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P 3
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Effectiveness and safety of tenofovir alafenamide/emtricitabine/bictegravir as first line regimen in people with HIV: a retrospective observational study

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Background

- Integrase based regimens are recommended by international guidelines as first line options for people with HIV (PWH).
- Tenofovir alafenamide/emtricitabine/bictegravir (TAF/FTC/BIC) is a single tablet regimen which has demonstrated high genetic barrier to resistance and a good safety profile in randomized clinical trials.
- We aimed to assess the durability and safety of TAF/FTC/BIC in newly diagnosed PWH and reasons for discontinuation in a non-experimental context.

Study Design

- We conducted a single center retrospective observational study including all PWH with a new HIV diagnosis between 1st August 2019 and 7th February 2024 at the Infectious Disease Department (Luigi Sacco Hospital, Milan, Italy).
- Subjects included have been followed until TAF/FTC/BIC interruption, death, administrative censoring or 25th March 2024 whichever occurred first.
- Reasons for TAF/FTC/BIC interruption were collected and categorized as simplification, death, drug to drug interaction, toxicity, pregnancy, virological failure and enrolment in a randomized clinical trial.
- Durability of TAF/FTC/BIC was estimated by means of Kaplan Meier curves and durability according to biological sex and CD4 cell count (< vs >350 cell/mm3) was assessed by means of log rank test.

Results

During the study period 236 PWH started TAF/FTC/BIC as first line regimen with a median time of observation of 13 (IQR 4-27) months. Most PWH were cis male (178/236, 75.4%), 21 (8.9%) were transgender women and the remaining 37 (15.7%) were cis female with a median age at diagnosis of 37 years (IQR 29-48) (Table 1). The main mode of HIV acquisition was with male-to-male sexual contact (107/236, 45.3%) followed by heterosexual contact (71/236, 30.1%). The median CD4 cell count at diagnosis was 302 cell/mm3 (IQR 117-467). Ninety (38.1%) individuals presented with a CD4 cell count <200 cell/mm3, 64 (27.1%) with an AIDS defining condition and 30 (12.7%) with an HIV-RNA >500,000 cp/mL. Fifty-three individuals (22.5%) interrupted TAF/FTC/BIC during the study period: 34 (14.4%) simplification, 9 toxicities (3.4%), 4 (1.7%) clinical trial enrolment, 2 (0.8%) died, 1 (0.4%) pregnancy, 1 (0.4%) virological failure and 2 (0.8%) for other reasons (Figure 1). The estimated durability of TAF/FTC/BIC at 12 and 24 months was 84.8% (95%CI 78.6%-89.3%) and 75.5% (95%CI 67.6%-82.6%), respectively (Figure 2). No significant difference in terms of durability was observed according to biological sex (p=0.285) and CD4 cell count strata (p=0.973).

Table 1: Characteristics of the study population.

Characteristics of study population		Overall (n=236)	TAF/FTC/BIC continuation (n=183)	TAF/FTC/BIC interruption (n=53)
Male sex at birth, n (%)		199 (84.3)	152 (83.1)	47 (88.7)
Age at diagnosis, median years (IQR)		37 (29-48)	38 (29-48)	37 (30-46)
Mode of HIV acquisition, n (%)	MSM	128 (45.3)	98 (42.6)	30 (54.7)
	HE	71 (30.1)	54 (29.5)	17 (32.1)
	IDU	7 (3.0)	5 (2.7)	2 (3.8)
	NR	30 (12.7)	26 (14.2)	4 (7.5)
Ethnicity, n (%)	Caucasian	151 (64.0)	109 (59.6)	42 (79.2)
	African	15 (6.4)	13 (7.1)	2 (3.8)
	Hispanic	65 (27.5)	57 (31.1)	8 (15.1)
	Asian	5 (2.1)	4 (2.2)	1 (1.9)
AIDS-defining condition, n (%)		64 (27.1)	44 (24.0)	20 (37.7)
HIV-RNA > 500.000 cp/mL at ART start, n (%)		30 (12.7)	23 (12.6)	7 (13.2)
CD4 < 350/mmc at ART start, n (%)		126 (53.4)	97 (53.0)	29 (54.7)
Co-infections, n (%)	HCV-Ab +	14 (5.9)	11 (6.0)	3 (5.7)
	HBsAg +	6 (2.5)	6 (3.3)	0 (0.0)

Figure 1: Reasons for TAF/FTC/BIC interruption

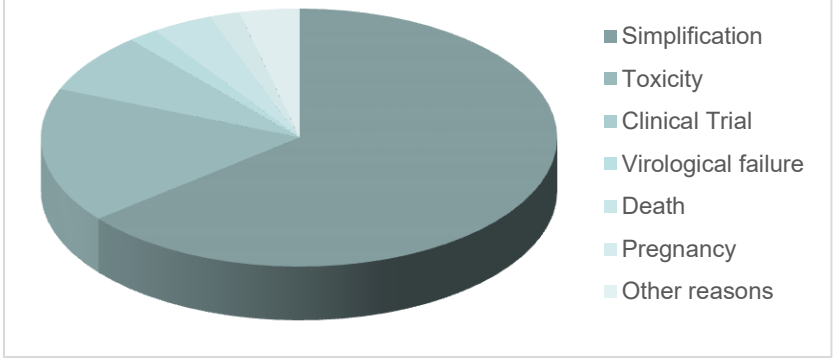
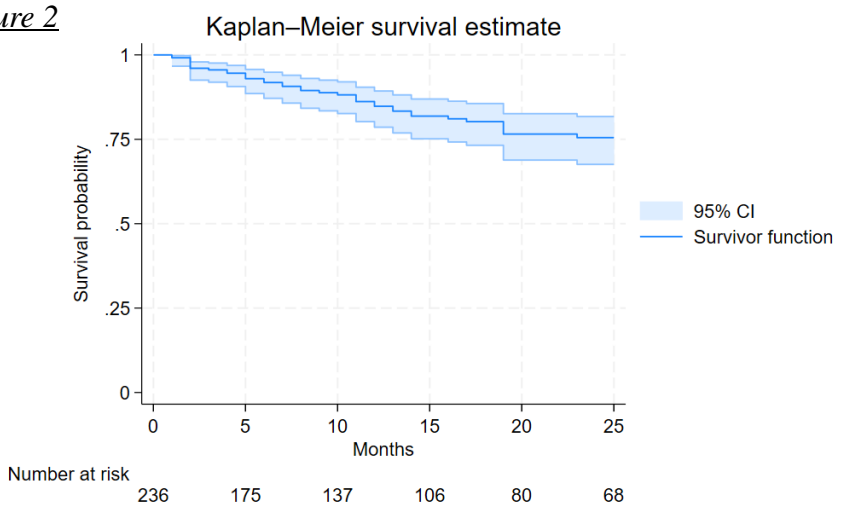


Figure 2



Conclusions

- In our cohort of newly diagnosed PWH TAF/FTC/BIC showed a good durability up to 75% after 2 years since the treatment start.
- Few interruptions appeared to be related to drug toxicities and a low rate of virological failure was observed although the high proportion of PWH who presented late or with an AIDS defining condition.

References

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