A prospective study on changes in anti-reflux barrier function of the esophageal gastric junction after anti-reflux surgery

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The aim of the study is to investigate whether there are differences in esophagogastric junction distensibility, acid entrapment in the hiatal sac and rate of TLESRs in the pre and post-surgery state.

Ethical review	Approved WMO
Status	Pending
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Observational invasive

Summary

ID

NL-OMON34264

Source
ToetsingOnline

Brief title
Distensibility and acid pocket after anti reflux surgery

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
heartburn, operation

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Acid Pocket, anti-reflux surgery, Distensibility, GERD

Outcome measures

Primary outcome

Esophagogastric junction distensibility

Secondary outcome

Rate of TLESRs

Acid entrapment in the hiatal sac

Rate of reflux

Questionnaire score

Study description

Background summary

Gastric content is prevented from re-entering the esophagus by the esophagogastric junction (EGJ) formed by the lower esophageal sphincter (LES) and crural diaphragm 1. In patients suffering from gastroesophageal reflux disease (GERD) this barrier function is compromised and reflux of gastric content can occur freely causing symptoms (heartburn, regurgitation) as well as damage to the esophagus (esophagitis)2. Most reflux episodes occur during Transient Relaxations of the Lower Esophageal Sphincter (TLESR) 3. These are spontaneous sphincter relaxations and are not induced by swallowing.
An anatomical abnormality which can contribute to GERD is a hiatal hernia4. A hiatal hernia is characterized by a displaced LES which no longer coincides with the crural diaphragm at the esophageal gastric junction. This can lead to dysfunction of anti-reflux barrier and is therefore often associated with GERD4. A recent study investigated the role of the hiatal hernia and the so-called postprandial acid pocket5. The acid pocket is an unbuffered pool of acid floating on top of the meal in the proximal stomach, where it is the most important source of refluxate5. The most important finding of a recent study was that in patients with a large hiatal hernia, the acid pocket may be trapped in the hiatal sac above the diaphragm allowing acid reflux to occur during episodes of low LES pressure5.

The exact mechanisms by which anti-reflux surgery prevents gastroesophageal reflux are still unclear. Currently, it is believed that three mechanisms may play a role. The first mechanism is anatomical restoration of the EGJ by repairing a hiatal hernia if present. This could theoretically lead to decreased entrapment of the acid pocket in the hiatal sac. Second, the rate of TLESRs has been demonstrated to decrease in patients that underwent anti-reflux surgery as well as there is a decrease in the association of TLESRs with acid reflux6. The third mechanism by which antireflux surgery causes a reduction in reflux episodes is a decreased distensibility of the EGJ. This change in distensibility has previously been demonstrated to differ between patients after anti-reflux surgery and normal subjects7,8. However, these three mechanisms have not yet been investigated by measuring before and after anti-reflux surgery except for the rate of TLESRs.

We hypothesize that in patients after anti-reflux surgery there is, beside the proven decrease in TLESRs, also 1) a decreased distensibility and 2) decreased acid entrapment in the hiatal sac when compared to the pre-surgery state.

Study objective

The aim of the study is to investigate whether there are differences in esophagogastric junction distensibility, acid entrapment in the hiatal sac and rate of TLESRs in the pre and post-surgery state.

Study design

A prospective study using combined high-resolution manometry/pH/impedance measurements and scintigraphy and an EndoFLIP measurement before and after patients undergoing anti-reflux surgery.

Study burden and risks

Patients have to stop PPI or medication influencing GI-motility and have to travel to the AMC. There are no known risks associated with the investigations.

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

Patients scheduled for anti-reflux surgery

Exclusion criteria

Inability to stop the use of medication influencing GI motility for one week
Inability to stop the use of proton pump inhibitors for one week
Participation in another study with exposure to radiation within the last year
Pregnancy

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	22-07-2010
Enrollment:	10
Type:	Anticipated

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	NL33013.018.10