

INPLASY

The efficacy of traditional Chinese medicine on chronic hepatitis B patients complicated with nonalcoholic fatty liver disease: A systematic review and meta-analysis

INPLASY202450018

doi: 10.37766/inplasy2024.5.0018

Received: 06 May 2024

Published: 06 May 2024

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ADMINISTRATIVE INFORMATION

Support - Special Subject of Medical Research of Longhua District Medical Association (2023LHMA02).

Review Stage at time of this submission - The review has not yet started.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202450018

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 06 May 2024 and was last updated on 06 May 2024.

INTRODUCTION

Review question / Objective To evaluate the efficacy and safety of traditional Chinese medicine (TCM) on chronic hepatitis B patients (CHB) complicated with nonalcoholic fatty liver disease (NAFLD).

1.Type of articles and participants: Randomized clinical trials (RCTs) and CHB complicated with NAFLD.

2.Intervention and control: TCM (decoction and Chinese patent medicine) plus anti-HBV therapies (telbivudine, entecavir, tenofovir, adefovir dipivoxil, and interferon). The control groups were treated with anti-HBV therapies alone.

3.Observation: (1) Liver function; (2) Blood lipid; (3) Ultrasound results; (4) Body mass index; (5) Safety; (6)HBV DNA.

Rationale Some RCTs showed that compared with anti-HBV therapy alone, TCM combined with anti-HBV therapy could improve liver function in CHB

patients complicated with NAFLD, and some RCTs reported that there was no statistical difference in liver function between two groups.

Condition being studied The prevalence of NAFLD has increased among the general population and CHB patients worldwide, and lots of CHB have co-existing fatty liver. Concurrent fatty liver is common in patients with HBV virus infection and is an independent risk factor increasing the incidence of HBV-associated HCC.

METHODS

Search strategy PubMed, Cochrane Library, Embase, Web of Science, China National Knowledge Infrastructure database, Wanfang Data, China Biomedical Literature database, and VIP Chinese Journal Full-text database. The following search terms are used: "hepatitis B" AND "fatty liver OR steatohepatitis" AND "randomized".

Participant or population Patients met the diagnostic criteria for CHB and NAFLD.

Intervention The treatment groups were treated with anti-HBV therapies (telbivudine, entecavir, tenofovir, adefovir, and interferon) and TCM (decoction and Chinese patent medicine).

Comparator The control groups were treated with anti-HBV therapies alone.

Study designs to be included RCTs.

Eligibility criteria 1) Patients are only diagnosed with NAFLD or CHB; 2) Patients are not treated with anti-HBV therapies; 3) Indicators did not involve liver function or blood lipid; (4) Control groups include TCM; (5) Repetitive articles, protocol, plagiarized literature, case report, theoretical studies, review, and experimental research.

Information sources PubMed, Cochrane Library, Embase, Web of Science, China National Knowledge Infrastructure database, Wanfang Data, China Biomedical Literature database, and VIP Chinese Journal Full-text database.

Main outcome(s) Liver function, including Alanine aminotransferase (ALT), serum total bilirubin (TBIL), aspartate transaminase (AST), albumin (ALB); (2) Blood lipid, including triglyceride (TG), total cholesterol (TC), high-density lipoprotein cholesterol (HDL-C), Low-Density Lipoprotein Cholesterol (LDL-C).

Additional outcome(s) Ultrasound results (fatty liver, diameter of splenic vein, spleen thickness, internal diameter of the portal vein); Body mass index; Safety; HBVDNA.

Data management Microsoft Excel (2013).

Quality assessment / Risk of bias analysis Cochrane risk of bias tool.

Strategy of data synthesis For continuous variables, mean difference (MD) or standardized mean difference (SMD) were used. The risk ratio (RR) was utilized to assess the dichotomous variables. The results were calculated with 95% confidence intervals. Heterogeneity between articles was assessed by the I² test. When the value of I² is less than 50%, the fixed effect model was used to perform the analysis, and if the value of I² is more than 50%, the random effect model or descriptive analysis was performed.

Subgroup analysis Not Applicable.

Sensitivity analysis Evaluate the combined results and heterogeneity after removing the included studies one by one.

Language restriction English or Chinese.

Country(ies) involved China.

Keywords TCM; hepatitis B; fatty liver; randomized controlled trials; meta-analysis.

Dissemination plans Article.

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