Radiofrequency Ablation of Barrett’s Esophagus: Short-Term Results

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Background. The presence of Barrett’s esophagus (BE) increases the risk of esophageal cancer. Total regression of BE is uncommon with medication or laparoscopic fundoplication, and endoscopic techniques to obliterate BE have varied results. This study evaluated the early results of a balloon-based catheter radiofrequency ablation (RFA) system in patients with medically refractory reflux symptoms and biopsy-proven BE.

Methods. The medical records of 27 consecutive patients who underwent RFA for BE from March 2005 through January 2007 were reviewed. Esophagogastroduodenoscopy was performed before ablation to document presence of BE and no cancer and at 8 weeks after the RFA to assess the presence of residual BE.

Results. Mean patient age was 53.6 ± 12.5 years; 16 (59%) were men. The average length of the Barrett segment treated was 4.6 ± 4.7 cm. Two patients (7.4%) had low-grade dysplasia. No patient had high-grade dysplasia and cancer. There was no periprocedural morbidity or at follow-up, no postprocedure dysphagia or stricture. In all patients, the BE was completely replaced with normal squamous epithelium. Symptoms regressed in 16 patients (60%) with RFA and proton pump inhibitor therapy. Eleven required an antireflux procedure for persistent symptoms.

Conclusions. Short-term results show that RFA for BE is safe and achieves 100% replacement of intestinal metaplasia. RFA of BE combined with fundoplication may be offered to patients with BE and medically refractory reflux symptoms. Long-term endoscopic surveillance is needed to determine if the risk of cancer is reduced with this bimodality therapy.
scopic balloon-based circumferential catheter RFA procedure.

Radiofrequency Ablation Device

The Halo360 RFA system (Barrx Co, Sunnyvale, CA) consists of an RF energy controller source, a sizer balloon catheter, and the RFA balloon catheter. The RF controller is preset to deliver 12 J/cm², which previous studies have determined offers complete ablation beyond the lamina propria [8]. The RFA balloon is 3 cm long and consists of 60 electrode rings spaced narrowly together every 500 µm in a bipolar fashion. Once the esophageal diameter is measured using the sizer balloon, the RFA catheter is positioned in place, the balloon is inflated, and the energy source delivers RFA to the surface of the esophagus circumferentially for 300 msec.

Radiofrequency Ablation Procedure

All procedures were performed under general anesthesia. Patients were placed supine, and a flexible esophagogastroduodenoscope was advanced for visualization and surveillance. The Z line was identified, and the Barrett segment was measured relative to the Z line and to the superior edge of the visualized segment. Mucous was removed with 20 mL of acetic acid (1%) to allow better tissue contact with the electrode.

A guidewire was advanced and left in place while the esophagogastroduodenoscope was removed. A sizer catheter was then used up to 10 times to define the average circumference at the Barrett segment throughout its entire length and choose the appropriate size for the ablation balloon catheter. With the wire still in place, the ablation balloon was passed into the esophagus under direct visualization and aligned at the superior aspect of the Barrett segment. Once placement was confirmed, the current was turned on to the ablation catheter while simultaneously suctioning with the scope to further approximate the esophageal walls to the ablation catheter. The balloon was then deflated and the esophageal surface viewed for signs of mucosal surface sloughing. Multiple firings were performed to completely cover the entire length of the BE because a single firing of the RFA balloon system covers only 30 mm, thus the Halo360 system can overlap treated areas.

The patients were extubated in the operating room and all were discharged to home within 2 hours of the procedure. All patients were treated with omeprazole, 40-mg twice a day, for 30 days and then 40-mg once a day thereafter.

Postablation Endoscopy

Follow-up included return office visits and any other hospital visits including admissions and emergency department consultations. Patient’s reflux symptoms, including regurgitation, chest pain, cough, other respiratory symptoms, heartburn, nausea and vomiting, and dysphagia, were documented. All patients were scheduled for repeat endoscopy with biopsy under conscious sedation 8 weeks after the ablation procedure. All patients will undergo annual endoscopic surveillance with four-quadrant biopsy for the next 5 years.

Procedural data were analyzed retrospectively. Values are reported as mean ± standard deviation. The Emory University Institutional Review Board approved the informed consents for prospective use of the Halo360 RFA balloon-based catheter system for the treatment of BE and retrospective data collection.

Pathology

Biopsy specimens were evaluated by one of two pathologists who also evaluated the initial Barrett specimen. Histologic examination was used to determine the presence of post-RFA BE and buried glands.

Results

The 27 patients were a mean age of 53.6 ± 12.5 years; 16 (59%) were men. Most patients complained of dyspepsia (86%), followed by acid reflux (67%). Other symptoms are listed in Table 1. All 27 patients (100%) had taken PPIs for an average of 4.3 ± 2.5 years. Five patients (18.5%) had previously been diagnosed with BE at a median time of 36 months. Their diagnosis was reconfirmed during the initial endoscopy in our institution. The remaining patients underwent esophagogastroduodenoscopy (EGD) at our institution and were found to have BE on biopsy. The average length of the Barrett segment was 4.6 ± 4.7 cm.

Table 1. Initial Presenting Symptomsa

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Patients, No. (%)</th>
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<tbody>
<tr>
<td>Dyspepsia</td>
<td>23 (85)</td>
</tr>
<tr>
<td>Regurgitation</td>
<td>18 (67)</td>
</tr>
<tr>
<td>Cough</td>
<td>5 (18)</td>
</tr>
<tr>
<td>Nausea</td>
<td>3 (11)</td>
</tr>
<tr>
<td>Dysphagia</td>
<td>1 (4)</td>
</tr>
<tr>
<td>None</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

a Most patients complained of dyspepsia combined with at least one other symptom. All patients were taking proton pump inhibitors at the time of presentation.

Table 2. Initial Endoscopy Findingsa

<table>
<thead>
<tr>
<th>EGD Findings</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hiatal hernia</td>
<td>17 (63)</td>
</tr>
<tr>
<td>Ulceration</td>
<td>3 (11)</td>
</tr>
<tr>
<td>Stricture</td>
<td>2 (8)</td>
</tr>
<tr>
<td>H pylori</td>
<td>2 (8)</td>
</tr>
<tr>
<td>BE segment length, cm</td>
<td></td>
</tr>
<tr>
<td>1 to 3</td>
<td>13 (48)</td>
</tr>
<tr>
<td>4 to 6</td>
<td>9 (33)</td>
</tr>
<tr>
<td>&gt;6</td>
<td>5 (18)</td>
</tr>
<tr>
<td>Low-grade dysplasia</td>
<td>2 (8)</td>
</tr>
</tbody>
</table>

a All patients had biopsy proven Barrett’s esophagus at endoscopy. Two patients had low-grade dysplasia. No patient had high-grade dysplasia or cancer.

BE = Barrett’s esophagus; EGD = esophagogastroduodenoscopy.
Pre-RFA strictures, ulcerations, and other endoscopy findings are listed in Table 2. Five patients (18.5%) had undergone previous antireflux procedures. Histologically, 2 patients (7.4%) had low-grade dysplasia and none had cancer.

All patients returned within 2 to 4 weeks of their initial EGD to undergo Halo360 RFA. There was no perioperative morbidity, and all patients went home on the day of the procedure. At follow-up, no patients reported dysphagia or had clinical evidence of stricture formation. Postoperative EGD was performed in all patients at least 8 weeks after RFA, and in 25 (93%), the BE was completely replaced with normal squamous epithelium (Fig 1). One patient had mild esophagitis, and 2 patients underwent a second RFA session secondary to an extended length of the original Barrett’s mucosa greater than 6 cm.

As for symptoms, 16 patients (60%) had regression of their reflux symptoms with RFA and PPI therapy; the 5 patients who had prior reflux procedures were in this group. However, 11 patients (40%) had persistent reflux symptoms to PPI medical treatment only after RFA and underwent a subsequent antireflux procedure (Table 3). All 11 patients were symptom-free after undergoing the antireflux procedure. Only 8 of the 27 patients (30%) had 24-hour pH testing after the Halo360 RFA; 100% showed significant reflux with mean Demeester scores greater than 40 ± 11. All 8 patients were in the group that had persistent reflux symptoms and required a subsequent antireflux procedure. Manometric studies were done in 11 (41%) of the 27 patients before and after the Halo360 RFA. No change was noted in peristaltic activity or lower esophageal sphincter pressures before or after the RFA procedure.

**Comment**

The incidence of Barrett’s metaplasia of the esophageal lining is on the rise [5, 9]. Reflux of biliary and gastric

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**Table 3. Symptoms After Radiofrequency Ablation**

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Patients, No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dyspepsia</td>
<td>11 (41)</td>
</tr>
<tr>
<td>Regurgitation</td>
<td>5 (19)</td>
</tr>
<tr>
<td>Cough</td>
<td>1 (4)</td>
</tr>
<tr>
<td>Nausea</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Dysphagia</td>
<td>0 (0)</td>
</tr>
<tr>
<td>None</td>
<td>16 (59)</td>
</tr>
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</table>

*Sixteen patients had no symptoms at the 8-week follow up after radiofrequency ablation, whereas 11 patients had continued dyspepsia and subsequently underwent an antireflux operation. No patient had dysphagia to suggest stricture formation.*

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Fig 1. Endoscopic view at (A) initial presentation of a patient with Barrett’s esophagus, (B) immediately after ablation with the circumferential radiofrequency ablation balloon and sloughing of the mucosa, and (C) at 8 weeks showing normal distal esophageal mucosa.
contents into the esophagus is viewed to be the insults resulting in this metaplasia [10]. This premalignant condition puts the patient at a risk of developing cancer at 0.5% per patient per year [11, 12]. Said in other terms, patients with BE have 40 times the risk of the normal population of progressing to develop adenocarcinoma of the esophagus. As more BE patients are being identified, recommendations for routine surveillance have been established to detect progression to dysplasia and adenocarcinoma [3].

Endoscopic ablative therapies have shown success in reversing dysplasia and at times ablating metaplastic cells [13]. However, use of these techniques has often been reserved for patients with proven dysplasia, especially high-grade dysplasia that is not amenable to esophagectomy. This is due to evidence in postoperative esophagectomy tissue of islands of BE, high-grade dysplasia, and adenocarcinoma buried in the specimen [4, 14].

Recently, RFA was introduced as a promising new ablative technique. Studies have shown that compared with laser or thermal ablation, it provides uniform and controlled ablative therapy at a consistent depth. This uniformity in ablation is accomplished because of the balloon-based catheter that delivers the RF energy in a 360-degree fashion. This delivery system also allows for controlled depth of ablation above the muscularis mucosa, which prevents stricture formation. Dunkin and colleagues [8] showed a dose response for ablation depth with 12 J/cm² going to muscularis mucosa and a median procedure time of less than 28 minutes. These pilot studies had no reported strictures [8].

In the current study, the 2-month endoscopic follow-up showed complete histologic elimination of the intestinal metaplasia after RFA ablation, including the 2 patients with low-grade dysplasia. In the 2 patients with extended BE segments (8 and 9 cm) who underwent repeat RFA at the 2-month follow-up EGD, repeat EGD at 4 months from the first RFA showed complete histologic regression of the BE. These 2 patients underwent repeat RFA because we were concerned that the extended length of BE (>6 cm) being treated might cause stricture formation, which has been reported with the use of photodynamic therapy in patients with BE exceeding 6 cm [15].

No dysphasia or stricture formation occurred in the 27 patients after RFA. Even though the endoscopic follow-up was short in our series, most strictures that develop after treatment from the other thermal and chemical ablation modalities usually occur within 3 weeks of treatment [16]. Therefore, a postprocedural EGD at 2 months should capture all strictures that would occur after our RFA procedure.

Physiologic knowledge would suggest that a circumferential injury to the lining of the esophagus would result in a high rate of stricture formation. Although this may be the case for photodynamic therapy and thermal ablations, no strictures were observed in this study. This may be a result of controlling the depth of the ablation effect. Depth control is partly related to a tightly spaced bipolar array, which limits the depth of the electrical field generated during the ablation. Energy density and power are controlled by the system, eliminating variability. The high-power treatment (300 W) permits rapid heating, thus preventing long “on” times and deep thermal conduction. As a result, controlling the depth protects the submucosa and likely preserves the ability of the esophagus to reestablish a normal squamous epithelium and avoid stricture formation [8, 17].

In contrast, the classical ablation therapies, including laser, multipolar electrocoagulation, or thermal ablation, have achieved between 70% and 100% complete ablation. Yet, a myriad of complications are documented with these modalities, including odynophagia, chest pain, strictures, and perforations due to the challenge of controlling the depth of the ablation [14]. Photodynamic therapy using photosensitive chemicals stimulated by light to perform the ablation achieves complete ablation in only 5% to 60%, with complications including acute odynophagia, chest pain, vomiting, and strictures [15, 16]. None of these studies recommend the cessation of surveillance endoscopy.

In the current study, none of our patients complained of persistent symptoms secondary to the procedure, although the population size was small. In efficacy trials conducted by Sharma and colleagues [18], 5 of 100 patients observed transient symptoms of chest pain, abdominal pain, dysphasia, and sore throat that resolved within 2 to 4 days.

The postablation results showed complete disappearance of intestinal metaplasia and also of low-grade dysplasia in 2 patients, with no evidence of buried glands in the biopsy samples. In this series no biopsy specimens showed specialized columnar epithelium covered by a layer of squamous epithelium with no communication with the surface, thus buried glands. This correlates with results obtained in our institution in a previous study where 9 patients with high-grade dysplasia underwent ablation therapy immediately before esophagectomy, with pathology showing complete ablation with no hidden viable foci or glands in 90% of the examined tissue and the remaining sample with intestinal metaplasia present at the margin of one ablation area secondary to incomplete overlap [19].

These results indicate that circumferential RFA shows less periprocedural morbidity and more complete ablation compared with other endoscopic ablative methods. Therefore, if there is no Barrett’s mucosa remaining after ablation, then there can be no buried Barrett’s mucosa to be at risk of developing into a malignancy.

Many factors contribute to the usefulness of routine endoscopy in these patients, including patient compliance and concomitant antireflux treatment. This combination has focused on minimizing the progression of BE but not completely eliminating the underlying mucosal abnormalities. For instance, the combination of surveillance and use of PPI in patients only caused 5-year incidence rates of dysplasia of 11% and 37%, and the 10-year incidence rates were 21% and 58% for patients on PPI, and those not on PPI, respectively. The median time to dysplasia was 4.9 years for patients on PPIs, and 2.3 years for patients not on PPI [20–22]. Others documented
that there was no regression of the metaplastic segments but a slowing of low-grade and high-grade dysplasia appearance [23].

Surveillance should still follow RFA until long-term regression has been shown, then modification of surveillance recommendations could be assessed. In the current study, 16 patients in the current study had resolution of their reflux symptoms and opted to continue with medical therapy. Long-term follow-up of these patients is needed to further establish the efficacy of RFA in combination with medical treatment only for eradication of BE.

Recent research has concentrated on advocating antireflux operations, mainly Nissen fundoplication, for BE patients. Initial studies showed no differences between PPIs and antireflux procedures with respect to preventing BE from progressing to dysplasia and adenocarcinoma [20, 24]. Several later studies showed a small benefit of antireflux operations over PPIs in preventing progression to adenocarcinoma [6, 7]. The argument of the antireflux operation proving to be more efficient than medical treatment in this sense, perhaps because it completely prevents acid and bilio-pancreatic reflux to the esophagus with its mechanical barrier [25]. Antireflux operations have also been shown to reduce the expression of genetic and carcinogenic markers such as cyclooxygenase-2 [26].

Eleven of our patients underwent laparoscopic Nissen fundoplication because of refractory symptoms and showed complete symptom resolution postoperatively, whereas 16 patients had resolution of their symptoms after RFA. One might think the symptoms would increase after RFA because regrowth of normal squamous epithelial, but possibly this epithelium may be different than the normal squamous epithelium and be denervated. Therefore, it will be important to continue endoscopic surveillance of these patients.

In view of the limited yet promising results of antireflux operations and RFA, a combination therapy focusing on surgical elimination of the source of reflux and ablative elimination of existing metaplasia warrants further studying. This combination may also work to increase comfort level to proceed with fundoplication, knowing that the existing metaplasia is ablated before changing the existing anatomy with the fundoplication wrap. Long-term endoscopic surveillance will be required to determine if RFA will alleviate the need for long-term endoscopic surveillance, which is currently recommend for life.

In conclusion, this study shows excellent short-term results of the circumferential Halo 360 RFA system. There were no periprocedural morbidities, and pathology results indicated complete eradication of BE in all patients. Short-term results show that RFA for BE is safe and achieves 100% replacement of BE with normal squamous epithelium and no buried glands. Radiofrequency ablation of BE in combination with fundoplication may be offered to patients to alleviate the risk of BE-associated esophageal cancer and to relieve persistent reflux symptoms. A prospective endoscopic surveillance study is needed to determine if the risk of cancer is reduced with this combination. This study could help also determine if long-term endoscopic surveillance is required after successful acid elimination and RFA of BE.

References
8. Dunkin BJ, Martínez J, Bejarano PA, et al. Thin-layer abla
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DISCUSSION

DR PAUL H. SCHIPPER (Portland, OR): One of the reasons we put this paper on the program is it represents a new technology, and this is one of our members who is using this technology. I am curious to see how many people are actually doing this, using the Barrx system.

(Show of hands).

DR SCHIPPER: Probably about five, six. How many people have somebody in their institution, gastroenterologists or otherwise, using this system?

(Show of hands).

DR SCHIPPER: Quite a few more. That was a well-presented paper. I think this study represents a safety study showing us it can be done and it can be done safely. The study that all of us are looking for is to see the effectiveness, and so my first question to you is hypothetical. We know that in those patients who had Barrett’s esophagus, a small group of them develop low-grade dysplasia, a smaller group high-grade dysplasia, and in that group we have esophageal cancer. We would really like to have the same thing happen as has happened in colon cancer, where we can identify a polyp, we can take it out, and we can decrease the mortality of that cancer, but it has been a very difficult thing to get a handle on in the esophagus. How many patients with Barrett’s esophagus do you think we will need to be doing a Barrx procedure on in order to decrease the rate of esophageal cancer?

My second question is on surveillance. We know that we should be surveilling for cancer with Barrett’s esophagus, or at least we think we are. Once you do this procedure, what is your responsibility then to go back and take further looks? And is it okay just to look at the tissue and say that is okay, that is squamous, or are we still obligated to do biopsies of the areas that have been ablated?

DR ELDAIF: Thank you. Those are two very good questions. I will start with the first question, which is stating the number of Barrx treatments in order to decrease the incidence of esophageal cancer. Again, as more patients are identified with Barrett’s esophagus, we have at this point statistics that say 0.5 patients per year that have just intestinal metaplasia will go on to develop esophageal cancer. So that puts them at an increased risk compared to the population, up to 40 times. So I can’t say, well, let’s just do it 40 times and then we will even it out with the population. But what can I say is, I don’t have a specific number; but, if we can treat the Barrett’s esophagus early on in its disease state, meaning its intestinal metaplasia, we can certainly decrease the incidence of propagating the disease to that of adenocarcinoma status. And there are differences between the risks of patients that have Barrett’s esophagus without dysplasia and the patients with high-grade as well as low-grade dysplasia. So if we can maintain a Barrett’s-free environment or at least decreasing the grade of the dysplasia or eliminating it from progressing to dysplasia, I think we would see a decrease in the incidence of esophageal cancer in the future.

DR SCHIPPER: So if your number is 0.5 patients per year with Barrett’s progress to cancer, and correct me on this if I am wrong, if you reduce the risk of cancer in this population by 50%, it would probably be about 400 patients that you would need to do to prevent one esophageal cancer?

DR ELDAIF: Per year. Math was never my forte, but I think the more patients that we can catch early on in the disease state the better that we can help these patients. As far as your second question, what is our responsibility for surveillance, I think, again, this is a short-term study, and we ought to be surveilling these patients for 1, maybe 2 years until we figure out that this is actually working in the long-term, and then once we have more numbers, either with prospective multicenter studies, then we are going to be able to achieve better guidelines. For right now the guidelines that the American Society of Gastroenterology have for Barrett’s esophagus is that if you have no dysplasia, it is 2 to 3 years endoscopic surveillance; low-grade, 1 and 6 months; and high-grade is every 3 months of endoscopy.

DR BRIAN MEYERS (St. Louis, MO): With the biopsies every 2 cm?

DR ELDAIF: With the biopsy.

DR DAVID R. JONES (Charlottesville, VA): I enjoyed your presentation. I have just a few questions for you. First, as part of your protocol did you biopsy afterwards or did you just look and say there was squamous epithelium? I think that is important to really confirm that there is no residual Barrett’s there as opposed to just looking at the epithelium. Second, Barrett’s epithelium often comes up in tongues and you deliver this RFA in a 360-degree manner. Is there any downside to using the Barrx for just an isolated tongue, for instance, of Barrett’s epithelium and not where it is circumferential?

Finally, what does this actually cost, and has there been any kind of cost-effective analyses? Particularly I would think it may be more cost-beneficial compared to surveillance, but you are still going to have to undergo surveillance with this. So do you have any idea for that, at least as to a cost, or is there any data about how it would be relative to surveillance, biopsies, etcetera? I enjoyed your presentation.

DR ELDAIF: Thank you very much. I will answer your last question first. As far as cost-effectiveness, obviously this is new technology. There haven’t been cost-effectiveness studies comparing long-term surveillance to ablation, but I perceive that once we establish guidelines using this ablation technique, I
think the cost-effectiveness will show itself to be better with these patients. If you just completely destroy their intestinal metaplasia, then you can lengthen the surveillance timing between endoscopies.

As far as when we went back for follow-up, we did biopsy all patients, so we did have histology as far as their posttreatment follow-up.

And your second question was about specific tongues or specific spots. In this study we looked at radiofrequency ablation using this 360 system, and there is also another system that can do spotted treatment, and that could be achieved with this other system. And it allows the same depth, with the same depth not going beyond the muscularis mucosa, and so, yes.

DR MILLER: It is called the Halo 90. If you have an island, you can do that. Your question is good, because if you only had an island, would you need to do a 360? I appreciate your comments, but it is a Halo 90 and you can do spot checks, and there have been validation studies. The majority of these done were for high-grade dysplasia and so forth at other institutions.

DR DOUGLAS E. WOOD (Seattle, WA): Two very brief questions. One, in our experience with ablative procedures that then subsequently have an esophagectomy for a variety of reasons, there is a significant presence of submucosal islands of residual gland tissue from the Barrett’s that is obviously at risk for potentially hidden cancer development that is not visible on endoscopy. Do you have any experience of the presence or absence of that in your experience?

And the second question relates to esophagectomy after this procedure. Have you done any esophagectomies? Is there very much peri-esophageal inflammation that complicates or confounds esophagectomy in patients that have been treated with this system?

DR ELDAIF: Thank you very much for both questions. This is just a back-up slide that I have as far as some of the pilot studies; three of them were done in our institution. And I will answer your esophagectomy question with the esophagectomy trial here. This trial was just, again, one of the feasibility trials that we did. And these patients had high-grade dysplasia and they were referred to Dr Miller for esophagectomy; but before that they had a session of, obviously with obtaining the consent from the patients, they had a Barrx session. Then the postoperative specimen was looked at, and it was evaluated for the presence of Barrett glands or the presence of adenocarcinoma or high-grade dysplasia. Out of the 13 patients, there was only 1 patient that had positive results, and that is due to a technique of the ablation. They did not overlap the segments. He had a greater than 6-cm segment and they failed to overlap the segments, and the cancer was found in that area that was not treated. The other 10 patients, and again, this is a small feasibility study, did not have any evidence of high-grade dysplasia or adenocarcinoma.

DR JOSEPH I. MILLER, JR (Atlanta, GA): Just a real quick thing. This is not a procedure that should be taken lightly. I personally operated, not done within Emory, but have operated on two people perforated from this Halo system within 24 hours in the last 6 months. The proprietors of the system don’t want to hear that, but it is not a benign procedure. These were both done right outside of Emory in the community. But if a gastroenterologist is going to do this procedure, he probably should be aware it is not totally benign. He should have thoracic surgery backup for the perforation.

DR ROBERT CERFOLIO (Birmingham, AL): You said 3?

DR J. MILLER: I have operated on 2. I know of a third. But I have only personally operated on 2, and they all presented within 24 hours of having had the procedure.

DR D. MILLER: In all the trials there has never been a perforation documented. But I think what it is, Joe, a lot of these GI [gastrointestinal] guys are jumping on this bandwagon. Thirty-six percent of GI physicians do some type of ablation therapy. That was from the American Gastroenterology survey. So all these guys are putting these scopes down, argon and PDT [photodynamic therapy] and everything. So you have really got to look at that.

And, Doug, to answer your question, when we did these esophagectomies, there was some edema outside, and in the feasibility, 12 joules is what we picked out. When we did 20 joules, that esophagus was very edematous, almost like a bagel. So it was a little tough at that time. But there was no Barrett’s glands or anything like that.

We are very lucky at Emory that we have this control within our system, and our GI medicine guys did not think this was cost effective for them, and this was a study that we looked at in regards to reflux.