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GI&Hepatology News

September 2019

Volume 13 / Number 9

Courtesy Dr. Suzanne Meiring.

Dr. Annieke C.G. van Baar found that endoscopic duodenal mucosal resection improved glycemia in patients with type 2 diabetes.

Endoscopic duodenal mucosal resection found effective in T2D

BY DOUG BRUNK

MDedge News

Among patients with suboptimally controlled type 2 diabetes who use oral glucose-lowering medication, endoscopic duodenal mucosal resection (DMR) can be implemented safely and effectively, results from a multicenter, international, phase 2 study demonstrated.

"DMR elicited a substantial improvement in parameters of glycemia as well as a decrease in liver transaminase levels at 24 weeks, which was sustained at 12 months post procedure," researchers led by Annieke C.G. van Baar, MD, wrote in a study published online in Gut.

For the study, Dr. van Baar, of the department of gastroenterology and hepatology at Amsterdam University Medical Center, and colleagues at seven clinical sites enrolled 46 patients with type 2 diabetes who were on stable glucose-lowering medication

See **Resection** · *page 20*

Test could inform care of patients with pancreatic cysts

BY JENNIFER SMITH

MDedge News

A newly developed test could help clinicians more accurately identify which patients with pancreatic cysts require surgery, according to researchers.

The test, CompCyst, incorporates clinical and imaging data as well as data on genetic and biochemical markers associated with pancreatic cancer.

CompCyst proved more effective than standard practice in estimating the risk of cancer so as to differentiate patients who should undergo surgery from patients who require monitoring and those who need no additional care.

Simeon Springer, PhD, of Ring Therapeutics in Cambridge, Mass., and colleagues described the development and testing of CompCyst in Science Translational Medicine.

The researchers collected data from 875 patients who had undergone surgical resection of pancreatic cysts. The team used clinical, imaging, and molecular data from 436 of those patients to train CompCyst to classify patients into three categories.

- Patients with benign, nonmucin-producing cysts who do not require surgery or monitoring

See **Cysts** · *page 31*

Vitamin D supplementation may improve ulcerative colitis

BY WILL PASS

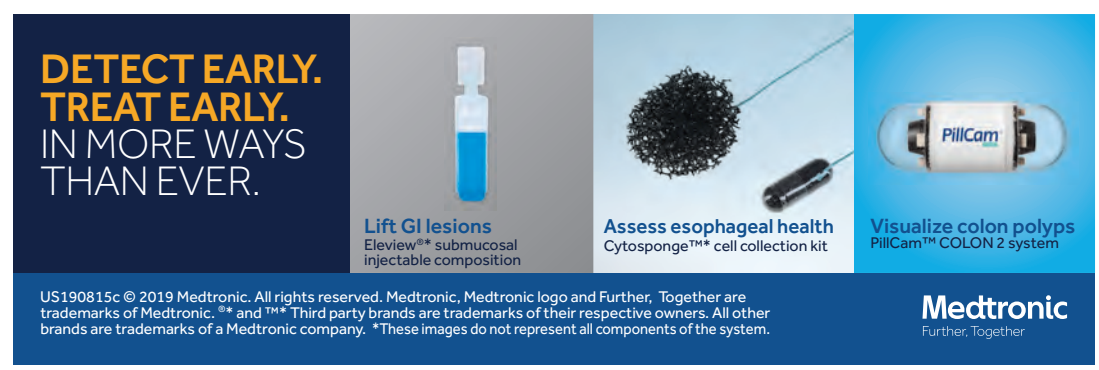
MDedge News

Vitamin D supplementation may lead to significant improvements in ulcerative colitis (UC), based on a placebo-controlled trial involving 60 patients with active disease.

Those who achieved vitamin D levels greater than 40 ng/mL were most likely to benefit, reported lead author Rizwan Ahamed Z, MD, of the Postgraduate Institute of Medical Education and Research in Chandigarh, India, and colleagues. They noted that the findings contribute much-needed clinical data to a largely

See **Vitamin D** · *page 32*

INSIDE



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LETTER FROM THE EDITOR:

The month of new beginnings is here

This month's Letter from the Editor is guest authored by Dr. Megan A. Adams

September is a month of new beginnings, as summer transitions to fall, kids go back to school, and we return to more consistent work routines, refreshed and reinvigorated after some well-deserved time off with family and friends.

Among our cover stories this month is a study showing a novel application of deep learning to inform clinical care of patients with pancreatic cysts. We also feature several high-impact studies from AGA's journals, including a large randomized controlled trial by Dr. Paul Moayyedi and colleagues, demonstrating that PPI therapy may be unnecessary in the majority of patients on oral anticoagulants, despite current guideline recommendations. This study has the potential to substantially change clinical practice, particularly in the context of the current discussion regarding PPI benefits and harms, and our transition to value-based care. We also highlight a proof-of-concept study demonstrating a potential role for probiotics (specifically *Bifidobacteria*) in reducing the risk of NSAID-related gastrointestinal bleeding, and another study showing a possible role for clopidogrel in chemoprevention of colorectal cancer. Both articles are accompanied by expert commentaries highlighting their potential effect on clinical practice.

Dr. Adams

A large study by Dr. Paul Moayyedi and colleagues demonstrates that PPI therapy may be unnecessary in the majority of patients on oral anticoagulants, despite current guideline recommendations.

Our September issue also emphasizes the importance of professional advocacy by chronicling the participation of four AGA leaders (Dr. Carr, Dr. Kaufman, Dr. Ketwaroo, and Dr. Mathews) in the 2019 Alliance of Specialty Medicine Fly In, a multisociety effort to lobby legislators on key issues such as reducing prior authorization burdens and minimizing the strict constraints of step-therapy protocols. We also are pleased to acknowledge the future leaders of gastroenterology by recognizing the 17 exceptional fellows who demonstrated their passion for advancing GI clinical care by presenting their institutional quality improvement projects at a special session at DDW® 2019. We hope you find these stories to be thought provoking, inspiring, and directly relevant to your clinical practice – thank you for reading!

Megan A. Adams, MD, JD, MSc
Associate Editor

DDSEP 9
Digestive Diseases Self-Education Program

Quick quiz

Q1. A 43-year-old woman presents to the office after Roux-en-Y surgery for weight loss. She has a strong family history of gallstones, and asks about measures to prevent gallstone formation after her surgery.

Which of the following agents has potential efficacy to reduce gallstone formation for this patient?
A. Conjugated estrogens
B. Ursodeoxycholic acid
C. Fenofibrate
D. Simvastatin
E. Cholestyramine

Q2. A 56-year-old male with known chronic pancreatitis presents with progressive abdominal pain, weight loss, and obstructive jaundice and a bilirubin of 8 mg/dL. A CT scan with contrast reveals a 4-cm mass in the pancreas head. There is no lymphadenopathy and vascular architecture is maintained.

What is the next best step in management?
A. Pancreaticoduodenectomy (Whipple procedure)
B. Lateral pancreaticojejunostomy procedure (Peustow) procedure
C. EUS +/- FNA
D. MRI/MRCP
E. ERCP with bile duct brushing and stent

The answers are on page 20.

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Pantoprazole not needed for most patients on anticoagulant/antiplatelet therapies

BY WILL PASS
MDedge News

For most patients taking antiplatelet and/or anticoagulant therapies, the proton pump inhibitor (PPI) pantoprazole is unnecessary, based on findings from the prospective COMPASS trial, which involved more than 17,000 participants.

Pantoprazole may reduce the risk of bleeding from gastroduodenal lesions, but it is unlikely to prevent upper-gastrointestinal events, reported lead author Paul Moayyedi, MB ChB, PhD, AGAF, of McMaster University in Hamilton, Canada, and colleagues.

The investigators wrote in Gastroenterology, "Guidelines suggest that patients receiving the combination of antiplatelet and anticoagulant therapy should receive PPIs to reduce the risk of upper-GI bleeding. However ... there are no randomized data to support the use of PPI therapy in patients taking oral anticoagulants, and a paucity of data relating to aspirin."

To fill this knowledge gap, the investigators recruited 17,598 participants from 33 countries who had stable peripheral artery disease and cardiovascular disease. Participants were randomized to one of three groups: 100-mg aspirin once daily, 5-mg rivaroxaban twice daily, or a combination of 2.5-mg rivaroxaban twice daily with 100-mg aspirin once daily. This part of the trial was discontinued before completion because of early cardiovascular advantages associated with combination therapy over aspirin alone, and related findings were reported previously.

While combination therapy did reduce cardiovascular risks, it had less favorable effects on gut health, highlighted by an associated increase in major GI bleeding events. Despite early cessation of the cardiovascular portion of the trial, the pantoprazole regimen was continued, offering a look at the effect of long-term PPI use on gut health.

At baseline, about two-thirds of participants (64%) were not taking a PPI, requiring randomization to either 40-mg pantoprazole once daily or matching placebo. The primary efficacy outcome was time to first upper-GI clinical event, defined as a composite of the following: upper-GI obstruction, perforation, at least five gastroduodenal erosions with at least 3 days of GI pain, symptomatic gastroduodenal ulcer involving at least 3 days of GI pain, overt upper-GI bleeding of unknown origin, occult bleeding (drop in hemoglobin of at least 2 g/dL), overt bleeding with a gastroduodenal lesion (active bleeding during endoscopy), or a symptomatic gastroduodenal ulcer involving at least 3 days of GI pain. In addition to this measure, the investigators evaluated a post-hoc endpoint with a looser definition of peptic ulcer events, most notably eliminating the requirement that a lesion be actively bleeding during endoscopy.

Most patients in the trial (78%) were male, and 23% were current smokers. Smaller proportions of the population were taking a nonsteroidal anti-inflammatory drug (5%) and/or had a history of peptic ulcer disease (2.6%). The median follow-up was 3.01 years, ranging from 2.49 to 3.59 years. Permanent discontinuations occurred at approximately equal rates in the pantoprazole (21%) and placebo (22%) group, after a median of 11 months (338 days). In both groups, more than 96% of participants who continued treatment took their medications as prescribed at least 80% of the time.

Pantoprazole may reduce the risk of bleeding from gastroduodenal lesions, but it is unlikely to prevent upper-gastrointestinal events.

Analysis showed that upper-GI events occurred marginally less often in the pantoprazole group than the placebo group, but without statistical significance (1.2% vs. 1.3%; $P = .35$). Of the outcomes measured, only overt bleeding of gastroduodenal origin detected by radiography or endoscopy was statistically less common in the pantoprazole group than the placebo group, with a 48% reduced rate (0.2% vs. 0.4%; $P = .03$). No statistical efficacy differences or statistical interactions were detected between population subgroups.

"The data suggest that routine use of PPI therapy is not warranted for patients receiving low-dose rivaroxaban with or without aspirin for the prevention of atherothrombotic events in patients with stable coronary artery disease or symptomatic peripheral artery disease, as there was no overall impact on clinical upper-GI events or upper-GI bleeding," the investigators wrote. "This is in contrast to previous systematic reviews of randomized trials reporting that PPIs were associated with a 50%-70% reduction in bleeding and symptomatic peptic ulcers related to nonsteroidal anti-inflammatory drugs, including in the critical care setting."

Post-hoc analysis, which allowed for a broader definition of upper-GI events related to gastroduodenal ulcers, revealed a slightly greater reduction in risk of bleeding lesions in patients taking pantoprazole, compared with placebo (hazard ratio, 0.45), and additional risk reductions for peptic ulcers (HR, 0.46) and erosions (HR, 0.33). Ultimately, pantoprazole reduced the combined rate of post-hoc events by 56%.

The investigators noted that these ulcer- and erosion-reducing effects of pantoprazole align with previous reports. "It is therefore possible that PPIs might be beneficial for patients at particularly high risk for peptic ulcer disease who are also taking aspirin and/or anticoagulants," the investigators concluded.

The COMPASS trial was funded by Bayer AG. The investigators disclosed additional relationships with Allergan, Takeda, Janssen, and others.

ginews@gastro.org

SOURCE: Moayyedi P et al. Gastro. 2019 May 2. doi: 10.1053/j.gastro.2019.05.056.

Clopidogrel matches aspirin for reducing risk of colorectal cancer

BY WILL PASS
MDedge News

Clopidogrel appears to reduce the risk of colorectal cancer (CRC) as much as low-dose aspirin, based on a case-control study involving more than 15,000 cases.

Risk of CRC was reduced by 20%-30% when clopidogrel was given alone or in combination with aspirin, reported lead author Antonio Rodríguez-Miguel of Príncipe de Asturias University Hospital in Madrid and colleagues. This finding adds support to the hypothesis that low-dose aspirin is chemoprotective primarily because of its antiplatelet properties, they noted.

"The mechanism of action of low-dose aspirin to explain its protective effect is subject to debate," the investigators wrote in Clinical Gastroenterology and Hepatology. "Although aspirin is a nonsteroidal anti-inflammatory drug (NSAID) and these drugs are known to prevent CRC through the inhibition of cyclooxygenase (COX)-2 in epithelial and stromal cells in the large bowel, at low doses (75-300 mg/d) aspirin has only transient effects on this isozyme, while permanently inactivating platelet COX-1 and suppressing thromboxane A_2 production. The apparent lack of dose-dependence of the chemoprotective effect of aspirin, as well as the potential role of locally activated platelets in upregulating COX-2 expression in adjacent nucleated cells of the intestinal mucosa, have led [to] the postulation that low-dose aspirin could exert its chemoprotective effect via its antiplatelet action."

Although previous studies have explored the chemoprotective potential of other antiplatelet agents, such as clopidogrel, the resultant body of evidence remains small. In 2017, for example, Avi Leader, MD, and colleagues reported that the chemoprotective effect of dual-antiplatelet therapy (DAPT) with clopidogrel and aspirin was superior to aspirin monotherapy, based on an

Continued on page 8

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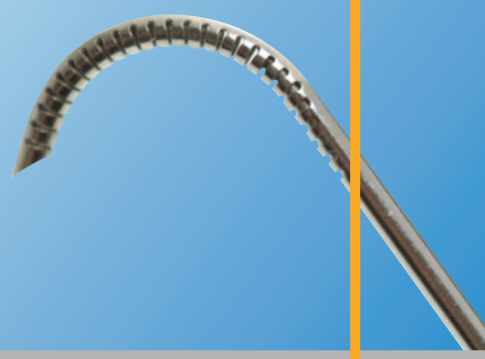

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Probiotic protects against aspirin-related intestinal damage

BY WILL PASS
MDedge News

The probiotic *Bifidobacterium breve* Bif195 could protect patients from aspirin-related gut damage, according to investigators.

Healthy volunteers given aspirin and Bif195 had significantly less damage and fewer ulcers in their small intestines than did control participants who received aspirin alone, reported lead author Brynjulf Mortensen, PhD, an employee of Chr. Hansen A/S, and colleagues in Gastroenterology. These findings may be relevant for millions of people, the investigators noted, because 30% of Americans older than 40 take low-dose acetylsalicylic acid (ASA/aspirin) for cardiovascular disease (CVD).

NSAID-associated gastrointestinal issues are a long-standing and well-known problem, but the pathogenesis of this process in the small intestine appears more complex than in the stomach. The investigators pointed out that proton pump inhibitors, which limit gastropathy by suppressing acid, may actually worsen issues in the small intestine via disruption of microbiota.

"Whereas acid and pepsin are the principal luminal aggressors in NSAID-gastropathy, bile and indeed bacteria are the luminal factors in NSAID-enteropathy," the investigators wrote.

"Given that deleterious compositional changes to the microbiota, in addition to direct effects on mucus and epithelial tissue, may increase the risk of NSAID-enteropathy, we hypothesized that an intervention targeting microbiome-host interactions may offer an attractive, preventative strategy," they wrote. The investigators noted that previous human trials using probiotics for NSAID-enteropathy have been inconsistent; however, they suggested that *Bifidobacteria* remain worthy candidates because of their reported abilities to outcompete pathogenic

Watch this story's Video Insights at
youtube.com/playlist?list=PLO3AD5A5D4C8BE131.

Continued on following page

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additional 8% risk reduction. The present study aimed to build on such findings with evaluation of a Mediterranean cohort, which could reduce confounding lifestyle factors, owing to a lower rate of cardiovascular morbidity than other populations.

The nested, case-control study involved 15,491 cases of CRC and 60,000 controls who were randomly selected and frequency matched by sex, age, and year of indexing. Data were drawn from Base de datos para la Investigación Farmacoepidemiológica en Atención Primaria (BIFAP), a Spanish medical record database with more than 7 million patients. Records of patients involved in the present study were screened for prescription of three antiplatelet agents: low-dose aspirin, clopidogrel, and triflusal. Additional categorization identified current users, recent users, past users, and nonusers. The effects of clopidogrel and aspirin were evaluated separately, as monotherapies, and together, as DAPT.

Demographically, the mean age of the entire study population was 68.6 years, with a slight male predominance (59%). Median follow-up was similar between cases and controls, at approximately 3 years, ranging from about 1.5 to 6 years. Cases showed higher rates of gout, alcohol abuse, acute digestive diseases, and peripheral artery disease, whereas controls were more likely to have histories involving stroke, acute myocardial infarction, chronic digestive diseases, and constipation.

Controls were more likely to be current aspirin users than patients diagnosed with CRC (12.8% vs. 12.2%), giving an associated adjusted odds ratio (AOR) of 0.83. Risk reduction became statistically apparent after 180 days of aspirin usage, with an AOR of 0.79, and more prominent in the 1- to 3-year range, with an AOR of 0.73. This chemoprotective effect faded rapidly with discontinuation.

Current clopidogrel usage led to a comparable level of risk reduction, with an AOR of 0.80. It wasn't until a year of continuous clopidogrel monotherapy that risk reduction became statistically significant, with an AOR of 0.65, which dropped to 0.57 between years 1 and 3.

Turning to a matched comparison of aspirin or clopidogrel monotherapy versus DAPT, the investigators found similar rates of chemoprotection. Current aspirin usage of any duration offered an adjusted risk reduction of 17%, compared with 25% for clopidogrel, and 29% for DAPT. Beyond 1 year of continuous and current usage, the superiority of DAPT was called into question, as clopidogrel monotherapy offered the greatest risk reduction, at 37%, compared with 22% for aspirin, and 22% for DAPT. Risk analyses involving triflusal lacked statistical significance.

Watch this story's Video Insights at
youtube.com/playlist?list=PLO3AD5A5D4C8BE131.

"The results of the present study are compatible with a chemoprotective effect of clopidogrel against CRC, equivalent in magnitude to the one observed for low-dose aspirin," the investigators wrote. "This finding indirectly supports the hypothesis that the chemoprotective effect of low-dose aspirin is mediated mostly through the permanent inactivation of platelet COX-1."

The investigators pointed out that the chemoprotective effects of antiplatelet therapy begin to appear early in treatment, independently from lifestyle factors, but risk reduction depends on current usage. Although short-term usage of either aspirin or clopidogrel was associated with an increased risk of CRC, the investigators suggested that this was more likely a perceived risk rather than an actual one. "In our view, this observation could be explained in part by a detection bias, owing to an increased risk of GI bleeding induced by antiplatelet agents that could lead to a greater number of colonoscopies, and, as a result, an early cancer diagnosis," they wrote.

The study was funded by the Fundación Instituto Teófilo Hernando. Dr. García-Rodríguez disclosed a relationship with CEIFE, which has received funding from Bayer and AstraZeneca.

ginews@gastro.org

SOURCE: Rodríguez-Miguel et al. Clin Gastroenterol Hepatol. 2018 Dec 20. doi: 10.1016/j.cgh.2018.12.012.

The role of aspirin in reducing the risk of colorectal cancer is well established, although the mechanisms of actions are not entirely clear. One possible mechanism is through inhibition of the cyclooxygenase-1 (COX-1) pathway. The authors investigated the role of aspirin but also clopidogrel, another antiplatelet drug that works through inhibition of the COX-1 pathway in reducing the risk of CRC in a case-control study from Spain. CRC cases were randomly matched with cancer-free controls, and the use of aspirin and clopidogrel as a risk factor for CRC was studied. Not surprisingly, aspirin use was associated with reduced risk of CRC by 17%, However, what's new is that the use of clopidogrel was associated with reduced risk of CRC by 20% also but use of dual therapy (aspirin plus clopidogrel) did not confer additional benefit. The results did not differ by patient age or sex. The caveat is that history of CRC screening or colonoscopy was not known for cases or controls, and many other confounders, such as diet, exercise, and other lifestyle and medication history that may account for the differences could not be easily teased apart. If confirmed by others, these data suggest an additional beneficial effect of antiplatelet agent clopidogrel in reducing risk of CRC, if taken for more than 1 year. The study opens the door to exploring mechanisms by which antiplatelet agents may reduce risk of CRC, and the potential role of other antiplatelet agents in reducing risk of CRC.

Dr. Shaukat

Aasma Shaukat, MD, MPH, AGAF, GI section chief Minneapolis VAMC and professor of medicine, University of Minnesota, Minneapolis. She has no conflicts of interest.

Continued from previous page

bacteria, strengthen the intestinal epithelial layer, and modulate inflammation. "Our strain selection was based on the anti-inflammatory properties of certain *Bifidobacteria* and experimental preclinical evidence for a role of *Bifidobacteria* in NSAID-associated ulceration."

The double-blind, placebo-controlled trial involved 75 healthy volunteers aged 18-40 years who lived a sedentary lifestyle; during the study, they refrained from medications and bacterial products that might alter gastrointestinal function. Participants were randomized in a 1:1 ratio to received Bif195 or placebo for 8 weeks. Aspirin 300 mg was given daily to all participants for the first 6 weeks. At six time points, video capsule endoscopy was performed to determine the effect of treatment. The primary endpoint was intestinal damage, reported as area under the curve (AUC) for Lewis score, which incorporates stenosis, villous edema, and ulcers. The main secondary endpoint focused on ulcers, quantified by a separate AUC. Six other secondary endpoints evaluated symptoms, blood intestinal fatty acid binding protein (I-FABP), red spots visualized on video capsule endoscopy, and calprotectin.

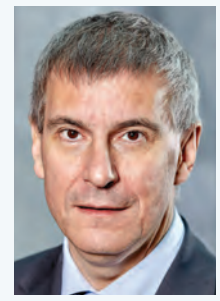
After the 8-week period, 66 of 75 participants remained in the trial. Significantly less intestinal pathology was encountered among patients who received Bif195 than among those who did not. Specifically, for Lewis score, AUC in the Bif195 group was 3,040 plus or minus 1,340 arbitrary units (au), compared with 4,351 plus or minus 3,195 au in the placebo group (P = .0376). For ulcers alone, the Bif195 cohort had an AUC ulcer number of 50.4 plus or minus 53.1 au, versus 75.2 plus or minus 85.3 au for the placebo arm (P = .0258). Fecal calprotectin was also significantly lower in the Bif195 group than in the placebo group, whereas the remaining five secondary endpoints did not achieve statistical significance.

Fecal microbiome analysis revealed changes were limited to a marked increase in the total *B. breve* population in the Bif195 arm, the investigators wrote. These data provide further evidence that microbial intervention strategies can be clinically efficacious without inducing major alterations in the overall microbial population structure.

"The trial results indicate that *Bifidobacterium breve* Bif195 confers significant and objectively verifiable protection against small-intestinal damage caused by a 6-week ASA challenge in healthy volunteers," the investigators wrote.

The study was funded by Chr. Hansen A/S. One author reported additional support from the Science Foundation Ireland.

Gastrointestinal bleeding related to NSAID use is a significant cause of morbidity and mortality in patients taking these drugs. The risk of NSAID-related peptic ulcer can be reduced by PPI therapy, but no intervention has been proven to reduce ulceration beyond the duodenum in NSAID users. Animal models suggest the gut microbiota may be important in the development of NSAID-related small-bowel intestinal injury, but how this translates to patients is unclear.



Dr. Moayyedi

Mortensen et al. conducted the first randomized trial of *Bifidobacterium breve* (Bif195) to prevent aspirin-induced small-bowel injury as determined by video capsule endoscopy in healthy volunteers taking 300-mg aspirin for 6 weeks. They reported a significant reduction in small-bowel ulceration, as well as overall small-bowel injury score in the group randomized to Bif195, compared with placebo. There was also a statistically significant reduction in fecal calprotectin in the probiotic group. This is a proof of concept study, and the clinical implications of these findings are unclear. This study evaluated healthy volunteers taking a higher dose of aspirin than usually used for cardioprotection over a relatively short time period.

Bif195 should be evaluated in a phase 3 clinical trial involving patients requiring NSAIDs over a longer time frame, with small-bowel bleeding being the main clinical endpoint. These are fascinating results and suggest protection from NSAID-related small-bowel injury may be added to the growing list of conditions that manipulating gut microbiota may treat

Paul Moayyedi, MB ChB, MPH, PhD, AGAF, is the Audrey Campbell Ulcerative Colitis Research Chair and assistant dean of research at McMaster University. He is also the principal investigator of the Inflammation, Microbiome, and Alimentation: Gastro-Intestinal and Neuropsychiatric Effects network. He has no conflicts of interest.

SOURCE: Mortensen B et al. Gastroenterology. 2019 May 13. doi: 10.1053/j.gastro.2019.05.008.

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CLINICAL CHALLENGES AND IMAGES

What's your diagnosis?

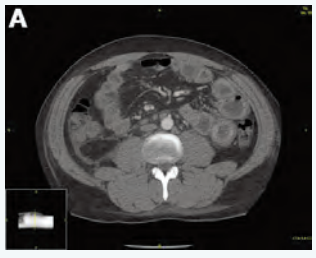
By Obaidullah Aseem, MD, Daniel S. Childs, MD, and Conor G. Loftus, MD. Published previously in Gastroenterology (2018;154[5]:1241-3.

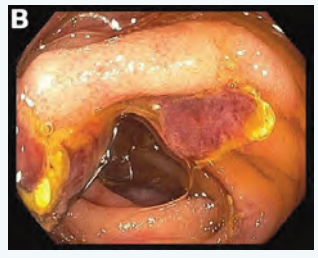
A 34-year-old man with a medical history of psoriasis, on adalimumab, presented with a 2-week history of progressively worsening abdominal pain, nausea, vomiting, melenic diarrhea, subjective fevers, and generalized weakness. One week into the illness, he developed progressive bilateral extremity and scrotal swelling.

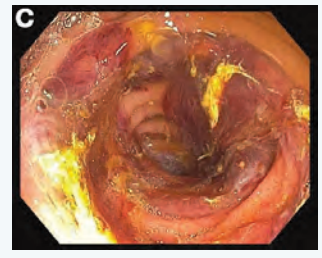
His vital signs included a temperature of 36.8°C, heart rate of 104 beats per minute, respiratory rate of 18 breaths per minute, and a blood pressure of 114/71 mm Hg. The physical examination was notable for a well-nourished appearance, diffuse abdominal tenderness to palpation without distension, organomegaly, or rigidity, and pitting lower extremity edema. Laboratory evaluation showed hemoglobin 10.3 g/dL (normal, 13.5–17.5 g/dL), leukocytes 10 × 10^9/L (normal, 3.5–10.5 × 10^9/L), platelets 212 × 10^9/L (normal, 150–450 × 10^9/L), sodium 131 mmol/L (normal, 135–145 mmol/L), creatinine 1 mg/dL (normal, 0.8–1.3 mg/dL), albumin 1.8 g/dL (normal, 3.5–5.0 g/dL), and C-reactive protein 53 mg/L (normal, less than 8 mg/L). Liver chemistries were all normal. Urinalysis was unremarkable with normal urine protein levels. The enteric pathogen panel by polymerase chain reaction was negative. Computed tomography (CT) of the abdomen and pelvis showed marked circumferential wall thickening with mural enhancement of multiple loops of jejunum (Figure A). Small-bowel enteroscopy showed diffuse erosions in the entire duodenum and many oozing superficial ulcers with edematous and erythematous mucosa in the proximal jejunum (Figures B, C). CT scan of the chest showed right lower lobe consolidation associated with a large right pleural effusion, and mediastinal, bilateral, hilar and abdominal lymphadenopathy (Figure D). Endobronchial ultrasound-guided transbronchial biopsy of lymph nodes was positive for oval-shaped organisms exhibiting narrow-based budding on GMS stain (Figure E).

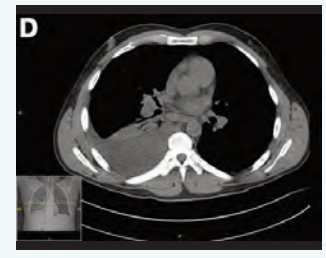
Based on the clinical scenario and images, what is the most likely diagnosis?

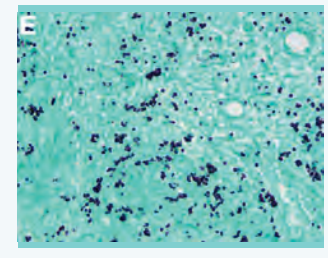
The diagnosis is on page 15.











Inflammation reduces QoL in NAFLD, not fibrosis

BY WILL PASS
MDedge News

A variety of demographic and disease-related factors contribute to poorer quality of life in patients with nonalcoholic fatty liver disease (NAFLD), based on questionnaires involving 304 European patients.

In contrast with previous research, lobular inflammation, but not hepatic fibrosis, was associated with worse quality of life, reported lead author Yvonne Huber, MD, of Johannes Gutenberg University in Mainz, Germany, and colleagues. Women and those with advanced disease or comorbidities had the lowest health-related quality of life (HRQL) scores. The investigators suggested that these findings could be used for treatment planning at a population and patient level.

"With the emergence of medical therapy for [nonalcoholic steatohepatitis (NASH)], it will be of importance to identify patients with the highest unmet need for treatment," the investigators wrote in Clinical Gastroenterology and Hepatology, emphasizing that therapies targeting inflammation could provide the greatest relief.

To determine which patients with NAFLD were most affected by their condition, the investigators used the Chronic Liver Disease Questionnaire (CLDQ), which assesses physical, mental, social, and emotional function, with lower scores indicating poorer health-related quality of life. "[The CLDQ] more specifically addresses symptoms of patients with chronic liver disease, including extrahepatic manifestations, compared with traditional HRQL measures such as the [Short Form–36 (SF-36)] Health Survey Questionnaire," the investigators explained. Recent research has used the CLDQ to reveal a variety of findings, the investigators noted, such as a 2016 study by Alt and colleagues outlining the most common symptoms in noninfectious chronic liver disease (abdominal discomfort, fatigue, and anxiety), and two studies by Younossi and colleagues describing quality of life improvements after curing hepatitis C virus, and negative impacts of viremia and hepatic inflammation in patients with hepatitis B.

The current study involved 304 patients with histologically confirmed NAFLD who were prospectively entered into the European NAFLD registry via centers in Germany (n = 133), the United Kingdom (n = 154), and Spain (n = 17). Patient data included demographic factors, laboratory findings, and histologic features. Within 6 months of liver biopsy, patients completed the CLDQ.

The mean patient age was 52.3 years, with slightly more men than women (53.3% vs. 46.7%). Most patients (75%) were obese, leading to a median body mass index of 33.3 kg/m^2. More than two-thirds of patients (69.1%) had NASH, while approximately half of the population (51.4%) had moderate steatosis, no or low-grade fibrosis (F0-2, 58.2%), and no or low-grade lobular inflammation (grade 0 or 1, 54.7%). The three countries had significantly different population profiles; for example, the United Kingdom had an approximately 10% higher prevalence of type 2 diabetes and obesity compared with the entire cohort, but a decreased arterial hypertension rate of a similar magnitude. The United Kingdom also had a significantly lower mean CLDQ score than that of the study population as a whole (4.73 vs. 4.99).

Generally, patients with NASH reported worse quality of life than that of those with just NAFLD. On a histologic level, hepatic steatosis, ballooning, and lobular inflammation predicted poorer quality of life.

Analysis of the entire cohort revealed that a variety of demographic and disease-related factors negatively impacted health-related quality of life. Women had a significantly lower mean CLDQ score than that of men (5.31 vs. 4.62; *P* less than .001), more often reporting abdominal symptoms, fatigue, systemic symptoms, reduced activity, diminished emotional functioning, and worry. CLDQ overall score was negatively influenced by obesity (4.83 vs. 5.46), type 2 diabetes (4.74 vs. 5.25), and hyperlipidemia (4.84 vs. 5.24), but not hypertension. Laboratory findings that negatively correlated with CLDQ included aspartate transaminase (AST) and HbA_{1c}, whereas ferritin was positively correlated.

Generally, patients with NASH reported worse quality of life than that of those with just NAFLD (4.85 vs. 5.31). Factors contributing most to this disparity were fatigue, systemic symptoms, activity, and worry. On a histologic level, hepatic steatosis, ballooning, and lobular inflammation predicted poorer quality of life; although advanced fibrosis and compensated cirrhosis were associated with a trend toward reduced quality of life, this pattern lacked statistical significance. Multivariate analysis, which accounted for age, sex, body mass index, country, and type 2 diabetes, revealed independent associations between reduced quality of life and type 2 diabetes, sex, age, body mass index, and hepatic inflammation, but not fibrosis.

"The striking finding of the current analysis in this well-characterized European cohort was that, in contrast to the published data on predictors of overall and liver-specific mortality, lobular inflammation correlated independently with HRQL," the investigators wrote. "These results differ from the NASH [Clinical Research Network] cohort, which found lower HRQL using the generic [SF-36 Health Survey Questionnaire] in NASH compared with a healthy U.S. population and a significant effect in cirrhosis only." The investigators suggested that mechanistic differences in disease progression could explain this discordance.

Although hepatic fibrosis has been tied with quality of life by some studies, the investigators pointed out that patients with chronic hepatitis B or C have reported improved quality of life after viral elimination or suppression, which reduce inflammation, but not fibrosis. "On the basis of the current analysis, it can be expected that improvement of steatohepatitis, and in particular lobular inflammation, will have measurable influence on HRQL even independently of fibrosis improvement," the investigators concluded.

The study was funded by H2020. The investigators reported no conflicts of interest.

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SOURCE: Huber Y et al. CGH. 2018 Dec 20. doi: 10.1016/j.cgh.2018.12.016.

Top AGA Community patient cases

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. In case you missed it, here are the most popular clinical discussions shared in the forum recently:

1. Combination therapy with Entyvio (http://ow.ly/jS7C30phgMe) – The GI community shared their experiences with combination therapy of Entyvio and immunomodulators in patients with ulcerative colitis who have developed antibodies to anti-TNF therapy.

2. Small bowel ulcerations in anemic patient with rheumatoid arthritis (http://ow.ly/mDjc30phgKX) – Read an update on this patient with rheumatoid arthritis who was experiencing recurrent abdominal pain associated with iron-deficiency anemia diagnosed with multiple small bowel ulcers.

3. When losing weight is too difficult (http://ow.ly/4Has30phgSi) – How do you approach NAFLD patients who have a difficult time committing to a weight-loss treatment plan?

Access these clinical cases and more discussions at https://community.gastro.org/discussions.

Prior authorization and step therapy: My visit to Capitol Hill

BY AVINASH G. KETWAROO, MD, BAYLOR COLLEGE OF MEDICINE, HOUSTON

As an early-career gastroenterologist, I have become increasingly aware of the impact of advocacy in championing legislation important to our patients. Initially naive about health care advocacy, I owe much to AGA in preparing and arranging for opportunities to speak with elected officials and their staff on GI-related priorities and bills. As a member of the AGA Congressional Advocates Program, I received training and support in visiting Capitol Hill, discussing specific legislation and upcoming bills, writing op-eds, and hosting site visits.

Most recently, AGA sponsored my attendance at the Alliance of Specialty Medicine Annual Advocacy Fly In. With colleagues from around the country – in specialties ranging from ophthalmology to dermatology – we listened to invited congressional representatives and senators on important bills that can directly affect the care we provide to our patients. We had the opportunity to ask questions of these legislators, many of whom were fellow physicians, and gain advice on effective advocacy, as well as build camaraderie with our colleagues in other specialties who face similar issues.

With colleagues from Texas, and assisted by Kathleen Teixeira, AGA vice president, government affairs, we visited the offices of our congressional representatives and senators throughout the afternoon. During our meetings with congressional staff, we stressed the importance of making changes to current prior authorization and step-therapy approaches to make it easier for our patients to access the right treatments as soon as possible. We also discussed the importance of supporting graduate medical education to ensure we have a future cohort of gastroenterologists and other specialists to meet the rising demands of our population. We were well received, and the briefs prepared by the alliance and AGA, as well as tips on effectively communicating our positions, made the whole process seamless. Discussing our own personal experiences and sharing patient stories, we found our meetings to be productive and insightful.

Now, I hope to host my congresswoman, Rep. Lizzie Fletcher, D-Tex., for a site visit locally at Baylor, after a successful meeting with her aide on Capitol Hill.

None of this would have been possible without AGA's support in arranging these presentations, meetings, and physically supporting us throughout the process. I encourage all of you to utilize AGA in advocating for our patients. It is fun, high impact, and incredibly insightful!

How to get involved in advocacy

Interested in advocacy but not sure how to or whether you have time in your busy schedule? AGA has an array of options for how you can be active in advocacy. Some take as little as 5 minutes.

Letter writing. AGA uses GovPredict, an online advocacy platform that allows members to contact their member of Congress with just a few clicks. AGA develops messages on significant pieces of legislation, key efforts in Congress or on issues being advanced by federal agencies that have a great effect on gastroenterology. AGA's ongoing letter writing campaigns can always be found on gastro.org, but be sure to keep an eye out for advocacy emails, AGA eDigest, and social media, so you do not miss your opportunity to take action on timely issues. AGA encour-

During our meetings with congressional staff, we stressed the importance of making changes to current prior authorization and step-therapy approaches to make it easier for our patients to access the right treatments as soon as possible.

Continued on page 19

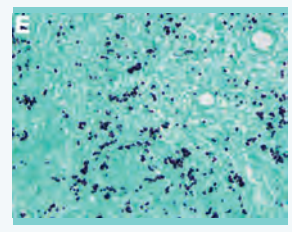
CLINICAL CHALLEGES AND IMAGES

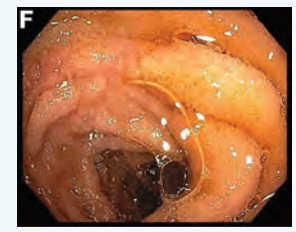
The diagnosis

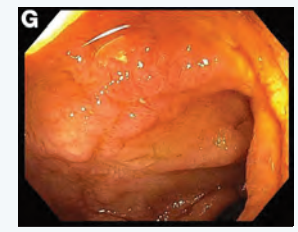
Answer to: "What is your diagnosis? on page 9: Erosive protein-losing enteropathy secondary to disseminated histoplasmosis

This patient was treated with amphotericin B and transitioned to oral itraconazole with frequent blood level monitoring to ensure absorption. His symptoms improved gradually. Small-bowel enteroscopy 3 weeks after presentation showed a normal duodenum and healing, superficial ulcers in the proximal jejunum (Figure E, F, G). Blood albumin levels had recovered to 3.1 g/dL (normal, 3.5–5.0 g/dL).

Protein-losing enteropathy (PLE) is a rare syndrome characterized by loss of serum proteins in the gastrointestinal (GI) tract, resulting in significant hypoproteinemia and consequent edema.[1] PLE can also result in ascites, pleural and pericardial effusions, and, in prolonged cases, malnutrition. There are a variety of causes of PLE that can be broadly grouped into erosive GI disorders, disorders of increased GI mucosal permeability, and disorders of increased interstitial pressure. The clinical presentation depends on the underlying etiology, but commonly includes generalized edema owing to hypoproteinemia and resulting reduced oncotic pressure. GI symptoms are not frequently observed. The initial step in evaluating a patient with symptoms concerning for PLE is to rule out more common causes of hypoproteinemia, such as renal or hepatic disease, and malnutrition. To confirm enteric protein loss, alpha 1-antitrypsin clearance with a 24-hour stool collection is commonly and reliably used. Treatment of PLE is centered on treating the underlying cause while monitoring and treating malnutrition, including micronutrient deficiencies.







Fungal infections are a rare cause of PLE, but important to recognize as a potential complication of tumor necrosis factor–therapy, because these medications are commonly used for a variety of autoimmune diseases.[2] Although histoplasmosis is an uncommon cause of GI inflammation, disseminated histoplasmosis causing PLE has been previously reported.[3] In our patient, *Histoplasma capsulatum* infection caused diffuse GI ulcers, which allowed protein loss in the GI tract (erosive PLE). Antifungal treatment resulted in healing of intestinal ulcers and correction of hypoalbuminemia, thereby confirming the diagnosis of PLE and obviating the need for a confirmatory alpha 1-antitrypsin clearance study.

References

1. Umar SB, DiBaise JK. Protein-losing enteropathy: case illustrations and clinical review. Am J Gastroenterol. 2010;105:43-9.
2. Tsiodras S, Samonis G, Boumpas DT. et al. Fungal infections complicating tumor necrosis factor alpha blockade therapy. Mayo Clin Proc. 2008;83:181-94.
3. Kok J, Chen SC, Anderson L, et al. Protein-losing enteropathy and hypogammaglobulinaemia as first manifestations of disseminated histoplasmosis coincident with Nocardia infection. J Med Microbiol. 2010;59:610-3.

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THE OFFICIAL NEWSPAPER OF THE AGA INSTITUTE

AGA participates in 2019 Alliance of Specialty Medicine Fly In

Thank you to the following members who joined us to advocate for some of the most pressing issues facing gastroenterologists and our patients at the 2019 Alliance of Specialty Medicine Fly In. Our advocates met with House and Senate offices to push for reducing prior authorization burdens and minimizing the strict constraints of step-therapy protocols.

- Rotonya M. Carr, MD, University of Pennsylvania Health System
- Peter Kaufman, MD, AGAF, Capital Digestive Care, Bethesda, Md.
- Avinash G. Ketwaroo, MD, Baylor College of Medicine, Houston
- Simon C. Mathews, MD, Johns Hopkins Medicine, Baltimore

Prior authorization

Prior authorization is a tedious process and management tool that requires physicians to obtain preapproval for medical treatments or tests before rendering care to their patients. Patients experience significant barriers to medically necessary care because of prior authorization requirements for services that are eventually routinely approved. H.R. 3107, the Improving Seniors' Timely Access to Care Act, would increase transparency and accountability and reduce the burdens of prior authorization.

Step therapy

Step-therapy treatment, or "fail first," requires patients to try and fail medications before insurers agree to cover the initial therapy prescribed by their health care provider. While this protocol may initially act as a cost-containment mechanism, it can ultimately lead to more expensive health care costs because of devastating patient complications. H.R. 2279, the Safe Step Act, would provide a clear and timely appeals process when a patient has been subjected to step therapy.

Twitter highlights

@CongressmanRuiz from Cali combats #steptherapy with the bipartisan Safe Step Act (H.R. 2279). #Patients should be given a clear, equitable & transparent appeals process concerning step therapy. Urge your member of Congress to take action: https://t.co/q4ljhu-MO9X#specialtydocs pic.twitter.com/B2zvRT-6mG5

— AGA (@AmerGastroAssn) July 16, 2019

"Thank you, GI docs. I had colon cancer and a GI surgeon saved my life." Thank you, @RepMarkGreen, for supporting reducing prior authorization. https://t.co/kc9fWnA8XB #specialtydocs

— AGA (@AmerGastroAssn) July 17, 2019

The Alliance of Specialty Medicine is a coalition of national medical societies representing specialty physicians in the United States.

This conference took place July 15-17, 2019, at the Liaison Washington Capitol Hill in Washington, DC.

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Continued from page 15

ages its members to share letter writing campaigns with their colleagues, as well as posting them on social media.

Meetings with your member of Congress. In-person meetings are an excellent opportunity to share with your member of Congress, or their staff, how the issues that affect gastroenterology affect you, your patients, and your practice. AGA has a plethora of resources to help you set up a meeting with your member of Congress, including up-to-date issue briefs, tips and tricks for productive meetings, and webinars on how to host an on-site visit. AGA staff is always more than happy to help you arrange a meeting either in Washington, DC, or your home state. If you are interested in arranging a meeting with your member of Congress, please contact AGA Public Policy Coordinator, Jonathan Sollish, at jsollish@gastro.org or 240-482-3228.

AGA PAC. AGA PAC is a voluntary, nonpartisan political organization affiliated with and supported by AGA. The only political action committee supported by a national gastroenterology society, its mission is to give gastroenterologists a greater presence on Capitol Hill and a more effective voice in policy discussions. AGA PAC supports candidates who support our policy priorities, such as fair reimbursement, cutting regulatory red tape, supporting patient protections and access to specialty care, and sustained federal funding of digestive disease research. If you are interested in learning more, contact AGA Government and Political Affairs Manager, Navneet Buttar, at nbuttar@gastro.org or 240-482-3221.

Congressional Advocates Program. This grassroots program is aimed at establishing a stronger foundation for our current and future advocacy initiatives by creating state teams to work on advocacy on the local, state, and national levels. Participation can include a wide variety of activities, ranging from creating educational posts on social media to meeting with members of Congress. Members of the Congressional Advocates Program are mentored and receive advocacy training by AGA leadership and staff. Participating members receive an AGA Congressional Advocate Program Certificate, a Digestive Disease Week® (DDW) badge ribbon, policy badge on the AGA Community, and recognition on AGA's website. Applications for the next cycle will be released in 2019.

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17 fellows advancing GI and patient care

These fellows showcased their commitment to advancing our field through their quality improvement projects presented at DDW® 2019.

Each year during Digestive Disease Week®, AGA hosts a session titled "Advancing Clinical Practice: GI Fellow-Directed Quality-Improvement Projects." During the 2019 session, 17 quality improvement initiatives were presented – you can review these abstracts in the July issue of Gastroenterology in the "AGA Section," www.gastrojournal.org/issue/S0016-5085(19)X0009-8. Kudos to the promising fellows featured below, who all served as lead authors for their QI projects.

Manasi Agrawal, MD
Lenox Hill Hospital, New York City
@ManasiAgrawalMD
Jessica Breton, MD
Children's Hospital of Philadelphia
Adam Faye, MD
Columbia University Medical Center, New York City
@AdamFaye4
Shelly Gurwara, MD
Wake Forest Baptist Health Medical Center, Winston-Salem, N.C.
Afrin Kamal, MD
Stanford University, Calif.
Ani Kardashian, MD
University of California, Los Angeles
@AniKardashianMD
Sonali Palchaudhuri, MD
University of Pennsylvania, Philadelphia
@sopalchaudhuri
Nasim Parsa, MD
University of Missouri Health System, Columbia
Sahil Patel, MD
Drexel University, Philadelphia
@sahilr
Vikram Raghu, MD
Children's Hospital of Pittsburgh
Amit Shah, MD
Children's Hospital of Philadelphia
Lin Shen, MD
Brigham and Women's Hospital, Boston
@LinShenMD
Charles Snyder, MD
Icahn School of Medicine at Mount Sinai, New York City
Brian Sullivan, MD
Duke University, Durham, N.C.
Ashley Vachon, MD
University of Colorado Anschutz Medical Campus, Aurora
Ted Walker, MD
Washington University/Barnes Jewish Hospital, St. Louis, Mo.
Xiao Jing Wang, MD
Mayo Clinic, Rochester, Minn.
@IrisWangMD

ginews@gastro.org

Dr. Juanita Merchant: A researcher to be reckoned with

Juanita Merchant, MD, PhD, is a renowned gastroenterologist whose contributions to the understanding of chronic inflammation and its association with gastric cancer have been called game-changing. She has built a remarkable career that spans more than 2 decades. Early on, she received the 1998 AGA-R. Robert & Sally D. Funderburg Research Award in Gastric Cancer from the AGA Research Foundation. That funding was key to her career. Dr. Merchant was able to intensify her investigation into how chronic inflammation can drive cancer cell growth in the upper gastrointestinal tract, possibly changing physicians' approach to diagnosis and treatment. As we reflect on her trailblazing research, which originated at the University of Michigan, Ann Arbor, and now continues at the University of Arizona in Tucson, we celebrate Dr. Merchant as our AGA Research Foundation researcher of the month.

Dr. Merchant, a professor of medicine in the University of Arizona department of medicine and chief of the division of gastroenterology and hepatology, used the AGA grant to focus on an important signaling pathway that regulates gastric acid levels in the stomach. The Merchant lab AGA-funded project specifically focused on exploring how Hedgehog signaling regulates gastric homeostasis and when dysregulated contributes to gastric cancer. Building on this research over the years, Dr. Merchant has identified potential biomarkers for gastric cancer in chronic Helicobacter-infected patients' blood. If physicians are aware that a patient's Hedgehog-regulated immune cells in the stomach are supporting the development of gastric cancer, then they can begin to monitor the individual more closely to detect the disease at an early stage.

Dr. Merchant

Gastric cancer is the fourth most common malignant disease and the second leading cause of cancer-related death worldwide. In the United States, more than 26,000 people were diagnosed with the disease in 2018, according to the National Cancer Institute.

Read more and get to know Juanita Merchant, MD, PhD by visiting: https://www.gastro.org/news/dr-juanita-merchant-a-researcher-to-be-reckoned-with-1

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Help AGA build a community of investigators through the AGA Research Foundation. Your donation to the AGA Research Foundation can fund future success stories by keeping young scientists working to advance our understanding of digestive diseases. Donate today at www.gastro.org/donateonline.

DDSEP 9
Digestive Diseases Self-Education Program

Quick quiz answers

Q1. Correct Answer: B

Rationale

Risk factors for gallstone formation include increased age, female gender, pregnancy, dyslipidemia, diabetes, obesity and rapid weight loss – especially after gastric bypass surgery. Medications such as hormone replacement therapies/ oral contraceptive agents, fibrates, somatostatin analogues also increase gallstone risk. Currently, there is evidence suggesting potential benefit of prophylactic cholecystectomy during Roux-en-Y gastric bypass, given the potential risk of gallstone formation with rapid weight loss following surgery. However, there is also data from randomized controlled trials that the use of ursodeoxycholic acid following surgery may help reduce risk of gallstone formation for this group of patients.

Reference

Stokes et al. Ursodeoxycholic acid and diets higher in fat prevent gallbladder stones during weight loss: A meta-analysis of randomized controlled trials. 2014. Clin Gastroenterol Hepatol. 2014;12:1090-1100.

Q2. Correct Answer: A

Rationale

In a patient with chronic pancreatitis and a pancreatic mass, the most likely etiology is adenocarcinoma. This patient has radiologically resectable pancreas cancer. There is no evidence of lymphadenopathy or vascular invasion. Performing an ERCP with stent placement to relieve biliary obstruction has not been shown to be of benefit in patients with a resectable pancreatic mass. In fact, surgical outcomes are worse if a stent is placed in the bile duct. Surgical consultation should be obtained and the patient should undergo pancreaticoduodenectomy. EUS is sometimes done, but most cases of resectable disease should go straight to surgery.

Reference

Ghaneh P, et al. Biology and management of pancreatic cancer. Gut 2007;56(8)1134-52.

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Durable glycemic response

Resection *from page 1*

to undergo DMR. The procedure "involves circumferential hydrothermal ablation of the duodenal mucosa resulting in subsequent regeneration of the mucosa," they wrote. "Before ablation, the mucosa is lifted with saline to protect the outer layers of the duodenum." DMR was performed under either general anesthesia or deep sedation by a single endoscopist at each site with extensive experience in therapeutic upper GI endoscopy.

The mean age of the study participants was 55 years; 63% were male. Of the 46 patients, 37 (80%) underwent complete DMR and results were reported for 36 of them. A total of 24 patients had at least one adverse event related to DMR (52%), mostly GI symptoms such as diarrhea, abdominal pain, nausea, and oropharyngeal pain. Of these, 81% were mild. One serious adverse event was considered to be related to the procedure, which "concerned a patient with general malaise, mild fever, and increased C-reactive protein level on the first day after DMR," the researchers wrote. "The mild fever resolved within 24 hours and [C-reactive protein] level normalized within 3 days."

During follow-up measures taken 24 weeks after their DMR, hemoglobin A_{1c} fell by a mean of 10 mmol/mol (P less than .001), fasting plasma glucose by 1.7 mmol/L (P less than .001), and the Homeostatic Model Assessment of Insulin Resistance improved significantly (P less than .001). In addition, the procedure resulted in a moderate reduction in weight (a mean loss of 2.5 kg) and a decrease in hepatic transaminase levels. The effects were sustained at 12 months.

While the majority of patients showed a durable glycemic response over 12 months, a minority exhibited less benefit from DMR and required additional glucose-lowering medication at 24 weeks. "Approximately two-thirds of the patients who required addition of antidiabetic medication in the latter phase of study had undergone insulin secretagogue medication withdrawal at screening. For future study, it may not be necessary to discontinue these medications."

Dr. van Baar and colleagues acknowledged limitations of the study, including its open-label, uncontrolled design. "Nevertheless, this study forms the requisite solid foundation for further research, and controlled studies are currently underway."

The study was funded by Fractyl Laboratories. Dr. van Baar reported having no financial conflicts. Four study authors reported financial relationships with numerous pharmaceutical and device companies.

dbrunk@mdedge.com

SOURCE: van Baar ACG et al. Gut. 2019 Jul 22. doi: 10.1136/gutjnl-2019-318349.

Frequent heartburn affects

UP TO **75%** of sufferers at night[1]

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†Based on a post hoc analysis of 2-week data from 2 previously published identical phase IV, multicenter, randomized, double-blind, placebo-controlled trials that demonstrated efficacy and safety of esomeprazole 20 mg once daily in the morning in subjects with sleep disturbances due to reflux and frequent nighttime heartburn.

‡Complete resolution of heartburn was defined as 7 consecutive days without heartburn.

§First resolution defined as a study day when patients recorded "NO" sleep disturbances due to frequent heartburn on daily diary card.

References: 1. National Sleep Foundation. Ease heartburn at bedtime. https://sleep.org/articles/ease-heartburn-bedtime/. Accessed August 6, 2018. **2.** Johnson DA, Le Moigne A, Hugo V, Nagy P. Rapid resolution of sleep disturbances related to frequent reflux: effect of esomeprazole 20 mg in two randomized, double-blind, controlled trials. *Curr Med Res Opin.* 2015;31(2):243-250.

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09/18

Developments in gastric cancer

BY PRATEEK SHARMA, MD

Gastric cancer is the fifth most common malignancy worldwide with high mortality and morbidity.

In the United States, gastric cancer accounts for 1.6% of all cancers with an estimated 27,510 cases in 2019 per the SEER database. Although the incidence of gastric cancer has been decreasing in the United States, there have been trends suggesting an increased rate in select populations, especially in the young Hispanic population aged 20-49 years (SEER Cancer Statistics Review [CSR] 1975-2015).

Risk factors for gastric cancer include increasing age, male sex, presence of intestinal metaplasia, and varying degrees of dysplasia (Endoscopy. 2019;51[4]:365-88). Gastric cancer is primarily characterized into two subtypes: intestinal type, which is the more common type associated with gastric intestinal metaplasia (GIM), and the diffuse type, which is genetically determined.

GIM, a precancerous lesion, is defined as the replacement of the normal gastric mucosa by intestinal epithelium and can be limited (confined to one region of the stomach) or extensive (involving more than two regions of the stomach). Risk factors for GIM include *Helicobacter pylori* infection, age, smoking status, and presence of a first-degree relative with gastric cancer. Histologically, GIM is characterized as either complete – defined as the presence of small intestinal-type mucosa with mature absorptive cells, goblet cells, and a brush border – or incomplete – with columnar "intermediate" cells in various stages of differentiation, irregular mucin droplets, without a brush border. Extensive and incomplete type of GIM is associated with a higher risk of gastric cancer (Endoscopy. 2019;51[4]:365-88).


Dr. Sharma

Gastric cancer screening has been shown to be effective in countries with a high incidence of gastric cancer. However, in low-incidence countries, at-risk patients can be identified based on epidemiology, genetics, and environmental risk factors as well as incidence of *H. pylori*, and serologic markers of chronic inflammation such as pepsinogen, and gastrin (Am J Gastroenterol. 2017;112[5]:704-15). *H. pylori* eradication has been shown to reduce the risk of developing gastric adenocarcinoma in patients with *H. pylori*-associated GIM. For detection of dysplasia and early gastric cancer, patients with GIM should undergo a full systematic endoscopy protocol of the stomach with clear photographic documentation of gastric regions and pathology.

On standard white-light endoscopy, GIM appears as small gray-white, slightly elevated plaques surrounded by mixed patchy pink and pale areas of mucosa causing an irregular uneven surface. Sometimes GIM can present as patchy erythema with mottling.

On the other hand, presence of features such as differences in color, loss of vascularity, elevation or depression, nodularity or thickening, and abnormal convergence or flattening of folds should raise suspicion for gastric dysplasia or early gastric cancer. Presence of GIM on endoscopy should be documented in detail with photographic evidence including the location and extent of GIM, and obtaining mapping biopsies that include at least two biopsies from the antrum (from lesser and greater curve) and from the body (lesser and greater curve). Endoscopic surveillance is recommended every 3 years in patients with extensive GIM affecting the antrum and body, incomplete GIM, and a family history of gastric cancer.

Dr. Sharma is professor of medicine and director of fellowship training, division of gastroenterology and hepatology, University of Kansas, Kansas City. He has no conflicts of interest.

Colonoscopy: Can we get better?

BY DOUGLAS K. REX, MD, AGAF

In a study presented at the AGA Presidential Plenary session at Digestive Disease Week (DDW)® 2019, Pilonis et al. from Poland reported that a negative high-quality screening colonoscopy (to the cecum and performed by a doctor with an adenoma detection rate [ADR] over 20%) is associated with a substantial reduction in colorectal cancer risk and death. The benefit persisted for at least 16 years after the colonoscopy. A study by Brenner et al. in Germany found that protection lasted more than 20 years after a negative colonoscopy.

We are now at the 50-year anniversaries of colonoscopy and polypectomy. The drivers for the remarkable growth of colonoscopy, including as a screening test in some countries, have been unparalleled sensitivity and the capacity for single-session diagnosis and treatment. CT colonography has not achieved widespread use for a variety of reasons, but an important issue has been the steady improvement in colonoscopy resulting from development and expansion of quality initiatives and technical advances in imaging. CT colonography has not matched these improvements, with recent comparative studies consistently demonstrating that colonoscopy has superior sensitivity, especially for flat and serrated lesions. Similarly, capsule colonoscopy does not match the sensitivity of colonoscopy, requires extensive preparation, and is diagnostic only. These factors limit even the future role of capsule colonoscopy to a small group of patients who fear the invasive aspect of colonoscopy.


Dr. Rex

In the past decade, Endocuff has emerged as a dominant mucosal exposure device, resulting in gains in ADR of 7% in meta-analyses. Recent evidence shows that Endocuff is the first device to allow both faster withdrawal and improved detection.

Tools for highlighting precancerous lesions are making real progress. High-definition optics is included in the list of technologies that improve detection, and only high-definition instruments should be purchased in 2019 and beyond. Although recently considered ineffective for detection, brighter illumination modes have brought electronic chromoendoscopy back. A recent meta-analysis found that the brighter illumination with narrow-band imaging in the most recent version of Olympus colonoscopes, when combined with excellent preparation, produces substantial gains in detection compared with white-light examination.

Similarly, the new series of Fujinon colonoscopes contains two alternative imaging platforms called "blue-light imaging" and "linked-color imaging", both of which are associated with detection gains in multiple randomized trials. Chromoendoscopy with methylene blue MMX, delivered orally in pills given with the bowel preparation, recently has been shown to increase detection in a single large, randomized, controlled trial. Although not FDA approved, pending the results of a second study currently being organized, these results suggest yet another avenue for improved detection.

The first two randomized trials of artificial intelligence programs that highlight polyps have been reported, and both produced substantial gains in ADR. Despite these technical developments, high-definition white light colonoscopy alone can provide remarkably high ADRs when applied by a trained endoscopist who understands the full spectrum of endoscopic appearances of precancerous colorectal lesions and applies meticulous inspection technique.

There is still great room for improvement, including the tolerability of bowel preparation and the safety of colonoscope insertion and resection methods. Screening colonoscopy at intervals of 15 years or longer is likely to enter guidelines. Despite its inherently invasive character, the progressive improvements in colonoscopy quality and technology have thus far prevented the disruption of screening colonoscopy. Colonoscopy will continue to be a viable screening option until a truly convenient, noninvasive, affordable test that provides long-lasting protection is developed.

Dr. Rex is professor of medicine and director of endoscopy in the division of gastroenterology and hepatology at Indiana University Medical Center in Indianapolis. He has been a consultant for Olympus, Boston Scientific, Medtronic, Aries, and Braintree Laboratories; he has received research support from EndoAid, Olympus, and Medivators. He maintains ownership in Satisfai Health.

Upper and lower gastroenterology – the state of the art

BY DAVID A. KATZKA, MD

In the upper GI section of the Postgraduate course program, Ikuo Hirano, MD, AGAF, educated us on the refractory patient with eosinophilic esophagitis, reinforcing the need for chronic maintenance treatment and the complementary role of dilation. Gregory Ginsberg, MD, AGAF, elucidated the specific strategies needed for gastric polyps with advice on which to leave and which to resect. Sachin Wani, MD, AGAF, carefully outlined the changing landscape of Barrett's esophagus with emphasis on our move to ablate rather than observe low-grade dysplasia.

In the difficult area of treating gastroparesis, Linda Nguyen, MD, acquainted us with some of the newer medications for this disorder and discussed the emerging role of endoscopic pyloromyotomy. Michael Camilleri, MD, AGAF, delivered a thorough analysis on the concept of leaky gut with data-driven recommendations on testing and the lack of adequate treatment. Finally, William Chey, MD, AGAF, gave perspective to diagnosis and treatment of small-bowel bacterial overgrowth, particularly with its role in irritable bowel syndrome.


Dr. Katzka

In the lower GI section of the course, Sunanda Kane, MD, AGAF, gave a wonderful overview the present and emerging biologics for treatment of inflammatory bowel disease (IBD). David Rubin, MD, AGAF, shared his expertise and vast experience for best management of ulcerative colitis while Edward Loftus Jr., MD, AGAF, discussed the fact and fiction of diet-based therapy in IBD. This was followed by a timely lecture by Christina Ha, MD, AGAF, on the need to think well outside the GI tract in IBD, discussing infections, cancers, and vaccinations in patients with IBD. The IBD section finished with an erudite and timely lecture by Marla Dubinsky, MD, evaluating the controversy over use of biosimilars in our clinical practice. The remainder of the lower GI section started with AGA President David Lieberman, MD, AGAF, analyzing recent data on the need to move the colonic cancer screening age to 45 years, particularly in African Americans. Following this was a timely talk by Xavier Llor, MD, PhD, on when to suspect and how to test for the expanding definition of Lynch syndrome. Lin Chang, MD, AGAF, delivered the penultimate clinical lecture on management of irritable bowel syndrome based on her many years of clinical expertise in this area. Finally, Gail Hecht, MD, AGAF, a former AGA president, summarized the exciting world of microbiome research from the recent annual Gut Microbiota for Health World Summit. All in all it was considered one of the best AGA Postgraduate courses by many and we look forward to even greater improvements for 2020.

Dr. Katzka is professor of medicine and head of the Esophageal Interest Group at the Mayo Clinic in Rochester, Minn. He is on the advisory boards for Shire and Celgene.

The postgraduate course on liver, pancreas, and biliary tract

BY JOSEPH AHN, MD, MS, MBA, AGAF

The course was framed with the theme, "The Practice of Gastroenterology: The Literature and the Art," with each speaker highlighting not only the relevant updates in the literature, but also sharing the insights into the art of medical practice. The course incorporated an audience response system to fully utilize the available educational technology and increase participant engagement.

Manal Abdelmalek, MD, provided an update on the hot topic of nonalcoholic fatty liver disease, including new developments in pharmacotherapy. The AGA President-elect, Hashem El-Serag, MD, MPH, AGAF, delivered a state-of-the-art presentation on the burgeoning burden of hepatocellular carcinoma and cutting-edge multidisciplinary management. Vijay Shah, MD, AGAF, then reminded us of the persistent presence of alcoholic liver disease in the United States and the controversies surrounding liver transplantation in this setting. Steven Flamm, MD, AGAF, completed the liver session by sharing the secrets of managing the complications of cirrhosis.


Dr. Ahn

The second session, on the pancreas and biliary tract, was headed by Timothy Gardner, MD, who shared the pearls of the management of pancreatitis. Michelle Kim, MD, AGAF, provided fresh and up-to-date insights on the management of pancreatic and biliary cancer, including updated technological options. Finally, Marcia Canto, MD, discussed the hot topic of pancreatic cancer and whether screening should be instituted. Both of these sessions had designated time set aside for panel discussions with questions from the audience.

Dr. Ahn is professor of medicine and director of clinical hepatology at Oregon Health & Science University, Portland. He has no relevant conflicts of interest.

Large prospective trial offers reassurance for long-term PPI use

BY WILL PASS
MDedge News

Aside from a possible increased risk of enteric infections, long-term use of the proton pump inhibitor (PPI) pantoprazole appears safe in patients with stable atherosclerotic vascular disease, according to a prospective trial involving more than 17,000 participants.

In contrast with published observational studies, the present trial found no associations between long-term PPI use and previously reported risks such as pneumonia, fracture, or cerebrovascular events, according to lead author Paul Moayyedi, MB ChB, PhD, AGAF, of McMaster University in Hamilton, Ont., and colleagues.

"To our knowledge, this is the largest PPI trial for any indication and the first prospective randomized trial to evaluate the many long-term safety concerns related to PPI therapy," the investigators wrote in Gastroenterology. They noted that patients are often alarmed by "sensational headlines" about PPI safety. "There are balancing articles that more carefully discuss the risks and benefits of taking PPI therapy but these receive less media attention," the investigators added.

The present, prospective trial, COMPASS, involved 17,598 participants from 33 countries with stable peripheral artery disease and cardiovascular disease. "We use the term participants, rather than patients, as not all of those taking part in this research would have been patients throughout the trial but all participated in the randomized controlled trial," the investigators wrote.

In addition to evaluating the safety of pantoprazole, the study was initially designed to measure the efficacy of pantoprazole for preventing upper gastrointestinal events in participants taking rivaroxaban and/or aspirin, which, in combination, were recently shown to reduce cardiovascular outcomes among patients with stable cardiovascular conditions. As such, participants in the trial were randomized to one of three groups: 100-mg aspirin once daily, 5-mg rivaroxaban twice daily, or 2.5-mg rivaroxaban twice daily combined with 100-mg aspirin once daily. The primary efficacy outcomes for these three groups were stroke, myocardial infarction, and cardiovascular death. This portion of the trial was discontinued early because of evidence that showed the superiority of combina-

Continued on following page

AGA issues guideline for watery diarrhea

BY JIM KLING
MDedge News

A new guideline from the American Gastroenterological Association (AGA) aims to help physicians diagnose the cause of chronic watery diarrhea, particularly to exclude diagnoses other than functional diarrhea or diarrhea-predominant irritable bowel syndrome (IBS). The guideline, published in Gastroenterology, does not apply to patients with concerning presentations like weight loss/anemia, diarrhea with signs of fat malabsorption, bloody diarrhea, cases with a family history of inflammatory bowel disease (IBD), colon cancer, or celiac disease or to those who have traveled to diarrheal disease–related regions.

To rule out IBD, physicians can use either fecal calprotectin (threshold value of 50 microg/g, sensitivity, 0.81; specificity, 0.87) or fecal lactoferrin (threshold, 4.0-7.25 mcg/g; pooled sensitivity for IBD, 0.79; specificity, 0.93). Neither erythrocyte sedimentation rate (ESR) nor C-reactive protein (CRP) should be used to diagnose IBD because tests have shown low pooled sensitivity and specificity. CRP might be useful in settings in which fecal lactoferrin or calprotectin tests are not available or covered by insurance.

Patients should be tested for giardia infection, using the antigen test or PCR, because this pathogen is common in the United States and easily treated.

Patients who have not recently traveled to or from high-risk areas should not be tested for ova and parasites because this is unlikely to identify a culprit. There are other guidelines for treating patients who have traveled to high-risk countries.

Celiac disease should be tested for using immunoglobulin-A tissue transglutaminase (IgA tTG) and a second test (IgG tTG and IgG or IgA deamidated gliadin peptide, or DGP) in case the patient has IgA deficiency that could lead to a false negative on the primary test. Thresholds of 7-15 AU/mL in IgA tTG typically provide sensitivity and specificity greater than 90%. A quantitative IgA level found to be normal confirms the IgA tTG test. In abnormal findings, either IgG tTG or a test for IgG DGP can be used. If no information on IgA levels is available, IgG tTG or IgG DGP can be combined with IgA tTG. Positive celiac disease tests should be confirmed by duodenal biopsy.

Bile acid diarrhea should be tested for in the United States by measuring total bile acids in a 48-hour stool collection to document increased fecal bile acids, or serum fibroblast growth factor 19, to identify defective feedback of bile acid synthesis. The Selenium HomotauroCholic Acid Test (SeHCAT) has moderate diagnostic efficiency, but it is not available in North America. A measurement of serum levels of 7alpha-hydroxy-4-cholesten-3-one (C4), which measures bile acid synthesis, is not yet available.

No recommendation was made for using available serologic tests for the diagnosis of IBS because existing evidence suggests they lack the diagnostic accuracy needed for routine use.

The guideline development was funded by AGA and had no outside funding.

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SOURCE: Smalley W et al. Gastroenterology. 2019 Jul 11. doi: 10.1053/j.gastro.2019.07.004.

Continued from previous page

tion therapy over aspirin alone; however, the pantoprazole component of the trial continued, as planned, for 3 years.

At baseline, about two-thirds of participants (64%) were not taking a PPI, requiring randomization to either 40-mg pantoprazole once daily or matching placebo. Pantoprazole safety outcomes centered on those previously reported by observational studies, including dementia, chronic kidney disease, gastric atrophy, fracture, cancer, pneumonia, diabetes mellitus, chronic obstructive lung disease, *Clostridiodoides difficile* infection, and other enteric infections. Hospitalization rates for noncardiovascular and cardiovascular events were also reported. Data were gathered via questionnaires, which were conducted every 6 months.

Most patients in the trial (78%) were male, and 23% were current smokers. Smaller proportions of the population were taking an NSAID (5%) or had a history of peptic ulcer disease (2.6%). The median follow-up was 3.01 years. Permanent discontinuations occurred at approximately equal rates in the pantoprazole (21%) and placebo (22%) group after a median of 11 months (338 days). In both groups, more than 96% of participants who continued treatment took their medications as prescribed at least 80% of the time.

Analysis of cardiovascular outcomes revealed no significant differences between placebo and pantoprazole groups. Of all the evaluated safety measures, only enteric infections differed significantly between groups, occurring at a higher rate in the pantoprazole group than in the placebo group (1.4% vs. 1.0%; odds ratio, 1.33; 95% confidence interval, 1.01-1.75). Although *C. difficile* infection was more common among pantoprazole users, only 13 such events occurred, precluding statistical analysis.

The investigastors noted that the increased rate of enteric infection among PPI users was still lower than rates reported by systematic reviews. "The data in the current randomized trial were not adjusted for multiple testing so this result should be interpreted with caution," they wrote. Although acid suppression may allow for increased ingestion of pathogenic organisms, which could theoretically increase the risk of enteric infection, the investigators stated that the benefits of PPIs likely outweigh their risks.

The COMPASS trial was funded by Bayer AG. The investigators disclosed additional relationships with Bayer, Allergan, Takeda, Janssen, and others.

ginews@gastro.org

SOURCE: Moayyedi P et al. Gastro. 2019 May 29. doi: 10.1053/j.gastro.2019.05.056.

AGA Resource
AGA patient education on GERD can help your patients better understand and manage the disorder. Post this education on your practice website or share with your patients at https://www.gastro.org/practice-guidance/gi-patient-center/topic/gastroesophageal-reflux-disease-gerd.

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AGA=American Gastroenterological Association.

References: 1. Schiller LR, Emmett M, Santa Ana CA, Fordtran JS. Osmotic effects of polyethylene glycol. *Gastroenterology*. 1988;94(4):933-941. **2.** Hammer HF, Santa Ana CA, Schiller LR, Fordtran JS. Studies of osmotic diarrhea induced in normal subjects by ingestion of polyethylene glycol and lactulose. *J Clin Invest.* 1989;84(4):1056-1062. **3.** Survey of 672 consumers, August 2017, Bayer Consumer Health. **4.** Bharucha AE, Dorn SD, Lembo A, Pressman A; American Gastroenterological Association. American Gastroenterological Association medical position statement on constipation. *Gastroenterology*. 2013;144(1):211-217.

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USPSTF recommends against pancreatic cancer screen

BY LUCAS FRANKI
MDedge News

The U.S. Preventive Services Task Force has issued a statement reaffirming its 2004 guideline, which recommended against screening for pancreatic cancer in asymptomatic adults, according to task force member Douglas K. Owens, MD, of the Veterans Affairs Palo Alto (Calif.) Health Care System and associates.

Pancreatic cancer is uncommon, with an age-adjusted annual incidence of 12.9 cases per 100,000 person-years; however, pancreatic cancer is the third most common cause of cancer death because mortality is high. The mortality rate is 11.0 deaths per 100,000 person-years, and an estimated 45,750 people will die from the disease in 2019.

The studies included in the review found no evidence that screening for pancreatic cancer or treatment of screen-detected pancreatic cancer improves morbidity or mortality.

In 2004, the USPSTF issued a D recommendation for pancreatic cancer screening in asymptomatic adults without a family history of pancreatic cancer or a genetic disorder that increases the risk of cancer. For the 2019 update, the task force conducted a systematic review of 13 studies that assessed the benefits and harms of screening for pancreatic cancer, the diagnostic accuracy of screening tests for pancreatic cancer, and the benefits and harms of treating screen-detected or asymptomatic pancreatic cancer.

According to the USPSTF, the studies included in the review found no evidence that screening for pancreatic cancer or treatment of screen-detected pancreatic cancer improves morbidity or mortality, found adequate evidence that the magnitude of the benefits of screening for pancreatic cancer in asymptomatic adults can be bounded as no greater than small, and found adequate evidence that the magnitude of the harms of screening for pancreatic cancer and treatment of screen-detected pancreatic cancer can be bounded as at least moderate.

Because no new evidence was found supporting pancreatic cancer screening in asymptomatic adults, "the USPSTF reaffirms its previous conclusion that the potential benefits of screening for pancreatic cancer in asymptomatic adults do not outweigh the potential harms," the task force members noted.

The task force authors reported no disclosures related to the recommendation statement.

lfranki@mdedge.com

SOURCE: Owens DK et al. JAMA. 2019 Aug 6. doi: 10.1001/jama.2019.10232.

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Monitor for surgery

Cysts *from page 1*

- Patients who require monitoring because they have mucin-producing cysts with low- or intermediate-grade dysplasia
- Patients who have invasive cancer or high-grade dysplasia and require surgery

The researchers then tested CompCyst in the remaining 426 patients (validation cohort), comparing CompCyst with standard practice, which involves use of clinical and imaging criteria only.

'An important aspect of this paper is the comparison between the performance of our test and current clinical practice. Because the histopathology of all cysts was known from surgical specimens, we could determine, in retrospect, what the optimal treatment should have been.'

"Our aim [in developing CompCyst] was not to replace current knowledge derived from clinical data and imaging characteristics with molecular testing but, rather, to integrate all these aspects together," study author Marco Dal Molin, MD, of Johns Hopkins University, Baltimore, said in a press conference. "An important aspect of this paper is the comparison between the performance of our test and current clinical practice. Because the histopathology of all cysts was known from surgical specimens, we could determine, in retrospect, what the optimal treatment should have been."

Histopathology showed that 53 patients in the validation cohort had a benign, nonmucin-producing cyst and did not require any additional intervention. Standard practice correctly identified 19% (n =10) of these patients, while CompCyst correctly identified 60% (n = 32).

There were 140 patients who had mucin-producing cysts with low- or intermediate-grade dysplasia. Standard practice correctly identified 34% (n = 48) of these patients, while CompCyst correctly identified 49% (n = 68).

"Overall, the use of CompCyst would have avoided unnecessary surgery in 60% of the patients in this study," Dr. Dal Molin said.

Surgery was needed in 152 patients in the validation cohort. Standard practice correctly identified 89% (n = 135) of these patients, while CompCyst correctly identified 91% (n = 138). Neither method would have recommended discharge for any patient who actually required surgery, the researchers noted.

Based on these results, the researchers are hoping to make

Continued on following page

There are several reasons why your patients should get probiotics from food:

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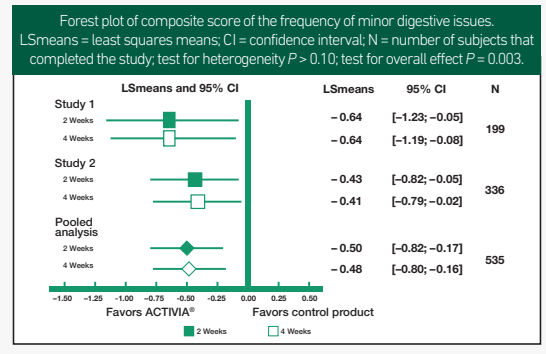
- Some individuals have trouble swallowing, or just don't like pills; but yogurt is easy and enjoyable to consume.



ACTIVIA may help reduce the frequency of minor digestive discomfort.*

Two double-blind, randomized, placebo-controlled studies, and a pooled analysis of these studies, show that ACTIVIA may help reduce the frequency of minor digestive discomfort like bloating, gas, abdominal discomfort, and rumbling.[1,2]*

Both studies were designed to investigate the effect of ACTIVIA on different gastrointestinal (GI) outcomes, including GI well-being and frequency of minor digestive discomfort, in healthy women.

In both studies, and in the pooled analysis, the composite score of the frequency of minor digestive issues over the two-[3] and four-week[1,2] test periods in the ACTIVIA group was significantly lower ($P<0.05$) than that in the control group.

*Consume twice a day for two weeks as part of a balanced diet and healthy lifestyle. Minor digestive discomfort includes bloating, gas, abdominal discomfort, and rumbling.
1. Guyonnet et al. *Br J Nutr.* 2009;102(11):1654-62. **2.** Marteau et al. *Neurogastroenterol Motil.* 2013;25(4):331-e252. **3.** Marteau et al. *Nutrients.* 2019;11(1):92.
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Continued from previous page

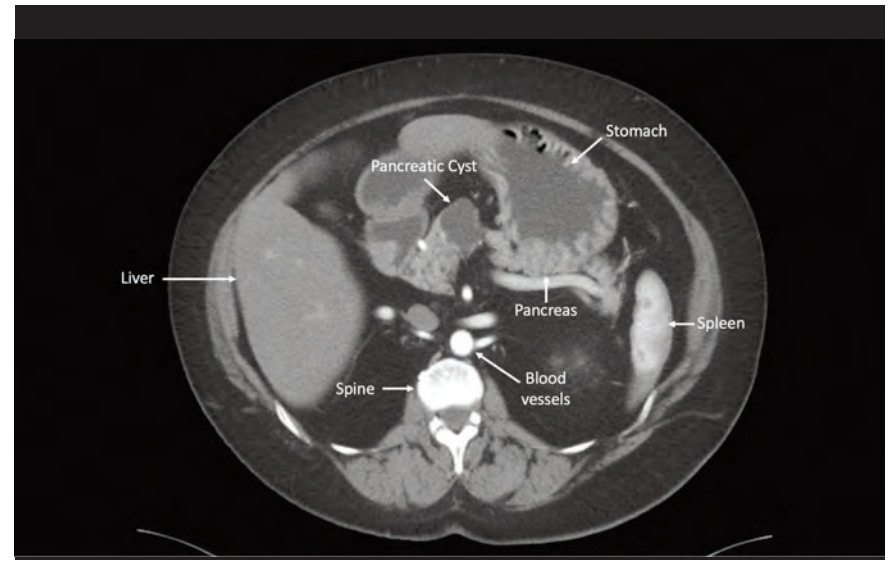
CompCyst available to patients at Johns Hopkins within the next 6-12 months.

"In the long term, we hope that a new, prospective study will be carried out, which will gain approval of this test by the FDA [Food and Drug Administration]," said study author Bert Vogelstein, MD, of Johns Hopkins, at the press conference. "Then, at that point, we hope the technology can be commercialized and offered to the public."

This research was supported by the Lustgarten Foundation for Pancreatic Cancer Research, the Virginia and D.K. Ludwig Fund for Cancer Research, the Sol Goldman Pancreatic Cancer Research Center, the Michael Rolfe Pancreatic Cancer Foundation, the Benjamin Baker Scholarship, and the National Institutes of Health. The researchers reported relationships with Thrive Earlier Detection, Personal Genome Diagnostics, Eisai-Morphotek, Sysmex Inostics, Nexus Strategy (Camden Partners), NeoPhore, and CAGE.

ginews@gastro.org

SOURCE: Springer S et al. Sci Transl Med. 2019 Jul 17. doi: 10.1126/scitranslmed.aav477.



JOHNS HOPKINS

Gut mucosal immunity

Vitamin D *from page 1*

theoretical subject area.

"[T]he discovery of vitamin D receptors on lymphocytes, monocytes, and dendritic cells initiated various studies which have highlighted the role of vitamin D in regulating gut mucosal immunity and gut barrier," the investigators wrote in Journal of Clinical Gastroenterology. "In experimental interleukin (IL)-10 knockout mice models, vitamin D deficiency was found to result in severe colitis, progressive wasting, and high mortality. However, vitamin D supplementation not only prevented but also ameliorated symptoms of colitis in the mice model."

Human studies have revealed similar associations between vitamin D supplementation and inflammatory bowel disease, such as a study by Jørgensen and colleagues that found a lower risk of relapse in Crohn's disease, and another by Sharifi and colleagues that showed injectable vitamin D could reduce erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) in patients with UC. Still, the investigators suggested that more clinical data are needed, particularly for outcomes after vitamin D therapy. In addition to providing such data, the present trial was also the first of its kind to test oral nano vitamin D_3, which may have better bioavailability than conventional supplements.

The investigators initially recruited 110 patients with active UC who had an ulcerative colitis disease activity index (UCDAI) of at least 3. After screening, 50 patients were excluded because they had vitamin D levels greater than 40 ng/mL, were already taking a vitamin D supplement, had severe UC requiring hospitalization, or exhibited severe systemic illness. The remaining 60 patients were randomized in a 1:1 ratio to receive either 60,000 IU nano vitamin D_3 once daily for 8 days, or placebo. Disease parameters, which were measured at baseline and then again at 4 weeks, included UCDAI, ESR, CRP, and fecal calprotectin. The primary outcome was response, defined as a UCDAI reduction of at least 3 points. Secondary outcome measures included stool frequency, stool consistency, and remission (UCDAI less than 3); in addition, the investigators evaluated histologic, endoscopic, fecal, and serum inflammatory markers.

The majority of patients in the study were men (60%), with a mean age of 36 years. Most patients had moderate UC (73.3%), while smaller proportions had severe (18%) or mild (8%) disease. All patients were taking a 5-aminosalicylic acid oral compound and some (16.6%) were also taking azathioprine. At baseline, the mean vitamin D level was 14 ng/mL. Most patients (70%) were diagnosed with vitamin D deficiency, based on measurements below 20 ng/mL. The remaining patients were diagnosed with insufficiency (13%; 20-30 ng/mL) or suboptimal levels (17%; 30-40 ng/mL).

From baseline to 4-week follow-up, median vitamin D level in the supplement group increased from 15.4 to 40.83 ng/mL, compared with a much smaller increase in the placebo group, from 13.45 to 18.85 ng/mL. Compared with the placebo group, significantly more patients given nano vitamin D_3 achieved a UCDAI 3-point reduction (53% vs 13%; $P = .001$); this translated to a Pearson correlation coefficient (rho) of –0.713, between vitamin D level and UCDAI. Similar, albeit less strong, inverse relationships were detected between vitamin D level and CRP (rho = –0.603) and calprotectin (rho = –0.368).

Benefits observed in the supplement group also extended to stool frequency, stool consistency, and histologic measures. Those who achieved a vitamin D level greater than 40 ng/mL were 4 times more likely to have a UCDAI 3-point reduction than those who did not meet the same criteria (80% vs 20%; $P = .038$). Independent predictors of response included baseline histologic activity (odds ratio, 1.92), and to a greater extent, vitamin D supplementation (OR, 9.17). No patients achieved remission, which the investigators attributed to the relatively short study duration.

Minor, self-limiting side effects occurred in 13.3% and 10% of patients given the vitamin D supplement and placebo, respectively.

"[T]he present study showed significant improvement in all inflammatory parameters of the disease including clinical, endoscopic, histopathologic, and serum and fecal markers of inflammation, all of which paralleled each other in showing [the benefit of] oral nano vitamin D supplementation," the investigators concluded. They advised that larger, longer-term studies are needed before the findings can be generalized to all patients with active UC.

The investigators disclosed no external funding or conflicts of interest.

ginews@mdedge.com

SOURCE: Ahamed R et al. J Clin Gastroenterol. 2019 Jul 24. doi: 10.1097/MCG.0000000000001233.

HUNTERANN/THINKSTOCK

FDA finds increased blood clot, death risk associated with Xeljanz

BY LUCAS FRANKI
MDedge News

The Food and Drug Administration has issued a safety alert approving new boxed warnings about increased blood clot and mortality risk associated with the 10-mg, twice-daily dose of tofacitinib (Xeljanz), as well as a new limitation for patients with ulcerative colitis receiving the medication.

Tofacitinib, a Janus kinase inhibitor, was first approved by the FDA in 2012 for the treatment of rheumatoid arthritis (RA). An indication for psoriatic arthritis was added in 2017, and one for ulcerative colitis was added in 2018.

Patients with symptoms of thrombosis also receiving tofacitinib should immediately discontinue the medication. Tofacitinib should not be given to patients with ulcerative colitis unless they are not treated effectively with a TNF inhibitor.

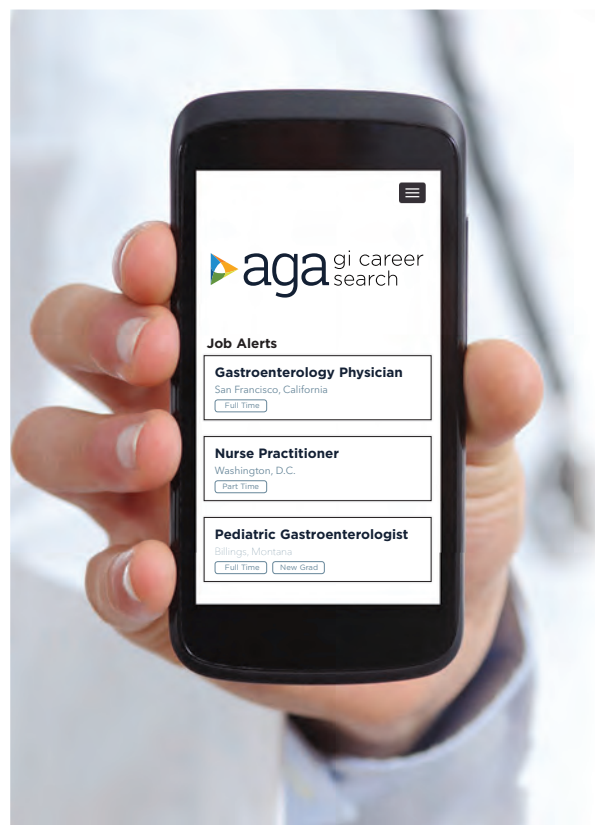
After the 2012 approval, the FDA commissioned a postmarketing trial in patients with RA on background methotrexate to evaluate safety and the risk of cancer, heart-related events, and infection. The 5- and 10-mg tofacitinib twice daily doses are being analyzed in an ongoing study in comparison with a tumor necrosis factor (TNF) inhibitor.

An interim analysis of the trial's data, as of January 2019, found an increased risk of blood clots and death in patients receiving 10-mg tofacitinib twice daily, compared with the TNF inhibitor and the twice-daily, 5-mg dose. Overall, there were 19 cases of blood clots in the lung out of 3,884 patient-years of follow-up in patients who received tofacitinib 10 mg twice daily, compared with 3 cases out of 3,982 patient-years in patients who received TNF inhibitors. There were also 45 cases of death from all causes during follow-up for tofacitinib 10 mg twice daily, compared with 25 cases in patients who received TNF inhibitors.

Patients with symptoms of thrombosis also receiving tofacitinib should immediately discontinue the medication. Tofacitinib should not be given to patients with ulcerative colitis unless they are not treated effectively with a TNF inhibitor or do not tolerate TNF inhibitors; ulcerative colitis patients should receive the lowest effective dosage, and if the higher dosage is necessary, it should be limited to the shortest amount of time possible, the FDA noted.

lfranki@mdedge.com

PNQ19-9



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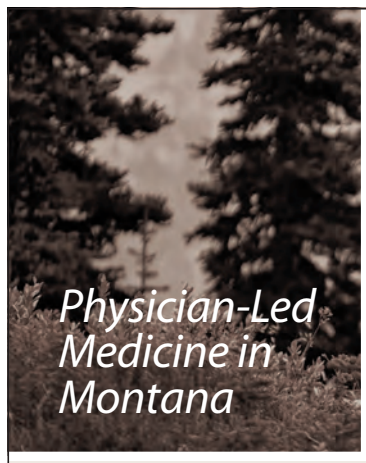

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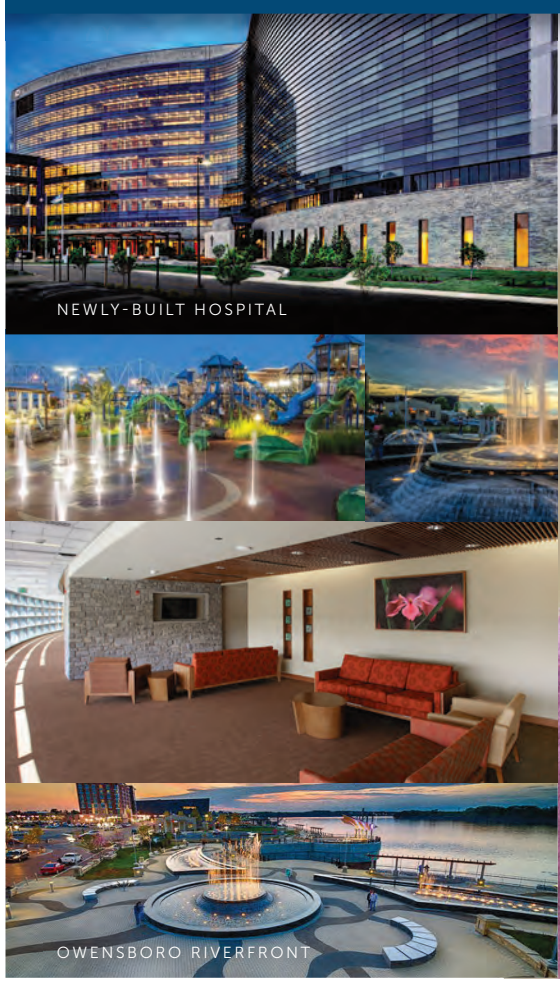

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➤ **PRACTICE MANAGEMENT TOOLBOX:**

Customer service in the medical practice – Are you losing additional revenue opportunities?

BY JIM TURNER, MBA, MHA

If you work in health care or manage a medical practice, you are aware of all the radical changes in technology, medicine, social values, and interpersonal relations over the past few years and you probably do not expect the next several years to be less stressful and less uncertain. To ensure your practice and your provider's success, you may need to adjust how your team interacts with patients – starting with the first area of patient interaction.

Patients who seek care for their health problems are looking for some measure of kindness when they approach the window of your office's receptionist. Many are already apprehensive about their clinical condition and adding to that problem is their concern about the financial impact of their visit on the family's budget. The medical group's unwillingness to rethink how it greets patients as they approach the receptionist sets the stage for the patient to feel mishandled or underappreciated.

This initial patient interaction stage must be evaluated and recognized as an area of improvement. If not handled properly, it will significantly affect how a medical practice or provider is graded as a group in the field of patient experience and managing patient expectations. Every medical office needs to recognize that people hold on to negative experiences and are not likely to change their mind after that negative experience. The best way to avoid negative bias is to prevent it from happening in the first place.

Listed below are the five additional patient experience mistakes that can cost your group, if they are not recognized as being priorities for both your staff and your patients.

Mistake #1 - Educated patients are taking control of their health care.

When health care is treated like any other paid service, an unhappy patient will move along to a new facility or doctor if they have a bad interaction – whether it is with the doctor or the support staff. Educating, training, or adjusting staff to make changes needed is required to ensure that your staff understands the value of patient appreciation and providing the patient with a positive experience.

Mistake #2 - Patients are customers, and just like customers, patients have options.

It should be recognized that patients are customers who are concerned about their future and do not want to be in a medical practice requesting help. They feel vulnerable and out of their routine comfort zone. Reminding your staff that a patient is a customer who has multiple health care choices, but chose to come to your practice, will help your staff understand the value of providing your patient with a positive experience.

Mistake #3 - Dr. Google is becoming the patient's best friend.

Research indicates that many patients arrive at the doctor's office with some information already on

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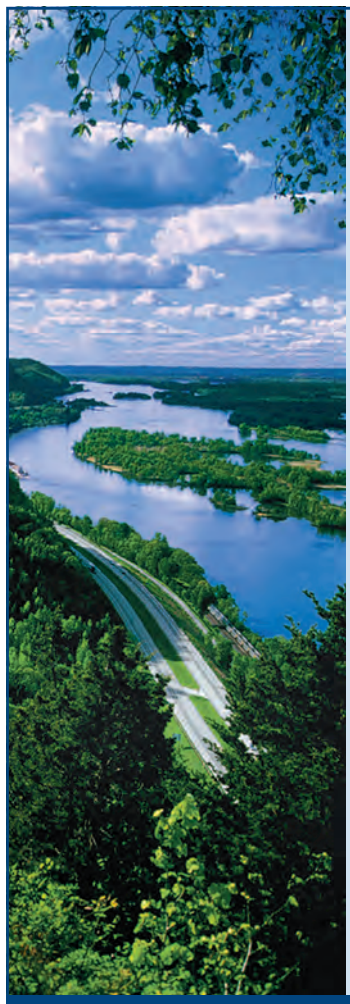

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their condition. Various websites already have provided the patient with free access to learn about their health condition. Popular medical sites such as WebMD.com give the patient the preliminary education they are looking for, so they are already armed with medical information even before they see the doctor or their support staff.

Mistake #4 - Surveys are carrying more weight.

Outside surveys are becoming even more popular and are carrying additional weight when combined with various social media outlets. All types of surveys and reviews are being used to measure not only the care the patient received, but also the interpersonal relationship between the patient and the doctor, and the patient's experience with the medical practice's support staff. Some surveys cover all levels in the practice area, down to the cleanliness of the reception area or the patient's treatment area, and even the adequacy of the parking lot. These surveys are conditioning patients to recall their entire experience. With a patient experience plan in place, excellent service becomes second nature and will be recognized by those surveyed.

Mistake #5 - Patient-centered care is customer service too.

It's not just about the obvious. Excellent patient (customer) service extends beyond a pleasant demeanor. The patient experience does not start or end at the doctor's office. Perception is built by gathering information from multiple channels, whether it is through review sites, office visits, or surveys. It is necessary to consider the importance of those channels when looking to build patient loyalty.

To avoid the mistakes listed above, the more progressive medical practices are training their staff to anticipate the customer service needs of their patients, much like other major service industries. By rolling out a patient/customer experience training program, they can prevent these mistakes from ever happening and affecting their potential revenue. This training should focus on integrating the following strategies into their daily work habits to provide their patients with exceptional customer service while they are guests in their practice.

1) Patients are the lifeline to building the future of their practice.

Patients are comparing their health care services to other companies that routinely provide high-end services to their clients. Whether groups like it or not, their front-line personnel are compared to five-star hotel receptionists, who are expected to greet their customers both pleasantly and professionally after a long day of traveling and required business functions. Every medical group must understand that patients have options when they select a medical practice and they expect to be treated with respect and transparency, and not as just another person to be cared for at the end of a long day. The same level of service needs to be delivered in the doctor's office no matter what time of day because for that patient, the personal problems and subsequent disposition of the medical staff is not their problem. All they want is someone to listen and help them take care of their medical problem. Their long-term loyalty to the group will be solely dependent on how well each personal interaction is handled. Remember that the patient is a person first and not just a customer. We must approach each patient with humanity first, and then customer service.

Whether groups like it or not, their front-line personnel are compared to five-star hotel receptionists, who are expected to greet their customers both pleasantly and professionally after a long day of traveling and required business functions.

2) Be courteous and respectful.

Remind your staff to be courteous, always polite, and to use good manners. By treating a patient how they expect to be treated, you are showing the patient that you respect them and care for not only their health but also their feelings. The health care worker must understand that the patient is viewing their interactions with staff and providers as being symbolic of the overall group's brand identity. The group's leadership needs to select and train their workforce to recognize their importance in how patients view their clinical offerings and their interactions with the patient.

3) Never show indifference to patients.

Losing patients before they complete their treatment regimen is a significant liability issue for any medical practice. In an article written by

Continued on following page

aga research foundation

Research Funding Opportunities

The AGA Research Foundation is excited to announce the start of its 2020 research awards cycle. This year the foundation will award over $2 million in research funding to support researchers in gastroenterology and hepatology. The first two grants open for applications focus on digestive cancers and are due on Aug. 7, 2019.

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AGA-Caroline Craig Augustyn & Damian Augustyn Award in Digestive Cancer

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- AGA Research Scholar Awards
- AGA-Takeda Pharmaceuticals Research Scholar Award in IBD
- AGA-Gastric Cancer Foundation Ben Feinstein Memorial Research Scholar Award in Gastric Cancer

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RSH19-16

Continued from previous page

Strive Labs CEO and cofounder, Scott Hebert, DPT, wrote: "Patient churn is too big of a problem to ignore, and it can have a profound impact on your clinic's bottom line." In addition to the rather obvious missed revenue opportunity, a churning patient represents a practice liability, because an unsatisfied patient is significantly more likely to leave you a negative review online — or turn the experience with your practice into a cautionary tale for friends and family members. Either way, it's bad for business — and your reputation.

4) Don't contradict, argue, or match wits.

It's tough for a health care worker who is continually being bombarded in a high-pressure environment to agree to disagree. When a person feels they are right or that their perception is the only logical one, they can be very stubborn in their understanding, and they will dig in their heels. It takes a strong person to allow others to have their opinion and not be judgmental about it. Any customer or patient relations training program to be deployed in a medical office must include skill training to teach the staff member how to diffuse an argument or disagreement. This situation can be dispersed by training your staff to consider the source of the conflict, respect the patient's perception, and then teach the staff member to tell the patient that they never thought of it that way and ease away from the discussion. Their absence will help diffuse the situation.

5) Tell patients you appreciate their business.

How you relate to a patient will speak volumes to them about how much you appreciate their loyalty, all because they chose your practice for their health care. All patient and customer training programs should include discussions on making eye contact, shaking with a firm grasp, and always closing a personal encounter on a sincere and positive note. Health care workers need to understand that they are in the service business and that the patients they care for have options and they can easily walk out of the medical practice and share any negative experience on social media. Educating and reminding your staff on how easily a patient can leave your practice or share their experience with others needs to be recognized and discussed at all the group's town hall meetings.

6) Use plain terms and simple explanations.

We all want to appear to be super intelligent by trying to use complex terms to describe a situation because it creates leverage with the other parties engaged in the conversation. While some of this may be necessary when educating patients on their condition, any additional complex terms can easily annoy or even confuse the patient who is only there seeking help. Health care workers need to talk in a manner that keeps the patients engaged and helps them understand the topic at hand. The worker needs to use everyday vernacular examples, so the patient quickly understands the reason that brought them to the clinic and what they need to do to get some relief from what ails them. Using this method when discussing a patient's condition isn't just for the patient's benefit because many confused patients ultimately call the office later in the day only to ask additional questions, which uses your staff's time.

7) Good manners will get you everywhere.

Emily Post wrote, "Manners are a sensitive awareness of the feelings of others. If you have that awareness, you have good manners, no matter what fork you use." Proper manners are behaving in a way that is both aware of and considerate of the people around us. A person with good manners treats everyone with kindness and respect. It is knowing how to get along without causing offense or harm, no matter how much the current interaction is going south – especially when you are engaged in a tough conversation.

8) Keep seeing health care as a calling.

t health care workers need to know that their vocation of caring for sick and injured patients is a calling and not just a job and all training programs designed to teach customer service need to stress this point. Practicing your vocation means that you will work hard to eliminate all barriers that exist between the patient and the health care worker. Too often we underestimate the power of a simple touch, a smile, a kind word, a listening ear, an honest compliment, or the smallest act of caring – all of which have the potential to turn a life or a bad interaction into a magical moment for both the patient and the health care worker. One that has meaning and a bit of affirmation of the dignity of both individuals interacting to find some common ground.

9) Stay in touch with patients.

The group needs to find ways to keep in contact with their patients, whether it is by giving them tips on how to remain healthy or the need for proactive and preventive medicine. The use of technology and social media, as well as handing out freebies at health fairs, giving patients informational brochures upon discharge, or even cards telling them how to contact the practice in case of emergencies, is quite helpful. Calling your patients is a significant signal that your group values the health and welfare of your patients. A phone call from either the doctor or their assistant goes further than any advertisement when building brand and doctor loyalty.

10) Keep your promises.

Do what you say you are going to do, should be a commonly shared mantra for the medical practice. While changing your mind from time to time when circumstances prevent you from keeping a promise, is just part of being flexible in life, regularly breaking promises to other people isn't healthy. Here's how to keep your promises: Pay close attention to your words – every word you communicate (through speaking or writing), as a patient may take your words as a promise. Study your patterns of making promises. Figure out when you tend to make careless promises and study the situations in which you do, so you can understand why you're promising what you don't intend to do. Take time and careful consideration before making a promise to someone. Don't rush yourself into a promise that you won't be able to keep. Stop yourself before you make a vow, delaying your decision long enough to think it through carefully. The more careful you become about making promises, the easier it will be to keep them.

The last step of deploying a patient/customer service program is handling the change in management that is required to train the staff. Accepting "No, we are not changing any part of the group to meet the needs of our patients better" is unacceptable. Usually, you will be introducing this program to employees that have been in a group for a while and so to get them to buy into the new ideas will require constant reinforcement. It may take some time to align the focus of the group from the neutral zone to the notion that there are new deliverables that would better serve your patients. The following rules will be helpful when beginning your training program:

Rule #1 – Be consistent. Every policy, procedure, and list of priorities sends a message – make sure it's the right message.

Rule #2 – Ensure quick successes. Look for ways to get the group's employees to buy into the program – early on after its deployment.

Rule #3 – Symbolize the new identity. Make sure the group's logos and branding support the new identity of the group and the culture change.

Rule #4 – Celebrate all the group's successes. Make sure the group's employees recognize the work efforts involved as well as the success the group will enjoy. Stress the fact that the work completed will significantly enhance the care and service levels to the patients, which should feed the ego of the group to do more and more in the future.

And lastly, do not forget how vital the buy-in is of the clinicians of the group. They must be introduced early to the new patient/customer service program and embrace it so that their employees will recognize that these efforts are focused on providing a high quality of care throughout the enterprise. As the French philosopher Albert Schweitzer once stated, "Example is not the main thing in influencing others, it's the only thing."

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Mr. Turner is chief executive officer of Indianapolis Gastroenterology and Hepatology.

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