

SmartPill®

Title

Comparison of gastric emptying of a nondigestible capsule to a radio-labelled meal in healthy and gastroparetic subjects

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Key Points

1. A total of 87 healthy patients and 61 gastroparetic patients, all with a history of gastroparesis, were enrolled in this study. Of these, 125 subjects were included in the final analysis to compare gastric emptying scintigraphy (GES) and the SmartPill wireless motility capsule (WMC) to measure gastric emptying.
2. The correlation between the two tests was 0.73, with a sensitivity and specificity similar to GES-4 hour, suggesting that this method is reasonable for clinical evaluation of delayed gastric emptying.
3. This study demonstrates a clinically significant correlation between capsule Gastric Emptying Time (GET) and scintigraphy for the evaluation of gastric function (>0.7). The emptying of the nondigestible capsule occurs after a digestible meal empties, assessing a unique aspect of gastric emptying that is related to meal emptying.
4. GET of the capsule distinguishes healthy subjects from subjects with gastroparesis, is well-tolerated and safe, and represents a novel technique to assess upper GI symptoms of nausea, vomiting, bloating, abdominal pain and early satiety potentially caused by gastroparesis. This novel wireless pH and motility capsule offers an office-based alternative to scintigraphy.

Abstract:

Background: Gastric emptying scintigraphy (GES) using a radio-labelled meal is used to measure gastric emptying. A nondigestible capsule, SmartPill, records luminal pH, temperature, and pressure during gastrointestinal transit, providing a measure of gastric emptying time (GET).

Aims: To compare gastric emptying time and GES by assessing their correlation, and to compare GET and GES for discriminating healthy subjects from gastroparetics.

Methods: Eighty-seven healthy subjects and 61 gastroparetics enrolled with simultaneous SmartPill and GES. Fasted subjects ingested a capsule and a [(99m)Tc]-SC radio-labelled meal. Images were obtained every 30 min for 6 h. Gastric emptying time and percentage of meal remaining at 2/4 h were determined for each subject. The sensitivity/specificity and receiver operating characteristic analysis of each measure were determined for each subject.

Results: Correlation between GET and GES-4 h was 0.73 and GES-2 h was 0.63. The diagnostic accuracy from the receiver operating characteristic curve between gastroparetics and healthy subjects was GET = 0.83, GES-4 h = 0.82 and GES-2 h = 0.79. The 300-min cut-off time for GET gives sensitivity of 0.65 and specificity of 0.87 for diagnosis of gastroparesis. The corresponding sensitivity/specificity for 2 and 4 h standard GES measures were 0.34/0.93 and 0.44/0.93, respectively.

Conclusion: SmartPill GET correlated with GES and discriminates between healthy and gastroparetic subjects offering a nonradioactive, standardized ambulatory alternative to scintigraphy.

Table 1. Median emptying times in minutes for gastric emptying time (GET) and median per cent of meal retained for GES-2 h and GES-4 h with corresponding 95% confidence intervals (CI)	Median (CI)	
	Gastric emptying measure	
	Healthy subjects	Gastroparetic subjects
GET (min)	215 (199–225), n = 77	>360 (320, >360), n = 48
GES-2 h (% of meal retained)	25% (23–37%), n = 87	51% (42–58%), n = 59
GES-4 h (% of meal retained)	1% (1–1.4%), n = 87	9% (4–13%), n = 59