INPLASY PROTOCOL

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Support: **None.**

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Conflicts of interest:
None declared.

Meta-analysis of the value of transient elastography in the diagnosis of hepatic fibrosis staging in fatty liver disease

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Review question / Objective: **Fatty liver disease is a clinicopathological syndrome characterized by excessive fat storage and steatosis in hepatocytes. Fatty liver disease is seriously threatening the health of the Chinese people, becoming the second largest liver disease after viral hepatitis, the incidence is increasing, and the age of onset is getting younger and younger. In this study, TE was evaluated for the diagnostic value of TE in the diagnosis of hepatic fibrosis in patients with fatty liver disease by comparing TE with liver biopsy in the diagnosis of hepatic fibrosis in patients with fatty liver disease. P: Fatty liver disease liver fibrosis; I: Transient elastography (TE); C: Liver biopsy; O: Sensitivity (Sen), specificity (Spe); S: Diagnosis.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 08 October 2022 and was last updated on 08 October 2022 (registration number INPLASY2022100030).

INTRODUCTION

Review question / Objective: **Fatty liver disease is a clinicopathological syndrome characterized by excessive fat storage and steatosis in hepatocytes. Fatty liver disease is seriously threatening the health of the Chinese people, becoming the second largest liver disease after viral hepatitis, the incidence is increasing, and the age of onset is getting younger and younger. In this study, TE was evaluated for the diagnostic value of TE in the diagnosis of hepatic fibrosis in patients with fatty liver disease by comparing TE with liver biopsy in the diagnosis of hepatic fibrosis in patients with fatty liver disease. P: Fatty liver disease liver fibrosis; I: Transient**

elastography (TE); C: Liver biopsy; O: Sensitivity (Sen), specificity (Spe); S: Diagnosis.

Condition being studied: Fatty liver disease is a clinicopathological syndrome characterized by excessive fat storage and steatosis in hepatocytes. Hepatic fibrosis is the pathological repair of chronic damage by the liver, which may be related to autophagy and is an important link in the development of various autoimmune liver diseases to cirrhosis. At the same time, autoimmune liver disease is difficult to cure, if the disease is seen in the early stage, it can block or even reverse the process of liver fibrosis further progressing to cirrhosis. Therefore, it is of great significance to make an early diagnosis of liver fibrosis and assess the stage at which it is located. Percutaneous liver biopsy is currently the "gold standard" for diagnosing liver fibrosis, but because the resulting specimen is small, it is still difficult to fully represent all lesions of the liver, there may be errors, and liver biopsy is an invasive test, there are bleeding, organ perforation, sepsis and other risks, patients are difficult to accept, so it is relatively difficult to popularize. Transient elastography (TE) can determine the status of liver fibrosis by measuring liver hardness values, and has been approved for clinical use in Europe, Asia Pacific and the United States.

METHODS

Search strategy: Computer search of CBM, CNKI, Wanfang, Weipu, Reading Show, Pubmed, Embase, Cochrane Library, Web of science, OVID, SCOPUS, ProQuest published literature on TE diagnosis of fatty liver disease liver fibrosis staging, using the search method of combining theme words and free words, the search time limit is to build the library until 2022-09-30. English search terms include Fatty Liver、fatty liver disease、FLD、alcoholic liver disease、ALD、alcoholic fatty liver disease、AFLD、Nonalcoholic fatty liver disease、NAFLD、Metabolic-dysfunction-associated fatty liver disease、MAFLD、Hepatic Fibrosis、Fibrotouch, FI、Elasticity Imaging Techniques、elasticity imaging technique、Transient elastography、TE、Noninvasive elastography、Fibroscan、diagnosis.Chinese search terms include fatty liver, fatty liver disease, alcoholic liver disease, non-alcoholic fatty liver disease, non-alcoholic fatty liver disease, metabolism-associated fatty liver disease, liver fibrosis, transient elastography technology, elastography technology, diagnosis.

Participant or population: Patients with fatty liver disease liver fibrosis, regardless of age.

Intervention: Transient elastography (TE).

Comparator: Liver biopsy.

Study designs to be included: Diagnosis.

Eligibility criteria: 1 :Inclusion criteria (1) Type of study: published diagnostic tests on the accuracy of TE diagnosis of fatty liver disease liver fibrosis; (2) The research object is a patient with fatty liver disease and liver fibrosis, and the age is not limited. (3) Histopathological staging of liver biopsy is used as the gold standard for diagnosis. Histological staging is divided by S0-S4. S0 is free of fibrosis; S1 is mild fibrosis; S2 is moderate fibrosis; S3 for advanced liver fibrosis; S4 is cirrhosis. S0-1 indicates no significant fibrosis; Occurs with fibrous septal or bridging fibrosis, i.e. Scheuer and METAVIR ≥ S2 or ISHAK≥S2 as defined as significant fibrosis; Scheuer and METAVIR≥ S3 or ISHAK≥ S4 define advanced liver fibrosis. (4) In this article, the original data such as true positive number (TP), false positive number (FP), false negative number (FN), true negative number (TN) can be directly or indirectly obtained.2 :Exclusion criteria (1) documents that cannot extract raw data; (2) There is no literature that does not match the research content such as TE and liver biopsy; (3) Basic research such as animal experiments; (4) Review, conference

papers, lectures, systematic reviews and case reports.

Information sources: Computer search of CBM, CNKI, Wanfang, Weipu, Reading Show, Pubmed, Embase, Cochrane Library, Web of science, OVID, SCOPUS, ProQuest published literature on TE diagnosis of fatty liver disease liver fibrosis staging, using the search method of combining theme words and free words, the search time limit is to build the library until 2022-09-30.

Main outcome(s): Sensitivity,Sen/ Specificity,Spe.

Data management: NoteExpress.

Quality assessment / Risk of bias analysis: Two reviewers independently assessed the methodological quality of the included studies using the diagnostic test quality assessment tool QUADAS (Quality Assessment of Diagnostic Accuracy Studies), independently evaluated the selected literature in Review Manger 5.3 software, and made a literature quality evaluation chart.

Strategy of data synthesis: Using STATA14.0 and Meta Disc software, calculate the point estimates of Sen, Spe, positive likelihood ratio (+LR), negative likelihood ratio (-LR), diagnostic ratio ratio (DOR) and their corresponding 95% CI. Plot the SROC curve to determine whether there is threshold effect heterogeneity and calculate the AUC and its 95% CI. If the Q statistics correspond to P≤0.1, it indicates that there is heterogeneity caused by non-threshold effects in this study, and the use of MeTa regression to explore the source of heterogeneity is statistically significant, and P<0.05 is the difference.

Subgroup analysis: Subgroup studies were conducted based on factors such as the patient's age, marital status, type of disease, etc.

Sensitivity analysis: If any one of the literature data is deleted, the combined results of the remaining documents are not much different from those of the undeleted, which means that the sensitivity analysis has passed.

Country(ies) involved: China.

Keywords: Fatty liver disease; Hepatic fibrosis; Transient elastography technology; diagnosis.

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