

X-CUBE 90/70 point Shear-Wave Elastography (pSWE)

Executive Summary

ALPINION study has demonstrated that point Shear-Wave Elastography is a well-set technique for the non-invasive evaluation of liver fibrosis, considering TE as the reference method. Although a limited number of subjects were evaluated at the hospital in this study, liver stiffness measurements were shown to be useful for discriminating different stages of fibrosis. It is important to note that a small number of subjects with intermediate stages of fibrosis were evaluated in this study, and that a mix of disease etiologies were present. Therefore, the values shown may not be directly applicable to other patient populations. data was acquired using X-CUBE 90 equivalent software and the SC1-7H probe. The results are applicable to X-CUBE 90 and 70.

Optimal Cutoff value of pSWE for Liver Fibrosis Staging

Liver Fibrosis Staging	TE Stage	kPa	m/s
Normal – Mild	F1	<5.7kPa	< 1.38m/s
Mild – Moderate	F2	5.7 kPa – 8.03 kPa	1.38 m/s – 1.64 m/s
Moderate – Severe	F3	8.03 kPa – 10.35 kPa	1.64 m/s – 1.86 m/s
Cirrhosis	F4	>10.35 kPa	>1.86 m/s

Recommendations for performing liver stiffness measurements with the X-CUBE 90/70 pSWE Technique

1. Patients should fast at least 4 hours before the examination
2. Measurement should be taken at an intercostal space with the patient in the supine or slight lateral decubitus (30°) position with right arm in extension
3. Measurements should be taken at neutral breathing during a breath hold
4. Measurements should be taken at least 15~20mm below liver capsule in pSWE to avoid the reverberation area
5. Results can be reported in meters per second or in kilopascals
6. X-CUBE 90/70 can scan B-mode images during cooling time after push pulse output. However, pSWE acquisition is not possible during the cooling time
7. The depth at which the shear wave is most strongly induced is 4-4.5cm from the transducer, which is the optimal location for obtaining measurements. The X-CUBE 90/70 systems acoustic push pulses are attenuated with increasing depth, limiting adequate shear wave generation
8. Ten measurements should obtain with pSWE, and the final result should be expressed as the median together with the IQR/M
9. Fewer than 10 measurements with pSWE can be obtained (at least five); however, the IQR/M should be within the recommended range
10. The most important reliability criterion is an IQR/M of $\leq 30\%$ of the 10 measurements (pSWE) for kilopascals and $\leq 15\%$ for measurements in velocity (in meters per second)
11. Adequate B-mode liver imaging is a prerequisite for point shear waves are tracked with B-mode

Note.- IQR/M = interquartile range – to – median ratio, pSWE = point SWE, SWE = Shear-Wave Elastography

Evaluation of the usefulness of point Shear-Wave Elastography for diagnosis of liver fibrosis and validation of cut-off value for each stage of liver fibrosis

Sae-Jin Park, MD

Department of Radiology, Seoul Metropolitan Government - Seoul National University Borame Medical Center, Seoul, Korea

Background

To estimate the validity of the point Shear-Wave Elastography (pSWE) method by evaluating its accuracy for assessing liver stiffness.

Methods

This study included 37 patients who had undergone liver stiffness using FibroScan using Transient Elastography (FibroScan, Echosens). 7 patients with reliability measurement index (RMI) of less than 0.5 and interquartile range/median ratio (IQR / M) of more than 30% were excluded. So, total patients were 30 (Table 1). Measurement of the liver stiffness from pSWE using the X-CUBE 90 (Alpinion Medical Systems) was performed (Figure 1). The performance of pSWE was compared to that of FibroScan as a reference standard. Receiver operating characteristic curve analyses were performed to calculate the area under the receiver operating characteristic curve (AUC) for $F \geq 2$, $F \geq 3$ and $F = 4$.



Figure 1. ALPINION MEDICAL SYSTEMS X-CUBE 90/70 Ultrasound Machine

© http://www.alpinion.com/en/product/product_list_ultra.do

Table 1. Demographics of study population

	Total (n = 30)
Sex (Male: Female)	17: 13
Age (years) *	54.3 ± 14
Etiology of liver disease (%)	
Hepatitis B	9 (30)
Hepatitis C	6 (20)
Alcohol	2 (6.7)
Autoimmune hepatitis	1 (3.3)
NBNC	1 (3.3)
NASH	11 (36.7)
Grade of fibrosis (%) (FibroScan)	
F1	17 (56.7)
F2	6 (20)
F3	3 (10)
F4	4 (13.3)
Liver stiffness, kPa * (pSWE)	7.47 ± 5.87

Note. – NBNC = non-B non-C, NASH = Non-Alcoholic Steato-Hepatitis, pSWE = point Shear-Wave Elastography

* mean ± standard deviation

- Numbers in parentheses mean percentages

Results

Liver stiffness at the F1, F2, F3, and F4 stages were 4.6, 7.2, 10, and 14.8 kPa, respectively (P<0.001) (Table 2, Figure 2). The liver stiffness value could distinguish significant fibrosis (F ≥ 2) with an AUC of 0.99 (cutoff value, 5.7 kPa, P<0.001), severe fibrosis (F ≥ 3) with an AUC of 1.00 (cutoff value, 8.03 kPa, P<0.001), and liver cirrhosis (F = 4) with an AUC of 1.00 (cutoff value, 10.35 kPa, P<0.001) (Table 3).

Table 2. Median liver stiffness values in fibrosis stage

	Total (n = 30)				P-value
	F1 (n = 17)	F2 (n = 6)	F3 (n = 3)	F4 (n = 4)	
Liver stiffness, kPa (IQR)	4.6 (4.4-5.4)	7.2 (6.0-7.6)	10 (9.3-10.3)	14.8 (11.8-25)	< 0.001

IQR: interquartile range

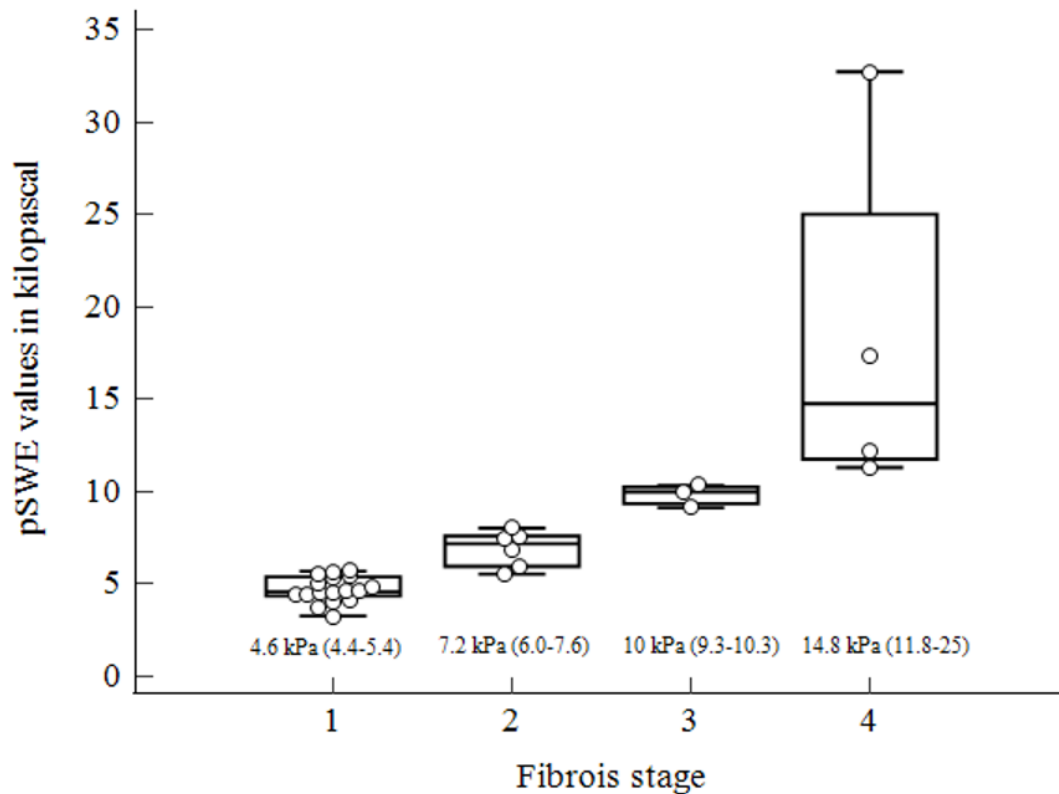


Figure 2. Distribution of stiffness values according to fibrosis stage. Median values, interquartile ranges, ranges, and numbers of outliers are given for each fibrosis stage. point Shear-Wave Elastography (pSWE).

Table 3. Diagnostic performance of pSWE for liver fibrosis

Stage	Cutoff	AUC (95% CI)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	P-value*
F≥2	>5.7	0.99 (0.868-1.00)	92.3	100	100	94.4	< 0.001
F≥3	>8.03	1.00 (0.884-1.00)	100	100	100	100	<0.001
F=4	>10.35	1.00 (0.884-1.00)	100	100	100	100	<0.001

Diagnostic accuracy of each variable in association with fibrosis stage. The performance of the selected best cutoff values was indicated. AUC=the area under the receiver operating curve; PPV, positive predictive value; NPV, Negative predictive value; *Determined using receiver operating characteristic curve analysis.

Conclusion

The liver stiffness values on pSWE can provide excellent diagnostic performance in evaluating the fibrosis stage in various liver diseases.

References

[1] The EFSUMB Guidelines and Recommendations for the Clinical Practice of Elastography in Non-Hepatic Applications: Update 2018: Adrian Săftoiu, Odd Helge Gilja, Paul S Sidhu, Christoph F Dietrich, Vito Cantisani, Dominique Amy, Michael Bachmann-Nielsen, Flaviu Bob, Jörg Bojunga, Marko Brock, Fabrizio Calliada, Dirk André Clevert, Jean-Michel Correas, Mirko D'Onofrio, Caroline Ewertsen, André Farrokh, Daniela Fodor, Pietro Fusaroli, Roald Flesland Havre, Michael Hocke, André Ignee, Christian Jenssen, Andrea Sabine Klauser, Christian Kollmann, Maija Radzina, Kumar V Ramnarine, Luca Maria Sconfienza, Carolina Solomon, Ioan Sporea, Horia Ștefănescu, Mickael Tanter, Peter Vilmann. *Ultraschall Med* 2019 Aug;40(4):425-453

[2] Update to the Society of Radiologists in Ultrasound Liver Elastography Consensus Statement Richard G. Barr, MD, PhD • Stephanie R. Wilson, MD • Deborah Rubens, MD • Guadalupe Garcia-Tsao, MD • Giovanna Ferraioli, MD. *Radiology* 2020; 296:263–274