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Case Report
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Effectiveness and Safety of Turoctocog Alfa Pegol (N8-GP) in a Severe Hemophilia a Patient with Multiple Comorbidities

Coluccia A[1] and Schiavoni M[2]*

[1]Department of Internal Medicine, Veris Delli Ponti Hospital-Scorrano-ASL Lecce, Italy

[2]Department of Internal Medicine, Veris Delli Ponti Hospital-Scorrano-ASL Lecce, Italy

Abstract

Life expectancy of individuals with Hemophilia A (HA) is approaching that of the general population. Multiple comorbidities, including cardiovascular disease with the need of invasive diagnostic and therapeutic procedures represent an emerging problem in the community of people with HA.

We present a patient with severe HA and multiple comorbidities, frequent haemorrhagic episodes, and needing chronic antiplatelet treatment. Our case shows that the switch from standard rFVIII to turoctocog alfa pegol allowed to reduce the number of infusions without bleeding episodes, despite the need for invasive cardiovascular procedures and the necessity of chronic antiplatelet therapy, in association to an improvement of the quality of life.

Keywords: Haemophilia A; Aging; Comorbidities; EHL; Turoctocog alfa pegol

Introduction

Prophylactic therapy represents the cornerstone of care for patients with Hemophilia A (HA), to reduce mortality and chronic arthropathy [1-4]. When started early in life, prophylaxis is highly effective in preventing joint damage and life-threatening bleeds (i.e., intracranial hemorrhage) [5-7]. However, prophylaxis regimens requiring 2 to 3 weekly infusions are challenging, being associated with pain and discomfort, daily life limitations, depression, and anxiety [8,9].

In recent years, new recombinant factor VIII (rFVIII) molecules with Extended Plasma Half-Life (EHL) have been developed with the aim of reducing the number of infusions while maintaining higher trough levels of FVIII in plasma [10-13]. One of the approaches to prolong the circulation time while preserving the biological activity is the covalent link of Polyethylene Glycol (PEG) chains to therapeutic proteins. The pharmacokinetic properties of polyethylene-glycolylated FVIII determine increased trough concentrations with fewer yearly injections and reduced treatment burden for most patients as compared to prophylactic regimens with standard half-life products [14].

Thanks to the advancements in the therapeutic approach, life expectancy of individuals with hemophilia is approaching that of the general population. Aging is associated with risk factors such as hypertension, obesity, diabetes, and hypercholesterolemia also in people with hemophilia [15,16]. Consequently, cardiovascular disease represents an emerging problem in the community of people with HA. In this respect, antiplatelet and anticoagulant drugs represent a cornerstone in the management and prevention of arterial and venous thromboembolic events [17]. However, the use of any antithrombotic therapy exposes patients to an increased risk of bleeding, making the balance between thrombosis and hemostasis even more delicate in patients with hemophilia.

In this report, we describe the management and clinical outcomes of a patient with severe HA and multiple comorbidities, frequent hemorrhagic episodes, and needing chronic antiplatelet treatment.

Case Presentation

The patient is a 49-year-old white man with severe HA (baseline FVIII levels < 1%) and no history of inhibitors. His relevant medical history includes overweight (weight 90 kg, height 180 cm, BMI 27.8 kg/m^2), type 2 diabetes, hypertension, and coronary heart disease. The patient is a

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Correspondence:
Antonella Coluccia, Department of Internal Medicine, Hemophilia and Rare Coagulopathies Center Veris Delli Ponti Hospital-Scorrano-ASL Lecce, Italy, E-mail: antonellacoluccia40@gmail.com

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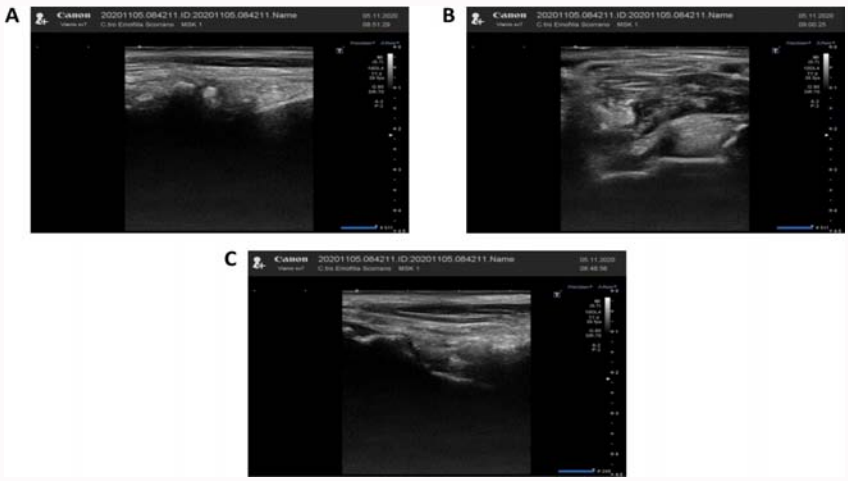

Figure 1: Ultrasound picture of the patient's joint status (A: left ankle; B: Right ankle; C: Left elbow).

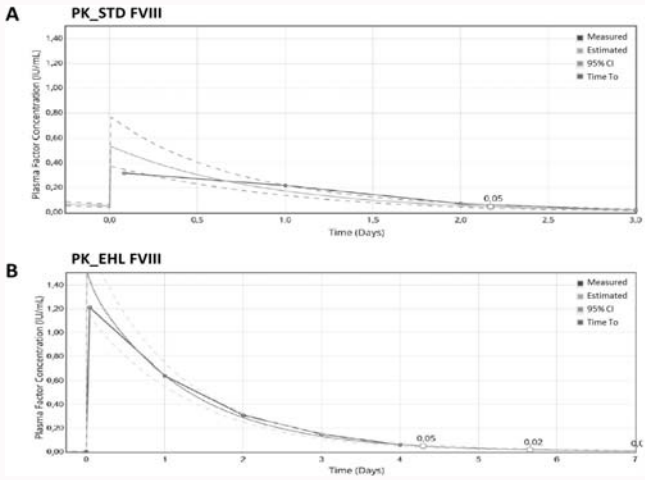

Figure 2: Pharmacokinetic profiles with standard FVIII (A) and turoctocog alfa pegol (B).

past-smoker and is on treatment with metformin, empagliflozin, angiotensin receptor blocker, beta-blocker, and calcium channel blocker.

As for HA medical history, the patient was initially treated with blood/plasma transfusions and subsequently with plasma derived FVIII concentrate 2000 I.U. i.v. "on demand" until 2010. Over the years, he developed hemophilic arthropathy with the following target joints: right and left ankle, left knee, and left elbow. The HEAD US SCORE was 3 for left and right ankle, 2 for left elbow, and 3 for left knee, while the HJHS score was 15. The patient reports occasional use of paracetamol/Cox2 inhibitors. Figure 1 shows the ultrasound picture of the patient's joint status. In 2021, an ABR of 20 was recorded (mainly at the left ankle and left elbow).

In May 2022, the switch to a glycopegylated rFVIII (turoctocog alfa pegol) was proposed, with the aim of reducing the number of infusions, increasing protection, and reducing the number of bleeding episodes. Current prophylaxis regimen consisted of a dosage of 45 IU/kg every 4 days.

Pharmacokinetic (PK) parameters were calculated by the Web Accessible Population Pharmacokinetic Service-Hemophilia (WAPPS-HEMO) online tool before and after the switch from the standard FVIII to turoctocog alfa pegol. PK profiles are shown in the Figure 2. PK analysis revealed differences between standard rFVIII and turoctocog alfa pegol, particularly for in vivo recovery, clearance, half-life, trough level and volume of distribution. The switch from standard FVIII to turoctocog alfa pegol was associated with a reduction in the monthly number of infusions from 12-15 to 7-8.

In August 2022, the patient had an episode of acute pulmonary edema. In November 2022, due to recurrent episodes of angina, he underwent a CT scan for coronary arteries, which documented a critical stenosis of the anterior interventricular branch and a doubtful stenosis of the proximal right coronary artery. On 16 December 2022 he underwent coronary angiography with angioplasty and since that date he has been treated with acetylsalicylic acid 100 mg/daily.

As of April 2024, no bleeding episode is occurred, the patient reports improved quality of life and is undergoing physical/rehabilitative activity (gym 1 day a week).

Discussion

Improvements in medical care have led to a remarkable increase in the life expectancy of patients with bleeding disorders. The growing population of older adults with HA is at risk of age-related comorbidities and needs various elective and emergent age-related procedures. Antithrombotic treatment such as antiplatelet or anticoagulant therapy is frequently needed for several cardiovascular interventions and requires a careful individualized approach.

We present a patient with severe HA and multiple comorbidities, frequent haemorrhagic episodes, and needing chronic antiplatelet treatment. Our case shows that the switch from standard rFVIII to turoctocog alfa pegol allowed to reduce the number of infusions without bleeding episodes, despite the need for invasive diagnostic and therapeutic cardiovascular procedures and the necessity of chronic antiplatelet therapy.

Evidence based guidelines on the management of antithrombotic therapies in ageing patients with hemophilia are lacking, due to the paucity of such patients in clinical trials. This case is an example that these patients, if adequately assessed, treated and monitored, and despite the high risk of bleeding, can have a safe access to the same therapeutic interventions as non-hemophilia patients, according

to the state of the art for cardiovascular disease prevention and treatment.

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