INAHTA Brief

## Title Non-invasive Diagnostic Tests for Liver Fibrosis

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 Reference
 Technology Review Report 011/2018, online:

 <a href="http://www.moh.gov.my/index.php/database\_stores/store\_view\_page/30/332">http://www.moh.gov.my/index.php/database\_stores/store\_view\_page/30/332</a>

## Aim

To assess the diagnostic accuracy/efficacy, safety, costeffectiveness and organizational issue of non-invasive diagnostic tests for liver fibrosis compared with liver biopsy

# **Conclusions and results**

A total of 186 titles were identified through several databases and other sources. There were 12 studies included in this review: two health technology assessments (HTA), six systematic review (SR) and meta-analysis (MA), two SR only and two diagnostic accuracy studies. The studies were conducted in China, USA, UK, Germany, France, Korea, Iran and Canada.

## Effectiveness

There was good level of retrievable evidence on diagnostic accuracy of non-invasive diagnostic test for liver fibrosis to suggest:

-Imaging techniques which are Transient Elastography (TE) and Shear Wave Elastography (SWE) had higher diagnostic accuracy compared to biochemical markers.

-Diagnostic accuracy of imaging techniques and biochemical markers improved with increasing stage of fibrosis

-Among the biochemical markers, NAFLD fibrosis score (NFS), aspartate aminotransferase to platelets ratio index (APRI) or enhanced liver fibrosis (ELF®) and fibrosis-4 index (FIB-4) had the highest diagnostic accuracy according to the stages of fibrosis.

-The diagnostic accuracy of TE and SWE were similar and varies depending on severity of fibrosis and population.

**Safety**: There was no evidence retrieved on the adverse events of non-invasive diagnostic tests for liver fibrosis. The adverse events associated with the ELF test, FibroTest, and FibroMAX were those associated with diagnostic venepuncture generally: primarily pain and bruising, with occasional vasovagal reactions and very rarely potentially disabling nerve injuries. The contraindications specified for FibroTest, FibroMAX, and FibroScan all relate to the mode of operation of the test, and do not relate to any potential for harm in patients with the relevant characteristics, although they will restrict their practical utility.

# Organizational

# Training

None of the studies reported that non-invasive diagnostic liver fibrosis test required training. However, one article

mentioned that the ultrasound and shear wave elastography were performed by more than five years'

experience sonologists in routine liver scanning and validated ultrasound elastography.

## **Cost/Cost-effectiveness**

One HTA reported on cost-effectiveness for non-invasive liver test (NILT) with liver biopsy as a reference standard. They reported that the incremental cost per correct positive diagnosis for patient with NAFLD were dominated or extendedly dominated by liver biopsy. As there were no established cost-effectiveness thresholds for this measure, they have not confirmed that the ICERs for the biopsy would represent good value for money. The base-case results implied that the most cost-effective strategy was to use liver biopsy only to diagnose cirrhosis in patients with ALD, with an ICER of £822.33. They found that treating every patient with HCV without prior testing was costeffective with ICER of £9204. For patient with HBeAgpositive disease, only hyaluronic acid (AST/ALT/FibroTest) and magnetic resonance were cost-effective with ICER of £19,612. While for patient with cirrhosis, the most costeffective test to use was Forns index with an ICER of £1926.

#### Recommendations (if any)

Non-invasive techniques can be used for liver fibrosis. However, patient selection criteria are warranted.

#### Methods

The following electronic databases were searched through the Ovid interface: Ovid MEDLINE® In-process and other Non-indexed citations and Ovid MEDLINE® 1946 to present, EBM Reviews - Cochrane Central Register of Controlled Trials - August 2018, EBM Reviews - Cochrane Database of Systematic Reviews - 2005 to September 2018, EBM Reviews - Health Technology Assessment – 4th Quarter 2017, EBM Reviews – NHS Economic Evaluation Database 1st Quarter 2017, and EMBASE. Searches were also run in EMBASE. Google Scholar was used to search for additional web-based materials and information.

The references of retrieved articles were scrutinised for additional articles. No limits were applied. The last search was conducted on 7 February 2019.

#### Further research/reviews required

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Written by

