

Atazanavir + ritonavir vs. Lopinavir-ritonavir
CASTLE Study

Atazanavir + Ritonavir vs. Lopinavir-ritonavir in Treatment-Naïve CASTLE: Study Design

Study Design: CASTLE

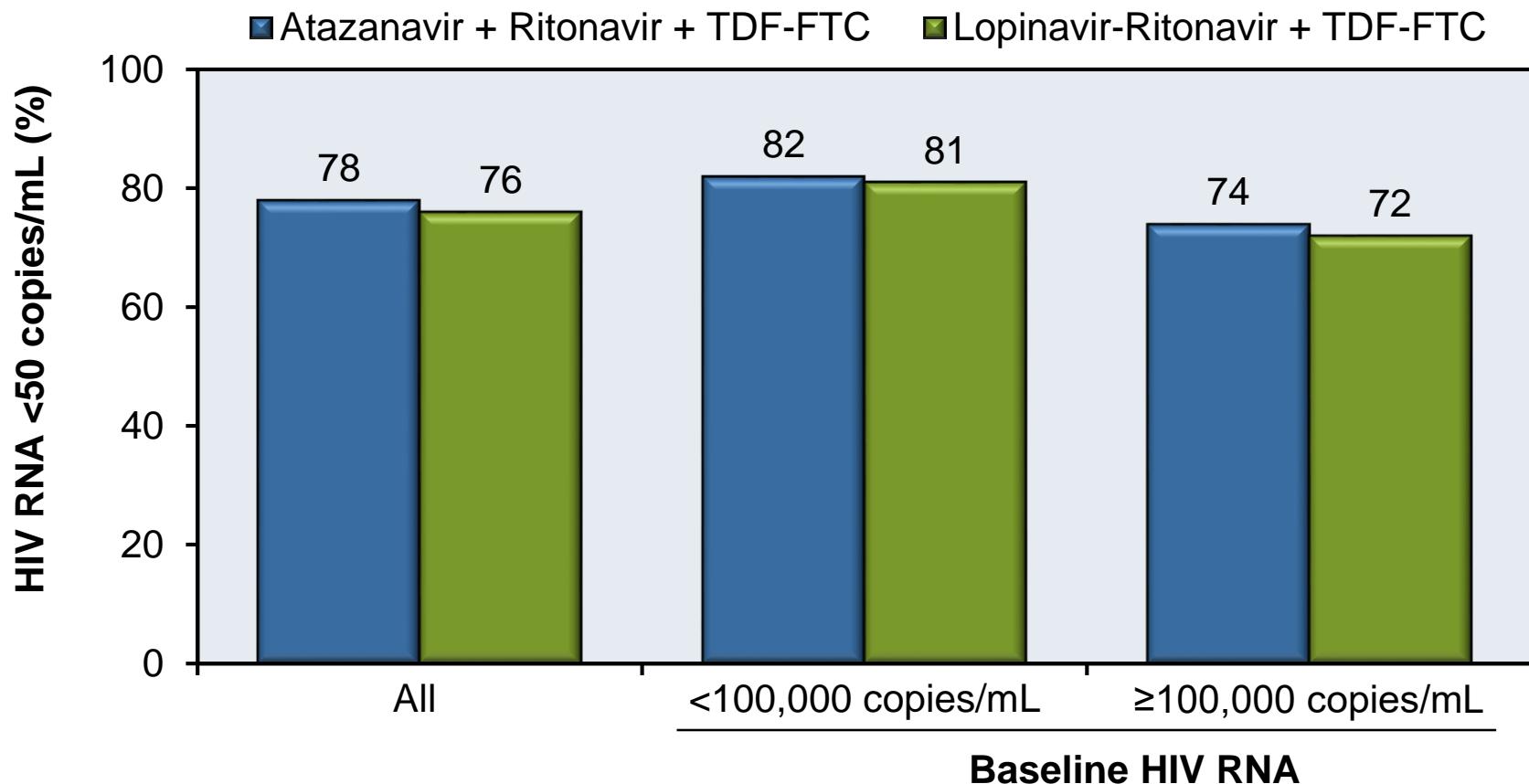
- Background:** Randomized, open label trial to evaluate the comparative efficacy of once-daily atazanavir + ritonavir versus twice-daily lopinavir-ritonavir, each with fixed dose tenofovir DF-emtricitabine, in treatment-naïve adults with HIV infection
- Inclusion Criteria (n = 883)**
 - Age ≥18
 - Antiretroviral treatment-naïve
 - HIV RNA >5000 copies/mL
 - No CD4 count restrictions
- Treatment Arms**
 - Atazanavir 300 mg QD+ Ritonavir 100 mg QD + Tenofovir DF-emtricitabine QD
 - Lopinavir-ritonavir 400-100mg BID + Tenofovir DF-emtricitabine QD

**Atazanavir + Ritonavir +
Tenofovir DF-Emtricitabine
(n = 440)**

**Lopinavir-ritonavir +
Tenofovir DF-Emtricitabine
(n = 443)**

Atazanavir + Ritonavir vs. Lopinavir-ritonavir in Treatment-Naïve CASTLE: Results

Week 48: Virologic Response, by Baseline HIV RNA (ITT: CVR, NC= F*)

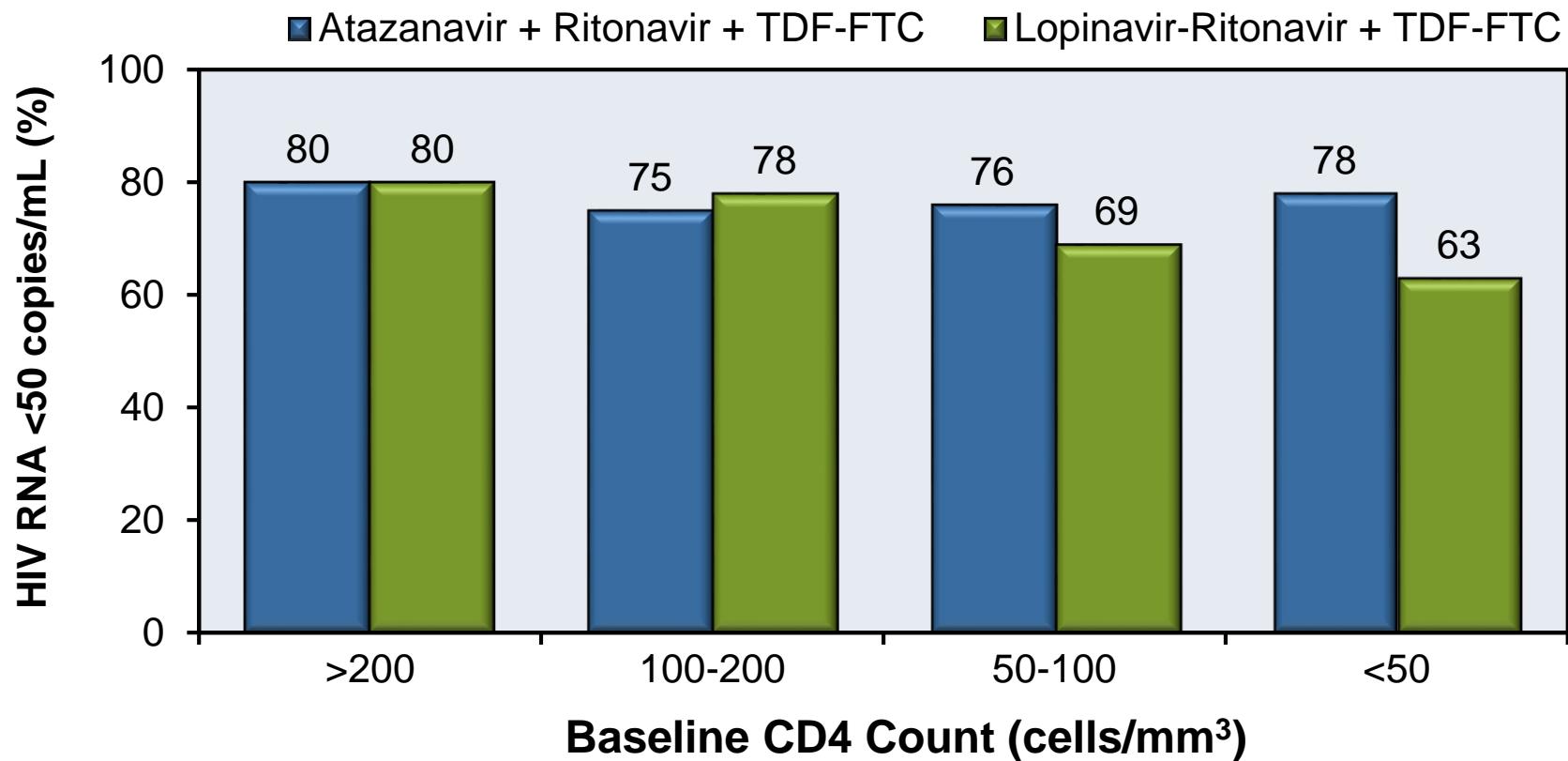


*ITT= intent to treat; CVR = confirmed virologic response; NC = non completer = failure

Source: Molina JM, et al. Lancet. 2008;372:646-55.

Atazanavir + Ritonavir vs. Lopinavir-ritonavir in Treatment-Naïve CASTLE: Results

Week 48: Virologic Response, by Baseline CD4 Cell Count

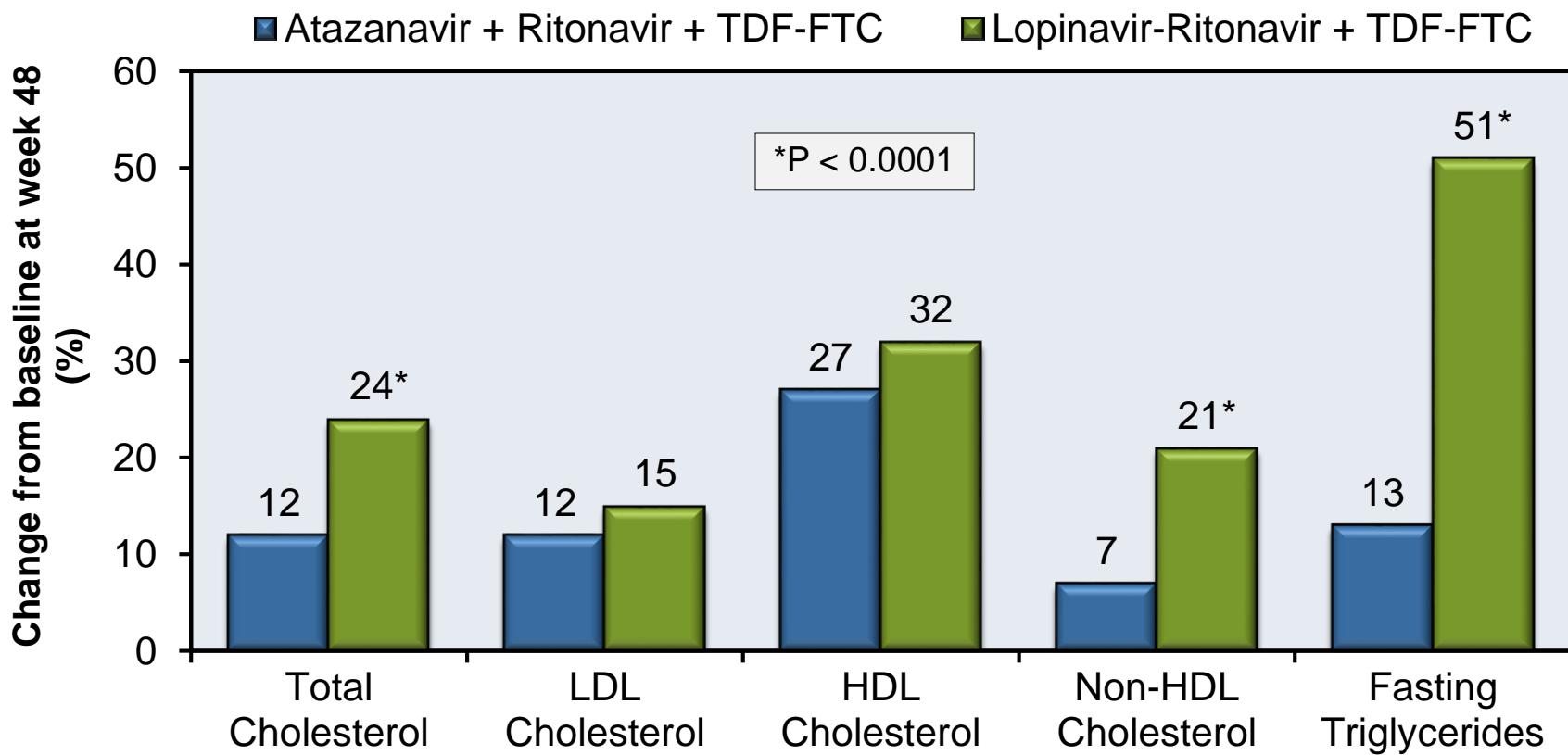


*ITT= intent to treat; CVR = confirmed virologic response; NC = non completer = failure

Source: Molina JM, et al. Lancet. 2008;372:646-55.

Atazanavir + Ritonavir vs. Lopinavir-ritonavir in Treatment-Naïve CASTLE: Results

Week 48: Change in Fasting Lipids from Baseline



Source: Molina JM, et al. Lancet. 2008;372:646-55.

Atazanavir + Ritonavir vs. Lopinavir-ritonavir in Treatment-Naïve CASTLE: Conclusions

Interpretation: “In treatment-naive patients, atazanavir/ritonavir once-daily demonstrated similar antiviral efficacy to lopinavir/ritonavir twice-daily, with less gastrointestinal toxicity but with a higher rate of hyperbilirubinaemia.”

Acknowledgment

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