



Abstract Category

7.5 - Treatment Simplification

PS4/2 - Use of twice daily darunavir as a substitution for dual boosted PIs in virologically suppressed patients: primary endpoint results of a pilot randomized clinical trial

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Background: Dual-boosted protease inhibitor (PI) containing regimens were historically used to achieve virologic suppression in PI-experienced HIV+ individuals. Darunavir (DRV/r) containing regimens can achieve suppression in a range of patients including those with a history of PI resistance. We performed a randomized pilot study of substituting darunavir as a single boosted PI in virologically suppressed patients taking any dual boosted PI regimen.

Methods: Twenty-four virologically suppressed (>12 weeks) subjects were randomized (1:1) to switch (n=12) to DRV/r 600 mg BID for 48 weeks or continue their dual boosted PIs for 24 weeks, with a cross over to DRV/r at week 24 for an additional 24 weeks. All had viral load and safety assessments, with treatment satisfaction questionnaires.

Results: Demographics were similar in both groups. Baseline dual PIs were: ATV/SQV/r (6), ATV/LPV/r (7), SQV/LPV/r (7), FPV/LPV/r (3), NLF/SQV/r (1). Virologic suppression was maintained in both groups through 24 weeks. A few virologic "blips" were noted but no virologic failure was seen in either arm through week 24. There were no grade 3 or 4 adverse events. There were favorable trends in some lipid fractions: Triglycerides: Switch arm: 206 mg % +/- 208 at BL to 176 +/- 156 wk 24; Control 252 +/- 290 to 252 +/- 262 wk 24. There was a favorable trend on a validated Likert scale of treatment preference for the switch arm assessing the new vs. prior regimen: the score was +2.6 (scale -3 to +3) comparing week 4 to baseline. The mean wholesale cost savings (US\$) for ARVs was \$217 +/-201 per patient per month.

Conclusions: These pilot data suggest that DRV/r can be substituted for some dual boosted PIs with evidence of maintaining virologic suppression while improving treatment satisfaction as a result of the switch. These data support making a switch for cost savings as well.

Oral Presentation

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