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Long-Term Outcomes of Dolutegravir and Efavirenz-400 as first-line ART in Cameroon

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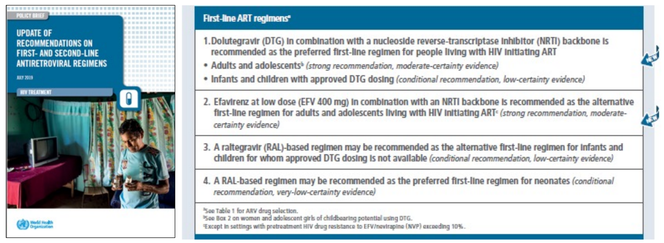
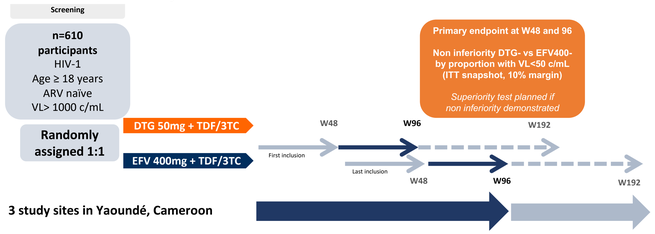
BACKGROUND

WHO recommends dolutegravir 50mg (DTG) as first-line antiretroviral treatment (ART) and efavirenz 400mg (EFV400) as second option since 2019. Efficacy and safety of both ART in real living conditions in low- and middle-income countries (LMIC) were previously demonstrated by the NAMSAL study group and provided solid elements for these recommendations (ref). Yet, it took up to three years of follow-up for the remarkable efficacy in favor of DTG to be established. Here data for the fourth year of follow-up are reported



METHODS

NAMSAL was an open-label, multicenter, randomized, phase 3 non inferiority trial conducted in Cameroon over 96-week, post-trial follow-up was conducted as a prospective cohort until 192-week. HIV-1 infected ARV-naive adults with HIV-RNA viral load (VL) >1000 copies/mL were randomized and maintained in the base arm (1-DTG:1-EFV), each combined with tenofovir-disoproxil-fumarate (TDF)/lamivudine (3TC). The primary endpoint was the proportion of participants with a VL of less than 50 copies/mL at week 48; secondary outcomes were assessed with superiority-test.



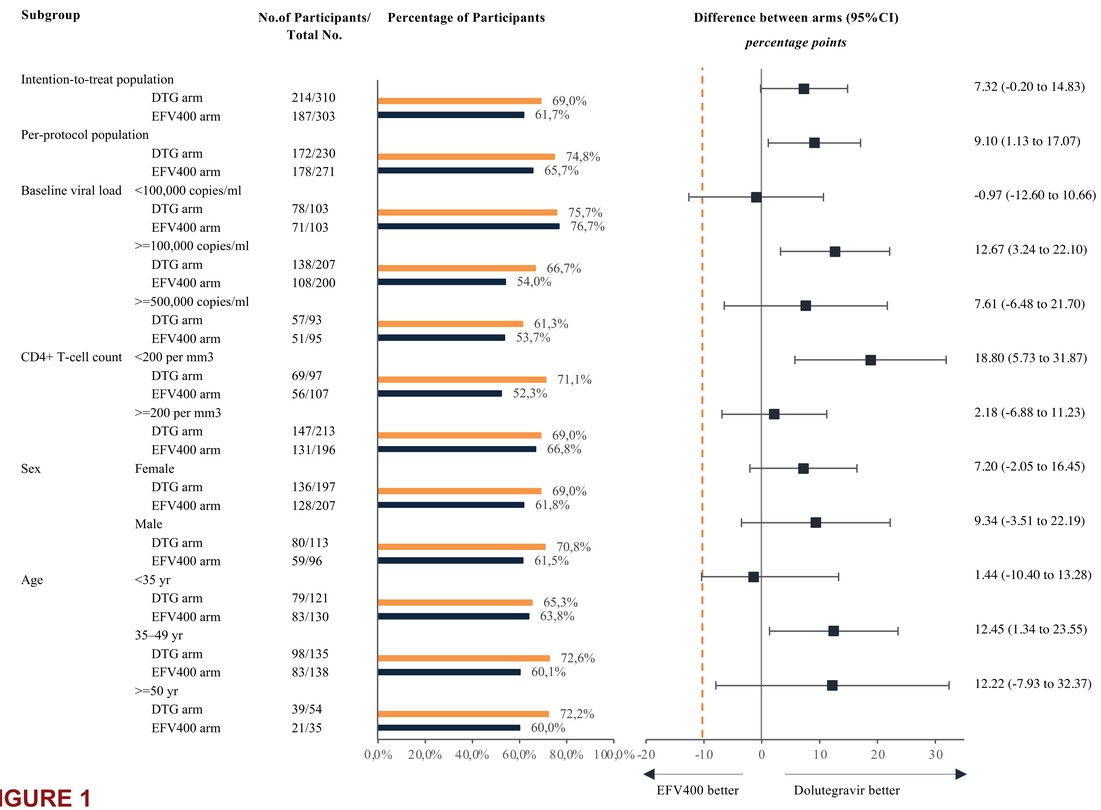


FIGURE 1

Efficacy on the viral load (<50 copies/mL) according to subgroups at 192 weeks

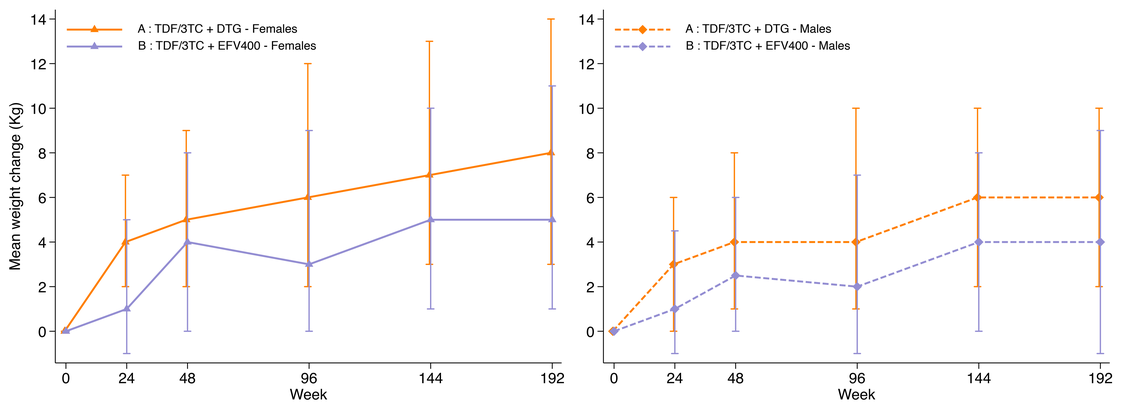


FIGURE 2

Evolution of the body weight gain change over the time': Right – Women, Left - Men

RESULTS

At week 192, a higher proportion of the DTG group (69%, 214/310) achieved a VL < 50 copies/mL than did the EFV400 group (62%, 187/303; difference, 7.3%; CI-95%, [-0.20;15.45], p-value=0.057; Figure 1). Per-protocol results were close to ITT, 75% (DTG: 172/230) and 66% (EFV400: 178/271) respectively (difference, 7.9%; CI-95%, [0.3;16.27], p-value=0.035). During the fourth-year of follow-up, five (DTG: 2; EFV400: 3) new virological failures (WHO-definition) without related resistance mutations (NNRTI+/-NRTI) were observed. 24 new severe adverse-events (SAE) were observed (DTG: 13, EFV400: 11). Over four years mean weight gain was more important in women compared to men (Women: DTG +8.0 Kg, EFV400 +5.0 Kg, p-value=0.010; Men: DTG +6.0 Kg, EFV400 +4.0 Kg, p-value=0.024; Figure 2). Incidence of obesity in women was 17% and 11% (p=0.140) respectively, in men 26% and 3% (p<0.001) respectively.

CONCLUSIONS

Fourth-year of follow-up of HIV-1 infected ARV-naive adults in LMIC, who were started on DTG-based and low-dose EFV-based regimen, suggests durability of DTG-based and EFV400-based regimens; low EFV-related and no DTG-related resistance mutations rates were observed. However, weight gain tendency is important among women on DTG; a close cardiovascular and metabolic monitoring should be recommended to take into account risks related to weight-gain.

ADDITIONAL KEY INFORMATION

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