

## **CHARACTERISATION OF OCCULT HEPATITIS B IN BLOOD DONORS (P-195)**

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Poster Session: 6.2 Blood Safety - Transfusion Transmitted Disease (TTD) – Hepatitis

Monday, 25 June 2007

### **BACKGROUND**

Hepatitis B and its virus (HBV) have been studied for many years both clinically and biologically. In Italy mandatory screening for Hepatitis B includes only the HBsAg test. In April 2006 the Health Ministry recommended in all the Country to perform NAT test for HBV on single unit or on minipool maximum 10 samples size. HBcAb IgG test is not mandatory for screening in all the Regions ; In Piedmont region HBV-DNA test for all donors (single or minipool) was recommended since 01/01/2006 (DGR 56-1206 24/10/2005); HBcAb IgG test is recommended for only new donors from July 2005. In our department routinely HBV-DNA screening on blood donations was introduced in June 2004 to complete the NAT screening for HIV1-RNA HCV-RNA. HBcAb IgG test was introduced since April 2004 (only for new donors)

### **AIMS**

In this work we evaluated serological and molecular characterisation of occult HBV in blood donors. With this kind of study we try to provide information on a nearly unknown part of HBV natural history.

### **METHODS**

Serological screening and markers test for Hepatitis B are performed by ABBOTT PRISM and AXSYM. NAT screening is performed in single sample with PROCLEIX® ULTRIO® Assay on PROCLEIX® TIGRIS® System in minipool 6 sample size by Cobas S 201 System Roche. Analytical sensitivity for HBV-DNA: detection limit (D.L.) 95% calculated by Probit Analysis for neat sample is 8,4 UI/ml (fiducial limit 5,85 – 15,25). Clinical sensitivity for HBV was estimated by comparison between ULTRIO and PRISM and AXSYM (ABBOTT) for HBsAg assay testing 10 seroconversion panel (Impath BCA) Precocity versus ABBOTT PRISM for HbsAg for undiluted samples is 14 days (fiducial limits 11-19); vs AXSYM for undiluted samples is 16 days (10-21). Molecular characterisation of occult HBV is performed by qualitative and quantitative PCR in house and genotyping and sequencing of the virus.

### **RESULTS**

285,564 blood units were tested since June 2004 till December 2006, with ABBOTT PRISM for HBsAg, with PROCLEIX ULTRIO Assay Technology for HBV-DNA; 14,102 units from new donors were tested also for HBcAb IgG with AXSYM ABBOTT. 7.4% of new donors were HBcAb positive, 3.5% of them were HBV-DNA positive. We put in our study 20 donors (5 females and 15 males): 17 (4 females, 13 males) HBsAg negative, HBcAb IgG positive, HBV-DNA positive; and 2 (1 female 1 male) HBsAg negative, HBcAb IgG negative, HBcAb IgM negative, HBV-DNA negative; and 1 male HBsAg negative, HBcAb IgG negative, HBV-DNA doubt result. Among 17 HBcAb IgG positive 9 showed Anti s, 2 were anti s negative and 6 not tested for anti s, 3 showed HBeAb. The molecular characterisation of HBV is in progress, the results will be showed at the Congress.

### **CONCLUSIONS**

there is virtually no data on two critical issues relevant to transfusion: 1) what is the infectivity of blood units containing occult HBV-DNA with or without anticore or anti-s outside the window period, 2) what is the significance for the donor of being deferred because of occult HBV in terms of possibility of transmitting the infection. Yet a number of important questions remains unanswered.