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Real-world utilization, treatment frequency, and bleeding outcomes on damoctocog alfa pegol in hemophilia A care: insights from a German cohort within the CHESS II study

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CONCLUSIONS

- **While limited in sample size, the results suggest damoctocog alfa pegol may reduce patient treatment burden and overall annual treatment utilization in the German real-world setting, while providing improved or equivalent bleeding outcomes.**
- **The different dosing regimens utilized in real-world settings support the need for treatment individualization.**

OBJECTIVE

This analysis examines real-world treatment and utilization patterns of damoctocog alfa pegol in Germany following the CHESS II (Cost of Hemophilia in Europe: a Socioeconomic Survey II) methodology, a European, retrospective, burden-of-illness study.

INTRODUCTION

- Hemophilia A is a rare inherited bleeding disorder caused by mutations in the gene coding for coagulation factor VIII (FVIII).
- The current standard of care for management of severe hemophilia A in Europe involves self-administered prophylactic FVIII replacement therapy, which has substantial treatment burden for the patient.[1]
- Recombinant FVIII (rFVIII) therapies with extended half-lives (EHL) are available, offering reduced frequency of administration and resultant treatment burden vs standard half-life (SHL) rFVIII products. Non-factor therapies are also available.
- Damoctocog alfa pegol (BAY 94-9027, Jivi®, Bayer) is a site-specifically PEGylated, extended half-life, recombinant FVIII product, indicated for prophylaxis and treatment of bleeds in previously treated patients aged ≥12 years with hemophilia A.[2]
- Damoctocog alfa pegol has the potential to provide patients with more flexible dosing regimens and the option for extended dosing intervals maintaining an equivalent factor level trough, however real-world utilization data is scarce.

STUDY DESIGN AND METHODS

Data source

- CHESS II is a retrospective, cross-sectional population-based burden-of-illness study, conducted from 2019–2020 across Europe, carried out by the University of Chester in partnership with UK Haemophilia Society. The survey aimed to quantify the real-world socioeconomic burden of hemophilia. CHESS methodology was previously published.[3]
- Treating physicians provided demographic, clinical, and health care utilization information on hemophilia patients treated in the real-world, including ambulatory and secondary care data with a lookback period of 12 months. Patients were also invited to provide health-related quality of life, and work productivity and activity impairment information.

Study population

- The data analyzed were collected from a subset of CHESS II patients who switched to damoctocog alfa pegol in Germany in 2020. Patients were male, ≥18 years old, diagnosed with inherited non-inhibitor hemophilia A, and were treated prophylactically with damoctocog alfa pegol for at least 3 months in the real-world setting.

Analysis

- Demographic and clinical baseline characteristics were summarized for all patients and stratified by condition severity.
- The primary objective of this analysis was to describe real-world utilization and treatment frequency of damoctocog alfa pegol.
- Secondary objectives included an exploration of IU utilization pre- and post-switch to damoctocog alfa pegol, in relation to bleeding outcomes, as measured by annualized bleeding rate (ABR).

RESULTS

- Thirty-two hemophilia A patients met the inclusion criteria (3 [9%] moderate and 29 [91%] severe), the majority were white (94%) and engaged in full-time employment (72%) (**Table 1**). Mean (SD) time since damoctocog alfa pegol switch was 37.7 (18.9) weeks and 21 (66%) patients were treated with SHL rFVIII prior to switching (**Table 1**).
- Utilization data were available for 30 patients.
  - Post-switch, weekly IU/kg utilization was reduced by 31% overall, 37% for patients previously on SHL products, 13% for patients previously on EHL products and 19% for patients previously on plasma-derived factors (**Table 2**).
  - Annual utilization data are presented in **Figure 1.**
  - Post-switch, infusion frequency and IU utilization reduced in 93% and 83% of patients, respectively. Mean (SD) utilization observed with damoctocog alfa pegol was 3486 (684.2) IU/kg/year (or 67 IU/kg/week) vs 5040 (1,890.8) IU/kg/year (or 97 IU/kg/week) on previous treatment. Mean number of infusions per year reduced from 126.5 (29.64) pre-switch to 67.9 (14.4) per year post-switch.
- Supplemental bleeding data were available in 22 patients.
  - In this sub-cohort, 82% experienced a reduction in ABR, 9% reported an increase, and 9% no change. Reductions in IU utilization and infusion frequency were reported in 91% and 100% of patients, respectively.
  - Mean (SD; median) ABR reduced from 4.6 (4.4; 2.2) to 2.1 (1.8; 1.5) (**Figure 2**) and mean (SD) utilization reduced from 5591 (1920.9) IU/kg/year pre-switch to 3530 (774.9) IU/kg/year post-switch.

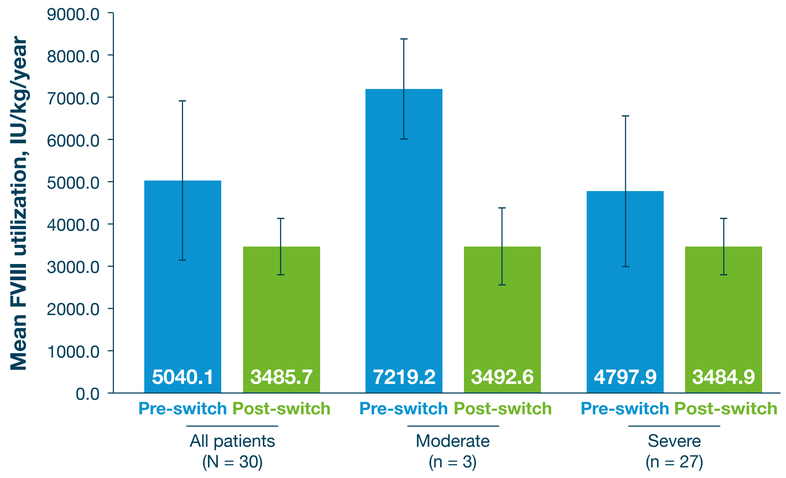
Table 1: PATIENT DEMOGRAPHICS AND CLINICAL CHARACTERISTICS

	All patients (N = 32)	Moderate (n = 3)	Severe (n = 29)
Mean age, years (SD)	24.7 (5.3)	25.3 (4.2)	27.6 (5.4)
Mean weight, kg (SD)	79.2 (7.3)	79.3 (2.1)	79.2 (7.7)
Race/Ethnicity, n (%)			
White/Caucasian	30 (94)	3 (100)	27 (93)
Black/Afro-Caribbean	1 (3)	-	1 (3)
Middle Eastern	1 (3)	-	1 (3)
Education Level, n (%)			
Secondary school	1 (3)	-	1 (3)
High school	4 (13)	-	4 (14)
Vocational training	16 (59)	2 (67)	17 (59)
Bachelor's degree	5 (16)	1 (33)	4 (14)
Master's degree	3 (9)	-	3 (10)
Employment Status, n (%)			
Full-time employed	23 (72)	3 (100)	20 (69)
Part-time employed (<30 hours per week)	2 (6)	-	2 (7)
Self-employed	2 (6)	-	2 (7)
Student	5 (16)	-	5 (17)
Prior FVIII Treatment, n (%)			
Recombinant SHL	21 (66)	2 (67)	19 (66)
Recombinant EHL	6 (19)	1 (33)	5 (17)
Plasma-derived FVIII	5 (16)	-	5 (17)
Target trough levels on previous treatment, n (%)			
Yes	3 (15)	2 (100)	1 (16)
No	17 (85)	-	17 (94)
Mean ABR pre-switch	4.6 (N = 22)	4.3 (n = 3)	4.7 (n = 19)
Damoctocog alfa pegol treatment duration, n (%)			
3–6 months	13 (41)	-	13 (45)
>6 months	19 (59)	3 (100)	16 (55)
Damoctocog alfa pegol infusion frequency per week, n (%)			
Twice a week	2 (6)	1 (33)	1 (3)
Every 5 days	18 (56)	-	18 (62)
Every 7 days	12 (38)	2 (67)	10 (35)
Comorbidities, n (%)			
Angiodysplasia	1 (3)	-	1 (3)
Anxiety	1 (3)	-	1 (3)
Attention deficit (hyperactivity) disorder	1 (3)	-	1 (3)
Depression	3 (9)	1 (33)	2 (7)
Fatigue	3 (9)	-	3 (10)
Gingivitis	1 (3)	-	1 (3)
HIV	-	-	-
Hepatitis B	-	-	-
Hepatitis C	-	-	-
Obesity	2 (6)	-	2 (7)
Osteoarthritis	1 (3)	-	1 (3)
Other	1 (3)	-	1 (3)
Smoking	3 (9)	1 (33)	2 (7)
Type II diabetes mellitus	2 (6)	-	2 (7)
None	16 (50)	1 (33)	15 (52)

Table 2: IU WEEKLY UTILIZATION BEFORE AND AFTER DAMOCTOCOG ALFA PEGOL SWITCH

	Previous Treatment Drug Class			
	All (N = 30)	SHL (n = 19)	EHL (n = 6)	Plasma-derived FVIII (n = 5)
Damoctocog alfa pegol treatment duration, months, mean (SD)	8.9 (4.3)	9.1 (4.4)	10.9 (4.2)	5.9 (2.4)
Previous treatment IU weekly utilization per kg, mean (SD)	96.9 (36.4)	110.2 (37.1)	81.8 (22.4)	64.7 (17.2)
Damoctocog alfa pegol IU weekly utilization per kg, mean (SD)	67.0 (13.2)	69.4 (12.5)	71.4 (10.7)	52.7 (9.9)
Reduction in utilization after switch, mean %	–31	–37	–13	–19

Figure 1: FVIII USE PRE- AND POST-SWITCH TO DAMOCTOCOG ALFA PEGOL



Damactocog alfa pegol annual utilization per kg by infusion frequency, mean (SD; n)

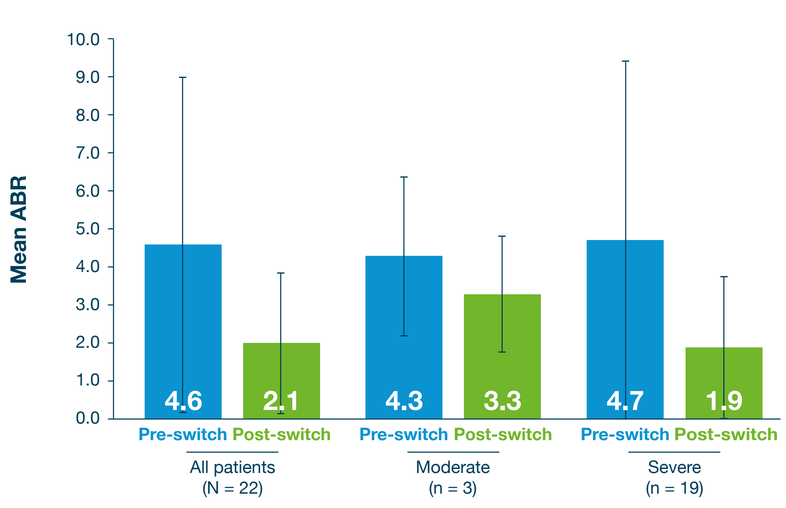
Twice a week	4,297.2 (357.5; 2)	4,550 (-; 1)	4,044.4 (-; 1)
Every 5 days	3,811.0 (509.5; 17)	-	3811.0 (509.5; 17)
Every 7 days	2,835.4 (391.0; 11)	2,963.9 (106.1; 2)	2,806.8 (429.6; 9)

Damactocog alfa pegol weekly utilization per kg by infusion frequency, mean (SD; n)

Twice a week	82.6 (6.9; 2)	87.5 (-; 1)	77.8 (-; 1)
Every 5 days	73.3 (9.8; 17)	-	73.3 (9.8; 17)
Every 7 days	54.5 (7.5; 11)	57 (2.0; 2)	54.0 (8.3; 9)

FVIII, factor VIII.

Figure 2: MEAN ABR PRE- AND POST-SWITCH TO DAMOCTOCOG ALFA PEGOL



ABR, annualized bleeding rate.

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Disclosures: **WZ:** Bayer employee; **EFG:** HCD employee; **JO'H:** HCD employee; **TB:** HCD employee.

References: **1.** Srivastava A *et al. Haemophilia* 2020;26(Suppl 6):1–158. **2.** Jivi EU SmPC. https://www.ema.europa.eu/en/medicines/human/EPAR/jivi. Accessed October 2022. **3.** O'Hara J *et al. Orphanet J Rare Dis* 2017;12:106.

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