Prospective Study of the relationship of HB_sAB test results in Haemophiliacs to the risk of contracting Hepatitis B after transfusion of factor VIII concentrates.

Introduction:- Recent evidence from the study of two outbreaks of Hepatitis B due to certain batches of Hemofil, confirm the previously suspected association of a positive passive HA test for HB_sAB with active immunity to Hepatitis B. The numbers of patients in this study were, however, small, and did not give any information as to what titre in the passive HA test is indicative of relative or absolute immunity. The value of less sensitive methods of testing for HB_sAB also needs to be assessed.

Object of Study:- To assess the value of the regular testing of serial specimens of serum obtained from Haemophiliacs on regular replacement therapy for HB_sAB. The results of these tests will be assessed by studying the incidence of Hepatitis B infection in patients regularly tested for HB_sAB.

Proceedure:- Directors of Haemophilia Centres who agree to participate in this study will be asked to obtain samples of serum from each patient to be included in the study. They should be obtained when the patient attends the Haemophilia Centre for treatment, or when a patient on home treatment attends the Centre for fresh supplies of factor VIII concentrate.

1. Specimens. These should be sent to Dr J. Craske, Public Health Laboratory, Withington Hospital, West Didsbury, Manchester M20 2LR. They should be accompanied by a routine laboratory request form, which should be marked "HB Antibody Study". Patients will thereafter be bled at three monthly intervals, and the repeat specimens sent to Manchester PHL.

It is suggested that this study should run for one year from January 1st 1976 in the first instance. At the end of this time Haemophilia Centres will be asked to complete a record of all factor VIII containing material transfused to each patient in 1976. This can be done at the time of the annual returns to the Oxford Haemophilia Centre, and on the same forms, using the MRC Cryoprecipitate Working Party forms nos 1 and 3. The only difference will be that form 1 will be completed for every patiant included in the study, whether or not he develops hepatitis. If a patient develops hepatitis during the course of this study, the details will be recorded on the MRC Cryoprecipitate Working Party form no 3 in the usual way. This study can be carried out at the same time as the annual return.

Directors will be circularised by letter as was done in the Hemofil Retrospective Survey. Forms returned to Oxford will be sent on to Dr Craske in Manchester, subject to the consent of the Haemophilia Centre Diractor.

2. Further Follow Up. This will be carried out one year after the last blood blood specimen is taken from each patient to see if further cases of Hepatitis B occur. This could be carried out in conjunction eith the 1978 annual return. If it is decided to continue this project for more than one year, then the last follow up will be carried out one year after the last bloood specimens are taken.

3. Selection of Cases. It is hoped that about 70 cases will be included in the study. Cases will be selected by the lacal Haemophilia Centre Diractor so as to include both mild and severe haemophiliacs. Particular attention will be paid to 1. The problem of treating a severe bleed in a mild haemophiliac who has never been previously treated with large pool factor VIII concentrates.

2. The criteria for the use of large pool factor VIII concentrates for home treatment, prophyllactic therapy, and for covering major operations.

Directors wishing to participate in this project should get in touch with Dr craske at Manchester PHL. He will keep a register of all cases involved in this study.

This project is not intended to be an addition to the prospective study already being organised at certain large Haemophilia Centres by Dr Kirk and Dr Craske. It is hoped to interest Centres not taking part in the above project to participate in this study.

Dr J.Craske

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