Once-Daily versus Twice-Daily Lopinavir-ritonavir

M02-418 Trial

Once-daily versus twice-daily Lopinavir/r in Treatment-Naïve
M02-418: Study Design

Study Design: M02-418

- **Background**: Randomized, open-label, phase 3 study to evaluate the efficacy, pharmacokinetics, and tolerability of once-daily versus twice-daily lopinavir and ritonavir in combination with tenofovir and emtricitabine in treatment-naïve patients with HIV infection
- **Inclusion Criteria (n = 190)**
  - Age ≥18
  - Antiretroviral-naïve
  - HIV RNA ≥1000 copies/mL
  - No CD4 criteria
- **Treatment Arms**
  - Lopinavir-ritonavir 800/200 mg QD + TDF + FTC
  - Lopinavir-ritonavir 400/100 mg BID + TDF + FTC

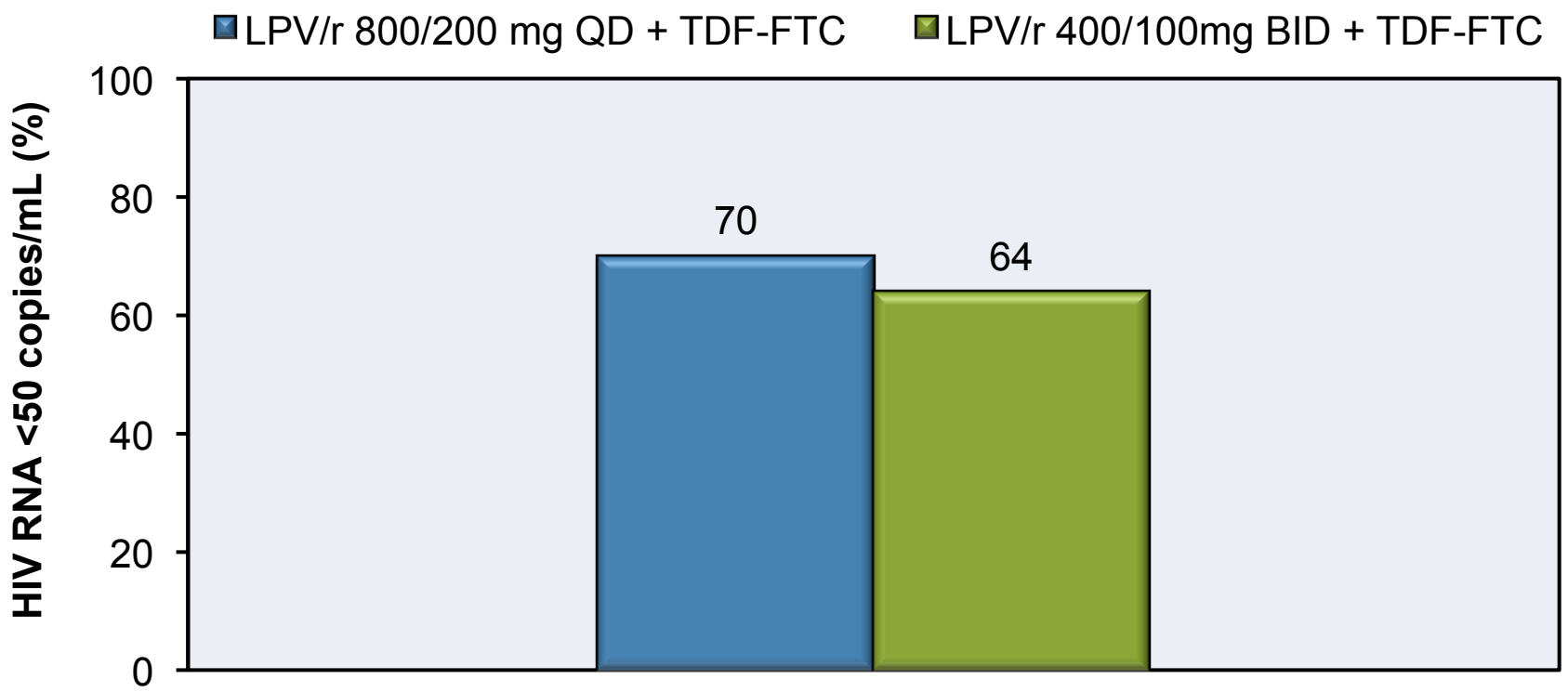
LPV/r 800/200 mg QD + TDF + FTC
(n=115)

LPV/r 400/100 mg BID + TDF + FTC
(n = 75)

Source: Johnson MA, et al. J Acquir Immune Defic Syndr. 2006;43:153-60.

Once-daily versus twice-daily Lopinavir/r in Treatment-Naïve M02-418: Results

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



Source: Johnson MA, et al. J Acquir Immune Defic Syndr. 2006;43:153-60.

Once-daily versus twice-daily Lopinavir/r in Treatment-Naïve M02-418: Results

Most Common Adverse Events and Grade 3/4 Laboratory Abnormalities		
Adverse Event	**LPV/r 800/200mg QD** (n= 115)	**LPV/r 400/100mg BID** (n=75)
Diarrhea	16%	5%
Nausea	9%	8%
Vomiting	3%	4%
AST >5x ULN	5%	3%
ALT >5x ULN	4%	3%
Triglycerides (>750 mg/dL or 8.47 mmol/L)	5%	4%
Amylase > 2x ULN	7%	5%

Source: Johnson MA, et al. J Acquir Immune Defic Syndr. 2006;43:153-60.

Once-daily versus twice-daily Lopinavir/r in Treatment-Naïve
M02-418: Conclusions

Conclusions: "Through 48 weeks, a once-daily regimen of lopinavir/ritonavir + TDF + FTC appears to have similar virologic and immunologic responses in antiretroviral-naive subjects as the same regimen with lopinavir/ritonavir administered twice daily. Both regimens were relatively well tolerated, and no LPV or TDF resistance was observed."

Source: Johnson MA, et al. J Acquir Immune Defic Syndr. 2006;43:153-60.

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National HIV Curriculum

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