Once-Daily Maraviroc in Treatment-Naïve

A4001078 Trial

Once-Daily Maraviroc plus Ritonavir-Boosted Atazanavir
A4001078: Study Design

Study Design: A4001078 Study

- **Background**: Phase 2b, randomized, open label pilot study evaluating a once-daily, dual-therapy regimen of maraviroc and boosted atazanavir in comparison to standard triple therapy in HIV-infected treatment-naïve patients
- **Inclusion Criteria (n = 121)**
  - Age ≥ 16
  - Antiretroviral-naïve patients
  - R-5 tropic virus
  - HIV RNA ≥1000 copies/mL
  - CD4 ≥100 cells/mm^3
- **Treatment Arms** (all medications once daily)
  - Maraviroc 150 mg + Atazanavir 300 mg + Ritonavir 100 mg
  - Tenofovir DF-Emtricitabine + Atazanavir 300 mg + Ritonavir 100 mg

Maraviroc QD + Atazanavir + Ritonavir
(n = 60)

Tenofovir DF-Emtricitabine + Atazanavir + Ritonavir
(n = 61)

Source: Mills A, et al. J Acquir Immune Defic Syndr. 2013;62:164-70.

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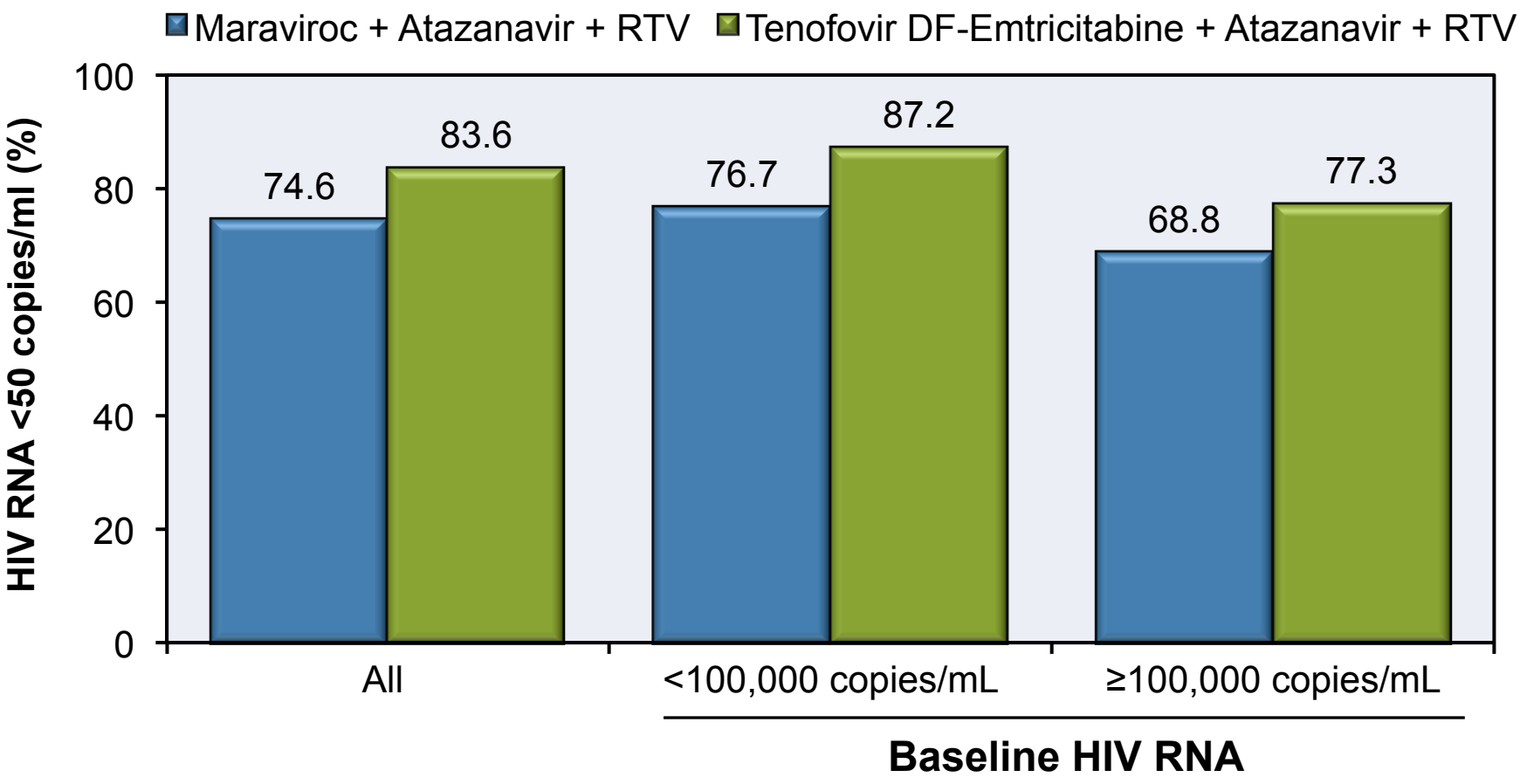
A4001078: Results

Week 48: Virologic Response (Missing or Discontinued = Failure)



Source: Mills A, et al. J Acquir Immune Defic Syndr. 2013;62:164-70.

Once-Daily Maraviroc plus Ritonavir-Boosted Atazanavir
A4001078: Conclusions

Conclusions: "The virological activity and immunological benefit of once-daily MVC + ATV/r were confirmed. Indirect hyperbilirubinemia and associated signs were the most commonly reported adverse effects in both study treatment groups and were not associated with significant transaminase increases. No drug resistance occurred."

Source: Mills A, et al. J Acquir Immune Defic Syndr. 2013;62:164-70.

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National HIV Curriculum

AETC AIDS Education & Training Center Program
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