Outcome of per oral endoscopic myotomy (POEM) in sigmoid achalasia at a median follow up of 17 months

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ABSTRACT - Background - Advanced achalasia cardia (AC) represents the end stage in the natural history of AC. Role of per oral endoscopic myotomy (POEM) in this technically difficult subset is emerging. Methods - Retrospective review of the patients who had undergone POEM for advanced AC with sigmoid esophagus. We assessed the technical success, clinical success and adverse event rate. Pre and post POEM Eckardt score (ES), integrated relaxation pressure-4sec (IRP-4), lower oesophageal sphincter pressure (LESP) and height and width of barium column at 5 minutes were noted. Results - Of the 85 patients who underwent POEM for AC, 10 patients had advanced AC with sigmoid esophagus of which eight were sigmoid and two were advanced sigmoid. The clinical and technical success was 100% with significant reduction of ES, IRP-4, LESP and height and width of barium column at 5 minutes. One patient had a minor adverse event in the form of mucosal injury that was closed with hemoclips. At a median follow up of 17 months there was no recurrence. Conclusion - Our study demonstrates POEM to be a safe and effective modality of treatment in this technically difficult subset of AC with sigmoid morphology.

Keywords - Achalasia cardia; sigmoid esophagus; POEM; efficacy.

INTRODUCTION

Achalasia cardia (AC) is a uncommon esophageal motility disorder characterized by absent peristaltic activity in the esophageal body with incomplete relaxation of the sphincter mechanism of the lower esophagus(1). Traditional therapies include pneumatic dilatation (PD) and laparoscopic hellers myotomy (LHM), however, both have their inherent limitations^(2,3). Per oral endoscopic myotomy has emerged as a minimally invasive incisionless endoscopic game changer therapy in the treatment of AC with robust data showing excellent efficacy and safety(4).

Sigmoid AC is considered as an end stage in the natural history of AC where the esophagus, due to prolonged functional obstruction at the LES, becomes tortuous and excessively dilated with twisting of the axis (FIGURE 1A and 1B). Around 10% of the patients go on to develop the end stage sigmoid morphology despite receiving treatment⁽⁵⁾. Traditionally esophagectomy was considered as the only treatment option for the end stage sigmoid achalasia cardia^(6,7). Treatment in such cases becomes important and necessary due to risk of malignancy⁽⁵⁾. Many of these patients have severe comorbidities that preclude esophagectomy as a therapeutic option. per oral endoscopic myotomy (POEM) due to its minimally invasive nature can be a relief for such patients. Over the years with more experience, now data has emerged showing good efficacy and safety of POEM in sigmoid AC(8-10). Maintaining appropriate axis during tunnelling is a key step for the success of the procedure. POEM in the setting of sigmoid AC, however, becomes challenging due to the tortuosity which may potentially deviate the direction of the tunnel away from the LES. Here, we share our experience about the efficacy and safety of POEM in this technically difficult subgroup of sigmoid AC.

METHODS

We did a retrospective review of our prospectively maintained database of patients who underwent POEM for achalasia cardia from August 2018 till March 2021. The institute's ethics committee approved the study and the need for informed consent of the patient to participate in the study was waived due to the retrospective nature of the study. However, all the patients gave written informed consent for the POEM procedure. We enrolled patients who had evidence of sigmoid AC. The definition of the sigmoid AC was adapted as per the Japanese Esophageal Society descriptive rules of achalasia⁽¹¹⁾. When the angle between two straight lines drawn along the long axis of the esophagus (α angle) was <135° it was defined as sigmoid (Sg) and when the α angle was <90° it was defined as advanced sigmoid (aSg). High resolution manometry (HRM) with integrated relaxation pressure at 4 sec (IRP-4) and lower esophageal sphincter pressure (LESP) were recorded and the type of AC was classified as per the Chicago V.3.0 classification⁽¹²⁾. Pre POEM Eckardt score (ES), timed barium esophagogram (TBE) with height and width of column at 5 minutes, and prior treatment in the form of pneumatic dilatation, medical therapy or hellers myotomy were also noted.

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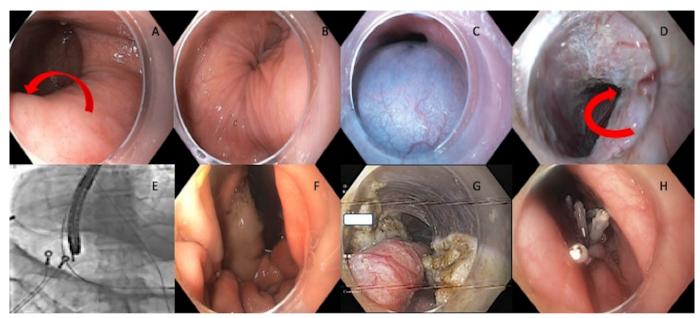


FIGURE 1. A) Endoscopic image showing dilated and tortuous esophageal lumen with red arrow showing deviation of the axis; B) Endoscopic image showing twisting of the axis; C) Creation of mucosal bleb by submucosal injection; D) Tunnel with tortuosity; E) Fluoroscopy guided tunneling to prevent deviation away from lower esophageal sphincter; F) Extent of gastric side of the tunnel seen through retroflexed view; G) Myotomy; H) Closure of the mucosal incision with hemoclips.

Procedural details

After written informed consent, POEM procedure was performed. A high definition gastroscope (GIF HQ 190, Olympus, Tokyo, Japan) fitted with a distal attachment (D-201-11804, Olympus, Tokyo, Japan) was used for the procedure under CO₂ insufflation (UCR, Olympus, Tokyo, Japan) through a low flow tubing (MAJ-1742, Olympus, Tokyo, Japan). Upper gastrointestinal endoscopy was done a day prior to clear the esophagus of any food residue. Preprocedure intravenous antibiotics and proton pump inhibitors were administered. The procedure was done under general anaesthesia in supine position. The steps of the procedure were as follows-By taking either anterior (2° clock position) or posterior approach (5° clock position) a submucosal bleb was created by injecting 10–15 mL of the solution of indigo carmine and saline (FIGURE 1C). A linear incision was given over the bleb with the help of triangular tip knife with jet function (TTJ knife, Olympus, Tokyo, Japan) attached to an electrosurgical generator (ENDO cut Q mode-effect 3, cut duration 1 and interval 6, ERBE, Tubingen, Germany) followed by undermining of the edges to gain entry into the submucosal space. Submucosal tunnelling was done with help of spray coagulation mode (50 W, effect 2) (FIGURE 1D). During tunnelling, maintenance of the appropriate axis was ensured by repeatedly coming out of the tunnel to confirm that the mucosal bluish elevation was directed towards the lower esophageal sphincter (LES) and not deviating away from it. In cases of aSg, Savary Gillard guidewire (Cook Medical, USA) was passed across the LES into the stomach prior to the procedure. This wire was then used fluoroscopically as a guide for maintaining the axis (FIGURE 1E). Tunneling was continued across the LES and into the gastric side for atleast 3 cm. The gastric side was confirmed by 1) appearance of spindle shaped vessels; 2) roomier tunnel; 3) large perforators; 4) retroflexion in the stomach showing bluish bleb of the tunnel (FIGURE 1F). Once the tunneling was complete, myotomy was initiated 2 cm distal to the incision site and completed till the end of the tunnel (FIGURE 1G). During tunnelling and myotomy any bleeding vessel was tackled and haemostasis was ensured. Smaller vessels were tackled with spray coagulation alone while larger vessels were coagulated used coagrasper (soft coagulation mode- 80 W, effect 4). During the procedure, if there was mucosal injury it was closed with hemoclips. The procedure was halted transiently with change of ventilator setting for faster diffusion of CO2 in cases of capnoperitoneum or capnomediastinum/capnothorax. Needle aspiration for capnoperitoneum and intercostal drain with under water seal for capnothorax were used if the above measures failed. Once the myotomy was complete and haemostasis confirmed, the incision site was closed with the help of hemoclips (FIGURE 1H).

Post procedure care and follow up

Patient were kept nil per oral for 24 hours and after that started on liquid diet and discharged on day 3. Soft diet was advised for 1 week along with proton pump inhibitors. Normal diet was advised thereafter. Patients underwent HRM and TBE on 2 months follow up. Subsequently, yearly follow up was done either physically on outpatient basis or telephonically and ES was calculated.

Outcomes

The primary outcome was clinical success defined by reduction of post procedure ES to $\leq 3^{(13)}$. The secondary outcomes were technical success defined by completion of all steps including myotomy and adverse events were defined as per American Society of Gastrointestinal Endoscopy (ASGE) lexicon⁽¹⁴⁾.

Statistical analysis

All the data were entered into a spreadsheet and analysed using the SPSS (version 21.0, SPSS Inc; Chicago, USA) software. Continuous variables were expressed as mean ± standard deviation or median (interquartile range). Normally distributed, continuous

variables were compared using the student t test, or else Mann-Whitney U test was used. Dichotomous variables were compared using chi square test/Fischer exact test as applicable. The P value of less than 0.05 was taken as statistically significant.

RESULTS

During the period from August 2018 to March 2021 we performed 85 POEM procedures for AC patients. Out of these 85 cases, 10 patients had sigmoid type of esophagus. Eight patients had sigmoid esophagus (Sg) while two had advanced sigmoid (aSg) as per the Japanese Esophageal Society descriptive rules of achalasia. The mean age of the patients was 49.6±13.5 years and 50% were females. The median duration of the disease was 4.5 (1-13) years. Out of the 10 patients, HRM could be performed in eight while the catheter could not be passed in the remaining two cases. All were type I AC as per the Chicago V 3.0 classification with mean IRP-4 of 15.6±7.9 and mean LESP of 33.8±16.9. Timed barium esophagogram, available for seven patients, showed mean pre POEM height and width at 5 min of 12.5±5.9 cm and 5.5±2.8 cm, respectively. The mean pre POEM Eckardt score was 9.2±1.7. Of the 10 patients, four were treatment naive, three were on medical therapy, two had underwent prior PD and one had undergone PD and was currently on medical therapy. (TABLE 1 summarizes the baseline characteristics of the patients who underwent POEM for sigmoid AC).

TABLE 1. Baseline characteristics and intraoperative findings of the patients who underwent per oral endoscopic myotomy for sigmoid achalasia cardia.

Variable	N=10	
Age	49.6±13.5 years	
Females	5 (50%)	
Type of Sigmoid achalasia cardia	Sg-8	
	ASg-2	
Type of achalasia cardia	All type 1 (8/10)	
Previous treatment received	Medical therapy (MT)-3	
	Pneumatic dilation (PD)-2	
	Both PD and MT-1	
	None-4	
Mean diameter of oesophagus	5.57±2.8 cm	
Duration of disease	4.5 (1–13) years	
Intra operative findings	Median (range)	
Entry time	4.5 (1–20) min	
Tunnel time	55.5 (20–99) min	
Myotomy time	26.5 (8-46) min	
Tunnel length	11.5 (8–17) cm	
Myotomy length	8.5 (5–12) cm	
Closure time	17 (7–32) min	
Overall time	108 (57-169) min	
No of clips	7 (4–12) clips	

Intraprocedural findings

Seven of the 10 cases were done with posterior approach while the remaining three through anterior approach. The median total procedure time was 108 (57–169) min {entry time-4.5 (1–20) min, tunnel time-55.5 (20–99) min, myotomy time-26.5 (8–46) min and closure time-17 (7–32) min}. The median tunnel and myotomy length were 11.5 (8–17) cm and 8.5 (5–12) cm respectively. One patient developed type II mucosal injury which was closed with hemoclips. The median length of hospital stay was 2.5 (2–5) days. (TABLE 1 summarizes the intraoperative findings of the patients who underwent POEM for sigmoid AC).

Outcomes

The technical success was achieved in 100% with all undergoing a successful myotomy. At a median follow up of 17.5 (4–28) months the clinical success was achieved in 100% of patients with a significant reduction in ES (9.2 \pm 1.7 vs 0.6 \pm 0.9, *P*-<0.001). One patient had presented with retrosternal pain and regurgitation at last follow up and was found to have erosive esophagitis (Los Angeles- Grade B). HRM and TBE at 2-month post POEM were available in eight and seven patients respectively and paired pre and post POEM evaluations for seven patients. There was a significant decrease in the mean IRP-4 ($15.6\pm7.9 \text{ vs } 5.2\pm6.1, P-0.019$) and LESP values $(33.8\pm16.9 \text{ vs } 8.6\pm8.9, P\text{-}0.01)$ post POEM. Similarly there was significant reduction in the height $(12.5\pm5.9 \text{ vs } 3.3\pm2.1.$ P-0.006) and width (5.5 \pm 2.8 vs 2.8 \pm 2.4, P-<0.001) of column at 5 minutes in TBE post POEM (FIGURE 2,3 and 4). (TABLE 2 summarizes the Pre and post POEM values of IRP-4, Mean LESP, TBE and ES to assess the efficacy of POEM).

DISCUSSION

Our study demonstrates the technical and clinical success of POEM for sigmoid AC of 100% at a median follow up of 17.5 (4–28) months. Only one patient had a minor adverse event in the form of mucosal injury that was tackled intraoperatively with no post-operative consequences.

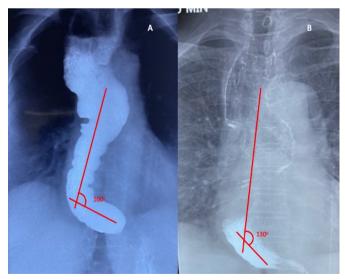


FIGURE 2. Pre and post per oral endoscopic myotomy timed barium esophagogram of Sg showing minimal hold up of contrast at 5 min with improved α angle from $100^{\rm o}$ to $130^{\rm o}$.

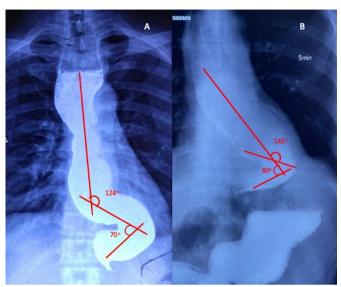


FIGURE 3. Pre and post per oral endoscopic myotomy timed barium esophagogram of aSg showing minimal hold up of contrast at 5 min with improved α angle from 124° to 145° and 70° to 80°.

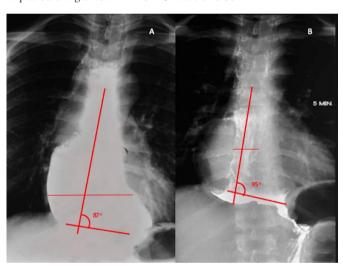


FIGURE 4. Pre and post per oral endoscopic myotomy timed barium esophagogram of aSg with megaesophagus showing minimal hold up of contrast at 5 min with reduction of the diameter and slight improvement in α angle from 87° to 95°.

TABLE 2. Pre and post POEM values of IRP-4, Mean LESP, TBE and ES to assess the efficacy of POEM.

Variables	Pre	Post	P value
IRP-4	15.6±7.9	5.2±6.1	0.019
Mean LESP	33.8 ± 16.9	8.6 ± 8.9	0.01
TBE width at 5 min	5.5 ± 2.8	2.8 ± 2.4	< 0.001
TBE height at 5 min	12.5 ± 5.9	3.3 ± 2.1	0.006
ES	9.2 ± 1.7	0.6 ± 0.9	< 0.001

POEM: per oral endoscopic myotomy; LESP: lower esophageal sphincter pressure; TBE: timed barium esophagogram; ES: Eckardt Score; IRP-4: integrated relaxation pressure at 4 sec.

About one tenth of patients with AC go on to develop end stage disease despite treatment wherein the esophagus has anatomical distortion with tortuosity and twisting of the axis which becomes sigmoid shaped with or without excessive dilatation⁽⁵⁾. Traditionally, esophagectomy has been the treatment option for this subset with advanced AC with efficacy between 75–100%⁽¹⁵⁾. However, the morbidity and mortality associated with it was high (upto 27% and 2% respectively) with impaired quality of life⁽¹⁵⁾. Although LHM has a reported success rate of 50–100%⁽¹⁶⁾, performing myotomy might be challenging.

During the initial years of POEM, it was thought that POEM in sigmoid anatomy would be difficult due to the tortuosity of the track and twisting of the axis. Concerns were raised regarding the efficacy of the procedure as well. However, over the ensuing years, POEM has shown promise in this difficult-to-treat cohort as well. The efficacy of POEM in advanced AC with sigmoid and/ or megaesophagus in previous reported studies has been between 63–100%(8-10,17-22). Liu D et al. have shown lower efficacy (63%)(21) in the subgroup of advanced AC having both sigmoid morphology and megaesophagus. Our study has shown the efficacy of 100% with no recurrence at a median follow up of 17 months.

The adverse event rate reported in previous studies has been in the range of $6\text{--}46\%^{(8\text{--}10,17\text{--}22)}$. The two studies of Hu WL et al. and Lv L et al. (17,18) had included minor expected inconsequential events such as subcutaneous emphysema and capnoperitoneum and capnomediastinum/capnothorax which usually resolves spontaneously, thus over inflating the adverse events rate. Otherwise, POEM has been reported to be a safe procedure in the subset of advanced AC as well. Our study also had only one adverse event of mucosal injury which was tackled intraoperatively with hemoclips without any further consequences.

Several modifications of the technique of POEM have been described to circumvent the anatomical difficulty faced especially in advanced sigmoid morphology where we encounter extreme twists and tortuosity. A wider tunnel reaching upto half the circumference of the esophagus might help in crossing the twists and starting the myotomy 1-2 cm distal to the entry incision might help shorten the tunnel⁽¹⁸⁾. A short tunnel and myotomy may be helpful in scenario where we get a straight path just above the gastroesophageal junction (GEJ) in a dilated and tortuous esophagus⁽²³⁾. When we encounter submucosal fibrosis where tunnelling becomes difficult, simultaneous submucosal and muscle dissection may come to the rescue⁽²⁴⁾. In our study, in one of the cases of advanced sigmoid AC we did fluoroscopy guided POEM by keeping a steel guidewire as a landmark to reach the GEJ (FIGURE 1E).

Our study has several limitations. This is a retrospective study with small sample size and hence would have some inherent confounding factors. Moreover, paired values of IRP-4 and TBE were not available for all the patients. Nabi Z et al. had shown deterioration of ES and TBE with time for this subset of patients⁽⁸⁾. Thus, longer follow up would be warranted to comment on true efficacy of POEM in our cohort.

CONCLUSION

Our study shows POEM to be a safe and effective treatment modality for advanced AC with sigmoid morphology. However, larger randomized controlled trials are needed to confirm our findings.

Authors' contribution

Conception and design: Mandavdhare HS. Analysis and interpretation of data: Mandavdhare HS and Samanta J. Drafting of the article: Mandavdhare HS. Critical revision of the article for important intellectual content: Mandavdhare HS, Samanta J, Jafra A, Singh H, Gupta P, Dutta U. Final approval-all authors.

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RESUMO – Contexto – Acalasia cárdia avançada representa o estágio final na história natural do megaesôfago. Está emergindo o papel da miotomia endoscópica peroral (POEM) neste subconjunto tecnicamente difícil. Métodos – Foi realizada uma revisão retrospectiva dos pacientes submetidos a POEM para tratamento do megaesôfago avançado. Avaliamos o sucesso técnico, o sucesso clínico e a taxa de eventos adversos. O escore de Eckardt, pré e pós POEM, a pressão integral de relaxamento de 4 seg (IRP-4), a pressão do esfíncter inferior do esôfago e a altura e largura da coluna de bário em 5 minutos, foram anotadas. Resultados – Dos 85 pacientes submetidos a POEM para acalasia cárdia, 10 pacientes apresentaram acalasia cárdia avançado com esôfago com aspecto sigmoide, dos quais dois eram muito avançados. O sucesso clínico e técnico foi de 100% com redução significativa do escore de Eckardt, do IRP-4, da pressão do esfíncter inferior do esôfago e da altura e largura da coluna bário em 5 minutos. Um paciente teve um pequeno evento adverso na forma de lesão mucosa que foi fechada com hemoclipes. Em um seguimento mediano de 17 meses não houve recorrência. Conclusão – Nosso estudo demonstra que a POEM é uma modalidade segura e eficaz de tratamento neste subconjunto tecnicamente difícil de megaesôfago com morfologia sigmoide.

Palavras-chave – Acalasia cárdia; esôfago sigmoide; POEMA; eficácia.

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