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Pre-treatment Eckardt score is a simple factor for predicting one-year peroral endoscopic myotomy failure in patients with achalasia

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Abstract

Background Peroral endoscopic myotomy (POEM) is a novel treatment for achalasia with excellent outcomes. But the predictor for treatment failure is not well defined. This study was aimed to prospectively investigate the factors for predicting failed POEM.

Methods From June 2011 to May 2015, a total of 115 achalasia patients treated by POEM were included for the retrospective cohort study from Nanfang Hospital and the First People's Hospital of Yunnan Province. Patients were followed up with Eckardt score, high-resolution manometry and endoscope. POEM failure was defined as primary failure (Eckardt score failed to decrease to 3 or below) and recurrences (decrease of Eckardt score to 3 or below, then rise to more than 3) during one-year follow-up. Univariate and multivariate Cox regression analyses were performed to assess the predictive factor. For the associated factor, receiver operating characteristic curve (ROC) was utilized to determine the cutoff value of the predicting factor.

Results The failure rate of POEM after 1 year was 7.0% (8/115), including 5 primary failure cases and 3 recurrences. Multivariate analysis showed higher pre-treatment Eckardt score was the single independent factor associated with POEM failure [9.5 (6–12) vs. 7 (2–12), odds ratio (OR) 2.24, 95 confidence interval (95% CI) 1.39–3.93, $p = 0.001$]. The cutoff value (Eckardt score $\geq$9) had 87.5 sensitivity (95% CI 47.3–99.7%) and 73.8% specificity (95% CI 64.4–81.9%) for predicting failed POEM.

Conclusions Pre-treatment Eckardt score could be a predictive factor for failed POEM. Eckardt score $\geq$9 was associated with high sensitivity and specificity for predicting POEM failure.

Keywords Achalasia · Peroral endoscopic myotomy · Eckardt score

Achalasia is a disorder of esophagus classically present with progressive dysphagia to solids and liquids, chest pain, regurgitation, and sometimes weight loss, and it occurs rarely, with an estimated incidence of 1 in 100,000 per year [1, 2]. In spite of an increasing understanding of its pathophysiology, the etiology of achalasia still remains unknown [3]. Current treatments like endoscopic dilation or Heller myotomy focus on disruption of the LES, with different advantages and drawbacks [4, 5].

POEM has been a novel alternative treatment option for esophageal achalasia. This technique enables endoscopists to complete a myotomy of esophageal circular muscle fibers across the esophagogastric junction (EGJ) and into the stomach through a submucosal tunnel. Pasricha et al. [6] initially described the feasibility of this technique in pig

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model in 2007, and then Inoue et al. [7] firstly reported their experience of performing this treatment method in human beings successfully. Since then, more than 3000 POEM procedures have been performed worldwide with promising clinical outcomes [8]. As POEM continues to gain popularity, many studies focus on its long-term efficacy and safety.

While various studies shed light on the promising efficacies of POEM on achalasia, factors influencing clinical outcome have been rarely investigated. Werner et al. [9] reported older age and endoscopic reflux signs were predictors of successful outcome in a two-year follow-up. In this study, we aimed to assess possible factors predicting POEM treatment outcome during one-year follow-up.

Patients/materials and methods

Inclusion of achalasia patients

This is a retrospective analysis of a prospectively collected POEM database for the treatment of achalasia in two tertiary medical centers. The database was confidential and secured from any personnel unrelated to the study. Data in Nanfang Hospital were from June 2011 to May 2015, and data in First People's Hospital of Yunnan Province were from March 2013 to January 2015.

Achalasia was diagnosed based on clinical symptoms, barium esophagram, upper endoscopy and high-resolution manometry. Achalasia was further categorized according to Chicago classification [10]. Sigmoid achalasia was diagnosed as dilated and tortuous esophagus seen at barium esophagram. Exclusion criteria for this study were patients with coagulopathy, pregnancy, American Society of Anesthesiologists (ASA) stage $\geq$4, and patients who withdraw the informed consent. The study protocol was approved by the institutional review board of Nanfang Hospital (NFEC-201211-K2) and adhered to the Declaration of Helsinki. Informed consent was obtained from all participating patients. The database was part of a large POEM study registered at ClinicalTrials.gov (Registration No. NCT01768091).

POEM procedures, follow-up protocol and outcome definitions

Two experienced endoscopists (Dr Wei Gong from Nanfang Hospital and Dr Yanmin Chen from the First People's Hospital of Yunnan Province) performed standard POEM procedure as described by Inoue et al. [7] under general anesthesia and CO_2 insufflation. The submucosal entry was made 6–10 cm above the esophagogastric junction (EGJ), in the 1–2 o'clock position on the anterior esophagus to aim for a straight tunnel ending at the lesser curvature at the cardia. A tunnel was created into the proximal stomach by dissection of the submucosal layer. Myotomy was initiated 3 cm below the entry and was extended 2–3 cm into the proximal stomach. The circular muscle layer was dissected, and the longitudinal muscle layer was preserved. The entry was closed by metal clips. After the procedure, patients were kept non per os (NPO) and received antibiotics, proton pump inhibitors (PPIs) and intravenous fluids for 3 days. Then, they began to take liquid food and gradually changed to solid food. They were discharged with PPIs for 4 weeks.

The first follow-up was scheduled at 1 month by clinical interview using Eckardt score. The second follow-up was made at 3 months using endoscopy and high-resolution manometry. The third and fourth follow-up was made at 6 and 12 months using Eckardt score.

Post-treatment Eckardt score that failed to decrease to 3 or below was defined as primary failure (Eckardt score >3). Recurrences were defined as initial decrease of Eckardt score to 3 or below and then rise to more than 3 during the follow-up period. Both primary failure and recurrence were POEM failures [9]. Early experience was defined as 20 or less POEM cases ($\leq$20) and more than 20 cases (>20) was defined as late experience [11].

Statistics

Continuous data were described as means with standard deviations or medians with ranges. Categorical data were described using counts with percentages. Decrease in Eckardt score items was compared by Mann–Whitney U test. POEM failure in the follow-up period was reported by Kaplan–Meier curves and compared by log-rank test. Univariate followed by forward multivariate Cox regression was used to find out the possible factors associated with POEM failure and to exclude confounding factors. For the associated factor, receiver operating characteristic curve (ROC) and Youden index were utilized to determine the cutoff value of the predicting factor. Two-sided p value <0.05 was considered statistically significant. Standard statistics software was used (SPSS version 23.0, IBM Co., NY, USA).

Results

Patient characteristics

A total of 123 achalasia patients were consecutively enrolled in the database. Apart from 8 patients lost to follow-up, a total of 115 patients were included for analysis (Table 1, 90 from Nanfang Hospital and 25 from First Hospital of Yunnan Province). The mean age was 38.4 $\pm$ 11.6 years. The male to female ratio was 1.3:1.

Table 1 Baseline clinical and procedural characteristics of included patients

Age, mean ± SD, years	38.4 ± 11.6
Gender, male/ female	65:50
Symptom duration, median (range), months	48.0 (1–252)
Pre-treatment Eckardt score, median (range)	7.0 (2–12)
Previous interventions, *n (%)*	
Pneumatic dilation	22 (19.1)
Botox dilation	2 (1.7)
Heller myotomy	3 (2.4)
Pre-treatment LES resting pressure, mean ± SD, mmHg	35.4 ± 14.9
Pre-treatment LES relaxation pressure, mean ± SD, mmHg	28.2 ± 11.8
Chicago classification, *n(%)*	
Type I	16 (13.9)
Type II	81 (70.4)
Type III	18 (15.7)
Pre-treatment maximal esophageal diameter, mean ± SD, cm	43.3 ± 15.3
Sigmoid Esophagus, *n (%)*	14 (12.2)
Myotomy length in POEM, mean ± SD, cm	9.0 ± 3.2
Adverse events, *n (%)*	
Cervical emphysema	10 (8.7)
Pneumothorax	2 (1.7)
Bleeding	2 (1.7)

LES Lower esophageal sphincter, *SD* standard deviation

Twenty-seven patients received previous treatments (22 pneumatic dilation, 2 botox injection and 3 Heller myotomy). There were 16 type I, 81 type II and 18 type III achalasia patients. POEM was performed successfully in all patients. Ten patients had cervical emphysema, 2 had pneumothorax, and 2 had bleeding during the procedure, which was managed successfully.

One-year clinical outcome after POEM

At the end of one-year follow-up, the POEM procedure was successful in 107 patients (Fig. 1A, 93.0%). Five patients had primary failure after one-month follow-up, and 3 patients had recurrence following an initial improvement after 6 months, accounting for a total failure rate of 7.0% (Table 2). In the sub-item of Eckardt score in the failed POEM group, the dysphagia score decreased significantly less than the successful POEM group (Fig. 1B, mean reduction: -0.7 ± 0.8 vs. -2.0 ± 0.8, $p < 0.001$). The reduction of chest pain, regurgitation and weight loss score were insignificant between the two groups.

COX regression analysis of factors predicting failed POEM

In univariate Cox regression analysis, pre-treatment Eckardt score was found to be the significant factor associated

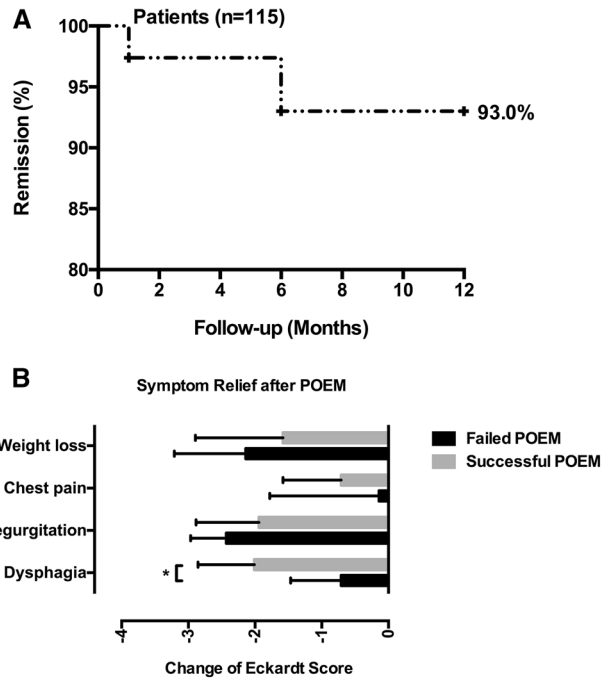

Fig. 1 **A** Overall remission rate of POEM after one-year follow-up, with a total failure rate of 7.0%. **B** Differences in symptom improvement of Eckardt score sub-items. Compared with weight loss, regurgitation and chest pain, failed POEM had less satisfactory relief in dysphagia score. * Level of significance $p < 0.001$. *POEM*, peroral endoscopic myotomy

Table 2 Eckardt score change in patients with POEM failure after one-year follow-up

Patient no.	Gender	Age, years	Eckardt score			
			Baseline	1 month	6 month	12 month
1	M	48	12	2	4	4
2	F	41	9	1	4	4
3	F	24	9	2	4	4
4	F	20	10	4	5	4
5	F	48	9	6	5	5
6	F	22	11	5	5	5
7	M	44	12	5	4	5
8	M	41	6	5	8	7

with POEM failure (Table 3, OR 1.89, 95% CI 1.30–2.75, $p = 0.001$). Pre-treatment maximal esophageal diameter was insignificantly associated with treatment success (OR 0.93, 95% CI 0.85–1.01, $p = 0.074$). Age, gender, previous treatment, different endoscopists, POEM learning curve, sigmoid esophagus, Chicago classification, pre- and post-treatment LES pressure, myotomy length as well as post-treatment reflux esophagitis were not found to be significantly associated with POEM failure. In multivariate Cox regression model, pre-treatment Eckardt score was the single independent factor for predicting failed POEM (OR 2.24, 95% CI 1.39–3.93, $p = 0.001$). In subgroup Cox regression model (Supplementary Table 1, univariate followed by forward multivariate analysis), pre-treatment Eckardt score was also the independent factor for predicting primary failure (OR 2.67, 95% CI 1.30–5.48, $p = 0.008$) as well as recurrence (OR 2.85, 95% CI 1.17–6.97, $p = 0.021$). It should be noted that the number of failed POEM in subgroup analysis is small.

ROC analysis of pre-treatment Eckardt score in predicting failed POEM

The area under the ROC curve for pre-treatment Eckardt score was 0.83 (Fig. 2, 95% CI 0.75–0.90, $p < 0.001$). The Youden index was 0.61, and suggested cutoff value was >8 (≥9). Pre-treatment Eckardt score ≥9 was associated with 87.5% sensitivity (95% CI 47.3–99.7%), 73.8% specificity (95% CI 64.4–81.9%), 3.3 positive likelihood ratio (95% CI 2.2–5.0) and 0.2 negative likelihood ratio (95% CI 0–1.1) for predicting POEM failure.

Kaplan–Meier analysis of factors predicting failed POEM

For patients whose pre-treatment Eckardt score was ≥9, significantly less patients were in remission after one-year follow-up than patients whose pre-treatment Eckardt score was <9 [Fig. 3, 26/33 (78.8%) vs. 81/82 (98.8%), log-rank test $p < 0.001$]. The mean duration of remission in Eckardt score ≥9 group was shorter than that in Eckardt score <9 group (10.4 (95% CI 9.3–11.5) months vs. 11.9 (95% CI 11.6–12.1) months].

Discussion

POEM is a promising endoscopic procedure with excellent short-term and long-term efficacy for achalasia. Inoue et al. [7] first reported excellent short-term outcome without additional treatment in all achalasia patients after a mean 5-month follow-up. In Swanstrom LL's study, dysphagia relief persisted for all patients after a mean follow-up of 11.4 months [12]. Additionally, a total success rate of 78.5% after a minimum follow-up of 2 years was reported by Yuki et al. [9]. Furthermore, Talukdar et al. [13] conducted a meta-analysis comparing the efficacy of POEM and surgical myotomy, which suggested similar clinical outcomes as reduction in Eckardt score and adverse events with shorter operative time for POEM.

Traditionally, surgical myotomy remains the most efficacious for treatment of achalasia [14]. There are a few studies addressing the factors associated with treatment success. Khajanchee et al. [15] followed 121 consecutive achalasia patients after laparoscopic Heller myotomy with Toupet fundoplication for 9 months. Severe preoperative dysphagia was suggested to be associated with poorer outcome (OR 11.31, 95% CI 1.45–88.22, $p = 0.01$). Similarly, Gaissert et al. [16] conducted a longer follow-up in 64 patients after surgical myotomy. The mean follow-up duration was 153 months and more than half of the patients reported at least mild dysphagia. Multivariate analysis found that recurrence of dysphagia within 6 months after surgery was the only predictor for late failure while sigmoid esophagus, fundoplication and reflux symptoms were not. Surprisingly, in Kilic A's long-term outcome study for 6.4 years, failed surgical myotomy had lower preoperative LES pressure (13.8 vs. 33.0 mmHg, $p = 0.035$), which was the only predictive factor for treatment failure other than prior therapy, symptom duration and sigmoid esophagus [17].

Table 3 Univariate Cox regression analysis of factors predicting failed POEM

Variables	Successful POEM (n = 107)	Failed POEM (n = 8)	Failed POEM		
			OR	95% CI	*p*
Gender, *n*					
Female	45	5	1		
Male	62	3	0.23	0.53–9.33	0.272
Age, mean ± SD, years	38.5 ± 11.6	36.0 ± 11.9	0.98	0.93–1.04	0.567
Symptom duration, median (range), months	60 (1–252)	24 (12–90)	0.98	0.96–1.01	0.133
Previous treatment, *n*					
No	84	7	1		
Yes	23	1	1.90	0.23–15.44	0.549
Endoscopists, *n*					
Dr W from NFH	83	7	1		
Dr Y from FPHYNP	24	1	2.00	0.25–16.26	0.516
POEM experience, *n*					
Early	37	3	1		
Late	70	5	0.92	0.22–3.85	0.909
Pre-treatment Eckardt score, median (range)	7 (2–12)	9.5 (6–12)	1.89	1.30–2.75	0.001*
Chicago classification, *n*					
Type I	15	1	1		
Type II	74	7	0.70	0.09–5.69	0.739
Type III	18	0	0.01	0–1.36 × 10^5	0.601
Sigmoid esophagus, *n*					
No	93	8	1		
Yes	14	0	24.62	0–2.37 × 10^5	0.494
Pre-treatment maximal esophageal diameter, mean ± SD, mm	46.0 ± 14.6	35.6 ± 5.9	0.93	0.85–1.01	0.074
Pre-treatment LES resting pressure, mean ± SD, mmHg	36.8 ± 14.9	36.1 ± 10.4	1.00	0.95–1.06	0.909
Pre-treatment LES relaxation pressure, mean ± SD, mmHg	29.5 ± 11.6	28.1 ± 11.9	0.99	0.93–1.06	0.775
Post-treatment LES resting pressure, mean ± SD, mmHg	12.5 ± 6.1	10.4 ± 6.3	0.95	0.84–1.09	0.467
Post-treatment LES relaxation pressure, mean ± SD, mmHg	8.8 ± 4.0	8.3 ± 5.5	1.02	0.85–1.22	0.849
Myotomy length, mean ± SD, cm	8.9 ± 3.0	11.2 ± 5.2	1.08	0.91–1.28	0.368
Post-treatment reflux esophagitis, *n*					
No	93	5	1		
Yes	14	3	3.69	0.88–15.45	0.074

POEM Peroral endoscopic myotomy; *LES* lower esophageal sphincter; *SD* standard deviation; *NFH* Nanfang Hospital; *FPHYNP* First People's Hospital of Yunnan Province

* $p < 0.05$

Studies addressing factors associated with POEM failure or success are rare. Age and post-treatment reflux esophagitis were first reported to be independent predictors of treatment success [9]. While in this study, pre-treatment Eckardt score was found to be the single factor associated with both primary POEM failure and recurrence in achalasia patients. Eckardt score ≥9 was associated with high sensitivity and specificity in predicting POEM failure. Eckardt score could be a predictive factor for POEM failure after one-year follow-up.

It is interesting to find that higher pre-treatment Eckardt score is associated with higher POEM failure. The Eckardt score was first introduced by Eckardt et al. [18] as the measurement of outcome in achalasia patients treated by pneumatic dilation. It has four symptom items including weight loss, dysphagia, chest pain and regurgitation. It is a simple and useful system for evaluation of pneumatic dilation and Heller myotomy historically [19]. As the emerging POEM, it is widely used for evaluating clinical response of POEM, in which post-treatment Eckardt score

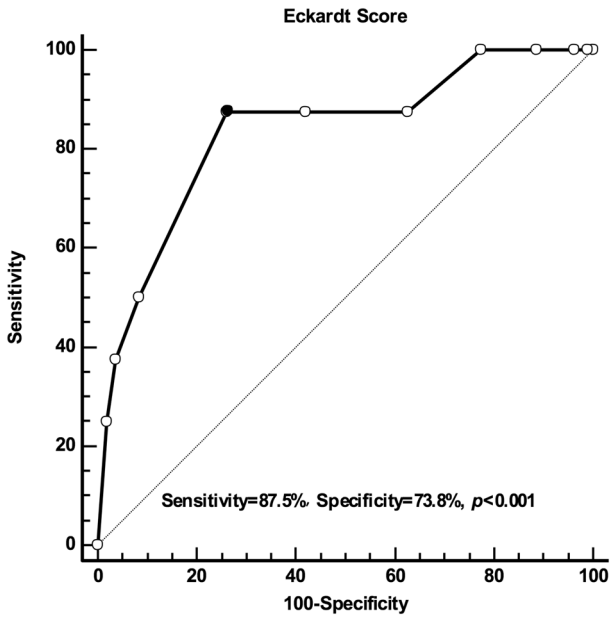

Fig. 2 Receiver operating characteristic curve for pre-treatment Eckardt score in predicting POEM failure. Suggested criterion was Eckardt score ≥9. *POEM*, peroral endoscopic myotomy

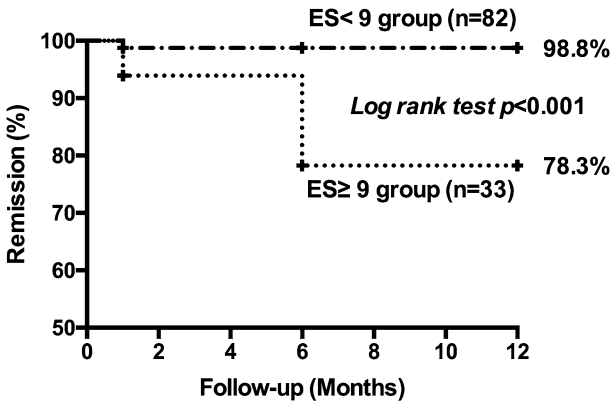

Fig. 3 Kaplan Meier graph of factors predicting POEM failure. Group of pre-treatment Eckardt score ≥9 had less remission rate than group of pre-treatment Eckardt score <9. *POEM*, peroral endoscopic myotomy. *ES*, Eckardt score

≤3 is considered treatment success [9, 20]. Further analysis suggested that only dysphagia was relieved significantly less in failed POEM group, regardless of comparable pre- or post-treatment LES pressures. This finding was similar with outcome studies on surgical myotomy that dysphagia was the predictive factor for treatment failure [15, 16]. In addition, Youssef et al. [21] found that relief of dysphagia after Heller myotomy improves vitality, mental health and general health. The unsatisfactory improvement of dysphagia after POEM might also influence long-term quality of life. Higher pre-treatment Eckardt score may predict this poor prognosis.

It was assumed that the endoscopist factors like learning curve, different endoscopists and myotomy length might influence the outcome. Kuriaan et al. [22] found that mastery of POEM measured by the length of procedure and technical errors was after 20 cases for experienced endoscopists. Using this cutoff value as learning curve analysis, there was no significant outcome difference between early and late POEM experience in the included achalasia patients. Also for different experienced endoscopists, the POEM was "technically successful" and the clinical outcome was also similar in univariate Cox regression. The myotomy length was not associated with treatment failure. Our unpublished study suggested that shorter myotomy (<7 cm) had similar efficacy as longer myotomy (>7 cm). Teitelbaum et al. [23] also suggested that extended proximal esophageal myotomy in POEM had no further effect on gastroesophageal junction distensibility and longer esophageal myotomy was unnecessary.

LES tone was not correlated with POEM failure in this study, and it is unexplainable that dysphagia improvement was not correlated with manometric change after POEM. This finding is in accordance with Khajanchee YS' study that dysphagia instead of LES pressure was with negative prognosis for surgical myotomy [15]. In previous studies on manometric findings to predict treatment success for pneumatic dilation, no manometric predictors were found [24, 25]. Werner et al. [9] reported higher LES resting pressure in failed POEM group. But in multivariate study, it was not the predictor. On the contrary, Kilic A's long-term study showed that lower LES pressure was associated with treatment failure in surgical myotomy [17]. Whether LES tone has influence on POEM failure needs to be clarified in further studies.

Timed barium esophagram was not performed in our study. It has been suggested by Moon JT's study that Eckardt score improvement after pneumatic dilation was not correlated with improvement in radiologic esophageal transit [26]. The result is debatable. Vaezi et al. [27] reported that timed barium esophagram was a better predictor of long-term success after pneumatic dilation in achalasia than symptom assessment. As for POEM, Sternbach et al. [28] suggested that timed esophagram for achalasia did not predict long-term outcomes. Owing to paucity of relative studies, more future investigations are warranted.

It was traditionally believed that type III achalasia had the lowest treatment success [29]. However, Heller myotomy was still suggested as the golden standard therapy [30]. Interestingly, we found that type III achalasia seemed to have better clinical response to POEM with 100% success rate than type I and type II, although the p value was insignificant [18/18 (100%) vs. 74/81 (91.4%) vs. 15/16 (93.8%), log-rank test $p = 0.426$]. POEM has been

recently reported on treating type III achalasia and showed promising clinical efficacy, even comparative with surgical myotomy [30, 31]. Type III achalasia might be a predictor for POEM, but further studies are needed.

Severe esophageal dilation was reported to have a significant negative effect on treatment outcome [32]. Surprisingly, our study showed that narrower esophageal diameter was found to be insignificantly associated with treatment failure in univariate Cox regression. Possible reasons might be that the majority of Chicago classification in our failure group was type II (type I/II/III: 1:7:0). However, there were more type I achalasia patients in success group (type I/II/III: 15:74:18). The esophageal diameter in type I achalasia was much more wider than types II and III achalasia (type I/II/III: 59.8 ± 15.7 mm vs. 43.9 ± 13.8 mm vs. 37.0 ± 9.3 mm, $p < 0.001$) owing to decompensation [32]. In addition, the number of patients was still few in failure group and the trend might be the result of type II error in statistics. In multivariate Cox regression, no relation was found with treatment failure (OR 0.93, 95% CI 0.84–1.02, $p = 0.126$). Furthermore, sigmoid esophagus is the advanced stage of achalasia, in which the esophagus is remarkably dilated and tortuous [33]. Endoscopic treatments such as balloon dilation and botox injection are less effective [34]. Both surgical myotomy and POEM have been demonstrated to be successful for such condition. Hu et al. [35] tried POEM on 32 patients with sigmoid esophagus. The treatment success was 96.8% after a mean follow-up of 30 months. In addition, sigmoid esophagus was not found to be associated with treatment failure in surgical myotomy [16]. Neither was found to be predicting POEM failure in our study. POEM might be an alternative treatment for such an advanced disease.

This study has limitations. Firstly, there might be a problem using the widely accepted definition of treatment success as post-treatment Eckardt score ≤3. It would possibly seem to be "successful" in four of our included patients whose pre-treatment Eckardt score was ≤3 (pre-treatment Eckardt score: 2, 3, 3, 3 [mainly dysphagia score]; post-treatment Eckardt score: 0, 0, 1, 0, respectively). Moderate to severe dysphagia was successfully relieved in those four patients. Excluding those four patients, pre-treatment score was still the single predictive factor for POEM failure in multivariate Cox regression (OR 2.39, 95% CI 1.42–4.01, $p = 0.001$). However, Inoue et al. [36] newly defined POEM success as a reduction of more than 4 points in his recent series study of 500 achalasia patients. It was also impossible for the reduction of more than 4 points in patients whose pre-treatment Eckardt score was ≤3. So in future outcome studies, special cautions should be taken in patients whose pre-treatment Eckardt score was ≤3. Secondly, because achalasia is a rare disease, the number of patients undergone POEM was limited, though we collected data from two medical centers. In analyzing the association between Chicago classification and POEM failure, the number of type I and type III patients in failed POEM groups was very few and type II error could possibly exist in such small sample size. Besides, in analyzing pre-treatment esophageal diameter and treatment failure, type II error might also exist because of lacking type I and type III patients in failure group. Thirdly, the follow-up time was 1 year in our study, and the result could not be possibly generalized to years beyond 12 months. Further studies conducted in multiple centers with larger sample size and longer follow-up time are warranted to clearly define other possible predictors for POEM failure.

In conclusion, pre-treatment Eckardt score could be a simple factor for predicting both primary failure and recurrence in achalasia patients 1 year after POEM. Eckardt score ≥9 was associated with high sensitivity and specificity for predicting POEM failure.

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Compliance with ethical standards

Disclosures Yutang Ren, Xiaowei Tang, Yanmin Chen, Fengping Chen, Yingying Zou, Zhiliang Deng, Jianuan Wu, Yan Li, Silin Huang, Bo Jiang and Wei Gong declared no conflict of interests.

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