Study population

PE2/37

Background

• Three antiretrovirals from two classes have long been the standard of care for people living with HIV (PLWH).

• Newer, more powerful antiretrovirals have introduced the potential for effective therapy with fewer agents.

• Dolutegravir/rilpivirine (DTG/RPV) was the first single tablet, once-daily regimen of interest.

Objective

To compare the effectiveness and durability of DTG/RPV versus 3-Drug (3-DR) regimens for effective therapy with fewer agents.

Newer, more powerful antiretrovirals have introduced the potential for effective therapy with fewer agents.

Study population

To standard three-drug regimens (3-DR) in a real-world population.

Methods


• Inclusion Criteria:
  o HIV-1 positive, HIV-2 negative, ≥13 years of age
  o Initiated a 2-DT (DTG/RPV) or 3-DR (DTG, EVG, RAL, DRV, RPV, or ATV) regimen ≥2 NRTIs, boosted or unboosted) between 1JAN2018 and 30JUN2018
  o Last viral load <50 copies/mL on or before initiation of regimen of interest
  o No exposure to DTG/RPV prior to initiation

• Baseline: Date of initiation of 2-DT or 3-DR of interest

• Study outcomes:
  o Virologic failure: ≥1 VL <200 copies/mL + ≥1 VL ≥200 copies/mL
  o Discontinuation: Modification or discontinuation of regimen of interest
  o Follow-up until:
    o Regimen discontinuation
    o Death or Study end (31DEC2018)

Analysis

• Description of patient characteristics and outcomes
  o Categorical variables: Pearson’s chi-square or Fisher exact tests
  o Continuous variables: Wilcoxon rank-sum

• Time to discontinuation and virologic failure:
  o Kaplan-Meier methods
  o Multivariable Cox Proportional Hazards models

Results

Table 1. Baseline Demographic and Clinical Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>DTG/RPV (n=259)</th>
<th>3-DR (n=2,792)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age ≥50 years</td>
<td>143 (55.2%)</td>
<td>1,093 (39.1%)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Female sex</td>
<td>38 (14.7%)</td>
<td>534 (19.1%)</td>
<td>0.2303</td>
</tr>
<tr>
<td>African American race</td>
<td>78 (30.1%)</td>
<td>1,131 (40.5%)</td>
<td>0.0011</td>
</tr>
<tr>
<td>Hispanic ethnicity</td>
<td>88 (34.0%)</td>
<td>719 (25.8%)</td>
<td>0.0041</td>
</tr>
<tr>
<td>Care in Southern US</td>
<td>172 (66.4%)</td>
<td>1,355 (48.5%)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Hx of AIDS</td>
<td>68 (26.3%)</td>
<td>777 (27.7%)</td>
<td>0.5880</td>
</tr>
<tr>
<td>CD4 Count &gt;500 cells/µL</td>
<td>205 (79.2%)</td>
<td>1,986 (71.1%)</td>
<td>0.1100</td>
</tr>
<tr>
<td>Hx of Syphilis</td>
<td>27 (10.6%)</td>
<td>1,001 (35.9%)</td>
<td>0.0094</td>
</tr>
<tr>
<td>Any Comorbidity</td>
<td>224 (86.5%)</td>
<td>2,218 (79.4%)</td>
<td>0.0067</td>
</tr>
</tbody>
</table>

Figure 1. Distribution of Core Agents Among the 3-DR Group

Figure 2. Unadjusted Cumulative Probability of Discontinuation of 2-DT versus 3-DR

Figure 3. Unadjusted Cumulative Probability of Virologic Failure of 2-DT versus 3-DR

Key Findings

- DTG/RPV users differed from 3-DR users notably (Table 1)
  o DTG/RPV users were older, more likely to be Hispanic, to live in the southern US, and have comorbidities
  o 3-DR users were younger, more likely to be African American, and have a history of syphilis (an indicator of a complex lifestyle)
  - DTG/RPV users were followed for less time, experienced fewer discontinuations, and did not differ in sustained suppression compared to 3-DR users (Table 2, Figure 2)
  - Virologic failure was uncommon early and did not differ between DTG/RPV and 3-DR users (Table 3, Figure 3)
- Strengths: Large, diverse population of PLWH in the US
- Limitations: No reasons for those who discontinued or resistance data for those who failed

Discussion

This research was funded by ViiV Healthcare, Research Triangle Park, NC, USA.

Table 3. Virologic Failure with 2-DT versus 3-DR

<table>
<thead>
<tr>
<th>Outcome</th>
<th>DTG/RPV (n=259)</th>
<th>3-DR (n=2,792)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Virologic failure, n (%)</td>
<td>3 (1.3%)</td>
<td>44 (2.0%)</td>
<td>0.7972</td>
</tr>
<tr>
<td>Incidence Rate*</td>
<td>1.16 (0.35, 3.79)</td>
<td>1.38 (0.43, 4.43)</td>
<td>0.8085</td>
</tr>
<tr>
<td>Unadjusted HR^</td>
<td>1.0</td>
<td>1.38 (0.43, 4.43)</td>
<td>0.8085</td>
</tr>
<tr>
<td>Adjusted HR®</td>
<td>1.0</td>
<td>1.38 (0.43, 4.43)</td>
<td>0.8085</td>
</tr>
</tbody>
</table>

*IR=Incidence Rate per 100 person-years (95% CI)
®HR=Hazard Ratio (95% CI)

*IR adjusted for age, sex, race, region, CD4 cell count, history of comorbidities

Acknowledgements

This research would not be possible without the generosity of people living with HIV and their OPERA caregivers. Additionally, we are grateful for the following individuals: Aneilete Torres (SAS programming), Jeff Briney (QA), Bernie Stooks (Database Arch & Mgmt), Judy Johnson (Med Terminology Classification), Raynay Mood (Site Support)

Support

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