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Clinical Assessment and Continuum of Care of Chronic Hepatitis B Patients in a Low-Income Setting in Africa

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Abstract

Background: Chronic Hepatitis B (CHB) infection is a major public health problem in the world. Cameroon has a high prevalence, estimated at about 11.2%. In Cameroon, the management of CHB remains very challenging. This study aimed to assess the clinical characteristics and the steps of the Continuum of Care (CoC) of chronic hepatitis B patients. **Methods:** We conducted a hospital-based retrospective cohort study. We reviewed files of CHB patients who were diagnosed and followed up from January 2014 to December 2017 at the Douala General Hospital, a tertiary hospital in Cameroon. The CoC was assessed as follows: step 1—enrolment in care, step 2—basic work up done, step 3—antiviral treatment initiation, step 4—viral load suppression. Descriptive statistics were used to summarize proportions, the Kaplan-Meier curve was used to estimate retention in care and multivariate analysis was used to test for association with treatment initiation. **Results:** We consulted a total of 1120 records of patients with CHB. We retained 1033 patients in the study, giving a proportion of 92%. The mean age at diagnosis was 33.7 (±12.0) years. There was a male predominance with the proportion of 59.4% (sex ratio of 1.48). Among the 1033 patients enrolled in care, 492 (47.6%) completed the basic work up, 121 (11.7%) were initiated on antiviral treatment, and viral load suppression was achieved in 53 (5.1%). According to multivariate analysis, male gender (AOR = 2.1; 95%CI [1.2 - 3.5]; p = 0.007), older age > 34 years (AOR = 0.03; 95%CI [0.003 - 0.033]; p = 0.004), and having a health insurance (AOR = 5.7; 95%CI [3.0 -

10.9]; $p < 0.001$) were the factors independently associated with treatment initiation. **Conclusion:** The study clearly showed a decreasing proportion of patients at various steps of the CoC, with treatment initiation mostly influenced by some sociodemographic factors. The real need to develop strategies to improve the CoC of CHB in Cameroon is therefore very necessary.

Keywords

Cohort Study, Chronic Hepatitis B, Continuum of Care, Douala-Cameroon

1. Background

Chronic Hepatitis B (CHB) infection remains a challenging global health problem [1]. An estimated 257 million people are infected with Hepatitis B Virus (HBV) worldwide [2]. In 2015, hepatitis B resulted in 887,000 deaths from liver-related complications [2]. The infection can lead to lethal consequences [3]. It is a common cause of liver disease and liver cancer [4]. The prevalence of chronic HBV infection is considerably higher in Asia and Sub-Saharan Africa [5] [6]. The prevalence of CHB in Cameroon is high estimated to be 11.2% according to a systematic review and meta-analysis in 2017 [7]. Therefore, CHB is a major public health problem in Cameroon, but strategies to control this emerging health problem are still to be improved. Previous studies in Sub-Saharan Africa revealed that HBV vaccine coverage remains low (around 79% of vaccine coverage for Africa as a whole) [8]. Less than 1% of adults who are positive for HBsAg at the community level had been previously tested and were aware of their diagnosis [8]. Furthermore, there is a low treatment rate of CHB patients, with a treatment initiation of about 4.8% in DGH [9], and a problematic follow-up monitoring, falling short of recommendations [10]. There is thus a need to describe the gaps in the clinical assessment of chronic hepatitis B patients through evaluation of the Continuum of Care. This evaluation will provide a baseline for development of effective public health strategies and establishment of efficient interventions programmed to optimize the care of CHB patients [11]. It demonstrates an integrated approach to health and medical management [12]. The treatment of chronic hepatitis B has markedly evolved during recent years, with only pegylated interferons before 2014 to generic oral direct-acting antiviral medications. This is consistent with subsidization made by the state as part of the program with USD 4 per month for lamivudine, USD 9 per month for tenofovir, and USD 93 per week for peg IFN [13]. In Cameroon, there's no universal health insurance. While a few who are wealthy are under private insurance, the rest, which is the majority, pay for their health care on their own. The introduction of generic drugs at a lower cost in the treatment of viral hepatitis B in Cameroon since 2014 has increased accessibility and above all will prevent the evolution to complications such as cirrhosis and liver cancer. The effective implementation of this plan can be ensured by assessing the progress in care of CHB patients. This evaluation can identify points of intervention to im-

prove treatment outcomes of these patients in a low-income setting. Also, this critical assessment of program implementation and along with the continuum of care will offer epidemiologists and policymakers a framework for a better planning for future adequate interventions. The aim of this study was to evaluate the management of chronic hepatitis B patients through assessment of the steps of their continuum of care. We hope our findings will provide a basis for development of adequate intervention programs.

2. Patients and Methods

2.1. Study Design and Procedure

We conducted a hospital-based retrospective cohort study over a period of 48 months, from January 1st, 2014 to December 31st, 2017. The study was carried out at Douala General Hospital (DGH) a tertiary health facility in Cameroon, which plays the role of a university teaching hospital. It is situated in Cameroon's economic capital Douala in the Littoral region. It receives mainly the population in Douala (which is about 3 million people), neighboring regions, and even some neighboring countries. DGH is the major treatment center of CHB in Cameroon. In 2014 the state of Cameroon set up approved treatment centers for the management of patients with viral hepatitis. DGH is part of health training courses, benefiting from an approved treatment center. It is in this treatment center that the decision to start treatment against the viral hepatitis B infection is made. There is a committee made up of all hepatologists in the city of Douala who meet once a month to decide on the treatment of patients. The hepatologist discusses with his patients on the choice of treatment before presenting the file to the treatment center. But the committee can decide on the basis of the elements of the file to change the treatment protocol. Available protocols were: lamivudine 100 mg, Tenofovir Disoproxil Fumarate (TDF) 300 mg, Pegylated Interferon (peg IFN) 1.80 µg. These medications were subsidized at lower cost by the state, which makes them available in a centralized structure in treatment centers.

The study was carried out at the outpatient department, which was managed by three qualified hepato-gastroenterology consultants. We received patients coming from different regions of Cameroon and even from neighboring countries. The proportion of CHB was about 10 % of outpatient consultation in hepato-gastroenterology unit.

We reviewed all the files of CHB patients older than 18 years. CHB was defined as the persistence of HBsAg beyond six months. We first consulted the consultation registries to search the records of patients followed for viral hepatitis B. Records of patients were hard copy files and were kept in the archives of the outpatient unit. We collected data available in the files based on the questionnaire we had developed. A file was considered complete when it included age, sex and elements of step 1 of CoC defined as the specialist consultation with a confirmed CHB diagnosis. Files of patients with HIV and HCV co-infection, HCC and decompensated cirrhosis at the time of diagnosis were excluded.

A structured questionnaire was designed and pre tested to collect sociodemographic data such as sex, age and date at diagnosis; marital status, mode of payment of hospital bills (having a health insurance or not which is total or partial coverage of health expenditures), occupation, laboratory investigations such as, liver enzymes and function, viral markers, liver fibrosis and also treatment characteristics.

These laboratory investigations were done in the laboratory of the DGH, which is a well functional laboratory (subjected to periodic quality control and validation). The normal values of transaminases (ALT and AST) were set at less than 40 IU/l for each. Viral markers were represented by the presence or absence of HBeAg defined as positive or negative using Elisa method.

HBV DNA quantification was done using COBAS TaqMan HBV test with high-purity extraction (Roche Diagnostics) on patient's plasma (500 µl) as per the manufacturer's protocol. The lower threshold was set at 20 IU/ml. This was a real-time PCR assay based on dual-labeled hybridisation probe targeting the precore and core regions.

Liver fibrosis was assessed using fibrotest and transient elastography. Fibrotest is not performed in Cameroon. The blood samples were collected as specified by respective test procedures and sent for analysis to a BioPredictive laboratory, Cerba-France. Results of these analyses were sent by mail or fax within 10 days. Transient elastography was done in a private clinic in Douala, by the same operator; the WHO cut-off values were used, which were 7 kPa for significant fibrosis (F2) and 11 kPa for cirrhosis (F4) [2].

Treatment options were Tenofovir Disoproxil Fumarate (TDF) 300 mg per day, Pegylated Interferon 180 µg per week, and lamivudine 100 mg per day. The treatment protocol was chosen in consultation meeting by the hepatologists who made up the therapeutic committee of the DGH treatment center. Criteria of treatment were significant fibrosis, elevated liver enzymes upper than twice normal range, and viral load upper than 2000 UI/ml according EASL recommendations.

2.2. Continuum of Care of Chronic Hepatitis B Patients

The steps of CHB CoC were assessed using 3 core indicators: testing, treatment and viral load suppression of the World Health Organization (WHO) [2] Continuum of Care and was modified as follows: step 1—the enrolment in care: defined as the specialist consultation with a confirmed CHB diagnosis, step 2—basic work up done: defined as the basic initial work up done: the transaminases (AST, ALT), and the HBV DNA quantification, step 3—treatment initiation: number of patients with CHB infection who are currently receiving treatment or have received treatment at least once in time for at least 30 days, and step 4—viral load suppression: number of patients with chronic HBV infection on treatment whose HBV DNA is not detectable (HBV DNA ≤ 20 IU/ml), based on viral load measurement within 12 months following antiviral treatment. The effectiveness of the recom-

mended work up was assessed using WHO guidelines of management. Lost to follow up was defined as no consultation within the last 12 months of the study period; this was revealed by the absence of follow-up note in the file.

Pretherapeutic assessment was evaluated as follows:

- HBV-related tests: HBeAg, HBV DNA; HDV antibody;
- Liver disease severity tests: PT, albumin, platelets level;
- Liver tests: ALT, AST, ALP, GGT.

Follow-up monitoring of disease activity was evaluated as at least annual:

- ALT, AST, HBV DNA;
- Fibrosis assessment using fibrotest or transient elastography.

HCC monitoring was evaluated as at least US and AFP assessment, every 6 months in cirrhotic patients and yearly in noncirrhotic patients.

2.3. Statistical Analysis

Data obtained were entered using the software Census and Survey Processing System (CSPro) version 7, and analysed with the software Statistical Package for Social Science (SPSS) version 23. These data were presented using frequency tables and charts. Dependent variable CoC was evaluated as enrolment in care, basic work up done, treatment uptake, and viral load suppression.

Logistic regression by univariate and multivariate analyses was used to look for factors associated with the initiation of treatment against CHB. The follow-up duration of CHB patients was evaluated by the Kaplan-Meier curve. Statistical significance was set at p-value < 0.05 at 95% confidence interval.

3. Results

3.1. Baseline Characteristics

We consulted a total of 1120 records of patients with CHB. We retained 1033 patients in the study, giving a proportion of 92%. The median (IQR) declared duration from CHB diagnosis to enrolment in care was 36 (23 - 51) months. The mean age at diagnosis was 33.7 (±12.0) years and the majority of patients (496) were aged 30 - 45 years. There was a male predominance of 59.4%. In the study population, 6.4% had a health insurance. A history of surgery was the most identified risk factor, found in 10.6 %. About half (52%) of the population had HDV antibody assessed, of which 40 (7.5%) were positive. About one quarter of the population had a serum ALT greater than normal (24.4%), and about two-thirds had HBV DNA less than 2000 IU/ml (Table 1).

Continuum of care of chronic hepatitis B patients

After confirmation of CHB diagnosis, 1033 patients were enrolled in care corresponding to step 1. Amongst the population enrolled in care during the baseline work up, about 60% of the population had transaminases assessed and 51.8% had HBV DNA quantified. A total of 492 (47.6%) had their transaminases + viral load assessed, thus completing step 2 (Figure 1). Following baseline and follow-up evaluation, 14.2% (149/1033) of the study population were eligible for treatment. 121

Table 1. Baseline characteristics of the study population.

Variables (1033)	n/N (%)	Mean (STD)
Sociodemographic characteristics		
Age (years)		33.7 (12.0)
<30 years	467/1033 (45.2)	
Gender		
Male	616/1033 (59.6)	
MOP		
No health insurance	925/997 (89.5)	
Risk factors		
History of surgery	110/972 (10.6)	
Family history of HBV infection	44/540 (4.3)	
Comorbidities		
Co-infection HVD	40/535 (7.5)	
Diabetes	16/1002 (1.6)	
Alcohol consumption	373/1008 (37)	
CKD	7/802 (0.9)	
Laboratory characteristics		
Liver enzymes		
ALT ≥ 40 IU	152/623 (24.4)	
AST ≥ 40 IU	128/622 (20.6)	
Viral markers		
HBeAg negative	397/502 (79)	
HBV DNA < 2000 IU/ml	396/579 (68.8)	
qHBsAg ≥ 1000 IU/ml	118/164 (71.9)	
Liver fibrosis		
Significant fibrosis (F2 - F3)	72/256 (28.1)	
Cirrhosis	43/256 (16.7)	

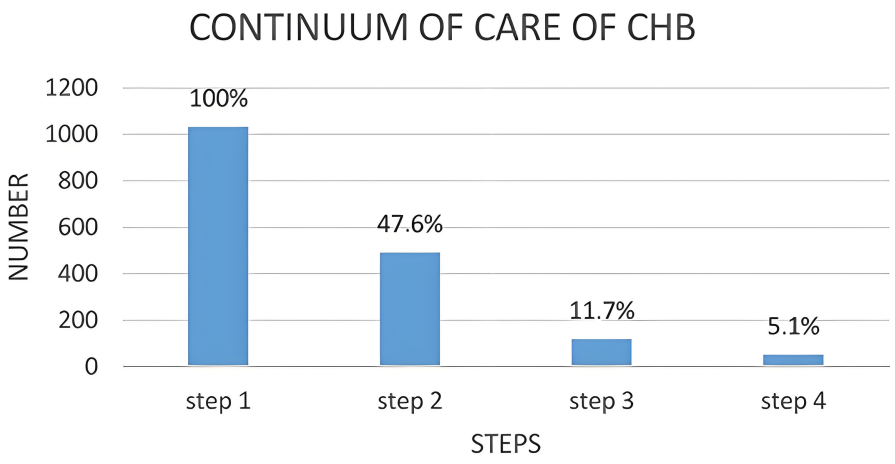

Figure 1. Representation of the Continuum of Care (CoC).

(11.7% of the total population) were effectively initiated on treatment. Amongst them, 108 (10%) received tenofovir (TFV), 10 (0.9%) received pegylated interferons (peg IFN), 2 patients (0.2%) received both TFV and peg IFN, and 1 (0.1%) received lamivudine (3TC). Following treatment initiation, out of the 121 patients initiated on treatment, 53 patients (5.1% of the total population) achieved viral load suppression within 12 months (Table 2).

Over the study period, 286 (27.6%) patients remained in care. The mean duration of follow-up was 9.93 months (Figure 2). We weren't able to evaluate the loss of Ag HBs.

Table 2. Summary of the Continuum of Care of chronic hepatitis B.

Steps	Counts	Percentages
Step 1: Enrolment in care	**1033**	**100%**
Transaminases done	620	60%
HBV DNA done	535	51.7%
Step 2: Basic work up done (transaminases + HBV DNA)	**492**	**47.6%**
Eligible for treatment	149	14.2%
Not eligible for treatment	299	28.9%
Step 3: Treatment initiation to antiviral medications for least 28 days	**121**	**11.7%**
TDF	108	10.2%
Peg IFN	10	0.9%
3TC	1	0.1%
TDF + peg IFN	2	0.2%
Step 4: Viral load suppression within 12 months following treatment initiation	**53**	**5.1%**

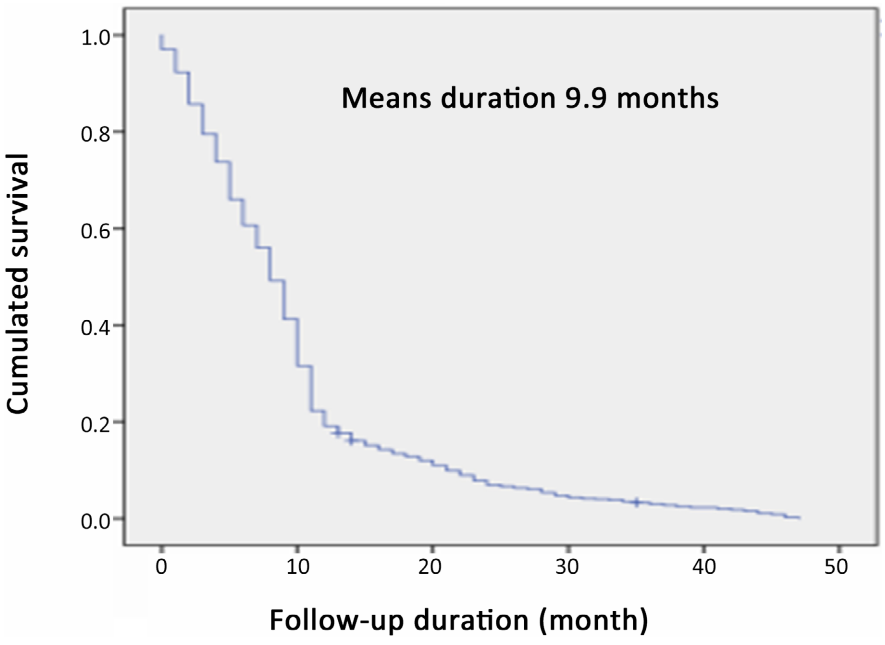

Figure 2. Kaplan-Meier estimate of the retention in care.

Table 3. Multivariate analysis of factors associated with treatment uptake.

Variable	Univariate analysis		Multivariate analysis	
	OR (95%CI)	p value	AOR (95%CI)	Adjusted p value
Male gender	1.9 [1.2 - 2.8]	0.003	2.1 [1.2 - 3.5]	**0.007**
Age > 34 years	13.7 [3.9 - 47.6]	<0.001	0.03 [0.003 - 0.33]	**0.004**
Patient with insurance	4.8 [2.8 - 8.4]	<0.001	5.7 [3.0 - 10.9]	**<0.001**
CKD	5.3 [1.2 - 23.8]	0.048	0.22 [0.045 - 1.07]	0.060

3.2. Associated Factors with Treatment Initiation

In the multivariate analysis, male gender (AOR = 2.1; 95%CI [1.2 - 3.5]; p = 0.007), older age > 34 years (AOR = 0.03; 95%CI [0.003 - 0.033]; p = 0.004), and having a health insurance (AOR = 5.7; 95%CI [3.0 - 10.9]; p < 0.001), were the factors independently associated with treatment initiation (Table 3).

4. Discussion

The aim of our study was to evaluate the steps of the CoC of CHB patients at the Douala General Hospital, which comprised enrolment in care, basic work up done, treatment initiation, and viral load suppression. This was done in order to provide a useful framework, to establish effective interventions at each step and for improvement in CHB care.

In this study, 1033 participants with a confirmed diagnosis of CHB (HBsAg positive for at least 6 months) were enrolled in care, 492 (47.6 %) had completed the minimal but crucial work up, which was made up of transaminases + quantification of HBV DNA, 149 (14.2%) were eligible for antiviral treatment, of which 121 (11.7%) were effectively initiated on treatment. Following treatment initiation, 53 (5.2%) had their viral load suppressed. Older age (>34 years), male gender, and having a health insurance were factors associated with treatment initiation.

Safe and effective vaccines against hepatitis B have been available since 1982 [14]. Hepatitis B vaccine was introduced in the Expanded Program of Immunization in Cameroon in 2005 in order to reduce childhood HBV transmission and for eradication of the disease [15].

It is strongly recommended that HBV serological testing be offered to individuals who are part of a population with a high prevalence or who are at risk of HBV infection. Circumstances of diagnosis in our setting are mainly during blood donation [16], screening prior to vaccination, a routine medical check-up, a work up for infertility. There is no systematic screening for HBV as for HIV, even in people known to be at high risk, like family contacts of HBV-infected patients, patients on haemodialysis, patients who underwent a surgery, previously transfused individuals, despite the fact that we are in a highly prevalent country [17]. Promoting HBV screening, especially in the high-risk populations, should be prioritized by health care givers to improve the CoC, as early screening is cost-effective and has benefits in the quality of life. The use of rapid diagnostic tests, is recommended to ease

access to diagnosis, especially in our setting, considering its low cost, and the fact that it can be done by any trained person, but laboratory-based immuno assays remain the preferred techniques for diagnosis [18]. Following HBV diagnosis, patients are referred for further management by a specialist. The fact that patients are being referred causes a great number of lost to follow-up [19]. The consultation of the specialist was considered as the enrolment in care. The patients we reviewed in our study were already tested and enrolled in care, corresponding to step 1.

Following enrolment, clinical evaluation and proper counselling were done, followed by a pretherapeutic work up. For pretherapeutic evaluation during clinical assessment of CHB patients, it is recommended that they should be screened for HDV antibodies, as it is an additive cause of severe liver disease and is common in CHB patients. It helps in the decision-making of treatment eligibility and the type of treatment to initiate. HDV screening is systematically requested for all CHB patients in DGH, but only 535 (52%) patients were effectively assessed for HDV co-infection. Our results demonstrate how HDV screening remains poor in our context, though essential in CHB patients, and this may be worse in health facilities where it is not yet a systematic practice. Of the 535 patients assessed, 40 (7.5%) were positive. This prevalence is similar to that found by Seetlani *et al.* in central Africa (8.3%), the 10.5% obtained by Luma *et al.* in Cameroon, and to the 5.9% of Celen *et al.* in Türkiye [20]-[22]. The result is divergent from that of Seetlani *et al.* in Pakistan, who had a prevalence of 58.6% [21]. Such a big difference can be explained by the known epidemiology of HDV infection that shows a high prevalence of HDV infection found in the western regions of Asia, Eastern Europe, South America, Mediterranean countries, than in the rest of world. The basic work up (transaminases + HBV DNA), which is crucial to identify people in need of antiviral therapy, was done by only 47.6% (492) of those enrolled in care. Our result is divergent from the findings of Spradling *et al.* in US, where only 0.6% did not have ALT assessment, and 18% HBV DNA assessment at least once [23]. The difference observed may be due to the fact that the work up is very costly for our setting (about USD 550 for the complete baseline work up and about USD 182 for only transaminases + viral load), with just a small proportion having a health insurance; also, the HBV DNA quantification can be done only in few reference laboratories. We hope that new low-cost methods for identification of viral replication will be developed in order to facilitate the clinical evaluation of patients. HCC surveillance is recommended in all cirrhotic (F4) patients, with a 6-monthly US (±AFP) [24] [25].

The actual regimen for treatment of CHB is generic oral direct-acting antiviral drugs, which are available only in 2 towns in Cameroon, and the prescriptions must be made only by gastroenterologists. The regimen of treatment provided by the public health system is tenofovir + emtricitabine combination, tenofovir and lamivudine. For those coinfected with HDV, peg IFN is the treatment regimen. In our study, 14.2% of the study population was found to be eligible for treatment

and 11.7% effectively commenced on treatment. Our results concur with the study of Shankar *et al.* in US, Jung *et al.* in US, who obtained a treatment uptake of 10% [26] [27]. Our finding was higher than that of Allard *et al.* in Australia (5%) [28]; this difference may be due to the fact that we considered only those enrolled in care not the entire CHB population ever diagnosed in the country, and also lower than the result of Fiacre Bagnaka Eloumou *et al.*, in Cameroon, 4.8% [9]; the study period may explain this difference since our study was conducted when oral direct acting antiviral medications were made available in Cameroon. Our result was far much lower than that obtained by Celen *et al.* in Türkiye who had a treatment uptake of 61.3% [22] [28], this difference can be due to the fact that, a great proportion of patients in our study do not do the baseline investigations to identify those in need of antivirals and also, the need of antiviral therapy, may be observed during follow up with continuous monitoring of disease activity as CHB is a dynamic disease; but here in our setting follow up remains less effective and decision to initiate therapy relies mostly on the baseline evaluation following enrolment. In 2015, it was estimated that less than 1% of people with CHB were receiving treatment, and the targets are to have 5 million patients receiving treatment by 2020 and 80% of the eligible patients treated by 2030 [29]. This low treatment rate in our context may be a reflection of the fact that not all treatment-eligible patients can be identified, as a great number of patients are not properly evaluated, and though consistent subsidization has been made on antiviral medications, it remains not affordable for many patients. Also, many patients don't want to commit to lifelong treatment as long as they remain asymptomatic.

Viral load suppression is the outcome of a successful antiviral therapy within 12 months of treatment. In our study, only 53 (5.1%) patients had an undetectable viral load within 12 months following treatment. This low percentage may be explained by the fact that many patients did not undergo HBV DNA quantification following treatment. Furthermore, suboptimal treatment adherence emerged as the most commonly identified reason for failure to achieve viral suppression after antiviral therapy [30]. Some patients completely drop out of care as they are asymptomatic, whereas CHB treatment is a lifelong therapy [31]. A critical challenge in CHB patient care is recurrent stockouts of antiviral medications, which disrupt treatment and undermine viral suppression. We did not have any data allowing us to assess the suppression of HBsAg or the decrease in quantitative HBsAg levels to <1000 IU/ml.

Some sociodemographic characteristics were associated with treatment initiation. People of older age were more likely to receive treatment, as older people in our setting tend to be more financially stable to afford investigations, which are crucial to identify the need for antiviral therapy. Additionally, since CHB progresses over time, older individuals are inherently more prone to requiring antiviral therapy. Having a medical insurance contributes as a major element to CHB care, which concurs with the finding of Liou *et al.* in US [30] and may be explained by the fact that health insurance allows continuous patient's monitoring, and covers

the financial aspects of CHB therapy.

Through concerted collaboration, CHB care providers and public health professionals are able to improve the outcomes at each step of the CHB CoC. Though patients enter in the continuum following different pathways, and dynamically progress differently, the ultimate goal remains achievement of a suppressed viral load. Achieving this and the WHO's 2030 goal of eliminating HBV as a major public health threat requires strengthening outcomes across every step of the CoC. This entails enhancing population education, improving provider capacity, integrating and expanding viral hepatitis services, and reinforcing disease surveillance. This study was conducted in a retrospective design, with review of records that are susceptible to missing data and misclassification errors. In order to stratify steps of continuum of care, the questionnaire was adapted to medical records, as the files were not conceived to serve the purpose of the research; DGH being one of the biggest health facilities in Cameroon, patients consulting there may have different characteristics, therefore they may not be representative of the whole CHB population. Our study did not evaluate screening, linkage to care, and treatment adherence as data on these steps were scarce.

Despite these limitations, this is the first study that demonstrates a clear profile of the gaps in the continuum of CHB care in a major CHB treatment centre in Cameroon. We strongly believe our findings would serve as a call for concern in the management of CHB in Cameroon, provide the basis to establish new strategies for interventions at each step of the CHB care, and improve health practices related to HBV.

5. Conclusion

The decreasing proportions of patients at all the steps of the CoC were clearly demonstrated, revealing the fact that it remains less optimal in the DGH. We hope these results will offer epidemiologists and policymakers a framework for identifying gaps in the care of CHB patients in Cameroon in order to develop interventions to optimize the CoC of CHB.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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List of Abbreviations

3TC	Lamivudine
ALT	Alanine Aminotransferase
AST	Aspartate Aminotransferase
AOR	Adjusted Odds Ratio
CoC	Continuum of Care
CHB	Chronic Hepatitis B
CKD	Chronic Kidney Disease
DGH	Douala General Hospital
HBeAg	Hepatitis B envelope Antigen
HBsAg	Hepatitis B surface Antigen
HBV	Hepatitis B Virus
HCC	Hepatocellular Carcinoma
HCV	Hepatitis C Virus
HDV	Hepatitis Delta Virus
HIV	Human Immunodeficiency Virus
PCR	Polymerase Chain Reaction
PegIFN	Pegylated Interferon
TDF	Tenofovir Disoproxil Fumarate
WHO	World Health Organization