



Research Article

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Prevalence of Hepatitis B Virus Markers among Blood Donors in Qassim Region, Saudi Arabia

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ABSTRACT

Hepatitis B is a virus that infects almost 400 million patients worldwide. The pandemic of HBV has therefore become a focus of attention in many countries as they work to reduce the risk of transmission. One of these countries is Saudi Arabia where Hepatitis B is classified as hyper-endemic. The aim of this study is to establish the prevalence of HBV markers among blood donors in the Qassim region, Saudi Arabia. Serological markers of HBV were studied in 32,531 blood donors from six blood donation centers using commercially available kits, over a period of 2 Hijri years or from November 4, 2013 to October 13, 2015 at Qassim region, Saudi Arabia. The prevalence of confirmed positive test results of this virus was evaluated and studied. During the conduct of the study, prevalence rates of 0.42% were positive for hepatitis B virus markers. There was an overall reduction in the prevalence of HBV among Qassim blood donors in this period by 0.10%. Noticeable reduction was seen in central hospital, where the rate dropped by 0.20%, while other cities showed different variations. This study estimated that 320 units (2.05%) of blood were discarded due to positive markers for HBV. The prevalence rate of HBV markers among blood donors in Qassim region is lower as compared to other regions in Saudi Arabia. The reduction in the prevalence of Hepatitis B could represent an improvement in donor selection, although there were small variations between cities and further precautions should be considered.

Keywords: *Hepatitis B; Blood Donors; Markers; Qassim.*

INTRODUCTION

Since the first blood transfusion involving humans was performed in 1667, scientists have achieved huge steps forward in using blood transfusions to save many lives that would have died from loss of blood. However, blood with its components, can be a tool of mortality and severe morbidity because it can carry so many risks. One of the complications that blood and its components can cause is the transmission of disease in transfusion processes. This can cause significant morbidity, both long and short term, and it sometimes cannot be identified due to lack of tests or adequate sensitivity. One such disease is hepatitis B (HBV), which was the first hepatitis virus identified. [1] Around the world, almost 2 billion people have been exposed to the hepatitis B virus. [2] This huge number has drawn the attention of scientists to the importance of blood safety and the threats that patients may face, especially when the data shows that one million patients die annually from chronic hepatitis B infection or from one of its complications [1]. Thus, in 1971, the hepatitis B surface antigen (HBsAg) test was implemented in screening tests of blood donors [3], and this is just one of several safeguards in place to prevent HBV being transmitted.

In recent years, there has been increased public concern regarding the safety of blood and blood products with respect to transfusion-transmitted infections, mainly HBV, hepatitis C virus (HCV), and human immunodeficiency virus (HIV). [4] In the Kingdom of Saudi Arabia, the average prevalence rate of HBsAg (hepatitis B surface antigen) in the adult population in 1988 was approximately 8%, while 60% had evidence of past exposure to HBV. [5, 6] Also, a high prevalence of HBV infection among children was reported in 1992. Approximately 7% of apparently healthy children less than 10 years of age were positive for HBsAg and 20% were positive for at least one of the markers of HBV. [7] The prevalence of HBsAg in healthy blood donors ranges from 2.7% to 9.8%. [6] However several surveys of voluntary blood donors in the Kingdom of Saudi Arabia have shown marked regional variations in the prevalence of HBV[8-11].

This study was carried out to determine and discuss the prevalence of HBV in Saudi Arabia, and particularly among the blood donors in Qassim region. As this virus has been classified as hyper-endemic in Saudi Arabia [12], it is important to know the blood safety levels compared with the figures from other countries and what additional precautionary measures should be created to secure much safer blood transfusion processes. Moreover, recommendations based on the existing policies and data from the Qassim Ministry of Health and Blood Banks were provided in accordance with the results of this study.

MATERIALS AND METHODS

The study was conducted in Qassim region located in Central Saudi Arabia. The region has a population of 1,219,184. According to data compiled in 2011 by the Central Department for Statistics and Information in Saudi Arabia (last updated in 2010 IHSA) [13], in Qassim, there are six blood donation centers located in the following cities: two blood centers in Buraydah, the capital city of Qassim region, one belonging to the King Fahad Specialist Hospital and considered the central blood bank in the region, and the other at the Maternity and Children's hospital. The other blood donation centers are in Unayzah (King Saud Hospital), in Arrass (Arrass Hospital), in Almidhnab (Almidhnab Hospital) and in Albukayriyah (Albukayriyah Hospital).

A retrospective review of all donor results from the six (6) Blood Bank Centers for a 2-year period (using Hijri Calendar) from November 4, 2013 to October 13, 2015 was carried out. These two periods are referred in the study as 2014 and 2015. A total number of 32,531 donors were screened with an age ranging from 18 to 60 years old. All donors underwent mandatory routine screening for serological tests and nucleic acid testing (NAT). The serology results for 2014 were done using Dynex (ELISA immunoassay). Whereas in 2015, all samples collected from different blood centers are sent to the central blood bank in King Fahad Specialist Hospital for screening. Results of hepatitis B markers (HBs Ag, Anti-HBs and Anti-HBc) were done with ARCHITECT i2000SR (a chemiluminescence immunoassay method) in the central blood bank. NAT for individual testing was done by *Cobas taqman*, and the results were obtained from the directory of Laboratories and Blood Banks in the Qassim health institution, to which every blood bank must submit all results from reactive and non-reactive donors every quarter.

RESULTS

A total of 32,531 screened donors from all six blood bank centers were reviewed in the study. For the period of 2014, a total of 15,599 donors were screened while 16,932 donors in 2015, with an increment of 8.54% (Table 1). The prevalence of HBsAg among blood donors was found to be 74 (0.47%) and 63 (0.37) in the two periods. The prevalence of anti-HBc for the two-year period (2014 & 2015) was 998 (6.40%) and 1077 (6.36%) cases respectively (Table 2).

Table 1: Number of blood donor in Qassim region for the two-year period (2014 & 2015)

City	Blood Centre		2014	2015	Percentage difference
Buraydah	King Fahad Hospital		6893	7364	6.38 %
	MCH Hospital		2701	3220	19.21 %
Almidhnab	Almidhnab Hospital		932	890	-4.51 %
Unayzah	King Saud Hospital		2046	2182	6.65 %
Albukayriyah	Albukayriyah Hospital		796	960	20.60 %
Arrass	Arrass Hospital		2231	2316	3.81 %
Total			15599	16932	8.54 %

Table 2: Prevalence of anti-HBc and anti-HBS among blood donors

City	Blood Centre	2014 (%) (04-11-2013 to 24-10-2014)			2015 (%) (25-10-2014 to 13-10-2015)		
		Anti-HBc	Anti-HBs >100	Anti-HBs <100 or nonreactive	Anti-HBc	Anti-HBs >100	Anti-HBs <100 or nonreactive
		Buraydah	King Fahad Hospital	381 (5.53)	200 (2.90)	181 (2.63)	425 (5.77)
	MCH Hospital	92 (3.41)	87 (3.22)	5 (0.19)	94 (2.92)	94 (2.92)	0 (0)
Almidhnab	Almidhnab Hospital	74 (7.94)	61 (6.55)	13 (1.39)	63 (7.08)	48 (5.39)	15 (1.69)
Unayzah	King Saud Hospital	181 (8.85)	155 (7.58)	26 (1.27)	178 (8.16)	157 (7.20)	21 (0.96)

Albukayriyah	Albukayriyah Hospital	38 (4.77)	30 (3.77)	8 (1.01)	94 (9.79)	75 (7.81)	19 (1.98)
Arrass	Arrass Hospital	232 (10.40)	145 (6.50)	87 (3.90)	223 (9.63)	109 (4.71)	114 (4.92)
	Total out of anti-HBc		62.5%	37.5%		48.88%	51.12%
	Total	998 (6.40)	678 (4.35)	320 (2.05)	1077 (6.36)	684 (4.04)	393 (2.32)
	Total out of anti-HBc		67.93%	32.06%		63.50%	36.49%

All samples that showed positive for Anti-HBc were tested further for Anti-HBs. According to the guidelines of the Saudi MOH, any sample that has a result of more than 100(IU/ml) will be considered as an acceptable unit, while any result for Anti-HBs that showed less than 100 (IU/ml) will be considered as a discarded unit, and the blood will not be issued to a patient. In 2014, about 998 blood samples from all blood bank centers were positive for Anti-HBc. Of these, 678 (67.93%) were tested further for Anti-HBs and showed a result of >100(IU/ml), which accounts to 4.35% from 15,599 donors. On the other hand, 320 samples showed <100(IU/ml) or were non-reactive (32.10%) which accounts for 2.05 % from 15,599 donors (Table 2).

A total of 16,932 donor samples were subjected to Anti-HBc test and 1077 (6.36%) were reactive for Anti-HBc in 2015. Of which, 684 (4.04%) accounting to 63.5% were reactive for further testing Anti-HBs (>100IU/ml). On the other hand, 393 results which is 2.32% of 16,932 donors were found either non-reactive for Anti-HBs or had less than 100(IU/ml).

The highest number of donors was observed in King Fahad Specialist hospital (KFSH) where the central blood bank is located. The numbers of screened donors were 6893 and 7364, in 2014 and 2015, respectively, with an increment of 6.38%. Noticeably, the center had a decrease in HBsAg in the two-year period with 0.54% and 0.34% respectively (Table 3). Albukayriyah Hospital had almost the lowest number of donors with 796 and 960 donors in 2014 and 2015, respectively (Table 1). The prevalence of HBsAg in this hospital was found to be 0.50% and 0.52%, respectively.

Arrass Hospital had the highest prevalence of positive Anti-HBc with 10.40% in 2014 and 9.63% in 2015, reflecting a considerable attention. All of these samples (232) were subjected to Anti-HBs test in which 145 (62.5%) were reactive (>100 IU/ml) and 87 (37.5%) were either reactive for <100 IU/ml or non-reactive during the 2014 period. In 2015, from 2316 donors, 9.63% out of total was positive for Anti-HBc, and 4.71% had Anti-HBs >100 IU/ml and 4.92% had Anti-HBs of <100IU/ml or were non-reactive (Table 2).

In the Qassim region, the number of discarded units due to positive f HBsAg and Anti-HBs of <100(IU/ml) or of being non-reactive was 394 units (2.52%) out of 15,599 donors for the year 2014. In 2015, the number of discarded units showed a varying pattern between the positive results for HBsAg and Anti-HBs, although the total number had increased to 456 units (2.69%). There was an increment from 320 units (2.05%) to 393 units (2.52%) for the Anti-HBs result in the two periods. On the other hand, HBsAg reactive units was 74 (0.47%) in 2014 and 63 units (0.37%) in 2015 indicating a declining trend (Table 3).

Table 3: Prevalence of HBsAg among blood donors

City	Blood Centre	2014 (%)	2015 (%)	Percentage difference
Buraydah	King Fahad Hospital	37 (0.54)	25 (0.34)	0.20%
	MCH Hospital	14 (0.52)	13 (0.40)	0.12%
Almidhnab	Almidhnab Hospital	6 (0.64)	4 (0.45)	0.19%
Unayzah	King Saud Hospital	5 (0.24)	4 (0.18)	0.06%
Albukayriyah	Albukayriyah Hospital	4 (0.50)	5 (0.52)	-0.02%
Arrass	Arrass Hospital	8 (0.36)	12 (0.52)	-0.16%
	Total	74 (0.47)	63 (0.37)	0.10%

DISCUSSION

Hepatitis B virus was once considered hyper-endemic in Saudi Arabia [12]. The estimated prevalence of HBV in healthy blood donors ranges from 2.7% to 9.8% [6, 12]. Similarly, the results of this study also indicate that of the apparently healthy blood donor in Qassim region, 0.42% was positive for hepatitis B virus markers. This prevalence for HBV markers is lower than that reported in the Eastern region (6.7%), the southwestern region (5.4%) and to the estimated overall prevalence in Saudi Arabia. Numerous surveys have shown that there is marked regional variation in the prevalence of HBV [8-11] and this is affected by several factors including the size of the population, the number of beds and the specialty of the hospital. The distribution of HBV worldwide shows variations depending on geographical location. In China, 1.4% of blood donors were reported to be positive for HBV. [14] High rates of chronic infections were also found in the Indian subcontinent, as 2% to 5% of blood donors were estimated to be infected. [15] In Europe, the prevalence of HBV in blood donors ranged from 0% to 5.2%, and in the United States the prevalence ranged from 0.4% to 1.0% among blood donors [16, 17].

In the study conducted by Mehdi et al. [12] on the same region (Qassim), the prevalence of HBV and HCV among blood donors from 1995 to 1997 reported a rate of 3.43%. It must be taken into account that there was no NAT testing during this study. This could mean that there was a likelihood of transmitting the occult hepatitis B virus that is characterized by the presence of the hepatitis B virus with an undetectable level of the hepatitis B surface antigen. Aljarbou [2] predicted that the number of infection rates would increase substantially by 2011 to 2013. However, our study showed that although blood donors do not represent the whole population, there was a noticeable decline on the number of incidents of HBV at the same hospital (KFSH-BB) dropping from 0.54% to 0.34% in 2014 and 2015. Another large study that collected all incidents of HBV in Saudi Arabia between 2009 and 2013 showed that there was a significant decrease in HBV in that time [18].

The reduction of prevalence can be attributed to the successful implementation of the vaccination program as well as to increased awareness among the public, particularly through the national premarital screening program (PMS) which was implemented in 2004 [19] with testing for HBV, HIV and HCV included from 2008. [20] The study of Aljarbou [2] from 2008 to 2010, investigated 8,082 subjects through the PMS screening and found that the annual number of incidents of HBV increased by 1.4%. Thus, there is a need for collaborative agreements between blood bank departments or blood donor care clinics. The latter shall be discussed in detail, and also the PMS department in each hospital.

HBV infection in Saudi Arabia is transmitted and acquired mainly by horizontal transmission and is strongly associated with family history [19] and particularly when sharing others' property, for example, toothbrushes. Moreover, a well-known procedure in Saudi Arabia known as "cupping" (Hijama) for therapeutic purposes where blood is drawn by sucking from different areas of the body is also practiced. This procedure has been found to be one of the most important sources of HBV infection in Yemen where 3.9% of patients are infected due to Hijama. [21] This procedure is now mostly done in private clinics with single-use equipment. Nevertheless, the MOH has established guidelines to ensure the safety of blood components and stated that "any donor who has used Hijama must be deferred for one year". Although, this guideline could increase the number of deferred donors, the Saudi MOH has a plan to conduct this procedure in governmental hospitals, and in this way the deferral time might be decreased.

On the other hand, any positive marker of HBV detected during the donor screening will be subjected to further testing. According to the MOH guidelines[22], the whole batch should be withheld from the donors' units and should not be released to a patient, even if the other results are non-reactive, until a repeat sample from the blood unit matches the previous result. If there is any discrepancy, the whole batch is repeated by taking blood samples from each unit to identify the exact issue. Although, this procedure is considered an extra barrier to ensure blood safety, this would also affect the blood inventory due to the delay in releasing the results and the consumption of reagents.

Based on the results of this study, an estimated number of 320 (2.05%) units of blood were discarded due to unmet MOH requirements regardless of other criteria and causes for discarding units. Therefore, the more blood is obtained from healthy volunteer donors, the more blood will be available and safer at all times for the patients.

CONCLUSION

Having discussed the figures provided and made comparisons between certain cities regarding their blood donors, the study shows a lower prevalence rate of HBV markers among blood donors in Qassim region as compared to other regions in Saudi Arabia. Furthermore, this study does not represent the whole population of the Qassim region, neither is it a community-based study, thus we encourage other researchers to do further research involving the entire population, including gender and age criteria to find out how the immunization has reduced the incidence of HBV. Nationality should also be included in the study to estimate the impact of immigration on the prevalence of HBV and to understand the anticipated effect of mutation of HBV on the assays that are used for blood screening. Likewise, a further study on the residual risk of HBV among blood donors should be conducted in the future to see what level of safety blood donations have reached in Saudi Arabia.

RECOMMENDATIONS

Having gone through the literature and considered the status of safety of blood and blood products in Saudi Arabia, the following recommendations are made:

1. Blood Donor Care Clinic (BDCC)

- A- Here the blood donor would find more information and care about his health status when making his previous donation or during any future donation, for instance the anemic donor would be identified and advised regarding healthy foods and the appropriate time for their next donation. Moreover, there would be follow up with those donors whose blood pressure or pulse rate were too high, because most of those donors would normally never come again. This BDCC area would do the same job and increase public awareness [23].
- B- The BDCC would be responsible for offering hepatitis B vaccine to regular donors in order to protect them from exposure to HBV as well as to have sustainable and continuous donations. Moreover, it would follow up with booster doses, more especially when a low titer of anti-HBs are identified after immunization as this will continue to reduce over the next 12 months. [21]
- C- Follow up with donors who have had the hepatitis B vaccine to return to the donor program 28 days after vaccination, as approved by the FDA. [24]

- D- The BDCC should have the authority to refer donors to specialized clinics according to their findings. As well as having the authority to request donors to report for laboratory tests, for example, the ferritin test would be used to measure the iron status of the regular blood donor. This clinic would also be able to do some additional tests.
- E- For research purposes and improvement projects.
- F- A collaborative contract should be drawn up between the premarital screening department and the BDCC to report any new case that has been infected with a virus. Thus the BDCC will check whether there has been any previous donation, and questions will be asked of the infected patient as to whether he/she has donated before or not.
2. Modification of the blood donor questionnaires according to the local prevalence of the virus. For example, the consent of the blood donor should include the HBV status of the donor.
3. All physicians must go through a comprehensive program (educational program) to learn to what extent blood is safe and the fundamental help that clinicians can provide to reduce the risk of transmission by reducing the amount of exposure to blood by using alternatives.
4. Hepatitis B immunization should be recommended for all multi-transfused patients as they are exposed to greater volumes of blood [21].
5. All donors vaccinated against HBV should be deferred for 28 days as the FDA recommends, because if there is no deferral, this would make little disruption to blood donations, especially when blood is tested positive and is therefore deferred for 56 days to complete the minimum donation interval as an alternative to the 28 days. Moreover, this would involve resource management.

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