Characteristics of Early Adopters of a Two-Drug Regimen (Dolutegravir/Rilpivirine) for Treatment of Human Immunodeficiency Virus Type 1 in the United States

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The Longitudinal Cohort

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BACKGROUND

- Combination antiretroviral therapies (ART) have resulted in longer lifespans and an aging population of people living with HIV (PLWH).[1, 2]
- Two-drug ART regimens minimize drug exposure, reduce risks for adverse effects, drug-drug interactions, and long term toxicities.[3, 4]
- In 2017, Juluca® (dolutegravir/rilpivirine; DTG/RPV), the first complete treatment regimen containing only two antiretroviral (ARV) drugs in a single tablet to treat HIV-1 was approved for use in ART-experienced patients currently suppressed on a stable regimen with no history of treatment failure or resistance to either DTG or RPV.[5]

OBJECTIVE:

Characterize the early utilization of DTG/RPV in the US

METHODS

Study Population

- Observational clinical cohort analysis
  - Data from the Observational Pharmaco-Epidemiology Research and Analysis (OPERA) database
  - Prospectively collected electronic medical record (EMR) data
  - More than 90,000 PLWH from 84 clinics across 18 states, District of Columbia, and Puerto Rico
  - Collaboration of over 400 caregivers nationwide
- Inclusion Criteria:
  - HIV-1-positive
  - ≥18 years of age
  - Prescribed DTG/RPV between January 1, 2018 and June 30, 2018
- Exclusion Criteria:
  - PLWH co-infected with HIV-2
  - Previously initiated DTG/RPV as part of a clinical trial

Data Analysis

- Index: Date of DTG/RPV initiation
- Follow-up period: January 1, 2018 to June 30, 2018
- Overall and stratified analyses were conducted
- Patient demographic characteristics were described at index
- Clinical and treatment characteristics were described using a baseline of 12 months unless otherwise specified.

RESULTS

Figure 1. DTG/RPV Initiators by Regimen Components, ART History, and Virologic Status at Initiation (N=456)

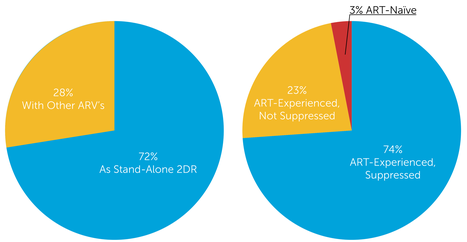


Figure 2. Demographic Characteristics of DTG/RPV Initiators (n=456, thick bars) Compared to the Active OPERA Population (N=46,177, thin bars)

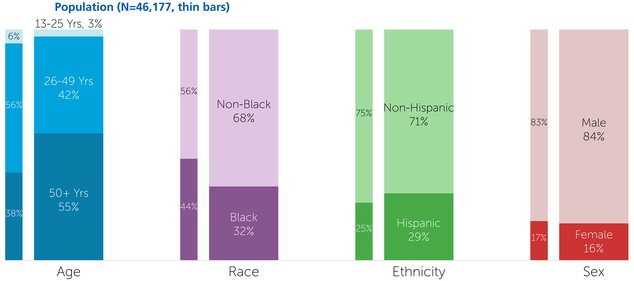
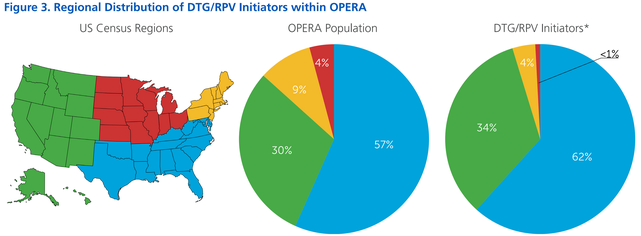
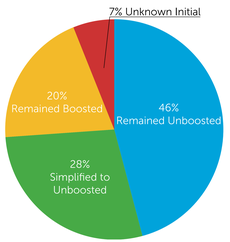


Figure 3. Regional Distribution of DTG/RPV Initiators within OPERA



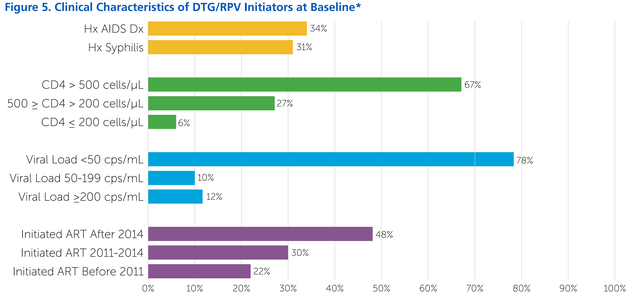
* Sum of percentages may not exactly equal 100 due to rounding.

Figure 4. Regimen Simplification Among DTG/RPV Initiators*



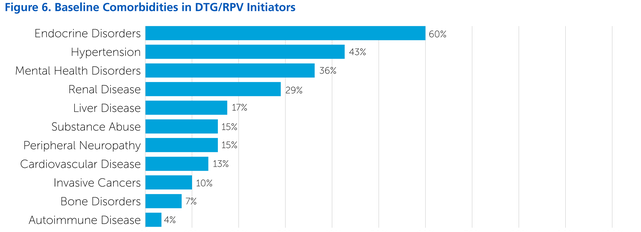
* Sum of percentages may not exactly equal 100 due to rounding.

Figure 5. Clinical Characteristics of DTG/RPV Initiators at Baseline*



* Sums of percentages may not exactly equal 100 due to rounding.

Figure 6. Baseline Comorbidities in DTG/RPV Initiators



DISCUSSION

- Most patients were ART-experienced, initiating DTG/RPV as a stand-alone, two-drug regimen.
- At initiation, most patients had undetectable viral loads or had viral loads between 50 and 199 copies/mL. Few patients had viral loads ≥200 copies/mL.
- Regimens were frequently simplified.
- Comorbidity was prevalent: 86% of patients had ≥1 comorbid condition. 60% ≥1 endocrine disorder, 43% hypertension, 36% a mental health disorder and 29% renal disease.
- In patients living with HIV-1 infection and other concomitant chronic illnesses, DTG/RPV may be an important option for clinician's needing to simplify an HIV regimen.
- Limitation: While the OPERA cohort follows up to 7% of the HIV epidemic in the US, it may over- or underestimate specific subpopulations.

KEY FINDINGS:

Early initiators of DTG/RPV were primarily treatment-experienced individuals older than 50 years of age with virologic and immunologic control but challenged by significant comorbid conditions.

REFERENCES

1. Wandeler G, Johnson LF, Egger M. Trends in life expectancy of HIV-positive adults on antiretroviral therapy across the globe: comparisons with general population. *Current opinion in HIV and AIDS*. 2016;11(5):492-500.
2. Teeraananchai S, Kerr S, Amin J, Ruxrungtham K, Law M. Life expectancy of HIV-positive people after starting combination antiretroviral therapy: a meta-analysis. *HIV Medicine*. 2017;18(4):256-266..
3. McKinnon JE, Mellors JW, Swindells S. Simplification strategies to reduce antiretroviral drug exposure: progress and prospects. *Antivir Ther*. 2009;14(1):1-12.
4. Baril JG, Angel JB, Gill MJ, et al. Dual Therapy Treatment Strategies for the Management of Patients Infected with HIV: A Systematic Review of Current Evidence in ARV-Naive or ARV-Experienced, Virologically Suppressed Patients. *PLoS One*. 2016;11(2):e0148231.
5. US Food and Drug Administration. FDA approves first two-drug regimen for certain patients with HIV. FDA News Release 2017; https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm586305.htm.

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