### The NEW GASTROENTEROLOGIST



GRADIANC

Scientific

A Quarterly Supplement to GI & Hepatology News | Fall 2017

**17 Social Media** 

Understanding Social Media in Gl Practice

#### 13 Legal Issues

Legal Issues for the Gastroenterologist: Part II

### *Cholangiopancreatoscopy* Recent Advances 8

### *Letter* From the editor

Bryson W. Katona is an instructor of medicine in the division of gastroenterology at the University of Pennsylvania.

#### Dear Colleagues,

In this issue of The New Gastroen*terologist*, the feature article examines recent advances in the field of cholangiopancreatoscopy. In this article, William Sonnier, Meir Mizrahi (University of South Alabama), and Douglas Pleskow (Beth Israel Deaconess) provide a fantastic overview of the technologic advances in the field of cholangiopancreatoscopy as well as the clinical indications for this procedure and the risks involved. Also in this issue. Deborah Fisher (Duke University) and Darrell Gray (Ohio State University) provide advice about how to appropriately and responsibly handle social media. This is an incredibly important topic, given the increasing pervasiveness of social media in many aspects of our personal and professional lives.

Additionally, Madelin Siedler (AGA) and Yngve Falck-Ytter (Case-Western) demystify the process by which AGA guidelines are developed by outlining the workflow from inception to final publication. Also, Yamini Natarajan, Richa Shukla, and Jordan Shapiro (Baylor College of Medicine) provide an update about a recent meeting with their local representative, Gene Green (Texas's 29th congressional district), who is the Ranking Member for the Committee on Energy and Commerce's Subcommittee on Health.

Finally, in this issue is the second part in a series on legal issues for gastroenterologists. In this article, which is again authored by a very experienced group of attorneys, many important issues are covered, including what steps should be taken if you are sued, what you should and should not do after being sued, as well as tips on how to best prepare for both deposition and trial.

If there are topics that you would be interested in writing or hearing about in *The New Gastroenterologist*, please let us know. You can contact me (bryson.katona@uphs.upenn. edu) or the Managing Editor of *The New Gastroenterologist*, Ryan Farrell (rfarrell@gastro.org).

> Sincerely, Bryson W. Katona, MD, PhD Editor in Chief

#### The NEW GASTROENTEROLOGIST

Editor in Chief Bryson W. Katona, MD, PhD

#### **AGA Institute Staff**

Vice President of Publications Erin C. Landis Managing Editor Ryan A. Farrell Senior Medical Illustrator Sarah L. Williamson

#### AGA Institute Governing Board

President Sheila E. Crowe, MD, AGAF President-Elect David A. Lieberman. MD, AGAF Vice President Hashem B. El-Serag, MD, MPH, AGAF

Secretary/Treasurer Francis M. Giardiello, MD, AGAF

#### Frontline Medical News Staff

Editor Lora T. McGlade Senior Designer Dolly Johnson Production Manager

Rebecca Slebodnik

VP/Group Publisher: Director, FMC Society Partners Mark Branca

> CEO, Frontline Medical Communications Alan J. Imhoff

Copyright © 2017 Frontline Medical Communications Inc.

All rights reserved. No part of this publication may be reproduced or transmitted in any form, by any means, without prior written permission of the Publisher. Frontline Medical Communications Inc. will not assume responsibility for damages, loss, or claims of any kind arising from or related to the information contained in this publication, including any claims related to the products, drugs, or services mentioned herein.

#### **ON THE COVER**

Dr. Douglas K. Pleskow

Photo by Moamen Gabr, MD



## IN THIS ISSUE

**O8 FEATURE STORY** Recent Advances in Cholangiopancreatoscopy



**13 LEGAL ISSUES** Legal Issues for the Gastroenterologist: Part II

**15** Advocacy Advocacy in Action: Meeting Congressman Gene Green



**17 SOCIAL MEDIA** Understanding Social Media in GI Practice: Influence, Learn, Prosper

### DDSEPeight Digestive Diseases Self-Education Program

## QUESTIONS // Answers on page 19

Q1: Which of the following factors reduces perception of acid reflux events in a patient with gastroesophageal reflux disease?

- A. Younger age
- B. Sleep deprivation
- C. Acute auditory stress
- D. Death of a spouse
- E. Esophageal intestinal metaplasia

Q2: A 68-year-old woman with alcoholic chronic pancreatitis has constant, disabling pain. She has previously tried gabapentin, celecoxib, and antioxidants with partial improvement. She currently takes nonenteric coated pancrealipase (90,000 IU per meal) and controlled-release oxycontin. CT of the abdomen demonstrates a few small punctate calcifications in the head of the pancreas, a 1-cm calculus in the genu with a markedly dilated pancreatic duct in the body and tail, and moderate distal atrophy. There are no pseudocysts. She discusses further options to treat her pain.

Which intervention will most likely improve her pain and quality of life over the next 5 years?

A. Continued medical therapy and increased dose of pancreatic enzymes

- B. Lateral pancreaticojejunostomy (Peustow procedure)
- C. ERCP with lithotripsy and stent placement
- D. EUS-guided celiac plexus block
- E. Total pancreatectomy with islet autotransplantation

For more information about DDSEP<sup>®</sup> visit gastro.org/ddsep

### News from the AGA

#### **Advice on Achieving Work-Life Balance**

Successfully maintaining a balance between your personal and professional lives is a difficult concept to grasp and practice to enforce. Is this thing called "work-life balance" within reach or just some elusive circumstance people talk about? The AGA Community Early Career Group was the hub for discussions on ways early-career gastroenterologists can modify their day-to-day approach to help prevent burnout.

We consolidated the advice and tips shared into a series of articles and resources to help students, trainees, and early career members get a little closer to balancing their work and professional lives. Here are some highlights:

#### **Choose work-life "integration"**

If your career and your personal life were a successful relationship, remember that it's not always 50/50, and be sure to allow forgiveness and reparation when needed.

#### **Maternity leave**

When it comes to starting a family, think about your current training or career climate and how you can make it work. Be transparent with your supervisor so there aren't any surprises, and plans can be made in advance to cover for your time away. Prepare to be flexible from the beginning.

#### Learn when to say "no"

Saying "yes" to too many things not only leads to overextending yourself beyond your capabilities, but you could also be losing time on what is important to you. Choose one night a week when you can work late – pack a snack, and give yourself a hard stop the rest of the week. Keep patient documentation as a daytime/work task.

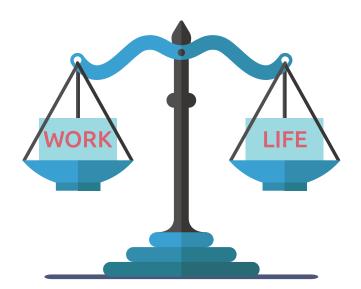
#### Communication is key

When your partner or spouse is just as busy, it's important to keep a joint calendar up to date and make plans far in advance. Also, create a routine: Try making time once a month to discuss calendars and anticipated events, face-toface. When life throws a divot in your path, don't lose sight of your priorities.

#### Make time for family and friends

Your career can take over as much of your life as you will allow. Making time for family and friends is rewarding and vacations, staycations, long weekends or even day trips can be great "resets."

View the tip sheet and other work-life balance resources in the AGA Community Early Career Group library at http://community.gastro.org/WorkLife.



#### **New Clinical Guidelines and Practice Updates**

The latest AGA Clinical Practice Guideline, published in *Gastroenterology*, is on the role of therapeutic drug monitoring (TDM) in the management of IBD. It focuses on the application of TDM for biologic therapy, specifically anti-tumor necrosis factor- $\alpha$  (TNF) agents, and for thiopurines, and addresses questions on the risks and benefits of reactive TDM, routine proactive TDM, or no TDM in guiding treatment changes.

View the full guideline, technical review, and patient guide

at www.gastro.org/guidelines.

In addition to guidelines, please check out the most recent Clinical Practice Updates (CPU) in *Gastroenterology* and *Clinical Gastroenterology and Hepatology* (*CGH*), which are often accompanied by a practice quiz from one of the authors, via the AGA Community. Visit http://community. gastro.org/guidelinecpu to test your knowledge. The most recent CPU, published in the September issue of *CGH*, focuses on GI side effects related to opioid medications.

#### Be Part of the Meeting to Transform IBD

If you treat patients with inflammatory bowel disease, conduct IBD research, or plan to pursue a career in IBD, join us for the inaugural Crohn's & Colitis Congress<sup>™</sup>, taking place Jan. 18-20, 2018, in Las Vegas, NV. The Crohn's & Colitis Foundation (formerly CCFA) and AGA have joined together to develop a must-attend program for the entire IBD care team. Expand your knowledge, network with your peers as well as IBD leaders across multiple disciplines, and get inspired to improve care for patients with Crohn's disease and ulcerative colitis.

You may also be interested in the free precongress workshop – The Lloyd Mayer, MD, Young IBD Investigators Clinical, Basic, and Translational Research Workshop. This half-day precongress workshop is targeted to early-career clinical, basic, and translational researchers as well as senior researchers and will feature a mix of research presentations by young investigator colleagues, keynote presentations, and panel discussion, featuring established IBD researchers. The theme this year is focused around grant proposals and will include two mock grant review sessions.

Learn more about the Crohn's & Colitis Congress and register: http://crohnscolitiscongress.org.

### AGA Outlook

For more information about upcoming events and award deadlines, please visit http://www.gastro.org/education and http://www.gastro.org/research-funding.

#### **Upcoming Events**

#### Nov. 16-17, 2017; Nov. 29-30, 2017; Dec. 13-14, 2017; Jan. 10-11, 2018; Jan. 23-24, 2018;

2-Day, In-Depth Coding and Billing Seminar Become a certified GI coder with a 2-day, in-depth training course provided by McVey Associates, Inc. 11/16-17 (Charlotte, NC); 11/29-30 (New Orleans, LA); 12/13-14 (Dallas, TX); 1/10-11 (Pittsburgh, PA); 1/23-24 (Houston, TX)

#### Nov. 30, 2017; Dec. 14, 2017; Jan. 16, 2018; Jan. 18, 2018; Feb. 22, 2018; Mar. 22, 2018

#### Reimbursement, Coding, and Compliance for Gastroenterology

Improve the efficiency and performance of your practice by staying current. 11/30 (Charleston, WV); 12/14 (Richmond, VA); 1/16 (Phoenix, AZ); 1/18 (Grand Rapids, MI); 2/22 (Edison, NJ); 3/22 (St. Charles, MO)

#### Dec. 1, 2017

Digestive Disease Week® 2018 Abstracts Abstracts may be submitted for consideration to DDW<sup>®</sup> 2018 online beginning on Oct. 19, 2017. The submission site will close on Dec. 1, 2017. The late-breaking submission period runs from Feb. 1 to 15, 2018. Visit ddw.org/abstracts.

#### Dec. 9, 2017; Dec. 19, 2017; Feb. 24, 2018; Apr. 11, 2018

AGA Regional Practice Skills Workshops These workshops are free half-day courses that address the practice skill needs of trainees and early-career GIs. 12/9 (Los Angeles, CA); 12/13 (New York, NY); 2/24 (Columbus, OH); 4/11 (Philadelphia, PA)

#### Jan. 18-20, 2018

Crohn's & Colitis Congress™ (A Partnership of the Crohn's & Colitis Foundation and AGA)

Expand your knowledge, network with IBD leaders and get inspired to improve patient care. Las Vegas, NV

#### Jun. 2-5, 2018

DDW<sup>®</sup> 2018 DDW is the premier meeting for the GI professional. Washington, D.C.

### Awards Application Deadlines

**AGA-Elsevier Pilot Research Award** Application Deadline: Jan. 12, 2018

**AGA-Elsevier Gut Microbiome Pilot Research Award** Application Deadline: Jan. 12, 2018

AGA-Caroline Craig Augustyn & Damian Augustyn Award in Digestive Cancer Application Deadline: Jan. 12, 2018

AGA-Pfizer Young Investigator Pilot Research Award in Inflammatory Bowel Disease Application Deadline: Jan. 12, 2018

AGA-Rome Foundation Functional GI and Motility Disorders Pilot Research Award Application Deadline: Jan. 12, 2018

AGA-Allergan Foundation Pilot Research Award in Irritable Bowel Syndrome Application Deadline: Jan. 12, 2018

AGA-Boston Scientific Technology and Innovation Pilot Award Application Deadline: Jan. 12, 2018

AGA-Allergan Foundation Pilot Research Award in Gastroparesis Application Deadline: Jan. 12, 2018

AGA-GRG Fellow Abstract Award Application Deadline: Feb. 2, 2018

AGA-Moti L. & Kamla Rustgi International Travel Awards Application Deadline: Feb. 2, 2018

AGA Student Abstract Award Application Deadline: Feb. 2, 2018

### An Unusual Cause of Recurrent Severe **Abdominal Colic** Published previously in Gastroenterology (2016:151:819-21)

#### By Kai Deng, PhD, Renwei Hu, MD, and Yan Zhang, PhD

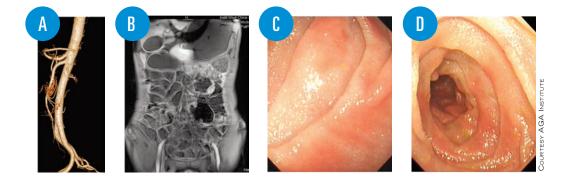
Dr. Deng, Dr. Hu, and Dr. Zhang are in the department of gastroenterology. West China Hospital, Sichuan University, Sichuan Province, China.

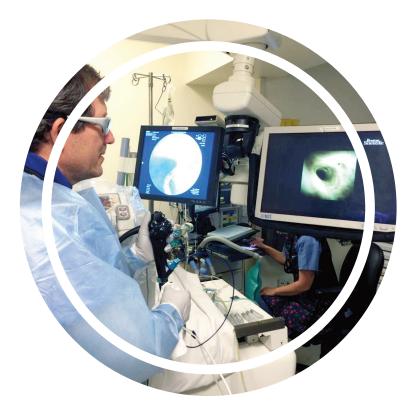
56-year-old man with severe colic, periumbilical pain, and constipation for 18 months was referred to our hospital. He complained of unbearable pain that occurred on and off every 2-3 months. He did not have fever or hematochezia. Four weeks before he came to our hospital, he went to another local hospital, where gastroscopy and colonoscopy were performed and nothing abnormal was observed. However, the patient also had abdominal computed tomography angiography (CTA) and right ileocolic artery stenosis was highly suspected. Then, the patient received treatment for ischemic bowel disease and no improvement in his symptoms was reported. On admission to our hospital, the patient's vital signs were normal. He had brown stains on his teeth. The chest examinations were normal. The abdominal examination revealed hypoactive bowel sounds and mild diffuse abdominal tenderness without rebound. Laboratory investigation showed hepatitis B infection (DNA level  $5.78 \times 10^5$  copy/mL, and liver function within normal range), and mild anemia (hemoglobin concentration 103 g/L). The tests for serum iron, folate,

and vitamin  $B_{12}$  levels all showed negative results. The urine and stool tests yielded normal results. Tests for autoimmune diseases showed negative results. Gastroscopy, colonoscopy, and abdominal CTA (Figure A) were repeated and yet again produced normal results. Magnetic resonance enterography showed parts of the small bowel walls thickening in the left upper abdomen (Figure B). Double-balloon endoscopy revealed patchy redness and congestion at two sites between 50 cm (Figure C) and 150 cm (Figure D) from the pylorus. Some time after the patient was admitted, his symptoms deteriorated so much so that he attempted suicide. Question: Which of the following choices is the most likely cause of the patient's abdominal colic?

- A. Ischemic bowel disease
- B. Lead poisoning
- C. Functional abdominal pain syndrome
- D. Abdominal type allergic purpura

#### See the Answer on page 20.





# The Light at the End of the Tunnel: Recent Advances in Cholangiopancreatoscopy

By William Preston Sonnier, MD,\* Meir Mizrahi, MD,\* and Douglas K. Pleskow, MD



Dr. Sonnier is a general gastroenterology fellow, division of gastroenterology, University of South Alabama; Dr. Mizrahi is director of advanced endoscopy, division of gastroenterology, University of South Alabama; Dr. Pleskow, is clinical chief, department of gastroenterology, Beth Israel Deaconess Medical Center, and associate professor of medicine, Harvard Medical School, Boston. Dr. Sonnier and Dr. Mizrahi have no conflicts of interest. Dr. Pleskow serves as a consultant to Boston Scientific. \*The first two authors contributed equally to this paper

#### Introduction

Direct visualization of the biliary ductal system is quickly gaining importance among gastroenterologists. Since the inception of cholangioscopy in the 1970s, the technology has progressed, allowing for ease of use, better visualization, and a growing number of indications. Conventional endoscopic retrograde cholangiopancreatography (ERCP) is successful for removal of bile duct stones (with success rates over 90%);<sup>1</sup> however, its use in the evaluation of potential biliary neoplasia has been somewhat disappointing. The diagnostic yield of ERCP-guided biliary brushings can range from 30% to 40%.<sup>2-4</sup> An alternative to ERCP-guided biliary brushings for biliary strictures is endoscopic ultrasound (EUS)-directed fine needle aspiration (FNA), but the reported sensitivity remains poor, ranging from 43% to 77% with negative predictive values of less than 30%.<sup>5-7</sup> These results leave much to be desired for diagnostic yield.

The newest method of evaluating pancreaticobiliary pathology is with direct visualization using cholangioscopy. The advantages of this modality include the ability to obtain direct visualization as well as targeted biopsies of suspicious lesions. The first fiberoptic cholangioscope was introduced in 1965 and the first use of peroral cholangioscopy was reported in the mid 1970s.<sup>8,9</sup> Early models were limited by their delicacy, relative immmobility, lack of dedicated irrigation channel, and need for two endoscopists using a "mother baby" design. Fiberoptic single-operator cholangiopancreatoscopy (FSOCP) was first introduced in 2006 by Boston Scientific (Marlborough, MA).<sup>10</sup> It was designed to address the previously stated shortcomings of the first-generation cholangioscopy devices. Since its introduction, it has gained worldwide popularity in the diagnosis and management of pancreaticobiliary pathology and complex biliary stones.

The initial model employed a reusable fiber optic optical probe, a disposable

cholangioscope access and delivery catheter, and disposable small-caliber biopsy forceps. The components can be introduced through a duodenoscope that has a minimum working channel diameter of 3.4 mm. The original FSOCP catheter is attached to the duodenoscope by a silastic belt just below the operating channel, allowing for single operator use. The access and delivery catheter has an outer diameter of 10 F and three separate ports: an optical port, two dedicated 0.6-mm irrigation channels, and a 1.2-mm accessory channel that accepts various accessories including the small-caliber biopsy forceps, electrohydraulic lithotripsy (EHL) fibers, or a holmium laser probe. The catheter has fourway tip deflection. The fiberoptic probe does have limitations, including its limited field of view, fragility of the fiber, and need for adjustment of the lens focus.

Because of these limitations, a digital single-operator cholangioscope (DSOCP) was developed and introduced in 2014 (Boston Scientific, Marlborough, MA). In the DSOCP system, the light is generated by two independent light-emitting diodes and a complementary metal-oxide semiconductor digital camera chip. Improvements included a wider 120-degree field of view, dedicated irrigation and aspiration channels/connections, suction channel, and redesigned accessory channel. The cholangioscope is entirely disposable. The processor receives video signals from the catheter, processes the signals and outputs video images to an attached monitor. The newer digital-based platform has shown promising results, including higher diagnostic yield and shorter ERCP completion time when compared with similarly performed procedures using the fiberoptic-based platform.<sup>11</sup>

#### **Clinical indications**

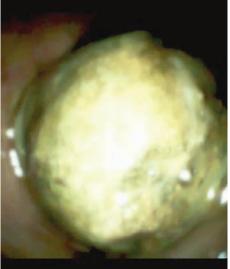
Direct visualization and biopsy of indeterminate biliary strictures has resulted in greatly improved diagnostic accuracy and collection of adequate



Figure 1. Intraductal lesion is shown in direct visualization; intraductal endoscopic ultrasound confirmed the presence of varices.



Figure 2. Intraductal lesion is shown after stone clearance by EHL.

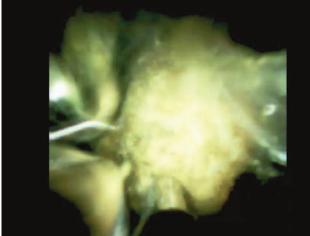


SCIENT

Figure 3. Large intraductal stone appears on DSOCP.



Figure 4: Demonstration of EHL probe. The setting as noted should be 100 watts and 20 shots per cycle.



PHOTOS COURTESY BOSTON SCIENTIFIC

Figure 5: Intraductal EHL: The EHL probe is located near the stone and the lithotripsy is performed. The bilary duct needs to be immersed with water to increase electric wave delivery and to protect the duct wall from injury.

tissue (Figures 1,2). In a recent systematic review, the pooled sensitivity and specificity of cholangioscopy-guided biopsies in the diagnosis of malignant biliary strictures was 61% (95% confidence interval, 55%-65%) and 98% (95% CI, 96%-99%), respectively. Direct comparison of small-caliber direct biopsies with standard brushings and biopsies showed small-caliber direct biopsies having a sensitivity of 76.5% versus 5.8% and 29% with standard brushes and biopsies, respectively.<sup>12</sup> The pooled sensitivity and specificity

cholangioscopy with targeted biopsies in the diagnosis of cholangiocarcinoma was 66.2% and 97.0%, respectively.12 Studies have shown that small-caliber forceps obtain tissue adequate for pathologic evaluation in 82%-97% of biopsy samples retrieved.13-17 Three prospective trials have evaluated the diagnostic accuracy of small-caliber forceps for indeterminate biliary lesions. The accuracy ranged from 72% to 85% with a sensitivity of 49%-82%, specificity of 82%-100%, positive predictive value of 100%, and negative predictive value of 69%-100%.15-17 The improved diagnostic accuracy of cholangioscopy for indeterminate biliary strictures stems from its direct visualization ability. Traditional sampling techniques (cytology brushings and fluoroscopically guided biopsies) are plagued by low sensitivity and

of six studies using

negative predictive value caused by a relatively high false-positive rate.

DSOCP appears to have improved accuracy over fiberoptic equipment. In a recent multicenter observational study in patients undergoing digital cholangioscopy, the guided biopsies resulted in adequate tissue for histologic evaluation in 98% of patients. In addition, the sensitivity and specificity of digital cholangioscope-guided biopsies for diagnosis of malignancy was 85% and 100%, respectively.<sup>11</sup>

Conventional ERCP is successful in

most cases of biliary stone extraction but, in 5%-10% of cases, stones can be difficult to remove because of size, location above strictures, or adherence to the bile duct wall<sup>18</sup> (Figure 3). In addition, lithotripsy with standard fluoroscopic guidance can cause stone fragments to get lost. In one study, 29% of ERCP-lost gallstones were diagnosed by post-hoc cholangioscopy.19 A number of studies have documented a high success rate of FSOCP- or DSOCP-guided lithotripsy, ranging from 90% to 100%<sup>13,14,16,20,21</sup>. In addition, cholangioscopy can circumvent the need for mechanical lithotripsy. EHL is used for the majority of cases, but use of a holium laser has also been described.<sup>20,21</sup> The dedicated irrigation channels on the FSOCP/DSOCP system give the ability to continuously fill the biliary system with fluid, which is required for EHL (Figures 4,5).

Diagnostic pancreatoscopy has advantages in the diagnosis and future management of malignancies and intraductal papillary mucinous neoplasms (IPMNs). In addition, pancreatic duct stones can easily be managed with digital pancreatoscopy and lithotripsy (EHL or laser lithotripsy). A study that included 115 patients that were followed for at least 2 years showed that pancreatoscopy was able to diagnose 63% of pancreatic cancers, 80% of benign strictures, and 95% of intraductal papillary mucinous neoplasms based on visual appearances. The authors were able to discern neoplasia based on visual findings, including coarse or granular mucosa, protrusion, papillary tumor, and tumor vessel.<sup>22</sup> In a similar study, patients with confirmed intraductal papilliary mucinous neoplasms (IPMN) underwent peroral pancreatoscopy and/or intraductal ultrasound preoperatively. The detected protruding lesions were classified into five groups: granular mucosa, fish-egg with or without vascular images, villous type, and vegetative type. The diagnostic accuracy of peroral pancreatoscopy in differentiating benign IPMN from malignant ones was 88% with a sensitivity and specificity of 100% and 71% in the main duct type, respectively, and sensitivities and specificities of 43% and 100% of branch type, respectively.<sup>23</sup>

DSOCP also has therapeutic implications for other pancreatic diseases. Pancreatic duct obstruction can be caused by stones and strictures. A large multicenter study of 1,000 patients with chronic pancreatitis revealed obstruction of the main pancreatic duct (MPD) in 50%; with 32% being caused by strictures and stones, while 18% were due solely to stones.<sup>24</sup> Currently accepted treatments for pancreaticolithiasis include extracorporeal shock wave lithotripsy, ERCP with stone clearance, and stenting or surgery (pancreaticojejunostomy) but these techniques have limitations and can incur morbidity.

DSOCP has recently been evaluated as an alternative technique in treating MPD stones. In a recent study, Bekkali et al reviewed their 3-year experience of digital pancreatoscopy and EHL for pancreatic duct stones. Of the pancreatoscopy procedures performed, 7% were for pancreatic stones. All the patients had painful chronic pancreatitis, radiographic evidence of a dilated pancreatic duct, and MPD stone disease. Stone fragmentation and pancreatic duct decompression were achieved in 83% without complications. Two patients required two EHL procedures to achieve clearance. In the single patient with failed clearance, pancreatoscopy revealed the stone to be in adjacent parenchyma and not in the pancreatic duct. All patients with successful pancreatoscopy and EHL had pain relief and marked improvement during follow up.<sup>25</sup>

Other less common diagnostic indications for DSOCP include evaluation of cystic lesions of the biliary tract, verifying clearance of bile duct stones, bile duct ischemia evaluation after liver transplantation, hemobilia evaluation, removal of a bile duct foreign body, and evaluation of bile duct involvement in the presence of an ampullary adenoma.<sup>3,14,15,20,26,27</sup>

#### **Risks and complications**

In general, complications from cholangioscopy systems are similar to traditional ERCP. These complications can range from relatively mild to potentially life-threatening sequelae including: cholangitis, bacteremia, abdominal pain, pancreatitis, hypotension, nausea, liver abscesses, radiculopathy, bile duct drilling (from the guide-wire), clinically insignificant amylase and lipase elevation, and systemic inflammatory response syndrome.24 A large retrospective study evaluated whether ERCP with cholangiopancreatoscopy was associated with higher rates of complication than ERCP alone. A total of 4,214 ERCPs were included, of which 402 ERCPs with cholangiopancreatoscopy were analyzed. Adverse event rates for the ERCP alone group and ERCP with cholangiopancreatoscopy were 2.9% and 7.0%, respectively, with an odds ratio of 2.5. This study revealed a significantly higher rate of cholangitis, which the authors proposed was due to the saline irrigation needed for visualization during the procedure.<sup>28</sup> Duodenal perforation appears to be rare and was treated conservatively.14,29

#### Conclusions

Direct visualization of the biliary and pancreatic ductal system with fiber-optic and now digital-based platforms have greatly expanded the diagnostic and therapeutic capabilities available to gastroenterologists in the diagnosis and management of biliary and pancreatic disorders. The digital single-operator cholangiopancreatascope system offers greater diagnostic yield of pancreaticobiliary disorders over conventional diagnostic sampling techniques. In addition, direct visualization has expanded our therapeutic ability in complex stone disease allowing laser-based therapies that are not available with traditional fluoroscopic based techniques. Cholangiopancreatoscopic techniques and indications are rapidly expanding and will continue to expand the diagnostic and therapeutic armamentarium available to gastroenterologists.

#### References

1. Cohen S., et al. Gastrointest Endosc. 2002;56:803–9

2. Lee J.G., et al. Am J Gastroenterol. 1995;90:722-6.

3. De Bellis M., et al. Gastrointest Endosc. 2003;58:176-82

4. Fritcher E.G., et al. Gastroenterology. 2009;136:2180-6.

5. Rosch T., et al. Gastrointest Endosc. 2004;60:390-6.

6. Byrne M.F., et al. Endoscopy. 2004;36:715-9.

7. DeWitt J., et al. Gastrointest Endosc. 2006;64:325-33.

8. Rosch W., Endoscopy. 1976;8:172-5.

9. Takekoshi T., Takagi K. Gastrointest Endosc. 1975;17:678-83.

10. Chen Y.K. Gastrointest Endosc 2007;65:303-11.

11. Navaneethan U., et al. Gastrointest Endosc 2016;84:649-55.

12. Navaneethan U., et al. Gastrointest Endosc 2015;82: 608-14.

13. Chen Y.K., Pleskow DK. Gastrointest Endosc. 2007;65:832-41.

14. Draganov P.V., et al. Gastrointest Endosc. 2011;73:971-9.

15. Ramchandani M., et al. Gastrointest Endosc. 2011;74:511-9.

16. Chen Y.K., et al. Gastrointest Endosc. 2011;74:805-14.

17. Draganov P.V., et al. Gastrointest Endosc. 2012;75:347-53.

18. Classen M., et al. Endoscopy 1988;20:21-6.

19. Parsi M.A., et al. Gastrointest Endosc 2008;67:AB102.

20. Fishman D.S., et al. World J Gastroenterol. 2009;15:1353-8.

21. Maydeo A., et al. Gastrointest Endosc. 2011;74:1308-14.

22. Yamao K., et al. Gastrointest Endosc 2003;57:205-9.

23. Hara T., et al. Gastroenterology 2002;122:34-43.

24. Rösch T., et al. Endoscopy. 2002;34:765-71.

25. Bekkali N.L., et al. Pancreas. 2017;46:528-30.

26. Adwan H., et al. Dig Endosc. 2011;23:199-200.

27. Ransibrahmanakul K., et al. Clin Gastroenterol Hepatol. 2010;8:e9.

28. Pereira P., et al. J Gastrointestin Liver Dis, June 2017;Vol. 26(No 2):165-70.

29. Kawakubo K., et al. Endoscopy 2011;43:E241-2.

### **2017 AGA POSTGRADUATE COURSE THE FULL SCOPE OF GI ADVANCES RESOURCES** A PROGRAM OF THE AGA INSTITUTE

### **Experience the Live Course From Home**

Take advantage of early bird savings by ordering the resources today and stepping onto a pathway for optimal care that will guide your clinical decisions all year long.

#### **Online Sessions**

Watch sessions with over 30 hours of educational content and earn CME and MOC.

#### USB

No internet necessary. This product features full-color presentation slides and complete audio.

#### **Combo Package**

Save up to \$65 off of the regular combined price by ordering the USB/online sessions combo package.

#### eSyllabus

Download this comprehensive outline of course content to your smart phone, tablet or computer.



Order your resources today at www.gastro.org/PGCR.

### Legal Issues for the Gastroenterologist: Part II

By Peter J. Hoffman, Esquire (Member and Chair of the Professional Liability Group), Andrew J. Bond, Esquire (Associate), Andrew F. Albero, Esquire (Associate), Alexandra Rogin, Esquire (Associate), Brittany C. Wakim, Esquire (Associate), Eckert Seamans Cherin & Mellott, LLC, Philadelphia.



n the previous issue of *The New Gastroenterologist*, we discussed statistics and the basis on which most gastroenterologists are sued as well as what you can do to minimize this risk. In this second article, we discuss steps to assist in your defense in the event you have been sued. The following suggestions are based on our experience as defense attorneys who practice in the arena of medical malpractice.

If you have been sued, it is imperative that you notify your insurer immediately, as this may be required under your policy for coverage. It is also best practice to notify the carrier and/or the hospital (if it occurred at the hospital) of any incident or serious event, bad outcome, or letters from lawyers representing the patients. This allows for early investigation and, in some cases, intervention.

Do not, under any circumstances, add or alter the plaintiff's medical records. Although you have continued access to electronic medical records, accessing or altering these documents leaves an electronic trail. Attorneys are now frequently requesting an "audit trail" during discovery, which shows who and when someone accessed or altered relevant medical records. Additionally, it is likely that the plaintiff's counsel has already obtained and reviewed records for their client. As such, counsel will notice any alterations and will require an explanation as to the same. If you did alter any medical records, it is important that you notify your attorney about the specifics of such.

You should not discuss anything about the case with anyone other than your spouse and attorney. This will prevent plaintiff's counsel from deposing additional witnesses and limit the amount of people potentially forced to testify.

After you have secured an attorney, it is critical that you arrange a meeting to develop a positive relationship early in the litigation process. This is important for many reasons. A medical malpractice case can be a long and arduous process which requires that you be involved with your attorney during the course of the litigation. For the attorney-client relationship to be successful, it is imperative that you know and feel comfortable with your attorney and develop confidence and trust in her. Without this trust, it will be difficult for you to accept various decisions or suggestions that the attorney believes are in your best interest. Conversely, the attorney should get to know you and understand your background, as this will assist in your representation.

A good relationship with you will also aid your attorney in educating herself on medical concepts relating to your case. Remember, your attorney most likely has not attended medical school and many of the medical concepts will initially be new to her. By the time trial arrives, however, your attorney will be very familiar with the medical issues in your case. This learning process can be expedited with your assistance and research.

Finally, be sure to respond fully and honestly to questions from your attorney, regardless of whether you view it as harmful, irrelevant, or unimportant. Anything you tell your attorney is confidential and protected by privilege. Your attorney is your ally. It is her job to help you. Thus, it is essential that you respond fully and honestly to all questions posed by your attorney and disclose all possibly relevant information.

#### Your deposition

At some point during the lawsuit,

the plaintiff's attorney will take your deposition. The plaintiff's attorney will strive to obtain concessions that establish the standard of care, breach of the standard, causation, and damages.

Your deposition is not the time for you to provide explanations. It is the time for you to concisely answer specific questions posed by counsel without volunteering any additional information. Ultimately, trials build on what occurs during depositions.

Preparation is key. Be open to advice or criticisms from your lawyer. Try to eliminate any quirks or habits that interfere with the substance of your testimony or perceived credibility.

A deposition is not a casual conversation; nor is it a test of your memory. Limit your answers to personal knowledge; never guess or speculate.

If you do not know the answer to a question, or do not remember something, it is perfectly acceptable for you to say so. Answer only questions that you understand. You are allowed to ask the plaintiff's counsel to repeat or rephrase questions.

Once you have answered a question, stick to your answer if it is accurate. It is fine to change an answer, but do not change it simply because the plaintiff's counsel is pushing you to do so.

Aggressive interrogation by opposing counsel may occur. Never argue or quibble with the plaintiff's lawyer; leave all arguing to your lawyer. A witness who is calm, courteous, and confident is more likely to appear credible. The plaintiff's attorney may request that your deposition be videotaped. If this is the case, be mindful of your mannerisms, tone of voice, and appearance. The videotape may end up being played in front of a jury.

Finally, and most importantly, always tell the truth. Discuss any anticipated issues or concerns with your lawyer before your deposition.

#### Preparing for trial

A trial can last anywhere from 1 to 3 weeks. Your daily presence (including at the jury selection before the trial begins) is mandatory and in your own best interest. Your lawyer will have little control over the date on which the trial will occur. That date will be set by a judge, who will not be sympathetic to your scheduling problems. Be prepared to cancel patients' appointments and any procedures already scheduled. The jury's perception of you can be influenced by your presence and demonstrated dedication to your defense.

#### Conclusion

In summary, remember that there are things you can do both before and after you are sued to minimize litigation and its impact. As mentioned previously, before a lawsuit, and as a regular part of your practice, it is important that you stay current with medical advances, that you take the time to create a relationship with your patients involving quality communication, and that you thoroughly and legibly document all aspects of care provided.

After a suit is filed against you, make sure you notify your insurer immediately, do not alter any records or discuss the case with anyone other than your lawyer or spouse, and do all you can to create a productive and honest relationship with your lawyer. This relationship will be invaluable as you do the difficult and time-consuming work of preparing for your deposition and trial, and it can help you endure and successfully navigate the litigation process.

### The Importance of Follow-Up: Further Advice on How to Decrease the Risk of Being Sued

common basis for establishing a malpractice liability claim against a physician is the failure to follow up or track a patient's test results. In today's world, there is an increasing number of moving parts involved in any given patient's care. A particular patient may be treated by numerous physicians, all of whom use different record systems. Electronic medical record systems have made records more accessible and easier to track, but they also present a new set of challenges.

Every physician needs to determine how they plan to track test results. The ideal system would allow a physician to quickly get back any lab or diagnostic test that he or she orders. All staff members should know how the physician's system works. Otherwise, test results might accidentally be filed before the physician reviews them or a miscommunication could prevent test results from being delivered. Whatever choice of system, it is key to follow and effectively use the program every time.

Additionally, it can be beneficial to let the patient know when he or she can expect to hear about their results, as failure to keep the patient reasonably informed can create a new set of patient concerns and anxiety. Ultimately, establishing a well-defined system for record tracking can help physicians avoid malpractice liability claims because of a failure to follow up.

### Advocacy in Action: Meeting Congressman Gene Green

By Yamini Natarajan, MD, Richa Shukla, MD, and Jordan Shapiro, MD



Dr. Natarajan is assistant professor, Dr. Shukla is assistant professor, and Dr. Shapiro is a second-year fellow; all are in the section of gastroenterology and hepatology, Baylor College of Medicine, Houston.

he hospital is often the intersection between a patient's medical illness and their social and financial issues. As physicians, it is important to recognize that patient care encompasses not only prescribing medications and performing procedures but also practicing systems-based medicine: ensuring social and financial barriers do not impede access to, and delivery of, care. Some of these barriers cannot be eliminated by one individual practitioner; they can only be improved by working with government representatives and policy makers to make systemic changes. For gastroenterologists, advocacy involves educating patients, practitioners, and our government representatives about issues related to GI illnesses and the importance of ensuring access to GI specialty care and treatment for all patients who require it.

AGA, via the Government Affairs Department, facilitates advocacy by providing policy briefs and position statements to facilitate informed discussions with government representatives. The AGA Young Delegates program has recently taken this one step further and arranged for GI fellows and young faculty to meet members of Congress in their districts to discuss important policy matters. On Aug. 22, 2017, we had the opportunity to host Congressman Gene Green (D-Tex., District 29) at Baylor College of Medicine, Houston, Congressman Green serves on the Committee on Energy and Commerce and is the Ranking Member for its Subcommittee on Health: he also serves on several other subcommittees including Energy and Power, Environment and Economy, and Oversight and Investigations. During our visit, we discussed topics, including protecting National Institutes of Health funding, increasing access to specialty care, and needing coverage for preventive services like cancer screening and colonoscopy reimbursement.

Academic institutions share the aim of conducting high-quality research to further advances in medicine. These research projects are often funded through NIH grant programs. Unfortunately, these programs

are often the target of budget cuts, which can affect not only primary research but also downstream economic growth. An analysis by United for Medical Research found that, for every \$1 spent in NIH grants, \$2 of economic output is generated.<sup>1</sup> In 2016, these programs led to 379,000 jobs and \$64 billion in economic activity nationally. AGA calls for increased NIH funding to maintain pace with inflation.<sup>2</sup> We discussed how projects funded by the NIH have led to important advances in gastroenterology at our own institution. For example, NIH-funded research by Hashem B. El-Serag, MD, MPH, and Fasiha Kanwal, MD, MSHS, has produced studies to evaluate biomarkers and improving screening techniques in hepatocellular carcinoma.<sup>3,4</sup>

Health care cost sharing and delivery have been a focus of the current session of Congress. Attempts have been made to repeal the Affordable Care Act; and while none have passed so far, this will continue to be a contentious topic of debate. AGA advocates that any future health care bills ensure patient access and coverage



From the left are Dr. Jordan Shapiro, Congressman Gene Green, Dr. Richa Shukla, and Dr. Yamini Natarajan.

of specialty care, ensure coverage/ access to evidence-based preventive screening tests, maintaining of current laws that prohibit discrimination based on pre-existing conditions and sex, and maintaining a ban on lifetime caps. With Congressman Green, we discussed the burden of digestive disease nationally and the need to maintain access and coverage for our patients. We shared the difficulties some of our patients face with access to preventive care services and the differences across the three pavilions we serve (private tertiary care center, county hospital, and VA hospital). Congressman Green, an important advocate for colorectal cancer prevention, discussed his personal experiences with affected friends and family and expressed commitment to the importance of making health care, especially cancer-screening, accessible and available to all.

Notably, Congressman Green has also sponsored the Removing Barriers for Colorectal Cancer Screening Act. After the passage of the ACA, deductibles and coinsurance fees are waived for colon cancer screening tests. However, once a polyp is removed on a screening colonoscopy, the procedure becomes

reclassified as a therapeutic procedure, meaning the patient will have to pay coinsurance.<sup>5</sup> Coinsurance costs can be 20%-25% of the Medicare-approved amount. In essence, a patient may go into a procedure with the expectation that it is free, only to find out that they will receive a significant bill because polyps were removed. It puts the gastroenterologist in a difficult position, knowing that removal of polyps would increase cost to the patient, however, waiting for a repeat procedure would be redundant and lead to possible loss of follow-up. The Removing Barriers to Colorectal Cancer Screening Act would correct this by waiving the coinsurance for a screening colonoscopy even if polyps were removed.

As physicians, we are uniquely positioned to represent the needs of our patients. We appreciate the AGA facilitating that voice by providing updates on legislation and coordinating meetings between senators and members of Congress and practicing gastroenterologists and GI fellows. These meetings are an important opportunity to network and share our experiences. Congressman Green was very interested to hear our perspectives as health care providers. It was enlightening to hear about his experiences on the Health Subcommittee and learn about its procedures. We would strongly encourage other AGA members to take advantage of this important program.

#### References

1. Ehrlich E. (2017). NIH'S Role in Sustaining the U.S. Economy. United for Medical Research. Accessed at http://www.unitedformedicalresearch. com/wp-content/uploads/2017/03/NIH-Role-in-the-Economy-FY2016.

2. AGA Position Statement on Research Funding. Accessed at http://www.gastro.org/take-action/ top-issues/research-funding.

3. El-Serag H.B., Kanwal F., Davila J.A., Kramer J., Richardson P. A new laboratory-based algorithm to predict development of hepatocellular carcinoma in patients with hepatitis C and cirrhosis. Gastroenterology. 2014;May146(5):1249-55.

4. White D.L., Richardson P., Tayoub N., Davila J.A., Kanwal F., El-Serag H.B. The updated model: An adjusted serum alpha-fetoprotein-based algorithm for hepatocellular carcinoma detection with hepatitis C virus-related cirrhosis. Gastroenterology. 2015;Dec 149(7):1986-7.

5. AGA Position Statement on Patient Cost-Sharing for Screening Colonoscopy. Accessed a: http:// www.gastro.org/take-action/top-issues/patient-cost-sharing-for-screening-colonoscopy.

### Understanding Social Media in GI Practice: Influence, Learn, and Prosper

By Deborah A. Fisher, MD, MHS, and Darrell M. Gray II, MD, MPH



Dr. Fisher is associate professor in the department of medicine, division of gastroenterology, Duke University, Durham, N.C., VA Medical Center. Twitter: @DrDeborahFisher, Dr. Gray is assistant professor, department of medicine, division of gastroenterology, hepatology and nutrition, Ohio State University College of Medicine. Twitter: @DMGrayMD.

This information was presented at a Meet-the-Professor Luncheon at DDW® 2017. More for in-depth details than are described in this article, refer to this session on DDW on Demand (http://www.ddw.org/education/session-recordings).

one are the days when social media was primarily used by millennials and those early adopters on the diffusion-of-innovation curve. Now, baby boomers and laggards alike are using social media to communicate with the world around them. Furthermore, health and health care issues are common topics in the social media universe.

Eight in 10 Internet users seek health information online and 74% of these health information seekers use social media.<sup>1,2</sup> Additionally, when they look online, they are more likely to trust information from doctors (61%) than from hospitals (55%), insurers (42%), or pharmaceutical companies (37%).<sup>3</sup> Therefore, there is tremendous opportunity for physicians to engage patients, policy makers, advocacy groups, and other health care influencers in order to share reliable information. Yet, we must do so responsibly. There is a considerable degree of misinformation circulated in social media, and we believe that physicians should help combat this by providing accurate information.

In addition, as physicians, we are in a special position to advocate for our patients and our profession. By doing this via social media, we can extend our reach beyond our clinics, endoscopy suites, and research labs and do so much faster than other methods. For example, it is estimated that it would take 38 years for radio to reach 50 million users, 13 years for television to reach 50 million users, but only 1.5 years for Facebook to reach 50 million users.<sup>4</sup>

On a more individual level, social media can help you stay up-to-date on best practices, breakthroughs, and controversies in medicine. It can help you take control of your online reputation rather than letting it be the default Google search results. Social media can also be a vehicle through which you build your offline network of potential colleagues, collaborators, and supporters as well as facilitate speaking, consulting, research, and other professional opportunities.

We hope that we have convinced you to actively participate in social media professionally. Next, we would like to share our top six best practices for responsible use.

**Understand and define your goals.** We have broadly laid out our rationale but that is different from your specific, desired outcomes. If you do not know what you are trying to accomplish, you will have no idea if you are successful or if what you are doing is working versus whether you should try different strategies. Social media does take time; therefore, you should be strategic and goal oriented.

Nuture your social media presence. If you explore social media ▲ ∎and find it is not for you, it is better to disable your accounts than to simply have a trail of ghost accounts. It looks worse to have a neglected account than no account at all. Caring for your account(s) with regular and deliberate posts drives much of this time commitment. However, there are some ways to be more efficient, such as integrating your social media platforms by linking to your website (i.e., your "landing page"), blog, and other accounts. Use the same photo for all of your accounts and websites and be sure to include "Dr" or "MD" in your username. Also, with a platform such as Hootsuite (https://hootsuite. com), you can schedule tweets - allowing you to upload content at your convenience while still reaching your audience at an optimal time - as well as post the same content to multiple platforms.

helps you build your community. Also, people appreciate vetted content in the great web of misinformation available. You can facilitate audience engagement by including graphics, photos, and videos and by engaging and responding to other posts. Importantly, having a disclaimer on your account (e.g., retweets are not endorsements, posts are not medical advice) is never a substitute for knowing/vetting what you are sharing.

Exercise caution when responding to medical quesitions on social media and/ or sharing patient information. While we encourage engagement, you should never answer specific medical questions. This develops a doctor-patient relationship and creates legal "duty." It could even constitute practicing without a license, if the person asking the question lives in another

Social media can also be a vehicle through which you build your offline network of potential colleagues, collaborators, and supporters.

**3** Share reliable/vetted information in your area of expertise and interest. Do not try to be all things to all people. Focus on content that distinguishes you and meets your goals. On the other hand, this should not be all about you; this can be boring, difficult, and give the impression that all you care about is self-promotion. No more than a quarter to a third of the content should be about you, and the rest should be curated content from other reliable sources. Sharing with attribution

state. Instead, provide general information about a condition, especially as a link to a reliable site (www. gastro.org/patient-care/patientinfo-center) and suggest seeking care from their local medical professional. Along these lines, do not share any potentially identifiable patient information without documented permission. In addition to the obvious (e.g., patient name, photos, medical documents with identifiers), avoid stories of care, complications, rare conditions, or identifiable specimens. With an approximate date and the location of your practice, it may be very easy for someone to determine the patient's identity.

Be careful with all of your social media accounts including **U** any "personal" accounts. While the American College of Physicians (ACP) and the Federation of State Medical Boards (FSMB) recommend maintaining separate personal and professional accounts,<sup>5</sup> we believe this gives a false sense of security. Once you upload a post to any social media platform you lose control over what others do with that information (photo, etc). We agree with the FSMB recommendation against friending patients on Facebook,<sup>5</sup> but some platforms, such as Twitter, allow people to follow you without you necessarily following them. In fact, having your patients follow your Twitter account may be a useful way to provide general information about certain conditions (e.g., inflammatory bowel disease) or increase awareness about preventive care (e.g., colorectal cancer screening).

**6** Know and adhere to the social media policies of your practice, institution, organization, or employer. Most academic institutions have social media policies, and they are becoming more widely adapted to other settings. While you may just get a metaphorical slap on the wrist for not following the rules, I think we all would agree that it would be a tragedy to get fired over a social media post.

However, none of the above best practices are a substitute for being intentional and mindful when sharing information on social media, whether it be Facebook, Twitter, Instagram, Youtube, or another platform. What does being intentional and mindful on social media mean? Absolutely avoid commenting/posting about patients, colleagues, or your workplace in any way that could be perceived to be negative. Declare conflicts of interest where applicable (i.e., if you're a consultant for a pharma company, avoid endorsing a drug without declaring your conflict). Above all else, don't post anything that you wouldn't mind being on a billboard or mainstream news.

Participation is an investment of your most valuable resource: time. Therefore, know your goals and revisit these goals and your success in reaching them regularly. Start small and expand as your time and interest allows. Finally, minimize your exposure to risk by keeping our guidance and your institutional policies in mind and always pause before you post.

You can find out more about the AGA, its programs, and publications via our social media outlets, including:

Twitter: @amergastroassn @AGA\_CGH @AGA\_CMGH @AGA\_Gastro

Facebook: @AmerGastroAssn @cghjournal @cmghjournal @gastrojournal

#### References

1 Von Muhlen M., Ohno-Machado L. J Am Med Inform Assoc. 2012;19(5):777-81. 2 Childs L.M., Martin C.Y. Am J Health System Pharm. 2012;69(23):2044-50. 3. Social media "likes" healthcare. From marketing to social business – 2012 Report https://www.pwc.com/us/en/health-industries/ health-research-institute/publications/health-

care-social-media.html.

4. www.martinsights.com/social-media-marketing/social-media-strategy/new-global-social-media-research/.

5. Online Medical Professionalism: Patient and Public Relationships: Policy Statement From the American College of Physicians and the Federation of State Medical Boards. Ann Intern Med. 2013;158(8):620-7.

# Digestive Diseases Self-Education Program Control ANSWERS // From page 3

#### Q1: ANSWER: E

#### RATIONALE

Esophageal sensation perceived by esophageal nociceptors is transmitted through spinal afferent pathways to higher cortical centers, which are susceptible to both peripheral and central sensitization in the predisposed individual. Such sensitization can occur in the setting of stressful situations, such as auditory stress, sleep deprivation, affective disorders, and other life events including grief. Esophageal perception decreases with age. Intestinal metaplasia (Barrett's esophagus) is less perceptive to acid stimulation, and hence is a protective mechanism that develops in patients with a genetic predisposition in the setting of acid exposure. Patients with Barrett's esophagus have a lower sensitivity to chemical,

thermal, as well as mechanical stimulation compared to reflux patients without Barrett's esophagus.

#### References

 Fass R., Naliboff B.D., Fass S.S., et al. The effect of auditory stress on perception of intraesophageal acid in patients with gastroesophageal reflux disease. Gastroenterology. 2008;134(3):696-705.
Schey R., Dickman R., Parthasarathy S., et al.
Sleep deprivation is hyperalgesic in patients with gastroesophageal reflux disease. Gastroenterology. 2007;133(6):1787-95.

3. Byrne P.J., Mulligan E.D., O'Riordan J., et al. Impaired visceral sensitivity to acid reflux in patients with Barrett's esophagus. The role of esophageal motility. Dis Esoph. 2003;16(3):199-203.

#### Q2: ANSWER: B

#### RATIONALE

The patient has a favorable anatomy

for a surgical drainage procedure such as a lateral pancreaticojejunostomy (Peustow procedure). Surgery has been noted to provide superior pain relief over 5 years compared with endoscopy. Hospital costs and length of stay were similar between the groups. Continued medical therapy is unlikely to add further benefit on top of what she has already achieved. Endoscopic ultrasound-guided celiac plexus block will provide only temporary pain relief. There are limited long-term data on the effectiveness of total pancreatectomy with islet autotransplantation in alleviating pain.

#### Reference

1. Cahen D.L., Gouma D.J., Laramée P., et al. Long-term outcomes of endoscopic vs surgical drainage of the pancreatic duct in patients with chronic pancreatitis. Gastroenterology. 2011;141(5):1690-5.







### The Answer // From page 7

he correct answer is B. The lead levels in serum and urine were tested (517 mcg/L, 0-400 mcg/L; 131.7 mcg/L, 0-70.38 mcg/L). A diagnosis of lead poisoning was made. Three days after chelation treatment, his symptoms disappeared and did not recur in the follow-up.

We carefully reviewed the patient's history and found that he had been using jineijin, a traditional Chinese medicine (TCM) drug, which is made with dried endothelium corneum gigeriae galli (Figure E), at about 500 g/month and squama mantis (a TCM drug, at less than 5 g/month) as dietary supplements for 3 years. The level of lead in ground jineijin (Figure F, the drug the patients consumed is mainly processed by mixing ground jineijin and honey; Figure G, the deposit left after the elution of honey in Figure F is ground jineijin) and squama mantis was measured with inductively coupled plasma optical emission spectrometry, which proved to be 3,389 mg/kg, much higher than the maximal limit allowed for drinking water (less than 0.01 mg/kg). It is estimated that the patient's daily lead intake from ground jineijin and squama mantis approximated 50 mg/day (acceptable limit being 100-300 mcg/day)<sup>1</sup> in the past 3 years.

Jineijin has traditionally been used in China to alleviate nausea and vomiting.<sup>2</sup> With the rapid development of industry, heavy metal pollution of water and soil has been a widespread problem.<sup>3</sup> Heavy metal enrichment may appear in poultry exposed to environmental population. Therefore, the lead content of jineijin obtained from poultry with high levels of lead exposure can easily exceed maximum acceptable limits. In this patient, long-term high-dosage consumption of jineijin may have been the source of lead exposure.

#### Acknowledgments

We thank Linshen Xie, MD, department of environmental health and occupational diseases, No. 4 West China Teaching Hospital, Sichuan University, for offering some clinical data. We thank the patient for giving permission to share his information.

#### References

1. National Research Council (US). Safe Drinking Water Committee. Drinking water and health. National Academy Press. Washington, D.C. 1977;1:309.

2. State Administration of Traditional Chinese Medicine. Advanced Textbook on Traditional Chinese Medicine and Pharmacology. New World Press, Beijing. 1995. (vol. 2).

3. Hui Hu, Q.J., Kavan, P. A study of heavy metal pollution in China: Current status, pollution-control policies and countermeasures. Sustainability. 2014;6:5820-38.

This article has an accompanying continuing medical education activity, also eligible for MOC credit, Learning objective: Upon completion of this examination, successful learners will be able to identify the features of lead poisoning.



### Trustworthy Recommendations: A Closer Look Inside the AGA's Clinical Guideline Development Process

By Madelin R. Siedler and Yngve T. Falck-Ytter, MD, AGAF



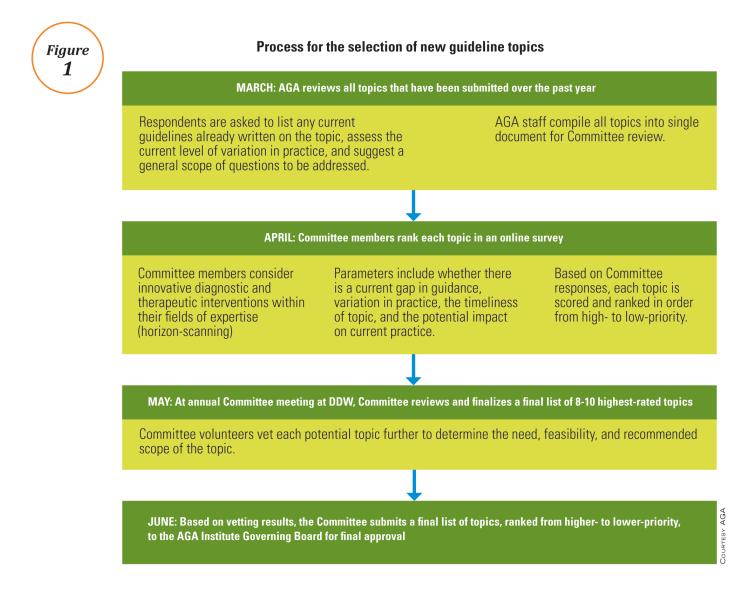
Ms. Siedler is the director of clinical practice at the AGA Institute national office in Bethesda, Md.; Dr. Falck-Ytter is a professor of medicine at Case-Western Reserve University, Cleveland, chair of the AGA Institute Clinical Guidelines Committee, and chief of the division of gastroenterology at the Louis Stokes VA Medical Center in Cleveland. The authors disclose no conflicts of interest.

he AGA understands how important it is for busy physicians to have access to the most trustworthy, actionable, and evidence-based guidelines in order to achieve the highest possible quality of patient care. According to a 2016 survey, AGA members ranked guidelines as the most important of all AGA-specific benefits, giving guidelines an average of 4.61 out of 5 (where 5 was defined as "extremely important"). The AGA's guidelines landing page (www.gastro.org/guidelines) has long been the most frequently accessed page on the AGA website.

It is clear to AGA leaders and staff that guidelines are of great importance to our members and this awareness is reflected in the amount of time and resources spent to develop them. In developing guidelines, our goal is twofold: to maintain a high level of rigor and trustworthiness through the utilization of an evidence-based approach while remaining transparent, open, and responsive to the needs of our members, patients, and the public at large. The purpose of this article is to give the reader an in-depth understanding of the process used by the AGA to develop clinical guidelines, from the conception of topics to their eventual publication (Figure 1).

#### The life cycle of an AGA guideline

In 2010, the AGA Institute officially adopted the GRADE (Grades of Recommendation Assessment, Development, and Evaluation) methodology for the development of all future guidelines. Since the publication of our first GRADE-based guideline in 2013, the AGA has developed and published 12 guidelines with an additional 11 more to be published by 2019. Based on the systematic rigor of the GRADE approach, the AGA's guideline development process was created to result in clinical recommendations that are not only evidence



based but actionable and responsive to varying patient needs and preferences at the point of care.

All told, a single AGA guideline costs around \$45,000 and takes approximately 24 months to complete and publish. Currently, the AGA is working to pilot new methods of shortening the time to publication through the development of rapid reviews within a focused topic (e.g., opioid-induced constipation).<sup>1</sup> The development of each guideline requires a team of one or more specially trained GRADE methodologists, two or more content experts, a medical librarian, a panel of three or more guideline authors, two AGA staff members, and the Clinical Guidelines Committee Chair.

Determining the guideline topics. Each AGA guideline begins as a simple idea submitted through the annual call for topics, which is open to the public. At their annual meeting at Digestive Disease Week<sup>®</sup>, the 15 members of the AGA Institute Clinical Guidelines Committee (CGC) review the entire list of submissions and rank a list of eight or more topics that they believe are the most timely, relevant, and weekly basis to review the search results question-by-question and develop the technical review of evidence that will form the basis of the clinical recommendations. For each PICO, the technical review assesses the entire body of evidence and rates the overall quality of evidence gathered for each outcome related to the PICOs (from "very low" to "low" to "moderate" to "high").

Rating the quality of evidence. Ratings of the quality of evidence for each PICO are based not only on the methodology used in the scientific studies (e.g., whether each study is an observational study or a randomized controlled trial) but additional categories such as publication bias (i.e., whether there is reason to believe there is a disproportionate representation of positive results in the literature) or indirectness (i.e., how directly applicable the study population and interventions are to real-life clinical scenarios). In this way, outcomes informed by randomized controlled trials might be "rated down" to a moderate quality of evidence because of indirectness, whereas a body of evidence from observational

The development of each guideline requires a team of one or more specially trained GRADE methodologists, two or more content experts, a medical librarian, a panel of three or more guideline authors, two AGA staff members, and the Clinical Guidelines Committee Chair.

impactful to the field of gastroenterology. This may include a combination of completely new topics and updates of older, out-of-date guidelines. The AGA Institute Governing Board then determines a final list of four or more topics to immediately begin development.

Determining the focused questions. First, the entire team of physician-authors determines a list of focused questions that the guideline will address. This list of focused questions is translated into a table of Population, Intervention, Comparison, Outcomes (PICOs) that operationalize the general questions into search terms utilized by the medical librarian to run the systematic search as well as define the final scope of the guideline. The focused questions and related PICOs are sent to the Governing Board for review and approval.

*Developing the technical review.* Over the next several months, the methodologist and content experts meet on a

FALL 2017

studies may be "rated up" because of large effect.

Drafting the clinical recommendations. The technical review presents the findings of the literature along with the authors' assessment of the evidence quality. At a face-toface meeting, these results are presented by the technical review authors to the guideline panel, who are responsible for developing the official guideline document. The role of the guideline panel is to understand the quality of evidence and determine an ultimate list of clinical recommendations and assign a strength (strong or conditional) to each recommendation, all while considering important factors such as the balance between benefits and downsides, potential variability in patients' values and preferences, and impact on resource utilization. Oftentimes, but not always, recommendations based on higher-quality evidence for which most patients would request the recommended course of action translate into strong recommendations. Recommendations based on lower-quality evidence and those for which there is a higher variability in patient values or issues surrounding resource utilization are more likely to be conditional.

In addition to the guideline document, the guideline panel also drafts a Clinical Decision Support Tool, which illustrates the clinical recommendations within a visual algorithm. At the same time, AGA staff draft a patient summary that explains the recommendations in plain language. This summary can be used by physicians to improve clinical communication and shared decision making with their patients.<sup>2</sup>

*Revising the guideline.* Each AGA technical review goes through two layers of review: once by an anonymous peer-review panel of three content experts, and again during a 30-day public comment period in which both the technical review and guideline are posted for public input. The authors take all input into consideration while finalizing the documents, which are sent to the Governing Board for final approval. Once approved by the Board, the technical review, guideline, and all related materials are submitted for publication in *Gastroenterology*. In addition to print publication, each guideline is disseminated on the AGA website and through the official Clinical Guidelines mobile app (available via the App Store and Google Play), which includes interactive versions of the Clinical Decision Support Tools and plain-language summaries that can be sent via e-mail to patients at the point of care. The AGA is currently pursuing future directions for the dissemination and implementation of our guidelines, such as the seamless integration of clinical recommendations into electronic health records to further

improve decision making and facilitate quality measurement and improvement.

#### Conclusion

Not all clinical guidelines are created with equal rigor. Clinicians should examine guidelines closely and consider whether or not they follow the Institute of Medicine's standards for trustworthy clinical guidelines: Is the focus on transparency? Is a rigorous conflict of interest system in place that eliminates major sources of financial and intellectual conflict? Was an unconflicted GRADE-trained methodologist involved in ensuring that a systematic review process is followed and the method of rating the quality of evidence and strength of recommendation follows published principles? Are the recommendations clear and actionable?<sup>3</sup> AGA Institute guidelines are developed with the goal of striking a balance between presenting the highest ideals of evidence-based medicine while remaining responsive to the needs of everyday practitioners dealing with real patients in real clinical settings.

#### References

1. Hanson B., Siedler M., Falck-Ytter Y., Sultan S. Introducing the rapid review: How the AGA is working to get trustworthy clinical guidelines to practitioners in less time. AGA Perspectives. 2017; in press.

2. Siedler M., Allen J., Falck-Ytter Y., Weinberg D. AGA clinical practice guidelines: Robust, evidence-based tools for guiding clinical care decisions. Gastroenterology. 2015;149:493-5.

3. Institute of Medicine: Standards for developing trustworthy clinical practice guidelines. Available at http://www.nationalacademies.org/hmd/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust/Standards.aspx. Last accessed May 2017.

### **Snapshots from the AGA Journals**

Endoscopists who took 1 minute longer detected significantly more upper GI neoplasms

August 2017 Gastroenterology (doi: 10.1053/j.gastro.2017.05.009)

**Key clinical point:** Adding about 1 minute to an upper endoscopy might significantly increase the detection of upper gastrointestinal neoplasms.

Major finding: Slow endoscopists (with a mean duration for the procedure of 3 minutes and 25 seconds) had a detection rate of 0.28%, while fast endoscopists (2 minutes and 38 seconds) had a detection rate of 0.20% (*P* = .005). **Data source:** A single-center retrospective study of 111,962 individuals who underwent esophagogastroduodenoscopy in South Korea between 2009 and 2015. **Disclosures:** Funders included the Ministry of Education, Science, and Technology; the Ministry of Science, ICT, and Future Planning; and the Ministry of Health & Welfare, South Korea. The investigators reported having no conflicts of interest.





#### **Commentary**



Prateek Sharma, MD, is a professor of medicine in the division of gastroenterology and hepatology, Veterans Affairs Medical Center, University of Kansas, Kansas City, Mo. He has no conflicts of interest.

creening and surveillance practices remain one of the major indications for performing upper endoscopy in patients to detect esophageal (adenocarcinoma in the West; squamous cell in the East) and gastric cancer (in the East). The goal of the initial endoscopy is to detect precancerous lesions (such as Barrett's esophagus and gastric intestinal metaplasia) and, if detected, to grade them properly and evaluate for the presence of dysplasia and cancer in subsequent surveillance examinations.

The primary aim of the retrospective study by Park et al. was to determine the association between the duration of upper endoscopy and the rate of upper GI neoplasia cases detected during the procedure. Endoscopists spending more than 3 minutes were more likely to diagnose lesions during esophagogastroduodenoscopy than were those who spent less time during the procedure. While the study has limitations, including its retrospective nature, the performance of an adequate number of biopsies, and the type of endoscopes utilized, it does highlight a more important issue - the role of quality endoscopy for the detection of upper GI neoplasia. Besides the time spent during upper endoscopy (like the colonoscopy withdrawal time), other considerations during index endoscopy, to ensure a quality examination, are careful inspection of the mucosa and detection of lesions during endoscopy. A high-quality examination of the esophageal mucosa can lead to an increase in detection of dysplasia and cancer in patients with Barrett's esophagus. A recent study determined that, when endoscopists spent approximately a minute per centimeter extent of Barrett's esophagus, they had a higher detection rate of neoplastic lesions. Such a "quality examination" could be easily implemented and should be the minimal standard in surveillance of patients with Barrett's esophagus. In summary, after the initial attention to quality colonoscopy, we are now in the process of moving to assessing quality in upper endoscopy. Details of endoscopic techniques and duration of endoscopic examination are the first steps. In a specialty driven by evidence-based guidelines, quality indicators become most important to ensure appropriate diagnosis, surveillance, and treatment.

#### **Colonic microbiota encroachment linked to diabetes**

September 2017 Cellular & Molecular Gastroenterology and Hepatology (2017;2[4]:205-21. doi: 10.1016/j.jcmgh.2017.04.001)

**Key clinical point:** Microbiota encroachment into colonic mucosa characterizes type 2 diabetes in humans.

**Major finding:** Regardless of whether they were obese or normal weight, patients with diabetes had bacterial-epithelial colonic distances that were one-third of those in euglycemic individuals (*P* less than .001).

**Data source:** A study of 42 Veterans Affairs patients with and without type 2 diabetes mellitus. **Disclosures:** Funders included the National Institutes of Health, VA-MERIT, and the Crohn's and Colitis Foundation of America. The investigators had no relevant conflicts of interest.



#### Commentary



Mark R. Frey, PhD, is associate professor of pediatrics, biochemistry, and molecular medicine at the Saban Research Institute, Children's Hospital Los Angeles, USC. He has no conflicts of interest.

r. Chassaing and his colleagues examined the possible importance of the bacteria-free layer adjacent to the colonic epithelium in metabolic syndrome. A shrinking of this layer, termed "bacterial encroachment,"

has been associated with human inflammatory bowel disease as well as mouse models of colitis and metabolic syndrome, but the current study represents its first clear demonstration in human diabetes. In a cohort of 42 patients, the authors found that the epithelial-bacterial distance was inversely correlated with body mass index, fasting glucose, and hemoglobin  $A_{1c}$  levels.

The primary predictor of encroachment in these patients was dysglycemia, not body mass index. This could not have been tested in standard mouse models where, because of the nature of the experimental insult, obesity and dysglycemia are essentially linked. Comparing obese human patients with and without dysglycemia, however, showed that encroachment is clearly correlated only with failed glucose regulation. But in coordinated experiments with a short-term murine dysglycemia model, high glucose levels were not sufficient to elicit encroachment, suggesting a more complex metabolic circuit as the driver.

Going forward, a key question will be whether the narrowed sterile layer above the epithelium is a cause or consequence of low-grade intestinal inflammation and chronic metabolic changes. Bacterial encroachment also may be part of the mechanism for the inflammatory effects of dietary emulsifiers, which the authors previously showed can drive colitis.

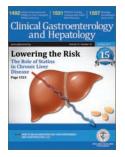
#### Statin use cuts risks in compensated cirrhosis

October Clinical Gastroenterology and Hepatology (doi: 10.1016/j.cgh.2017.04.039)

**Key clinical point:** Statin therapy was associated with a significantly lower risk of hepatic decompensation, death, and progressive portal hypertension in patients with chronic liver diseases with compensated cirrhosis.

**Major finding:** For these patients, statin therapy was associated with about a 46% decrease in the risk of hepatic decompensation and mortality (risk ratios, 0.54) and with a 27% drop in the risk of portal hypertension and variceal bleeding (RR, 0.73).

**Data source:** A systematic review and meta-analysis of 10 cohort studies and three randomized controlled trials (121,058 patients). **Disclosures:** The reviewers acknowledged the American Gastro enterological Association Foundation, a T. Franklin Williams Scholarship Award, the National Institutes of Health, and the National Library of Medicine. They reported having no relevant conflicts of interest.



#### Commentary



Guadalupe Garcia-Tsao, MD, is professor of medicine at Yale University, chief of digestive diseases at the VA-CT Healthcare System, and director of the clinical core of the Yale Liver Center, New Haven, Conn. She had no conflicts of interest.

he main mechanism in the development of cirrhosis in patients with chronic liver disease (CLD) is increased hepatic fibrogenesis. The initial consequence of cirrhosis is portal hypertension, which is the main driver of decompensation (defined as the presence of ascites, variceal hemorrhage, or encephalopathy).

Portal hypertension initially results from an increase in intrahepatic resistance, which in turn results from distortion of liver vascular architecture (mostly due to fibrosis) and from intrahepatic vasoconstriction (mostly due to endothelial cell dysfunction).

Statins are widely used for reducing cholesterol levels and cardiovascular risk. However, statins ameliorate endothelial dysfunction and have additional antifibrotic, anti-inflammatory, and antithrombotic properties, all of them of potential benefit in preventing progression of CLD/cirrhosis. In fact, statins have been shown to reduce portal pressure in cirrhosis.

In a meta-analysis of 13 studies, Kim

et al. demonstrated that statin use is associated with a 58% lower risk of developing cirrhosis/fibrosis progression in patients with CLD (not statistically significant), while in patients with compensated cirrhosis of any etiology, statin use was associated with a statistically significant 46% lower risk of developing decompensation and death.

Most studies in the meta-analysis were observational/retrospective. Although the authors jointly analyzed three randomized controlled trials, only one of the trials looked at clinical outcomes. This important double-blind, placebo-controlled study in patients with recent variceal hemorrhage showed a significantly lower mortality in patients randomized to simvastatin.

Therefore, although the evidence is not yet sufficient to recommend the widespread use of statins in patients with CLD/cirrhosis, providers should not avoid using statins in patients with CLD/cirrhosis who otherwise need them. In fact, they should actively look for indications that would justify their use.



### Share Your Capital Research

June 2-5, 2018 Exhibit Dates: June 3-5 Walter E. Washington Convention Center Washington, DC www.ddw.org/abstracts

Monumental Developments in Science & Medicine **Washington, DC** 

# 2018

#### **Call for Abstracts**

Share your capital research and breakthroughs at Digestive Disease Week® (DDW) 2018 in Washington, DC. Reveal your work to leaders in the field of digestive diseases. By submitting your abstract for consideration for DDW 2018, you become part of the momentum to establish, discuss and promote basic, clinical and translational research on a global scale.

Bringing monumental developments in science and medicine to the forefront, DDW is the leader in creating connections between GI academicians, clinicians, researchers, fellows and students.

Accepted abstracts will be published in the online supplement to *GIE: Gastrointestinal Endoscopy* or *Gastroenterology.* 



#### **Abstract Submission Period:**

BEGINS:<br/>ENDS:Thursday, Oct. 19, 2017, at 9 a.m. ETENDS:Friday, Dec. 1, 2017, at 9 p.m. ET

To submit your abstract, view informational videos, read submission guidelines and get answers to frequently asked questions, visit **www.ddw.org/abstracts.**