Valvuloplasty as alternative to Toupet fundoplication for the minimal invasive treatment of gastroesophageal reflux disease: a randomized controlled trial

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON41979

Source
ToetsingOnline

Brief title
VANTAGE trial

Condition

- Other condition
- Gastrointestinal signs and symptoms
- Gastrointestinal therapeutic procedures

Synonym
Gastro-esophageal reflux disease

Health condition

middenrif

Research involving
Human

Sponsors and support

Primary sponsor: Meander Medisch Centrum
Source(s) of monetary or material Support: eigen financiering; enkele fondsen worden aangeschreven

Intervention

Keyword: Fundoplication, Hiatal hernia, Reflux disease, Valvuloplasty

Outcome measures

Primary outcome

- Success rate, objective (defined as % of patients with normal values of

reflux measured by pH and impedance monitoring)

Secondary outcome

- Success rate, subjective (defined as % of patients with Visick score I or II)

- Dysphagia (% of patients with complaints of functional dysphagia following

the Rome III criteria, duration is determined by absence of complaints and

normalisation of diet)

- Cost-effectiveness (determined using quality of life, duration of surgery,

length of hospital stay, sick leave duration, medication usage, and other

direct and indirect costs measured by iMTA MCQ/PCQ)

Safety

- Mortality rate (defined as in-hospital mortality or out of hospital mortality

within 30 days)

- Complication rate (intra-operative complication rate)

- Conversion rate

- Disease related reoperation rate (% patients requiring redo surgery for

persisting complaints or* recurrence)

Study description

Background summary

Gastroesophageal reflux disease (GERD) is a common chronic disease in western countries, associated with frequent general practitioner consultations and high health-care cost.

In 2010, a total of 2.58 million people (15.5% of the total population) used acid suppression medication. The number of chronic users, defined as 3 or more prescriptions a year and/or 180 days a year, is almost 7% of the population. When attempts are made to reduce the dosage or stop the medication entirely, these efforts are successful in only 30%. The remainder of patients has an immediate recurrence of symptoms. This results to 800 000 patients with chronic PPI use.

An alternative to pharmacological treatment is antireflux surgery. Laparoscopic Toupet fundoplication is currently the golden standard for antireflux surgery, resulting in relieve of symptoms in 88%-95% of patients, both in short- and long-term studies.

When the cost-effectiveness of pharmacological treatment is compared to laparoscopic antireflux surgery, surgery is more expensive initially, but is the most cost-effective solution long-term after a break-even point at 8 years. Also patients that undergo surgery for their acid reflux consistently report a higher quality of life than those with just pharmacological treatment.

Considering the increasing evidence of superiority of surgical management of pharmacological treatment, the need arises to determine which surgical procedure is the most beneficial to patients with regards of acid control, duration of hospital stay, speed of recovery, quality of life and cost-effectiveness.

The new gastroesophageal valvuloplasty is a laparoscopic technique with equal if not better surgical and recovery-related results, with prospected lower per-procedure and indirect costs.

Study objective

This monocenter randomized controlled trial aims to compare postoperative outcomes of a laparoscopic valvuloplasty with a Toupet fundoplication in patients with GERD with a maximum hiatal hernia of 3cm. In addition, an economic evaluation of the new intervention will be done in order to determine cost-effectiveness and costs per quality-adjusted life-year (QALY).

Study design

Prospective, interventional, double-blinded (patient and researcher), monocenter randomized controlled trial comparing a laparoscopic gastroesophageal valvuloplasty to laparoscopic Toupet fundoplication.

Intervention

Laparoscopic gastroesophageal valvuloplasty: Via laparoscopy, using three sutures a part of the esophagus is folded (similar to the way parts of a telescope slide in each other) into the stomach, creating a valve on the inside to prevent gastric acid to enter the esophagus.

Study burden and risks

The valvuloplasty is a technique that only slightly differs in the way the stomach is handled compared to regular fundoplication. The main benefit of valvuloplasty is that there is no longer any need to dissect all the blood vessels on the left side of the stomach. The ligament connecting to the spleen also remains in place.

When omitting the dissection of the short gastric vessels, a disposable sealing device (e.g. Ligasure or Harmonic scalpel) costing ¤500,- is no longer required. The reduction of dissection also results in fewer complications, less postoperative dysphagia and shorter hospital stay, possibly daycare.

Follow-up by the surgeon will proceed as needed, unchanged by trial participation. Further trial follow-up will take place by using questionnaires which take a maximum of 30 minutes to fill in. No additional physical and physiological discomfort is expected to be associated with trial participation.

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

Adults with objectively proven gastroesophageal reflux disease and a maximum hiatal hernia of 3cm who are eligible for antireflux surgery.

Exclusion criteria

High BMI (>=30), large hiatal hernia (>=3cm), achalasia, previous upper-GI surgery or inability to understand the Dutch language or fill in the questionnaires.

Study design

Design

Study type:	Interventional
Intervention model:	Other

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2015
Enrollment:	160
Type:	Anticipated

Ethics review

Approved WMO Date:	09-10-2015
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	22-02-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL52398.100.15