Double Blinded Randomized Study of Temporary Gastric Electrical Stimulation (GES): Preliminary Results of Endostim Study (Endoscopic Stimulation Temporarily Implanted Mucosally)

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Introduction: Permanently implanted Gastric Electrical Stimulation has been shown to be a successful therapy for many aspects of gastroparesis (GP). Recently endoscopic temporary GES, (GIE 2005), has been advocated as a method to rapidly determine possible beneficial effects of this therapy. However, temporary GES (Temp GES) has not been studied in a blinded manner.

Patients: We studied 58 patients, (11 males, 47 females, mean age 46 years) with the symptoms of GP and underlying diagnosis: (Idiopathic (ID), n=38 ; Diabetes Mellitus (DM), n=13 ; Post-surgical (PS), n= 7) in a randomized placebo-controlled cross over study of temp GES as two consecutive 4-day sessions.

Methods: After baseline assessments of symptoms (including vomiting), and health related quality of life (HRQOL), patients underwent endoscopic placement of Temp GES on day 1 and then had devices turned ON/OFF through day 4 when another assessment was done. Patients were crossed over to OFF/ON days 5 through day 8 when final assessments were performed. Results were compared by t-tests within and between groups and reported as mean +/- SE.

Results: 28 patients had ON-OFF and 30 patients had OFF-ON; 45 of 58 patients finished all 8 days. When analyzed for all patients ON verses all patients OFF both vomiting frequency and HRQOL improved significantly (p< 0.05). When analyzed for the first session, the results were even more significant: the mean number of days vomiting decreased from 1.4 OFF to 0.4 ON (p= 0.001) and the mean number of days with nausea deceased from 1.6 OFF to 0.8 ON (p= 0.002).

Conclusions: This blinded comparison of temporary endoscopic GES is the first evidence based study of its effectiveness. Further stratification of results from the EndoSTIM study should provide additional information about which gastroparesis patients may benefit most from temporary GES.