Improving practicality of radiofrequency ablation for eradication of Barrett's mucosa: A randomized trial comparing three different treatment regimens for circumferential ablation using the HALO360 System.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21516

Source
NTR

Health condition

Barrett's esophagus; Barrett's dysplasia; early Barrett's neoplasia; radiofrequency ablation; endoscopy; Intestinal metaplasia; intraepithelial neoplasia.

Sponsors and support

Primary sponsor: AMC Amsterdam
Source(s) of monetary or material Support: BARRX Medical, Sunnyvale, CA, USA. (material support)

Intervention

Outcome measures

Primary outcome

Percentage of endoscopically visual surface regression of BE epithelium at 3 months as scored by two endoscopists blinded to the treatment regimen by using endoscopic images of the Barrett's esophagus prior to and 3 months after the the first treatment session (e.g. 80% of the Barrett's epithelium in regression). And, by using standardized case record forms on which the size and aspect of the Barrett's esophagis prior to and after the first treatment session are registered.

Secondary outcome

1. Duration of the procedure (registered on the case record form);

2. Amount and type of sedative medication necessary (registered on the case record form);

3. Number of introductions of the ablation device and endoscope (registered on the case record form);

4. Complications (prospectively registered in the 3months interval after treatment using case record forms);

5. Patient's discomfort after HALO360 treatment (using a standardized questionnaire).

Study description

Background summary

Three different protocols for the initial balloon-based circumferential radiofrequency ablation treatment will be compared. One regimen is the standard currently used regimen, two other regimens are simplified regimens.

Study objective

The simplified HALO360 ablation regimen result in an easier and faster ablation procedure, while maintaining efficacy and safety.

Study design

Primary outcome is scored 3 months after RFA. Secondary outcomes are scored during and after the RFA procedure.

Intervention

Circumferential balloon-based endoscopic radiofrequency ablation using the HALO system for Barrett's early neoplasia. These treatment sessions take approximally 30-60 minutes.

Treatment protocol: HALO360 procedure:

The esophagus is evaluated using white light (WL) high-resolution endoscopy and narrow band imaging (NBI). The extent of columnar lined esophagus is documented according to the Prague C&M classification and the number and localization of islands of Barrett's are noted. A pullback video recording (WL+NBI) of the Barrett's segment is obtained. If this is not possible, still images (WL+NBI) for every cm of the BE while pulling back from the top of the gastric folds (TGF). Patients are subsequently randomized to circumferential ablation with the HALO360 system using the simplified or the standard ablation regimen.

Standard HALO360 ablation regimen:

After mapping and randomization, the Barrett's segment is flushed with the mucolytic agent acetylcysteine (1%) followed by flushing with tap water. Subsequently, a guide wire is inserted into the duodenum and the endoscope is removed. A non-compliant sizing balloon (BÂRRX Medical, Sunnyvale, CA) is then introduced over the guide wire and positioned 4 cm above the proximal margin of BE. The balloon is then automatically inflated to 4 psi (0.28 atm) and the internal esophageal diameter is automatically calculated based on baseline balloon volume/geometry and the inflated pressure/volume. Sizing is repeated moving distally, for every 1 cm of BE until the transition to cardia is detected by a rapid increase in calculated diameter. After previous ER, the advice is to use an ablation catheter that is one step smaller in diameter than the diameter advised by the sizing procedure. After the ablation catheter has been introduced over the guide wire, the endoscope is introduced and under visual control the BE is ablated at an energy level of 12 J/cm2 at 300 Watt with working proximal to distal using visual repositioning. A small overlap (i.e. <1cm) between ablation zones is allowed. The endoscope is removed followed by removal of the ablation catheter and the guide wire. Before the second ablation pass, the coagulum is cleaned off the balloon catheter. The endoscope is reintroduced to irrigate and suction the ablation zone. A distal attachment cap will 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 and the endoscope is removed, after reintroduction of the guide wire. The ablation catheter is reintroduced over the guide wire to repeat the ablation, after reintroduction of the endoscope to allow for ablation under vision. 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.

Simple HALO360 ablation regimen 1:

In the simplified ablation regimen 1 flushing with the mucolytic agent acetylcysteine (1%) is not performed, but the esophageal wall will be flushed with water through the flushing channel of the endoscope. Pre-RFA sizing, selection of the appropriate ablation balloon, and the first ablation pass are performed according to the guidelines description above. After the first ablation the ablation balloon is not removed but advanced distally into the stomach. The treated surface is cleaned by pushing of the debris with the distal cap, which has been attached to the endoscope before ablation. No high-pressure flushing is performed after cleaning the ablation zone with the cap. After cleaning of the treatment area, a second ablation at 12 J/cm2 at 300 Watt is performed.

Simple HALO360 ablation regimen 2:

In the simplified ablation regimen 2 flushing with the mucolytic agent acetylcysteine (1%) is not performed, but the esophageal wall will be flushed with water through the flushing channel of the endoscope. Pre-RFA sizing and selection of the appropriate ablation balloon, are performed according to the guidelines description above. The ablation is not done in two passes but in one pass. Ablation will be performed twice at the same level, followed by moving the balloon distally to the consecutive ablation zone which is ablated twice too. After ablating the whole Barrett’s segment, the endoscope will be removed followed by the balloon and guidewire. This regimen is even faster than regimen1. Only one pass with the ablation balloon has been done.

Contacts

Public
Academic Medical Center
Bldg. C2-210, Meibergdreef
J.J.G.H.M. Bergman
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5669111
Scientific
Academic Medical Center
Bldg. C2-210, Meibergdreef
J.J.G.H.M. Bergman
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5669111

Eligibility criteria

Inclusion criteria

1. Scheduled HALO360 ablation for BE with flat low-grade dysplasia (LGD) or high-grade dysplasia (HGD) or for BE (with or without neoplasia) after prior endoscopic resection (ER) for lesions containing HGD or and early cancer;

2. Review of histopathology specimens by a local expert pathologist;

3. Written informed consent.

Exclusion criteria

1. In case of prior ER: A specimen showing carcinoma with positive vertical resection margins, deep submucosal invasion (≥ T1sm2), poorly or undifferentiated cancer (G3 or G4), or lymphatic/vascular invasion;

2. Patients unable to give informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2008
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion

Date:	03-09-2010
Application type:	First submission

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
NTR-new	NL2388
NTR-old	NTR2495
Other	METC AMC : 08/272
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A