




Emofilia

# ANAPHYLACTIC REACTION TO RECOMBINANT ACTIVATED FVII IN A MILD HEMOPHILIA A PATIENT WITH INHIBITOR: A CASE REPORT

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**Background.** A small proportion of patients with mild haemophilia A develop factor VIII inhibitors, which can convert a mild disorder into a severe spontaneous bleeding. Intensive perioperative use of factor VIII and some specific mutations induce a particularly high risk for inhibitor development, but risk factors are incompletely understood. Management aims to control the bleeding mainly with by-passing agents and to eradicate the inhibitor when the spontaneous clereance doesn't occur. Emicizumab provides effective prophylaxis in difficult-to-treat mild haemophilia A patients with inhibitor. However, bypassing agents, preferably recombinant activated factor FVII, are required for effective bleed management. No serious adverse events have been described so far with the use of recombinant activated factor VII.

**Case Report.** A 54-years old man affected with mild haemophilia (FVIII level 7%) was referred to our hospital from another center for a prothesic knee surgery due to advance haemohilic artropaty on October 2025. On demand therapy with plasmatic FVIII was maintained until the surgery with very few infusion over the years and no history of inhibitor. The surgery was managed with blous of FVIII immediately before, then with continuous infusion for the first four days and again boulus of plasmatic FVIII for three weeks included rehabilitation period. No inhibitor was detected at discharge from the hospital. After one month, spontaneous muscle haematoma of left thigh happened and the coagulation check showed severe decrease of FVIII (<1%) with high title inhibitor (20 UB) and mild anemia (Hb level of 9 g/l). Recombinant activated FVII (approximately ten infusions) was used to control the bleeding with improvement of it and after one week the patient start prophylaxis with Emicizumab. At the beginning of Genuary 2026 the patient reported a leg trauma with tibial haematoma so two infusions of recombinant FVII was repeted. At the second infusion severe hypotension, desaturation, vomit and transient loss of consciousness occurred and the diagnois of anaphylactic reaction was made. Treatment with intravenously steroid, anthistamin, hydratation and adrenaline was administrated with slow improvement of general condition. Actually patient is maintaing emicizumab treatment, inhibitor is still at high tile (49 UB) and no other bleeding has been developed until now. Activated prothrombic complex concentrate is available in case of bleeding, for a low-dose using. Survellance of inhibitor title is actively maintained and discussion about future management of the case, included immunotholerance is still ongoing.

**Conclusions.** To our knowledge this is the first report of anaphylactic reaction to recombinant FVII. This adverse event rapresents a challenge in the management of a mild hamophilia case with inhibitor due to the limited approach in case of bleeding.