

Patient-reported outcomes for patients treated with peginterferon beta-1a: Plegridy Observational Program interim analysis

OBJECTIVE

To describe the impact of peginterferon beta-1a on patient-reported outcomes (PROs) for patients with relapsing forms of multiple sclerosis (RMS) enrolled in the Plegridy Observational Program (POP).

CONCLUSIONS

- Over 5 years, PROs remained stable for newly diagnosed and non-newly diagnosed patients with RMS treated with peginterferon beta-1a in POP, as shown by numerical decreases in the proportions of patients with “extreme problems” and by increases in overall health status.
- Interpretation of these results is limited by the decrease in patient numbers from baseline to 5 years.
- However, these long-term results are consistent with a previously published comparison of peginterferon beta-1a clinical effectiveness over a period of up to 6 years in newly diagnosed and non-newly diagnosed patients.¹
- These results indicate that peginterferon beta-1a can provide improvements in outcomes that are important for both newly diagnosed and non-newly diagnosed patients with RMS.



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Introduction

- Assessment of PROs is important for monitoring patients receiving disease-modifying therapies (DMTs) for multiple sclerosis (MS).
 - These outcomes are useful for understanding the impact of MS care on outcomes that matter most to people with MS.²
- POP (NCT02230969) explores the real-world safety and effectiveness of peginterferon beta-1a, providing an opportunity to collect patient-centric outcome information.
 - POP is fully enrolled and ongoing in approximately 130 sites across 14 countries.

Methods

- Data reflect the fifth interim data cut as of February 2021.
- Newly diagnosed and non-newly diagnosed patients were defined as previously described.^{1,3}
 - Newly diagnosed were defined as those diagnosed with RMS ≤1 year prior to consent and no prior DMT treatment.
 - Non-newly diagnosed patients were defined as those diagnosed >1 year prior to study consent and/or with prior DMT treatment.
- PROs were assessed using the 3-Level European Quality of Life (Euro-QoL) 5-Dimension (EQ-5D-3L) Health Questionnaire, which includes 5 dimensions (mobility, self-care, usual activities, pain/discomfort, anxiety/depression), with 3 levels per dimension (no problems, some problems, and extreme problems).⁴
- Current overall health status was rated using a calibrated visual analog scale (Euro-QoL Visual Analog Scale [EQ-VAS]), with 0=worst and 100=best.

Results

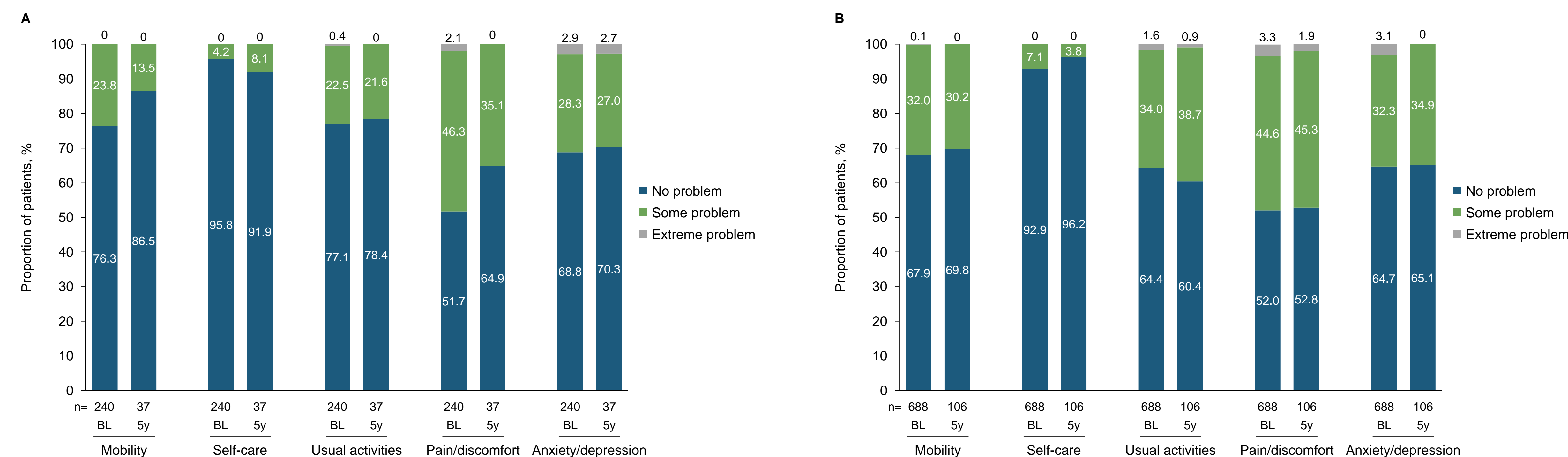
- The effectiveness analysis population included 1168 patients, of whom 292 (25.0%) were newly diagnosed and 876 (75.0%) were non-newly diagnosed.
- Baseline demographic and disease characteristics were similar, although newly diagnosed patients had a shorter mean (standard deviation [SD]) time since MS symptom onset in comparison with non-newly diagnosed patients (4.2 [6.45] vs 12.7 [8.87] years) and more mean (SD) relapses in the 12 months prior to enrollment (0.9 [0.66] vs 0.3 [0.64]) (Table 1).
 - After 5 years of treatment, proportions of newly diagnosed and non-newly diagnosed patients reporting “no problem” were 86.5% and 69.8% for mobility, 91.9% and 96.2% for self-care, 78.4% and 60.4% for usual activities, 64.9% and 52.8% for pain/discomfort, and 70.3% and 65.1% for anxiety/depression, respectively.
- At baseline, among patients who completed the EQ-5D-3L, 5.4% (13 of 240) of newly diagnosed and 8.1% (56 of 688) of non-newly diagnosed patients reported “extreme problems” for ≥1 dimension, with those proportions decreasing to 2.7% (1 of 37) and 2.8% (3 of 106), respectively, at year 5 (Figure 1A, 1B).
 - At year 5, mean (SD) EQ-VAS scores had increased in both groups (newly diagnosed 81.9 [10.72]; non-newly diagnosed 79.4 [16.61]; $P=0.9353$).
- At baseline, overall health status, assessed by mean (SD) EQ-VAS score, was similar for the newly diagnosed and non-newly diagnosed groups (77.9 [17.71] vs 77.4 [16.72]; $P=0.4181$) (Figure 2).
 - At year 5, mean (SD) EQ-VAS scores had increased in both groups (newly diagnosed 81.9 [10.72]; non-newly diagnosed 79.4 [16.61]; $P=0.9353$).

Table 1. Baseline demographic and disease characteristics by newly diagnosed patient status (effectiveness analysis population)

Characteristic	Newly diagnosed (n=292)	Non-newly diagnosed (n=876)	Overall (N=1168)
Age at enrollment, mean (SD), years	37.9 (11.66)	45.9 (12.08)	43.9 (12.47)
Sex, n (%)			
Female	219 (75.0)	667 (76.1)	886 (75.9)
Male	73 (25.0)	209 (23.9)	282 (24.1)
Race, n (%)			
Asian	0	2 (0.2)	2 (0.2)
Black or African American	8 (2.7)	36 (4.1)	44 (3.8)
Native Hawaiian or Other Pacific Islander	0	1 (0.1)	1 (0.1)
White	46 (15.8)	329 (37.6)	375 (32.1)
Other	5 (1.7)	5 (0.6)	10 (0.9)
Not reported ^a	233 (79.8)	503 (57.4)	736 (63.0)
Geographic region			
Pacific	4 (1.4)	20 (2.3)	24 (2.1)
North America	60 (20.5)	376 (42.9)	436 (37.3)
Europe	228 (78.1)	480 (54.8)	708 (60.6)
Age at MS diagnosis, mean (SD), years ^b	36.6 (11.02)	36.1 (10.18)	36.2 (10.39)
Years since MS symptoms, mean (SD) ^c	4.2 (6.45)	12.7 (8.87)	10.6 (9.12)
Relapses in the prior 12 months, mean (SD)	0.9 (0.66)	0.3 (0.64)	0.5 (0.70)
EDSS score, mean (SD) ^d	1.4 (1.08)	1.9 (1.54)	1.8 (1.44)

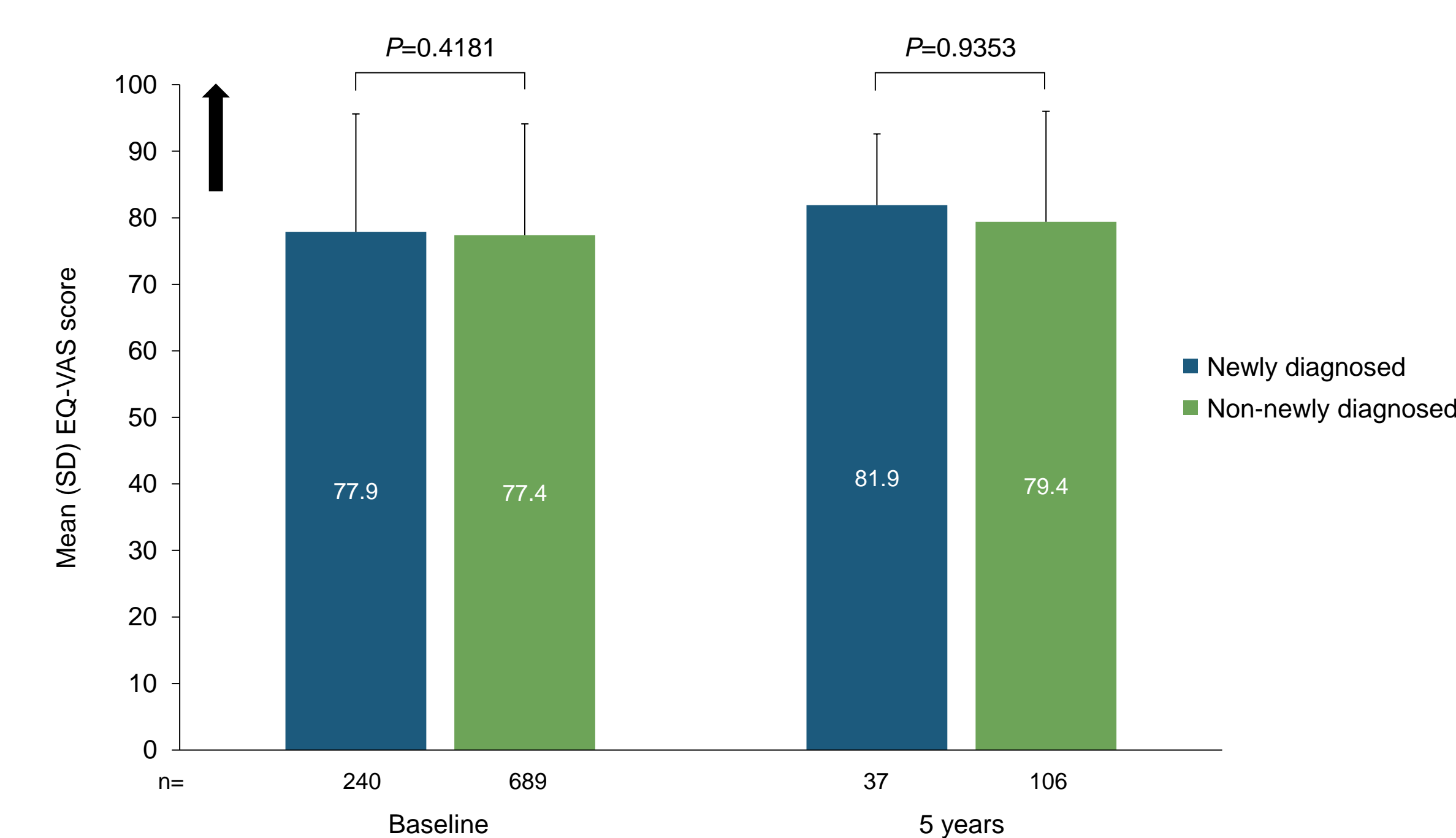
EDSS, Expanded Disability Status Scale. ^aNot reported because of confidentiality reasons; ^bData available for 874 non-newly diagnosed patients; ^cData available for 291 newly diagnosed and 866 non-newly diagnosed patients; ^dData available for 121 newly diagnosed and 299 non-newly diagnosed patients.

Figure 1. EQ-5D-3L Health Questionnaire responses at baseline and after 5 years of treatment for (A) newly diagnosed patients and (B) non-newly diagnosed patients (effectiveness analysis populations)



5y=5 years; BL=baseline.

Figure 2. EQ-VAS scores by newly diagnosed patient status at baseline and after 5 years of treatment (effectiveness analysis population)



Arrow indicates direction of improvement in EQ-VAS score. P values for the difference between newly diagnosed and non-newly diagnosed patients are based on Wilcoxon rank sum test.