

Lopinavir-Ritonavir plus either Raltegravir or 2-3 NRTIs
SELECT Trial

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SELECT: Study Design

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- **Background:** Randomized, phase 3, 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=412)**
 - Age ≥18 years
 - On initial ART containing NNRTI for ≥24 weeks
 - No virologic failure
 - Naïve to protease inhibitors
 - No known broad NRTI resistance
- **Treatment Arms***
 - Lopinavir-ritonavir + Raltegravir
 - Lopinavir-ritonavir + 2 or 3 NRTIs

**Lopinavir-ritonavir 400-100 QD
+ Raltegravir 400 mg BID**
(n = 258)

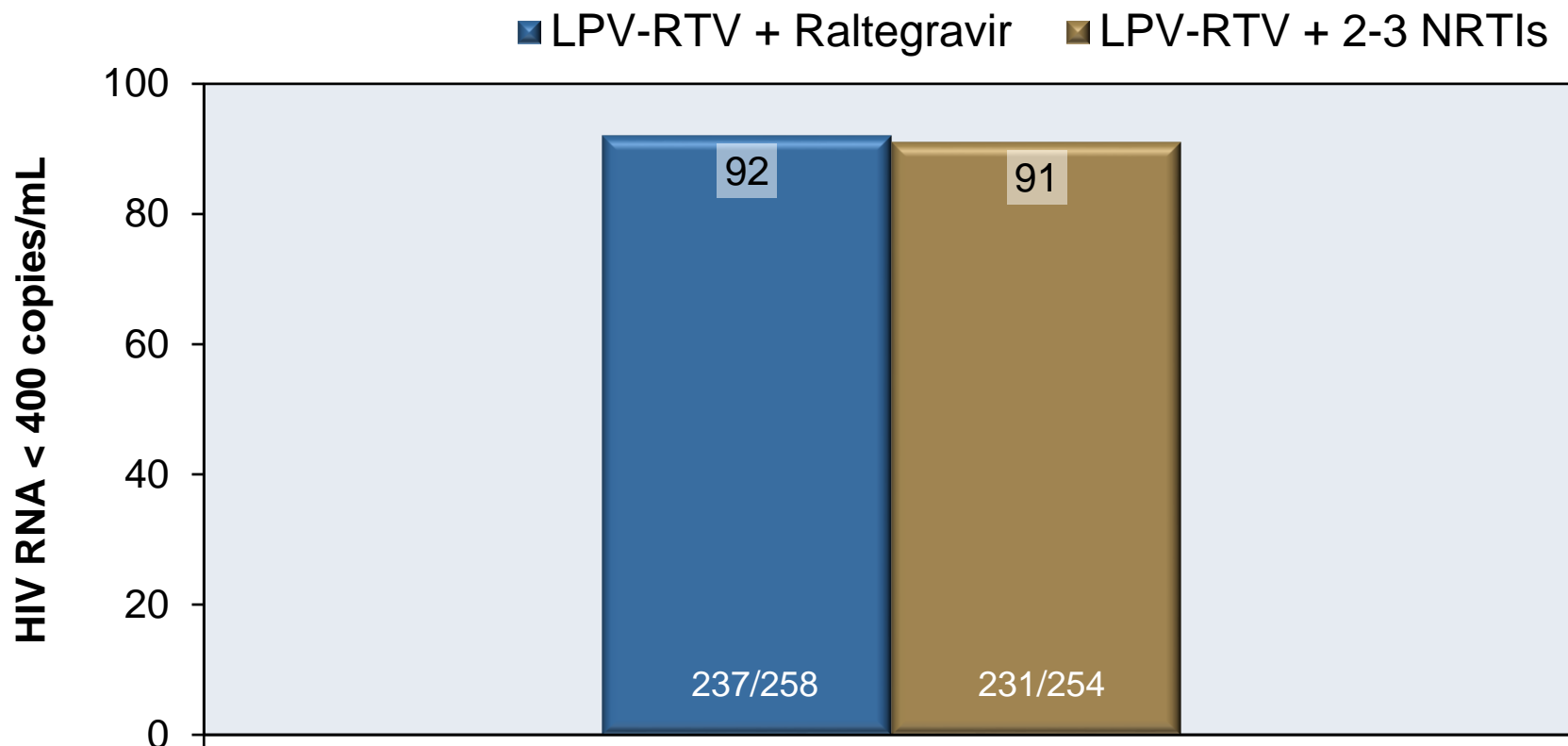
**Lopinavir-ritonavir 400-100 QD
+ 2-3 NRTIs**
(n = 254)

*95% in RAL group and 97% in NRTI group had at least 1 NRTI RAM at baseline

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SELECT: Results

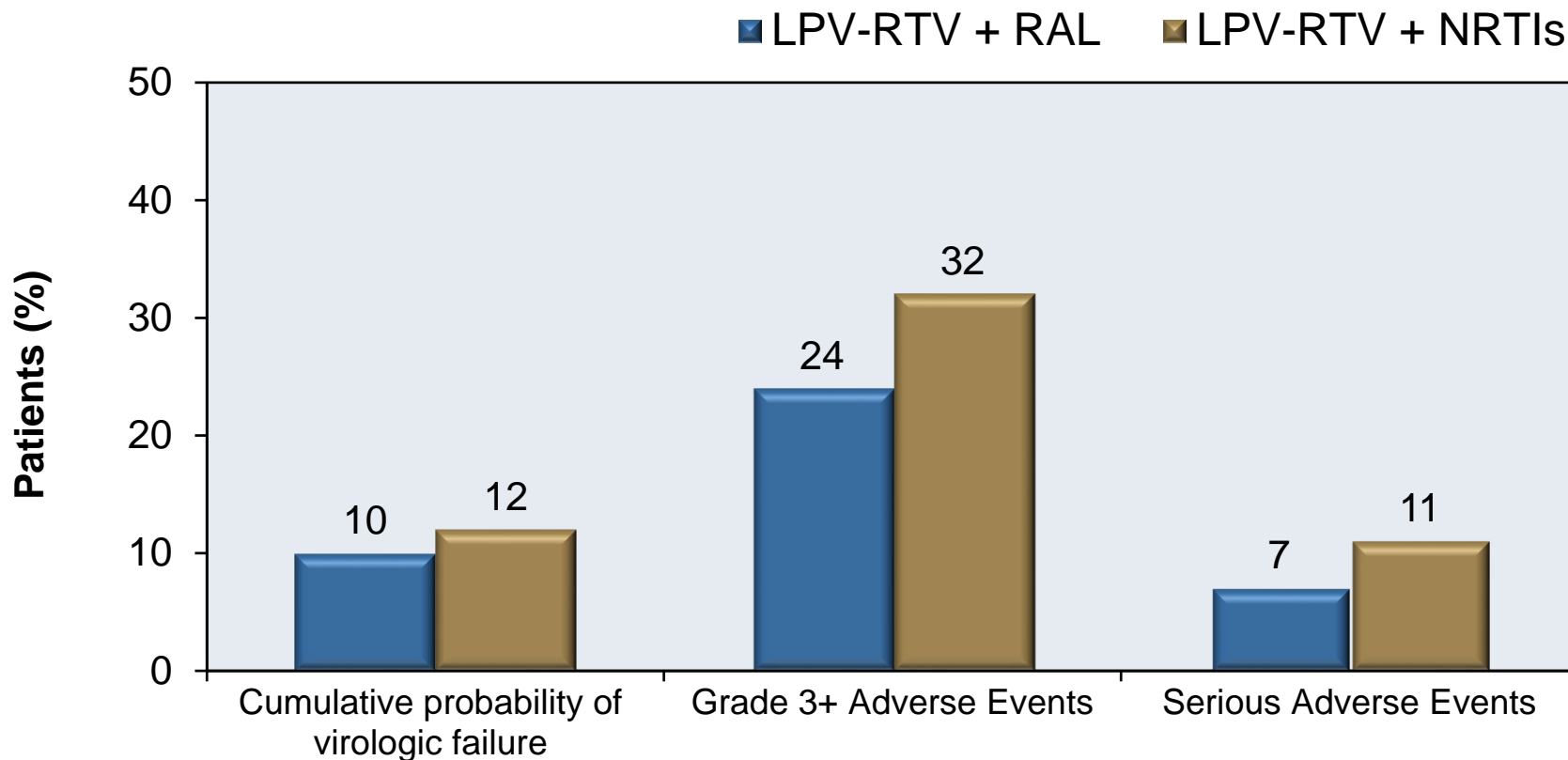
Week 48: Virologic Response (Missing Data Ignored)



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SELECT: Results

Virologic Failure and Adverse Events



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SELECT: Results

HIV Resistance Testing at Virologic Failure		
	LPV-RTV + RAL (n = 258)	LPV-RTV + NRTIs (n = 254)
Patients with virologic failure, n (%)	46 (18%)	50 (20%)
Any mutation at virologic failure	85%	90%
New resistance mutations at virologic failure	26%	29%

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SELECT: Conclusions

Interpretation: “In settings with extensive NRTI resistance but no available resistance testing, our data support WHO's recommendation for ritonavir-boosted lopinavir plus NRTI for second-line antiretroviral therapy. Ritonavir-boosted lopinavir plus raltegravir is an appropriate alternative, especially if NRTI use is limited by toxicity.”

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