Virological and Immunological Responses of Efavirenz-Based HAART Regimen Initiated in HIV-Infected Patients at CD4 < 100 Versus CD4 ≥ 100 Cells/mm^3 □

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Objective: *To compare virological and immunological responsiveness of efavirenz (EFV)-based highly active anti retroviral therapy (HAART) between patients with baseline CD4 < 100 and CD4 ≥ 100 cells/mm^3.*
Material and Method: *A prospective cohort study in antiretroviral-naive HIV-infected patients was conducted between February and April 2002. Donated HAART regimen, consisting of stavudine, didanosine, and EFV was initiated. The primary outcome was time to undetectable HIV RNA, < 50 copies/mL. Patients were followed up every 12 weeks until 48 weeks (the end of the study).*
Results: *Forty-six patients were included, 21 patients for CD4 < 100 cells/mm^3 and 25 patients for CD4 ≥100 cells/mm^3. Median CD4 cell counts of these corresponding groups were 26.5 and 177 cells/mm^3. Patients' characteristics were similar between the two groups except CD4. The probability of undetectable HIV RNA at 12, 24, 36, and 48 weeks were 57.1% (95%CI, 37.7-78.1%), 76.2% (95%CI, 56.9-91.3%), 80.9% (95%CI, 62.3-94.0%), and 90.5% (95%CI, 68.9-99.1%) for the former group; and 64.0% (95%CI, 45.8-81.8%), 92.0% (95%CI, 77.5-98.6%), 96.0% (95%CI, 83.0-99.7%), and 96.0% (95%CI, 83.0-99.7%) for the latter group. Median time to undetectable HIV RNA was 12 weeks for both groups. Median CD4 change at 48 weeks was 171 and 132 cells/mm^3, respectively (p = 0.232). The adverse events were similar between the two groups.*
Conclusion: *Initiation of EFV-based HAART regimen in HIV-infected patients at CD4 < 100 and ≥ 100 cells/mm^3 gains similar immunological and virological response.*

Keywords: *AIDS, CD4, Efavirenz, Highly active antiretroviral therapy, HIV*

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Highly active anti retroviral therapy (HAART) has been widely used for the treatment of HIV-infected patients with successful immune restoration, reductions in morbidity and mortality[1,2]. Efavirenz (EFV) is a non nucleoside reverse transcriptase inhibitor (NNRTI) that has shown effective antiretroviral efficacy and has also been reported to possess equivalent potency to protease inhibitor (PI)-based regimen[3,4]. Although EFV-based regimen has been shown to be effective in advanced HIV-infected patients[4-6], it has not been widely used for the treatment of profoundly immunosuppressed HIV-infected patients. Only a few studies have focused on patients who commence therapy with a CD4 cell count < 100 cells/mm^3[5-7]. Data for virological and immunological response in these advanced patients, which are a large proportion of HIV-infected patients in the developing countries, are still limited[8,9]. The authors therefore conducted a cohort study to

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assess and compare the efficacy of EFV-based regimen initiated between patients with CD4 < 100 versus ≥ 100 cells/mm^3.

Material and Method

Study subjects and study design

A prospective cohort study of HIV-infected patients, who attended the Infectious Diseases Clinic, Ramathibodi Hospital, Mahidol University, Bangkok, Thailand, between February and April 2002, was conducted. These patients were 15 years or older and were na□ve to antiretroviral therapy. HAART regimen consisting of stavudine (d4T), didanosine (ddI), and EFV, donated by Mahidol University and the Ministry of Public Health, was initiated. Patients were followed up every 12 weeks until 48 weeks after initiating treatment (the end of the study). Clinical status, tolerability, adverse events, CD4 cell count, and HIV RNA were assessed. HIV RNA was determined by Amplicor HIV-1 Monitor test, version 1.5, Roche Diagnostics, Indianapolis, USA. The present study was approved by the institutional review board and written informed consent was given.

The study factor was whether patients had baseline CD4 < 100 or ≥ 100 cells/mm^3. Demographic and baseline clinical data (e.g., sex, age, previous opportunistic infections (OIs), baseline CD4 cell count, baseline HIV RNA and medical history) were extracted from the medical records. The primary outcome of interest was time to undetectable HIV RNA (< 50 copies/mL), which was calculated by subtracting the date of the first undetectable HIV RNA with the date starting treatment. The secondary outcomes were an immunological response, change of CD4 cell count over time, and tolerability. Discontinuation of HAART, which was defined as interruption of any antiretroviral drugs was also recorded and described.

Statistical analysis

Means ± SD, median, and frequencies (%) were used to describe the patients' characteristics. Kaplan-Meier test was applied to estimate probability and median time of undetectable HIV RNA. A log-rank test was used to compare the median time between the CD4 <100 and ≥100 cells/mm^3 groups. The Cox proportional hazard model was used to determine the chance of undetectable HIV RNA by adjusting for confounding factors (i.e. previous OIs,). All analyses were performed using STATA version 8.0[10]. A p value less than 0.05 was considered statistically significant.

Results

Forty-six patients were included in the present study. Of these, 21 patients had baseline CD4 cell count < 100 and 25 patients had baseline CD4 cell count ≥ 100 cells/mm^3. The baseline patients' characteristics among groups are described in Table 1. The history of previous major OIs were higher in CD4 cell count < 100 cells/mm^3 group (5, 24%) than CD4 cell count ≥ 100 cells/mm^3 group (1, 4%), but this difference was not significant (p = 0.079). Previous OIs included tuberculosis (4 patients), cryptococcosis (1), and disseminated *Mycobacterium avium* complex (1). Median (range) CD4 cell count was 26.5 (5-99) cells/mm^3 in the former

Table 1. Baseline characteristics of patients in the baseline CD4 < 100 and ≥ 100 cells/mm^3 group (n = 46)

Characteristics	Patients with baseline CD4 < 100 cells/mm^3 n = 21 (%)	Patients with baseline CD4 ≥ 100 cells/mm^3 n = 25 (%)	p-value*
Gender			0.226
Male	13 (61.9)	11 (44.0)	
Female	8 (38.1)	14 (56.0)	
Mean age ± SD (years)	37.4 ± 6.6	38.0 ± 7.9	0.793+
Previous major OIs			
Yes	5 (23.8)	1 (4.0)	
No	16 (76.2)	24 (96.0)	0.079
Median CD4 cell count (range) (cells/mm^3)	26.5 (5-99)	177 (101-474)	<0.01
HIV RNA (copies/mL)			0.536
< 100,000	9 (42.9)	13 (52.0)	
≥ 100,000	12 (57.1)	12 (48.0)	

* Fisher's exact test, + unpaired t test
OIs, opportunistic infections

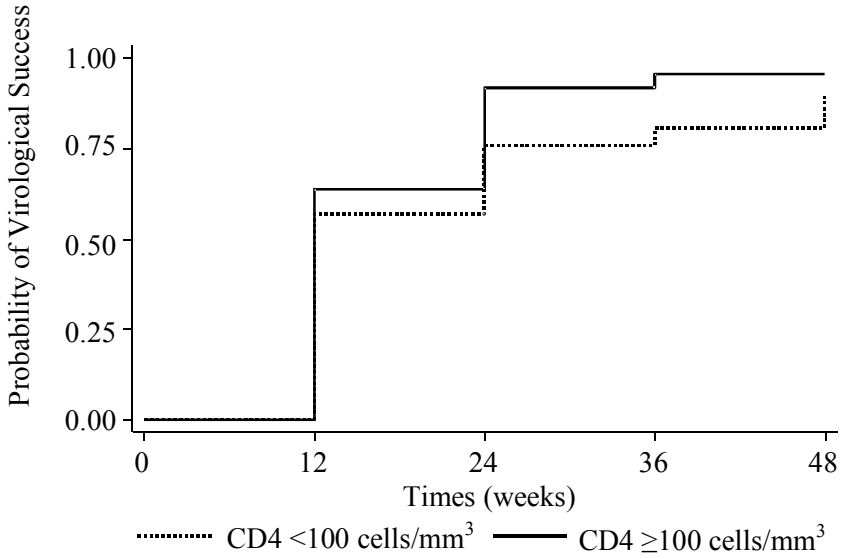

Fig 1. Probability of virological success after initiation of HARRT

group and 177 (101-474) cells/mm^3 in the latter group ($p < 0.01$). Proportion of patients with HIV RNA ≥ 100,000 copies/mL was higher in the former group (57.1%) than the later group (48.0%) but there was no statistical significance.

Overall probability of undetectable HIV RNA is estimated in Table 2. The authors found that the probability of success at 24 weeks and 48 weeks were 85% (95% Confidence Interval (CI): 73.0-93.3%) and 93% (95%CI: 81.6-98.3%), respectively. Probability curves between groups were plotted and compared, Fig. 1. The authors found that 12-, 24-, 36-, and 48-weeks undetectable rates were 57.1% (95%CI, 37.7-78.1%), 76.2% (95%CI, 56.9-91.3%), 80.9% (95%CI, 62.3-94.0%), and 90.5% (95%CI, 68.9-99.1%) for the CD4 cell count < 100 cells/mm^3 group. The corresponding values were 64.0% (95%CI, 45.8-81.8%), 92.0% (95%CI, 77.5-98.6%), 96.0% (95%CI, 83.0-99.7%), and 96.0% (95%CI, 83.0-99.7%) for the CD4 cell count ≥ 100 cells/mm^3 group. Median times of virological success were 12 weeks for both groups ($p = 0.261$).

Variables (i.e. gender, and HIV RNA level) were also assessed whether they were associated with time to undetectable HIV RNA. Median time to undetectable HIV RNA of these variables are described and compared in Table 3. Baseline HIV RNA was significantly associated with time to virological success, i.e. patients who had baseline HIV RNA < 100,000 copies/mL would take 12 weeks to achieve success, whereas those patients who had HIV RNA ≥ 100,000 copies/mL would take 24 weeks ($p < 0.01$).

The Cox proportional hazard model was applied to assess the effect of baseline CD4 level by adjusting for previous OIs and HIV RNA. Table 4. The authors found that CD4 level at baseline and previous OIs was not associated with time to virological success ($p = 0.337$ and 0.290, respectively). However, there was a trend of the association between HIV RNA baseline

Table 2. Probability to success at each time point

Time (weeks)	Total	Treatment failure	Lost to follow up	Probability	95%CI
12	46	28	0	0.609	0.472-0.748
24	18	11	0	0.848	0.730-0.933
36	7	2	2	0.891	0.783-0.960
48	3	1	2	0.928	0.816-0.983

CI, confidence interval

Table 3. Median times to virological success and virological success rates by prognostic factors

Factors	Number of successes	Total	Person-weeks	Success rate/ 100 person-weeks	Median time (weeks)	p-value
Sex						
Male	21	24	468	0.04	12	0.575
Female	21	22	420	0.05	12	
Age (years)						
< 40	28	30	552	0.05	12	0.380
≥ 40	14	16	336	0.04	12	
CD4 cell count (cells/mm^3)						
< 100	18	21	444	0.04	12	0.261
≥ 100	24	25	444	0.05	12	
HIV RNA (copies/mL)						
< 100,000	22	22	336	0.06	12	<0.01
≥ 100,000	20	24	552	0.04	24	

Table 4. Determination of chance of undetectable HIV RNA for confounding factors, using the Cox proportional hazard analysis

Factors	Hazard ratio	Standard error	p-value	95%CI
CD4 cell count (cells/mm^3)				
< 100	1.39	0.47	0.337	0.7-2.7
≥ 100	1			
Previous OIs				
Yes	1.67	0.80	0.290	0.6-4.3
No	1			
HIV RNA (copies/mL)				
<100,000	1.79	0.58	0.073	0.9-3.4
≥ 100,000	1			

OIs, opportunistic infections; CI, confidence interval

and time to undetectable HIV RNA, i.e., patients who had baseline HIV RNA < 100,000 copies/mL had about 78% (HR = 1.78, 95%CI, 0.95-3.38) higher chance to reach undetectable HIV RNA than patients who had HIV RNA ≥ 100,000 copies/mL. However, this difference was not significant (p = 0.073).

Changing in the CD4 count (CD4 count at 48 weeks - CD4 count at baseline) was assessed. The authors found that median (range) CD4 change were 171 (20-615) and 132 (31-505) cells/mm^3 for CD4 cell count < 100 cells/mm^3 group and CD4 cell count ≥ 100 cells/mm^3 group, respectively (p = 0.232).

Only three patients (all were CD4 cell count ≥ 100 cells/mm^3 group) reported having adverse drug events, which were lactic acidosis (2 patients) and central nervous system symptoms (1). These patients had to discontinue the study regimen due to adverse drugs reaction and a new regimen was prescribed. Two patients of each group were lost to follow up. No new opportunistic infection occurred and all patients were alive until the end of study.

Discussion

The results of the present study show that the efficacy of the EFV-based HAART regimen was similar in patients with CD4 cell count lower or higher than 100 cells/mm^3. However, the efficacy might be different according to baseline HIV RNA level, i.e. patients with HIV RNA > 100,000 copies/mL would take a longer time of undetectable HIV RNA than patients with HIV RNA < 100,000 copies/mL.

Antiretroviral therapy reduces HIV-related mortality and morbidity for patients with substantial CD4 cell depletion[1] as well as patients with advanced HIV disease[11]. NNRTI-based regimen is a preferred regimen for treatment of HIV-infected patients because

of its good efficacy, well tolerated, less long-term toxicities[12-14], and relatively less costly than PI-based regimens in developing countries. Consequently clinicians have been somewhat reluctant to use NNRTI-based regimen in patients with advanced AIDS and opportunistic diseases.

Previous studies had found that virological response is better if therapy is initiated before CD4 has progressed to CD4 < 200 cells/mm^3[15-17]. Although the present study was focused in more advanced patients (CD4 < 100 cells/mm^3) than previously reported, the authors found that the probability of achieving undetectable HIV RNA within 48 weeks after treatment for all patients was very high (93%). In addition, the median time to undetectable HIV RNA and change of CD4 cell count at 48 weeks for both groups, CD4 <100 cells/mm^3 and CD4 ≥100 cells/mm^3, were similar.

The most common adverse effects for EFV were central nervous system disturbances and resulted in discontinuing treatment[18]. The present study found very low central nervous system disturbances, only 2%. However, lactic acidosis, which might be due to a combination of d4T and ddI in the regimen[19,20], was also found, 4%. Immune reconstitution syndrome (IRS), which often occurred in patients with advanced immunodeficiency and starting an antiretroviral therapy at low CD4 cell counts[21], was not found in the present study.

There might be a role for protease PI-based regimen in patients with more advanced HIV disease where some feel the response to NNRTI-base regimen may not be potent. The present results suggest that use of EFV-based regimens is beneficial in patients with low CD4 cell counts. Treatment with an EFV-based regimen in severe immunosuppressed HIV-infected patients, compared with PI-based regimen resulted in a superior virologic response with no difference in immunologic or clinical effectiveness[7]. Patients with low CD4 cell counts and high HIV RNA are in need of immediate aggressive treatment. Any delay in treatment carries with it a risk of development of OIs.

The limitations of the present study are small sample size and short follow-up period. A longer period of follow-up is needed to determine the probability of failure. NRTI backbone, d4T plus ddI, is an antiretroviral component not recommended as part of antiretroviral regimen due to high incidence of toxicities according to an updated guideline[12]. However, the present study was initiated before this updated guideline and all the antiretroviral drugs were donated. The present results have demonstrated that EFV-based HAART in patients with CD4 <100 cells/mm^3 is effective and support the use of EFV-based HAART in this population.

In summary, the outcomes of EFV-based regimens in patients with advanced HIV infection with CD4 < 100 cells/mm^3 in terms of virological and immunological responses are favorable and are not different from those in patients with CD4 ≥100 cells/mm^3. However, a further large-long-term study that would assess the final outcome is needed.

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การตอบสนองทางไวรัสและทางภูมิต้านทานของสูตรยาต้านไวรัสที่มีอีฟาไวเรนซ์ระหว่างผู้ป่วยติดเชื้อเอชไอวีที่มีปริมาณซีดีสี่น้อยกว่า 100 เซลล์/ลบ.มม.และมากกว่าหรือเท่ากับ 100 เซลล์/ลบ.มม.

ศศิโสภิณ เกียรติบูรณกุล, สมนึก สังฆานุภาพ, ศศิวิมล รัตนสิริ, วีรวัฒน์ มโนสุทธิ, อัษฎา วิภากุล, อัมรินทร์ ทักขิญเสถียร

วัตถุประสงค์*: เพื่อเปรียบเทียบการตอบสนองทางไวรัสและทางภูมิต้านทานของสูตรยายาต้านไวรัสที่มีอีฟาไวเรนซ์ระหว่างผู้ติดเชื้อที่มีปริมาณซีดีสี่น้อยกว่า 100 เซลล์/ลบ.มม.และมากกว่าหรือเท่ากับ 100 เซลล์/ลบ.มม.*

วัสดุและวิธีการ*: การศึกษาแบบไปข้างหน้าในผู้ติดเชื้อเอชไอวีที่ไม่เคยได้รับการรักษาด้วยยาต้านไวรัสมาก่อนระหว่างเดือนกุมภาพันธ์ถึงเดือนเมษายน พ.ศ. 2545 ยาต้านไวรัสที่ได้รับการบริจาคที่ใช้ในการศึกษาคือ สตาวูดีน ดีดาโนซีน และอีฟาไวเรนซ์ ผลการศึกษาปฐมภูมิคือ ระยะเวลาที่ไม่สามารถวัดปริมาณเชื้อเอชไอวีได้ (น้อยกว่า 50 คอปปี้/มล.) ผู้ป่วยได้รับการติดตามทุก 12 สัปดาห์ เป็นเวลา 48 สัปดาห์ (สิ้นสุดการศึกษา)*

ผลการศึกษา*: ผู้ป่วยทั้งหมด 46 ราย มีผู้ป่วย 21 และ 25 ราย อยู่ในกลุ่มที่มีซีดีสี่น้อยกว่า 100 เซลล์/ลบ.มม.และซีดีสี่ตั้งแต่ 100 เซลล์/ลบ.มม. ตามลำดับ ค่ามัชฌิมของซีดีสี่ของผู้ป่วยทั้ง 2 กลุ่มคือ 26.5 และ 177 เซลล์/ลบ.มม. คุณสมบัติของผู้ป่วยทั้ง 2 กลุ่มเหมือนกันยกเว้นค่ามัชฌิมของซีดีสี่ความน่าจะเป็นในการที่จะวัดปริมาณเชื้อเอชไอวีไม่ได้ที่ 12, 24, 36 และ 48 สัปดาห์คือ ร้อยละ 57.1 (ค่าช่วงความเชื่อมั่นร้อยละ 95, ร้อยละ37.7-78.1) ร้อยละ 76.2 (ค่าช่วงความเชื่อมั่นร้อยละ 95, ร้อยละ 56.9-91.3) ร้อยละ 80.9 (ค่าช่วงความเชื่อมั่นร้อยละ 95, ร้อยละ 62.3-94.0) และร้อยละ 90.5 (ค่าช่วงความเชื่อมั่นร้อยละ 95, ร้อยละ 68.9-99.1) ในผู้ป่วยกลุ่มแรกและร้อยละ 64.0 (ค่าช่วงความเชื่อมั่นร้อยละ 95, ร้อยละ 45.8-81.8) ร้อยละ92.0 (ค่าช่วงความเชื่อมั่นร้อยละ 95, 77.5-98.6%) ร้อยละ 96.0 (ค่าช่วงความเชื่อมั่นร้อยละ 95, 83.0-99.7%) และร้อยละ 96.0 (ค่าช่วงความเชื่อมั่นร้อยละ 95, ร้อยละ 83.0-99.7) ในผู้ป่วยกลุ่มหลัง ผู้ป่วยร้อยละ 50 ของผู้ป่วยทั้ง 2 กลุ่มจะวัดปริมาณเชื้อเอชไอวีไม่ได้ที่ 12 สัปดาห์ ค่ามัชฌิมของการเปลี่ยนแปลงซีดีสี่ที่สัปดาห์ที่ 48 คือ 171 และ 132 เซลล์/ลบ.มม. ตามลำดับ (p = 0.232) พบผลข้างเคียงของยาเท่ากันในผู้ป่วยทั้ง 2 กลุ่ม*

สรุป*: การเริ่มยาต้านไวรัสด้วยสูตรที่มีอีฟาไวเรนซ์ในผู้ติดเชื้อเอชไอวีที่มีซีดีสี่น้อยกว่า 100 เซลล์/ลบ.มม.และมากกว่าหรือเท่ากับ 100 เซลล์/ลบ.มม. มีการตอบสนองทางภูมิต้านทานและไวรัสที่เหมือนกัน*