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Assessment of Individual Donor Nucleic Acid Test (ID-NAT) For Human Immunodeficiency Virus 1 & 2 and Hepatitis B & C Virus in Blood Donors

Dr. Tarun Kumar[1], Dr.Seema Solanki[2], Dr.Manav Vadhera[3], Dr. Jessica Kaushal[4], Dr Neeeaj Joshi[5]

[1]Assistant professor, Department of transfusion medicine, MM Medical College and Hospital, Solan, HP

[2]Assistant professor, Department of Microbiology, MM Medical College and Hospital, Solan, HP

[3]Private Consultant, Fortis hospital, Ludhiana, Punjab

[4]MBBS, Govt. Medical College & Hospital, Amritsar, Punjab

[5]Senior resident, Department of internal medicine, MMMC & Hospital,Kumarhatti, Solan, HP

Corresponding author:

Dr Neeeaj Joshi, Senior resident, Department of internal medicine, MMMC & Hospital , Kumarhatti, Solan H.P (173229), Email ID: joshineeraj941@gmail.com

Abstract

Background:*The present study was undertaken for assessing Individual Donor Nucleic Acid Test (ID-NAT) For Human Immunodeficiency Virus 1 & 2 and Hepatitis B & C Virus in Blood Donors.*

Materials & methods:*The present study was undertaken for assessing Individual Donor Nucleic Acid Test (ID-NAT) For Human Immunodeficiency Virus 1 & 2 and Hepatitis B & C Virus in Blood Donors. All the blood samples of blood donors were screened by ID NAT and ELISA for HIV1&2, HCV and HBV. Samples from donated blood units would be screened by ID NAT byProcleix® Ultriopluselite® Assay (Panther® Grifols Diagnostic Solutions Inc. Emeryville, USA)and by Enzyme-Linked Immunosorbent Assay (ELISA). Results of ELISA and NAT tests were compiled every day. Units which were reactive by any tests were segregated and kept in quarantine area, and sent for disposal using biohazard labels. We assessed the seroprevalence of HIV1&2, HCV and HBV by ID NAT testing among the entire voluntary and replacement donors between 18-65 years of age. All the results were recorded in Microsoft excel sheet and were analysed by SPSS software.*

Results:*A total number of 26474 blood donors were screened for HIV-1 & 2, HCV & HBV over duration of one year. Out of them, 13998 were voluntary donors and 12476 were replacement donors. Among total 741 reactive donors 587 donors were first time donors and 154 donors were repeat donors. Out of total 360 (48.9%) replacement reactive samples 222(61.6%) samples were sero positive NAT positive, 112(31.1%) and 26(7.2%) were reactive only by NAT. among 381(51.1%) voluntary reactive samples,206(54%) were reactive on both serology and ID-NAT,239(33.3%) samples have sero yield and 48(12.6%) were ID-NAT yield samples.*

Conclusion:*It was detected that 74 donor sample which were reactive by ID-NAT only they were non-reactive on serology. 222 patients were protected from above mentioned viral infections who were going to receive blood and blood components donated by these 74 NAT reactive donors which were missed by serology assay because of window period.*

Key words:Human Immunodeficiency Virus, Nucleic acid

INTRODUCTION

Since the introduction of HAART and the dramatic improvement in the prognosis of individuals with HIV, liver disease due to chronic viral hepatitis has become an important cause of morbidity and mortality in co-infected individuals. This fact brought a serious concern about the growing problems of HIV/AIDS pandemic in sub Saharan Africa; where the transmission is predominantly through sexual route and most of the people in these region are already been exposed to HBV by the time they become sexually active to acquire HIV infection, with minority being exposed to both viruses more or less simultaneously. Evidences indicate that HIV positive individuals are more likely to be infected with HBV, to be chronic carrier and have a higher HBV replication rate than HIV negative individuals. In addition, it is evident that immuno-suppression brought about by HIV infection may cause re-activation or re-infection in those previously exposed to HBV; further more HIV infection exacerbates liver disease in HBV co-infected individuals and there is an even greater risk of liver disease when HIV and HBV co-infected patients are treated with HAART.[1- 3]

The risk of disease transmission by blood transfusion is extremely low, particularly in developed nations. This situation is a consequence of a number of interlocking safety measures, including the selection of safe populations from which donors are drawn, careful donor questioning, laboratory testing, record keeping, and the use of quality systems and good manufacturing practices. These approaches have evolved over the years, and perhaps the most change has been seen in the area of blood testing. Indeed, blood collectors have now added nucleic acid amplification techniques to the battery of tests directed toward the safety of the blood supply. However, although transmission of known agents has almost been eliminated, residual fear of the unknown, fueled by a continuing stream of newly emerging or newly recognized microbes, continues.[4- 7] Hence; the present study was undertaken for assessing Individual Donor Nucleic Acid Test (ID-NAT) For Human Immunodeficiency Virus 1 & 2 and Hepatitis B & C Virus in Blood Donors.

MATERIALS & METHODS

The present study was undertaken for assessing Individual Donor Nucleic Acid Test (ID-NAT) For Human Immunodeficiency Virus 1 & 2 and Hepatitis B & C Virus in Blood Donors. All the blood samples of blood donors were screened by ID NAT and ELISA for HIV1&2, HCV and HBV. Samples from donated blood units would be screenedby ID NAT byProcleix® Ultriopluselite® Assay (Panther® Grifols Diagnostic Solutions Inc. Emeryville, USA)and by Enzyme-Linked Immunosorbent Assay (ELISA). Results of ELISA and NAT tests were compiled every day. Units which were reactive by any tests were segregated and kept in quarantine area, and sent for disposal using biohazard labels.

All blood donors were asked to fill up a donor registration form providing demographic data and health related information. Doctor reviewed the donor's history and health related information. Demographic details of each donor were noted. Written consent was taken after explaining the procedure as well as test to be done on the donated blood. The study population were divided into three age groups as 18-30 years, 31-45 years and 46-65 years. Blood was drawn from a vein at the antecubital fossa using an aseptic technique. Unique

donor identification sticker was pasted on primary, satellite bag and on donor's form.5ml pilot tube used for sample collection also given the same identification no(bar coded).two pilot tubes were use one for ELISA and second for NAT. Bags with 350ml used for blood donors who are more than 45kg and 450 ml bag who are weighted more than 60kg.After collection of required volume of blood, needle removed from donor' vein, the pilot tubes filled with blood. After this pilot tubes b sent for NAT testing and ELISA.We assessed the seroprevalence of HIV1&2, HCV and HBV by ID NAT testing among the entire voluntary and replacement donors between 18-65 years of age. All the results were recorded in Microsoft excel sheet and were analysed by SPSS software.

RESULTS

A total number of 26474 blood donors were screened for HIV-1 & 2, HCV & HBV over duration of one year. Out of them, 13998 were voluntary donors and 12476 were replacement donors. Among total 741 reactive donors 587 donors were first time donors and 154 donors were repeat donors. Out of total 741 reactive samples majority were from male donors (97.7%) and only 2.3% were from female donors. Voluntary donors were 376 (2.7%) and 365 (2.9%) were replacement donors. First time donors were 587 (79.2%) and 154(20.8%) were repeat donors. A total of 26474 donors samples were tested for HIV 1 & 2, HCV &HBV by ID-NAT. Out of them 74 samples (0.28%) were NAT reactive, while these samples were non-reactive on ELISA serology. Among the reactive samples, 24 (32.4%) were reactive for HBV and 50 (67.6%) for HCV and none were reactive for HIV 1 & 2. Thus out of total samples 1 in 1103 was reactive for HBV and 1 in 530 was reactive for HCV. 667 (90.0%) samples were reactive on serology and 74 (10%) samples were non-reactive on serology. 502 (76%) samples were initial reactive on ID-NAT and 239 (32.3%) samples were initial non-reactive on ID-NAT. On repeat testing 502 (76%) samples were reactive on ID-NAT and 239 (32.3%) samples were non-reactive on ID-NAT. In a total of 741 reactive donors, more than half were HCV reactivein (65.6%), followed by almost quarter were HBV reactive (26.6%) followed by HIV1&2 (7.2%).there were five co infected samples on serology. Out of total 360 (48.9%) replacement reactive samples 222(61.6%) samples were sero positive NAT positive, 112(31.1%) and 26(7.2%) were reactive only by NAT. among 381(51.1%) voluntary reactive samples,206(54%) were reactive on both serology and ID-NAT,239(33.3%) samples have sero yield and 48(12.6%) were ID-NAT yield samples.

Table 1: NAT Yield of donor samples

COMMENT	NAT YIELD	PERCENTAGE
HBV	24	32.4
HCV	50	67.6
Total	74	100

Table 2: Sero Yield of Donor Samples

SEROLOGY IR	NO. OF CASES	PERCENTAGE
Non-Reactive (NR)	74	10.0
Reactive(R)	667	90.0
Total	741	100.0

Table 3: Discriminatory on ID-NAT and serology

DISCRIMATORY	NO. OF CASES	PERCENTAGEAGE
HBV	197	26.6%
HBV/HIV	2	0.3%
HCV	486	65.6%
HCV/HBV	2	0.3%
HIV	53	7.2%
HIV/HCV	1	0.1%
Total	741	100.0%

Table 4: Comparative yield of serology and ID NAT

Variable	NO. OF CASES	PERCENTAGE
SERO POSITIVE NAT POSITIVE	428	1.6
SERO YIELD	239	0.9
NAT YIELD	74	0.28
Reactive	741	2.8
Total donation	26474	100

DISCUSSION

Nucleic acid testing (NAT) is a molecular technique for screening of blood units donated by allvoluntary and replacement blood donors to reduce the risk of transfusion transmitted infections (TTIs) in the recipients, thus providing an additional layer of blood safety. It was introduced in the developed countries in the late 1990s and early 2000s and presently around 33 countries in the world have implemented NAT for human immunodeficiency virus (HIV) and around 27 countries for hepatitis B virus (HBV). NAT technique is highly sensitive and specific for viral nucleic acids. In 2005, the South African National Blood Service introduced individual-donation (ID) nucleic acid test (NAT) screening for human immunodeficiency virus (HIV) RNA, hepatitis C virus (HCV) RNA, and hepatitis B virus (HBV) DNA.[6-8]Hence; the present study was undertaken for assessing Individual Donor Nucleic Acid Test (ID-NAT) For Human Immunodeficiency Virus 1 & 2 and Hepatitis B & C Virus in Blood Donors.

In our study 26474 blood donors samples were tested. 74 samples were ID-NAT reactive and were serologically non-reactive for any of the three viruses. Among these 74 NAT yield samples, 24 (1 in 1103) were reactive for HBV and 50 (1 in 530) were reactive for HCV and no sample was reactive for HIV-1&2. Out of 74 NAT yield samples 16 HCV NAT yield samples were Replacement blood donors among them 15 were male donors and 01 were female blood donor. There were 34 NAT yield voluntary donors and all were male voluntary donors. There were 10 male replacement donors and 14 male voluntary donors in HBV yield. There were no female reactive donors in HBV Yeild.NAT yield for HIV-1&2 were zero. The prevalence of HIV-1&2, HCV and HBV were 0%, 0.2% and 0.1% respectively in ID-NAT.In present study NAT yield for all reactive samples is 1 in 358(1.35%) which is much more than above studies. ID-NAT screening can add extra layer of safety for those recipients who get multiple blood and component transfusions like thalassemia patient, cancer patients and

hemophilia patients. Such patient need repeated, regular and lifelong blood transfusion, and such patients are at higher risk of being infected form TTIs. National Thalassemia Welfare Society did a survey on 551 multiple transfuse thalassemia patients among them 33 were HIV positive, 89 were HCV positive and 43 were HBV positive. But in our center, out of 199 multiple transfuse thalassemia patients, 22(11.1%) were HCV reactive and 1(0.5%) patient was HIV reactive. TTIs in thalassemia patients were HCV (2.2-4.4%), HBV(1.2-7.4%) followed by HIV(0-9%). HCV is the major problem in Punjab as prevalence of HCV is more than others TTIs. This can be reduced by screening blood by ID-NAT.[9, 10]Tsoi WC et al conducted a study on enhanced detection of hepatitis B virus in Hong Kong blood donors after introduction of a more sensitive transcription-mediated amplification. They screened all donations for HBV by ID-NAT and by serological assay simultaneously. They observed greater than twofold WP NAT yield and tenfold increase in sensitivity in detecting HBV.[11]

CONCLUSION

It was detected that 74 donor sample which were reactive by ID-NAT only they were non-reactive on serology. 222 patients were protected from above mentioned viral infections who were going to receive blood and blood components donated by these 74 NAT reactive donors which were missed by serology assay because of window period.

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