No reactivation of Hepatitis B in African patients on tenofovir free regimens for treatment of HIV: results from the switch to DTG/3TC (Sungura) study

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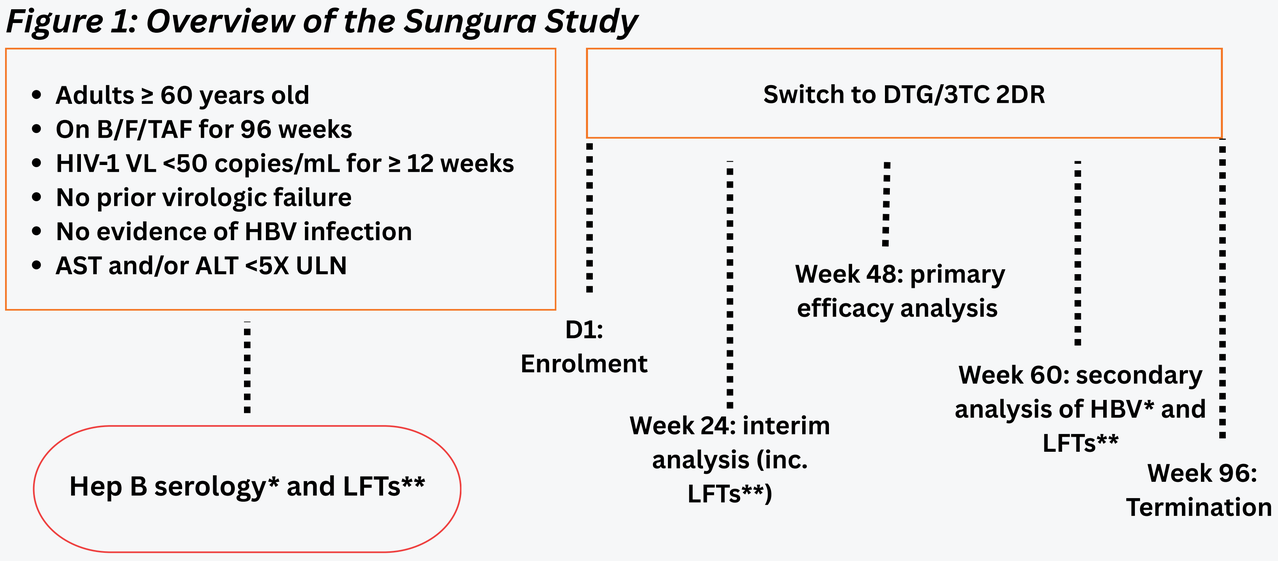
BACKGROUND

- Tenofovir is active against both HIV and hepatitis B virus (HBV)
- As comorbidities such as kidney and bone disease become more common, two-drug regimens (2DRs) that exclude tenofovir are increasingly used due to lower toxicity and potentially lower cost
- Reactivation remains a potential risk in those with previous HBV exposure in whom tenofovir is withdrawn, especially in low resource settings with high HBV prevalence and low HBV vaccination of adults

METHODS

- The Sungura study (NCT06444620) is a phase 3, single-arm clinical trial at multiple sites in Kenya
- Eligible participants are aged ≥60 years, on B/F/TAF for ≥96 weeks, with VL <50 copies/mL and no prior virologic failure
- We excluded those with evidence of HBV infection:
  - HBsAg positive, or
  - HBsAg negative with HBcAb positive and HBsAb <10 IU (prior infection without immunity)

Figure 1: Overview of the Sungura Study



*Hep B serology: HBsAg, HBV DNA
**LFTs: AST, ALT, GGT, ALP, Albumin, Total Protein, Total Bilirubin

- We evaluated the incidence of HBV reactivation using HBV DNA quantification in participants with prior HBV exposure, new HBsAg positivity, or elevated liver transaminases at week 60
- The study is continuing to week 96

RESULTS

- Between July and September 2024, 227 participants on B/F/TAF were screened with 197 enrolled in the study; the table below summarizes their baseline characteristics including some of the co-morbidities

Table 1: Baseline Characteristics

Characteristic	Total (n=197)
Age (years); median (min, max)	66 (62, 81)
Female Sex	97 (49%)
Time on ART (years)	12.0 (9.5,12.5)
Hypertension	138 (70%)
Impaired fasting glucose or diabetes mellitus	32 (16%)
Dyslipidemia	46 (23%)
Grade 3 creatinine clearance abnormality	61 (31%)
Body-mass index category (kg/m2)	
Underweight (< 18.5)	5 (2%)
Normal (18.5-24.9)	79 (40%)
Overweight (25.0-29.9)	67 (34%)
Obese (≥ 30)	46 (23%)
ASCVD 10-year predicted risk score category	
Low risk (< 5.0%)	1 (0.5%)
Borderline risk (5.0-7.4%)	20 (11%)
Intermediate risk (7.5-19.9%)	127 (65%)
High risk (≥20%)	45 (24%)

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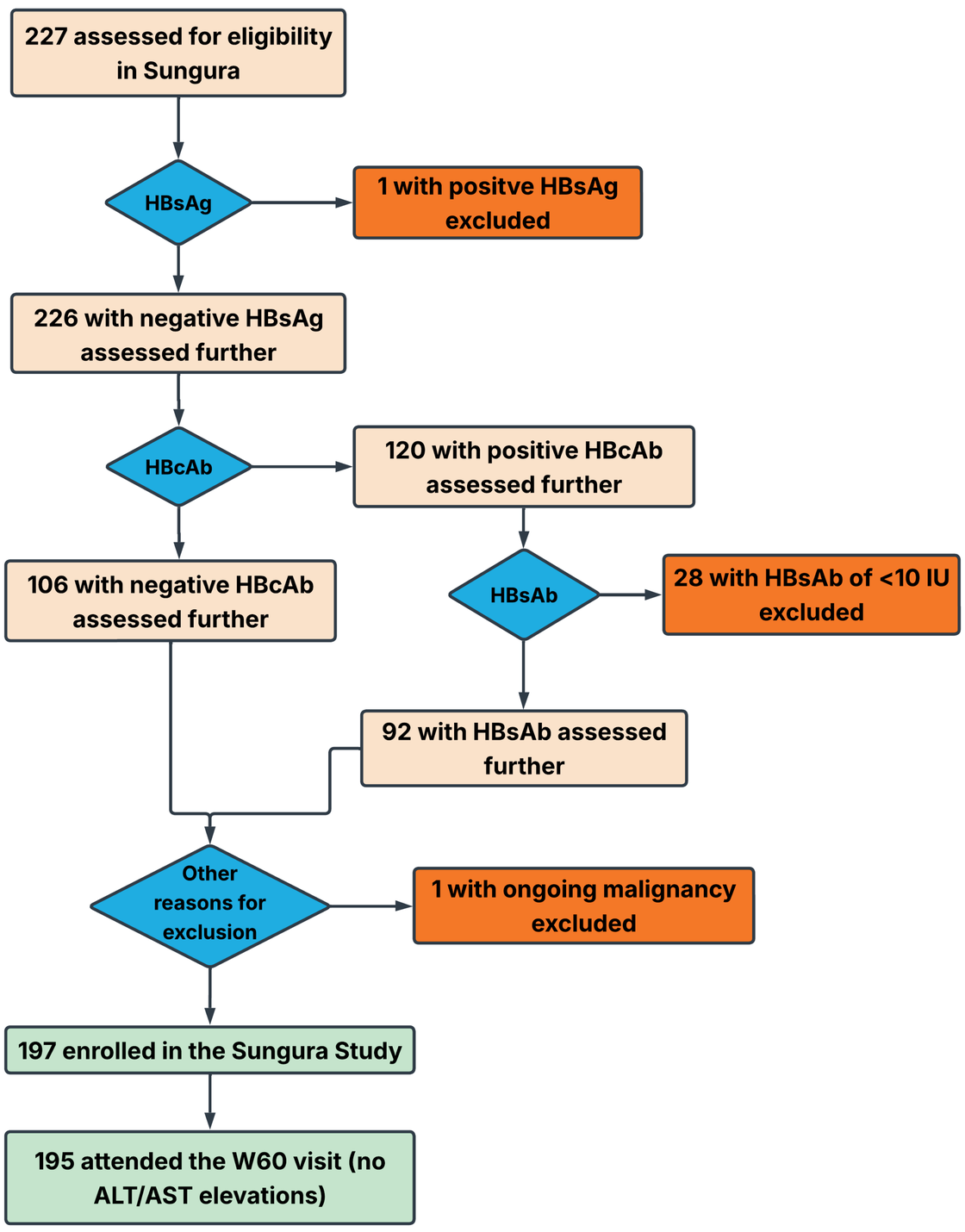
RESULTS contd.

- 29 participants were excluded due to evidence of HBV infection (fig 2)

Figure 2: Screening, Enrolment and Follow-up



- 195 (99%) participants completed the week 60 visit
- No new positive HBsAg
- Among the 92 participants with prior HBV exposure at baseline, **90 (98%) had undetectable HBV DNA** while 1 had HBV DNA of 5 IU/mL
  - Repeat HBV DNA for this participant was undetectable at week 72
  - 1 participant died during follow-up, unrelated to HBV

CONCLUSION

- The absence of new HBV infections or reactivation is reassuring for the use of tenofovir sparing, two drug regimens in PLWH with prior hepatitis B exposure
- Efforts to provide HBV vaccination should continue

ACKNOWLEDGEMENT

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