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Prevalence of Liver Cirrhosis on patients with Chronic Hepatitis B during treatment by Tenofovir Disoproxil 300 mg only at The NGaoundere Protestant Hospital in Adamawa Region Cameroon

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ABSTRACT

Introduction: Hepatitis virus B infection are the major public Health concern with the implementation of hepatitis immunization program in 1984 and the chronic viral hepatitis therapy program in 2003, its prevalence rate has dropped from 8% to 2% - 7% in the past few years. However, the Global Hepatitis Report (2017) estimated that nearly 257 million people worldwide were still living with chronic HBV infection, which would increase the risk of liver fibrosis, liver cirrhosis and hepatocellular carcinoma (HCC) in those infected.

Methods: It is descriptive cross – sectional study prevalence of liver cirrhosis done on 20 patients tested positives with HBV confirmed by the following exams such as ELISA HBV, Viral Load HBV, Hepatitis D Serology Test and Five HBV Biomarkers among 75 patients presented some clinical manifestations of Chronic Hepatitis at the NGaoundere Protestant Hospital in Adamawa Region Cameroon from June 2023 to August 2023 after receiving Ethical Clearance and Research Authorization from The Health Work of the Evangelical Lutheran Church of Cameroon (HWELCC) Chairman. Convenience sampling was done. The analysis included management of risk factors, clinical manifestations, diagnostic methods, treatment and complications of Chronic Hepatitis B.

Results: The prevalence of chronic hepatitis B on 75 patients was 26,66% and Out to 20 patients tested positive of chronic hepatitis, the prevalence of Liver Cirrhosis were 85%.

Conclusions: This study showed that the prevalence of Liver Cirrhosis estimated high to the patients tested positive with chronic hepatitis B despite tenofovir disoproxil 300 mg received caused by the non-management of Hepatitis B genotype and complications

Keywords: *Hepatocellular Carcinoma, Liver Cirrhosis, Hepatitis B, Hepatitis C*

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1. INTRODUCTION

Hepatitis is a general term referring to an inflammation of the liver. It occurs as a result of infection with various pathogens exposure to alcohol, medications, chemicals and toxins, and autoimmune disorders, Colin JF et al. (1999). There are five types of hepatotropic viruses; Hepatitis A,B,C,D and E (HAV, HBV, HCV, HDV and HEV), named according to the order in which there were discovered, Thio CL, et al., (2002). In the 1960s, only two types were known (A and B), but by the late 1970s, and beyond, new viruses (C and E) were discovered, hepatitis viruses are either Ribonucleic acid (RNA) like hepatitis A,C,D and E, or Deoxyribonucleic (DNA) viruses like hepatitis B, Central Bureau of Health Intelligence (2016). The five hepatotropic viruses are broadly classified into group namely, enteric and parenteral.

[See Annex — Table : Classification of Hepatotropic Group Viral Type]

According to the Dr S. Venkatesh and Dr R.K. Dhiman (2018), viral hepatitis is recognized as a public health problem globally various etiological agents (Hepatitis A, B, C, D and E viruses) have been implicated that can lead to acute, chronic or sequel of chronic infection. While hepatitis A and E are often the cause for sporadic or outbreaks of hepatitis, hepatitis B and C can either clear spontaneously or can lead to chronic infection, and there after sequelal like cirrhosis and hepatocellular carcinoma (HCC), Chun HM, Roediger MP, Hullsiek KH, et al., (2012). Chronic HBV infection accounts for 40 – 50% of HCC and 20 – 30% cases of cirrhosis in the World and chronic HCV infection accounts for 12 – 32% of HCC and 12 – 20% of cirrhosis, Colin JF, Cazals-Hatem D, Lioriot MA, et al (1999). Transmission of HBV and HCV can occur via sexual, blood – blood contact or vertically

(Mother – to – child), there are several known high – risk groups for acquiring a HBV or HCV infection, these include people interned in prisons, people who inject drugs, people with multiple sexual partners, migrants originating from endemic regions and new – borns from HBV or HCV chronically infected mothers called vertical transmission, Lozano R, Naghavi M, Foreman K, Lim S, Shiburya K, Aboyans V, et al (2010). The risk of developing chronic HBV infection depends on the age at infection, chronic infection results in 90% of infants infected at birth, in 30 to 50% of children infected between the age of one to four year, and in 1 to 10% of those infected at older age or as results, WHO, Global Hepatitis Report (2017). According to Schweitzer et al (2014), an estimated 248 million people were chronically infected with Chronic Hepatitis B and C Worldwide in 2010. WHO Executive Board (2019), Peter Byass (2014)

2. RELATED WORKS

HBV, a double – stranded DNA virus, belongs to the family of hepad viruses, HBV infection is a global public health problem, McMahon BJ (2009). Perinatal transmission and occasionally horizontal transmission early in life most common in high prevalence areas, sexual contact and percutaneous transmission also contribute to the transmission of HBV, Boyles TH and Cohen K (2011). HBV is an entirely vaccine – preventable disease. Patients with chronic HBV infection have a 15 to 40 per cent risk of developing cirrhosis, liver failure and / or HCC, and 15 to 25 per cent risk of dying from HBV related liver diseases, Mc Maham BJ (2009). The HBV genotypes influence the spectrum of disease, the risk of HCC and the response to antiviral treatment genotypes A,D and E are the predominant HBV genotypes in Africa, genotype A predisposes to chronicity with an elevated risk

of HCC, but has an increased response rate to interferon therapy, the relative risk of HCC is four times higher in the people affected, Burnett RJ, Ngobeni JM, Francois G, et al.(2007). Genotype D has a reduced response rate to interferon therapy, and acute infection is associated with increased risk of acute liver failure. HBV is transmissible via perinatal, percutaneous or sexual exposure to HBV – infected body fluids including serum, saliva, semen and vaginal fluids, Mc Maham BJ (2009). All HBs-Ag positive individuals more infections as they have higher rates of HBV replication, Schweitzer A, Horn J, Mikolajczyk RT, Krause G, Ott JJ (1965 and 2013).

According to Ott J, Stevens G, Groeger J, Wiersma S (2012), the clinical presentation of chronic HBV infections is variable, the risk of chronicity is dependent on age of acute infection; 70 to 95 per cent for infants exposed perinatally (HbeAg – positive Mother), 25 to 50 per cent for children aged between one and five years, six to 10 per cent for five to 20 years and one to three per cent for adults older than 20 years. It is important to establish the phase of chronic infection as this determines the risk of cirrhosis and HCC, the frequency of follow up and the need for treatment, Boyles TH, and Cohen K (2011). Many patients with chronic HBV are asymptomatic (unless they have decompensated cirrhosis or have non – specific symptoms such as fatigue, some patients experience exacerbation of the infection which may be asymptomatic, mimic acute hepatitis or manifest as hepatic failure, Andersson MI, Maponga TG, Ijaz S, et al (2013). Physical examination may be normal, or there may be stigmata of chronic liver disease, jaundice, splenomegaly, ascites, peripheral edema, upper gastrointestinal bleed and

encephalopathy may be present in patients with decompensated cirrhosis, McMahon BJ (2009).

There are five different phases of chronic infection such as HbeAg positive chronic HBV infection (immune Tibrant), HbeAg positive chronic HBV (immune clearance), HbeAg negative chronic infection (immune control), HbeAg negative chronic HBV (immune escape) and occult HBV, Maynard JE. (1990). The syndrome of fulminant HBV is characterized by jaundice, hepatic encephalopathy, coagulopathy (INR is more than 1,5) occurring within eight weeks of the onset of the acute illness. Its complications include development of acute portal hypertension, hepatorenal syndrome, cardiorespiratory dysfunction, metabolic disturbances, raised intercranial pressure, life threatening cerebral edema, susceptibility to bacterial and fungal infections, Hoffmann CJ, Thio CL. (2007). In this case, survival rates are estimated for 12 to 36 per cent and liver transplantation is the first therapy choice.

HBV surface antigene (HbsAg) is the key marker in the diagnosis of HBV infection. Laboratory testing during chronic phase reveals elevation in the concentration of alanine (ALT) and asparate (AST) aminotransferase levels; values up to 1000 to 2000 international units /L are typically seen during the chronic phase with ALT being higher than AST, Burnett RJ, Ngobeni JM, Francois G, et al. (2007). The serum bilirubin concentration may be normal in patients with anicteric hepatitis but the prothrombin time is the best indicator of prognosis, Delemos and Mark w. Russo (2019). Routine assessment of HbsAg – positive persons is needed to guide management and indicate the need for treatment, this generally includes assessment serological markers of HBV infection, measurement of HBV DNA levels, assessing

severity of liver disease by liver enzymes, non – invasive tests (NITs) such as asparate aminotransferase (AST) to platelet ration index (APRI), FIB – 4, transient elastography (Fibroscan) and liver biopsy, Schaefer S (2005)

Current treatment of chronic viral hepatitis B with interferon and nucleoside analogues have remained unsatisfactory with seroconversion of hepatitis B virus from a replicative to a non-replicative state occurring in only 15-32% of patients, Lau GK, Piratvisuth T, Luo KX, Marcellin P, Thongsawat S, et al. (2005). Along with this high rate of treatment failure, is the prohibitive cost of these medications especially interferon-based medications and associated numerous side effects. This is especially true in Nigeria where out of pocket payment for healthcare services is still very much the rule, Conjeevaram HS, Lok AS (2003). Many patients are therefore too eager to explore the use of complementary and alternative treatment with their optimistic and somewhat sketchy evidence of benefit, Wellington K, Jarvis B (2001)

It is important to establish the phase of chronic HBV and the need for anti – viral therapy depending on disease activity, HBV DNA level, the presence of advanced fibrosis, cirrhosis or the use of immunosuppressive therapy, Kramvis A and Kew MC (2005). The objectives of treatment are virological suppression, biochemical remission, histological improvement and prevention of complications such as Cirrhosis, Hepatocarcinoma and Extrahepatic manifestations, Zhou Y and Holmes EC (2007). Its management includes assessment of liver disease prior to therapy, there are age and disease duration, complications, of chronic HBV, assessment of compliance with follow up visits and medication, family history of HBV infection, complications of cirrhosis and HCC, full

blood count and differential count, liver profile, like total bilirubin, conjugated bilirubin, ALT, AST, ALP, Gamma GT, serum albumin and INR to assess synthetic function and serum creatinine, Schaefer S (2005). It is also important to control serological assessment which includes HbsAg, HbeAg and anti Hbe +/- IgM anti HBc (low positive with a flare), IgG anti HBc (if assessing for occult HBV or previous cleared infection. The decision to start treatment is based on the likelihood of sustained response to treatment and the risk of hepatic morbidity and mortality. In general, the indications are based on three criteria such as serum HBV DNA levels, serum alanine aminotransferase (ALT) levels and severity of liver disease, Araujo NM (2015).

Antiviral therapy is the most important treatment for patients with chronic HBV infection. In addition, there are anti – inflammatory, anti – oxidation, liver protection drugs, anti – fibrosis drugs and Immune regulatory treatment option, WHO (2017). Treatment is long term and there is a risk of relapse after suspension. Currently, there are five antiviral drugs such as lamivudine, telbivudine, entecavir, adefovir and tenofovir. Chronic HBV infection is a risk factor for developing HCC, even in the absence of cirrhosis. In Hong Kong, CHB accounts for 80% of incident HCC. Antiviral therapy does not completely eliminate the risk for HCC, Mc Mahon BJ (2009). Therefore, surveillance for HCC is crucial in reducing the morbidity and mortality of HBV infection. HCC may still develop even after spontaneous HBsAg loss, but the risk is lower if HBsAg loss is achieved at a younger age and in the absence of significant fibrosis, Chun HM, Roedigero MP, Hull Sick KH et al (2012).

Cirrhosis and HCC are the two major long-term complications of CHB. Patients with cirrhosis

and HCC require close follow-up and sometimes inpatient care with multi-disciplinary management, Yang HI, Lu SN, Liaw YF et al (2002). For instance, patients with cirrhosis may require endoscopic screening for varices, admissions for abdominal paracentesis or treatment of hepatic encephalopathy. Patients with HCC often require multi-disciplinary care involving physicians, surgeons, oncologists, and radiologists to formulate the best treatment strategy, Araujo NM (2015).

3. MATERIALS & METHODS

It is descriptive cross – sectional study prevalence of liver cirrhosis done on 20 patients tested positives with HBV confirmed by the following exams such as ELISA HBV, Viral Load HBV, Hepatitis D Serology Test and Five HBV Biomarkers among 75 patients presented some clinical manifestations of Chronic Hepatitis at the NGAoundere Protestant Hospital in Adamawa Region Cameroon from June 2023 to August 2023 after receiving Ethical Clearance and Research Authorization from The Health Work of the Evangelical Lutheran Church of Cameroon (HWELCC) Chairman. Convenience sampling was done. The analysis included management of risk factors, clinical manifestations, diagnostic methods, treatment and complications of Chronic Hepatitis B.

Convenience sampling was done, all the cases of elective Chronic Hepatitis B admitted during the study period were included. Age > 20 residents in Cameroon. The simple size was 25 Hepatitis calculated was calculated using the formula $n = (Z^2 \times p \times q) / e^2$ where n = minimum sample size, z = confidence interval, $p= q= 1 - p$ and e = margin of error, 5%.

The Adamawa region is a constituent region of the republic of Cameroon, it borders the Centre

and East regions to the south, the Northwest and West regions to the Southwest, Nigeria to the West, the Central African Republic to the East, and the North region to the North. This mountainous area forms the barrier between Cameroon's forested South and Savana North. At almost 64,000 km² in land area, the Adamawa is the third largest of Cameroon's ten regions.

The Health Work of the Evangelical Lutheran Church of Cameroon (HWELCC) possesses three large hospitals namely: The Ngaoundere Protestant Hospital (NPH), the NGAoubela Protestant Hospital (NGBELAPH) and the Garoua Boulai Protestant Hospital (GBLAIPH) and several Health Centres and Clinics, we have marked our passage particularly at the NGAoundere Protestant Hospital

The data for this study were collected using structured questionnaires, entered and analysed in Microsoft Excel 2016, confidence interval was calculated along with frequency and percentages for binary data. The inclusion criteria included only patients (adults) tested positive with Liver Cirrhosis, aged from 18 years old.

4. RESULTS & DISCUSSION

To assess the prevalence of Liver Cirrhosis to these HBV Patients, we collected and analyzed data on patient's characteristics, clinical manifestations, diagnostic methods used, types of treatment given and some complications occurred before, during and after treatment.

[See Annex — Table 1. Results of Patient Characteristics]

[See Annex — Table 2. Results of Chronic Hepatitis B Clinical Manifestations]

[See Annex — Table 3. Results of Exams and Tests done to confirm Chronic Hepatitis B Patients]

[See Annex — Table 5. Results of Chronic Hepatitis B Treatment]

[See Annex — Table 6. Results of Hepatitis B Complications analyzed on 100 Patients]

The results concerned exams, tests, treatment and complications occurred during the period of study used by the Hospital to manage chronic hepatitis B to the patient tested positive with HBV. 100% patients have done Elisa Hepatitis B, 45% have done viral load HBV and Hepatitis B Serology, 100% for five biomarkers HBV, 70% for abdominal ultrasounds and 0% for genotype HBV and Liver Function Tests. Tenofovir disoproxil 300 mg has been the only drugs given to these patients. Consequently, we obtained 85% of these 20 patients with liver cirrhosis during the only treatment by tenofovir disoproxil 300 mg. This issue should be solved if the patient had complete their exams by Genotype HBV, Liver function Test and others related tests in order to manage the complications of Chronic Hepatitis B. Certain parameters include the problem of low income observed to some patients. The cost of genotype HBV, viral load HBV and Liver Function Tests are very expensive. Long-term treatment (5+ years) with 300 mg Tenofovir Disoproxil Fumarate (TDF) for Chronic Hepatitis B (CHB) effectively suppresses HBV DNA, leading to significant regression of cirrhosis in 71–74% of patients and low, newly diagnosed hepatocellular carcinoma (HCC) rates (2.1–4.0%). Despite this, cirrhosis remains a significant baseline condition, with studies showing 48.3% of patients may have liver cirrhosis before starting TDF, Lancet (2013).

5. CONCLUSION

The shortcomings observed in the diagnosis and treatment of Chronic Hepatitis B in patients at the Protestant Hospital in N'Gaoundere have caused multiple complications such as Liver

Cirrhosis, Fulminant Hepatitis and Pulmonary Embolism, death and non-cure of patients.

The management of Hepatitis B at the N'Gaoundere is not effective and is subject to several challenges, namely: the absence of internists and gastroenterologists, poorly qualified staff, lack of in-depth diagnostic equipment, lack of appropriate drugs for the treatment of viral Hepatitis B infection, unsuitable and outdated technical platform... From the recommendations, we recommend to the management of the Hospital to install a good practice of treatment of chronic Hepatitis B.

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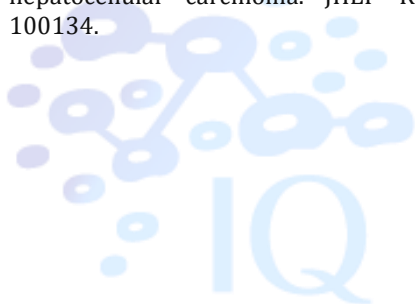
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CONFLICTS OF INTEREST

The authors declare no conflict of interest in relation to this work.

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ANNEXES

Annex I

Hepatotropic Viral Type	Genetic	Classification Group		
		DNA	Enteric	Parenteral
HAV	Yes	No	Yes	No
HBV	No	Yes	No	Yes
HCV	Yes	No	No	Yes
HDV	Yes	No	No	Yes
HEV	Yes	No	Yes	No

Annex II — Table 1. Results of Patient Characteristics

Chronic Hepatitis B Patient Characteristics	Patients	
	n	%
Nationalities		
Cameroonians	20	100
Age (Years Old)		
18 – 35	11	55,00
36 - 55	7	35,00
55 – Over	2	10,00
Marital Status		
Single	9	45,00
Married	8	40,00
Divorced	3	15,00

Annex III — Table 2. Results of Chronic Hepatitis B Clinical Manifestations

Clinical Manifestations	Abdomen Distention		Ascites		Jaundice		Legs Swelling (Godet)		Hepatosplenomegaly	
	n	%	n	%	n	%	n	%	n	%
Patient	20	100	18	90,00	16	80,00	11	55,00	17	85,00

Annex IV — Table 3. Results of Exams and Tests done to confirm Chronic Hepatitis B Patients

Exams and Tests Done	Elisa HBV		Viral Load HBV		5 HBV Biomarkers		Hepatitis Delta Serology		Ultrasounds		HBV Genotype		LFTs	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Patient	20	100	9	45,00	20	100	9	45,00	14	70,0	0	0	0	0

Annex V — Table 5. Results of Chronic Hepatitis B Treatment

Treatment Received by HBV Patients	Tenofovir Disoproxil 300 mg		Tenofovir Alafenamide 25 mg		Peginterferon alfa 2 a		Interferon alfa 2 b		Entecavir and/or Adefovir		Lamivudine	
	n	%	n	%	n	%	n	%	n	%	n	%
Patient	20	100	0	0	0	0	0	0	0	0	0	0

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Annex VI — Table 6. Results of Hepatitis B Complications analyzed on 100 Patients

Complications of Chronic Hepatitis B	Liver Cirrhosis		Hepatocellular Carcinoma		Fulminant Hepatitis		Pulmonary Embolism		Cardiac Liver		Digestive Bleeding	
	n	%	n	%	n	%	n	%	n	%	n	%
Patient	17	85	0	0	4	20	7	35	0	0	0	0