Enhanced liver fibrosis: A non invasive blood test that aids the assessment

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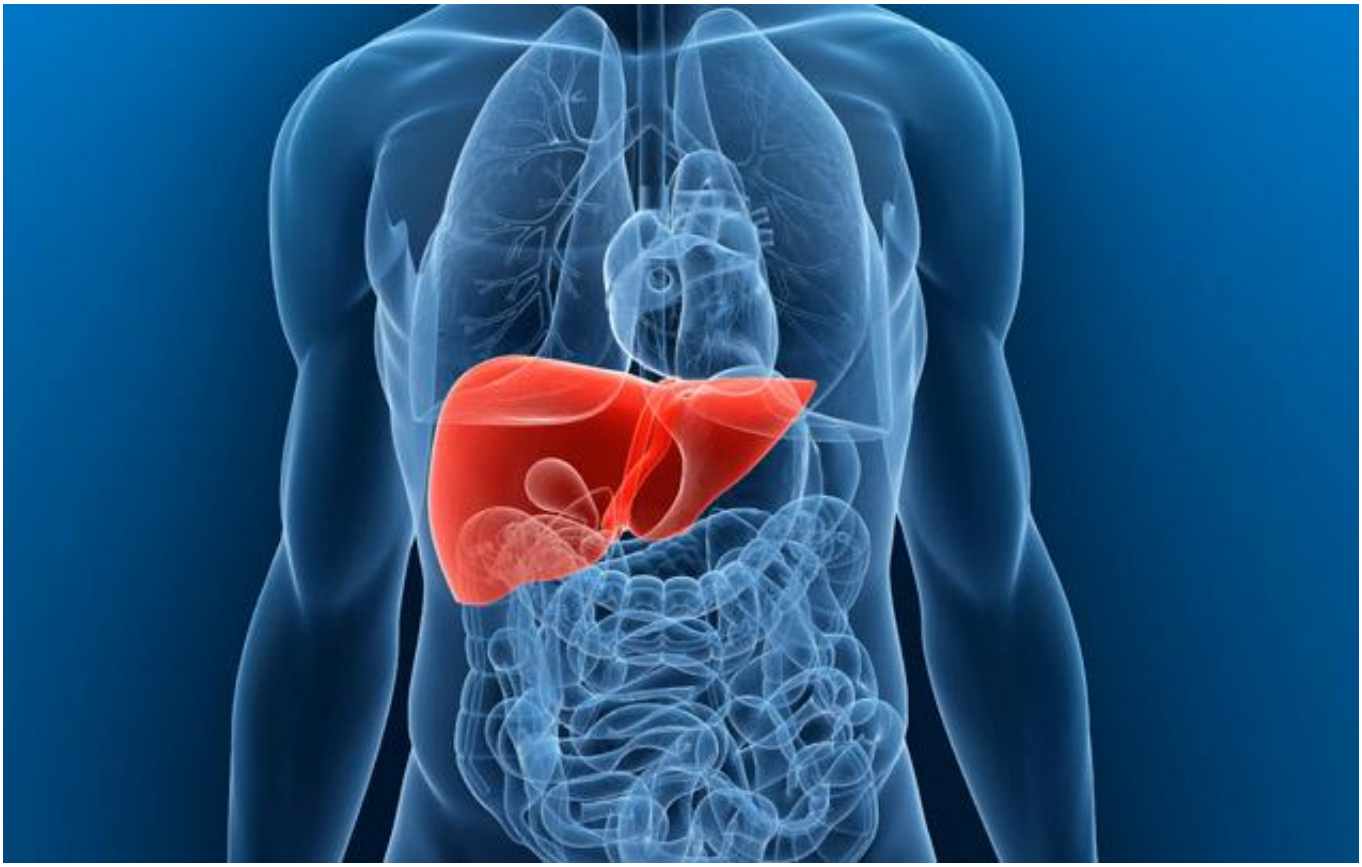

Chronic liver disease (CLD) is a leading cause of death globally. Significant contributors include viral Hepatitis B and C (HBV, HCV), Alcoholic liver disease (ALD), and Non-alcoholic fatty liver disease (NAFLD), although several other aetiologies exist and some of these causes may co-exist. Management of patients with CLD requires assessment and staging of fibrosis to identify those most at risk and in need of treatment or lifestyle modification. Suppression or reversal of fibrosis, and possibly even early cirrhosis, can restore liver functionality and minimize complications such as the development of portal hypertension or hepatocellular carcinoma. Biopsy has long been considered the gold standard for diagnosis, but in recent years significant limitations have been acknowledged that compromise both sensitivity and diagnostic accuracy.

Non-invasive alternatives to biopsy have recently become available, including both imaging modalities and blood tests. Enhanced Liver Fibrosis (ELF) test is a novel blood test that measures levels of three direct markers [Hyaluronic acid (HA), Amino-terminal propeptide of type III collagen (PIIINP), and Tissue inhibitor of matrix metalloproteinase 1 (TIMP-1)] of fibrosis and utilizes an algorithm to generate a numeric score. Application of this score to patients with chronic liver disease allows physicians to better assess fibrotic progression and can significantly reduce the number of

patients requiring biopsy. This article provides an overview of the current published evidence on the clinical utility of the ELF test.

Limitations of Biopsy

1. Fibrosis is not always homogeneous within a biopsy sample. Note the different conclusions that could be reached depending on the length of the biopsy sample and the placement of the collection needle
2. Biopsy is inherently invasive and contraindicated in some (such as patients on anticoagulation therapy and those with advanced cirrhosis).
3. Patients are generally reluctant to undergo repeat biopsy, limiting its use in monitoring fibrotic changes and treatment efficacy.

Alternatives to Biopsy

Blood tests for fibrosis vary in design but usually utilize a panel of markers associated with liver damage, dysfunction, or the fibrotic process itself. In contrast to biopsy, which only evaluates approximately 0.002% of the total liver mass on average, blood tests (especially those utilizing markers directly associated with fibrosis versus just liver damage) offer the possibility of measuring the extent of total liver fibrosis, and can supply clinically relevant information across the continuum of fibrogenic disease.

Direct Serum Markers of Fibrosis

Direct markers of fibrosis measure biochemical markers of the fibrotic biochemistry itself. Fibrosis is a complex process involving both fibrogenesis (scar tissue formation) and fibrolysis (tissue repair).

ELF Test: A Multimarker Algorithm that Generates a Single Score

The ELF markers and algorithm were originally investigated and validated in a large study of over 1,000 patients with multiple forms of chronic liver disease,

including HCV, ALD, and NAFLD, for the detection of fibrotic damage. Blood samples were obtained from patients within 6 months of biopsy.

Subsequent work has established additional positive clinical performance for ELF, both in these common forms of liver disease and others, such as Primary biliary cirrhosis (PBC), Primary sclerosing cholangitis, Hepatitis B (HBV), and Autoimmune hepatitis. Adult and paediatric populations have been studied with ELF, with the test performing well in both.

ELF score guidance