

## Life after per-oral endoscopic myotomy: long-term outcomes of quality of life and their association with Eckardt scores

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**Background and Aims:** The clinical efficacy of per-oral endoscopic myotomy (POEM) has been commonly established by reduction in the Eckardt score (<3) after the procedure. However, achalasia can lead to significant impairment in the patient's quality of life that may go beyond the 4 classic achalasia symptoms as measured by the Eckardt score. The aims of our study were to evaluate the effect of POEM on short-term and long-term health-related quality of life (HRQOL) and to assess the association between HRQOL and Eckardt scores.

**Methods:** Single-center, prospective, cohort study of consecutive POEMs during a 3-year period. Eckardt and HRQOL scores as measured by the short-form survey questionnaire (SF-36) were obtained at baseline and at various intervals after POEM. Comparison of the mean scores was described by using univariate linear regression. The association between Eckardt scores and HRQOL were calculated by using a linear, mixed-model analysis.

**Results:** POEM was performed in 143 consecutive patients (54% male; mean  $\pm$  standard deviation [SD] age, 56.9  $\pm$  17.9 years). At long-term follow-up (mean 16.4 months, range 12-40), both the HRQOL baseline mental and physical component scores improved significantly from 61.5  $\pm$  2.2 to 71.2  $\pm$  3.6; ( $P < .021$ ) and from 55.8  $\pm$  2.2 to 63.6  $\pm$  3.3; ( $P = < .034$ ), respectively. Mixed-model analysis showed a significant association between Eckardt and all HRQOL scores ( $P < .001$ ).

**Conclusion:** POEM improved all dimensions of HRQOL as measured by the SF-36 survey at both short-term and long-term follow-up. A strong association was seen between Eckardt scores and all HRQOL domains. Further studies with the use of disease-specific HRQOL instruments are warranted. (Clinical trial registration number: NCT01832779.) (Gastrointest Endosc 2018; ■:1-6.)

Achalasia is a rare esophageal motility disorder characterized by loss of inhibitory motor neuron function. This impairment results in aperistalsis and loss of lower esophageal sphincter (LES) relaxation, leading to diminished food bolus propulsion.<sup>1</sup> At present, all durable treatment options are aimed at the disruption of the LES. Until recently, laparoscopic Heller myotomy and pneumatic dilation were considered the standard first-line therapy for achalasia.<sup>2</sup> Per-oral endoscopic myotomy (POEM), initially introduced in clinical practice in 2008 by Inoue et al,<sup>3</sup> has now become an established therapy because

of its minimally invasive approach along with demonstrated short-term to mid-term efficacy and excellent safety profile.<sup>4-6</sup> Additionally, when compared with laparoscopic Heller myotomy, POEM has been shown to have comparable clinical outcomes with less morbidity and shorter hospital length of stay.<sup>7</sup>

The typical clinical manifestations of achalasia include dysphagia, chest pain, regurgitation, and weight loss, which are all captured by the Eckardt score.<sup>8</sup> Therefore, the Eckardt score is routinely used to assess the clinical efficacy of any achalasia therapy including POEM. Nonetheless, it is

*Abbreviations:* HRQOL, health-related quality of life; LES, lower esophageal sphincter; POEM, per-oral endoscopic myotomy; QOL, quality of life; SF-36, short form 36.

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well-recognized that achalasia is a systemic condition that can lead to significant debilitation and impairment of quality of life (QOL)<sup>9,10</sup> that may go beyond the 4 cardinal achalasia symptoms, thereby impacting patients' physical and emotional well-being. Data on the impact of POEM on QOL are very limited because most outcome measurements traditionally have been measured by the Eckardt score. Thus, the aim of our study was to evaluate the effect of POEM on short-term and long-term health-related quality of life (HRQOL) parameters and to assess the association between Eckardt scores and HRQOL over time.

## METHODS

### Patients

This was a single-center prospective cohort study that was approved by the Institutional Review Board at the University of Florida (trial number: NCT01832779). All patients signed procedure and research informed consent forms. The study period was from March 2013 to October 2016. Preoperative evaluation included upper endoscopy, timed barium esophagram, and high-resolution manometry. Patients were classified according to the Chicago Classification of esophageal motility disorders.<sup>11</sup> Patient criteria for inclusion were as follows: underwent POEM as clinically indicated, able to provide research informed consent, and age  $\geq 18$  years. Patient criteria for exclusion were unwillingness and/or inability to provide informed consent, pregnancy, or any contraindication for the POEM procedure.

### POEM procedure

The POEM procedure was performed as previously described.<sup>3,12</sup> In summary, all patients were given a clear liquid diet for 48 hours before the procedure. A proton-pump inhibitor and prophylactic intravenous antibiotics were initiated on the day of the procedure. Perioperative anticoagulation and antiplatelet therapy were managed according to the current American Society for Gastrointestinal Endoscopy guidelines.<sup>13</sup> All procedures were done with the patient under general anesthesia with endotracheal intubation and positive pressure ventilation. Carbon dioxide was used for endoscopic insufflation.

A mucosal entry point was established, and submucosal tunneling was then done followed by selective circular muscle myotomy in the esophagus and full-thickness myotomy at the LES and cardia. Closure of the mucosal entry was then achieved with placement of endoscopic clips. Postoperatively, all patients were hospitalized for observation and underwent a CT esophagram the day after their procedures. If no leak was detected, then oral intake was initiated.<sup>14</sup>

### Data collection

Patient and procedure data were collected prospectively and entered into a de-identified database. Data obtained

before the procedures included demographic characteristics, type of achalasia, Eckardt score, duration of disease, prior endoscopic or surgical therapy, and HRQOL scores. Procedural and immediate post-procedural data included technical success, intraoperative adverse events, procedure duration, hospital length of stay, and delayed adverse events. On discharge, all patients who underwent POEM were scheduled for clinic follow-up at 1 to 3 months, 6 to 9 months, 12 months, and then yearly. Eckardt and HRQOL scores were obtained at each clinic visit and were recorded in our database.

### Measured outcomes

Clinical success was determined by the Eckardt score and defined by post-POEM score  $\leq 3$  measured at the last available follow-up visit. HRQOL scores were measured by the short form 36 (SF-36) questionnaire. SF-36 is a validated generic HRQOL survey that aims to capture the emotional and physical aspects of a patient's life. This HRQOL construct has shown to be applicable in comparing relative disease burden and treatment effect between general and diseased populations.<sup>15</sup> SF-36 is designed to assess 8 health care domains that include the following: general health, bodily pain, social functioning, emotional well-being, energy and/or fatigue, role limitation because of emotional problems, role limitation because of physical health, and physical functioning. Every domain is scored from 0 to 100, with a higher number indicating a greater perceived quality of life. Composite scores were calculated by using means of physical (general health, bodily pain, role limitation because of physical health, and physical function) and emotional and/or mental (social functioning, emotional well-being, energy and/or fatigue, role limitation because of emotional problems) relevant domains to create both a physical component summary and a mental component summary score, as previously described.<sup>16</sup> Eckardt and SF-36 scores were then evaluated both at baseline and at specified time intervals after POEM: 1 to 3 months, 6 to 9 months, 12 months, and then annually thereafter. Adverse events were recorded, and their severity was graded according to the American Society for Gastrointestinal Endoscopy lexicon.<sup>17</sup>

### Statistical analysis

Descriptive statistics for categorical variables were summarized by using proportions, and those for continuous variables were summarized by using means and standard deviations (SD). One-way analysis of variance was used to describe univariate associations between a continuous response variable and a categorical exposure variable of interest. The assumption of equal variances between groups was tested by using Bartlett's statistic method. To correct for multiple testing, the Bonferroni method was used when the exposure variable had more than 2 groups. Multiple linear regression with robust standard errors accounting for heterogeneity between clusters was initially

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