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Hepatitis B and C virus-associated malignant transformation in human liver (viral 'safe haven') produces a cytotoxic antimalignin antibody immune response

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AIMS: Since the detection of hepatocellular carcinoma as a consequence of Hepatitis B and C virus (HB/CV) infection in humans decades earlier has been possible only late in the growth of the malignancy, the aim was to determine if the antimalignin antibody in serum (AMAS) test might permit earlier diagnosis and earlier treatment. METHODS: AMAS determination was performed blind in 1,346 US and Asian individuals interspersed at random whose serum was shipped in dry ice to Oncolab. RESULTS: AMAS is increased in concentration above 134 ug/ml, as early as one to three years after infection, in 34.6% of patients with cirrhosis, in 36.4% with HB/CV hepatitis, and later in 75% with clinical carcinoma, compared to a 'false positive' rate of only 2-4% of U.S. and 8% of Asian healthy controls. The sequences of two epitopes of malignin have been determined by hydrolysis and mass spectrometry, then synthesized. These 12 MER and 16 MER synthetic peptides (CAVAX®) on injection increase by 250% to 700% the concentration of antimalignin antibody which is cytotoxic to transformed cells at picograms (femtomoles)/cell permitting release of virus extracellularly where it is more susceptible to anti-viral compounds. CONCLUSIONS: Since AMAS is not increased in concentration in other viral disorders nor in HB/CV positive but otherwise healthy controls not associated with he2atitis, cirrhosis or malignancy, it is assumed that the increase in antimalignin antibody observed in this study signifies what it did in the previous study of 8,090 individuals, that is, the presence of malignant cells. The determination of the concentration of antimalignin antibody in Hepatitis B/C-positive individuals 1) permits study of the earlier stages of viral carcinogenesis in humans, and 2) can aid in the treatment of earlier stages of malignant transformation in Hepatitis B/C infection. 3) We propose that in virus-transformed cells the virus is not required to leave the cell since cell death is postponed: thus a 'safe haven'.