Autoplex, A New Controlled Activated Prothrombin Complex Concentrate

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120 bleeding episodes were treated with Autoplex®, a new controlled activated prothrombin complex concentrate, in 60 factor-VIII-deficient patients who exhibited elevated factor VIII inhibitor levels.

53 haemarthroses, 26 soft tissue bleeds, and 18 miscellaneous bleeding episodes were treated. Also, 23 surgical procedures were undertaken.

87% of all bleeds had favourable clinical responses, of which 67 were categorized by the investigators as excellent and 37 good clinical responses. 10 (8%) exhibited fair and 5 (4%) no clinical response to Autoplex. One response was unterminable. There were no clinical failures in the 28 open bleeds studied.

The mean total doses (U/kg) administered to patients were as follows: haemarthroses, 66; soft tissue bleeds, 92 U/kg, and open bleeds, 104–1,711.

A low correlation was found between decreases in PTT and PT as a function of dose.

There was no indication of DIC in any of the patients.

Side effects occurred in 36 of 453 infusions (8%). These side effects were mild and transient in nature, ranging from headache (most common, 8) to urticaria.

No anamnestic response was observed with any of the patients in the study.