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ORIGINAL ARTICLE

Treatment compliance with first line disease-modifying therapies in patients with multiple sclerosis. COMPLIANCE Study^{☆,☆☆}



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KEYWORDS

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Abstract

Introduction: Non-adherence to disease-modifying therapies (DMTs) in multiple sclerosis may be associated with reduced efficacy. We assessed compliance, the reasons for non-compliance, treatment satisfaction, and quality of life (QoL) of patients treated with first-line therapies.

Methods: A cross-sectional, multicenter study was conducted that included relapsing multiple sclerosis patients. Compliance in the past month was assessed using Morisky-Green test. Seasonal compliance and reasons for non-compliance were assessed by an ad-hoc questionnaire.

Treatment satisfaction and QoL were evaluated by means of TSQM and PRIMUS questionnaires.

Results: A total of 220 patients were evaluated (91% relapsing-remitting); the mean age was 39.1 years, 70% were female, and the average time under treatment was 5.4 years. Subcutaneous interferon (IFN) β-1b was used in 23% of the patients, intramuscular IFN β-1a in 21%, subcutaneous IFN β-1a in 37%, and with glatiramer acetate in 19%. The overall compliance was 75%, with no significant differences related to the therapy, and 81% did not report any seasonal variation. Compliant patients had significantly lower disability scores and time of diagnosis, and greater satisfaction with treatment and its effectiveness. Discomfort and flu-like symptoms were the most frequent reasons for non-compliance. The satisfaction and QoL were associated with less disability and number of therapeutic switches.

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◊ Researchers contributing to the COMPLIANCE Study are listed in Appendix 1.

PALABRAS CLAVE
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glatirámero;
Cumplimiento;
Satisfacción;
Calidad de vida

Conclusions: The rate of compliance, satisfaction and QoL in multiple sclerosis patients under DMTs is high, especially for those newly diagnosed, less disabled, and with fewer therapeutic switches. Discomfort and flu-like symptoms associated with injected therapies significantly affect adherence.

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Cumplimiento terapéutico con terapias modificadoras de la enfermedad de primera línea en pacientes con esclerosis múltiple. Estudio COMPLIANCE

Resumen

Introducción: La falta de cumplimiento terapéutico en la esclerosis múltiple puede asociarse a menor eficacia. En este estudio evaluamos el cumplimiento terapéutico, las razones para su incumplimiento, satisfacción con el tratamiento y calidad de vida (CdV) de pacientes en terapia de primera línea (terapias modificadoras de la enfermedad [TME]).

Métodos: Estudio transversal, multicéntrico, de pacientes con EM que cursa a brotes. El cumplimiento en el último mes se evaluó mediante test de Morisky-Green, el cumplimiento estacional y las razones para el incumplimiento mediante cuestionario *ad-hoc*, y la satisfacción y CdV a través de los cuestionarios TSQM y PRIMUS.

Resultados: Se evaluaron 220 pacientes (un 91% remitentes-recidivantes); la media de edad fue 39,1 años, el 70% eran mujeres y el tiempo en tratamiento 5,4 años. El 23% estaba tratado con interferón (IFN) β-1b subcutáneo, el 21% con IFN β-1a intramuscular, el 37% con IFN β-1a subcutáneo y el 19% con acetato de glatirámero. El cumplimiento global fue del 75%, sin diferencias significativas en función del TME, y no refirieron cambios estacionales el 81%. Los pacientes cumplidores presentaban significativamente menores valores de discapacidad y de tiempo de diagnóstico, y mayor satisfacción con el tratamiento y su efectividad. Las molestias y los síntomas seudogripales fueron las razones más frecuentes para el incumplimiento. La satisfacción y la CdV se relacionaron con una menor discapacidad y número de cambios terapéuticos.

Conclusiones: En pacientes con TME el grado de cumplimiento, satisfacción y CdV son altos, en especial para aquellos de diagnóstico reciente, menos discapacitados y con menos cambios terapéuticos. Las molestias y síntomas seudogripales asociados a las terapias inyectadas influyen en el cumplimiento.

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Introduction

Multiple sclerosis (MS) is the most frequent cause of neurological disability unrelated to trauma among young adults.¹ The most common disease course (80%) is relapsing-remitting MS (RRMS), which is characterised by self-limited attacks of neurological dysfunction resulting in residual functional deficit as damage accumulates. Approximately 50% of RRMS patients will eventually present a progressive secondary course with increasing disability, called secondary-progressive MS (SPMS). SPMS disability is independent of relapses, although they can appear sporadically.²

Disease-modifying therapies (DMT) constitute the current first-line treatment option for RRMS and SPMS since they reduce relapse rate and slow disability progression. DMTs include interferon beta-1a (IFNβ-1a), interferon beta-1b (IFNβ-1b), and glatiramer acetate, which can be administered either subcutaneously (SC) or intramuscularly (IM).³ Treatment adherence is defined by the World Health Organization as the combination of compliance (taking the medication according to prescribed dosage and schedule)

and persistence (taking it from the beginning until it is discontinued). Poor adherence seems to contribute to lack of effectiveness in treatments for chronic illnesses.⁴ Although several studies have demonstrated the importance of adhering to these treatments in order to control not only relapse rate but also MS progression,^{5–8} adherence rates range from 41% to 88%.⁹ The principal reasons for not adhering to treatments include perceived lack of effectiveness and secondary effects.¹⁰

Reduced quality of life (QoL), resulting from the physical, psychological, and social alterations occurring in MS, is also linked to motivation to adhere to a DMT^{11,12} and constitutes a prognostic factor for the course of the disease.^{13,14} Several studies of other chronic illnesses have shown that both QoL and adherence are directly related to treatment satisfaction.^{15–17}

Our main purpose is to assess the level of therapeutic compliance of MS patients with relapses who are treated with first-line DMTs. We also aim to ascertain the reasons for non-adherence, describe seasonal compliance, determine the level of treatment satisfaction, and evaluate QoL in our patients. Furthermore, we intend to examine the connection between compliance and treatment satisfaction and

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