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Interferon-beta-1a treatment has a positive effect on quality of life of relapsing–remitting multiple sclerosis: Results from a longitudinal study

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ABSTRACT

Purpose: The impact of interferon beta (IFNβ) therapy on a patient's quality of life (QoL) has not been completely clarified. This multicenter, independent, observational and longitudinal study was aimed to evaluate the impact of different pharmaceutical formulations of IFNβ-1a on QoL in patients affected by relapsing–remitting multiple sclerosis (RRMS).
Methods: The multiple sclerosis quality of life-54 questionnaire was used to assess patients' QoL.
Results: 394 (66%) patients completed the two-year study; 152 were treated with IFNβ-1a i.m. weekly injected (group a), 152 with IFNβ-1a 44 μg s.c. injected three times a week (group b) and 90 were untreated (group c). After two years, a significant increase was found in the physical health composite score ($\Delta = +3.1$ in group a, $\Delta = +3$ in group b, $p < 0.05$ in both), mental health composite score ($\Delta = +4.7$ in group a, $\Delta = +5.5$ in group b, $p < 0.001$ in both), in eight MSQoL sub-items of group a and in seven sub-items in group b. Conversely, the untreated group showed a slight decrease in seven domains. The variable "therapy with DMDs" was associated with improved QoL.
Conclusion: QoL of RRMS could be improved by IFNβ-1a treatment, despite natural history data which seem to demonstrate that QoL could get worse over the time.

1. Introduction

Multiple sclerosis shows a number of needs which are not completely satisfied by the use of interferon beta (IFNβ) [1–3]. It is generally believed that IFNβ could impact and deteriorate the quality of life (QoL) of people with MS [4–6]. IFNβ therapy is known to be associated with both systemic and local adverse effects [7,8], which can also occur after decades of treatment, as shown by several extension phase III and post marketing studies [9,10]. Thus, discontinuation of treatment is frequent, particularly in the first few months after starting IFNβ therapy [11]. The main reasons leading to the suspension of therapy are forgetting to administer the injection, perceived lack of efficacy, and side effects [12,13]. Various strategies to improve adherence and mitigate the negative impact of IFNβ have been successfully suggested including educative programs, injection devices and dedicated nurse assistance [13–15]. The impact of IFNβ-therapy on the patient's QoL has not been completely clarified, as there are conflicting evidences among the studies [5,6,16–23]. Nevertheless, the majority of the authors confirmed the positive influence of treatment with IFNβ on QoL [20–23].

Main aim of our study was to longitudinally investigate the global impact of different pharmaceutical formulations of IFNβ-1a therapy on QoL in a large sample of Italian patients affected by RRMS. Secondarily, we evaluated whether occurrence of exacerbation and EDSS variation could influence QoL of treated and untreated MS patients.

2. Methods/patients section

2.1. Study design

This was an independent, non-sponsored, multicenter, national, observational and longitudinal study. A contract research organization (Medepha, Genoa, Italy) housed the database and performed the statistical analyses.

2.2. Setting

Longitudinal evaluation was carried out for a period of two years, from January 2004 to December 2006 in 40 Italian MS centers. Patients were assessed at each center every six months. T0 was the baseline evaluation at enrolment; T1–T2–T3–T4 represent the successive

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evaluations; T5 was the last evaluation, performed 2 years after the T0 baseline assessment.

2.3. Participants

Patients with a clinically or laboratory-supported definite diagnosis of RRMS [24–26] had to satisfy the following inclusion criteria: expanded disability status scale (EDSS) [27] score 1.0–5.5; 18 years or older; able to give written informed consent; and naïve to treatment with IFNβ. Patients who had been treated with steroids the month before inclusion were not enrolled. Other exclusion criteria were progressive course of the disease, liver or renal disease, or serious concomitant diseases. The sample was subgrouped in patients without exacerbations and patients with one or more exacerbations. Patients were also stratified as worsened or stable-improved on their EDSS score. At each center, principal investigators (PI) selected consecutive referral patients who were eligible for this study and who were suitable for treatment with IFNβ. It must be pointed out that in 2004–2006, IFNβ-1a was considered as the drug of first choice because of the higher frequent occurrence of neutralizing antibodies (NABs) in patients treated with IFNβ-1b [28].

Ethical consent was provided by the Ethical Committee of the University of Catania, which approved the protocol. Successively, each MS center involved in the study submitted the study protocol to their local ethical committee. Before the enrolment, each patient gave their informed written consent to participate in the study.

2.4. Variables

Delta variations of MSQoL-54 sub-items were considered as an outcome measure investigating the impact of either different IFNβ formulations or the no treatment status on MS patients QoL.

Exacerbations and EDSS status were considered as possible variables influencing QoL.

Age, sex, education, disability and IFNβ treatment were considered as variables included in the model to identify possible predictors of QoL of these patients.

2.5. Measurement

The disease specific multiple sclerosis quality of life-54 questionnaire (MSQoL-54) [29], validated in the Italian version [30] was used to assess the QoL of all patients. Two composite scores, physical health (PHCS) and mental health (MHCS), can be derived from a weighted combination of scale scores. In addition, there are the following subscales: physical function (PH), role limitation physical (RP), role limitation emotional (RE), bodily pain (BP), emotional well-being (EWB), energy (E), health perception (HP), social function (SF), cognitive function (CF), health distress (HD), sexual function (SxF), change in health (CH), satisfaction with sexual function (SSxF), and overall quality of life (OQoL).

Table 1
Clinical and demographic characteristics of the eligible patients, analyzed cohort, and lost to follow up.

	Eligible PTS	Analyzed cohort	Lost to follow up
	no. = 593	no. = 394	no. = 199
	N. (%)	N. (%)	N. (%)
Sex			
Male	178 (30)	118 (30)	60 (30)
Female	415 (70)	276 (70)	139 (70)
Age			
18–30 years	173 (29)	114 (29)	59 (30)
31–40	233 (39)	142 (36)	91 (46)
41–50	140 (24)	106 (27)	34 (17)
>50	46 (8)	32 (8)	14 (7)
Missing data	1		1
EDSS			
0–2	417 (70)	276 (70)	141 (71)
2.5–3.5	134 (23)	91 (23)	43 (22)
4–5.5	42 (7)	27 (7)	15 (7)
Occupation			
Employed	368 (62)	244 (62)	124 (62)
Housewife	118 (20)	79 (20)	39 (20)
Student	45 (7)	32 (8)	13 (6)
Unemployed	50 (8)	35 (9)	15 (7)
Missing data	12 (2)	4 (2)	8 (4)
Education			
0–5 years	27 (4)	24 (6)	3 (1)
6–8	167 (28)	110 (28)	57 (29)
9–13	315 (53)	209 (53)	106 (53)
Degree	81 (14)	51 (13)	30 (15)
Missing data	3 (1)		3 (1)
Disease duration			
0–2 years	338 (57)	219 (56)	119 (60)
3–5	126 (21)	87 (22)	39 (19)
6–10	66 (11)	44 (11)	22 (11)
>10	58 (10)	41 (10)	17 (8)
Missing data	5 (1)	3 (1)	2 (1)

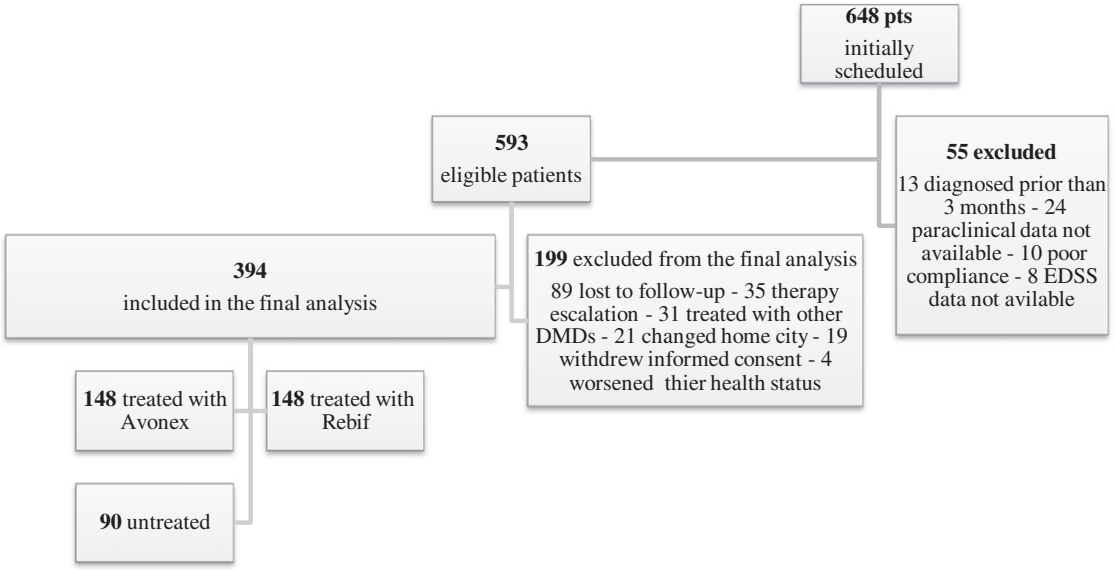

Fig. 1. Disposition of patients from baseline to T5.