Journal of Infection and Public Health 12 (2019) 296–300

Contents lists available at ScienceDirect

Journal of Infection and Public Health

journal homepage: http://www.elsevier.com/locate/jiph

Abstracts of SSMMID 2019

Initial viral load decline and response rates by baseline viral load strata with dolutegravir plus lamivudine versus dolutegravir plus tenofovir disoproxil fumarate/emtricitabine: pooled results from the GEMINI studies

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Background: At 48 weeks in the GEMINI-1 and GEMINI-2 studies (NCT02831673 and NCT02831764), the 2-drug regimen (2DR) dolutegravir (DTG) + lamivudine (3TC) was non-inferior compared with the 3-drug regimen (3DR) DTG + tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) in achieving plasma HIV-1 RNA <50 c/mL in treatment-naive adults with baseline HIV-1 RNA ≤500,000 c/mL. To better understand the potency of DTG + 3TC compared with the 3DR, we explored the rapidity of initial viral load (VL) decline and efficacy response rates in those with baseline VL >100,000 c/mL.

Methods: Participants were randomized 1:1 to receive DTG 50 mg + 3TC 300 mg once daily or DTG 50 mg + TDF 300 mg/FTC 200 mg once daily (stratified by baseline HIV-1 RNA and CD4 + cell count). The primary endpoint was proportion of participants with HIV-1 RNA <50 c/mL at Week 48 (using snapshot algorithm, ITT-E population), with a 10% non-inferiority margin. As a post hoc analysis, mean change $\log_{10}$-transformed HIV-1 RNA from baseline and 95% CIs were calculated at Weeks 4, 8, 12, 16, 24, 36, and 48. Proportions of participants with plasma HIV-1 RNA <50 c/mL at Week 48 (using snapshot) for the 2DR versus 3DR therapy by baseline HIV-1 RNA strata ≤100,000 c/mL, >100,000 c/mL, >250,000 c/mL, and >400,000 c/mL were also analyzed.

Results: In the pooled analysis, at Week 48, 91% (655/716) of participants in the 2DR group versus 93% (669/717) in the 3DR group achieved HIV-1 RNA <50 c/mL (adjusted treatment difference, −1.7%; 95% CI, −4.4 to 1.1). Twenty percent (140/716) in the 2DR group and 21% (153/717) in the 3DR group had baseline HIV-1 RNA >100,000 c/mL (including 2% with baseline VL >500,000 c/mL). Similar rapid VL log decline was observed in both treatment groups overall (median change from Baseline at Week 4: −2.77 $\log_{10}$ c/mL in the 2DR group, and −2.80 $\log_{10}$ c/mL in the 3DR group) and in participants with baseline VL >100,000 c/mL (median change from Baseline at Week 4: −3.38 $\log_{10}$ c/mL in the 2DR group, and −3.40 $\log_{10}$ c/mL in the 3DR group). High and similar response rates were seen in participants across baseline VL strata below and above 100,000 c/mL. For participants with baseline VL ≤100,000 c/mL, 91% (526/576) in the 2DR group versus 94% (531/564) in the 3DR group achieved HIV-1 RNA <50 c/mL (adjusted treatment difference, −2.8%; 95% CI, −5.8 to 0.2); for participants with baseline VL >100,000 c/mL, 92% (129/140) in the 2DR group versus 90% (138/153) in the 3DR group achieved HIV-1 RNA <50 c/mL (adjusted treatment difference, 1.9%; 95% CI, −4.5 to 8.4). A consistent response pattern was also observed in the HIV-1 RNA strata >250,000 c/mL, and >400,000 c/mL.

Conclusions: Viral load decline with the 2DR DTG + 3TC was rapid and comparable to that of the 3DR DTG + TDF/FTC. Response rates in participants with baseline HIV-1 RNA >100,000 c/mL were high with DTG + 3TC, consistent across strata, including participants with HIV-1 RNA >400,000 c/mL, and similar to the 3DR group. These data demonstrate a high potency of DTG + 3TC, similar to that of a standard-of-care 3DR.

https://doi.org/10.1016/j.jiph.2019.02.003

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1876-0341/