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Original Research Article

Nucleic Acid Amplification Technique (NAT) versus Chemiluminescence Immunoassay (CLIA) for Screening of Hepatitis C in Donated Blood Units: A Comparative Study at Western Rajasthan Blood Centre

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Abstract:

Background & Objectives: Transfusion transmitted infections are a cause of concern in the provision of safe blood. The real challenge of blood transfusion lies in minimising risks and optimising clinical benefits. Therefore our study was done to compare NAT versus CLIA for screening of Hepatitis C.

Materials and Methods: A prospective study was conducted on a total number of (n=2553) eligible donors who had donated during the period of one year {April 2023 to March 2024} and their samples were tested by serology CLIA at our institute's serology laboratory. All the negatively tested samples by CLIA were sent to the Blood Centre RNT Medical College, Udaipur, Rajasthan for retesting by using (NAT).

Results: A total of 2553 random seronegative blood donors were included in this study. These 2553 donors were screened by individual donor (ID) NAT. There was no NAT yield for HCV of the 2553 random seronegative donors.

Conclusion: Among the 2553 samples tested by NAT all were non-reactive for mandatory transfusion transmissible diseases. Stringent donor screening and serology testing of whole blood donations helps in minimizing the risk of transmission of TTIS largely.

Introduction

Blood is a remedy and an essential drug, but it comes with a risk. Blood donation is a very important and lifesaving intervention in the field of medical sciences but transfusion transmitted infections (TTI) remains a serious health issues across the globe. [1-2] The global mortality caused by viral hepatitis is higher than that caused by HIV infection. [3] The World Health Organization (WHO) estimated that approximately 71 million people (3% of World population) were living with chronic hepatitis C virus (HCV) worldwide and 399000 people died from cirrhosis, hepatocellular carcinoma, and liver function failure caused by HCV infection in 2015. [4,5] Seroprevalence of HIV, HCV and HBV among blood donors in India according to NACO are 0.12, 0.30, and 0.92% respective. [6,7]

This study was carried out keeping in mind the Comparison of Nucleic Acid Amplification (NAT) with Chemiluminescence Immuno Assay (CLIA) as a screening test for HCV among blood donors at a blood centre attached to a tertiary care hospital in western Rajasthan.

Materials and Methods:

A prospective study was conducted in the Department of Immunohaematology & Transfusion Medicine, Sardar Patel Medical College and Associated Groups of Hospitals, Bikaner, Rajasthan on a total number of (n =2553) eligible donors who had donated during the period of April 2023 to March 2024 and their samples were tested by serology (Chemiluminescence Immuno Assay) at our institute's in house serology laboratory. All the negatively tested samples by CLIA were sent

to the Blood Centre RNT Medical College, Udaipur, Rajasthan for retesting by using Nucleic Acid Amplification Technique (NAT).

The selection and deferral of blood donors were done on the guidelines issued by NACO and the Ministry of Health and Family Welfare of India. Donors with a body weigh to f > 45kgs, Hb>/ =12.5g/dl and belonging to the age group of 18–65yrswere allowed to donate blood. 'High risk behaviour' donors were not allowed to donate blood.

For each donation, sample were collected in two vacutainers containing anticoagulant EDTA (ethylene diamine tetra acetic acid). The samples were centrifuged at 1000 rpm for 2 minutes to separate the plasma. Out of the two vacutainers, one used for serological detection of HCV by chemiluminescence in the in house laboratory while the other vacutainer was transported to RNT Medical College, Udaipur for further retesting with the help of NAT. The NAT test is conducted by the Procleix Ultrio Elite Assay. It involves detection of HIV RNA, HCV RNA, and HBV DNA by target amplification of Transcription-Mediated Amplification (TMA) and detection of the amplification products (amplicon) by the Hybridization Protection Assay (HPA).

The samples were screened for HCV using CLIA. In the presence of complimentary antigen and antibody, the paratope of the antibody binds to the epitope of the antigen to form an Ag-Ab or an immune complex.

Estimating the levels of such immune complex by use of labelled antibodies form the basis of CLIA. [8,9]

Results

A total of 2553 random seronegative blood donors were included in this study. These 2553 donors were screened by individual donor (ID) NAT. There was no NAT yield for HCV of the 2553 random seronegative donors . The donors' age varied from a minimum of 18 years to a maximum of 65 years. The mean (±SD) and median age of the participating donors were 28.98 ± 8.05 and 27 years respectively. A maximum of 1042 (40.8%) donors belonged to an age group of 18-25 followed by 945 (37.01%) donors in the age group of 26-35 years and 566 donors (22.16%) in the age bracket of 36-65 (Table 1). Male donors constituted 98.74% i.e. 2521 whereas females were only 32 in number (Table 2). In our study the majority of donors were non-remunerated voluntary donors comprising 68.35% of total while 31.65% were replacement donors

Out of 37,744 tests done by CLIA, 191 were positive for HIV, indicating that 0.50% of the tested samples were HIV positive. Out of 37,744 tests, 171 were positive for HCV, representing 0.45% of the total tested samples. HBV had the highest positivity rate among the TTIs tested, with 433 positive cases out of 37,744, accounting for 1.14% of the sample.227 out of 37,744 tests were positive for Syphilis, which is 0.60% of the sample. There were no positive cases of Malaria in the 37,744 tests conducted, resulting in a 0.00% positivity rate. When CLIA result of blood donors tested for HCV the vast majority of blood donors were non-reactive for HCV, indicating that 99.5% of the donors were HCV-free. Only small percentages (0.45%) of the donors were reactive for HCV, which translates to 171 individuals out of the 37,744 tested. This low positivity rate for HCV among the tested blood donors suggests a relatively low prevalence of HCV in this donor population.

Table 1: Age- group wise distribution of blood donors

Age- group(years)	Frequency	Percentage
18-25	1042	40.82%
26-35	945	37.01%
36-45	468	18.33%
46-55	82	3.22%
56-65	16	0.62%
Total	2553	100

Table 2: Gender wise distribution of blood donors

Gender	Frequency	Percentage
Male	**2521**	**98.75%**
Female	**32**	**1.25%**
Total	**2553**	**100%**

Table 3:Frequency of replacement and voluntary donors

Replacement/ voluntary	Frequency	Percentage
Voluntary	**1745**	**68.35%**
Replacement	**808**	**31.65%**
Total	**2553**	**100%**

Table 4: Distribution of various TTI's tested by CLIA

TTI	Frequency of Positivity	Percentage	Tested by CLIA
HIV	191	0.50%	**37744**
HCV	171	0.45%	**37744**
HBV	433	1.14%	**37744**
Syphilis	227	0.60%	**37744**
Malaria	0	0.00%	**37744**

Table 5: CLIA Result of Blood Donors tested for HCV

CLIA Result	Frequency	Percentage	Total
Non Reactive	**37573**	**99.5%**	**37744**
Reactive for HCV	**171**	**0.45%**	**37744**

Discussion

Blood transfusion is lifesaving but is no trisk free. Transfusiontran smitted in fections (TTIs) poseagreatrisk to blood safety.

In this study we performed NAT screening for HCV RNA on 2553 seronegative blood donor samples which were screened for TTIS at our blood centre's in-house CLIA laboratory. NAT screening was done at the NAT centre of RNT MEDICAL COLLEGE UDAIPUR, for which the samples were transported there.

We didn't find any HCV NAT yield in our study; the reasons may be a small sample size and also may be due to use of advanced CLIA technique at our institution.

Interestingly Dong J et al, Safic Stanic et al, Jain et al, [10] Chandrashekhar S et al, [11] Chigurupati et al, [12] Baruah et al didn't get any HCV NAT yield which corresponds to our study result for HCV NAT yield of zero. The study by Jain et al was conducted in Jaipur at one of the apex centres in the state of Rajasthan and therefore shares similar demography with that of our region of study. Therefore no NAT yield for HCV in both the studies demonstrates low prevalence of HCV in the general population of this region and also strengthens our study's findings of zero NAT yield for hepatitis C.

In India screening for HIV, hepatitis B, and hepatitis C is based on serological testing with recent introduction of NAT testing in few centres. Even after implementing the more sensitive, newest generation of serological tests, a considerable residual risk of transfusion of these viruses' remains. Only countries with a high prevalence and incidence of infection are likely to yield significant number of window period donations. [13-14]

It is clear from the above discussion that CLIA has greatly reduced transfusion transmitted infections and addition of NAT may be useful, but seeing the additional cost in a restricted budget in resource poor countries like India makes it expendable.

Table 6 : Comparison of various Indian studies with the present study

S. N.	Place	Author	Sam-ple Size(n)	Period of Study	Multicentre /single centre study	Year of Publica-tion	ELA/NAT+ Samples /NAT yield
1	New Delhi	Mak-rooet.al(54)	22,277	15 months	Single Centre	2007	0
2	Rajasthan	Jain et.al(58)	47,558	21 months	Single Centre	2012	1
3	Andhra Pradesh	Chigurupati et.al.(68)	8,000	12 months	Single Centre	2015	0
4	Punjab	Kumar et.al.(5)	32,978	12 months	Single Centre	2015	1
5	Gujrat	Mishra et.al(70	79,532	30 months	Single Centre	2017	5
6	Karnataka	Ashwani Kolur et.al(77)	3183	54 months	Single Centre	2019	0
7	Rajasthan	Madiha et.al	2553	12 months	Single Centre	2024	0

Conclusion

Our study shows that the vast majority of blood donors tested were non-reactive for HCV, indicating that 99.5% of the donors were HCV-free. Only small percentages (0.45%) of the donors were reactive for HCV, which translates to 171 individuals out of the 37,744 tested. We did not get any HCV NAT yield in our study shows that CLIA being an advanced technique is very much effective in minimizing the risk of transmission of TTIS. In a resource poor country like India, implementation of an expensive technique like NAT is not feasible. To establish NAT requires space, good infrastructure, highly trained personnel alongside expensive equipment and assays. Therefore, we conclude that the cost factor and the results we have got in our study seems it unnecessary to implement NAT as a mandatory test across blood centres in the country.

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