

The incidence of perioperative complications during anaesthesia for Peroral Endoscopic Myotomy (POEM) in oesophageal achalasia

Gepubliceerd: 03-05-2021 Laatste bijgewerkt: 18-08-2022

We aim to compare the anesthetic strategies used in the Amsterdam UMC, location AMC, and determine the incidence of complications (in particular, aspiration) with relation to the type of induction method used.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26349

Bron

Nationaal Trial Register

Verkorte titel

POEM

Aandoening

Oesophageal achalasia

Ondersteuning

Primaire sponsor: Department of Anesthesiology, Amsterdam University Medical Center, location AMC

Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The incidence of perioperative complications, in patients undergoing Peroral Endoscopic Myotomy (POEM), for oesophageal achalasia, in the different induction and intubation techniques.

Toelichting onderzoek

Achtergrond van het onderzoek

Oesophageal achalasia is a disease which is defined as the impaired relaxation of the lower oesophageal sphincter (LES) and a lack of peristalsis in the distal oesophagus. This causes an accumulation of ingested liquids and foods in the oesophagus, which can lead to clinical symptoms including dysphagia, regurgitation and chest pain.

Oesophageal manometry is required to establish the diagnosis and a barium oesophagogram is performed when manometry gives equivocal results. The oesophagogram produces the classic "bird's beak sign". Using a population-based approach, the incidence of treated achalasia is 1.63/100,000 with a prevalence of 10.82/100,000. The disease occurs at all ages, but more often in patients between the ages of 25 and 60 years and can be idiopathic. In some cases, associations with achalasia-like motor abnormalities can be made, including amyloidosis and neurofibromatosis type I.

Treatment of oesophageal achalasia is aimed at decreasing the LES resting pressure, to assist the passage of the accumulated liquids and foods into the stomach. There are multiple therapies for treating oesophageal achalasia, including pneumatic dilation and a laparoscopic Heller myotomy. Peroral endoscopic Myotomy (POEM) is a recently developed revolutionary therapy, which utilizes an interventional endoscopy to create a myotomy. Numerous studies have demonstrated that POEM produces comparable, if not superior results, compared to standard laparoscopic Heller myotomy. When compared to pneumatic dilation, POEM is more durable and efficient without the need for repetition.

The procedure is performed under general anaesthesia with endotracheal intubation. Due to the accumulation of oesophageal liquids and foods, patients potentially have a higher risk of complications, including aspiration. Multiple strategies are used to reduce this risk, varying from positioning techniques (supine- or seated position), induction techniques (Rapid Sequence Induction (RSI), Awake Fiberoptic Intubation (AFOI) or a normal induction), increased preoperative fasting times, preoperative endoscopic screening and possible emptying of oesophageal contents. Löser et al., concluded in a recently published review that international institutional practices vary broadly, and evidence-based recommendations regarding anaesthesia are still lacking.

Worldwide there is a lack of evidence which induction and intubation strategy should be used. This research will compare the strategies used in the Amsterdam UMC, location AMC regarding the risk of complications, including aspiration. This data may help to optimize the anesthesiological approach used in Peroral Endoscopic Myotomy without compromising

patient safety.

Doel van het onderzoek

We aim to compare the anesthetic strategies used in the Amsterdam UMC, location AMC, and determine the incidence of complications (in particular, aspiration) with relation to the type of induction method used.

Onderzoeksopzet

Timepoints: Baseline: fasting times, T1 = incidence of aspiration and other complications immediately after anesthetic induction, T2 = incidence of aspiration and other complications at end of POEM procedure, T3 = incidence of aspiration and other complications at follow-up 3-7 days after POEM

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age ≥ 18 years
- Patients already operated on or scheduled for Peroral Endoscopic Myotomy in Amsterdam UMC, location AMC

- Willing and able to sign consent-letter for the re-use of care data

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Patients who objected against the re-use of their care data
- Patients who do not sign a consent letter for the re-use of their care data

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	26-05-2021
Aantal proefpersonen:	300
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies	
Datum:	03-05-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9504
Ander register	METC AMC : W21_268 # 21.295

Resultaten