

## Diagnostic value of Serum Mac-2 Binding Protein Glycosylation Isomer in liver fibrosis: A systematic review and meta-analysis

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### ADMINISTRATIVE INFORMATION

**Support -** No.

**Review Stage at time of this submission -** Data analysis.

**Conflicts of interest -** None declared.

**INPLASY registration number:** INPLASY2023100086

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

### INTRODUCTION

**Review question / Objective** To comprehensively evaluate the diagnostic value of serum M2BPGi for liver fibrosis staging in patients with chronic viral hepatitis (CVH) or non-alcoholic fatty liver disease (NAFLD).

**Condition being studied** The early detection of liver fibrosis in patients with chronic liver disease is of great significance for their treatment, as it can reduce the risk of fibrosis related complications and HCC. Therefore, there is an increasing need to identify non-invasive biomarkers to assess the degree of liver fibrosis while reducing reliance on liver biopsy.

### METHODS

**Participant or population** Patients with viral hepatitis or NAFLD Patients with CVH or NAFLD.

**Intervention** Not applicable.

**Comparator** Not applicable.

**Study designs to be included** Retrospective or Prospective.

**Eligibility criteria** Literature inclusion criteria: (1) Patients with viral hepatitis or NAFLD  $\geq$  18 years old; (2) a precise classification of liver fibrosis using pathological diagnosis as the gold standard; (3) Patients tested for M2BPGi; and (4) the total number of occurrences of M2BPGi identification as true positive (TP), false positive (FP), true negative (TN), or false negative (FN) in each case group, either directly or indirectly. Exclusion criteria for literature: (1) experiments on animals, cellular experiments, Case reports, conference abstracts, reviews, comments, letters, meta-analyses and systematic reviews; (2) patients without a clear diagnosis based on liver biopsy; (3) Sample size

less than ten cases; (4) Inability to extract 2 × 2 tables of true positives (TP), false positives (FP), false negatives (FN), and true negatives (TN); (5) Repeated publication of the same data; and (6) Full text of English literature not found.

**Information sources** The PubMed, Embase, MEDLINE, Web of Science, and Cochrane Library databases were searched.

**Main outcome(s)** The pooled sensitivity, specificity, and the summary area under the curve (sAUC) of M2BPGi in the diagnosis of significant fibrosis ( $\geq$  F2) were 0.65 (95% CI: 0.57-0.71), 0.79 (95% CI: 0.72-0.84), and 0.78 (95% CI: 0.74-0.81), respectively. The pooled sensitivity, specificity, and the sAUC of M2BPGi in the diagnosis of extensive fibrosis ( $\geq$  F3) were 0.76 (95% CI: 0.71-0.80), 0.75 (95% CI: 0.68-0.81) and 0.81 (95% CI: 0.77-0.84), respectively.

**Quality assessment / Risk of bias analysis** The quality of the included studies was assessed using the Quality Assessment of Diagnostic Accuracy Studies (QUADAS-2) tool. Publication bias was assessed with Deeks' funnel plot.

**Strategy of data synthesis** All data evaluation and picture generation were completed by Stata software (Version 14.0; Stata Corp LP; Texas, United States) and Meta-Disc 1.4. The pooled values of sensitivity, specificity, positive likelihood ratio (PLR), negative likelihood ratio (NLR), diagnostic odds ratio (DOR), and the summary area under the curve (sAUC) were summarized using the "MIDAS" module. Diagnostic accuracy was evaluated using the sAUC. The Meta-Disc software was used to test for threshold effects and assessment criterion was the Spearman correlation coefficient. Heterogeneity between studies was assessed using Cochran's Q statistic) in Stata. A fixed-effects method was used when  $I^2 < 50\%$  or P-value was  $< 0.10$ . If not, it was suitable to use a random-effects model. Meta-regression and subgroup analysis were used to explore the sources of heterogeneity.

**Subgroup analysis** Meta-regression and subgroup analysis were used to explore the sources of heterogeneity.

**Sensitivity analysis** Sensitivity analysis was used to assess the influence of individual studies on heterogeneity and observe the stability of the summary statistics.

**Country(ies) involved** China.

**Keywords** Mac -2-binding protein glycosylation isomer; Liver fibrosis; diagnosis; Meta-analysis; Noninvasive diagnostic index.

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