Switching from Lopinavir/Ritonavir (LPV/r) Soft Gel Capsule (SGC) to Tablet Formulation improves Tolerability in Indigent AIDS Clinic

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BACKGROUND

1. Because the new tablet formulation lacks oleic acid [3], an excipient believed to contribute to gastrointestinal (GI) intolerance with the SGC, it has been speculated that the tolerability of LPV/r would improve with the use of the tablet form.

2. In this study, a phase IV tolerability assessment was conducted in HIV-infected subjects who were switched from the SGC to the tablet formulation of LPV/r. Self-reported daily bowel habit, quality of life (QOL), and fasting lipid profile obtained prior to the switch were compared to similar data obtained 12 weeks post-formulation change.

METHODS

1. This was a prospective cohort study that enrolled clinically stable HIV-infected subjects receiving LPV/r-based antiretroviral (ARV) regimen.

2. Methods: Seventy-four HIV-infected subjects on LPV/r-based regimens were enrolled prior to (25/74) or within 8 weeks (49/74) after switching from LPV/r SGC to Tablet. Formulation preference and satisfaction were assessed post-switch. Tolerability assessments included bowel habit (BH), global condition improvement (GCI), and ACTG symptom distress module (ASDM). Tolerability, QOL, and fasting lipids pre-switch were compared to Wk4 and Wk12. Baseline QOL and BH were recalled for those subjects enrolled post-switch.

RESULTS

1. At Week 4, more patients preferred LPV/r Tablet to SGC (74% vs. 8%) and satisfaction with the Tablet formulation was expressed. Significant improvement in bowel habit was reported at Week 4 (mean change in BH-score: -0.281, p=0.002) and maintained through Week 12 (p=0.014).

2. Switching from LPV/r SGC to Tablet resulted in significant improvement in GI tolerability with a resulting positive impact on subjects' overall well being (GCI). Overall LPV/r tolerability improved with the switch. At Week 4, 45% of subjects felt "better", 45% felt "about the same", 5% "worse", and 5% did not respond. These GCI-improvements were maintained through Wk12 (p=0.001). Correlation was seen between the BH-score and GCI-improvement at Week 4 (p=0.017) and waned by Week 12.

3. There was not enough evidence to conclude a change in QOL due to the switch in drug formulation as measured by MOS-HIV PHS, MOS-HIV MHS, or ASDM scores (Table 2).

4. Interestingly, a mean reduction in triglycerides of 33 mg/dL (18%), unrelated to lipid-lowering therapy, was observed at Wk12 (n=33, p=0.035).

REFERENCES


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