in lipid parameters were observed. Treatment-related AEs occurred in 17/39 (44%) patients (all Grade 1–2) and 1 patient discontinued DCR treatment due to rash.

Conclusion. In this "real-world" cohort of treatment-experienced patients, we observed that DTG functional monotherapy and DTG plus a non-cytosine nucleoside analog maintained long-term virologic control and was well tolerated. These data supports use of DTG as a partner for dual DCRs given its high efficacy in patients with underlying ARV resistance.

TABLE 1-Baseline demographic and clinical characteristics

Characteristic	N=39
Median Age (range)	53 (40-74)
Sex	
Male, n (%)	36 (92)
Female, n (%)	3 (8)
Race/Ethnicity	
Caucasian, n (%)	31 (80)
Black, n (%)	4 (10)
Hispanic, n (%)	4 (10)
Other, n (%)	0
Median BMI (range)	25.9 (17.3-36.4)
Baseline HIV Viral Load	
<50 copies/mL, n (%)	22 (56)
51-200 copies/mL, n (%)	6 (15)
201-399 copies/mL, n (%)	8 (21)
≥400 copies/mL, n (%)	3 (8)
Median Baseline CD4+ cell count, cells/mm³ (range)	564 (92-1217)
HIV Disease status	
Asymptomatic, n (%)	32 (82)
Symptomatic, n (%)	7 (18)
AIDS, n (%)	0
Prior ARV Experience	
>2 NRTIs, n (%)	25 (64)
≥1 NNRTI, n (%)	28 (72)
0 PIs, n (%)	6 (15)
1 PI, n (%)	13 (33)
≥2 PIs, n (%)	20 (51)
1 INSTI, n (%)	22 (56)
>1 INSTI, n (%)	2 (5)
Median Number of ARV regimens prior to DCR (range)	4 (1-11)
Baseline DCR	
DTG functional monotherapy, n (%)	19 (49)
DTG+non-cytosine nucleoside analog, n (%)	20 (51)
DTG+TDF, n (%)	9 (23)
DTG+ABC, n (%)	11 (28)
Baseline genotypic resistance	
Overall Group, n	39
Pattern of NRTI RAMs	
M184V/I alone, n (%)	16 (41)
M184V/I+ 1 NRTI RAM, n (%)	5 (13)
M184V/I + > 1 NRTI RAM, n (%)	18 (46)
Number of RAMS	
NRTI RAMs, median (range)	2 (0-9)
NNRTI RAMs, median (range)	2 (0-6)
PI RAMs, median (range)	4 (0-14)
INSTI RAMs, median (range)	0 (0-3)
DTG functional monotherapy, n (%)	19 (49)
NRTI RAMs, median (range)	5 (2-9)
INSTI RAMs, median (range)	0 (0-3)
DTG+non-cytosine nucleoside analog, n (%)	20 (51)
NRTI RAMs, median (range)	1 (0-8)
INSTI RAMs, median (range)	0 (0-1)

Abbreviations. BMI, body mass index; ARV, antiretroviral; NRTI, nucleoside reverse transcriptase inhibitor; NNRTI, non-nucleoside reverse transcriptase inhibitor; PI, protease inhibitor; INSTI, integrase strand transfer inhibitor; DCR; DTG containing regimen; DTG, dolutegravir; TDF, tenofovir disoproxil fumarate; ABC, abacavir; RAM, resistance associated mutation

FIGURE 1-Virologic Outcomes through Week 96

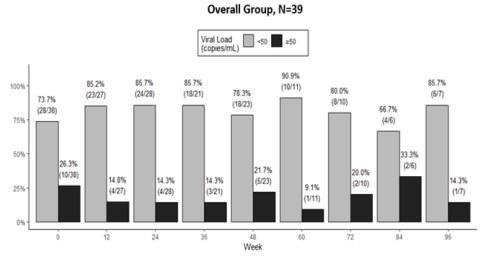
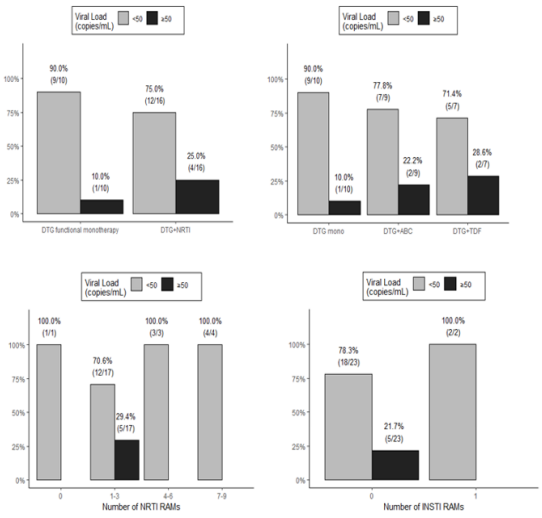


FIGURE 2-Subgroup Analysis of virologic outcomes at Week 48



Abbreviations. DTG, dolutegravir; NRTI, non-cytosine reverse transcriptase inhibitor; mono, functional monotherapy; ABC, abacavir; TDF, tenofovir disoproxil fumarate; RAM, resistance associated mutation; INSTI, integrase strand transfer inhibitor

Disclosures. **All authors:** No reported disclosures.

2487. Low Rate of Virologic Failure in Antiretroviral Experienced Patients Prescribed Once Daily Raltegravir

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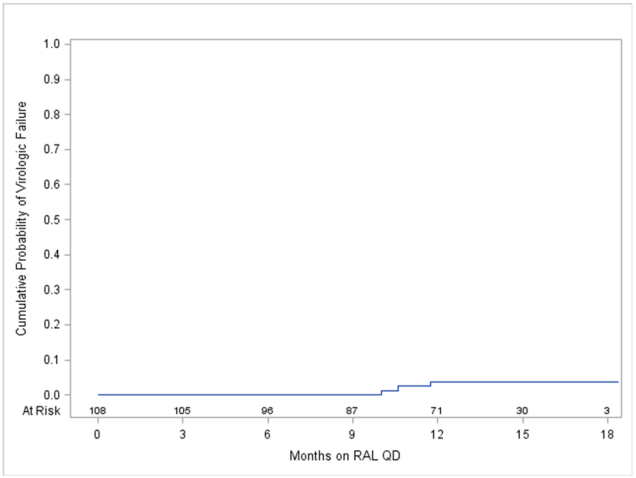
Background. Raltegravir has been used to treat HIV infection for over a decade. In 2017, a 1200 mg, once-daily, formulation of raltegravir (RALQD) was approved. We sought to characterize the utilization and effectiveness of RALQD in ART-experienced, virologically suppressed, HIV+ adults in a real-world cohort of patients treated in the United States.

Methods. HIV+ adults, suppressed to <50 copies/mL at RALQD initiation (7/1/2017–December 31/2017), were identified in the OPERA® Observational Database, a collaboration following 100,000 people living with HIV through electronic medical records. Patients were followed until RALQD discontinuation, death, or study end (December 31/2018). Demographic and clinical characteristics were described at initiation. The primary study outcome was the incidence of virologic failure (VF), defined as 2 consecutive viral load (VL) test results > = 200 copies/mL or 1 VL ≥ 200 copies + RALQD discontinuation. Kaplan–Meier methods were used to describe VF.

Results. The study eligible population (n = 121) was older (median 54 years, IQR: 44, 61) than the overall ART experienced OPERA population (median 47 years, IQR: 35, 55), equally as likely to be male (84% vs. 83%), or African American (38%), but more likely to be Hispanic (23% vs. 20%) and receiving care in the southern United States (61% vs. 56%). RALQD initiators were also more likely to be heavily treatment experienced (≥3 lines ART) than the overall ART experienced OPERA population (57% vs 43%). They were also more likely to have at least one comorbid condition complicating their care (88% vs. 72%), most frequently hyperlipidemia (50%), hypertension (47%), anemia (26%), anxiety disorders (25%) and diabetes (22%). Half of all RALQD initiators had ≥3 comorbidities at the time of RALQD initiation. Two-thirds of RALQD initiators had baseline CD4 cell counts >500 cells/μL. Median (IQR) time on RALQD was 57 weeks (43–65); 89% of RALQD initiators had ≥1 VL test result during follow-up. Among these patients, VF occurred in 3 patients at a rate of 2.7 (0.9, 8.4) per 100 person years of observation. Figure 1 depicts Kaplan–Meier curves.

Conclusion. RALQD was found to be an effective treatment option in ART experienced patients who are virologically suppressed at initiation, and who often face challenges associated with managing comorbid conditions.

Figure 1. Virologic Outcomes in Treatment-Experienced, Virologically Suppressed RALQD Initiators



Disclosures. **All authors:** No reported disclosures.

2488. Virologic Failure in ART Naïve Patients Initiating on a Dolutegravir or Elvitegravir-Based Regimen

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Background. Robust pharmacoeconomic modeling is dependent on high quality inputs, preferably from randomized clinical trials (RCT), but not all needed head to head comparisons occur in RCTs. We compared virologic outcomes in an antiretroviral (ART) naïve population initiating a dolutegravir (DTG) or elvitegravir (EVG)-based regimen using clinical trial-like criteria.

Methods. ART-naïve adults, initiating a DTG- or EVG-based regimen and meeting all study eligibility criteria (Figure 1) were identified in the OPERA® Observational Database, a collaboration of HIV caregivers following 100,000+ people living with HIV (PLWH) through electronic medical records. PLWH were followed from the date of first prescription until DTG- or EVG discontinuation, death, or study end (July 31, 2018). The primary outcome was verified (2 consecutive viral load (VL) ≥200 copies/mL or 1 VL ≥200 copies + discontinuation) virologic failure (VF), defined as either failure to achieve suppression (<50 copies/mL) prior to 36 weeks or failure to maintain suppression once achieved. Survival analyses were conducted with Kaplan–Meier methods and multivariate Cox Proportional Hazards modeling.

Results. A total of 1,688 (DTG) and 2,537 (EVG) met all eligibility criteria. Median (IQR) length of follow-up in the DTG users was 21 months (14–30), in the EVG users was 20 (14–32) months. Figure 2 characterizes baseline demographic/clinical characteristics. Figures 3 and 4 depict Kaplan–Meier curves and Cox model results, respectively. VF was experienced by 8.2% DTG and 10.9% EVG initiators at a rate (95% CI) per 1,000 person-years of 40.2 (33.8, 47.8) and 51.3 (45.3, 58.1), respectively. Younger age (18–25), being African American, having a baseline CD4 count ≤ 200, or having a government-based payer (ADAP, Ryan White, Medicaid, or Medicare) at baseline were associated with a significant ($P < 0.05$), increased hazard of VF. Initiating on DTG or initiating therapy with a lower baseline VL was associated with a significant, reduced hazard of VF. Compared with DTG, the adjusted hazard ratio for VF was 1.29 (95% CI: 1.02, 1.63) for EVG.

Conclusion. Among ART-naïve patients, DTG users were significantly less likely to experience virologic failure than EVG users after adjustment for important baseline covariates.

Figure 1. Study Inclusion/Exclusion Criteria

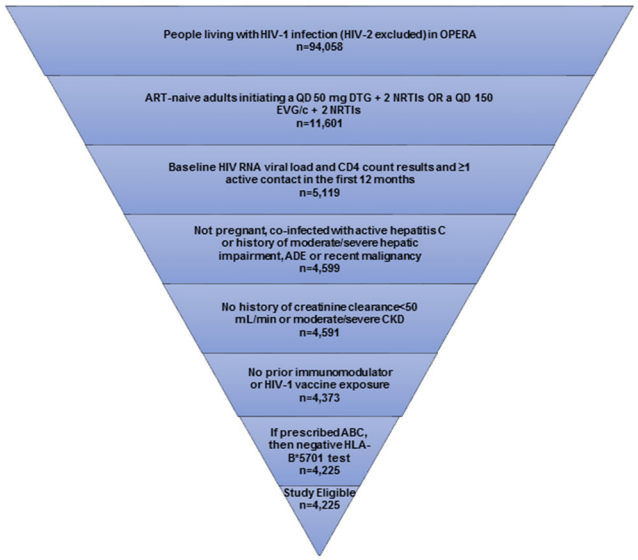


Figure 2: Demographic & Clinical Characteristics of Study Population

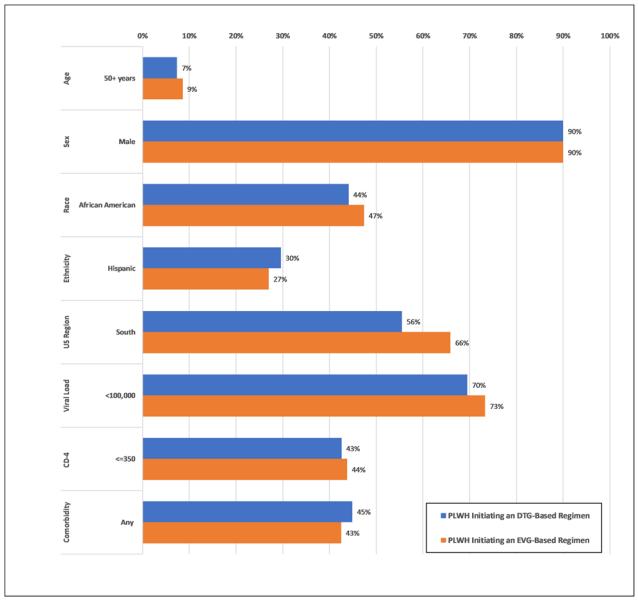


Figure 3. Unadjusted Cumulative Probability of Virologic Failure over Time on Core Agent

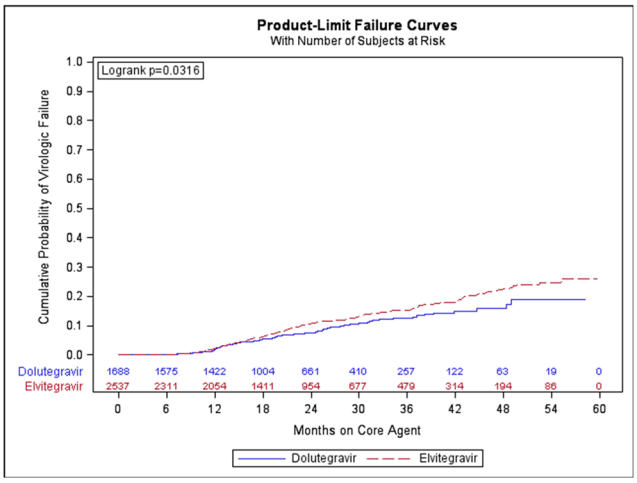
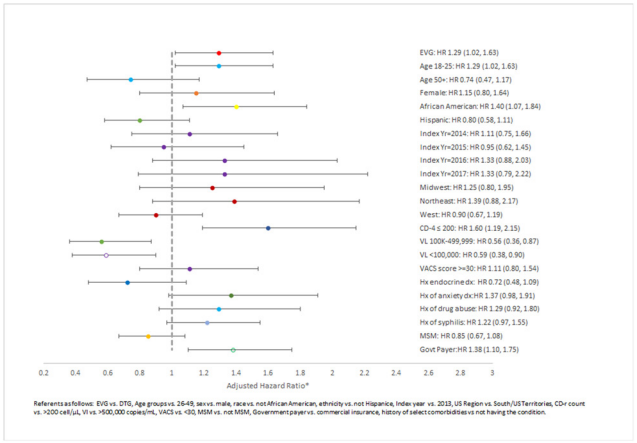


Figure 4. Virologic Failure, Cox Model Results



Disclosures. **All authors:** No reported disclosures.

2489. Adverse Events with Biktarvy: Post-Marketing Study

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Background. Bictegravir (BIC)/emtricitabine (FTC)/tenofovir alafenamide (TAF) was FDA approved in February 2018. There are no published post-marketing data evaluating safety and efficacy. After large uptake of BIC/FTC/TAF at our institution, reports of rash prompted a real-world review. The purpose of this study was to assess one year post-marketing safety and tolerability of BIC/FTC/TAF.

Methods. This retrospective, observational, pharmacoepidemiologic study was conducted one year post-approval of BIC/FTC/TAF, between February 2018 and March 2019 at the University of South Carolina Immunology Center. Adults receiving BIC/FTC/TAF were included. Drug discontinuation and treatment-related adverse effects were evaluated. Baseline demographics and serial laboratory data were collected.

Results. A total of 201 patients were assessed. Of those, the majority were treatment experienced (181, 90%), African American (137, 68%) males (132, 65%) with a mean age of 46 years (range 20–76 years). Four patients were transgender. 135 (67%) had a BMI of ≥ 25 kg/m^2 and 77 (38%) had a BMI of ≥ 30 kg/m^2. At baseline, 146 (72.6%) had virologic suppression (VS) (< 200 copies/mL) with a mean CD4 count of 529 cells/mm^3 (range < 35–1573 cells/mm^3). VS was maintained in 145/146 and subsequently reached in 47/55 (85.5%) at first follow-up. Of the 201, 18 (8.9%) patients reported adverse drug events (ADEs) for a total of 19 events (10 rash, 2 dizziness, 1 nausea/vomiting, 1 headache, 1 diarrhea, 1 loss of appetite, 1 weight gain, 1 fatigue, 1 insomnia). Eleven (5%) patients discontinued therapy; nine (4%) due to ADEs (7 rash, 1 insomnia and loss of appetite, and 1 feeling unwell). One patient with high AST/ALT at baseline increased from 129/243 U/L to 234/394 U/L, respectively. No other laboratory abnormalities were reported.