Comparison of a novel ingestible gas-sensing capsule with the wireless motility capsule for the assessment of regional gastrointestinal transit in healthy adults

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Background:
Assessment of regional gastrointestinal (GI) transit provides valuable information in diagnosing/subtyping functional GI disorders. It may guide therapeutic choice & monitoring of success. However, it is understudied in clinical medicine due to the need for cumbersome imaging techniques with radiation exposure, or the TGA/FDA-approved wireless motility capsule (WMC), for which cost limits access. The novel Atmo™ gas-sensing capsule is a single-use, ingestible device that telemetrically evaluates concentrations of gases and temperature in real-time during transit through the GIT and has the potential to overcome these limitations.

Aims:
Using the WMC as the reference-standard, in healthy subjects, the aims were:
1. To compare the whole-gut transit of the two capsules;
2. To evaluate the gas-sensing capsule for the accuracy of key landmark detection - specifically gastrooduodenal (GDJ) and ileocaecal junctions (ICJ);
3. To compare regional transit times;
4. To define interobserver agreement of landmark assessments; and
5. To assess safety and tolerability.

Methods:
Protocol: Following an 8-hour overnight fast, healthy volunteers ingested a standardised cereal bar and then the gas-sensing capsule and WMC in random order with an additional 6-hour fast prior to resuming their habitual diet. Landmark assessment: Evaluated independently by two observers with a third adjudicator for disparate results.
• Time0 was at ingestion and Final time was at excretion (defined by temperature drop or signal loss at time of bowel movement).
• GDJ and ICJ: For WMC, assessed as per established protocol. For gas-sensing capsule, a ‘basic’ set of rules was used for the first series of capsules and an ‘advanced’ set were used for the final 26 studies (using capsule prototype 2.1 with more advanced capabilities).

Analyses: Regional transit times were calculated and compared by Wilcoxon matched-pairs signed rank test and agreement was assessed using Bland-Altman analyses. Intra-class correlation coefficient (ICC) was used to assess inter-observer agreement in the detection of the landmarks identified using the gas-sensing capsule and the WMC.

Results:
Subjects: n=60; 41 male, median age 34 y, BMI 24 kg/m². Useable data were obtained in 58 gas-sensing capsule and 59 WMC studies.

Simultaneous passage of WMC & gas-sensing capsules occurred in 69% (41/59) of studies. Figure 1 depicts paired total transit times for each participant.

Landmark detection:
• GDJ was identified in 53/59 (89%) of WMC and 53/58 (91%) of gas-sensing capsule studies.
• ICJ was identified in 57/59 (97%) of WMC and 55/58 (95%) of gas-sensing capsule studies.

Table 1. Comparison of regional transit times between gas-sensing capsule (prototype 2.1) and WMC (hours, median/IQR).

There was no statistically significant difference between WMC vs gas-sensing capsule transit times (P>0.1 in all regions). Transit time was not affected by order of ingestion or patient characteristic (age, height, weight, BMI, smoking status) on univariate analysis.

Safety and tolerability:
There were no capsule related serious adverse events.
• 11 participants described mild symptoms “possibly” or “probably” related to capsule ingestion.
• 3 abdominal x-rays were performed to confirm excretion of the capsule (n=2 gas-sensing capsule, n=1 WMC).

Conclusions:
The gas-sensing capsule
• Traverses the gut at a similar rate to the WMC;
• Accurately defines landmarks using the “advanced” set of rules;
• Has excellent interobserver agreement in defining landmarks and
• Acceptable agreement in assessment of regional transit times; and
• Is safe and well-tolerated.

Automation of landmark assessment would increase clinical utility. Validation in further populations (healthy and unhealthy) is required.

Conflicts of Interest: PG and AS are shareholders in Atmo Biosciences.