ADVANCING INTESTINAL METHANOGEN OVERGROWTH MANAGEMENT WITH LONGITUDINAL BREATH METHANE SAMPLING

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Aim

This study evaluates the performance of the OMED Health® Breath Analyzer for measuring breath hydrogen and methane, compared to the gold-standard in-clinic HMBT, and explore its feasibility for continuous, real-time breath monitoring to track treatment response in patients with IMO, during both herbal antimicrobial and antibiotic therapies.

Introduc-

Intestinal methanogen overgrowth (IMO) is characterized by the excessive presence of methane-producing archaea in the gut and is associated with gastrointestinal (GI) symptoms such as bloating, abdominal pain, and constipation[1]. In-clinic and send-out hydrogen and methane breath tests (HMBTs) are commonly used for diagnosis.

HMBTs typically involve a challenge test (ingestion of a glucose or lactulose substrate) with IMO defined by a breath methane peak exceeding 10 ppm at any time[2]. However, these assessments require patient preparation and are limited by the fixed number of breath samples taken during the test.

Here, we evaluate the OMED Health® Breath Analyzer for its ability to accurately measure breath methane and hydrogen. We present preliminary data demonstrating its potential for diagnosis and longitudinal monitoring of IMO treatment response in a real-world setting.

Results

Device Comparison

A total of 243 breath samples were collected from 54 participants, with complete data available for hydrogen and methane measurements across both devices.

These data enabled direct comparison of hydrogen and methane concentrations between the OMED Health® Breath Analyzer and the gold-standard in-clinic HMBT instrument. Measurements showed comparable error distributions for both gases. A slight positive bias was observed in OMED hydrogen readings relative to the in-clinic HMBT (Figure 3A); however, as demonstrated this did not affect the diagnostic accuracy of the device.

Diagnostic Concordance

IMO and SIBO diagnostic results generated using OMED Health® Breath Analyzer were compared against the in-clinic HMBT instrument, showing >90% concordance. The confusion matrix (Figure 3B) illustrates the number and proportion of matched and mismatched outcomes. High concordance was observed, with only one IMO false positive and one SIBO false negative identified.

Case Study: IMO Monitoring with OMED

Patient A was diagnosed with IMO on May 7, 2024, with a daily average methane level of 23.6 ± 1.79 ppm. Following initiation of herbal antimicrobial therapy on June 13, methane levels decreased from 35.7 ppm to 2.64 ppm over two weeks.

Subsequent continuous, non-fasting monitoring revealed a rebound in methane, leading to a second IMO-positive diagnosis on July 16 (average: 24.3 ± 3.79 ppm). A follow-up course of antibiotics reduced levels from 32.8 ppm to 3.56 ppm within two weeks, after which the patient reported IMO-negative. By September, methane levels remained low (3.07 ± 0.94 ppm). These findings are summarized in Figures 3C and 3D.

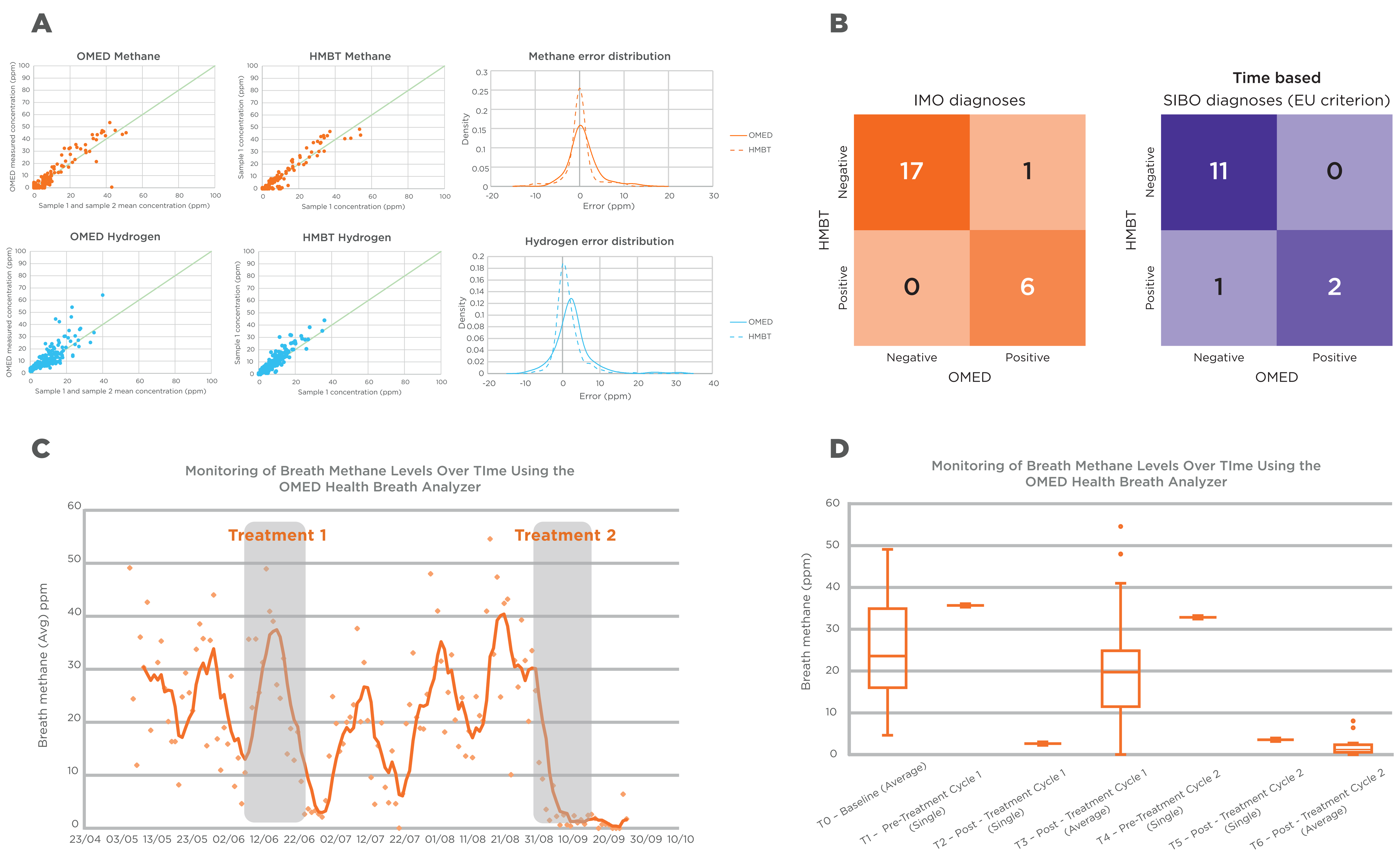

Figure 3 - A) Comparison of average hydrogen and methane values from the HMBT (mean of two consecutive samples) with corresponding OMED Health® Breath Analyzer measurements, including error distributions. B) Diagnostic performance of the OMED Health® Breath Analyzer compared to gold-standard HMBT testing for IMO and SIBO. High concordance was observed, with >90% accuracy for both diagnoses (per EU criteria). C) Daily average breath methane levels in Patient A before and after treatment 1, with recurrence and resolution following treatment 2. D) Mean breath methane levels in Patient A pre- and post-treatment 1 and 2, showing treatment response and sustained reduction post-treatment 2.

Method

OMED Health® Breath Analyzer - the OMED Health® Breath Analyzer is a handheld device that measures hydrogen and methane concentrations in real time from exhaled breath. The device uses metal oxide sensor (MOS) technology, combined with diffusion and PTFE membranes to reduce interference from volatile organic compounds (VOCs) and condensation, ensuring stable and reliable measurements (figure 1). Data are recorded and displayed via a companion smartphone app (figure 2).

Breath Collection and Analysis - hydrogen and methane concentrations from participant breath samples were measured using two methods: a gold-standard in-clinic HMBT instrument (Gastrogenius™ Breath Monitor[3]) and the OMED Health® Breath Analyzer. Each participant provided three breath samples spaced three minutes apart and in the following sequence: in-clinic instrument, OMED Health® device, in-clinic instrument. To control for change in absolute gas concentration between breath samples, the two readings from the in-clinic instrument were averaged (AVG HMBT) and used for comparison.

Diagnostic Classification - a subset of participants was assessed for IMO (n = 24) and small intestinal bacterial overgrowth (SIBO; n = 14), using both the in-clinic HMBT instrument and the OMED Health® device. IMO was defined as any methane reading >10 ppm during the test. SIBO was defined as a >10 ppm rise in hydrogen within 65 minutes of lactulose ingestion (EU criterion).

Case Study – the presented case study highlights a patient diagnosed with IMO and treated initially with herbal anti-microbial and subsequent antibiotic therapies. Breath data were collected using the OMED Health® Breath Analyzer to monitor treatment response over time.

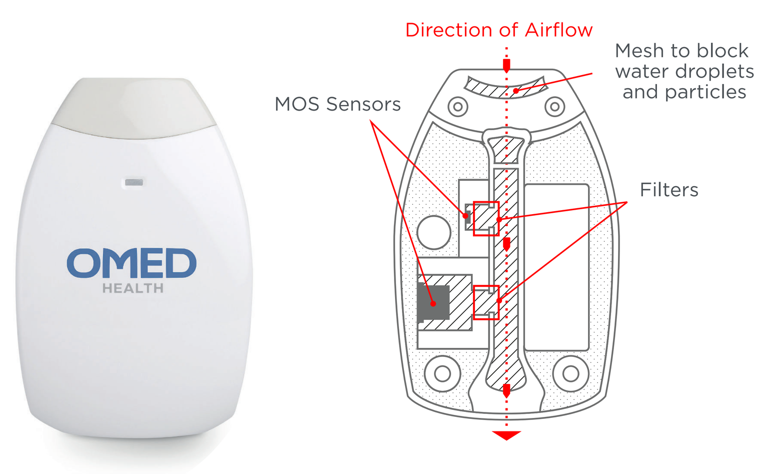

Figure 1 - Schematic of the OMED health® Breath Analyser, showing the (patent pending) airflow path, filter design, and MOS technology.

Figure 2 - The OMED Health Breath Analyzer and companion mobile app provides a direct, real-time readout of breath hydrogen and methane levels.

The companion mobile app also supports the breath sampling protocol, records breath measurements and facilitates the logging of food/drink and the tracking of symptoms and lifestyle.

Conclusion

Longitudinal sampling is increasingly recognized for enabling real-time analysis and establishing personalized baselines, supporting a shift from static to continuous monitoring in clinical care, exemplified by the transition from fingerprick to continuous glucose monitoring in diabetes.

Applying this approach to breath analysis, the OMED Health® Breath Analyzer enables efficient detection and real-time monitoring of treatment response in GI conditions such as IMO. In this study, the device showed >90% diagnostic concordance with the gold-standard in-clinic HMBT for both IMO and SIBO, supporting its potential clinical utility.

Beyond IMO, breath methane monitoring shows promise in broader contexts, including gut motility, inflammatory regulation, and metabolic health[4]. These findings highlight the value of at-home breath testing under clinical guidance to ensure accurate interpretation and optimized treatment outcomes.

Contact Information

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