

## PREVALENCE OF HBsAg AND ANTI-HCV IN SAUDI BLOOD DONORS

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Hepatitis B and C play a significant role in post-transfusion hepatitis.<sup>1</sup> The prevalence of hepatitis B virus in healthy carriers varies, being as low as 0.1% to 1% in blood donors in the U.K. and U.S.<sup>2</sup> and as high as 15% in Southeast Asia and the Far East.<sup>1</sup> The overall prevalence of hepatitis B in Saudi Arabia is reported to be 6.7%.<sup>3</sup> Similarly, the prevalence of HCV antibodies in random blood donors is between 0.2% and 2% in the U.S., Europe, Japan, and Britain.<sup>4,5</sup> It is reported to be 1.5% in Saudi Arabia.<sup>6</sup>

Aach et al. have reported that high levels of serum alanine aminotransferase (ALT) may indicate viral hepatitis.<sup>7</sup> To reduce the incidence of post-transfusion hepatitis, the American Association of Blood Banks (AABB) formerly required that ALT be used to screen blood donors.<sup>8</sup> However, ALT screening lacks the sensitivity to detect all infectious units of blood. Despite the introduction of sensitive screening methods for detecting viral hepatitis (B and C), the problem of post-transfusion hepatitis is still encountered, though not as frequently.<sup>9</sup>

The aim of the present study was to determine the prevalence of HBsAg and anti-HCV in Saudi blood donors with normal and elevated ALT levels, and to evaluate the utility of ALT screening in healthy blood donors.

### Patients and Methods

Between January 1992 and January 1995, 15,006 blood donors were screened at King Fahad National Guard Hospital (KFNGH), Riyadh, Saudi Arabia. This hospital serves a nonurban, largely Bedouin, military population in the central region of the country.

A detailed standardized donor questionnaire (40 questions), determination of body weight and a physical examination were administered to all potential donors,

according to the AABB requirements.

Fresh capillary blood for the measurement of ALT was taken from eligible donors by puncturing the tip of the finger. Those with normal ALT levels underwent phlebotomy and had serological tests for hepatitis B and C performed. Those who showed ALT values greater than 38 U/L were considered abnormal based on local patient population study, and were consequently excluded from donation. ALT levels were measured on a Reflotron analyzer (Boehringer-Mannheim, Mannheim, Germany). A 100% correlation was found between Reflotron and the International Federation of Clinical Chemistry method for measurement of ALT levels. ALT levels of 38 U/L or less were considered normal, as determined by population mean + 2.0 standard deviations (SD). One hundred consecutive blood donors with high ALT level (>38 U/L) were tested for HBsAg and anti-HCV by enzyme immunoassay methods (AUSZYME monoclonal enzyme immunoassay method and second-generation ELISA, Abbott Laboratories, North Chicago, IL).

In the AUSZYME monoclonal enzyme immunoassay procedure, beads coated with mouse monoclonal antibody to hepatitis B surface antigen (anti-HBs) are incubated with serum or plasma, and mouse monoclonal anti-HBs peroxidase (horseradish) conjugate (anti-HBs:HRPO). During the incubation period, any HBsAg present is bound to the solid phase antibody and subsequently reacted with the anti-HBs:HRPO. Unbound material is aspirated and the beads are washed. A solution of ortho-phenylene diamine (OPD) containing H<sub>2</sub>O<sub>2</sub> is then added to the mixture, and after incubation a yellow-orange color develops in proportion to the amount of HBsAg. Absorbance values of less than the cut-off are considered positive or reactive. Reactive specimens were confirmed by retesting.

For the assay anti-HCV antibodies, serum was reacted with polystyrene beads coated with recombinant HCV antigen. Any antibody present in the patient sample, fixes to the coated beads. After removing the unbound materials and washing the beads, anti HCV antibody remaining bound to the solid phase was detected by incubating the bead-antigen-antibody complex with a solution containing horseradish peroxidase-labeled goat antibodies directed against human immunoglobulin. Unbound enzyme

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conjugate was then removed and the beads were washed. Lastly, OPD solution containing H<sub>2</sub>O<sub>2</sub> was added to produce a color and the absorbance was read as before.

The exclusion criteria for donation included one or more of the following: 1) high ALT level; 2) positive donor history (history of jaundice, intravenous drug abuse, sexual promiscuity, etc.); 3) low body weight (<50 kg); 4) low hematocrit level (<0.38); and 5) age (<17 years or >65 years).

### Results

None of the study group showed signs or symptoms of liver disease. A total of 1,247 donors (8.3%) were rejected for being underweight and therefore did not complete the donation process.

Table 1 shows the breakdown of 6746 donors who were rejected from donation. Of these 4,161 donors (30.2%) were rejected for having a high ALT level and the rest were rejected for other reasons, despite normal ALT.

Table 2 shows HBsAg and anti-HCV results among donors with a normal ALT. Of 7013 units of blood, 6657 units (95%) were found to be negative for HBsAg and anti-HCV; 284 (4.0%) donors were found to be positive for HBsAg and 72 (1.0%) donors were positive for anti-HCV.

Table 3 shows the ALT ranges of 100 consecutive donors with elevated ALT. Among those, seven donors were positive for HBsAg and four were anti-HCV positive, while one was positive for both. Ninety-nine (99%) donors had ALT levels less than 200 U/L.

### Discussion

The prevalences of HBsAg and anti-HCV in our blood donor population studied with normal ALT levels were 4% and 1%, respectively. These results are lower than previously reported,<sup>6,11</sup> as we have excluded donors likely to have viral hepatitis, i.e., elevated ALT.

Thirty percent of our donors were found to have an elevated ALT level, in contrast to 2.3% in the Western countries.<sup>10</sup> HBsAg and anti-HCV were present two and four times more frequently, respectively, in donors with an elevated ALT level than in donors with a normal ALT. However, 87% of our donors with an elevated ALT level were negative for HBsAg and anti-HCV, suggesting that the reasons for ALT elevation in the vast majority of donors might not be due to infection with hepatitis B and/or C. The reasons for the ALT elevation in our particular group of donors are diverse and include fatty liver and physical exercise (the vast majority of our donors are military recruits), which are the two most common causes (unpublished observation), other viral hepatitises, hepatitis B and C that may not yet have seroconverted, metabolic liver disease, alcohol intake, drug-induced

TABLE 1. Breakdown of 6746 blood donors who were rejected from donating blood.

Rejected donors	Year			Total
	1992 (%)	1993 (%)	1994 (%)	
High ALT level	880 (22.2)	1510 (28.6)	1771 (30.7)	4161
Positive donor history	287 (7.3)	456 (8.6)	728 (12.6)	1471
Low hematocrit level	46 (1.2)	86 (1.6)	127 (2.2)	259
Other miscellaneous reasons	296 (7.5)	184 (3.5)	375 (6.5)	855

TABLE 2. HBsAg and anti-HCV results in 7013 blood donors with normal serum alanine aminotransferase (ALT) levels.

	Year			Total
	1992 (%)	1993 (%)	1994 (%)	
Eligible donors	2286	2549	2178	7013
Positive HBsAg	68 (3.0)	105 (4.1)	111 (5.1)	284 (4.0)
Positive anti-HCV	11 (0.5)	25 (1.0)	36 (1.6)	72 (1.0)

TABLE 3. Serum alanine aminotransferase (ALT) levels of 100 consecutive donors who were rejected from donating blood.

Number of donors	ALT range IU/L
56	39-60
24	61-80
12	81-100
7	100-200
1	200-500
0	>500

hepatitis and others. It is unlikely that acute hepatitis B and/or C (i.e., seronegative) contribute significantly to ALT elevation in our donors, since none have risk factors, symptoms or signs, and only one had a substantially elevated ALT. We need to shed more light on the exact etiology of ALT elevation through a systematic prospective study to determine whether viral hepatitis (particularly early hepatitis C) might be an important contributing factor to ALT elevation.

Since ALT is neither sensitive nor specific for viral hepatitis, and results in the elimination of a large number of otherwise healthy blood donors, particularly in our population, and has clearly not reduced the incidence of post-transfusion hepatitis in the era of anti-HCV testing,<sup>12,13</sup> we agree with the recent AABB recommendation that it should not be performed routinely in addition to anti-HCV testing.

In conclusion, the prevalence of HBsAg and anti-HCV in our healthy blood donors is 4% and 1%, respectively, in those with a normal ALT level and 8% and 5%, respectively, in those with elevated ALT level.

Furthermore, although ALT screening serves as a discriminant in filtering out most blood donors with viral hepatitis, utilization of this screening test in our population results in the exclusion of a large number of donors who are not infected with viral hepatitis. We recommend that ALT screening not be used in the Saudi population now that routine and specific hepatitis B and C screening of all blood donors has become available. On the other hand, ALT screening in addition to anti-HCV testing should be prospectively evaluated to determine whether it reduces further the incidence of post-transfusion hepatitis from other causes. These recommendations are in agreement with the recent new recommendation of the AABB to omit routine ALT screening for blood donors (communication with AABB).

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