Surgical Endoscopy (2023) 37:2247–2252
https://doi.org/10.1007/s00464-022-09437-x

2022 SAGES ORAL

[S156] Comparing outcomes of per-oral pyloromyotomy and robotic pyloroplasty for the treatment of gastroparesis

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Received: 30 March 2022 / Accepted: 4 July 2022 / Published online: 28 July 2022

Abstract

Background Gastroparesis is characterized by delayed gastric emptying without a significant obstructive pathology and is estimated to effect more than 5 million adults in the United States. Therapies for this condition are divided into two categories: gastric electrical stimulation or pyloric therapies to facilitate gastric emptying. Pyloric procedures include pyloroplasty, a well-documented procedure, and per-oral endoscopic myotomy (POP), a relatively novel endoscopic procedure that disrupts the pyloric muscles endoscopically. There is a paucity of literature comparing the two procedures. The aim of this study is to compare the outcomes of these two techniques.

Methods Under an IRB protocol, data were collected prospectively from September 2018 through April 2021 at our institution for patients undergoing POP ($n=63$ patients) or robotic pyloroplasty (RP) ($n=48$). Preoperative and postoperative data including sex, race, age, BMI, and Gastroparesis Cardinal Symptom Index (GCSI) score were analyzed using univariate and multivariate analysis.

Results There was no significant difference in sex, age, and BMI for both cohorts, but patients with RP were more likely to have private insurance, pre-op reflux, and PPI ($p<.05$ for all). Patients who underwent POP had significantly shorter operative time compared to RP (median 27 min vs 90, $p<0.001$). The average change between preoperative and postoperative GCSI scores was significantly decreased for both interventions (POP mean = 8.2, RP 16.8, $p<0.001$ both). However, comparing both data, RP has significantly better improvement in postoperative GCSI score than POP in both univariate ($p<0.001$) and multivariate analysis ($p=0.030$). This was reflected in the individual symptoms with nausea ($p<0.001$), ability to finish meal ($p=0.037$), abdomen visibly larger ($p=0.037$) and bloating ($p=0.022$) all showing improvement in both groups, but with RP having a more significant decrease in the scoring of these symptoms than POP. There was no significant difference in the number of postoperative complications (POP 19% vs RP 13%, $p=0.440$).

Conclusion Even though both interventions are significantly associated with improvement of symptoms in patients with gastroparesis, our data demonstrates that robotic pyloroplasty has a superior response in comparison to per-oral endoscopic myotomy for the management of these symptoms. Per-oral pyloromyotomy has a similar complication rate to robotic pyloroplasty with a shorter operative time.

Keywords Pyloroplasty · Per-oral pyloromyotomy · POP · Gastroparesis

Gastroparesis is a syndrome of objectively delayed gastric emptying in the absence of mechanical obstruction. Its cardinal symptoms include nausea, vomiting, early satiety, belching, bloating, and/or upper abdominal pain [1]. The epidemiology of gastroparesis is somewhat ill defined, as many patients are given the diagnosis-based purely on symptoms and lacking confirmatory tests. However, the data suggest that the overall prevalence is about 0.16 percent, effecting approximately 5 million adults in the United states [2]. It also appears that the incidence is increasing, likely secondary to increased testing as well as to the increased incidence of diabetes, particularly among children and young adults. This syndrome arises from several known etiologies including diabetes mellitus, viral infections, medications,

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post-surgical (vagotomy), neurologic disease, autoimmune disease, and idiopathic causes.

Initial treatment of gastroparesis tends to be a combination of antiemetics and promotility medications, as well as dietary modifications. Surgical intervention is an option after failure of attempted conservative management of symptoms. Surgical intervention is divided into 2 categories: gastric electrical stimulation or pyloric therapies. The concept of pyloric therapy is to facilitate gastric emptying. Surgical pyloric therapies include pyloroplasty and the relatively novel per-oral endoscopic myotomy (POP) [3].

There is a paucity of data in the literature comparing these the two techniques of pyloroplasty (RP) and per-oral pyloromyotomy. The purpose of this study is to compare the effectiveness of endoscopic per-oral pyloromyotomy to the established pyloroplasty, using the Gastroparesis Cardinal Symptom Index (GCSI) score [4].

Methods

After approval from the Institutional Review Board, patient data were prospectively collected from September 2018 through April 2021 at our institutions for patients undergoing per-oral pyloromyotomy (POP) or robotic pyloroplasty (RP). Data were stored in a secure HIPAA compliant, password protected, database. Patients were offered per-oral endoscopic myotomy or pyloroplasty and procedures were performed per-patients' wishes. It is noted that the majority of non-governmental insurance policies regarded POP as a non-reimbursable experimental procedure. Patients with non-governmental insurance wishing for a POP were scheduled for a pyloroplasty. Patient preoperative characteristics including sex, race, age, BMI, reflux, presence of diabetes, and GCSI score were analyzed. Perioperative variables included readmission, length of operation, minor and major post-operative complications and death. Postoperatively, the GCSI score and other variables were prospectively collected. Follow-up was at 1 month and 3 months. Those who were lost to follow-up were excluded from the final analysis.

The Gastroparesis Cardinal Symptoms Index is the most common validated survey done to evaluate the severity of gastroparetic symptoms [4]. This is done by scoring three different categories: nausea and vomiting, post-prandial fullness and bloating. This done on a 0 to 5 value point system (with 0 being no symptoms and 5 severe)(Table 1). Gastric emptying scintigraphy (GES) was used as a diagnostic tool for preoperative evaluation and enrollment, using technetium-99 m sulfur colloid labeled egg meal. This is measured at baseline and then at subsequent hourly intervals [5]. Postoperative GES was not utilized in our analysis because a significant number of patients were unwilling or unable to undergo this test.

Procedural details

Robotic pyloroplasty

Patients are placed in the supine position. A total of four robotic ports are placed in the upper abdomen and a 12 mm port is placed in the lower quadrant. To confirm the exact position of the pylorus, an upper endoscopy is performed, and the duodenum is intubated. An incision is made in a longitudinal fashion from the stomach through the mucosa across the pylorus and on to the duodenal bulb for a total of 4 cm. This is then closed in the described Heineke-Mikulicz technique. The endoscope is then utilized to perform an air leak test, after which it is withdrawn. Patients are admitted and an upper GI series is performed post-operative day 1, after which a clear liquid diet is started. Typical length of stay is 48 h.

Endoscopic per-oral pyloromyotomy

Patients are placed in the same supine position. Under general anesthesia, an endoscope is passed through the oral cavity into the stomach and the pylorus is identified. A submucosal bleb is created along the lesser curvature using an endoscopic needle and colloid solution, 3 cm proximal to the pylorus. A mucosotomy is created. A submucosal tunnel is then formed

Table 1 Gastroparesis Cardinal Index Score

Symptom scale	Symptom	None	Very mild	Mild	Moderate	Severe	Very severe
	Nausea	0	1	2	3	4	5
Nausea/vomiting	Dry heaving	0	1	2	3	4	5
	Vomiting	0	1	2	3	4	5
	Stomach fullness	0	1	2	3	4	5
Fullness/early satiety	Not able to finish a meal	0	1	2	3	4	5
	Fullness after eating	0	1	2	3	4	5
	Loss of appetite	0	1	2	3	4	5
	Bloating	0	1	2	3	4	5
Bloating/distention	Belly visibly larger	0	1	2	3	4	5

utilizing both blunt dissention and monopolar cautery. The circular fibers of the pyloric muscle are identified and divided using electrocautery. The myotomy is extended to the level of the duodenum. The muscularis of the duodenum is clearly identified by being much thinner than the muscularis of the pylorus. The endoscope is removed from the tunnel and clips are utilized to close the mucosotomy. After a post-operative upper GI series is performed, the patients are sent home the same day.

Statistical methods

Pre-operative characteristics and demographics were summarized and compared between surgical groups using Fisher test for binary/categorical variables, two sample *t*-test for approximately normal continuous variables, and the Mann Whitney U test for non-normal variables. For patients with a recorded pre-operative and post-operative GCSI score, the score difference (pre-operative minus post-operative) was computed; positive score changes represented a reduction in symptoms and a better outcome. The paired *t*-test was used to investigate change in GCSI from pre-operative to post-operative within each group, and a difference in symptom improvement by surgery type was considered using a two sample *t*-test with the difference scores. The correlation between pre-operative GCSI score and GCSI score change was investigated using the overall cohort. (The correlations stratified by surgery type are similar, so results are not included.) Multivariate linear regression for GCSI score change was performed using surgery type and any significant confounders. Symptom change was investigated by taking the difference between the pre-operative 0 to 5 Likert values minus the value of post-operative Likert values[4]. Improvement within symptom category was assessed using the Wilcoxon signed rank test (non-parametric version of the paired *t*-test) on symptom change scores for each surgery type, and the difference in symptom improvement between surgery types was considered by the Mann Whitney U test on symptom change scores. Due to multiple comparison concerns, false discovery rate adjusted *p*-values were utilized across the 9 symptom categories for each comparison type (within POP; within RP; between POP and RP). Throughout, we considered an available case analysis using only patients with known data for each comparison; however, we did investigate whether dropout was associated with demographics or other pre-operative characteristics. All statistical analysis was performed using the R statistical software, version 3.6.2.

Results

There were a total of 63 patients (57%) who underwent per-oral pyloromyotomy and 48 patients (43%) who underwent robotic pyloroplasty over the sample time period. Preoperative characteristics are summarized in Tables 2 and 3. The two surgery groups were similar in terms of most demographic and clinical characteristics. Patients receiving the robotic pyloroplasty had higher rates for preoperative gastroesophageal reflux symptoms (79% vs 13% for POP, $p < 0.001$) and proton pump inhibitor use (82% vs 24%, $p < 0.001$),while patients receiving POP surgery had higher rates of government insurance (75% vs 44% for pyloroplasty, $p = 0.002$). While not statistically significant, there was some evidence that pyloroplasty had more severe baseline symptom burden as measured by GCSI (pyloroplasty: mean = 3.83 ± 0.67; POP: 3.56 ± 0.82; $p = 0.060$).

Differences in perioperative characteristics are also shown in Tables 2 and 3. POP had a statistically significant shorter operative time than pyloroplasty (median 27 vs median 90 min; $p < 0.001$). Minor post-operative complications occurred in both groups and included pneumonia, fever and ileus, with no significant differences between the 2 cohorts ($p = 0.440$). There was 1 major complication (leak following a POP), identified 24 h postoperatively. This was repaired in an open fashion. The only death in this series was the same patient, who died from a self-administered overdose of promethazine at home post-operative day 20. Postoperative readmissions were significantly higher in the POP group compared to RP (19% POP had at least one readmission vs 6% pyloroplasty, $p = 0.044$).

Table 2 Pre-operative and perioperative characteristics by surgery type

	POP		RP		p-value
	N	%	N	%	
	63	57	48	43	
Male sex	10	16	4	8	0.265
Black/AA race	9	14	3	6	0.226
Government insurance	47	75	21	21	**0.002**
ASA classification					0.331
2	14	22	12	26	
3	46	68	34	72	
4	6	10	1	2	
Reflux	8	13	34	79	**< 0.001**
Proton pump inhibitors	15	24	37	82	**< 0.001**
Diabetic	18	29	14	31	0.832
Hypertension	19	30	18	40	0.31
Post-Op Complication	12	19	6	13	0.44
Major Complication/Death	1	2	0	0	1
Number of post-op re-admits					**0.044**
0	50	81	45	94	
1	9	15	3	6	
2	3	5	0	0	

Bold numbers indicate statistical significance

Table 3 Pre-operative and perioperative characteristics by surgery type

	POP		RP		*p*-value
Age at surgery (mean, SD)	43.9	14.1	47.4	12.4	0.165
BMI at surgery (mean, SD)	28.7	8.2	27.3	5.5	0.657
GCSI Pre-op score (mean, SD)	3.55	0.83	3.83	0.69	0.06
Length of operation (minutes, range)	27	13–34	90	75–111	**< 0.001**

Bold numbers indicate statistical significance

Table 4 Post-operative characteristics for patient with follow-up

	POP (*n* = 47/56%)		Pyloroplasty (*n* = 37/44%)		*p*-value
	Mean	Standard deviation	Mean	Standard deviation	
GCSI post-op score	2.53	1.22	1.95	1.14	***0.026***
Change in GCSI score	0.92	1.18	1.87	1.15	***< 0.001***

Bold numbers indicate statistical significance

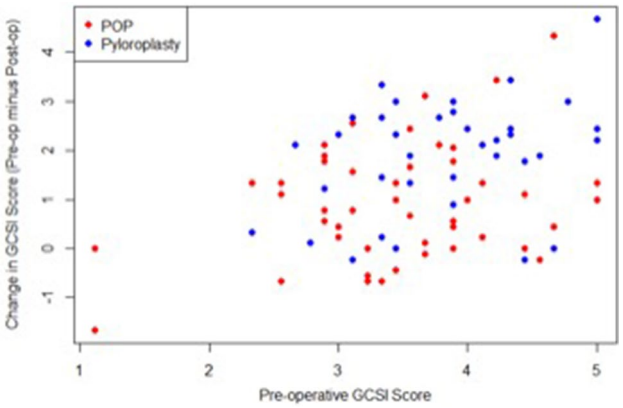

Fig. 1 Scatterplot for Pre-op GCSI score versus Score Change

Table 5 Multivariate linear Regression Model for GCSI Score Change (Pre-op minus Post-op)

	Beta estimate	95% confidence interval	*p*-value
Pyloroplasty	0.77	0.08, 1.47	***0.03***
Pre-op GCSI score	0.46	0.14, 0.79	***0.006***
Private insurance	−0.26	−0.8, 0.28	0.338
Pre-op reflux	0.01	−0.87, 0.95	0.929
Pre-op PPI use	0.03	−0.78, 0.84	0.945

Bold numbers indicate statistical significance

Follow-up data were available for 74 of the initial 111 patients. Comparing those lost to follow-up, to those with postoperative data, there was no significant difference with respect to type of surgery ($p = 0.912$), pre-operative GCSI ($p = 0.133$), or any other demographic other than race (African-American patients had a higher rate of loss to follow-up). Patients with follow-up data, therefore, appear to be representative of the original cohort. Post-operative characteristics are shown in Table 4. RP patients have significantly lower post-op GCSI scores than POP patients ($p = 0.026$). Considering the difference between pre-operative and post-operative GCSI scores, POP patients showed a mean decrease of 0.91 point (SD = 1.18, paired *t*-test $p < 0.001$), while RP patients showed a mean decrease of 1.87 points (SD = 1.16, paired *t*-test $p < 0.001$). Hence, RP recipients had a significantly greater decrease in GCSI scores than POP patients (Delta = 0.95, 95% CI 0.44 to 1.47, $p < 0.001$).

As shown in Fig. 1, on average, patients with higher/worse pre-operative GCSI scores saw larger improvements in the GCSI score (correlation = 0.37, $p < 0.001$). Multivariate linear regression was performed controlling for the confounders of the pre-operative GCSI score, namely insurance status, presence of reflux symptoms, and PPI use. The correlations stratified by surgery type are similar, so results are not included. Table 5 further shows that RP is associated with a significantly greater score decrease than POP (beta = 0.77; 95% CI = 0.08 to 1.47, $p = 0.030$) when controlling for private insurance, reflux symptoms and PPI use. Rates of symptom continuation and recurrence between groups were not statistically different (Table 6; $p = 0.110$ and 0.498, respectively). Four patients after POP crossed over to RP for inadequate control of symptoms. Cross over happened between 6 and 12 months after POP.

Individual symptoms within the GCSI score were also examined (Table 5). Both groups showed statistically significant decreases in each symptom. However, when comparing the symptom improvement between groups, the RP group had a significantly greater decrease in GCSI score than POP for the following symptoms: nausea ($p = 0.024$), ability to finish a meal ($p = 0.024$), loss of appetite ($p = 0.024$), bloating ($p = 0.024$), and belly visibly larger ($p = 0.035$).

Table 6 Change in individual symptom from pre-op to post-op by surgery type

Symptom	POP		Pyloroplasty		Difference between groups
	N = 37 (57%)		*N* = 28 (43%)		
	Change (median range)	Within group *p*-value	Change (median/range)	Within group *p*-value	
Nausea	1 [0–2]	0.001	2 [1–3]	< 0.001	**0.024**
Dry heaving	1 [0–2]	0.05	2 [0–3]	< 0.001	0.189
Vomiting	1 [0–1]	0.002	1.5 [0–2]	< 0.001	0.096
Gastric fullness	1 [0–2]	0.001	2 [1–3]	< 0.001	0.26
Ability to finish meal	1 [0–2]	0.001	2 [1–3]	< 0.001	**0.024**
Fullness after eating	1 [0–2]	0.001	2 [1–3]	< 0.001	0.088
Loss of appetite	1 [0–2]	0.023	2 [1–3]	< 0.001	**0.024**
Bloating	1 [0–2]	0.004	2 [1–3]	< 0.001	**0.024**
Belly visibly larger	1 [0–2]	0.001	2 [1–3]	< 0.001	**0.035**

Discussion

Gastroparesis is a chronically debilitating disease that leads to significant patient morbidity and is likely to increase in prevalence due to the increase in predisposing chronic medical conditions such as diabetes mellitus.

In the normal functional stomach, autonomic nerve impulses generated by the interstitial cells of Cajal (ICC) allow for a coordinated contraction of the muscularis, associated with relaxation of the pylorus and emptying of ingested contents into the small intestine. Histologic evaluation has confirmed the loss of the ICC and loss of enteric autonomic fibers as well as muscular fibrosis as the causes of gastroparesis [6–8]. In addition, multiple studies have demonstrated that pyloric dysfunction also plays a significant role in delayed gastric emptying [9, 10].

Initial treatment of gastroparesis is non-operative and includes medical therapies, such as prokinetic agents, and lifestyle modifications, such as smaller, more frequent meals [11]. Unfortunately, a significant number of patients have refractory symptoms despite these approaches. As a result, patients seek surgical options for treatment. Gastric electrical stimulation (GES), whereby a generator implanted in the anterior abdominal wall supplies electrical impulses through leads implanted in the antrum, had been an established treatment for gastroparesis [7, 12]. However, this procedure is not without its complications including hardware infection, erosion, and requirement for further surgery for battery replacement. Another downside for GES is the cost of the device, and the cost of surgery for battery replacements.

Pyloroplasty had been a known gastric emptying procedure for decades, utilized during surgical intervention after vagotomy for peptic ulcer disease and also in combination with esophagogastrectomy. Within the last few years, studies have supported pyloric muscle interruption, or pyloroplasty, as a reasonable alternative for the treatment of gastroparesis [13, 14], with sustained symptom relief in a significant number of patients [15]. More invasive surgical options have classically included rather morbid operations including subtotal or total gastrectomy, or gastric bypass with Roux-en-Y reconstruction [16, 17]. Symptom resolution from these interventions is not guaranteed and given their morbidity, delaying or avoiding them altogether would be preferable.

Per-oral endoscopic pyloromyotomy is a novel approach utilizing therapeutic endoscopy, described by Khashab et al. in 2013 [3]. Landreneau et al. compared a propensity matched cohort of 30 patients who underwent POP versus laparoscopic pyloroplasty and demonstrated a decrease in GCSI and gastric emptying rate in both groups. There was no significant difference in post-operative complications [18].

As seen in our results above, there is a significant difference in postoperative GCSI outcomes with both robotic pyloroplasty and per-oral pyloromyotomy (RP 3.83 to 1.95 $p < 0.001$; POP 3.56 to 2.51 $p < 0.001$). There was also a significant difference between the two groups with respect to the amount of improvement in GCSI score. Those with RP seemed to have a superior response compared to POP (p value < 0.001).

There are two hypotheses as to why this could occur. Principally, the full thickness 6 cm division of the muscularis and the subsequent transverse restructuring of the pyloric channel significantly increases the intraluminal diameter at the pylorus. During POP, the pyloric muscle is divided using cautery; however, a full thickness division is avoided, to prevent transmural perforation. This does not allow for the same increase in the intraluminal diameter, theoretically leading to lesser improvement in post-operative symptoms. A second theory is that there could be a small amount of residual pyloric muscle retained during POP. Although the pyloric muscle is clearly identified during the endoscopic procedure, the incision does not extend unto the duodenum. Similarly, division of the circular fibers does not extend as high up the lesser curvature, possibly resulting in some retained pyloric function.

It is not clear why there is a significant difference in the prevalence of preoperative reflux symptoms between the 2 cohorts.

Seventy nine percent of RP patients had reflux, versus 13% of POP. Gastroparesis is associated with gastroesophageal reflux disease because of poor emptying of gastric contents. Jehangir et al. [19] found a significant correlation between the severity of reflux symptoms and GCSI, a weak correlation between reflux symptoms and gastric emptying scans, and no correlation between reflux symptoms and pH-metry. Our data do not reflect this correlation, as there is no difference between preoperative GCSI scores in both cohorts.

Despite our data suggesting that the pyloroplasty is a superior intervention to decrease the GCSI score, individual symptom scores significantly improved in both cohorts. The improvement is, however, better in most categories if RP is performed (Table 5). This is likely secondary to the complete restructuring of the pyloric channel that occurs after pyloroplasty.

There are important limitations to our study. This was a single institution study performed by a single surgeon. Although this is a larger series with 63 patients, a larger cohort will allow a deeper analysis of the perioperative outcomes of this complex clinical condition. Many studies include a gastric emptying scan following pyloric therapies for gastroparesis. It was, however, difficult to obtain a post-operative gastric emptying scan, especially if patients were feeling better. As a result, few gastric emptying scans were performed and are not representative of our cohort. For this reason, the emptying scan not included in our study. This could make our series difficult to directly compare to other series on this disease. In addition, in some patients, only the total GCSI is recorded, explaining the discrepancy between the number of patients with recorded GCSI and number of patients with specific symptoms recorded.

Conclusion

Both robotic pyloroplasty and per-oral endoscopic pyloromyotomy are associated with significant symptom improvement in patients with gastroparesis. Robotic pyloroplasty has a superior response compared to per-oral endoscopic myotomy. Per-oral pyloromyotomy has a similar complication rate to robotic pyloroplasty with a shorter operative time.

Declarations

Disclosures Joshua Clapp, Jeremy Gaskins, Farid Kehdy has no conflicts of interest or financial ties to disclose.

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