P059

96 WEEKS EFFECTIVENESS AND TOLERABILITY OF DTG+ 3TC IN NAIVE PATIENTS: The REDOLA study

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Background

DTG/3TC therapy is a preferred regimen for people living with HIV (PLHIV) in international guidelines, due to the efficacy observed in clinical trials. However, information in real-life cohorts is still scarce.

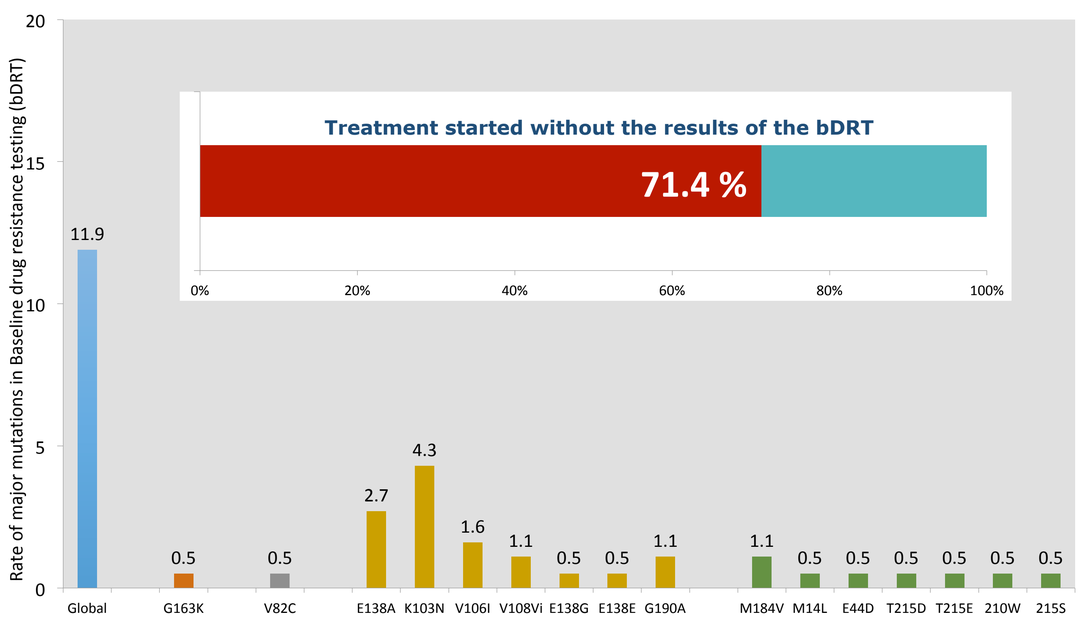
Materials and Methods

Multicenter retrospective and prospective cohort study of ART-naïve PLHIV starting DTG/3TC as first-line regimen before 31/March/2020. Confirmed virological failure (CVF): two consecutive plasma HIV-RNA≥50 c/mL. The study was funded by ViiV Healthcare.

Results

185 patients were included. Treatment was started without the results of the baseline drug resistance testing (bDRT) results in 71.4% of cases, which subsequently confirmed baseline resistance mutations in 22 patients (11.9%). Two of them needed to change ART due to the presence of M184V mutation.

Figure 1 y 2: Major mutations in Baseline drug resistance testing (bDRT)



Baseline characteristics		Patients (p) (N = 185)
Age (years) (median – IQR)		33 (27-41)
Gender	Male	168 (90.8%)
	Female	16 (8.7%)
	Transgender woman	1 (0.5%)
HIV transmission	MSM	156 (84.3%)
	MSW	26 (14.1%)
	IDU	3 (1.6%)
Country – region	Spain	94 (50.8%)
	Latinamerican	77 (41.6%)
	Europe	6 (3.3%)
	Others	7 (4.3%)
CD4 cells/mm^3 (median – IQR)	Basal CD4+	446 (342-608)
	CD4 < 200	10 (5.4%)
HIV-1 VL (c/mL)	≥ 100,000 c/mL	45 (24.3%)
	< 100,000 c/mL	140 (75.7%)
Hepatitis B co-infection	HBsAg +	0%
	Anti-HBc +	41 (22.2%)
	Anti-HBs +	121 (65.4%)
Hepatitis C co-infection (IgG HCV +)		8 (4.3%)
Median time from diagnosis to start of treatment (weeks)		6 (IQR: 2-12)

One patient had CVF at week 96 (79 and 365 c/mL) and continues DTG/3TC (third determination with <50 c/mL); no resistance-associated mutations (RAM) emerged. Eleven patients (5.9%) discontinued treatment: three due poor adherence, with a single HIV- RNA≥50 c/mL and no emerging resistance; three due to CNS side effects (1.6%); two after receiving bDRT (M184V mutation); one due to an extrapulmonar tuberculosis (IRIS) and another two to be included in a clinical trial. Finally, 18 patients (9.7%) were lost to follow-up. There were no significant changes in the lipid profile. The mean weight gain in a subgroup of patients (N=70) was 2.6 ± 5.6 kg

Figure 3: Results of Effectiveness Analysis: Virologic Outcomes at Week 96

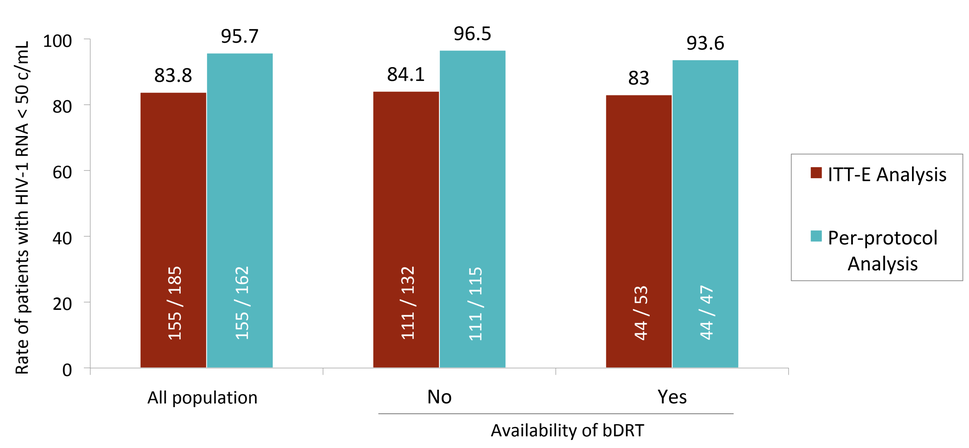
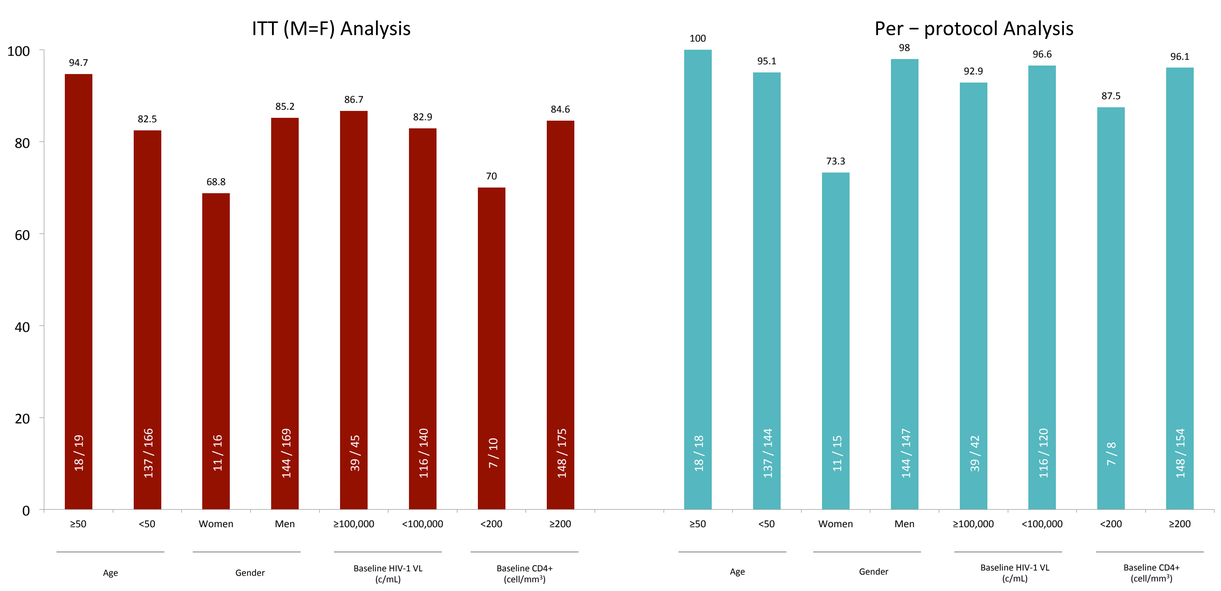


Figure 4: Results of Effectiveness Analysis: Stratified Analysis



Intention to treat (ITT-E) analysis: missed patients=failures
Per-protocol analysis: treatment-related discontinuations = failures

Table: Patients on DTG+3TC considered VF in ITT analysis

Nº	Snapshot criteria	Basal VL (c/mL)	HIV-1 RNA VL > 50 c/mL	Reason	Final ART
1	CVF[a]	102,000	w96 (79 c/mL)	CFV (Continued on DTG/3TC)	DTG/3TC (Actually VL < 50 c/mL)
1	Discontinued DTG/3TC*	779	w24 (409 c/mL)	Physician criteria (1 VL > 50 c/mL)	DTG/3TC
1	Discontinued DTG/3TC**	353,898	w72 (1,179 c/mL)	Stop treatment (1 VL > 50 c/mL)	DTG + ABC/3TC
1	Discontinued DTG/3TC**	135,800	w92 (36,153 c/mL)	Stop treatment (1 VL > 50 c/mL)	DRV/c/TAF/FTC
2	Per protocol	1,875 / 29,300	-	M184V	DRV/c/TAF/FTC; DTG/RPV
3	AE	142 / 219 / 1,696	-	CNS AE	RPV+TDF/FTC; DRV/c/TAF/FTC; RPV/TAF/FTC
2	Per protocol	209 / 15,400	-	Clinical trial	-
1	Other	16,100	-	TB infection	EFV/TDF/FTC
18	LTFU			LTFU	-

ITT: Intention-to-treat; ART: Antiretroviral treatment; VL: viral load; CNS AE: Central nervous system adverse event; CVF: confirmed virological failure. LTFU: Lost to follow-up.
aCVF: 79 c/mL at w-96. First repeated test: 365 c/mL. Second determination: < 50c/mL. Actually: < 50 c/mL (on DTG/3TC)
*Due to physician criteria (only one VL ≥ 200 c/mL but the patient stopped the treatment)
**Patients discontinued treatment for being out of country due to covid-19 pandemic

Conclusions

In a real-life multicenter cohort of ART-naïve PLHIV, treatment initiation with DTG/3TC, showed high effectiveness and tolerability, without treatment emergent resistance through 96 Weeks. Starting treatment without knowing results of the baseline drug resistance test did not have an impact on the effectiveness of the regimen.