#### Asian Pacific Journal of Tropical Biomedicine

journal homepage: www.apjtb.com



Document heading doi: 10.12980/APJTB.4.2014APJTB-2013-0035 © 2014 by the Asian Pacific Journal of Tropical Biomedicine. All rights reserved.

### Determinants of immunological failure among clients on the first line treatment with highly active antiretroviral drugs in Dar es Salaam, Tanzania

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#### ARTICLE INFO

# Article history: Received 12 Dec 2013 Received in revised form 12 Feb 2014 Accepted 18 Apr 2014 Available online 13 Jun 2014

Keywords:
Immunological failure
Highly active antiretroviral treatment

#### ABSTRACT

**Objective:** To determine socio-cultural, demographic and highly active antiretroviral therapy (HAART) program-related factors associated with immunological failure (IF) among clients on HAART in Dar es Salaam care and treatment clinics.

Methods: A 1:2 matched case control study was done from February to April 2012 in HIV/AIDS care and treatment clinics in Dar es Salaam. Data were collected from National AIDS Control Program (NACP) data base and patient's charts to obtain 60 sets of study participants who were interviewed using the structured questionnaire. Data analysis was done by using EPI Info 3.5.1 version

**Results:** The mean age of all study participants was  $(42.00\pm9.07)$  years with 35% (63) being males. History of poor antiretroviral therapy (ART) adherence due to exposure to drug holiday with loss to follow up  $(OR=11.96; 95\% \ CI=2.07-69.26)$ , history of changing care and treatment clinics  $(OR=12.07; 95\% \ CI=2.10-69.27)$  and the lack of treatment supporter  $(OR=23.26; 95\% \ CI=1.85-291.66)$  were found to be strongly associated with the occurrence of first line HAART-IF.

Conclusions: HAART-IF in Dar es Salaam is associated with ART programmatic and patients' centered challenges. There is a need to review the approaches on ensuring ART adherence, clients follow up and referral system so as to reduce the incidence of IF as we move to a more decentralized peripheral drug picks clinical initiative.

#### 1. Introduction

Africa South of Sahara is still the World's most highly affected region with HIV/AIDS and accounts for approximately 70% of the global disease burden[1]. It is now about ten years since the commencement of antiretroviral therapy (ART) scales up in most parts of this continent but only 40% of those who need the service are reached[2]. Care

and treatment to people living with HIV/AIDS (PLHIV) has improved the outcome of the disease in both developed and developing countries by reducing significantly the mortality rates[3-8].

Rapid scale up of ART services in Tanzania together with other parts of Africa face challenges which affect the delivery of the expected services to people in need. These includes shortages of skilled and experienced personnel; lack of sustainable funding; low coverage in rural settings; low socioeconomic status among PLHIV; effects of stigma; ART adherence issues; ART drug resistance and immunological failure (IF) among people on highly active antiretroviral therapy (HAART)[9–12].

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Foundation Project: Supported by Catholic University of Health and Allied Sciences, (Grant No. CSF/02/2012).

Treatment IF is a state where the clients who have been on ART experience 50% drop of the CD4 count or return to the baseline count in six month with a history of good adherence to treatment<sup>[13]</sup>.

Studies in East Africa show a high prevalence of IF ranging from 8% to 57% among clients on first line HAART and furthermore the magnitude increases as the time of follow up increases[14–16]. It is well known that virological failure is a better marker of HAART failure as opposed to IF[14], but financial constraints hinder universal access to this method in many resource limited settings like Tanzania making IF a pivotal marker not only to predict virological failure but also to guide change of the treatment regimen.

Non adherence to treatment has been reported to be major cause of IF[14,16], whereas stigma, food security, social support, income and tuberculosis co-morbidity have been reported to affect ART adherence[15,17-20]. Despite evidence from other areas on the socio-cultural and demographic factors as well as HAART program-related challenges which partly or wholly result into treatment IF, little is known among HIV/AIDS clients attending care and treatment clinics (CTC) in Dar es Salaam, Tanzania.

#### 2. Materials and methods

#### 2.1. Study design and sampling process

A 1:2 matched case control study was conducted at Mwananyamala, Temeke, Mnazi Mmoja and Mbagala Hospitals in Dar es Salaam from February to April 2012 in HIV/AIDS CTC. Data collection process used the National AIDS Control Program (NACP) data base together with patient's charts to sort 180 study participants [60 qualified cases of IF and 120 controls (without IF)]. The study cases were the clients on first line HAART for at least one year with immunological failure (50% drop of the CD4 count from the peak value in six month or return to the baseline CD4 count). The study controls were clients on the first line HAART for at least one year of follow up with good treatment immunological response (i.e. clients without any history CD4 count drop of more than 25% in a period of six month). The obtained cases were matched with two controls by using sex, age group, baseline CD4 count and ART follow up time as matching variables.

#### 2.2. Data collection techniques and tools

The data was collected by using a structured questionnaire

administered equally to both cases and control. Data pertaining to social demographic variables, ART baseline information, adherence, stigma assessment, history of ART loss to follow up, HIV co-morbidity, self-reported food security, nutrition, income and social support were inquired. The measurement of HIV related stigma was made by using three important parts of Berger's scale of HIV stigma<sup>[21]</sup>. The scores were given using Likert's scale (strongly agree; agree; disagree; strongly disagree) with a score range of 16-64 points as a minimum to the maximum. The study members with scores less 32 were considered less stigmatized and individuals with the scores more than or equal to 32 were considered as more stigmatized. History of adherence to antiretroviral drugs for the past six month was sought basing on patient clinical files and self-reporting. Any history of adherence of less than 95% was considered poor. Assessment of food security was based on physical and financial accessibility foods throughout the year and threeday nutritional history was taken. The income of less than one USD per person per day in the family was considered as exposure to low income.

#### 2.3. Data analysis

Data pertaining to socio-demographic characteristics, ART baseline information, adherence status, stigma, food security and other variables were entered into Excel sheet®, cleaned and exported to Epi info software version 3.5.1 for analysis according to the objectives of the study. Frequency distribution of the socio-demographic characteristics were described and compared the cases with the controls. The bivariate analysis using maximum likelihood estimates of the categorical variables was done using a cross tabulation of the cases and the controls to determine the association of the variables. Odds ratio was calculated with their respective confidence interval. Furthermore, the variables with P < 0.05in the bivariate analysis were subjected to conditional logistic regression to get the independent predictors of IF measured by adjusted odds ratio (aOR) together with their respective confidence interval.

#### 2.4. Study clearance and ethical considerations

The study ethical clearance was obtained from the Institutional Review Board (IRB) of the Muhimbili University of Health and Allied Sciences. A written informed consent from each ART client was sought and confidential handling of clinical information was carefully observed by using anonymous codes.

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