SQV and LPV-RTV in Treatment-Experienced Children

HIV-NAT 017

SQV and LPV-RTV in Treatment-Experienced Children
HIV-NAT 017: Study Design

Study Design: HIV-NAT 017

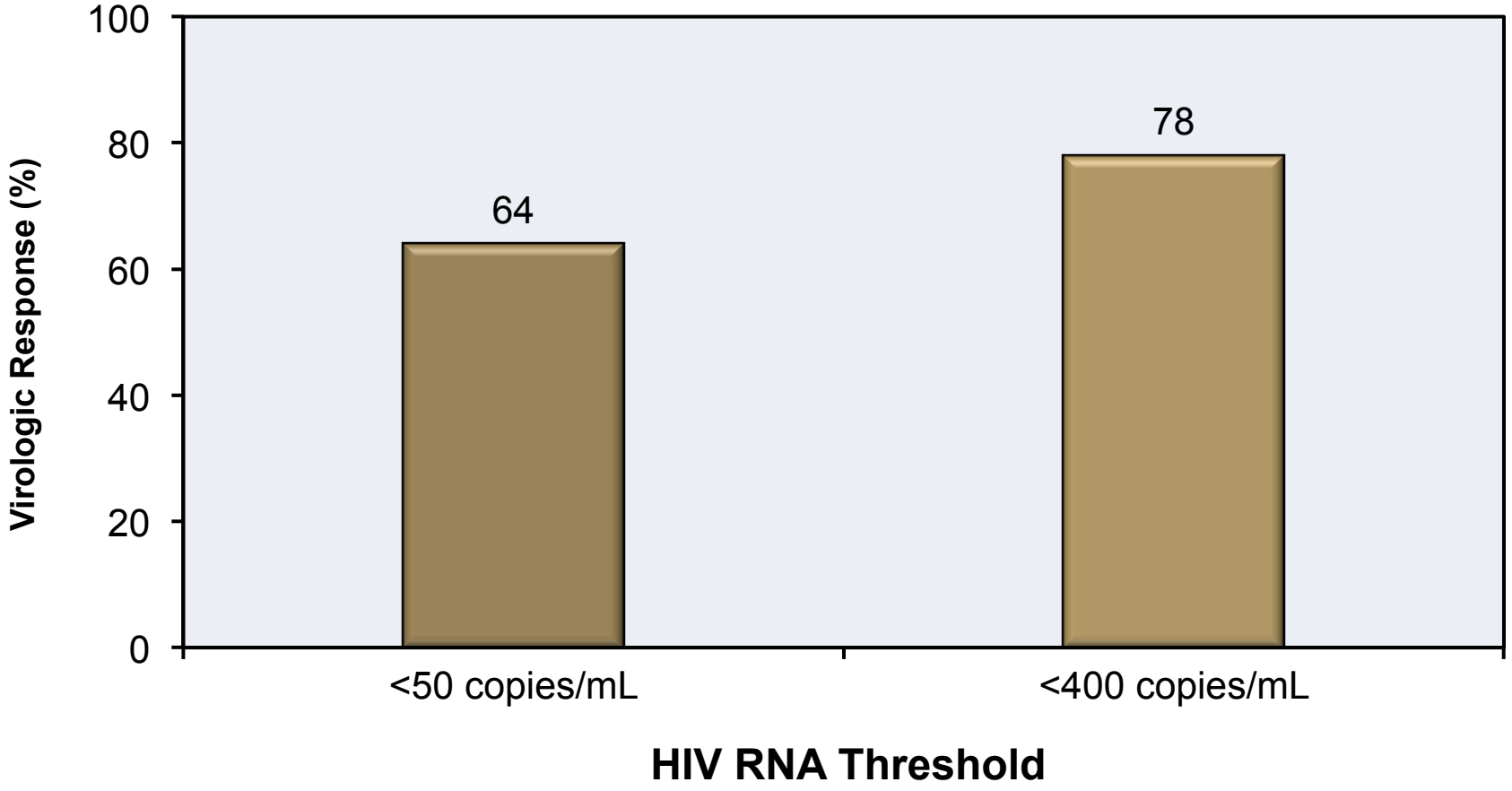
- **Background**: Single-arm, open-label, prospective phase IV study to assess the efficacy, safety, pharmacokinetics, and resistance of double boosted protease inhibitors, saquinavir (SQV) and lopinavir-ritonavir (LPV-RTV), in children with HIV infection who have failed nucleoside reverse transcription inhibitors and/or non-nucleoside reverse transcription inhibitors-based regimens
- **Inclusion Criteria (n = 50)**
  - Children <16 years of age
  - PI naïve and failing NRTI and/or NRTI/NNRTIs
- **Treatment Arms**
  - Saquinavir 50 mg/kg BID + Lopinavir-ritonavir 230/57.5 mg/m^2 BID +/- lamivudine 4 mg/kg BID (only in children who previously had not taken it)

→ **SQV + LPV-RTV +/- 3TC**
(n = 50)

Source: Kosalaraksa P, et al. Pediatr Infect Dis J. 2008;27:623-8.

SQV and LPV-RTV in Treatment-Experienced Children
HIV-NAT 017: Results

Week 48: Virologic Response (ITT)



Source: Kosalaraksa P, et al. Pediatr Infect Dis J. 2008;27:623-8.

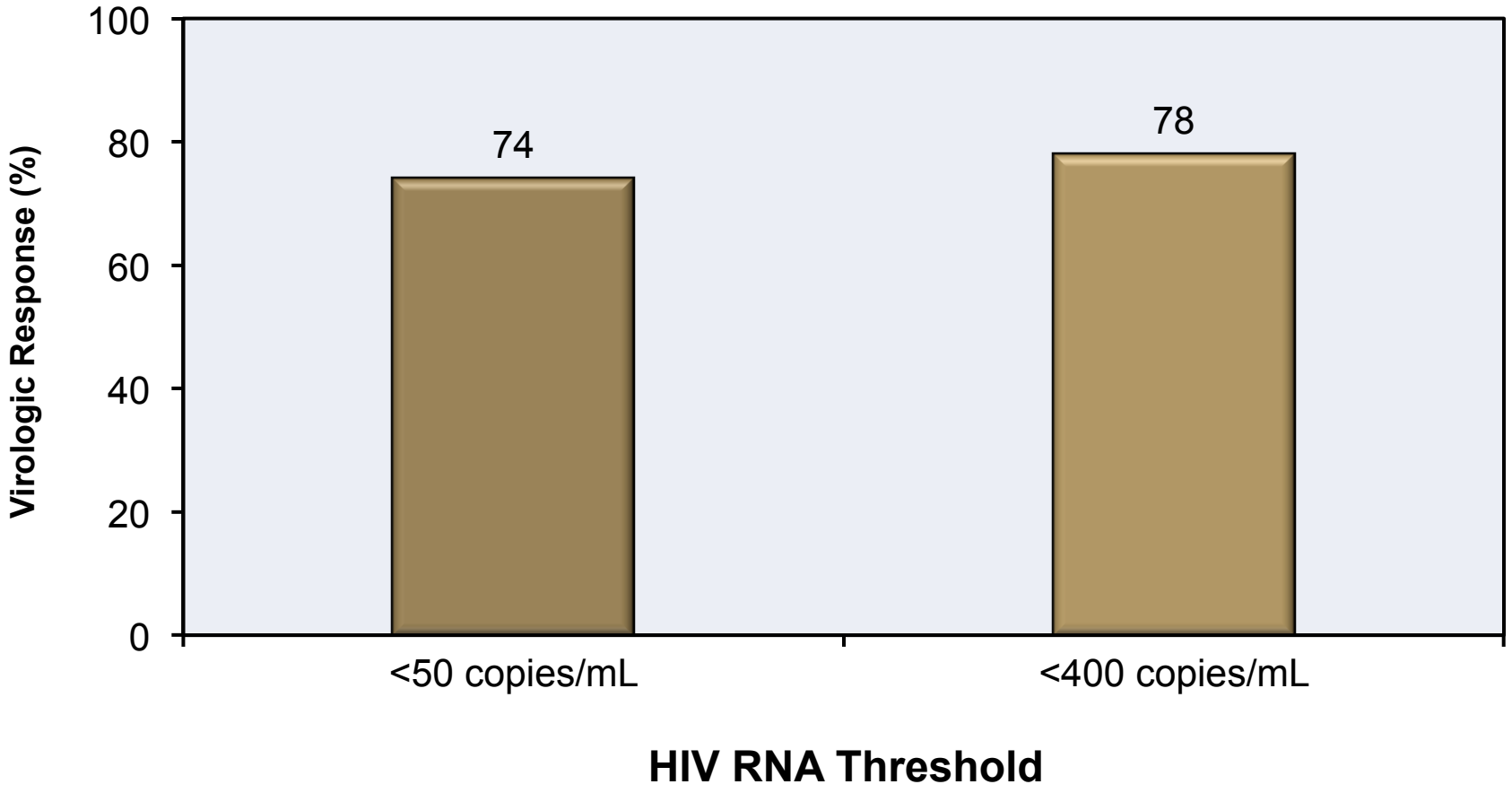
SQV and LPV-RTV in Treatment-Experienced Children
HIV-NAT 017: Conclusions

Conclusions: "Double boosted SQV/LPV/r resulted in significant CD4 rise and VL decline at 48 weeks. Hyperlipidemia was common. Cmin of both PIs exceeded therapeutic concentrations. Poor adherence caused failure in 10%. No major PI mutations were found."

Source: Kosalaraksa P, et al. Pediatr Infect Dis J. 2008;27:623-8.

SQV and LPV/r in Treatment-Experienced Children
HIV-NAT 017: Results

Week 96: Virologic Response (ITT)



Source: Bunupuradah T, et al. Antivir Ther. 2009;14:241-8.

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.

National HIV Curriculum

AETC AIDS Education & Training Center Program
National Coordinating Resource Center