


REVIEW

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Peroral Endoscopic Myotomy (POEM) for the treatment of achalasia in an Egyptian cohort

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Abstract

Background and study aims Peroral endoscopic myotomy (POEM) has been regarded as a novel and minimally invasive therapy for the treatment of achalasia. Data from the Middle East and North Africa (MENA) region and Arabic countries are scarce, and this study represents the first study from this area. The aim of this study was to assess the efficacy and safety of POEM in an Egyptian cohort.

Patients and methods This is a prospective study that included 34 Egyptian patients who underwent POEM for achalasia.

Results This study included 19 (55.9%) males with a median age of 33.5 years (range: 11–75 years). 16 (47.1%) patients had previous pneumatic balloon dilation, and 1 (2.9%) patient had previous surgical myotomy. The median Eckardt score pre-POEM was 9 (range: 4–12). The median integrated relaxation pressure for 4 s (IRP4s) was 25.6 mmHg (range: 11.5–49.4 mmHg). High-resolution manometry showed that 12 patients had type I achalasia (35.2%), 18 patients had type II achalasia (52.9%), and 4 patients had type III achalasia (11.7%). The median procedure time was 120 min (range: 75–260 min). Technical success was achieved in all patients (100%), and clinical success was achieved in 33/34 patients (97.1%). There was no significant difference in success rates among different types of achalasia (p 0.208). There was a significant reduction in the Eckardt score ($P < 0.0001$) and IRP4s values pre- and post-POEM ($P < 0.0001$). There was also a significant increase in the body mass index of the patients (P 0.006) during a median follow-up of 10 months (range: 6–24 months).

Conclusions POEM is a safe, effective, and feasible treatment option for achalasia in an Egyptian cohort. POEM is becoming an attractive option and is gaining patient satisfaction.

Keywords POEM (peroral endoscopic myotomy), Esophageal achalasia, Third space endoscopy, NOTES (natural orifice transluminal endoscopic surgery), Egypt

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Introduction

Achalasia is an esophageal motility disorder characterized by failure of relaxation of the lower esophageal sphincter (LES) with or without an aperistaltic esophageal body [1, 2]. It is a rare disorder with an approximate incidence of 1.6 every 100,000 population [3]. It has an equal gender distribution across all ages, with no racial predilection, and a peak incidence between the ages of 30 and 60 [4]. The exact etiology is unknown; however, it is postulated to be a result of gradual degeneration of the myenteric nerve plexus leading to unopposed LES excitation [5, 6]. There are several treatment modalities for achalasia, including medical treatment (such as calcium channel blockers and nitrates), endoscopic pneumatic balloon dilation (PBD), botulinum toxin injection (BTI) and laparoscopic Heller's myotomy (LHM) [7]. Peroral endoscopic myotomy (POEM) is a newly introduced endoscopic surgery using natural orifice transluminal endoscopic surgery (NOTES) [8]. POEM was first performed in humans by Prof. Haruhiro Inoue in Tokyo, Japan, in 2008, and the data were first published in 2010 [9]. It is now considered one of the first lines of management of achalasia [8]. POEM is an example of third space endoscopy in which a tunnel is created in the gastrointestinal wall and in the submucosa of the esophageal wall to perform a myotomy [10]. The first POEM performed in Egypt by Egyptian physicians was in February 2018 [11]. Data from Arabic countries and the Middle East and North Africa (MENA) region are limited, and this is the first report from Africa. The aim of this study was to analyze the outcomes of POEM and to assess the efficacy and safety of POEM in an Egyptian cohort.

Patients and methods

1. Study Design and Patients: This study is a prospective study that was designed to analyze data from 34 patients who underwent POEM for achalasia at Kasr Alainy Hospital, Cairo University. All types of symptomatic (by Eckardt score > 3—Table 1) manometrically proven primary idiopathic achalasia (type I, II and III) were included. Patients who experienced recurrence after previous balloon dilation or Heller's myotomy were also included. Patients with marked submucosal fibrosis, such as after radiotherapy, radiofrequency ablation, or endoscopic mucosal resection, were excluded. Patients with bleeding disorders and portal hypertension were also excluded. The diagnosis of achalasia was confirmed by endoscopy, barium swallow and high-resolution manometry (HRM). Barium esophagograms showing different types of achalasia are shown in Fig. 2. Written informed

Table 1 Eckardt score to detect severity of Achalasia

Symptoms / Score	0	1	2	3
Dysphagia	None	Occasional	Daily	With every meal
Chest Pain	None	Occasional	Daily	With every meal
Regurgitation	None	Occasional	Daily	With every meal
Weight Loss	None	< 5 kg	5–10 kg	> 10 kg

The minimum score is zero and the maximum is 12

consent was obtained from all patients before the procedure, after thoroughly explaining the potential risks, success rates and long-term outcomes. Patient demographics and related medical history data (age, sex, and body mass index [BMI]), comorbidities, disease duration, Eckardt score, esophageal manometry using HRM to diagnose and classify achalasia according to the Chicago classification version 3 (Figs. 1, 2 and 3), previous therapy (balloon dilation or surgery), procedure details (procedure time, number of clips, technical success, intraoperative adverse events, postoperative adverse events, and duration of hospital stay), clinical success, patient satisfaction and follow-up were evaluated. The severity of adverse events was graded according to the American Society for Gastrointestinal Endoscopy lexicon [12].

2. Sample Size: A minimum sample size of 27 is required to have 90% power to assess the alternative hypothesis—there is a reduction in Eckardt score after treatment of < 3 points. The median pretreatment score was 8.7, the mean posttreatment score was 1.2 and the mean correlation was approximately 0.5 using the paired t test, with a significance level of 0.05. The null hypothesis states that the difference between the post- and pretreatment scores is 0.
3. POEM Settings: All patients signed informed consent before the procedure. They were placed in a supine position under general anesthesia with endotracheal intubation. High definition therapeutic gastroscopy was performed with an auxiliary water channel (GIF-1TH 190 Olympus Corp., Tokyo, Japan). A transparent cap (D-201–11802, Olympus) was fitted to the end of the scope to provide better visualization of the submucosa and to help in dissection. Carbon dioxide (CO₂) insufflation was used throughout the entire procedure. Endo Cut Q (effect 3, duration 3) and forced coagulation (50 W, effect 2) were the electro-surgical settings used (VIO-300D, ERBE, Tubingen, Germany). The solution used for injection was sterile 0.9% saline mixed with 1% methylene blue. A hybrid knife (T-type or I-type, ERBE, Germany) was used. Hybrid knives help in cutting coagulation and injec-

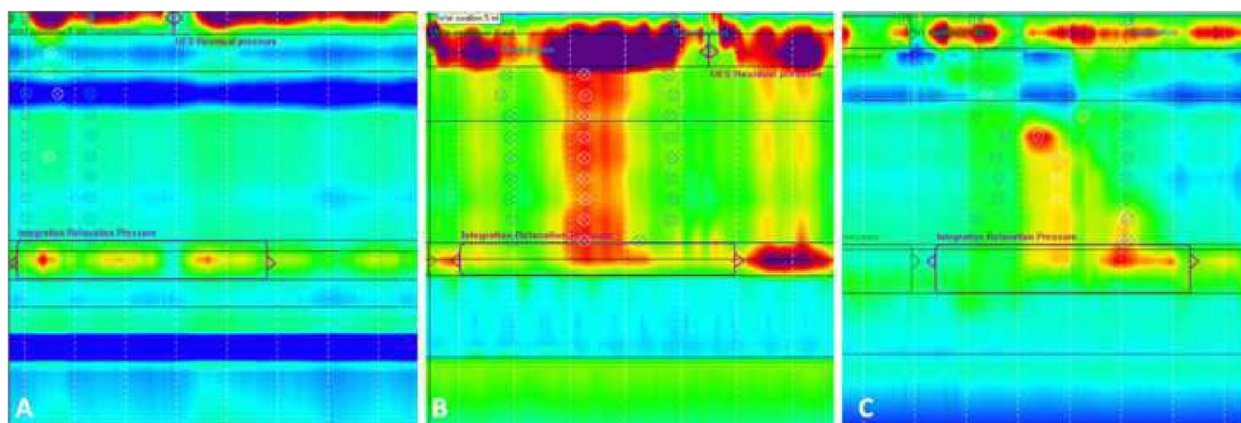


Fig. 1 High-resolution manometry showing different types of achalasia (IRP4s > ULN and 100% failed peristalsis or spasm). **A** Type I: No contractility. **B** Type II: > 20% panesophageal pressurization. **C** Type III: > 20% spasm (DL < 4.5 s). IRP4s: integrated relaxation pressure for 4 s, DL: distal latency

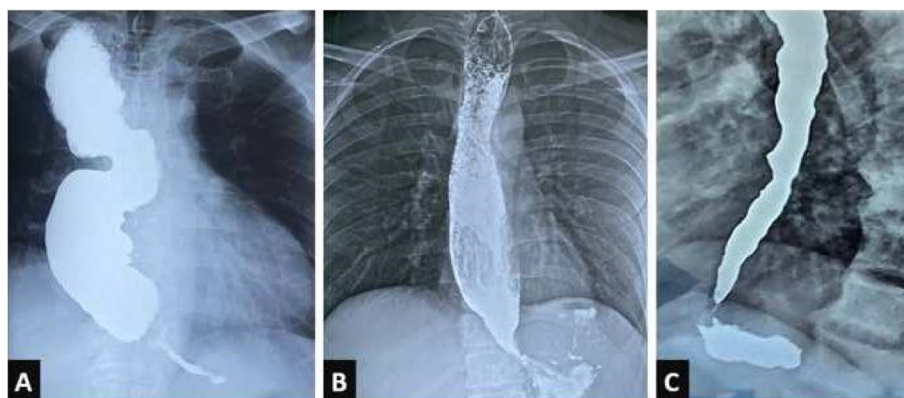


Fig. 2 Barium esophagograms showing different types of achalasia with characteristic smooth tapering of their lower ends. **A** Showing dilated tortuous esophagus (sigmoid type) in a patient with type I achalasia. **B** Barium esophagogram of a patient with type II achalasia. **C** Barium esophagogram of a patient with type III achalasia

tion [13]. Coagulation forceps (FD-410 LR, Olympus Corp., Tokyo, Japan) were used when large blood vessels were encountered or bleeding could not be stopped with knife coagulation.

4. POEM Procedure: The POEM procedure was performed as follows: (Fig. 3) (a) Proper cleaning of the esophagus and identification of the cardia. (b) The spinal cord was identified as a longitudinal bulge located at 6 o'clock with the patient in the supine position. A submucosal cushion was created by submucosal injection of saline with methylene blue at 5 o'clock (just to the right of the spinal cord), usually 10 cm above the cardia. This is called the posterior approach and was performed in all patients. (c) A mucosal incision was made. (d) A submucosal tunnel was created from the mucosal entry until 2 cm distal to the cardia. (e) Myotomy started from proxi-

mal (oral side) to distal (stomach side), 2 cm below the tunnel opening. Selective myotomy (cutting the circular muscle only) was performed first (proximal), followed by full thickness myotomy (cutting both circular and longitudinal muscle fibers) when approaching the cardia (3 cm proximal to the cardia) down to 2 cm distal to the cardia. (f) After hemostasis, the mucosal entry was closed with endoclips. Mucosal injuries encountered were closed with endoclips. Identification of the gastroesophageal junction (GEJ) during POEM is sometimes challenging. Many methods are usually used altogether to distinguish the cardia from the tunnel side. First, the depth of insertion of the scope from the incisors is recorded before tunneling is started. Second, the submucosal space becomes narrowed, increasing the resistance to the scope's passage followed by a sense of release

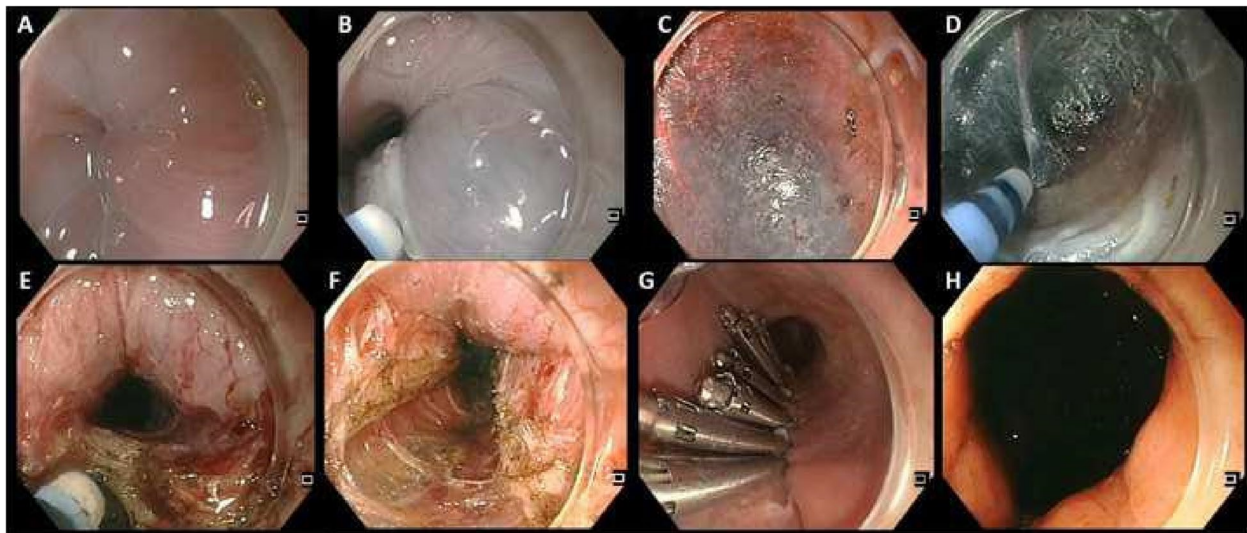


Fig. 3 Peroral endoscopic myotomy (POEM) steps; **a** identification of the spastic cardia; **b** creation of submucosal bleb and tunnel entry 10 cm above the cardia; **c** creation of the tunnel with the mucosa at 12 o'clock and the muscle at 6 o'clock and submucosa in between; **d** coagulation of a blood vessel in the submucosa using a hybrid knife; **e** selective myotomy to the circular muscle using a hybrid knife; **f** full thickness myotomy (cutting both circular and longitudinal muscles) performed at the cardia; **g** closure of the tunnel opening with endoclips; and **h** widening of the cardia after POEM

after the scope passes to the wider gastric submucosal space. Third, the appearance of palisade vessels is characteristic of the cardia. Fourth, the blue bulge identified on the retroflexion of the scope in the fundus of the stomach is called the blue sign.

5. **Perioperative Management** All patients who underwent the POEM procedure were hospitalized. Before the POEM procedure, blood tests, including complete blood counts, liver function tests, renal function tests and coagulation profiles, were performed on all patients. Prophylactic antibiotics were started intravenously before the procedure in the form of metronidazole and a 3rd generation cephalosporin. Antibiotics and proton pump inhibitors (PPIs) were continued after the procedure during their hospital stay. The patients were usually kept nothing by mouth (NPO) for 24–48 h. Analgesics were administered for all patients after the procedure. Early mobilization and elastic stockings were recommended for patients to guard against deep venous thrombosis (DVT). The temperature, chest and abdominal symptoms and signs of patients were carefully monitored during the postoperative period. For persistent increases in temperature above 38°C, antibiotics were automatically upgraded. According to our local protocol, chest X-ray with upper abdominal cuts was performed on all patients after the procedure. In cases of suspicion of mediastinitis or leakage, a chest CT with oral contrast was performed before starting the oral diet. It

was needed in only 3 patients who were diagnosed with aspiration pneumonia (two patients) and pulmonary embolism (one patient), and the latter was confirmed with CT pulmonary angiography. Patients were discharged on PPIs for two months.

6. **Follow-Up:** Patients were followed up at fixed intervals: 6, 12, 18, and 24 months. The follow up was mainly based on their clinical symptoms; Eckardt scores were calculated again for the patients. BMIs were also calculated. High-resolution manometry was performed once during the follow-up period to calculate the LES resting pressure and IRP4s. The first endoscopic follow-up was arranged within 6 months after POEM to observe wound healing and monitor for potential reflux.
7. **Outcome Parameters** The primary outcome parameter was the assessment of technical and clinical success. Technical success was defined as the ability to complete the whole procedure without any need for further surgical intervention. Clinical success was defined as an Eckardt score of 3 or less. The secondary outcome parameter was to detect the manometric changes after POEM (drop in IRP4s).

Statistical analysis

Data were analyzed using Statistical Package for the Social Sciences version 20 for Windows 2010. Abnormally

distributed data are described as medians (IQRs). Categorical data were described in the form of numbers and percentages. Related samples-Wilcoxon signed rank tests were used to compare pre- and post procedure data. A p -value < 0.05 was considered significant.

Results

This study included a total of 34 patients; 19 (55.9%) patients were males, and 15 (44.1%) patients were females. Their ages ranged from 11 to 68 years, with a median age of 33.5 years. Sixteen patients underwent previous balloon dilation (47.1%), and one patient underwent previous surgical myotomy (3.2%) (Table 2). Before the POEM procedure, all patients reported dysphagia, regurgitation, chest pain and weight loss. The Eckardt score ranged from 4 to 12, with a median of 9. High-resolution manometry performed for the patients showed that 12 patients had type I achalasia (35.2%), 18 patients had type II achalasia (52.9%), and 4 patients had type III achalasia (11.7%) (Table 2). The POEM procedure was achieved successfully in all patients (technical success 100%), with a median procedure time of 120 min (range: 75–260 min). The median hospital stay was 3 days (range: 2–10 days). Some procedure-related adverse events were observed, such as mucosal tears (3; 8.8%), pneumoperitoneum requiring underwater seal (3; 8.8%), pneumonia (14; 40%), and subcutaneous emphysema (grade I) (2; 5.9%). Pneumoperitoneum requiring underwater seal was indicated with a tense abdomen and an increase in the peak airway pressure during the procedure. It was managed with a 20 mm gauge needle placed in the right iliac fossa with air bubbles coming out until relaxation of the abdominal wall and normalization of the peak airway pressure. Patients were followed up with X-ray imaging after the procedure. Two patients developed aspiration pneumonia (5.9%), one patient developed a DVT and pulmonary embolism (2.9%), and one patient developed DVT (2.9%). The 2 patients with DVT, after thorough investigation, turned out to have coagulation disorders that were precipitated by the procedure with no similar events before. None of the patients developed mediastinitis or esophageal leakage. The follow-up period of the patients ranged from 6 to 24 months, with a median of 10 months. Approximately one-third of the patients had endoscopic evidence of GERD. Patients were asked to evaluate the procedure and their satisfaction, giving it a score out of 10. Patient satisfaction ranged from 7 to 10, with a median of 9 (Table 3). Technical success was achieved in all 34 patients (100%). Clinical success was achieved in 33/34 patients (97.1%). There was a significant drop in the Eckardt score, rise in BMI and drop in IRP4s, with P values of < 0.0001 , 0.006 and < 0.0001 ,

Table 2 Demographic data of the patients (total = 34)

Age (years)	
Range	11–68
Median (IQR)	33.5 (27)
Gender (Number, %)	
Female	15 (44.1%)
Male	19 (55.9%)
Comorbidities	
Diabetes	1 (2.9%)
Hypertension	2 (5.9%)
3A syndrome ^a	1 (2.9%)
Hypothyroidism	1 (2.9%)
Thyrotoxicosis	1 (2.9%)
Ischemic heart disease	1 (2.9%)
Renal impairment	1 (2.9%)
COPD	1 (2.9%)
BMI^b	
Range	13.3–37.6
Median (IQR) ^c	23.7 (10.2)
Disease duration (years)	
Range	0.5–16
Median (IQR)	3 (3)
Type of achalasia	
Type 1	12 (35.2%)
Type 2	18 (52.9%)
Type 3	4 (11.7%)
IRP (4s)^d	
Range	11.5–49.4
Median (IQR)	25.6 (19.5)
Previous therapies (number, %)	
Surgery	1 (3.2%)
Endoscopic dilation	16 (47.1%)
1 Session of dilation	9 (26.5%)
2 Sessions of dilation	4 (11.5%)
3 Sessions of dilation	2 (5.9%)
6 Sessions of dilation	1 (2.9%)
Eckardt score	
Range	4–12
Median (IQR)	9 (3)

^a 3A achalasia, alacrimia and Addison's disease, ^b BMI body mass index, ^c IQR interquartile range

^d IRP4s integrated relaxation pressure for 4 s

respectively. Only one patient with type I achalasia had an Eckardt score of 9 preprocedure and IRP4s of 30.7 mmHg. After the 6-month follow-up, his Eckardt score dropped to 4, and his IRP4s score dropped to 18.7. However, he was satisfied, gained 11 kg and did not want further intervention. There was no significant difference in the clinical success rate (the drop in Eckardt score) among different types of achalasia, with a p -value of 0.208 (Fig. 4).

Table 3 Procedure details and follow-up

Procedure time (minutes)	
Range	75–260
Median (IQR)	120 (76)
Myotomy length	
Range	8–10 cm
Median (IQR)	10 (0)
Number of clips used	
Range	4–12
Median (IQR)	6 (2)
Technical success (Number, %)	34 (100%)
Hospital stay (days)	
Range	2–10
Median (IQR)	3 (1)
Intraprocedural adverse events (Number, %)	
Mucosal tear	3 (8.8%)
Pneumoperitoneum needing UWS ^d	3 (8.8%)
Pneumoperitoneum	14 (40%)
Surgical emphysema	2 (5.9%)
Postprocedural adverse events	
Aspiration pneumonia	2 (5.9%)
DVT ^a and pulmonary embolism	1 (2.9%)
DVT	1 (2.9%)
Follow-up period (months)	
Range	6–22
Median (IQR) ^c	10 (6)
BMI (kg/m²)	
Range	15.2–43.5
Median (IQR)	26.3 (10)
Endoscopic evidence of GERD^b	10 (29.4%)
Eckardt score (Post-procedure)	
Range	0–4
Median (IQR)	1 (2)
Clinical success (number, %)	33/34 (97.1%)
Patient's satisfaction (0–10)	
Range	7–10
Median (IQR)	9 (2)
IRP4s (postprocedure)^e	
Range	3.1–18.7
Median (IQR)	10.8 (8.2)

^a DVT deep venous thrombosis, ^b GERD gastroesophageal reflux disease, ^c IQR interquartile range, ^d UWS under water seal

^e IRP4s integrated relaxation pressure for 4 s

Discussion

Just a decade ago, the only treatment modalities for achalasia were BTI, PBD or LHM [14]. LHM is considered an invasive and definitive line of management for achalasia with long-term outcomes [15]. Meanwhile,

PBD is considered not less effective but less invasive; however, long-term outcomes have always been questioned [16–18]. BTI has limited value owing to its short-term outcomes and the need for multiple sessions, so it is usually performed when other options are not suitable [19]. POEM has caused a paradigm shift in treating esophageal motility disorders, POEM covers the drawbacks of the abovementioned modalities [20]. Definitive treatment (myotomy) plus its minimally invasive nature is performed endoscopically [21]. In addition, it allows for longer myotomies, especially in type III achalasia, than LHM, which cannot perform more than a 6 cm myotomy from the esophageal side [22]. Owing to this fact, POEM is considered optimal for managing other motility disorders that require a longer myotomy, such as Jackhammer's esophagus [23–25]. Additionally, its use has been applied to other diseases: Z-POEM for managing Zenker's diverticulum [26], G-POEM (gastric POEM) for gastroparesis or pylorospasm [27] and submucosal tunneling endoscopic resection (STER) for submucosal tumors [28]. The efficacy and safety of POEM have been proven in various studies in the last few years [29–32]. The experience of POEM is usually from Asian countries [33–35] and the USA [36]. The data from the MENA region and Arabic countries are very limited. In this study, we present the first Egyptian experience and the first publication from Africa. The technical success rate was 100%, and the clinical success rate was 97%, which is consistent with many studies [29–35]. There is no age limitation for POEM provided the wide range used, 11 to 75 years old. There were no limitations regarding the type of achalasia or associated comorbidities. There were no limitations regarding previous interventions; it was performed post-PBD and post-LHM. No major adverse events were encountered. Most of the adverse events were gas-related complications, such as pneumoperitoneum, and a small percentage required underwater seal drainage with a 20 cm gauge syringe during the procedure and warranted no further management postprocedure. Only one patient required further intervention, and this patient presented with acute pulmonary embolism. After reviewing the literature, we could not find a consensus on when to administer anticoagulation post-POEM. We preferred to place an IVC filter as a bridge before anticoagulation [11]. This patient was proven to have factor V Leiden deficiency. The median hospital stay was 3 days, which makes it cost effective. In this study, clinical success showed no statistically significant differences among the different types of achalasia. However, it has already been stated in the

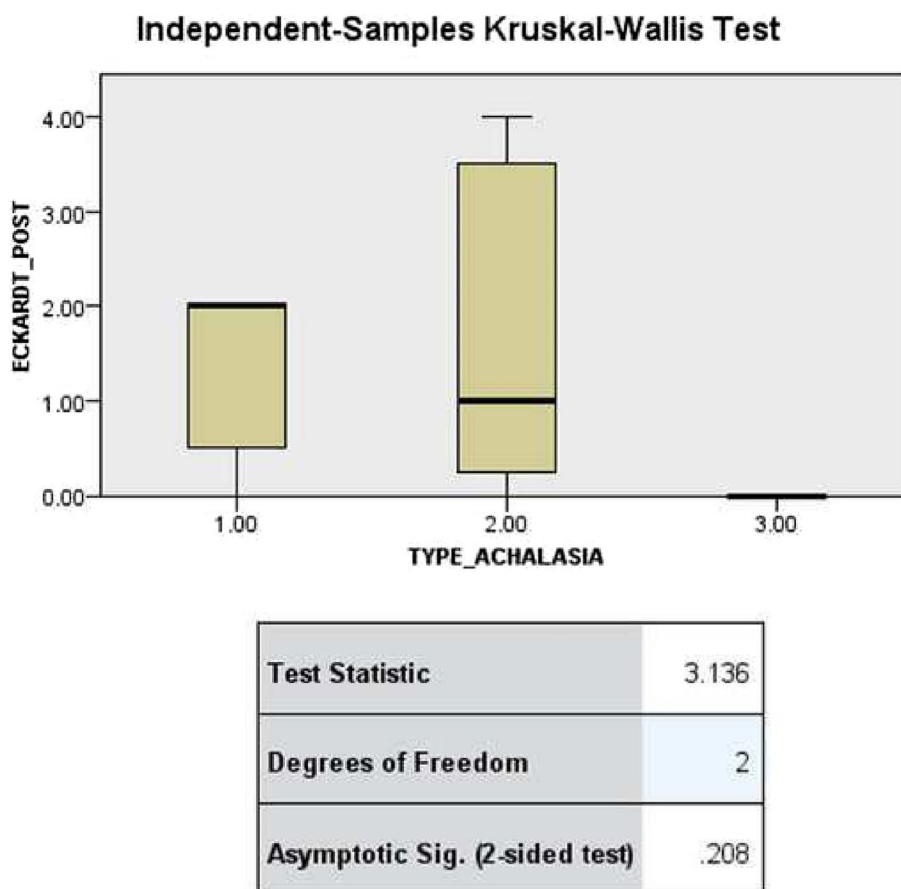


Fig. 4 Comparison of the clinical success rate (drop in Eckardt score) among different types of achalasia using the Kruskal–Wallis test

Table 4 Comparing data pre- and post-POEM

Variables	Pre- POEM Median (IQR)	Post- POEM Median (IQR)	P-value
Eckardt score	9 (3)	1 (2)	<0.0001
BMI	23.7 (10.2)	26.3 (10)	0.006
IRP4s	25.6 (19.7)	10.2 (8.2)	<0.0001

BMI body mass index, IRP4s integrated relaxation pressure for 4 s

literature that type II achalasia obtains the maximum benefit from POEM(33). The problem of GERD post-POEM is still a major concern [37]. Too long a myotomy is a predisposing factor for reflux, while too short a myotomy is a predisposing factor for recurrence. Therefore, it is always a matter of balance, which is why tailored myotomy depending on HRM is preferred [38]. Most reflux post-POEM is asymptomatic and detected by pH testing. In our patients, PH testing was not available in all cases, so we relied on endoscopic evidence of GERD. Patient satisfaction was very rewarding, with a median score of 9 out of 10.

Conclusion

To conclude, this is the first study with regard to POEM to be performed in an Egyptian cohort. This proves that POEM is a safe, effective, and feasible modality for treating achalasia. POEM is becoming a more convenient option and is gaining patient satisfaction (Table 4).

Abbreviations

- POEM Per oral endoscopic myotomy
- MENA Middle East and North Africa
- IRP4s Integrated relaxation pressure for 4 s
- NOTES Natural orifice transluminal endoscopic surgery
- LES Lower esophageal sphincter
- PBD Pneumatic balloon dilation
- BTI Botulinum toxin injection
- LHM Laparoscopic Heller’s myotomy
- HRM High resolution manometry
- BMI Body mass index
- GEJ Gastro-esophageal junction
- PPI Proton pump inhibitors
- NPO Nothing by mouth
- DVT Deep venous thrombosis
- GERD Gastro esophageal reflux disease
- Z-POEM Zenker per oral endoscopic myotomy
- G-POEM Gastric per oral endoscopic myotomy
- STER Submucosal tunneling endoscopic resection
- IVC Inferior vena cava

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Authors' contributions

Shaimaa Elkholy planned the study design and one of the team who performed the cases (Guarantor), Kareem Essam was involved in reporting the data, one of the team who performed the cases, Gina Gamal was involved in data reporting during the follow up and doing the manometry pre & post procedure, Karim A Maurice was involved in the data collection, Zeinab A was involved in the data analysis & interpretation while Mohamed Elsherbiny was involved in manuscript writing and one of the team who performed the cases, Hany Haggag involved in performing the cases, Abeer Awad and Kerolis Yousef were involved in manuscript writing.

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Declarations**Ethics approval and consent to participate**

This work had been approved from the ethical committee of the internal medicine department of faculty of medicine, Cairo University.

Competing interests

The above-mentioned authors had no conflict of interests.

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