Reflux characteristics in patients with suspected laryngopharyngeal reflux; a prospective study using ambulatory pH/impedance measurements

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We aim to investigate the reflux characteristics in patients with LPR and healthy controls using pH/impedance measurements. A second analysis will be to compare total number of proximal reflux events in PPI responders and non-responders.

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

Summary

ID

NL-OMON34249

Source
ToetsingOnline

Brief title
LPR measured by impedance measurements

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
throat irritation due to stomach acid

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

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

Intervention

Keyword: impedance measurement, Laryngo-pharyngeale reflux

Outcome measures

Primary outcome

Total number of mixed reflux that reach the proximal esophagus

Secondary outcome

Laryngoscopic evidence after 3 months of PPI therapy

RSI questionnaires after 3 months of PPI therapy

Study description

Background summary

Laryngopharyngeal reflux (LPR) is movement of gastric content into the laryngopharyngeal cavity where damage to vocal cords and pharynx can occur. The upper part of the esophagus is anatomically connected to the laryngopharyngeal cavity and divided by the upper esophageal sphincter (UES) which prevents movement of gastric content out of the esophagus into the laryngopharyngeal cavity. Therefore, LPR can only occur during relaxation of the upper esophageal sphincter. Symptoms ascribed to LPR are dysphonia or hoarseness, cough, globus pharyngeus, throat clearing and dysphagia.
Current diagnostic tools that are routinely used in the diagnosis of LPR are laryngoscopy and a clinical symptom questionnaire. When diagnosed with clinical symptoms and laryngoscopy, PPI response can not be predicted, as 50% of suspected LPR patients responds to PPI therapy(1).
Dual probe pH-metry has also been used as a tentative diagnostic tool in suspected LPR. using dual probe pH monitoring, it has been demonstrated that there is increased proximal reflux in patients suffering from RL compared to GERD patients and healthy subjects (2). The rate of proximal reflux measured by dual probe pH has not been shown to be a prognostic marker for PPI response(1). However, in this study only 6 PPI responsive patients were included. Both studies demonstrate that there is a PPI responsive and a PPI unresponsive subgroup of patients with suspected LPR, which appear equally divided among LPR suspected patients. However, to make this differentiation current diagnostic tools are insufficient.

A relatively new diagnostic tool is esophageal impedance measurement(2). Compared to conventional single probe pH-metry, impedance measurement has the advantage of accurately measuring proximal extent of reflux. It can also detect non-acidic reflux and gas reflux and is able to differentiate pure fluid reflux from gas-liquid reflux, the so called mixed reflux. The ability to detect mixed reflux is of particular importance in LPR as demonstrated by Babaei et al, who observed that UES relaxation was the predominant response during reflux events with air in the reflux in healthy subjects (92%)(3). This is important in LPR patients since relaxation of the upper esophageal sphincter is necessary to allow movement of gastric content into the laryngopharyngeal necessary for LPR.
Two studies have used impedance measurements in LPR suspected patients. Kawamura et al measured 10 patients with reflux characteristics in patients with suspected LPR using impedance located inside the UES and a dual probe pH-metry(4). The authors found that the number of total reflux events in the proximal esophagus was higher in the LPR group than in the GERD group as well as the ratio of distal esophageal reflux events reaching the proximal esophagus(4). Khan et al measured reflux events in LPR patients unresponsive to PPI therapy and in patients with typical reflux symptoms and found no significant differences between these two groups. However, methodological concerns have been raised for both studies limiting their value since the studies are limited by small sample size. Furthermore, the study population of the study by Khan et al is subject to selection bias as only patients that are unresponsive to PPI therapy(5) and both studies using impedance measurements did not use impedance measurement as a prognostic tool for PPI response.
We hypothesize that in patients with clinically suspected LPR there are more proximal mixed gaseous liquid reflux events compared to healthy controls. Furthermore, we hypothesize that in patients with suspected LPR, PPI response correlates with number of proximal mixed gaseous-liquid reflux events.

Study objective

We aim to investigate the reflux characteristics in patients with LPR and healthy controls using pH/impedance measurements. A second analysis will be to compare total number of proximal reflux events in PPI responders and non-responders.

Study design

A prospective study using ambulatory pH/impedance measurements

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

Written informed consent
Minimum age: 18 years
20 LPR suspected patients: reflux finding score of >7 and RSI questionnaire >13
10 healthy volunteers

Exclusion criteria

Surgery of the GI tract other than appendectomy or cholecystectomy
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
Infectious and allergic causes of laryngitis

Patients with aerodigestive malignancies and/or radiation therapy

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):	01-07-2010
Enrollment:	30
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	NL32906.018.10