# Non-invasive prediction of clinically significant portal hypertension in patients with compensated advanced chronic liver disease of different aetiologies

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## Introduction

Patients with compensated advanced chronic liver disease (cACLD), defined according to the Baveno VI criteria based on a liver stiffness measurement (LSM) ≥10 kPa, are at risk of developing clinically significant portal hypertension (CSPH). Identifying cACLD patients with CSPH is essential for implementing personalized therapeutic strategies.

## Aim

We aimed to non-invasively stratify the CSPH risk in patients with cACLD of different etiologies and to predict the probability of liver decompensation (LD) using the Baveno VII criteria and the Baveno VII criteria implemented with spleen stiffness measurement (SSM). Moreover, we applied the newly proposed Non-Invasive CSPH Estimated Risk (NICER) model (Jachs M. et al). The NICER model was previously used in a large population of patients, the majority of whom were affected by steatotic liver disease.

## Method

- **Study**: Monocentric retrospective observational
- **Patients**: 191 consecutive cACLD patients, defined by LSM ≥ 10kPa, from the liver clinic of the University Hospital of Novara who underwent vibration-controlled transient elastography (VCTE)-based LSM and SSM.
- **Study period**: December 2022 and April 2024
- **Procedures**: All the patients underwent LSM and SSM by VCTE using FibroScan® 630 Expert on the same day. Esophagogastroduodenoscopy (EGDS) was proposed to all patients with LSM > 20 kPa and platelets count < 150000/mcl according to Baveno VI guidelines and in all patients with SSM >40 kPa.
- **Diagnostic criteria to stratify CSPH risk:** The Baveno VII criteria were applied (***Table 1***), along with the single SSM cut-off (≤40 kPa vs. >40 kPa) and the dual SSM cut-offs (≤25 kPa and SSM ≥55 kPa). The NICER model (***Figure 1***) was computed as published: Logit = -6.40032480 + ln(SSM) ×1.96952565 + ln(LSM) ×1.83093447 - BMI ×0.12882190 – platelets (PLT) ×0.01850461. kPa.

| | Rule out CSPH | Rule in CSPH |
|---|---|---|
| **Baveno VII - LSM alone** | LSM ≤15 kPa + PLTs ≥150x10$^3$/mmc | LSM >25 kPa |
| **Baveno VII - LSM + SSM (single cut-off)** | at least 2 of the following: LS ≤15 kPa, PLTs ≥150x10$^3$/mmc, SSM ≤40 kPa | at least 2 of the following: LS >25 kPa, PLT <150x10$^3$/mmc, SSM >40 kPa |
| **Baveno VII - LSM + SSM (double cut-off)** | at least 2 of the following: LS ≤15 kPa, PLTs ≥150x10$^3$/mmc, SSM ≤25 kPa | at least 2 of the following: LS >25 kPa, PLT <150x10$^3$/mmc, SSM ≥55 kPa |

***Table 1***. *Diagnostic criteria to rule out or rule in CSPH according to Baveno VII consensus.*

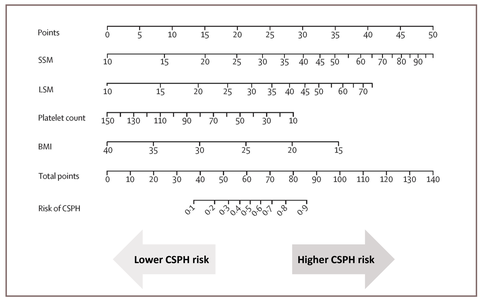


***Figure 1***. *Diagnostic criteria to stratify CSPH risk according to NICER nomogram. Adapted from Jachs M. et al.*

## Results

***Table 2*** shows the characteristics of the 191 cACLD patients at the time of VCTE examinations. Among the 152 patients who underwent EGDS, 61 (31,9%) had oesophageal varices and 13 (6.8%) of them were at high risk for bleeding (F2-F3). Forty patients (20.9%) were on nonselective beta-blockers treatment. ***Figure 2*** illustrates the ability of different diagnostic criteria to stratify CSPH risk. Applying the Baveno VII criteria: 36 patients (18.8%) were at low risk for CSPH (rule-out CSPH), 66 (34.5%) at high risk (rule-in CSPH), 89 (46.6%) in the grey zone. Using the Baveno VII SSM criteria with a single cut-off: 71 patients (37.2%) were at low risk, 94 (49.2%) at high risk, 26 (13.6%) in the grey zone. Using the Baveno VII-SSM with dual cut-offs: 71 patients (37.2%) were classified as low risk, 66 (34.5%) as high risk, and 54 (28.3%) in the grey zone.

| Features | Values |
|---|---|
| **Males ^** | 110 (58%) |
| **Age, years *** | 66 (58.3-74.1) |
| **BMI, kg/mq *** | 25.8 (22.3-29.2) |
| **Obesity ^** | 35 (18%) |
| **LSM, kPa *** | 19.1 (13.4-32.2) |
| **SSM, kPa *** | 42 (28.1-52.8) |
| **CAP, dB/m *** | 236 (202-280) |
| **Platelets, x 10$^3$/mcl *** | 139 (100-181) |
| **INR *** | 1.15 (1.1-1.3) |
| **Albumin, g/dl *** | 4.1 (3.8-4.4) |
| **Total bilirubin, mg/dl *** | 0.97 (0.7-1.5) |

***Table 2***. *Patients' characteristics at the time of VCTE examination.*
*^ Categorical variables are described as absolute frequencies (N) with relative proportion.*
** Continuous variables as median with interquartile range (IQR).*

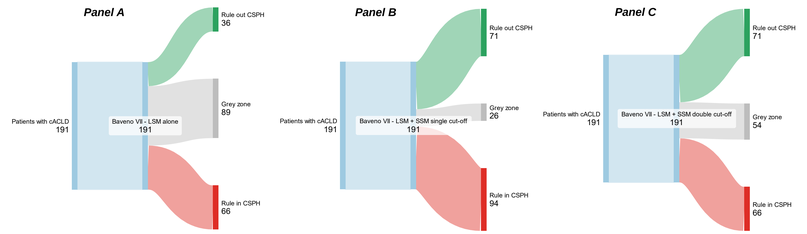


***Figure 2***. *Comparison of diagnostic criteria ability to stratify CSPH risk. Panel A shows Baveno VII criteria using LSM alone; Panel B and C show Baveno VII criteria combining both LSM and SSM using single and double cut-offs, respectively.*

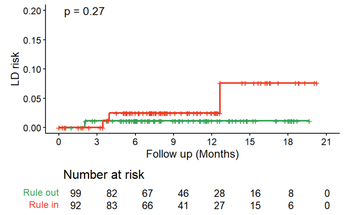


***Figure 3***. *Probability of liver disease decompensation stratified according to the risk of CSPH calculated by NICER (≤75% versus >75%).*
*LD: liver decompensation.*

Based on the NICER model, the median CSPH risk in the 191 patients was 65%. CSPH risk distribution was: <25% 80 patients (41.9%), >75% 92 patients (48.2%). Among the 152 patients who underwent EGD, esophageal varices were found in 11.5% of patients with a CSPH risk <25% and in 82% of patients with a CSPH risk >75% (p<0.0001). During follow-up (median 8.4 months), 4 patients developed LD. In patients with CSPH risk >75% calculated using NICER, the probability of LD at 12 and 15 months was 2.5% and 7.6%, respectively, compared to 1.1% at both time points in patients with a CSPH risk ≤75% (p=0.27) as shown in ***Figure 3***.

## Conclusions

The addition of SSM to the Baveno VII criteria reduces the diagnostic grey zone, enabling improved risk stratification for CSPH in cACLD patients. CSPH risk estimation using the NICER model provides additional non-invasive support for predicting CSPH.

## References

1. de Franchis R, Bosch J, Garcia-Tsao G, Reiberger T, Ripoll C; Baveno VII Faculty. Baveno VII - Renewing consensus in portal hypertension. J Hepatol. 2022
2. Jachs M, Odriozola A, Turon F, et al. Spleen stiffness measurement by vibration-controlled transient elastography at 100 Hz for non-invasive predicted diagnosis of clinically significant portal hypertension in patients with compensated advanced chronic liver disease: a modelling study. Lancet Gastroenterol Hepatol. 2024.