DOI: NJLM/2015/15693:2083

Review Article

Internal Medicine Section

Transfusion Transmitted Infection-An Update in India

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ABSTRACT

Transfusion transmitted infections (TTI) are a major problem associated with blood transfusion. Although the risk of transfusion-transmitted infections is lower than ever, the supply of blood products remains subject to contamination with known and yet to be identified pathogens. Only proper donor screening, sensitive screening tests and effective inactivation procedures can ensure the reduction and risk of acquiring transfusion transmitted infections. This review, thus addresses the changes that lead to the decreasing prevalence of transfusion transmitted infection in India and also the future strategies to be adopted to eliminate the risk of new inborne pathogens in India.

Keywords: Blood transfusion, Donor screening, Screening test, Inactivation procedures

INTRODUCTION

Transfusion medicine is a significant young field which has been developed in the second half of the last century. After the starting of the blood transfusion in the early 1940s, various transfusion associated problems have been associated. Transfusion transmitted infections (TTI) was first noted in late 1940s. The current strategies which include proper medical examination, screening of blood, filtration of blood to remove leucocytes, chemical inactivation of any infectious agent if present and haemovigilance system that help to identify emerging new TTI threats; by facilitating quality assurance, quality control and the ability to monitor all steps in the transfusion chain have produced a marked decrease in transfusion transmitted infection in recent years in India. The risk of infection by a contaminated blood unit today is comparatively lower than observed 30 years back. In the current review; much emphasis has been given to the Indian studies conducted in the year from 2012 to 2014 regarding current prevalence of TTI. This review thus addresses to the changes of TTI in India in the current era [1,2].

AIM

The aim of the present review is to provide an eye view to the changes in the screening methods for TTI from the 1940s to the recent time that lead to the decreasing prevalence of TTI. This review will address to the future strategies which is to be adopted for the further safety of the blood products in view of prevention of TTI. The data mentioned in the review are collaborated with the NACO (National Aids Control Organization) report from 2006 to 2014.

TRANSFUSION TRANSMITTED INFECTIONS OVERVIEW

Currently TTI can be divided into:-[2]

a. **Viral-** HIV, Hepatitis B virus, Hepatitis C virus, Hepatitis A virus, Hepatitis G virus, Human T-cell lymphotrophic virus (HTLV), Cytomegalovirus, West Nile virus, Epstein–Barr virus.

b. **Bacteria--** *Treponema Pallidum, Yersinia enterocolitica, Escherichia coli, Streptococcus* sp.

c. **Parasite-***Plasmodium* sp*, Babesia microti*

d. **Emerging-** Prions.

However, NACO (National Aids Control Organization) recommends the testing of 5 TTIs. They are HIV, HBV, HCV, Malaria and Syphilis [3].

PLACE	HIV	HBV	HCV	SYPHILIS	AUTHOR & YEAR
Lucknow [3]	0.08%	0.24%	0.001%	0.008%	Tulika C et al., (2014)
Ahmedabad [4]	0.162%	0.977%	0.108%	0.234%	Nirali S et al., (2013)
Gujarat [5]	0.14%	0.38%	0.06%	0.14%	Pragnesh. J. Patel (2015)
Uttarakhand [6]	0.19%	0.63%	0.20%	0.02%	Bhawna S et al., (2014)
Andhra Pradesh [7]	0.27%	0.71%	0.14%	0.10%	Leena MS et al., (2012)

[Table/Fig-1]: Comparison of various studies shows the prevalence of transfusion transmitted HIV, HBV, HCV and Syphilis:-[3-7]

TRANSFUSION TRANSMITTED VIRAL INFECTIONS

HIV

HIV causes AIDS (Acquired Immuno Deficiency Syndrome). This syndrome was recognized in 1981, well before the discovery of the causative virus. HIV was first isolated from the cells of an infected patient in 1983 (HIV-1). The virus was subsequently identified as the causative agent of AIDS [2]. In India, HIV infection was first detected in Chennai among commercial sex workers in 1986.There was an estimated 5.21 million HIV infected persons at the end 2004 (NACO Annual Report 2004) [8]. In 1986 a second type of HIV, HIV-2, was identified in certain areas of West Africa. In 2005, it was estimated by the WHO that 38 million people were living with HIV worldwide, 4.1 million were newly infected and 2.8 million had died of AIDS [9,10].

After the first, second and third generation ELISA, fourth generation ELISA was introduced with the hope of reducing the window period to (15-18) days and is used nowadays as a screening test for HIV which detects both p24 antigen and antibody to HIV [11,12]. In India, the major companies manufacturing fourth generation ELISA are J.Mitra, Span Diagnostics, Biorad. The sensitivity for all these is 100%. A recent study conducted by Vedita et al., showed the prevalence of HIV as 0.3% [13].

The use of chemiluminescence further reduced the incubation period to (11-15) days. The sensitivity of HIV by fully automated chemiluminescence is 100% which is more than fourth generation ELISA. The seropositive samples can be retested by 4th generation ELISA. Some Government set up blood banks test seropositive samples by Western blot technique which is regarded as the confirmatory test for HIV [14,15]. Though NAT (Nucleic Acid Testing) is not a mandatory screening test for TTIs as per Drug and Cosmetic Act, but it is used in some centres in India to reduce the residual risk of borderline and seronegative donations. The implementation of viral NAT system has greatly helped to reduce the residual risk of viral transmission by reducing the time for effective detection to (5-11) days. After the minipool NAT, individual NAT (ID-NAT) system is introduced. The importance of ID-NAT is further illustrated by Dr. Kavita Chatterjee in AIIMS; Delhi. From January 2014-July 2014, 6949 routine blood donor samples were tested using Panther ID-NAT system. The assay results were correlated with routine serology testing. 20 samples out of 6949 samples were found reactive in ID-NAT but non-reactive in serology [16,17].

Prevalence of HIV among blood donors in India in 2013 was 0.27% [NACO Report 2013].

The implementation of NAT and chemiluminescence assay in recent years has significantly reduced the prevalence of HIV in India [18].

HBV

HBV was fond in humans by Blumberg and co-workers in the serum of an Australian aborigine, which they called Australia antigen [1]. With a 3.7% point prevalence, that is, over 40 million HBV carriers, India (second to China) is considered to have an intermediate level of HBV endemicity with 1 million Indians at risk for HBV and about 100,000 die from HBV infection [NCDC Newsletter, 2014] [19]. According to the WHO report on prevention of HBV in India, prevalence of HBsAg among general population ranges from 0.1% to 11.7% [20]. A recent study conducted by Vedita et al., showed the prevalence of HBV as 1.18% [21].

HBV surface antigen (HBsAg) fails to detect the presence of HBV during the window period though it is routinely included in the donor screening. Presence of HBsAg in a patient with post transfusion hepatitis does not necessarily indicate transfusion associated HBV infection. The presence of IgM anti-HBc (HBV core protein) which is positive in recent infection but not in chronic infection is the only serological test to confirm transfusion associated HBV infection. Some studies have shown that the discard of blood units with isolated high titer of anti-HBc (even when HBsAg is negative) is helpful in reducing the chances of post transfusion hepatitis B infection. This fact has lead incorporation of testing of anti-HBc in some blood bank. This strategy is however, not adopted in our country [1,2].

HBsAg screening has been part of blood screening since 1972. In recent years, use of enhanced chemiluminescence and 4th Generation ELISA with detects both antibody to HBV and HBsAg, has reduced the prevalence HBV.The major companies manufacturing 4th generation ELISA kits are J.Mitra, Span Diagnostics Limited, Transasia, Biomedicals. The widely accepted confirmation test for HBV is HBsAg neutralization test based on the conventional ELISA method. Vitros HBsAg confirmatory Kit is used for qualitative confirmation of HBsAg done in some centers. Unlike HIV testing; NAT HBV DNA testing has not eliminated the necessity for serological testing for HBV carrier donors. However, implementation of NAT has revealed occult HBV infection (OBI) in blood donors. Occult HBV is transmissible by blood transfusion, although the transmission rate is considered to be very low [2,22,23].

Safe and effective HBV vaccination plays a target role in the prevention and control of HBV infection. WHO recommends routine infant vaccination along with catch up immunization for adolescents and high risk population. Universal immunization against hepatitis B has been introduced in India in the year 2002 in 10 states followed by countrywide operation in 2011. Recently, a pentavalent vaccine to HBV has been introduced in some states [24].

HCV

HCV is the most common cause of post transfusion Non-A, Non-B hepatitis all over the world. The majority of patients with Non-Non-B hepatitis later tested positive for HCV after testing for anti-HCV became widespread in the 1990s.Once

infected with HCV, the virus travels via the blood to the liver where it replicates. Fulminant lethal acute HCV can occur rarely. Acute illness is usually mild or anicteric. Overt jaundice is seen in only 5% cases.50-80% cases progress to chronic hepatitis with some developing cirrhosis or hepatocellular carcinoma [1,25].

The prevalence of HCV antibodies in blood donors in developed countries ranges from 0.4 - 2%. Seroprevalence in blood donors is (0.28-0.53) %. Surveillance studies in Europe and in the US documented a significant reduction in the risk of HCV [2]. The prevalence of HCV in general population in India and seroprevalence in blood donors in India (NACO Annual Report 2009-2010) are <2% and 0.4% [26]. The population prevalence of HCV in India is 1% [NCDC Newsletter, January-March 2014] [19]. The recent study by Vedita et al., showed the prevalence of HCV as 0.16% [21].

There has been a significant reduction in the prevalence of HCV, probably due to the availability of diagnostic kits as well as increased awareness among the blood donors. 3rd generation HCV ELISA kits detect the antibodies which will appear at least after 1 month of infection. The available 4th generation ELISA kits detects both the capsid antigen and the antibodies and thereby reduces the window period to a great extent. The sensitivity and specificity of 3rd generation ELISA manufactured by J.Mitra is 100% and 97.4% respectively. BIORAD manufactures the 4th generation ELISA in India [13-15].

The specific diagnosis of HCV infection requires serological and/or molecular based (NAT) assays. NAT of plasma intended for fractionation and of blood donations for HCV RNA began in the late 1990s. A study has shown that individual NAT yield is 3 with 6949 samples tested [16]. Recombinant Immunoblot Assay (RIBA) is used in some centres for qualitative evaluation of seropositive samples. The further reduction in transfusion transmitted HCV begins with improved donor screening [17].

PARASITIC INFECTION

Malaria

Malaria is the first reported transfusion transmitted infection. Malaria is endemic in tropical and sub-tropical regions of Africa with up to 300 million infections and 1 million deaths annually. It is caused by one of the four species of *Plasmodium* (*falciparum, vivax, malariae* and *ovale*).

In India, the two major human malaria species in India are *p. falciparum* and *P. vivax* has been reported. *P. malariae* and *P. ovale* are comparatively rare. The vector responsible to cause malaria in India is *Anopheles culicifacies* [27].

In India, strategies adopted to prevent occurrence of transfusion transmitted malaria are:-[28]

a). Mandatory deferral of donors with fever (presumably malaria) in the last 3 months.

b. To test donated blood for presence of malaria infection.

Thick and thin peripheral smear examination of blood though considered the gold standard for malaria diagnosis for decades is quite labor-intensive and requires adequate technical skill and manpower. This has spurred the development of several non microscopic malaria rapid detection tests (RDT) based on the detection of malaria parasite antigen in whole blood. Semi immune malaria high risk donors can be identified by malaria antibody screening by enzyme immunoassays (EIA). Malaria antibody test can be done by malaria antibody ELISA (Pan Malaria Antibody CELISA) which detects specific IgG antibody against *P. falciparum, P. vivax, P. malariae and P. ovale* [29,30].

PLACE	SEROPRE-VALENCE	AUTHOR & YEAR	STUDY PERIOD
Andhra Pradesh [7]	0.129%	Leena MS et al., (2012)	2004 to 2010
Mangalore [11]	0.01%	Kirana P et al., (2015)	2008 to 2012
Lucknow [3]	0.01%	Tulika C et al., (2014)	2008 to 2012

[Table/Fig-2]: Comparison of various studies shows the prevalence of malaria as:-[3,7,11]

The sensitivity of malaria RDT is dependent on several factors, including the rate of flow of blood upto the nitrocellulose strip, the adherence of antibody (Ab) to the strip, ability of the Ab to bind antigen (Ag) and the integrity of the Ab-dye conjugate. It is recommended that the sensitivity of the kit should detect at least 95% of *P. falciparum* infection/cases in 200 parasites per µl of blood and higher at higher parasite density (WHO 2000, WHO 2003), specificity of most of the RDT cards are 55% [31].

BACTERIAL INFECTION

Syphilis

Syphilis is a sexually transmitted infection caused by bacterial spirochetes, *Treponema pallidum*.

The first case of transfusion-transmitted syphilis was reported in 1915. By 1941, 138 cases had been reported in the literature. Most reported cases were discovered to have occurred when donors were in the primary or secondary stage of disease. Most reported cases were discovered to have occurred when donors were in the primary or secondary stage of disease. The World Health Organization (WHO) estimated that there are 12 million new cases of syphilis each year, with more than 90% occurring in developing nations. The risk of transfusion-transmitted syphilis is particularly high in developing countries with limited blood supplies where the blood is collected from family donors and transfused within hours. The risk of transfusion-transmitted syphilis is closely related to risk factors in the blood donor, in particular sexual behavior since the disease is primarily transmitted by the sexual route [32]. Strategies proposed by WHO to prevent transfusion transmitted syphilis:-[4].

i. Selection of low-risk donors and screening for the disease using efficient laboratory methods.

ii. Application of pathogen reduction technology.

iii. Rational use of blood products.

The prevalence of syphilis among blood donors in India was recently reported to be 0.7%. WHO states that to minimize the risk of syphilis infection through the route of transfusion:-[7]

a) Screening should be performed using a highly sensitive and specific test for treponemal antibodies: either TPHA or enzyme immunoassay.

b) In populations where there is a high incidence of syphilis, screening should be performed using a non-treponemal assay: VDRL or RPR.

For screening test in blood banks for syphilis, mostly Rapid Plasma Reagin (RPR) test is used and for confirmatory *Treponema pallidum* Haemagglutination assay or CLIA (Chemiluminescent Immunoassay) which detects both IgG and IgM antibodies to *Treponema pallidum*. CLIA has resplaced the earlier times used Chemiluminescent microparticle Immunoassay test (CMIA). The sensitivity of RPR is only 58%. The confirmatory test mostly used in Indian centres is TPHA (*Treponema pallidum* Haemagglutination Assay) test which is 99.5% sensitive and 99.4% specific [33].

CURRENT RISK OF TRANSFUSION TRANSMITTED INFECTION

The risk for major transfusion transmissible infections continues to decline as a result of continually strengthening interventions and because of more general improvements in public health. We are well aware of the common TTI mentioned above in south Asian countries. However, there are infections which are not routinely screened in blood transfusion services (BTS) in this part of world. There are many infections which can be transmitted through blood transfusions but it is not possible to screen for these rare or very common diseases [34]. Some of these are:-

Ebola virus

Ebola virus disease (EVD; also Ebola hemorrhagic fever, or EHF), or simply Ebola, is a disease of humans and other primates caused by ebola viruses. The virus spreads by direct contact with body fluids, such as blood, of infected human or other animals. This may also occur through contact with an item recently contaminated with bodily fluids. There has been a current outbreak of Ebola in West Africa in March 2014. Though in India, only one case has been reported, still there remains a chance of transmission [34,35].

Parvovirus B19

Parvovirus B19 (PV-B19) is a non enveloped erythrovirus which infects hematopoietic cells. Transfusion transmissions of PV-B19 with mild and non-life threatening symptoms even in immune compromised patients have been reported in several studies. There is a paucity of reports on B-19 infection in Indian subcontinent. This study was carried out on 1000 healthy voluntary blood donors from North India and 399 (39.9%) showed evidence of B-19 infection (IgG) [36].

Cytomegalovirus (CMV) infection

The prevalence of anti CMV (IgG) in Indian subcontinent is about 95%. About 5% of screened donor population have IgM antibody. CMV infection can be prevented by issuing leukoreduced (by 3rd/4th generation filters) blood products to the needy patients [37].

West Nile Virus

West Nile Virus (WNV) is a mosquito born RNA virus of the flavivirus family. It was first isolated in North America continent. No study proves the association of WNV to transfusion in Indian subcontinent. However, some studies have found WNV neutralizing antibodies (about 20-30%)in human sera collected from Tamil Nadu, Karnataka, Andhra Pradesh, Maharashtra, Gujarat, Orissa and Rajasthan [2,36].

NEWER STRATEGIES

The concept of pathogen inactivation in blood components is to eliminate the risk of known and unknown pathogens. In developing countries like India, where infections are rampant, blood transfusions are highly risky and cheap; pathogen inactivation methods are highly desirable. The current methods employed in some developed countries employs use of methylene blue, solvent detergent plasma and exposure of Ultraviolet A (UV-A) radiation. The current methods employed in some countries employs use of methylene blue, solvent detergent plasma and exposure of Ultraviolet A (UV-A) radiation [38].

It is quite clear that there is a decrease in prevalence of familiar transfusion transmitted infections due rigorous donor screening, development of sensitive and newer laboratory techniques including molecular PCR and NAT. But HBsAg infection still continues to be a menace to the society because, in spite of decreasing trend, incidence of the disease is still very high in general population [19]. The following steps can be followed to reduce the risk of HBV:-

- The first step to tackle the burden of HBV in India is to have a more accurate assessment of the burden of the disease with population based multicentric studies.
- Areas of high endemicity levels within each State should be mapped out.
- Intravenous drug users (IVD users) need to be educated about transmission of infection and to avoid sharing of needles and syringes.
- A strategy to test for anti-HBc should be included in the donor screening protocols.

Transfusion transmitted malaria incidence is also of concern in certain parts of India. Chemoprophylaxis should be given to travelers travelling to malaria endemic are [30].

CONCLUSION

There is a constant increase in emerging viral, bacterial and parasitic agents that are transmitted similarly by transfusion but are not routinely tested. Therefore, an approach for proper detection and implementation of pathogen inactivation methods are to be adopted.

Newer strategies are to be adopted in order to minimize transfusion transmitted infections and provide safer blood product as there is changing in population dynamics. Hence, National Haemovigilance system should be enrolled in all the health care set ups, including both private and government medical colleges to provide safer blood products and should be matched with the view of the physicians offering the blood transfusion.

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FINANCIAL OR OTHER COMPETING INTERESTS:
None.

Date of Publishing: **Oct 01, 2015**