# Outcomes and quality-of-life assessment after gastric per-oral endoscopic pyloromyotomy (with video) CME

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**Background and Aim:** Gastric per-oral endoscopic pyloromyotomy (GPOEM) is emerging as a promising option for the treatment of gastroparesis. This study assessed outcomes and quality of life after GPOEM for gastroparesis, performed in an endoscopy unit at a major tertiary referral center.

**Methods:** We performed a retrospective review of patients who had undergone GPOEM from June 2015 to July 2016. Data were collected from electronic medical records and included patient demographics, endoscopy records, hospitalization records, clinic visits, and electronic messages. Scores for the Short Form 36 (SF36) and Gastroparesis Cardinal Symptom Index (GCSI) were obtained pre-procedure (16 patients), at 1 month (16 patients), at 6 months (13 patients), and at 12 months (6 patients) after the GPOEM procedure was performed.

**Results:** Sixteen consecutive patients, 13 women and 3 men (mean age, 44.76 ± 14.8 years), who underwent GPOEM were enrolled. GPOEM was technically successful in all cases. Thirteen of 16 (81%) patients had a significant improvement in the mean GCSI after GPOEM: 3.40 ± 0.50 before the procedure (16 patients) to 1.48 ± 0.95 ($P = .0001$) at 1 month (16 patients), 1.36 ± 0.9 ($P < .01$) at 6 months (13 patients), and 1.46 ± 1.4 ($P < .01$) at 12 months (6 patients) follow-up. Mean duration of the procedure was 49.7 ± 22.1 minutes. Mean myotomy length was 2.94 ± 0.1 cm. Mean length of hospital stay was 2.46 ± 0.7 days. No adverse events occurred with GPOEM. The SF36 questionnaire demonstrated a significant improvement in quality of life in several domains that was sustained through 6-months' follow-up. Mean 4-hour gastric retention on gastric emptying scans decreased from 62.9% ± 24.3% to 17.6% ± 16.7% ($P = .007$) after GPOEM.

**Conclusions:** GPOEM results in improvement in the overall symptoms of gastroparesis measured by GCSI, objective assessment of improvement in gastric emptying, and improvement in multiple domains on validated quality-of-life inventories in SF36 over a follow-up period of 6 months. (Gastrointest Endosc 2017;86:282-9.)

*(footnotes appear on last page of article)*

## INTRODUCTION

Gastric per-oral endoscopic pyloromyotomy (GPOEM) is emerging as a promising novel treatment option for gastroparesis, a chronic debilitating motility disorder with few therapeutic options.[1-3] Many factors have been identified as the cause of the disease, including diabetes mellitus, GI infection, vagal nerve injury, and neurologic diseases such as multiple sclerosis; however, a significant proportion of the patients have idiopathic gastroparesis without any underlying cause.[1,3] Patients with gastroparesis typically have postprandial fullness, nausea, retching, vomiting, bloating, abdominal distension, and upper abdominal discomfort. These symptoms have detrimental effects on patients' quality of life and represent the main target of therapy. Traditionally, gastroparesis is managed by a stepwise algorithm beginning with dietary modifications, medical therapy including prokinetic, antiemetic,

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and analgesic agents, and endoscopic interventions such as intrapyloric botulinum injection, leaving surgical interventions such as gastric electrical stimulation, laparoscopic pyloroplasty, and gastrostomy as a last resort.[1,4] More recently, surgical pyloroplasty[5] and transpyloric stenting[6] have been shown to be beneficial, suggesting that pyloric spasm has a role in gastroparetic symptoms. However, management of gastroparesis is still quite challenging. The medication for gastroparesis, metoclopramide, approved by the U.S. Food and Drug Administration has short-term effects, and its use is also associated with neurologic adverse effects.[7] Many patients do not respond to conventional treatment and surgical interventions.[5,8,9] In addition, surgery for gastroparesis is an invasive approach that may not be suitable for many patients.

Since its first introduction in humans followed by encouraging results in small case series,[10,11] GPOEM has become an appealing minimally invasive therapeutic modality for patients with refractory symptoms.[5,8,9] Given its novelty, existing data on the procedural technique, safety, and efficacy are sparse. The purpose of this study was to systematically assess the clinical outcomes and improvement in quality of life after GPOEM in patients with severe gastroparesis symptoms who have been refractory to or could not tolerate conventional therapy.

## METHODS

### Patients, SF36, GCSI

This is a retrospective study evaluating the clinical benefits of GPOEM in patients with medically refractory gastroparesis. The study was approved by the Institutional Review Board at Emory University. Beginning in June 2015, patients who were evaluated at our institution for refractory gastroparesis and not responding to dietary modifications and prokinetic medications were offered GPOEM based on a protocol approved by the Institutional Review Board. Patients who failed the gastric electrical stimulator therapy were also offered the procedure. All patients had nausea and vomiting as their predominant symptom. Exclusion criteria included patients with an inability to tolerate general anesthesia, patients with any contraindications to an endoscopy, patients with narcotic dependence, and patients with abdominal pain as the predominant symptom because of concern for overlapping functional pain. All patients who underwent GPOEM until July 2016 were included. Preoperative assessment of all patients included confirmation of gastroparesis by a 4-hour gastric emptying scan (GES) and standard upper GI endoscopy to exclude gastric outlet obstruction. The data collected included patient demographics, cause and duration of gastroparesis, previous failed treatments, GCSI, endoscopic data, length of myotomy, total duration of procedure, and intraoperative and postoperative adverse events. SF36 data were obtained after patients gave consent and before GPOEM (16 patients), and follow-up SF36 was completed at 1 month (16 patients), 6 months (13 patients), and 1 year (6 patients) after GPOEM. For scheduling practicality, the follow-up period may vary within a month of the allotted follow-up time point per study protocol.

The GCSI is based on 3 categories and 9 subsets: postprandial fullness/early satiety (4 subsets); nausea/vomiting (3 subsets), and bloating (2 subsets).[12] The score for each index ranged from 0 to 5. A total score (range, 0-45) was obtained for each patient and reported as a mean GCSI in this study.

The primary outcome of the study was clinical success rate. Clinical success was defined as an improvement in symptoms measured by a decrease in mean GCSI, a significant decrease in at least 2 subsets of cardinal symptoms, and no hospitalization for gastroparesis-related symptoms. Secondary outcomes were status in retention percentages on 4-hour GES, quality-of-life (SF36) inventories, and adverse events.

### GPOEM procedure

An interventional endoscopist, assisted by a trainee in most cases, performed the procedures. All of the procedures were performed with the patient under general anesthesia in the endoscopy suite, with the patient in supine position. Patients were kept on a clear liquid diet for 2 days before GPOEM and nothing by mouth after midnight the day of planned GPOEM. Patients were administered 4.5 g of piperacillin/tazobactam intravenously or 500 mg of levofloxacin intravenously (if allergic to penicillin) shortly before or during the procedure and during hospitalization on nothing by mouth. Oral antibiotics were prescribed on discharge for 5 days. A gastroscope (GIF-H190; Olympus, Tokyo, Japan) with a transparent distal cap attachment (MH 588; Olympus) was used for all procedures. The esophagus and the stomach were cleared of any retained particulate matter with water lavage and suction. A hook knife (Olympus) or an I-type Hybrid knife (Erbe, Tübingen, Germany) was used to perform mucosal incision. Carbon dioxide was used for insufflation (UCR; Olympus) in all cases throughout the procedure. A coagrasper (FD-411QR; Olympus) was used to achieve hemostasis in the submucosal plane in the soft coagulation mode (ERBE, Germany) when needed.

After a routine upper GI endoscopic examination, a mucosal entry site was identified consistently at the 5 o'clock position, approximately 5 cm proximal to the pylorus along the greater curvature of the stomach. The steps in GPOEM are described in our previous report.[13] Briefly, a submucosal bleb was created with a premixed methylene blue/normal saline (5 mL/500 mL) solution using a sclerotherapy needle (Olympus). A 2-cm mucosal incision was made with a hook knife or an I-type Hybrid knife. A submucosal tunnel was created by dissection of