Risk factors for Hepatitis B virus co-infection among HIV patients attending comprehensive care clinics in Makueni County, Kenya

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Abstract- The effect of hepatitis B virus (HBV) infection on the natural history of human immunodeficiency virus (HIV) disease remains uncertain. Nearly one third of people who are infected with HIV are also infected with hepatitis B and both infections have similar transmission routes. Therefore this study was conducted to determine the risk factors for Hepatitis B virus co-infection among HIV patients attending comprehensive care clinics in Makueni County, Kenya

This was a prospective cohort study among patients seeking HIV services in Makueni County. Newly diagnosed patients with HIV and co-infected with HBV aged 18 years and above and had not started ARVS recruited in the study.

A total of 258 were recruited, majority (63%) of the study participants in both HIV/HBV positive and HIV/HBV negative arms of the study were females. The mean age of the participants was 31 years and most(32% of them in the HIV/HBV cohort were aged 26-30 years while in HIV cohort most(26%) were aged 31-35 years.Condom use,number of sexual partners and smoking or taking alchol were significantly associated with HIV/HBV co-infection at p=0.038,p=0.001,p=0.000) respectively.Demographic characteristics e.g Age,gender,level of education,marital status,employment status did not show any association.

The study further highlight that females are more vulnerable to HBV co-infection more than their male counterparts,which may have accounted for the increased prevalence among females. Nonetheless, awareness on the means of preventing these infections such as the use of condoms, having one sexual partner and avoiding use of alcohol or smoking will greatly reduce the prevalence of HIV/HBV prevalence in both rural and urban areas.

Index Terms- HBV,ARVS,HIV,Risk factors

I. Introduction

The Hepatitis B Virus (HBV) and Human Immunodeficiency Virus (HIV) are viruses that share certain epidemiological characteristics such as risk populations and transmission routes. This puts HIV positive individuals at risk of co-infection with hepatitis B. For HIV and HBV co-infection (HIV/HBV), the sero prevalence ranges from 6.3% to as high as 39% (Uneke *et al.*, 2005, Mendes *et al.*, 2000)

In countries with intermediate and high HBV endemicity, the main routes of transmission of HBV are perinatal or in early childhood. In these countries, HBV co-infection rates are 10-20% (Lee *et al.*,2000,Nyirenda *et al*.,2008,Diop *et al.*,2008).The rate of progression and complications from viral hepatitis has been reported to be accelerated in patients with HIV co-infection (Puoti *et al.*,2002,Thio *et al.*,2009). HIV/HBV co-infected individuals are 6 times more likely to develop chronic hepatitis B than HIV negative individuals. In addition, HIV infected individuals are more likely to lose previously developed protective anti-HBs antibody and develop acute hepatitis B infection; this risk is also associated with lower CD4+ counts (Carter *et al.*,2011). However, it has been established that hepatitis B infection does not hasten HIV disease progression or severity (Carter *et al.*, 2011). Hence, it is important to identify them early to reduce the morbidity, delay mortality and improve quality of life in HIV/AIDS patients (Rewari *et al.*, 2003).

The prevalence of chronic hepatitis depends on age at the time of infection and the mode of HBV transmission, which varies from region to region. Different regions of the world reported various prevalence of chronic HBV infection from high (> 8%), intermediate (2 - 7%), to low (< 2%). Prenatal transmission is the main route of HBV transmission in areas with high HBV endemicity; whereas in low endemic areas, HBV infection occurs in well-defined high-risk groups such as, intravenous drug users (IDUs), male having sex with males (MSM), health care workers, and regular recipients of blood or patients going under hemodialysis (Hou J *et al.*,2005). According to a HIV cohort study in the US, among 2769 participants, 1078 (38.9%) had HBV infection in the observation course. Chronic Hepatitis B was detected in 117 (10.9%) patients with HIV under the study. Therefore 40% of the co-infection with both viruses was detected each year. However, a similar study also from the US showed HIV/HBV co-infection in 4.47% of HIV positive individuals. HIV/HBV co-infections were associated with males, black race, MSM, (Intravenous Drug User) IDU, concurrent IDU, and heterosexual activity or unknown in New York City (Chun *et al.*, 2010, Kim *JH et al.*,2008). Studies from Nigeria, Botswana, and Brazil showed the prevalence of Hepatitis B surface antigen (HBsAg) 6.6%, 5.3%, and 4.7%, respectively. The result of risk factor analysis showed that infection through male homosexual

contact had the highest rate, 64 (74.4%), and 16 (18. 6%) were IDUs (Adekunle *et al.*,2011,Patel.,*et al* 2011,Mendes *et al.*, 2011) If a person is co-infected with both HBV and HIV, management of both diseases can be complicated, so a visit to the appropriate specialists is vital.Some anti-retrovirals, which are usually prescribed to treat HIV, can eventually lead to antiviral resistance or liver-associated problems. One or both infections will require treatment and must be carefully managed. Treatment differs from person to person (Weibaum *et al.*,2008)

Numerous consensus studies have focused on the importance of co-infection, the effect of HIV infection on HBV, and also the importance of checking anti HBc level before HBV vaccination (Weibaum *et al.*,2008).Evaluation of HBV risk factors is an important point to control and prevent its further spread of the disease within the populations. This research is therefore an attempt to further investigate the risk factors for Hepatitis B virus co-infection among HIV patients attending comprehensive care clinics in Makueni County, Kenya and come up with best strategies to prevent and control further spread of Hepatitis B to both people infected with HIV and those not infected.

II. Methods

Study Site

The study was carried out in three selected comprehensive care clinics in Makueni County which is 144 KM south of Nairobi the capital city of Kenya with a population of 930,530 with a current prevalence of HIV been 5.6%.

Study Design

This was a prospective cohort study among patients seeking services in comprehensive care clinics in Makueni County.

Study populations

HIV Patients aged 18 years and above seeking services in comprehensive care clinics in Makueni County.

Inclusion criteria

- ✓ HIV patient above 18 years registered at the facility
- ✓ New HIV patient diagnosed with HBV and above 18 years
- ✓ New HIV patients with no HBV infection and above 18 years
- ✓ Willing to participate and ready to give informed consent

Exclusion Criteria

- ✓ Patients on antiretroviral drugs who had been diagnosed positive for HBV
- ✓ Those who are very sick
- ✓ Previously vaccinated for HBV
- ✓ Transfer in HIV patients on ARVS

Sample size determination

The study utilized sample size formula for comparing two proportions by Casagrande *et al* (1978) to obtain the minimum sample size. The minimum sample size per group was calculated as 107. Allowing for 20% non- completeness/loss to follow up; the sample size was adjusted upwards to 129. The study targeted to recruit a minimum of 129 HIV patients with HBV co-infection and 129 HIV patients without HBV making a total of 258. A total of 258 participants gave informed consent and were recruited for the study. 128 HIV/HBV and 130 HIV participants were later recruited and joined to be part of the study. This was achieved considering 95% CI and 5% margin of error.

III. Sampling procedure

Makueni County has 57 comprehensive care clinics and three facilities were purposively selected for the study because they have high number of HIV patients seeking services and also represent rural and urban areas. Makueni county referral has approximately monthly new HIV enrollments of 60 patients, Makindu hospital has 50 and Emali model clinic has 35.Proportionate sampling was used to calculate the number of clients required from each hospital guided on by HIV monthly testing data. Makueni county referral produced 53, Makindu hospital 45 and Emali model gave 31 and convenient method was used to recruit the participants in each facility. The study was composed of two arms of patients, newly HIV diagnosed with HBV co-infection and those without. Both HIV and HBV testing was conducted using rapid test methods. The group found to be negative for HBV was vaccinated for Hepatitis B after enrollment to the study while the positive ones were treated. All these groups were initiated ARVS after enrollment and followed up for six months. In the two groups baseline information was collected at enrollment to the study, their CD4 count and viral load tests and recorded. Follow up of six months was scheduled for the study participant's then end line information collected together with HBV test, CD4 count, and viral load test done.Individual data was collected using semi-structured questionnaire by the help of a trained research assistant

Sample collection, storage, transportation and processing

Approximately, 4mls of blood was collected using a vacutainer bottle and 2mls put in plain and EDTA bottle for every study participant at baseline and at the end of the study. Blood was stored at room temperature and analysis for CD4 and HBV was done at the facility since all these facilities have laboratories which can carry out these tests hence no transportation was required. The DBS samples for viral load were collected and kept at room temperature and taken to the nearby G4S (courier) office for transportation to KEMRI (Centre for virus Research) Nairobi for processing of HIV Viral load test.

IV. Data collection

Administration of questionnaire

After getting informed written consent individual data was collected using semi-structured questionnaire by help of a trained research assistant. This comprised of HIV patients seeking comprehensive care services in that facility where the study was conducted. Demographic characteristics and risk factors for HBV co-infection were captured in the questionnaire. Training of research assistant on data collection and study protocols was done in Makindu hospital after which the pre-testing of the questionnaires was carried at the same facility for quality purposes. Data for each study participant was collected at baseline

and follow-up which was at sixth month using interviewer-administered questionnaire.

Data management and analysis

Double data entry method was used to ensure quality and consistence. Data cleaning was undertaken to identify and correct errors made during questionnaire filling and data entry. Data processing and analysis was done using the Statistics Package for Social Science (SPSS) software version 20.0. Descriptive data was presented using frequency tables. Cross tabulation involving Chi square test was used to compare variables. Values of less than or equal to 0.05 was considered significant. A multivariate analysis was conducted using logistic regression analysis to rule out for confounding variables.

Ethical considerations

The scientific and ethical research committee of Kenya Medical Research Institute granted ethical approval to carry out the study (certificate no KEMRI/RES/7/3/1). Permission was sought from leaders in the County Ministry of Health department of HIV/AIDS and Medical superintendent of the facilities where the study took place. Written consent for the purpose of this study was obtained from all participants and the objectives of the study were made clear prior to obtaining the informed consent.

V. Results

Socio-demographic and socio-economic characteristics of the study participants

Majority (63%) of the study participants in both HIV/HBV positive and HIV/HBV-negative arms of the study were females. The mean age of the participants was 31 years and most(32% of them in the HIV/HBV cohort were aged 26-30 years while in HIV cohort most(26%) were aged 31-35 years.More than seventy eight percent of the participants in each of the groups were married.Of these 77% in the HIV/HBV and 98% in the HIV group were in monogamous marriage.More than half of the study participants in each of the groups had attained secondary level of education.In both groups more than a third of the study participants were in formal employment and majority lived in rural areas.There were no significant differences in the characteristics of the participants in the two groups.(Table 1)

Table 1: Socio-demographic and socio-economic characteristics of the study participants

Demographic Information	Characteristics	Laboratory Blood Specimen Results			
		HBV/ HIV (n) (%)	HIV (n) (%)	Total (n) (%)	p-value
Gender	Male	47(36.7)	47(36.2)	94(36.4)	0.925
	Female	81(63.3)	83(63.8)	164(63.6)	
	Total	128(100.0)	130(100.0)	258(100.0)	
Age Category	21-25	28(21.9)	25(19.2)	53(20.5)	0.56
	26-30	42(32.8)	33(25.4)	75(29.1)	
	31-35	30(23.4)	34(26.2)	64(24.8)	
	36-40	18(14.1)	26(20.0)	44(17.1)	
	41-45	6(4.7)	9(6.9)	15(5.8)	
	46-50	3(2.3)	1(0.8)	4(1.6)	
	51-55	1(0.8)	2(1.5)	3(1.2)	
	Total	128(100.0)	130(100.0)	258(100.0)	
Marital Status	Married	102(79.7)	102(78.5)	204(79.1)	0.714
	Single	19(14.8)	23(17.7)	42(16.3)	
	Divorced	4(3.1)	4(3.1)	8(3.1)	
	Windowed	3(2.3)	1(0.8)	4(1.6)	
	Total	128(100.0)	130(100.0)	258(100.0)	
Education level	Primary	28(21.9)	29(22.3)	57(22.1)	0.353
	Secondary	68(53.1)	68(52.3)	136(52.7)	
	Tertiary (college/University)	29(22.7)	33(25.4)	62(24.0)	
	No formal education	3(2.3)	0(0.0)	3(1.2)	
	Total	128(100.0)	130(100.0)	258(100.0)	
Employment status	Self employed	45(35.2)	46(35.4)	91(35.3)	0.865
	Employed	47(36.7)	51(39.2)	98(38.0)	
	Not employed	36(28.1)	33(25.4)	69(26.7)	
	Total	128(100.0)	130(100.0)	258(100.0)	
Residence	Urban area	63(49.2)	52(40.0)	115(44.6)	0.136

Rural area	65(50.8)	78(60.0)	143(55.4)
Total	128(100.0)	130(100.0)	258(100.0)

Risk factors for HIV/HBV co-infection among HIV patients attending comprehensive care clinics in Makueni county, Kenya

The study established that few of the participants use condoms while having sex compared to majority (61.6 %) of them who do not use and this showed statistical significance with HIV/HBV co-infection at p=0.0380.Having more than more than one partner and consumption of alcohol or smoking showed to increase chances of HIV patient to be co-infected with Hepatitis B. History of family members having been infected with Hepatitis B before,blood transfusion and having been screened before for Hepatis B before. did not show relationship of one acquiring the disease (Table 2)

Table 2: Risk factors for HIV/HBV co-infection

		Laboratory Blood Specimen Results			
Risk Factors	**Characteristics**	**HBV/ HIV (n) (%)**	**HIV (n) (%)**	**Total (n) (%)**	**p-value**
Use condoms while having sex	Yes	41(32.0)	58(44.6)	99(38.4)	0.038
	No	87(68.0)	72(55.4)	159(61.6)	
	Total	128(100.0)	130(100.0)	258(100.0)	
Number of Sexual Partners	One	80(62.5)	108(83.1)	188(72.9)	0.001
	Two	47(36.7)	22(16.9)	69(26.7)	
	More than two	1(0.8)	0(0.0)	1(0.4)	
	Total	128(100.0)	130(100.0)	258(100.0)	
Screened for Hepatitis B	Yes	4(3.1)	3(2.3)	7(2.7)	0.686
	No	124(96.9)	127(97.7)	251(97.3)	
	Total	128(100.0)	130(100.0)	258(100.0)	
Smoke or take alcohol	Yes	80(62.5)	45(34.6)	125(48.4)	0.000
	No	48(37.5)	85(65.4)	133(51.6)	
	Total	128(100.0)	130(100.0)	258(100.0)	
Family member(s) had Hepatitis B infection	No	55(43.0)	58(44.6)	113(43.8)	0.790
	I don't know	73(57.0)	72(55.4)	145(56.2)	
	Total	128(100.0)	130(100.0)	258(100.0)	
Done Blood Transfusion	Yes	2(1.6)	0(0.0)	2(0.8)	0.152
	No	126(98.4)	130(100.0)	256(99.2)	
	Total	128(100.0)	130(100.0)	258(100.0)	
Vaccinated against Hepatitis B	No	128(100.0)	130(100.0)	258(100.0)	
	Total	128(100.0)	130(100.0)	258(100.0)	

VI. Discussion

More females (63%) were co-infected with HBV than males (37%) however this didn't show any statistical significance (p=0.925) furthermore our findings were similar to another study which revealed that though more females (3.59%) than the males (3.27%) were seropositive, they were comparable (p = 0.91) in HBsAg seropositivity (Omatola *et al.*,2019). This finding also supports the report of (Sule *et al.*,2010) from the same setting that both male and female were apparently equal in exposure to HBV. Previous studies (Omatola *et al.*,2017,Mustapha *et al.*,2004,Donbraye *et al.*,2014,Terwase *et al.*,2015) reported similar findings. The higher ratio of females to male in this study may be attributed to the fact that more females than males' visits hospitals for medical attention in Nigeria, a reason previously reported (Uneke *et al.*,2005)

Windowed, single and divorced persons were less affected by HBV co-infection than married individuals however there was no statistical significance on marital status and HIV/HBV co-infection these results are not similar to others done where analysis by marital status showed that the widowed patients significantly had higher HBsAg prevalence (Omatola *et al.*,2017) and also not in conformity with other studies which found significant association of marital status with HBV infection (Sule *et al.*,2011) in Kogi State,(Sirisena *et al.*,2002) in Plateau State,(Ezegbudo *et al.*,2004) in Anambra State and (Mohammed *et al.*,2015) in Kanu State.The possible reason could be due to the fact that windowed, single and divorced persons may have one or less partners as compared to married individuals where each of the partners may have several partners increasing their chances of been pre-disposed to HBV.Married people tend to trust each other much and their chances of using protective devices during sexual intercourse are low compared to the other group.

Educational related HBsAg sero prevalence revealed higher HBV infection in HIV patients with secondary education compared to those with no formal education, primary and tertiary levels of education and there was no significant difference between patient's educational status and HBsAg sero-positivity (p=0.353). This finding does not supports the assertion(Ezegbudo *et al.*,2004) that prevalence rates of infections such as HIV, HBV and HIV/HBV co-infection were inversely associated with educational status. The possible explanation could be HBV is majorly transmitted through sexual contact without using protection and majority of secondary students are at their adolescent's age where they may be tempted to do sex more compared to their counterparts. At primary level children are young and may fear to do sex or have no knowledge of sex while those in tertiary(college/university) are more enlightened and even if they will do sex majority have knowledge and can use protective methods in fear of unwanted pregnancy and sexually transmitted diseases.

Our study found strong association between alcohol consumption and HIV/HBV co-infection (P=0.00) in this study is in conformity with previous report of (Ndako *et al.*,2012), but contradicts finding of (Mbaawuaga *et al.*,2014).People who consume high rate of alcohol are likely more promiscuous and the fact that they may also fail to protect themselves through correct and consistent condom use could be a possible explanation for the higher predisposition to concomitants HIV/HBV infection.

In this study number of sexual partners was significantly associated with Hepatitis B virus among HIV patients, having multiple partners increased the chances of one contracting HBV.HBV is known to be commonly transmitted through sexual intercourse without using protection or contact with a person infected with HBV, the more partners one has increases chances of contracting the disease. This is not in agreement with a study which found HIV status to be associated with high-risk sexual behaviours variables but did not find these variables to be associated with HBV. After adjustment, the number of sexual partners and age at first sex were associated with HIV status but lacked a significant association with HBV status (Shevell *et al.*,2015). This study revealed condom use showed statistically significant association with HBV infection. Condoms are known to protect individuals having sex with sexually transmitted diseases and this was consistent with other studies (Balew *et al.*, 2014)

Among the study participants who were vaccinated against Hepatitis B vaccine no one had acquired the disease at the end of our study and there were no side effects reported by those who were vaccinated. Majority of the participants both HIV/HBV co-infected and HIV/HBV mono-infected had not taken the Hepatitis B vaccine before. From our results it has shown that vaccination of Hepatitis B as a preventive measure of protecting one from acquiring the disease. None of the HIV/HBV positive participants had Hepatitis B vaccination before and this explains the importance of vaccination.This results are in agreement with a study which was done to determine whether vaccine for hepatitis B virus is effective in protecting people who have HIV against hepatitis B virus infection and if the vaccine is safe in people living with HIV found that the vaccine was safe and none of the patients vaccinated acquired Hepatitis B showed improved immunity against hepatitis B among people living with HIV and taking antiretroviral therapy at 12 months. This immunity was lost once they stopped taking antiretroviral therapy (Okwen *et al.,* 2014).

History of having blood transfusion before was not statistically significant with HBV co-infection this is consistent with other studies which found risk factors history of blood transfusion, unsafe injection, tooth extraction, history of surgery, catheterization, abortion, tattooing and having a history of family liver disease did not show statistically significant association with HBV infection(Erena et al.,2014).

VII. Conclusion

More females were co-infected with HBV than males. Taking alcohol/smoking, having multiple partners and not using condoms were found to be significantly associated with HBV co-infection. Majority of the participants didn't have vaccination against HBV before nor did they have any knowledge of their family history in relation to Hepatitis infection. People need to be educated on ways of transmission and prevention of Hepatitis B and government should support and spearhead the vaccination of all individuals and more emphasis to be put on people living with HIV since their immune system is weak and susceptible to co-infection with Hepatitis B virus.

Competing of interest

We declare that there is no conflict of interest regarding publication of this manuscript.

Authors' contributions

Geoffrey Maitha development of the concept and manuscript, Gideon Kikuvi, Peter Wanzala and Fredrick Kirui critically reviewing of the document from its conception, up to manuscript submission and the final approval. All authors read and agreed to the final version of this manuscript and equally contributed to its contents and to the management of the case.

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