

Safety and feasibility of same day discharge after per oral endoscopic pyloromyotomy in refractory gastroparesis: a pilot study

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Abstract

Background: Gastroparesis is a debilitating medical condition with limited treatment options. Gastric per-oral pyloromyotomy (G-POEM) has emerged as a promising treatment option with remarkable short-term clinical success shown in multiple studies. While the post-procedure protocol is not standardized across many centers, the majority of the centers observes these patients in the hospital after the procedure for monitoring. In this single-center prospective study, we evaluated the safety and feasibility of same day discharge after the G-POEM procedure.

Methods: All the patients with refractory gastroparesis undergoing G-POEM from October 2019 to March 2020 were enrolled. A total of 25 patients were enrolled in the procedure. Based on the pre-defined criteria, patients were either discharged on the same day after the procedure or admitted to the hospital for further observation. The patient and procedure-related data were extracted from the chart review. Univariate analysis was performed (chi-squared test) on categorical variables after organizing categorical variables as numeric counts or percentages. The student *t* test was performed on continuous variables after reporting as mean and standard deviation. For analysis with a smaller sample size, Fisher exact and Mann-Whitney tests were used.

Results: A total of 25 patients were enrolled. The technical success of G-POEM was 100% and clinical success was 80% (20/25) at 1-month follow-up. Of the 25 patients, 9 patients (36%) were discharged on the same day according to the procedure from the recovery unit. Of the remaining 16 patients who were admitted to the hospital post-procedure, 10 (40%) were admitted due to procedure-related causes while other admissions were either pre-planned or due to social reasons. The average Charlson comorbidity index was lower in the same day discharge group ($P < 0.05$). The number of patients requiring double myotomy was higher in the same day discharge group ($P < 0.05$). The overall complication rate of G-POEM in the study cohort was 12% (3/25) with all complications being mild without any severe adverse events.

Conclusion: G-POEM is a safe and effective method of treatment for refractory GP with higher clinical success in short-term follow-up. The same day discharge after G-POEM is safe and feasible in >50% of patients with close periprocedural monitoring.

Keywords: G-POEM; Pyloromyotomy; Gastroparesis; Gastric per-oral pyloromyotomy

Introduction

Gastroparesis is a chronic debilitating motility disorder of the stomach leading to refractory nausea, vomiting, abdominal fullness, early satiety, and in severe cases can also lead to failure to thrive.^[1,2] The overall incidence and prevalence of GP are on the rise with more recently approximately 150% rise in the prevalence affecting up to 4% of the population.^[1,3] The estimated prevalence of GP currently is 9.6 for males and 37.8 in females per 100,000 persons.^[4,5] Refractory GP is also associated with significant morbidity. The treatment options of refractory

GP are limited including medical management with metoclopramide, erythromycin, and domperidone. However, these options face significant limitations due to adverse effect profiles and tachyphylaxis.^[6] Other options, such as pyloric botulinum toxin, gastric pacemaker, and surgical pyloroplasty, have shown to have substantially limited data currently.^[7]

Gastric pyloromyotomy has emerged as a novel approach of pylorus-directed therapy and in the early phase has shown clinical success ranging from 70% to 90% in patients with refractory gastroparesis (RG).^[6,8-11] The first gastric per-oral pyloromyotomy (G-POEM) was reported in

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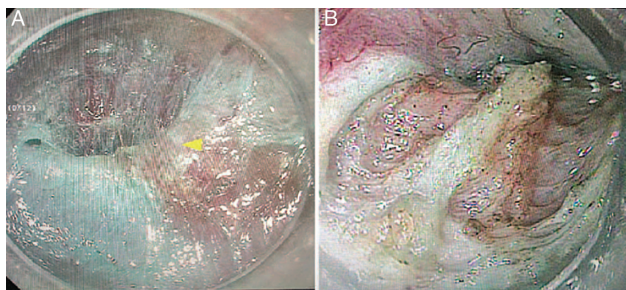


Figure 1: (A) Pyloric ring identified, (B) double myotomy incision.

human in 2013 and since then many specialized centers in the United States as well as globally have reported data on the outcomes of G-POEM.^[12] Most reported studies remain retrospective at this point. The G-POEM procedure is a spectrum of submucosal endoscopy. The steps of the procedure are outlined in [Figure 1] and involve creating a submucosal tunnel to identify the pyloric ring followed by direct myotomy on the pyloric ring.

Since the G-POEM is a recent advancement in the treatment of GP, there remains a lack of standardization in regard to pre-procedure, intra-procedural, and post-procedural steps across different centers offering this modality. As the reported data evolve, there seems to be a good agreement in terms of an outcome measure for G-POEM as a treatment option, however, guidelines for pre- and post-procedural care for these patients still appear to be quite variable. One such data point is post-procedural disposition. As G-POEM is a relatively new concept and in theory an endoscopic substitute for surgical pyloromyotomy, the usual practice across different centers including ours is to admit patients post-procedure for observation.^[13,14] The primary reason for admission is to watch for any post-procedural complications and overnight monitoring of these patients. Our practice used to be similar to this as well. However, as our experience in performing the G-POEM procedure has grown, we have adopted to develop a protocol to facilitate same day discharge after G-POEM patients in suitable patients.

In this study, we evaluate the safety and feasibility as well as outcomes of same day discharge after the G-POEM procedure in our center. To our knowledge, this is the first report of such study.

Methods

Ethical approval

This study was approved by the Ethics Committee of Emory University (No.00089650). Written informed consent was obtained from all the participants.

G-POEM procedure

Pre-procedure care

Our protocol is to see all patients with RG in our clinic, to discuss their disease course, and to discuss the procedure along with the risk and benefits in detail. RG was defined

as gastroparesis that failed dietary and medical therapy. Once patients understand and agreed to proceed with the procedure after our demonstration, they were scheduled in 2 to 4-week period depending on the severity of their symptoms. Antiplatelet and anticoagulation medications were held as per American Society for Gastrointestinal Endoscopy guidelines for an elective procedure. All patients underwent pre-operative evaluation with the anesthesiology department as routine. They remained on a clear liquid diet for 72 h before the procedure and nil per os (NPO) from midnight on the day of the procedure to ensure adequate gastric clearance on the procedure day.

Intra-procedural

All the procedures were performed by the experienced senior endoscopist (Q.C.) with experience in performing >200 G-POEM procedures before the study. All patients received antibiotics before the procedure against gram-negative coverage. All procedures were done under general anesthesia and in the supine position. All procedures were done with a gastroscope (GIF-H190; Olympus, Tokyo, Japan) with a distal cap attachment (MH-588). A pre-mixed solution using 500 mL of normal saline, 2 mL of methylene blue, and 10 ml of 1:10,000 epinephrine was prepared and used for lifting and separation of the mucosal and muscular layers. We used exclusively CO₂ for insufflation during the procedure. Once the upper endoscopy exam was confirmed and any ulcerated/obstructive lesions were excluded, the G-POEM procedure was performed with the following steps: (1) A mucosotomy incision was made at 5 o'clock orientation approximately 5 cm proximal to the pylorus in the antrum area after the mucosa was lifted by injection of the mixed methylene solution. A Hybrid A knife was used for the incision. (2) The mucosotomy incision was extended and the submucosal tunnel was entered. (3) The submucosal dissection was performed till the pyloric ring was reached. (4) Once the pyloric ring was identified [Figure 1], either single or double direct myotomy was performed on the ring. (5) The submucosal tunnel was then closed with the placement of Endoclips (Micro-Tech, Nanjing, China). If any intra-procedural bleeding was encountered, bleeding was controlled with the cautery function of the hybrid knife or with the use of coagulation grasper forceps. Throughout the procedure, the nursing staff continued the abdominal exam every 5 min to evaluate for abnormal abdominal distension and crepitus. The anesthesia staff and the proceduralist closely monitored the PCO₂ and peak pressure on the ventilator as a rise in these parameters is an early indicator of capnoperitoneum. At the end of the procedure, the final examination was performed. If no significant abdominal distention or subcutaneous emphysema was noted and as far as peak pressures were within normal range, patients were extubated and moved to a recovery unit.

Post-procedure

The post-procedure care algorithm is shown in [Figure 2]. All patients were observed in the post-procedure area for 2 h. Any patient who experienced any abdominal pain requiring a dose of intravenous (IV) narcotics or any significant complication during the procedure (excessive

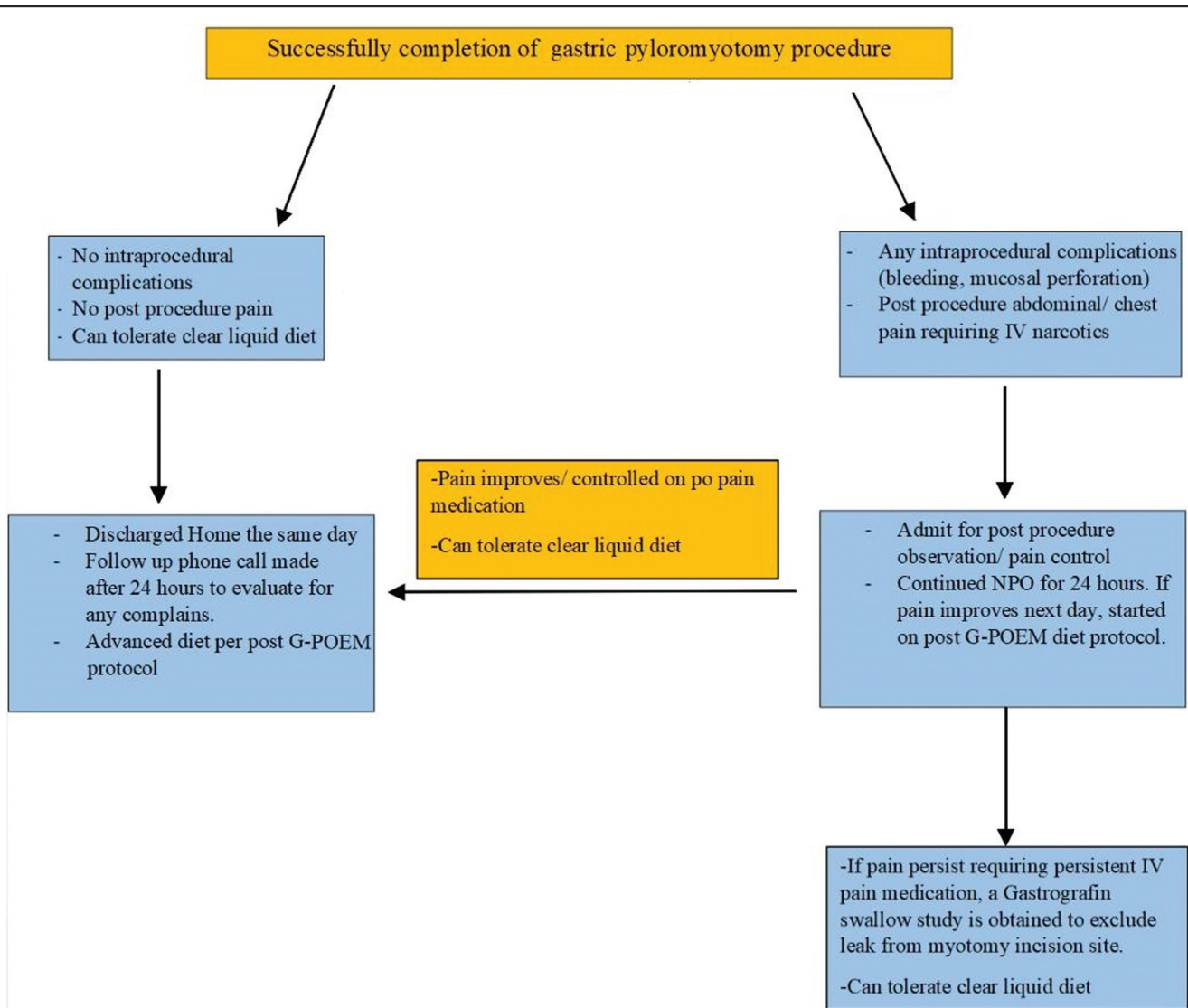


Figure 2: Algorithm of post-procedure disposition after G-POEM in patients with RG. G-POEM: Gastric per-oral pyloromyotomy; IV: Intravenous; NPO: Nil per os; RG: Refractory gastroparesis.

bleeding, suspected full-thickness myotomy concerning for contained perforation) were admitted for post-procedure observation. Few patients were planned for admitting before the procedure due to comorbid conditions. If the patients were admitted, they were kept NPO for a day and given a trial of clear liquids the next morning. The patients who experienced no post-procedural pain or any other issues in the recovery unit were given a trial of clear liquids and if tolerated well then they were discharged on the same day. All patients were given a total of 5 days of antibiotics. They were kept on clear liquids for 3 days followed by 3 days of full liquid diet then 4 days of soft diet then advancing to a regular diet. If the patients were discharged on the same day, the next day a phone call was made to check on the patients. All patients were followed in the gastrointestinal (GI) clinic after 4 weeks with a repeat gastric emptying study (GES).

The adverse events were divided into two categories: intra-procedural and post-procedural. The post-procedural

adverse events were then again divided into immediate post-procedure (<24 h) and delayed complications (>48 h).

Data collection

The data were collected prospectively in our G-POEM patient registry. The data were then analyzed retrospectively from the period of October 1, 2019 to March 31, 2020. A total of 25 patient-related data including demographics, disease duration, pre- and post-procedure Gastroparesis Cardinal Symptom Index (GCSI) and GES as well as procedure-related factors such as duration of the procedure, trainee involvement, any adverse events, and post-procedure length of stay (LOS) were also collected.

Statistical analysis

Univariate analysis was performed (chi-squared test) on categorical variables after organizing categorical variables as numeric counts or percentages. The student *t* test was

performed on continuous variables after reporting as mean and standard deviation. For analysis with a smaller sample size, Fisher exact and Mann–Whitney tests were used.

Results

Patient characteristics

A total of 25 patients underwent the G-POEM procedure for RG from October 1, 2019 to March 31, 2020. The average age was 48.8 ± 16.5 years. Of the 25 patients, 88% were female and 44% had diabetic gastroparesis. The average duration of the disease was 38.3 months. The average pre-procedure GCSI score was 3.9 ± 0.8 [Table 1].

Procedure outcomes

The procedure was successfully performed in all 25 patients (Technical success 100%). The average duration of the procedure was 41 ± 16 min. The trainee was involved in 100% of the procedures. Of the 25 patients, 15 (60%) had single myotomy and 10 (40%) had double myotomy.^[14] The average post-procedure GCSI score at 1-month follow-up was 2.0 ± 0.9 and at 1 month, clinical success (defined as an average of 1 point reduction in average GCSI score) was achieved in 20 out of 25 patients (80%).

Adverse events

All the patients were monitored closely for an adverse event. The patients who were discharged on the same day of the procedure were called by the care team the next day to evaluate for any complaints. All patients were given access to the patient portal and 24/7 emergency line to

contact the on-call GI physician for any issues. All the patients were seen in the GI clinic at the 4-week follow-up with repeat GES.

There were two patients with minor intra-procedural complications. One patient had intra-procedural bleeding with a mild amount of bleeding which required coagulation grasper forceps to control the bleeding. Another patient had a mucosal injury while submucosal dissection. The defect was closed with the placement of endoclips. There was one early post-procedure complication. One patient developed mild capnoperitoneum. However, patient was able to be extubated and capnoperitoneum resolved within 72 h and was safely discharged from the hospital. Thus, the overall complication of combined intra-procedural and post-procedure complication rate was 12%, however, all the complications were mild and there were no severe AEs noted in this study cohort. Out of nine patients who were discharged the same day of the procedure, one patient developed delayed pain 48 h after the procedure. The patient came to the ER and had unremarkable blood work and imaging. The patient was discharged with 3 days of narcotics and did well after discharge.

Same day discharge vs. post-procedure admits

A total of 9 out of 25 (36%) patients were discharged on the same day. Sixteen (64%) patients required post-procedure admission for further monitoring with an average LOS of 1.06 ± 0.25 days. Out of 16 patients requiring admission, three were admitted for social concerns due to lack of adequate support at home, and another patient who lived 4 h away from the hospital without a ride to drive back the same day. From the rest of the 13 patients, three were planned admits due to concern of multiple medical comorbidities and careful monitoring. A total of ten patients were admitted for complaints of abdominal pain in the recovery area requiring a dose of IV narcotics (8 patients, 32%), minor intra-procedural complications (2 patients, 8%). Comparison between same day discharge group and post-procedure admit group is shown in Table 1. The average Charlson comorbidity index (CCI) was lower in patients of the same day discharge group when compared with the patients requiring admission post-procedure (2.4 ± 1.8 vs. 4.2 ± 1.7 , $P = 0.03$). In the same day discharge group, a significantly higher number of patients had double myotomy when compared with patients requiring post-procedure admission (67% vs. 25%, $P = 0.04$). Otherwise, there was no difference in average age, gender, the average duration of the disease, or the procedure or average GCSI score between these two groups [Table 2].

Discussion

G-POEM has emerged as a novel therapy for RG. The concept of G-POEM is derived from surgical gastric pyloromyotomy. The initial mucosotomy incision followed by submucosal dissection provides safe access to the pyloric ring and pyloromyotomy without the need for any external incision.^[15,16] As the field of submucosal endoscopy evolves, G-POEM has shown a promising minimally invasive approach to treat patients with RG.

Table 1: Characteristics of the patients with RG (n = 25).

Characteristics	Total
Average age, years	48.8 ± 16.5
Gender	
Male	3 (12)
Female	22 (88)
Average pre-procedure GCSI score	3.9 ± 0.7
Nausea/vomiting	3.7 ± 0.8
Early satiety	4.0 ± 0.8
Bloating	3.7 ± 1.1
Duration of disease, months	
<12	7
12–24	6
24–48	8
>48	4
Previous therapy	
Metoclopramide	24 (96)
Domperidone	4 (16)
Botox	6 (24)
Gastric pacemaker	1 (4)

Data are presented as n, n (%) or mean \pm standard deviation. GCSI: Gastroparesis Cardinal Symptom Index; RG: Refractory gastroparesis.

Table 2: Comparison of same day discharge group to a post-procedure admission group.

Characteristics	Same day discharge	Post-procedure admit	P value
Average age, years	57.3 ± 15.3	44.1 ± 15.4	0.06
Gender			0.23
Male	2 (22)	1 (6)	
Female	7 (78)	15 (94)	
Average duration of disease, months	29.5	43.2	0.35
Etiology			0.08
Diabetes	6 (67)	5 (31)	
Non-diabetic	3 (33)	11 (69)	
Average duration of the procedure, min	39.7 ± 7.9	41.8 ± 19.3	0.71
Type of myotomy			0.04
Single	3 (33)	12 (75)	
Double	6 (67)	4 (25)	
Average GCSI score			
Pre-procedure	4.1 ± 0.5	3.7 ± 0.8	0.25
Post-procedure	2.1 ± 0.6	1.9 ± 1.0	0.52
CCI	2.4 ± 1.8	4.2 ± 1.7	0.03
Reasons for admission	-	Abdominal pain: 12 Social reasons: 4	

Data are presented as *n* (%) or mean ± standard deviation. CCI: Charlson comorbidity index; GCSI: Gastroparesis Cardinal Symptom Index.

One of the benefits of the minimally invasive approach, the integrated part involves post-procedure care after the procedure. Currently, while there are no defined guidelines for post-G-POEM care, at most centers including ours, the current practice is to admit patients after the procedure for observation.^[14] To our knowledge, this pilot study is the first report evaluating the safety of same day discharge after G-POEM.

We enrolled a total of 25 patients with RG who underwent G-POEM. A total of nine out of 25 (37%) patients were able to be discharged on the same day without any issues. There were no issues or complications in the patients who were discharged home the same day who were followed up with 24 to 48 h follow-up phone calls made by the care team. Of the remaining 16 patients, three patients were planned admits due to multiple comorbidities and three patients were admitted due to lack of ride to go home on the same day. Hence, a total of 15 out of 25 patients (60%) could be discharged on the same day if we exclude the admission for social reasons. From the reported literature, the majority of the centers currently have adopted practice to admit all patients undergoing G-POEM. As per the most recent systemic review summarizing data from ten studies on G-POEM including 292 patients, the average LOS was reported to be 3.4 days ranging from 1.3 to 6 days.^[17] The overall complication rate reported in the same systemic review was 6.8%; however, the systemic review did not comment on mild vs. severe AEs. A prior systemic review on global outcomes published by our team had shown an average incidence of severe AEs of 6.7%.^[6] In our study, while the overall complication rate was 12%, all the complications were mild and did not require any further intervention. We did not encounter any serious adverse events in our patient cohort. It is possible that our low rate of severe complications might have facilitated same day discharge as well as shorted average LOS than reported in prior studies; the complication rate might also

vary based on the center experience as well as multiple patient and procedural factors.

Upon comparing the group with same day discharge after the procedure to the group with patients requiring post-procedure admission, the latter had a significantly higher CCI score (4.2 ± 1.7 *vs.* 2.4 ± 1.8, *P* = 0.03). This is in line with multiple prior studies that have shown higher rates of hospitalization and higher LOS in patients with higher CCI admitted to the hospital for post-surgical care or acute medical condition.^[18,19] In our study, while two patients were planned to have elective admission after the procedure due to higher comorbidities (CCI of six and seven, respectively), the difference in CCI remained significant between the two groups even after excluding these two patients. This is a critical finding as perhaps, if further proven as a reliable indicator in larger studies in the future, we can use CCI to plan elective admit *vs.* same day discharge while planning the G-POEM procedure. Also, identifying patients with low CCI who might be suitable for same day discharge can reduce the overall healthcare cost and offset the cost associated with this procedure. Patients in the same day discharge group also had a higher proportion of double myotomy when compared with patients requiring post-procedure admission (67% *vs.* 25%, *P* = 0.04). A double myotomy is a technique we have adopted where two approximately 2 cm long myotomy incisions are made on pyloric ring side by side when compared with single myotomy where only one incision is made. We have published our experience comparing single *vs.* double myotomy where we observed higher clinical success in patients with double myotomy.^[14] We hypothesize that double myotomy might offer higher relaxation of the pyloric ring by more effective disruption of the pyloric ring and less pyloric edema and eventual fibrosis in long term after the procedure leading to less pain and nausea after the procedure. However, this remains a hypothesis and the exact mechanism remains unclear.

In this study, we report our experience in the safety and feasibility of same day discharge after G-POEM. If G-POEM can be offered as an outpatient procedure without the need for post-procedure hospital admissions, this will be a significant evolution in this field of submucosal endoscopy. This can help to avoid exposing patients to the risk of hospital stay, reduce the burden on healthcare costs by avoiding expenditure required for a hospital stay as well as offset the cost associated overall with the procedure. The study does have several limitations. It is a retrospective analysis from our prospective database. All the procedures were performed by QC with experience of performing >200 G-POEMs and might not be applicable in other centers with limited experience with performing G-POEM. Finally, our sample size is too small for effective logistic regression, hence causal association cannot be established. This is the first pilot study showing the feasibility of G-POEM as an outpatient procedure. Further larger-scale prospective studies will help further to validate this finding for continued evolution in this field.

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