EFSUMB Elastography guidelines

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Why Guidelines?

- **The objective of a Guideline of Elastography, is *to describes the characteristics of each technique and each device*, based on the latest knowledge, and *to teach users to be able to make the correct diagnosis of stiffness in different organs*, using ultrasound elastography**.

Who must produce Guidelines?

- International Societies (World or Continental Societies, like WFUMB or EFSUMB) or National Societies or maybe groups with extensive experience in this field!

Why so many Guidelines?

- “Guidelines must provide **the latest knowledge and understanding of elastographic devices**, particularly those widely used for the diagnosis of liver fibrosis”.
- In this field, that is very new and dynamic, **the news come very quick**!

Published Guidelines that include Liver Elastography

- **EFSUMB Guideline**
- **Japanese Guideline**
- **Romanian Guideline**
- **RSNA Guideline**
- **EASL Guideline**
- **WFUMB Guideline**
- **AGA Guideline**
- **New EFSUMB Guideline 2017**
- **WFUMB Guideline 2018-*submitted paper***

EFSUMB Guideline on Elastography

- **Ultraschall in Med (EJU) 2013**; 34: 169–184
- DOI http://dx.doi.org/10.1055/s-0033-1335205

- **EFSUMB Guidelines and Recommendations on the Clinical Use of Ultrasound Elastography**

  Part 1: Basic Principles and Technology

J. Bamber, D. Cosgrove, C. F. Dietrich, J. Fromageau, J. Bojunga, F. Calliada, V. Cantisani, J.-M. Correas, M. D'Onofrio, E. E. Drakonaki, M. Fink, M. Friedrich-Rust, O. H. Gilja, R. F. Havre, C. Jenssen, A. S. Klauser, R. Ohlinger, A. Saftoiu, F. Schaefer, **I. Sporea**, F. Piscaglia

EFSUMB Guidelines

- **Ultraschall Med. (EJU) 2013** Jun;34(3):238-53.
- doi: 10.1055/s-0033-1335375. Epub 2013 Apr 19

- **EFSUMB guidelines and recommendations on clinical use of ullrasound elastography.**

Part 2: Clinical applications

- Cosgrove D, Piscaglia F, Bamber J, Bojunga J, Correas JM, Gilja OH, Klauser AS, **Sporea I**, Calliada F, Cantisani V, D'Onofrio M, Drakonaki EE, Fink M, Friedrich-Rust M, Fromageau J, Havre RF, Jenssen C, Ohlinger R, Săftoiu A, Schaefer F, Dietrich CF

EFSUMB Guidelines

- This Guidelines look **in the first part** to the **physical aspects of Elastography**, to the **types of elastography (*strain and shear waves elastography-SWE*).**
- **Second part** look to the use of Elastography **for different organs** and pathologies: **liver, breast, prostate, lymph nodes, pancreas (EUS), digestive tube and muskulo-skeletal**.

Japanese Guideline

- J Med Ultrasonics (**2013**) 40:325–357
- DOI 10.1007/s10396-013-0460-5

- **JSUM ultrasound elastography practice guidelines: liver**

- Masatoshi Kudo • Tsuyoshi Shiina • Fuminori Moriyasu • Hiroko Iijima •
- Ryosuke Tateishi • Norihisa Yada • Kenji Fujimoto • Hiroyasu Morikawa •
- Masashi Hirooka • Yasukiyo Sumino • Takashi Kumada

Romanian National Guidelines

- **Med Ultrason 2014,** *2, 123-138*
- DOI: 10.11152/mu.2013.2066.162.is1sb2

- **Romanian National Guidelines and Practical Recommendations on Liver Elastography**

- **I. Sporea**, Simona Bota, A. Săftoiu, Roxana Șirli, Oana Grădinaru-Taşcău, Alina Popescu, Monica Lupşor Platon, Carmen Fierbinţeanu-Braticevici, D. I. Gheonea, Larisa Săndulescu, R. Badea

- ***Under the auspices of Romanian Society of Ultrasound in Medicine and Biology (SRUMB)***

Society of Radiologists in Ultrasound Consensus Conference Statement

Elastography Assessment of Liver Fibrosis: Society of Radiologists in Ultrasound Consensus Conference Statement[1]

Richard G. Barr, MD, PhD
Giovanna Ferraioli, MD
Mark L. Palmeri, MD, PhD
Zachary D. Goodman, MD, PhD
Guadalupe Garcia-Tsao, MD
Jonathan Rubin, MD, PhD
Brian Garra, MD
Robert P. Myers, MD, MSc
Stephanie R. Wilson, MD
Deborah Rubens, MD
Deborah Levine, MD

The Society of Radiologists in Ultrasound convened a panel of specialists from radiology, hepatology, pathology, and basic science and physics to arrive at a consensus regarding the use of elastography in the assessment of liver fibrosis in chronic liver disease. The panel met in Denver, Colo, on October 21–22, 2014, and drafted this consensus statement. The recommendations in this statement are based on analysis of current literature and common practice strategies and are thought to represent a reasonable approach to the noninvasive assessment of diffuse liver fibrosis.

©RSNA, 2015

Radiology 2015; 276:845-61

EASL Guideline [Castera L, et al. EASL-ALEH Clinical Practice Guidelines: Non-invasive tests for evaluation of liver disease severity and prognosis. European Association for Study of Liver; Asociacion Latinoamericana para el Estudio del Higado. J Hepatol. 2015 Jul;63(1):237-264]

Serum biomarkers	Measurement of liver stiffness			
	Transient elastography	ARFI (pSWE)	2D-SWE	MR elastography
Advantages				
• Good reproducibility • High applicability (95%) • No cost and wide availability (non-patented) • Well validated • Can be performed in the outpatient clinic	• Most widely used and validated technique: standard to be beaten • User-friendly (performed at bedside; rapid, easy to learn) • High range of values (2-75 kPa) • Quality criteria well defined • Good reproducibility • High performance for cirrhosis (AUROC >0.9) • Prognostic value in cirrhosis	• Can be implemented on a regular US machine • ROI smaller than TE but location chosen by the operator • Higher applicability than TE (ascites and obesity) • Performance equivalent to that of TE for significant fibrosis and cirrhosis	• Can be implemented on a regular US machine • ROI can be adjusted in size and location and chosen by the operator • Measures liver stiffness in real-time • High range of values (2-150 kPa) • Good applicability • High performance for cirrhosis	• Can be implemented on a regular MRI machine • Examination of the whole liver • Higher applicability than TE (ascites and obesity) • High performance for cirrhosis
Disadvantages				
• Non-specific of the liver • Unable to discriminate between intermediate stages of fibrosis • Performance not as good as TE for cirrhosis • Cost and limited availability (proprietary) • Limitations (hemolysis, Gilbert syndrome, inflammation…)	• Requires a dedicated device • ROI cannot be chosen • Unable to discriminate between intermediate stages of fibrosis • Applicability (80%) lower than serum biomarker: (obesity, ascites, operator experience) • False positive in case of acute hepatitis, extra-hepatic cholestasis, liver congestion, food intake and excessive alcohol intake	• Unable to discriminate between intermediate stages of fibrosis • Units (m/sec) different from that of TE (kPa) • Narrow range of values • (0.5-4.4 m/sec) • Quality criteria not well defined • Prognostic value in cirrhosis?	• Further validation warranted • Unable to discriminate between intermediate stages of fibrosis • Quality criteria not well defined • Learning curve? • Influence of inflammation?	• Further validation warranted especially in comparison with TE • Not applicable in case of iron overload • Requires a MRI facility • Time-consuming • Costly

WFUMB (World Federation on Ultrasound in Medicine and Biology) Guidelines -2015

- **WFUMB guidelines and recommendations for clinical use of ultrasound elastography: Part 1: basic principles and terminology**

Shiina T, Nightingale KR, Palmeri ML, Hall TJ, Bamber JC, Barr RG, Castera L, Choi BI, Chou YH, Cosgrove D, Dietrich CF, Ding H, Amy D, Farrokh A, Ferraioli G, Filice C, Friedrich-Rust M, Nakashima K, Schafer F, **Sporea I**, Suzuki S, Wilson S, Kudo M.

Ultrasound Med Biol. 2015 May;41(5):1126-47

- **WFUMB guidelines and recommendations for clinical use of ultrasound elastography: Part 2: breast**

Barr RG, Nakashima K, Amy D, Cosgrove D, Farrokh A, Schafer F, Bamber JC, Castera L, Choi BI, Chou YH, Dietrich CF, Ding H, Ferraioli G, Filice C, Friedrich-Rust M, Hall TJ, Nightingale KR, Palmeri ML, Shiina T, Suzuki S, **Sporea I**, Wilson S, Kudo M.

Ultrasound Med Biol. 2015 May;41(5):1148-60

- **WFUMB guidelines and recommendations for clinical use of ultrasound elastography: Part 3: liver**

Ferraioli G, Filice C, Castera L, Choi BI, **Sporea I**, Wilson SR, Cosgrove D, Dietrich CF, Amy D, Bamber JC, Barr R, Chou YH, Ding H, Farrokh A, Friedrich-Rust M, Hall TJ, Nakashima K, Nightingale KR, Palmeri ML, Schafer F, Shiina T, Suzuki S, Kudo M.

Ultrasound Med Biol. 2015 May;41(5):1161-79

AGA Guideline

- Lim J, Flamm S, Singh S, Falck-Ytter Y T and the Clinical Guidelines Committee of AGA:
- **American Gastroenterological Association Institute Guideline on the Role of Elastography in the Evaluation of Liver Fibrosis.**
- Gastroenterology 2017;152:1536-1543

- ***Focused on Transient Elastography!***

New EFSUMB Guideline - 2017

- **EFSUMB Guidelines and Recommendations on the Clinical Use of Liver Ultrasound Elastography, update 2017 (short version, long version)**
- Christoph F Dietrich, Jeffrey Bamber, Annalisa Berzigotti, Simona Bota, Vito Cantisani, Laurent Castera, David Cosgrove, Giovanna Ferraioli, Mireen Friedrich-Rust, Victor de Ledinghen, Robert J. de Knegt, Odd Helge Gilja, Rüdiger Stephan Görtz, Thomas Karlas, Fabio Piscaglia, Bogdan Procopet, Adrian Saftoiu, Paul S. Sidhu, **Ioan Sporea**, Maja Thiele

- ***Ultraschall Med. 2017 ; 38: 349-372***
- *doi: 10.1055/s-0043-103952*

New EFSUMB Guideline - 2017

- ***Cover all Shear Wave Elastographic (SWE) methods : Transient Elastography, point SWE and Real Time (2-D) SWE.***
- ***Show that Strain liver elastography is not ready for daily practice.***
- **Make very practical recommendations about how to use ultrasound based liver elastography!**

1. Dietrich CF, Bamber J, Berzigotti A et al: EFSUMB Guidelines and Recommendations on the Clinical Use of Liver Ultrasound Elastography, update 2017. *Ultraschall Med. 2017; 38: 349-372.*

Ultrasound based Liver Elastography can be devided:

1. Shear Waves Elastography:

a) Transient Elastography-TE (FibroScan)

b) Point Shear wave- pSWE [using Acoustic Radiation Force Impulse Quantification (ARFI): VTQ (Siemens), **Elast PQ** (Phillips), Hitachi, Esaote]

c) Real Time Shear Wave Elastography- 2D SWE [SuperSonic Imaging Elastography (SSI) (Aixplorer) GE, Toshiba, Philips]

2. Strain Elastography (RTE)

Elastography training

- **RECOMMENDATION 1**
- The ***operator must acquire appropriate knowledge and training in ultrasound elastography*** (LoE 5, GoRC). Strong consensus (13/0/0, 100%)

- **RECOMMENDATION 2**
- Data acquisition should be undertaken by ***dedicated and specially trained personnel***. For ***pSWE and 2D-SWE, experience in B-mode ultrasound is mandatory*** (LoE 5, GoR C). Strong consensus (13/0/0, 100%)

Examination technique

RECOMMENDATION 3

Measurement of liver stiffness by SWE should be performed through a right intercostal space in supine position, with the right arm in extension, during breath hold, avoiding deep inspiration prior to the breath hold (LoE 2b, GoR B). Strong consensus (18/0/0, 100%)

RECOMMENDATION 4

Measurement of liver stiffness by SWE should be performed by experienced operators (LoE 2b, GoR B). Strong consensus (18/0/0, 100%)

RECOMMENDATION 5

Measurement of liver stiffness by pSWE and 2D-SWE should be performed at least 10 mm below the liver capsule (LoE 1b, GoR A) . Strong consensus (18/0/0, 100%)

Confounding factors

- **RECOMMENDATION 6**
- ***Patients should fast for a minimum of 2 hours and rest for a minimum of 10 minutes before undergoing liver stiffness measurement with SWE*** (LoE 2b, GoR B). Majority consensus (13/2/3, 72%)
- **RECOMMENDATION 7**
- The ***major potential confounding factors (liver inflammation indicated by AST and/or ALT elevation >5 times the normal limits, obstructive cholestasis, liver congestion, acute hepatitis and infiltrative liver diseases) should be excluded*** before performing LSM with SWE, in order **to avoid overestimation of liver fibrosis** (LoE 2b, GoR B), and/or should be considered when interpreting the SWE results (LoE 1b, GoR B). Broad consensus (15/0/1, 94%)

Technical aspects for SWE

- **RECOMMENDATION 8**
- ***SWE within the normal range can rule out significant liver fibrosis*** when in agreement with the clinical and laboratory background (LoE 2A, GoR B). Broad consensus (17/ 0/1, 94%)

Transient Elastography

- **RECOMMENDATION 9**
- ***10 measurements should be obtained. An IQR/M≤30% of the 10 measurements is the most important reliability criterion*** (LoE 1b, GoR A). Strong consensus (17/0/0, 100%)

- **RECOMMENDATION 10**
- ***Values obtained with the XL probe are usually lower than with the M probe***. Therefore, no recommendation on the cut-offs to be used can be given (LoE 2B, GoR B). Broad consensus (13/1/3, 77%)

Point and 2D-SWE

- **RECOMMENDATION 11**
- ***Adequate B-mode liver image is a prerequisite for pSWE and 2D-SWE measurements*** (LoE 5, GoR D). Strong consensus (18/0/0, 100%)
- **RECOMMENDATION 12**
- ***The median value of at least 10 measurements should be used for liver elastography by pSWE*** (LoE 2b, GoR B). Strong consensus (18/0/0, 100%)
- **RECOMMENDATION 13**
- For ***2D-SWE a minimum of three measurements should be obtained; the final result should be expressed as the median together with the interquartile range*** (LoE 2b, GoR B). Strong consensus (18/0/0, 100%)

Strain Elastography

- **RECOMMENDATION 14**
- ***Methods to objectively assess strain are being developed, but currently cannot be recommended in clinical practice*** (LoE 5, GoR D). (Consensus 18/0/0, 100%).

Examination

- **RECOMMENDATION 15**
- The ***results with the lowest variability in comparing different pSWE or 2D-SWE systems were obtained at a depth of 4– 5 cm from the transducers*** (with convex transducers) (LoE 4, GoR C). ***Accordingly, this location is recommended if it is technically suitable***. Broad consensus (17/0/1, 94%)

HCV chronic infection

- **RECOMMENDATION 16**
- ***TE can be used as the first-line assessment for the severity of liver fibrosis in patients with chronic viral hepatitis C. It performs best with regard to the ruling out of cirrhosis*** (LoE 1b, GoR A). Broad consensus (17/0/1, 94%)

- **RECOMMENDATION 17**
- ***pSWE as demonstrated with VTQ® can be used as the first-line assessment for the severity of liver fibrosis in patients with chronic viral hepatitis C. It performs best with regard to the ruling out of cirrhosis*** (LoE 2a, GoR B). Broad consensus (17/0/1, 94%)

- **RECOMMENDATION 18**
- ***2D-SWE as demonstrated with SSI can be used as a first-line assessment for the severity of liver fibrosis in patients with chronic viral hepatitis C. It performs best with regard to the ruling out of cirrhosis*** (LoE 1b, GoR A). Broad consensus (17/0/1, 94%)

HCV patients follow up

- **RECOMMENDATION 19**
- ***SWE is not recommended to monitor fibrosis changes during anti-HCV treatment*** (LoE 3, GOR D). Strong consensus (18/0/0, 100%)
- **RECOMMENDATION 20**
- ***LSM changes after successful anti-HCV treatment should not affect the management strategy (e.g. surveillance for HCC occurrence in patients at risk)*** (LoE 3, GOR D). Broad consensus (16/0/1, 94%)

HBV patients: TE

- **RECOMMENDATION 21**
- ***TE is useful in patients with CHB to identify those with cirrhosis. Concomitant assessment of transaminases is required to exclude flare up (elevation >5 times upper limit of normal).*** (LoE 1b, GoR A). Broad consensus (17/1/0, 94%)
- **RECOMMENDATION 22**
- ***TE is useful in inactive HBV carriers to rule out fibrosis*** (LoE 2, GOR B). Strong consensus (18/0/0, 100%)

HBV patients (point and 2D-SWE)

- **RECOMMENDATION 23**
- ***pSWE as demonstrated with VTQ® is useful in patients with CHB to identify those with cirrhosis*** (LoE 2a, GoR B). Strong consensus (18/0/0, 100%)
- **RECOMMENDATION 24**
- ***2D-SWE as demonstrated with SSI is useful in patients with CHB to identify those with cirrhosis*** (LoE 3a, GoR C). Broad consensus (17/0/1, 94%)

HBV patients follow up

- **RECOMMENDATION 25**
- **LSM changes under HBV treatment should not affect the management strategy (e.g. surveillance for HCC occurrence in patients at risk)** (LoE 2b, GOR B). Strong consensus (16/0/0, 100%)

NAFLD patients: TE

- **RECOMMENDATION 26**
- **TE can be used to exclude cirrhosis in NAFLD patients** (LoE 2a, GoR B). Broad consensus (13/0/3, 81%)

Alcoholic Liver Disease: TE

- **RECOMMENDATION 27**
- **TE can be used to exclude cirrhosis in patients with alcoholic liver disease, *provided that acute alcoholic hepatitis is not present*** (LoE2b,GoRB).Strongconsensus (15/0/0, 100%)

Portal Hypertension

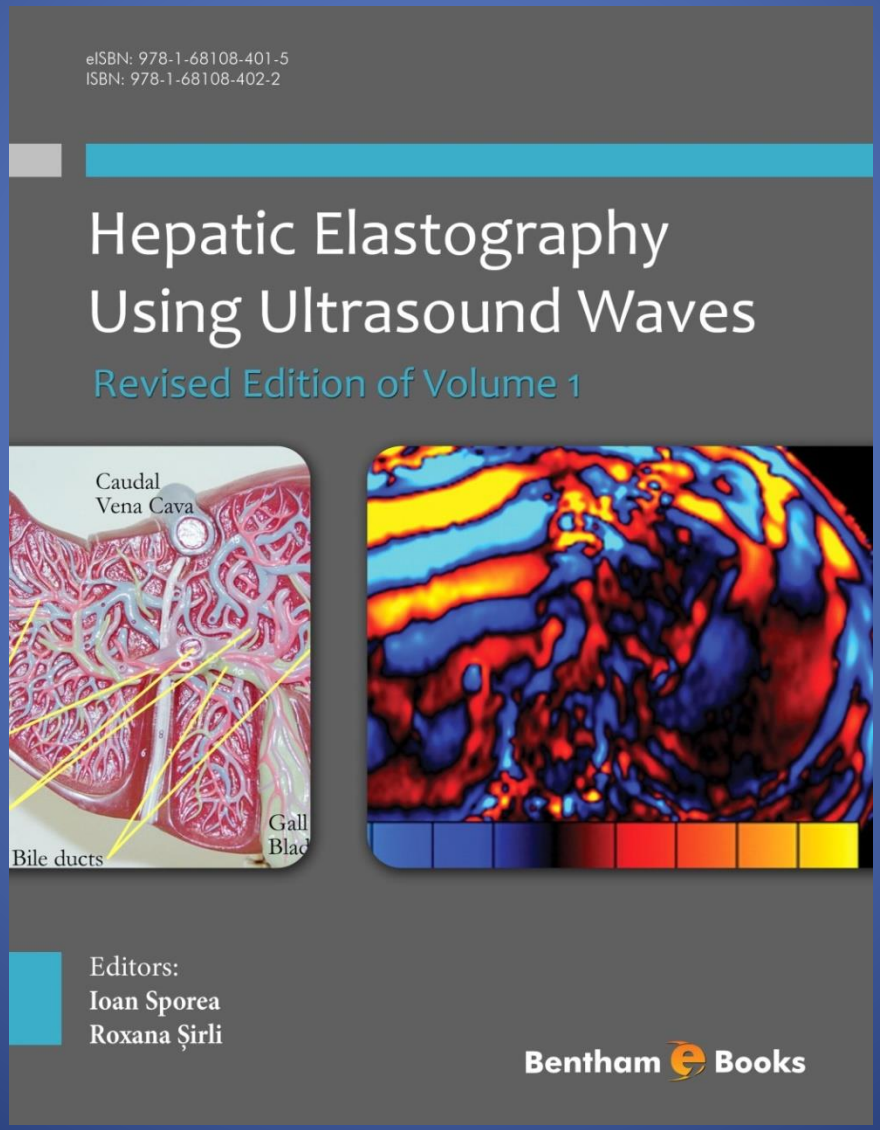
- **RECOMMENDATION 28**
- ***LSM with T is useful to identify patients with a high likelihood of having clinically significant portal hypertension (HVPG ≥10mmHg)*** (LoE 2b, GoR B). Strong consensus (15/0/0, 100%)
- **RECOMMENDATION 29**
- ***Liver stiffness using TE combined with platelet count is useful to rule out varices requiring treatment*** (LoE 2b, GoR B). **Although preliminary results are encouraging, there is insufficient evidence to recommend pSWE and 2D-SWE in this setting**. Broad consensus (13/0/1, 93%)

CONCLUSIONS

- **In conclusion, the body of evidence regarding the value of elastographic methods for liver fibrosis evaluation is large enough *to enable their use in daily hepatological activity*.**
- **The new EFSUMB Guidelines on Liver Elastography 2017 (1), support this reality.**

1. 1. Dietrich CF, Bamber J, Berzigotti A et al: EFSUMB Guidelines and Recommendations on the Clinical Use of Liver Ultrasound Elastography, update 2017. *Ultraschall Med. 2017; 38: 349-372.*

E-book on Liver Elastography, *revised Edition*, was published recentely (**free download**): http://ebooks.benthamscience.com/book/9781681084015





18th World Federation for Ultrasound in Medicine and Biology Congress

MAY 26-29, 2021
Timisoara, Romania

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