COVERAGE AND DISCONTINUATION OF LONG-ACTING CABOTEGRAVIR vs ORAL PREP IN THE ITALIAN PrIDE COHORT

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BACKGROUND

PrEP with oral tenofovir disoproxil fumarate/emtricitabine (F/TDF) may be frequently discontinued or poorly adhered to. Long-acting cabotegravir (CAB-LA) may overcome adherence challenges and enhance prevention coverage. Evidence from European real-world settings is lacking.

METHODS

All PrEP users (PrU) enrolled in the PrIDE cohort from December 2024 (date of CAB availability) to August 15, 2025 (date of cut) were included.

PrEP coverage was defined as the proportion of days covered (PDC) after the first injection or refill over the follow-up and was compared between the CAB-LA and F/TDF groups using the Wilcoxon rank sum test. Predictors of poor coverage (defined as >4 weeks delay from target CAB injection and <4 pills/week for F/TDF) were assessed by a multivariable logistic regression. Incidence rates (IR) per 100 person-years (PY) of discontinuation (defined as lost for >180 days or definitive interruption) were compared across groups using a Poisson test. The 1-year probability of discontinuation was assessed by Kaplan-Meier.

Table 1. Main characteristics of study population

Variable	Overall N = 2852 (100%)[1]	Oral N = 2403 (84%)[1]	Long acting N = 449 (16%)[1]	p-value[2]
Sex at birth				**<0.001**
Male	2,808 (98.5%)	2,375 (98.8%)	433 (96.4%)	
Female	44 (1.5%)	28 (1.2%)	16 (3.6%)	
Age (years)	38.0 (32.0, 46.0)	38.0 (32.0, 46.0)	39.0 (33.0, 47.0)	**0,036**
Place of birth				**0,045**
Italy	2,483 (87.1%)	2,079 (86.5%)	404 (90.0%)	
Abroad	369 (12.9%)	324 (13.5%)	45 (10.0%)	
Education level				**<0.001**
Middle school or less	102 (3.6%)	85 (3.5%)	17 (3.8%)	
High school	822 (28.8%)	677 (28.2%)	145 (32.3%)	
University	1,899 (66.6%)	1,633 (68.0%)	266 (59.2%)	
Unknown	29 (1.0%)	8 (0.3%)	21 (4.7%)	
Gender identity				0,58
Cisgender	2,776 (97.3%)	2,338 (97.3%)	438 (97.6%)	
Transgender	51 (1.8%)	42 (1.7%)	9 (2.0%)	
Non binary	25 (0.9%)	23 (1.0%)	2 (0.4%)	
Sexual orientation				**0,034**
GBMSM	2,782 (97.5%)	2,350 (97.8%)	432 (96.2%)	
Bisexual Female	19 (0.7%)	12 (0.5%)	7 (1.6%)	
Heterosexual	51 (1.8%)	41 (1.7%)	10 (2.2%)	
Setting				**<0.001**
Hospital based	2,008 (70.4%)	1,564 (65.1%)	444 (98.9%)	
Community-based	844 (29.6%)	839 (34.9%)	5 (1.1%)	
HIRI-MSM score (categories)				**<0.001**
<10	474 (16.6%)	427 (17.8%)	47 (10.5%)	
10+	2,378 (83.4%)	1,976 (82.2%)	402 (89.5%)	
PrEP naive				<0.001
No	1,797 (63.0%)	1,440 (59.9%)	357 (79.5%)	
Yes	1,055 (37.0%)	963 (40.1%)	92 (20.5%)	

[1] n (%); Median (Q1, Q3)
[2] Pearson's Chi-squared test; Wilcoxon rank sum test; Fisher's exact test

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RESULTS

Of the 2,852 PrU included, 16% (449) were on CAB: most were Italian (87%), cis-MSM (97%), and 47% aged 29-40. PrEP naïve were 40% in oral and 20% in LA PrU, respectively (Table 1). The median PDC was higher in the LA group compared to the oral group (Figure 1A). In the latter, the risk of poor coverage was 2.71 (95%IC 0.98-6.25) in transgender/non-binary vs. cisgender people (p=0.037) and 0.49 (0.29-0.80) in community vs. hospital-based settings (p=0.006). The low number of CAB events precludes powered analysis. Overall, 95.7% of injections were administered on time (Figure 2).

FIGURE 1. Proportion of days covered (PDC) by PrEP drug for oral and Long-acting injectable PrEP.

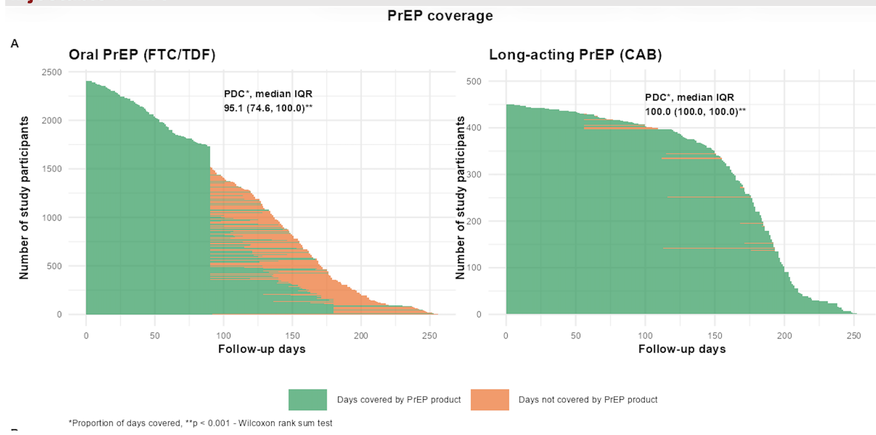
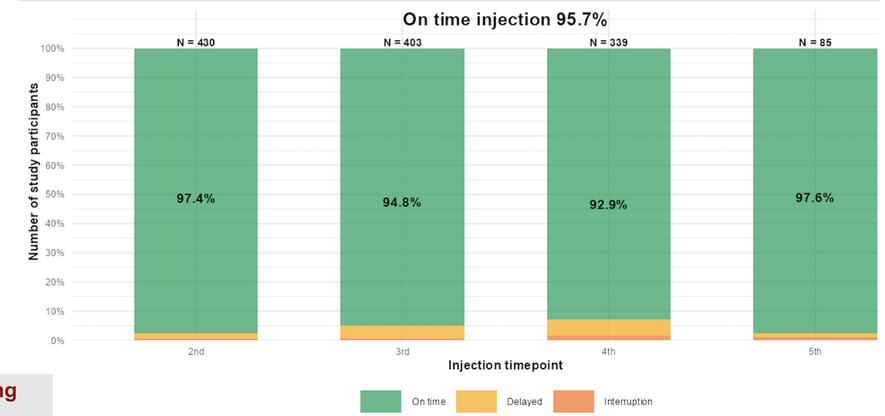


FIGURE 2. Adherence to the injection schedule for LAI PrEP users.

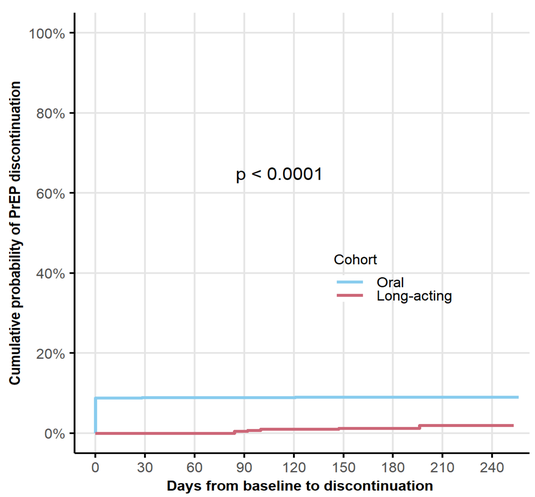


Among the 6 CAB interruptions (1 for allergic reaction, 2 for reduction in risk perception, 2 for side effects, and 1 for logistic issues), 5 switched to F/TDF. Median follow-up time was 123 days (52-164) for oral and 179 (154-197) for CAB-LA (p<0.001). The IR for PrEP discontinuation was higher in the oral [29.27/100PY (25.49-33.45)] than in the CAB group [2.89 (1.06-6.29)] (p<0.001).

The 1-year probability of discontinuation was 9% (7.8-10.1) for oral and 2% (0.2-3.8) for LAI (Figure 3).

No seroconversions were observed.

FIGURE 3. Kaplan-Meier for the 1-year probability of discontinuation of oral vs LAI PrEP.



CONCLUSIONS

In the Italian experience of the PrIDE cohort, cabotegravir provides higher coverage and a lower discontinuation rate compared to oral PrEP. Our data confirm that cabotegravir can address adherence and persistence challenges associated with oral PrEP, also in real-life settings.

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PLAIN LANGUAGE SUMMARY

In the Italian PrIDE cohort, long-acting cabotegravir injections showed more consistent PrEP coverage and fewer discontinuations than daily oral PrEP.