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Original article

Safety and efficacy of the modified peroral endoscopic myotomy with shorter myotomy for achalasia patients: a prospective study

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SUMMARY. **Peroral endoscopic myotomy (POEM) has been developed as a minimally invasive endoscopic treatment for achalasia for years. However, the optimal length of submucosal tunnel and myotomy of muscle bundles during procedure of POEM has not yet been determined, so we aim to assess safety and efficacy of modified POEM with shorter myotomy of muscle bundles in achalasia patients. Consecutive achalasia patients had been performed modified POEM with shorter myotomy, and assessed by symptoms, high-resolution manometry, and barium swallow examinations before and 3 months after POEM for safety and efficacy evaluation. Modified POEM with shorter submucosal tunnel (mean length 6.8 cm) and endoscopic myotomy of muscle bundles (total mean length 5.4 cm) were completed in 46 consecutive achalasia patients. During the 3-month follow up in all cases, significant improvement of symptoms (a significant drop in the Eckardt score 8.4 ± 3.2 vs. 2.7 ± 1.9; $P < 0.001$), decreased lower esophageal sphincter pressure (39.4 ± 10.1 vs. 24.4 ± 9.1 mmHg; $P < 0.001$) and integrated relaxation pressure (38.6 ± 10.4 vs. 25.7 ± 9.6 mmHg; $P < 0.01$), and a drop in height of esophagus barium-contrast column (5.4 ± 3.1 vs. 2.6 ± 1.8 cm; $P < 0.001$) were observed. The frequencies of adverse events were lower in those under endotracheal anesthesia and CO_2 insufflations compared with intravenous anesthesia and air insufflations. Only three patients were found to have gastroesophageal reflux disease on follow up. Modified POEM with shorter myotomy under endotracheal anesthesia and CO_2 insufflations shows its good safety and excellent short-term efficacy in the treatment of achalasia. But further studies are warranted to assess the long-term efficacy.**

KEY WORDS: **achalasia, peroral endoscopic myotomy, safety and efficacy, shorter myotomy.**

INTRODUCTION

Achalasia is a chronic benign disease with a subtle onset and symptoms that may progress gradually for years before exact diagnosis. It is the most common primary motility disorder of the esophagus; however, it occurs rarely, with an annual incidence of approximately 0.03–1/100 000 per year.[1,2] Achalasia affects men and women equally and may occur at any age. Based on the high-resolution manometry (HRM) recordings recently, achalasia can be easily diagnosed now. According to the Chicago Classification of HRM,[3–6] the classification criteria for achalasia are an integrated relaxation pressure (IRP) ≥ 15 mmHg with absent peristalsis (type I) or pan-esophageal pressurization to >30 mmHg (at least 20% of swallows, type II) or spastic contraction (at least 20% of swallows, type III). Despite increasing understanding of its pathophysiology, the etiology of achalasia remains largely unknown, while all current treatments have their own advantages and disadvantages. Therapy is focused mainly on forced relaxation of the lower esophageal sphincter (LES) by endoscopic (pneumatic dilation) or surgical means (laparoscopic Heller's myotomy, LHM). For many years, repeated endoscopic pneumatic dilation has commonly been the treatment of choice, leading to therapeutic success in 70–80% of cases,[7] and the success rates of Heller's myotomy ranging between 89 and 100%,[8] leading to

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continuously increasing enthusiasm for the surgical approach. In 2007, Pasricha *et al.* developed a novel endoscopic myotomy technique in the animal model, using a submucosal tunnel.[9] In 2010, Inoue *et al.*[10] reported the first human study in which the specific technique of peroral endoscopic myotomy (POEM) was introduced. According to the study of Inoue *et al.*,[10] compared with the first seven patients in the series operated with a relatively shorter myotomy (mean length 4.9 cm plus 1.0 cm at the gastric side), the latter 10 patients operated with extended myotomy (mean length 10.4 cm) had better symptom improvement. Now the procedure of POEM with long myotomy treatment of achalasia has been adopted worldwide. But is it really an imperative necessity to have a procedure of POEM with long myotomy? Few papers have reported the relativity between the lengths of myotomy in procedure of POEM and the outcome for achalasia patients. Based on the facts that achalasia is a primary motor disorder of LES dysfunction with discordant relaxation of the LES, as well as the excellent short-term outcome of endoscopic pneumatic dilation or LHM, we suppose patients with achalasia may end up to a satisfactory outcome with shorter myotomy in procedure of modified POEM, which only focused on the forced relaxation of the LES. The aim of this prospective pilot study was to investigate the safety and feasibility of the modified POEM, and to assess short-term efficacy by using a validated achalasia symptom score, esophageal HRM, and esophageal barium swallow examination.

METHODS

Patients

Consecutive adult patients (age greater than 18 years old) with primary achalasia, who successfully finished the established evaluations (symptoms, HRM, esophagogastroduodenoscopy and upper gastrointestinal barium swallow) were included in this study. Patients with previous esophageal or gastric surgery (except pneumatic dilation and POEM), malignant, or precancerous esophageal lesions were excluded.

Outcome measurements

All patients completed dysphagia symptom score, HRM, upper endoscopy, and barium swallow examination before and 3 months after the modified POEM.

Symptoms and quality of life (QOL) evaluation

All patients completed Mayo Dysphagia Questionnaire – 30 Day (MDQ-30)[11] and Eckardt score questionnaire,[12] in which severity of symptoms was evaluated with questions about the frequency of esophageal symptoms such as dysphagia, regurgitation, retrosternal pain, and weight loss; and severity of their influence on QOL ranked from none to severe degrees.

Barium swallow

The degree of esophageal dilatation was classified according to the diameter of the esophageal lumen,[10,13] i.e. grade I (<3.5 cm), grade II (3.5–6 cm), and grade III (>6 cm). The height of the barium stasis column was also measured. Sigmoid-type achalasia was classified into two types according to the degree of tortuosity of the esophageal lumen seen in barium swallow.[10,13] Sigmoid type 1 (S1) shows a tortuous esophagus without U-turns in a proximal direction, while the sigmoid type 2 is characterized by severely tortuous esophagus with U-turns.

HRM

The data of LES pressure and IRP were recorded based on pressure data of 10 wet swallows. According to the manufacturer's data, the normal range for LES pressure with this device is from 10 to 45 mmHg, mean IRP ≤20.5 mmHg (Sandhill Scientific Inc.®, Highlands Ranch, CO, USA).

Esophageal 24-hour pH-impedance monitoring

On follow up, patients were encouraged to have the 24-hour pH monitoring 3 months after POEM to rule out complication of gastroesophageal reflux disease (GERD), especially for those presented with reflux related symptoms (e.g. heartburn and regurgitation).

Procedure of the modified POEM

Achalasia patients were admitted 2 days before the POEM procedure to remove food remnants from the esophagus (via fasting and suction from nasogastric tube) and to rule out contraindications. POEM with shorter myotomy was performed under intravenous anesthesia or endotracheal anesthesia. POEM procedures were performed as described by Inoue *et al.*[10,13] (Fig. 1). All procedures were performed in the endoscopy suite by a single operator (J. Wang). A forward-viewing upper endoscope (GIF 260J, Olympus, Hamburg, Germany) was used with a transparent distal cap (MH 588, Olympus). Air or CO_2 gas was used for insufflation during the procedures. An initial mucosal incision was made in the 2–3 o'clock position on the right lateral esophagus. This was done to aim for a straight tunnel ending to the lesser curvature at the cardia. An ESD IT Knife (Insulation-tipped Diathermic Knife, Olympus) was used to access the submucosa and dissect the submucosal tunnel, and KD-640L Triangle Tip Knife (Olympus) to dissect muscle bundles in the esophagus and cardia according

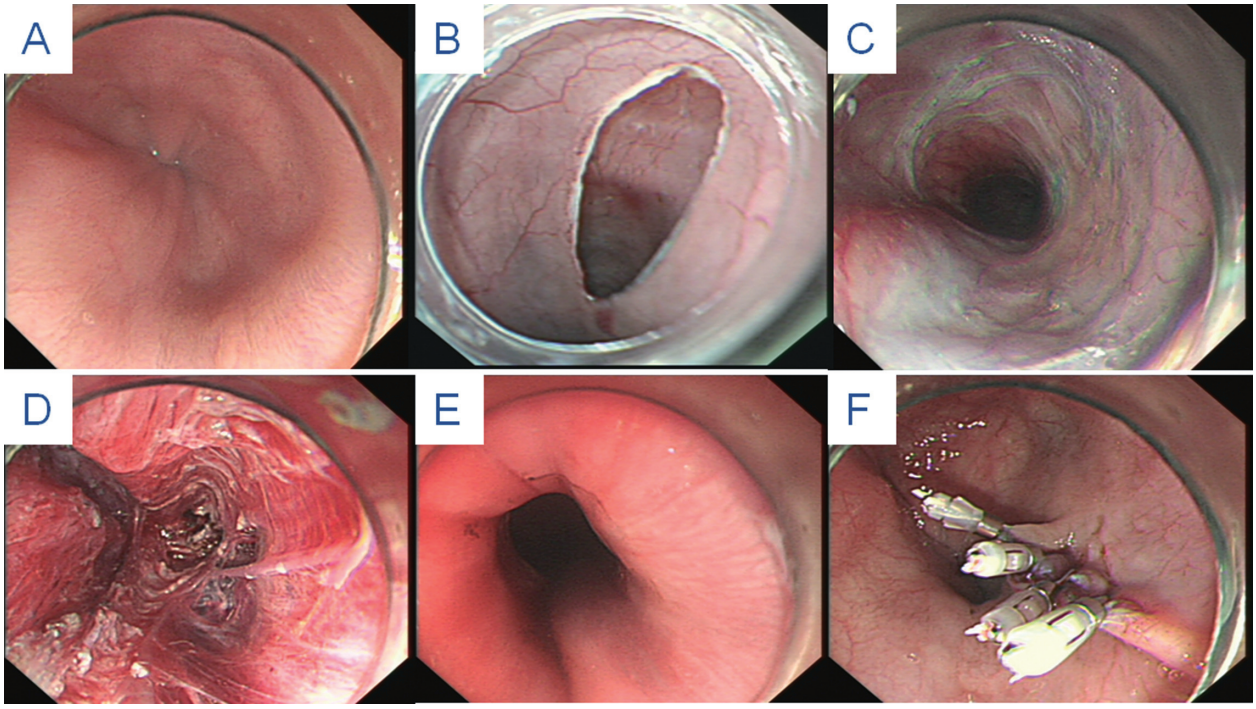

Fig. 1 Peroral endoscopic myotomy (POEM) procedure. (A) Tightly closed cardia before POEM. (B) After injection of saline and methylene blue, a 2-cm incision was made into the mucosa as an entry. (C) A submucosal tunnel from the mid-esophagus to the gastric cardia was created using an insulation-tipped knife. (D) The circular muscle bundle are dissected using the triangle-tip knife. (E) The relaxed cardia after dissection of LES. (F) The mucosal entry is closed using standard endoscopic clips.

to the surgical standards of Heller myotomy. Identification of appropriate length of the submucosal tunnel and myotomy in the esophagus and the cardia was done based on the length of LES based on esophageal manometry. The following landmarks were used for anatomical orientation: the LES leads to a narrowing in the tunnel, and after passing the distal LES, a widening of the space can be observed while maneuvering the endoscope, combined with the parameters of the HRM. The length of submucosal tunnel was only1–2 cm above the proximal LES in the esophagus and 1–2 cm under the distal LES into the cardia, and the length of myotomy was 1–2 cm shorter than that of submucosal tunnel. Dissection of the muscle bundles began at 1–2 cm distal to the mucosal entry and extended 1–2 cm into the cardia. When a transmural dissection at the cardia was performed, the surrounding peritoneal tissue could be identified, and the length of an adequate myotomy was established. During the procedure of transmural dissection, the circular muscle bundles were cut first, and then the endoscope was pulled out of the tunnel into the esophageal lumen to identify the degree of LES distention. If the endoscope passed difficultly through the narrowed LES, the vertical muscle bundles (full-thickness dissection) were cut for satisfactory relaxation of LES. Closure of the mucosal entry site was performed using standard endoscopic clips (HX-110UR EZ Clip Reusable Rotatable Clip Fixing Device and HX-610-135L Single Use Clips; Olympus). Patients were hospitalized for 24–48 hours after POEM and on liquid diet for an additional 12–24 hours. Patients were discharged with daily double-dose proton pump inhibitor (PPI) and soft diet for 2 weeks. Patients were advised to discontinue PPI medication 4 weeks after POEM. The information of operation duration, length of submucosal tunnel and muscular bundle dissection, and adverse events of the procedure were collected.

Follow-up measurements

All patients were scheduled for investigations on a follow up visit 3 months after POEM for symptoms and QOL evaluation, as well as upper endoscopy, HRM, and barium swallow. Additionally, the occurrence of abnormal esophageal 24-hour pH monitoring, symptoms, and endoscopic manifestations of GERD were also assessed.

Statistical analysis

The paired Student's *t*-test was applied to analyze changes of Eckardt score, parameters of HRM, and barium swallow before and 3 months after POEM.

RESULTS

Patient characteristics

Forty-six consecutive patients (17 male; mean age 36 years old) were included and had the

Table 1 Symptoms and quality of life of 46 achalasia patients evaluated with Mayo Dysphasia Questionnaire – 30 Day (MDQ-30) before POEM

Parameter		*n*	%
Dysphagia symptom	—	46	100
History	<1 year	12	26
	1–5years	28	61
	>5 years	6	13
Frequency of dysphagia in the past 30 days	Several times a week	9	20
	Daily	4	9
	Every meal	27	59
	Every swallow	6	13
Aggravation of dysphagia in the past 30 days	Change a little or hardly	30	65
	Moderately changed	12	26
	Changed very much	4	9
Severity of dysphagia in past 30 days†	Mild (0–3)	4	9
	Moderate (4–6)	16	35
	Severe (7–10)	26	56
Time to eat an average meal	<15 min	0	0
	16–30 min	11	24
	31–60 min	33	72
	>60 min	2	4
Weight loss in the past 30 days	Changed hardly at all	10	22
	1–2.5 kg	24	52
	>2.5 kg	12	26
Effect on quality of life in past 30 days	Mild	6	13
	Moderate	31	67
	Severe	9	20

†Visual analogue scale of dysphagia severity were evaluated by patients themselves from 0–10(mild~severe). POEM, peroral endoscopic myotomy.

modified POEM treatment between January 2012 and February 2013. Before inclusion, eight patients had received other treatments with one of them having previous unsuccessful POEM and the others having at least one dilation endoscopically.

Symptoms and QOL were recorded with MDQ-30 and Eckardt score as shown in Table 1. Seventy-one percent of the included patients had suffered from more than 1-year disease history before diagnosis. The most common complaints were dysphagia (100%), prolonged meal time (100%, >15 minutes), and weight loss (88%). Seventy-two percent of them complained of dysphagia with every meal or even every swallow, and 87% of them who self-rated these discomforts had moderate to severe effect on QOL. However, only 9% of patients had severely aggravating dysphagia within 30 days before POEM. Up to 91% of patients were with Eckardt score more than 4.

All of them successfully finished HRM examination, and were divided into type I (26 case, 57%), type II (19 cases, 41%), and type III (1 case, 2%) according to the Chicago Classification Criteria.

As the barium swallow results showed, seven patients with sigmoid-shaped (S1) and 39 with non-sigmoid esophagus. There were 14 cases of grade I esophageal dilatation, 24 cases of grade II, and eight cases of grade III (>6 cm).

POEM procedure

All 46 patients completed the modified POEM procedure Table 2 with endoscopic air (for the first 11 cases) or CO_2 insufflations under intravenous anesthesia (for the first seven cases) or endotracheal anesthesia. The average operating time of procedure was 85 minutes (range 70–110 minutes) under intravenous anesthesia versus 42 minutes (range 30–80 minutes) under endotracheal anesthesia. According to the HRM findings and barium swallow examination, as well as confirmed by endoscopy before POEM, the mean length of LES was 3.6 cm (range 3.3–4.3 cm). The average length of submucosal tunnel and the length of muscle bundle dissection were 6.8 cm (range 4.0–10.0 cm) and 5.4 cm (range 3.5–7.5 cm), respectively. Dissection of the muscle bundle was about 4.3 cm (range 3.0–5.5 cm) in the esophagus above the gastroesophageal junction and extended to about 1.1 cm (range 1.0–2.0 cm) below gastric cardia. Fifteen patients (33%) had only sphincter circular muscle bundle dissected while the rest had full-thickness muscle bundle dissection. The total frequencies of adverse events (Table 3), such as bleeding (defined as amount of bleeding > 5mL), perforation, pneumothorax, pneumoperitoneum, and pneumoderm were 7 (15%), 6 (13%), 14 (30%), 12 (26%), and 17 (37%), respectively. Furthermore, the frequencies of the adverse events, such as bleeding, perforation, pneumothorax, pneumoperitoneum, and pneumoderm, were lower in those under endotracheal anesthesia compared WITH intravenous anesthesis (4/39 vs. 3/7, 4/39 vs. 2/7, 8/39 vs. 6/7, 7/39 vs. 5/7, and 11/39 vs. 6/7, respectively); and these adverse events were also lower with CO_2 insufflation than with air insufflation (4/35 vs. 3/11, 3/35vs. 3/11, 6/35 vs. 8/11, 6/35 vs. 6/11, and 8/35 vs. 9/7, respectively). Those with different thickness of muscle bundle dissection had similar incidence of adverse events. The mean postoperation hospital stay was 2.9 days (range 1–6 days).

Table 2 Operation information of the modified POEM for 46 ahcalasia patients

Parameter		Data
Operating time, mean (range), min	Total (*n* = 46)	52 (30–120)
	Intravenous anesthesia (*n* = 7)	85 (70–110)
	Endotracheal anesthesia (*n* = 39)	42 (30–80)
Muscle incision, *n* (%)	Circular muscle only	15 (33)
	Full thickness	31 (67)
Length of submucosal tunnel, mean (range), cm	Total	6.8 (4.0–10.0)
	Esophageal	5.6 (3.5–9.0)
	Gastric cardia	1.1 (1.0–2.0)
Myotomy length, mean (range), cm	Total	5.4 (3.5–7.5)
	Esophageal	4.3 (3.0–5.5)
	Gastric cardia	1.1 (1.0–2.0)
Postoperative hospital stay, mean (range), day		2.9 (2–6)

POEM, peroral endoscopic myotomy.

Table 3 Adverse events during and after POEM

Adverse events	Total (*n*)	Anesthesia		Gas insufflation		Muscle bundle cut	
		Intravenous	Endotracheal	Air	CO_2	Circular	Full thickness
Bleeding	7	3/7	4/39	3/11	3/35	3/15	4/31
Perforation	6	2/7	4/39	3/11	3/35	2/15	4/31
Pneumothorax	14	6/7	8/39	8/11	6/35	5/15	9/31
Pneumoperitoneum	12	5/7	7/39	6/11	6/35	3/15	9/31
Emphysema	17	6/7	11/39	9/11	8/35	6/15	11/31
GERD	7	1/7	6/39	2/11	5/35	1/15	6/31

GERD, gastroesophageal reflux disease; POEM, peroral endoscopic myotomy.

Three-month follow up

All patients fulfilled 3-month follow up and efficacy assessment (Table 4 and Figs 2,3). Self-assessed treatment success, mainly as defined by a post-myotomy Eckardt score ≤3, was achieved in 100% of 46 cases. Eckardt score pretreatment was significantly higher (8.4 ± 3.2) compared with post-treatment score (2.7 ± 1.9) ($P < 0.001$). Eighty-seven percent (40/46) of patients had gained weight 3 months after POEM. The height of postoperation barium column in esophagus was significantly lower than preoperation (2.6 ± 1.8cm vs. 5.4 ± 2.1cm, $P < 0.001$), but no obvious changes in diameters of esophagus before and after POEM was found. The LES pressure and IRP (pretreatment vs. post-treatment) measured by HRM were 39.4 ± 10.1 mmHg vs. 24.4 ± 9.1 mmHg ($P < 0.001$) and 38.6 ± 10.4 mmHg vs. 25.77 ± 9.6 mmHg ($P < 0.001$), respectively. Interestingly, 11 patients restored certain degree of their esophageal peristalsis (Fig. 3). Additionally, there were only seven (15%) patients complicated with GERD detected by symptoms or endoscopy at 3 months after POEM.

DISCUSSION

Achalasia is a rare neurodegenerative esophageal disease that primarily involves the myoenteric plexus of the esophagus, especially LES, the vagal trunks, and the dorsal vagal nucleus, leading to inability of the LES to relax and loss of esophageal body peristalsis,[14] which correlates with clinical, manometric, radiologic, and pathological manifestations of achalasia.[15–17] Main symptoms of patients involved in this study were dysphagia, prolonged time of meal, weight loss, and poor QOL. Patients complained of moderate to severe dysphagia (with every meal or even every swallow) were with higher grade dilation of esophagus on barium swallow. Most patients have suffered from dysphagia for more than a year without any changes of the dysphagia recently.

The goal of therapy is mainly to provide relaxation of persistent LES spasm as to relieve symptoms, improve esophageal emptying, and prevent extreme dilation of esophageal lumen. And several available treatments, such as pharmacologic treatment (includes nitrate and calcium antagonists, as well as

Table 4 Clinical efficacy of POEM with shorter myotomy in 46 achalasia patients

Parameter	Pre-POEM	Post-POEM	*P*-value
Eckardt score, mean ± SD	8.4 ± 3.2	2.7 ± 1.9	<0.001
Effect on quality of life in past 30 days			
None	0	0	—
Mild	6	28	—
Moderate	31	18	—
Severe	9	0	—
Gain weight, *n* (%)			
Changed hardly at all	—	6 (13%)	—
1–2.5 kg	—	30 (65%)	—
>2.5 kg	—	10 (22%)	—
Barium swallow, mean ± SD, cm			
Diameter of esophagus	4.9 ± 2.2	4.1 ± 2.3	0.86
Height of barium column	5.4 ± 2.1	2.6 ± 1.8	<0.001
HRM parameters, mean ± SD, mmHg			
LES pressure	39.4 ± 10.1	24.4 ± 9.1	<0.001
IRP	38.6 ± 10.4	25.7 ± 9.6	<0.001

HRM, high-resolution manometry; IRP, integrated relaxation pressure; LES, lower esophageal sphincter; POEM, peroral endoscopic myotomy; SD, standard deviation.

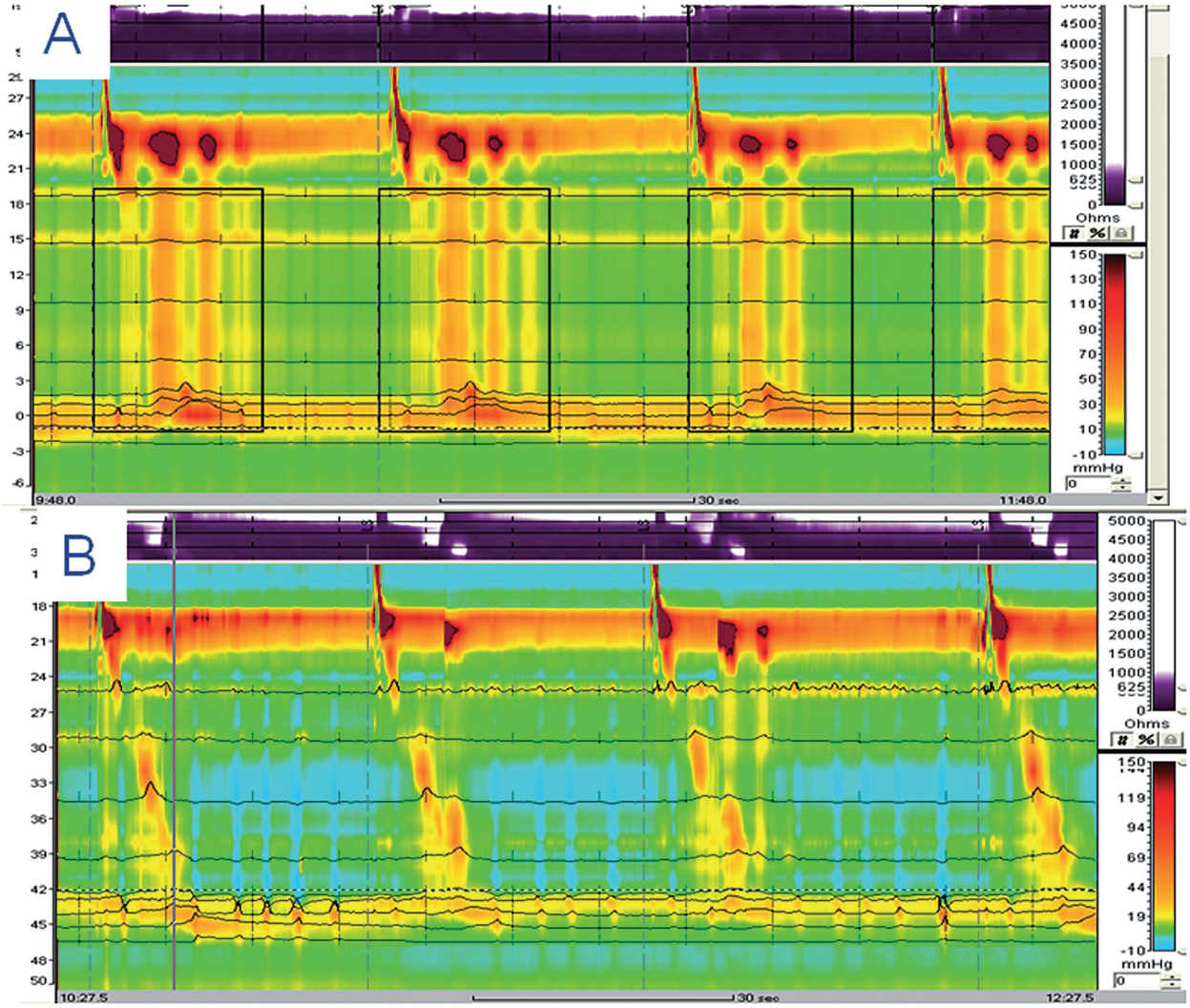

Fig. 2 High-resolution manometry (A) before and after (B) peroral endoscopic myotomy (POEM) for one of the patients. (B) Fraction of esophageal peristalsis was observed after POEM.

endoscopic botulinum toxin injection), endoscopic esophageal balloon dilatation, and laparoscopic esophagomyotomy (Heller's surgery), have been applied to manage achalasia in the past decades, but none of these treatment options have achieved optimal or satisfactory effects for achalasia patients.[18–24] With the introduction of POEM in treatment of achalasia in human by Inoue,[10] this technology with long myotomy has been developed into an international experience. Inoue *et al.*[25] continued applying this method to 105 achalasia patients (including 16 cases of patients with sigmoid-shaped esophagus) and showed its good short-term safety and efficacy. Afterwards, Zhou *et al.* from China (42 cases reported),[26] von Renteln *et al.* from Germany (16 cases reported),[27] and Swanström *et al.* from America (5 cases reported)[28] tested the feasibility of POEM and confirmed its similar curative effect on achalasia patients as Inoue. However, all the above studies had used the procedure method of POEM proposed primarily by Inoue with the long myotomy (about 10 cm). But esophageal manometry had showed that the length of LES was just 3.2 cm (range 2.4–4.0 cm) for normal volunteers.[29] So we supposed that the modified POEM with shorter myotomy could also achieve the same effects on achalasia patients as the long-segment myotomy but with less risk of complications and shorter time of operation as long as it ensured to cut LES fully enough.

And as we all know, HRM has an important role in diagnosis and classification of achalasia,[5,6] also in efficacy evaluation of achalasia during endoscopic or surgical therapy.[21,30–32] In our study, according to the results of HRM, the mean length of LES was about 3.6 cm (range 3.3–4.3 cm), quite near to the reported normative data.[29] And we performed the modified POEM according to data of HRM and barium swallow, resulting in shorter submucosal tunnel (only 6.8 cm) and LES sphincter muscle bundle dissection (only 5.4 cm).

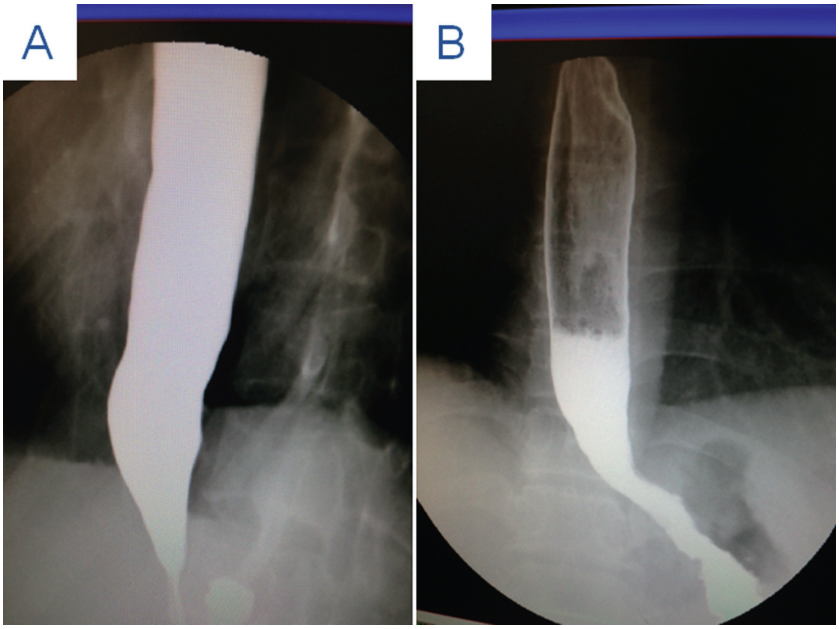

Fig. 3 Barium swallows (A) before and (B) after peroral endoscopic myotomy (POEM) for one of the patients.

Short-term (3 months) follow up showed that all included patients achieved satisfactory effects evaluated with symptoms and QOL improvements (MDQ-30 and Eckardt score), lower height of barium column in esophagus (barium swallow), and decreased LES pressure and IRP (HRM findings).

There is still no conclusion on the thickness of muscle bundle dissection. Past experience showed that even without cutting off of the longitudinal muscle bundle, only circular muscle bundle dissection was sufficient to lower down LES pressure to normal range. But one meta-analysis showed that Heller's surgery could keep patients in long-time remission, mainly becasuse of its full-thickness muscle bundle dissection to make sure of persist relaxation of LES.[33] Von Renteln *et al.* also performed POEM with full-thickness myotomy for six cases of achalasia patients, which remained in long-time symptom remission after procedure.[27] Some research showed that 83% of patients that had full-thickness myotomy could restore rapid esophageal emptying, but 56% of patients that had only circular muscle bundle dissection would still have delayed esophageal emptying.[34] In our study, circular and full-thickness muscle bundle dissection had gained similar effects on achalasia patients.

More interesting, certain extent of peristalsis was observed in some patients after modified POEM in this study, which may be associated with shorter muscular dissection and kept most function of muscle bundles of esophagus. But we still were uncertain about it. Chen *et al.*[35] also found distal esophageal peirstalsis after endoscopic dilation in several patients. Loqan *et al.*[36] reported that after Heller's surgery, 4/7 subjects showed partial esophageal peristalsis and less synchronized contractions, and they thought this change was insignificant and could not conclude that surgery would help to restore peristalsis. However, this may need further investigation.

The safety of this procedure was also evaluated. Generally, the adverse events of POEM (like perforation, pneumoperitoneum, pneumothorax, and pneumoderm) and complication of GERD were not frequent as with other previous studies.[26–28] Our data also showed there were longer time of operation and more adverse events when under intravenous anesthesia and air insufflations compared with endotracheal anesthesia and CO_2 insufflations, which confirmed that it was safer to perform procedure of POEM with endotracheal anesthesia and CO_2 inflations.[37–39]

CONCLUSIONS

Our experience of modified POEM with shorter myotomy under endotracheal anesthesia and CO_2 insufflations shows its good safety and satisfactory short-term efficacy for achalasia patiens. Further studies are warranted to assess the long-term efficacy of modified POEM and to compare POEM with other treatment modalities.

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