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Initial experience with peroral endoscopic myotomy for treatment of achalasia in children☆☆☆

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ABSTRACT

Background: Achalasia is a primary esophageal motility disorder characterized by aperistalsis of the esophagus and failed relaxation of the lower esophageal sphincter that presents rarely in childhood. The peroral endoscopic myotomy (POEM) procedure is an emerging treatment for achalasia in adults that has recently been introduced into pediatric surgical practice.

Methods: This is a prospective case series of all children referred to Stanford University Lucile Packard Children's Hospital with manometry-confirmed achalasia who underwent a POEM procedure from 2014 to 2016.

Results: We enrolled 10 subjects ranging in age from 7 to 17 years ($M = 13.4$). The mean pre- and 1-month post-procedure Eckardt scores were 7 ($SD = 2.5$) and 2.4 ($SD = 2$) ($p < 0.001$), respectively. The median procedure time for the entire cohort was 142 min (range 60–259 min) with ongoing improvement with increased experience ($R^2 = 0.6$, $p = 0.008$). There were no major adverse events.

Conclusion: The POEM procedure can be successfully completed in children for the treatment of achalasia with demonstrated short-term post-operative improvement in symptoms. The adoption of advanced endoscopic techniques by pediatric surgeons may enable development of unique intraluminal approaches to congenital anomalies and other childhood diseases.

Level of evidence: Treatment Study – Level IV

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Achalasia is a primary esophageal motility disorder characterized by aperistalsis of the esophagus and failed relaxation of the lower esophageal sphincter [1,2]. The estimated worldwide incidence of achalasia in children is 0.02–0.31 cases per 100,000 with male predominance and a mean age at diagnosis of 10 years [3,4]. The most common presenting signs and symptoms of achalasia in children are dysphagia, regurgitation, heartburn, chest pain, and weight loss [5].

The heterogeneity in disease presentation often results in misdiagnosis and delays in definitive management. There are several subtypes of achalasia that are categorized based on high-resolution manometric findings. Type I disease is characterized by absent distal esophageal pressurization, Type II disease is characterized by panesophageal pressurization, and Type III disease is characterized by 2 or more spastic contractions with or without periods of pressurization [6]. Subtype

classification of patients with achalasia is clinically important, as those with Type II disease are more likely to respond positively to operative intervention.

Traditional management of achalasia includes graded esophageal dilation or laparoscopic esophageal myotomy with fundoplication [7]. Botulinum toxin injection, calcium channel blockers, or long-acting nitrates are less effective long-term treatments for achalasia that are used in select patients who are not candidates for definitive surgical management. The peroral endoscopic myotomy (POEM) procedure is an emerging treatment for achalasia in adults that was first described by Pasricha et al. in 2007 in a porcine model and by Inoue et al. in 2010 in humans [8,9]. Although outcomes in adults have demonstrated promise, this procedure has only recently been introduced into pediatric surgical and gastroenterology practices [10–13]. Given the novelty of performing this procedure in children, additional studies are needed to obtain a better understanding of post-operative outcomes, challenges in training, and effective translation of the POEM procedure from adults to children. The purpose of this case series was to evaluate our initial experience with performing POEM procedures in children and to characterize endoluminal functional imaging pre- and post-myotomy.

☆ Conflicts of interest: None

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1. Methods

This was a single-institution, single-surgeon case series of all children <18 years of age referred to Stanford University Lucile Packard Children's Hospital from 2014 to 2016 with manometry-confirmed achalasia who underwent a POEM procedure. The pediatric surgeon performing the procedure had completed an additional year of fellowship training in adult minimally invasive surgery including endoscopy and extensive training sessions specifically in the POEM technique in live animal and human cadaveric models. Initial sessions were performed with the assistance of experienced adult surgeons with ongoing sessions completed to gain confidence and efficiency in each step of the procedure. The training period was ended after performance of 5 cases without complication in a similar timeframe to that of experienced surgeons. Finally, an adult surgeon with experience in the POEM procedure was present for the first clinical case.

The study was approved by the Stanford University Institutional Review Board. Children and their families were counseled regarding standard endoscopic and surgical treatments for achalasia and availability of POEM according to protocol. Children and families who consented to proceed with the investigative study underwent the POEM procedure. Demographic, pre- and post-procedure validated Eckardt scores, intra-operative endoluminal functional imaging before and after myotomy, and procedural details were collected and analyzed using descriptive statistics and independent- and paired-sample *t*-tests. The "learning plateau" and "learning rate" were derived according to the methods described by Feldman et al. by performing a nonlinear regression inverse curve fit ($Y = a - b/X$) with consecutive case number as the independent variable and procedure time as the dependent variables [14]. The "learning plateau" was defined as the theoretical best procedure duration that could be achieved with infinite experience ($X = \infty$) and the "learning rate" was defined as the number of procedures needed to be performed to achieve 90% of the learning plateau ($Y = 0.9a$). In addition, we performed a linear regression to evaluate effects of procedure duration with experience. Statistical significance was determined based on two-sided design-based tests evaluated at an alpha of 0.05.

1.1. Endoluminal functional imaging

Endoluminal functional imaging, or endoluminal planimetry of the gastroesophageal junction was obtained using a commercially available EndoFLIP® (Endoluminal Functional Lumen Imaging Probe) Imaging System (Crospon Medical Devices, Galway, Ireland). The imaging

system consists of a probe that is capable of measuring intraluminal cross-sectional area and pressures using volume controlled distension [15,16]. Representative images of data obtained from the EndoFLIP® Imaging System are shown in Fig. 1. Pre- and post-procedure luminal diameter, area, and distensibility were measured to a goal pressure of 30 mmHg.

1.2. Operative technique and post-operative care

The operative technique performed was similar to that described by Pauli et al. with slight modifications to accommodate structural anatomic size differences in children [17]. The procedures were performed using a standard upper endoscope with carbon dioxide insufflation and oblique plastic cap fixated at its distal end. Using Indigo carmine, a submucosal bleb was developed approximately 8–10 cm proximal to the gastroesophageal junction (GEJ) at 3–4 o'clock. A 1–2 cm mucosotomy was then made and a submucosal tunnel developed along the esophagus past the GEJ by at least 2 cm. The scope was withdrawn from the tunnel and extent of dissection confirmed by retroflexion within the stomach. The scope was then re-inserted into the submucosal tunnel and the myotomy was performed. Finally, the mucosotomy was approximated with endoscopic clips. The children were kept nil per os (NPO) for 24 h and subsequently underwent a water-soluble contrast esophagram to assess for esophageal leak and passage of contrast distally prior to discharge. All children were discharged on a full liquid diet for 2 weeks, transitioned to a regular diet thereafter, and were prescribed a proton pump inhibitor for 6 months.

2. Results

We enrolled 10 subjects from 2014 to 2016 between the ages of 7 and 17 years (mean = 13.4 years). Additional demographic and disease subtype characteristics are shown in Table 1. The POEM procedures were completed in all cases without the need for conversion to laparoscopic or open surgical approaches. The median (range) submucosal tunnel length was 12 (10–13) cm, the median myotomy length was 7 (4–9) cm, and the median number of endoscopic clips placed was 8.5 (6–12). The median (range) procedure time for the entire cohort was 142 (60–259) minutes with ongoing improvement with increased experience ($R^2 = 0.6$, $p = 0.008$) (Fig. 2). The learning plateau was 107.1 procedure duration minutes ($R^2 = 0.195$, $p = 0.2$) and the number of cases performed needed to achieve 90% of the learning plateaus was 9.6. Mean pre- and post-procedure endoluminal functional imaging

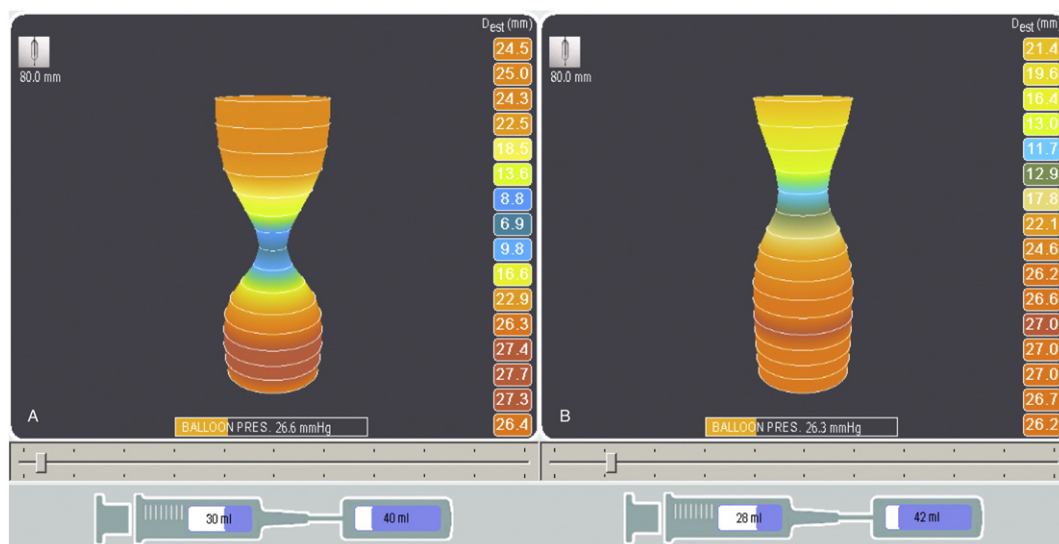


Fig. 1. Representative functional endoluminal imaging data (A) pre- and (B) post-myotomy.

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