

INGESTIBLE GAS-SENSING CAPSULE FOR WHOLE GUT TRANSIT

Prospective comparison with wireless pH-motility capsule (SmartPill) in gastroparesis and chronic constipation

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BACKGROUND

Assessment of regional gut transit time (gastric emptying time [GET] and colonic transit time [CTT]) is used to evaluate patients suspected of dysmotility.

Traditional methods of assessment, radio-opaque markers and scintigraphy, are considered the gold standard methods of assessment for CTT and GET, respectively; however, they are limited in that they measure only a single regional transit with each test.

The SmartPill (Fig 1.) is an FDA-approved method that has the ability to assess all regional transit in one test, although it has struggled to achieve reimbursement.

The Atmo Gas Capsule (Fig. 2) is a novel ingestible electronic capsule validated in healthy participants but its performance in those with dysmotility is unknown.

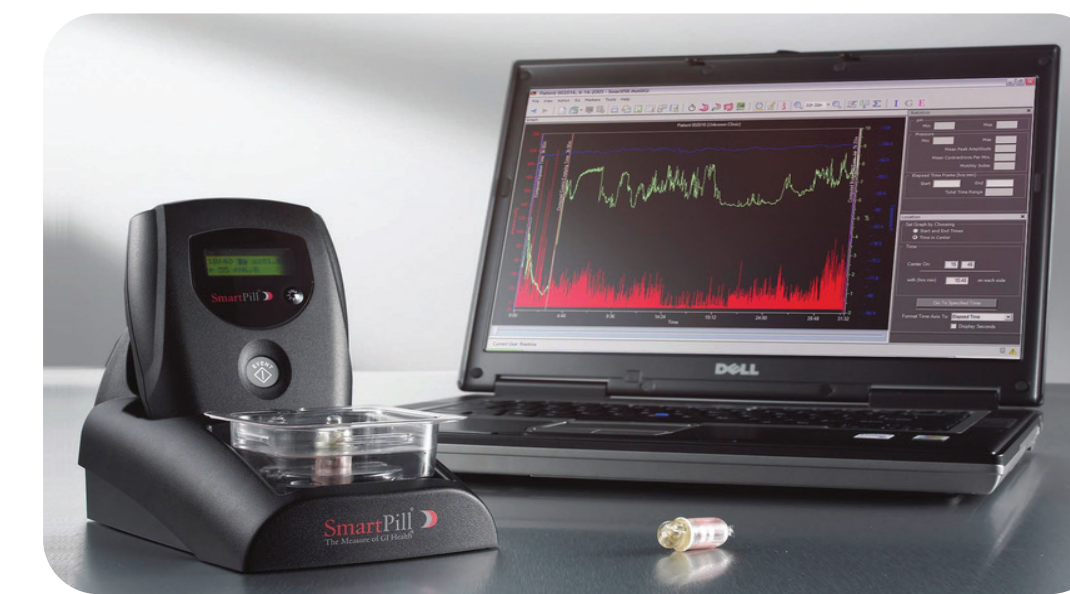


Figure 1. SmartPill system consisting of capsule, receiver, reader dock and laptop.



Figure 2. Atmo Gas Capsule system consisting of capsule, receiver and belt, tablet, and Atmo bar.

AIM

To validate Atmo Capsule measurements to the SmartPill measurements in the evaluation of GET and CTT in patients with symptomatic gastroparesis and/or constipation evaluated at multiple centres.

METHODOLOGY

Patients were recruited from outpatient clinics at MacArthur Clinical School, Western Sydney University (NSW, Australia) and the Alfred Hospital (VIC, Australia) to undergo simultaneous measures of gut transit time using SmartPill (Fig. 3) and Atmo Capsule (Fig. 4) (cutoffs for delayed GET >5 h, and delay CTT >59 h).

The study was designed to demonstrate gastrointestinal location assessment in patients who had normal and delayed transit as determined by the SmartPill. Participants fasted for at least 8 h prior to consuming a standard meal (SmartBar) before the capsules were ingested in randomised order. Participants continued to fast for a further 6 h post-ingestion. Capsule excretion was defined by temperature drop, signal loss, or visual confirmation at time of bowel motion.

Regional transit times were calculated and compared by Wilcoxon matched-pair signed rank test and agreement was assessed using Bland-Altman analysis. Intra-class correlation coefficient was used to assess inter-observer agreement in the detection of the landmarks identified using the gas-sensing capsule and the SmartPill.

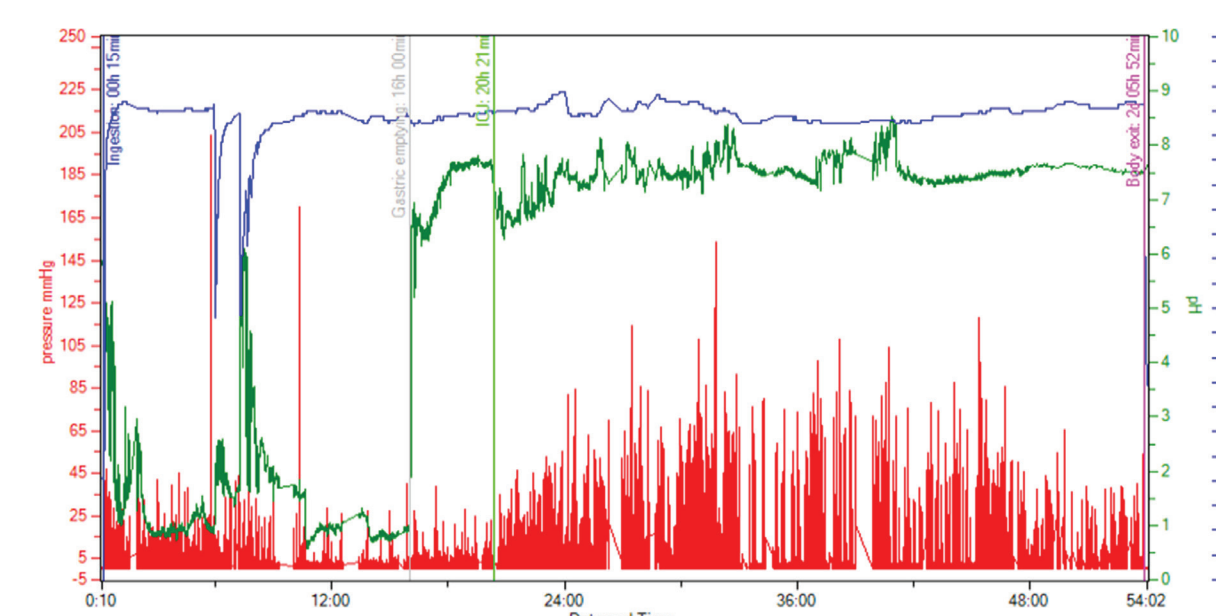


Figure 3. Example of SmartPill measurements of pH, pressure and temperature in the evaluation of regional gut transit.

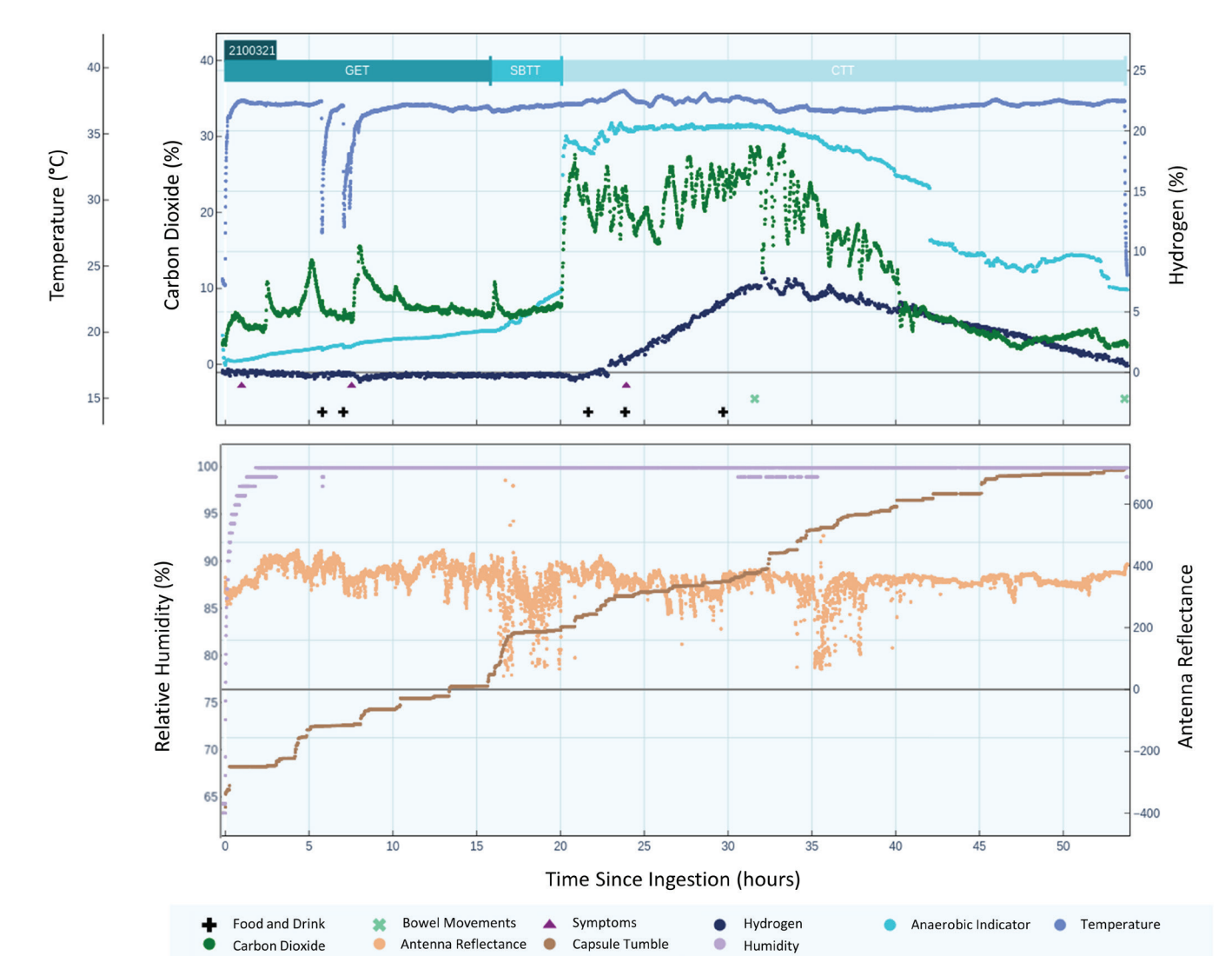


Figure 4. Example of Atmo measurements of temperature, relative humidity, hydrogen concentration, carbon dioxide concentration, along with indicators of anaerobic environment, capsule tumble, and antenna reflectance in the evaluation of regional gut transit.

RESULTS

Participant Recruitment

- 48 patients recruited
- 38 female
- 43 eligible
- Av. age 39.5 yr (std 16)

Regional Gut Transit Times

Table 1. Regional and whole gut transit times determined by SmartPill and Atmo

Transit Region	SmartPill hr (IQR)	Atmo hr (IQR)
Gastric Emptying Time (GET)	2.9 (2.1 – 4.2)	3.1 (1.8 – 4.3)*
Small Bowel Transit Time (SBTT)	4.3 (3.6 – 5.3)	4.3 (3.6 – 5.8)*
Orocaecal Transit Time (OCTT)	7.6 (6.4 – 12.4)	7.0 (5.9 – 11.7)*
Colonic Transit Time (CTT)	43 (19 – 71)	43 (22 – 70)*
Whole Gut Transit Time (WGTT)	52 (25 – 86)	50 (29 – 88)*

*Wilcoxon p-value >0.01 suggests not statistically different to SmartPill

Bland-Altman Agreement Analysis

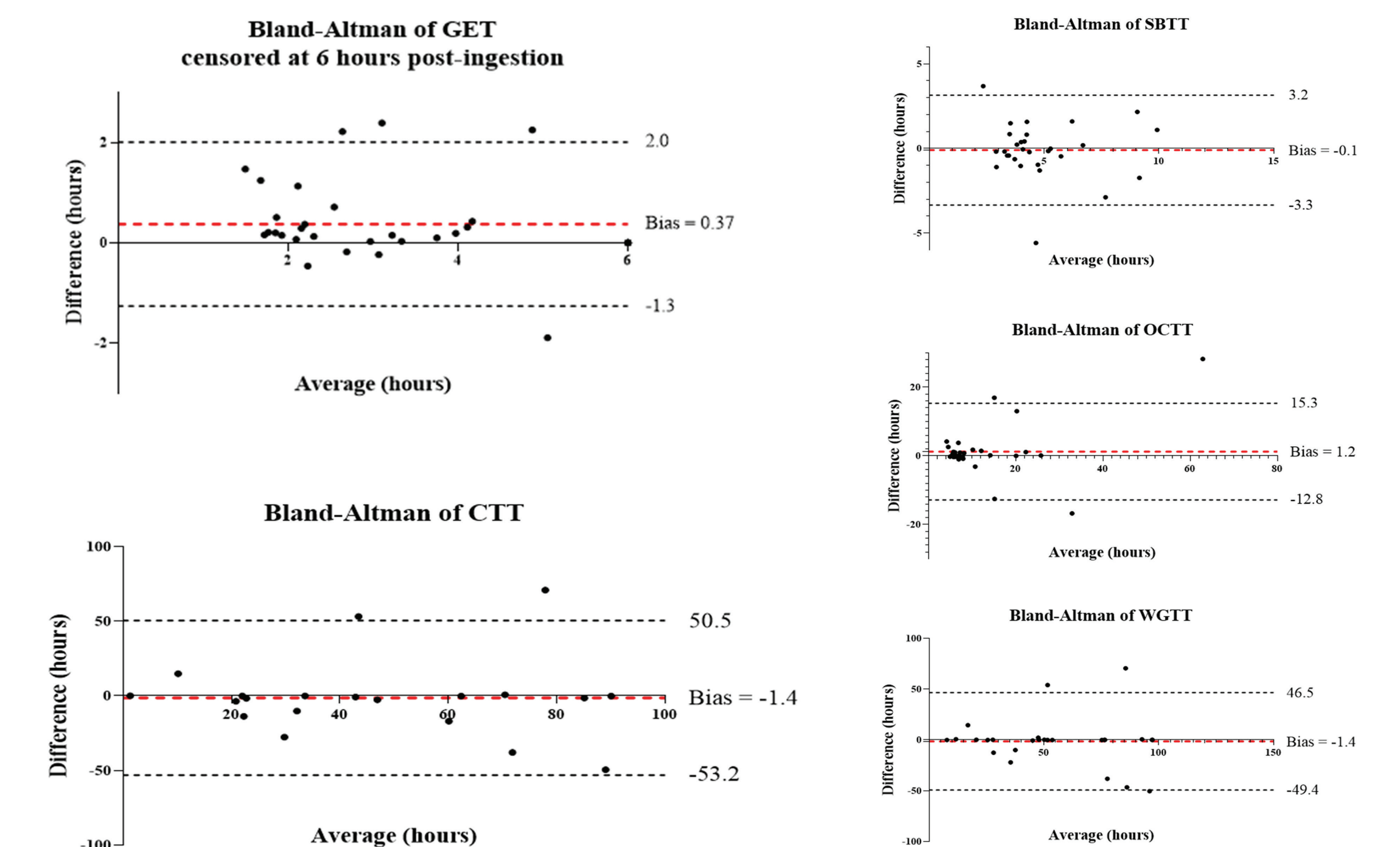


Figure 5. Bland-Altman agreement analysis of GET, SBTT, OCTT, CTT and WGTT by SmartPill and Atmo. The upper and lower limits of agreement are two standard deviations above and below the mean difference (solid line). Dotted lines enclose 95% of the observed inter-observer differences.

Diagnostic Agreement

SmartPill identified 6 (out of 32) patients with delayed GET and 14 (out of 34) patients with delayed CTT, which corresponds to 83% and 79% agreement with Atmo Capsule, respectively.

CONCLUSION

The overall transit time and diagnostic agreement validates Atmo Capsule relative to SmartPill in measurements of GET and CTT in a multicenter clinical study of symptomatic gastroparesis and/or constipation patients.



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