

# Effectiveness of generic efavirenz based HAART in HIV-1 infected patients in INDIA: 2 years follow up

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## Background

- Long-term efficacy data are available with efavirenz based HAART
- Efavirenz based HAART is a current standard of care in HIV-1 infected patients
- Few clinical data on effectiveness of generic efavirenz based HAART is available
- Generic branded antiretrovirals has improved availability, affordability and accessibility

## Objectives

- Primary objective is to assess immunological effectiveness and durability of efavirenz based HAART
- Compare effectiveness in treatment naïve and experienced group
- Secondary objectives is to assess adverse drug reactions associated with efavirenz based HAART

## Methods

- Setting: - Tertiary care center
  - Infectious disease Clinic, Ahmedabad
  - Department of Infectious Disease, Sterling Hospital, Ahmedabad
- Design: Observational, non-randomized, longitudinal, cohort study
  - Self financed
  - Generic antiretrovirals were used
    - Efavirenz and 2NRTI (cost 60 US \$ /month)
  - Follow-up
    - Clinical evaluations monthly
    - CD4/CD8 counts quarterly
    - Viral load assay were not performed due to financial constrains
  - Adherence was assessed by self-reporting
  - Patients with minimum three months follow up were included in analysis

## Methods: Statistical analysis

- Age and sex distribution between two groups were analyzed by using T-test and chi-square analysis respectively
- Improvement in CD4 cell count was assessed by using Kaplan-Meier product-limit survival estimation for all the patients and then stratified by treatment groups
- All the results were adjusted for age and sex by using multivariate analysis techniques

## Results

- 447 patients were initiated with efavirenz based HAART since August 2001
- Group A: antiretroviral naïve (n=385)
- Group B: treatment experienced [protease inhibitor] (n=62)

Table 1: Baseline characteristics

Characteristics	Group A (n=385)	Group B (n=62)	X <sup>2</sup> /t	p value
Age (Median[range])				
Male	37(3-72)	37(8-64)	t=0.48	0.6284
Female	36(5-60)	38(26-56)		
Sex				
Male	286(74.3%)	49(79.0%)	X <sup>2</sup> =0.63	0.4235
Female	99(25.7%)	13(20.9%)		
Baseline CD4 count Median(range)	91(1-390)	215(2-613)	t=9.91	0.0001

Table 2: Median CD4 levels at various time points

Months→	0	3	6	9	12	15	18	21	24
Group A Median CD4 count	91	241	255	292	320	350	379	440	377
Group A Range	1-390	21-1751	1-1322	26-991	6-900	89-854	96-838	133-1807	147-997
n=	385	385	281	213	158	118	87	63	41
Group B Median CD4 count	215	281	318	287	310	312	296	274	365
Group B Range	2-631	38-893	37-736	82-839	149-767	142-744	122-816	212-816	233-681
n=	62	62	51	38	21	19	15	8	4

\* Log Rank Test chi-sq =34.13 p=0.028, \* Wilcoxon Test chi-sq = 5.11 p=0.023

Figure 1: Rise in median CD4 count

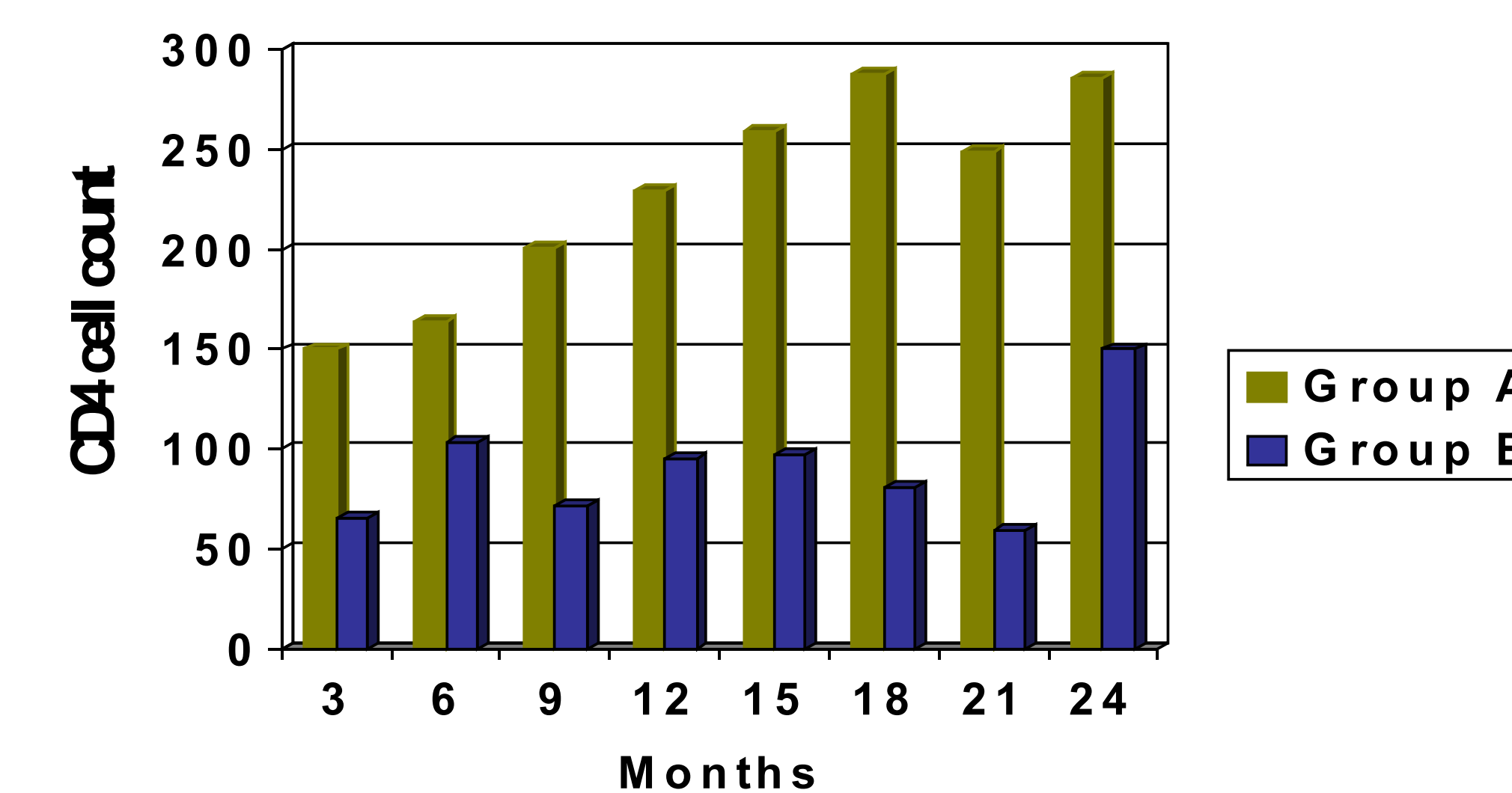


Table 3: NRTI used

NRTI used	Group A(n=385)	Group B(n=62)	Test	p value
d4T+3TC	354(91.9%)	22(35.5%)	X <sup>2</sup> =143	0.0001
AZT+3TC	22(5.7%)	12(19.4%)		
d4T+ddi	7(1.8%)	9(30.6%)		
AZT+ddi	1(0.3%)	6(9.6%)		
3TC+ddi	1(0.3%)	3(4.8%)		

Table 4: Treatment outcome

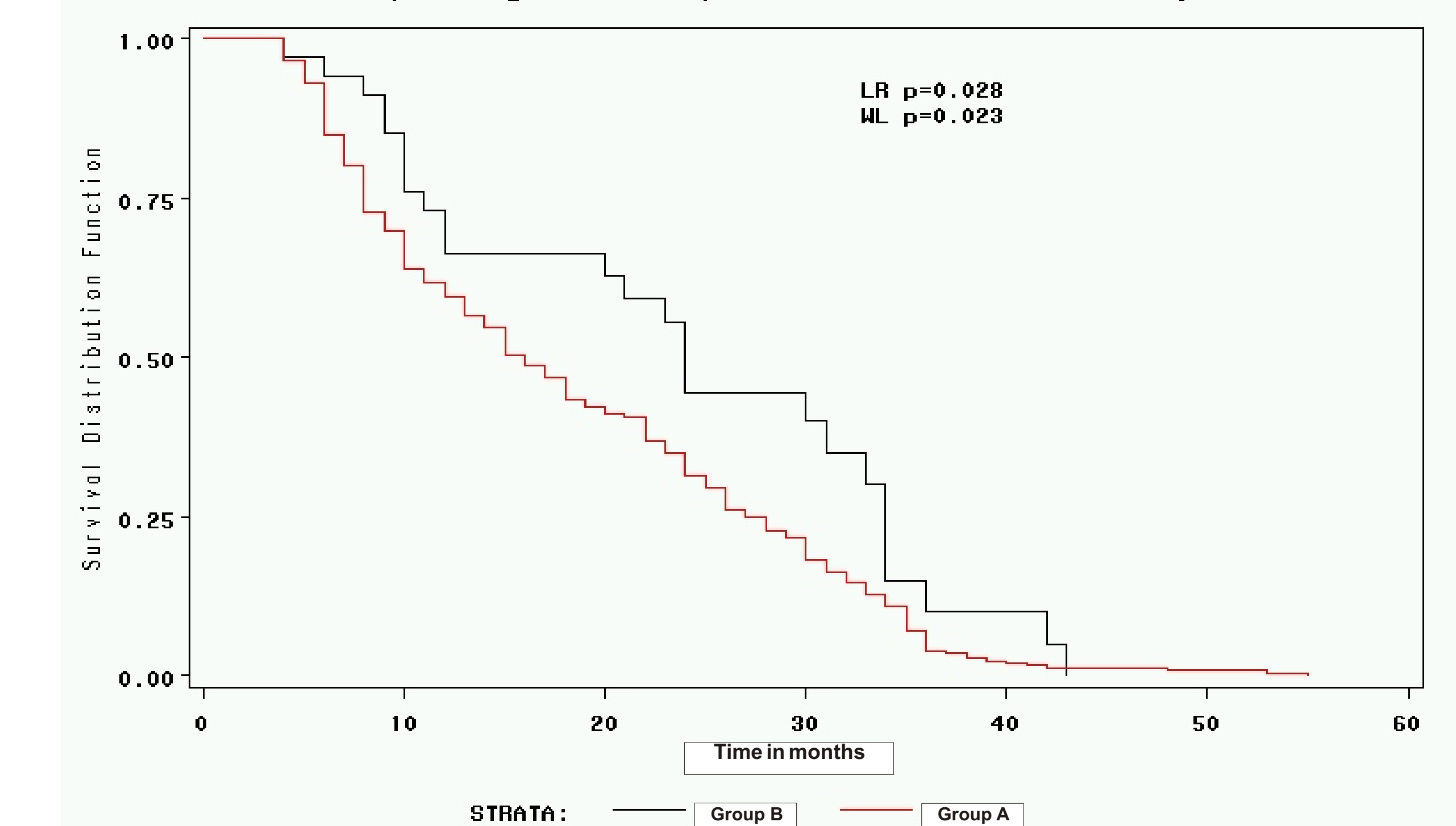
Parameters	Group A(n=385)	Group B(n=62)	Test	p value
Changed to NVP	28(7.27%)	2(3.22%)	X <sup>2</sup> =0.41	0.52
Changed due to failure	27(7.01%)	14(22.58%)		
Changed due to SE	2(0.51%)	0		
Lost to follow up	62(16.1%)	13(20.1%)	X <sup>2</sup> =0.73	0.39
Irregular follow up	38(9.8%)	4(6.5%)		

Table 5: Adverse drug reactions

Adverse effects	Group A (n=385)	Group B (n=62)	Test	p value
Neurological side effects	78 (20.25%)	11(17.74%)	X <sup>2</sup> =0.21	0.64
Hepatitis	25(6.49%)	4 (6.45%)	X <sup>2</sup> =0.07	0.79
GI disturbances	24(6.23%)	3 (4.83%)	X <sup>2</sup> =0.02	0.88
Skin Rash	11(2.85%)	1 (1.61%)	X <sup>2</sup> =0.02	0.88
Neuropathy	91 (23.60%)	18 (29.03%)	X <sup>2</sup> =0.84	0.35

Figure 2:

K-M curve depicting CD4 improvement over time by Treatment



## Conclusions

- Generic efavirenz based HAART is effective and also well tolerated during two years of follow-up period
- Antiretroviral naïve patients have better CD4 cells improvement compared to treatment-experienced patients

## Limitations of study

- Observational and non-randomized
- Viral load response was not measured for defining effectiveness of HAART