Theory and Practice of Science and Technology
2025, VOL. 6, NO. 12, 72-74
DOI: 10.47297/taposatWSP2633-456915.20250612

The Diagnostic and Prognostic Value of Transient Elastography in Primary Biliary Cholangitis

Rui Zhang[1], Lina Cui[2], Dawei Ding[2], Ying Han[2]*

[1]Xi'an Medical University, Xi'an, Shaanxi, 710021, China

[2]State Key Laboratory of Holistic Integrative Management of Gastrointestinal Cancers, National Clinical Research Center for Digestive Diseases, Xijing Hospital of Digestive Diseases, The Air Force Military Medical University, Xi'an, Shaanxi, 710032, China

ABSTRACT

Transient elastography (TE) has emerged as a pivotal noninvasive tool for assessing the liver stiffness measurement (LSM) in patients with primary biliary cholangitis (PBC). This review provides a comprehensive analysis of its diagnostic performance and its role in prognostic stratification. In terms of diagnosis, TE has demonstrated superior accuracy for staging liver fibrosis across multiple validation studies, achieving area under the receiver operating characteristic curve (AUROC) values as high as 0.99 for the detection of cirrhosis, consistently outperforming standard serological indices such as the AST-to-platelet ratio index (APRI) and the fibrosis-4 index (FIB-4). The prognostic significance of TE is profound and multifaceted. The LSM is strongly and independently correlated with the development and severity of portal hypertension and is a major driver of clinical outcomes in patients with PBC. LSM values ⩾15 kPa indicate a significantly increased risk of hepatic decompensation, which is consistent with the Baveno VII consensus. In addition, the combination of TE and platelet counts can also effectively reduce unnecessary endoscopic screenings for varices.

KEYWORDS

Primary biliary cholangitis; Transient elastography; Liver fibrosis, diagnosis; Prognosis

1 Introduction

The latest Baveno VII guidelines suggest that TE can serve as a noninvasive diagnostic tool for compensated advanced chronic liver disease (cACLD) and portal hypertension. The guidelines introduced the '5 kPa rule' for the first time, defining a range of LSM thresholds of 10, 15, 20, and 25 kPa, which reflects the idea that the relative risk of decompensation events and liver-related deaths gradually increases, regardless of the cause of chronic liver disease [1]. This recommendation not only establishes the LSM value as a 'cut-off point' for predicting prognosis but also makes the ability of TE to predict the prognosis of patients with chronic liver disease more applicable in clinical settings.

Primary biliary cholangitis (PBC) is a chronic, progressive cholestatic disease. Unlike other liver diseases, portal hypertension (PH) can occur in the early stages of PBC before cirrhosis has progressed. The incidence of PH is approximately 24.2% [2]. These findings suggest that monitoring portal hypertension is crucial for the prognosis of PBC patients.

Therefore, this study aims to clarify the application value of transient elastography in the diagnosis and prognosis of primary biliary cholangitis, as well as the factors affecting TE detection results.

2 Diagnostic Value of TE in PBC

The LSM value detected by TE is associated with the degree of liver fibrosis and pathological stage in PBC patients and has high diagnostic efficacy for advanced fibrosis (F⩾2), significant fibrosis (F⩾3) and cirrhosis (F=4). A retrospective study of 150 patients in France revealed that the LSM had a higher diagnostic efficacy for severe liver fibrosis and cirrhosis, with AUROC values of 0.95 and 0.99, respectively, and a sensitivity and specificity of 90%. The accuracy of diagnosing significant fibrosis was also higher (AUROC 0.91), but the sensitivity was lower, at only 67% [3]. There proposed a new grading standard for PBC liver biopsy, namely, the Nakanuma score[4]. For the first time, a prospective study in Japan graded 74 PBC patients using these scoring criteria. The results revealed that the LSM value with 23.7 kPa as the cut-off had an AUROC of 0.907 for the diagnosis of Nakanuma stage 4, indicating extremely high diagnostic accuracy [5]. The above studies indicate that, under different pathological scoring criteria, TE demonstrates high diagnostic efficacy for liver fibrosis, particularly in the stages of significant fibrosis and cirrhosis.

However, some discrepancies exist in the research conclusions regarding the diagnostic efficacy of TE for early mild fibrosis. An earlier large-scale retrospective study from a single centre revealed that when the cut-off value was set at 7.1 kPa, the AUROC was 0.80, with a sensitivity of 100%, indicating extremely high diagnostic accuracy and sensitivity [6]. However, the data from a multicentre study in the United States were not very satisfactory. When 6.6 kPa was used as the

* **Corresponding Author:** Ying Han, hanying1@fmmu.edu.cn

cut-off value, the AUROC was maintained at 0.70, but the sensitivity was only 50% [7].

The advantages of TE are also evident compared with other noninvasive tests. Specifically, TE outperforms other imaging methods. Compared with pSWE, TE has greater diagnostic specificity for diagnosing fibrosis at all stages. The sensitivity of TE for diagnosing F⩾2, F⩾3, and F=4 is 70%, 90%, and 93%, respectively, with a specificity of 80%, 93%, and 99%, respectively. For F⩾2, pSWE has a sensitivity of 80% and a specificity of 77%; for F⩾3, it has a sensitivity of 91% and a specificity of 82%. For F=4, pSWE has a sensitivity of 100% and a specificity of 79%, but the diagnostic specificity for all stages is lower than that of TE [8]. TE exhibits comparable diagnostic performance to that of two-dimensional shear waves. In terms of histological stage, the ROC curves constructed using TE-LSM and SWE-LSM data were significantly different for stages ⩾2 (0.824 vs. 0.823, p=0.9764), ⩾3 (0.918 vs. 0.907, p=0.6443), and 4 (0.907 vs. 0.902, p=0.8763) [9]. MRE, the second most frequently used noninvasive examination tool after TE, still has lower diagnostic accuracy than TE does. The optimal LS thresholds for MRE in predicting histological fibrosis stages ⩾F1, ⩾F2, ⩾F3, and =F4 are 3.80 kPa (AUC 0.50), 3.80 kPa (AUC 0.60), 3.70 kPa (AUC 0.71), and 4.60 kPa (AUC 0.82), respectively. In contrast, the optimal LS thresholds for TE in predicting these stages are 6.60 kPa (AUC 0.70), 7.00 kPa (AUC 0.65), 7.50 kPa (AUC 0.73), and 14.40 kPa (AUC 0.94), respectively, with all AUROC values being higher than those of MRE [7].

Furthermore, TE also demonstrated high diagnostic efficacy when used in combination with other non-invasive indicators. A study in Greece compared the diagnostic performance of FMVCTE and TE-FMVCTE (TE combined with FMVCTE) for diagnosing autoimmune liver disease. The results showed that the AUROC of TE combined with FMVCTE in predicting ⩾F3 fibrosis was significantly better than that of the other three markers (FMvirus, APRI, and FIB-4)[10]. According to Joshita et al., when the optimal cut-off values for LSM and M2BPGi are set at 7.00kPa and 1.00, respectively, the combined index of LSM ⩾7.0 kPa and M2BPGi ⩾1.00 provides a higher accuracy in estimating disease progression to intermediate or advanced stages (i.e., Nakanuma stage 3 or 4), with an AUROC value of 0.74, which is superior to the diagnostic performance of LSM and M2BPGi individually[5].

3 Prognostic Value of TE in PBC

The previous European Association for the Study of the Liver (EASL) clinical practice guidelines recommend the use of noninvasive tests (including VCTE) for diagnosis and disease staging at baseline and follow-up, indicating that the deterioration of the LSM value can predict patient prognosis and be used to detect PBC progression [11]. In addition, the Baveno VII guidelines also propose the "5 kPa principle", which defines a range of LSM thresholds of 10, 15, 20, and 25 kPa to indicate that the relative risk of decompensation events and liver-related deaths gradually increases regardless of the cause of chronic liver disease (B. 1) [1]. This emphasizes the necessity of incorporating fibrosis staging into the risk stratification management of patients with PBC.

Another important factor affecting the prognosis of PBC patients is portal hypertension (PH), which often occurs in the early stage of PBC. According to research statistics, at baseline, the incidence rate of PBC combined with clinically significant portal hypertension (CSPH) was 47.2%, among which the incidence rate in PBC patients at the early histological stage was 20.6%, accounting for approximately half of the total affected population [12]. Therefore, diagnosing portal hypertension as early as possible will increase the survival rate of patients with PBC, reduce the risk of liver transplantation or death, and improve the prognosis of these patients. As mentioned in the Baveno VII guidelines, although the concept of CSPH is driven by HVPG, noninvasive tests are sufficiently accurate for estimating CSPH in clinical practice (A.1) (New). TE detection of an LSM ⩽15 kPa and a platelet count ⩾150×10^9/L can rule out CSPH in cACLD patients (sensitivity and negative predictive value >90%) (B.2) (New)[1]. This highlights the ability of the LSM value to predict portal hypertension. However, research using the Baveno VII standard to assess portal hypertension in PBC patients is lacking; thus, more clinical evidence is needed to determine its applicability in PBC patients.

Esophageal varices are among the more common complications of portal hypertension. According to the Baveno VII guidelines, endoscopic screening can be avoided for patients who regularly undergo TE and platelet examination follow-up, whereas endoscopic screening for esophageal varices should be performed for patients with an LSM ⩾20 kPa or a PLT count ⩽150 x 10^9/L [1]. A large cohort study revealed that in PBC patients, an LSM >12.1 kPa was the threshold for predicting oesophageal or gastric varices; 77% of patients could avoid endoscopic screening, with a false-negative rate of 20.3% and a false-positive rate of 29.7% [13]. These findings suggest that an LSM >12.1 kPa can be used as a threshold for predicting the risk of esophageal or fundic varices in PBC patients and that more than half of patients can avoid endoscopic screening. The prognostic value of the LSM in predicting oesophageal or gastric varices was first demonstrated by Baveno VI [14] in 2015.

4 Influencing Factors of TE Testing

Like most tests, TE testing is influenced by numerous factors. Here, we highlight several factors relevant to patients with PBC. Bile stasis, a clinical feature of PBC, increases the misdiagnosis rate for predicting portal hypertension. A large-scale, multicentre study in Italy revealed that, the cholestasis increases the misdiagnosis rate of noninvasive prediction

results of TE for portal hypertension and reduces the diagnostic efficiency [15]. However, PBC-related liver inflammation had no significant effect on LSM diagnosis and was not sufficient to impair the diagnostic performance of LSM, which may be related to the mild PBC-related liver inflammation [3].

5 Outlook

This article elaborates on the diagnostic and prognostic value of TE in PBC patients, demonstrating that TE has extremely high accuracy in diagnosing liver fibrosis stages, particularly in patients with progressive, significant, or cirrhotic fibrosis. TE can be used to accurately identify and differentiate these stages, aiding clinicians in assessing the severity of liver fibrosis in PBC patients. However, there is still some debate regarding the diagnostic effectiveness of TE for early-stage PBC-related fibrosis, with no definitive conclusion yet. In terms of prognostic value, both the earlier Baveno VI and the latest Baveno VII guidelines include the LST value from TE tests. The latest Baveno VII consensus document introduces the use of splenic stiffness assessment to evaluate portal hypertension, indicating that the prognostic value of TE is increasingly recognized in clinical practice.

Funding

This study was funded by National Natural Science Foundation of China ((NO: 82270551); Key Research and Development Program of Shaanxi Province ((NO: 2024SF-GJHX-16);Xijing Hospital 2025 Boost Project (NO: XJZT25ZH08)

About the Author

Rui Zhang, a Master student at the Xi'an Medical University, Her research interests is diagnosis and treatment of autoimmune liver disease.
Ying Han, M.D., Ph.D.: Xijing Hospital of Digestive Diseases.

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]. J Hepatol. 2022;76(4):959–974.

[2] Hu YF, Li SX, Liu HL, Du ZX, Wang SS, Chen MY, et al. Precirrhotic Primary Biliary Cholangitis with Portal Hypertension: Bile Duct Injury Correlate [J]. Gut Liver. 2024;18(5):867–876.

[3] Corpechot C, Carrat F, Poujol-Robert A, Gaouar F, Wendum D, Chazouillères O, et al. Noninvasive elastography-based assessment of liver fibrosis progression and prognosis in primary biliary cirrhosis[J]. Hepatol Baltim Md. 2012,56(1):198–208.

[4] Nakanuma Y, Zen Y, Harada K, Sasaki M, Nonomura A, Uehara T, et al. Application of a new histological staging and grading system for primary biliary cirrhosis to liver biopsy specimens: Interobserver agreement. Pathol Int[J]. 2010,60(3):167–174.

[5] Joshita S, Yamashita Y, Sugiura A, Uehara T, Usami Y, Yamazaki T, et al. Clinical utility of FibroScan as a non-invasive diagnostic test for primary biliary cholangitis[J]. J Gastroenterol Hepatol. 2020,35(7):1208–1214.

[6] Shen Y, Chen H, Wu SD, Jiang W. Accuracy of transient elastography in assessing fibrosis at diagnosis in individuals with autoimmune liver disease[J]. J Hepatol. 2023,78(1):e33–e34.

[7] Osman KT, Maselli DB, Idilman IS, Rowan DJ, Viehman JK, Harmsen WS, et al. Liver stiffness measured by either magnetic resonance or transient elastography is associated with liver fibrosis and is an independent predictor of outcomes among patients with primary biliary cholangitis[J]. J Clin Gastroenterol. 2021,55(5):449–457.

[8] Duarte-Rojo A, Taouli B, Leung DH, Levine D, Nayfeh T, Hasan B, et al. Imaging-based noninvasive liver disease assessment for staging liver fibrosis in chronic liver disease: A systematic review supporting the AASLD Practice Guideline[J]. Hepatol Baltim Md. 2024,81(2):725–748.

[9] Zhang Y, Meng F, Hu X, Zhang T, Han X, Han J, et al. Comparative diagnostic efficacy of two-dimensional shear wave and transient elastography in predicting the risk of esophagogastric varices and histological staging in patients with primary biliary cholangitis[J]. BMC Gastroenterol. 2024,24(1):396.

[10] Zachou K, Lygoura V, Arvaniti P, Giannoulis G, Gatselis NK, Koukoulis GK, et al. FibroMeter scores for the assessment of liver fibrosis in patients with autoimmune liver diseases[J]. Ann Hepatol. 2021,22:100285.

[11] European Association for the Study of the Liver. Electronic address: easloffice@easloffice.eu, Clinical Practice Guideline Panel, Chair:, EASL Governing Board representative:, Panel members: EASL Clinical Practice Guidelines on non-invasive tests for evaluation of liver disease severity and prognosis - 2021 update[J]. J Hepatol. 2021,75(3):659–689.

[12] Zhang Y, Lai HY, Chen J, Lai RM, Lin XY, Lin S, et al. Clinically significant portal hypertension in patients with primary biliary cholangitis: Clinicopathological features and prognostic value[J]. Ann Hepatol. 2025,30(1):101577.

[13] Zhang Y, Huang CY, Meng FK, Hu X, Huang XJ, Chang J, et al. Non-invasive assessment of esophageal and fundic varices in patients with primary biliary cholangitis[J]. Eur Radiol. 2025,35(4):2330-2338.

[14] de Franchis R, Baveno VI Faculty. Expanding consensus in portal hypertension: Report of the Baveno VI Consensus Workshop: Stratifying risk and individualizing care for portal hypertension[J]. J Hepatol. 2015,63(3):743–752.

[15] Calvaruso V, Celsa C, Cristoferi L, Scaravaglio M, Smith R, Kaur S, et al. Non-invasive assessment of portal hypertension in patients with primary biliary cholangitis is affected by severity of cholestasis[J]. Clin Gastroenterol Hepatol. 2025,23(10):1766-1775.e7.