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Switch to bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) among vulnerable HIV-infected individuals: evidence for long-term efficacy.

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Background

While multi-tablet antiretroviral (ARV) therapy combinations have proven effective historically, single tablet regimens (STRs) are associated with higher rates of sustained virological suppression and patient satisfaction. This is especially true of STRs including unboosted integrase strand transfer inhibitors (INSTIs) with an increased barrier to resistance, better tolerability, and fewer drug interactions. This may be particularly beneficial for marginalized patient populations, with challenges of decreased adherence (including unplanned treatment interruptions) and lower tolerance for side effects. We have previously demonstrated sustained virologic suppression over 18 months among 41/43 HIV-infected active injection drug users following a switch of prior ARV therapy to the STR bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) in the setting of prior transient viremia. We sought to evaluate whether this benefit would be maintained over an additional 24 months of follow-up.

Methods

The subjects in this study consisted of the 43 individuals from the inception cohort for this protocol, who had previously been switched to and been receiving B/F/TAF for 18 months. They remained enrolled in a multi-disciplinary program of care, with B/F/TAF provided with continued adherence support, including daily observed therapy if clinically indicated. If therapy was interrupted for any length of time (due to disengagement or for any other reason), B/F/TAF was reinitiated at the earliest possible time. The end point of this analysis is the rate of virologic suppression in the study cohort after an additional 24 months of follow up, for a total of 42 months after initiating B/F/TAF SVR therapy.

Results

Total 45 subjects were included in this analysis: median age 55 (34-66) years, 11% female, 20% indigenous, 37.8% men who have sex with men, and all participants were actively using drugs, with 91.1% using fentanyl. At 18 months of follow up, we noted median CD4 count 612 (range 26-1490, 95% CI: 508.1-717.3) cells/mm^3. Of the 45 subjects, 43 subjects in the analysis cohort remained available for follow-up to month 18. One subject discontinued therapy after week 4 due to intercurrent social and mental health issues, not associated with B/F/TAF. One individual left the province of British Columbia, with the last HIV viral load at week 12 being < 40 copies/ml plasma.

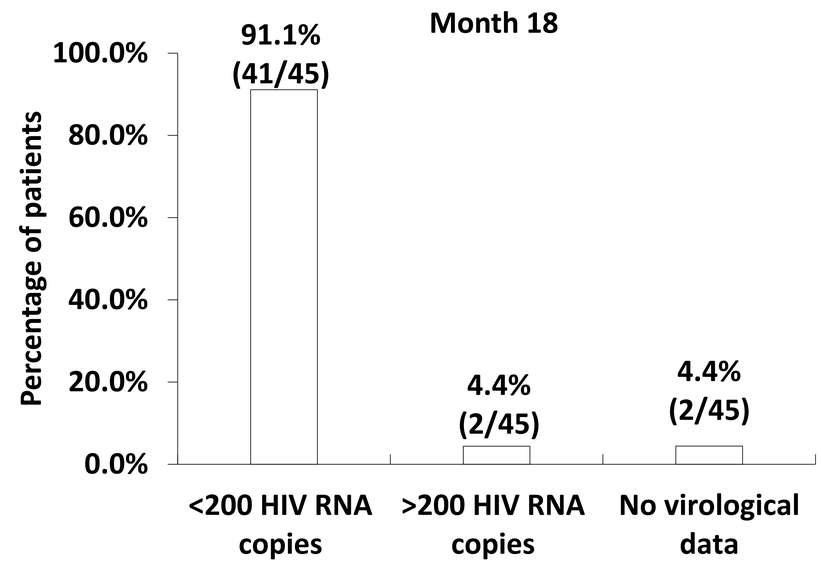
Characteristics	N=45 N (%)
Median Age (range)	55 (34-66)
Sex, n (%)	
Female	5 (11%)
Male	40 (88.9%)
Ethnicity, n (%)	
Caucasian	33 (73.3%)
Indigenous	9 (20%)
Other	3 (6.6%)
MSM, n (%)	17 (37.8%)
HIV-1 RNA <200 copies per ml, n (%)	42 (93.3%)
Median CD4 cell count (range)	620 (36-1490)
CD4+ Count, n (%)	
>200	5 (11.1%)
≥200-≤500	13 (28.8%)
≥500	27 (60%)
Drugs used, n (%)	
Opiates	41 (91.1%)
Amphetamines	16 (35.6%)
Cocaine	11 (24.4%)
Benzodiazepines	10 (22.2%)
Others (ketamine, MDMA, GHB)	5 (11.1%)

Characteristics	N=45 N (%)
Methods of Drug use, n (%)	
Injection	11 (24.4%)
Smoke	11 (24.4%))
Both	13 (28.9%)
Fentanyl Users, n (%)	41 (91.1%)
Median Age (range)	51 (34-63)
Male, n (%)	36 (87.8%)
Female, n (%)	5 (12.2%)
Opioid Agonist Therapy n (%)	25 (55.6%)
Median Age (range)	55 (34-66)
Male, n (%)	20 (80%)
Female, n (%)	5 (20%)
Primary resistance-associated mutations	
NRTI, n (%)	15 (33.3%)
NNRTI, n (%)	14 (31.1%)
PI, n (%)	3 (6.7%)
HIV-HCV co-infection, n (%)	8 (17.8%)
HIV-HBV co-infection, n (%)	1 (2.2%)

Table 1. Baseline demographic and disease characteristics.

Results Continued

At 18 months of follow up, we noted virologic suppression in 41 cases, with 2 having measures of 5640 and 892 copies/mL. At month 42, all 43 patients remained in follow up, with no treatment discontinuations due to toxicity. 41/43 had viral loads of <200 HIV RNA copies, and both participants with detectable HIV RNA at month 18 had viral suppression at month 42. Two cases of >200 HIV RNA (1520 & 3000 copies/mL) were documented at month 42, following therapeutic interruptions. In both cases, virologic suppression was achieved after resumption of B/F/TAF.



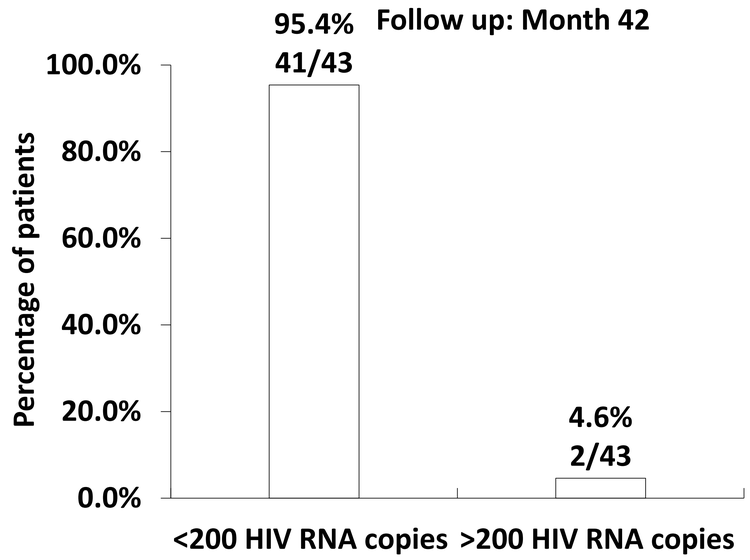


Figure 1. HIV Virological outcomes on month 18 (top) and month 42 (bottom).

Conclusion

Among a group HIV-infected injection drug users experiencing transient viremia, switching to B/F/TAF remains effective in the long-term. Its efficacy (even in the setting of its resumption after extended treatment interruptions) and its tolerability make it a particularly useful therapeutic option in this vulnerable population.

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