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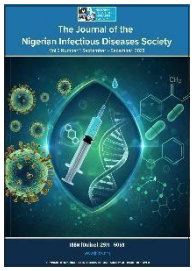

Original Article

Clinical Profile of Newly Diagnosed Chronic Hepatitis B Infected Patients in Kano, Nigeria

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ABSTRACT:
Chronic Hepatitis B infection is a public health disease of the liver that may transformed to cirrhosis, and subsequently to hepatocellular carcinoma. Objectives: This study was carried out to determine the clinical and laboratory profiles in the patients with chronic hepatitis B infection in Aminu Kano Teaching Hospital. **Methods:** This was a descriptive cross-sectional study of consecutively recruited 204 consenting treatment naïve CHB patients over a period 6 months after excluding HCV, HIV and metabolic syndrome, using administered questionnaires to obtain the biodata and blood sample were taken for the immunological panel, LFTs and HBV DNA levels. The data obtained was analyzed using SPSS version 20.
Result: Two hundred and four (204) patients, males (72.1%), took part in the study. Their ages ranged from 19 to 48 years with a mean of 31.4±7.4. About 49.2% of the patients had HBV-DNA levels greater than 2000 IU/mL with significant male preponderance (p = 0.03), 171 patients (83.8%) of the patients were *HBeAg* negative. Male patients had a significantly higher ALT levels compared to females (22.5 vs 15, p = 0.01). Treatment was indicated in 27 (13.2%) of the patients based on abnormal ALT level plus high HBV DNA and positive family history of HCC and health worker with normal ALT but high HBV DNA.
Conclusion: The study showed that most chronic HBV infection in Kano were males with higher HBV DNA level, and *HBeAg* negative. Also, it showed that serum ALT, HBV DNA counts and clinical profiles consideration were essential for possible commencement of treatment to avert the undesirable consequences.

Keywords: Chronic HBV Infection, LFT, ALT, HBV DNA, CLD, HCC

INTRODUCTION

Hepatitis B virus (HBV) infection is an important public health problem with estimated global prevalence of 257 million.[1] The global burden of the disease, injuries and risk factors study estimated that 1,030,000 and 75,000 people died respectively of liver cirrhosis and HCC in 2010.[2] Similarly, liver cirrhosis ranked 12th and HCC 16th among the 235 causes of death, and the latter was the 3rd commonest cause of cancer death after lung and stomach.[2] HBV infection is a blood borne pathogen that is hyper-endemic in most parts of the sub-Sahara Africa.[3] In Africa, an estimated 65 million people are said to be chronically infected with HBV infection. Thus, Africa with 12% of the world's population carries approximately 18% of the global burden of HBV infection[4] and Nigeria falls in the global high prevalence zone for HBV infection where prevalence is estimated to be 5-10%. Indeed, a pooled prevalence of 13.4% was reported from the recent meta-analysis of studies from different parts of the country.[5]

The higher prevalence rates in older children supports the established fact that most HBV transmission in Africa occur in early childhood and mostly horizontals.

The HBV DNA level and liver function test as well as the serological markers must be succinctly looked into in order to institute appropriate management plan.[6] It is well established that the HBV infection progresses to liver diseases, and the tendency for this progression is dependent on many clinical parameters which include older age, male gender, higher level of Alanine aminotransferase (ALT) and HBV DNA level.[7]

The World Health Organization (WHO),[8] American Association for the Study of Liver Diseases (AASLD),[9] European Association for the Study of Liver (EASL)[10] and Society for Gastroenterology and Hepatology in Nigeria (SOGHIN)[11] guidelines advocate for treatment in the presence of significant necro-inflammation as evidenced by high ALT and high viral load decision as per existing treatment guidelines. Accordingly, it is desirable to have information on the clinical, virologic and immunologic characteristics of treatment naive patients with HBV infection in Nigeria to guide treatment.

METHODOLOGY

The study was conducted at Aminu Kano Teaching Hospital (AKTH) Kano, north-western geopolitical zone of Nigeria with a population of about 10million people based on 2006 National census. The study was a descriptive cross-sectional study.

The number of patients that were recruited into the study was calculated using the formula for determining characteristics in a cross-sectional study i.e. $n = z2pq/d2$ plus 10% attrition. Therefore, minimum calculated sample size = 204 patients.

All patients newly diagnosed with CHB infection without co-infection with HCV, HIV and above 18 years of age were consecutively recruited from December 2019 to October 2020, into the study after signing the informed consent form for the study until the desired sample size was achieved. And 10mls of blood samples were taken for the Liver Function Test, HBV immunologic panel and HBV DNA level.

The immunologic markers (HBeAg, anti-HBcAb, anti-HBeAb and anti-HBsAg) were done using commercially available enzyme-linked immunosorbent assay (ELISA) kits, while biochemical (LFTs) tests were performed using routine automated analyzers. The serum HBV DNA levels was quantified using ABI 7300 machine with LIFERIVER PCR kit with the lower limit of detection being < 5 IU/ml.

Ethical clearance was obtained from the Ethics and Research committee of AKTH for the study. Ref. No. NHREC/21/08/2008/AKTH/EC/2612 dated 9th September, 2019.

The provision of the Helsinki declaration as revised by the 64th World Medical Assembly was duly observed. Data collected from the patients were kept confidential.

Data collected was cleaned, entered and analyzed using the SPSS version 20. The clinical profiles, serum ALT; and HBV DNA level of the respondents were presented using mean, standard deviation, median and range while frequencies, percentages and charts was used to summarize qualitative variables. In all tests of significance, $P<0.05$ was considered statistically significant.

RESULTS

Socio-demographic characteristics of patients

A total of 204 patients consisting of 147 (72.1%) males and 57 (27.9%) females took part in the study. Their ages ranged from 19 to 48 years with a mean age 31.4 ±7.4.

Table 1 shows the socio-demographic characteristics of the patients studied. About half (52.5%) of the patients were married, and had tertiary education (55.7%). Patients' occupations include civil service (34.4%), farming (21.3%) and handiwork (6.6%). Other occupations accounted for 13.1% while about one quarter (24.6%) were unemployed. Twenty-four (11.5%) were healthcare workers. Majority (86.8%) were Muslims while 27 (13.2%) were Christians.

Table 1. Age and sex distribution of treatment naïve patients with chronic HBV infection

Gender/Age	n (%)	Min	Max	Mean age (SD)
Male	147 (72.1)	19	48	31.5 ± 8.0
Female	57 (27.9)	21	42	31.2 ± 5.8
Total	204 (100)	19	48	31.4 ± 7.4

Min: Minimum, Max: Maximum, SD: Standard deviation,

Table 2. Demographic characteristics of treatment naïve patients with chronic HBV infection

Characteristics	Frequency	Percentage
Marital status		
Single	97	47.5
Married	107	52.5
Occupation		
Civil service	70	34.3
Farming	43	21.1
Artisans	13	6.4
None	28	13.7
Unemployed	50	24.5
Health care worker		
Yes	24	11.8
No	180	88.2
Educational status		
Quranic	3	1.5
Primary	10	4.9
Secondary	77	37.7
Tertiary	114	55.9
Religion		
Muslims	177	86.8
Christians	27	13.2

ALT levels vis-à-vis HBeAg and HBV DNA level among treatment naïve patients with chronic HBV infection:
The median (interquartile range) ALT levels were 22 (13-26.5) IU/L. A total of 184 patients (90.2%) had ALT levels less than the upper limit of normal (40 IU/ L) while the remaining patients (9.8%) exceeded the ULN (> 40 IU/L). Male patients had a significantly higher ALT levels compared to females (22 .5 vs 15 IU/L, p = 0.01). The percentage of abnormal ALT in male (11.4%) was higher than that in female (5.9%). As shown in table 6, the ALT levels significantly decreased with increasing age groups, with highest occurrence of abnormal ALT among younger patients. Average ALT levels did not significantly differ between HBeAg positive and negative patients, and across different levels of HBV DNA. (p= 0.18 and 0.69 respectively).

Table 3: ALT levels based on selected variables among treatment naïve patients with chronic HBV infection

Variables	ALT n (%)		
	Normal (≤ 40 IU/L)	Abnormal (> 40IU/L)	p-value
All	184 (90.2)	20 (9.8)	
Sex			0.01
Male	163 (88.6)	16 (11.4)	
Female	21 (94.1)	4 (5.9)	
Age group			0.01
≤ 20	6 (66.7)	3 (33.3)	
21 to 30	87 (93.5)	6 (6.5)	
31 to 40	71 (86.6)	11 (13.4)	
> 40	20 (100)	0	
HBeAg Status			0.18
Positive	33 (100)	0	
Negative	151 (88.3)	20 (11.7)	
HBV DNA (IU/mL)			0.69
< 2000	96 (47.1)	7 (3.4)	
2000 to 19999	21 (10.3)	7 (3.4)	
≥ 20000	67 (32.8)	6 (3.0)	

**Significant at p< 0.05*

Treatment Indication selection: According to guidelines, criteria for CHB treatment include:
(1) HBeAg reactive/non-reactive, (2) serum HBV DNA levels above 2,000 IU/ml; (3) serum ALT levels above the traditional ULN (~40 IU/ L); and (4) treatment may be considered in certain individuals with detectable HBV DNA level and family history of HCC and/ or healthcare workers in direct contact with patients and Nigerians >30years.[10,11]
Among the 204 patients, 7(3.4%) had family history of HBV related HCC with HBV DNA count above 20,000 IU/ml) and another 7(3.4%) were health- workers whose HBV DNA > 20,000 IU/ml. Thus, these subjects 14 (6.8%) have indication for CHBV treatment.

Clinical and laboratory features of treatment indicated, and treatment not indicated patients with chronic HBV infection: Of 204 patients with chronic HBV infection, 27 (13. 2%) met criteria for treatment based on elevated HBV DNA levels and serum ALT (including the seven (7) each of health workers and family history of HBV related CLD). All of whom ALT and HBV DNA count were plotted in table 4).

Table 4 Comparing laboratory features of treatment indicated, and treatment not indicated patients with chronic HBV infection.

Features	n (%), Treatment Indicated	Treatment not-indicated
Number of patients	27 (13.2)	177 (86.8)
↑HBVL/↑ALT	13 (6.3)	-
↑HBVL/↓ALT	14(6.9)	74(36.3)
↓HBVL/↑ALT	-	7(3.4)
↓HBVL/↓ALT	-	96(47.1)

HBVL=Hepatitis B Viral Load, ↑HBVL= >2000IU/ml, ↓HBVL = <2000IU/ml, ↑ALT = >40IU/ml, ↓ALT < 40IU/ml

DISCUSSION

Hepatitis B virus is a global pandemic disease which has a significant tendency for chronicity and undesirable consequences. Importantly it is ranked second among the environmental carcinogens. The most worrisome is the high propensity to cause serious morbidity and mortality. Nigeria being in a hyper-endemic region, with a huge burden of CHB patients in its population, needs robust studies so as to identify patients who are eligible for treatment.

Socio-demographic characteristics

Age: The study involved 204 eligible chronic HBV patients, their mean age was 31.4 ±7.4 years with age range from 19 to 48 years. In a study done in southern part of the country by Akande et al[12] where 300 patients were recruited for the study, the age range was 18 to 74 and a mean of 37 ± 10.5 years and median of 36. 5 years. The wide age variation between the northern and southern parts of the country is likely due to difference in health seeking behavior across the regions. In Bangladesh, Alam et al[13] carried out a study which showed quite lower mean age, 26.5 ± 8.5, and the age range was 14–55 years. Similar to southern Nigeria, Esmaeelzadeh et al [14] in Iran , observe the mean age to be 8 ± 11 years (14-79 years). This may be due to the inclusion of younger age group (<18years) as well as HBV related CLD in their study.

Sex: In this study, most of the patients were male 147 (72.1%). This is in line with literature, that persistence of HBV infection has been said to be associated with male sex, and that progression is common with male, as also demonstrated by Zhu et al[15] and by the study of Akande et al,[12] where 169 (56%) were male while 131 (44%) were female.

Similarly, a study from Eritrea by Hamida et al[16] had male predominance as well, 218 (71.5%) were males as well as in Bangladesh where Alam et al[13] reported male to female ratio was 4.6:1 and in Iran by Esmaeelzadeh et al[14] with 110 men (73.3%).

Educational status: Most of the patients (55. 9%) were educated up to tertiary institution while few patients (1.5%) limited their education to only Quranic School. This is may encourage adherence to treatment and regular clinic follow-up. Occupation: Civil service took the largest portion (34.3%) of the occupational distribution, while handiwork (artisan) is the less common (13.7%) among the patients. Since medical treatment in Nigeria is largely out- of-pocket, the cost of life long treatment burden probably would be lessen.

HBV DNA level and HBeAg status of treatment naïve patients with chronic HBV infection:

In this study, about half (49. 2%) of the patients had HBV-DNA levels greater than 2, 000IU/ ml, most of them were HBeAg negative (83. 8%, 95 % CI: 74. 3 to 92. 9%) with no statistical correlation with age and sex. This was similar to a study from the intermediate provinces in China by Wu et al,[17] reported 46.0% of patients to have HBV DNA >2000 IU/ml. However, the findings in Eritrea study by Hamida1 et al[16] show a small number of patients (22. 0%) had HBV DNA greater than 2, 000IU/ ml and are directly proportional to age, and male preponderance, however most of the patients were HBeAg negative with wider percentage variation (93.2% vs 83 .8%).

ALT level among treatment naïve patients with chronic HBV infection: A very small number of patients (9.8%) had ALT ULN (> 40 IU/L) with male patients' preponderance (p= 0.01), and inversely related to age. Average ALT levels did not significantly differ between HBeAg positive and negative patients, and across different levels of HBV DNA. This is in contrast to findings in an earlier study by Esmaeelzadeh et al[14] from Iran where 89 (59. 7%) out of 150 patients had ALT levels above 40 IU/L. The ALT levels were below the ULN in 270 (9.0%), 1-2 times the ULN in 852 (29%) and > 2 times the ULN in 1869 (63%). This variation is not unexpected as racial differences affect the pattern of ALT level presentation, also each HBV genotype peculiar to each region has been shown to have influence on ALT level pattern.

Clinical and laboratory features of treatment indicated, and treatment not indicated patients with chronic HBV infection: Of all the features, HBV DNA, and ALT were significant treatment criteria (table 4), twenty- seven (13.2%) of the 204 patients met the criteria for treatment; of these, a significant proportion had a viral load of more than 2,000 IU /mL (49.5%), ALT levels above the upper limit of normal (9.8 %). This is within the generally acceptable range 0f 5-10% of the patients diagnosed with Chronic HBV infection would require treatment while 90-95% were Inactive state.[9,10,11,12] However, from the Japan study, Seoet al[18] found about 32.0% of their study population required therapy. Additionally, the study showed that 50% of HBeAg positive patients met the criteria for treatment compared to 39.2% HBeAg negative patients, this is probably due to the very high HBV DNA associated with HBeAg +ve.

CONCLUSION

This study demonstrated the predominance of HBeAg-negative infection in our environment which signified a low HBV replication and low infectivity. Also, most of the patients with CHB infection in our study were asymptomatic. However, some patients despite elevated HBV DNA (>2000 IU/ml, HBeAg -ve) still have low ALT levelsn. It is therefore, important in our setting to review the cut-off level of ALT since most Africans were known to have lower ALT level so has not to miss the benefit from early treatment and aversion of the consequences attributable to the disease.

Declarations

Competing interests: None Declared

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Conflict of Interest: None

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