Bictegravir Use for Perinatally Acquired HIV as Second-Line Therapy

853

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Bictegravir/emtricitabine/tenofovir alafenamide showed high efficacy and tolerability in a real-world, treatment-experienced, perinatally acquired HIV cohort despite extensive prior drug resistance mutations.

BACKGROUND

- People with perinatally acquired HIV (PWPHIV) often have prior exposure to a wide range of antiretroviral therapy (ART) from birth.
- Higher rates of virological failure in PWPHIV when compared to adults may lead to the development of drug resistance mutations (DRMs), including to integrase inhibitors (INSTI).[1,2]
- Bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) is a once-daily, single tablet regimen licensed for individuals weighing ≥14kg.
- Real-world data on second-line use of B/F/TAF in perinatal HIV (PHIV) is limited.
- **We assessed efficacy, tolerability and safety of second-line B/F/TAF use in a PHIV cohort.**

METHODS

- Retrospective cohort study of all PWPHIV attending a tertiary service at Imperial College Healthcare NHS Trust in London, United Kingdom, who had ever received B/F/TAF as subsequent-line therapy, up to 31st August 2025.
- Only PWPHIV with prior virological failure on a previous regimen, prompting ART switch, were included. Virological failure was defined as a confirmed viral load (VL) >200c/mL.
- Duration on B/F/TAF was calculated from the individual's start date until discontinuation/switch to another ART, or 31 August 2025, whichever occurred first.
- **Two groups were identified at B/F/TAF switch: those with prior virological failure but currently suppressed (<200c/ml) and those with detectable viraemia.**
- **Past ART regimens, VL & CD4 count, side effects and DRMs were recorded pre- and post-B/F/TAF switch.**

RESULTS

Characteristic	Total cohort (n=93)
Age in years, median (IQR, range)	26 (22-30, 5-36)
Female, n (%)	55 (59)
Black ethnicity, n (%)	80 (86)
Virologically suppressed at switch to B/F/TAF, n (%)	51 (55)
Past ART regimens, median (IQR)	5 (3-6)
Duration on B/F/TAF (months), median (IQR)	35 (17-40)
Past drug resistance mutations, n (%)	34 (67)
INSTI	0
NRTI	3 (9)
NNRTI	10 (29)
NRTI+NNRTI	21 (62)
Emergent drug resistance mutations on B/F/TAF, n (%)	0
Viraemic at switch to B/F/TAF, n (%)	42 (45)
Viral load at switch (c/mL), median (IQR)	19900 (1180-71350)
Past ART regimens, median (IQR)	4 (3-5)
Duration on B/F/TAF (months), median (IQR)	34 (20-49)
Past drug resistance mutations, n (%)	27 (64)
INSTI	1 (4)
NRTI	3 (11)
NNRTI	13 (48)
NRTI+NNRTI	7 (26)
NRTI+NNRTI+PI	3 (11)
Emergent drug resistance mutations on B/F/TAF, n (%)	5 (5)
INSTI	1 (20)
NRTI	3 (60)
INSTI+NRTI	1 (20)
Discontinued B/F/TAF, n (%)	15 (16)
Due to INSTI DRMs	3 (20)
Preference for long-acting injectable ART	2 (13)
Side effects	10 (67)
Mood/sleep disturbance	4 (40)
Weight gain	2 (20)
Rash	1 (10)
Tinnitus	1 (10)
Migraine	1 (10)
Vomiting	1 (10)

Table 1 Study population characteristics. IQR: interquartile range. B/F/TAF: bictegravir/emtricitabine/tenofovir alafenamide. ART: antiretroviral therapy. NRTI: nucleoside reverse transcriptase inhibitor. NNRTI: non-nucleoside reverse transcriptase inhibitor. INSTI: integrase strand transfer inhibitor. PI: protease inhibitor. DRM: drug resistance mutation.

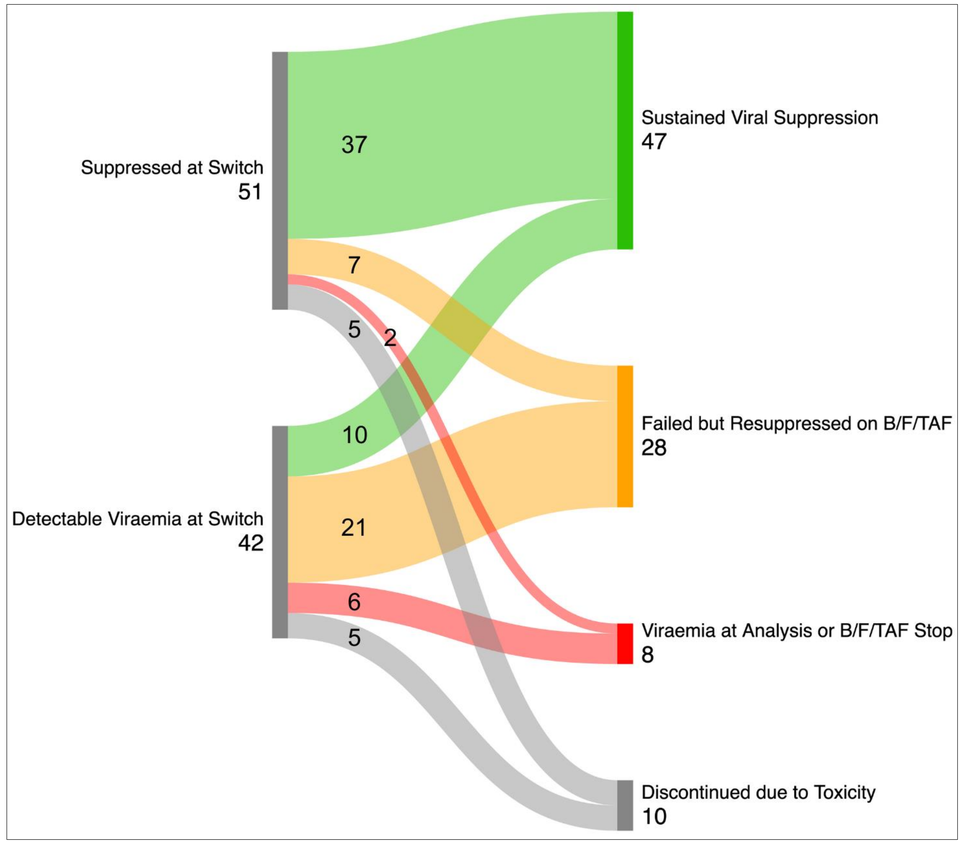


Figure 1 Virological outcomes following switch to B/F/TAF from prior ART regimen, measured at time of analysis or B/F/TAF discontinuation. Viral suppression defined as VL <200c/mL.

CONCLUSION

- As the search for a cure for HIV continues, access to antiretroviral therapy that is safe, tolerable, and effective remains a critical part of long-term management.
- In this cohort of people living with perinatal HIV, B/F/TAF as second/subsequent line therapy demonstrated high efficacy, safety, and tolerability, with low rates of discontinuation and emergent resistance.
- **Despite extensive prior DRMs, 76% achieved or sustained virological suppression, while emergent DRMs (5%) and discontinuations due to toxicity (11%) were rare.**
- Further data is needed to better understand outcomes of B/F/TAF use in special populations including in children and in pregnant individuals.

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