

baseline DRV RAMs was 2 (1–5) (Table 1). At Week 48, 20 (91%) had HIV-1 RNA <50 copies/mL; 2 (9%) virologic non-responders had HIV-1 RNA of 82 and 59,637 copies/mL and reported noncompliance (Figure 1). There was no significant change in median CD4+ count from baseline to Week 48 (+22, 95% confidence interval (CI): [-116.5; 56.0]). Once-daily DRV was associated with a significant median increase in HDL cholesterol (+82, 95% CI: [37.0; 101.0]) and a significant median decrease in LDL cholesterol (-60, 95% CI: [-89.5; -31.0]). There were no significant changes in the proportion of patients on lipid lowering therapy at baseline and week 48 (p = 0.33). There were no self-reported AEs or Grade 3–4 lab abnormalities through Week 48.

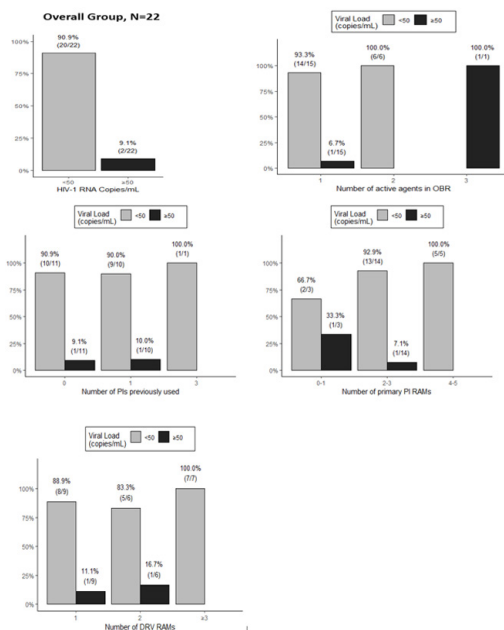
**Conclusion.** Once-daily DRV maintained virologic control in this cohort of treatment-experienced patients with 1 or more baseline DRV RAMs and was safe and well-tolerated. This suggests that once-daily DRV may be effective in this population however further data are needed to validate this as a viable treatment option.

**TABLE 1—Baseline demographic and clinical characteristics**

Characteristic	N=22
<b>Median Age (range)</b>	53 (21, 77)
<b>Sex</b>	
Male, n (%)	20 (91)
Female, n (%)	2 (9)
<b>Race/Ethnicity</b>	
Caucasian, n (%)	8 (36)
Black, n (%)	3 (14)
Hispanic, n (%)	5 (23)
Other, n (%)	6 (27)
<b>Median BMI (range)</b>	27.7 (19.9, 40.8)
<b>Baseline HIV Viral Load</b>	
<50 copies/mL, n (%)	18 (82)
51–200 copies/mL, n (%)	2 (9)
201–399 copies/mL, n (%)	0
≥400 copies/mL, n (%)	2 (9)
<b>Median Baseline CD4+ cell count, cells/mm<sup>3</sup> (range)</b>	608.5 (293, 1268)
<b>HIV Disease status</b>	
Asymptomatic, n (%)	18 (82)
Symptomatic, n (%)	4 (18)
AIDS, n (%)	0
<b>Prior ARV Experience</b>	
0 PIs, n (%)	7 (32)
1 PI, n (%)	13 (59)
≥2 PIs, n (%)	2 (9)
>2 NRTIs, n (%)	8 (36)
≥1 NNRTI, n (%)	13 (59)
1 INSTI, n (%)	17 (77)
>1 INSTI, n (%)	2 (9)
Median Number of ARV regimens prior to DCR (range)	3 (1, 7)
<b>Baseline DCR (# of active ARVs excluding DRV)</b>	
1 active agent, n (%)	15 (68)
2 active agents, n (%)	6 (27)
3 active agents, n (%)	1 (5)
<b>Baseline genotypic resistance</b>	
NRTI RAMs, median (range)	6 (0, 12)
NNRTI RAMs, median (range)	1 (0, 4)
INSTI RAMs, median (range)	0 (0, 1)
PI RAMs, median (range)	9 (2, 15)
Primary PI RAMs, median (range)	3 (0, 5)
DRV RAMs, median (range)	2 (1, 5)

**Abbreviations.** BMI, Body Mass Index; ARV, antiretroviral; PI, protease inhibitor; NRTI, Nucleoside Reverse Transcriptase Inhibitor; NNRTI, Non-Nucleoside Reverse Transcriptase Inhibitor; INSTI, Integrase Strand Transfer Inhibitor; DCR, DRV containing regimen; RAMs, resistance associated mutations

**FIGURE 1—Subgroup Analysis of Virologic outcomes at Week 48**



**Abbreviations.** OBR, optimized background regimen; PI, protease inhibitor; RAMs, resistance associated mutations; DRV, darunavir

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

**2483. Characteristics and Outcomes Over First 12 Months of a Two-Drug Regimen (Dolutegravir/Rilpivirine) for Treatment of HIV-1 in the United States**  
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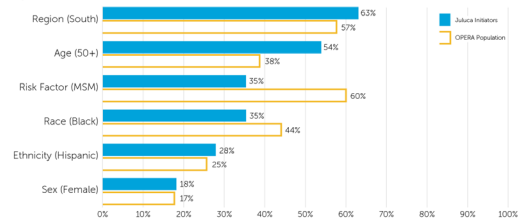
**Background.** In 2017, the first complete antiretroviral regimen (ART) containing only two drugs, dolutegravir/rilpivirine (DTG/RPV), was approved for treatment of HIV-1 in virologically suppressed (<50 copies/mL) patients on a stable ART regimen for ≥6 months with no history of treatment failure/resistance to DTG or RPV. Our objective was to characterize early utilization/outcomes of DTG/RPV in a real-world population.

**Methods.** HIV-1+ individuals initiating DTG/RPV from January 1, 2018 to December 31, 2018 were identified in the OPERA Database. Outcomes were evaluated among the virologically suppressed subgroup who initiated in the first 6 months. Discontinuation (d/c) was defined as cessation of DTG/RPV. Virologic failure (VF) was defined as either 2 consecutive HIV viral loads (VL) ≥ 200 copies/mL OR 1 VL ≥ 200 copies/mL + d/c. Population was observed from DTG/RPV start (index) until the first of: (a) d/c, (b) death, or (c) study end (December 31, 2018). Demographic and clinical characteristics were described at index. Kaplan–Meier methods were used to describe d/c and VF.

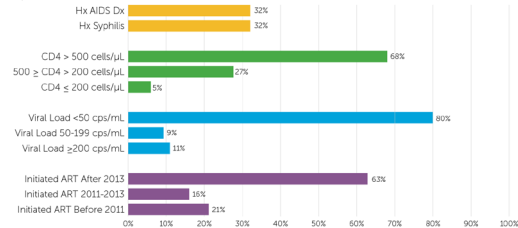
**Results.** A total of 880 patients were prescribed DTG/RPV in the first 12 months; demographic and clinical characteristics are described in Figures 1 and 2. Most (76%) DTG/RPV users were virologically suppressed at initiation (n = 671). Among the 197 (22%) ART experienced, viremic initiators, a third had a baseline VL ≥ 50 but <200. Few patients were ART naïve (n = 12, 1%). Index VL was unavailable for 21 (5%) initiators. Comorbidity was prevalent: 59% had ≥1 endocrine disorders; 42% hypertension, and 33% mental disorders. For the virologically suppressed at initiation, with ≥6 months of follow-up (n = 340); median (IQR) days on DTG/RPV was 248 (204–299); 88% remained on DTG/RPV at study end. Among the 42 (12.4%) discontinued patients, 41% were virologically stable (<200 copies/mL) at d/c. Median (IQR) days to d/c was 58 (29–141) (Figure 3). Most patients (n = 288, 85%) had ≥ 1 VL during follow-up; 79% (n = 270) had ≥1 VL during the first 24 weeks. Among these, VF occurred in 1.5% patients. Median (IQR) time to VF was 5.1 (2.0–9.2) months (Figure 4).

**Conclusion.** While DTG/RPV initiators were primarily ART-experienced, virologically suppressed individuals older than 50 years of age challenged by significant comorbid conditions, the frequency of d/c or VF in the first 12 months was low.

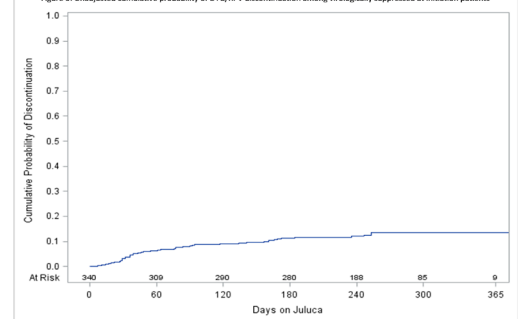
**Figure 1. Baseline demographics of patients initiating DTG/RPV**

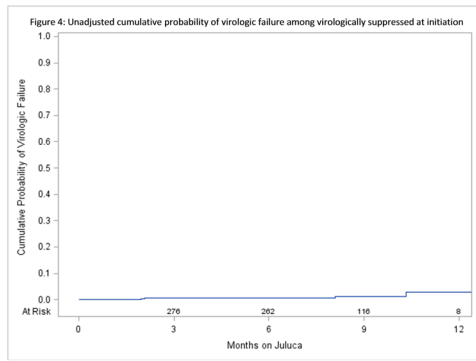


**Figure 2. Baseline clinical characteristics of patients initiating DTG/RPV**



**Figure 3: Unadjusted cumulative probability of DTG/RPV discontinuation among virologically suppressed at initiation patients**





**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

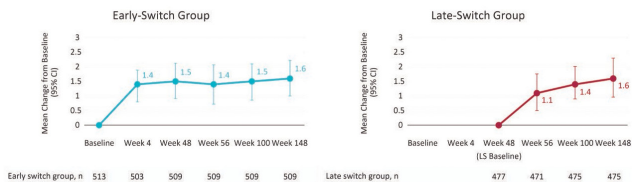
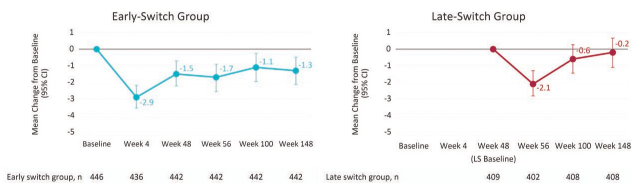


Figure 2: Change from Baseline/LS Baseline in SDM Symptom Bother Score by Study Visit



**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  $\geq 4$  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  $\geq 50$  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<sup>3</sup>, 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<sup>3</sup>, 95% confidence interval: [14.18, 165.9]). No significant changes