

The pathophysiological importance of lower esophageal sphincter distensibility in gastroesophageal reflux disease

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

Summary

ID

NL-OMON34232

Source

ToetsingOnline

Brief title

LES distensibility in GERD

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: distensibility, Gastro-esophageal reflux disease, high resolution manometry, pH/impedance

Outcome measures

Primary outcome

Esophagogastric junction distensibility

Secondary outcome

Questionnaire scores

Rate of TLESRs

Rate of reflux

LES pressure

Study description

Background summary

Background

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 disturbed 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 not induced by swallowing. The rate of TLESRs as well as associated gastroesophageal reflux differs between postprandial and fasting condition in both GERD patients and healthy volunteers(4,5).. However, the rate of TLESRs in GERD patients does not differ from healthy volunteers and therefore does not offer an explanation for the occurrence of pathologic reflux in GERD patients suggesting a different underlying mechanism(6).

GERD patients can be further divided in patients with and without a hiatal hernia(7). A hiatal hernia is an anatomical abnormality characterized by a displaced LES which no longer coincides with the crural diaphragm at the EGJ. This abnormality is associated with a higher prevalence of GERD. It has been

shown that TLESRs, although still partially responsible, play a less pronounced role in GERD patients with hiatal hernia(8). Since a hiatal hernia is present in a large number of healthy subjects and a hiatal hernia comparable in size and nature can be present in GERD patients, with different severity of disease, the existence of a hiatal hernia is not solely responsible for the increased rate of esophageal reflux in GERD patients suggesting a different underlying mechanism.

EGJ barrier function can be assessed by measuring its distensibility (9). We hypothesize that a difference in EGJ distensibility is responsible for the failure of EGJ barrier function. An increased distensibility in GERD patients could theoretically lead to an increase in the rate of reflux which contributes to GERD severity and symptoms.

Furthermore, we hypothesize that there is a difference between GERD patients with and without a hiatal hernia. Since the EGJ no longer consists of two contributing muscles, EGJ distensibility could theoretically be increased in GERD patients with hiatal hernia(7) leading to an increase in the rate of reflux which contributes to GERD severity and symptoms.

Traditionally, barrier function of the EGJ is studied by manometry and esophageal pH measurement. Basal LES pressure and rate of TLESRs is measured by high-resolution manometry(10), the occurrence of gastroesophageal reflux is measured by pH/impedance measurement(11). Previous research has not shown a clear relationship between LES pressure and rate of reflux. Recently, a new method has been developed that enables measurement of EGJ distensibility, the so-called functional luminal imaging probe (EndoFLIP®, Crospon Inc., Carlsbad, USA)(12). Before development of the EndoFLIP it was not possible to measure EGJ distensibility. Kwiitek and coworkers assessed EGJ distensibility in GERD patients with EndoFLIP and observed that symptomatic GERD patients exhibit a more distensible EGJ compared to controls. Kwiitek et al suggested that this increased distensibility may be an important mechanism by which greater refluxate volume enters the esophagus(13). However, the role of EGJ distensibility in the pathogenesis of GERD is not known and insights in the role of EGJ distensibility on reflux characteristics and esophageal characteristics that are known to play a role in the pathogenesis of GERD are lacking.

Study objective

Therefore, the aim of this study is to determine whether differences in EGJ distensibility lead to different rates of esophageal reflux by comparing EGJ distensibility with esophageal reflux characteristics, esophageal pressure characteristics and GERD symptoms in GERD patients with and without hiatal hernia and healthy volunteers.

Study design

Study Design:

A prospective study using combined high-resolution pressure/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

9 GERD patients with a hiatal hernia

9 GERD patients with no hiatal hernia or a hiatal hernia < 2cm
9 healthy volunteers

Exclusion criteria

Surgery of the GI tract other than appendectomy or 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
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	09-04-2010
Enrollment:	27
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	NL32269.018.10