Characteristics of Early Adopters of a Two-Drug Regimen (Dolutegravir/Lamivudine) for Treatment of Human Immunodeficiency Virus Type 1 (HIV-1) in a Real-World Setting

Gerald Pierone[1], Kathy Schulman[2], Jennifer Fusco[2], Vani Vannappagari[3], Jean Van Wyk[4], Leigh Ragone[3], Andrew Zolopa[3], Gregory Fusco[2]

[1]Whole Family Health, Vero Beach, FL, USA, [2]Epividian Inc., Durham, NC, USA, [3]ViiV Healthcare, Research Triangle Park, NC, USA, [4]ViiV Healthcare, London, United Kingdom

OPERA® The Longitudinal Cohort

Background

- In April 2019, dolutegravir/lamivudine (DTG/3TC) was approved for the treatment of HIV-1[1]
  - 50 mg DTG/ 300 mg 3TC fixed dose combination
  - Single tablet, once daily regimen
  - Limited to individuals with no known substitutions associated with resistance to the individual components or hepatitis B co-infection
  - Second two-drug regimen (2-DR) approved; first approved 2-DR for treatment-naive people living with HIV (PLWH)

Objective

To characterize early utilization of DTG/3TC in a real-world setting

Methods

Study population

- OPERA cohort
  - Prospectively captured, routine clinical data from electronic health records in the US (147 cities in 18 states & Puerto Rico)
  - ~8% of PLWH in care in the U.S.
- Inclusion criteria
  - People living with HIV
  - 13 year of age or older
  - Initiated DTG/3TC without any other simultaneous antiretrovirals
- Observation period: May 1, 2019 to October 31, 2019

Stratification

- Treatment-naïve
- Treatment-experienced
  - Suppressed: viral load (VL) < 200 copies/mL
  - Not suppressed:
    - VL ≥ 200 copies/mL
    - No baseline VL

Analyses

- An observational clinical cohort analysis of PLWH prescribed DTG/3TC in the OPERA cohort
- Baseline defined as initiation of DTG/3TC
- Demographic and clinical characteristics described at baseline using:
  - Medians and interquartile range (IQR) values for continuous data
  - Relative frequencies and proportions for categorical data

Results

Figure 1. Early Adopters of DTG/3TC in the OPERA Cohort; May – Oct 2019 (N=723)

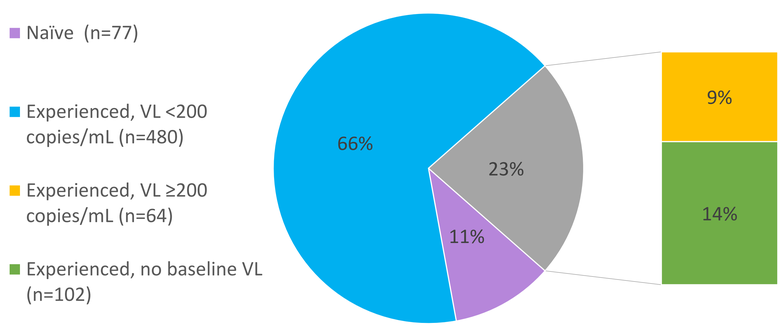


Figure 2. Prior regimen core agent among treatment-experienced (n=646)

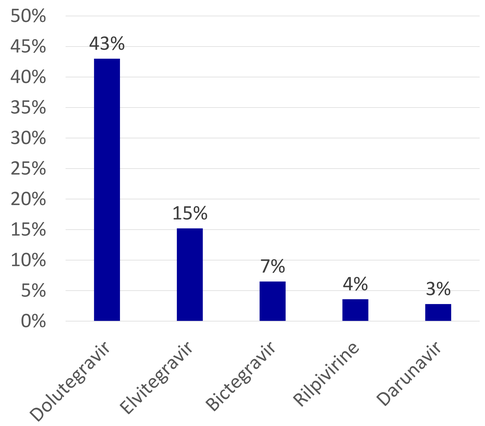
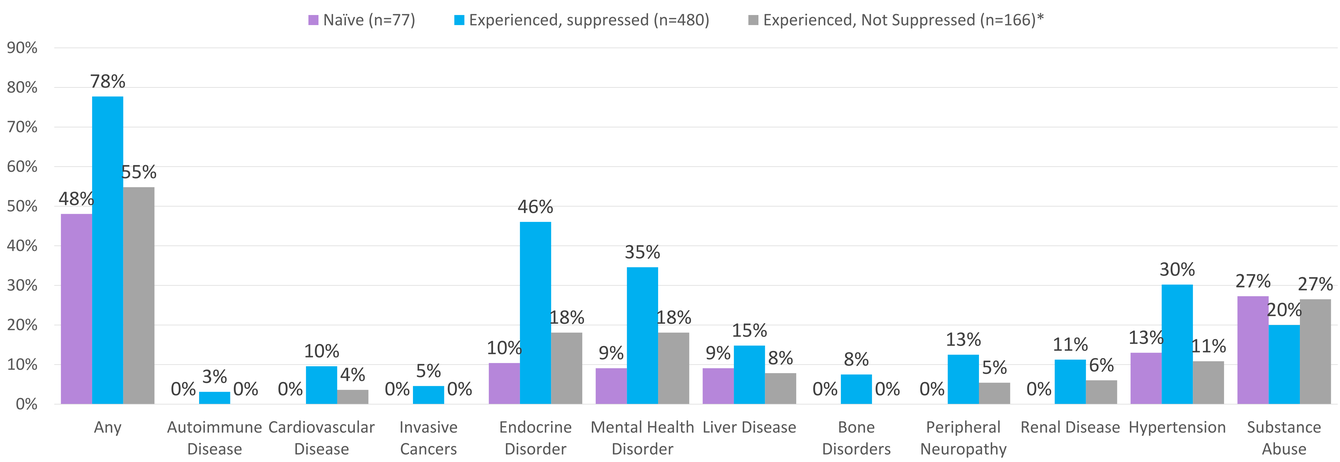


Table 1. Characteristics at DTG/3TC Initiation

	Naive (n=77)	Experienced, suppressed (n=480)	Experienced, Not Suppressed* (n=166)
Age, median (IQR)	31 (26-37)	44 (34-55)	34 (28-45)
Female sex, n (%)	9 (12)	66 (14)	24 (15)
Black race, n (%)	41 (53)	156 (33)	70 (42)
Hispanic ethnicity, n (%)	19 (25)	128 (27)	45 (27)
Months in OPERA at Index, median (IQR)	0 (0-1)	39 (19-68)	1 (0-24)
# of ART classes, median (IQR)	NA	3 (2-4)	0 (0-2)
Months on Prior Regimen, median (IQR)	NA	17 (8-30)	11 (3-29)
History of AIDS, n (%)	11 (14)	126 (26)	33 (20)
VL (log copies/mL), median (IQR)	4.7 (4.0-5.2)	1.3 (1.3-1.3)	4.1 (2.9-4.8)
CD4+ (cells/mm^3), median (IQR)	431 (281-546)	732 (557-927)	567 (318-731)

*102 (61.4%) PLWH did not have a baseline VL available

Figure 3. Diagnoses of Comorbid Conditions at Initiation of DTG/3TC



*102 (61.4%) PLWH did not have a baseline VL available

Discussion

- Characteristics varied significantly by group
  - DTG/3TC was most often prescribed to treatment-experienced and suppressed PLWH
  - Treatment naïve PLWH prescribed DTG/3TC were younger, male, and Black race
  - All groups had median CD4+ counts >350 cells/mm^3
- Comorbid conditions were common among naïve and treatment experienced PLWH initiating DTG/3TC
- After a median (IQR) duration of 4.3 (3.2-6.0) months, 91% of patients remained on the regimen

Key Findings

Early initiators of DTG/3TC, the second 2-DR approved, were primarily treatment-experienced individuals less than 50 years of age with virologic and immunologic control.

References

1. US Food & Drug Administration. FDA approves first two-drug complete regimen for HIV-infected patients who have never received antiretroviral treatment. Accessed at https://www.fda.gov/news-events/press-announcements/fda-approves-first-two-drug-complete-regimen-hiv-infected-patients-who-have-never-received. Accessed 4June2020.

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Contact Information:
Jennifer Fusco
p: (224) 632-1863,
@: Jennifer.fusco@epividian.com