Finding the Sweet Spot

GERD treatment ranges from PPIs to endoscopic surgery — is there a middle ground?

Articles by John G. Hunter, MD; Peter J. Kahrilas, MD; and John E. Pandolfino, MD.
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A key goal of AGA Perspectives is to provide brief updates on rapidly evolving areas of gastroenterology and hepatology. One such topic is the issue of endoscopic therapy for GERD, which has returned to the GI landscape after problematic outcomes in the early 2000s. In this issue’s featured point-counterpoint section, the debate about the merits or lack thereof of endoscopic therapy is joined by Drs. Peter J. Kahrilas, John G. Hunter and John E. Pandolfino who bring their considerable knowledge to bear on this topic. Also in the esophageal content sphere, Dr. Stuart Spechler provides some clarity to the confusing issue of PPI-responsive esophageal eosinophilia, an area of considerable importance in the approach to eosinophilic esophagitis.

Biologic therapy for IBD is increasingly complex and Dr. Barrett G. Levesque delivers a practical user’s guide to biologics that provides a useful framework for practitioners. Additionally, treatment of hepatitis C has advanced dramatically in the past few years, and the approach to the topic of acute HCV infections is discussed by Dr. David Kaplan.

In the area of practice management, the issue of electronic communications with patients is rapidly evolving. The pros, cons and implications of such communications are reviewed by Kayla and Andrew Feld. AGA’s clinical practice councillor, Dr. Lawrence Kosinski, updates us on the emerging issue of population management, an area of importance in the rapidly evolving health-care environment. Finally, Dr. Andrew Chan describes the vital work of the AGA Institute Research Policy Committee.

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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. Or you can tweet us at @AmerGastroAssn or @DrGaryFalk.

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Finding the Sweet Spot

GERD treatment ranges from PPIs to endoscopic surgery — is there a middle ground?
ENOSOCOPIC TREATMENT IS BACK

You need to understand where we are starting from. Treating gastroesophageal reflux disease (GERD) with a pill that stops acid secretion by the stomach is like treating a flood by removing the trees from the river. Trees in a flood cause some of the downstream damage, but a well-placed dam is generally more effective at minimizing flood damage from both trees and water. Nonetheless, proton pump inhibitor (PPI) administration is the primary treatment for GERD today for two reasons: PPIs work in most people with moderate/severe GERD, and are the least invasive and safest treatment. We have no argument with these facts.

From another perspective, optimal GERD treatment utilizes the least invasive method(s) capable of controlling the symptoms and the damage created by gastroesophageal reflux for each individual with this diagnosis. For most patients, PPIs are sufficient, but for the 40 percent of individuals with moderate/severe GERD who are dissatisfied with PPI treatment, another option is desirable. This is the niche that laparoscopic fundoplication might have filled, yet, for many individuals, the “invasiveness” jump from a PPI to a laparoscopic fundoplication is, well, just too great a leap. In addition, there is the fear of dysphagia and gas-related side effects.

For over a decade, many hoped that endoscopic techniques and devices would fill the gap between PPI administration and laparoscopic fundoplication. To be successful, endoscopic treatment must be effective at alleviating symptoms poorly controlled by PPI, particularly regurgitation. Additionally, it is important that endoscopic treatments be safe and free of significant side effects. Until recently, endoscopic procedures to address GERD were overpromised and underdelivered.

None of this is news to any GI doctor, surgeon or device developer who has invested time and/or money in this niche. The landscape is littered with the remains of endoscopic sewing machines, injectables, plicators and thermal coagulators. While many gastroenterologists and surgeons developed and studied the utility of these devices, there is littered with the remains of endoscopic sewing machines, injectables, plicators and thermal coagulators. While many gastroenterologists and surgeons developed and studied the utility of these devices, there is still no therapy that fits this profile and thus I am left with a careful discussion with my patients focused on balancing the risks and benefits of the medical, surgical and endoscopic options. Certainly if a patient has disrupted anatomy and a large hiatus hernia, the options here are very limited and I feel very comfortable sending them for anti-reflux surgery and hernia repair. I have a harder time with patients who have a small hernia or seemingly normal anatomy who continue to have objective findings of continued pathologic acid gastroesophageal reflux; I would love to have a less invasive option than surgery for these particular patients. Although surgery is also effective in this patient population, it still has significant risks of dysphagia, gas and bloating, and there are many patients who are searching for a less-invasive approach.

Unfortunately, there is no therapy that fits this profile and thus I am left with a careful discussion with my patients focused on balancing the risks and benefits of the medical, surgical and endoscopic options. Certainly if a patient has disrupted anatomy and a large hiatus hernia, the options here are very limited and I feel very comfortable sending them for anti-reflux surgery and hernia repair. I have a harder time with patients who have a small hernia or seemingly normal anatomy who continue to have objective findings of continued pathologic acid gastroesophageal reflux; I would love to have a less invasive option than surgery for these particular patients. Although surgery is also effective in this patient population, it still has significant risks of dysphagia, gas and bloating, and there are many patients who are searching for a less-invasive approach.

When confronted with these patients, I typically try to encourage weight loss, make some minor dietary changes that target the pattern of reflux and work my way through a myriad of medications, such as baclofen.
was a “fringe” element; these were primarily surgeons who worked on ways to construct a valve (a fundoplication) with the endoscope, hoping to replicate the function of a Nissen fundoplication without the incisions or side effects. While 360 degree fundoplication still requires laparoscopic surgery, we can create an anterior fundoplication with the EsophyX device (EndoGastric Solutions, San Mateo, CA) and probably can accomplish the same with the Medigus device (Medigus, Tel Aviv, Israel). We do not yet know if these endoscopic 180 to 270 degree endo-fundoplications function as well as a laparoscopic fundoplication, but we do know that they work, and in certain circumstances, they provide better reflux symptom control than a properly administered PPI.

How do we know this?

Three randomized clinical trials of transoral fundoplication versus PPI for patients with prominent regurgitation symptoms while on PPI were reported in the last 18 months. While each of these trials offered a slightly different slant, all three showed that symptom control, particularly regurgitation and quality of life, could be better improved with transoral fundoplication, rather than with PPI. The two American trials, TEMPO and RESPECT, were different in one fundamental way; the RESPECT trial included a sham surgery arm, demonstrating the remarkable short-term benefit of a sham procedure. Forty-five percent of those with ‘troublesome’ regurgitation on standard PPI dosing experienced an elimination of their regurgitation symptoms after a 30-to-60 minute endoscopy and esophageal dilation under general anesthesia. Nevertheless, the patients in the fundoplication/placebo group perceived better regurgitation control than patients in the sham/PPI group (67 percent vs. 45 percent, p<0.05). The sham/PPI group had a much higher proportion of early failures than the transoral fundoplication group (36 percent vs. 11 percent, p<0.01). Furthermore, 30 of 42 patients in the sham arm elected to be crossed over to transoral fundoplication once the blind was revealed, independent of their response to sham surgery. The major shortcoming of these randomized clinical trials is the short follow-up period (one year maximum). In the Dutch trial, evidence of valve degradation occurred in 60 percent after one year. However, in single-center case series, success rates of 75 to 80 percent were reported three to six years after transoral fundoplication. The variability in reported outcomes, like that with laparoscopic fundoplication, could be a result of patient selection or operative technique. Because of tighter study management in the transoral fundoplication trials, patient selection was better controlled than in many trials of laparoscopic fundoplication. The ideal patient for a transoral

Is endoscopic GERD treatment back? Yes, it certainly is and it should be offered to appropriate patients.
alginites and, potentially, promotility agents if the patient has evidence of gastroparesis. The overall yield of this approach is marginal and we need something better. One potential class of therapy that has been put forward as an option for these difficult patients is focused on endoscopic augmentation of the anti-reflux barrier and thus endoscopic anti-reflux therapies are making a comeback. Theoretically endoscopic therapy makes sense, as the primary determinant of reflux is movement of gastric refluxate through the anti-reflux barrier. The endoscopic techniques attempt to do this via a variety of mechanisms, such as suturing, plication, bulking and delivery of radiofrequency energy to reduce compliance through muscle hypertrophy or fibrosis. The excitement regarding these techniques has always focused on this biologic plausibility.

With this in mind, I am always reminded of the quote by George Bernard Shaw, “If history repeats itself, and the unexpected happens, how incapable must man be of learning from experience?” Obviously, there were some problems with the endoscopic anti-reflux procedures in the past and now that they are back, we should proceed with caution. Two devices, Stretta (Mederi Therapeutics Inc, Norwalk, CT) and EsophyX (EndoGastric Solutions, San Mateo, CA), are FDA approved and currently being used in clinical practice. The Stretta procedure was first approved by FDA in 2000, and was one of the earliest endoscopic devices conceived to treat reflux. The ultimate goal of Stretta is to augment the anti-reflux barrier and the mechanism of action is theorized to be secondary to the remodeling of the lower esophageal sphincter (LES), induced by the application of radiofrequency energy. There have been questions regarding its efficacy in terms of overall effect on LES tone, esophageal acid exposure and PPI utilization when one assesses randomized clinical trials. However, one consistent effect is a reduction in symptoms and although this cannot be correlated directly with objective measures, the safety profile of the procedure is acceptable. Thus it is reasonable to further assess where Stretta may help in terms of the truly refractory patient population.

Although transoral incisionless fundoplication (TIF) saw some setbacks with devices like the NDO Endoscopic Plication System (NDO Surgical, Mansfield, MA) device leaving the market, there is renewed interest in this approach and a newer device, EsophyX (EndoGastric Solutions), is currently being used in clinical practice. The main difference with EsophyX is the ability to perform circumferential, transmural plications that more closely mimic fundoplication. Recently a multicenter randomized controlled trial was performed that assessed EsophyX plus placebo with a sham surgery and PPI therapy. The results from this trial suggest that EsophyX is able to reduce troublesome regurgitation in a larger proportion of patients than PPIs alone (67 percent vs. 45 percent). Additionally, there was a significant reduction in acid exposure compared to the PPI treatment group. However, the main issue with all of the plicator devices has been the durability of the procedure and we will need to wait and see whether this plication device will hold up.
DID YOU KNOW ...

The AGA Center for GI Innovation and Technology is currently working to collect real-world data on endoscopic therapies for GERD through the AGA STAR Registry. As a neutral objective broker, the center has partnered with EndoGastric Solutions® to create an observational research registry to collect data on patient outcomes with laparoscopic nissen fundoplication surgery versus transoral incisionless fundoplication. Once we reach 500 patients, the center will provide guidance to back future technology decisions for GERD patients.

Learn more at www.gastro.org.
ENDOSCOPIC TREATMENT IS BACK

fundoplication has no hiatal hernia or a very small hernia (<2 cm), a Hill Grade valve of I-II, typical symptoms of heartburn and regurgitation, normal esophageal manometry and at least partial response to PPI therapy. Elements of technique deemed important by the experienced endoscopist include the “rotational” technique, where the device is rotated aggressively into the anterior and posterior cardiophrenic “grooves,” and the liberal application of fasteners. Outcomes are better when more than 16 fasteners are used. These technical “pearls” reveal procedural evolution and increasing surgeon proficiency with transoral fundoplication as the technique is passed along. Additionally, the EsophyX II device is being simplified, with several of the complex steps eliminated in the recently released iteration of the EsophyX Z device. The fasteners are also being improved to increase durability. Transoral fundoplication outcomes are dependent upon operator skill and results may vary.

Returning to the original question: is endoscopic GERD treatment back? Yes, it certainly is and it should be offered to appropriate patients (criteria above) who have troublesome symptoms, despite optimally dosed PPIs, but who have little interest in laparoscopic fundoplication. Recently, AMA assigned a CPT code for the transoral incisionless fundoplication (432XX1) and the appropriate relative value unit (RVU) is under review. The RVU will be established later this year and the new code will take effect in January 2016. It may take a little longer for professional society practice guidelines to catch up and for third-party carriers to include coverage for transoral fundoplication. Most importantly, we need to provide good training for all GI endoscopists and surgeons interested in this technique to assure safety and high-quality outcomes.

REFERENCES

PROCEED WITH CAUTION

NOT YET - CONTINUED FROM PAGE 7

So, in the end, endoscopic anti-reflux procedures are not really back, as they were never really gone. Suboptimal efficacy, major complications and issues with durability lessened the enthusiasm in the past and our current desperation to help these difficult patients has brought these tools back into our armamentarium. The good news is that refinements to these techniques have made them safer and probably more effective. Hopefully we have learned something from our previous experience and history will not repeat itself. As more trials are performed that support true efficacy above and beyond PPI therapy, I will gladly welcome these devices back with open arms.

REFERENCES

Obviously, there were some problems with the endoscopic anti-reflux procedures in the past, and now that they are back, we should proceed with caution.
Starting Treatment of Acute HCV Early: Is This the Best Option?

David E. Kaplan, MD, MSc
Medicine and Research Services, Corporal Michael J. Crescenz VA Medical Center, Philadelphia PA; Division of Gastroenterology, Department of Medicine, University of Pennsylvania

Acute hepatitis C continues to be encountered less frequently in routine GI clinical practice, except in relatively well-defined hot spots. The majority of acute hepatitis C cases are asymptomatic and usually escape early detection unless due to surveillance or luck, when abnormal liver enzyme tests are found. Symptomatic cases may manifest such protean symptoms that mild associated jaundice goes unnoticed by both patients and health-care providers alike.
Many cases, generally estimated in the 25 to 40 percent range, resolve spontaneously without intervention, leaving only an isolated positive HCV antibody IgG seromarker of prior infection. Spontaneous resolution, more common in young, female, non-HIV co-infected and IL-28B gene CC carriers, usually occurs within six months after initial presentation.

In the era of interferon-based therapy, early initiation of antiviral therapy, optimally within three to 12 months of initial presentation in non-resolving patients, was strongly associated with superior sustained virological response (SVR) rates, approximately 70 to 75 percent in intention-to-treat analyses. Delaying interferon therapy after one year yielded SVR rates similar to chronically infected individuals (less than 50 percent). As a result, a general consensus emerged that early treatment with or without a short observation period for spontaneous resolution yielded the best overall outcomes in this setting. However, selection of optimal candidates for and patient acceptance of interferon treatment created significant obstacles to interferon-based treatment of acute hepatitis C.

With modern transfusion screening and universal precautions in health care, there are essentially three clusters of patients at risk for acute hepatitis C. The first and by far the largest fraction of cases emerges from active intravenous injection drug users. Indeed, an increase of acute hepatitis C in young injection drug users has been well-documented in multiple areas of the U.S., primarily among non-Hispanic white individuals aged 15 to 24 years. A second risk group includes HIV-infected and uninfected men who have sex with men and engage in high-risk sexual behavior primarily in large urban centers. The third group, which remains poorly quantified but fairly small, consists of iatrogenically exposed individuals with exposure to inadequately sterilized reusable medical equipment or breakdowns in universal precautions. While the first two groups consist predominantly of young individuals with few medical comorbidities at significant risk for repeated exposure, iatrogenic cases are more likely to arise in older individuals with significant comorbidities but at low risk for re-infection.

Few data inform clinicians on how to handle patients presenting with acute hepatitis C in the modern direct-acting antiviral era. Certain factors suggest that the early treatment approach may need to be reconsidered.

First, the emergence of resistance-associated variants was not an issue with interferon-based antiviral therapy, and thus suboptimal adherence, while impacting individual cure rates, would not have long-term, harmful effects. Second, the efficacy difference in early versus delayed therapy has disappeared with direct acting antivirals (DAAs). Third, while the relatively low cost of interferon did not prohibit multiple repeat treatment courses in initial non-responders or individuals who became re-infected serially over time, the current astronomically high cost of oral DAAs often discourages repeated courses of therapy.

With cure rates greater than 95 percent for non-cirrhotic treatment-naïve individuals with established chronic infection with current DAAs, the urgency of early therapy has dissipated. I would argue that all patients with acute hepatitis C, except health-care workers whose livelihoods could be negatively impacted by infection, can be safely observed for one year for spontaneous resolution before a treatment decision is made. Up to 40 percent of treatment courses and related costs could perhaps be obviated by such observation. At this time, there are no data to support abbreviated duration of oral antiviral therapy in acute infection; if these data are generated, then the cost/benefit ratio might shift towards favoring early therapy.

After allowing the natural outcome to evolve, I propose basing the subsequent treatment decision on two primary factors: 1. age and 2. likelihood of reinfection. Individuals with acute hepatitis C who are older than 50 years of age commonly exhibit rapid fibrosis progression, often developing cirrhosis within 10 years. Older individuals and those with a low risk of reinfection, e.g. iatrogenic exposures, should be promptly treated in the absence of spontaneous resolution.

For younger individuals with ongoing behaviors that risk reinfection, treatment can be safely delayed until successful risk factor modification can be achieved, e.g. stable enrollment in a substance abuse treatment program. Critics of this approach might argue that an opportunity to prevent downstream infections might be missed. However, I would argue that prospective data are needed on the putative benefits and potential harms (RAV, transmission, reinfection, retreatment costs, HCV-unrelated mortality) before universal therapy for acute HCV can be recommended.

REFERENCE

In 1993, Sander Van Deventer and colleagues wrote in the *Lancet*: “We report a girl with Crohn’s disease who was not responsive to medical therapy but in whom complete but temporary remission could be achieved by treatment with tumour-necrosis factor (TNF) monoclonal inhibitors.” Over two weeks, two infusions of anti-TNF (chimerical monoclonal c-A2, supplied by Centocor, Malvern USA) were given at 10mg/kg. Symptoms immediately improved after her first dose, and they reported complete endoscopic remission lasting three months. During the subsequent two decades after perhaps the boldest translational science leap from bench to bedside in the history of gastroenterology, multiple clinical trials have validated the efficacy of anti-TNF therapy for IBD. This efficacy was found despite inefficient symptomatic endpoints in Crohn’s disease and with only partial understanding of the pharmokinetics and pharmacodynamics of the drugs. The questions remain, how do we use these drugs to both induce and maintain remission in a chronic disease? How do we go reliably and safely beyond the three months of remission in that first patient? In more than two decades, much data has accumulated with which to try to answer these questions.

The totality of that data is beyond the scope of this column but forms the backbone of any user’s guide. However, there is still an important need for comparative and cost-effectiveness data to define treatment strategies with the best value.

I propose the “top-10” rules to consider for a user’s guide for biologics.

REFERENCES
10

Have a strategy.
Before the clinic visit, know the plan you are going to follow. I suggest a treat-to-target strategy of aiming for mucosal improvement and adequate drug concentrations. At a minimum, based on the REACT trial, consider early combination therapy in Crohn’s disease patients in order to reduce the chance of complications, hospitalizations and surgery.²

9

Buckle up before takeoff.
Remember to rule out latent infections, consider age and gender, and discuss risks and benefits carefully before starting the therapy. Discuss risks of disease progression, steroids and risks of biologics in the context of their potential benefits.

8

Measure twice, treat once.
Whether with a note in your report about the presence or absence of ulcers, a video or perhaps a reliable score, measure what you are aiming for and how it changes after you treat it. Define the disease diagnosis, extent and severity with endoscopy and imaging. Rule out pelvic or abdominal abscesses with appropriate imaging before starting biologics. Choose the appropriate therapy, then start your treatment and measure for improvement in your target.

7

A biologic is a foreign protein to that individual.
Non-self proteins are prone to antibody formation. Have a plan to try to reduce that risk. Combination therapy clearly reduces antibody formation and is a choice for many patients, and therapeutic monitoring may be another way to lower this risk.

6

All that leads to diarrhea is not IBD.
As we know, Clostridium difficile, bile salt diarrhea and IBS can lead to symptoms that are not amendable to biologics. Confirm the presence of inflammation with accurate tests.

5

There is not a “scar-be-gone-mab.”
Stenosis that does not resolve with therapy may need surgery and allow a second chance for that biologic to be effective after recovery of the patient.

4

Consider setons and antibiotics with biologics for fistulas.
They can help reduce the risk of abscess and improve healing rates.

3

You can’t drive far on an empty gas tank.
Remember to check the concentration of the drug when you have persistent symptoms despite your therapy. Plenty of antibody and no drug is unlikely to treat disease. High drug clearance may lead to failure or relapse. Primary non-response means that there is drug present, but it is not effective.

2

If at first you don’t succeed, try to optimize your approach when trying again.
Consider combination therapy, another dosing mechanism or another mechanism of action. Consider clinical trials before bowel damage or complications occur.

1

It depends.
When I was a wide-eyed IBD fellow, Dr. Ken Schroeder began his advice in response to many questions with “It depends.” Similarly, the specifics for applying these rules of thumb will depend on a myriad of factors that you encounter in clinic and on a quickly evolving evidence base. Future tests of value, whether economic simulation modeling, comparative effectiveness trials or newer methodologies, such as the cluster-randomization trial, will help guide us to well-informed clinical decision making with biologic therapy.
INDICATION
HARVONI is indicated for the treatment of chronic hepatitis C (CHC) genotype 1 (GT 1) infection in adults.

Please see Brief Summary of full Prescribing Information on the following pages.
HARVONI IS THE FIRST AND ONLY SINGLE-TABLET REGIMEN FOR HCV GT 1 PATIENTS BUILT ON A SOFOSBUVIR BACKBONE

Recommended treatment duration for HARVONI:

- 8 weeks: Can be considered in TN patients without cirrhosis who have pre-treatment HCV RNA <6 million IU/mL
- 12 weeks: • TN patients with or without cirrhosis • TE patients without cirrhosis
- 24 weeks: TE patients with cirrhosis

- Each HARVONI tablet contains 90 mg of ledipasvir and 400 mg of sofosbuvir

IFN = interferon, RBV = ribavirin, TE = treatment-experienced (patients who failed treatment with either Peg-IFN alfa + RBV or an HCV protease inhibitor + Peg-IFN alfa + RBV), TN = treatment-naïve

HARVONI DELIVERED HIGH CURE (SVR) RATES IN A BROAD RANGE OF GT 1 SUBJECTS

OVERALL CURE RATE ACROSS THREE HARVONI PHASE 3 TRIALS

- Overall cure rates were 94%-99% in the HARVONI Phase 3 clinical trials
- The HARVONI clinical trial program enrolled the most challenging subjects, regardless of GT 1a or 1b subtype, prior experience with therapy, or presence of cirrhosis

* Sustained virologic response (SVR) was the primary endpoint and was defined as HCV RNA <25 IU/mL at 12 weeks after the cessation of treatment. Achieving SVR is considered a virologic cure.

Study Designs:
- 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. ION-4: a randomized, open-label trial in GT 1 treatment-naïve subjects (N=865) with or without cirrhosis. Subjects were randomized in a 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. SVR rates for all subjects enrolled in the 24-week treatment groups (N=434) were not available at the time of interim analysis.
- ION-2: a randomized, open-label trial in GT 1 treatment-experienced subjects (N=440) 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.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

- Risk of Serious Symptomatic Bradycardia When Coadministered with Amiodarone: Amiodarone is not recommended for use with HARVONI due to the risk of symptomatic bradycardia, particularly in patients also taking beta blockers or with underlying cardiac comorbidities and/or with advanced liver disease. In patients without alternative, viable treatment options, cardiac monitoring is recommended. Patients should seek immediate medical evaluation if they develop signs or symptoms of bradycardia.

- Risk of Reduced Therapeutic Effect of HARVONI Due to P-gp Inducers: Rifampin and St. John’s wort are not recommended for use with HARVONI as they may significantly decrease ledipasvir and sofosbuvir plasma concentrations.

- Related Products Not Recommended: HARVONI is not recommended for use with other products containing sofosbuvir (SOVALDI®).
HARVONI WAS SAFE WITH LOW RATES OF DISCONTINUATIONS AND ADVERSE EVENTS (AEs) ACROSS CLINICAL TRIALS1-4

≤1% DISCONTINUATIONS DUE TO AEs1

• Adverse reactions (all grades) reported in ≥5% of subjects receiving 8, 12, or 24 weeks of treatment with HARVONI: fatigue (13%-18%), headache (11%-17%), nausea (6%-9%), diarrhea (3%-7%), and insomnia (3%-6%)1
• No hematologic monitoring or dose adjustments are required with HARVONI1

MORE THAN 110,000 PATIENTS HAVE BEEN PRESCRIBED HARVONI IN THE US6,b

#1 PRESCRIBED HCV TREATMENT IN THE US6,c

*This information is derived from IMS NPA Market Dynamics, IMS NPA Monthly data, IntegriChain DNA National, and 867 data; data reflect estimated patient starts from October 2014–April 2015.

**IMS Weekly NPA Market Dynamics from week-ending 10/24/14–5/15/15.

Help your patients get started on HARVONI with Support Path®

• Support Path is a suite of resources that assists with benefits investigations and prior authorizations, and identifies potential financial assistance for patients, such as the HARVONI co-pay coupon program

IMPORTANT SAFETY INFORMATION
ADVERSE REACTIONS
Most common (≥10%, all grades) adverse reactions were fatigue and headache.

DRUG INTERACTIONS
• In addition to rifampin and St. John’s wort, coadministration of HARVONI is also not recommended with carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifabutin, rifapentine, and tipranavir/ritonavir. Such coadministration is expected to decrease the concentration of ledipasvir and sofosbuvir, reducing the therapeutic effect of HARVONI.
• 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.

Consult the full Prescribing Information for HARVONI for more information on potentially significant drug interactions, including clinical comments.

Please see Brief Summary of full Prescribing Information on the following pages.
HARVONI® (ledipasvir 90 mg and sofosbuvir 400 mg) tablets, for oral use

Brief Summary of full Prescribing Information. See full Prescribing Information. Rx Only.

INDICATIONS AND USAGE: HARVONI is indicated for the treatment of chronic hepatitis C (CHC) genotype 1 infection in adults.

CONTRAINDICATIONS: None

WARNINGS AND PRECAUTIONS:

Serious Symptomatic Bradycardia When Coadministered with Amiodarone: Postmarketing cases of symptomatic bradycardia, as well as fatal cardiac arrest and cases requiring pacemaker intervention, have been reported when amiodarone is coadministered with HARVONI. Bradycardia has generally occurred within hours to days, but cases have been observed up to 2 weeks after initiating HCV treatment. Patients also taking beta blockers, or those with underlying cardiac comorbidities and/or advanced liver disease may be at increased risk for symptomatic bradycardia with coadministration of amiodarone. Bradycardia generally resolved after discontinuation of HCV treatment. The mechanism for this effect is unknown. Coadministration of amiodarone with HARVONI is not recommended. For patients taking amiodarone who will be coadministered HARVONI and patients taking HARVONI who need to start amiodarone, who have no other alternative, viable treatment options; and due to amiodarone’s long half-life for patients discontinuing amiodarone just prior to starting HARVONI: Counsel patients about the risk of serious symptomatic bradycardia; and cardiac monitoring in an in-patient setting for the first 48 hours of coadministration is recommended, after which outpatient or self-monitoring of the heart rate should occur on a daily basis through at least the first 2 weeks of treatment. Patients who develop signs or symptoms of bradycardia should seek medical evaluation immediately. Symptomatic bradycardia may include near-fainting or fainting, dizziness or lightheadedness, malaise, weakness, excessive tiredness, shortness of breath, chest pains, confusion or memory problems.

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 (SOVALDI®) 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 <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.

Postmarketing Experience

Cardiac Disorders: Serious symptomatic bradycardia has been reported in patients taking amiodarone who initiate treatment with HARVONI during post approval use of HARVONI. Because postmarketing reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

**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.
Studies in rats have demonstrated that tacrolimus, tenofovir DF or verapamil.

methadone, oral contraceptives, pravastatin, raltegravir, rilpivirine, 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.


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The mission of the AGA Institute Research Policy Committee is to promote basic and clinical research in gastroenterology and hepatology. Over the last year, the committee has furthered this mission by participating in a number of AGA-sponsored activities and events, including Digestive Disease Week® (DDW) 2015 and the Drug Discovery Conference.

First, the research policy committee fulfilled the AGA Institute Governing Board’s call to review and expand the AGA Strategic Plan’s objective and strategies related to research and innovation. For example, we provided recommendations to expand the number of research awards provided to young investigators and to continue the promotion of the important work of two of AGA’s centers: the AGA Center for Gut Microbiome Research and Education and the AGA Center for Diagnostics and Therapeutics.

Second, the research policy committee continues to cultivate strategic partnerships with industry to provide research funding. This included participation in the AGA-sponsored Drug Discovery Conference, in which AGA issued a call from members for research abstracts. These were submitted to a major pharmaceutical company for selection to attend an in-person meeting that subsequently led to funding agreements with AGA investigators for the development of therapeutic agents.

Third, the research policy committee supervised an overhaul of the selection process for AGA Research Scholar Awards, currently the AGA’s most coveted and substantial grant for young investigators. The selection process was restructured to provide applicants with written feedback from reviewers, in order to offer critical feedback for future grant proposals. In addition, the committee implemented a second layer of review from a panel of established investigators to ensure a standardized and fair review process.

Fourth, the research policy committee petitioned the AGA Institute Council to provide greater recognition of young investigators at DDW. For DDW 2015, session chairs recognized each young investigator presenting an oral abstract with a certificate. This is an important first step in enhancing the visibility of young investigators that will help encourage their future attendance at DDW and promote career-long loyalty to AGA.

Fifth, the research policy committee revised the award criteria for both the William Beaumont Prize in Gastroenterology and the AGA Distinguished Achievement Award to reduce overlap and provide distinct recognition for clinical/translational and basic research.

Finally, the committee sponsored an extremely popular session on research training in big data at DDW 2015 (see some Twitter feedback on this session below). We are looking forward to planning our next committee-sponsored session on precision medicine for DDW 2016.
Proton Pump Inhibitor-Responsive Esophageal Eosinophilia

WHAT IS IT?

Eosinophilic esophagitis (EoE) is an immune-mediated disease manifested clinically by symptoms of dysphagia, heartburn and chest pain, and histologically by esophageal eosinophilia. Gastroesophageal reflux disease (GERD) can cause similar symptoms and histological abnormalities and, occasionally, it can be difficult to distinguish EoE from GERD. Before the recent recognition of a condition called “proton pump inhibitor responsive esophageal eosinophilia” (PPI-REE), we physicians thought we could make that distinction with a trial of PPI therapy.

Initially our rationale for a PPI trial seemed sound — since gastric acid inhibition was the only important effect of PPIs — then only an acid-peptic disorder like GERD could respond to them. In 2007, a consensus report from the AGA Institute defined EoE as a primary clinicopathologic disorder characterized by esophageal symptoms, esophageal biopsies showing ≥15 eosinophils per high-power field, and the absence of pathologic GERD as evidenced by normal esophageal pH monitoring or lack of response to PPIs. This definition implied that EoE and GERD were mutually exclusive disorders that could be distinguished by a trial of PPI therapy.

But the PPI waters surrounding EoE were already muddied by the time that consensus report was published. In 2006, a report from Children’s Hospital in Boston described three patients with esophageal symptoms and dense eosinophilia that
resolved with PPI therapy, a finding initially construed as evidence that large numbers of eosinophils could be seen in peptic esophagitis. Later, in 2007, my colleagues and I published a report contending that the interaction between GERD and EoE might be complex, that the notion of establishing a clear distinction between the two disorders was too simplistic and that a favorable response to PPI therapy should not preclude a diagnosis of EoE. 1

Subsequent studies showed that some patients with typical EoE symptoms and esophageal eosinophilia, but no evidence of GERD by endoscopy or esophageal pH monitoring, nevertheless responded clinically and histologically to PPIs. This condition, which we now call PPI-REE, is not rare. Some 30 to 50 percent of patients with symptomatic esophageal eosinophilia respond to PPI therapy. A number of studies have now shown that the clinical, endoscopic, histologic and esophageal gene expression features of PPI-REE and EoE are virtually identical, and multivariate analyses have not identified any feature that can distinguish PPI-REE from EoE. 2

There are at least two possible explanations for PPI-REE:

1. Despite normal endoscopic and pH monitoring studies, PPI-REE patients have GERD-induced esophageal eosinophilia that responds to PPIs.

2. PPI-REE patients have EoE that responds to anti-inflammatory effects of PPIs that are independent of their effects on gastric acid secretion. Drs. Edaire Cheng and Xi Zhang, from our laboratory in Dallas, have published data supporting the latter explanation.

EoE is an allergic disorder with manifestations mediated by allergic (Th2) cytokines such as IL-4 and IL-13. It is thought that eosinophils accumulate in the esophagus of EoE patients because Th2 cytokines stimulate the esophagus to secrete eotaxin-3, a potent eosinophil chemoattractant. Using cultures of esophageal squamous cells from EoE patients, Drs. Cheng and Zhang have shown that omeprazole, in concentrations readily achieved in blood with conventional dosing, blocks Th2 cytokine-stimulated eotaxin-3 secretion. 3

By blocking esophageal production of this eosinophil chemoattractant, PPIs might decrease esophageal eosinophils and symptoms in EoE patients. This anti-inflammatory effect of PPIs is entirely independent of any effect on gastric acid secretion. However, it is also possible that subclinical acid reflux contributes to EoE pathogenesis and, by preventing that acid reflux, the antisecretory effects of PPIs also might benefit EoE patients. In either case, the notion that a positive response to PPIs precludes a diagnosis of EoE seems contrived and untenable.

We generally do not define diseases by their response to a single medication. For example, we do not consider mesalamine-responsive colitis a fundamentally different disease than ulcerative colitis that does not respond to mesalamine. Why do we do this for EoE when every clinical, histological and laboratory feature studied to date suggests that EoE and PPI-REE are the same disease? In my opinion, the major reason that investigators have created an arbitrary distinction between these conditions is the persistent notion that gastric acid inhibition is the only possible therapeutic effect of PPIs. This notion is so firmly entrenched in our collective medical psyche that we are reluctant to accept the premise that PPIs can do anything in the esophagus other than treat GERD. For now, a trial of PPIs for patients with symptomatic esophageal eosinophilia makes sense if for no other reason than it often works; 30 to 50 percent of patients get better, regardless of what we choose to call the condition.

We generally do not define diseases by their response to a single medication.

REFERENCES


Population health, one of the pillars of the triple aim, is defined as "the health outcomes of a group of individuals, including the distribution of such outcomes within the group," thus requiring providers to focus on their entire population of patients with specific diseases rather than the traditional "one-at-a-time" approach.

The focus on population health will impact our reimbursement as we move from fee for service to value-based payments. The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), signed in April 2015, creates a Merit-Based Incentive Payment System which, beginning in 2019, will convert fee-for-service into a value-based payment system with the goal of the majority of physicians’ income being value based. It will also provide incentives for practices to embrace alternative payment models for patients across their commercial and Medicare patients.

How do GIs participate in population health? How do we transform from a procedural-driven model to one based on value-based payments?

A majority of the wRVUs generated by gastroenterologists are commonly from the colonoscopy procedures performed for colorectal cancer screening, surveillance, and removal of lesions. Unfortunately, screening colonoscopy is a vulnerable “mature service” facing compressed margins, reduced fees and competition from new technology. Now is the time for GIs to build additional competitive advantages.

The next major diagnosis that drives significant revenue in a GI practice is IBD. A typical GI practice may derive about 25 percent of its revenue from the management and treatment of IBD. Management of IBD requires significant knowledge and expertise and, as such, should represent a competitive advantage for GIs. Unfortunately, most GI practices have not leveraged this opportunity.

Data from BlueCross BlueShield of Illinois (BCBSIL) revealed that their average IBD spend is $11,000 per commercial patient per year for Crohn’s disease. More than 50 percent of this spend is on inpatient treatment and complications of this condition. Yet gastroenterologists receive only 3.5 percent of this spend, despite being the most knowledgeable physicians about this disease. Tremendous variation in physician practice and hospitalization rates exists, which may persist even when normalized for patient risk and comorbidities. Clearly, there is an opportunity to improve care management and deliver value.

Population health requires a new level of patient engagement. Only a minority of patients who are admitted to a hospital for a complication of IBD were seen by a provider within 30 days prior to admission. This is the result of our “reactive medicine model,” where physicians are often not engaged until the patient realizes they have a problem that they cannot
fix themselves. Like submarines, patients “run silent and run deep,” surfacing only when they are in trouble and need help. Unfortunately, by that time, serious complications may have already ensued.

Project Sonar

Recognizing the need to address care management and patient engagement for patients with IBD, the 45-physician Illinois Gastroenterology Group developed Project Sonar, a care-management solution for patients with IBD. Project Sonar utilizes nurse care managers and physician medical directors in a team approach to coordinate care for patients with IBD, along with clinical decision support and patient engagement.

Complex clinical decision support tools are embedded into the practice’s EMR. These tools facilitate:

- Implementation of AGA’s Crohn’s Disease Care Pathway into the care workflow, with risk assessments for inflammation, disease burden and co-morbidities.
- Reporting CMS PQRS and AGA Digestive Health Registry IBD measures.
- Capture of clinical data fields for immunizations, labs and imaging results.

Patient engagement is facilitated through several structured questions derived from the Crohn’s Disease Activity Index sent to the patient’s smartphone via a proprietary platform/application. The “Sonar System” pings the patient, bringing structured data on patient-reported outcomes to the practice. Using these measurable responses, the slope of each patient’s “Sonar Score” can be followed over time. The data is fed back into the clinical decision support tools and dashboards used by the nurse care managers and physician medical directors for population health.

The success of Project Sonar in a 50-patient pilot in 2013 led to a partnership between Illinois Gastroenterology Group and BCBSIL in 2014 to develop a specialty-based intensive medical home, a joint initiative to improve the care of patients with Crohn’s disease. The intensive medical home utilizes the Project Sonar structure in an attributed population of IBD patients. Illinois Gastroenterology Group receives a supplemental per-member per-month care-management payment for each attributed/enrolled patient, and a shared savings opportunity at the end of each study period.

The data produced from the clinical decision support tools and Sonar Scores creates a unique set of physician risk assessments, medical decisions and patient-reported outcomes not typically available in most EMRs. These data are used to refine the care provided through the development of care algorithms, which update the clinical decision support tools and the content of the smartphone app.

Conclusion

Population health and value-based payments will mold and shape how we can position our GI practices. Three pillars are essential to our success:

1. Changing our focus from one patient at a time to improving the health of populations.
2. A team approach that embraces mid-level professionals, care managers, social workers, dietitians, pharmacists and others is required.
3. Engaging patients as partners in their care alongside their health-care team is crucial.

All of this requires changes to how we structure the policies, procedures and compensation models for our practices. Incorporating clinical decision support tools and patient engagement will be essential components for GI to manage cancer screening, IBD, liver disease, obesity, dyspepsia, GERD, etc.

Gastroenterologists can survive and thrive in the new population health. Through engaging with patients, decision support and demonstrating value, we can establish our competitive advantage. Enjoy the ride!
Email can be an efficient, rapid and valuable method for physicians to communicate with patients. As physicians and patients gain comfort conversing via email, it is important to ensure that both have an understanding of the risks that can accompany such methods of communication. We do not intend to discourage the use of email to patients (the senior author has been communicating by email with patients for over a decade), but merely want to ensure that sufficient precautions are taken.

The risks associated with email communication can be roughly divided into three categories:

1. Disclosure of confidential data.
2. Failure to meet standard of care.
3. Establishment of a duty.

Disclosure of confidential data

The use of ordinary email to communicate does not have sufficient protection to meet HIPAA regulatory standards.

Disclosure of protected health information (PHI) is prohibited by law and could lead to a fine as high as $1.5 million. Revelation of certain information (i.e. HIV status, mental health issues or other highly sensitive topics) could have serious consequences for the patient. Several rules and regulations already govern this area, with the primary purpose to require physicians to take appropriate precautions to protect the privacy of PHI.

The primary laws to consider are the HIPAA Privacy Rule (2000) and the HIPAA Security Rule (2003). The HIPAA
ONIC

Privacy Rule establishes national standards to protect the privacy of PHI, introducing limits on the use and disclosure of such information without patient authorization. It applies to health plans, health-care clearinghouses and health-care providers, and business associates.

The HIPAA Security Rule requires administrative, physical and technical safeguards to protect PHI. The safeguards include (1) identification and verification of every person or system requesting access to the protected information; (2) transmission security, i.e. data integrity controls and encryption; and (3) HIPAA-compliance of business associates.

The HIPAA protections have been strengthened by two additional bills, the HITECH Act (2010) and the Omnibus Rule (2013).

Physicians must ensure that they are only communicating with patients on encrypted, secured platforms that would prevent unauthorized or inappropriate access, use or disclosure, and that only necessary people have access to such platforms.

Failure to meet standard of care

Insufficient Advice

Interaction with a patient through email rather than an office visit does not reduce the physician’s need to meet a standard of care.

Timeliness

By nature, emails allow for a slower response time than in-person interactions, and therefore create the risk that urgent queries are left unanswered. AMA H-478.997, Guidelines for Patient-Physician Electronic Mail, establishes expectations for physicians’ email responses. These include: (a) establish turnaround time for messages; (b) inform patients about privacy issues; (c) inform patients of who, besides the addressee, processes the messages; (d) retain electronic and/or paper copies of email communications with patients; (e) establish types of transactions and sensitivity of subject matter permitted over email; (f) instruct patients to provide a proper subject for filtering the message; and include their name and patient identification number.

Miscommunication

Miscellaneous issues, such as misspelling or inaccuracies in voice recognition software, forwarding the email inappropriately or responding in an offensive or sarcastic manner, could also lead to liability. Email responses are recorded onto a system and errors can be permanently recorded.

Establishing a duty

Traditionally, a physician has no legal duty to accept a patient, regardless of the urgency of the situation. However, once the physician-patient relationship is established, the physician has a duty to provide competent care to the patient and could be held liable for failure to do so. Answering email queries from people who are not patients could lead, depending on the nature of communication, to the inadvertent establishment of a duty of care, leading to liability if things go wrong.

Key precautions to minimize risk when using email

1. Use a secure email platform and protect PHI with reasonable administrative, technical and physical safeguards to ensure confidentiality and prevent unauthorized or inappropriate access, use or disclosure.

2. Establish a turnaround time and list of topics covered in email, and ask patients to avoid email use for urgent matters.

3. Take care when emailing new people to not establish a physician-patient relationship unintentionally.

4. Alert patients of potential risks and limitations of using email.

5. Ensure that all necessary information can be communicated sufficiently well by both patient and physician over email. If not appropriate for email, suggest an office visit.

This article is intended for educational purposes only, and should not be relied upon for specific legal advice. For that you must contact a health-care attorney.
Classifieds

CALIFORNIA

UCSF Fresno Gastroenterology Opportunity

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 are 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 one-half hours away. Fresno is the only major city in the country with close proximity to three national parks, including renowned Yosemite National Park.

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

Visit our websites at: www.ucsfymds.com and www.fresno.ucsf.edu

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NEVADA

Enjoy the freedom from the expenses of office overhead and liability protection; appreciate the stability and rewards of VA employment as well as other benefits including paid vacation, holidays, sick leave, health and life insurance, and a retirement plan. Moving expenses are authorized; however, the Guaranteed Home Buyout Option is not. Relocation/Recruitment incentive may be authorized.

VA Sierra Nevada Health Care System, Reno, NV is accepting applications for a BC/BE U.S. citizen gastroenterologist. VASNHC is a primary teaching affiliate of the University Of Nevada School Of Medicine. VASNHC provides an excellent patient care environment with learning, teaching, and research opportunities, a state of the art endoscopy lab, and an advanced electronic medical records reporting system. Provide a variety of therapeutic and diagnostic GI procedures, including ERCP. Share knowledge and clinical expertise with academic affiliates, professional staff, and support personnel in our interdisciplinary approach to patient-centered care delivery. Work Schedule: Full Time, Monday - Friday, 7:30 a.m. - 4:00 p.m., and shared call coverage.

Reno is located on the eastern slope of the Sierra Nevada mountain range and is minutes away from the beautiful Lake Tahoe. San Francisco is a short flight or 4 hour drive. Reno also offers excellent year round recreational opportunities and continuous cultural and entertainment events and boasts an average of 255 days of sunshine per year. Nevada has no state income tax!

VA Sierra Nevada Health Care System
975 Kirman Ave., Reno, NV 89502
775-829-5630
Lenore Reinhard, RN, Healthcare Recruiter lenore.reinhard@va.gov
775-829-5648

TEXAS

Well-established GI practice, with a superb reputation in the Northwest suburbs of Houston, Texas, is currently seeking to further enhance our already highly acclaimed group of physicians. Our esteemed group has been providing outstanding gastrointestinal and liver care for patients in the North Houston, Humble/ Kingwood and Atascocita areas for the past 28 years.

The team approach with our group and its university trained physicians, skilled medical assistants and quality nursing staff makes each patient’s experience further unique and memorable. Furthermore, we are one of the only groups north of the Texas Medical Center (the largest medical center in the world) that utilizes specialty ancillary services and offers in-house procedures and services such as:

- Onsite Ultrasound Studies
- Onsite Capsule Endoscopy and Smart Pill Endoscopy
- Onsite Esophageal Manometry and PH Monitoring Studies
- Onsite Anorectal Manometry Studies
- Onsite Hydrogen and Urea Breath Test Studies
- Onsite Hemorrhoid Banding
- Onsite Fecal Incontinence Injections (Solesta Treatments)
- Onsite Remicaid Infusion Therapy

What do we offer incoming physicians?

The possibilities are endless; however, the qualified candidate chosen will receive a highly competitive salary, a weekend call rotation of 1 in 5, and a weekly rounding responsibility of only 1 hospital in any given week. In addition, 4 weeks paid time off (2 weeks vacation, 1 week sick & 1 week for CME). Partnership opportunity with our group can be available in as little as twelve to eighteen months of service.

The position we are currently recruiting for requires an individual with the ability to work as part of a collaborative team consisting of physicians, physician assistants, medical assistants, and clerical staff. The recruited physician will enjoy...
the ease of daily operations with fully integrated electronic health records, a state-of-the-art, modern gastrointestinal diagnostic center and a fully accredited endoscopy and surgery center. EUS & ERCP trained candidates are a plus.

**Why consider Houston?**

When people think of a thriving, up and coming city, they usually don’t think of Houston... however, take another look... Houston is an economic juggernaut! Houston is by far the country’s number one city for new job creation in the market; it is the home of America’s booming energy industry, is more diverse than New York City and lets you stretch a paycheck farther than anywhere else in the country. Add that to a thriving restaurant and cultural scene, over 50K acres of parks across the city and 19 museums, and you have a winning case for Houston as the best American city.

If you’re looking for a position in a thriving economy, in a beautiful city with plenty to offer, with warm weather and endless opportunities for growth, then this may be the perfect position to consider. For more information on our group, please visit our website [www.gimed.net](http://www.gimed.net). If you are interested in learning more about this opportunity, please feel free to contact us either by email at recruiter@gimed.net or by phone at 281-453-2032.

**VIRGINIA**

A highly respected, well-established private practice in Virginia Beach, VA seeks a BC/BE, fellowship trained, gastroenterologist to join a team of 10 physicians and four nurse practitioners the summer of 2016.

The practice has one primary office location with two beautiful on-site endoscopy suites capable of performing 28-30 procedures daily and one satellite office location within easy driving distance.

We cover call and services at one hospital across the street from our primary office location.

This is a terrific opportunity for a physician looking for a stimulating practice environment with flexibility for doing full range of endoscopic procedures and research opportunities. Enjoy a four-day work week and 1:8/9 call schedule.

The practice thrives on a balance between work and family life. We offer competitive compensation and generous benefit package inclusive of vacation, CME allowance, malpractice, health and dental, LTD, Life, retirement plan and relocation assistance. A two-year partnership track is available.

The Virginia Beach area is a perfect blend of culture, beautiful beaches, entertainment, sports, nature and history. With numerous universities, Eastern Virginia Medical School, excellent public schools and many private schools, educational opportunities abound.

Requirements: BC/BE in Gastroenterology Unrestricted DEA Virginia State Medical License or Eligible for Licensure

Contact: swoodrow@gastroltd.com, 757-481-4817 ext. 3321

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