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Original Research Article

Implementation of nucleic acid testing for transfusion transmitted infection screening of blood donation in a tertiary care centre in Odisha

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ABSTRACT

Background: Aim of any Transfusion is safe Transfusion. As per Honorable Supreme court guideline all TTIs must be screened for all registered blood banks across India. Blood banks in Odisha are equipped with screening facility to screen various transfusion transmissible diseases. Screening tests for these diseases are usually done by Rapid Test /Elisa Test.

Objective: In recent years, to reduce the window period of these diseases sophisticated testing methods like Nucleic Acid Testing (NAT) has been introduced in many blood centers in India. In this context Govt. of Odisha has introduced NAT screening in selected Govt. blood banks of the state through public private partnership mode (PPP). The present study has been done to evaluate the benefit & limitation of NAT testing over serological tests.

Materials and Methods: This is a retrospective study carried out in the blood centre, VIMSAR, Burla over the period from June 2016 to November 2020, where all Elisa negative samples were subjected to NAT screening.

Results: On screening a total of 83,820 blood donations, 349, sero reactive donations were detected. Out of 83,471, sero negative donations, when subjected to NAT screening, 356 showed positive. Out of these 88 HBV, 12 HCV & 256 HIV cases were detected.

Conclusion: Implementation of NAT along with serological testing in blood bank centers all over India will be an important step towards providing safe blood, The PPP mode applied in our state can help expand coverage of NAT testing. But as it is not economical so stringent donor-deferral should be followed for selection of eligible donors.

1. Introduction

Transfusion service has not been streamlined in our country till now. Voluntary blood donation camps are Over-crowded which makes things difficult for proper screening. Professional donors, still continue to donate blood, though it is not ethical.

India has a demand of 1.2 crore units for transfusion per year & a high prevalence of potential transfusion transmitted infection (TTIs). According to data published by NACO (National Aids Control Organization) & NBTC(National Blood Transfusion Council) the sero positivity of TTI among blood donors is highest for HBV (0.87%) followed by HCV (0.34%) Syphilis (0.17%), HIV (0.14%) & Malaria (0.06%). But there is wide variation among different states. [1]

In India as per Drug & Cosmetics act, 1940 all blood units collected for the blood centers are mandatorily to be screened for HIV 1/2, HBV, HCV by serology & for Malaria, Syphilis either by serology or by rapid kits.

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In Most of the blood banks calibration of major equipments are not done regularly. There is a huge lack of fund and infrastructure.[2] Also the quality of the testing results are not being properly validated.

Here in Odisha dedicated Blood Bank Officers are not posted in the blood banks. Our infrastructure are not well maintained due to lack of proper government motivation. In many blood banks the cold chain system for preserving blood/blood products is not proper due to lack of back up facility. To add to this in many Hospitals their is no SOP for judicious use of blood / blood products.

In 1990s Nucleic Acid testing was introduced in modern Blood banking. Amplification and Detection of target RNA OR DNA is the principle on which NAT operates.

NAT is considered as the advanced modality for screening in modern days of Blood banking as it has reduced the window period as comapared to ELISA.

Now a days NAT is being adopted by many developed countries. India is economically developing country, our majority of population belongs to middle socio economic classes, so it is big dilema for government and population to bear the expensive NAT, hence majority of our Blood banks still continue with ELISA/ RAPID test. Two types of NAT testing available namely ID NAT & MP NAT.

So, NAT screening when used as an adjunct to standard screening can potentially increases sensitivity & will be a tool to reduce the risk for TTIs especially in a country of high prevalence like India.

To implement NAT screening it requires a lot of logistic support like availability of infrastructure, skilled manpower & the cost involved in processing consumables & equipments.[3,4] To give justice to all this logistics support, as well as to cover wide spread donors, the Odisha Govt. has introduced NAT screening in 6 major Govt. blood bank centers through public private partnership mode (PPP)using-the Cobas Taq screen MPX test version 2.0 (MPX2) for blood screening. The Govt. also has subsidized 100% the cost of NAT testing for the patients. The state Blood Transfusion Council (SBTC) is the nodal body to supervise & monitor the 6 sites through a nodal officer.[5–8]

2. Materials and Methods

We conducted the study in Veer Surendra Sai Medical College, Burla for a period of four and half years from June 2016 to November 2020. Our College is one of the best in eastern part of India equipped with a good labatory. Population of Entire Western Odisha, few parts of Bihar, Jharkhand, Chhattisgarh are dependant on this Health Care Facility. The demand of blood and blood components are very high in our Institution. To provide safe blood we perform NAT along with ELISA. We collect the blood samples as per our SOP and perform ELISA, all sero negative ELISA samples are subjected to NAT.

NAT was performed by Roche Cobas Taqscreen MPX test v2.0 using cobes s201 system (Roche Molecular Systems). Cobes$^{(R)}$ Taqscreen MPX v2.0 is a qualitative multiplex test based on PCR & can detect and discriminate between HBV, HCV, HIV 1 & HIV-2 simultaneously. Donors samples were pooled in mini pools of six injecting the Hamilton Microlab star pipettor. NAT was performed following the manufactures-instruction for the assay in an automatic platform. A reactive mini pool was resolved by testing of single units of six members of the pool to identify the reactive donation & the viral cause of the reaction. The reactive donations were discarded as per the blood bank SOP & non-reactive units were released for transfusion as per in the planed screening protocol.

The 95% detection limit for MPx2 is shown in Table 1. The objective was to determine the NAT yield to validate the installation of NAT PCR system. Data variables in the study has been presented as an absolute or relative frequency in the form of percentage.

2.1. Study participants

A total of 83,820 - blood samples collected in VIMSAR Blood center, Burla over the time period were included in the study. All these donations were tested by ELISA method. A total of 83,471 - sero negative samples were tested by NAT.

Table 1:

Target	**95% on of Cobes Taqscreen MPX Test v2.0**
HBV	2.3IU/ml
HCV	6.8IU/ml
HIV-1 Group M	50.3IU /ml
HIV-1gpO	18.3 copies /ml.
HIV-2	57.4 copies/ml

Limit of Detection: LOD: The level at which 95% of test results would be expected to be reactive.

A Total of _349 sero reactive donations were detected ( ). Total sero reactivity was highest for HBV (0.28%) followed by HIV (0.08%) & HCV (0.06%).

MOLECULAR:

A total of 356 - NAT reactive donations were detected & the overall NAT yield was 0.43% -.

NAT reactivity for
HIV 88(0.11%)
HBV 256(0.31%)
HCV 12(o.01%)

3. Discussion

The experience of implementing NAT screening on a PPP mode implies the success of the pilot project. The data enumerated here shows the feasibility of NAT PCR

Table 2: Sero reactivity

Site	HBV reactive (n)(%)	HCV reactive (n)(%)	HIV reactive (n)(%)	Total SR(n)(%)
VIMSAR (N=83820)	236 0.28	47 0.06	66 0.08	349 0.42

Table 3: Natrectivity

Site	HBV	HCV	HIV	Total NAT Reactive Donations	Total NAT Yield	HBV Yield	HCV Yield	HIV Yield
VIMSAR (N=83471)	256	12	88	356	1:234	1:326	1:6955	1:948

technique applied in a mini pool model for screening the infectious diseases.

NAT implementation in Govt. blood bank is a state of art project of Odisha Govt. operated through PPP mode. The benefits of PPP mode include efficiency with focused strategies & resources & overcoming challenges of accountability -& affordability. The rate of detection of a high number of sero negative & NAT reactive donations in our study has revealed the significant -benefit of NAT screening & authenticate the decision to implement NAT project in the state. The govt. of Odisha has subsidized 100% cost of NAT testing for all people of state irrespective of their socio economic status. This has not only served equal quality medical facility for all the citizens, but also helped to a great extant in preventing viral infection transmission through blood transfusion. It has saved significant financial resources in management of these infected patients.

The National Aids Control Organization (NACO) under the Ministry of Health & Family Welfare & National Blood Transfusion Council (NBTC) has published a report on the assessment of blood banks in the state for the year 2015, where they have shown that, HBV had the highest sero positivity (0.87%) followed by HCV (0.34%) & HIV (0.14%).[3] Accordingly in our study highest percentage was observed with HBV,(0.28%) followed by HIV(0.08%) & HCV (0.06%) .

In India most studies report NAT yield of 1:2000 to 1:3000 (Jain et al 2012),[9] Chigurpati & Murthy 2015, Pathak & Chandrasekhar 2013, Chigrupati & Murthy 2016). As for our center, the NAT yield is similar to NAT yield reported by Chandra et al (Chandra et al 2016) through MINIPOOL testing in a Tertiary referral center in northern India.

When considering, the component therapy, by doing NAT testing about 3 times patients have been saved over a period of 4 and half yearsfrom these 3 types of dreaded viral infections.

In this way, in our study over a period of 41/2yrs., about 1068 recipients (356NAT positivity x3) have been saved.

NAT yield in our study is highest for HBV (256) followed by HIV (88) & HCV (12)

In India the incidence of HBV is much higher than HIV & HCV., The highest NAT yield for HBV found in our study for our centre is as par as the published data. And more interestingly this data is for pooled samples. This shows that the use of an assay with high sensitivity for HBV like the Cobes Taqscreen MPX2 test leads to high yield of NAT in minipool format. It is claimed that Cobas Taqscreen assays detects HBV infection less then 6IU10/ml in –concentration (Chandra T, et al 2016).[10] In places where the prevalence of HBV is high & there is more chance of window period donations, and occult infections with low viral load is high, this method of assay is very sensitive for detection & identification of HBV DNA.

In most of the reporting in India the HIV infection prevalence is low in comparison to HBV & HCV. The prevalence of HIV in the population of aged 15-49 years in Odisha is found to be 0.13%. But in our study we could find higher HIV NAT yield after HBV yield. One of the reasons for this is that lower -detection of HIV sero positivity. Besides being highly sensitive, the MPX2 NAT assay in the S201 system used in the study offers certain-additional advantages. It is-based on Real time PCR which is a proven technology for detection of DNA/RNA. The –multiplex and Multidye technology allows detection & real time target identification with a single test. Hence saving of single target assay result is not required & low sample volumes are required. The algorithm of screening requires testing of only sero-nonreactive donations. Pooling of samples is beneficial as fewer tests are to be performed, cost is lower & specificity-is improved. The system is completely automated -using ready to use reagents, requires no test calibration -, incorporates Amp Erase enzyme to avoid cross contamination and requires minimal manual intervention and maintenance.

In a study in North India ID NAT results were compared with serological methods for 37, 898 samples. Out of these, 1.49% were reactive by NAT, HIV-1(0.09%) HCV (more than 25%) & HBV (0.08%).

In a study by stramer et al, false positivity of NAT has been reported to be about 1 in 15,800 units for HIV & HCV NAT. This false positivity may be due to dross contamination.[5]

In some cases where viral load is low we may find false positive results. It has been observed that after the introduction of NAT for HBV screening the risk of HBV infection is reduced in many countries. [11]

The Nat yield reported by MP NAT of our centre is probably one of the highest reports ever reported by any other centre through MP NAT.

This NAT project has been implemented by the Govt. of Odisha under PPP model to supply safest blood products to all the patients in the major blood centers. It encourages the concept of implementing this project for other blood banks in the state. The most important aspect of this project is that, it is applicable for all APL & BPL people of the State & also without any processing charges. It has not only fulfilled the purpose of providing quality medical facility to citizens of our State but also for prevention of lethal viral infection in the recipients to a great extent, thereby saving a lot of financial burden of the state in the form of treatment of the infected recipients.

In India till now replacement donors still provide more that 45% of the collected blood units. But now a days due to increased awareness and sensitization for the voluntary blood donations, proper screening for TTIs testing has become the necessity of the time.

In a country like Germany they have followed MP-NAT screening. Although it is economical in comparison to ID-NAT, it has its own demerits also. In MP-NAT, once the test sample shows positive, all the six pooled samples results is blocked and again individually each sample is tested, their by prolonging the testing results time. [8]

In Developed countries like United Kingdom, NAT has reduced the risk of HCV by 95% & the HIV by 50%.

4. Conclusion

Every test has its own limitations it applies to NAT PCR too which only detects the presence of viral RNA/DNA. Some times the -the viral load is also too low to be picked up by Elisa Test. NAT PCR can be used as an adjunct to Elisa Test never a substitute for Elisa test.

The probability of transmission of Sero positive samples (HIV,HBV,HCV), in developing countries like India is found to be remarkable especially in thalasemic patients who need to receive frequent blood or component therapy due to window period transmission. [12]

Some risk of transmission still present in NAT-PCR because of window period infection, but it definitely lowers the-window period for HIV, HBV & HCV. [13]

The need for NAT depends on prevalence & incidence rate of infection in blood donors population, available resources & infrastructure.

Considering the high prevalence of viral infection, the number of transfusions & the high proportion of component separation in the country, need for Nat testing to prevent TTIs is absolute. The PPP model applied in Odisha State can serve as a pilot model for application in other states of India.

In a developing country like India we should focus on proper donor screening.

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6. Conflicts of Interest

No conflicts of interest.

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