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ReTRospective RebiSmart AdherenCE Rate data collection through iMed platform (TRACER): final results

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Objective

TRACER (ReTRospective RebiSmart AdherenCE Rate data) is an open-label Italian multicentre study that aims to collect data on treatment adherence and clinical outcomes in a large real life setting of Relapsing Remitting Multiple Sclerosis (RRMS) patients using RebiSmart to self-inject sc Interferon β-1a (IFNβ-1a) 22 or 44 mcg.

Materials and methods

- A cohort of RRMS patients with at least 12 months experience with RebiSmartTM was enrolled. The observation period begins with the first injection with RebiSmartTM (*baseline*) up to the last injection available. All data were retrospectively collected from the iMed database.
- *Primary endpoint*: proportion of patients with at least 80% of completed doses to the 12th month of treatment ("**treatment adherent**").
- *Secondary endpoints*: correlation of adherence with the patients' demographic and clinical characteristics, at baseline and during treatment; proportion of adherent patients in each trimester of the 24-month follow-up; causes of treatment discontinuation; rate of patients with serious adverse events (SAEs) during the treatment

Results

Data from 384 patients (67% female) were available *(Table 1)*. After 12 months, 342 (89.3%) were adherent *(Figure 1)*; 193 (93.2%) patients aged between 26 and 40 years at baseline were adherent (vs 79% of the ≤25 and 87.5% of the ≥41 year olds; p=0.006). Furthermore, 323 (90.5%) patients with baseline EDSS<4 showed ≥80% adherence (vs 71.4% in those with EDSS≥4; p=0.016). Of the 35 patients (9.1%) found to be non-adherent after 3 months of treatment, 54% were non-adherent between 3 and 12 months too, while only 6.7% of the adherent patients at 3 months were non-adherent between 3 and 12 months (OR 16.8; 95% CI: 7.1-39.8). Flu-like syndrome was the most frequent cause of reduced adherence (55.8%) *(Figure 2)*. No SAEs were reported.

Table 1.
Baseline demographical and clinical charateristics of the cohort. Values expressed as mean (±SD) and median (range)

Age , years	36 (±9,2)
Disease duration, months	74 (0-398)
EDSS	2 (0- 6)
Previous DMDs*	46%
Mean follow up, months	29 (±12)

*IFNβs, GA, Natalizumab, IS

Figure 1. *Percentage of adherent patients after 3, 6, 9, 12 and 24 months of treatment*

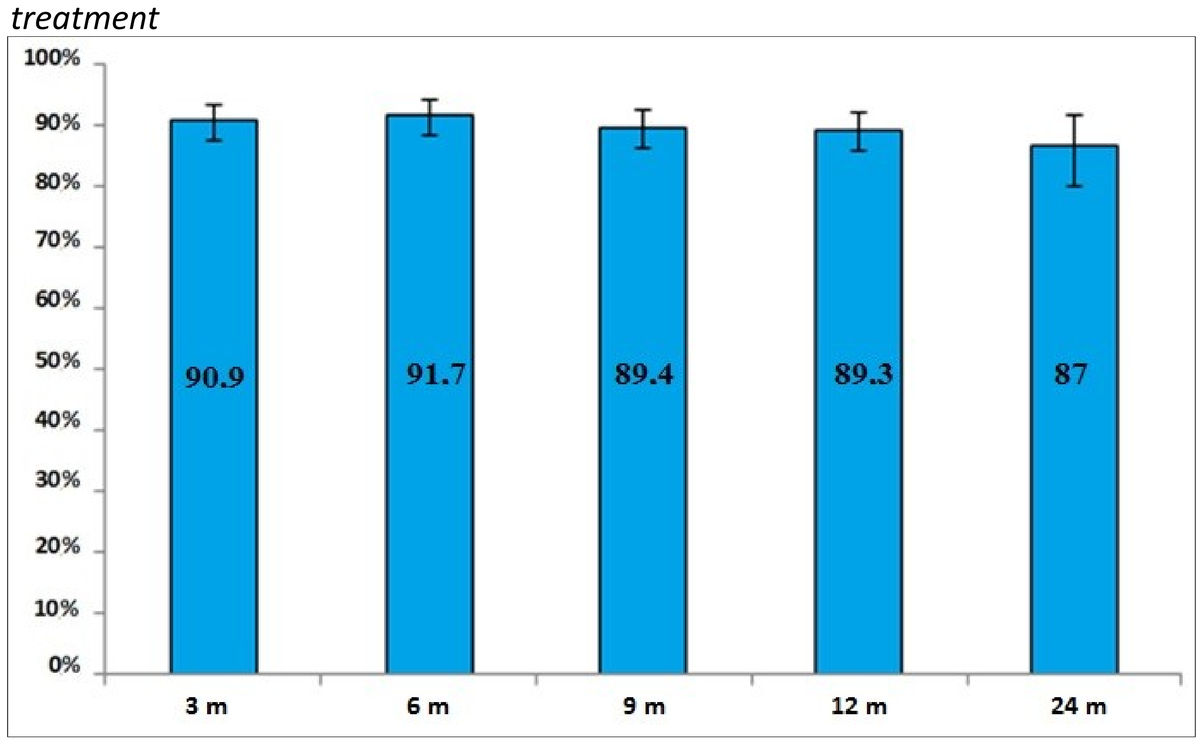
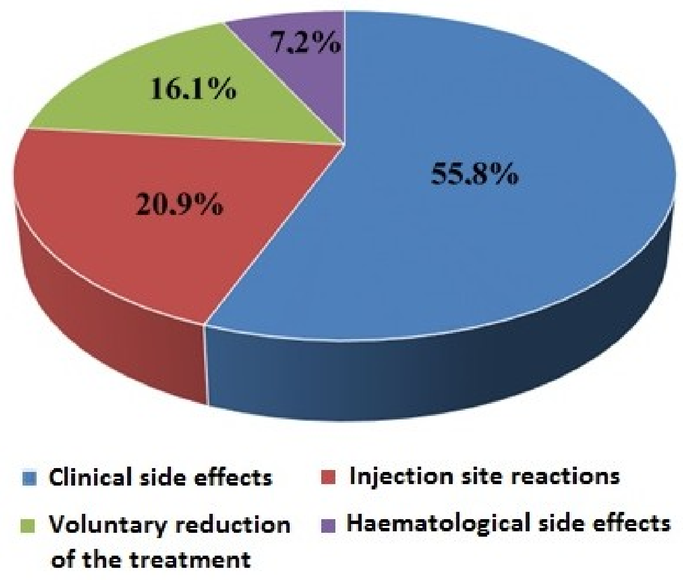


Figure 2. *Causes of discontinuity of treatment*



Conclusions

These results confirm high treatment adherence in RRMS patients using RebiSmart. ***In our cohort patients with age between 26 and 40 years and with EDSS score <4 at baseline were the most adherent. The status of "treatment adherent" in the first 3 months of therapy was predictive of higher adherence in the long term period.*** To identify baseline clinical and demographic characteristics could be useful to outline a profile of the treatment adherent patient in the clinical practice.

1.Sabaté E. Adherence to Long-Term Therapies: Evidence for Action. Geneva, Switzerland: World Health Organization, 2003

2.Devonshire V , Lapierre Y, Macdonell R , Ramo-Tello C, Patti F, Fontoura P, Suchet L, Hyde R, Balla I, Frohman E. M. and Kieseier B. C. for the GAP Study Group. European Journal of Neurology 2011; 18: 69–77