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ELEVATED ALT IN CHINESE BLOOD DONORS: PREDICTOR OF HCV NAT YIELD CASES OR CAUSE OF UNNECESSARY DONOR DEFERRAL?

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Background

In China blood donors are screened by 2 ALT determinations and 2 tests for the following pathogens: hepatitis B, hepatitis C, human immunodeficiency virus, and syphilis. Donors with elevated ALT or evidence of these pathogens are deferred. Recently we evaluated nucleic acid technology (NAT) screening using the Chiron PROCLEIX® HIV-1/HCV Assay, (Chiron Corp. Emeryville, CA US) as an additional safety measure.

Aims

To evaluate ALT as an HCV screening test by determining the association of elevated ALT with the presence of HCV RNA, resolving the question of whether an elevated ALT result is a good predictor of HCV NAT yield or the frequent cause of unnecessary donor deferral.

Methods

From November 2003 to May 2005, samples from 89,648 units - 87,032 screen negative (non-reactive for pathogens and normal ALT) samples and 2,616 screen positive samples (reactive for one of the aforementioned pathogens and/or elevated ALT)- were collected from centers in Beijing, Hangzhou, Guangzhou, Kunming, and Urumichi. ALT was measured either with Chinese speed rate assays or Reitman assays. Screen positive samples were individually tested and screen negative samples were tested in pools of 16 by the Procleix Assay. Reactive samples were resolved by the Procleix Discriminatory Assay to identify the reactive virus and were retested with an alternative 3rd generation anti-HCV assay and with 2 speed rate ALT assays. NAT yield cases were confirmed with an alternative NAT.

Results

Of 89,648 units tested, 88,056 were screen negative for pathogens; 89,109 (87,032 screen negative + 2077 screen positive) were anti-HCV non-reactive of which 3 were HCV NAT yield cases (0.003%); of these, 1 had normal ALTs on both tests (true normal ALT), 1 was anti-HIV reactive and had elevated ALT on both tests (true elevated ALT), and 1 had normal ALT on preliminary screen and elevated ALT on retest (false normal ALT). Of the 2,616 screen positive specimens, elevated ALT was the only screen abnormality found in 1024 (39.1%). HCV RNA was detected in 34/41(82.9%) of anti- HCV screening positive specimens with elevated ALT and in 148/498(29.7%) of anti- HCV screening positive specimens with normal ALT ($p < 0.001$).

Conclusions

NAT screening should further improve blood safety and eliminate the need for ALT screening. ALT elevation as a basis for donor deferral led to discarding 1024 (1.2%) of 88,056 units that were screen negative for pathogens. However, our data also suggested

that if NAT screening is not available, ALT screening should be continued, as elevated ALT was noted on at least 1 of 2 ALT determinations in 2 of 3 HCV NAT yield cases.