CHANGES IN BODY COMPOSITION AND OTHER ANTHROPOMETRIC MEASURES OF FEMALE SUBJECTS ON HIGHLY ACTIVE ANTIRETROVIRAL THERAPY (HAART): A PILOT STUDY IN KWAZULU-NATAL, SOUTH AFRICA

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Background and objectives. An understanding of the effect of highly active antiretroviral therapy (HAART) on various aspects of health, including nutritional status, is needed to ensure that population-specific guidelines can be developed for South Africa. This study aimed to investigate the changes in body composition and other anthropometric measures that occur in HIV-infected women after the initiation of HAART and to explore the relationship between these measures and CD4 lymphocyte count.

Design and setting. A longitudinal study was carried out at the Umkhumbane Community Health Centre, KwaZulu-Natal.

Subjects. 30 HIV-infected adult women who started HAART between March 2007 and October 2007.

Methods. Anthropometric measurements and bioelectrical impedance analysis were performed at baseline and 24 weeks after commencing HAART. CD4 lymphocyte counts were done at baseline and at the 24-week visit.

Results. There was a statistically significant increase in all anthropometric measures except waist-hip ratio and lean body mass. The mean weight change (± standard deviation) was 3.4±5.8 kg (p=0.006). Mean body mass index (BMI) (kg/m^2) increased from 25.6±5.7 to 27.3±5.6 (p=0.007). Seventy per cent of subjects gained weight, 18.5% had a stable weight and 11.1% lost weight. Subjects with lower CD4 lymphocyte counts experienced greater increases in weight, BMI, fat mass and body fat percentage. No significant association was found between anthropometric changes and change in CD4 count between baseline and the 24-week visit.

Conclusions. The findings demonstrate the value of including circumference measurements and body composition techniques as part of nutritional status assessment. Research is needed to determine the best methods of bringing about favourable anthropometric changes to enhance the health of patients on HAART.

As the patient load at antiretroviral clinics increases with the drive to meet the goals of the HIV, AIDS and STI Strategic Plan for South Africa, 2007 - 2011, there is a need to conduct research to enable the development of population-specific guidelines and policies. An understanding of the effect of highly active antiretroviral therapy (HAART) on various aspects of health of HIV-infected individuals in South Africa, including nutritional status, is needed.

Although there are data available from some African countries[1] indicating that HAART may result in changes in body composition and other anthropometric measures, no such figures for South African adults have been published in the peer-reviewed literature.

This prospective study was therefore carried out to investigate the changes, if any, that occur in HIV-infected women receiving HAART in a primary health care set-

ting in KwaZulu-Natal and to investigate associations between anthropometric measures and CD4 lymphocyte count.

METHODS

STUDY POPULATION

The study sample was drawn from patients on the MTCT-Plus Programme at Umkhumbane Community Health Centre, Cato Manor, KwaZulu-Natal. The majority of the patients live in the Cato Manor urban informal settlements, where the homes consist of shacks and low-cost housing, many without running water, electricity or a water-borne sewage system. The clinic serves a predominantly Zulu population. The first 30 women, 18 years of age or older, who started HAART for the first time between March 2007 and October 2007; met the eligibility criteria; and provided written informed consent were consecutively enrolled into the study. Exclusion criteria included current pregnancy or recent pregnancy (delivery in the previous 8 weeks) and any malignant disease. Individuals were eligible to commence HAART if they had a CD4 lymphocyte count of below 200 cells/µl, World Health Organization (WHO) clinical stage 4 disease irrespective of CD4 lymphocyte count, or WHO clinical stage 3 disease with a CD4 count of 200 - 350 cells/µl.[2]

Ethics approval was obtained from the Committee for Human Research at Stellenbosch University and the Bioethics Committee of the Nelson R Mandela School of Medicine, University of KwaZulu-Natal.

STUDY PROCEDURES

All measurements were performed on the day HAART was commenced and then again after 24 weeks on HAART. Anthropometric measurements were performed by the principal investigator and included weight, height, mid-upper arm circumference (MUAC), waist circumference and hip circumference. Standardised techniques and the same equipment were used for all measurements. The measurements were taken in duplicate and the mean of the two measurements was used.[3]

Weight was measured using an electronic scale and recorded to the nearest 0.1 kg. Subjects were weighed without shoes and wearing only light clothing. Height was measured using a stadiometer (SECA 225). Subjects were measured without shoes and standing in an upright position. The head was positioned in the Frankfort horizontal plane and the subjects were asked to relax their shoulders and stand with their arms at their sides.[3]

MUAC was measured on the right side for all subjects. The measurement was taken at the mid-point between the top of the acromion process of the scapula and the olecranon process of the ulna and was measured with the arm hanging freely at the subject's side.[4] Waist circumference was measured with the tape measure positioned around the abdomen at the mid-point between the lowest rib and the iliac crest after the subject had gently exhaled. Hip circumference was measured as the maximal circumference over the buttocks. Circumference measurements were performed using a flexible, inelastic tape measure (SECA). Height and circumference measurements were recorded to the nearest 0.1 cm.[4]

The body mass index (BMI) was calculated by dividing the weight of the subject by their height squared (kg/m^2) and the waist-hip ratio (WHR) was calculated by dividing the waist circumference by the hip circumference. The measurements obtained, as well as these indices, were then used to classify the individuals according to the WHO cut-off values.[5] Subjects were classified into the following BMI categories: underweight (<18.5); normal weight (18.5 - 24.9); overweight (25.0 - 29.9) and obese (≥30). A WHR greater than 0.85 indicates accumulation of abdominal fat, and a waist circumference of ≥80 cm and ≥88 cm identifies individuals at increased risk and substantially increased risk of cardiovascular disease, respectively.[5]

Bioelectrical impedance analysis (BIA) was performed using a quad-frequency analyser (Bodystat® QuadScan 4000 Hydration/Body Composition Monitoring Unit, Isle of Man, UK), which is a battery-operated unit that is connected to the body by electrodes, to allow a small electric current to pass through the body. A measurement of the impedance to the current in the body is then obtained and is used to estimate total body water (TBW) and calculate lean body mass (LBM) and body fat using regression equations. To enhance reliability, all the assessments were performed by the principal investigator and the analyser was calibrated before each analysis using the calibrator supplied by the manufacturer. Measurements were performed according to the manufacturer's instructions (Bodystat® QuadScan 4000 User's Guide) and using standardised procedures and electrode placements.[6]

It could not be assumed that the BIA equations built into the analyser by the manufacturer were suitable for use in black African HIV-infected women in South Africa, so we developed our own population-specific equation to calculate LBM as part of an ancillary study attached to the same study population. LBM was derived from the TBW, which was measured by the deuterium isotope dilution method, and impedance values were obtained using the abovementioned analyser in a sample of 50 HIV-infected women from the same study population. Stepwise multiple regression analysis was used to develop the prediction equation and the correlation coefficient was 0.873, showing a good fit between the values obtained from the equation using impedance values from the BIA and the deuterium dilution method. The subjects' impedance values obtained from the BIA were then used in the pre-

diction equation to calculate the LBM of the subjects in the current study. Fat mass (FM) was calculated by subtracting the LBM from total body weight. Body fat percentage (BF%) was calculated by dividing fat mass by body weight and multiplying the value by 100.

Viral loads were performed by *in vitro* NASBA® HIV-1 assay using the Nuclisens Easy-Q-HIV-1 Viral Load Method (bioMérieux SA, Mercy L'Etoile, France), and CD4 lymphocyte counts were done by flow-cytometry using the BD Facscalibur Method (Becton Dickinson, San Jose, CA, USA). A viral load of less than 25 copies/ml was considered undetectable as this is the lower detection limit of the Nuclisens Easy-Q-HIV-1 Viral Load Assay.

The HAART regimens used by the MTCT-Plus Programme are consistent with the WHO guidelines.[2] All subjects were prescribed the first-line HAART regimen, which is based on a combination of one non-nucleoside reverse transcriptase inhibitor (NNRTI), either nevirapine (NVP) or efavirenz (EFV), with two nucleoside analogue reverse transcriptase inhibitors (NRTIs), which consisted of lamivudine (3TC) and either stavudine (D4T) or zidovudine (AZT).

Although the national guidelines made provision for food parcels for patients on HAART, owing to provincial budgetary constraints the supply at the clinic was inconsistent and none of our patients was able to access these food parcels for any significant time period. No incentives were provided to patients to participate in the study, as all measurements were done during their routine visits.

STATISTICAL ANALYSES

Continuous variables were summarised using means and standard deviations (SDs) and were compared using paired *t*-tests. Categorical data were summarised using proportions and percentages. For the purpose of analysis, subjects with an undetectable viral load were assigned a viral load of 24 copies/ml or 1.4 $\log_{10}$ copies/ml. Subjects were also categorised according to their body weight changes between baseline and the 24-week visit as follows: weight loss, weight gain or weight stable. Correlation analysis was performed to investigate the relationship between variables and was expressed using Spearman's correlation coefficient. A *p*-value of less than 0.05 was considered statistically significant. The statistical analyses were carried out by a statistician using Statistica (Version 8; StatSoft 2007, Tulsa, OK, USA).

RESULTS

BASELINE CHARACTERISTICS

A total of 30 subjects were enrolled into the study. The participants had a mean age (± SD) of 30.9±5.6 years. Table I presents the baseline characteristics of the 30 women enrolled into the study, including the baseline socio-demographic, anthropometric and laboratory parameters.

The mean weight (± SD) of the subjects at baseline was 63.7±16.0 kg (range 40.5 - 109.6 kg), the mean BMI was 25.6±5.7 (range 14.5 - 37.8) and the mean BF% was 32.2±9.7% (range 7.1 - 48.0%). Only 2 (6.7%) of the subjects were underweight (BMI <18.5) at baseline, while 13 (43.3%) were of normal weight (BMI 18.5 - 24.9), 9 (30.0%) were overweight (BMI 25 - 29.9) and 6 (20.0%) were obese (BMI >30).

CHANGES IN ANTHROPOMETRIC MEASUREMENTS AFTER THE INITIATION OF HAART

Twenty-seven of the 30 subjects completed the 24-week follow-up period. Two subjects died and one was lost to follow-up before the 24-week visit. The mean weight, BMI, MUAC, waist and hip circumferences and WHR at baseline and 24 weeks after the initiation of HAART are set out in Table II. The values for LBM, FM and BF%, as determined by BIA, are also presented, as are the mean changes for each of the anthropometric measures.

Overall, there was a statistically significant increase in all anthropometric measures after the initiation of HAART, except for WHR and LBM (Table II). The mean weights (± SD) at baseline and after 24 weeks were 63.7±16.0 kg and 68.2±15.0 kg, respectively. This was an average weight change of 3.4±5.8 kg (p=0.006). A considerable proportion of the subjects (50%; N=15) had a BMI above the upper limit of the normal range at baseline, and this increased to 67% (N=18) by the 24-week visit, with 30% (N=8) of these subjects being obese. The mean BMI of the subjects at baseline was 25.6±5.7, and this increased to 27.3±5.6 by the 24-week visit (p=0.007).

Although the majority of the subjects gained weight (N=19; 70.4%) after 24 weeks on HAART, 3 (11.1%) lost weight and 5 (18.5%) had a body weight that remained stable. In those who gained weight the average weight gain was 5.6±5.3 kg (p=0.000) (range 1.2 - 24.7 kg). The subjects who lost weight, lost an average of 4.6±1.6 kg (p=0.037) (range 2.9 - 6.0 kg) by the 24-week visit.

The subjects experienced a mean (± SD) increase in CD4 lymphocyte count of 120±114 cells/µl (p=0.000) and a mean decrease in viral load of log 2.7±1.2 copies/ml (p=0.000) between baseline and the 24-week follow-up visit.

Of the 19 subjects who gained weight between baseline and the 24-week visit, 68.4% (N=13) gained mostly FM and 32.6% (N=6) gained mostly LBM. Three of the 5 subjects with a stable body weight lost FM and gained LBM, while the proportions of FM and LBM remained stable in the other 2. In the 3 subjects who lost weight after

TABLE I. BASELINE CHARACTERISTICS OF THE 30 WOMEN ENROLLED INTO THE STUDY

Characteristics	Subjects (*N*=30)
Age (yrs)	30.9±5.6
Education (yrs)	9±3
Employed	16 (53.3)
No piped water in home	11 (36.7)
No electricity in home	14 (46.7)
Previous pregnancy	30 (100)
No. of previous pregnancies	
1	6 (20.0)
2	15 (50.0)
3 or more	9 (30.0)
Initial HAART regimen	
AZT, 3TC, NVP	17 (53.3)
AZT, 3TC, EFV	8 (26.7)
d4T, 3TC, EFV	5 (16.7)
Weight (kg)	63.7±16.0
BMI (kg/m^2)	25.6±5.7
<18.5 (underweight)	2 (6.7)
18.5 - 24.9 (normal weight)	13 (43.3)
25 - 29.9 (overweight)	9 (30.0)
≥30 (obese)	6 (20.0)
MUAC (cm)	28.3±5.1
Waist circumference (cm)	84.5±11.6
Hip circumference (cm)	98.6±13.2
WHR	0.86±0.05
Waist circumference ≥80 cm	9 (30.0)
Waist circumference ≥88 cm	9 (30.0)
WHR >0.85	17 (56.7)
LBM (kg)	41.9±5.7
FM (kg)	21.8±11.2
BF%	32.2±9.7
CD4 cell count (cells/µl)	164±69
Viral load ($\log_{10}$ copies/ml)	4.5±1.2

Note: Data are number (%) of patients or mean ± SD.
HAART = highly active antiretroviral therapy; AZT = zidovudine; 3TC = lamivudine; NVP = nevirapine; EFV = efavirenz; d4T = stavudine; BMI = body mass index; MUAC = mid-upper arm circumference; WHR = waist-hip ratio; LBM = lean body mass; FM = fat mass; BF% = body fat percentage.

commencing HAART, the weight loss consisted mainly of LBM (4.8±3.8 kg; p=0.159).

Six subjects had evidence of disproportionate gains and losses in body circumference measurements. Three subjects experienced an increase in waist circumference and a simultaneous decrease in hip circumference, and 3 experienced an increase in waist circumference with a simultaneous decrease in hip circumference and MUAC.

RELATIONSHIP BETWEEN ANTHROPOMETRIC MEASURES AND CD4 LYMPHOCYTE COUNT

A statistically significant negative linear correlation was found between CD4 lymphocyte count at baseline and changes in weight (r_S=–0.40; p=0.04), BMI (r_S=–0.40; p=0.04), FM (r_S=–0.53; p=0.00) and BF% (r_S=–0.41; p=0.02) between baseline and after 24 weeks on HAART but not for MUAC, waist circumference, hip circumference, WHR or LBM. Correlation analysis found no significant linear association between changes in weight, BMI, MUAC, waist circumference, hip circumference, WHR, LBM, FM or BF% between baseline and the 24-week follow-up visit and changes in CD4 lymphocyte count. Change in CD4 lymphocyte count between baseline and 24 weeks was not significantly associated with any of the baseline anthropometric measurements, except for MUAC with which there was a modest but significant positive correlation (r_S=0.40; p=0.04).

DISCUSSION

In this study, subjects underwent significant changes in most of the anthropometric measures after just 24 weeks on HAART. Mean weight, BMI, MUAC, waist circumference, hip circumference, FM and BF% all increased significantly after the initiation of HAART. Only mean WHR and LBM did not increase significantly.

Comparison of the results of this study with those of previous studies is complicated, as the majority of the studies that have investigated the effect of HAART on anthropometric measures have been carried out on males in developed countries, few longitudinal studies have been conducted, and the methodology used has differed considerably.[7-11]

Although the majority of the subjects gained weight during the follow-up period, some had a body weight which remained stable and others lost weight. This is in accordance with the results of the study by Saghayam *et al.*[7] Some of our subjects gained significant amounts of weight (range 1.2 - 24.7 kg), with the majority of the weight gain in most subjects being attributable to an increase in FM, which is consistent with the findings of Silva *et al.*[12] Future studies should examine the health implications of gaining FM in subjects on HAART in South Africa.

Some studies have reported increases in LBM after the initiation of HAART,[10,11] which is associated with improved functional performance,[10] and identifying ways of improving LBM that are both effective and feasible may therefore prove valuable. Possible explanations for the improvement in LBM observed in some of the subjects in this study with a stable body weight include improvements in muscle mass as a result of an increase in activity levels associated with an overall improvement in health after starting HAART, or dietary changes.[11] In the 3

TABLE II. ANTHROPOMETRIC AND LABORATORY MEASURES AT BASELINE AND AFTER 24 WEEKS ON HAART

Characteristic	Baseline (*N*=30)	24 weeks (*N*=27)	Change	*p*-value
Weight (kg)	63.7±16.0	68.2±15.0	3.4±5.8	0.006
BMI (kg/m^2)	25.6±5.7	27.3±5.6	1.4±2.5	0.007
MUAC (cm)	28.4±5.1	29.8±4.4	1.1±2.1	0.009
Waist circumference (cm)	84.5±11.6	88.3±11.2	3.3±6.4	0.012
Hip circumference (cm)	98.6±13.2	102.1±11.8	2.6± 4.9	0.011
WHR	0.86±0.05	0.86±0.07	0.01±0.04	0.294
LBM (kg)	41.9±5.7	43.0±6.2	0.7±3.2	0.262
FM (kg)	21.8±11.2	25.2±9.5	2.7±4.5	0.005
BF%	32.2±9.7	35.7±7.0	3.0±5.2	0.006
CD4 cell count (cells/µl)	164±69	282±154	120±114	0.000
Viral load (log_{10} copies/ml)	4.5±1.2	1.7±0.8	–2.7±1.2	0.000
BMI categories				
<18.5 (underweight)	2 (6.7)	1 (3.7)		
18.5 - 24.9 (normal weight)	13 (43.3)	8 (29.6)		
25 - 29.9 (overweight)	9 (30.0)	10 (37.0)		
≥30 (obese)	6 (20.0)	8 (29.6)		
Waist circumference ≥80 cm baseline	9 (30.0)	9 (33.3)		
Waist circumference ≥88 cm baseline	9 (30.0)	11 (40.7)		
WHR >0.85	17 (56.7)	10 (37.0)		

Note: Data are mean ± SD or number (%) of patients.
HAART = highly active antiretroviral therapy; BMI = body mass index; MUAC = mid-upper arm circumference; WHR = waist-hip ratio; LBM = lean body mass; FM = fat mass; BF% = body fat percentage.

subjects who lost weight the loss was composed mostly of LBM, and this is well known to be prognostically unfavourable.[6] Two of the 3 subjects who lost weight were known to live in food-insecure households and the other reported intentional weight loss.

From the results, it can be seen that the baseline CD4 lymphocyte count before HAART initiation appears to have an inverse relationship with change in BMI, FM, and BF% between baseline and the 24-week visit. Subjects with lower CD4 lymphocyte counts experienced greater increases in weight, BMI, FM and BF%. The finding that subjects with more severe immunosuppression at baseline experienced greater increases in body weight on HAART is supported by the results of the study by Shikuma *et al.*[10] In a study by Mwamburi *et al.*,[9] changes in CD4 lymphocyte count after the initiation of HAART were associated with changes in weight, but others have found no relationship.[7] In our study the anthropometric changes were not significantly correlated with changes in CD4 lymphocyte count. Larger studies of longer duration should be carried out to examine the changes in anthropometric measures that occur after the initiation of HAART and to describe more clearly the relationship between anthropometric measures and immunological response as well as the overall health of subjects.

Another noteworthy observation was the disproportionate change in circumference measures seen in some subjects. This may indicate fat redistribution, during which it is common for subjects to experience fat loss from the buttocks and extremities, and/or an increase in abdominal FM.[13]

The finding that such a large proportion of the subjects in this study had a BMI above the upper limit of the normal range and that a considerable number had abdominal fat accumulation, as indicated by the WHR and waist circumference measurements, is cause for concern, firstly because of the well-known health risks associated with overweight and obesity in the general population, which include type 2 diabetes mellitus, hypertension, respiratory difficulties and dyslipidaemia.[5] Secondly, an

above-normal BMI may mean that a large proportion of HIV-infected individuals may not seek care, and health care professionals may not identify individuals for HIV testing as a result of the common misconception that they are 'healthy'[14] when in fact they may not only be HIV-infected but already eligible for HAART.

Although the risks of overweight and obesity in the HIV-infected population specifically, and especially in the era of HAART, are not known, because of the association between overweight and obesity and adverse health outcomes in the general population it seems prudent to ensure that subjects are cautioned against excessive weight gain. The issue of overweight and obesity warrants attention, and studies are urgently needed to determine the prevalence and significance of overweight and obesity in the HIV-infected population in South Africa. The optimal nutritional advice to be given to overweight and obese HIV-infected subjects remains to be determined.

This study had some limitations that need to be acknowledged. Firstly, only females were included in the study and the results therefore cannot be generalised to male subjects. Secondly, owing to the small sample size we were not able to control for potential confounding factors such as HAART regimen and clinical parameters, and the changes that were observed may therefore have been independently associated with other factors not analysed. We recommend that future studies include both genders and a large enough sample to allow for investigation according to HAART regimen, clinical staging and other morbidity factors to allow for the development of widely applicable guidelines.

In conclusion, the findings of this study demonstrate firstly the value of including circumference measurements and body composition assessment techniques as part of the assessment of nutritional status. The results show that merely following weight changes in subjects would mask underlying changes in body composition and changes in fat redistribution. We therefore suggest that programmes include waist and hip measurements and if possible BIA measurements, at least annually or ideally at 6-monthly intervals, in order to provide useful information to assist in patient management. Secondly, this study suggests that given that the majority of subjects who gained weight gained mostly FM and not LBM, there is a need for further research to develop interventions such as exercise training programmes to improve LBM and decrease abdominal obesity.[15] The long-term aim of HIV care and treatment programmes should not merely be to obtain virological suppression but also to improve overall health and quality of life.[16,17]

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