

Atazanavir versus Lopinavir-ritonavir in Prior PI Failure

# **AI424-043 Study**

# Atazanavir vs. Lopinavir-ritonavir in Previous PI Failure

## A1424-043: Study Design

### Study Design: A1424-043

- **Background:** Randomized, open label, phase 3 trial to evaluate the efficacy and safety of atazanavir versus lopinavir-ritonavir in adults with HIV infection and a history of PI failure
- **Inclusion Criteria (n = 290)**
  - Age  $\geq 16$
  - One previous PI-based regimen failure
  - $<10$ -fold phenotypic resistance to atazanavir and lopinavir-ritonavir
  - HIV RNA  $\geq 5000$  copies/mL
  - CD4 count  $\geq 50$  cells/mm<sup>3</sup>
  - No lipid-lowering therapy
- **Treatment Arms**
  - Atazanavir 400 mg once daily + 2 NRTIs (excluding tenofovir)
  - Lopinavir-ritonavir 400-100 mg twice daily + 2 NRTIs (excluding tenofovir)

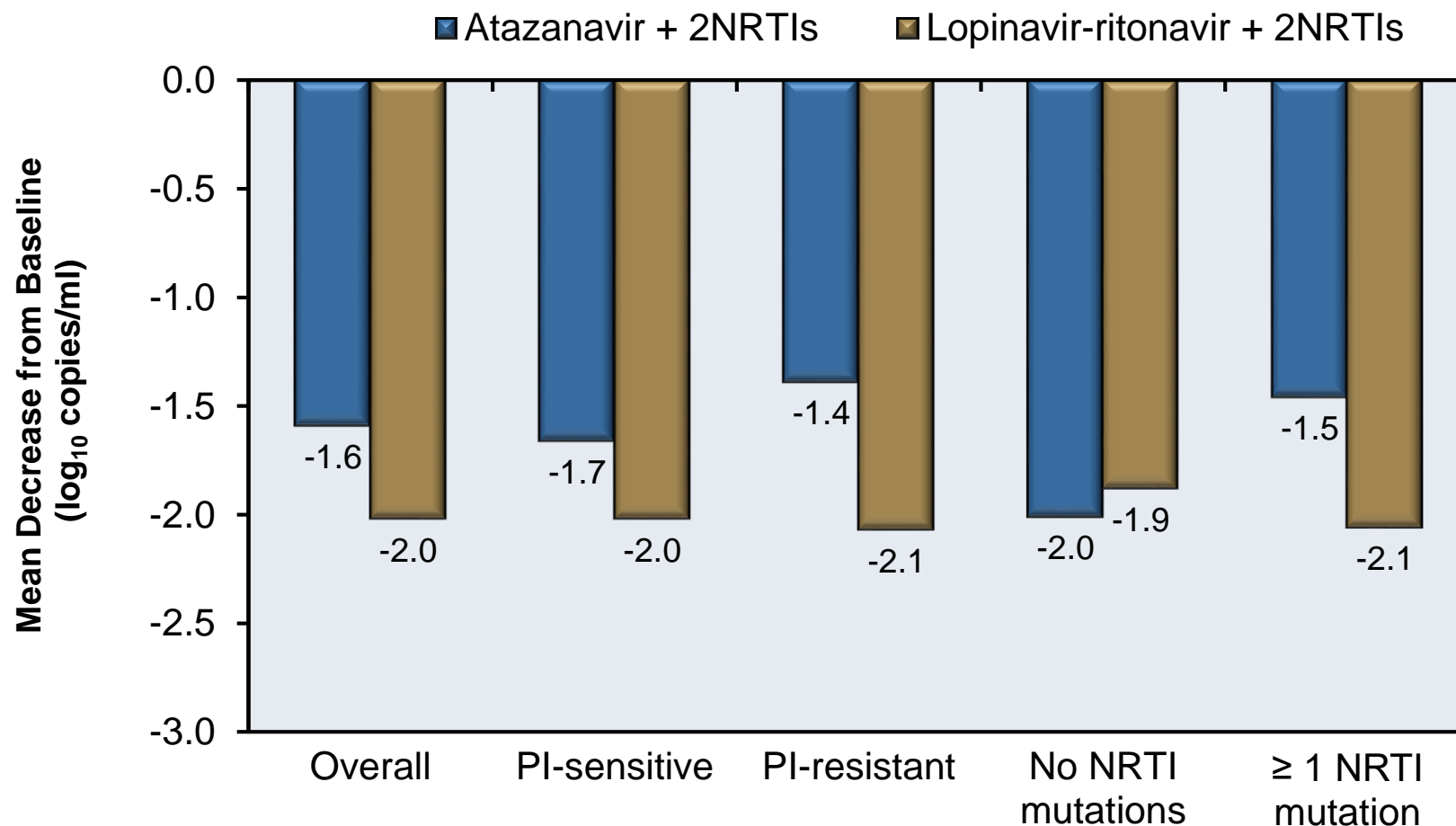
**Atazanavir 400 mg once daily  
+ 2 NRTIs**  
(n = 144)

**Lopinavir-ritonavir 400-100mg  
twice daily + 2 NRTIs**  
(n = 146)

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## AI424-043: Results

Week 48: Magnitude of Viral Suppression (Primary Efficacy Measure)

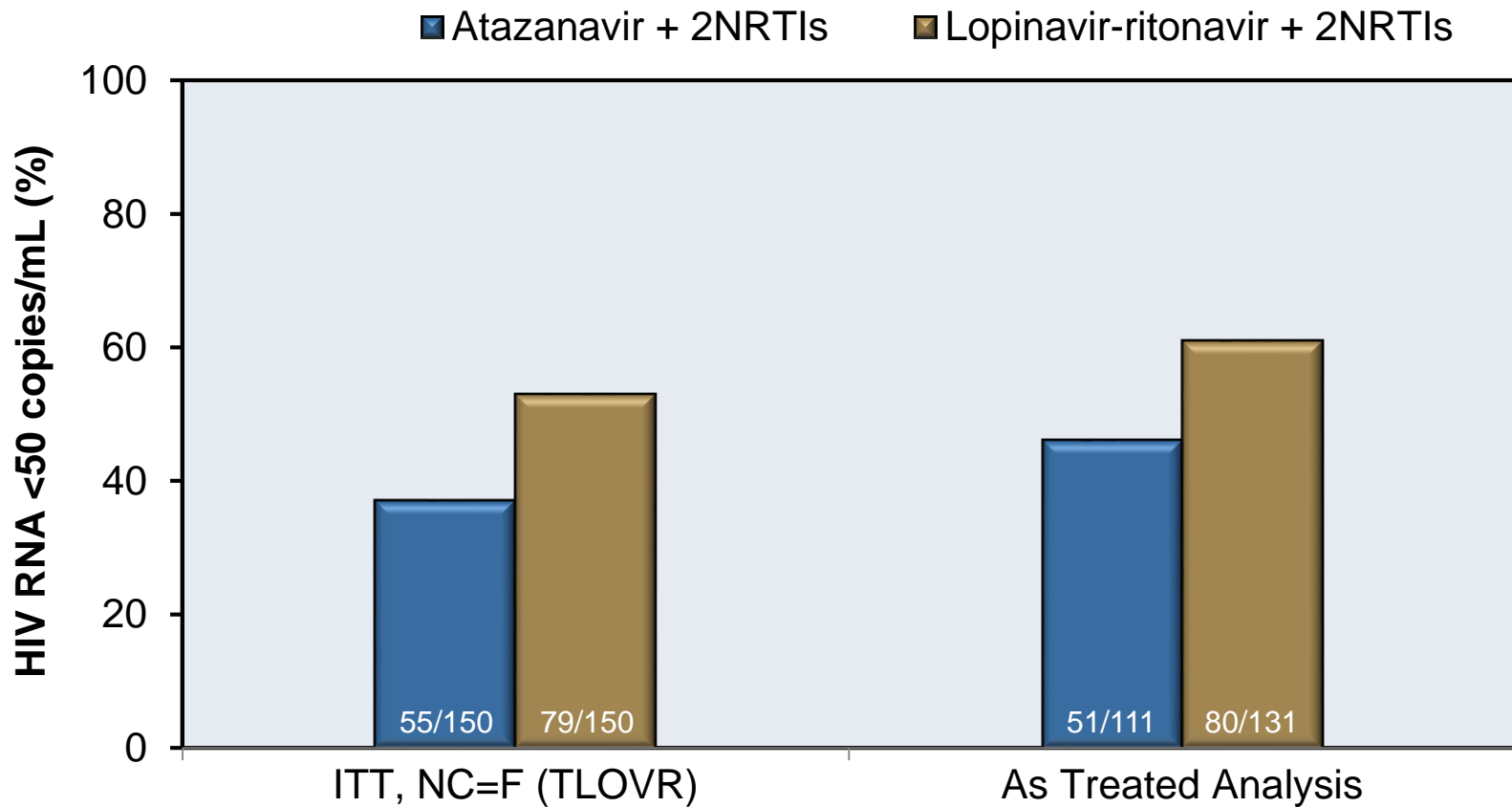


Source: Cohen C, et al. Curr Med Res Opin. 2005;21:1683-92.

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## AI424-043: Results

Week 48: Virologic Response



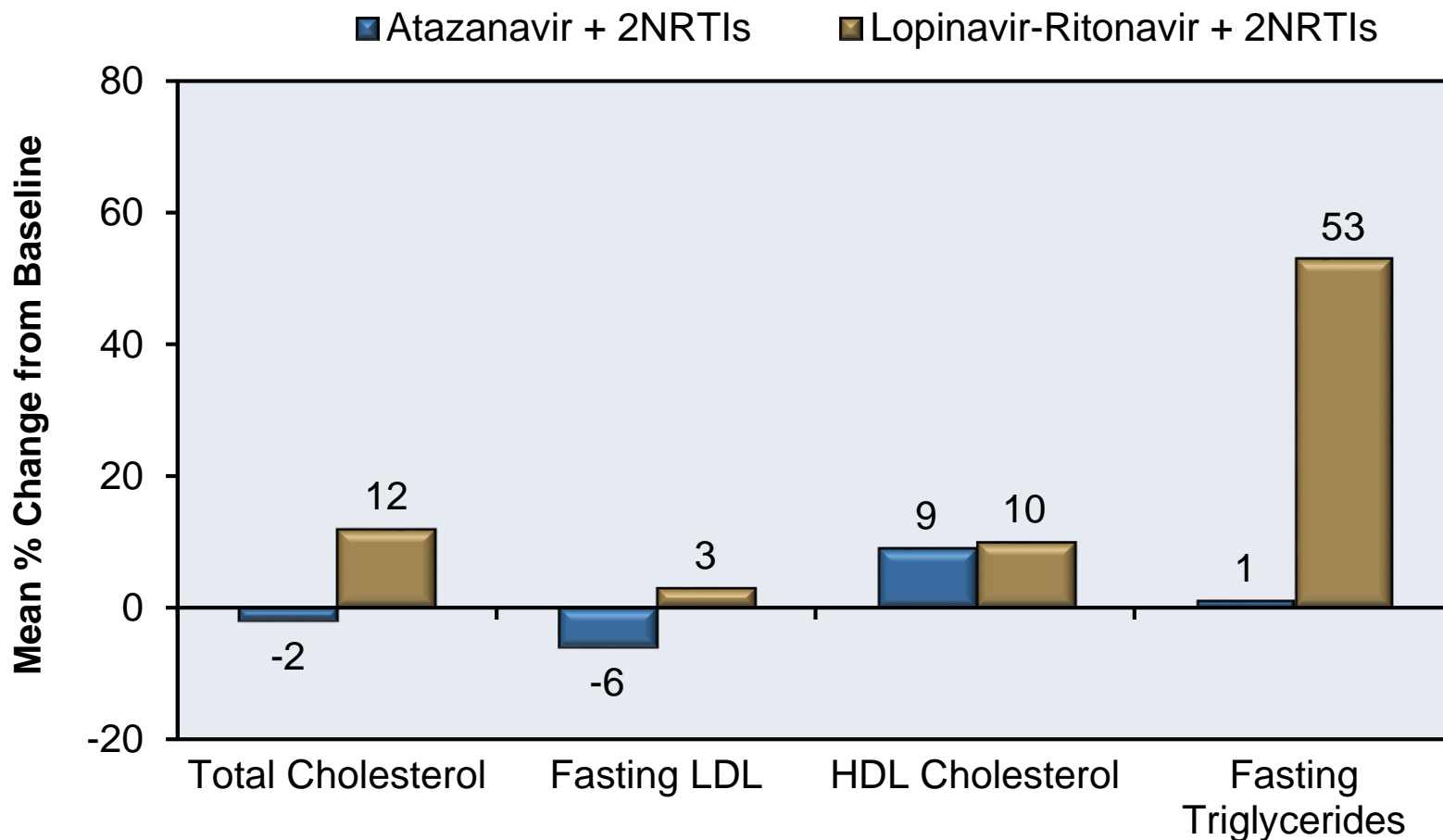
ITT: Intent-to-treat, NC=F: noncompleter=failure, TLOVR: time-to-loss-of virologic response

Source: Cohen C, et al. *Curr Med Res Opin.* 2005;21:1683-92.

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## AI424-043: Results

Week 48: Changes in Lipid Concentrations



Source: Cohen C, et al. Curr Med Res Opin. 2005;21:1683-92.

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## AI424-043: Conclusions

**Conclusions:** “While both treatments demonstrated good antiviral efficacy, relatively greater antiviral suppression was observed with lopinavir/ritonavir. In those patients with no NRTI mutations at baseline, both regimens demonstrated comparable virologic suppression. Atazanavir-treated patients demonstrated a superior lipid profile and required less frequent lipid-lowering treatment.”

# 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.*

