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**EVALUATION OF RITONAVIR (RTV)
COMBINATION WITH STAVUDINE (d4T)
LAMIVUDINE (3TC) IN HIV-INFECTED
CHILDREN IN FOUR NIGERIAN CENTRES**

¹Nigerian Army Reference Hospital, Yaba, Lagos, Nigeria; ²Lagos State
Teaching Hospital, Idi-Araba, Lagos, Nigeria; ³Central Public Health Institute,
Yaba, Lagos, Nigeria.

¹*E. Ekong**; ²*I. Grant-Isibor*; ³*A. Uwah*; ³*T. Igbu*

Background

Not much is reported about the efficacy of antiretroviral therapy in children especially in developing countries in resource limited settings where switch from one combination to another can be very expensive and infeasible. This is made worse by non-availability of liquid/ oral formulations of most of the drugs.

Objectives

To study the efficacy, tolerance, side effects and compliance of the triple therapy of RTV, d4T and 3TC on HIV-infected patients in four clinical centres in Nigeria.

Methods

- **Study Design:** Open label, randomized, multi-center, prospective study.
- **Number of Patients:** 29 HIV-infected children.
- **Study Period:** Feb 2000 to August 2001.
- **Data collected:** Demographic, clinical and ARV.
- **Baseline data:** AIDS-defining conditions (ADEs), weight, height, PCV, fetal Hb, G6PD levels, Hb genotype.

count especially lymphocytes, CD4+ and CD8+ c
biochemistry.

- **Regimens:** RTV 350-400 mg/m² bid, d4T 1 mg/kg
3TC 4mg/kg q12h. Treatment of Opportunistic
was concurrent.
- **Evaluation:** Four-weekly for efficacy, side effects
and adherence at weeks 4, 8, 12, 24, 32, 40, 48, and
- **Viral load:** Done only twice.

Range	3-15
Gender, n (%)	
Male	19 (65%)
Female	10 (35%)
Transmission (Perinatal)	26 (88%)
HIV-RNA (log₁₀ copies/mL)	
Mean	4.8
Range	2.8-5.6
AIDS Defining Conditions(ADEs),n (%)	4 (13.7%)
Prior Antiretroviral Experience, n (%) (AZT & NVP)	6 (20%)
Hb Genotype, n (%)	
SS	2 (6.9%)
SC	1 (3.45%)

Results

Week 8:

- **Median increase in CD4+ counts was 92 cells/mm³;**
- **Median increase in weight was 20%;**

Week 24:

- **Median CD4+ counts increase was a further 100 cells/mm³;**
- **ADEs were minimal;**
- **Two other children had their doses modified due to lactose intolerance with severe vomiting.**

By week 40:

- **Median CD4+ count increase was 119 cells/ml**
- **Viral load dropped by a further 1.8 log₁₀ copies/ml**

It is worth noting that mean viral load drop was 1.8 log₁₀ copies/ml four weeks after the first estimate. The most common opportunistic infections were oropharyngeal candidiasis, pneumonia and tuberculosis and were also treated. The G6PD deficient child developed severe jaundice and therapy was discontinued.

One child died from deranged LFTs at week 46.

In the HbSS and HbSC children, the percentage of sickle cells and reticulocytes were reduced during the period of treatment.

Also the numbers of vaso-occlusive and haemolytic complications were reduced since commencement of the drug combination. One child was lost to follow-up.

Conclusion

RTV, also available in liquid formulation, in combination with d4T and 3TC is very potent, safe, and well tolerated with minimal side effects in children.

This is especially useful in the developing world setting with limited resources where switch is expensive, and where antiretroviral therapy is necessary. This combination seems to control the sickling effects to HbSS and HbSC children.

Presenting author: Dr Ernest Ekong

Contact address: Nigerian Medical Association, 14 Reeve Road, Fela
Lagos, Nigeria.

e-mail: EEKONG@beta.linkserve.com

Phone: 234-1-2672374