



ORIGINAL ARTICLE

Cost-effectiveness assessment through theoretical cost-minimization analysis of the use of two gastro-resistant modified-release mesalazine formulations in the management of ulcerative colitis in Spain[☆]



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KEYWORDS

Ulcerative colitis;
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Abstract

Introduction: The prevalence of ulcerative colitis (UC) and its associated economic burden is increasing in Spain. Oral mesalazines, which are the recommended first-line treatment for mild-moderate UC, show considerable variability in their formulations and prices.

Objective: To carry out a cost-effectiveness assessment of the use of the two formulations of oral gastro-resistant modified-release mesalazine formulations marketed in Spain (Salofalk[®] and Mezavant[®]) for the phases of induction of remission and its maintenance.

Methods: We adapted internationally validated economic models for the management of UC to the Spanish setting. The adaptation focused on the use of oral gastro-resistant modified-release mesalazines. We conducted cost minimization analyses of remission induction (decision tree) and remission maintenance (Markov model).

Results: For the remission induction, Salofalk[®] 3 g/day was superior to (same effectiveness at lower costs) Mezavant[®] 3.6 g/day and 4.8 g/day in any treatment strategy that included oral gastro-resistant modified-release mesalazines. When compared with Mezavant[®] 2.4 g/day, Salofalk[®] was the most cost-effective option. For remission maintenance, all treatment strategies using Salofalk[®] were the most cost-effective option in all the scenarios considered.

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PALABRAS CLAVE

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Análisis de costes

Conclusion: Because of the lower cost per gram of Salofalk[®], any treatment strategy based on this drug is more cost-effective than Mezavant[®] for the treatment of mild-moderate UC, whether for the induction of remission or for its maintenance.

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Evaluación de coste-efectividad mediante análisis teórico de minimización de costes del uso de dos mesalazinas gastrorresistentes de liberación prolongada en el manejo de la colitis ulcerosa en España

Resumen

Introducción: La prevalencia de la colitis ulcerosa (CU) en España y su carga económica asociada están aumentando. La mesalazina oral, tratamiento recomendado como primera línea para la CU leve-moderada, presenta sensibles diferencias en cuanto a formulaciones y precios.

Objetivos: Estudio de coste-efectividad entre las 2 formulaciones orales de mesalazinas gastrorresistentes de liberación prolongada que existen en España (Salofalk[®] y Mezavant[®]) en las fases de brote y de mantenimiento de la remisión.

Métodos: Adaptación de modelos económicos de manejo de la CU validados internacionalmente, al uso de mesalazinas gastrorresistentes de liberación prolongada en España: análisis de minimización de costes para el tratamiento del brote (árbol de decisión) y mantenimiento de la remisión (modelo de Markov).

Resultados: En el tratamiento del brote, Salofalk[®] 3 g/día domina (ofrece igual resultado en salud a menor coste) a Mezavant[®] en dosis de 3,6 y 4,8 g/día en cualquier estrategia de tratamiento que incluya mesalazinas gastrorresistentes de liberación prolongada. Comparado con Mezavant[®] a dosis de 2,4 g/día, Salofalk[®] resulta la opción más coste-efectiva. En el modelo de mantenimiento, las estrategias basadas en Salofalk[®] 3 g/día son también dominantes para todos los escenarios considerados.

Conclusiones: El menor precio por gramo de Salofalk[®] hace que cualquier estrategia basada en Salofalk[®] sea más coste-efectiva que Mezavant[®] para el manejo de la CU leve-moderada, tanto para tratar el brote como para mantener la remisión.

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Introduction

Ulcerative colitis (UC) is a chronic inflammatory disease of the gastrointestinal tract, of partly known aetiology.¹ It mainly affects the colon and is characterized by flare-ups or relapses, followed by unpredictable periods of remission.^{2,3} Severity and extension vary among patients⁴ and in the same patient over time, thus requiring different treatment strategies adapted to each clinical situation.⁵

Like other European countries, Spain has seen a gradual rise in the incidence of UC,⁶ with an estimated total of 6–10 new cases per 100,000 population/year^{7–9} and an increasing impact on paediatric groups.¹⁰ Given the chronic nature of the disease and its low mortality rate, prevalence rates have increased in parallel with the economic burden of this disorder on the Spanish National Health System.

The main objective in the treatment of UC is to achieve and maintain disease remission. Treatment of patients with mild to moderate UC is based essentially on the use of 5-aminosalicylic acid (5-ASA or mesalazine) derivatives.^{4,11} The efficacy, effectiveness and safety of mesalazine as a first-line induction and remission maintenance therapy in mild to moderate UC is backed by ample scientific evidence.^{12–16} The total cost of this disease, however,

is increasing,¹⁷ although estimates vary greatly between different European countries.¹⁸ The impact of different mesalazine treatment strategies in each of these countries has proven to be a determining factor.¹⁹

Mesalazine is currently available in a wide variety of presentations, dosages, routes of administration, formulations and brands, differing mainly in the form of delivery of active mesalazine in the colon and the dosage.²⁰ In Spain, despite this wide range, the only once-daily oral gastro-resistant prolonged-release formulations are Mezavant (1.2g tablets) and Salofalk (granules available in various doses). According to the latest edition of the National Institute for Health and Care Excellence (NICE) guidelines for the treatment of UC, the British National Formulary²¹ states that the delivery characteristics of the different oral preparations of mesalazine may vary, and that these preparations should not be considered interchangeable; as such, they should be compared with each other independently. Studies and meta-analyses comparing these gastro-resistant prolonged-release preparations^{12–16} show that they do not differ in effectiveness or safety, so determining their cost-effectiveness is particularly important to help clinicians choose the correct treatment.

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