

a series of articles written by medical professionals about the management and treatment of hepatitis C

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## Use of FibroScan® in Clinical Practice

The FibroScan® is a non invasive modality which measures fibrosis of the liver by assessing parenchymal (tissue) stiffness. It has been evaluated in more than 400 peer-reviewed articles in most types of liver disease [1-12]. In April 2013, the Food and Drug Administration approved its use in the U.S., stating "FibroScan® is indicated for the measurement of shear wave speed in the liver. The shear wave speed may be used as an aid to clinical management of patients with liver disease."

FibroScan® is a painless, rapid test (about 15 minutes) which can be used to classify patients in terms of the severity of their liver fibrosis.

The "shear waves" created by the FibroScan® 502 machine measure the elasticity of the liver using a technique called Vibration-Controlled Transient Elastography (VCTE™). The measurement unit is the kPa (kilopascals): the higher the number, the more advanced is

the liver fibrosis. It is important to recognize that the stiffness levels vary according to the type of liver disease. For example, the cutoff for cirrhosis is lower in hepatitis C (HCV) and higher for alcoholic liver disease (ALD), as noted in the tables below.

*FibroScan® is a painless, rapid test (about 15 minutes) which can be used to classify patients in terms of the severity of their liver fibrosis.*

Liver biopsy has long been the gold standard to stage fibrosis in the liver. The disadvantages of biopsy are:

1. It is an invasive test,
2. It requires the patient to be hospitalized for half a day,
3. It is expensive (\$3,000),
4. It is associated with

certain risks, such as pain (20%) and bleeding (1%) which often require hospitalization

5. Death has been reported in 1/10,000 biopsies.

6. In addition, a liver biopsy samples only a very small piece of the liver, which can lead to incorrect staging if this sample is not representative of the rest of the liver. Thus,

[www.hcvadvocate.org](http://www.hcvadvocate.org)

liver biopsy can lead to sampling error, which may result in understaging of fibrosis; sampling error may occur in up to 25-30% of liver biopsies. Another limitation of liver biopsy is that different pathologists can interpret the same sample differently, which can result in discrepancies in liver disease staging.

*FibroScan® offers several advantages compared to liver biopsy:*

1. FibroScan® is a noninvasive test, it can be performed at the point of care,
2. There is no pain, and sedation is not required.
3. The test takes only 15 minutes to perform
4. It is significantly less expensive than liver biopsy
5. It hasn't been associated with any side effects.

6. The results of the test are instantaneous, so clinicians can use them to make decisions during patients' visits.

*However, FibroScan® does have some limitations:*

1. It is not as accurate as needle biopsy for those with mid-level liver disease.
2. It is not advised for patients with ascites, and/or morbid obesity.

The references below represent the most authoritative publications (including meta-analysis) on the performance of FibroScan® compared to other modalities [1-12]. The following have endorsed the use of FibroScan®:

- The FDA approved this technique in 2013
- Dr. Kurt J. Isselbacher, former Editor-in-chief of the New England Journal of Medicine: "FibroScan® has the potential to revolutionize

the care of patients with chronic liver disease by improving the management of their disease and lowering the cost of their care."

- AbbVie as well as other pharmaceutical companies use FibroScan® in their HCV clinical trials to stratify patients with different fibrosis stages
- NIH: "Elastography represents a significant step forward in attempting to overcome some of the deficiencies associated with needle liver biopsy" [13]

**Recommendations for the use of FibroScan®:**

References are in [ ]; HCV= Hepatitis C; HBV=Hepatitis B; NPV=Negative predictive value; PPV=Positive predictive value; US=ultrasound; AFP=Alfafetoprotein; F=fibrosis stage; HTN=hypertension

**Hepatitis C (HCV)**

Stiffness	Indicates	Advice
>12.9 [1,4]	Cirrhosis NPV=95%	US and AFP every 6 months for surveillance of Liver cancer. Strongly consider HCV therapy
≥9.6 [2]	Advanced fibrosis ≥F2	Strongly consider HCV therapy
<7.1 [2]	Lower level of fibrosis <F2 PPV >90%	Consider HCV therapy vs. observation

### Hepatitis B (HBV)

Stiffness	Indicates	Advice
>12.9 [3,4]	Cirrhosis NPV=94%	US and AFP every 6 months for surveillance of Liver cancer. Strongly consider HBV therapy
≥7.3 [5]	≥ F2 PPV=94%	Strongly consider HBV therapy
5.3-7.2	Lower level of fibrosis	Observation if low HBV viremia. Repeat FibroScan® in 1 year
<5.3 [5]	< F2 NPV=83%	Observation if low HBV viremia

### Non alcoholic fatty Liver (NAFLD)

Stiffness	Indicates	Advice
>10.2 [6]	Cirrhosis NPV=99%	Refer to Hepatology. US and AFP every 6 months for surveillance of Liver cancer
≥ 7.9 [7]	≥ F3 PV=97%	Refer to Hepatology, may need therapy (e.g. Vitamin E) or enter clinical trial
6-7.8	F2	May observe in primary care. Repeat FibroScan® in 1 year
<6	Lower level of fibrosis	Observe in primary care. Diet and exercise. Diabetes and hyperlipidemia control

### Alcoholic liver disease (ALD)

Stiffness	Indicates	Advice
>18.7 [8,9]	Cirrhosis PPV=90%	US and AFP every 6 months for surveillance of Liver cancer. Stop all alcohol
12.7-18.7 [8,9]	≥F3 Advanced fibrosis PPV=92%	Stop all alcohol. Consider US and AFP every 12 months for surveillance of Liver cancer
>8.2-12.6	≥F2 Advanced fibrosis PPV=100%	Stop all alcohol

### Any Cirrhosis

Stiffness	Indicates	Advice
<18 kPa [10]	Cirrhosis	Very low chance of complications due to portal HTN (6%)
≥18 kPa	Advanced cirrhosis	High chance of complications due to portal HTN (40-50%): recommend endoscopy to detect esophageal varices

## References

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The Mission of the Hepatitis C Support Project is to offer support to those who are affected by the hepatitis C Virus (HCV), hepatitis B Virus (HBV) and HCV coinfections. Support is provided broadly, through information and education, as well as access to support groups. The Project seeks to serve the HCV community as well as the general public.

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