Barrett’s Esophagus
Radiofrequency Ablation with the Barrx™ Technology
A Reference Book
Barrett’s Esophagus

What is Barrett’s esophagus?

- Barrett’s esophagus is a change that occurs within the cellular lining of the esophagus; the swallowing tube that carries foods and liquids from the mouth to the stomach.
- Barrett’s esophagus is associated with a 30-50 times increased risk for developing esophageal cancer.\(^1\)

Barrett’s esophagus is estimated to affect between 1.6 - 5.6% of people in the United States.\(^2, 3\)

How does Barrett’s esophagus develop?

- Gastroesophageal reflux disease (GERD) is a disorder in which stomach acid and enzymes cause injury to the esophageal lining; producing symptoms such as heartburn, regurgitation and chest pain.
- In some patients, the damage and inflammation associated with GERD can result in genetic changes which cause the cells to change from esophageal cells to intestinal cells. This change can be seen during an endoscopy procedure and is deemed Barrett’s esophagus.

It is estimated that 13% of the people who have chronic acid reflux also have Barrett’s esophagus.\(^1\)
How is Barrett’s Esophagus Diagnosed?

Endoscopy (Esophagoscopy)

- A small flexible tube with a light at the end (the endoscope) is passed through the mouth and into the esophagus. This tube has a camera that allows the physician to look at the lining of the esophagus.
- Endoscopy is a non-surgical procedure and is typically performed using moderate sedation.

Endoscopic Biopsy

- During the endoscopy, a sample of the tissue may also be obtained by the physician to confirm the diagnosis. This tissue sample may be used to further define the severity of the cellular changes, thus allowing a disease grade to be assigned (see Spectrum of Barrett’s Disease: Grading).
Spectrum of Barrett’s Disease: Grading\(^{6, 7}\)

Biopsy samples from Barrett’s esophagus tissue are examined under a microscope by a pathologist to confirm the diagnosis and grade the severity of cellular changes (dysplasia).

**Intestinal Metaplasia (IM), or Non-dysplastic Barrett’s Esophagus (NDBE)**
- The earliest stage of Barrett’s esophagus. Normal flat (squamous) cells are replaced with glandular intestinal cells.

**Low-grade Dysplasia (LGD)**
- The abnormal cells have begun to change in size, shape or organization.

**High-grade Dysplasia (HGD)**
- Cellular abnormalities are more pronounced with the nuclei of the cells (dark blue) being larger and more irregularly positioned.

**Adenocarcinoma (esophageal cancer)**
- The most disorganized cell appearance with invasion of the cells into deeper tissue layers.
Radiofrequency Ablation of Barrett’s Esophagus

Ablation

- “Ablation” is a technique where tissue is either heated or frozen until it is no longer viable or alive.
- Physicians have used various forms of ablation for nearly a century to treat a number of cancerous and pre-cancerous conditions, as well as to control bleeding.

Barrx™ Ablation Technology

- The Barrx™ technology delivers radiofrequency energy in a unique way, optimizing the removal of unwanted diseased tissue yet minimizing injury to normal esophagus tissue.
- Larger circumferential areas of Barrett’s tissue are treated with the Barrx™ 360 RFA balloon catheter, while smaller focal areas of Barrett’s tissue are treated with the family of endoscope-mounted Barrx™ RFA focal catheters.

In conjunction with an endoscopy, the Barrx™ 360 RFA balloon catheter or one of the RFA focal catheters deliver radiofrequency energy to the targeted tissue.

Standardization of the electrode pattern, energy, power and pressure against the tissue results in controlled ablation depth and uniform treatment.

Barrett’s Esophagus Diagnosis

Grading of Barrett’s Esophagus

RFA of Barrett’s Esophagus

What to Expect

After the Procedure

Treatment and Follow-up Regimen

Clinical Trial Results

References
What to Expect

Before the procedure

Patients should follow the instructions provided by the physician or the nursing staff before the procedure.

The following pre-procedure instructions were provided to patients in clinical trials:

- No eating or drinking after midnight the day before the procedure.
- Arrange to have someone drive the patient home after the procedure.
- The patient should speak to his/her physician about stopping any aspirin or blood-thinning medication prior to the procedure. Generally, a patient is asked to stop these medications seven days prior to and seven days after the RFA procedure, but the patient must check with the prescribing physician before stopping any medication.

The day of the procedure

- The treatment is typically performed in an outpatient setting and no incisions are involved.
- Ablation is performed in conjunction with an upper endoscopy procedure.
- While the actual procedure time in clinical studies has been less than 30 minutes, there is preparation required prior to the start of the procedure, and patients are monitored for a specific time afterwards.4,5
After the Ablation Procedure

Symptoms

Patients may experience some chest discomfort and difficulty swallowing for several days after the procedure, both of which are managed with medications provided by the physician. In clinical trials, these symptoms typically resolved within 3-4 days. Patients are provided with anti-secretory medications to promote healing of the esophagus.\textsuperscript{8, 11, 12}

SAMPLE DISCHARGE INSTRUCTIONS BASED ON CLINICAL TRIALS\textsuperscript{13}

It is very important that a patient follows the discharge instructions provided by the physician or the nursing staff after the procedure to ensure limited time of discomfort and proper healing of the esophagus.

- Maximize anti-secretory regimen (for example, esomeprazole or Nexium 40 mg twice per day for 1-3 months, followed by at least 40 mg per day thereafter).
- Antacid/lidocaine mixture per oral prn.
- Liquid acetaminophen with or without codeine per oral prn.
- Anti-emetic medication per rectum prn.
- Sucralfate oral suspension, one gram up to 4 times per day.
- Full liquid diet for 24 hours, then advancing to soft diet for 1 week.
- Avoid aspirin or non-steroidal anti-inflammatory medications for 7 days (per physicians’ instructions).
- Patient instructed to contact treating physician immediately for significant chest pain, difficulty swallowing, fever, bleeding, abdominal pain, difficulty breathing, vomiting or other warning signs provided by the physician, so that the physician may complete the appropriate diagnostic work-up (contrast radiography, CT scan or endoscopy) and/or provide the appropriate therapeutic intervention in order to avoid further complications.
- If the patient seeks care for a digestive issue from any healthcare personnel—other than the treating physician—in the six months following the ablation procedure, the treating physician who performed the ablation procedure should be consulted before any treatment is initiated.

THE INFORMATION PROVIDED IS INTENDED ONLY AS A GUIDE OR SAMPLE FOR PHYSICIANS AND NURSES WHO PROVIDE INSTRUCTION TO PATIENTS AFTER ESOPHAGOSCOPY AND ABLATION OF ESOPHAGEAL TISSUE. THIS INFORMATION IS NOT INTENDED TO INSTRUCT THE HEALTH CARE PROFESSIONAL IN THE PRACTICE OF MEDICINE AND SHOULD NOT REPLACE PROFESSIONAL JUDGMENT. ALTHOUGH WE SUPPLY THIS INFORMATION TO THE BEST OF OUR KNOWLEDGE, IT IS ALWAYS THE HEALTH CARE PROFESSIONAL’S RESPONSIBILITY TO CREATE THEIR OWN VERSION OF THIS INFORMATION ACCORDING TO INDIVIDUAL PATIENT REQUIREMENTS, FACILITY POLICY, PHYSICIAN PREFERENCE AND STANDARD OF CARE.
**Follow-up**

A follow-up appointment is scheduled within two months to assess the response to the treatment.

- If there remains any residual Barrett’s tissue, additional ablative therapy may be recommended (see sample from chart).
- In clinical studies, most patients required one circumferential ablation procedure and one or two focal ablation procedures.  

**Surveillance**

Medical societies recommend surveillance for patients diagnosed with Barrett’s esophagus. Patients undergo an upper endoscopy procedure with biopsies on a regular basis for the remainder of their lifetime. The frequency of endoscopy is determined by the grade of the Barrett’s esophagus and the treatment regimen dictated by the physician. 

**GERD**

Successful elimination of the Barrett’s esophagus tissue does not cure pre-existing GERD or associated symptoms.

The physician will guide the patient regarding long-term GERD therapy.

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* Endoscopic biopsy: a sample of the tissue is obtained by the physician to confirm diagnosis, grade of disease, or further define the severity of the cellular changes.

This information is based on clinical trials. Patient management is at the discretion of the physician.
Clinical Trials

Results

Clinical evaluations have been completed in the United States and Europe demonstrating the safety and efficacy of the Barrx™ technology for treating all types of Barrett’s tissue.

- The “Ablation of Intestinal Metaplasia” (AIM) trial showed that 98.4% of patients with baseline non-dysplastic IM were completely free of all Barrett’s tissue at 2.5 years of follow-up.  

- The AIM-LGD and AIM-Dysplasia Trials applied RFA in a LGD patient population, and report complete eradication of all dysplasia in >90% of cases.  

- Results from several US and European trials have applied RFA in a HGD patient population, and report complete eradication of HGD in >90% of cases.

Long-term durability of Barrx™ technology was also studied. Here are key findings:

- In the AIM-II study, which followed non-dysplastic patients for five years, there was a durable complete response to RFA in 92% of patients.

- In the AIM-Dysplasia study, which followed dysplastic Barrett’s subjects, RFA therapy was found, “to have an acceptable safety profile, is durable, and is associated with a low rate of disease progression, for up to three years.”

Society Guidelines

If you’d like to learn how radiofrequency ablation (RFA) is regarded by key endoscopy and gastroenterology societies, please visit:

- Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)  

- American Gastroenterology Association (AGA)  
  http://www.gastro.org/practice/medical-position-statements

Key

LGD = Low-grade Dysplasia
HGD = High-grade Dysplasia
AMC = Academic Medical Center
To learn more about Barrett’s esophagus

Go to: www.CureBarretts.com

Ask your physician about treating your Barrett’s esophagus with the Barrx™ ablation technology.

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*Important Reminder: This information is intended only to provide general information and not as a definitive basis for diagnosis or treatment in any particular case. It is very important that you consult your doctor about your specific condition, contraindications and possible complications. This treatment is contraindicated in patients who are pregnant, have had prior radiation therapy to the esophagus, esophageal varices at risk for bleeding, have eosinophilic esophagitis, or prior Heller myotomy. Possible complications may include: mucosal laceration, perforation of the esophagus requiring surgery, infection, bleeding and stricture formation requiring dilation. The overall complication rate reported for this procedure, covering the period from April 2005 to July 2012, is approximately 0.24%.21

REFERENCES

13. Instructions for Use Documents for the Barrx™ 360 Soft Sizing Balloon/360 RFA Balloon Catheter (P/N 717-0016-XX) and Barrx™ 90 RFA Focal Catheter (P/N 717-0015-XX).
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