

LPV-RTV + 3TC vs. LPV-RTV + 2 NRTIs in Virologically Suppressed
OLE Trial

LPV-RTV + 3TC vs. LPV-RTV + 2 NRTIs in Virologically Suppressed OLE: Study Design

Study Design: OLE

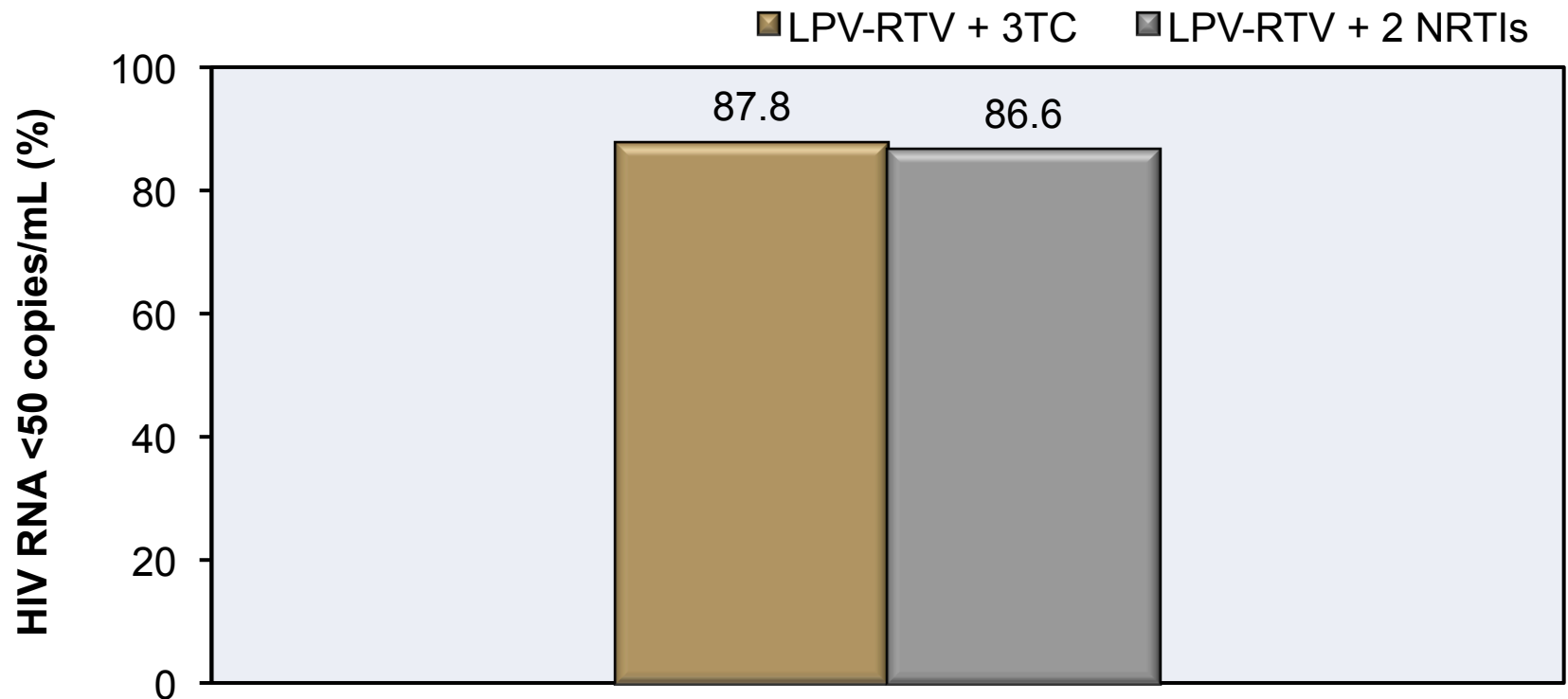
- **Background:** Randomized, open-label, non-inferiority, phase 3 trial to compare the dual treatment (lopinavir-ritonavir plus lamivudine) with triple treatment (lopinavir-ritonavir plus two NRTIs) in treatment-experienced persons with suppressed HIV RNA levels
- **Inclusion Criteria (n = 250)**
 - Age ≥ 18
 - Taking LPV-RTV + (3TC or FTC) + 2nd NRTI for ≥ 2 months
 - HIV RNA < 50 copies/mL for ≥ 6 months
 - No genotypic resistance (or history of failure) to LPV, ritonavir, 3TC, or FTC
- **Treatment Arms**
 - Lopinavir-ritonavir 400-100 mg BID + 3TC
 - Lopinavir-ritonavir 400-100mg BID + (3TC or FTC) + 2nd NRTI

Dual treatment
**Lopinavir-ritonavir
400-100 mg BID + 3TC**
(n = 123)

Triple treatment
**Lopinavir-ritonavir
400-100 mg BID + 2NRTIs**
(n=127)

LPV-RTV + 3TC versus LPV-RTV + 2 NRTIs in Virologically Suppressed OLE: Results

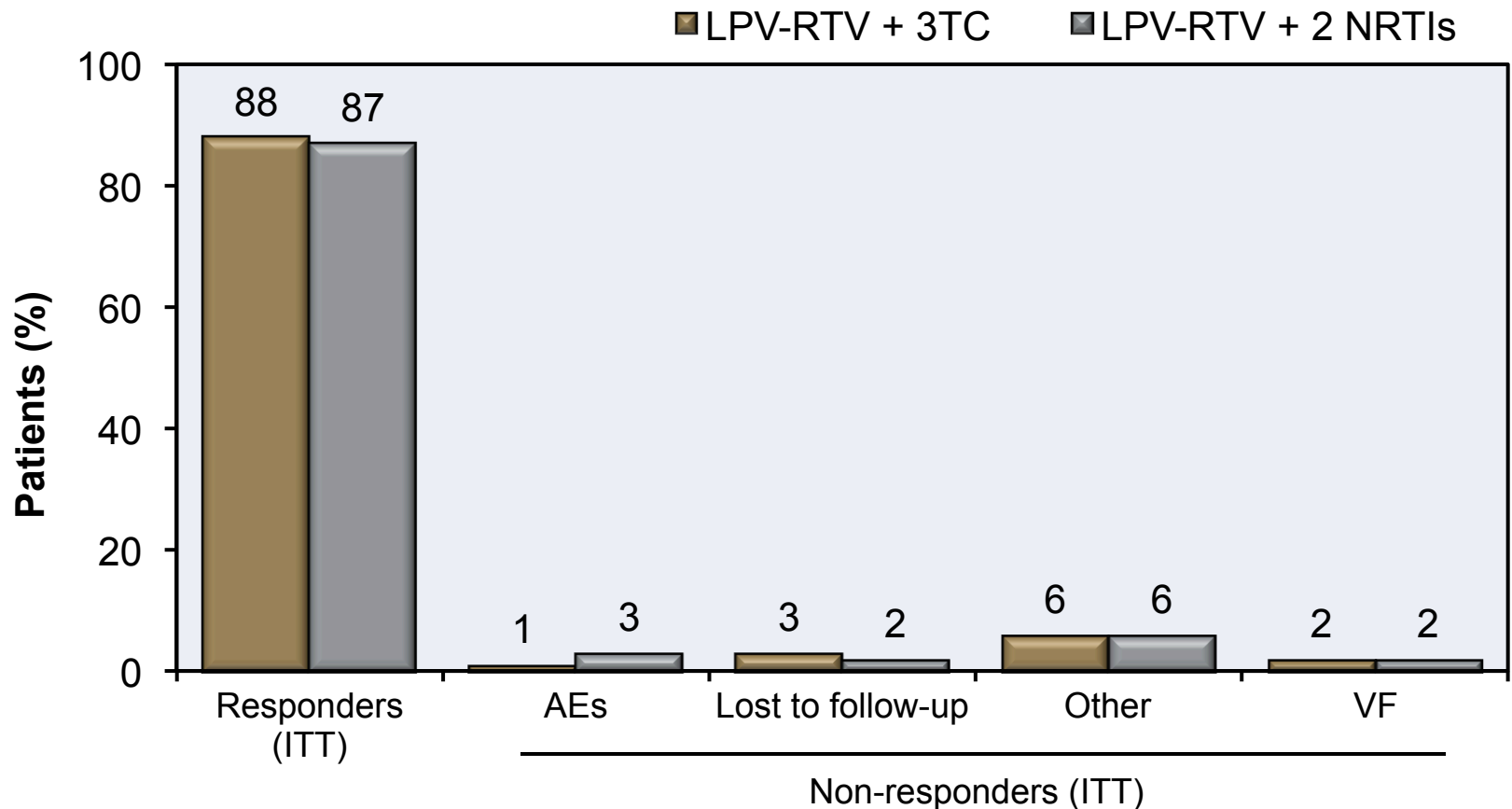
Week 48: Virologic Response (ITT)



Source: Arribas JR, et al. *Lancet Infect Dis.* 2015;15:785-92.

LPV-RTV + 3TC versus LPV-RTV + 2 NRTIs in Virologically Suppressed OLE: Results

Week 48: Responders and Non-responders in ITT Population



LPV-RTV + 3TC versus LPV-RTV + 2 NRTIs in Virologically Suppressed OLE: Results

Summary of Adverse Events		
	LPV-RTV + 3TC (n = 118)	LPV-RTV + 2 NRTIs (n = 121)
Any adverse event	53%	58%
Grade 3 or 4 adverse event	7%	6%
Serious adverse event	4%	7%
Discontinuation due to adverse event	1%	3%
Death	0	0

Source: Arribas JR, et al. *Lancet Infect Dis.* 2015;15:785-92.

LPV-RTV + 3TC versus LPV-RTV + 2 NRTIs in Virologically Suppressed OLE: Conclusions

Interpretation: “Dual treatment with lopinavir-ritonavir plus lamivudine has non-inferior therapeutic efficacy and is similarly tolerated to triple treatment.”

Acknowledgment

The **National HIV Curriculum** is an AIDS Education and Training Center (AETC) Program resource funded by the United States Health Resources and Services Administration. The project is led by the University of Washington and the AETC National Coordinating Resource Center.

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