Enferm Infecc Microbiol Clin. 2015;33(3):156–165

Enfermedades Infecciosas y Microbiología Clínica

www.elsevier.es/eimc

Original article

Costs and cost-efficacy analysis of the 2014 GESIDA/Spanish National AIDS Plan recommended guidelines for initial antiretroviral therapy in HIV-infected adults

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ARTICLE INFO

Article history:
Received 11 April 2014
Accepted 25 May 2014
Available online 28 August 2014

Keywords:
Cost
Efficacy
Efficiency
HIV
AIDS
Antiretrovirals
Therapy

ABSTRACT

Introduction: GESIDA and the National AIDS Plan panel of experts suggest preferred (PR) and alternative (AR) regimens of antiretroviral treatment (ART) as initial therapy in HIV-infected patients for 2014. The objective of this study is to evaluate the costs and the efficiency of initiating treatment with these regimens.

Methods: An economic assessment was made 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 by considering only differential direct costs: ART (official prices), management of adverse effects, studies of resistance, and HLA B*5701 testing. The setting is Spain and costs correspond to those of 2014. A sensitivity deterministic 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 ranges from 5133 Euros for ABC/3TC + EFV to 11,949 Euros for TDF/FTC + RAL. The efficacy varies between 0.66 for ABC/3TC + LPV/r and ABC/3TC + ATV/r, and 0.89 for TDF/FTC/EVG/COBI. Efficiency, in terms of cost/efficacy, ranges from 7546 to 13,802 Euros per responder at 48 weeks, for ABC/3TC + EFV and TDF/FTC + RAL respectively.

Conclusion: Considering ART official prices, the most efficient regimen was ABC/3TC + EFV (AR), followed by the non-nucleoside containing PR (TDF/FTC/RPV and TDF/FTC/EFV). The sensitivity analysis confirms the robustness of these findings.

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http://dx.doi.org/10.1016/j.eimc.2014.05.016
0213-005X/

Análisis de costes y de coste/eficacia de las pautas recomendadas por GESIDA/Plan Nacional sobre el Sida en 2014 para el tratamiento antirretroviral inicial en adultos infectados por el VIH

Palabras clave:
Costes
Eficacia
Eficiencia
VIH
Sida
Antirretrovirales
Tratamiento

RESUMEN

Introducción: El panel de expertos de GESIDA/Plan Nacional del Sida ha recomendado pautas preferentes (PP) y alternativas (PA) de tratamiento antirretroviral (TARV) como terapia de inicio en pacientes infectados por VIH para 2014. El objetivo de este estudio es evaluar los costes y la eficiencia de iniciar tratamiento con estas pautas.

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 sólo costes directos diferenciales: fármacos (a precio oficial), manejo de efectos adversos, estudios de resistencias y determinación de HLA B*5701. El ámbito es España, con costes de 2014. Se realizó análisis de sensibilidad determinista construyendo tres escenarios para cada pauta: basal, más favorable y más desfavorable.

Resultados: En el escenario basal, los costes de iniciar tratamiento oscilaron entre 5.133 euros para ABC/3TC + EFV y 11.949 euros para TDF/FTC + RAL. La eficacia osciló entre 0,66 para ABC/3TC + LPV/r y ABC/3TC + ATV/r, y 0,89 para TDF/FTC/EVG/COBI. La eficiencia, en términos de coste/eficacia, osciló entre 7.546 y 13.802 euros por respondedor a las 48 semanas, para ABC/3TC + EFV y TDF/FTC + RAL, respectivamente.

Conclusión: Considerando el precio oficial del TARV, la pauta más eficiente fue ABC/3TC + EFV (PA), seguida de las PP que contienen no nucleósidos (TDF/FTC/RPV y TDF/FTC/EFV). El análisis de sensibilidad confirmó la robustez de estos hallazgos.

Introduction

Antiretroviral treatment (ART) has drastically reduced human immunodeficiency virus (HIV)-related morbidity/mortality. In fact, ART has changed the disease's natural course,[1,2] and has made it possible for patients' life expectancy to approach that of the general population.[3,4] 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.[5–8] 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.[9–16]

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 2014 treatment guidelines. Their recommendations include several preferred (PR) and alternative regimens (AR) supported by randomized clinical trials (RCT) and the expert panel's opinion.[17] However, in the context of limited resources any therapeutic intervention must be applied efficiently. Thus, both costs incurred and the results obtained by the different ART must be examined to identify the most efficient regimens within those recommended by the GESIDA/PNS guidelines as PR or AR. Evidently, in addition to the drugs, there are other costs to consider including those incurred while managing adverse effects (AE) or the costs of drug-resistance studies, among others. Studies published between 2011 and 2013 evaluated the efficiency of ART preferred regimens according to GESIDA/PNS.[18–20] Regimens recommended for 2014 as PR differ from those recommended in 2013 and the recommendations now include AR in the list. In addition, new scientific evidence and substantial changes in costs very likely rendered the 2013 study results obsolete.[20]

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 2014 guidelines as recommended initial therapies for HIV-infected patients who have not received previous ART, i.e., treatment-naïve patients.

Methods

The first step was to form a scientific committee (SC) of 18 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 RCT studies used as scientific evidence, and providing expert opinion when the scientific evidence was insufficient.

Design

The design is an 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 PR and AR recommended by GESIDA/PNS (Table 1). The analysis is performed from the payer's perspective: the Spanish National Health System (NHS) and, thus, only direct costs are considered. The setting is Spain and the model's time horizon is 48 weeks. This is a cost and cost/efficacy study because ART outcomes are based on CT findings (efficacy).

Models of economic evaluation

The model of economic analysis consists of as many decision trees as recommended regimens there are. Each decision tree is built based on the data from the CT assessing the corresponding regimen and it reproduces the regimen's characteristics in terms of efficacy, AE, and reasons for withdrawal (Table 1 and Fig. 1).