

LPV-RTV versus LPV-RTV + ZDV-3TC in Treatment-Naïve  
**MONARK Trial**

# LPV-RTV versus LPV-RTV + ZDV-3TC in Treatment-Naïve MONARK: Study Design

## Study Design: MONARK

- **Background:** Randomized, pilot, open-label, phase 3 trial comparing the efficacy and safety of lopinavir-ritonavir monotherapy with lopinavir-ritonavir in combination with zidovudine-lamivudine in treatment-naïve patients with HIV infection
- **Inclusion Criteria (n = 136)**
  - Age  $\geq 18$
  - Antiretroviral-naïve
  - HIV RNA  $< 100,000$  copies/mL
  - CD4 count  $> 100$  cells/mm<sup>3</sup>
  - Exclusions for certain protease or NRTI mutations
- **Treatment Arms**
  - Lopinavir-ritonavir 400-100 mg BID
  - Lopinavir-ritonavir 400-100 mg BID + ZDV-3TC 150-300mg BID

**LPV/r 400/100 mg BID**  
(n=83)

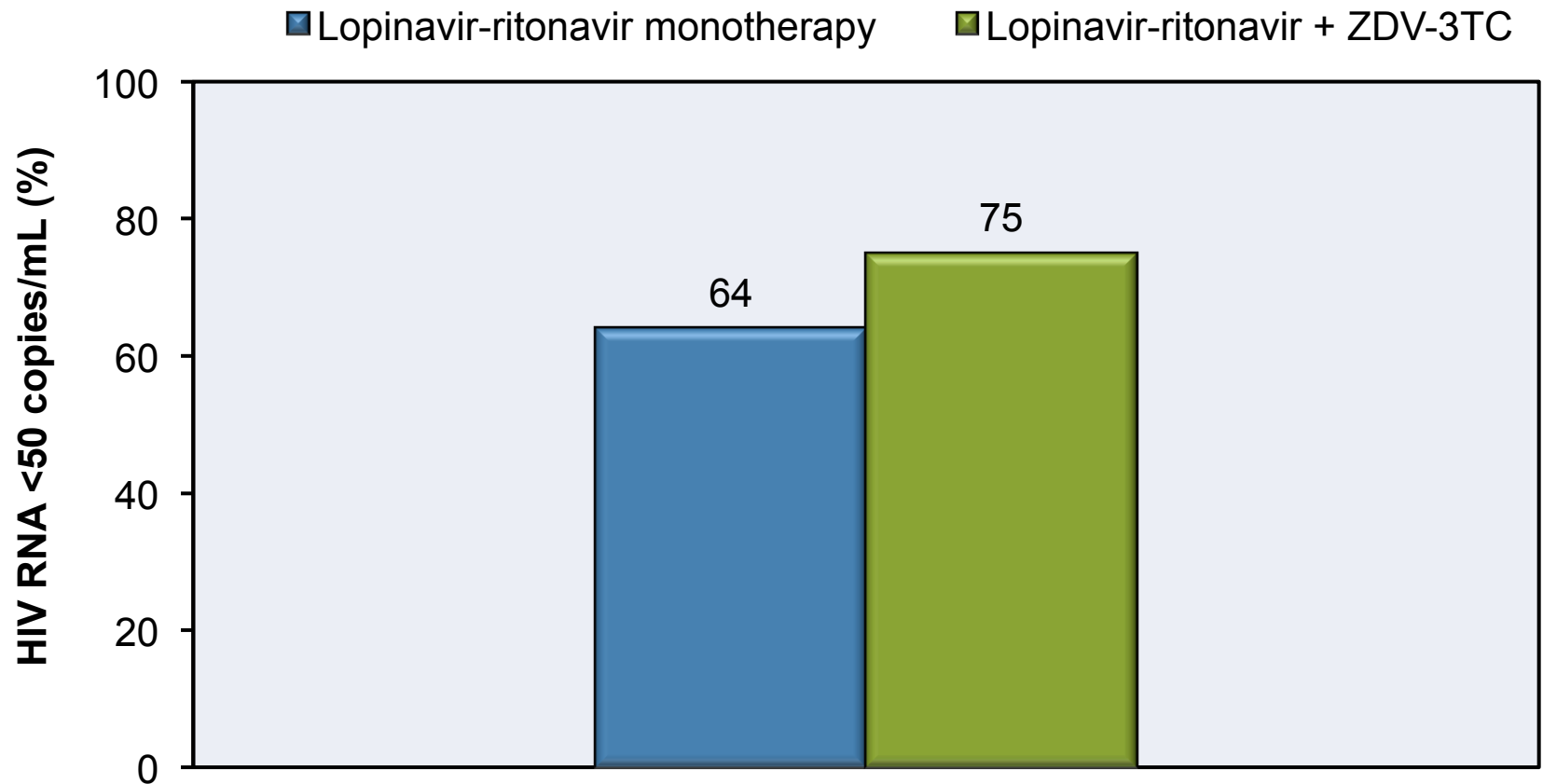
**LPV/r 400/100 mg BID +  
ZDV-3TC**  
(n =53)

**MONARK = MON**otherapy **A**nti**R**etroviral **K**aletra

Source: Delfraissy JF, et al. *AIDS*. 2008;22:385-93.

# LPV-RTV versus LPV-RTV + ZDV-3TC in Treatment-Naïve MONARK: Results

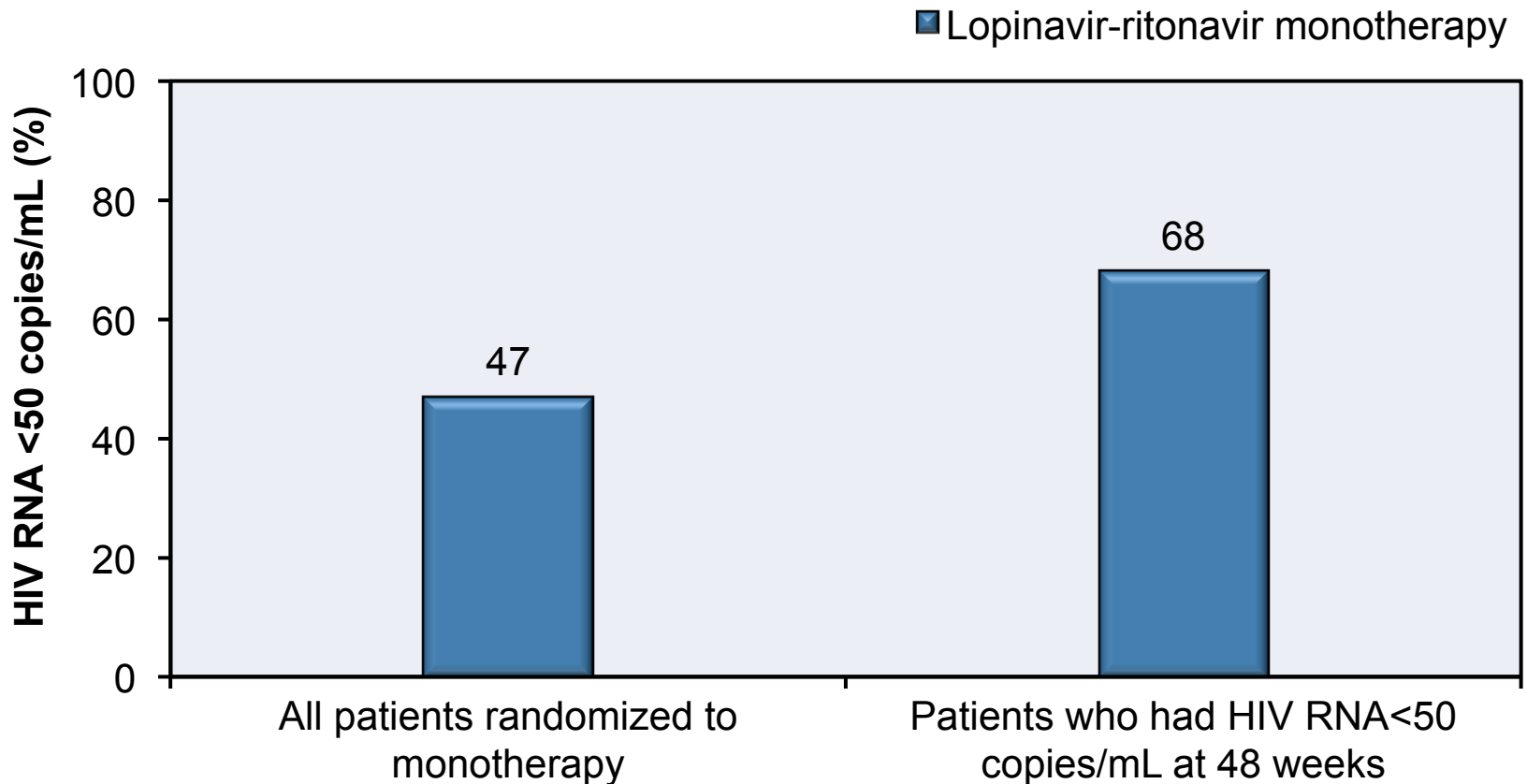
Week 48: Virologic Response (ITT, Missing=Failure)



Source: Delfraissy JF, et al. AIDS. 2008;22:385-93.

# LPV-RTV versus LPV-RTV + ZDV-3TC in Treatment-Naïve MONARK: Results (monotherapy arm at 96 weeks)

Week 96: Virologic Response (ITT)

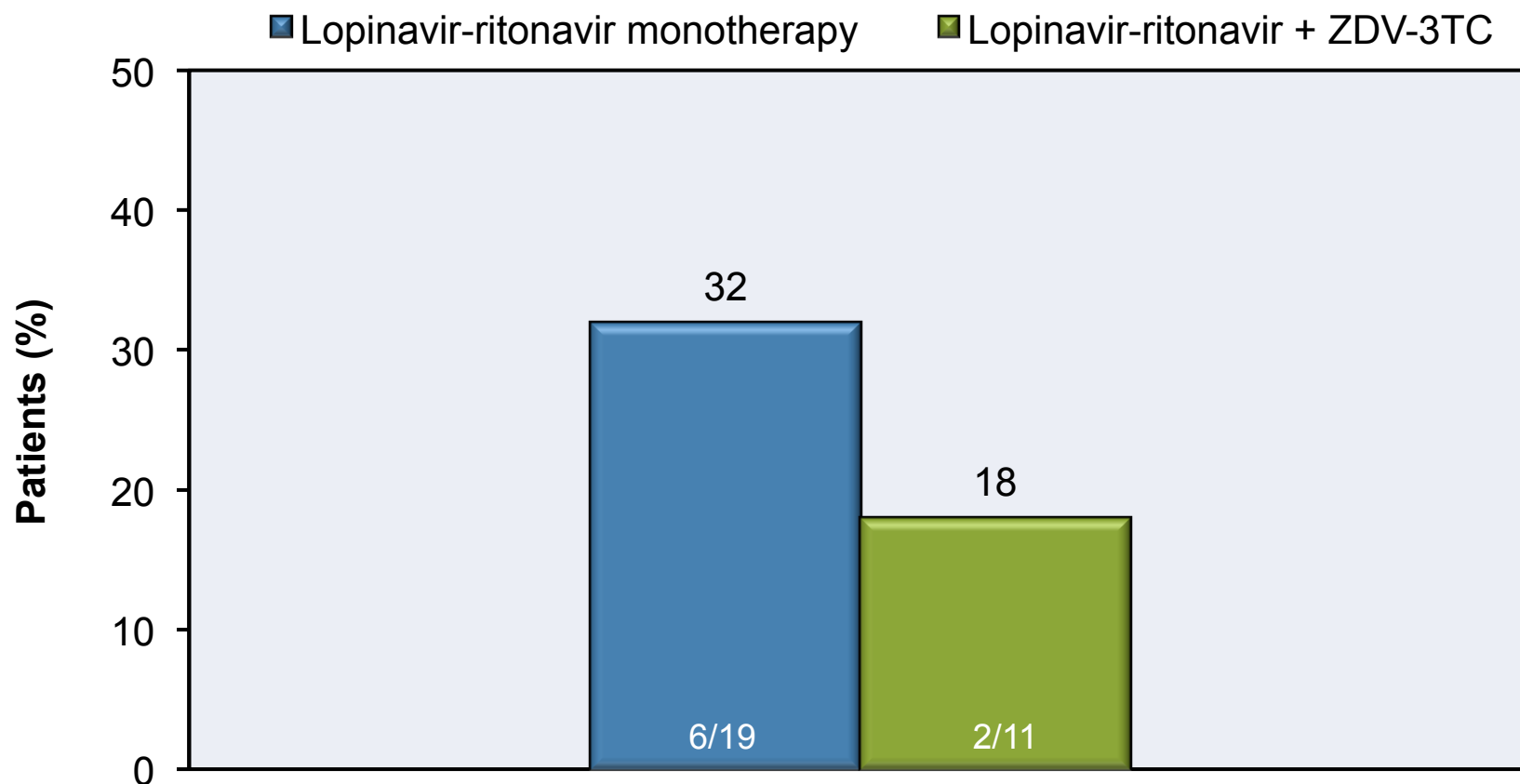


# LPV-RTV versus LPV-RTV + ZDV-3TC in Treatment-Naïve MONARK: Result

<b>Tolerance of study medications</b>		
<b>Adverse event or Laboratory Abnormality</b>	<b>LPV-RTV Monotherapy (n = 83)</b>	<b>LPV-RTV + ZDV-3TC (n = 53)</b>
Diarrhea	6%	8%
AST and/or ALT elevation	12%	8%
Serious adverse event	12%	8%
Discontinuations	16%	23%

# LPV-RTV versus LPV-RTV + ZDV-3TC in Treatment-Naïve MONARK: Results (immunologic substudy)

Week 60: Residual Viremia by Ultrasensitive PCR



Source: Tran TA, et al. J Antimicrob Chemother. 2015;70:2627-31.

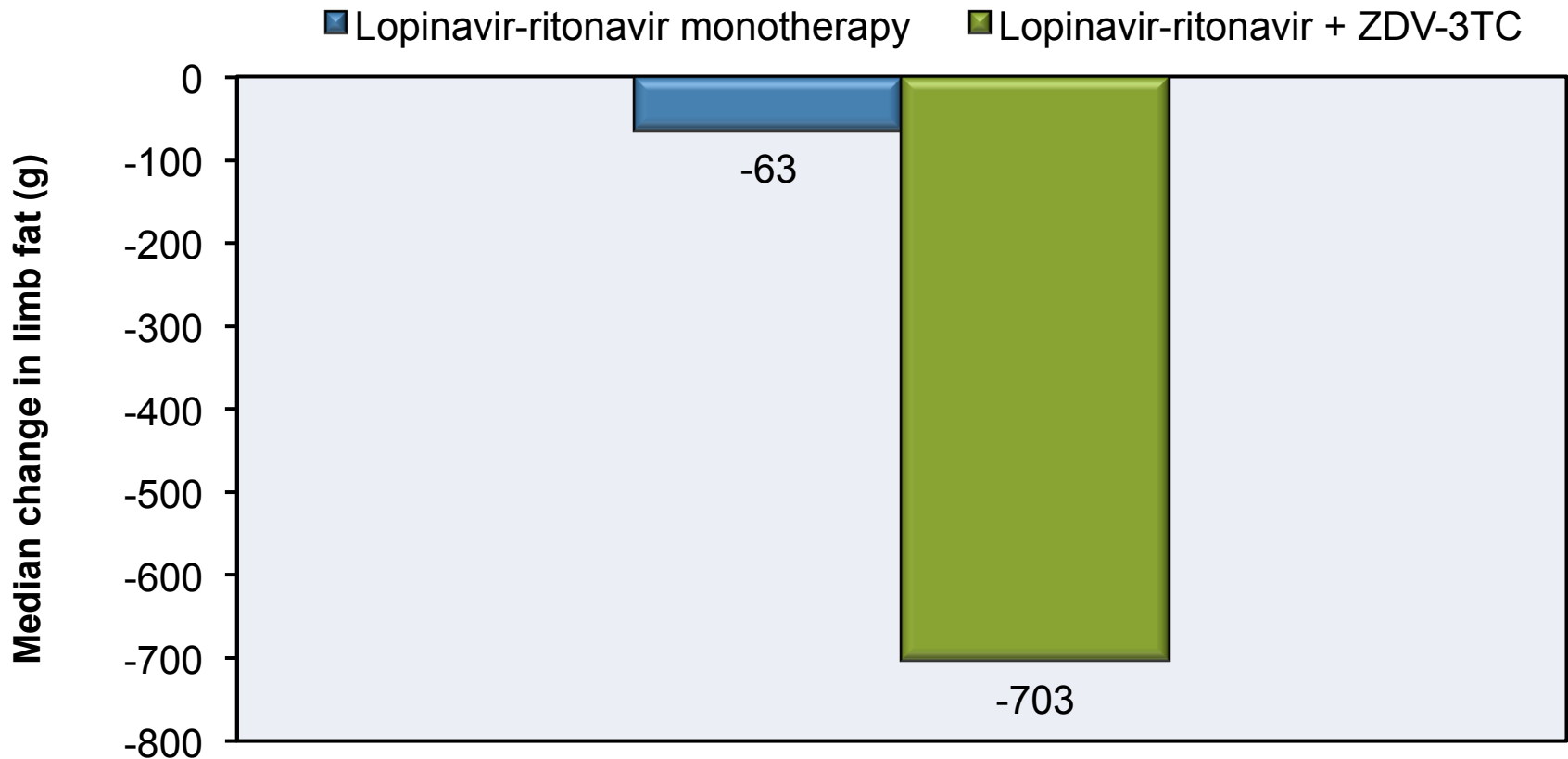
# Lopinavir/r Monotherapy vs. LPV/r + AZT-3TC in Treatment-Naïve MONARK: Results

Protease inhibitor resistance analysis		
	LPV/r monotherapy (n = 83)	LPVr/r + ZDV-3TC (n = 53)
Major PI resistance-associated mutations*	6%	0%

\*Major PI resistance-associations detected in lopinavir-ritonavir monotherapy arm: M46I at Week 40, L76V at Week48, M46I and L76V at Week 48, L10F and V82A at Week 72, and L76V at Week 84.

# LPV-RTV versus LPV-RTV + ZDV-3TC in Treatment-Naïve MONARK: Results (metabolic substudy)

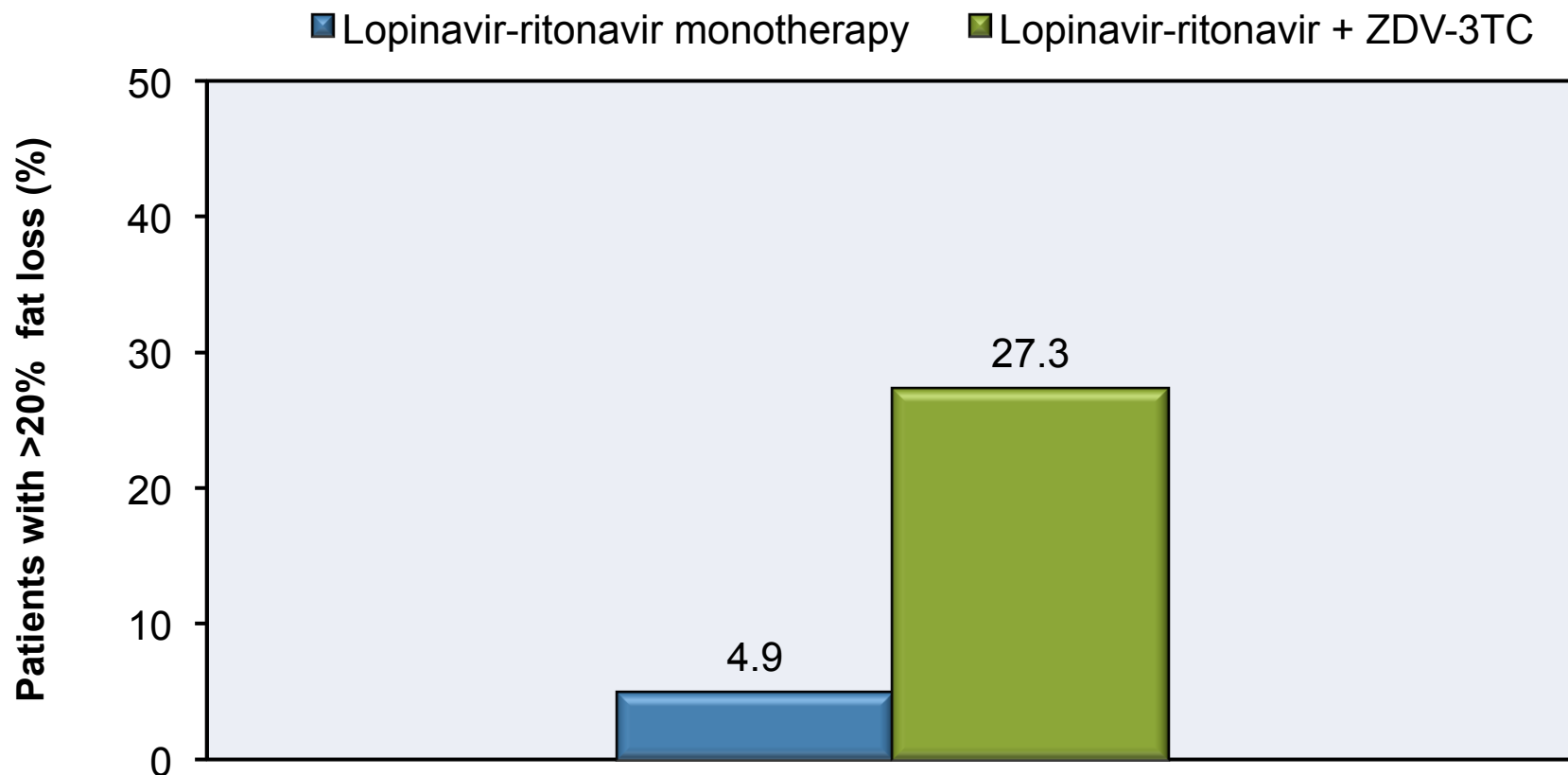
Week 48: Changes in Limb Fat from Baseline





# LPV-RTV versus LPV-RTV + ZDV-3TC in Treatment-Naïve MONARK: Results (metabolic substudy)

Week 48: Change in Limb Fat from Baseline



# LPV-RTV versus LPV-RTV + ZDV-3TC in Treatment-Naïve MONARK: Conclusion

**Conclusion:** “Our results suggest that lopinavir/ritonavir monotherapy demonstrates lower rates of virological suppression when compared with lopinavir/ritonavir triple therapy and therefore should not be considered as a preferred treatment option for widespread use in antiretroviral-naïve patients.”

# 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.

*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.*

