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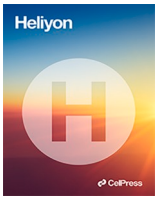

Research article

Trajectory and predictors of adherence to Nucleos(t)ide analogues medication among patients with chronic hepatitis B

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ABSTRACT

Objectives: To investigate the developmental trajectory of medication adherence and its predictors in chronic hepatitis B (CHB) patients taking nucleos(t)ide analogues.
Methods: A longitudinal study was conducted. Patients with CHB who met the inclusion criteria were selected using convenience sampling. Follow-ups were conducted at baseline, 3 months, 6 months, 9 months, and 12 months. Medication adherence was assessed using a medication adherence scale. Group-based trajectory modeling (GBTM) was used to explore medication adherence trajectories, and repeated measures ANOVA was used to describe changes in each trajectory. Unordered multinomial logistic regression analysis was used to explore predictive factors.
Results: A total of 305 patients completed all follow-ups. Medication adherence was categorized into four trajectory groups: low adherence (4.9 %), decreasing adherence (24.3 %), increasing adherence (48.2 %), and high adherence (22.6 %). Multinomial logistic regression results showed that HBV-infected discrimination, depression, self-efficacy, and social support were significantly different among different medication adherence levels ($p < 0.05$).
Conclusions: Medication adherence trajectories in patients with CHB exhibit heterogeneity. Healthcare professionals can develop personalized treatment plans based on patients' social and psychological characteristics to improve medication adherence.

1. Introduction

Chronic Hepatitis B is a chronic inflammatory liver disease caused by Hepatitis B Virus (HBV) infection. HBV infection is a significant global public health concern, with approximately 257 million people worldwide being chronically infected with HBV, and over 30 million cases of CHB, approximately 887,000 deaths occur annually due to HBV-related diseases [1,2]. Studies show that approximately 25 % of untreated chronic HBV patients will eventually die from complications like cirrhosis or liver cancer. For male patients, this risk increases to about 50 % [3].

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The World Health Organization (WHO) has set the goal of "eliminating viral hepatitis as a public health hazard by 2030", but the current rates of diagnosis and treatment for CHB are relatively low, with only 22 % and 15 % in China, respectively [4]. Nucleos(t)ide analogues are effective in treating CHB by suppressing HBV DNA replication, reducing hepatic inflammation and fibrosis [3,4]. The long-term benefit of antiviral therapy depends on patient adherence. Non-adherence can lead to uncontrolled viral replication, the emergence of drug resistance, and disease exacerbation [5]. Model studies suggest that compared to optimal adherence (95 %), lower adherence (65 %) could result in an additional 2.6 million deaths among CHB patients over 15 years [3]. However, medication adherence among CHB patients is generally low, with approximately 30 %–50 % of patients exhibiting varying degrees of non-adherence during long-term treatment [6]. Medication adherence is influenced by multiple factors and exhibits continuity and dynamics, with different individuals showing different adherence trajectories [7]. Yet, there is a lack of research on medication adherence trajectories among CHB patients, highlighting the need to explore their continuous changes and analyze the factors affecting heterogeneous trajectories to facilitate timely intervention targeting modifiable factors.

2. Materials and methods

2.1. Participants

Convenient sampling method was used to select the patients who visited the outpatient department of infectious diseases in Tertiary A Hospital in Suqian from September to December 2022 as the investigation object of this study. This study has been approved by the Medical Ethics Committee with approval number 20220041. The inclusion criteria were as follows: Age $\geq$18 years old; Meeting the diagnostic criteria for CHB in the 2019 "Guidelines for the Prevention and Treatment of CHB"; Taking Nucleos(t)ide Analogues for$\geq$3 months; Willing to participate and able to cooperate actively. The exclusion criteria were: Patients with psychiatric disorders or consciousness disorders; Patients with cirrhosis, liver cancer, or other genetic metabolic liver diseases; Patients with concomitant infections such as Hepatitis A Virus (HAV), Hepatitis C Virus (HCV), Hepatitis D Virus (HDV), Hepatitis E Virus (HEV), Human Immunodeficiency Virus (HIV), etc.; Patients with other severe systemic diseases or pregnancy.

2.2. Sample size calculation

The sample size calculation for this study is based on the sample size formula for proportions, $n = 400Q/p$, where n is the sample size, p is the compliance rate, and $Q = 1\text{-}p$. According to relevant domestic literature, the medication compliance rate is around 60 %. Based on a 60 % compliance rate, the sample size is 267. Considering the study duration is one year, which is relatively long, with an estimated 20 % loss to follow-up, and taking into account the available resources, the final sample size is 305 participants. In addition to the baseline assessment, participants underwent follow-up evaluations at 3, 6, 9, and 12 months.

2.3. Assessment Tools

2.3.1. General information questionnaire

Self-designed based on literature review. Demographic sociologic variables included included age, gender, duration of illness, type of health insurance, education, occupation, monthly income, current place of residence, duration of antiviral treatment, and type of medication taken.

The five assessment scales used in the study have previously been demonstrated to have good reliability and validity and are widely used in related research. In this study, these scales also showed good reliability and validity, with Cronbach's α coefficients all above 0.8.

2.3.2. Morisky medication adherence scale (MMAS)

The Morisky Medication Adherence Scale consists of 8 items, with a total score of 8 points. Scores less than 6 indicate poor adherence, scores between 6 and 7 indicate moderate adherence, and a score of 8 indicates good adherence [8].

2.3.3. Self depression rating scale (SDS)

The depression scale is assessed using the Depression Self-Rating Scale developed by William in 1965. This scale has good reliability and validity and is used to assess depressive symptoms over the past week [9].

2.3.4. Social support rating scale (SSRS)

The scale includes three dimensions (objective support, subjective support, and utilization of support). Higher total and subscale scores indicate better social support [10].

2.3.5. Chronic HBV infection discrimination scale (CHBIDS)

The scale was developed by Feng in 2012 based on the specific situation of Chinese patients with chronic hepatitis B virus infection. A higher score indicates a more severe situation of humiliation and discrimination. The scale has reasonable reliability and validity and can objectively reflect the discrimination experienced by patients with chronic hepatitis B [11].

2.3.6. Self-efficacy for managing chronic disease (CDSES)

This scale aims to assess the confidence of patients in managing various tasks and challenges associated with chronic diseases. A higher total score indicates stronger self-efficacy in self-management [12].

2.4. Data analysis

Statistical analysis was performed using SPSS 26.0 and SAS 9.2 software. Mean ± standard deviation (x ± s) was used to indicate continuous variables, and constitutive ratios were used to indicate categorical variables. Analysis of variance (ANOVA) and $\chi 2$ test were used for comparison between groups.

Group-based trajectory model was constructed with medication adherence scores as the dependent variable and five time points as independent variables. Changes in medication adherence levels across trajectories were described using repeated measures ANOVA. Using multinomial logistic regression analysis to examine whether there are differences among different independent variables in heterogeneous trajectory categories.

3. Results

3.1. Participants

There were 360 patients who met the inclusion criteria, and 345 patients completed the baseline survey. During the 12-month follow-up, 40 patients were lost, and finally 305 patients completed the full follow-up at 5 time points. The general sociological data showed a predominance of males (75.4 %) with ages concentrated in the 18–44 years range (68.2 %). The majority of patients were married (93.8 %), and 43.9 % had attained a college education or higher. Approximately 51.1 % of patients had a disease duration of less than 5 years, and entecavir was the most commonly used antiviral drug (60.7 %).

3.2. GBTM

We used GBTM to identify the trajectory changes in adherence to nucleos(t)ide analogues in patients with chronic hepatitis B. Model fitting was accomplished using the PROC TRAJ procedure developed by Nagin and his colleagues based on SAS [13]. Our aim was to balance model applicability and simplicity, achieving this by combining fit indices with professional interpretability to construct the group-based trajectory model. Fit indices for model performance included Average posterior probability (Avepp%), Proportions per class, Bayesian Information Criterion (BIC), BIC difference between the two models (ΔBIC), and Relative entropy (Ek). Initially, we fitted square trajectory models for six groups (Table 1). By comparing the fit indices of different models and the interpretability of trajectory forms, we ultimately selected a four-group trajectory model. Then, using a stepwise strategy of increasing or decreasing orders, we iteratively fitted trajectory models with linear, quadratic, and cubic terms until all orders had p-values less than 0.05, ensuring statistically significant differences in the fitted models to obtain the optimal trajectory paths (Fig. 1).

The medication adherence varies with distinct characteristics among the different groups (Table 2). Patients in the low adherence group (Group 1) had poor initial adherence levels, and the five-measurement developmental trajectory was non-significant although there was a slight upward trend ($F = 1.018$, $p = 0.44$). Patients in the decreasing adherence group (Group 2) had a moderate level of initial adherence, with a medication adherence score of 5.67 ± 1.16 at baseline, which trended downward over time, decreasing to 4.79 ± 0.96 at the T4 time period, with statistically significant differences in adherence scores between time periods ($F = 5.737$, $P < 0.001$). The medication adherence score of patients in the increasing adherence group (Group 3) was 5.96 ± 0.97 at baseline and tended to increase with time, rising to 6.92 ± 0.59 at the T4 time period, with statistically significant differences in adherence scores across time periods ($F = 25.509$, $P < 0.001$). Patients in the high adherence group (Group 4) had the highest level of adherence and were relatively stable, with no statistically significant difference in medication adherence scores between time periods ($F = 1.802$, $P =$

Table 1
1–6 Group trajectory models evaluation Metrics.

Group	*Avepp(%)*	*OCC*	P_j*(%)*	π_j*(%)*	$BIC^{\#2}$	$\triangle BIC^{\#2}$	E_k
1Group (2)	100.00	.	100.00	100.00	−2770.51		0.000
2Group (2 2)	94.44–98.52	61.7–18.4	21.64–78.36	21.59–78.41	−2426.84	343.67	0.916
3Group (2 2 2)	97.82-94.96-97.42	732.1-24.2-37.0	5.90-44.59-49.51	5.78-43.75-50.47	−2185.75	241.09	0.922
4Group (2 2 2 2)	99.85-96.03-93.10-97.31	12852.3-74.1-15.7-114.4	4.92-24.26-48.20-22.62	5.07-24.59-46.29-24.05	−2050.53	135.22	0.908
5Group (2 2 2 2 2)	99.88-97.23-91.29-93.21-97.82	16415.0-151.0-28.1-33.4-180.9	4.92-18.69-27.87-28.85-19.67	4.96-18.89-27.15-29.12-19.89	−1987.14	63.39	0.913
6Group (2 2 2 2 2 2)	1641610.96-15102.00-2813.16-3050.89-1014.13-.	.-.-.-.-.-.	4.96-18.89-27.15-29.12-11.47-8.42	99.88-97.23-91.29-92.61-56.79-.	−2001.80	−14.66	0.846

Note: Avepp: Average Posterior Probability; BIC: Bayesian Information Criterion; △BIC: Delta Bayesian Information Criterion; Ek: Relative entropy. A good model fit is characterized by: (1) an Overall Classification Correctness (OCC) greater than 5 for each class; (2) a strong consistency between the posterior probabilities (Pj) of group members and the actual group membership probabilities (πj).

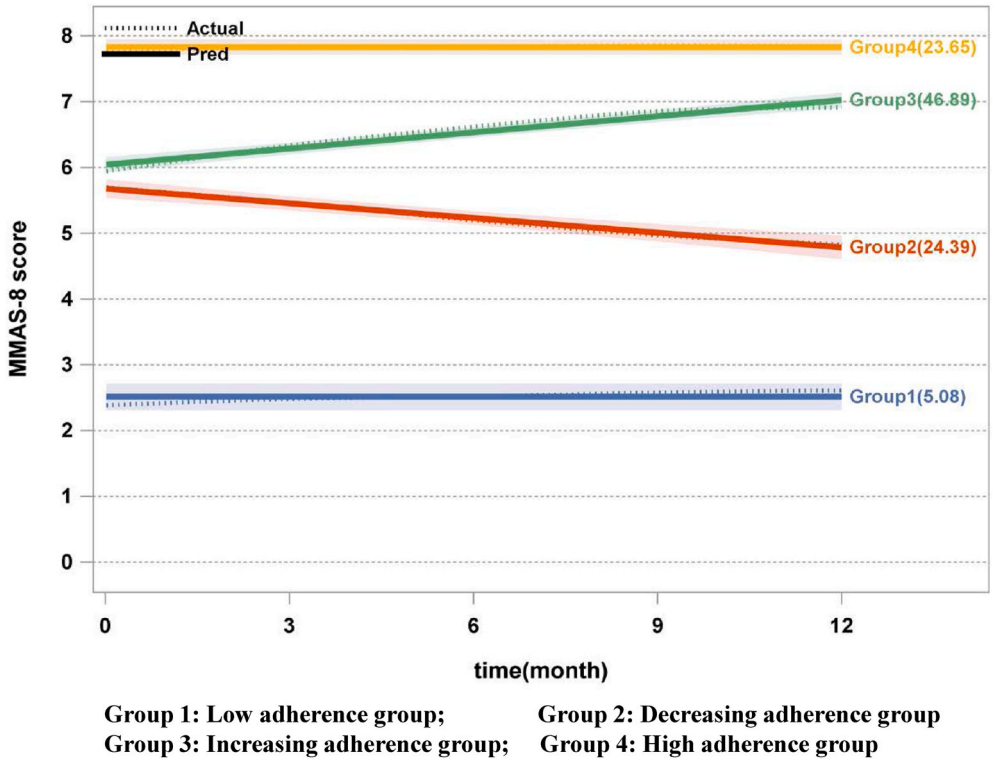

Fig. 1. Four groups GBTM trajectory Plots.

Table 2
Changes in MMAS-8 scores across four groups of medication adherence trajectories.

	low adherence	decreasing adherence	increasing adherence	high adherence	*Z*-value	*P*-value
	(n = 15)	(n = 74)	(n = 147)	(n = 69)		
baseline	2.33 ± 1.03	5.67 ± 1.16	5.96 ± 0.97	7.81 ± 0.44	164.569	<0.01
3 months	2.43 ± 1.08	5.45 ± 0.95	6.33 ± 0.66	7.87 ± 0.31	206.489	<0.01
6 months	2.46 ± 0.74	5.14 ± 0.67	6.63 ± 0.56	7.88 ± 0.32	241.994	<0.01
9 months	2.53 ± 0.99	4.95 ± 0.76	6.85 ± 0.57	7.89 ± 0.34	245.968	<0.01
12 months	2.60 ± 0.91	4.79 ± 0.96	6.92 ± 0.59	7.87 ± 0.45	235.946	<0.01
F	1.018	5.737	25.509	1.802		
P	0.44	<0.001	<0.001	0.139		
Inter-group effects		$F = 715.759$	$P < 0.01$			
Intra-group effects		$F = 0.622$	$P = 0.647$			
Intra-group * Inter-group		$F = 29.040$	$P < 0.001$			

Note: n = number of cases; the medication adherence score for each period is expressed as mean ± standard deviation.

0.139).

Single-factor analysis results showed that disease duration, SDS, SSRS, CHBIDS and CDSES differed significantly among different medication adherence trajectory groups ($P < 0.05$) (Table 3). Using the medication adherence trajectory subgroups as the dependent variable, and disease duration as the independent variable, with SDS, SSRS, CHBIDS and CDSES as covariates, unordered multinomial logistic regression analysis was conducted (Table 4). Compared to the low adherence group, patients in the decreasing adherence group, increasing adherence group, and high adherence group had higher self-efficacy. Additionally, patients in the high adherence group had lower levels of HBV discrimination, higher levels of social support, and lower levels of depression.

4. Discussion

Numerous scholars have applied GBTM in the field of chronic diseases to explore different trajectories and changing characteristics of medication-taking behaviors in patients with chronic diseases. A systematic review on medication adherence trajectories and influencing factors among patients with chronic diseases demonstrated that adherence trajectories and predictive factors might be

Table 3
Baseline characteristics by adherence trajectory grouping.

	N = 305, (n (%)/M(P25, P75))					
	low adherence	decreasing adherence	increasing adherence	high adherence	*χ2/H*	*P*-value
Age						
18-44	11 (5.29)	43 (20.67)	106 (50.96)	48 (23.08)	–	0.405*
45-59	4 (4.49)	27 (30.34)	38 (42.70)	20 (22.47)		
60+	0 (0.00)	4 (50.00)	3 (37.50)	1 (12.50)		
Gender						
Male	13 (5.65)	59 (25.65)	109 (47.39)	49 (21.30)	$\chi^2 = 2.61$	0.455
Female	2 (2.67)	15 (20.00)	38 (50.67)	20 (26.67)		
Ethnicity						
Han	15 (5.03)	73 (24.50)	145 (48.66)	65 (21.81)	–	0.244*
Minority	0 (0.00)	1 (14.29)	2 (28.57)	4 (57.14)		
Marriage						
Married	15 (5.24)	67 (23.43)	139 (48.60)	65 (22.73)	–	0.815*
Unmarried	0 (0.00)	4 (33.33)	6 (50.00)	2 (16.67)		
Divorced	0 (0.00)	3 (42.86)	2 (28.57)	2 (28.57)		
Address						
Urban	9 (4.39)	50 (24.39)	101 (49.27)	45 (21.95)	$\chi^2 = 0.63$	0.889
Rural	6 (6.00)	24 (24.00)	46 (46.00)	24 (24.00)		
Culture						
Below primary school	4 (4.60)	23 (26.44)	47 (54.02)	13 (14.94)	$\chi^2 = 7.41$	0.285
Below high school	3 (3.57)	24 (28.57)	34 (40.48)	23 (27.38)		
college and above	8 (5.97)	27 (20.15)	66 (49.25)	33 (24.63)		
Income						
<3000 yuan	6 (6.74)	25 (28.09)	42 (47.19)	16 (17.98)	$\chi^2 = 3.78$	0.707
3000–5000 yuan	4 (3.77)	23 (21.70)	55 (51.89)	24 (22.64)		
>5000 yuan	5 (4.55)	26 (23.64)	50 (45.45)	29 (26.36)		
disease duration						
<5 years	5 (3.21)	33 (21.15)	82 (52.56)	36 (23.08)	$\chi^2 = 13.70$	**0.033**
5–10 years	8 (7.62)	22 (20.95)	48 (45.71)	27 (25.71)		
>10 years	2 (4.55)	19 (43.18)	17 (38.64)	6 (13.64)		
Payment						
pay one's own expenses	0 (0.00)	12 (27.91)	22 (51.16)	9 (20.93)	$\chi^2 = 3.46$	0.749
Employee insurance	8 (5.84)	30 (21.90)	66 (48.18)	33 (24.09)		
Resident insurance	7 (5.60)	32 (25.60)	59 (47.20)	27 (21.60)		
Anti-viral drug						
Entecavir	10 (5.71)	47 (26.86)	83 (47.43)	35 (20.00)	–	0.194*
Tenofovir	4 (3.39)	22 (18.64)	61 (51.69)	31 (26.27)		
Double medicine	1 (8.33)	5 (41.67)	3 (25.00)	3 (25.00)		
***CHBIDS* [$M(P_{25},P_{75})$]**	81 (78,82)	74 (71,76)	67 (64,72)	56 (42,61)	$H = 158.92$	**<0.001#**
***CDSES* [$M(P_{25},P_{75})$]**	22 (18,30)	36.5 (34,39)	45 (40,48)	53 (48,59)	$H = 170.08$	**<0.001#**
***SDS* [$M(P_{25},P_{75})$]**	65 (61,66)	49.5 (45,55)	45 (43,49)	38 (36,41)	$H = 135.44$	**<0.001#**
***SSRS* [$M(P_{25},P_{75})$]**	29 (28,32)	34. (32,36)	36 (34,38)	40 (38,42)	$H = 131.74$	**<0.001#**

Note: "*" indicates Fisher's exact probability method; "#" indicates rank sum test.

similar among specific population groups across different disease states [14].

In this study, most patients were at moderate or poor levels of medication adherence during the 12-month follow-up, consistent with previous studies [15]. How to achieve and maintain "good" medication adherence among CHB patients remains a crucial issue. We found that patient self-efficacy has a positive predictive effect on medication adherence among CHB patients, which was consistent with the results of studies by Kong [16] and Huang [17]. Self-efficacy directly influences patients' self-management behaviors, confidence in treatment plans, and ultimately shapes their good medication adherence during long-term treatment [18]. Discrimination against HBV-infected individuals constitutes a potential major barrier to the successful implementation of HBV infection prevention, diagnosis, and treatment strategies [19]. This study found that in the heterogeneous trajectory of medication adherence among patients with CHB, the level of HBV-infected individuals' discrimination in the low adherence unchanged group was 1.3 times higher than that in the high adherence group. The discrimination not only affects the psychological state of patients but also extends to various aspects of their social interaction and medical behavior [20]. More importantly, this pressure may lead to a decrease in patients' medication adherence or even treatment interruption [21]. Furthermore, discrimination against HBV-infected individuals may directly decrease patients' self-efficacy [22].

This study also found that in the heterogeneous trajectory of medication adherence, the level of depression in patients with consistently low adherence was 1.28 times higher than that in patients with consistently high adherence. The higher the level of depression, the worse the medication adherence of the patients. Studies have shown that compared to healthy individuals, the prevalence of depression is higher among patients with chronic hepatitis B, with 20%–40 % of HBV patients experiencing varying degrees of depression [23–25]. Depressive symptoms may lead to a decreased interest and motivation in treatment plans, doubts about the necessity and effectiveness of treatment, reduced enthusiasm for medication, consequently leading to lower medication adherence

Table 4
Unordered multi-class logistic regression.

	Variables		*β*	*Wald*	*P value*	*OR(95%CI)*
Group2- Decreasing adherence	Intercept		−8.304	0.392	0.531	
	CHBIDS		−0.078	0.41	0.522	0.925 (0.729,1.174)
	CDSES		0.244	6.207	**0.013**	1.276 (1.053,1.546)
	SSRS		0.435	2.334	0.127	1.546 (0.884,2.702)
	SDS		−0.062	0.63	0.427	0.939 (0.805,1.096)
	Disease duration	<5 years	−1.681	1.312	0.252	0.186 (0.01,3.305)
		5–10 years	−2.722	3.197	0.074	0.066 (0.003,1.299)
		>10 years				
Group3- Increasing adherence	Intercept		−17.405	1.506	0.22	
	CHBIDS		−0.145	1.29	0.256	0.865 (0.674,1.111)
	CDSES		0.486	20.785	**<0.001**	1.626 (1.319,2.004)
	SSRS		0.556	3.57	0.059	1.743 (0.979,3.102)
	SDS		−0.058	0.472	0.492	0.944 (0.8,1.113)
	Disease duration	<5 years	−1.438	0.862	0.353	0.237 (0.011,4.942)
		5–10 years	−2.246	1.961	0.161	0.106 (0.005,2.452)
		>10 years				
Group4-High adherence	Intercept		−13.068	0.73	0.393	
	CHBIDS		−0.267	4.095	**0.043**	0.766 (0.591,0.992)
	CDSES		0.583	25.876	**<0.001**	1.792 (1.431,2.243)
	SSRS		0.684	4.905	**0.027**	1.983 (1.082,3.633)
	SDS		−0.245	6.078	**0.014**	0.783 (0.644,0.951)
	Disease duration	<5 years	−0.125	0.005	0.944	0.882 (0.028,28.155)
		5–10 years	−1.396	0.585	0.444	0.248 (0.007,8.854)
		>10 years				

Note: Reference Group - Group 1-low adherence.

[21]. Therefore, for CHB patients with depressive symptoms, besides regular medication treatment, attention to their mental health status is also needed.

Many studies have shown that social support is positively correlated with medication adherence in patients, with increased social support closely associated with improved medication adherence [26]. Research indicates that the level of social support among patients in the sustained high adherence group is 1.98 times higher than that of patients in the consistently low adherence group. Adequate social support can enhance patients' motivation and confidence in treatment in various aspects, thus improving medication adherence. When formulating treatment plans, healthcare teams should emphasize the role of social support, encourage patients to actively engage in social support networks, and thereby enhance treatment experiences and overall health conditions [27].

The COVID-19 pandemic may have various impacts on the adherence to nucleos(t)ide analogue medications among patients with chronic hepatitis B. We analyzed patient medication adherence data before and during the pandemic and compared it with previous baseline data. The results show that despite disruptions in medical services and drug supply chains during the pandemic, the overall change in medication adherence was not significant. Many patients coped with the challenges brought by the pandemic by increasing their use of telemedicine services and utilizing multiple medication purchasing channels, such as pharmacies and online platforms. These coping strategies may have helped mitigate the potential negative impact of the pandemic on adherence. Furthermore, the impact of the pandemic on medication adherence varies by region, and with appropriate support and management, adherence can be effectively maintained. This conclusion can help guide future clinical practice and policy-making to ensure that patients continue to receive effective treatment support during similar public health emergencies.

4.1. Limitations

Considering the practical circumstances, this study only selected patients from a single hospital for the survey. Compared to the broad population of CHB patients, the sample in this study may lack representativeness. Future studies should consider conducting multicenter research with large sample sizes and combining qualitative research for in-depth comparative analysis to make the findings more convincing and generalizable.

Additionally, this study assessed patients' medication adherence through self-reports, which are subjective and may differ from the actual situation. This could impact the study's findings, and more objective methods to evaluate medication adherence should be employed in future research.

5. Conclusion

This study views medication adherence as a continuous process of group behavior change among patients in the context of long-term medication therapy and proposes four potential categories of medication adherence groups. Preliminary exploration suggests that patients' medication adherence is significantly influenced by socio-psychological factors, with self-efficacy and social support playing positive roles in medication adherence, while depression and discrimination against HBV-infected individuals lead to decreased medication adherence. Unlike existing studies that focus on patient-related factors, disease-related factors, and treatment-related

factors, this study identifies socio-psychological factors that provide a new perspective for subsequent medication adherence interventions. The sample size of this study is relatively limited, and future large-scale studies are expected to validate this viewpoint.

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Data availability statement

The data in this study is confidential. Please contact the corresponding author when needed.

CRediT authorship contribution statement

Lin Zhang: Writing – review & editing, Writing – original draft, Supervision, Project administration, Investigation, Data curation. **Jinping Tian:** Methodology, Formal analysis. **Di Xu:** Methodology, Data curation. **Yunyue Liu:** Data curation. **Zhenjiang Zhang:** Writing – review & editing, Supervision, Resources, Project administration.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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