Noninvasive liver fibrosis assessment

ElastPQ ultrasound shear wave elastography

Richard G. Barr, MD, PhD, FACR, Diagnostic Radiology, Hitchcock Imaging, Youngstown, OH

Liver disease – cause and prevalence

Diffuse liver disease is one of the major health problems in the world. It can result from many causes, including viral hepatitis (Hepatitis B or Hepatitis C), non-alcoholic or alcoholic fatty liver disease, autoimmune hepatitis, drug-induced liver injury, primary biliary cirrhosis, and several other less frequent etiologies. It is estimated that 360 million and 180 million people worldwide are infected with viral hepatitis B and C respectively. Between 500,000 and 700,000 people die annually as a result of Hepatitis B virus infection, and more than 350,000 people are estimated to die each year from Hepatitis C-related liver disease.[1-3] Chronic liver damage results in hepatic fibrosis, characterized by an increase in extracellular matrix material produced by fibroblast-like cells. This process results in liver fibrosis that can progress to cirrhosis with distortion of normal liver architecture and portal hypertension.

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Diagnosis and staging of liver disease

Accurately staging the degree of liver fibrosis is extremely important to determine if antiviral therapy is appropriate, and to predict treatment outcome and malignant potential. With current drug therapy, early stage fibrosis may be reversible.[4]

The histologic evaluation of liver biopsies is carried out using scoring systems that produce values for various categories of inflammation (grade), and fibrosis (stage). There are several scoring systems, all categorizing similar features. In the assessment of chronic HCV hepatitis, the most reproducible scoring system is the Metavir. On the Metavir scoring system, liver fibrosis is evaluated semi-quantitatively and staged on a five-point scale from 0 to 4 (F0: absent; F1: enlarged fibrotic portal tract; F2: peri-portal or initial portal-portal septa but intact architecture; F3: architectural distortion but no obvious cirrhosis; and F4: cirrhosis).[5]

The gold standard for diagnosis and staging of liver fibrosis has been liver biopsy. In addition to being an invasive procedure with potential complications of bleeding and severe pain, sampling error is an intrinsic problem due to the small sample size in a heterogeneous process.[6,7] Inter-observer variability also limits diagnostic consistency.[8-10] The development of several blood markers such as platelets, hyaluronic acid, type IV collagen, aminotransferase/platelet ratio index (APRI) and algorithm based serum models (Fibro Index, FIB-4, and Fibro Test) have been used but are affected by factors unrelated to the liver.

ElastPQ – a new era in liver disease assessment

A new technique called ElastPQ uses ultrasound shear wave elastography to provide a noninvasive, reproducible, and easily performed method of assessing liver fibrosis. A special pulse sequence technique that uses existing transducers produces shear waves in tissue and then measures the propagation speed of the waves. Now liver stiffness samples can be acquired during a routine ultrasound examination of the liver. According to a recent study, using shear wave elastography may help reduce or avoid conventional liver biopsies.[11] Instead of a costly and painful biopsy procedure, an easy ultrasound exam becomes the routine method to assess liver disease status.

Liver fibrosis staging	Metavir score	kPa	m/s
Normal	F0	2.0 – 4.5	.81 – 1.22
Normal – Mild	F0 – F1	4.5 – 5.7	1.22 – 1.37
Mild – Moderate	F2 – F3	5.7 – 12.0	1.37 – 2.00
Moderate – Severe	F3 – F4	12.0 – 21.0+	2.00 – 2.64+

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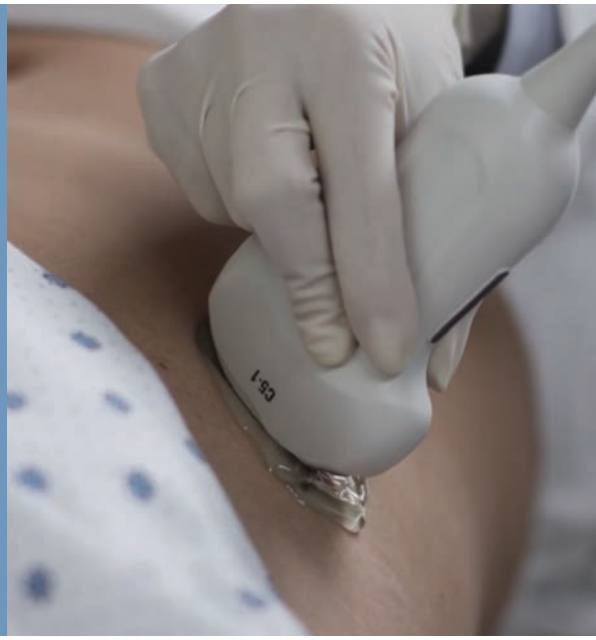

Performing an ElastPQ shear wave examination

With increasing fibrosis, the liver becomes stiffer, which can be monitored using shear wave elastography.[12,13] With this technique, during an ultrasound exam, a region of interest (ROI) is placed in an area of the liver taking care not to include large vasculature or biliary structures. An intercostal imaging approach targeting segments 7 or 8 of the liver has been shown to provide more reliable measurements. Serial measurements are taken while the patient suspends respiration and a report is generated. The average of these measurements is then used to estimate the degree of liver stiffness and correlate with a predicted biopsy Metavir score.

Although this technique typically shows strong correlation, there are several confounding factors that may distort results, such as liver inflammation, liver congestion, and biliary obstruction. In some cases, distinguishing normal from very mild disease may be difficult; also, some moderate and severe disease may look similar.

The potential for change in clinical practice and reduction in medical costs

Recently, the United Kingdom's NICE (National Institute for Health and Care Excellence) updated their clinical guidelines for managing patients with chronic viral Hepatitis B infections.[14] The newest guidelines recommend that transient elastography is offered as the initial test for liver disease in adults newly referred for assessment, and annual reassessment of liver disease using transient elastography is offered to adults who are not taking antiviral treatment. The guidelines only target liver biopsy in very specific conditions. This provides a less invasive approach to managing liver disease and offers the opportunity to control medical costs.

When compared to transient elastography exams, Philips ElastPQ shear wave elastography has been found to show similar accuracy and is an image-guided exam that shows precisely where stiffness measurements are taken. ElastPQ has also been shown to allow measurements in patients with high BMI (Body Mass Index) and patients with ascites.

As clinical practice standards of care adapt to appropriate use guidelines, ElastPQ elastography may offer an ideal way to routinely monitor liver tissue stiffness, and reduce other, more costly and invasive methods of testing. CMS CPT add-on codes[15] for provider tracking of elastography exams exist currently and provide the preliminary steps for future reimbursement.

Key take-aways for ElastPQ liver stiffness assessment

- Easily combine a routine ultrasound imaging exam of the liver anatomy with targeted tissue stiffness values
- Assess liver fibrosis in patients with clinically suspected disease even before abnormalities are detected with ultrasound imaging
- Evaluate and obtain a baseline stiffness value in patients with chronic liver disease
- Follow up patients under treatment to monitor progression, stabilization or regression of liver disease
- Help avoid the need for liver biopsies when elastography results are consistent with other clinical findings

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