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Beyond Biopsy: The Cost Benefits of ShearWave Elastography for Liver Diagnosis

By Aymeric Guibal, MD, PhD

Biopsy is currently the chief modality for assessing the stages of progressive liver disease. Liver biopsies are expensive, invasive procedures with distinct sampling limitations; they carry a non-negligible morbidity rate and are associated with rare but potentially lethal complications. These drawbacks have led researchers to develop non-invasive alternatives for evaluating the liver, including combining B-mode images with real-time Shear-Wave™ Elastography (SWE™) to discover the extent and stiffness of liver lesions. With one billion people worldwide suffering from hepatitis B virus (HBV) and nearly 300 million with the hepatitis C virus (HCV), plus a steady rise in fatty liver and alcoholism remaining a significant health issue globally, the impact of this non-invasive method in assessing the liver cannot be overstated.

Recent studies have assessed the applications, effectiveness, and advantages of this new technology with convincing results.^{1–3} While the benefits for patients are becoming better established with each study, the broader economic context of these findings is worth investigating. User independent, non-invasive, and quantifiable, a technique such as SWE is achieving excellent diagnostic sensitivity and specificity while minimizing the number of biopsies and related complications.

SWE has advantages that improves patients' health outcomes and yields substantial savings to healthcare providers.

First, it provides a real-time image of liver stiffness and is used to non-invasively assess the liver. The technology has been demonstrated to reduce the costs and complications of biopsies (including infection, damage to viscera, and hemorrhaging) and repeat biopsies during treatment follow up. These efficiencies also improve physician workflow and patient throughput.

Second, if a biopsy is necessary, SWE helps to overcome sampling errors. As SWE is able to survey a large region of the liver in real time on a color coded map of stiffness, the physician can use this information to guide the biopsy, rendering an accurate sampling of the disease progression.

Costly Complications of Liver Biopsy

While the most common adverse effect of liver biopsy procedures is pain, the most harmful complication is excessive bleeding. Intraperitoneal hemorrhage is the worst form of post-procedure bleeding, but less severe instances can also necessitate additional attention and care. Significant bleeding after a liver biopsy occurs in 1–2% of patients who are biopsied and this can sometimes lead to a blood transfusion or even surgery. Overall, between 2–3% of liver biopsied patients are hospitalized due to an adverse event.⁴

The costs of managing these complications are significant. The median direct

cost of hospitalization for complications from biopsy procedures is \$4579, with some cases reaching as high as \$29,641.⁵

While the morbidity rate for liver biopsy is non-negligible, the rate of fatal complications is considered acceptable for the procedure. (These complications have been reported in up to 0.01–0.3% of biopsied patients.) With a non-invasive method, these risks are entirely mitigated. It is widely accepted that non-invasive diagnostic tools for assessing liver disease leads to better patient outcomes and better clinical management. Avoiding the complications of an invasive liver biopsy also leads to major economic savings by avoiding any possible hospitalization fees and patient complications.

Sampling Limitations

There is great debate about the optimal number and size of liver biopsies needed to obtain an accurate reading and many experts have concluded that further study is needed.^{6–8} Errors of diagnosis can arise from the location of the sample as well as from an insufficient sample size. According to the *American Association for the Study of Liver Diseases*, “in nearly all liver diseases, parenchymal abnormalities are irregularly distributed, and sampling variability is almost inevitable.”⁵

An average liver biopsy costs between \$1000 and \$3000 to perform and therefore the combined costs of a liver biopsy plus any additional necessary sampling

in the industry

can be substantial.⁸ Further, these follow-up procedures (particularly if a second or third biopsy is indicated) run up the risk of adverse effects each time. In this light, gains to be had from improving diagnostic accuracy and those from minimizing complications are equally meaningful. Extrapolating those gains to situations where a patient may have multiple conditions, or where the treatment requires multiple biopsies (eg, fibrosis monitoring or assessing therapeutic progress), makes the strategic adoption of a non-invasive alternative to liver biopsy even more compelling.

The Technology

SWE offers both real time measurement of tissue stiffness and a color coded visual map of stiffness. This easy to use technology was developed in 2009 and has since been integrated into a complete ultrasound system. The system leverages technology to evaluate tissue elasticity for entire regions of interest. This result is displayed in a 2D color coded image superimposed over a B-mode image for anatomical correlation. The 2D SWE image shows spatial variations of liver stiffness and helps ensure the correct location to take measurements of the liver in the stiffest area, to guide biopsies or to follow treatment and changes in liver stiffness over time. See Figures 1 and 2.

The potential clinical benefits of SWE, particularly in combination with 2D imaging, are numerous:

- It is used to stage fibrosis non-invasively
- It is used in therapy follow up of all kinds
- It helps differentiate adenomas from fibrous nodular hyperplasia
- It could be helpful in distinguishing between hepatocellular carcinomas and cholangiocarcinomas
- It could improve the identification of hepatocellular carcinomas in cirrhotic livers

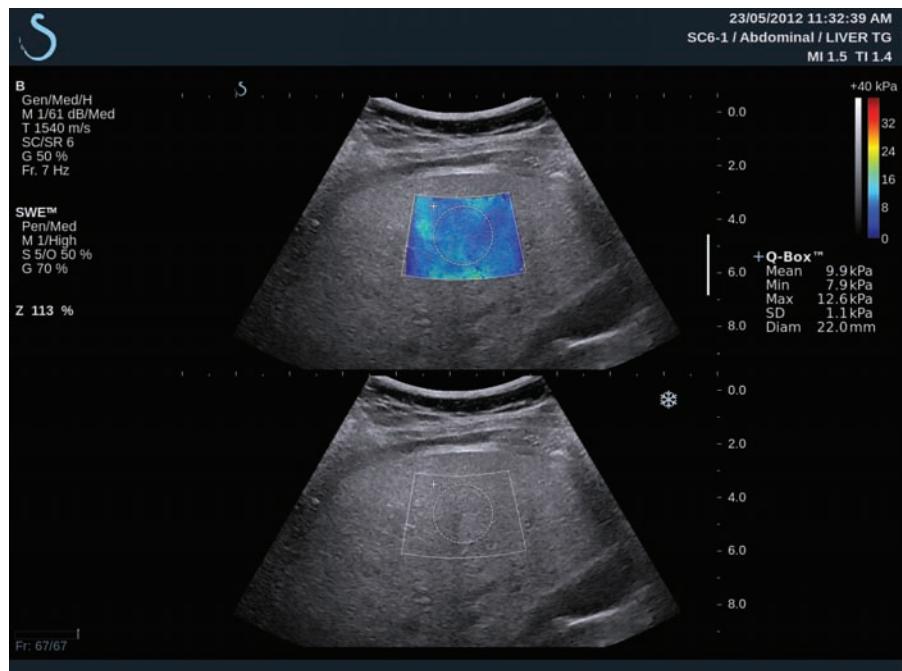


Figure 1. F3 Liver Fibrosis: SWE image demonstrating by 2D a fatty liver and with SWE a F3 Liver Fibrosis.

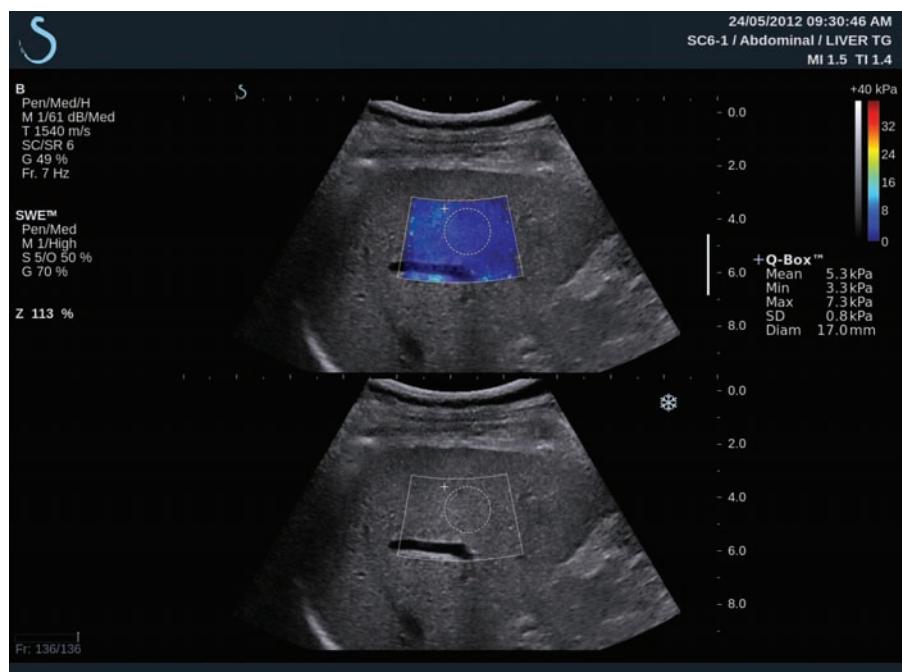


Figure 2. SWE Normal Liver: 2D demonstrates a very homogenous Liver with the collaboration of SWE showing no Liver Fibrosis.

As such, this tool is a very safe, efficacious, reproducible, and non-invasive way to assess liver diseases and provides important economic benefits to the healthcare system as a whole. 

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Aymeric Guibal, MD, PhD practices at Hospices Civils de Lyon, Hôpital Edouard Herriot, Service d'Imagerie Digestive in Lyon, France. he can be contacted at aymeric.guibal@gmail.com.

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