

A study-screening of blood donors for blood transmissible diseases

S.V. Shinde · G. V. Puranik

Abstract

Aims Blood donors are of voluntary and replacement type. All donors, especially voluntary, are considered as 'low risk' for seropositive status for Hepatitis B and C, HIV and syphilis. The present study endeavors to screen blood donors- a 'low risk' group and evaluate the resultant data.

Methodology We screened 23,068 donors serologically over 2 years for the above blood transmissible diseases. Serum alanine aminotransferase (ALT) and bilirubin were evaluated as surrogate markers in hepatitis B and C positive donors.

Results Seroprevalence rates were found to be HIV (1.96 %), syphilis (2.15 %), hepatitis B (1.98 %) and hepatitis C (0.9 %). Majority donors were voluntary (70.37 %) and male (96.2 %). However seroprevalence rates showed no significant difference: voluntary (7.02 %), replacement (6.67 %) male (6.85 %) and female (6.95 %). HCV and HIV showed highest (29.6 %) while HBV and HCV (2.5 %) showed lowest concomitance. Serum ALT and bilirubin were not effective surrogate markers. No demographic or behavioral variable was found as a significant risk factor.

Conclusion Thus, all donors need adequate privacy, information, counseling and motivation in order to reduce the seropositive rates in donors. Advent of sensitive tests renders surrogate markers redundant.

Keywords Concomitance · Seroprevalence · Surrogate marker

Introduction

Blood is the elixir of life. It is also the medium for transmission of diseases from donor to recipient. This however, can be managed through the elimination of commercial blood donors, a greater monitoring of voluntary donors and a mandatory pre-transfusion evaluation of blood units for HIV, Hepatitis B and C and syphilis. Tests of greater sensitivity have questioned the use of surrogate markers like serum ALT (Alanine amino transferase) and bilirubin for hepatitis. The advent of AIDS has also signaled the onset of multiple infections in a person of *high risk* behavior. Hence the present study endeavors to screen blood donors – a *low risk* group and evaluate the resultant data.

Materials and methods

The present study was conducted over a 2-year period from Jan 1999 to Dec 2000 at our blood bank. The study population was 23, 068 blood donors selected as per American Association of Blood Banks (AABB) protocol, of which 16,970 were voluntary and 6098 were replacement donors. Control population included 50 seronegative blood donors who were age- and sex-matched with the study group. The blood units were serologically tested using venereal disease

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research laboratory (VDRL) test for syphilis and commercially available Enzyme Linked Immunosorbent Assay (ELISA) kits for HIV and Hepatitis B and C. Serum ALT and bilirubin were evaluated as surrogate markers in control group and 255 donors who were seropositive for Hepatitis B and/or C in the year 2000. Control group (n=50) and 110 donors seropositive for hepatitis B or C in year 2000 were followed up in a look back survey for their demographic data and possible high-risk behavior. Statistical analyses were done using standard deviations and Chi square tests.

Results

Total donors in study group (n=23,068) comprised of 11,250 in year 1999 and 11,818 in year 2000. Table 1 gives their distribution by donor type and sex in 2 years. Majority of donors in 2 years were voluntary (n=16235, 70.37%) and male (n=22193, 96.2%). 85% (n=9563) and 78% (n=9218) donors in year 1999 and 2000 respectively belonged to age group of 18–37 years (mean age 29.7 ± 8.0). 1597 donors were found to be seropositive for atleast one of the 4 screened diseases over the 2 year period. Table 2 gives seroprevalence rates in voluntary and replacement donors in 2 years. The rates were 2.15%, 1.98%, 0.9% and 1.96% respectively in syphilis, hepatitis B and C and HIV. Seroprevalence rates in male donors in years 1999 and 2000 were 6.8 % (n=741) and 6.9 % (n=795) respectively while those in female donors were 7.0 % (n=30) and 6.9 % (n=31) respectively ($p > 0.05$). Seroprevalence rates were 6.7 %, 7.7% and 7.3 % in Hindu, Muslim and other donors respectively ($p > 0.05$). Both syphilis and hepatitis C showed a significant rising trend in 2 years of study, increasing from 201 to 292 and 92 to 124 respectively ($p < 0.05$), hepatitis B showed a significant decline from 253 to 192 ($p < 0.05$) while HIV showed a mild decline from 225 to 218 ($p > 0.05$). 81 of 1597 donors showed concomitant seropositivity i.e. for more than 1 screened disease, as given in table 3. Highest concomitance was observed between HCV and HIV

(29.6%) while hepatitis B virus (HBV) and hepatitis C virus (HCV) showed least concomitance (2.5%)

In year 2000, of the 316 units positive for either/and hepatitis B and C, 255 were evaluated for serum ALT and bilirubin while the other samples were hemolysed and hence unfit for evaluation. Table 4 and 5 shows the evaluation of serum ALT and bilirubin as surrogate markers. Mean (± 2 SD) serum ALT International Units per Litre (IU/L) was $30.0(\pm 30.0)$ for hepatitis B and $25.0 (\pm 28)$ for hepatitis C and $23.1(\pm 22.8)$ in control donors. Serum bilirubin had mean (± 2 SD) values of $0.38 (\pm 0.34)$ mg%, $0.32(\pm 0.28)$ mg% and $0.33(\pm 0.34)$ mg % in hepatitis B, hepatitis C and control group. Only 6.2 % and 6.6 % of donors with hepatitis B and C had serum ALT above M+2SD, while 4.3 % and 2.2 % respectively had serum bilirubin above M+2SD ($p > 0.05$).

110 donors positive for hepatitis B and/or C in year 2000 and 50 seronegative donors were followed up in a look back survey for their demographic profile and possible risk factors, as shown in table 6. HIV donors were not included in this survey since Food and Drug Administration (FDA) regulations do not permit notification of seropositive status to donors in the absence of counseling services. Among seropositive and control donors respectively, 2 and 1 had past blood transfusion, 7 and 2 had some past major surgery, 7 and 2 had past jaundice and 4 and 2 had jaundice in a family member and 20 and 7 gave history of alcoholism ($p > 0.05$). 1 seropositive donor had a tattoo. None of the donors gave a positive history of sexual exposure or intravenous drug (i.v.) abuse. None of the demographic or behavioral factors showed statistically significant association with the seropositive status.

Discussion

As per International Federation of Red Cross and Red Crescent [1], voluntary donors are defined as ‘persons who gives blood or other blood components of their own free will and who receive no payment for it, in cash or kind, including time off from work, small tokens, refreshments and

Table 1 Distribution of 23,068 donors by donor type and sex in year 1999 and 2000

Year	Donor type	Male Number (%)	Female Number (%)	Total Number (%)
1999	Voluntary (V)	7579(96)	310(4.0)	7889(100)
	Replacement (R)	3248(96.6)	113(3.4)	3361(100)
	Total	10,827(96.2)	423(3.8)	11,250(100)
2000	Voluntary	7956(95.3)	390(4.7)	8346(100)
	Replacement	3410(98.2)	62(1.8)	3472(100)
	Total	11,366(96.2)	452(3.8)	11,818(100)

reimbursement of travel cost.’ Our study found voluntary (V) and Replacement (R) donors to form 70.37% and 29.63% respectively. Sawanpanyalert et al [2] found a predominance of replacement donors while Ambika et al [3]

found a decline in replacement donors from 84.9% in 1989 to 69% in 1995 with a corresponding rise in voluntary donors. Ambika [3] and Munde et al [4] showed higher seroprevalence rates in replacement donors while our study did not show any significant difference.

Table 2 Seroprevalence rates of 4 screened diseases: voluntary vs. replacement donors

Disease	Voluntary Number (%)	Replacement Number (%)	Total Number (%)
Syphilis	347(2.1)	146(2.2)	493(2.15)
Hepatitis B	335(2.1)	110(1.6)	445(1.98)
Hepatitis C	153(0.9)	63(0.9)	216(0.9)
HIV	306(1.9)	137(2.0)	443(1.96)
Total	1141(7.02)	456(6.67)	1597(6.84)

p>0.05

Table 3 Concomitant seropositivity in donors (year 1999 and 2000)

Test	1999 No.(% of total)	2000 No.(% of total)	Total
HCV+HIV	08(22.9)	16(34.9)	24
VDRL+HIV	10(28.6)	09(19.6)	19
HBV+HIV	07(20.0)	04(8.6)	11
VDRL+HBV	06(17.1)	03(6.5)	09
HBV+HCV+HIV	02(5.7)	03(6.5)	05
VDRL+HCV	00(0.0)	04(8.6)	04
VDRL+HCV+HIV	02(5.7)	02(4.4)	04
VDRL+HBV+HIV	00(0.0)	03(6.5)	03
HBV+HCV	00(0.0)	02(4.4)	02
Total	35(100.0)	46(100.0)	81

Table 4 Serum ALT as surrogate marker in year 2000

	Hepatitis B Number(%)	Hepatitis C Number (%)	Control Number (%)
Number	164	91	50
<Mean	98(59.7)	57(62.6)	24(48)
Upto M+SD	33(20.1)	17(18.7)	18(36)
Upto Mean+2SD	23(14.0)	11(12.1)	6(12)
>M+2SD	10(6.2)	6(6.6)	2(4)

p>0.05

Table 5. Serum bilirubin as surrogate marker in year 2000

	Hepatitis B Number(%)	Hepatitis C Number (%)	Control Number (%)
Number	164	91	50
<Mean	117(71.3)	46(50.5)	40(80)
Upto M+SD	28(17.1)	29(31.9)	6(12)
Upto Mean+2SD	12(7.3)	14(15.4)	2(4)
>M+2SD	7(4.3)	2(2.2)	2(4)

p>0.05

Table 6. Comparative study between 110 seropositive donors (for hepatitis Band/or C) and 50 control donors.

	Seropositive donors (n=110)	Control donors (n=50)
Sex: Male	105	48
Female	5	2
Mean age (yrs)	29	27
Education status: Illiterate	9	2
Literate	101	48
Socio-economic status: Slum	10	3
Non-slum	100	47
Marital status: Unmarried	42	16
Married	68	34
Religion: Hindu	72	33
Muslim	17	6
Others	21	11
Donor type: Voluntary	80	37
Replacement	30	13
Donor: 1 st time donor	104	47
Repeat donor	6	3

p>0.05

Table 7. Comparative studies in Indian and Western literature of seroprevalence rates in donors

	Present study		Mumbai	DELHI	Vellore	Calcutta	Other countries
	1999	2000	NACO [13]	NACO [13]	NACO [13]	NACO [13]	
Syphilis	1.8	2.5	0.16	4.5	0.26	0.14	0.08 UK[14], 0.26 Japan[14]
HBV	2.3	1.6	2.07	3.2	3.0	0.2	0.7 Japan [15]
HIV	2.0	1.8	1.04	1.35	0.45	0.04	0.78[16], 2.3 Thailand[2]
HCV	0.8	1.09					0.18 UK 1.2 Japan 0.42 Germany, 0.5 USA, 0.68 France, 0.87 Italy [17]

All figures are in percentages

Ambika et al [3] found HBV+syphilis concomitance in 0.8% and 0.1% donors in 1994 and 1995-96 respectively. The corresponding rates for HBV+HIV were 0.6% and 0.4%. These were in accordance to our study. Study by Sung Lung Tsai [9], Saha et al [10] and Sheen [11] found that co-existence of HBV and HCV causes interference with HBV infection and expression and also causes clearance of HBV markers. This is lymphokine mediated in acute infection, while delayed clearance may be as a result of cumulative or sustained direct suppressive effect of HCV on HBV. Hence Ke Qin Hu [12] evaluated a combined Polymerase chain reaction (PCR) technique for detection of HBV DNA and HCV RNA and found it sensitive, specific and cost effective.

Table 7 [2, 13-17] shows the comparative seroprevalence rates in Indian and Western literature. Rates of all screened diseases in our study are lower than those in Delhi while they are in accordance with the rates in Mumbai. All diseases except HCV show higher rates in our study as compared to western countries.

The present study did not find either serum ALT or bilirubin to be valuable as surrogate markers for hepatitis B/C. This was corroborated by studies by Jolly et al [7] and Nabajyoti et al [6]. However Deloris [18] found ALT and anti-hepatitis B core antigen (HBc) antibody to be independent variables in transmission of infection from donor to recipient while Joseph et al [19] found significant association

between elevated ALT, Recombinant Immunoblot Assay (RIBA-2) test and high titer viremia by PCR for HCV.

Alonso et al [5] found 1st time donors, history of jaundice, past definite/potential blood transmission, tattooing and i.v drug abuse to be independent risk factors for HCV while Sawanpanyalert [2] found young age, male sex, 1st time donors, i.v drug abuse and sexual exposure as risk factors for HIV ($p < 0.05$). Our study, however, could not detect any significant risk factor. This stresses the need for donor privacy, informed consent and pre donation counseling before donor selection in both replacement and voluntary donors.

Conclusion

National Blood policy stresses on replacing all blood units by voluntary donors. However donor privacy, predonation counseling and a detailed history will ensure that replacement donors are not lost to blood banks. Widespread public motivation should also ensure participation by female donors. Evolution of sensitive tests for disease detection negates the utility of surrogate markers.

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