Lopinavir-Ritonavir plus either Raltegravir or 2-3 NRTIs

SECOND-LINE Trial

Lopinavir-Ritonavir plus either Raltegravir or 2-3 NRTIs
SECOND-LINE: Study Design

Study Design: SECOND-LINE

- **Background**: Randomized, parallel, open-label trial to compare dual therapy with lopinavir-ritonavir plus raltegravir with WHO 2nd line standard-of-care regimen of lopinavir-ritonavir plus NRTIs in persons with HIV.
- **Inclusion Criteria (n=541)**
  - Age ≥16 years
  - Received first-line ART with 2 NRTIs + 1 NNRTI for ≥24 weeks (no change in past 12 weeks)
  - No virologic failure
  - Naïve to PIs and integrase inhibitors
- **Treatment Arms**
  - Lopinavir-ritonavir + Raltegravir
  - Lopinavir-ritonavir + NRTIs

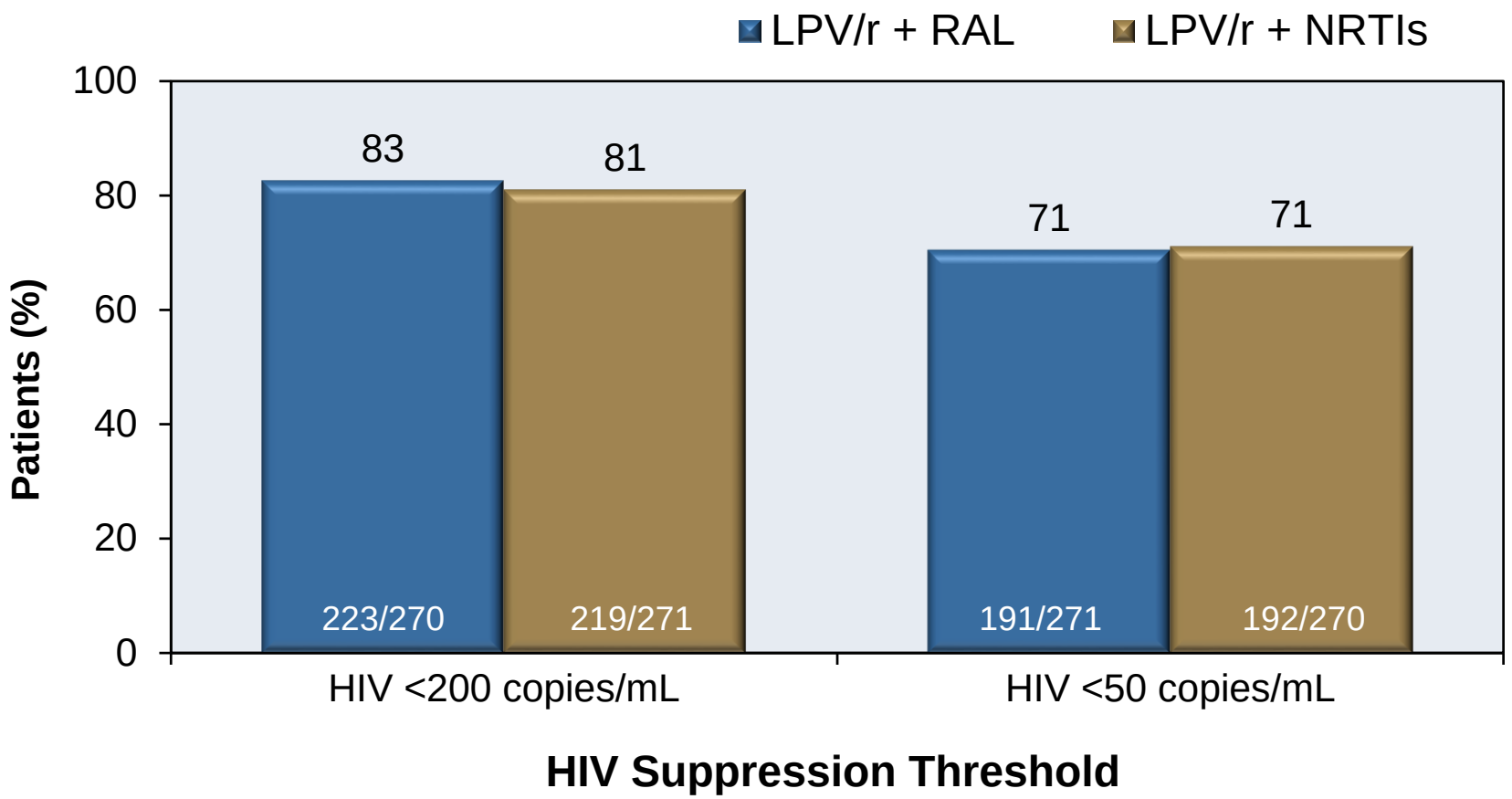
Lopinavir-ritonavir 400-100 mg (QD or divided BID) + Raltegravir 400 mg BID
(n = 271)

Lopinavir-ritonavir 400-100 mg (QD or divided BID) + NRTIs
(n =270)

Source: **Boyd MA, et al. Lancet. 2013;381:2091-9.**

Lopinavir-Ritonavir plus either Raltegravir or 2-3 NRTIs
SECOND-LINE: Result

Week 48: Virologic Response (Modified ITT)



Source: Boyd MA, et al. Lancet. 2013;381:2091-9.

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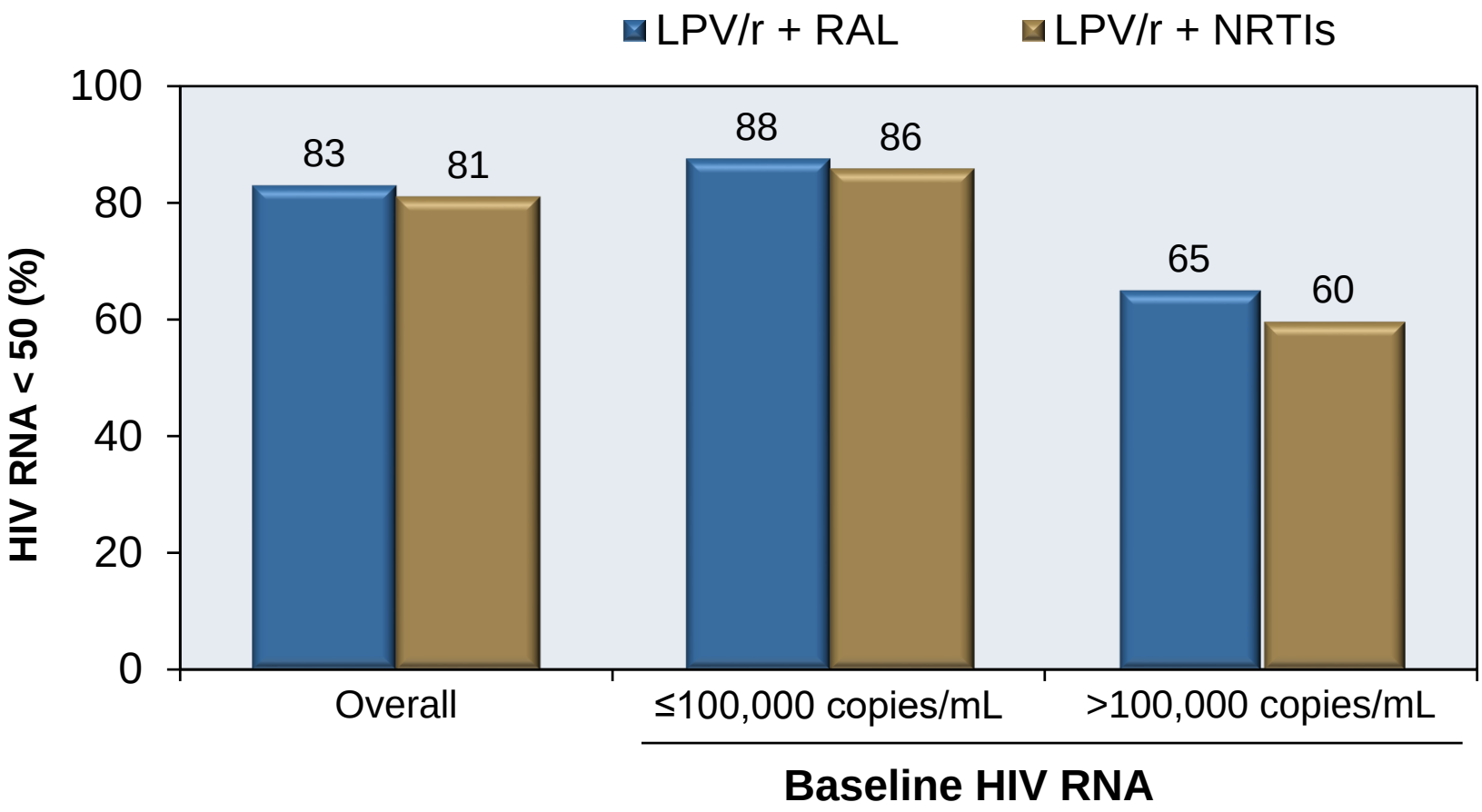
Lopinavir-Ritonavir plus either Raltegravir or 2-3 NRTIs
SECOND-LINE: Result

Week 48: Virologic Response (Modified ITT), by Baseline HIV RNA



Source: Boyd MA, et al. Lancet. 2013;381:2091-9.

Lopinavir-Ritonavir plus either Raltegravir or 2-3 NRTIs
SECOND-LINE: Result

Emergent Resistance Associated Mutations (RAMs) with Virologic Failure		
	Raltegravir (n = 271)	**Control (NRTIs)** (n = 270)
Virologic Failure with Resistance Data (Protease and reverse transcriptase)	42%	43%
Virologic Failure with Resistance Data (Integrase)	47%	46%
NtRTI-associated RAMs	0%	14%
Protease inhibitor-associated RAMs	0%	0%
Integrase inhibitor-associated RAMs	14.9%	0%
No new RAMs in protease, reverse transcriptase, or integrase	83%	86%

Source: Boyd MA, et al. Lancet. 2013;381:2091-9.

Lopinavir-Ritonavir plus either Raltegravir or 2-3 NRTIs
SECOND-LINE: Conclusion

Interpretation: “The raltegravir regimen was no less efficacious than the standard of care and was safe and well tolerated. This simple NtRTI-free treatment strategy might extend the successful public health approach to management of HIV by providing simple, easy to administer, effective, safe, and tolerable second-line combination antiretroviral therapy.”

Source: Boyd MA, et al. Lancet. 2013;381:2091-9.

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