Efficacy and Safety of Switching to DTG/3TC Dual Therapy From B/F/TAF Among Older Adults ≥60 Years

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Loice Achieng Ombajo[1,2], Joseph Nkuranga[1,2], Victor Omodi[1,2], Zian Muikamba[1,2], Edwin Otieno[1,2], Jeremy Penner[2,3], Michelle Kisare[4], Simon Wahome[5], Florentius Ndinya[6], Ricky Echesa[1,2] For the Sungura study group

[1]Department of Clinical Medicine and Therapeutics, University of Nairobi, Nairobi, Kenya, [2]Center for Epidemiological Modelling and Analysis, University of Nairobi, Nairobi, Kenya, [3]Department of Family Practice, University of British Columbia, Vancouver, Canada, [4]ViiV HealthCare, London, UK, [5]Kenyatta National Hospital, Nairobi, Kenya, [6]Jaramogi Oginga Odinga Teaching and Referral Hospital, Kisumu, Kenya

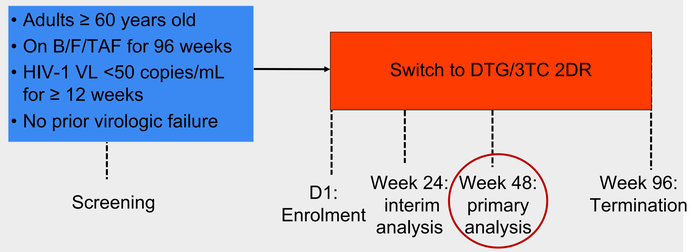
BACKGROUND

- Use of 2DR such as dolutegravir/lamivudine (DTG/3TC) minimises exposure to NRTIs
- This reduces drug toxicities that overlap with co-morbidities common in older persons living with HIV.
- The efficacy of DTG/3TC has been demonstrated in persons with no history of prior virological failure.
- We evaluated the efficacy and safety of switching older adults from B/F/TAF to DTG/3TC.

METHODS

- The Sungura Study (NCT06444620) is an open-label, single arm, 96-week study at two sites in Kenya.

Figure 1: Overview of the Sungura Study



- The primary endpoint was the proportion of participants with viral load ≥50 copies/mL at 48 weeks using the FDA snapshot algorithm.

RESULTS

- Between July and Sep 2024, 197 participants were enrolled and treated and included in the ITT-E analysis.

Table 1: Baseline Characteristics

Characteristic	Frequency (N = 197)
Age (years), median (min, max)	66.1 (61.9, 81.1)
Sex: Female	97 (49.2%)
Body-mass index (kg/m^2), median (IQR)	26.4 (23.0, 29.4)
Time on ART (years), median (IQR)	12.0 (9.5, 12.4)
Hypertensive at baseline	138 (70.1%)
Diabetes/Hyperglycemia at baseline	32 (16.3%)
Dyslipidemia at baseline	46 (23.4%)
Grade 2-3 CrCl abnormality	166 (84.3%)
Grade 2-4 lipid abnormality	114 (57.9%)
Grade 2-4 FBG abnormality	28 (14.3%)
ASCVD risk score category	
Low risk (<5%)	1 (0.5%)
Borderline risk (5% to 7.4%)	21 (10.7%)
Intermediate risk (7.5% to 19.9%)	128 (65.3%)
High risk (≥20%)	46 (23.6%)

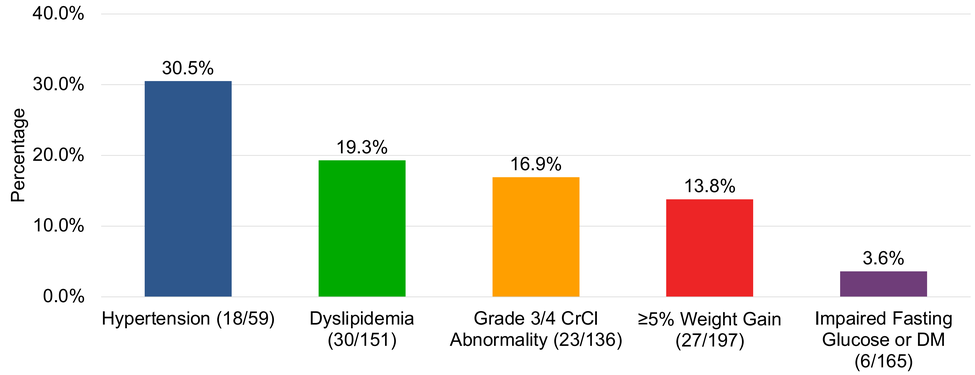
All participants on DTG/3TC dual therapy were virally suppressed at week 48 in an aging population living with HIV

Baseline and incident comorbidites were high

RESULTS contd…

- HBcAb was positive in 92 participants, all of whom had HBsAb levels ≥ 10 U/ml. Baseline prevalence of co-morbidities was high
- At week 48, 197 participants remained on DTG/3TC and none (0/197) had HIV viral load ≥50 copies/mL
- One participant required switch to TDF/3TC/DTG + DTG on the week 48 visit due to pulmonary tuberculosis requiring treatment with rifampicin.

Figure 2: Incident Comorbidities and Weight Change



- There were 11 serious adverse events with none related to the study drug (table 2).
- One participant with HBcAb positive at baseline had a grade 2 AST abnormality at week 48, the ALT was normal with no other features of hepatitis.
- The median change in 10-year ASCVD risk score was 0.0% (IQR -1.7 to 2.9).

PLAIN LANGUAGE SUMMARY

A number of people aged 60 years or older with HIV had other new or existing long-term health conditions. A two-drug treatment option combining dolutegravir and lamivudine effectively maintained viral suppression after 48 weeks. This simpler treatment may be a good option for older adults with HIV.

Table 2: Adverse Events

	Total (n = 197)
Any AE (total number of AEs)	**205**
AE occurring in > 5% of participants	
New or worsening dyslipidemia	30 (15.2%)
Worsening creatinine clearance	23 (11.7%)
URTI	16 (8.1%)
Malaria	14 (7.1%)
AE leading to study drug discontinuation – total (%)	**1 (0.5%)**
Tuberculosis	1 (0.5%)
Treatment-related Serious AEs total (%)	**0 (0.0%)**
Serious AEs (%)	**11 (5.6%)**
Central cord syndrome after RTA	1 (0.5%)
Peptic ulcer disease	1 (0.5%)
Acute kidney injury	1 (0.5%)
Right ankle fracture after RTA	1 (0.5%)
Osteoarthritis requiring total knee replacement	1 (0.5%)
Gastroenteritis	1 (0.5%)
LRTI	1 (0.5%)
Malaria	1 (0.5%)
Urethral stricture requiring surgical intervention	1 (0.5%)
Diabetic wound with cellulitis	1 (0.5%)
Pelvic malignancy	1 (0.5%)
Grade 3 or 4 laboratory abnormalities – total (%)	**66 (33.5%)**
Total cholesterol	5 (2.5%)
LDL	10 (5.1%)
Triglycerides	2 (1.0%)
Creatinine Clearance	45 (22.8%)
Fasting Glucose	4 (2.0%)

CONCLUSION

- At week 48, there was no virologic failure or withdrawal from the Sungura study.
- Co-morbidities were common, highlighting additional considerations for selecting antiretroviral agents for older populations.

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CONTACT

loisea@uonbi.ac.ke