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● *Original Contribution*

ASSESSING HEPATIC FIBROSIS USING 2-D SHEAR WAVE ELASTOGRAPHY IN PATIENTS WITH LIVER TUMORS: A PROSPECTIVE SINGLE-CENTER STUDY

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Abstract—The purpose of this study was to investigate the diagnostic performance of 2-D shear wave elastography (2-D-SWE) in evaluations of liver stiffness in patients with liver tumors before resection. A total of 121 consecutive patients with hepatocellular carcinoma (HCC) (n = 93), intra-hepatic cholangiocarcinoma (n = 6), mixed hepatocellular carcinoma and intra-hepatic cholangiocarcinoma (n = 6), liver metastases (n = 10) and benign tumors (n = 6) were prospectively enrolled in this study from June 2015 to March 2016. Three valid 2-D-SWE measurements for each patient and median liver stiffness values were calculated. Fibrosis staging was evaluated according to the METAVIR scoring system. A receiver operating characteristic curve analysis was used to assess diagnostic performance. In this study, we found that median liver stiffness values were significantly higher in patients with primary liver tumors than in those with liver metastases and benign tumors (11.80 kPa vs. 5.85 kPa, $p < 0.001$). In addition, liver stiffness, assessed using 2-D-SWE, was highly correlated with pathologically confirmed liver fibrosis stage. Liver fibrosis stage and liver stiffness values were analyzed using Spearman's correlation (0.708, $p < 0.001$). The median liver stiffness values were as follows: F1, 6.7 kPa; F2, 6.33 kPa; F3, 9.2 kPa; F4, 13.7 kPa. The area under the receiver operating characteristic curves of the liver stiffness values that predicted significant fibrosis (≥F2), severe fibrosis (≥F3) and cirrhosis (=F4) were 83.5%, 91.6% and 88.1%, respectively. According to the Youden index, the optimal cutoff values for predicting significant fibrosis (≥F2), severe fibrosis (≥F3) and cirrhosis (=F4) were 7.05 kPa (sensitivity = 74.6%, specificity = 100.0%), 9.45 kPa (sensitivity = 78.8%, specificity = 100.0%) and 11.1 kPa (sensitivity = 83.1%, specificity = 89.3%), respectively. We conclude that 2-D-SWE is a useful, accurate and non-invasive method for evaluating hepatic fibrosis in patients with liver tumors adapted to hepatectomy (ClinicalTrials.gov ID: NCT02958592). (E-mail: zhouzhg@sysucc.org.cn) © 2017 World Federation for Ultrasound in Medicine & Biology.

Key Words: **Shear wave elastography, Hepatic fibrosis, Liver tumor, Hepatocellular carcinoma, Liver metastases.**

INTRODUCTION

Hepatic resection is an effective treatment for select patients with liver tumors, including those with hepatocellular carcinoma (HCC), liver metastases or various benign diseases (de Ridder et al. 2016; Dhir et al. 2016; European Association for the Study of the Liver 2016; Kazaryan et al. 2010). Although post-hepatectomy outcomes have remarkably improved in recent decades because of improvements in surgical techniques and peri-operative care (Cucchetti et al. 2011; Ramacciato et al. 2003; Wu et al. 2005), post-hepatectomy morbidity remains high, especially in patients with liver fibrosis and cirrhosis. In recent years, many studies have reported that there is a correlation between the degree of liver stiffness (measured using transient elastography [TE]) and post-hepatectomy liver failure and morbidity (Fung et al. 2013; Nishio et al. 2016; Wong et al. 2013). It remains difficult to assess liver fibrosis before surgery without performing a traditional liver biopsy. Several emerging non-invasive techniques, including magnetic resonance (MR) elastography and ultrasonography (US)-based elastography, have recently been developed to estimate liver

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stiffness in patients with a variety of liver diseases (Li et al. 2016; Myers et al. 2012; Oudry et al. 2009; Rustogi et al. 2012; Yoon et al. 2014). US-based elastography techniques, such as TE (Sandrin et al. 2003), acoustic radiation force impulse (ARFI) (Lupsor et al. 2009) and shear-wave elastography (SWE) (Li et al. 2016), are more convenient than MR elastography because they are relatively inexpensive to perform and have better portability. Hence, they are more commonly used in current clinical practice.

Elastography provides a quantitative estimate of tissue stiffness based on the assumptions that the material is linear and symmetric and that the liver tissue is isotropic, homogeneous and incompressible (Muller et al. 2009). In SWE, a conventional ultrasound scanner is used to generate shear waves *via* US pulses. It provides a quantitative estimate of liver stiffness by estimating shear wave speed. Moreover, liver tissue stiffness can be imaged in real time using this modality, and a quantitative elastogram can be superimposed on an anatomic B-mode image. The region of interest can be measured by correlating the results with underlying conventional ultrasound imaging. Thus, an elastic modulus can be accurately measured, and these measurements are reproducible. Recently, an increasing number of studies have reported that there is a correlation between liver stiffness evaluated using 2-D-SWE and the degree of fibrosis determined using liver biopsy in patients with chronic liver disease (Ochi et al. 2012; Samir et al. 2015; Zheng et al. 2015). Liver tumors occur in various background parenchyma, including normal, fibrotic and cirrhotic livers. However, only a few studies have evaluated the utility of SWE for assessing the stiffness of the background liver parenchyma before surgery in patients with liver tumors (Lu et al. 2015; Tian et al. 2016; Zhuang et al. 2017).

The aim of this study was to evaluate the diagnostic efficacy of 2-D-SWE for staging liver fibrosis in liver background parenchyma in patients with liver tumors who underwent hepatic resection. The pathology of the surgically resected tissue was used as a reference standard.

METHODS

Patient population

A total of 121 consecutive patients were prospectively recruited from our center between June 2015 and March 2016. Written informed consent was obtained from all patients before their enrollment. All procedures performed in studies involving human participants were conducted in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

This prospective study was approved by the institutional review board at the Sun Yat-sen University Cancer Center and performed in accordance with the approved guidelines. The trial was registered at ClinicalTrials.gov as NCT02958592.

The inclusion criteria were as follows: (i) patients with a solid focal liver lesion that was pathologically proven or diagnosed using imaging methods such as conventional US, CT or MRI; (ii) patients scheduled to undergo a hepatectomy; and (iii) patients with a lesion ≥1.0 cm in diameter. The exclusion criteria were as follows: (i) patients with a history of chemotherapy and (ii) patients unable to properly hold their breath.

Performance of 2-D-SWE

All patients underwent real-time 2-D-SWE at a frequency of 6 MHz using an Aixplorer ultrasound system (Super-Sonic Imaging S.A., Aix-en-Provence, France) equipped with an SC6-1 convex probe. The patients had fasted overnight and were asked to lie in a supine position with their upper arms maximally abducted to increase the intercostal space. A probe was placed in the intercostal space using gentle compression. First, measurements of the anteroposterior diameter of the right and left liver lobes, the length and thickness of the spleen, the inner diameters of the portal and spleen veins and the size and location of liver tumors were obtained as conventional B-mode images. Then, in an area free of tumor and large vessels, a section of liver parenchyma more than 2 cm away from the liver lesion was located after the imaging mode was changed to 2-D-SWE. Next, an elastography box was positioned at least 1 to 5 cm away from the liver capsule, and the patient was instructed to hold her or his breath for a few seconds to allow the 2-D-SWE signal to stabilize. A circular region of interest (ROI) with a fixed diameter of 20 mm was placed on the 2-D-SWE imaging area, and the 2-D-SWE image was defined and qualified when the elastography color map was more than 90% filled. The mean of the Young's modulus of the liver tissue within the ROI was expressed in kilopascals (kPa) and recorded (Fig. 1). A 2-D-SWE image was acquired for three different sections per patient, and the mean of the three measurements was calculated. All 2-D-SWE procedures were performed by a doctor with 9 y of experience in the use of conventional US and 2 y of experience in performing 2-D-SWE. The doctor was blinded to the patients' histologic and clinical data.

Liver specimens and histology

The pathologic results of all included liver tumors were as follows: 93 patients (76.8%) had hepatocellular carcinoma (HCC), 6 patients (5.0%) had intra-hepatic cholangiocarcinoma (ICC), 6 patients (5.0%) had mixed HCC and ICC and the remaining 16 patients (13.2%)

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