Peroral Endoscopic Myotomy Achieves Similar Clinical Response but Incurs Lesser Charges Compared to Robotic Heller Myotomy

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ABSTRACT

Background/Aim: Several uncontrolled studies comparing peroral endoscopic myotomy (POEM) and Heller myotomy have demonstrated equivalent short-term efficacy and safety. However, no data exists rergarding the cost of POEM and how it compares to that of robotic Heller myotomy (RHM). The primary aim of this study was to compare the inpatient charges incurred in patients who underwent POEM or RHM for the treatment of achalasia. Patients and Methods: A retrospective single center review was conducted among 52 consecutive POEM patients (2012-2014) and 52 consecutive RHM patients (2009-2014). All RHM procedures included a Toupet fundoplication and were performed via a transabdominal approach. All POEM procedures were performed by a gastroenterologist in the endoscopy unit. Clinical response was defined by improvement of symptoms and decrease in Eckardt stage to ≤I. All procedural and facility charges were obtained from review of the hospital finance records. Results: There was no difference between POEM and RHM with regards to age, gender, symptom duration, achalasia subtype, manometry findings, or Eckardt symptom stage. There was no significant difference in the rate of adverse events (19.2% vs 9.6%, P = 0.26) or the length of stay (1.9 vs. 2.3, P = 0.18) between both groups. Clinical response rate of patients in the POEM groups was similar to that in the RHM group (94.3% vs. 88.5%, P = 0.48). POEM incurred significantly less total charges compared to LHM (14481 vs. 17782, P = 0.02). Conclusions: POEM when performed in an endoscopy unit was similar in efficacy and safety to RHM. However, POEM was associated with significant cost savings (\$3301/procedure).

Key Words: Achalasia, charges, dysphagia, Heller myotomy, peroral endoscopic myotomy

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Peroral endoscopic myotomy (POEM) has revolutionized the management of patients with achalasia and spastic esophageal disorders.^[1-5] The main shortcoming of botulinum toxin injection in the treatment of achalasia is its limited efficacy and low durability in patients who respond.^[6] Pneumatic dilation is associated with good initial response rate but symptom recurrence is common. In addition, it is associated with a nontrivial perforation rate.^[6] Robotic Heller

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myotomy (RHM) is the surgical equivalent to POEM and is associated with excellent short and long-term outcomes. Main shortcomings include its invasiveness and the need for concomitant fundoplication.^[2]

There are only a few studies reporting the results of RHM. Multiple retrospective studies have compared POEM and laparoscopic HM (LHM) and showed comparable perioperative outcomes.^[7-11] As expected, POEM was associated with shorter procedural times, shorter length of hospital stay (LOS), and quicker return to activities of daily

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living. One prospective study suggested better short-term dysphagia relief with POEM as compared to LHM with fundoplication.^[10]

Therefore, POEM appears to offer equivalent clinical outcomes as compared to LHM. POEM is, however, less invasive and may eliminate nonspecific surgical complications.^[2,7] Importantly, it has also been suggested that POEM may result in cost savings because it is typically performed in the endoscopy unit and is associated with shorter procedural times and shorter LOS. However, no data currently exists regarding the cost of POEM and no studies have compared the cost of both POEM and RHM. The primary aim of this study was to compare inpatient charges incurred in patients who underwent POEM or RHM for the treatment of achalasia.

PATIENTS AND METHODS

This retrospective single center study was approved by the Institutional Review Board for Human Research and complied with Health Insurance Portability and Accountability Act (HIPAA) regulations at Johns Hopkins Hospital. Consecutive patients who underwent POEM for achalasia between January 2012 and November 2014 were included. These patients were compared to an equivalent number of consecutive patients who had undergone transabdominal RHM for achalasia between March 2009 and November 2014. Some patients from the POEM and RHM cohorts were included in other published studies by our group. In all patients, the diagnosis was based on a combination of clinical presentation, barium esophagram, and manometric findings. The achalasia subtype was based on the Chicago classification.^[12,13] Patients with spastic esophageal disorders (aside from type III achalasia) and altered surgical anatomy were excluded. Patients in the POEM and RHM cohort were identified by review of the institution's billing database. Relevant clinical (prior therapy, Eckardt stage), manometric findings, length of myotomy, and procedure time were abstracted. Pre-procedural and post-procedural symptoms (e.g., Eckardt stage) were also recorded. Adverse events were graded according to the ASGE lexicon's severity grading system.^[14]

Clinical response was defined by improvement of symptoms and decrease in Eckardt stage to $\leq I$ [Table 1]. The length of follow up for patients was defined as the time from the procedure to the date of the last clinical follow up. Our clinical outcomes were length of myotomy, procedure duration, length of hospital stay, rate of adverse events, and incurred charges.

Peroral endoscopic myotomy procedures

POEM procedures were performed in the endoscopy suite as previously described by Khashab *et al.*^[1] using high-definition

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The Saudi Journal of Gastroenterology gastroscopes fitted with transparent caps under general anesthesia and insufflation using carbon dioxide. A triangular tip (TT) knife (KD 640L, Olympus, Japan) was used for all procedures. Prior to commencing the mucosal incision, the length of myotomy was decided based on the findings of high-resolution esophageal manometry (HREM) and/or the proximal level of visible spastic contractions seen endoscopically. A submucosal cushion was then created followed by a longitudinal mucosal incision. Subsequently, the endoscope was inserted into the submucosal space. The fibers of the submucosal space were dissected and a tunnel was created, which extended 2-3 cm into the proximal part of the stomach. Then, a selective inner circular myotomy or full-thickness myotomy was performed. The mucosal incision was closed using endoscopic hemostatic clips. Patients were subsequently admitted for observation. An esophagram was obtained on day 1, and a soft diet was commenced after no extravasation was noted. Subsequently, patients were sent home once they were tolerating oral diet.^[1]

Robotic Heller myotomy procedures

RHM procedures were performed using the daVinci™ robotic system (Intuitive Surgical, Inc., Palo Alto, Cal, USA) via a transabdominal approach. The diaphragmatic hiatus was dissected open to allow for mobilization of the medial esophagus to at least 6 cm proximal to the esophagogastric junction (EGJ). A myotomy of both the circular and longitudinal muscle layers was performed from at least 6 cm proximal to the EGJ to 2-3 cm into the proximal stomach using hook electrocautery. The open jaws of a grasper (2.5 cm) were used to measure myotomy length. The crura was then loosely approximated to allow for the passage of a 5 mm diameter instrument through the hiatus. Patients then underwent a 270° posterior (Toupet) fundoplication or anterior 180° (Dor) fundoplication for postoperative reflux control. A posterior Toupet fundoplication was performed preferentially unless excessive angulation of the EGJ resulted or mucosal perforation occurred, in which case an anterior Dor fundoplication was utilized. Patients were admitted for inpatient hospital stay and discharged home once pain was controlled and they were able to tolerate oral diet.

Calculation of charges

The charges incurred were obtained from review of the finance records for each patient and are presented in USD (\$). Due to the method of billing in the United States, for consistency, we elected to use charges incurred as opposed to actual charges as there is usually inconsistency between payers in the proportion of the requested charges that were actually paid. In addition to the total charges, we performed a subgroup analysis and evaluated charges according to various aspects of the procedure and inpatient stay (supplies, operating room or endoscopy suite charges, radiologic studies, etc.).

Table 1: Eckar	dt symptom scoring and s	taging		
Score	Dysphagia	Retrosternal pain	Regurgitation	Weight loss
0	None	None	None	None
1	Occasional	Occasional	Occasional	<5 kg
2	Daily	Daily	Daily	5-10 kg
3	Every meal	Every meal	Every meal	>10 kg
	Stage 0	Stage 1	Stage 2	Stage 3
Score total	0-1 (Remission)	2-3 (Remission)	4-6 (Failure)	>6 (Failure)

Statistical analysis

Results are reported as mean \pm standard deviation (SD) and/or range for quantitative variables, and absolute and relative frequencies for categorical variables. Outcomes between pre and post procedure parameters were compared using the Student's *t*-test (paired *t*-test/Wilcoxon where applicable) for continuous variables and the Chi-square test for categorical variables. Chi square test/Fisher's exact test and *t*-test/Mann–Whitney U test were used to compare patient and procedural characteristics between the two groups. Statistical significance was based on two-sided design-based tests evaluated at $\alpha = 0.05$. Statistical analysis was performed using SPSS version 16 (SPSS Inc, Chicago, IL, USA).

RESULTS

During the study period, a total of 52 patients underwent POEM in the endoscopy unit while 52 patients underwent RHM. Among patients who underwent POEM, the majority were males (n = 27, 52%) with a mean age of 47.48 ± 16.95 years. The mean duration of symptoms was 4.6 ± 4.72 years. The majority of patients had severe symptoms with Eckardt stage III in 43 and stage II in 9. Type II achalasia was present in 39 (75%) patients, while the remainder of the patients had either type I (n = 1)or type III (n = 12) achalasia. A total of 18 patients had had prior endoscopic therapy (botulinum toxin injection and/or pneumatic dilation) whereas 5 patients had had combination of prior endoscopic therapy and Heller myotomy. Among patients who underwent RHM, the majority were males (n = 28, 54%) with a mean age of 46.92 ± 16.70 years. The mean duration of symptoms was 5.2 ± 4.65 years. The majority of patients also had severe symptoms with Eckardt stage III in 44 and stage II in 8. All patients had achalasia; type I in 12, type II in 20, type III in 3, and unknown type in the remaining 17 patients. A total of 25 patients had had prior endoscopic therapy, 2 prior Heller myotomy, and 5 patients a combination of prior endoscopic therapy and Heller myotomy.

There was no difference between the POEM and RHM groups with regards to age, gender, symptom duration,

achalasia subtype, HREM findings or Eckardt symptom stage at baseline [Table 2]. Patients in the POEM cohort were less likely to have a sigmoid esophagus (2.8% vs. 20%, P = 0.02).

With regards to intraprocedural characteristics, patients in the POEM cohort had a significantly longer length of myotomy (11.6 cm vs. 8.6 cm, P < 0.0001). Moreover, the procedure time was significantly shorter in the POEM as compared to the RHM group (106 min vs. 263 min, P < 0.0001). There was no significant difference in the rate of adverse events (none were severe) (19.2% vs 9.6%, P = 0.26). The 5 adverse events recorded in the POEM cohort included 1 pneumothorax and 4 mucosotomies. In the RHM cohort, the adverse events included 4 urinary tract infections and 1 wound infection. The LOS was 1.9 d vs. 2.3 d (P = 0.18) between both groups. Clinical response rate of patients in the POEM groups was similar to that in the LHM group (94.3%) vs. 88.5%, P = 0.48). Duration of follow-up (months) was significantly longer in the POEM group (15.62 \pm 12.0 vs. $8.90 \pm 11.20, P = 0.004$).

POEM incurred significantly less total charges compared to RHM (\$14481 vs. \$17782, P = 0.02) [Table 3]. In detail, POEM in-room charges were significantly less (\$5070 vs. \$7616, P < 0.001), though that of supplies were more (\$4394 vs \$3240, P < 0.001). When the charges incurred due to the procedure itself (in-room, supplies, drugs) were compared, POEM was associated with cost savings (\$9756 vs. \$11136, P = 0.015). In addition, the charges incurred due to the inpatient hospital stay were significantly less with POEM (\$2771 vs. \$5206, P = 0.006) [Table 3].

DISCUSSION

Multiple prospective and retrospective studies assessed the outcomes of POEM in patients with achalasia and spastic esophageal disorders and showed excellent short and mid-term clinical efficacy and safety.^[1,4,15-17] Comparative studies between POEM and LHM showed that clinical efficacy and safety were similar between both techniques.^[7-10] However, there currently exists no studies that have assessed charges associated with the POEM procedure or how POEM and RHM compare with respect to charges. It has been

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or both groups						
	POEM (<i>n</i> =52)	RHM (<i>n</i> =52)	Р			
Age, mean±SD	47.48±16.95	46.92±16.70	0.750			
Female, <i>n</i> (%)	25 (48.07)	24 (46.15)	1			
Symptom duration, years,	4.6±4.72	5.2±4.65	0.501			
mean±SD						
Eckardt symptom stage,						
n (%)						
0	0	0	NA			
I	0	0	NA			
II	9	8	1			
III	43	44	1			
Achalasia subtype, n (%)						
I	1 (2)	12 (23)	0.000			
II	39 (75)	20 (57.1)	0.103			
III	12 (23)	3 (8.7)	0.091			
Prior therapy, n (%)						
None	29 (55.8)	19 (36.5)	0.076			
Endoscopic	18 (34.6)	25 (48)	0.171			
LHM	0	2 (3.8)	0.495			
LHM + Endoscopic	5 (9.6)	6 (11.7)	1			
Esophageal dilatation	1 (2)	10 (19.2)	0.023			
stage III or sigmoid						
esophagus, <i>n</i> (%)						
HREM, mmHg,						
mean±SD						
Residual pressure	26.82±11.95	28.44±12.2	0.595			
Basal pressure	37.78±24.4	35.25±17.25	0.687			
POEM: Peroral endoscopic my	POEM: Peroral endoscopic myotomy, LHM: Laparoscopic Heller myotomy,					

Table 2: Comparison of baseline patient characteristics of both aroups

HREM: High resolution esophageal manometry, RHM: Robotic Heller myotomy

Table 3: Comparison o RHM	f charges	between PC	EM and		
Charges	POEM	RHM	Р		
In room charges	\$5070	\$7616	<0.001		
Supplies	\$4394	\$3240	<0.001		
Intraprocedural charges (in-room, supplies, drugs)	\$9756	\$11136	0.015		
Inpatient stay charges	\$2771	\$5206	0.006		
Total	\$14481	\$17782	0.02		
POEM: Peroral endoscopic myotomy, RHM: Robotic Heller myotomy					

proposed that POEM may be associated with cost savings considering its less invasive nature, which translates into shorter procedural times and easier post-procedural care. In addition, POEM is typically performed in the endoscopy unit^[1,18,19] rather than operating theater, with the latter entailing higher charges. However, it must be acknowledged that RHM is performed with a fundoplication as opposed to POEM which does not. Therefore, the costs of late adverse events and their management (PPI use, fundoplication) would be additional.

The baseline characteristics of the cohort were similar aside from patients in the POEM cohort were significantly less likely to have type I achalasia or a sigmoid esophagus. This may have biased the results in favor of POEM as a tortuous and dilated esophagus may have made RHM technically challenging and more time consuming. Further, this may have contributed to RHM patients having a longer procedure time and therefore associated charges.[8-11]

The primary aim of this study was to compare inpatient charges incurred in patients who underwent POEM or RHM for the treatment of achalasia. Shaligram et al. compared the clinical outcomes and costs of RHM vs LHM and found similar clinical outcomes but higher costs with RHM.^[20] In addition to costs, the procedure duration is known to increase with RHM vs LHM.^[21] Although the length of myotomy was significantly longer in the POEM group, procedure time was significantly shorter. Both procedures were highly and equally efficacious. Similarly, POEM and RHM were equally safe without occurrence of severe events in either group. Importantly, POEM incurred significantly less total charges compared to RHM with an average saving of \$3300 per procedure. This was mainly driven by cost saving due to in-room charges and inpatient hospital stay.

It was interesting to note that despite the similar LOS between the POEM and RHM cohort, the charges incurred during the inpatient stay were substantially lower in the POEM group. First, there was a subtle (17%), though not statistically significant shorter length of stay, which may have had a partial influence on the costs. Another explanation is that patients in the POEM cohort were admitted as an "extended recovery" as opposed to an "inpatient admission" in the RHM group. Moreover, it is possible that the bed stay in the surgical ward was more costly than a medical ward bed. Finally, it is conceivable (though not assessed in this study) that increased acuity and post procedure support was required in those who underwent RHM.

Approximately 2000 Heller myotomy procedures are performed annually in the United States.^[22] This is a conservative estimate as LHM volume has increased because of the adoption of a laparoscopic transabdominal approach.^[22] Therefore, POEM may result in at least \$6,600,000 in annual saving in the United States alone. More importantly, POEM offers a less invasive approach for the treatment of achalasia as compared to LHM. This results in more rapid recovery and possibly an improved quality of life of these patients.

Definitive comparative randomized trials between POEM and RHM are awaited and needed to confirm the

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non-inferiority of POEM in terms of efficacy and safety. Cost-effectiveness comparison of both procedures is also warranted taking into consideration effectiveness, cost, and patients' quality of life.

The current study is the first to suggest that POEM is associated with cost saving as compared to RHM. Our results are also in line with other studies that showed that POEM is equally effective and safe when compared to RHM. However, the study has some limitations. All procedures were done by experts at a tertiary center and, thus, the results may not be generalizable. The study is retrospective with inherent limitations due to its design. RHM results (procedure duration) and charges may be different to standard laparoscopic procedures. There was a significantly greater proportion of patients in the surgical arm that had sigmoid esophagus as compared to POEM, which may have biased the results in favor of POEM. Although POEM is done in the endoscopy unit at our institution, our results may not be applicable to institutions where POEM procedures are performed in the operating room. Furthermore, it is unclear if similar differences in charges would be seen outside the United States. It should be highlighted that the differences in charges between POEM and RHM will most likely increase further as the procedural accessories for POEM become less costly and as more POEMs are performed on an outpatient basis.

CONCLUSION

In conclusion, POEM when performed in an endoscopy unit was similar in efficacy and safety to RHM. However, POEM was associated with significant cost savings (\$3300/procedure). The downstream costs of POEM and RHM are yet to be ascertained but are of critical clinical significance. Future studies will need to review the costs of managing relapse and longer term adverse events such as gastroesophageal reflux.

Financial support and sponsorship Nil.

Conflicts of Interest

Mouen Khashab is consultant for Boston Scientific and Olympus America. Vivek Kumbhari is a consultant for Boston Scientific and Apollo Endosurgery. Anthony Kalloo is a founding member, equity holder and consultant for Apollo Endosurgery. All other authors have no relevant conflicts of interest to disclose.

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