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Democratising Liver Assessment: A New Tool for Identifying MASLD/MASH at any Point of Care

An overview of a new tool that converts highly validated ultrasound technology into a software-based application, enabling any clinician to assess and quantify liver stiffness at the point of care and democratise liver assessment—a critical need in light of the increasing prevalence and care burden of MASLD and MASH worldwide.

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key points

- Metabolic dysfunction-associated steatotic liver disease (MASLD) is the leading cause of chronic liver disease.
- MASLD and metabolic dysfunction-associated steatohepatitis (MASH), the active inflammatory form of MASLD, are expected to rise steadily over the next 25 years.
- A new tool converts highly validated ultrasound technology into a software-based application, enabling clinicians to assess and quantify liver stiffness at the point of care.
- The tool consists of a handheld transducer with imaging guidance and a software application loaded onto a consumer laptop or tablet.
- It uses non-invasive transient elastography to generate a liver stiffness measurement, measurements of other tissue properties related to liver steatosis, and an automated report identifying the patient's risk or disease classification.

Modelled on the same principles of softwarisation that brought high-quality photography to the iPhone, a new tool converts highly validated ultrasound technology into a software-based application, enabling any clinician to assess and quantify liver stiffness at the point of care. The Hepatoscope® from E-Scopics® consists of a handheld transducer with imaging guidance and a software application loaded onto a consumer laptop or tablet. The system application uses non-invasive transient elastography to generate a liver stiffness measurement (LSM), measurements of other tissue properties related to liver steatosis, and an automated report identifying the patient's risk or disease classification. Its ease of use and portability can be understood as democratising liver assessment—a critical need in light of the increasing prevalence and care burden of MASLD and MASH worldwide.

Rising Burden of Liver Disease

MASLD (metabolic dysfunction-associated steatotic liver disease, formerly NAFLD or non-alcoholic fatty liver disease) is characterised by fat deposits in the liver and refers to a spectrum of long-term conditions. Though it is often asymptomatic, its progressive form can lead to hepatocellular carcinoma (HCC) and cirrhosis. In the U.K., MASLD is the leading cause of chronic liver disease, estimated to affect 1 in 3 adults in the country. Recent estimates put the overall prevalence of MASLD at a quarter of the global adult population (Rinella et al. 2023), and both MASLD and metabolic dysfunction-associated steatohepatitis (MASH, formerly NASH or non-alcoholic fatty liver steatohepatitis), the active inflammatory form of MASLD, are expected to rise steadily over the next 25 years.

This rapidly rising prevalence will have serious consequences for global health: by

2050, liver-related deaths are projected to increase from 0.4% of all deaths worldwide to 1%. It also has massive financial implications; annual liver-related expenditures already reach tens of billions in the U.S. (Deverbhavi et al. 2023).

Stemming this tide of disease requires a much wider assessment of patients at risk, enabling earlier referrals to liver specialists and achieving better outcomes with existing interventions.

More Interventions in Development

These interventions are proliferating. MASLD is a metabolic disease, so its rise is linked to other forms of metabolic disorders such as type 2 diabetes (T2DM) and high blood pressure. With obesity being a significant risk factor for all three diseases, the advent of semaglutide to address obesity is a promising development for patients with MASLD and those at risk for MASH. Among several studies aimed at evaluating the effects of these drugs on people with MASLD, one study tied semaglutide use to a significant decrease in insulin resistance and liver enzymes, as well as improved liver steatosis in 70% of patients (reducing semiquantitative US staging by at least one full class) (Volpe et al. 2022).

The pharmaceutical industry is also seeking to develop treatments for MASH itself. Madrigal Pharmaceuticals' new drug application for Resmetirom for treating adult MASH patients with liver fibrosis, is now FDA approved.

Better Stratification, More Effective Care

New clinical practice guidelines respond to the mounting burden of liver disease and seek to maximise the effectiveness of interventions and treatments. These guidelines reflect research-based conclusions that early identification and appropriate intervention lead to better health outcomes for patients with MASLD-MASH (Lim et al. 2017; AACE 2022).

Stemming this tide of disease requires a wider assessment of patients at risk, enabling earlier referrals to liver specialists and achieving better outcomes

The American Association of Clinical Endocrinology and the American Gastroenterological Association have each issued a recommendation that patients be assessed for MASLD-MASH and its associated complications in their clinics; primary care is another important site for screening patients. Because the risk factors for liver disease are the same as those for T2DM and hypertension, places like diabetes centres are also logical places to perform frontline liver assessment.

As this last example illustrates, patients who are most at risk for MASLD-MASH are often already receiving some form of regular care. The problem has been getting the tools to screen for liver fibrosis to these locations and having someone qualified and available to operate them. First-line serological panels play a valuable role in this evaluation, but they suffer from false positives and are unable to distinguish between intermediate stages of liver fibrosis. The ideal form of surveillance at sites like primary care offices and gastroenterology and endocrinology clinics would be technology that uses premier ultrasound technology to accurately compute a liver stiffness measurement (LSM) at the point of care—without requiring an additional hire or tying up existing staff in time-consuming training.

With its imaging guidance, software-generated scan, and automatic reporting, the system application can be used by any healthcare staff at these sites. This tool will help clinics meet their practice guidelines by detecting advancing liver disease when interventions are most likely to be effective.

How It Works

Unlike existing tools for assessing liver stiffness, the intelligence of the device is not located in a stationary ultrasound machine or even in a "point-of-care" ultrasound machine: the processing of the image,

quantification of liver stiffness, and measurement of related tissue properties is not performed within its hardware (a familiar, easily manipulated transducer) at all. Similar to the applications found on a smartphone, it has miniaturised and softwarised—or dematerialised—the relevant technologies, so that the processing power comes both from the application on the associated tablet or computer and the cloud.

The advantages of this approach include avoiding the limitations of cost and user expertise necessary to operate a hardware-based ultrasound system. They also include the ease associated with any upgrades. The trade-offs or problems of specific hardware, which can only be improved through physical attention, can be addressed remotely in a software-based application. Also, similar to the smartphone example, these upgrades can run in the background of the device/computer, reducing the need for device downtime.

Ultrasound-as-a-Service

Because of the immense need, its potential global benefits, and the new clinical recommendations in the U.S., point-of-care liver assessment was the first application offered by the system's developer. But the application is part of a larger concept called Ultrasound-as-a-Service (UaaS).

Instead of requiring major capital investment, UaaS provides clinicians with an inexpensive transducer and a subscription to its software. In this case, the software addresses the problem of MASLD-MASH. However, future applications could be added to the platform. Some software-based applications are already being developed for clinical areas beyond the liver. One area of attention will likely be the assessment of inflammatory bowel diseases, using dedicated ultrasound modalities to characterise the bowel wall.

> This ultrasound tool will help clinics meet their practice guidelines by detecting advancing liver disease when interventions are most likely to be effective

Currently, this system application has FDA and CE approval, and its primary use is to generate LSMs to improve prompt referrals to liver specialists and increase the effectiveness of care. Additional uses exist, however, including helping to monitor the effectiveness of new drugs acting on liver steatosis and creating treatment pathways depending on individualised responses to interventions.

Conclusion

The massive global burden of MASLD-MASH, the consequences of its later stages to quality of life and health, and the numerous costs associated with its management demand that clinicians survey at-risk populations more closely and implement treatment or monitoring more quickly. To date, the constraints of hardware cost and user expertise have stymied these efforts. The system application provides the diagnostic power and assessment specificity where they can do the most good: in low-access locations and the front-line clinics where at-risk patients are already undergoing care.

Conflict of Interest

None.

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