Docket #: S22-145

24-hour Ambulatory Monitoring Based Autonomic and Gastric Myoelectric Evaluation

Stanford researchers have developed a patient classification method (healthy, idiopathic, diabetic, etc.) based on a quantitative assessment score derived from autonomic and gastric electrocardiogram (ECG) and electrogastrogram (EGG) data. The autonomic and gastric motility-based metrics, or 'scores', encapsulate key clinically relevant autonomic nervous system and digestive system function and health information, with specific focus on sympathetic and parasympathetic regulation and gastric motility. All the physiological signals used are from non-invasive , user-friendly devices that can be worn continuously for days. Devices include (but are not limited to) upper abdominal patches containing electrode arrays and smartwatch-like devices. Currently, there are no devices that provide both ambulatory 24-hour monitoring and physiologically relevant and quantitative analytics for identifying patients with gastro-intestinal disorders, Parkinson's, or migraines as precursor to a diagnostic biomarker. This Stanford autonomic and gastric myoelectric differentiator method can be the first step towards dynamic quantitative markers to track severity, disease progression, and treatment response for combined autonomic and GI phenotypes.

Stage of Development – Proof of Concept
Researchers developed and reduced the model to practice from a limited set of 24-hour electrocardiogram (ECG) and high-resolution electrogastrogram (HR-EGG) data for functional GI illnesses. Future research includes additional validation and refinement with a larger dataset and addressing other diseases, including migraine and Parkinson's.

Applications

- General health tracking
- **Non-invasive, ambulatory, autonomic and gastric function monitoring device** - online monitoring system available to patients and clinicians to track health status, symptoms, and response to treatments in between clinician appointments.
    - Scores from this invention can be inputs to predictive or classification models to **diagnose disease, predict individual progression, predict treatment response.**
    - **Individual insight to inform clinical management and personalized treatment plans**, including type, timing, and dosage of medication, timing of meals and sleep, and the potential therapeutic value of non-pharmacologic solutions such as vagal nerve stimulation.

Advantages

- Unmet medical need - There are currently no devices that provide both ambulatory 24-hour monitoring and physiologically relevant and quantitative analytics.
- Simple, non-invasive, and reliable – Proof of concept (limited) dataset results are 89% accurate in separating healthy controls from patients overall, and 79% accurate in separating three subgroups of subjects: healthy controls, diabetic gastroparesis, and idiopathic gastroparesis.

Publications

- Subramanian, S., Kunkel, D. C., Nguyen, L., & Coleman, T. P. (2022). Exploring the Gut-Brain Connection in Gastroparesis with Autonomic and Gastric Myoelectric Monitoring. *medRxiv*, 2022-10.

Patents

- Published Application: WO2024086853

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