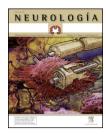


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ORIGINAL ARTICLE

Cost-effectiveness analysis of interferon beta-1b as treatment for patients with clinically isolated syndrome suggestive of multiple sclerosis in Spain*,**



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KEYWORDS

Efficiency; Costs; Multiple sclerosis; Expanded Disability Syndrome Scale; Interferon beta 1b; Clinically isolated syndrome

Abstract

Introduction: The BENEFIT study has demonstrated the benefits of early treatment with interferon beta 1b (IFN β -1b). The objective of this study was to estimate the efficiency of early vs. delayed IFN β -1b treatment in patients with clinically isolated syndrome (CIS) suggestive of multiple sclerosis (MS) in Spain.

Methods: A Markov model reflecting the social perspective was developed with time horizons ranging from 2 years to lifetime. A cohort of 1000 patients with CIS, whose health status had been measured on the Expanded Disability Symptom Scale (EDSS), included patients who received early IFNβ-1b treatment and those who did not. Data from the BENEFIT study were used to model EDSS progression and transitions to MS. Costs were estimated from published literature. Patient utilities were derived from EQ-5D data and published data. Mortality was estimated using life tables and EDSS data. Costs (\in at 2013 rates) and outcomes were discounted at 3% per annum. A probabilistic sensitivity analysis was performed.

Results: In the base case, both the incremental cost utility ratio (ICUR) and the incremental cost effectiveness ratio (ICER) of IFNβ-1b vs. no treatment were dominant (more effective and less costly) from a social perspective. From the perspective of the Spanish Health System, the ICUR was \in 40 702/QALY and the ICER was \in 13/relapse avoided.

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^{**} Previous versions of this study (2009 data) have been published as:

Arbizu T, Piñol C, Casado V, Caloyeras JP. Coste utilidad de interferón beta en el tratamiento de pacientes con síndrome desmielinizante aislado sugestivo de esclerosis múltiple en España. XXVIII Jornadas de la Asociación de Economía de la Salud. Málaga, 17—19 de junio 2009. Gaceta Sanitaria. 2009;23 Espec Cong 2:65.

Arbizu T, Piñol C, Casado V. Cost-utility of interferon beta-1b in the treatment of patients with a clinical isolated syndrome suggestive of multiple sclerosis in Spain. ISPOR 12th Annual European Congress. Paris, France, 24–27 October 2009. Value in Health. 2009;12(7):A370. *E-mail address*: carme.pinyol@gmail.com

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Conclusion: Early treatment with IFN β -1b after a CIS vs. delayed treatment is efficient from a social perspective, but it may not be efficient from the perspective of the NHS which does not take non health-related costs into account.

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PALABRAS CLAVE

Eficiencia; Costes; Esclerosis múltiple; Expanded Disability Syndrome Scale; Interferón beta 1b; Síndrome desmielinizante aislado Análisis de coste-efectividad del interferón beta-1b en el tratamiento de pacientes con síndrome desmielinizante aislado indicativo de esclerosis múltiple en España

Resumen

Introducción: El estudio BENEFIT ha mostrado los beneficios del uso precoz del interferón beta 1b (IFN β -1b). El objetivo del trabajo fue estimar la eficiencia del tratamiento precoz vs. diferido del IFN β -1b en pacientes con un síndrome desmielinizante aislado (SDA) indicativo de esclerosis múltiple (EM) en España.

Métodos: Se desarrolló un modelo de Markov desde la perspectiva social, con un horizonte temporal de 2 años hasta toda la vida. Una cohorte de 1.000 pacientes con SDA y estados de salud definidos por la Expanded Disability Syndrome Scale (EDSS) fue tratada o no con IFNβ-1b al inicio. Los datos del BENEFIT se usaron para la progresión en la EDSS y las transiciones a EM. Los costes se estimaron de la literatura. Las utilidades derivaron del EQ-5D y publicaciones y la mortalidad de tablas de mortalidad y de la EDSS. Costes (€ de 2013) y resultados se descontaron al 3% anual. Se realizó un análisis de sensibilidad probabilístico.

Resultados: En el caso base, tanto la razón de coste utilidad incremental (RCUI) como la razón de coste efectividad incremental (RCEI) del IFNβ-1b vs. no tratamiento fueron dominantes (más eficaz y menos costoso) bajo la perspectiva social. Bajo la perspectiva del SNS, la RCUI fue de 40.702 €/AVAC y la RCEI de 13 €/recaída evitada.

Conclusión: El tratamiento precoz con IFN β -1b después de un SDA frente al tratamiento diferido es eficiente desde la perspectiva social, pero puede no ser eficiente desde la perspectiva del SNS al no tener en cuenta los costes no sanitarios.

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Introduction

Multiple sclerosis (MS) is an inflammatory disease of the central nervous system characterised by progressive demyelination. Most MS patients present severe physical disability and cognitive impairment.¹

According to a recent study conducted in La Rioja, Spain, MS has a prevalence of 65 cases per 100 000 population and predominantly affects young women. The mean annual cost per patient with MS amounts to \leq 24272, with direct costs representing around 60% of the total cost.

The first manifestation of the disease in 85% of the young adults who develop clinically definite MS (CDMS) is an event resulting from isolated demyelination of the optic nerves, brainstem, or spinal cord. ^{1,4} This event is called 'clinically isolated syndrome', or CIS.

Disease-modifying treatments (DMT) such as interferon beta-1b (IFN β -1b) are the standard first-line of treatment for MS outbreaks, since they have been shown to reduce the exacerbation rate and slow disease progression in clinical trials. $^{1,5-7}$

According to the Betaferon® in Newly Emerging Multiple Sclerosis for Initial Treatment (BENEFIT)⁸ trial, early treatment after a CIS suggestive of MS reduces the risk of conversion to CDMS by 41% compared with delayed

treatment. Furthermore, several studies have shown that early treatment reduces the risk of disease progression by 40% to 45% compared with delayed treatment. $^{7-10}$

Whereas the cost-effectiveness of treatments for MS has been thoroughly studied, this is not the case for CIS suggestive of MS. $^{11-15}$

The aim of this study was to estimate the cost-effectiveness in Spain of IFN β -1b in patients with a CIS suggestive of MS.

Material and methods

Description of the model

We used MS Excel® to create a Markov model to estimate the costs and benefits of a hypothetical cohort of 1000 patients (mean age: 30 years, 70% of whom were women, in line with the population of the BENEFIT study) with a CIS who were treated with IFN β -1b (250 mg every other day) either right after a CIS suggestive of MS (early treatment) or at onset of CDMS (delayed treatment). 9,10 We used the model to simulate results for time horizons from 2 years to lifetime. Patient's lifespans were divided into 6-month cycles.

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