Barrett’s Esophagus

Radiofrequency Ablation with the HALO 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 an increased risk for developing esophageal cancer.

Approximately 3.3 million adults in the United States have Barrett’s esophagus.1,2

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.3
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 conscious sedation medications.

Endoscopic Biopsy
- During the endoscopy, a sample of the tissue may also be obtained by the physician to confirm diagnosis as well as grade or further define the severity of the cellular changes.

Endoscopic visual of Barrett’s within the esophagus. The Barrett’s tissue is salmon-colored compared to the pink-colored normal tissue.
Grading of Barrett’s Esophagus

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 general term that refers to the heating of unwanted or diseased cells to the point of cell death.
- Ablation has also been used for the control of bleeding (hemostasis).

HALO Ablation Technology
- The HALO 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 balloon-based HALO360™ ablation catheter, while smaller focal areas of Barrett’s tissue are treated with the endoscope-mounted HALO™ catheter.

In conjunction with an endoscopy, the HALO360™ or the HALO™ ablation catheter delivers 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.
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 recently conducted clinical trials:

- No eating or drinking after midnight the day before the procedure.
- Arrange to have someone drive the patient home after the procedure.
- If a patient takes aspirin or blood thinning medication, he or she will receive instructions from their doctor when to stop taking them 7 days before each endoscopy (a 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.\(^8,9\)
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-acid medications to promote healing of the esophagus.\textsuperscript{8,9}

DISCHARGE INSTRUCTIONS BASED ON CLINICAL TRIALS\textsuperscript{10}

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 ensure 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 in the 6 months following the ablation procedure, other than the treating physician, the treating physician 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 2 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.\(^8,9\)

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

Clinical evaluations have been completed in the United States and Europe demonstrating the safety and efficacy of the HALO 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.

LGD = Low-grade Dysplasia
HGD = High-grade Dysplasia
AMC = Academic Medical Center

Complete Response Rate for RFA in Published Clinical Trials

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<th>Complete Response Rate</th>
<th>Intestinal Metaplasia</th>
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<td>98.4%</td>
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* Cure rates based on initial diagnosis and one or more clinical trials.
† In clinical studies, most patients required one circumferential ablation procedure and one or two focal ablation procedures.

Complete response defined per trial (i.e. all biopsies obtained at last visit demonstrate absence of abnormal pathological finding).
To learn more about Barrett’s esophagus
go to: www.barrx.com/Patients_and_Families

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, 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 is approximately < 0.2%

REFERENCES
10. Instructions for Use Documents for the HALO360/HALO360+ (P/N 717-0004-XX) HALO90 (P/N 717-00002-XX) Ablation Catheters.

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