

board Test (GPT) and Pictorial Fit-Frailty Scale (PFFS). Data are shown as numbers (percentage) or median (IQR).

Results All participants [median age 58 (51-64) years] were on antiretroviral treatment with HIV RNA <50 copies/mL. We recorded a long HIV duration [14.3 (4.2-19.5) years] and high CD4 count [537 (400-774) cells/mm³]. Comorbidities were common, including dyslipidemia (40.0%), hypertension (37.8%), anxiety/depression disorders (24.4%), and diabetes (17.8%). Moderate/severe depressive symptoms were reported by 7 (BDI-II ≥20, 6.5%) participants while moderate/severe anxiety by 30 (HAMA ≥18, 27.7%). We observed poor sleep quality (PSQI ≥5) and low quality of life (EQ-5D-5L <90%) in 52 (54.2%) and 83 (84.7%) individuals. Low cognitive performance (MACE ≤23) and impaired fine motor function (non dominant hand GPT ≥2SD) were recorded in 23 (21.3%) and 29 (29.6%) study participants. PFFS frailty index was 0.16 (0.09-0.20) and identified 19 (17.6%) and 10 (9.3%) as moderately or severely frail: the domains mostly reported as abnormal were polypharmacy (36, 37.9%), social connections (26, 26.8%), and fatigue (13, 13.4%). Frailty index was associated with sleep quality (rho=0.413, p<0.001), depressive symptoms (rho=0.596, p<0.001), anxiety (rho=0.577, p<0.001), and quality of life (rho=-0.505, p<0.001).

Conclusions In optimally treated PWH with durable virological control, the PFFS identifies individuals at increased risk of multidimensional impairment and worse patient-reported outcomes, including depression, anxiety, sleep disturbance, reduced quality of life. The PFFS may represent a practical first-line screening tool to flag patients warranting comprehensive geriatric or multidisciplinary assessment.

Antiretroviral therapy

P20

B/F/TAF VS DTG: SIMILAR DURABILITY, DIFFERENT REASONS FOR DISCONTINUATION. RESULTS OF A REAL-LIFE STUDY

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10.1136/sextrans-ICAR-2026.115

Abstract P20 Table 1 Main characteristics of 2359 PWH enrolled in the Bictegravir and Dolutegravir SCOLTA cohorts

	Bictegravir N=1002		Dolutegravir-2DR N=595		Dolutegravir-3DR N=762		P
	N	%	N	%	N	%	
Age, years (mean, SD)	48.1	12.6	49.3	12.5	46.5	12.0	0.0002
Males	760	75.8	447	75.1	581	76.2	0.89
Caucasian ethnicity	866	86.4	538	90.4	680	89.2	0.03
Risk factor for HIV acquisition							<0.0001
Past IDU	129	12.9	77	12.9	124	16.3	
Sexual	692	69.1	474	79.7	538	70.6	
Other	181	18.1	44	7.4	100	13.1	
Status							<0.0001
Experienced	589	58.8	457	76.8	384	50.4	
Switch from first line	134	13.4	68	11.4	99	13.0	
Naive	279	27.8	70	11.8	279	36.6	
HCV positive (141 missing)	153	15.3	86	14.5	158	20.7	0.005
CDC stage (56 missing)							<0.0001
A	504	50.3	377	63.4	379	49.7	
B	241	24.1	127	21.3	201	26.4	
C	208	20.8	84	14.1	182	23.9	
Detectable HIVRNA (1731 experienced)	117	16.2	49	9.3	89	18.4	<0.0001
CD4 count, cell/mm ³ (median, IQR)	522	317-782	690	483-901	482	249-759	<0.0001
Previous regimen (1731 experienced)							
NNRTI	60	8.3	184	35.0	169	35.0	<0.0001
PI	113	15.8	202	38.5	221	45.8	<0.0001
INSTI	503	69.5	199	37.9	77	15.9	<0.0001
Hypertension	209	20.9	126	21.2	118	15.5	0.007
Diabetes	59	5.9	28	4.7	34	4.5	0.35
Dyslipidaemia	193	19.2	121	20.3	105	13.8	0.002
ART treatment duration (1801 experienced), years (median, IQR)	8.5	3.5-16.9	10.5	5.5-18.1	9.1	4.0-16.8	0.003

ART: antiretroviral treatment; HCV: hepatitis C virus; IDU: intravenous drug use; INSTI: integrase strand transfer inhibitor; IQR: interquartile range; NNRTI: non-nucleoside reverse transcriptase inhibitor; PI: protease inhibitor; PWH: people with HIV; SD: standard deviation.

Abstract P20 Table 2 Reasons for 568 discontinuations

	Bictegravir N=1002		Dolutegravir-2DR N=595		Dolutegravir-3DR N=762		DTG-2DR aHR (95% CI)	p	DTG-3DR aHR (95% CI)	p
	N	%	N	%	N	%				
Overall	199	19.9	113	19.0	254	33.3	0.86 (0.68-1.10)	0.23	1.17 (0.97-1.42)	0.10
<i>Competitive model</i>										
Adverse event	37	18.6	29	25.7	85	33.2	1.35 (0.83-2.25)	0.21	3.10 (2.09-4.60)	<0.0001
Simplification	53	26.6	9	8.0	72	28.1	0.26 (0.13-0.54)	0.0003	1.13 (0.78-1.62)	0.52
Switch to long acting	27	13.6	27	23.9	1	0.4	1.35 (0.78-2.35)	0.29	0.03 (0.00-0.23)	0.0007
Treatment failure	6	3.0	3	2.6	11	4.3	n.e.	>0.20	n.e.	>0.20
Death	6	3.0	4	3.5	14	5.5	n.e.	>0.20	n.e.	>0.20
Other	18	9.0	13	11.5	28	10.9	n.e.	>0.20	n.e.	>0.20
Lost to follow-up	52	26.1	28	24.8	45	17.6	0.82 (0.52-1.32)	0.42	0.68 (0.45-1.03)	0.07

Background Nowadays, the INSTI-based regimens with bictegravir (BIC) and dolutegravir (DTG) represent the cornerstone of antiretroviral treatment (ART). Our study aimed to investigate the durability of bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) and DTG-based regimens and their safety in a real-life setting.

Methods Consecutive people with HIV (PWH) enrolled in the SCOLTA project who either initiated their first ART with, or switched to a regimen containing BIC or DTG combination were included. DTG-based regimens comprised 2-drug regimens (2DR) with atazanavir, darunavir, rilpivirine or lamivudine (3TC) and 3-drug regimens (3DR) with 3TC/abacavir, F/TAF or F/TDF. PWH were followed up until treatment discontinuation and grade 3-4 adverse events (AE) were recorded. The observation was truncated to 48 months. Hazard ratios (HRs) and 95% confidence intervals (CIs) for discontinuation were estimated using the Cox proportional hazards model. A multivariate model including all variables that differed significantly between treatment groups or were associated with treatment interruptions was run, with a retention criterion set at $p=0.20$. A competitive model was also performed for each cause of discontinuation.

Results Of 2668 enrolled PWH, 2359 were treated with one of the included regimens and had at least one follow-up visit: 1002 in B/F/TAF (42.3%), 595 (25.2%) in DTG-2DR and 762 (32.3%) in DTG-3DR regimens. In the DTG-2DR group, the most represented regimens were DTG/3TC (382, 64.2%) and DTG/RPV (134, 22.6%); in the DTG-3DR group, it was DTG/3TC/ABC (445, 58.4%). The baseline characteristics are reported in table 1.

Forty-eight months after the study started, 199 (19.8%), 113 (19.0%) and 256 (33.6%) respectively discontinued the cohort treatment (reference B/F/TAF: HR 0.86, 95% CI 0.68-1.10 for DTG-2DR, HR 1.18, 95% CI 0.98-1.43 for DTG-3DR). In the multivariate model for any cause discontinuation (including sex, CD4, risk factor for HIV acquisition, CDC stage, naïve status, HIVRNA at T0, dyslipidemia and current ART regimen), higher CD4 at T0 were associated with lower risk. In contrast, female sex, past intravenous drug use, naïve status and entering the study with previous ART treatment but detectable HIVRNA were associated with higher risk of discontinuation.

In the competitive model, no difference emerged between treatment in the risk of discontinuation due to switch to LA, treatment failure, loss to follow-up or death. On the contrary, risk was higher in the DTG-3DR group (aHR 3.17, 95% CI 2.13-4.70) when discontinuation was due to AEs and lower in the DTG-2DR group when due to simplification (aHR 0.26, 95% CI 0.13-0.54) (table 2).

Conclusions In our cohort, a similar durability and safety profile was observed for BIC and DTG. Discontinuations due to adverse events were more frequent in the DTG-3DR group.

These findings highlight that regimen composition may influence treatment interruptions beyond the choice of INSTI.

P27 DURABILITY AND REASONS FOR DISCONTINUATION OF LONG-ACTING CABOTEGRAVIR/RILPIVIRINE IN VIROLOGICALLY SUPPRESSED ADULTS WITH HIV: A MULTICENTER REAL-WORLD EXPERIENCE IN TUSCANY (LAHIV)

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10.1136/sextrans-ICAR-2026.116

Background Long-acting cabotegravir plus rilpivirine (CAB+RPV) is the first intramuscular antiretroviral regimen approved for maintenance of HIV-1 virological suppression. Real-world data on durability and reasons for discontinuation are still limited.

Methods This multicenter observational study included adults with HIV-RNA <50 copies/mL from 11 centres in Tuscany, Italy, including academic and non-academic institutions, reflecting a regional real-life setting. Participants were followed from the first CAB+RPV injection until treatment discontinuation, death, or last visit. Discontinuation (TD) was defined as regimen switch or two consecutive missed injections and was prospectively recorded, then classified a posteriori as virological failure (VF), toxicity/adverse reactions, patient-related reasons, or medical decisions. VF was defined as two consecutive HIV-RNA >50 copies/mL or a single HIV-RNA >1000 copies/mL. Kaplan-Meier analyses estimated treatment durability.

Results We included 244 participants, contributing 330.3 person-years of follow-up (median 1.5 years, IQR 0.6-2.1). Median age was 51.3 years (IQR 44-57), 79.9% were male (table 1). Twenty-seven participants (11.7%) discontinued CAB+RPV, corresponding to a TD rate of 8.1 per 100 py (95% CI 5.6-11.9). Median time to TD was 42 weeks (95% CI: 14-72).