Real-World Data on Hemophilia A Patient Usage of BAY 94-9027 and BAY 81-8973 Stratified by Adult Age Groups in the ATHNdataset

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CONCLUSION

- These retrospective data reveal a larger percentage of patients with target joints in the older age groups.
- Annualized bleeding rates (ABRs) are generally low for both products and across all three age groups but seem to be lowest in the 40 to <60 age group with Bay 81-8973 and in the ≥60 age group with Bay 94-9027.
- Product regimens trend towards lower frequencies in the oldest age group.
- These data should be interpreted with caution owing to limitations of real-world studies.

OBJECTIVE

- This retrospective dataset analysis aims to evaluate treatment trends and effectiveness with BAY 94-9027 and BAY 81-8973 across 3 different adult age groups of patients with hemophilia A (PWHA) in a real-world setting.

INTRODUCTION

- Damoctocog alfa pegol is a B-domain deleted recombinant Factor VIII (rFVIII), site specifically PEGylated with a 60 kDa (dual-branched) polyethylene glycol to extend its half-life, first approved in the USA in August 2018 for use in previously treated adults and adolescents (aged 12 years or older) with congenital hemophilia A.[1]
- Octocog alfa is an unmodified, full-length, standard half-life rFVIII product approved in March 2016, indicated for prophylaxis and on-demand treatment of bleeding events in adults and children with congenital hemophilia A.[2]
- The ATHNdataset is sponsored by the American Thrombosis and Hemostasis Network, including 15,304 PWHA as of the cutoff date, 11/30/2023.
- Today, most hemophilia A patients experience a similar life expectancy as the general population, thanks to the progress in treatment options. This aging population faces metabolic changes, joint arthropathy and age-related co-morbidities. Little is known how elderly hemophilia patient care should be adapted to their specific needs.[3]

METHODS

- Adult PWHA treated with BAY 94-9027 and BAY 81-8973 in the ATHNdataset, were stratified into 3 age groups, from 20 to <40, 40 to <60 and ≥60 years.
- Data included demographics, bleed rates, treatment frequencies and target joint status.
- Query dates were between January 1, 2010 and November 30, 2023.

Acknowledgments
This analysis was supported by Bayer. Medical writing services were provided by Kushali Patel, PharmD, RPh, an employee of Bayer, in accordance with Good Publication Practices (GPP) 2022.

Data Availability
The data that support the findings of this study originate from the ATHNdataset and are available from the ATHN. Restrictions apply to the availability of these data, which were used under the license for this study. Data inquiries can be made by emailing ATHN at support@athn.org

Disclosures
MC, none to declare. JC, Bayer employee. TS, research funding support to employer from Spark, BioMarin, Pfizer; speakers bureau/honoraria for non-CME from Octapharma, Novo Nordisk, CSL Behring, Genentech, BioMarin, Takeda, Grifols; consultation/advisory board fee Octapharma, Genentech, Novo Nordisk, CSL Behring, Bayer, BioMarin, Takeda, HEMA Biologics, Kedrion, Pfizer; patent holder of Octapharma, Genentech, CSL Behring, Novo Nordisk, Takeda, BPL, BioMarin, Grifols, Pfizer

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RESULTS

TABLE 1: PATIENT DEMOGRAPHICS, DISEASE CHARACTERISTICS, DISEASE HISTORY, AND TREATMENT DURATIONS IN PATIENTS TREATED WITH BAY 94-9027 AND BAY 81-8973

A

BAY 94-9027 (N=264, 100%)	20 to <40 years	40 to < 60 years	≥ 60 years
	Prophylaxis (n=139, 53%)	Prophylaxis (n=50, 19%)	Prophylaxis (n=16, 6%)
Age			
Mean	30.7	48.0	66.9
Median	31.3	48.7	65.7
Weight (kg)			
Mean	84.0	87.0	81.0
Median	81.1	82.8	79.1
BMI			
Mean	27.0	28.0	28.0
Median	25.8	27.0	24.8
Sex, n (%)			
Male	136 (98)	49 (98)	14 (88)
Female	3 (2)	1 (2)	2 (12)
Race, n (%)			
White	114 (82)	39 (78)	14 (88)
Black or African/American	19 (14)	3 (6)	0 (0)
Asian	4 (3)	6 (12)	1 (6)
Mixed Race	1 (0.5)	1 (2)	1 (6)
American Indian or Alaska Native	0 (0)	0 (0)	0 (0)
Unknown	1 (0.5)	1 (2)	0 (0)
Ethnicity, n (%)			
Not Hispanic	110 (80)	40 (80)	14 (88)
Hispanic	27 (20)	10 (20)	2 (12)
Unknown	0 (0)	0 (0)	0 (0)
Disease Severity, n (%)			
Severe	110 (80)	35 (70)	9 (56)
Moderate	20 (14)	8 (16)	3 (19)
Mild	9 (6)	7 (14)	4 (25)
Unknown	0 (0)	0 (0)	0 (0)
Time taking BAY 94-9027, years			
Mean	2.6	2.4	2.0
Median	2.7	1.9	1.1
BAY 94-9027 IU/dose			
Mean	3761.2	3956.4	4082.9
Median	3500.0	3755.0	4000.0
BAY 94-9027 IU/kg			
Mean	45.6	46.0	49.0
Median	45.0	44.9	46.1
History of Infection, n (%)			
HBV	4 (3)	5 (10)	4 (25)
HCV	15 (11)	35 (70)	9 (56)
HIV	0 (0)	19 (38)	5 (31)
History of FVIII inhibitor, n (%)			
Yes	24 (17)	3 (6)	1 (6)
No	115 (83)	47 (94)	15 (94)
Patients with target joints, n (%)	6 (4)	7 (14)	1 (6)
Target joints prior taking BAY 94-9027, n	6	11	0
Target joints while taking BAY 94-9027, n	0	1	0
Target joints after stopping BAY 94-9027, n	1	0	0
Unknown, n	0	0	8

B

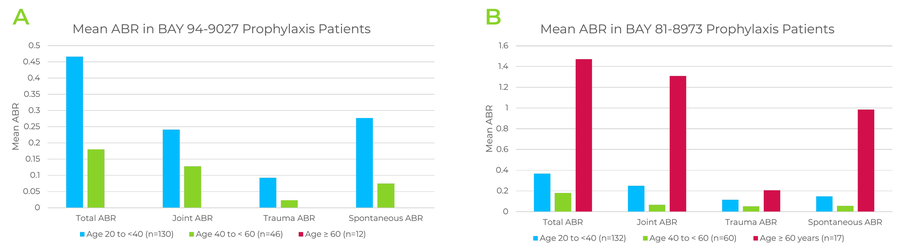
BAY 81-8973 (N=550, 100%)	20 to <40 years	40 to < 60 years	≥ 60 years
	Prophylaxis (n=148, 27%)	Prophylaxis (n=62, 11%)	Prophylaxis (n=21, 4%)
Age			
Mean	29.7	47.4	65.7
Median	29.7	45.9	64.6
Weight (kg)			
Mean	92.9	89.9	88.8
Median	89.0	87.0	86.0
BMI			
Mean	29.9	29.0	29.1
Median	28.0	28.0	29.0
Sex, n (%)			
Male	140 (95)	59 (95)	20 (95)
Female	8 (5)	3 (5)	1 (5)
Race, n (%)			
White	106 (72)	49 (79)	14 (67)
Black or African/American	27 (18)	7 (11)	6 (29)
Asian	7 (5)	4 (6)	0 (0)
Mixed Race	2 (1)	1 (2)	1 (4)
American Indian or Alaska Native	3 (1.5)	0 (0)	0 (0)
Native Hawaiian or Other Pacific Islander	1 (0.5)	0 (0)	0 (0)
Unknown	2 (1)	1 (2)	0 (0)
Ethnicity, n (%)			
Not Hispanic	117 (79)	55 (89)	20 (96)
Hispanic	30 (10)	7 (11)	1 (4)
Unknown	1 (1)	0 (0)	0 (0)
Disease Severity, n (%)			
Severe	114 (77)	41 (66)	13 (62)
Moderate	16 (11)	11 (18)	6 (29)
Mild	18 (12)	10 (16)	2 (9)
Unknown	0 (0)	0 (0)	0 (0)
Time taking BAY 81-8973, years			
Mean	3.4	3.2	2.1
Median	2.5	2.6	1.1
BAY 81-8973 IU/dose			
Mean	3321.0	3528	3445.0
Median	3000.0	3125	3000.0
BAY 81-8973 IU/kg			
Mean	37.0	40.0	39.0
Median	35.0	40.0	40.0
History of Infection, n (%)			
HBV	1 (1)	9 (15)	3 (14)
HCV	19 (13)	42 (68)	17 (81)
HIV	2 (2)	17 (27)	13 (62)
History of FVIII inhibitor, n (%)			
Yes	19 (13)	6 (10)	1 (5)
No	129 (87)	56 (90)	20 (95)
Patients with target joints, n (%)	6 (4)	2 (3)	4 (20)
Target joints prior taking BAY 81-8973, n	5	4	9
Target joints while taking BAY 81-8973, n	0	0	2
Target joints after stopping BAY 81-8973, n	0	0	1
Unknown, n	1	0	0

At data cut-off, 205 (78%) PWHA were treated prophylactically and 58 (22%) episodically with BAY 94-9027, while 231 (42%) were treated prophylactically and 318 (58%) episodically with BAY 81-8973, all being at least 20 years old. **(Table 1)**

- The youngest age group of 20 to <40 years contained 139 (53%) PWHA using BAY 94-9027 prophylactically, while there were 50 (19%) in the 40 to <60 and 16 (6%) in the ≥60 years group.
- Over 55% of patients in all age groups had severe disease. Viral infections were most common in the ≥40-year-olds and target joints were noted highest in the 40 to <60 years group (14%). **(Table 1A)**

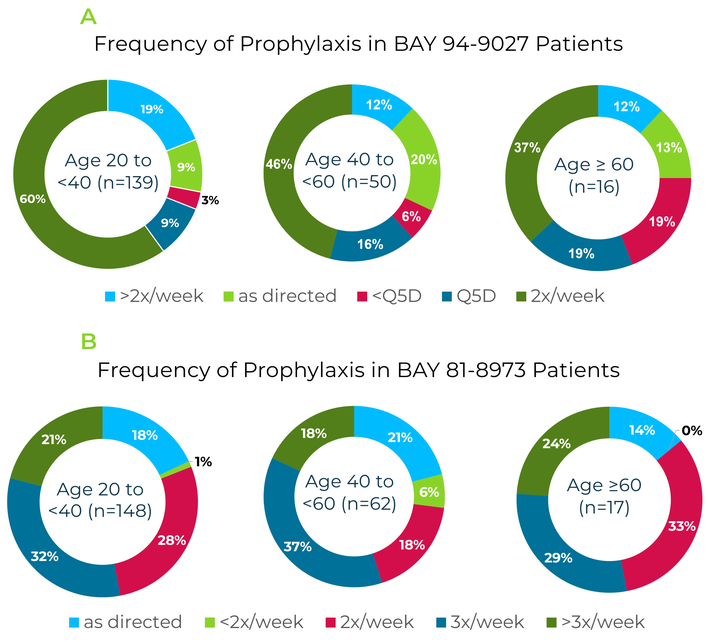
- The youngest age group of 20 to <40 years comprised 148 (27%) PWHA using BAY 81-8973 prophylactically, while there were 62 (11%) in the 40 to <60 and 21 (4%) in the ≥60 years group.
- Over 60% of patients in all age groups had severe disease. Viral infections were most common in the ≥60 years age group and 20% of these had target joints. **(Table 1B)**

FIGURE 1: MEAN ANNUALIZED BLEEDING RATES IN PATIENTS TREATED WITH BAY 94-9027 AND BAY 81-8973



- Highest total ABR of 0.47 was observed in the 20 to <40 years group, followed by 0.18 in the 40 to <60 and 0.00 in the ≥60 age groups. **(Figure 1A)**
- Highest total ABR of 1.48 was observed in the ≥60 years group, followed by 0.38 in the 20 to <40 and 0.18 in the 40 to <60 age groups. **(Figure 1B)**

FIGURE 2: FREQUENCY OF PROPHYLAXIS REGIMENS IN PATIENTS TREATED WITH BAY 94-9027 AND BAY 81-8973



- A ≤Q5D BAY 94-9027 regimen was mostly used by the oldest age group (38%), while the 20 to <40 age group had the highest usage of a ≥2x/week regimen at 79%. **(Figure 2A)**
- A ≤2x/week BAY 81-8973 regimen was mostly used by the oldest age group (33%), while the 40 to <60 age group saw the highest usage of a ≥3x/week regimen at 55%. **(Figure 2B)**

Poster presented at the HTRS congress, Coronado, CA, USA, March 13-15, 2025