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HEPATITIS B IN BLOOD DONORS: RELATION BETWEEN HBV-DNA VIRAL LOAD AND OTHER SEROLOGICAL MARKERS

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Background

Routine HBV-DNA screening of blood donations in our department was introduced in June 2004 to complete the NAT screening. In Piedmont, Italy, NAT screening for HCV of blood donations was mandatory by DGR 28-3449 since 4.11.20

Aim

In this work we evaluated a relation between HBV-DNA viral load and other serological markers

Methods

Chiron technology single-minipool (8 sample size) ULTRIO Procleix Assay is used for NAT screening. PRISM ABBOTT SYSTEM is used for serology screening and for HBsAg Confirmatory Assay. Analytical sensitivity for HBV-DNA: detection limit (D.L.) 95% calculated by Probit Analysis for neat sample was 8,4 UI/ml (fiducial limit 5,85 – 15,25).

Clinical sensitivity for HBV estimated by comparison between ULTRIO, PRISM (Abbott) and AXSYM (Abbott) for HBsAg assay, testing 10 seroconversion panel (Impath BCA) shows precocity of ULTRIO Procleix Assay vs. Abbott PRISM HBsAg: undiluted samples 14 days (fiducial limits 11-19); minipool 11 days (0-17); vs. AXSYM undiluted samples 16 days (10-21) minipool 12 days (0-19).

Between June 2004 and December 2004 45.000 blood units were tested for HBsAg, HCV-Ab, HIV-Ab with Abbott PRISM SYSTEM and for HCV-RNA, HIV-RNA, HBV-DNA with ULTRIO Procleix Technology; 3500 new donors were screened also for HBcAb with AXSYM Abbott.

Results

214 new donors antiHBc positive were found (6,1% of new donors) of which 46 antiHBc isolated positive (1,3% of new donors) and 168 antiHBc positive antiHBs positive (4,8% of new donors) were found. Among 45,000 blood units 11 were HBsAg confirmed positive (0,02%), in this group 9 (82%) were HBV-DNA positive: 8 (89%) from new donors and only 1 (11%) from periodic donor. All the 11 HBsAg positive were antiHBc positive.

5 specimens (4 periodic donors, 1 new donor) were repeat reactive in NAT screening, but not confirmed by discriminatory assay, used to establish if the reactive sample is positive for HCV-RNA, HIV-RNA or HBVDNA. All the 5 samples were antiHBc positive. This suspicious cases are now searched for HBV viral load and DNA sequence.

Conclusions

In our study frequency of HBV-DNA positive in HBsAg reactive blood donors is 82%; frequency of HBV-DNA positive but not confirmed in antiHBc positive is 2,3%. In Italy and in many other countries screening of hepatitis B in blood donors is limited to HBsAg testing, however if anti HBc testing and sensitive HBV nucleic acid amplification testing for routine screening are not prescribed, HBV-DNA viraemia might remain unrecognized. Anti HBc screening detects HBsAg EIA negative, HBV viremic donors at a rate comparable to the estimated residual risk for HBV window period infections . The low viral load in the HBV DNA positive samples suggests that minipool NAT will not detect most potentially infectious units from anti HBc positive donors