Acquired hemophilia strikes without warning
A rare, spontaneous, and potentially deadly condition
- Only 1 to 2.5 per million people are affected annually
- Characterized by an inhibitory antibody to FVIII that appears spontaneously
- 80% of patients experience severe or life-threatening bleeding

Often involving a delayed diagnosis
- 10% of patients experience bleeding 4 to 7 days before diagnosis

Acquired hemophilia is challenging to diagnose

Delays in diagnosis and treatment put patients at risk

Early diagnosis can save lives
- Urgent laboratory diagnosis is recommended when unexplained bleeding with no previous history occurs

Data were collected from the European Acquired Haemophilia (EACH2) registry.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Normal range</th>
<th>Acquired hemophilia</th>
</tr>
</thead>
<tbody>
<tr>
<td>aPTT</td>
<td>25-38 seconds</td>
<td>↑</td>
</tr>
<tr>
<td>PT</td>
<td>11-13 seconds</td>
<td>Normal</td>
</tr>
<tr>
<td>FVIII Func</td>
<td>50-200% activity or 0.1 arbitrary units</td>
<td>↑</td>
</tr>
</tbody>
</table>

APTT is Prothrombin Time, PT is Partial Thromboplastin Time. *Normal range may vary among different laboratories.

Consult a hematologist if results show an isolated, prolonged aPTT, consult a hematologist immediately.

Control the bleed with NovoSeven® RT

Thrombotic events were seen in 4% of patients with acquired hemophilia
- 95% effective as first-line therapy
- Monitor patients for signs or symptoms of activation of the coagulation system and for thrombosis.

Indications and Usage
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 hemophilia A or B with inhibitors, congenital Factor VII (FVII) deficiency, and Glanzmann’s thrombasthenia with refractoriness to platelet transfusions, with or without antibodies to platelets
- Treatment of bleeding episodes and peri-operative management in adults with acquired hemophilia

Important Safety Information
- Serious arterial and venous thrombotic events following administration of NovoSeven® RT have been reported.
- Discuss the risks and explain the signs and symptoms of thrombotic and thromboembolic events to patients who will receive NovoSeven® RT.
- Monitor patients for signs or symptoms of activation of the coagulation system and for thrombosis.

Please see accompanying Prescribing Information.

For more information, please visit Novo Nordisk’s website.

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

**The patient**
- A 17-year-old man with hematuria

**Initial presentation**
- Presented to a physician complaining of hematuria, which had been noted for the past 6 days
- Has been experiencing superficial bleeding for the last 3 weeks
- Medical history of type 2 diabetes and benign prostatic hyperplasia
- Has a previous history of bleeding

**Initial evaluation**
- Physical exam showed palpable renal masses and superficial bleeding on the right thigh and arm
- Coagulation testing was not done
- Patient was admitted for transfusion and further management

**Diagnosis**
- A 1:1 aPTT mixing study after 2 hours of incubation at 37°C showed aPTT was 50.1 seconds
- Repeat aPTT was 82.4 seconds
- Patient was referred to a benign hematologist for follow-up
- FVIII levels were found to be 6%. Patient was diagnosed with mild congenital hemophilia A
- A 1:1 aPTT mixing study after 2 hours of incubation at 37°C showed an aPTT of 76.5 seconds with a normal PT and a normal INR
- Coagulation studies were performed and showed an aPTT of 76.5 seconds with a normal PT and a normal INR
- FVIII levels were found to be 6%. Patient was diagnosed with mild congenital hemophilia A
- Treatment with FVIII infusions was given over 5 days with no clinical improvement

**Management**
- Patient was started on a treatment course for acute bleeding with 70 mcg/kg of NovoSeven® RT every 2 to 3 hours until hemostasis was achieved
- Urine analysis was clear after 4 days
- Patient then began immunosuppressive treatment and continued for 6 months
- Hypersensitivity reactions, including anaphylaxis, have been reported with NovoSeven® RT.
- Administer only if clearly needed in patients with known hypersensitivity to NovoSeven® RT, any of its components, or mouse, hamster, or bovine proteins. Should symptoms occur, discontinue and administer appropriate treatment.
- Exercise caution when administering NovoSeven® RT to patients with an increased risk of thrombotic events.
- Factor VII deficient patients should be monitored for prothrombin time (PT) and factor VII coagulant activity (FVII:C). If FVII:C fails to reach the expected level, or PT is not corrected, or bleeding is not controlled after treatment with the recommended dose, antibody formation may be suspected and analysis for antibodies should be performed.
- Laboratory coagulation parameters (PT/INR, aPTT, FVII:C) have shown no direct correlation to achieving hemostasis.
- Using NovoSeven® RT first-line improved efficacy vs. salvage therapy.
- Treatment with FVIII infusions was given over 5 days with no clinical improvement
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