

# GI & Hepatology News

January 2021

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BRIAN WILSON

Dr. Maureen M. Leonard of MassGeneral Hospital for Children said patients with seronegative enteropathy tend to have a poorer prognosis than those with classic celiac disease.

## AGA Clinical Practice Update: Seronegative enteropathies

BY WILL PASS

MDedge News

The American Gastroenterological Association has published a clinical practice update for the diagnosis and management of seronegative enteropathies.

Seronegative enteropathies are commonly encountered by gastroenterologists, but accurate diagnosis can be complicated by a wide array of etiologies, misinterpreted histologic findings, suboptimal serology testing,

and use of immunosuppressive agents that mask serology findings, reported lead author Maureen M. Leonard, MD, of MassGeneral Hospital for Children in Boston, and colleagues.

"Previous work detailing the prevalence of seronegative celiac disease [CeD], diagnosis of seronegative villous atrophy, and management recommendations for seronegative villous atrophy are available," the investigators wrote in Gastroenterology. "However,

See **Enteropathy** • page 18

## CMS finalizes 2021 physician pay rule with E/M changes

*Protest, support seen among societies*

Medicare officials stuck with their plan to increase payments for office visits for primary care and several other specialties that focus on helping patients manage complex conditions such as diabetes. In doing so, Medicare also finalized cuts for other fields, triggering a new wave of protests. While gastroenterology is estimated to experience a 4% cut, other fields are expecting cuts up to 10%.

The final version of the 2021 Medicare physician fee schedule was unveiled on the night of Dec. 1. The Centers for Medicare & Medicaid Services posted an unofficial copy

of the rule, which will later be published in the Federal Register.

CMS said it completed work on this massive annual review of payments for clinicians later than it usually does because of the demands of the federal response to the COVID-19 pandemic. The 2021 physician fee rule takes effect on Jan. 1, 2021, within a 30-day period instead of the usual 60-day time frame.

The rule, which runs to more than 2,100 pages, makes myriad changes in Medicare policies, including rules on telehealth, and expands the roles of nurse practitioners and

See **Pay rule** • page 21

## Liver-related deaths decline after Medicaid expansion under ACA

BY NEIL OSTERWEIL

MDedge News

Liver-related deaths declined and liver transplant waitlist inequities decreased in states that

implemented Medicaid expansion under the Affordable Care Act (ACA), results of an innovative study showed.

About 1 year after Medicaid expansion began on

Jan. 1, 2014, the rate of liver-related mortality in 18 states that took advantage of expanded coverage began to decline, whereas the rate of liver-related

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## LETTER FROM THE EDITOR

# Happy New Year! May 2021 be better

Happy New Year! We all are counting on 2021 to be much different and better than 2020. As politics and politicians enhance divisiveness in our country, science and scientists will save us. The power of collective science, careful data analysis, and cautious interpretation has never been more evident than during this pandemic. Unfortunately, we still are learning the most effective means of communicating scientific knowledge where development is iterative and rarely definitive in the early stages of hypothesis testing. Once again, we see the destructive power and effectiveness of the techniques detailed in *The Merchants of Doubt* (<https://www.merchantsofdoubt.org/>).

I choose to focus on successes of scientists and our care delivery workforce. In a mere 11 months, researchers created a new vaccine methodology, tested its safety and efficacy against COVID-19, and provided it to experts building the logistic infrastructure to vaccinate billions of people. Simultaneously, thousands of health care workers risked their lives in a daily battle against Coronavirus and saved countless lives. This is why we became scientists and providers.

I had difficulty choosing page one articles this month because of the wealth of material. On page one, we read about the most dramatic changes to Medicare E/M documentation in the last 30 years (resulting in an estimated 4% decrease in overall GI reim-

bursements). Another article reports on real reductions in liver-related deaths in states that expanded Medicaid coverage, once again demonstrating that we save lives if people have access to health care. The third article on page one discusses seronegative enterop-



Dr. Allen

Articles highlighted in this month's issue show us that scientific inquiry, research, and solution-finding are alive and well.

athies – a difficult diagnosis but one with emerging answers.

Elsewhere in *GI and Hepatology News*, read about best practices to care for elderly IBD patients, and interesting information that may lead to more targeted obesity therapies.

Articles highlighted above and others in this month's issue show us that scientific inquiry, research, and solution-finding are alive and well.

*"The good thing about science is that it's true whether or not you believe in it"*

—Neil deGrasse Tyson

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

## Top AGA Community patient cases

Physicians with difficult patient scenarios regularly bring their questions to the AGA Community (<https://community.gastro.org>) to seek advice from colleagues about therapy and disease management options, best practices, and diagnoses.

The upgraded networking platform now features a newsfeed for difficult patient scenarios and regularly scheduled

Roundtable discussions with experts in the field.

In case you missed it, here are some clinical discussions and Roundtables in the newsfeed this month:

- Which of the following patients needs a liver biopsy and why? (<https://community.gastro.org/posts/23108>)
- Next steps for a Crohn's patient (<https://community.gastro.org/posts/23000>)
- Fecal calprotectin versus histology (<https://community.gastro.org/posts/22969>)
- Collecting and sending specimen for disaccharidase assay (<https://community.gastro.org/posts/23092>)

Roundtables (<https://community.gastro.org/discussions>)

- Q&A with CRC task force: Endoscopic Recognition and Management Strategies for Malignant Colorectal Polyps

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



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# Normal gut colonizer regulates serotonergic system, appears to influence behavior

BY AMY KARON

MDedge News

Together, *Bifidobacterium dentium* and its acetate metabolite regulate key parts of the serotonergic system and are associated with “a functional change in adult behavior,” according to a report published in *Cellular and Molecular Gastroenterology and Hepatology* (2021;11:221-48).

Human gut microbiota had been known to regulate serotonin (5-hydroxytryptamine) production by gut cells, but underlying mechanisms had been unclear. This study showed that a common bacterial colonizer of the healthy adult gut stimulates serotonin (5-hydroxytryptamine, or 5-HT) release from enterochromaffin cells in both mice (in vivo) and humans (in vitro), wrote Melinda A. Engevik, PhD, of Baylor

**“*B. dentium* modulates the serotonergic system in both the intestine and the brain[, which] likely influences behavior, and suggests that supplementation ... may be able to partially rescue behavioral deficits induced by shifts in the intestinal microbiota.”**

College of Medicine, Houston, and associates. “*B. dentium* modulates the serotonergic system in both the intestine and the brain[, which] likely influences behavior, and suggests that supplementation with a single, carefully selected, bacterial strain may be able to partially rescue behavioral deficits induced by shifts in the intestinal microbiota,” they added.

In a prior study, *B. dentium* modulated sensory neurons in rats with visceral hypersensitivity. In mammals, serotonin is primarily produced and released by enterochromaffin cells in the gut. To discover whether acetate – a short-chain fatty acid metabolite of *B. dentium* and some other microbiota – induces this pathway, the researchers first confirmed that *B. dentium* itself lacks the gene pathway for 5-HT production, and that growth media inoculated with *B. dentium* do not subsequently contain 5-HT. Next, they treated adult germ-free mice with either sterile media, live *B. dentium*, heat-killed *B. dentium*, or live *Bacteroides ovatus* (another commensal gut microbe). Gram staining and fluorescence in situ hybridization (FISH) confirmed that live *B. dentium* colonized mouse ileum and colon. Mass spectrometry, immunostaining, and quantitative polymerase chain reaction showed that mice treated with live *B. dentium*, but not *B. ovatus*, had greater intestinal concentrations of acetate, 5-HT, 5-HT receptors (2a and 4), serotonin transporter, and the gene that encodes free fatty acid receptor 2 (FFAR2), through which acetate signals. Furthermore, “[i]ncreases in 5-HT were

“Gut-brain axis” is a widely used term that refers to the idea that the functions of these two organs are linked by bidirectional communication. The gut plays host to a large community of microbes and increasing data suggest that metabolites generated by these microbes can alter nervous system function. Such findings raise the exciting possibility that microbes and/or their metabolites could be used to treat a variety of disorders that involve gut-brain axis dysfunction, from irritable bowel syndrome (IBS) to Parkinson’s disease. To realize this possibility, researchers will need to establish clear mechanistic links between microbes, their products, and effects on host physiology. This study by Engevik and colleagues represents an important advance, demonstrating how a single microbe that commonly colonizes the healthy human intestine, *Bifidobacterium dentium*, is sufficient to stimulate the gut to make serotonin, a powerful signaling molecule known to influence visceral sensitivity, gut motility, and mood.

One key approach to understanding the effects of microbes on host function is to study germ-free mice, which are raised such that they are never exposed to microbes. Germ-free mice have a wide range of immune and neurologic deficits, highlighting how essential

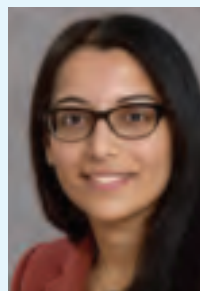
observed in enteroendocrine cells directly above enteric neurons,” the researchers said.

They also performed RNA in situ hybridization of mouse brain tissue, which showed significantly increased expression of 5-HT-receptor 2a in the *B. dentium*-treated compared with germ-free controls. Mice were caged with specified numbers of marbles so the researchers could find out if these changes also modified behavior. Those with complete gut microbiota buried an average of 25% of the marbles, *B. dentium*-monocolonized mice buried 15%, and germ-free mice buried fewer marbles. Hence, even short-term monocolonization by a bacterium that acts on the serotonergic system might help normalize behavior, even later in life, the researchers said. They noted that *B. dentium*-treated and germ-free mice performed similarly on both balance beam and footprint tests, suggesting that treatment with *B. dentium* does not affect motor coordination.

In humans, enterochromaffin cells released more 5-HT when exposed to *B. dentium* or acetate. Taken together, the findings “highlight the importance of *Bifidobacterium* species, and specifically *B. dentium*, in the adult microbiome-gut-brain axis,” the researchers wrote. Probiotic strains such as *Lactobacillus* and *Bifidobacterium* species are thought to improve health by means of signaling pathways, including

microbes are to host function. Previous work has shown that germ-free mice have diminished serotonin levels and abnormal behavior. Exposure to human microbiota could rescue some of these impairments but it was unclear which microbes or signals were essential. This study shows that supplementing germ-free mice with *B. dentium* is sufficient to stimulate the gut to ramp up serotonin production, alter gene expression in the brain, and rescue some behavioral deficits. Acetate, a short-chain fatty acid produced by *B. dentium*, was crucial for this phenomenon. This work not only identifies *B. dentium* as a promising candidate for therapeutic development, it also emphasizes the value of rigorous studies that probe functional interactions between microbes and the nervous system.

Meenakshi Rao, MD, PhD, is a principal investigator at Boston Children’s Hospital, division of gastroenterology, hepatology, and nutrition, and assistant professor of pediatrics at Harvard Medical School, also in Boston. She has no conflicts relevant to this study. She receives research support from Boston Pharmaceuticals for unrelated work and has participated on a scientific advisory board for Takeda Pharmaceuticals.



Dr. Rao

## Key clinical point

Acetate produced by *Bifidobacterium dentium* stimulated serotonin production by mouse and human enterochromaffin cells. *B. dentium* increased serotonin receptor expression in the gut and brain and modified behavior in mice.

the serotonergic system, they noted. “Our findings support the modulation of the serotonergic system by a model gut microbe, *B. dentium*, and provide a potential mechanism by which select microbes and their metabolites can promote endogenous, localized 5-HT biosynthesis. We speculate this may be an important bridging signal in the microbiome-gut-brain axis.”

The National Institutes of Health, BioGaia AB, and the RNA In Situ Hybridization Core facility supported the work. Two coinvestigators disclosed ties to BioGaia AB, Seed, Biomica, Plexus Worldwide, Tenza, Mikrovia, Probiotech, and Takeda. Dr. Engevik and the other investigators reported having no conflicts of interest.

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**SOURCE:** Engevik MA et al. *Cell Molec Gastro Hepatol*. 2021;11:221-48. doi: 10.1016/j.jcmgh.2020.08.002.

# Autologous fecal microbiota transplantation helped maintain weight loss after 'green' Mediterranean diet

BY AMY KARON  
MDedge News

A high-polyphenol, calorie-restricted Mediterranean diet supplemented with green tea and the Mankai strain of duckweed optimized the microbiome for autologous fecal microbiota transplantation, which maintained both weight loss and insulin sensitivity after the diet ended, ac-

cording to the findings of a novel clinical trial.

Eight months after the diet ended, 17% of individuals in the autologous fecal microbiota transplantation (aFMT) group had regained weight, compared with 50% of those who received oral placebo ( $P = .02$ ). Gains in weight circumference were 1.89 cm and 5.05 cm, respectively ( $P = .01$ ), and changes in fasting insulin levels

were 1.46 (standard deviation, 3.6 mIU/mL) and 1.64 mIU/mL (SD, 4.7 mIU/mL;  $P = .04$ ). Notably, aFMT did not achieve these results after weight loss on a typical Mediterranean diet, with or without calorie restriction. "Diet-induced weight loss can be preserved, along with glycemic control, for months after a diet via aFMT capsules. A high-polyphenols, green plant-based or Mankai diet better

optimizes the microbiome for an aFMT procedure," Ehud Rinott, an MD, PhD student at Ben-Gurion University of the Negev in Beer-Sheva, Israel, and his associates wrote in *Gastroenterology*.

Significant weight regain after dieting is common and undermines cardiometabolic strides. In animal studies, FMT from lean to obese individuals induces both weight

*Continued on page 10*

# Cryoballoon, cryospray found equivalent for eradicating Barrett's

BY AMY KARON  
MDedge News

Cryoballoon and cryospray ablation were equivalent for eradicating dysplastic Barrett's esophagus, according to the findings of a single-center retrospective study of 71 ablation-naïve patients.

At 18 months, rates of complete eradication of dysplasia were 95.6% in patients who received cryoballoon therapy and 96% in recipients of cryospray, reported Mohammed Alshelleh, MD, of Northwell Health System, a tertiary care system in New Hyde Park, N.Y. Rates of complete eradication of intestinal metaplasia were 84.75% and 80%, respec-

through a low-pressure catheter that is not directly in contact with the esophagus.

For the study, the investigators retrospectively compared rates of complete eradication of dysplasia, and complete eradication of intestinal metaplasia, among ablation-naïve patients at their institution who had received one of these two cryogenic modalities between 2015 and 2019. All patients were treated at least twice, at 3-month intervals, and were followed for least 12 months, or until complete eradication of intestinal metaplasia was confirmed by at least one endoscopic biopsy. In all, 46 patients received cryoballoon therapy and 25 received cryospray.

Outcomes between the two modalities showed no significant differences in subgroups stratified by baseline histology, nor were there significant differences in rates of postprocedural stricture (8.7% in the cryoballoon group vs. 12% in the cryospray group). However, the investigators acknowledged that the study was underpowered.

Overall, clinicians tended to prefer cryoballoon because it uses prefilled nitrous oxide cartridges, making it unnecessary to fill up a large nitrogen tank or use a "cumbersome decompression tube," the investigators wrote. "However, in patients with a very large hiatal hernia or if there was a need to treat in a retroflexed position, spray cryotherapy was used given its ease of use over cryoballoon in these scenarios. Finally, cryospray is more amenable to treat larger surface areas of Barrett's versus the focal cryoballoon that treats focal areas, and thus was the cryotherapy choice for a long segment of Barrett's."

The investigators reported receiving no grant support. One investigator disclosed ties to Olympus America, Pentax Medical Research, and Ninepoint Medical.

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**SOURCE:** Alshelleh M et al. *Tech Innov Gastrointest Endosc*. 2020 Jul 26. doi: 10.1016/j.tige.2020.07.004.

The role of cryotherapy in Barrett's esophagus eradication continues to evolve. Early data on liquid nitrogen (LN) cryospray included patients who failed radiofrequency ablation or had long segment or nodular disease, resulting in eradication rates lower than those for RFA. More recent studies, with cohorts similar to RFA studies, show comparable results with LN cryospray and the newer nitrous



Dr. Greenwald

oxide cryoballoon. Cryotherapy tends to produce less postprocedure pain compared with RFA, especially when treating longer segments, and this is a common reason for choosing cryotherapy. This study by Alshelleh et al. compared complete eradication rates of dysplasia and intestinal metaplasia between cryospray and cryoballoon in a retrospective single-center study. Complete eradication rate of dysplasia was 95%-96% and that of intestinal metaplasia was 80%-85%, comparable with reported results for RFA.

How do these technologies differ? The cryoballoon catheter is self-contained and relatively inexpensive, while cryospray requires a console with LN tank and a decompression tube venting nitrogen gas during spray. The cryoballoon can treat only a small mucosal area with each freeze (although a hemicircumferential catheter is under study), while cryospray can "paint" a larger area with LN. A new cryospray catheter is under development that delivers circumferential treatment over several centimeters of tissue, like the RFA balloon catheter. The ability of the cryospray device to deliver essentially unlimited cold energy makes it useful in ablation of esophageal cancer, as well as for pulmonary and ENT applications. Expect improvement in both technologies, along with a better understanding of their role in ablation of Barrett's and other tissues.

How do these technologies differ? The cryoballoon catheter is self-contained and relatively inexpensive, while cryospray requires a console with LN tank and a decompression tube venting nitrogen gas during spray. The cryoballoon can treat only a small mucosal area with each freeze (although a hemicircumferential catheter is under study), while cryospray can "paint" a larger area with LN. A new cryospray catheter is under development that delivers circumferential treatment over several centimeters of tissue, like the RFA balloon catheter. The ability of the cryospray device to deliver essentially unlimited cold energy makes it useful in ablation of esophageal cancer, as well as for pulmonary and ENT applications. Expect improvement in both technologies, along with a better understanding of their role in ablation of Barrett's and other tissues.

*Bruce D. Greenwald, MD, is a professor of medicine in the division of gastroenterology and hepatology at the University of Maryland, Baltimore. He receives research funding from and serves as a consultant for Steris.*

**"In patients with a very large hiatal hernia or if there was a need to treat in a retroflexed position, spray cryotherapy was used given its ease of use over cryoballoon in these scenarios."**

tively. However, selection bias was likely, and a post hoc power calculation suggested that the cryospray group was underpowered by four patients. "Prospective studies are needed to confirm [these] data," Dr. Alshelleh and associates wrote in *Techniques and Innovations in Gastrointestinal Endoscopy*.

For treatment-naïve individuals, prospective studies suggest that cryotherapy may be less painful and as effective as radiofrequency ablation, but no studies have directly compared the two commercially available systems: a cryogenic balloon catheter (C2 Cryoballoon, Pentax Medical, Montvale, N.J.) that delivers cryogenic nitrous oxide ( $-85^{\circ}\text{C}$ ) into an inflated balloon in direct contact with the esophageal mucosa, and a spray cryotherapy system (truFreeze, Steris Endoscopy, Mentor, Ohio), which flash-freezes the mucosa to  $-196^{\circ}\text{C}$  by delivering liquid nitrogen

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# GI & HEPATOLOGY NEWS

THE OFFICIAL NEWSPAPER OF THE AGA INSTITUTE





# Endoscopic intragastric balloon improved NASH parameters

BY AMY KARON

MDedge News

**E**ndoscopically placed intragastric balloons were safe and effective for managing nonalcoholic fatty liver disease (NAFLD), according to the findings of an open-label, prospective study of 21 patients.

Six months after balloon placement, nonalcoholic fatty liver disease activity scores (NAS) had improved in 18 of 20 biopsied patients (90%), with a median decrease of 3 points (range, 1-4 points). Magnetic resonance elastography showed that fibrosis had improved by 1.5 stages in half of patients (10 of 20). "Other than post-procedural pain (in 5% of patients), no serious adverse events were reported," Fateh Bazerbachi, MD, of Massachusetts General Hospital in Boston, and associates wrote in *Clinical Gastroenterology and Hepatology*.

Nonalcoholic fatty liver disease affects approx-

imately 70% of obese adults and half of obese children, meaning that tens of millions of individuals are affected in the United States alone. Lifestyle changes rarely induce more than 10% body weight loss, the threshold for "meaningful

**"Endoscopic bariatric therapies are garnering more attention as potential strategies to address these shortcomings in obesity care and its comorbidities, [but] their influences on the driving and prognostic parameters of NAFLD remain unclear."**

improvement in NASH [nonalcoholic steatohepatitis]," and bariatric surgery is not recommended for managing mild or moderate obesity and often is not desired by patients who do qualify, the researchers noted. "Endoscopic bariatric therapies

are garnering more attention as potential strategies to address these shortcomings in obesity care and its comorbidities, [but] their influences on the driving and prognostic parameters of NAFLD remain unclear."

In all, 81% of the study participants were women, with a mean age of 54 years and an average body mass index of 44 kg/m<sup>2</sup>. At baseline, more than half had NAS scores of 4 or 5 and histologic fibrosis scores of 2 or 3. Baseline hemoglobin A1c levels averaged 7.4% (range, 5.1%-11.1%) and 29% of patients had impaired glucose tolerance. After receiving endoscopic ultrasound (EUS)-guided core liver biopsies, patients received an endoscopically placed fluid-filled intragastric balloon (Orbera, Apollo Endosurgery, Austin, Tex.). The balloon was removed 6 months later and magnetic resonance elastography and a second core biopsy were performed.

One patient did not receive an exit biopsy

*Continued on following page*

*Continued from page 8*

loss and metabolic improvements, and limited data point to similar benefits in humans. However, allogenic FMT in humans raises safety concerns and "practical barriers," Mr. Rinott and his associates noted. Hypothesizing that aFMT of microbiota obtained at nadir weight might prevent postdiet rebounds, they randomly assigned 294 obese or dyslipidemic adults (average age, 52 years) to receive the calorie-restricted "green" Mediterranean diet or a standard Mediterranean diet with or without calorie restrictions for 6 months.

At this time, microbiota obtained from fecal samples were frozen in colorless, odorless oral capsules that were considered indistinguishable from placebo capsules. Ninety participants who had lost at least 3.5% of their body weight (average loss, 8.3 kg) were then rerandomized in a double-blinded manner to receive once-daily aFMT or placebo capsules during months 8 through 14.

In all, 96% of participants consumed at least 80% of the capsules, a high rate of compliance. No adverse events from aFMT were reported. Metagenomic se-

quencing and 16s ribosomal RNA sequencing showed that only the "green" Mediterranean diet induced significant alterations in the gut microbiome during the weight-loss phase. In a complementary study of obese mice, autologous transplantation of microbiota obtained at nadir weight confirmed that adding Mankai during weight loss helped protect against subsequent regain and loss of insulin sensitivity.

All diets in this study emphasized vegetables while reducing sugars, salt, dietary cholesterol, trans and saturated fats, and poultry,

and omitting processed and red meats. The "green" and standard calorie-restricted Mediterranean diets both limited calories to 1,500-1,800 per day for men and 1,200-1,400 per day for women (women comprised only 9% of study participants). In these two diets, fats – mainly monounsaturated and polyunsaturated – made up 40% of calories (including 28 g walnuts per day, containing 440 mg polyphenols), while carbohydrates were limited to less than 40 g per day in the first 2 months and then gradually increased to 80 g per day. The green Mediterranean diet added 3-4 cups of green tea daily and a shake containing 100 g of Mankai, which provided another 800 mg of polyphenols. All participants received free gym memberships and were told to exercise throughout the study (aerobic exercise for 45-60 minutes three to four times weekly, and resistance exercise two to three times weekly).

Funders included the Israeli Science Foundation, Israeli Ministry of Health, Israel Ministry of Science and Technology, German Research Foundation, California Walnuts Commission, and others. Mr. Rinott had no conflicts. Three coinvestigators disclosed ties to CoreBiome, Hinoman, and Mybiotics.

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**SOURCE:** Rinott E et al. *Gastroenterology*. 2020 Aug 25. doi: 10.1053/j.gastro.2020.08.041.

**I**n their recent publication in *Gastroenterology*, Rinott et al. investigated whether autologous transplantation of diet-modified microbiota, delivered through oral capsules, prevented weight regain in abdominally obese individuals that were subjected to dietary regimens to induce weight loss. Transplantation of one's own

fecal microbiota collected after a calorie-restricted green Mediterranean diet (containing extra polyphenols) seemed to maintain metabolic improvements in comparison to placebo treatments during weight regain.



Dr. Hanssen

This study once more links alterations of the gut microbiome to changes in metabolic phenotype, and further identifies alterations of the gut microbiome as a causal factor in the development of cardiometabolic diseases such as diabetes. This study also provides some exciting prospects from a therapeutic point of view.

The use of allogenic fecal microbiota transplantation is now considered in the context of a range of noninfectious diseases that are linked to an altered gut microbiome.

However, practical concerns may limit the use of allogenic

FMT on a large scale in clinical practice, as careful and repeated donor screening is needed to ensure the safety of this procedure. The current study in *Gastroenterology* provides another means of improving the composition of the gut microbiome by modifying the individual's own microbiome and reusing it for autologous transplantation to prolong certain beneficial changes made to it.

*Nordin M.J. Hanssen, MD, is in the department of internal medicine, school for cardiovascular diseases, faculty of health, medicine, and life sciences, Maastricht University, Amsterdam. He has no conflicts of interest relevant to this publication.*

Continued from previous page

(because of starting anti-thrombotic therapy) and thus was excluded from the final analysis.

Of 20 patients, 16 (80%) had at least a two-point improvement in NAS at 6 months, and half had NAS scores of less than 2, indicating remission of NASH. Three of 20 patients (15%) showed improvements in mild fibrosis, 12 showed no change, and 5 showed worsening. Patients lost an average of 11.7% of body weight (standard deviation, 7.7%;  $P = .01$ ), BMI dropped by a mean of 5.2 (SD, 0.75;  $P = .01$ ), and A1c fell by an average of 1.3% (SD, 0.5%;  $P = .02$ ). Waist circumference also decreased significantly (mean, -14.4 cm; SD, -2.2 cm;  $P = .001$ ), as did hip circumference, fasting glucose, AST, ALT, and AST-to-platelet ratio index. "Percent total body weight loss did not correlate with reductions in NAS or fibrosis," the researchers noted.

Together, these findings suggest that intragastric balloon

placement "may allow a reversal in the natural history of NAFLD and NASH, despite the short duration of the intervention," they concluded. "The logistics of IGB [intragastric balloon] placement will enable accurate risk stratification of these patients in a safe and reproducible manner, obviating the need for additional investigations, and clarifying the real risk of patients afflicted with NAFLD."

Apollo Endosurgery provided intragastric balloons, and Medtronic provided SharkCore needles. The senior author and two coinvestigators disclosed ties to Apollo Endosurgery, Medtronic, Metamodix, Boston Scientific, Cairn Diagnostics, Aspire Bariatrics, Johnson and Johnson, AstraZeneca, Genfit, Gila Therapeutics, and several other companies. The other investigators reported having no conflicts of interest.

ginews@gastro.org

**SOURCE:** Bazerbach F et al. Clin Gastroenterol Hepatol. 2020 Apr 30. doi: 10.1016/j.cgh.2020.04.068.

Obesity is a well-known risk factor for the development of nonalcoholic fatty liver disease (NAFLD) and nonalcoholic steatohepatitis, the latter of which is expected to become the leading indication for liver transplantation. As such addressing the steatosis in these patients is critical. A drop of even 5%-10% of total body weight with diet and exercise can result in significant improvement in liver disease.

Unfortunately, achieving this weight loss is challenging. For the appropriate candidate, bariatric surgery offers the most effective and durable route to weight loss. However, not all patients qualify, and uptake of surgery in appropriate candidates remains low. As such, other treatment options are needed. Endoscopic bariatric therapies, including intragastric balloons, are one such treatment option that may provide significant improvement in hepatic steatosis. However data to support this remain limited.

In this article, Dr. Bazerbach and

colleagues work to advance the case for intragastric balloons as a successful treatment option for NAFLD. They performed a prospective, open-label study on 21 patients treated with an intragastric balloon for 6 months.

Using gold-standard histology and noninvasive magnetic resonance elastography before and after therapy, they show significant improvement in NAFLD activity score (median change, 3 points; range, 1-4) over a short duration of treatment.

Interestingly, the collection of the liver biopsy sample is done via endoscopic ultrasound, which can be easily performed during placement and removal of this intragastric balloon. While promising, follow-up studies are needed to show sustained improvement in NAFLD after the balloon is removed.

Wasif M. Abidi, MD, PhD, is assistant professor of medicine, gastroenterology, Baylor College of Medicine, Houston. He is a consultant for Apollo endosurgery.



Dr. Abidi

## CLINICAL CHALLENGES AND IMAGES

### What is your diagnosis?

By Andrea Fisher, Alexander Podboy, MD, and Vijay Pottathil, MD. Published previously in *Gastroenterology* (2019;157[1]:29-30).

**Question:** A 68-year-old man presented to our emergency department with sudden-onset melena and associated orthostatic hypotension. Past medical history was notable for an esophagectomy with colonic interposition secondary to accidental caustic alkaline ingestion at age 17, a history of unprovoked pulmonary embolism while on warfarin anticoagulation, and group 2-4

pulmonary hypertension on aspirin.

Physical examination was relevant only for mild tenderness in the epigastrium. Initial laboratory evaluation demonstrated a hemoglobin of 6.7 g/dL, an elevated international normalized ratio at 2.1, and a normal platelet count at 251,103/microL. Blood urea nitrogen and creatinine were also elevated (85 mg/dL and 1.88 mg/dL, respectively).

Nine months before his current presentation, he was evaluated for episodic dysphagia with associated prandial and postprandial chest discomfort and shortness of breath, which he reported had been gradually worsening over the past 20 years. The patient had undergone an exhaustive cardiopulmonary evaluation with cross-sectional imaging (Figure A, neoesophagus bracketed) and it was suspected that his symptoms were partially explained by retained food in his neoesophagus. A promotility agent was prescribed but no intervention was performed.

The patient was hemodynamically stabilized with aggressive fluid resuscitation and blood products. An urgent bedside esophagogastroduodenoscopy was performed. An ulcer with a visible vessel was identified in the duodenal bulb and treated with both mechanical clipping and cauterization. However, incidental findings were noted within the esophagus (Figures B, C).

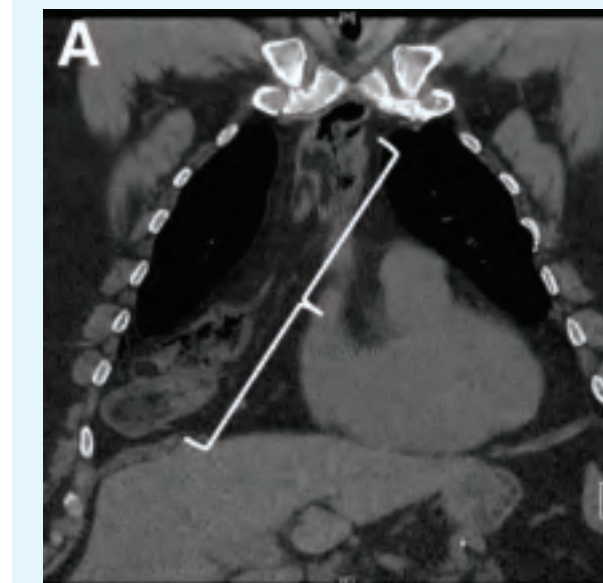
Based on the clinical history, what is the



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most likely underlying etiology for the incidental findings in the esophagus?

The diagnosis is on page 12.





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## Your patients with *C. difficile* now have a new resource

The AGA GI Patient Center has released a new resource to support patients infected with *C. difficile*. The resource includes "Understanding *C. diff* infection" video and a patient brochure entitled "Navigating Your *C. diff* Diagnosis."

*C. diff*, a bacterium known to cause bad GI symptoms like nausea and watery diarrhea, infects nearly 500,000 Americans every year and often calls for hospitalization. The AGA GI Patient Center has curated a new patient education page to assist and

to share directly with your patients to prepare them for their visit. The article includes *C. difficile*-specific guidance on:

- Symptoms.
- Risk factors.
- Getting tested.
- Treatment.
- Complications.

Share this new resource with your patients by printing, linking from your practice website, or emailing the link to your patients. Visit [gastro.org-cdiff](http://gastro.org-cdiff) to view the new video and brochure.

The "Navigating Your *C. diff* Diagnosis" brochure

was reviewed by Rajeev Jain, MD, AGAF, AGA Patient Education Advisor, Texas Digestive Disease Consultants, Dallas, and Alexander Khoruts, MD, AGA Center for Gut Microbiome Research and Education Scientific Advisory Board, University of Minnesota, Minneapolis. AGA members will also receive print copies of the new brochure this month.

*This program was supported by an independent educational grant from Ferring Pharmaceuticals, Inc.*

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## What your patients need to know about biologics and biosimilars

The AGA GI Patient Center has released a new brochure entitled "Biologic and biosimilar medicines: What you need to know." The new brochure includes interactive elements like quizzes, medication sheets, symptom tracker, and the option of audibly listening to the pages.

The brochure provides patients with:

- An overview of the immune system.

- Background on immune-mediated conditions.
- Biologics and biosimilars: What are they?
- Information on biosimilars and generics.
- Cost of biologics and biosimilars.
- The importance of adhering to their treatment plan.
- Tips to start the conversation with their provider.

- Safety of biologics and biosimilars.

Share this new resource with your patients by printing, linking from your practice website, or emailing the link to your patients. Visit the AGA GI Patient Center page dedicated to biosimilars for more at [gastro.org/biosimilars](http://gastro.org/biosimilars).

AGA members will also receive print copies of the new brochure this month. Order additional copies for

your practice at [http://www.agaresources.com/order\\_biosimilars.php](http://www.agaresources.com/order_biosimilars.php).

The brochure was reviewed by Jami Kinnucan, MD, and Rajeev Jain, MD, AGAF, AGA Patient Education Adviser.

View the interactive brochure at <https://bit.ly/2JYE5tL>.

*This brochure was funded by an independent medical education grant from Pfizer Inc.*

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## CLINICAL CHALLENGES AND IMAGES

### The diagnosis

#### Answer to "What is your diagnosis?" on page 11: Tubulovillous adenoma within a colonic interposition

In addition to the source of the bleeding from peptic ulcer disease, the upper endoscopy revealed a large adenomatous polyp along with evidence of significant diverticular disease throughout the interposed colon. The polyp was later resected completely and histopathologic evaluation confirmed the polyp to be a tubulovillous adenoma without dysplasia (Figures D, E).

Esophageal replacement by colonic interposition is a rare surgical procedure typically used only in advanced esophageal cancers, end-stage stricturing disease, or severe caustic ingestions.<sup>1</sup> Because of the scarcity of cases, there is little known regarding the long-term outcomes of the procedure.<sup>1</sup>

There are a growing number of reports showing the presence of colon polyps within the interposed colon.<sup>2,3</sup>

These polyps range from simple adenomas to high-grade adenocarcinomas.<sup>2,3</sup> In the majority of cases, the interposition was performed later in the patient's life, leading to the potential that the polyp or subsequent adenocarcinoma arose from a missed lesion. However, in our case the interposition was performed in adolescence, more than 50 years before presentation, strongly suggesting that the lesion likely occurred de novo.

Fecal retention is thought to contribute to polyp development and diverticula in the colon, but in the case of our patient the segment of colon used for his neoesophagus would have been exposed to stool only until adolescence. It is possible that

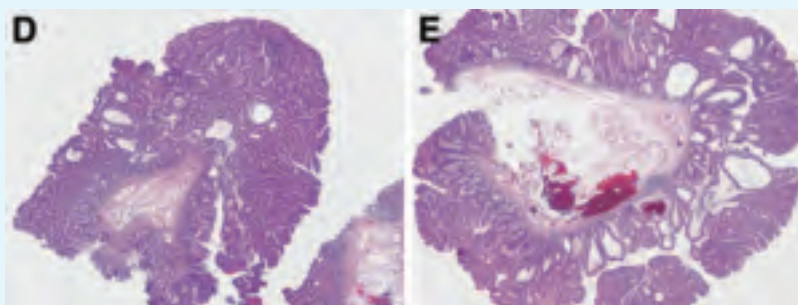
significant stasis of food owing to poor peristaltic activity in the interposed colonic segment and the presence of diverticula may have both contributed to polyp development. The fact that diverticular pouches are identified directly under the polyp would seem to support the role of food retention in polyp formation (Figures B, C). This case shows that the molecular pathogenesis of colon polyp formation is likely preserved, irrespective of the presence of stool or the physical location of the colon. Had our patient not received an endoscopy for his GI bleed, the adenomatous polyp would not have been identified and removed.

Given our findings, GIs should be aware of this condition in this patient population and long-term surveillance endoscopies should be considered in all patients with colonic interpositions.

#### References

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# GI & HEPATOLOGY NEWS

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# Transplant waitlists considered

Liver from page 1

deaths in 14 states that did not expand Medicaid continued to climb, reported Nabeel Wahid, MD, a resident at Weill Cornell Medicine, New York.

The differences in liver-related mortality between Medicaid expansion and nonexpansion states were particularly pronounced in people of Asian background, in Whites, and in African Americans, he said in an oral abstract presentation during the virtual annual meeting of the American Association for the Study of Liver Diseases.

"The expansion of government health care programs such as Medicaid may improve liver-related mortality and liver transplant waitlist placement," he said.

The implementation of the ACA resulted in "a pretty dramatic increase in the number of Americans with health insurance today, and there's a lot of literature out there looking at a variety of domains throughout health care that have found that Medicaid expansion increased access and decreased disparities in care," he added.

For example, a report published in 2019 by the nonpartisan National Bureau of Economic Research Priorities showed a significant reduction in disease-related deaths in Americans aged 55-64 years in Medicaid expansion states compared with nonexpansion states.

In addition as previously reported, before Medicaid expansion, African Americans were 4.8% less likely than were Whites to receive

timely cancer treatment, defined as treatment starting within 30 days of diagnosis of an advanced or metastatic solid tumor. After Medicaid expansion, however, the difference between the racial groups had dwindled to just 0.8% and was no longer statistically significant.

"However, specifically in the realm of liver transplantation and liver disease, there's very limited literature showing any sort of significant impact on care resulting from Medicaid expansion," Dr. Wahid said.

## Listing-to-death ratio

To test their hypothesis that Medicaid expansion decreased racial disparities and improved liver-related deaths and transplant waitlist placement, Dr. Wahid and colleagues compared liver-related deaths and liver transplants listings between Medicaid expansion and nonexpansion states in the 5 years before expansion (2009-2013) and after expansion (2014-2018). They excluded all states without transplant centers as well as patients younger than 25 or older than 64, who were likely to be covered by other types of insurance.

They obtained data for listing from the United Network for Organ Sharing (UNOS) and on end-stage liver disease from the Centers for Disease Control and Prevention's WONDER database.

They also used a novel measure called the listing-to-death ratio (LDR), a surrogate endpoint for

waitlist placement calculated as the ratio of listings for liver transplantation relative to the number of deaths from liver disease, with a higher LDR score corresponding to improved waitlist placement.

They found that, throughout the entire study period, Medicaid expansion states had lower liver-related deaths, higher liver transplant listings, and higher LDR.

Using joinpoint regression to examine changes at a specific time point, the investigators determined that the annual percentage change in liver-related deaths increased in both nonexpansion states (mean 4.3%) and expansion states (3.0%) before 2014. However, beginning around 2015, liver-related deaths began to decline in expansion states by a mean of -0.6%, while they continued on an upward trajectory in the nonexpansion states, albeit at a somewhat slower pace (mean APC 2% from 2014 through 2018).

Among all racial and ethnic groups (Whites, African Americans, Hispanics, and Asians) liver-related deaths increased from 2014 to 2018 in nonexpansion states, with the highest annual percentage change in Asians, at slightly more than 8%. In contrast, among Asians in the expansion states, liver-related deaths over the same period increased by less than 1%, and in both Whites and African Americans liver-related deaths declined.

In addition, starting in 2015, the annual percent change in LDR increased only in expansion states primarily because of fewer end-stage liver disease deaths (the LDR equation's denominator) rather than increased listings (its numerator).

## 'No-brainer'

"The obvious message is that transplant is costly, and patients need to be insured to get a liver transplant, because nobody is paying for this out of pocket. So if more candidates are insured that will reduce disparities and improve access to liver transplant for those who need it," said Elliot Benjamin Tapper, MD, of the University of Michigan, Ann Arbor, who was not involved in the study.

"It's a no-brainer that the lack of insurance accessibility for the most vulnerable people in the United States meant that they were dying of cirrhosis instead of being transplanted," he said in an interview.

He also commended the authors on their use of population-based data to identify outcomes.

"We know how many people are listed for liver transplant, but we don't know how many people could have been listed. We know how many people are transplanted, but we don't know how many people with decompensated cirrhosis should have been given that chance. We lacked that denominator," he said.

"The innovation that makes this particular paper worthwhile is that, in the absence of that denominator, they were able to construct it, so we can know from other data sources distinct from the waitlist rolls how many people are dying of cirrhosis."

No study funding source was reported. Dr. Wahid and Dr. Tapper reported no conflicts of interest.

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**SOURCE:** Wahid N et al. AASLD 2020, Abstract 153.

# 'Excellent short-term outcomes' seen in HCV-positive liver transplants to HCV-negative recipients

BY MARK S. LESNEY, PHD

MDedge News

Liver transplantation using hepatitis C virus (HCV)-seropositive grafts to HCV-seronegative recipients resulted in "excellent short-term outcomes," according to the results of a prospective, multicenter study reported in the *Journal of Hepatology*.

A total of 34 HCV- liver transplantation recipients received grafts from HCV+ donors (20 HCV viremic and 14 nonviremic) from January 2018 to September 2019, according to Bashar Aqel, MD, of the Mayo Clinic, Phoenix, and colleagues. Seven of the grafts were obtained from donation after cardiac death (DCD). Six recipients underwent simultaneous liver/kidney (SLK) transplant, and four patients were repeat transplants.

## Sustained viral response

None of the recipients of an HCV nonviremic graft developed HCV viremia. However, all 20 patients who received HCV viremic grafts had HCV viremia confirmed within 3 days after liver transplant. Direct-acting antiviral (DAA) treatment was started at the median time of 27.5 days in these patients.

All 20 patients successfully completed the treatment and achieved a sustained viral response. In addition, the DAA treatment was well tolerated with minimal adverse events, according to the researchers.

However, one patient died after having developed HCV-related acute membranous nephropathy that resulted in end-stage kidney disease. In addition, a recipient of an HCV nonviremic graft died with acute myocardial infarction 610

days after receiving liver transplant, the authors reported.

"This multicenter study demonstrated LT [liver transplantation] using HCV-seropositive grafts to HCV-seronegative recipients resulted in acceptable short-term outcomes even with the use of DCD grafts and expansion into SLK or repeat LT. However, a careful ongoing assessment regarding patient and graft selection, complications, and the timing of treatment is required," the researchers concluded.

The study was funded in part by the McIver Estate Young Investigator Benefactor Award. The authors reported they had no potential conflicts.

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**SOURCE:** Aqel B et al. *J Hepatol*. 2020 Nov 11. doi: 10.1016/j.jhep.2020.11.005.



# Should your practice be acquired by private equity?

**Yes** But you should absolutely lean-in, listen, and learn.

The physician leadership team at Atlanta Gastroenterology Associates has been focused on developing strategies and partnerships that strengthen our ability to thrive in our marketplace while also fending off threats to our mission. The path to forming the managed services organization (MSO) United Digestive through our agreement with the private equity firm Frazier Healthcare Partners was arduous and required a significant investment of resources and time. Like at Atlanta Gastroenterology Associates, many influential leaders within our field have concluded that the investment of a private equity firm to build an MSO led by professional business executives will reduce the administrative stresses looming over the traditional independent GI business model. Now, and after almost 2 years as a member of United Digestive, I unequivocally believe my ability to provide timely, high-quality, and affordable care to my community is currently more stable and in a stronger position for the future.

*Marc Sonenshine, MD, MBA, is a partner in United Digestive and chair of medicine at Northside Hospital, Atlanta. He has no conflicts.*



Dr. Sonenshine

## A note of caution

Is private equity good for gastroenterology? The answer is not a definitive “yes” or “no”; it is “depends.”

Private equity is an alternative investment strategy focused on assets not listed on a public exchange. Capital usually is derived from investors who can tolerate risk with the hope of a high return such as pension funds, university endowments, and high-net worth individuals. Capital is collected within a fund (or funds) managed by a professional team who invests in, or buys private companies using internal capital leveraged with debt. Assets and governance both are sold to fund managers, who restructure operations, centralize or standardize workflows, acquire similar companies to achieve economies of scale, and eventually resell the new company to another entity (usually a larger private equity fund). Typically, the resale (second bite) occurs 5-7 years after initial acquisition and during that 5- to 7-year period, private equity funds expect a substantial (10%-20%) annual return on investment resulting from revenue enhancement, new service lines, and overhead reduction.

*John I Allen, MD, MBA, AGAF, is clinical professor of medicine, department of internal medicine, division of gastroenterology and hepatology, Institute for Healthcare Policy and Innovation, University School of Medicine, Chief Clinical Officer, University of Michigan Medical Group, Ann Arbor. He has no disclosures.*



Dr. Allen

Dear colleagues and friends,  
The Perspectives series continues! Few

current issues in Gastroenterology practice are as passionately debated as those associated with private equity. In this edition, our own Dr. Allen and Dr. Kahi Dr. Sonenshine explain private equity’s evolution in the GI field, dispel misconceptions, and dissect the central question of whether it is right for your practice. Thank you for your support, and I hope you will find the discussions enlightening and relevant to your practices. As always, I welcome your comments and suggestions for future topics at [ginews@gastro.org](mailto:ginews@gastro.org).

*Charles J. Kahi, MD, MS, AGAF, is professor of medicine, Indiana University School of Medicine, Indianapolis. He is also an Associate Editor for GI & Hepatology News.*



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# Obesity phenotyping matches patients with more effective interventions

BY MITCHEL L. ZOLER, PHD  
MDedge News

A phenotype-guided strategy for systematically matching weight-loss patients to their potentially ideal weight-loss drug

roughly doubled treatment efficacy, compared with usual practice, in a single-center, randomized study with 268 patients.

After classifying 68 patients into one of four obesity phenotypes through a series of tests and

then tailoring drug treatment to the identified phenotype of each patient, researchers observed a 79% rate of greater than 10% weight loss versus baseline after 12 months. In contrast, in 200 patients who received weight loss–drug

therapy selected by routine means, 35% achieved greater than 10% loss compared with their starting weight, Andres J. Acosta, MD, said at the virtual ObesityWeek® Interactive 2020 meeting.

The phenotype-guided strategy also led to an average 16% weight loss from baseline after 12 months, compared with a 9% average loss among the usual-care controls, reported Dr. Acosta, a gastroenterologist at the Mayo Clinic in Rochester, Minn.

**A “one-size-fits-all approach to weight loss treatment is not working,” Dr. Acosta said. “Our long-term goal is to develop a personalized approach to obesity management.”**

A “one-size-fits-all approach to weight loss treatment is not working,” he declared. “Our long-term goal is to develop a personalized approach to obesity management.”

## Further advantages of personalized weight loss

“The better we can match treatment to a patient’s needs, the more likely it will succeed. That’s not a brand new idea. They are trying to standardize the way that we classify the disorders that play a role in why a person gains weight or has trouble losing weight,” commented John D. Clark III, MD, an internal medicine physician and weight-management specialist at UT Southwestern Medical Center in Dallas.

The increased weight-loss levels that Dr. Acosta reported in patients who underwent the study’s phenotyping protocol and received tailored treatment “are similar to the numbers we see when a patient’s treatment is the right fit for them. You see weight loss in these ranges,” Dr. Clark said in an interview.

The study run by Dr. Acosta and his associates consisted of two phases. First, they established normal and abnormal ranges for four different obesity phenotypes by studying 100 patients with obesity. The patients underwent an extensive and uniform workup designed to classify their obesity phenotype.

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#### Four obesity phenotypes

The researchers categorized patients into one of four types:

- Disordered initial eating satiation, called “hungry brain,” and assessed by measuring food intake at a buffet, ad libitum meal.
- Disordered maintenance of satiety, called “hungry gut,” assessed by both a gastric-emptying study as well as patient self-assessment for postprandial fullness.
- “Emotional hunger,” assessed with two questionnaires.
- Disordered energy expenditure, called “slow burn,” assessed by measuring basal metabolic rate, and self-reports of both exercise and nonexercise activity.

Dr. Acosta estimated that the complete workup to assess all four potential phenotypes costs about \$1,200.

The researchers then applied the 75th percentile value from each of these assessments to 450 patients with obesity in their clinic to see the prevalence of the four phenotypes. They identified a single phenotype in 58% of these patients, including 18% with hungry gut, 16% with hungry brain, 12% with emotional hunger, and 12% with slow burn. An additional 27% of the patients were positive for two or more phenotypes (including 9% who were positive for all four phenotypes), and 15% did not test positive for any of the four phenotypes.

#### Phenotype-guided treatments

They then applied their findings in a prospective randomized study that matched a drug intervention to each of the four phenotypes during a year-long, comprehensive weight-loss program at the Mayo Clinic’s Weight Management Clinic. The study randomized 100 patients to the phenotype-driven arm, with 68 of these patients receiving their assigned drug, and 200 patients served as controls. Patients averaged about 47 years old, and their average body mass index was about 41 kg/m<sup>2</sup>.

The investigational arm included 30 patients classified as having a hungry brain, with 20 of these patients treated with phentermine plus topiramate and 10 treated with lorcaserin (before it was withdrawn by the Food and Drug Administration); 12 with hungry gut and treated with liraglutide (Saxenda); 19 with emotional hunger who received naltrexone SR/bupropion SR (Contrave); and seven with slow burn who received phentermine.

The control arm included 200

patients seeking weight-loss treatment at Mayo who did not undergo phenotyping and received their drug treatment based on their personal preference in consultation with their Mayo physician. In this group, drug treatment broke down as 106 patients (53%) on phentermine plus topiramate, 41 (21%) on liraglutide, 34 (17%) on phentermine alone, 14 (7%) on naltrexone SR/bupropion SR, and 5 patients (3%) on lorcaserin (percentages total 101% because of rounding).



Dr. Acosta

and lorcaserin and fewer treated with phentermine or phentermine and topiramate ER. All patients were eligible to also receive behavioral interventions as needed.

“We do a lot of testing to identify the phenotype,” in addition to gathering additional clues from a detailed history, said Dr. Acosta. Patients identified with more than one phenotype in routine practice at Mayo are often begun on more than one drug. When phenotyping fails to classify a patient, Dr. Acosta puts the patient on a low-calorie diet and then does a follow-up assessment “to see if the phenotype pops up as a metabolic adaptation.”

“This is something we’re all working toward” in the obesity management field. “How can we better identify the underlying causes in a way that can fit into the work flow. How can we move from research to things we can use daily in the clinic,” observed Dr. Clark. “We need a lot more investigation to determine how well this works in the real world. Are there other tools we can use that are not as expensive” as what Dr. Acosta used for this study?

“For this proof of concept study, it made sense to be very rigorous, but that probably is not realistic for every patient. What are other ways to get this information, or perhaps only use an extensive workup when initial weight loss attempts are unsuccessful,” Dr. Clark suggested.

Dr. Acosta is a consultant to Rhythm Pharmaceuticals and General Mills and has received research support from Novo Nordisk, Rhythm Pharmaceuticals, Satiogen, and Vivus. Dr. Clark had no disclosures.

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## Eight best practices identified

Enteropathy from page 1

there is limited evidence to guide clinicians regarding the minimal serologic tests necessary, the role of the gluten-free diet in diagnosis and management, and the role of an expert pathologist in evaluating the diagnosis of seronegative enteropathy.”

Patients with seronegative enteropathy tend to have a poorer prognosis than those with classic CeD and other causes of villous atrophy, the investigators noted, but with an accurate diagnosis, distinct therapies can be highly effective.

After a comprehensive literature review, Dr. Leonard and colleagues reached consensus on eight best practice advice statements.

First, the investigators advised clinicians to review histologic findings with an experienced pathologist specializing in gastroenterology, as an expert can ensure proper duodenal orientation, and possibly link a specific finding with an etiology. Communications with pathologists

should also incorporate medical, travel, and medication history.

“Clinicians should pay particular attention to obtaining a thorough medication history to determine whether a patient is taking an angiotensin II receptor antagonist, such as olmesartan, which has been described as causing enteropathy,” the investigators wrote. “In some cases, this has led patients to be incorrectly diagnosed with refractory CeD. Other medications, including azathioprine and mycophenolate mofetil, among others, also have been reported to cause enteropathy, which resolves with discontinuation of medication.”

According to Dr. Leonard and colleagues, histologic findings suggestive of Crohn’s disease should prompt HLA testing, which requires careful attention to detail and thorough review.

“It is prudent that the gastroenterologist or CeD specialist review all alleles tested and reported (or obtain the alleles if not reported)

by the laboratory,” they wrote.

If HLA testing is positive, then the patient should begin empiric treatment with a gluten-free diet, followed by clinical and endoscopic reassessment after 1-3 years.

If HLA testing is negative, then a battery of tests may be needed to detect alternative etiologies, such as

**“Clinicians should pay particular attention to obtaining a thorough medication history to determine whether a patient is taking an angiotensin II receptor antagonist.”**

giardiasis, small intestinal bacterial overgrowth, HIV, and others.

“In cases where an underlying cause was identified, a follow-up esophagogastroduodenoscopy with biopsy might not be indicated, according to the etiology identified, treatment, and clinical status,” the investigators wrote.

Even with a comprehensive work-up, clinicians may be unable to

identify an etiology. This outcome may be relatively common, the investigators suggested, citing a study of 200 cases of seronegative villous atrophy (*Gut*. 2017;66:1563-72), of which 18% had no identifiable etiology. Yet finding an etiology may ultimately be unnecessary, as 72% of idiopathic cases resolved without intervention within 9 months, suggesting transient villous atrophy.

Still, intervention is needed for clinically unstable patients with idiopathic seronegative villous atrophy. Dr. Leonard and colleagues recommended first-line treatment with budesonide, starting at 9 mg daily. Depending on clinical status and response, subsequent therapies may include azathioprine or prednisone.

The clinical practice update was commissioned and approved by the AGA. The investigators disclosed additional relationships with Takeda Pharmaceuticals, HealthMode, Anokion, and others.

ginews@gastro.org

**SOURCE:** Leonard MM et al. *Gastroenterology*. 2020 Sep 30. doi: 10.1053/j.gastro.2020.08.061.

## AGA: Recommendations for managing IBD in elderly patients

BY WILL PASS

MDedge News

The American Gastroenterological Association has published a Clinical Practice Update for management of inflammatory bowel disease (IBD) in elderly patients, including 15 best practice advice statements.

According to lead author Ashwin N. Ananthakrishnan, MD, MPH, of Massachusetts General Hospital and Harvard Medical School, both in Boston, and colleagues, this topic is becoming increasingly relevant, as the population is aging, and prevalence of IBD among elderly is rising approximately 5% per year.

“Up to 15% of IBD in North America and Asia is diagnosed after the age of 60 years,” the investigators wrote in *Gastroenterology*. They noted that “care of elderly IBD patients poses unique challenges with respect to diagnosis and therapeutic decision-making.”

Challenges include greater frequency of comorbidities, increased risk of infection with anti-tumor necrosis factor therapy, increased risk of lymphoma with thiopurine therapy, greater likelihood of surgical complications, and, for Crohn’s disease, an elevated mortality rate,

according to the update.

Another challenge is a lack of data.

“It should be noted that most clinical data to inform these practices are based on observational data or indirect evidence as elderly IBD patients comprise a very small proportion of subjects enrolled in IBD clinical trials or long-term pharmacovigilance initiatives,” the investigators wrote.

### Diagnosis

Dr. Ananthakrishnan and colleagues first suggested that clinicians remain vigilant for IBD in elderly people, in consideration of the 15% prevalence rate in this subpopulation.

For elderly individuals with a low probability of IBD, the investigators recommended fecal calprotectin or lactoferrin to determine if endoscopy is needed. For elderly patients with chronic diarrhea or hematochezia, plus moderate to high suspicion of IBD, colorectal neoplasia, or microscopic colitis, they recommended colonoscopy.

Lastly, the expert panel suggested that elderly patients presenting with segmental left-sided colitis and diverticulosis may also have Crohn’s disease or IBD unclassified.

### Treatment

There is a recurring emphasis on treatment personalization, which should be informed by patient goals and priorities, risk/presence of severe disease, chronological age, functional status, independence, comorbidities, frailty, and several other age-associated risk factors (e.g., venous thromboembolism).

Concerning specific therapies, the investigators cautioned against systemic corticosteroids for maintenance therapy; instead, nonsystemic corticosteroids (e.g., budesonide) are favored, or possibly early biological therapy if budesonide is not indicated. When selecting a biologic, Dr. Ananthakrishnan and colleagues recommended those associated with a lower risk of malignancy and infection (e.g., ustekinumab or vedolizumab).

The advantages of thiopurine monotherapy being oral and relatively inexpensive, compared to biologics, and having a long track record of success in maintenance of remission must be balanced against the need for ongoing serological monitoring and increased risk of some malignancies.

Finally, the expert panel recommended that all elderly patients receive multidisciplinary care, which

may include primary care providers, mental health professionals, nutritionists, and other specialists. It may also be productive to consult with family and caregivers during treatment planning.

### Health maintenance

The investigators recommended that elderly patients with IBD adhere to vaccination schedules, ideally before starting immunosuppression.

Second, Dr. Ananthakrishnan and colleagues advised that cessation of colorectal cancer surveillance may be considered in elderly patients with IBD; however, this decision should take into account a variety of factors, including comorbidities, age, life expectancy, likelihood of endoscopic resection, and surgical candidacy.

The review was commissioned and approved by the AGA Institute Clinical Practice Updates Committee and the AGA Governing Board. The investigators disclosed relationships with Gilead, Sun Pharma, Kyn Therapeutics, and others.

ginews@gastro.org

**SOURCE:** Ananthakrishnan AN et al. *Gastroenterology*. 2020 Sep 30. doi: 10.1053/j.gastro.2020.08.060.



# Histologic remission found unrelated to UC relapse

BY HEIDI SPLETE

MDedge News

**R**elapse in ulcerative colitis (UC) patients with endoscopic remission was unaffected by histologic remission status, based on data from a retrospective study of 269 adults.

Data from previous studies suggest that histologic remission may be the strongest predictor of prognosis of disease course, wrote Neeraj Narula, MD, of McMaster University, Hamilton, Ont., and colleagues.

"However, it is unclear if UC patients who have achieved endoscopic healing have additional benefit in clinical outcomes if they have achieved histologic remission as well," they said.

In a study published in *Alimentary Pharmacology and Therapeutics*, the researchers identified 269 adults with UC who had endoscopic remission. Of these, 53 had normal histology, 138 had histologically inactive colitis, and 78 had histologically active colitis.

Overall, clinical relapse occurred in 64 patients, including 12 with normal histology (22.6%), 32 with inactive colitis (23.2%), and 29 with active colitis (25.6%).

No significant difference occurred in the time to relapse in patients with inactive vs. active colitis (adjusted hazard ratio, 1.17;  $P = .67$ ) or in patients with normal histology vs. inactive histology (AHR, 0.67;  $P = .39$ ). The median time to relapse was 2.92 years, 3.0 years, and 4.0 years in the normal, inactive, and active groups, respectively. Factors associated with a shorter time to relapse included older age at colonoscopy, use of 5-aminosalicylic acid, and disease extent in cases of pancolitis and left-sided colitis.

The study findings were limited by several factors including the possibility of bias in histologic scoring, lack of objective measures of disease activity, and the lack of uniformity in histologic assessment, the researchers noted. However, the study was large compared with previous studies and adjustments for known confounding factors were made, they said.

## More research needed

"I was rather surprised by the findings, as a majority of studies have shown that histologic healing more accurately predicts clinical relapse than endoscopic remission in UC," Atsushi Sakuraba, MD, of the University of Chicago, said in an interview.

"This was a retrospective study, so no firm conclusion can be made," said Dr. Sakuraba. Going forward, prospective studies are needed that match for confounders such as pos-

tendoscopy medication use, age, and disease extent, Dr. Sakuraba said.

Lead author Dr. Narula disclosed honoraria from Janssen, AbbVie, Takeda, Pfizer, Merck, and Ferring. Dr.

Sakuraba had no conflicts to disclose. [ginews@gastro.org](mailto:ginews@gastro.org)

**SOURCE:** Narula N et al. *Aliment Pharmacol Ther.* 2020 Nov 1. doi: 10.1111/apt.16147.



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# What to keep in mind as 2021 begins

## FROM THE AGA PRACTICE MANAGEMENT AND ECONOMICS COMMITTEE

As 2020 comes to a close, most of us are looking forward to a (hopefully) brighter 2021. This year has been full of challenges and new experiences, but we have learned a lot. Pandemic or not, there are some things that you and your practice can do to ensure that you are prepared to make 2021 a success.

### Tips for your practice

**Assess staff morale:** It seems simple but checking in with your staff can go a long way. Everyone is dealing with challenges both in and out of the workplace. Check in, show them you care, and think of ways that you can make their work a positive experience in the new year. During our May 2020 GI division chief townhall, John Inadomi, MD, gave a great presentation on the importance of staff morale during the pandemic.

**Listen to colleagues:** Find out about their experiences, challenges, and solutions. In October, the American Gastroenterological Association held a town hall with some great information and resources called “Adapting to Changing Practice Paradigms.” The agenda covered topics from telehealth to private equity and planning for the next potential wave of COVID-19.

**Celebrate the wins:** It can often feel like not much went right in 2020, but we did accomplish significant wins for GIs, including achieving payment parity for telephone evaluation and management (E/M) visits with video visits, increases in digestive disease and GI cancer research funding, and inclusion/expansion of GI cancers research opportunities. We couldn’t have done it without you, though, and we will continue to need your help to move important

issues forward in 2021. Get involved today! Visit “Get Involved” under Advocacy and Policy on [www.gastro.org](http://www.gastro.org).

**Prepare for E/M changes:** The Current Procedural Terminology (CPT) E/M for new and established patient office/outpatient codes (99201-99205, 99211-99215), guidelines, and Medicare payments will undergo major changes beginning Jan. 1, 2021. See the AGA’s coding and reimbursement experts’ article from the March 2020 issue of *GI & Hepatology News*, “Prepare for major changes to E/M coding starting in 2021,” to learn about the changes and get resources to help practices prepare.

**Keep up with new Medicare payment rules:** The release of the 2021 physician payments and rules for the Medicare program was delayed this year because of the COVID-19 public health emergency. We were dismayed to learn that Medicare did not make any changes that substantively mitigated the expected cuts to most specialties. Instead of a 5% cut for GI, the Centers for Medicare & Medicaid Services now projects GI will experience a 4% payment cut for 2021. AGA is calling on Congress to pass legislation to stop the cuts. This situation is evolving quickly. Watch for AGA member alerts for breaking news and resources, including the AGA’s “Medicare plans significant payment cuts for 2021.”

**Stay current on telehealth and telephone E/M coverage:** The commercial payer community came together to cover telehealth (video visits) and telephone E/M at the beginning of the COVID-19 pandemic but have since regularly teased the end of coverage only to extend it just before it expires. It’s impossible to predict what each payer will do, but you can use the following

resources to keep current on most payers’ policies and correct coding/reporting for telehealth and telephone E/M:

- “Current State Laws & Reimbursement Policies” from the Center for Connected Health.
- “Coding for Telehealth & Virtual Visits During COVID-19” from the AGA University.

**Check to see if you can report on additional quality measures:** AGA has expanded the Merit-Based Incentive Payment System (MIPS) measure portfolio by assuming ownership and stewardship of two hepatitis C virus (HCV) measures from PCPI, including annually checking for HCV in active injection drug users (measure 387) and performing a one-time screening for HCV among patients at risk (measure 400). As a result, gastroenterologists can now report on even more GI-specific measures. There have been the following two changes to GI-specific measures in 2021:

- Measure 275: “Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy” now includes coding to allow reporting for all age groups, including pediatric populations.
- Measure 439: “Age Appropriate Screening Colonoscopy” now includes all colonoscopies for patients 50 years and older; however, there’s an exclusion for those patients between the ages of 50 and 85 years.

These changes will help more gastroenterologists qualify for these measures.

*G. Anton Decker, MD, is chair of the AGA Practice Management and Economics Committee, Mayo Clinic International; Dawn Francis, MD, is chair-elect of the AGA Practice Management and Economics Committee, Mayo Clinic, Jacksonville, Fla. They have no conflicts of interest.*

## Dates and deadlines to remember

### January 2021

- Jan. 1 – MIPS Performance Year 2021 begins.
- Jan. 4 – Submission window opens for MIPS Performance Year 2020.
- Changes to Improvement Activity category go into effect (if approved in final rule).

### March 2021

- March 31 – First snapshot for Qualifying Participant (QP) determinations and MIPS APM participation.

### April 2021

- April 1 – Registration begins for CMS web interface and Consumer Assessment of Healthcare

Providers and Systems (CAHPS) for MIPS survey.

### June 2021

- June 30 – Second snapshot for QP determinations and MIPS APM participation.
- June 30 – Registration ends for CMS web interface and CAHPS for MIPS survey.

### July 2021

- CMS publishes proposed reimbursement values for 2022 in the Medicare Physician Fee Schedule proposed rule.
- CMS “Targeted Review” opens once CMS makes your MIPS payment adjustment available.
- July 1 – MIPS Performance Feed-

back Available. CMS will provide you with performance feedback based on the data you submitted for Performance Year 2020. You can use this feedback to improve your care and optimize the payments you receive from CMS in the future.

### August 2021

- Aug. 31 – Targeted Review period closes (appeals process).

### September 2021

- AMA releases CPT 2022 book, including a new CPT code for Peroral Endoscopic Myotomy (POEM).

### October 2021

- Oct. 3 – Last day to start a

90-day performance period for promoting Interoperability and Improvement Activities.

### November 2021

- CMS finalizes reimbursement values for 2022 in the MPFS final rule. New payment rates take effect Jan. 1, 2022.

### December 2021

- Dec. 31 – Quality Payment Program Exception Applications window closes.
- Dec. 31 – MIPS Performance year 2020 ends.
- Dec. 31 – Fourth snapshot for full TIN APMs (Medicare Shared Savings Program).



# Impacts vary by specialty

Pay rule from page 1

physician assistants.

The most contentious item proposed for 2021 was a reshuffling of payments among specialties as part of an overhaul of Medicare's approach to valuing evaluation and management (E/M) services. There was broader support for other aspects of the E/M overhaul, which are intended to cut some of the administrative hassle clinicians face.

"This finalized policy marks the most significant updates to E/M codes in 30 years, reducing burden on doctors imposed by the coding system and rewarding time spent evaluating and managing their patients' care," CMS Administrator Seema Verma said in a statement. "In the past, the system has rewarded interventions and procedures over time spent with patients – time taken preventing disease and managing chronic illnesses."

In the final rule, CMS summarized these results of the E/M changes in

Table 106. CMS largely stuck with the approach outlined in a draft rule released in August, with minor changes in the amounts of cuts and increases.

Specialties in line for increases under the 2021 final physician fee schedule include allergy/immunology (9%), endocrinology (16%), family practice (13%), general practice (7%), geriatrics (3%), hematology/oncology (14%), internal medicine (4%), nephrology (6%), physician assistants (8%), psychiatry (7%), rheumatology (15%), and urology (8%).

In line for cuts would be anesthesiology (–8%), cardiac surgery (–8%), emergency medicine (–6%), general surgery (–6%), infectious disease (–4%), neurosurgery (–6%), physical/occupational therapy (–9%), plastic surgery (–7%), radiology (–10%), and thoracic surgery (–8%). The changes also would lead to an expected 4% decrease for gastroenterology. The

GI societies are among the groups pressing Congress to intercede.

CMS had initially set these changes in 2021 pay in motion in the 2020 physician fee schedule. The agency subsequently faced significant opposition to its plans. Many physician groups sought to waive a "budget-neutral" approach to the E/M overhaul, which makes the offsetting of cuts necessary. They argued this would allow increased compensation for clinicians whose practices focus on office visits without requiring offsetting cuts from other fields of medicine.

The American Medical Association is among those urging Congress to prevent or postpone the payment reductions resulting from Medicare's budget neutrality requirement as applied to the E/M overhaul.

In a Tuesday statement, AMA President Susan R. Bailey, MD, noted that many physicians are facing "substantial economic hardships due to COVID-19."

By AMA's calculations, CMS's planned 2021 E/M overhaul could

result in "a shocking reduction of 10.2% to Medicare payment rates," according to Dr. Bailey's statement. The AMA strongly supports other aspects of the E/M changes CMS finalized, which Dr. Bailey said will result in "simpler and more flexible" coding and documentation.

The Surgical Care Coalition, which represents about a dozen medical specialty associations, is asking members of Congress to block the full implementation of the E/M overhaul.

In a Dec. 1 statement, the coalition urged the passage of a bill (HR 8702) that has been introduced in the House by a bipartisan duo of physicians, Rep. Ami Bera, MD (D-Calif.), and Rep. Larry Bucshon, MD (R-Ind.). Their bill would effectively block the cuts from going into effect on Jan. 1, 2021. It would provide an additional Medicare payment for certain services in 2021 and 2022 if the otherwise applicable payment is less than it would have been in 2020. AGA has been advocating for passage of this bill

*Continued on following page*

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Continued from previous page

before the end of the 116th Congress and urges GIs to contact their lawmakers to prevent these cuts to specialty care. While the GI societies are in support of the bill, they have expressed concerns regarding the financial cliff H.R. 8702 would create. With the payment cuts pushed to 2023, this financial cliff would require physicians to return to Congress to prevent future cuts once the 2-year delay is up.

The Medicare E/M overhaul

“was a dangerous policy even before the pandemic, and enacting it during the worst health care crisis in a century is unconscionable. If Congress fails to act, it will further strain a health care system that’s already been pushed to the brink due to the COVID-19 pandemic and undermine patient care,” said John A. Wilson, MD, president of the American Association of Neurological Surgeons, in a statement.

Also backing the Bera-Bucshon bill is the American College of

Emergency Physicians. In a statement on Tuesday, ACEP President Mark Rosenberg, DO, MBA, urged Congress to act on this measure.

“Emergency physicians and other health care providers battling on the front lines of the ongoing pandemic are already under unprecedented financial strain as they continue to bear the brunt of COVID-19,” Dr. Rosenberg said. “These cuts would have a devastating impact for the future of emergency medicine and could seriously

impede patients’ access to emergency care when they need it most.”

### “Long overdue”

But there also are champions for the approach CMS took in the E/M overhaul. The influential Medicare Payment Advisory Commission (MedPAC) has argued strongly for keeping the budget-neutral approach to the E/M overhaul.

In an Oct. 2 comment to CMS about the draft 2021 physician fee schedule, MedPAC Chairman Michael E. Chernew, PhD, said this approach would “help rebalance the fee schedule from services that have become overvalued to services that have become undervalued.”

This budget-neutral approach also “will go further in reducing the large gap in compensation between primary care physicians (who had a median income of \$243,000 in 2018) and specialists such as surgeons (whose median income was \$426,000 in 2018),” Dr. Chernew wrote.

In a Tuesday tweet, Robert B. Doherty, senior vice president of governmental affairs and public policy for the American College of Physicians, said CMS had “finalized long overdue payment increases for primary and comprehensive care including an add-in for more complex visits.”

The American Academy of Family Physicians joined ACP in a Nov. 30 letter to congressional leaders, urging them to allow Medicare “to increase investment in primary care, benefiting millions of Medicare patients and the program itself, and reject last minute efforts to prevent these essential and long-overdue changes from going fully into effect on January 1, 2021.”

In the letter, AAFP and ACP and their cosigners argued for a need to address “underinvestment” in primary care by finalizing the E/M overhaul.

“Given that six in ten American adults have a chronic disease and four in ten have two or more chronic conditions, why would we, as a country, accept such an inadequate investment in the very care model that stands to provide maximum value to these patients?” they wrote. “Since we know that individuals with a longitudinal relationship with a primary care physician have better health outcomes and use fewer health care resources, why would we continue to direct money to higher-cost, marginal value services?”

Based on reporting from Medscape.com.



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# Liver injury linked to COVID-19–related coagulopathy

BY EMILY WILLINGHAM

There is a link between liver injury and a tendency toward excessive clotting in patients with COVID-19, and the organ’s own blood vessels could be responsible, new research shows.

The effect of IL-6 on the liver sinusoidal endothelial cells lining the liver blood vessels creates a prothrombotic environment that includes the release of factor VIII, said investigator Matthew McConnell, MD, from Yale University, New Haven, Conn.

Dr. McConnell presented the results at the virtual annual meeting of the American Association for the Study of Liver Diseases.

These associations offer insights into why COVID-19 patients with underlying liver disease can experience “devastating complications” related to improper blood vessel function in the organ, he added.

For their study, Dr. McConnell and colleagues analyzed data on ALT and hypercoagulability from 68 adults treated at Yale–New Haven Hospital. The liver and coagulation tests were administered within 5 days of each other.

The team set the ALT cutoff for liver injury at three times the upper limit of normal. Patients with two or more parameters indicating excessive clotting were considered to have a hypercoagulable profile, which Dr. McConnell called “a signature clinical finding of COVID-19 infection.”

Patients with high levels of ALT also experienced elevations in clotting-related factors, such as fibrinogen levels and the activity of factor VIII and factor II. Furthermore, liver injury was significantly associated with hypercoagulability ( $P < .05$ ).

Because COVID-19 is linked to the proinflammatory IL-6, the investigators examined how this cytokine and its receptor affect human liver sinusoidal cells. Cells exposed to IL-6 and its receptor pumped out factor VIII at levels that were significantly higher than in unexposed cells ( $P < .01$ ).

Exposed cells also produced significantly more von Willebrand factor ( $P < .05$ ), another prothrombotic molecule, and showed increased expression of genes that induce the expression of factor VIII.

There is utility in the findings beyond COVID-19, said Dr. McConnell. They provide “insights into complications of critical illness, in general,

in the liver blood vessels” of patients with underlying liver disease.

Dr. McConnell has no conflicts.

*A version of this article originally appeared on Medscape.com.*

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