

Switch of Virally Suppressed Adults ≥ 60 Years From First-Line ART to B/F/TAF: Week 96 Results

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BACKGROUND

- Antiretroviral options for older adults are limited by age-related co-morbidities and drug toxicities
- We evaluated whether a first-line switch strategy in older adults ≥60 years old to bicitgravir / emtricitabine / tenofovir alafenamide (B/F/TAF) maintains viral suppression while minimizing contribution to comorbidities

METHODS

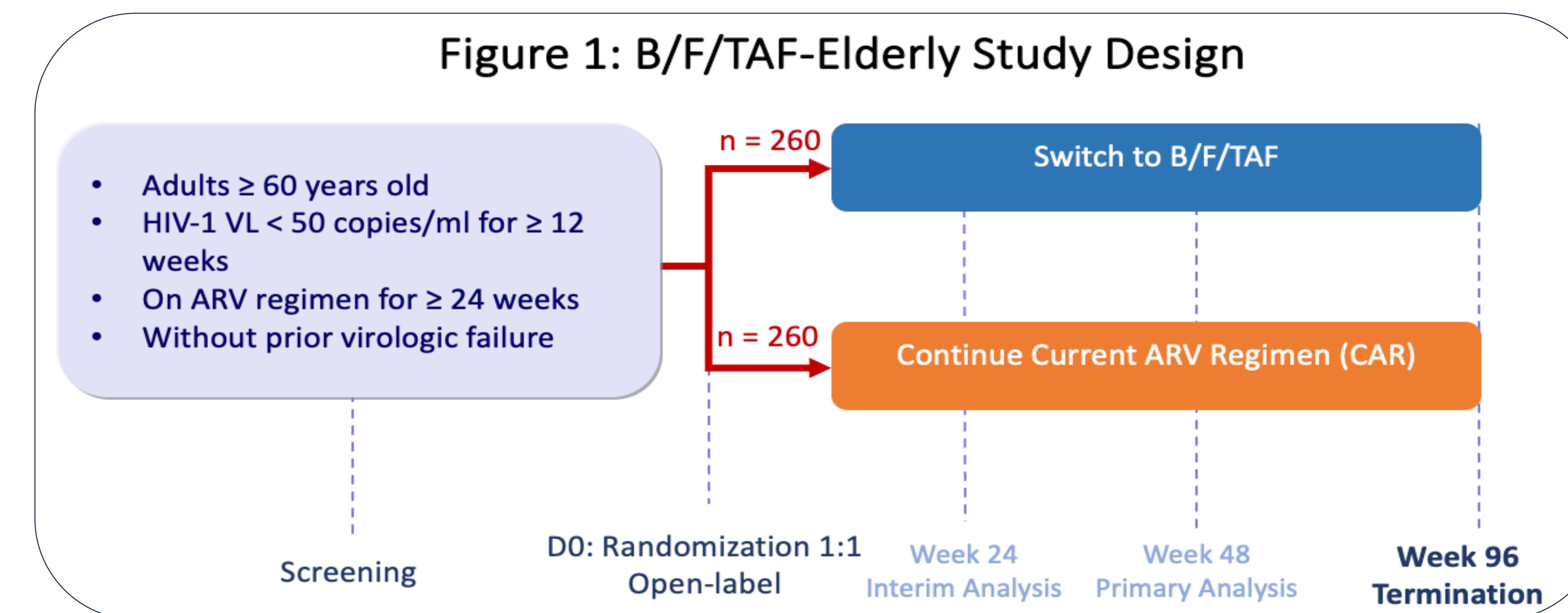
- This was an open-label, randomized, non-inferiority trial conducted at two sites in Kenya (ClinicalTrials.gov ref NCT05243602)
- Participants were randomized to switch to B/F/TAF or continue current ARV regimen (CAR) (see figure 1)
- We report the key secondary outcomes at week 96:
 - proportion of participants with VL ≥50 copies/mL using the FDA snapshot algorithm with a 4% noninferiority margin
 - mean percentage change in lumbar spine BMD, safety and incident co-morbidities

RESULTS

- Between Feb and May 2022, 520 participants were randomized (260 B/F/TAF, 260 CAR) and a subset of 296 had BMD monitoring (143 B/F/TAF, 153 CAR)
- Baseline characteristics were balanced between arms (see table 1) and 111 (37.5%) participants of the BMD population had osteoporosis

Variable	B/F/TAF arm (n = 260)	CAR arm (n = 260)
Age in years, median (min, max)	64.0 (60.0, 79.0)	64.0 (60.0, 79.0)
Female sex, n (%)	124 (48%)	143 (55%)
Black race, n (%)	260 (100%)	260 (100%)
Body-mass index in kg/m ² , median (IQR)	25.9 (23.2, 29.4)	27.0 (23.4, 30.5)
Creatinine clearance < 60 mL/min, n (%)	85 (33%)	87 (34%)
Grade 2-4 lipid abnormality, n (%)	129 (50%)	127 (49%)
Time on ART in years, median (IQR)	9.5 (7.2, 9.8)	9.5 (6.7, 9.7)
Currently on TDF-containing regimen, n (%)	245 (94%)	250 (96%)

A first-line switch strategy to B/F/TAF was effective and safe in a population of older African adults ≥ 60 years old and was associated with less requirement for treatment modification due to declining kidney function



RESULTS contd...

- At week 96, 7/260 participants (2.7%) in each arm had VL ≥50 copies/mL (difference [95% CI], 0% [-2.8 to 2.8]), meeting non-inferiority (see figure 2)

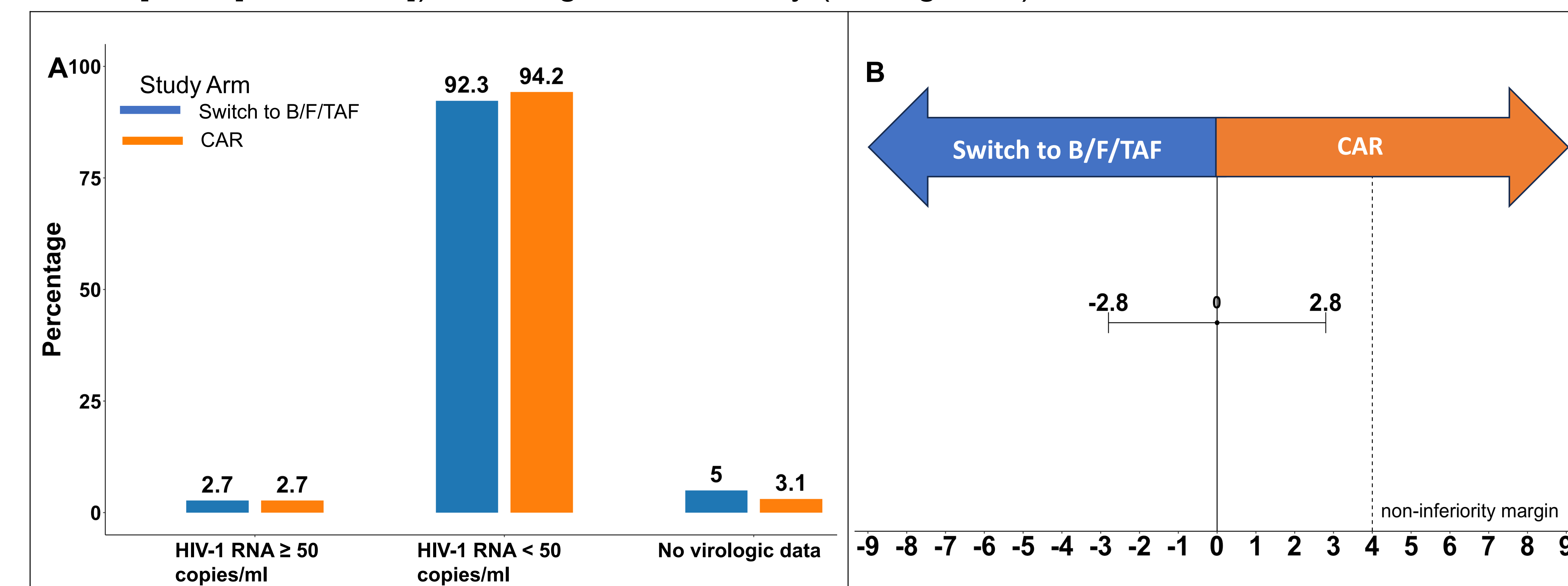
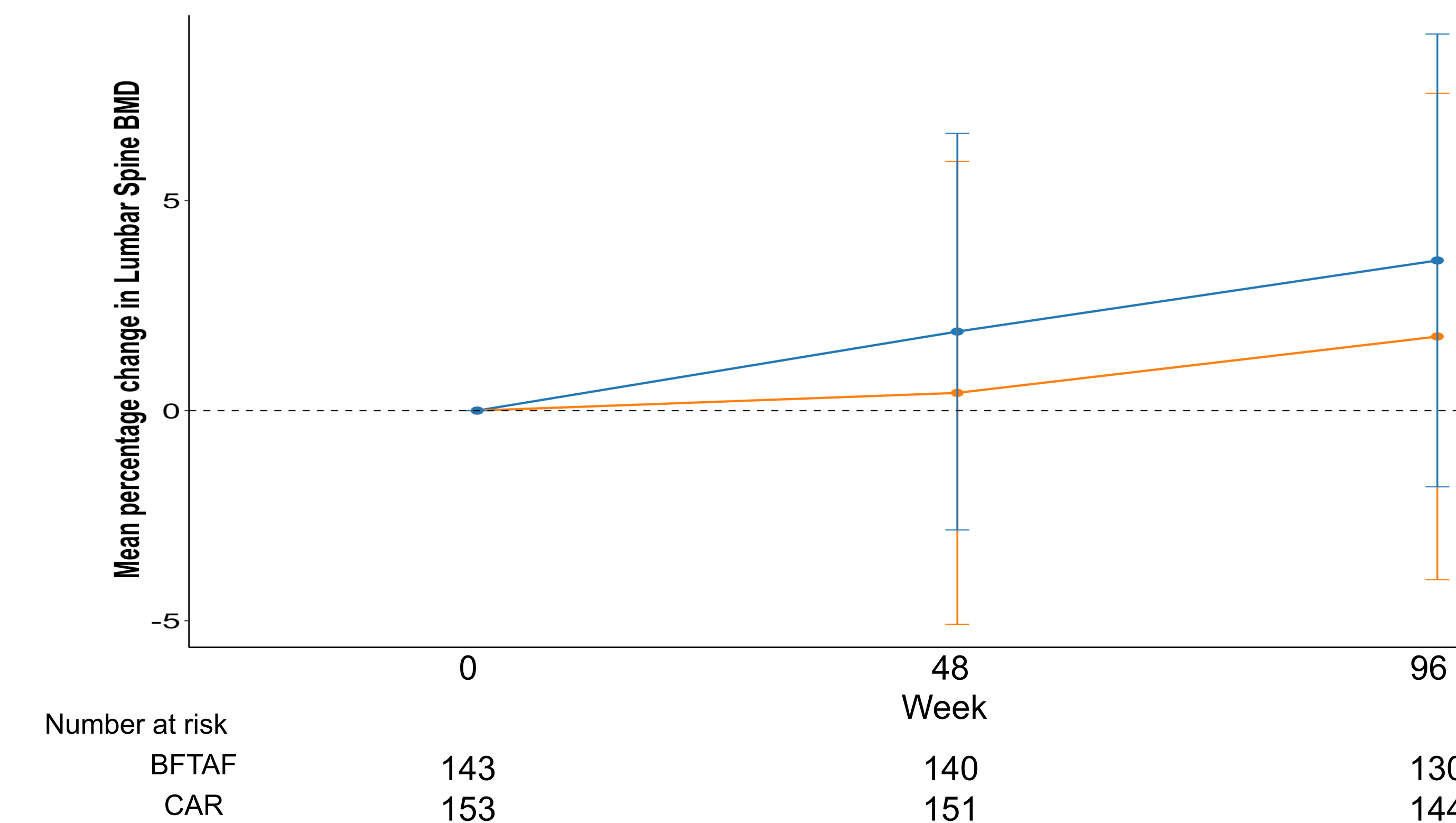


Figure 2: Efficacy at Week 96

A virologic outcomes at week 96 in the intention-to-treat-exposed population by US Food and Drug Administration Snapshot algorithm. B. Treatment difference in the analysis of the population. Abbreviations: B/F/TAF, bicitgravir/emtricitabine/tenofovir alafenamide; current antiretroviral regimen

RESULTS contd...

- The mean percentage change in lumbar spine BMD was +3.98% (SD 6.10) on B/F/TAF and +2.29% (SD 6.02) on CAR (difference [95% CI], 1.70 [0.25 to 3.14], p=0.021)



- There were no treatment-related SAEs in either arm
- Participants discontinuing study drug due to any AE were 1 (0.4%, due to TB) on B/F/TAF and 30 (11.5%, due to declining kidney function) on CAR
- The change in creatinine clearance from baseline was 1.7% on B/F/TAF and -3.5% on CAR
- Change in weight was 0% on B/F/TAF and -2.6% on CAR; 13.4% and 6.4% of participants on B/F/TAF and CAR respectively had >5% weight gain
- Incident hypertension was 60/166 (51.7%) in the B/F/TAF arm and 46/100 (49.1%) on CAR
- Incident dyslipidemia was 69/207 (33.3%) on B/F/TAF and 58/218 (26.6%) on CAR

CONCLUSION

Switch to B/F/TAF was non-inferior, safe, and associated with less requirement for treatment modification due to declining kidney function compared to CAR in a population of older African adults

ACKNOWLEDGEMENT

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