Safety and Tolerability of Once Daily BIC/FTC/TAF for Post-Exposure Prophylaxis

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Background

- The use of antiretrovirals for post-exposure prophylaxis (PEP) is well-established, though completion rates with most regimens have been suboptimal because of pill burden or side effects.
- The purpose of the current study has been to evaluate the single tablet combination of Bictegravir (BIC), Emtricitabine (FTC), and Tenofovir Alafenamide (TAF) for PEP, administered orally as a single daily pill for 28 days after a high risk exposure.

Methods

- The analyses assessed the clinical experience of participants enrolled in a prospective clinical trial of open label BIC/FTC/TAF who were recruited through referrals in a Boston community health center specializing in HIV care, as well as via self-referral after a community education campaign.
- Eligible participants needed to present for PEP within 72 hours of a high risk exposure (per CDC Guidelines) and be willing to consent to prospective monitoring over the subsequent 3 month period.
- SAS® 9.4 was used to analyze data, with statistical significance determined at the alpha 0.05 level. Chi square tests were conducted to assess if BIC/FTC/TAF differed with respect to side effects and completion rates compared to historical PEP regimens.

Sociodemographic Profile of BIC/FTC/TAF Users (N=48)

Age	Median 32 (range 22-71)	
Race;/Ethnicity	White	79.2%
	Black/African American	4.2%
	Mixed	12.4%
	Asian/Pacific Islander	4.2%
	LatinX	8.3%
Sexual Orientation/Gender Identity	Gay/Cisgender (CG) Male	75.0%
	Bisexual/CG Male	12.5%
	Heterosexual/CG Male	4.2%
	Heterosexual/CGFemale	4.2%
	Queer/Transgender Male	2.1%
	Don't Know/CG Male	2.1%
Educational Status	Graduate School	35.4%
	College Graduate	35.4%
	Some College	22.9%
	High School or Equivalent	6.3%

Results

- Of 48 enrollees, the median age was 32 years (range: 22-71), with 79.2% being white, and 8.3% Latinx
- Most (87.5%) were cisgender gay or bisexual men.
- Most (70.8%) completed college +/- advanced degrees.
- Behaviors that led to PEP initiation included: receptive anal (49.7%), insertive anal (43.6%), receptive oral (15.4%), and insertive or receptive vaginal sex (7.7% for each).
- The most commonly reported adverse events by PEP patients using BIC/FTC/TAF were nausea +/- vomiting (15.0%), fatigue (6.0%), and diarrhea (6.0%).
- One participant noted mild gastrointestinal discomfort and another reported flatulence. All but one of the symptoms were grade 1, and only one symptom (grade 2 fatigue) was associated with product discontinuation.
- The only lab abnormalities were noted in 2 participants with elevated transaminases and 1 with decreased creatinine clearance. These changes did not lead to product discontinuation, reverting to normal after the regimen was completed.
- Of the fully evaluable participants, 85.4% completed the regimen as prescribed, and 10.4% stopped or modified the regimen; 2 did not return for follow-up.
- No HIV seroconversions have been detected in the study.
- Compared to historical PEP regimens, BIC/FTC/TAF was significantly less likely to cause product-related symptoms, notably less likely to be associated with diarrhea, fatigue, and headaches than the Quad Pill.

Regimen completion rates among BIC/FTC/TAF users versus those using other PEP regimens, Fenway Health, Boston, 2000–2020.

	AZT/3TC/PI (N = 119) %	TDF/FTC+RAL (N = 100) %	EVG/c/FTC/TDF (N= 100) %	BIC/FTC/TAF (N = 48) %
Completed as Prescribed	38.8 ****	57.0***	71.0 ^	85.4
Stopped or Modified	14.0	28.0**	15.0	10.4
Lost to Follow-Up	47.3****	15.0 (15)^	14.0	4.2

BIC/FTC/TAF = referent group
AZT/3TC/PI = Zidovudine/Lamivudine/Protease Inhibitor
TDF/FTC+RAL = Tenofovir disoproxil fumarate coformulated with emtricitabine plus raltegravir bid
EVG/c/FTC/TDF = tenofovir disoproxil fumarate, emtricitabine, elvitegravir, cobicistat coformulated

****p = 0.0001
***p = 0.001
**p = 0.01
*p = 0.02
^p = 0.05

Most commonly reported adverse events among BIC/FTC/TAF PEP users versus those using other PEP regimens, Fenway Health, Boston, 2000–2020.

	AZT/3TC/PI (N = 119) %	TDF/FTC+RAL (N = 100) %	EVG/c/FTC/TDF (N= 100) %	BIC/FTC/TAF (N = 48) %
Recruited	Jan 2000 – May 2004	Mar 2008 – Mar 2010	May 2013 – Nov 2015	May 2018 – Dec 2019
Diarrhea	58.8****	21.0 *	38.0****	6.0
Fatigue	48.5****	14.0	28.0***	6.0
Nausea/vomiting	58.8****	27.0	28.0	15.0
Headache	11.8***	15.0****	14.0****	0.0
Dizziness/Lightheadedness	8.4**	10.0 **	6.0*	0.0
Body/Muscle/Joint Pain or Aches and/or Overall Discomfort	10.9	8.0	2.0	2.0

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Conclusions

- This was the first evaluation of single tablet combination of BIC and TAF when used in combination with FTC for PEP.
- This regimen was safe and well-tolerated when used as PEP, with occasional mild gastrointestinal side effects and fatigue, and limited, reversible lab abnormalities.
- Daily BIC/FTC/TAF for PEP compares very favorably with historical regimens, including other integrase strand transfer inhibitors.
- The excellent safety profile and the high completion rates suggest that BIC/FTC/TAF should be considered for use as PEP.

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