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

Emmanuel Tsochatzis¹, Jean Baptiste Hiriart², Monica Lupșor-Platon³, Fabrizio Bronte⁴, Jerome Boursier⁵, Fabio Marra⁶, Athanasios Kostas⁷, Audrey Payance⁸, Edgar Brodkin¹, Laurent Castera⁸, George Papatheodoridis⁷, Umberto Arena⁶, Paul Cales⁵, Vincenza Calvaruso⁴, Victor de Ledinghen², Massimo Pinzani¹

uarena@tin.it; laurent.d.castera@gmail.com; audrey.payance@aphp.fr;
vincenza.calvaruso@unipa.it; victor.deledinghen@chu-bordeaux.fr;
fabriziobronte@gmail.com; monica.lupșor@umfcluj.ro; JeBoursier@chu-angers.fr;
paul.cales@univ-angers.fr; gepapath@med.uoa.gr; edgarbrodkin@nhs.net;
fabio.marra@unifi.it; jean-baptiste.hiriart@chu-bordeaux.fr

1. UCL Institute for Liver and Digestive Health, Royal Free Hospital and UCL, London, UK
2. INSERM U1053, Bordeaux University, Bordeaux, France
3. Department of Medical Imaging, Regional Institute of Gastroenterology and Hepatology „Prof. Dr. Octavian Fodor”, University of Medicine and Pharmacy "Iuliu Hatieganu" Cluj-Napoca, Romania
4. Gastroenterology and Hepatology Section, DIBIMIS, University of Palermo School of Medicine, Palermo, Italy
5. Liver-Gastroenterology Department, University Hospital, Angers, France
6. Department of Experimental and Clinical Medicine, University of Florence, Florence, Italy
7. Academic Department of Gastroenterology, Medical School of National and Kapodistrian University of Athens, Laiko General Hospital, Athens, Greece
8. Service d'Hépatologie, Hôpital Beaujon, Assistance Publique-Hôpitaux de Paris, Clichy, France
**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 ≥F3. The interquartile range/median ratio (IQR/M) was used for the assessment of TE reliability as previously published: "very reliable" (IQR/M ≤0.10), "reliable" (0.10< IQR/M ≤0.30, or IQR/M >0.30 with LS median <7.1 kPa), and "poorly reliable" (IQR/M >0.30 with LS median ≥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±12.7, BMI 26.7±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.