# THE PERFORMANCE OF VELACUR AGAINST LIVER BIOPSY FOR ASSESSING FIBROSIS AND STEATOSIS

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## CONCLUSIONS

This biopsy-based study validates the previous findings with Velacur in MASLD and MASH patients. Velacur is an effective method for detecting fibrosis and steatosis, with AUROC's above 0.8. The reported AUROC's for Velacur in this cohort of patients with liver histology results were in line with or better than the reported AUC's for VCTE.

## BACKGROUND

As non-invasive biomarkers have become the standard of care for diagnosis and monitoring of patients with metabolic dysfunction-associated steatotic liver (MASL) and metabolic dysfunction-associated steatohepatitis (MASH), it is essential to understand how they compare to liver histology. Velacur is an ultrasound-based liver assessment tool that can be used to measure liver stiffness and attenuation at the point of care. This is the first study to validate the performance of Velacur in a cohort of patients with MASLD/MASH, with recent liver biopsy findings.

## METHODS

This prospective open label study recruited consecutive patients at Fresno Clinical Research Center (Fresno, California). Patients with suspected or confirmed MASLD/MASH who had or were planning to undergo a biopsy within 3-6 months were enrolled. Patients received a Velacur scan during their clinical appointment, either before or after the liver biopsy. All biopsies were read locally at the same pathology lab, by one of three pathologists. Biopsies were labeled according to the NASH CRN scoring system.

For this interim analysis, the AUROC for Velacur for detection of fibrosis at any level (≥ F1), significant fibrosis (≥ F2) and advanced Fibrosis (≥ F3) were calculated. For liver fat, the detection of moderate steatosis (≥ S2) was calculated.

| CHACTERISTICS | RESULTS |
|---|---|
| Number of enrolled subjects | 40 |
| Number of analyzed subjects | 35 |
| Age: mean (± std) | 56.9 ± 12.6 years |
| BMI: mean (± std) | 33 ± 5.8 kg/m2 |
| Gender (% female) | 40% |
| Race (% non-white) | 60% |
| Days between scan and biopsy | 81 ± 85 days |
| | |
| Fibrosis Distribution | |
| Patients with ≥ F1 | 30 |
| Patients with ≥ F2 | 15 |
| Patients with ≥ F3 | 14 |
| | |
| Steatosis Distribution | |
| Patients with ≥ S2 | 24 |

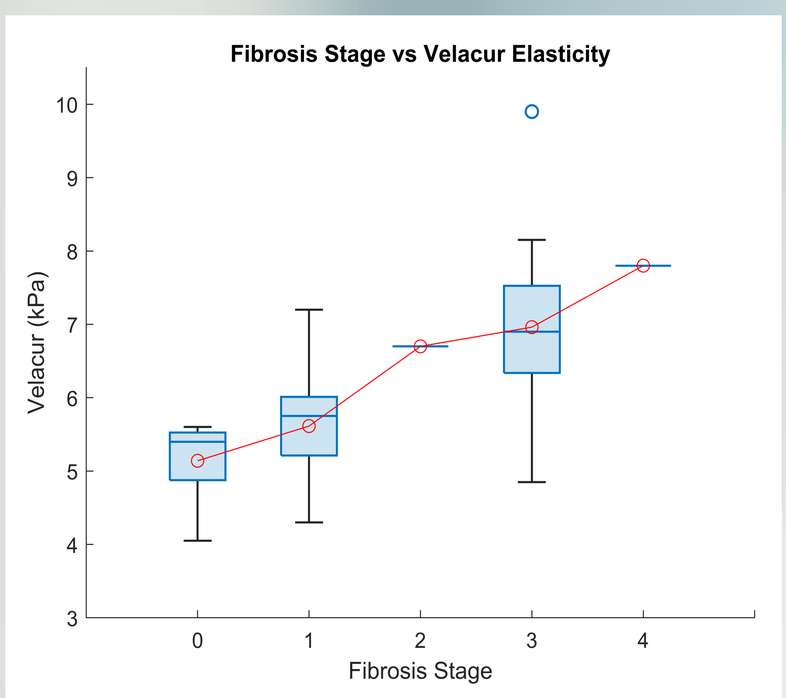
## RESULTS

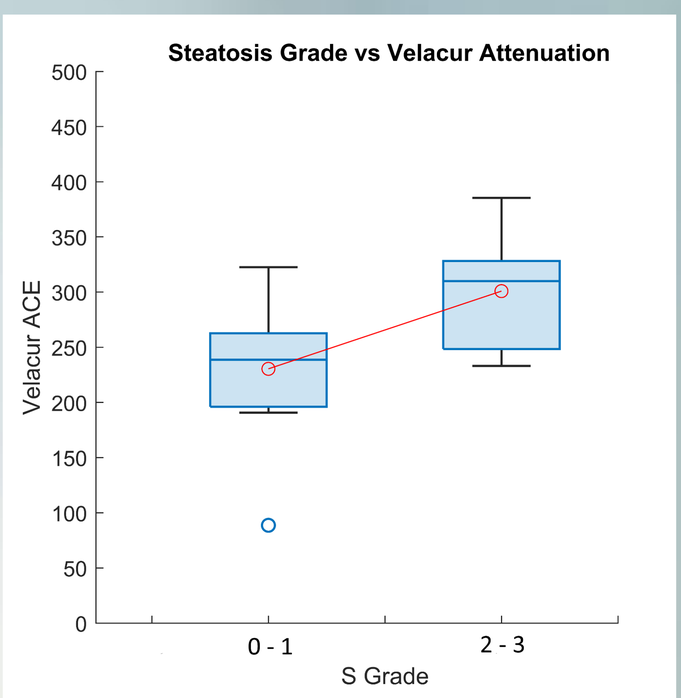
Of the 40 subjects recruited so far, 38 have biopsy data. Three subjects were removed due to poor quality scans. 35 subjects were included in this analysis.

The number of subjects with fibrosis in stages ≥F1, ≥F2 and ≥F3 is 30, 15 and 14 respectively. For steatosis, 11 had grade S0 or S1 and 24 had grades S2 or S3. The mean time between the biopsy and Velacur scan was 81 ± 85 days.

The AUROC (95% CI) for the detection of significant fibrosis was 0.87 (0.71-0.97) and for the detection of moderate steatosis, the AUROC was 0.82 (0.56-0.93).

| METRIC | Velacur Results | VCTE Literature Results |
|---|---|---|
| AUROC for detecting: | | |
| Any Fibrosis | 0.83 (0.70-0.96) | 0.82 (0.76-0.88)[1]<br>0.67 (0.56-0.78)[2] |
| Significant Fibrosis | 0.87 (0.69-0.97) | 0.86 (0.82-0.91)[1]<br>0.86 (0.77-0.95)[2] |
| Advanced Fibrosis | 0.86 (0.64-0.97) | 0.84 (0.78-0.90)[1]<br>0.80 (0.67-0.93)[2] |
| | | |
| Moderate Steatosis | 0.82 (0.56-0.93) | 0.73 (0.64-0.81)[3] |




1: **Hsu** C, et al. Magnetic Resonance vs Transient Elastography Analysis of Patients With Nonalcoholic Fatty Liver Disease: A Systematic Review and Pooled Analysis of Individual Participants. *Clinical Gastroenterology and Hepatology*. 2019
2: **Park** CC, et al. Magnetic Resonance Elastography vs Transient Elastography in Detection of Fibrosis and Noninvasive Measurement of Steatosis in Patients With Biopsy-Proven Nonalcoholic Fatty Liver Disease. *Gastroenterology*. 2017
3: **Imajo** K, et al. Magnetic Resonance Imaging More Accurately Classifies Steatosis and Fibrosis in Patients With Nonalcoholic Fatty Liver Disease Than Transient Elastography. *Gastroenterology*. 2016;

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