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Predictors of Loss of Virologic Response in Subjects Who Simplified to Lopinavir/Ritonavir Monotherapy from Lopinavir/Ritonavir Plus Zidovudine/Lamivudine

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Abstract

Previous studies have demonstrated that lopinavir/ritonavir monotherapy maintained plasma HIV-1 RNA suppression in a large proportion of antiretroviral naive subjects. However, more subjects receiving lopinavir/ritonavir monotherapy experienced confirmed virologic rebound >50 copies/ml compared to a standard three-drug HAART regimen. In this study, we sought to determine the factors associated with maintenance of virologic suppression in subjects receiving lopinavir/ritonavir monotherapy. Antiretroviral-naive HIV-1-infected volunteers were randomized 2:1 to initiate a lopinavir/ritonavir-based combination regimen followed by simplification to lopinavir/ritonavir monotherapy or an efavirenz-based triple combination therapy and followed for 96 weeks. Potential predictors of time to loss of virologic response included baseline demographics, baseline HIV-1 RNA levels, baseline CD4⁺ T cell counts, adherence as determined by 4-day subject recall, duration of HIV-1 RNA <50 copies/ml prior to simplification, and lopinavir concentrations. By the Cox proportional hazards model, higher reported adherence levels and higher baseline CD4⁺ T cell counts were associated with a greater likelihood of maintaining virologic suppression while receiving lopinavir/ritonavir monotherapy. Lopinavir concentrations, including trough concentrations, were not significantly associated with virologic outcomes. This analysis suggests that adherence and higher baseline CD4⁺ T cell counts may help to predict who will sustain virologic suppression with lopinavir/ritonavir monotherapy. The data also suggest that measuring lopinavir concentrations is not useful in predicting virologic response in these patients.

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Predictors of Loss of Virologic Response in Subjects Who Simplified to Lopinavir/Ritonavir Monotherapy from Lopinavir/Ritonavir Plus Zidovudine/Lamivudine

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Abstract

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Introduction

THE INTRODUCTION OF COMBINATION antiretroviral therapy resulted in a marked reduction in HIV-1-associated mortality, long-term suppression of human immunodeficiency virus type 1 (HIV-1) infection, and immunologic reconstitution.¹ However, these therapies can be associated with complex dosing schedules, significant toxicities, and high cost. A number of approaches to simplifying treatment have been investigated and have included initial monotherapy as well as combination therapy followed by simplification to monotherapy after variable periods of successful suppression of plasma viremia.

Several pilot studies of lopinavir/ritonavir monotherapy following induction with combination antiretroviral therapy have suggested that monotherapy may be an effective therapeutic option for treating antiretroviral-naive subjects.²⁻⁶ The largest of these studies, the OK04 study, demonstrated that among 177 antiretroviral naive subjects who experienced virologic suppression with a regimen of lopinavir/ritonavir and two nucleoside reverse transcriptase inhibitors (NRTIs) and simplified treatment to lopinavir/ritonavir monotherapy or continued triple combination therapy, similar rates of virologic suppression (HIV RNA <50 copies/ml) were maintained through 48 weeks (85% versus 90%, respectively; $p = 0.31$).⁷

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