Liver stiffness assessed with the help of the propagation map of a latest software for 2D shear wave elastography: preliminary results

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Aims and objectives

In chronic viral hepatitis the stage of liver fibrosis influences patient’s prognosis and survival. The recent availability of interferon-free regimens has allowed the eradication of hepatitis C virus in up to 90% of cases. In this clinical scenario, noninvasive methods for staging liver fibrosis, such as liver fibrosis biomarkers or ultrasound (US) elastography techniques, have been widely accepted also by clinical guidelines [1].

There are three methods for non-invasive assessment of liver fibrosis based on shear waves: vibration controlled transient elastography (VCTE), point shear wave elastography (pSWE) , and 2D shear wave elastography (2D-SWE). VCTE is only available on the FibroScan device (Echosens, France) and a controlled vibrating external ‘punch’ is used to generate shear waves, whereas pSWE and 2D-SWE are available in several US equipment and both use acoustic radiation force impulse technology (ARFI) to generate shear waves [2-4].

In 2D-SWE the map of the shear wave speed, which can be converted into tissue stiffness by using the Young’s modulus, is color-coded and displayed inside a sample box. The value of liver stiffness is obtained by placing an ROI inside the sample box. A 2D-SWE technique has been implemented in the Aplio 500 system (Toshiba, Japan).

The aim of this study was to assess the value of the propagation map of the latest release of the software for 2D-SWE by evaluating the agreement with the results obtained with VCTE, which is the most validated method for noninvasive assessment of liver stiffness.
Methods and materials

Study design

From September 7th to October 9th 2015, consecutive individuals referred to the ultrasound unit of the infectious diseases dept. of our institution for liver stiffness assessment with the FibroScan device, who voluntarily accepted to undergo also 2D-SWE measurement with the Aplio 500 system, were prospectively enrolled. Subject's characteristics were recorded.

The operator (G.F.) performing the liver stiffness measurements (LSMs) with the US system was blinded to the LSMs obtained with the FibroScan device by two independent operators (L.M. and R.L.). The two machines were used in a random order. The study protocol was approved by the institution’s ethics committee and all participants gave their informed written consent.

VCTE measurements

Measurements of liver stiffness were performed on the right lobe of the liver through the intercostal spaces on patients lying in the dorsal decubitus position with the right arm in maximal abduction, following the examination procedure previously described [5]. As reported in the literature, only LSMs with 10 validated measurements and an interquartile range/median ratio (IQR/M) <30% for values higher than 7.1 kPa were considered reliable [6]. The M+ probe of the FibroScan device was used for all examinations.

2D SWE measurements

The color-coded 2D-SWE image of tissue stiffness and the propagation map of the shear waves are displayed inside a sample box over a conventional B-mode image, side by side. A proper propagation is displayed by parallel lines, being the intervals between lines constant. When the lines are distorted and not parallel to each other the reliability of the obtained data is low. LSMs were performed by using the abdominal convex probe. The reliability of the data was verified by observing the propagation map.

The examinations were performed in the right lobe of the liver through intercostal spaces, with the subject lying supine with the right arm in maximal abduction. While breathing normally, the patients were instructed to hold the breath for few seconds during the acquisition.

Protocol for LSMs:

- Sampling of liver segment 7 or 8;
- Sample box positioned at least 1 cm below the Glisson's capsule;
- Clear contour of the liver capsule, preferably displayed as a straight horizontal line;
- Size of the 2D-SWE sample box set at 3x3 cm;
- ROI for the measurement circular and 1 cm in diameter;
- Simultaneous display of the color-coded 2D-SWE image and of the propagation map of the shear wave;
- Continuous mode for pre-confirmation of scanning window and one shot for measurement of tissue stiffness in order to obtain higher image quality;
- Reliability of the data verified by observing the contour lines;
- On the still image the shear velocity measurement was obtained by placing the ROI in the area where the shear waves propagated uniformly (assessed by looking at propagation map) and there were not black spots in the sample box of the color-coded 2D shear wave image;
- Only one measurement for each acquisition.

When no reliable propagation map was obtained in consecutive acquisitions in a period of 10 minutes LSMs were considered failures.

Figure 1 and Figure 2 show reliable propagation maps whereas Figure 3 shows a not reliable propagation map.

The median value of 10 consecutive measurements was used for statistical analysis.

Statistical analysis

Descriptive statistics were produced for demographic characteristics for this study sample of patients.

Agreement between LSMs values obtained with the two systems was assessed with the Lin's concordance correlation coefficient (CCC) [7]. CCC combines measures of both precision and accuracy to determine how far the observed data deviate from the line of perfect concordance (i.e., the line at 45 degrees on a square scatterplot). CCC increases in value as a function of the nearness of the data's reduced major axis to the line of perfect concordance (the accuracy of the data) and of the tightness of the data about its reduced major axis (the precision of the data). CCC ranges in values from 0 to +1. A CCC value of 0 indicates that most of the error originates from differences in measurements between operators. As CCC values approach 1, the measurement differences between the different operators are becoming negligible and more consistent. Inter-observer agreement was classified as poor (0.00 to 0.20), fair (0.21 to 0.40), moderate (0.41 to
0.60), good (0.61-0.80), excellent (0.81 to 1.00) [8]. The CCC was reported with a 95% confidence interval (CI).

The data analysis was performed with the STATA statistical package (release 13.1, 2014, Stata Corporation, College Station, Texas, USA).
Fig. 1: The color-coded 2D-SWE image of tissue stiffness and the propagation map of the shear waves are displayed inside a sample box over a conventional B-mode image, side by side. The lines of the propagation map are parallel to each other and the intervals between them is constant, thus measurement is considered reliable.

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Fig. 2: A proper propagation map obtained in a patient with liver cirrhosis. In stiffer liver the interval between consecutive lines is wider.

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**Fig. 3:** The lines of the propagation map are distorted and not parallel to each other, thus the reliability of the data is considered to be low.

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Results

Sixty-one patients [44 males; 17 females; mean age, 55.7 (12.6) years] were enrolled. Thirty-nine patients were affected by chronic hepatitis C, 10 patients were HIV positive, two patients were HCV/HIV co-infected, one patient had liver cirrhosis of unknown etiology, and the remaining 9 patients received LSMs for other etiologies of liver disease.

Failures occurred in seven cases with the 2D-SWE and in one case with both 2D-SWE and VCTE. The failures with the 2D-SWE were due to the inability of the patient to hold the breath in 5 cases and to poor ultrasound image in 2 cases.

No statistically significant difference was observed between the mean values obtained with the two techniques: 12.4 (SE:1.7) kilopascal with VCTE and 11.1 (SE:1.1) kilopascal with 2D-SWE ($p=0.52$ after log transformation) (Figure 4).

CCC was 0.84 (95% CI: 0.79-0.89). The mean difference between the stiffness values of VCTE and 2D-SWE was 1.3 (95% CI, -9.7 - 12.3) kilopascal. Bland-Altman analysis showed that there was a good agreement between the two methods (Figure 5).
**Fig. 4:** Distribution of the liver stiffness values obtained with the vibration controlled transient elastography (VCTE) technique of the FibroScan device and with the 2D shear wave elastography (2D-SWE) technique of the Apio 500 system. Values are normalized by log-transformation. Violin plots include a marker for the median of the data, a box indicating the interquartile range, and spikes extending to the upper- and lower-adjacent values, as in standard box plots.

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**Fig. 5:** Bland-Altman plot of differences in kilopascal of the liver stiffness values obtained with VCTE and 2D-SWE. The solid line (y=0) is a line of perfect average agreement. The dotted line represents the mean of difference in kilopascal. The dashed lines define the limits of agreement [mean of the differences (2 SD)].

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Conclusion

These preliminary results show that the propagation map of the latest software for 2D shear wave elastography implemented in the Aplio 500 system is a useful tool for the assessment of liver stiffness because it helps in choosing the area of liver parenchyma where measurements are likely more reliable.
References