VELACUR: INITIAL RESULTS IN DISCRIMINATION OF PATIENTS AND HEALTHY VOLUNTEERS BASED ON FIBROSIS AND STEATOSIS

Michael Curry1, Edward Tam2, Caitlin Schneider3, Noha Abdelgellil1, Tarak Hassani4, Nezam Afshali1
1 Beth Israel Deaconess Medical Center, Boston, MA
2 Vancouver, BC, CA
3 Sonic Incytes, Vancouver, BC
4 Southern California Background Research Center, Coronado

INTRODUCTION
Diagnostic core liver biopsy for assessing liver health has significant drawbacks including sampling bias and patient pain, leading to poor patient compliance. Liver elasticity, or stiffness, is correlated with histological liver fibrosis stage and offers a non-invasive method for assessment and monitoring of liver fibrosis. Ultrasound tissue attenuation is correlated with liver fat content, and is an increasingly important parameter given the rise of non-alcoholic fatty liver disease. Elasticity is most commonly measured by shear wave speed in Transient Elastography (FibroScan®) or shear wavelength in steady-state elastography as in Magnetic Resonance Elastography (MRE). MRE is the non-invasive imaging method that provides the most accurate assessment of clinical fibrosis stage, when compared to biopsy.

AIM
To evaluate the ability of a Velacur™ prototype to discriminate between healthy volunteers and those with clinically diagnosed non-alcoholic fatty liver disease (NAFLD) or previous Hepatitis C virus (HCV) infection. Exploratory objectives looked at the concordance and correlation between Velacur and MRE.

METHODS
We use a prototype elasticity measurement system (VelacurTM, previously known as Liver Incytes, Incytes, BC, Canada) comprising of an ultrasound probe and an activation unit, to excite shear waves in the patient. A curvilinear abdominal ultrasound probe is used to image the liver. Velacur uses a waterproof ultrasound probe, a control unit, and a laptop to run software. The control unit coordinates the signals and the activation unit which creates shear waves in the patient. A curvilinear abdominal ultrasound probe is used to image the liver. Using a sweep motion of the probe, multiple planes of ultrasound data at a depth of 15 cm are acquired over 30 degrees, in the sagittal plane. Above the liver shows the large region which is used to measure the average elasticity and attenuation.

RESULTS
Above: The components of the Velacur prototype, including the ultrasound probe, the laptop to run software, the control unit to coordinate the signals and the activation unit which creates shear waves in the patient. A curvilinear abdominal ultrasound probe is used to image the liver. Using a sweep motion of the probe, multiple planes of ultrasound data at a depth of 15 cm are acquired over 30 degrees, in the sagittal plane. Right: The cohort separation result for FibroScan and the Velacur prototype. Velacur was able to differentiate the two cohorts with similar AUCC to FibroScan. Only healthy volunteers without cirrhosis or patients with steatosis were included in the cohort separation.

Above: Graphs of the concordance coefficient (r4) between Velacur and MRI and MRE in black and FibroScan CAP and MRI-PDDF in red. Dotted line shows 1 to 1 line, while the solid lines are linear fits which cross the origin. Near Above: Graphs of the correlation coefficient (r4) between Velacur ACE and MRI-PDDF in black and FibroScan CAP and MRI-PDDF in red.

Far Above: Graphs of the concordance coefficient (r4) between Velacur and MRE in black and FibroScan and MRE in red. Dotted line shows 1 to 1 line, while the solid lines are linear fits which cross the origin. The study sponsors would like to acknowledge the help and participation of all the volunteers and patients who agreed to take part in this study, as well as the work and dedication of the staff at all the clinical sites.

CONCLUSIONS
The results from this study demonstrate the promise of this technique for quantitative non-invasive assessment of fibrosis and attenuation in volunteers and patients with chronic liver disease. The ability for this Velacur™ prototype, to discriminate between healthy volunteers and patients with liver disease is comparable to FibroScan®, used in current clinical practice. All AUROCs were greater than 0.85 for both fibrosis and attenuation measurements.

There is excellent concordance between Velacur elasticity and MRE, at 0.80. The correlation between Velacur attenuation and MRI-PDDF results is also excellent.

The Velacur prototype has proved that it:
• Can recognize advanced disease
• Can scan patients with high BMI, up to 42 kg/m²
• Has larger measured volume than current clinical care
• Shows higher correlation with MRE
• Correlates well with MRI-PDDF
• Has benefits of portability and accessibility

These qualities make it suitable for point-of-care diagnosis and regular patient monitoring during and after treatment.

REFERENCES