OP 16. The utility of combined anti-hepatitis b core antigen and hepatitis b surface antibody testing strategy as first line donation testing and for re-evaluation of previous hepatitis DNA positive/serology negative donors at the South African National Blood Services

Charl Coleman[1]; Diane Buys[1]; Solly Machaba[1]; Wendy Sykes[1]; Marion Vermeulen[1]; Allan Naidoo[1]

[1] - SANBS

Background

The South African National Blood Service (SANBS) tests all donations for Hepatitis B virus (HBV) using Individual Donation Nucleic Acid Testing (ID-NAT) and Hepatitis B Surface antigen (HBsAg). Testing for antibodies to Hepatitis B core antigen (Anti-HBc) is not performed as a first line test as it has been indicated that as much as 70% of the South African population are exposed to Hepatitis B in their lifetime. Currently, Anti-HBc is used as a confirmatory test for HBV DNA+/HBsAg- donations and as a supplementary test for donors who previously tested NAT non repeat reactive or who have history of hepatitis. Anti-HBc+ donations are made available for patient use provided the anti-HBs titre exceeds 100 IU/ml and HBsAg and NAT are negative. Anti-HBc is performed as a first line test in some countries which adds a safety margin by excluding occult hepatitis B donors.

The aim of this study is to determine the rate of anti-HBc+, anti-HBs+ and anti-HBs titre levels in NAT-/HBsAg- donors. In addition, it aims to assess initial HBV NAT+, HBsAg- returning donors and the impact of re-instating such donors who test anti-HBc and anti-HBs only positive (titre >100 IU/ml) on a follow up sample.

Methods

A cross-sectional study of 3446 NAT- (Ultrio Plus, Grifols) /HBsAg- (Prism HBsAg, Abbott) donations for anti-HBc (Cobas, Roche) to determine anti-HBc prevalence. All anti-HBc positive donations with sufficient plasma were tested for anti-HBs titre (Roche Cobas).

Donors who tested HBV DNA+/HBsAg- on their initial donation between 2011 and April 2015 who returned were assessed for NAT, HBsAg, anti-HBc and anti-HBs reactivity.

Results

Of the 3446 HBV DNA-/HBsAg- donors, 322 tested Anti-HBc positive (9.34%). Anti-HBs reactivity was detected in 203/246 (82.5%) of the anti-HBc positive samples. In 165 of the 246 anti-HBc positive donors the anti-HBs titre exceeded 100 IU/ml (67.1%). The prevalence of an anti-HBs titre >100 IU/ml amongst anti-HBs positives in this group was 81.3% (165/203).

Sixty-nine initial HBV DNA+/HBsAg- donors were confirmed on a follow up sample. Of these 35 (50.7%) donors seroconverted to HBsAg. Twenty-three (33.3%) tested HBV DNA and HBsAg negative but anti-HBc positive on follow up. In addition, all 23 were anti-HBs positive and 11 also tested anti-HBc IgM positive. Of the 12 donors that only tested anti-HBc total positive 11 had an anti-HBs titre of >100 IU/ml (average titre 725 IU/ml).

Discussion/Conclusions

In a scenario where first line anti-HBc and anti-HBs universal screening is implemented, an additional 3.08% donations would be discarded resulting in approximately 25000 units per annum. With limitations in the current donor base and constant blood shortage this is probably still not a viable option.

Currently 15.9% of HBV WP donors who return anti-HBc+, anti-HBs >100 with no other reactive results, are being reinstated as blood donors resulting in about 6 donations per annum. This allows for consistent application of the anti-HBc+/anti-HBs >100 IU/ml re-instatement policy.