SNB.008.6696

Abstracts of the 18th Congress of the International Society of Blood Transfusion

Munich, July 22–27, 1984

S. Karger · Basel · München · Paris · London · New York · Tokyo · Sydney

S 5-02

HEPATITIS - A TRANFUSIONISTS VIEW

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In a non remunerated donor system which employs third-generation hepatitis B tests, hepatitis B following transfusion of fresh single donor blood and blood components is extremely rare. Clinically apparent Non A Non B post transfusion hepatitis is also a small problem. Although a few transfused patients develop asymptomatic elevations of liver enzymes, the importance of this remains undefined. Thus for the recipient of blood or single-donor components the benefits of improved donor testing are not quantifiable.

The transfusion centre which supplies plasma for fractionation, and the clinician using large pool plasma fractions, face quite different problems, since present-day coagulation factor concentrates have a very high risk of transmitting NANB hepatitis.

This may be improved by a combination of approaches including: use of small pool alternative products for suitable patients, reduction of number of donors contributing to fractionation pools "dedication" of batches for designated patients, improved fractionation technology, chemical or physical sterilisation or immunological intervention. The potential value and limitation of these approaches will be reviewed.

S 5-03

VIRAL HEPATITIS: IMMUNE PROPHYLAXIS

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Immune prophylaxis of viral hepatitis is possible for Hepatitis A and Hepatitis B but not for Hepatitis non-A, non-B.
Normal Serum Immunoglobulin has been used in the prevention or attenuation of Hepatitis A in the deleloped countries.
For the post-exposure prophylaxis a single intramuscular injection of at least 0.02 ml 16% immunoglobulin per kg bodyweight is recommended. For the pre-exposure prophylaxis -travellers to endemic areas- different amounts and different schedules are recommended with a minimum of 0.02 ml per kg bodyweight. For replacement of the pre-exposure passive immunization in developed countries and for the immunization of the population in endemic areas where sanitation and living conditions are rapidly improving, active immunization with a Hepatitis A vaccine will be preferred in the near future. How far passive-active immunization will be needed in unknown, but can be expected.
For more than 10 years passive immunization with Hepatitis B Immunoglobulin (HBIg) has been started. Although the HBIg (>100 IU/ml) has been standardized almost from the beginning, different schedules and different amounts have been recommended for the pre- and post-exposure prophylaxis dependent on the way of contamination and dependent on the country. These recommendations have to be or have been rewritten after the introduction of the Hepatitis B vaccines especially the pre-exposure prophylaxis. Pre-exposure prophylaxis with HBIg can be replaced by active immunization with vaccines; in case of vaccination failure, e.g. in hemodialysis patients, still the HBIg has to be recommended. In the post-exposure prophylaxis the HBIg is still recommended in combination with active immunization especially in new borns as recently has been shown. Addition of HBIg to pool plasma derivatives, which are potentially infectious is still preferred.

S 5-04

PASTEURISATION OF FACTOR VIII AND FACTOR IX CONCENTRATES

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There is now considerable interest in different heat treatment methods for the inactivation of viral contaminants in coagulation factor concentrates (1,2). Nevertheless, to be suitable, a method should result in both an adequate viral kill and a good product yield so that self-sufficiency can be maintained.

We have used sorbitol and glycine as stabilisers and have found good recoveries of both FVIII and FIX activity after heating in solution at 60°C for 10 hours (3).

In a subsequent study of viral inactivation using a range of model viruses we found that sugar stabilisation reduced the degree of viral heat inactivation compared to a standard albumin solution stabilised with caprylate. For example, heating at 60°C inactivated a challenge of 8.5 logs of vaccinia/ml in 30 minutes using caprylate stabilised albumin, but only 4 logs after 10 hours using sorbitol (or sucrose) stabilisation.

More severe heating conditions have therefore been developed to increase the degree of viral inactivation without major loss of coagulation factor activity. In the presence of 65% sorbitol and 1.7% glycine a FVIII solution, prepared by zinc fractionation (4), was heated at 60°C for 9.5 hours followed by 0.5 hours at 70°C giving a 77% recovery of clotting activity over the heating step with inactivation of at least 7 logs of vaccinia virus/ml. In this process, careful control of pH, ionised calcium concentration and temperature are all important to avoid major loss of FVIII activity. Further viral inactivation may be achieved by adding ethanol to the stabilised FVIII solution.

A FIX concentrate has been pasteurised in a similar manner giving about 60% recovery of clotting activity over the heating step with no increase in thrombogenicity as measured by standard in vitro tests (NAPTT, TgtSO).

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2. G. Dolana et al. Clinical Research 30:A722 (1982)
3. A.J. MacLeod et al. Thromb. Haemostasis 50:432 (1983)
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