Abstract No 79.

Evaluation of the Effect of Seasonal Weather Variations on Adherence and Effectiveness of Subcutaneous Interferon β-1a Administered by Rebismart® in Patients with Relapsing Multiple Sclerosis: Final Results of the 1-Year, Observational GEPAT-SMART Study

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INTRODUCTION

- Flu-like syndrome and injection site reactions have been associated with poor adherence to interferons. However, little is known about whether tolerability and adherence to treatment can be influenced by the weather.

OBJECTIVES

- To assess the impact of seasonal weather variations on adherence to subcutaneous interferon beta-1a (scIFNβ-1a) treatment in relapsing-remitting multiple sclerosis (RRMS) patients using the RebiSmart® autoinjector over one year.

METHODS

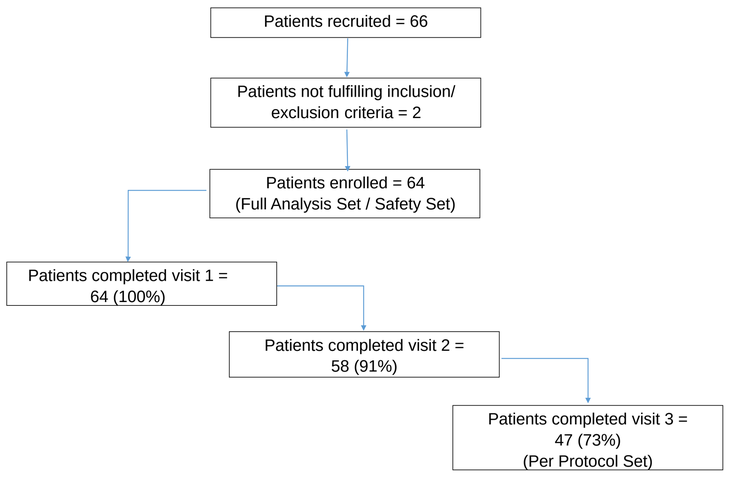
Study Design

- This is a multicentre, prospective observational study in Greece. Sixty four RRMS adult patients with Expanded Disability Status Scale (EDSS) scores < 6 receiving scIFNβ-1a/RebiSmart® for ≤ 6 weeks were enrolled in the study. From these, 47 completed all study visits (Per Protocol Set [PPS]; Figure 1).
- The primary endpoint was adherence over 12 months, defined as 100 times the number of injections actually administered, divided by the expected number of injections over the defined time period (month, season, year).
- Secondary endpoints included number of relapses, disability and adverse events. Patients were evaluated at baseline and at months 6 and 12.

Statistics

- This poster was prepared according to the STROBE (STrengthening the Reporting of OBservational studies in Epidemiology) guideline for reporting observational studies. Descriptive statistics were calculated for all study variables.
- Seasonal and monthly variance of the adherence level was analyzed by One Way Analysis of Variance (ANOVA). Pre- and post-treatment relapse rate was compared by the Wilcoxon signed-rank test. Pearson's r-test was used to study correlation between variables.

Figure 1. Patient Flow Diagram



RESULTS

- Mean annual adherence to scIFNβ-1a/ RebiSmart® was 97.93% ± 5.704 with no significant monthly, seasonal or geographical variations (**Figure 2; Table 2**).
- However, the fact that in the summer months the number of patients that provided adherence data declined might have introduced selection bias.

Figure 2. Main Efficacy Outcomes and Mean Annual Adherence

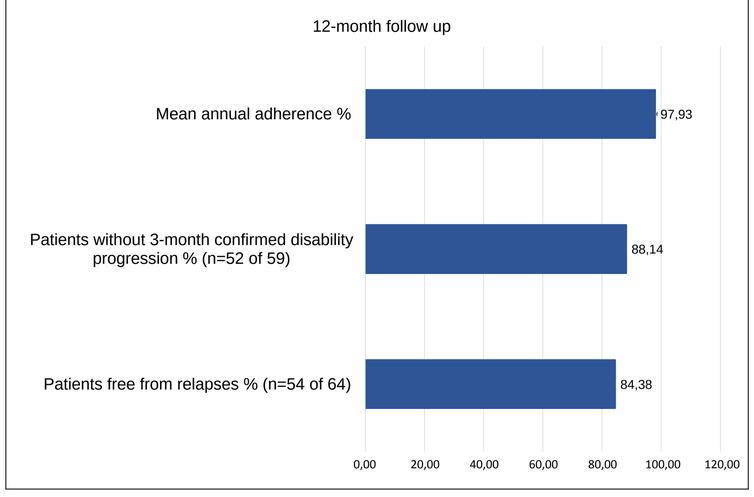


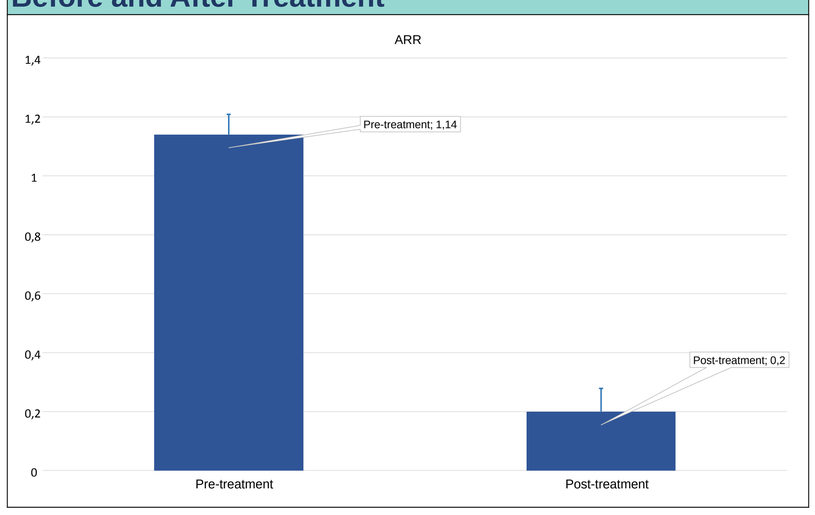
Table 1. Median and Mean Monthly Adherence

Month	N	Mean ± SD	Median
Jan	60	97.54 ± 10.409	100
Feb	60	97.56 ± 8.513	100
Mar	59	98.34 ± 7.192	100
Apr	57	98.60 ± 6.826	100
May	57	98.67 ± 6.795	100
Jun	53	98.21 ± 5.560	100
Jul	52	98.45 ± 5.777	100
Aug	49	98.873 ± 2.935	100
Sep	52	98.46 ± 4.073	100
Oct	53	99.01 ± 2.963	100
Nov	52	97.933 ± 6.282	100
Dec	59	98.17 ± 6.721	100

SD, standard deviation

- Mean relapse rates in the pre- and post- treatment were 1.1 ± 0.47 and 0.2 ± 0.54 respectively (P < 0.001, PPS; Figure 3).

Figure 3. Annualised Relapse Rate in the 12 Months Before and After Treatment



ARR, Annualised Relapse Rate;

- Eighteen patients (38%) showed improvement, 19 stabilized (40%) and ten worsened (22%) in terms of disability progression at 3 months. EDSS did not correlate with pre- (r = 0.024, P = 0.87) or post-treatment relapses (r = 0.022, P = 0.88) (**Figures 4 & 5**).

Figure 4. Correlation of Pre- and Post- Treatment Relapses with EDSS at 12 Months.

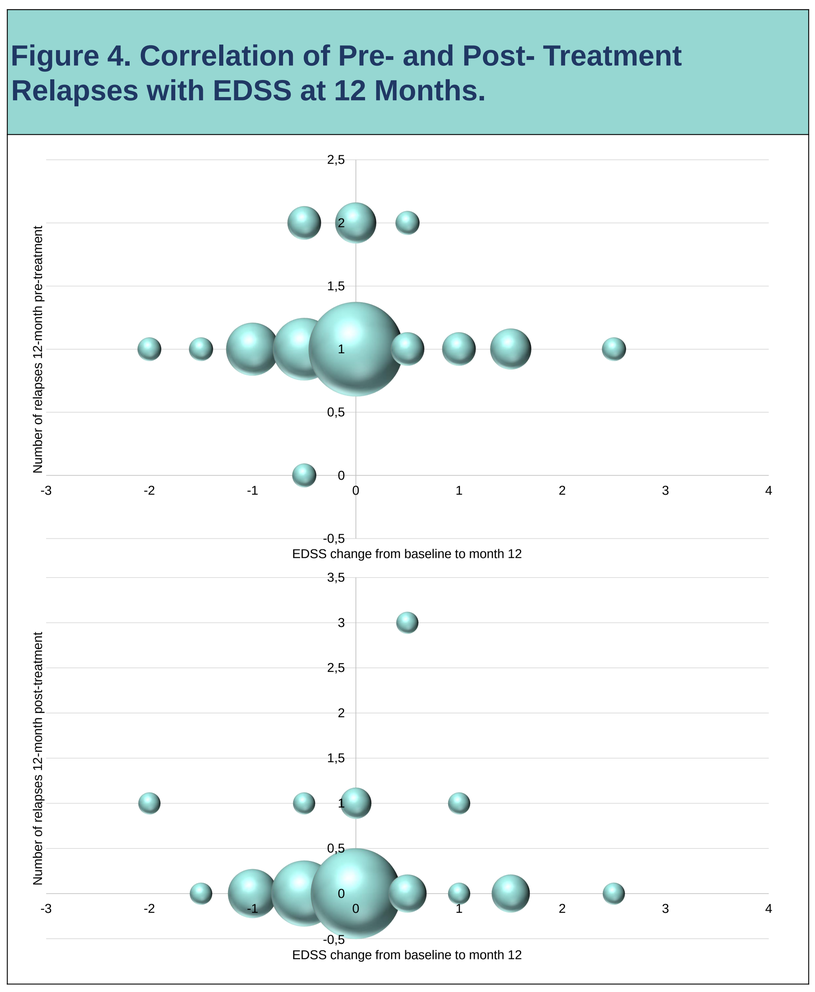
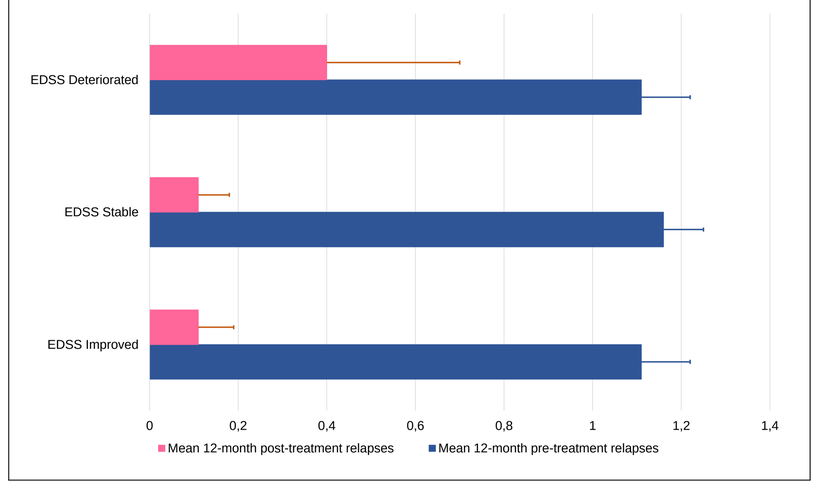
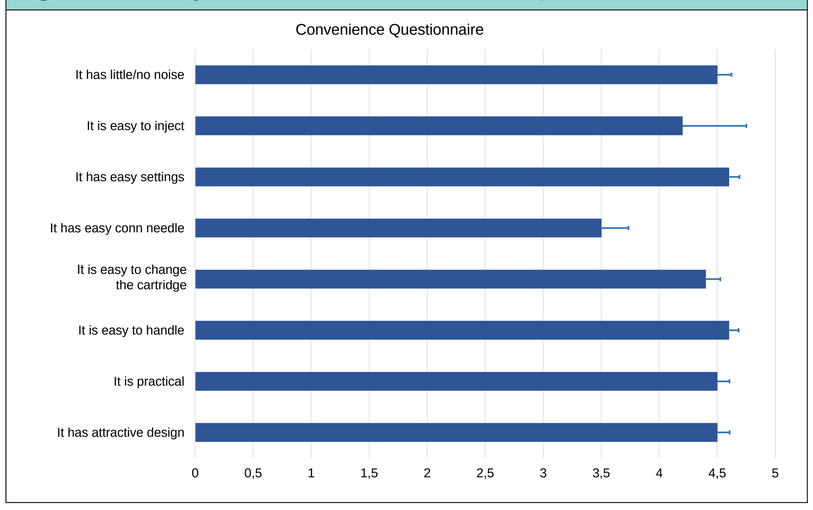


Figure 5. Mean Number of Relapses in the 12 Months Pre- and Post- Treatment, in Patients with Worsened, Stable, or Improved EDSS at 12 Months



EDSS, Expanded Disability Status Scale.

Figure 6. Responses to Convenience Questionnaire



CONCLUSIONS

- **Our study demonstrates that adherence to SC IFN with RebiSmart® was high and was independent of seasonal changes. Efficacy on relapses was consistent with published studies.**

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DISCLOSURES

S.N. Deftereos, D. Sakellariou and F. DeLorenzo are employees of Merck Hellas. M. Arvanitis was an employee of Merck Hellas at the time of study design

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