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Original article

Baveno VII Criteria for the Exclusion of Esophageal Varices in a Peruvian Population: Cross-Sectional Study

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Abstract

Introduction: Esophageal varices represent one of the main complications in patients with liver cirrhosis. The main objective was to determine the diagnostic performance of the new Baveno VII criteria to exclude the presence of esophageal varices in compensated advanced chronic liver disease (cACLD), in an independent Peruvian population. **Materials and methods:** A cross-sectional study, including patients with cACLD, upper digestive endoscopy, and transient hepatic elastography from January 2017 to December 2019. **Results:** The mean age was 59.4 (12.9) years, while the mean measurement of liver stiffness was 27.21 (14.6) kPa. The prevalence of esophageal varices was 85.6%; non-alcoholic fatty liver disease (NAFLD) (63.6%) was the most prevalent etiology, followed by viral hepatitis (14.4%). For esophageal varices exclusion, Baveno VII criteria for all etiologies demonstrated adequate sensitivity and negative predictive value (sensitivity: 96.7%; 95% confidence interval [CI]: 92.3%-98.8%; negative predictive value: 76.9%, 95% CI: 56.4% -91%). However, better diagnostic performance was found when applying the Baveno VII criteria without considering NAFLD patients (sensitivity: 98.4%, 95% CI: 79.2% -99.2%; negative predictive value: 90.9%, 95% CI: 79.2% -99.2%). This would prevent 14% of endoscopic studies with a 9% risk of failing to detect esophageal varices. **Conclusions:** The Baveno VII criteria present good diagnostic performance for the exclusion of esophageal varices, especially in patients with cACLD without NAFLD, in an independent Peruvian population.

Keywords

Esophageal varices, gastrointestinal endoscopy, liver cirrhosis, portal hypertension.

INTRODUCTION

Latin America has one of the highest prevalences of mortality associated with liver disease[1]. However, there is limited epidemiological information specific to our context[2]. In Peru, chronic liver disease imposes a considerable economic burden on the healthcare system[3,4].

Gastrointestinal bleeding is one of the most frequent complications (39.4%) of compensated advanced chronic liver disease (cACLD). Approximately half of the patients with liver cirrhosis develop esophageal varices, and this percentage can reach 40% in those with a recent diagnosis[5,6].

The prognosis of chronic liver disease depends on the degree of portal vein pressure increase. Clinically significant portal hypertension (CSPH) is diagnosed with values above 10 mm Hg measured by the hepatic venous pressure gradient (HVPG)[7-9]. CSPH is associated with the development of complications related to cirrhosis, such as esophageal varices (EV), ascites, and hepatic encephalopathy[10,11]. Additionally, upper gastrointestinal endoscopy

(EGD) is a direct method to detect varices and assess the risk of bleeding. However, the invasive nature of HVPG and EGD limits their routine use[12].

Various non-invasive diagnostic methods have been proposed to monitor the progression of hepatic fibrosis, with transient liver elastography being one of them[13-19]. The latest update of the Baveno criteria recommends using non-invasive methods to identify advanced chronic liver disease and the presence of clinically significant portal hypertension. Therefore, this study aims to evaluate the diagnostic performance of the new Baveno criteria (liver stiffness less than 15 kPa and platelet count greater than 150×10^9/L) [20] to exclude the presence of esophageal varices in an independent sample of the Peruvian population with cACLD.

MATERIALS AND METHODS

Study Design

This study is a retrospective, cross-sectional analysis of patients with compensated advanced chronic liver disease who were treated in the gastroenterology service at Hospital Nacional Arzobispo Loayza in Lima, Peru.

Study Population

The study included 209 patients with liver cirrhosis who underwent endoscopic and elastographic evaluations between January 2017 and December 2019. Based on etiology, they were classified into four groups: metabolic dysfunction-associated steatotic liver disease (MASLD), alcoholic liver disease (ALD), viral liver disease (chronic hepatitis B and C infections), and autoimmune liver disease (primary biliary cholangitis, autoimmune hepatitis, and primary sclerosing cholangitis).

The diagnosis of MASLD was based on ultrasonographic evidence of fatty liver along with the presence of one or more of the following criteria: abdominal circumference (≥90 cm for men and ≥80 cm for women), overweight or obesity, diabetes *mellitus*, or evidence of metabolic risk factors (blood pressure ≥ 130/85 mmHg, triglycerides ≥ 1.70 mmol/L, HDL-C < 40 mg/dL for men and < 50 mg/dL for women, HOMA-IR ≥ 2.5)[21]. Alcohol intake was considered the primary cause if no other underlying reason was identified. The diagnoses of viral hepatitis were confirmed by detecting positive viral markers for hepatitis B and C infections. Autoimmune liver diseases were diagnosed based on positive antibody tests, imaging studies, and liver biopsies when necessary. The diagnosis of cACLD was established through clinical data, radiological findings, or liver biopsy.

Inclusion criteria for patients were those who had undergone upper gastrointestinal endoscopy and liver elastography within three months of biochemical studies. Exclusion criteria included patients with secondary prophylaxis for esophageal variceal bleeding, post-transplant patients, pregnant women, and patients with heart failure.

Data Collection

The following variables were collected: age, sex, platelet count, international normalized ratio (INR), creatinine, albumin, total and fractionated bilirubin, Child-Pugh score, and MELD-Na score.

Endoscopic Evaluations

Endoscopic evaluations were performed under the supervision of two well-trained endoscopists. Esophageal varices were classified into two categories: low risk, defined by a diameter less than 5 mm and absence of red signs, and high risk, characterized by a diameter greater than 5 mm with or without red signs[22].

Measurement of Liver Stiffness

Liver stiffness was measured using transient liver elastography (FibroScan® model 502, Echosens, Paris, France), conducted by trained hepatologists. Measurement quality was ensured with at least ten measurements, a success rate of ≥ 60%, and an interquartile range (IQR/M) ≤ 30%. M or XL probes were used as necessary.

Statistical Analysis

Statistical analysis was conducted using RStudio v.1.1.463. Quantitative variables were presented as means and standard deviations, while qualitative variables were expressed as absolute values and proportions. The Kolmogorov-Smirnov or Shapiro-Wilk test was used to verify the normal distribution of the data. Kruskal-Wallis or ANOVA tests were used for numerical data, while the chi-square test was employed for categorical variables. Diagnostic performance was assessed through sensitivity, specificity, negative predictive value, positive predictive value, percentage of missed esophageal varices, and percentage of upper gastrointestinal endoscopies avoided. Statistical significance was set at a p-value < 0.05.

Ethical Considerations

This study adhered to ethical research guidelines and was approved by the ethics and research committee of Hospital Nacional Arzobispo Loayza in Lima, Peru, under protocol number 170302020.

RESULTS

Clinical Profile of Patients with Esophageal Varices

The average age of the patients was 59 years, with 57.4% of the study population being female. The most common etiology of cACLD was MASLD (63.6%), followed by viral hepatitis (14.4%). A total of 179 patients presented with esophageal varices (85.6%), with the majority classified as high risk (63.1% compared to 36.9%). **Table 1** summarizes the clinical and biochemical findings.

Patients with low-risk esophageal varices showed significantly lower elastography measurements (27.1 ± 9.8 kPa compared to 32.1 ± 15.1 kPa, $p < 0.0001$). Significant differences were also observed between the groups in terms of platelet count, bilirubin, albumin, and INR values.

Diagnostic Performance of Transient Liver Elastography and Platelet Count for the Exclusion of Esophageal Varices

The Baveno VII criteria demonstrated high diagnostic accuracy for ruling out esophageal varices with a cut-off point of < 15 kPa, showing a sensitivity of 96.7% and a negative predictive value of 76.9% (**Table 2**).

In the sub-analysis of patients with cACLD excluding those with MASLD, the diagnostic performance for ruling out esophageal varices improved, with a sensitivity of 98.4% and a negative predictive value of 90.9% (**Table 3**).

Table 1. Characterization of Clinical and Biochemical Parameters Among Different Groups*

Parameter	All (n = 209)	No Varices (n = 30)	Varices (n = 179)		*p*-Value
			Low Risk (n = 66)	High Risk (n = 113)	
Age (years)	59.44 ± 12.9	64.5 ± 11.4	59.6 ± 11.8	57.9 ± 13.7	0.0815
Female. n (%)	120 (57.4)	24 (80)	44 (67)	52 (46)	0.0007
Etiology. n (%)					
MASLD	133 (63.6)	17 (57)	41 (62)	75 (66)	0.0022
Viral	30 (14.4)	4 (13)	11 (17)	15 (13)	
Autoinmune	25 (12)	9 (30)	10 (15)	6 (5)	
ALD	21 (10)	-	4 (6)	17 (15)	
Platelets (x 10^9 cells/L)	148.3 ± 75.2	206.4 ± 87.1	149.9 ± 74.7	131.9 ± 64.1	<0.0001
Bilirubin (mg/dL)	1.7 ± 2.4	1.1 ± 0.9	1.5 ± 1.7	2.1 ± 2.9	0.0003
Albumin (g/dL)	3.78 ± 0.6	4.2 ± 0.5	4 ± 0.6	3.5 ± 0.6	<0.0001
Creatinine (mg/dL)	0.83 ± 0.8	1.2 ± 2.01	0.8 ± 0.3	0.7 ± 0.2	0.5027
INR	1.2 ± 0.2	1.1 ± 0.3	1.2 ± 0.3	1.3 ± 0.2	<0.0001
MELD-Na	11.7 ± 4.5	10.7 ± 4.1	10.9 ± 4.7	12.44 ± 4.4	0.0067
Child-Pugh. n (%)					
≤ 6 points	108 (51.7)	28 (93)	47 (71)	33 (29)	<0.0001
≥ 7 points	101 (48.3)	2 (7)	19 (29)	80 (71)	
LSM. kPa (mean)	27.21 ± 14.6	9.3 ± 1.6	27.1 ± 9.8	32.1 ± 15.1	<0.0001

*Numerical variables were compared using the Kruskal-Wallis test; categorical variables were compared using the chi-square test. INR: international normalized ratio; MELD: model for end-stage liver disease; LSM: liver stiffness measurement. Author's own research.

Table 2. Sensitivity and Negative Predictive Value of Liver Stiffness Measurement and Platelet Count for Excluding Esophageal Varices Across All Etiologies

LSM Cut-Off Points	Varices	No Varices	Sensitivity (95% CI)	NPV (95% CI)
<15 kPa	13	30	92.7 (87.9-96.1)	69.8 (53.9-82.8)
<15 kPa + ≥150 x 10^9/L platelets	6	20	96.7 (92.3-98.8)	76.9 (56.4-91)

CI: confidence interval; kPa: kilopascals; LSM: liver stiffness measurement; NPV: negative predictive value. Author's own research.

Table 3. Sensitivity and Negative Predictive Value of Liver Stiffness Measurement and Platelet Count for Excluding Esophageal Varices in Patients Without MASLD

LSM Cut-Off Points	Varices	No Varices	Sensitivity (95% CI)	NPV (95% CI)
<15 kPa	4	13	93.6 (84.3-98.2)	76.5 (50.1-93.2)
<15 kPa + ≥150 x 10^9/L platelets	1	10	98.4 (97.3-99.9)	90.9 (58.7-99.8)

CI: confidence interval; kPa: kilopascals; LSM: liver stiffness measurement; NPV: negative predictive value. Author's own research.

In terms of optimizing patient selection for ruling out esophageal varices, our study found that the use of gastrointestinal endoscopies in the overall population could be reduced upper by 12%, though with the risk of missing 23% of patients with esophageal varices. However, when excluding patients with MASLD from the analysis, the reduction in upper gastrointestinal endoscopies increased to 14%, with a lower risk of missing esophageal varices (9%) (**Figure 1**).

DISCUSSION

This study aimed to evaluate the effectiveness of the new Baveno VII criteria for excluding esophageal varices in patients with compensated liver cirrhosis. Our findings indicate a higher prevalence of esophageal varices compared to previous studies[23-25]. To avoid invasive diagnostics and reduce the number of endoscopic procedures, we applied the Baveno VII criteria (liver stiffness less than 15 kPa and platelet count greater than 150 × 10^9/L) for the exclusion of esophageal varices in our population. Our results demonstrate that the new Baveno criteria exhibit good diagnostic performance for excluding esophageal varices in patients without MASLD (sensitivity: 98.4%, negative predictive value: 90.9%). Additionally, applying these criteria could reduce upper gastrointestinal endoscopies by 14% with a low probability of missing esophageal varices (9%).

The high percentage of esophageal varices (85.6%) in our study may be attributed to the predominance of MASLD (63.6%) as the most prevalent etiology, aligning with demographic changes observed in our region[26]. Patients with MASLD are more likely to develop clinically significant portal hypertension, even in the early stages of hepatic fibrosis, compared to other etiologies[27,28].

The improvement in both sensitivity and negative predictive value may be attributed to the evaluation of patients with MASLD, which reduces the diagnostic accuracy of transient liver elastography. MASLD is defined by the presence of hepatic steatosis (demonstrated by imaging or liver histology) and metabolic risk factors[21]. Hepatic steatosis can alter the liver's viscoelastic properties[29]. Additionally, previous studies have not found a direct relationship between the degree of fibrosis and portal pressure measurements in patients with MASLD[27,30], suggesting the presence of subclinical portal hypertension in early and extensive stages of fibrosis[31]. From a technical standpoint, vibration-controlled transient elastography has limitations in its reliability for certain patients, particularly those with obesity, due to the greater distance between the skin and the liver caused by adipose tissue[13,32,33]. Pons and colleagues[13] found that patients with non-alcoholic steatohepatitis (NASH) and liver stiffness values similar to those in our population had a lower incidence of clinically significant portal hypertension. Including body mass index in the analysis could improve the non-invasive diagnosis of clinically significant portal hypertension, as proposed by the Anticipate study[34]. Therefore, hepatic steatosis and patients' physical characteristics can influence the accuracy of liver stiffness measurements.

As previous studies have highlighted, the etiology of advanced chronic liver disease can negatively impact the

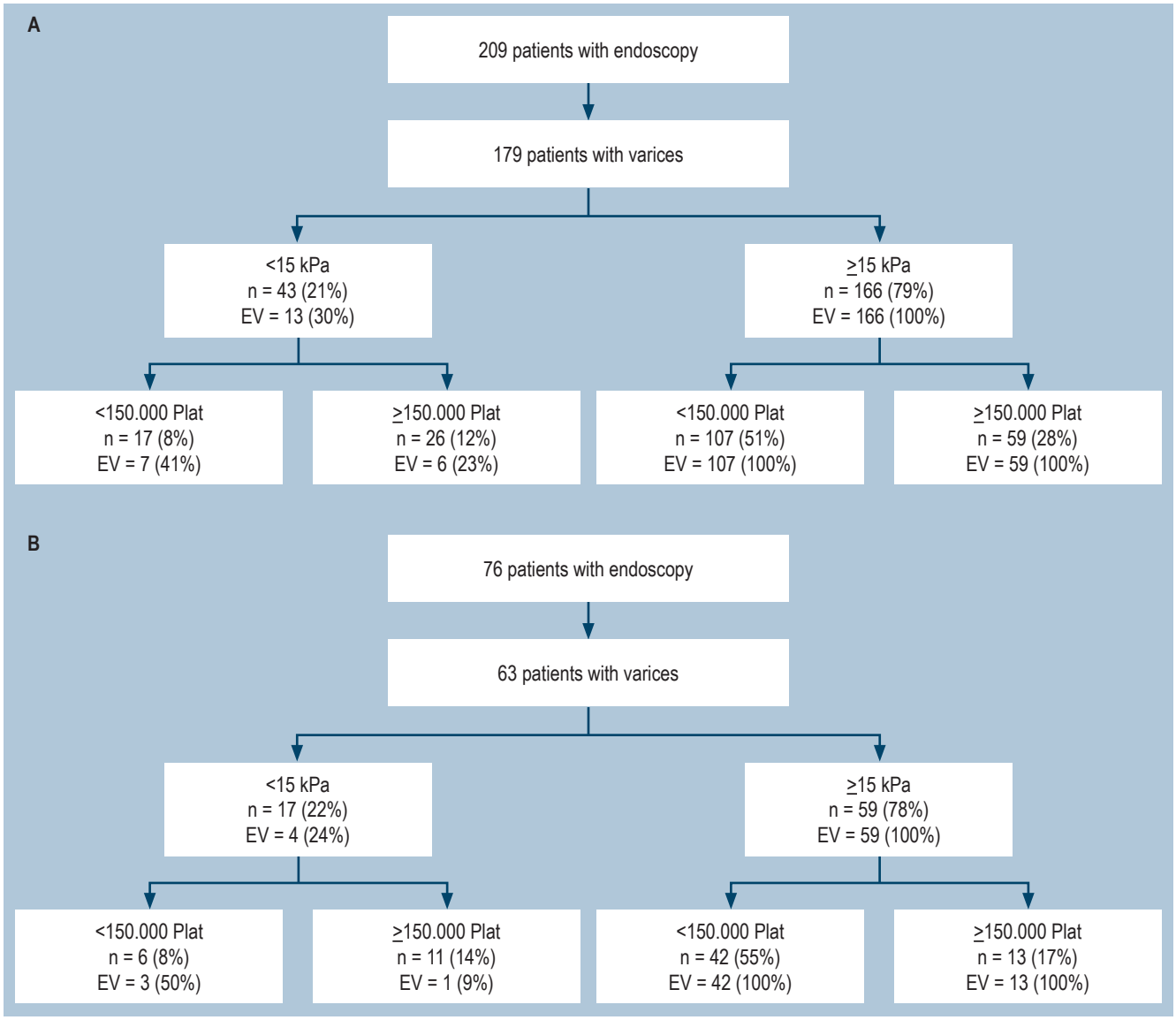

Figure 1. Performance Characteristics of the Baveno VII Criteria Across All Etiologies (**A**) and Excluding MASLD (**B**). Plat: platelets; EV: esophageal varices. Author's own research.

diagnostic performance of liver elastography for excluding esophageal varices[21-23]. In this independent sample of the Peruvian population, the Baveno VII criteria demonstrated good efficacy in reducing the need for endoscopic studies, with a decreased rate of missed esophageal varices in patients with cACLD without MASLD. This suggests that implementing these criteria is beneficial in daily clinical practice.

This is the first Peruvian study to apply the new Baveno consensus criteria for excluding the presence of esophageal varices in patients with liver cirrhosis who have no history of decompensation due to gastrointestinal bleeding. While endoscopic evaluation remains mandatory for patients with liver cirrhosis, the availability of liver elastography in some centers allows for the application of the Baveno criteria to avoid unnecessary upper gastrointestinal endoscopies. Our findings align with previous studies indicating that the diagnostic performance of transient liver elastography for excluding esophageal varices is reduced in patients with MASLD[35-37].

There are several limitations to this study. First, the sample size was small, necessitating a larger prospective study. Second, the cross-sectional design limits our ability to establish a causal relationship between different etiologies and diagnostic performance. Third, since the study was

conducted at a single center, the conclusions are restricted to our study population. Lastly, interobserver variability in liver stiffness measurements can impact results; however, all procedures were performed by two hepatologists who adhered to the same protocol and validity criteria for transient liver elastography measurements.

CONCLUSION

The new Baveno criteria have proven useful in preventing unnecessary upper gastrointestinal endoscopies, thus reducing the risk of missing esophageal varices in patients with cACLD without MASLD in an independent Peruvian population. Future large-scale prospective studies are recommended to validate and expand these results.

Author Contributions

CCC, RZH, AZ, and JGR contributed to the conceptualization and methodology of the study. RHZ, JGR, CCC, and WCC conducted the investigation. BCS, RZH, CCC, WCC, and AZ built the database and performed the statistical analysis. AZ, RZH, and BCS validated the study results. AZ and JGR managed the research project, and AZ provided administrative support. All authors were involved in drafting and approving the manuscript.

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Conflict of Interest

The authors declare no conflicts of interest related to this study.

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