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Original Article

Open peroral endoscopic myotomy for the treatment of achalasia: a case series of 82 cases

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SUMMARY. **During peroral endoscopic myotomy (POEM), creation of the tunnel is highly technically demanding and mucosal injury is one of the most common potential complications. We explored a method without a submucosal tunnel, which we call open peroral endoscopic myotomy (O-POEM). This study aimed to assess the feasibility and safety of O-POEM. O-POEM was performed on 82 patients with achalasia. Treatment success was defined as an Eckardt score of less than or equal to 3 after the myotomy. Adverse events including operative and postoperative adverse events were recorded. Treatment success and procedure-related adverse events were analyzed. After a median follow-up of 18 months (range: 6–26 months), the treatment success (Eckhart score ≤3) was achieved in 96.3% of cases (mean score pre- vs. post-treatment (7.4 vs. 1.8); $P < 0.001$) with a recurrence of 3 cases. Ten patients (12.2%) had adverse events consisting of 2 cases of mediastinitis, 1 case of post-O-POEM bleeding, 1 case of subcutaneous emphysema, 6 cases of pleural effusion. Two cases of mediastinitis required intraprocedural drainage, and other patients were managed by endoscopy and conservative medical treatment. There were no deaths. No patients required surgical conversion. Clinical reflux occurred in 15.9% of patients (13/82). O-POEM was reliable and effective for the treatment of achalasia. In addition, O-POEM might be a better option for patients with severe submucosal fibrosis.**

KEY WORDS: **achalasia, endoscopic treatment, esophageal dysmotility.**

INTRODUCTION

Achalasia is a rare esophageal motility disorder that is characterized by the absence of esophageal peristalsis and impaired relaxation of the lower esophageal sphincter (LES).[1] Conventionally, POEM has become an attractive alternative to endoscopic pneumodilation (PD) and laparoscopic Heller myotomy (LHM). Previous studies have demonstrated a high rate of efficacy of POEM in patients with achalasia.[2] However, separation of tissue planes and the establishment of a submucosal tunnel during POEM is highly technically demanding and challenging, especially in patients with severe submucosal fibrosis, such as failed Heller myotomy or sigmoid-shaped esophagus.[3,4] And mucosal injury is one of the most common perioperative adverse events of POEM, which occurs in approximately 1.6% to 25.8% of procedures.[5] In this study, we investigated a method of direct peroral endoscopic myotomy without a submucosal tunnel for the treatment of achalasia, which we call open peroral endoscopic myotomy (O-POEM).[6-8] The current data of O-POEM for the management of patients with achalasia have not yet been studied extensively. Therefore, we retrospectively reviewed data from patients who underwent O-POEM for achalasia to assess its safety, feasibility, and efficacy.

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MATERIAL AND METHODS

Patients

All consecutive patients who underwent O-POEM at the West China Hospital, a tertiary referral center in China from August 2016 to May 2018 were eligible for inclusion. The diagnostic measurements of achalasia were based on the Eckardt symptom score, barium esophagography, esophagogastroduodenoscopy (EGD), and high-resolution manometry (HRM), which is the gold standard of achalasia diagnosis. Standard demographic and clinicopathologic data were collected, including age, sex, disease duration, pretreatment and posttreatment Eckardt score, body mass index (BMI), the rate of treatment success, complications, operative

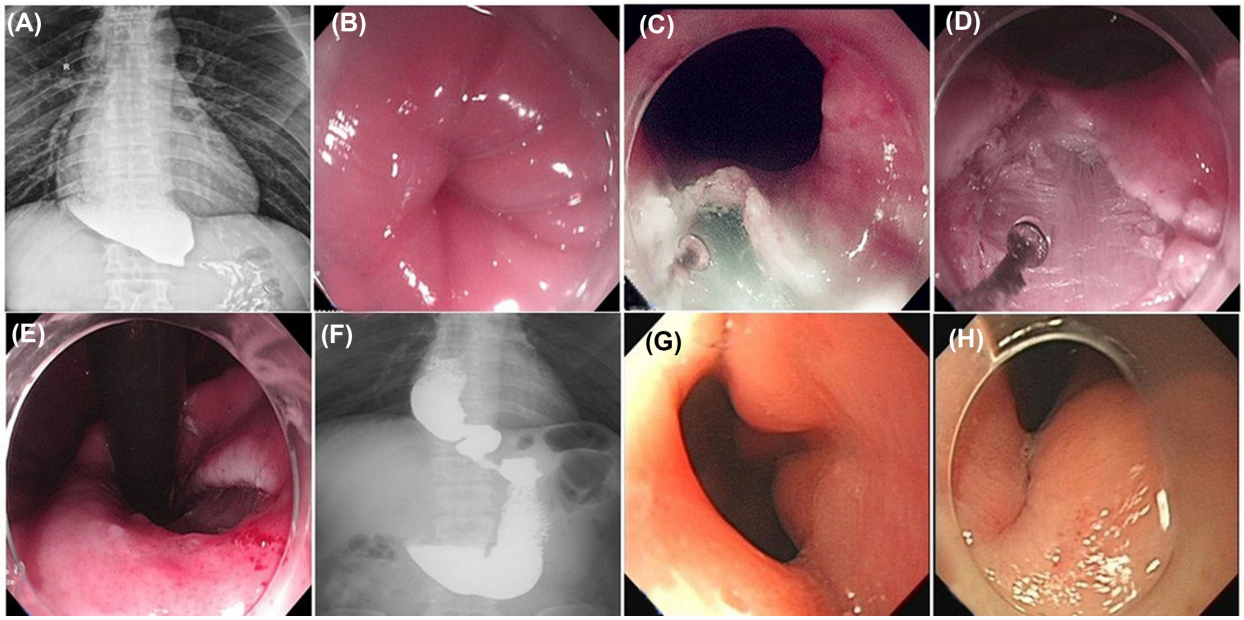

Fig. 1 Open peroral endoscopic myotomy (O-POEM). (A) Preoperative barium radiograph showing the beak-shaped appearance of a distal esophagus. (B) Preoperative gastroscopy showing a tightly closed cardia. (C) Submucosal saline injection and mucosotomy. (D) Cutting off a circular layer of the esophagus. (E) Retroflexion sight of fundus after myotomy. (F) Postoperative barium radiograph showing rapid passage of barium from the esophagus into the stomach. (G) Postoperative gastroscopy with a relaxed cardia. (H) Retroflexion sight of postoperative fundus revealed healing mucosa in the site of O-POEM.

time, hospitalization, reflux esophagitis, and recurrence. A retrospective review of these data was conducted. The study was approved by the Institutional Review Board of West China Hospital. Informed consent was obtained from all the enrolled patients.

O-POEM procedure

Procedures were performed in the endoscopy unit with patients under general anesthesia with endotracheal intubation to maintain supine position. A high-definition gastroscope (GIF-Q260J, Olympus, Tokyo, Japan) fitted with a transparent cap (D-201–11,802) was used. Carbon dioxide insufflation was adopted throughout the procedure. A high-frequency generator (VIO 200D, ERBE, Tübingen, Germany) was used for all O-POEM procedures, and a knife (HybridKnife, JET2, APC2) was applied to dissect the mucosa, submucosal fibers, and circular layer. The O-POEM steps were as follows: (1) A submucosal injection with sterile saline solution and mucosal incision (6–10 cm above the gastroesophageal junction at the 5–6 o'clock position) was created until it extended at least 2 cm beyond the gastroesophageal junction (EGJ) into the proximal stomach. (2) The extension of the longitudinal submucosal fibers was performed proximally to distally based on the mucosal incision. (3) Then, selective myotomy of the circular muscle was performed for a minimum length of 4–6 cm up the esophagus and 2 cm distal to the EGJ (Video S1, Figs 1,2). During this procedure, we tried to perform selective myotomy of the circular muscle carefully to avoid cutting longitudinal muscle layer. However, the longitudinal muscle is too thin to be protected. Sometimes, it even splayed itself. After complete myotomy, a smooth passage of the endoscope through the EGJ with minimal resistance should be present. Gastric decompression with a nasogastric tube (NGT) was performed for all the O-POEM patients because acid secretion may affect the healing of injury. A nasogastric tube was inserted into the gastric lumen under endoscopy guidance. Not only it helps the NGT across the EGJ but also guards against accidental perforation caused by the NGT (puncturing the longitudinal muscle layer or pleura). All the O-POEM procedures were performed by experienced POEM operators.

Postprocedure management

Postoperative management was individualized. Prophylactic antibiotics were given intravenously 30 minutes before O-POEM and continued for 1–3 days postoperatively, and intravenous protein pump inhibitors (PPIs) were continued throughout the hospital stay. A follow-up contrast esophagogram using water-soluble contrast material was scheduled the following day after O-POEM to ensure no leak from the myotomy site and guide timing of initiation of a liquid diet. Patients had no oral intake for 1–2 days after O-POEM and were then allowed a liquid diet on the postoperative day 2–3 if no complication sign was present. However, the exact time of gastric decompression and advancement of diet varied among patients. The average length of hospital stay for postprocedural

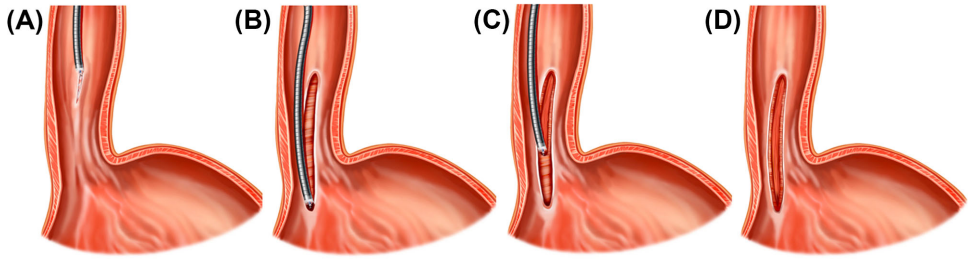

Fig. 2 The open peroral endoscopic myotomy (O-POEM) technique. (A) Submucosal injection and mucosal incision. (B) Submucosal dissection. (C) Selective myotomy of the circular muscle. (D) Complete myotomy of the circular muscle.

observation is 6 days and a longer hospital observation was needed if necessary. Patients with a high fever or discomfort are recommended to have a blood test first, and postprocedure chest CT is recommended for symptomatic patients. Drainage or decompression was performed in patients with symptomatic pleural effusion or pneumothorax as described by Zhou *et al*.[9] At discharge, patients were given a double dose of PPIs and a soft diet for 2 weeks.

Follow-up

All patients were followed-up at the outpatient clinic. We assessed postoperative EGD, barium esophagraphy, manometry, Eckardt score, and postoperative gastroesophageal reflux disease (GERD) symptoms. A follow-up endoscopy at 1, 6, and 12 months after O-POEM was scheduled for each patient. They also underwent barium esophagraphy 1 month after O-POEM. The initial follow-up HRM was at 3 months postoperatively. When they could not be followed up, we contacted them via telephone every 3 months postoperatively to check for the achalasia-related symptom scores and post O-POEM reflux symptoms. The end point of followed up was any recurrence of achalasia (Eckhart score >3).

Outcome parameters and definitions

The primary outcome was treatment success, defined as an Eckardt score ≤3 at 3 months postoperatively. Secondary outcomes were adverse events. Any event related to O-POEM procedure that prevents completion of the planned procedure and/or requires another procedure to solve the event, resulting in prolongation of existing hospital stay, or subsequent medical consultation were also defined as adverse events (AEs).[10] Classification according to the severity of adverse events was applied to grade the AEs.[11] The complications of O-POEM included bleeding requiring intervention, mediastinitis, subcutaneous emphysema, pneumoperitoneum, pleural effusion, and so on. Chicago classification system was used to evaluate the esophageal manometry findings.[12] We applied the same definition of submucosal fibrosis, which was published in previous publication:[13] the presence of poor mucosal lifting after injection, fibrotic, and sclerotic tissues in the submucosal space, adhesion between mucosa and muscle. Operative time was defined as the total number of minutes required to perform initial incision until the end of the O-POEM procedure. The length of hospitalization referred to the number of days that patients spent in the hospital. Endoscopic findings of reflux esophagitis were defined using the Los Angeles classification system.[14] Recurrence was defined as recurrent symptoms of achalasia, based on an Eckhart score >3 at 3 months after treatment.

Statistics

Continuous data were reported as the means with SDs. Before the analysis, the variables were checked for a normal distribution, and if the data were not normally distributed, univariable analysis was performed using the Mann-Whitney test for continuous variables. Continuous variables were compared using Student's t test. Fisher's exact test was used to compare the incidence rate of adverse events between different subgroups if necessary. A two-tailed $P < 0.05$ was deemed statistically significant. All statistical analyses were conducted using the SPSS version 22.0 (SPSS, Inc., Chicago, IL, USA).

RESULTS

Eighty-two patients (male/female: 35/47; mean age: 44.6 years; range: 14–84 years) were included in this study, with a median follow-up of 18 months (range: 6–26 months). Patient and procedure characteristics are shown in Tables 1 and 2. Before endoscopic myotomy, pneumatic balloon dilation had been performed in 29 cases (35.4%), botox injection in 5 cases (6.1%), stent in 1 case (1.2%), Heller myotomy in 3 cases (3.7%), and traditional POEM in 2 cases (2.4%). The average disease duration was 8.7 years (range: 1–50 years). A total of 70 patients (85.4%) received HRM before O-POEM according to the Chicago classification. Twenty-two patients (26.8%) had type I

Table 1 Patient characteristics

Patient characteristics	Data ($n = 82$)
Male, no. (%)	35 (42.7%)
Age, mean (range), years	44.6 (14–84)
Duration of symptoms, mean (range), years	8.7 (1–50)
Chicago classification, no. (%)	
Type I	22 (26.8%)
Type II	39 (47.6%)
Type III	9 (11.0%)
No data	12 (14.6%)
Type of achalasia, *n*	
Nonsigmoid	65 (79.3%)
Sigmoid	17 (20.7%)
Type 1	13 (15.8%)
Type 2	4 (4.9%)
Previous therapy, *n* (%)	
None	42 (51.2%)
Pneumatic dilation	29 (35.4%)
Botox injection	5 (6.1%)
Stent	1 (1.2%)
Heller myotomy	3 (3.7%)
POEM	2 (2.4%)

POEM, peroral endoscopic myotomy.

Table 2 Procedure-related parameters

Parameters	Data
Technical success, *n* (%)	82 (100)
Operation time, min, median (IQR); [range]	20.0 (16–25); [10–45]
Mucosal length, cm	
Total, median (IQR); [range]	9.0 (8–10); [6–13]
Myotomy length, cm	
Total, median (IQR); [range]	8.0 (7–9); [4–11]
Submucosal fibrosis, *n* (%)	5 (6.1)
Hospital stay, d, median (IQR); [range]	6 (5–8); [4–30]
Complications, *n* (%)	10 (12.2)
Mediastinitis	2
Post-O-POEM bleeding	1
Subcutaneous emphysema	1
Pleural effusion	6
Follow-up period, median (IQR); [range] (months)	18.0 (13–22); [6–26]
Treatment success (Eckardt score ≤3), *n* (%)	79 (96.3%)
Recurrence, *n* (%)	3 (3.7%)

IQR, interquartile range.

achalasia, 39 patients (47.6%) had type II achalasia, 9 patients (11.0%) had type III achalasia, and 12 patients (14.6%) had unspecified type because of no data. Thirteen patients (15.8%) were classified as S1 type and 4 patients (4.9%) of S2 type according to the classification of Inoue.[15] Five cases (6.1%) were classified as submucosal fibrosis. O-POEM was performed successfully without technical difficulties in all patients. The mean procedure time for O-POEM was 20.0 minutes (range: 10–45 minutes). The median length of the mucosal and myotomy for O-POEM was 9 cm (range: 6–13 cm) and 8 cm (range: 4–11 cm), respectively. The median hospital stay for O-POEM was 6 days (range: 4–30 days). A timed barium esophagram was observed during follow-up. A follow-up endoscopy performed for each patient revealed healing mucosa in the area of O-POEM. After a median follow-up of 18 months (range: 6–26), the treatment success (Eckhart score ≤3) was achieved in 96.3% of cases. There were 3 patients (3.7%) who were lost to follow-up at 12 months after O-POEM.

Treatment success

Esophageal manometry, upper endoscopy, and interview (Eckardt score, GERD symptoms) data at 3-month after O-POEM were available in 52 (63.4%), 75 (91.5%), and 82 patients (100.0%), respectively. Other patients did not undergo follow-up manometry due to the medical condition of the local healthcare settings, and some patients refused to undergo manometry examinations, etc. A significant reduction in symptoms was achieved preoperative Eckardt score (median, range, preoperative, 7.4 (4–12) vs. postoperative, 1.8 (0–5), $P < 0.0001$), with a significant reduction in LES pressure (median, range, preoperative, 29.4 mmHg (19.2–42.8 mmHg) vs. postoperative, 13.2 mmHg (10.2–17.2 mmHg), $P < 0.0001$). There were only 3 cases (3.7%) in which experienced recurrence during the follow-up and they had achalasia type III (Table 2 and Table 3).

Adverse events

Adverse events were observed in 10 patients (12.2%) and listed in detail in Table 2. Minor and severe AEs had a frequency of 8.5% (7 cases) and 3.7% (3 cases), respectively. Among the 3 severe AEs, 1 case of mediastinitis was observed in a 54-year-old man with achalasia type III. Mediastinitis combined with pleural effusion was confirmed by chest CT. An early endoscopy demonstrated esophageal ulcer of the O-POEM area with severe surrounding mucosal edema. In addition, closed thoracic drainage and anti-inflammatory treatment was performed and the patient was discharged 30 days later. Another case of mediastinitis was observed in a 27-year-old man with achalasia type II. An early chest CT demonstrated mediastinitis combined with pleural effusion. Thoracic drainage and antiinfective therapy were performed and the patient was discharged 15 days later. One case of severe AEs was post-O-POEM bleeding, which occurred in a 58-year-old man with achalasia type II. In the patient with a history of melena and gastrointestinal bleeding was confirmed by a fecal occult blood test. Laboratory investigations revealed a significant decrease in hemoglobin level within 48 hours (before POEM, 15.0 g/dL; after POEM, 10.4 g/dL). His upper GI endoscopy showed ulcers with overlying

Table 3 Treatment outcomes: Eckardt score, lower esophageal sphincter pressure

Variable	Before O-POEM	2 month after O-POEM	*P* value
Eckardt score, median (range)	7.4 (4–12)	1.8 (0–5)	<0.0001
LES pressure, mmHg, median (range)	29.4 (19.2–42.8)	13.2 (10.2–17.2)	<0.0001
GERD symptoms only, *n* (%)	–	6 (7.3%)	–
Endoscopic findings of reflux esophagitis only, *n* (%)	–	3 (3.7%)	–
Grade A	–	2	–
Grade B	–	1	–
Grade C	–	0	–
Grade D	–	0	–
GERD symptoms and esophagitis on EGD, *n* Overall, *n* (%)	–	4 (4.9%) 13 (15.9%)	–

LES, lower esophageal sphincter; GERD, gastroesophageal reflux disease.

clot involving the O-POEM area, which was managed by endoscopic vessel coagulation and clips. Then therapy with PPI and tranexamic acid was performed. Hemostasis was achieved in this patient without blood transfusion.

The overall rate of minor AEs related to O-POEM was 7/82(8.5%), consisting of 6(7.3%) pleural effusion, and 1 (1.2%) cutaneous emphysema. The 6 patients of pleural effusion and cutaneous emphysema were diagnosed on the basis of CT findings. However, there is no need for drainage or decompression and they recovered from symptoms with conservative medical management. Twenty patients (24.4%) developed signs of fever or temperature >38°C within 24 to 48 h after O-POEM. No O-POEMs required surgical intervention. There were no deaths.

When patients were analyzed in different subgroups according to previous therapy, 6 patients (6/42; 14.3%) with the history of previous therapy developed adverse events while 4 patients (4/40; 10.0%) without the history of previous therapy experienced adverse events ($P = 0.738$). Only 1 patient (1/5; 20%) with submucosal fibrosis developed adverse events in contrast to 9 patients (9/77; 11.7%) without submucosal fibrosis ($P = 0.487$). The comparison of incidence rate of adverse events between the sigmoid esophagus patients and nonsigmoid groups did not show any significant differences 8 patients (8/65; 12.3%) and 2 patients (2/17; 11.8%), respectively; ($P = 1.000$). Therefore, neither the previous therapy, submucosal fibrosis nor sigmoid esophagus, had any influence on the incidence rate of adverse events between different subgroups (Table 4).

Three of 82 patients (3.7%) only had endoscopic findings of reflux esophagitis (2 cases of Los Angeles classification A and 1 case of Los Angeles classification B). Six of 82 patients (7.3%) complained of GERD symptoms such as heartburn or regurgitation with negative endoscopic findings. Besides, other 4 patients (4.9%) had both esophagitis on EGD and GERD symptoms. Thus, the overall clinical reflux complication rate was 15.9% (13/82) in the current study (Table 3).

Table 4 Fisher's exact test was used to compare the incidence rate of adverse events between different subgroups

Variables	Patients experienced AEs	Patients without AEs	*P* value
Previous therapy, *n*			0.738
Nonprevious therapy	6	36	
Previous therapy	4	36	
Submucosal fibrosis, *n*			0.487
Nonsubmucosal fibrosis	9	68	
Submucosal fibrosis	1	4	
Sigmoid esophagus, *n*			1.000
Nonsigmoid	8	57	
Sigmoid	2	15	

AEs, adverse events.

DISCUSSION

In fact, Ortega performed the first successful direct peroral endoscopic myotomy without a submucosal tunnel for achalasia in 1980.[16] However, in that study, endoscopic myotomy was performed using a modified needle knife and an old type of electrosurgical unit to dissect the muscle layer directly through the mucosal layer. Without a high-definition gastroscope, a transparent cap, a submucosal injection, or patients under general anesthesia with endotracheal intubation, it is hard to achieve visual control of the movement of the needle tip to dissect the mucosa, submucosal fibers, and circular layer step by step. Because of the estimated high risk of esophageal perforation and leak, endoscopic myotomy was not developed further until the development of POEM.[17] However, studies of traditional POEM have shown that creation of the tunnel during traditional POEM is technically demanding and it should be taken into account that mucosal injuries are one of the most common adverse events.[18] On the other hand, with the development of endoscopic techniques, we have found O-POEM to be a feasible and safe treatment option for achalasia with relatively few adverse events.[6-8]

In our analysis, it shows that O-POEM appears to be a highly effective treatment for achalasia, resulting

in a short-term success rate higher than 95%, and significantly improved symptom scores and manometry outcomes, which seems comparable with other studies.[2] The postoperative evaluation demonstrated a decrease in Eckardt score and improvement of symptoms, with only 3 cases of recurrence. Gastroscopy and radiographic follow-up showed a wider cardia and easy passage of barium into the stomach. In our study, the overall clinical reflux complication rate of O-POEM was 15.9%, which was comparable to traditional POEM.[19] The overall AEs related to O-POEM were noticed in 12.2% of patients. Severe AEs only had a frequency of 3.7%. Because we considered the CT incidental findings of pleural effusion, and subcutaneous emphysema without relevant clinical symptoms as minor complications in our study. Therefore, as compared with traditional POEM, minor and severe AEs are somewhat higher after O-POEM.[20] However, most O-POEM-related AEs are usually self-limiting and do not require surgery. The most common AE was pleural effusion, which was diagnosed on the basis of the CT findings and occurred in six patients. Only two patients with mediastinitis combined with pleural effusion were treated with thoracic drainage. Delayed bleeding was encountered in one patient. Endoscopic management includes coagulation and clips were performed and hemostasis was achieved in this patient without blood transfusion. All the other patients responded to conservative management and no further therapy was required.

Compared with conventional POEM procedures with creation of submucosal tunnel, the major advantage of O-POEM is simple and quick. In this case series, the mean O-POEM procedure time was 20.0 minutes, which was considerably lower than that of traditional POEM.[21] Moreover, this O-POEM method without a submucosal tunnel will possibly decrease the volume of gas within the working field. Therefore, O-POEM may reduce the risk of insufflation-related adverse events. In our study, the overall rate of cutaneous emphysema was 1.2%, which was considerably lower than that of traditional POEM.[11] However, it needs to be mentioned and discussed. Sometimes it was difficult to define a clear separation of circular and longitudinal muscular layers, and the longitudinal muscle is too thin to be protected and sometimes it even splayed itself. It can possibly lead to potential infection-related AEs associated with O-POEM. Therefore, prophylactic antibiotics are routinely administered before POEM and continued for a few days to prevent potential infection.

On the other hand, the current published literature suggests that previous therapies can lead to submucosal fibrosis and it is difficult to extend endoscopic dissection and separation of tissues because of submucosal fibrosis.[13] In addition, due to the fibrosis, another concern is related complications, such as mucosal injury and gas-related complications.[4,5] Although our study shows that neither the previous therapy, submucosal fibrosis nor sigmoid esophagus, had any influence on the incidence rate of adverse events between different subgroups. The treatment of achalasia patients with sigmoid-shaped esophagus or submucosal fibrosis has been controversial. Our preliminary results show that O-POEM can become one of the options for the treatment of achalasia, especially in patients with complex achalasia with severe submucosal fibrosis. By using O-POEM, it is easy to extend dissection and separation of tissue planes into the proximal esophagus, making such an approach especially favorable for treatment of complex achalasia with severe submucosal fibrosis, such as failed Heller myotomy or sigmoid-shaped esophagus. In this study, we tried O-POEM in five patients with severe submucosal fibrosis. It showed a moderate efficacy and the results were comparable with previous studies.[4]

There are some limitations of this study. First, limitations such as our small number of patients should be considered. Second, a total of 52 patients (63.4%) underwent HRM at 3 months postoperatively. Due to the local medical condition and other reasons, the remaining patients did not undergo follow-up manometry. In addition, only short-term follow-up information was obtained to evaluate for efficacy alone. Long-term outcomes of O-POEM need to be analyzed.

Our preliminary results show that O-POEM is a feasible and effective treatment of achalasia. We think that it may not be necessary to perform O-POEM for all achalasia patients, but it may be indicated for patients with severe submucosal fibrosis, where the submucosal tunnel will be highly technically demanding.

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SUPPORTING INFORMATION

Additional Supporting Information may be found in the online version of this article at the publisher's website: O-POEM.mov

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