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Acoustic radiation force impulse elastography for non-invasive assessment of disease stage in patients with primary biliary cirrhosis: A preliminary study

D.-K. Zhang [a,*], M. Chen [a], Y. Liu [a], R.-F. Wang [a], L.-P. Liu [b], M. Li [a]

[a] Department of Ultrasound, The 302 Hospital of PLA, 100039 Beijing, China
[b] Department of Ultrasound, The First Hospital Affiliated to Shanxi Medical University, 030001 Taiyuan, China

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AIM: To investigate the diagnostic performance of the acoustic radiation force impulse (ARFI) elastography for the assessment of primary biliary cirrhosis (PBC) stage.

MATERIALS AND METHODS: Sixty-one patients with PBC in which liver biopsy and ARFI elastography measurements were performed in the same session were included in the study. The diagnostic performance of ARFI elastography for predicting the PBC stage was determined from the area under receiver operating characteristics (AUROC) curve analysis.

RESULTS: ARFI elastography correlated significantly with histological stage ($r = 0.74$, $p < 0.001$) in patients with PBC. The AUROC of ARFI elastography for predicting histological stage equal to or higher than II, III, and equal to IV were 0.83, 0.93, and 0.91, respectively. The optimal cut-off values of ARFI elastography were 1.51 m/s, 1.79 m/s, and 2.01 m/s for PBC stage equal to or higher than II, III, and equal to IV, respectively.

CONCLUSION: ARFI elastography is an acceptable and powerful technique for quantitative assessment of PBC stage.

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Introduction

Primary biliary cirrhosis (PBC) is an autoimmune liver disease characterized by the presence in serum of highly specific anti-mitochondrial antibodies and progressive destruction of intrahepatic bile ducts, resulting in chronic cholestasis, portal inflammation, and fibrosis that can lead to cirrhosis and, ultimately, liver failure. Large case series have reported prevalence rates of PBC ranging between 19 and 402 cases per million.[1] Histological lesions of PBC are classically divided into four stages ranging from portal-tract inflammation with predominantly lymphoplasmacytoid infiltrates and septal and interlobular bile ducts loss (stage I) to cirrhosis (stage IV).[2] Determination of the stage of PBC is important for prognostic and therapeutic decisions in patients. Liver biopsy is the reference standard for the assessment of liver histological staging in PBC at present. However, it is invasive and is associated with a relatively high risk of life-threatening complications.[3–5] In addition, the accuracy of liver biopsy has been questioned for reasons of sampling errors and intra-observer and interobserver variations.[6–8] Therefore, liver biopsy is not a perfect reference standard, leading to an increasing demand for a non-invasive and reliable test.

Acoustic radiation force impulse (ARFI) elastography is a new technique for measuring liver stiffness and it has been

* Guarantor and correspondent: Da-Kun Zhang, Department of Ultrasound, The 302 Hospital of PLA, No. 100, Xi Si Huan Zhong Lu, Beijing 100039, China. Tel.: +86 13699277203.
E-mail addresses: zdk002@163.com, d507k@sina.com (D.-K. Zhang).

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widely applied for the diagnosis of liver fibrosis in chronic viral liver disease caused by hepatitis virus B or C and in those with non-alcoholic fatty liver disease.[9–13] However, whether ARFI elastography values in a selected group of patients with PBC reflect histological staging has not been reported. The aim of the present study was to assess the diagnostic performance of ARFI elastography for the evaluation of various stages of PBC.

Materials and methods

Patients

Sixty-one consecutive patients with PBC who underwent a liver biopsy (LB) and ARFI elastography measurement at the ultrasound departments in the 302 hospital of PLA between October 2011 and June 2013 were included in the study. The diagnosis of PBC was confirmed by at least two of the following criteria: (1) biochemical evidence of cholestasis based mainly on alkaline phosphatase elevation; (2) presence of anti-mitochondrial antibody; (3) histological evidence of non-suppurative destructive cholangitis and destruction of interlobular bile ducts.[14] Exclusion criteria were ascites, hepatocellular carcinoma, a positive serology for hepatitis B or C viruses, overlap syndrome with autoimmune hepatitis or primary sclerosing cholangitis, a history of alcoholic abuse, and all other causes of chronic liver injuries except PBC. For each patient, comprehensive blood liver tests (i.e., aspartate transaminase, alanine aminotransaminase (ALT), serum albumin, γ-glutamyltransferase, total bilirubin, triglycerides, cholesterol, and platelet count.) were performed no more than 3 days before the LB. The study was performed in accordance with the ethical guidelines of the Helsinki Declaration and approved by the ethics committee of the 302 hospital of PLA, and all individuals gave written informed consent before being enrolled in the study.

Liver stiffness measurements by ARFI elastography

ARFI was performed in all patients using a Siemens Acuson S2000™ ultrasound system. All Patients were fasting for at least 4 h at the time of the ARFI examination. The operator can select the position of detection by placing a measurement box (10 mm long and 5 mm wide) in the liver in the desired place. The ultrasound transducer probe automatically generates mechanical energy using short-duration acoustic pulses to generate localized displacements of the examined liver tissue. The displacements result in shear-wave propagation away from the region of excitation and are tracked using ultrasonic correlation-based methods.[15] The patients were examined in a supine position with the right arm in maximum abduction. Scanning was performed between the ribs in the right liver lobe (for instance, in the eight segment) in order to avoid cardiac motion, with minimal scanning pressure applied by the operator. During scanning, patients were asked to stop breathing for a moment, in order to minimize breathing motion. The measurement box was placed 1–2 cm below the surface of the liver. Ten valid measurements were performed in each patient, and a median value was calculated, the result being expressed in metres per second.

Liver histological staging

LB was performed using a 16 G disposable true-cut needle (C.R Bard, Covington, GA, USA) under percutaneous ultrasound guidance in the ultrasound department. Liver samples were fixed in formalin and paraffin embedded. All biopsy specimens were analysed by an expert liver pathologist without knowledge of liver stiffness measurement and ultrasound result. Histological stage was determined according to the Ludwig's classification.[16] Liver biopsy specimens of at least 15 mm of length containing a minimum of 10 portal spaces were considered suitable for histological staging.

Statistical analysis

The data obtained from our patients were collected in a Microsoft Excel file, and statistical analysis was performed using the Statistical Package for the Social Sciences (version 17.0, SPSS, Chicago, IL, USA). Results are presented as the mean ± SD, counts, and percentages. Liver stiffness measurements (LSM) were not normally distributed. Therefore, the results of this test were compared with the categories of the consensus fibrosis stage using Kruskal-Wallis non-parametric analysis of variance. Spearman's test was used for correlation analysis. The diagnostic performances of ARFI elastography was assessed using receiver operating characteristics (ROC) curves. The sensitivity, specificity, accuracy, positive (PPV) and negative predictive value (NPV) were calculated. Optimal cut-off values were chosen to maximize the sum of sensitivity and specificity. For all tests, significance was achieved at $p < 0.05$.

Results

Description of the study population

Sixty-one PBC patients underwent LB within the study period. Five patients were excluded due to poor quality of liver biopsy. Therefore, 56 patients were analysed; clinical details are summarized in Table 1. There were 10 men and 46 women, with a mean age of 45 ± 11 years. There were 17 patients (30.36%) in histological stage I, 17 (30.36%) in stage II, 13 (23.21%) in stage III, and nine (16.07%) in stage IV. No serious complication occurred following LB, and only minor complications, such as post-biopsy pain were observed.

LSM values according to PBC stage and diagnostic performance of ARFI elastography

The respective mean values of ARFI elastography for histological stage I, II, III, and IV were 1.35 ± 0.32 m/s, 1.56 ± 0.34 m/s, 2.29 ± 0.67 m/s, and 2.76 ± 0.62 m/s in PBC ($p < 0.0001$ by Kruskal–Wallis analysis). Spearman's correlation coefficient between ARFI measurements and liver

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