

Prospective Study

Peroral endoscopic myotomy for achalasia in patients aged ≥ 65 years

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Author contributions: Li CH and Liu DL designed the study; Li CJ, Tan YY, Wang XH and Liu DL acquired the clinical data; Li CJ, Wang XH and Liu DL analyzed the data; Li CJ, Tan YY and Liu DL wrote and revised the paper.

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Abstract

AIM: To investigate the safety and efficacy of peroral endoscopic myotomy (POEM) for achalasia in patients aged ≥ 65 years.

METHODS: From November 2011 to August 2014, 15 consecutive patients (aged ≥ 65 years) diagnosed with achalasia were prospectively recruited and all underwent POEM at our institution. Eckardt score, lower esophageal sphincter (LES) pressure, esophageal diameter, SF-36 questionnaire, and procedure-related complications were used to evaluate the outcomes.

RESULTS: All 15 patients were treated successfully by POEM, with a median operation time of 55 min. Median myotomy length was 10 cm. Three patients underwent circular myotomy and 12 full-thickness myotomies. Symptoms remitted in all cases during post-POEM follow-up of 6-39 mo. Eckardt score reduced significantly (pre-operation vs post-operation: 8.0 vs 1.0, $P < 0.05$). Median LES pressure decreased from 27.4 to 9.6 mmHg ($P < 0.05$). Median diameter of the esophagus was significantly decreased (pre-operation vs post-operation: 51.0 mm vs 30.0 mm, $P < 0.05$). Only one patient had reflux, which was resolved with oral proton pump inhibitors. No serious complications related to POEM were found. The quality of life of the 15 patients improved significantly after POEM.

CONCLUSION: POEM is a safe and effective technique for treatment of achalasia in patients aged ≥ 65 years, with improvement in symptoms and quality of life.

Key words: Achalasia; Peroral endoscopic myotomy;

Elderly; Efficacy; Quality of life

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Core tip: Peroral endoscopic myotomy (POEM) is a novel technique for treatment of achalasia, and has shown exciting results in clinical studies. However, little is known about its efficacy in elderly patients. In the present study, 15 achalasia patients aged ≥ 65 years received POEM. Eckardt score, lower esophageal sphincter pressure, esophageal diameter, SF-36 questionnaire, and procedure-related complications were used to evaluate the outcomes. Our study showed that POEM is a safe and effective therapy for achalasia in elderly patients, with improvement in symptoms and quality of life.

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INTRODUCTION

Achalasia is an esophageal motility disorder characterized by aperistalsis of the esophageal body and impaired lower esophageal sphincter (LES) relaxation^[1]. Although it occurs only rarely, with an estimated annual incidence between 0.3 and 1.5 per 100000 population and a prevalence of 1/10000, the disease is more common in older people, and the highest incidence appears in the seventh decade of life^[2,3]. Clinical symptoms of achalasia include dysphagia, chest pain, and regurgitation. The disease course is usually chronic, with progressive dysphagia and weight loss over several months to years, which severely impairs quality of life, even resulting in aspiration pneumonia. Thus, proper treatment is of vital importance. Current treatment modalities for achalasia in elderly patients include medical treatment, endoscopy and surgery. Laparoscopic Heller myotomy (LHM) is the most definitive and successful treatment of choice. However, its safety and efficacy in elderly patients remain controversial, and some gastroenterologists recommend balloon dilatation as the primary therapy^[4,5], whereas others prefer botulinum toxin injection^[6].

Peroral endoscopic myotomy (POEM) is a novel technique for treatment of achalasia, and has shown exciting results in clinical studies^[7-9]. However, the relative risk of POEM in patients aged ≥ 65 years has yet to be determined. It is also unclear whether POEM in these patients is as effective as it is in younger patients. Our aim was to evaluate the safety and efficacy of POEM in patients aged ≥ 65 years and report our preliminary experience in this pilot study.

MATERIALS AND METHODS

Patients

This study was approved by the Ethics Committee of the Second Xiangya Hospital of Central South University, Changsha, China. The enrollment criteria were as follows: (1) patients diagnosed with achalasia by established methods of esophagogastroduodenoscopy (EGD), esophageal manometry and barium esophagography on the basis of symptoms; (2) patients aged ≥ 65 years; and (3) patients who consented to receive POEM. Patients who could not tolerate anesthesia and those with severe cardiopulmonary disease or blood coagulation disorders were excluded. For patients diagnosed with severe achalasia (Eckardt score ≥ 6 , esophageal diameter ≥ 6 cm, or sigmoid-type esophagus), full-thickness myotomy was recommended, while others underwent circular myotomy.

From November 2011 to August 2014, 15 consecutive patients were enrolled. There were six men and nine women with a median age of 67 years (range, 65-84 years) (Table 1). Written informed consent was obtained from all the patients before the procedure. All of them were informed of possible adverse events and other possible treatment options.

POEM procedure

Prophylactic intravenous antibiotics and proton pump inhibitors (PPIs) were introduced before the procedure. POEM was performed under general anesthesia *via* tracheal intubation using a standard single-channel endoscope (GIF-Q260Z; Olympus, Tokyo, Japan) with a transparent cap (D-201-11802; Olympus) attached to the front. CO₂ was used as the air supply from the endoscope. Other equipment and accessories included a high-frequency generator (ICC 200; Erbe, Tübingen, Germany), argon plasma coagulation unit (APC300; Erbe), injection needle (NM-4L-1; Olympus), hybrid knife (Erbe), dual knife (KD-650L; Olympus), and hemostatic clips (HX-600-135; Olympus).

The POEM procedure was performed as follows: (1) A submucosal injection (mixed solution of 100 mL saline + 2 mL indigo carmine + 1 mg epinephrine) was administered into the right posterior esophageal wall at 8-10 cm above the esophagogastric junction (EGJ); (2) To create the tunnel entry, a longitudinal mucosal incision of > 2 cm was made using a dual or hybrid knife, and submucosal dissection with the range of ≥ 0.5 cm was performed along both sides of the longitudinal incision; (3) A submucosal tunnel was created, passing over the EGJ, and 3 cm into the proximal stomach. The width of the submucosal tunnel was ≥ 3 cm; (4) Myotomy was started from 2-3 cm below the tunnel entry. Three patients underwent circular myotomy alone and nine received full-thickness myotomy within the range of 6 cm from the EGJ; and (5) After careful hemostasis, several metal clips were applied to close the mucosal entry (Figure 1).

Table 1 Demographics, clinical and operative data in elderly patients treated with peroral endoscopic myotomy

Patient characteristics	
Sex, female/male, <i>n</i>	9/6
Age, median (range), yr	67 (65-84)
Duration of symptoms, yr	17 (4-40)
Primary procedure, <i>n</i>	
Heller surgical myotomy	1
Pneumatic dilatation	4
Self-expanding metallic stent	1
Interval between primary procedure and POEM, median (range), yr	8.0 (2-20)
Procedure-related parameters	
Operating time, median (range), min	55 (40-110)
Mode of myotomy	
Circular myotomy	3
Full-thickness	12
Submucosal tunnel length, cm	13 (13-15)
Myotomy length, median (range), cm	
Total	10 (9-13)
Esophageal	7 (6-11)
Gastric	3 (2-3)
Eckardt score	
Pre-operation	8 (5-10)
Post-operation	1 (0-3)
LES pressure, mmHg	
Pre-operation	27.4 (22.8-33.5)
Post-operation	9.6 (7.2-13.1)
Diameter of esophagus, mm	
Pre-operation	51 (43-57)
Post-operation	30 (24-35)
Complications, <i>n</i>	
Reflux esophagitis	1
Follow-up, median (range), mo	18 (6-39)

POEM: Peroral endoscopic myotomy.

Postoperative management

Patients were kept nil by mouth for 24 h, a liquid diet for 3 d, and resumed gradually a normal diet within 2 wk. Intravenous PPI and antibiotics were used for 3 d. On postoperative day 2, thoracoabdominal X-ray was performed to check for the occurrence of emphysema, pneumothorax, pneumoperitoneum and pleural effusion.

Outcome and follow-up

Primary outcome was treatment success defined as a reduction in the Eckardt score to ≤ 3 during follow-up. Secondary outcomes included quality of life, esophageal diameter, LES pressure, and procedure-related parameters such as operation time, myotomy length, and rate of complications. Patients were scheduled for a follow-up visit at 1, 3, 6 and 12 mo after POEM, followed by EGD annually to observe the status of esophageal closure and check for any objective sign of reflux esophagitis. Esophageal manometry was also performed to determine LES pressure and barium esophagography was performed to measure esophageal diameter. Patients were contacted *via* telephone to obtain a current Eckardt score. SF-36 questionnaires were collected preoperatively, and at 1 and 6 mo after POEM.

Statistical analysis

Statistical analysis was performed using SPSS version 21.0 software (Chicago, IL, United States). As for the small sample, all the data were expressed as median and range, and analyzed by Wilcoxon rank sum test. $P < 0.05$ was considered statistically significant.

RESULTS

Clinical and operative data

Of the 15 patients, three had hypertension and the other 12 had no comorbidity. Five (33%) patients had received endoscopic therapy and one (7%) Heller myotomy, and the other nine patients had not received prior treatment for achalasia. Demographics, clinical and operative data are summarized in Table 1. The duration of symptoms ranged from 4 to 40 years with a median of 17 years. POEM was successfully completed in all 15 patients, with a median operation time of 55 min. The median length of the submucosal tunnel was 13.0 cm, and median myotomy length was 10.0 cm.

Comparison of clinical symptoms, LES pressure, esophageal diameters and SF-36 domain scores before and after POEM

Follow-up duration ranged from 6 to 39 mo with a median of 18 mo. The results were excellent in terms of symptomatic improvement in all the patients. Treatment success, as defined by a post-POEM Eckardt score ≤ 3 , was achieved in all cases. Median post-treatment Eckardt score was 1, which was obviously decreased compared with 8 before treatment ($P < 0.05$). Median LES pressure decreased from 27.4 to 9.6 mmHg ($P < 0.05$). Median esophageal diameter was dramatically decreased from 51.0 to 30.0 mm ($P < 0.05$). SF-36 data were obtained at 1 and 6 mo after the operation. These results are described in Table 2 with medians and interquartile ranges and further depicted in Figure 2. Role Limitations due to Emotional Problems and Emotional Well-being domains did not demonstrate any significant differences in scores at any time point. However, Physical Functioning, Role Limitations due to Physical Problems, Energy/Fatigue, Social Functioning, Pain and General Health scores were all significantly higher at 1 and 6 mo ($P < 0.05$).

Complications

Complications occurred in only one case. The patient experienced reflux symptom 2 mo after POEM, and EGD revealed esophagitis, which was relieved after oral PPI therapy. No complications occurred in the rest of the patients during the operation and follow-up.

DISCUSSION

All treatments for achalasia aim to reduce LES pressure with three goals of relieving symptoms, improving

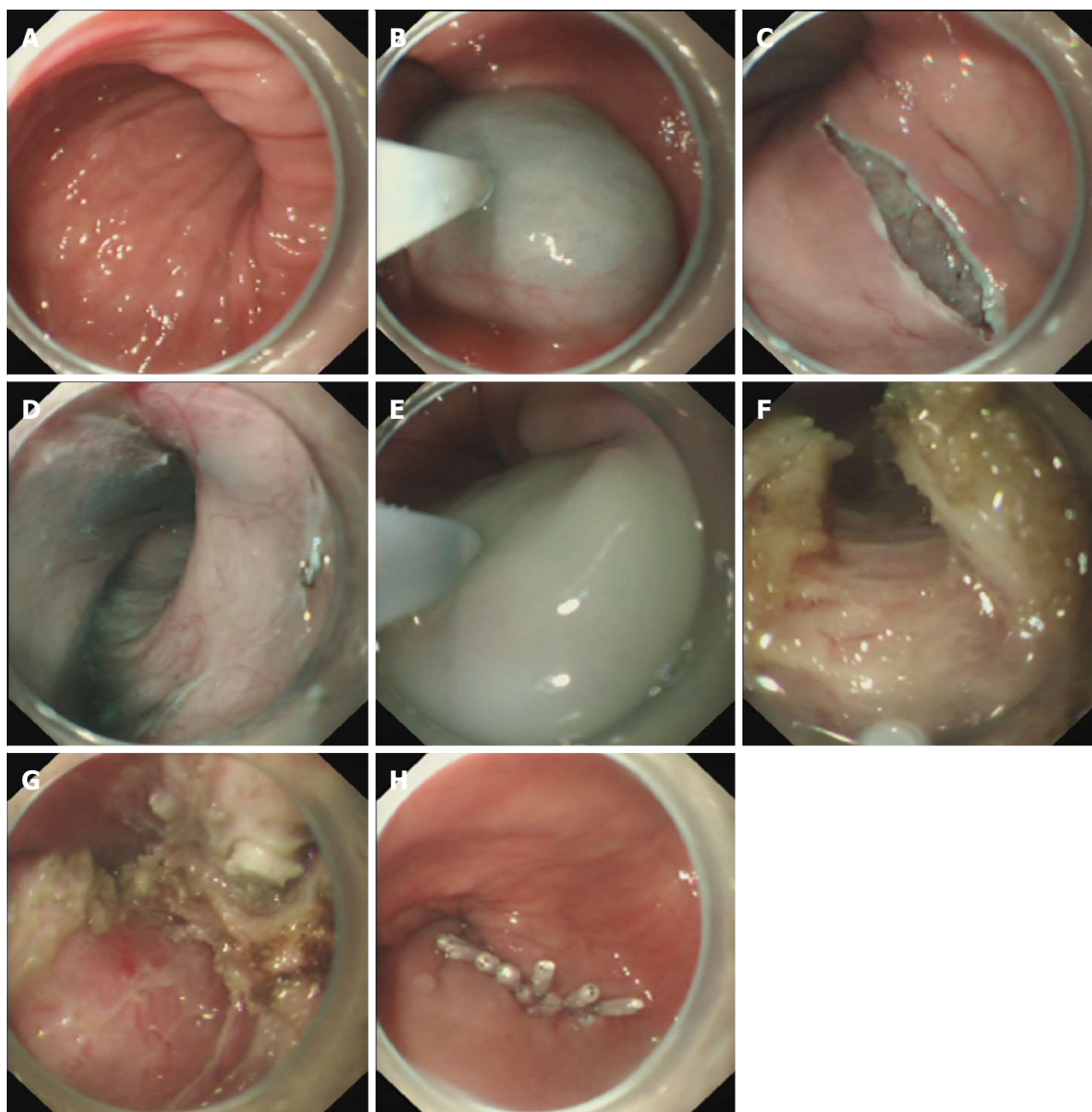


Figure 1 Case illustration of endoscopic full-thickness myotomy. A: A twisting esophagus was shown before POEM; B: Submucosal injection was made to provide a cushion; C: A longitudinal mucosal incision was made as the tunnel entry; D: Submucosal tunnel creation; E: Submucosal injection to the esophageal cavity to preset the tunnel route; F-G: Endoscopic full-thickness myotomy, peri-esophageal membrane could be seen; H: The mucosal entry was closed with several clips. POEM: Peroral endoscopic myotomy.

esophageal emptying, and preventing development of mega-esophagus^[10]. Current treatments for achalasia include pharmacological and endoscopic therapy (injection of botulinum toxin, pneumatic balloon dilation, and POEM) and surgical myotomy^[10]. Medical treatment with nitrates or calcium antagonists has been largely abandoned due to its poor efficacy and significant side effects. LHM is the most definitive and successful treatment for elderly patients with no contraindications for the surgical procedure^[11]. Nevertheless, it is still an invasive procedure, and it often leads to complications such as perforation, esophageal reflux, and stricture. Therefore, endoscopic treatment is recommended as the first-line option due to poly-morbidity (hypertension, cardiac diseases and diabetes) in elderly patients. Endoscopic dilation

and botulinum toxin injection are safe and effective in aged patients, but the effect tends to attenuate over time, and repeated treatment is thus needed. POEM is a novel endoscopic treatment for achalasia and has shown exciting results^[7-9,12]. Compared with Heller myotomy, POEM bears the advantages of shorter duration of operation and hospitalization, lower complication rate, and a similar short-term efficacy^[13]. However, the safety and efficacy of POEM in elderly patients has yet to be well documented. Six centers have reported POEM for only a total of 14 achalasia patients aged 84-97 years^[14]. In our pilot study, a total of 15 achalasia patients aged 65-84 years underwent POEM at our hospital. Symptoms remitted in all cases, and no serious complications or recurrence were noted during follow-up of 6-39 mo. SF-36 questionnaires

Table 2 SF-36 domain scores before operation and at 1 and 6 mo after operation

	Preoperative	1 mo after operation	P value	6 mo after operation	P value
Physical functioning	85 (75-90)	90 (85-90)	0.005	90 (85-95)	0.001
Role limitations due to physical problems	100 (50-100)	100 (81-100)	0.007	100 (100-100)	0.009
Role limitations due to emotional problems	100 (67-100)	100 (100-100)	0.110	100 (100-100)	0.055
Energy/fatigue	80 (50-80)	85 (80-85)	0.002	85 (80-85)	0.002
Emotional well-being	80 (72-88)	84 (80-88)	0.084	84 (80-84)	0.079
Social functioning	100 (67-100)	100 (78-100)	0.013	100 (100-100)	0.010
Pain	68 (52-100)	84 (72-100)	0.009	92 (84-100)	0.005
General health	52 (35-77)	77 (57-77)	0.000	87 (72-97)	0.000

All scores expressed as median with interquartile range.

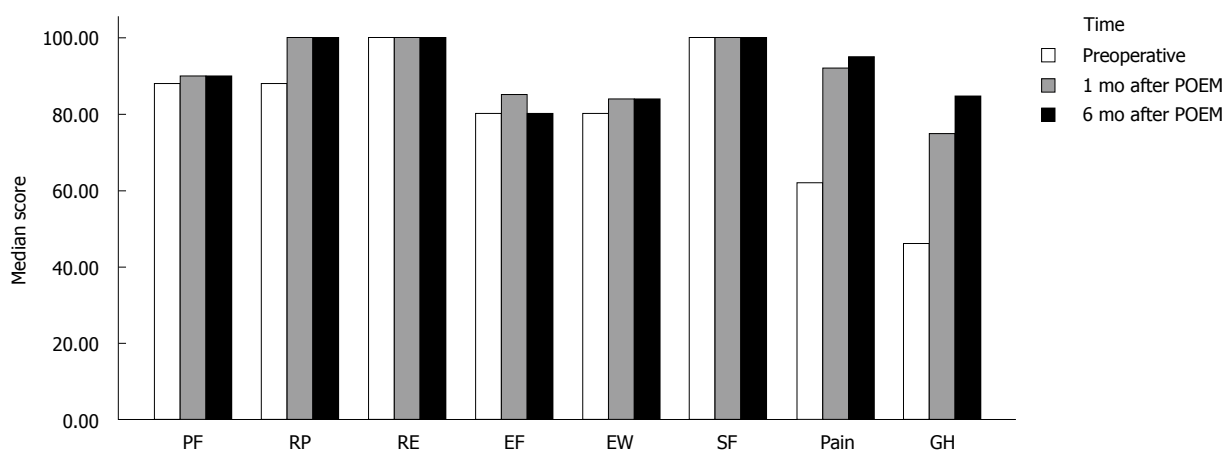


Figure 2 Quality of life outcomes (SF-36 domain).

demonstrated a significant improvement in quality of life. This indicates that POEM is an effective and safe technique for achalasia in elderly patients.

However, we should pay attention to the following points during POEM for achalasia in elderly patients. First, elderly patients usually complain of long-term symptoms and some may have a dilated or distorted esophagus, even with sigmoid-type esophagus. In these cases, creating a straight submucosal tunnel is technically difficult because of the "tunnel maze". Second, some elderly patients have undergone endoscopic or surgical treatments prior to POEM. Although a few studies have shown that POEM is safe and effective for achalasia patients in the setting of prior interventions^[15,16], POEM may be technically difficult due to the presence of fibrosis of varying degrees and altered intramural planes resulting from prior procedures. In our experience, submucosal injection into the esophageal cavity with a mixed solution containing indigo can be used to preset tunnel routes to ensure a straight tunnel into the proximal stomach. Moreover, we can avoid the most fibrotic site by the same method. When encountering fibrotic submucosa near the LES during initial tunnel dissection, caution should be used to avoid thermal injury to the mucosa. In case of difficulty in making a safe submucosal passage when traversing the LES, we can start myotomy prematurely in order to

gain access to the distal esophagus and proximal gastric wall. In the present study, one patient had sigmoid-type esophagus and six had undergone prior treatments, and all of them underwent POEM uneventfully. Six of them gained sustained symptomatic improvement. One patient experienced reflux symptoms 2 mo after POEM, and EGD revealed esophagitis, which was relieved after oral PPI therapy.

During POEM, a selective circular myotomy preserving the longitudinal outer esophageal muscular layer is designed to avoid entering the pleural space and reduce morbidity^[17]. However, completeness of myotomy is the prerequisite of sufficient and long-term reduction of LES pressure, and is the basis for the excellent results of conventional surgical myotomy^[1,18]. Two clinical studies have demonstrated that full-thickness myotomy may be superior for rapid esophagogastric emptying and reducing operation time, without increasing procedure-related adverse events and clinical reflux complications^[12,19]. Given the fact that full-thickness myotomy theoretically results in long-term symptom remission, we performed full-thickness myotomy in 12 patients. Although 15 patients may not be sufficient for a comparative study of circular and full-thickness myotomy, only one patient had reflux esophagitis in the full-thickness myotomy group, which was relieved after oral PPI

therapy. However, because the follow-up period was short, whether full-thickness myotomy has better long-term efficacy than circular myotomy needs further study.

In conclusion, POEM is safe and effective in elderly patients with achalasia. It is a less-invasive endoscopic procedure for achalasia, and shows good results without causing serious complications. Although the sample size was small and duration of follow-up was short, this new method showed satisfactory initial results. A large randomized controlled study is needed to evaluate the long-term efficacy of POEM compared with other treatments for achalasia in elderly patients.

COMMENTS

Background

Current treatment modalities for achalasia in elderly patients include medical treatment, endoscopy, and surgery. Medical treatment has been largely abandoned due to its poor efficacy and significant side effects. Laparoscopic Heller myotomy is now the most definitive and successful treatment of choice. Nevertheless, it is still an invasive procedure, and often yields complications such as perforation, esophageal reflux and stricture. Conventional endoscopic treatment such as endoscopic dilation, stent insertion and botulinum toxin injection has been shown to be safe and effective in aged patients, but the effect tends to attenuate over time and repeated treatment is often needed.

Research frontiers

Peroral endoscopic myotomy (POEM) is a novel technique for treatment of achalasia. The current research hotspot is how to perform it successfully while simultaneously reducing the procedure-related complications.

Innovations and breakthroughs

This is the first study to investigate the safety and efficacy of POEM for the treatment of achalasia in elderly patients. The authors shared some useful experience in POEM for end-stage achalasia.

Applications

The study results suggest that POEM is safe and effective in elderly patients with achalasia. It is a less-invasive endoscopic procedure, and shows good results without causing serious complications.

Terminology

POEM represents a natural orifice endoscopic surgical technique for scarless Heller myotomy for the treatment of achalasia. It utilizes a submucosal tunnel approach that offsets the mucosal and muscular incisions and thus allows secure closure with a few clips on the mucosotomy site.

Peer-review

This is an interesting study that presents the outcome of POEM in 15 AC patients aged 65 years or older, recorded with lower esophageal sphincter-pressure esophageal diameter and QoL (SF 36) as endpoints.

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