PO137

German Clinical Experience of Switching From Octocog Alfa to Damoctocog Alfa Pegol in Patients With Haemophilia A

Natascha Marquardt[1], Georg Goldmann[1], Kerstin Herbst[1], Jennifer Nadal[1], Johannes Oldenburg[1]

[1]Institute of Experimental Haematology and Transfusion Medicine, University Clinic Bonn, Bonn, Germany

CONCLUSIONS

- **Treatment with damoctocog alfa pegol resulted in reduced factor VIII (FVIII) utilisation compared with prior octocog alfa treatment. Total annualised bleeding rates (ABRs) were maintained**
- **This single-centre experience provides real-world evidence supporting the use of damoctocog alfa pegol as an effective alternative therapy for individuals currently receiving octocog alfa**

INTRODUCTION

- Haemophilia A is a rare X-linked genetic disorder characterised by deficiency of coagulation FVIII; individuals with severe haemophilia A have FVIII levels that are less than 1% of that expected in a healthy person[1]
- Untreated haemophilia A can lead to recurrent bleeding episodes causing cumulative damage and arthropathy. This can be managed with prophylactic treatment to reduce bleeding events and subsequent joint damage[1]
- Damoctocog alfa pegol (BAY 94-9027, Jivi®) is an extended half-life FVIII treatment indicated for use in previously treated patients aged ≥12 years with haemophilia A[2]
- We report an intra-patient comparison to evaluate the effectiveness and utilisation of damoctocog alfa pegol vs the standard half-life recombinant FVIII, octocog alfa (BAY 81-8973, Kovaltry®), in a real-world setting[2,3]

METHODS

- This single-centre, observational, intra-patient comparison study was performed using data from the Haemophilia Treatment Centre Bonn, Germany
- Patients with haemophilia A aged ≥12 years were included
- Baseline demographics and clinical characteristics at the time of switch from octocog alfa to damoctocog alfa pegol were reported
- Pre- and post-switch data on ABRs, infusion frequency and utilisation were also collected

RESULTS

Baseline characteristics

- Baseline characteristics at the time of switch are presented in **Table 1**

Table 1: BASELINE DEMOGRAPHICS AND CLINICAL CHARACTERISTICS AT THE TIME OF SWITCH FROM OCTOCOG ALFA TO DAMOCTOCOG ALFA PEGOL

Variable	Patients (N = 46)
Disease severity, n (%)	
Mild	0
Moderate	6 (13)
Severe	40 (87)
Age (years)	
Median (Q1; Q3)	37.0 (29.0; 54.0)
Sex, n (%)	
Male	46 (100)
Female	0
BMI	
Mean (SD)	25.8 (±6.43)
Weight (kg)	
Mean (SD)	82.5 (±24.84)
History of inhibitors, n (%)	
With previous inhibitors	8 (17.3)
High response	6 (13.0)
Low response	2 (4.3)
Without previous inhibitors	38 (82.6)
Number of target joints	
Mean (SD)	0.03 (±0.16)

BMI, body mass index; Q, quartile; SD, standard deviation.

- Overall, 46 patients switched to damoctocog alfa pegol, of whom 40 (87%) had severe disease and 6 (13%) had moderate disease
  - Median (Q1; Q3) age at the time of switch was 37.0 (29.0; 54.0) years
  - Individuals received damoctocog alfa pegol for 12 months

Annualised bleeding rates

- Median (Q1; Q3) spontaneous and joint ABRs both remained at 0 (0; 0)
- Median (Q1; Q3) total and traumatic ABRs were 0.33 (0; 1.00) and 0.28 (0; 0.66) with octocog alfa and 0 (0; 1.00) and 0 (0; 1.00) with damoctocog alfa pegol, respectively
- Further ABR data are presented in **Table 2**

Table 2: MEDIAN ANNUALISED BLEEDING RATES PRE- AND POST-SWITCH†

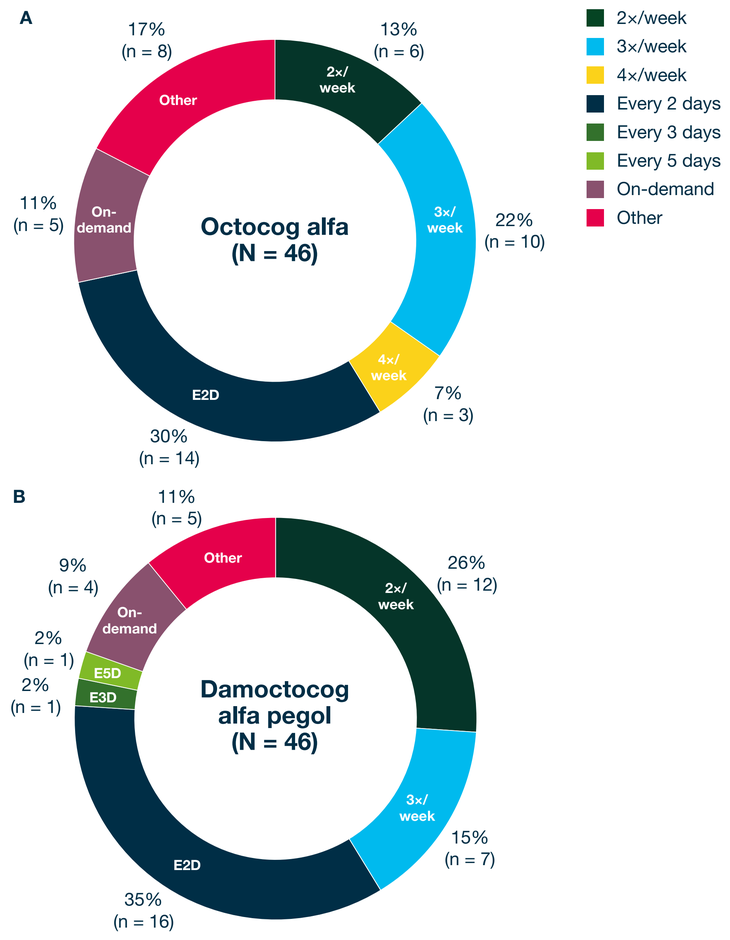
ABR, median (Q1; Q3)	Octocog alfa	Damoctocog alfa pegol	Intra-patient difference
Total ABR	0.33 (0; 1.00)	0 (0; 1.00)	0 (–0.33; 0.01)
Spontaneous ABR	0 (0; 0)	0 (0; 0)	0 (0; 0)
Joint ABR	0 (0; 0)	0 (0; 0)	0 (0; 0)
Non-joint ABR	0 (0; 33.00)	0 (0; 1.00)	0 (0; 0)
Traumatic ABR	0.28 (0; 0.66)	0 (0; 1.00)	0 (–0.33; 0)

†Pre-switch ABR was calculated using data for 3 years of octocog alfa treatment; post-switch ABR was calculated using data from the first year of damoctocog alfa pegol treatment.
ABR, annualised bleeding rate; Q, quartile.

Infusion frequency

- Pre-switch, treatment with octocog alfa was received two times per week (n = 6), three times per week (n = 10), four times per week (n = 3), every 2 days (n = 14) and on demand (n = 5)
- Post-switch, treatment with damoctocog alfa pegol was received two times per week (n = 12), three times per week (n = 7), every 2 days (n = 16), every 3 days (n = 1), every 5 days (n = 1) and on demand (n = 4)
- Infusion frequencies are presented in **Figure 1**

Figure 1: FREQUENCY OF INFUSIONS PRE-SWITCH (A) AND POST-SWITCH (B)



E2/3/5D, every 2/3/5 days.

Dosing

- Mean doses per infusion of octocog alfa and damoctocog alfa pegol were similar across infusion frequencies in patients who remained on continuous prophylaxis, as presented in **Table 3**

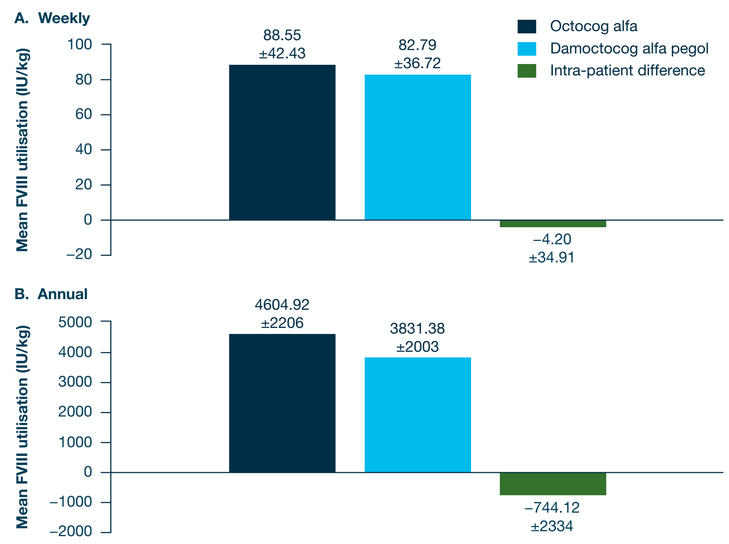
Table 3: MEAN DOSE PER INFUSION (IU/KG) IN PATIENTS ON CONTINUOUS PROPHYLAXIS

Dose per infusion (IU/kg)	Octocog alfa	Damoctocog alfa pegol
2×/week	33.64	34.87
3×/week	24.52	25.10
4×/week	28.02	–
Every 2 days	26.58	27.69
Other	26.12	26.71

Utilisation

- The mean weekly and mean annual doses were numerically lower with damoctocog alfa pegol compared with octocog alfa (**Figure 2**)
- Median (Q1; Q3) weekly and annual utilisation were 80.45 (57.46; 106.42) and 4183.91 (2988; 5534) with octocog alfa and 76.46 (57.14; 100) and 3815.33 (2346; 5069) with damoctocog alfa pegol, respectively
- Overall, patients treated with damoctocog alfa pegol had numerically lower mean numbers of infusions per year compared with those treated with octocog alfa (139 vs 177, respectively) as presented in Figure 2 inset table

Figure 2: WEEKLY (A) AND ANNUAL (B) UTILISATION OF OCTOCOG ALFA AND DAMOCTOCOG ALFA PEGOL



	Octocog alfa	Damoctocog alfa pegol	Intra-patient difference
Mean (SD) infusions/year	177 (±70)	139 (±73)	–34.66 (±79.4)

FVIII, factor VIII; SD, standard deviation.

Safety findings

- There were no safety signals reported in the population analysed
- One individual experienced prolonged bleeding from puncture sites post-switch and was excluded from analysis

Aknowledgements: This study was supported by Bayer. Medical writing assistance was provided by Lianne Holloway, Darwin Health Communications, fully funded by Bayer.

Disclosures: **NM:** speaker/consultant and grant/research support: Bayer, Chugai, CSL Behring, Novo Nordisk, Octapharma, Pfizer, Roche, Shire/Takeda. **GG:** consultant: Bayer, Chugai, CSL Behring, Novo Nordisk, Pfizer, Shire, Sobi. Honoraria: Bayer, Baxalta, CSL Behring, Octapharma, Pfizer, Roche, Shire, Sobi. Scientific advisory board: Bayer, BPL, CSL Behring, Novo Nordisk, Pfizer, Sobi. Travel support: Novo Nordisk, Octapharma, Pfizer, Shire. **KH:** nothing to disclose. **JN:** employee: University Hospital Bonn. **JO:** speaker bureau fee and consultant: Bayer, Biogen, Biomarin, Biotest, CSL Behring, Chugai, Freeline, Grifols, LFB, Novo Nordisk, Octapharma, Pfizer, Roche, Sobi, Sparks, Takeda. Grant/research support: Bayer, Biotest, CSL Behring, Octapharma, Pfizer, Sobi, Takeda.

References: **1.** O'Hara J et al. *Orphanet J Rare Dis* 2021;16:33. **2.** Bayer. JIVI® Summary of product characteristics. Last updated November 2021. Available from: https://www.ema.europa.eu/documents/product-information/jivi-epar-product-information_en.pdf Accessed December 2022. **3.** Bayer. KOVALTRY® Summary of product characteristics. Last updated July 2022. Available from: https://www.ema.europa.eu/documents/product-information/kovaltry-epar-product-information_en.pdf Accessed December 2022.

bit.ly/EAHAD2023Marquardt

This poster was presented at EAHAD 2023, 7–10 February