Published in final edited form as:
J Acquir Immune Defic Syndr. 2005 February ; 38(2): 174–179. doi:10.1097/01.qai.0000145351.96815.d5.

The TREAT Asia HIV Observational Database:

Baseline and Retrospective Data

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Abstract

Background—Relatively little is known regarding HIV disease natural history and response to antiretroviral treatments among Asian people infected with HIV. The Therapeutics Research, Education, and AIDS Training in Asia (TREAT Asia) HIV Observational Database (TAHOD) is a recently established collaborative observational cohort study that aims to assess HIV disease natural history in treated and untreated patients in the Asia-Pacific region.

Methods—Observational data are collected on HIV-infected patients from 11 sites in the Asia-Pacific region. Data are centrally aggregated for analyses, with the first baseline and retrospective data transferred in September 2003. Retrospective data were analyzed to assess the response to highly active antiretroviral treatment (HAART) over a 6-month period in terms of changes in CD4 count and proportions of patients achieving an undetectable HIV viral load (<400 copies/mL).

Results—By the end of May 2004, 1887 patients had been recruited to the TAHOD. Seventy-two percent of patients were male, with median age 36 years. Seventy-eight percent of patients reported HIV infection through heterosexual contact. Forty-three percent of patients had a previous AIDS diagnosis, of whom 55% had tuberculosis. The mean 6-month CD4 count increase was 115 cells/μL (SD = 127) after starting triple-combination therapy. Smaller CD4 count increases were associated with a higher CD4 count before starting treatment, prior treatment with monotherapy or double therapy, and treatment with a HAART regimen containing a nucleoside reverse transcriptase inhibitor (NRTI) and/or protease inhibitor (PI) but without a non-nucleoside reverse transcriptase inhibitor (NNRTI). Five hundred and ninety-eight patients started HAART and had a viral load assessment at 6 months, with 69% attaining an undetectable viral load. Older

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patients, patients not exposed to HIV through heterosexual contact, and patients treated with HAART containing NRTIs and NNRTIs but without PIs were found to be more likely to achieve an undetectable level.

Conclusion—Analyses of retrospective data in the TAHOD suggest that the overall response to HAART in Asian populations is similar to that seen in Western countries.

Keywords

HIV; antiretroviral treatment; observational database; Asia and the Pacific

TREAT Asia (Therapeutics Research, Education, and AIDS Training in Asia) Asia is a cooperative network of clinicians throughout Asia and the Pacific that aims to expand the capacity for broader introduction of HIV/AIDS treatments in the region. The TREAT Asia HIV Observational Database (TAHOD) is the first collaborative study by the TREAT Asia network. At present, there are relatively few data available regarding HIV disease in the Asia and Pacific region. It is known that the natural history of HIV is different in certain respects in the region compared with Western countries; for example, higher rates of tuberculosis in HIV-infected patients have been reported from the Asia and Pacific region.[1,2]

The objectives of this article are, first, to describe the TAHOD working procedure and methods; second, to summarize baseline data on patients so far recruited to the TAHOD; and third, using baseline and retrospective data, to assess the rate of decline in CD4 count in untreated patients and the CD4 and viral load response in patients receiving antiretroviral treatment.

METHODS

The TAHOD is a collaborative observational cohort study that involves 11 sites in the Asia and Pacific region (Appendix). Criteria for site selection were based on the ability to contribute data in an appropriate format within the initial 3-year period, and also tried to retain sites so as to represent countries across the region. Available funding limited patient recruitment to 200 patients per site. With limited resources, it was thought that recruiting an entirely representative sample of all patients attending a site was unachievable. Instead, the emphasis was placed on recruiting patients who were thought likely to remain in follow-up. Each site identified patients with regular clinic follow-up and then recruited a consecutive sample of such patients, aiming to recruit patients receiving and not receiving antiretroviral treatment at the time of recruitment. Although this recruitment approach does not provide patient samples that are entirely representative of patients attending a site, the expected good follow-up rates ensure that robust analyses can be made regarding the natural history of HIV disease on and off antiretroviral treatment.

Data collected included (1) demography (date of the clinical visit; age; gender; ethnicity; exposure category; date of the first positive HIV test; HIV-1 subtype; and date and result of hepatitis B, hepatitis C, and syphilis tests); (2) stage of disease (CD4 and CD8 cell count, HIV viral load test date and result, AIDS-defining illness [defined according to 1993 Centers for Disease Control and Prevention (CDC) revision of the AIDS case definition[3]], and date and cause of death); (3) treatment (prior and current prescribed antiretroviral treatments, reason for treatment changes [eg, treatment failure, clinical progression, adverse events], and prophylactic treatments for opportunistic infection). All data were entirely observational, with tests or interventions performed only to clinical guidelines at each site. For each subject at first inclusion into the database, data on the stage of HIV disease and antiretroviral and prophylactic treatments were recorded prospectively and retrospectively,

including all information available on each patient's case history. Reasons for stopping antiretroviral drugs are collected prospectively only. Standardization of causes of death is ensured by completion of a standardized cause of death form. Data were combined via standardized formats using Microsoft Excel software and transferred electronically (compressed with password protection) to the National Center in HIV Epidemiology and Clinical Research (NCHECR) for central aggregation. The initial baseline data presented was transferred in September 2003, with updated data provided in March and September each year. Ethical approval for the study was obtained from the University of New South Wales Ethics Committee. Each site also approached a local ethics committee for approval. Because all data forwarded to the NCHECR are collected in an anonymous fashion, informed consent of subjects was not a requirement, except if required by a site's local ethics committee.

Baseline data from the TAHOD patients transferred between September 2003 and May 2004 were summarized to characterize the cohort. In addition, the following analyses were based on retrospective data:

1. Rates of change in CD4 counts among patients not receiving antiretroviral treatment. Patients were included in analyses if they had 2 or more assessments available while not on antiretroviral treatment. Analyses were performed using linear regression.
2. The response to antiretroviral treatment over a 6-month period in terms of changes in CD4 count and HIV viral load in patients who had previously started highly active anti-retroviral treatment (HAART). Patients were included in analyses if they had at least 1 assessment before and at least 1 assessment after treatment.

CD4 count response was summarized as the average change in CD4 count from baseline to 6 months and was analyzed using linear regression. HIV viral load response was analyzed as the proportion reaching undetectable (<400 copies/mL) using logistic regression. In the second analysis, combination of antiretroviral treatment used was included as a covariate and was categorized into 3 treatment classes: combinations including a nucleoside reverse transcriptase inhibitor (NRTI) and/or a protease inhibitor (PI) but excluding a nonnucleoside reverse transcriptase inhibitor (NNRTI), combinations including at least 1 NNRTI but excluding PIs, and combinations including an NNRTI and a PI.

RESULTS

By the end of May 2004, 1887 patients had been recruited to the TAHOD (Table 1). Most patients were male, with median age of 36 years. The main ethnic groups were Chinese, Indian, and Thai. Most patients (78%) were infected through heterosexual contact. Forty-three percent of patients had a previous AIDS-defining illness, of whom 55% had tuberculosis and 31% had *Pneumocystis carinii* pneumonia. Eight percent of all the patients had a CDC category B illness, and 4% had a papular pruritic eruption (PPE) but without AIDS.

Three hundred sixty-two patients had more than 1 CD4 count reported retrospectively while not on antiretroviral treatment. The average rate of CD4 change (per month since the first CD4 count) was a decrease of 0.9 cells/μL (95% confidence interval [CI]: −5.0 to 3.2; $P = 0.6$). Retrospective data were available for 713 patients who had at least 1 CD4 count before starting HAART and another CD4 count 6 months (within 3–9 months) after starting HAART. The mean change was 115 cells/μL (standard deviation = 127; Table 2). Smaller CD4 count increases were associated with a higher CD4 count before starting treatment, prior treatment with monotherapy or double therapy, and treatment with a HAART regimen containing an NRTI and/or PI but without an NNRTI. Five hundred ninety-eight patients

had started HAART and had a viral load assessment after 6 months, with 69% reaching an undetectable viral load (Table 3). Older patients, patients not exposed to HIV through heterosexual contact, and patients treated with HAART containing an NRTI and NNRTI but without a PI were found to be more likely to achieve an undetectable level.

DISCUSSION

This article presents baseline and retrospective data from the initial phase of the TAHOD cohort. Among patients not on antiretroviral treatment, there was a nonsignificant decrease in CD4 count of 0.9 cells/μL each month. Among patients who started HAART and had a baseline and 6-month CD4 count measurement, the mean 6-month CD4 count increase was 115 cells/μL. Among patients who started HAART and had a viral load assessment at 6 months, 69% of patients had an undetectable viral load.

A higher rate of AIDS-defining illnesses at study entry was found among the TAHOD patients (43% of patients) compared with that found in cohorts in Western countries (18%–19% in Australia[4] and 21% in the Antiretroviral Cohort Collaboration[5]). More importantly, tuberculosis was the most frequently reported AIDS-defining illness among the TAHOD patients compared with those in Western countries, where *P. carinii* pneumonia and Kaposi's sarcoma are most common.[4,6]

The rate of CD4 change among the TAHOD patients while not on antiretroviral treatment was similar to the rate found in Western countries whether the patients were homosexual men (+0.24 to −42.7 cells per month in the United States[7] and −5.6 cells per month in the Netherlands[8]) or injecting drug users (−3.2 cells per month in Baltimore, MD, USA[9]).

Individuals treated with HAART experience reductions in viral load and restoration of CD4 cell counts. Smith et al[10] observed a monthly increase of 11.6 cells/μL after an increase of 97.2 cells in the first month among treatment-naive patients whose viral loads remained below 500 copies/mL for prolonged periods. In the EuroSIDA study, Mocroft et al[11] found that among 413 patients who received at least 3 drugs in which at least 1 new PI or NNRTI was included, 69% subsequently experienced at least a 1 log decline in viral load and 49% achieved a viral load <500 copies/mL. In the OzCombo trials,[12,13] naive patients administered 2 NRTIs plus indinavir experienced a mean CD4 count increase of 125 to 150 cells/μL at 6 months and 58% had an HIV viral load <50 copies/mL at 12 months, whereas naive patients receiving 2 NRTIs plus nevirapine experienced a mean CD4 count increase of 100 to 150 cells/μL and 70% to 80% achieved a viral load <50 copies/mL. Using retrospective data from the TAHOD, patients starting HAART experienced a mean CD4 count increase of 115 cells/μL at 6 months, with 69% of patients achieving an undetectable viral load, which was comparable to results from other studies in Western countries.

In our analyses, patients receiving a HAART regimen containing an NRTI and NNRTI but excluding a PI had better responses at 6 months after starting treatment in terms of CD4 count increases and HIV viral load. Although similar findings have been reported in other cohort studies,[14] this result may reflect selection biases to different treatment regimens at different sites within the TAHOD and should be interpreted cautiously. Our analyses also indicated that in terms of HIV viral load 6 months after starting HAART, patients infected with HIV through heterosexual contact seemed to respond more poorly than patients infected through homosexual contact. Unlike Galai et al,[15] who followed their patients from seroconversion, most patients in the TAHOD did not have a clear seroconversion date and might be at various stages of disease progression. Analyses of prospective data from the TAHOD, as such data become available, should provide more robust assessments of the effect of these and other covariates on patients' responses to HAART.

There are a number of limitations to be considered in relation to the findings. First, analysis of the rate of CD4 change and response to HAART in terms of CD4 cell count and viral load were based on retrospective data. With data transfer provided twice each year, prospective data will become available for further analyses. Second, the TAHOD patients, recruited based on clinicians' judgment of good follow-up, cannot be seen as entirely representative of HIV patients in the Asia-Pacific region. However, studies on the natural history of HIV disease and responses to antiretroviral treatment can still be derived from a cohort of TAHOD patients with good follow-up, albeit with some limitation on generalizability of findings. Third, there were variations in terms of diagnostic criteria and clinical definitions as well as assay technique or reagents across the TAHOD participating sites. Standardized data collection forms and data management training for each site were used to try to maximize consistency.[4]

Analyses of retrospective data in the TAHOD suggest that the overall response to HAART in Asian patient populations is similar to that seen in Western countries. The TAHOD is expected to recruit more than 2000 patients when fully recruited. Potential sites in countries such as Indonesia and Viet Nam are likely to contribute data to the TAHOD in the near future. With prospective follow-up, the TAHOD should be able to assess the natural history of HIV disease and response to antiretroviral treatments in patients from the Asia and Pacific region. Future analyses based on prospective follow-up data include identifying predictors of short-term risk of clinical progression and the risk and predictors of mycobacterial tuberculosis among the TAHOD patients.

Acknowledgments

The Therapeutics Research, Education, and AIDS Training (TREAT) network and the TREAT Asia HIV Observational Database (TAHOD) are funded by a grant from the American Foundation for AIDS Research. The National Centre in HIV Epidemiology and Clinical Research is funded by the Australian Government Department of Health and Ageing, and is affiliated with the Faculty of Medicine, The University of New South Wales.

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APPENDIX

The TREAT Asia HIV Observational Database: F. Zhang,[*] H. Zhao, and N. Han, Beijing Ditan Hospital, Beijing, China; P. Li[*] and M. P. Lee, Queen Elizabeth Hospital, Hong Kong, China; Y. M. A. Chen,[*] W. W. Wong, and D. C. C. Wang, Taipei Veterans General Hospital and AIDS Prevention and Research Center, National Yang-Ming University, Taipei, Taiwan; N. Kumarasamy,[*†] S. Anand, and J. A. Cecelia, YRG Center for AIDS Research and Education, Chennai, India; S. Pujari[*] and K. Joshi, HIV Project, Ruby Hall Clinic, Pune, India; C. K. C. Lee[*] and S. Kaur, Hospital Kuala Lumpur, Kuala Lumpur, Malaysia; A. Kamarulzaman[*] and S. Kaur, University of Malaya, Kuala Lumpur, Malaysia; R. Ditangco[*] and R. Capistrano, Research Institute for Tropical Medicine, Manila, The Philippines; N. I. Paton[*] and M. Yap, Tan Tock Seng Hospital, Singapore; P. Phanuphak,[*] U. Siangphe, and M. Khongphattanayothing, HIV-NAT/The Thai Red Cross AIDS Research Center, Bangkok, Thailand; A. Vibhagool,[*] S. Kiertiburanakul, and W. Kiatatchasai, Ramathibodi Hospital, Bangkok, Thailand; J Chuah,[*] W. Fankhauser. and B. Dickson, Gold Coast Sexual Health Clinic, Miami, Queensland, Australia; K. Frost[*] and S. Wong, American Foundation for AIDS Research, New York, NY, USA; D. A. Cooper,[*] M. G. Law,[*] K. Petoumenos, and J. Zhou,[*] National Center in HIV Epidemiology and Clinical Research, the University of New South Wales, Sydney, Australia.

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TABLE 1

Patient Characteristics and Prior AIDS-Defining Illness

Total	1887	First year diagnosed with HIV (114 missing)	
Age (y) at entry to TAHOD (6 missing)		Before 1997	229 (13%)
Median (range)	36 (18–90)	1997–1999	440 (25%)
<20	4 (<1%)	2000–2002	800 (45%)
20–29	270 (14%)	2003–2004	304 (17%)
30–39	915 (49%)	CDC clinical classification for HIV infection*	
40–49	459 (24%)	Category A	926 (49%)
50+	233 (12%)	Category B	156 (8%)
Gender		Category C	805 (43%)
Male	1353 (72%)	Baseline CD4 count† (cells/μL) (222 not tested)	
Female	533 (28%)	<50	135 (8%)
Transgender	1 (<1%)	50–199	381 (23%)
Ethnicity		200–499	841 (50%)
Chinese	826 (44%)	500+	308 (19%)
Indian	442 (24%)	Median (range)	291 (0–1472)
Thai	420 (22%)	Baseline HIV viral load† (copies/mL) (796 not tested)	
Philippine	121 (6%)	Not detectable (<400 copies/mL)	692 (63%)
Malay	47 (2%)	400–10,000	141 (13%)
Caucasian	19 (1%)	10,000+	258 (24%)
Other	12 (1%)	Median (range)	399 (399–7,500,000+)
Exposure category (34 missing)		Antiretroviral treatment at entry to TAHOD	
Heterosexual contact	1453 (78%)	Not on treatment	517 (27%)
Homosexual contact	216 (12%)	Mono/double therapy	97 (5%)
Reception of blood/product	67 (4%)	3+(NRTI ± PI − NNRTI)‡	241 (13%)
Heterosexual contact and IDU	33 (2%)	3+(NRTI + NNRTI − PI)‡	961 (51%)
IDU only	13 (1%)	3+(NNRTI + PI ± NRTI)‡	71 (4%)
Other	72 (4%)		

Prior AIDS-Defining Illness§	No. Patients	% AIDS Patients	Prior AIDS-Defining Illness§	No. Patients	% AIDS Patients
Mycobacterial tuberculosis	439	54.5	Cryptosporidiosis	11	1.4
Pneumocystis carinii pneumonia	253	31.4	Cytomegalovirus	8	1.0
Desophageal candidiasis	61	7.6	Recurrent pneumonia	8	1.0
Cryptococcosis/extrapulmonary	55	6.8	Histoplasmosis	5	0.6
Herpes simplex	51	6.3	Kaposi's sarcoma	5	0.6
Cytomegalovirus retinitis	50	6.2	Leukoencephalopathy	4	0.5
Toxoplasmosis	49	6.1	HIV encephalopathy	3	0.4
Salmonella septicemia	40	5.0	Lymphoma/brain	3	0.4
Nontuberculosis mycobacterial diseases	35	4.4	Lymphoma/Burkitt	2	0.3
Candidiasis/bronchi, trachea, lung	32	4.0	Isosporiasis	1	0.1
Penicilliosis	26	3.2	Lymphoma/immunoblastic	1	0.1

Prior AIDS-Defining Illness[§]	No. Patients	% AIDS Patients	Prior AIDS-Defining Illness[§]	No. Patients	% AIDS Patients
HIV wasting syndrome	24	3.0			

[*] According to Centers for Disease Control and Prevention's 1993 revised classification for HIV infection.

[†] CD4 count, HIV viral load measured at time of entry to TAHOD (CD4 within 180 days, HIV viral load within 365 days).

[‡] HAART: 3 + (NRTI ± PI − NNRTI), combination of 3 or more drugs includes NRTI and/or PI but excludes NNRTI; 3 + (NRTI + NNRTI − PI) combination of 3 or more drugs includes NRTI and at least 1 NNRTI but excludes PI; 3 + (NNRTI + PI ± NRTI), combination of 3 or more drugs includes NNRTI and PI and/or NRTI.

[§] Patients can report more than 1 prior AIDS-defining disease but only the first AIDS-defining disease of each type was counted per patient.

IDU, injecting drug user.

TABLE 2

Factors Associated With Change in CD4 Counts Among Patients Receiving HAART Treatment

			Univariate Analysis		Multivariate Analysis	
	No. Patients	**Mean CD4 (cells/μL) Change**	**Difference***	***P***	**Difference***	***P***
Gender						
Male	552	119.4				
Female	161	98.4	−21.0	0.064	−15.4	0.175
Age (y) when HAART started						
<31	174	112.8				
31–40	335	122.8	10.0	0.398	2.8	0.808
41+	203	102.8	−10.0	0.444	−12.7	0.323
Not known	1	125.0				
Exposure category						
Heterosexual contact	546	117.6				
Other	167	104.9	−12.7	0.257	−3.0	0.787
Baseline CD4 count (cells/μL)						
<200	548	119.3				
200–350	117	117.3	−2.0	0.876	−1.9	0.886
351+	48	54.7	−64.6	0.001	−50.3	0.008
HAART (3 or more drugs)						
NRTI ± PI − NNRTI	245	84.2				
NRTI + NNRTI − PI	446	131.9	47.7	<0.001	29.9	0.004
NNRTI + PI ± NRTI	22	105.2	21.0	0.451	34.1	0.213
Having mono/double therapy before starting HAART						
No	486	133.7				
Yes	227	73.9	−59.8	<0.001	−54.2	<0.001

* Difference were compared with the first category of each variable.

TABLE 3

Factors Associated With HIV Viral Load Below Detectable Level Among Patients Receiving HAART Treatment

			Univariate Analysis		Multivariate Analysis	
	No. Patients	**No. HIV Viral Load Undetectable (%)**	**OR**	***P***	**OR (95% CI)**	***P***
Gender						
Male	443	300 (68%)				
Female	155	115 (74%)	1.4	0.133	1.5 (0.9–2.3)	0.077
Age (y) when HAART started						
<31	133	88 (66%)				
31–40	265	176 (66%)	1.0	0.960	1.1 (0.71–1.8)	0.623
41+	198	151 (76%)	1.6	0.045	1.8 (1.1–3.1)	0.017
Not known	2	0 (0%)				
Exposure category						
Heterosexual contact	437	307 (70%)				
Homosexual contact	98	75 (77%)	1.4	0.215	1.9 (1.1–3.2)	0.023
Other	63	33 (52%)	0.5	0.005	0.4 (0.2–0.6)	0.001
Baseline viral load test (copies/mL)						
<5000	78	57 (73%)				
5000+	299	196 (66%)	0.7	0.209	0.7 (0.4–1.2)	0.170
Not tested before	221	162 (73%)	1.0	0.969	0.8 (0.5–1.6)	0.569
HAART (3 or more drugs)						
NRTI ± PI − NNRTI	260	166 (64%)				
NRTI + NNRTI − PI	312	229 (73%)	1.6	0.014	1.7 (1.2–2.6)	0.006
NNRTI + PI ± NRTI	26	20 (77%)	1.9	0.188	2.0 (0.8–5.2)	0.168
Having mono/double therapy before starting HAART						
No	380	273 (72%)				
Yes	218	142 (65%)	0.7	0.087	0.7 (0.5–1.0)	0.067