



Validation of Baveno VII criteria for clinically significant portal hypertension by two-dimensional shear wave elastography

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Abstract

Background The Baveno VII consensus proposed criteria for the non-invasively diagnosis of clinically significant portal hypertension (CSPH) in patients with compensated advanced chronic liver disease (cACLD). The performance of Baveno VII criteria for assessing CSPH by two-dimensional shear wave elastography (2D-SWE) had not been well validated. We aimed to validate the performance of Baveno VII criteria for rule-in and rule-out CSPH by 2D-SWE.

Method This is an international multicenter study including cACLD patients from China and Croatia with paired liver stiffness measurement (LSM), spleen stiffness measurement (SSM) by 2D-SWE, and hepatic venous pressure gradient (HVPG) were included. CSPH was defined as HVPG ≥ 10 mmHg.

Result A total of 146 patients with cACLD were enrolled, and finally 118 patients were included in the analysis. Among them, CSPH was documented in 79 (66.9%) patients. Applying the Baveno VII criteria for rule-out CSPH by 2D-SWE, [LSM ≤ 15 kPa and platelet count $\geq 150 \times 10^9/L$] OR SSM < 21 kPa, could exclude CSPH with sensitivity $> 90\%$ (93.5 or 98.7%) but negative predictive value $< 90\%$ (74.1 or 85.7%). Using the Baveno VII criteria for rule-in CSPH by 2D-SWE, LSM ≥ 25 kPa OR SSM ≥ 50 kPa, could diagnose CSPH with 100% specificity and 100% positive predictive values.

Conclusion Baveno VII criteria by 2D-SWE showed a good diagnostic performance for ruling in but not for ruling out CSPH, which might become an emerging non-invasive elastography tool to select the patients who needed non-selective beta blocker therapy.

Keywords Baveno VII criteria · Clinically significant portal hypertension · Two-dimensional shear wave elastography · Liver stiffness measurement · Spleen stiffness measurement

Introduction

Among patients with compensated advanced chronic liver disease (cACLD), the occurrence of portal hypertension takes main responsibility for severe clinical consequence, such as variceal hemorrhage, ascites, hepatic encephalopathy [1, 2]. To date, the well-accepted method for the assessment of portal hypertension is hepatic venous pressure gradient (HVPG), but which is less tolerable, invasive, and costly [3]. The threshold of clinically significant portal hypertension (CSPH) was defined as HVPG ≥ 10 mmHg [4].

Patients with cACLD who progress to CSPH have a sharply increased risk of liver related decompensated events.

Currently, liver stiffness measurement (LSM) and spleen stiffness measurement (SSM) by characterized as its feasibility, noninvasiveness, and high diagnostic accuracy, have become the surrogate method for assessing CSPH [5, 6]. According to Baveno VII consensus in portal hypertension, LSM by transient elastography (TE) ≥ 25 kPa shows greater than 90% specificity and positive predictive value (PPV) for rule-in CSPH, and [LSM by TE ≤ 15 and platelet count (PLT) $\geq 150 \times 10^9/L$] shows greater than 90% sensitivity and negative predictive value (NPV) for rule-out CSPH [7]. In addition, SSM by TE can be used to exclude and identify CSPH (SSM < 21 kPa and SSM > 50 kPa, respectively) [7]. The Baveno VII consensus pointed out that it is necessary

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to verify the thresholds of SSM for evaluating CSPH by devices other than TE [7].

Despite the extensive use of LSM by TE, it is not recommended for the performance in patients with ascites and its dependability descends with the increasing weights [8–10]. Due to higher stiffness of spleen comparing with liver, SSM using a probe in 50 Hz modal may be limited by the upper limit of measurement, which is 75 kPa [11]. In terms of the LSM/SSM by TE, it is unseen to exact the localization of the region of interest. To overcome these, two-dimensional shear wave elastography (2D-SWE), on the basis of conventional ultrasound images, uses acoustic radiation force to generate shear waves, and can also form color coded images with different stiffness in the sampling frame, so as to effectively avoid non-target structures and obtain more reliable tissue stiffness values [12, 13]. In addition, the maximum threshold of 2D-SWE for measuring tissue stiffness is 300 kPa, which is sufficient for spleen stiffness. In recent years, many studies have shown that the performance of 2D-SWE is equivalent to or even better than that of TE in assessing fibrosis and CSPH [14, 15]. Thus, the primary objective of this study was to evaluate the 2D-SWE as an alternative non-invasive test for rule-in and rule-out CSPH under Baveno VII criteria in patients with cACLD. The secondary objectives were (1) to compare the LSM/SSM by 2D-SWE between CSPH and non-CSPH group, (2) to inquire the link between LSM/SSM by 2D-SWE and HVPG.

Patients and methods

Patient enrollment

We conducted an international, retrospective, multicenter study which included patients with cACLD underwent HVPG, LSM, and SSM by 2D-SWE from three medical centers (The Third People's Hospital of Taiyuan, Zhongshan Hospital Affiliated to Fudan University, and University hospital Dubrava, Zagreb) between January 2016 and December 2022. The study was approved by the local Ethics Committee and was performed in accordance with the last revised version of the Helsinki Declaration.

Inclusion criteria were as followed: (1) age ranging from eighteen to seventy-five; (2) diagnosed cACLD whose value of LSM by 2D-SWE > 8 kPa [16]; (3) in the absence of decompensated events (e.g., ascites, esophageal variceal bleeding, and hepatic encephalopathy); (4) underwent HVPG examination; (5) underwent 2D-SWE examination for LSM and SSM; (6) with written informed consent. Exclusion criteria were mentioned below: (1) more than 6-month interval between HVPG and 2D-SWE; (2) LSM or SSM for non-compliance with quality control standard; (3) unsuccessful LSM or SSM; (4) prior primary prophylaxis

(e.g., endoscopic ligation or sclerotherapy, utility of non-selective beta blocker [NSBB]); (5) splenectomy, absent spleen or splenic embolism); (6) hepatocellular carcinoma; (7) insufficient serological data. A detailed flow chart of the study is provided in Fig. 1.

HVPG measurement

Well-trained radiologists measured HVPG with the transjugular balloon catheterization [17]. After carrying out local anesthesia at the puncture site located in right internal jugular vein generally, the catheter reached the right hepatic vein (approximately 1 cm from the initial segment of hepatic vein) with the assistance of digital subtraction angiography and the free hepatic venous pressure (FHVP) was assessed simultaneously. Afterwards, since the inflated balloon occluded the right hepatic vein, the wedged hepatic venous pressure (WHVP) was assessed. HVPG was calculated as the difference between WHVP and FHVP. Repeated three measurements for HVPG and then took an average.

Liver and spleen stiffness measurement

LSM and SSM were assessed by 2D-SWE from Supersonic Imagine Aixplorer Ultimate ultrasound system and the XC6-1 transducer (Supersonic Imagine, SSI, France) by the trained and qualified operator, blinded to the HVPG and serological data of patients.

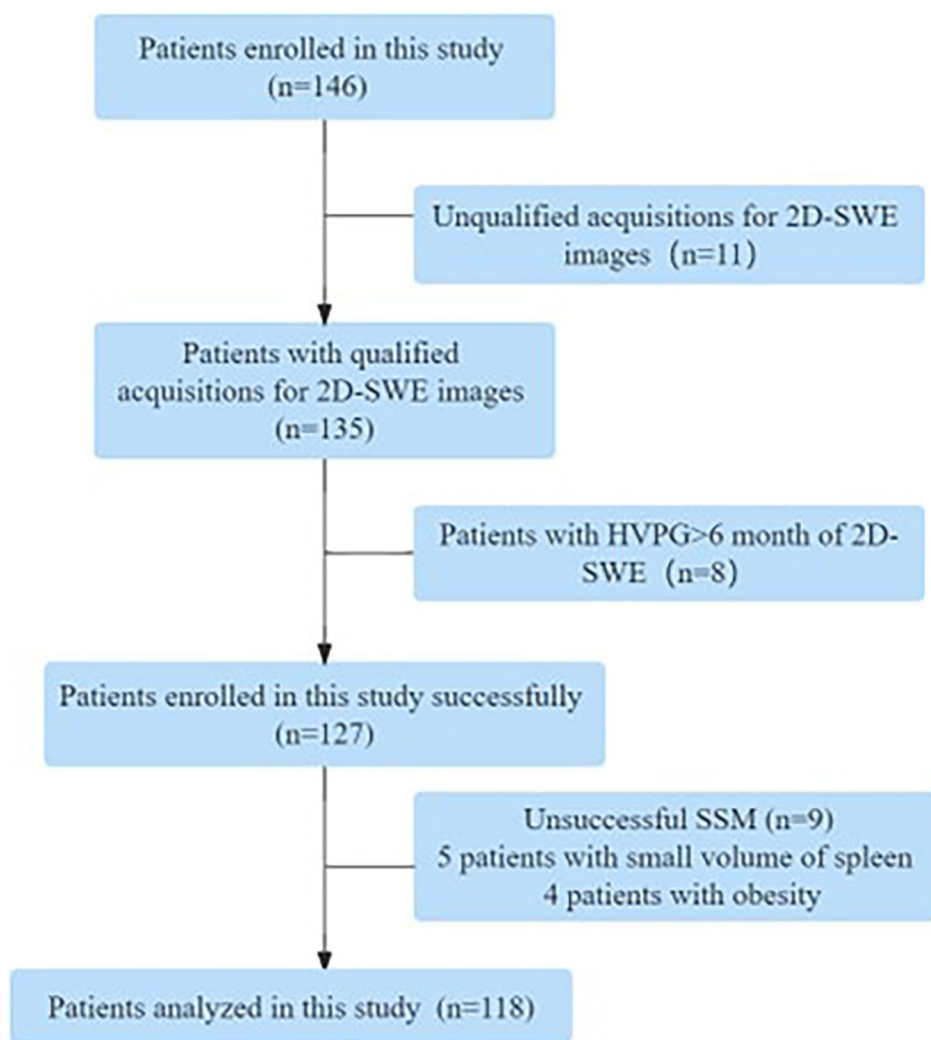
LSM were measured with patients in supine position and maximum abduction of right arm, through intercostal space, in the right liver lobe for the optimal acoustic window. The region of interest was located about 2–3 cm below the liver capsule in the absence of large vessels and bile ducts. Patients held 3–5 s suspended breathing for a suitable image with stability index > 80%. SSM was performed in the right lateral decubitus position with the left arm raised on the head to expose intercostal space fully. The region of interest was placed about 1–2 cm below the spleen capsule. The remaining steps are the same as above.

In each case, the stiffness of the liver and spleen was measured at least three times. The values of LSM and SSM were depicted in kilopascals (kPa). The final LSM and SSM were recorded as the median of multiple measurements. As for the reliable of LSM and SSM, the interquartile range/median ratio < 30% [18, 19].

Assessment of CSPH by Baveno VII criteria

According to Baveno VII consensus, Baveno VII criteria was defined as [LSM ≤ 15 kPa and PLT ≥ 150 × 10⁹/L] OR SSM < 21 kPa for ruling out CSPH while LSM ≥ 25 kPa OR SSM > 50 kPa for ruling in CSPH. The

Fig. 1 Flow chart of the enrolled patients. 2D-SWE, two-dimensional shear wave elastography; HVPG, hepatic venous pressure gradient; SSM, spleen stiffness measurement



well-recognized standard for CSPH was HVPG value was equal or greater than 10 mmHg.

Statistical analysis

The statistical analysis was performed via SPSS 22.0 software (IBM, Armonk, New York) and R language (4.1.2, R Core Team, 2021). Continuous variables were presented as median and interquartile range. Categorical variables were presented as frequencies and percentages. For testing significant difference of continuous data between two groups, the Mann–Whitney U test and the T test were used for abnormal and normal distribution, respectively. The sensitivity, specificity, PPV, and NPV were applied for estimating diagnostic accuracy of model. A p value < 0.05 was statistically considered into significance.

Results

Patient characteristics

The baseline characteristics are presented in Table 1. A total of 118 patients with cACLD were enrolled in the study. Among them, CSPH was documented in 79 (66.9%) patients. The majority patients were male (71.2%) and the median age was 57 (46–64) years. Hepatitis B infection was the primary etiology of cACLD (56.8%), followed by alcoholic liver diseases (13.6%), non-alcoholic fatty liver diseases (6.8%), hepatitis C infection (6.8%), and others. For the overall patients, the median values of HVPG, LSM, and SSM were 12.0 (7.8–16.3) mmHg, 14.4 (11.0–24.3) kPa, and 32.1 (26.2–41.5) kPa, respectively.

Table 1 Baseline characteristics of study cohort

	Total cohort (n = 118)
Age, median (IQR), year	57 (46–64)
Male, n (%)	84 (71.2)
Body mass index, median (IQR), kg/m ²	25.3 (22.8–28.0)
Etiology, n (%)	
Hepatitis B infection	67 (56.8)
Alcoholic liver disease	16 (13.6)
NAFLD	8 (6.8)
Hepatitis C infection	8 (6.8)
Autoimmune liver disease	4 (3.4)
Primary biliary cirrhosis	2 (1.6)
Others	13 (11.0)
Platelet count, median (IQR), × 10 ⁹ /L	110.5 (78.8–167.8)
Alanine aminotransferase, median (IQR), U/L	27.5 (19.0–45.0)
Aspartate aminotransferase, median (IQR), U/L	31.5 (23.0–55.5)
Albumin, median (IQR), g/L	40.0 (36.0–44.0)
Bilirubin, median (IQR), μmol/L	16.9 (12.2–23.5)
HVPG, median (IQR), mmHg	12.0 (7.8–16.3)
LSM, median (IQR), kPa	14.4 (11.0–24.3)
SSM, median (IQR), kPa	32.1 (26.2–41.5)

IQR interquartile range, NAFLD non-alcoholic fatty liver disease, HVPG hepatic venous pressure gradient, LSM liver stiffness measurement, SSM spleen stiffness measurement

LSM/SSM by 2D-SWE among patients with CSPH and non-CSPH group

Among patients underwent 2D-SWE, the LSM values were significantly higher in CSPH group than in non-CSPH group ($p < 0.001$) (Fig. 2a). Similarly, the remarkable difference of SSM values was found in patients with CSPH and non-CSPH group ($p < 0.001$) (Fig. 2b). In contrast, non-CSPH

patients had an obvious higher PLT than those in patients with CSPH ($p < 0.001$) (Fig. 2c).

Relationship between HVPG and LSM/SSM by 2D-SWE

By analyzing the link between HVPG and LSM/SSM values by 2D-SWE, HVPG values had significant positive correlation with LSM values ($r = 0.548$, $p < 0.001$) as well as SSM values ($r = 0.561$, $p < 0.001$), respectively. The correlation plots are shown in Fig. 3.

Baveno VII criteria for ruling out CSPH by 2D-SWE

Among 118 patients underwent 2D-SWE successfully, according to Baveno VII criteria ($LSM \leq 15$ kPa and $PLT \geq 150 \times 10^9/L$), 27 (27/118, 22.9%) were ruled out CSPH, 7 of whom was misdiagnoses as non-CSPH, actually $HVPG \geq 10$ mmHg, sensitivity and NPV were 91.1% (72/79) and 74.1% (20/27), respectively. Of the 7 misclassified patients, 71.4% (5/7) were infected with hepatitis B. Further, $SSM < 21$ kPa could merely rule out 7 (7/118, 5.9%) patients with CSPH, one of whom was at CSPH, sensitivity and NPV were 98.7% (78/79) and 85.7% (6/7) (Table 2).

Baveno VII criteria for ruling in CSPH by 2D-SWE

In the whole patients, in line with Baveno VII criteria ($LSM \geq 25$ kPa), 26 (26/118, 22.0%) were ruled in CSPH, all of whom were with $HVPG \geq 10$ mmHg, specificity and PPV were 100%. Likewise, as rule-in criteria was transformed to $SSM > 50$ kPa, 12 (12/118, 10.2%) patients were incorporated into CSPH, all of whom were at CSPH, specificity and PPV were 100% (Table 3).

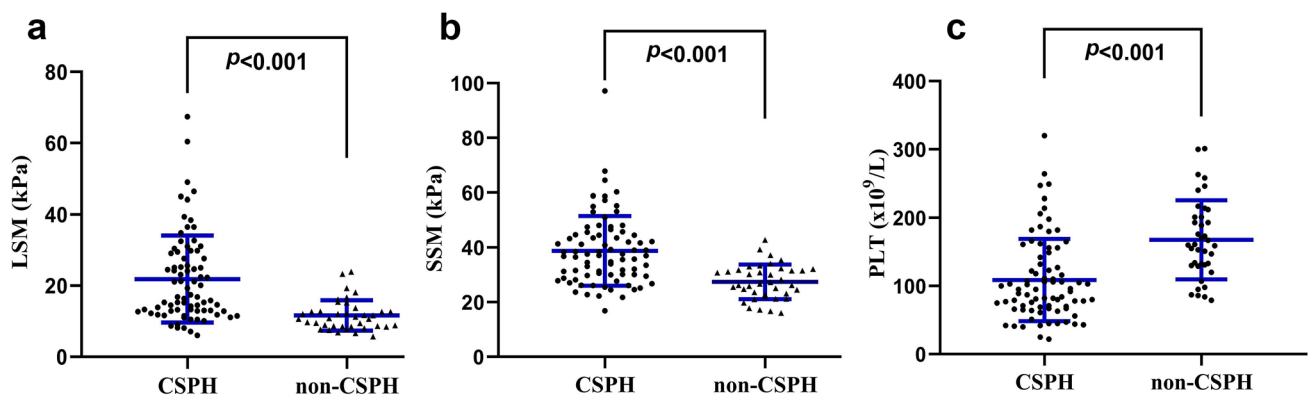


Fig. 2 Distribution of LSM, SSM, and PLT according to the CSPH and non-CSPH group. **a**, Distribution of LSM in CSPH and non-CSPH group; **b**, Distribution of SSM in CSPH and non-CSPH group;

c Distribution of PLT in CSPH and non-CSPH group. CSPH, clinically significant portal hypertension; LSM, liver stiffness measurement; SSM, spleen stiffness measurement; PLT, platelet count

Fig. 3 Correlation between HVPG and LSM and SSM measured by two-dimensional shear wave elastography. **a** Correlation between HVPG and LSM; **b** Correlation between HVPG and SSM. HVPG, hepatic venous pressure gradient; LSM, liver stiffness measurement; SSM, spleen stiffness measurement

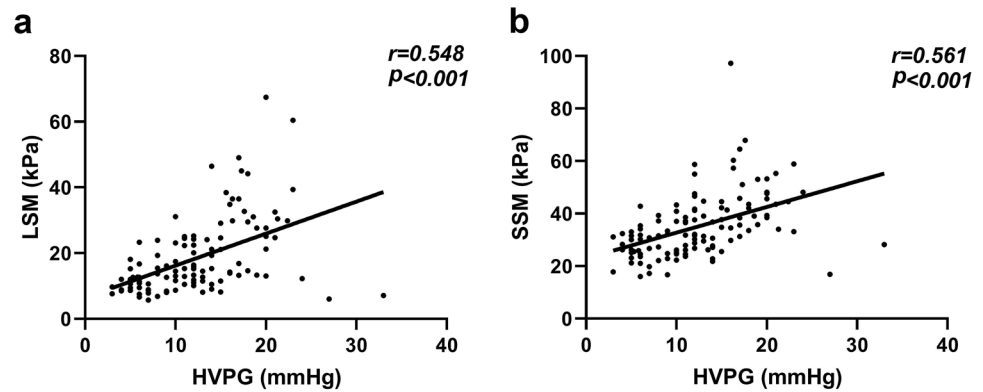


Table 2 Performance of Baveno VII criteria for ruling out clinically significant portal hypertension by two-dimensional shear wave elastography

	Sensitivity	NPV	Rule out CSPH
LSM (2D-SWE) \leq 15 kPa and PLT \geq $150 \times 10^9/L$	72/79 (91.1%)	20/27 (74.1%)	27/118 (22.9%)
SSM (2D-SWE) $<$ 21 kPa	78/79 (98.7%)	6/7 (85.7%)	7/118 (5.9%)

Data are presented as n (%) or n/N (%), where N is the total number of related cases

CSPH clinically significant portal hypertension, LSM liver stiffness measurement, SSM spleen stiffness measurement, PLT platelet count, 2D-SWE two-dimensional shear wave elastography, NPV negative predictive value

Table 3 Performance of Baveno VII criteria for ruling in clinically significant portal hypertension by two-dimensional shear wave elastography

	Specificity	PPV	Rule in CSPH
LSM (2D-SWE) \geq 25 kPa	39/39 (100%)	26/26 (100%)	26/118 (22.0%)
SSM (2D-SWE) $>$ 50 kPa	39/39 (100%)	12/12 (100%)	12/118 (10.2%)

Data are presented as n (%) or n/N (%), where N is the total number of related cases

CSPH clinically significant portal hypertension, LSM liver stiffness measurement, SSM spleen stiffness measurement, 2D-SWE two-dimensional shear wave elastography, PPV positive predictive value

Performance of the Baveno VII criteria by 2D-SWE for stratification patients with cACLD

According to the cutoff value proposed by the Baveno VII criteria, we divided the total cohort into three groups, Baveno VII criteria ruling out CSPH, gray zone, and Baveno

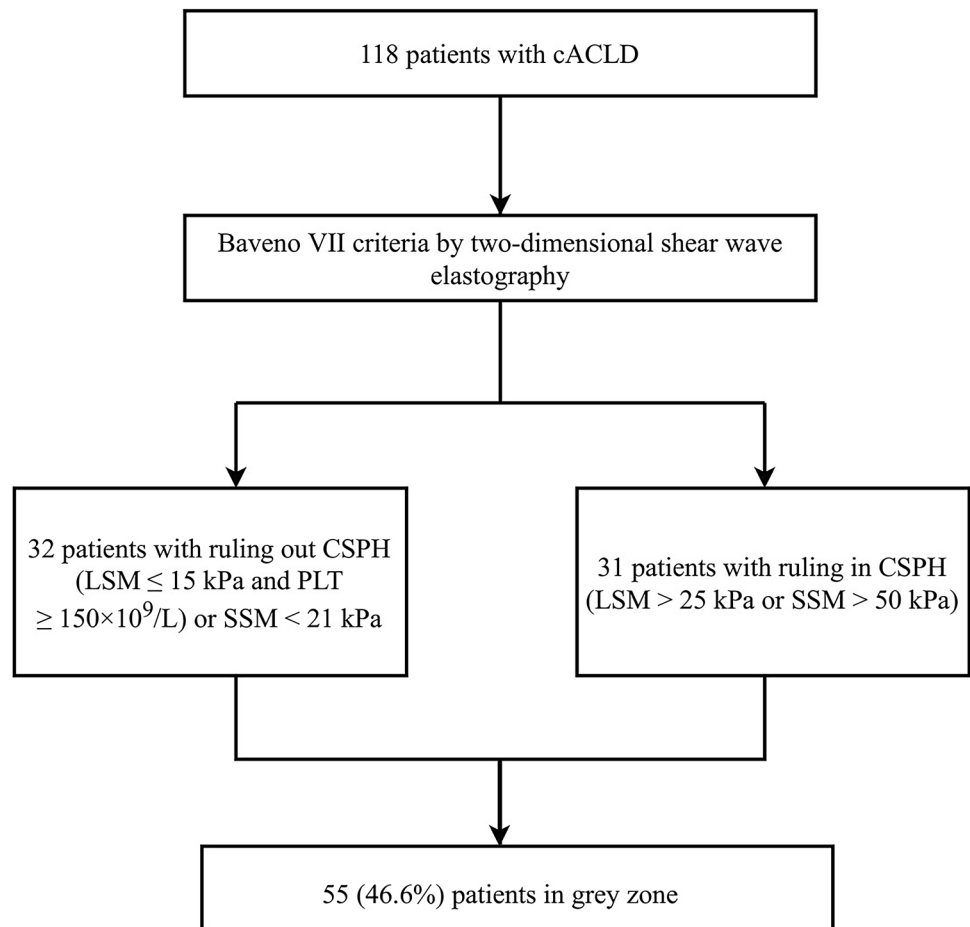
VII criteria ruling in CSPH, to create a scatter plot of the HVPG distribution in different groups. Unsurprisingly, HVPG was significantly higher in the Baveno VII criteria ruling in CSPH group than in the gray zone ($p < 0.001$) and Baveno VII criteria ruling out CSPH groups ($p < 0.001$) (Supplementary Fig. 1). Applying the Baveno VII criteria by 2D-SWE, the number of patients meeting the rule-out and rule-in criteria was 32 and 31, respectively. Therefore, 46.6% (55/118) of patients were finally included in the gray zone (Fig. 4). Of the 55 patients in the gray zone, 40 had CSPH (72.7%).

Discussion

This retrospective international multicenter study is the first to investigate the performance of Baveno VII criteria for rule-in and rule-out CSPH by 2D-SWE among patients with cACLD. Of the total, as Baveno VII criteria for ruling out CSPH was met, [LSM \leq 15 kPa and PLT \geq $150 \times 10^9/L$] OR SSM $<$ 21 kPa, the NPV was below 90% in spite of the high sensitivity with 91.1 and 98.7%. Conversely, LSM \geq 25 kPa OR SSM $>$ 50 kPa has 100% of specificity and PPV for ruling in CSPH. Thus, it is plausible for us to reckon that Baveno VII criteria by 2D-SWE also showed favorable performance for diagnosing the presence of CSPH exclusively.

CSPH is recognized as the predictor of clinical decompensation in cACLD patients [20]. Currently, the measurement of HVPG is still the reliable method for assessing the portal pressure and clinical complications [17], which is equal or greater than 10 mmHg diagnosed as CSPH. Considering to the invasive procedure and poor compliance of HVPG, an increasing number of clinical studies has focused on the non-invasive test for assessing CSPH in recent years. 2D-SWE, as an elastography tool for non-invasive liver stiffness qualification, also has been validated in staging hepatic fibrosis [21, 22]. Furthermore, some previous studies have showed that LSM and SSM by 2D-SWE were significantly

Fig. 4 Performance of the Baveno VII criteria by two-dimensional shear wave elastography for stratification patients with cACLD. cACLD, compensated advanced chronic liver disease; CSPH, clinically significant portal hypertension; LSM, liver stiffness measurement; SSM, spleen stiffness measurement; PLT, platelet count



correlated with HVPg [23–25]. Simultaneously, our study found the positive link between LSM or SSM by 2D-SWE and HVPg, which is disposed in Fig. 3. However, existing research for validating diagnostic accuracy of Baveno VII criteria for assessing CSPH by 2D-SWE remained scant. In line with Baveno VII consensus, values with specificity and PPV $\geq 90\%$ or sensitivity and NPV $\geq 90\%$ can be regarded as cutoff for rule-in or rule-out CSPH [7]. In the international multicenter study, our results showed that Baveno VII criteria (LSM ≥ 25 kPa or SSM > 50 kPa) by 2D-SWE could reliably diagnose CSPH with specificity and PPV which were up to 100%, despite the relatively low rule-in rate with 22.0 and 10.2%. Conversely, Baveno VII criteria [(LSM ≤ 15 kPa and PLT $\geq 150 \times 10^9/L$) OR SSM < 21 kPa] could not be used to exclude CSPH as the NPV was 74.1 and 85.4%, respectively. Applying LSM ≤ 15 kPa and PLT $\geq 150 \times 10^9/L$, 27 (27/118, 22.9%) were ruled out CSPH, 7 of whom was misdiagnoses as non-CSPH. Of the 7 misclassified patients, 71.4% (5/7) were infected with hepatitis B. This may be causing that the original study [26] proposing the above cutoff values enrolled patients with etiologies that were overwhelmingly hepatitis C infection, alcoholic and

non-alcoholic hepatitis (more than 90%) and did not apply to patients with hepatitis B.

Variceal hemorrhage is a common and severe complication of cACLD patients, which is associated with a 6-week mortality rate of between 15 and 25% [27, 28]. NSBB has been recommended as the long-term prophylactic regimen among patients with high risk varices, since it can reduce the risk of bleeding and mortality [28]. Currently, the main indication for NSBB therapy has shifted from high risk varices into CSPH, which has been mentioned in the Baveno VII consensus [7]. This implies that it is urgently necessary to devote more energy in diagnosing CSPH by non-invasive methods among patients with cACLD. Since the diverse elastography modalities have been embedded into the ultrasound machines for multiparametric assessment of liver disease, it is inevitable to validate the diagnostic accuracy of the emerging elastography techniques [29]. According to Baveno VII consensus [7], TE, as the wide-accepted elastography tool, was suggested for LSM and SSM to assess CSPH with a good diagnostic performance. However, the LSM by TE can appear discrepancy, which included obesity and ascites [8–10]. It is difficult for visual control in

the process of LSM and SSM. Additionally, SSM by TE in the traditional modal, using a 50 Hz probe, can be constrained for exceeding the upper limit of measurement by 75 kPa [11]. Due to various limitations from TE, some clinical researches were launched to investigate the diagnostic accuracy of LSM and SSM by 2D-SWE for assessing CSPH. A meta-analysis which including 328 patients from five studies showed that LSM by 2D-SWE < 14 kPa could rule out CSPH with 91% sensitivity and > 32 kPa could rule in CSPH with 89% specificity [30]. However, among the cirrhosis patients included in meta-analysis, only 27% were in the compensatory period, which inevitably led to selection bias. Grgurevic et al. conducted a cross-sectional study, including 76 patients with cACLD underwent LSM by 2D-SWE, showed that LSM ≤ 13.5 kPa and PLT ≥ 150 × 10⁹/L could rule out CSPH [31]. Likewise, Jansen et al. putted forward that LSM ≤ 16.0 kPa OR SSM ≤ 21.7 kPa were able to rule out CSPH, and LSM > 29.5 kPa OR SSM > 35.6 kPa were able to rule in CSPH in 158 cirrhotic patients [25]. Hereby, LSM and SSM by 2D-SWE showed the promising potential for diagnosing or discarding CSPH, and non-inferior to those by TE. The inconsistent cutoff values based on 2D-SWE prevent its widespread application in clinical practice. In our study, we investigated the diagnostic performance of 2D-SWE in accordance with Baveno VII criteria for ruling in and ruling out CSPH and corresponding results suggested that the cutoff values of LSM and SSM for ruling in CSPH are also feasible to 2D-SWE, while ruling out CSPH are the opposite.

The strengths of the present study are that this is an international, multicenter study for assess the performance of Baveno VII criteria for ruling in and ruling out CSPH by 2D-SWE in patients with cACLD and it can alleviate the selecting bias. However, our study existed some disadvantages. First, we could not compare the diagnostic performance of LSM and SSM by 2D-SWE and that by TE for ruling in and ruling out CSPH, as subjects were not undergoing TE. Second, considering a finite number of patients enrolled into this study, we were unable to ascertain the same excellent performance of Baveno VII criteria for identifying CSPH by 2D-SWE based under diverse etiologies. Furthermore, our study was a retrospective study and a large proportion of patients with cACLD did not undergo HVPG, which inevitably resulted in selection bias. Finally, the 2D-SWE was performed by trained operators, we could not guarantee the exclusion of reporting bias because the inter-observer concordance of 2D-SWE was not exclusively estimated in our study.

In conclusion, Baveno VII criteria by 2D-SWE showed a good diagnostic performance for ruling in but not for ruling out CSPH, which might become an emerging non-invasive elastography tool to select the patients who needed NSBB therapy.

Supplementary Information The online version contains supplementary material available at <https://doi.org/10.1007/s12072-024-10657-7>.

Author contributions Study concept and design: RH, CL, IG, YG, HX, JL, and XQ. Supervision of the study: XQ and JL. Acquisition of data and technical support: YL, XYW, AM, KP, YZ, YH, KW, JW, MS, and QZ. Interpretation of data: RH and CL. Drafting of the manuscript: RH and JL. All authors approved this version for submission.

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Data availability Data are available from the corresponding author upon reasonable request.

Declarations

Conflict of interest Ruiling He, Chuan Liu, Ivica Grgurevic, Ying Guo, Huixiong Xu, Jiacheng Liu, Yunfang Liu, XiaoYan Wang, Hongmei Shi, Anita Madir, Kristian Podrug, Yuli Zhu, Yongli Hua, Kun Wang, Jing Wen, Meiqin Su, Qun Zhang, Jie Li and Xiaolong Qi disclose no conflicts.

Ethical approval The study was approved by the local Ethics Committee and was performed in accordance with the last revised version of the Helsinki Declaration.

Consent to participate Informed consent was obtained from the patient in this study.

Consent for publication Informed consent for publication was obtained from all authors.

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