# PREVALENCE OF ANTIBODIES TO HUMAN T-LYMPHOTROPIC VIRUS TYPES I AND II AMONG SAUDI ARABIAN BLOOD DONORS

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In 1980 and 1982, Gallo et al. described the isolation of human T-cell lymphotropic virus type I (HTLV-I)<sup>1</sup> and type II (HTLV-II).<sup>2</sup> In the majority of cases, infection with these viruses does not cause diseases. However, HTLV-I infection has been etiologically associated with neoplastic diseases<sup>3</sup> and a variety of demyelinating neurologic disorders.<sup>4-5</sup> The association of HTLV-II with leukemia pathogenesis is not well established,<sup>6</sup> however, some cases of neurological disease have been reported.<sup>7</sup>

HTLV-I infection may be transmitted via blood transfusion. Cellular blood components transmit the virus with 20%-63% efficiency.<sup>8,9</sup> Among recipients of HTLV-I-contaminated blood components, the mean interval from infection to antibody seroconversion is 40 days (range, 20-90 days).<sup>9,10</sup>

The transmission of HTLV-II via blood transfusion has been documented.<sup>11</sup> HTLV-I is now recognized to occur worldwide, although it is characteristically endemic in Japan, the Caribbean, Southern Italy, New Guinea, Africa, and the Seychelles,<sup>12</sup> as well as in several countries in the Middle East.<sup>13-14</sup>

In the present study, we took sera from volunteer Saudi blood donors and hemodialysis patients over a three-year period to determine the prevalence of HTLV-I/II among Saudi blood donors, and to examine the cost effectiveness of HTLV screening in Saudi blood banks.

### **Materials and Methods**

Samples from 9949 apparently healthy Saudi blood donors were screened for antibodies to HTLV-I/II by enzyme immunoassay (EIA) from Abbott, U.S.A. In addition, serum from 30 patients with chronic renal failure on hemodialysis who had previously received multiple blood transfusions was also re-tested. This was carried out at the King Fahad Armed Forces Hospital, Jeddah, between September 1995 and October 1998. All samples that tested reactive by EIA were sent to the Mayo Medical Laboratories, Rochester, U.S.A. for confirmatory testing. Five indeterminate samples tested by Western blot (WB) were sent to to Bioscientia Institute for Laboratory Analyses, Ingelheim, Germany, for further testing by polymerase chain reaction (PCR) assay. Interpretative criteria of WB according to the American Association of Blood Banks is as follows:<sup>15,16</sup>

Negative.....No viral bans present. Indeterminate.....Viral bands present but criteria for a positive result not met. Positive....Criteria viral bands present. The criteria of positive results are summarized as follows: HTLV-I......p19 or p24, plus GD21 and rgp 46-I.

HTLV-II......p24, GD21, and rgp 46-II.

HTLV......p19 or p24, plus GD 21.

#### Results

None of the multitransfused hemodialysis patients had detectable antibodies to HTLV-I/II. Nineteen (0.19%) of the blood donor samples tested reactive by EIA. Of the samples sent for WB, two had insufficient sample for analysis, three gave negative results, and fourteen were indeterminate. All of the five samples sent for PCR gave negative results. These five samples were indeterminate on WB. The approximate cost of reagents for the EIA was 17 Saudi Riyals (SR17, approximately \$4.50) per donor unit screened. This is equivalent to SR169,000 (\$45,066) during the period covered, and does not include staff costs for what is a relatively labor intensive assay. The cost of WB analysis was SR225 (\$60) per test and of PCR analysis was SR1344 (\$358) per test.

# Discussion

In Saudi Arabia, routine screening of blood donors for HTLV-I/II was first adopted at King Faisal Specialist Hospital and Research Centre in Riyadh in 1989,<sup>17</sup> and was followed by most of the Saudi blood banks at the end of 1995. In September 1995, we started to screen all donors for HTLV-I/II, and after three years we had screened 9949 Saudi donors. None of them had a positive result with confirmatory testing. Fourteen of the donors were indeterminate by WB, and were referred to the Department of Preventive Medicine for clinical evaluation, and for a repeat of the test if indicated. None of them had traveled outside the Kingdom (Blood Bank questionnaire). Five of the samples which gave indeterminate results by WB were

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re-tested by PCR, which gave negative results. The interesting finding is that none of the 30 multitransfusion hemodialysis renal patients tested positive through the screening of more than 10 transfusions. Also, no Saudi donor had tested positive in previous studies,<sup>17,18</sup> except for nine samples which tested positive by WB from 33,908 Saudi donors screened in the Eastern Province, which has a low prevalence rate of 0.022%.<sup>19</sup>

The majority of EIA-reactive results<sup>14,19</sup> were indeterminate by Western blot. The samples tested again by WB still gave the same results. Careful interpretation of WB indeterminate patterns can avoid the unnecessary generation of excess false-positive results.<sup>15</sup> We recommend using PCR assay for further confirmatory testing. PCR tests the viral nucleic acid sequences and constitutes a very useful addition to antibody testing, as it reflects virus replication.<sup>15,16</sup>

We recommend that each donor center should have a common policy to ensure the safety of both donor and the patient, and that these policies and standards follow most of the AABB (American Association of Blood Banks) standards, but with appropriate modification for Saudi Arabia. We conclude that HTLV-I/II is rare among Saudi blood donors, and that routine screening for HTLV-I/II for Saudi donors does not appear to be required or cost effective. The introduction of screening for HTLV-I/II in blood banks is appropriate to study the prevalence of these viruses in Saudi Arabia and to screen high-risk donors.

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