Efavirenz 400 mg versus 600 mg, with TDF-FTC

ENCORE1 Trial

Efavirenz 400 mg versus Efavirenz 600 mg, with TDF-FTC
ENCORE1: Study Design

Study Design: ENCORE1

- **Background**: Randomized, double-blind, placebo-controlled study comparing the safety and efficacy of two doses of efavirenz, in combination with co-formulated tenofovir DF and emtricitabine
- **Inclusion Criteria (n = 636)**
  - Antiretroviral-naïve
  - Age ≥16 years
  - HIV RNA ≥1000 copies/mL
  - CD4 count >50 and <500 cells/mm^3
- **Treatment Arms**
  - Efavirenz 400 mg QD + TDF-FTC QD
  - Efavirenz 600 mg QD + TDF-FTC QD

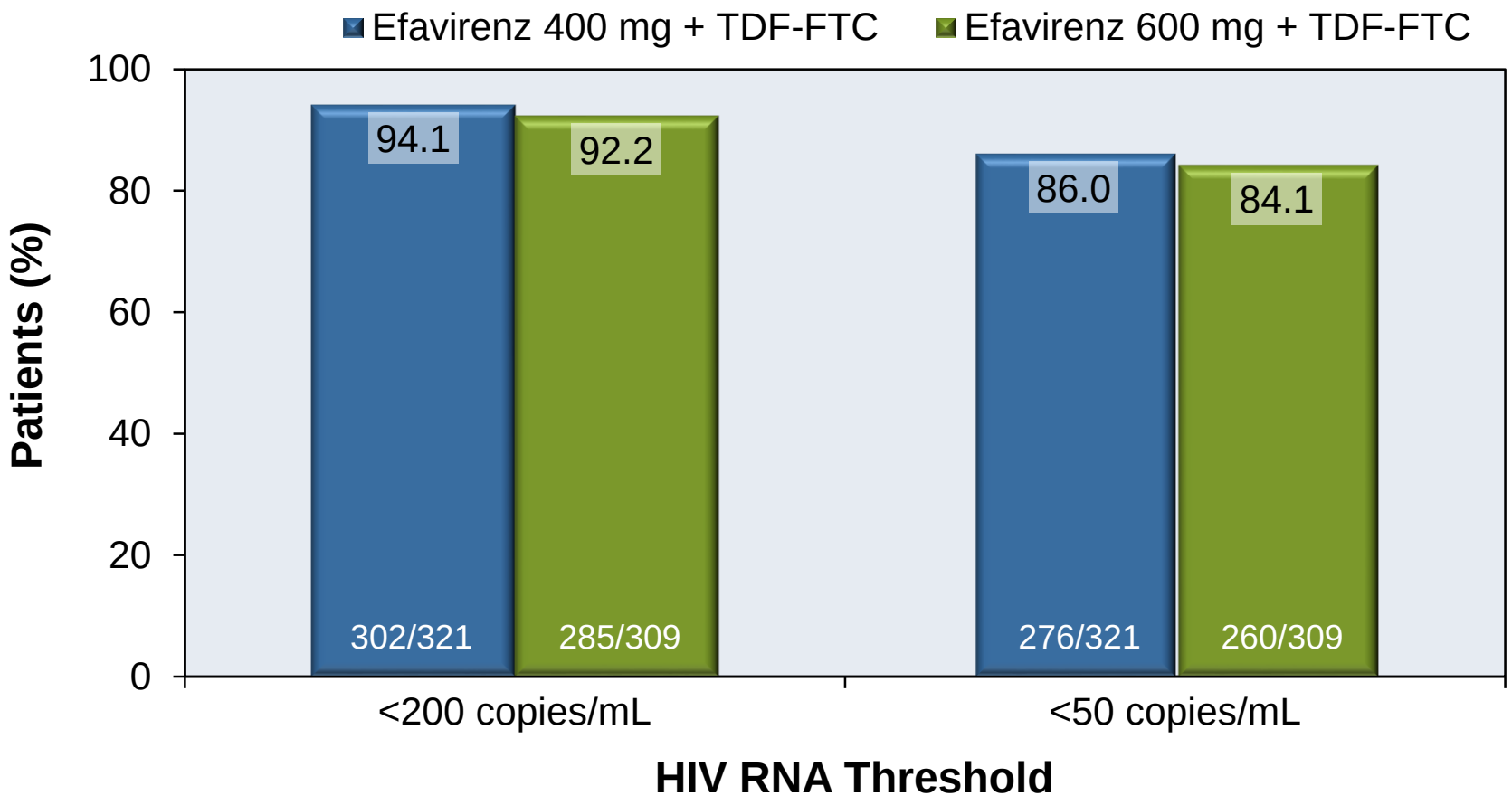
Efavirenz 400 mg + TDF-FTC QD
(n = 321)

Efavirenz 600 mg + TDF-FTC QD
(n = 309)

Source: ENCORE1 Study Group. Lancet. 2014;383:1474-82.

Efavirenz 400 mg versus Efavirenz 600 mg, with TDF-FTC
ENCORE1: Results

Week 48: Virologic Response (Modified Intention-to-Treat)



Source: ENCORE1 Study Group. Lancet. 2014;383:1474-82.

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Efavirenz 400 mg versus Efavirenz 600 mg, with TDF-FTC
ENCORE1: Results

Overall Adverse Events		
Variable	**EFV 400 mg** n (%)	**EFV 600 mg** n (%)
Number of adverse events	1173 (49.8%)	1182 (50.2%)
Serious adverse events		
Total number of serious adverse events	31 (46.2%)	36 (53.7%)
Number with serious adverse events	23 (7.17%)	22 (7.12%)
Number with serious adverse events related to study drug	3 (0.93%)	4 (1.29%)
Adverse events probably related to study drug		
Patients with adverse events related to study drug	118 (36.8%)	146 (47.2%)
Patients stopping drug due to drug related adverse event	6 (1.9%)	18 (5.8%)

Source: ENCORE1 Study Group. Lancet. 2014;383:1474-82.

Efavirenz 400 mg versus Efavirenz 600 mg, with TDF-FTC
ENCORE1: Conclusions

Interpretation: “Our findings suggest that a reduced dose of 400 mg efavirenz is non-inferior to the standard dose of 600 mg, when combined with tenofovir and emtricitabine during 48 weeks in ART-naive adults with HIV-1 infection. Adverse events related to the study drug were more frequent with 600 mg efavirenz than with 400 mg. Lower dose efavirenz should be recommended as part of routine care.”

Source: ENCORE1 Study Group. Lancet. 2014;383:1474-82.

Acknowledgment

The **National HIV Curriculum** is an AIDS Education and Training Center (AETC) Program supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of an award totaling $800,000 with 0% financed with non-governmental sources. This project is led by the University of Washington's Infectious Diseases Education and Assessment (IDEA) Program.

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