BACKGROUND

- Doravirine (DOR) is the newest non-nucleoside reverse transcriptase inhibitor (NNRTI) to be developed.
- DOR is available as a single agent or coformulated with lamivudine (3TC) and tenofovir disoproxil fumarate (TDF).
- It has efficacy and safety have been established in antiretroviral therapy (ART) naive and experienced people with HIV (PWH)\(^1\).
- DOR was approved in the United States by the FDA on 30AUG2018 and in Europe by the European Medicines Agency on 22Nov2018.
- While the European AIDS Clinical Society (EACS) recommends DOR for ART-naive adults,\(^2\) the US Department of Health and Human Services recommends DOR in certain clinical conditions\(^3\).

OBJECTIVE

To characterize doravirine users and describe treatment patterns before and with doravirine in the US.

METHODS

Study Population

- OPERA\(^{®}\) observational cohort.
  - Prospectively captured, routine clinical data from electronic health records from 96 clinics in the US (22 states, 1 US territory).
  - >148K people with HIV (PWH) as of July 2022, representing ~14% of people with diagnosed HIV infection in the US\(^4\).
- Inclusion criteria
  - Diagnosis of HIV infection with laboratory confirmation.
  - Initiated switched to DOR between 30AUG2018 and 30NOV2021.
  - 18 years old at DOR initiation/switchover.
- Index date: Date of first DOR-containing regimen initiation during the study period.

Analyses

- Descriptive statistics for demographic, clinical, and ART patterns stratified by viral load (VL) at DOR initiation, among ART-experienced PWH with baseline viral load.
- Sankey diagram to illustrate pathways from prior ART regimens to DOR-containing regimens, among PWH with ART experience or unknown prior experience.

RESULTS

Figure 1. Study population

Table 1. Baseline characteristics of ART-experienced PWH with baseline viral load, \(N = 789\)

<table>
<thead>
<tr>
<th>VL &lt;50 copies/mL</th>
<th>VL &lt;50 to &lt;200 copies/mL</th>
<th>VL ≥200 copies/mL</th>
<th>No baseline VL</th>
</tr>
</thead>
<tbody>
<tr>
<td>((N = 434))</td>
<td>((N = 122))</td>
<td>((N = 233))</td>
<td>((N = 24))</td>
</tr>
<tr>
<td>Median age (IQR)</td>
<td>54 (43, 61)</td>
<td>54 (45, 59)</td>
<td>49 (38, 56)</td>
</tr>
<tr>
<td>Male sex, n (%)</td>
<td>328 (76)</td>
<td>99 (81)</td>
<td>163 (70)</td>
</tr>
<tr>
<td>Black race, n (%)</td>
<td>145 (33)</td>
<td>45 (37)</td>
<td>145 (62)</td>
</tr>
<tr>
<td>History of AIDS-defining events, n (%)</td>
<td>168 (39)</td>
<td>49 (40)</td>
<td>117 (50)</td>
</tr>
<tr>
<td>Comorbidities, n (%)(^4)</td>
<td>392 (90)</td>
<td>115 (94)</td>
<td>208 (89)</td>
</tr>
<tr>
<td>Median VACS index (IQR)</td>
<td>22 (12, 34)</td>
<td>18 (12, 28)</td>
<td>35 (19, 52)</td>
</tr>
</tbody>
</table>

Table 2. Treatment patterns among ART-experienced PWH with baseline viral load, \(N = 789\)

<table>
<thead>
<tr>
<th>VL &lt;50 ((N = 434))</th>
<th>VL &lt;50 to &lt;200 ((N = 122))</th>
<th>VL ≥200 ((N = 233))</th>
<th>Median calendar year of ART initiation (IQR)</th>
<th>NNRTIs included in prior regimen, n (%)</th>
<th>DOR/3TC/TDF single tablet formulation, n (%)</th>
<th>Anchor agent, n (%)</th>
<th>DOR only</th>
<th>DOR + other anchor agent(^6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014 (10, 2017)</td>
<td>60 (14)</td>
<td>112 (26)</td>
<td>139 (32)</td>
<td>295 (68)</td>
<td>18%</td>
<td>8% PI</td>
<td>9% PI + INSTI</td>
<td></td>
</tr>
<tr>
<td>2016 (2012, 2017)</td>
<td>5 (7)</td>
<td>11 (9)</td>
<td>12 (10)</td>
<td>194 (83)</td>
<td>24%</td>
<td>6% DOR + INSTI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2015 (2012, 2018)</td>
<td>18%</td>
<td>13%</td>
<td>39 (17)</td>
<td>18%</td>
<td>18%</td>
<td>DOR + NNRTI</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

DISCUSSION

- In the US, between 30AUG2018 and 30NOV2021, DOR was most often prescribed to:
  - ART-experienced PWH (Figure 1).
  - PWH with comorbidities and elevated mortality risk (Table 1).
- Overall, the single agent formulation (DOR alone) was often preferred over the single tablet formulation (DOR/3TC/TDF) (Table 2).
- However, the single tablet formulation was more commonly used for PWH with baseline VL <50 copies/mL than those with baseline VL ≥50 copies/mL (Table 2).
- Multiple patterns of ART regimen sequences from prior to next regimen were observed.
- DOR was used in combination with other anchor agent(s) in 68% of experienced PWH with baseline VL <50 copies/mL and 83%-90% of those with baseline VL ≥50 copies/mL (Table 2).
- Once prescribed, DOR use was often maintained despite regimen readjustment (i.e., changes in other core agents while maintaining DOR) occurring in 38% of experienced PWH (Figure 2).
- These findings highlight the intricacy of ART regimen selection in a population who may have complex needs.

KEY FINDINGS

- In the US, DOR has been preferentially prescribed to ART-experienced PWH, in combination with other anchor agents.
- Treatment patterns suggest the need to accommodate complex needs in this population.

REFERENCES


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