Lopinavir-RTV + Raltegravir vs. Lopinavir-RTV + TDF-FTC

PROGRESS Trial

Lopinavir-RTV + Raltegravir vs. Lopinavir-RTV + TDF-FTC
PROGRESS: Study Design

Study Design: PROGRESS

- **Background**: Randomized, open-label non-inferiority trial comparing efficacy, safety, and tolerability of lopinavir-ritonavir with either raltegravir or tenofovir DF-emtricitabine in treatment-naïve persons with HIV.
- **Inclusion Criteria (n = 206)**
  - Antiretroviral-naïve patients
  - Age ≥18 years
  - HIV RNA ≥1000 copies/mL
  - Antiretroviral therapy naïve
  - No resistance to lopinavir, TDF, or FTC
- **Treatment Arms**
  - Lopinavir-RTV BID + Raltegravir BID
  - Lopinavir-RTV BID + TDF-FTC QD

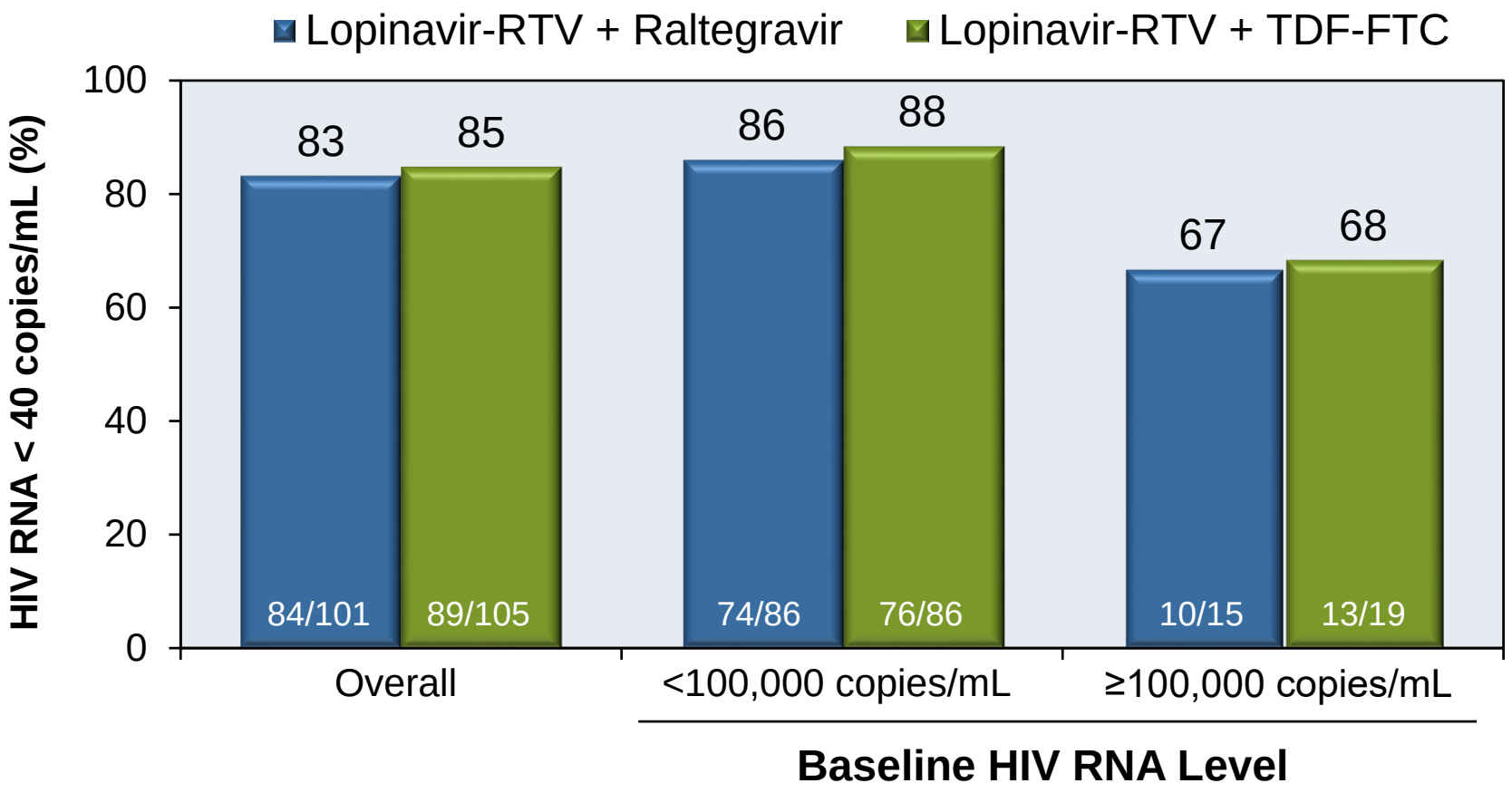
Lopinavir-ritonavir BID + Raltegravir BID +
(n = 101)

Lopinavir-ritonavir BID + TDF-FTC QD
(n = 105)

Source: Reynes J, et al. HIV Clin Trials. 2011;12:255-67.

Lopinavir-RTV + Raltegravir vs. Lopinavir-RTV + TDF-FTC
PROGRESS: Result

Week 48 Virologic Response (FDA-TLOVR Algorithm)



Source: Reynes J, et al. HIV Clin Trials. 2011;12:255-67.

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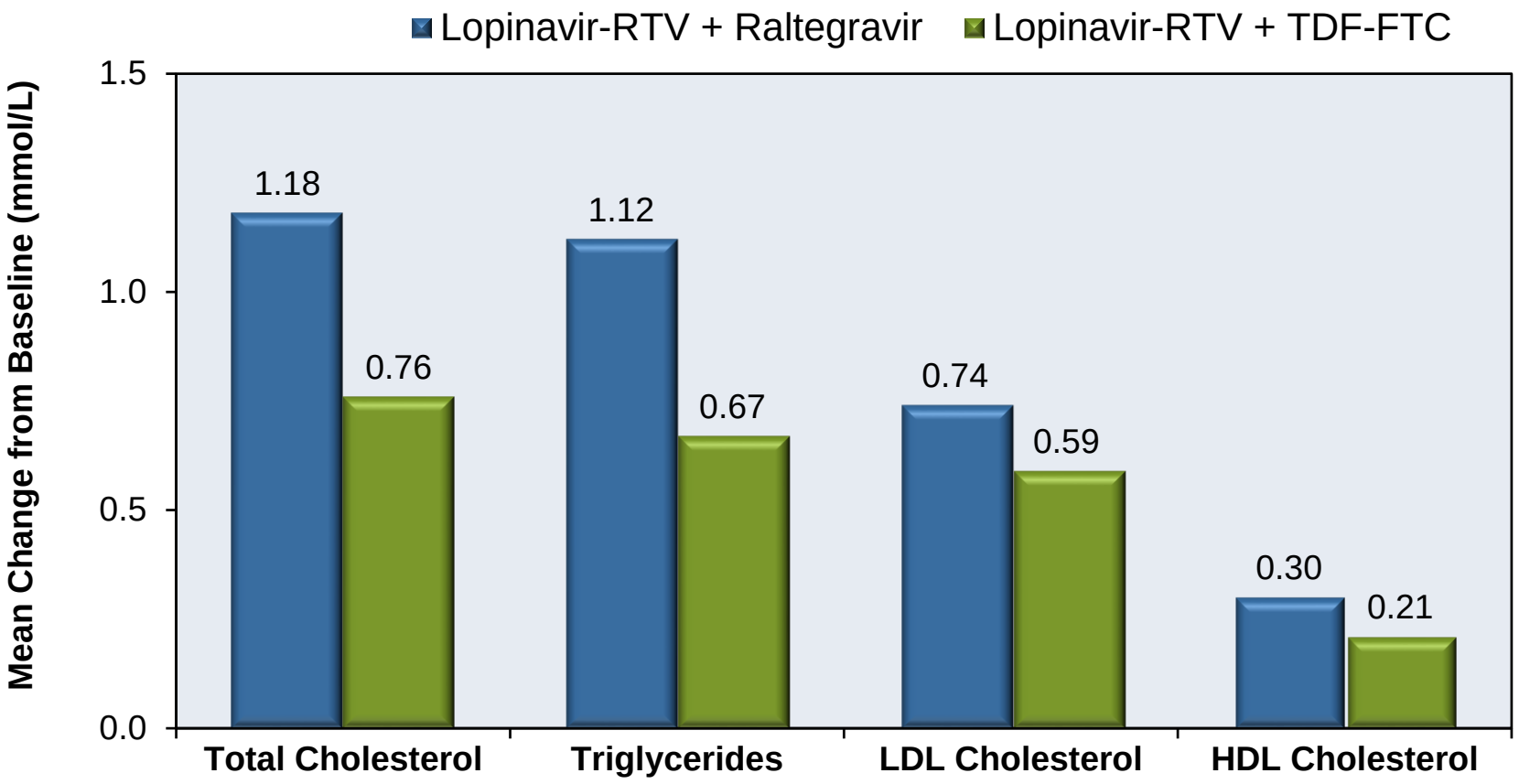
Lopinavir-RTV + Raltegravir vs. Lopinavir-RTV + TDF-FTC
PROGRESS: Result

Possibly/probably Treatment-Related Moderate to Serious Adverse Events Occurring in ≥2% of Subjects in Either Arm		
Variable	**LPV-RTV + RAL (n = 101)**	**LPV-RTV + TDF-FTC (n = 105)**
Any adverse event (%)	27.7%	27.6%
Hyperlipidemia	13.9%	8.6%
Diarrhea	7.9%	13.3%
Alanine Aminotransferase increased	2%	1%

Source: Reynes J, et al. HIV Clin Trials. 2011;12:255-67.

Lopinavir-RTV + Raltegravir vs. Lopinavir-RTV + TDF-FTC
PROGRESS: Result

Week 48: Analysis of Lipids



Source: Reynes J, et al. HIV Clin Trials. 2011;12:255-67.

Lopinavir-RTV + Raltegravir vs. Lopinavir-RTV + TDF-FTC
PROGRESS: Conclusions

Conclusions: “The HIV treatment regimen of LPV/r + RAL resulted in noninferior efficacy and comparable safety and tolerability compared with a traditional NRTI-containing regimen through 48 weeks of treatment. These results support further evaluation of the LPV/r + RAL regimen.”

Source: Reynes J, et al. HIV Clin Trials. 2011;12:255-67.

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