

Incidence of False Sero-Negative Blood Donor Cases for Hepatitis-C In Public And Private Hospitals Of City District Faisalabad

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ABSTRACT

Background: Hepatitis C is a worldwide public health problem nowadays. World Health Organization (WHO) estimates that 3 percent of the world population is infected with HCV. Voluntary blood donors have a very high prevalence of HCV infection especially in the developing world. The blood and blood components can be obtained from volunteer donors, direct donors, paid donors, or through autologous donation. Hence the donors should be carefully interviewed and tested before blood donation. **Objectives:** To assess the incidence of false sero-negative Hepatitis-C blood donors and evaluate the costs, benefits and effectiveness of specific Tests of Hepatitis-C in public and private hospitals of city district, Faisalabad. **Study Design:** It was a cross-sectional hospital based study. **Setting and Duration:** The study was conducted in 3 public sector and 3 Private sector Hospitals of City district of Faisalabad. The study was conducted for one Year during 2010-2011. **Sampling procedure:** Non-probability Convenient sampling technique was employed. **Sample size:** The study included 600 blood donors who deposited their blood in the blood banks of the above hospitals for transfusion purposes. **Results:** The majority of the blood donors 70.83% were between the age of

18-25 years. Despite the fact that all the donors, in government and private hospitals groups respectively were found initially negative for hepatitis C on routine diagnostic test, yet considerable number of individuals, 14 (4.60%) and 46 (15.33%) in government and private hospitals groups, respectively were found unexpectedly positive for hepatitis C when scrutinized on ELISA diagnostic test. The results were found to be statistically significant when the P value was less than 0.05 ($P < 0.05$). **Conclusion:** All the individuals irrespective of their group were screened to be sero-negative for hepatitis -C, when tested on the routine laboratory test. But when their blood serum was tested by ELISA method, a sizeable number of individuals in both government and private hospital groups were screened as sero-positive for HCV. This state of uncertain performance of the routine laboratory test has given rise to unreliability of the diagnosis of hepatitis C by the routine test. It is, therefore, strongly recommended that only ELISA method should be ordered for authentic diagnosis of hepatitis C. **Key Words:** Blood Donors, ELISA Test, Sero-positive Hepatitis C, Sero-negative Hepatitis C. False Sero-negative Hepatitis C.

INTRODUCTION

Hepatitis C is a worldwide public health problem

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nowadays¹. World Health Organization (WHO) estimates that 3 percent of the world population is infected with HCV and around 170 million individuals are chronic carriers who are at risk of developing liver cirrhosis and liver cancer. In many countries, particular population subgroups, such as voluntary blood donors have a very high prevalence of HCV infection especially in the developing world². Hepatitis C is

diagnosed by a blood test that can detect antibodies reacting to the hepatitis C virus. A positive test shows that the person is infected, as the body naturally makes antibodies to try and fight the hepatitis C virus. However, the test will not show a positive reaction for some months after being infected, as the body will take time to make these antibodies³. In addition, many symptomatic acute HCV cases are not laboratory confirmed since testing of patients for HCV markers is not commonly done².

The Institute of Hematology and Blood Transfusion Services, Punjab and other Blood Transfusion Services in the province of Punjab started screening for HCV in April 2000 and the prevalence of HCV, amongst the transfusion transmitted infections (TTIs) being screened for in the Punjab, was the highest⁴. Blood banks have obligation to provide adequate and safe blood supply to the community. In addition, strictly enforced screening guidelines and eligibility requirements, to make sure that donated blood will not harm the donor or the recipient, have reduced the number of people who are fit to donate blood. The blood and blood components can be obtained from volunteer donors, direct donors, paid donors, or through autologous donation⁵⁻⁶⁻⁷, hence the donors should be carefully interviewed and tested before blood donation.

THE RATIONALE OF THE STUDY

There are reports of transmission of infection with a variant of hepatitis C virus to several recipients after transfusion of a single infected donor blood. The risk of transmitting blood-borne infectious diseases remain a major source of worry to both blood donors and recipients⁸⁻⁹; Where as the highest prevalence of HCV (4.1%) is in transfusion transmitted infections (TTIs)⁴. Keeping in view the high frequency of HCV in Pakistan, nationwide efforts are required to identify HCV infected peoples¹⁰. Economic costs of viral infections are significant and their related deaths and disabilities are likely to have the greatest impact on the capabilities of communities especially in developing countries like Pakistan. Viral infection costs can be reduced by finding and applying more sensitive and specific diagnostic methods¹¹⁻¹²⁻¹³. Early diagnosis and prompt treatment of HCV, therefore, should be taken as first and foremost action towards prevention and control of the disease to reduce its burden and complications. The study conducted is to play a role towards prevention and control of liver disorders in the

community at Faisalabad; since no other study of this kind has been carried out in the region before.

OBJECTIVES

- To assess the incidence of false sero-negative Hepatitis-C blood donors in public and private hospitals of city district, Faisalabad.
- To evaluate the costs, benefits and effectiveness of specific Tests of Hepatitis-C

MATERIAL AND METHODS

Study Design: It was a cross-sectional hospital based study.

Study Setting and Duration: The study was conducted in 3 public sectors and 3 Private Hospitals of City district of Faisalabad. The study was conducted for one year during 2010-2011.

Sampling procedure: Non-probability Convenient sampling technique was employed.

Sample size: The study included 600 blood donors who deposited their blood in the blood banks of the above hospitals for transfusion purposes.

Inclusion Criteria: All the blood donors of either sex apparently declared sero-negative (non-reactive) for Hepatitis-C and given fitness for blood donation were included in the study.

Exclusion Criteria: All apparently Sero-positive (reactive) cases for Hepatitis-C were not included in the study.

Data Collection: Study Tools. A structured questionnaire was developed, consisting of open and close-ended questions to interview the blood donors from whom informed consent was obtained.

Medical History: Medical history including any history of present or previous liver disease in case of each individual was taken. Clinical signs and symptoms of liver disease if any, were also recorded.

Laboratory Investigations: The serum samples of all the non-reactive (sero-negative) individuals for Hepatitis-C were retested using Enzyme-linked immunosorbent assay (ELISA) kits supplied by a standard Pharmaceutical diagnostics company (Human Diagnostics, Germany).

Data processing & Analysis: Different codes for various entries according to the questionnaire were allocated with the help of the programmer. Requisite variables and indices were identified to the data analyst to facilitate data processing and analysis on SPSS version-10.

Results & Analysis: All the data have been categorized and tabulated to reveal the physical characteristics, clinical presentations and laboratory investigations of blood donors who were labeled as sero-negative for hepatitis C and hence, allowed to donate blood to the recipients. The donor individuals were included from the government and private hospitals of the city District, Faisalabad; those were, therefore, grouped as government hospitals donors and private hospitals donors.

Table-1
Distribution of Blood Donors according to the Sex, Age and Marital Status

Groups of Individuals		
Distribution of Donor individuals in different sexes within government and private hospitals groups.		
Sex	Government	Private
Male	255 (85.0%)	213 (71.0%)
Female	45(15.0%)	87(29.0%)
Total	300 (100%)	300 (100%)
Distribution of donor individuals in different age groups within government and private hospitals groups.		
Age in Years	Government	Private
18-25	192 (64.00%)	233 (77.66%)
25-35	65 (21.66%)	56 (18.67%)
> 35	43 (14.34%)	11 (3.67%)
Total	300 (100%)	300 (100%)
Distribution of donor individuals with respect to marital status within government and private hospitals groups.		
Marital Status	Government	Private
Married	103 (34.33%)	85 (28.33%)
Unmarried	197 (65.67%)	215 (71.67%)
Total	300 (100%)	300 (100%)

Sex-wise Distribution: In both the groups of government and private hospitals individuals, majority of the individuals, 255 (85.66%) and 213 (71.66%) respectively were males as compared to females. Males were also found in majority 255 (85.00%) in government hospitals group against private group. Nevertheless, number of females in private hospitals groups, 87 (29.0%) was greater than their number in government hospitals group, 45 (15.00%). The results were found to be statistically highly significant ($P < 0.01$) when the data was put to Pearson chi-square and likelihood ratio calculations (Table-1).

Age-wise Distribution: The data on age-wise distribution of the individuals in both government and private hospitals groups revealed that majority of them 192 (64.00%) and 233 (77.66%) respectively, were in the younger age group of 18-25 years. The data further revealed that the number of individuals decreased towards older age groups. The data also revealed that private hospitals groups appeared comprising of more younger individuals, 233 (77.66%) to be in the age group of 18-25 years. The results came out to be significant ($P < 0.05$) (Table-1).

Marital Status: The data revealed that there were more unmarried individuals against married ones in both the government and private hospitals groups, 197 (65.67%) and 215 (71.67%), respectively. On the other hand, less number of individuals 85 (28.33%) were found married in private hospitals group as compared to 103 (34.33%) in government hospitals group. The results were, however, found non-significant ($P > 0.05$) (Table-1).

Table-2
Distribution of donors in different blood groups within government and private hospitals

Blood Groups	Groups of individuals	
	Government	Private
A (-ve)	8 2.67%	8 2.67%
A (+ve)	85 28.33%	66 22.00%
AB (+ve)	19 6.33%	20 6.67%
B (-ve)	14 4.67%	25 8.33%
B (+ve)	92 30.67%	109 36.33%
O (-ve)	16 5.33%	13 4.33%
O (+ve)	66 22.00%	59 19.67%
Total	300 (100%)	300 (100%)

Frequency of different blood groups: The data revealed that majority of the individuals in both the government and private hospitals groups had B (+ve) group, 92(30.67%) 109 (36.33%)and respectively; while 8(2.67%) individuals had blood group A(-ve) in both groups of the government and private hospitals.

Whereas, the blood group A (+ve) was rated as the next frequency found to be 85(28.33%) and 66(22.00%) in both the government and private hospitals, respectively. The results were found to be non-significant as ($P > 0.05$) (Table-2).

Table-3
Distribution of Donors Individuals with history of contact with a jaundice patients, family history of hepatitis C, history of Blood transfusion within last 6 months, and razor sharing.

Groups of Individuals		
Distribution of donor individuals with history of contact with a jaundice patients within government and private hospitals groups.		
History of contact with jaundice Patient	Government	Private
Yes	7 (2.33%)	5 (1.67%)
No	293 (97.67%)	295 (98.33%)
Total	300 (100%)	300 (100%)
Distribution of donor individuals with family history of hepatitis C within government and private hospitals groups.		
Family History of Hepatitis C	Government	Private
Yes	26 (8.67%)	11 (3.67%)
No	274 (91.33%)	289 (96.33%)
Total	300 (100%)	300 (100%)
Distribution of donor individuals with history of blood transfusion histories in the last 6 months within government and private hospitals groups.		
History of Blood transfusion in last 6 months	Government	Private
Yes	18 (6.00%)	9 (3.00%)
No	282 (94.00%)	291 (97.00%)
Total	300 (100%)	300 (100%)
Distribution of donor individuals with history of razor sharing within government and private hospitals groups.		
History of razor sharing	Government	Private
Yes	18 (6.00%)	17 (5.67%)
No	282 (94.00%)	283 (94.33%)
Total	300 (100%)	300 (100%)

History of Contact with Jaundice Patients: The data revealed that quite a few individuals, 7(2.33%) and 5(1.67%) in government and private hospitals groups respectively, had the history of contact with some Jaundice patient. The ratio of individuals in both the groups was found to be almost equal. The results were, therefore appeared to be non-significant ($P > 0.05$) (Table-3)

Family history of Hepatitis C: The data exhibited that most of the individuals, 274(91.33%) and 289(96.33%) in government and private hospitals groups respectively, were having no family history for hepatitis C. nevertheless, private hospitals group had more individuals with no family history as compared to government hospitals group. The result were found to be statistically significant ($P < 0.05$) (Table-3).

Table-4
Distribution of Donor individuals with history of surgical procedures, drug addiction, yellow discoloration of eyes, and volunteer blood donation

Groups of Individuals		
Distribution of donor individuals with history of surgical procedures undergone in near past within government and private hospitals groups.		
History of surgical procedure in near past	Government	Private
Yes	18 (6.00%)	6 (2%)
No	282 (94.00%)	294 (98.00%)
Total	300 (100%)	300 (100%)
Distribution of donor individuals with history of drug addiction in past or at present within government and private hospitals groups.		
History of drug addiction	Government	Private
Yes	4 (1.33%)	10 (3.33%)
No	296 (98.67%)	290 (96.67%)
Total	300 (100%)	300 (100%)
Distribution of donor individuals with jaundiced eyes (yellow discoloration) with in government and private hospitals groups.		
Yellow discoloration of eyes (Jaundice)	Government	Private
Yes	14 (4.67%)	6 (2%)
No	286 (95.33%)	294 (98.00%)
Total	300 (100%)	300 (100%)
Distribution of volunteer blood donors with in government and private hospitals groups		
Volunteer donors	Government	Private
Yes	291 (97.00%)	298 (99.33%)
No	9 (3%)	2 (0.67%)
Total	300 (100%)	300 (100%)

Blood transfusion history: The data revealed that most of the individuals, 282(94.00%) and 291(97.00%) in government and private hospitals groups respectively, had no history of blood transfusion during the last 6 months. Nevertheless, the number of individuals in private hospitals group appeared to be a bit more as compared to their counterpart in government hospitals group. The result were therefore, found to be statistically non-significant ($P > 0.05$) (Table-3)

Razor sharing history: The data revealed that majority of the individuals, 282(94.00%) and 283(94.33%) in government and private hospitals groups respectively, had no history of razor sharing with others. The number of individuals in both the groups with no razor sharing history appeared to be almost equal. The results were found to be statistically non-significant ($P > 0.05$) (Table-3)

Surgical procedure history: The data revealed that majority of the individuals, 282(94.00%) and 294(98.00%) in government and private hospitals groups respectively, had no history of having undergone any surgical operation in the near past. Nevertheless, private hospitals group comprised of more individuals having no history of surgical procedure as compared to the individuals in government hospitals group. The results were found to be statistically significant ($P < 0.05$) (Table-4)

Drug addiction history: The data revealed that majority of the individuals, 296 (98.67%) and 290(96.67%) in government and private hospitals groups respectively had no history of drug addiction. The results were found to be statistically significant ($P < 0.05$) (Table-4).

Presenting with yellow discoloration of eyes (Jaundice): The data revealed that majority of the individuals in both government and private hospitals groups, 286(95.33%) and 294(98.00%) respectively, had no yellow discoloration of their eyes. In other way, the data revealed that there were lesser number of individuals having yellow discoloration of their eyes, 6(2.00%) in private hospitals group against 14(4.67%) in government hospitals group. The results appeared to be non-significant ($P > 0.05$) between the groups with no yellow discoloration of eyes. (Table-4).

Volunteer blood donation: The data revealed that majority of the individuals in both government and private hospitals groups, 291(97.00%) and 298(99.33%)

respectively, were volunteered to donate the blood. Nevertheless, more individuals, 298 (99.33%), who volunteered to donate the blood belonged to the private hospitals group. The results were found to be statistically significant ($P < 0.05$) (Table-4).

Table No-5
Distribution of donor individuals' status in initial hepatitis-C screening test and tested with ELISA test

Distribution of donor individuals' status in initial hepatitis-C screening test with in government and private hospitals groups.		
Initial Screening for HCV	Government	Private
Positive	0 (0.00%)	0 (0.00%)
Negative	300 (100%)	300 (100%)
Total	300 (100%)	300 (100%)
Distribution of donors status, when tested on ELISA test with in government and private hospitals groups.		
Results by ELISA test for HCV	Government	Private
Yes (+ve)	14 (4.67%)	46 (15.33%)
No (-ve)	286 (95.33%)	254 (84.67%)
Total	300 (100%)	300 (100%)

Initial Screening of Hepatitis-C: The data revealed that all the (100.00) % individuals in both government and private hospitals groups were found negative for Hepatitis-C as screened initially on routine diagnostic test (Table-5)

Screening for Hepatitis C by ELISA Test: The data revealed that despite of the fact that majority of the donors, all the donors in government and private hospitals groups respectively, were found initially negative for hepatitis C on routine diagnostic test, yet considerable number of individuals, 14 (4.67%) and 46 (15.33%) in government and private hospitals groups, respectively, were found unexpectedly positive for hepatitis C as scrutinized on ELISA diagnostic test. The results were found to be statistically significant ($P < 0.05$) (Table-5).

DISCUSSION

Hepatitis C has emerged as an alarming health problem in both developing and developed countries of the world¹⁴. Its unabated increasing trend has been taken by health authorities as the most concerning and most vigilance-requiring health matter. Hence, all-out efforts and sophisticated modern resources are being employed to ameliorate the pace of disease. Prophylactic measures have also been publicized for the prevention and control of this dangerous disease¹⁵. Achieving true and well-in-time diagnosis of hepatitis C is also amongst the measures being under taken to mitigate progression of disease¹⁶. But despite adopting careful diagnostic techniques and procedures uncertain results may still be expected. It is so happening that certain blood donors initially screened as sero-negative for hepatitis C on routine diagnostic test done by hospital blood bank laboratories may become sero-positive when tested on ELISA kit that is more sophisticated and accurate diagnostic technique for hepatitis C screening¹⁷. The present study was, therefore, planned to see the incidence of false seronegative cases amongst those who came up for blood donation at the local government and private hospitals of city district Faisalabad. All the reported cases had been investigated for hepatitis C by the routine diagnostic test as practiced usually at blood bank laboratories of the hospitals. Nevertheless, certain number of individuals out of those appeared to be seropositive when tested on more reliable, accurate and sophisticated scientific diagnostic technique of ELISA. The physical characteristics data of the blood donors, initially declared sero-negative for hepatitis C and said to be fit for donating blood, revealed that majority of the individuals were males aged between 18-25 years. This observation depicts that male, young and unmarried individuals are preferred and considered fit for blood donation, since healthy blood, free from any residual effects of disease, can only be obtained for transfusion purpose.

When tested for the blood groups, majority of the individuals in both the groups appeared to be B (+ve). Whereas, lesser number of individuals were found to be carrying blood groups with -ve Rh-factor, i.e. A (-ve), B (-ve), and O (-ve). The blood group A (-ve) was found in the least but equal number of individuals in both the groups. Significance of each blood group, whether with +ve or -ve Rh- factor, has been realized

in determining sectarianism of people living in community. Nevertheless, this determination is beyond the scope of this study.

All the other data revealed that majority of the individuals had well awareness about the spread of hepatitis-C. Hence, they appeared to have taken prophylactic measures against the disease. This is why they avoided, to come in contact with jaundiced person, repeated transfusions, sharing of razor or tooth brush and drug addiction. Such persons had no history of hepatitis-C, surgical operation and their eyes appeared to have no signs of jaundice that could have been due to hepatitis. The data revealed that majority of the blood donors donated blood voluntarily. This observation may be attributed to their noble passion of serving the humanity with their blood.

CONCLUSION AND RECOMMENDATIONS

All the individuals irrespective of their group were screened to be sero-negative for hepatitis -C, when tested on the routine laboratory investigation / test. But when their blood serum was processed and tested on ELISA method of screening, though majority of the individuals were still found seronegative for Hepatitis C, yet a sizeable number of individuals in both government and private hospitals groups were screened as sero-positive for HCV. This state of uncertain performance of the routine laboratory test has given rise to unreliability of the diagnosis of hepatitis C by the routine test.

It is, therefore, strongly recommended that only ELISA method should be ordered for authentic diagnosis of hepatitis C. This in return would ensure accurate and reliable finding about hepatitis C for its safe diagnosis well in time. The ELISA method can be considered as cost-effective if we look upon, its accuracy and authenticity, enabling earlier and effective management of hepatitis C.

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