

# Gastric peroral endoscopic myotomy versus surgical pyloromyotomy/pyloroplasty for refractory gastroparesis: systematic review and meta-analysis



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## ABSTRACT

**Background and study aims** Gastric per-oral endoscopic myotomy (G-POEM) has been recently compared with surgical techniques (i. e. pyloromyotomy and pyloroplasty) for managing patients with refractory gastroparesis. Given the varying results, we performed a systematic review and meta-analysis of available studies to assess the safety and efficacy of each technique.

**Patients and methods** A comprehensive review of the literature using the following databases was undertaken through July 29, 2022: MEDLINE, Embase, Web of Science, KCI – Koran Journal index, Global Index Medicus, and Cochrane. Comparative studies including case-control, cohort and randomized controlled trials (RCTs) were included. Random effects model using DerSimonian Laird approach was used to compare outcomes. Relative risk (RR) and mean difference (MD) were calculated for binary and continuous outcomes respectively.

**Results** A total of four studies with 385 patients (216 in the G-POEM group and 169 in the surgical group) were included. The mean age was 46.9 ( $\pm 3.41$ ) and 46.2 ( $\pm 0.86$ ) and the female proportion was 79.6% and 74.0% for the G-POEM and surgery group respectively. The mean procedural time (MD:  $-59.47$  mins,  $P < 0.001$ ) and length of hospital stay (MD:  $-3.10$  days,  $P < 0.001$ ) was significantly lower for G-POEM compared to surgery. The post procedure GCSI score (MD:  $-0.33$ ,  $P = 0.39$ ) and reduction in GCSI score preoperatively and postoperatively (MD:  $0.27$ ,  $P = 0.55$ ) was not significantly different.

**Conclusions** G-POEM appears promising as it may provide a cost-effective approach for managing refractory gastroparesis compared to surgical techniques. RCTs are needed to further confirm these results.

## Introduction

Gastroparesis is a functional disorder that is characterized by delayed gastric emptying in the absence of mechanical gastric outlet obstruction leading to symptoms including nausea, vomiting, pain, early satiety, and bloating [1]. The underlying etiologies can be multifactorial; however, the most observed are diabetes, postsurgical, or idiopathic [2]. Ye et al. demonstrated that the overall prevalence of gastroparesis was 267.7 per 100,000 US adults [3]. The management of gastroparesis entails lifestyle modification and/or use of prokinetic agents as first line therapy. In many patients, these agents tend to lose efficacy over time and patients require additional modalities for persistent or refractory symptoms. These include use of gastric stimulators, Roux-en-Y gastric bypass, pyloroplasty/pyloromyotomy, gastrojejunostomy, and/or subtotal gastrectomy [4].

An endoscopic approach called gastric per-oral endoscopic myotomy (G-POEM) has been evaluated in patients with refractory gastroparesis with notable clinical success [5]. During G-POEM, submucosal gastric tunneling is performed to approach, identify, and incise the musculature of the pylorus, similar to technique employed for POEM in the esophagus to treat patients with achalasia [6]. Recent meta-analyses have demonstrated varying clinical success and efficacy for G-POEM in managing refractory gastroparesis. Meyboodi et al. demonstrated that G-POEM was associated with reduction of mean Gastroparesis Cardinal Symptom Index (GCSI) value by  $-1.57$  (confidence interval (CI):  $-2.2$  to  $-0.9$ ) and mean gastric emptying by 22.3% (CI:  $-32.9\%$ – $11.6\%$ ) after 5 days [7]. Similarly, Kamal et al. showed reduction of GCSI by  $-1.4$  (CI:  $-1.9$ – $0.9$ ) at 1-year follow-up [8]. Neither of these meta-analyses compared G-POEM to surgical approach.

Given the lack of comparative data, we sought to perform a systematic review and meta-analysis of studies comparing the endoscopic approach i.e. G-POEM, to the surgical pyloromyotomy for managing refractory gastroparesis.

## Patients and methods

### Search strategy

This meta-analysis was conducted in accordance to guidelines provided by Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) [9]. A detailed search of the following databases was undertaken from inception through July 29, 2022: MEDLINE (PubMed interface, National Center for Biotechnology Information), Embase (Elsevier), Web of Science Core Collection (Clarivate), KCI – Koran Journal Index, Global Index Medicus, and Cochrane Central Register of Controlled Trials (Cochrane/Wiley). The initial search strategy was suggested by lead investigator (M.A.) that was further refined and executed by expert medical librarian (W.L.-S.) using appropriate medical subject headings and related vocabulary and syntax. The following keywords were utilized: “Pyloromyotomy,” “POEM,” “Endoscopy,” “Surgery,” and “Gastroparesis.” A sample search strategy using PubMed is highlighted in Supplementary Table 1. Our search was not restricted to language. Citations were imported and deduplicated using EndNote X9 bibliographic man-

agement software (Clarivate, Philadelphia, Pennsylvania, United States). We did not prepare a review protocol prior to screening/data extraction process.

### Study definitions

Symptoms related to gastroparesis were quantified using Gastroparesis Cardinal Symptom Index (GCSI) score, a previously validated survey that scores on post-prandial fullness, nausea/vomiting, and bloating [10]. Clinical success was defined as improved gastric emptying study (GES) and/or improvement in GCSI score based on individual study defined criteria on follow-up. The surgical group included patients that underwent either pyloromyotomy and/or pyloroplasty using any approach (open, laparoscopic, robotic).

### Inclusion/exclusion criteria

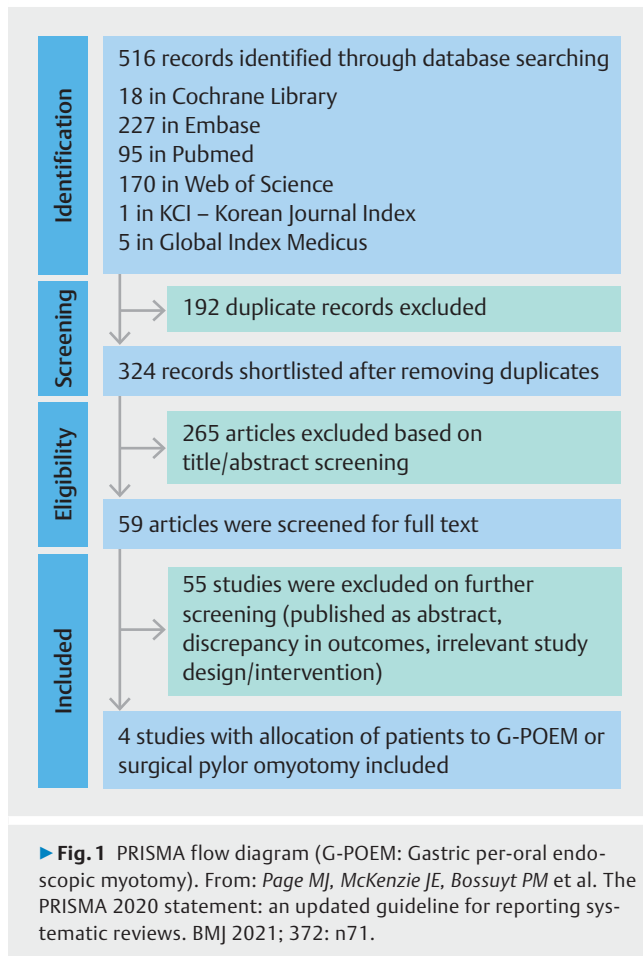
The studies were included based on following parameters: (1) Patients: Adult patients ( $\geq 18$  years old with refractory gastroparesis of any etiology); (2) Intervention: G-POEM; (3) Control: Surgical pyloromyotomy (laparoscopic, robotic, and/or open) and (4) Outcomes: Procedure duration, length of stay (LOS), complications, clinical success, post operative GCSI score. We included comparative studies i.e. case-control, retrospective/prospective cohort and/or randomized controlled trials (RCTs). We included abstracts if they met all study criteria. We excluded case reports, case series  $< 10$  patients, single arm studies, guidelines, and reviews. If more than one publication was notable for overlapping data, we included the most recent and updated study to capture the most comprehensive data.

### Screening and data collection

Study screening and data extraction was performed by two independent reviewers (M.A.) and (M.G.). The initial screening was performed using titles and abstracts. Pertinent studies were then further screened using full texts (where applicable). Data was extracted using Microsoft Excel (Microsoft, Redmond, Washington, United States). Data regarding demographics (age, gender), etiology of gastroparesis (diabetic, postsurgical, and unknown/idiopathic), type of surgery (robotic, laparoscopic, open), and outcomes (LOS, procedure duration, complications, clinical success, post operative GCSI score) were collected. Any discrepancy during screening and data extraction was resolved through mutual discussion.

### Data synthesis and analysis

Given the presumed heterogeneity of different surgical approaches and etiology of gastroparesis, Random effects model using DerSimonian-Laird approach was used a priori for pooling and comparing outcomes. A correction factor of “0.5” was added when outcomes were 0 for a given study. Relative risk (RR) for dichotomous outcomes and mean difference (MD) for continuous outcomes were calculated along with 95% confidence interval (CI) and *P* value.  $P < 0.05$  was considered significant for all assessed outcomes. Study heterogeneity was assessed using the  $I^2$  statistical and value  $> 50\%$  was considered substantial heterogeneity [11]. Statistical analysis was performed using



Open Meta Analyst (CEBM, University of Oxford, Oxford, United Kingdom).

The GCSI score was calculated for each group preoperatively and postoperatively. Comparison was made between postoperative GCSI score directly between the two groups as well as between the reduction/mean difference (MD) of preoperative and postoperative GCSI between the two groups.

A subgroup analysis was performed based on individual surgical techniques i.e. pyloroplasty or pyloromyotomy if two or more studies were available reporting outcomes.

### Bias assessment

The risk of bias for individual studies was performed using Newcastle Ottawa scale (NCOS) for observational/cohort studies and Cochrane risk of bias tool for RCTs [12, 13]. Publication bias was undertaken via funnel plot for qualitative assessment and Egger's regression analysis for quantitative assessment using *P* value. If publication bias was noted, we attempted the "trim-and-fill" method to assess the changes in effect size for respective outcome.

## Results

A total of 516 studies were identified, of which 324 remained after machine deduplication was undertaken. After rigorous screening, a total of four studies (1 abstract and 3 full texts) were selected for inclusion in the meta-analysis [14–17]. The details of study selection are highlighted in the PRISMA flow diagram (► **Fig. 1**). Of the included studies, all were observational. G-POEM was used as an intervention in all studies. For surgical techniques, two studies used pyloromyotomy [14, 16] and two studies used pyloroplasty [15, 17]. The demographic details and patient characteristics of included studies are summarized in ► **Table 1**.

A total of 385 patients were included (216 in the G-POEM group and 169 in the surgical group). The mean age was 46.9 ( $\pm 3.41$ ) and 46.2 ( $\pm 0.86$ ) for G-POEM and surgery, respectively. The female proportion was 79.6% and 74.0% for G-POEM and surgery, respectively. The outcomes for individual studies are shown in ► **Table 2**.

### Procedure duration

The mean procedure time was significantly lower for G-POEM compared to surgery (MD:  $-59.47$  min, CI:  $-87.57$  to  $-31.37$  min,  $P < 0.001$ ,  $I^2 = 96.6\%$ ) (► **Fig. 2a**). Consistent results were obtained on subgroup analysis for patients that underwent surgical pyloroplasty (MD:  $-66.24$  min, CI:  $-69.84$  to  $-62.64$  min,  $P < 0.001$ ,  $I^2 = 0\%$ ). The subgroup analysis although showed shorter duration for G-POEM compared to surgical pyloromyotomy however this result was not statistically significant (MD:  $-54.59$  min, CI:  $-123.95$ – $14.78$  min,  $P = 0.12$ ,  $I^2 = 95.65\%$ ).

### Length of stay

The LOS was significantly shorter for the G-POEM group compared to the surgical group (MD:  $-3.10$  days, CI:  $-4.21$  to  $-1.98$  days,  $P < 0.001$ ,  $I^2 = 27.4\%$ ) (► **Fig. 2b**). The subgroup analysis was possible for surgical pyloromyotomy only. Although lower LOS was noted for G-POEM, the result did not achieve statistical significance (MD:  $-4.93$ , CI:  $-10.80$ – $0.94$ ,  $P = 0.10$ ,  $I^2 = 62.7\%$ ).

### Post-GCSI score

The post-procedure GCSI was evaluated by all four studies and was not significantly different (MD:  $-0.33$ , CI:  $-1.09$ – $0.43$ ,  $P = 0.39$ ,  $I^2 = 89.6\%$ ) (► **Fig. 2c**). The subgroup analysis demonstrated higher post operative GCSI score for G-POEM group compared to surgical pyloroplasty group (MD:  $0.46$ , CI:  $0.02$ – $0.90$ ,  $P = 0.04$ ,  $I^2 = 0\%$ ). However, G-POEM showed lower post operative GCSI score compared to surgical pyloromyotomy group (MD:  $-0.91$ , CI:  $-1.39$  to  $-0.43$ ,  $P < 0.001$ ,  $I^2 = 65.82\%$ ).

The reduction in the GCSI score preoperatively and postoperatively between the G-POEM and surgical groups was compared and no difference was observed (MD:  $0.27$ , CI:  $-0.62$ – $1.16$ ,  $P = 0.55$ ,  $I^2 = 96.45\%$ ) (► **Fig. 2d**). Consistent result was obtained when G-POEM was compared to surgical pyloroplasty only (MD:  $-0.49$ , CI:  $-1.32$ – $0.34$ ,  $P = 0.25$ ,  $I^2 = 89.7\%$ ). G-POEM showed higher reduction of GCSI postoperatively compared to

► **Table 1** Study details and demographics of included patients.

Study, year		Landreneau, 2019	Pioppo, 2021	AbiMansour, 2020	Clapp, 2022
Type of study		Case control study	Retrospective	Retrospective	Prospective
Interventions		Group 1: G-POEM Group 2: Laparoscopic pyloroplasty	Group 1: G-POEM Group 2: Laparoscopic pyloromyotomy	Group 1: G-POEM Group 2: pyloromyotomy	Group 1: G-POEM Group 2: Robotic pyloromyotomy
Total patients		Group 1: 30 Group 2: 30	Group 1: 39 Group 2: 63	Group 1: 84 Group 2: 28	Group 1: 63 Group 2: 48
Mean age, (SD)		Group 1: 44.1 (13.5) Group 2: 45.4 (14.5)	Group 1: 49 (16.5) Group 2: 45.8 (10.3)	Group 1: 50.6 (16.9) Group 2: 46.2 (17.4)	Group 1: 43.9 (14.1) Group 2: 47.4 (12.4)
Female (%)		Group 1: 23 (76.7%) Group 2: (76.7%)	Group 1: 33 (84.6%) Group 2: 36 (57.1%)	Group 1: 63 (75.0%) Group 2: 22 (78.6%)	Group 1: 53 (84.1%) Group 2: 44 (91.7%)
Mean BMI, (SD)		Group 1: 24.9 (7.1) Group 2: 26.1 (6.7)	Group 1: 27.7 (7.7) Group 2: 27.6 (7.5)	Group 1: 6.09 (25.1) Group 2: 25.1 (5.2)	Group 1: 28.7 (8.2) Group 2: 27.3 (5.5)
Etiology of Gastroparesis	Diabetic	Group 1: 5 Group 2: 5	Group 1: 13 Group 2: 14	Group 1: 23 Group 2: 3	Group 1: NR Group 2: NR
	Postsurgical	Group 1: 6 Group 2: 6	Group 1: 4 Group 2: 16	Group 1: 23 Group 2: 12	Group 1: NR Group 2: NR
	Idiopathic/ unknown	Group 1: 19 Group 2: 19	Group 1: 22 Group 2: 33	Group 1: 38 Group 2: 13	Group 1: NR Group 2: NR
Length of follow-up		90 days	Postoperative	NR	90 days

BMI, body mass index; G-POEM, gastric per-oral endoscopic myotomy; NR, not reported; SD, standard deviation.

surgical pyloromyotomy group (MD: 1.09, CI: 0.60–1.57,  $P < 0.001$ ,  $I^2 = 66.32\%$ ).

### Clinical success/normal GES

Three studies assessed clinical success on follow-up. No significant difference in clinical success was noted for either group (OR: 0.98, CI: 0.32–3.00,  $P = 0.98$ ,  $I^2 = 49.34\%$ ) (► Fig. 3a). Subgroup analysis between surgical pyloromyotomy group and G-POEM was also consistent (OR: 0.95, CI: 0.14–6.69,  $P = 0.96$ ,  $I^2 = 74.7\%$ ).

The postoperative rate of normal GES was assessed by two studies and was not significantly different between the G-POEM and surgical groups (OR: 0.56, CI: 0.20–1.60,  $P = 0.28$ ,  $I^2 = 25.84\%$ ) (► Fig. 3b).

### Readmission/reintervention rate

Only two studies assessed the reintervention rates, and no significant difference was noted between the G-POEM and surgical group (OR: 1.27, CI: 0.31–5.13,  $P = 0.74$ ,  $I^2 = 0\%$ ). A subgroup analysis was not applicable (► Fig. 3c).

Only two studies assessed readmission rate and no significant difference was noted between the G-POEM and surgical groups (OR: 1.20, CI: 0.13–11.31,  $P = 0.87$ ,  $I^2 = 76.5\%$ ) (► Fig. 3d). Both studies used pyloroplasty and hence subgroup analysis for pyloromyotomy was not applicable.

### Adverse events

The overall rates of adverse events (AEs) were assessed by all studies and no significant difference was noted between G-POEM and surgery (OR: 39, CI: 0.13–1.18,  $P = 0.10$ ,  $I^2 = 69.5\%$ ) (► Fig. 3e). Subgroup analysis was consistent for G-POEM and surgical pyloroplasty (OR: 0.66, CI: 0.08–5.80,  $P = 0.71$ ,  $I^2 = 69.2\%$ ). Lower overall rates of AEs were noted for G-POEM compared to pyloromyotomy (OR: 0.23, CI: 0.11–0.49,  $P < 0.001$ ,  $I^2 = 0\%$ ).

### Risk of bias

The risk of bias using the NCOS is highlighted in Supplementary Table 2. The risk of bias was applicable for three studies with full text, and each had a score of 6 or more signifying moderate to low risk [15–17]. One study was an abstract and hence risk of bias assessment was not possible [14].

## Discussion

Gastroparesis is a debilitating disease that severely impairs the quality of life of affected patients. Unfortunately, there are limited interventions for the management of gastroparesis. The alteration of pyloric musculature via mechanical disruption, to reduce barriers to gastric outflow, using surgical and endoscopic techniques have been explored.

The approaches that have been performed to achieve pyloric muscle disruption include pyloroplasty or pyloromyotomy. The difference between the two techniques is that in pyloromyot-

► **Table 2** Outcomes for individual studies.

Study, year	Mean procedure duration, mins (SD)	Mean LOS, days (SD)	Mean Post-operative GCSI score, (SD)	Mean reduction in GCSI pre/post, (SD)	Clinical success	Normal GES	Complication rates	Reintervention rates	Readmission rates
Landreneau, 2019	G-POEM: 33.9 (18.8) Surgery: 99.9 (41.8)	G-POEM: 1.4 (1.0) Surgery: 4.6 (5.6)	G-POEM: 2.4 (1.5) Surgery: 2.3 (1.5)	G-POEM: 1.6 (0.3) Surgery: 1.7 (0.3)	G-POEM: 6 Surgery: 5	G-POEM: 8 Surgery: 7	G-POEM: 1 Surgery: 5	G-POEM: 1 Surgery: 1	G-POEM: 2 Surgery: 5
Pioppo, 2021	G-POEM: 58.0 (27.6) Surgery: 78.4 (13.1)	G-POEM: 1.3 (1.0) Surgery: 4.2 (0.7)	G-POEM: 1 (0.8) Surgery: 1.7 (0.6)	G-POEM: 2.8 (0.8) Surgery: 1.5 (0.7)	G-POEM: 36 Surgery: 52	G-POEM: NR Surgery: NR	G-POEM: 5 Surgery: 21	G-POEM: NR Surgery: NR	G-POEM: NR Surgery: NR
AbiMansour, 2020	G-POEM: 60.6 (29.6) Surgery: 151.8 (72.0)	G-POEM: 1.5 (2.4) Surgery: 10.9 (20.8)	G-POEM: 1.1 (1.3) Surgery: 2.3 (1.1)	G-POEM: 1.8 (1.6) Surgery: 1 (0.9)	G-POEM: 24 Surgery: 9	G-POEM: 12 Surgery: 6	G-POEM: 9 Surgery: 11	G-POEM: 8 Surgery: 2	G-POEM: NR Surgery: NR
Clapp, 2022	G-POEM: 25.3 (6.1) Surgery: 91.5 (10.4)	G-POEM: NR Surgery: NR	G-POEM: 2.5 (1.2) Surgery: 2.0 (1.1)	G-POEM: 0.9 (1.2) Surgery: 1.9 (1.2)	G-POEM: NR Surgery: NR	G-POEM: NR Surgery: NR	G-POEM: 12 Surgery: 6	G-POEM: NR Surgery: NR	G-POEM: 12 Surgery: 3

GCSI, Gastroparesis Cardinal Symptom Index; GES, gastric emptying study; G-POEM, gastric per-oral endoscopic myotomy; LOS, length of stay; NR, not reported; SD, standard deviation.

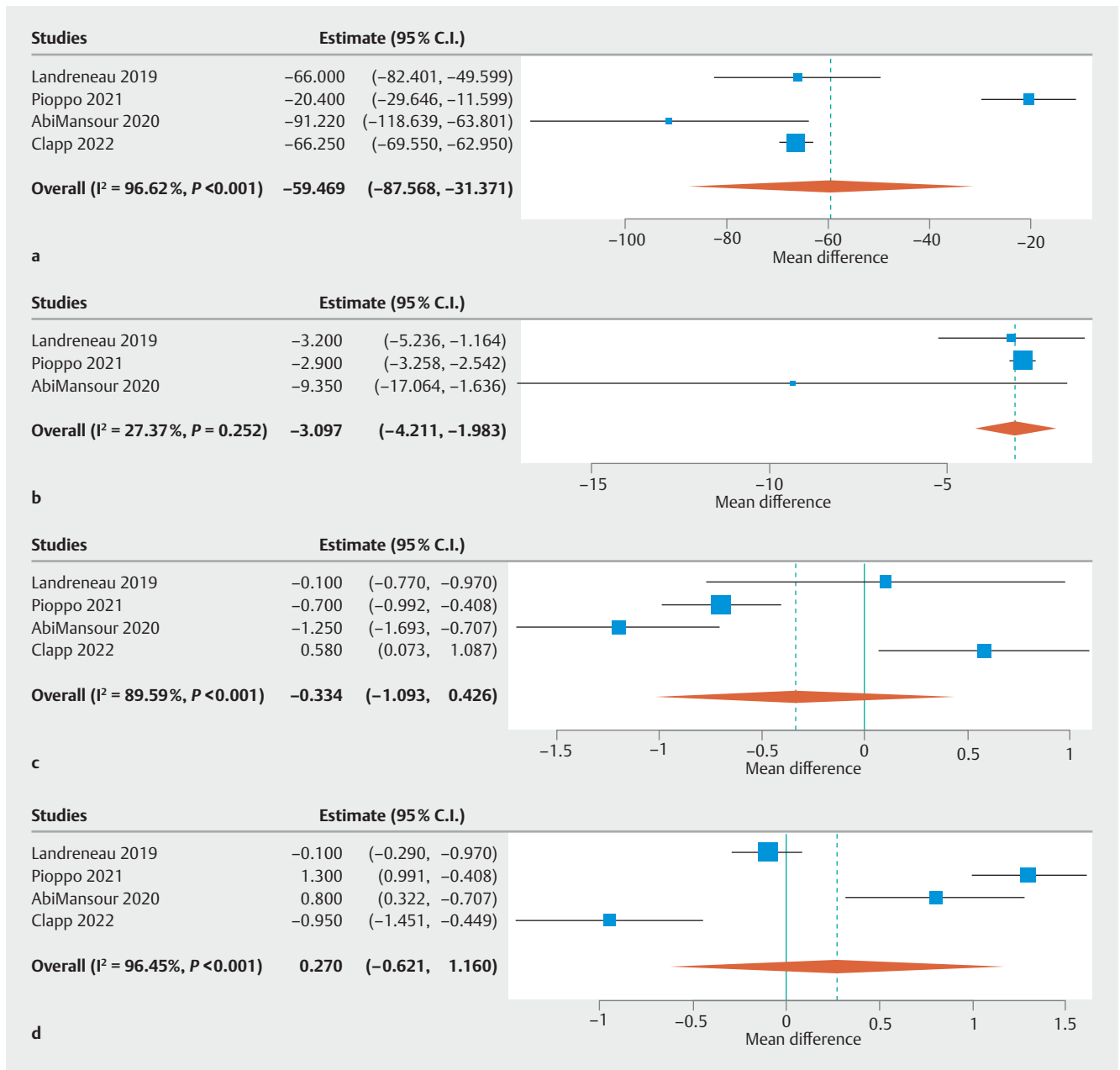
omy, a longitudinal incision is made in the avascular plane after the duodenum is grasped just distal to the level of pylorus. The muscle fibers are spread with a spreader and pyloric edges are mobilized thus confirming successful pyloromyotomy [16]. In pyloroplasty, a longitudinal incision is performed through the pylorus and the incision is then closed using Heineke-Mikulicz technique [15]. A previous retrospective study comparing these two techniques in children with delayed gastric emptying and gastroesophageal reflux did not find an advantage of one over the other [18]. Toro et al. assessed the impact of laparoscopic pyloroplasty on patients with gastroparesis and noted improvement of symptoms in 82% of patients postoperatively [19]. Similarly, Shada et al. described the largest single center experience for pyloroplasty and noted a 90% improvement in GES among affected patients following the procedure [20]. G-POEM has shown promise with similar efficacy compared to surgical techniques. Landreneau et al. demonstrated that G-POEM and laparoscopic pyloroplasty were similar in terms of postoperative GCSI score ( $2.4 \pm 1.5$  vs  $2.3 \pm 1.5$ ,  $P=0.85$ ) and improved GES (85.7% vs 83.3%,  $P=0.91$ ) [15]. In this study, we demonstrated that G-POEM resulted in similar efficacy to surgery with regard to the following parameters: postoperative GCSI score (MD:  $-0.33$ , CI:  $-1.09$ – $0.43$ ), reduction in GCSI score preoperatively and postoperatively (MD:  $0.27$ , CI:  $-0.62$ – $1.16$ ), and similar rates of obtaining a normal GES (OR:  $0.56$ , CI:  $0.20$ – $1.60$ ).

The major attractiveness of G-POEM is its cost-effectiveness. A previous study showed that G-POEM overall had a 26% lower procedural cost than surgical pyloroplasty [21]. In this study, we further demonstrated that G-POEM also reduced the overall

procedure time compared to surgery (MD:  $-59.47$  min, CI:  $-87.57$  to  $-31.37$  min) and overall length of hospital stay (MD:  $-3.10$  days, CI:  $-4.21$  to  $-1.98$ ), both of which may contribute to further reducing the cost. The overall lower procedural time reduces the risk of prolonged anesthesia as well.

We compare our study to a previously published article on similar topic by Mohan et al. The authors performed systematic review, pooled analysis and comparison between the two groups i.e. G-POEM and surgical pyloroplasty. The authors demonstrated similar clinical success between surgical pyloroplasty, and G-POEM based on GES and GCSI score which is in line with our analysis [22]. However, the authors could not perform the analysis of mean difference between pre- and post-GCSI score between the two groups due to lack of data. Further, the comparison of clinical success between two groups was made indirectly as all included studies except one were single arm. Our study only included comparative studies and hence we were able to perform comparative meta-analysis on more outcomes.

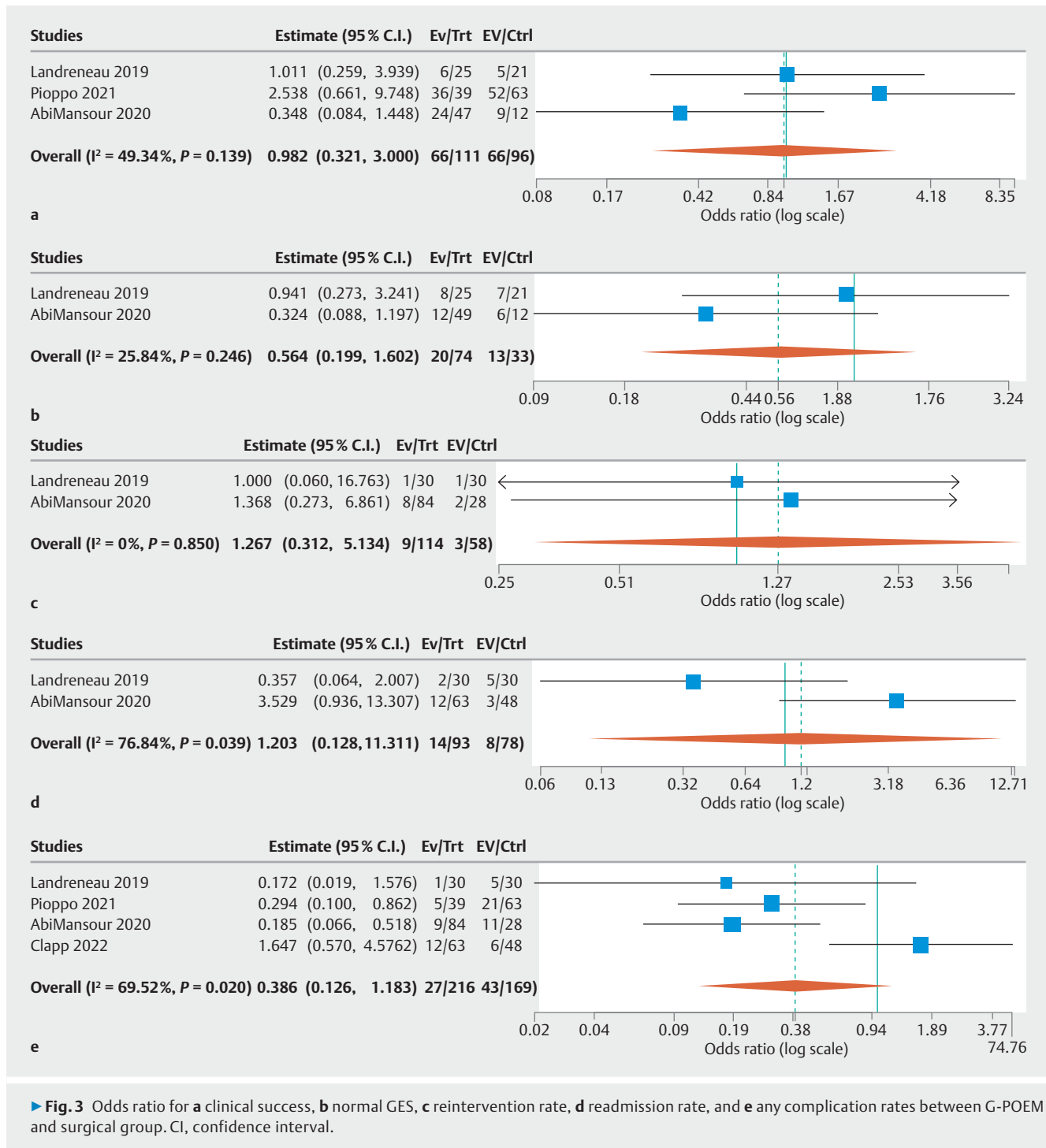
Interestingly, a lower overall postoperative GCSI was noted for surgical pyloroplasty compared to G-POEM, however, the reduction in GCSI preoperatively and postoperatively were comparable between the two groups. One major limitation of this analysis was that only two studies utilized pyloroplasty. Furthermore, one of the studies explored the efficacy of pyloroplasty using a laparoscopic approach and other study used a robotic technique. We were unable to account for this heterogeneity in our outcome. Future RCTs, directly comparing individual surgical approaches, can further expand on the relative benefits and efficacy of each technique.



► **Fig. 2** Mean difference for **a** procedure duration, **b** LOS, **c** postoperative GCSI, **d** preoperative/postoperative difference in GCSI between G-POEM and surgical group. CI, confidence interval; LOS, length of stay.

Our study had some notable limitations. The most important limitations were the lack of RCTs as well as low number of included studies with lower overall patients included in respective intervention groups. We were unable to account for outcomes based on specific etiology of gastroparesis, surgical access (open, laparoscopic, robotic), and prior exposure to other interventions such as medications (metoclopramide, erythromycin, domperidone) or botulinum toxin injection. Further, the included studies mostly included patients at highly advanced tertiary care centers, and hence the generalizability of the results is questionable. Lastly, the follow-up of patients was not consistent across the studies and hence important out-

comes such as duration and timing of improvement in symptoms, GES and reduction in GCSI were not consistently assessed. All these aspects can explain the high heterogeneity noted in our outcomes. Despite the limitations, this study provides the largest comprehensive comparative analysis currently available between G-POEM and surgery. We performed subgroup analysis based on type of surgery i.e., pyloroplasty vs pyloromyotomy and although few outcomes were different owing to the low number of studies, these were not clinically significant.



## Conclusions

In conclusion, G-POEM may be favored over surgical approach for refractory gastroparesis as it was more cost-effective while demonstrating comparable efficacy. Future randomized controlled trials (RCTs) should be performed to confirm these results.

## Competing interests

The authors declare that they have no conflict of interest.

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