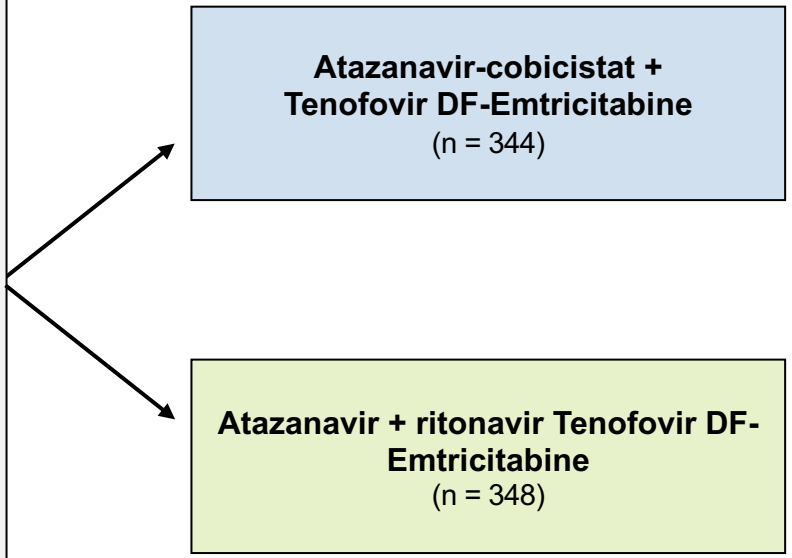
Atazanavir + [Cobicistat or Ritonavir] + TDF-FTC (Phase 3)

Study 114

Atazanavir + [Cobicistat or Ritonavir] + TDF-FTC (Phase 3) Study 114: Study Design

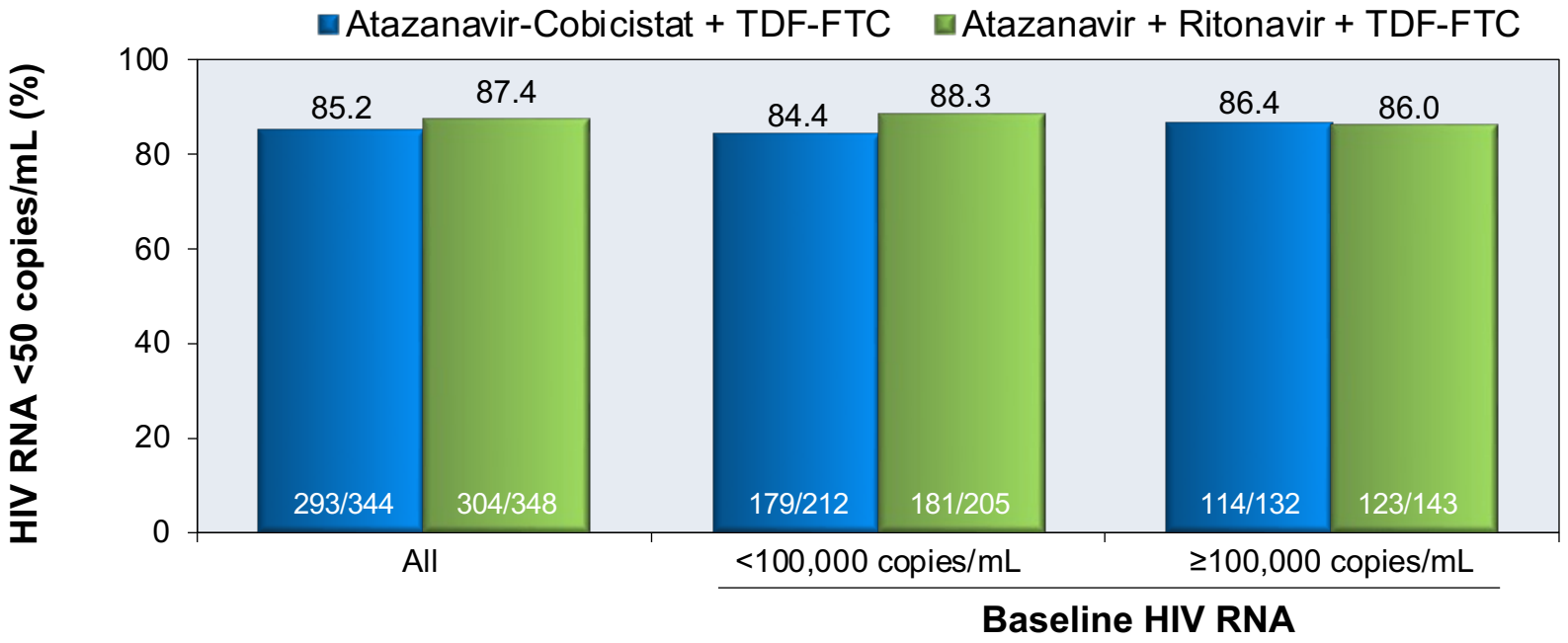
- **Background**: Randomized, double-blind, double-dummy, active controlled phase 3 trial to compare the safety and efficacy of cobicistat and ritonavir as pharmacokinetic enhancers administered with atazanavir and fixed-dose tenofovir DF-emtricitabine in treatment-naïve adults with HIV infection
- **Inclusion Criteria (n = 692)**
  - Age ≥18 years
  - Antiretroviral treatment-naïve
  - Sensitive to atazanavir, tenofovir, and emtricitabine
  - HIV RNA ≥5000 copies/mL
- **Treatment Arms (all once daily)**
  - Atazanavir-cobicistat (300/150 mg) + TDF-FTC
  - Atazanavir 300 mg + Ritonavir 100 mg + TDF-FTC



Source: Gallant JE, et al. J Infect Dis. 2013;208:32-9.

Atazanavir + [Cobicistat or Ritonavir] + TDF-FTC (Phase 3) Study 114: Results

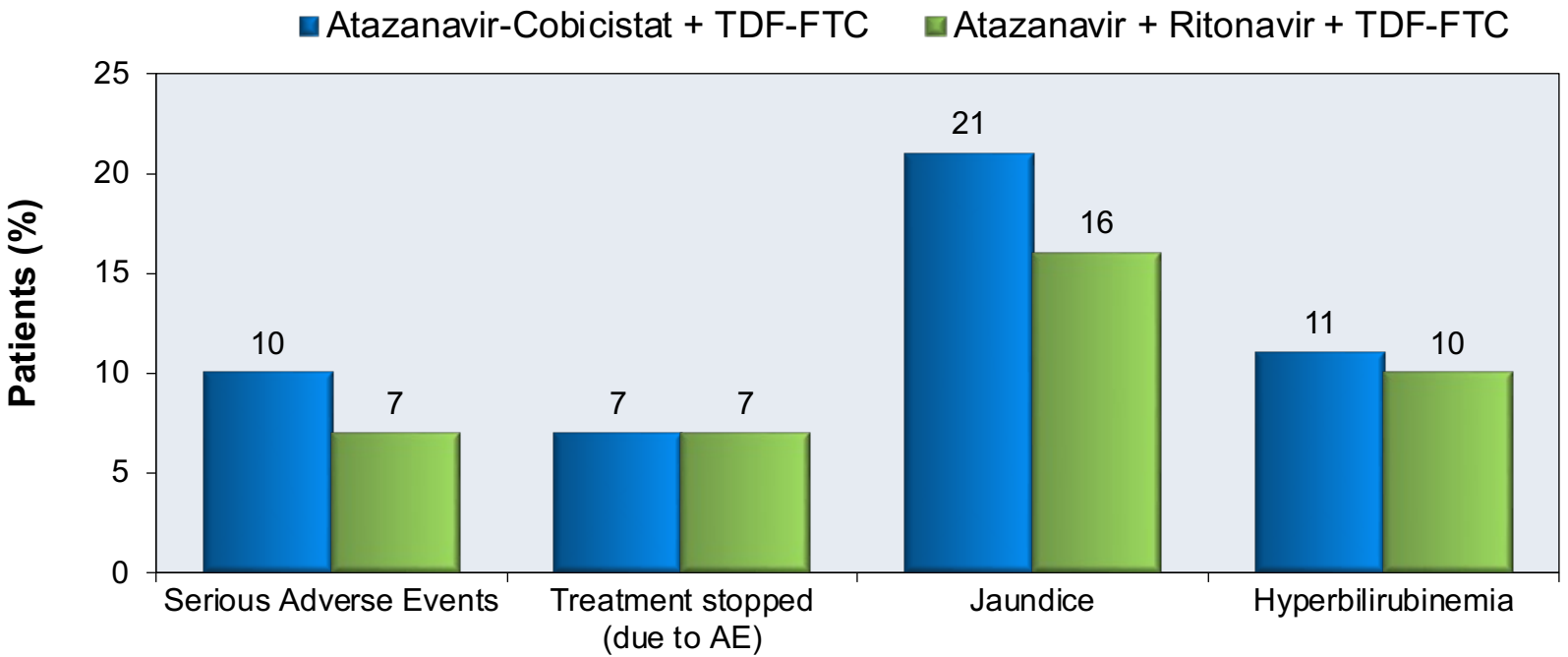
Week 48: Virologic Response (ITT, Missing=Failure)



Source: Gallant JE, et al. J Infect Dis. 2013;208:32-9.

Atazanavir + [Cobicistat or Ritonavir] + TDF-FTC (Phase 3) Study 114: Results

Adverse Events (AE) and Treatment Discontinuations



Source: Gallant JE, et al. J Infect Dis. 2013;208:32-9.

Atazanavir + [Cobicistat or Ritonavir] + TDF-FTC (Phase 3) Study 114: Conclusions

Conclusions: “COBI was noninferior to RTV in combination with ATV plus FTC/TDF at week 48. Both regimens achieved high rates of virologic success. Safety and tolerability profiles of the 2 regimens were comparable. Once-daily COBI is a safe and effective pharmacoenhancer of the protease inhibitor ATV.”

Source: Gallant JE, et al. J Infect Dis. 2013;208:32-9.

Acknowledgments

The **National HIV Curriculum** is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling $1,332,044 with 0% financed with non-governmental sources. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by HRSA, HHS, or the U.S. Government. For more information, please visit HRSA.gov. This project is led by the University of Washington's Infectious Diseases Education and Assessment (IDEA) Program.

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