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Maintenance Therapy Using Lopinavir/Ritonavir (LPV/r) Alone for Patients With Well-Controlled HIV-Infection

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Study Rationale

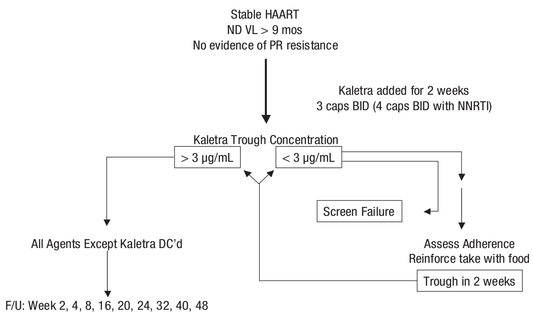
While potent HAART regimens have improved patient survival and dramatically lower the incidence of new opportunistic infections, the ability to maintain long-term viral suppression is often complicated by complex drug regimens, adverse drug events and long-term metabolic complications.

Recent data from a small prospective trial of LPV/r alone as initial therapy showed beneficial treatment responses[1]. In addition, good clinical and virologic responses were seen in a prior trial with saquinavir/ritonavir monotherapy as initial therapy[2]. Prior experience with induction-maintenance strategies has shown poor outcomes with less potent maintenance regimens. LPV/r alone may represent a viable option as maintenance therapy given its high potency, broad genetic barrier to resistance and tolerability. The purpose of this study was to evaluate LPV/r alone for maintenance therapy among patients with well-controlled HIV and no underlying protease (PR) resistance.

Methods

- Single-site, private practice prospective, 12-month observational study
- N=19
- Entry Criteria
  - On HAART
  - Non-detectable VL > 9 months
  - Nadir CD4 > 150 cells/mm^3
  - No evidence of Protease resistance by prior genotype
  - No history of VL > 400 on 2 clinic visits while on HAART
- If receiving LPV/r based therapy, a trough LPV concentration was obtained (HPLC with UV detection, LLQ 0.05 µg/mL, National Jewish Denver USA). If greater than 3.0 µg/mL (2 standard deviations from median trough values in LPV/r pharmacokinetic studies), all other agents except LPV/r were discontinued.
- If not receiving LPV/r based HAART, LPV/r 400/100 mg BID was added to existing HAART regimen for 2 weeks (533/133 mg BID if receiving NNRTIs). After 2 weeks a trough LPV concentration was obtained. If greater than 3.0 µg/mL, all other agents except LPV/r were discontinued.
- Patient adherence was monitored through medication diaries and pill counts.

Study Design



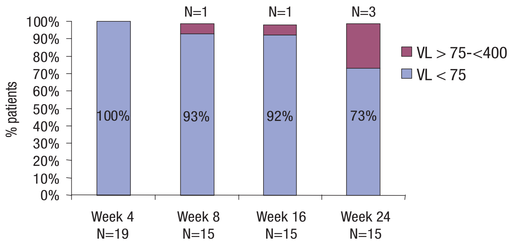
Results

Patient Demographics

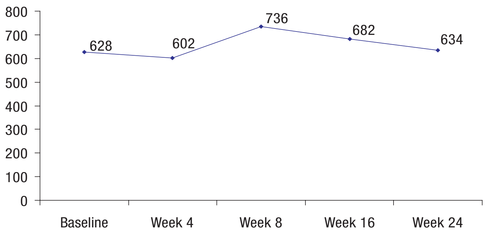
Gender	100% Male	N=19
Age (yrs) [range]^	42 [31 – 51]	
Yrs HIV + [range]^	5.5 [2 – 19]	
Previous AIDS DX		N=0
Prior # ART Regimens [range]	1 [1 – 6]	
Duration Prior ART Regimen (weeks) [range]^	34 [7 – 68]	
Receiving LPV/r at Baseline Having LPV/r added to Regimen	21% 79%	N=4 N=15
LPV/r Concentration (ug/ml) Prior to Discontinuation of other agents [range]^	5.76 [3.26 – 11.93]	

Results

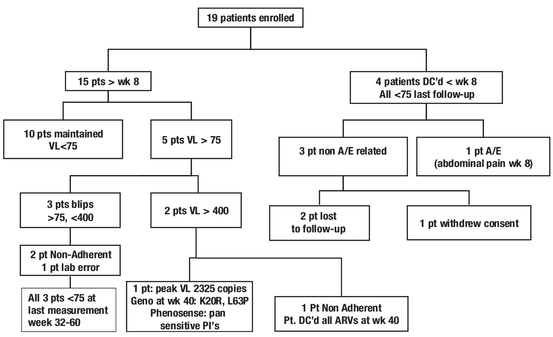
Virologic Results on Treatment Analysis



Immunologic Results: Median CD4 Cell Counts



Virologic Disposition



Median Lipid Change from Baseline

	Week 4	Week 8	Week 16	Week 24
N*	18	16	15	15
Total Chol	2%	10%	10%	7%
LDL	0%	15%	19%	3%
HDL	3%	16%	17%	5%
TG	41%	58%	65%	90%

*Lipid data available

Summary and Conclusions

LPV/r monotherapy was highly effective at maintaining virologic suppression and was generally well-tolerated. Viral blips (>75, <400) were noted in three patients and unexplained VF in one. Further studies of this strategy and resistance patterns that occur following viral breakthrough are warranted.

References

1. Gathe, et al., 43rd ICAAC 2003. H-845.
2. Cameron, et al., *AIDS* 1998.
3. Vernazza, et al., *AIDS* 2004.

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