Experience in the treatment of Cuban patients with severe bleeding using recombinant FVIIa.

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Introduction

The development of recombinant factor VIIa concentrate strongly improve the management of hemophilia A and B with inhibitors. Due to its unique effects on the hemostasis system it will be useful for other indications as well, including patients with congenital factor VII deficiency, with bleeding and liver function impairment, with quantitative and qualitative platelet defects, and individuals who have sustained multiple traumas. The efficacy of recombinant activated factor VII (rFVIIa, NovoSeven) in five patients is reported: four with hemophilia A with high-response inhibitors and one with severe hemorrhagic event and anticoagulant therapy.

Presentation of cases

Cases#1,2,3: We present 3 adolescents aged 13-18 years old. They were admitted to the hospital with abdominal pain on the lower sides (right or left)with radiation of pain to the legs.

All of them had previous history of spontaneus iliopsoas muscle hematoma. Historical peaks inhibitor: 52-80 UB/mL

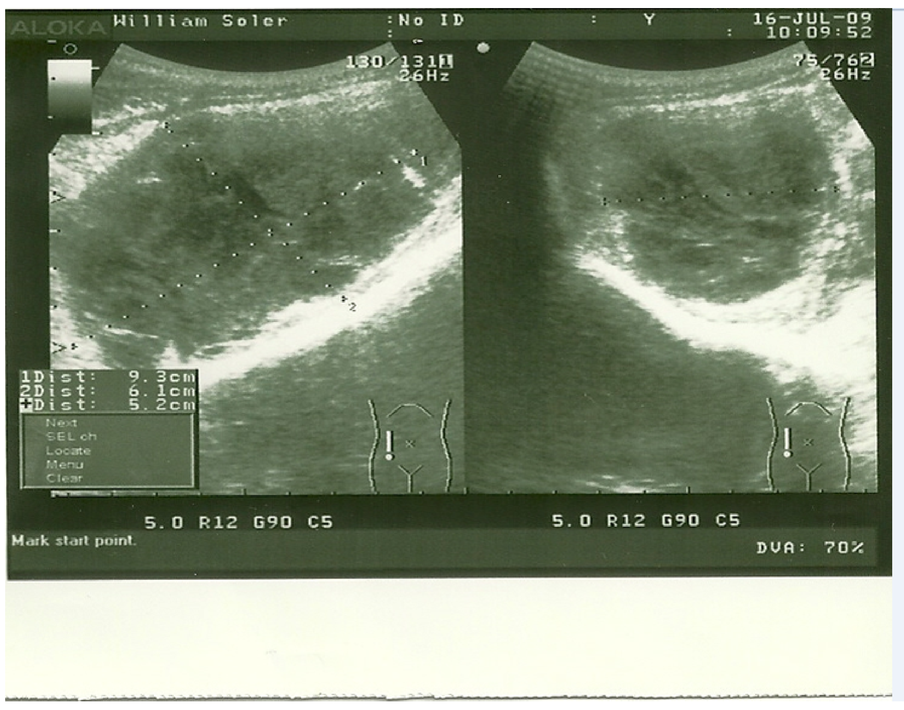
On physical examination they felt iliac fossa pain according to affected sites. First, The patients were treated with rFVIIa (90µg/kg) every three hours for three-five days according to the case, but the hematoma remained as large as ever.

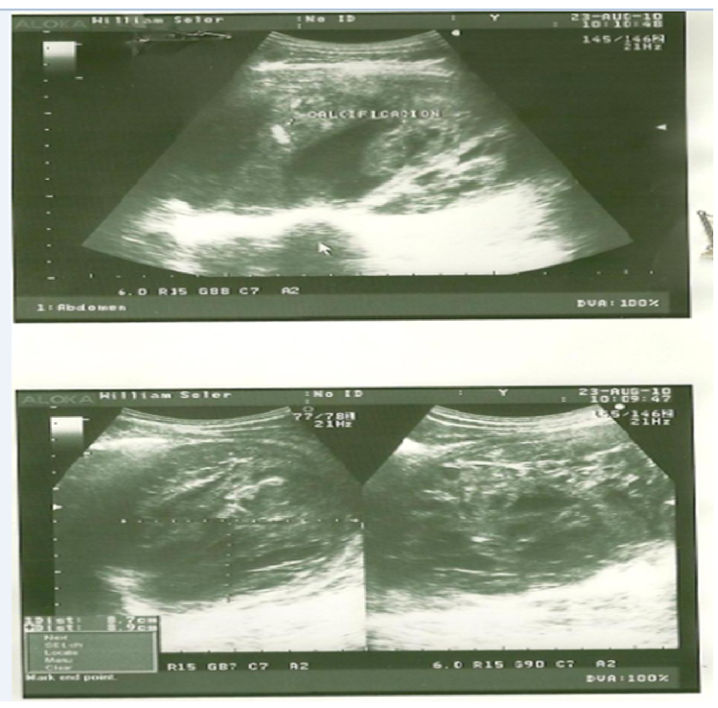
They remained in hospital until the hematoma decreased. After some days all of these patients made physical effort and they presented rebleeding in the same area. Two of them had a decrease in hemoglobin levels and they required transfusion of packed cells

A new therapy with rFVIIa was initiated. They stayed at the hospital for 19-51 days, they were discharged following standard recovery discharge criteria.

Case#4: An adult with moderate hemophlia A. After he made a big physical effort started with lower abdominal pain. He was admitted at the hospital with a large acute iliopsoas muscle hematoma 135x156mm, he had not a previous history of this type of hematoma.

He started with FVIII (100%). After a week of treatment, he began with inhibitors, 15 UB/mL, it continued to increasing and was unable to continue treatment with FVIII, the size of the hematoma was increasing also. He required transfusion of packed cells in the three ocassions treatment with rFVIIa was initiated immediately.He was recovering slowly. Nowadays he had a big fibroid tumor were the hematoma was.





Ultrasound images of the abdomen and pelvis at the emergency department confirmed the diagnosis in all cases.

Case#5: A 46-year-old man with hemoglobinopathy SC presented to the emergency room with spontaneous cutaneous hemorrhages, multiple ecchymoses and upper gastrointestinal bleeding A man presented a deep venous thrombosis of the leg some weeks ago. He had been given anticoagulant treatment . Initially patient had difficulties maintaining adequate anticoagulation . Suddenly he was admitted at the hospital, the patient was given fresh frozen plasma to correct his deranged coagulation profile and warfarin was discontinued.. The patient was managed conservatively with a poor answer. The hemoglobin levels diminish rapidly and he required transfusion of packed cells.

We began treatment with rFVIIa at a standard *dose* of *90 µg/kg* given repeatedly *every* 3 hours for 3 doses. The bleeding stopped and he wad discharged few days after.

Conclusions

- *Hematoma of psoas muscle is an severe frequent bleeding event in patients with hemophilia once again demonstrated that treatment with recombinant factor VIIa in patients with high responders is effective.*
- *The demonstrated safety of rFVIIa in a variety of indications and situations may be provided by the the localization of rFVIIa to the site of injury. This therapeutic is indicated also to revert anticoagulant therapy with excelent response.*

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