

EFFICACY AND SAFETY OF DOLUTEGRAVIR/LAMIVUDINE IN VIROLOGICALLY SUPPRESSED FEMALE VS MALE PARTICIPANTS FROM TANGO AND SALSA: POOLED 48-WEEK DATA

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Background: Women represent >50% of people with HIV; therefore, evaluating treatment outcomes in women is important. We present efficacy and safety from pooled TANGO and SALSA data, analyzed by sex.

Methods: This pooled analysis includes 48-week data from the phase 3 TANGO and SALSA trials evaluating switch to dolutegravir/lamivudine (DTG/3TC) vs continuing current antiretroviral regimen (CAR). We assessed efficacy (primary and key secondary endpoints: proportion with HIV-1 RNA ≥ 50 and < 50 c/mL; Snapshot, intention-to-treat–exposed population) and safety by sex. Mixed-models repeated-measures analysis was used for adjusted mean change from baseline in CD4+ cell count.

Results: Of 1234 participants (DTG/3TC, n=615; CAR, n=619), 20% were female. Among female participants, proportion with HIV-1 RNA ≥ 50 c/mL was 0.8% (1/133) for DTG/3TC vs 1.7% (2/117) for CAR (adjusted difference, -0.9%; 95% CI, -3.7, 1.9); results were similar among male participants and overall. Proportion with HIV-1 RNA < 50 c/mL was high in female (DTG/3TC, 91.0%; CAR, 88.9%; adjusted difference, 1.7%; 95% CI, -5.8, 9.2) and male participants. No female participants had confirmed virologic withdrawal (CVW). One male CAR participant had CVW (no resistance detected). Among female participants, adjusted mean change (SE) from baseline to Week 48 in CD4+ cell count was 74 (16) vs -19 (16) cells/mm³ for DTG/3TC vs CAR, respectively. Adverse events (AEs) occurred in 74% of female participants receiving DTG/3TC vs 71% continuing CAR, with few AEs leading to withdrawal (DTG/3TC, 2%; CAR, 3%) and more drug-related AEs with DTG/3TC (19%) vs CAR (5%). Safety was similar between sexes.

Conclusion: Switching to DTG/3TC maintained high rates of virologic suppression, with no reported resistance, and improved CD4+ cell counts in female participants vs CAR. AEs leading to withdrawal were infrequent and consistent between sexes. Results confirm the high efficacy, good safety, and high resistance barrier of DTG/3TC in women with HIV.

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