Osteoporosis among older persons living with HIV in Kenya: baseline results from the BFTAF elderly switch study

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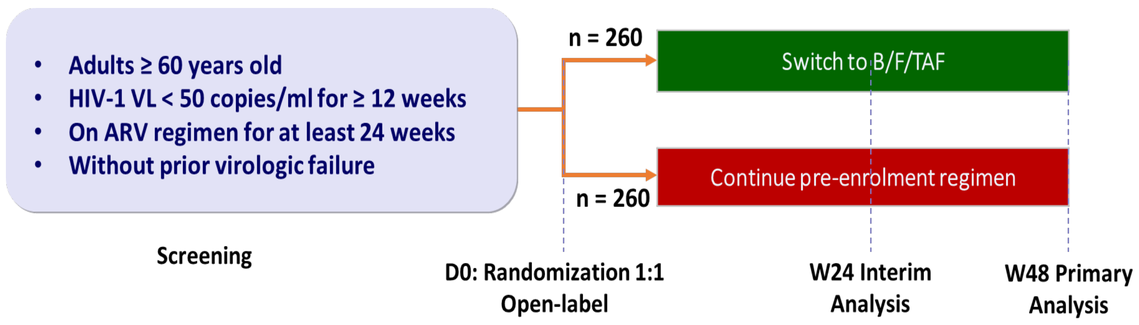
BACKGROUND

- Osteoporosis is becoming increasingly common among the aging population of people living with HIV (PLHIV)
- PLHIV share the same traditional risk factors for osteoporosis as people without HIV in addition to HIV-specific risk factors
- HIV and ARVs are associated with a deterioration in bone quality and ART initiation is associated with a transient acceleration in bone loss
- Specific ARVs, particularly boosted protease inhibitors and tenofovir disoproxil fumarate (TDF), are associated with greater reduction in bone mineral density (BMD) than other ARVs
- There is a paucity of data on osteoporosis among elderly PLHIV in sub-Saharan Africa
- We report the prevalence of osteoporosis and risk factors among HIV-1 positive elderly adults (≥ 60 years) who are virally suppressed on first-line ART receiving outpatient HIV care in Kenya at enrollment into a clinical trial

METHODS

- The BFTAF Elderly Switch Study is an open-label, randomized, active-controlled, non-inferiority trial conducted at two sites in Kenya
- It aims to evaluate the efficacy and impact on BMD of a switch strategy from current ARV regimen to B/F/TAF in virally suppressed HIV-1 positive elderly adults (≥ 60 years old) without prior virologic failure
- The study has two primary objectives: to evaluate the non-inferiority of switching to B/F/TAF as compared to maintaining the current regimen and to evaluate the change in BMD by study arm at 48 weeks

Figure 1: Study Overview



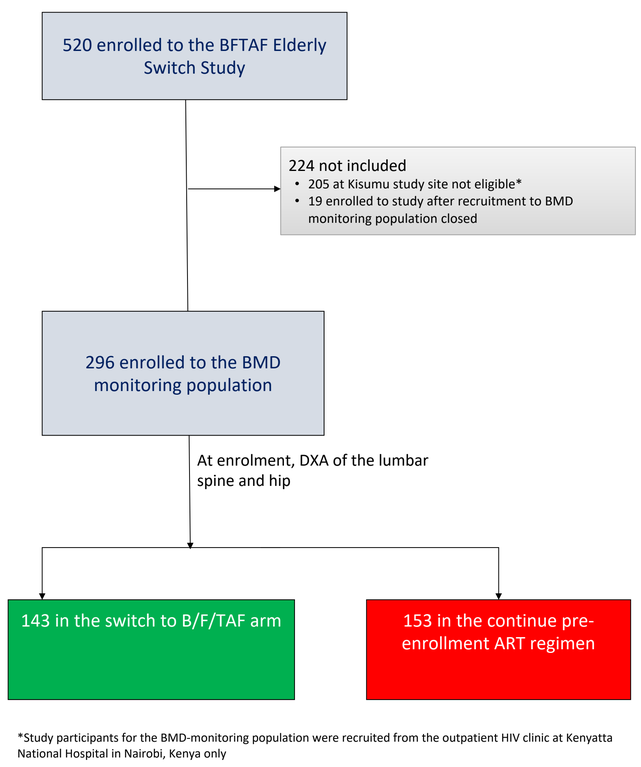
BMD Monitoring Population

- A sample of 296 patients were enrolled to the clinical trial and underwent dual-energy x-ray absorptiometry (DXA) of the lumbar spine and total hip using a Hologic Discovery A scanner with APEX software (version 4.5.3)
- Participants were classified as having osteoporosis or osteopenia using their lowest T-score from either lumbar spine or total hip
- Osteoporosis was defined as T-score ≤ –2.5 and osteopenia as a T-score between –1 and –2.5
- Participants with 10-year probability of hip fracture ≥ 3% or major osteoporotic fracture (hip, spine, forearm or shoulder) ≥ 20% based on Fracture Risk Assessment Tool (FRAX®) scores, or with a history of fragility fracture, were classified as qualifying for osteoporosis treatment based on FRAX®
  - Calculated using US (Black) reference population
  - Clinical risk factors used without entering femoral neck BMD score
  - HIV considered as secondary cause of osteoporosis

RESULTS

- Between February and May 2022, 520 enrolled in the main study
- Of these, 296 (56.9%) were screened for additional entry into the BMD monitoring population
- All 296 were enrolled; no participant was excluded due to the BMD monitoring eligibility criteria
- Screening for the BMD monitoring population stopped once the sample size was achieved
- All 296 underwent DXA at enrollment and are included in this analysis.

Figure 2: BMD Monitoring Population



*Study participants for the BMD-monitoring population were recruited from the outpatient HIV clinic at Kenyatta National Hospital in Nairobi, Kenya only

RESULTS continued…

Baseline Characteristics

- All participants were black African, 147 (49.7%) were female, median age was 64 years (range 60 to 77) and 280 (94.6%) were on tenofovir disoproxil fumarate (TDF)-containing regimens

Table 1: Baseline Characteristics

Variable	Total (n = 296)
Age in years, median (min, max)	64 (60, 77)
Female sex, n (%)	147 (49.7%)
Black race, n (%)	296 (100%)
Any alcohol use in past 12 months, n (%)	4 (1.4%)
Ever smoked, n (%)	7 (2.4%)
BMI in kg/m2, median (IQR)	27.5 (24.0, 30.9)
CrCl < 60 ml/min, n (%)	105 (35.6%)
TDF-containing regimen, n (%)	280 (94.6%)

BMD Findings

- Median BMD of the lumbar spine and total hip were 0.88 g/cm2 (IQR 0.78 to 1.00) and 0.88 g/cm2 (IQR 0.80 to 0.99), respectively, with median T-scores of -2.7 (IQR -3.5 to -1.6) and -1.3 (IQR -1.9 to -0.7), respectively
- Osteoporosis and osteopenia were found in 60.5% and 29.1% of participants, respectively
- Using FRAX score alone (without BMD results) only identified 7 (2.4%) participants who qualified for treatment of osteoporosis

Table 2: BMD Findings

Variable	Total (n = 296)
BMD lumbar spine in g/cm^2, median (IQR)	0.88 (0.78, 1.0)
BMD T-score lumbar spine, median (IQR)	-2.7 (-3.5, -1.6)
BMD total hip in g/cm^2, , median (IQR)	0.88 (0.80, 0.99)
BMD T-score total hip, median (IQR)	-1.3 (-1.9, -0.7)
BMD category, n (%)	
Normal	31 (10.5%)
Osteopenia	86 (29.1%)
Osteoporosis	179 (60.5%)
Treatment of osteoporosis recommended based on:	
FRAX and HIV (without BMD), n (%)	7 (2.4%)
FRAX and BMD, n (%)	10 (3.4%)

- In bivariate analysis comparing characteristics for participants with and without osteoporosis, female gender (p=0.02), lower BMI (p=0.004) and lower CrCl (p=0.006) were associated with osteoporosis

CONCLUSION

- The prevalence of osteoporosis among elderly PLHIV in Kenya is high
- DXA is not readily available in Kenya, and risk calculation without BMD did not identify the majority of participants who qualify for treatment of osteoporosis
- Additional data for this population is required on:
  - Subclinical fractures
  - Optimal ARV selection particularly in populations with widespread use of TDF
  - The impact of investment in osteoporosis screening and treatment, including population-specific risk calculators

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