

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

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Background

- In April 2019, dolutegravir/lamivudine (DTG/3TC) was approved for the treatment of HIV-1¹
 - 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-naïve 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)

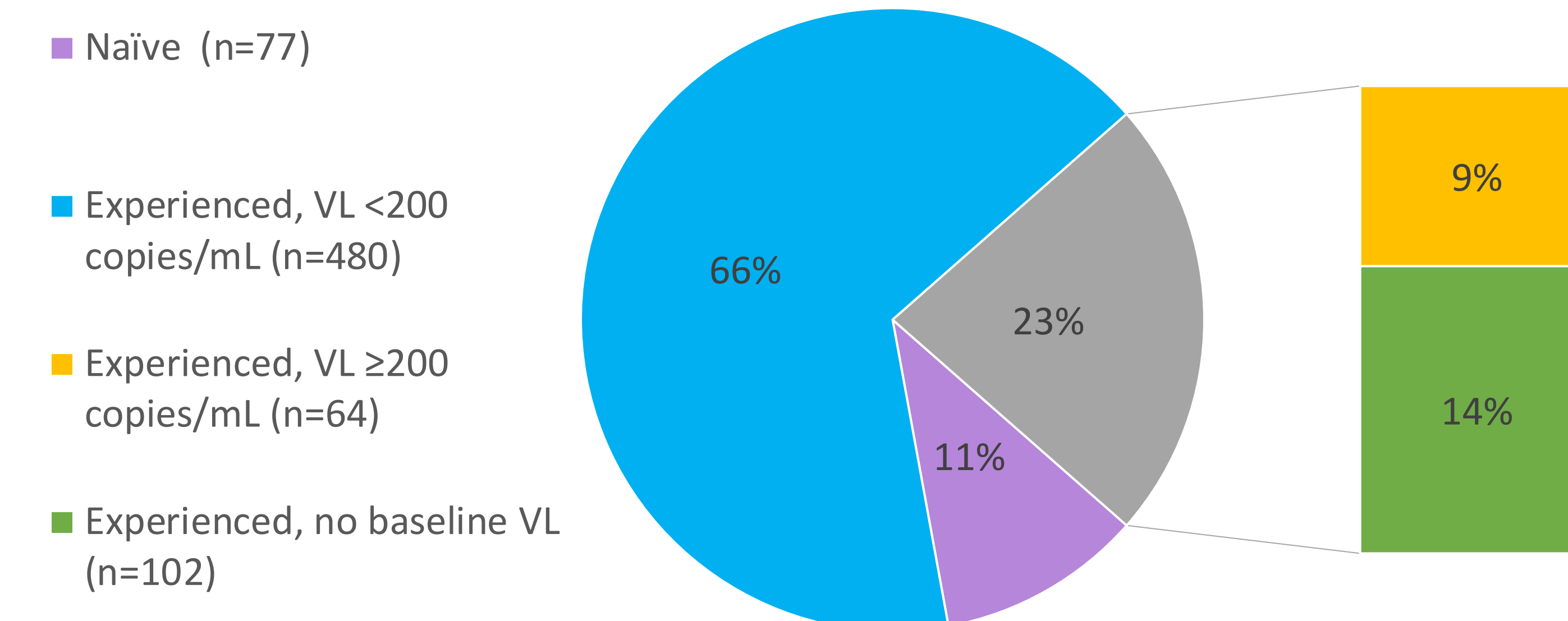


Figure 2. Prior regimen core agent among treatment-experienced (n=646)

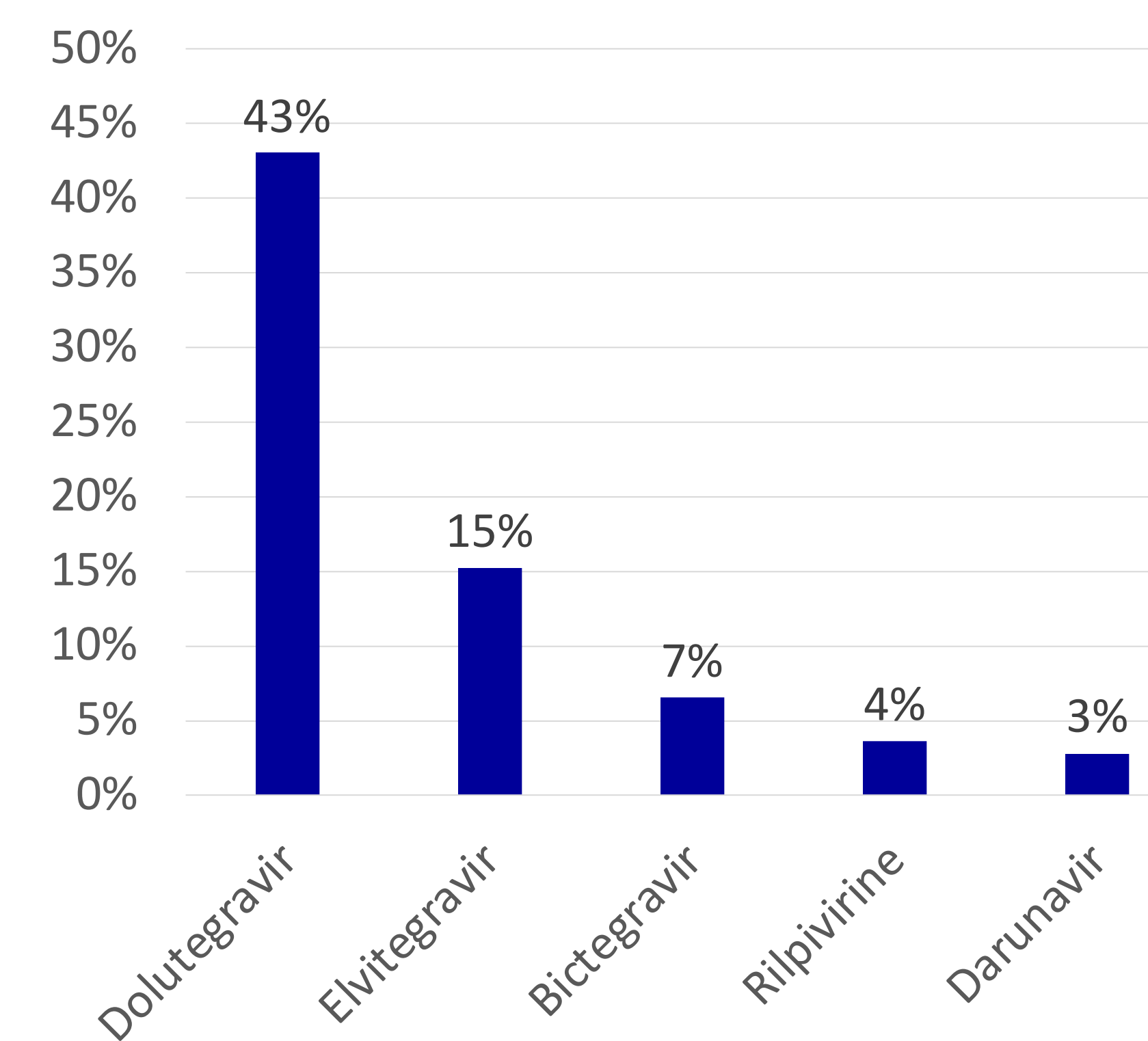
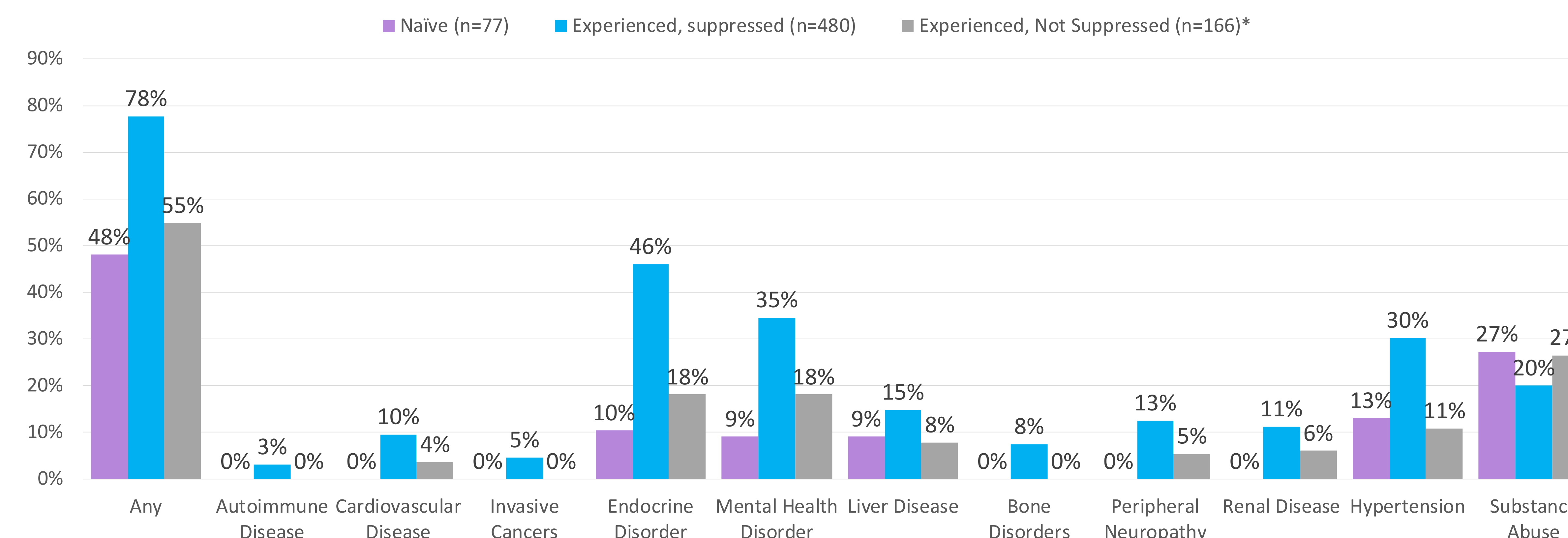


Table 1. Characteristics at DTG/3TC Initiation

	Naïve (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/mm³
- 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

- 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.

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), Laurence Brunet (poster layout)

Support

This research was sponsored by ViiV Healthcare



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