

Lopinavir-ritonavir versus Nelfinavir in Treatment-Naïve **M98-863 Trial**

Lopinavir-ritonavir versus Nelfinavir in Treatment-Naïve M98-863: Study Design

Study Design: M98-863

- **Background:** Randomized, double-blind, phase 3 study comparing the efficacy and safety of lopinavir-ritonavir plus stavudine and lamivudine versus nelfinavir plus stavudine and lamivudine in treatment-naïve patients with HIV infection
- **Inclusion Criteria (n = 653)**
 - Age ≥ 12
 - Antiretroviral-naïve
 - HIV RNA >400 copies/mL
 - No CD4 criteria
- **Treatment Arms**
 - Lopinavir-ritonavir 400-100 mg BID + stavudine + lamivudine
 - Nelfinavir 750 mg TID + stavudine + lamivudine

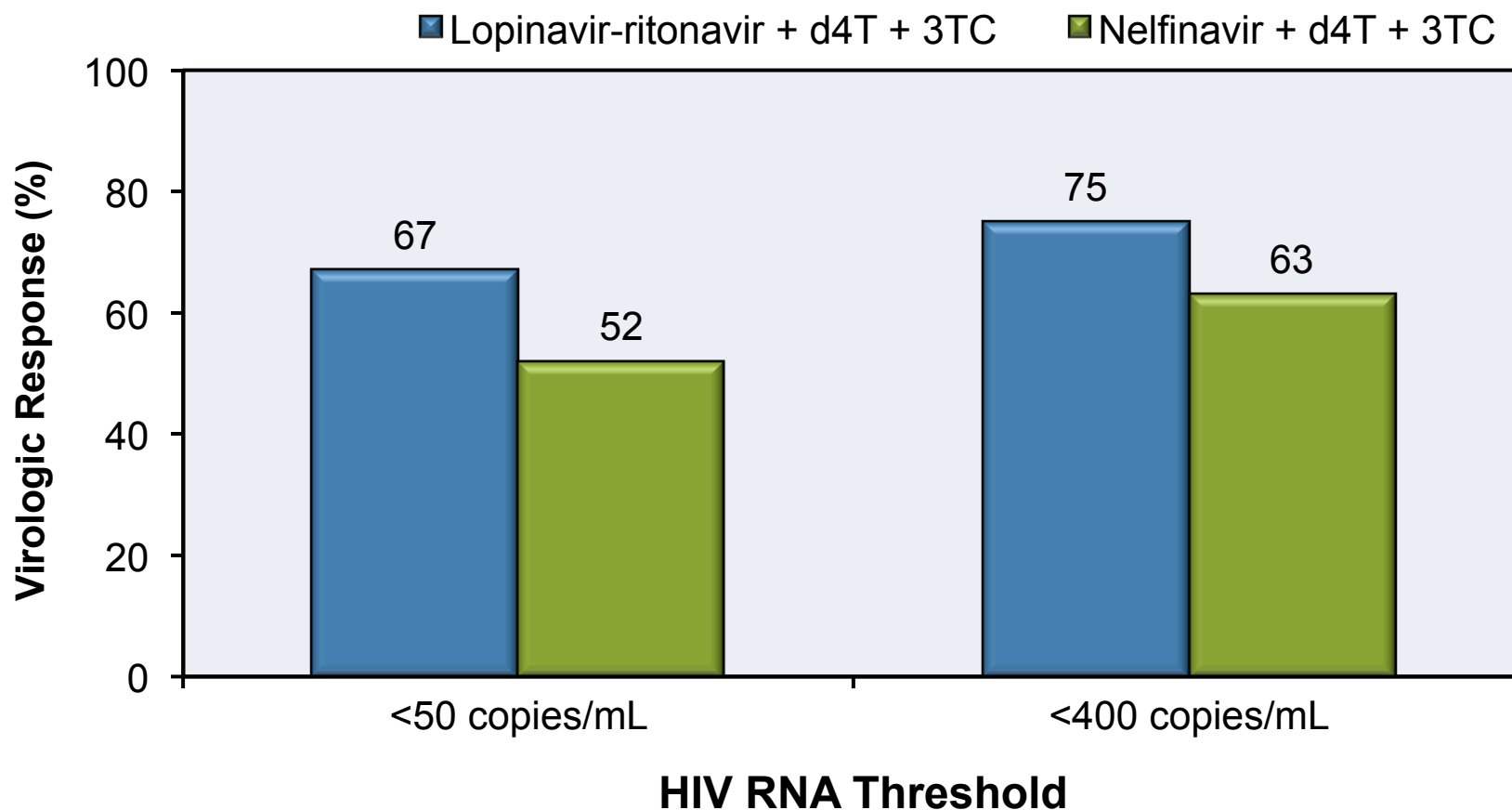
**LPV-RTV (400/100 mg
BID) + d4T + 3TC**
(n = 326)

**NFV 750 mg TID
+ d4T + 3TC**
(n = 327)

Stavudine = d4T; Lamivudine = 3TC

Lopinavir-ritonavir versus Nelfinavir in Treatment-Naïve M98-863: Results

Week 48: Virologic Response (ITT, Missing=Failure)



Lopinavir-ritonavir versus Nelfinavir in Treatment-Naïve M98-863: Results

Most Common Adverse Events and Grade 3 or 4 Laboratory Abnormalities		
Event or Abnormality	LPV-RTV + d4T + 3TC (n = 326)	NFV + d4T + 3TC (n = 327)
Abdominal pain	4.0%	3.1%
Asthenia	4.0%	3.4%
Headache	2.5%	1.8%
Diarrhea	15.6%	17.1%
Dyspepsia	2.1%	0.3%
Nausea	6.7%	4.6%
Vomiting	2.5%	2.4%
AST or ALT >5x ULN	4.5%	5.2%
Total cholesterol >300 mg/dL	9.0%	4.9%
Triglycerides >750 mg/dL	9.3%	1.3%

Source: Walmsley S, et al. N Engl J Med. 2002;346:2039-46.

Lopinavir-ritonavir versus Nelfinavir in Treatment-Naïve M98-863: Conclusions

Conclusions: “For the initial treatment of HIV-infected adults, a combination regimen that includes lopinavir-ritonavir is well tolerated and has antiviral activity superior to that of a nelfinavir-containing regimen.”

Acknowledgment

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