

SmartPill®

Title

Investigation of Colonic and Whole-Gut Transit With Wireless Motility Capsule and Radiopaque Markers in Constipation

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Key Points

1. A total of 165 subjects were enrolled, including 78 subjects with constipation and 87 healthy volunteers. Data from 148 subjects were available for analysis of transit time.
2. In this large study of radiopaque markers (ROMs), there was good correlation between the ROM technique and the SmartPill for colonic transit time (CTT) and whole gut transit time (WGTT). Also, SmartPill had high specificity (0.95) and reasonable sensitivity (0.46) for identifying an abnormal transit time in patients with constipation. These values were comparable with the ROM specificity and sensitivity of 0.95 and 0.40, respectively.
3. The advantage of the SmartPill technique is that the assessment can be performed under real-life physiological conditions, unlike scintigraphy or colonic manometry.
4. This large, prospective, and comparative study shows that a wireless motility capsule technique offers a novel and reliable measurement of CTT and WGTT in an ambulatory setting. The test has high specificity for identifying patients with slow transit constipation, and also can assess gastric emptying time (GET) and small-bowel transit time (SBTT).

Abstract:

Background and Aims: Colonic transit time (CTT) traditionally is assessed with radiopaque markers (ROMs), which requires radiation and is hindered by lack of standardization and compliance. We assessed regional and CTT with the SmartPill (SmartPill Corporation, Buffalo, NY), a new wireless pH and pressure recording capsule, in constipated and healthy subjects and compared this with ROM.

Methods: Seventy-eight constipated (Rome II) and 87 healthy subjects ingested a 260-kcal meal, a ROM capsule, and the SmartPill. Subjects wore a data receiver and kept daily stool diaries for 5 days. SmartPill recordings assessed CTT, whole-gut transit time (WGTT), small-bowel transit time (SBTT), and gastric emptying time. Abdominal radiographs on days 2 and 5 assessed ROM transit. Sensitivity/specificity and receiver operating characteristics (ROCs) of each technique and utility were compared.

Results: Gastric emptying time (GET), CTT, and WGTT were slower ($P < .01$) in constipated subjects than controls. CTT was slower in women than men ($P = .02$). Day 2 and day 5 ROM transits were slower ($P < .001$) in constipated subjects. Correlation of the SmartPill CTT with ROMs expelled on day 2/day 5 was $r = 0.74/r = 0.69$ in constipation, and $r = 0.70/r = 0.40$ in controls, respectively. The diagnostic accuracy of the SmartPill CTT to predict constipation from ROC was 0.73, with a specificity of 0.95. These were comparable with those of day 5 ROM (ROC, 0.71; specificity, 0.95).

Conclusions: The SmartPill is a novel ambulatory technique of assessing regional (gastric, small bowel, colonic) and WGTT without radiation. It reveals hitherto unrecognized gender differences and upper-gut dysfunction in constipation. It correlates well with ROM and offers a standardized method of discriminating normal from slow colonic transit.

Table 1. Median (25th–75th Percentiles) Values for CTT, WGTT, GET, and SBTT as Measured by the SmartPill in Constipated Subjects and Healthy Controls, and the Effects of Sex

| | Overall | | | Women only | | | Men only | | |
|---------|-------------------------|---------------------|---------|-------------------------|---------------------|---------|-------------------------------------|---------------------|---------|
| | Constipated (n = 67) | Healthy (n = 81) | P value | Constipated (n = 59) | Healthy (n = 39) | P value | Constipated ^a (n = 8) | Healthy (n = 42) | P value |
| CTT, h | 46.7 (24.0–91.9) | 21.7 (15.5–37.3) | <.0001 | 46.7 (24.0–91.9) | 24.7 (17.3–43.2) | .0013 | 50.9 (25.2–) | 18.7 (13.3–26.8) | .0264 |
| WGTT, h | 59.3 (39.7–97.9) | 29.7 (22.4–45.7) | <.0001 | 58.0 (39.7–97.9) | 33.9 (25.7–51.0) | .0004 | 72.2 (36.3–) | 25.6 (20.8–33.9) | .0115 |
| GET, h | 3.5 (3.0–4.2) | 3.0 (2.5–3.9) | .0123 | 3.4 (3.0–4.1) | 3.5 (2.7–4.2) | .8414 | 4.2 (3.6–) | 2.7 (2.4–3.7) | .0054 |
| SBTT, h | 4.2 (3.5–5.1) | 3.8 (3.2–4.7) | .0908 | 4.2 (3.5–5.2) | 3.8 (2.9–4.9) | .2530 | 4.4 (3.4–4.8) | 3.8 (3.3–4.5) | .4667 |

^aSeventy-fifth percentile not observed for CTT, WGTT, and GET because of capping of data.