

Die beiden erwähnten randomisierten Studien über POEM

JAMA | Original Investigation

Effect of Peroral Endoscopic Myotomy vs Pneumatic Dilation on Symptom Severity and Treatment Outcomes Among Treatment-Naive Patients With Achalasia: A Randomized Clinical Trial

Frauke A. Ponds, MD; Paul Fockens, MD, PhD; Aaltje Lei, BSc; Horst Neuhaus, MD, PhD; Torsten Beyna, MD; Jennis Kandier, MD; Thomas Frieeling, MD, PhD; Philip W. Y. Chiu, MD, PhD; Justin C. Y. Wu, MD, PhD; Vivien W. Y. Wong, BSc; Guido Costamagna, MD, PhD; Pietro Familiari, MD; Peter J. Kahrilas, MD, PhD; John E. Pandolfino, MD, PhD; André J. P. M. Smout, MD, PhD; Albert J. Bredenoord, MD, PhD

IMPORTANCE Case series suggest favorable results of peroral endoscopic myotomy (POEM) for treatment of patients with achalasia. Data comparing POEM with pneumatic dilation, the standard treatment for patients with achalasia, are lacking.

OBJECTIVE To compare the effects of POEM vs pneumatic dilation as initial treatment of treatment-naive patients with achalasia.

DESIGN, SETTING, AND PARTICIPANTS This randomized multicenter clinical trial was conducted at 6 hospitals in the Netherlands, Germany, Italy, Hong Kong, and the United States. Adult patients with newly diagnosed achalasia and an Eckardt score greater than 3 who had not undergone previous treatment were included. The study was conducted between September 2012 and July 2015, the duration of follow-up was 2 years after the initial treatment, and the final date of follow-up was November 22, 2017.

INTERVENTIONS Randomization to receive POEM (n = 67) or pneumatic dilation with a 30-mm and a 35-mm balloon (n = 66), with stratification according to hospital.

MAIN OUTCOMES AND MEASURES The primary outcome was treatment success (defined as an Eckardt score ≤ 3 and the absence of severe complications or re-treatment) at the 2-year follow-up. A total of 14 secondary end points were examined among patients without treatment failure, including integrated relaxation pressure of the lower esophageal sphincter via high-resolution manometry, barium column height on timed barium esophagogram, and presence of reflux esophagitis.

RESULTS Of the 133 randomized patients, 130 (mean age, 48.6 years; 73 [56%] men) underwent treatment (64 in the POEM group and 66 in the pneumatic dilation group) and 126 (95%) completed the study. The primary outcome of treatment success occurred in 58 of 63 patients (92%) in the POEM group vs 34 of 63 (54%) in the pneumatic dilation group, a difference of 38% (95% CI, 22%-52%); $P < .001$. Of the 14 prespecified secondary end points, no significant difference between groups was demonstrated in 10 end points. There was no significant between-group difference in median integrated relaxation pressure (9.9 mm Hg in the POEM group vs 12.6 mm Hg in the pneumatic dilation group; difference, 2.7 mm Hg [95% CI, -2.1 to 7.5]; $P = .07$) or median barium column height (2.3 cm in the POEM group vs 0 cm in the pneumatic dilation group; difference, 2.3 cm [95% CI, 1.0-3.6]; $P = .05$). Reflux esophagitis occurred more often in the POEM group than in the pneumatic dilation group (22 of 54 [41%] vs 2 of 29 [7%]; difference, 34% [95% CI, 12%-49%]; $P = .002$). Two serious adverse events, including 1 perforation, occurred after pneumatic dilation, while no serious adverse events occurred after POEM.

CONCLUSIONS AND RELEVANCE Among treatment-naive patients with achalasia, treatment with POEM compared with pneumatic dilation resulted in a significantly higher treatment success rate at 2 years. These findings support consideration of POEM as an initial treatment option for patients with achalasia.

TRIAL REGISTRATION Netherlands Trial Register number: NTR3593

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Author Affiliations: Author affiliations are listed at the end of this article.

Corresponding Author: Albert J. Bredenoord, MD, PhD, Department of Gastroenterology and Hepatology, Amsterdam UMC, Amsterdam, PO Box 22660, 1100 DD Amsterdam, the Netherlands (a.j.bredenoord@amsterdamumc.nl).

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ORIGINAL ARTICLE

Endoscopic or Surgical Myotomy in Patients with Idiopathic Achalasia

Yuki B. Werner, M.D., Bengt Hakanson, M.D., Jan Martinek, M.D., Alessandro Repici, M.D., Burkhard H.A. von Rahden, M.D., Albert J. Bredenoord, M.D., Raf Bisschops, M.D., Helmut Messmann, M.D., Marius C. Vollberg, M.Sc., Tania Noder, R.N., Jan F. Kersten, M.Sc., Oliver Mann, M.D., Jakob Izbiccki, M.D., Alexander Pazdro, M.D., Uberto Fumagalli, M.D., Riccardo Rosati, M.D., Christoph-Thomas Germer, M.D., Marlies P. Schijven, M.D., Alice Emmermann, M.D., Daniel von Renteln, M.D., Paul Fockens, M.D., Guy Boeckstaens, M.D., and Thomas Rösch, M.D.

ABSTRACT

BACKGROUND

Pneumatic dilation and laparoscopic Heller's myotomy (LHM) are established treatments for idiopathic achalasia. Peroral endoscopic myotomy (POEM) is a less invasive therapy with promising early study results.

METHODS

In a multicenter, randomized trial, we compared POEM with LHM plus Dor's fundoplication in patients with symptomatic achalasia. The primary end point was clinical success, defined as an Eckardt symptom score of 3 or less (range, 0 to 12, with higher scores indicating more severe symptoms of achalasia) without the use of additional treatments, at the 2-year follow-up; a noninferiority margin of -12.5 percentage points was used in the primary analysis. Secondary end points included adverse events, esophageal function, Gastrointestinal Quality of Life Index score (range, 0 to 144, with higher scores indicating better function), and gastroesophageal reflux.

RESULTS

A total of 221 patients were randomly assigned to undergo either POEM (112 patients) or LHM plus Dor's fundoplication (109 patients). Clinical success at the 2-year follow-up was observed in 83.0% of patients in the POEM group and 81.7% of patients in the LHM group (difference, 1.4 percentage points; 95% confidence interval [CI], -8.7 to 11.4 ; $P = 0.007$ for noninferiority). Serious adverse events occurred in 2.7% of patients in the POEM group and 7.3% of patients in the LHM group. Improvement in esophageal function from baseline to 24 months, as assessed by measurement of the integrated relaxation pressure of the lower esophageal sphincter, did not differ significantly between the treatment groups (difference, -0.75 mm Hg; 95% CI, -2.26 to 0.76), nor did improvement in the score on the Gastrointestinal Quality of Life Index (difference, 0.14 points; 95% CI, -4.01 to 4.28). At 3 months, 57% of patients in the POEM group and 20% of patients in the LHM group had reflux esophagitis, as assessed by endoscopy; at 24 months, the corresponding percentages were 44% and 29%.

CONCLUSIONS

In this randomized trial, POEM was noninferior to LHM plus Dor's fundoplication in controlling symptoms of achalasia at 2 years. Gastroesophageal reflux was more common among patients who underwent POEM than among those who underwent LHM. (Funded by the European Clinical Research Infrastructure Network and others; ClinicalTrials.gov number, NCT01601678.)

The authors' affiliations are listed in the Appendix. Address reprint requests to Dr. Rösch at the Department of Interdisciplinary Endoscopy, University Hospital Hamburg Eppendorf, Martinistr. 52, 20246 Hamburg, Germany, or at t.roesch@uke.de.

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Achalasie

Achalasia

[H. D. Allescher](#) , [H. Feussner](#) & [Y. Werner](#)

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Die Achalasie ist eine neuromuskuläre Erkrankung v. a. des intrinsischen Nervensystems des Ösophagus, die durch eine reduzierte oder aufgehobene Relaxation (Öffnung) des unteren ösophagealen Sphinkters (UÖS) und eine Störung der propulsiven Motilität in der tubulären Speiseröhre gekennzeichnet ist. Leitsymptome sind zunehmende Dysphagie für solide und flüssige Nahrungsbestandteile, retrosternales Druckgefühl beim Essen sowie aktive und später auch passive Regurgitationen von unverdauten Speisen. Die Diagnostik basiert auf der ausführlichen Anamnese, dem typischen endoskopischen Befund, der jedoch in der Frühphase fehlen kann, einem auffälligen radiologischen Verhalten und einer charakteristischen Funktionsdiagnostik (High-Resolution-Manometrie). Bei der Therapie stehen neben der pneumatischen Dilatation, die endoskopische perorale und die laparoskopische Myotomie zur Auswahl. Da die unterschiedlichen Formen der Achalasie ein individuelles Management erfordern, sollte die Therapieentscheidung möglichst interdisziplinär in einem spezialisierten Team erfolgen.



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