

Adherence, cognition and behavioral performance in relapsing-remitting MS (RRMS) patients using the electronic autoinjector RebiSmart: 1 and 2 year follow-up from the German multicenter RebiSmart study



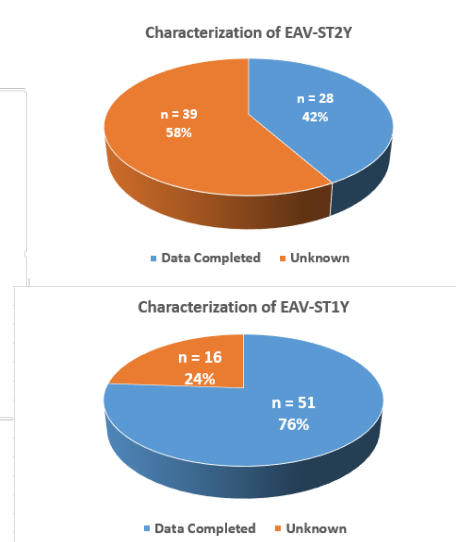
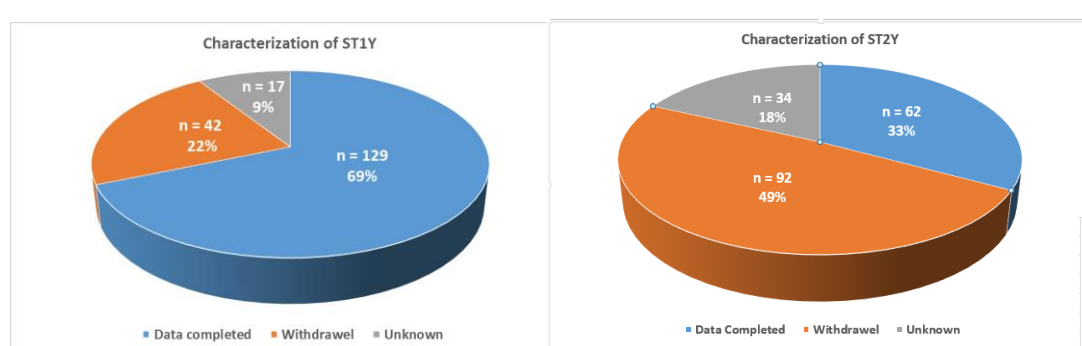
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Background and aims: Adherence is crucial for therapeutic success in chronic diseases. The electronic autoinjector RebiSmart™ is a unique device allowing objective assessment of interferon (IFN)β-1a sc administration. Our study investigated adherence pattern and cognitive-behavioral variables in RRMS patients using this device.

Methods: In a prospective, 24-month, non-interventional, multi-centre study we have been assessing quantitative (percentage of administered relative to prescribed injections) and qualitative adherence (percentage of weeks with three evenly-timed injections) in RRMS patients (18-65 yr, mean EDSS 1,6, mean disease duration of 5 years and female:male ratio of 75%:25%) at months 3/6/12/18/24 after baseline (BL) (see **Graphic 1**, **Table 1**). EDSS, clinical self-rating/NRS, quality of life/MusiQoL, fatigue/FSMC, depression/BDI, information processing/SDMT and word fluency/RWT were assessed also at BL. and at months 3/6/12/18/24

Results:



Graphic 1:

The first and second pie chart illustrate 188 patients entered the study (global study Group: GST), 129 provided complete adherence data over 12 months (per-protocol study group1: ST1Y) and 62 over 24 months (per-protocol study group2: ST2Y). 42 discontinued therapy within 12 months, another 50 within the 2nd year, 34 patients withdrew without clear data. 67/188 patients entered an additional support program of the Europa Apotheek Venlo (EAV). Dropout analysis revealed no significant differences between adherent and non-adherent patients; dropout in the EAV-group was not significantly different than that in non-EAVs but data (third and fourth pie chart) illustrated a trend for enhanced adherence of EAV-group without providing significant difference.

Mean in percent with SD	ST1Y	ST2Y
Quantitative Adherence, overall	96,3%, (SD: 8,1)	93,4%, (SD: 11)
Quantitative Adherence, min. 85% of all injections are taken	92,20%	83,90%
Qualitative Adherence, overall	88,9%, (SD: 16,1)	84,6%, (SD: 20,6)
Qualitative Adherence, min. 80% of all injections are taken 3-times per week	82%	74,20%
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Table 1:

Quantitative and qualitative Adherence in percent in ST1Y and ST2Y. For further analysis, only the 85% quant. and 80% qual. Adherence data were used.

EDSS, NRS, QoL, depression and cognition (verbal fluency, SDMT) remained stable within normal ranges throughout the observation period. As shown in **Figure 1** FSMC motor and cognitive score increased by 9.4% and 10.0%, respectively, across 12 months (ST1Y: p<0.002; p<0.035), and only cognitive fatigue by 8,4% (p<0,038) in the ST2Y group. Also MusiQoL subscale emotional well-being score increased by 7,7% in the ST1Y and 10,8% in the ST2Y group (ST1: p<0,38; ST2: p<0,35).

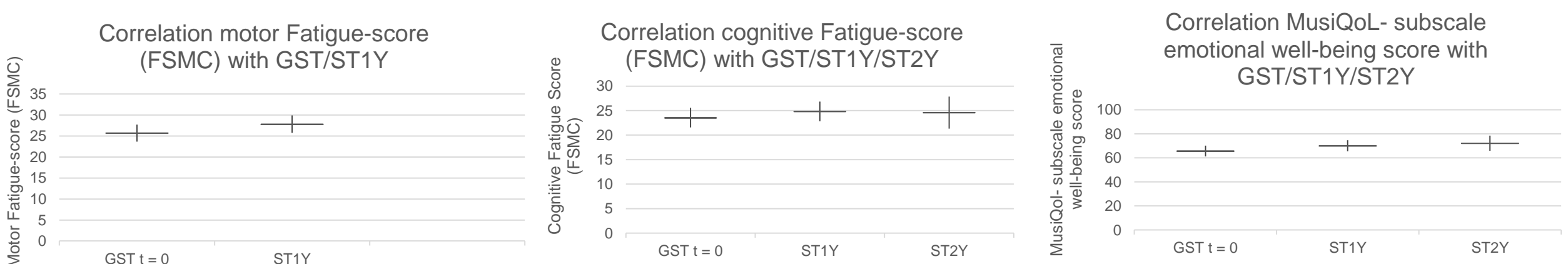
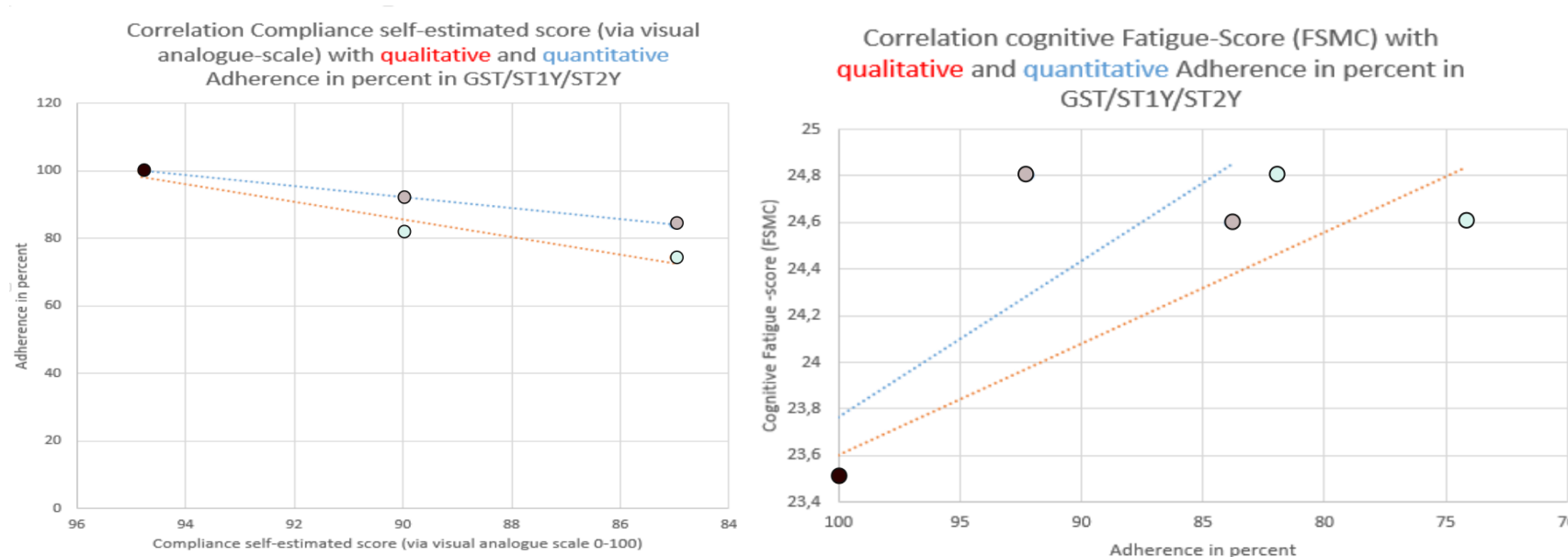


Figure 1: Correlation between motor Fatigue-score, cognitive Fatigue-score and MusiQoL- subscale emotional well-being score with GST/ST1Y and ST2Y. Results illustrated in text.



Likewise, there was both a statistically significant correlation between adherence and self-estimated compliance and a correlation between adherence and cognitive Fatigue score, as illustrated in **Figure 2** (p<0,01). Although these parameters did not indicate a substantial correlation. No further correlations could be made.

Figure 2: Correlation between Compliance self-estimated score and cognitive Fatigue-score with Adherence in GST (Black)/ST1Y (Grey) and ST2Y (Blue).

Conclusion: (1) Autoinjector RebiSmart™ proves high adherence for injectable DMTs in RRMS patients (2) High adherence results in stable clinical, cognitive and behavioral parameters. (3) Causes of fatigue increase are to be further explored. (4) Findings might indicate an advantage of a support-program concerning persistence.

Disclosures: FR, JG, RH, KG, CB, AK, ML, AB & HS received travel grants, congress fees and speakers` honoraria from Almirall, Bayer, Biogen, Genzyme, Merck, Novartis, Roche & Teva. DR, HS, ML & AB received research grants from Bayer, Biogen, Merck, Novartis and Teva. EAV received no grants from any third party.

Funding: The study has been supported by MerckSerono GmbH

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