Darunavir-Cobicistat + 2 NRTIs

Study 130

Darunavir-Cobicistat + 2 NRTIs
Study 130: Design

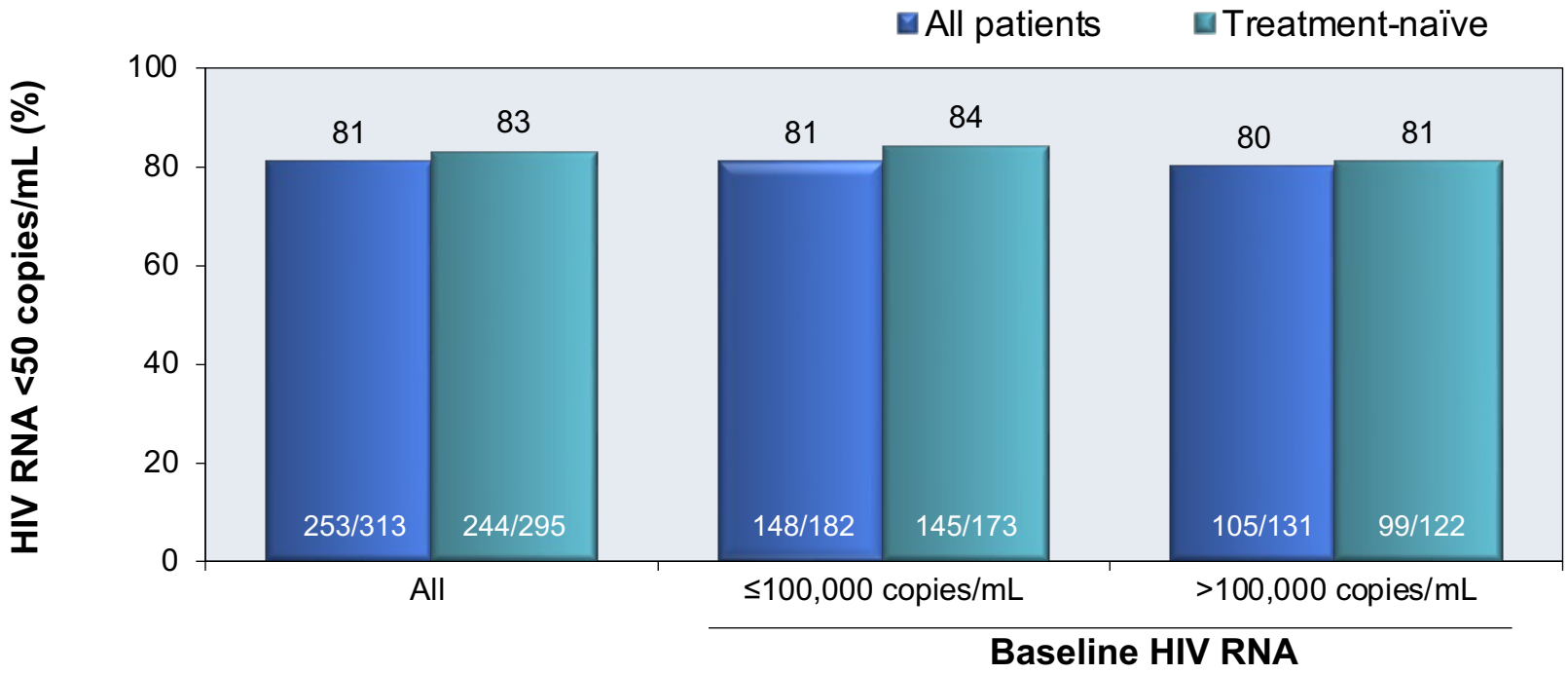
- **Background**: Phase 3b, open label, single-arm study to evaluate the safety and efficacy of cobicistat-boosted darunavir plus two NRTIs in antiretroviral treatment-naïve and treatment-experienced adults with HIV
- **Inclusions Criteria (n = 313)**
  - Antiretroviral treatment-naïve or –experienced
  - On stable ART for ≥12 weeks
  - HIV RNA ≥1000 copies/mL
  - GFR ≥80 mL/min
  - No darunavir-associated resistance mutations
  - Genotypic sensitivity to the two NRTIs
  - No past or current use of darunavir
- **Treatment Arms**
  - Cobicistat 150 mg QD + Darunavir 800 mg QD + 2 investigator-selected NRTIs

→ **Cobicistat + Darunavir + 2 NRTIs**
(n = 313)

Source: Tashima K, et al. AIDS Res Ther. 2014;11:39.

Darunavir-Cobicistat + 2 NRTIs
Study 130: Results

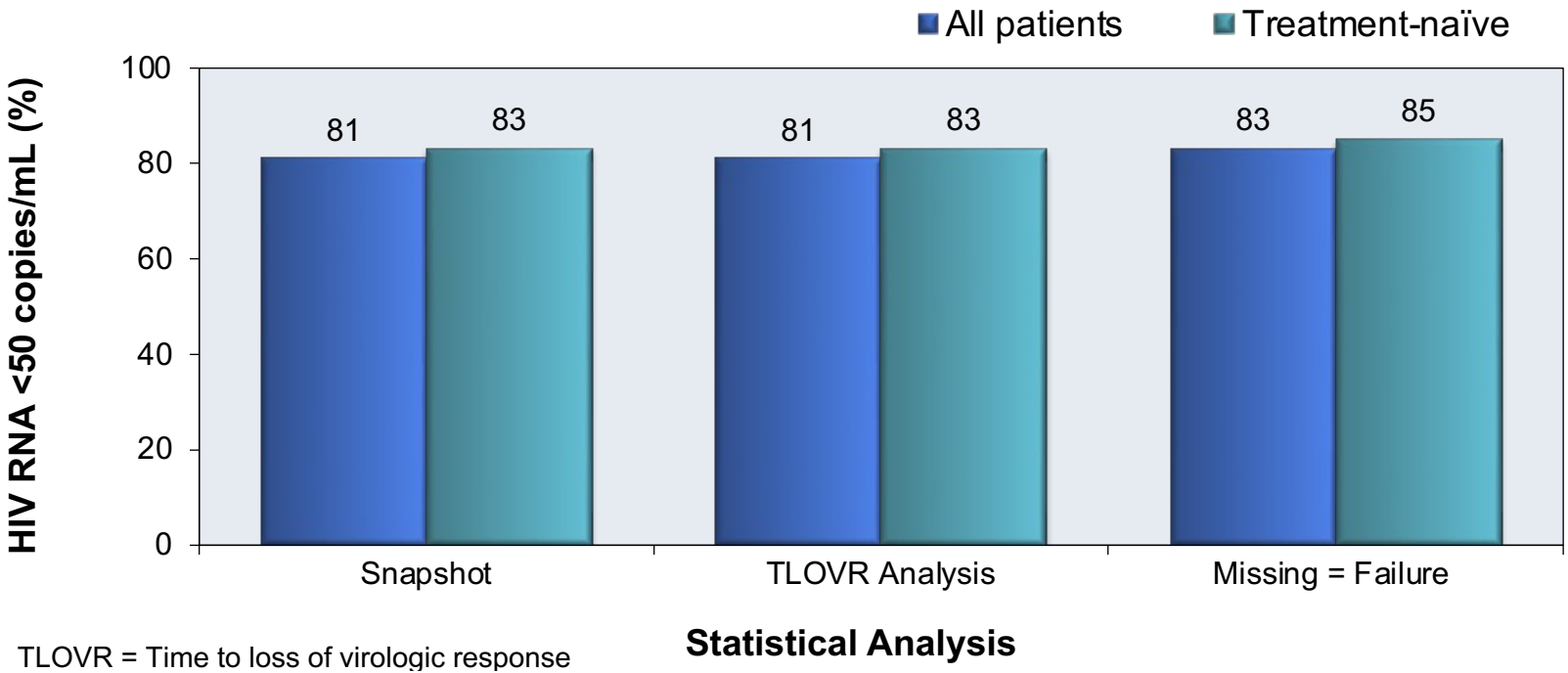
Week 48: Virologic Response (Intent-to-Treat FDA Snapshot Analysis)



Source: Tashima K, et al. AIDS Res Ther. 2014;11:39.

Darunavir-Cobicistat + 2 NRTIs
Study 130: Results

Week 48: Virologic Response, by Different Statistical Analyses



TLOVR = Time to loss of virologic response

Source: Tashima K, et al. AIDS Res Ther. 2014;11:39.

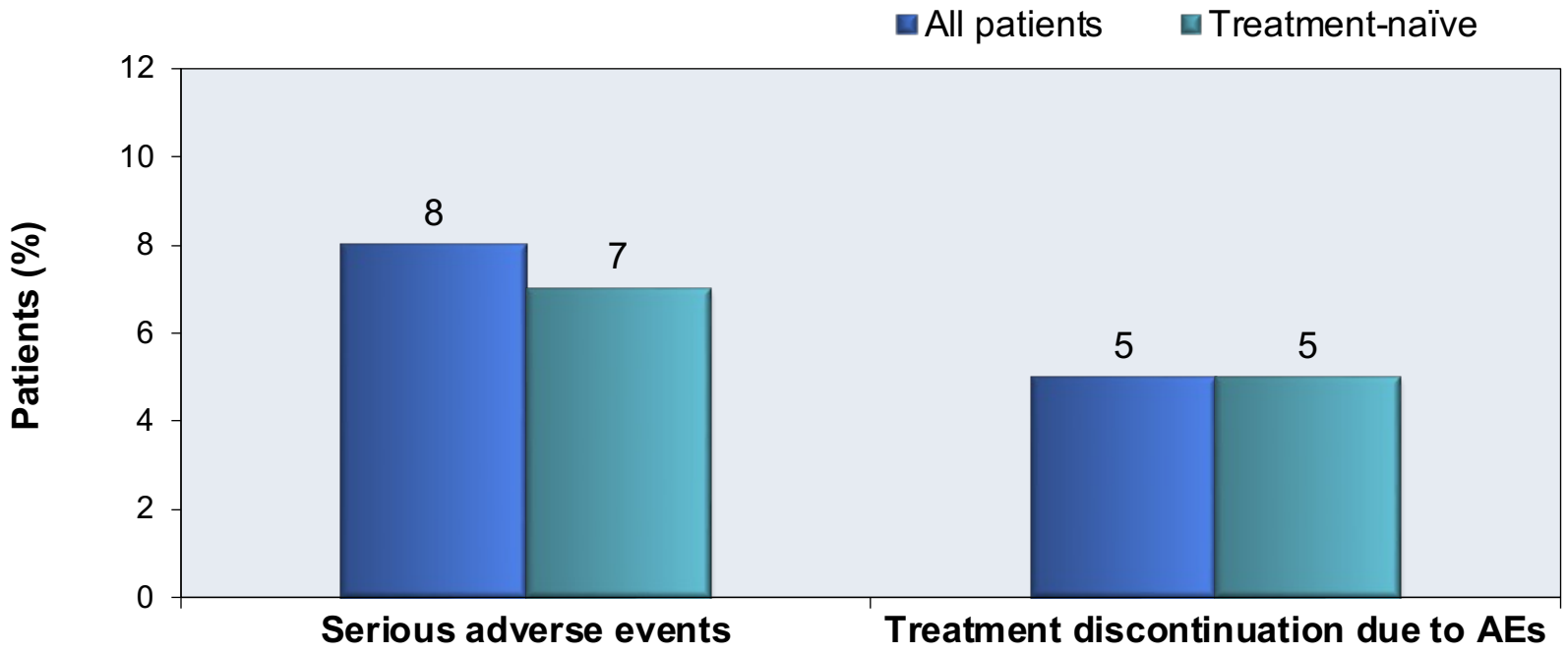
Darunavir-Cobicistat + 2 NRTIs
Study 130: Results

Week 48: Adverse events (any grade), occurring in ≥ 10% of patients		
Adverse Event	All Patients (N = 313)	Treatment-Naïve (N = 295)
Diarrhea	27%	27%
Nausea	23%	23%
Upper respiratory tract infection	14%	15%
Headache	12%	12%

Source: Tashima K, et al. AIDS Res Ther. 2014;11:39.

Darunavir-Cobicistat + 2 N(t)RTIs
Study 130: Results

Adverse Events and Treatment Discontinuations



Source: Tashima K, et al. AIDS Res Ther. 2014;11:39.

Darunavir-Cobicistat + 2 NRTIs
Study 130: Conclusion

Conclusion: “Darunavir/cobicistat 800/150 mg once daily was generally well tolerated through Week 48, with no new safety concerns. Pharmacokinetics, virologic and immunologic responses for darunavir/cobicistat were similar to previous data for darunavir/ritonavir 800/100 mg once daily.”

Source: Tashima K, et al. AIDS Res Ther. 2014;11:39.

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AETC AIDS Education & Training Center Program

National HIV Curriculum

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