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Establishment of a per oral endoscopic myotomy program at a rural tertiary care center

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Abstract

Background This study's purpose is to determine the application and effectiveness of a POEM program in the rural healthcare setting. Achalasia has a substantial impact on the lives of afflicted patients. Traditionally, a Heller myotomy with fundoplication has been the standard of care for treatment. In 2008, the first per oral endoscopic myotomy (POEM) was performed in Japan. Since 2017, our rural healthcare institution has performed approximately 60 POEMs.

Methods An IRB approved, single-institution retrospective review of patient outcomes after POEM was performed along with prospective analysis of post-operative surveys. An institutional cost analysis was also performed. Demographic and qualitative variables were measured and included PPI use, a Likert scale of 0–5 for progressively worsening symptoms of heartburn, dysphagia, and regurgitation. In addition, we included a Dysphagia Outcome and Severity Scale.

Results The number of myotomy operations increased from 4.5 per year to 28.8 per year after initiation of the POEM program. Mean Likert scale scores were 0.91, 0.73, and 1 for heartburn, dysphagia, and regurgitation, respectively. 72.5% percent of patients were satisfied with their present condition. 87.5% of patients reported minimal or no dysphagia on the Dysphagia Severity Scale. Intraoperative costs were \$2477 for laparoscopic myotomy and \$1650 for POEM. The capital expense of the equipment required to perform POEM was \$110,232. Average contribution margin per case was \$6024. The procedure pays off capital outlay upon completion of the 19th case.

Conclusions This study shows that patients have excellent symptom control after POEM. When compared to the institution's laparoscopic myotomy volume, POEM far surpasses in terms of operative volume and monetary benefit. Examination of these data shows that a rural hospital can successfully employ a state-of-the-art intervention when there is a population in need and an infrastructure in place.

Keywords POEM · Myotomy · Achalasia · Esophagus · Minimally invasive

The purpose of this study was to determine the application and effectiveness of a Per Oral Endoscopic Myotomy (POEM) program in the rural healthcare setting. Achalasia has a substantial impact on the quality of life of those afflicted by it. With an incidence of 1.6 per 100,000 new diagnoses made per year, it is becoming a more recognized disease entity that is primarily treated by surgical methods [1]. It has been established that non-surgical approaches such as pneumatic dilation do not have as long-lasting effects as a surgical myotomy [2, 3]. Traditionally, a Heller myotomy with fundoplication has been the standard of care for treating achalasia [4]. This is typically performed laparoscopically, which necessitates multiple small port sites that have a risk for pain, scarring, infection, and hernias. Many surgical patients are discharged home with narcotics, which is suboptimal given the national narcotic abuse epidemic our country is experiencing [5]. All of these factors led to the question of whether a myotomy could be performed in another, even less invasive manner.

In 2008 in Japan, the first POEM was performed on a human subject [6]. This technique involves creating a submucosal tunnel from the esophagus to the proximal stomach with an endoscope. An endoscopic myotomy is then

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performed from the esophagus, through the gastroesophageal junction (GEJ), and onto the stomach, thereby relieving the mechanical obstruction caused by the disease process. There are many technical aspects to the performance of POEM that are still being debated, such as the orientation, length, and layers of the myotomy [7, 8]. Despite the continued evolution of the technique, POEM has shown effectiveness with minimal harm, as described by Inoue et al. in 2015, where outcomes of their first 500 patients were presented [9]. Since 2017, our institution, which is located in a rural tertiary care center, has performed approximately 60 POEMs. This paper will describe our implementation and outcomes of POEM.

Materials and methods

An IRB approved, single-institution, retrospective review of patient outcomes after POEM was performed along with a prospective analysis of post-operative surveys. Review of the electronic health record (EHR) was performed to obtain demographic and qualitative variables. Demographic variables included age, sex, race, weight, and BMI. The qualitative variables measured included preoperative and post-operative proton pump inhibitor (PPI) use, operative time, complications, length of stay (LOS), patient reported Surgical Endoscopy (2021) 35:3981–3988

resolution of symptoms at first clinical follow-up, postop readmission, and previous abdominal surgery. It is our group's practice to perform a silent-GERD screening esophagogastroduodenoscopy (EGD) at 6–12 months after POEM for objective inspection and follow-up. The need for a postop interventional EGD outside of this routine screening was compiled.

Post-operative telephone surveys were performed and the time since POEM was documented as 0-1 month, 1-3 months, 3-6 months, 6-12 months, 12-24 months, 24-36 months, and greater than 36 months. Patients were asked if they were currently taking a PPI, and if they were off a PPI for how long they had been off. Patients were asked a series of questions in order to obtain scores on a Dysphagia Outcome and Severity Scale (DOSS) [10] and a modified Gastroesophageal Reflux Disease-Health Related Quality of Life Questionnaire (GERD-HRQL) [11] Likert scale. These scales are demonstrated in Figs. 1, 2. For the DOSS, this was graded on a scale of 1-7, with 7 being no symptoms of dysphagia. The modified GERD-HRQL Likert scale was scored 0-5 for progressively worsening symptoms of heartburn, dysphagia, and regurgitation with a higher score indicating worse symptoms. There were 6 questions related specifically to heartburn, 3 questions related to dysphagia, and 5 questions related to regurgitation. The maximum score possible for this scale was a 70. The patients were then asked if they felt satisfied, neutral, or dissatisfied

Fig. 1 Dysphagia Outcome and Severity Scale

Dysphagia Outcome and Severity Scale

- 7 = Within Normal Limits
 - No symptoms of dysphagia
 - Regular diet
- 6 = Minimum Problems
 - Some symptoms of dysphagia but no need for rehabilitation or exercise
 - Softened rice and food, direct therapy if necessary

5 = Oral Problems

- Significant symptoms in the pre-oral anticipatory stage or oral stage without aspiration
- Softened rice and food or paste food. Direct therapy in the hospital or at home

4 = Occasional Aspiration

- Possible aspiration or aspiration is suspected due to pharyngeal residue
- Dysphagia diet, regular diet, or use of intermittent oral catheterization. Direct therapy in the hospital or at home
- 3 = Water Aspiration
 - Aspiration of thin liquids; change in food consistency is effective
 - Dysphagia diet, thick liquids, or use of intermittent oral catheterization. Direct therapy in the hospital or at home

2 = Food Aspiration

- Food aspiration with no effect from compensatory techniques or food consistency changes
- Tube feeding or gastrostoma. Directs therapy in a professional medical organization

1 = Saliva Aspiration

- Unstable medical condition due to severe saliva aspiration
- Tube feeding or gastrostoma. Difficulty with direct therapy

Fig. 2 Modified Gastroesophageal Reflux Disease-Health Related Quality of Life Questionairre

Modified Gastroesophageal Reflux Disease-Health Related Quality of Life Questionnaire (GERD-HRQL) Likert Scale

Scale:

- 0 = No symptoms
- 1 = Symptoms noticeable but not bothersome
- 2 = Symptoms noticeable and bothersome but not every day
- 3 = Symptoms bothersome every day
- 4 = Symptoms affect daily activity
- 5 = Symptoms are incapacitating to do daily activities

Which best describes your experience over the past 2 weeks:

- 1. How bad is the heartburn?
- 2. Heartburn when lying down?
- 3. Heartburn when standing up?
- 4. Heartburn after meals?
- 5. Does heartburn change your diet?
- 6. Does heartburn wake you from sleep?
- 7. Do you have difficulty swallowing?
- 8. Do you have pain with swallowing?
- 9. If you take medication, does this affect your daily life?
- 10. How bad is the regurgitation?
- 11. Regurgitation when lying down?
- 12. Regurgitation when standing up?
- 13. Does regurgitation change your diet?
- 14. Does regurgitation wake you from sleep?

Total Score:

How satisfied are you with your present condition? Satisfied, neutral, or dissatisfied

with their present condition. All of these data were stored in a REDCap Database [12, 13]. An institutional cost analysis was performed to show the fiscal benefit of establishing a POEM program at our institution in 2017. Statistical analyses were performed using Microsoft Excel and REDCap.

Our hospital serves as the tertiary care center for a majority of the population of the Eastern region of North Carolina (ENC-41). This region is often referred to as ENC-41, which describes the 41 counties of North Carolina east of Interstate 95. The population of this region is 1.4 million. According to the 2010 Census, approximately 44% of the population of ENC-41 lives in a rural area, in contrast to 33% of the total population of North Carolina and 21% of the US population.

Results

We analyzed EHR data collected from 41 patients who underwent POEM at our institution from 2017 to 2019. Demographic data are displayed in Table 1. The average

Table 1Demographic data

Variable	Total $n = 41$	Standard deviation	
Mean age (years)	58	19.4	
Mean weight (kilograms)	76	19.9	
Mean BMI	27	6.2	
Sex			
Male	17 (41.5%)		
Female	24 (58.5%)		
Race			
Caucasian	25 (61%)		
African American	15 (36.6%)		
Native American	1 (2.4%)		
Pre-operative PPI Use	24 (58.5%)		
Post-operative PPI Use	27 (65.9%)		
Prior abdominal surgery	24 (60%)		

age of our population was 58 years. The average weight of our population was 76 kg. The average BMI of our population was 27. We had 17 males and 24 females (41.5% and 58.5%, respectively). We had 25 Caucasian patients, 15 African American patients, and one Native American patient (61%, 36.6%, and 2.4%, respectively). 24 (58.5%) patients were on a PPI prior to undergoing POEM, while 27 (66%) patients are now using PPIs post-operatively according to EHR review. 24 patients (60%) had undergone prior abdominal surgery. One patient had undergone a prior operation for acid reflux.

Table 2 describes intra- and post-operative findings. Our average operative time since implementation of POEM is 112 min. In 2017, we performed 14 POEMs with an average

 Table 2
 Intra- and post-operative findings

Variable	Total $n = 41$	Standard deviation
Mean operative time (minutes)	112	51.9
Complications	3 (7.3%)	
Mean length of stay (days)	2.5	2.8
Patient reported resolution of symp- toms at first post-op clinic visit	32 (78%)	
Need for Post-op EGD	9 (22%)	
30-Day readmission	1 (2.4%)	

operative time of 121 min. In 2018, we performed 21 POEMs with an average operative time of 116 min. Our data were collected up to September of 2019 and during those 9 months, we performed 6 POEMs for an average operative time of 73 min. A graph showing our operative times since implementation is displayed in Fig. 3.

Three (7.3%) patients had complications. One had a full thickness mucosotomy, one had post-operative ST changes ultimately requiring CABG, and one patient had a reactive pleural effusion and aspiration. Our average length of stay was 2.5 days and the median length of stay was one day. At their first post-op visit, 32 (78%) patients reported resolved symptoms. Nine (22%) patients required an off-protocol post-operative EGD. Only one patient required readmission within 30 days of their original POEM procedure.

Our post-operative patient survey was performed on 40 patients. One patient required an esophagectomy after POEM, before the survey had started, and therefore was not a candidate for the survey. Our results showed that 87.5% of patients reported a score of 6 or 7 on the DOSS, with an average score of 6.4 (see Table 3). GERD-HRQL results are shown in Table 4. The mean Likert scale scores were 0.91, 0.73, and 1 for the categories of heartburn, dysphagia, and regurgitation, respectively. The average total score of all 14 categories was 12.6 per person or a score of 0.90 per question for the entire cohort. DOSS and GERD-HRQL results as a function of time since POEM are shown in Table 5.

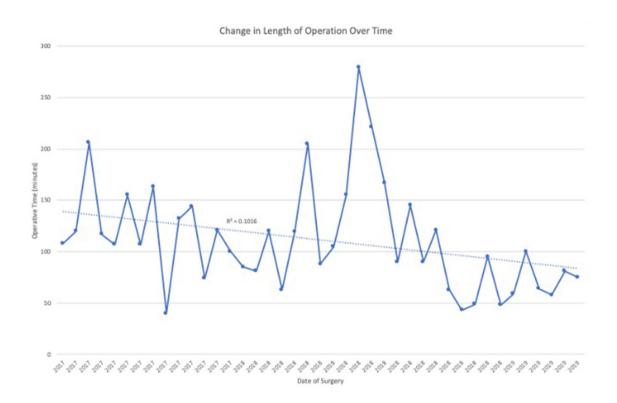


Fig. 3 Change in length of operation over time

 Table 3 DOSS survey results

DOSS score	Number of patients with this response	Percentage of total cohort $(n=40)$	
7	25	62.5%	
6	10	25%	
5	2	5%	
4	1	2.5%	
3	2	5%	
2	0	0%	
1	0	0%	

Table 4 GERD-HRQL survey results

Question	Average score from 0–5	Standard deviation	
How bad is the heartburn?	1.05	1.36	
Heartburn when lying down?	0.85	1.35	
Heartburn when standing up?	0.75	1.29	
Heartburn after meals?	1.125	1.45	
Does heartburn change your diet?	1.025	1.59	
Does heartburn wake you from sleep?	0.65	1.37	
Do you have difficulty swallowing?	1.15	1.56	
Do you have pain with swallowing?	0.725	1.48	
If you take medication, does this affect your daily life?	0.307	1.05	
How bad is the regurgitation?	1.325	1.65	
Regurgitation when lying down?	0.975	1.59	
Regurgitation when standing up?	1.125	1.62	
Does regurgitation change your diet?	1	1.63	
Does regurgitation wake you from sleep?	0.575	1.17	
Average total score	12.625	16.49	

72.5% percent of patients were satisfied with their present condition at the time of the phone survey.

An institutional cost analysis was performed at our institution for 2017. The laparoscopic myotomy intraoperative supply costs were \$2477 per case while the POEM intraoperative supply costs were \$1650 per case. This is a difference of \$827 per case. The capital expense of the equipment required to perform POEM was \$110,232. The average contribution margin per POEM case performed was \$6024, based off of hospital financial estimations of reimbursements and costs. The procedure paid off capital outlay upon completion of the 19th case. The number of myotomy operations increased from 4.5 per year for 2011–2016, up to 28.8 per year for 2017–2019 after initiation of the POEM program.

Discussion

In this study, we attempted to demonstrate the successful implementation of a POEM program in a rural tertiary healthcare setting. We aimed to quantify success by using the measurements of excellent clinical outcomes, increased case volume, and improved financial statistics. Based on the results of our DOSS and modified GERD-HRQL surveys, a majority of patients had a satisfactory subjective clinical outcome after their POEM. The number of myotomy operations performed by our department increased by over 600% per year after the implementation of POEM. Our institutional cost analysis demonstrated that the capital expense required to pay for POEM is met after the 19th case and at our institution, this was able to be accomplished within one year. The summation of these findings leads our department to the conclusion that implementation of POEM was successful.

The results of this study show that patients have excellent symptom control after POEM based on both the DOSS and the modified GERD-HRQL questionnaire used. 72.5% of patients reported being satisfied with their current condition. Not surprisingly, regurgitation had the highest average score on the modified GERD-HRQL questionnaire with a score of 1, which correlates to symptoms being noticeable but not bothersome. PPI use remained high before and after the POEM, which is not unexpected given the reflux that occurs after performing a myotomy with no wrap. The literature reports a reflux rate of 10–57% after POEM [14].

Time since operation	Number of patients	Average heartburn score	Average dysphagia score	Average regur- gitation score	Average total score	Average DOSS score
0–1 Month	0	N/A	N/A	N/A	N/A	N/A
1-3 Months	1	1.33	0	1	13	6
3–6 Months	4	0	0.67	0.05	2.25	6.25
6-12 Months	5	1.93	1.13	1.68	23.4	6.4
12-24 Months	23	0.88	0.59	0.88	11.39	6.48
24-36 Months	7	0.74	1.05	1.46	14.86	6.14
36 or more months	0	N/A	N/A	N/A	N/A	N/A

Table 5DOSS and GERD-HRQL results as a function oftime since surgery

This is comparable to the prevalence of reflux in patients undergoing Heller myotomy with a Dor or Toupet fundoplication. Rawlings et al. performed a randomized controlled trial comparing laparoscopic Dor versus Toupet fundoplication following a Heller myotomy for achalasia and found that 41.7% of the Dor group had pathologic reflux compared to 21.7% of patients in the Toupet group [15]. While we do not have objective pH data to report and no pre-op GERD-HRQL scores to compare, we feel that the scores themselves show good symptom control. The mean Likert scale scores of 0.91, 0.73, and 1 for the categories of heartburn, dysphagia, and regurgitation, respectively, show that on average patients either have no symptoms or symptoms that are noticeable but not bothersome.

Kumbhari et al. reported an adverse rate of 6% after POEM compared to 27% after Heller myotomy [16]. Our complication rate was similar to this at 7.3%. In regard to the complications experienced, one patient had a full thickness incision at the time of mucosotomy. This was recognized and closed at the end of the operation with endoclips. A swallow study performed post-operative day (POD) 1 did not show a leak. The patient was managed with empiric antibiotics for 5 days without further complications or signs of infection and was discharged on POD 5.

Another patient was found to have transient ST changes post-operatively and underwent a cardiac catheterization. This revealed significant left main coronary artery disease, prompting coronary artery bypass grafting (CABG). He had undergone evaluation by cardiology prior to performing the POEM and was felt to be at an acceptable risk for proceeding with surgery. His length of stay was 10 days.

The other patient who suffered a complication had severe autism spectrum disorder with a history of recurrent aspiration pneumonias. She had undergone a robotic Heller myotomy and Dor fundoplication at another institution, but had persistent dysphagia, regurgitation, and aspiration pneumonias. Manometry showed her to have an incomplete myotomy and non-relaxing LES. She therefore underwent POEM at our center. Despite a negative esophagram on POD 1, she developed tachycardia, a pleural effusion, and poor pulmonary mechanics on POD 2. Given her communication barriers from severe autism, endoscopic and thoracoscopic inspection and drainage were performed which confirmed no perforation. She required mechanical ventilation postoperatively from her complicated pneumonia, which ultimately required a tracheostomy. She was decannulated and discharged home on POD 14. Our center favors performance of tracheostomy early due to difficulties with airway and secretion management in this challenging population of patients [17].

In regard to the nine patients that required a post-op EGD outside of the normal screening protocol, one required an EGD and bronchoscopy to search for a source of possible hemoptysis or hematemesis. No obvious source was found. The 2nd patient was the patient who is described above who suffered the complication of aspiration pneumonia requiring tracheostomy. The 3rd patient required EGD and dilation 16 days after his POEM due to stricture. The 4th patient required a rdo POEM 2 years later. The 5th patient required EGD with dilation one month after her POEM, then a redo POEM one year later. The 6th patient required an EGD with dilation a little over a year after her POEM. The 7th patient required an EGD with dilation 3 months after her POEM. The 8th patient required an EGD with dilation 3 months after her POEM and ultimately received a Dor fundoplication. The 9th patient required a robotic Heller with Dor fundoplication 2 months after his original POEM. He is the patient mentioned as our only 30 day post-op readmission in the discussion section below.

Average length of stay was found to be 2.5 days; however, much of this can be attributed to the three complications noted above, as the median and mode of LOS is found to be 1 day. When these three patients are excluded from the calculation, the LOS drops down to 1.9 days, which is a more reasonable expectation for LOS after POEM. Marano et al. performed a systematic review and meta-analysis comparing POEM with laparoscopic Heller myotomy (LHM) and found that POEM patients had decreased LOS compared to LHM [18]. We only had one patient require readmission within 30 days of POEM. This POEM was difficult due to tortuosity and fibrosis in the muscular layer and the myotomy was only able to partially completed due to concern for perforation as the mucosa was unable to be separated from the muscle layers during tunneling near the esophagogastric junction. This patient ultimately required a robotic Heller myotomy with Dor Fundoplication 2 months after POEM.

Inoue's group in Japan has performed over 1000 cases and published their experience in 2016 [19]. Their center's trainees typically spend 4-6 months observing and assisting an experienced operator. The experienced operator then gradually allows the trainee to transition from performing various portions of the procedure to ultimately performing the procedure in its entirety. A study by Kurian et al. reported that performing 20 cases establishes mastery [20],¹ while a study by Patel et al. reported that 40 cases establish efficiency and 60 cases establish mastery [21]. Our institution's experience correlated with these data, as we have grown to four thoracic surgeons performing the procedure and have now expanded to training thoracic fellows in the technique as well. Figure 3 demonstrates that while there are occasional cases that are prolonged, our average length of operation has decreased over time as our experience has increased.

As described above, our institution's number of myotomy operations increased after adopting POEM. Our referrals increased dramatically after many of the gastroenterologists and primary care physicians in the community who had been treating this difficult patient population learned we were now doing POEMs. They became interested to send their patients to our center now that there was a less invasive way of treating achalasia. Also, while many centers in the community were doing Heller myotomies, for a time we were the only center in the state that was doing POEM. So instead of sending achalasia patients for Heller myotomies at their local hospital, the referring physicians were sending their patients for POEM at our institution. Part of what helped increase awareness in the physician community was that we began a marketing campaign to let the community know. We believe our program was a success because of our publicity, coupled with excellent surgical technique and outcomes.

We feel that it is important to offer a cutting-edge service to a disadvantaged population. A study by Kearney et al. found ENC-41 has a number of socio-vulnerability characteristics that are not equal to those of the rest of the state. When compared to the other 59 counties of North Carolina, our region has more individuals with disability (17.48 vs 15.78%), individuals with income below poverty (20.87 vs 18.76%), people under 18 and living in poverty (31.82 vs 27.24%), people over 65 in poverty (13.11 vs 10.80%), and non-white (37.23 vs 20.31%). The ENC-41 region averages 5.45 primary care physicians (PCP's) per 10,000 people, while the rest of the state has an average of 7.39 PCP's per 10,000 [22]. Black race has been identified risk factor for post-operative complications in patients undergoing surgery for benign esophageal disorders [23]. Our population has higher proportion of this at risk population than the rest of the state, so offering a new, less invasive technique for the same disease process to diminish their risk of post-operative complications is paramount. Our tertiary care center being the first in the state to offer a new minimally invasive treatment for achalasia was a great step in bringing equality of health to our healthcare disadvantaged region of North Carolina.

When compared to our institution's prior laparoscopic myotomy volume and considering the cost analysis presented above, the addition of the POEM procedure far surpasses in terms of operative volume and monetary benefit. Examination of these data shows that a rural hospital can successfully employ a state-of-the-art intervention when there is a population in need and an infrastructure in place.

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Compliance with ethical standards

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