Poster #2483

Characteristics and Outcomes Over First 12 Months of a Two-Drug Regimen (Dolutegravir/Rilpivirine) for Treatment of HIV-1 in the United States

Gerald Pierone[1], Kathy L. Schulman[2], Jennifer Fusco[2], Vani Vannappagari[3], Michael Aboud[4], Leigh Ragone[3], Gregory Fusco[2]

[1]Whole Family Health Center, Vero Beach, FL, USA; [2]Epividian, Durham, NC, USA; [3]ViiV Healthcare, Research Triangle Park, NC, USA; [4]ViiV Healthcare, London, UK

OPERA® The Longitudinal Cohort

Contact Information:
Kathy L. Schulman
4505 Emperor Blvd, Suite 220, Durham, NC 27703
p: (508) 243-1442 e: kathy.schulman@epividian.com

Background

- ART regimens containing 3 agents have long been the standard of care for HIV treatment
- The concept of treating with more powerful, but fewer agents is now being assessed
- Two-drug regimens (2-DR) may be of particular value for people living with HIV (PLWH) with varying degrees of frailty[1] (e.g. co-morbid disease burden, aging populations, multi-class resistance) due to:
  - the potential for impaired immunologic responses to ART[2,3]
  - high levels of polypharmacy[4]
  - the potential for drug-drug interactions[5]
- Dolutegravir/rilpivirine (DTG/RPV), the first complete ART regimen containing only two drugs, was approved in 2017

OBJECTIVE

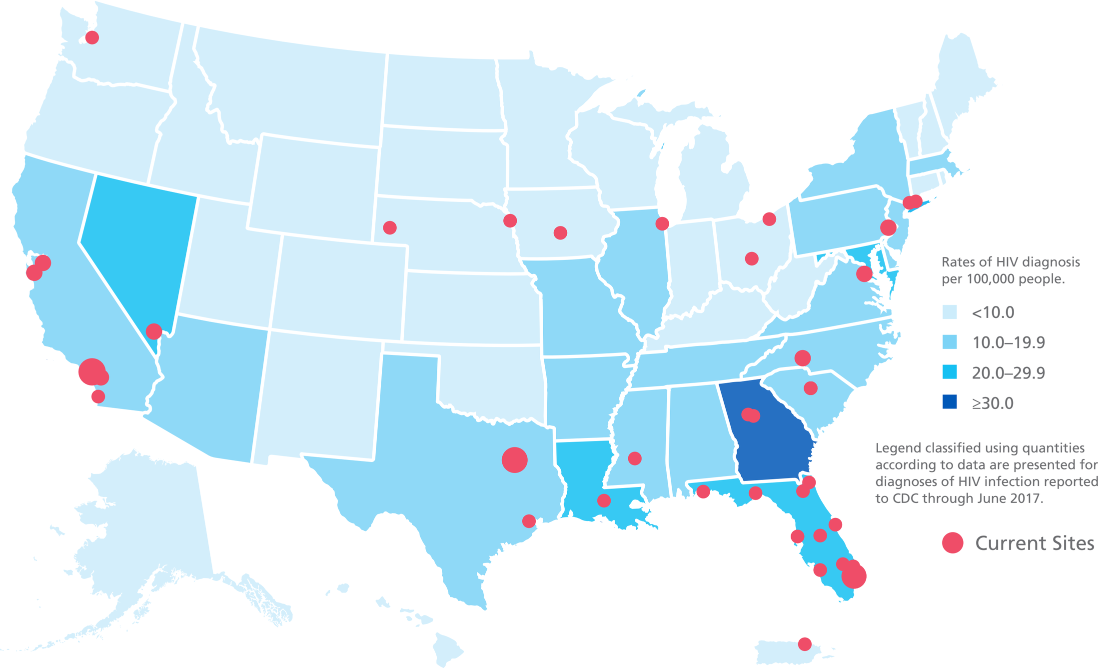
To characterize the early utilization and outcomes of DTG/RPV use in a real-world population in the US

Methods

Study population

- HIV-1 positive, HIV-2 negative PWLH age 13 years or older who initiated DTG/RPV between 1Jan2018 and 31Dec2018 in the OPERA Database
- The population was observed from DTG/RPV start (index) until the first of: a) DTG/RPV stop, b) death or c) study end (31Dec2018).

Figure 1: OPERA geographic distribution of sites and CDC (2017) state-by-state estimates of new HIV infections



Analyses

- Characterization of DTG/RPV initiators
- Durability and effectiveness outcomes assessed with Kaplan-Meier methods
  - Among ART-experienced, suppressed PLWH (i.e. history of ART use and viral load <50 copies/mL) who initiated DTG/RPV between 1Jan2018 and 30Jun2018 and ≥ 12 months of follow-up
  - Discontinuation (d/c) defined as cessation of DTG/RPV
  - Virologic failure (VF) defined as either 2 consecutive HIV viral loads (VL) ≥ 200 copies/mL OR 1 VL ≥ 200 copies/mL + DTG/RPV d/c

Results

Figure 2. Virologic status at initiation of DTG/RPV in the OPERA Cohort (n=880)

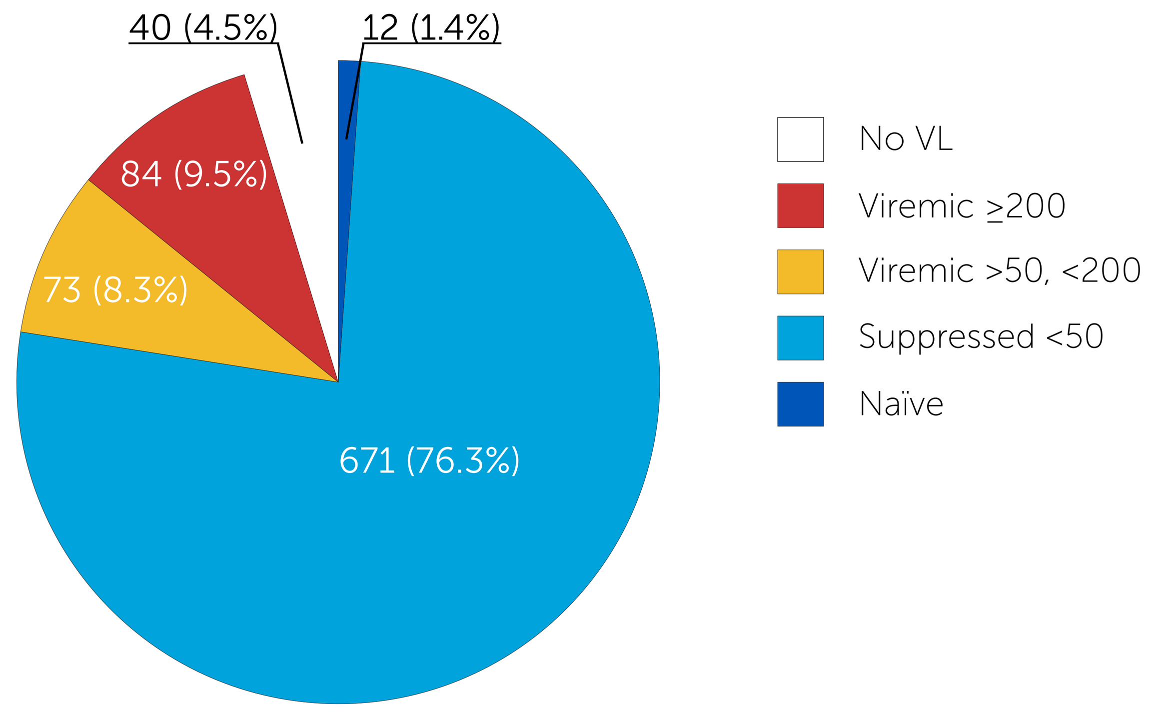


Figure 3. Baseline demographics of patients initiating DTG/RPV (n=880)

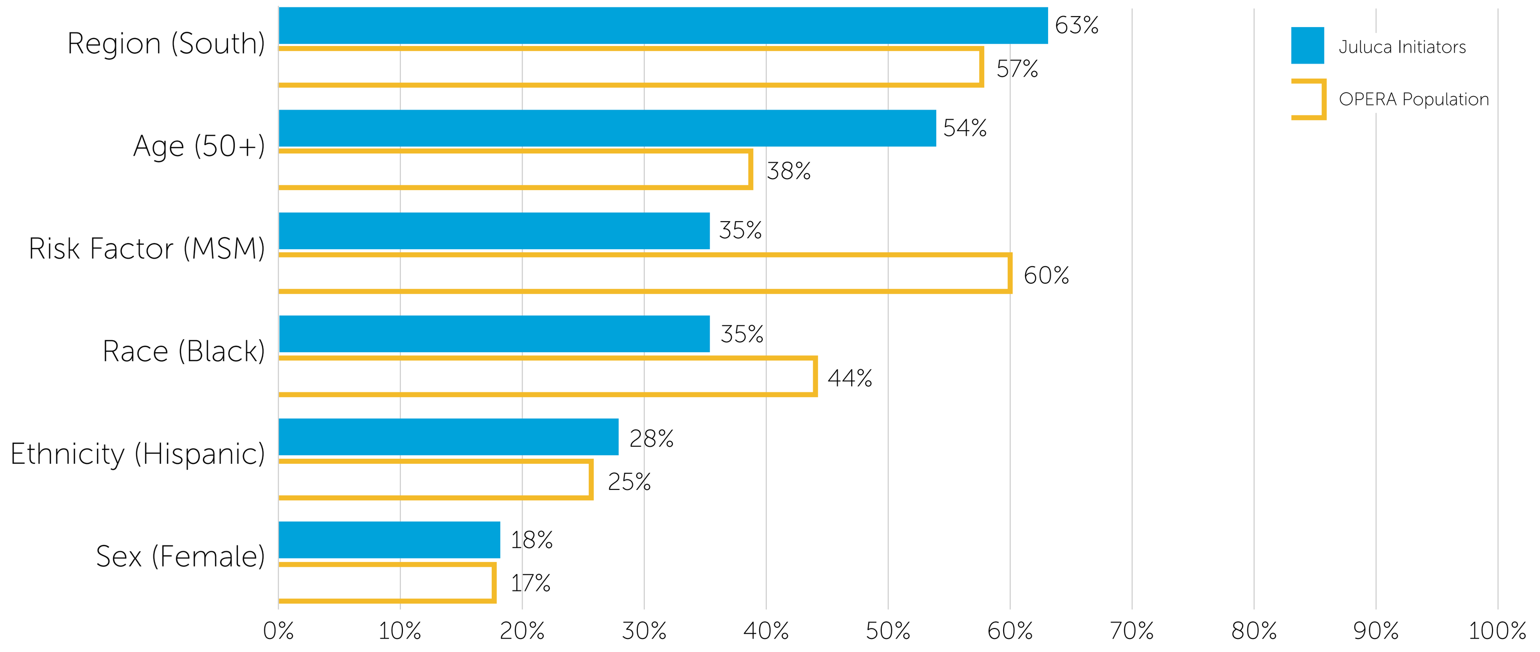
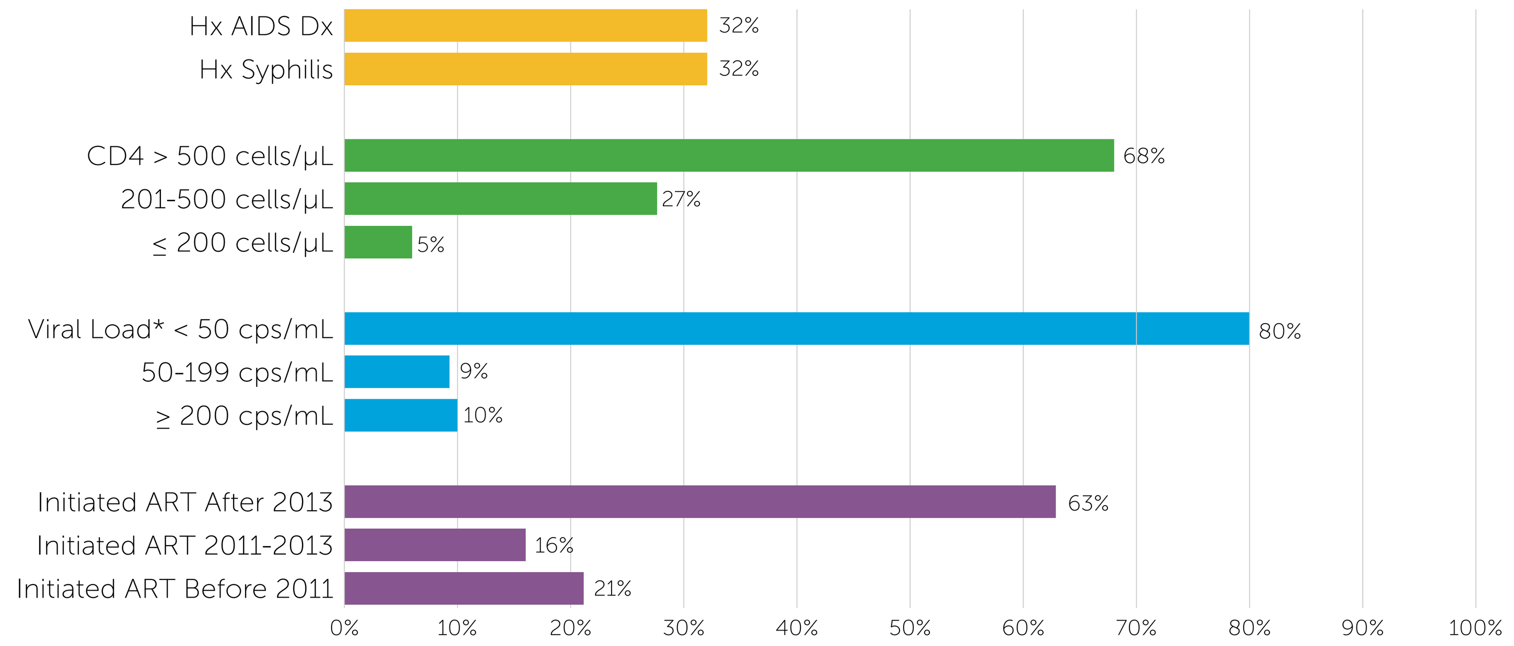


Figure 4. Baseline clinical characteristics of patients initiating DTG/RPV (n=880)



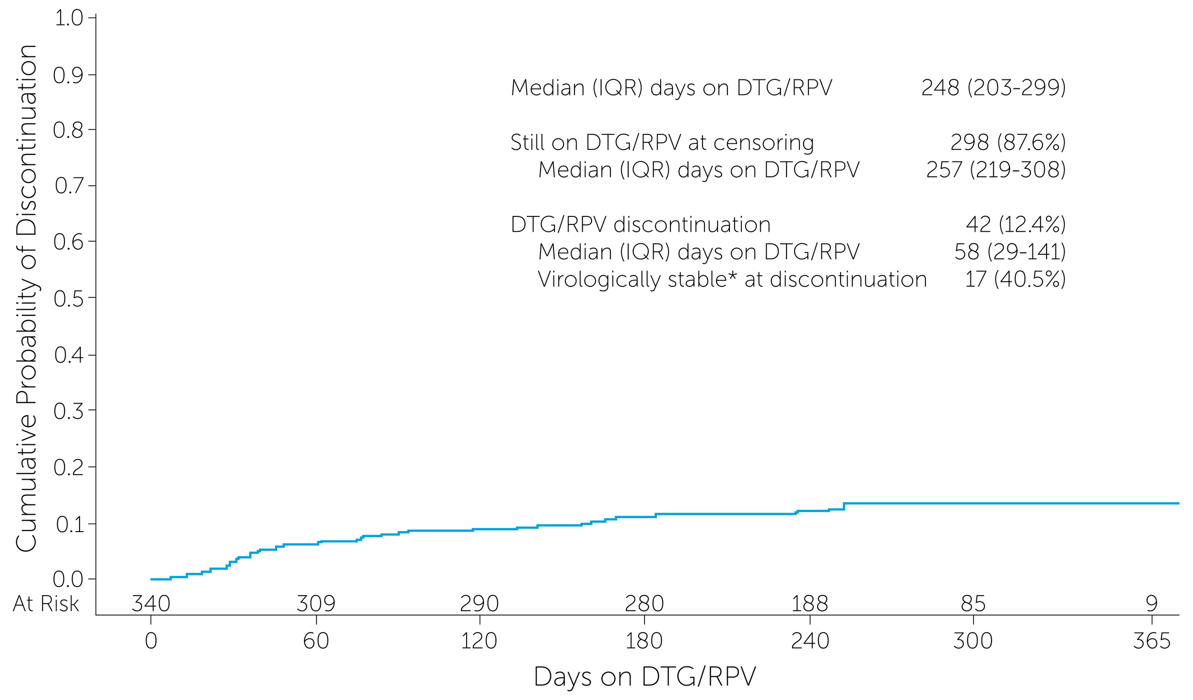
*Among those with a baseline viral load (n=840)

Table 1: Burden of Comorbid Conditions in PLWH Initiating DTG/RPV (n=868*)

Comorbidity, n (%)	Experienced Suppressed (N=671)	Experienced Not Suppressed (N=197)
Any Comorbidity Listed Below	587 (87.5%)	159 (80.7%)
Autoimmune Disease	29 (4.3%)	8 (4.1%)
Cardiovascular Disease	89 (13.3%)	20 (10.2%)
Invasive Cancers	80 (11.9%)	15 (7.6%)
Endocrine Disorders	422 (62.9%)	94 (47.7%)
Mental Health Disorders	232 (34.6%)	58 (29.4%)
Liver Disease	115 (17.1%)	40 (20.3%)
Bone Disorders	52 (7.7%)	17 (8.6%)
Peripheral Neuropathy	83 (12.4%)	27 (13.7%)
Renal Disease	198 (29.5%)	51 (25.9%)
Hypertension	290 (43.2%)	77 (39.1%)
Substance Abuse	92 (13.7%)	31 (15.7%)

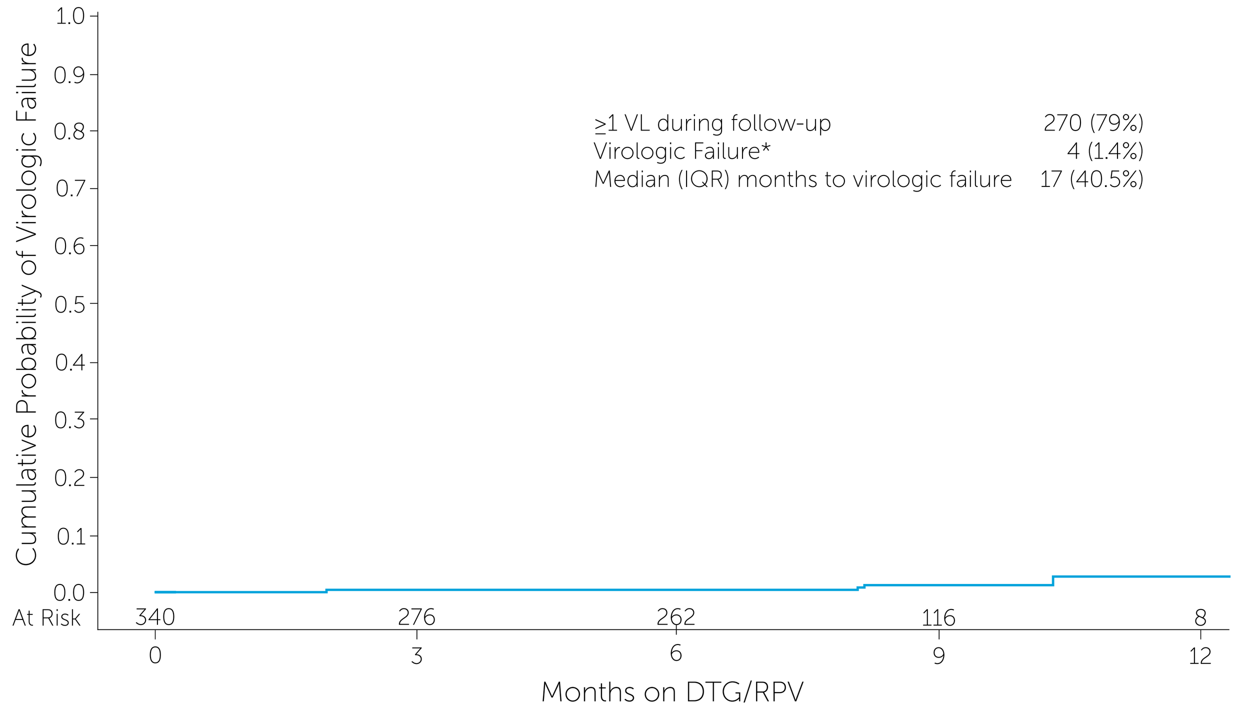
*Excluding 12 PLWH naïve to treatment at baseline

Figure 5. Regimen durability and unadjusted cumulative probability of DTG/RPV discontinuation among experienced, suppressed PLWH with up to 12 months follow up on DTG/RPV (n=340)



*Last viral load < 200 copies/mL

Figure 6. Unadjusted cumulative probability of virologic failure among experienced, suppressed PLWH with up to 12 months follow up on DTG/RPV and ≥1 follow-up viral load (n=288)



*Either 2 consecutive HIV viral loads (VL) ≥ 200 copies/mL OR 1 VL ≥ 200 copies/mL + DTG/RPV d/c

Discussion

- DTG/RPV prescribing in the OPERA cohort over the first 12 months of availability was primarily as a 2-drug regimen among ART-experienced patients who were virologically suppressed (<50 copies/mL)
- Most DTG/RPV initiators remained on treatment throughout follow-up and 40% of those who discontinued were still suppressed at switch
- Strengths: large real-world population, geographically distributed across the United States and Puerto Rico, diverse clinical sites from large metropolitan centers to rural country clinics with real-time collection of prospectively captured clinical data through electronic medical records
- Limitations: lack of a comparison group, absence of resistance data from those who failed their regimens

KEY FINDINGS

- Early initiators of DTG/RPV are older than the overall OPERA population and accordingly are challenged by an important burden of comorbid conditions
- Frequency of discontinuation or virologic failure in the first 12 months of DTG/RPV was low despite increased frailty

References

1. Ellman, T.M., et al., *A forgotten population: older adults with newly diagnosed HIV.* AIDS Patient Care STDs, 2014. 28(10): p. 530-6.
2. Althoff, K.N., et al., *Virologic and immunologic response to HAART, by age and regimen class.* AIDS, 2010. 24(16): p. 2469-79.
3. Kelley, C.F., et al., *Incomplete peripheral CD4+ cell count restoration in HIV-infected patients receiving long-term antiretroviral treatment.* Clin Infect Dis, 2009. 48(6): p. 787-94.
4. Mills A, Fusco J, Schulman KL, Henegar C, Zelt S, D'Amico R, Carpio F, et al. *The impact of antiretroviral tablet burden and polypharmacy on viral suppression in treatment-naïve patients.* in Infectious Disease Week. 2016. New Orleans, LA. .
5. Nachega, J.B., et al., *Lower pill burden and once-daily antiretroviral treatment regimens for HIV infection: A meta-analysis of randomized controlled trials.* Clin Infect Dis, 2014. 58(9): p. 1297-307.

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: Amelito Torres (SAS programming), Jeff Briney (QA), Bernie Stooks (Database Arch & Mgmt), Judy Johnson (Med Terminology Classification), Rodney Mood (Site Support), & Antonin Fusco (Poster Design).

Support

This research was sponsored by ViiV Healthcare.

ViiV Healthcare

Epividian®