

Gastric Myoelectrical Activity-Derived Threshold Predicts Resolution of Delayed Gastric Emptying and Symptom Outcome

Improvement Following Pyloric Balloon Dilation in Subset of Gastroparesis

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Introduction

Gastroparesis associated with pyloric outlet obstruction has been characterized by Electrogastrigraphy (EGG) with prominent 3 cycles-per-minute (3cpm) percent distribution of power.¹ Balloon dilation of structural outlet obstruction results in gastric emptying improvement.² Nonstructural or functional gastric outlet obstruction, characterized by hypernormal 3cpm gastric myoelectrical activity (GMA) has been shown to present similarly.¹ The aim of this study is to develop a model based upon specific EGG characteristics, predicting resolution of delayed gastric emptying and symptom improvement after pyloric balloon dilation in this subtype of gastroparesis.

Patients & Methods

Thirty patients with gastroparesis were divided into two groups. Subjects with 3cpm GMA values above measured population-based norms defined the hypernormal 3cpm GMA group vs. normal 3cpm GMA group, which remained within measured population-based norms.³ Both groups underwent standard water-load EGG, nuclear gastric emptying study, and standardized dyspepsia surveys before and 12 months post 20 mm pyloric balloon dilation. Primary analyses were performed using Student t-test, Mann-Whitney U-test, and Wilcoxon signed-rank test where appropriate. In instances where the distribution of differences for data was found to be non-normal using Shapiro-Wilk Test of Normality, non-parametric statistical methods were utilized. Analyses were used to compare EGG, gastric emptying, and standardized dyspepsia symptom scores before and after dilation. Baseline characteristics were analyzed using χ^2 test or Student unpaired t-test as appropriate.

	Number	Male	Female	Age (Years) Mean (SD)	Weight (kg) Mean (SD)	Diabetes (%)
Normal GMA	N=4	0	2	44.3 (6.5)	90.7 (30.1)	0
Hypernormal GMA	N=26	4	25	49.9 (14.2)	67.2 (14.5)	4 (13)
p-value			0.574	0.528	0.350	0.621

Table 1. Baseline Patient Characteristics

Results

A derived GMA 3cpm threshold (GMAT) predicted gastric emptying normalization and symptomatic improvement after pyloric balloon dilation. GMAT sensitivity and specificity predicting normalization were 96.15% and 75.00% respectively with 93.33% of patients correctly classified. Hypernormal 3cpm GMA subjects % distribution of power decreased significantly ($p \leq 0.005$). Normal 3cpm GMA subjects showed no significant change in activity at any time point ($p > 0.05$). Hypernormal 3cpm GMA patients normalized gastric emptying at 120 minutes ($p < 0.001$) in contrast to normal GMA subjects ($p = 0.252$). Hypernormal GMA subgroup symptoms of upper abdominal discomfort, discomfort worsened by eating, early satiety, fullness, nausea, and bloating improved ($p \leq 0.001$) vs. no improvement in normal 3cpm GMA subjects ($p > 0.05$).

	Normal GMA			Hypernormal GMA			Pre-Dilation Comparison p-value	Post-Dilation Comparison p-value	Normal (Pre) Hypernormal (Post) Comparison p-value
	Pre-Dilation Mean (SD)	Post-Dilation Mean (SD)	p-value	Pre-Dilation Mean (SD)	Post-Dilation Mean (SD)	p-value			
0 min.	29 (17.73)	13.14 (8.33)	0.191	53.5 (18.51)	36.14 (17.8)	0.003	0.020	0.018	0.461
10 min.	15.3 (4.52)	23.41 (5.12)	0.114	41.1 (20.3)	24.91 (12.05)	0.005	0.013	0.855	0.051
20 min.	22.67 (10.9)	20.91 (11.68)	0.883	52.75 (19.3)	30.82 (17.67)	$p < 0.001$	0.012	0.246	0.393
30 min.	24.94 (13.7)	21.76 (7.3)	0.748	56.38 (20.18)	34.92 (18.65)	$p < 0.001$	0.006	0.179	0.315

Table 2. EGG 3cpm Percent Power of Distribution Pre and Post Pyloric Balloon Dilation

Symptoms	Normal GMA			Hypernormal GMA			Pre-Dilation Comparison p-value	Post-Dilation Comparison p-value
	Pre-Dilation	Post-Dilation	p-value	Pre-Dilation	Post-Dilation	p-value		
Dyspepsia	3.75	3.75	1.00	5.92 (0-9)	0.56 (0-0)	< 0.001	0.331	0.060
Abdominal Discomfort (Upper)	6.50 (6-9)	6.25 (6-8.25)	0.317	7.84 (8-10)	2 (0-3)	< 0.001	0.289	0.064
Bloating	6.25 (6-8.25)	6.00 (6-8.25)	0.564	9.40 (9-11)	0.32 (0-0)	< 0.001	0.019	0.001
Discomfort Worsened by Eating	8.25 (8-8.25)	8.00 (7.75-8.25)	0.317	9.44 (8-11)	0.36 (0-0)	< 0.001	0.147	< 0.001
Early Satiety	7.25 (6.75-8)	7.00 (6.75-7.25)	0.317	5.32 (0-9)	0.48 (0-0)	0.001	0.746	< 0.001
Fullness	5.75 (5.25-8)	4.75 (4.5-6.25)	0.102	4.16 (0-8)	0.12 (0-0)	0.001	0.595	< 0.001
Nausea								

Table 3 Standardized Dyspepsia Scores Pre and Post Pyloric Balloon Dilation

Balloon Dilation of the Pylorus

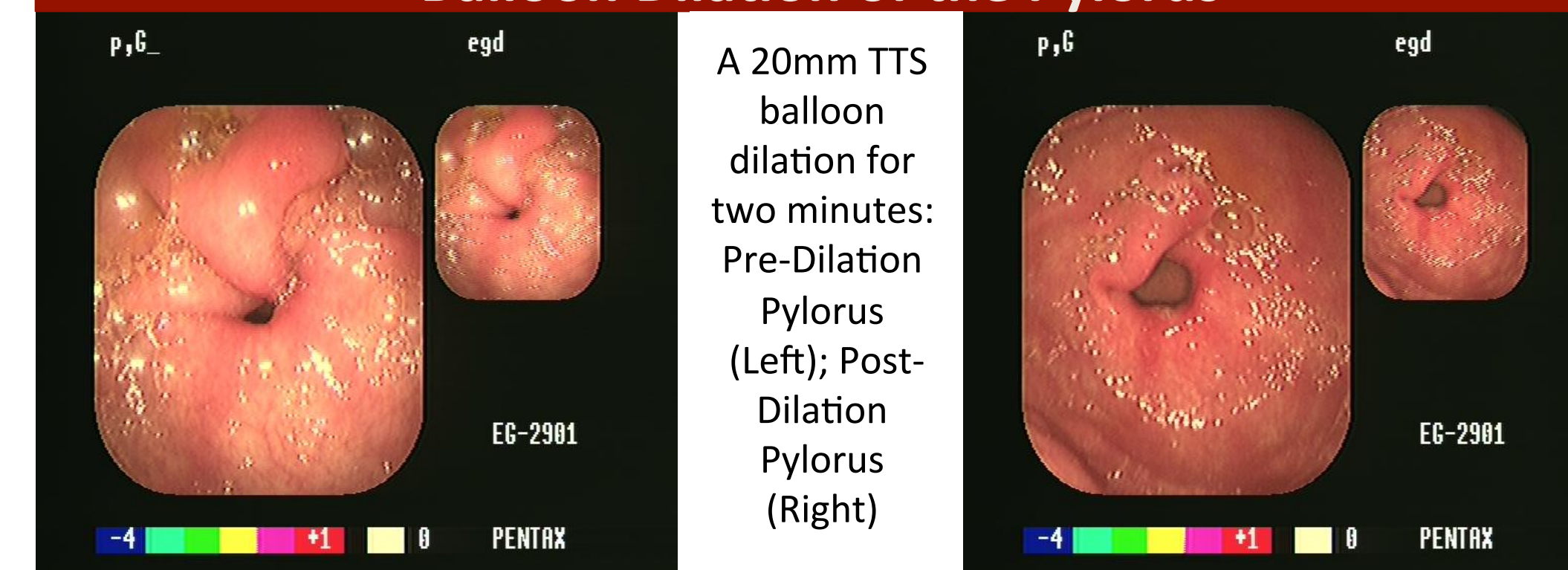


Figure 1. EGD Pre/Post Balloon Dilation

	Positive Diagnosis	Negative Diagnosis	Total	Performance Characteristics (95% CI)
Successful response to dilation	25	1	26	Sensitivity (PPV): 96.15 (80.36,99.90)
Unsuccessful response to dilation	1	3	4	Specificity (NPV): 75.00 (19.41,99.37)
				Correctly Classified: 93.33

EGG electrogastrigram, PPV positive predictive value, NPV negative predictive value

Table 4. Joint Activity Model Performance Characteristics

	Normal GMA			Hyper Normal GMA			Pre Dilution Comparison p-value	Post Dilution Comparison p-value
	Pre-Dilation	Post-Dilation	p-value	Pre-Dilation	Post-Dilation	p-value		
Mean % Emptied 90 minutes	37.00	29.50	0.116	33.93	71.81	$p < 0.001$	0.549	$p < 0.001$
Mean % Emptied 120 minutes	48.75	43.75	0.252	45.47	87.83	$p < 0.001$	0.597	$p < 0.001$

Table 5. Solid Phase Nuclear Gastric Emptying Study Pre and Post Pyloric Balloon Dilation

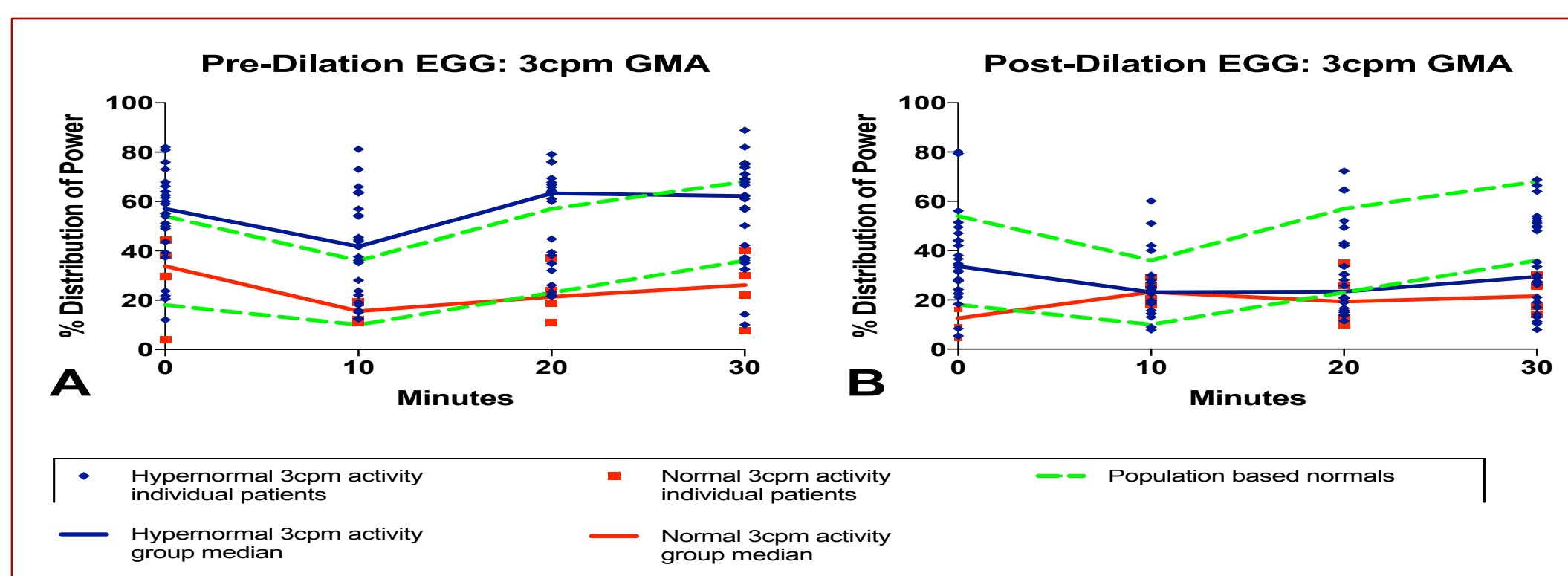


Figure 2. Effect of pyloric dilation on the percentage distribution of power in normal ranges before and 10, 20, and 30 minutes after the water load test in patients with gastroparesis and hyper or normal GMA. Pre-dilation EGG (A). Post-dilation EGG (B).

Linear Regression: Model Fit

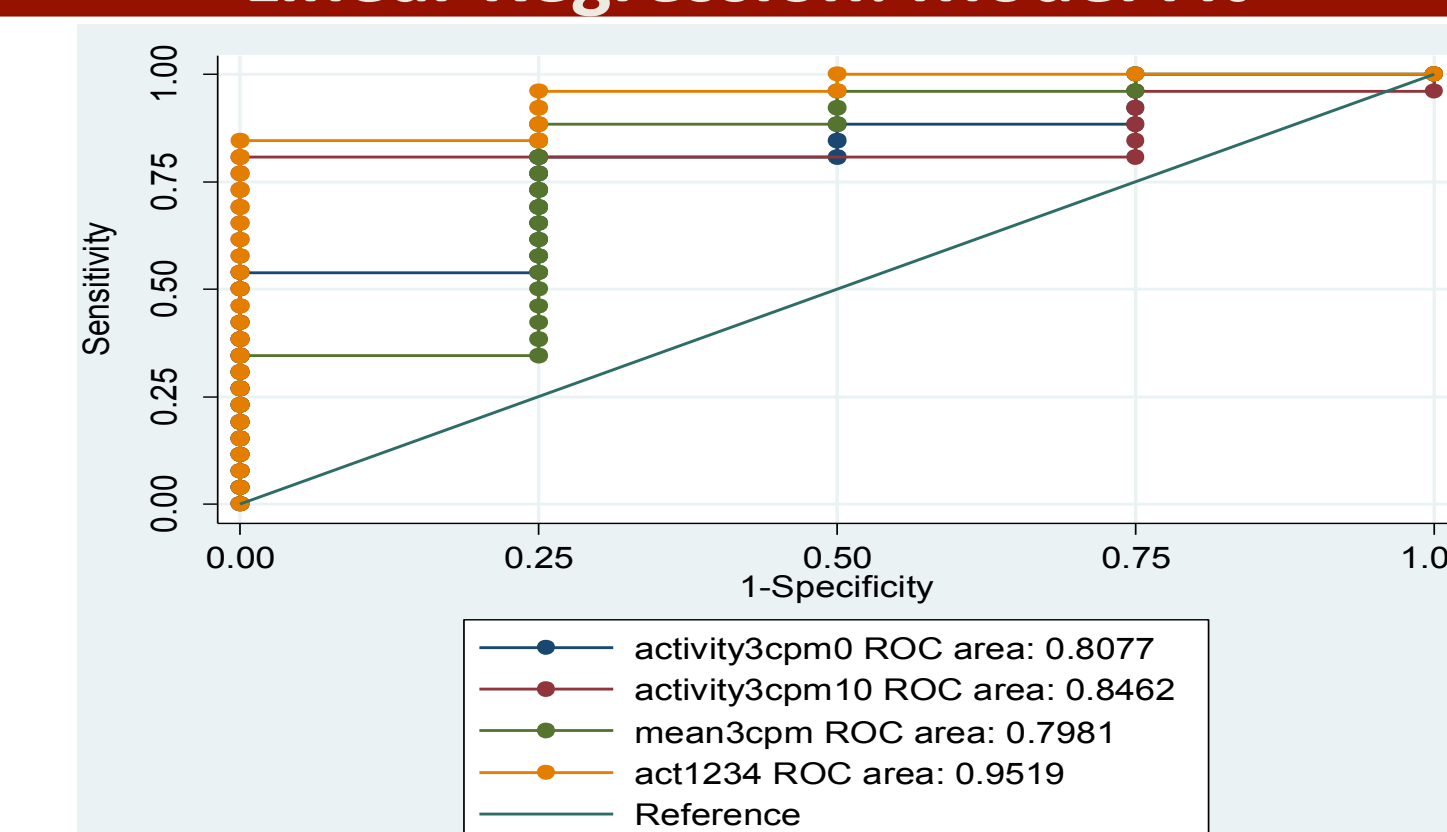


Figure 3. Association of Post-Dilation Success (% Emptying >60% at 120 minutes) with Pre-Dilation 3CPM Activity and Model Fit. Joint Activity Score Linear Regression: $-8.299 + 0.128(3CPM0min) + 0.210*(3CPM10min) + 0.074*(3CPM20min) - 0.073*(3CPM30min)$. Threshold value >0.59.

Conclusions

- EGG is able to define normal 3cpm GMA subtypes of gastroparesis.
- Using population normative data, EGG can further differentiate two sub-types of gastroparesis. One having the characteristic of normal 3cpm GMA and the other defined as hypernormal 3cpm GMA (exceeding the range of population based norms) or functional or non-structural pyloric outlet obstruction.
- The hypernormal 3cpm GMA subtype responded to endoscopic pyloric balloon dilation with resolution of gastroparesis, the return to normal of the 3cpm GMA levels, and resolution of symptoms.
- The normal 3cpm GMA control subgroup with gastroparesis did not respond to endoscopic pyloric balloon dilation.
- A 3cpm GMA threshold (GMAT) derived from a linear regression analysis of 3cpm GMA data predicted with 96% confidence the resolution of gastroparesis in response to endoscopic pyloric balloon dilation in hypernormal 3cpm GMA subtypes of gastroparesis.
- Combining EGG with GMAT predicted the resolution of gastroparesis and symptom improvement in response to endoscopic therapy.
- Further application of this noninvasive technology may allow determination of additional subtypes of gastroparesis and GMAT levels that could predict the response to other therapy such as BOTOX, pyloroplasty, gastric stimulation/pacing, or other treatments.

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