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**THE IMPACT OF HIGHLY
ACTIVE ANTIRETROVIRAL THERAPY
(HAART) IN SELECTED PRIVATE CLINICS
IN LUSAKA**

by

KASEYA O.R.CHIYEÑU MD

Thesis
(M. Med.)

Chi

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A dissertation submitted in partial fulfillment of the requirements for the Degree of Master of Medicine (Internal Medicine) of the University of Zambia

University of Zambia
School of Medicine



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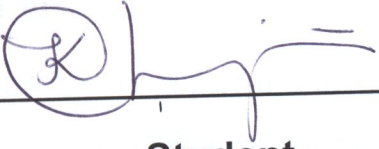
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DECLARATION

I hereby declare that the work presented in this study for the Master of Medicine has not been presented either wholly or partially for any other degree and is not being currently submitted for any other degree.

Signed  _____
Student

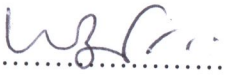


Signed  _____
Supervisor

Signed  _____
Co-supervisor

APPROVAL PAGE

This dissertation of OLIVER CHİYENU has been approved as fulfilling the requirements or partial fulfillment of the requirements for the award of Master of Medicine in INTERNAL MEDICINE by the University of Zambia.

Examiners

1. Signature.....  Date..... 1/06/05
- 2.. Signature.....  Date..... 01.06.05
3. Signature.....  Date..... 01/06/05

DEDICATION

I would like to dedicate this work to all those who have had the courage to face the monster and stare it down and never say die. Those who have had the courage to test and take treatment in an effort to relish the value that the near loss of life brings to life. Life, which we all long to improve one way or another. And now we think that our labours are worth the while because they are not overwhelmed with daily loss and failure as before. To these I say "muchismas gracias" for this invaluable gift of an extra lease on life and hope.

Kaseya

ACKNOWLEDGEMENTS

I would like to acknowledge the following people:

My parents, whom I hardly see these days, for their patience with my supposed preoccupation with work. For understanding when I said I needed time to do this.

Dr. Peter B. Mwaba, for the contagious enthusiasm with research and academics. For bothering as though it was yours. "Just bring what you have done and let's see!!!"

Dr. Isaac S. Zulu, for taking some of us under your wing and never looking at how difficult and hesitant the first few steps were. I wish you had shouted sometimes!

To all the MMED students in the Department of Medicine, who are under so much pressure. We just might make it here!!

ABBREVIATIONS

AIDS: Acquired Immune Deficiency Syndrome

ARVs: Antiretrovirals

ZDV- Zidovidine

MCTC: Mother to child transmission

HAART: Highly Active Antiretroviral Therapy

HIV: Human Immunodeficiency Virus

USA: United States of America

UTH: University Teaching Hospital

SUMMARY

INTRODUCTION

Use of Highly active antiretroviral drugs has been shown to improve quality of life and morbidity and mortality of HIV infected patients.

AIM:

To determine the impact of highly active antiretroviral therapy in Zambia.

METHODS:

A retrospective study of the review of 364 patients' files in four private clinics in Lusaka was carried out.

RESULTS:

A review of 364 patients' files was done. 165 patients were ineligible because results of HIV tests done were not available and one clinic refused to give consent to carry out the study. We therefore report on 199 files of patients treated with antiretroviral therapy. 110 were female and 87 were male and 2 had gender unrecorded. Cumulative decrease in admissions was noted. CD 4+ count values. A total of 6 patients in total had died during the period being reviewed.

CONCLUSION:

The study showed that the use of antiretroviral therapy reduced the morbidity and mortality in HIV infected patients.

6.0 INTRODUCTION

The advent of HIV/AIDS has brought pessimism to the practice of medicine, especially in the developing world. More so because of the discrepancy between the advances made in the knowledge of the biology of the human immunodeficiency virus (HIV) that causes the acquired immune deficiency syndrome (AIDS) and how far away medical science is from a cure to this deadly disease.¹ But the introduction of antiretroviral therapy for the treatment of HIV infection has ushered in another dimension to the management of HIV infection. With the widespread use of highly active antiretroviral therapy (HAART) in developed countries there has been a decline in the morbidity and mortality of HIV infected patients.²⁻⁶ The management of HIV infection has fast moved from that of solely prevention to treatment.

Prevention benefits only those who are not yet infected with the HIV, and those who are already infected do not benefit from prevention methods; their requirement being treatment, whether curative or otherwise, without which opportunistic infections and death are inevitable.

7.0 LITERATURE REVIEW

In Zambia, the HIV epidemic has taken its toll with a total number of people living with AIDS totalling 1,200, 000, of these 1,000,000 are adults and about 590, 000 are women.⁷ The prevalence of HIV on the general population has, however, declined⁸⁻⁹; and the last UNAIDS report revealed that HIV prevalence among urban women aged 15-29 had declined from 28.3% in 1996 to 24.1% in 1999. Among rural women of 15-24 years a similar decline was reported with the prevalence falling from 16.1% to 12.2%. The adult prevalence at the end of 2001 was 21.5%,⁷ although this was aggressively disputed by the Zambian government¹⁰. Recent national data reflect a further decline to 16% by the end of 2002.¹¹ In underdeveloped countries where antiretroviral (ARVs) drugs are unavailable the morbidity and mortality are high.¹²

Among the local people in Zambia there is much speculation on the treatment of HIV infection. This has been compounded by the seeming absence of a cure for HIV. As a result it is very easy for a people already accustomed to consulting traditional healers and so-called witch-doctors to seek solutions from anyone with claims of a cure. The claims to a cure are associated with various practices, such as having sex with a virgin, a daughter or a sister, including the use of herbs and legumes. HAART has been in use in Zambia since 1997, and has been prescribed mainly by private practitioners. Public hospitals and clinics run by the Government have been unable to provide ARVs, therefore, patients who come to government hospitals may not have

access to HAART. Lately, the government has begun a programme to supply ARVs to some hospitals in the country.

Studies in many developed countries have shown that the use of Highly Active Antiretroviral Therapy (HAART) has reduced the mortality and morbidity in HIV infected patients.²⁻⁶ This has brought about prolonged survival and symptom free periods among HIV infected patients.^{3, 13-14} However, in underdeveloped countries where antiretroviral therapy is not so readily available (due to costs) HIV patients are still plagued with opportunistic infections and mortality.

It is a paradox that countries in sub-Saharan Africa who form 10% of the world's population account for two-thirds of the world's total burden of disease, with a total of about 28, 500, 000 people infected with HIV by the end of 2001,¹⁵⁻¹⁶ and have the least access to life saving antiretroviral drugs.

The search for a cure has led to tremendous strides in how to combat HIV infection. Since zidovudine (ZDV) was introduced in 1987,¹⁷ the treatment of HIV infection has progressed from monotherapy, to double therapy, to triple therapy; with quadruple therapy now being advocated.¹⁸⁻¹⁹

For some time ZDV showed efficacy²⁰ in the treatment of AIDS and AIDS-related diseases. Double-therapy later showed greater efficacy than monotherapy.²¹⁻²³ And now, studies have shown that triple therapy (HAART) is superior to double-therapy in slowing down progression to AIDS.²⁴

8.0 JUSTIFICATION

Until now no study has been done in Zambia to document the use of HAART and its benefits in HIV infected individuals, even though HAART has been used in Zambia since 1997, especially in private practice.

The recent decision by the Government of the Republic of Zambia to embark on a pilot program to provide antiretroviral agents in select centres all over the country is based on reports from other countries on the benefits of HAART. A local study documenting the benefits of HAART in HIV infected patients within Zambia would lend greater credence to Government spending on ARVs.

This study documents the impact of HAART on morbidity and mortality in a resource limited country such as Zambia and compares with results in developed countries that are using ARVs for the treatment of HIV infection.

In addition, positive benefits should help dispel the perception that there is completely no hope for people infected with HIV. AIDS in developing countries has been associated with certain death, and the diagnosis of HIV infection is usually considered a death sentence.

The knowledge of the benefits of HAART may help motivate and increase the number of people who volunteer for HIV testing, which may in turn reduce the number of inadvertent infection with HIV and enhance the efforts made towards the prevention of infection.

9.0 OBJECTIVES

9.1 GENERAL OBJECTIVE

To study the impact of HAART on morbidity and mortality in patients seen at 4 private clinics in Lusaka, Zambia.

9.2 SPECIFIC OBJECTIVES

1. To determine the frequency of opportunistic infections before and after introduction of HAART
2. To determine the frequency of admissions for HIV related diseases before and after introduction of HAART

10.0 METHODOLOGY:

This was a retrospective study involving the review of patients' files who were and are seen at four Private Clinics for the treatment of HIV infection between the periods 1994 and 2002. The clinics were selected on because they have been treating HIV patients for the duration required by the protocol. The files were reviewed from the time the patient was first diagnosed as HIV positive. They were selected at random consecutively after every three files. Demographic data was collected, and incidences of opportunistic infections, admissions and mortality were also being recorded.

10.1 SETTING:

The study was carried out in 4 Private Clinics located in Lusaka.

MUTTI Clinic

CO-OPMED Clinic

St. John's Medical Centre

Hilltop Hospital

10.2 STUDY DESIGN

This was a retrospective study reviewing the records of patients on antiretroviral therapy at 4 private clinics in Lusaka.

10.3 STUDY SAMPLE SIZE

The sample size was calculated using EPI INFO 6.02 and to achieve 95% power 364 case records were randomly selected and reviewed. One clinic refused to give consent for the review of it's patients' files and at another clinic the majority of patients failed to meet some of the inclusion criterion as there was no record of them having had an HIV test before they started taking antiretroviral therapy.

10.3.1 INCLUSION CRITERIA

1. Age 16 and above
2. Tested HIV positive
3. Registered as attendant of any of the clinics mentioned

10.3.2 EXCLUSION CRITERIA

1. Age below 16 years
2. Tested HIV negative
3. Non-attendance to the clinic.

10.4 DATA COLLECTION PROCEDURE

Data was collected consecutively and randomly by the Principal investigator, with the help of 4 assistants and analyzed by a statistical analyst. The data was entered on Microsoft Access and analyzed using Epi Info 6.02.

10.5 ETHICAL CONSIDERATIONS

Permission was sought from and granted by the Research Ethics Committee of the University of Zambia; and permission was also sought from the four clinics where the research was to be carried out. There was no direct contact with the patients and the information obtained from the patients' record files was kept confidential.

11.0 RESULTS

One hundred and ninety-nine patients files were selected for review in the study, One hundred and sixty five were not reviewed. One private clinic did not give permission to have the patients' files reviewed because they were not convinced their patients' confidentiality would be maintained. At another clinic most of the patients were ineligible because we were unable to locate their HIV test results.

Of the total 199 patients, 110 were female, 87 were male and 2 did not have gender recorded (fig. 1). 188 were African, 2 were Asian, 4 Caucasian and 5 were not identified by race (fig. 2). The marital status revealed that 64% (119) of those seen were married, 17.2% (32) were single, 15.1% (28) were widowed, 3.2% (6) divorced and 0.5% (1) was separated.

The frequency of admissions was noted to have reduced over time. The admissions on initial diagnosis were 5.0% and 17.6%, and subsequent admissions showing a downward trend, with the last recorded admissions totaling 3% of the total seen. 6 deaths in total had been recorded. And the CD 4+ count showed an upward trend from the time of initial diagnosis to the last recorded readings.

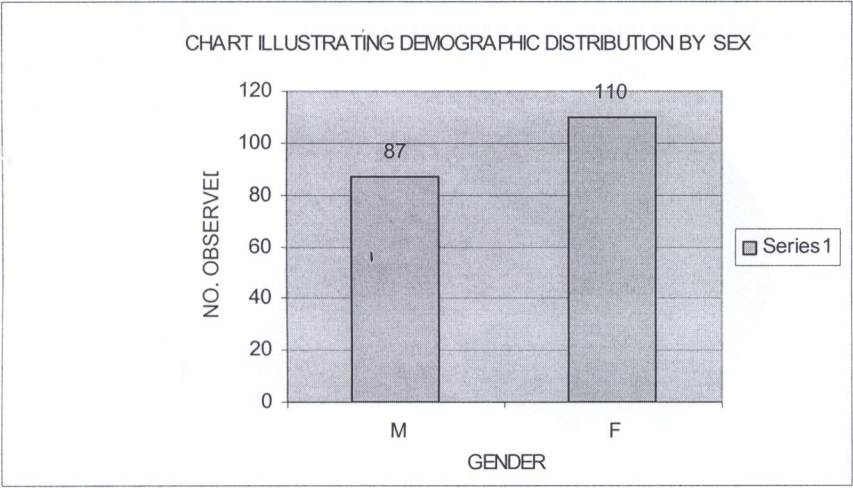


FIGURE 1: Distribution by Sex

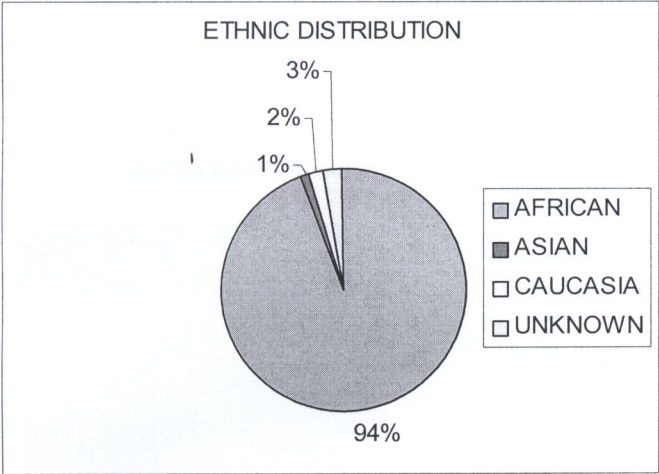


FIGURE 2: Distribution by race

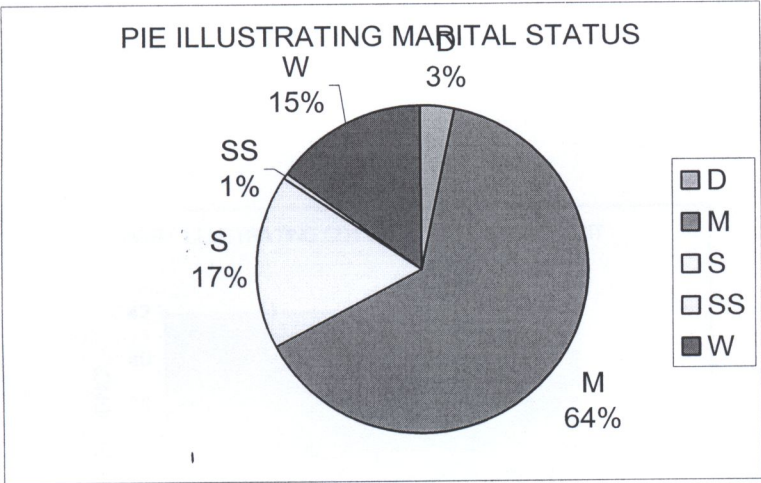


FIGURE 3: Distribution by marital status

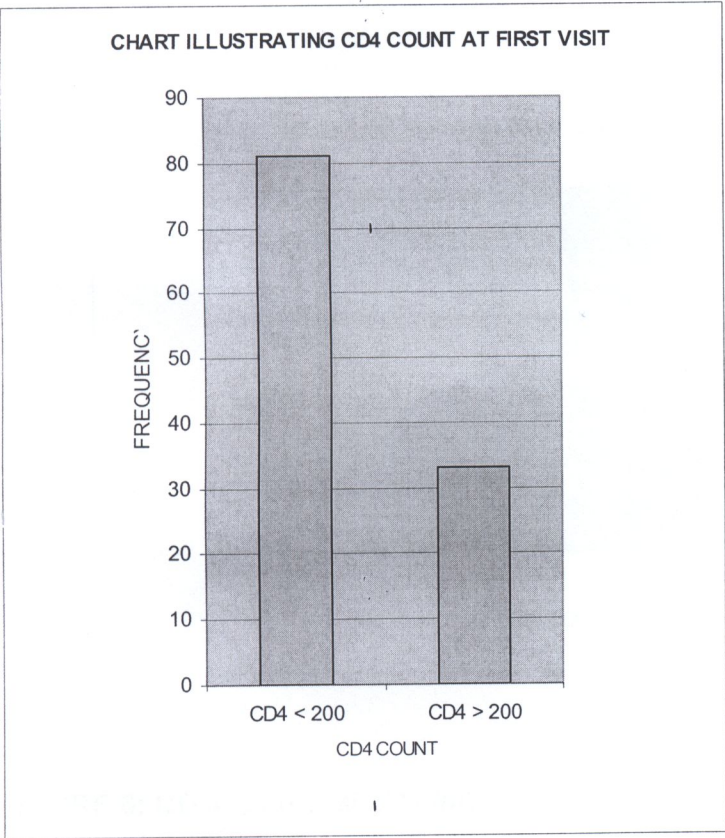


FIGURE 4: CD4+count at 1st visit

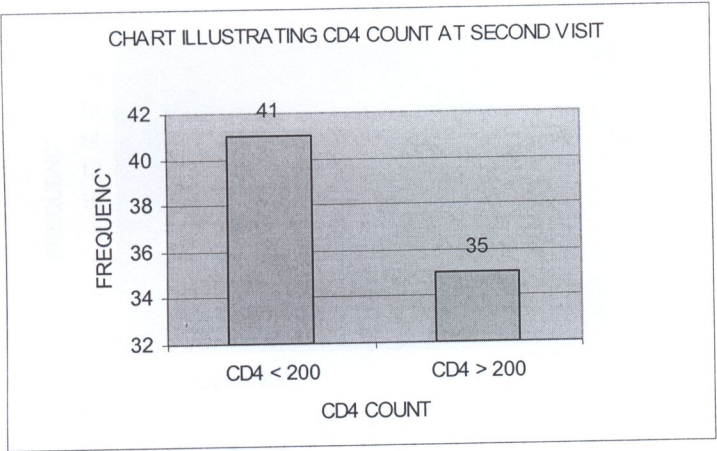


FIGURE 5: CD 4+count at 2nd visit

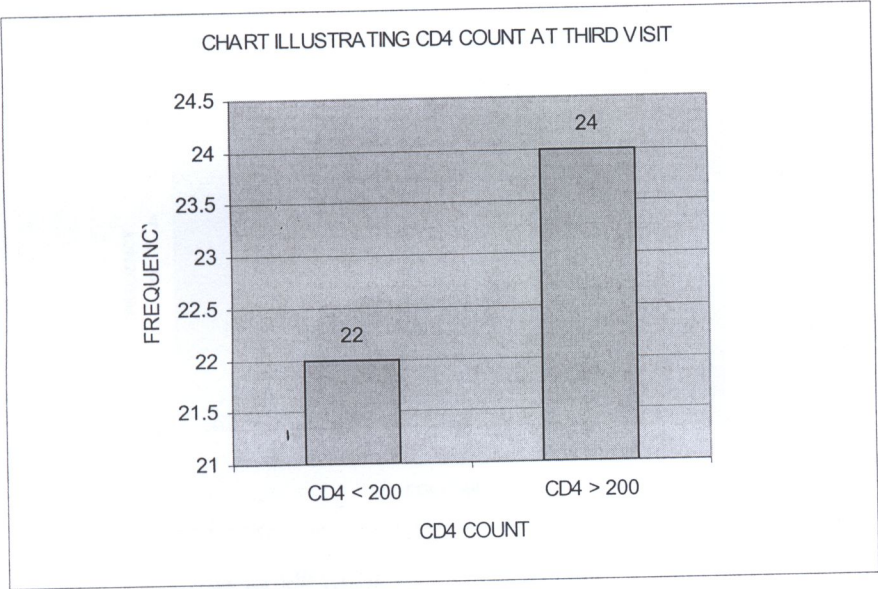


FIGURE 6: CD 4+count at 3rd visit

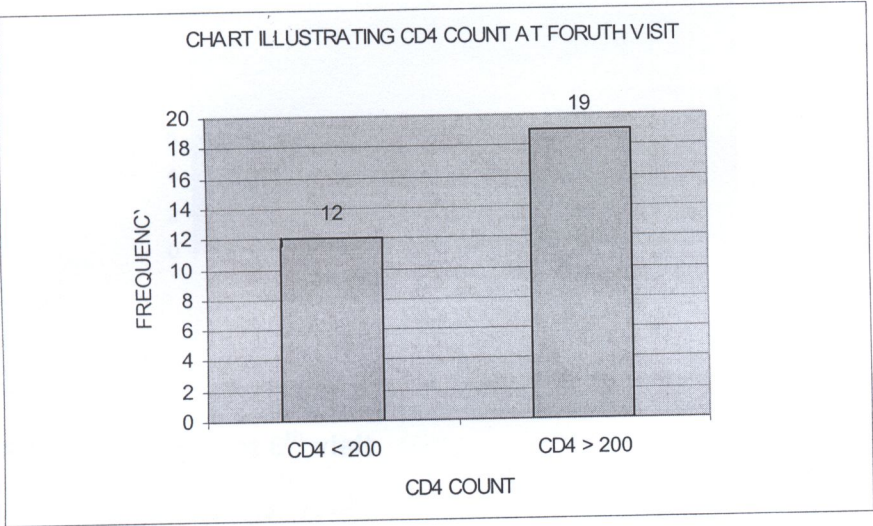


FIGURE 7: CD 4+count at 4th visit

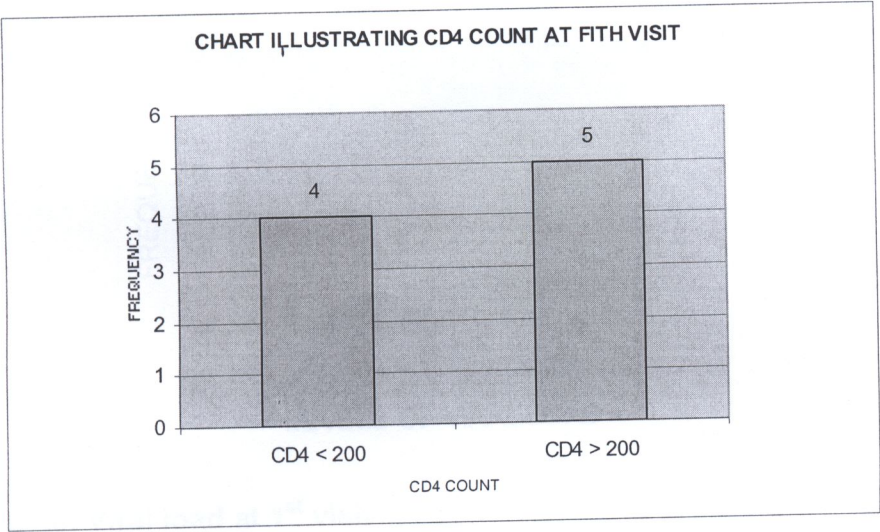


FIGURE 8: CD 4+count at 5th visit

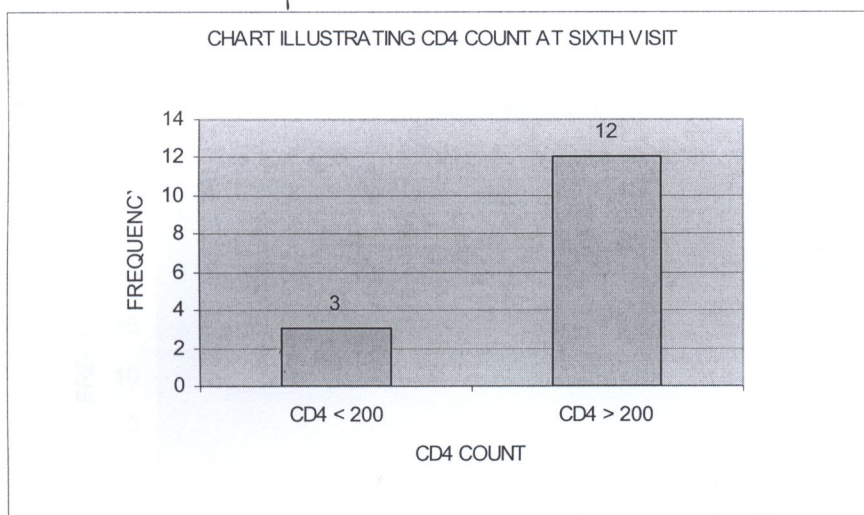


FIGURE 9: CD4+count at 6th visit

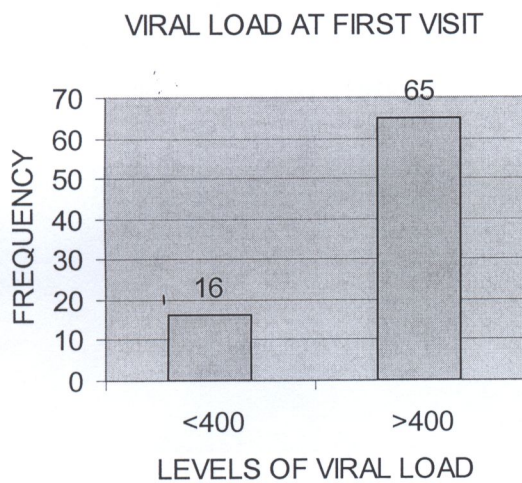


FIGURE 10: Viral load at 1st visit

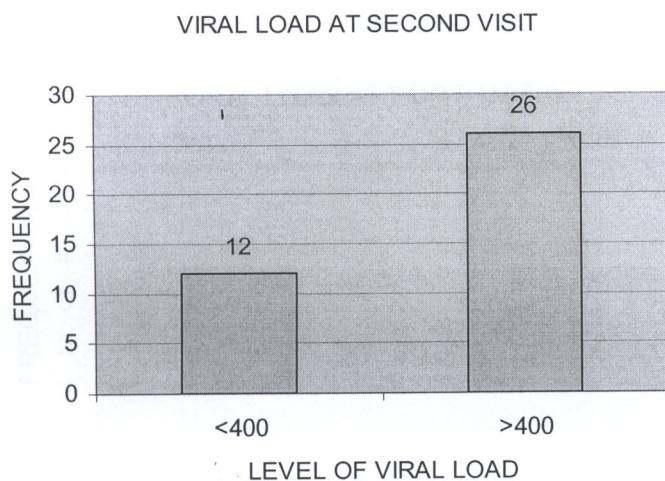


FIGURE 11: Viral load at 2nd visit

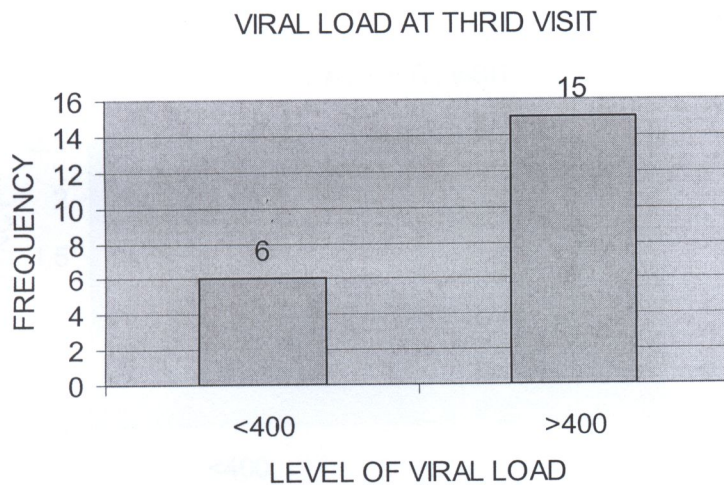


FIGURE 12: Viral Load at 3rd visit

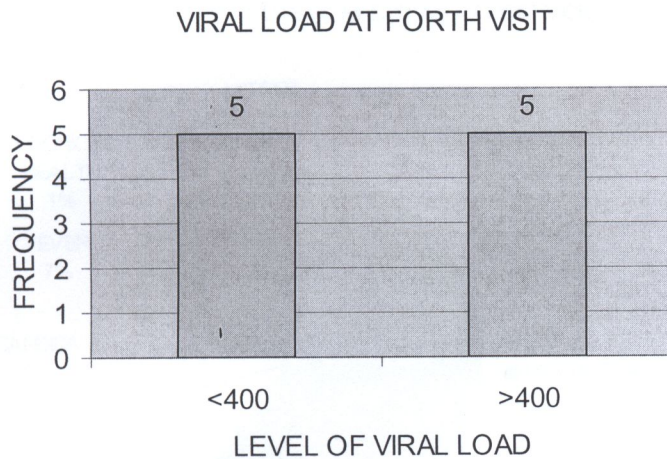


FIGURE 13: Viral Load at 4th visit

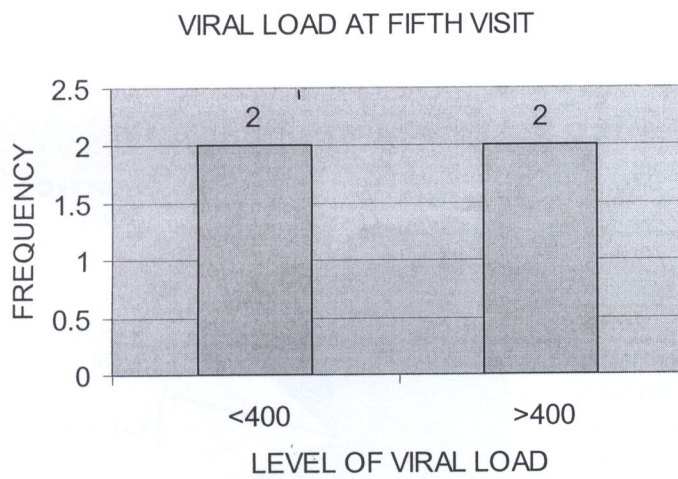


FIGURE 14: Viral Load at 5th visit

PIE ILLUSTRATING OPPORTUNISTIC INFECTIONS AT FIRST VISIT

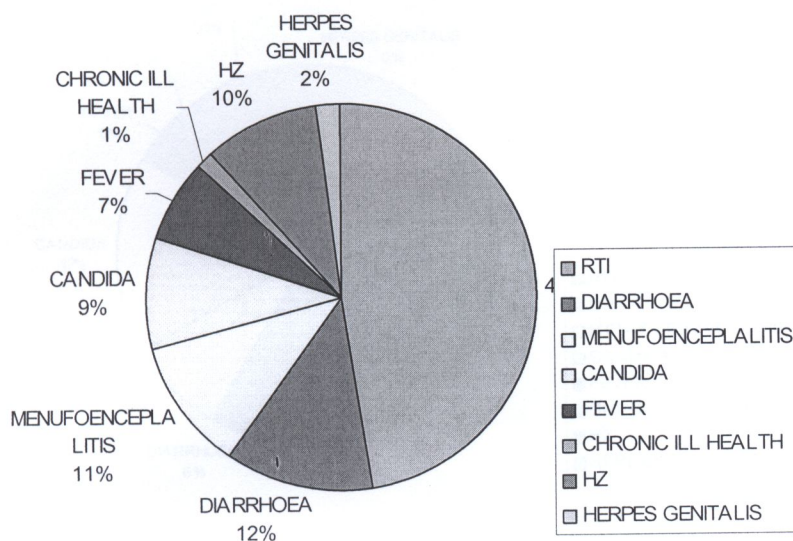


FIGURE 15: Opportunistic infections at 1st visit before HAART

PIE ILLUSTRATING OPPORTUNISTIC INFECTIONS AT 2ND VISIT

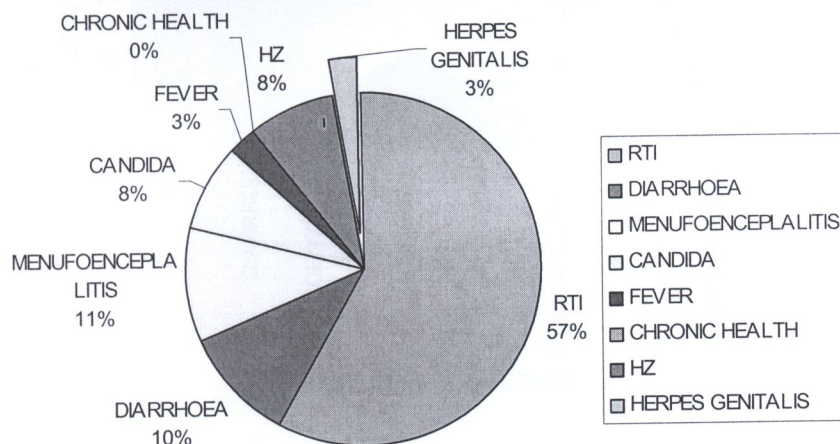


FIGURE 16: Opportunistic infections at 2nd visit before HAART

PIE ILLUSTRATING OPPORUNISTIC INFECTIONS AT 3RD VISIT

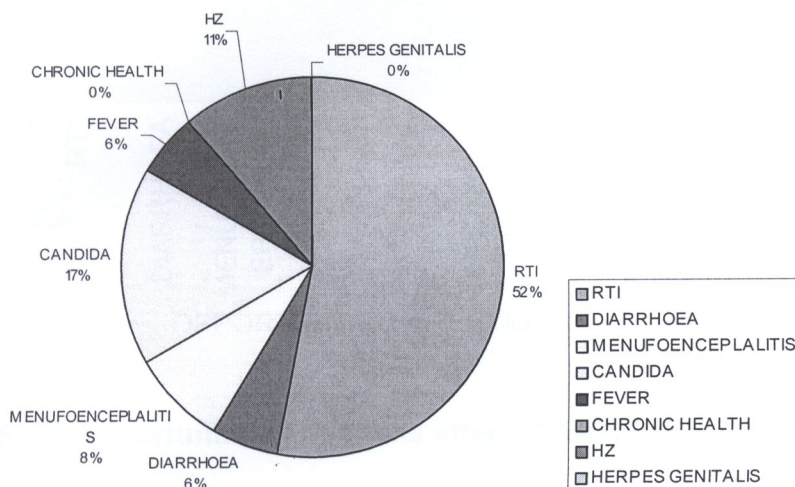


FIGURE 17: Opportunistic infections at 3rd visit before HAART

GRAPH ILLUSTRATING OPPORTUNISTIC INFECTION (AFTER) 1.

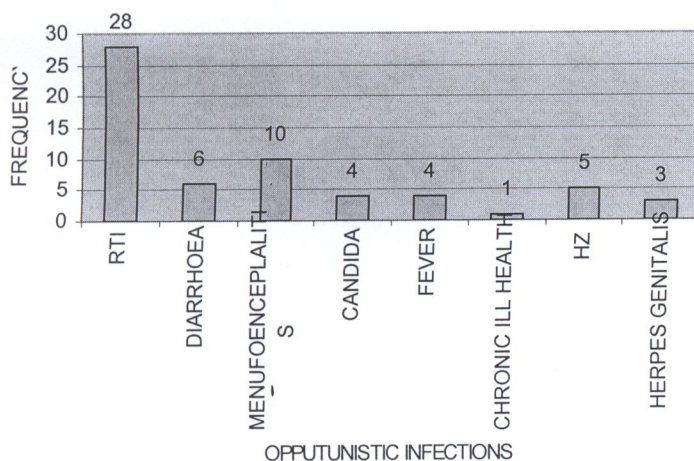


FIGURE 18: Opportunistic infections after HAART, first review

GRAPH ILLUSTRATING OPPORTUNISTIC INFECTIONS
(AFTER 2.)

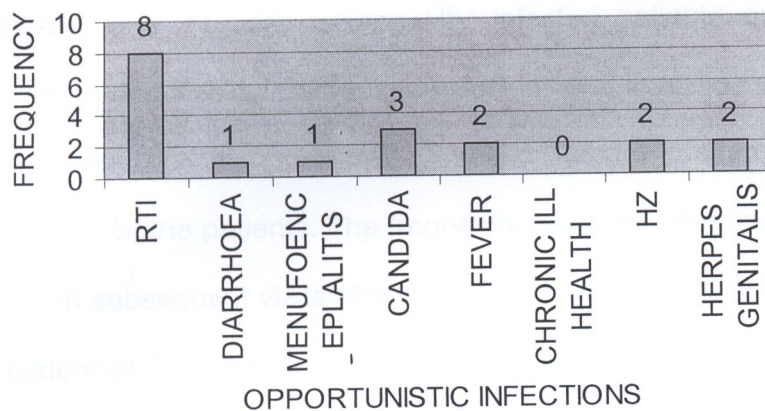


FIGURE 19: Opportunistic infections after HAART, second review

13.0 DISCUSSION

Overall, the study shows that the use of antiretroviral therapy reduces morbidity and mortality among HIV infected patients as evidenced by a corresponding rise in CD4+, reduction in viral load, increase in weight, an overall reduction in opportunistic infection, and improvement in the general well being of the patients. The frequently recorded "chronic ill health" is hardly found in subsequent visits after starting HAART. These findings coincide with experiences from previous research in developed countries. Most patients attended to had a long history of ill health and the institution of ARVs improved their quality of life and general well being.

The reduction in hospital admissions and opportunistic infections after starting HAART ultimately make HIV/AIDS a disease that can be managed on an outpatient basis as most chronic disease like hypertension and diabetes are managed.

The use of ARVs did not uniformly reduce morbidity nor mortality of each patient that was administered the drugs. In some cases the use of ARVs did not alter the progression of disease to death.

Instances of monotherapy and dual therapy were noted. These were attended with a poor clinical outlook and progressive decline in patients' health. This coincides with what has been reported in literature. The use of increasing combination therapy showed better response to treatment and improvement in quality of life. The continued use of monotherapy or dual therapy in this present era of HAART can only be attributed to lack of training on the part of the medical practitioner. It is hard to find justifiable reason in accusing a poor or erratic supply of drugs as they are in abundant supply; some may even be

obtained over the counter. And in addition, the majority of patients who attend private clinics can afford ARVs.

The arbitrary change of drug regimens was also quite evident in this study, in some cases with no reason given. This is evidenced by the paucity of recording of adverse events. In some cases, drugs abandoned in an initial regimen are introduced at a later date. This raises the question of resistance. Wanton prescribing of ARVs will inevitably introduce iatrogenic resistance to ARVs and a resource limited country can ill afford an epidemic of drug resistant strains.

The loss to follow-up is undermined in this study partly because it was an unforeseen difficulty as assumption is made that the patient is eager to get relief from his disease. But the long periods noted between one visit and the next, the irregular lengths of periods between one review and another may be explained by patients not coming to the clinic either because they feel better and see no need for medical attention, only to reappear worse off than before. Could the avoidance of further review be due to the high cost of drugs and investigations; or indeed the unstructured and high frequency of investigations (especially CD4+ and Viral Load) be a factor in the loss to follow-up, making these health institutions patient unfriendly. While the Government lobbies for lower prices for antiretroviral drugs from drug manufacturers the health institutions are unbridled in how much they charge for the management of HIV/AIDS.

Increased and improved use of HAART and lower costs of management (investigations and treatment) of HIV/AIDS would see a larger number of

people getting access to ARVs, improved quality of life of patients, reduction of opportunistic infections and reduced admissions which would in turn reduce the amount on money spent on hospitals and clinics via subsidies.

12.0 LIMITATIONS

The study was limited by

1. The choice of private clinics introduces a selection bias as this represents that part of the population able to pay for treatment.
2. The use of records retrospectively made it difficult to regulate management of patients and inherent errors in patient management are reflected in data collected.

12.0 LIMITATIONS

The study was limited by

1. The choice of private clinics introduces a selection bias as this represents that part of the population able to pay for treatment.
2. The use of records retrospectively made it difficult to regulate management of patients and inherent errors in patient management are reflected in data collected.

14.0 RECOMMENDATIONS

1. A harmonization of guidelines to be followed by both private and public health practitioners in the management of HIV infection and AIDS.
2. A regulation of the costs of treatment and management of HIV/AIDS patients would reduce disparities among practitioners and loss to follow up.
3. Regulate follow-up visits of all patients seen for HIV/AIDS related conditions whether on ARVs or not.
4. Encourage domicilial follow-up of patients by medical personnel, especially if these patients do not appear for scheduled visits.
5. Regulate dispensing of antiretroviral drugs with employment of modes of accountability.
6. Organize training programmes for health personnel in the management of HIV/AIDS.

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APPENDICES

APPENDIX 1

Specimen of Request letter to the 4 clinics

Kaseya O.R. Chiyeñu,
P.O. Box 39181,
LUSAKA.

30th May 2003.

THE CHIEF MEDICAL OFFICER
MUTTI CLINIC
LUSAKA

Dear Sir/Madam,

Re: REQUEST TO CARRY OUT RESEARCH AT YOUR PRACTICE

I am a Post-graduate student with the University of Zambia, School of Medicine. I would like to research the impact of antiretroviral agents as used in some private clinics in Lusaka. And since their use has been more consistent among private practitioners I would like the study to be carried out among some of the private clinics in Lusaka. I, therefore, write requesting consent to carry out the research in your clinic.

The study will involve reviewing patients' files. No personal contact will be made with patients. The records will be kept confidential and none of the patients' names will be used in the research records or in the publication.

Outlined below are the parameters to be evaluated:

Age (years)
Sex (M, F)
Residential
Race/Ethnicity-African, Caucasian, Asian, other
Occupation
Date of first diagnosis
Subsequent admission (s)
Admission diagnosis
Opportunistic infections/malignancies
Weight
CD 4⁺ cell count
Viral load
Treatment regimens prescribed
Adverse events
Alternative regimens

Yours faithfully,
Dr. Kaseya O.R. Chiyeñu

APPENDIX 2

Questionnaire

Age (years)

Sex (M, F)

Residential area

Race/Ethnicity-African, Caucasian, Asian, other

Occupation

Date of first diagnosis

Subsequent admission (s)

Admission diagnosis

Opportunistic infections/malignancies

Weight

CD 4⁺ cell count

Viral load

Treatment regimens prescribed

Adverse events

Alternative regimens