Section: Transfusion Medicine

Original Research Article

COMPARATIVE STUDY OF HIV, HCV AND HBV SCREENING BY THIRD AND FOURTH GENERATION ELISA IN DONATED BLOOD

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Abstract

Background: Transfusion-transmissible infections such as HIV, HCV and HBV are among the greatest threats to blood safety and potential serious chronic sequelae associated with readily transmitted agents. The implementation of these new highly sensitive 4th generation ELISA tests has significantly enhances early detection of HIV, HCV and HBV infection compare with 3rd generation ELISA. The objective is to compare the 4th generation ELISA with third generation ELISA for early detection of HIV, HCV and HBV infection among voluntary blood donors. **Materials and Methods:** This Cross-sectional study was conducted over one year period from August 2018- July 2019 in the Department of Transfusion Medicine, The Tamil Nadu Dr.MGR Medical University, Guindy, Chennai. All blood units were tested for HIV I&II, HCV antibodies and HBsAg using 3rd generation ELISA (Merilisa hiv 1 & 2 gen 3, Merilisa HCV and Merlisa HBsAg kits manufactured by Meril diagnostics). In addition donor units were screening with 4th generation HIV Ag-Ab, HCV Ag-Ab and HBsAg ELISA (Genscreen ULTRA HIV Ag-Ab kits, Monolisa HCV Ag-Ab ULTRA V2 kit and Monolisa HBsAg ULTRA ELISA kits manufactured by Bio Rad). **Result:** Among total 373 voluntary blood donor samples, 3 were found to be seroreactive for HBsAg by 3rd and 4th generation ELISA. Only one sample was found to be seroreactive for HCV by 4th generation ELISA, this was found to nonreactive by 3rd generation ELISA. None of the samples were reactive for HIV by both 3rd and 4th generation ELISA. **Conclusion:** In the present study, there is no difference in detection of HBsAg and HIV between 3rd and 4th generation ELISA. In detection of HCV by 4th generation ELISA is found to be more sensitive than 3rd generation ELISA.

INTRODUCTION

According to World Health Organization (WHO), blood donation should be absolutely voluntary, non-remuneration and the motive should be purely altruistic to help the unknown recipient.[1]

Blood Safety, thus, remains an issue of major concern in transfusion medicine in developing countries.

WHO supports countries in developing national blood systems to ensure timely access to safe and sufficient supplies of blood and blood products by following good transfusion practices to meet the patient's needs.[1]

The programme encourages to work towards self-sufficiency in safe blood and blood products based on voluntary unpaid blood donation. It provides policy guidance and technical assistance to ensure universal access to safe blood and blood products, thereby achieve universal health coverage.

WHO, in addition to promoting unpaid voluntary blood donation, recommends all donations should be mandatorily screened for highly prevalent infections which are likely to be transmitted by blood transfusion.

In India, it is mandatory to test every unit of blood collected for Hepatitis B, Hepatitis C, HIV, Syphilis and Malaria. If a donor is found to be positive to any of these five infections, their blood is considered infectious and discarded.[2]

The scrupulous screening for these infections is all the more important because the blood units donated by apparently healthy and asymptomatic blood donors carry infectious agents with them.[3]

In order to improve the standards of Blood and its components, the Central Govt. through Drugs Controller General of India, has formulated a comprehensive legislation to ensure better quality control system on collection, storage, testing and distribution ofblood and its components. Central Govt. amended from time to time the existing requirements of Blood Banks in the Drugs & Cosmetics Act, 1940 and Rules there under 1945 to meet the latest standards.[4]

Transfusion-transmissible infections such as HIV, HCV and HBV are among the greatest threats to blood safety and potential serious chronic sequelae associated with readily transmitted agents.[5]

Screening of blood donors first started in 1947.[6] Government of India has made mandatory to screen donated blood for HBV (since 1971), HIV (since 1989) and HCV (since 2001).[5,6]

The risks of giving blood during infectious window period were estimated as follows: for HIV, 1 in 4,93,000; for HCV, 1 in 1,03,000; and for HBV, 1 in 63,000.[7] In NACO guidelines83 2016 seroprevalence among blood donors in India for HIV is 0.26%, HCV 0.4 to 2 % and HBV 2 to 3%.

Nucleic acid testing (NAT) is a molecular technique for screening blood donations 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).[8]

In India, mandatory blood screening for HBV, HIV and HCV is done by serological tests for HBsAg and antibodies to HIV 1&2 and HCV. The screened seronegative donations are still at risk for TTIs and thus, need for a sensitive screening test arises to decrease this residual risk which has been reduced significantly over the last two to three decades in western countries where NAT has been implemented. NAT testing has been started in few centres in India, but it is not a mandatory screening test for TTIs as per Drug and Cosmetics Act, 1940 and the rules therein.[9]

Major barriers in implementing routine NAT testing in India are its high cost and lack of technical expertise in most of the blood centers.[10]

In India, currently using 3rd generation ELISA KITS which will detect either antigen or antibody. The 4th generation ELISA assays simultaneously detect antibodies against HIV-1 and 2 and the presence of p24 antigen and thus shorten the window period to about 14 days, as compared to about 22 days with 3rdgeneration,[11] for HCV simultaneous detection of Capsid Antigen and antibodies against NS1 to NS5 shortens the window period to about 10 to 20 days,[12] as compared to 59 days with 3rd generation ELISA, for HBV ultrasensitive kit detection of various subtypes of HBsAg and the most part of variants HBV strains thus detect in the window period to about 24 days, as compared 37 days with 3rd generation ELISA.[12] The implementation of these new highly sensitive 4th generation ELISA tests has significantly enhances early detection of HIV,HCV and HBV infection.[11]

Hence, this study is aimed to compare the 4th generation ELISA with third generation ELISA for early detection of HIV, HCV and HBV infection among voluntary blood donors.

MATERIALS AND METHODS

This Cross-sectional study was conducted over one year period from August 2018- July 2019 in the Department of Transfusion Medicine, The Tamil Nadu Dr.MGR Medical University, Guindy, Chennai. A total of 373 voluntary blood donors were selected.

The study was approved by the ethical committee of The Tamil Nadu Dr. MGR Medical University, Chennai. The donors were classified as upper, middle and lower socioeconomic status based on Kuppusamyclassification.[13]

Minimum required sample size = 284

Sample Collection

Serum was separated from donated samples of voluntary blood donors in a sterile plain test tube and stored at -20ºC for ELISA and PCR tests.

Inclusion Criteria

Those voluntary blood donors who fulfil the criteria as per DGHS guidelines.

Those blood donors who are willing to participate in thestudy.

Exclusion Criteria

- Those voluntary blood donors who do not fulfill the donor selection criteria as per the DGHS guidelines.
- Family and Replacement donors are not included in this study.
- Those blood donors who are not willing to participate in the study

Study Period

The total sample size was split month wise from August 2018 to July 2019.

Statistical Analysis

- Data analysis was done using SPSS software
- Demographic details were given in descriptive statistics
- Quantitative data was given in summary statistics
- $P<0.05$ was considered significant

RESULTS

Demographic analysis showed, of the 373 donors, 320 (85.8%) were males and 53 (14.2%) were females.

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Age distribution among the 373 blood donors were 49.1% in 18-20 years, 32.4% in 21-30 years, 9.4% in 31-40 years, 6.7 % in 41-50 years, 2.4% in >50 Years.

Percentage distribution of blood donors on the basis of Occupation were 33.3% of working (employed), 64.3% of students, 2.4% of others.

Percentage distribution of blood donors on the basis of Occupation were 33.3% of working (employed), 64.3% of students, 2.4% of others.

Most of our donors belong to middle socioeconomic status (89.8%) followed by low (5.1%) and high (5.1%).

Zonal Distribution of Voluntary Blood Donors

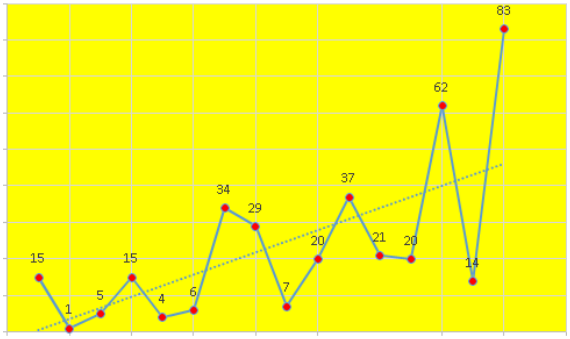

Figure 1: Zone of Distribution Total No of voluntary donors: 373

Zonal distribution of donors was on the basis of their residence in and around Chennai. Those within the city were divided further in to 15 zones. 290 donors were from 15 zones within Chennai city and 83 were from outside the city limits.

According to zones in the city there were 4% in zone 1, .3% in zone 2,1.3% in zone 3,4% in zone 4,1,1% in zone 5,1.6% in zone 6,9.1% in zone 7,7.8% in zone 8,1.9% in zone 9,5.4% in zone 10,9.9% in zone11, 5.6% in zone 12, 5.4% in zone 13, 16.6% in zone 14 and 3.8% in zone 15. The remaining 22.3% were from outside the limits of Chennai city.

Blood group distributions among the blood donors were 22.8% of 'A' group, 27.9% of 'B' group, 41.3% of 'O' group, 72% of 'AB' group, 0.5% of 'A2B' group and 0.3% of 'A2' group.

Rh distribution among donors were 351(94.1%) of Rh D positive group, 22(5.9%) of Rh negative group.

In our study there was none of the donor reactive for HIV by screening with 3rd and 4th generation HIV ELISA.

Among 373 donors, none of the donation seroreactive for HCV by screened with 3rd generation HCV ELISA whereas in 4th generation HCV Ag-Ab ELISA 1 donation (0.26%) showed seroreactive.

Among 373 donors, there was 3(0.80%) donation seroreactive for HBsAg by screening with 3rd generation HBsAg and 4th generation HBsAg-ULTRA ELISA.

Age distribution of seropositivity of the present study among the voluntary blood donors is seen in 21-30 years of age in which 3(121) donation (2.47%) seroreactive for HBsAg by screening with 3rd generation HBsAg and 4th generation HBsAg-ULTRA ELISA. None of the donation seroreactive for HCV by screened with 3rd generation HCV ELISA whereas in 4th generation HCV Ag-Ab ELISA 1(121) donation (0.83%) showed seroreactive.

Gender distribution of seropositive of present study, 3rd generation ELISA showed 3(0.94%) out of 4 positive donations and did not pick up 1(0.31%) out of 4 HCV positive donation whereas 4th generation ELISA picked all 4 (1.25%) out of 4 as positive reactions (3 HBsAg and 1HCV). None of the female donors were seropositive.

In our study the prevalence of HBsAg among student sub group was 1(240) seropositive donation (0.42%) whereas working (employed) sub group was 2(133) seropositive donation (1.61%) in both 3rd and 4th generation HBsAg ELISA. In HCV 1(133) seropositive donation (0.80%) was seen in working (employed) group by 4th generation ELISA which is not picked up by 3rd generation ELISA.

Socioeconomic status of seropositivity of the present study among the voluntary blood donors is seen in middle Socioeconomic status in which 3(335) donation (0.90%) seroreactive for HBsAg by screening with 3rd generation HBsAg and 4th generation HBsAg-ULTRA ELISA. None of the donation seroreactive for HCV by screened with 3rd generation HCV ELISA whereas in 4th generation HCV Ag-Ab ELISA 1(335) donation (0.30%) showed seroreactive.

In 3rd generation ELISA identified 1 HBsAg positive belonged to blood group O whereas 4th generation ELISA picked 2 (1 HBsAg and 1 HCV) belonged to blood group O. The remaining two (2)HBsAg Positive belonged to A1 blood group. In which both 3rd and 4th generation ELISA test 2 seroreactive samples.

In the present study Rh positive donors showed 3(351) seropositivity (0.85%) for HBsAg in both 3rd and 4th generation HBsAg ELISA whereas Rh negative donor showed 1(22) seropositivity (4.55%) only 4th generation HCV ELISA.

In this study 2 (233) HBsAg seroreactive donations (0.86%) belonged to first time donors and the remaining 1 (140) seroreactive donation (0.71%) belonged to a repeat voluntary blood donation which showed seroreactivity in 3rd & 4th generation HBsAg ELISA, 1(233) HCV seroreactive (0.86%) belonged to first time donation by 4th generation ELISA and did not pick up in 3rdgeneration HCV ELISA.

In our study, 3rd generation ELISA had 3 donor positive for HBsAg which was 0.80% and no one found positive for HCV. Whereas, 3 donors were positive for HBsAg which was 0.80% and there was 1 donor found to be positive for HCV which was 0.27% in 4th generation ELISA.

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All 3 samples which were HBsAg seroreactive by both 3rd and 4th generation ELISA showed the presence of HBV DNA by RT PCR.

Only one sample was seroreactive by 4th generation ELISA, that too was not detected by 3rd generation ELISA. RT PCR done on this sample revealed the presence of HCV RNA.

Table 1: Distribution of Blood Group.

S.no	Blood group	Percentage%
1	A1	22.8
2	B	27.9
3	O	41.3
4	A1B	7.2
5	A2B	0.5
6	A2	0.3
Total		100.0

Table 2: HIV Screening by 3rd and 4th Generation ELISA

HIV Screening	Reactive	Nonreactive	Indeterminate
3rd Generation	0	373	0
4th Generation	0	373	0

Table 3: Age distribution of seropositive of HCV & HBsAg by 3rdGeneration ELISA

Age group In years	3rd generation			4th generation		
	HCV seroreactive (Total donors)	HBsAg seroreactive (Total donors)	Total Seroreactive	HCV seroreactive (Total donors)	HBsAg seroreactive (Total donors)	Total Seroreactive
18-20	0(183)	0(183)	0(183)	0(183)	0(183)	0(183)
21-30	0(121)	3(121)	3(121)	1(121)	3(121)	4(121)
31-40	0(35)	0(35)	0(35)	0(35)	0(35)	0(35)
41-50	0(25)	0(25)	0(25)	0(25)	0(25)	0(25)
>50	0(9)	0(9)	0(9)	0(9)	0(9)	0(9)

Table 4: Gender distribution of seropositive of HCV & HBsAg by3rd & 4thGeneration ELISA

Sex	3rd generation			4th generation		
	HCV Seroreactive (Total donors)	HBsAg Seroreactive (Total donors)	Total Seroreactive	HCV Seroreactive (Total donors)	HBsAg Seroreactive (Total donors)	Total Seroreactive
Male	0(320)	3(320)	3(320)	1(320)	3(320)	4(320)
Female	0(53)	0(53)	0(53)	0(53)	0(53)	0(53)
Total			3(373)			4(373)

Table 5: Occupation distribution of seropositive of HCV & HBsAg by3rd & 4thGeneration ELISA

Occupation	3rd generation			4th generation		
	HCV Seroreactive (Total donors)	HBsAg Seroreactive (Total donors)	Total Seroreactive	HCV Seroreactive (Total donors)	HBsAg Seroreactive (Total donors)	Total Seroreactive
Working (employed)	0(124)	2(124)	2(124)	1(124)	2(124)	03(124)
Students	0(240)	1(240)	1(240)	0(240)	1(240)	1(240)
Others	0(9)	0(9)	0(9)	0(9)	0(9)	0(9)
Total			3(373)			4(373)

Table 6: Socioeconomic status distribution of seropositive of HCV & HBsAg by 3rd & 4thGeneration ELISA

Socioeconomic status	3rd generation		4th generation	
	HCV seroreactive (Total donors)	HBsAg seroreactive (Total donors)	HCV seroreactive (Total donors)	HBsAg seroreactive (Total donors)
High	0(19)	0(19)	0(19)	0(19)
Middle	0(335)	3(335)	1(335)	3(335)
Lower	0(19)	0(19)	0(19)	0(19)
TOTAL	0(373)	3(373)	1(373)	3(373)

Table 7: Blood group distribution of seropositive of HIV, HCV & HBsAg by 3rd & 4thGeneration ELISA

Blood group	3rd generation		4th generation	
	HCV Seroreactive (Total donors)	HBsAg Seroreactive (Total donors)	HCV Seroreactive (Total donors)	HBsAg Seroreactive (Total donors)
A1	0(85)	2(85)	0(85)	2(85)

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B	0(104)	0(104)	0(104)	0(104)
O	0(154)	1(154)	1(154)	1(154)
A1B	0(27)	0(27)	0(27)	0(27)
A2B	0(2)	0(2)	0(2)	0(2)
A2	0(1)	0(1)	0(1)	0(1)
Total	0(373)	3(373)	1(373)	3(373)

Table 8: Rh distribution of seropositive of HCV & HBsAg by 3rd & 4thGeneration ELISA

Rh typing	3rd generation		4th generation	
	HCV	HBsAg	HCV	HBsAg
	Seroreactive (Total donors)	Seroreactive (Total donors)	Seroreactive (Total donors)	Seroreactive (Total donors)
Positive	0(351)	3(351)	0(351)	3(351)
Negative	0(22)	0(22)	1(22)	0(22)
Total	0(373)	3(373)	1(373)	3(373)

Table 9: Distribution of seropositive of HCV & HBsAg by 3rd & 4thGeneration ELISA among first time & repeat donors

Number of Donation	3rd generation		4th generation	
	HCV	HBsAg	HCV	HBsAg
	Seroreactive (Total donors)	Seroreactive (Total donors)	Seroreactive (Total donors)	Seroreactive (Total donors)
First time	0(233)	2(233)	1(233)	2(233)
Repeat	0(140)	1(140)	0(140)	1(140)
Total	0(373)	3(373)	1(373)	3(373)

DISCUSSION

In the present cross sectional study, 373 voluntary blood donors were screened to compare the sensitivity of 3rd and 4th generation ELISA kits and also to know the prevalence of HIV, HCV and HBsAg.

Voluntary blood donors with asymptomatic infection of HIV, HCV and HBsAg during window period contribute to the risk of Transfusion Transmitted infection.

Our blood bank completely depends on voluntary blood donation. All the donors included in the study were voluntary blood donors.

In the present study,320 (85.8%) were males and 53 (14.2%) were females. Similarly, in the study done by Sachin Shivaji kapse et al., 135 86.6% were male donors and 13.4% were female donors. However in the study done by Sangita Patel et al.,[14] the overall sex distribution was 95.4% males and 4.6% females. The main reason for lower female donors were due to high prevalence of anaemia among Indian women and less female participation due to lack of awareness, motivation and education regarding voluntary blood donation.[15]

In the present study, the seroreactive of HBsAg and HCV were 0.8%, 0.27% respectively. None of the voluntary blood donors were found to be HIV seroreactive.

Similar study done by Arora et al.,[15] among replacement donors in state of Haryana the seroreactive of HBsAg, HCV and HIV were 1.4%, 0.9% and 0.3 % respectively. However, among voluntary blood donors in the same study, they found lower seroreactive for HBsAg and HCV viz., 0.3 and 0.12 % respectively, none were HIV seroreactive.

In the present study HIV seroreactive was estimated to be 0 per 373 donations (0%) using 3rd and 4thgeneration ELISA. In a study by Sheetal Malhotra et al., 16 HIV seroreactive was estimated to be 1.37 per 1000 donations (0.13%) using 3rd generation ELISA and 3.62 per 1000 donations (0.36%) by using the 4th generation ELISA. Their study was also done on only voluntary blood donors similar to our study, however slightly higher seroreactive by 4th generation ELISA was found to be due to higher false positive reactions (33 % of samples found seroreactive by 4th generation ELISA was found to be nonreactive by western blot study).

Kola sujatha et al,[17] in their study among voluntary blood donors from rural population in the state of Andhra Pradesh, found 0% HIV seroreactive by 3rd generation ELISA and 1% by 4th generation ELISA.

In the present study, HBsAg seroreactive was estimated to be same (0.8%) by both 3rd and 4th Generation ELISA. In a study among blood donors in Mumbai (both replacement and Voluntary), Sachin Shivaji kapse et al., found 1.1% HBsAg seroreactive by 3rd generation ELISA.[18]

Patel et al., in their study among voluntary blood donors in Gujarat, by 4th generation HBsAg ELISA found 0.63% HBV seroreactive.

In the present study, HCV seroreactive was estimated to be 0 per 373 donations using 3rd generation ELISA and 0.27 % (1 per 373 donors) HCV by 4th generation ELISA.

Makroo et al.,[19] study among blood donors (96.9% replacement and 3.1% voluntary) in New Delhi revealed 0.43% seroreactive by 3rd generation ELISA. Patel et al., study in Gujarat found 0.21% HCV seroreactive by 3rd generation ELISA. Akanksha et al,[20] in their study among blood

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donors in New Delhi (25.4% replacement and 74.6% voluntary) found 0.73% HCV seroreactive by 4th generation ELISA.

The wide variations in the seroreactive of HIV, HCV and HBV among the voluntary blood donors in different studies conducted in India is most probably due to the use of different methods of testing and use of different generation of ELISA test kits having different sensitivities and specificities.

In the present study, the most common age group of voluntary blood donors were less than 18-20 years (49.1%) and 32.4% in 21-30 years, 9.4% in 31-40 years, 6.7 % in 41-50 years, 2.4% in >50 Years. However the age distribution of seropositivity among the voluntary blood donors is seen in 21-30 years of age which is 3.3% and these is similar to the following studies,

In the study by Sachin Shivaji kapse et al.,[18] Majority of TTI positivity is among 18 – 27 years about 0.59%. (3rd generation). In the study by Ahmed et al.,[21] had 69.8% positive donors belonged to the age group of 18-30 years, and 28.3% belong to 31-45 years age group.

In the study conducted by Solomon Bisetegen et al.,[22] 65 (23.6%) of donors less than or equal to 30 years and 50 (43.9%) of donors greater than 30 years have evidence of at least one blood borne pathogen. (4th generation)

The present study had all seroreactive donation belonged to male gender which implies no female donors had seroreactivity. In which 3 donations belonged to HBV and 1 had HCV positivity. The 3rd generation ELISA showed 3 (0.94) out of 4 positive donations and did not pick up 1(0.31%) out of 4HCV positive donation. Whereas 4th generation ELISA picked all 4 (1.25%) out of 4 as positive reactions (3 HBsAg and 1HCV).

In the present study among the total of 373 voluntary blood donations 233 were first time donation and the remaining 140 were repeat donations. In which all3 HBsAg seroreactive donations, 2 (233) HBsAg seroreactive donations (0.86%) belonged to first time donors and the remaining 1 (140) 0.71% seroreactive donation belonged to a repeat voluntary blood donation which showed seroreactivity in 3rd generation ELISA.

However, 3rd generation ELISA did not pick up 1 HCV seroreactive donation. Further, in 4th generation ELISA picked up all 4 /4 seroreactive donations in which 3 HBsAg seroreactive donations, 2 (233) HBsAg seroreactive donations (0.86%) belonged to first time donation and the remaining 1 (140) 0.71% seroreactive donation belonged to a repeat voluntary blood donation and further, it also picked up 1 seroreactive HCV belonged to first time donation.

Similarly in the study conducted by Sachin Shivaji kapse et al,[18] 1.01% seroreactivity among 1st time donors and 0.38%seroreactivity in repeat donors the study was done by using 3rd generation ELISA kits.

In the study done by Sheetal Malhotra et al.,[16] had 1.61 /1000 1st time donors and, 1.23/1000 repeat donors found seroreactive in 3rd generation ELISA however in 4th generation ELISA 2.94/1000 showed seroreactive results and 0.69/1000 found to be in grey zone in both 1st time and repeat donors.

RT-PCR:

In this study, to confirm seropositive samples RT-PCR was done.

All 3 samples which were HBsAg seroreactive by both 3rd and 4th generation ELISA showed the presence of HBV DNA by RT PCR, thereby ruled out any false positive reactions.

Only one sample was seroreactive by 4th generation ELISA, that too was not detected by 3rd generation ELISA. RT PCR done on this sample revealed the presence of HCV RNA (2.8x105IU/ML, Genotype 1b), thereby ruled out false positive reaction by 4th generation ELISA.

The sample which was nonreactive by 3rd generation ELISA found to be reactive by 4th generation ELISA for HCV is due to the ability of 4th generation ELISA to detect HCV core antigen much earlier than HCV antibody by 3rd generation ELISA. The Syria Laperche et al.,[23] study on simultaneous detection HCV core antigen and anti-HCV antibodies on voluntary blood donors revealed 33 to 46% reduction in the HCV related TTI.

All the four seroreactive donors were given post-test counselling and were advised to refrain from high risk behaviour and also to self-exclude from future donations. All the four seroreactive donors was referred to medical gastroenterology department at a higher centre for counselling, Management and further follow up.

CONCLUSION

In the present study, there is no difference in detection of HBsAg and HIV between 3rd and 4th generation ELISA. In detection of HCV by 4th generation ELISA is found to be more sensitive than 3rd generation ELISA. However, it is imperative to do a study on larger number of samples to arrive at a definitive conclusion.

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