

Comparison of a novel ingestible gas-sensing capsule with the wireless motility capsule for assessment of intestinal motility

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Background:

An array of measurement techniques are available for assessment of regional gastrointestinal transit, but their clinical value is limited due to practicality and expense. The Atmo gas-sensing capsule transmits patterns of volatile organic compounds and gases telemetrically and provides an alternative method of assessing gut transit.

Aims:

1. To develop sets of rules using specific, transmitted data ('motility marker') that represent gastro-duodenal and ileo-caecal passage of the capsule.
2. To compare whether transit measurements by the gas-sensing capsule were comparable to those of a validated wireless motility capsule (WMC).

Methods:

Sets of rules that define gastro-duodenal and ileo-caecal transit were developed in healthy controls in preliminary studies using the 'motility marker'. The rules were validated in a cohort of irritable bowel syndrome (IBS) patients in a dietary intervention study for similar endpoints.

In a cross-sectional comparative study, transit measurements for the two capsules were compared. Following an 8-h overnight fast, subjects ingested a standardised cereal bar followed by the gas-sensing capsule and the WMC in random order.

WMC data were visually assessed independently by two trained investigators. Discrepancies were resolved by a third experienced assessor.

Gas-sensing capsule data were evaluated by the developing engineer and reviewed with the clinical investigators to validate the rules by which to define gastric emptying and ileocaecal junction (ICJ) to allow transit times to be calculated.

Results:

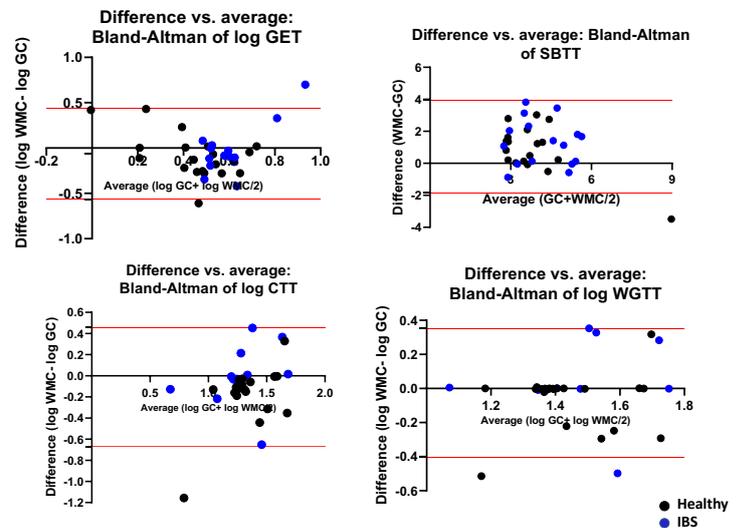
Subjects:

- 22 healthy volunteers (6 female, mean age 34 y, mean BMI 23 kg/m²) (23 studies, one failed due to patient compliance)
- 8 IBS (8 female, mean age 40 y, mean BMI 25kg/m²; 4 IBS-D, 3 IBS-C, 1 IBS-M) (18 studies)

Comparison of regional transit times between gas-sensing capsule vs WMC

Regional transit time median (IQR), h	Healthy		IBS	
	WMC	Atmo	WMC	Atmo
Gastric emptying time (GET)	2.7 (2.05-3.18)	3.5 (1.9 – 5.1)	3.5 (2.7-3.7)	4.1 (3.6 – 4.7)
Small bowel transit time (SBTT)	4.2 (3.57-4.85)	3.1 (2.3-3.6)	5.0 (3.9-6.2)	3.3 (2.4 – 4.4)
Orocaecal transit time	6.79 (6.2-7.8)	6.25 (4.6-7.0)	8.1 (7.0-9.0)	8.2 (7.1-8.7)
Colon transit time (CTT)	17.5 (14.34-20.72)	22.0 (20.0-31.0)	21.8 (15.6-40.3)	18.5 (14.8- 38.5)
Whole gut transit time (WGTT)	24.4 (22.3 -27.8)	25.0 (24.0-35.0)	30.0 (22.2- 49.0)	25.5 (22.6 – 47.2)

Bland-Altman plots showing good agreement in majority of individuals



There were no capsule related adverse events.

Three subjects required abdominal x-ray to confirm excretion of the capsule due to signal loss pre-defecation (2 WMC, 1 WMC+Atmo).

In those with complete data for both capsules, 57% of healthy volunteers and 56% of IBS subjects passed both capsules simultaneously.

Conclusions:

1. The novel (Atmo) gas-sensing capsule is safe.
2. Rules for the 'motility marker' perform well → transit times are comparable to those of the validated WMC.

The Atmo gas-sensing capsule shows promise as a tool to assess gut transit. A validation study to refine current rules for identification of key landmarks in a larger cohort is underway.

Conflicts of interest: PG and KB are shareholders in Atmo Biosciences

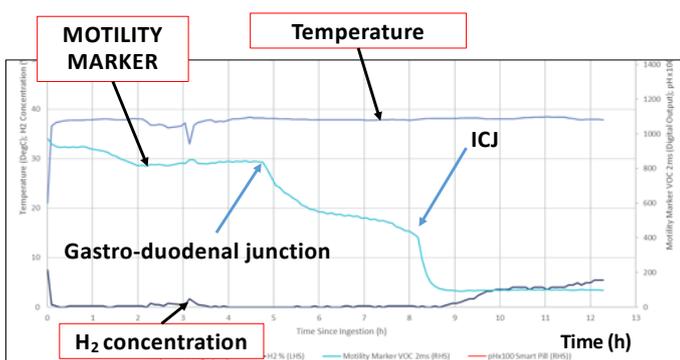


Figure 1: Example of a gas-sensing capsule readout