

## Safety and efficacy of switching people with HIV to dual treatment with 3TC/DTG and RPV/DTG in real life: results from the SCOLTA cohort

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### Background

After the publication of big randomized clinical trials (SWORD, TANGO, ASPIRE), between 2017 and 2018, lamivudine (3TC) +dolutegravir (DTG) and rilpivirine (RPV)+DTG were included among the recommended regimens for switching strategies in virologically suppressed PWH. However, real-life data regarding these two strategies are still scarce. Therefore, we aimed to describe our real-life cohort's characteristics to better understand the profile of people who started these DTG-based dual-regimens.

### Materials and Methods

We analysed data from SCOLTA (Surveillance Cohort Long-Term Toxicity Antiretrovirals) prospective database, including all experienced people with HIV who started treatment with 3TC/DTG or RPV/DTG. Demographical data, risk factors for HIV infection, viro-immunological data, and reasons for treatment interruption were collected.

### Results

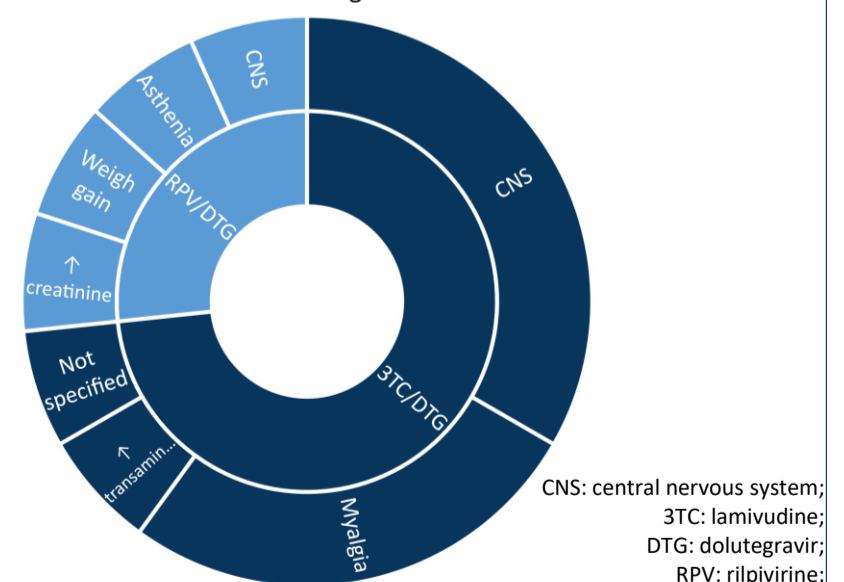
- ✓ We included 359 people, of which 265 (73.8%) were treated with 3TC/DTG and 94 (36.2%) were treated with RPV/DTG. There was no difference in age and gender between the two groups, while there was a difference in HIV risk factors, with a higher percentage of people injecting drugs in the RPV/DTG group. Also, patients treated with RPV/DTG had a longer HIV history than 3TC/DTG (9.9 vs. 13.2 years,  $p=0.0015$ ).
- ✓ Not all patients who started dual regimens had an undetectable HIV-RNA; indeed, 17 (4.7%) did not.
- ✓ Most people treated with RPV/DTG were previously treated with a NNRTI regimen (48.9%). General characteristics are summarized in Table 1.
- ✓ During follow-up, 203 people up to 208 treated with 3TC/DTG kept an undetectable HIV-RNA (97.6%), while 78 up to 84 (92.8%); in RPV/DTG group; regarding people who had a detectable HIV-RNA at baseline, 8/11 (72.7%) treated with 3TC/DTG achieved a stable undetectable HIV-RNA, vs. 4/5 (80%) treated with RPV/DTG.
- ✓ Regarding the interruption during the first two years, 31 (8.6%) people interrupted the treatment, of which 22 were in 3TC/DTG and 9 in RPV/DTG group, without statistical significant difference. Most common causes of interruption were adverse events (13, 3.62%) (Figure 1) and loss to follow-up (6, 1.67%).

**Table 1.** Characteristics of 359 people with HIV from an Italian cohort switching to a dual DTG-based regimen

	3TC/DTG (265)	RPV/DTG (94)	Overall (359)	p-value
Age, mean ( $\pm$ SD)	50.31 $\pm$ 11.76	52.18 $\pm$ 11.6	50.80 $\pm$ 11.73	0.1835
Female Gender, n(%)	53 (20.0)	29 (30.1)	82 (22.8)	0.0313
Ethnicity				0.3521
Caucasian	245 (92.5)	84 (89.4)	329 (91.6)	
Other	20 (7.5)	10 (10.6)	30 (8.4)	
Risk factors				0.0209
Other	21 (7.9)	8 (8.5)	29 (8.1)	
Sexual	219 (82.6)	67 (71.3)	286 (79.7)	
Intravenous drug use	25 (9.4)	19 (20.2)	44 (12.3)	
HIV-RNA (baseline)				0.7564
Undetectable	253 (95.5)	89 (94.7)	342 (95.3)	
Detectable	12 (4.5)	5 (5.3)	17 (4.7)	
Previous regimens				
PI	92 (34.7)	32 (34.0)	124 (34.5)	0.906
NNRTI	75 (28.3)	46 (48.9)	121 (33.7)	0.0003
INSTI	80 (30.2)	22 (23.4)	102 (28.4)	0.2102
BMI>30 (Kg/m <sup>2</sup> )	25.18 (3.69)	24.32 (3.84)	24.92 (3.75)	0.0744
CD4 count (cells/mm <sup>3</sup> )	781.4 (359.8)	720.7 (304.2)	765 (346.2)	0.1469
CD4/CD8	1.09 (0.61)	0.97 (0.61)	1.05 (0.61)	0.1319
HDL (mg/dl)	50.08 (15.07)	55.54 (16.82)	51.54 (15.72)	0.004
Total cholesterol (mg/dl)	197.2 (41.16)	200.6 (42.82)	198.14 (41.58)	0.4981
Glicemia (mg/dl)	91.7 (15.54)	94.4 (94.45)	92.43 (17.48)	0.1946
Weight (baseline), Kg	75.3 (13.72)	70.07 (13.21)	73.99 (13.77)	0.0017
Triglyceride (mg/dl)	116 (87.5-163)	115 (83-154)	116 (87-162)	0.5650
Years on ART	9.9 (5.4-14.9)	13.2 (7.1-20.6)	10.4 (5.8-16.8)	0.0015

3TC: lamivudine; DTG: dolutegravir; RPV: rilpivirine; PI: protease inhibitors; NNRTI: Non Nucleoside Reverse Transcriptase Inhibitor; INSTI: Integrase strand transfer inhibitors; BMI: body-mass index; HDL: high density lipoprotein; ART: anti-retroviral treatment

**Figure 1.** Adverse events reported by 13 people with HIV who interrupted a dual DTG-based regimen



### Conclusions

Both treatments showed a high safety and efficacy in our cohort. RPV/DTG seemed to be preferred for people who came from an NNRTI-based regimen and for those with a longer HIV treatment history.