EFV + ABC-3TC versus EFV + TDF-FTC

ASSERT Trial

Efavirenz + ABC-3TC versus Efavirenz + TDF-FTC
ASSERT: Study Design

Study Design: ASSERT Study

- **Background**: Randomized, open label phase 3 study comparing tenofovir DF-emtricitabine plus efavirenz with zidovudine-lamivudine plus efavirenz in antiretroviral-naïve adults with HIV
- **Inclusion Criteria (n = 385)**
  - Antiretroviral-naïve adults
  - Age ≥18 years
  - HIV RNA ≥1,000 copies/mL
  - HLA-B*5701 negative
  - CrCl ≥50 mL/min
  - No AIDS conditions or HBV infection
- **Treatment Arms**
  - Efavirenz + abacavir-lamivudine
  - Efavirenz + tenofovir DF-emtricitabine

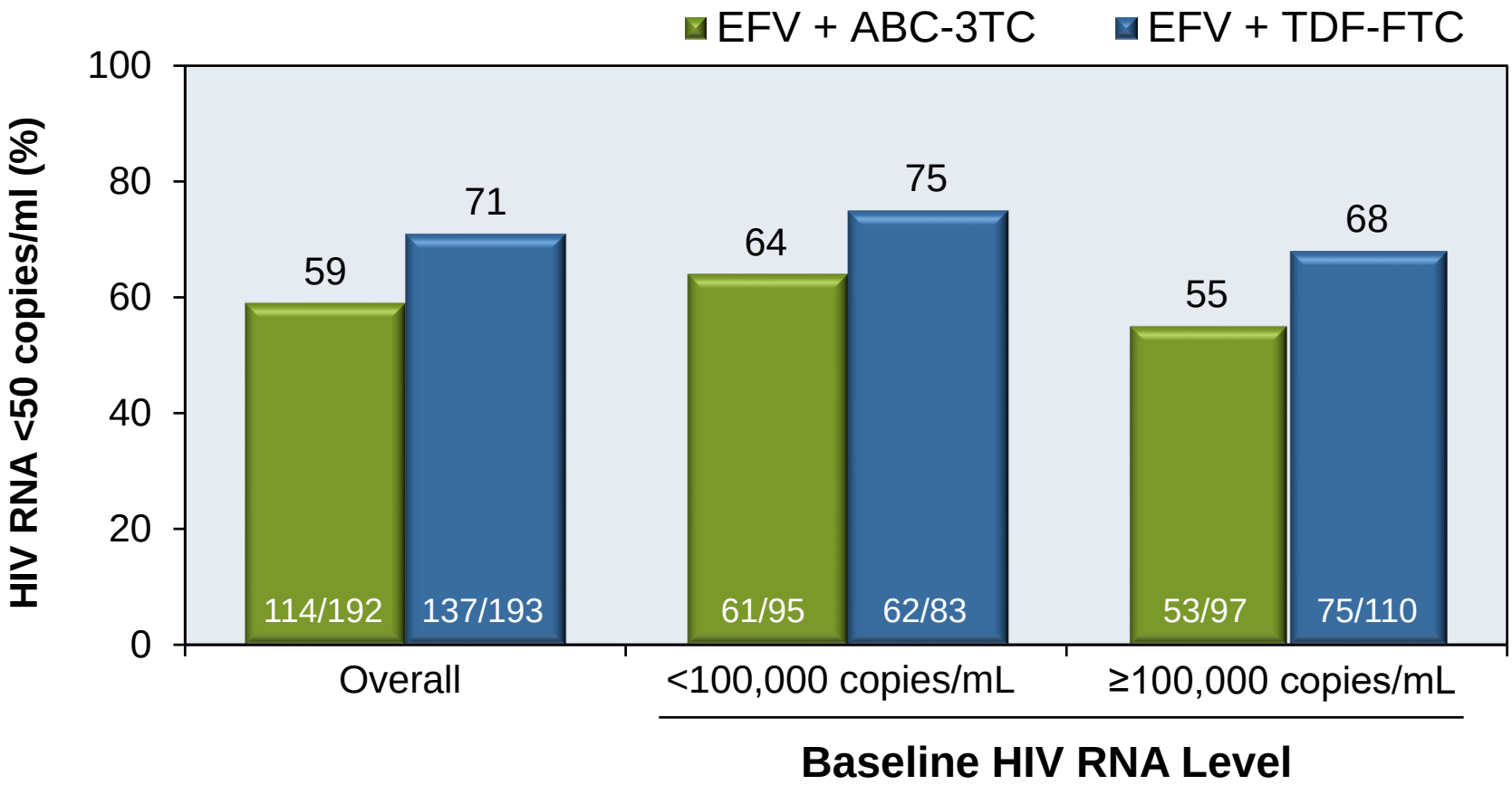
Efavirenz + ABC-3TC QD
(n = 192)

Efavirenz + TDF-FTC QD
(n = 193)

Source: Post FA, et al. J Acquir Immune Defic Syndr. 2010;55:49-57.

Efavirenz + ABC-3TC versus Efavirenz + TDF-FTC
ASSERT: Result

Week 48 Virologic Response (Intent-to-Treat Analysis)



Source: Post FA, et al. J Acquir Immune Defic Syndr. 2010;55:49-57.

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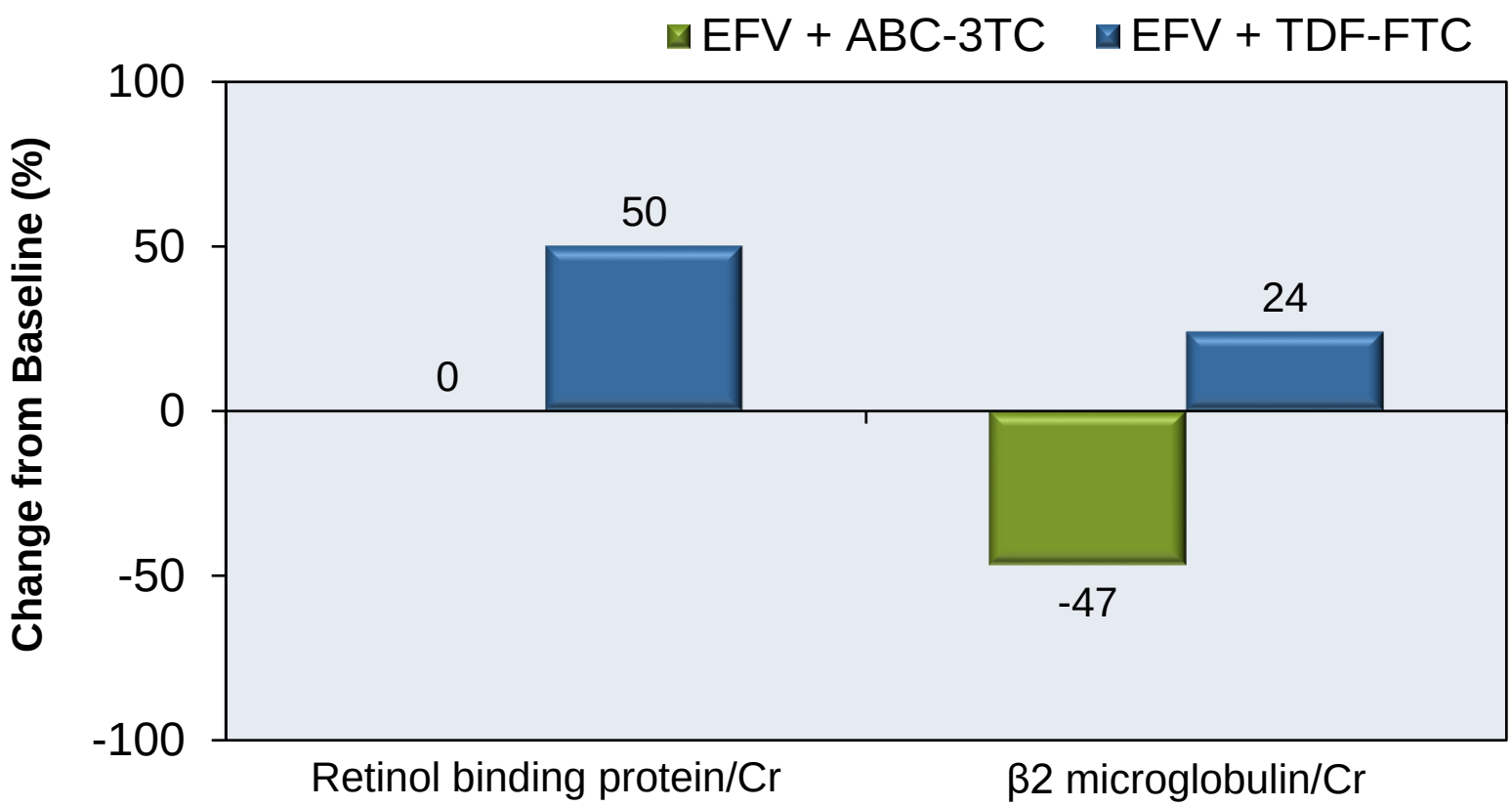
Efavirenz + ABC-3TC versus Efavirenz + TDF-FTC

ASSERT: Renal Biomarkers

Week 48: Changes in Markers of Renal Tubular Function



Source: Post FA, et al. J Acquir Immune Defic Syndr. 2010;55:49-57.

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Efavirenz + ABC-3TC vs. Efavirenz + TDF-FTC
ASSERT: Conclusions

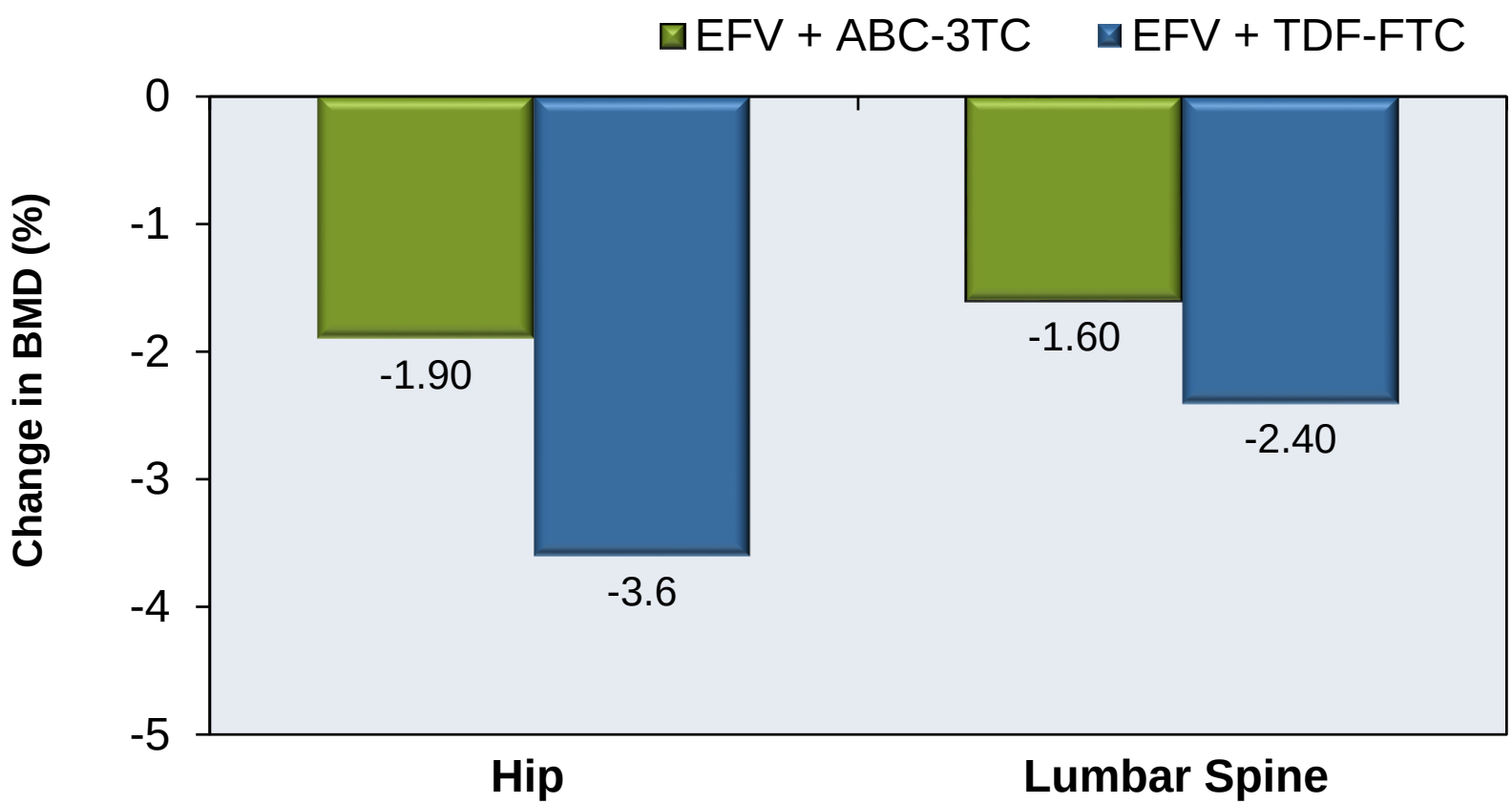
Interpretation: “The study showed no difference in estimated glomerular filtration rate between the arms, however, increases in markers of tubular dysfunction were observed in the tenofovir/emtricitabine arm, the long-term consequence of which is unclear. A significant difference in efficacy favoring tenofovir/emtricitabine was observed.”

Source: Post FA, et al. J Acquir Immune Defic Syndr. 2010;55:49-57.

Efavirenz + ABC-3TC versus Efavirenz + TDF-FTC

ASSERT: Bone Effects

Week 48: Changes in Spine and Hip Bone Mineral Density from Baseline



Source: Stellbrink HJ, et al. Clin Infect Dis. 2010;51:963-72.

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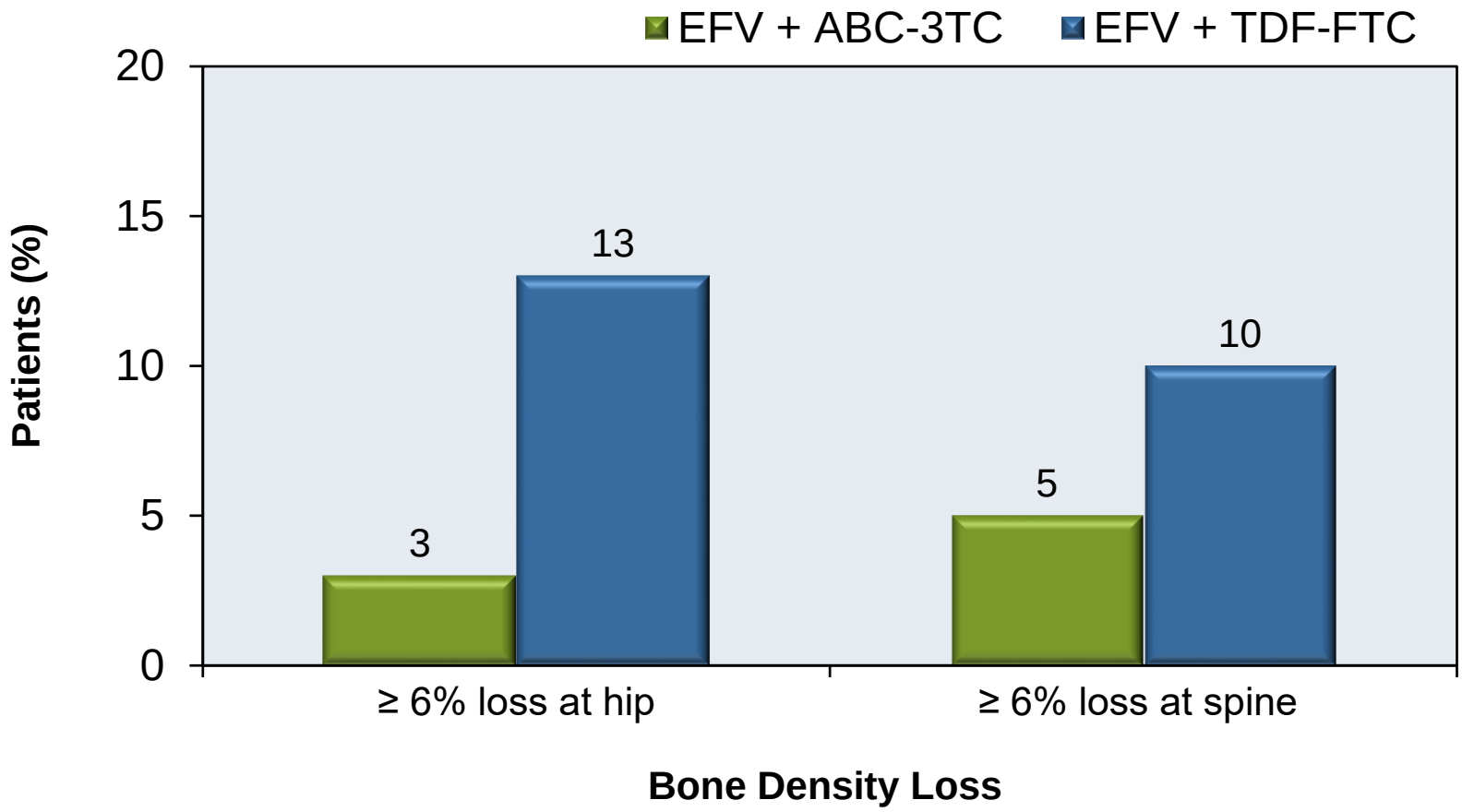
Efavirenz + ABC-3TC versus Efavirenz + TDF-FTC

ASSERT: Bone Effects

Week 48: Proportion of Subjects with Decrease in BMD from Baseline



Source: Stellbrink HJ, et al. Clin Infect Dis. 2010;51:963-72.

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