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ORIGINAL PAPER

Hepatitis B Virus Infection in Eastern Libya: Current Efforts for Overcoming Regional Barriers for Its Elimination

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Abstract

Approximately 2.2% of Libyans have chronic hepatitis B (CHB) and are at the highest risk of developing end-stage disease complications. Several resource-limited countries, including Libya, may be far from achieving the WHO goal of hepatitis B elimination by 2030 as a result of several testing and linkage to care (LTC) barriers. In Libya, data about the current HBV infection situation is scarce. Therefore, our study aimed to evaluate the trends of HBV in eastern Libya, Tobruk region, and try to identify the region-specific gaps and barriers that could potentially delay the WHO goal of HBV elimination. An eighteen-year retrospective review of records of the main district medical center in the region was done to estimate the trends of HBV infection and qualitative interviews with the clinical staff of the CHB registry in the region were conducted to investigate the current status of HBV management. Out of 392,952 records, 371 (0.09%) HBV-positive were recorded and declining trends of the infection were noticed over the study period. Until late 2019, there was no linkage to care or follow-up for people with HBV infection. However, a CHB registry was established in late 2019 to manage HBV infections in the region, yet there are several barriers such as the lack of diagnostic infrastructure for liver function assessment and antiviral treatment. Despite the significant decline observed in the occurrence of HBV infection and introduction of important HBV management steps such as establishment of the CHB registry, there are still several barriers that could delay the elimination of the infection.

Keywords Hepatitis B Virus Infection · Chronic Hepatitis B · Linkage to care · CHB Registry · Libya

Hepatitis B virus (HBV) infection remains an important public health concern, responsible for a significant rate of morbidity and mortality worldwide [1]. HBV is the most common chronic viral infection and as estimated by the World Health Organization (WHO) in 2019, globally, approximately 296 million people were living with chronic hepatitis B (CHB) with approximately 1.5 million new cases and 820,000 deaths annually, mostly for HBV complications such as liver cirrhosis and hepatocellular carcinoma (HCC) [1–3].

Globally, there has been a decrease in the prevalence of chronic HBV infection over time [4]. Owing to the advances in HBV care and therapy, the mortality from HBV infection has improved in recent years and a significant decrease in disability-adjusted life years (DALYs) has been observed in the last decade worldwide; however, there are differences in DALY improvements across countries and regions [5]. Despite the decrease in the prevalence of chronic HBV, there are still barriers and challenges to the achievement

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of the HBV WHO elimination goal, especially in low- and middle-income countries. Examples of these barriers and challenges include; access to screening, liver assessment and antiviral treatment [4, 6].

Due to the importance of the viral hepatitis infection, the WHO approved the Global Health Sector Strategy (GHSS) in 2016 to eliminate viral hepatitis as a major public health problem by 2030 by reducing the new cases by 90%, treating 80% of eligible people and reducing the annual mortality by 65% [7].

The epidemiology of HBV infection in Libya according to the National Center for Disease Control latest nationwide survey is 2.2% [8]; As classified by the WHO, Libya falls within the low limit of intermediate endemicity for HBV infection [9]. The HBV infection control program in Libya implemented several preventative policies to prevent HBV infection in the population such as the implementation of the free universal HBV vaccination for all newborns and screening of blood and blood products since the early 1990s [10]. In addition to the implementation of pre-invasive HBV screening tests to prevent HBV transmission in healthcare settings, [10, 11] HBV screening is mandatory for all immigrants and other people as part of their pre-employment and pre-marital medical examinations.

However, despite all these preventive and elimination strategies, Libya may be far from achieving the WHO goal of hepatitis B elimination by 2030 due to several barriers that potentially prevent the elimination of HBV in the region; these barriers include screening and linking HBV-positive people to care. To achieve the 2030 WHO HBV infection elimination objective, more efforts are required in terms of periodic calculation of the trends of infection and analysis of the HBV care gap and hurdles in our community [12]. Regarding the estimation of the trends of HBV infection in the community, it has been nearly 15 years since the latest estimation of HBV in Libya [8]. More recent surveys of the frequency of HBV in the population are essential to provide evidence for directing HBV control program efforts. However, due to a deteriorated healthcare system after the 2011 uprising [13]; conducting a large serologic survey was a challenging task due to the cost of such a study.

Using smaller populations, such as blood donors or other high-risk populations, for an estimation of the burden of disease might be a cost-effective way to overcome this barrier in developing nations, but the results of such surveys cannot be generalized to the entire population [14].

A significant advance in Libyan HBV management policy toward the WHO HBV elimination goal is the establishment of the CHB registry by the Libyan health authorities in late 2019 in the Tobruk region (Eastern Libya). The role of this registry is to improve the management of people with HBV infections and provide antiviral treatments to eligible individuals to stop the progression of the disease.

However, there is no recent data published about the burden of HBV infection and the infection management barriers in the country. Estimating the burden of HBV infection and understanding current gaps and barriers that influence HBV care among individuals living with CHB is important to improve public health efforts toward providing care services to prevent and treat HBV infection in the area.

Therefore, we conducted this study to provide an updated estimation of the burden of HBV in the region using data from the HBV blood test records of people who visited the main medical centre in the region for various reasons. In addition, we investigated the current HBV care cascade after the establishment of the CHB registry and identified the gaps and the barriers to improving LTC and proposed measures to improve HBV testing and linking to care to meet the 2030 goals of the WHO.2.

Materials and Methods

Study Design

Our study is an observational, cross-sectional study comprised of two parts; the first part was to estimate the trends of HBV infection in the region, and the second part was to investigate the current HBV LTC in the region and the barriers to HBV diagnosis and treatment. To achieve the first part was a challenge because there was no epidemiological data about HBV in the region since the last survey in 2008 and lack of resources made a nation-wide survey quite difficult due to the deteriorated healthcare quality in the last decade after the 2011 uprising [13]. The research team, therefore, conducted an eighteen-year retrospective review of the medical records of the main medical centre in the region.

Population and Setting

The first part of the study was conducted at the Tobruk Medical Centre (TMC). The TMC is the main tertiary hospital in the region, with a capacity of more than 700 beds. The hospital is located in Tobruk city, the capital of Butnan province, which is located on Libya's eastern Mediterranean coast and has a population of 195,088 as estimated in 2020 by the country's Bureau of Statistics and Census [15]. The Butnan province shares around 140-kilometer coastline along the Mediterranean Sea and an international border with Egypt in the east. Tobruk Medical Centre serves neighboring cities as well as Tobruk. (Fig. 1) The second part of the study was conducted at the chronic hepatitis B registry, which is located in the Liver Centre in Tobruk City. The

Fig. 1 A map shows the location of Tobruk city and the neighboring cities (within the red blank). Reprinted from ref [17].

CHB registry was established by the health authorities in late 2019 to manage people with CHB infections. The HBV registry is the only registry in the Tobruk region; it serves Tobruk city and the neighboring cities.

Variables

Variables of this study include age, sex, address, nationality, and HBsAg test results of the study participants. Study participants are people who visited the TMC for various medical and surgical procedures, and did the HBsAg tests as part of the medical centre's universal standard precautions before labor and pre-donation of blood between January 2003 and December 2020. All people with HBsAg positive test were included in the study.

The primary outcome of the study was the positive result of the Hepatitis B surface antigen (HBsAg) test. The HBsAg test was performed in the medical laboratory at the Tobruk Medical Centre using the commercially available enzyme-linked immunosorbent assay (ELISA).

Data Collection

All data was obtained using a standardized data collection form, the forms were extracted into an Excel sheet, cleaned and imported into SPSS software for analysis. The study team consists of two data collectors and a hepatologist.

The retrospective study aimed to retrieve the available data of people who visited TMC during the study period. All available data including age, sex, address, nationality, and HBsAg test results, was included. The second part of the study was to investigate the current HBV diagnosis and the care cascade in the region. The term care cascade as defined by WHO refers to "the continuum of services that persons living with hepatitis should receive as they go through various stages, from diagnosis to treatment to chronic care." [16].

Our study team arranged several visits to the CHB registry. During these visits, the study team inspected the registry workflow and interviewed the health professionals in an attempt to understand the barriers and gaps that could potentially prevent the WHO goal of HBV elimination by 2030. The team inspected the availability of diagnostic tests and instrumentation required for CHB diagnosis and follow-up

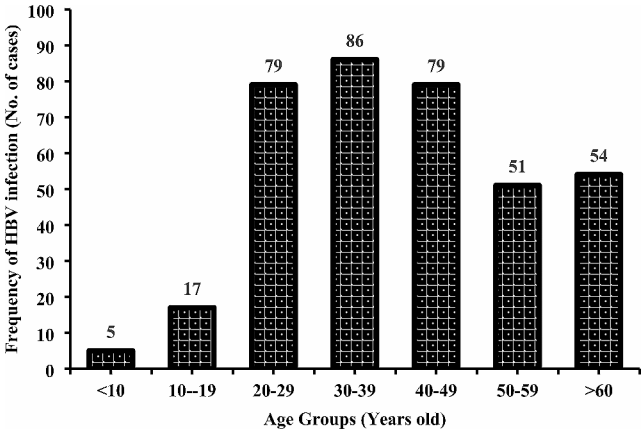

Fig. 2 Distribution of HBsAg positivity by age group

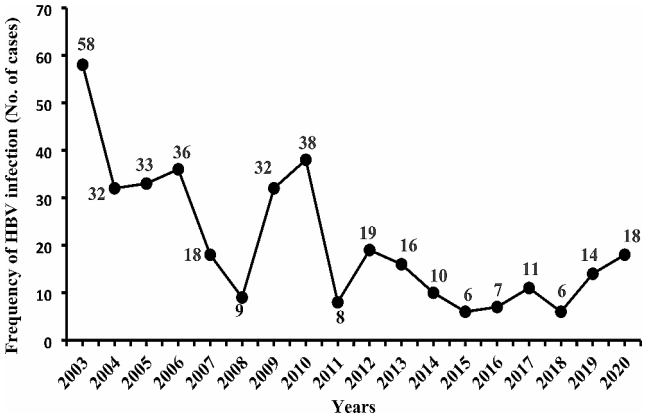

Fig. 3 Distribution of HBsAg positivity over the study period

including polymerase chain reaction (PCR) and fibroscan® and the availability of trained personnel.

Ethical Considerations

The study was conducted according to the guidelines of the Declaration of Helsinki, and approved by the Ethics Committee of the Libyan Medical Research Centre (Approval number: 0068/2023). The retrieved demographic and epidemiological data of patients were anonymous and the patient's data cannot be correlated to the results obtained.

Statistical Analysis

Microsoft Excel and SPSS software (Version 23, SPSS Inc.) were used to analyze the study data. The data were presented as frequencies and percentages and the patients' ages were displayed as mean ± standard deviation (SD). The chi-square test was utilized to determine any statistically significant differences between the study variables. The level of statistical significance was < 0.05.

Results

Estimation of HBV-Infection Burden in the Region

A total of 371 out of 392,952 (0.09%) individuals were found to be positive for HBsAg over the eighteen-year study period. The mean age of the affected people was 40.92; with a standard deviation (SD) of 16.5. The infection among males and females was found to be nearly similar, although it was slightly higher in females (51.8%). The majority of HBsAg-positive individuals were in the older age groups (Fig. 2).

The HBsAg-positive individuals were from different nationalities. The largest rate of HBsAg-positive people was among Libyans, with 341 cases (91.9%). They were followed by Egyptians with 11 cases (3%), Sudanese with 9 cases (2.4%), Palestinians with 3 cases (0.8%), Syrians with 2 (0.5%), and there were 5 cases from other nationalities, Iraqis, Chadians, Americans, Mauritanians, and one from an unspecified nationality.

Most of the cases were from the Tobruk region, comprising 323 cases (87.1%), followed by 25 cases (6.7%) from Derna city, and 7 cases (1.9%) from Albayda city. The remaining cases were from nearby cities and villages, each contributing small percentages. The frequency of HBsAg positivity was comparable among different occupation categories; however, it was higher among specific groups. Housewives accounted for 127 cases (320%), followed by civil servants with 92 cases (20%), self-employed individuals with 64 cases (20%) and other small categories. The rate of HBsAg fluctuated over the study period; however, it significantly declined in recent years. During the octennial period of 2003–2011, there were 264 cases ($p < 0.05$), but in the subsequent octennial period of 2012–2020, the number reduced to 107 cases (Fig. 3).

Chronic Hepatitis B Registry and Cascade of Care

When the patient first visits the CHB registry, the patient's identity and data are recorded confidentially by professional personnel. The first step after the patient's arrival is confirming the diagnosis of HBV; performing a complete medical examination and evaluating liver conditions for cirrhosis and HCC. Further, the patient history, risk factors and evaluation of eligibility for antiviral treatment were recorded too. In addition, a serologic screening is requested for the patient's household contacts. Then, a visit to the CHB registry is arranged for the patients' household contacts for HBV infection screening and counselling about the transmission of the infection and the risk factors of the infection.

However, in case any of the family member's immunity is below the protective level, the professional personnel request an HBV vaccine. Furthermore, the patient is tested for other viral infections, including hepatitis C virus (HCV), human immunodeficiency virus (HIV), and hepatitis D virus (HDV).

To confirm the patient's infectious status, infection activity markers and the liver condition are evaluated. Several serological and molecular tests are performed on the patient such as HBsAg, HBV DNA load, liver enzymes such as alanine aminotransferase (ALT) and aspartate aminotransferase (AST) and fibroscan. The patient's liver condition is followed up every 6 months. Also, abdominal ultrasound should be done every 6 months for screening for HCC. The number of registered CHB (chronic hepatitis B) patients was 243 cases, recorded from the last quarter of 2019, the date of the start of the CHB registry, up to the first quarter of 2023. Among the registered cases, 55% were female, and the highest rate of CHB was found in the age group of 55–65 years.

Barriers and Gaps to HBV Diagnosis and Treatment

Until late 2019, there was no linkage to care and treatment for people who were found positive for HBV infection; however, in recent years the Libyan health authorities established a CHB registry in the Tobruk region. The registry's objective was to confidentially document, test, monitor and treat eligible CHB people.

Our team noticed that the medical professionals adhered to the guidelines for the management of HBV infection, which were established with the establishment of the CHB registry in 2019 and according to the recent WHO guidelines for HBV management, [18] and that the CHB patients also followed the follow-up schedules. However, the registry lacked some important diagnostic and assessment instruments and trained personnel; these instruments include the PCR, endoscopic ultrasound (EUS) and fibroscan. Due to the lack of these instruments patients were requested to do these tests in the private sector.

The CHB registry provides free antiviral therapies to eligible individuals; however, a shortage of antiviral therapies occurs due to occasional discontinuations or delays in supply forcing patients to buy the antiviral medicine from private pharmacies at a high cost. The registry staff also noted a lack of awareness among both the public and health service providers, such as clinics and hospitals, regarding HBV infection, screening, and follow-up procedures for positive individuals.

Discussion

The frequency of HBV infection in this study was very low (0.09%) compared with the latest population serologic prevalence (2.2%) in 2008, [8] and also very low compared to some similar international studies [19–21]. The frequency of HBV infection showed a significant decline in the average HBV infections in the recent years 2012 to 2020 (107 cases) of the study period compared to the period from 2003 to 2011 (264 cases) ($p < 0.05$) (Fig. 3). This decline could be due to the improvement of the HBV infection control program in recent years, most importantly the universal newborn vaccination program. However, until a large population prevalence survey can be conducted, screening small populations such as blood donors and high-risk groups would be the only available method of estimating the burden of the disease [14].

The establishment of the CHB registry in the region has been a major leap toward better management of HBV infection. It has unified the HBV care procedures and has effectively enhanced the HBV LTC in the region. The adherence of people with CHB to the follow-up schedules was well-appreciated by the Registry staff. Previous studies have documented that patients with frequent visits are more likely to get routine HCC assessments compared to patients with fewer visits [22].

Reportedly, there was a lack of cooperation between the CHB registry and various community organizations and health sector organizations, including hospitals, clinics and health administrations. However, to achieve better CHB diagnosis and LTC, collaboration between the CHB registry and the above-mentioned health sectors is necessary. Establishing a patient navigation system in cooperation with the health sector and community organizations is the need of the hour to overcome the barriers related to HBV testing and LTC [23].

The universal HBsAg screening guideline in Libya includes people at increased risk, such as health care workers (HCWs), hemodialysis patients, infants of HBV-positive mothers, people with HIV and HCV, as well as blood donors, individuals undergoing pre-invasive medical interventions, and as a part of pre-marriage and pre-employment medical checkups. However, as HBV infection tends to be asymptomatic and people usually inadvertently detect their infectious status only after routine blood tests [24] and as the complications that the infection causes to the liver can be prevented if diagnosed at an early stage, [25] we recommend updating the HBV screening guidelines to include at least one-time universal screening for people who have not been tested before [26].

A lack of knowledge about the HBV infection among both the public and service providers was also observed by

the registry staff. Therefore, educational campaigns to raise awareness among the public and service providers about the disease and its complications are important and would increase the screening and linkage to care rate [27, 28]. The campaigns should emphasize that people with CHB can live normal lives without affecting their opportunities for marriage, getting a job or education [29].

Antiviral treatment is important to achieve suppression of viral activity and can prevent the development of further complications [30]. However, low-income people may not be able to afford antiviral treatment, diagnostic testing such as viral load and hepatic assessment testing such as fibroscan; therefore, supporting low-income people is an important step to accelerate HBV elimination. On the other hand, as the CHB registry is the only registry in the district, low-income people from remote areas in the district may not be able to maintain their follow-up schedules; therefore, to overcome this problem, the use of telemedicine as an alternative option for routine follow-ups of patients' needs to be encouraged [31].

Our study has several limitations. In addition to the descriptive studies limitations such as that the study relied only on the available data, some of which was not available, for example, some patient information, including the number of patients with liver cirrhosis and HCC, liver biochemistry and PCR assay findings, and information on household contact. Moreover, in the retrospective study, the number of people screened for HBsAg per year and the number of those undergoing invasive medical procedures, antenatal screening and blood donors were not available. Therefore, we were not able to estimate the prevalence of chronic HBV infection in each category.

Nevertheless, collecting and making these data available for future studies is crucial to enhance our understanding of the disease. In addition, there is a lack of generalizability; as the method we used to estimate the frequency of HBV infection may not accurately reflect the prevalence of the infection in the region. However, we opted for this method due to the high cost of conducting a major screening survey, which was not feasible. However, a larger serologic survey is still needed to accurately estimate the burden of the disease in the country.

On the other hand, this study has some strengths; the main strength is that it provides us with a broad assessment of the situation by a quick and affordable method. In addition, the insight into the progress of hepatitis B elimination in the region provided by this study could provide policymakers with the necessary information to improve HBV care and direct future research about HBV in the region.

Conclusions

Our study demonstrates improvement in the care of people with CHB in recent years after establishing the CHB registry; however, some screening and LTC barriers exist; most notably a lack of diagnostic and liver assessment infrastructures and other resources such as antiviral therapy. Our study recommends one-time universal hepatitis B screening, which would be complementary to the current HBV screening policy. Establishing cooperation between local health services, clinics and community organizations would achieve better screening and LTC. In addition, providing awareness programs about HBV management for both the public and healthcare providers would assist in promoting HBV LTC. In addition, establishing CHB registries across the country would improve the management of CHB-infected patients.

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Declarations

Conflict of interest All authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest or non-financial interest in the subject matter or materials discussed in this manuscript.

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