Improving practicality of radiofrequency ablation for eradication of Barrett*s mucosa: a randomized trial comparing two different treatment regimens for circumferential ablation using the HALO360 System

Published: 06-02-2009
Last updated: 06-05-2024

The aim of the study is to develop a shorter, less technical demanding and therefore less uncomfortable for the patient, procedure for the HALO360 treatment of Barrett's esophagus with early neoplasie, high-grade or low-grade dysplasia, without...

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

Summary

ID

NL-OMON32766

Source
ToetsingOnline

Brief title
Radiofrequency ablation with HALO360 system: improvement treatment regiment

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
Barrett's esophagus, early cancer

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,BARRx Medical Inc , 540 oakmead Parkway, Sunnyvale CA 94085

Intervention

Keyword: Barrett's esophagus, Dysplasia, Improvement treatment regime, Radiofrequency ablation

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

Secondary outcome

- Duration of the procedure

- Amount and type of sedative medication necessary

- Number of introductions of the ablation device and endoscope

- Complications

- Patient*s discomfort (VAS-score) after HALO360 treatment

Study description

Background summary

Endoscopic ablation therapy is used for treatment of selected patients with HGIN in a Barrett*s esophagus.(7;8) Endoscopic ablation therapy is used as an adjuvant treatment after ER for early Barrett*s cancer to treat any hidden areas of synchronous neoplasia and/or to reduce the rate of recurrences during follow-up. Photodynamic therapy (PDT) and Argon Plasma Coagulation (APC) are the most widely used techniques in this respect.(9-11) Both are associated with significant drawbacks: PDT is expensive and uncomfortable to the patient. In

addition, the genetic abnormalities of the Barrett*s mucosa remain unaltered after PDT and may even increase the genetic damage of the remaining epithelium.(12) APC is most effective at higher energy settings where it may be associated with perforation and stenosis, and requires multiple treatment sessions.(13) After PDT and APC, a substantial number of patients have residual Barrett*s epithelium or buried Barrett*s. (10;11)
Radiofrequency ablation (RFA) is a new endoscopic ablation technique that has been shown to be an easy, safe and effective treatment modality for complete eradication of Barrett*s esophagus (BE) containing early neoplasia. (23)
Compared to PDT and APC, RFA seems to be more easy to use, better tolerated by patients, and is not associated with esophageal stricturing or the occurrence of buried Barrett*s. (15;16)
In RFA, the Barrett*s segment is ablated by radiofrequency energy through two specially designed devices for circumferential and focal ablation respectively. The HALO360 System consists of a balloon which contains a spindle-shaped electrode on its outer surface. Balloons with different diameters and lengths of electrodes are available. For focal ablation a cap-based electrode, the HALO90 System is used. The instruments have been developed by BÂRRx Inc, California, USA and are FDA approved for ablation of Barrett*s mucosa.
Radiofrequency ablation (RFA, BÂRRX Medical, Sunnyvale, CA, USA) has been shown to be an easy, safe and effective treatment modality for complete eradication of Barrett*s esophagus (BE) containing early neoplasia. (15;16;17;18;19)
Currently, most patients undergo primary circumferential ablation with a balloon based electrode, the HALO360 System, followed by additional focal ablation using a cap-based electrode, the HALO90 System. The advised treatment regimen for HALO360 procedures consists of two ablation runs with extensive cleaning of the ablation zone after the first ablation. This procedure 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. We propose a simplified HALO360 ablation procedure in which prior mucolysis with acetylcysteine is omitted, the ablation zone is cleaned only with the use of a small distal attachment cap without additional high-pressure waterjet cleaning and without removal of the ablation balloon. We hypothesize that the simplified HALO360 ablation procedure results in an easier and faster ablation procedure, while maintaining efficacy and safety.

Study objective

The aim of the study is to develop a shorter, less technical demanding and therefore less uncomfortable for the patient, procedure for the HALO360 treatment of Barrett's esophagus with early neoplasie, high-grade or low-grade dysplasia, without loosing efficacy and safety.

Study design

Patients eligible for a HALO360 procedure will be randomized to the currently used standard HALO360 procedure or a simplified HALO360 procedure, both at an energy level of 2x12 J/cm2.

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 5 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:
In the simplified ablation regimen 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.
During the HALO360 procedure the following items will be specifically recorded for the purpose of this study:
1. Time of the first introduction of the endoscope and the time of final removal of the ablation balloon.
2. The number of introductions and removals of endoscope, sizing balloon and ablation balloon.
3. Kind and amount of sedatives used.
After the procedure the patients* discomfort will be quantified using a VAS-score-questionnaire. Patients will be asked to complete a questionnaire after the ablation procedure and after recovery from sedative medication.

At three months patients will undergo a high resolution endoscopy. The esophagus will be evaluated in the same way as at the pre-treatment endoscopy.The percentage of endoscopically visible surface regression of BE will be scored by two endoscopists, blinded for the administered treatment regimens, using images/videos taken immediately prior to HALO360 treatment and at the first post-HALO360-treatment endoscopy.

Intervention

Radiofrequency ablation to eradicate Barrett's mucosa

Study burden and risks

Patients will be treated with the HALO360 system according to the current protocol or the shorter procedure. There is no additional risk in case the patient is randomized to the shorter procedure. There are less introductions and removal of the endoscope and balloons. The procedure is also shorter in time.

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

- 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.
- Review of histopathology specimens by a local expert pathologist
- Written informed consent

Exclusion criteria

- In case of prior Endoscopic resection: a specimen showing carcinoma with positive vertical resection margins, deep submucosal invasion (* T1sm2), poorly or undifferentiated cancer (G3 or G4), or lymphatic/vascular invasion.
- Patients unable to give informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-12-2008
Enrollment:	36
Type:	Actual

Medical products/devices used

Generic name:	HALO360 system;Radiofrequency Balloon Device
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Application type:	First submission
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	NL24982.018.08