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Original Article

Safety and Effectiveness of Per Oral Endoscopic Myotomy (POEM) for Achalasia in Pakistani Population: An Experience of First 50 Patients

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Abstract

Objective: Peroral endoscopic myotomy (POEM) is a new procedure for doing myotomy in patients diagnosed with achalasia. POEM has been started at Lahore General Hospital, Lahore for the first time in the country and the aim of the study is to assess the safety and effectiveness of the first 50 POEM procedures.

Methods: All the patients of achalasia undergoing POEM from March 13th 2020 to June 8th 2022 at Lahore General Hospital, Lahore were enrolled. The primary outcome of the procedure was technical and clinical success. Clinical success was defined as post-POEM Eckardt score of ≤3 at 90 days and complete clearance of contrast on post-POEM gastrografin study. Secondary outcomes were pre and post-POEM integrated relaxation pressure (IRP), length of myotomy, procedure duration, rate of symptomatic GERD requiring pharmacological treatment, duration of hospital stay and adverse event rate.

Results: Fifty patients underwent the POEM procedure. In two patients, the procedure was completed in second attempt (technical success rate 96%). One patient did not return for follow-up. 49 patients were included for final analysis. Clinical success defined as post-POEM Eckardt scores of ≤3 at ≥90 days was achieved in 46 out of 49 (93.33%) patients while the post-POEM gastrografin study demonstrated complete clearance of contrast in 47 out of 49 (96%) patients. The median hospital stay after POEM was 2 days. There were no major adverse events. Symptomatic GERD post-POEM was documented in 12 out of 49 (24.49%) patients.

Conclusion: POEM is a safe and effective procedure for the treatment of achalasia in the Pakistani population.

Keywords: Achalasia, Dysphagia, Eckardt Score, Peroral Endoscopic Myotomy

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Introduction

Achalasia is an uncommon disorder of esophageal motility caused by progressive loss of functional inhibitory ganglion cells of the myenteric plexus.[1] Progression of dysphagia is caused by the lower esophageal sphincter's inability to relax and by inefficient peristalsis.[2]

Patients present with long-standing symptoms which include chest pain, weight loss, regurgitation, and dysphagia. Diagnosis of achalasia requires barium swallow, endoscopic examination, and high-resolution manometry. Endoscopic evaluation is necessary to exclude pseudo achalasia due to carcinoma involving gastro-esophageal junction.[3]

The goal of achalasia treatment is to lower the resting pressure of the LES. Different treatment modalities include pharmacologic therapy using oral nitrates, injection of botulinum toxin (BT), surgical management using laparoscopic Heller myotomy and endoscopic modalities including pneumatic balloon dilation and POEM. As no treatment so far can reverse the degeneration of ganglion cells; therefore, prolonged treatment and follow-up is necessary.[3] POEM is an effective modality of management for type I & II achalasia but is a preferred treatment for achalasia type III.[4]

Peroral endoscopic myotomy (POEM), was first described by Inoue et al in 2010, and expertise spread rapidly to the rest of the world.[5] Multiple studies have suggested the efficacy of POEM as an effective treatment for achalasia cardia in adults as well as children.[6-13] POEM can be done in all patients of achalasia even if previously treated and there is no age limit for the procedure. Other esophageal motility disorders like Jackhammer esophagus and distal esophageal spasm can also be managed with POEM effectively.[14-17] Complications include mucosal perforation, subcutaneous emphysema, capnoperitoneum, capnothorax, capnomediastinum, pleural effusion, infection, bleeding and GERD.[6,18]

Ours is the pioneer center to start the POEM procedure in Pakistan and the service was started under the mentorship of an expert endoscopist with more than 500 case volume in third space endoscopy just before COVID restrictions were being imposed. As our center was the first and only center in Pakistan where POEM service could be offered, the cases increased rapidly as the COVID settled.

Methods

This is a retrospective analysis of a prospectively enrolled cohort and includes all patients who underwent POEM from March 13th 2020 to June 8th 2022 at the Endoscopy Department, Lahore General Hospital, Lahore, Pakistan. The preprocedural evaluation included high-resolution esophageal manometry (HRM), barium swallow, gastroduodenoscopy and calculation of Eckardt Score. Gastrografin swallow was done on postoperative day 1 in all patients. Eckardt score was calculated on postoperative day 14, 30 and 90 and HRM was repeated after day 90.

Technique: Liquid diet was started 1 to 2 days before the procedure. Prophylactic IV Piperacillin & Tazobactam was administered just before the procedure and continued during the hospital stay. Patients were later shifted to oral Cefixime after discharge for 7 days. Patients having esophageal candidiasis on endoscopy were treated with Nystatin drops and oral/IV fluconazole before the procedure for 5 days. The procedure was performed under general anesthesia in a semi supine position with a 9.8 mm upper gastrointestinal endoscope (Olympus GIF HQ 190; Olympus Corp., Tokyo, Japan) having a transparent cap on the distal end. The transparent cap helps facilitate submucosal dissection and CO2 insufflation. A posterior myotomy approach was used in all patients. An electrosurgical unit of Erbe VIO 200 D was used. A 2 cm mucosal incision was given using a pure cutting current after a submucosal wheal was made by injecting 20-25 ml of Inj. Haemaccel mixed with methylene blue submucosally at least 7-10 cm proximal to the gastroesophageal junction. A submucosal tunnel was then made with careful dissection using an electrosurgical (ESD) knife at 30 Watts (W) coagulation current. Large caliber blood vessels were coagulated using Coagrasper at 60 W. The tunnel was extended distally across the gastroesophageal junction (GEJ) at least 2 cm into the proximal stomach in the triangle between the two major penetrating blood vessels while avoiding the sling fibers. The gastric extension of submucosal tunnel was indicated by the change in the vasculature, narrowing of the submucosal space, and visualization of muscle fibers at GEJ. A distal-to-proximal myotomy of circular muscle was carried out at 50W coagulation current, while avoiding the longitudinal muscle layer. A full thickness myotomy was done at the distal esophagus and proximal stomach. Adequate myotomy during procedure was confirmed by a resistance less insertion of the endoscope through the GEJ and a lax LES on retroflexion. The mucosal incision was then closed using hemostatic clips. (Figure 1)

All of the patients were evaluated with gastrografin swallow the following morning and started on ice cold liquids gradually increasing to a pureed diet. The majority of the patients were discharged 2 days after the procedure. Patients were allowed a regular diet 2 weeks after the procedure. (Table 1)

Outcomes: The primary study outcome was technical and clinical success at 90 days after POEM. Technical success was defined as successful completion of procedure (POEM) in first attempt while Clinical success was defined as sustained normalization of post-POEM Eckardt score of ≤ 3 at 90 days or greater and complete clearance of contrast on post-POEM gastrografin study as an additional criterion. Our secondary outcomes were measurement of pre and post-POEM IRP, length of myotomy, procedural duration, rate of symptomatic GERD requiring ongoing PPI therapy beyond 3 months, duration of hospital stay and the rate of different adverse events.

Statistics: Data was collected prospectively. Data is presented as mean ± standard deviation or median (range). The pre/post-POEM Eckardt score and pre/ post-POEM IRP score were compared using Student's paired t-test. P-value <0.05 was considered statistically significant.

Results

A total of 50 patients having achalasia cardia (mean age 40.66 years + 12.36 years, range 18–73 years; 30 men, 20 women) underwent POEM procedure in our department. The procedure was completed in second attempt in 2 patients (technical success rate of 96%) due to excessive bleeding from mucosal incision site and failure to make an adequate tunnel at entry point (one patient each). One patient could not be contacted for follow up at 90 days. Of these, 49 patients had achalasia cardia including type I (n=8, 16%), type II (n=33,

66%) and type III (n=8, 16%). Five patients had history of previous pneumatic balloon dilatation. Three patients had advanced sigmoid achalasia. (Table 2)

Table 1: *Diet after POEM*

Sr No.	Day after POEM	DIET
1	1-2	Ice cold Clear liquids, Ice cream, Frozen yoghurt, and thin gelatin
2	3-5	Custard, Kheer, yoghurt, smoothies and milk shakes
3	6-10	Soups, Shorbas, Dalia, Thin Kitchri, Mashed potatoes, poached eggs, egg puddings
4	10-15	Light curries, Thin curry pulses and soft rice.
5	After 15 Days	Regular Diet

Table 2: *Demographics of study patients.*

No. of Patients	50
Mean age, years (+ SD, range)	40.66±12.36 (18-73)
Male: Female	30:20
Disease duration (months)	18.6 (3-120)
▪ Type of Achalasia cardia (n=49)	
– Type I	8 (16%)
– Type II	33 (66%)
– Type III	8 (16%)
Previous therapy	
▪ Pneumatic balloon dilatation (PBD)	5
Advanced sigmoid achalasia	3

SD: Standard deviation, n: number.

The procedure was completed successfully in all patients. The median myotomy length was 8 cm (3-10 cm) on esophageal end and 2 cm (2-4cm) on gastric end and the submucosal incision was closed with a median of 7 hemostatic clips (range 4–14). The mean procedure time was 117.39±23.29 minutes (range 85–170) (Table 3).

Gastrografin contrast study was performed in all patients on next day and there was no case of esophageal leak. Patients were discharged after a median of 2 days post-POEM (range 2-14 days). Mean Eckardt score pre-POEM was 6.82 + 1.11 (range 4–9) and IRP was 36.54 + 21.92 mmHg (range 15–150). Primary outcome of a post-POEM Eckardt score of ≤3 at ≥ 90 days was achieved in Forty-six (93.87%) patients. The mean decrease in Eckardt score was 5.39 ($P < 0.0001$) while mean decrease in IRP was 21.83mmHg ($P < 0.0001$).

No major adverse events were recorded. Twelve patients (24.49%) had symptomatic GERD and were given PPI. No patient had GERD refractory to medical management. No patient had tension capnoperitoneum, 5 patients had

Table 3: *Operative findings and post-POEM results (n=49)*

Operating time (min) Mean (Range)	117.39±23.29 (85- 170)
Site of myotomy	
▪ Anterior	0
▪ Posterior	49
Length of myotomy (cm)	
▪ Esophageal (cm)	8 (3-10)
▪ Gastric (cm)	2 (2-4)
Adverse events:	
▪ Significant mucosal bleeding	0
▪ Mucosal injury requiring clipping	3
▪ Capnothorax	0
▪ Capnoperitoneum	12
▪ Tension Capnoperitoneum	0
▪ Capnomediastinum	5
▪ Capnopericardium	0
▪ Pleural effusion	0
▪ Myocarditis	1
No. of clips, median (range)	7 (4-14)
Technical Success	96%
Clinical success	46/49 (93.8%)
Reasons for technical failure	
▪ Excess bleeding from mucosal incision site	1
▪ Failure in submucosal tunnel dissection	1
Hospital stay (days), median (range)	2 (2-14)
▪ 30 days readmission rate	0
Eckardt score: Mean, (range)	
▪ Pre-POEM	6.82±1.1(4-9)
▪ Post-POEM	1.43±1.62(0-8)
▪ Patients having Eckardt score >3 post-POEM	3
▪ Mean improvement in Eckardt score	5.39(P<0.0001)
Manometry (IRP)mmHg: Mean (range)	
▪ Pre-POEM	36.54±21.92 (15-150)
▪ Post-POEM	14.38±9.67 (5-36)
▪ Mean decrease in IRP	21.83 (P <0.0001)
GERD (clinical)	12 (24.49%)
GERD Refractory to PPI	0

SD: Standard deviation, n: number, min: Minutes, cm: Centimeters, POEM: Per oral endoscopic myotomy, IRP: Integrated relaxation pressure, GERD: Gastroesophageal reflux disease, PPI: Proton pump inhibitor.

capnomediastinum requiring temporary cessation of procedure due to rise in end tidal CO2 > 60 kPa. One patient developed post-POEM myocarditis and had prolonged hospital stay which was attributed to COVID-19 infection and not due to POEM procedure. (Table 3)

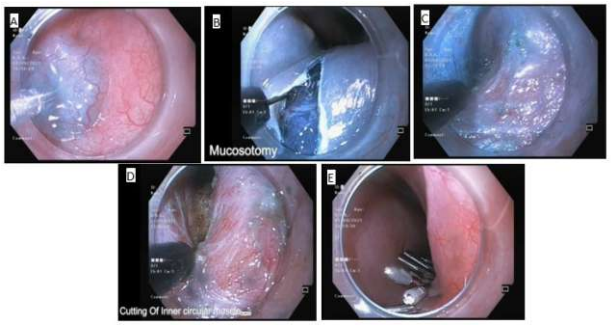

Figure 1: *Steps of POEM. A. Submucosal injection B. Mucosotomy C. Submucosal tunnel dissection D. Myotomy of inner circular muscle E. Mucosal incision closure using hemoclips.*

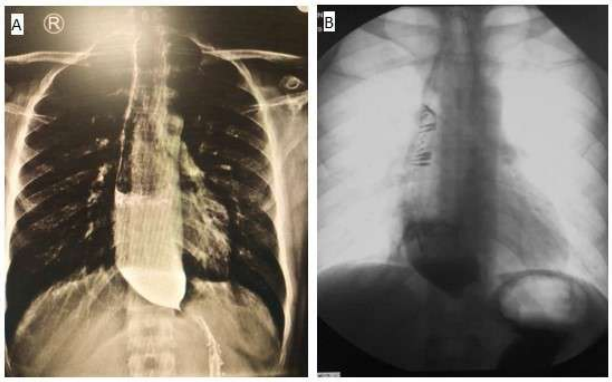

Figure 2: *A. Pre- POEM Barium swallow in a patient with achalasia showing bird peak appearance of distal esophagus with retained contrast. B. Post-POEM gastrograffin study of the same patient showing endoscopic hemoclips and contrast.*

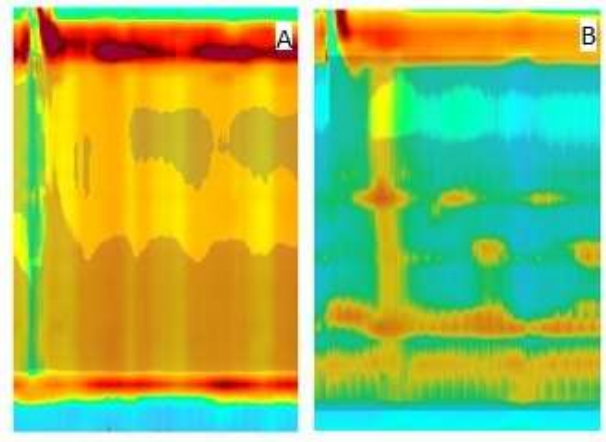

Figure 3: *A. Pre-POEM HRM tracing in a patient with type II Achalasia cardia showing pan esophageal pressurization, IRP was also increased. B. Post-POEM tracing of same patient after 90 days showing decreased esophageal pressurization and IRP as compared to initial manometry.*

Figure 4. *Instruments used in POEM. A. Triangular Tip Electrosurgical Knife B. Dual Knife C. ESD/ Insulated Tip (IT) Knife D. Transparent 4mm distal cap E. Coagrasper F. Injector Needle G. Electrosurgical unit-Erbe VIO 200 D.*

Discussion

The technical success was 96% (48/50). However, the success rate reached 100 % (50/50) when redo procedures were included, while the clinical success rate was (46/49, 93.87%) defined by Eckardt score of ≤3 at ≥90 days. Three patients could not achieve a primary outcome despite successful completion of myotomy, of these one patient was referred for laparoscopic Heller's Myotomy while two patients having advanced sigmoid achalasia have undergone pneumatic dilatation.

Our clinical success rate (93.87%) is comparable with other similar studies. A prospective trial of POEM for achalasia involving 8 centers in Japan with 233 patients showed an efficacy of 97.4% 1 year after POEM.[19] Ikebuchi Y et al analyzed 1200 POEM patients and clinical success rate was 95%.20 Nabi Z et al reported 408 patients from India who underwent POEM for achalasia with technical success in 396 (97%). However, clinical success rates were 94%, 91%, and 90% at 1, 2 and 3 years post-POEM, respectively.[21] Campagna RA et al reported 119 patients with POEM. Clinical follow-up for 100 patients was more than 4 years with a mean follow-up of 55 months. There was 88% clinical success overall.

Our study showed symptomatic GERD in 24.49% (12/49) of the patients while it was 33% (15/45) in the study performed by Campagna. The mean decrease in post-POEM IRP in our study was 21.83mmHg while Campagna reported improved esophageal physiology with a decrease in median IRP of 22mmHg which is comparable to our study.[22]

In a Canadian cohort, 51 POEM procedures were performed in 50 patients. 98% of patients achieved post-POEM Eckardt scores of ≤3 at ≥90 days.[23] Suryawanshi PR reported 24 patients of POEM with 100 % success

and complete symptom relief at 6 months post procedure. Symptomatic GERD was reported in one third of patients.[24] Masadeh M et al achieved clinical success in 92% patients and symptom control was seen in 88% of patients at 12 months.[25] Costamanga M et al reported technical success in 91% patients and clinical success in 100 %. No major complications were reported.[26]

Efficacy of POEM over 5 years was studied by Mckey C et al. Clinical success was achieved in 91% whereas long term success was achieved in 79% of patients (80% in achalasia patients, and 67% in DES patients). Post procedure mean Eckardt score at 6 months and 75 months was 1 and 2 respectively (p=0.204). 96% patients did not require reintervention for 5 years.[27] Tefas et al from Romania reported technical success in 100% patients (n=136) and clinical success in 87.5% of patients after single POEM procedure. After six months, one year, two years, and three years or more follow up, the success rate was 92.64%, 91.17%, 88.9% and 87.5% respectively while 12.5% of patients required further therapy.[28] He. C et al from China prospectively analyzed 115 patients of POEM for 36 months. Treatment was successful in 91.3 % of patients. Four patients had a late recurrence (after 3 years), eight patients had an early recurrence (between 3 months and 3 years) while four patients failed to respond to POEM within 3 months.[10]

Barbieri LA et al published a meta-analysis of 16 studies including 551 patients. The median follow up was 6 months (range 3–12 months) with median procedure duration of 156 minutes. The median length of myotomy in our study was 11 cm which is almost similar to this study (10cm). Technical and clinical success rates were 97% and 93%. This meta-analysis showed 14.5% adverse event rate with capnoperitoneum as the most frequent complication during POEM which was managed successfully with needle decompression. [29]

Patients with sigmoid achalasia who undergo POEM can experience improvement in LES pressure and esophageal angulation.[30] LES pressure and IRP were improved in our 3 patients with sigmoid achalasia, but clinical success could not be achieved likely due to ineffective esophageal motility in all these patients.

Clinical GERD post-POEM was documented in 12/49 (24.49%) patients in our study. This is also comparable with other studies. In one study, 24-hour pH study revealed GERD in 28.3% of patients, whereas 18.5% of patients had erosive esophagitis.[21] Most of these patients were asymptomatic. Increased pre operative Eckardt score was associated with post-POEM reflux. Arevalo G et al performed BRAVO pH study for 48 hours on post-POEM patients, which showed that 42% (15 out of 36) of the patients had esophageal reflux.[31] No patient in our cohort had GERD refractory to medical management.

Posterior vs. anterior myotomy approach was compared in a study of 63 patients. There was no significant difference between two groups in regards to demographic variables, outcome of treatment, Eckardt score, manometry findings, and adverse events.[32] An anterior approach is associated with increase the risk of GERD after POEM. Posterior myotomy was performed in all our patients.

Conclusion

POEM, a new service in Pakistan, is a safe and effective procedure for the treatment of achalasia in an experienced endoscopy setup and can be used as an alternative to pneumatic balloon dilatation and laparoscopic Heller myotomy. We are following the patients for long-term data on the procedure's durability and anticipate good long-term results consistent with other international studies.

Conflict of Interest: *None*

Funding Source: *None*

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