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● *Review*

A META-ANALYSIS FOR THE DIAGNOSTIC PERFORMANCE OF TRANSIENT ELASTOGRAPHY FOR CLINICALLY SIGNIFICANT PORTAL HYPERTENSION

Myung-Won You,* Kyung Won Kim,*† Junhee Pyo,‡ Jimi Huh,* Hyoung Jung Kim,*† So Jung Lee,*† and Seong Ho Park*

*Department of Radiology and Research Institute of Radiology, Asan Medical Center, University of Ulsan College of Medicine, Seoul, Korea; †Asan Liver Center, Asan Medical Center, University of Ulsan College of Medicine, Seoul, Korea; and ‡WHO Collaborating Center for Pharmaceutical Policy and Regulation, Department of Pharmaceutical Science, Utrecht University, Netherlands

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Abstract—We aimed to evaluate the correlation between liver stiffness measurement using transient elastography (TE-LSM) and hepatic venous pressure gradient and the diagnostic performance of TE-LSM in assessing clinically significant portal hypertension through meta-analysis. Eleven studies were included from thorough literature research and selection processes. The summary correlation coefficient was 0.783 (95% confidence interval [CI], 0.737–0.823). Summary sensitivity, specificity and area under the hierarchical summary receiver operating characteristic curve (AUC) were 87.5% (95% CI, 75.8–93.9%), 85.3 % (95% CI, 76.9–90.9%) and 0.9, respectively. The subgroup with low cut-off values of 13.6–18 kPa had better summary estimates (sensitivity 91.2%, specificity 81.3% and partial AUC 0.921) than the subgroup with high cut-off values of 21–25 kPa (sensitivity 71.2%, specificity 90.9% and partial AUC 0.769). In summary, TE-LSM correlated well with hepatic venous pressure gradient and represented good diagnostic performance in diagnosing clinically significant portal hypertension. For use as a sensitive screening tool, we propose using low cut-off values of 13.6–18 kPa in TE-LSM. (E-mail: medimash@gmail.com) **© 2016 World Federation for Ultrasound in Medicine & Biology.**

Key Words: **Transient elastography, Fibroscan, Portal hypertension, Liver stiffness measurement, Chronic liver disease.**

INTRODUCTION

Portal hypertension is an increase in blood pressure in the portal venous system and is a primary consequence of liver fibrosis and cirrhosis. As the severity of portal hypertension increases, it can result in complications such as the development of esophageal varices, variceal bleeding, ascites, spontaneous bacterial peritonitis and hepatorenal syndrome (Bureau et al. 2008). Therefore, it is important to estimate the severity of portal hypertension to ensure appropriate patient management.

Currently, the gold-standard method for estimating portal hypertension is measurement of the hepatic venous pressure gradient (HVPG) by catheterizing the hepatic vein using a balloon-tipped catheter. The HVPG is the gradient between the wedged (*i.e.,* balloon-occluded) hepatic venous pressure and the free hepatic venous pressure and represents pressure from the hepatic sinusoids (Carrion et al. 2006; Colecchia et al. 2012; Hong et al. 2013). In patients with liver cirrhosis with sinusoidal portal hypertension, the inter-sinusodal communications are blocked due to fibrosis, and the hepatic sinusoidal pressure equilibrates with the portal perfusion pressure. A normal range of HVPG is 0–5 mmHg. In general, portal hypertension is subclinical when the HVPG is 6–9 mmHg and becomes clinically significant, resulting in complications, when the HVPG is ≥10 mmHg. Therefore, the term clinically significant portal hypertension (CSPH) is usually defined as a portal pressure gradient ≥10 mmHg, as estimated by HVPG in many reports (Berzigotti et al. 2013; Procopet et al. 2013).

Measurement of HVPG requires a specialized angio-intervention unit. In addition, the invasive nature of the procedure and its high cost render HVPG measurement difficult to routinely perform in every medical

Address correspondence to: Kyung Won Kim, Department of Radiology and Research Institute of Radiology, University of Ulsan College of Medicine, Asan Medical Center, 88 Olympic-ro 43-gil, Songpa-gu, Seoul 138-736, Korea. E-mail: medimash@gmail.com

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center for the purpose of making a diagnosis or providing longitudinal follow up. Therefore, there has been growing interest in developing novel, non-invasive approaches to assess the severity of portal hypertension.

Transient elastography (TE) is an ultrasonography-based technology for liver stiffness measurement (LSM; hereafter referred as to TE-LSM) using the kilopascal scale and allows us to diagnose advanced liver fibrosis and cirrhosis (Augustin et al. 2014; Bureau et al. 2008). Recent studies have demonstrated that TE-LSM is well correlated with HVPG, can be used to estimate the severity of portal hypertension and can diagnose CSPH. Owing to the advantages of TE, including its non-invasiveness and ease of use, TE-LSM has begun to replace HVPG for diagnosing CSPH, at least at our medical institution.

Although several studies have evaluated the correlation of TE-LSM and HVPG and the diagnostic performance of TE-LSM to detect CSPH, the majority were retrospective studies with low-level evidence. There is a previous meta-analysis to examine TE accuracy in the diagnosis of CSPH; however, only five studies were analyzed (Shi et al. 2013). Generating a more evidence-based systematic summary would be of great help for more evidence-based, standardized management of liver cirrhosis patients. For this purpose, we performed this systemic review and meta-analysis to determine the correlation between TE-LSM and HVPG and to evaluate the performance of TE-LSM for the screening and monitoring of CSPH.

MATERIALS AND METHODS

Literature search strategy

A comprehensive search of the PubMed MEDLINE and EMBASE databases was conducted to identify relevant, original publications regarding the correlation between TE-LSM and HVPG measurement and the diagnostic performance of TE-LSM to diagnose CSPH in patients with chronic liver disease. The following search terms were used: (liver cirrhosis OR portal hypertension) AND (elastography) AND (HVPG OR "hepatic vein pressure gradient"). "Liver cirrhosis OR portal hypertension" was intended for the patient group and "elastography and hepatic vein pressure gradient" was intended for the imaging modality and its comparator. The search for bibliographies of included articles was also conducted. No beginning date limit was used. We searched the literature published before 30 August 2014. Our search was restricted to human patients and English-language studies. For management of the searched literature, Endnote version X7 (Thomson Reuters, New York, NY) was used.

Inclusion criteria

Studies investigating the correlation or diagnostic performance of TE for CSPH in patients with chronic liver disease were included. Studies that satisfied all of the following criteria were included: (i) population—patients who were evaluated for chronic liver disease and portal hypertension with both TE and HVPG; (ii) reference standard—CSPH should be defined as HVPG $\geq$10 mmHg; (iii) study designs—all observational studies (retrospective or prospective) and clinical trials that have received approval by an ethics committee or institutional review board; and (iv) outcomes—study results available to extract data such as correlation coefficient regarding the correlation between TE-LSM and HVPG and sensitivity, specificity regarding the diagnostic performance of TE-LSM to diagnose CSPH.

Exclusion criteria

The exclusion criteria were as follows: (i) case reports and case series with the sample size smaller than eight patients; (ii) review articles, editorials, letters, comments and conference proceedings; (iii) studies using imaging tools other than TE for liver stiffness measurement; (iv) studies that did not use HVPG as the reference standard; (v) studies that were not within the field of interest of this study; and (vi) studies with overlapping patients and data. Because CSPH is defined as HVPG $\geq$10 mmHg in this systematic review, we excluded studies which defined CSPH as HVPG $\geq$12 mmHg or other criteria. We included studies that used the transient TE using Fibroscan (EchoSens, Paris, France) and excluded other kinds of elastography, such as real time elastography, shear wave elastography, acoustic radiation force impulse elastography or magnetic resonance (MR) elastography, as TE has been widely used for the evaluation of liver fibrosis and was used in the majority of the included studies. We also excluded the study population with alcoholic hepatitis in the Lemoine et al. (2008) study (n = 48) because most of the included study population had the virus-related chronic liver disease.

Titles and abstracts identified by the search strategy were independently reviewed by two reviewers (K.W.K. and M.W.Y.). For all abstracts that met the inclusion/exclusion criteria or were potentially eligible, full articles were retrieved, independently reviewed and a consensus was reached in cases of discrepancy by the same reviewers.

Data extraction

From the selected studies, we extracted the following data to standardized data forms: (i) study characteristics such as authors, year of publication, hospital or medical school and study design; (ii) demographic and clinical characteristics of the patients (*i.e.,* age, sex, cause

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