Journal of the International AIDS Society

Poster presentation

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96 weeks pharmacoeconomic outcome of lopinavir/r monotherapy as maintenance strategy in HIV+ patients with suppressed viral load. OK04-PharmECO analysis

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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):P308 doi:10.1186/1758-2652-11-S1-P308

This abstract is available from: http://www.jiasociety.org/content/11/S1/P308

Purpose of the study

The OK04 clinical trial has shown, at 96 weeks, that lopinavir/ritonavir (LPV/r) monotherapy (MT) with re-introduction of nucleosides as needed was non-inferior to continuation of triple therapy (T) [1]. A pharmacoeconomic analysis from the perspective of the Spanish Healthcare System was performed to estimate cost-effectiveness of both study arms.

Methods

OK04 methodology, baseline characteristics, and 96-week efficacy/safety related outcomes showing non-inferiority have been described elsewhere [1]. Briefly, 198 patients were randomised 1:1 to the MT (n = 100) or T (n = 98). Virological efficacy was defined as absence of virological failure, i.e. two consecutive plasma HIV-RNA concentrations >500 copies/mL through 96 weeks from the start of the study without changes on randomized treatment. Therapeutic efficacy included the maintenance of undetectable viral load (<50 cop/mL) with the re-induction of nucleosides in MT arm (if necessary). Data on resource utilization related with follow-up, reported adverse events (AE) management, concomitant medications and extra-procedures were collected. Direct costs were computed from resource utilization in Spanish 2007 euros. Incremental cost-effectiveness ratio of MT vs. T (MT-T) was calculated. An annual 3% discount rate was applied both for costs and results. Sensitivity analyses were performed, including a Montecarlo simulation of 10,000 samples.

Summary of results

After 96 weeks, therapeutic efficacy was 84.5% (MT) vs. 76.8% (T) (MT-T = 7.6%). MT showed better results vs. T in time on therapeutic efficacy (incremental time mean, 3.7 weeks-patient), time on virological efficacy (incremental time mean, 2.3 weeks-patient), and the proportion of AEs related with study drug drop-outs (differential %, -8.0%). No difference was found on number of future treatment options. Differential costs were -5,563 €/patient, mainly due to antiretroviral-related differential drug acquistion costs. Economic analysis showed MT dominance in cost/therapeutic efficacy, cost/patient-week on therapeutic and virological efficacy, and cost/avoided drop-out related to the study drug. Probabilistic sensitivity analysis showed 93.65% scenarios where MT therapeutic efficacy was cost effective (77.5% dominant).

Conclusion

LPV/r MT (including re-introduction of nucleosides as needed) is an efficient option for maintenance therapy in HIV-infected patients when compared with LPV/r T. This may become a breakthrough treatment decision criterion in current health saving costs environment.

References

1. Arribas JR, *et al.*: **PS3/1. 11th EACS, Madrid, October 2007; PS3/1.** .