***Title*** Assessment of non-invasive methods for measuring liver fibrosis in chronic hepatitis B. Initial assessment and follow-up of non-treated adult patients

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**Aim**

The main objective is to determine the clinical utility of non-invasive methods for measuring fibrosis in the initial assessment and follow-up of chronic hepatitis B in untreated adults.

In the absence of sufficient demonstration of this clinical utility, the diagnostic performances of these non-invasive methods will be defined, in comparison with liver biopsy.

**Conclusions and results**

No study on clinical utility, i.e. the impact of non-invasive methods for measuring liver fibrosis on the management, clinical progression or quality of life of patients with chronic hepatitis B, has been identified.

Only two studies were selected to assess diagnostic performances. These relate to transient elastography (FIBROSCAN) only. Therefore, the analysis of the literature doesn't allow to assess the diagnostic performances of other non-invasive methods. The two selected studies have several methodological limitations and are not directly comparable with each other (different populations and diagnostic strategies). They present uncertain and imprecise results for the diagnostic performance of transient elastography (diagnostic accuracy of significant fibrosis [F ≥ 2] is 60 and 64%; diagnostic accuracy of cirrhosis [F = 4] is 73 and 75%).

Despite these limitations, a majority of the consulted practitioners believe that there is a place for non-invasive methods for measuring liver fibrosis in the management of chronic hepatitis B, especially in cases of suspected cirrhosis. This professional position is also reflected in the various identified clinical practice recommendations.

Overall, based on professional positions, transient elastography can be proposed for the diagnosis of cirrhosis (F4), in adult patients with untreated chronic hepatitis B and showing no obvious signs of cirrhosis. This use requires identifying specific diagnostic thresholds adapted to the different populations and communicating these to health professionals.

According to the previous work of HAS on non-invasive methods for measuring liver fibrosis, the time between transient elastography examinations within this context must not be less than 1 year, except for justified reasons. Similarly, this examination should be prescribed, performed and analysed in a specialised environment by health professionals with experience in interpreting the results and expertise in technical and diagnostic limitations of non-invasive methods (reliability criteria, factors influencing the elasticity of the liver, contra-indications, accuracy).

**Methods**

The assessment method used in this report includes:

- a critical analysis of clinical studies identified by a systematic review for the period from November 2008 to November 2013;
- a consultation of six stakeholders.

The conclusions of the assessment are reviewed by the National Commission for the Assessment of Medical Devices and Health Technologies and then validated by the HAS Board.

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