

LPV-RTV Monotherapy vs. LPV-RTV + 2 NRTIs  
**OK04 Trial**

# LPV-RTV vs. LPV-RTV + 2 NRTIs in Treatment-Experienced OK04: Study Design

## Study Design: OK04

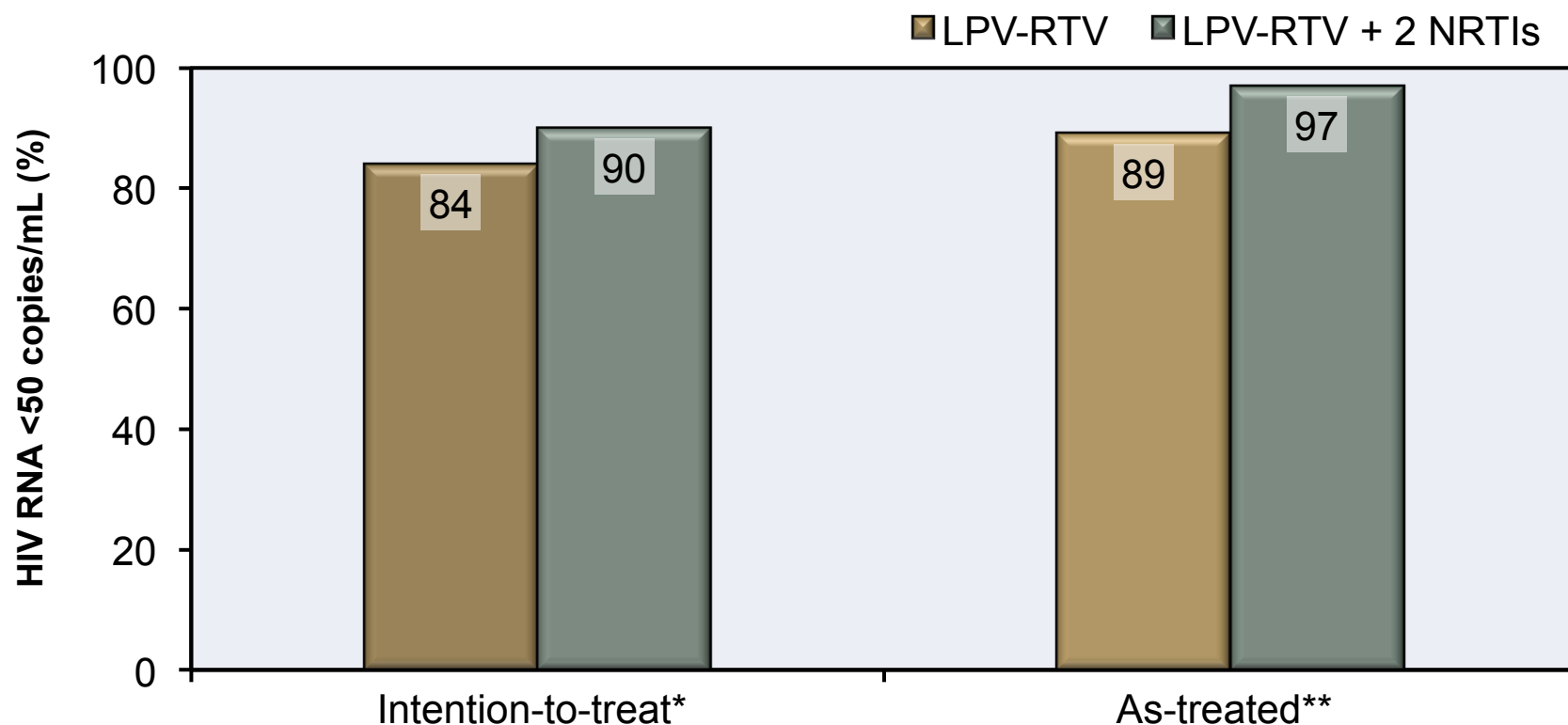
- **Background:** Randomized, open-label, phase III/IV study comparing lopinavir-ritonavir monotherapy with lopinavir-ritonavir and 2 NRTIs for maintenance of viral suppression in treatment-experienced patients with HIV infection
- **Inclusion Criteria (n = 205)**
  - Age  $\geq 18$
  - Taking LPV/r + 2 NRTIs for  $\geq 4$  weeks
  - HIV RNA  $< 50$  copies/mL for  $\geq 6$  months
  - No history of virologic failure on PI regimen
- **Treatment Arms**
  - Lopinavir-ritonavir 400-100 mg BID
  - Lopinavir-ritonavir 400-100 mg BID + 2 NRTIs (or 1 NRTI and tenofovir DF)

*Monotherapy group*  
**Lopinavir-ritonavir  
400-100 mg BID**  
(n = 100)

*Triple therapy group*  
**Lopinavir-ritonavir  
400-100 mg BID + 2 NRTIs**  
(n = 98)

# LPV-RTV vs. LPV-RTV + 2 NRTIs in Treatment-Experienced OK04: Results

Week 48: Virologic Response



\*ITT analysis: missing=failure, NRTI reintroduction=failure

\*\*As-treated analysis: NRTI reintroduction=failure, missing or change in therapy=censored

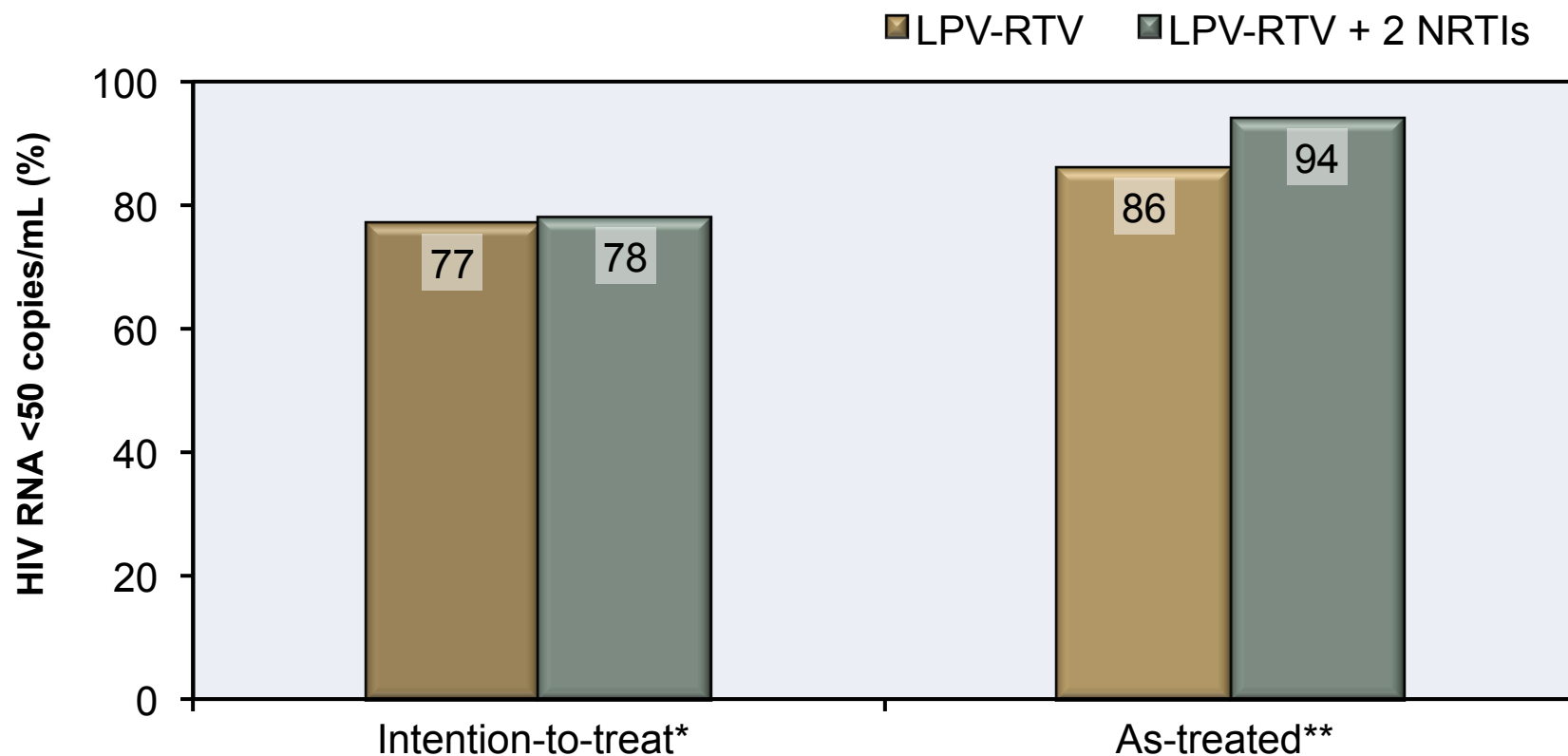
Source: Pulido F, et al. AIDS. 2008;22:F1-9.

# LPV-RTV vs. LPV-RTV + 2 NRTIs in Treatment-Experienced OK04: Conclusion

**Conclusion:** “In this trial, 48 weeks of lopinavir-ritonavir monotherapy with reintroduction of nucleosides as needed was non-inferior to continuation of two nucleosides and lopinavir-ritonavir in patients with prior stable suppression. However, episodes of low level viremia were more common in patients receiving monotherapy.”

# LPV-RTV vs. LPV-RTV + 2 NRTIs in Treatment-Experienced OK04: Results

Week 96: Virologic Response



\*ITT analysis: missing=failure, NRTI reintroduction=failure

\*\*As-treated analysis: reintroduction=failure, missing or change in therapy=censored

Source: Arribas JR, et al. *J Acquir Immune Defic Syndr.* 2009;51:147-52.

# Acknowledgment

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*The content in this slide set does not represent the official views of the U.S. Department of Health and Human Services, Health Resources & Services Administration.*

