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Switching to DOR/3TC/TDF Maintains HIV-1 Virologic Suppression Through Week 144 in the DRIVE-SHIFT Trial

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Background: In the primary analysis of the DRIVE-SHIFT trial, switching to doravirine/lamivudine/tenofovir disoproxil fumarate (DOR/3TC/TDF) maintained suppression of HIV-1 through week 48. Here, we present long-term efficacy and safety outcomes through week 144 of the DRIVE-SHIFT trial.

Methods: This phase 3, randomized, open-label trial evaluated switching from a stable antiretroviral regimen to once-daily DOR/3TC/TDF in adults with HIV-1 suppressed for ≥ 6 months and no previous virologic failure. Participants switched at day 1 [immediate switch group (ISG); n = 447] or week 24 [delayed switch group (DSG); n = 209]. Nine ISG participants who completed week

48 but did not enter extension-1 were excluded from week 144 efficacy analyses.

Results: At week 144, HIV-1 RNA < 50 copies/mL was maintained in 80.1% of the ISG (351/438) and 83.7% of the DSG (175/209), while 2.7% (12/438) and 4.8% (10/209), respectively, had HIV-1 RNA ≥ 50 copies/mL (Food and Drug Administration Snapshot approach). Protocol-defined virologic failure after switch occurred in 2.1% of ISG (9/438) and 3.3% of DSG (7/209); no viral resistance to doravirine was detected in 4 participants with samples available. Reductions in fasting lipids were observed at 24 weeks after switch and maintained through week 144. The mean weight change from switch to week 144 was +1.4 kg for ISG and +1.2 kg for DSG. The most common adverse events were nasopharyngitis (16.2%), headache (12.3%), and diarrhea (9.1%). Overall, 4.1% discontinued because of adverse events, and no deaths occurred.

Conclusions: These results confirm that switching to once-daily DOR/3TC/TDF is a generally well-tolerated option for maintaining viral suppression in adults considering a change in therapy.

Registration: ClinicalTrials.gov NCT02397096.

Key Words: doravirine, HIV-1, switch, long-term efficacy and safety, single-tablet regimen

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INTRODUCTION

Doravirine is a next-generation nonnucleoside reverse transcriptase inhibitor (NNRTI) with important attributes for the switch setting: a favorable resistance profile that is unique among NNRTIs,¹ no food restrictions,² and no interactions with statins, oral contraceptives, or gastric acid modifiers.^{3–5} We have previously reported the primary results of the DRIVE-SHIFT trial, which found that switching to a single-tablet regimen of doravirine 100 mg with lamivudine 300 mg and tenofovir 300 mg (DOR/3TC/TDF) was noninferior to continuing a stable antiretroviral regimen in virologically suppressed adults with HIV-1, with no viral resistance to doravirine, and a favorable safety profile over 48 weeks of treatment.⁶ Here, we present efficacy and safety results through week 144 of the DRIVE-SHIFT trial. Because weight gain and obesity have been increasing in people with HIV receiving antiretroviral therapy,^{7,8} we have included a post hoc analysis of changes in weight and body mass index (BMI) after switching to DOR/3TC/TDF.

METHODS

DRIVE-SHIFT (NCT02397096) is a phase 3, open-label, randomized controlled trial to evaluate switching from a stable antiretroviral regimen to DOR/3TC/TDF. Details of the study methodology have been previously reported, along with the primary and secondary end points through week 48.⁶ Participants who completed the week 48 visit were eligible to enter study extension-1 and continue receiving open-label DOR/3TC/TDF for an additional 96 weeks (up to week 144). Participants with protocol-defined virologic failure (PDVF) were discontinued from the trial, regardless of adherence to study therapy; PDVF was defined as 2 consecutive measurements of HIV-1 RNA ≥ 50 copies/mL at least 1 week apart.

All randomized participants who received at least 1 dose of DOR/3TC/TDF were included in the safety analyses; participants who completed the base study but did not continue to extension-1 were excluded from the efficacy analysis after week 48. Virologic outcomes were assessed with the Food and Drug Administration Snapshot approach (all missing data were counted as failures regardless of the reason) and the observed failure (OF) approach (values missing because of discontinuation for lack of efficacy were counted as failures). Mean changes in fasting lipids from the time of switch to 24 weeks after switch and to week 144 were summarized using the last-observation-carried-forward approach for missing data or data collected after changes in lipid-lowering therapy.

Weight change, percent weight change, and shift in BMI category after switch to DOR/3TC/TDF were examined in a post hoc analysis. Mean and median weight change, with 95% confidence interval, by time since switch to DOR/3TC/TDF were calculated, adjusting for baseline variables that have been associated with weight change, that is, weight at time of switch, race (Black or non-Black), ethnicity (Hispanic or others), sex, age, previous therapy class (cobicistat-boosted elvitegravir, NNRTI, or ritonavir/cobicistat-boosted PI), baseline CD4⁺ T-cell count, and log of baseline HIV-1 RNA. A repeated-measure mixed-effect model was used to estimate adjusted mean change, and a quantile regression model was used to estimate adjusted medians. For percent change in weight from time of switch to week 144, the proportion of participants in each of the following categories was calculated: $\leq -10\%$, $> -10\%$ to $\leq -5\%$, $> -5\%$ to $\leq 0\%$, $> 0\%$ to $< 5\%$, $\geq 5\%$ to $< 10\%$, and $\geq 10\%$. The proportion of participants with a shift in BMI category from time of switch to week 144 was calculated using standard BMI categories: underweight, BMI < 18.5 ; normal weight, BMI ≥ 18.5 to < 25 ; overweight, BMI ≥ 25 to < 30 ; and obese, BMI ≥ 30 .

RESULTS

A total of 656 participants switched to DOR/3TC/TDF during the base study. Most participants were men (84.5%) and White (76.8%); median age was 43 years (see Table, Supplemental Digital Content 1, <http://links.lww.com/QAI/B625>). The previous antiretroviral therapy regimen was a boosted PI in 70.4% of participants, an NNRTI in 24.1%, and boosted elvitegravir in 5.5%. Of the 609 participants who completed the base study, 600 entered extension-1. Sixty-four

participants discontinued DOR/3TC/TDF before week 144 (see Trial Profile, Supplemental Digital Content 2, <http://links.lww.com/QAI/B625>). The most common reasons for early discontinuation were withdrawal by subject ($n = 28$) and adverse events (AEs, $n = 12$).

Efficacy

At week 144, virologic suppression (HIV-1 RNA < 50 copies/mL) was maintained in 80.1% (351/438) of immediate switch group (ISG) participants and 83.7% (175/209) of delayed switch group (DSG) participants, while 2.7% (12/438) and 4.8% (10/209), respectively, had HIV-1 RNA ≥ 50 copies/mL. The remaining participants had no virologic data available at week 144 (Fig. 1), primarily because of treatment discontinuation for reasons other than AEs or death (ie, lost to follow-up, noncompliance with study drug, physician decision, pregnancy, and withdrawal by subject). By the OF approach, HIV-1 RNA < 50 copies/mL was maintained in 96.7% of the ISG (351/363) and 94.6% of the DSG (175/185) at week 144.

Sixteen participants met PDVF criteria after switching to DOR/3TC/TDF: 7 of 656 (1.1%) in the base study (weeks 0–48) and 9 of 647 (1.4%) in the extension (weeks 48–144). Ten participants had HIV-1 RNA < 100 copies/mL at failure; only 5 participants had > 200 copies/mL. At the final study visit, 8 participants with PDVF were resuppressed (7 with HIV-1 RNA < 40 copies/mL) and 4 had low-level viremia (between 50 and 70 copies/mL). Four participants with PDVF, and 3 who discontinued without PDVF, had samples with sufficient HIV-1 RNA for resistance testing (> 400 copies/mL); none developed genotypic or phenotypic resistance to doravirine, lamivudine, or tenofovir.

Safety

Drug-related AEs were less common during the 96-week extension (4.5%) than during the 48-week base study (19.7%). Serious AEs were more common during the extension (8.2%) than during the base study (4.0%), possibly because of the longer duration of the extension (96 vs 48 weeks). One serious AE that occurred during the extension (acute myocardial infarction) was considered drug related and resolved with no change in study therapy. No participants died during treatment with DOR/3TC/TDF or within 14 days of treatment discontinuation. Discontinuation due to an AE was less common during the extension (1.2%) than during the base study (2.9%). Of the 7 AEs that resulted in discontinuation from the extension, 5 were considered drug related (osteoporosis, headache, increased creatinine, increased hepatic enzyme, and hyperphosphaturia), and 2 were considered serious but not drug related (necrotizing fasciitis and acute kidney injury). The most commonly reported AEs of any causality were nasopharyngitis (16.2%), headache (12.3%), and diarrhea (9.1%); these events were rated as mild intensity by 73.6%, 74.1%, and 75.0% of participants, respectively.

Grade 3 or 4 laboratory changes were generally similar between the 96-week extension and the 48-week base study (see Table, Supplemental Digital Content 3, <http://links.lww.com/QAI/B625>). At week 144, the mean change from

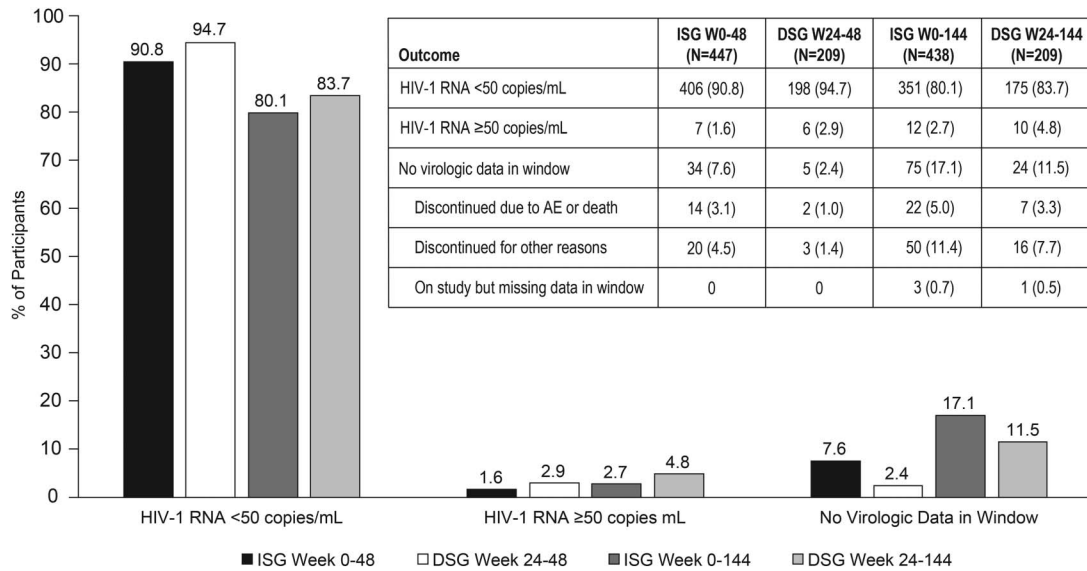


FIGURE 1. Virologic outcomes after switch to DOR/3TC/TDF (FDA Snapshot approach). Nine participants in the ISG who completed the base study (with HIV-1 RNA <40 copies/mL) but did not enter extension-1 were excluded from the week 144 analysis. ISG, immediate switch group. DSG, delayed switch group; FDA, Food and Drug Administration.

baseline in serum creatinine was 0.04 mg/dL in the ISG and DSG. Grade 3 or 4 changes in serum creatinine were rare, occurring in 1.2% (7/596) and 0.3% (2/596) of participants, respectively, during extension-1. Substantial reductions in fasting low-density lipoprotein cholesterol (LDL-C), non-high-density lipoprotein cholesterol (non-HDL-C), total cholesterol, and triglycerides were observed in both treatment groups at 24 weeks after switch and were maintained through week 144 (see Figure, Supplemental Digital Content 4, <http://links.lww.com/QAI/B625>). The mean change (95% confidence interval) in the total cholesterol to HDL-C ratio from time of switch to week 144 was -0.36 (-0.47 to -0.25) in the ISG and -0.03 (-0.48 to 0.42) in the DSG.

At 24 weeks after switch to DOR/3TC/TDF, the adjusted mean weight gain was 0.7 kg in the ISG and 0.5 kg in the DSG (Fig. 2A). Weight gain remained modest in both groups through week 144: the adjusted mean gain was 1.4 kg at ~2.8 years after switch in the ISG and 1.2 kg at ~2.3 years after switch in the DSG. Adjusted median weight changes over time (see Figure, Supplemental Digital Content 5, <http://links.lww.com/QAI/B626>) were consistent with the adjusted mean changes.

From time of switch to week 144, ~40% of participants lost weight or had no change in weight, ~30% gained less than 5%, ~20% gained 5%–10%, and ~8% gained 10% or more (Fig. 2B). Participants with <5% weight gain had larger decreases in total cholesterol, LDL-C, non-HDL-C, triglycerides, and the total cholesterol to HDL-C ratio, and smaller decreases in HDL-C than participants with ≥5% weight gain (see Table, Supplemental Digital Content 6, <http://links.lww.com/QAI/B627>).

In both treatment groups, the adjusted mean weight gain was not significantly different between men and women, Black and non-Black race, or Hispanic/Latino and other

ethnicities (see Figure, Supplemental Digital Content 7, <http://links.lww.com/QAI/B628>). The adjusted mean weight gain from time of switch to week 144 was similar for participants who switched from a boosted PI regimen (ISG 1.4 kg, DSG 1.3 kg) and those who switched from an NNRTI regimen (ISG 1.5 kg, DSG 1.3 kg) but was slightly lower for those who switched from a boosted INSTI (elvitegravir) regimen (ISG 0.8 kg, DSG 0.6 kg). The latter group was relatively small, and most had also received tenofovir alafenamide in their previous regimen (17/20 in the ISG and 7/9 in the DSG).

At the time of switch to DOR/3TC/TDF, 2.2% of participants were underweight (BMI <18.5), 48.1% were normal weight (BMI ≥18.5 to <25), 33.0% were overweight (BMI ≥25 to <30), and 16.7% were obese (BMI ≥30). Most participants (82.6%) remained in the same BMI category at week 144 (see Figure, Supplemental Digital Content 8, <http://links.lww.com/QAI/B629>). Of the 445 participants who were not obese at time of switch, 18 (4.0%) became obese by week 144; most of these participants (16/18) were overweight when they switched to DOR/3TC/TDF. Of the 89 participants who were obese at time of switch, 8 (9.0%) were no longer obese by week 144.

DISCUSSION

This 144-week analysis of the DRIVE-SHIFT trial demonstrates the long-term efficacy of DOR/3TC/TDF in virologically suppressed adults who switched from a stable antiretroviral regimen that included a boosted PI, boosted elvitegravir, or an NNRTI. Very few participants (16/656, 2.4%) met criteria for PDVF after switching to DOR/3TC/TDF, and only 5 (<1%) participants had HIV-1 RNA >200 copies/mL at time of failure. At the final study visit, 75% of participants with PDVF were resuppressed or had very low-level viremia. No viral resistance to doravirine was identified;

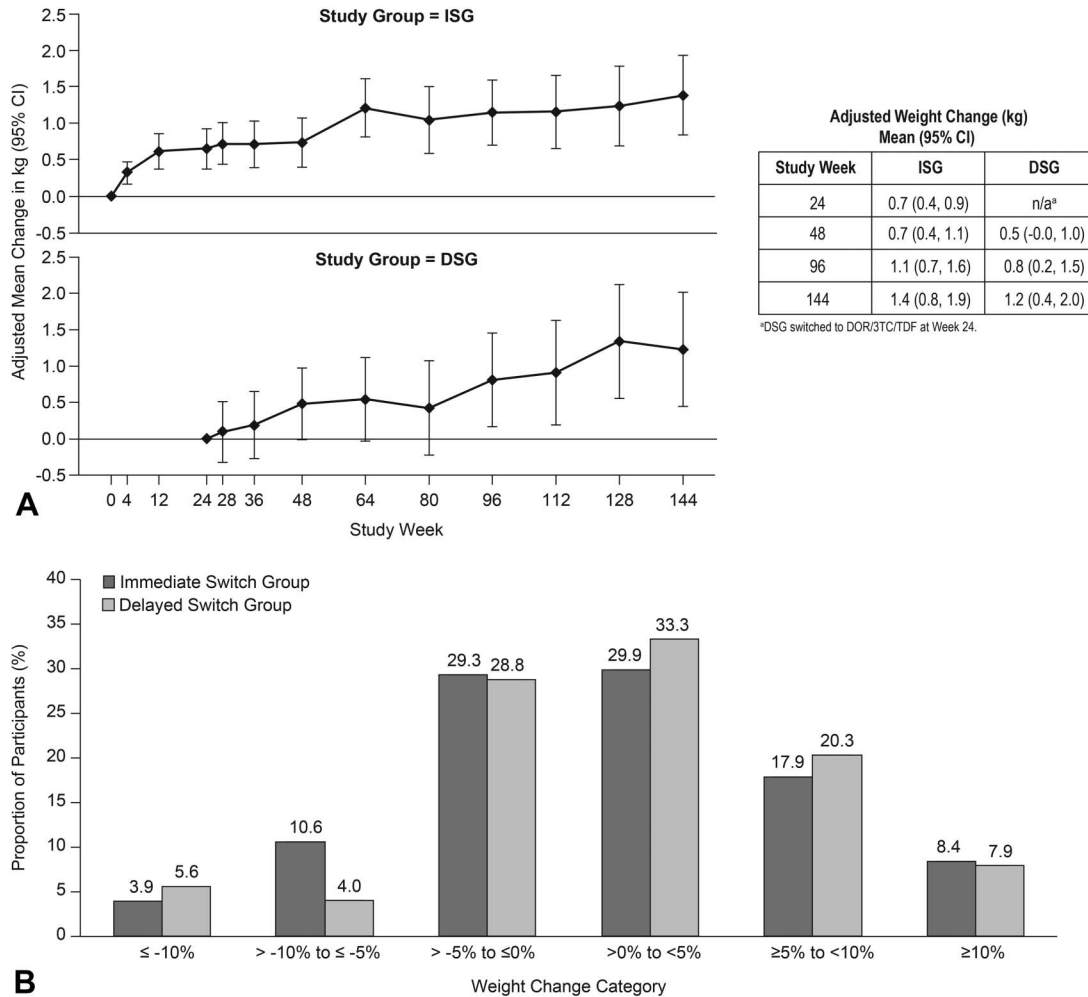


FIGURE 2. Weight change after switch to DOR/3TC/TDF. A, Mean change (95% CI), adjusted for weight at time of switch, race (Black/non-Black), ethnicity (Hispanic/others), sex, age, previous therapy class, baseline CD4⁺ T-cell count, and baseline HIV-1 RNA. B, Proportion of participants by percent change in weight at week 144. CI, confidence interval.

however, only a small number of participants (4 with PDVF and 3 who discontinued without PDVF) had samples with sufficient HIV-1 RNA for resistance testing.

No safety concerns related to long-term exposure to DOR/3TC/TDF were found in this study. DOR/3TC/TDF was generally well tolerated for up to 144 weeks, with no deaths and low rates of serious drug-related AEs and discontinuation due to drug-related AEs. Substantial reductions in fasting lipids occurred by 24 weeks after switching to DOR/3TC/TDF and were maintained over the next 2 years. The long-term safety profile of DOR/3TC/TDF in treatment-experienced adults who switched to this regimen is consistent with the safety profile in treatment-naive adults who received a doravirine-based regimen for up to 96 weeks.^{9–11} Weight gain over 144 weeks was modest: the mean change of 1.2–1.4 kg after more than 2 years on DOR/3TC/TDF was no higher than would be expected in an otherwise healthy population.^{12–14} Mean weight gain was not significantly different by sex, race, or ethnicity. More than 70% of participants experienced less than 5% weight gain, and 83%

of participants remained in the same BMI category as at the time of switch. These findings are consistent with the minimal weight gain observed after initiation of a doravirine regimen in treatment-naive adults with HIV-1.¹⁵

Limitations of our study include lack of diversity in the study population, which was predominantly men (84%), White (77%), <65 years old (97%), and hepatitis B/C negative (96%). Additional research on DOR/3TC/TDF in women, other racial/ethnic groups, the elderly, and people with chronic hepatitis is needed. Similarly, only 5.5% of participants were previously on an integrase inhibitor (elvitegravir), which was always given with cobicistat and usually with tenofovir alafenamide, so we cannot draw conclusions regarding the effect on weight of switching from an integrase inhibitor to DOR/3TC/TDF.

In summary, virologic suppression was maintained for over 2 years in adults with HIV-1 who switched to DOR/3TC/TDF from a boosted PI, boosted elvitegravir, or an NNRTI. Rates of virologic failure were low, and no evidence of resistance to doravirine was found. Switching

to DOR/3TC/TDF was associated with a favorable safety profile, an improved lipid profile, and minimal weight gain in participants who were treated for up to 144 weeks. These results confirm that switching to once-daily DOR/3TC/TDF is an effective and generally well-tolerated option for maintaining viral suppression in patients considering a change in therapy.

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