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GI & HEPATOLOGY NEWS

THE OFFICIAL NEWSPAPER OF THE AGA INSTITUTE

MAYO CLINIC, ROCHESTER, MINN.

Dr. Andres J. Acosta is lead author of AGA's new practice guide to help GIs join the multidisciplinary, long-term treatment of obesity.

AGA releases POWER – an obesity guide

BY SHARON WORCESTER
Frontline Medical News

The obesity epidemic has reached critical proportions. A new practice guide from the American Gastroenterological Association aims to help gastroenterologists engage in a multidisciplinary effort to tackle the problem.

The guide, entitled "POWER: Practice Guide on Obesity and Weight Management, Education and Resources," includes a comprehensive clinical process for assessing and safely and effectively managing patients with obesity, as well as a framework focused on helping practitioners navigate the business operational issues related to the management of obesity. Both are in press for the May issue of Clinical Gastroenterology and Hepatology (2016. doi: 10.1016/j.cgh.2016.10.023).

The POWER model recognizes obesity as an epidemic and as an economic and societal burden that should be embraced as a chronic, relapsing disease best managed across a flexible care cycle using a team approach.

Gastroenterologists are uniquely positioned to help provide that care, whether as a team leader and developer or by joining forces with an existing care team, according to the lead au-

See **Obesity** · *page 14*

Foreign doctors may lose U.S. jobs after visa program suspension

BY ALICIA GALLEGOS
Frontline Medical News

While much of the drama surrounding the Trump administration's immigration policy has centered on the so-called travel ban, changes to a specialized visa program may have a bigger impact on foreign doctors in the United States and the employers who hope to hire them.

Starting April 3, U.S. Citizenship and Immigration Services (USCIS) is temporarily suspending its expedited processing of H-1B visas, a primary route that is used by highly skilled foreign physicians and students to practice and train in the United States.

Under the existing "premium processing" system, foreign medical graduates – usually sponsored by a U.S. institution – pay an extra $1,200 when submitting an H-1B petition to ensure a response from USCIS within 15 days. Standard processing of H-1B applications takes 6-10 months. USCIS is terminating the expedited reviews for up to 6 months to address long-standing H-1B petitions and to reduce backlogs, according to a March announcement by the agency.

In the meantime, many foreign medical students and physicians will lose

See **Visa program** · *page 4*

INSIDE

Rectal Ca proportion in young doubled

BY MARY ANN MOON
Frontline Medical News

The proportion of rectal cancer cases diagnosed in people younger than 55 years doubled over the past 2 decades, according to a report published online in the Journal of the National Cancer Institute.

In contrast, the proportion diagnosed in people older than 55 years has decreased over the last 4 decades, said Rebecca L. Siegel, MPH, strategic director of surveillance information services of surveillance and health services research at the American Cancer Society and her associates.

They examined time trends in colorectal cancer (CRC) incidence using data from nine geographical areas in the Surveillance, Epidemiology, and End

See **Rectal cancer** · *page 18*

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CLINICAL CHALLENGES AND IMAGES

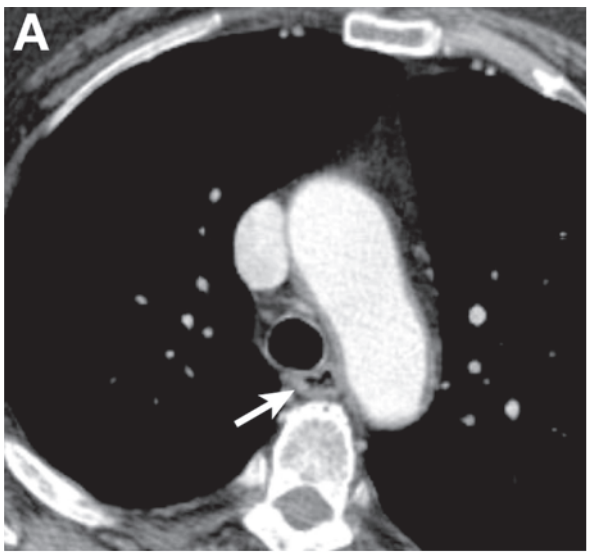
What's your diagnosis?

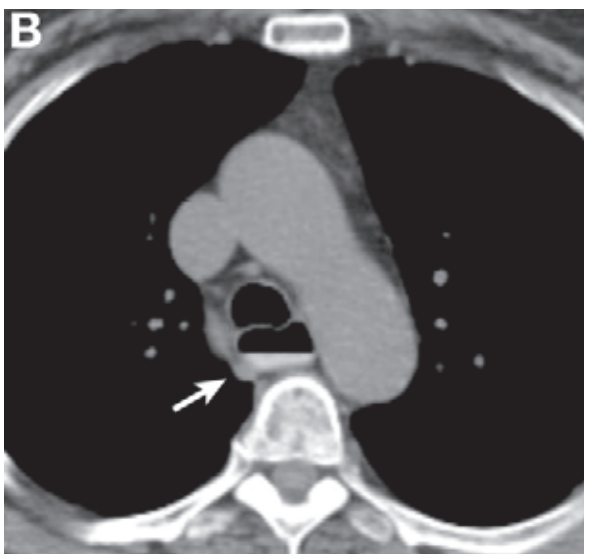
By William R. Brown, MD, and Elizabeth K. Dee, MD. Published previously in Gastroenterology (2013;144:34, 252, 253).

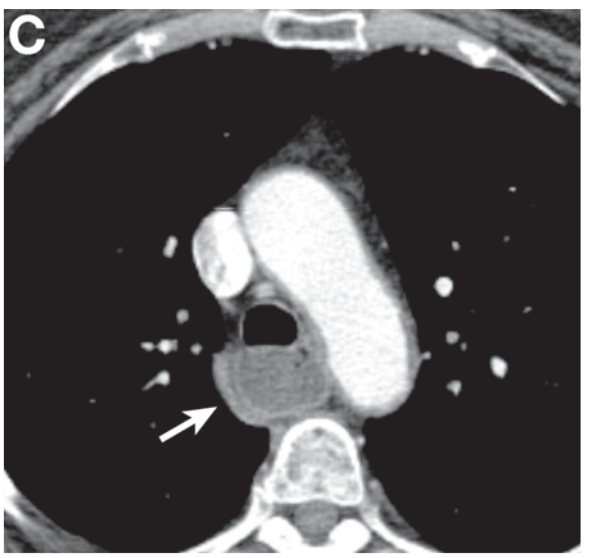
A 67-year-old woman with neuroendocrine small-cell lung cancer (SCLC), recurrent after chemotherapy and radiation therapy, complained of recent-onset dysphagia. She noticed regurgitation of liquids and some solid-food dysphagia. She had lost 20 pounds in the past 2 months. She had no past history of gastroesophageal reflux symptoms or esophagitis. Physical examination reveals no significant abnormalities, but she had had a peripheral sensory neuropathy that improved with treatment of her SCLC. Laboratory tests are unremarkable except for a positive Hu IgG serum anti–neuronal nuclear antibody test – an antibody that is associated with SCLC.

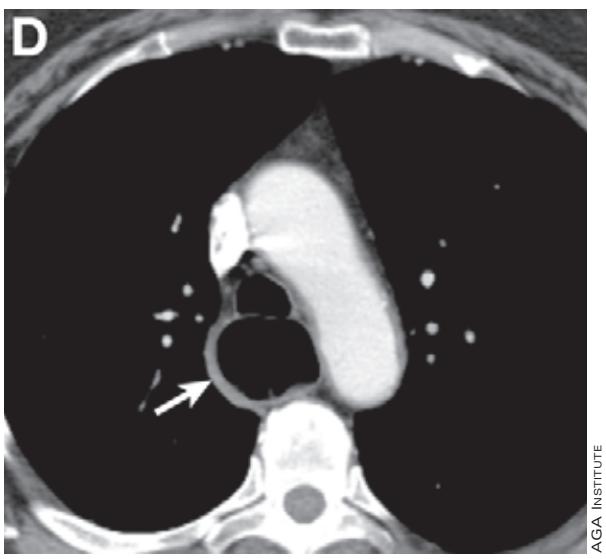
On serial computed tomography chest examinations, the esophagus had appeared normal (Figure A, arrow). Two months later, the esophagus was slightly dilated and contained contrast (Figure B). On examinations 5 and 7 months later, the esophagus had become even more dilated and was fluid or gas filled (Figures C, D). At esophagogastroduodenoscopy, the esophagus was diffusely dilated, without contraction, and with retained food and secretions. The endoscope passed into the stomach without much resistance, and no lesion was seen on forward view or retroflexion at the gastroesophageal junction.

The diagnosis appears on page 18.









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References: 1. IMS Health, NPA Weekly, July 2016. **2.** Rex DK, Di Palma JA, Rodriguez R, McGowan J, Cleveland M. A randomized clinical study comparing reduced-volume oral sulfate solution with standard 4-liter sulfate-free electrolyte lavage solution as preparation for colonoscopy. *Gastrointest Endosc*. 2010;72(2):328-336. **3.** Rex DK, Schoenfeld PS, Cohen J, et al. Quality indicators for colonoscopy. *Gastrointest Endosc*. 2015;81(1):31-53. **4.** SUPREP Bowel Prep Kit [package insert]. Braintree, MA: Braintree Laboratories, Inc; 2012.

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16-00927T August 2016

U.S. training for foreign docs in peril

Visa program *from page 1*

top training spots and jobs as their H-1B applications linger in the system, said Jennifer A. Minear, a Richmond, Va.–based attorney and national treasurer for the American Immigration Lawyers Association.

Changing rules, uncertain futures

Amr Marawan, MD, is not sure if a job offer will fall through or if he will be able to work in the United States at all over the next year.

Dr. Marawan, a native of Cairo, Egypt, will finish his internal medicine residency at the University of Tennessee, Chattanooga, in June and had planned to pursue a cardiology fellowship under a continuation of his J-1 visa. After the 2016 election, he decided instead to take a position as assistant professor of internal medicine at Virginia Commonwealth University in Richmond.

He now faces a conundrum. His J-1 visa expires in June and his position at VCU is slated to start in July, but the premium processing program terminates in April. If forced to wait the typical 6-10 months for standard processing, he may lose the position.

"There's no way we can finish the [approval process] before June," he said. "And now, if we wait and file the H-1B in June, it will take months to get approved. During that time, I cannot work."

Immigration attorneys have been inundated with similar stories, said Adam Cohen, a Memphis attorney. USCIS has delayed premium processing in the past, but not to this extent, he said. While foreign physicians and students are scrambling to file their H-1B petitions before April 3, there is no guarantee that the applications will be expedited, Mr. Cohen added. It's possible USCIS will be unable to get to every application and will simply refund the premium processing fee, he said.

Foreign medical students face rough road

Medical students also may be detoured by the premium processing ban. Students who planned to train under an H-1B visa had to wait until Match Day on March 17 to file their H-1B petitions, Ms. Minear said. There is little chance they can complete all paperwork and state approvals needed in order to submit an H-1B application before April 3.

"What this really means is that physicians effectively cannot do their residencies or fellowships in H-1B status this year because they cannot file the petitions in time for a July 1 start date," Ms. Minear said.

Matthew Shick, JD, government relations director for the Association of American Medical Colleges noted that the premium processing suspension will have a great impact on faculty, scientists, and hospital staff.

Medical students applying for J-1 visas also may experience processing delays because of President Trump's March 6 Executive Order on immigration. A provision in that order increases uniform screening procedures for all visa classes and nationalities, while another provision suspends the Visa Interview Waiver Program.

Taskforce requests carve-out

The IMG Taskforce is urging USCIS to exempt physicians from the pre-

Continued on following page

FLASHBACK TO JULY 2010

2007-**10-Year Anniversary**-2017

In the July 2010 issue of *GI & Hepatology News*, Howard Levy, MD, reviewed a number of strategies for recognizing hereditary colon cancer, specifically Lynch syndrome. At that time, the Evaluation of Genomic Applications in Practice and Prevention (EGAPP) working group had recommended universal molecular tumor testing. The EGAPP recommendation was the first of several ensuing endorsements of universal tumor testing using immunohistochemistry (IHC) or microsatellite instability (MSI) analysis. For example, the AGA Guideline on Diagnosis and Management of Lynch Syndrome (Gastroenterology. 2015;149[3]:777-82) issued a strong recommendation for tumor testing. We have learned about reflexive BRAF or promoter hypermethylation testing and, in some cases, tumor sequencing for double somatic mutations to identify sporadic MSI-high cases. While tumor testing is widely endorsed and is cost effective, implementation and quality control still remain challenges in clinical practice.

In addition to widespread endorsement of tumor testing, there have been a number of important developments in our understanding of Lynch syndrome. A recent publication estimated the prevalence of mismatch-repair gene mutations associated with Lynch syndrome at 1 in 279. Cancer risks in Lynch syndrome are significantly elevated over the general population, and it has become clear that there are distinct risk estimates depending on the gene that is mutated. New risk prediction models, such as PREMM1,2,6, have improved test characteristics over Amsterdam and Bethesda criteria for identification of mutation carriers. The Colorectal Adenoma/Carcinoma Prevention Programme (CAPP) trials have shown that aspirin is chemopreventive in Lynch syndrome. Survival in Lynch syndrome patients who develop colorectal cancer is over 90% based on results from a prospective database. Immune checkpoint inhibitor therapy has been shown to be effective in treatment of metastatic MSI-high colorectal cancer including from Lynch syndrome patients. Immunotherapy has also shown to be effective in patients with biallelic mismatch repair deficiency (BMMRD), a childhood cancer syndrome characterized by brain and gastrointestinal tumors, among others.

More generally, the advent of multigene panel testing by next-generation sequencing has enabled assessment of many genes simultaneously in the evaluation of hereditary colorectal cancer. Two recent studies characterized the contribution of germline mutations in colorectal cancer patients underscoring the impact of known and emerging genes (JAMA Oncol. 2016; Dec 15 [Epub ahead of print]; J Clin Oncol. 2017; Jan 30 [Epub ahead of print]). The field has made substantial progress since 2010, and the future looks very bright for continued advancement in the recognition and management of hereditary colorectal cancer.


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Patients given a choice of screening methods had better adherence than those referred for one specific test, said Dr. John M. Inadomi.

Patient Choice Can Promote CRC Screening

BY MICHELE SULLIVAN
Elsevier Global Medical News

NEW ORLEANS — Patients who are given a choice between different screening methods are significantly more likely to follow through on colorectal cancer screening than are those told to undergo either colonoscopy or fecal occult blood testing.

"We usually assume that the presence of choices can paralyze people into indecision, and instead of making the choice, they defer," said Dr. John M. Inadomi, AGAF, at the annual Digestive Disease Week.

"We were concerned that, in the case of colorectal screening, giving a choice of screening methods might actually lead to noncompliance," he explained.

Dr. Inadomi, who led the study while at the University of California, San Francisco, found just the opposite when he and his colleagues conducted a randomized trial with 1,000 patients who were at average risk of colorectal cancer.

The participants were randomized to one of three screening recommendations: fecal occult blood testing (FOBT), colonoscopy, or the individual patient's choice between the two. The investigators then followed each group for 12 months to evaluate compliance with the screening.

The study was conducted in San Francisco, and the participants reflected the city's diversity: 34% were Latino, 30% were Asian, 18% were black, 15% were white, and 3% were other. A total of 53% were women.

The investigators removed as many barriers to adherence as possible by reducing or eliminating cost, providing rides, giving instructions for preparation in the patient's preferred language, allowing direct screening access without a GI referral, and limiting wait time to 2 weeks.

Overall, 65% of patients followed through on their recommended screening. But there were significant differences in

See **Patient Choice** • *page 11*

Infliximab With Azathioprine Found Effective in Crohn's

Clinical remission rates were highest.

BY MARY ANN MOON
Elsevier Global Medical News

Infliximab in combination with azathioprine is better at inducing clinical remission than is infliximab alone, which in turn is superior to azathioprine monotherapy for patients with moderate to severe Crohn's disease, according to a report in the New England Journal of Medicine.

Combining infliximab and azathioprine is the most effective of the three approaches, said Dr. Jean Frédéric Colombel of the Université Lille Nord de France and his associates.

"Treatment guidelines generally recommend initiating treatment with first-line agents, including mesalamine and systemic corticosteroids, followed by azathioprine, with anti-TNF therapies (such as infliximab) reserved for patients in whom conventional therapies have failed," the investigators noted.

They compared the effectiveness of infliximab alone, infliximab plus azathioprine, and azathioprine alone in patients who were corticosteroid dependent, who were being considered for a second course of systemic corticosteroids within 1 year, or who had not responded to mesalamine or budesonide treatment.

The study subjects were naive to azathioprine, 6-mercaptopurine, methotrexate, and all anti-TNF agents.

In the double-blind trial conducted at 92 medical centers in Europe, the United States, and Israel, adults with moderate to severe Crohn's disease were randomly assigned to receive infusions of infliximab plus daily oral placebo capsules (169 patients), oral azathioprine capsules plus placebo infusions (170 patients), or combined active therapies (169 patients) for 30 weeks. They were then

See **Crohn's** • *page 10*

INSIDE

Test Detects Minimal Encephalopathy

BY BRUCE JANCIN
Elsevier Global Medical News

VIENNA — The same neuropsychologic test used by National Football League teams to assess players for the effects of concussion appears to be effective for diagnosing minimal hepatic encephalopathy.

The Immediate Post-Concussion Assessment and Cognitive Testing (ImPACT v4.0) is a well-validated, computer-based neuropsychologic test that takes about 10 minutes.

It's user friendly, billable as a neuropsychologic test, available in 13 languages, can be administered by anybody in the office, and produces immediate results without need for a clinical neuropsychologist to interpret the scores, Dr. Michel H. Mendler explained at the annual International Liver Congress sponsored by the European Association for the Study of the Liver.

"ImPACT could become a new standard for minimal hepatic encephalopathy testing, both in routine clinical practice and to evaluate treatments,"

See **Test** • *page 2*

Sonia S. Kupfer, MD, is assistant professor of gastroenterology, director of the Gastrointestinal Cancer Risk and Prevention Clinic at the University of Chicago, and an Associate Editor of GI & Hepatology News.

LETTER FROM THE EDITOR: Hang on for the ride


DR. ALLEN

Since our last edition of *GI & Hepatology News*, GOP leadership has released the American Health Care Act, a bill that would repeal and replace the Affordable Care Act. This bill, 7 years in the making, is opposed by most medical organizations, all Democrats, and a significant number of conservative Republicans. The Congressional Budget Office has predicted loss of insurance for 24 million Americans coupled to a reduction in the Federal deficit of $337 billion (each over 10 years) for the initial bill (at press time the bill was being modified). The wealthiest 0.1% of income earners would see an average tax reduction of $197,000. At press time, is was not clear that the bill would pass the House and it appears to have even less chance in the Senate.

In other news, the AGA has released a superb new practice guide on management of obesity aimed at community practicing gastroenterologists. We also read about the alarming increase in rectal cancer rates in younger patients (AGA Institute Vice President David A. Lieberman, MD, AGAF, adds a commentary). You will meet the new AGA Governing Board members and learn more about the upcoming Digestive Disease Week®. Don't miss articles about arsenic and mercury in gluten-free diets and how gut yeast may exacerbate IBD (perhaps we can't scoff at the "yeast hypothesis" anymore). Associate Editor Megan A. Adams MD, JD, MSc, alerts us about covert recording of our patient discussions.

Finally, a late addition to page 1 concerns the impact of slowing H-1B visas, a process used by many foreign physicians who are attempting to secure faculty or community practice positions. The effects will be chilling and reduce access to care, especially in rural communities.

For anyone motivated by current events to contact your political representatives, remember the Advocacy section of AGA's website (www.gastro.org/take-action).

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

Continued from previous page

mium processing ban. In a March 8 letter to the agency, the task force outlined examples of how IMGs benefit the country and described how application delays could harm patient care.

"The hope is that this would encourage a review and a rethink of that shift and that upon that review, H-1B cap exempt petitions would across the board be considered for continued premium processing," Ms. Harris said in an interview.

A group of U.S. senators also has requested that USCIS reconsider the premium processing suspension as it relates to physicians. Sen. Amy Klobuchar (D-Minn.) said that the suspension will exacerbate physician shortages, particularly in rural areas.

"USCIS will be monitoring this workload during the coming months and will evaluate any time-sensitive impacts prior to the resumption of premium processing services," Ms. Gwathmey said in an interview.

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FROM THE AGA JOURNALS

Infectious enteritis quadrupled short-term risk of IBS

BY AMY KARON
Frontline Medical News

More than 10% of patients developed irritable bowel syndrome (IBS) within a year after infectious enteritis, which gave them a more than fourfold greater risk than that of controls, according to a systematic review and meta-analysis of 45 studies reported in the April issue of Gastroenterology (doi: 10.1053/j.gastro.2016.12.039).

"Protozoal and bacterial enteritis confer the greatest overall risk, although the magnitude of increased risk diminishes with time since exposure," Fabiane B. Klem, MD, and Akhilesh Wadhwa, MD, of Mayo Clinic in Rochester, Minn., and their associates wrote in the April issue of Gastroenterology. Other significant risk factors for postinfectious IBS (PI-IBS) included female sex, clinically severe infections, antibiotic therapy, and comorbid psychological distress, they said.

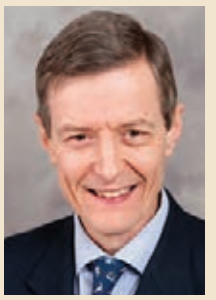
PI-IBS can last at least a decade after resolution of campylobacteriosis, shigellosis, salmonellosis, giardiasis, and norovirus infections, even when patients have no other risk factors for IBS, the researchers noted. To update and expand the most recent meta-analysis of this topic (Aliment Pharmacol Ther. 2007;26:535-44), the investigators searched Ovid Medline, EMBASE, Web of Science, and Cochrane Database of Systematic Reviews for studies published from 2006 through Aug. 31, 2015. This search yielded 45 studies, including 30 studies comparing infected patients with controls, who were usually matched by age, sex, and geographic location.

In all, 10.1% of patients with infectious enteritis developed IBS in the next 12 months (95% confidence interval, 7.2-14.1) – a 4.2-fold increase in risk, compared with that of controls (risk ratio, 4.2; 95% CI, 3.2-5.7). This risk subsequently dropped, but remained significantly elevated (RR, 2.3; 95% CI, 1.8-3.0), compared with controls. "Of patients with enteritis caused by protozoa or parasites, 41.9% developed IBS; of patients with enteritis caused by bacterial infection, 13.8% developed IBS," the researchers emphasized.

Patients with these infections remained at elevated risk of PI-IBS even after 1 year. Viral enteritis

Continued on page 10

The phenomenon of IBS developing after a bout of gastroenteritis was first reported in 1950. The authors of this excellent meta-analysis identified 45 studies, 29 in the last decade, including a total of 21,421 participants with exposure to gastroenteritis. The pooled prevalence for PI-IBS was 11.5% (95% CI, 8.2%-15.8%) but with considerable heterogeneity, which the authors attempted to explain by subgroup analyses.


DR. SPILLER

The authors report that protozoal infection seems to have a higher rate of PI-IBS than bacterial or viral infection, though some caution is warranted, since these figures rely on reports from just one outbreak of giardiasis in Bergen, Norway (Scand J Gastroenterol. 2012;47:956-61). However, if true, this might suggest that a different immune response could be responsible, a feature that others have suggested might predispose particular individuals to PI-IBS (Gut. 2016;65[8]1279-88).

Pediatric series showed similar risk ratios to adults at 4.1 versus 3.8, respectively. Age strongly influences immune response and older age was protective in several studies, but other studies found no effect. This may relate to an inadequate age range since the differences were most marked in those older than 60 years (BMJ. 1997;314:779-82).

The meta-analysis confirms the consistent increased risk in female patients (odds ratio, 1.69), anxiety (OR, 1.97), and somatization (greatest RR, 4.05), all common risks for the development of IBS but not specific to PI-IBS.

Infection produces a striking increase in gut permeability (Gut. 2000;47:804-11), a feature of IBS whose molecular basis has been demonstrated by a series of elegant studies (Gut. 2017 Jan 12 [Epub ahead of print]; Gut. 2015;64:1379-88) demonstrating altered tight junctions and immune activation in IBS with diarrhea. The authors found treatment with antibiotics increased the risk of PI-IBS but whether this is attributable to confounding by indication is unclear.

This meta-analysis indicates that PI-IBS potentially is the most common cause of IBS, given that both the Centers for Disease Control and Prevention in the United States and community surveys in the United Kingdom (BMJ. 1999;318:1046-50) indicate that gastroenteritis affects around one in five of the population each year. If the incidence of PI-IBS is around 10%, modeling suggests PI-IBS could account for the majority of new cases (J Neurogastroenterol Motil. 2012;18:200-4).

Robin Spiller, MD, is professor of gastroenterology, NIHR Nottingham Digestive Diseases Biomedical Research Unit, Nottingham Digestive Diseases Centre, University of Nottingham (England). He has no relevant conflicts of interest.

Point-of-care assay caught acetaminophen toxicity

BY AMY KARON
Frontline Medical News

A rapid point-of-care assay for acetaminophen-related liver toxicity had a sensitivity of 100% and a specificity of 86%, compared with etiologic diagnosis, based on the results of a multicenter study published in the April issue of Clinical Gastroenterology and Hepatology.

The test might help guide treatment decisions for these patients in the emergency department and intensive care unit, said Dean W. Roberts, PhD, of the University of Arkansas, Little Rock, and his associates.

About 45% of acute liver failure cases in the United States stem from acetaminophen toxicity, but the diagnosis can be hard to confirm because the drug has a short half-life and patients often cannot or will not report an overdose, which also may consist of multiple exposures, limiting the interpretability of the Rumack nonogram. High-pressure liquid chromatography with electrochemical detection (HPLC-EC) accurately detects acetaminophen-protein adducts (3-[cysteine-S-yl] acetaminophen) released by lysed hepatocytes into the peripheral circulation, but this test requires specialized equipment and skilled personnel, the researchers noted (Clin Gastroenterol Hepatol. 2016 Sep 15. doi: 10.1016/j.cgh.2016.09.007).

Therefore, they developed AcetaSTAT, a competitive lateral flow immunoassay designed to detect acetaminophen-protein adducts in 27 minutes. To compare its performance with that of clinical diagnosis and HPLC-EC results, they evaluated charts and serum samples from 19 healthy adults, 33 adults with acetaminophen-induced liver failure from the Acute Liver Failure Study Group, and 29 registry members of similar age and sex who were considered to have nonacetaminophen acute liver failure. Based on past research, the investigators set a positive HPLC-EC test threshold of 1.0 nmol or greater, which corresponded to a band intensity of 1,200 on AcetaSTAT.

The point-of-care assay was positive in all 33 patients diagnosed with acetaminophen toxicity, for a test sensitivity of 100%, the researchers reported. The median band amplitude for cases was 584 (range, 222-1,027), significantly lower

Continued on following page

FROM THE AGA JOURNALS

Open-capsule PPIs linked to Roux-en-Y ulcer healing

BY AMY KARON
Frontline Medical News

The use of proton pump inhibitors in opened instead of closed capsules was associated with a significantly shorter median healing time among patients who developed marginal ulcers after Roux-en-Y gastric bypass, in a single-center retrospective cohort study.

In contrast, the specific class of proton pump inhibitor (PPI) did not affect healing times, wrote Allison R. Schulman, MD, and her associates at Brigham and Women's Hospital, Boston. The report is in the April issue of Clinical Gastroenterology and Hepatology (doi: 10.1016/j.cgh.2016.10.015). "Given these results and the high prevalence of marginal ulceration in this patient population, further study in a randomized controlled setting is warranted, and use of open-capsule PPIs should be considered as a low-risk, low-cost alternative," they added.

Roux-en-Y gastric bypass is one of the most common types of gastric bypass surgeries in the world, and up to 16% of patients develop postsurgical ulcers at the gastrojejunal anastomosis, the investigators noted. Acidity is a prime suspect in these "marginal ulcerations" because bypassing the acid-buffering duodenum exposes the jejunum to acid from the stomach, they added. High-dose PPIs are the main treatment, but there is no consensus on the formulation or dose of therapy. Because Roux-en-Y creates a small gastric pouch and hastens small-bowel transit, closed capsules designed to break down in the stomach "even may make their way to the colon before breakdown occurs," they wrote.

They reviewed medical charts from patients who developed marginal ulcerations after undergoing Roux-en-Y gastric bypass at their hospital from 2000 through 2015. A total of 115 patients received open-capsule PPIs and 49 received intact capsules. All were followed until their ulcers healed.

For the open-capsule group, median time to healing was 91 days, compared with 342 days for the closed-capsule group (*P* less than .001). Importantly, capsule type was the only independent predictor of healing time (hazard ratio, 6.0; 95% confidence interval, 3.7-9.8; *P* less than .001) in a Cox regression model that included other known correlates of ulcer healing, including age, smoking status, the use of nonsteroidal anti-inflammatory drugs, *Helicobacter pylori* infection, the length of the gastric pouch, and the presence of fistulae or foreign bodies such as sutures or staples.

The use of sucralfate also did not affect time to ulcer healing, reflecting "many previous studies showing a lack of definitive benefit to this medication," the researchers said. The findings have "tremendous implications" for health care utilization, they added. Indeed, patients who received open-capsule PPIs needed significantly fewer endoscopic procedures (median, 1.2 versus 1.8; *P* = .02) and used fewer health care resources overall ($7,206 versus $11,009; *P* = .05) compared with those prescribed intact PPI capsules.

This study was limited to patients who developed ulcer symptoms and underwent repeated surveillance endoscopies after surgery, the researchers noted. Selection bias is always a concern with retrospective studies, but insurers always covered both types of therapy and the choice of capsule type was entirely up to providers, all of whom consistently prescribed either open- or closed-capsule PPI therapy, they added.

The investigators did not acknowledge external funding sources. Dr. Schulman and four coinvestigators reported having no competing interests. One coinvestigator disclosed ties to Olympus, Boston Scientific, and Covidien.

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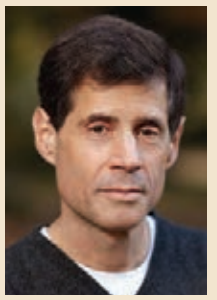
Proton pump inhibitors (PPIs) are frequently employed to treat marginal ulcers after Roux-en-Y gastric bypass (RYGB). In a retrospective study, Schulman et al. compared intact vs. "open" PPI capsules. As justification, the authors indicate that PPI capsules pass very distally before they break down in RYGB patients, sometimes even making their way to the colon – although they provide no supporting reference for this statement. They state that "this may be overcome by use of a soluble form of PPI," but don't state what is meant by "soluble PPI" or how the open-capsule PPI was delivered. Among the PPIs they reported using to compare intact vs. open capsules was Protonix [pantoprazole] which is not produced as a capsule, and soluble Prevacid [lansoprazole], which is an orally disintegrating tablet that should provide characteristics similar to an "open capsule." PPI capsules provide PPI in enteric-coated granules, which are designed to protect the PPI from acid degradation in the stomach of individuals with intact gastrointestinal tracts and allow more of the PPI dose to reach the small intestine where it is absorbed. If capsules really fail to release their enteric-coated granules until very distally in RYGB patients, bypassing this step to allow earlier release of PPI makes intuitive sense; formulations such as suspensions and rapidly disintegrating tablets that deliver enteric-coated granules without capsules are currently available. However, if this is an issue, administering a suspension of uncoated PPI with bicarbonate potentially might be the most attractive option, given more rapid absorption than PPI delivered as enteric-coated granules.



DR. LAINE

Loren Laine, MD, AGAF, professor of medicine, digestive diseases, Yale University, New Haven, Conn. He has no conflicts of interest.

Continued from previous page

than that for patients with nonacetaminophen acute liver failure (3,678; range, 394-8,289; *P* less than .001) or for controls (8,971; range, 5,151-11,108; *P* less than .001). Band amplitude correlated inversely with adduct levels because AcetaSTAT is a competitive immunoassay – the presence of adducts decreases reactions at the test band, the investigators reported.

AcetaSTAT results were negative for 25 of 29 patients who were initially diagnosed with nonacetaminophen liver failure, for a test specificity of 86%, a positive predictive value of 89%, and a negative predictive value of 100%. Among the remaining four "false positives," three tested near or above the toxicity threshold on HPLC-EC and were considered positive after further review, the investigators said. The fourth false-positive case was HPLC-EC–negative autoimmune hepatitis.

AcetaSTAT might not catch cases very early after acetaminophen overdose or that have only mild toxicity, the researchers noted. Nonetheless, it can help guide treatment decisions "at the point of clinical care," they said. "Because the survival rate of acetaminophen acute liver failure is more favorable than that of other causes of acute live failure, assay results could impact future physician referral patterns and reduce medical costs associated with additional tests to determine the etiology of liver injury."

The National Institute of Diabetes and Digestive and Kidney Diseases funded the study. Dr. Roberts and two coinvestigators are part owners of Acetaminophen Toxicity Diagnostics and have submitted a patent application for the AcetaSTAT serum assay used in this study. There were no other disclosures.

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FROM THE AGA JOURNALS

Bacterial DNA predicted infections with prednisolone

BY AMY KARON
Frontline Medical News

High baseline levels of circulating bacterial DNA increased the odds of serious infections by nearly fivefold in patients receiving prednisolone for severe alcoholic hepatitis, even after controlling for MELD score and white blood cell count, investigators reported in the April issue of Gastroenterology (2016 Dec 31. doi: 10.1053/j.gastro.2016.08.029).

"Patients with severe alcoholic hepatitis given prednisolone are at greater risk for developing serious infections and infections after treatment than patients not given prednisolone, which may offset its therapeutic benefit," Nikhil Vergis, MD, and his associates wrote in Gastroenterology. "Level of circulating bacterial DNA before treatment could identify patients at high risk of infection if given prednisolone, which could be used to select therapies for patients with severe alcoholic hepatitis."

Guidelines recommend prednisolone for managing severe alcoholic hepatitis (SAH), although this medication nearly doubled the risk of serious infections in the randomized, double-blind STOPAH (Steroids or Pentoxifylline for Alcoholic Hepatitis) trial (N Engl J Med. 2015;372:1619-28).

To further explore rates and predictors of infections in STOPAH, the researchers analyzed longitudinal data on incident infections for 1,092 trial participants who received either prednisolone (40 mg daily) or pentoxifylline (400 mg three times daily). For 731 patients, they also examined whether baseline circulating levels of 16s ribosomal bacterial DNA were associated with infections.

A total of 135 patients (12%) had an infection at baseline, 251 (23%) developed infections during treatment, and 89 (8%) developed infections after treatment, the investigators reported. Prednisolone therapy was not associated with infections during treatment, but was associated with a nearly 30% rise in the odds of serious post-treatment infections compared with pentoxifylline (odds ratio, 1.27; 95% confidence interval, 1.27-2.92; *P* = .002). Prednisolone recipients who developed infections were significantly more likely to die within 90 days than those who did not, even after controlling for end-stage liver disease or Lille score (OR, 2.5; 95% CI, 1.4-4.3; *P* = .002). Antibiotic therapy appeared to significantly reduce the risk of mortality among infected prednisolone recipients (13% vs. 52%; OR, 0.13; 95% CI 0.04-0.47; *P* = .002).

There was "a striking association between bacterial DNA and the development of infection within 7 days in patients treated with prednisolone," the researchers reported. These patients had a median baseline circulating DNA level of 20.9 pg/mL, while prednisolone recipients who did not develop infections had a median baseline bacterial DNA level of 8.3 pg/mL (*P* = .004). Bacterial DNA predicted infections with an area under receiver operating characteristic curve of 0.70 (95% CI, 0.58-0.83; *P* = .003), which substantially exceeded the curve for white blood cell count (0.58).

A cut-off value of 18.5 pg/mL was 80% specific for predicting infection within 7 days of prednisolone therapy, the investigators also reported. Bacterial DNA level did not, however, predict infections within 7 days of pentoxifylline therapy, and pentoxifylline was not linked with infections that were serious, infections during treatment, or infections after treatment. (*P* =.08).

Using bacterial DNA levels to guide prednisolone prescription also appeared to reduce 90-day mortality in this patient population, although the effect achieved borderline statistical significance, the researchers said. "Larger prospective randomized studies are needed to definitely report whether bacterial DNA–guided therapy can [have an] impact on mortality in severe alcoholic hepatitis, and perhaps in other acute inflammatory conditions" in which immunosuppression is required, they added.

The National Institute for Health Research and Wellcome Trust and Medical Research Council provided funding. Dr. Vergis and 10 coinvestigators disclosed no conflicts of interest. Senior author Mark Thursz, MD, and one coinvestigator disclosed ties to Gilead, Bristol-Myers Squibb, AbbVie, Abbott, and Norgine.

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also significantly increased the risk of PI-IBS, but risk dropped to baseline levels after a year.

Among 10 pooled studies of IBS subtypes, 46% of patients had mixed IBS, 39% had diarrhea-predominant IBS, and 15% had constipation-predominant IBS. Female sex doubled the odds of PI-IBS (odds ratio, 2.2; 95% CI, 1.6-3.1) in 11 pooled studies. Significant clinical risk factors for PI-IBS included diarrhea lasting more than 7 days (eight studies; OR, 2.6; 95% CI, 1.5-4.6), bloody stool (four studies; OR, 1.9; 95% CI, 1.1-3.0), and antibiotic therapy during infectious enteritis (seven studies; OR, 1.7; 95% CI, 1.2-2.4).

Multiple reports linked PI-IBS to clinical psychological distress at the time of infectious enteritis. Specific risk factors included depression based on the Hospitalization Anxiety and Depression Scale (five studies; OR, 1.5; 95% CI, 1.2-1.9), anxiety based on the Hospital Anxiety and Depression Scale (four studies; OR, 2.0; 95% CI, 1.3-2.9), somatization (four studies; OR, 4.1; 95% CI, 2.7-6.0), and neuroticism (two studies; OR, 3.3; 95% CI, 1.6-6.6). Isolated studies also implicated hypochondriasis, extroversion, negative illness beliefs, stress, sleep disturbance, and adverse life events in the preceding year, the researchers said.

They found no evidence of publication bias, but noted a substantial amount of heterogeneity among studies.

The National Institutes of Health and the American Gastroenterological Association funded the work. The investigators reported having no conflicts of interest.

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AGA announces new Governing Board members

AGA is pleased to announce new AGA Institute Governing Board designate-elects for 2017-2018.

Hashem B. El-Serag, MD, MPH, AGAF, is the vice president-elect designate. Dr. El-Serag is professor and chair of medicine, Baylor College of Medicine, Houston, TX. He is the editor of *Clinical Gastroenterology and Hepatology* until July 2017, and serves on the AGA Institute Leadership and Publications Committee.

Lawrence S. Kim, MD, AGAF, is the secretary/treasurer-elect designate. Dr. Kim is a partner at South Denver Gastroenterology, P.C., Littleton, CO. He currently serves on the AGA Institute Clinical Practice Updates, Audit, and Finance and Operations Committees. Dr. Kim has previously served as an AGA Institute Private Practice Councillor.

Dr. El-Serag and Dr. Kim begin their terms immediately following Digestive Disease Week® (DDW) 2017.

ginews@gastro.org


DR. KIM


DR. EL-SERAG

New joint Crohn's & colitis congress to start next year

AGA and the Crohn's & Colitis Foundation are partnering to cosponsor a new annual conference for health care professionals and researchers. By joining the nation's leading IBD patient organization with the premier GI professional organization, this will be the must-attend IBD conference, bringing state-of-the-art care together with the latest research to advance prevention, treatment, and cures for IBD patients.

Save the date – Jan. 18-20, 2018, in Las Vegas. Get ready to expand your knowledge and network with other leaders! Stay tuned for our website launch and more details coming this spring.

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A gift in your will: Getting started

A simple, flexible and versatile way to ensure The AGA Research Foundation can continue our work for years to come is a gift in your will or living trust, known as a charitable bequest. To make a charitable bequest, you need a current will or living trust.

Your gift can be made as a percentage of your estate. Or you can make a specific bequest by giving a certain amount of cash, securities, or property. After your lifetime, the AGA Research Foundation receives your gift.

It's simple – just a few sentences in your will or trust are all that is needed. The official bequest language for the AGA Research Foundation is: "I, [name], of [city, state, ZIP], give, devise, and bequeath to the AGA Research Foundation [written amount or percentage of the estate or description of property] for its unrestricted use and purpose."

When planning a future gift, it's sometimes difficult to determine what size donation will make sense. Emergencies happen, and you need to make sure your family is taken care of first. Including a bequest of a percentage of your estate ensures that your gift will remain proportionate no matter how your estate's value fluctuates over the years.

Contact us for more information at foundation@gastro.org or visit http://gastro.planmylegacy.org/.

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AGA offers free patient education tools on IBS

Approximately 35 million Americans are affected by irritable bowel syndrome (IBS). April is IBS Awareness Month, which is a perfect time to ensure you have the resources to care for your IBS patients.

To help your IBS patients, AGA provides credible, accessible education information on the following topics in English and Spanish.

- What is irritable bowel syndrome?
- Symptoms
- Getting tested
- Newly diagnosed
- Treatment
- Complications

Visit www.gastro.org/IBS to access our patient materials.

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See you at DDW and the AGA Postgraduate Course

AGA looks forward to seeing our members at Digestive Disease Week® (DDW) 2017, May 6-9 in Chicago. If you're not yet registered for the meeting, visit www.ddw.org to reserve your spot.

Please also join us for the 2017 AGA Postgraduate Course. The 2017 course is set for May 6 and 7, 2017, in conjunction with DDW. This 1.5-day course is designed to help you step beyond basic learning and get the full scope of GI advances. You will measure, learn, and apply the newest advances that will help you make confident decisions for your patients.

The course will feature six general sessions:

- Hot Topics (abdominal pain and opioid therapy, microbiome and obesity, viral hepatitis, and fecal microbiota transplantation)
- IBD: It's a Beautiful Day (IBD) to discuss Inflammatory Bowel Disease (IBD)
- The Biliary Tree and Pancreas
- Love the Liver
- All Guts and Glory: Esophagus, Stomach and Small Intestine
- Bringing Up the Rear: Disorders of the Colon and Rectum

The course will also include 29 breakout sessions. These focused, small-group sessions allow you to delve deeper into specific clinical topics and provide direct access to internationally renowned faculty.

To learn more about the AGA Postgraduate course, visit pgcourse.gastro.org.

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DDSEPeight
Digestive Diseases Self-Education Program

Quick quiz

Q1. A 25-year-old woman presents with postprandial regurgitation, typically after dinner. She initially had both heartburn and regurgitation. After she started esomeprazole 40 mg once a day 8 weeks ago, her heartburn completely resolved. An upper endoscopy, performed due to ongoing regurgitation symptoms, reveals a normal esophagus, and a 2-cm sliding hiatal hernia.

Which of the following agents can provide adjunctive benefit?
A. Baclofen
B. Metoclopramide
C. Hyoscyamine
D. Sucralfate
E. Cholestyramine

Q2. A 56-year-old woman presents with epigastric pain and is found to have a 3-cm submucosal mass with thickened rugal folds in the gastric body. Biopsies of the mass show mucosa-associated lymphoid tissue (MALT) lymphoma. There is no evidence of *Helicobacter pylori* infection in the biopsies.

What is the best next step in this patient's care?
A. Refer to oncology for chemotherapy
B. Upper GI radiographic study
C. Perform *H. pylori* breath test
D. Measure gastric pH
E. Refer for surgical resection

The answers are on page 26.

GIs are well suited to treat obesity

Obesity *from page 1*

thor of the practice guide, Andres J. Acosta, MD, PhD.

"Every single gastroenterologist is at the front line of this obesity epidemic. Before patients develop diabetes or joint problems or cardiovascular disease, they are already in our clinics, they already

DR. STREETT

have [gastroesophageal reflux disease], they have nonalcoholic fatty liver disease, they have colon cancer – and those conditions present even earlier than the other complications of obesity," said Dr. Acosta of the Mayo Clinic, Rochester, Minn.

The guide is a model for addressing obesity – the root cause of many of these conditions – rather than simply treating its symptoms, he added.

The approach to obesity management promoted by POWER involves four phases along a continuum of care: assessment, intensive weight loss intervention, weight stabilization and reintensification when needed, and prevention of weight regain.

It is designed for flexibility across different practice types and different patient needs, according to Sarah Streett, MD, AGAF, who is also an author of the practice guide and the episode-of-care framework (Episode-of-Care Framework for the Management of Obesity: Moving Towards High Value, High Quality Care Model). The episode-of-care framework was developed to "help gastroenterology practices assess their ability to participate in and implement an episode of care for obesity, and understand the essentials of coding and billing for these services," according to an AGA press release.

Lifestyle changes are the cornerstones of obesity management and maintenance of weight loss, but the POWER model includes much more, as it incorporates guidance on the use of pharmacotherapy, bariatric endoscopy, and surgery.

"We tried to make it extremely simple, bringing it down to the busy clinician level," Dr. Acosta said. "We want to be able to embrace and tackle obesity ... in a very straightforward manner."

Gastroenterologists shouldn't be afraid of taking on obesity, he added.

"We feel comfortable managing extremely complicated medications, so we should be able to handle the obesity medications. We are already endoscopists ... so we want all gastroenterologists to say, 'I can do this, too; I can incorporate this into my practice,' " he said.

Further, gastroenterologists already have a relationship with bariatric surgeons, so referring those with obesity for surgery if appropriate is also simple, he added.

When it comes to the four phases of care, each should be addressed separately using the best evidence available. Realistic goals should be set, and only when those goals are met should care move to the next phase, according to the guide. Learn how to implement the AGA Obesity Practice Guide at www.gastro.org/obesity.

The assessment phase should include a medical evaluation to identify underlying etiologies, screen for causes of secondary weight gain, and identify related comorbidities. A nutrition evaluation should focus not only on nutritional status and appetite, but also on the patient's relationship with food, food allergies and intolerances, and food environment. A physical activity/exercise evaluation should explore the patient's activity level and preferences, as well as limiting factors such as joint disease.

"Every single gastroenterologist is at the front line of this obesity epidemic. Before patients develop diabetes or joint problems or cardiovascular disease, they are already in our clinics."

A psychosocial evaluation is particularly important, as behavioral modification is a critical component of successful obesity management, and some patients – such as those with a low score on the weight Efficacy Lifestyle Questionnaire Short-Form – may benefit from referral to a health care professional experienced in obesity counseling and behavioral therapy.

Gastroenterologists already work with other specialists, including nutritionists, psychiatrists, and psychologists within their institutions and communities, so the POWER model is an extension of that.

"That's what this proposes – a multidisciplinary team effort," he said.

The approach to treatment should be based on the findings of these assessments.

"Physicians should discuss all the appropriate options and their expected weight loss, potential side effects, and figure in the patient's wishes and goals. Furthermore, physicians should recognize special comorbidities that may favor one intervention over another," the authors wrote.

The intensive weight loss intervention phase should be based on modest initial weight loss goals, which increase the likelihood of success, increase patient confidence, and encourage ongoing efforts to lose weight. Further, modest weight loss vs. larger amounts of weight loss is more easily achieved and maintained. In addition to lifestyle changes, an evaluation of whether other interventions are needed is important, particularly in patients with weight regain or plateaus in weight loss.

The weight stabilization and intensification therapy for relapse phase is essential to prevent weight regain and its associated consequences. This phase introduces patients to the attitudes and behaviors that are likely to lead to long-term maintenance of weight loss, the authors note.

The prevention of weight regain phase – a maintenance phase – is unique among obesity care guidelines, and is a critical component of obesity management, Dr. Acosta said.

"Helping patients lose weight and keep it off requires a comprehensive and sustained effort that involves devising an individualized approach to diet, behavior, and exercise," he and his colleagues wrote.

In addition to detailed steps and tips for moving through this care cycle, the POWER guide also details the various tools to facilitate adherence to a healthier diet and lifestyle. Various medications, including phentermine, extended-release phentermine/topiramate, lorcaserin, and liraglutide are described, as are various types of bariatric endoscopy and bariatric surgery.

A section on addressing the unique needs of obese children and adolescents is also included in the guide for those gastroenterologists who treat children.

"Obesity really begins in childhood, so it is a pediatric disease in its origin, so it was important to us to incorporate issues unique to children for our pediatric GI colleagues," Dr. Streett said.

Importantly, the practice guide was developed with input from the Society of American Gastrointestinal and Endoscopic Surgeons, The Obesity Society, the Academy of Nutrition and Dietetics, and the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition. And the program has been endorsed with additional input by the American Society for Gastrointestinal Endoscopy, American Society for Metabolic and Bariatric Surgery, American Association for the Study of Liver Diseases, and the Obesity Medicine Association.

"Obesity is something that has physiological, nutritional, dietetic, socioeconomic, and behavioral aspects, and we need to have a multipronged approach for success."

This collaborative approach is also unique among existing guidelines, and is important, given the need for practitioners across the care spectrum to work together to address obesity, she said.

"What we've been doing [individually] hasn't worked successfully, so that is something that people recognize in the field of medicine: Obesity is something that has physiological, nutritional, dietetic, socioeconomic, and behavioral aspects, and we need to have a multipronged approach for success. We need patients to be hearing similar messages and having their care integrated," she said, adding that "as we move toward a value-based schema, this is the perfect disorder to address in that way."

Dr. Acosta is a stockholder of Gila Therapeutics and serves on the scientific advisory board or board of directors of Gila Therapeutics, Inversago, and General Mills. Dr. Streett reported having no disclosures.

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GI & HEPATOLOGY NEWS

THE OFFICIAL NEWSPAPER OF THE AGA INSTITUTE

Colorectal tumors: ESD passes long-term test

BY JIM KLING
Frontline Medical News

Endoscopic submucosal dissection (ESD) of superficial colorectal tumors has a favorable long-term outcome, with 94.6% overall survival and 100% disease-specific survival at a median 79 months of follow-up, reported Kenjiro Shigita, MD, of the department of gastroenterology and metabolism, Hiroshima (Japan) University Hospital, and his associates.

The technique is more complicated than endoscopic mucosal resection, but continued advances in the technology and increasingly available training have made it safer than it was, Dr. Shigita and associates wrote (Gastrointest Endosc. 2017. doi: 10.1016/j.gie.2016.07.044).

"This is a provocative study that demonstrates the long-term effectiveness of endoscopic submucosal dissection of superficial colon cancers," said John I. Allen, MD, MBA, AGAF, professor of medicine at the University of Michigan, Ann Arbor, in an interview. He emphasized that the technique can be used successfully only by adequately trained, skilled endoscopists.

Dr. Shigita and associates analyzed data from 222 patients (224 tumors) at their institution for a minimum of 5 years, or until death (median 79 months). Overall survival was 94.6%; disease-specific survival was 100%.

Patients received follow-up colonoscopy at 1 year if they had a histologic complete resection, defined as horizontal margin negative and vertical margin negative. Those with a histologic positive margin underwent additional colonoscopies at 6 months and 1 year following the ESD procedure.

The en bloc resection rate was 89.7% (201/224), the histologic complete resection rate was 85.7% (192/224), and the R0 resection rate was 83.0% (186/224). R0 was defined as histologic complete resection and no risk of lymph node metastasis as determined by histology.

Delayed bleeding occurred in 6.3% of cases (14/224) and perforation in 5.4% (12/224). All of the adverse events were successfully managed during the procedure.

In 201 tumors, no further surgical resection was performed. In this sample, the local recurrence rate was 1.5%, and none were metastatic. Of these procedures, 179 were en bloc; 22 were piecemeal. One of the en bloc procedures had a recurrence (0.6%), compared with two of the piecemeal procedures (9.1%, $P = .038$).

The study is limited by the fact that it is retrospective and was performed at a single center; the authors stressed the importance of surveillance. "The possibility of local recurrence should be taken into account after piecemeal resection or histologic incomplete resection, and the likelihood of metachronous tumors should be considered," they wrote.

The study was funded by the Japan Agency for Medical Research and Development. The authors reported having no financial conflicts. Dr. Allen reported having no financial conflicts.

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IgG4-related disease can strike any organ system

BY BRUCE JANCIN
Frontline Medical News

SNOWMASS, COLO. – Progress in the understanding and treatment of immunoglobulin G4–related disease is occurring "at lightning speed," John H. Stone, MD, said at the Winter Rheumatology Symposium sponsored by the American College of Rheumatology.

"We now have a fairly coherent understanding of the pathophysiology of this disease," said Dr. Stone, professor of medicine at Harvard Medical School and director of clinical rheumatology at Massachusetts General Hospital, both in Boston.

This new understanding of IgG4-RD, he added, is opening the door to novel treatments.

"This is not a new disease. It was there when we were all in medical school, and for hundreds of years before that. But it's really only in the last decade that we have come to understand that the disease can affect literally every organ system in the body with syndromes that we once thought were isolated organ-specific syndromes," the rheumatologist said.

IgG4-RD is an immune-mediated fibroinflammatory condition characterized histopathologically by three hallmark features in involved tissue: obliterative phlebitis, storiform fibrosis, and a dense lymphoplasmacytic infiltrate. Clinically, IgG4-RD often presents as a mass lesion that can affect any organ.

"I have many patients who've undergone modified Whipple procedures because they were thought to have adenocarcinoma of the pancreas," according to Dr. Stone.

Other common presentations include Riedel's thyroiditis, autoimmune pancreatitis, sclerosing cholangitis, sialadenitis, dacryoadenitis, periaortitis, an eosinophilic rash, and pseudotumor of the lung, lymph nodes, or orbits.

"Retroperitoneal fibrosis is a common and underappreciated manifestation. It may be the most common subsyndrome associated with IgG4-related disease," he observed.

Another common presentation involves atopic disease – asthma, allergic rhinitis, eczema, eosinophilia, nasal polyps – developing out of the blue in middle age or later life. This observation led some other investigators to posit that IgG4-RD is a T-helper type 2–driven disease, an assertion debunked by Dr. Stone and coworkers (Allergy. 2014 Feb;69[2]:269-72).

Dr. Stone and his coinvestigators have published the largest series of patients with biopsy-proven IgG4-RD reported to date (Arthritis Rheumatol. 2015 Sep;67[9]:2466-75). The average age at disease onset was 50 years. Of note, multiorgan involvement was the norm: 24% of patients had two organs involved, and 38% had three or more.

Analysis of this large patient series has led Dr. Stone to a surprising conclusion about the nature of IgG4-RD: "We have greatly overemphasized the importance of IgG4 in this condition," he asserted.

Indeed, a mere 51% of the patients with clinically active untreated IgG4-RD in his series had an elevated serum IgG4 level. Dr. Stone characterized IgG4 as "kind of a wimpy antibody" incapable of driving the disease process because it is a noninflammatory immunoglobulin. This has led to speculation that IgG4 functions as what he termed an "antigen sink," attempting to bind antigen at sites of inflammation.

But while an elevated serum IgG4 is of limited utility for diagnostic purposes, Dr. Stone and coworkers have demonstrated that it is of value as a predictor of relapse. Among patients with a treatment-induced remission, those in the top quartile in terms of baseline pretreatment serum IgG4 were 6.2-fold more likely to relapse (Rheumatology [Oxford]. 2016 Jun;55[6]:1000-8).

Levels of circulating plasmablasts as measured by peripheral blood flow cytometry, especially IgG4-positive plasmablasts, have proven much more helpful than serum IgG4 levels as a diagnostic tool, a reliable biomarker of disease activity, and a therapeutic target. Levels of these short-lived CD19+CD38+CD27+ plasmablasts are enormously elevated independent of serum IgG4 in patients with active IgG4-RD.


BRUCE JANCIN/FRONTLINE MEDICAL NEWS

Dr. John H. Stone

"One of the questions I'm most often asked is whether IgG4-related disease is a premalignant condition. My answer is no. The plasmablast expansion is oligoclonal, not polyclonal," Dr. Stone continued.

Treatment with rituxumab

Glucocorticoids remain the first-line therapy in IgG4-related disease, but it's essential to bear in mind that their long-term efficacy in this immune-mediated fibroinflammatory disease is the exception rather than the rule, Dr. Stone said.

"I typically start with prednisone at 40 mg/day, and there's a dramatic response in these patients. Then I taper them off after 2-3 months. If 2-3 months doesn't put them into a long-term sustained remission, it's time to go to something else," said Dr. Stone.

So what's the next move, then, after steroids fail? Dr. Stone was a pioneer in the strikingly successful use of B-cell depletion via rituximab (Rituxan) in patients with IgG4-RD.

First, he and his coinvestigators demonstrated that this off-label use of rituximab led to rapid clinical and histologic improvement (Ann Rheum Dis. 2015 Jun;74[6]:1171-7). Then, they showed it also causes levels of circulating plasmablasts, serum IgG4, and biomarkers of fibrosis to plunge, suggesting B-cell depletion may halt the destructive process of collagen deposition that characterizes this disease (Ann Rheum Dis. 2015 Dec;74[12]:2236-43).

Dr. Stone reported receiving IgG4-RD-related research funding from and serving as a consultant to Genentech and Xencor.

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CLINICAL CHALLENGES AND IMAGES

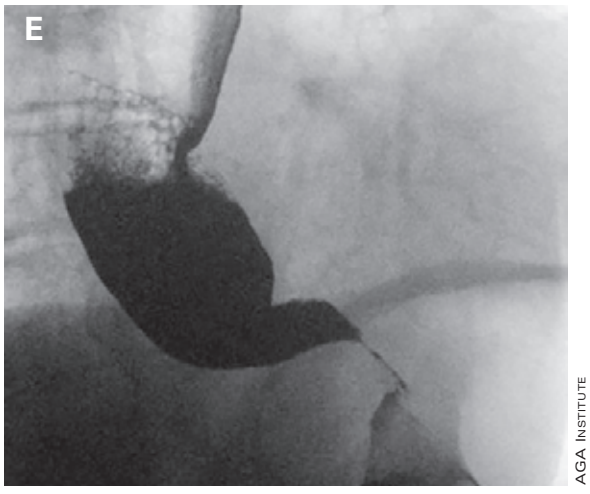
The diagnosis

Answer to "What's your diagnosis?" on page 2: Pseudoachalasia in paraneoplastic syndrome, with radiographic documentation of onset and evolution

A barium esophagogram revealed an esophagus with characteristic features of achalasia: dilatation, retention of air and fluid, and a "bird's beak" configuration distally (Figure E). Botulinum injection into the distal esophagus provided the patient with partial relief of her swallowing symptoms.

Evidence supporting the diagnosis of pseudoachalasia associated with paraneoplastic syndrome in this patient is 1) the development of characteristic features of achalasia in association with SCLC, the cancer that is most often associated with paraneoplastic achalasia[1]; 2) a serum antibody characteristic of SCLC-associated paraneoplastic syndrome; 3) peripheral neuropathy attributed to paraneoplastic syndrome; and 4) absence of an obstructive neoplasm at the gastroesophageal junction.

Pseudoachalasia associated with malignancy may occur by one of three mechanisms[1-3]: 1) primary or secondary carcinoma located at or near the gastroesophageal junction, 2) neural invasion of the esophagus, or 3) as a component of the paraneoplastic syndrome. Pseudoachalasia associated with a paraneoplastic syndrome is rare (an estimated 1 in 750,000), although it may be becoming more common.[1] The relatively rapid onset of dysphagia is a reported feature of pseudoachalasia, in contrast with the more gradual onset in primary achalasia. Our report documents radiographically the progression within a few months from a normal-diameter esophagus to a very dilated, poorly functioning esophagus. We know of no similar report. Botulinum toxin injection has been reported effective in a few cases.[1]



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Obesity, lack of exercise culprits?

Rectal cancer *from page 1*

Results program regarding people aged 20 years and older who were diagnosed between 1974 and 2013. They used a statistical tool called age-period-cohort modeling to help differentiate factors that influence all age groups (period effects), such as changes in medical practice, from factors that vary by generation (cohort effects), which typically result from behavioral changes (J Natl Cancer Inst. 2017. doi: 10.1093/jnci/djw322).

The study population comprised 490,305 patients.

The incidence of rectal cancer increased by 3.2% per year during the study period among patients aged 20-29 years and in those aged

Continued on following page

Continued from previous page

30-39 years. It didn't begin rising until the 1990s in adults aged 40-49 years and 50-54 years, and then it rose by a smaller amount – 2.3% per year. In contrast, the incidence of rectal cancer generally declined throughout the 40-year study period among adults aged 55 and older.

Because of these opposing trends, there was a net increase in rectal cancer of 4% per year for people in their 20s together with a net decrease of 2% per year for those aged 75 years and older.

The decreasing rate of rectal cancer in older adults "may partly reflect detection and removal of precancerous lesions during clinical inspection of the rectum, which was common practice well before formal [CRC] screening. Inherent differences within the colorectum in the way environmental factors initiate and or promote carcinogenesis, as well as the influence of unknown risk factors, may also have contributed," Ms. Siegel and her associates said.

The temporal pattern was somewhat different for colon cancer. The risk of colon cancer declined "for successive generations during the first half of the 20th century but has escalated back to the level of those born circa 1890 for current birth cohorts."

"The strong birth cohort effects we observed signal relatively recent changes in exposures that influence risk," including excess body weight, high intake of processed meat, low intake of dietary fiber, and low levels of physical activity. "New strategies to curb the obesity epidemic and shift Americans toward healthier eating and more active lifestyles" are needed, the researchers said.

In addition, both clinicians and the public must be educated about the rising probability of the disease in people younger than 55 years. Timely follow-up of symptoms, regardless of patient age, must be emphasized. Younger adults are nearly 60% more likely than are older adults to be diagnosed with advanced CRC, largely because they delay seeking medical care. The disease simply isn't "on the radar" of young adults or their providers, the investigators added.

This study was supported by the American Cancer Society and the National Institutes of Health. Ms. Siegel and her associates did not provide their conflicts of interest.

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PERSPECTIVE

Some trends in colorectal cancer may have dietary and environmental influences

Colorectal cancer has been a "good news" story over the past 10-15 years. In the United States we have seen 30% reduction in both incidence and mortality over 10 years. This may be due to many factors, including increased rates of screening. The increased use of aspirin for cardiovascular protection, NSAIDs for joint and muscle pain, and hormone replacement therapy, and reductions in smoking all likely contribute to the trend in CRC reduction.

DR. LIEBERMAN

Despite this good news, there is further evidence of rising incidence of CRC in individuals less than 54 years over the past 30 years. Rates of both colon and rectal cancer are increasing for 20- to 54-year-olds. This age group represent a small absolute risk of CRC, accounting for less than 10% of CRC, but the trend is disturbing and begs explanation. Obesity, diabetes, and metabolic syndrome are increasing in younger individuals, and these are potential risk factors for CRC.

New or changing environmental exposures may place younger people at risk. The introduction of industrialized food in our diet over the past 4 decades could have both direct and indirect effects. It is possible that some food chemicals could be carcinogenic, but it is also quite possible that alteration of the microbiome by diet and environmental factors could lead to development of neoplasia in predisposed individuals. The use of antibiotics in our food chain may alter the microbiome.

There is considerable state-to-state variation in rates of CRC incidence and mortality. This is not new, but remains largely unexplained. The highest risk appears to be in the so-called "Rust Belt" and deep South, raising questions about environmental exposures that might predispose to CRC. Lower rates in states like Texas, Colorado, and California may be influenced by the population mix. There is evidence that Hispanics may have lower age-adjusted risk of CRC than blacks and whites, so higher proportions of low-risk groups could impact the statewide risk of CRC. The differences between high-risk (West Virginia's death rate of 23.4/100,000) and low-risk (Utah's death rate 8.7/100,000) are too large to be explained by demographic differences alone, and strongly suggests an environmental culprit.

David Lieberman, MD, AGAF, is professor of medicine; chief of the division of gastroenterology and hepatology, Oregon Health &Science University, Portland; and Vice President of the AGA Institute.

Colorectal cancer mortality highest in W.Va., lowest in Utah

BY RICHARD FRANKI
Frontline Medical News

Mortality from cancers of the colon and rectum is expected to be about 15.6 per 100,000 in 2017, with the highest rate in West Virginia and the lowest in Utah.

Approximately 50,260 colorectal cancer deaths are predicted for the year in the United States by the American Cancer Society in its Cancer Facts & Figures 2017, based on 2000-2014 data from the National Center for Health Statistics. With the population currently around 321 million, that works out to an expected death rate of 15.6 per 100,000 population. Doing a little more math produces death rates of 23.4 per 100,000 for West Virginia and 8.7 for Utah.

Incidence rates for colon and rectum cancer were 46.9 per 100,000 for men and 35.6 for women for 2009-2013, according to data from the North American Association of Central Cancer Registries, the ACS reported.

Utah had the lowest incidence rate over that time period for both men (36.1 per 100,000) and women (28.2 per 100,000), and Kentucky had the highest for both, with rates of 59.6 for men and 43.7 for women, the ACS said.

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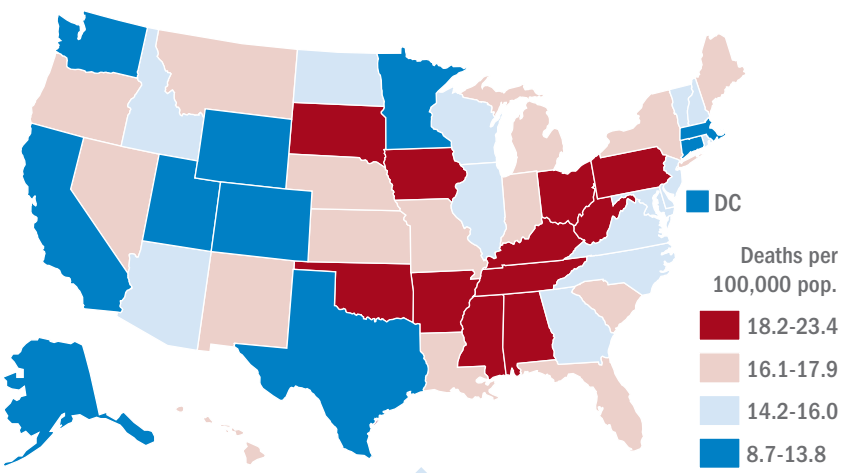
Estimated colon and rectum cancer death rates for 2017



Lowest expected rate: Utah **8.7**

23.4 Highest expected rate: West Virginia

Expected national rate: 15.6 colorectal cancer deaths per 100,000 population.

Note: Based on 2000-2014 mortality data from the National Center for Health Statistics.
Source: American Cancer Society

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HCV testing stagnant among baby boomers

BY JIM KLING
Frontline Medical News

Despite the urging of the United States Preventive Services Task Force and other organizations in 2013, the percentage of baby boomers who underwent testing for hepatitis C virus (HCV) infection had barely changed 2 years later – from 12.3% in 2013 to 13.8% in 2015.

The numbers are particularly troubling because new and improved antiviral drugs offer cures that could forestall liver cancer, cirrhosis, and other potential complications, with shorter regimens and fewer side effects than older regimens.

New guidelines often take time to get adopted by public health and medical communities, but the authors expected some increase. "It just remained pretty low. It was a little bit surprising," said study coauthor Stacey Fedewa, PhD, strategic director of risk factors and screening surveillance at the American Cancer Society.

Other reactions were more forceful. "Kind of pathetic, isn't it?" said John D. Scott, MD, assistant director of the Hepatitis and Liver Clinic at Harborview Medical Center.

The researchers analyzed 2013 and 2015 data from the National Health Interview Survey, which included records for 21,827 baby boomers with HCV testing data. The slight increase overall of 12.3% to 13.8% was small, though statistically significant (P = .013). Some populations fared better: Compared with the privately insured, those with Medicare plus Medicaid (prevalence ratio, 1.83; 95% confidence interval, 1.32-2.53) or Medicaid only (PR, 1.35; 95% CI, 1.04-1.76) were more likely to have been tested, as were those with military insurance (PR, 1.62; 95% CI, 1.16-2.26).

It's entirely possible to increase testing rates, according to Dr. Scott, who has a grant from the Centers for Disease Control and Prevention to study ways to increase uptake. "Probably the easiest thing to do is just incorporate this information into your [EHR] and make it part of your alerts and standard preventative practices. Try to automate a lot of this."

More broadly, the importance of testing needs to be emphasized, according to Paul J. Thuluvath, MD, AGAF, medical director at the Institute of Digestive Health and Liver Disease at Mercy Medical Center, Baltimore.

The study was funded by the American Cancer Society. Dr. Scott received research funding from Merck and serves on the data safety and monitoring board for Tacere Therapeutics. Dr. Thuluvath has received funding from Gilead and has received speaking fees from Gilead and AbbVie.

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AGA resource
AGA's HCV Clinical Service Line can help you understand quality standards, and improve the process of care for patients: www.gastro.org/patient-care/conditions-diseases/hepatitis-c.

Gluten-free diets related to high arsenic, mercury levels

BY DEEPAK CHITNIS
Frontline Medical News

Individuals who adopt a gluten-free diet are putting themselves at risk for uncommonly high levels of arsenic and mercury, according to the findings of a recent study published in Epidemiology.

"Despite [less than] 1% of Americans having diagnosed celiac disease, an estimated 25% of American consumers reported consuming gluten-free food in 2015, a 67% increase from 2013," wrote the authors of the study, led by Maria Argos, PhD, of the University of Illinois at Chicago. "Despite such a dramatic shift in the diet of many Americans, little is known about how gluten-free diets might affect exposure to toxic metals found in certain foods," they noted.

Dr. Argos and her colleagues analyzed data collected from the National Health and Nutrition Examination Survey (NHANES), which included self-reported questionnaires in which subjects indicated what type of diet they were on, if any. Data on those who indicated that they followed a gluten-free diet were analyzed to determine if their urinary and blood biomarkers indicated any exposure to toxic metals. A total of 7,471 subjects from the NHANES were included in the analysis.

"We accounted for the complex sampling design of NHANES [by] using Taylor series linearization and sampling weights, per the NHANES analytic guidelines, to ensure unbiased and nationally representative estimates," the authors explained.

A total of 73 subjects identified themselves as following a gluten-free diet. Within this group, the mean total arsenic level in urine was found to be 12.1 mcg/L, compared to 7.8 mcg/L for the other 7,398 subjects. Levels of dimethylarsinic acid averaged 5.3 mcg/L for those who were gluten free, but only 3.7 for everyone else, while cadmium and lead levels were also slightly higher for gluten-free individuals: 0.18 mcg/L vs. 0.16 mcg/L, and 0.40 mcg/L vs. 0.37 mcg/L, respectively.

CHAMELEONSEYE/THINKSTOCK

Blood analyses showed that total mercury levels were also substantially higher in the gluten-free group, at a mean of 1.3 mcg/L compared to 0.8 mcg/L. While cadmium levels were the same between the two – both showed a mean level of 0.29 mcg/L – lead measured 1.1 mcg/dL and inorganic mercury measured 0.30 mcg/L, compared to 0.96 mcg/L and 0.28 mcg/L in everyone else, respectively.

Geometric mean ratios showed that total arsenic, total arsenic 1, and total mercury levels had the largest disparity between the two groups. Total arsenic registered a 1.5 (95% CI, 1.2-2.0), total mercury a 1.7 (95% CI, 1.1-2.4), and total arsenic 1 a 1.9 (95% CI 1.3-2.6), meaning the gluten-free group had nearly double the risk for higher levels than those on other diets.

"These findings may have important health implications since the health effects of low-level arsenic and mercury exposure from food sources are uncertain but may increase the risk for cancer and other chronic diseases," Dr. Argos and her coauthors concluded, adding that "future studies are needed to more fully examine exposure to toxic metals from consuming gluten-free foods."

The study was funded by a grant from the National Institutes of Health. Dr. Argos and her coauthors did not report any relevant financial disclosures.

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Norovirus reporting tool yields real-time outbreak data

BY MARY ANN MOON
Frontline Medical News

NoroSTAT, the Centers for Disease Control and Prevention's new program with which states can report norovirus outbreaks, yields more timely and more comprehensive epidemiologic and laboratory data, which allows a faster and better-informed public health response to such outbreaks, according to a report published in the Morbidity and Mortality Weekly Report.

The CDC launched NoroSTAT (Norovirus Sentinel Testing and Tracking) in 2012 to permit the health departments in selected states to report specific epidemiologic and laboratory data regarding norovirus outbreaks more rapidly than usual – within 7 business days, said Minesh P. Shah, MD, of the Epidemic Intelligence Service and the division of viral diseases, CDC, Atlanta, and his associates.

NoroSTAT significantly reduced the median interval in reporting epidemiologic data concerning norovirus from 22 days to 2 days.

They analyzed outbreak data reported by five states (Minnesota, Ohio, Oregon, Tennessee, and Wisconsin) that initially participated in the program against data reported the usual way by the other states, plus Washington DC and Puerto Rico. They focused on the 3 years before and the 3 years after NoroSTAT was implemented.

NoroSTAT significantly reduced the median interval in reporting epidemiologic data concerning norovirus from 22 days to 2 days and significantly reduced the median interval in reporting relevant laboratory data from 21 days to 3 days.

The percentage of reports submitted within 7 business days increased from 26% to 95% among the states participating in NoroSTAT, while remaining low – only 12%-13% – in nonparticipating states. The number of complete reports also increased substantially, from 87% to 99.9%, among the participating states.

These improvements likely result from NoroSTAT's stringent reporting requirements and from the program's ability "to enhance communication between epidemiologists and laboratorians in both state health departments and at CDC," Dr. Shah and his associates said (MMWR. 2017 Feb 24;66:185-9).

NoroSTAT represents a key advancement in norovirus outbreak surveillance and has proved valuable in early identification and better characterization of outbreaks. It was expanded to include nine states in August 2016, they added.

This study was sponsored by the Centers for Disease Control and Prevention.

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Common gut yeast may exacerbate IBD

BY JENNIE SMITH
Frontline Medical News

HandmadePictures/Thinkstock

An ubiquitous yeast strain may play a role in exacerbating inflammatory bowel disease (IBD), an animal study showed.

While research has shown that the composition of gut microbiota in people with IBD is different from that of healthy people, most of the attention has been focused on bacteria. The roles of other microorganisms, including yeasts, are still poorly understood.

In research published in Science Translational Medicine, Tyson Chiaro, of the University of Utah, Salt Lake City, and his colleagues inoculated sterile mice with either of two fungal species: *Rhodotorula aurantiaca* – an environmentally acquired yeast found in milk and fruit juices – or *Saccharomyces cerevisiae* – Baker's yeast – for which some people with Crohn's disease have been shown to have elevated antibodies.

The mice were inoculated gradually over a period of a week to mimic consumption of food enriched with yeast products. The researchers then treated the mice with drugs to induce colitislike symptoms and analyzed colon tissues for damage. Mr. Chiaro and his colleagues found that colonization with *S. cerevisiae*, but not with *R. aurantiaca*, aggravated colitis and resulted in epithelial damage leading to greater gut permeability (Sci Transl Med. 2017;9[380] pii: eaaf9044]).

Mr. Chiaro and his colleagues then investigated whether heat-killed *S. cerevisiae* also induced aggravated colitis and found that it did not, suggesting that a metabolically active organism was required to aggravate disease. Mr. Chiaro and his colleagues performed screens of fecal metabolites in the mice and found that *S. cerevisiae* colonization enhanced purine metabolism, resulting in increased uric acid production.

To test whether this purine pathway was aggravating colitis, the researchers blocked it with allopurinol (10 mg/kg). The *S. cerevisiae*–inoculated mice that were treated with allopurinol had reduced uric acid levels and ameliorated colitis symptoms. The results suggest that allopurinol might be of more clinical value in treating IBD than previously thought. The drug has been used in patients with Crohn's disease to increase the efficacy of other IBD medications, and "many patients who received adjunctive allopurinol therapy were reported to have major clinical improvement," Mr. Chiaro and his colleagues noted. The results "suggest that some of the improvement might come from preventing yeast-induced–uric acid buildup in the intestine. Thus, allopurinol treatment in some IBD patients with adverse reactions to yeast and high uric acid might be of therapeutic benefit and should be explored."

Mr. Chiaro's coauthors reported a variety of individual grant and fellowship awards, including from the National Institute of Allergy and Infectious Disease and the National Institutes of Health. None declared commercial conflicts of interest.

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DDSEP eight
Digestive Diseases Self-Education Program

Quick quiz answers

Q1. Answer: A

While heartburn responds well to acid suppression with a proton pump inhibitor, regurgitation does not necessarily improve. It is well known that reflux persists despite acid suppression; in some patients, this manifests as troublesome postprandial regurgitation. Transient LES relaxations (TLESRs) are the prime mechanism for persisting reflux, in patients both with and without hiatal hernias.

Baclofen, a gamma amino butyric acid B (GABA-B) agonist, inhibits TLESRs and has potential to improve persisting regurgitation. Metoclopramide has been demonstrated to have no adjunctive value in treating reflux disease. Hyoscyamine and sucralfate are similarly not of particular benefit in this setting. Cholesytramine is a bile salt–binding resin that has value in the management of postcholecystectomy diarrhea.

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Q2. Answer: C

Rationale: MALT lymphomas are associated with *H. pylori* infection in 80%-90% of cases. *H. pylori* triggers a B-cell clonal expansion leading to lymphoma. Detection of chronic *H. pylori* using histology is directly dependent on the number of mucosal biopsies. Negative *H. pylori* testing should prompt an alternative test for *H. pylori* (either breath or stool antigen test). Treatment of *H. pylori* is successful in achieving complete remission in up to 80% of cases. Surveillance after treatment of MALT lymphoma is indicated, though the exact protocol has not been established.

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More pushback from docs after CBO scores GOP plan

BY GREGORY TWACHTMAN
Frontline Medical News

Physician groups continue to push back against a Republican plan to repeal and replace the Affordable Care Act following a Congressional Budget Office analysis that showed up to 24 million patients would not be insured under the plan.

According to the CBO analysis, 14 million more patients would become uninsured in the first year of the American Health Care Act than under current law, with most dropping coverage because of the repeal of the ACA's individual health insurance mandate.

By 2020, an additional 7 million patients would lose coverage largely because of the bill's rollback of expansion in favor of a per capita allotment to states to cover their Medicaid population.

"In 2026, an estimated 52 million would be uninsured, compared with 28 million who would lack insurance that year under current law," according to the CBO analysis.

The increase in uninsured patients does not sit well with physician leaders.

American Medical Association President Andrew Gurman, MD, called the uptick in uninsured "unacceptable."

"While the Affordable Care Act was an imperfect law, it was a significant improvement on the status quo at the time, and the AMA believes we need continued progress to expand coverage for the uninsured. Unfortunately, the current proposal – as the CBO analysis shows – would result in the most vulnerable population losing their coverage," Dr. Gurman said in a statement.

"In 2026, an estimated 52 million would be uninsured, compared with 28 million who would lack insurance that year under current law," according to the CBO analysis.

According to the CBO analysis, the individual health insurance market "would probably be stable in most areas under either current law or the legislation." However, there could be large premium increases for some patients, based on age group.

Tom Price, MD, secretary of the Department of Health & Human Services, criticized the CBO projections.

"The CBO report's coverage numbers defy logic," he said in a statement. "They project that zeroing out the individual mandate – allowing Americans to choose whether to have insurance – will result in 14 million Americans opting out of coverage in 1 year. For there to be the reductions in coverage they project in just the first year, they assume 5 million Americans on Medicaid will drop off of health insurance for which they pay very little, and another 9 million will stop participating in the individual and employer markets. These types of assumptions do not translate to the real world, and they do not accurately estimate the effects of this bill."

Rep. Kevin Brady (R-Tex.), chairman of the House Ways & Means Committee, also disputed the increase in the uninsured population.

"The American Health Care Act is a dramatic departure from Obamacare, which forced Americans to buy expensive, one-size-fits-all health insurance," Chairman Brady said in a statement. "Our legislation gives individuals and families the freedom to access health care options that are tailored to their needs, not Washington's."

Rep. Brady and Dr. Price also pointed out that the AHCA is just the first step of a three-step process, which will include a review of ACA regulations as well as passage of further legislation aimed at providing high-quality care at lower costs. However, those cannot be scored by CBO as those details have yet to be released, the GOP leaders pointed out.

The CBO analysis predicts that premiums for those buying insurance in the individual marketplace would have an increase of 15%-20% from 2018 to 2019, but starting in 2020, average premiums are expected to decrease from states using federal government funds to help offset costs from high users of health care and more younger people coming into the health insurance market.

"By 2026, average premiums for single policyholders in the nongroup market under the legislation would be roughly 10% lower than under current law," according to the analysis, although since the law allows for higher premiums for older individuals, the congressional budget watchdog sees the provisions of the AHCA as "substantially reducing premiums for young adults and substantially raising premiums for older people."

The CBO estimates that enacting this legislation would reduce federal deficits by $337 billion over the 2017-2026 period, mainly from reductions in Medicaid spending and the elimination of the current premium subsidies, though the deficit reduction is somewhat offset by the refundable premium tax credits that replace the ACA's subsidies.

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PRACTICE MANAGEMENT TOOLBOX: Approach to covert recording by patients of encounters with GI providers

BY MEGAN A. ADAMS, MD, JD, MSC

Last year, while sedated for colonoscopy, a patient covertly recorded conversations among endoscopy staff and providers. Comments about the patient were egregious and resulted in loss of employment and a large financial settlement. The reality of today's world is that we all are subject to constant (real or potential) surveillance. Nothing is private and nothing recorded is temporary, yet physicians value private, conversations with our patients. When a patient records a visit, either covertly or overtly, most physicians pause and have some emotional reaction (either positive or negative). Some welcome the ability to communicate accurately to a wider audience, while others believe the act of recording violates an interpersonal bond. In this month's column, Dr. Adams discusses legal and ethical ramifications when a patient records our clinical interactions. She offers an excellent analysis and practical risk management strategies. Personally, I follow my wife's dictum to act like I am always on camera.

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

Patients and physicians were collectively horrified last year when news broke of a Virginia man who recorded conversations among his gastroenterologist, anesthesiologist, and other endoscopy unit staff while sedated for his colonoscopy, including a number of disparaging remarks about the patient. Among other objectionable comments, providers mocked the patient for being demanding in the preprocedure area and for the amount of sedation he required, made comments implying that he had syphilis or tuberculosis, and discussed avoiding the patient following the procedure via an urgent "fake page."[1] The patient sued, resulting in a $500,000 judgment against the anesthesiologist for defamation and malpractice, including punitive damages. Although this case clearly represents an extreme example of unprofessional behavior, it also raises thought-provoking questions regarding the evolving relationship between patients and their physicians as well as the legal and ethical implications of covert recording that deserve further discussion.


DR. ADAMS

In this era of personal digital devices, there is increased opportunity for covert electronic recording of medical encounters by patients and families. Although this practice may be a consequence of underlying distrust between patient and physician, if discovered it may ultimately lead to further erosion of trust, negatively impacting ongoing medical care and further compromising the patient-physician relationship.

This article reviews the current state of knowledge regarding the frequency of and motivation for covert patient recording of medical encounters, and the legal and ethical principles informing this area.

Continued on page 37

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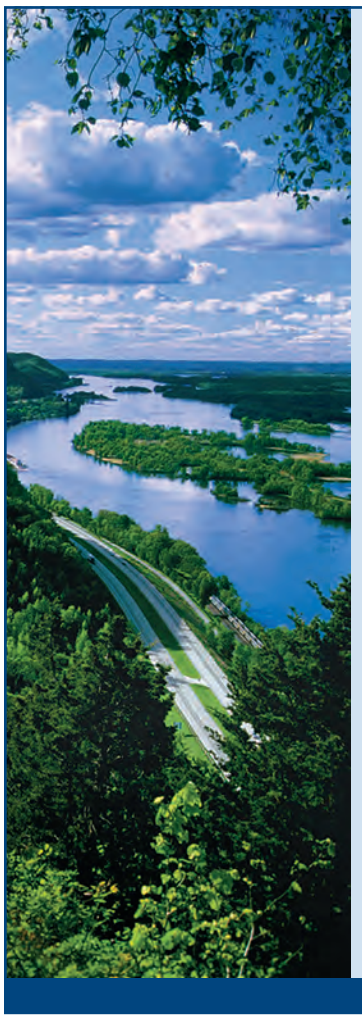

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It concludes by proposing several strategies gastroenterologists can use to mitigate risk of liability while also preserving the patient-physician relationship and upholding professional autonomy.

Weighing the benefits and harms of patient electronic recording

Patient recording of medical encounters, whether covert or overt, presents both benefits and risk of harm. Theoretically, recording medical encounters could assist patients in remembering and/or better understanding recommendations provided by their physicians. It may also secondarily improve patient compliance and overall engagement in medical care, and help patients accurately communicate recommendations to family members and other caregivers not immediately available during the clinical encounter. Patients may also view these recordings as a mechanism for empowerment, allowing them to shift the power dynamic between patient and provider.[2,3] However, there is also the potential for recorded comments to be taken out of context or misinterpreted, leading to confusion on the part of the patient or family.

Overt recording of medical encounters also may alter physician decision making, leading to more aggressive testing and expense for the patient and health care system. Even worse, covert recording of medical encounters (if discovered) may irreparably harm the physician-patient relationship by introducing distrust and causing the physician to take a more defensive posture in subsequent dealings with a given patient.

Recent research has shed new light on the potential frequency of patient covert recording of medical encounters, suggesting that it is alarmingly common. In a mixed-methods study of 130 patients in the United Kingdom recruited via radio and social media, 15% of respondents indicated having secretly recorded a clinical encounter and an additional 11% personally knew someone who had covertly recorded.[4] Those reporting having covertly recorded were significantly more likely to be male and less educated than those who had not. An additional 35% of respondents indicated that they would consider covertly recording a clinical encounter in the future. Although the generalizability of these results may be challenged based on the potential for sampling bias, the results suggest a shifting paradigm in the way in which patients view the physician-patient relationship and a fundamental breakdown in communication and erosion of trust.

The underlying motivations for patient recording of medical encounters are complex and multifaceted. These recordings seem to be a relatively new phenomenon, and one that elicits strong reactions, positive and negative, on the part of patients, physicians, and society.[2] Qualitative studies reveal that, whether covertly or overtly recording, most patients are driven by a common desire to replay, relisten, and/or share the recording with family, friends, and other caregivers.[4] Indeed, the patient involved in the previously mentioned litigation purportedly intended to record the postcolonoscopy discharge instructions from his gastroenterologist, only to later discover much more. Patients who record covertly report being motivated by a fear of being denied permission to record, or by prior experiences of poor quality care and the prospect of gathering verifiable evidence to support their experience. In contrast, patients who ask permission to record seem to be motivated primarily by a desire to preserve or enhance the physician-patient relationship.[4] These insights are valuable in that they allow clinicians to view medical encounters from the perspective of patients, understand the power dynamics at play, and ultimately use this information to enlighten future care.

Legal guidance: "One-party" versus "all-party" consent

Although the prospect of covert patient recording may be unsettling to physicians, is it illegal? Because of a paucity of legal precedent in this area, the legal landscape is rather murky. Through the provisions of the Electronic Communications Privacy Act, federal law prohibits the interception and disclosure of wire, oral, or electronic communications without specific consent of at least one party to the conversation.[5] This so-called "one-party" consent standard affords a baseline level of legal protection. A handful of states offer additional protection under state law by requiring all parties to the conversation to consent to the recording (so-called "all-party" consent). Virginia, where the audio recording of the previously mentioned colonoscopy took place, is a "one-party" consent state.[6] In contrast, such states as California and Florida have adopted an "all-party" consent rule.[7,8] However, uncertainty remains. For instance, if medical providers have a conversation in the same room as a sedated patient during a medical procedure on that patient, is the patient a "party" to the conversation? Furthermore, can such a conversation be considered private when held in front of a patient during a medical procedure? Is the patient in such a scenario "eavesdropping"? Given a lack of legal precedent in the form of case law and the unique features of each clinical scenario, this is likely to remain an area of significant legal ambiguity. Although the possibility of covert patient recording may be unnerving for providers, the reality is that in most cases it is likely legally permissible.

Ethical principles: Navigating an evolving physician-patient relationship

The relationship between physician and patient, a core aspect of medical ethics, has evolved markedly over time. This relationship was historically paternalistic: The patient was seen to be dependent on the physician's professional authority in determining the appropriateness of care, and patient's preferences were seen as secondary to physician judgment. In recent years, however, the physician-patient relationship has evolved toward one privileging patient-centered care and shared decision making based on a patient's unique values, beliefs, and preferences.[9,10] Concomitantly, the public's view of doctoring has transitioned from "unquestioning acceptance of physician authority to a more 'consumerist' view accompanied by a questioning and bargaining approach to medicine, physicians and the medical encounter."[11] In this context, many patients, attorneys, bioethicists, and patient advocates see patient recording of medical encounters as a legitimate check on the health care system, ensuring transparency and honesty and empowering patients to become more active participants in their medical care.[2]

Policy responses

Although there has been growing recognition of the existence of patient recording of medical encounters, there have been few direct policy responses to date. One notable example was an effort by Wisconsin legislators in 2015 to mandate that any place where surgery is performed (including hospitals, ambulatory surgical centers, and other sites) offer patients the option to have their procedure videotaped and audiotaped.[12] The proposed legislation was written broadly enough to encompass gastroenterologists performing routine endoscopic procedures under sedation. Recordings would have been treated as part of the patient's health care record, and been admissible as evidence in subsequent legal proceedings relating to the medical care provided. Although this bill ultimately failed to pass pursuant to a Joint Resolution in the Wisconsin Senate in April 2016, it is a pointed example of the possible policy actions that may govern this area in the future.

In 2012, the UK National Institute for Health and Clinical Excellence issued a guidance document focused on improving the patient experience of care, which recommends that clinicians routinely ask patients if they would like to take notes and/or record the clinical encounter.[13] Although not explicitly referencing covert recording, this guidance effectively aims to promote increased transparency by openly encouraging recording as a component of optimal medical practice. Although the American Medical Association Code of Ethics offers guidance regarding physicians recording patient encounters, it does not comment on recording by patients themselves.[14]

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Take-away points:

1. Patient recording of medical encounters has become increasingly common given widespread use of personal digital devices.
2. Whether covert or overt, patient recording of medical encounters presents both potential benefits and risk of harm.
3. While the prospect of patient covert recording may be unsettling to providers, it is not necessarily illegal.
4. This article presents strategies gastroenterology providers can use to mitigate legal risk while also enhancing patient-provider communication.

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Risk management strategies for gastroenterology providers

So, how can gastroenterologists and other providers protect themselves in a world of covert recording, while also preserving their relationships with patients and optimizing medical care? First, despite their harried days and varied responsibilities, gastroenterologists must recognize the possibility of covert recording and seek to maintain professionalism in all clinical environments, whether in an examination room or in an endoscopy suite with a sedated patient. Physicians set the tone for the entire team, and also have an obligation to intervene if other members of the medical team are not adhering to professional standards. Although physicians and other medical providers often use cynical and derogatory humor as a coping mechanism given the heavy workload and amplified stressors of the clinical environment, it is important to be mindful of how such comments are perceived by patient bystanders.[15,16] Although achieving a robust therapeutic alliance with a patient can take months, this trust can be easily broken by a single flippant remark by the physician.

Second, rather than assuming a defensive posture driven by fear of medical liability, it is vital for gastroenterologists to directly confront situations in which covert recording is suspected while also preserving the physician-patient relationship. In fact, by openly encouraging patient recording as a matter of routine practice, gastroenterologists can promote an environment of trust and transparency and bolster the therapeutic alliance between patient and provider.[5] This approach also encourages providers to hone their communication skills, and ensure they are communicating essential medical information clearly and succinctly and conveying medical nuance where appropriate. For example, in a clinic setting, a patient with inflammatory bowel disease who records might better remember or understand the risks and benefits of various treatment strategies and common side effects of medications such as azathioprine and biologics. Patients recording medical encounters in the endoscopy suite might better recall postprocedure instructions, including recommended follow-up intervals and risks of postendoscopy complications. In this era of shared decision making and patient-centered care, optimizing both physician delivery of and patient understanding and recall of essential medical information is of critical importance.

Finally, although adoption of the above practices would serve the dual goals of enhancing patient-provider communication and mitigating legal risk, certain systems interventions may further minimize the risk of covert recording. For instance, endoscopy units can store patients' personal effects, including electronic devices, in a locker outside the endoscopy room rather than on the gurney. Retrieving patient belongings before postprocedure instructions are delivered would protect the patient's ability to record this advice for future recall.

Conclusions

Recording by patients of clinical encounters, whether covert or overt, has become increasingly common as a result of the digital revolution. These recordings most often represent an attempt by the patient to gain more information relevant to their medical care. Rather than being threatened by this new reality, gastroenterologists should consider embracing this practice as an opportunity to enhance effective communication with patients, encourage shared decision making, and deliver truly patient-centered care.

Acknowledgments

This article is intended as general commentary and should not be interpreted as conferring legal advice applicable to individual circumstances. Do not act or rely on information contained in this article without first

seeking the advice of a personal attorney.

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