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Original article

Costs and cost-efficacy analysis of the 2016 GESIDA/Spanish AIDS National Plan recommended guidelines for initial antiretroviral therapy in HIV-infected adults

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ABSTRACT

Introduction: GESIDA and the AIDS National Plan panel of experts suggest preferred (PR), alternative (AR), and other regimens (OR) for antiretroviral treatment (ART) as initial therapy in HIV-infected patients for the year 2016. The objective of this study is to evaluate the costs and the efficacy of initiating treatment with these regimens.

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, only taking into account differential direct costs: ART (official prices), management of adverse effects, studies of resistance, and HLA B*5701 testing. The setting is Spain and the costs correspond to those of 2016. A sensitivity deterministic analysis was conducted, building three scenarios for each regimen: base case, most favourable, and least favourable.

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Results: In the base case scenario, the cost of initiating treatment ranges from 4663 Euros for 3TC + LPV/r (OR) to 10,894 Euros for TDF/FTC + RAL (PR). The efficacy varies from 0.66 for ABC/3TC + ATV/r (AR) and ABC/3TC + LPV/r (OR), to 0.89 for TDF/FTC + DTG (PR) and TDF/FTC/EVG/COBI (AR). The efficiency, in terms of cost/efficacy, ranges from 5280 to 12,836 Euros per responder at 48 weeks, for 3TC + LPV/r (OR), and RAL + DRV/r (OR), respectively.
Conclusion: Despite the overall most efficient regimen being 3TC + LPV/r (OR), among the PR and AR, the most efficient regimen was ABC/3TC/DTG (PR). Among the AR regimes, the most efficient was TDF/FTC/RPV.
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Análisis de costes y de coste/eficacia de las pautas recomendadas por GESIDA/Plan Nacional sobre el Sida en 2016 para el tratamiento antirretroviral inicial en adultos infectados por el VIH

Palabras clave:
Costes
Eficacia
Eficiencia
VIH
Sida
Tratamiento antirretroviral

R E S U M E N

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 2016. 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 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 2016. Se realizó análisis de sensibilidad determinista construyendo 3 escenarios para cada pauta: basal, más favourable y más desfavorable.
Resultados: En el escenario basal, los costes de iniciar tratamiento oscilaron entre 4.663 euros para 3TC + LPV/r (OP) y 10.894 euros para TDF/FTC + RAL (PP). La eficacia osciló entre 0,66 para ABC/3TC + ATV/r (PA) y ABC/3TC + LPV/r (OP), y 0,89 para TDF/FTC + DTG (PP) y TDF/FTC/EVG/COBI (PA). La eficiencia, en términos de coste/eficacia, osciló entre 5.280 y 12.836 euros por respondedor a las 48 semanas, para 3TC + LPV/r (OP) y RAL + DRV/r (OP), respectivamente.
Conclusión: Aunque globalmente la pauta más eficiente fue 3TC + LPV/r (OP), considerando solamente las PP y las PA, la pauta más eficiente fue ABC/3TC/DTG (PP). De las PA, la más eficiente fue TDF/FTC/RPV.
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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.[3,4] 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 2016 treatment guidelines. Their recommendations include 4 preferred regimens (PR), 7 alternative regimens (AR), and 8 referred as other regimens (OR) according to the scientific evidence from 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 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 2015 evaluated the efficiency of ART recommended regimens by GESIDA/PNS.[18–22] Regimens recommended for 2016 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 2016 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 16 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,

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