive immunity, and innate immunity. Simultaneously, the same patients had reduced levels of protein biomarkers linked with protection against fibrosis and tissue damage. Network analysis added weight to these findings by demonstrating a significant correlation between ASCA IgA/IgG and protein biomarkers tied to innate immunity and lack of factors for tissue protection.

The investigators disclosed relationships with Janssen, AbbVie, Galapagos, and others.

Rectal cancer risk is higher 10 years post colectomy

BY WILL PASS
MDedge News

FROM GASTRO HEP ADVANCES

Patients with inflammatory bowel disease (IBD) who undergo subtotal colectomy and diverted rectum may face a "markedly increased" risk of rectal cancer (RC) in the diverted rectum at 10 years post colectomy, shows a Danish population-based cohort study.

These findings suggest that more intensive long-term surveillance is needed for colectomized patients with IBD, wrote researchers who were led by Tine Jess, MD, DMSc, of the Center for Molecular Prediction of Inflammatory Bowel Disease, Aalborg University, Copenhagen.

"Our nationwide population-based cohort study covering 4 decades shows that despite a relatively low absolute number of RC cases following colectomy for IBD, the risk of RC is markedly increased 10 years after the surgery. This calls for better long-term surveillance of colectomized IBD patients," the authors wrote in Gastro Hep Advances (2023 May 12. doi: 10.1016/j.gastha.2023.05.001).

Previous studies have suggested that patients with IBD have an increased risk of rectal cancer after colectomy.

The new study was based on an analysis of data from more than 9 million individuals in the Danish Civil Registration System between 1978 and 2018. The analyses were restricted to risk of rectal cancer in the population with diverted rectum.

The final dataset included 4,931 patients with IBD who had subtotal colectomy and diverted rectum, 49,251 matched patients with IBD who did not undergo colectomy, and 246,550 matched individuals without IBD to serve as a background population. Within these groups, rectal cancer occurred at a rate of 0.9%, 0.4%, and 0.4%, respectively, hinting at an increased risk of rectal cancer after colectomy among patients with IBD.

This signal was clarified by comparing rates of rectal cancer 10 years before and after colectomy. Rates 10 years before colectomy were not significantly different between groups.

Comparing colectomized IBD patients with the noncolectomized IBD patients at the 10-year postcolectomy mark revealed an eightfold increased risk of rectal cancer (hazard ratio, 7.56; 95% confidence interval, 5.21-10.86). Risk was slightly lower for patients with Crohn's disease (HR, 5.10; 95% CI, 2.41-10.81) than for those with ulcerative colitis (HR, 9.42; 95% CI, 6.18-14.36). A comparison at the same time point for colectomized IBD patients versus the background population showed an even higher relative risk for rectal cancer, up 10-fold (HR, 10.01; 95% CI, 7.20-13.94).

In a Danish population-based cohort study, Akimenko and colleagues identify a markedly increased risk of rectal cancer 10 years after colectomy in patients with a diverted rectum. This risk is 8-fold compared to a matched IBD cohort without colectomy, 10-fold compared to the background population, and slightly higher in ulcerative colitis than Crohn's disease. The relative risk is similar to that identified in a Swedish nationwide study.


Dr. Gergely

The study benefits from a large, unselected cohort and its use of a matched IBD population without colectomy. However, it is not sufficiently powered to assess cancer risk in patients with ileo-rectal anastomosis (IRA) or ileal pouch-anal anastomosis (IPAA), thus limiting its generalizability. The lengthy 40-year inclusion period, while providing strength in numbers, may also impact the study findings, as significant changes have occurred in IBD management during this timeframe.

The authors herald an important reminder that post-colectomy IBD patients are not out of the woods with regards to rectal cancer risk. Inconsistency exists among providers when it comes to surveillance intervals in these patients. The study highlights the need for specific surveillance guidelines for this group, particularly in patients with a diverted rectum. Additional studies are needed to assess risk in patients with IRA or IPAA.

Maté Gergely, MD, is an assistant professor of medicine in gastroenterology at Washington University School of Medicine, St. Louis. He has no relevant disclosures.

Researchers concluded the long-term risk of rectal cancer post colectomy increased among patients with IBD. "To reduce the risk of CRC in IBD, endoscopic surveillance guidelines have been developed both nationally and internationally. However, guidelines do not include clear recommendations for patients with a residual rectum, ileo-rectal anastomosis, or ileal pouch-anal anastomosis. The Danish guidelines, the Danish Society of Gastroenterology and Hepatology, mention a potential increased risk of rectal cancer post colectomy.

The investigators disclosed no conflicts of interest. ■

AGA CPU focuses on noninvasive tests in patients with NAFLD

BY WILL PASS
MDedge News

FROM GASTROENTEROLOGY

Noninvasive testing allows for routine risk stratification and long-term monitoring of patients with nonalcoholic fatty liver disease (NAFLD), offering a safer, more practical approach than biopsy, according to a recent Clinical Practice Update Expert Review by the American Gastroenterological Association.

The update, published in Gastroenterology (2023 Aug. 4. doi: 10.1053/j.gastro.2023.06.013), includes eight best practice advice statements.

"The healthcare burden of longitudinal management of patients with NAFLD is significant. The emergence and utilization of noninvasive testing (NIT) in gastroenterology practices has the potential to significantly enhance the care of patients with NAFLD by improving detection of patients with advanced fibrosis who are at increased risk for cirrhosis, hepatic decompensation, and HCC [hepatocellular carcinoma], thereby facilitating timely clinical management," wrote authors who were led by Julia J. Wattacheril, MD, MPH, of the Columbia University–New York Presbyterian Hospital nonalcoholic fatty liver disease program and center for liver disease and transplantation.

"In this Expert Review, we have provided clinicians with best practice advice for optimal utilization of NITs in patients with NAFLD," the authors wrote.

Consensus recommendations for implementing NITs in practice are scarce, giving rise to the present clinical practice update. The expert panel reviewed available evidence for these tests during longitudinal care of patients with advanced fibrosis as a means of predicting liver-related outcomes and informing treatment decisions.

The authors recommend 8 best practice considerations.

1) Encourages use of NITs for risk stratification during the diagnosis of NAFLD, typically in the form of vibration-controlled transient elastography, shear wave elastography, or magnetic resonance elastography, all of which have been validated. "Ultrasound-based 3-dimensional elastography and iron-corrected T1 magnetic resonance imaging, although used less frequently, are emerging technologies."

2) Patients with a fibrosis 4 index (FIB-4) less than 1.3 are unlikely to have advanced hepatic fibrosis, based on this threshold's strong negative predictive value.

Still, clinicians should remember that this FIB-4 threshold may be less reliable among patients younger than 35 years or older than 65 years, making it necessary to also consider other clinical measurements.

3) The use of 2 or more NITs among patients with a FIB-4 score greater than 1.3 is recommended.

4) Clinicians should follow the manufacturer's specifications when implementing noninvasive

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AGA CPU: Preventing complications with ostomies

BY WILL PASS
MDedge News

FROM CLINICAL GASTROENTEROLOGY AND HEPATOLOGY

The American Gastroenterological Association has published a new Clinical Practice Update for the management of enteral ostomies, which are common in the management of patients with colorectal cancer, inflammatory bowel disease, diverticular disease, intestinal trauma, and intestinal perforation.

Approximately 750,000 people in the United States live with an ostomy, including colostomy, ileostomy, and continent ileostomy. Complications and challenges with self-care are common among patients with an enteral stoma, but most available guidance documents fail to offer management principles beyond the immediate perioperative period, wrote authors of the guidance which was led by Traci Hedrick, MD, of the University of Virginia Health, Charlottesville.

The update was published online in Clinical Gastroenterology and Hepatology (2023 Jul 25. doi: 1016/j.cgh.2023.04.035). It includes best practice updates for managing short- and long-term complications, and perioperative considerations.

Early high ostomy output, defined by ostomy output greater than fluid intake that occurs within 3 weeks of stoma formation, causing dehydration, is a short-term complication associated with ostomies. It is more common among patients with an ileostomy than a colostomy, and requires rapid evaluation for infection and other associated complications. The cornerstone of treatment is rehydration, usually intravenously during hospital stay. Additional treatments may include bulking agents, antimotility agents, antisecretory agents, anti-inflammatory agents, adaptation-promoting agents, and surgery to reverse the ostomy.

Other short-term complications include ostomy leakage, stomal retraction, and mucocutaneous separation.

Dermatological problems are the most common of long-term complications. These typically involve skin irritation due to leakage. Other dermatological complaints include folliculitis, fungal rash, and allergic reaction to the appliance. Each of

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testing. Misuse may lead to "discordant results and adverse events."

5) To increase the positive predictive value for detecting advanced fibrosis, NITs are best interpreted in the context of relevant clinical data, such as physical exam and endoscopy findings.

6) Liver biopsy should be considered for patients with NIT results that are indeterminate or discordant; conflict with other clinical, laboratory, or radiologic findings; or when alternative etiologies for liver disease are suspected.

7) Serial longitudinal monitoring using NITs for assessment of disease progression or regression may inform clinical management.

8) Patients with NAFLD and NITs results suggestive of advanced fibrosis (F3) or cirrhosis (F4) should be considered for surveillance of liver complications

The investigators have relationships with AstraZeneca, BMS, and others. ■

AGA CPU: Practical management strategies for bloating, distention, and belching

BY JENNIE SMITH
MDedge News

FROM GASTROENTEROLOGY

A new Clinical Practice Update from the American Gastroenterological Association on belching, abdominal bloating, and distention offers practical management strategies for a class of disorders that, while highly prevalent, can be confusing to clinicians because of their nonspecific and overlapping symptomatology and wide range of possible causes.

The expert review, published online in Gastroenterology (2023 Jul 13. doi: 10.1053/j.gastro.2023.04.039), is the first guidance dedicated to these specific disorders, which, when not caused by bacteria, food intolerance, or autoimmune disease, are increasingly viewed as stemming from dysregulation of the brain-gut axis, and therefore responsive to interventions such as biofeedback therapy and central nervous system modulators, including antidepressants referred to as neuromodulators because of their pain-modulating effects in the gut.

Baharak Moshiree, MD, of Atrium Health, Wake Forest Medical University, Charlotte, N.C., the lead author, said the guidance is aimed at GI specialists as much as primary care physicians and other providers who treat patients with these disorders.

Clinicians may not always know which diagnostic studies to order for a patient with bloating, distention, or belching, Dr. Moshiree said, and since large randomized controlled trials in these patient groups are not available, making evidence-based treatment recommendations is challenging. Because the disorders are ubiquitous, "there's a lot of social media attention around them, and these include fad diets and drugs labeled as medical foods, like probiotics, that patients will often try."

The guidance includes 15 best practice advice statements along with two diagnostic and treatment algorithms, one for belching and the other for bloating and distention.

For belching, the authors stress discerning between gastric and supragastric belching using clinical history and examination, and if needed, impedance Ph monitoring. For supragastric belching, or esophageal belching, treatment considerations may include cognitive behavioral therapy, biofeedback training, and neuromodulator (antidepressant) drugs either alone or combined with psychological therapies.

Abdominal bloating and distention should be diagnosed using the Rome IV criteria, and in patients with suspected carbohydrate enzyme deficiencies, dietary restriction of potentially problematic carbohydrates or breath testing may be used to rule out intolerance. In a subset of at-risk patients, "small bowel aspiration and glucose- or lactulose-based hydrogen breath testing may be used to evaluate for small intestinal bacterial overgrowth," the guidance says. Blood testing may be used to rule out celiac disease, and, if positive, a definitive diagnosis should be confirmed with small bowel tissue biopsy obtained during an upper

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PEARLS from the PROS

Hepatic presentations of celiac disease

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

Celiac disease can present with extraintestinal manifestations, including liver disease, with a spectrum ranging from elevated liver biochemistries to advanced cirrhosis. Liver biopsy findings may include variable degrees of steatosis, inflammation, and fibrosis.

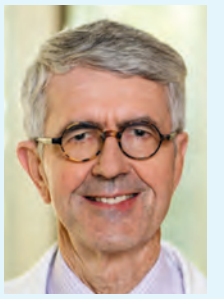
In one case we have seen, the patient presented with unexplained ascites and features suggestive of Budd-Chiari syndrome. The serum ascites albumin gradient was 2.3 with a total protein of 0.8 g/dL, and albumin 0.5 g/dL, with an ascitic WBC count of 88/mm^3.

Echocardiography showed an ejection fraction of 80%. Transjugular liver biopsy revealed a normal hepatic venous pressure gradient but marked sinusoidal dilatation and congestion with hepatocyte atrophy and focal necrosis suggestive of vascular outlet obstruction (Figure 1).

Hepatic venography, however, showed no evidence of Budd-Chiari syndrome. When seen in consultation, pertinent observations included Irish ancestry, a history of occasional diarrhea, short stature, osteoporosis, and an atrophic spleen on computed tomography. An IgA transglutaminase antibody was positive, and a small-bowel biopsy confirmed celiac disease (Figure 2).

On a gluten-free diet, the patient's symptoms resolved, with clinical and laboratory abnormalities returning to normal. She lived another 20 years before dying of primary pulmonary hypertension. Recognition of an unusual hepatic manifestation of celiac disease led to effective management. ■

Dr. Friedman



Dr. Martin

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

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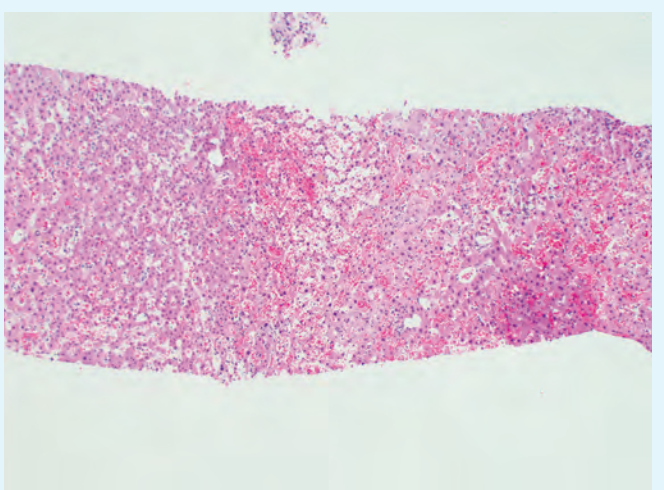
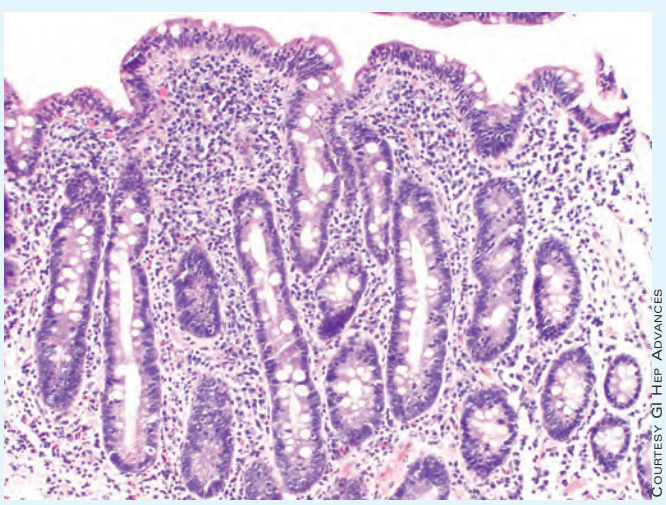


Figure 1



Courtesy GI Hep Advances

Figure 2

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endoscopy, Dr. Moshiree and her colleagues wrote.

Endoscopy and imaging should be restricted to patients with alarm features such as vomiting or weight loss, rapid worsening of symptoms, or an abnormal physical exam. Tests such as gastric emptying transit studies should not be routinely ordered unless nausea and vomiting are present. Similarly, whole-gut motility studies should be ordered only if there are symptoms suggestive of motility disorders, with testing carried out at specialized centers.

When constipation occurs with bloating, clinicians should use anorectal physiology testing to rule out a pelvic-floor disorder, which, if present, can be treated with pelvic-floor biofeedback training. Constipation in the context of bloating may also be treated with laxatives.

When constipation occurs with bloating, clinicians should use anorectal physiology testing to rule out a pelvic-floor disorder, which, if present, can be treated with pelvic-floor biofeedback training. Constipation in the context of bloating may also be treated with laxatives. Probiotics are not advised as treatment for bloating and distention in this guidance, given a lack of robust studies. However, neuromodulators may help reduce visceral or gut hypersensitivity and improve psychological comorbidities if these are present, the authors wrote.

Conditions treated with dietary modifications should be overseen by dietitians, and diaphragmatic breathing and neuromodulators can be used to treat a condition called abdominophrenic dyssynergia, the guidance says.

"We tried to make it clinically useful," Dr. Moshiree said of the practice update, which was not the result of systematic reviews or meta-analyses of multicenter randomized controlled trials. The update contains no ratings on its recommendations and does not grade the evidence used. Rather, the three coauthors looked to results from published randomized trials and observational studies, along with their own expert opinion.

For example, the guidance's best practice advice on abdominophrenic dyssynergia came from single-center studies in Italy where bloating improved with use of biofeedback therapy for this condition. Although this was a single-center study, experts have found that biofeedback therapy is helpful for relaxing pelvic-floor muscles which can help bloating and distension symptoms.

A 2021 narrative review by Brian E. Lacy, MD, and David Cangemi, MD, of the Mayo Clinic in Jacksonville, Fla., helped inform the framework for this clinical practice update.

Dr. Moshiree disclosed financial relationships with Salix, AbbVie, Medtronic, and Takeda. Authors Douglas Drossman, MD, and Aasma Shaukat, MD, also disclosed industry support. ■

Continued from page 19

these must be addressed based on the nature and underlying cause of the complication.

Other long-term complications include chronic high ostomy output, parastomal hernia, and stomal prolapse.

Clinicians should be aware of the psychological impact on patients. They may fear having a leakage or emitting an odor. "Difficulty with self-care should be addressed through preoperative and postoperative education. Preoperative education and stoma site marking has been shown to improve quality of life and decrease peristomal skin and pouching complications," the authors wrote. Health care providers should discuss and manage expectations for life with an ostomy, including managing ostomy output, maintaining pouching appliances, and the regular passage of mucus from the native rectum.

"High-quality ostomy care begins at the preoperative visit with wound ostomy and continence consultation. Stoma education and counseling are essential to prevent complications and manage patient expectations for living with a stoma. The early diagnosis and management of both early and late ostomy complications require ongoing communication between patients and care teams. Multidisciplinary coordination is imperative to prevent hospital readmissions and to improve the quality of life for our patients living with ostomies," the authors wrote.

The investigators disclosed relationships with Johnson & Johnson, AbbVie, BMS, and others. ■

New AGA CPU highlights G-POEM for gastroparesis

BY WILL PASS
MDedge News

FROM GASTROENTEROLOGY

The American Gastroenterological Association has published a Clinical Practice Update (CPU) on gastric peroral endoscopic myotomy (G-POEM) for gastroparesis.

Authored by Mouen A. Khashab, MD, director of therapeutic endoscopy at Johns Hopkins Medicine, Baltimore; Andrew Y. Wang, MD, AGAF, chief of interventional endoscopy, University of Virginia, Charlottesville; and, Qiang Cai, MD, PhD, chief of gastroenterology, Ochsner LSU Health Shreveport (La.), the update covers patient selection, procedural considerations, and adverse events.

"G-POEM is being performed worldwide to treat patients with refractory gastroparesis," the investigators wrote in Gastroenterology (2023 Apr 20. doi: 10.1053/j.gastro.2023.02.027). "G-POEM is an overall safe procedure with high technical success rates, particularly when performed by an endoscopist experienced in third-space endoscopy. Even if the durable clinical success of G-POEM is in the 50-60% range, this represents a huge clinical benefit to patients with refractory gastroparesis, which is a disease associated with substantial morbidity, poor quality of life, and a paucity of safe and effective treatments."

The authors listed treatment alternatives, noting how associated clinical data have fallen short.


Dr. Khashab

"Although endoscopic pyloric balloon dilation, intrapyloric botulinum toxin injection, gastric electrical stimulation, and transpyloric stenting have been used in patients [with gastroparesis] who have not responded to medical therapy, published studies concerning these therapies have been inconsistent, shown no benefit, or lacked methodologic rigor," they wrote.

"G-POEM is an overall safe procedure with high technical success rates, particularly when performed by an endoscopist experienced in third-space endoscopy... However, serious AEs can occur and have been reported."

Patient selection

G-POEM should be considered in patients with medically refractory gastroparesis due to diabetes, prior surgery, or idiopathic causes. Candidates should undergo endoscopy to confirm no mechanical obstruction, as well as a solid-phase gastric emptying scan to confirm delayed emptying, with ideal candidates showing at least 20% retention at 4 hours, as this threshold has been linked with better clinical outcomes.

G-POEM is most beneficial when moderate to severe symptoms are present, the investigators wrote, particularly vomiting and nausea. The Gastroparesis Cardinal Symptom Index (GCSI) can be used to determine severity, with a score greater than 2 indicating moderate to severe presentation.

Procedural considerations

The CPU offers detailed procedural considerations, including preparation and equipment, technical guidance, and postprocedural strategy.

"G-POEM should only be performed by interventional endoscopists with expertise or training in third-space endoscopy," Dr. Khashab and colleagues wrote. "Although experience in endoscopic submucosal dissection (ESD) is not mandatory before performing G-POEM, it likely shortens the learning curve."

After reviewing emerging data, the authors suggested the time has come to consider G-POEM as a routine, evidence-based procedure that deserves appropriate reimbursement by financial stakeholders.

Equipment minimums are also described, including "a high-definition gastroscope, with a waterjet, affixed with a clear distal cap" and "a modern electrosurgical generator capable of modulating power based on tissue resistance and circuit impedance."

While G-POEM is typically performed via a greater-curvature approach, similar outcomes have been documented for a lesser-curvature approach, Dr. Khashab and colleagues wrote. This alternative technique may increase difficulty of pyloromyotomy, they added.

Postprocedural care may involve an overnight stay, according to the update, with an upper GI study on the subsequent day to ensure no contrast leakage, though this is not mandatory.

Adverse events

"G-POEM is generally safe when performed by trained and/or experienced endoscopists, and adverse events (AEs) are uncommon. However, serious AEs can occur and have been reported," investigators wrote.

Reported AEs included capnoperitoneum, inadvertent mucosotomy, thermal-mucosal injury, abdominal pain, bleeding, gastric ulceration, and dumping syndrome.

Insurance companies called to action

After reviewing emerging data, the authors suggested the time has come to consider G-POEM as a routine, evidence-based procedure that deserves appropriate reimbursement by financial stakeholders. "Many insurers still consider G-POEM investigational and refuse to cover this procedure for patients with medically refractory gastroparesis. As the safety and clinical effectiveness of G-POEM is now well supported, insurance companies and payors should cover G-POEM for patients with significant gastroparesis," they wrote.

The investigators disclosed relationships with Boston Scientific, Medtronic, and Olympus, among others. ■

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