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SHALL WE DANCE? EXTENDING TANGO'S RESULTS TO CLINICAL PRACTICE

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BACKGROUND

- Results from the TANGO study highlight the high efficacy and tolerability of lamivudine (3TC) and dolutegravir (DTG) as a switch strategy.
- However, trials' populations often differ from real-practice settings.
- We aimed to confirm the study's findings in our multicenter cohort

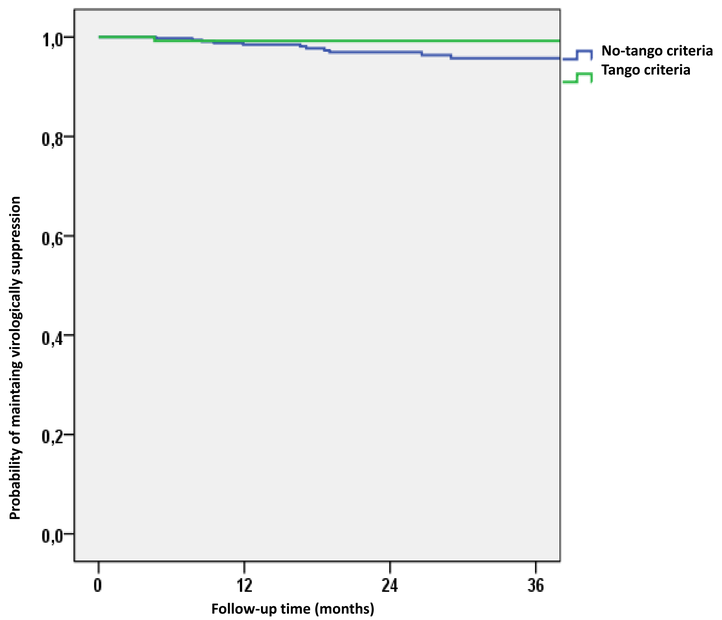
METHODS

- This was an observational study enrolling HIV-infected, virologically suppressed patients switching to 3TC+DTG, divided into 2 groups based on their adherence to the TANGO inclusion criteria.
- We collected patients' history, virological, immunological assessment at baseline, 48, 96 and 144 weeks.
- We performed Kaplan-Meier survival analysis to evaluate time to virological failure (VF, defined by 2 consecutive HIV-RNA determinations≥50 cps/mL or a single HIV-RNA≥1000 cps/mL) and treatment discontinuation (TD), Cox-regression to find predictors of VF or TD and linear mixed model for repeated measures to identify significant changes in immunological parameters.

RESULTS

- We analyzed 557 patients: 145 (26.0%) met the TANGO inclusion criteria (TANGO group, TG).
- During 248 PYFU in the TG and 776 PYFU in the non-TG, 1 and 11 VF occurred in the 2 groups respectively.
- The estimated probability of maintaining virological suppression was 99.2% (SD±1.6) at 48, 96 and 144 weeks in the TG, and 98.5% (SD±1.4) at 48 weeks, 97.7 (SD±1.8) at 96 weeks and 95.7% (SD±2.6) at 144 weeks in the non-TG (log-rank p=0.189).
- Respecting TANGO's criteria did not affect the risk of VF (aHR 0.35, 95%CI 0.04-2.84; p=0.327), even after adjusting for age, anti-HCV serostatus and HIV duration.
- Estimated probabilities of remaining on 3TC+DTG were 86.6% (SD±5.9) at week 48 and 79.5% (SD±7.5) at weeks 96 and 144 in the TG, and 85.8% (SD±3.5), 78.9% (SD±4.3) and 73.9% (SD±5.1) at weeks 48, 96 and 144 in the non-TG (log-rank p=0.654), with no significant increase in the hazard of TD for the TG after adjustment for age, gender, HIV risk factor, CD4 nadir, HIV duration and time on ARV. A significant increase in CD4 cell count (mean change at 96 weeks, +87 cell/µL in TG and +40 cell/µL in the non-TG) and CD4/CD8 ratio (mean change at 96 weeks, +0.05 in the TG and +0.07 in the other) was observed over time in both groups.

- Results from our multicenter study are in line with the results from the TANGO study.
- We found virological efficacy of 3TC+DTG also in the population that do not meet Tango inclusion criteria.



	TANGO group n=145	No-TANGO group n=412	P value
Age (years), Median (IQR)	49 (40-55)	53 (47-58)	**<0.001**
Male sex	111 (76.6)	281 (68.2)	**0.058**
Caucasian	128 (88.3)	389 (94.4)	**0.023**
Risk factor for HIV infection:			**<0.001**
- Heterosexual	56 (38.6)	169 (41.0)	
- MSM	37 (25.5)	108 (26.2)	
- IDU	15 (10.4)	86 (20.9)	
- Others/Unknown	37 (25.5)	49 (11.9)	
CDC C	20 (13.8)	62 (15.0)	0.854
Anti HCV positive	25 (17.2)	101 (24.5)	0.076
Zenith HIV-RNA (log_{10} copies/mL), median (IQR)	4.95 (4.45-5.35)	4.89 (4.37-5.43)	0.780
Nadir CD4+ cell count (cells/mm³), median (IQR)	278 (140-395)	212 (93-309)	**0.001**
HIV Subtype non-B	5 (3.4)	13 (3.2)	0.875
Years from HIV diagnosis, median (IQR)	9 (5-17)	18 (10-24)	**<0.001**
Years of ART exposure, median (IQR)	7 (3-12)	13 (8-19)	**<0.001**
Months on virologically suppression, median (IQR)	61.5 (31.5-103.1)	95.4 (51.5-126.9)	**<0.001**
CD4+ cells count at baseline (cells/mm³), median (IQR)	692 (453-912)	660 (500-876)	0.826
Previous virological failure	/	223 (54.1)	NA
Previous ART regimen:			**<0.001**
- 2NRTI + bPI	22 (15.2)	55 (13.3)	
- 2NRTI + NNRTI	87 (60.0)	55 (13.3)	
- 2NRTI + INI	32 (22.0)	57 (13.8)	
- Dual/Mono	4 (2.8)	220 (53.4)	
- Others	0 (0)	25 (6.2)	
M184V mutation at the last genotype	/	45 (10.9)	NA
Reason for switch to DTG+3TC:			**<0.001**
- Simplification/ proactive switch	49 (33.8)	106 (25.7)	
- Dyslipidemia	5 (3.4)	87 (21.1)	
- GI toxicity	13 (9.0)	31 (7.5)	
- Renal toxicity	13 (9.0)	18 (4.4)	
- Osteopenia/osteoporosis	20 (13.8)	7 (1.7)	
- Other toxicities	10 (6.8)	10 (2.4)	
- Drug-drug interaction	6 (4.1)	30 (7.3)	
- Others/Unknown	29 (20.1)	123 (29.9)	

CONCLUSIONS

Results from our multicenter study are in line with the results from the TANGO study and their applicability to everyday clinical practice.

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