



Barrett's Esophagus



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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 between 1.6 - 5.6% of people 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 three 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 moderate 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.⁴⁻⁶

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

Barrett's esophagus patients have approximately a 0.3% to 0.6% chance of disease progression to cancer each year.⁷⁻¹⁰ In addition, recent studies suggest progression risk is cumulative over time, reporting progression to high-grade dysplasia or cancer in 7% of BE patients at 10 years.^{9,10}



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 three 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 three months, or be referred for more definitive therapy immediately.^{11,12}

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 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.¹³

What is the treatment option using Barrx ablation technology?

Barrx ablation technology is a very specific type of ablation, in which thermal (heat) energy is delivered in a precise and highly controlled manner.

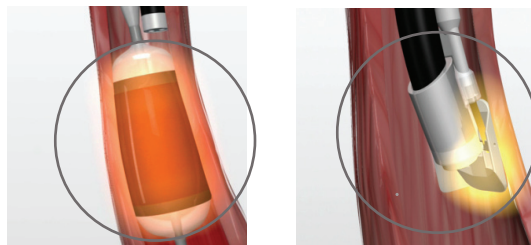
Barrett’s esophagus tissue is very thin and is, therefore, a good candidate for removal with ablative energy. Delivery of ablative energy with Barrx technology can achieve complete removal of the diseased tissue without damage to the normal underlying structures.

Clinical studies have demonstrated the Barrett’s tissue can be completely eliminated with Barrx ablation technology in 98.4% of patients.^{14,15}

What happens during treatment with Barrx ablation technology?

Ablation therapy is performed in conjunction with upper endoscopy. The treatment is performed in an outpatient setting and no incisions are involved. Barrx ablation technology consists of two different device types: a balloon catheter in various sizes and a series of RFA focal catheters. The Barrx™ 360 RFA balloon catheter is capable of treating larger areas of circumferential Barrett’s esophagus, while the Barrx™ RFA focal catheters are used to treat smaller areas.

Barrx™ 360 RFA Balloon Catheter Barrx™ 90 RFA Focal Catheter



Depending on the extent of the Barrett’s, the Barrx™ 360 RFA balloon catheter or one of the RFA focal catheters 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.^{14,16,17} 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.^{14,16-18}

A follow-up appointment is scheduled within 2-3 months to assess the response to treatment. If any Barrett’s tissue remains, 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.CureBarretts.com

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

Provided as a service by Covidien.

*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 February 2012, is approximately 0.23%.¹⁵

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