aga American Gastroenterological Association

Official newspaper of the AGA Institute

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GI&Hepatology News

January 2022

Volume 16 / Number 1

Courtesy Grishma Hirode

"We wanted to see if the patients stabilize after that year. Are they just having relapses within the first year, and then they're inactive carriers? ... It is important to look at what happens among these patients who stop and if there is a way to tell which way they're going to go," said Grishma Hirode, from the University of Toronto.

Be cautious with HBV drug withdrawal

BY JIM KLING
MDedge News

More than half of chronic hepatitis B e antigen–negative patients who withdraw from nucleoside or nucleotide analogue therapy experienced relapse within 4 years, according to a new study that looked at patients from 11 centers in Europe, North America, and Asia.

"We wanted to see if the patients stabilize after that year. Are they just having relapses within the first year, and then they're inactive carriers? Especially patients who don't achieve [hepatitis B surface antigen; HBsAg] loss. Is that mildly active disease? Would they have been better off being retreated, or are they better off [staying off] therapy? It is important to look at what happens among these patients who stop and if there is a way to tell which way they're going to go," said Grishma Hirode, who is a PhD candidate at the University of Toronto. Ms. Hirode presented the multinational study at the virtual annual meeting of the American Association for the Study of Liver Diseases.

The study provided a clear picture: "They do not

See **Withdrawal** · *page 17*

AGA Clinical Practice Update: Commentary

Surveillance after ESD for dysplasia and early GI cancer

BY WILL PASS
MDedge News

The American Gastroenterological Association recently published a Clinical Practice Update: Commentary outlining surveillance strategies following endoscopic submucosal dissection (ESD) of dysplasia and early gastrointestinal cancer considered pathologically curative.

The suggested practice advice, which was put together by Andrew Y. Wang, MD, AGAF, of the University of Virginia, Charlottesville and colleagues, offers timelines and modalities of surveillance based on neoplasia type and location, with accompanying summaries of relevant literature.

"Long-term U.S. data about ESD outcomes for early GI neoplasia are only beginning to emerge," the authors wrote in Gastroenterology (2021 Dec. doi: 10.1053/j.gastro.2021.08.058). "As such, the current clinical practice regarding endoscopic surveillance intervals and the need for other testing (such as radiographic imaging) after

See **Surveillance** · *page 19*

INSIDE

ESD vs. cEMR: Rates of complete remission in Barrett's compared

BY BRANDON MAY
MDedge News

Treatment with endoscopic submucosal dissection (ESD) is associated with higher rates of complete remission of dysplasia at 2 years, compared with cap-assisted endoscopic mucosal resection (cEMR) in patients with Barrett's esophagus with dysplasia or early-stage intramucosal esophageal adenocarcinoma (EAC), according to study findings.

Despite the seeming advantage of ESD

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LETTER FROM THE EDITOR

The present and future of virtual care in GI

The rapid and unprecedented expansion of virtual care in response to COVID-19 is likely to leave a permanent mark on how health care is delivered. While this expansion has been critical in the near term in caring for our patients while minimizing risk of exposure during the pandemic, it is vital to be forward thinking in considering the ongoing value of virtual care in optimizing routine patient care and in reaching our high-need patients in rural and other underserved areas. We are likely to hear more in the coming months regarding the short- and long-term impacts of virtual care expansion as we transition away from COVID and begin to consider how to maximize use of virtual care in our routine practice. Many questions and challenges remain, including creating a sustainable postpandemic regulatory and payment landscape, defining the optimal balance between virtual and in-person care, assessing whether virtual care is a substitute for in-person care or simply additive, and understanding the impacts of virtual care on outcomes. On the latter questions, a recent study from Kaiser Permanente Northern California (JAMA Netw Open. 2021;4[11]:e2132793) found that primary care visits conducted virtually resulted in modestly higher rates of follow-up outpatient office visits than initial in-person visits, but no significant difference in 7-day ED visits or hospitalizations. Whether these results are generalizable to GI patient populations is unclear.

Dr. Adams

Many questions remain, including defining the optimal balance between virtual and in-person care.

Highlights from this month's issue of GIHN include a study evaluating the impact of a "virtual" liver transplant center on access to liver transplant listing among patients in rural areas, another suggesting lower serologic response to COVID-19 vaccines among patients with IBD, a new AGA Clinical Practice Update: Commentary offering tips regarding surveillance after endoscopic submucosal dissection for dysplasia and early-stage GI cancer, and results from a phase 3 clinical trial demonstrating the efficacy of upadacitinib for treatment of moderate to severe ulcerative colitis.

And while the winter weather here in Michigan may suggest otherwise, DDW 2022 is just around the corner – registration opens on Jan. 19, and we look forward to the GI community coming together, whether in person in sunny San Diego or virtually at home or office, for this hybrid conference.

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

Top case

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

Vivy Tran, MD, wrote in "Definitive diverticular hemorrhage: Diagnosis and management":

Diverticular hemorrhage is the most common cause of colonic bleeding, accounting for 20%-65% of cases of severe lower intestinal bleeding in adults. Urgent colonoscopy after purging the colon of blood, clots, and stool is the most accurate method of diagnosing and guiding treatment of definitive diverticular hemorrhage. The diagnosis of definitive diverticular hemorrhage depends upon identification of some stigmata of recent hemorrhage in a single diverticulum, which can include active arterial bleeding, oozing, non-bleeding visible vessel, adherent clot, or flat spot. Although other approaches, such as nuclear medicine scans and angiography of various types (CT, MRI, or standard angiography), for the early diagnosis of patients with severe hematochezia are utilized in many medical centers, only active bleeding can be detected by these techniques.

Would love to hear how diverticular bleeds are managed at your institution.

See how AGA members responded and join the discussion: https://community.gastro.org/posts/25694.

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The AGA Institute headquarters is located at 4930 Del Ray Avenue, Bethesda, MD 20814, ginews@gastro.org.

GI & Hepatology News (ISSN 1934-3450) is published monthly for $230.00 per year by Frontline Medical Communications Inc., 7 Century Drive, Suite 302, Parsippany, NJ 07054-4609. Phone 973-206-3434

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COVID vaccines: Lower serologic response in IBD

BY BRANDON MAY
MDedge News

Patients with immune-mediated inflammatory diseases (IMIDs), such as inflammatory bowel disease and rheumatic conditions, have a reduced serologic response to a two-dose vaccination regimen with mRNA COVID-19 vaccines, according to the findings of a meta-analysis.

"These results suggest that IMID patients receiving mRNA vaccines should complete the vaccine series without delay and support the strategy of providing a third dose of the vaccine," wrote study authors Atsushi Sakuraba, MD, of the University of Chicago Medicine, and colleagues in Gastroenterology (2021. doi: 10.1053/j.gastro.2021.09.055).

During the COVID-19 pandemic, concerns were raised about the susceptibility of patients with pre-existing conditions to infection with the novel coronavirus, the authors noted. Likewise, ongoing concerns have centered on the risk of worse COVID-19–related outcomes among patients with IMIDs who are treated with immunosuppressive agents.

Since the onset of the pandemic, several registries have been established to gauge the incidence and prognosis of COVID-19 in patients with IMID, including the Surveillance Epidemiology of Coronavirus Under Research Exclusion (SECURE)–Inflammatory Bowel Disease (IBD) registry and the COVID-19 Global Rheumatology Alliance 75 (C19-GRA), which includes patients with rheumatic diseases.

Authorization of COVID-19 mRNA vaccines provided hope that the COVID-19 pandemic could soon come to an end given the overwhelming safety and efficacy data supporting the use of these vaccines for preventing hospitalization and death. Despite these data, little is known regarding the efficacy of mRNA COVID-19 vaccines in patients with IMIDs and/or patients treated with immunosuppressive therapies, as these patients were excluded from the regulatory vaccine studies (N Engl J Med. 2020 Nov;383:1920-31).

The study by Dr. Sakuraba and colleagues was a meta-analysis of 25 observational studies that reported serologic response rates to COVID-19 vaccination in a pooled cohort of 5,360 patients with IMIDs. Data regarding the reference population, medications, vaccination, and proportion of patients who achieved a serologic response were extracted from the observational studies and included in the meta-analysis.

In the analyzed studies, serologic response was evaluated separately after one or two vaccine doses. The researchers also examined the post-vaccine serologic response rate in patients with IMIDs versus controls without IMIDs.

A total of 23 studies used the BNT162b2 or mRNA-1273 vaccines, while 3 studies reported that 50%-75.9% of patients received the AZD1222 vaccine. Some studies also included patients who received other COVID-19 vaccines, including CoronaVac, BBV152, and Ad26.COV2.S.

While 6 studies assessed serologic response to COVID-19 after just 1 dose, 20 studies assessed the post-vaccination serologic response following 2 doses. In most cases, researchers evaluated serologic response at 2-3 weeks after the first dose. After the second vaccine dose, most studies examined serologic response at 1-3 weeks.

The serologic response after 1 dose of the mRNA vaccines was 73.2% (95% confidence interval, 65.7-79.5). In a multivariate metaregression analysis, the researchers found that a significantly greater proportion of patients with IMIDs who took anti-tumor necrosis factor (anti-TNF) therapies had a lower serologic response rate (coefficient, –2.60; 95% CI, –4.49 to –0.72; *P* =.0069). The investigators indicated this "likely contributed to the difference in serologic response rates and overall heterogeneity."

Studies with patients with IBD reported a lower serologic response rate compared with studies that included patients with rheumatoid arthritis (49.2% vs. 65.0%, respectively), which the investigators explained was likely reflective of the increased use of anti-TNF agents in patients with IBD.

After 2 doses of the mRNA vaccines, the pooled serologic

Continued on following page

Messenger RNA vaccines against COVID-19 play a certain role in controlling the pandemic. There has been no clear evidence about the efficacy of vaccination against various vaccine-preventable diseases in patients with IMIDs including IBD, but this global pandemic has led to huge progress in this field. This study by Sakuraba et al. helps us to interpret such information by putting 25 recent studies together. Unfortunately but not unexpectedly, patients with IMIDs were shown to have a lower serologic response to the vaccine, especially if they were treated with anti-TNF therapy. However, this study was incapable of showing the influence of other immunosuppressive therapies such as steroids, antimetabolites, and biologics. It is also still unclear whether their antibody titer would decrease sooner than that in the general population.


Dr. Kobayashi

Large-scale registries of IBD patients suggest that their disease itself is not a risk for severe COVID-19; however, lower effectiveness of vaccination may result in a serious disadvantage in this patient population, compared with others. Therefore, results from this study strongly suggest that it is critical for patients with IBD not only to complete the regular 2-dose vaccination but also to consider the booster shot to maintain immunity for the upcoming months. Further studies are needed to optimize the vaccination strategy specifically in this patient population.

Taku Kobayashi, MD, PhD, is the associate professor and vice director of the Center for Advanced IBD Research and Treatment and codirector of department of gastroenterology, Kitasato University Kitasato Institute Hospital, Tokyo. He has received lecture and advisory fees from Janssen, Pfizer, and Takeda.

Comparative data sought

Remission *from page 1*

over cEMR, the study found similar rates of complete remission of intestinal metaplasia (CRIM) between the treatment groups at 2 years.

The study authors explained that ESD, a recent development in endoscopic resection, allows for en bloc resection of larger lesions in dysplastic Barrett's and EAC and features less diagnostic uncertainty, compared with cEMR. Findings from the study highlight the importance of this newer technique but also emphasize the utility of both treatments. "In expert hands both sets of procedures appear to be safe and well tolerated," wrote study authors Don Codipilly, MD, of the Mayo Clinic in Rochester, Minn., and colleagues in Clinical Gastroenterology and Hepatology (2020 Nov. doi: 10.1016/j.cgh.2020.11.017).

Given the lack of comparative data on the long-term outcomes of cEMR versus ESD in patients with neoplasia associated with Barrett's esophagus, Dr. Codipilly and colleagues examined histologic outcomes in a prospectively maintained database of 537 patients who underwent endoscopic eradication therapy for Barrett's esophagus or EAC at the Mayo Clinic between 2006 and 2020. Only patients who had undergone either cEMR (n = 456) or ESD (n = 81) followed by endoscopic ablation were included in the analysis.

The primary endpoint of the study was the rate and time to complete remission of dysplasia (CRD), which was defined by the absence of dysplasia on biopsy from the gastroesophageal junction and tubular esophagus during at least one surveillance endoscopy. Researchers also examined the rates of complications, such as clinically significant intraprocedural or postprocedural bleeding that required hospitalization, perforation, receipt of red blood cells within 30 days of the initial procedure, and stricture formation that required dilation within 120 days of the index procedure.

Patients in the ESD group had a longer mean length of resected specimens (23.9 vs. 10.9 mm; $P < .01$) as well as higher rates of en bloc (97.5% vs. 41.9%; $P < .01$) and R0 resection (58% vs. 20.2%; $P < .01$). Patients were generally balanced on other basic baseline demographics, including age, sex distribution, and smoking status.

Over a median 11.2-year follow-up period, a total of 420 patients in the cEMR group achieved CRD. In the ESD group, 48 patients achieved CRD over a median 1.4-year follow-up period. The 2-year cumulative probability of CRD was lower in patients who received cEMR versus those who received ESD (75.8% vs. 85.6%, respectively). In a univariate analysis, the odds of achieving CRD were lower in cEMR versus ESD (hazard ratio, 0.41; 95% confidence interval, 0.31-0.54; $P < .01$).

According to multivariate analysis, two independent predictors of CRD included ESD (hazard ratio, 2.38; $P < .01$) and shorter Barrett's segment length (HR, 1.11; $P < .01$).

The investigators also assessed whether advancements made in cEMR technique have contributed to the findings in an analysis of patients who underwent cEMR (n = 48) with ESD (n = 80) from 2015 to 2019. In this analysis, the researchers found that the odds of CRD were lower than that of ESD (HR, 0.67; 95% CI, 0.45-0.99). Additionally, higher odds of achieving CRD in the cEMR group were observed in years between 2013 and 2019 (n = 129), compared with years 2006-2012 (n = 112) (HR, 2.09; 95% CI, 1.59-2.75; $P < .01$).

Demographic and clinical variables were incorporated into a Cox proportional hazard model to identify factors associated with decreased odds of CRD. This analysis found that decreased odds of CRD were associated with longer Barrett's esophagus segment length (HR, 0.90; $P < .01$) and treatment with cEMR versus ESD (HR, 0.42; $P < .01$).

Over median follow-up periods of 7.8 years in the cEMR group and 1.1 years in the ESD group, approximately 78.5% and 40.7% of patients, respectively, achieved CRIM. While those in the ESD group achieved CRIM earlier, the cumulative probabilities of CRIM were similar by 2 years (59.3% vs. 50.6%; HR, 0.74; 95% CI, 0.52-1.07; $P = .11$). Shorter Barrett's esophagus segment was the only independent predictor of CRIM (HR, 1.16; $P < .01$).

The researchers noted that the study population may have included patients with more severe disease than that in the general population, which may limit the generalizability of the findings. Additionally, the lack of a randomized design was cited as an additional study limitation.

In spite of their findings, the researchers explained that "continued monitoring for additional outcomes such as recurrence are required for further elucidation of the optimal role of these procedures in the management of" neoplasia associated with Barrett's esophagus."

The study was funded by the National Cancer Institute and the Freeman Foundation. The researchers reported no conflicts of interest with any pharmaceutical companies.

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When compared with cap-assisted endoscopic mucosal resection (cEMR), endoscopic submucosal dissection (ESD) of visible abnormalities within a Barrett's segment leads to higher R0 resection rates in patients with Barrett's-related neoplasia. However, its superiority over cEMR with regards to clinical and histological outcomes has remained in question. The current study by Codipilly and colleagues attempts to address this issue by comparing histologic outcomes of cEMR versus ESD in dysplastic Barrett's.

Dr. Jawaid

After following 537 patients who underwent cEMR and ESD, the study found those who underwent ESD were more likely to achieve clinical remission of dysplasia (CRD) at 2 years (75.8% vs. 85.6%, respectively; $P < .01$) with a hazard ratio of 2.38 ($P < .01$), likely attributed to the higher rates of en bloc (97.5%) and R0 resection (58%) in the ESD group. However, regarding clinical remission of intestinal metaplasia (CRIM), there was no difference between the two groups after 2 years, suggesting mid-term outcomes remain the same between both resection techniques, so long as ablation is performed of the remaining Barrett's segment.

Since therapies that achieve CRIM, rather than primarily CRD, decrease risk of recurrence, the current study suggests ESD is not superior to cEMR in preventing recurrence for Barrett's-related neoplasia, and either technique may be employed based on local expertise. However, ESD is more effective for achieving CRD and may be preferable for lesions greater than 15 mm or lesions where superficial submucosal invasion is suspected and providing an accurate histopathologic specimen would help direct appropriate oncologic therapy. Further, long-term randomized clinical trials are needed to address differences in recurrence between both treatment modalities.

Salmaan Jawaid, MD, is an assistant professor of medicine in interventional endoscopy at Baylor College of Medicine, Houston. He has no relevant conflicts of interest.

Continued from previous page

response was 83.4% (95% CI, 76.8%-88.4%). Multivariate metaregression found that a significantly greater proportion of patients who took anti-CD20 treatments had a lower serologic response (coefficient, –6.08; 95% CI, –9.40 to –2.76; $P < .001$). The investigators found that older age was significantly associated with lower serologic response after 2 doses (coefficient, –0.044; 95% CI, –0.083 to –0.0050; $P = .027$).

For the non-mRNA COVID-19 vaccines, the rates of serologic response after 2 doses were 93.5% with AZD1222, 22.9% with CoronaVac, and 55.6% with BBV152.

Compared with controls without IMIDs, those with IMIDs were significantly less likely to achieve a serologic response following 2 mRNA vaccine doses (odds ratio, 0.086; 95% CI, 0.036-0.206; $P < .001$). The investigators noted that there were not enough studies to examine and compare serologic response rates to adenoviral or inactivated vaccines between patients and controls.

In terms of limitations, the researchers wrote that additional studies examining humoral and cellular immunity to COVID-19 vaccines are needed to determine vaccine efficacy and durability in patients with IMIDs. Additionally, there is a need for studies with larger patient populations to determine serologic response to COVID-19 vaccines in the broader IMID population.

The researchers reported no funding for the study and no relevant conflicts of interest with the pharmaceutical industry.

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PRACTICE MANAGEMENT TOOLBOX

Quality measurement in gastroenterology: A vision for the future

BY DAVID A. LEIMAN, MD, MSHP; KENNETH I. FREEDMAN, MD, MS, MBA, AGAF; AND CHIOMA IHUNNAH ANJOU, MD, MPH

Modern efforts to monitor and improve quality in health care can trace their roots to the early 20th century. At that time, hospitals initiated mechanisms to ensure standard practices for privileging clinicians, reporting medical records and clinical data, and establishing supervised diagnostic facilities. Years later, Avedis Donabedian, MD, published "Evaluating the Quality of Medical Care," which outlined how health care should be measured across three areas – structure, process, and outcome – and became a foundational rubric for assessing quality in medicine.

Over the ensuing decades, with the rise of professional society guidelines and increasing government involvement in the reimbursement of health care, establishing benchmarks and tracking clinical performance has become increasingly important. The passage of the Affordable Care Act subsequently established a formal, legislative mandate for assessing clinical quality tied to reimbursement. Although the context, consequences, and details for reporting have evolved, quality tracking is now firmly entrenched across clinical practice, including gastroenterology. One such mechanism for this is Merit-Based Incentive Payment System (MIPS), which is a quality payment program (QPP) administered by the Centers for Medicare & Medicaid Services. Today, both government and private payers are assessing measurements and improvements of quality to satisfy the "Quintuple Aim" of achieving better health outcomes, seeking efficient cost of care, improving patient experience, improving provider experience, and enhancing equity through the reduction health inequalities.

As we transition from a fee-based to a value-based care model, several important developments relevant to the practicing gastroenterologist are likely to occur as the broader landscape of quality reporting will continue shifting. This article will outline a vision of the future in quality measurement for gastroenterology.

Gastroenterologists have relatively few specialty-specific measures on which to report. The widespread use of the adenoma detection rate for screening colonoscopy does represent a success in quality improvement because it is easily calculated, is reproducible, and has been consistently associated with clinical outcomes. But the overall measure set is limited to screening colonoscopy and the management of viral hepatitis, meaning large areas of our practice are not included in this set. Developing new metrics related to broader areas of practice will be necessary to address this current shortcoming and increase the impact of quality programs to clinicians. Indeed, a recent environmental scan performed by the Core Quality Measures Collaborative, a public-private coalition of leaders working to facilitate measure alignment, proposed future areas for development, including gastroesophageal reflux disease, nonalcoholic fatty liver disease, and medication management.

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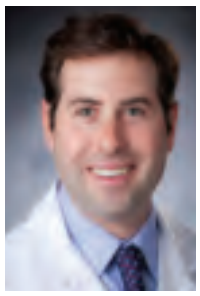
The American Gastroenterological Association, through its defined process of guideline-to-measure development, has responded by creating metrics for the management of acute pancreatitis, Lynch syndrome screening, and eradicating *Helicobacter pylori* in the context of gastric intestinal metaplasia; additionally, previously defined measures exist for Barrett's esophagus and inflammatory bowel disease. Therefore, gastroenterologists can expect to report on an expanding collection of measures in the future.

However, recognizing that not all measures may be equally applicable across populations and acknowledging the importance of risk adjustment, incorporating at least an assessment for risk stratification in their future development are vital. Specifically, social risk factors will need to be accounted for during development in ways that might include risk adjustment or stratification by groups. Increasing data demonstrate that clinician performance can vary by population served and that social determinants of health (SDoH) should be incorporated into an assessment of outcomes. Risk stratification may allow clinicians or practices to report outcomes by group without jeopardy of incurring performance-based penalties. However, the ultimate goal should be reducing inequities and closing care gaps rather than inadvertently lowering the bar for clinicians who primarily treat disenfranchised populations. Eventually, any new measures aiming to be included in a QPP require formal validity testing, which can delay their inclusion in such a set. Yet including stratification in their development will provide a more robust and accurate assessment of quality of care delivered according to one's catchment and help serve to minimize the effects of SDoH on quality reporting.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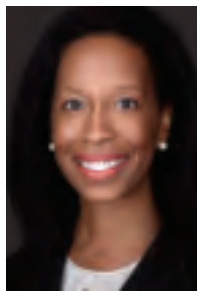
Dr. Anjou

Another way that quality measurement may account for a more comprehensive assessment of care delivered is by bundling similarly provided services, even those across multiple specialties. Such a future model is the MIPS Value Pathways, currently under development by CMS. While the exact make-up and reporting structure remains to be determined, a group of related metrics – for example, for colonic health – would likely be grouped together. This model might include an evaluation of a practice's performance in screening colonoscopy, Lynch testing practices, and inflammatory bowel disease management, which could also be relevant to surgeons, pathologists, and oncologists. This paradigm could serve to increase quality alignment across specialties and reinforce a commitment toward improving care delivery and fulfill a value-based mandate.

Within this framework, though, a shared challenge across specialties exists for the capture and reporting of clinical data. The financial and time costs for quality reporting are well documented; therefore, any future vision of quality must address means to ease this reporting burden. Accounting for this would be especially impactful to independent as well as small- to moderate-sized practices, which must provide their own resources for collecting and reporting, with the QPP payment adjustments often insufficient to replace lost revenue or expenses. Some administrative relief has been provided by CMS during the current COVID-19 pandemic, but this focused on allowing select clinicians to avoid reporting rather than addressing the fundamental challenges presented by extracting and documenting quality measures. In future, an increasing emphasis will likely be on the use of artificial intelligence (AI), such as natural language processing, combined with discrete code extraction for tracking performance. While AI has the advantage of a more hands-free approach, such a system would itself require monitoring for performance to avoid unintended consequences.

Ultimately, providing high-quality care and improving patient outcomes are universal goals, though demonstrating this aspiration by reporting on quality metrics can be challenging. Quality measurement, though, is now firmly integrated into the fabric of clinical medicine. In the future, more facets of practice will be measured, patient-level factors and cross specialty reporting will increasingly be emphasized, and administrative burdens will be reduced.

Dr. Leiman is assistant professor of medicine at Duke University, Durham, N.C., cochair of the Core Quality Measure Collaborative Gastroenterology Workgroup, and chair of the AGA's Quality Committee. Dr. Freedman is medical director, SE Territory, Aetna/CVS Health, and cochair of the Core Quality Measure Collaborative Gastroenterology Workgroup. Dr. Anjou is a practicing clinical gastroenterologist at Connecticut GI, Torrington, and recent member of the AGA Quality Committee. The authors reported no conflicts related to this article.

How to be charitable this year

After an unexpected and challenging year and as the new year begins, there are some ways you can make a difference, without giving up assets you may need today.

- **Beneficiary designation.** Adding the AGA Research Foundation as a beneficiary of your retirement plan or other assets is simple and you don't need to leave your home to complete the gift. Since the funds are granted after your lifetime, you can maintain your family budget today.
- **Gift in your will.** With as little as one sentence, you can create a brighter tomorrow at the AGA Research Foundation without parting with assets today. You can designate the AGA Research Foundation as the beneficiary of a specific asset or, as many of our donors do to ensure that their family is protected, as the recipient of a percentage of the total estate.
- **Grant from your donor advised fund (DAF).** This popular one-stop giving solution lets you care for multiple causes and organizations with minimal paperwork. Consider it a charitable savings account where money waits until you're ready to distribute it. And when you use your existing DAF to recommend a grant, it means you can invest in our future without impacting your budget today.
- **Distribution from your IRA.** If you are 70½ years or older, you can use your IRA to make a gift directly to the AGA Research Foundation without having to pay income tax on the distribution. Beginning in the year you turn 72, you must take your required minimum distribution (RMD). You can use a gift from your IRA to satisfy all or part of your RMD.

Learn more at https://gastro.planmylegacy.org.

New update on perforation management

The new AGA Clinical Practice Update on Endoscopic Management of Perforations in Gastrointestinal Tract: Expert Review offers a practical approach to prevent GI perforations, as well as detect subtle signs of and endoscopically manage them.

Best practice advice

- The area of perforation should be kept clean to prevent any spillage of gastrointestinal contents into the perforation by aspirating liquids and, if necessary, changing the patient position to bring the perforation into a nondependent location while minimizing insufflation of carbon dioxide to avoid compartment syndrome.
- Use of carbon dioxide for insufflation is encouraged for all endoscopic procedures, especially any endoscopic procedure with increased risk of perforation.
- All endoscopists should be aware of the procedures that carry an increased risk for perforation such as any dilation, foreign body removal, any per oral endoscopic myotomy (Zenker's, esophageal, pyloric), stricture incision, thermal coagulation for hemostasis or tumor ablation, percutaneous endoscopic gastrostomy, ampullectomy, endoscopic mucosal resectio, endoscopic submucosal dissection, endoluminal stenting with self-expanding metal stent, full-thickness endoscopic resection, endoscopic retrograde cholangiopancreatography in surgically altered anatomy, endoscopic ultrasound (EUS)–guided biliary and pancreatic access, EUS-guided cystogastrostomy, and endoscopic gastroenterostomy using a lumen apposing metal stent.

Review all 16 best practice advice statements in Clinical Gastroenterology and Hepatology (cghjournal.org).

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GI & HEPATOLOGY NEWS

THE OFFICIAL NEWSPAPER OF THE AGA INSTITUTE

Monitor carefully for flare-ups

Withdrawal *from page 1*

stabilize after 1 year. They have relapses, and these relapses aren't mild fluctuations," said Ms. Hirode. Another study, which was presented during the same session and investigated a national cohort in Taiwan, also found a high rate of flare-ups and re-treatment out to 4 years.

The RETRACT-B study presented by Ms. Hirode collected data on 945 patients from 11 centers in North America, Europe, and Asia. Overall, 66% had at least one relapse within 1 year of drug withdrawal. At 2 years, 40% had a sustained remission without HBsAg loss, as had 20% at 4 years; 44% had sustained remission or HBsAg loss at 2 years, as did 30% at 4 years.

Subgroup analyses found differences between some populations: 48% of Whites and 28% of Asians had sustained remission or HBsAg loss, and 30% of Whites and 20% of Asians had sustained remission without HBsAg loss. Patients who were HBsAg positive at start of therapy were more likely to have a sustained remission or HBsAg loss (36% vs. 28%; $P < .05$) and to have a sustained remission without HBsAg loss (31% vs. 19%; P < .05). HBsAg levels below 100 IU/mL at cessation was also associated with a greater chance of sustained remission or HBsAg loss (58% vs. 24%; $P < .05$) and sustained remission without HBsAg loss (24% vs. 20%; $P < .05$). Not having a relapse within the first year after cessation was also associated with greater chance of sustained remission or HBsAg loss (50% versus 19%; $P < .05$) and sustained remission without HBsAg loss (37% vs. 13%; $P < .05$).

The Taiwan cohort study examined the repercussions of a government policy that limited reimbursement of nucleotide/nucleoside analogues to a fixed duration of time. Among 10,192 eligible patients, researchers at I-SHOU University found a 6.58% 4-year cumulative incidence of severe flare-ups after discontinuation (95% confidence interval, 5.91%-7.30%), defined as serum ALT levels higher than five times the upper limit of normal plus serum bilirubin levels above 2 mg/dL.

The overall incidence of flare-ups was 30.66% over 4 years (95% CI, 29.37%-31.96%). Higher risk of flare-up was associated with older age (hazard ratio for each 10 years, 1.19; $P < .0001$), male sex (HR, 1.76; $P < .0001$), a diagnosis of cirrhosis (HR, 1.84; $P < .0001$), and a history of hepatic decompensation (HR, 1.45; $P = .044$).

The 4-year incidence of re-treatment was 48.74% (95% CI, 46.55%-50.90%)

The mortality rate was 0.63% at 4 years after a flare-up (95% CI, 0.44%-0.87%), and the combined rate of mortality or liver transplant was 0.79% (95% CI, 0.58%-1.05%). Risk factors for higher mortality included older age (per 10 years; HR, 1.70; $P < .0001$), a diagnosis of cirrhosis (HR, 6.12; $P < .0001$), and hypertension (HR, 2.29; $P = .029$).

The results of both studies suggest that withdrawal from medication should be done cautiously, and patients monitored for relapse and re-treatment, according to Anna Lok, MD, AGAF, who was asked for comment. Dr. Lok is a professor of internal medicine, director of clinical hematology, and assistant dean for clinical research at the University of Michigan, Ann Arbor.

Between the two studies, "the message is that this approach can benefit some patients, but if the goal of treatment withdrawal is to increase the rate of hepatitis B surface antigen loss, only a small percentage of patients would benefit. Contrary to studies in Europe, the rates of HBsAg loss in studies with predominantly Asian patients are much lower," said Dr. Lok.

The new studies provide guidance as for which patients might safely stop treatment; specifically, she suggested, young White patients who have a low HBsAg level when treatment is stopped. "But you probably shouldn't be trying it in older Asian patients who still have high HBsAg titer, because the chance of them relapsing is very high and the chance of benefit is very low," she said.

"One has to be very careful in selecting which patients you're going to try this on. And if you do want to try, you've got to make sure that you monitor patients very carefully so treatment can be promptly resumed if necessary because some of the patients can have a severe flare and they can even develop liver failure, and this should never be tried in patients with cirrhosis" said Dr. Lok.

Ms. Hirode and Dr. Lok have no relevant financial disclosures.

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CLINICAL CHALLENGES AND IMAGES

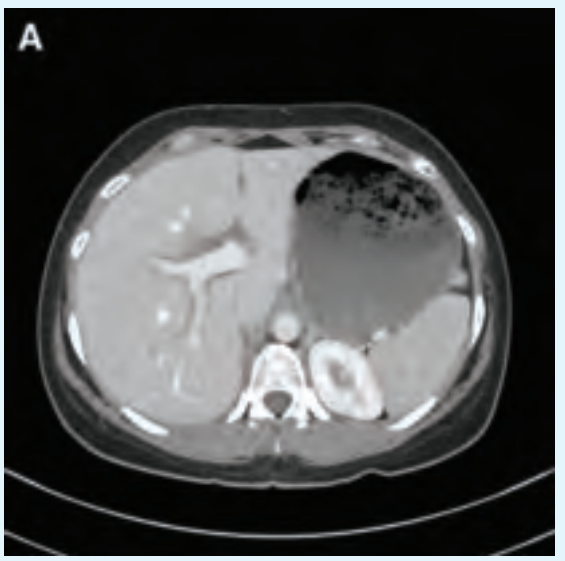
The question

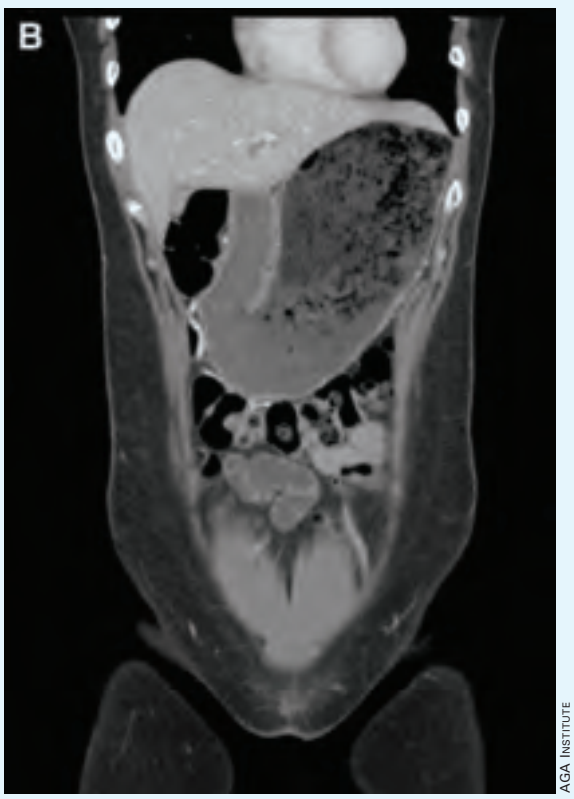
BY AMRIT K. KAMBOJ, MD; ADAM C. BLEDSOE, MD; AND AMINDRA S. ARORA, MB, B.CHIR

Previously published in Gastroenterology (2019 Dec;157[6]:1485-6).

A 33-year-old woman presented with a 10-day history of painless jaundice. During this time, she also noted decreased appetite, malaise, and pruritus. On occasion, she would have heartburn and belching that would improve with an antacid. She denied any right upper-quadrant pain and weight loss. She was not currently taking any medications, including acetaminophen. She had a past medical history of methamphetamine use in recent remission. She had recently been incarcerated for about 1 month.

Upon arrival to the emergency department, she had normal vital signs. Laboratory studies (reference range in parenthesis) demonstrated hemoglobin 13.9 g/dL (11.6-15.0 g/dL), leukocytes 5.7 × 10^9/L (3.4-9.6 × 10^9/L), alanine aminotransferase 1,625 U/L (7-45 U/L), aspartate aminotransferase 432 U/L (8-43 U/L), alkaline phosphatase 149 U/L (35-104 U/L), total bilirubin 5.3 mg/dL (<1.3 mg/dL), direct bilirubin 4.5 mg/dL (0.0-0.3 mg/dL), amylase 137 U/L (26-102 U/L), and lipase 75 U/L (12-61 U/L). Both a urinalysis with microscopy and urine drug screen were unremarkable. Ultrasound examination of the gallbladder showed a mildly edematous gallbladder wall without cholelithiasis, gallbladder distention, or pericholecystic fluid. Common bile duct was normal caliber. A computed tomography scan of the abdomen/pelvis was also obtained with representative features highlighted in Figure A, B.





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What is the most likely etiology of the patient's condition?

The answer is on page 21.

‘Virtual’ center boosts rural liver transplant listings

BY JIM KLING
MDedge News

A “virtual” liver transplant center servicing Vermont and New Hampshire has improved access to liver transplant listing among patients in rural areas of the region, according to a new analysis.

The virtual center was established in 2016 at Dartmouth Hitchcock Medical Center, and it allows patients to receive pre–liver transplant evaluations, testing, and care and posttransplant follow-up there rather than at the liver transplant center that conducts the surgery. The center includes two hepatologists, two associate care providers, and a nurse liver transplant coordinator at DHMC, and led to increased transplant listing in the vicinity, according to Margaret Liu, MD, who presented the study at the virtual annual meeting of the American Association for the Study of Liver Diseases.

“The initiation of this Virtual Liver Transplant Center has been able to provide patients with the ability to get a full liver transplant workup and evaluation at a center near their home rather than the often time-consuming and costly process of potentially multiple trips to a liver transplant center up to 250 miles away for a full transplant evaluation,” said Dr. Liu in an interview. Dr. Liu is an internal medicine resident at Dartmouth Hitchcock Medical Center, Lebanon, N.H.

“Our results did show that the initiation of a virtual liver transplant center correlated with an increased and sustained liver transplant listing rate within 60 miles of Dartmouth over that particular study period. Conversely there was no significant change in the listing rate of New Hampshire zip codes that were within 60 miles of the nearest transplant center during the same study period,” said Dr. Liu.

“We essentially do all of the pre–liver transplant workup, a formal liver transplant evaluation, and then the whole packet gets sent to an actual liver transplant center to expedite the process.”

The center receives referrals of patients who are potential candidates for liver transplant listing from practices throughout New Hampshire and Vermont, or from their own center. Their specialists conduct full testing, including a full liver transplant workup that includes evaluation of the patient’s general health and social factors, prior to sending the patient to the actual liver transplant center for their evaluation and transplant surgery. “We essentially do all of the pre–liver transplant workup, a formal liver transplant evaluation, and then the whole packet gets sent to an actual liver transplant center to expedite the process of getting listed for liver transplant. We’re able to streamline the process, so they get everything done here at a hospital near their home. If that requires multiple trips, it’s a lot more doable for the patients,” said Dr. Liu.

The researchers defined urban areas as having more than 50,000 people per square mile and within 30 miles of the nearest hospital, and rural as fewer than 10,000 and more than 60 miles from the nearest hospital. They used the Scientific Registry of Transplant Recipients to determine the number of liver transplant listings per zip code.

Between 2015 and 2019, the frequency of liver transplant listings per 10,000 people remained nearly unchanged in the metropolitan area of southern New Hampshire, ranging from around 0.36 to 0.75. In the rural area within 60 miles of DHMC, the frequency increased from about 0.7 per 10,000 in 2015 to about 1.4 in 2016 and 0.9 in 2017. There was an increase to nearly 3 in 10,000 in 2018, and the frequency was just over 2 in 2019.

The model has the potential to be used in other areas, according to Dr. Liu. “This could potentially be implemented in other rural areas that do not have a transplant center or don’t have a formal liver transplant evaluation process,” said Dr. Liu.

While other centers may have taken on some aspects of liver transplant evaluation and posttransplant care, the Virtual Liver Transplant Center is unique in that a great deal of effort has gone into covering all of a patient’s needs for the liver transplant evaluation. “It’s really the formalization that, from what I have researched, has not been done before,” said Dr. Liu.

The model addresses transplant listing disparity, as well as improves patient quality of life through reduction in travel, according to Mayur Brahmania, MD, of Western University, London, Ont., who moderated the session. “They’ve proven that they can get more of their patients listed over the study period, which I think is amazing. The next step, I think, would be about whether getting them onto the transplant list actually made a difference in terms of outcome – looking at their wait list mortality, looking at how many of these patients actually got a liver transplantation. That’s the ultimate outcome,” said Dr. Brahmania.

He also noted the challenge of setting up a virtual center. “You have to have allied health staff – addiction counselors, physical therapists, dietitians, social workers. You need to have the appropriate ancillary services like cardiac testing, pulmonary function testing. It’s quite an endeavor, and if the program isn’t too enthusiastic or doesn’t have a local champion, it’s really hard to get something like this started off. So kudos to them for taking on this challenge and getting this up and running over the last 5 years,” said Dr. Brahmania.

Dr. Liu and Dr. Brahmania have no relevant financial disclosures.

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Note from the AGA
AGA applauds researchers who are working to raise our awareness of health disparities in digestive diseases. AGA is committed to addressing this important societal issue head on. Learn more about AGA’s commitment through the AGA Equity Project (www.gastro.org/Equity).

Clearer guidance sought

Surveillance *from page 1*

ESD considered curative by histopathology is extrapolated from data derived from Asia and other countries, from concepts learned from polypectomy and piecemeal endoscopic mucosal resection (EMR), and from guideline recommendations after local surgical resection."

The authors went on to suggest that current recommendations for post-ESD surveillance, including international guidelines "are based more so on expert opinion than rigorous evidence."

The present update was written to offer additional clarity in this area by providing "a reasonable framework for clinical care and launch points for future research to refine and standardize optimal post-ESD surveillance strategies."

Foremost, Dr. Wang and colleagues suggested that post-ESD surveillance is necessary because of a lack of standardization concerning the definition of complete resection, along with variable standards of pathological assessment in Western countries, compared with Japan, where pathologists use 2- to 3-mm serial sectioning and special stains to detect lymphovascular invasion, "which is essential to accurate histopathologic diagnosis and determination of curative resection."

According to the authors, surveillance endoscopy should be performed with a high-definition endoscope augmented with dye-based or electronic chromoendoscopy, and ideally with optimal magnification.

"Although no supporting data are available at this time, it is prudent and may be reasonable to obtain central and peripheral biopsies of the post-ESD scar," the authors wrote, noting that relevant mucosa should be checked for metachronous lesions.

Esophageal dysplasia and esophageal squamous cell carcinoma

Following curative resection of low-grade or high-grade esophageal squamous dysplasia, the authors suggested follow-up esophagogastroduodenoscopy (EGD) initially at intervals of 6-12 months, while advising against endoscopic ultrasonography and radiographic surveillance.

In contrast, Dr. Wang and colleagues suggested that superficial esophageal squamous cell carcinoma removed by ESD may benefit from a shorter interval of endoscopic surveillance, with a range of 3-6 months for first and second follow-up EGDs. Clinicians may also consider endoscopic ultrasonography with each EGD, plus an annual CT scan of the abdomen and chest, for 3-5 years.

"A limitation of ESD is that the at-risk esophagus is left in place, and there is a possibility of developing local recurrence or metachronous neoplasia," the authors wrote. "Although local recurrence after ESD deemed pathologically curative of esophageal squamous cell carcinoma is infrequent, the development of metachronous lesions is not."

Barrett's dysplasia and esophageal adenocarcinoma

For all patients, curative removal of Barrett's dysplasia or esophageal adenocarcinoma should be followed by endoscopy with mucosal ablative therapy at 2-3 months, with treatments every 2-3 months until complete eradication of intestinal metaplasia is achieved, according to Dr. Wang and colleagues.

After complete eradication, patients should be endoscopically screened from 3 to 12 months, depending on the degree of dysplasia or T-stage of adenocarcinoma, followed by screening procedures ranging from 6 months to 3 years, again depending on disease type.

"Endoscopic resection of visible Barrett's neoplasia without treatment of Barrett's esophagus has been associated with significant recurrence rates, so the objective of treatment should be endoscopic resection of visible or nodular dysplasia, followed by complete ablation of any remaining Barrett's esophagus and associated (flat and/or invisible) dysplasia," the authors wrote.

Gastric dysplasia and gastric adenocarcinoma

According to the update, after curative resection of gastric dysplasia, first follow-up endoscopy should be conducted at 6-12 months. Second follow-up should be conducted at 12 months for low-grade dysplasia versus 6-12 months for high-grade dysplasia, with annual exams thereafter.

Continued on following page

Are GI hospitalists the future of inpatient care?

Taking ownership not "call"


Dr. Tau

In my experience, a GI hospitalist provides mutual benefit to patients, employers, and consulting physicians. The patient benefits from more expedient consultations and expert endoscopic therapy, which translates to shorter hospitalizations and improved outcomes. The employer enjoys financial benefits because busy outpatient providers can stay busy without interruption. Consulting physicians enjoy having to call only a single phone number for trusted help from a familiar physician who does not rotate off service. Personally, the position provides the volume to develop valuable therapeutic endoscopy skills and techniques. With one stable physician at the helm, a sense of ownership can develop, rather than a sense of survival until "call" is over.

J. Andy Tau, MD, practices with Austin Gastroenterology in Austin, Tex. He disclosed relationships with Cook Medical and Conmed.

Not so fast...


Dr. Mehendiratta

Providing inpatient GI care is complicated. Traditional models rely on physicians trying to balance outpatient obligations with inpatient rounding and procedures, which can result in delayed endoscopy and an inability to participate fully in multidisciplinary rounds and family meetings. The complexity of hospitalized patients often requires a multidisciplinary approach with coordination of care that is hard to accomplish in between seeing outpatients. GI groups, both private practice and academics, need to adopt a strategy for inpatient care that is tailored to the hospital system in which they operate.

Vaibhav Mehendiratta, MD, is a gastroenterologist with Connecticut GI PC, Hartford, and an assistant clinical professor in the department of medicine at the University of Connecticut, Farmington. He has no relevant conflicts of interest to disclose.


Dr. Ketwaroo

Dear colleagues and friends,

After an excellent debate on the future of telemedicine in GI in our most recent Perspectives column, we continue to explore changes in the way we traditionally provide care. In this issue, we discuss the GI hospitalist service, a relatively new but growing model of providing inpatient care. Is this the new ideal, allowing for more efficient care? Or are traditional or alternative models more appropriate? As with most things, the answer often lies somewhere in the middle, driven by local needs and infrastructure. Dr. Tau and Dr. Mehendiratta explore the pros and cons of these different approaches to providing inpatient GI care. I look forward to hearing your thoughts and experiences on the AGA Community forum and by email (ginews@gastro.org).

Gyanprakash A. Ketwaroo, MD, MSc, is an assistant professor of medicine at Baylor College of Medicine, Houston. He is an associate editor for GI & Hepatology News.

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Please find full-length versions of these debates online at MDedge.com/gihepnews/perspectives.

Continued from previous page

For T1a early gastric cancer, the first two follow-up endoscopies should be performed at 6-month intervals, followed by annual exams. T1b Sm1 disease should be screened more aggressively, with 3- to 6-month intervals for first and second follow-up EGDs, plus CT scans of the abdomen and chest and/or endoscopic ultrasound every 6-12 months for 3-5 years.

"For lesions where a curative resection was achieved based on clinical criteria and histopathologic examination, surveillance is performed primarily to detect metachronous gastric cancers," the authors wrote.

Colonic dysplasia and adenocarcinoma

According to the authors, adenomas with low-grade dysplasia or serrated sessile lesions without dysplasia removed by ESD should be rechecked by colonoscopy at 1 year and then 3 years, followed by adherence to U.S. Multi-Society Task Force recommendations.

For traditional serrated adenomas, serrated sessile lesions with dysplasia, adenomas with high-grade dysplasia, carcinoma in situ, intramucosal carcinoma, or dysplasia in the setting of inflammatory bowel disease, first follow-up colonoscopy should be conducted at 6-12 months, 1 year later, then 3 years after that, followed by reversion to USMSTF recommendations, although patients with inflammatory bowel disease may benefit from annual colonoscopy.

Finally, patients with superficial T1 colonic adenocarcinoma should be screened more frequently, with colonoscopies at 3-6 months, 6 months, and 1 year, followed by adherence to USMSTF recommendations.

"The current Japanese guideline [Dig Endosc. 2020 Jan;32(2):19-239] suggests that recurrence or metastasis after endoscopic resection of T1 (Sm) colonic carcinomas occurs mainly within 3-5 years," the authors noted.

Rectal dysplasia and adenocarcinoma

Best practice advice suggestions for rectal dysplasia and adenocarcinoma are grouped similarly to the above advice for colonic lesions.

For lower-grade lesions, first follow-up with flexible sigmoidoscopy is suggested after 1 year, then 3 years, followed by reversion to USMSTF recommendations. Higher-grade dysplastic lesions should be checked after 6-12 months, 1 year, then 3 years, followed by adherence to USMSTF guidance, again excluding patients with inflammatory bowel disease, who may benefit from annual exams.

Patients with superficial T1 rectal adenocarcinoma removed by ESD deemed pathologically curative should be checked with flexible sigmoidoscopy at 3-6 months, again at 3-6 months after first sigmoidoscopy, then every 6 months for a total of 5 years from the time of ESD, followed by adherence to USMSTF recommendations. At 1 year following ESD, patients should undergo colonoscopy, which can take the place of one of the follow-up flexible sigmoidoscopy exams; if an advanced adenoma is found, colonoscopy should be repeated after 1 year, versus 3 years if no advanced adenomas are found, it should be followed by adherence to USMSTF recommendations. Patients with superficial T1 rectal adenocarcinoma should also undergo endoscopic ultrasound or pelvic MRI with contrast every 3-6 months for 2 years, followed by intervals of 6 months for a total of 5 years. Annual CT of the chest and abdomen may also be considered for a duration of 3-5 years.

Call for research

Dr. Wang and colleagues concluded their update with a call for research.

"We acknowledge that the level of evidence currently available to support much of our surveillance advice is generally low," they wrote. "The intent of this clinical practice update was to propose surveillance strategies after potentially curative ESD for various GI neoplasms, which might also serve as reference points to stimulate research that will refine future clinical best practice advice."

The article was supported by the AGA. The authors disclosed relationships with MicroTech, Olympus, Lumendi, U.S. Endoscopy, Boston Scientific, Steris, and others.

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The diagnosis

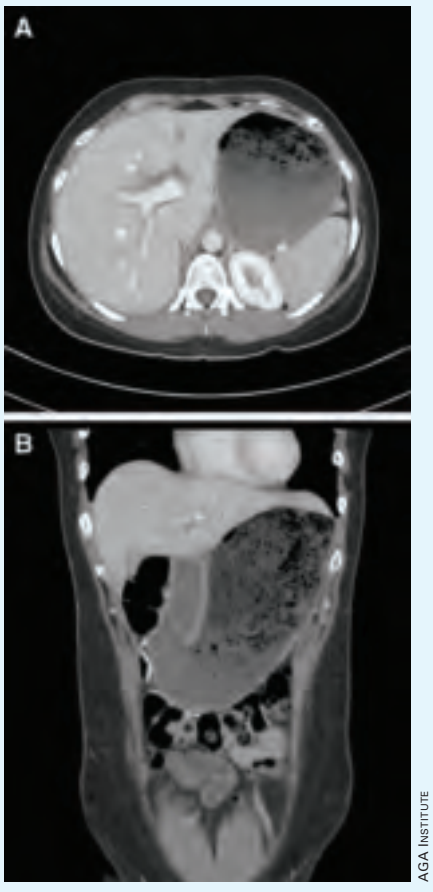
Answer to "What's your diagnosis?" from page 17: Infectious gastroparesis secondary to acute hepatitis A infection.

A computed tomography scan of the abdomen/pelvis demonstrated marked gastric distention without obvious obstructing mass and normal caliber small bowel and colon. Additional laboratory workup revealed a positive hepatitis A IgM antibody. Hepatitis B surface antigen and core IgM antibody were negative, as was the hepatitis C–virus antibody. Human immunodeficiency virus antigen and antibody were negative. An esophagogastroduodenoscopy was performed that showed a large amount of food in a dilated and atonic stomach.

With conservative treatment, the patient's liver enzymes trended down over the next 2 days to alanine aminotransferase 993 U/L, aspartate aminotransferase 244 U/L, and direct bilirubin 3.8 mg/dL. At the time of discharge, she was tolerating soft foods without any difficulty. She was educated on taking appropriate precautions to avoid transmitting the hepatitis A infection to others. Her risk factor for hepatitis A was recent incarceration.

Here we highlight a rare case of infectious gastroparesis secondary to hepatitis A infection. Hepatitis A virus is a small, nonenveloped, RNA-containing virus.[1] It typically presents with a self-limited illness with liver failure occurring in rare cases. Common presenting symptoms including nausea, vomiting, jaundice, fever, diarrhea, and abdominal pain. Laboratory abnormalities include elevations in the serum aminotransferases, alkaline phosphatase, and total bilirubin.[2] The diagnosis is confirmed with a positive hepatitis A IgM antibody. The most common route of transmission is the fecal-oral route such as through consumption of contaminated water and food or from person-to-person contact.[1] Individuals can develop immunity to the virus either from prior infection or vaccination.

Gastroparesis refers to delayed emptying of gastric contents when mechanical obstruction has been ruled out. Common causes of gastroparesis include diabetes mellitus, medications, postoperative complications, and infections. Infectious gastroparesis may present acutely after a viral prodrome and symptoms may be severe and slow to resolve.[3]



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References

1. Lemon SM. N Engl J Med. 1985 Oct 24;313(17):1059-67.
2. Tong MJ et al. J Infect Dis. 1995 Mar;171 Suppl 1:S15-8.
3. Bityutskiy LP. Am J Gastroenterol. 1997 Sep;92(9):1501-4.

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PROFESSIONAL OPPORTUNITIES

Upadacitinib delivers rapid response in UC

BY WILL PASS
MDedge News

Induction therapy with the Janus kinase inhibitor upadacitinib is superior to placebo for patients with moderately to severely active ulcerative colitis (UC), regardless of prior biologic treatments, based on results of the phase 3 U-ACHIEVE trial.

Clinical responses in the upadacitinib group occurred as soon as 2 weeks and were sustained through the 8-week study period, reported lead author Silvio Danese, MD, PhD, of Humanitas Clinical and Research Center IRCCS and Hunimed, Milan.

"Despite availability of multiple treatment options, many patients with ulcerative colitis do not achieve disease remission with current therapies and unmet therapeutic need remains, especially in patients with moderate to severe disease," said coauthor Peter Higgins, MD, PhD, AGAF, of the University of Michigan, Ann Arbor, who presented findings at the annual meeting of the American College of Gastroenterology.

The U-ACHIEVE trial involved 474 patients with moderate to severe UC randomized to receive either upadacitinib induction therapy (45 mg once daily; n = 319) or placebo (n = 155). The primary endpoint was clinical remission at week 8.

The study population was "very sick" and "very experienced," Dr. Higgins said, noting that approximately half of the patients had inadequate responses to prior biologics, and within this subgroup of inadequate responders, approximately two-thirds of the patients had received more than one prior biologic. According to Dr. Higgins, this helps explain why 12.3% of the patients in the placebo group discontinued therapy, compared with just 3.8% in the upadacitinib group – because most patients involved were "quite ill."


Dr. Singh

At week 8, 26.1% of the patients in the upadacitinib group had achieved clinical remission, versus 4.8% of the patients given placebo (26.1% vs. 4.8%; $P < .0001$). Clinical response at week 2 followed a similar pattern (60.1% vs. 27.3%; $P < .001$), as did clinical response at week 8 (72.6% vs. 27.3%; $P < .0001$).

Serious and severe adverse events were more common in the placebo group, and patients in the placebo group more frequently discontinued therapy because of treatment-related adverse events. While rates of serious infection were similar between groups, patients taking upadacitinib had higher rates of neutropenia and lymphopenia.

Based on these findings, the investigators concluded that upadacitinib induction therapy is superior to placebo for clinical remission and clinical response regardless of previous treatment failure.

According to Jordan E. Axelrad, MD, of New York University Langone Health, the findings reflect a real-world setting and clinicians should take note of the rapid response observed with upadacitinib.

"This was a relatively sick group, so you know this reflects what we're seeing in clinical practice," Dr. Axelrad said in an interview. "Clinical response was detected as early

as week 2, and that's extremely important to highlight, because a lot of our drugs that we have on the market – some of these biologics – may take a little time to work. Having a drug that can work fast and is effective is critical."

Dr. Axelrad suggested that second-line JAK inhibitors like upadacitinib, which target JAK proteins more selectively than first-generation agents, may alleviate some lingering concerns about JAK inhibitor safety; still, optimal treatment sequencing remains unclear.

"With more selective inhibition, you're getting less of that side-effect profile," Dr. Axelrad said, noting that long-term data are needed to confirm this likelihood. "The real question moving forward is: Will upadacitinib replace first-generation JAK inhibitors as a category, or, because of the broader safety profile, will it come earlier in the positioning of where we put our drugs for colitis?"

"Should [further clinical trials] demonstrate superior safety to nonselective JAK inhibitors, upadacitinib could be a first-line option for patients who don't want to be taking an infusion or injection, more especially so for those that are already biologically experienced, or need something fast."

Siddharth Singh, MD, director of the IBD Center at the University of California, San Diego, called U-ACHIEVE a "pivotal trial" that demonstrated the "remarkable efficacy" of upadacitinib for moderate to severe ulcerative colitis; still, he noted that drug sequencing remains undetermined.

"It's unclear whether or not it'll be the best in class for JAK inhibitors right now," Dr. Singh said in an interview. "A lot of that hinges on the safety of this drug. In terms of positioning, it depends on whether the [Food and Drug Administration] requires patients to have failed anti–[tumor necrosis factor] therapy before using this drug, like tofacitinib."

That may depend on long-term data, he suggested.

"Right now, it is hard to comment on the relative safety of upadacitinib versus tofacitinib," Dr. Singh said. "While the JAK1 selectivity may contribute to efficacy by allowing us to use a higher dose, it's unclear whether the higher dose of this medication is any safer than tofacitinib. Longer-term, 5- to 7-year registry studies of real-world data are warranted to examine risk of cardiovascular disease, thromboembolism, malignancy, and mortality with upadacitinib.

"How to sequence and position these therapies in real-world practice is a key question," he concluded.

The study was supported by AbbVie. The investigators disclosed additional affiliations with Genentech, Ferring, AstraZeneca, and others. Dr. Axelrad has previously consulted for AbbVie. Dr. Singh has received research funding from AbbVie, Pfizer, and Janssen in the last 24 months, as well as personal fees from Pfizer for an ad hoc grant review.

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