

MANAGING HEPATITIS C: ADVANCES IN TREATMENT & EVALUATION

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Improvements to the efficacy and side effects of hepatitis C medications have simplified the disease management calculus, tipping the scales towards treatment.

The availability of effective oral medication has also raised the bar for clinicians: is there a way to make similar progress in the evaluation side? What would it take to stage the disease quickly, safely, and without discomfort for the patient?

The stiffness of the patient's liver tissue, categorized at a certain stiffness as "fibrosis," provides hepatologists important diagnostic information about the extent and stage of hepatitis C. Liver biopsy has long been the gold standard for obtaining this information. However, biopsies are time-consuming invasive procedures that routinely cause patients pain and, in some rare instances, lead to greater complications such as internal bleeding. These procedures take up clinical staff time, necessitate bed space, and incur instrument and room sterilization costs. Lastly, they are subject to not insignificant sampling limitations, as each biopsy takes only a small sample from a large organ.

A non-invasive alternative to biopsy, shearwave elastography (SWE), is better suited to the new landscape of hepatitis C management. Amplifying the power of conventional ultrasound technique to quantify tissue stiffness and map the extent of the fibrosis in real time, SWE can be performed in about a minute during a routine clinic visit, and it poses none of the risks of complications.

A host of studies have determined the effectiveness of SWE; one ultrasound system with this technology, the Aixplorer from SuperSonic Imagine (Aix en Provence, France), earned FDA approval in 2013 for its real-time quantification of tissue elasticity in kilopascals (kPa).^{1,2,3} High-speed acquisition of images is required to interpret extremely fast-moving shear waves (in the Aixplorer's case, the acquisition is up to 200 times faster than conventional ultrasound systems). From this high-speed platform, the technology produces a two-dimensional, color-coded map of tissue elasticity overlaid on a B-mode image for anatomical correlation.

What does SWE mean for hepatitis C patients?

The bottom line for people with hepatitis C is that SWE helps them get appropriate treatment for their disease without the need to undergo a biopsy. According to the American Liver Foundation, the risks involved in biopsy include internal bleeding, injury to the lung, gallbladder or kidney, and infection. While the likelihood of major complications from biopsy is exceedingly small, the more common risks and requirements are nonetheless a burden. These include an unavoidable outpatient visit, including a recovery period; discomfort; and the

fact that the sample must be sent out to be analyzed, a delay that can promote patient anxiety and will certainly delay treatment (if only for a short time). SWE scans, on the other hand, can be done by a physician in a quick clinic visit, and patients can see their results in real time in an intuitive, color-coded display.

The benefits and minimized risks of using a non-invasive alternative to biopsy are compounded when you take into account the need for follow-up and/or clarifying assessments. Even with the most current advanced treatment—with which nearly 90 percent of hepatitis C patients are cured of the virus—patients still need to come in for a follow-up evaluation to establish efficacy and determine any future action. Patient progress can be displayed simply and immediately by comparing a real-time scan to an earlier scan of the same region—an exercise that takes only minutes of a clinic visit.

What does SWE mean for hepatologists?

There are some clinical challenges that SWE solves and others that it doesn't. The advantages include that the technique is non-invasive, performed at the point of care, and completed in a matter of minutes. It can also improve accuracy in some cases, as when it is used in conjunction with B-mode imaging to reduce the sampling error that comes from selective biopsies. The ability to adjust the region of interest and scan in real-time can also minimize follow-ups due to variability in sampling.

Where SWE cannot ease the pressure of clinical decision-making, however, is in mid-range patients whose fibrosis is neither high nor low, or when the tissue stiffness has not improved dramatically after treatment. Deciding how to frame the disease to the patient and deciding when to end monitoring are both instances where hepatologists will need to make tricky judgment calls similar to the ones that are used surrounding treatment.

What does SWE mean for hospitals treating hepatitis C patients?

Changes in clinical evaluation technologies and in medication for hepatitis C have prompted adjustments on the reimbursement end of things—as recent decisions from the Centers for Medicare & Medicaid Services indicate. SWE is likely to play a role in the ongoing shift toward value-based health care. The advantages of SWE for assessing liver fibrosis are aligned with the simultaneous goals of better health outcomes (including fewer complications) and less costly care. Hospitals stand to gain from replacing biopsy with this non-invasive option: 1) they save money by avoiding the overhead associated with liver biopsies; 2) they improve patient satisfaction by saving people time, eliminating extra co-pays for outpatient procedures, and avoiding biopsy-related complications.