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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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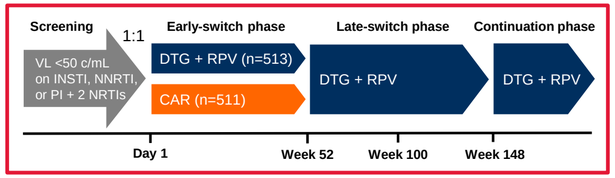
Introduction

- Most antiretroviral regimens consist of ≥3 drugs from 2 distinct classes to achieve and maintain durable virologic suppression
- 2-drug regimens provide a good treatment option for patients with virologic suppression who want to simplify their therapy or reduce the risk of long-term toxicities associated with using a 3- or 4-drug regimen over their lifetime
- In the phase III studies SWORD-1 and SWORD-2, the 2-drug regimen of dolutegravir + rilpivirine (DTG + RPV) demonstrated high efficacy and was noninferior to the continuation of a 3- or 4-drug antiretroviral regimen in virologically suppressed HIV-1–infected adults at 48 weeks[1]
  - Longer-term follow-up has since demonstrated that a high level of virologic suppression was maintained through Week 148 after switching to DTG +RPV[2]
- The pooled patient-reported outcome measures at Week 48 from the SWORD-1 and SWORD-2 studies demonstrated improvement in levels of treatment satisfaction and symptom burden in patients who switched to DTG + RPV[3]
- This analysis describes change after switching to DTG + RPV in patient-reported outcome measures at Week 148 in the pooled SWORD-1 and SWORD-2 studies

Methods

- SWORD-1 (NCT02429791) and SWORD-2 (NCT02422797) are phase III, randomized (1:1), multicenter, open-label, parallel-group, noninferiority studies (Figure 1)
  - A full description of the study design, including eligibility criteria and endpoints, has been previously reported[1]

Figure 1. Study Design of the Identical SWORD-1 and SWORD-2 Studies



Study Populations

- Participants were randomized to switch to DTG + RPV (early-switch [ES] group) on Day 1 or to continue on their current antiretroviral regimen (CAR) for 52 weeks
- CAR participants who maintained HIV-1 RNA <50 c/mL at Week 48 switched to DTG + RPV at Week 52 (late-switch [LS] group)
- The latest assessment before switch to DTG + RPV at Week 52 served as the LS baseline (BL) for the LS group

Patient-Reported Outcomes Assessments

- The HIV Treatment Satisfaction Questionnaire, status version (HIVTSQs), is a 10-item, self-reported instrument that measures treatment satisfaction overall and by specific domains[4]
  - For the HIVTSQs, high scores represent greater treatment satisfaction (range, 0-60)
- The Symptom Distress Module is a 20-item, self-reported measure that addresses the presence of and perceived distress linked to symptoms associated with HIV infection or its treatment[5]
  - The symptom bother score assesses the level of bother with a total score for all symptoms ranging from 0 (no symptoms present) to 80 (all symptoms present at worst level)
- The European Quality of Life 5-Dimensional 5-Level instrument is a standardized questionnaire that profiles patient function and rates global health state by assessing mobility, self-care, usual activities, pain/discomfort, and anxiety/depression[6]
  - A global health status score of 1 indicates perfect health
- Change from BL in these endpoints was calculated for the ES participants over 148 weeks. Change from LS BL for LS participants was calculated over 96 weeks from Week 52 to Week 148

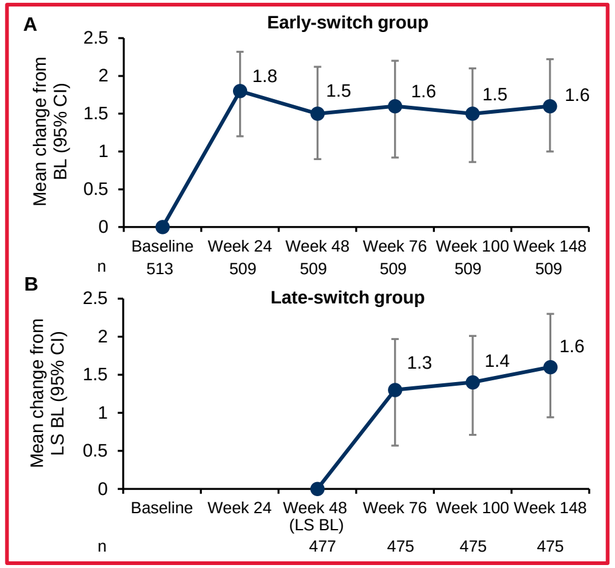
Results

- Primary results for SWORD-1 and SWORD-2 have been previously reported[1,2]

HIV Treatment Satisfaction Questionnaire, status version

- High treatment satisfaction scores were reported pre-switch (eg, BL and LS BL) in the ES and LS groups: mean (SD) scores, 54.4 (6.4) and 54.3 (7.2), respectively
- After switching to DTG + RPV, treatment satisfaction increased and was maintained through Week 148 in both groups (Figure 2)

Figure 2. Change From BL/LS BL in HIVTSQ Total Score by Study Visit in the (A) Early-Switch and (B) Late-Switch Groups



BL, baseline; HIVTSQ, HIV Treatment Satisfaction Questionnaire; LS, late-switch. Vertical bars represent 95% CI.

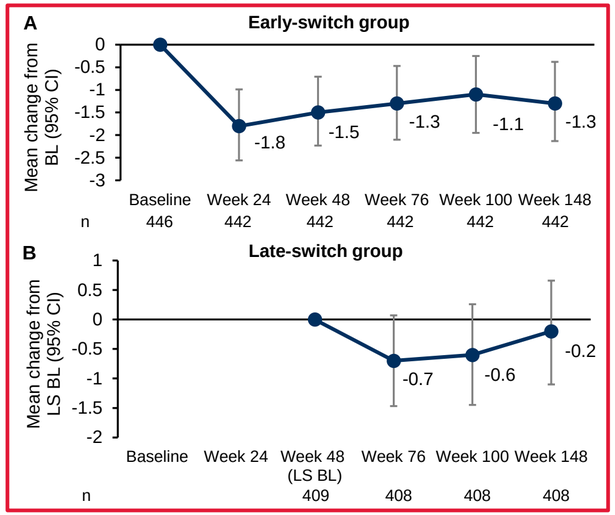
Symptom Distress Module

- Low levels of treatment burden were reported pre-switch: mean (SD) BL and LS BL symptom bother scores were 9.6 (10.0) in the ES DTG + RPV group and 10.3 (11.0) in the LS DTG + RPV group
- Patient-reported symptom bother never worsened after switching to DTG + RPV in either the ES or LS group
  - Participants in the ES DTG + RPV group reported modest improvement from BL in symptom bother, which was maintained over 148 weeks (Figure 3A)
  - There was little change in symptom bother in the LS group (Figure 3B)

European Quality of Life 5-Dimensional 5-Level Instrument

- Pre-switch health status was very high in the ES and LS groups (EQ-5D mean utility score, 0.96 and 0.94, respectively) and remained stable in both groups at all time points

Figure 3. Change From BL/LS BL in SDM Symptom Bother Score by Study Visit in the (A) Early-Switch and (B) Late-Switch Groups



BL, baseline; LS, late-switch; SDM, Symptom Distress Module. Vertical bars represent 95% CI.

Conclusions

- High levels of treatment satisfaction and a low level of symptom burden were reported by participants entering the study and were improved or maintained after switching to DTG + RPV
- These results provide supportive long-term evidence that the 2-drug regimen of DTG + RPV is a well-tolerated, alternative treatment option for virologically suppressed patients who are on a 3- or 4-drug regimen and have not experienced previous virologic failure

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