

Barrett's Esophagus



A photograph of a man with grey hair, wearing a brown long-sleeved shirt and tan pants, riding a bicycle. He is smiling and looking towards the camera. The background is a hilly, grassy landscape under a bright sky. Overlaid on the image is a diagram of the human digestive system. A circular inset shows a cross-section of the esophagus and stomach, with a red area indicating the site of Barrett's esophagus. The diagram is semi-transparent, allowing the man and the background to be seen through it.

What is Barrett's esophagus?

Barrett's esophagus is a pre-cancerous condition affecting the lining of the esophagus, the swallowing tube that carries foods and liquids from the mouth to the stomach.

Barrett's esophagus is estimated to affect about 3.3 million adults in the United States.^{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 with GERD, the normal esophagus cells are damaged. Over time, this damage can result in inflammation and genetic changes that cause the cells to become altered. The tissue takes on a different appearance and microscopically is no longer esophageal tissue, but rather becomes intestinal tissue. This is called "intestinal metaplasia" or Barrett's esophagus. If a patient has GERD symptoms more than 3 times per week, they should consult their physician.

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?

A diagnosis of Barrett's esophagus requires that the patient undergo an upper endoscopy procedure by their physician, typically a gastroenterologist or surgical endoscopist. Endoscopy is a non-surgical procedure and is performed using conscious sedation. Barrett's esophagus tissue appears as a different color on examination, which directs a biopsy of the tissue for pathology evaluation. A finding of intestinal cells in the esophagus (intestinal metaplasia) confirms a Barrett's esophagus diagnosis.

What are the different types of Barrett's esophagus?

There are different types or "grades" of Barrett's esophagus, according to biopsy and microscopic findings. These "grades" include: intestinal metaplasia (IM) without dysplasia, IM with low-grade dysplasia, and IM with high-grade dysplasia. "Dysplasia" refers to inherent abnormalities of a tissue or cell that make it more cancer-like and disorganized. While the presence of dysplasia may raise the risk of cancer, it is not considered cancer.^{4, 5} Ultimately, higher grades of dysplasia may be considered cancer if there are signs of tissue invasion.

What are the risks to the patient who has Barrett's esophagus?

Barrett's esophagus increases the risk for a patient to develop esophageal adenocarcinoma (a specific type of cancer.) While all grades of Barrett's esophagus place the patient at this higher risk, low-grade and high-grade dysplasia are the highest risk sub-types.⁶

How is Barrett's esophagus managed?

Joint recommendations from medical societies recommend that a patient with Barrett's esophagus should 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 Barrett's esophagus. A patient with IM without dysplasia will undergo surveillance endoscopy approximately every 3 years. The frequency for a patient with low-grade dysplasia is much higher (every 6-12 months) due to the increased risk for cancer development. A patient with IM with high-grade dysplasia may undergo surveillance endoscopy every 3 months, or be referred for more definitive therapy immediately.⁷

In addition to surveillance endoscopy approaches for Barrett's esophagus, there are treatment options that include endoscopic and surgical therapy to eliminate the Barrett's tissue completely. Patients should consult with their physician to determine what the optimal approach is for their particular disease state.

What is the treatment option using the HALO ablation technology?

"Ablation" is a technique where tissue is heated 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 precancerous conditions, as well as to control bleeding. The HALO ablation technology is a very specific type of ablation, in which heat energy is delivered in a precise and highly-controlled manner.

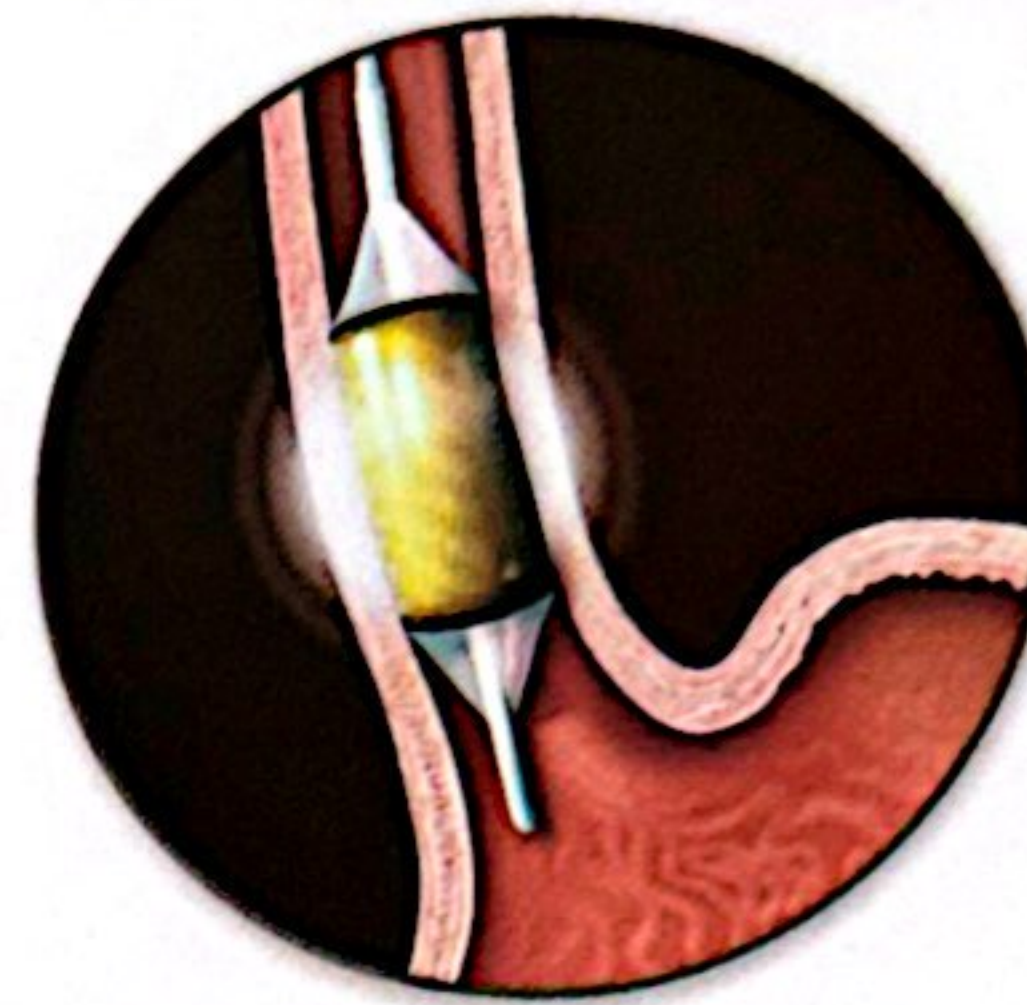
Barrett's esophagus tissue is very thin and is therefore a good candidate for removal with ablative energy. Delivery of ablative energy with the HALO ablation technology is therefore capable of achieving complete removal of the diseased tissue without damage to the normal underlying structures.

Clinical studies have demonstrated the Barrett's tissue can be completely eliminated with the HALO ablation technology in 98.4% of patients.^{8,9}

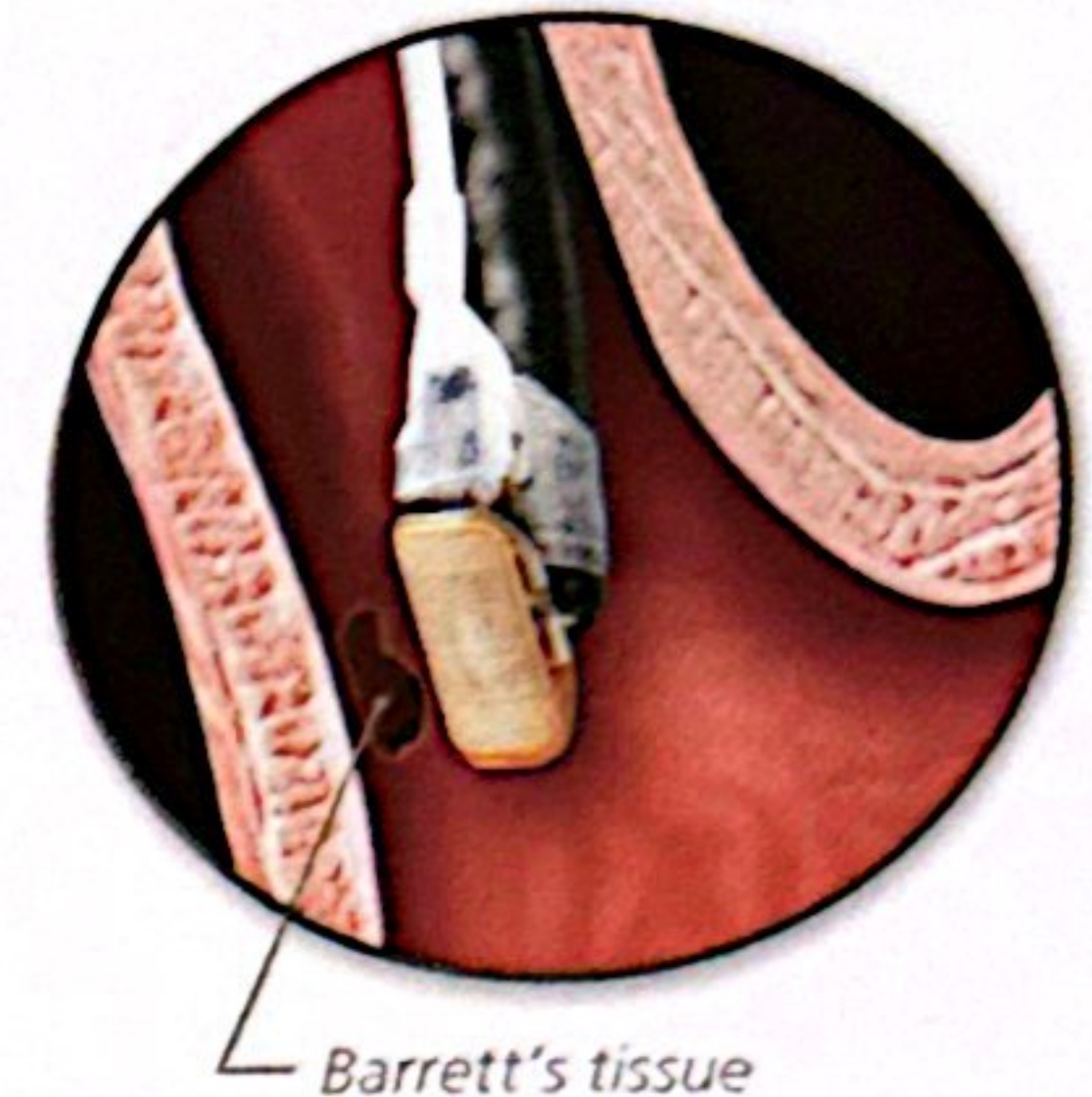
What happens during treatment with the HALO ablation technology?

Ablation therapy is performed in conjunction with upper endoscopy. The treatment is performed in an outpatient setting and no incisions are involved. The HALO ablation technology consists of two different devices; the HALO³⁶⁰ and HALO⁹⁰ ablation catheters. The HALO³⁶⁰ ablation catheter is capable of treating larger areas of circumferential Barrett's esophagus, while the HALO⁹⁰ ablation catheter is used to treat smaller areas.

HALO³⁶⁰ Ablation Catheter



HALO⁹⁰ Ablation Catheter



Depending on the extent of the Barrett's, the HALO³⁶⁰ or HALO⁹⁰ ablation catheter is introduced into the esophagus and used to deliver energy to the targeted areas.

What to expect after treatment?

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.^{9*} Patients are provided with anti-acid medications to promote healing of the treated esophagus and replacement of the diseased Barrett's tissue with a normal, healthy esophagus lining.¹⁰

A follow-up appointment is scheduled within 2-3 months to assess the response to treatment. If there remains any residual Barrett's tissue, additional therapy may be recommended.

How is GERD managed after a successful ablation?

Successful elimination of the Barrett's esophagus tissue does not cure pre-existing GERD or the associated symptoms. The physician will guide the patient regarding long-term GERD therapy.

To learn more about Barrett's esophagus

Go to:

www.barrx.com/Patients_and_Families

Ask your physician about treating your Barrett's esophagus with the HALO 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, 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 <0.02%.⁹

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