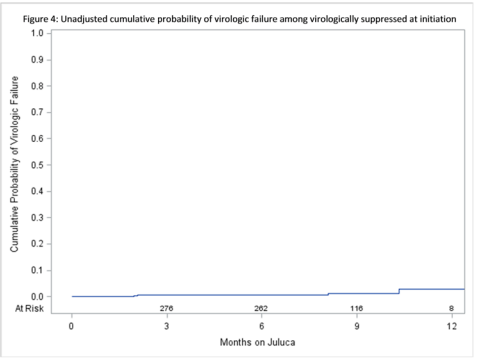

Disclosures. **All authors:** No reported disclosures.

2484. Patient Reported Outcomes After Switching to a 2-Drug Regimen of Dolutegravir + Rilpivirine: Week 148 Results from the Sword-1 and Sword-2 Studies

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Background. The SWORD-1 and SWORD-2 studies previously demonstrated that high rates of virologic suppression were maintained for 148 weeks after switching virologically suppressed HIV-1 infected adults from their current 3- or 4-drug antiretroviral regimen (CAR) to the 2-drug regimen (2DR) of dolutegravir + rilpivirine on Day 1 (Early Switch (ES) DTG+RPV group). This abstract reports the pooled SWORD-1/2 results of patient reported outcomes (PRO) measures through Week 148.

Methods. HIV Treatment Satisfaction Questionnaire (HIVTSQ) and Symptom Distress Module (SDM) were secondary PRO endpoints in the SWORD trials. For HIVTSQ, high scores represent greater treatment satisfaction (range 0 to 60). SDM was assessed using the Symptom Bother Score with low values indicating less symptom bother (range 0 to 80). The EQ-5D-5L measure of general health status was assessed as an exploratory endpoint with maximum utility score of 1 to indicate perfect health. Change from Baseline in these endpoints was calculated for the ES subjects (over 148 weeks). Subjects randomized to CAR switched to DTG+RPV at Week 52 (Late Switch (LS) DTG+RPV group) and change from LS Baseline (i.e., last pre-switch assessment) was calculated (over 96 weeks).

Results. Low Symptom Bother (9.6 and 10.3) and high TSQ scores (54.4 and 54.3) were reported pre-switch in the ES and LS groups, respectively.

ES subjects reported modest improvements from Baseline in both symptom burden and overall treatment satisfaction in all visits through Week 148 (Figures 1 and 2). Among the LS group, there was little change in symptom burden but similar improvement in treatment satisfaction. Pre-switch health status was high in ES and LS groups (EQ-5D mean utility: 0.96 and 0.94, respectively) and remained stable in both groups at all time points.

Conclusion. High treatment satisfaction and low symptom burden that were observed in patients under CAR were maintained long term after switching to DTG+RPV. These results corroborate DTG+RPV as a well-tolerated 2DR alternative treatment option in patients currently suppressed on other 3/4-drug regimens without previous virologic failure.

Figure 1: Change from Baseline/LS Baseline in HIVTSQ Total Score by Study Visit

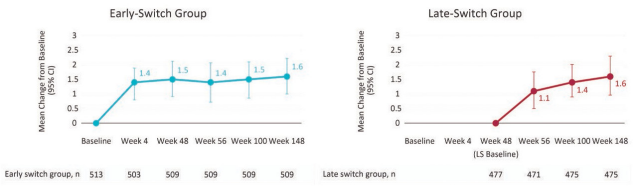
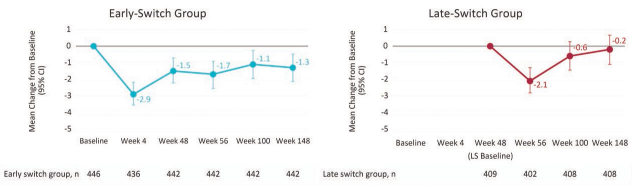


Figure 2: Change from Baseline/LS Baseline in SDM Symptom Bother Score by Study Visit



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

2485. Real-world Experience with Dolutegravir Plus Rilpivirine Two-Drug Regimen

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Background. Three-drug regimens (3DRs) have long been the mainstay of antiretroviral treatment (ART) for HIV. Dolutegravir-based two-drug regimens (DTG 2DRs) are now accepted alternatives to 3DRs, with the first 2DR single tablet regimen (STR), Juluca (DTG/rilpivirine [RPV]), FDA-approved in 2017. This study evaluated treatment patterns of DTG+RPV in clinical practice to understand use prior to availability of DTG/RPV STR.

Methods. A retrospective medical chart review was conducted across 10 US sites identified as using any DTG 2DRs. Eligible patients were adults initiated on DTG 2DR prior to July 31, 2017 and followed up to January 30, 2018. This analysis describes a subgroup who received DTG+RPV 2DR. Patient demographics, clinical characteristics and treatment history were abstracted from medical charts. Analyses were descriptive.

Results. From an overall sample of 278 DTG 2DR patients, 66 received DTG+RPV 2DR. In this DTG+RPV subgroup, mean age was 56 years, 79% were male and 68% were Caucasian. Most were treatment-experienced (97%), with an average 15.5 years of prior ART; 48% had received ≥ 4 prior regimens. The most common physician reported reasons for initiating DTG+RPV were avoidance of potential long-term toxicities (53%), toxicity/intolerance of ARVs (20%) and treatment simplification/streamlining (15%). Prior to initiation of DTG+RPV, 70% of patients were virologically suppressed (< 50 copies/mL); of those, 98% remained suppressed after switching to DTG+RPV. Of the 30% of patients with detectable viral load prior to DTG+RPV initiation, 60% achieved and maintained virologic suppression on DTG+RPV. Mean time on DTG+RPV was 1.6 years. Only 5 (8%) patients discontinued DTG+RPV by data cut-off, and one patient was lost to follow-up. Reasons for discontinuation were virologic failure (n = 2), treatment simplification/streamlining (n = 2) and toxicity/intolerance (n = 1). Physicians reported that most patients (91%) achieved the desired outcome from DTG+RPV use.

Conclusion. Prior to commercial availability of DTG/RPV STR in the United States, DTG+RPV was used primarily in treatment experienced patients, most commonly to avoid potential long-term toxicities. A high proportion of patients achieved the desired outcome and maintained virologic suppression while receiving DTG+RPV.

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

2486. Clinical Outcomes of Patients Treated with Dolutegravir Functional Monotherapy or Dolutegravir plus an Active Non-cytosine Nucleoside Analog: A Retrospective Observational Cohort Study of Treatment-Experienced Patients

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Background. Dual dolutegravir (DTG)-containing regimens (DCRs) are currently approved for the treatment of antiretroviral (ARV) naïve and experienced patients with HIV-1 infection. DTG monotherapy has resulted in unacceptable rates of virologic failure and subsequent development of DTG resistance. Here, we evaluate the "real-world" efficacy and "barrier to resistance" of DCRs containing 0–1 active ARVs.

Methods. This is a retrospective observational study evaluating clinical outcomes of treatment-experienced patients on combination DCRs found to be on DTG functional monotherapy or DTG plus an active non-cytosine analog between 2013 and 2014. The primary endpoint was virologic suppression (HIV-1 RNA< 50 copies/mL) at week 48. Virologic failure (VF) was defined as confirmed HIV-1 RNA≥ 50 copies/mL 12 weeks after initiating DTG or any time after achieving HIV-1 RNA< 50 copies/mL. Adherence, adverse events (AEs) and laboratory parameters were analyzed throughout the study.

Results. Thirty-nine patients were included in the analysis, 19 (49%) were on DTG functional monotherapy and 20 (51%) were on DTG plus a non-cytosine nucleoside analog. The median age (range) was 53 (40–74) years, median baseline CD4+ count (range) was 564 (92–1217) cells/mm^3, 22 (56%) had baseline HIV-1 RNA< 50 copies/mL, and 24 (62%) had previously used INSTIs (Table 1). At Weeks 48 and 96, virologic suppression was observed in 78.3% and 86% of patients respectively (Figures 1 and 2). Among 7 VFs (2 on DTG functional monotherapy, 5 on DTG plus a non-cytosine nucleoside analog), there was no evidence of treatment-emergent resistance to DTG. There was a significant median increase in CD4+ count from baseline to Week 48 (+90 cells/mm^3, 95% confidence interval: [14.18, 165.9]). No significant changes

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

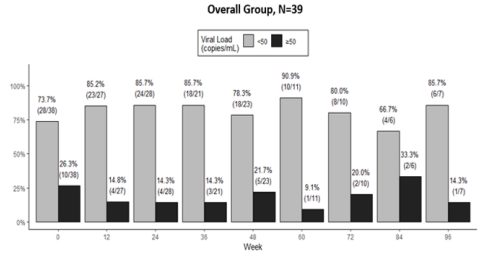
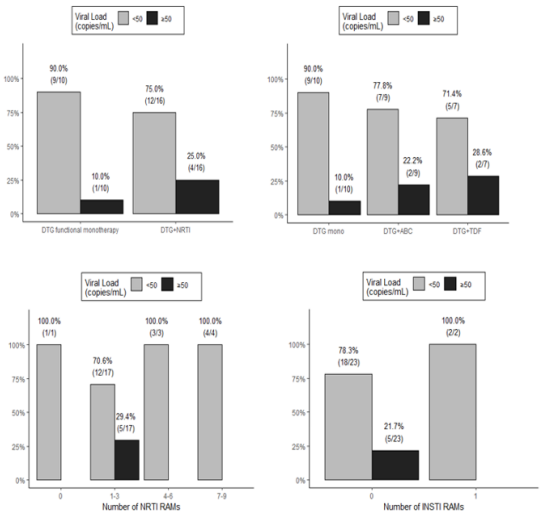


FIGURE 2-Subgroup Analysis of virologic outcomes at Week 48



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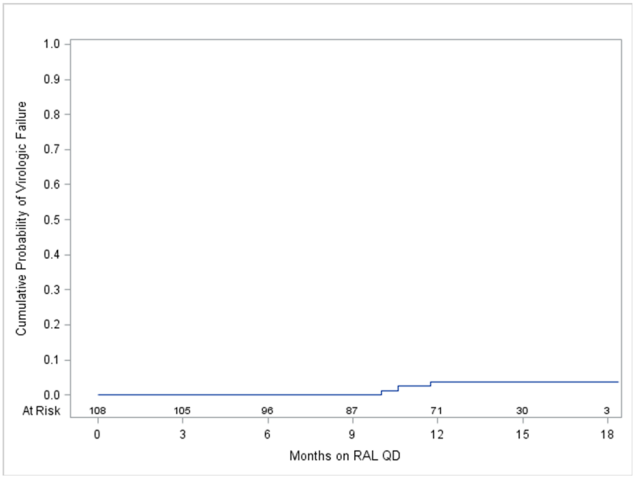
Background. Raltegravir has been used to treat HIV infection for over a decade. In 2017, a 1200 mg, once-daily, formulation of raltegravir (RALQD) was approved. We sought to characterize the utilization and effectiveness of RALQD in ART-experienced, virologically suppressed, HIV+ adults in a real-world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