



Enfermedades Infecciosas y Microbiología Clínica

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Original article

Costs and cost-efficacy analysis of the 2017 GESIDA/Spanish National AIDS Plan recommended guidelines for initial antiretroviral therapy in HIV-infected adults

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ARTICLE INFO

Article history:

Received 24 February 2017

Accepted 11 April 2017

Available online xxx

Keywords:

Costs

Efficacy

Efficiency

HIV

AIDS

Antiretroviral therapy

ABSTRACT

Introduction: GESIDA and the Spanish National AIDS Plan panel of experts have recommended preferred (PR), alternative (AR) and other regimens (OR) for antiretroviral therapy (ART) as initial therapy in HIV-infected patients for 2017. The objective of this study was to evaluate the costs and the efficiency of initiating treatment with PR and AR.

Methods: Economic assessment of costs and efficiency (cost-efficacy) based on decision tree analyses. Efficacy was defined as the probability of reporting a viral load <50 copies/mL at week 48, in an intention-to-treat analysis. Cost of initiating treatment with an ART regimen was defined as the costs of ART and its consequences (adverse effects, changes of ART regimen and drug resistance studies) during the first 48 weeks. The payer perspective (National Health System) was applied considering only differential direct costs: ART (official prices), management of adverse effects, resistance studies and HLA B*5701 screening. The setting was Spain and the costs correspond to those of 2017. A deterministic sensitivity analysis was conducted, building three scenarios for each regimen: base case, most favourable and least favourable.

Results: In the base case scenario, the cost of initiating treatment ranged from 6882 euro for TFV/FTC/RPV (AR) to 10,904 euros for TFV/FTC + RAL (PR). The efficacy varied from 0.82 for TFV/FTC + DRV/p (AR) to 0.92 for TAF/FTC/EVG/COBI (PR). The efficiency, in terms of cost-efficacy, ranged from 7923 to 12,765 euros per responder at 48 weeks, for ABC/3TC/DTG (PR) and TFV/FTC + RAL (PR), respectively.

Conclusion: Considering ART official prices, the most efficient regimen was ABC/3TC/DTG (PR), followed by TFV/FTC/RPV (AR) and TAF/FTC/EVG/COBI (PR).

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<http://dx.doi.org/10.1016/j.eimc.2017.04.002>

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Análisis de costes y de coste/eficacia de las pautas recomendadas por GESIDA/Plan Nacional sobre el Sida en 2017 para el tratamiento antirretroviral inicial en adultos infectados por el VIH

R E S U M E N

Palabras clave:

Costes
Eficacia
Eficiencia
VIH
Sida
Tratamiento antirretroviral

Introducción: El panel de expertos de GESIDA/Plan Nacional del Sida ha recomendado pautas preferentes (PP), pautas alternativas (PA) y otras pautas (OP) para el tratamiento antirretroviral (TARV) como terapia de inicio en pacientes infectados por VIH para 2017. El objetivo de este estudio es evaluar los costes y la eficiencia de iniciar tratamiento con PP y PA.

Métodos: Evaluación económica de costes y eficiencia (coste/eficacia) mediante construcción de árboles de decisión. Se definió eficacia como la probabilidad de tener carga viral < 50 copias/mL en la semana 48 en análisis por intención de tratar. Se definió coste de iniciar tratamiento con una pauta como los costes del TARV y de todas sus consecuencias (efectos adversos, cambios de pauta y estudio de resistencias) que se producen en las siguientes 48 semanas. Se utilizó la perspectiva del Sistema Nacional de Salud, considerando solo costes directos diferenciales: TARV (a precio oficial), manejo de efectos adversos, estudios de resistencias y determinación de HLA B*5701. El ámbito es España, con costes de 2017. Se realizó un análisis de sensibilidad determinista construyendo 3 escenarios para cada pauta: basal, más favorable y más desfavorable.

Resultados: En el escenario basal, los costes de iniciar tratamiento oscilaron entre 6.882 euros para TFV/FTC/RPV (PA) y 10.904 euros para TFV/FTC+RAL (PP). La eficacia osciló entre 0,82 para TFV/FTC+DRV/p (PA) y 0,92 para TAF/FTC/EVG/COBI (PP). La eficiencia, en términos de coste/eficacia, osciló entre 7.923 y 12.765 euros por respondedor a las 48 semanas, para ABC/3TC/DTG (PP) y TFV/FTC+RAL (PP), respectivamente.

Conclusión: Considerando el precio oficial del TARV, la pauta más eficiente fue ABC/3TC/DTG (PP), seguida de TFV/FTC/RPV (PA) y TAF/FTC/EVG/COBI (PP).

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Introduction

Antiretroviral treatment (ART) has changed the human immunodeficiency virus (HIV) disease's natural course,^{1,2} and has made it possible for patients' life expectancy to approach that of the general population.³⁻⁵ ART is usually based on a three-drug approach with the goal of lowering the plasma viral load to undetectable levels, i.e., below a threshold of less than 50 copies/mL, and keep it suppressed as long as possible. In most cases, current ART regimens lead to a partial restoration of the immune system, both in quantity and quality, depending in part on the degree of baseline immunodeficiency levels.⁶⁻⁹ Thus, as a whole, ART is considered one of the top medical interventions in medical history in terms of cost/efficacy ratios, including developing countries.¹⁰⁻¹⁷

Expert panels from the AIDS Study Group (GESIDA for its Spanish acronym) of the Spanish Society of Infectious Diseases and Clinical Microbiology (SEIMC for its Spanish acronym) and the (Spanish) AIDS National Plan (PNS for its Spanish acronym) have issued their 2017 treatment guidelines. Their recommendations include 6 preferred regimens (PR), 7 alternative regimens (AR), and 10 referred as other regimens (OR) according to the scientific evidence from randomized clinical trials (RCT) and the expert panel's opinion.¹⁸ However, in the context of limited resources any therapeutic intervention must be applied efficiently. Thus, both costs incurred and outcomes obtained by the different ART must be examined to identify the most efficient regimens within those recommended by the GESIDA/PNS guidelines. There are other costs to consider, in addition to the drugs, including those incurred while managing adverse effects (AE) or the costs of drug-resistance studies, among others. Studies published between 2011 and 2016 evaluated the efficiency of ART recommended regimens by GESIDA/PNS.¹⁹⁻²⁴ Regimens recommended for 2017 differ from those recommended in previous years. In addition, new scientific evidence and changes in costs suggest the appropriateness of a new and updated economic evaluation of the current ART recommendations.

Consequently, the need for this new cost evaluation arose. The purpose of this study is to evaluate the costs and the efficiency (cost/efficacy) of the ART regimens proposed by the GESIDA/PNS 2017 guidelines as preferred and alternative initial therapies for HIV-infected patients who have not received previous ART (treatment-naïve patients).

Methods

The first step was to form a scientific committee (SC) of 19 Spanish experts identified by GESIDA (this paper's authors except AJB and PL) with experience in the clinical management of HIV-infected patients. SC's tasks included providing general advice, validating the assumptions made as part of the economic evaluation, supplying the RCTs used as scientific evidence, and providing expert opinion when the scientific evidence was insufficient.

Design

Economic assessment of the costs and efficiency (cost/efficacy) by building decision trees with deterministic sensitivity analysis. The decision trees were built for the calculation of costs, efficacy, and efficiency for each of the regimens recommended by GESIDA/PNS as PR and AR (Table 1). The analysis was performed from the payer's perspective: the Spanish National Health System (NHS) and, thus, only direct costs were considered. The setting is Spain and the model's time horizon is 48 weeks. This work is a cost and cost/efficacy analysis because ART outcomes are based on RCT findings (efficacy).

Models of economic evaluation

The model of economic analysis consists of as many decision trees as PR and AR. Each decision tree was built based on the data from the RCTs assessing the corresponding regimen and it

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