WHICH TREATMENT OPTION TO CHOOSE?

Does pneumatic dilation still have a role in the treatment of achalasia?

Articles by
Arjan Bredenoord, MD, and Joel E. Richter, MD, FACP, MACG
Note From the Editor

One of the exciting things about the field of gastroenterology is the pace of change in both our fundamental understanding of disease processes and the translation of this understanding into improved diagnostic and therapeutic strategies. This issue of AGA Perspectives illustrates several areas of rapid advance in digestive disease with implications for our patients. Achalasia remains a relatively rare disease with an incompletely understood pathogenesis. However, multiple treatment options exist and considerable excitement has been generated by the peroral endoscopic myotomy (POEM) procedure. Our point-counterpoint debate features Dr. Arjan Bredenoord advocating for POEM as the preferred approach for achalasia therapy, whereas Dr. Joel Richter advocates for a continued role for an old therapy, namely pneumatic dilation. You will find both points of view compelling.

Perhaps no topic leads to more exasperation by gastroenterologists than the proton pump inhibitors adverse event dilemma of today. This problem, and potential simple solutions for the readership are provided by Dr. Daniel Freedberg. Another frustrating disease for many decades is gastroparesis, a condition with few simple answers since the removal of cisapride from the market. Dr. Michael Camilleri provides insights into the varied mechanisms causing gastroparesis symptoms and highlights novel drugs under development as well as older drugs that may help our patients today.

Other “hot” topics in this issue include clinically meaningful disease endpoints for eosinophilic esophagitis, the emerging landscape of the microbiome in inflammatory bowel disease and finally, a counterpoint by Dr. Zobair Younossi to the recent Cochrane review that questioned the value of our new antiviral therapies for hepatitis C virus infection. With DDW and the summer around the corner, I hope you enjoy these provocative and practical perspectives.

Best,

Gary W. Falk, MD, MS, AGAF
EDITOR
@DrGaryFalk
Achalasia is a chronic disorder and hence, treatment should be aimed at the long term. Generally, there are three different treatment options for achalasia that can provide a permanent effect: pneumatic dilation, peroral endoscopic myotomy (POEM) and Heller myotomy. Endoscopic injection with botulinum toxin at the lower esophageal sphincter (LES) always has a temporary effect; after three to six months the LES pressure is back to the pretreatment state and the symptoms will have returned.

CHOSEN PNEUMATIC DILATION

GO WITH AN ALTERNATIVE

Dr. Bredenoord has given lectures for Laborie, Dr. Falk Pharma and Shire. He has received research support from Bayer, Nutricia and Given.

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Partial protection.

The best treatments for achalasia disrupt the lower esophageal sphincter (LES) improving symptoms and esophageal emptying while preventing the progression to megaesophagus. The oldest of these treatments is brusque esophageal dilation, first performed in a patient with a dilated esophagus with a whale bone by Sir Thomas Willis in 1674. Over the last 75 years, these dilators have evolved from metal expanding arms to rubber latex balloons to inflatable balloons.

PRO - CONTINUE ON PAGE 7

CON - CONTINUE ON PAGE 6

Does pneumatic dilation still have a role in the treatment of achalasia?

Arjan Bredenoord, MD

Joel E. Richter, MD, FACP, MACG

Chose pneumatic dilation or go with an alternative.
the current Microvasive Rigiflex pneumatic balloon system (Boston Scientific, Boston, MA). These balloons are a polyethylene polymer, mounted on a flexible catheter usually passed over a guidewire, 10 cm long and comes in three diameters (30, 35 and 40 mm). The original procedure seems grotesque but even as recently as 35 years ago, I recall doing this procedure with a Brown-McHardy bag with the patient in the sitting position and no anesthesia, as the idea was narcotics might relax the LES and prevent a good tear. It’s a wonder the patients ever came back, except for the fact that Heller myotomy through a thoracotomy incision was an even more morbid procedure. Fortunately, we now do pneumatic dilation as an outpatient procedure with conscious or propofol sedation and it adds less than five minutes to a standard upper endoscopy. So why is pneumatic dilation seemingly “dying art” and will I be the last dinosaur to be performing this procedure? Said another way, where have all the true esophagogists gone – maybe they are all Barrett’s specialists now? Let me try to convince you that “old is still good” and “everything that goes gone – maybe they are all Barrett’s specialists now?”

**CON - CONTINUED FROM PAGE 5**

It is easy: Done as an outpatient procedure, patients usually return to work or play the next day. As I recently described in detail,2 the procedure is added to an upper endoscopy to screen for possible pseudoachalasia. All use a graduated system beginning first with the 30 mm balloon and progressing if necessary to the 35 mm and 40 mm balloons in separate sessions over two to four week intervals. Sometimes for young healthy men, the 35 mm balloon can be used originally as their LES is more difficult to tear. Also, I always start with a 35 mm balloon after Heller myotomy as the LES scarring makes pneumatic dilation for all balloon sizes less successful.

The key to successful pneumatic dilation is accurate placement of the balloon which I prefer to do by fluoroscopy but can be done endoscopically. The balloon is located so the waist caused by the non-relaxing LES impinges on the middle oesophageal markers. The balloon is slowly distended until the waist is flattened. This usually requires 7 to 15 psi of air, which I hold for one minute while monitoring balloon position fluoroscopically. Others keep the balloon distended for 15 to 20 seconds and some do a repeat dilation before discharge to exclude a perforation. Patients can then travel home, I rest better, but they have my cell number if a later problem (rare) arises.

**Where do you stand?**

**@DrGaryFalk**

**PRO - CONTINUED FROM PAGE 8**

In approximately 1 to 3 percent of dilations a perforation occurs, which can result in mediastinitis and sepsis, prolonged hospitalization, emergency surgery and death.

On average, a single session of pneumatic dilation gives relief for five to seven years and can be repeated as necessary.
their symptoms and prevent peptic strictures. For a subset of patients, this will not even be sufficient, and they will have heartburn for the rest of their lives or develop complications of longstanding reflux disease.

Perhaps even more important reasons why not to perform pneumatic dilations are the advantages of the alternatives: Heller myotomy and POEM in particular. When one studies the results of the European Achalasia Trial carefully, it is clear that a single Heller myotomy is as efficacious as a number of pneumatic dilations. The POEM trial presented at DDW last year showed that POEM is clearly more efficacious than a series of pneumatic dilations and that it carries a lower risk of complications.

Clearly, there are also disadvantages of POEM and Heller and the results of pneumatic dilation are actually not as bad as pictured above. But a balanced view is not the desired outcome — a “Con” perspective. I leave it therefore to the reader to form an opinion after also reading the “Pro” perspective.

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Putting PPI Adverse Effects in Perspective

Daniel Freedberg, MD
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Proton pump inhibitors (PPIs) perennially rank among the top three classes of oral medications by sales in the United States. In the U.S., 10 to 15 percent of adults have used a PPI within the last year and eight to 10 percent have used a PPI within the last 30 days. Yet simultaneously there seems to be tremendous concern regarding the safety of PPIs: articles appear nearly daily describing increased risk for heart attack, kidney disease, fracture, *Clostridium difficile* infection, dementia and even all-cause death. Popularized by the lay press, these findings cause understandable consternation to our patients. What are we to do?

There is a major challenge inherent in this time-honored study design: patients who use PPIs differ at baseline from those who do not. Patients who use PPIs are older, have more comorbidities, are more likely to be hospitalized and are more likely to have hospitalizations that are long in duration with a high severity of illness. In every conceivable category, the patients who use PPIs are sicker. No one maintains that these differences were caused by the PPIs because they were present at baseline (i.e., before the patient took the PPI). But the baseline differences must be dealt with because sicker patients are also more likely to have bad outcome Y which would bias the study results. So, statistics are used to adjust for measurable baseline differences between the patients who did and did not receive PPIs, to equalize the baseline disparities between groups. The challenge comes because differences that are unmeasured, such as the differences in severity of diabetes or in the intensity of hospitalization, cannot be adjusted for: These leftover differences (called “residual confounding”) tend to increase the strength of the association between the PPI and bad outcome Y. In other words, residual confounding generates bias against PPIs. When datasets are large and observed associations are weak, small amounts of residual confounding create false associations.

Educate patients

Large retrospective studies publish relative risks, but patients should care about absolute risks. Physicians play an important patient education role in this respect. If a PPI triples the relative risk of bad outcome Y but the absolute incidence of Y is one per billion then the absolute excess risk of the PPI is $(1 \times 3) - 1 = 2$ per billion — an insignificantly small number. (In fairness this same point could be made for some drug studies purporting to show a strong relative benefit. If the study is large, the absolute benefit may be meaningless.) PPI adverse effect studies are very large and consistently show very weak relative risks which translates into exceedingly small absolute risks. Risk for enteric infections is an exception, with excess relative risks of two-to-six fold. Yet even for enteric infections this translates into small absolute risks of three to 20 per 100,000 patient-years. Small absolute risks are hard to weigh. Putting it in perspective, this risk is comparable to the annual risk of a car accident resulting in hospitalization. Will that make you stop driving?

Stop PPIs that are not indicated

The problem with PPIs is not that they are dangerous but that they are overprescribed. Many patients receive a PPI inappropriately for stress ulcer prophylaxis in the hospital, and then have the PPI inappropriately continued as an outpatient. Patients with uncomplicated gastroesophageal reflux disease (GERD) symptoms who report improvement after PPIs usually do very well with rare/intermittent PPIs. Countless patients take long-term PPIs for non-specific upper abdominal symptoms or for exclusively atypical symptoms of GERD. These patients are taking drugs that are no better than placebos. Gastroenterologists are certainly not the only physicians guilty of overprescribing PPIs but we may be in a unique position to take patients off PPIs.

Tapering PPIs takes time and effort, but it is time well spent. Rare side effects occur from PPIs like they do from all drugs (e.g., hypomagnesemia or acute interstitial nephritis). These are one in a million events but, if it happens to your patient who took a long-term PPI for a vague indication, you will regret it. Polypharmacy, which PPIs contribute to substantially, has serious consequences. Polypharmacy leads to medication errors, drug-drug interactions and demeans the medicines that actually matter. When PPIs are not indicated, they should be stopped.

Conclusion

There are sound reasons to believe that most of the adverse effects associated with PPIs are not in fact caused by PPIs. If PPIs do have serious adverse effects (e.g., increased risk for enteric infections) the absolute risks involved are so low that fear of these risks should not drive the decision of whether or not to take a PPI. When PPIs are prescribed appropriately, their benefits exceed any real or potential risks. When PPIs are not prescribed appropriately, they have no benefits and should be aggressively discontinued. [1]
Quick Hits: Patient Care

Hope on the Horizon

For Patients with Gastroparesis Symptoms

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Dr. Camilleri is vice chair of the AGA Research Foundation.
Dr. Camilleri has received research support for studies with Relamorelin.

Rochester, MN
Gastroenterology and Hepatology, Mayo Clinic, and Epidemiological Research, Division of CAMILLERI, MICHAEL

What’s new in the management of gastroparesis?

First, there is increased recognition that the symptoms of gastroparesis may result not only from delayed gastric emptying, but also from several motor or sensory disorders of the upper gut, particularly the stomach. Hence, getting the right diagnosis for the patient’s symptoms is an essential first step. The classical diagnostic approach to gastroparesis is based on the combination of symptoms of gastroparesis, absence of gastric outlet obstruction or ulceration, and delay in gastric emptying. Similar symptoms may result from impaired gastric accommodation.

In a cohort of 1,287 patients presenting to a tertiary care center with upper gastrointestinal symptoms, there was an approximately equal number with delayed gastric emptying, impaired gastric accommodation, a combination of both or absence of both. This is consistent with the recognition that “gastroparesis and related disorders” represent a broader spectrum of gastric neuromuscular dysfunction that may present with prominent symptoms such as early satiety and postprandial fullness; these symptoms may result from impaired gastric accommodation, in addition to delayed gastric emptying. This reflects the overlap of “gastroparesis” with functional dyspepsia. Impaired gastric accommodation may be recognized with validated methods where available (SPECT and MRI), or with screening tests such as the size of the proximal stomach on the gastric scintiscan taken immediately after radiolabeled meal ingestion, or by means of a water load or nutrient drink test.

A second advance is the recognition that gastroparesis results from iatrogenic causes, including bariatric and other gastric surgery and, more commonly, from medications. The two most relevant drug classes responsible for gastroparesis are all opioids and anti-diabetic medications such as pramlintide and GLP-1 agonists (e.g. exenatide and liraglutide), but not dipeptidyl peptidase IV inhibitors such as vildagliptin and sitagliptin.

A third advance in gastroparesis is the application of new medical treatments which are on the horizon or are used off label to target these underlying mechanisms. Medications should be adjusted to dietary changes: a high-fat, solid meal increased overall symptom relief for patients with functional dyspepsia.

New drugs for gastroparesis

Relamorelin is a ghrelin receptor agonist that stimulates gastric body and antral contractions, accelerates gastric emptying, and has been shown in phase 2A and 2B studies to increase gastric emptying of solids and reduce symptoms, particularly nausea, fullness, bloating and pain. Relamorelin is currently being tested in phase 3 trials which should also provide information on optimal dose of this subcutaneous treatment.

Prucalopride (1-2mg/day), a 5-HT4 receptor agonist, is approved in most countries (other than the U.S.) for the treatment of chronic constipation. It accelerates gastric emptying and was shown in a preliminary report to relieve symptoms in 28 patients with idiopathic gastroparesis.

New drugs for impaired gastric accommodation

The acetylcholinesterase inhibitor, acetobutanol, enhances gastric accommodation, relieves dyspeptic symptoms and is approved in Japan for treatment of dyspepsia.

Approved drugs used off label

Although not proven efficacious in a randomized, controlled trial in patients with gastroparesis, nortriptyline (tricyclic antidepressant) is used for relief of pain. In a study conducted in patients with functional dyspepsia, amitriptyline improved symptoms in patients who did not have delayed gastric emptying, and it modestly improved sleep quality. The typical doses for both drugs are 25mg/day.

Mirtazapine (15mg/day), with its central adrenergic and serotonergic activity, provides symptom relief for patients with functional dyspepsia, amitriptyline and has been shown in a randomized, placebo-controlled study to improve sleep quality. The typical doses for both drugs are 25mg/day.

Suggested reading

Until future superior measures are developed, or effective and accessible biomarkers are discovered, a combined and integrated assessment is most prudent.

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The problem is, we still don’t know whether the dysbiosis in IBD is the cause or the consequence — i.e. bacterial adaptation for survival — of the disease state. Very early, at the preclinical stage. My group has already shown that this is possible for CD and in principle should be even easier for UC. Such an approach might allow us to look back far enough in time to see how it all began (in addition to potentially providing opportunities to block disease progression). We are currently sequencing intestinal tissue samples from patients at disease onset and comparing them to established CD patients and controls. These data might offer clues about the role of the microbiome in IBD and might guide further research into this issue — as we complete a larger pre-clinical multicenter study in the U.S.

Clearly the answer might be more complex than the cause-or-effect question that we have asked. The truth might lie in between. For example, Haller and Buttó have hypothesized that in IBD, initial focal changes in tissue integrity might lead to focal areas of inflammation resulting in the selection of a dysbiotic bacterial community which might in turn be associated with the propagation of a disease phenotype. In other words, dysbiosis could be a consequence of inflammation and yet could drive the process once it has started. While enormous progress has been made in the technology necessary to finely map the microbial population in the gut, we still do not know what it precisely does and how it impacts disease.

Pursuing knowledge is a noble task. Finding the cause of or the cure for — IBD is a daunting one.
The Evidence Supporting the Comprehensive Benefits of the New Anti-Viral Regimens for Treatment of Hepatitis C Infection

In 2018, there is substantial evidence that the hepatitis C virus (HCV) infection is a systemic disease associated with adverse clinical, economic, and patient-reported outcomes (PROs). Specifically, the clinical consequences of HCV infection can lead to both hepatic and extrahepatic manifestations. In this context, HCV infection increases the risk of liver-related and overall mortality. Additionally, HCV infection can also negatively influence patient-reported outcomes as documented by severe impairment of health-related quality of life and lower worker productivity. Finally, there is substantial evidence that HCV infection is responsible for enormous economic burden related to the direct, indirect, and intangible costs of HCV infection to the individuals and the society. It is also important to recognize that eradicating HCV and achieving sustained virologic response (SVR, a surrogate marker for HCV cure with survival benefit) can improve clinical outcomes, economic outcomes, and patient-reported outcomes.

Although long-term post-SVR data have substantiated the benefit of SVR using the old regimens, there have been questions raised about the long-term benefits of the new all oral, interferon-free direct-acting antiviral agents (DAAs) for treatment of HCV infection. In fact, a systematic review published by the Cochrane group raised concerns about the true long-term benefits of the new DAA regimens. In the context of the conclusions of this meta-analysis, one must assess recent evidence supporting the benefits of SVR with DAAs and examine a number of issues with the Cochrane Review. It is also important to emphasize increasing evidence supporting the benefit of SVR with the new anti-HCV regimens. In a recent large study, patients who achieved SVR with either interferon or DAA containing regimens experienced significant reductions in both liver and non-liver complications and mortality. Data specifically related to the benefits of DAAs came from another systematic review and meta-analysis published in the Annals of Internal Medicine in 2017 which included 42 studies of FDA-approved DAA regimens. This study concluded that the majority of DAA regimens demonstrated great success as evidenced by their high rates of SVR. This data was further supported by another study which clearly showed the benefit of DAAs by improving the hepatic function of the liver transplant candidates with HCV leading to the delisting of these patients. In multiple other studies which were presented at the international scientific meetings in 2017, achieving SVR with the DAAs was shown to lead to a reduction in the hepatic complications in patients with HCV-related cirrhosis.

There is also substantial data that achievement of SVR with DAAs can lead to a reduction in the cardio-vascular manifestations of HCV infection as well as a significant reduction in the risk of HCC. Finally, SVR with DAA has been shown to improve patients’ survival. In fact, a study using data from Electronically Retrieved Cohort of HCV Infected Veterans, documented the mortality benefit of those HCV infected patients who were treated with DAAs. Furthermore, a large prospective analysis of data from the Therapeutic Option For Hepatitis B And C A French Nationwide Cohort Study, provides additional support of improvement in survival of patients with HCV infection who achieved SVR with DAA treatment. In addition to the clinical benefits achieved with DAAs, there is also substantial evidence that achieving SVR with DAAs can lead to improvement of PROs such as health-related quality of life (HRQL) and worker productivity. Finally, these regimens have been shown to be cost-effective in the United States and other Western countries and can bring value to the patient and the society.

In the context of this substantial mounting evidence, it is necessary to re-examine the Cochrane Review’s conclusions. Furthermore, it is important to note some methodologic flaws with this review. In fact, a number of the studies included in the Cochrane Review were non-relevant since these regimens had previously been shown to be ineffective or unsafe and could not be used in clinical practice. This is in contrast to the previously mentioned systematic review which only focused on FDA approved, clinically relevant regimens. Another flaw of the Cochrane analysis was to ignore the impact of DAA regimens on HRQL and patient reported outcomes, an important outcome of increasing importance to the FDA and Medicare.

In summary, the current evidence supports the high-efficacy and the safety of the approved DAA regimens for treatment of chronic HCV infection. In fact, these efficacy data coupled with the PRO evidence indicate that treatment of HCV with the new DAAs not only lead to high SVR rates but also to an improvement in survival and patient-reported outcomes and to a reduction in the future economic burden of HCV infection. Therefore, HCV cure by the new regimens provides comprehensive benefits not only to patients but also to the entire society.

REFERENCES

To purchase or view the available resources, please visit gastro.org/PGCR.
To Editor Dr. Gary Falk

I read the debate articles by Dr. Luke John Day and Dr. Louis Korman regarding training of non-physicians to perform endoscopy with great interest. I appreciate that both sides of the argument were presented to balance the debate. Debate is important, but some positions may not deserve equal time. It is unwise and unnecessary as detailed nicely in Dr. Korman’s position. A discussion on refining medical school and the match as well as increased funding for residencies/fellowships would be a more appropriate debate. Mid-levels (nurse practitioners (NP) and physician assistants (PA)) cannot be adequately trained as they are not physicians. Almost any person could be taught to perform a skill such as endoscopy. Other physicians such as surgeons and family medicine perform endoscopies and they help to increase access in an appropriate manner. Gastroenterology fellowship has recently increased from two years to three to four years. The training obtained in fellowship is not solely based on acquiring endoscopy skills. Mid-levels have not gone through the rigors of medical education. In addition, the education of NPs particularly is not standardized and has vastly changed.

The debate should not be viewed as an endorsement of one side or another but simply a platform for debate. That said, this article in no way reflects AGA’s position on any standards set by physicians can easily be circumvented through legislation. With recent aggressive lobbying, mid-levels are already practicing medicine under the guise of advanced practice nursing in many states. NPs have independent or unsupervised practice in 23 states, the District of Columbia and counting. There is an interstate compact bill in the Nebraska legislature for reciprocity of their licenses across states. There is a bill to offer a Doctor of Medical Science (DMS) to some PAs in Tennessee. Pharmacists and psychologists are also pushing for more independence in prescribing medications.

In some states, nurse anesthetists (CRNA) perform independent of physician anesthesiologists. A patient could see a family nurse practitioner (FNP) and have a colonoscopy or other procedure performed by a NP and anesthesia administered by a CRNA and never see a physician? Will a mid-level adequately treat ulcers, manage Crohn’s disease or screen for colon cancer syndromes? Physicians must take a better stand in protecting our patients. Primary care physicians, emergency medicine and hospitalist/intensivists have been replaced by mid-levels in some areas. Patients may be encouraged to see the mid-levels because “it’s the same as seeing the doctor” or “you will get seen faster” or “she is really nice.” Patients are unaware or misinformed of the difference in education and clinical training.

Many gastroenterologists can attest to increased unnecessary referrals and testing from mid-levels due to minimal or lack of supervision. This often backlogs specialists’ referrals and increases patient wait times contributing to the perceived physician shortages. Like many gastroenterologists, I work well with mid-levels in my practice. There is a well-defined role for mid-levels in GI care within a physician-led model. The role does not include performing endoscopies.

Sincerely,

Suwebatu T. Ojudi-Shiyabude, MD

Gary Falk’s Response

I have the privilege of serving as editor of AGA Perspectives, an AGA magazine which prides itself on providing perspectives on a variety of current issues in gastroenterology and hepatology including controversial topics in the field. A recent debate on the topic of training non-physicians to do endoscopy has resulted in considerable interest. While the “NO” side of the debate has received a little over 800 views online, the “YES” side has received more than 7,000 views in less than one month. I would like to remind our readers that the point-counterpoint debate is just that – a debate on an ongoing controversial issue in digestive diseases. The debate should not be viewed as an endorsement of one side or another but simply a platform for debate. That said, this article in no way reflects AGA’s position on this topic and the opinions expressed are solely those of the author.

I encourage AGA members to share their thoughts on this topic here. If this is an issue that matters to you, we should continue the healthy dialogue graciously started by Drs. Luke John Day and Louis Korman and help AGA know where members stand on this topic.

Thank you all for your comments and opinions so far. Because AGA Perspectives is a forum for opinions, we welcome this open dialogue surrounding its content.
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