Acquired hemophilia.

A rare, spontaneous, and potentially deadly condition¹

• Prolonged bleeding following surgery

aPTT=activated partial thromboplastin time.

• Gastrointestinal, urological, retroperitoneal, or postpartum bleeding

• Purpura and soft-tissue hemorrhage

Signs include:

• Isolated prolonged aPTT²

• Pathology and soft tissue hemorrhage²

• Gastric/rectal, urological, retroperitoneal, or postpartum bleeding²

• Prolonged bleeding following surgery

Associated with severe and life-threatening bleeding

Only 1 to 1.5 per million people are affected yearly

A rare, spontaneous, and potentially deadly condition

dermatologic disorders, and pregnancy; however, in approximately

® RT.

We recommend that the diagnosis

® RT in clinical

to patients with an increased risk of

® RT is administered concomitantly with Coagulation

— Huth-Kühne et al,

® RT and administer appropriate treatment.

thrombosis.

have been reported.

• Monitor patients for signs or symptoms of activation of the coagulation system and for

• Discuss the risks and explain the signs and symptoms of thrombotic and thromboembolic

• Serious arterial and venous thrombotic events following administration of NovoSeven® RT

achieving hemostasis.

bleeding is not controlled after treatment with the recommended doses, antibody formation

coagulant activity (FVII:C). If FVII:C fails to reach the expected level, or PT is not corrected, or

® RT in patients with an increased risk of

® RT is administered concomitantly with Coagulation

® RT.

NovoSeven® RT (Coagulation Factor VIIa [Recombinant]) is a coagulation factor indicated for:

• Treatment of bleeding episodes and peri-operative management in adults and children with

® RT, with or without antibodies to platelets

® RT to patients with an increased risk of

® RT in patients with an increased risk of

® RT is administered concomitantly with Coagulation

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An acquired hemophilia case in which delayed diagnosis put a patient at risk

CASE STUDY

The patient:
A 60-year-old man with GI bleeding.

Initial presentation:
• Patient presented to the emergency department with GI bleeding and no underlying risk factors.
• Baseline coagulation studies showed normal levels of FVIII.

Initial evaluation:
• Local hematologist/oncologist consulted by the emergency department physician.
• APTT was found to be prolonged at 90 seconds. With an immediate 1:1 mixing study, the APTT was decreased to 85 seconds.

The delay:
• A 1:1 aPTT mixing study performed only immediately at the time of results was not sufficient to diagnose acquired hemophilia.
• As the laboratory reports the mixing study results in seconds, not as "corrected" or "not corrected," physicians must appropriately evaluate the study results themselves.

For hematologist/oncology specialists:
• Earlier consult with a hematologist/oncologist or benign hematologist could support earlier diagnosis.
• Failure to properly diagnose acquired hemophilia in this case led to prolonged hospitalization and unsuccessful treatment with large doses of FVIII.

For pharmacists:
• Use of 100,000 units of FVIII over 10 days could have served as a red flag to consider the diagnosis of acquired hemophilia.
• Communication between the pharmacist and health care team could support earlier diagnosis of acquired hemophilia.

For nonspecialist HCPs:
• Acute bleeding in combination with an isolated prolongation of the APTT should prompt an early consult with a hematologist.
• As the laboratory reports the mixing study results in seconds, not as "corrected" or "not corrected," physicians must appropriately evaluate the study results themselves.

Management:
• Patient began treatment with NovoSeven® RT (Coagulation Factor VIIa [Recombinant]) 90 mcg/kg every 2 hours until hemostasis was achieved.
• Patient was discharged from the hospital with oral NovoSeven® RT.

Key takeaway:
Failure to properly diagnose acquired hemophilia in this case led to prolonged hospitalization and unsuccessful treatment with large doses of FVIII.

Important Safety Information (over)

Warnings and Precautions:
• Serious arterial and venous thrombotic events have been reported in clinical trials and postmarketing surveillance.
• The minimum effective dose has not been determined.
• The efficacy of NovoSeven® RT used for first-line versus salvage therapy has not been determined.
• The ICD-9-CM code for acquired hemophilia is 286.529.9

Recommended dosing of NovoSeven® RT (Coagulation Factor VIIa [Recombinant])

| Treatment of acute bleeding episodes | 70 mcg/kg to 90 mcg/kg every 2 to 3 hours until hemostasis is achieved |
| Treatment of prophylaxis for the duration of the surgery | 70 mcg/kg to 90 mcg/kg every 2 to 3 hours until hemostasis is achieved |

Theoretical adverse events within clinical data:
• 4% in patients with acquired hemophilia

Theoretical adverse events within clinical data:
• 4% in patients with acquired hemophilia

Please see accompanying Prescribing Information.

The only bypassing agent FDA approved for acquired hemophilia²

An international consensus recommends the use of NovoSeven® RT as first-line treatment¹

Using NovoSeven® RT first-line improved efficacy²,³

First-line treatment
95% effective

Salvage therapy
80% effective

Approved therapy with established reimbursement codes⁷

For hematology/oncology specialists:
• Failure to properly diagnose acquired hemophilia in this case led to prolonged hospitalization and unsuccessful treatment with large doses of FVIII.
• 1:1 aPTT mixing studies and their appropriate interpretation are critical to the proper diagnosis of acquired hemophilia.
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