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EFFECTIVENESS AND SAFETY OF DUAL THERAPY WITH CO-PACKED DTG AND 3TC COMPARED TO TRIPLE THERAPY IN CLINICAL PRACTICE IN ARGENTINA

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Background:

- Argentina approved a generic presentation of not co-formulated DTG 50 mg + 3TC 300 mg as a co-pack of 2 tablets for daily administration in 1 blister (ZEVUVIR L Pack®)
- This presentation is available in the public and private health sectors. There are no real-world data on its effectiveness and safety.
- We describe persistence, safety, and virologic suppression rates (VSR) at 6, 12, and 18 months of co-packed DTG + 3TC vs. DTG based triple therapy (with either XTC/TDF or 3TC/ABC) as switching strategies in clinical practice.

Material and Methods:

- Retrospective observational cohort study, period 10/2019-11/2023 in a reference HIV center in Argentina.
- We included experienced people living with HIV (PLWH) with virological suppression (viral load <50 copies/mL) who switched to DTG regimens

Results:

- Out of 599 PLWH, 245 (40.9%) switched to dual therapy (DT) with the co-pack and 354 (59.1%) to triple therapy (TT): 138 to 3TC/ABC and 197 to XTC/TDF.
- Baseline characteristics: 68% were men; TT group was younger (median 47 vs 50 years) and had a higher prevalence of previous virological failure (7.5 vs 0.8%). Selected variables are described in **Table 1**.
- Previous treatments were mainly based on first-generation NNRTIs (41%) and boosted PIs (37%).
- Main reasons for change differed between groups, with higher frequency of toxicity prevention in the co-pack group (24.9 vs 14%) and ongoing toxicity in TT group (35.5 vs 27%).
- Rates of persistence, viral suppression, adverse events and median weight and CD4T-cell count at 6, 12 and 18 months are shown in **Tables 2, 3 and 4**, respectively.
- Viral suppression rate is illustrated in **Figure 1**.

Table 1. Baseline characteristics of treatment experienced PLWH who switched to co-packed 3TC/DTG (dual therapy) vs. DTG-based triple therapy, Argentina.

	Overall, N = 599[1]	**Dual therapy (3TC-DTG)** N = 245[1]	**Triple therapy (DTG-based)** N = 354[1]	**p-value**[2]
Sex at birth, male	407/598 (68%)	159/244 (65%)	248/354 (70%)	0.2
Age at the start of DTG (years)	48 [40-56]	50 [40-57]	47 [40-54]	**0.035**
Presence of comorbidities:[3]	316/488 (65%)	137/209 (66%)	179/279 (64%)	0.8
Viral load <50 c/mL	599/599 (100%)	245/245 (100%)	354/354 (100%)	
CD4 T-cell count (cell/mm³)	651 [468-853]	658 [469-874]	650 [466-830]	0.6
AIDS-defining event[4]	11/590 (1.9%)	-	11/348 (3.2%)	**0.004**
Treatment				**0.029**
INSTI	110/599 (18%)	44/245 (18%)	66/354 (19%)	
NNRTI	245/599 (41%)	117/245 (48%)	128/354 (36%)	
Other	23/599 (3.8%)	8/245 (3.3%)	15/354 (4.2%)	
PI	221/599 (37%)	76/245 (31%)	145/354 (41%)	
Therapy type				**<0.001**
3TC	245/599 (41%)	245/245 (100%)	-	
3TC/ABC	138/599 (23%)	-	138/354 (39%)	
3TC/TDF or FTC/TDF	197/599 (33%)	-	197/354 (56%)	
FTC/TAF	12/599 (2.0%)	-	12/354 (3.4%)	
Other	7/599 (1.2%)	-	7/354 (2.0%)	

[1]n/N (%); Median [Q1-Q3]

[2]Pearson's Chi-squared test; Wilcoxon rank sum test; Fisher's exact test

[3]dyslipidemia: 190 (59.7%), hypertension: 89 (28%), obesity: 63 (19.8%), neuropsychiatric: 50 (15.7%), osteopenia-osteoporosis: 49 (15.4%), diabetes: 34 (10.7%), renal disorders: 31 (9. 7%), other cardiovascular (iam, peripheral cardiovascular disease): 31 (9.7%), gastrointestinal disorders: 28 (8.8%), asthma/epoc : 19 (6%), solid neoplasm: 19 (6%), blood dyscrasias: 15 (4.7%), autoimmune disease: 6 (1.9%), cirrhosis: 5 (1.6%)

[4]pneumocystis jiroveci pneumonia: 3 (27.3%), extrapulmonary tuberculosis: 3 (27.3%), pulmonary tuberculosis: 3 (27.3%), esophageal candidiasis: 2 (18.2%), kaposi's sarcoma: 2 (18.2%)

Table 2. Rates of persistence, viral suppression, adverse events and median weight and CD4T-cell count at 6-month follow up in experienced PLWH who switched to co-packed 3TC/DTG (dual therapy) vs. DTG-based triple therapy, Argentina.

	Dual therapy (3TC-DTG) N = 216[1]	**Triple therapy (DTG-based)** N = 339[1]	**OR [CI95%]**	**p-value**[2]
Persistence	212/214 (99%)	330/332 (99%)	0.64 [0.05-8.9]	0.6
Viral load <50 c/mL	188/190 (99%)	253/256 (99%)	0.90 [0.07-7.9]	>0.9
CD4 T-cell count (cell/mm³)	665 [470-840]	657 [509-818]		>0.9
Weight	79 [69-92]	72 [59-81]		**0.034**
Adverse events attributable to DTG?	1/213 (0.5%)	4/328 (1.2%)	0.38 [0.01-3.9]	0.7

[1]n/N (%); Median [Q1-Q3]

[2]Fisher's exact test; Wilcoxon rank sum test

Table 3. Rates of persistence, viral suppression, adverse events and median weight and CD4T-cell count at 12-month follow up in experienced PLWH who switched to co-packed 3TC/DTG (dual therapy) vs. DTG-based triple therapy, Argentina.

	Dual therapy (3TC-DTG) N = 169[1]	**Triple therapy (DTG-based)** N = 314[1]	**OR [CI95%]**	**p-value**[2]
Persistence	167/167 (100%)	300/308 (97%)	Inf [0.94-Inf]	0.055
Viral load <50 c/mL	151/154 (98%)	232/240 (97%)	0.58 [0.10-2.5]	0.5
CD4 T-cell count (cell/mm³)	674 [501-869]	629 [492-873]		0.5
Weight	76 [70-87]	74 [63-85]		0.4
Adverse events attributable to DTG?	0/167 (0%)	2/300 (0.7%)	0.00 [0.00-9.6]	0.5

[1]n/N (%); Median [Q1-Q3]

[2]Fisher's exact test; Wilcoxon rank sum test

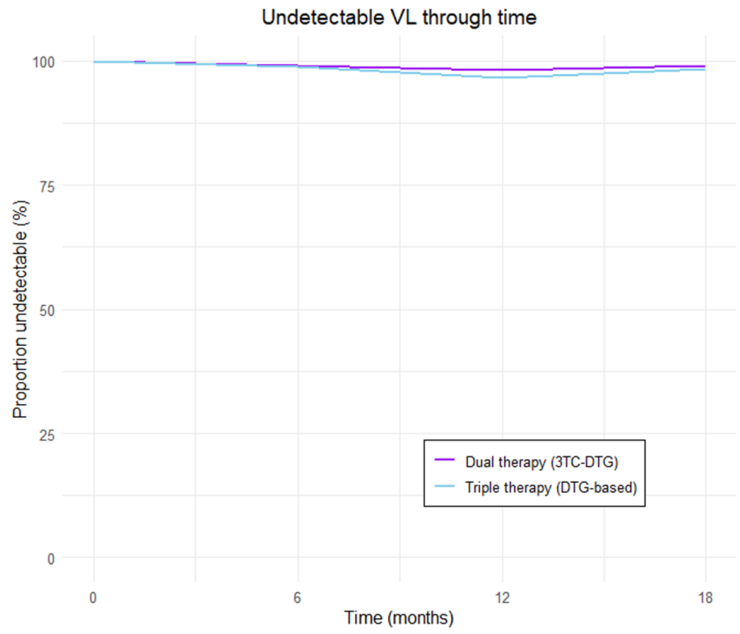
Table 4. Rates of persistence, viral suppression, adverse events and median weight and CD4T-cell count at 18-month follow up in experienced PLWH who switched to co-packed 3TC/DTG (dual therapy) vs. DTG-based triple therapy, Argentina.

	Dual therapy (3TC-DTG) N = 128[1]	**Triple therapy (DTG-based) N = 259**[1]	**OR [CI95%]**	**p-value**[2]
Persistence	122/125 (98%)	243/251 (97%)	1.3 [0.31-8.0]	>0.9
Viral load <50 c/mL	100/101 (99%)	177/180 (98%)	0.59 [0.01-7.5]	>0.9
CD4 T-cell count (cell/mm³)	642 [472-870]	649 [498-873]		0.6
Weight	76 [67-97]	76 [63-90]		0.6
Adverse events attributable to DTG?	1/121 (0.8%)	1/246 (0.4%)	2.0 [0.03-161]	0.6

[1]n/N (%); Median [Q1-Q3]

[2]Fisher's exact test; Wilcoxon rank sum test

Figure 1. Virologic suppression rate over time in in experienced PLWH who switched to co-packed 3TC/DTG (dual therapy) vs. DTG-based triple therapy, Argentina.



Conclusions:

- DTG + 3TC in a co-pack presentation provided high levels of persistence and VSR in clinical practice with a low rate of adverse events.
- Its effectiveness and safety were comparable to those of the available DTG-based triple regimens in Argentina.
- This study provides valuable real-world data specific to the Argentine context, which is essential for informing local treatment guidelines and health policies.