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The Value of Fibroscan® in Assessing the Liver Status and Presence of MASLD/MASH in patients with chronic hepatitis B and Monitoring Changes by Antiviral Therapy: Faraday Study

Study Protocol

Patients aged 18 years and older with HBsAg positivity for more than six months and HBV-DNA level >2,000 IU/ml were included in the study. Written informed consent was obtained from all participants. The exclusion criteria were established as presence of cirrhosis, alcohol consumption >140 g/week for women and 210 g/week for men, hepatitis C, hepatitis D and/or HIV coinfections.

The baseline characteristics including patient demographics, BMI, comorbidities, LSM and CAP via transient elastography (FibroScan®), liver ultrasound, HBV serology, platelet count, ALT, HBV viral load.

All patients underwent liver biopsy before initiating antiviral therapy, with a maximum interval of two week between liver biopsy and the FibroScan®.

Transient elastography was performed by a certified operator, using the M probe for patients with skin to capsule distance < 2.5 cm or an XL probe for patients with skin to capsule distance > 2.5 cm. Patients were fasted for > 2 h before FibroScan®. At least 10 successful measurements were performed and recorded.

Fibrosis stage by Liver Stiffness Measurement (LSM) and steatosis by Controlled Attenuation Parameter (CAP) were investigated on FibroScan® for MASLD and MASH. Obese or diabetic patients with a CAP value >240 dB/m were considered MASLD. Patients with normal BMI and nondiabetic patients had at least two risk factors for metabolic dysfunction were also considered to have MASLD. Patients with MASLD and concomitant necroinflammation in the liver were

considered as MASH. Necroinflammation was considered as LSM ≥7.2 kPa in patients with MASLD or LSM >5.5 kPa in patients with liver injury (histologic and/or ALT>NSU).

The study protocol was approved by the Ethics Committee of Dicle University (Protocol number: 2022/261).

Statistical Analysis

The IBM SPSS 21.0 statistical software for Windows was used for the statistical evaluation of the research data. The measurable variables were presented as the mean ± standard deviation (SD), while the categorical variables were presented as the number and percentage (%). Spearman's rho correlation analysis was performed to determine the relationship between the variables. The hypotheses were bidirectional, and $p \leq 0.05$ was considered statistically significant.