

Noninvasive Assessment of Liver Fibrosis by Measurement of Stiffness in Patients With Chronic Hepatitis C

Marianne Ziol,¹ Adriana Handra-Luca,¹ Adrien Kettaneh,² Christos Christidis,³ Frédéric Mal,³ Farhad Kazemi,⁴ Victor de Lédinghen,⁵ Patrick Marcellin,⁶ Daniel Dhumeaux,⁷ Jean-Claude Trinchet,⁸ and Michel Beaugrand⁹

Liver fibrosis is the main predictor of the progression of chronic hepatitis C, and its assessment by liver biopsy (LB) can help determine therapy. However, biopsy is an invasive procedure with several limitations. A new, noninvasive medical device based on transient elastography has been designed to measure liver stiffness. The aim of this study was to investigate the use of liver stiffness measurement (LSM) in the evaluation of liver fibrosis in patients with chronic hepatitis C. We prospectively enrolled 327 patients with chronic hepatitis C in a multicenter study. Patients underwent LB and LSM. METAVIR liver fibrosis stages were assessed on biopsy specimens by 2 pathologists. LSM was performed by transient elastography. Efficiency of LSM and optimal cutoff values for fibrosis stage assessment were determined by a receiver-operating characteristics (ROC) curve analysis and cross-validated by the jack-knife method. LSM was well correlated with fibrosis stage (Kendall correlation coefficient: 0.55; $P < .0001$). The areas under ROC curves were 0.79 (95% CI, 0.73-0.84) for $F \geq 2$, 0.91 (0.87-0.96) for $F \geq 3$, and 0.97 (0.93-1) for $F = 4$; for larger biopsies, these values were, respectively, 0.81, 0.95, and 0.99. Optimal stiffness cutoff values of 8.7 and 14.5 kPa showed $F \geq 2$ and $F = 4$, respectively. **In conclusion**, noninvasive assessment of liver stiffness with transient elastography appears as a reliable tool to detect significant fibrosis or cirrhosis in patients with chronic hepatitis C. (HEPATOLOGY 2005;41:48-54.)

Quantification of liver fibrosis by noninvasive means is a major challenge that has stimulated the search for new approaches. The prognosis and clinical management of chronic liver dis-

eases are highly dependent on the extent of liver fibrosis, as complications mainly occur in patients in the advanced stages.¹ This is particularly true in patients with chronic hepatitis C (CHC), which is the leading cause of cirrhosis in western countries. Liver biopsy (LB), the reference method for assessing liver fibrosis, is an invasive and expensive procedure that is not well accepted by patients,² especially when repeated examinations are needed. Moreover, its accuracy in assessing fibrosis is questionable, as reproducibility is poor due to sampling errors, and even in adequately sized specimens, intraobserver and interobserver discrepancies are seen.³⁻⁷ Transient elastography is a new technique that rapidly and noninvasively measures mean tissue stiffness.⁸ The purpose of this prospective, multicenter study was to compare liver stiffness measurement (LSM) obtained with a new medical device (Fibroscan), based on ultrasound transient elastography, with the available gold standard, which is fibrosis stage assessed on a biopsy sample. To minimize the drawbacks of this reference method, histological sections were read blindly using the validated METAVIR scoring system,⁹ and the comparison between both methods was performed in the whole population of patients

Abbreviations: CHC, chronic hepatitis C; LB, liver biopsy; LSM, liver stiffness measurement; ROC, receiver-operating characteristics.

From ¹UPRES EA 3406, University of Paris 13, Bobigny, France, and Department of Pathology, AP-HP, Jean Verdier Hospital, Bondy, France; ²UPRES EA 3409, University of Paris 13, Bobigny, France, and Department of Internal Medicine, AP-HP, Jean Verdier Hospital, Bondy, France; and ³Department of Hepatology and Gastroenterology, AP-HP, Jean Verdier Hospital, Bondy, France, and Department of Digestive Diseases, Institut Mutualiste Montsouris, Paris, France; ⁴Department of Hepatology and Gastroenterology, AP-HP, Jean Verdier Hospital, Bondy, France; ⁵Department of Hepatology and Gastroenterology, Haut Lévêque Hospital, Pessac, France; ⁶Department of Hepatology and INSERM U481, Beaujon Hospital, Clichy, France; ⁷Department of Hepatology and Gastroenterology, AP-HP, Henri Mondor Hospital, Créteil, France; ⁸UPRES EA 3409, University of Paris 13, Bobigny, France, and Department of Hepatology and Gastroenterology, AP-HP, Jean Verdier Hospital, Bondy, France; and ⁹UPRES EA 3410, University of Paris 13, Bobigny, France, and Department of Hepatology and Gastroenterology, AP-HP, Jean Verdier Hospital, Bondy, France.

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Address reprint requests to: Pr. M. Beaugrand, Service d'Hépatogastro-entérologie, Hôpital Jean Verdier, avenue du 14 juillet, 93143 Bondy Cedex, France. E-mail: michel.beaugrand@jvr.ap-hop-paris.fr; fax: (33)1 48 02 62 02.

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