

EFFECTIVENESS AND SAFETY OF A DUAL THERAPY WITH BOOSTED DARUNAVIR AND DOLUTEGRAVIR IN PATIENTS WITH AN ADVANCED HIV INFECTION

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INTRODUCTION: The benefits of new antiretroviral drugs (ARV) allow treatment simplification and a reduction of potential toxicity associated to antiretroviral treatment (ART) in patients who have previously been exposed to many ART combinations and have a long-term, difficult-to-manage HIV infection.

OBJETIVES: To analyze the effectiveness, defined as the capability of the treatment to achieve a viral suppression with a viral load <50copies/mL, and safety, defined as the emergence of adverse events, of a dual therapy (DT) with dolutegravir plus boosted darunavir (DTG+bDRV) in these patients.

METHODS: These are the results of an observational, multi-center, restrospective study in HIV patients to analyze the effectiveness of DTG+bDRV after 24 weeks. Two analyses were carried out: "ITT-Snapshot" (proportion of patients with VL < 50 copies/mL at, or after, week 24 of all patients with complete follow up, including treatment discontinuations) and "Observed Data" (proportion of last VL < 50 copies/mL of all patients with any VL determinations after switch to DT).

RESULTS: Data from **109 patients of 6 spanish hospitals** were collected and analyzed. Patients had an average age of 50 years, a median CD4+ nadir of 76 cel/ μ L and 6 years of previous exposure to ART (*Table 1*). The main reason for switch was simplification/optimization (*Table 2*).

Table 1. Baseline characteristics

	N= 109
Age, years, mean	50
Gender, male, n (%)	75 (68.8%)
Time since HIV diagnosis, years, median (IQR)	21(12-24)
CD4 Nadir, median (IQR)	76 cel/μL (35-194)
History of AIDS, n (%)	61(56%)
Nº previous ART combinations, median (IQR)	6 (3-10)
Time on ART, years, median (IQR)	12 (5-20)
Previous ART included, n (%)	
NRTI	88 (80.7%)
NNRTI	72 (66.1%)
PI	95 (87.2%)
	76 (69.7%)
Baseline VL:	
< 50 copies/mL, n (%)	43 (39.4%)
>200copies/mL, n (%)	23 (21.1%)
Baseline CD4 count, median (IQR)	607 (365-854)

Table 2. Reason for switch

Simplification/Optimization, n (%)	67 (61.5%)
virological failure, n (%)	27 (23.9%)
Toxicity/Intolerance, n (%)	8 (7.3%)
Other, n (%)	7 (6.4%)

Figure 1. Results and patient disposition at 24 weeks

109 patients received

DTG+bDRV 29 patients discontinued study treatment due to: - 2 were lost to follow-up - 8 still have no VL determinations after the switch - 3 have discontinued the DT due to adverse events (1 insomnia and 2 digestive issues) - 12 haven't completed 24 weeks yet - 4 haven't come to the week 24 visit 81 patients continue on treatment at 24 weeks 5 patients have VL > 50 copies/mL at 24 weeks: - 2 achieved viral resuppression (VL<50) without switching from the DT - 3 were patients with evident poor treatment adherence, with no drug resistance mutations.

OBSERVED DATA ANALYSIS
93.8%

ITT-SNAPSHOT ANALYSIS
74.3%

76 patients have undetectable

VL (<50 copies/mL) at 24 weeks

CONCLUSIONS: This study shows that dual therapy with DTG+bDRV is an attractive alternative as a simplification/rescue strategy, presenting high virological effectiveness in patients with and advances and difficult-to-treat HIV infection.



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Figure 1. Results and patient disposition at 24 weeks

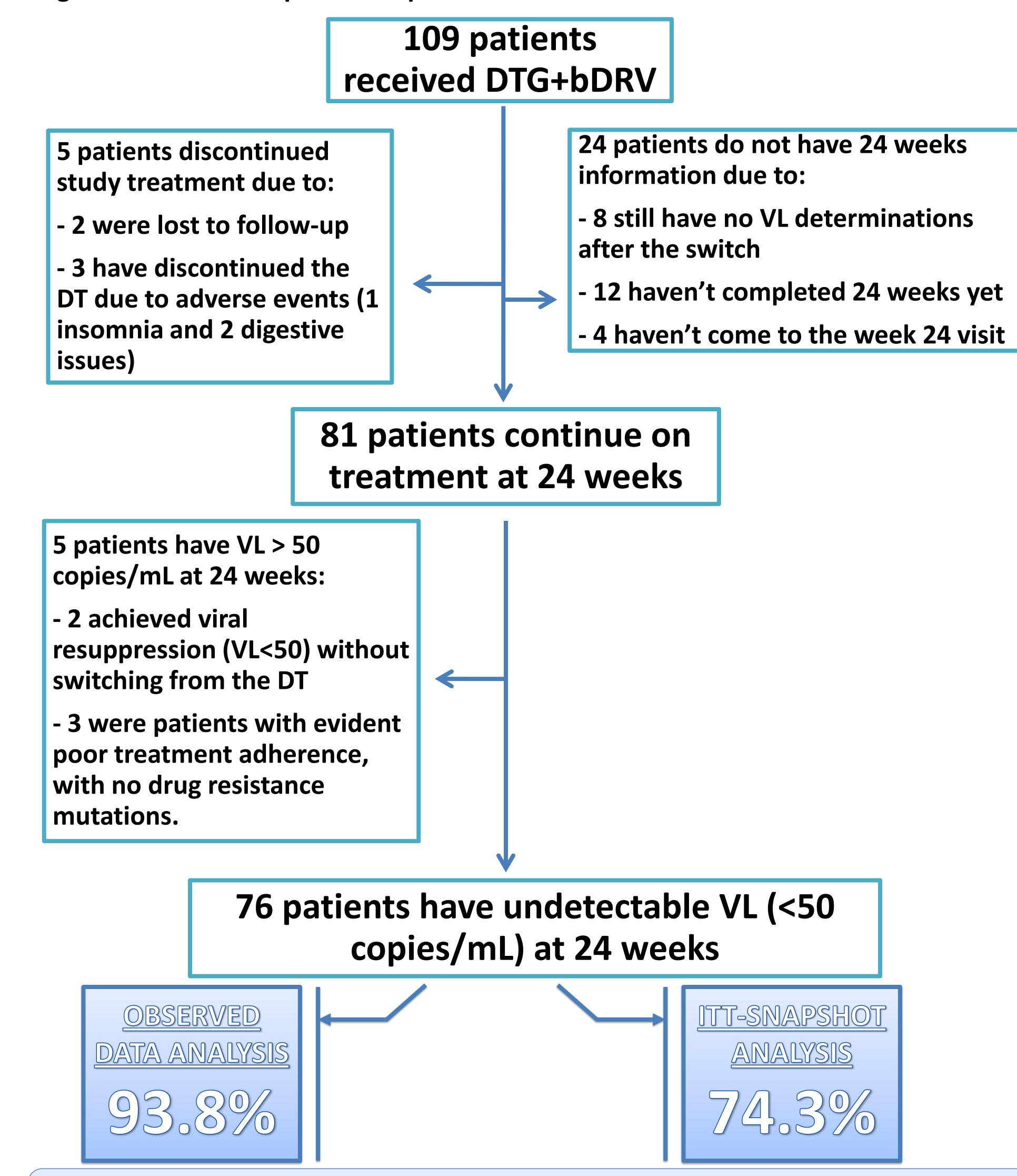


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