Antiretroviral therapy without nucleoside reverse transcriptase inhibitors:
Dual therapy with darunavir/p and rilpivirine. Safety and efficacy in clinical practice. RIDAR 2.0

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INTRODUCTION

The toxicity of conventional antiretroviral treatments (ART), coupled with aging and comorbidities in patients with HIV, have prompted the search for new strategies that do not involve the use of nucleoside analogues. One of the available options is dual therapy with darunavir/p (DRV/p) and rilpivirine (RIL). To date, no clinical trials have demonstrated the efficacy and safety of this combination, and the available evidence comes only from real-world data. The aim of this study was to evaluate the results of a 48-week course of DRV/p + RIL in clinical practice in Spain.

PATIENTS AND METHODS

This was a multicenter, retrospective, observational study conducted in 19 Spanish hospitals. All patients over 18 years of age who began dual therapy with DRV/p + RIL, whether for toxicity or to improve adherence, simplify treatment or prevent complications, between May 2012 and December 2017 were included in the study. Patients with active AIDS, hepatitis B, pregnant women, and those with mutations associated with DRV/p and RIL resistance were excluded. The following data were collected from patients' clinical records: sociodemographic data, HIV-related data (including history of prior treatments), reason for beginning dual therapy, CD4+ count, and viral load at 24 and 48 weeks after starting treatment. The statistical analysis was performed using the IBM SPSS package (version 22).

RESULTS

We included 301 patients; 76.1% were men, and median age was 49 (42-54) years. Viral load was undetectable in 81.4% of patients after 24 weeks of treatment and in 89.2% of patients with available information after 48 weeks of treatment.

Table1. *Baseline patient characteristics*

		N (%)
SEX	Men	229 (76.1)
	Women	72 (23.9)
AGE (YEARS)	Median (IQR)	49 (42-54)
YEARS SINCE DIAGNOSIS	Median (IQR)	14 (7-22)
STAGE	A	114 (49.4)
	B	50 (21.6)
	C	67 (29.0)
NUMBERS OF PREVIOUS TREATMENTS	1	37 (12.6)
	2	71 (24.2)
	3-5	112 (38.2)
	6 -8	55 (18.9)
	9 or more	18 (6.1)
BASELINE VIRAL LOAD	Undetectable	202 (68.3)
	50-1000 copies/ml	69 (23.3)
	>1000 copies/ml	25 (8.4)
BASELINE CD4+ (cells/µl)	Mean ± SD	651 ± 309
BASELINE CD4 (%)	Mean ± SD	27.8 ± 10.0
PREVIOUS ART	Nucleoside	268 (89.6)
	Non-nucleoside	224 (76.5)
	Unboosted protease inhibitors	60 (24.7)
	Boosted protease inhibitors	221 (81.3)
	Integrase inhibitors	36 (15.8)
	CCR5 antagonists	3 (1.4)
	Fusion inhibitors	4 (1.9)
PREVIOUS TREATMENT	Monotherapy	9 (3.0)
	Dual therapy	129 (43.1)
	Triple therapy	106 (35.5)
	Other options	55 (18.4)

RESULTS

Figure 1. *Study patient population*

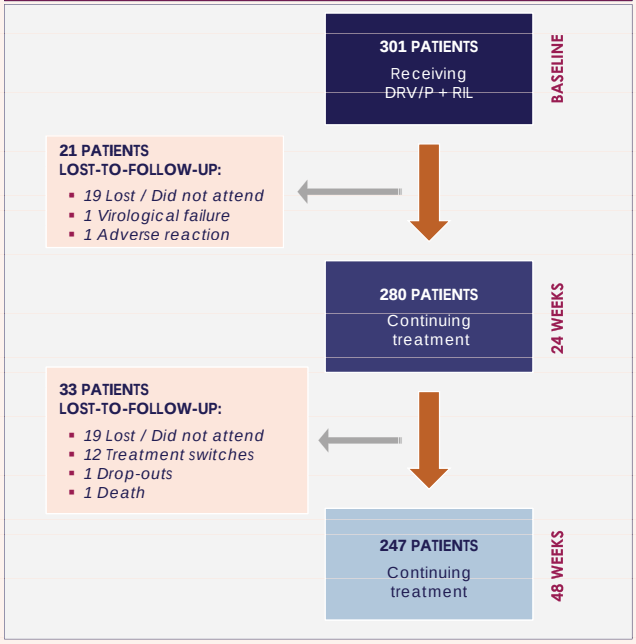

Figure 2. *Viral load of study patients*

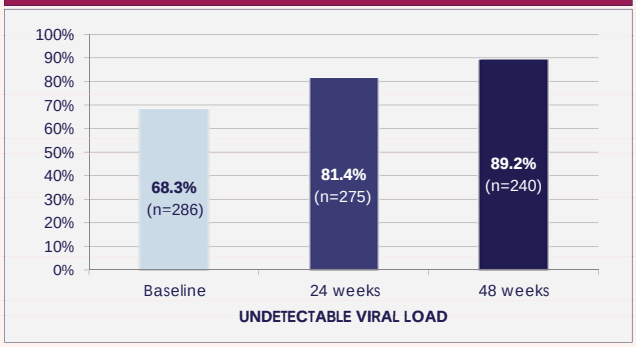

Table 2. *Reasons for starting dual therapy*

	N (%)
ADHERENCE	90 (29.9)
PREVENTION OF COMPLICATIONS	82 (27.1)
SIMPLIFICATION	109 (36.2)
TOXICTY	100 (33.2)

CONCLUSIONS

Dual therapy with DRV/p + RIL is a necessity in routine clinical practice and is highly effective and safe. It can therefore be considered as therapeutic option mainly in patients who do not tolerate the traditional analogues, or who have resistance mutations that rule out other more simple therapeutic strategies.