

Nevirapine (NVP) versus Efavirenz (EFV) based antiretroviral treatment (ART) in naïve Indian patients: comparison of effectiveness in clinical cohort

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Background:

- Comparable efficacy in 2NN study
- NnRTI based therapy is recommended as first line therapy in HIV infected individuals
- EFV based ART is more expensive than NVP in India.
- Generic branded antiretrovirals has improved availability, affordability and accessibility

Objectives

- To compare the immunologic effectiveness of both these regimens in antiretroviral naïve HIV-1 infected Indian patients.

Methods

- **Setting:** Tertiary care centers
 - Department of Infectious Disease, Sterling Hospital, Ahmedabad
 - Department of HIV medicine, Ruby Hall clinic, Pune India.
- **Design:** Observational, non-randomized, longitudinal, cohort study.

Methods:

- Antiretroviral naïve HIV-1 patients receiving efavirenz + 2nRTI (n= 254) and nevirapine +2nRTI(n= 857) from April 2000 were followed up.
- Self financed

Methods: Drugs

- Generic ARV's used
 - Nevirapine arm receives fixed dose combinations (FDC)-simplified therapy d4T+3TC+NVP (n=643) or AZT+3TC+NVP (n=214) 1 tab PO q12h – 2 pills per day, cost 28 US\$/month
 - Efavirenz arm receives FDC of d4T+3TC (n=218) or AZT+3TC (n=36) 1 tab PO q12h plus 1 tab Efavirenz 600mg qd at bed time – 3 pills per day, cost 60US\$/month

Methods:

- Follow-up
 - Clinical evaluations were performed monthly
 - CD4/CD8 counts quarterly
 - Viral load assay were not performed due to financial constrains
- Patients with minimum three months follow up were included in analysis.

Methods: statistical analysis

- Baseline characteristics between the groups were analyzed by Fischer's exact test (binary) and Mann Whitney test (continuous).
- Median CD4 counts were determined at each time points.
- We fitted a random effects model to assess the differences in the improvement in CD4 counts over time between the two treatment arms.

Results:

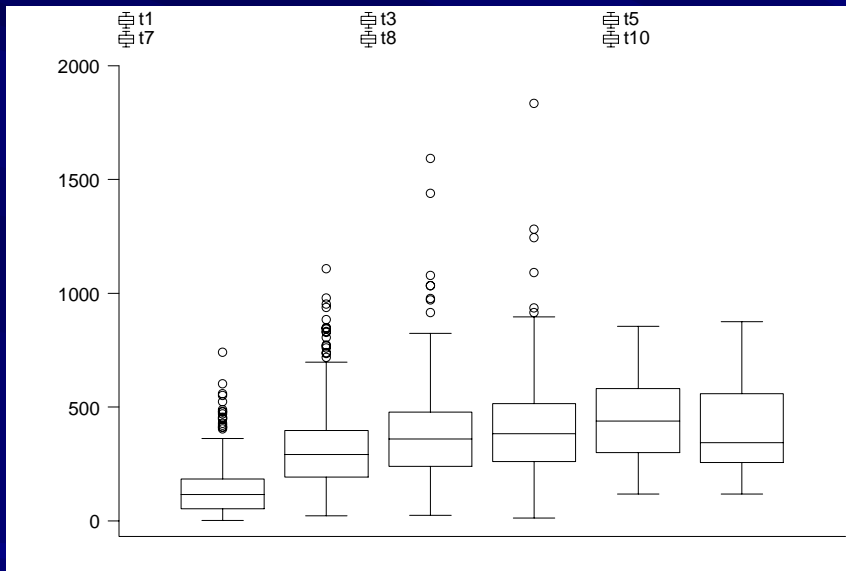
- 857 and 254 patients in NVP and EFV arms respectively were studied.
- Baseline characteristics, including CD4 counts ($p=0.17$) were similar between the two groups.

Baseline Characteristics

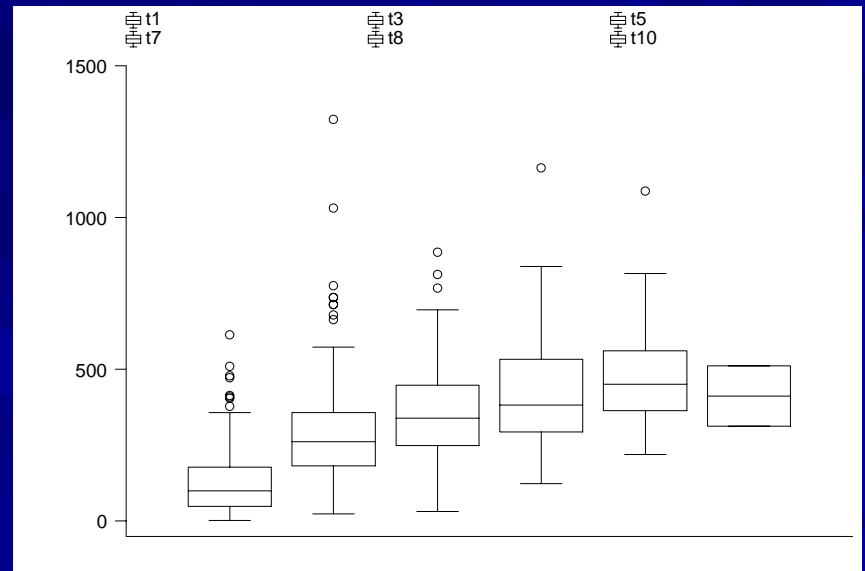
Characteristics	NVP arm n=857	EFV arm n= 254
Age (mean SD)	36.14 (\pm 9.07)	37.65 (\pm 10.12)
Gender		
Male	668 (77.9%)	188 (74.0%)
Female	189 (22.1%)	66 (26.0%)
Baseline CD4 (median)	115/cmm	99/cmm

Box plot NVP and EFV arm

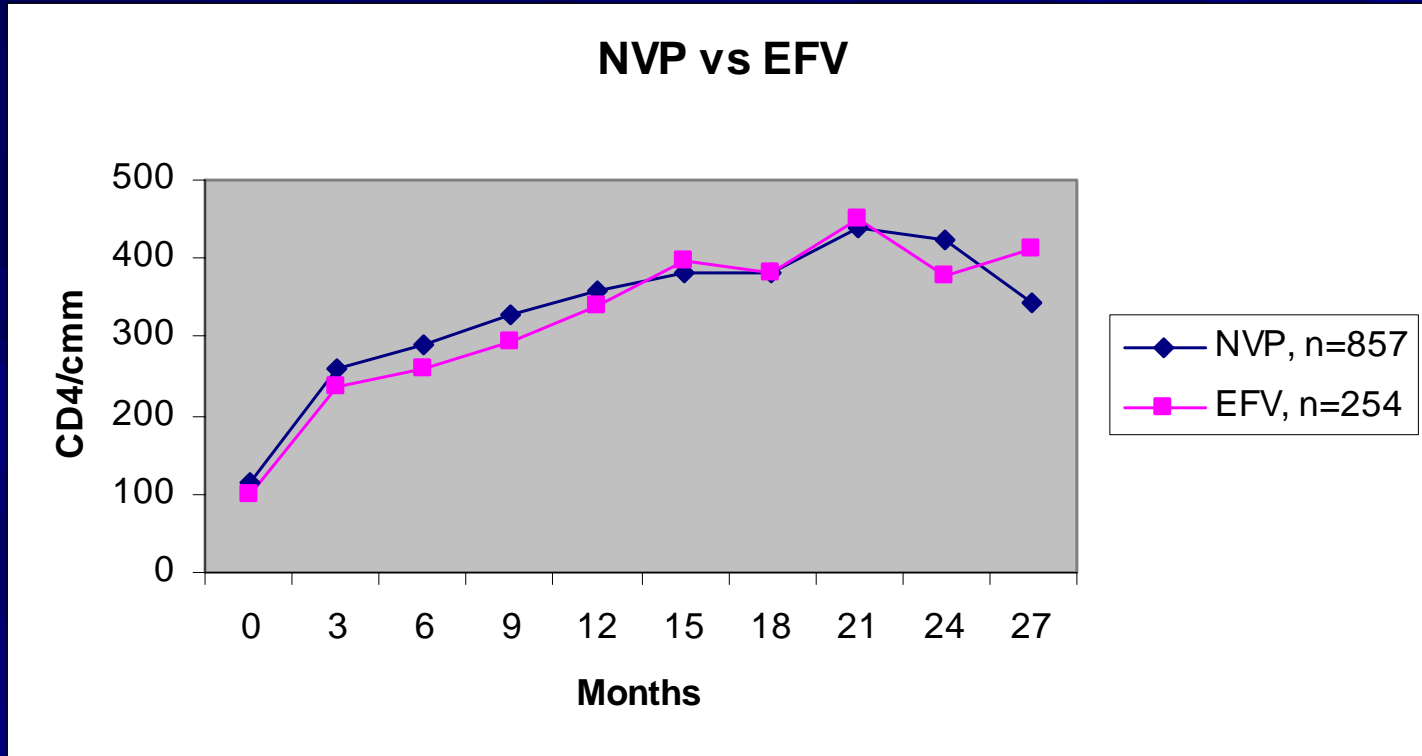
For NVP arm



For EFV arm



CD4 response



Months	0	3	6	9	12	15	18	21	24
NVP n=	857	622	673	329	463	161	235	61	97
EFV n=	254	238	235	161	121	65	47	20	09

Results:

- In the random effects model, there was an increase of 40.97 ($p < 0.05$) units of CD4 cell counts with an unit increase in time in the NVP arm as against a 44.75 ($p < 0.05$) units of increase in CD4 cell counts in the EFV group with an unit increase in time, which is significant for both groups.
- However, at any given point of time there was no difference in the rate of increase of CD4 count between the two treatment arms ($p=0.58$).

Major Adverse reactions

■ Adverse reaction	NVP	EFV	P=
1. Hepatitis	3.2%	0	0.0085
2. Skin rash	6.6%	2.32%	0.0146
3. CNS disturbances	0.93%	20.15%	<0.0001
4. Lipid abnormalities	9.10%	9.84%	0.3606

1. Distal sensory neuropathy (clinical) 17.38

21.21%

Conclusion

- Antiretroviral naïve Indian patients had significant & durable rise in CD4 cells in response to NVP and EFV based HAART
- This study also shows equivalent immunological effectiveness amongst NVP and EFV based regimen in a developing country scenario, which is in line with the results of the 2NN study.
- Limitations of study
 - observational and non-randomized
 - Viral load response was not measured for comparison of effectiveness