Transfusion transmitted infections

Screening strategies for TTI

P222 | Abstract withdrawn

P223 | Multivariate linear regression analysis of four mandatory blood screening serology markers in national blood centre & 12 regional blood centre of Thai Red Cross Society, Thailand.

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Background: The Four Transfusion transmissible infections (TTIs) namely, Human immunodeficiency virus (HIV), Hepatitis B virus (HBV), Hepatitis C virus (HCV), Treponema pallidum (syphilis) are mandatorily screened for all the blood donations at all blood centres in Thailand for the provision of a safe blood supply. The National Blood centre (NBC) and 12 regional blood centres (RBC) of Thai Red Cross Society (TRCS), Thailand utilise Alinity i immunoanalyser (Abbott Diagnostics, IL) to perform the HIV Ag/Ab combo, HBsAg, anti-HCV and syphilis serology screening since Sep 2019. We recently conducted method verification and correlation of these four Alinity i screening assays between NBC and RBCs using multivariate linear regression (MLR) before the implementation of new Alinity i analysers in Nov 2022 for the routine blood screening in the blood centres.
Aims: To perform MLR analysis of four TTIs screening markers - HIV Ag/Ab combo, HBsAg, anti-HCV and syphilis on 32 Alinity i immunoanalysers in NBC and 12 RBCs of Thai Red Cross Society, Thailand for the result correlation.
Methods: MLR analysis was performed using 50 donor plasma samples (25 negative and 25 positive) for each TTI screening marker that is, HIV Ag/Ab combo, HBsAg, anti-HCV and syphilis provided by NBC to all the RBCs. Total of 32 Alinity i analyser at NBC and 12 RBC were included in the study.
Results: MLR analysis of all the 4 TTIs markers on 32 Alinity i analyser at NBC and 12 RBCs demonstrated excellent correlation between the expected and the observed results with HIV R^2 ≥ 0.99, HBV R^2 ≥ 0.89, HCV R^2 ≥0.99 and syphilis R^2 ≥0.96.
Summary/Conclusions: The study showed excellent correlation for all the 4 evaluated TTIs markers on 32 Alinity i analyser at NBC and 12 RBCs of Thai Red Cross Society. Robust MLR results not only provided objective evidence towards high performing blood screening serology in the TRC labs before the implementation but also allowed us to set the baseline standard for future monitoring of the labs performance.

P224 | Prevalence of acute hepatitis E virus infections in Swiss blood donations 2018–2020

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Background: Hepatitis E virus (HEV) genotype 3 is the major cause of acute viral hepatitis in several European countries. It is acquired mainly by ingesting contaminated pork, but has also been reported to be transmitted through blood transfusion. Although most HEV infections, including those via blood products, are usually self-limiting, it may become chronic in immunocompromised persons. It is thus essential to identify HEV infected blood donations to prevent transmission to vulnerable recipients.
Aims: Prior to the decision whether to introduce HEV RNA screening for all Swiss blood donations a 2-year nationwide prevalence study was conducted. The findings of the study is presented.
Methods: All blood donations were screened in pools of 12-24 samples at five regional blood donation test centres using the commercial HEV RNA assays from Roche Molecular Systems, Inc. and from Grifols Diagnostic Solutions. The HEV RNA positive pools were subsequently resolved to the individual donation (X donation). On the X-donations the viral load, HEV IgG and IgM serology and the HEV genotype were determined. Follow-up investigations where conducted on future control donations (X+1) and previous archived donations of the donor (X-1) where available.
Results: Between Oct 2018 and Sept 2020, 541,349 blood donations were screened and 125 confirmed positive donations were identified (prevalence 1:4,331 donations; Table 1). At the time of blood donation, the HEV RNA positive individuals were symptom-free. The median viral load was 554 IU/mL (range: 2.01 - 2,500,000 IU/ml). Men (88; 70%) were more frequently infected than women (37; 30%) as compared with the sex distribution in the Swiss donor population (57% male / 43% female, $p < 0.01$). Of the 106 genotyped cases (85%), all belonged to genotype 3 (Table 2). Two HEV sub-genotypes predominated; 3h-s (formerly 3s), a variant endemic

P224 - Table 1: Characteristics HEV RNA-positive blood donations

Number donations screened	541,349	
Number HEV RNA positive	125	
HEV prevalence	1:4,331	
HEV median viral load	554 IU/ml	
HEV viral load range	2.01 - 2,500,000 IU/ml	
Number males/females (%); median age; viral load	males: 88 (70); 47.5 y; 734 IU/ml	females: 37 (30); 38.4 y; 266 IU/ml

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P224 - Table 2: Distribution of HEV sub-genotype 3 identified

HEV sub-genotypes	Number (%)
HEV 3h-s	42 (40)
HEV 3c	40 (38)
HEV 3f	10 (9)
HEV 3ra	5 (5)
HEV 3e	2 (2)
HEV 3a	1 (1)
various HEV 3 (3/3o/3t)	6 (6)
Total	**106**

in the Swiss pig population and which is practically confined to Switzerland and 3c, a variant often encountered in northern Europe. The remaining sub-genotypes are all known to circulate in Europe. Five 3ra genotypes were identified, a variant associated with rabbits. 85 (68%) X donations were negative for HEV IgM and IgG. The remaining 40 (32%) were positive for HEV IgG and/or IgM and are consistent with an active infection. We found no markers of previous HEV in the 91 analysed archive samples (X-1) (Table 3). Three donors were HEV IgG positive in the X-1 donation suggesting insufficient immunity to prevent HEV reinfection. Time of collection of the 91 (72.8%) analysed X+1 donations varied between 2.9-101.9 weeks (median of 35 weeks) after X donation. As expected, none of those tested were positive for HEV RNA. Most donors (90; 98.9%) were positive for anti-HEV IgG / IgM (i.e. seroconversion). HEV IgM positive (24; 26%) indicates an often long persistence of IgM antibodies post HEV infection.

Summary/Conclusions: The data collected during the first year of the study provided the basis for the decision to establish mandatory HEV RNA universal screening of all Swiss blood donations in minipools.

P225 | 21 years experience in NAT screening of blood donors: analysis of data recorded at ASST-Spedali Civili, Brescia (Italy)

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Background: Since October 31, 2001 all the donations collected in Brescia (Italy) and in its province are tested using a molecular qualitative screening for HIV1-2, HCV, HBV (HBV-DNA since March 30, 2006) at the NAT Laboratory of the ASST Spedali Civili Brescia. In 21 years, until October 31, 2022, 1.344.637 donations have been screened.

Aims: Evaluating the role of NAT screening in the detection of transfusion trasmitted viruses

Methods: Data about donations from the last 21 years were investigated retrospectively. Blood samples were collected in EDTA tubes.

Until February 2014, the units were tested by ID-NAT (Individual donor nucleic acid test) using TMA (transcription-mediated amplification) technology: from October 2001 to March 29, 2006 by a semiautomated system (e-sas), the Procleix HIV/HCV Assay, then by Procleix Ultrio Assay (HIV/HCV/HBV) and, from August 2008, using Tigris automated system. In February 2014, minipool Multiplex PCR was introduced: maximum 6 samples were analysed using Cobas s201, then Cobas 6800; since October 5, 2016 the units were tested individually by MPX using Cobas 6800.

According to the Italian law, all initially reactive samples (IR) were retested in duplicate on the pilot screening tube and in triplicate from the fresh frozen plasma (FFP) collected from respective donations.

The serological status of IR donors was also investigated. Anti-HBc test was performed on HBV-DNA IR samples to identify occult HBV infections (OBI).

All the IR donations were discarded

Results: From the 781.113 donations tested by TMA, 1121 were IR (352/256.999 tested only for HIV and HCVRNA); a discriminatory test was performed on IR samples: 5 were confirmed HCV positive (1 anti-HCV negative), 15 HIV positive (2 anti-HIV negative) and 22 HBV positive (19 HbsAg negative).

174.999 samples were screened in minipool using MPX; 204 were IR: 11 were HBV repeat reactive (RR), 1 also HBsAg+ while 17 were IR and HBcAb+.

Out of 388.525 individual donations tested by MPX, 597 were IR: 1 was HIV RR and Anti-HIV +, 43 were HBV RR while 89 were HBV-DNA IR and HBcAb+

Summary/Conclusions: According to our experience, the introduction of NAT screening for three viruses on blood donations has improved blood safety in Italy by reducing the transfusion transmitted risk and the window period: 16 HIV (2 seroconversions), 5 HCV (1 seroconversion), 4 acute hepatitis B and 178 OBI were detected.

Our analysis support the effectiveness of using NAT for detection of OBI.

P226 | ID-NAT screening of donated blood: A one year experience

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Background: Since the introduction of nucleic acid testing (NAT) of donated blood, there is a growing evidence concerning the impact on blood safety associated with the shortening of the window period and detection of occult infections.

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