

# Effect of Nutritional Intervention on Patients with Gastroparesis

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## Background

- Gastroparesis (GP) is a clinical syndrome diagnosed via three components: presence of symptoms, absence of mechanical outlet obstruction, and objective evidence of delayed gastric emptying into the duodenum.
- Commonly reported symptoms include nausea, vomiting, upper abdominal pain, early satiety, abdominal fullness and bloating.
- Typical etiologies include diabetes (40 % in long standing Type 1, 10-20% in Type 2), post-surgical-13%(Bariatric, Nissen fundoplication, etc.), idiopathic - 36% (post-viral), medications (opiates, anticholinergic), as well as less common causes including connective tissue diseases, infiltrative disorders, and neurologic disorders.
- Management includes correction of dehydration and electrolyte abnormalities, nutritional support, and improved glycemic control in patients with diabetes, as well as pro-kinetic agents (Metoclopramide, etc.), use of Botox, and gastric pacemakers for refractory cases.
- Patient Assessment of Gastrointestinal Disorder Symptom Severity Index [PAGI-SYM] is a verified assessment of the severity of symptoms of patients with gastroparesis.
- Prior studies have validated its use in the clinical monitoring of such symptoms.

## Study Aims

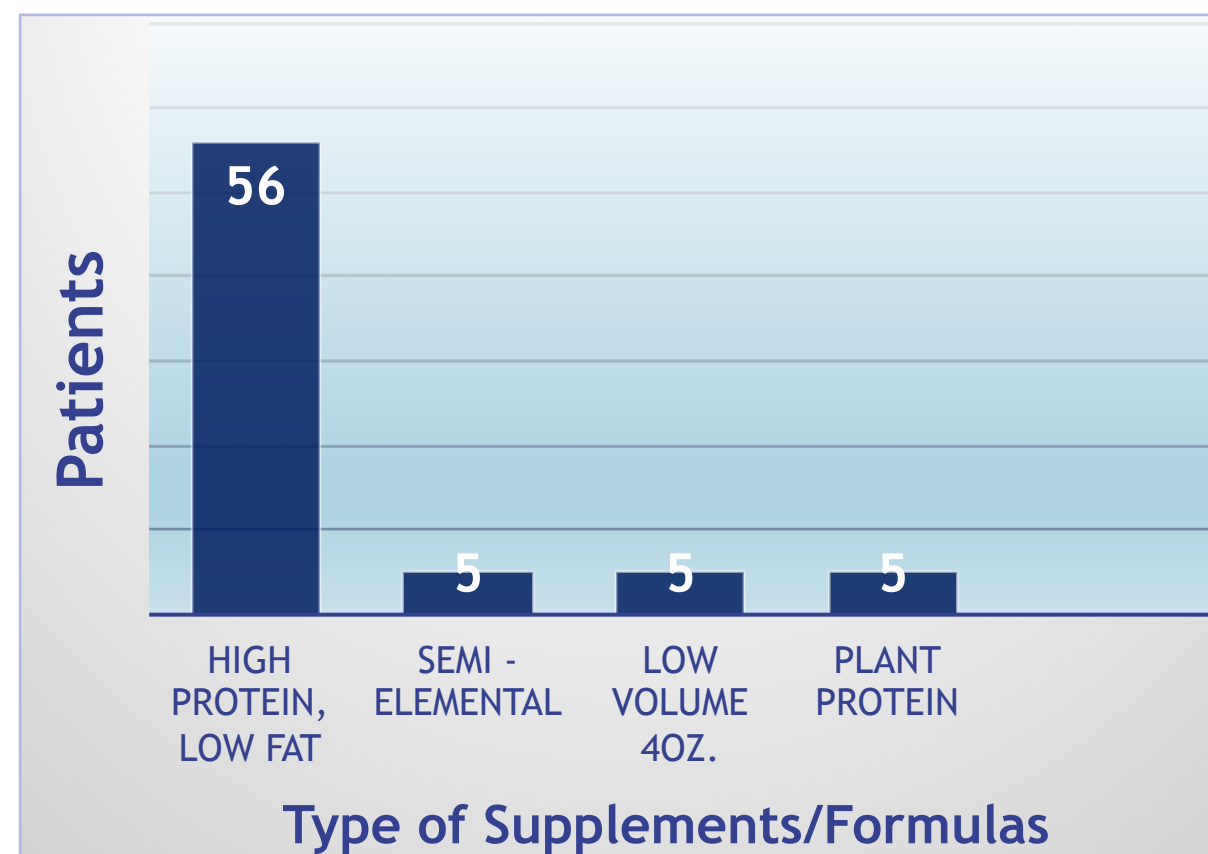
- Utilize the PAGI-SYM survey as an assessment tool in following clinical symptoms of patients with GP.
- Determine if a formal consultation with a Registered Dietitian (RD) provided benefit to patients documented gastroparesis.

## Methods

- Prospective study of 71 GP patients of various etiologies as well as various treatment modalities.
- Patients diagnosed with GP via gastric emptying studies formally met with a RD where they were introduced to the PAGI-SYM survey and were educated regarding a GP diet: reduction of meal size, decreased fiber, decreased fat, increased liquid intake, and supplemental oral nutrition – (high protein, low-fat),(semi-elemental),(low volume),(plant protein).[Table 1].

**Table 1. Registered Dietitian (RD) GP Diet Recommendations**

1. Small, frequent meals
2. Fiber and Fat restriction
3. Soft food diet; masticate well
4. Avoid alcohol and carbonated beverages
5. Separate solids from liquids
6. Sit upright for 1-2 hours after eating
7. Adequate hydration
8. Vitamin supplementation
9. Liquid supplements/formulas
10. Personalized GP meal plans



**Table 2. Change of distribution of PAGI-SYM over time**

	Estimate	95% CI	p
1 <sup>st</sup> follow up†	-6.2	(-9.1, -3.3)	<0.001
2 <sup>nd</sup> follow up	-7.8	(-10.8, -4.8)	<0.001
3 <sup>rd</sup> follow up	-11.1	(-14.0, -8.2)	<0.001

CI: confidence interval

P: p value

†: Estimates about follow-up were relative to baseline PAGI-SYM score.

**Table 3: Estimate of average PAGI-SYM score at baseline**

	Estimate	95% CI
Unknown	51.0	(43.3, 58.8)
Post-surgical	52.3	(40.2, 64.5)
Post-viral	56.4	(38.7, 74.1)
Diabetes	65.1	(48.2, 82.0)
Other*	49.7	(26.2, 73.2)

**Table 4. Mixed Effect Regression Model on PAGI-SYM Score**

	Estimate	95% Confidence Interval (CI)	p-value
<b>Time</b>			
Baseline	54.9	(47.0, 62.9)	
1 <sup>st</sup> follow-up	48.9	(40.9, 56.9)	<0.00
2 <sup>nd</sup> follow up	47.2	(39.2, 55.2)	
3 <sup>rd</sup> follow up	43.9	(35.8, 51.9)	
<b>Etiology</b>			
Unknown	44.8	(37.2, 52.4)	
Post-surgical	46.1	(34.1, 58.2)	
Post-viral	50.2	(32.6, 67.8)	
Diabetes	58.9	(42.1, 75.8)	
Other*	43.5	(20.0, 66.9)	0.58
<b>Medical Therapy</b>			
Yes	55.9	(46.6, 65.2)	0.03
None	41.6	(30.5, 52.6)	
<b>Prior Endoscopic Therapy (e.g. Botox)</b>			
Yes	50.2	(38.1, 62.3)	0.65
None	47.2	(39.4, 55.1)	
<b>Both Medical and Endoscopy</b>	62.2	(46.8, 77.6)	0.16

## Methods (continued)

- Initial encounter stratified patients based on prior treatment modalities, medications, etc. and generated a PAGI-SYM score which would be tracked every two weeks for a total of six weeks via phone calls from physicians and RD.
- Mixed effect regression as well as measures of central tendency were used to analyze the data.

## Results

- There was a significant decrease in PAGI-SYM scores indicating a decrease in the severity of symptoms with RD consult [Table 2].
- On average, there was a 6-point decrease in the score (95% confidence interval (CI): -9.1, -3.3) at first follow-up; an 8-point decrease (95%CI: -10.8, -4.8) at second follow-up; and an 11-point decrease (95%CI: -14.0, -8.2) at third follow-up in patients with GP and a RD consult [Table 2].
- Pre-RD PAGI-SYM baseline scores were averaged by etiology [Table 3]
- Patients on concurrent medical therapy (Reglan, etc.) had significantly higher PAGI-SYM values compared to those not on medical therapy, however there was no significant difference associated in patients utilizing an RD and on prior medical therapy vs those who met with an RD and not on prior medical therapy [Table 3].
- Prior Botox therapy did not have a significant effect on PAGI-SYM score during the dietary intervention period [Table 4].

## Conclusions

- Following a GP diet, namely, adhering to small sized meals, decreased fiber intake, decreased fat intake, and increased fluid intake (relative to solid foods), oral supplementation when implemented under the guidance of a RD, as well as reinforcement through follow up, plays a significant role in improving symptoms of GP.
- Although prior studies have demonstrated modest improvement in GP symptoms via diet changes, these studies were of short duration (1 day to 4 weeks) and did not incorporate a RD consult.
- Our study indicates that regardless of their prior medical treatment options, patients with GP benefit from a formal consult with a dietitian.
- Future studies could assess decreased need of medications or use of Botox injections on patients following their personalized diet.