For achalasia, are balloon treatments a thing of the past? Experts debate the newest treatment (POEM), compared with conventional treatment methods.

Articles by Thomas Rösch, MD, and G.E. Boeckxstaens, MD, PhD PAGE 4
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One of the most exciting advances in therapeutic endoscopy is the peroral endoscopic myotomy (POEM) for achalasia. Enthusiasm for this technique is mounting around the world and exciting new data will be presented at this year’s DDW. Currently, a key question is where POEM fits in the therapeutic armamentarium for achalasia, especially given the lack of direct comparison trials to the tried-and-true techniques of pneumatic dilation and Heller myotomy. In our point-counterpoint debate, Thomas Rosch, MD, and Guy Boeckxstaens, MD, PhD, provide thoughtful commentary on this issue from the perspective of their extensive expertise with these techniques.

In this issue, James M. Scheiman, MD, AGAF, provides the readership with concise take-home points from the AGA pancreatic cyst practice guideline and technical review. This issue also includes updates on the detection of flat colon polyps, cancer surveillance in IBD, management of HCV genotype 3, along with implications of the common dilemmas of constipation and fecal incontinence. From a policy perspective, Carla H. Ginsburg, MD, MPH, AGAF, provides the perspective of the AGA Public Affairs and Advocacy Committee on the implications of the current Congress for the GI community, which now includes passage of SGR reform.

Other updates from AGA include an overview of the new AGA Strategic Plan by AGA President John I. Allen, MD, MBA, and announcement of the new publication, The New Gastroenterologist, which targets fellows in training as well as early career gastroenterologists. We hope you enjoy this issue.

Gary W. Falk, MD, MS, AGAF
EDITOR

We welcome member feedback on all of the perspectives presented in this issue. Send your letters and comments to communications@gastro.org and include “AGA Perspectives” in the subject line.

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UP, UP AND GOING AWAY?
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**POEM: THE NEW MINIMALLY INVASIVE STANDARD?**

While endoscopists have tried to expand the limitations of GI endoscopy and go beyond the wall of the GI tract, not much has come out for broad applications, so far. The NOTES epidemic (NOTES standing for natural orifice translumenal surgery) has faded away, and we do not know whether it may come back at a later point in time. There was, however, one aspect that — as a NOTES side effect, so to speak — developed into a new and revolutionary endoscopic technique: when thinking about how to effectively close a transmural hole for endoscopic access into the abdominal cavity or into the mediastinum, U.S. researchers found that a stepwise approach, first through the mucosa, then a few centimeters parallel in the submucosa, and finally out through the muscularis, would perhaps be a safe way for later closure (Fig 1a). This principle was then adopted by another U.S. group to perform myotomy (Fig 1b) in pigs and later adopted by Haru Inoue for application in patients. He also called it peroral endoscopic myotomy and gave it the nice acronym, POEM.

We adopted this technique early with the help of Haru Inoue and have stuck to it since then with not only enthusiasm, but also with the necessary skepticism derived from scientific assessment. POEM is a technique that attracts a lot of interest due to its novelty — it is the first clinical endoscopic procedure to work (almost) outside of the GI tract, even if in a rare disease — and its technical beauty. Not surprising, the first case series, as is usual with limited patient numbers and short follow-up, showed the usual 90 percent results for POEM and hailed POEM with retrospective comparisons to laparoscopic Heller myotomy, already in the form of “metaanalyses.”

**CONVENTIONAL TREATMENT**

Achalasia is a motor disorder of the esophagus resulting from progressive loss of enteric neurons. It is characterized by aperistalsis and impaired relaxation of the lower esophageal sphincter (LES), which leads to chronic dysphagia, regurgitation and chest pain. Even to date, in an era of exponential medical progress and increased insight in disease mechanisms, treatment of patients with achalasia is still rather primitive and confined to mechanical disruption of the LES.

Already in 1674, Sir Thomas Willis successfully dilated the LES in a patient with achalasia using a cork-tipped whalebone. To date, this approach has evolved to pneumatic dilation (PD), a technique that stretches the LES by insufflation of a rigid balloon positioned across the esophagogastric junction. In most centers of expertise, treatment starts with a balloon of 30 mm in diameter followed by a 35 mm balloon, also referred to as graded PD. The alternative conventional treatment of achalasia in 2015 is laparoscopic Heller myotomy (LHM). In brief, during laparoscopy, the circular muscle layer of the LES is carefully cut with extension of the myotomy 1.5 to 3 cm towards the stomach and more proximal into the esophageal body for at least 6 cm above the esophagogastric junction. Moreover, to avoid excessive gastroesophageal reflux, an anti-reflux procedure is routinely added to the procedure. Mainly due to the impressive short-term success rates of LHM (above 90 percent), this technique has been embraced with great enthusiasm and, at least in the U.S., has largely replaced PD.

In the past few years, mainly triggered by retrospective studies evaluating the long-term success rates of PD, it became clear that success rates...
before any randomized data were available. Application in almost every situation — achalasia type I-III, spastic motility disorders, after failed Heller, after failed POEM as a redo, in children, etc. — almost always produced fantastic results.

So, what do we really know about POEM apart from the fact that we are thrilled by its aesthetics as performing endoscopists? I am convinced that we can perform it at selected centers (hopefully) with enough expertise, not only in POEM, but also in achalasia and manometry, as well as in Heller myotomy and esophageal rescue procedures. I’m also certain that we can treat the vast majority of our patients without major accidents — even if some complication series show substantial rates of mostly minor adverse events.6-9 Long-term efficacy data (i.e., 5 to 10 year results) is not yet available; reflux is another worry and might be higher than with Heller myotomy by 10 to 15 percent depending on the method of measurement (clinical, treatment requirement, pHmetry, endoscopy).10

Effectiveness seems to decrease over time and may approach 80 percent at one to two years follow-up.5 How this compares to Heller we do not know, and we are eagerly awaiting the five-year results of the randomized trial of Heller versus balloon dilatation headed by my co-discussant. The second issue is reflux; it could be that reflux and effectiveness are inversely related (i.e., if we cut more, we get more reflux), but also better clinical efficacy (i.e., less

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in achalasia gradually and significantly decline in time. Although more than 90 percent of achalasia patients initially respond to PD, only 40 percent can be classified as successfully treated after more than 15 years of follow-up. Also for LHM, series of longer follow-up are increasingly reported with a similar drop in success rate to 65 to 85 percent after five years.

Although it may seem that the success rate is smaller for LHM than for PD, it should be emphasized that different definitions of treatment success have been used in most studies. Notably when identical outcome measures are used for both LHM and PD, similar results are found. Indeed, in a retrospective study comparing long-term (six years) success rates of patients treated at the Cleveland Clinic Foundation, success rates of graded PD and LHM declined equally in both groups from 90 percent and 89 percent at six months to 44 percent and 57 percent at six years, respectively, suggesting comparable efficacy for LHM and PD. The latter was recently confirmed in the European Achalasia Trial, a large multicenter randomized study prospectively comparing LHM and PD. Two hundred and one achalasia patients were included and followed on a yearly basis. After a follow-up of at least five years, both LHM and PD had comparable success rates of 84 percent and 82 percent, respectively, indicating that in contrast to the initial enthusiasm in favor of LHM, PD is equally effective as treatment for achalasia, even after a follow-up period of at least five years.

Knowing that achalasia is a chronic disorder requiring long-standing care and follow-up, the choice of treatment should be based largely on long-term results. Moreover, safety, costs and patient burden are important components determining this process. As discussed above, both techniques have been proven to be efficient and are widely accepted and introduced into clinical practice. PD has the advantage to be endoscopy-based and non-invasive; it does not require anesthesia and can even be performed on an ambulatory basis. It does, however, contain the risk (2 to 4 percent) of esophageal perforation, a severe complication that if diagnosed early can be managed conservatively. Moreover, patients have to undergo more than one procedure due to the higher risk of recurrent symptoms. LHM, on the other hand, is (minimally) invasive and requires anesthesia and hospitalization, but it has been proven to be safe. Hence, both techniques have their pros and cons, suggesting that, in practice, the choice of treatment will largely depend both on the expertise of the treating physician and the preference of the patient. In any case, both treatments have proven their value in terms of efficacy and safety.

Putting POEM In Its Place

Since the first report on peroral endoscopic myotomy or POEM in 2010 by Inoue et al., the discussion on the optimal treatment of achalasia received a new impulse. Although this technique is elegant and technically impressive, it is still too premature to accept as an alternative to PD or LHM.
recurrences). Monitoring of reflux by a patient’s symptoms but also by occasional endoscopic control (often minor reflux is asymptomatic) is essential, and we should probably routinely administer low-dose PPI after POEM if we do not control for (asymptomatic) reflux.

I am convinced that POEM will find its place in the armamentarium of therapy for idiopathic achalasia, even if precise definition of its role will take several more years. It is currently not clear whether special forms of achalasia and motility disorders are better treated by POEM than other procedures. One of the really good things with POEM is that — in contrast to most other endoscopic (and surgical) interventions — it is being assessed within randomized trials. My group is currently heading a study comparing POEM with Heller, and two more studies are ongoing comparing POEM with balloon, one headed by my co-discussant and the other by a group in Amsterdam. So we will know better, albeit not soon.

**REFERENCES**


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**CLASSIC - CONTINUED FROM PAGE 7**

is definitely elegant and technically impressive, at least in my mind, it is still too premature to accept as an alternative to PD or LHM. Data published so far only report on small patient numbers with a very short follow-up, complications are minimized and hardly any failures are reported. Moreover, only in a minority of studies are objective outcome measures used or functional tests performed to evaluate the impact on LES/ esophageal function.

Apart from this publication bias, it is of concern to observe the great enthusiasm and eagerness of many endoscopists to learn this new technique, even though the efficacy and long-term complications, such as GERD (in some studies above 50 percent of patients) and fibrosis, are still to be awaited. Moreover, the technique requires high endoscopic skills, as evidenced by the long learning curve of up to 40 procedures, questioning how this quota will be achieved knowing that achalasia is such a rare disease. It is therefore with great relief to observe that higher quality studies are finally appearing in literature using similar objective outcome measures as used in previous PD and LHM studies.

Most important, randomized prospective multicenter studies are ongoing comparing PD versus POEM (including one coordinated by our unit in Leuven) as well as LHM versus POEM, which will hopefully provide evidence-based data to objectively position POEM as treatment for achalasia.

So, before introducing POEM into routine clinical care and before considering it as a valuable alternative for PD or LHM, we should await the results of these prospective studies. Until then, let us continue to propose PD or LHM as treatment for achalasia until we (hopefully) can transplant neurons to really cure our patients.
The New Gastroenterologist: Insights for Fellows & Young GIs

This free publication exclusively serves the needs of GI fellows and young GIs. Read it to gain the critical insight you'll need to succeed in your career. The New Gastroenterologist features updates on hot clinical topics, perspectives on post-fellowship career pathways, primers on pertinent financial and insurance topics, inspiring stories from our GI colleagues, and a plethora of other resources that will be useful for the young GI community.


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Gastroenterologists are frequently consulted regarding the management of a pancreatic cystic lesion discovered incidentally on cross-sectional imaging. Given the high prevalence of pancreatic cysts (up to 25 percent of the population age 70 or greater), it is important to pursue high-quality and high-value clinical strategies for cyst surveillance and management. The new AGA guidelines, published in the April issue of *Gastroenterology*, provide evidence-based recommendations derived from an exhaustive systematic review and quality assessment of the literature. On some key points, these new guidelines differ significantly from previous consensus statements that reflected the expert opinion of authors from surgical referral centers of excellence. By focusing on the evidence, and including the primary-care perspective in their development, the AGA practice guideline on pancreatic cysts offers a fresh take on the need for invasive testing and aggressive surveillance, while carefully considering the risks and benefits of different management strategies in this patient population.

The new guidelines emphasize that pancreatic cysts are very common, but in most circumstances, they carry a very low risk of malignancy. Even for asymptomatic cysts greater than 2 cm the risk is estimated as approximately 0.25 percent. Furthermore, the systematic review found the incidence of malignant transformation of pancreatic cysts under surveillance is less than 0.5 percent per year. The new guidelines emphasize thoughtful cyst characterization to optimize initial-risk stratification, as well as identify value-driven strategies for subsequent utilization of cross-sectional imaging and endoscopic ultrasound. Parallels with our approach to Barrett’s esophagus abound. Adenocarcinoma of the esophagus and pancreas are both deadly conditions, rising in incidence and often requiring morbid surgery. Early estimates of esophageal cancer risk led to aggressive surveillance and a low threshold for surgery, which scaled back significantly as a better recognition of the risk and natural history of the disease became available. A key challenge in the pancreatic cyst field is the low quality of evidence in the literature. This leads to conditional recommendations in many instances. The AGA review provides a research agenda to address the gaps in the literature.

So what are the key take-home messages for the new guidelines?

First, these recommendations refer only to those with incidentally found cysts. Main duct IPMN and those with familial pancreatic cancer risk are not covered by the new guideline. For patients with symptoms related to the cyst, management is entirely different, as are the risks and benefits of aggressive intervention. The new guidelines encourage providers to discuss in detail the risks of malignancy, the limitations of imaging and EUS/FNA, and morbidity and mortality associated with surgery. For many elderly patients and/or those with medical comorbidity, surveillance leading to surgery offers no established survival benefit despite substantial morbidity and cost.
Second, cancer risk is greater in cysts that have “worrisome” features. Size alone does not always indicate the need for invasive testing with EUS+/FNA or surgery, unless accompanied by pancreatic ductal dilation, whereas a solid component in the cyst wall often indicates the need for more intensive evaluation. In this patient population, evaluation by experts, optimally in a multidisciplinary setting, is recommended.

Next, for most patients, frequent surveillance by cross-sectional imaging is not supported by the literature. Furthermore, given the radiation exposure, CT should not be a preferred modality. In the absence of worrisome features or concerning EUS/FNA results, a one-year surveillance MRI, and if negative, followed by an MRI every two years, is recommended. This recommendation is based on the extremely low rate of malignant degeneration noted in the technical review. While this may be viewed as controversial, there is little evidence to support even this aggressive approach. Most cysts will never progress, subjecting patients to surgery and its attendant morbidity and mortality for a cyst that would have never harmed them; this leads to equipoise regarding intensive surveillance.

Finally, the guidelines emphasize that it is reasonable to stop surveillance for many patients with no change in cyst characteristics over five years. The new recommendations also highlight that surveillance has no role in patients unable or unwilling to undergo surgery. Albeit controversial, this recommendation emphasizes an approach to surveillance that considers all the evidence and is individualized to a particular patient’s risk factors, age, medical comorbidity, as well as personal preferences. The costs of aggressive, open-ended imaging are large. Findings of the technical review question whether such imaging in many cases represents an appropriate use of resources.

To Sum It Up …

The AGA guidelines encourage practitioners to consider the benefits and costs of pancreatic cyst management. The great majority of individuals with a cyst have a very low risk of developing malignancy. The new guidelines advocate a more selective use of invasive testing, surgery and surveillance.

To view all of AGA’s guidelines and clinical decision support tools, visit www.gastro.org/guidelines.
Nonpolypoid colorectal neoplasms — those whose shape is slightly raised, completely flat or depressed compared to the surrounding mucosa — can present challenges for even seasoned gastroenterologists. Their subtle morphologies can make detection tricky. Complete resection may require different techniques than those used for sessile polyp removal. As a trainee and faculty member, I have studied flat lesions and now routinely remove them in my practice. In this article, I aim to provide a perspective on why they are important and how gastroenterologists can optimize their detection and removal.

Flat Neoplasms: How Prevalent Are They?

Current literature supports that nonpolypoid colorectal neoplasms (NP-CRNs) are relatively common, have more advanced pathology than their polypoid counterparts, and contribute to interval colon cancer. NP-CRNs, once thought to be rare, are now known to be common in Western populations. In prospective colonoscopy studies in the U.S. and Europe, 6 to 24 percent of patients had at least one nonpolypoid colorectal neoplasm. In addition, NP-CRNs were more likely to harbor high-grade dysplasia than polypoid neoplasms, regardless of size. A population-based study on colon cancers found that cancers in patients who had undergone a recent colonoscopy were more likely to have flat morphology than prevalent cancers.

Optimizing Detection

Detection of flat neoplasm is a learned skill, requiring time and effort. Endoscopists who trained specifically in detection of NP-CRNs had initial low rates of detection following training, but improved significantly
over time.3 Though few trials have specifically addressed techniques to optimize detection, the following recommendations are suggested:

• **An excellent bowel prep, with split dose:** important all-around, but critical in the detection of NP-CRNs. In addition, several studies have found NP-CRNs to be predominantly located in the right colon, where suboptimal preps tend to be worse. In the case of fair preps, care should be given to thorough washing and suctioning.

• **Learn to recognize the features of NP-CRNs:** these can include a red appearance and disruption in the vascular pattern and delicate grooves that line the colon. One great visual resource is ASGE's learning video "Diagnosis of Flat and Depressed Colorectal Neoplasms."4

• **Highlight the mucosa if needed:** the application of diluted indigo carmine onto the surface where a nonpolypoid lesion is suspected can accent its presence and dramatically help to distinguish its borders. Mix one 5cc vial of indigo carmine in 20ccs of water, place in a 50cc narrow-tipped syringe, and include an air column within the syringe. Then plunge the fluid into the working channel of the colonoscope.

### Optimizing Removal

Small flat (but not depressed) adenomas under ~8 mm can typically be removed with cold snare, taking care to resect a rim of surrounding normal tissue so that resection is complete.

Endoscopic mucosal resection is the preferred resection method for larger or depressed NP-CRNs. In endoscopic mucosal resection, fluid is injected via an injection needle into the submucosa beneath the neoplasm, creating a bulge that lifts it up. The tissue is then hot snared. For an optimal lift, adjust the needle dynamically to bring the bulge high into the lumen, with the assistant injecting forcefully. Inject using a mixture of saline and indigo carmine (a few drops of indigo carmine mixed in 10mm saline) to outline the border of the NP-CRN, and use a stiff oval snare (such as the 10 and 20mm Olympus SD-210 and 230) to facilitate tissue capture. Use of blended cautery (ERBE Endo Cut Q) allows for cutting with minimal coagulation. Clips to close the resection defect are an option.

Why use endoscopic mucosal resection for these lesions? The method has at least two advantages to simple snaring. First, it creates a more "polypoid" form that allows the snare to grab the tissue; otherwise, the snare can slip over the flat neoplasm, a frustrating dilemma. Secondly, snaring a large NP-CRN without the heightened submucosal bulge runs the risk of grabbing too much tissue and resecting too deeply, posing the potential for perforation — either immediate or delayed, from extensive burn to the muscle.

### NP-CRN: Improving our Understanding and Endoscopic Care

Flat and depressed colorectal neoplasms, or NP-CRNs, are known to be common worldwide and harbor more advanced pathology than their polypoid counterparts. They are possibly a key element to the missed and partially resected lesions that lead to interval cancer. Research is under way that will improve our understanding of the colon cancer risk associated with NP-CRNs. Even more importantly, gastroenterologists who train to detect and resect these lesions will find more of them and improve their patient care.

### REFERENCES

The treatment of hepatitis C has undergone a revolution in the past two years. Historically, genotype 1 has been the most difficult genotype to treat, with genotypes 2 and 3 achieving higher sustained virological response (SVR) rates with pegylated interferon and ribavirin. Part of the limitation of achieving high sustained response rates was the side effect profile of the interferon backbone with or without direct acting antiviral agents. In 2013, we witnessed the approval of the first all-oral regimen for genotypes 2 and 3, the nucleotide polymerase inhibitor sofosbuvir with weight-based ribavirin, as well as the recommendation of combining sofosbuvir with the protease inhibitor simeprevir for treatment of genotype 1 hepatitis C infection as an all-oral regimen. These treatment options for the first time eliminated the backbone of interferon, providing treatment options for those with previous contraindications to hepatitis C therapy and those who had previously failed interferon based therapies, with a side-effect profile that was markedly improved over interferon-based therapies.
Preliminary data suggests that second generation NS5A inhibitors with improved EC50 against genotype 3 may allow clinicians to experience the same success as we have seen with genotype 1.

In 2014, this momentum continued with FDA approval of the combinations of sofosbuvir/ledipasvir, paritaprevir/ritonavir/ombitasvir/dasabuvir with/without ribavirin, and sofosbuvir/velpatasvir with/without ribavirin, which has led to SVR rates well over 90 percent in all populations with chronic hepatitis C genotype 1 regardless of disease severity and treatment history. Other studies have demonstrated high sustained response rates for genotypes 2, 4 and 6 with all-oral therapies that mirror the success seen with genotype 1, though some of these studies have small sample sizes. Moreover, other special populations — including HIV/hepatitis C coinfected individuals and those who have undergone orthotopic liver transplant — no longer achieve SVR at lower rates than treatment-naïve populations.

Despite these successes, genotype 3 hepatitis C, particularly those with cirrhosis who have failed prior therapy, remains a population in need of additional strategies to achieve SVR. The current standard of care for genotype 3 is the nucleotide polymerase inhibitor sofosbuvir with weight-based ribavirin for 24 weeks. This recommendation comes from the Valence study where treatment-naïve and treatment-experienced patients with genotype 3 hepatitis C infection received 24 weeks of sofosbuvir with ribavirin. High SVR rates were seen in those who were treatment-naïve without or with cirrhosis (93 percent and 92 percent, respectively), with treatment-experienced, non-cirrhotic patients achieving SVR at a slightly lower rate of 85 percent. However, treatment-experienced genotype 3 cirrhotic patients experienced a lower SVR rate of 60 percent. Worldwide, this group remains the most difficult to treat of all hepatitis C populations.

Additional strategies have been explored for this population. One study retreated these patients with sofosbuvir in combination with our previous backbone peginterferon and ribavirin, and in this small study, 10 of 12 genotype 3 cirrhotic patients achieved an SVR (83 percent). Because our current standard of care is with just one direct-acting antiviral agent, another strategy is to combine multiple direct-acting antiviral agents. The logical combination is with a NS5A inhibitor, which like the nucleotide polymerase sofosbuvir is pan-genotypic. Several studies have explored this possibility. A previous report in genotype 3 patients have suggested that 24 weeks of sofosbuvir and the NSSA inhibitor, dasabuvir, could achieve high rates of SVR, though those with cirrhosis who were previously treated were not studied.

The combination of sofosbuvir and daclatasvir for a duration of 12 weeks was explored in a recent study that demonstrated high SVR rates in non-cirrhotic genotype 3 patients; however, treatment-naïve and treatment-experienced cirrhotic patients with hepatitis C genotype 3 achieved SVR rates of 58 percent and 69 percent, respectively, not different than SVR rates achieved with our current gold standard. Additional trials are ongoing to explore whether longer durations of this combination and/or addition of ribavirin may improve SVR rates with sofosbuvir/daclatasvir (NCT02304159, NCT02319031).

Another NS5A inhibitor, ledipasvir, which is approved for genotype 1 hepatitis C, has also been explored in combination with sofosbuvir for genotype 3 infection. One small study in treatment-experienced genotype 3 cirrhotic patients administered ledipasvir, sofosbuvir and ribavirin for 12 weeks. In this preliminary report, 16 of 22 individuals (73 percent) achieved SVR. While these SVR rates are good by historical standards, they do not match the SVR rates seen with other genotypes.

With our currently approved therapies worldwide, our retreatment options for genotype 3 cirrhotic patients require additional strategies to achieve SVR rates comparable to those with genotype 1. Preliminary data suggests that second generation NS5A inhibitors with improved EC50 against genotype 3 may allow clinicians to experience the same success as we have seen with genotype 1. Sofosbuvir in combination with GS-5916, NS5A inhibitor with a lower EC50 for genotype 3 (12 pM) demonstrated high SVR rates of 96 percent (25 of 26 patients) when given with ribavirin for 12 weeks. Phase 3 trials are fully enrolled (NCT02201953) that will determine the optimal duration of therapy with GS5816 with results expected by the end of 2015. Results of these trials will hopefully offer treatment options for non-responding cirrhotic genotype 3 patients such that they have the same opportunity to achieve SVR at the same high rates as hepatitis C genotype 1 infected hepatitis C patients who have failed previous therapies.

REFERENCES


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**Study Designs**

**ION-1:** a randomized, open-label trial evaluating HARVONI with or without ribavirin (RBV) in GT 1 treatment-naïve subjects (N=865) with or without cirrhosis. Subjects were randomized in a 1:1:1:1 ratio to receive HARVONI for 12 weeks, HARVONI + RBV for 12 weeks, HARVONI for 24 weeks, or HARVONI + RBV for 24 weeks, and stratified by presence or absence of cirrhosis and HCV genotype (1a vs 1b).

**ION-3:** a randomized, open-label trial in GT 1 treatment-naïve subjects (N=647) without cirrhosis. Subjects were randomized in a 1:1:1 ratio to receive HARVONI for 8 weeks, HARVONI + RBV for 8 weeks, or HARVONI for 12 weeks, and stratified by HCV genotype (1a vs 1b).

SVR12 was the primary endpoint and was defined as HCV RNA <25 IU/mL at 12 weeks after the end of treatment.\(^1\) Achieving SVR is considered a virologic cure.\(^2\)

RBV was not shown to increase the response rates observed with HARVONI in ION-1 or ION-3. Therefore, the HARVONI + RBV arms are not presented.\(^1\)

**IMPORTANT SAFETY INFORMATION**

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| Treatment-experienced patients with cirrhosis | 24 weeks |

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IMPORTANT SAFETY INFORMATION (continued)

DRUG INTERACTIONS

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- Coadministration of HARVONI is not recommended with simeprevir due to increased concentrations of ledipasvir and simeprevir. Coadministration is also not recommended with rosuvastatin or co-formulated elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate due to increased concentrations of rosuvastatin and tenofovir, respectively.

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**CONTRAINDICATIONS:** None

**WARNINGS AND PRECAUTIONS:**

Risk of Reduced Therapeutic Effect Due to P-gp Inducers: Concomitant use may significantly decrease ledipasvir and sofosbuvir concentrations and may lead to a reduced HARVONI effect. Use of HARVONI with P-gp inducers (e.g., rifampin or St. John’s wort) is not recommended.

Related Products Not Recommended: Use of HARVONI with products containing sofosbuvir (SOVALD®) is not recommended.

**ADVERSE REACTIONS:**

The safety assessment of HARVONI was based on pooled data from three Phase 3 clinical trials in subjects with genotype 1 CHC with compensated liver disease (with and without cirrhosis) who received HARVONI for 8 (N=215), 12 (N=539) and 24 (N=326) weeks. Adverse events led to permanent treatment discontinuation in 0%, <1% and 1% of subjects receiving HARVONI for 8, 12 and 24 weeks, respectively.

**Adverse Reactions** (adverse events assessed as causally related by the investigator): The most common adverse reactions (≥10%; all grades) were fatigue and headache. Adverse reactions (all grades; majority Grade 1) observed in ≥5% of subjects by treatment duration were:

- **HARVONI for 8 weeks:** fatigue (16%); headache (11%); nausea (6%); diarrhea (4%); and insomnia (3%)
- **HARVONI for 12 weeks:** fatigue (13%); headache (14%); nausea (7%); diarrhea (3%); and insomnia (5%)
- **HARVONI for 24 weeks:** fatigue (18%); headache (17%); nausea (9%); diarrhea (7%); and insomnia (6%)

Direct comparison across trials should not be made due to differing trial designs.

**Laboratory Abnormalities:**

- **Bilirubin Elevations:** Bilirubin elevations of greater than 1.5x ULN were observed in 3%, <1% and 2% of subjects treated with HARVONI for 8, 12 and 24 weeks, respectively.
- **Lipase Elevations:** Transient, asymptomatic lipase elevations of greater than 3x ULN were observed in <1%, 2% and 3% of subjects treated with HARVONI for 8, 12 and 24 weeks, respectively.
- **Creatine Kinase:** Creatine kinase was not assessed in Phase 3 trials of HARVONI. Isolated, asymptomatic creatine kinase elevations (Grade 3 or 4) have been previously reported in subjects treated with sofosbuvir in combination with ribavirin or peginterferon/ribavirin in other clinical trials.

**DRUG INTERACTIONS:**

Ledipasvir is an inhibitor of the drug transporters P-gp and breast cancer resistance protein (BCRP) and may increase intestinal absorption of coadministered substrates for these transporters. Ledipasvir and sofosbuvir are substrates of P-gp and BCRP while the inactive sofosbuvir metabolite GS-331007 is not. P-gp inducers (e.g. rifampin or St. John’s wort) may decrease ledipasvir and sofosbuvir concentrations leading to reduced HARVONI effect; use of HARVONI with P-gp inducers is not recommended.

Established and Potentially Significant Drug Interactions: The drug interactions described are based on studies conducted in healthy adults with either HARVONI, the components of HARVONI as individual agents, or are predicted drug interactions that may occur with HARVONI. This list includes potentially significant interactions but is not all inclusive. An alteration in dose or regimen may be recommended for the following drugs when coadministered with HARVONI:

- **Acid Reducing Agents:** Ledipasvir solubility decreases as pH increases. Drugs that increase gastric pH are expected to decrease ledipasvir concentration.
- **Antacids:** Separate HARVONI and antacid administration by 4 hours.
- **H₂-receptor antagonists:** Doses comparable to famotidine 40 mg twice daily or lower may be administered simultaneously with or 12 hours apart from HARVONI.
- **Proton-pump inhibitors:** Doses comparable to omeprazole 20 mg or lower can be administered simultaneously with HARVONI under fasted conditions.
- **Antiarrhythmics (digoxin):** Increased digoxin concentration. Monitor digoxin therapeutic concentration during coadministration with HARVONI.
- **Anticonvulsants (carbamazepine; phenytoin; phenobarbital; oxcarbazepine):** Decreased ledipasvir and sofosbuvir concentrations leading to reduced HARVONI effect. Coadministration is not recommended.
- **Antimycobacterials (rifabutin; rifampin; rifapentine):** Decreased ledipasvir and sofosbuvir concentrations leading to reduced HARVONI effect. Coadministration is not recommended.
- **HIV Antiretrovirals**
  - Regimens containing tenofovir disoproxil fumarate (DF) and an HIV protease inhibitor/ritonavir (emtricitabine/tenofovir DF plus atazanavir/ritonavir; darunavir/ritonavir or lopinavir/ritonavir): The safety of increased tenofovir concentrations has not been established.
Brief Summary (cont.)

Consider alternative HCV or antiretroviral therapy. If coadministration is necessary, monitor for tenofovir-associated adverse reactions. Refer to VIREAD or TRUVADA prescribing information for renal monitoring recommendations.

- **Efavirenz/emtricitabine/tenofovir DF:** Monitor for tenofovir-associated adverse reactions. Refer to VIREAD, TRUVADA or ATRIPLA prescribing information for renal monitoring recommendations.

- **Elvitegravir/cobicistat/emtricitabine/tenofovir DF:** The safety of increased tenofovir concentrations has not been established. Coadministration is not recommended.

- **Tipranavir/ritonavir:** Decreased ledipasvir and sofosbuvir concentrations leading to reduced HARVONI effect. Coadministration is not recommended.

- **HCV Products (simeprevir):** Increased ledipasvir and simeprevir concentrations. Coadministration is not recommended.

- **Herbal Supplements (St. John's wort):** Decreased ledipasvir and sofosbuvir concentrations. Coadministration is not recommended.

- **HMG-CoA Reductase Inhibitors (rosuvastatin):** Significant increase in rosuvastatin concentrations and risk of rosuvastatin associated myopathy, including rhabdomyolysis. Coadministration is not recommended.

**Drugs without Clinically Significant Interactions with HARVONI:** Based on drug interaction studies conducted with HARVONI or its components, no clinically significant drug interactions have been observed or are expected when used with the following drugs individually: abacavir, atazanavir/ritonavir, cyclosporine, darunavir/ritonavir, efavirenz, emtricitabine, lamivudine, methadone, oral contraceptives, pravastatin, raltegravir, rilpivirine, tacrolimus, tenofovir DF or verapamil.

Consult the full Prescribing Information prior to and during treatment with HARVONI for potential drug interactions; this list is not all inclusive.

**USE IN SPECIFIC POPULATIONS:**

**Pregnancy:** HARVONI is Pregnancy Category B; there are no adequate and well-controlled studies in pregnant women. HARVONI should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

**Nursing Mothers:** Studies in rats have demonstrated that ledipasvir and GS-331007 are secreted in milk but had no effect on nursing pups. It is not known if HARVONI and its metabolites are secreted in human breast milk. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for HARVONI and any potential adverse effects on the nursing child from the drug or from the underlying maternal condition.

**Pediatric Use:** Safety and effectiveness of HARVONI have not been established in pediatric patients.

**Geriatric Use:** Clinical trials of HARVONI included 117 subjects aged 65 and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out. No dosage adjustment of HARVONI is warranted in geriatric patients.

**Renal Impairment:** No dosage adjustment of HARVONI is required for patients with mild or moderate renal impairment. The safety and efficacy of HARVONI have not been established in patients with severe renal impairment (eGFR <30 mL/min/1.73m²) or end stage renal disease (ESRD) requiring hemodialysis. No dosage recommendation can be given for patients with severe renal impairment or ESRD.

**Hepatic Impairment:** No dosage adjustment of HARVONI is required for patients with mild, moderate or severe hepatic impairment (Child-Pugh Class A, B or C). Safety and efficacy of HARVONI have not been established in patients with decompensated cirrhosis.

**References:**

Throughout the course of my fellowship, I was consistently amazed by the popularity of topics geared toward fellows and young career gastroenterologists. Career-development talks were always well-attended, both at my institution as well as at national meetings, financial seminars were often standing-room only, visiting professors were consistently asked about their advice to the younger GI community, and conversations among young GI colleagues throughout the GI community often revolved around the same core set of topics. Yet, despite all of the “buzz,” the young GI community lacked a dedicated resource to address these topics, which could both unite and serve all young gastroenterologists. A publication devoted solely to the needs and interests of the young GI community could certainly fill in this gap.

To that end, AGA is delighted to announce the newest addition to its publication armamentarium, The New Gastroenterologist: Insights for Fellows & Young GIs. This new quarterly publication will be the first of its kind in the gastroenterology community to specifically target the needs of fellows and young-career gastroenterologists, while at the same time undoubtedly having global appeal to gastroenterologists in all stages of their careers.

Each issue of The New Gastroenterologist will feature a selection of exceptional expert-authored articles that provide focused updates on “hot” clinical topics, perspectives on post-fellowship career pathways, primers on pertinent financial and insurance topics that are important to all gastroenterologists, inspiring stories from our young GI colleagues, and a plethora of other resources that will be useful for the young GI community. Given the ever-increasing demands on our time, the ultimate goal of this new publication is to provide a concise, high-yield and informative collection of articles that can not only be read and digested quickly, but can also be effectively incorporated to improve our professional careers.

The inaugural issue of The New Gastroenterologist will be distributed in print with April’s GI & Hepatology News, and will also be available freely online at www.gastro.org and www.gihepnews.com. This inaugural issue will feature an exciting update on the current state of HCV therapy, a perspective on pursuing an advanced endoscopy fellowship, and a fantastic story of a young GI’s memorable research experience in Africa.

Additionally, this issue will include tools that will be helpful to all gastroenterologists, including primers on both disability insurance and the development of successful clinical trials. In addition to these expert-authored articles, the first issue, as well as subsequent issues of The New Gastroenterologist, will help maintain clinical sharpness through DDSEP® 7 questions and clinical/image challenges, will highlight recent high-impact papers in the field, and will also provide AGA news and a calendar of pertinent events for the young GI community. After the initial release in April of 2015, subsequent issues of The New Gastroenterologist will then be released on a quarterly basis.

As the editor of The New Gastroenterologist, it has been a true pleasure helping to develop this publication, and I, as well as the AGA leadership, are eagerly anticipating its launch. We hope that The New Gastroenterologist will quickly become a key resource that is part of every fellow and young GI’s panel of regular reading, while at the same time being equally enjoyed by all gastroenterologists.

We look forward to hearing your feedback about The New Gastroenterologist, and we would also welcome your ideas for future issue topics. Please send questions or comments to me at bryson.katona@uphs.upenn.edu or Erin Dubnansky at edubnansky@gastro.org.

Health-Care Burden and Costs of Constipation and Fecal Incontinence: The Silent Afflictions

"Doctor, I feel tied to the bathroom, I spend hours and can’t get it out, life sucks. Likewise, “Doctor I am afraid to go out, I don’t wear whites, I have stopped socializing, and I don’t eat out anymore for fear of soiling myself, nobody knows, it is most embarrassing.” Do these patient grievances sound familiar, have we all not heard this, and if so are we listening to these complaints? Are we attempting to find out “what and why” just as we do for a GI bleed or jaundice? Are we helping them, or are we wrapped up in our daily ritual of 15-minute consults and 20-minute procedures and just don’t have the time for these “nuisance symptoms”?

And who are these individuals, and what are they describing? Is this a rare phenomena? Certainly not, and you may be surprised to learn that chronic constipation affects one in six Americans. It is the third leading symptom prompting an outpatient clinic visit, and the fourth leading physician diagnosis for gastrointestinal disorders. Telephone interviews with 10,018 individuals gave an estimated prevalence of 14.7 percent. It disproportionately affects more women, and those who are overweight. Pregnancy is also associated with a higher prevalence of constipation. But, its prevalence has been underestimated, its natural history is unknown, and it may not resolve quickly, since 89 percent had similar symptoms one year apart, and 45 percent had symptoms for five years.

Constipation affects daily life and resulted in 13.7 million days of restricted activity, also 12 percent missed work or school, and 60 percent had impaired ability to work. Also, it is associated with increased psychological distress, significant impairment of health-related quality of life, and poses a major health-care burden. The mean cost in 2010 per discharged patient was $17,518, and that increased several fold between 1997 and 2010.

And now, let’s discuss the equally distressing problem of stool leakage. Fecal incontinence is usually defined as the unintentional loss of solid or liquid stool, whereas flatus incontinence describes leakage of gas. Sadly, many individuals hide the problem from their families, friends and even doctors. Consequently, health-care providers have had difficulty in identifying those affected by fecal incontinence. Estimates of its prevalence range from 7 to 15 percent in community-dwelling women and 8 percent in men, and substantially higher among care-seeking populations, home-care populations and adults in long-term care setting.

Although anal sphincter or neurological injury stemming from either obstetric trauma or pregnancy itself remains a leading cause, other significant risk factors include white race, depression, chronic diarrhea, urgency and urinary incontinence. But the inability to control what is regarded as a natural bodily process not only results in a loss of self-esteem and confidence but also leads many to become social recluses. When they gather courage to seek help, providers often fail to attribute sufficient importance to their symptom. Less than one third of patients with fecal incontinence had disclosed this problem.
Health-Care Burden and Costs of Constipation and Fecal Incontinence: The Silent Afflictions

...to a provider; and only 17 percent with fecal incontinence were asked about the symptom when presenting for gynecologic care. Barriers include: a lack of understanding of the condition; embarrassment; the belief that fecal incontinence is a normal part of aging; unfamiliarity with whom to discuss this problem; priority of other medical conditions; and pessimism that there are no options or physicians can't help. Also, the caregiver burden is significantly greater for fecal incontinence than for urinary incontinence as measured by hours of care, emotional distress and health deterioration in family caregivers. Another important consideration is the emotional consequences of fecal incontinence often exceed the physical manifestations. Fecal incontinence has a devastating impact on the quality of life, and this correlates with symptom severity. Consequently, the full cost burden of fecal incontinence is substantial. The total per patient annual estimated cost of providing care for this condition (2012 dollars) was higher in the U.S. ($4,111) compared to Netherlands ($3,521). Also, in the U.S., between 1998 and 2003, approximately 3,500 surgeries — predominantly overlapping anal sphincteroplasty — were performed annually for fecal incontinence with a total hospital cost of $34.1 million (adjusted to 2012 USD). These data are not mere statistics but speak volumes of these unvoiced problems and their consequences. Clearly, chronic constipation and fecal incontinence are not only common but also pose a major health-care burden and carry a significant impact both on the individual patient as well as on the society. I trust these hard facts and perspectives will resonate with you as you manage your next patient with these problems, and hope that you will strive to provide them with the best care possible.

REFERENCES


The field of colon cancer surveillance in inflammatory bowel disease (IBD) unfortunately still remains one of controversies and seeming contradictions. This perspective will highlight key questions and controversies on this topic for 2015 as well as key principles that are not in dispute.

2015 is when the real debate on chromoendoscopy for IBD surveillance begins.

Chromoendoscopy is a technique whereby dye spray (indigo carmine or methylene blue) is applied to the colonic mucosa during colonoscopy to detect subtle dysplastic lesions. The topic of surveillance and chromoendoscopy has been placed at the forefront of clinical care with publication of a consensus statement on surveillance in IBD patients. This publication was approved by the governing boards of AGA, ASGE and five other international societies.
Key question for debate is whether chromoendoscopy is the new standard of care for IBD surveillance in centers with high-definition scopes.

The consensus publication does not give a clinical recommendation per se, but rather it reports numerical agreement on clinical statements, the strength of recommendation and the grade of evidence. Statement 3, relevant to many gastroenterologists in the U.S. reads:

“When performing surveillance with high-definition colonoscopy, chromoendoscopy is suggested rather than white light colonoscopy.”

This guideline was endorsed by 84 percent of the 21 voting members (gastroenterologists, endoscopists, pathologists), but was given only a conditional recommendation and the evidence was rated as low quality. The question up for debate is whether this conditional recommendation based on low quality data is sufficient to create standards that affect the practice of every gastroenterologist and patient with IBD in the U.S. The alternative is to continue to support the measured approach endorsed in the previous 2010 AGA guidelines that considered “chromoendoscopy with targeted biopsies an acceptable alternative to white light endoscopy for endoscopists who have experience in this technique.”

Is there a chromoendoscopy paradox?

A paradox is a statement that, despite sound reasoning from acceptable premises, leads to conclusions that are not logical or self-contradictory. For example, with regard to chromoendoscopy, reports on the superiority of dye spray chromoendoscopy over white light colonoscopy would suggest chromoendoscopy should be the standard of care, except that there is uncertainty on whether small lesions that would have not been detected otherwise are of clinical significance compared to those detected on random biopsies. In addition, optimistic reports of IBD related colon cancer rates finally nearing that of the general population would lead to the natural conclusion that our current cancer prevention strategies are effective, not that there is a need for new techniques for preventing colon cancer in IBD patients. Even so, as a community, we should encourage efforts to improve the yield of IBD surveillance colonoscopy and dye spray chromoendoscopy is one tool readily available.

Should IBD colon cancer surveillance be performed by every gastroenterologist?

This is an unaddressed question in our field. For decades, whether it is taking random biopsies or using dye spray chromoendoscopy or how dysplasia is described (flat, DALM, ALM, etc.), IBD colon cancer prevention has been treated differently and has been more complicated than in non-IBD patients. In 2015, we are at a crossroads and will need to decide if newer techniques should be considered a modification of a core activity already performed in non-IBD patients (colon cancer prevention via colonoscopy) or if it should be its own niche and boutique procedure, left for those with sufficient time to conduct intense exams or working knowledge of these complexities. From a patient convenience and continuity of care perspective, it would clearly be best for IBD patients to receive cancer prevention exams where they receive regular care.

Key IBD colon cancer surveillance principles unlikely to change in 2015:

1. Inflammation in the colon is an important risk factor for dysplasia and colorectal cancer in IBD.

2. Published guidelines for surveillance in IBD agree that the first screening colonoscopy should be performed in all patients eight to 10 years after diagnosis and immediately in patients with primary sclerosing cholangitis (PSC) to determine extent. Exceptions are patients with proctitis or Crohn’s disease isolated exclusively to the small bowel, who do not harbor a higher risk of colon cancer.

3. Intervals between colonoscopies vary between one and three years depending on the guidelines. PSC patients should undergo yearly colonoscopy.

4. Most dysplasia is visible and each minute of withdrawal increases dysplasia detection. Visible dysplastic lesions may be subtle and without careful examination may blend more readily to the background of inflamed mucosa or inflammatory polyps. It is important to sample and biopsy any areas that may be slightly more erythematous or nodular or that look distinct in any way from the underlying inflamed mucosa.

5. There is no evidence at this time to support the use of “virtual” chromoendoscopy (NBI, iscan) for IBD colon cancer surveillance.
What Does the NEW CONGRESS MEAN FOR GI?

The new majority Republican Congress, while off to a timid start, would like to demonstrate that they can govern rather than just have their legislation sent back with a veto from Obama. Although they will continue to debate the future of health-care reform, they are focused on 2016 and making sure that the Republican Congress adds to the chances of a Republican replacing Obama.

Many of the issues that are highlights for the new Congress affect our specialty.

First and foremost is the Affordable Care Act (ACA), which is now in its fifth year. This year under the law, individuals will be required to purchase health insurance or pay a fine, while additional mandatory reporting requirements are being implemented specific to physicians. As many as 10 million people already have health insurance on the exchanges and although the Republicans would like it repealed, they know that it would be difficult to take insurance away from that many people. However, the law can be tweaked and that is their intention.

Revisions to the ACA can take many forms: loosening the requirement that most employers provide health-care insurance, changing the definition of full-time workers required to be offered health-care insurance by their employers as working 40 hours or more, rather than 30 hours. Arguments for and against this exist, but bipartisan consensus could exist in Congress to revise the employer mandate provision, which is on the top of the list for reform.

The failure of the health-care system is another issue that the Republicans will likely target. Yet, in April, in a major bipartisan achievement for Congress and quite a victory for the health-care community, the House and Senate finally passed legislation repealing the Sustainable Growth Rate formula. This flawed formula limited growth in spending for physician services by linking updates to target rate of spending growth. This new legislation now will transition physicians to a more value-based payment system and provide structural reforms to the Medicare program. The basic plan is to move out of the classic fee for service model and put in place alternative payment models such as Accountable Care Organizations and bundled payment arrangements. The belief is that the Republicans are readying themselves for a broad reform debate in the hopes that there will be a Republican president and entitlement reform in 2017.

Repeal of the Independent Payment Advisory Board (IPAB) (a group advising Congress on spending cuts) will be an issue targeted by the new Congress, and there remains bipartisan support to eliminate it. Republicans continue to cut funding to implement IPAB, and no advisors to date have been appointed to the board, so it has essentially been ineffective. Another less-controversial cost-containing issue is getting biosimilar drugs to the market in a timely way. Biosimilar drugs are thought of as an equivalent of generic drugs.

New Congress, New Issues?

- Obamacare Employer Mandate
- Health-Care Costs
- Independent Payment Advisory Board
- 21st Century Cures Act
- Tax on Medical Devices
drugs for biologics. Aiding the path for biosimilars to enter the U.S. market would save the government and consumers billions of dollars.

One bill that has broad support in the Republican controlled Congress is the ‘21st Century Cures Act,’ which would dramatically alter the ways pharmaceutical and medical device products are approved and made available for patients in the U.S. Although its’ stated purpose is to modernize medicine, it is mostly focused on streamlining the drug-approval process and extending market exclusivity (and therefore, profits) for drugs. Several promising features of the bill include a fast lane for breakthrough medical devices and drugs, expanded access programs for the very sick, and a section encouraging telemedicine and new technologies.

With Republicans now controlling both chambers of Congress, the chances for repealing the 2.3 percent tax on medical devices are better than ever. Yet abolishing the tax won’t be easy, even though Republicans rank it as a top priority it faces a possible Obama veto. Overriding a potential veto would be hard since those who support the ACA are concerned with the loss of revenue needed to preserve the health-care law.

And so the question … “What does the new Congress mean for gastroenterology?” As the new Congress attempts to dismantle the ACA piece by piece, it means that physicians need to understand the key issues, the politics and the contentious questions. They need to voice their concerns whether it is regarding access issues for our patients, fair physician reimbursement, mandatory reporting requirements, or supporting new technologies and drugs. They need to be proactive and make sure their voice is heard. Actually, what other choice do we really have?

The House Speaker promised, “… at some point, we’ll move to replace Obamacare.”

Join the AGA Government Affairs Committee for a special session at DDW® 2015:

Why Should Physicians Be Involved in the Political Process? An Insider’s View.
The session will be moderated by the incoming committee chair, Peter S. Margolis, MD, AGAF, and feature a discussion with two physician members of Congress. Add this session to your calendar: Tuesday, May 19, 8–9:30 a.m.
I’m proud to share with you the new strategic plan of the AGA. Thanks to the hundreds of members who worked to ensure that the plan is responsive to the needs of thousands in the gastroenterology community and their patients.

Throughout the process of developing the strategic plan, the phrase “start something that matters,”1 echoed through my head. In 1897, a group of physicians started the AGA to make a difference in the lives of their colleagues and their patients.

Since that time, AGA has been the driving force behind advances that matter in gastroenterology and hepatology research and practice. We have made staggering scientific discoveries and applied them to improve patient care. But we still have so much more to learn, and that’s why the AGA Strategic Plan matters.

AGA is, at our heart, a learning organization. This new strategic plan will lead us to new discoveries in GI science, new tools to improve patient care, new ways to educate ourselves and the GIs of the future. Together we will shape a bright future for gastroenterology and our patients.

Ultimately, the AGA Strategic Plan will mobilize the resources of our organization to fulfill our mission of advancing the science and practice of gastroenterology.

Overview of the Plan

Two words describe each of the three fundamental AGA areas as illustrated in the triangular portion of the plan. For example practice and quality were paired intentionally to emphasize their close connection and the AGA’s increasing commitment to increasing the “value” (defined as quality per unit cost) of our GI and liver care.

Research is critical to our advancing science, but needs to be coupled with AGA’s commitment to promote innovation in medical device and therapeutic advances, through the AGA Center for GI Innovation and Technology and the AGA Center for Diagnostics and Therapeutics.

Finally, education must be paired with training our physician and provider workforce in new and emerging technologies.

The plan includes specific reference to patients. Throughout the four goals and supporting strategies, patient engagement, patient voice and patient experience all are emphasized.

VIEW OUR STRATEGIC PLAN ONLINE AT WWW.GASTRO.ORG/ABOUT.
CALIFORNIA

UCSF Fresno and the Central California Faculty Medical Group (CCFMG) are seeking a full-time faculty member for the gastroenterology division. Applicants should be board certified or board eligible in gastroenterology. Responsibilities will include patient care, teaching residents and fellows, endoscopic procedures, and clinical research. Interest and expertise in hepatology is required. Faculty appointment with UCSF will be commensurate with the applicant’s background and accomplishments. The UCSF Fresno gastroenterology division is a growing division currently utilizing a newly expanded endoscopy suite. In addition they have an ACGME-accredited GI fellowship.

The program is based in Fresno, California, where residents enjoy a high standard of living combined with a low cost of living. The result is a quality of life uniquely Californian, yet surprisingly affordable. Limitless recreational opportunities and spectacular scenery is all accessible in a community with abundant affordable housing. While there is much to see and do in Fresno, the city is ideally located for fast, convenient getaways to the majestic Sierra (just 90 minutes away) as well as the scenic Central Coast, just two and a half hours away.

Please apply online at: https://aprecruit.ucsf.edu/JPF00030

Fresno is the only major city in the country with close proximity to three national parks, including renowned Yosemite National Park.

COLORADO

Gastroenterology of the Rockies is one of the leading GI practices in Colorado. To meet the growing needs of the communities we serve, Gastroenterology of the Rockies is recruiting a board-certified/board-eligible gastroenterologist to join our successful and thriving practice covering the greater Denver and Boulder areas.

Job Description: Our Gastroenterologists provide primarily general GI care as a part of a practice consisting of 14 board-certified gastroenterologists and five physician assistants, located across five clinical sites, which include four physician owned endoscopy centers, clinical research department, and a GI pathology lab.

Requirements: General clinical gastroenterologist, (board certified or board eligible).

This unique opportunity includes:

- Partnership track with strong reputable group.
- State-of-the-art infrastructure.
- Fully electronic environment, Meaningful Use attested.
- Professionally managed.
- Outstanding quality with easy access to the metropolitan amenities of Denver and the outdoor activities of the Rocky Mountains.
- Exceptional schools.

Direct Contact Information:
Bryan Fischer
resumes@gastrorockies.com
Phone: 720-932-7711

MISSOURI

Saint Luke’s Hospital (SLH), a 600-bed tertiary hospital in Kansas City is searching for a BC/BE gastroenterologist. Interest in functional GI/motility disorders will complement the existing interests in the group. Join a 10-physician practice based at the beautiful Plaza district in midtown Kansas City. Saint Luke’s Hospital is the primary teaching hospital for the University of Missouri-Kansas City (UMKC). Appointment will be at assistant/associate professor level and will involve education of fellows, residents and medical students.

Kansas City (population — 2 million) is known as the “City of Fountains” and features professional sports, jazz, world class BBQ, beautiful lakes and parks and access to three of the top ranked public school districts in the U.S. Recently voted as having one of the “Kid Friendliest” suburbs by USA TODAY.

This employment opportunity with Saint Luke’s Physician Specialists offers an excellent compensation and benefits package and is part of Saint Luke’s Health System, a prominent 11-hospital not-for-profit health system based in Kansas City. All inquiries are confidential.

Please email your CV and letter of interest to:
Sreeni Jonnalagadda, MD, FASGE
Professor of Medicine, UMKC
Section Chief, Gastroenterology, SLH
Director of Interventional Endoscopy, SLH
ssj@saint-lukes.org
Phone: 816-932-6916

Mick Allison
Director of Physician Recruitment and Retention
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For more than 20 years, UpToDate® has provided dedicated physicians like you with current, evidence-based answers to your clinical questions. UpToDate is the online, continuously updated clinical information resource that gastroenterologists trust to help them make the right point-of-care decisions.

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With UpToDate, you can access accurate and reliable clinical information around the clock, and find the answers you need when and where you need them — quickly and easily. Plus, with a personal subscription, you can earn AMA PRA Category 1 Credit™ for every topic you research in UpToDate.

1. UpToDate Individual Subscriber Survey, October 2014, N=15,990

Loma Linda University Faculty Medical Group, Division of Gastroenterology, is seeking a full-time Gastroenterologist with a focus on nutrition. The ideal candidate will have clinical expertise in nutrition, including enteral and parenteral replacement therapies, as well as research experience to capitalize on the unique nutrition databases available at Loma Linda. Mentorship and protected time will be provided for career development.

The Division of Gastroenterology includes 18 faculty practicing at the University Hospital and the VA. The mission of the Loma Linda University Faculty Medical Group and the hospitals it serves is to deliver whole-person care at a world class level of clinical excellence. The Medical Center serves as the largest tertiary referral source in both Riverside and San Bernardino counties with a surrounding population approaching 4 million.

Loma Linda is located between Los Angeles and Palm Springs. Nestled at the foot of the San Bernardino mountains, we have convenient access to beaches, cities, skiing, hiking and a variety of other outdoor activities. This region also has excellent private and public school systems.

Interested individuals should contact:
Michael Volk, MD, MSc
Director of Transplant Hepatology
Division Head of Gastroenterology
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2015 JAMES W. FRESTON CONFERENCE
A RENAISSANCE IN THE UNDERSTANDING AND MECHANISMS OF IBS

COURSE DIRECTORS Lin Chang, MD, AGAF, and Margaret Heitkemper, PhD

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For more information, visit www.gastro.org/frestonibs.