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Outcome of HAART in patients with tuberculosis in the Themba Lethu clinical cohort

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DECLARATION

I, Zeh Akiy Zacheaus (student number: 0705645J) am a post-graduate student registered for the degree / programme Msc Med in Epidemiology and Biostatistics in the Wits School of Public Health.

I am submitting this research report as partial fulfillment; to the award of the fore mentioned degree and hereby declare the following:

- I confirm that the work submitted for the above course and module, is my own work, except where I have stated otherwise
- I have followed the required conventions in referencing the thoughts and ideas of others

Signature: Date:

DEDICATION

This work is gratefully dedicated to my late father Mr. Akiy Buh Donatus and all my nephews and nieces; Javea, Denzel, Mbong, Angel and Afoh.

Zeh Akiy Zacheaus

January 2007

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LIST OF ABBREVIATIONS

AIDS	Acquired Immune Deficiency Syndrome.
ALT	Alanine Aminotransferase.
ART	Antiretroviral Therapy.
ARV	Antiretroviral.
AST	Aspartate Aminotransferase.
BMI	Body Mass Index.
CD_4	Glycoprotein surfaces helper T cells act as receptor for HIV.
CDC	Centers for Disease Control and Prevention.
CHRU	Clinical HIV Research Unit.
CI	Confidence Interval.
CSV	Comma Seperated Value.
HAART	Highly Active Antiretroviral Therapy.
Hb	Hemoglobin.
HIV	Human Immunodeficiency Virus.
HJH	Helen Joseph Hospital.
KM	Kaplan Meier.
LFT	Liver Function Test.
MTB	Mycobacterium tuberculosis.
PEPFAR	President's Emergency Plan for AIDS Relief.
RR	Rate Ratio.
SAS	Statistical Analysis Software.
SSA	Sub-Saharan Africa.
TB	Tuberculosis.
TB-	Tuberculosis Negative.
TB+	Tuberculosis Positive.
TLC	Themba Lethu Clinic.
UNAIDS	Joint United Nations Programme on HIV/AIDS.
USAID	United States Agency for International Development.
WHO	World Health Organization.

ABSTRACT

Introduction: The burden of disease due to HIV/AIDS and tuberculosis remains great for many countries around the world. Continuing attention must be devoted to these epidemics if we ever hope to one day contain their devastating effects on humankind. The objective of this study is to; to evaluate and compare cohort treatment outcomes of HIV infected TB patients and HIV infected non-TB patients treated with HAART at the Themba Lethu Clinic between 1st April 2004 and 1st April 2007. To measure outcomes in CD_4, viral load, hemoglobin, liver function tests, weight, BMI, loss to follow up and death and to compare this outcomes between HIV patients who have had TB and HIV patients who have never had TB.

Materials and Methods: information collected of patients for three years shall be used to carry out analysis. A total of 5818 patients were included in the cohort sample. 19.23% (1,048) of the patients had been diagnosed with TB at some point in time while 80.77% (4,770) had never been diagnosed with TB. Mean baseline CD_4 cell counts were 113.47cells/mm^3 for non TB patients and 88.85cells/mm^3 for those who have ever had TB. This baseline CD_4 counts are considered 2 months prior to ARV start and 1 month post the start of ARV. Baseline means for weight, BMI, AST and ALT were also taken into consideration by the two patient groups. Clinical out come was assessed and evaluated by comparing incidence of designated end points either as survival or failures. Incidence of deaths and loss to follow up was also compared in the two groups of patients.

Results: Among HIV non TB patients, incidence rate of them having CD_4 counts greater than 200 was at 36.47 persons per 10000 person days while for the patients who had been diagnosed with TB incidence of CD_4 rising to above

200 was lower at 34.19persons per 10000 person days. A rate ratio of 0.94 (95% CI 0.85 - 1.03) showed no true difference in the two groups. When looking at deaths in the two groups of patients, incidence in those who had TB was 3.84 deaths per 100 patient years and 4.16 deaths per 100 patient years for the non TB group with RR 0.93 and CI 0.66 - 1.28. Differences in incidence and outcomes were noticed in Hb gain, weight and BMI change, Liver function test changes over time and loss to follow up "defaulters". Survival curves were modeled to show trend of change and log rank test were used to ascertain equality of survival curves. Where log rank p. values < 0.05 were noticed among survival curves of weight, BMI, AST, ALT, Hb and Loss to follow up. This again showed differences in weight, BMI, hemoglobin, AST, ALT and loss to follow up while no statistical differences were recognized between the two groups of patients when considering changes in CD_4, deaths and Viral load over time as log rank test failed to reject the null hypothesis of similar curves.

Conclusion: Data indicated that similarity and differences between HIV TB patients and HIV non TB patients could vary along certain outcomes. But one sure point is both groups of patients had an equal chance of staying alive when properly treated with ARV/HAART.