Study	Population	Intervention	Results	Validity/Conclusion
McCallum et al, 2010. **Study type**: Crossover RCT. **Objective:** To evaluate the efficacy and safety of Enterra therapy in patients with intractable nauseas and vomiting from diabetic gastroparesis (DGP). **Primary outcomes:** % reduction in weekly vomiting frequency (WVF) during the ON period relative to OFF period. **Secondary outcomes:** % reduction in WVF at 12 months relative to baseline. Symptom scores and QoL. **N of patients:** N=55 received the device, 45 randomized. **Blinding:** Double-blind. **Follow-up:** 12 months. 88.6%omplete	**Inclusion criteria:** 1. Age ≥18 years. 2. Symptomatic gastroparesis due to DM or idiopathic. 3. Unresponsive or intolerant to prokinetic and antiemetic drugs tried for 1 month. 4. Had at least 7 episodes of vomiting during a consecutive-day period on a 28-day diary. 5. With gastric retension of >10% at 4 hours, or >60% at 2 hours. 6. Able to accurately complete and fill the diary and questionnaire throughout the study. 7. On a stable dose of prokinetic agents for ≥30 days before baseline and be willing to continue the dose throughout the study unless contraindicated. **Exclusion criteria:** 1. Other underlying illness or cause affecting the gastric motility. 2. Other primary disorders leading to vomiting, or swallowing disorders. 3. Perineal dialysis. 4. Daily narcotics for abdominal pain. 5. Drug or alcohol dependency. 6. Life expectancy <12 months. 7. Other implanted devices. 8. Pregnancy. 9. Undergone radiation therapy to upper abdomen. 10. Planning a MRI. **Patient Characteristics:** Mean age 38.3 years (range 20-63), 65.5% females, mean BMI 26.4 kg/m^2 , mean duration of GP symptoms 5.9 years (range 1-38 y), median vomiting 16.8 episodes/week. All had delayed gastric emptying, median retention 75.5% at 2 hours, 46.5% at 4 hours. 94.5% were insulin dependent. 23.6% required oral nutritional support, 14.8% enteral and 3.6% parenteral.	The study was conducted in 8 centers in the US. All patients underwent implantation of the Enterra system using either laparoscopy or laparotomy approach. The system was turned ON for 1.5 months after which they were randomized to one of 2 treatment arms: 1. Three months ON followed by three months OFF. Or 2. Three months OFF followed by three months ON. At the end of the crossover period, the device was programmed ON for 4.5 months. All patients were required to record daily vomiting episodes in a 28-day diary. GE was evaluated after a solid meal at baseline at 12 months and annually using a standardized scintigraphy method and a low-fat test meal.	**Weekly vomiting frequency (WVF) 6 weeks after implantation (before randomization)** Median WVF episodes: At baseline 19.5; at 6 weeks 4.75*; p value <0.001 *57% reduction from baseline **Results at the cross- over phase:** **ON State** / **OFF state** / **P value** **WVF*, median (Interquartile range)**: 3.81 (0.75-14.0) / 4.25 (0.38-15.1) / .215 **Frequency symptom score** (mean ± SD)** Vomiting: 2.31 ± 1.43 / 2.03 ± 1.48 / 0.057 Nausea: 2.81 ± 1.31 / 2.42 ± 1.56 / 0.369 Early satiety: 1.89 ± 1.47 / 1.47 ± 1.44 / .0493 Bloating: 1.83 ± 1.43 / 2.03 ± 1.58 / 0.170 Fullness: 1.44 ± 1.38 / 1.64 ± 1.46 / 0.011 Epigastric pain: 1.31 ± 1.37 / 1.28 ± 1.41 / 0.295 Epigastric burning: 0.92 ± 1.18 / 1.03 ± 7.48 / 0.090 TSS†: 12.5 ± 7.10 / 11.89 ± 7.48 / 0.903 *N=32 subjects provided diary data to assess WVF at cross-over phase ** N=39 subjects. For each individual a score 0=absent, and 4+ extremely frequent (≥7/wk) The total is the sum of all the individual scores. † Overall frequency symptom score **% reduction of WVF at 12 months compared to baseline** **Analysis** / **N** / **Median % reduction (Interquartile range)** / **P value** Completed case: 36* / 67.8 (23.7-92.4) / <0.001 ITT **: 45 / 66.5 (17.7-90.7) / <0.001 *N=39 finished 12 months follow-up, and only 36 subjects provided diary data to assess WVF. Median WVF 19.5 episodes at baseline and 4.25 at 12 months. ** Only the observations made with the device ON were carried forward for the intention to treat analysis. • Quality of life and gastric emptying were significantly improved compared to baseline **Adverse events:** Total 732 events -687(93.9%) were patient-related, 438 (64% serious (225 hospitalization in 40 patients) -45 (6.1%) were therapy or device related, 15/45 (33%) were serious. -3 patients required surgical intervention -Mortality: 7/55 (12.7%) died at one year; none related to the therapy.	The study was a double-blind, multicenter cross-over RCT. However, it had the disadvantage of lacking a washout periods between the ON stage after implantation, and between the cross- over stages of the study. This makes it hard to determine whether the improvement in symptoms was actually due to the treatment or just a placebo effect of the therapy. GES was not compared to other therapies and the trial included patients who failed therapy for a low as one month. The results of the study show no significant difference in the WVF or other symptoms between the ON and OFF modes, but a significant improvement WVF in the first 6-week unblinded period after implantation vs. baseline, which could have been carried over during the OFF mode.