Safety and Efficacy of the Self Sizing Radiofrequency ablation balloon for eradication of Barrett's esophagus: an uncontrolled multicenter feasibility study

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The aim of the study is to assess the efficacy and safety of the self-sizing RFA ballon for eradication of Barrett's mucosa with low-grade, high-grade and early neoplasia

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON41109

Source
ToetsingOnline

Brief title
Self sizing RFA balloon for Barrett's esophagus

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
Dysplasia in Barrett's, precancerous esophageal mucosa

Research involving
Human

Sponsors and support

Primary sponsor: GI solutions, a subsidiary of Covidien, Inc. (Formerly BARRX Medical, Inc.)
Source(s) of monetary or material Support: Ministerie van OC&W,GI

Solutions;Covidien;Sunnyvale CA;USA

Intervention

Keyword: Barrett, Dysplasia, Radiofrequency ablation

Outcome measures

Primary outcome

1) Percentage of endoscopically visual surface regression of BE epithelium at 3 months, as scored by two independent endoscopists.

Secondary outcome

1) Number of Adverse events:

The number of patients who reported acute (periprocedural), early (<48 hrs) or late (>48 hrs) complications.

2) Duration and acceptability of the ablation procedure:

Time of first introduction of the endoscope, time of the first introduction of the Self-sizer balloon and the time of final removal of the Self-sizer balloon are recorded during the endoscopy.

Study description

Background summary

Radiofrequency ablation is an established endoscopic technique for eradication of Barrett*s esophagus which has been investigated in a variety of study designs (including two randomized trials), and settings (US and EU, tertiary academic centers, community referral centers).9-13 Radiofrequency ablation is associated with an acceptable safety profile, high rates of complete eradication of dysplasia and intestinal metaplasia, durability of effect, and a significant relative risk reduction for neoplastic progression.9-13 As a result, radiofrequency ablation is considered standard of care for patients with high-grade dysplasia, as well as for residual Barrett tissue after endoscopic resection of early cancer.14

Currently, most patients undergo primary circumferential ablation with a balloon based electrode, the Barrx360 System, followed by additional focal ablation using a cap-based electrode, the Barrx90 System. The Barrx360 procedure starts with the introduction of a sizing balloon to measure the internal esophageal diameter, because the ablation balloon comes in different sizes (18-31mm). The sizing balloon is used to take multiple measurements of the esophageal diameter and assists the endoscopist in choosing an ablation catheter with the appropriate diameter. Subsequently, the sizing balloon is removed and the BE segment can be treated with one of the five sizes of the ablation balloon. The advised standard treatment regimen for Barrx360 procedures consists of two ablation runs with extensive cleaning of the ablation zone after the first ablation (1x-clean-1x). The entire treatment procedure is time-consuming, as it consists of many different steps and requires multiple introductions and removals of the endoscope, sizing catheters and ablation balloons which are impractical and uncomfortable to the patient. By incorporating the sizing balloon and the Barrx360 ablation balloon into a single device, the use of a separate sizing balloon and the need for having multiple sized balloon catheters are eliminated. The new Self Sizing RFA balloon catheter is a circumferential balloon catheter, and consists of a 4cm long bipolar electrode that is furled around a balloon. This single balloon catheter can unfurl in size ranges including 18-31mm, making it possible to size and treat the BE segment in a single step.
The current study is designed as an uncontrolled feasibility study using the Self Sizing RFA balloon for circumferential ablation of Barrett*s esophagus with early neoplasia.

Study objective

The aim of the study is to assess the efficacy and safety of the self-sizing RFA ballon for eradication of Barrett's mucosa with low-grade, high-grade and early neoplasia

Study design

Enrollment
Thirty patients will be enrolled in this study. If a patient is eligible for the study after the mapping endoscopy, and/or after endoscopic resection, and no abnormalities (visible lesions and/or severe stenosis) are observed during the endoscopy, the patient will undergo treatment with the Self Sizing RFA Balloon catheter treatment using the standard protocol .

4.4 Endoscopic resection at baseline
For patients with a visible abnormality mandatory endoscopic resection is performed. In case there is no suspicion on submucosal infiltration of the lesion the choice of ER technique will be left to the discretion of the endoscopist, with a preference for the ER-cap technique or endoscopic

submucosal dissection (ESD) for type 0-Is lesions and the multi-band mucosectomy (MBM) technique for type 0-II lesions. In case of suspicion on submucosal infiltration, the resection is preferably performed using the ER-cap or the ESD technique, since this will result in a larger and deeper resection specimen than with the MBM technique.
Prior to the ER procedure, the extent of columnar lined esophagus is documented according to the Prague C&M classification.15
During the ER procedure, biopsies from the remaining Barrett*s segment (4Q/2cm) will be obtained immediately after the endoscopic resection, to evaluate the histological status of the remaining mucosa and to exclude the presence of cancer. If complete endoscopic resection of all visible abnormalities has been achieved during the ER procedure and the biopsies from the residual Barrett*s segment, as obtained immediately after the ER, do not show invasive cancer the patient is eligible for RFA.

4.5 Ablation procedure
4.5.1 Inspection of the Barrett*s segment
The esophagus is evaluated using white light high-resolution endoscopy (WLE) and narrow band imaging (NBI). The extent of columnar lined esophagus is documented according to the Prague C&M classification [ref] and by taking still images with WLE+NBI at 1 cm intervals. In the absence of visible abnormalities and no severe stenosis, patients will be eligible for circumferential ablation with the Self Sizing RFA balloon using the standard ablation regimen.

4.5.2 Standard ablation regimen
After mapping, the Barrett*s segment is flushed with the mucolytic agent acetylcysteine (1%) followed by flushing with tap water. The Self Sizing RFA balloon (GI Solutions Covidien, Sunnyvale, CA) is then introduced and positioned at the desired treatment zone. The device is inflated, and the electrode unfurls until the electrode contacts the esophageal wall. Under visual control the BE is ablated (12 J/cm2 at 230 Watt) working proximal to distal using visual repositioning. A small overlap (i.e. <1cm) between ablation zones is allowed. After the first ablation pass, the endoscope is removed followed by removal of the ablation catheter. The coagulum is cleaned off the balloon catheter. The endoscope is reintroduced to irrigate and suction the ablation zone. A distal attachment cap may be attached to the tip of the endoscope to gently wipe of the coagulum from the ablated segment. After irrigating and suctioning the debris away as much as possible, the ablation zone is cleaned by forcefully flushing water through a spraying catheter. The stomach is emptied and deflated, the endoscope is removed and the ablation catheter is reintroduced to repeat the ablation. After this second ablation no additional cleaning of the ablation zone is required. First, the endoscope is removed, followed by careful removal of the ablation catheter.
4.6 Medication and discharge regimen
All patients will be on a maintenance dose of a proton pump inhibitor (by preference esomeprazole) at a dosage of 40 mg twice a day during the whole treatment period and follow-up. This medication is supplemented with ranitidine

300 mg at bedtime and sucralfate suspension four times a day (after each meal and prior to bedtime) for a period of two weeks following all RFA procedures.
4.7 Follow-up
At 3 months, the first post-treatment endoscopy will be performed with WL high resolution endoscopy and NBI. Still images with WLE+NBI will be obtained at 1-cm intervals throughout the extent of the original Barrett*s segment, to assess the percentage of endoscopically visible surface regression of BE (3.10.1), and any visible adverse events. Further treatment and follow-up are performed according to standard guidelines. After complete removal of BE is achieved, patients will be scheduled for surveillance endoscopy after six months, twelve months and annually thereafter with WLE plus NBI and 4-quadrant biopsies from the gastric cardia (immediately below the neosquamocolumnar junction), off protocol.

Intervention

Radiofrequnecy ablation to eradicate barrett's mucosa

Study burden and risks

The ablation procedure with the self-sizing balloon will be less complicated, because sizing of the inner esophagus is not performed as done in the RFA procedure according the general guidelines. This will shorten the procedure and less number of introductions of the gastroscope.
During the procedure with the self-sizing balloon, accurate imaging before and after the ablation will increase the procedure time.
Overall, the procedure time will be more or less the same as the regular balloon-based ablation.
The self-zing balloon has the same pressure (4 psi) and the same radiofrequency energy (12j/cm2). We expect no additional risk for patients participating in the study more than patients undergoing the regular ablation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Patients aged 18-85 years, with biopsy proven LGD, HGD or EC in a BE confirmed after expert pathology review.
2. Scheduled circumferential ablation for BE with flat HGD, or for BE after prior endoscopic resection (ER) for lesions containing HGD or EC (<2 cm and <50% of the circumference).
3. Pretreatment biopsies and/or ER specimens reviewed by a local expert pathologist.
4. Written informed consent.

Exclusion criteria

1. Patients with a BE segment < 2cm or >10 cm prior to ER.
2. Any prior endoscopic ablation treatment.
3. Significant esophageal stenosis prior to initial treatment, preventing passage of a therapeutic endoscope OR any prior endoscopic dilatation for esophageal stenosis.
4. Presence of esophageal varices.
5. Anti-coagulant therapy (apart from aspirin or NSAID) that cannot be discontinued prior to ER or RFA, OR uncorrectable hemostatic disorders.
6. In case of prior ER: patients with ER of multiple lesions in a single ER session are not eligible, if one of the resections measures more than the aforementioned size criteria, OR if resections of different lesions are not separated by a free circumferential segment of at least 1 cm.
7. In case of prior ER: a specimen showing carcinoma with positive vertical resection margins, deep submucosal invasion (>T1sm1), poorly or undifferentiated cancer (G3 or G4), or lymphatic/vascular invasion.
8. In case of prior ER: invasive cancer in any of the biopsies obtained at high-resolution

endoscopy after ER.
9. An interval >6 months between the last high-resolution endoscopy with biopsies and RFA. An interval < 6 weeks between ER and RFA.
10. Patients unable to give informed consent.

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-09-2014
Enrollment:	24
Type:	Actual

Medical products/devices used

Generic name:	self-sizing RFA balloon
Registration:	No

Ethics review

Approved WMO Date:	24-09-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-09-2014
Application type:	Amendment

Review commission: METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL49843.018.14