The safety and efficacy of the use of Biktarvy (bictegravir, emtricitabine and tenofovir alafenamide) with boosted Darunavir in clinical practice

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Background

- Biktarvy is indicated for use as a complete regimen not to be taken with any other antiretroviral.
- Bictegravir is a metabolite of CYP3A4 and tenofovir alafenamide is a substrate of p-glycoprotein. Coadministration of darunavir boosted with the inhibitors cobicistat or ritonavir is expected to increase bictegravir AUC by 74% and increase tenofovir AUC and Cmax by 105% and 142%, respectively.
- The aim is to evaluate the indications, safety and efficacy for switching to Biktarvy with boosted darunavir.

Method

- A retrospective cohort analysis of people switched to Biktarvy with boosted darunavir were reviewed using electronic medical records.
- A collaboration was formed between GSTT and Lewisham and Greenwich hospital.

Results

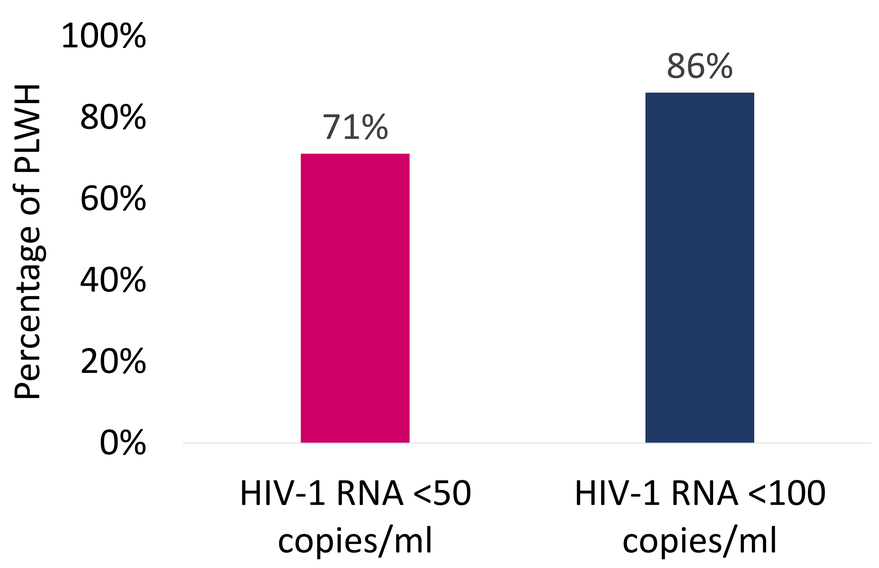
- 7 people were identified on Biktarvy with boosted darunavir.
- All were treatment experienced living with HIV for a median of 21 years. All having greater than 5 (5-20) previous ART switches.
- All people had previous resistance with major mutations; 7 with NRTI, 4 with NNRTI and 4 with PI.
- There were no discontinuations or reported ADRs and no biochemical changes to indicate toxicities.
- People developed a median weight gain of 1kg (1-14kg).

Table 1: Baseline characteristics	N=7
Sex, n (%)	Male: 5 (71%) Female: 2 (29%)
Median age, years	49
Ethnicity - Black (Caribbean, African, other) - Chinese	 86% 14%
Mean Nadir CD4 (cells/µL)	357
Mean baseline viral load (copies/ml)	1,079,565
Median length of exposure on boosted Biktarvy	1 year
Mean CD4 count at time switch (cells/µL)	573

- 6 (86%) people had a viral load below 100copies/ml at week 24 of which 4 people were detectable before switching (Figure 1).
- The remaining person that had a detectable VL post switch it was documented that this was adherence driven.

Table 2: ART and reason for intensification	
Reason for ART intensification	
Resistance/ virological failure	4
Simplification/ adherence	3
Increased cardiovascular risk	2
CNS disturbance	2
Drug-drug interactions	1
TDF tubulopathy	1
Glycosuria	1
ART regimen	
Biktarvy/ DRV 800mg OD/ RTV 100mg OD	3
Biktarvy/ DRV 600mg BD/ RTV 100mg BD	2
Biktarvy/ Rezolsta (Darunavir800mg/cobicistat 150mg)	2

Figure 1: Virological outcomes at week 24



Conclusion

- All people tolerated Biktarvy with boosted darunavir with no reported side effects or discontinuations. All people either maintained or achieved virological suppression.
- The findings are limited by small numbers and short follow up time.
- The fixed dosing formulation of Biktarvy restricts the dose modification of tenofovir alafenamide with boosted darunavir.