SEROPREVALENCE OF HIV, HBV, HCV AND SYPHILIS AMONG BLOOD DONORS IN KIMS BLOOD BANK HUBBALLI, KARNATAKA, A TERTIARY CARE HOSPITAL

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Abstract- Introduction: With every unit of blood there is 1% chance of transfusion associated problems including transfusion transmitted infections (TTI). These TTIs include hepatitis B (HBV), hepatitis C (HCV), Human Immunodeficiency Virus (HIV), syphilis, and less commonly malaria, toxoplasmosis, brucellosis, other viral infections. The process of preventing the transmission of TTIs through blood transfusion presents one of the greatest challenges of transfusion medicine. Aim: The aim of our study was to find out the seroprevalence of infectious markers of TTIs among the blood donors. Materials and methods: A 9 years retrospective study was carried out in the blood bank of KIMS, Hubballi, Karnataka, from January 2007 to December 2015. From the donor’s blood units, 5 ml blood samples were obtained for serological testing. All the samples were screened for HIV, HCV, HBV by ELISA and RPR for syphilis. Results: A total of 80312 apparently healthy donors were analyzed for prevalence of TTIs of which 50735 (63.17%) were replacement donors and 29577 (36.83%) were voluntary donors. The overall prevalence of TTIs was 2047/80312 (2.5 %). The overall prevalence of HIV, HBV, HCV and syphilis among donors were 283(0.35%), 1556 (1.9%), 195 (0.2%) & 13(0.01%) respectively. Conclusion: The current infectious disease pattern and trends in donor population can help in planning of future blood transfusion related health challenges. Encouraging female population as well as voluntary blood donors for blood donation will increase the number of donors and safe donor pool. Key words- HBV, HCV, HIV, Prevalence, TTI.

Introduction
Blood transfusion therapy has been the mainstay of several medical-surgical therapeutics since 1930 [1]. But the first successful human to human blood transfusion was performed by Dr. James Blundell, an obstetrician, who transfused 8 oz (227 ml) of blood to a patient of postpartum hemorrhage in 1818[2]. There are 3 types of blood donors: voluntary/unpaid, family/replacement, and professional/paid [3,14]. A voluntary blood donor intentionally donates blood without pursuing any remuneration, whereas a replacement donor is requested to do so by the patient or his associates [4]. WHO Global Database on Blood Safety (GDBS) suggests that a total of around 112.5 million blood donations are collected annually, with approximately half of it coming from high-income countries, astringent to 19% of earth's population. Ten nations vouch for 65% of blood collections worldwide, and India is the third highest bidder in this respect after United States and China [3]. With almost 112.5 million units of yearly collections and 90% voluntary donors, India is expected to bang on the WHO target of 100% voluntary donations by 2020, much before due date[5]. There is 1% chance of transfusion associated problems including transfusion transmitted infections (TTI) with every unit of blood [6]. These TTIs include hepatitis B (HBV), hepatitis C (HCV), Human Immunodeficiency Virus (HIV), syphilis, and less commonly malaria, toxoplasmosis, brucellosis, other viral infections [7]. Since viral infections are the major cause for morbidity and mortality in blood recipients, prevention of these transmissible TTIs through blood transfusion is one of the greatest challenges for transfusion medicine [8]. The Drug and Cosmetic Act, 1945 and its amendments require that all blood donations must be screened against the five major infections: HIV I & II, HBsAg, HCV, syphilis, and malaria [9,10]. Consequently, NACO recommended 3rd or 4th generation ELISA/HIV I & II test kits with high sensitivity as the default test for use at blood banks for screening donated blood [11]. Blood transfusion departments not only screen TTI, but they also provide information about the prevalence of these infections in populations [12]. Blood safety interventions in the developed nations have greatly reduced the overall risk of TTIs [13]. Of the 112.5 million blood donations are collected annually, more than 18 million units of blood are not screened for TTIs [15]. Hence, majority of it is unlikely to be totally free of the risks of TTIs. In India, Government of India published National Blood Policy in the year 2002. The objective of the policy is to provide safe, adequate quality of blood, blood components and products. All blood banks are empanelled by the government and all authorized centers have been instructed to follow blood safety guidelines as listed by the National Aids Control Organization (NACO). Stricter control over the quality of blood and its products has been done to ensure that only non-reactive blood and blood components are released for clinical use [16]. The present study was carried out with the aim to find out the seroprevalence of infectious markers of TTIs among the blood donors at blood bank of Karnataka Institute of Medical Sciences (KIMS), Hubballi, Karnataka, over a period of 9 years from January 2007 to December 2015 and compare it with other recent studies.

Materials and Methods
Nine year retrospective study was carried out in the blood bank of Karnataka Institute of Medical Sciences (KIMS), Hubballi, Karnataka, from January 2007 to December 2015. A detailed pre donation questionnaire was included in the donor registration form. Information regarding occupation, previous surgery, .......
hospitalization, tattoo marks and high risk behaviour was obtained. According to regulations, haemoglobin levels had to be above 12.5 gm/l, weight above 45kg, age between 18 to 60 years. A consent was taken from every donor. From the donor's blood units, 5 ml blood samples were obtained for serological testing. All the samples were screened for HIV, HBV, HCV by standard ELISA kits and RPR for syphilis. Kits used for rapid tests were Meriscreen HIV 1-2 WB, Hepaview, SD-HCV. All these tests were done as per the guidelines in the blood bank, Karnataka Institute of Medical Sciences (KIMS), Hubballi, Karnataka.

Results

A total of 80312 apparently healthy donors were analysed for prevalence of TTIs of which 50735 (63.17%) were replacement donors and 29577 (36.83%) were voluntary donors. Among them, 77306 (96.26%) were males and 3006 (3.74%) were females as shown in [Table-1].

Table-1 Year Wise distribution of Voluntary/Replacement and Male/Female donors from 2005-2017

| Year | Voluntary Donors | Replacement Donors | Male Donors (% | Female Donors (% | Total Donors |
|------|------------------|-------------------|----------------|----------------|-------------|
| 2007 | 3402             | 5058              | 8089           | 371            | 8460        |
| 2008 | 2961             | 5385              | 8042           | 334            | 6377        |
| 2009 | 2723             | 7980              | 10248          | 255            | 10563       |
| 2010 | 2454             | 6063              | 8251           | 266            | 8917        |
| 2011 | 3349             | 5371              | 8410           | 310            | 8720        |
| 2012 | 5012             | 4202              | 8847           | 367            | 9214        |
| 2013 | 3258             | 5167              | 10788          | 347            | 8425        |
| 2014 | 3403             | 5057              | 8254           | 306            | 8660        |
| 2015 | 2985             | 6482              | 9047           | 300            | 9457        |
| Total | 29577            | 50735             | 77306          | 3006           | 80312       |

The overall prevalence of TTIs was more among male donors compared to female donors as shown in [Table-4]. Female donors were in less of our study due to anemia which was more prevalent in Hubballi-Dharwad region and social phobia.

Discussion

In the western world the transmission rates of HIV, HBV, HCV and syphilis through blood transfusion have been reported to be around 1 in 2.5 million, 1 in 0.5-1 million, 1 in 2-4 million, 6 in a million respectively [26,27]. The seroprevalences of various infectious markers from different parts of India [35-48] and within Karnataka [32,33,46,48,50] are given in [Table-5 and 6] respectively.

Table-5. Comparative study showing seroprevalence of TTI indifferent regions of India

| Regions                  | Study     | HIV (%)  | HBV (%) | HCV (%) | Syphilis (%) | Author | Year |
|--------------------------|-----------|----------|---------|---------|--------------|--------|------|
| Eastern India            | Kolkata   | 0.66%    | 1.41%   | 0.54%   | 0.23%        | Prasanthi K | 2016 |
| North India              | Rajasthan | 0.42%    | 1.24%   | 0.62%   | 0.65%        | Rupali Mandal | 2016 |
| Western India            | Gujarat   | 0.16%    | 0.60%   | 0.10%   | 0.52%        | Om Bhadarya  | 2016 |
| Central India            | Chattisgarh | 0.53%   | 1.76%   | 0.20%   | 0.07%        | Alok Kumar   | 2016 |
| Northern India           | Delhi     | 0.24%    | 1.18%   | 0.43%   | 0.23%        | R.N Makroo   | 2015 |
| South India              | Mumbai    | 0.10%    | 0.16%   | 0.18%   | 0.89%        | Dev Raj Aya  | 2017 |
| Karnataka                | Hubballi  | 0.35%    | 1.9%    | 0.2%    | 0.01%        | Suja S Girya | 2017 |

The overall prevalence of TTIs was more among replacement donors as shown in [Table-4]. Female donors were in less of our study due to anemia which was more prevalent in Hubballi-Dharwad region and social phobia.

Table-6 Comparative study showing seroprevalence of TTI in different regions of Karnataka

| Regions                  | Study     | HIV (%)  | HBV (%) | HCV (%) | Syphilis (%) | Author | Year |
|--------------------------|-----------|----------|---------|---------|--------------|--------|------|
| East Karnataka           | Tumkur   | 0.08%    | 0.50%   | 0.11%   | 0.11%        | Raman M H | 2016 |
| West Karnataka           | Mangalore | 0.06%    | 0.34%   | 0.06%   | 0.11%        | Fernand es | 2016 |
| Central Karnataka        | Dhekshina | 0.08%    | 0.53%   | 0.09%   | 0.59%        | K.Latha mani | 2001 |
| South Karnataka          | Bhadravathi | 0.13%  | 0.96%   | 0.03%   | 0.28%        | Vint Anand  | 2016 |
| Present study (North Karnataka) | Hubballi | 0.35%    | 1.9%    | 0.2%    | 0.01%        | Suja S Girya | 2017 |
As of 2015, around 2.1 million Indians were infected with HIV. With a prevalence of 0.26%, India has the third largest HIV epidemic in the world [17]. However, its prevalence among sub-continenal donors fluctuates through literatures, from 0.02 to 8.5% [18]. For HIV, India is third only to South Africa and Nigeria in terms of the overall number of people living with HIV [33]. According to India HIV Estimations 2015, released by NACO, Karnataka has a HIV prevalence of 0.45% [28]. 0.1% of blood donors in Hubballi-Dharwad region, as well as in whole of Karnataka, were HIV positive [29]. Despite that, very little is learnt about the seroprevalence of HIV and other TTIs among blood donors here. In the present study, prevalence of HIV was found to be 0.35%. Seroprevalence of HIV in various recent Indian studies reported to range between 0.06-0.6% [35-48]. Seroprevalence of HIV in Karnataka according to various studies range between 0.06-0.44% [32,33,46-48]. The majority of known cases of post-transfusion hepatitis has been caused by hepatitis B (HBV) or hepatitis C virus (HCV) [2]. Prevalence of HBV infection varies geographically between 0.1 and 11.7% [18]. In India, it lingers within 2 to 8% among general population and 1 to 2% among blood donors [19-21]. World Health Organization has placed India in the intermediate zone (2-7% prevalence rates) of prevalence of hepatitis B [34]. Majority of infections in our study was HBV. Seroprevalence of HBV in our blood donors was 1.9%. Prevalence of HBV in various recent Indian studies range between 0.45 to 1.9% [35-48]. Seroprevalence of HBV in Karnataka according to various studies range between 0.34-1.9% [32,33,46-48]. Globally, around 3% people are infected with HCV [22]. Around 0.4 to 19.2% blood donors test positively for HCV worldwide. Contrastingly, a low cumulative HCV prevalence below 2% has been reported from our country [20-21,23-25]. Prevalence of HCV in various recent Indian studies range between 0.098-0.85% [35-48]. Seroprevalence of HCV in Karnataka according to various studies range between 0.03-0.23% [32,33,46-48]. In the present study, prevalence of HCV was found to be 0.2%. Overall VDRL reactivity in our study is 0.01%, which is comparable to various studies in Karnataka which varies between 0.01-0.28% [32,33,46-48] and other recent Indian studies which varies between 0.01-0.89% [35-48].

Conclusion
In order to achieve a low rate of transmission, effective donor screening and proper testing of blood for TTIs should be done. The donor screening strategies include taking the elaborate medical history, performing preliminary clinical examination and screening for infectious markers. Screening tests for these infectious markers include rapid kit test & ELISA test for HIV, HBV, HCV & VDRL [30]. Other measures to prevent transmission of TTIs includes using autologous transfusions whenever possible, patients requiring regular transfusion therapy (e.g., hemophiliacs and thalassaeasms) should be given HBV vaccine, exclusion of all professional donors and high-risk donors such as homosexuals, bisexuals, intravenous drug abusers.

In spite of following all these measures, transmission of infection can occur, primarily because of the inability of the test to detect the disease in the ‘window’ period of infection, immunologically variant viruses, immune-silent carriers and inadvertent laboratory testing errors [31]. Detection of infection during window period can be done by Nucleic acid testing (NAT). But NAT is available in a few centers in India [32]. Knowing the prevalence of TTIs, among blood donors gives an idea about the epidemiology of these diseases in the community and helpful in formulating strategies for improving the management of a safe blood transfusion. The current infectious disease pattern and trends in donor population can help in planning of future blood transfusion related health challenges. Encouraging female population as well as voluntary blood donors for blood donation will increase the number of donors and save donor pool. There is need to look back phenomenon and donor notification, donor counselling to prevent further transmission of the infection. Though the prevalence of HIV and HBV are decreasing still there is need to improve and implement strict donor selection and sensitive screening tests which can minimize the risk of acquiring TTIs with special emphasis on HCV infection.

Application of research
With the knowledge of current TTI’s disease pattern and trends in donor population, encouraging female unpaid voluntary donors for blood donation, not only increases number of donors, but also the safe donor pool.

Future Perspective
Pathogen Reduction Technology (PRT) is a proactive strategy to mitigate the risk of transfusion-transmitted infections. It has the potential to transform how blood products reach patients. These systems include Mirasol® Pathogen Reduction Technology, INTERCEPT®, and THERAFLEX®. The current interest in the blood industry is the development of pathogen inactivation technologies that can treat whole blood (WB) and red blood cell (RBC). As of early 2017, only the Intercept plasma and platelet system has been approved for use in the United States. The Mirasol system has recently undergone phase III clinical trials for treating WB in Ghana and has demonstrated some efficacy toward malaria inactivation and low risk of adverse effects. A 2nd generation of the INTERCEPT® S-303 system for WB is currently undergoing a phase III clinical trial. Both methodologies are applicable for WB and components derived from virally reduced WB or RBC [51].

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