Prevalence of Chronic Hepatitis B Infection in Patients with Systemic Lupus Erythematosus: Viral Reactivation and Impact on Disease Activity

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Background: Hepatitis B virus (HBV) infection is prevalent in many parts of the world, especially in South East Asia, and reactivation of HBV can occur after patients receive immunosuppressive agents. Systemic Lupus Erythematosus (SLE) is one of the most important autoimmune diseases because of its high morbidity and mortality rates. Most SLE patients need corticosteroid and immunosuppressive drugs as a treatment regimen; however, there are conflicting recommendations for screening for HBsAg in patients undergoing immunosuppressive therapy and diverse theories about the impact of chronic HBV infection on clinical manifestations of SLE and its activity. As there is no data on the prevalence of HBV infection in Thai SLE patients, and its secondary aim was to determine the impact of HBV infection in SLE patients.

Material and Method: A cross-sectional study was conducted between November 2013 and February 2014 to determine the prevalence of HBV infection in Thai SLE patients in Rajavithi Hospital. All participants were screened for Hepatitis B surface Antigen (HBsAg). Clinical manifestations of SLE such as arthritis, rash, nephritis, lupus nephritis, were recorded, and abnormal laboratory investigations, including serological tests, were noted, together with details of all medications used. Data of SLE patients with HBsAg positive were compared with those of HBsAg-negative patients.

Results: One hundred and thirty-four Thai SLE patients were included in the study, and the prevalence of HBV infection in these patients was 1.5% (2/134), which is lower than in the Thai general population. No differences were found between clinical manifestations of SLE, abnormal laboratory investigations, and treatments of patients with HBsAg positive SLE patients and those of HBsAg-negative patients. Neither HBsAg-positive SLE patients nor those who were HBsAg negative had cirrhosis or hepatocellular carcinoma. Neither group had evidence of acute transaminitis during their disease course, even though one patient had high HBV viremia and had not received any antiviral prophylaxis.

Conclusion: The results showed that the prevalence of chronic HBV infection in SLE patients was lower than in the general population. Even though they had received high doses of corticosteroid and immunosuppressive agents, no HBV reactivation was found in these SLE patients with chronic HBV infection.

Keywords: Systemic lupus erythematosus, Hepatitis B virus, Prevalence, Impacts

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Hepatitis B virus (HBV) is a contagious disease that can be transmitted from the blood or body fluids of an infected person and by vertical transmission from mothers to their offspring. The prevalence of chronic hepatitis B infection is about 5% worldwide, but differs between regions. Infection rates are highest in southeast Asia and in sub-Saharan regions, reaching levels as high as $8.0\text{-}20.0\%^{(1)}$. In

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Thailand the prevalence of chronic HBV infection from healthy blood donors decreased from 7.14% in 1974 to 2.63% in 2009, and this may have been a result of the national health program of HBV vaccination⁽²⁾. HBV infection can attack hepatocytes and cause both acute and chronic infection. Chronic HBV infection causes many serious complications such as hepatitis, hepatic failure, cirrhosis or even hepatocellular carcinoma. Systemic lupus erythematosus (SLE) is an autoimmune disease whose activity waxes and wanes during its natural course, and the use of glucocorticoid and immunosuppressive drugs cannot usually be avoided in these patients. At present, there are inconsistent recommendations with regard to screening for HBV infection in order to facilitate antiviral prophylaxis

in SLE patients before starting treatment with glucocorticoid and immunosuppressive drugs. A recent study of HBV patients being treated with immunosuppressive drugs found that HBV could be reactivated under these circumstances and suggested giving antiviral prophylaxis to patients at high risk of reactivation⁽³⁾. Data regarding the effects of HBV infection in the natural course of SLE is still scanty. A previous study using indirect immunofluorescence showed an association between HBV infection and active lupus nephritis, finding a high prevalence of HBV-associated antigen deposition in the renal tissue of patients with SLE, which resulted in greater build-up of immuloglobulin deposits in the mesangial and vascular loop region than in SLE patients without these deposits⁽⁴⁾. On the other hand, a recent study found that mice infected with HBV had a lower prevalence of SLE and less severe glomerulonephritis(5). The objective of the present study was to determine the prevalence of HBV infection in SLE patients and to identify the association between chronic HBV infection and SLE clinical manifestation and activity.

Material and Method

The protocol of this research was reviewed and approved by the ethics committee of Rajavithi Hospital (No. 184/2556). All SLE patients who followedup at the out-patients rheumatology clinic, Rajavithi Hospital, between November 2014 and February 2015 were consecutively invited to take part in the study. All participants had to fulfil 1997 SLE classification criteria⁽⁶⁾, be aged more than 18 years old, and give informed consent. Enrolled patients were tested for HBV surface antigen (HBsAg) which was analyzed using the chemiluminescent microparticle immuneassay (CMIA) technique (Abbot model Architect system). All clinical parameters of SLE manifestation and disease activity were collected, including complete blood count (CBC), aspartate aminotransferase (AST), alanine aminotransferase (ALT), total bilirubin (TB), directed bilirubin (DB), alkaline phosphatase (ALP), antinuclear antibodies (ANA), anti-double stranded antibody (antidsDNA), urinalysis (UA), and urine protein creatinine ratio (UPCR). Glucocorticoid and immunosuppressive drugs used were also recorded. All participants were evaluated for SLE disease activity using SLEDAI2K which is an ordinal scale ranging from 0 to 105. The higher scores imply high disease activity and scores lower than 4 imply inactive disease. Chronic HBV infection was identified by positive HBsAg from blood tests. Reactivation was defined as clinical and

laboratory findings indicating acute viral hepatitis with no other causes such as drug-induced or acute lupus hepatitis.

Statistical analysis

Prevalence rates were calculated and presented as percentages while continuous variables were expressed as mean \pm SD. Categorical variables were shown as number (percent), and Independent-T test or Mann-Whitney U test were used to compare the means of the 2 groups as appropriate. Chi-square or Fisher's exact test were used as appropriate for comparing proportions. All reported *p*-values were 2-sided with *p*<0.05 set as the threshold for statistical significance.

Results

Four hundred SLE patients were followed-up at the Outpatients Department of the Rheumatology Clinic, Rajavithi Hospital. A total of 134 patients were screened and their baseline characteristic were evaluated. The participants were divided into 2 groups based on their HBsAg status, and the data of the two groups, including age, SLE disease manifestation, medication used and SLEDAI2K, were recorded (Fig. 1).

The prevalence of chronic HBV infection and viral reactivation

A total of 134 SLE patients were included in the study. Mean age was 37.22±11.77 years, the vast majority of the patients (98%) were female, and only two (1.5%) were positive for HBsAg. With regard to medical reimbursement status, 62 of the 134 (46.6%) were in Thailand's universal coverage (UC) scheme, 44 (33.1%) had social security coverage, 17 (12.8%) had private sector coverage, 9 (6.8%) were in the government scheme, and 1 (0.8%) paid independently. One of the patients with HBsAg positive had private sector coverage and the other had social security coverage. A total of 53 of the 132 (40.2%) SLE patients with negative HBsAg lived in the Bangkok area, while



Fig. 1 Study flowchart for patient enrollment.

the others (59.8%) lived in rural areas. Both HBsAg positive patients lived in the Bangkok area. Twenty-three of the 132 (17.4%) patients with HBsAg negative had at least one episode of transaminitis, but the two patients with HBsAg positive did not. The demographic data of the two groups are shown in Table 1.

The impact of chronic HBV infection on SLE manifestation and SLE disease activity

All 134 SLE patients were evaluated for SLE disease manifestation and SLEDAI2K. The mean SLEDAI2K of all SLE patients was 13.45 ± 5.52 . Patients with positive HBsAg were found to have lower SLEDAI2K than patients with negative HBsAg (p=0.02). There was no difference between the clinical characteristics or autoantibodies in the two groups. Data are shown in Table 2.

There was no statistical significance between medications used by the two groups. Data are presented in Table 3.

One patient with HBsAg positive was a 29-year-old teacher who had had SLE for 11 years. She had active lupus nephritis and seizure, and she was

treated with high doses of corticosteroid, with an accumulative dose of 20 grams, cyclophosphamide and azathioprine. Her SLEDAI2K was 10, and serologic test for HBV revealed HBsAg positive, antiHBs negative, antiHBcIgG positive, HBeAg positive and antiHBe negative. Test for HBV DNA showed >177 iu/ml (log >8.23 log iu/ml). She received no antiviral treatment, and there was no evidence of transaminitis during the course of the disease, even though this patient had high viremia. She had moderately active disease activity with a SLEDAI score of 10, and she had chronic kidney disease due to active lupus nephritis. Another patient with HBsAg positive was a 47-year-old female who had had SLE for 9 years. Her cumulative dose of corticosteroid was 4 grams, and HBV serology revealed HBsAg positive, antiHBs negative, antiHBc IgG positive, HBeAg positive, antiHBe negative. Test for HBV DNA revealed <20 iu/ml (log <1.3 log iu/ml). She was treated with lamivudine 150 mg per day. After treatment, her HBV serological status reversed from HBeAg positive to negative and antiHBe negative to positive. She had no evidence of transaminitis or HBV reactivation during the disease course.

Table 1. Demographic data of SLE patients

	HBsAg negative $(n = 132)$	HBsAg positive (n = 2)	<i>p</i> -value*
	(n = 132)	(n – 2)	
Female (%)	130 (98.0)	2 (100)	0.802
Age (year) (mean \pm SD)	37.20 <u>+</u> 11.81	38 <u>+</u> 12.73	0.931
Duration of SLE (mean \pm SD)	8.97 <u>+</u> 6.51	10.00 <u>+</u> 1.41	0.834
Comorbid diseases (%)			
Hypertension			
DM	7 (5.3)	0/2	0.732
CAD	2 (1.5)	0/2	0.864
CVA	1 (0.75)	0/2	0.893
Osteoporosis	13 (9.8)	0/2	0.612
Osteoarthritis	10 (7.6)	0/2	0.671
Malignancy	4 (3.0)	0/2	0.790
Breast cancer	1		
Cervical cancer	2		
GIST	1		
Medical reimbursement			0.472
Thailand universal coverage	49 (37.1)	0	
Social security	60 (45.5)	1	
Government scheme	13 (9.8)	1	
Private sector coverage	9 (6.8)	0	
Self-payment	1 (0.7)	0	

Values are presented as n (%), SD = standard deviation

^{*} Chi-square

Table 2. Comparison of SLE clinical manifestation of patients with HBsAg positive and HBsAg negative

Clinical manifestation of SLE	HBsAg	HBsAg	<i>p</i> -value*	
	negative $(n = 132)$	positive $(n = 2)$		
		(/		
Photosensitivity	36 (27.3)	0	0.392	
Malar rash	60 (45.5)	1 (50.0)	0.903	
Oral ulcer	46 (34.8)	1 (50.0)	0.662	
Discoid rash	37 (28.0)	1 (50.0)	0.491	
Arthritis	95 (72.0)	1 (50.0)	0.492	
Seizure	10 (7.6)	0	0.153	
Psychosis	13 (9.8)	0	0.818	
AIHA	51 (38.6)	0	0.263	
Leucopenia	37 (28.0)	0	0.381	
Thrombocytopenia	21 (16.0)	0	0.542	
Nephritis and/or proteinuria)	63 (47.7)	1 (50)	0.954	
UPCR (mean \pm SD)	2.82 <u>+</u> 4.26	2.32	0.912**	
Anti-dsDNA positive	86 (88.7)	2 (100)	0.613	
ANA pattern				
Homogenous	68 (51.8)	2 (100)	0.634	
Cytoplasmic	8 (6.0)	0	0.934	
Nucleolar	25 (19.2)	0	0.816	
Speckle	72 (54.2)	0	0.649	
Peripheral	10 (7.2)	0	0.921	
Anti-centromere	2 (1.2)	0		
Vasculitis	25 (18.9)	0	0.502	
Organic brain syndrome	4 (3.0)	0	0.804	
Visual disturbance	4 (3.0)	0	0.792	
Lupus headache	2 (1.5)	0	0.861	
Myositis	6 (4.5)	0	0.763	
Hematuria	7 (5.3)	0	0.744	
Proteinuria	61 (46.2)	1 (50)	0.921	
Pyuria	1 (0.8)	0	0.903	
Alopecia	113 (85.6)	1 (50)	0.164	
Pleurisy	8 (6.1)	0	0.722	
Pericarditis	5 (3.8)	0	0.781	
SLEDAI2K	13.34±5.34	10.5±0.70	0.022**	

Values are presented as n (%)

Discussion

Data gathered from Thai healthy blood donors revealed that the prevalence of chronic HBV infection decreased from 4.2% in 1978 to 2.63% in 2009⁽²⁾. This lower incidence of chronic HBV infection in the Thai population may be due to the government vaccination program; however, chronic HBV infection still causes serious complications, especially in immunocompromised patients. There have been many reported cases of HBV reactivation in patients with hematologic malignancy who received chemotherapy causing high morbidity and mortality either due to

HBV reactivation itself or because of their other disease outcomes⁽⁷⁾. SLE is one of the most important autoimmune diseases, having high rates of mortality and morbidity. As a result of the wax-and-wane nature of the disease activity, most SLE patients need treatment with corticosteroid and immunosuppressive drugs. It has been proposed that chronic infection is part of the etiology of SLE. The study by Looi et al showed evidence of HBV-associated antigen deposits within the kidney in 63.8% of biopsies from SLE patients⁽⁸⁾ which is consistent with another study by Wang et al which also found the deposition of HBsAg in a kidney

^{*} Chi-square test; ** student t-test

Table 3. Comparison of medication used in group with HBsAg positive and that of HBsAg negative patients

Medication use	HBsAg negative	HBsAg positive	<i>p</i> -value*
Chloroquine	73 (55.3)	1 (50)	0.881
Hydroxychloroquine	61 (46.2)	1 (50)	0.923
Cyclophosphamide	20 (15.2)	1 (50)	0.197
Azathioprine	63 (47.7)	1 (50)	0.289
Mycophenolate mofetil	21 (15.9)	0	0.542
Cyclosporin	1 (0.8)	0	0.898
Methotrexate	21 (15.9)	0	0.544
Cummulative dose of prednisolone (gram) (mean \pm SD)	22.29 ± 18.89	12.09 ± 11.29	0.451**

Values are presented as n (%)

biopsy of lupus nephritis patients was 50.6%, with a resultant increase in immunoglobulin deposits in the mesangial and vascular loop region of the kidney biopsy⁽⁴⁾. There is a paucity of information about the prevalence of chronic HBV infection in SLE patients in Thailand. The present study found that its prevalence was only 1.5%, which is lower than in the general population, and this is similar to the findings of a previous study by Chen et al, who also found a lower prevalence of chronic HBV infection in SLE patients than in the general population⁽⁹⁾. The lower incidence of chronic HBV infection in SLE patients may be caused by the wide variety of HBV screening techniques used. Another reason may hypersecretion of interferon alpha found in the sera of SLE patients which has a protective role in combating HBV infection(10). Another hypothesis can be found in the study of Sui M et al(11) which compared the prevalence of chronic HBV infection in patients with and without autoimmune diseases. He found a lower prevalence of chronic HBV infection in patients with autoimmune diseases than in patients without them, and he proposed that patients with autoimmune diseases had more effectively clear HBV than patients without them⁽¹¹⁾. We also found that SLEDAI2K in SLE with chronic HBV infection group was lower than in patients without chronic HBV infection, which may be explained by the findings of a study by Lin et al which found that that HBV infection may play a protective role in SLE pathogenesis due to the altered function of dendritic cells⁽¹²⁾; moreover, HBV may induce host immunological tolerance by increasing the number of regulatory T cells in peripheral blood mononuclear cells(13). There is sparse data regarding the impact of chronic HBV infection and HBV reactivation in SLE patients, especially in those who

are on immunosuppressive drugs. HBV reactivation is increasingly being encountered and has caused significant morbidity and mortality. Guidelines on the prevention and treatment of hepatitis B virus reactivation during immunosuppressive drug therapy(14) have suggested that in order to prevent HBV reactivation, patients who need immunosuppressive drugs should undergo risk stratification based on HBV serological status and type of immunosuppressive drugs in order establish whether they should be given antiviral prophylaxis. Two patients had positive HBsAg in the present study. Both of them were at high risk of HBV reactivation as a result of receiving high accumulative doses of corticosteroid, and one of the patients had received concurrent cyclophosphamide. One of them had high HBV viremia, and the other had low HBV viremia. But surprisingly, there was no evidence of acute hepatitis flare in either patient. Our study showed that patients with HBsAg positive who were on immunosuppressive drugs and used high accumulative doses of corticosteroid showed no evidence of viral reactivation or transaminitis. The study of Xuan et al found a rate of hepatitis B virus reactivation in 12 rheumatologic patients of about 16.6% (2/12) with median follow-up duration of 41 years⁽¹⁵⁾.

Conclusion

The prevalence of chronic HBV infection in SLE patients in Thailand is only 1.5%, which is lower than in the general Thai population; furthermore, SLE patients with chronic hepatitis B in the present study were found to have lower SLEDAI2K. There was no evidence of hepatitis B virus reactivation occurring during the course of the disease, even though the patients had high viral viremia and were simultaneously

^{*} Chi-square test; ** student t-test

on high doses of corticosteroid and immunosuppressive drugs. Our study had some limitations: due to the small sample size and short study period, it could not establish the impact of HBV infection on SLE disease activity or the long-term consequences of chronic HBV infection. Further studies are required to determine the role of antiviral therapy in SLE patients with concurrent immunosuppressive drugs.

What is already known on this topic?

HBV infection is prevalent in many part of the world. Even though trend of the new infection in general population is decreasing due to good immunization program but the serious consequences after chronic HBV infection are still remain. The present study also shows lower rate of chronic HBV infection in SLE patients compares with general population which is in the same way as the previous studies.

What this study adds?

There is scantly data about the effect of chronic HBV infection in SLE patients who use high dose corticosteroid with or without immunosuppressive drugs. This study shows no viral reactivation in 2 SLE patients who had chronic HBV infection and concurrently use steroid and immunosuppressive drug even though they had not received antiviral prophylaxis. Long term consequence of chronic HBV infection such as cirrhosis and hepatocellular carcinoma are not found in this study.

Potential conflicts of interest

None.

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ความชุกของภาวะการติดเชื้อไวรัสตับอักเสบ บี เรื้อรังในผู[้]ป่วยเอสแอลอี: ภาวะการกำเริบกลับซ้ำของไวรัสบี และผลกระทบต[่]อ ภาวะการกำเริบของโรค

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ภูมิหลัง: ภาวะการติดเชื้อไวรัสดับอักเสบ บี ยังสามารถพบได้แพร่หลายในหลายส่วนของโลก โดยเฉพาะอย่างยิ่งแถบเอเชียตะวันออกเฉียงใต ้การกำเริบ กลับซ้ำของเชื้อไวรัสดับอักเสบ บี สามารถเกิดขึ้นได้ในผู้ป่วยที่ได้รับการรักษาด้วยยากดภูมิคุ้มกันเอสแอลอี เป็นหนึ่งในโรคทางด้านอิมมูโนวิทยา ้ที่มีความสำคัญ เนื่องจากสามารถทำให้เกิดภาวะทุพลภาพและการเสียชีวิตได้ ผู้ป่วยเอสแอลอีสวนใหญ่มีความจำเป็นต้องได้รับการรักษาด้วย ยาคอดิโคสเตียรอยด์ และหรือ ยากดภูมิคุมกันปัจจุบันยังมีความสับสนของคำแนะนำในการตรวจคัดกรองหาการติดเชื้อไวรัสตับอักเสบบีในผู้ป่วยเอสแอลอี นอกจากนั้นแล้วยังมี ข้อมูลจำกัดในเรื่องผลกระทบของภาวะการติดเชื้อไวรัสตับอักเสบบีเรื้อรังต[่]ออาการ อาการแสดงของผู*้*ป่วยเอสแอลอี รวมไปถึงภาวะการกำเริบของโรคเอสแอลอี และการกำเริบกลับซ้ำของไวรัสตับอักเสบบีในผู้ป่วยเอสแอลอีที่ได้รับการรักษาด้วยยาคอดิโคสเตียรอยด์ และหรือยากคภูมิคุ้มกัน เนื่องจากปัจจุบันยังไม[่]มีข้อมูลความชุกของภาวการณ์ติดเชื้อไวรัสดับอักเสบเรื้อรังในผู*้*ป่วยเอสแอลอีในประเทศไทย ้ ดังนั้นวัตถุประสงค์แรกของงานวิจัยนี้ ได้แก่ การประเมินความชุกของภาวะการติดเชื้อไวรัสตับอักเสบ บี เรื้อรัง ในผู้ป่วยเอสแอลอีและวัตถุประสงค์รองได้แก่ การประเมินผลกระทบจากภาวะ การติดเชื้อไวรัสตับอักเสบ บี ต่ออาการและอาการแสคงภาวะการกำเริบของโรคเอสแอลอี วัสดุและวิธีการ: การศึกษานี้เป็นการศึกษาแบบตัดขวางเพื่อทำการศึกษาหาขวามชุกของการติดเชื้อไวรัสตับอักเสบบีเรื้อรังในผูป่วยเอสแอลอี ที่ไดรับการรักษาติดตามอาการที่โรงพยาบาลราชวิถี ในระหวางเดือนพฤศจิกายน พ.ศ. 2556 ถึง เดือนกุมภาพันธ์ พ.ศ. 2557 โดยผูเขารวมการศึกษาทุกราย จะได้รับการคัดกรองตรวจหา Hepatitis B surface Antigen (HBsAg) โดยมีการเก็บข้อมูลของอาการและอาการแสดงของโรคเอสแอลอี เช่น ข้ออักเสบ ผื่น ไดอักเสบ ภาวะโปรตีนรั่วในปัสสาวะ รวมไปถึงการเก็บข้อมูลจากห้องปฏิบัติการ ได้แก่ การตรวจซีโรโลจี และเก็บข้อมูลของยาตาง ๆ ที่ใช้ในการรักษาโรค ขอมูลที่ใดจะถูกทำการแบงเป็นสองกลุ่มตามผลบวกของ Hepatitis B surface Antigen (HBsAg) และนำมาเปรียบเทียบกัน ผลการศึกษา: มีผู้ป่วยเอสแอลอี เข้ารวมการศึกษาทั้งสิ้น 134 ราย ความชุกของภาวะการติดเชื้อไวรัสตับอักเสบบีเรื้อรังที่ใดจากการศึกษานี้มีค่าเทากับ 1.5% (2/134) ซึ่งเป็นอัตราที่ต่ำกวาที่ตรวจคัดกรองพบในประชากรไทยโดยทั่วไป นอกจากนั้นไมพบความแตกตางของอาการและอาการแสดงของ . ผูป่วยเอสแอลอี ความผิดปกติของผลตรวจทางหองปฏิบัติการรวมไปถึงยาที่ใชในการรักษาโรคในผู้เขารวมการศึกษาทั้งสองกลุ่ม ไม**่**พบภาวะดับแข็ง และมะเร็งตับ hepatocellular carcinoma ในผู้ป่วยเอสแอลอีที่มีภาวะการติดเชื้อไวรัสตับอักเสบบีเรื้อรังและกลุ่มผู้ป่วยที่ไม่มีอาการ ติดเชื้อไวรัสตับอักเสบ บี เรื้อรัง นอกจากนั้นยังไมพบวามีการเกิดภาวะตับอักเสบในผูป่วยรายที่มีภาวะการติดเชื้อไวรัสตับอักเสบ บี เรื้อรัง และได้รับการรักษาด้วย ยาคอดิโคสเตียรอยค์และยากคภูมิคุ้มกัน แม้วามีผู้ป่วยหนึ่งรายที่มีจำนวนไวรัสในกระแสเลือดในระดับสูงและไม่ใครับการรักษาค้วยยาต้านไวรัสใค ๆ สรุป: ผลการศึกษานี้ชี้ใหเห็นวาความชุกของการติดเชื้อไวรัสตับอักเสบบีเรื้อรังในผู้ป่วยเอสแอลอี มีระดับต่ำกวาในประชากรทั่วไป แม้วาผู้ป่วยเอสแอลอี ที่มีการคิดเชื้อไวรัสตับอักเสบเรื้อรังจะไครับการรักษาดวยยาคอติโคสเตียรอยด์และยากดภูมิคุ้มกันในระดับสูง แค่ไม่พบการกำเริบกลับซ้ำของไวรัสตับอักเสบบี ในระหวางการดำเนินโรคของผู้ป่วย