



Laparoscopic gastric stimulator placement for recalcitrant gastroparesis: 5 Year Outcomes from a single institution.

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Background

- Laparoscopic placement of a gastric electrical stimulator (GES) has been shown to improve gastroparesis symptoms in patients with recalcitrant gastroparesis
- Only 3 previous studies have investigated 70 or more patients and followed them for over 48 months out from surgery
- Explant rates range from 0% to 12 % in published case series, however this may significantly underestimate the amount of devices removed due to short interval follow up.
- Some case series report a reduction in gastroparesis symptoms in the majority of patients after gastric stimulator placement
- Other case series reported success with weight gain after GES placement and the ability to stop supplemental nutrition.

Methods

- This retrospective case series identified 76 patients with recalcitrant gastroparesis who underwent laparoscopic GES placement at our institution from 2009 through 2017.
- GESs were placed in patients with typical symptoms of gastroparesis refractory to medical management and abnormal 4h nuclear gastric emptying studies.
- The following data were collected pre-operatively and at the most recent follow up visit: weight; BMI; use of anti-emetics, promotility agents, and narcotics; and number of device explants, complications, and deaths.
- Scaled response scores were recorded pre-operatively and at the 3 most recent follow up visits using the Total Symptom Score for Severity (TSS-S) and Frequency (TSS-F) to describe the patient's gastroparesis symptoms (nausea, vomiting, epigastric pain, early satiety, and postprandial bloating) on a 20 point scale.
- We excluded scores recorded while the patient's Enterra battery was dead.

Results

Patient Characteristics

- Gastroparesis was either idiopathic (n=47, 62%), associated with diabetes (n=27, 36 %), or post-surgical (n=2, 3 %).
- The mean age at time of surgery was 40 years old (19-67 range) and 84 % patients were female (64 patients).
- A temporary endoscopically-placed gastric electrical stimulator was trialed pre- operatively on 22 patients, all with reduced symptom scores following the temporary pacer

Complications and Device Removal

- At the most recent follow up visit (median 4.9 years, range: <1 month to 10.1 years), the GES remained implanted in 61/76 (80.3 %) patients.
- GES explanation was performed in 16/76 patients (21.1 %) due to: planned pregnancy (1), conversion to gastric bypass (1), need for Whipple for pancreatic cancer (1), pain at the generator (7), no response to treatment (4), infection of the generator (1), and need for MRI (1). One patient who had the device removed for pain, underwent re-insertion of GES only 3 months later for recurrent gastroparesis symptoms.
- In 8/76 patients (10.5%) complications occurred, which included pain (6), shocking/twitching (3), flipped generator (1), and infection (2).
- There were no deaths related to the device, but 3/76 patients died after placement from arrythmia (1), recurrent cancer (1), or an unknown reason (1).

Symptom Scores and BMI

- In 55 patients with scaled response data, TSS-S and TSS-F scores decreased in 75% and 80% after GES placement. Averaging scores from the 3 most recent follow up visits, there was also a significant decrease in the mean TSS-S (14.4 to 10.4) and mean TSS-F (14.1 to 11.00) (both, $p<0.001$).
- At most recent follow up, 13/66 (19.6 %) patients were able to discontinue antiemetics ($p=0.0031$) and 30/50 patients (60 %) were able to discontinue promotility agents ($p=0$).
- For patients with initial BMI of 25 or less (n=39), the average BMI change was +2.4 and the average weight change was +12.7 lbs

Conclusions

- Laparoscopic placement of a GES significantly improves symptoms in patients with recalcitrant gastroparesis in the long term.
- Though device placement is safe, non-life-threatening complications occur in 10.5 % of patients, and ultimately 21.1 % of patients have a device explant, which is considerably higher than reported in the literature.
- Gastroparesis patients that undergo laparoscopic GES placement had a significant increase in BMI, and this increase was most dramatic in those with a pre op BMI<26.
- A significant number of patients were able to stop using their antiemetics and promotility agents after gastric pacemaker placement, however there was no change in number of patients using narcotics.
- Laparoscopic gastric stimulator remains a viable option for symptom control with patients with recalcitrant diabetic or idiopathic gastroparesis, however complications and a > 20 % explant rate needs to be considered.

Bibliography

1. McCallum RW, Lin Z, Forster J, et al. Gastric electrical stimulation improves outcomes of patients with gastroparesis for up to 10 years. Clin Gastroenterol Hepatol 2011;9:314–319
2. Keller DS, Parkman HP, Boucek DO, et al. Surgical outcomes after gastric electric stimulator placement for refractory gastroparesis. J Gastrointest Surg 2013;17:620–626.
3. Anand C, Al-Juburi A, Familoni B, et al. Gastric electrical stimulation is safe and effective: a long-term study in patients with drug-refractory gastroparesis in three regional centers. *Digestion*. 2007;75(2-3):83-89.
4. Forster J, Sarosiek I, Delcore R, Lin Z, Raju GS, McCallum RW. Gastric pacing is a new surgical treatment for gastroparesis. *Am J Surg*. 2001;182(6):676-681.
5. Abell TL, Johnson WD, Kedar A, et al. A double-masked, randomized, placebo-controlled trial of temporary endoscopic mucosal gastric electrical stimulation for gastroparesis. *Gastrointest Endosc*. 2011;74(3):496-503.e3.
6. McCallum RW, Sarosiek I, Parkman HP, et al. Gastric electrical stimulation with Enterra therapy improves symptoms of idiopathic gastroparesis. Neurogastroenterol Motil 2013;25:815–836.
7. McCallum RW, Lin Z, Sarosiek I et al. Symptom resonses, long-term outcomes and adverse events beyond 3 years of high-frequency gastric electrical stimulation for gastroparesis. Neurogastroenterol Motil 2006; 18:18-27.
8. Zoll B, Jehangir A, Malik Z, Edwards M, et al. Gastric Electric Stimulation for Refractory Gastroparesis. J Clin Outcomes Manag. 2019 January; 26(1): 27-38.
9. McCallum RW, Lin Z, McElhinney C et al. Chronic gastric electrical stimulation for gastroparesis reduces the use of prokinetic and/or antiemetic medications and the need for hospitalizations. Dig Dis Sci 2005;50:1328–1334.