Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner. Rx only.

Risk Information: The following are transient side effects that may be expected after treatment: chest pain, difficulty swallowing, painful swallowing, throat pain and/or fever. Complications observed at a very low frequency include: mucosal laceration, minor and major acute bleeding, stricture, perforation, cardiac arrhythmia, pleural effusion, aspiration, and infection. Potential complications that have not been observed include: death. Please refer to the product user manual or medtronic.com/gi for detailed information.

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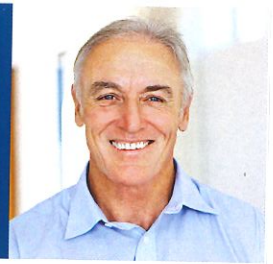
BARRETT'S ESOPHAGUS PATIENT DISCUSSION REFERENCE GUIDE



About Barrett's Esophagus

Barrett's esophagus (BE) patients have approximately a 0.3% to 0.6% chance of disease progression to cancer each year,[1-4] while Barrett's esophagus patients with low-grade dysplasia (LGD) have a 6.6% to 13.6% per year chance of progressing to high-grade dysplasia (HGD) or cancer.[5-9] In addition, studies suggest progression risk is cumulative over time, reporting progression to HGD or cancer in 7% of BE patients at 10 years.[4]

Barrett's esophagus puts patients 50 times or more at risk of developing cancer of the esophagus than the general population.[3,10]

Esophageal cancer is one of the most aggressive cancers[11,12] with only an 18% chance of surviving 5 years after diagnosis.[11]

Treatment of Barrett's Esophagus: Medical Society Statements and Other Facts

GI society guidelines suggest that patients with HGD and LGD should not just be watched.[13,14] Data supports that radiofrequency ablation (RFA) significantly reduces progression to cancer in HGD,[5] LGD,[5,6,7] and non-dysplastic Barrett's esophagus (NDBE) patients.[15]

NDBE patients who have factors that could place them at higher risk of disease progression should be considered for intervention.[13,14]

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Further, Together

About RFA Therapy

The Barrx™ radiofrequency ablation (RFA) system has been used in over 216,000 procedures and more than 70,000 patients worldwide since it was made available to patients in 2005.[16] RFA restores the natural esophageal squamous epithelium in the majority of patients.[5,17]

Over 200 peer-reviewed publications have documented the technology's ability to remove Barrett's esophagus with a very low complication rate. One study showed that among patients with non-dysplastic Barrett's esophagus, complete response to therapy was seen in 98% of patients at 2.5 years and 92% of those patients remained disease free after 5 years.[18]

RFA is effective at reducing risk for esophageal adenocarcinoma (EAC), even when applied outside tertiary care centers.[15]

About the Procedure[19]

This is an outpatient procedure with prep similar to an upper endoscopy. Most patients recover 1 hour after the procedure and are discharged.

Complete eradication of Barrett's esophagus usually takes 3 to 4 treatments, which are done 2-3 months apart.

Discomfort: You may experience one or more of the following symptoms after treatment:

- Chest discomfort
- Sore throat
- Difficulty or pain with swallowing
- Nausea/vomiting

These symptoms should improve with each day. You will be provided with several medications and specific instructions to make you as comfortable as possible.

Diet: Full liquid diet for 24 hours, then advancing to soft diet for 7 days.

Risks of Progression for Non-dysplastic Barrett's Esophagus	
IM advancing to high-grade dysplasia or esophageal cancer	7.3%/10 yrs[3]
IM advancing to esophageal cancer	2.9%/10 yrs[3]

Risks of Progression of Confirmed Low-Grade Dysplasia Barrett's Esophagus	
LGD advancing to esophageal cancer	8.8%/3 yrs[6]
LGD advancing to high-grade dysplasia or esophageal cancer	26.5%/3 yrs[6] 6.6%-13.6%/year[5-9,20]

Risk Factors Associated with Esophageal Adenocarcinoma

Risk Factor	Relative Risk (RR) or Odds Ratio (OR) Impact of Risk	Source
Male	Relative risk (RR*) of 7.1 as compared to women	*Cancer* 2012;118:2338
Caucasian	RR of 1.65-5.5 as compared to other racial groups	*Cancer* 2012;118:2338
Obesity[21]	RR of 1.71 for BMI* 25-30 RR of 2.34 for BMI ≥ 30 for esophageal and gastric cardia adenocarcinoma RR of 2.73 for BMI ≥ 30 for esophageal adenocarcinoma	*Ann Oncol.* 2013 Mar;24(3):609-17
Smoking	RR of 2.32 for current and 1.62 for former smokers	*Epidemiology* 2011;22:344
Hiatal hernia ≥ 4 cm	OR* of 10.63	*Cancer* 2007;109:668
Barrett's segment[22] ≥ 3 cm	OR of 3.72 for BE length 4-6 cm OR of 5.96 for BE length 7-9 cm OR of 6.97 for BE length 10-12 cm OR of 10.27 for BE length ≥ 13 cm Increasing segment length appeared to be associated with increased risk of EAC.	*Clin Gastroenterol Hepatol.* 2013;11(11):1430-6
Family history	RR of 6.2 in familial as compared to sporadic BE	*Dis Esophagus* 2007;20:53
Duration of BE	RR of 3.2 for a duration of BE > 10 years	*Am J Gastroenterol* 2011;106:1231

* Relative Risk: A measure of the risk of a certain event happening in one group compared to the risk of the same event happening in another group. http://www.cancer.gov/dictionary?CdrID=618613
* Odds Ratio: An odds ratio (OR) is a measure of association between an exposure and an outcome. The OR represents the odds that an outcome will occur given a particular exposure, compared to the odds of the outcome occurring in the absence of that exposure. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2938757/
* Body Mass Index (BMI): A measure of body fat based on height and weight. http://www.nhlbi.nih.gov/guidelines/obesity/BMI/bmicalc.htm