

# EASL Clinical Practice Guidelines

Update 2021



## Non-invasive evaluation of liver disease severity and prognosis

**Recommendations related to**

**FibroScan<sup>®</sup>**  
by echosens

## Foreword

These new EASL guidelines are a big step forward towards non-invasive management of patients with liver diseases and provide an **unprecedented level of recommendation** to Echosens solutions.

## Key takeaways

- **These new EASL Guidelines are very prescriptive for FibroScan® parameters.**
  - LSM by TE receives support from 13 “strong recommendations” and 4 other recommendations or supportive statements.
  - CAP™ is now mentioned in the guidelines, with clear cut-off for steatosis diagnosis.
  - SSM is now recommended as an additional NIT to further improve risk stratification and refine the risk of high-risk varices.
  
- **These new EASL Guidelines position FibroScan® as the cornerstone NIT for the future of liver disease management, all along the liver care continuum and across all population groups.**
  - ...all along the liver care continuum, with a pivotal role in the 2 pathways presented in the guideline:
    - for early patient identification, in 1<sup>st</sup> line after Fib-4, either in primary care, diabetology clinic or liver clinic
    - for advanced liver disease patient management, portal hypertension and HCC risk stratification
  - ...across all population groups, mentioned in 18 recommendations or statements:
    - In NAFLD/NASH, ALD, HCV (including post SVR), PBC/PSC/AIH and as well as in at-risk population (such as patients with metabolic risk factors and/or harmful use of alcohol) (after Fib-4).
  
- **These new EASL Guidelines place FibroScan® as the NIT of reference, combining standardization, clinical performance and accessibility.**
  - All recommended cut-off values are clearly specified for LSM by TE.

## General population

- Upon referral of a patient with FIB-4 over 1.3, the use of TE and/or patented serum tests should be used to rule out/in advanced fibrosis (cf. Fig. 1) (LoE 2, strong recommendation).

## Alcohol-related liver disease

- Rule-out advanced fibrosis → LSM by TE <8 kPa preferred when available [LoE 3; strong recommendation]
- For referral of at-risk patients (rule-in advanced fibrosis) → LSM by TE ≥12-15 kPa (after considering causes of false positives) [LoE2; strong recommendation]
- In patients with elevated liver stiffness and biochemical evidence of hepatic inflammation, LSM by TE should be repeated after at least 1 week of alcohol abstinence or reduced drinking [LoE 3; strong recommendation]

## HCV post-SVR/post-antiviral therapy

- For patients with cACLD previous to antiviral therapy, LSM post-SVR could be helpful to refine the stratification of residual risk of liver-related complications; yearly repetition of LSM can be carried out while waiting confirmatory data [LoE3]

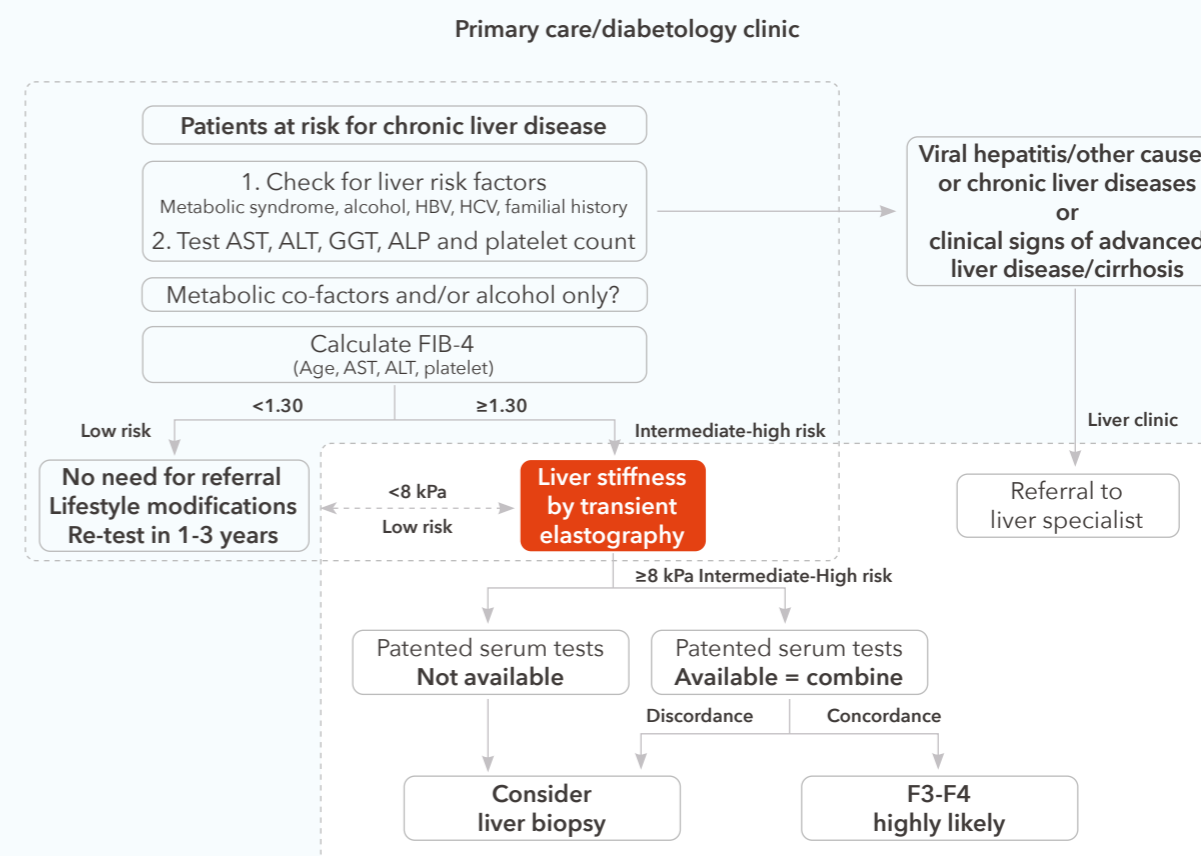
## NAFLD/NASH

- Although there has not been a general consensus for cut-off values, CAP values above 275 dB/m might be used to diagnose steatosis, since they have showed over 90% sensitivity to detect steatosis
- Rule-out advanced fibrosis → LSM by TE <8 kPa [LoE 1; strong recommendation]
- LSM by TE (and serum scores) should be used to stratify the risk of liver-related outcomes in NAFLD [LoE 3; strong recommendation]

## Cholestatic and autoimmune liver disease

- In PBC
  - Rule-in severe fibrosis/cACLD → LSM by TE >10 kPa [LoE 3; strong recommendation]
  - Discrimination of early and advanced stage disease at baseline → LSM by TE < or > 10 kPa and biochemical parameters [LoE 3; strong recommendation]
  - During treatment, risk stratification should be based on assessment of response by using continuous and/or qualitative criteria of response and LSM by TE [LoE 3; strong recommendation]
- In PSC
  - Rule-in advanced fibrosis in compensated patients with normal bilirubin and normal bilirubin without high-grade stenosis → LSM by TE > 9.5 kPa [LoE 3; weak recommendation]
  - LSM by TE correlates with outcomes and should be used for risk stratification both at baseline and during follow-up [LoE 3; strong recommendation]
- In AIH patients, LSM by TE can be used in patients who are being treated to monitor the disease course together with transaminases and IgG, and to stage live fibrosis after at least 6 months of immunosuppressive therapy [LoE 3; weak recommendation]

FIGURE 1 Proposed use of NITs in patients observed in primary care or outside the liver clinic



## Compensated advanced chronic liver disease and portal hypertension

- Rule-out cACLD → LSM by TE < 8-10 kPa [LoE 3; strong recommendation]
- Rule-in cACLD → LSM by TE > 12-15 kPa [LoE 3; strong recommendation]
- Diagnose CSPH in patients with cACLD → LSM by TE > 20-25 kPa [LoE 1; strong recommendation]
- Rule-out high-risk varices and avoid endoscopic screening in patients with cACLD due to untreated viral hepatitis, HIV-HCV coinfection, alcohol, NAFLD, PBC, and PSC → LSM by TE < 20 kPa and platelet count > 150 G/L (BAVENO VI criteria) [LoE 1a; strong recommendation]

(cf. Fig. 2)

Recommendations included in 2015 Clinical Practice Guidelines not revised in the 2021 update remain applicable.

## Additional statements

- “Spleen stiffness” is added as “additional NITs to further improve risk stratification for CSPH” as well as “additional tool to redefine the risk of high-risk varices in cACLD”
- “Liver stiffness can be used in addition to clinical variables and accepted risk scores to stratify the risk of HCC in patients with cACLD due to HBV”
- “Inter-system variability should be taken into account when interpreting the results of different elastography techniques, since values, ranges and cut-offs [from different US-based elastography devices] are not comparable” (LoE 3, strong recommendation).

### Acronyms

- LoE: Level of Evidence
- NAFLD: Non-alcoholic Fatty Liver Disease
- NASH: Non-alcoholic Steatohepatitis
- PBC: Primary Biliary Cholangitis
- PSC: Primary Sclerosing Cholangitis
- AIH: Autoimmune Hepatitis
- LSM: Liver Stiffness Measurement
- TE: Transient Elastography
- CPG: Clinical Practice Guideline
- NITs: Non Invasive Tests
- cACLD: Compensated Advanced Chronic Liver Disease
- CSPH: Clinically Significant Portal Hypertension
- HCC: Hepatocellular Carcinoma
- HBV: Hepatitis B Virus
- FIB-4: Fibrosis-4 Index
- SVR: Sustained Virological Response
- CAP: Controlled Attenuation Parameter

### Organization

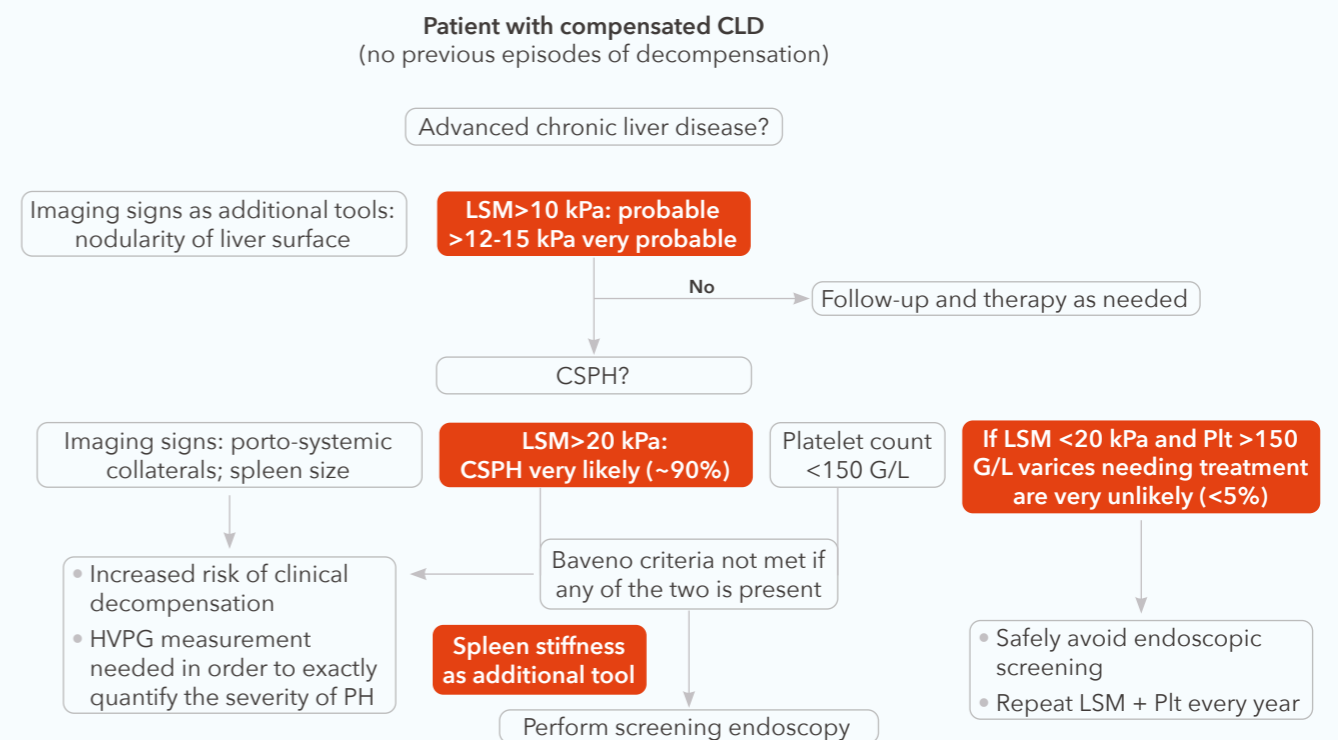
#### Grading

- Level of evidence (LoE) - 1; 2; 3; 4; 5
- Strength of recommendation - strong; weak

#### Format

- Based on PICO questions
  - 1 - P - patient, population, problem
  - 2 - I - intervention, prognostic factor or exposure
  - 3 - C - comparison or intervention (if appropriate)
  - 4 - O - Outcome
- Divided into 6 population groups, with 17 PICO questions
  - 1 - General population
  - 2 - Alcohol-related liver disease
  - 3 - HCV post-SVR/post-antiviral therapy
  - 4 - NAFLD/NASH
  - 5 - Cholestatic and autoimmune liver disease (PBC, PSC, AIH)
  - 6 - Compensated advanced chronic liver disease and portal hypertension

**FIGURE 2** Proposed use of NITs for risk stratification in patients with compensated CLD





because liver health matters

Products in the FibroScan® range are a class IIa medical device according to Directive EEC/93/42 and is manufactured by Echosens™. This device is designed to be used in a physician's office to measure the stiffness and ultrasonic attenuation of the liver in patients with liver disease. It is expressly recommended to carefully read the guidance and instruction of the users' guide and labeling of the device. Results obtained must be interpreted by a physician experienced in dealing with liver disease, taking into account the complete medical record of the patients. This marketing material is not intended for US audience. Non contractual pictures. CE 0459 - ISO 13485 Fast™ calculator is a tool for clinicians, computed from LSM and CAP (obtained from FibroScan® device) and AST blood parameter measurement, to aid in the identification of a patient with suspicion of NAFLD as being at risk for active fibrotic NASH ( $NASH+NAS \geq 4 + F \geq 2$ ). It was developed based on a prospective multicenter cohort and published in peer-reviewed literature. Fast™ is presented as an educational service intended for licensed healthcare professionals. Fast™ is presented as an educational service intended for licensed healthcare professionals. While these scores are about specific medical and health issues, it is not a substitute for or a replacement of personalized medical advice and is not intended to be used as the sole basis for making individualized medical or health-related decisions.

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