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Efficacy of Heat Treatment of Factor VIII Concentrate

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Abstract. Two batches of heat-treated factor VIII concentrate were found to contain anti-HIV-positive plasma donations. The batches were dry-heat-treated at 68 °C for 2 and 24 h, respectively. No HIV seroconversions occurred in 13 susceptible haemophiliacs receiving a total of 540 bottles of these factor VIII preparations.

Introduction

The human immunodeficiency virus (HIV) is known to be transmitted in human clotting factor concentrates. Since December 1984 the Scottish National Blood Transfusion Service (SNBTS) has employed a policy of dry heat treatment of lyophilisied factor VIII (FVIII) concentrate. This programme was established before screening of individual blood donations for anti-HIV was introduced. We have retrospectively identified two batches of heat-treated FVIII concentrate which contained anti-HIV-positive plasma donations. The cohort of hemophiliacs transfused with these two batches of FVIII concentrate have been followed up for evidence of HIV infection.

Methods

Anti-HIV antibodies were detected by enzyme immunoassays and confirmed by immunoblotting. Donor screening for anti-HIV began in October 1985 and at subsequent donor sessions a small number of individuals who had donated previously were found to be positive. Their records were examined to identify any blood products to which their earlier donations had contributed. Stored serum samples from previous donations were tested for anti-HIV. Two batches of heat-treated FVIII concentrate, each containing a single HIV seropositive donation, were identified. Batch A was dry-heat-treated at 68 °C for 2 h; batch B was dry-heat-treated at 68 °C for 24 h. Transfusion records were examined to identify all haemophiliacs who received FVIII concentrate from batch A or B. Evidence for HIV infection was sought by testing stored serum samples for anti-HIV. The patients have subsequently been followed up prospectively.

Results

Batch A was infused between December 1984 and February 1985. Ten patients received FVIII from this batch. Four patients were anti-HIV seropositive before treatment and therefore 6 patients were available for evaluation. They had received a mean of 41.3 bottles (range 10–125) of batch A. All 6 have remained HIV-seronegative after 33 months' follow-up. Batch B was infused between December 1985 and February 1986. Thirteen patients received FVIII from this batch. Six patients were anti-HIV-seropositive before receiving batch B; thus 7 patients were available for evaluation. They received a mean of 41.4 bottles (range 20–65) of batch B. All 7 have remained HIV-seronegative after 21 months' follow-up.

Discussion

No new seroconversions have occurred amongst haemophiliacs treated at this centre since heat treatment of FVIII concentrate was initiated by SNBTS in December 1984. By retrospective studies we have identified two batches of FVIII concentrate which each contained an HIV-seropositive donation from individuals later found to be anti-HIV-seropositive. In both cases stored reference serum collected at the time of the donation was anti-HIV-positive, leaving no doubt that both batches had been contaminated with HIV. This study indicates

that the relatively mild heat treatment applied to these batches prevented transmission of HIV infection in this cohort of haemophiliacs. However there is evidence from other centres of seroconversions following transfusion of FVIII concentrate heated by a variety of methods [1–3]. Factors other than the heating conditions such as the viral load within the plasma pool may also contribute to the infectivity. It is likely that each of the plasma pools from which batch A and B were made only contained a single anti-HIV-positive donation, whereas products which have transmitted HIV despite heat treatment may have been derived from plasma more heavily contaminated with HIV. Because of these reports, and to further increase the margin of safety, a more rigorous heating process for SNBTS FVIII concentrate preparations is now used (80°C for 72 h) in the hope of completely eliminating HIV (and possibly also hepatitis) transmission.

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