Radiofrequency ablation (RFA; HALO®)

Basics

Radiofrequency ablation (RF ablation; RFA; HALO®; GI Solution, Covidien, USA) is a novel technology for the effective and durable minimal invasive endoscopic elimination of Barrett’s esophagus (±dysplasia and early stage cancer). Barrett’s esophagus is a premalignant tissue of the innermost layer (mucosa) of the esophagus (gullet). Barrett’s esophagus develops as a consequence of the reflux. Reflux in turn causes inflammation and genetic changes, which format the tissue for progression to cancer. Via low- and high grade dysplasia (dysplasia; greek: dysplasein: misformation) Barrett’s esophagus may progress to cancer. Barrett’s esophagus harbors a 0.5% annual risk for cancer development. This means that 1 out of 10 patients with Barrett’s esophagus will develop cancer in 20 years. Barrett’s esophagus without dysplasia and a colon polyp share the SAME cancer risk. Therefore, in terms of cancer prevention, Barrett’s esophagus and a colon polyp require the same treatment: removal. Colon polyp and Barrett’s esophagus is removed by polypectomy and RFA, respectively.

RFA Indications

RFA indications include Barrett’s esophagus without dysplasia, Barrett’s esophagus with dysplasia and early stage cancer restricted to the most inner layer of the esophagus (mucosa). In the presence of endoscopically visible lesions (nodes, polyps, ulcer) RFA is combined with endoscopic mucosal resection (EMR). Here, under endoscopic vision, the endoscopist cuts out the abnormal tissue (node, polyp, ulcer) with a special knife. The tissue is then processed for pathologic examination.

RFA contraindications

RFA contraindications include pregnancy, comorbidities (heart, lung, blood pressure, kidney and liver disease), blood clotting disorder, esophageal diseases (ulcer, tumor, diverticula, varices), diabetes, connective tissue disease (scleroderma, lupus erythematoses) and the inability to sign written consent.

Preparation & management

Preparation for RFA is identical to gastroscopy. We conduct RFA after 6 hours fast. If the procedure is performed before noon, do not take blood pressure and heart medication in the morning. You are allowed to take the morning does of hormones (thyroid), antacid, proton pump inhibitor (PPI) and vitamin pills. Consult your physician for the discontinuation of your blood clotting medication. We conduct RFA in the day care setting. However, if you wish, you may also be admitted overnight. The experienced members of our team perform RFA in our cooperating hospitals.

RFA: how it works

Here we describe the RFA technology and the steps of the procedure.

RFA Technology

RFA technology includes the foot pedal operated generator of the RF energy (HALOflex®) and the tools
for the delivery of the RF energy to the esophagus. The devices for the RF energy delivery are connected to the HALO®flex® generator. We use the following devices for the delivery of the RF energy to the Barrett’s esophagus:

**HALO 60®**

The HALO 60® is a small electrode plate for focal ablation (=treatment of small areas of Barrett’s esophagus). The HALO 60® electrode is mounted to the tip of the endoscope and thus introduced into the esophagus. Under endoscopic vision the RF energy pulse is delivered and kills the Barrett’s tissue.

**HALO 90®**

The HALO 90® is a larger electrode plate for focal ablation (=treatment of larger areas of Barrett’s esophagus). The HALO 90® electrode is mounted to the tip of the endoscope and thus introduced into the esophagus. Under endoscopic vision the RF energy pulse is delivered and kills the Barrett’s tissue.

**HALO 360®**

The HALO® 360 is a balloon mounted catheter and includes the sizing balloon and the treatment balloon. HALO 360®is used for circumferential ablation. During the operation the sizing and the treatment balloon are connected to the generator. The sizing balloon is used for the assessment of the diameter of the esophagus: this gives the dimension of the treatment balloon. On its surface the treatment balloon incorporates the electrodes. Under endoscopic vision the deflated treatment balloon is introduced into the esophagus, positioned at the level of the Barrett’s segment. Upon pedal activation of the generator, the balloon inflates, distends, the electrode gets contact with the innermost layer of the esophagus. In this position the RF energy pulse is delivered to the Barrett’s esophagus. Following the RF energy pulse the balloon deflates and is ready for additional treatment. The sizing and the treatment balloon are introduced into esophagus via a guide wire under endoscopic vision. This maneuver prevents perforation. RF energy pulse is 10J / m2 or 12 J / m2 for Barrett’s esophagus without and with dysplasia/early stage cancer (respectively).

**RFA procedure**

We conduct RFA under general anesthesia. The RFA procedure starts with the endoscopic assessment of the Barrett’s esophagus. Following sizing the HALO® 360 treatment balloon is introduced into the esophagus under endoscopic vision. The balloon is positioned at the level of the Barrett’s esophagus and the RF energy is delivered. Then the white necrotic tissue is scrapped off. Then the ablation is repeated and the treatment ended.

For HALO 60® and 90® the electrode plate is mounted in the tip of the endoscope and thus introduced into the esophagus. Under endoscopic vision the electrode is pushed to the surface of the Barrett’s esophagus and 2 RF energy pulses (12 J / m2) are delivered to the tissue. Then the necrotic white tissue is scraped off and 2 additional RF energy pulses are delivered to the esophagus. Then we skip to next treatment area.
Endoscopic image during radiofrequency ablation, using the HALO 360 balloon catheter. Yellow arrow marks the ablated tissue after successful treatment.

Prognosis

RFA eliminates Barrett’s esophagus and prevents cancer development. We conduct gastroscopy 2-3 months after RFA to verify the effect of the treatment.

Results after RFA

After 1-4 RFA treatments Barrett’s esophagus (±dysplasia) is eliminated in more than 90% of the cases. Durability: after 5 years Barrett’s esophagus remains eliminated in 92% of the cases. Barrett’s esophagus without dysplasia: in 70% of the cases Barrett’s esophagus without dysplasia is eliminated after 1 RFA session. 30% of the cases require 2 – 4 treatment sessions. The number of treatment sessions required for effective elimination increases with the length of the Barrett’s mucosa. Barrett’s esophagus with dysplasia: in 90% of the cases Barrett’s esophagus with dysplasia is eliminated after 2-4 treatment sessions.

RFA and anti reflux surgery

RFA eliminates Barrett’s esophagus. RFA does not eliminate the cause: the reflux. During anti reflux surgery (fundoplication) we wrap the fundus of the stomach around the lower portion of your esophagus. This procedure creates an effective anti reflux mechanism and prevents reflux after RFA. Recent data showed that effective fundoplication potentiates the effect of RFA. Thus Barrett’s esophagus without dysplasia was eliminated in 75% cases vs. 95% cases after RFA without vs. RFA with fundoplication, respectively. We are pleased to inform you about the treatment of your Barrett’s esophagus.

Complications after RFA
Complications after RFA are rare (0.2% after more than 90,000 applications) and include perforation, bleeding, nausea, vomiting, abdominal discomfort, chest pain, and fever. Patients may perceive pain in the neck and throat for 1-2 days after RFA. To prevent the development of pain, fever and discomfort patient after the procedure, our anesthesiologist administers respective medications at the start of RFA.

**Expert opinion**

**Sebastian Schoppmann (Surgeon, Vienna):**

Here we talk about cancer prevention. Colon polyps and Barrett’s esophagus have the same cancer risk (0.5% annual risk). Therefore, colon polyps and Barrett’s esophagus have to be removed in order to prevent progression to cancer. There is no doubt to remove a colon polyp. In the case of Barrett’s esophagus many physicians are still restrictive and wait until dysplasia or early cancer develop. As a surgeon I know what esophageal cancer means for the patient: pain, suffering, stress, chemotherapy, major surgery, short survival. Therefore we offer removal of Barrett’s esophagus by radiofrequency ablation. This is modern cancer prevention for reflux patients.

**Fritz Wrba (Pathologist, Vienna):**

The pathologist sees the benefit of treatment at the cellular level. Radiofrequency ablation is very effective, in 70% of the cases the Barrett’s mucosa is eliminated and replaced by a non-Barrett’s mucosa. 30% need additional treatments. It shows us that Barrett’s behaves like polyps in the colon. As you remove it at one site it may re-develop at another. However, regular endoscopic ablation saves the esophagus and the life of the patient.

Martin Riegler (Surgeon, Vienna). Radiofrequency ablation removes the Barrett’s esophagus. It does not remove cause of the disease, the reflux. Therefore we offer combined radiofrequency ablation and anti-reflux surgery (fundoplication). At present radiofrequency ablation is not allowed in combination with the magnetic ring operation. The RF energy is suggested to affect the function of the ring.

**Literature**

10. O’Connell K, Velanovich V. Effects of Nissen fundoplication on endoscopic endoluminal