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Original Article

Hepatoprotective effects of modified Yiguanjian decoction in pregnant patients with chronic hepatitis B

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Abstract: Objective: To investigate the efficacy of modified Yiguanjian decoction (MYGD) as a hepatoprotective treatment for pregnant patients with chronic hepatitis B (CHB). Methods: Pregnant patients with CHB hospitalized from October 2022 to December 2024 were enrolled and divided into a MYGD group (n = 88) and a conventional group (n = 83). The efficacy, traditional Chinese medicine (TCM) syndrome scores, liver function indicators (alanine aminotransferase, aspartate aminotransferase, total bilirubin, total bile acids), serum liver fibrosis markers (type III procollagen, type IV procollagen, hyaluronidase, laminin), portal vein diameter, spleen length, spleen thickness, pregnancy-related indicators (uterine artery resistance index (RI), serum estriol (uE3)), and clinical safety were observed and statistically analyzed. Results: Compared with the conventional group, the MYGD group showed significantly higher efficacy, after treatment (all $P < 0.05$). The TCM syndrome score was significantly reduced, liver function indicators and serum liver fibrosis markers decreased, portal vein diameter and spleen length shortened, spleen thickness and RI decreased, and uE3 levels increased (all $P < 0.05$). The clinical safety was comparable between the two groups ($P > 0.05$). Conclusion: The combined use of MYGD significantly improved the treatment effect in pregnant patients with CHB, and improved symptoms, liver function, and the degree of liver fibrosis, with good safety.

Keywords: Yiguanjian decoction, chronic hepatitis B, liver function, liver fibrosis, efficacy

Introduction

Chronic hepatitis B (CHB) is a global public health challenge. According to the 2024 World Health Organization (WHO) report, there are 254 million people infected with hepatitis B virus (HBV) worldwide [1]. The prevalence of hepatitis B surface antigen (HBsAg) among women of childbearing age in China is 6.61%, which is still a high prevalence area of hepatitis B [2]. Among pregnant women infected with HBV, especially those with abnormal liver function, the probability of pregnancy and postpartum complications is significantly increased [3]. HBV also poses a long-term health threat to infants, that may lead to cirrhosis or hepatocellular carcinoma (HCC) in adulthood [4]. Aggressive antiviral treatment effectively alleviates clinical symptoms and reduces complications [5]. Tenofovir disoproxil fumarate, given as tablets, is a prodrug of tenofovir. Its components are rapidly cleaved by tissue and plasma esterases to generate tenofovir and promote its conversion to tenofovir diphosphate, thereby effectively inhibiting HBV polymerase/reverse transcriptase and exerting antiviral effects [6]. This drug is used for the prophylactic treatment of pregnant women with CHB and elevated viral load (> 200,000 IU/mL) to block mother-to-child vertical transmission, and it is well tolerated in the mid-to-late stages of pregnancy [7, 8]. In the current treatment regimen for HBV infection during pregnancy, traditional Chinese medicine (TCM) is an important supplementary approach. Clinical evidence shows that TCM treatment can enhance antiviral effects and inhibit liver fibrosis, with definite efficacy and good safety [9]. Ji et al. [10] have confirmed that combined TCM treatment has a liver-protective effect and can significantly reduce the risk of hepatocellular carcinoma in CHB patients. Modified Yiguanjian (MYGD) is a classic TCM formula that is widely used in the treatment of chronic liver diseases (such as cirrhosis and liver fibrosis) [11, 12]. It exerts an anti-fibrotic effect by indirectly regulating the protein kinase B (Akt)/adenosine 5'-monophosphate (AMP) activated protein kinase (AMPK)/

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transcription factor EB (TFEB) pathway, thereby improving liver function. MYGD also suppresses the progression of cirrhosis through its antioxidant effects, thereby protecting liver function. At present, there is limited research on the hepatoprotective effects of MYGD on pregnant women with CHB, and conventional antiviral regimens alone have limited efficacy. This study tested MYGD on pregnant women with CHB to investigate its efficacy and safety as a hepatoprotective therapy, aiming to provide new treatment options and clinical guidance for improving their coutcome.

Materials and methods

Case selection

A retrospective analysis was conducted on 171 pregnant women with CHB hospitalized at Suzhou Fifth People's Hospital from October 2022 to October 2024. They were divided into a MYGD group (88 cases) and a conventional group (83 cases). All pregnant women received antiviral therapy in line with the *Guidelines for the Prevention and Treatment of Chronic Hepatitis B* [13] and the "Management Guidelines for Hepatitis B Virus Infection in Pregnancy" [14].

Diagnostic criteria for CHB: Clinical manifestations: The course of the disease exceeds 6 months or the onset date is unclear, accompanied by chronic hepatitis-related symptoms, signs and abnormal laboratory tests; symptoms include fatigue, aversion to oily food, discomfort in the liver area, etc.; typical signs include liver disease facies, palmar erythema, spider angiomas, telangiectasia in the chest, hard and enlarged liver, and splenomegaly.

Pathogenic diagnosis: Positive serum HBsAg, hepatitis B e antigen (HBeAg), and/or hepatitis B e antibody (anti-HBe); positive HBV deoxyribonucleic acid (HBV-DNA); and persistently or repeatedly elevated serum alanine aminotransferase (ALT).

Ultrasound examination was used as a reference for the diagnosis of chronic hepatitis: (1) Mild: no significant abnormalities in the liver and spleen; (2) Moderate: increased echogenicity in the liver, mild hepatosplenomegaly, clear course of intrahepatic vessels (mainly hepatic veins), no dilation of portal vein and splenic vein; (3) Severe: significantly increased and unevenly distributed echogenicity in the liver, rough liver surface, blunted edges, unclear or slightly narrowed and tortuous intrahepatic ductal structures; dilation of portal vein and splenic vein, splenomegaly, and occasional "double-layer sign" in the gallbladder.

Inclusion and exclusion criteria: Inclusion Criteria: Women aged 20-50 years; confirmed by ultrasound with a singleton intrauterine pregnancy and a viable embryo (fetus); no prior related treatments; no contraindications to the treatment regimen used in this study; complete clinical data.

Exclusion criteria: Concomitant infection with hepatitis A, C, D, or E viruses; Epstein-Barr virus, cytomegalovirus, or rubella virus; decompensated cirrhosis; gestational hypertension, gestational diabetes, hyperemesis gravidarum, or uncontrolled thyroid disease; fetal structural abnormalities or conception through assisted reproductive technology; concurrent conditions that may cause liver dysfunction, including alcoholic liver disease, autoimmune liver disease, drug-induced hepatitis, hyperthyroidism, and hyperemesis gravidarum; serious primary diseases of the heart, lungs, kidneys, or hematology, such as malignant tumors or AIDS; presence of emotional or organic mental disorders; history of alcohol or drug abuse. This protocol was approved by the Ethics Committee of the Fifth People's Hospital of Suzhou, with the approval No. of (2023) Hospital Ethics Review No. (029).

Grouping method

The 171 subjects were divided into the MYGD group (n = 88) and the conventional group (n = 83). If HBV-DNA > 2×10^5 IU/mL, antiviral treatment was administered.

Treatment methods

The conventional group received the following liver-protective regimen: Atomolan (0.6 g; manufacturer: Yaopharma Co., Ltd.; approval number: H19991067; dosage: 2.4 g, once daily, intravenous drip), and compound glycyrrhizic acid injection (Mineron, 20 mL/vial; manufacturer: Minophagen Pharmaceutical Co., Ltd. Zama Factory; approval number: J20130071; dosage: 40-60 mL, once daily, intravenous

drip); the antiviral regimen was: Tenofovir disoproxil fumarate tablets (Viread; 300 mg; manufacturer: AstraZeneca; approval number: JX20080009; dosage: one tablet daily, orally).

The MYGD group was administered MYGD (orally). The regimen was as follows: one dose per day, decocted in water to make two bags, one bag orally in the morning and evening. The formula for the MYGD: Beishashen (Glehnia littoralis) 10 g, Shudihuang (Rehmannia glutinosa preparata) 10 g, Maidong (Ophiopogon japonicus) 10 g, Wuweizi (Schisandra chinensis) 10 g, Gouqizi (Lycium barbarum) 15 g, Chuanlianzi (Melia toosendan) 6 g, Danshen (Salvia miltiorrhiza) 15 g, Danggui (Angelica sinensis) 6 g. All patients were treated for 2 weeks.

Outcome measures

(1) Comparison of the efficacy before and after treatment in the two groups. Efficacy judgment criteria [15]: a. Markedly effective: After treatment, the patient's symptoms basically disappeared or were significantly relieved, liver function indicators returned to normal, and the TCM syndrome score decreased by > 70%; b. Effective: After treatment, the patient's symptoms were relieved, liver function indicators improved, and the TCM syndrome score decreased by 30% to 70%; c. Ineffective: None of the above criteria were met. Total effective rate = Markedly effective rate + Effective rate.

(2) TCM syndrome scores were compared between the two groups, mainly including hypochondriac pain, abdominal distension, emotional depression, and fatigue. Symptoms were scored as follows: none, mild, moderate, and severe, respectively, with scores of 0, 2, 4, and 6.

(3) Changes in liver function indicators were compared between the two groups before and after treatment, including alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin (TBIL), and total bile acids (TBA). These were detected using a fully automated biochemical analyzer (Shanghai Jumu Medical Equipment Co., Ltd., Atellica CH930).

(4) Serum liver fibrosis markers, including type III procollagen (PCIII), type IV procollagen (PCIV), hyaluronic acid (HA), and laminin (LN). These were detected using a real-time quantitative polymerase chain reaction (PCR) instrument (Tiangen Biotech (Beijing) Co., Ltd.).

(5) The portal vein diameter and spleen size were compared between the two groups before and after treatment. Spleen size mainly includes the spleen's longest diameter and thickness, measured using liver ultrasound.

(6) Pregnancy-related indicators were compared between the two groups before and after treatment, mainly measuring the uterine artery resistance index (RI) and serum estriol (uE3).

(7) Clinical safety was compared between the two groups after treatment, mainly based on the number and incidence of gastrointestinal discomfort, elevated blood pressure, and skin rash. Among the above indicators, the primary endpoints included treatment efficacy, TCM syndrome scores, liver function indicators, serum liver fibrosis markers, and clinical safety. Secondary endpoints included portal vein diameter, spleen size, and pregnancy-related indicators.

Statistical methods

SPSS 26.0 statistical software was used for analysis. Normally distributed continuous data were expressed as a mean ± standard deviation ($\bar{x} \pm s$). Non-normally distributed measured data were expressed as median (interquartile range) [M(P25, P75)], and categorical data were expressed as percentages (%). t-tests, paired t-tests, nonparametric tests, x^2 tests, or Fisher's exact test were used. $P < 0.05$ was considered significant.

Results

Comparison of general data

There were no significant differences between the MYGD group and the conventional group in terms of age, gestational age, disease duration, body mass index (BMI), pregnancy history, or disease severity (all $P > 0.05$), indicating that the two groups were comparable (**Table 1**).

Comparison of efficacy

The total effective rate in the MYGD group was 90.91%, significantly higher than the 74.70% in the conventional treatment group, with a significant difference ($P = 0.005$, **Table 2**).

Table 1. Comparison of general data

Factor	MYGD group (n = 88)	Conventional group (n = 83)	χ^2/t/Z	P
Age (years)	29.93 ± 4.67	29.51 ± 4.86	0.576	0.565
Gestational age (weeks)	21.00 (16.00, 24.75)	20.00 (17.00, 24.00)	-0.537	0.591
Disease duration (years)	4.50 (3.00, 6.00)	4.00 (3.00, 6.00)	-0.563	0.573
BMI (kg/m^2)	23.15 ± 2.19	22.73 ± 2.37	1.204	0.230
Pregnancy history			0.086	0.769
Unipara	50 (56.82)	49 (59.04)		
Multipara	38 (43.18)	34 (40.96)		
Disease severity			0.340	0.560
Mild	13 (14.77)	15 (18.07)		
Moderate	75 (85.23)	68 (81.93)		
Severe	0 (0.00)	0 (0.00)		

Note: MYGD, modified Yiguanjian decoction; BMI, body mass index.

Table 2. Comparison of efficacy

Factor	MYGD group (n = 88)	Conventional group (n = 83)	χ^2	P
Markedly effective	38 (43.18)	32 (38.55)		
Effective	42 (47.73)	30 (36.14)		
Ineffective	8 (9.09)	21 (25.30)		
Total effective rate	80 (90.91)	62 (74.70)	7.970	0.005

Note: MYGD, modified Yiguanjian decoction.

Comparison of TCM syndrome scores

Prior to treatment, there were no significant differences between the two groups in TCM syndrome scores for hypochondriac pain, abdominal distension, emotional depression, or fatigue (all P > 0.05). After treatment, the TCM syndrome scores in all groups decreased significantly (all P < 0.01), and the scores in all dimensions were even lower in the MYGD group (all P < 0.01, **Table 3**).

Comparison of liver function

Before treatment, the differences were observed in pre-treatment ALT, AST, TBIL, and TBA between the two groups (all P > 0.05). After treatment, all of the above indicators decreased significantly in both groups (all P < 0.001), and the values in the MYGD group were even lower (all P < 0.001, **Table 4**).

Comparison of serum liver fibrosis markers

Before treatment, there were no significant differences in the levels of PCIII, PCIV, HA, or LN between the two groups (all P > 0.05). After treatment, all indicators showed a significant decreasing trend (all P < 0.001), and the levels of PCIII, PCIV, HA, and LN in the MYGD group were significantly lower (all P < 0.001, **Table 5**).

Comparison of portal vein diameter and spleen size

Before treatment, there were no significant differences in portal vein diameter, spleen length, and spleen thickness between the two groups (all P > 0.05). After treatment, all indicators showed a significant decreasing trend (all P < 0.01), and the levels in the MYGD group were significantly lower (all P < 0.001, **Table 6**).

Comparison of pregnancy-related indicators

Before treatment, there were no significant differences in pregnancy-related indicators such as RI or uE3 between the two groups (both P > 0.05). After treatment, the RI decreased significantly in both groups, with a lower decrease in the MYGD group; uE3 levels increased significantly in both groups, with a significantly higher increase in the MYGD group (both P > 0.05, **Figure 1**).

Comparison of clinical safety

Statistical analysis was performed on the number of cases experiencing gastrointestinal dis-

Table 3. Comparison of changes in TCM syndrome scores

Factor	MYGD group (n = 88)	Conventional group (n = 83)	Z	P
Costal pain (point)				
Before treatment	4.00 (3.00, 4.00)	4.00 (3.00, 5.00)	-0.966	0.334
After treatment	2.00 (1.00, 2.00)***	3.00 (2.00, 3.00)**	-7.809	< 0.001
Epigastric fullness and abdominal distension (point)				
Before treatment	2.00 (2.00, 4.00)	2.00 (0.00, 4.00)	-0.061	0.951
After treatment	0.00 (0.00, 2.00)***	2.00 (0.00, 2.00)**	-3.003	0.003
Emotional depression (point)				
Before treatment	4.00 (4.00, 4.00)	4.00 (4.00, 4.00)	-0.360	0.719
After treatment	4.00 (4.00, 4.00)	4.00 (2.00, 4.00)	-3.409	0.001
Fatigue (point)				
Before treatment	4.00 (2.00, 4.00)	4.00 (4.00, 4.00)	-0.459	0.646
After treatment	2.00 (0.00, 2.00)***	2.00 (0.00, 4.00)**	-3.954	< 0.001

Note: ***P < 0.001, **P < 0.01, intra-group comparison with pre-treatment results. MYGD, modified Yiguanjian decoction; TCM, traditional Chinese medicine.

Table 4. Comparison of liver function

Factor	MYGD group (n = 88)	Conventional group (n = 83)	t	P
ALT (U/L)				
Before treatment	240.99 ± 98.10	241.40 ± 97.49	0.027	0.978
After treatment	48.68 ± 25.86***	101.14 ± 38.42***	10.528	< 0.001
AST (U/L)				
Before treatment	146.33 ± 58.37	145.36 ± 56.41	0.110	0.912
After treatment	34.89 ± 7.06***	45.11 ± 19.84***	4.538	< 0.001
TBIL (μmol/L)				
Before treatment	12.20 ± 3.54	11.96 ± 4.81	0.373	0.710
After treatment	6.69 ± 1.85***	8.22 ± 1.50***	5.919	< 0.001
TBA (μmol/L)				
Before treatment	8.76 ± 2.44	8.18 ± 3.31	1.309	0.192
After treatment	3.96 ± 2.21***	5.18 ± 1.65***	4.071	< 0.001

Note: ***P < 0.001, intra-group comparison with pre-treatment results. MYGD, modified Yiguanjian decoction; ALT, alanine aminotransferase; AST, aspartate aminotransferase; TBIL, total bilirubin; TBA, total bile acids.

Table 5. Comparison of serum liver fibrosis markers

Factor	MYGD group (n = 88)	Conventional group (n = 83)	t	P
PCIII (μg/L)				
Before treatment	299.08 ± 83.75	290.34 ± 70.55	0.736	0.463
After treatment	126.60 ± 21.07***	161.76 ± 42.00***	6.978	< 0.001
PCIV (μg/L)				
Before treatment	297.83 ± 66.19	281.31 ± 63.84	1.659	0.099
After treatment	82.09 ± 25.86***	154.58 ± 30.41***	16.824	< 0.001
HA (μg/L)				
Before treatment	385.48 ± 79.68	383.84 ± 74.42	0.139	0.890
After treatment	114.45 ± 53.66***	196.36 ± 66.97***	8.851	< 0.001
LN (μg/L)				
Before treatment	261.42 ± 32.19	259.64 ± 30.13	0.373	0.710
After treatment	86.07 ± 24.78***	145.86 ± 28.42***	14.686	< 0.001

Note: ***P < 0.001, intra-group comparison with pre-treatment results. MYGD, modified Yiguanjian decoction; PCIII, type III procollagen; PCIV, type IV procollagen; HA, hyaluronidase; LN, laminin.

Table 6. Comparison of portal vein diameter and spleen size

Factor	MYGD group (n = 88)	Conventional group (n = 83)	Z/t	P
Portal vein diameter (mm)				
Before treatment	14.00 (12.00, 15.00)	14.00 (12.00, 15.00)	-0.229	0.819
After treatment	11.00 (10.00, 12.00)***	12.00 (11.00, 13.00)**	-3.540	< 0.001
Spleen length (mm)				
Before treatment	98.07 ± 5.64	98.84 ± 4.63	0.973	0.332
After treatment	94.98 ± 3.91***	96.88 ± 4.73**	2.870	0.005
Spleen thickness (mm)				
Before treatment	45.53 ± 5.01	44.98 ± 4.31	0.768	0.444
After treatment	40.06 ± 3.89***	42.31 ± 4.08**	3.692	< 0.001

Note: ***P < 0.001, **P < 0.01, intra-group comparison with pre-treatment results. MYGD, modified Yiguanjian decoction.

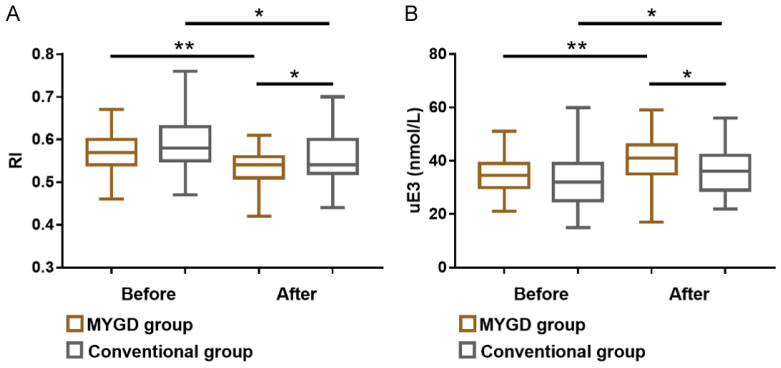

Figure 1. Comparison of Pregnancy-related indicators. A. RI before and after treatment. B. uE3 before and after treatment. Note: **P < 0.01, *P < 0.05. MYGD, modified Yiguanjian decoction; RI, resistance index; uE3, serum estriol.

comfort, elevated blood pressure, and skin rash in both groups. The total incidence of adverse reactions in the MYGD group was 18.18%, which was not significantly different from the 10.84% in the control group (P > 0.05, **Table 7**).

Discussion

HBV infection poses a significant challenge to global public health. Approximately 5.76% of women of childbearing age in China are chronic HBV carriers [16]. During pregnancy, changes in hormone levels and physiologic changes in the immune system can alter the natural course of the disease, leading to reactivation of the HBV and subsequent reactivation phase, which in turn triggers acute exacerbations of CHB [16]. Aggressive antiviral and hepatoprotective therapy can significantly improve liver function and reduce mother-to-child transmission [17]. Although TCM has a long history of treating hepatitis B and has been proven to have anti-inflammatory, anti-fibrotic, and anti-cirrhotic effects, research on the management of acute exacerbations of hepatitis B during pregnancy is still limited.

MYGD is a classic formula with a concise composition, possessing the effects of nourishing the liver and kidneys, and regulating liver qi. It contains no strong blood-activating or qi-depleting ingredients. This formula is widely used clinically, especially for chronic hepatobiliary diseases, and can improve liver biochemical indicators, exerting anti-inflammatory, liver-regulating, bile-promoting, liver-fibrotic delay [18], viral replication inhibition, and anti-cirrhotic effects [19]. MYGD has a definite curative effect and can effectively shorten the course of treatment and delay the progression of the disease. However, there are few studies on the treatment plan of TCM for CHB during pregnancy, and only a small number of small sample studies exist. MYGD is mainly composed of tonifying medicines and does not contain excessive blood-activating or dampness-draining agents, which aligns with the treatment principle of "tonifying and consolidating the fetus" during pregnancy. As a classic prescription for treating "hypochondriac pain" and "accumulation", it corresponds to the TCM pathogenesis description of CHB. Therefore, this study explored the liver protection application of MYGD in pregnant women with CHB dur-

Table 7. Comparison of clinical safety

Factor	MYGD group (n = 88)	Conventional group (n = 83)	χ^2	P
Gastrointestinal discomfort	7 (7.95)	4 (4.82)		
Blood pressure increased	5 (5.68)	3 (3.61)		
Rash	4 (4.55)	2 (2.41)		
Total	16 (18.18)	9 (10.84)	1.843	0.175

Note: MYGD, modified Yiguanjian decoction.

ing pregnancy and observed significant efficacy, with the total effective rate increasing to 90.91% after application. The study of Liu et al. [20] showed that the total effective rate of MYGD in treating patients with primary Sjögren's syndrome was higher than that of conventional western medicine treatment, which is consistent with the results of this study. Additionally, Yin et al. [21] reported that MYGD effectively prevents bone loss in osteoporosis induced by glucocorticoids, and its mechanism may be related to the regulation of taurine and low taurine metabolic pathways. Previous studies have shown that MYGD inhibits the progression of chronic liver disease by mediating pathophysiologic processes such as immune responses, inflammation, energy metabolism, and oxidative stress [22].

In this study, MYGD exerts integrated effects by nourishing yin, softening the liver, tonifying the kidney, invigorating blood, and unblocking the meridians, which precisely targets liver-kidney yin deficiency and meridian stagnation - the core TCM pathogenesis in pregnant women with CHB.

As a formula, Beishashen, Shudihuang, Maidong, and Gouqizi nourish yin and blood, soften the liver and tonify the kidney, thereby stabilizing yin and blood in pregnancy; Danggui, and Danshen are considered to promote blood circulation, remove stasis, and improve microcirculation, alleviating meridian obstruction and enhancing uteroplacental perfusion; Wuweizi astringes and lowers transaminases, while Chuanlianzi soothes the liver and clears heat. Together, these herbs protect the liver, reduce enzymes, improve liver function and inhibit liver fibrosis, while also benefiting fetal development and placental function without increasing adverse reactions.

Consistent with previous studies, MYGD has been shown to ameliorate liver injury, inflammation, and fibrosis through multiple mechanisms, including regulating the Wnt/β-catenin pathway, inhibiting oxidative stress and lipid peroxidation, suppressing macrophage M1 polarization, and modulating inflammatory cytokines [23-27]. Moreover, MYGD improves portal hypertension-related imaging indices and may even exert beneficial effects on metabolic and cognitive function [28], supporting its potential as a safe and effective adjunctive therapy in pregnant women with CHB.

This study had certain limitations and needs further improvement. First, basic research was not conducted to explore the mechanism of action of this combined therapy. In the future, animal experiments or *in vitro* studies should be added to explore the potential therapeutic mechanism and target. Second, long-term efficacy and prognosis assessments of more than five years were not conducted. In the future, long-term follow-up data of more than five years should be provided to further explore the potential advantages of the combined therapy. Finally, the effects of the two treatment regimens on patients' quality of life and sleep were not evaluated. Supplementing relevant data will help clarify the clinical effect of the combined therapy. Further research will be carried out in the above aspects.

In summary, for pregnant patients with CHB, the MYGD enhanced the efficacy, alleviated symptoms, effectively improved liver function, inhibitd liver fibrosis, and demonstrated favorable safety. This formula is a beneficial supplement to the treatment regimen for pregnant women infected with HBV during pregnancy, and deserves further attention.

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Disclosure of conflict of interest

None.

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