



Research Article

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Comparison of Outcomes of Per-Oral Endoscopic Myotomy for Primary Achalasia Among Geriatric and Younger Patients: A Single Center Study

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Abstract

Background: Geriatric patients with primary achalasia have high disease burden and are often left untreated. POEM is a promising treatment for older patients with high treatment success rate and safety. Locally, there is no existing study on the comparison of POEM outcomes in young versus older patients.

Methods: Records of all primary achalasia patients who underwent POEM at our institution between January 2015 to December 2021 were reviewed. Patients were categorized into two groups: young (Sample size was determined using equivalence test. Fisher's Exact Test or Pearson's Chi Square Test, and Mann Whitney U Test for independent samples were employed to analyze the difference of categorical and continuous variables, respectively, between the two age groups. A p-value <0.05 was considered as statistically significant.

Results: The study included 49 patients: Group A (n=40) and Group B (n=9). The technical success rate is 100% since all patients on both groups had complete myotomy without significant differences in operative time, submucosal tunnel length, esophageal and gastric myotomy, and number of endoscopic clips. Clinical success of POEM was similar for both groups, as all patients have an Eckardt score of 0 post-POEM. Adverse event rate was low and mild in terms of severity, with no significant difference between the two age groups. The median length of hospital stay was 5 days for both age groups.

Conclusion: This study demonstrated high clinical and technical success rate as well as low complication rate of POEM among older patients with primary achalasia similar to the results in the younger age group. With this, we recommend POEM as a safe and effective treatment option for elderly patients with primary achalasia.

Keywords

POEM, Achalasia, Geriatrics

Introduction

The impact of achalasia as a chronic esophageal motility disorder significantly affects the quality of life due to symptoms of occasional chest discomfort, dysphagia and regurgitation. Its pathology is secondary to inadequate relaxation of the lower esophageal sphincter (LES) due to progressive ganglion cell degeneration in the myenteric plexus [1].

The effect of advancing age in esophageal motility among patients with achalasia is still unknown. What is known is that these symptoms cause greater impairment and debilitation among elderly [1]. It was noted that healthy older people have lower population of ganglion cells in the intramural myenteric plexus which was associated with decreased esophageal peristalsis [2].

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All available treatment options for achalasia are aimed at facilitating bolus transit across the LES which includes pharmacotherapy, chemical paralysis through botulinum toxin A (Botox) injection, mechanical dilation through pneumatic balloon dilation, and surgical dilation [3].

Among younger patients with achalasia, Laparoscopic Heller myotomy (HM), albeit an invasive procedure, is considered as the treatment of choice due to high success rate [4]. Its safety among geriatric achalasia patients still needs further analysis. The high risk of perforation at 4-7% in interventions such as balloon dilation and laparoscopic HM is of concern among the geriatric population [1,5]. Other treatment options including pharmacologic regimen most of the time offer short-lived results and incomplete relief which wanes through time [3].

The development of Per-oral Endoscopic Myotomy (POEM) by Dr. Inoue, et al., in 2010 revolutionized the treatment strategies in achalasia. In a meta-analysis on the comparative efficacy of POEM and Heller myotomy by Park, et al., it showed that when it comes to short-term efficacy, POEM was superior to HM. However there was no noted difference in reflux symptoms and pH level monitoring [4].

The disease burden of achalasia among geriatric patients remains as there is still controversy on the treatment recommendation in this particular subgroup hence there is a large percentage of them left untreated [6]. Due to presence of comorbidities, treatment options offered to geriatrics include mechanical dilation, Botox injection and pharmacotherapy. Barriers to undergoing endoscopic or surgical interventions may be due to perceived risks and complications among elderlies.

In review of 148 achalasia patients who underwent POEM in Japan, 37% of which (n=55) were elderly (aged ≥ 65 years) while 63% were younger (<65 years), it showed evidence of safety and effectiveness of POEM for patients of advanced age. The operative details, outcomes and treatment success rates were comparable in the two groups. Since it is a minimally invasive approach, the findings in this study suggest that POEM, with its promising results, can be a preferred therapeutic intervention among geriatrics with achalasia [6].

However, currently, there are insufficient studies regarding treatment options for primary achalasia in the local setting. In this study, we aim to compare the success rate and safety of POEM for primary achalasia among elderly versus younger patients with the hope to contribute to existing evidence on the clinical indication of POEM.

Materials and Methods

This is a retrospective, cross-sectional, analytical study conducted at De La Salle University Medical Center, in Dasmariñas, Cavite, Philippines through chart review from the Medical Records Section. The Institutional Review Board and Ethics Committee approved the study. Admitted patients with primary achalasia who underwent POEM at DLSUMC from January 2015 to December 2021 were included. Pediatric patients (0 to 18 years old), adults (19 to 64 year old) and elderly patients (≥ 65 years old) with achalasia were included

and analyzed. Inclusion Criteria include: 1) patients diagnosed with primary achalasia and underwent POEM; 2) patients may or may not have prior treatment for primary achalasia; 3) patient must be admitted at DLSUMC for POEM between January 2015 to December 2021. Patients diagnosed with other esophageal disorder such as Diffuse esophageal spasm, Barrett's esophagus etc. were excluded.

A total of 49 patients met the inclusion criteria and were included in the study analysis. Information gathered include clinicodemographic profile including age, gender, achalasia subtype, duration of symptoms, comorbidities and prior treatments received from primary achalasia. Data on assessing clinical success included pre and post POEM Eckardt score. Technical success data on the other hand included information on completion of myotomy, procedural time, and myotomy length (esophageal and gastric). The rate and severity of different adverse events were also included such as esophageal hemorrhage/perforation, hypotension, pleural effusion, lung infection, conversion to surgical procedure. Lastly, the length of hospital stay was also included in chart review.

Statistical analysis

This study primarily aimed to determine if there is significant difference in the success rate and safety of POEM in primary achalasia among younger patients vs geriatrics. The outcome variables include clinical success, technical success, rate and severity of adverse events and length of hospital stay. Confounding variables include patient's coexisting comorbidities, prior treatments received for primary achalasia and the duration of achalasia symptoms. These confounders may be difficult to eliminate since there is a limited number of primary achalasia patients who underwent POEM in the institution and patient characteristics. Continuation of this study to include more subjects will help improve the effect of these confounders.

Distributions of continuous variables, such as the pre- and post-POEM Eckardt scores, procedural time, submucosal tunnel length, myotomy length, number of endoscopic clips and length of hospital stay, were presented using the median and the first and third quartiles. Meanwhile, categorical variables, such as age group, gender, achalasia subtype, comorbidities, prior treatments for primary achalasia, completion of myotomy and the presence and severity adverse events were described using frequency counts and percentages.

Fisher's Exact Test or Pearson's Chi Square Test, and Mann Whitney U Test for independent samples were employed to analyze the difference of categorical and continuous variables, respectively, between the two age groups. Statistical analyses were conducted using SPSS v26. For this study, a p-value <0.05 was considered as statistically significant.

Results

The study included 49 patients divided into 2 groups: Group A young patients (n=40) and Group B geriatrics (n=9). Table 1 shows the demographics and baseline characteristics of primary achalasia patients. The median age of patients in

Table 1: Demographics and baseline characteristics

Variables	All Patients n = 49		Group A (< 65 years old) n = 40		Group B (>= 65 years old) n = 9		p-value
	<i>n (%) or median (Q1, Q3)</i>	<i>n (%) or median (Q1, Q3)</i>	<i>n (%) or median (Q1, Q3)</i>	<i>n (%) or median (Q1, Q3)</i>			
Age at POEM, in years	34.0	(29.0, 58.0)	31.0	(26.3, 45.8)	72.0	(67.0, 73.0)	0.000^a
Gender							0.463 ^b
Male	25	(51.0%)	19	(47.5%)	6	(66.7%)	
Female	24	(49.0%)	21	(52.5%)	3	(33.3%)	
Achalasia subtype							0.130 ^c
Type I	12	(24.5%)	8	(20.0%)	4	(44.4%)	0.195 ^b
Type II	9	(18.4%)	8	(20.0%)	1	(11.1%)	1.000 ^b
Type III	1	(2.0%)	0	(0.0%)	1	(11.1%)	0.184
Unspecified	27	(55.1%)	24	(60.0%)	3	(33.3%)	0.266
Pre-POEM Eckardt Score	11.0	(9.0, 12.0)	11.0	(9.3, 12.0)	10.0	(8.5, 12.0)	0.533 ^a
Comorbidities							
Hypertension	9	(18.4%)	4	(10.0%)	5	(55.6%)	0.006^b
Diabetes mellitus	3	(6.1%)	1	(2.5%)	2	(22.2%)	0.083 ^b
Respiratory disease	2	(4.1%)	2	(5.0%)	0	(0.0%)	1.000 ^b
Others	4	(8.2%)	2	(5.0%)	2	(22.2%)	0.149 ^b
None	35	(71.4%)	31	(77.5%)	4	(44.4%)	0.096 ^b
Prior treatments							
Botox	4	(8.2%)	3	(7.5%)	1	(11.1%)	0.569 ^b
Pneumatic dilation	10	(20.4%)	8	(20.0%)	2	(22.2%)	1.000 ^b
Botox and dilation	2	(4.1%)	1	(2.5%)	1	(11.1%)	0.337 ^b
None	37	(75.5%)	30	(75.0%)	7	(77.8%)	1.000 ^b

Note: p-values in bold are statistically significant

^a Mann-Whitney U Test

^b Fisher's Exact Test

^c Pearson's Chi Square Test

Table 2: Technical and Clinical Outcomes of POEM

Variables	All Patients n = 49		Group A (<65 years old) n = 40		Group B (>=65 years old) n = 9		p-value
	<i>n (%) or median (Q1, Q3)</i>		<i>n (%) or median (Q1, Q3)</i>		<i>n (%) or median (Q1, Q3)</i>		
Technical success							
Procedural time (minutes)	90.0	(67.0, 122.0)	85.0	(67.0, 114.3)	95.0	(63.5, 167.0)	0.339 ^a
Submucosal tunnel length (cm)	15.0	(13.0, 18.0)	15.5	(13.0, 18.0)	15.0	(12.5, 16.5)	0.352 ^a
Esophageal myotomy length (cm)	10.0	(10.0, 12.0)	10.0	(10.0, 11.8)	10.0	(9.0, 13.5)	0.657 ^a
Gastric myotomy length (cm)	3.0	(3.0, 3.0)	3.0	(3.0, 3.0)	3.0	(2.0, 3.0)	0.255 ^a
Number of endoscopic clips	7.0	(6.0, 8.5)	8.0	(6.0, 8.8)	7.0	(6.5, 9.5)	0.909 ^a
Duration of hospital stay (days)	5.0	(4.0, 6.0)	5.0	(4.0, 6.0)	5.0	(4.0, 5.5)	1.000 ^a
Adverse effects							
Esophageal hemorrhage	1	(2.0%)	1	(2.5%)	0	(0.0%)	1.000 ^b
Lung infection	4	(8.2%)	4	(10.0%)	0	(0.0%)	1.000 ^b
Pneumoperitoneum/ Pneumomediastinum	2	(4.1%)	1	(2.5%)	1	(11.1%)	0.337 ^b
Presence and severity of adverse effect/s							0.889 ^c
No adverse effect	43	(87.8%)	35	(87.5%)	8	(88.9%)	1.000 ^b
Grade 1	5	(10.2%)	4	(10.0%)	1	(11.1%)	1.000 ^b
Grade 2	1	(2.0%)	1	(2.5%)	0	(0.0%)	1.000 ^b

^a Mann-Whitney U Test

^b Fisher's Exact Test

^c Pearson's Chi Square Test

the young age group was 31 years old (Q1-Q3: 29-58), while that in the geriatric age group was 72 years old (Q1-Q3: 67-73). No significant difference was found in the gender distribution and the percentage of patients with diabetes mellitus, respiratory disease and other comorbidities between the two age groups. However, there is a higher percentage of geriatric patients with hypertension compared to the young age group (55.6% Vs. 10.0%, $p = 0.006$). Meanwhile, none of the patients have cerebrovascular or cardiovascular diseases.

No significant difference between the young and geriatric age groups was found in the distribution of achalasia subtypes and in the percentage of patients that underwent treatments prior to POEM. The severity of symptoms pre-POEM, as measured by the Eckardt score, was also similar between both groups (11.0 Vs. 10.0, $p = 0.533$).

Table 2 demonstrates the technical and the clinical outcomes of POEM among patients with primary achalasia. POEM peri-procedural analysis showed no significant differences in operative time (85 min Vs. 95 min, $p = 0.339$), submucosal tunnel length (15.5 cm Vs. 15.0 cm, $p = 0.352$), esophageal myotomy length (10 cm Vs. 10 cm, $p = 0.657$), gastric myotomy length (3.0 Vs. 3.0, $p = 0.255$), and number of endoscopic clips (8 Vs. 5, $p = 0.909$) between the young and geriatric patients, respectively. Thus, the technical success rate is 100% since all patients had complete myotomy. The median length of hospital stay was 5 days for both age groups ($p = 1.000$).

Clinical success of POEM was similar for both groups, as all patients have an Eckardt score of 0 post-POEM. Moreover, a similar percentage of young and old patients did not report an AE within 24 to 48 hours post-POEM (87.5% Vs. 88.9%, $p = 1.000$). For those with AE post-POEM, no significant difference between the two age groups was found in the percentage who had esophageal hemorrhage, lung infection and pneumoperitoneum or pneumomediastinum. In terms of severity, most have only developed a Grade 1 AE (10% Vs. 11.1%, $p = 1.000$), while only one patient, belonging in the young age group, had a Grade 2 AE. Meanwhile, none of the patients have developed hypotension, esophageal perforation, pleural effusion, atelectasis, or have converted to a surgical procedure.

Discussion

This is the first local study comparing the outcomes of POEM among younger and elderly patients with primary achalasia. Based on the results, both age groups had similar and high clinical and technical success rates upon comparing the outcomes of POEM. Symptom relief post POEM was remarkable correlating with the effectiveness of POEM for primary achalasia even for elderly patients. Low complications and severity were observed with no life-threatening conditions encountered.

Primary achalasia peaks during the third to fourth decade of life and later after the sixth decade of life which coincides with the mean age at POEM of the patients in this study, 31 and 72 years old respectively [7]. The disease burden among geriatric patients remains due to presence of

comorbidities, perceived risks and complications of definitive surgical intervention and controversy on the treatment recommendation for the advanced age group [6]. Majority of the patients on both age groups, more than 75%, were treatment-naïve prior to POEM. This coincides with previous findings that about 60% of achalasia patients older than 75 years old were left untreated [2,6]. Among the elderly patients with previous treatment, botox injection (11%) and pneumatic dilation (22%) or the combination of both (11%) were documented. No patient underwent Heller's myotomy which is the considered as the definitive treatment for primary achalasia [4].

The presence of comorbidities among patients with primary achalasia is associated with several challenges in performing complex procedures such that they have less physiological reserve on top of underlying comorbidities making them at higher risk for surgical procedures and anesthesia [5,6]. In terms of comorbidities, there is a significantly higher percentage of elderly patients with hypertension ($p = 0.006$) and 22.2% of them had diabetes mellitus. No patients reported to have cardiovascular or cerebrovascular disease. Despite having comorbidities, only 11.1% of the elderly age group developed AE, specifically pneumomediastinum post POEM with low severity (grade 1). In the young age group, only one patient developed grade 2 AE with lung infection. In an international multicenter study by Chen, et al., in 2017, they evaluated the clinical efficacy and safety of POEM in 76 octogenarians which showed adverse event in 14.5% of patients in which majority were graded as mild and only one event graded as severe [5].

In terms of duration of hospitalization, this study noted no significant difference on the days of hospital stay of patients with a median of 5 days ($p = 1.000$). This however is relatively longer in comparison to the median length of stay of patients of 1 day for both age groups who underwent POEM in a study by Sanaka, et al., [1].

Clinical success defined as Eckardt score of ≤ 3 post POEM was achieved such that all patients in both age groups had a score of 0. The pre POEM Eckardt score was not statistically significant ($p = 0.533$). Moreover, technical success defined as completion of myotomy was observed in all patients also on both age groups. Its variables such as procedural time, submucosal tunnel length, esophageal and gastric myotomy length and, number of endoscopic clips showed no significant difference between the two age groups. The study by Sanaka, et al., in 2020 on POEM for geriatric patients with achalasia showed similar treatment success rates between the two groups (94.9% young Vs. 94.7% in old patients) [6]. This is also consistent with the results of the multicenter study of Chen, et al., technical and clinical success rate with 93.4% and 90.8%, respectively [5].

Our study has several limitations which can be improved with subsequent follow-up studies. First, this is a retrospective study such that follow-up period of at least 6 months and long-term outcomes were not included. The number of patients included in the study was not well distributed in between the two age groups despite including all patients who underwent

POEM during the specified study period. Lastly, clinical success is best documented using high resolution esophageal manometry which however was not performed in all included patients since it is expensive and not readily available in the institution where the study was conducted [8-21].

Summary Box

This study demonstrated high clinical and technical success rate as well as low complication rate of POEM among older patients with primary achalasia, similar to the results in the younger age group. Hence, to answer the research question, we accepted the null hypothesis that there is no significant difference in the success rate and safety of POEM for both younger and older age groups. With this, we recommend POEM as a safe and effective treatment option for elderly patients with primary achalasia. With the perceived limitations, subsequent follow-up study is recommended.

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