

*COMPARING THE IMPACT OF BODY
SURFACE GASTRIC MAPPING AND
GASTRIC EMPTYING SCINTIGRAPHY ON
CLINICAL MANAGEMENT IN SUSPECTED
GASTROPARESIS*

NCT06411574

Study Protocol

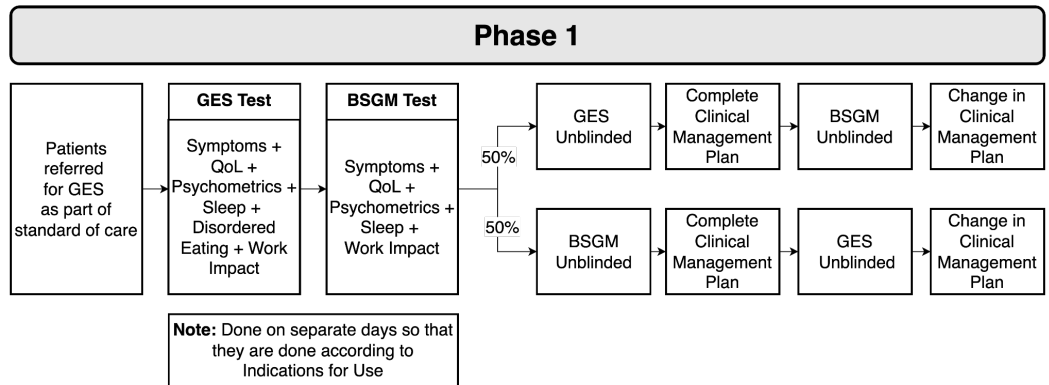
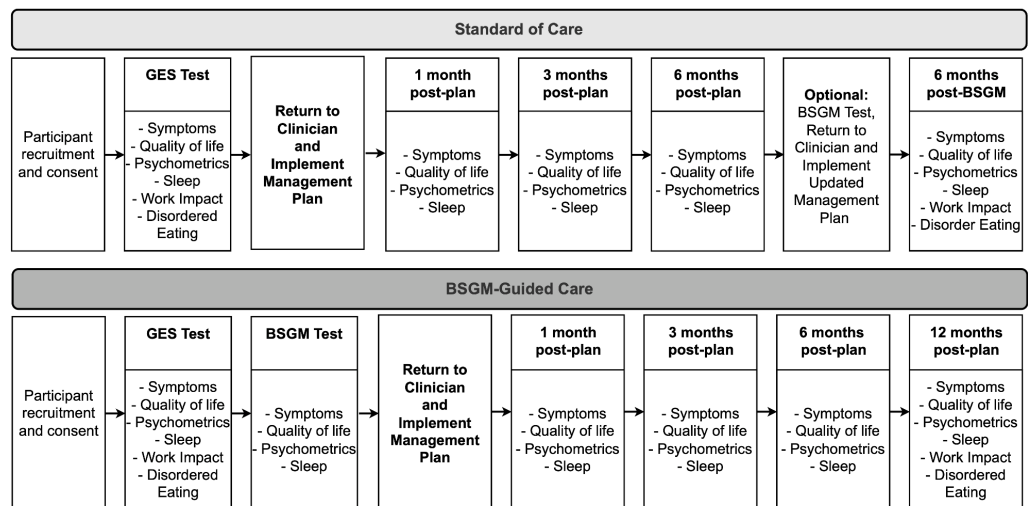
15 Feb 2024

BSGM vs Scintigraphy Clinical Management Protocol

Title	The impact of body surface gastric mapping vs gastric emptying scintigraphy on clinical management in suspected gastroparesis
Study Design	Two arm, randomised, prospective trial
Study Population	Adult patients with chronic gastroduodenal symptoms referred to gastric emptying scintigraphy in a general gastroenterology clinic.
Study Aims	Aim 1: To evaluate the impact of gastric emptying scintigraphy vs BSGM results on clinical decision making. Aim 2: To evaluate longitudinal changes in patient-reported outcomes for standard of care vs BSGM-guided care.
Study Duration	3 years. Phase 1: 6 months for recruitment + 6 months for data analysis/write up. Phase 2: 18 months for recruitment + 6 months for data analysis/write up.
Brief Summary	Gastroparesis is a chronic and debilitating gastric disease associated with poor quality of life, psychological distress, frequent hospitalisations, and high healthcare utilisation and associated costs (1–5). It is defined by persistent upper gastrointestinal symptoms and delayed gastric emptying with no mechanical gastric outlet obstruction (6). Gastric emptying scintigraphy (GES) is the current gold standard for diagnosing gastroparesis but its clinical utility is currently being questioned. Current management strategies, primarily medication-based, have often been found to be ineffective, largely due to an incomplete understanding of the disease's pathophysiology, with only 30% of patients experiencing symptom improvement (7,8). Body surface gastric mapping (BSGM) using Gastric Alimetry® (Alimetry Ltd., New Zealand) is a new test of gastric function for non-invasively assessing gastric motility using simultaneous high-resolution electrogastrography and validated symptom profiling. BSGM has demonstrated clinical utility in the assessment of gastric function through patient phenotyping in a variety of cohorts, including patients with nausea and vomiting disorders, diabetes, delayed gastric emptying, and post-gastric surgery (9–15). Clinical application of these phenotypes has also aided in changing management decisions, which reduced healthcare utilisation and associated costs (15,16). Our previous study revealed that the detection of gastric motility abnormality rates were higher using Gastric Alimetry compared to GES (43% vs 23%) (14). Therefore, Gastric Alimetry improves patient phenotyping, which may have implications for aiding the diagnosis and management of patients. However, how these motility test results differentially influence clinical management in patients is uncertain. This exploratory study proposes a two arm, prospective trial to assess the clinical impact of BSGM compared to the standard of care (GES). The ultimate aim is to establish the clinical decision rule for BSGM to better guide future clinical management approaches.

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Hypothesis	Compared to GES, the introduction of BSGM into clinical practice would: 1) Change clinical management decisions (promote intervention changes and reduce the need for additional testing). 2) Increase clinician certainty. 3) Improve symptoms. 4) Improve quality of life.
Randomisation / Intervention	In Phase 1, patients will be randomly assigned into: GES then BSGM or BSGM then GES.
Blinding	In phase 1, the first management plan will be blinded to the other test; the second management plan will be unblinded to both tests.
Sites	Western Sydney University
Inclusion Criteria	• Aged over 18 years old • Meeting Rome IV Criteria for FD and/or CNVS • Referred for gastric emptying scintigraphy • Normal gastroscopy • Negative or treated H. Pylori status
Exclusion Criteria	• Pregnant or breast-feeding • Inability to perform BSGM test: history of severe skin allergies or sensitivity to cosmetics or lotions; chronically damaged or vulnerable epigastric skin (fragile skin, wounds, inflammation); unable to remain in a relaxed reclined position for the test duration. • Previous BSGM test
Study Procedure	In Phase 1, each subject will separately undergo baseline assessment with a GES and BSGM test along with validated symptom, quality of life, health psychology, sleep and work impairment questionnaires (PAGI-SYM, PAGI-QOL, EQ-5d, PHQ-8, GAD-7, BIPQ-R, PSS-4, WPAI:GH, AGBW Survey, SQS). Based on these test results, the referring clinician will devise two management plans for treatment using a standardised form: 1) unblinded to one test (GES or BSGM) but blinded to the other test; and 2) unblinded to both tests (GES + BSGM). They will be asked to recommend any changes to interventions (medications, diet, surgery referral or other) and additional testing. Only test results with good test quality will be included. In Phase 2, those in Phase 1 will undergo BSGM-guided care based on their combined management plan (GES + BSGM) and followed up over a 12 month period. Patients will be followed up at 1 month, 3 months, 6 months and 12 months using the myCap (REDCap) app to facilitate remote and prompted feedback of the validated questionnaires. In parallel with Phase 1 patients, a separate set of patients will be recruited to undergo standard of care (GES only) and followed up with the same questionnaires over 12 months. After 6 months, those on the standard of care arm will be given the option to be crossed over to BSGM-guided care, undergo a BSGM test, treated according to the new management plan, and followed up over 6 months.

Method**Phase 1:****Phase 2:****Interim Analysis**

An interim analysis for the primary outcome will be conducted when n=10 is reached for phase 1.

Outcome Measures**Phase 1**

Primary Outcome: Change in clinical management decisions due to the combined test results.

Secondary Outcome:

- Change in clinical management decisions based on order of motility test results.

Phase 2

Primary Outcome: Change in symptoms (GCSI, PAGI-SYM) from baseline to 6 months.

Secondary Outcomes:

- Quality of life: PAGI-QOL, EQ-5D
- Health psychology: STAI-6, PHQ-8, GAD-7, PSS-4, AGBW Survey
- Work impact: WPAI:GH
- Disordered Eating: ESP, EDE-Q
- Sleep: SQS

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Sample Size	Given this is a pilot study, there are no pre-existing indicators to determine optimal sample size. As per the recommendations for pilot studies (17), we aim to recruit 10-15 patients. These results will inform the clinical decision rule on patient outcomes in order to estimate the required parameters in a future clinical trial.
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