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CHARDAY PENN/GETTY IMAGES

The delineation of responsibility for care among gastroenterologists, primary care providers, and surgeons often isn't clear, researchers said.

How does fragmented care affect IBD outcomes?

BY WILL PASS
MDedge News

Poor continuity of care may lead to worse outcomes among patients with active inflammatory bowel disease (IBD), according to data from more than 20,000 veterans.

Even in the Veterans Health Administration health care system, which "may provide the ideal environment for care coordination," patients with active IBD had "substantial variation" in dispersion of care, leading to more frequent surgical interventions, corticosteroid use, and hospitalizations, reported lead author Shirley Cohen-Mekelburg, MD, MS, of the University of Michigan, Ann Arbor, and colleagues.

"Health care in the United States is marked by substantial fragmentation, with patients pursuing and receiving care from multiple clinicians, often at different institutions," the investigators wrote in JAMA Network Open (2020 Sep 1. doi: 10.1001/jamanetworkopen.2020.15899).

See **Fragmented** · *page 28*

First AI device for colonoscopy: Extra set of expert 'eyes'

BY PAM HARRISON

The first artificial intelligence (AI) endoscopy module developed specifically to help detect adenomas during routine colonoscopy is making its debut following approval by the Food and Drug Administration.

The GI Genius module is the first and only commercially available computer-aided detection system that uses AI to identify colorectal polyps during routine colonoscopy.

The technology is compatible with most standard video endoscopy systems and has been "trained" to identify colonic lesions that are possibly cancerous, according to Medtronic, the distributor of the device.

"I think that anything we can do within a reasonable cost that enhances quality and patient outcomes during colonoscopy warrants very close consideration," David Johnson, MD, professor of medicine and chief of gastroenterology, Eastern Virginia Medical School, Norfolk, said in an interview.

He was not involved with the development of the GI Genius system but has worked with a similar AI device that is used in conjunction with colonoscopy.

"The whole development of the technology for AI

See **AI** · *page 24*

INSIDE

AGA Clinical Practice Update

Bleeding gastric varices managed

BY AMY KARON
MDedge News

When classifying gastric varices during endoscopy, experts suggest not only describing their location but also their size and whether any high-risk stigmata, such as discolorations and platelet plugs, are present.

In a clinical practice update from the American Gastroenterological Association, Zachary Henry, MD, of the University of Virginia, Charlottesville, and associates also proposed an alternative nomenclature for locating gastric varices (GV). "In practice, most gastroenterologists use

See **Varices** · *page 10*

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LETTER FROM THE EDITOR

What's lost and what's saved

DDW is now history. While rejoicing that DDW happened (as opposed to when it couldn't in 2020), the virtual format precluded all those hallway conversations, meetings with mentors, and small group (after hour) discussions. This year, AGA saved

Dr. Allen

The pandemic forced rapid adoption of virtual care and alternative care delivery models.

substantial monies in travel costs. Of note, at Michigan Medicine, we track the miles patients did not have to travel because of our conversion to virtual care (currently about 30% of all ambulatory visits). To date, our "virtual first" protocol has saved over 24 million patient travel–miles since February 2020 (average of 62 miles per patient visit).

The pandemic forced rapid adoption of virtual care and alternative care delivery models. As patients adapted to telehealth, businesses saw opportunities. Health systems have begun to downsize their brick-and-mortar footprints for both clinical and office space. Hospital at Home models are developing as viable alternatives to inpatient care using a hybrid system of on-site nurses and remote physician supervision. Digital health start-ups are developing rapidly, and equity funding for digital health companies has reached an all-time high of $26.5 billion in 2020 ("State of Healthcare Report: Investment & Sector Trends To Watch." CB Insights). Multiple companies went public through traditional initial public offerings or special purpose acquisition companies. Sameer Berry, MD, recently collected an inventory of major GI digital health companies counted at least 16 with more appearing each month. These companies focus on management of a single condition (for example irritable bowel syndrome or celiac) or full-service virtual GI care that includes "at-risk" financial contracts.

Dr. Adams

I am delighted to announce that Megan Adams, MD, JD, MSc, has been chosen to be the fourth editor in chief of GI & Hepatology News. She and her team will transition into editorial control during Fall 2021. I have known Megan since meeting her at an AGA young faculty function almost 10 years ago. She is extremely talented and knowledgeable about gastroenterology from a variety of viewpoints. She has recruited a strong and dedicated editorial board. I have enjoyed the last 5 years leading the current board as we have brought breaking news to the GI community. I wish to publicly thank our editorial board and the Frontline staff who monthly publish AGA's official newspaper.

John I. Allen, MD, MBA, AGAF
Editor in Chief

aga community

Top cases from AGA Community

Physicians with difficult patient scenarios regularly bring their questions to the AGA Community (https://community.gastro.org) to seek advice from colleagues about therapy and disease management options, best practices, and diagnoses. The following is a preview of a recent popular clinical discussion.

Dr. Ketwaroo

In the post "Cessation of surveillance colonoscopy," Gyanprakash A. Ketwaroo, MD, asked the following:

Wanted to get your thoughts on how you approach stopping surveillance colonoscopy for older adults. Do you use decision support tools, assessing life-expectancy, prior polyp history, etc.? Or is it more practical to defer to PCP for goals of care discussion prior to surveillance colonoscopy at certain age (e.g., 75 or 80)?

See how AGA members responded and join the discussion: https://community.gastro.org/posts/24089.

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Advertising Offices 7 Century Drive, Suite 302, Parsippany, NJ 07054-4609 973-206-3434

Editorial Offices 2275 Research Blvd, Suite 400, Rockville, MD 20850, 240-221-2400

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Short meal-to-bed time raises reflux risk in pregnancy

BY HEIDI SPLETE
MDedge News

A shorter period between eating and going to sleep increased the risk of gastroesophageal reflux disease (GERD) during pregnancy by approximately 12%, according to data from 400 women.

GERD is a common condition in pregnancy because of changes in gastrointestinal motility caused by hormonal changes, and a short meal-to-bed time (MTBT) also has been associated with increased GERD symptoms, but data on the impact of MTBT on GERD in pregnant women in particular are lacking, wrote Duc T. Quach, MD, of the University of Medicine and Pharmacy in Ho Chi Minh City, Vietnam, and colleagues.

In a cross-sectional study published by the investigators in the Journal of Clinical Gastroenterology (2021 Apr 1. doi: 10.1097/MCG.0000000000001399), the researchers identified 400 pregnant women aged 18 years and older in various stages of pregnancy who were seen at a single hospital in Vietnam. A short MTBT was defined as going to bed 2 hours or less after eating. Primary outcomes were GERD, defined as troublesome heartburn and/or regurgitation at least once a week, and reflux-related insomnia, defined as trouble initiating or maintaining nighttime sleep. Participants also reported the number of days of troublesome reflux symptoms and frequency of reflux-related insomnia over the last 7 days.

A total of 154 participants had a diagnosis of GERD, for an overall prevalence of 38.5%, similar to that seen in studies of GERD and pregnancy, the researchers noted, and of those with GERD, 20 participants (13.0%) reported reflux-related insomnia.


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The overall prevalence of heartburn, regurgitation, nausea with or without vomiting, and epigastric pain were 11.8%, 35.8%, 30.0%, and 5.5%, respectively. A total of 139 women reported reflux symptoms on at least 2 of the past 7 days, and 40 women reported both daytime and nighttime reflux symptoms.

Short meal-to-bed time shows strongest association

A short MTBT was the strongest predictor of GERD in multivariate analysis (odds ratio, 12.73; 95% confidence interval, 2.92-55.45; *P* = .001); previous history of reflux symptoms (OR, 9.05; 95% CI, 5.29-15.50; *P* < .001) and being in the third trimester versus first or second of pregnancy (OR, 1.66, 95% CI, 1.03-2.69; *P* = .039) also remained significant predictors in a multivariate analysis. In addition, nighttime short MTBT (but not daytime short MTBT) was the strongest risk factor for reflux-related insomnia (OR, 4.60), although alcohol consumption

Continued on following page

Stopping the bleeding is only the beginning

Varices *from page 1*

the Sarin classification with the main distinction being cardiofundal versus lesser curvature GV. However, the vascular supply and corresponding therapy for GV and esophageal varices are often different, so a merged classification, such as Sarin's, can be problematic for therapeutic planning purposes," they wrote in Clinical Gastroenterology and Hepatology (2021 Jan 22. doi: 10.1016/j.cgh.2021.01.027), referring to the classification system published by Shiv K. Sarin, MD, DM, AGAF, and colleagues. They suggested that a merged classification, such as Sarin's (Hepatology. 1992;16:1343-9), can be "problematic for therapeutic and planning purposes" because "the vascular supply and corresponding therapy for GV and [esophageal varices] are often different." Instead, they advised that an "alternative nomenclature based on location within the stomach is clearer and facilitates correlation with vascular imaging." Another approach is to add risk factors for bleeding, such as an estimate of variceal size and high-risk stigmata (discolored marks, platelet plugs), to Sarin classification.

Diagnosis and treatment of bleeding GV are complex, and multidisciplinary management by hepatologists, interventional radiologists, and interventional endoscopists is optimal, the experts wrote. Data and clinical guidelines do not support primary prophylaxis to prevent bleeding of GV. The authors offered an algorithm for initial management of suspected portal hypertensive GV bleeding based on both endoscopic and vascular anatomy; it includes assessment of circulatory and respiratory status, vasoactive drug administration, antibiotic prophylaxis, and more.

An early goal is confirming bleeding source and attempting to classify the bleeding site; this can be complicated by presence of intragastric blood that obscures the cardia and fundus and underlying GV. Further steps may include temporizing: "Temporizing measures to halt active bleeding are often not the definitive treatment of choice to prevent rebleeding from GV, whereas definitive measures such as endoscopic cyanoacrylate injection (ECI) or endovascular treatments are often not feasible in the acute, diagnostic setting."

Diagnosis and treatment of bleeding gastric varices are complex, and multidisciplinary management by hepatologists, interventional radiologists, and interventional endoscopists is optimal.

When definitive endoscopic treatment is preferred, ECI of bleeding GV is the therapy of choice because other approaches may be complicated by location and bleeding risk of GV, although band ligation may be appropriate in lesser-curve GV. Specific ECI techniques have not been compared directly in studies, according to the update authors; however, "the specific cyanoacrylate agent should favor the fastest polymerization time to avoid embolization and inducing GV bleeding." This has meant 4-carbon (butyl) preparations are preferred to 8-carbon (octyl) preparations, they noted.

After treatment, endoscopy is performed every 2-4 weeks so that the ECI can be repeated as needed until obliteration is complete. The experts suggested that, after eradication of GV, an endoscopic reevaluation within 3-6 months should be scheduled, then annually thereafter. Any de novo or recurrent GV during the long-term follow-up may require additional imaging and multidisciplinary exploration to determine potential mechanisms and need for alternative treatments, the authors advised.

According to the practice update, transjugular intrahepatic portosystemic shunt (TIPS) can be used when the GV is receiving significant inflow from the coronary vein or the patient has significant complications from portal hypertension. When TIPS is used, the experts suggest also performing endovascular sclerosis or direct embolization of GV, if possible. For patients with a gastrorenal shunt, balloon-occluded retrograde transvenous obliteration (BRTO) of bleeding GV is considered optimal if local expertise is available and the patient lacks severe complications from portal hypertension. Endoscopy should be performed within 48 hours after BRTO to confirm obliteration of the vascular flow. If residual flow is detected, "cyanoacrylate injection should be performed," the experts wrote. To confirm that GV are obliterated and check for any vascular complications, they suggest performing CT or MRI in 4-6 weeks after BRTO and then as clinically indicated. In addition, surveillance endoscopy is important to identify and treat any esophageal varices that could have been worsened by increased portal pressures.

No funding sources were reported. The experts reported having no conflicts of interest.

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Continued from previous page

and a history of reflux-related symptoms also remained significant in multivariate analysis.

"Interestingly, the number of days during which reflux symptoms were experienced during the last 7 days sequentially increased across subgroups of participants with no short MTBT, either daytime or nighttime short MTBT, and with both daytime and nighttime MTBT," the researchers wrote. At 4-7 days, none of the patients with no short MTBT reported reflux symptoms, compared with 7.5% of those with either daytime or nighttime MTBT and 20.9% of those with both daytime and nighttime MTBT.

Dr. Gellad

The study findings were limited by several factors, including the inability to accurately record participants' diets and the potential for overestimating the odds ratio of risk factors in patients with reflux-related insomnia because of the small numbers. However, the results support findings from previous studies and suggest that dietary modifications could provide a nonpharmacological treatment target for managing GERD in pregnant women, they concluded.

Behavioral intervention may benefit pregnant women

The study is important because heartburn and regurgitation are common challenges during pregnancy, Ziad Gellad, MD, MPH, AGAF, of Duke University, Durham, N.C., said in an interview. "Understanding risk factors for these conditions can be helpful in designing behavioral and pharmaceutical therapeutic interventions."

The link between short MTBT and increased risk for GERD is well-known, said Dr. Gellad. "Lengthening the time to laying supine after a meal is a common recommendation given to patients with GERD and is included in published GERD guidelines." Although pregnant woman may have been excluded from trials on which the guidelines and recommendations are based, "it is reasonable to expect that findings would translate to this population that is generally higher risk for reflux," he noted.

Dr. Gellad was interested to see the dose response between MTBT and reflux, with those patients having both daytime and nighttime short MTBT experiencing reflux more often than those with short MTBT in only one of those time periods (4-7 days vs. 1-3 days).

The key message for clinicians is that, for all individuals, pregnant or not, "avoiding late night meals and short meal-to-bed time is an appropriate behavioral intervention to recommend for patients with troublesome heartburn or regurgitation," Dr. Gellad emphasized. However, more research is needed in some areas, "implementation studies would be helpful to understand how best to educate patients on behavioral modifications known to decrease reflux symptoms."

The study received no outside funding. The researchers had no financial conflicts to disclose. Dr. Gellad had no relevant financial disclosures, but serves as a member of the GI & Hepatology News board of editors.

ginews@gastro.org

IL-6 trans-signaling targeted by olamkicept in IBD

BY AMY KARON
MDedge News

The selective interleukin-6 (IL-6) trans-signaling inhibitor olamkicept was well tolerated and induced clinical remissions in 3 of 16 adults with moderately to severely active inflammatory bowel disease (IBD), and remission was associated with clear alterations in levels of phospho-STAT3 (pSTAT3) in the intestinal mucosa, researchers reported.

In a 12-week, open-label, prospective phase 2a trial, patients received up to seven infusions of 600 mg olamkicept (sgp130Fc) every 2 weeks. Clinical remissions occurred in two of nine patients with ulcerative colitis and one of seven patients with Crohn's disease. The overall rate of clinical response was 44%, which included five patients with ulcerative colitis and two patients with Crohn's disease. Transcriptome isolation and high-throughput RNA sequencing of mucosal tissue specimens showed that clinical remitters had a decrease from baseline to week 14 in the expression of tumor necrosis factor, IL-1A, REG1A, IL-8, IL-1B, and LILRA, a known composite molecular surrogate for mucosal inflammation (Gut. 2017 Sep;66[12]:2087-97). In addition, exposing whole-blood samples to a recombinant IL-6/IL-6R fusion protein mimicked physiologic IL-6 activity and demonstrated that pSTAT3 levels dropped within 4 hours of the first olamkicept infusion and throughout treatment. "Our overall finding of decreased pSTAT3-positive cells in remission patients indicates that STAT3 is crucially involved in the mechanism of action of olamkicept," wrote Stefan Schreiber, MD, of University Medical Center Schleswig-Holstein, Campus Kiel (Germany) together with his associates. The study is published in Gastroenterology (2021 Apr. doi: 10.1053/j.gastro.2021.02.062).

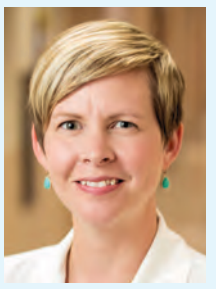
Blocking the IL-6/ILR receptor can induce IBD remissions but causes "profound immunosuppression," the investigators noted. Building on prior findings that chronic proinflammatory IL-6 activity is primarily mediated by trans-signaling of a complex of IL-6 and soluble IL6R that engages the gp130 receptor (PLoS Biol. 2017 Jan. doi: 10.1371/journal.pbio.20000800), the researchers developed a "decoy protein," sgp130Fc (now known as olamkicept), which "exclusively blocks" IL-6 proinflammatory trans-signaling. This decoy protein showed promise in preclinical studies, with no evidence of immunosuppression, they wrote. To further evaluate olamkicept, they recruited adults with moderately to severely active ulcerative colitis or Crohn's disease from two centers in Germany. The primary clinical assessment was remission, defined as a Mayo score under 2, with a bleeding score of 0 and an endoscopy score of less than 1 for patients with ulcerative colitis, and a Crohn's Disease Activity Index of less than 150 for patients with Crohn's disease.

Of the 16 patients, 10 completed the trial. At week 14, endoscopic responses were observed in six patients, all of whom also had a clinical response, and all three patients with clinical remissions also had endoscopic remissions. "The drug was well tolerated in all 16 treated individuals, similar to the results of the [two prior] phase 1 trials," the researchers wrote. Although significant immunosuppression and intestinal perforations were not seen, 13 patients developed adverse events. There were five serious adverse events, two of which were cardiac in nature. A larger placebo-controlled trial is underway to further evaluate safety.

University Hospital Schleswig-Holstein sponsored the study. Ferring AG provided funding and donated the olamkicept. Analyses were funded by EU H2020 SYSCID and EU H2020 Innovative Medicines Initiative 2 Joint Undertaking. Dr. Schreiber reported having coinvented IP and having ties to Pfizer, Bristol Myers Squibb, and Roche. Four coinvestigators disclosed ties to Ferring, AbbVie, Chugai, Roche, Regeneron, Pfizer, Sanofi, Conaris, and Genentech Roche. The other researchers reported having no conflicts of interest.

ginews@gastro.org

Proinflammatory cytokine inhibition has revolutionized the care of patients with moderate to severe inflammatory bowel disease (IBD). However, some patients don't respond, never gain remission, or lose response. Therefore, the search continues for more effective therapies. The study by Schreiber and colleagues highlights the importance of continued innovation surrounding inflammatory pathways.


Dr. Horst

In the early 2000s, clinical trials were undertaken with an IL-6R monoclonal antibody in Crohn's disease. These trials showed efficacy, but patients had significant serious adverse events secondary to excessive immunosuppression including abscesses, perforation, and death. Encouragingly, several of the patients with IBD in this small phase 2a, 12-week, open-label trial showed a clinical response.

The authors did extensive evaluation of the tissue and molecular effects and discovered possible differential target engagement with interleukin-6 transcriptional inhibition which is encouraging. Notably, however, there were a high number of reported adverse events. Per the authors, these were nonspecific and not indicative of severe immunosuppression. Importantly, there were no intestinal perforations.

Intense optimism for new mechanisms will remain tempered as we have seen other therapies hold promise but fail in larger randomized trials. However, it is encouraging to see how continued work on proinflammatory pathways into more targeted inhibitory approaches can lead to potential new therapies in IBD.

Sara Horst, MD, MPH, FACG, is an associate professor in the division of gastroenterology, hepatology, and nutrition at Vanderbilt University Medical Center, Nashville, Tenn. She reports having been a consultant for Gilead, Takeda, and Janssen and receiving unrestricted grant funding from UCB.

DDSEP 9
Digestive Diseases Self-Education Program

Quick Quiz

Q1. A 37-year-old woman with no significant past medical history presents for further evaluation of chronic constipation with straining. She denies significant abdominal pain, gastrointestinal bleeding, or weight loss. There is no family history of colorectal neoplasia or inflammatory bowel disease. She has not responded to many laxatives and undergoes anorectal manometry with balloon expulsion testing.

Which of the following results suggests a diagnosis of dyssynergic defecation?

A. Absent rectoanal inhibitory reflex (RAIR).
B. Expulsion of water-filled balloon in 3 minutes.
C. Defecation index of 2.0.
D. Decreased anal sphincter pressure during simulated defecation.

Q2. A 66-year-old woman with a history of atrophic gastritis presents for evaluation of intermittent diarrhea. She denies abdominal pain, weight loss, GI bleeding, or a family history of colorectal neoplasia or IBD. Physical exam is normal. Labs including thyroid function testing, celiac screen, and C-reactive protein are normal. A colonoscopy with random colon biopsies is normal.

What is the best next step in the management of this patient?

A. Measure chromogranin A.
B. Start eluxadoline.
C. Video capsule endoscopy.
D. Glucose hydrogen breath test.

The answers are on page 22.

Low-fat diet upped quality of life in ulcerative colitis

BY AMY KARON
MDedge News

For patients with mild or remitted ulcerative colitis, a catered, low-fat, high-fiber diet improved quality of life and stool markers of dysbiosis and inflammation, according to the findings of a small crossover trial.

Patients with inflammatory bowel disease often ask what they should eat, but few studies have addressed that question, Julia Fritsch, of the University of Miami and her associates wrote in Clinical Gastroenterology and Hepatology (2021 May. doi: 10.1016/j.cgh.2020.05.026).

Building on previous findings that a high-fat diet may contribute to inflammatory bowel disease (Am J Gastroenterol. 2011 Apr;106[4]:563-73), they randomly assigned 38 adults whose ulcerative colitis was in remission or mild (with a flare within the past 18 months) to receive either a low-fat diet (with 10% of daily calories from fat and high amounts of fruit and vegetables) or an "improved American standard diet" (with 35%-40% of daily calories from fat but more fruit and vegetables than Americans typically eat). Each diet was catered, delivered to patients' homes, and lasted 4 weeks, followed by a 2-week washout period, after which each participant switched to the other diet.

Of the 38 patients, 17 completed the study. Food recall surveys over 24 hours showed that both diets were healthier than what participants ate at baseline, and daily web-based food diaries (such as www.nutrihand.com/Static/index.html) confirmed that more than 94% of patients adhered to the amount of fat in each diet.

Even though participants in both groups ate only about half of the provided fruits and vegetables, the primary outcome of quality of life based on the short inflammatory bowel disease questionnaire (SIBDQ) significantly improved from a median of 4.98 (interquartile range, 4.1-6.0) at baseline to 5.77 (IQR, 5-6.4) with the low-fat diet and 5.55 (IQR, 4.75-6.25) with the improved American standard diet. Both diets also produced significant improvements in quality of life as measured by the 36-Item Short Form Survey and in disease activity as measured by the partial Mayo score.

Notably, however, only the low-fat diet significantly reduced serum amyloid A, which is a marker of mucosal inflammation, and intestinal dysbiosis, which was quantified by 16S RNA ribosomal sequencing. "Of note, there were several variables that were associated with changes in the microbiota composition," the researchers wrote. These included the SIBDQ, C-reactive protein, interleukin-6, interleukin-1 beta, and 32 dietary components such as protein, potassium, iron, and zinc.

"These data suggest that even patients in remission [from ulcerative colitis] could benefit from a healthier diet," the investigators concluded. "Just as importantly, neither diet exacerbated symptoms, which is notable given the higher fiber in both catered diets." They called catering "a feasible way to perform a diet intervention study with high adherence," noting that "catering a diet for a patient with IBD for a year costs between $19,000 and $21,000 per patient. The cost of a patient on a biologic such as ustekinumab is approximately $130,752 to $261,504."

The study was supported by the Crohn's and Colitis Foundation Broad Medical Research Program, Micky and Madeleine Arison Family Foundation Crohn's and Colitis Discovery Laboratory, and the Martin Kalser Chair. The senior author disclosed ties to Boehringer Ingelheim, Gilead, AbbVie, Seres Therapeutics, Shire, Landos, Pfizer, and several other pharmaceutical companies. The other researchers reported having no conflicts of interest.

ginews@gastro.org

Diet plays an important role in Crohn's disease and ulcerative colitis. Most patients with these diseases look to incorporate dietary modification as part of the treatment plan to achieve and maintain remission. With the development of tools that allow us to sequence the gut microbiome at high resolution, the role of dietary therapy for these diseases is being studied with increasing scientific rigor.


Dr. Ananthakrishnan

In a crossover study of 17 patients with ulcerative colitis in remission or with only mild disease, Fritsch and colleagues demonstrated that adherence to a low-fat, high-fiber diet was associated with an improvement in the health-related quality of life, a decrease in C-reactive protein, and beneficial changes in the gut bacteria including reduced abundance of *Actinobacteria* and an increase in organisms with anti-inflammatory potential such as *Faecalibacterium prausnitzii*. In conjunction with prior experimental studies that suggested an increase in risk of colitis with high fat intake, this study provides some evidence for recommending a lower fat intake in patients with established inflammatory bowel disease (IBD). Furthermore, an increase in fruits, vegetables, and fiber intake even in those with a standard American diet was associated with a modest beneficial effect, challenging the longstanding unsupported dogma of broadly limiting all fiber intake in those with established IBD.

The much-needed progress in the scientific study of diet in IBD will provide us with the important answers that our patients are looking for.

Ashwin Ananthakrishnan, MD, MPH, is an associate professor of medicine at Massachusetts General Hospital and Harvard Medical School, both in Boston. He has no conflicts relevant to this commentary to declare.


Lisovskaya/Getty Images

Consider risk for Barrett's after bariatric surgery

BY HEIDI SPLETE
MDedge News

Barrett's esophagus occurred in nearly 12% of patients who underwent esophagogastroduodenoscopy after sleeve gastrectomy, but it was not associated with postoperative gastroesophageal reflux disease (GERD), based on data from 10 studies that totaled 680 adult patients.

Sleeve gastrectomy has become more popular in recent years as an effective strategy for patients with severe obesity, wrote Bashar J. Qumseya, MD, of the University of Florida, Gainesville, and colleagues. However, GERD is a common concern for patients undergoing sleeve gastrectomy and is the major risk factor for Barrett's esophagus. However, the prevalence of Barrett's esophagus in the sleeve gastrectomy population has not been examined.

AGA Resource
Help your patients better understand the risks, testing, and treatment options for Barrett's esophagus by sharing education from the AGA GI Patient Center: www.gastro.org/BE.

In a meta-analysis published in Gastrointestinal Endoscopy (2021 Feb;93[2]:343-52.e2), the researchers reviewed 10 studies that totaled 680 patients who underwent esophagogastroduodenoscopy 6 months to 10 years after a sleeve gastrectomy procedure. The primary outcome was Barrett's esophagus prevalence in sleeve gastrectomy patients, with the prevalence of erosive esophagitis and GERD at follow-up as secondary outcomes.

Overall, 54 patients developed Barrett's esophagus, for a pooled prevalence of 11.6%, and all cases were nondysplastic and de novo. There was no significant association between Barrett's esophagus and the presence of postoperative GERD, the researchers said (odds ratio, 1.74; $P = .37$).

However, the rate of erosive esophagitis increased by 86% in five studies with long-term follow-up and by 35% in two studies with short-term follow-up, which suggests an increased risk of 13% each year after sleeve gastrectomy, the researchers noted.

Besides the risk of Barrett's esophagus after sleeve gastrectomy, "the risk of [erosive esophagitis] is also of significant interest and shares the same pathophysiology with [Barrett's esophagus] and GERD," they emphasized.

The study findings were limited by several factors including the small sample size and the focus on Barrett's esophagus rather than erosive esophagitis or GERD as the primary outcome, the researchers noted. However, the results indicate that sleeve gastrectomy patients are at increased risk for Barrett's esophagus, and larger studies are needed to better understand the pathophysiology. Furthermore, although there is some debate regarding the risk of GERD and erosive esophagitis after sleeve gastrectomy, the authors wrote that the data from their study showed a "consistent and substantial trend" toward more erosive esophagitis after sleeve gastrectomy.

"Gastroenterologists, primary care providers, and bariatric surgeons should be aware" of the data and should discuss the risks of sleeve gastrectomy with patients before the procedure, including the risks and benefits of postprocedure screening for Barrett's esophagus, they concluded.


CHRISPOLE/THINKSTOCK

Consider surveillance for Barrett's

The study is important because of the increased rates of GERD and potentially Barrett's esophagus that have been noted after sleeve gastrectomy, Gyanprakash A. Ketwaroo, MD, MSc, of Baylor College of Medicine, Houston, said in an interview.

"Many of these studies have been small, and the findings of meta-analyses have been limited by high heterogeneity," he noted. "With the rise in popularity of sleeve gastrectomy, it is important to accurately assess potential long-term complications."

Dr. Ketwaroo said he was not surprised by the study findings given several reports of increased GERD after sleeve gastrectomy. "Given the accepted pathophysiology of Barrett's esophagus, I anticipated increased risk of Barrett's esophagus after sleeve gastrectomy as well.

"Clinicians should consider surveillance for Barrett's esophagus after sleeve gastrectomy, and possible early proton pump inhibitor use for both GERD/erosive esophagitis and Barrett's esophagus chemoprophylaxis. Patients with longer-segment or dysplastic Barrett's esophagus prior to sleeve gastrectomy may have to be monitored more closely after surgery," he said.

Dr. Ketwaroo noted that the study was limited by the small sample size, "with only approximately 50 patients with Barrett's esophagus after surgery among 680 overall." He emphasized that "we will need a much larger prospective study to confirm this finding. Additionally, I would want to explore if sleeve gastrectomy increases rate of progression of dysplasia in those who develop Barrett's esophagus."

The study received no outside funding. Lead author Dr. Qumseya had no financial conflicts to disclose. Dr. Ketwaroo serves on the GI & Hepatology News editorial advisory board.

ginews@gastro.org

Bariatric surgery may cut cancer risk in patients with obesity who have liver disease

BY MARLENE BUSKO

In a large cohort of insured working adults with severe obesity and nonalcoholic fatty liver disease (NAFLD), the rate of incident cancer was lower during a 10-month median follow-up period among those who underwent bariatric surgery. The rate was especially lower with regard to obesity-related cancers. The risk reduction was greater among patients with cirrhosis.

Among almost 100,000 patients with severe obesity (body mass index >40 kg/m^2) and NAFLD, those who underwent bariatric surgery had an 18% and 35% lower risk of developing any cancer or obesity-related cancer, respectively.

Bariatric surgery was associated with a significantly lower risk of being diagnosed with colorectal, pancreatic, endometrial, and thyroid cancer, as well as hepatocellular carcinoma and multiple myeloma (all obesity-related cancers). The findings are from an observational study by Vinod K. Rustgi, MD, MBA, AGAF, and colleagues, which was published online March 17, 2021, in Gastroenterology (doi: 10.1053/j.gastro.2021.03.021).

It was not surprising that bariatric surgery is effective in reducing the malignancy rate among patients with cirrhosis, the researchers wrote, because the surgery results in long-term weight loss, resolution of nonalcoholic steatohepatitis (NASH), and regression of fibrosis.

"Cirrhosis can happen from fatty liver disease or NASH," Dr. Rustgi, a hepatologist at Robert Wood Johnson Medical School, New Brunswick, N.J., explained to this news organization. "It's becoming the fastest growing indication for liver transplant, but also the reason for increased rates of hepatocellular carcinoma."

Current treatment for patients with obesity and fatty liver disease begins with lifestyle changes to lose weight, he continued. "As people lose 10% of their weight, they actually start to see regression of fibrosis in the liver that is correlated with [lower rates of] malignancy outcomes and other deleterious outcomes." But long-lasting weight loss is extremely difficult to achieve.

Future studies "may identify new targets and treatments, such as antidiabetic-, satiety-, or GLP-1-based medications, for chemoprevention in NAFLD/NASH," the investigators suggested.

Although "bariatric surgery is a more aggressive approach than lifestyle modifications, surgery may provide additional benefits, such as improved quality of life and decreased long-term health care costs," he and his coauthors wrote.

Rising rates of fatty liver disease, obesity

An estimated 30% of the population of the United States has NAFLD, the most common chronic liver disease, the researchers noted in their article. The prevalence of NAFLD increased 2.8-fold in the United States between 2003 and 2011, in parallel with increasing obesity.

Cancer is the second greatest cause of mortality among patients with obesity and NAFLD, Dr. Rustgi said, after cardiovascular disease. Cancer mortality is higher than mortality from liver disease.

Obesity-related cancers include adenocarcinoma of the esophagus, cancers of the breast (in postmenopausal women), colon, rectum, endometrium (corpus uterus), gallbladder, gastric cardia, kidney (renal cell), liver, ovary, pancreas, and thyroid, as well as meningioma and multiple myeloma, according to a 2016 report from the International Agency for Research on Cancer working group (N Engl J Med. 2016; 375:794-8).

Obesity-related cancer accounted for 40% of all cancer in the United States in 2014 – 55% of cancers in women, and 24% of cancers in men, according to a study published in Morbidity and Mortality Weekly Report in 2017 (doi: 10.15585/mmwr.mm6639), as previously reported by this news organization.

Several studies, including one presented at Obesity Week in 2019 and later published (Surg Obes Relat Dis. 2020 Nov;16[11]:1648-54), have shown that bariatric surgery is linked with a lower risk for cancer in general populations.

One meta-analysis reported that NAFLD is an independent risk factor for cholangiocarcinoma and colorectal, breast, gastric, pancreatic, prostate, and esophageal cancers. In another study, NAFLD was associated with a twofold increased risk for hepatocellular carcinoma and uterine, stomach, pancreatic, and colon cancers, Dr. Rustgi and colleagues noted.

Does bariatric surgery curb cancer risk in liver disease?

The researchers examined insurance claims data from the national MarketScan database from Jan. 1, 2007, to Dec. 31, 2017, for patients aged 18-64 years who had health insurance from 350 employers and 100 insurers. They identified 98,090 patients with severe obesity who were newly diagnosed with NAFLD during 2008-2017.

Roughly a third of the cohort (33,435 patients) underwent bariatric surgery. From 2008 to 2017, laparoscopic sleeve gastrectomies increased from 4% of bariatric procedures to 68% of all surgeries. Laparoscopic adjustable gastric band and laparoscopic Roux-en-Y gastric bypass procedures fell from 35% to less than 1% and from 49% to 28%, respectively.

Patients who underwent bariatric surgery were younger (mean age, 44 vs. 46 years), were more likely to be women (74% vs. 62%), and were less likely to have a history of smoking (6% vs. 10%).

During a mean follow-up of 22 months (and a median follow-up of 10 months), there were 911 incident cases of obesity-related cancers. A total of 258 patients who underwent bariatric surgery developed an obesity-related cancer (an incidence of 3.83 per 1,000 person-years), compared with 653 patients who did not have bariatric surgery (an incidence of 5.63 per 1,000 person-years).

The researchers noted that study limitations include the fact that it was restricted to privately insured individuals aged 18-64 years with severe obesity. In addition, "the short median follow-up may underestimate the full effect of bariatric surgery on cancer risk," they wrote.

The authors disclosed no relevant financial relationships.

A version of this article first appeared on Medscape.com.

FDA approves frontline immunotherapy for gastric cancers

BY SHARON WORCESTER

The U.S. Food and Drug Administration has approved the immunotherapy nivolumab (Opdivo, Bristol-Myers Squibb) in conjunction with certain chemotherapies for the frontline treatment of advanced or metastatic gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma.

This is the first immunotherapy approved for the frontline treatment of gastric cancers, the agency says in a press release.

The approval comes after nivolumab received Priority Review and Orphan Drug designations for this indication.

"Today's approval is the first treatment in more than a decade to show a survival benefit for patients with advanced or metastatic gastric cancer who are being treated for the first time," Richard Pazdur, MD, director of the FDA's Oncology Center of Excellence and acting director of the Office of Oncologic Diseases in the FDA's Center for Drug Evaluation and Research, stated in an FDA press release.

Efficacy in the gastric cancer setting was demonstrated in the randomized, phase 3, open-label CheckMate 649 study of 1,518 untreated patients. Median survival was 13.8 months among those treated with nivolumab, compared with 11.6 months with chemotherapy alone (hazard ratio, 0.80; P = .0002).

Common side effects experienced by patients in the nivolumab group included peripheral neuropathy, nausea, fatigue, diarrhea, vomiting, decreased appetite, abdominal pain, constipation, and musculoskeletal pain.

A version of this article first appeared on Medscape.com.

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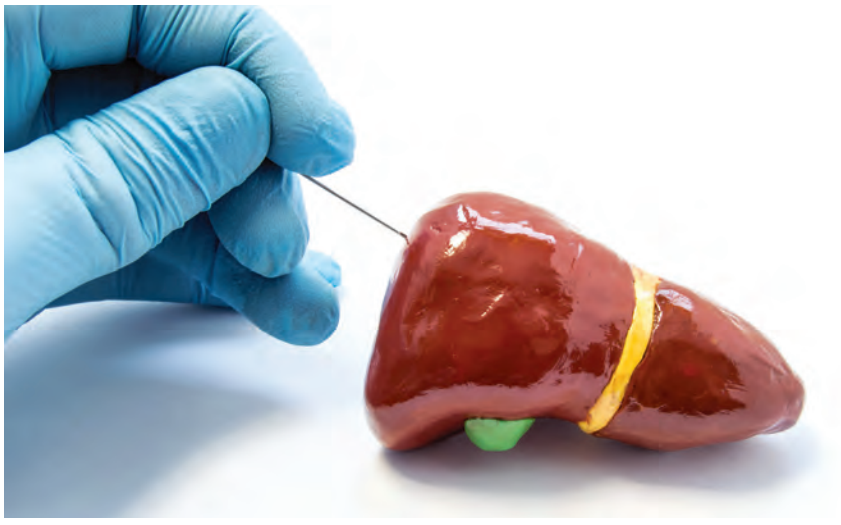
GI & HEPATOLOGY NEWS
THE OFFICIAL NEWSPAPER OF THE AGA INSTITUTE

Look beyond liver biopsy for NAFLD diagnosis

BY HEIDI SPLETE
MDedge News

Nonalcoholic fatty liver disease (NAFLD) was present in approximately two-thirds of patients who did not undergo a liver biopsy. These patients were more likely to be non-White and older, as well as have normal ALT levels, which shows potential gaps in knowledge about this population.

Data from studies of patients diagnosed with NAFLD that require biopsy among their inclusion criteria may be subject to selection and detection bias, wrote A. Sidney Barritt, MD, of the University of North Carolina at Chapel Hill, and colleagues. The researchers sought to compare characteristics of patients with NAFLD who were diagnosed using clinical criteria and those diagnosed via liver biopsy.



SHIDLOVSKI/GETTY IMAGES

In a study published in Hepatology Communications (2021 Feb 21. doi: 10.1002/hep4.1689), the researchers reviewed data from TARGET-NASH, a longitudinal, observational cohort study designed to follow patients with NAFLD in clinical practice to provide data on the effectiveness of treatments.

"TARGET-NASH represents a large cohort of NAFLD patients from multiple sites and can provide us with real-world information on progression of disease in patients with NAFLD and particular risk factors that may be clinically relevant," Zachary Henry, MD, MS, of the division of gastroenterology & hepatology at the University of Virginia Health System in Charlottesville, said in an interview. "This is one of the first studies from this database, and as time goes on, we will see more large-population data like this to answer specific questions for NAFLD patient."

Surprising findings

The researchers included 3,474 patients aged 18 years and older who were enrolled in the TARGET-NASH study between Aug. 1, 2016, and March 4, 2019. The study participants were classified according to severity of liver disease: NAFLD (30%), nonalcoholic steatohepatitis (NASH, 37%), and NAFLD cirrhosis (33%).

A total of 766 patients were diagnosed with NASH based on clinical criteria without biopsy, and all met the criteria for abnormal ALT and steatosis based on imaging. In addition, these patients had at least one secondary diagnostic criteria: body mass index greater than 30 kg/m^2 (74%), type 2 diabetes (42%), and dyslipidemia (54%). Significant independent predictors of liver biopsy included younger age, White race, female gender, diabetes, and elevated levels of ALT.

Elevated ALT increased the odds of liver biopsy by 14% per 10-point rise, according to the study. A machine learning model showed that non-White patients with ALT less than 69 IU/mL had a 6% chance of liver biopsy. By comparison, White patients had a 21% chance of biopsy with ALT between 29 IU/mL and 69 IU/mL that dropped to 10% if the ALT was less than 29 IU/mL.

However, ALT remains a "suboptimal surrogate" for disease severity, the researchers noted. "How a normal ALT is defined and how a normal ALT range may vary across different laboratories may play a role in its utility as a diagnostic tool as well."

Notably, mental health diagnoses accounted for nearly half (49%) of comorbid conditions, followed by cardiovascular disease (19%), and osteoarthritis (10%). The prevalence of these conditions emphasizes the challenges of managing patients with NAFLD with diet and exercise alone because mental and physical problems may impede progress, the researchers wrote.

The study findings were limited by several factors including the inability to determine health care provider intent, as well as undocumented factors related to patients and providers that might influence a biopsy decision, such as assessment of disease severity, the researchers noted. In addition, they noted that the mostly White study population treated in specialty settings might not generalize to other populations or primary care.

However, the findings are strengthened by the large study population and real-world setting, the researchers emphasized. "These data provide context for the selection bias that may be present in many registries and randomized, controlled trials of therapies for NAFLD, where biopsy is required for inclusion," and show potential knowledge gaps about the patient population less likely to undergo biopsy.

Knowledge gaps and implications

The study is important because of the need to identify patient factors that predict histologic versus clinical diagnosis of NAFLD as the number of patient registries and clinical trials for NAFLD increase, Bubu Banini, MD, of Yale University, New Haven, Conn., said in an interview. "This information helps to elucidate selection and ascertainment bias and place findings from NAFLD registries and clinical trials into context."

Dr. Banini said that some of the findings were to be expected, while others were not.

"Historically, males and non-Whites are less likely to participate in registries and clinical trials, compared to females and Whites. However, I was surprised to find that these discrepancies further paralleled the likelihood of undergoing liver biopsy even among those who chose to participate. In addition, while mental health disorders (such as anxiety and depression) are a fairly prevalent comorbidity in patients with NAFLD, I was surprised to find that NAFLD patients with mental health disorders were more likely to undergo liver biopsy compared to those without these disorders. I would have expected the reverse," he noted.

"These findings highlight the gaps in knowledge regarding the impact of demographic and psychosocial factors on choice and assess to care among patients with NAFLD, and the need for further studies to address these gaps," she emphasized.

"A number of [studies] such as TARGET-NASH are doing away with the requirement for liver biopsy for participation; hence, it is less likely that selection bias related to liver biopsy would be a problem in these [studies] if clinical diagnosis is considered as a surrogate for histological diagnosis," Dr. Banini added.

"On the contrary, many NAFLD clinical trials require liver biopsy for inclusion." As nicely demonstrated in the current study, "this inclusion criterion may introduce selection bias," she said. "Awareness of potential biases would hopefully inform the design and recruitment strategy for registries and clinical trials in order to overcome these issues."

"I think the results of this study may actually point to a larger issue within medicine in general, which is a difference in care provided to minority communities," Dr. Henry said. "Whether this is intentional, related to unconscious bias on the part of providers, or related to a significant mistrust between minority communities and their health care providers is unclear but certainly needs to be addressed."

He noted that the purpose of TARGET-NASH is to enroll all patients with NAFLD regardless of biopsy. "Over time, as we have more data on these patients, we will have a better understanding of both diagnostic and therapeutic decisions in patients with NAFLD."

The study was supported by Target RWE, sponsor of the TARGET-NASH study. TARGET-NASH is a collaboration of academic and community investigators and the pharmaceutical industry. Lead author Dr. Barritt had no financial conflicts to disclose, but many study coauthors disclosed relationships with multiple pharmaceutical companies, including those involved in the TARGET-NASH study. Dr. Banini currently serves on the NASH advisory board for Boehringer Ingelheim. Dr. Henry reported no disclosures, although his institution is one of the enrollment sites for TARGET-NASH.

ginews@gastro.org

AGA Shark Tank 2021: A simple design survives

BY WILL PASS
MDedge News

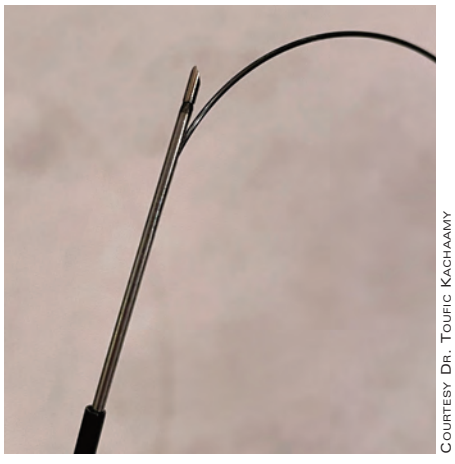
FROM THE 2021 AGA TECH SUMMIT

William of Ockham would have been proud because, at this year's American Gastroenterological Association's Shark Tank pitch competition, one product clearly demonstrated Ockham's razor that sometimes the simplest solution is best – and came away as the winner at the 2021 AGA Tech Summit sponsored by the AGA Center for GI Innovation and Technology (www.gastro.org/cgit).

Out of five innovative products, all aimed at improving outcomes in patients with gastrointestinal disorders, the winner was ... drumroll please ...

A needle.

That's it. A needle. But it's not like most other needles.



Courtesy Dr. Toufic Kachaamy

Dr. Toufic Kachaamy's EUS-guided access needle won the AGA's Shark Tank.

Winner: Toufic Kachaamy, MD, FASGE, AGAF – The endoscopic ultrasound–guided access needle

This EUS-guided access needle, invented by Dr. Kachaamy, enterprise clinical leader at Cancer Treatment Centers of America, Phoenix, is a simple device that overcomes a longstanding challenge presented by endoscopic retrograde cholangiopancreatography (ERCP): biliary access.

Dr. Kachaamy

Many "ERCPs are considered difficult, and sometimes fail, depending on the center and the endoscopist," Dr. Kachaamy said during his virtual presentation. "Most failures are due to failed initial access to the bile duct."

Indeed, one study cited a failure rate in ductal cannulation of 5%-15% even in experienced hands (Gastrointest Endosc. 1999;49[1]:58-61).

Failure can have several consequences, Dr. Kachaamy noted, including increased complications, higher cost, delayed care, longer hospitalization, and greater likelihood of patient transfer.

He went on to explain why biliary access can be so challenging and how this EUS-guided access needle helps address these issues.

"[The] two main limitations [during EUS–guided biliary access] are directing the wire into the narrowed areas and the wire shearing as we are manipulating the wire to get it to where we want it," Dr. Kachaamy said. "[This EUS-guided access needle] is a 19- to 22-gauge, rotatable needle with a smooth, side exit for the wire to allow wire manipulation and direction without shearing."

Dr. Muthusamy

Dr. Kachaamy highlighted the simple design, which will keep the production cost below $300 per unit, and suggested that failed ERCPs are just the first potential indication of many. Future uses may include gallbladder access, peri-GI collection, gastrojejunostomy, and others.

In an interview, Dr. Kachaamy reacted to the win, which follows 2 years of collaborative development with Cancer Treatment Centers of America.

"For people who are innovators, there's nothing that feels more rewarding than their ideas being recognized as adding something to the field and potentially helping people and patients," he said. "So [this is] very, very, very exciting. Very rewarding. Pride would probably be the best way I'd describe it."

He said that this EUS-guided access needle will be commercially available within 1-2 years, pending regulatory approval. Meanwhile, he and colleagues seek a strategic partner.

A shark speaks

V. Raman Muthusamy, MD, AGAF, immediate past chair of the AGA Center for GI Innovation and Technology and director of endoscopy at UCLA Health System, moderated the Shark Tank session, calling it "the highlight" of the AGA Tech Summit.

Dr. Muthusamy and four other "sharks," including a gastroenterologist, venture capitalist, regulatory device reviewer, and physician entrepreneur, scored the pitches using three categories: the quality of the pitch, the level of innovation and impact on the field, and the quality of the business plan and overall feasibility.

"We saw a full spectrum [of innovations]," Dr. Muthusamy said. "I think it was an enjoyable session."

Behind closed doors, the sharks narrowed the field to two top contenders. Ultimately, however, there could be only one winner: Dr. Kachaamy. Their decision aligned with a "Fan Favorite" audience poll.

"A lot of [Dr. Kachaamy's win] had to do with the potential applications and commonality of the problem," Dr. Muthusamy said in an interview. He highlighted how this EUS-guided access needle allows for an immediate response to ERCP failure without the need for a second procedure.

Dr. Muthusamy noted that several product designs previously failed to

Continued on following page

DDSEP 9
Digestive Diseases Self-Education Program

Quick Quiz answers

Q1. Correct answer: B. Expulsion of water-filled balloon in 3 minutes.

Rationale

The balloon expulsion test is highly suggestive of dyssynergia. A balloon expulsion time of greater than 2 minutes is abnormal. An absent RAIR can be seen in Hirschsprung's disease or megarectum. Defecation index equals maximum rectal pressure during attempted defecation divided by minimum anal residual pressure during attempted defecation. A normal defecation index is greater than 1.5. Decreased anal sphincter pressure during simulated defecation is normal and therefore not consistent with dyssynergic defecation.

References

Bharucha AE et al. Gastroenterology. 2013 Jan;144(1):218-38.

Wald A et al. Am J Gastroenterol. 2014 Aug;109(8):1141-57.

Q2. Correct answer: D. Glucose hydrogen breath test.

Rationale

The etiology of small intestinal bacterial overgrowth (SIBO) is complex but may include an issue with altered antibacterial defense mechanisms, such as achlorhydria from atrophic gastritis. SIBO can be diagnosed by a glucose hydrogen breath test, and therefore, it is the best next step in the management of this patient's symptoms given the history of atrophic gastritis. Chromogranin A testing and video capsule endoscopy are used in the diagnostic evaluation of suspected carcinoid syndrome and inflammatory bowel disease, respectively, and may be indicated in the subsequent evaluation of this patient's symptoms. In addition, both of these diagnoses are unlikely to cause intermittent diarrhea. Eluxadoline is an agent that combines a mu-opioid receptor agonist and a delta-opioid receptor antagonist and is indicated for the treatment of irritable bowel syndrome – diarrhea predominant (IBS-D). The diagnosis of IBS requires the presence of abdominal pain and is unlikely in an elderly patient with new onset of symptoms; therefore, this is not the diagnosis in this patient's case.

Reference

Bures Jan et al. World J Gastroenterol. 2010 Jun 28;16(24):2978-90.

Continued from previous page

achieve what this EUS-guided access needle has the potential to do.

For innovators who didn't make the cut this year, or those with products still in development: "We encourage our colleagues and members of the AGA to continue to apply to this program," Dr. Muthusamy said.

Other fish in the sea

Four other innovators entered the AGA Shark Tank this year. Here are snippets of their pitches:

Hans Gregersen, MD, PhD, MPH, AGAF – Fecobionics

"Fecobionics is a simulated electronic stool with the consistency and shape of normal stool," Dr. Gregersen said.

The balloon device, which contains multiple sensors, provides "real-time, quantitative, and mechanistic insights by simulating defecation."

"It ... is inserted into the rectum," Dr. Gregersen said. "It measures multiple pressures; it has gyroscopes that measure orientation; we can compute the bending of the device; and we can calculate the shape of the device."

Fecobionics has "diagnostic potential for patients with fecal incontinence and for subtyping patients with constipation," said Dr. Gregersen, highlighting fewer false positives than current technology, alongside greater efficiency and lower cost.

Dr. Gregersen is a research professor at California Medical Innovations Institute, San Diego.

Mary J. Pattison, RN – Trans-Abdominal Gastric Surgical System (TAGSS)

TAGSS is a trans-abdominal gastric access device that "represents a novel and exciting means to address multiple gastrointestinal conditions that are without a standardized approach," Ms. Pattison said. "Placed as simply as a [percutaneous endoscopic gastrostomy tube], TAGSS offers disruptive technology to address [gastroesophageal reflux disease], fundoplication, achalasia, gastroparesis, gastric tumors, and even obesity in a safe, efficient, and cost-effective manner. TAGSS offers the first true hybrid approach for endoscopic/laparoscopic collaboration."

Ms. Pattison is a nurse clinician and endoscopy assistant at WestGlen GI Consultants, Weston, Mo.

Pankaj Rajvanshi, MD, FAASLD – Healthswim App

"At this time, most patient education is provided by Dr. Google," Dr. Rajvanshi said, "and we want to change that. We have built a platform which allows you, the physician, to create custom, curated, credible content that can be delivered seamlessly to your patients on an ongoing basis." With the Healthswim app, patients subscribe to providers, allowing access to physician-approved content, and receive provider updates via social media feeds.

Dr. Rajvanshi is a gastroenterologist at Swedish Medical Center, Seattle.

Ali S. Karakurum, MD, FACP, FACG – A Device for Removal of Esophageal Food Impactions

"I would like to propose ca device that consists of a clear overtube, a collapsible plastic cylindrical basket secured to the distal end of the overtube ... and a snare wire attached to the distal end of the basket which is controlled by the snare handle externally," Dr. Karakurum said. "The device is ... gradually advanced over the scope for the basket to encompass the food bolus under direct visualization. Once the food bolus is within the basket, the wire loop at the end of the basket is closed via the external handle, securing the food bolus in the basket for safe removal."

Dr. Karakurum is a gastroenterologist at Advanced Gastroenterology & Endoscopy, Port Jefferson, N.Y.

Finalists are not required to provide disclosures; Dr. Muthusamy disclosed relationships with the medical device industry.

ginews@gastro.org

This AI is here to help, not replace

DEVICE *from page 1*

is done by inputting repetitive images into the computer, where it develops what is called the 'neural network,' " he explained.

The computer then draws upon the "education" of this neural network to identify different types of colonic lesions, "and the more inputs that are put into the computer to enhance the neural network, the more capable the program becomes in the identification of variants and lesion size and characteristics," Dr. Johnson added.

During routine colonoscopy, the GI Genius system generates visual markers – essentially, small green squares – and a low-volume sound whenever the software detects a region of interest.

These squares are superimposed on the video generated by the endoscope camera to alert the colonoscopist to regions that may require closer assessment, either visually, by tissue sampling, or by removal of the lesion itself.

"Colonoscopy is a durable screening and surveillance strategy, but it's not perfect [because] it depends on a physician's skill and their ability to pick up polyps in the colon," Jeremy Glissen Brown, MD, of Beth Israel Deaconess Medical Center, Boston, said in an interview. He has also worked with an AI device.

Studies of adenoma detection during "all-comer" colonoscopies show that the rate of missed lesions ranges from a low of 6% to 40%, "so polyps are still missed during colonoscopy, and any technology that can solve parts of that problem is welcome," Dr. Glissen Brown commented.

Clinical trial data that led to approval

The recent FDA approval of the GI Genius device was based on a prospective, randomized trial that was published in Gastroenterology in 2020 (doi: 10.1053/j.gastro.2020.04.062). That trial involved 700 patients who were being screened or followed with colonoscopy every 3 years or longer. Participants underwent either white-light standard colonoscopy with the assistance of the GI Genius technology or standard white-light colonoscopy alone.

Results showed that the combination of standard colonoscopy and the GI Genius module identified laboratory-confirmed adenomas or carcinomas in 54.8% patients, compared with 40.4% of patients who underwent colonoscopy alone – a difference of 14%.

In the Gastroenterology article, the authors wrote that the "14% absolute increase in adenoma detection rate obtained by computer-aided detection (CADe) in our study indicates that failure in polyp recognition is a clinically relevant cause of miss rate. Of note, the efficacy of CADe in reversing such miss rate also indicates that the same operator who missed the lesion in the first place was able to correctly diagnose it when the lesion was presented by the CADe. This underlines that the main cognitive challenge in polyp recognition is the discrimination between the candidate lesion and the surrounding healthy mucosa, whereas its correct characterization as neoplastic tissue that occurs after CADe detection is apparently a much easier task."

The authors also noted that they did "not assess the actual number of false-positive activations by the system, as this would have altered the routine setting of our study," but they refer to a study published in Gut in 2020 (doi: 10.1136/gutjnl-2019-319914) in which false-positive frames were seen in fewer than 1% of frames from the whole colonoscopy.

Physicians can probably learn to use an AI system such as GI Genius in about a week.

Because the new device improves on the ability of colonoscopy to detect lesions overall, it can reduce the risk for the occurrence of interval cancers between colonoscopies, Medtronic suggests.

Previous research has shown that every 1% increase in the adenoma detection rate results in a 3% decrease in the risk for colorectal cancer (N Engl J Med. 2014;370:1298-306).

"More than 19 million screening colonoscopies are performed in the United States each year. ... Detection of adenomas during colonoscopy is an important quality metric," James Weber, MD, a gastroenterologist affiliated with Texas Digestive Disease Consultants, Southlake, commented in a Medtronic press release.

"The addition of AI can increase the quality of colonoscopies, potentially improving diagnosis and outcomes for colon cancer patients," he added.

Dr. Weber is also the CEO of GI Alliance, a physician-led national health care platform of independent GI practices in six states in the United States.

Computer-aided detection

Unlike other computer-aided detection technologies, GI Genius does not characterize or "diagnose" a lesion, nor does it replace laboratory sampling as a means of confirming a cancer diagnosis.

The technology acts essentially as an extra set of expert "eyes" to detect suspicious lesions during colonoscopy, which should prove helpful, Dr. Johnson and Dr. Glissen Brown both commented.

"When a gastroenterologist looks at the video image, typically, our eyes are focused in the center of that image – that's where our 20/20 vision is," Dr. Johnson explained.

The computer has 20/20 vision over the whole image, including the periphery, "so the technology really gives an extremely expanded acuity of vision and highlights areas that we may need to investigate further," he added.

Dr. Glissen Brown was involved in a trial (Gut. 2019 Oct;68[10]:1813-9) of another AI device – the real-time automatic polyp detection system (Shanghai Wision AI). That study showed an increase in colonoscopic polyp and adenoma detection rates, but this was mainly because of a higher number of diminutive adenomas detected by the automatic detection system, Dr. Gliseen Brown said. There was no important difference in the number of larger adenomas detected with the device and the number detected without it.

However, there was a significant increase in the detection of hyperplastic polyps when the automatic detection system was used. "We definitely want to look at the false-positive rate – both the false-positive rate under the camera when we are doing colonoscopy and under the microscope when we do biopsies," Dr. Glissen Brown acknowledged.

In numerous prospective studies of various computer-aided detection technologies such as the GI Genius system, the false-positive rate resulting in the performance of biopsy of insignificant lesions is relatively low, he said.

"Ultimately, the decision to remove or biopsy a lesion is with the physician, because the GI Genius technology just points the provider to the area of concern, and then it's up to them to look at it and decide whether it needs to be biopsied or not," Dr. Glissen Brown said.

"So the technology serves more as a digital safety net and points the physician in the right direction, so it shouldn't lead to much in the way of histologic false positives," he noted.

The only potential disadvantage to using an AI system such as the GI Genius module is the time it might take for endoscopists to learn how to use it and how much the technology might increase the time required to perform the procedure, he added.

For about 18 months, Dr. Johnson has been running a clinical trial with a similar type of AI technology during colonoscopy. He has found that the learning curve for using these systems is "inordinately short." Dr. Glissen Brown agreed and suggested that, if physicians are already performing colonoscopies regularly, they could probably learn to use an AI system such as GI Genius in about a week.

In his experience, Dr. Johnson has found that the delay caused by use of an AI system during colonoscopy is "minimal."

If there is any delay at all, "we know that time in the colon on withdrawal increases the detection of polyps, so more time during withdrawal may be a good thing," he added. It should be noted that endoscopy societies recommend a withdrawal time of at least 6 minutes, which is one of the metrics used to ensure the quality of a colonoscopy, Dr. Glissen Brown explained.

Indeed, the pivotal study upon which the FDA approved the GI Genius module required a minimum withdrawal time of 6 minutes. Participants said they did not find that using the GI Genius increased withdrawal time, he added.

"I think there is enough prospective evidence at this point to suggest that this technology may really be of benefit to clinicians with a lot of different skill levels, so I would be eager to know how clinicians interact with it in the clinical setting," Dr. Glissen Brown commented.

Dr. Johnson agreed, noting that "even the good can get better."

Dr. Johnson disclosed relationships with this news organization, CRH Medical, the American College of Gastroenterology Research Institute, and HyGIeaCare. Dr. Glissen Brown disclosed no relevant financial relationships.

A version of this article first appeared on Medscape.com.

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Reference: 1. IsHak WW, Pan D, Steiner AJ, et al. Patient-reported outcomes of quality of life, functioning, and GI/psychiatric symptom severity in patients with inflammatory bowel disease (IBD). *Inflamm Bowel Dis.* 2017;23(5):798-803.

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How ergonomics can prevent endoscopist injuries

BY WILL PASS
MDedge News

FROM THE 2021 AGA TECH SUMMIT

Endoscopists are at high risk of musculoskeletal issues, and a multifaceted strategy is needed to reduce rates of injury, including better body posture and endoscopic suite layout, according to leading experts.

Latha Alaparthi, MD, AGAF, director of committee operations at Gastroenterology Center of Connecticut, Hamden, and assistant clinical professor at Yale University, New Haven, Conn., noted that female gastroenterologists are at particular risk because they often work with outsize equipment and suboptimal room setup.

"I think it's something for us to recognize, and [we need to] find ways to protect ourselves," Dr. Alaparthi said during a virtual presentation at the 2021 AGA Tech Summit sponsored by the AGA Center for GI Innovation and Technology (www.gastro.org/cgit.)

Prevalence of musculoskeletal injuries in gastroenterology

Gastroenterologists spend 43% of their time performing procedures, Dr. Alaparthi said, and all those hours take a toll on the body. Up to 89% of gastroenterologists report musculoskeletal symptoms – most often back pain, followed by neck pain and hand pain.

Even newcomers to the field are at risk, she added, noting that 47% of gastroenterology fellows report injury in their first year of training.

"As female gastroenterologists, we are even more at risk," said Dr. Alaparthi. This is partly due to differences in equipment and room design, which "take into consideration 5% of female average measurements and 95% of that of males."


Dr. Alaparthi

Dr. Alaparthi recounted her colleague's experience in leaving gastroenterology for the pharmaceutical industry after experiencing ongoing neck pain.

"She called me and said 1 week after she stopped doing endoscopies, her neck pain was gone."

For gastroenterologists of any gender, musculoskeletal injuries can cause pain and suffering, reduced quality of life, lost or reduced work output, short-term or permanent disability, lost wages, and impediment to career advancement. Yet physicians aren't the only stakeholders affected by these injuries. Employers stand to lose financially from decreased productivity and increased compensation costs.

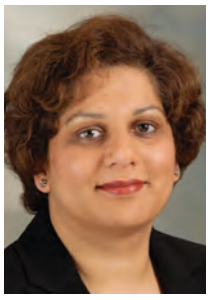
"[Injuries have] implications not just to the individual but to the company and to patient care," Dr. Alaparthi said.

"We definitely need programs to provide comprehensive work force injury prevention and protection specific to GI endoscopy – not just for gastroenterologists, but for the whole team involved."

Ergonomics in endoscopy training

Presenting after Dr. Alaparthi, Katherine Garman, MD, AGAF, associate professor of medicine and vice chief of research, gastroenterology, at Duke University, Durham, N.C., offered ways to incorporate ergonomics into an endoscopy training curriculum.

"Ergonomics evaluates how a job can best fit to an individual, instead of forcing an individual to fit into a job," Dr. Garman said. "[This] is a really important concept when we think about training,"


Dr. Shafi

Yet this concept may run counter to most fellows' natural instinct to fit in and avoid being obtrusive, she noted.

"We need to think about empowering [fellows] from the very beginning to be proactive about how [they] interact with the equipment and the space," Dr. Garman said. "[They should know] it is perfectly acceptable to adjust the monitor height, move the bed height to an appropriate level, and make the space comfortable ... at the beginning of what should be a long, productive career."

Dr. Garman offered several more key points to include in a training program, including increased postural awareness, microbreaks during procedures, and early intervention for prior injuries that may increase risk.

In a recently published study (Gastrointest Endosc. 2021 Feb 6. doi: 10.1016/j.gie.2021.01.045), Dr. Garman and colleagues invited a physical therapist into the endoscopy suite, allowing for real-time assessment of ergonomic positioning and posturing, as well as wellness planning. Out of eight participating endoscopists, all said that the posture education and procedure suite recommendations were helpful.

In the endoscopy suite

In the next presentation, Mehnaz Shafi, MD, AGAF, professor of medicine and ad interim chair of the department of gastroenterology, hepatology, and nutrition at MD Anderson Cancer Center, Houston, described how clinicians and institutions can create ergonomically optimized endoscopy suites.

She began by reviewing specific causes of injury, including repetitive motion, high pinch force, and awkward posture, the latter of which can lead to microtrauma, inflammation, and connective tissue injury.

According to Dr. Shafi, endoscopists should stand in a neutral position with back straight and knees slightly bent. The patient should be positioned at the edge of the bed, which should be 85-120 cm off the floor. Monitors should be 93-162 cm off the floor and 15-25 degrees below eye level. When interacting with multiple monitors, endoscopists should rotate their entire bodies to maintain a neutral position. Hands and elbows also should be kept neutral, with less than 10 degrees of angulation from the height of the bed. To ensure safer hand grip, Dr. Shafi suggested removing any cord loops that may increase tension and using a towel to more evenly distribute gripping force.

The presenters reported having no conflicts of interest.

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Digital GI Corner: Digital navigation to automate patient engagement and reduce procedure no-shows

BY ASHISH ATREJA, MD, MPH, FACP, AGAF

Patient navigation as a best practice for GI procedures

Colonoscopy is the preferred method for colorectal cancer (CRC) screening. Among scheduled outpatient colonoscopies, key metrics like no-show rates and poor bowel preparation can be as high as 25% in some facilities. These missed appointments and repeated calls with patients have been an important source of wasted resources, poor patient outcomes, and revenue loss for endoscopy facilities (estimated to be up to $1 million dollars for 10-member GI practice).

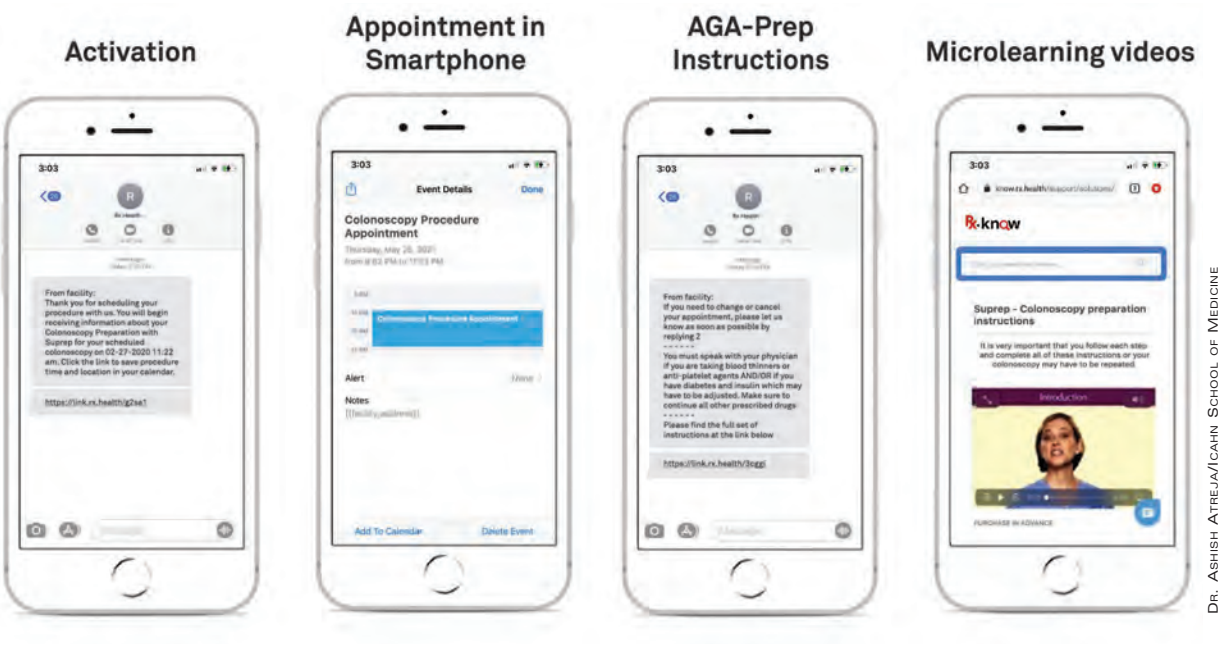
Studies have shown that patient navigation (PN), a patient-centered approach, overcomes barriers in health care delivery, thus improving adherence to CRC screening. Typically, navigators are specialized health practitioners who fill a variety of functions, including providing updates and instructions to patients, as well as assisting with test-related fears. Despite the overall cost-effectiveness, PN programs require significant resources from hospitals or medical groups. The continued focus in the United States on value-based medicine has provided an urgent need for cost-effective treatments that are also readily available to most physicians.

Digital navigation to automate navigation for colonoscopy and other GI procedures

Digital navigation (DN) is a new navigation technique that enables patients to receive appointment updates, resources related to a treatment or condition, stepwise bowel prep directions, and other periprocedural guidance in an automated and convenient manner (see Figure). Given the widespread use of mobile phones, DN has the ability to change the way doctors and health care providers work. This led to Mount Sinai Health System, New York, conducting a quality improvement program to automate and evaluate the effectiveness of an automated text messaging and web-based "digital navigation" platform for decreasing colonoscopy appointment no-show rates.

If a valid phone number was available in the patient's electronic medical record chart and they did not opt out of receiving text message communications from the Mount Sinai Health System, patients over the age of 18 years who were scheduled for a colonoscopy at either of Mount Sinai Hospital, Mount Sinai Morningside, or Mount Sinai West were automatically sent DN SMS messages.

The RxUniverse software platform (Rx.Health, New York) was used to send DN content through SMS to all eligible patients. The software platform interfaces with the EMR and endoscopy system (Provation) to automatically extract patient phone number and appointment details.



Examples of how a digital navigation smartphone app can help patients are shown, including adding appointments to their calendars and providing bowel prep instructions.

Dr. Ashish Atreja/Icahn School of Medicine

Impact of digital navigation and patient engagement

This study at Mount Sinai Health System demonstrated that patient engagement with SMS-based navigation is strongly predictive of colonoscopy completion. Patients with high engagement with digital navigation are about four times more likely to complete colonoscopy. Of all covariates included in the model, high DN engagement level had the largest effect size (odds ratio, 3.97), compared with no engagement. For health systems with patient navigators, targeting patients who are unlikely to engage DN or are low-engagers may be a more efficient use of person-to-person navigation.

Value-based reimbursement and cost-effectiveness have emerged as core principles in American health care reform, possibly requiring the creation of affordable, cost-effective approaches. Our research at Mount Sinai Health System suggested that SMS-based navigation can be a potential cost-effective strategy for reducing no-show rates. Beyond appointment no-shows, adequate bowel preparation is another important component of the preprocedure navigation process. Insufficient bowel preparation requires a repeat procedure, as poor visualization of the colon results in reduced therapeutic benefit from screening colonoscopy. We've shown in previous studies that our DN platform can increase bowel preparation efficiency, which results in lower rates of aborted procedures.

Missed colonoscopies not only cause longer wait times for patients, but they also cost the average facility $725 a day in lost revenue. It has been found through studies that traditional PN is cost-effective, with additional revenue generated from increased colonoscopy completion rates exceeding the costs of program implementation. While formal cost analyses have not been conducted on DN, estimates have shown around $1 million in annual savings for an average ambulatory surgery center or 10-member GI practice.

Looking ahead: AGA digital transformation network

After positive results for the Rx.Health's platform were seen at Mount Sinai Health System, the American Gastroenterological Association partnered with Rx.Health to provide the GI community with a GI endoscopy transformation network. The core purpose of this endoscopy transformation network is to take an evidence-based approach and use digital medicine to positively affect key metrics and safety around periprocedural care and support "procedure bundles." To illustrate the specific case of colonoscopy, these included the following: enhancing colorectal cancer surveillance rates though a comprehensive screening test strategy, decreasing no-show rates through shared decision-making and better preprocedure engagement, improving rates of adequate bowel preparation, benchmarking safety of procedures nationwide, and ensuring patient satisfaction and adequate recall for repeat procedures. These metrics represent key sources of revenue loss for provider organizations and, more importantly, have negative implications on patient care.

This collaboration is now supporting the implementation and expansion of the digital navigation program to all GI procedures at more than 15 different sites across the country.

Dr. Atreja is an adjunct associate professor at the Icahn School of Medicine at Mount Sinai, New York, and chief information officer and chief digital health officer at UC Davis Medical Center, Sacramento. The Icahn School of Medicine has licensed technology to Rx.Health. Dr. Atreja has no other conflicts to disclose

45 researchers awarded millions in research funding

The Foundation introduced new awards in the 2021 awards cycle addressing diversity of GI investigators and the need for GI-specific COVID-19 research.

The American Gastroenterological Association is excited to announce the 45 researchers inducted into the 2021 class of AGA Research Foundation Awards Program recipients.

In the 2021 awards cycle, the AGA Research Foundation will provide more than $2.5 million in research funding to investigators working on projects that will further enhance our understanding of gastrointestinal and liver conditions and ultimately lead to the development of better treatment options for digestive diseases patients.

"This year, we made several enhancements to our awards portfolio to address current priorities for AGA and the field – we launched a new COVID-19 research award and established a summer undergraduate research fellowship to introduce talented underrepresented minority students into GI research," said Robert S. Sandler, MD, MPH, AGAF, chair of the AGA Research Foundation. "We continue to change our funding program to meet the needs of GI research. What does not change is our long-standing commitment to support the research careers of talented early-career investigators."

The AGA Research Foundation Awards Program recruits, retains, and supports the most promising researchers in gastroenterology and hepatology. With funding from the foundation, recipients have protected time to take their research to the next level.

To view the full list of recipients, go to https://gastro.org/press-releases/the-aga-research-foundation-awards-45-gifted-researchers-with-over-2-5-million-in-research-funding/.

The AGA Research Awards Program is made possible thanks to generous donors and funders. Learn more about the AGA Research Foundation at http://foundation.gastro.org.

➤IBS & INTESTINAL DISORDERS

Better care coordination is needed

Fragmented *from page 1*

"Fragmented care has been associated with poor chronic disease outcomes, higher health care use, duplication in testing, and increased costs of care."

In the VHA, these issues prompted creation of the Patient Aligned Care Team (PACT), a medical home model in which primary care physicians coordinate clinical teams of specialists and other health care practitioners. But coordination can be challenging with chronic medical conditions like IBD, according to Dr. Cohen-Mekelburg and colleagues.

Dr. Cohen-Mekelburg

"High-quality care for IBD includes not only disease-specific management of symptoms but also disease-specific preventive care, such as immunizations and cancer screening, to prevent associated adverse outcomes," the investigators wrote. "Identifying which physician is responsible for managing each aspect of care requires some degree of coordination and makes patients with IBD vulnerable to care fragmentation."

AGA Resource

Help your patients better understand their IBD treatment options by sharing AGA's patient education, "Living With IBD," in the AGA GI Patient Center at www.gastro.org/IBD.

Worse outcomes tied to poor first-year continuity

To evaluate care fragmentation within the VHA, the investigators identified 20,079 veterans with IBD who had at least one outpatient encounter with the system between the beginning of 2002 and the end of 2014. Continuity of care (COC) was calculated with the Bice-Boxerman COC index, which measures how much a patient's care is connected with a distinct physician (Med Care. 2016 May;54[5]:e30-4). The investigators used the first-year COC as the primary independent variable.

In the first year of care, the median COC index was 0.24 (interquartile range, 0.13-0.46). The investigators noted that this figure was lower than reported by previous studies involving patients with several other chronic conditions, including IBD.

After controlling for covariates and adjusting for facility-related clustering, the investigators found a lower COC index in the first year was associated with a higher rate of worse outcomes in the subsequent 2 years, including surgical interventions (adjusted hazard ratio, 1.72; 95% confidence interval, 1.43-2.07), hospitalizations (aHR, 1.25; 95% CI, 1.06-1.47), and outpatient flares requiring corticosteroids (aHR, 1.11; 95% CI, 1.01-1.22). Conversely, improving COC index score by 0.1 reduced risk of outpatient flare (aHR, 0.69; 95%CI, 0.58-0.82), hospitalization (aHR, 0.57; 95%CI, 0.41-0.79), and surgical intervention (aHR, 0.25; 95% CI, 0.16-0.38).

Further analyses showed that the relationship between lower COC and worse outcomes carried across measures such as baseline use of an immunomodulator or biological agent, as well as subgroups such as patients with nonsevere IBD and nonsurgical patients.

Among those treated by a VHA gastroenterologist, a lower level of COC was associated with a higher rate of surgical interventions, but not hospitalizations or outpatient flares. Physician-specific COC index scores were highest for primary care providers (0.54), followed by gastroenterologists (0.25) and surgeons (0.17). However, lower physician-specific COC scores did not translate to worse IBD outcomes.

"The level of COC among patients with IBD in the present VHA cohort was ... lower than the values described in previous studies of veterans in the VHA system, including a study of VHA-Medicare dual enrollees who were especially prone to fragmented care because of their ability to seek care both inside and outside of the VHA system," the investigators wrote, referring to a 2018 study (Ann Intern Med. 2018;168[9]:631-9). "The difference in COC among patients with IBD vs. patients without IBD is likely multifactorial and may be associated with confusion about physician accountability and lack of focus on coordination in IBD multidisciplinary care. Patients with IBD require care by primary care providers, gastroenterologists, and surgeons, but the delineation of responsibility by physician is often unclear."

'Better care, not just more care,' is needed

"These outcomes cannot be improved with a more robust treatment armamentarium alone," according to Jason K. Hou, MD, MS, AGAF, FACG, interim chief of gastroenterology and hepatology at Michael E. DeBakey VA Medical Center and associate professor of medicine at Baylor College of Medicine, Houston, who cowrote a simultaneously published editorial, which was also authored by David I. Fudman, MD (JAMA Netw Open. 2020 Sep 1. doi: 10.1001/jamanetworkopen.2020.16122).

"Examples exist of improving care coordination and outcomes through patient-aligned care teams in primary care and medical specialty homes for IBD," Dr. Hou said in an interview. "However, significant barriers to widespread implementation remain."

Dr. Hou

Dr. Hou offered several possible approaches to overcome these barriers.

"We need improved methods to identify and follow high-risk patients most likely to have complications and health care utilization," he said. "We need an investment by payers and health care systems on care coordination so the identified high-risk patients can receive timely testing, referral, and treatment. These changes require reevaluation of how the health care system incentivizes health care to provide better care, not just more care."

The investigators reported grants from the U.S. Department of Veterans Affairs and the National Institutes of Health and financial relationships with AbbVie, UCB, and Takeda. Dr. Hou reported no conflicts of interest.

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Online survey: What do patients search for?

BY JIM KLING
MDedge News

A new online survey of inflammatory bowel disease (IBD) patients found that individuals seeking information on social media are generally satisfied with the care that they get from their health care providers. However, the online activity suggested a desire for more information, especially with respect to supportive needs like diet and complementary/alternative medicine (CAM).

The study was led by Idan Goren, MD, and Henit Yanai, MD, of Rabin Medical Center, Petah Tikva, Israel (J Clin Gastroenterol. 2021 Apr 21. doi: 10.1097/MCG.0000000000001551).

The researchers suspected that social media users with IBD were looking for information they weren't getting from their provider, so the researchers set out to identify those specific unmet needs. In a pilot exploratory phase of their investigation, they conducted an initial survey followed by an analysis of social media posts, then they conducted a second phase with a survey based on the findings in the pilot exploration.

The initial survey was conducted within a social media platform in Israel called Camoni, where patients can interact with each other and with health care providers who have experience treating IBD, including gastroenterologists, dietitians, and psychologists. The survey included 10 items about disease characteristics, information needs, information search habits, and other factors. The subsequent analysis step included individual posts on the network between January 2014 and January 2019; the investigators categorized posts by the topics of interest brought up in the initial survey and determined the frequency of posts related to each category.

Out of the 255 respondents to this initial survey, 72% reported satisfaction with the information they received in person. In addition, 67% said that search engines like Google were their most important source of disease-related information, 58% reported relying heavily on websites, and 53% reported relying on health care providers. The most common topics of interest were diet (65%), medications and their potential adverse effects (58%), disease management (48%), and CAM (43%).

AGA Resource
Help your patients better understand their IBD treatment options by sharing AGA's patient education, "Living With IBD," in the AGA GI Patient Center at www.gastro.org/IBD.

After this pilot exploratory phase, the researchers developed a structured survey that they used in IBD-based forums on Facebook and other social networks. Data were collected from this survey during a 4-week period in November 2019.

About half of the 534 respondents to the more widely distributed follow-up survey were in Israel. Overall, 83% reported using IBD-related medications, 45% of which were biologics. Out of the 534 respondents, 70% primarily received treatment from IBD referral centers. Interestingly, 77% said that they would prefer to rely on social media that is guided by health care providers, but only 22% reported that they actually used such a network. Responding along a visual analog scale, they reported general

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New oral protein shows promise for ulcerative colitis

BY HEIDI SPLETE
MDedge News

A plant-based fusion protein is safe and effective for inducing favorable immune modulation in patients with mild to moderate ulcerative colitis with no immune-suppression side effects reported.

OPRX-106, an orally administered BY2 plant cell–expressing recombinant tumor necrosis factor fusion protein, has demonstrated effectiveness as an anti–TNF-alpha therapy, according to Einat Almon, PhD, of Protalix Biotherapeutics, and colleagues.

"Oral immune therapy is based on the concept of oral administration of nonabsorbable compounds which target the gut immune system to redirect the systemic immune system toward an anti-inflammatory direction, without immunosuppression," the researchers said.

A phase 1 study of OPRX-106 in healthy human volunteers showed safety and immune modulatory effects at doses of 2, 8, or 16 mg/day.

In this phase 2a clinical trial published in the Journal of Clinical Gastroenterology (2021 Feb 1. doi: 10.1097/MCG.0000000000001314), the researchers enrolled 24 patients with ulcerative colitis (11 male and 13 female) aged 23-73 years, with an average age of 42.6 years. Patients received either 2 mg or 8 mg of OPRX-106 at least once daily for 8 weeks. All patients were monitored for 6 hours after receiving medication on day 1 and week 8 for pharmacokinetic sampling, and a lower endoscopy was performed at week 8.

After 8 weeks, 67% of the patients demonstrated clinical response and 28% showed clinical remission. Clinical response and clinical remission were defined by a specific set of criteria including improvement in the Mayo score. Clinical response was a "decrease in the Mayo score of at least 3 points, decrease in the subscore for rectal bleeding of at least 1 point, [and] a rectal bleeding subscore of 0 or 1." Clinical remission at week 8 was defined as "clinically symptom-free, Mayo score of ≤2 with no individual subscore exceeding 1 point after treatment, histopathological improvement in Geboes histologic grading from baseline to week 8, improvement in high sensitivity C-reactive protein levels from baseline to week 8, improvement in fecal calprotectin levels from baseline to week 8, and changes in systemic immune modulation parameters from baseline to week 8."

In addition, 89% of the patients experienced some degree of improvement in their Mayo scores, 61% had mucosal improvement, and 33% achieved mucosal healing.

No side effects associated with general immune suppression were reported. No patients discontinued the study because of adverse events, the researchers said. However, overall, 40 adverse events were reported in 15 patients; 95% of these were mild to moderate and 40% were reported as treatment related. No differences appeared in adverse events related to the two doses.

Evidence of a systemic anti-inflammatory effect was seen with a decrease in serum levels of the pro-inflammatory cytokines interleukin-6 and interferon-gamma that correlated with the clinical response, the researchers noted. Similarly, an increase in the CD3+CD4+CD25+-Foxp3+ subset of suppressor lymphocytes correlated with clinical response.

The study findings were limited by the small sample size, open-label design, and lack of control subjects. However, by targeting the gut immune system, the drug "may provide an answer to the long-term immune suppression encountered in patients with chronic disorders who use these agents for prolonged periods of time, in addition to loss of response due to neutralizing antibodies," they concluded.

Findings provide foundation for further research

"Conducting a study of a novel treatment for ulcerative colitis is valuable and timely because the available options are limited," Atsushi Sakuraba, MD, of the University of Chicago, said in an interview. "The currently available TNF antagonists are administered intravenously or subcutaneously and bear the risk of infectious complications, so the development of an agent that can be administered orally with fewer side effects is of importance."

Although the data are preliminary, Dr. Sakuraba emphasized that the take-home message for clinicians is that "the present open-label study consisting of a small number of subjects demonstrated that OPRX-106 was effective and safe in active ulcerative colitis, so further investigation is warranted. Larger-powered, randomized, placebo-controlled studies are needed to confirm these findings."

The study was supported by Protalix Biotherapeutics; Dr. Almon and several coauthors are employed by Protalix Biotherapeutics. Dr. Sakuraba had no financial conflicts to disclose.

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Continued from previous page

satisfaction with their routine IBD care (mean score, 79 ± 27 out of 100), their providers' effectiveness of communication (82 ± 24), and the providers' ability to understand patient concerns (73 ± 28). Those who were active in social media rated accessibility of IBD service as 68 ± 30. Exploration of topical interest found the most common to be diet (46%), lifestyle (45%), CAM (43%), diagnostic test interpretation (34%), and specialist referrals and reviews (31%).

The general satisfaction with information from health care providers contrasted with some previous studies that had shown that patients seeking information online often felt the opposite: For example, a 2019 Canadian survey found that only 10%-36% of IBD patients believed they received adequate information on IBD issues during clinical visits (World J Gastroenterol. 2019 Aug 14;25[30]:4246-60). The authors of the current study speculated that the incongruence might be explained by the fact that the current survey included patients with greater disease burden, who might get more attention during clinic visits than might patients with milder illness.

"In conclusion, our results indicate that patients' activity on [social media] appears to be independent of their satisfaction with formal IBD care and rather reflects the contemporary need for ongoing information, particularly focused on supportive needs, such as diet and CAM," the investigators wrote.

"Try not to Google everything"

The findings weren't surprising, but the researchers found that patients seeking information online often have a high level of disease burden, as evidenced by biologics use and a majority being seen by specialists. That's worrisome, said Jason Reich, MD, a gastroenterologist in Fall River, Mass., who has also studied social media use among IBD patients but was not involved in this study. "The last person you want getting poor-quality information is someone with pretty active disease," said Dr. Reich in an interview.

Dr. Reich agreed with the authors that IBD specialists should consider having a dietitian in their clinic, or at least refer patients to dietitians early on. He also advocated for gastroenterologists (and all physicians, really) to have an online presence, if possible. "At least make themselves and their office accessible. I always tell my patients, if you have questions, try not to Google everything online and just shoot me a message through the portal instead," said Dr. Reich. He added that nurses can handle such duties, especially those trained in IBD.

"Personally, I don't mind sending my short messages back and forth. Especially if it's just a question. That's easy enough to do when it takes maybe a minute or 2."

The authors disclosed no funding sources. Dr. Reich has no relevant financial disclosures.

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