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Evaluating the Efficacy of Crushed Bictegravir/Tenofovir Alafenamide/Emtricitabine Administered via Tube

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Background

- Oral ingestion may be impractical for hospitalized individuals requiring enteral feeding, resulting in administration of crushed or dissolved bictegravir/tenofovir alafenamide/emtricitabine (BIC/TAF/FTC)
- Limited clinical evidence exists regarding the efficacy of crushed or dissolved BIC/TAF/FTC and no clarity around this in the manufacturer label
- A crossover trial evaluating the bioavailability of dissolved and crushed single tablets of BIC/TAF/FTC showed dissolved BIC/TAF/FTC is preferred over crushed tablets in adults unable to swallow tablet whole[1]

OBJECTIVE: Determine whether administering crushed or dissolved BIC/TAF/FTC maintains viral suppression in persons living with HIV

Methods

- Multicenter retrospective chart review from Massachusetts General Hospital and Brigham and Women's Hospital
- Inpatient administration data was extracted based on the enteral route of administration (e.g., G-tube, J-tube) to identify patients who received crushed/dissolved BIC/TAF/FTC from December 2016 to December 2023
- Individuals were included if they received at least 7 days of crushed or dissolved BIC/TAF/FTC and had a viral load (VL) within 1 year of treatment
- Data analyzed utilizing descriptive statistics

Figure 1. Enrollment

54 patients evaluated

35 Excluded

22 Received less than 7 days of crushed/dissolved BIC/TAF/FTC

13 Had no VL within 1 year of follow-up

19 patients included in analysis

Endpoints

Primary Endpoint

Continued or achieved viral suppression (<200 copies/mL) following 7 days of crushed/dissolved BIC/TAF/FTC within 1 year follow-up

Secondary Endpoints

Change in ART during hospital admission

Development of resistance within 1 year follow-up

Results

After at least one week of crushed/dissolved BIC/TAF/FTC, 89% of adults were virally suppressed and in care within one year. Further therapeutic drug monitoring efforts are needed to evaluate efficacy of long-term use of crushed/dissolved BIC/TAF/FTC.

Figure 2. HIV Viral Loads Over Time Following Initiation of Crushed BIC/TAF/FTC

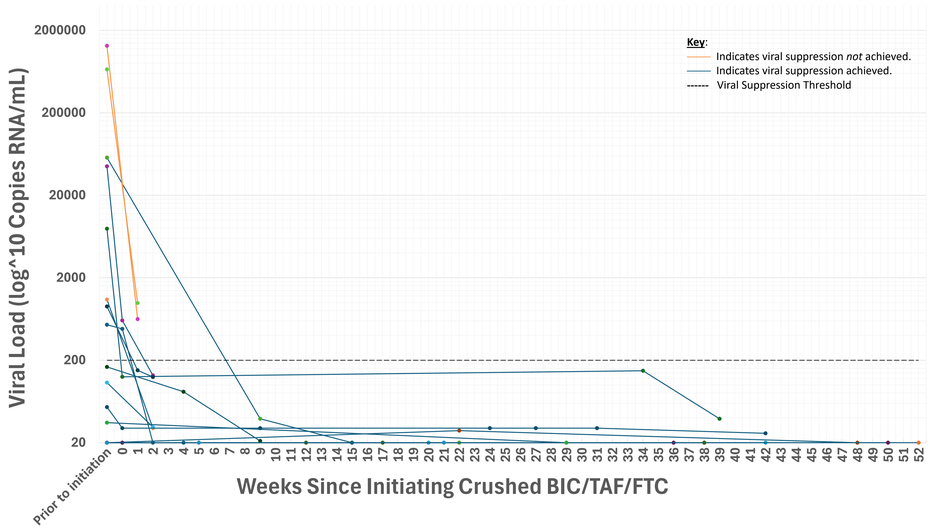


Table 1. Study population characteristics

Characteristic	Total Cohort (N=19)
Age (years), median (IQR)	54 (47.5, 66.5)
Male, n (%)	16 (84)
Virally suppressed or undetectable prior to start, n (%)	11 (58)
Resistance prior to crushed/dissolved BIC/TAF/FTC, n (%)	8 (42)
INSTI, n (%)	0 (0)
NRTI, n (%)	5 (26)
NNRTI, n (%)	4 (21)
PI, n (%)	4 (21)
Duration of crushed/dissolved BIC/TAF/FTC, median days (IQR)	19 (7.5, 64)
Intensive care unit admission during hospitalization, n (%)	16 (84)
Intubation as reason for enteral tube, n (%)	14 (74)
Crushed BIC/TAF/FTC for administration, n (%)	8 (42)
Dissolved BIC/TAF/FTC for administration, n (%)	2 (11)
Adults with at least 1 missed dose, n (%)	6 (32)

Table 2. Outcomes of crushed/dissolved BIC/TAF/FTC

Characteristic	Total Cohort (N=19)
Virally suppressed within 1 year, n (%)	17 (89)
Remained undetectable, n (%)	11 (58)
Achieved viral suppression, n (%)	6 (31)
Therapy change during admittance, n (%)	2 (11)
Development of resistance within 1 year, n (%)	0 (0)
Crushed/dissolved BIC/TAF/FTC continued after discharge, n (%)	3 (16)

Table 3. Mortality

Characteristic	n=8
Death during treatment, n	8
HIV-related cause, n (%)	2 (25)
Infection-related cause, n (%)	5 (63)
Other/unknown**,** n (%)	1 (12)
Comorbid conditions contributing to death n (%)	6 (75)

Conclusion

- 89% of participants were virally suppressed and within care at 1 year
  - All participants who did not meet the primary end point were either lost to care or deceased
- In individuals who were not virally suppressed at the initiation of crushed/dissolved BIC/TAF/FTC, significant reductions in VL were observed
- While there were eight deaths in the analyzed cohort, 75% of patients were in critical care settings and had comorbid conditions which contributed to death
- Providing dissolved (preferred) or crushed BIC/TAF/FTC via enteral tube is a reasonable alternative to changing antiretroviral therapy

References

1. Hocqueloux L, Lefeuvre S, Bois J, et al. Bioavailability of dissolved and crushed single tablets of bictegravir, emtricitabine, tenofovir alafenamide in healthy adults: the SOLUBIC randomized crossover study. J Antimicrob Chemother. 2022;78(1):161-168. doi:10.1093/jac/dkac369

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