

## Analysis of risk factors of chronic hepatitis B patients with Viremia: a meta-analysis

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**Review Stage at time of this submission** - Preliminary searches.

**Conflicts of interest** - None declared.

**INPLASY registration number:** INPLASY202370107

**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 26 July 2023 and was last updated on 26 July 2023.

**INTRODUCTION**

**Review question / Objective** Hepatitis B virus (HBV) infection is a serious health problem worldwide and low-level viremia (LLV) represents a growing problem in anti-viral treatment. Low-level viremia(LLV) is a term used to describe HBV-DNA levels that are higher than the lower limit of detection but lower than 2000 IU/ml.LLV is an independent risk factor for end-stage liver disease and HCC.This study aims to explore the pathogenic risk factors of LLV, pay attention to high-risk populations, and dynamically monitor them to reduce the occurrence of LLV.

**Condition being studied** Existing studies have found that LLV can cause drug resistance, Virology breakthrough, and even related to the occurrence and development of liver fibrosis, cirrhosis and liver cancer. There is currently limited research on

LLV prediction models and dynamic changes in HBV serological markers. At present, there are few studies on the risk factors of low level viremia in chronic hepatitis B patients, and most of the studies are small samples, so the quality of evidence is still unknown.

**METHODS**

**Search strategy** Taking pubmed as an example  
 #1 ((hepatitis b[MeSH Terms]) OR (hepatitis b[Title/Abstract])) OR (hepatitis b)  
 #2 ((hypoviremia[Title/Abstract]) OR (hypoviremia)) OR ((low level viremia) OR (low level viremia[Title/Abstract]))  
 #3 ((risk factor\*) OR (risk factor\*[Title/Abstract])) OR ((influencing factor\*[Title/Abstract]) OR (influencing factor\*))  
 #4 #1 AND #2 AND #3

(((((risk factor\*) OR (risk factor\*[Title/Abstract])) OR ((influencing factor\*[Title/Abstract]) OR (influencing factor\*))) AND (((hepatitis b[MeSH Terms]) OR (hepatitis b[Title/Abstract])) OR (hepatitis b))) AND (((hypoviremia[Title/Abstract]) OR (hypoviremia)) OR ((low level viremia) OR (low level viremia[Title/Abstract])))).

**Participant or population** Patients with chronic hepatitis B.

**Intervention** Exploration of risk factors without intervention.

**Comparator** Low level viremia occurs or does not occur.

**Study designs to be included** The study types are Cohort study, Case-control study and cross-sectional study.

**Eligibility criteria** (1) Research type Cohort study, Case-control study and cross-sectional study; (2) Research The subjects were Chinese people and met the diagnostic criteria for hepatitis B; (3) The outcome index was the occurrence of Low level viremia; (4) Chinese and English literature.

**Information sources** Chinese and English databases such as China National Knowledge Infrastructure (CNKI), Wanfang Date, VIP, Sinomed, PubMed, EMBASE, The Cochrane Library, and Web of Science were searched by computer.

**Main outcome(s)** Risk factors of Low level viremia, such as sex, age, therapeutic schedule (regime), baseline HBeAg positivity ratio, higher baseline HBsAg levels, higher baseline HBV-DNA levels and higher ALT levels, etc.

**Data management** The literature screening was conducted independently by two reviewers, and the literature was organized and checked using Endnote X9.1 software. Data extraction was conducted independently by two researchers using a data extraction form designed by Excel. Discrepancies were resolved by discussion or referral to a third reviewer.

**Quality assessment / Risk of bias analysis** The Newcastle Ottawa Quality Assessment Scale (NOS) was used to score the quality of the documents included in the cohort and Case-control study. The documents were classified into low quality documents 1~3 points, medium quality documents 4~6 points, and high quality documents 7~9 points. The cross-sectional study

was rated using the AHRQ cross-sectional study quality evaluation criteria, with 0-3 being low-quality literature, 4-7 being medium quality literature, and 8-11 being high-quality literature.

**Strategy of data synthesis** Perform meta-analysis using Stata 14.0 software. The influencing factors were combined using odds ratio (OR) and 95% confidence interval (95% CI) to measure the effect. Use I<sup>2</sup> test to evaluate the size of heterogeneity. If P>0.1 and I<sup>2</sup><50%, there is no heterogeneity, and a fixed effect model is used; If P<0.05 indicate significant heterogeneity, a random effects model should be used and sensitivity analysis or subgroup analysis should be conducted. Publication bias in the analysis of influencing factors for inclusion of ≥ 10 articles.

**Subgroup analysis** Use Meta Law of Return to find the source of heterogeneity and conduct subgroup analysis.

**Sensitivity analysis** Sensitivity analysis is conducted through a one by one exclusion method.

**Language restriction** Chinese and English literature.

**Country(ies) involved** China.

**Keywords** Low level viremia; Chronic hepatitis B; Serum HBV DNA; Risk factors.

#### Contributions of each author

Author 1 - lu Xie - XL had given substantial contributions to the conception of the manuscript, analysis, data interpretation.

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