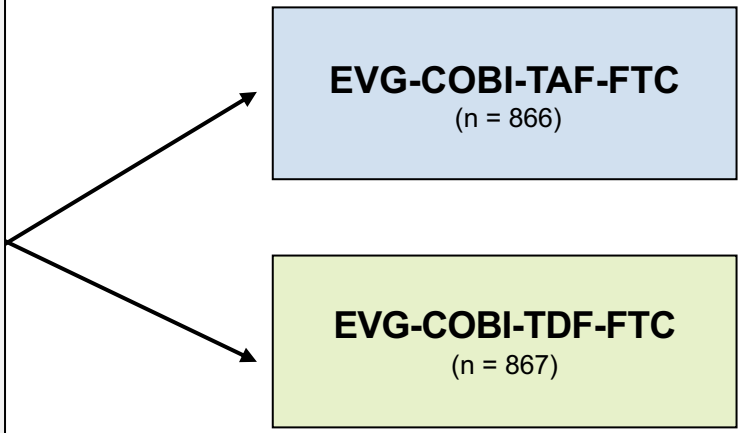
EVG-COBI-TAF-FTC versus EVG-COBI-TDF-FTC

Study 104 and Study 111

EVG-COBI-TAF-FTC versus EVG-COBI-TDF-FTC
Study 104/111: Design

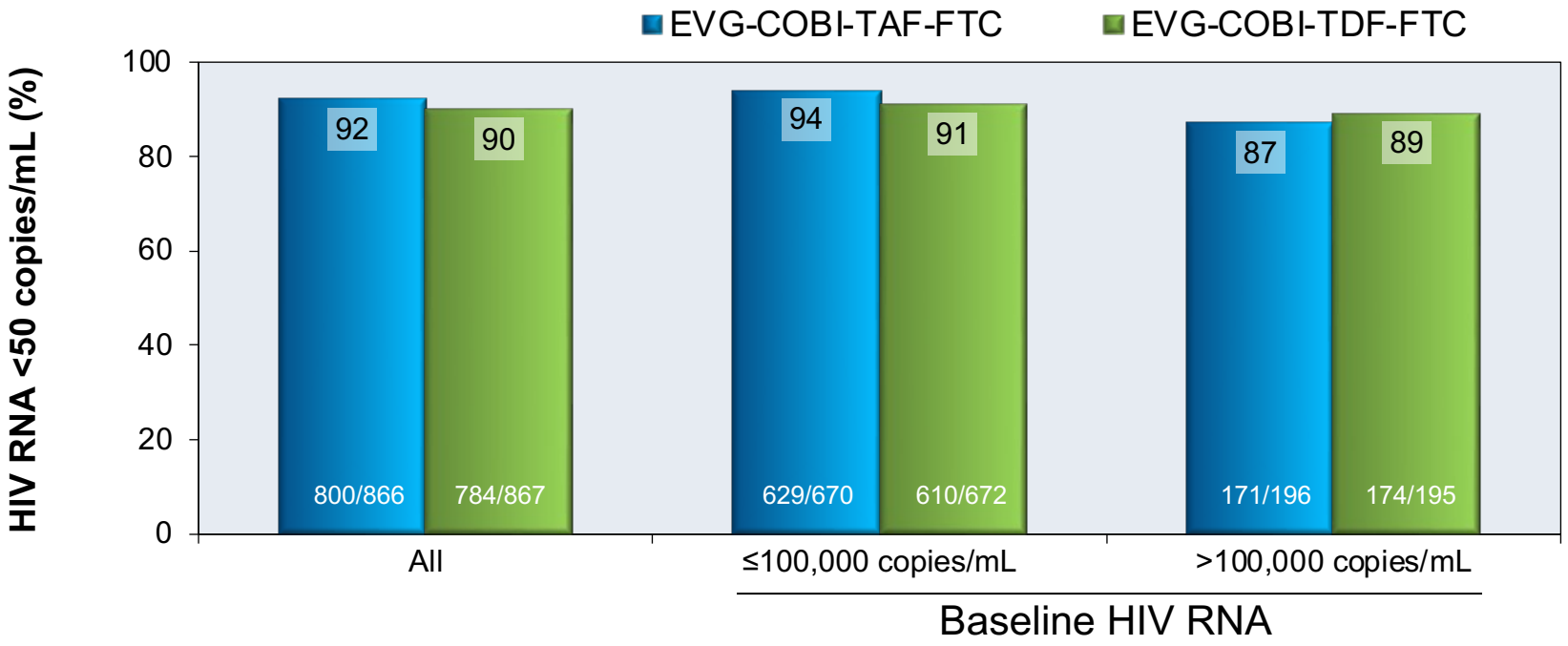
- **Background**: Randomized, double-blind, phase 3 trial comparing elvitegravir-cobicistat-tenofovir alafenamide-emtricitabine with elvitegravir-cobicistat-tenofovir DF-emtricitabine
- **Inclusion Criteria** (n = 1,733)
  - Antiretroviral-naïve patients
  - Age >18
  - HIV RNA ≥1000 copies/mL
  - Any CD4 count allowed
  - No AIDS conditions in prior 30 days
- **Treatment Arms**
  - Elvitegravir-Cobicistat-TAF-FTC
  - Elvitegravir-Cobicistat-TDF-FTC



Source: Sax PE, et al. Lancet. 2015;385:2606-15.

EVG-COBI-TAF-FTC versus EVG-COBI-TDF-FTC
Study 104/111: Result

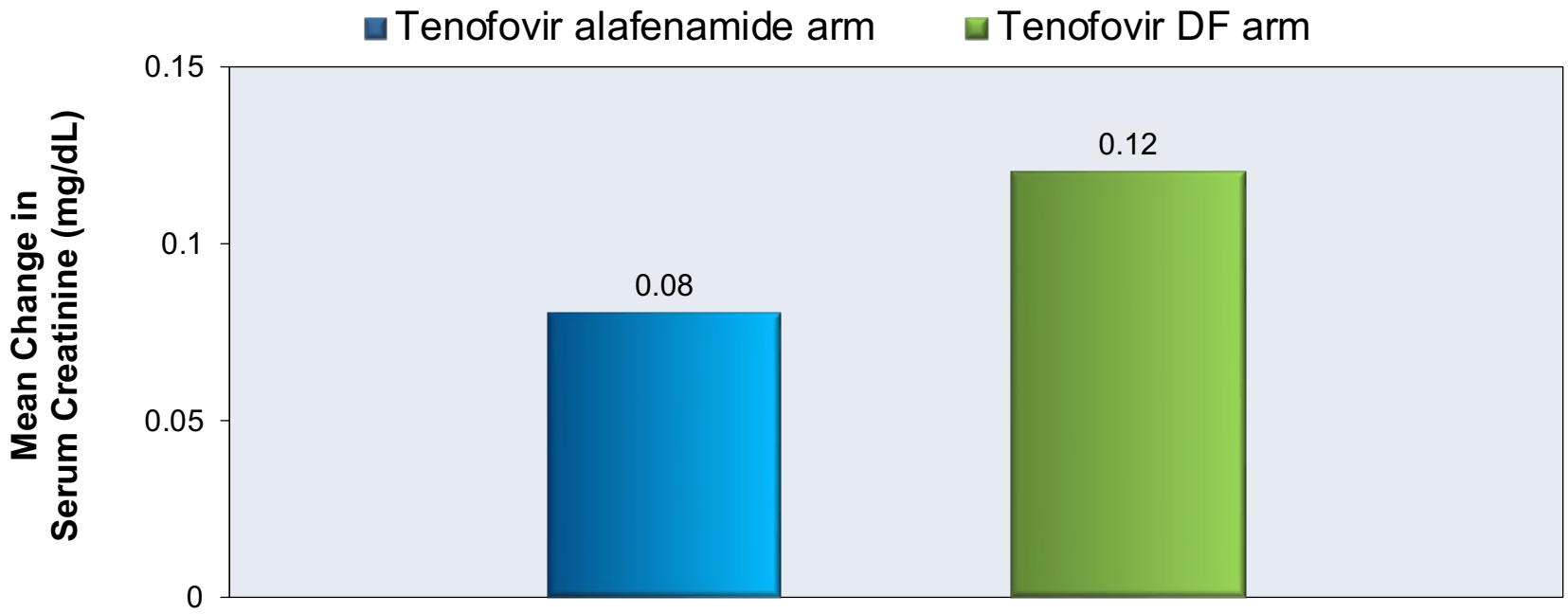
Week 48 Virologic Response



Source: Sax PE, et al. Lancet. 2015;385:2606-15.

EVG-COBI-TAF-FTC versus EVG-COBI-TDF-FTC
Study 104/111: Adverse Effects

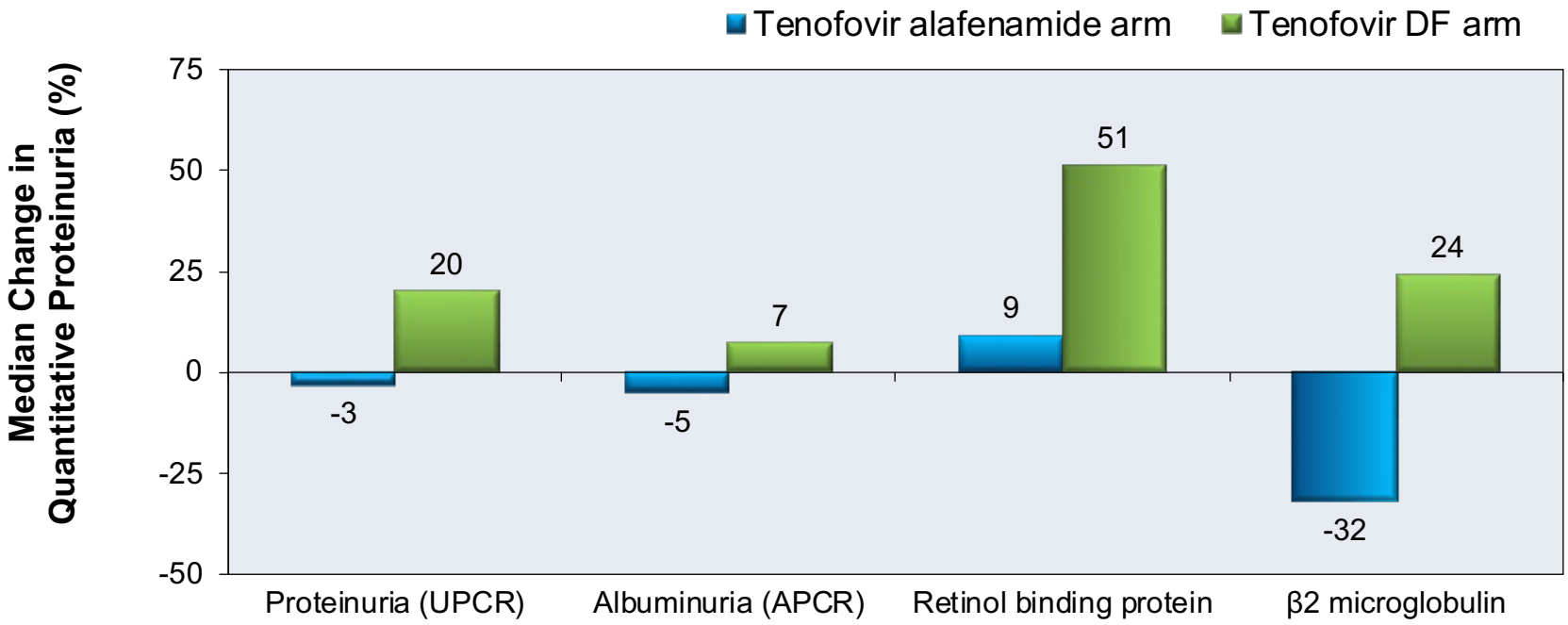
Week 48 Change in Serum Creatinine from Baseline



Source: Sax PE, et al. Lancet. 2015;385:2606-15.

EVG-COBI-TAF-FTC versus EVG-COBI-TDF-FTC
Study 104/111: Adverse Effects

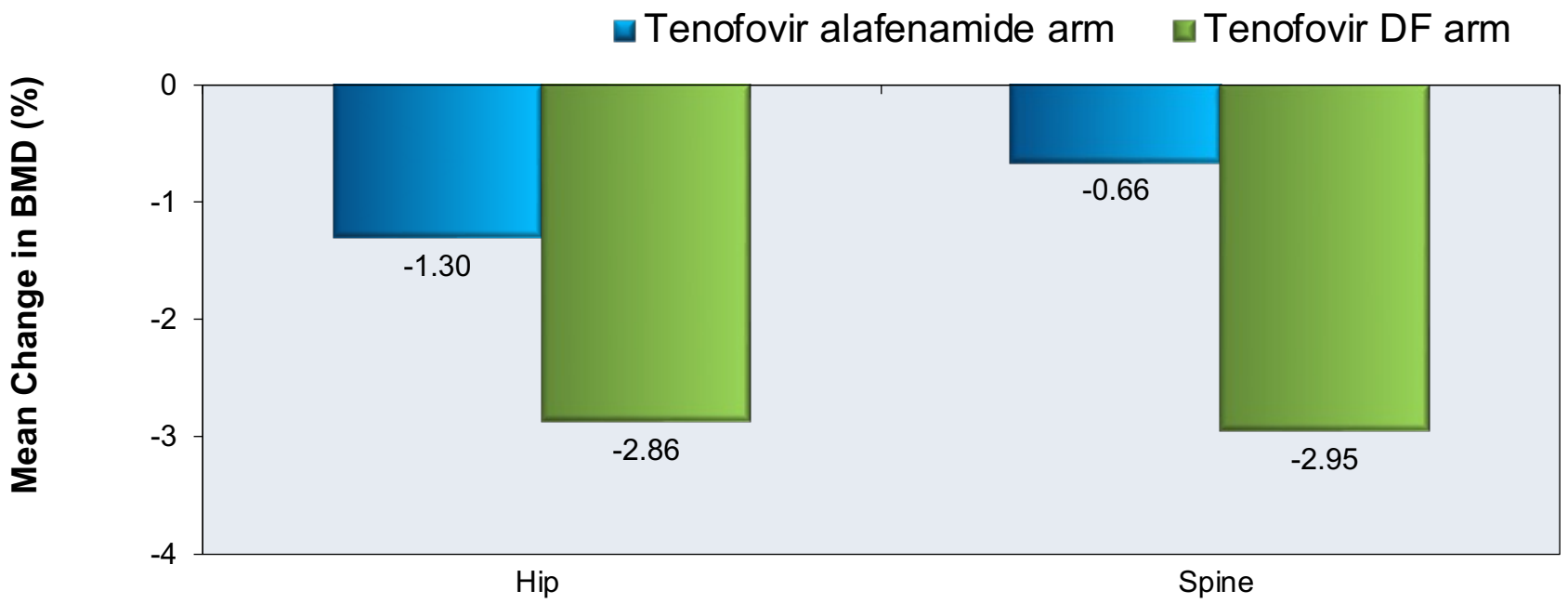
Week 48 Changes in Quantitative Proteinuria from Baseline



Source: Sax PE, et al. Lancet. 2015;385:2606-15.

EVG-COBI-TAF-FTC versus EVG-COBI-TDF-FTC
Study 104/111: Adverse Effects

Week 48 Changes in Spine and Hip Bone Mineral Density (BMD)



Source: Sax PE, et al. Lancet. 2015;385:2606-15.

EVG-COBI-TAF-FTC versus EVG-COBI-TDF-FTC Study 104/111: Adverse Effects

Week 48 Changes in Lipid Parameters

Median Change from Baseline to Week 48	EVG-COBI-TAF-FTC (n = 866)	EVG-COBI-TDF-FTC (n = 867)	P Value
Total cholesterol	+29	+14	<0.001
LDL	+14	+5	<0.001
HDL	+8	+4	<0.001
Triglycerides	+19	+8	0.027
Total cholesterol:HDL ratio	+0.1	+0.1	0.84

Source: Sax PE, et al. Lancet. 2015;385:2606-15.

EVG-COBI-TAF-FTC versus EVG-COBI-TDF-FTC Study 104/111: Conclusions

Interpretation: “Through 48 weeks, more than 90% of patients given E/C/F/tenofovir alafenamide or E/C/F/tenofovir disoproxil fumarate had virological success. Renal and bone effects were significantly reduced in patients given E/C/F/tenofovir alafenamide. Although these studies do not have the power to assess clinical safety events such as renal failure and fractures, our data suggest that E/C/F/tenofovir alafenamide will have a favourable long-term renal and bone safety profile.”

Source: Sax PE, et al. Lancet. 2015;385:2606-15.

Acknowledgments

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AETC AIDS Education & Training Center Program

National HIV Curriculum

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