Trial success for liver disease breath test

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Credit: Owlstone Medical

Cambridge-based company Owlstone Medical, co-founded by alumnus Billy Boyle, has experienced trial success for its liver disease breath test, following a study involving patients from Addenbrooke's Hospital.

Owlstone Medical is developing a non-invasive, easy-to-use breath test that can be taken in primary care settings for the diagnosis of advanced non-alcoholic steatohepatitis (NASH)—a leading global cause of chronic liver disease. The technology is also being adapted to detect cancer.

In a new study, published recently in the *Journal of Clinical and Translational Hepatology*, a set of volatile organic compounds (VOCs) are identified that can determine patients with liver disease and separate them based on severity.

Exhaled breath contains more than 1,000 VOCs as well as microscopic aerosol particles, originating from the lungs and airways. According to Owlstone Medical, Breath Biopsy provides a new way to access these rich sources of biological information by collecting and analyzing breath samples.

The published paper is part of Owlstone Medical's PAN-study, carried out with Cambridge University Hospitals NHS Foundation Trust (CUH).

Samples were collected from 46 CUH patients with advanced liver disease and compared with 42 healthy patients to identify VOCs that differ significantly between the groups, and which appear to be driven by impairment of liver function. From this, a model with strong correlation to disease severity was generated that holds great promise for liver disease detection and monitoring.

Following further trials and development, it is hoped the breath test will be available in the next few years to help diagnose liver disease.

Around one in four adults develop non-alcoholic fatty liver disease (NAFLD) in their lifetimes, with approximately 20% of those progressing to NASH. Having a liver biopsy has long been the gold standard to test for liver disease, however it is costly, invasive, and can have serious complications, making it unsuitable for broad use in screening for disease.

The ultimate aim of creating non-invasive breath tests is to support early detection and precision medicine of diseases including cancer, asthma,

chronic obstructive pulmonary disease (COPD) and liver disease.

Professor Rebecca Fitzgerald is one of the authors of the paper and Director of the Early Cancer Institute at the University of Cambridge.

She said, "We have been very pleased to work with Owlstone Medical to deliver this important trial—simple tests such as a breath test, which are easy and convenient for patients, could transform the way we diagnose disease, including cancer."

Billy Boyle is one of the original co-founders of Owlstone Inc, founded in 2004 as a spin-out from the Department of Engineering at the University of Cambridge. Owlstone Medical was spun out from Owlstone Inc in 2016 to develop and commercialize FAIMS in medical applications.

Billy began to focus on the medical applications of FAIMS technology after his wife Kate was diagnosed and later died of colon cancer as a result of a late diagnosis.

Commenting on the results of the study, he said, "Previously we demonstrated the potential of limonene as a biomarker for liver disease severity, however liver disease is complex, and comprehensive evaluation of liver function is not possible from a single biomarker.

"Now, following this additional excellent work by our internal team and external collaborators, we are pleased to be able to report this expanded set of VOCs, many of which are of exogenous origin and so may be suitable for development into Exogenous Volatile Organic Compound (EVOC) probes."

More information: Giuseppe Ferrandino et al, Breath Biopsy® to Identify Exhaled Volatile Organic Compounds Biomarkers for Liver

Cirrhosis Detection, *Journal of Clinical and Translational Hepatology* (2023). DOI: 10.14218/JCTH.2022.00309