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UHC proceeds with advance notification

BY MEGAN BROOKS

United Healthcare (UHC) has announced it will not go forward with a plan to require prior authorization for colonoscopies and other endoscopic procedures.

Instead, the giant health insurer will adopt an "advance notification" program for nonscreening and nonemergent gastrointestinal procedures.

The company has not made any changes to their policy regarding screening colonoscopies for preventive care, and the advance notification policy does not impact screening colonoscopies.

UHC alerted physicians to changes to the program on May 31, including updated notices on UHCProvider.com with a new Frequently Asked Questions document.

The advance notification program "will not result in the denial of care for clinical reasons or for failure to notify and will help educate physicians who are not following clinical best practices. Provider groups who do not submit advance notification during this period will not be eligible for the United Healthcare Gold Card program," a spokesperson for the company said.

The previously announced Gold Card program, which is scheduled to start in early 2024, would

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Pediatric Crohn's

Strong benefit seen with adalimumab-methotrexate combination

BY MEGAN BROOKS

FROM DDW 2023

Findings from a landmark clinical trial in pediatric Crohn's disease show a clear benefit of adding methotrexate to treatment with the tumor necrosis factor inhibitor (TNFi) adalimumab (Humira), but not to infliximab therapy.

Children initiating treatment with adalimumab plus a low dose of methotrexate experienced a twofold reduction in treatment failure, note the authors of the largest, double-blind, randomized trial to date in pediatric Crohn's disease. However, children initiating infliximab, another TNFi, had similar outcomes with or without methotrexate.

"We believe these results are practice changing," said principal investigator Michael Kappelman, MD, MPH, professor of pediatrics at University of North Carolina.

All patients with pediatric Crohn's disease starting on adalimumab, and their parents, should be informed that combining the drug with low-dose oral methotrexate improves treatment effectiveness, he said.

"Those without contraindications should be offered combination therapy, and shared decision-making should be incorporated into final treatment decisions. In contrast, most patients starting infliximab are not likely to experience added

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INSIDE

Paid leave boosts cancer screening

BY WALTER ALEXANDER

MDedge News

An analysis of 61 cities in the United States where employers allow paid work absences for preventive medical services, such as colon cancer screenings, shows that having the option of paid leave does in fact influence one's decision to have preventive cancer screenings.

"Our results provide evidence for policymakers considering legislative or regulatory solutions to address insufficient screening adherence and highlight an understudied benefit of expanding paid sick leave coverage," wrote authors who were led by Kevin Callison, PhD, of the Tulane University School of Public Health and Tropical Medicine, New Orleans.

The findings were

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LETTER FROM THE EDITOR

Disconnecting to reconnect

I recently returned from a bucket list trip rafting the full length of the Grand Canyon via the Colorado River. It was a spectacular trip, filled with thrilling rapids, awe-inspiring hikes through slot canyons, and swimming in the turquoise waters of Havasu Falls.

For those of you who are fortunate to have experienced a similar adventure, I think you'll agree one of the best things about the trip (aside from the breathtaking scenery) was the ability to completely unplug. Not only did I travel without my trusty laptop, but cell service was nonexistent. The effect of this forced digital detox was magical.

Mentally disconnecting from work without the constant distraction of email and EHR alerts allowed for deeper conversations and more genuine connection. In the frenetically paced world of modern health care where clinicians are reachable wherever they are in the world (even on vacation) and boundaries between life and work have become blurred, there are increasingly fewer times like this when we can fully disconnect. Yet, doing so is critical, particularly for the clinician community, which is grappling with increasing levels of burnout and its consequences. As you embark on your well-deserved summer vacations, I hope you will take the opportunity to meaningfully disconnect from work to reconnect more fully not only with your family and friends but also with yourself.

Dr. Adams

"Mentally disconnecting from work without the constant distraction of email and EHR alerts allowed for deeper conversations and more genuine connection."

In this month's issue of GI&Hepatology News, we update you on AGA's ongoing advocacy efforts to challenge UnitedHealthcare's plans to impose increased administrative burdens on GI practices relating to routine GI procedures. We also highlight a landmark clinical trial in pediatric Crohn's disease recently published in Gastroenterology. In our quarterly Perspectives column, Dr. Mariam Naveed and Dr. Petr Protiva outline important considerations regarding when to stop surveillance for colorectal neoplasia in elderly patients. Finally, our July Member Spotlight features gastroenterologist Dr. Russ Arjal, who shares his experiences launching Telebelly Health, an entirely virtual GI practice. ■

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

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AGA invests in EvoEndo's single-use endoscopy system

The American Gastroenterological Association has announced that the association's venture capital fund, GI Opportunity Fund 1, has invested in EvoEndo®, a medical device company developing platforms for unsedated transnasal endoscopy (TNE).

"AGA is proud to support EvoEndo and its innovative technology that has the potential to improve care, save time, resources, and cost for hospitals and the GI community at large," said Michael L. Kochman, MD, AGAF, MASGE, adviser for the AGA GI Opportunity Fund and professor of medicine, Penn Medicine, Philadelphia.

The EvoEndo Single-Use Endoscopy System received FDA 510(k) clearance in February 2022. The system includes a sterile, single-use, flexible gastroscope designed for unsedated transnasal upper endoscopy and a small portable video controller. The EvoEndo Comfort Kit (not part of the cleared EvoEndo System) includes virtual reality goggles for patient distraction during the unsedated transnasal endoscopy procedure.

Unsedated TNE can be used to evaluate and diagnose a wide range of upper GI conditions that may require frequent monitoring, including eosinophilic esophagitis, dysphagia, celiac disease, gastroesophageal reflux disease, Barrett's esophagus, malabsorption, and abdominal pain.

"AGA is proud to support EvoEndo and its innovative technology that has the potential to improve care, save time, resources, and cost for hospitals and the GI community at large."
— Michael L. Kochman, MD, AGAF, MASGE

"We are grateful for the support of the AGA, which is a testament to our ongoing commitment to improving GI outcomes with our technology," said Jonathan T. Hartmann, CEO at EvoEndo. "The AGA has always been at the forefront of improving GI care. Our team could not be more excited that they have recognized EvoEndo. We look forward to continuing to expand adoption of our technology to the GI community, its physicians, and their patients."

TNE enabled by EvoEndo's Single-Use Endoscopy System allows hospitals to move endoscopy procedures from an ambulatory procedural suite to an office-based environment and allows the "traditional" sedation procedure rooms to be used for more complex, therapeutic cases.

The EvoEndo Model LE Gastroscope is intended for the visualization of the upper digestive tract in adults and pediatric patients, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, and duodenal bulb in patients over the age of 5. ■

Trailblazer for women in gastroenterology, Dr. Barbara H. Jung takes over as AGA president

Barbara H. Jung, MD, AGAF, has been inducted as the 118th president of the AGA Institute. She currently serves as the first woman Robert G. Petersdorf professor and chair of internal medicine at the University of Washington, Seattle, and is the fourth woman to lead the American Gastroenterological Association as its president.


Dr. Jung

Dr. Jung is an expert in the field of transforming growth factor-beta superfamily signaling in colon cancer.

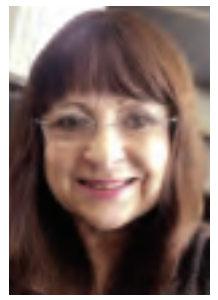
Dr. Jung is an international expert in the field of transforming growth factor–beta superfamily signaling in colon cancer and has made significant contributions at AGA prior to becoming president, most recently as a member of the finance and operations committee, chair-elect of the audit committee and vice chair of the AGA Research Foundation.

Born in Portland, Ore., and raised in Munich, Germany, Dr. Jung's parents provided unconditional support for her career choice in medicine and nurtured her leadership skills throughout her childhood.

Her academic career began at Ludwig Maximilians University of Munich followed by postdoctoral studies in colon cancer at the Sidney Kimmel Cancer Center in San Diego and eventually culminating in an internal medicine residency at the University of California, San Diego.

Dr. Jung joined the AGA Governing Board in June 2021 as vice president and served as president-elect prior to assuming the top leadership role. Over her time as an AGA member (which started during fellowship), Dr. Jung has also served on the AGA Audit Committee, AGA Registry Research and Publications Committee, AGA Research Policy Committee, and AGA Innovation and Technology Task Force. In 2017, she co-organized the AGA Academic Skills Workshop to train the next generation of gastroenterologists. ■

Investing in the future of GI


Dr. Barrett

Without help from other funding sources, talented young investigators struggle to continue their research, build their research portfolios, and obtain future federal funding. This leads to promising investigators walking away from GI research frustrated by a lack of support. Investigators in the early stages of their careers are particularly hard hit.

Decades of research have revolutionized the care of many digestive disease patients. These patients, as well as everyone in the GI field – clinicians and researchers alike – have benefited from discoveries made by dedicated investigators, past and present.

Creative young researchers are poised to make groundbreaking discoveries that will shape the future of gastroenterology. Unfortunately, declining government funding for biomedical research puts this potential in jeopardy. We're at risk of losing an entire generation of researchers if we don't act now.

To fill this gap, the AGA Research Foundation invites you to support young investigators' research careers, allowing them to make discoveries that could ultimately improve patient care and even cure diseases.

"We are at the threshold of key research advances that will cure digestive diseases. We have the manpower, we have trained the people, now we need to have the security that they can stay in research and advance these cures," said Kim Elaine Barrett, PhD, AGAF, AGA legacy society donor and AGA governing board member.

By joining others in supporting the AGA Research Foundation, you will ensure that young researchers have opportunities to continue their life-saving work.

Learn more or make a contribution at www.foundation.gastro.org. ■

Member SPOTLIGHT

Launching an entirely virtual health care GI practice

BY JENNIFER LUBELL

MDedge News

At first, the prospect of starting a new novel practice was daunting, said Russ R. Arjal, MD, AGAF, a gastroenterologist in San Luis Obispo, Calif., who in 2021 launched Telebelly Health, a virtual care gastroenterology clinic that partners with health systems to offer GI care services throughout the country.

Dr. Arjal, who as a cofounder of Telebelly Health also serves as chief medical officer and president of the practice, previously served as vice president of Puget Sound Gastroenterology and practiced in the Seattle area for 13 years. He served as vice president of clinical affairs for Gastro Health, the nation's second-largest gastroenterology group, which acquired the Puget Sound practice in 2019. But then in 2021, he founded Telebelly with Sheri Rudberg, JD, MBA, who serves as CEO of the business; Alex Brown, who leads product development; and Nakort Valles, who serves as the company's chief technology officer.

Building a new business whose goal is to transform GI health care delivery has been his biggest challenge to date. "I am proud of Telebelly because its goals are goals we all share, which is to try to get people in the door and take good care of them," Dr. Arjal said.

"Prior to Telebelly, I led a large regional GI group in a competitive marketplace. Now, with Telebelly, building a team with a vision to transform the space has been the biggest challenge I have taken on."
— Russ Arjal, MD

Through virtual care clinics like Telebelly Health, patients can see a provider who is affiliated with a practice, even if the provider is in another state provided he or she is licensed in the patient's home state. Some states have passed legislation to permanently allow out-of-state clinicians to practice telehealth in their state if they follow the state's requirements. In some states, that may amount to accepting an out-of-state medical license or requiring out-of-state clinicians to pass an exam.

Telebelly Health has served thousands of patients since September when the practice was launched. "We are scaling pretty quickly and will be doubling the number of providers in the next couple of months," Dr. Arjal said.

In this Q&A, he talks more about his new business venture and his vision for the future of medicine.

Question: Why did you choose GI?
Answer: I wanted to do something that was cognitive where I interacted with and really got to know patients. I also wanted to be a proceduralist. I never wanted to be a surgeon – I knew that wasn't for me. I fell in love with GI the first year in med school. I thought the pathology was interesting, and what GIs did in the acute setting as well as the outpatient setting was compelling.

Russ R. Arjal, MD

Dr. Russ R. Arjal

Q. What achievement are you most proud of?
A. Prior to Telebelly, I led a large regional GI group in a competitive marketplace. Now, with Telebelly, building a team with a vision to transform the space has been the biggest challenge I have taken on. It's still a work in progress, but we've had a great start. Starting a company wasn't easy. It was something that I didn't know a lot about, so I had to take a fair bit of risk. I wasn't sure if I had it in me at the beginning. It's not something I'd ever done before, so I was testing myself. I am proud that we were able to launch the company and have successfully scaled it. It's been more successful than I expected.

Q. Describe your biggest practice-related challenge and what you are doing to address it.
A. Access to care. I think it's very hard to see somebody with GI expertise and it certainly got worse during the pandemic. In my previous role, we used advanced practice providers. We tried to implement technology, sometimes effectively, sometimes not. But in general, we wanted to try to increase the supply of providers and compress these patient journeys to get people in the door. But that's still a very difficult challenge we're all trying to solve.

Q. What teacher or mentor had the greatest impact on you?
A. I would say two: James Trotter, MD, a hepatologist at the University of Colorado where I trained. He had a terrific impact in the sense that he was 100% focused on patients and got to know them as people. This taught me what it meant to be a clinician that was sort of a humanist. He cared so much for his patients that I still think about what Jim would do in a room today, 15 years after I finished my fellowship.

When I started my first job at Puget Sound Gastroenterology in the Seattle area, Robin Sloane, MD, was one of the senior partners of the group. I had a lot to learn after finishing fellowship. He was wonderful and gracious and really taught me a ton about the practical aspects of medicine. I felt this was an extension of my training in that he was a real clinician who really cared deeply for his patients. If I hadn't met those two, my career and maybe my view of just what I did day-to-day would be different. They were both very, very impactful for me.

Q. Outside of teachers and mentors, who has had the strongest influence on your life?
A. Two people: My mother and my wife. My mother was a single parent and we were immigrants to the country. She was an ambitious woman who didn't let anything stop her. I certainly learned a ton about resilience, work ethic. She's somebody who always treated people well. My wife also supported and believed in me, and without her, I would not have had the courage to start a company.

Q. Describe a scene of your vision for the future.
A. I think we need to change our mindset in terms of how we interact with patients. I think there's going to be a lot of clinical testing that is performed away from the physician's office. It's going to become more democratized and more decentralized. And I think in the future, patients will have more agency in how they interact with the system. I think artificial intelligence will potentially augment all of this as well. We'll have patients who are more engaged, have more choice and easier access to expert care. They'll come in with more information on their hands and they won't have to wait as long. I think the wait times to get to a GI clinic now are way too long.

What I'd also like to see are providers spending more time doing things that they're trained to do rather than documentation, summarizing data, and dealing with administrative headaches. I think almost everybody has that goal, but I think that's achievable.

I want providers to have an iron man or iron woman suit when they see a patient, to have more data at their fingertips, to spend more time with the patients and have smarter visits.

Q. What did you fear most early in your career?
A. Failure for the most part, and comfort. For a long time, I wanted to start a company

Continued on following page

No paid leave for 30% of workers

Paid leave *from page 1*

published earlier this year in the New England Journal of Medicine (2023 Mar 2. doi: 10.1056/NEJMsa2209197).

Despite an Affordable Care Act provision eliminating most cost-sharing for cancer screening, the rate for recommended breast and colorectal cancer screening among U.S. adults is lower than 70%. Work commitments, time constraints, and the prospect of lost wages are frequently cited as contributing factors to this underuse of preventive care. Researchers hypothesized that having paid sick leave coverage for the use of preventive services could improve adherence to cancer screening guidelines. With continued failure to pass a bill mandating federal paid sick leave legislation, nearly 30% of the nation's workforce lacks this coverage. Rates are lower for low-income workers, women, and underserved racial and ethnic groups, the authors write.

Despite an Affordable Care Act provision eliminating most cost-sharing for cancer screening, the rate for recommended breast and colorectal cancer screening among U.S. adults is lower than 70%.

Coverage mandates have become politically contentious. While 17 states, 4 counties, and 18 cities have mandated provision of paid sick leave to qualified workers in the absence of a federal policy, 18 states have passed preemption laws banning municipalities from adopting mandated paid sick leave.

In this study, researchers examined the rate of colorectal and breast cancer screening at 12- and 24-month intervals among people living in 1 of 61 cities. Before paid sick leave mandates were put in place, cancer screening rates were similar across the board. But once mandates were put in place, cancer screening rates were higher among workers affected by the mandate by 1.31% (95% CI, 0.28-2.34) for 12-month colorectal cancer screening, 1.56% (95% CI, 0.33-2.79) for 24-month colorectal cancer screening, 1.22% (95% CI, −0.20 to 2.64) for 12-month mammography (a 2.5% relative increase from the premandate level), and 2.07% (95% CI, 0.15-3.99) for 24-month mammography (a 3.3% relative increase from premandate rates).

"However, these estimates are averages across all workers in our sample, many of whom likely already had paid sick leave coverage prior to the enactment of a mandate," Dr. Callison said in the interview. "In fact, in other work related to this project, we estimated that about 28% of private sector workers gain paid sick leave when a mandate is enacted. So then, if we scale our findings by the share of workers actually gaining paid sick leave coverage, our estimates are much larger – a 9%-12% increase in screening mammography and a 21%-29% increase in colorectal cancer screening."

Prior studies showing positive associations between having paid sick leave coverage and whether someone receives cancer screenings are likely confounded by selection bias because they compare workers who have such coverage to those who do not, Dr. Callison and colleagues state in their paper.

ROMASET/GETTY IMAGES

"Although the lack of paid sick leave coverage may hinder access to preventive care, current evidence is insufficient to draw meaningful conclusions about its relationship to cancer screening," the authors write, citing that particularly health conscious workers may take jobs offering sick leave coverage.

"Although the lack of paid sick leave coverage may hinder access to preventive care, current evidence is insufficient to draw meaningful conclusions about its relationship to cancer screening," Callison et al.

Through quasi-experimental design, the present study aimed to overcome such confounding issues. Its analytic sample, using administrative data from the Merative MarketScan Research Databases, encompassed approximately 2.5 million person-specific records per year for the colorectal cancer screening sample. The researchers' mammography sample included 1.3 million person-specific records per year of the period examined.

The associations cited above translate into a relative colorectal cancer screening increase of 8.1% in the 12-month adjusted model and a 5.9% relative increase from the premandate rate in the 24-month adjusted model.

"Although these appear to be modest effects, spread across a large population, these indicate a fairly substantial gain in cancer screenings," Dr. Callison said.

Dr. Callison and his team are in the process of developing a follow-up proposal that would examine the effects of paid sick leave on downstream outcomes of the cancer care continuum, such as timing from diagnosis to treatment initiation. "We also hope to examine who benefits from these additional screens and what they mean for health equity. Data limitations prevented us from exploring that issue in the current study," he said.

Dr. Callison had no conflicts associated with this study. ■

Continued from previous page

and change the space. Fear of failure has been ingrained in me and I think that's true for a lot of physicians. I had always been a perfectionist.

Q. What gives you the most joy in your day-to-day practice?

A. Seeing patients is by far the thing I enjoy most. I don't love documenting or digging up information, but I like getting to know folks. In general, I'm a social person and my outpatient clinic gives me the most joy, probably more than anything else.

Q. How do you stay current with advances in your field?

A. I'm curious about all new things, so I stay current through traditional means: I go to conferences regularly, I take postgraduate courses, I listen to podcasts, talk to colleagues, and read journals on a regular basis. But there are a lot of adjacent sources I pay attention to as well, such as nonmedical journals and nonmedical podcasts. I talk to folks outside the space and try to learn from them as well.

Q. What habits have you established that have benefited your career?

A. I do the same thing every day before my clinic days or my endoscopy days. I make reading a part of each day so I can slow down and be more present. Every day I try not to perform just what I do workwise, but I try to find some balance either with my family, or through exercise. I think I've been pretty good at separating work life from personal life. ■

Lightning round

Texting or talking?
Talking

Favorite junk food?
Peanut butter M&Ms

How many cups of coffee do you drink daily?
3

What is your second career choice?
Venture capitalist

Introvert or extrovert?
Both

AGA concerned with UHC policy

UHC *from page 1*

eliminate prior authorization requirements for providers that meet certain eligibility criteria.

The American Gastroenterological Association remains "extremely concerned" that UHC's advance notification program is a "temporary patch" likely to have significant repercussions for patient access. The organization says the program only temporarily postpones prior authorization requirements set to impact the insurer's 27.4 million commercial beneficiaries while increasing the administrative burden on clinicians.

The AGA called the program "nebulous" and "poorly defined." It would ostensibly require physicians to input "copious" amounts of highly complex and granular patient data prior to performing colonoscopies and endoscopies, the AGA says.

AGA President Barbara H. Jung, MD, AGAF, said UHC's "slap-dash approach to rolling out a policy that will ultimately control patient access to critical, often life-saving, medical procedures flies in the face of common sense and responsible medical practice."

"It also indicates that UHC does not currently have data that show any significant overutilization of critical endoscopy and colonoscopy procedures that would ostensibly justify this program or prior authorization. UHC is not acting in good faith, and its actions will compromise patient access to potentially lifesaving procedures," Dr. Jung added.

Recent data show 62% of high-risk patients in the United States who had polyps removed had evidence of delayed or no use of surveillance colonoscopies after 10 years.

"If other prior authorization requirements imposed on patients for specialty care are any indication, we expect to see negative patient outcomes with an enormous cost to patient well-being and physician resources," AGA Vice President Lawrence Kim, MD, wrote in a news release.

"If other prior authorization requirements imposed on patients for specialty care are any indication, we expect to see negative patient outcomes with an enormous cost to patient well-being and physician resources."

"Given the high percentage of eventual approvals by insurers mandating prior authorization, we anticipate there will be little to no benefit from this prior authorization requirement. When utilized this way, it becomes a nonsensical and harmful policy," Dr. Kim added.

AGA says it will continue to work closely with its members to assess the full impact of the new requirements and urges UHC to make endoscopy procedures more accessible to patients.

A recent American Medical Association survey on prior authorization found that one-third (33%) of doctors said the insurance barrier has led to a serious adverse event such as hospitalization, permanent disability, or death for a patient in their care. Nearly half (46%) of physicians reported that prior authorization has led to immediate care and/or emergency department visits.

In a 2023 survey of AGA membership, conducted before UHC announced its proposed prior authorization policy, 95% of respondents said prior authorization restrictions have impacted patient access to clinically appropriate treatments and patient clinical outcomes. And 84% said the burdens associated with prior authorization policies have increased "significantly" (60%) or "somewhat" (24%) over the last 5 years. ■

Pediatric Crohn's study praised as important

Crohn's *from page 1*

benefits from low-dose oral methotrexate," Dr. Kappelman added.

The study was published online in Gastroenterology (2023 Mar 31. doi: 10.1053/j.gastro.2023.03.224) and was presented in May in Chicago at the annual Digestive Disease Week® (DDW).

Impactful study

"This is an important study, published in a very high-ranking journal, that will have a huge impact on how we practice," said Jacob Kurowski, MD, medical director of pediatric inflammatory bowel disease program at Cleveland Clinic Children's. He was not involved in the study.

Treatment with a TNFi, including infliximab and adalimumab, is a mainstay of pediatric Crohn's disease therapy. However, not all patients achieve remission, and many lose response over time.

"This is an important study, published in a very high-ranking journal, that will have a huge impact on how we practice," — Jacob Kurowski, MD, Cleveland Clinic Children's

The current trial compared the effectiveness and safety of adding a low dose of oral methotrexate to adalimumab or infliximab vs. TNFi therapy alone in 297 children with Crohn's disease. The mean age was 13.9 years, and about two-thirds were boys. None had a prior history of TNFi therapy.

Participants initiating infliximab or adalimumab were randomly allocated (1:1) to oral methotrexate or placebo. Of them, 110 infliximab initiators and 46 adalimumab initiators received methotrexate, while 102 infliximab initiators and 39 adalimumab initiators were given placebo. Methotrexate was administered as a weekly dose of 15 mg for children weighing 40 kg or more, 12.5 mg for children 30 kg to less than 40 kg, and 10 mg for children 20 kg to less than 30 kg. All participants received pretreatment with ondansetron 4 mg (or placebo) to prevent nausea and folic acid (1 mg per day). Participants were followed for 12-36 months.

The primary outcome was a failure to achieve or maintain steroid-free remission defined by occurrence of any of the following:

- Short Pediatric Crohn's Disease Activity Index (SPCDAI) score of less than 15 by week 26.
- Failure to complete a steroid taper by week 16.
- SPCDAI score of 15 or higher as a result of active Crohn's disease at two or more consecutive visits beyond week 26.
- Hospitalization or surgery for Crohn's disease beyond week 26.
- Use of corticosteroids for Crohn's disease for 10 or more weeks cumulatively beyond week 16.
- Discontinuation of anti-TNF and/or study drug for lack of effectiveness or toxicity.

Overall, 88 of 297 children (30%) experienced treatment failure, including 57 of 212 (27%) on infliximab and 31 of 85 (36%) on adalimumab. Overall, 40 of 156 children (26%) on combination therapy and 48 of 141 (34%) on monotherapy experienced treatment failure.

Kaplan Meier analysis of the overall population showed a nonsignificant trend toward lower event rates with combination therapy (hazard ratio, 0.69; 95% confidence interval, 0.45-1.05; $P = .08$).

After stratification by TNFi, there was no difference in time to treatment failure among infliximab initiators between combination and monotherapy (HR, 0.93; 95% CI, 0.55-1.56; $P = .78$). In contrast, among adalimumab initiators, combination therapy was significantly associated with a longer time to treatment failure (HR, 0.40; 95% CI 0.19-0.81; $P = .01$).

There was a nonsignificant trend toward lower development of antidrug antibodies with combination therapy (risk ratio 0.72 with infliximab and 0.71 with adalimumab). This trend is in line with adult studies and adds substantially to the pediatric literature on this topic, the researchers note.

No differences in patient-reported outcomes were observed. There were slightly more adverse events with combination therapy, as expected, but fewer serious adverse events.

Shared decision-making

Dr. Kappelman noted that the study was not designed to answer the question of which is better – adalimumab plus methotrexate or infliximab alone.

"This is an area for future research. At this point, we believe it is an individualized decision, and appropriate counseling is needed to support shared decision-making," he said.

The trial was not designed to evaluate the role of proactive therapeutic drug monitoring. However, proactive therapeutic drug monitoring is endorsed in the ImproveCareNow Model IBD Care guidelines and was considered standard of care at the 35 study sites.

The findings "suggest strong consideration of using combination therapy for pediatric Crohn's disease patients initiating adalimumab, but not infliximab," Dr. Kappelman and colleagues say.

"Dissemination and implementation of these findings should lead to improved outcomes in this patient population, including consideration of deimplementation of combination therapy in infliximab-treated patients," they add.

The decision about which approach to use is still very dependent on patients and their providers, Dr. Kurowski said.

"The study shows that you can safely use infliximab as monotherapy, with low risk of antibody formation, while utilizing proactive therapeutic drug monitoring and dose optimization," he said. "The study also shows that adalimumab in combination with low-dose methotrexate can be strongly considered when needed."

The researchers' standardization of methotrexate doses by weight "is another significant contribution and provides a guide for clinicians," Dr. Kurowski added.

The study was funded by grants from the Patient-Centered Outcomes Research Institute, the Helmsley Charitable Trust, and National Institute of Arthritis and Musculoskeletal and Skin Diseases. Dr. Kappelman has consulted for AbbVie, Janssen, Pfizer, Takeda, and Lilly; holds shares in Johnson & Johnson; and has received research support from Pfizer, Takeda, Janssen, AbbVie, Lilly, Genentech, Boehringer Ingelheim, Bristol-Myers Squibb, Celtrion, and Arena Pharmaceuticals. Dr. Kurowski reports no relevant financial relationships.

DDW is sponsored by the American Association for the Study of Liver Diseases, the AGA, the American Society for Gastrointestinal Endoscopy, and the Society for Surgery of the Alimentary Tract.

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Surveillance colonoscopy: When and how to stop

Dear colleagues,
Colonoscopy is the bread and butter of endoscopy. Multidisciplinary updates continue to support screening colonoscopy in reducing the risk of developing colorectal cancer. But there has been debate about the best use of resources, especially with increased recognition of colorectal cancer (CRC) in younger patients, and successive guidelines lengthening the intervals for most surveillance colonoscopy.

In particular, when do we feel comfortable recommending cessation of surveillance colonoscopy especially in those who are 75-85 years old? Routine colonoscopy remains a very low-risk procedure even in older patients with multiple comorbidities.

Here, Dr. Petr Protiva and Dr. Mariam Naveed address this issue and provide differing perspectives on approaching surveillance colonoscopy in the elderly.


Dr. Ketwaroo

We welcome your thoughts on this issue on Twitter at @AGA_GIHN.

Gyanprakash A. Ketwaroo, MD, MSc, is associate professor of medicine, Yale University, New Haven, Conn., and chief of endoscopy at West Haven (Conn.) VA Medical Center. He is an associate editor for GI&Hepatology News.

Striking a balance: Deciding the optimal age to cease surveillance for CRC

BY PETR PROTIVA, MD, MPH

The appropriate age to stop surveillance for colorectal neoplasia remains uncertain. Screening for average-risk individuals is typically stopped at age 75, but personalized screening with shared decision-making may continue until age 85.[1] Evidence suggests that any survival benefit of screening past age 86 would be outweighed by the harm of screening and/or natural mortality. Nevertheless, determining the optimal age for surveillance in those with a history of neoplasia still poses some challenges. The issue is confounded as many clinicians use the terms "screening" and "surveillance" interchangeably. It should be noted that screening implies the individual is at average risk, while surveillance refers to those at elevated risk because of a personal history of colonic adenomas or cancer.


Dr. Protiva

Comorbidities and life expectancy

Despite recent staggering setbacks and a drop in the average life expectancy in the United States, the proportion of individuals older than 65 years old has been steadily increasing to a currently estimated 58.9 million – 16.8% of the U.S. population – and is projected to increase in the future.[2] However, the prevalence of comorbidities also increases with age, and these are crucial factors to weigh in the decision-making process. Severe comorbid conditions, such as chronic obstructive pulmonary disease, cirrhosis, chronic hepatitis, chronic renal failure, dementia, and congestive heart failure can limit a patient's ability to undergo surveillance and diminish or negate its benefits. There are online tools that help clinicians estimate life expectancy and time to benefit (that is, time between the intervention and its benefit), such as the Lee or Schonberg index.[3] Consensus on time to colorectal screening benefit is about 9-10 years, but may be much shorter for surveillance. Striking a balance between the potential benefits of continued surveillance and the risks and burdens imposed on older adults with limited life expectancy is essential for making well-informed decisions.

Age-related risk increase and risk of neoplasia in the surveillance population:

The absolute risk of developing colorectal cancer is dependent on age. In adults aged 45-49, it is 33.4/100,000, rising to 135.6 in those 70-74 years old; in persons aged 85 and older, it is 234.7/100,000.[4] A significant challenge in determining the appropriate age to stop surveillance is the additional individual risk based on baseline polyp characteristics. It seems reasonable to treat low-risk adenomas similarly to screening and stop surveillance by 85 or

See **BALANCE** *on following page*

The GI specialist should guide the decision to maintain surveillance in older adults.

BY MARIAM NAVEED, MD

Endoscopic screening and surveillance for CRC in older adults (≥ 75 years old) is a medical "gray area" that needs more high-quality data to inform clinical decision-making. In the most recent 2022 clinical guideline update from the U.S. Multisociety Task Force on Colorectal Cancer, the recommendation to stop CRC screening in average-risk patients older than 86 years is well supported because of colonoscopy-associated mortality risk outweighing the benefits of adenoma detection and removal. By comparison, screening recommendations for average-risk individuals between 76 to 85 years old are ambiguous and ultimately the decision to proceed with colonoscopy in this clinical population should be individualized based on shared decision-making between the provider and patient. Of note, the same guideline provides no specific guidance for ongoing surveillance in the same age group and similarly suggests a shared decision-making approach.[1]


Dr. Naveed

As a practicing gastroenterologist in the retirement capital of Florida, older adults comprise a large portion of my clinical practice. I have noticed several aspects unique to this demographic that merit special consideration. For example, a significant percentage of these patients are seasonal (that is, "snowbird") patients that have multiple sets of doctors (set of physicians in their home state and another set in Florida). Consequently, fragmentation of clinical data enables opportunities for colonoscopies to be wrongly ordered (either in an inappropriate time frame and/or for inaccurate indications). In my own practice, when such a patient is referred for consideration of CRC surveillance, any/all external records must first be obtained and validated as a prerequisite for appropriate clinical counseling and informed decision-making. Additionally, consideration of periprocedural risks is particularly relevant in older adults, secondary to both the increased rate of direct complications and the likelihood of pre-existing comorbidities affecting completion of a safe colonoscopy. Factors that can be easily overlooked include higher rates of poor bowel preparation and corresponding decreased completion rates. Moreover, if the patient has a history of high-risk adenomas or worrisome family history warranting ongoing evaluation, but they also have high-risk comorbidities, I will frequently involve the patient's cardiologist or pulmonologist to provide medical clearance prior to offering CRC screening/surveillance.

In addition to the clinical ambiguity of appropriateness of continued CRC screening/

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BALANCE *continued from previous page*
86 years old in most cases. The decision process is less clear in individuals with advanced lesions or a personal history of colon cancer. The prevalence of advanced adenomas on the baseline exam is about 15% and greater than 20% on the follow-up exam if the index adenoma(s) were at least 20 mm in diameter. For five or more adenomas at baseline, the prevalence of advanced lesions on follow-up exam is about 20%. On the other hand, a negative surveillance colonoscopy (that is, no polyps found) is associated with far fewer advanced lesions on follow-up.

Colonoscopy

The safety of colonoscopy in older adults should be considered. The colonoscopy procedure is generally very safe, but is associated with a higher risk of post-procedure complications after outpatient colonoscopy in patients 75 years and older. In addition, comorbidities such as anemia, cardiac arrhythmia, heart failure, hypertension, chronic kidney disease, liver disease, smoking history, and obesity are also risk factors. It should be noted that high-quality colonoscopy is key to the detection and full removal of neoplastic lesions and risk reduction. The inability to achieve adequate colon preparation for any reason or undertaking colonoscopy in patients at high risk for complications reduces its benefit.

Who should oversee surveillance, the primary care physician or gastroenterologist

Should a gastroenterologist oversee the decision on surveillance in older adults based on a combination of age, estimated procedure risk and benefits, patient preferences, and current guidelines? Certainly, it seems appropriate and that this is what most specialists think, according to a recent survey of gastroenterologists and primary care physicians (PCPs) on this topic.[5] Perhaps, not surprisingly, most PCPs disagreed – PCPs are thoroughly familiar with their patients' up-to-date comorbidities, functional status, and preferences, and they have the benefit of knowing them for a long time. They also integrate diagnostic results from multiple subspecialists, sometimes from different states. The role of PCPs is critical in centers that offer open-access colonoscopy. Gastroenterologists may be the most appropriate authority to evaluate older individuals for continued surveillance, but in most busy practices these patients are seen by mid-level practitioners. Specialists play an important role if the PCP is uncertain whether surveillance is still indicated or in older patients with a history of advanced adenoma. Therefore, the colonoscopy report or subsequent communication after pathology results are returned should include a recommendation for future surveillance and a clear provision for discontinuing the surveillance in case of future health decline.

Conclusion

Determining the optimal age to discontinue surveillance for colorectal neoplasia involves evaluating multiple factors. Although the age limit is clearer for average-risk screening and low-risk lesion surveillance, uncertainty remains for individuals with advanced neoplasia history. Significant factors in this decision-making process include subsequent neoplasia risk, comorbidities, life expectancy, and age-related risks associated with colonoscopy. Cooperation between PCPs and subspecialty physicians is essential in making surveillance decisions for older adults. PCPs are well positioned to consider detailed patient comorbidities, functional status, and patient preferences, especially with the help of online life-expectancy estimators for most elderly or comorbid patients. To assist in this process, gastroenterologists should state clearly in their procedure report and subsequent pathology letters whether surveillance is recommended and that it is conditional on future comorbidities and should be discontinued if the patient's health significantly declines. ■

Dr. Protiva is associate professor of medicine, Yale University, and director of the colon cancer screening program, VA Connecticut Healthcare System, West Haven. Dr. Protiva has no relevant disclosures.

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GUIDE *continued from previous page*
surveillance in the setting of advanced age, there is also the question of which provider is best positioned to counsel patients regarding this decision-making. Does the onus fall on the gastroenterologist (the proceduralist ultimately performing the procedure) or the PCP (who is likely more familiar with the patient's overall health profile)? In a recent survey, more than 50% of PCPs reported feeling uncertain in their understanding of risk versus benefit stratification of continued CRC screening in older adults.[2] While there may be justification for both classes of providers to be involved, in my opinion, the decision to maintain or halt surveillance in older adults should be primarily guided by the gastroenterologist who is better equipped to provide individualized guidance regarding the nuanced risks of disease progression in these patients with prior history of adenomas, and who is clinically responsible for any procedure-related complications.

In an era of cost containment, insurance companies are increasingly placing barriers for approving surveillance and diagnostic colonoscopies. Thus, we need to be ever mindful of appropriately allocating resources to best benefit patients. The data on incidence of polyps and CRC in older adults are inconsistent and even difficult at times for a gastroenterologist to interpret. Therefore, in my opinion, the onus should not fall solely on the PCPs who are not routinely familiar with this information. We as gastroenterologists typically have greater domain-specific knowledge regarding current data and updated guidelines.

Gastroenterologists should wield this expertise to regulate overly liberalized recommendations for continued surveillance in fragile patients, or conversely to intervene in settings of prematurely halting surveillance in high-risk populations with appropriate life expectancy to experience disease progression. It is critical to carefully consider patient-individualized life expectancies, avoid surveillance in patients without clinically significant polyps, avoid over-weighting previous abnormal prior colonoscopies without reviewing more current procedure results, and take time to discuss patient preferences. As proceduralists, we must also be mindful of intrinsic biases towards performing surveillance in patients who are not likely to benefit from this intervention, and several studies have reported on the overuse of surveillance colonoscopies in the form of repeating surveillance earlier than recommended or in the context of limited life expectancy.[3]

Finally, it is necessary to emphasize that PCPs are critical allies for promoting overall patient health, especially in scenarios where recommendations to discontinue surveillance may not coincide with patient preference. It has been reported that patients usually do not consider poor overall health relevant to decisions regarding CRC surveillance (which I have also experienced to be true).[4] In these scenarios, partnering with the PCP can be strategic, as patients may be more inclined to trust the guidance of their more familiar physician. At the end of the day, regardless of which provider takes ownership of initiating the discussion surrounding surveillance colonoscopy in older adults, communication is key between all providers and the patient to ensure optimal outcomes.

As the U.S. population continues to age, the demographic of patients aged 65 and older is projected to nearly double by 2060.[5] Decisions regarding ongoing surveillance for CRC will continue to be frequent and increasingly relevant. The importance of studies generating high-quality data to inform appropriate guidelines specific to this population cannot be understated. ■

Dr. Naveed is a gastroenterologist and director of the gastroenterology and hepatology fellowship program at AdventHealth Medical Group, Altamonte Springs, Fla. Dr. Naveed had no relevant disclosures.

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Upadacitinib promising in UC and Crohn's

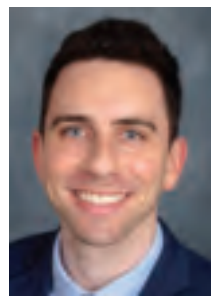
BY JENNIE SMITH

MDedge News

FROM CLINICAL GASTROENTEROLOGY AND HEPATOLOGY

Treatment-resistant patients with active ulcerative colitis and Crohn's disease saw high remission rates and fast response after being switched to upadacitinib, according to results from a real-world study at a Chicago treatment center.

The results suggest that upadacitinib may be an appropriate salvage treatment for patients who have failed other advanced therapies, including tofacitinib.



Dr. Friedberg

For their research, published in Clinical Gastroenterology and Hepatology (2023 Mar 7. doi: 10.1016/j.cgh.2023.03.001), Scott Friedberg, MD, and colleagues at the University of Chicago's Inflammatory Bowel Disease Center, looked at results from 44 patients diagnosed with ulcerative colitis and 40 with Crohn's disease, all with active luminal or perianal disease. All patients in the study had previous exposure to tumor necrosis factor inhibitors, and nearly 90% had exposure to two or more advanced therapies, including tofacitinib (n = 17), before being switched to upadacitinib.

Upadacitinib (Rinvoq, AbbVie) is the second small-molecule Janus kinase (JAK) inhibitor approved for ulcerative colitis by the Food and Drug Administration in March 2022 after tofacitinib (Xeljanz, Pfizer) in 2018. Upadacitinib received an additional indication in May 2023 as a treatment for Crohn's disease. It selectively inhibits JAK1, while tofacitinib inhibits JAK1 and JAK3.

Among the ulcerative colitis patients in Dr. Friedberg and colleagues' study (mean age, 39 years; 48% female), 85% had a clinical response and 82% achieved clinical remission by week 8. Of nine patients previously treated with tofacitinib, seven (78%) achieved remission at 8 weeks.

Some 76% of the Crohn's disease patients in the study (mean age, 37 years; 53% female) saw clinical response by 8 weeks, and 71% achieved remission by that time. More than 60% of all participants who had increased fecal calprotectin and C-reactive protein levels at baseline saw normalization of these biomarkers by week 8.

Some patients saw an especially fast response, with 36% of the ulcerative colitis patients and 56% of the Crohn's patients experiencing clinical remission by week 2.

Acne was the most common reported adverse event, occurring in 23% of patients. Only one serious adverse event, an anemia requiring hospitalization, occurred during the study.

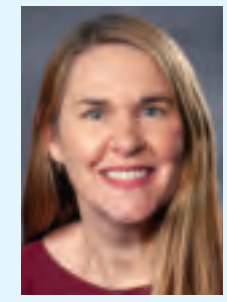
No wash-out period occurred before starting patients on upadacitinib. There were no adverse events seen associated with this strategy, Dr. Friedberg and colleagues noted, a finding with important implications for real-world practice.

"When patients with active IBD are sick, starting a new therapy as soon as it is available is not only reasonable, it is required," the investigators wrote. Additionally, the findings support the use of upadacitinib in ulcerative colitis patients with previous exposure to tofacitinib, as "selectivity of JAK targets may have different effectiveness profiles."

Upadacitinib's rapid onset "has multiple advantages," the investigators wrote, "not only by being an option for severely active disease but also by allowing for a rapid taper or complete avoidance of corticosteroids."

Several of Dr. Friedberg's coauthors disclosed financial relationships with drug manufacturers, including AbbVie. ■

Understanding the efficacy, onset of action and safety of newly approved inflammatory bowel disease (IBD) therapies is difficult in the absence of real-world data as clinical trial populations are much more restrictive and typically do not reflect the patient populations seen in most IBD clinics. This single-center study by Friedberg and colleagues reports on their experience with upadacitinib use in patients with ulcerative colitis (UC) and Crohn's disease (CD). One key finding of this study is the rapid onset of action with high rates of clinical response and remission within 2 weeks of initiation (60% and 36%) for UC and (50% and 56%) for CD. Further, these high rates of clinical response and remission were noted despite exposure to multiple prior therapies (including prior tofacitinib use), which has been a limitation with other IBD therapies.



Dr. Gaidos

With the concerns for safety of tofacitinib use, another Janus kinase inhibitor, raised by the ORAL surveillance study (N Engl J Med. 2022;386:316-26), many patients and practitioners are concerned about the safety of upadacitinib use. This study highlighted the low rate of adverse events including no incidences of herpes zoster infection, venous thromboembolism or major adverse cardiovascular events. Acne was noted to be the most common adverse event, occurring in 22% of the study population.

Further research is needed to assess the long term clinical and endoscopic response rates as well as long-term safety assessments however, these results will facilitate conversations with patients who could potentially benefit from treatment with this new therapy.

Jill K. J. Gaidos, MD, FACG, AGAF, is director of clinical research for the Yale Inflammatory Bowel Disease Program, New Haven. She disclosed receiving research funding from AbbVie.

New guideline weighs treatment options for chronic constipation

BY JENNIE SMITH

MDedge News

FROM GASTROENTEROLOGY

A new practice guideline aims to help clinicians navigate an increasingly crowded field of over-the-counter and prescription treatment options for chronic idiopathic constipation in otherwise healthy people.

The guideline, co-published in June in Gastroenterology (doi.org/10.1053/j.gastro.2023.03.214) and in the American Journal of Gastroenterology (doi:10.14309/ajg.0000000000002227), was developed jointly by the American Gastroenterological Association and the American College of Gastroenterology. It marks the AGA's first update on chronic idiopathic constipation (CIC), also called functional constipation, in a decade.

In an interview, guideline lead author Lin Chang, MD, of the University of California, Los Angeles, noted that CIC – defined as constipation lasting at least 3 months in the absence of malignancy or obstruction, a medication side effect, or inflammatory bowel disease – is common, affecting between 8% and 12% of all U.S. adults. Most will be treated by primary care physicians, not specialists, Dr. Chang said. And most will see their physicians having already tried different over-the-counter treatments.

"The criteria for CIC or functional constipation hasn't really changed" since the last AGA guideline on it was published in 2013, Dr. Chang said, adding that the diagnostic standard currently used is the Rome IV criteria for functional constipation. "There are just more medications right now than there were 10 years ago."

The new guideline, into which evidence from 28 studies was integrated, offers recommendations regarding different types of fiber; the osmotic laxatives polyethylene glycol, magnesium oxide, and lactulose; and the stimulant laxatives bisacodyl, sodium picosulfate, and senna. It also assesses the secretagogues lubiprostone, linaclotide, plecanatide, and the serotonin type 4 agonist prucalopride.

One commonly used agent in clinical practice, the stool softener

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docusate sodium, does not appear in the guideline, as there were too little data available on it to make an assessment, Dr. Chang said. Fruit-based laxatives were excluded because they were the subject of a recent evidence review. Lifestyle modifications such as exercise, surgical interventions, and probiotics were not assessed.

The guideline's strongest recommendations are for polyethylene glycol, sodium picosulfate, linaclotide, plecanatide, and prucalopride, with conditional recommendations for fiber, lactulose, senna, magnesium oxide, and lubiprostone.

As costs of the recommended therapies vary from less than $10 a month to over $500, the authors also included price information, noting that "patient values, costs, and health equity considerations" must be factored into treatment choices. "For polyethylene glycol there's a strong recommendation, although the certainty of evidence was moderate," Dr. Chang said. "And with fiber, even though we made only a conditional recommendation based on the evidence, our remarks and our algorithm make clear that it should be considered as a first-line treatment."

In general, "if someone has more mild symptoms, you should try fiber or increase their fiber intake in their diet," Dr. Chang commented. "If that doesn't work, try over-the-counter remedies like polyethylene glycol. Then if symptoms are more severe, or if they fail the first-line treatments, then you go to prescription agents."

In clinical practice, "there always considerations besides scientific evidence of safety and efficacy," Dr. Chang stressed. "You have to personalize treatment for the patient." A patient may present having already failed with fiber, or who does not want to use magnesium or can't afford a costlier agent.

The guidelines contain implementation advice that might guide choice of therapy or dosing. With the prescription osmotic laxative lactulose, for example, "you may not wish to use it as a first-line treatment because bloating and flatulence are very common," Dr. Chang said. "Our implementation advice makes that clear." For senna, a stimulant laxative derived from the leaves of the senna plant and for which quality evidence is limited, the guideline authors stressed that patients should be started on low doses to avoid cramping.

Dr. Chang said that, while the new guideline covers medication options for otherwise healthy adults, clinicians should be mindful that patients presenting with CIC might still have a defecatory disorder. "A person could also have pelvic floor dysfunction as a primary cause or contributing factor. If someone fails fiber or polyethylene glycol, consider a digital rectal examination as part of the physical exam. If this is abnormal, consider referring them for anorectal manometry."

Untreated constipation carries risks, Dr. Chang noted, but "sometimes people with bothersome symptoms don't treat them because they're worried they'll become dependent on treatment. It's a dependency in the sense that you have to treat any chronic condition, such as high blood pressure or diabetes, but the treatments aren't addictive, except for some stimulant laxatives to which people can develop tolerance."

Hemorrhoids and defecatory disorders can occur over time because of straining, Dr. Chang said. "The pelvic wall can also get very lax, and that is hard to fix. Or, one can develop a rectal prolapse. Another thing that happens when people have longstanding constipation for many years is they start losing the urge to have a bowel movement."

For more information, see the related clinical decision support tool in Gastroenterology. The guideline's development was funded by the AGA and ACG, without industry support. Authors with conflicts of interest regarding a specific intervention or drug were not allowed to weigh in on those interventions. ■

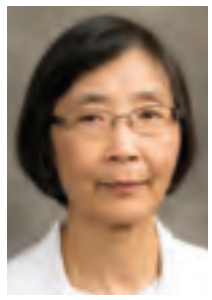
AGA Plenary

Breakthroughs and challenges in hepatology

BY ANNA SUK-FONG LOK, MD, AGAF

AT DDW 2023

CHICAGO – It has been an exciting time to be a hepatologist. During my career, I have witnessed some of the miracles in modern medicine. The most notable is the progress from discovery of the hepatitis C virus (previously non-A, non-B hepatitis) in 1989 to a near 100% cure with 8-12 weeks of oral medications in just 30 years, culminating in the The Nobel Prize in Physiology or Medicine in 2020.



Dr. Lok

This remarkable feat is matched by the progress from discovery of the hepatitis B virus (initially coined Australia antigen) and a 1976 Nobel Prize to an effective vaccine in 1981, to a list of antiviral drugs approved beginning in 1992 (with currently available nucleos(t)ide analogues associated with near zero risk of antiviral drug resistance even when used as monotherapy), to demonstration that both hepatitis B vaccine and antivirals can prevent liver cancer. Other major breakthroughs include blood-based and image-based noninvasive assessment of liver fibrosis obviating the need for liver biopsy to stage liver disease, and multiple systemic therapies for advanced liver cancer.

However, there remain many challenges. While we have the tools to eliminate hepatitis B and hepatitis C, resources and coordinated efforts are needed to realize this feasible goal. Development of a vaccine for hepatitis C and a cure for hepatitis B will facilitate this goal.

The biggest present-day challenges in hepatology are the epidemics of nonalcoholic fatty liver disease (NAFLD) and alcohol-associated liver disease (ALD), particularly since both are increasingly impacting young people, socially disadvantaged populations, and those with mental health problems. Social isolation and mental and financial stressors associated with the COVID pandemic have aggravated both NAFLD and ALD, which have now become the leading indications for liver transplantation. Multipronged approaches, including public policies and education, destigmatization, easy access to mental health care, provider training, and provision of multidisciplinary care, are needed to curb this tsunami. NAFLD affects more than 30% of the global population, and screening with simple biomarker(s) followed by liver stiffness measurement using elastography has been proposed to identify patients with or at high risk of advanced fibrosis or cirrhosis for specialist care. NAFLD is a heterogeneous disease and the requirement for paired liver biopsies to demonstrate benefit have made drug development challenging. Better phenotyping of disease and surrogates for outcomes are needed. Liver cancer is one of the top cancer killers globally, but it is also a preventable cancer-making prevention and early treatment of liver disease a top public health priority. ■

Dr. Lok is director of clinical hepatology and assistant dean for clinical research, University of Michigan Medical School, Ann Arbor. She disclosed research grants with AstraZeneca, Kowa, and Target. She has served as a consultant/adviser to Abbott, Chroma, GlaxoSmithKline, Roche, Virion, and Novo Nordisk. These remarks were made during one of the AGA Postgraduate Course sessions held at DDW 2023. DDW is sponsored by the American Association for the Study of Liver Diseases (AASLD), the AGA, the American Society for Gastrointestinal Endoscopy (ASGE) and The Society for Surgery of the Alimentary Tract.

AGA Postgraduate Course

Esophageal diseases: Key new concepts

BY RENA YADLAPATI, MD, MSHS, AGAF

AT DDW 2023

CHICAGO – Several key updates in esophagology were presented during the esophagus session (Sp75) at the AGA Postgraduate Course 2023 that was held in May during Digestive Disease Week®. These include novel care approaches for esophageal diseases that were published in recent AGA best practice updates on gastroesophageal reflux disease (GERD), extraesophageal reflux, and Barrett's esophagus, as well as randomized clinical trial data examining therapeutic approaches for erosive esophagitis and eosinophilic esophagitis.

Here are a few highlights: Complications of chronic gastroesophageal reflux include erosive esophagitis for which healing and maintenance of healing is crucial to reduce further erosive sequelae. Healing is typically achieved with pump inhibitor (PPI) therapy. Potassium competitive acid blockers are active prodrugs that bind to the H+/K+ ATPase and have been demonstrated to have a more potent and faster onset in suppressing gastric acid secretion, compared with PPIs.

In a recent phase 3 randomized trial of more than 1,000 adults with erosive esophagitis, the potassium competitive acid blocker vonoprazan was found to be noninferior to lansoprazole in inducing and maintaining healing of erosive esophagitis. Overall, the proportions of subjects that achieved healing by week 8 and maintained healing up to 24 weeks were higher with vonoprazan, when compared with lansoprazole, with a greater treatment effect seen in subjects with severe erosive esophagitis (Los Angeles grade C or D) (Laine L et al. Gastroenterology. Jan 2023;164[1]:61-71).

Screening patients at risk of Barrett's esophagus, another erosive sequelae of chronic GERD, is critical

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for early detection and prevention of esophageal cancer. Upper GI endoscopy is standard for Barrett's screening; however, screening rates of at-risk populations are suboptimal.

In a recent retrospective analysis of a multipractice health care network, only 39% of a screen-eligible population were noted to have undergone upper GI endoscopy.


Dr. Yadlapati

These findings highlight the critical need to improve screening for Barrett's, including potential of the newer nonendoscopic screening modalities such as swallowable capsule devices combined with a biomarker or cell-collection devices, as well as the need for risk stratification/prediction tools and collaboration with primary care physicians (Eluri S et al. Am J Gastroenterol. Nov 2022;117[11]:1764-71).

Therapeutic options for eosinophilic esophagitis (EoE) have expanded over the past year. Randomized trials demonstrate the efficacy of varied therapeutic approaches including the monoclonal antibody dupilumab as well as topical corticosteroids such as fluticasone propionate orally disintegrated tablet and budesonide oral suspension.

In terms of food elimination diets, a recent multicenter randomized open-label trial identified comparable rates of partial histologic remission with both a traditional six-food elimination diet and a one-food animal milk elimination diet in patients with EoE, though those treated with a six-food elimination were more likely to achieve complete remission (< 1 eosinophil/high power field). Results suggest elimination of animal milk alone is an acceptable initial dietary therapy for EoE, with potential to convert to six-food elimination or alternative therapy when histologic response is not achieved (Kliewer K. Lancet Gastroenterol Hepatol. [published online Feb 2023]). ■

Dr. Yadlapati is an associate professor in gastroenterology at the University of California, San Diego. She disclosed relationships with Medtronic (Institutional), Ironwood Pharmaceuticals (Institutional), Phathom Pharmaceuticals, and Ironwood Pharmaceuticals. She serves on the advisory board with stock options for RJS Mediagnostix.

These remarks were made during one of the AGA Postgraduate Course sessions held at DDW 2022.

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