

Diabetic Complications Consortium

Application Title: An Integrated Assessment of Gastric Functions

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1. Project Accomplishments:

Funding to pursue this research was received in Fall of 2022.

In the time since receiving funding, patient accrual has been completed, data preparation has been completed and analysis is in progress.

Twelve healthy participants and 25 patients with upper gastrointestinal symptoms participated in the study between February and June 2022. Six patients (4 with normal GE and 2 with delayed GE) did not return the GCSI-DD and were excluded from the analyses relating to symptoms. Unfortunately, within the timeframe of the project, only 2 patients with rapid gastric emptying were recruited. This was insufficient to power the arm of the study evaluating patients with rapid GE. To this cohort were added 4 symptomatic patients from the pilot study. These patients met the same inclusion and exclusion criteria and completed the same research protocol as outlined in the study methods.

2. Specific Aims:

Aim 1. To evaluate the relationship between gastric antral motility and GE assessed with scintigraphy in healthy people and patients with diabetic gastroenteropathy.

Results: Antral contraction waves were clearly visible on continuous gastric scintigraphy. After filtering the scintigraphic time-count data contractions were evident in the gastric antrum and body but not in the fundus or background. Moreover, waveforms were not extracted from randomly generated time-count data. These findings supported our hypothesis that the waves identified in the antrum were truly gastric contractions.

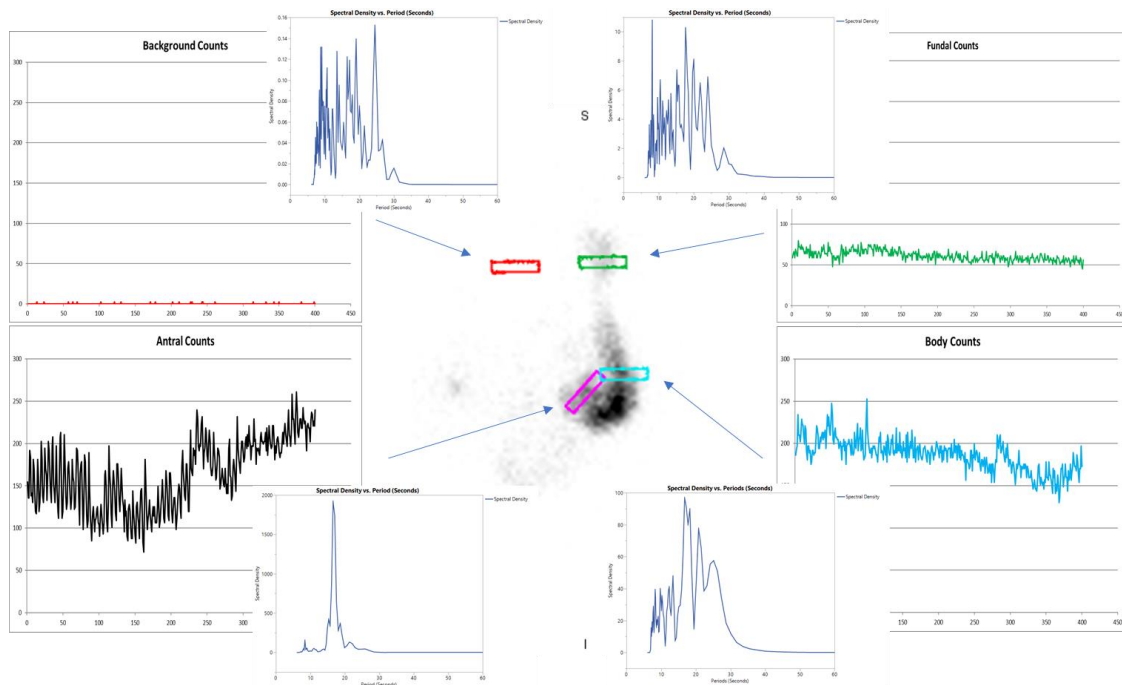
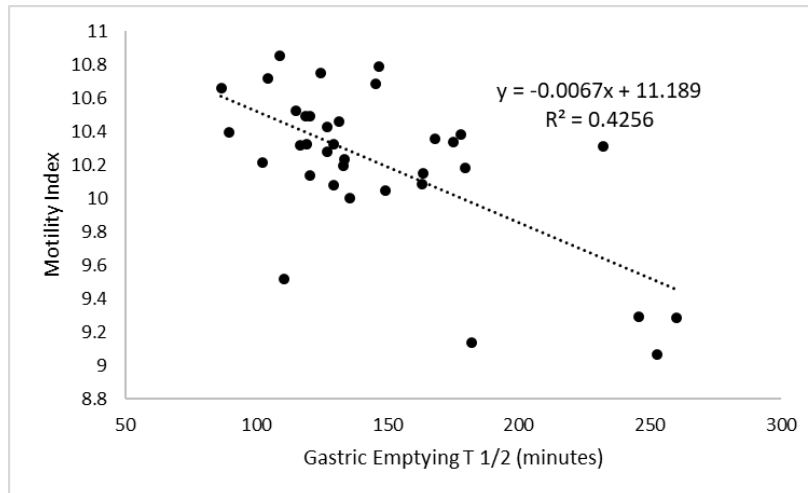


Figure 1. Scintigraphic image of the stomach (center) from which scintigraphic time-activity curves for the regions of interest in the antrum (black), body (blue), fundus (green) and background (red) were derived. The scales of the Y-axis on the time-activity curves are identical. Inset are the transformed data demonstrating the dominant frequency of the contractions. Note that the maximum value of the y-axis varies from 2000 (antrum) to 0.016 (background).

Contraction frequency, as determined by Fourier Transformation of the filtered scintigraphic antral time-count data, was slightly greater than 3 cycles per minute in all participants; there was no significant difference amongst the groups. Neither did mean contraction amplitude differ amongst the groups. However, the motility index, calculated using the following formula, $MI = \ln(\text{sum of percentage amplitudes} * \text{number of contractions} + 1)$, differed amongst the groups, increasing numerically from delayed GE to rapid GE. The motility index correlated with both gastric emptying at 1 hour and the gastric emptying half time in regression analyses.



Aim 2. To compare gastric antral motility measured with MRI vs. scintigraphy.

Results: During the COVID pandemic patients spent less time in Rochester, MN. It was not possible to schedule research MRI scans within the timeframe patients were attending for their clinical evaluation. Consequently, with the agreement of the funding institution, aim 2 was discontinued as a component of the clinical research.

Aim 3. To evaluate the contribution of GE, gastric motility, and gastric accommodation evaluated with MRI, and symptoms during a GE study, to daily symptoms in patients with upper GI symptoms.

Results: as mentioned in Aim 2, MRI was not pursued in the final research protocol. The scintigraphic intra-gastric distribution of a meal at 1 hour after meal consumption was used as a surrogate.

The meal-induced symptom score correlated strongly with the GCSI-DD mean total score ($\rho=0.92$, $P<0.001$). For patients alone, the correlation between meal-induced symptoms and the mean GCSI-DD score ($\rho=0.82$, $P<0.001$). However, the GCSI-DD total score did not correlate with motility index ($\rho=0.02$, $P=1.0$), the intra-gastric distribution of the meal at 1 hour ($\rho=0.11$, $P=1.0$) or GE $t_{1/2}$ ($\rho=0.36$, $P=0.25$) but did correlate with the total meal symptom score ($\rho=0.92$, $P<0.001$). In a multiple variable model with the same factors as predictor variables, 80% of the variance in the GCSI-DD was explained, predominantly by the meal-induced symptoms score ($F=112.0$, $P<0.001$) which was the only significant predictor.

3. Publications:

None to date