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Case Report

Prophylactic use of NovoSeven in surgical procedures in a patient with coagulation disorders in the course of abdominal actinomycosis

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ABSTRACT

Introduction: Recombinant activated factor VII (rVIIa – NovoSeven, Novo Nordisk Pharm, Denmark) is commonly used in the treatment of coagulation disorders. At present, numerous studies are being carried out with reference to expanding the indications for this drug, especially in preventing perioperative bleedings in patients at a high risk for bleeding as a result of various coagulation disorders such as hemophilia.

Aim: The aim of this work was to assess the effectiveness of a prophylactic use of rVIIa in patients with complex coagulation disorders before surgery or invasive procedures.

Materials and methods: This paper presents a case report concerning a patient with abdominal actinomycosis hospitalized at the Intensive Care Unit (ICU), who developed peritonitis and severe coagulopathy of a complex etiology and required massive transfusions of blood products. During his 200-day hospitalization, initial treatment comprised invasive procedures without the preventive use of rVIIa; however, later on due to severe bleedings accompanying treatments, NovoSeven was administered as a preoperative prophylaxis. After treatment, blood loss related to invasive procedures and transfusion requirements were assessed and compared to no drug use during the invasive procedures as well as during prophylactic NovoSeven administration.

Results and discussion: Preoperative use of NovoSeven resulted in reducing significant perioperative bleedings; moreover, there was a decrease in the requirement for postoperative blood transfusions.

Conclusions: Supplementation of morphotic blood elements and coagulation factors in the form of fresh frozen plasma and cryoprecipitate frequently does not result in obtaining the desired outcome of clinically effective hemostasis. The additional supply of rVIIa in such cases enables one to control bleeding. Preventive use of NovoSeven seems to be effective in reducing the

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frequency of perioperative bleedings that require blood products transfusions, particularly in patients with complex coagulopathy.

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1. Introduction

Recombinant activated factor VII (rVIIa – NovoSeven, Novo Nordisk Pharm, Denmark) is commonly used in the treatment of coagulation disorders. Originally, it was registered to be applied in congenital hemophilia, acquired hemophilia with inhibitors, factor VII deficiency, Glanzmann's thrombasthenia with antiplatelet antibodies or platelet resistance.^{3,8} Presently, numerous studies are being carried out concerning the "off-label" use of this drug. Thus far, NovoSeven has been proven to be effective in the treatment of bleedings in patients on oral anticoagulation and heparin, in patients with liver diseases and uremia, in patients with massive bleedings triggered by injury or trauma without any pre-existing hemorrhagic diathesis, in the case of intracranial hemorrhage, post-partum bleeding, and as a prophylaxis in emergency surgery in patients treated with acenocoumarol.

NovoSeven has also been studied as a prophylactic measure aimed at reducing blood autotransfusions prior to prostatectomy, hip replacement, liver transplantation as well as in cardiac surgery.^{1,5,6,7,8,9,10} This paper discusses an effective prophylactic use of NovoSeven in a patient with multiple organ dysfunction syndrome (MODS) in abdominal actinomycosis.

2. Aim

The aim of this paper is to evaluate the effectiveness of a prophylactic use of rVIIa in a patient with a complex coagulation disorder prior to surgery and invasive procedures.

3. Materials and methods

A 48-year old patient was admitted to the ICU due to MODS (APACHE II, score – 33, predicted mortality – 87.7%) and septic shock following numerous laparotomies due to peritonitis in the course of actinomycosis. Originally, the patient was operated on due to the perforation of a sigmoid tumor and peritonitis. Histopathological tests of the tumor revealed an *Actinomyces israelii* infection. During his hospitalization, in association with MODS, the patient developed, i.a., significant and treatment-resistant hemorrhagic diathesis, complicated with numerous mucosal bleedings, including respiratory tract bleeding, and numerous hemorrhages into the peritoneal cavity. The patient required several surgical interventions. He underwent repeated large veins and peripheral arterial cannulations; he needed massive fluid resuscitation, including blood product transfusions. In the initial period of treatment, surgical interventions were associated with massive losses of blood due to coexisting coagulation disorders. The patient required supplementation with red blood cell concentrate (RBCC), coagulation factors, and

platelets. Despite massive transfusions of blood products, there occurred clinically significant hemorrhages, necessitating the administration of NovoSeven in therapeutic doses of 90 µg/kg of body weight. The observed hemorrhagic diathesis was of multiple etiologies. It was dominated by: thrombocytopenia resistant to platelet transfusions, disseminated intravascular coagulation when severe bleeding was not observed, plasmatic diathesis associated with coagulopathy due to a depletion and deficiency in the production of coagulation factors as a result of liver failure, and thrombocytopenia associated with uremia.

Initially, NovoSeven was indicated due to the massive loss of blood occurring during invasive procedures as well as because of spontaneous hemorrhages from postoperative wounds, gastrointestinal tract, and respiratory tract – despite the supplementation of coagulation factors, controlling disorders of acid-base balance, ensuring normothermia, and eliminating uremia. During the 2nd month of the treatment, due to the aforementioned, life-threatening bleedings, it was decided to introduce a drug that would prevent them. It was resolved to put the patient on "off-label" treatment with rVIIa as a prophylactic measure before elective surgeries, large veins and arterial cannulations, and bronchoscopy. This drug was administered in a dose of approximately 30 µg/kg of body weight (2.4 mg or 2.0 mg). Once, due to the possibility of directly life-threatening hemorrhage, the dose was increased to 90 µg/kg of body weight (7 mg).

After the completion of the treatment, blood loss associated with invasive procedures and the perioperative volume of transfused blood products (RBCC) were compared concerning the periods with and without NovoSeven prophylaxis.

Initially, the drug was used intraoperatively on 5 occasions as a life-saving measure following hemorrhage; 4 of these surgeries were elective (3 laparotomies, 1 wound revision following laparotomy). During these procedures 25.6 mg of NovoSeven (on average 6.4 mg) were administered. In total, postoperatively within the first 24 h 22 units of RBCC (on average 5.5 units per procedure) were transfused (Table 1).

Table 1 – Procedures with emergency administration of rVIIa – elective.

Procedure	Quantity of administered NovoSeven (mg)	Quantity of transfused RBCC units
Laparotomy – replacement of drains in the peritoneal cavity	9.6	10
Wound revision following laparotomy	6.0	4
Laparotomy – evacuation of interloop abscesses	6.0	4
Laparotomy – evacuation of subphrenic abscess	4.0	4
Total	25.6	22

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