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Courtesy Dr. David Hudesman

Dr. David Hudesman and coworkers found that biologics and JAK inhibitors were safe in a series of patients who contracted COVID-19.

COVID-19: Case series suggests biologics safe

BY M. ALEXANDER OTTO

MDedge News

Use of biologics and Janus kinase (JAK) inhibitors was not associated with worse outcomes in 86 people with inflammatory diseases who contracted COVID-19, according to a case series from New York University Langone Health.

"We are not seeing worse outcomes with overall use of either. It's reassuring" that the data support continued use during the pandemic, said rheumatologist and senior investigator Jose Scher, MD, an associate professor at New York University.

There have been concerns among rheumatologists, gastroenterologists, and dermatologists that underlying inflammatory diseases and the agents used to treat them would impact outcomes in COVID-19.

Dr. Scher and colleagues, including coauthor David Hudesman, MD, medical director of the Inflammatory Bowel Disease Center at NYU Langone Medical Center, wanted to address

See **Biologics** · *page 17*

Pandemic: Employers cut doc pay, bonuses–What's your recourse?

BY LEIGH PAGE

Employed physicians have had to take large pay cuts, give up bonuses, or go on leave, or have even been terminated. In many cases, these actions violate their contract. How can they fight them?

Michael D., MD, a colorectal surgeon employed in a large surgical practice in Georgia, is still trying to make sense of a late-night directive from the practice, received in late March.

The practice had just started seeing a steep decline in appointments because of the COVID-19 pandemic. In a hastily arranged group phone call at 11:00 p.m., the CEO told the group that they would be taking a 50% reduction in salaries, their bonuses for work already done were being withheld, and they would have to use their paid time off (PTO) in order to get their full March salary.

"It's been over 2 weeks now, and still we've seen nothing formalized in writing," said Dr. D., who asked that his name not be used because he was told that, under no circumstances, should anyone talk to the media.

Asking for big sacrifices

As the pandemic has intensified, employed physicians have started to see massive changes in their payment arrangements, from having

See **Recourse** · *page 25*

Gastroenterology groups map a return to elective endoscopy

BY LAIRD HARRISON

Gastroenterologists can safely return to elective procedures when adequate personal protective equipment (PPE) is available, professional societies say.

Noting that some states have already lifted restrictions imposed to guard against COVID-19, the American Gastroenterological Association and the Digestive Health Physicians Association on April 27 announced guidelines for resuming procedures delayed by the pandemic.

"Gastroenterologists are looking for some framework, however fluid it

See **Endoscopy** · *page 24*

INSIDE

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LETTER FROM THE EDITOR

Starting to assess the toll

This morning, Megan A. Adams (a *GI & Hepatology News* Associate Editor and a Michigan faculty member) and I held an hour-long video conference with all of our Michigan GI fellows. Our four third-year fellows talked about their job search and employment plans for July. Three will join academic centers (UNC, University of Wisconsin, Henry Ford) and one will enter private practice (Atlanta Gastroenterology). I was glad to hear that all had been reassured that their positions were secure despite the COVID-19 impact. As I speak with colleagues across the country, all (whether health system physicians, academic faculty, or community gastroenterologists) are experiencing the financial, emotional, and operational effects of this pandemic. This is an experience that will define our professional careers.


Dr. Allen

As one of three chief clinical officers at Michigan Medicine, I am part of a four-person team that leads the faculty medical group and the ambulatory portion of our health system. Each of our segments (ambulatory, adult hospital, children's hospital, and medical school) have targets for sustained cost reductions that total $400 million and Michigan Medicine (as published in the news) plans to reduce our workforce (nonfaculty) by 1,400. We have a hiring freeze, leaders are taking salary reductions, and we have instituted other painful, cost-saving measures. The physician leaders we hired just 12 months ago to oversee a new faculty group structure were thrust into a firestorm. Department chairs, division chiefs, nursing and administrative leaders all are having to make heart-wrenching cost-cutting decisions. Together, we have to make individual reductions in force or retain decisions about people we work with daily. This emotional toll will never truly heal for anyone involved.

We have a backlog of 12,000 surgeries and 8,000 endoscopy procedures that have been deferred.

There will be little time to recover. We are scrambling to reopen safely, with a planned process. We have a backlog of 12,000 surgeries and 8,000 endoscopy procedures that have been deferred. Eight-hundred children are behind in their well-child medical care, frightened patients are sitting home with critical aortic stenosis, dangerous hypertension, growing cancers, and other urgent medical needs. Private practices are facing the same issues, financial pressures, and emotional toll.

Anna Quindlen once said, "Grief is a whisper in the world, but a clamor within." Recognize the toll this is taking and don't be alone with your grief.

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

Top AGA Community patient cases

The AGA Community (https://community.gastro.org) received a makeover – the upgraded networking platform now features a newsfeed for difficult patient scenarios and regularly scheduled Roundtable discussions with experts in the field. In case you missed it, here are the most popular clinical discussions happening in the newsfeed:

- UC patient with new diagnosis of breast cancer (https://community.gastro.org/posts/20142)
- COVID testing before elective procedures (https://community.gastro.org/posts/21106)
- Remdesivir and hepatic failure (https://community.gastro.org/posts/21130)
- Doses of antibiotics for IBS-D patient (https://community.gastro.org/posts/19749)
- Vedolizumab and sinus migraines (https://community.gastro.org/posts/20204)

Follow and ask experts your questions in Roundtable:

- Resumption of elective endoscopy during COVID-19
- COVID-19 and GI: Caring for IBD
- Q&A with EoE guideline authors
- Q&A with the U.S. Multi-Society Task Force on Colorectal Cancer: follow-up after normal colonoscopy and polypectomy

View all upcoming Roundtables in the community at https://community.gastro.org/discussions.

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Nucleoside polymers show early promise in HBV

BY AMY KARON
MDedge News

For patients with chronic hepatitis B virus (HBV) infection, triple-combination therapy with tenofovir disoproxil fumarate, pegylated interferon alfa-2a (TDF-pegIFN), and either of two investigational nucleic acid polymers was tolerable and led to long-term functional cures in an open-label phase 2 trial.

The addition of either REP 2139 or REP 2165 to backbone TDF-pegIFN therapy produced functional cures in 39% of patients without exacerbating treatment-induced neutropenia or thrombocytopenia, said Michel Bazinet, MD, of Replicor in Montreal and his associates. "Increases in levels of transaminases were significantly more frequent ($P < .001$ vs. controls) and greater ($P = .002$ vs. controls) in the nucleic acid polymer groups but did not produce symptoms, correlated with [an] initial decrease in hepatitis B surface antigen [HBsAg], and normalized during therapy and follow-up," the investigators wrote in Gastroenterology.

Nucleic acid polymers (NAPs) suppress the assembly and secretion of HBV subviral particles. NAP monotherapy is active against HBV but usually does not provide long-term virologic control. In a small study, adding pegIFN or thymosin alpha-1 to an investigational NAP achieved virologic control (HBsAg positive, HBV DNA ≤ 2,000 IU/mL, and normal alanine aminotransferase levels) in eight of nine patients.

Building on these findings, two triple-combination NAP regimens were evaluated in 40 noncirrhotic HB envelope antigen–negative adults with chronic HBV infection. After 24 weeks of TDF monotherapy, participants were randomly assigned to either 48 weeks of REP 2139 or REP 2165 plus backbone therapy with TDF and pegIFN, or 24 weeks of backbone therapy followed by 48 weeks of triple-combination treatment. Patients were then followed without treatment for 24-48 weeks.

Backbone TDF-pegIFN therapy produced no HBsAg seroconversions, and HBsAg levels dropped by more than 1 $\log_{10}$ IU/mL in only three patients. In contrast, triple-combination NAP therapy produced HBsAb seroconversions (up to 233,055 mIU/mL) for 60% of patients. Among 36 patients followed for 24-48 weeks after completing treatment, 78% maintained virologic control and 39% showed functional cures (HBsAg < 0.05 IU/mL, undetectable HBV DNA, and normal ALT). "Additional follow-up is planned to confirm the long-term stability of [these] outcomes," the researchers said.

Both NAPs were formulated with chelated magnesium to improve their tolerability. Although 95% of patients experienced transaminase flares, these "self-resolved or declined during continuing NAP therapy and normalized in 32 of 34 (94%) of participants completing 48 weeks of follow-up," the researchers said. In keeping with prior studies, transaminase flares were associated with early declines in HBsAg but not with altered liver function or liver disease symptoms.

The study was conducted at three sites in Maldova. Most participants were men with HBV genotype D infection. "During follow-up, viral rebound occurred in participants [in whom] HBsAg was still detectable at the end of 48 weeks of combination therapy (≥ 57.9 IU/mL), who did not complete therapy, or [for whom] HBsAg clearance occurred very late in therapy," the researchers wrote. Thus, "persistent exposure to pegIFN while HBsAg is cleared may be important for the establishment of virologic control and functional cure."

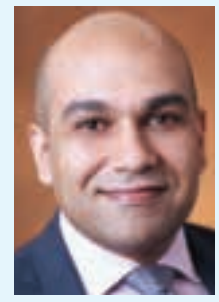
They recommended evaluating NAP plus nucleos(t)ide analogue (NUC) therapy to assess response in the absence of pegIFN. Such studies should enroll "NUC-experienced participants with well-controlled HBV DNA."

Replicor provided funding. Dr. Bazinet and the senior investigator reported that they are employees and shareholders of Replicor and have invented patents that Replicor holds. One coinvestigator reported compensation from Replicor to his institution. The remaining 11 coinvestigators reported having no relevant financial disclosures.

ginews@gastro.org

SOURCE: Bazinet M et al. Gastroenterology. 2020 Mar 5. doi: 0.1053/j.gastro.2020.02.058.

Since the advent of the curative direct-acting antiviral therapy for hepatitis C, increased efforts have been devoted toward finding a cure for chronic hepatitis B. The integration of hepatitis B virus (HBV) into the host genome is a major barrier to the complete cure (eradication of HBV DNA from hepatocytes and serum). Consequently, functional cure (sustained clearance of HBV surface antigen with viral DNA eradication from serum) has become the sought after outcome in clinical trials. Current treatment of active hepatitis B targets viral DNA suppression mostly using life-long oral nucleos(t)ide analogue or infrequently using a 1-year course of interferon. Both of these therapies have been generally successful in suppressing serum levels of HBV DNA but functional cure rates have been minimal. In the current study, Dr. Bazinet and colleagues evaluated tenofovir disoproxil fumarate and pegylated interferon-alpha in conjunction with weekly administration of either of two investigational nucleic acid polymers (REP 2139-Mg or its rapidly cleared analogue REP 2165-Mg) in a randomized phase 2 trial for 48 weeks followed by up to 48 weeks off any therapy. Notably, the functional cure rate observed on follow-up was 39%, compared with 0% on tenofovir or tenofovir and interferon when used before adding the study medications. No serious adverse events were associated with either investigational drug. As expected, interferon-related thrombocytopenia and neutropenia developed. This study offers promising safety and efficacy data and it brings us one step closer to functional cure on the path of one day achieving the holy grail of complete cure of HBV.


Dr. Izzy

Manhal Izzy, MD, is assistant professor of medicine, Vanderbilt University Medical Center, division of gastroenterology, hepatology, and nutrition, and transplant hepatology at the Vanderbilt Clinic, Nashville, Tenn. He has no conflicts.

Total underwater colonoscopy can surmount technical challenges

BY AMY KARON
MDedge News

Total underwater colonoscopy can surmount challenges with insertion, simplify endoscopic mucosal resection, and lessen pain and the need for sedation, according to a "Here and Now: Clinical Practice" article published in Clinical Gastroenterology and Hepatology.

At the same time, total underwater colonoscopy has not been shown to significantly affect adenoma miss rates, requires a longer insertion and overall procedure time, and cannot be performed without adequate bowel preparation, wrote Joseph C. Anderson, MD, of the Department of Veterans Affairs Medical Center in White River Junction, Vt., and the Geisel School of Medicine at Dartmouth, Hanover, N.H.

He noted that total underwater colonoscopy is not the same as water immersion or water exchange, both of which involve infusing water while inserting the colonoscope and then distending the colon with carbon dioxide to visualize the mucosa during withdrawal. During total underwater colonoscopy, insertion, examination, and resection all are carried out with the lumen filled with water. Air is suctioned out, and the air valve is kept off.

This approach can surmount problems with insertion stemming from either severe angulation (often of the sigmoid colon), or redundant colon (excessive looping)

Continued on following page

Health care costs nearly doubled for NAFLD patients

BY AMY KARON
MDedge News

The health care costs of patients with nonalcoholic fatty liver disease (NAFLD) were nearly twice that of matched population controls, according to the results of a longitudinal cohort study.

Patients with biopsy-confirmed nonalcoholic steatohepatitis (NASH) were hospitalized an average of 0.27 times per year versus 0.16 times for controls ($P < .001$), for an annual incremental cost of $635, reported Hannes Hagström, MD, PhD, of Karolinska University Hospital in Stockholm. Patients with NAFLD also made significantly more outpatient care visits than controls ($P < .001$), he said. "Patients with advanced fibrosis [had] the highest costs, suggesting that reducing fibrosis progression is important to reduce future health care costs" in patients with NASH, Dr. Hagström and his associates wrote in Clinical Gastroenterology and Hepatology.

The retrospective longitudinal cohort study included all 646 patients diagnosed with biopsy-confirmed NAFLD at two hospitals in Sweden between 1971 and 2019. Patients with other liver diseases were excluded, as were heavy drinkers: men who drank more than 30 g of alcohol (just under 4 units) daily and women who drank more than 20 g daily. Each patient with NAFLD was matched with 10 population controls matched by age, sex, and county of residence.

Over a mean of 19.9 years of follow-up (range, 0-40 years), patients with NASH were hospitalized a total of 3,478 times, an average of 5.4 hospitalizations per patient. Controls were hospitalized an average of 3.2 times during the same time period ($P < .001$ vs. NASH patients). "This corresponded to a higher incremental cost in NAFLD patients of $635 per year (95% confidence interval, $407-$864; $P < .001$)," the researchers reported.

Between 2001 and 2009, patients with NAFLD averaged 5.4 more outpatient visits than controls ($P < .001$), with annual averages of 1.46 versus 0.86 visits ($P < .001$). Consequently, patients with NASH incurred $255 more per year in annual outpatient care costs. Liver disease accounted for 6% of outpatient care costs among NASH patients versus 0.2% of costs among controls.

"Cumulative costs in the [fibrosis stage 3 and 4] subgroup were relatively matched with the control population until around year 4 after biopsy, when costs diverged," the researchers said. "This could possibly be an effect of the larger F3 population developing cirrhosis and increasing costs due to decompensation events."

They noted that the rising prevalence of NAFLD will further burden health care budgets. "Costs [among patients with NASH] were higher in conjunction with liver biopsy, which is why using noninvasive diagnostic methods (e.g., transient elastography) is likely to reduce total costs," they added. Of note, although patients with NAFLD also incurred somewhat more per year in prescription costs, the difference was not statistically significant.

The study was supported by Stockholm City Council, the Bengt Ihre Foundation, the County Council of Östergötland, and Gilead. The researchers reported having no conflicts of interest.

ginews@gastro.org

SOURCE: Hagström H et al. Clin Gastroenterol Hepatol. 2019 Sep 12. doi: 10.1016/j.cgh.2019.10.023.

The possibility of FDA approval of NASH-modifying drugs later this year brings the hope of improving outcomes for patients with NAFLD. Inevitably, the cost-effectiveness of those drugs also will be scrutinized as we evaluate their impact in the coming years. To that end, Hagstrom et al. provide useful insight regarding the real-world costs of medical care among patients with histologically staged NAFLD in Sweden.


Dr. Balakrishnan

Their main finding is that medical costs for a patient with NAFLD over 20 years is double that for a random control patient from the general population.

It is worth taking a deeper dive into the factors that drove the cost differential. First, higher inpatient and outpatient specialty care costs accounted for the incremental cost of NAFLD care; drug costs were materially similar in the two groups, albeit examined over a very short time period in the study due to limited national registry data. Second, the cost differential was largest in the first year of diagnosis and attributed to the cost of liver biopsy and related expenses. Last, as one would expect, the cost differential was largest between patients who had stage 3-4 fibrosis, possibly explained by the costs of NASH-related complications.

While we hope that NASH-modifying drugs will reduce the risk of liver-specific complications, the cumulative financial impact of such therapies remains to be seen. On the one hand, short-term costs may increase because of the direct expense of the NASH-modifying drugs plus additional expenses related to management of side effects. In addition, it is likely patients treated with NASH-modifying drugs will need more frequent assessments of liver disease severity to evaluate whether the medication is working, which even if done noninvasively, is likely to add to medical costs. In the long term however, NASH-modifying treatments may reduce the risk of NAFLD complications over time, mitigating the cumulative cost of NAFLD care. The true net effect remains to be seen. In the meantime, we need further studies that quantify costs of NAFLD care – ideally by disease severity and that provide greater insight into the cost of caring for the complications of NASH progression, including liver disease clinical decompensations and transplant.

Maya Balakrishnan, MD, MPH, is an assistant professor, department of medicine, section of gastroenterology & hepatology, Baylor College of Medicine, Houston, and director of hepatology at Ben Taub General Hospital, Houston. She has no conflicts of interest.

Continued from previous page

that does not respond to abdominal pressure, colonoscope stiffening, or a change in position, Dr. Anderson noted. He explained that, unlike air, water does not maximally distend the lumen and therefore does not exacerbate angulation. "When I am in the ascending colon and cannot reach the cecum, I turn off the air valve, aspirate all gas, infuse water, and complete the insertion underwater," he said. "Another advantage of water in patients with angulated sigmoid colons is that its use could prevent [the] excessive use of air and potential barotrauma of the cecum, even when using carbon dioxide."

The use of water can aid endoscopic mucosal resection (EMR) because polyps tend to float into view (including from hard-to-visualize areas, such as folds) and into the snare, he said. "Because water has a magnifying property, underwater EMR may allow for easier delineation of the polyp's border, also facilitating complete removal."

Nonetheless, it remains unclear whether the use of total underwater colonoscopy significantly affects adenoma detection rates. In a recent study, Dr. Anderson and his coinvestiators randomly assigned 121 patients to undergo either colonoscopy with carbon dioxide insufflation, followed by total underwater colonoscopy, or the same examinations in the reverse sequence (Gastrointest Endosc. 2019;89:591-8). Adenoma miss rates were statistically similar between groups. Although water decreases green mucus and residual stool and suspends "unsuctionable" particles (e.g., seeds) into the cecal lumen, where colonoscopists can better see past them, water also increases the production of white mucus, which can be difficult to remove during withdrawal, Dr. Anderson said.

He cited meta-analyses in which colonoscopies performed with water, without sedation or with minimal sedation, were associated with less pain and a higher likelihood of performing a complete examination than when only air was used. "I find this [approach] particularly useful in older, thinner patients, especially women," Dr. Anderson said. "In addition, in patients with multiple comorbidities, cecal intubation often can be achieved safely with minimal sedation."

Dr. Anderson reported having no relevant conflicts of interest.

ginews@gastro.org

SOURCE: Anderson JC. Clin Gastroenterol Hepatol. 2020 Feb 25. doi: 10.1016/j.cgh.2020.02.042.

GI symptoms affected 1 in 4 hospitalized for COVID-19

BY AMY KARON
MDedge News

Gastrointestinal symptoms affected 26% of hospital employees hospitalized with presumptive COVID-19 infection, according to the results of a study from Wuhan, China.

Among nonmedical personnel in the study (median age, 62 years), 63% of those with GI symptoms were female (P = .03), wrote Zili Zhou of Huazhong University of Science and Technology, Wuhan, and associates. Gastrointestinal symptoms correlated significantly with lower hemoglobin levels, increased levels of inflammatory markers, and poorer liver function, but not with clinical complications or mortality, they noted. However, "most patients were still hospitalized at the time of [manuscript] submission, [which made it] difficult to further assess the correlation between GI symptoms and clinical outcomes," they wrote in Gastroenterology.

Reverse transcriptase polymerase chain reaction has detected COVID-19 in patients' stool, and COVID-19's primary receptor for cellular entry, the angiotensin-converting enzyme 2 (ACE2) receptor, "is highly expressed not only in lung AT2 cells but also in absorptive enterocytes in the ileum and colon," the investigators wrote. They compared laboratory and clinical findings among 254 adults with and without GI symptoms who were admitted to Wuhan's main hospital with presumptive COVID-19 pneumonia between Dec. 20, 2019, and Feb. 9, 2020. All patients were employed by the hospital.

Gastrointestinal symptoms affected 26% of patients and most commonly included diarrhea (18%), nausea (8%), vomiting (6%), and abdominal pain (2%), the researchers reported. Arrhythmias and shock were rare, affecting less than 0.5% of patients. A total of 16 patients (6%) died.

The 161 nonmedical staff in the study were older and, therefore, were evaluated separately from medical staff (respective medians, 36 and 62 years; interquartile ranges, 31-41 years and 49-69 years). Among nonmedical staff, GI symptoms correlated with significantly lower hemoglobin levels (117 g/L [range, 106-127] vs. 133 g/L [range, 114-141], P = .03), and significantly higher levels of C-reactive protein (7.3 mg [range, 2.9-6.6] vs. 3.8 mg (1.8-5.8), P = .021) and alanine aminotransferase (64.1 U/L [range, 51.2-64.4] vs. 46.6 U/L [range, 31.9-61.2]; P = .049). Gastrointestinal symptoms also correlated significantly with fatigue, sore throat, and dizziness. Although the nonmedical cohort included five more males than females, females made up nearly two-thirds (63%) of individuals with GI symptoms (P = .03).

Although 25% of medical staff in the study had GI symptoms, GI symptoms did not correlate with other symptoms or with laboratory findings. This might be because "most of the infected medical staff were younger nurses without comorbidities," the investigators wrote. "In addition, there [was] less delay from the onset of symptoms to hospital admission."

For the overall cohort, the most prevalent symptoms were fever (84%), fatigue (52%), productive cough (42%), dry cough (42%), and myalgia (34%). Although these symptoms are typical of COVID-19 infection, most patients were not tested for the virus, "which will inevitably lead to several patients without [COVID-19 pneumonia] being included," the investigators noted.

The National Nature Science Foundation of China provided funding. The investigators reported having no relevant conflicts of interest.

ginews@gastro.org

SOURCE: Zhou Z et al. Gastroenterology. 2020 Mar 18. doi: 10.1053/j.gastro.2020.03.020.

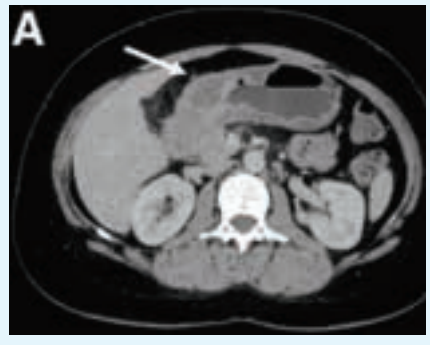
Correction

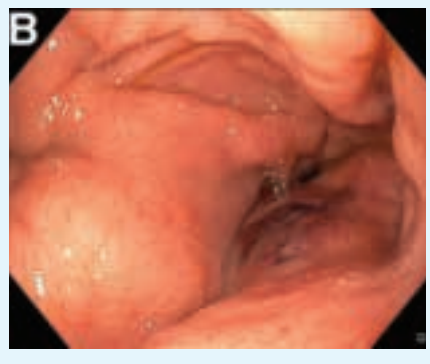
In the story "AGA guideline favors biologics for moderate/severe UC" featured on the front page of the April 2020 issue, the second sentence misrepresents the overall guideline. The sentence is taken out of context and is not a key recommendation. The description of tofacitinib's use for UC maintenance therapy is correct, but it was not a key recommendation. Please disregard it.

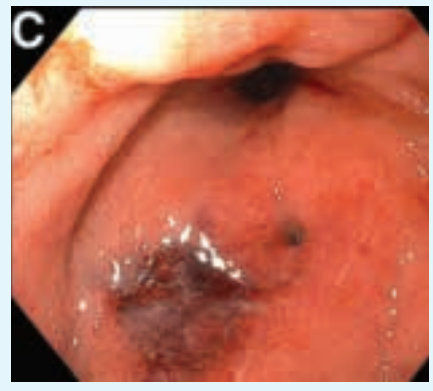
CLINICAL CHALLENGES AND IMAGES

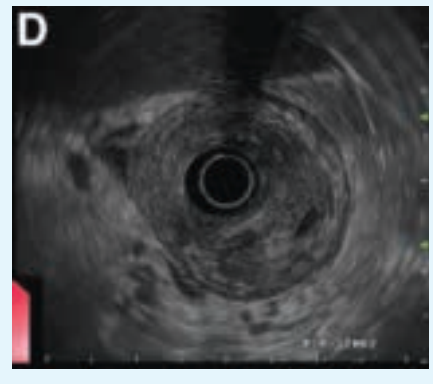
What is your diagnosis?

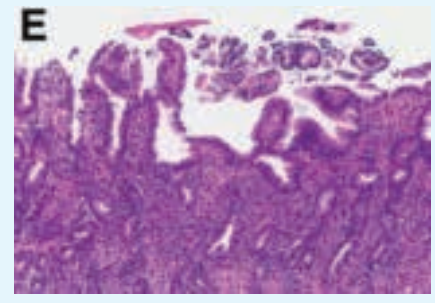
By Gina Treichler, MD, Antonia Töpfer, and Bernhard Morell, MD. Published previously in Gastroenterology (2019;156[8]:2142-3).

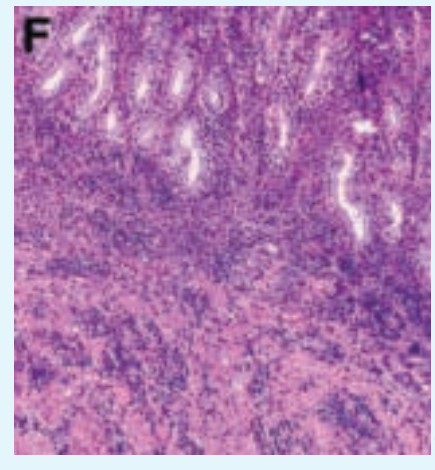












AGA Institute

A previously healthy 41-year-old woman presented with upper abdominal pain, nausea, vomiting, and fever for 4 days. On admission, the patient was febrile (40.1°C); her blood pressure, heart rate, and peripheral oxygen saturation were normal. Laboratory findings were notable for a C-reactive protein of 190 mg/L (reference range, less than 5 mg/L) along with a white cell count of 21,600/mm^3 (reference range, 4,500–10,500/mm^3). Liver enzymes, pancreatic lipase, and bilirubin were within normal limits. A CT scan of the abdomen revealed wall thickening of the gastric antrum (Figure A). Gastroscopy showed a heavily distorted gastric antrum with a fistula (Figure B, C). Consecutively, endoscopic ultrasound examination was performed, confirming circumferential thickening of the antral wall up to 20 mm with inhomogeneous hypoechogenic areas within the submucosa (Figure D). Deep endoscopic forceps biopsies were obtained. Histopathologic examination revealed extensive infiltration of the mucosa and submucosa by neutrophils (Figure E, F) and microbial cultures were positive for *Streptococcus spp.* (*S. pyogenes, viridans* group streptococci) and *Rothia mucilaginosa*.

The diagnosis is on page 18.

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GI & HEPATOLOGY NEWS

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New COVID-19 guidance for gastroenterologists

AGA has published new expert recommendations in *Gastroenterology*: AGA Institute Rapid Review of the GI and Liver Manifestations of COVID-19, Meta-Analysis of International Data, and Recommendations for the Consultative Management of Patients with COVID-19.

Key guidance for gastroenterologists:

- **GI symptoms are not as common in COVID-19 as previously estimated:** The overall prevalence was 7.7% (95% CI 7.4 to 8.6%) for diarrhea, 7.8% (95% CI: 7.1 to 8.5%) for nausea/vomiting, and 3.6% (95% CI 3.0 to 4.3%) for abdominal pain. Notably, in outpatients, the pooled prevalence of diarrhea is lower (4.0%).
- **However, COVID-19 can present atypically, with GI symptoms:** COVID-19 can present with diarrhea as an initial symptom, with a pooled prevalence of 7.9% across 35 studies, encompassing 9,717 patients. Most often, diarrhea is accompanied by other upper respiratory infection symptoms. However, in some cases, diarrhea can precede other symptoms by a few days, and COVID-19 may present as isolated GI symptoms prior to the development of upper respiratory infection symptoms.
- **Monitor patients with new diarrhea, nausea, or vomiting for other COVID-19 symptoms:** Patients should inform gastroenterologists if they begin to experience new fever, cough, shortness of breath, or other upper respiratory infection symptoms after the onset of GI symptoms. If this occurs, testing for COVID-19 should be considered.
- **Abnormalities in liver function tests should prompt thorough evaluation:** Liver test abnormalities can be seen in COVID-19 (in approximately 15% of patients); however, available data support that these abnormalities are more commonly attributable to secondary effects from severe disease, rather than primary virus-mediated liver injury. Therefore, it is important to consider alternative etiologies, such as viral hepatitis, when new elevations in aminotransferases are observed.

For all seven evidence-based recommendations and a detailed discussion, review the full publication in *Gastroenterology*.

Authors: Shahnaz Sultan, Osama Altayar, Shazia M. Siddique, Perica Davitkov, Joseph D. Feuerstein, Joseph K. Lim, Yngve Falck-Ytter, Hashem B. El-Serag on behalf of the AGA.

ginews@gastro.org

Win! CMS to pay for phone visits same as in-person appointments

Since the beginning of the pandemic, AGA has objected to the Centers for Medicare & Medicaid Services' (CMS) low reimbursement rate for evaluation and management (E/M) services provided by telephone. Today, CMS fixed the problem. **Retroactive to March 1, 2020, CMS will pay E/M services provided by telephone at the same rate as in-person, office/outpatient E/M services.**

Thanks to everyone who helped us push CMS to address this issue. AGA worked together in coalition with other specialties and Congress on resolving this problem from the start of the pandemic.

Here are more details:

- Medicare's updated guidance to physicians states, "Medicare payment for the telephone evaluation and management visits (CPT codes 99441-99443) is equivalent to the Medicare payment for office/outpatient visits with established patients effective March 1, 2020.
- The CMS press release outlined the new rates for telephone E/M:
- CMS is also increasing payments for these telephone visits to match payments for similar office and outpatient visits. This would increase payments for these services from a range of about $14-$41 to about $46-$110. The payments are retroactive to March 1, 2020.

We are pleased CMS listened to our message and has addressed this issue. Join the discussion on the AGA Community.

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Meet Congressman Roger Marshall, MD, R-KS

This article is brought you by AGA PAC, a voluntary, non-partisan political organization affiliated with and supported by AGA and the only political action committee supported by a national gastroenterology society. Its mission is to give gastroenterologists a greater presence on Capitol Hill and a more effective voice in policy discussions.

The 116th Congress is well represented by the physician community, featuring a total of 17 physicians: 3 in the U.S. Senate and 14 in the House of Representatives. One of the physicians in the House, Rep. Roger Marshall, MD, R-KS, is an OBGYN by trade who is currently serving his second term in Congress. First elected in 2016, he arrived in Washington as one of only two physicians in his freshman class. He actively engaged in health care policy from the very beginning, working across party lines on a range of health care issues facing Capitol Hill. Upon entering Congress, he proactively reached out to AGA as well as other specialty physician organizations to learn our priority issues and expressed his desire to serve as a champion of the physician community.

In addition to the two committees he sits on, Dr. Marshall also serves as the chairman of the health task force for the Republican Study Committee. Additionally, Dr. Marshall is a member of the GOP Doctors Caucus, a coalition of 21 Republican medical providers with a mission statement "to utilize medical expertise to develop patient-centered health care reforms focused on quality, access, affordability, portability, and choice." The GOP Doctors Caucus was instrumental in pushing for a permanent repeal of the sustainable growth rate (SGR) and helped to coalesce bipartisan, bicameral support for repeal legislation in the 113th Congress. The GOP Doctors Caucus continues to be active in the current Congress, advocating for policies that strengthen both the patient and provider communities.

As a member of the GOP Doctors Caucus and as a physician held in high regard by his House colleagues, Dr. Marshall is uniquely situated to advance agendas and legislative priorities that promote sound health care policy. He willingly works across the aisle with his Democratic counterparts on legislation of importance to the physician and patient community. Dr. Marshall recently worked with one of his Democratic, physician colleagues, Rep. Ami Bera, MD, D-CA, on the Improving Seniors Timely Access to Care Act, legislation addressing prior authorization burdens in Medicare Advantage plans. Dr. Marshall has vocalized the importance of physicians getting involved in the political process and to that effect, spoke to AGA members at AGA's annual Advocacy Day about his experience as a physician running for Congress and the importance of physician advocacy.


Dr. Marshall

Dr. Marshall is running for the open Senate seat in Kansas. Given that Dr. Marshall has reiterated his desire to continue to work with the physician community to ensure access to care for our patients, AGA looks forward to supporting Dr. Marshall's Senate candidacy and continuing to work with him and his office on issues and initiatives to advance the science and practice of gastroenterology.

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GI fellows: Go online to access curated learning resources today

AGA just released GI Distance Learning, agau.gastro.org/diweb/catalog/q/GI-Distance-Learning, a new initiative providing AGA trainee members and medical residents a complementary set of curated education and career development resources available online. A part of AGA University, GI Distance Learning enables you to enhance your knowledge in a number of GI-related topics at your own pace from the comfort of home.

Through GI Distance Learning, you will have free access until Aug. 1 to the 800+ questions and answers included in the DDSEP® 9 Question Bank. Assess your knowledge, identify gaps in learning, and stay current on the latest advances in GI and liver disease.

To access the Question Bank free of charge:

- Visit AGA University and sign in to your AGA account.
- Go to the DDSEP 9 Question Bank.
- Add the Question Bank to your Cart and Checkout.
- Type **DDSEP9Distance** in the Discount Code box.
- Apply the discount and submit your order.
- Use the My Courses link to access the Question Bank.

During the COVID-19 pandemic, many of us are struggling with the new normal and changes in our daily routines. Resiliency, emotional intelligence, and strategies for combatting burnout become increasingly important. The following on-demand resources from GI Distance Learning can help.

- Resilient Leadership
- Emotional Intelligence
- Strategies to Combat Burnout in GI and Maintaining Work/Life Balance

Continue to check back regularly at AGA University as we will continue to add resources to GI Distance Learning in the coming weeks.

ginews@gastro.org

➤ CORONAVIRUS ROUNDUP

Antibody test requirements strengthened, advance payment program suspended, and more

BY LUCAS FRANKI
MDedge News

FDA tightens requirements for COVID-19 antibody tests

The Food and Drug Administration has announced tighter requirements for companies developing COVID-19 tests in an attempt to combat fraud and better regulate products coming into the market.

The new policy, updated on May 4, requires commercial antibody test developers to apply for Emergency Use Authorization (EUA) from the FDA within 10 business days of the date they notified the FDA of their validation testing or from the date of the May 4 policy, whichever comes later, and also provides specific performance threshold recommendations for test specificity and sensitivity.

The FDA also introduced a more streamlined process for the support of EUA submissions and review. Two voluntary EUA templates for antibody tests are available for the facilitation, preparation, and submission of EUA requests.

Advance payment program to clinicians for COVID-19 relief suspended

The Centers for Medicare & Medicaid Services will suspend its Medicare advance payment program for clinicians and will reevaluate how much to pay hospitals through particular COVID-19 relief initiatives. The decision was made "in light of historical direct payments made available through the Department of Health & Human Services' Provider Relief Fund," the CMS said.

In the past 5 years before the COVID-19 crisis, the CMS approved about 100 total requests for advanced Medicare payment, mostly connected to natural disasters. Since March, the CMS approved more than 21,000 applications for advanced Medicare payment Part A and almost 24,000 applications for Part B, for a combined of cost of nearly $100 billion.

Remdesivir now 'standard of care' for COVID-19

Hospitalized patients who had COVID-19 with lung involvement and who received remdesivir recovered faster than did similar patients who received placebo, according to a data analysis.

Patients who received remdesivir had a time to recovery 31% faster than for those who received placebo. There was a potential survival benefit as well, with a mortality rate of 8.0% for those receiving remdesivir and 11.6% for those who received placebo.

On the basis of the analysis, remdesivir "will be the standard of care" for patients with COVID-19, Anthony S. Fauci, MD, said in a press conference. "Whenever you have clear-cut evidence that a drug works, you have an ethical obligation to let the people in the placebo group know so they could have access."

Infectious disease experts say testing is key to reopening

The Infectious Diseases Society of America has said that the ability to conduct mass testing is key to opening up the American economy, issuing recommendations that outline the steps that would be necessary in order to begin easing physical distancing measures.

Some of the recommended steps include widespread testing and surveillance; the ability to diagnose, treat, and isolate individuals with COVID-19; scaling up health care capacity and supplies to manage recurrent episodic outbreaks; and maintaining physical distancing to prevent recurrent outbreaks.

"The recommendations stress that physical distancing policy changes must be based on relevant data and adequate public health resources and capacities and calls for a rolling and incremental approach to lifting these restrictions," Thomas File Jr., MD, president of IDSA, said in a press briefing.

Obesity can shift severe COVID-19 to younger age groups

The younger an ICU patient with severe COVID-19 is, the more obese that patient tends to be, according to a new analysis published in The Lancet. The study's lead author, David Kass, MD, said that comorbidities in ICU patients studied in Italy and China included hypertension, cardiovascular disease, and type 2 diabetes.

When the epidemic accelerated in the United States, older age was identified as a risk factor. Obesity had not yet been added to this list.

Dr. Kass and colleagues did a quick evaluation of the link between body mass index and age of patients with COVID-19 admitted to ICUs at Johns Hopkins University, University of Cincinnati, New York University, University of Washington, Florida Health, and University of Pennsylvania.

He suggested mechanisms to explain why obesity predisposes patients with COVID-19 to severe disease:

- Obesity places extra pressure on the diaphragm while lying on the back, restricting breathing.
- Reports suggest that cytokine storms and immune mishandling of the virus are why it's more severe than other coronaviruses. So the underlying proinflammatory state of obesity could explain higher risk.
- The ACE-2 receptor to which the SARS-CoV-2 virus attaches is expressed in higher amounts in adipose tissue than the lungs.

Frontline associate editor Mr. Franki compiled this column from reports first published on MDedge.com and Medscape.com.

Data support continued use

Biologics *from page 1*

the issue, so they reviewed the experience in their own health system of patients with inflammatory diseases – most commonly psoriatic arthritis, RA, and Crohn's disease – who were assessed for COVID-19 from March 3 to April 3.

Fever, cough, and shortness of breath were the most common symptoms. The infection was confirmed by polymerase chain reaction in 59 (69%) and highly suspected in 27.

A total of 62 patients (72%) were on JAK inhibitors or biologics at baseline, including 38 (44%) on tumor necrosis factor inhibitors.

Dr. Scher

Overall, 14 patients (16%) were hospitalized with COVID-19, which is consistent with the 26% hospitalization rate among the general population in New York City.

Baseline biologic and JAK inhibitor use was lower among hospitalized patients than among those who weren't hospitalized (50% vs. 76%), and the hospitalization rate was only 11% among 62 subjects who had been on the agents long term, more than a year among most.

Hospitalized patients tended to be slightly older (mean, 50 vs. 46 years) with a higher prevalence of hypertension, diabetes, and chronic obstructive pulmonary disease. They also had a higher prevalence of RA (43% vs. 19%), methotrexate use (43% vs. 15%), and use of hydroxychloroquine (21% vs. 7%) and oral glucocorticoids (29% vs. 6%).

It's unknown what to make of those findings for now, Dr. Scher said. The study didn't address differences in the severity of the underlying inflammatory illness, but a new and significantly larger case series is in the works that will analyze that and other potential confounders.

Dr. Scher noted that he's particularly interested in drilling down further on the higher prevalence of RA and methotrexate in hospitalized patients. "We want to understand those signals better. All of this needs further validation," he said.

Of the 14 hospitalized patients, 11 (79%) were discharged after a mean of 5.6 days. One died in the ED, and two remained hospitalized as of April 3, including one in the ICU.

The investigators are contributing to COVID-19 registries for inflammatory disease patients. The registries are tending to report higher hospitalization rates, but Dr. Scher noted they might be biased toward more severe cases, among other issues.

As for the current situation in New York City, he said that the "last week in March and first 3 in April were indescribable in terms of admissions, intubations, and deaths. Over the last week or so, it has calmed down significantly."

There was no external funding.

Rebecca Haberman, MD, reported ties to Janssen, and Dr. Scher reported ties to Janssen, Novartis, Pfizer, and other companies.

aotto@mdedge.com

SOURCE: Haberman R et al. N Engl J Med. 2020 Apr 29. doi: 10.1056/NEJMc2009567.

AGA Clinical Practice Update: Functional heartburn

BY AMY KARON
MDedge News

Recognizing the presence of functional heartburn is vital to prevent unnecessary acid-suppressive therapy and invasive antireflux treatments, which are ineffective and "might even lead to harm," cautions a new clinical practice update from the American Gastroenterological Association.

Proton pump inhibitors (PPIs) "have no therapeutic value in functional heartburn," unless patients also have gastroesophageal reflux disease (GERD), Ronnie Fass, MD, of MetroHealth System in Cleveland, and coauthors wrote in Gastroenterology. If clinical work-up finds no clear evidence of GERD, "an attempt to discontinue PPI therapy is warranted," they added. Likewise, antireflux surgery and endoscopic treatments for GERD "have no therapeutic benefit in functional heartburn and should not be recommended." However, histamine$_2$ receptor antagonists (H_2RAs) "may have an independent benefit in functional heartburn from an esophageal pain modulatory effect."

Heartburn consists of burning or discomfort that radiates retrosternally from the epigastrium. Patients may report reflux, regurgitation, chest pain or discomfort, fullness, water brash, belching, or a sour and bitter taste in the mouth. Functional heartburn is heartburn that persists after at least 3 months of maximal (double-dose) PPIs taken before meals. Confirming functional heartburn requires high-resolution manometry to rule out major esophageal motor disorders, esophageal endoscopy with biopsy to rule out structural abnormalities and mucosal disorders (e.g., erosive esophagitis, Barrett's esophagus, and eosinophilic esophagitis), and either pH monitoring while off PPI therapy or pH-impedance monitoring on therapy if patients have proven GERD. According to the clinical practice update, pH studies should document physiologic acid exposure in the distal esophagus that is unlinked to symptoms (i.e., both a negative symptom index and a negative symptom association probability).


Dr. Fass

Functional heartburn resembles GERD, but symptoms are unrelated to acid exposure. Balloon distension studies indicate that patients with functional heartburn experience both esophageal and rectal hypersensitivity. Anxiety and mood disorders also are highly prevalent, and patients "will likely not improve unless esophageal perception and underlying affective disorders are adequately managed," Dr. Fass and coauthors emphasized.

In keeping with this approach, limited evidence from clinical trials supports the first-line use of neuromodulator therapies, including selective serotonin reuptake inhibitors, tricyclic antidepressants, the serotonin 4 receptor antagonist tegaserod, and H_2RAs (e.g., cimetidine, famotidine, nizatidine). The only SSRI studied thus far in functional heartburn is fluoxetine. In a placebo-controlled trial of patients with normal endoscopy and heartburn that had not responded to once-daily PPI therapy, 6 weeks of fluoxetine (20 mg daily) significantly outperformed double-dose omeprazole ($P < .001$) for the primary endpoint of heartburn-free days. "This superior therapeutic effect of fluoxetine was seen only in the subset of patients with a normal pH test," the experts noted.

In another placebo-controlled trial, the neuromodulator tegaserod (a serotonin 5-HT$_4$ receptor partial agonist) significantly improved tolerance of esophageal pressure during balloon distension and significantly decreased heartburn and regurgitation in patients with functional heartburn. Melatonin (6-mg dose at bedtime for 3 months), which "also has a pain modulatory effect in the gastrointestinal tract," significantly improved symptom-related quality of life, compared with nortriptyline and placebo in a randomized, three-arm trial.

Acupuncture and hypnotherapy also have shown benefit in small studies of functional heartburn and may be appropriate as monotherapy or adjunctive treatment, according to the clinical practice update. In a small randomized study, 10 acupuncture sessions delivered over 4 weeks significantly improved daytime and nighttime heartburn and acid regurgitation scores, compared with double-dose PPI. "Mean general health score was significantly improved only in those receiving acupuncture," the experts noted. Hypnotherapy was associated with significant improvements in symptoms, visceral anxiety, and quality of life in an uncontrolled study of nine patients.

Although the overall prevalence of functional heartburn is unclear, it has been detected in 21%-39% of PPI-refractory patients evaluated with pH-impedance monitoring, Dr. Fass and associates wrote. Because functional heartburn and GERD can co-occur, some patients with functional heartburn may develop long-term complications of GERD, such as Barrett's esophagus or peptic stricture. The experts noted, "this is anticipated to be rare, and the vast majority of patients with functional heartburn will have compromised quality of life, rather than organic complications over time."

The experts reported having no funding sources and no relevant conflicts of interest.

ginews@gastro.org

SOURCE: Fass R et al. Gastroenterology. 2020 Feb 1. doi: 10.1053/j.gastro.2020.01.034.

CLINICAL CHALLENGES AND IMAGES

Answer to "What is your diagnosis?" on page 11: Phlegmonous gastritis

The diagnosis

The patient was treated with intravenous antibiotics (amoxicillin/clavulanic acid 6.6 g/d) and a proton pump inhibitor (esomeprazole 80 mg/d). Within a few days, her clinical status improved and abdominal ultrasound examination documented regression of the gastric wall thickening. Laboratory screening for predisposing factors such as diabetes mellitus, infection with human immunodeficiency virus, or immunoglobulin deficiency were negative and there was no clinical evidence of Crohn's disease. Antibiotic treatment was stopped after 2 weeks. Six months later, follow-up gastroscopy was performed confirming complete resolution of the inflammatory changes in the stomach.

Phlegmonous gastritis is a rare but potentially life-threatening bacterial infection of the gastric wall. Since its first description in 1862, about 500 cases have been reported worldwide. Whereas the original reports dating back to the preantibiotic area suggest very high mortality rates in the range of 90%, phlegmonous gastritis still represents a life-threatening condition.[1,2] In about one-half of the cases, acquired immunodeficiency states such as diabetes mellitus, human immunodeficiency virus, or alcoholism are identified as predisposing factors. In addition, gastric biopsies may herald the development of phlegmonous gastritis. *Streptococcus spp.* account for the majority of the cases, which can be isolated in about 70% of patients.[1] Other organisms such as *Staphylococcus spp.*, *Escherichia coli, Haemophilus influenzae*, and *Proteus* or *Clostridium spp.* have been described as pathogens associated with this uncommon condition. Affected patients typically present with nonspecific symptoms such as abdominal pain, fever, nausea, vomitus, hematemesis, or diarrhea. In light of the devastating natural course of phlegmonous gastritis, timely preemptive administration of broad-spectrum antibiotics along with a high index of suspicion are paramount. A computed tomography scan and transabdominal ultrasound examination are useful as initial tests, whereas endoscopic ultrasound examination typically demonstrates a diffusely thickened, hypoechogenic submucosal wall layer that is not commonly found in patients with other submucosal lesions, such as carcinoid or leiomyoma. The diagnosis can be confirmed by endoscopic forceps biopsy provided that sufficient submucosal tissue is included.[1] Surgery should be considered only for cases refractory to conservative treatment.

ginews@gastro.org

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Claims review builds case for NAFLD/NASH screening

BY M. ALEXANDER OTTO
MDedge News

Nonalcoholic fatty liver disease isn't being diagnosed early enough; by the time it's caught, patients often have advanced complications such as decompensated cirrhosis or hepatocellular carcinoma (HCC), according a review of Medicare claims data for 2007-2015.

Among 10,826,456 enrollees – about 20% of the Medicare population – 621,253 had International Classification of Diseases codes for NAFLD/nonalcoholic steatohepatitis (NASH), yielding a prevalence of 5.7%. That's substantially lower than modeling estimates of 30% in the general population, indicating that there is "considerable underdiagnosis of NAFLD in real-world clinical practice," and that less severe disease, and the opportunity to treat it before it progresses, is being missed, said investigators led by Rohit Loomba, MD, director of the NAFLD Research Center at the University of California, San Diego.

When the team excluded patients with other causes of liver disease such as alcohol abuse or viral hepatitis, they were left with a study population of 260,950 subjects; 71.1% had NAFLD/NASH alone, and 28.9% had NAFLD cirrhosis, almost all of them first diagnosed with decompensated cirrhosis. More than half of the 581 HCC patients had no previous diagnosis of cirrhosis.

The cumulative risk of progression of NAFLD to cirrhosis over the 8-year study period was 39%, and from compensated cirrhosis to decompensated cirrhosis, it was 45%. Among a subgroup of 258 patients with compensated cirrhosis, 19% progressed to decompensated cirrhosis or HCC, or died, over a median of a year and a half.

The findings "highlight the urgent need for an algorithm to identify individuals at higher risk of NAFLD/NASH," so the disease is caught at a point when lifestyle and medical interventions might halt or delay progression, the team said.

The findings 'highlight the urgent need for an algorithm to identify individuals at higher risk of NAFLD/NASH,' so the disease is caught at a point when lifestyle and medical interventions might halt or delay progression, the team said.

Screening isn't currently recommended in guidelines because of the limited efficacy of current treatments, but "with promising novel NAFLD/NASH interventions currently under development and review," the team said it might be time to rethink the issue.

Most patients with early NAFLD/NASH have nonspecific symptoms, which makes screening difficult. However, the investigators identified several independent predictors of disease progression and death, including cardiovascular disease – present among 68.7% of subjects – dyslipidemia (84.1%), diabetes (55.5%), and renal impairment (24.3%).

The finding "supports the evaluation of certain variables" in a screening algorithm, "including advanced age and certain components of metabolic syndrome. Furthermore, important variables in previously developed noninvasive NAFLD/NASH staging algorithms including body mass index and biomarkers for liver function and insulin resistance may also warrant evaluation as components of an identification algorithm," the team said.

It's possible the study overestimated the risks of disease progression and mortality with NAFLD/NASH because patients with more severe disease were probably more likely to have been identified in Medicare data, the investigators said.

The mean age of the NAFLD/NASH subjects was 67.4 years, and 60% were women.

The work was funded by Gilead. Two authors are Gilead employees, and the rest, including Dr. Loomba, reported funding and other ties to the company.

aotto@mdedge.com

SOURCE: Loomba R et al. Aliment Pharmacol Ther. 2020 May 5. doi: 10.1111/apt.15679.

AGA Resource
To help your patients better understand NASH, visit the AGA GI Patient Center at https://www.gastro.org/practice-guidance/gi-patient-center/topic/nonalcoholic-steatohepatitis-nash.

AGA CPU: Surveillance for HCC in patients with NAFLD

BY AMY KARON
MDedge News

Physicians should consider liver cancer screening for all patients with nonalcoholic fatty liver disease (NAFLD) and cirrhosis, according to a new clinical practice update from the American Gastroenterological Association.

Screening "should be offered for patients with cirrhosis of varying etiologies when the risk of hepatocellular carcinoma is approximately at least 1.5% per year, as has been noted with NAFLD cirrhosis," wrote Rohit Loomba, MD, of the NAFLD Research Center at the University of California, San Diego, and associates. Although patients with noncirrhotic NAFLD also can develop hepatocellular carcinoma, "[a]t this point, we believe that [the benefit of screening] is restricted to patients with compensated cirrhosis or those with decompensated cirrhosis listed for liver transplantation," they wrote in Gastroenterology.

Liver cancer in NAFLD often goes undetected until it is advanced enough that patients are not candidates for curative therapy. Current guidelines provide limited recommendations on which patients with NAFLD to monitor for hepatocellular carcinoma, how best to do so, and how often. To fill this gap, Dr. Loomba and associates reviewed and cited 79 published papers and developed eight suggestions for clinical practice.

Patients with NAFLD and stage 0-2 fibrosis are at "extremely low" risk for hepatocellular carcinoma and should not be routinely screened, the practice update stated. Advanced fibrosis is a clear risk factor but can be challenging to detect in NAFLD – imaging is often insensitive, and screening biopsy tends to be infeasible. Hence, the experts suggest considering liver cancer screening if patients with NAFLD show evidence of advanced fibrosis or cirrhosis on at least two noninvasive tests of distinct modalities (that is, the two tests should not both be point-of-care, specialized blood tests or noninvasive imaging). To improve specificity, the recommended cut-point thresholds for cirrhosis are 16.1 kPa for vibration-controlled transient elastography and 5 kPa for magnetic resonance elastography.

Screening ultrasound accurately detects hepatocellular carcinoma in patients with cirrhosis who have a good acoustic window. However, ultrasound quality is operator dependent, and it can be difficult even for experienced users to detect mass lesions in overweight or obese patients. Thus, it is important always to document parenchymal heterogeneity and beam attenuation, and whether the entire liver was visualized. If ultrasound quality is inadequate, patients should be screened every 6 months with CT or MRI, with or without alpha-fetoprotein, according to the practice update.

The authors advised clinicians to counsel all patients with NAFLD and cirrhosis to avoid alcohol and tobacco. "Irrespective of NAFLD, the bulk of epidemiological data support alcohol drinking as a major risk for hepatocellular carcinoma," they note. Likewise, pooled studies indicate that current smokers are at about 50%-85% greater risk of liver cancer than never smokers. The experts add that, "[al]though specific data do not exist, we believe that e-cigarettes may turn out to be equally harmful and patients be counseled to abstain from those as well."

They also recommended optimally managing dyslipidemia and diabetes among patients with NAFLD who are at risk for hepatocellular carcinoma. Statins are safe for patients with NAFLD and dyslipidemia and may lower hepatocellular carcinoma risk, although more research is needed, according to the experts. For now, they support "the notion that the benefits of statin therapy among patients with dyslipidemia and NAFLD significantly outweigh the risk and should be utilized routinely." Type 2 diabetes mellitus clearly heightens the risk of hepatocellular carcinoma, which metformin appears to reduce among patients with NAFLD, cirrhosis, and type 2 diabetes. Glucagon-like peptide–1 receptor agonists and some thiazolidinediones also appear to attenuate liver steatosis, inflammation, degeneration, and fibrosis,

Continued on following page

Before pandemic, gastro earnings were steady

BY LUCAS FRANKI
MDedge News

COVID-19 has changed many things in the medical landscape as practices have closed and many physicians are transitioning to telemedicine.

Medscape's latest physician survey, conducted from Oct. 4, 2019, to Feb. 10, 2020, illustrates what gastroenterology looked like just before the coronavirus arrived.

While the average GI salary did rise from 2019, the increase was minimal, going from $417,000 in 2019 to $419,000 in 2020. In comparison, average income for all specialists was $346,000 in this year's survey, up by 1.5% from the $341,000 earned in 2019, Medscape reported.

Many gastroenterologists felt unfairly compensated in 2020, with only 52% reporting that they were satisfied with their salary. This was on the lower end of the 29 specialties included in the survey, which ranged from nephrology at 44% to oncology, emergency medicine, and radiology at 67%.

There was a notable disparity in the number of hours men spent seeing patients in comparison with women – while female GIs worked 38.3 hours a week, male GIs worked 42.5 hours. The average specialist saw patients 38 hours a week. Disparity was also evident in a higher salary for men: $430,000 versus $375,000. The number of hours GIs spent on paperwork and administration was roughly middle of the pack at 14.3 hours a week.

The respondents were Medscape members who were invited to participate. The sample size was 17,461 physicians, and compensation was modeled and estimated based on a range of variables across 6 years of data. The sampling error was ±0.74%.

lfranki@mdedge.com

Continued from previous page

but it remains unclear if these effects ultimately lower cancer risk.

It is unclear if obesity directly contributes to hepatocellular carcinoma among patients with NAFLD, but obesity is an "important risk factor" for NAFLD itself, and "weight-loss interventions are strongly recommended to improve NAFLD-related outcomes," the experts wrote. Pending further studies on whether weight loss reduces liver cancer risk in patients with NAFLD, they called for lifestyle modifications, pharmacotherapy, or bariatric surgery or bariatric endoscopy procedures to optimally manage obesity in patients with NAFLD who are at risk for liver cancer.

The authors disclosed funding from the National Institute of Environmental Health Sciences, the National Center for Advancing Translational Sciences, the National Institute of Diabetes and Digestive and Kidney Diseases, the Cancer Prevention & Research Institute of Texas, and the Center for Gastrointestinal Development, Infection and Injury. Dr. Loomba disclosed ties to Intercept Pharmaceuticals, Bird Rock Bio, Celgene, Enanta Pharmaceuticals, and a number of other companies. Two coauthors disclosed ties to Allergan, AbbVie, Conatus Pharmaceuticals, Genfit, Gilead, and Intercept. The remaining coauthor reported having no conflicts of interest.

ginews@gastro.org

SOURCE: Loomba R et al. Gastroenterology. 2020 Jan 29. doi: 10.1053/j.gastro.2019.12.053.

Local COVID prevalence a decider

Endoscopy *from page 1*

might be, to guide them in the next 2-4 weeks," Paul Berggreen, MD, secretary of the DHPA, said in an interview.

The AGA and DHPA guidelines envision a return to elective procedures in areas where COVID-19 cases have been declining for at least 2 weeks and where they are permitted by government directives.

Decisions hinge on the availability of testing, Dr. Berggreen said. The guidelines recommend polymerase chain reaction (PCR) tests for COVID-19 infections prior to elective endoscopy. When these tests are not available, a daily temperature log for 10 days prior to the procedure may substitute, they say.

However, if no PCR test is done, the guidelines call on all procedure room personnel to use N95 masks or the equivalent. If these masks aren't available, "consider delaying resumption of endoscopic procedures," the guidelines say. The procedure should also be postponed or moved to an inpatient setting in the event of a positive test, according to the guidelines.

Only if the patient has a negative test result should the procedure go forward with the use of standard surgical masks rather than N95 masks or the equivalent, the guidelines say.

The mask recommendations differ slightly from a decision tree put forward during an American College of Gastroenterology webinar on April 27, ACG President Mark Pochapin, MD, told this news organization.

The ACG decision tree takes into consideration local prevalence of COVID-19. "In a low-prevalence area if you have a negative test you can wear a regular surgical mask if the patient wears a surgical mask," Dr. Pochapin said.

Dr. Berggreen

The ACG decision tree also envisions the possibility of endoscopy with surgical masks along with face shields in areas with low prevalence of COVID-19, even in the absence of testing, if a patient doesn't have symptoms.

In contrast, the ACG decision tree calls for N95 or elastomeric masks in areas of high prevalence even with a negative test and a negative symptom screen. And it calls for a hospital procedure with an N95 or elastomeric mask in patients with either a positive symptom screen or a positive test.

In addition to masks, the AGA and DHPA guidelines recommend use of other PPE, such as water-resistant gowns, shoe covers, scrubs, double-gloving, and surgical head coverings.

They recommend daily screening of endoscopy center staff with temperature checks and surveys of COVID-19 symptoms and exposure.

Moreover, they call for social distancing of patients, visitors, and staff, and high-level disinfection of endoscopes. They recommend against endotracheal intubation of patients undergoing elective upper endoscopy.

The number of states allowing elective procedures is changing by the day, Dr. Berggreen said. In Arizona, where he practices, Gov. Doug Ducey (R) removed all restrictions on elective procedures starting May 1. But other states, where caseloads have been higher, including New York and Massachusetts, have yet to follow suit.

"We are still in kind of a holding pattern," Richard Hodin, MD, AGAF, chief of gastrointestinal surgery at Massachusetts General Hospital in Boston, said in an interview. Currently his facility is doing procedures only when a patient's life is in danger.

The availability of testing also ranges widely from one practice to another. New York University, where Dr. Pochapin is director of gastroenterology, is able to do its own tests. Dr. Berggreen's practice, Arizona Digestive Health in Phoenix, has assigned staff to swab patients in its parking lot and then send the samples to a lab by courier for analysis.

Dr. Berggreen said his practice has been essentially closed for the past month. In May, he expects his team will do about 30% of its normal volume. They will not start with purely elective procedures, such as following up on a polyp, but with semi-urgent cases, said Dr. Berggreen.

"Elective procedures can still be delayed a little bit longer," he said. "But we're trying to take care of our patients that are not purely elective: somebody with abdominal pain that you think is very likely a stomach ulcer, somebody with rectal bleeding or persistent diarrhea that's really impacting their life and you're thinking this could be an inflammatory condition of the colon."

Dr. Berggreen said he is reassured by a recent survey of 968 health care workers in Northern Italy who conducted gastrointestinal endoscopy there during the COVID-19 outbreak. Only 4.3% of respondents tested positive for COVID-19, and 85.7% of these infections occurred before the introduction of PPE and measures to reduce cases. Results were similarly encouraging for patients.

Only if the patient has a negative test result should the endoscopic procedure go forward with the use of standard surgical masks rather than N95 masks or the equivalent, the guidelines say.

Providing more endoscopy will relieve many patients, Dr. Berggreen said. "We all understand the need to limit the spread of the coronavirus but we also have patients who are going to start to have more struggles and potentially worse outcomes by sitting on a condition that requires endoscopy to diagnose and appropriately manage."

Neither Dr. Berggreen, Dr. Pochapin, nor Dr. Hodin reported any relevant financial interests. The authors of the survey did not report a source of funding or any relevant financial interests.

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Don't agree to contract changes

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to take large pay cuts to termination.

"In my 11 years of work on physician contracts, I have never seen changes as drastic as these," said Kyle Claussen, a physician contract attorney and CEO of Resolve, a company based in Columbia, Mo., that advises physicians on their careers. He has heard from more than 100 doctors about these proposed changes in their contracts and related matters.

In many cases, these actions violate the employed physicians' contracts, said Ericka Adler, a physician contract attorney at Roetzel & Andress in Chicago. "Some employers are acting out of desperation and are not making legally sound decisions," Ms. Adler said.

Making unfounded unilateral changes

Ms. Adler said some employers are simply issuing a letter to all doctors. "It goes something like, 'Just to let you know, we are cutting compensation effective immediately,' and this may apply ... to all doctors," she said.

"But the problem with letters is that this is a contractual matter," she said. "The employer needs to renegotiate each doctor's contract."

Employers might insist that the unilateral changes are based on terms in the contract, but this is usually unfounded, both lawyers said. A "force majeure" clause would allow the employer to set aside terms under specified emergencies, and the pandemic might be one of them. But Mr. Claussen said force majeure clauses are rare in physician contracts, and Ms. Adler said she has never seen one.

Lacking a force majeure clause, employers may turn to a common-law doctrine that allows employers to set aside a contract when it is impossible to perform its terms, owing to "an unexpected intervening event." But this tactic is also questionable, says Ms. Adler. "This is a very high standard and unlikely to be satisfied."

Desperately amending contracts

Lacking a cause to take unilateral action, many employers are trying to amend their physician contracts.

"Doctors are trying to decide how they will react to these documents," Mr. Claussen said. "If they don't sign, they run the risk of being terminated." At the time of the interview, he was expecting termination letters for some of these doctors to start coming in the first week May.

In response to these amendments, "doctors want to reach out to their employers and see if something can be negotiated," he said. Some employers have been amenable, others not.

Ms. Adler said the amendments typically offer open-ended arrangements favoring the employer. Also, when the employer owes the physician for services already performed, the amendments don't promise to pay them the full amount owed, she said.

Ms. Adler advises doctors to ask for a provision that restoration of their original salary will occur at a definite point in time, such as 30 days after the organization is back at previous volume. And if the doctor is owed money, the doctor should ask for full payment – and allow the employer to pay the doctor back over a period, she says.

Just since late March, employers have been pushing for several specific changes in doctors' employment status. Here are some changes that Mr. Claussen and Ms. Adler have been seeing.

Withholding quarterly bonuses

In March, just before quarterly bonus payments were due, employed physicians started getting notices that they would not get the bonus, Mr. Claussen said. This covered work already done, and it amounted to a lot of money because practices were busy then.

"Not paying bonuses is a very big deal because they can make up to 50% of a physician's total compensation," Mr. Claussen said. He added that unilaterally withholding those

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PROFESSIONAL OPPORTUNITIES

Private practice to private equity–backed MSO – Perspectives from the United Digestive team: Part 1

BY NEAL PATEL, MD, AND MARC SONENSHINE, MD, MBA

Author's note: This the first of a two-part series. In December 2018, Atlanta Gastroenterology Associates partnered with Frazier Healthcare Partners to form the practice management company United Digestive (UD). Since that time, colleagues across the country have evaluated their own private equity prospects and partnerships, as well as monitored the progress of our transition.

Our guiding principle is to provide a best-in-class operational infrastructure, so independent gastroenterologists can focus on delivering the highest quality patient care. Thus, in the first year, significant efforts and capital have been invested into UD's scalable platform to promote organic growth, as well as facilitate a smooth transition for other groups and physicians joining the team. So how are things going? Enjoy this two-part article where we reached out to several team members from all levels within the organization and asked them to share their personal experiences – both highlights and challenges – during UD's first year.

During the COVID-19 crisis, how has UD management responded? How has the UD management services organization (MSO) model affected partner level physician (PLP) compensation?
Marc Rosenberg, MD, UD Physician Executive Committee member

- "Immediately, the entire leadership team recognized the threat of COVID to our community, patients, staff, and business. A multidisciplinary task force including clinical and business leaders utilized our PE partner's vast resources, local hospital expertise, national societal recommendations, and colleagues' experiences from around the country to focus on protocols and procedures to protect our patients and staff. A few of the team's timely decisions included closing the majority of our patient-fronting services, transitioning to telehealth, hiring an infection control consultant, allowing physical distancing of our staff with off-site work, instituting symptomatic pathways, donating personal protective gear to local hospitals, covering all benefits as well as providing resources to obtain government benefits to furloughed team members, developing a provider wellness program, and encouraging hospital coverage considerations for high-risk providers. I also know the team is focusing on how we re-open at the appropriate time with necessary safety considerations, like investigating testing options and ensuring appropriate PPE is in place.

'During uncertain times, like the COVID-19 crisis, it is reassuring to partners to know that they are not responsible for the cost of infrastructure (i.e. leases, capital equipment, EHR system, consultants, etc.) and staffing.'

"As for UD physician partner compensation, our model is uniquely organized such that the MSO covers all overhead expenses with partners contributing a fixed per-

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funds, without a change in the contract, is legally questionable.

In addition to these changes on past bonuses, he said employers are now trying to temporarily end bonuses going forward through contract amendments. "It's not a good idea to sign this," he said.

Leaving doctors paid on pure production in the lurch

As volume falls, some hospitals and practices are shutting down doctors' offices for all but emergencies, leaving their employed doctors with practically nothing to do. Doctors paid purely on their productivity are devastated by this change because their income virtually goes to zero, Mr. Claussen said.

He said office shutdowns are particularly common for specialists because hospitals have been stopping elective procedures during the pandemic.

Having doctors on pure production means that employers can keep doctors hired without having to pay them, Mr. Claussen said.

In any case, both lawyers agreed that doctors on a pure production model are in an untenable situation right now. Ms. Adler said they are not earning money but are still technically at work, so they cannot collect unemployment compensation, which would give them some income.

Forcing doctors to use paid time off

To provide some pay for doctors who have no volume, many employers are forcing these doctors to use up their PTO days, which typically amount to about 4 weeks, Mr. Claussen said. "These doctors have no choice in the matter," he said.

Furthermore, while on PTO, they are being required to take call. Employers are still obligated to cover call, and there may not be enough doctors still working to fill the call schedule. But making doctors do this work on their time off may be a violation of the contract, Mr. Claussen said.

Terminating physicians

Doctors who have little to do are often put on furlough. This means they don't get paid but they keep their benefits, Ms. Adler said. The next step, she said, is to lay them off, with the stated intention of rehiring them. Once laid off, she said, they can get unemployment payments. In some cases, employers are just terminating them. Once terminated, physicians might have to repay a signing bonus or they might lose their malpractice coverage, forcing them to buy a tail. They could also be subject to a noncompete clause, which would not allow them to practice in the area, she said.

Terminating without cause typically requires 60-90 days' notice, which both sides might use to negotiate some changes in the contract. But Ms. Adler said some employers are firing doctors with cause, and are using legally questionable reasons to do so.

She expects many fired doctors will file wrongful termination lawsuits.

Delaying start dates for new physicians

Typically, graduating residents and fellows signed with their new employers months ago and are ready to start working on July 1. But some employers are pushing back the start date for several months, Mr. Claussen said.

Mr. Claussen has been helping several clients in this situation. He said these delays are often a clear violation of the employment contract. Some employers have agreed to a new start date in an amended contract.

What can physicians do?

When employers present changes to them, physicians often feel their hands are tied, Ms. Adler said. In these dangerous times, they are expected to make sacrifices to keep the organization from going out of business.

Even if they wanted to file suits against their employer, "they can't go to court right now because the courts are closed," Ms. Adler said. "Employers are banking on doctors not doing anything."

In most cases, however, doctors don't have to act right away, she said. "You can wait months, even years, to file a lawsuit, depending on the state and the cause of action." Ms. Adler recommended that doctors make it clear that they don't agree with the changes.

Thanks to recent federal changes, employers have to have some ways to continue paying physicians, Ms. Adler said. Medical practices with fewer than 500 employees can get loans from the federal government that would not have to be repaid if they met certain stipulations, such as hiring back all the employees they terminate, she said.

Mr. Claussen suggested persuading employers to postpone rather than eliminate payments. "The aim is that the organization will be back on its feet at that time."

He said he is trying to limit the contract amendments to 1 or 2 months. Because the situation caused by the pandemic is so fluid, "this allows for flexibility," he said.

Ms. Adler doubts employers would accept short-term changes with a definite end date because such changes would not be in the employer's interest. But Mr. Claussen said one employer has agreed to reevaluate its contracts in June.

Both lawyers agreed that many employers are trying to work with their physicians. "In 90% of the cases I have seen, both sides cooperate,"

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centage of a partner's collections, while others typically share overhead expenses. During uncertain times, like the COVID-19 crisis, it is reassuring to partners to know that they are not responsible for the cost of infrastructure (i.e., leases, capital equipment, EHR system, consultants, etc.) and staffing."

With formation of UD as an MSO, has your day-to-day work life changed or your clinical decision making been impacted?

Aja McCutchen, MD, UD Physician Executive Committee Member

- "With the formation of UD, my daily work life has changed very little; however, with their focus on improving 'back-office' functions, my schedule is now fully optimized by reducing gaps from cancellations with same-day/next-day scheduling. [Also] the patient experience has been enhanced with decreased wait times, easier appointment scheduling, and quicker access to support staff. The procurement of business intelligence tools, and, more importantly, the implementation of dashboards, has provided much needed visibility across the organization allowing managerial decisions to be driven by accurate data.

  "From a clinical decision-making standpoint, Atlanta Gastroenterology was already armed with strong clinical teams and committees. We have been able to build upon our pre-existing committees and optimize their ability to steward best practices. This translates to consistency across the organization in the delivery of evidence-based, comprehensive GI care."

Kimberly Orleck, PA-C, Advanced Practice Provider (APP) Supervisor

- "The formation of UD has not affected my clinical decision-making abilities. In fact, this new platform is dedicated to empowering and establishing APPs as independent clinicians with appropriate physician oversight. As a result, I have welcomed more administrative responsibilities and have become more involved in business meetings and decision making. We have worked together to better utilize APPs."

Physician compensation improvement is typically a key concern for physicians who work with private equity MSOs. How has UD performed for its partner-level physicians in year one?

Dr. Rosenberg

- "The MSO has helped to improve physician income – slowly at first and now on a steeper trajectory. We have been ahead of expected income improvement based on models we reviewed when evaluating the formations of an MSO in potential partnership with Frazier Healthcare Partners. United Digestive's EBIDTA, of which each partner-level physician owns a significant percentage through shares from rollover proceeds, has grown impressively in 1 year. This has been achieved mostly through significant organic growth and to a lesser degree through mergers and acquisitions. UD has helped to enhance [income] through increased reimbursements from payor negotiated contracts, new revenue-generating service lines, and operational efficiencies."

Dr. Patel and Dr. Sonenshine are with Atlanta Gastroenterology Associates in Atlanta, which is part of United Digestive. They have no conflicts.

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