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Partial Treatment Interruption (PTI) of PI-Based HAART Regimens in HIV-Infected Children

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INTRODUCTION

- **Current treatment recommendations for HIV-infected children suggest using a combination of Reverse Transcriptase (RTI) and Protease Inhibitors (PI)**
- **Adherence to these regimens is often suboptimal due to poor PI palatability, toxicities, dosing schedules and psychosocial factors**
- **Therapy simplification consisting primarily of RTI combinations, termed partial treatment interruption (PTI) may be an option**

OBJECTIVE

To describe the short and long - term clinical, virologic and immunologic outcomes in a cohort of pediatric patients undergoing PTI

METHODS

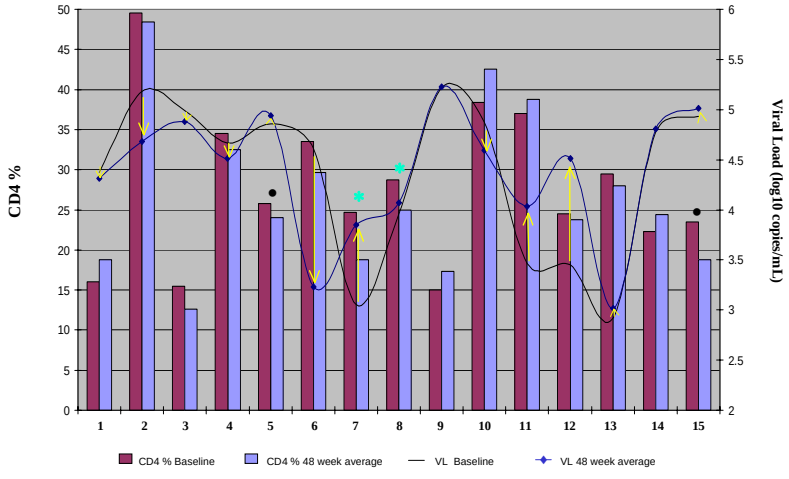
- **This is a retrospective study involving a cohort of fifteen perinatally HIV-infected children who stopped the PI component of their combination ART because of virologic failure, non-adherence or toxicities. These children remained on a multi - reverse transcriptase inhibitor regimen for 48 to 96 weeks**
- **Baseline VL and CD4 % are graphed as the average of their results within 3-4 months before PTI; 24, 48, and 96 week data points represent the average of all data points within that period plus one data point after that cutoff**

Subject	CDC class	Age at PTI (years)	Sex	Race	Regimen Before	Regimen After	Time on PTI (years)
1	B2	6.9	M	AA	ZDV /3TC/ NFV	ZDV/3TC	0.98
2	C1	4.9	M	AA	d4T /3TC /NFV	d4T /3TC	2.85
3	B3	10.2	M	H	TDF/ 3TC/ ZDV/ LPVr /EFV	TDF /ZDV 3TC/ EFV	0.67
4	A1	5.8	M	AA	d4T/ddI/ HU /RTV	d4T /ddI/ HU	3.68
5	B2	11.1	M	C	ZDV/3TC/RTV/SQV	ZDV/3TC	1.04
6	N1	12.9	M	H	d4T /3TC/NFV	d4T /3TC	2.53
7	B1	12.6	F	AA	ZDV/3TC/NFV/ADV	ZDV/3TC	2.59
8	C1	14.5	M	H	IDV/ZDV/3TC	ZDV/3TC	2.41
9	B3	10.9	M	H	TDF/ddI /EFV	ZDV/3TC	0.87
10	N1	3.0	F	C	ZDV/3TC/NFV	ZDV/3TC	3.37
11	A1	5.0	M	C	ZDV/3TC/NFV	ZDV/3TC	3.25
12	A2	4.0	F	AA	ZDV/3TC/NVP/LPVr	ZDV/3TC/NVP	1.39
13	A2	16.0	F	H	ADV/NFV/3TC /d4T	d4T/ 3TC	2.31
14	B1	11.4	M	H	d4T /3TC /LPVr	ZDV/3TC/ TDF ddI	0.82
15	A2	9.2	F	H	ZDV/3TC /LPVr	ZDV/3TC	0.94

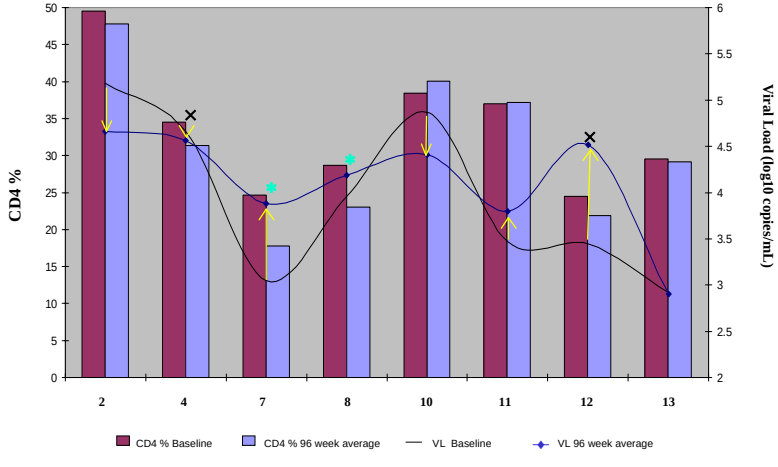
RESULTS

CD4 % and Viral Load after PTI

48 weeks



96 weeks



- Over the first 24 weeks 14/15 children maintained a CD4 % within 5% of their baseline. At week 48, 4/15 subjects had a CD4% decrease of ≥ 5% (6.7-9.5%, •). By week 96, 4/8 patients (×), including 2 from week 48 (*), had a decline in their CD4 % of ≥ 5% (7.5-9.5%). Persistent elevations in VL were not observed.
- During their PTI, no child had CDC defined clinical disease progression.
- Antiretroviral therapies were well tolerated and no significant toxicities were observed.
- Statistical comparisons of CD4 % and VL at different time points were not significant.
- No specific baseline features were identified as prognostic factors for better outcome or longer stability on a simplified PTI regimen.

CONCLUSIONS

- **No significant immunologic, virologic or clinical deterioration was observed in our cohort of patients undergoing PTI.**
- **Simplification of therapy by PTI may provide a safe, effective and durable option in patients non-adherent and / or intolerant of PI based HAART.**
- **As a temporizing measure, this therapeutic approach may allow for medical stability until new drugs become available.**
- **Prospective studies needed for:**
  - **Defining PTI: a) stopping PI, b) stopping PI and intensification with additional RTIs**
  - **Exploring impact of PTI on HIV pathogenesis: replication capacity, viral fitness, cellular tropism and geno / phenotypic changes**