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Effectiveness and safety of HAART regimens containing tenofovir DF + saquinavir or fosamprenavir in HIV patients: sub-analysis from PROTECTION study

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Purpose of the study

The concomitant use of tenofovir DF (TDF) in combination with different protease inhibitors (PIs) has been widely investigated, especially in treatment-naïve patients. Although some data exist in treatment-experienced patients receiving TDF with the commonly used PIs, such as atazanavir or lopinavir, data from other TDF+PI combinations are lacking.

Methods

The PROTECTION cohort included retrospective data from 1,428 HIV patients treated with different TDF+PI combinations from 80 HIV clinics in Spain. We have performed a sub-analysis of those patients whose HAART regimens included at TDF in combinations including saquinavir (SQV) or fosamprenavir (FPV).

Summary of results

Tables 1 and 2.

The most prevalent adverse event was diarrhoea in the SQV cohort (11%) and hypertrigliceridaemia in the FPV cohort (4%). Only four patients (2%) withdrew their treatment due to an adverse event. One patient (0.5%) with baseline mild renal impairment (GFR: 63 mL/min) withdrew his treatment due to a grade 1 GFR decrease.

Conclusion

In this cohort, concomitant use of TDF with SQV or FPV was associated with good tolerability and an adequate rate of viral effectiveness, suggesting these combinations are suitable as rescue therapy in highly treatment-experienced patients.

Table 1: Baseline characteristics.

	FPV Cohort (n = 105)	SQV Cohort (n = 98)
% Male	74%	65%
Mean Age (years)	43	41
Primary HIV risk factor (%)	IVDU (53%)	IVDU (53%)
CDC C status (%)	44%	34%
Main reasons for TDF based regimen (%)	Virological failure (59%) Toxicity management (19%)	Virological failure (48%) Simplification (20%)
Previous time on ARV; Months. Median (IQR)	70 (21–111)	73 (34–111)
Most common acompanying NRTIs	3TC or FTC (36%) AZT or d4T (26%) ddI (11%)	3TC or FTC (65%) AZT or d4T (7%) ddI (13%)
Median BL HIV RNA, c/mL (log)	3.9	3.3
Mean BL CD4 count (cell/mm3)	335	387

BL = Baseline; ARV = antiretrovirals.

Table 2: Efficacy outcomes.

	FPV Cohort (n = 105)	SQV Cohort (n = 98)
% viral failure	22%	13%
Mean time of follow-up (months)	10.5	9.6
Mean CD4 count increase*	+84 cells/mm3	+12 cells/mm3

*In those subjects with 48 week data available (n = 36 and 26 for FPV and SQV cohorts, respectively).