

Validation of the Baveno VI elastography criteria for the definition of compensated advanced chronic liver disease: an individual patient meta-analysis

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Background/aims: The Baveno VI consensus recommendations propose the use of liver stiffness (LS) by transient elastography (TE) as a tool for suspected compensated advanced chronic liver disease (cACLD): a LS<10 KPa in the absence of other clinical signs rules out and a LS>15 KPa is highly suggestive of cACLD. We aimed to validate these criteria in an individual patient meta-analysis.

Methods: We included patients from eight centres (Bordeaux n=1335, Cluj n=1180, Palermo n=808, Angers n=518, Firenze n=334, Royal Free n=303, Athens n=154, Beaujon n=75) who had a liver biopsy and TE within 6 months. We only included patients with well-compensated liver disease and a diagnosis of chronic hepatitis B (CHB), chronic hepatitis C (CHC) or non-alcoholic fatty liver disease (NAFLD). METAVIR was used as the staging system for fibrosis and cACLD was defined as a fibrosis stage of \geq F3. The interquartile range/median ratio (IQR/M) was used for the assessment of TE reliability as previously published: "very reliable" (IQR/M \leq 0.10), "reliable" (0.10< IQR/M \leq 0.30, or IQR/M >0.30 with LS median <7.1 kPa), and "poorly reliable" (IQR/M >0.30 with LS median \geq 7.1 kPa).

Results: There were 4707 patients evaluated; in 247 (5.2%), TE was not technically possible and 267 (5.7%) had a poorly reliable measurement, therefore 4198 were considered for the analysis. Mean age was 49.8 \pm 12.7, BMI 26.7 \pm 4.9 kg/m², 52.8% were males and the majority had CHC (n=2609, 62%) followed by NAFLD (n=894, 21.2%) and CHB (n=695, 16.6%). Fibrosis distribution was: F0 433 (10.3%), F1 1320 (31.4%), F2 1227 (29.2%), F3 689 (16.4%), F4 529 (12.6%). A LS<10 KPa had an 86.8% specificity for ruling out cACLD and a LS>15 KPa had a 96.8% sensitivity for ruling in cACLD. Use of the

dual cut-off would result at 671 (16%) patients being classified as indeterminate and would require a further diagnostic test.

Conclusions: Liver stiffness by TE at a cut-off of >15 has an excellent sensitivity for ruling in cACLD, while a cut-off of <10 has a moderate specificity for ruling out cACLD and should be interpreted in the clinical context of each individual case.