Relationship between combination of baseline viral load and CD4 cell count, and Week 48 or 96 responses to rilpivirine (RPV) or efavirenz (EFV) in treatment-naive HIV-1-infected adults: pooled analysis from the Phase III ECHO and THRIVE trials

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Introduction

- RPV (ECHO/THRIVE) is now approved by the U.S. FDA and Canada for use in combination with tenofovir disoproxil fumarate (TDF) and emtricitabine (FTC) for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults.
- ECHO (Janssen Research and Development, LLC) and THRIVE (Janssen R&D, Inc.) are phase 3 trials comparing RPV as part of combination antiretroviral therapy (ART) with EFV as part of ART in treatment-naive HIV-1-infected adults.

Methods

- Patients (N=368) were randomized 1:1 to receive RPV 25 mg qd or EFV 600 mg qd plus TDF/FTC (N=1368) at baseline.
- The primary endpoints were virologic response, with virologic success defined as achieving a viral load <50 c/mL at Week 48 or 96.
- Baseline CD4 cell count was one of 3 categories (≤ 200, 200–350, ≥ 350 cells/mm3).

Results

- There was a strong inverse correlation between baseline viral load and CD4 cell count e.g. for groups (≥ 500,000 c/mL (and by background regimen in THRIVE). Given the small size of the >500,000 c/mL group, subgroup analysis was conducted.
- Patients with baseline viral load >100,000 c/mL AND CD4 cell count ≥ 350 cells/mm3 did not have a higher response rate compared to patients with CD4 cell count ≤ 200 cells/mm3.
- Patients with viral load >100,000 c/mL and CD4 cell count <50 cells/mm3 had low response rates regardless of treatment assignment.
- The effect of viral load on treatment response was largely, but not completely explained by the effect of baseline viral load given the low rate of viral load response seen in patients with viral load >100,000 c/mL and CD4 cell count <50 cells/mm3.
- The median baseline viral load >100,000 c/mL was 350 (range 7, 833,300,000) (18,000–59,000).
- There was a strong inverse correlation between baseline viral load and CD4 cell count e.g. for groups (≥ 500,000 c/mL (and by background regimen in THRIVE). Given the small size of the >500,000 c/mL group, subgroup analysis was conducted.
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- The effect of viral load on treatment response was largely, but not completely explained by the effect of baseline viral load given the low rate of viral load response seen in patients with viral load >100,000 c/mL and CD4 cell count <50 cells/mm3.
- The median baseline viral load >100,000 c/mL was 350 (range 7, 833,300,000) (18,000–59,000).

Conclusions

- There was a strong inverse correlation between baseline viral load and CD4 cell count, and Week 48 or 96 responses to rilpivirine (RPV) or efavirenz (EFV) in treatment-naive HIV-1-infected adults: pooled analysis from the Phase III ECHO and THRIVE trials.

Acknowledgments and disclosures

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References


Virologic outcomes at Weeks 48 and 96 by baseline viral load and CD4 cell count

- For patients with baseline viral load ≤ 200,000 c/mL, in general a comparable and high percentage of patients with significant viral load at entry (CD4 cell count ≥ 350 cells/mm3) and viral load >100,000 c/mL had a greater confirmed baseline viral load and CD4 cell count the higher their baseline CD4 cell count was.
- For patients with viral load >100,000 c/mL, the rate of virologic success at an ITT-TLOVR was significantly higher for patients with baseline viral load >100,000 c/mL and CD4 cell count ≥ 350 cells/mm3.
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