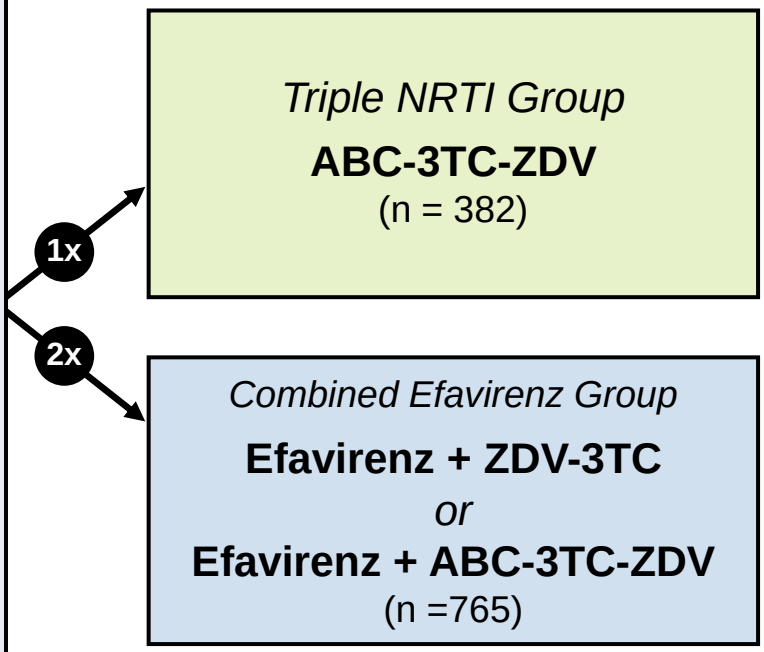
Triple NRTIs versus Efavirenz + 2-3 NRTIs

ACTG 5095 Trial

Triple NRTIs versus Efavirenz + 2-3 NRTIs
ACTG 5095: Study Design

Study Design: ACTG 5095

- **Background**: Randomized, double-blind, placebo-controlled, phase 3 trial comparing 3 protease inhibitor-sparing antiretroviral therapy regimens in antiretroviral-naïve patients
- **Inclusion Criteria (n = 1147)**
  - Age ≥18 years
  - Antiretroviral-naïve
  - HIV RNA ≥400 copies/mL
- **Treatment Arms**
  - Triple NRTI: ABC-3TC-ZDV
  - Combined Efavirenz: ZDV-3TC + Efavirenz*
  - Combined Efavirenz: ABC-3TC-ZDV+ Efavirenz*

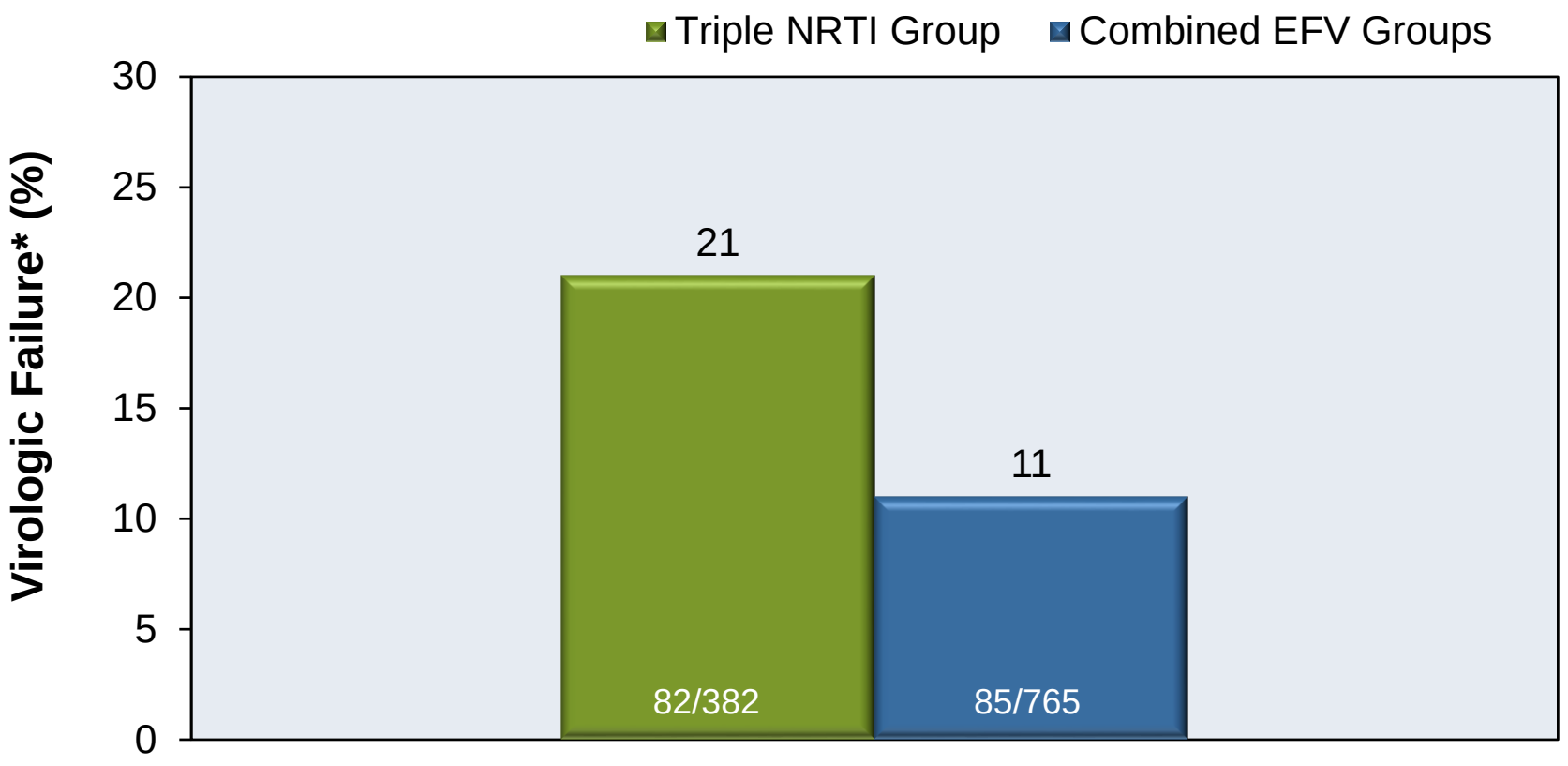


*Efavirenz arms combined for analysis

Source: Gulick RM, et al. N Engl J Med. 2004;350:1850-61.

Triple NRTIs versus Efavirenz + 2-3 NRTIs
ACTG 5095: Results

Week 48: Virologic Failure

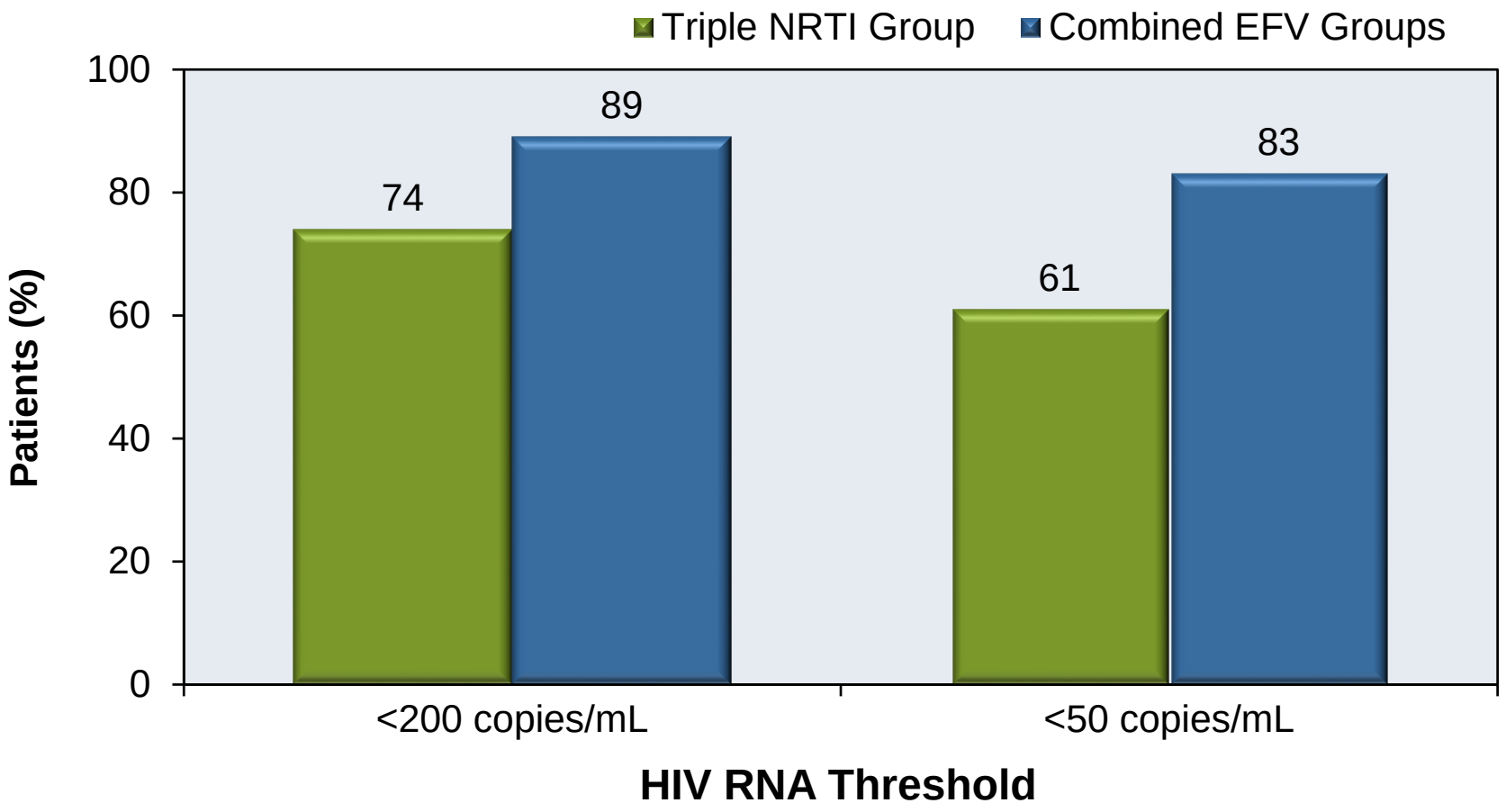


*Virologic failure = two successive HIV-1 RNA values ≥200 copies/mL ≥16 weeks after randomization

Source: Gulick RM, et al. N Engl J Med. 2004;350:1850-61.

Triple NRTIs versus Efavirenz + 2-3 NRTIs
ACTG 5095: Results

Week 48: Virologic Response



Source: Gulick RM, et al. N Engl J Med. 2004;350:1850-61.

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Triple NRTIs versus Efavirenz + 2-3 NRTIs
ACTG 5095: Conclusions

Conclusions: “In this trial of the initial treatment of HIV-1 infection, the triple-nucleoside combination of abacavir, zidovudine, and lamivudine was virologically inferior to a regimen containing efavirenz and two or three nucleosides.”

Source: Gulick RM, et al. N Engl J Med. 2004;350:1850-61.

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