Journal of the International AIDS Society

Poster presentation

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Economic modeling of the combined effects of HIV disease, heart disease and lipoatrophy based on ACTG 5142 trial data

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from Ninth International Congress on Drug Therapy in HIV Infection
Glasgow, UK. 9–13 November 2008

Published: 10 November 2008

Journal of the International AIDS Society 2008, **11**(Suppl 1):P312 doi:10.1186/1758-2652-11-S1-P312

This abstract is available from: http://www.jiasociety.org/content/11/S1/P312

Purpose of the study

Antiretroviral (ARV) regimens may be statistically non-inferior in clinical trials, but have very different economic outcomes due to differences in costs and adverse event profiles. Given the heavy cost burden of HIV disease, it is important to consider economic issues when selecting an ARV regimen. This study examines the cost and consequences of initiating an ARV regimen including LPV/r or EFV, using data from a recent clinical trial in a previously published model of HIV-disease.

Methods

We populated the Markov model of HIV-disease with data from A5142 study to estimate the economic outcomes of starting ARV therapy with a PI-containing regimen as compared to an NNRTI-containing regimen, given their virologic and immunologic efficacy and effects on cholesterol and lipoatrophy. CNS toxicities and GI tolerability were not included in the model because of their transient nature, low cost remedies and lack of economic impact. CD4+ T-cell counts and the HIV-1 RNA (viral load) values from the study, were used to assign a specific health state (HS) to each patient for each quarter-year. The resulting frequencies used as "raw" data directly into the model obviate the reliance on statistical tests, and allow the model to reflect actual patient behavior in the clinical trial. An HS just below the last observed HS was used to replace a missing value.

Summary of results

The modeled estimates (undiscounted) for the LPV/r-based regimen results in 1.41 quality-adjusted life months (QALMs) gained over a lifetime compared to the EFV-based regimen. The LPV/r-based regimen incurs $7,458 (1.8%) greater cost over a lifetime due to differences in drug costs and survival. The incremental cost-effectiveness ratio using the discounted cost and QALYs is $88,829/QALY. Most of the higher costs accrue before the 7th year of treatment and are offset by subsequent savings. The estimates are highly sensitive to the effect of lipoatrophy on quality of life, but not to the effect of cholesterol levels.

Conclusion

Initiating an LPV/r-containing regimen on ARV-naive patients appears cost-effective compared to an EFV-based regimen, when the cost and consequences of lipoatrophy are included.