Long term outcomes of EGJ distensibility, rate of TLESRs and reflux mechanisms in patients unresponsive and responsive to anti-reflux surgery

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The aim of this study is to determine whether differences in rate of TLESRs, acid reflux associated TLESRs and EGJ distensibility can provide an explanation for different responses to anti-reflux surgery by comparing long term reflux mechanisms in...

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

Summary

ID

NL-OMON34168

Source
ToetsingOnline

Brief title
Long term outcomes anti-reflux surgery on barrier function

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
heartburn

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: anti-reflux surgery, distensibility, gastroesophageal reflux, transient lower esophageal sphincter relaxation

Outcome measures

Primary outcome

Esophagogastric junction distensibility

Rate of TLESRs

Secondary outcome

Questionnaire scores

Rate of reflux

LES pressure

Barium swallow evaluation

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 usually 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. GERD can be further complicated by the existence of a hiatal hernia4. A hiatal hernia is an anatomical abnormality 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.

Initial management in GERD patients is medical therapy using proton pomp

inhibitors (PPI) 5. In patients that are intolerant for PPI therapy or patients that keep persistent troublesome symptoms despite PPI therapy, anti-reflux surgery is indicated 5. Recently, Broeders et al reported 10 year outcomes of anti-reflux surgery, the so called Nissen fundoplication 6. Although initial response is often good, as many as 25% - 28% of the patients has become daily PPI-dependent again and/or has reflux symptoms 10-years after anti-reflux surgery. GERD could be objectified in 30% - 40% of this subgroup of patients and abnormal pH-metry was measured in 20%-30% 6. Furthermore, 5% - 10% of the patients underwent surgical revision due to recurrent GERD within 10 years 6. Despite the problems that can occur after anti-reflux surgery it is not completely understood why some do not respond to anti-reflux surgery and why others (72% - 75%) have a good response to anti-reflux surgery and do not require further medical therapy and/or have symptoms.
The exact mechanisms by which anti-reflux surgery prevents gastro-esophageal reflux are still unclear, currently, it is believed that three mechanisms play a role. The first mechanism is anatomical restoration of the EGJ by repairing a hiatal hernia if present. Second, the rate of TLESRs has been demonstrated to decrease in patients that underwent anti-reflux surgery as well as a decrease in the association of TLESRs with acid reflux7. The third mechanism, , is a decreased distensibility of the EGJ 8,9.
We hypothesize that in patients that do not respond to anti-reflux surgery there is an absent or less pronounced decrease in rate of TLESRs and its reflux association, as well as a less pronounced decrease in EGJ distensibility.

Study objective

The aim of this study is to determine whether differences in rate of TLESRs, acid reflux associated TLESRs and EGJ distensibility can provide an explanation for different responses to anti-reflux surgery by comparing long term reflux mechanisms in patients unresponsive to and responsive to anti-reflux surgery.

Study design

A prospective study using combined high-resolution manometry/pH/impedance measurements, ambulant pH/impedance measurement and EndoFLIP measurement.

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 with recurrent reflux after anti reflux surgery
patients responsive to anti-reflux surgery

Exclusion criteria

Surgery of the GI tract other than anti-reflux surgery, appendectomy, cholecystectomy
Motility disorders of the GI tract leading to delayed gastric emptying or altered intestinal motility
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

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):	10-05-2010
Enrollment:	20
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	NL32528.018.10