PEG-IFN BETA-1A PRE-FILLED PEN (PLEGRIDY®) IMPROVES SATISFACTION IN PATIENTS WITH RELAPSING-REMITTING MULTIPLE SCLEROSIS WHO WERE DISSATISFIED WITH OTHER SUBCUTANEOUS INTERFERONS

PLATINUM STUDY

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Conclusions

This study suggests that, in RRMS patients unsatisfied with interferons other than Peg-IFN beta-1a, it may represent a treatment choice able to improve patient's satisfaction, quality of life and adherence, maintaining a comparable clinical efficacy.

Introduction

- Subcutaneous (SC) interferons beta (IFN-beta) are effective therapies for the treatment of relapsing-remitting multiple sclerosis (RRMS). Factors such as dosing schedule, needle intolerance and side effects may impact patient satisfaction with treatment. Improvement of patient satisfaction may increase the adherence to treatment and the patients' quality of life.
- The Platinum study was aimed at evaluating the impact of switching to Peg-IFN beta-1a (125 µg SC every two weeks) from other injectable subcutaneous interferon therapies, on treatment satisfaction, adherence and other patients reported outcomes (PROs) in an Italian real-world setting.

Objectives

- The primary objective was to investigate whether Peg-IFN beta-1a improves the satisfaction of RRMS patients unsatisfied with injectable subcutaneous Interferons, as measured by the Abbreviated Treatment Satisfaction Questionnaire to Medication (TSQM-9), at 12 weeks post initiation of Peg-IFN beta-1a.
- The secondary objectives were to evaluate the impact of Peg-IFN beta-1a treatment on patients' satisfaction at 24 weeks; on short-term patients' adherence; on patient's fatigue, on disease activity and physical disability as well as patient-reported health related quality of life.

Methods

Study Design and Patients

- The multicentre, open-label, phase IV PLATINUM study, was conducted in 32 Italian centres. Eligible patients were RRMS according to 2010 McDonald criteria, between 18 and 65 years, with Expanded Disability Status Scale (EDSS) score between 0.0 and 5.0 and treatment with injectable subcutaneous Interferons with score <58 in the "convenience satisfaction" domain of abbreviated TSQM. Exclusion criteria were pregnancy or breast-feeding, depression or other psychiatric disorders and any contra-indications to treatment with Peg-IFN beta-1a.

Endpoints and Outcome Measures

- The primary endpoint was changes from baseline in the score of convenience satisfaction domain of TSQM-9 questionnaire at 12 weeks.
- Secondary endpoints included changes from baseline to Week 24 on the following PRO scales: patients' adherence assessment, adapted Multiple Sclerosis Treatment Concerns Questionnaire (MSTCQ), Multiple Sclerosis International Quality of Life questionnaire (MusiQoL) and Fatigue Severity Scale (FSS).

Statistical Analysis

- Descriptive statistics of baseline, Week 12 and Week 24 values, of all the collected variables as well as the relevant changes from baseline were presented as mean, and standard deviations, along with median values and ranges. A generalized linear mixed model for repeated measurements was used to evaluate the relationship between changes in patient's total score, social-demographic factors (age, sex) and clinical characteristics (ARR, EDSS, time since MS diagnosis, treatment duration). All analyses were performed on the Full Analysis Set (FAS) consisting of all enrolled patients who took at least one dose of the study medication. The ANOVA for repeated measures was performed to compare the changes from baseline at 12 and 24 weeks in Global Index and FSS.

Results

- 193 patients were enrolled and 166 (86%) completed the study, receiving Peg-IFN beta-1a for 24 weeks.
- Patients switching to Peg-IFN beta-1a from other SC interferons reported a significant improvement ($p<0.001$) of Convenience Score and all other scores of TSQM-9 questionnaire at 12 and 24 weeks ($p< 0.001$; Fig 1).
- Adapted Sclerosis Treatment Concerns Questionnaire MSTCQ score was also significantly improved from baseline to each visit ($p<0.01$; Fig 2).
- MusiQoL total scores showed statistically significant increases from baseline to week 12 and week 24 ($p<0.001$).The effect of the time (visits) on the changes of Global Index was also statistically significant ($p<0.01$; Fig 3).
- Peg-IFN beta-1a attained very high adherence to the treatment (93.8% at 24 weeks) with a stable annualized relapse rate (ARR). Adverse events (AE), recorded on 82 patients (42%), were mild or moderate. The most common AE was flu-like syndrome (29.2%).
- AEs leading to discontinuation were reported for 15 patients (7.8%).

Figure 1 - Improvement in overall TSQM scores from baseline

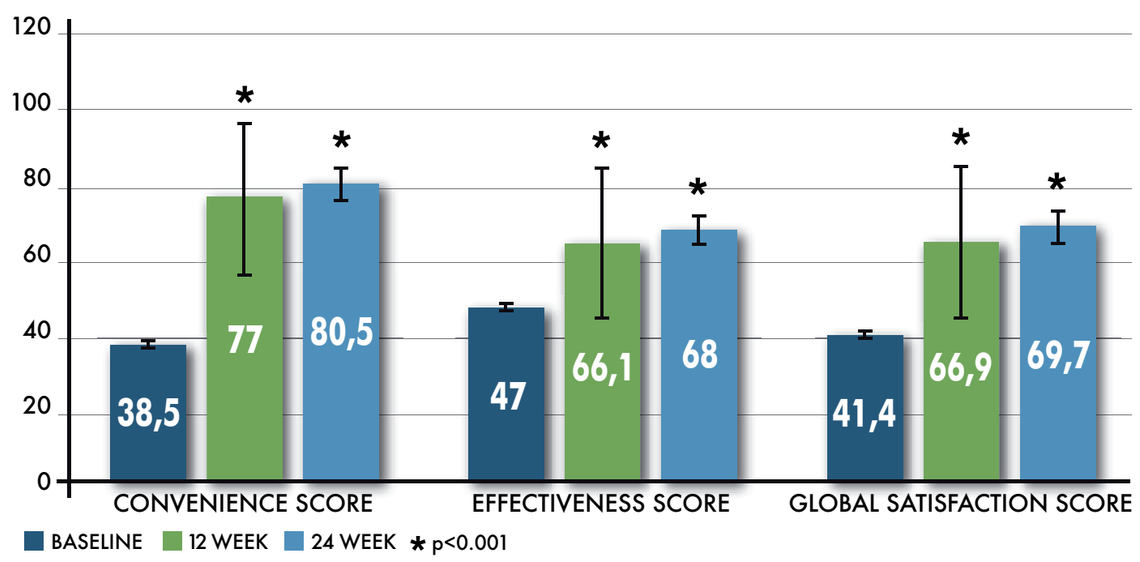


Figure 2 - Mean (± SD) total score in MSTCQ from baseline

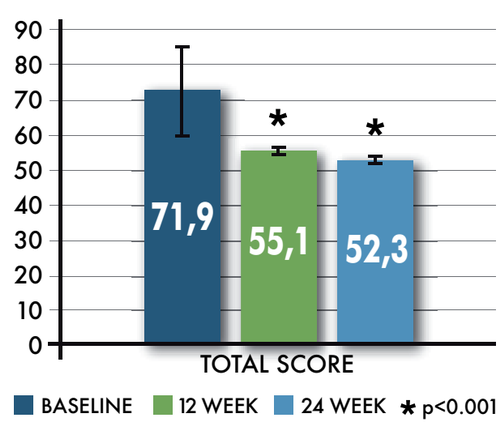
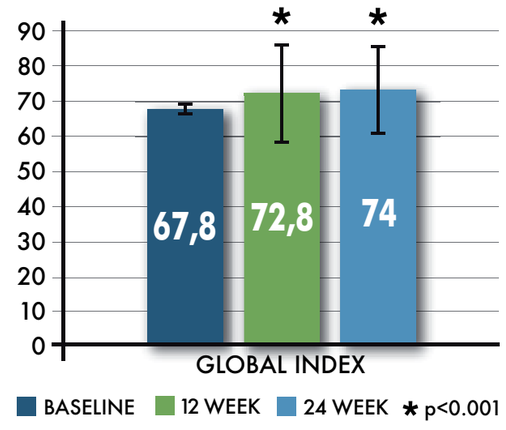


Figure 3 - Mean (± SD) Global index related to MusiQol



Keywords: Peg-IFN beta-1a, multiple sclerosis, adverse event, adherence, treatment satisfaction

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Disclosures

- DC: Advisory Board for Bayer Schering, Biogen, Merck-Serono, Teva and honoraria from Almirall, Bayer Schering, Biogen, Genzyme, GW Pharmaceuticals, Merck Serono, Novartis, Sanofi-Aventis, Teva. Principal investigator for Bayer Schering, Biogen, Novartis, Merck Serono, Sanofi-Aventis, Teva.
- FB and RF: honoraria from Almirall, Merck, Novartis, Sanofi, Teva and Biogen and advisory boards for Teva, Biogen, Merck and Novartis.
- LMEG: travel grants to attend scientific events or speaker honoraria from Merck Serono, Biogen Idec, Sanofi-Aventis, Teva Pharmaceutical Industries Ltd., Roche, Novartis and Bayer Schering Pharma; institutional research support from Biogen Idec and Serono Foundation.
- RT: advisory boards and honoraria from Biogen Idec, Merck-Serono, Novartis, Roche, Sanofi-Genzyme and Teva. Principal investigator for Biogen, Merck Serono, Novartis, Roche, Sanofi Genzyme, and Teva.
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