

# Pyloric Endoscopic Myotomy as treatment for patients with symptom of gastric outlet obstruction after oesophagectomy with gastric conduit.

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Primary objectives 1. To evaluate the efficacy, feasibility and safety of G-POEM in patients with symptoms delayed gastric emptying after oesophagectomy with gastric tube reconstruction, based subsequently on the clinical success rate at 3 months,...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Gastrointestinal motility and defaecation conditions
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON49332

### Source

ToetsingOnline

### Brief title

The PEMpoco study.

### Condition

- Gastrointestinal motility and defaecation conditions

### Synonym

acquired pylorus stenosis, delayed emptying of stomach

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht

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

## **Intervention**

**Keyword:** Delayed Gastric Emptying, Endoscopic, Oesophagectomy, Pyloromyotomy

## **Outcome measures**

### **Primary outcome**

1. Efficacy of G-POEM defined as success rate at 3 months, reported as patient reported outcome measurements (PROMS) using a 6 point Likert scale, answering the question: \*How do you rate your symptoms after the G-POEM procedure as compared to the situation before the procedure?\* 1. symptoms fully disappeared, 2. significant improvement, 3. mild improvement, 4. no change, 5. bit worse, 6. significantly worse.

A score of 1 or 2 is considered clinical success.

2. Feasibility of G-POEM defined as technical success of G-POEM procedure (i.e. the ability to perform a complete pyloromyotomy).

3. Safety of G-POEM based on:

- Peri-operative G-POEM complications: perforation, bleeding, cardiopulmonary events.
- All severe adverse events (SAEs) defined as any unwanted events occurring within 5 days after G-POEM resulting in >72 hours prolonged admission, admission to a medium or intensive care unit, additional unplanned endoscopic procedures, unplanned radiological (e.g. coiling) or surgical interventions, or blood transfusion or death.

### **Secondary outcome**

1. Durability of G-POEM, defined as the clinical success rate at 12 months

reported as PROMs (see main study parameter 1).

2. Success rate at 3 and 12 months based on:

- Objective parameters: post-G-POEM gastric emptying time on nuclear scintigraphy, post-G-POEM gastric emptying time on barium swallow, post-G-POEM EndoFlip measurement, post-G-POEM gastroscopy findings.
- Subjective parameters: Gastric Cardinal Symptom Index (GCSI), dumping symptom score, regurgitation symptom score.

3. Possible predictors for success or failure of G-POEM, based on:

- Objective parameters: pre-G-POEM gastric emptying times on nuclear scintigraphy, pre-G-POEM gastric emptying on barium swallow, pre-G-POEM EndoFlip, pre-G-POEM gastroscopy (e.g. retention and/or dilation of gastric tube), previous success on BOTOX injection.
- Subjective parameters (patient reported outcomes): Gastric Cardinal Symptom Index (GCSI), dumping symptom score, regurgitation symptom score.

4. Adverse events (AEs) defined as any unwanted events that arise following treatment and/or that are secondary to the treatment; events classified as severe adverse events (SAEs) are mentioned as primary endpoint.

5. (changes in) Quality of life, based on SF-36 questionnaire.

## Study description

### Background summary

Oesophagectomy with gastric tube reconstruction is the cornerstone of the treatment of patients diagnosed with a malignant esophageal tumor. In this procedure, the vagal nerves are inevitably damaged. This has several potential consequences. Since the vagal nerve has important regulatory effects on

gastroenteral motility, disturbances in this respect are commonly encountered. As far as gastropyloric motility is concerned, truncal vagotomy can lead to antral hypo- or dysmotility (also described as gastroparesis) and pylorospasm (inability of the pylorus to relax when appropriate). This combination can cause a significantly delayed emptying of the gastric tube, mainly for solids. This subsequently may lead to an array of symptoms such as: postprandial fullness, early satiety, heartburn, and regurgitation and aspiration (resulting in recurrent pneumonias). On the other hand, however, vagotomy can result in accelerated gastric emptying for liquids which can cause a syndrome often referred to as dumping syndrome. In the one patient, dumping syndrome is more prominent, whereas in the other gastroparesis (severely delayed gastric emptying for solids) is predominant. There are no predictive factors for which patient will develop what syndrome (if any). It is however a serious problem, seen as 4-50% of patients suffer from symptoms of delayed gastric emptying (2). Delayed gastric emptying caused by hypo- or dysmotility of the stomach, otherwise described as gastroparesis, is also encountered in other situations than post-oesophagectomy: gastroparesis is a well-known complication of diabetes, but can occur in a variety of other diseases, and can be idiopathic. The primary therapeutic approach is to prescribe dietary advises and/or prokinetic drugs. These measures are usually not very effective. As an alternative, more invasive treatments can be undertaken directed to the pylorus, using either pneumatic dilatation, intrapyloric injection with botulinum toxin (Botox), or surgical drainage (pyloroplasty or pyloromyotomy). However, there is little data on the efficacy of these treatments, especially in patients that underwent oesophagectomy; most studies are conducted in patients suffering from gastroparesis of other causes. Recently, a minimally invasive, endoscopic means to perform a myotomy has been developed: in 2010, Inoue and colleagues described what they named a Per-Oral Endoscopic Myotomy (POEM) of the lower esophageal sphincter in patients with achalasia. In this technique, endoscopic submucosal tunneling was utilized to safely perform a full myotomy of the sphincter (3). POEM is nowadays considered a safe and valid treatment option for achalasia. More recently, however, the same principle has been directed to the pyloric sphincter, currently referred to as G-POEM (Gastric Per-Oral Endoscopic myotomy) or PEM (Pyloric Endoscopic Myotomy). This technique has been studied in small case series in patients with various causes of gastroparesis, mainly in diabetes induced gastroparesis. One single center study conducted by Gonzalez et al., evaluated the efficacy of G-POEM in patients suffering from refractory gastroparesis. They reported a clinical success rate of 85% and a 71 % success rate, without any adverse events (4). Later, the same research group published a multicenter case series of patients who underwent G-POEM for refractory gastroparesis. This study also showed a clinical success rate of 85% (4). As mentioned above, 4-50% patients who undergo oesophagectomy with gastric tube reconstruction suffer from symptoms of delayed gastric emptying, without a proper form of treatment up until now. However, the studies conducted in patients with severe diabetes induced gastroparesis/delayed gastric emptying are promising.

Therefore, this study aims to evaluate the feasibility, efficacy, safety and durability of the G-POEM in patients suffering from delayed gastric emptying after oesophagectomy with gastric tube reconstruction.

In addition, we wish to find objective markers for prediction of response to G-POEM in this patient category; one of these being an EndoFlip measurement. Measuring resting pressure and distensibility of the pylorus has up until now not been possible. Recently, there have been studies looking at the usefulness of the EndoFlip device. Gourcerol et al. used the Endoflip device to assess functional characteristics of the pylorus in patients with gastroparesis and healthy volunteers. They concluded that in patients with gastroparesis the pyloric compliance is decreased. Another study conducted by Malik et al. showed similar results but also evaluated the distensibility of the pylorus at various balloon volumes. The latter showed that symptoms of delayed gastric emptying were increased when distensibility of the pylorus was less than 10mm<sup>2</sup>/mmHg. Based on the above mentioned studies, this study also aims to identify if pyloric resting pressures and distensibility correlate with patients suffering from delayed gastric emptying and if this can be used as a predictive marker for treatment success.

(See protocol for references).

## **Study objective**

### Primary objectives

1. To evaluate the efficacy, feasibility and safety of G-POEM in patients with symptoms delayed gastric emptying after oesophagectomy with gastric tube reconstruction, based subsequently on the clinical success rate at 3 months, technical success rate and the occurrence of severe adverse events.

### Secondary objectives

1. To evaluate the durability of G-POEM in patients with symptoms of delayed gastric emptying after oesophagectomy with gastric tube reconstruction, based on clinical success rate at 12 months.
2. To evaluate the efficacy and durability of G-POEM based on:
  - Objective parameters: gastric emptying time on nuclear scintigraphy, gastric emptying time on barium swallow, gastroscopy, EndoFlip measurement.
  - Subjective parameters: symptom scores for gastric emptying, dumping, and nocturnal regurgitation.
3. To identify possible predictive factors for the success or failure of G-POEM in this patient category, based on:
  - Objective parameters: pre-G-POEM gastric emptying time on nuclear scintigraphy, pre-G-POEM gastric emptying time on barium swallow, pre-G-POEM gastroscopy, pre-G-POEM EndoFlip measurement, previous success on BOTOX injection.
  - Subjective parameters: symptom scores for gastric emptying, dumping, and nocturnal regurgitation.

4. To evaluate the effect on Quality of Life.

## **Study design**

Prospective uncontrolled multi center intervention study. Patients will be recruited from the RAKU (University Medical Center Utrecht and St. Antonius Hospital) and Amsterdam University Medical Centers. Study procedures can be performed in all these three hospitals.

## **Intervention**

G-POEM, gastric per-oral endoscopic myotomy of pylorus. A minimally invasive endoscopic pyloromyotomy.

## **Study burden and risks**

With regards to the G-POEM patients will not be subjected to extra risks. If patients don't enroll in the study they will be offered the same treatment possibility. However, patients enrolling in this study will be asked to fill in several questionnaires at 3 different timepoints. Firstly, at baseline, followed by 3 months and 1 year after treatment. This will require circa 1.5-2 hours (for all questionnaires).

Furthermore, patients will undergo an EndoFlip measurement, as mentioned earlier in this form, this measurement will not be subject to extra risks.

## **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

Research population: Adult patients (18 years) with refractory symptoms of delayed gastric emptying after oesophagectomy with gastric tube reconstruction (>3 months ago).

1. At least > 3 months after oesophagectomy with gastric tube reconstruction.
2. Age between 18-90 years.
3. Presence of delayed gastric emptying based on symptoms and at least one of the following objective parameters indicating delayed gastric emptying:
  - Delayed gastric emptying on nuclear scintigraphy,
  - Delayed gastric emptying on timed barium swallow,
  - Retention of solids in the gastric tube seen during gastroscopy, and/or
  - Good symptomatic response on botulinum toxin injection in the pylorus (response lasted at least 2 months).
4. Signed written informed consent.

### Exclusion criteria

1. Other causes for delayed gastric emptying: post-operative complications, leakage, mechanical obstructie, medication use of the patient (e.g. opioids).
2. Previous surgical drainage (pyloroplasty or pyloromyotomy).
3. Previous attempt at G-POEM.
4. Uncontrollable bleeding disorders.

## Study design

### Design

**Study type:** Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

## Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	18-03-2021
Enrollment:	33
Type:	Actual

## Medical products/devices used

Generic name:	EndoFlip
Registration:	Yes - CE intended use

## Ethics review

Approved WMO	
Date:	07-10-2020
Application type:	First submission
Review commission:	METC NedMec

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

ID: 22297  
Source: NTR  
Title:



## In other registers

Register	ID
CCMO	NL70978.041.19
Other	wordt na goedkeuring geregistreerd
OMON	NL-OMON22297