

3. the decay curve of factor VIII is arbitrarily assumed to be either monophasic or biphasic;
4. in biphasic curves, the time-concentration data points are arbitrarily assigned either to the  $\alpha$  or the  $\beta$  phase of factor VIII kinetics without employing the commonly used techniques for nonlinear least-squares fits.

To better evaluate these problems, appropriate examples based on decay curves reported in the literature are presented and particular emphasis is placed on the extent to which the estimated kinetic parameters are influenced by the use of inappropriate methodology.

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The use of porcine factor VIII (Hyate-C<sup>®</sup>) to treat hemophilia A patients without inhibitors.

High-purity porcine FVIII (Hyate-C<sup>®</sup>) was used to cover essential surgery in 4 patients who had received little or no previous blood products, with the intention of avoiding any exposure to the AIDS-related virus (ARV) and the hepatitis viruses. The patients had no inhibitors to human or porcine FVIII:C. Good levels of FVIII:C activity were maintained during and for about 7 days following surgery, when progressive resistance was noted in all patients. No reactions to the infusions or signs of thrombocytopenia were observed. The acquired anti-porcine FVIII:C inhibitor did not cross-react with the patient's own FVIII:C. There was no clinical, biochemical or serological evidence of ARV or hepatitis virus infection. T helper/T suppressor cell ratios remained unchanged from preinfusion values. Discrepancies between results from one- and two-stage FVIII:C assays were noted and studies on the half-life of the infused material were carried out on 2 patients.

We conclude that porcine FVIII:C is a useful alternative to human FVIII:C concentrate in mild hemophilia A patients who are requiring essential surgery.

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Safety of continuous flow filtration plasmapheresis.

The replacement therapy of hemophiliacs in Italy is largely performed with commercial concentrates from foreign countries. The fractionation of blood is unable to provide enough plasma for manufacturing clotting factor concentrates and albumin. On the other hand, plasmapheresis is rarely done in Italian blood banks.

This study was performed to evaluate the biocompatibility of a new device (Filtral) for plasmapheresis by filtration (PIF) in regard to the donors safety and to assess the quality of plasma collected. In 58 volunteer donors we studied the variation of the following blood parameters immediately before and at the end of PIF and in the collected plasma: blood cells, APTT, PT, factor VIII:C, factor VIII:Ag, factor VIII:WFRCof, factor IX, protein C, fibrinogen, protein electrophoresis,  $\beta$ -thromboglobulin and platelet factor 4. A small increase in hematocrit and hemoglobin was observed at the end of PIF. A decrease in protein concentration, especially albumin, may be due to the coating of the filter's foreign surface. The increase in  $\beta$ -thromboglobulin and platelet factor 4 observed in donors at the end of PIF shows that platelets were aggregated and partially degranulated during blood filtration. On the other hand, the stimulation of platelet aggregation was transient: in a few donors we observed a complete return to normal value 24h after the end of PIF. Factors VIII:C and IX:C were completely unaffected by PIF. Fibrinogen and protein C were decreased at the end of PIF at limits of statistical significance. In the plasma collected a small decrease in total proteins and clotting factors was observed, but the normal VIII:C/VIII:Ag ratio allows any derangement of factor VIII complex to be ruled out. No adverse reactions were observed.

Our findings suggest that PIF membrane procedure is free from hazards and that good quality plasma may be obtained in a very short time.