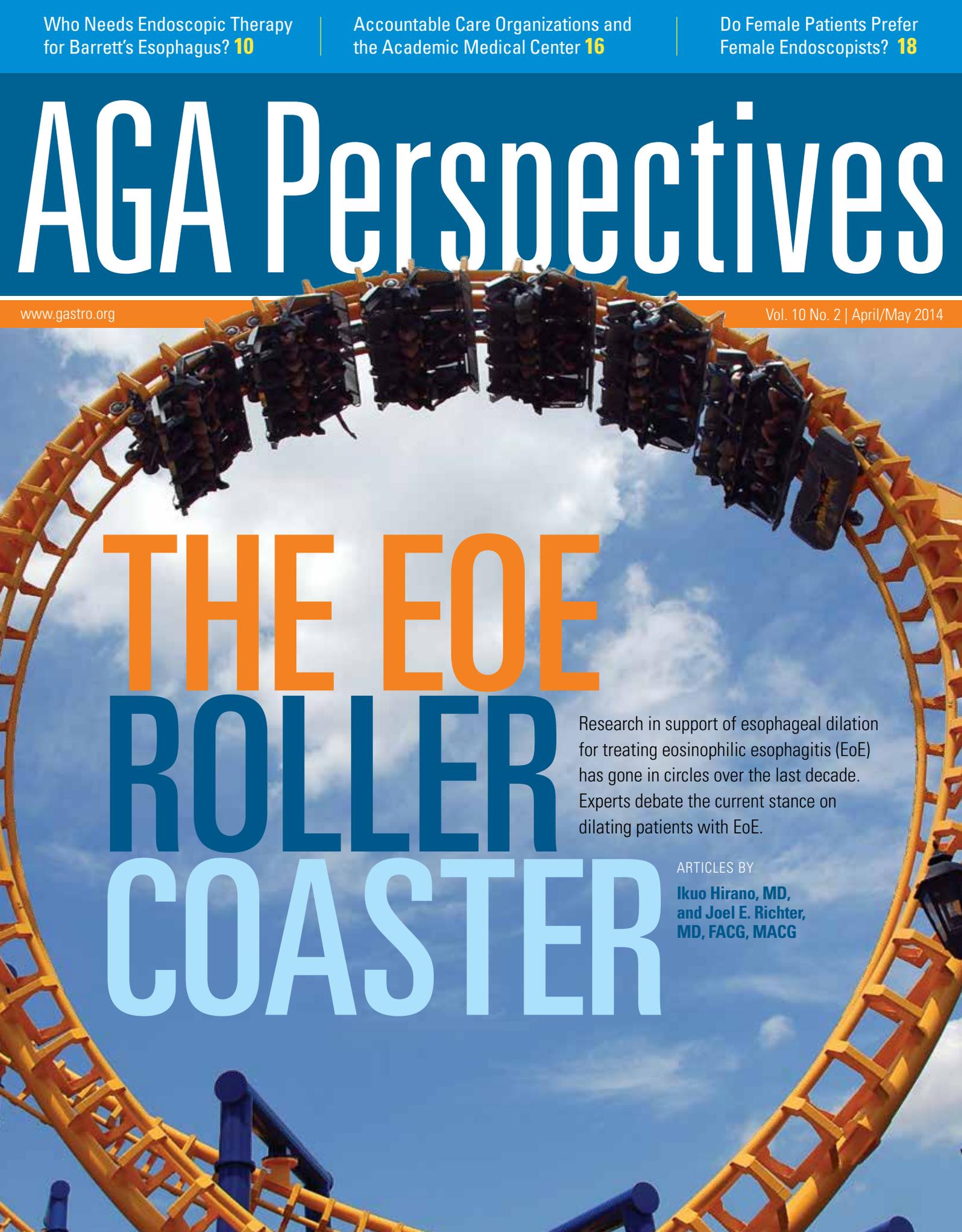


# AGA Perspectives

www.gastro.org

Vol. 10 No. 2 | April/May 2014



## THE EOE ROLLER COASTER

Research in support of esophageal dilation for treating eosinophilic esophagitis (EoE) has gone in circles over the last decade. Experts debate the current stance on dilating patients with EoE.

ARTICLES BY

**Ikuko Hirano, MD,  
and Joel E. Richter,  
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## In this issue

# THE EOE ROLLER COASTER

Experts debate the current stance on dilating patients with EoE.

ARTICLES BY

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Funding for *AGA Perspectives* is  
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*AGA Perspectives*, ISSN 1554-3366 (print) and ISSN 1555-7502 (online), is published bi-monthly by the AGA Institute, 4930 Del Ray Ave., Bethesda, MD 20814.

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# Note From the Editor



This issue of *AGA Perspectives* provides a focus on the esophagus, particularly Barrett's, but also management of dysphagia and eosinophilic esophagitis. Barrett's continues to be an area of controversy with a strong disconnect between the compelling data that it is a major risk factors for adenocarcinoma of the esophagus and the efficacy of ablations dysplastic lesions, contrasted with a general lack of data on efficacy of endoscopic screening and surveillance. We all have clear cases where an early cancer was detected and managed endoscopically with many cutting-edge new tools. In this issue, many of the leading investigators in these fields discuss whom to screen and survey and whether to perform endoscopic ablation and resection therapy. While these articles will not end the controversy, they provide valuable insight from the experts on dealing with these patients.

This is also the spring season which brings our annual epidemic of eosinophilic esophagitis into the forefront. It's appropriate that we discuss whether or not to dilate eosinophilic disease of the esophagus. Drs. Hirano and Richter, two of the world's leading esophagologists, provide contrasting opinions on whether we should dilate in this setting.

We round out the issue with important topics related to accountable care organizations and how to plan for them, a very nice discussion on preparing for an advanced endoscopy fellowship, and last but not least, a superb discussion on how to manage female patients requesting a female gastroenterologist/endoscopist. I hope you enjoy this issue.

**Michael B. Wallace, MD, MPH**  
EDITOR

We welcome member feedback on all of the perspectives presented in this issue. Send your letters and comments to [communications@gastro.org](mailto:communications@gastro.org) and include "AGA Perspectives" in the subject line.

## TAKE THE DISCUSSION ONLINE

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# TAKE A RIDE ON THE EOE ROLLER COASTER

Research in support of esophageal dilation for treating eosinophilic esophagitis (EoE) has gone in circles over the last decade. Experts debate the current stance on dilating patients with EoE.



## DILATE YOUR PATIENTS WITH EOSINOPHILIC ESOPHAGITIS

**T**he odyssey of esophageal dilation for treating eosinophilic esophagitis (EoE) has been like a roller coaster going up and down. While at the Cleveland Clinic, we reported the first series of patients with ringed esophagus treated with esophageal dilation.<sup>1</sup> All had eosinophils on their biopsies but the term “eosinophilic esophagitis” had not yet come into vogue in the adult GI world. These 19 patients (mostly young men) were treated with PPIs and careful dilation to 14 to 15 mm. Telephone follow-up after two years found all but one patient doing well with their dysphagia decreased from daily to one-to-two times a month. Two years later, Straumann *et al.*<sup>2</sup> presented similar results in 30 adult EoE patients of whom 11 required esophageal dilation, with on average, nine months of dysphagia relief.

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## DO NOT DILATE YOUR PATIENTS WITH EOSINOPHILIC ESOPHAGITIS

**E**osinophilic esophagitis (EoE) is a “chronic, immune/antigen-mediated esophageal disease characterized clinically by symptoms related to esophageal dysfunction and histologically by eosinophil-predominant inflammation.”<sup>1</sup> The rapid rise in prevalence of EoE over the past two decades is not only the result of increased recognition, but also likely a reflection of the rise in atopic disease in general. While no therapies have yet been approved by the U.S. Food and Drug Administration, a number of medical and diet therapies have demonstrated clinical effectiveness in prospective and randomized controlled trials. My opponent, a leading authority in the field of esophagology, champions esophageal dilation as the most appropriate, primary therapy for EoE. While I have the utmost respect for Dr. Richter, I believe that he should put down his “weapon of massive dilation” in favor of an evening of refined dining with an elimination diet.

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However, 2003 to 2010 was marked as the “dark ages for EoE esophageal dilation” as isolated letters and case reports suggested that dilation could kill your patient, it did not work and the complication rates were high (5 percent perforation rate and 7 percent hospitalized for chest pain). Based on these commentaries, the 2007 EoE Consensus Conference



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*Dr. Richter has no conflicts to disclose.*

recommended that medical and dietary therapy for EoE be attempted before the performance of esophageal dilation.

In 2010, the “enlightened renaissance” for esophageal dilation was heralded by three separate reports (two U.S., one European) confirming average relief of dysphagia for 22 to 24 months with minimal complications and no perforations.<sup>3-5</sup> The world of EoE is now a better place with the 2011 consensus report noting that “healthy young and middle-aged patients, who, if given the option, might prefer periodic dilation to regular use of a medication or an elimination diet.”<sup>6</sup> Nevertheless, many community gastroenterologists are still reluctant to dilate their EoE patients, especially those with fibrostenotic disease. Here are my recommendations after dilating more than 200 EoE patients in the last 15 years with only two hospitalizations for painful esophageal tears responding to medical therapy.

**1. It works!** The three recent studies<sup>3-5</sup> in 109 EoE patients found clinical improvement in 91 percent of EoE patients treated only with esophageal dilation to esophageal diameters of 16 to 17 mm. The mean number of dilation sessions was two and average symptom relief was 22 to 24 months. Complications were rare — only three mucosal tears and no perforations. However, the mucosal eosinophil count did not change. These results are identical to my personal experience in three regions of the U.S. — Cleveland, Philadelphia and South Florida — and much longer than any reported success with anti-inflammatory medications reported in the literature.

**2. It's easy and adds only two to three minutes to an endoscopy session.** Since the esophageal lumen can be narrowed in multiple sites or diffusely, I prefer Savary Guilliard or Maloney bougies as my dilators of choice. They give superior tactile assessment of lumen narrowing as the bougies gradually increase the diameter along the entire length of the esophagus. Others advocate TTS balloons preferring the better control with radial dilating forces and the ability to immediately assess the degree of esophageal tearing. However, the balloons are cumbersome as they may need repositioning several times to span a narrowed esophagus, the procedure is more time consuming and the TTS balloons are not reusable and thus more expensive.

**3. The stricture did not develop overnight, so don't rush the dilation.** My goal is to eventually get the patient to a bougie diameter of 16 to 18 mm where they can eat a regular meal and have no fear of food impactions. The more severely narrowed the esophagus (i.e., less than 9 mm),

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## Therapy of EoE: a novel treatment paradigm for a novel disease

Since the 16th century, esophageal dilation has been the primary means of therapy for dysphagia associated with esophageal strictures. Over the years, this strategy has been a highly effective means of dealing with achalasia, Schatzki ring, cervical webs, peptic strictures and radiation strictures. In the new millennium, EoE has rapidly emerged as a leading cause of dysphagia amongst adults.<sup>2</sup> There is little doubt that esophageal dilation is a highly effective means to deal with the fibrostenotic manifestations of EoE. EoE, however, is a novel disorder with an immune pathogenesis that is distinct from the previously mentioned esophageal disorders. The notion that dysphagia might respond to medications or elimination of dietary antigens is an innovative and foreign concept. The primarily food-antigen stimulated, Th2 inflammatory response in EoE induces remodeling effects that are mediated by IL-5, IL-13 and TGF $\beta$ 1.<sup>3</sup> The resultant transmural, structural alterations are evidenced by histologic identification of esophageal subepithelial fibrosis and ultrasonographic detection of marked expansion of the mucosa, submucosa and muscularis mucosa.



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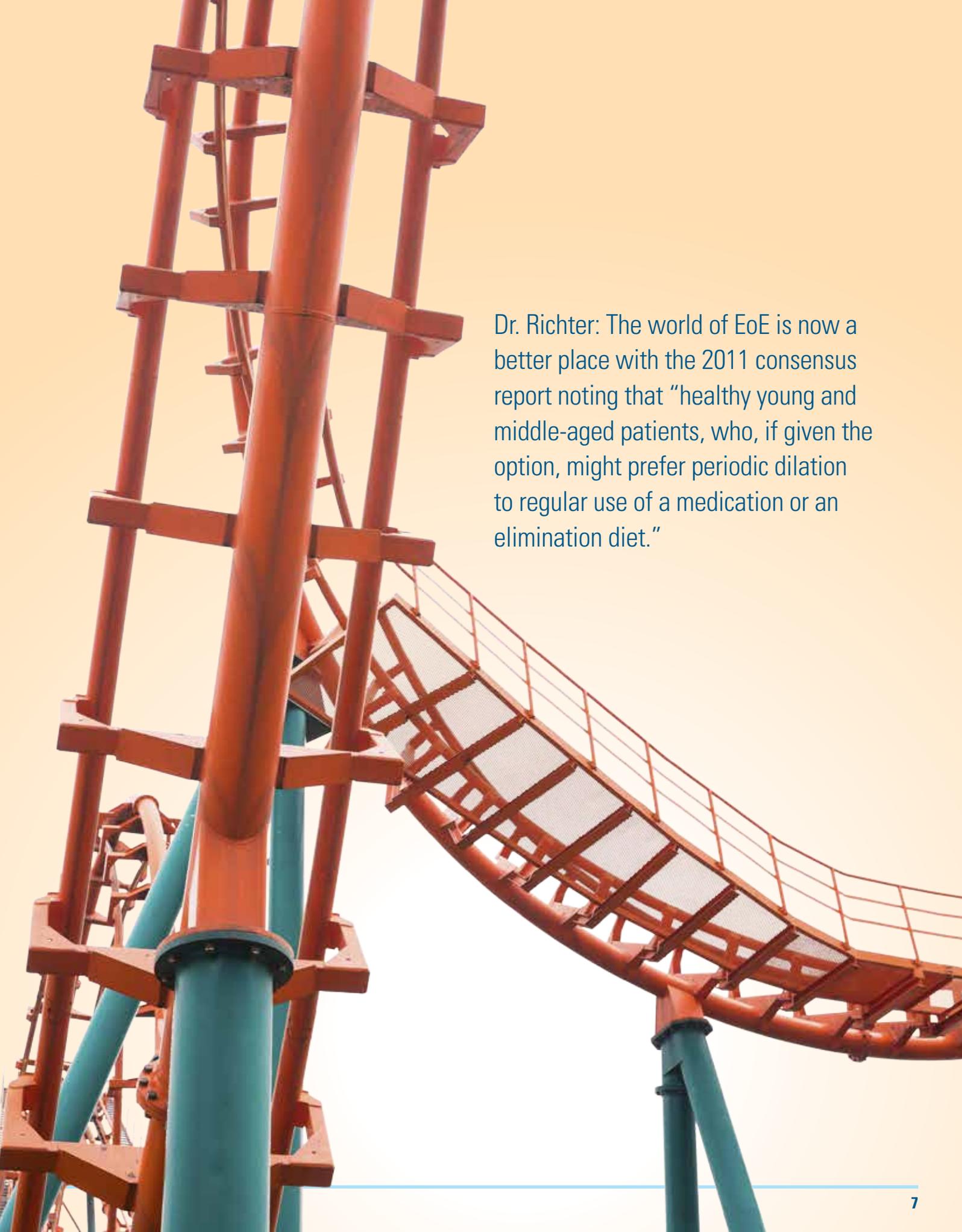
In clinical practice, the remodeling can be macroscopically apparent in the form of esophageal strictures and narrow caliber. Esophageal distensibility measurements using the functional luminal imaging probe provides detailed quantification of esophageal remodeling in EoE.<sup>4</sup> Reduced distensibility in EoE has been associated with the outcome of food impaction risk.<sup>5</sup> Furthermore, recent studies have demonstrated that the duration of untreated EoE is a major risk factor for the development of esophageal stricture, with the prevalence of stricture doubling with each decade of untreated disease.<sup>6</sup> It stands to reason that the primary treatment of EoE should be directed at arresting this inflammation to prevent future stricture development and not just focus on existing strictures.

Decades of experience, and Dr. Richter's own pivotal clinical trial in GERD, have demonstrated that healing of erosive esophagitis is associated with reduced dysphagia and reduced need for esophageal dilation in the management of esophageal peptic strictures.<sup>7</sup> Why should the management of strictures in EoE, also the result of chronic esophageal inflammation, be viewed any differently? Furthermore, fibrosis is not the only determinant of reduced luminal caliber in EoE. Mucosal/submucosal inflammatory infiltration or “edema” is evident endoscopically, histologically and endosonographically. Motility effects of esophageal eosinophilia have also been characterized as direct or indirect consequences of remodeling.

## Don't forget the kids!

The argument that esophageal dilation is appropriate therapy for patients with EoE does not apply to children. Children with EoE present with symptoms of pain, food aversion, nausea and

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Dr. Richter: The world of EoE is now a better place with the 2011 consensus report noting that “healthy young and middle-aged patients, who, if given the option, might prefer periodic dilation to regular use of a medication or an elimination diet.”

## DILATE - CONTINUED FROM PAGE 6

then the patient will likely need two-to-three sessions separated by three-to-four weeks to reach this goal. The “rule of threes” has not been tested in EoE, but moderate resistance and blood on the dilator are indications to halt the dilation session.

**4. Don't look for esophageal tears; they will only worry you!** There is no data that the presence of mucosal tears represent anything more than a successful dilation as the extent and depth of these tears do not correlate with chest pain, the need for narcotic analgesia or hospitalization. Rather, my management is guided by the post-dilation clinical scenario and monitored by telephone calls.

**5. No pain, no gain!** All patients are forewarned about the potential of mild-to-moderate post dilation pain. Pain may last three-to-four days and usually responds to OTC analgesia and rarely requires narcotics. In the Swiss experience<sup>3</sup>, 74 percent of patients experienced post-dilation pain, but more than 75 percent found esophageal dilation a simple method of treating EoE and would do it again.

**6. It's safe if performed properly.** According to Evan Dellon, almost 500 EoE patients representing nearly 1,000 dilations have cumulatively been reported and there have been three esophageal perforations and no deaths.<sup>7</sup> This rate

(0.3 percent) is not dissimilar to that quoted for standard esophageal dilation in a non-EoE population.

**7. It's cost effective.** A preliminary report from Vanderbilt estimated a six-week course of fluticasone at \$740, whereas esophageal dilation without adverse events was \$840. Patients with severe disease may require prolonged medical therapy with possible adverse steroid effects; while on average EoE patients require dilation only every other year.

**8. It remodels and may permanently open the esophagus.** After esophageal dilation, the esophagus does not rapidly return to its original narrowed state. In fact, serial dilation acutely and maintenance dilations on average biannually remodels the esophageal rings and strictures, thereby allowing the prolonged relief of dysphagia and fear from food impaction.

Yes, Dr. Hirano, I do use swallowed steroids and elimination diets selectively — primarily in my patients with the inflammatory EoE profile or those with fibrostenotic disease who still have more than 25 eosinophils/hpf after a two-month PPI trial. However, more than 70 percent of my patients, especially those with fibrostenotic EoE, are very happy on PPIs with periodic esophageal dilation. Give it a try — it's easy and your patients will like it. ■

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## DO NOT DILATE - CONTINUED FROM PAGE 6

vomiting that often mimics a pediatric presentation of GERD.<sup>8</sup> Dysphagia, food impaction and esophageal strictures are unusual manifestations in children.<sup>9</sup> Similarly, not every adult with EoE has evidence of esophageal stricture. Tissue inflammation is likely an important determinant of symptoms in these particular cohorts, with downstream remodeling consequences.

## Complications of esophageal dilation: “Richter-scale” rifts in the esophagus

Esophageal dilation is not without risk. Early reports of esophageal perforations occurring from dilation, endoscopic extraction of food impaction and even diagnostic endoscopy raised substantial concern regarding the safety of dilation in EoE. While subsequent, larger series have reported greater safety in the performance of dilation, complications still occur.<sup>10</sup> Deep, intramural crevices extending for several centimeters are common following dilation in EoE. A large series from Mayo clinic identified three perforations and one episode of major hemorrhage as a result of dilation in 161 patients.<sup>11</sup> In the largest reported series, our group in conjunction with Drs. Schoepfer and Straumann reported no perforations in 474

dilations in 207 patients.<sup>12</sup> Severe, post procedural chest pain, however, is common with several reported cases that have required inpatient evaluation. Based on a patient questionnaire, 74 percent reported chest pain after dilation.<sup>10</sup> In Dr. Richter's early study with Dr. Morrow, 19 patients with a ringed esophageal and esophageal eosinophilia were treated with dilation and “several patients” required narcotic analgesics for chest pain.<sup>13</sup> Moreover, the reported safety of dilation is based on reports from specialized centers for esophageal disorders. The increased safety of dilation reported in recent years likely reflects the experience of clinicians who have adopted a more conservative approach to dilation in EoE.<sup>7, 10</sup>

## Can medical and diet therapy reverse or prevent existing esophageal strictures in EoE?

Numerous studies have demonstrated the clinical effectiveness of medical and diet therapies in the absence of esophageal dilation. Both forms of therapy result in convincing reduction and in many cases complete histologic normalization of eosinophilic inflammation. Evidence also points to reductions in esophageal remodeling. Significant improvement in esophageal diameter, albeit modest, has been demonstrated in a prospective trial with caliber quantified by means of barium esophagram.<sup>14</sup>

Symptom improvement in dysphagia has generally tracked with a reduction in eosinophilic inflammation in several, but not all, prospective trials using both elimination diet and topical steroids.<sup>15-19</sup> In a randomized placebo-controlled trial, Dr. Straumann demonstrated that budesonide decreased dysphagia severity, esophageal eosinophilia, subepithelial fibrosis as well as TGF $\beta$ 1 expression after only 15 days of therapy.<sup>17</sup> Furthermore, his one-year, follow-up maintenance trial of low-dose budesonide led to a significant decrease in mucosal thickness measured by endoscopic ultrasonography.<sup>20</sup> Lucendo and colleagues demonstrated a reduction, albeit non-significant, in subepithelial fibrosis and significant reduction in fibrosis mediators following a year of topical fluticasone in adults with EoE.<sup>19</sup> Studies in pediatric EoE have demonstrated a reduction in subepithelial fibrosis in patients treated with both topical steroids and elimination diet.<sup>21</sup> Together, these studies provide evidence that medical therapy can at least partially reverse existing remodeling effects in EoE.

### Clinical guidelines for dilation: what are the evidence and consensus recommendations?

Consensus statements for EoE endorsed by three major medical societies have recommended “careful” esophageal dilation for patients failing medical or diet therapies or those with severe stenosis. Dilation was not recommended as primary therapy to be used in isolation.<sup>1, 22, 23</sup> My opponent, Dr. Richter, was in fact a co-author on these guidelines, and has thereby endorsed this approach. Retrospective data have demonstrated that medical therapy for EoE can reduce the utilization of esophageal dilation in EoE. Furthermore, a recently completed randomized controlled trial completed by Dr. Vaezi and colleagues compared esophageal dilation combined with medical therapy to medical therapy alone in adults with EoE (personnel communication). No difference in the primary outcome of dysphagia was demonstrated, again highlighting the effectiveness of medical therapy in EoE.

Clearly, more work is needed to fully understand the role of medical and diet therapies in reversing the remodeling effects in EoE. Remodeling is a fundamental determinant of both the clinical symptoms and major complications of EoE.<sup>24</sup> While

Dr. Hirano: Dilation should only be done with discretion and viewed as adjunctive therapy, targeting aspects of esophageal remodeling that are not amenable to medical and diet therapies.

esophageal dilation is effective and generally safe, it does nothing to arrest the chronic inflammatory process that leads to strictures.<sup>12</sup> Dilation should not be utilized for children and adults with an inflammatory phenotype that lacks the symptoms or signs of fibrostenosis. Medical and diet therapies, therefore, remain fundamental to the appropriate management of EoE to eliminate active inflammation and prevent the progression of esophageal fibrostenosis.

Should we dilate? Yes, but dilation should only be done with discretion and viewed as adjunctive therapy, targeting aspects of esophageal remodeling that are not amenable to medical and diet therapies. ■

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# WHO NEEDS ENDOSCOPIC THERAPY FOR BARRETT'S ESOPHAGUS?



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Takeda Pharmaceuticals and Oncoscope. He is a  
consultant for Oncoscope.*

**Y**ou have been to the national meetings, have seen the training videos and have convinced your hospital to make the investment in equipment to do endoscopic ablative therapy. Now comes the hard question: who do you treat?

In reality, this is a question that you should have asked yourself before you obtained the equipment. When contemplating any endoscopic service, you need to ensure that you will have adequate volume to stay proficient in the technique. If you are in a solo or small practice which sees few patients in need of endoscopic therapy, it may be better to refer those patients to someone doing higher volumes, since that endoscopist is likely to be better at the procedure than you are. On the other hand, if you are in a large practice, or will receive referrals from other practitioners in your community to do endoscopic therapy, then it makes sense to move forward.

The next hurdle you face is how to get trained. It is difficult in the U.S. for the working clinician to get training in new procedures, and it is difficult for hospitals to decide what experience is necessary to credential a practitioner in advanced procedures. Our professional organizations have moved to address these shortcomings with hands-on courses, training centers and visiting-clinician programs. However, even with these venues, the vital, proctored, hands-on experience necessary for competence is often lacking. Pragmatically, for this procedure, I would suggest that the practitioner at minimum undergo a formal didactic session on the procedure (available at many societal venues), and then perform multiple procedures proctored by a physician experienced in the procedure. How many is enough? Ideally, our yardstick for competence would be criterion-based, and not number-based (i.e., have they mastered the skill?). But from training many fellows, I would suggest that, for radiofrequency ablation, at least five balloon-based

and five focal procedures are necessary at minimum to become familiar with the equipment.

Who you choose to treat should reflect an understanding of the risks of the procedure, the efficacy of the procedure and the risk of cancer in the patient if left untreated. While some of these variables are still somewhat unclear, recent literature sheds light on these questions. The only current risk stratifier, degree of dysplasia, strongly predicts cancer risk. Patients with Barrett's esophagus (BE) and high-grade dysplasia (HGD) have an annual risk of progression to cancer of 6 to 19 percent; conversely, annual progression rates for those with BE and no dysplasia are 0.2 to 0.6 percent.<sup>1</sup> The risks of the procedure, however, are relatively static regardless of the degree of dysplasia, and vary in most series between 3 to 10 percent overall, with stricture being predominant. With respect to the efficacy of endoscopic therapy, while there is some variability in the literature, a relative risk reduction of 70 to 90 percent seems achievable.

In light of these numbers, who with BE to treat with endoscopic therapy becomes clearer. Patients with intramucosal cancer and patients with HGD have an aggressive natural history. Further, both of these lesions have a morbid competing management strategy, esophagectomy. Additionally, in the case of HGD, level-one evidence demonstrates that radiofrequency ablation results in a high rate of reversion to neosquamous epithelium and a low rate of progression to cancer.<sup>2</sup> Therefore, endoscopic ablative therapy is the strategy of choice in these patients.

For patients with BE and low-grade dysplasia (LGD), rates of progression to cancer are lower (1 percent or so in meta-analyses). However, recent level-one data demonstrate a marked decrease in the risk of progression to HGD and cancer in subjects with LGD undergoing ablative therapy, compared to controls undergoing endoscopic surveillance.<sup>3</sup> Given the large relative risk

reduction associated with endoscopic therapy, the risk of progression in the untreated patient, and the good safety profile of the intervention (at least as demonstrated with radiofrequency ablation), BE with LGD confirmed by a second pathologist is appropriate for consideration of ablative therapy. This is especially true in the younger patient with few co-morbidities, who presumably has a large number of life-years at stake.

Is ablative therapy appropriate for patients with non-dysplastic BE? Unlike the case for BE with HGD or LGD, no level-one evidence demonstrates a protective effect of ablative therapy in such subjects. The number of patients needed to be enrolled in such a study makes it a prohibitive undertaking. Our inability to stratify risk in the large number of non-dysplastic BE patients makes it difficult to target therapy. Indeed, for every 20 such patients treated with endoscopic therapy, 19 or more would likely accrue no benefit, because they were never destined to develop cancer in the first place. All 20 patients would, however, assume the risks and costs of the procedure.

In the case of subjects with non-dysplastic BE, this calculus might be changed if we could use additional risk factors to identify a subgroup of patients at higher risk for progression. Few such predictors are available in common clinical practice. The length of the BE segment appears to be such a risk factor,<sup>4</sup> although its strength as a stratifier of risk is not clear. Similarly, age appears in some studies to be a predictor of cancer risk. Unfortunately age may also predict risk of complications of endoscopic therapy. Family history of BE or esophageal adenocarcinoma in multiple first- and second-degree relatives may identify a subgroup of patients with a different risk profile as well.

As long as the risk-benefit calculus of ablative therapy in subjects with non-dysplastic BE remains unsettled, it is premature to offer ablative therapy to all such subjects in your practice. In my practice, I have offered ablative therapy to non-dysplastic BE patients with a family history of esophageal neoplasia, as well as patients with substantial long-segment BE (greater than 5 to 6 cm) at a young age; these subjects represent less than 5 percent of the total population treated with ablative therapies at our center. Further work will tell whether these applications of ablative therapy in the non-dysplastic population are appropriate.

For the remainder of patients with non-dysplastic BE sent for consideration of endoscopic therapy, we continue to recommend periodic endoscopic surveillance at three-to-five year intervals. We also acknowledge that the value of endoscopic surveillance is unknown, and this strategy may not be protective against death from cancer.<sup>5</sup> In addition, we re-emphasize to them their low risk of progression. We also tell them that both technology and our knowledge base about BE will continue to march forward. Even a five-year delay in endoscopic therapy is likely to bring substantial improvements in technique and outcomes — consider the evolution of these technologies in the previous decade! The additional data we collect while a non-dysplastic BE patient undergoes a cycle or two of endoscopic surveillance might clarify who with non-dysplastic BE should be selected for more aggressive therapy. Whether it is a biomarker panel, a cumulative risk score or other clinical indicators which predict risk, such data will eventually allow us to pick those BE patients most likely to progress to cancer, and to focus our efforts and attention on them. ■

Who you choose to treat should reflect an understanding of the risks of the procedure, the efficacy of the procedure and the risk of cancer in the patient if left untreated.

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# BARRETT'S ESOPHAGUS IS IT TIME TO STOP LIFELONG SURVEILLANCE?



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*Drs. Gaddam and Sharma have no  
conflicts to disclose.*

**B**arrett's esophagus (BE) is a well-established risk factor for esophageal adenocarcinoma.<sup>1</sup> Based on SEER database studies, the incidence of esophageal adenocarcinoma has been dramatically rising in the last three decades.<sup>2</sup> Due to lack of alternative interventions to stem the rise of esophageal cancer, the focus has remained on diagnosis and surveillance of patients with BE. Therefore, current guidelines by all GI societies recommend enrollment of patients with BE in surveillance programs.

For many years now, endoscopic surveillance of all patients with BE seemed to make sense. Previous studies showed high risk of esophageal cancer in non-dysplastic BE (approximately 1 to 2 percent/year) and, based on small retrospective surgical case series, there appeared to be some merit to endless continued surveillance. However, over the last few years, several important papers were published that have changed our understanding of the natural history of non-dysplastic BE. In 2011, Hvid-Jensen *et al.* reported a low annual incidence of esophageal cancer of 0.12 percent in a large population-based cohort study on 11,028 Danish patients with BE.<sup>3</sup> This was lower than

the previously reported rate of 0.5 percent per year. Furthermore, a cohort study published by our group last year showed that this low risk of cancer was non-linear; the risk of cancer appeared to decrease over time<sup>4</sup> — especially after five negative surveillance endoscopies. A case-control study based on the U.K.'s Clinical Practice Research Datalink, showed that only 2 percent of BE patients died of esophageal cancer over a 10-year period — they were more likely to die from other unrelated causes. Finally, in 2013, Corley *et al.*, in a case-control, community-based study showed that surveillance offered no mortality benefit from esophageal adenocarcinoma.<sup>5</sup>

So is there any alternate to surveillance; can we ablate the BE and forget surveillance or should we do nothing? There has been great interest in the long-term durability of a wide variety of endoscopic eradication therapies that are available today. A landmark paper by a multi-center randomized controlled trial, published in 2009, showed promising short-term results with successful eradication of dysplasia and intestinal metaplasia by radiofrequency ablation.<sup>6</sup> In the BE research community, there was



a sense of excitement about the availability of safe and effective treatments for non-dysplastic BE with the hope of achieving a “cure.” However, the recent data on low progression rates and recurrence rates up to 25 to 30 percent during long-term follow up have curbed our enthusiasm in this regard; complete eradication of intestinal metaplasia has been shown to be anything but perfect, leading to surveillance (again) post ablation — not a cost effective approach as shown by Hur C. *et al.*<sup>7</sup>

The other alternative is not doing anything i.e., are we ready to abandon ship on surveillance and ablation? For sure in those individuals with irregular z lines or intestinal metaplasia at the gastroesophageal junction, doing nothing appears to be appropriate. How about the other BE patients? Risk stratification is the key! While we are waiting for the right panel of biomarkers, there has been progress in assessing clinical and endoscopic features for predicting high-risk BE patients. A risk stratification tool based on a multicenter cohort of 3,600 patients

**60 YEARS AFTER THE FIRST REPORTED CASE,**  
there is not even a definition for Barrett’s esophagus that is accepted worldwide.

using endoscopic and clinical/demographic factors to predict patients that are likely to have or progress to high-grade dysplasia or cancer was recently reported.<sup>8</sup> This is currently in the process of external validation and if successfully validated, it will help

risk stratify patients based on clinical and endoscopic features alone. We hope that a panel of biomarkers, combined with clinical and demographic factors will eventually be identified that are capable of predicting high-risk patients who are likely to progress to cancer. These patients may require intensive surveillance or primary prevention with safe and effective endoscopic eradication.

Barrett’s esophagus continues to be an area of controversy; this is evident in the fact that even 60 years after the first reported case, there is not even a definition for BE that is accepted worldwide. Similarly, in the field of surveillance of BE, the data are continuously evolving. Despite the vast improvement in our understanding of the disease over the last two decades, BE continues to be “unfinished business” that challenges researchers. The question “is it time to stop surveillance on my Barrett’s patients?” is a difficult one to conclusively answer at this time, but the newer data certainly point us away from lifelong surveillance. ■

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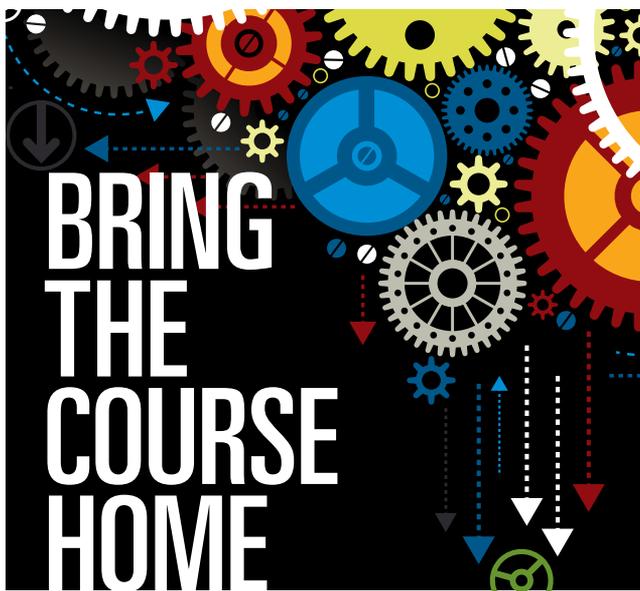


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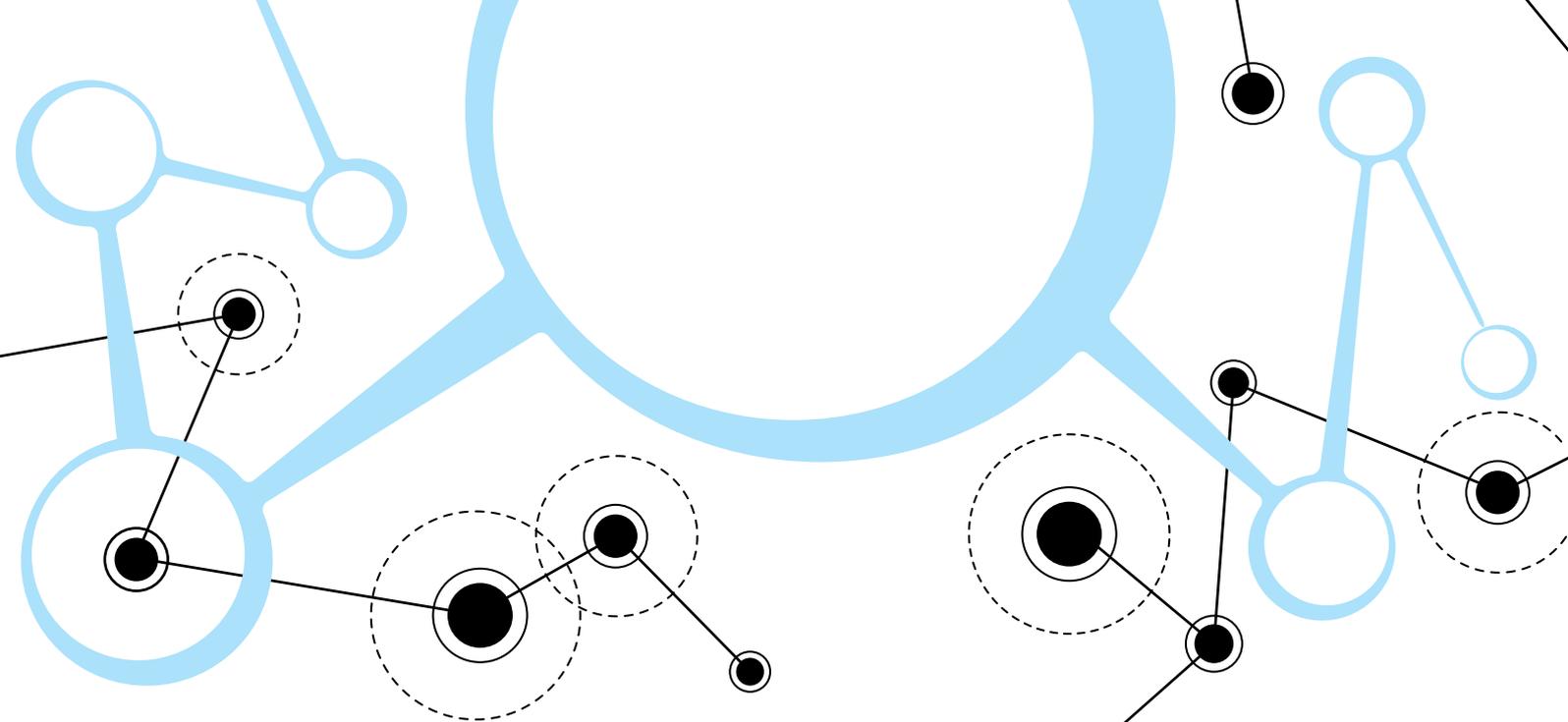
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# ACCOUNTABLE CARE ORGANIZATIONS

## AND THE ACADEMIC MEDICAL CENTER



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*Mr. Viviano has no conflicts to disclose.*

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The term accountable-care organization (ACO) is widely used in today's health-care environment, but the definition remains imprecise and somewhat ambiguous. In short, the two ways to approach the term include the "official" definition and the broader use that is becoming increasingly common today. The formal definition from CMS is a "groups of doctors, hospitals and other health-care providers, who come together voluntarily to give coordinated high-quality care to their Medicare patients." CMS has launched pilot projects or "official" ACOs that were established by the Affordable Care Act and include programs such as the Medicare Shared Savings Program, the Advance Payment ACO Model and the Pioneer ACO Program, which hospitals and health-care providers can electively join. While this form of ACO now covers more than five million people in the U.S., the more generic term is expected to also add to the transformation of the landscape of the health-care industry.

In the absence of establishing an official ACO through Medicare, the term can also refer to

ACO = group of doctors, hospitals and other health-care providers, who come together voluntarily to give coordinated high-quality care to their Medicare patients.

the general direction in which many health-care organizations are beginning to structure themselves. Health-care entities are forming joint ventures, clinically integrated networks

and formal partnerships with the continuum of care and creating value as the main focuses. There is also a push to develop health plans that efficiently manage risk-based contracts. With the changes underway through the Affordable Care Act, the success of an organization may rest in its ability to manage population health as a whole. Promotion of strong preventive and primary care as main pillars of a system's agenda is one of health care's major themes. The responsibility of health-care organizations shifts from simply diagnosing and treating disease to educating patients and promoting healthy lifestyles. Organizations become focused on caring for a patient across the entire continuum of care, from pre-admission to post-discharge. The integration and coordination within an organization that is extended to its affiliates and partners can improve the overall efficiency and quality of a patient's episode of care. Elements like synchronized electronic medical records, quality initiatives and patient education across an integrated network can greatly advance population health as a whole.

Academic medical centers (AMCs) are feeling increased pressures to form coordinated networks and integrate their services in this changing environment. AMCs are unique in that their mission includes education and research in addition to providing clinically excellent care. Sequestration cuts threaten research portfolios and related portions of this mission, while clinical enterprise margins are under extreme duress. Placing a strong emphasis on value across the entire organization is essential as measures must be taken to become more efficient by both reducing duplication and waste and to carefully coordinate care. Many AMCs are focused on improving cost and expanding revenue base. There is pressure to aggressively cut expenses and examine a growing number of partnership or alignment opportunities with outside physician groups and health-care organizations. Challenges are also presented by balancing the needs and expectations of faculty within a clinical enterprise. Today, many AMCs are moving toward a shared governance approach in which clinical, academic and research functions report

to a single board or group of leaders. Department chairs and physician leaders are given more comprehensive responsibilities as they work with executives toward the AMC's unique mission and vision. This type of shared governance aligns the strategic goals of the various missions of an AMC and allows the organization to be more nimble and responsive in its respective market.

The presence of ACOs, formal or informal, will become more prevalent as we move into the future of health care in the U.S. In addition, AMCs will face extraordinary pressure in the future. AMCs that are soundly structured with shared governance and management will be able to respond to challenges more efficiently and proactively. Integrated AMCs that focus on population health are positioning themselves well for the future. The evolution of health care will continue over time and the development of these types of organizations should prove to be beneficial to the patient and the health-care environment as a whole. ■

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# DO FEMALE PATIENTS PREFER FEMALE ENDOSCOPISTS?



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and the ACG Practice Parameter Committee.*

*"I am so glad you are a woman!" I have heard this remark over and over when I see a woman scheduled for a colonoscopy.*

**A**s a female gastroenterologist in practice for more than 15 years, I have frequently encountered women who prefer to have a female physician perform their colonoscopy.

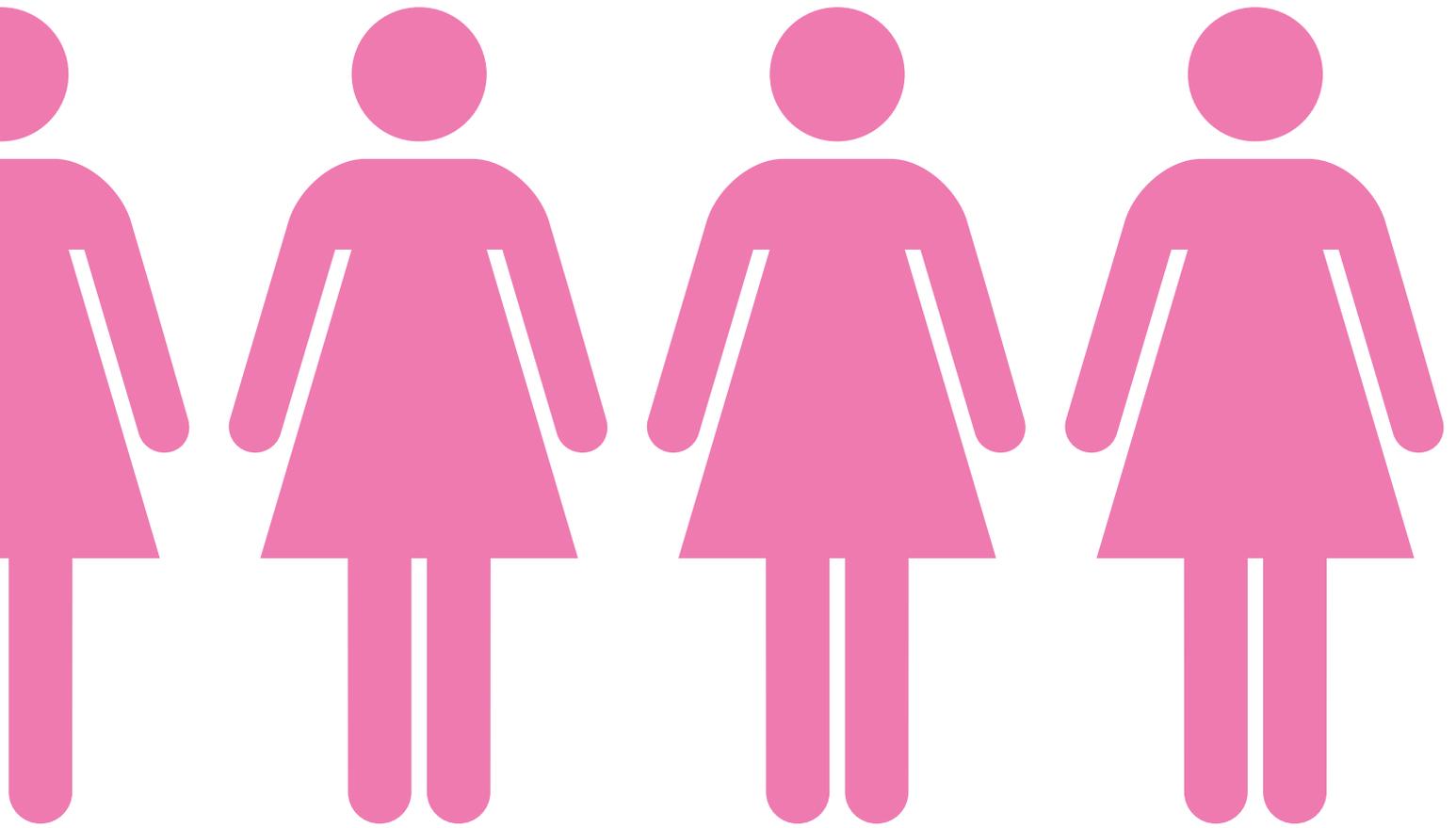
This preference is certainly not universal. Many women do not express gender partiality. In my experience, a woman's preference for the same gender endoscopist appears to be strongly associated with her geographic origin. Middle Eastern women almost invariably, and South Asian women frequently, request a female physician, even an all-female team. This is probably rooted in culture and religion. A woman referred by a female internist or gynecologist is more likely to request a female gastroenterologist, presumably highlighting the patient's inherent preference for a female physician. A large number of my referrals come from female physicians. Women with a history of physical or sexual abuse will consistently request a female gastroenterologist, and generally request a clinic visit prior to the endoscopic procedure as opposed to open-

access endoscopy.<sup>1</sup> Women undergoing an initial screening colonoscopy appear more specific in their preference for a same gender endoscopist.

Why does this preference exist? Some women have told me they feel less self-conscious or embarrassed with the same-gender endoscopist. A few women said that a female gastroenterologist would better appreciate their concern for pain and would be gentler during the procedure.

Men, in contrast, do not appear to be fastidious about the gender of their endoscopist. I recall only one male patient in my 15 years of practice who requested that I not do his procedure because of his discomfort with a female endoscopist.

Situations in which I have not experienced a request for a female endoscopist are if a woman is acutely sick or is admitted to the hospital. For these patients, the severity of their illness or the urgency for procedure appears to take precedence over physician-gender concerns.



Objective studies on the gender of the endoscopist are few, but a preference of women to have a woman endoscopist — even if it costs more — has been reported.<sup>2</sup> I informally polled about 50 women, including friends, colleagues and neighbors ages 40 to 65. Two-thirds said they would prefer a female gastroenterologist. A third of the women felt the gender of the endoscopist did not matter, and that colonoscopy did not usually result in a long-term patient-physician relationship unlike the relationship with an obstetrician or a gynecologist. A few of the women with an existing male gastroenterologist indicated they would prefer a female even though their current gastroenterologist was competent.

In my urban, academic GI group of 14, there are two female gastroenterologists. In the past 3.5 years, the two of us performed 3,000 colonoscopies, all comers, 60 percent of which were on women. We completed 750 first-time screening colonoscopies, 67 percent

of these were on women, indicating a selection bias on the part of the patient as our practice does not inquire about gender preference when scheduling a procedure, but tries to accommodate if requested.

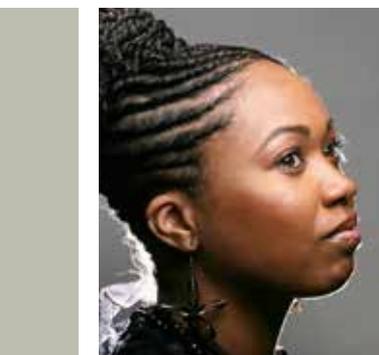
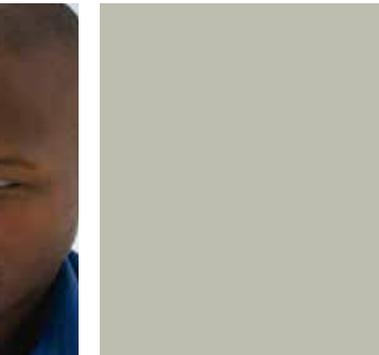
It remains to be seen whether post-procedure satisfaction with a female gastroenterologist is equal to pre-procedure expectation and whether it differs from experience with a male gastroenterologist. More gender concordance studies on both men and women would be useful, and if a preference for female endoscopists is widely applicable, there are implications for women being hired in private or academic practices as well as women considering gastroenterology as a career option. Women currently constitute about half of the medical students in the U.S.; however, the number of women training in gastroenterology remains disproportionately low at about 16 percent.

Besides endoscopy, in gastroenterology overall, nearly 60 percent of patients are women, and many disorders are more commonly seen in women including IBS, biliary disease and autoimmune liver diseases. Female gender influences perception of visceral pain and health-seeking behavior. Women are screened at lower rates for CRC than are men, although they are at equal risk for the disease. They are also more likely to have incomplete colonoscopies. A distinct awareness of women's GI health needs will be of benefit to all gastroenterologists and may influence gender selection of the gastroenterologist by the patient.

As we move to more personalized health care in gastroenterology and beyond and aim to provide higher quality care and comfort, perhaps gender preference questions should be sought more frequently and the wishes of both men and women complied with as much as possible. ■

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## SHOULD WE SCREEN WOMEN AND NON-CAUCASIANS FOR

# BARRETT'S ESOPHAGUS?



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### REFERENCE:

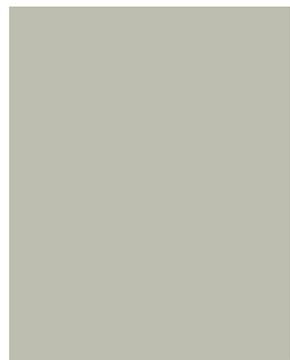
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While the rate of rise in incidence of esophageal adenocarcinoma (EAC) has slowed somewhat, this malignancy is still associated with a dismal prognosis. Risk factors for EAC include male gender, Caucasian race, central obesity, smoking and a history of reflux. Barrett's esophagus (BE), the precursor lesion to EAC, is easily identifiable on routine upper endoscopy and can be monitored for the development of precancerous changes. We generally assume that by performing endoscopic surveillance in our BE patients, we can detect high-grade dysplasia and EAC at early stages, when it is still easily treatable. Therefore, shouldn't we perform screening endoscopies with the goal of identifying all patients with BE?

While this line of reasoning seems logical, the issue is not at all straightforward, as multiple factors go into the decision to perform any type of screening test. While the incidence of EAC is rising, it is relatively low compared to other GI cancers such as colon or even pancreas. However, mortality in esophageal cancer is extremely high, and thus there may still be significant benefit to detection at early, asymptomatic stages. Another consideration is cost, including medical (from unnecessary tests or treatments), psychological (to the patient) and financial (to the health-care system).

In the GI practice setting, we perform endoscopy not to screen for EAC but rather for Barrett's esophagus, the precursor lesion. However, the overwhelming majority of BE patients will not progress. I tell my BE patients without dysplasia that, over the next five-to-10 years, they have only a 1 to 2 percent chance of developing esophageal cancer. By performing endoscopic





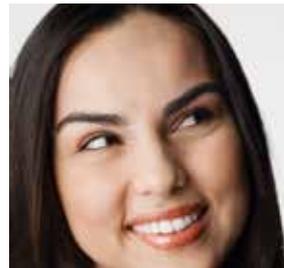
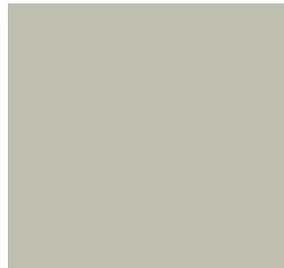
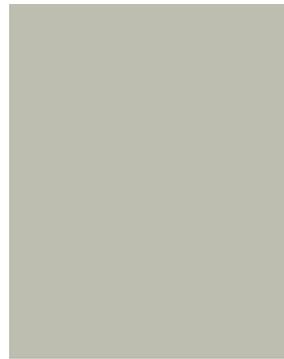
surveillance, we subject our BE patients to numerous costly endoscopies when most will ultimately die from something other than EAC. On the other hand, an endoscopy is a relatively low-risk procedure, and maybe we can catch those unlucky progressors early simply through endoscopic surveillance. Interestingly though, a recent well-conducted study examining data from Northern California showed that BE patients under surveillance did not have a decreased risk of death from EAC compared to those who did not get surveillance.<sup>1</sup> In other words, surveillance for patients with BE may have little if any benefit in terms of reducing the number of deaths due to esophageal cancer.

So how does this relate to the initial question: should we screen women and non-Caucasians for BE? As most of us as gastroenterologists have recognized from clinical experience, BE is much more common in Caucasians and males. Let us assume for a moment that endoscopic surveillance is indeed beneficial. In general, cancer prevention efforts should be targeted to those patients at higher risk; there are more than 2,000 cases of male breast cancer per year, but we do not perform screening mammograms in men. The professional societies provide some guidance by suggesting that we screen patients who have risk factors for EAC. Remarkably, nearly 90 percent of all EAC cases occur in men. The incidence of EAC in Caucasians is also two-to-four times higher than in non-Caucasians. While Caucasian males are clearly the highest risk group for EAC, we should not off-hand dismiss females and non-Caucasians from EAC prevention strategies. A 60-year-old female with chronic GERD, central adiposity and a heavy smoking history potentially warrants screening.

Furthermore, screening low-risk groups is reasonable if the cost is minimal and we have a highly effective intervention, in this case to reduce deaths from EAC. Unfortunately, endoscopy is relatively expensive, and the benefit of surveillance (regardless of gender or race) is questionable. If we perform screening endoscopy on all patients, then a very large number of patients would need to be screened to possibly prevent a single death from EAC.

**While Caucasian males are clearly the highest risk group for EAC, we should not off-hand dismiss females and non-Caucasians from EAC prevention strategies.**

However, our views on screening for BE may change over the next several years. Use of cheaper, less invasive tests such as transnasal endoscopy or a brush cytology capsule on a string would resolve many screening cost issues. There is also a push in the field toward identifying markers of risk stratification for BE, which would allow for interventions aimed at high-risk patients, who, theoretically, would derive the most benefit. The low-risk majority would then need little to no follow-up. If these developments come to fruition, then there may be increased enthusiasm for screening all populations. Until then, we should continue to individualize screening recommendations after assessing the likelihood of BE based on each patient's risk factors, regardless of sex or race. ■



# STARTING DOWN A NEW PATH?

*The AGA Perspectives Fellows' Corner is brought to you  
by the AGA Trainee and Young GI Committee.*

## TIPS FOR PURSUING AN ADVANCED ENDOSCOPY FELLOWSHIP

The decision to pursue an advanced endoscopy fellowship (AEF) is a challenging yet exciting one, requiring careful reflection on one's personal and professional goals. Once the decision has been made to pursue the unique training a fourth-year fellowship offers, a prospective fellow must critically analyze the experience offered by individual AEF programs, and identify the "right" program by asking key questions designed to match the applicant with the program that best complements his or her goals and interests.

The first and most obvious considerations for potential AEF applicants are personal. Typically, at least six years of post-graduate education precede an AEF year, and the impact of an additional year of training on one's time, family and finances can be daunting. Pursuing an additional year of fellowship training delays meaningful contribution to massive student debt, and often may also require relocation for completion of training. Furthermore, learning advanced endoscopic skills requires a substantial time commitment, with increased participation in emergent procedures and significant call responsibilities. All of these factors have a highly individualized impact on applicants and their families and require careful consideration.

A frequently asked question is whether a desire to remain in academics or private practice should be factored into the decision-making process to pursue an AEF. Invariably, the need exists for skilled therapeutic endoscopists in both practice settings. With that said, one consideration for those contemplating a career as solo practitioners is the widely accepted notion that procedural volume is directly correlated with the complication rates of some advanced procedures. Solo practitioners, especially those in small cities, may find it difficult to achieve the necessary numbers of these complex procedures in order to maintain competency.

My personal path to an AEF included a lot of soul searching and a great deal of homework; time and energy I consider well spent. Having carefully weighed the above factors, I decided by the second year of my GI fellowship to pursue an AEF. I actively immersed myself in clinical research, attended a number of hands-on conferences, became a regular at my university's multidisciplinary pancreaticobiliary conference, and gained as much exposure to therapeutic endoscopy as possible. I examined my clinical and research interests and aligned myself with individuals in my division who I wished to emulate.

Over the last few years, changes to the application process have provided even more opportunities for applicants to explore the field and pursue activities to strengthen their resume. The AEF match process has evolved from a process of rolling admissions, in which applications were submitted early in the second year of fellowship and

positions solidified as early as December of that year, to one which is far more friendly to the AEF applicant. The current process allows GI fellows to take advantage of their second year of fellowship to explore their options. Applications are now delayed until the latter half of the academic year, interviews are conducted from April to June, and the AEF match takes place during the first few weeks of July. I encourage all fellows considering a fourth year to make full use of this additional time and to take advantage of every available opportunity.

Having made the decision to pursue an AEF, the next phase in the process was to critically appraise each fellowship program. I asked myself what I hoped to gain from my fourth year training experience. Did I want to spend the year focusing all my effort on mastering EUS, or would I consider a program with exposure only to ERCP? Was I willing to consider a two-year program with one year of exposure to each skill? Finally, how important was it to become skilled in a wide variety of other advanced techniques such as endoscopic mucosal resection, radiofrequency ablation and enteral stenting? I ultimately made the decision to apply only to programs with exposure to a number of these advanced procedures. Appreciating the direct correlation between procedural volume and technical competence, I spoke with fourth-year fellows and program directors specifically about the volume of procedures I could anticipate exposure to during my fourth year. I considered how much of my time would be spent performing advanced procedures as opposed to time spent in clinic or on consultative services in the hospital. The "right" answer to these questions will depend on the individual preferences and goals of each applicant. I found the right fit at the University of Michigan in Ann Arbor.

Pursuing an AEF and selecting the right program is a very personal decision. The process requires a great deal of time and dedication, but offers endless possibilities. I was presented with opportunities to become involved in national committees, to review for a preeminent gastroenterology journal and to pursue scholarly activities. Additionally, I developed lifelong relationships with many of the individuals I respect most in this field and gained the technical skills to begin the next step in my career as a therapeutic endoscopist at a busy academic medical center. I now spend the majority of my clinical time performing the advanced procedures I learned during my fourth year. My advanced endoscopy year was undoubtedly the best professional year of my life. It required great personal sacrifice and hard work, but it resulted in a payoff I never could have imagined. ■



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Dr. Kubiliun has no  
conflicts to disclose.

My personal path to an advanced endoscopy fellowship included a lot of soul searching and a great deal of homework; time and energy I consider well spent.

# EMERGING BARRETT'S ESOPHAGUS IN ASIA

EXPERTS SHED LIGHT ON  
DIFFERING DIAGNOSIS  
CRITERIA AND PREVALENCE  
ACROSS THE WORLD.



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*Drs. Shiotani and Haruma have no conflicts to disclose.*

## Definition and Diagnosis

A widely accepted definition of Barrett's esophagus (BE) requires the endoscopic appearance of a columnar-lined esophagus (CLE) and an esophageal biopsy demonstrating specialized intestinal metaplasia (SIM), which is known to predispose to the development of dysplasia and esophageal adenocarcinoma (EAC). However, in the U.K. and Japan, BE is defined simply as CLE, and SIM is not required for the diagnosis. Moreover, most Western studies use the proximal margin of the longitudinal gastric folds as the landmark to determine the esophago-gastric junction (EGJ) (as defined by the Prague C and M criteria), while many Japanese and some Korean studies use the distal margin of the palisade vessels for determination of the EGJ. Ultra-short segment BE (<1 cm), a common form of BE described in Asia, is not considered BE at all by the latest British definition. These different criteria for identifying the EGJ and for defining BE endoscopically and histologically may account for some of the disparities among Western and Asian countries in studies on BE.

A number of endoscopic methods, including chromoendoscopy, have been used for the optical detection of SIM. Magnification endoscopy with narrow-band imaging (ME-NBI), which provides better detail of the mucosal and vascular patterns of minute lesions, has been reported to be helpful in identifying SIM and dysplasia in BE. Several classification systems have been developed for BE evaluation using ME-NBI, and we recently reported detection of an intestinal phenotype (with expression of intestinal markers such as CDX2 and MUC2) in 95 percent of CLE with a tubular/villous pattern observed by ME-NBI.<sup>1</sup>

## Epidemiology

The reported prevalence of BE in patients with gastroesophageal reflux disease (GERD) is higher than in the general population. The reported prevalence of short segment BE (SSBE) and long segment BE (LSBE) in Western countries ranges from 1.1 to 17.2 percent and 0.5 to 7.2 percent, respectively, while those prevalences in Asia range from 0.04 to 20 percent and 0.01 to 6.6 percent.<sup>2</sup> The LSBE prevalence in Asia is still extremely low and less than 1 percent in most reports, although the prevalence of BE is increasing. In reports from Japan, the highest rates of BE described are 19.9 percent for histologic BE and 43 percent for endoscopic BE, which is almost exclusively SSBE. This high incidence of SSBE may be due not only to differences in BE criteria used, heightened endoscopists' awareness of BE and increased availability of NBI, but also due to the reduction of *H. pylori* infection.

## Barrett's EAC

Since 1975, the incidence of EAC in the U.S. has increased by more than 500 percent. Unlike the clear-cut rising incidence of EAC in the West, the incidence trend in Asia is less clear. In Singapore, there has been a large increase in EAC and a relative decrease in squamous cell carcinoma, while the incidence of both cancers in Japan remains relatively unchanged. Moreover, the incidence of EAC is declining in Hong Kong, but remains unchanged in Taiwan and Korea.

## Risk Factors for BE

Male gender, advancing age, hiatal hernia, as well as lifestyle and diet-related factors

such as visceral obesity, metabolic syndrome, meat, tobacco and alcohol consumption have been reported to be risk factors for BE and EAC. In contrast, *H. pylori* infection and fruit and vegetable intake appear to be protective factors. *H. pylori* infection is reported to be relatively infrequent in patients with BE, especially LSBE. Pangastritis and corpus gastritis with decreased acid production caused by *H. pylori* infection has been proposed as the protective factor in BE.

Some studies suggest that genetic factors might account for the significant inter-racial differences in the incidence of BE and EAC. In both the U.K. and U.S., studies have shown a higher incidence of BE and EAC in Caucasians as compared to Black and non-Asian ethnicities (OR 3.55, 95 percent C.I. 1.85-6.85). In the multi-racial Malaysian population, the incidence of BE is significantly higher in Indians than in Malays and Chinese. Rajendra *et al.*<sup>3</sup> have described an association of GERD and BE with the HLA-B07 gene, which is common in both Caucasians and Indians, but not in East and Southeast Asians.

The natural history of SSBE is not fully understood, and the factors associated with its elongation of the columnar metaplasia are also unclear. In most cases, BE is thought to reach its maximum length when it first develops, with little subsequent change over time. In an earlier study from our group, the cumulative incidence of elongation of SSBE was 3.3 percent over a follow-up period of five years, and risk factors for elongation were the absence of atrophic gastritis, the presence of reflux esophagitis and flame-shaped SSBE.<sup>4</sup> ■

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