Loss to Follow-up in a Community Clinic in South Africa:

Role of Sex, Pregnancy, and CD4 Count

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ABSTRACT

Background: Faith-based organizations have expanded access to antiretroviral therapy (ART) in community clinics across South Africa. Loss to follow-up (LTFU), however, limits both the potential individual and population treatment benefits and is an obstacle to optimal care.

Objective: To identify patient characteristics associated with LTFU 6 months after starting ART in a large South African community clinic.

Methods: Patients initiating ART between April 2004 and October 2006 in one South African Catholic Bishops' Conference HIV treatment clinic who had at least one follow-up visit were included in the analysis. Standardized instruments were used for data collection. Routine monitoring was performed every 6 months following ART initiation. Rates of LTFU over time were estimated by the Kaplan-Meier method. The Cox proportional hazard regression was used to examine the impact of age, baseline CD4 count, baseline HIV RNA, sex and pregnancy status on LTFU.

Results: Data from 925 patients (age>14 years, median age 36 years, 70% female, of whom 16% were pregnant) were included in the analysis. Fifty one patients (6%) were lost to follow-up 6 months after ART initiation. The univariate analysis showed that younger age (≤30 years) (HR: 2.14, 95% CI: 1.05–4.38) and pregnancy for women (HR: 3.75, 95% CI: 1.53–9.16) were significantly associated with higher LTFU rates. When stratified by baseline CD4 count, sex, and pregnancy status, pregnant women with lower baseline CD4 count (≤200 /μl) had 6.06 times the hazard (95% CI: 2.20–16.71) of LTFU at 6 months compared to men.

Conclusions: HIV-infected pregnant women initiating ART were significantly more likely to be lost to follow-up in a community clinic in South Africa. Interventions to successfully retain pregnant women in care are urgently needed.

INTRODUCTION

South Africa has the highest number of people living with HIV in the world.[1] The estimated number of HIV-infected individuals is 5.7 million, and 350,000 people died from AIDS-related complications in 2007.[1, 2] About one-third of all pregnant women in South Africa are HIV-infected.[3, 4] The consistent growth of the HIV epidemic has led to a rapid expansion of HIV care and treatment.[2]

Many non-governmental organizations operate mentoring and support programs for HIV-infected people in resource-limited countries.[5 6] In South Africa, faith-based organizations play a significant and expanding role in providing HIV care and access to antiretroviral therapy (ART).[7, 8] One of the largest ART treatment programs is jointly run by the Southern African Catholic Bishops' Conference (SACBC) and the Catholic Relief Services (CRS) and is funded by the US President's Emergency Plan for AIDS Relief (PEPFAR).[9] The ART treatment program operated by the SACBC and the CRS is spread widely across South Africa and has been involved in locally-based HIV responses in many South African communities.[10]

Evaluating the outcomes of patients initiating ART is a critical task for ART treatment programs. However, outcome evaluation is generally based only on those patients who remain in care.[11] High rates of loss to follow-up (LTFU) diminish treatment options and substantially limit the effectiveness of ART strategies.[12, 13] Furthermore, a growing body of evidence suggests heterogeneity in rates of LTFU for men and women.[14] Pregnancy may also contribute to higher rates of suboptimal retention in care.[15] There is thus an urgent need to better understand LTFU in patients who initiate ART. Our objective was to identify the impact of sex, pregnancy status, and CD4 count on LTFU 6 months after ART initiation in one of the largest SACBC/CRS treatment programs in South Africa.

METHODS

Setting

This study was conducted in Tapologo, one of the SACBC/CRS HIV treatment clinics. The Tapologo HIV/AIDS program works with mine worker communities outside the Rustenburg region in the North West province of South Africa.[16] Through a network of caregivers, Tapologo currently provides home-based care, local clinical consultation, and support services to migrant workers and men and women living in informal settlements around the mines.[17] The clinic population consists of urban adults (age>14 years) within the mining community who received ART from home-based caregivers. The caregivers are supported financially by the platinum mines, the SACBC, and other partners, and the clinic employs doctors, nurses, counselors and adherence monitors.[17] Treatment protocols closely follow South African National Department of Health guidelines.[18, 19] Adherence education is given both before and during ART. **The services offered for pregnant women through Tapologo clinic include counseling and emotional support, HIV/AIDS education and awareness, positive living, food security and nutrition. Available clinical services include HIV testing, treatment of tuberculosis and other life-threatening diseases, general medical care, and treatment of sexually transmitted and opportunistic infections.**

Study sample

The cohort included HIV-infected patients who either developed AIDS or had a CD4 count that met criteria for ART initiation based on South African National Department of Health guidelines at the time of the study (CD4≤200/μl).[19] Patients initiating ART between January 2004 and October 2006 and eligible for at least one follow-up visit were included in the analysis. After ART initiation, **patients were followed every 6 months, with CD4 counts and HIV RNA tests done at each clinic visit.**

Data elements

Standardized data reporting forms were used for data collection. Demographic characteristics at baseline included date of birth (or age) and sex. Clinical characteristics included: WHO stage at enrollment, height, weight, pregnancy status for women, functional status, and ART history. CD4 count and HIV RNA were measured at the initiation of ART and at each clinic visit. All records were maintained by the local site.

Definition of outcomes

The outcome for the study was defined as the proportion of LTFU in patients initiating ART. We considered two definitions for LTFU: the 'clinic-based' definition and the 'data-based' definition. The *clinic-based* definition was determined by the Tapologo-based provider as failure to return for a scheduled consultation or medication pickup within 6 months after ART initiation.[13] We used the clinic-based definition in the main analysis.

The *data-based* definition was determined as a lack of recorded information in the database on a patient returning for a 6-month visit. Specifically, the patient was determined as LTFU according to the data-based definition if no information was recorded with respect to the date of the 6-month follow-up visit and there was no laboratory testing (CD4 or HIV RNA tests) within 6 months of ART initiation. The data-based definition was used in sensitivity analyses.

Statistical analysis

The analysis was performed using data available on April 30, 2007, on all patients with at least 6 months of follow-up time. At 6 months after ART initiation, patients who had unknown drop-out status, had ART discontinued by their physician, had voluntarily discontinued treatment, **or** were transferred out of the program, or who were deceased, were censored**.** Thus, study time for each patient was calculated from the date of ART initiation until the date of drop-out, if known, or the date 6 months after ART initiation, if the date of drop-out was unknown. For patients who were lost to follow-up at 6 months after ART initiation, study time was calculated from the date of ART initiation until the date of LTFU. Kaplan-Meier estimates were used to analyze the cumulative probability of LTFU. The log-rank test was used to examine differences in LTFU rates within subgroups of patients.

All demographic and clinical variables were grouped as categorical: age (≤30, 31-40, >40 years), sex and pregnancy status (pregnant women, non-pregnant women, men), baseline CD4 count (≤200/μl, >200/μl), and baseline HIV RNA (≤100,000 copies/ml, >100,000 copies/ml). To determine the potentially joint effect of baseline CD4 and sex and pregnancy status on LTFU, we stratified pregnancy status by baseline CD4 count for women (>200/μl and ≤200/μl). We did not do so for men because there were no LTFU events for men with baseline CD4>200/μl. Such stratification resulted in a variable with five categories: pregnant women with CD4≤200/μl, pregnant women with CD4>200/μl, non-pregnant women with CD4≤200/μl, non-pregnant women with CD4>200/μl, and men. For individual and stratified variables, hazard ratios with corresponding 95% confidence intervals (CI) for LTFU were analyzed through Cox proportional hazard regression. Two-sided p-values <0.05 were considered statistically significant. Analyses were performed using SAS software (version 9.1 or higher, SAS Institute Inc., Cary, North Carolina, USA).

RESULTS

Cohort characteristics

Among adult patients (age>14 years) accessing SACBC/CRS in Tapologo, 925 met the criteria for analysis. The median age was 36 years (interquartile range (IQR), 29–44). Six hundred and forty-five of the 925 patients (70%) were female, of whom 16% were pregnant. At ART initiation, the median CD4 count was 111/µl (IQR, 41–214/µl) and the median HIV RNA was 4.9 $\log_{10}$ copies/ml (IQR, 4.4–5.4). Upon initiating ART, approximately 45% of patients had baseline HIV RNA>100,000 copies/ml; 72% of patients and one-third of pregnant women had a baseline CD4≤200/µl (Table I).

Reasons for discontinuing ART

Three hundred twenty-two patients (35%) **discontinued ART within 6 months of ART initiation.** Among these patients, 37 (11%) were discontinued by physician recommendation, 21 (7%) transferred out of the Tapologo program, 213 (66%) died, and 51 (16%) were lost to follow-up (the clinic-based definition). Patients with unknown drop-out status were considered as remaining in care and were subsequently censored 6 months after ART initiation.

Association between patient characteristics and LTFU six months after ART initiation

Kaplan-Meier analysis indicated that during the period of observation, the cumulative probability of LTFU 6 months after ART initiation was 6% (95% CI: 4–7%) for the cohort. When stratified by age, baseline HIV RNA and CD4 count, and sex and pregnancy status, log-rank tests showed the cumulative probability of LTFU was significantly different across the sex and pregnancy subgroups (p=0.01). The cumulative probability of LTFU 6 months after ART initiation was 12% (95% CI: 5–18%) for pregnant women, 6% (95% CI: 4–8%) for non-pregnant women, and 3% (95% CI: 1–5%) for men (Table II).

To quantify the effect of all characteristics on LTFU, Cox proportional hazard regression analyses were carried out (Table II). Results showed that younger age (≤30 years) (HR: 2.14, 95% CI: 1.05–4.38), and pregnancy for women (HR: 3.75, 95% CI: 1.53–9.16) were significantly related to higher LTFU rates at 6 months from ART initiation. However, in terms of the overall effect, sex and pregnancy status was the only factor showing a statistically significant association with LTFU (p=0.01).

Although we did not find overall the association between baseline CD4 and LTFU at 6 months, there was a significant impact on LTFU related to pregnancy in the lower CD4 stratum. If baseline CD4 was ≤200/µl, pregnant women had 3.62 times of hazard of LTFU compared to non-pregnant women (95% CI: 1.52–8.62). To examine this joint effect, sex and pregnancy status was further stratified by baseline CD4, and proportional hazard regression analyses were conducted. The analysis demonstrated that pregnant women with baseline CD4≤200/µl had the highest risk of LTFU 6 months after ART initiation (HR: 6.06; 95% CI: 2.20–16.71), followed

by non-pregnant women with baseline CD4>200/µl (HR: 2.91; 95% CI: 1.19–7.11) and pregnant women with baseline CD4>200/µl (HR: 2.44; 95% CI: 0.80–7.46) (Table III, Figure 1).

Sensitivity analysis: the impact of the definition of LTFU

To detect the impact of alternative definitions of LTFU, we conducted sensitivity analyses using the data-based definition of LTFU. Using the data-based definition of LTFU, 95 patients (10%) were lost to follow-up 6 months after initiating ART. Proportional hazard regression analysis showed pregnant women with baseline CD4≤200/µl had the highest risk of LTFU 6 months after ART initiation (HR: 2.67, 95% CI: 1.12–6.35), followed by pregnant women with baseline CD4>200/µl (HR: 2.40, 95% CI: 1.14–5.05) and non-pregnant women with baseline CD4>200/µl (HR: 2.29, 95% CI: 1.24–4.24) (Table III). The overall joint effects of baseline CD4 and sex and pregnancy status on LTFU were similar for both clinic- and data-based definitions of LTFU.

DISCUSSION

In the community-based cohort of 925 adult patients who were eligible for ART in South Africa, we conducted analyses to identify patient characteristics associated with LTFU 6 months after ART initiation. We found that sex and pregnancy status were significantly related to LTFU and that pregnant women had the highest risk of LTFU.

In many ART programs in resource-limited settings, LTFU has become a major problem for optimal care of HIV-infected individuals.[13, 15, 20] Several studies have described associations with LTFU in ART treatment programs in South Africa. These studies used chart reviews to investigate patient characteristics predicting LTFU in large ART treatment programs in public hospitals. Causes of LTFU during ART in these studies included: financial difficulty, lack of patient knowledge that ART needs to be lifelong, hospitalization or illness, medication toxicity, CD4 count increase, and death.[20, 21] Little work has focused on the relationship between LTFU and sex and pregnancy status.[15] With an HIV prevalence among pregnant women in South Africa of 20-30%, further understanding of LTFU among pregnant women on ART could help improve retention of these patients in care and may also decrease risk of mother to child HIV transmission.[8, 15, 22] This study identified patient characteristics including sex and pregnancy status associated with LTFU in patients who began ART in the Tapologo program, one of Southern African Catholic Bishops' Conference/Catholic Relief Services' HIV care and treatment clinics in North West province, South Africa.

Although the data provided insufficient statistical evidence to support an association between baseline clinical characteristics (HIV RNA or CD4 count) and LTFU 6 months after ART initiation, the distributions of these clinical characteristics in pregnant women were different from non-pregnant women and men. In addition, the stratified analysis in baseline CD4≤200/μl showed pregnant women were more likely to be lost to care than non-pregnant women. This evidence indicates the possible joint effects of clinical characteristics and sex and pregnancy status. To detect the joint effects of baseline CD4 and sex and pregnancy status, we stratified pregnancy status by baseline CD4 count for women because there were no LTFU events for men with high baseline CD4 counts based on the preliminary results. A Cox proportional hazard model was analyzed to quantify the joint effects on LTFU. To examine the impact of different definitions on LTFU, we carried out sensitivity analyses using a second standardized (data-based) definition of LTFU. The results showed that, although HIV-infected non-pregnant women who initiated ART and had higher CD4 counts were significantly more likely to be lost to care, pregnant women initiating ART at all stages of HIV disease were at substantial risk of LTFU, with its attendant risk of developing an AIDS-defining illness or of death. **The data presented in the paper suggested that the relationship between CD4 count and LTFU among women was modified by pregnancy status. Women with high CD4 counts were at similar risk of LTFU regardless of pregnancy status. In contrast, pregnant women with low CD4 counts were at increased risk for LTFU compared to non-pregnant women. We hypothesize this discrepancy is due to the increased burden of health and social conditions, including pregnancy, that HIV-infected women face. With respect to higher rates of LTFU among the women with higher CD4, one explanation may be the stigma associated with HIV disease.**

This study had several limitations. First, the reasons pregnant women stopped treatment were not available. In mine worker communities in South Africa, many of the women live in shacks with no stable income and with no stable partner to support them. Many have no access to potable water, decent sanitation facilities, or adequate nutrition. Although the ART program in this study was a local clinic that provided community-based care at no cost, pregnancy itself represents a financial burden for women and their families. The higher proportion of LTFU among pregnant women may arise from no financial support as well as increased prenatal care costs. Since many women who cluster around the mines are from other parts of South Africa or other countries, physical relocation may be a risk factor for failure to return for further visits. Another explanation of LTFU among pregnant women may be that some of these patients may transfer out of the SACBC/CRS ART treatment programs to maternal care facilities or to hospitals without informing local clinic staff. **To ensure that pregnant women receive timely treatment and care for HIV during pregnancy and the postpartum period, improvement in linkage with other ARV centers and maternal services via data sharing to systematically monitor patients is critical.** Patient records were maintained by the local site; however, there were no data for approximately 10% of the Tapologo patients. In order to perform this analysis, we conservatively assumed that patients with missing current treatment status were in care. This likely underestimated the rates of LTFU.[11] **Finally, this study was limited to one clinic in the programs of the SACBC/CRS. It may therefore not be representative of the overall population of persons with HIV disease initiating ART in South Africa.**

This was the first systematic study of LTFU in the programs of the SACBC and CRS in South Africa. Pregnant women with HIV disease initiating ART were at the greatest risk of being lost to follow-up. To ensure the best outcomes for HIV-infected women, as well as to prevent HIV transmission from mother to child, interventions to successfully retain pregnant women in care are urgently needed.

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RESEARCH ETHICS COMMITTEE APPROVAL

This research was approved by the Research Ethics Committee of the University of Cape Town, Cape Town, South Africa (Rec Ref: 169/2007).

CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

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Table I. Baseline characteristics of HIV-infected patients initiating ART in the Tapologo community clinic in South Africa

Characteristics	Men N=280	Non-pregnant Women N=541	Pregnant Women N=104	Total N=925
Age (years), N (%)				
≤30	39 (14)	157 (29)	73 (70)	269 (29)
31 - 40	93 (33)	209 (39)	29 (28)	331 (36)
>40	148 (53)	175 (32)	2 (2)	325 (35)
Baseline HIV RNA (copies/ml), N (%)				
≤100,000	136 (49)	284 (53)	87 (84)	507 (55)
>100,000	143 (51)	252 (47)	17 (16)	412 (45)
Baseline CD4 count (cells/μl), N (%)				
≤200	220 (79)	411 (76)	35 (34)	666 (72)
>200	58 (21)	125 (23)	69 (66)	252 (27)

ART: antiretroviral therapy; IQR: interquartile range

Table II. Association between demographics, clinical characteristics and rates of loss to follow-up at 6 months (clinic-based definition)

	Total	LTFU	Hazard Ratio	
	N (%)	N (%)*	(95% CI)	p-value
Total	**925 (100)**	51	---	---
Age (years)				0.11
≤30	**269 (29)**	20 (7)	2.14 (1.05–4.38)	
31 - 40	**331 (36)**	19 (6)	1.53 (0.74–3.16)	
>40	**325 (35)**	12 (4)	1.00	
Baseline HIV RNA (copies/ml)				0.17
≤100,000	**507 (55)**	35 (7)	1.51 (0.83–2.72)	
>100,000	**416 (45)**	16 (4)	1.00	
Baseline CD4 Count (cells/µl)				0.73
≤200	**666 (72)**	34 (5)	0.90 (0.50–1.62)	
>200	**252 (27)**	17 (7)	1.00	
Sex and pregnancy status				0.01
Pregnant Women	**104 (11)**	12 (12)	3.75 (1.53–9.16)	
Non-pregnant Women	**541 (58)**	31 (6)	1.98 (0.91–4.30)	
Men	**280 (30)**	8 (3)	1.00	

Clinic-based definition: failure to return for a scheduled consultation or medication pickup within 6 months after ART initiation; LTFU: loss to follow-up; CI: confidence interval.

***% refers to the proportion of those LTFU among patients within each group.**

Table III. Cox proportional hazard regression of LTFU at 6 months on baseline CD4 and sex and pregnancy status for both the clinic-based and the data-based definitions

	Clinic-based Definition (p-value = 0.01)		Data-based Definition (p-value = 0.02)	
	LTFU N (%)*	**Hazard Ratio (95% CI)**	**LTFU N (%)***	**Hazard Ratio (95% CI)**
Total	51	---	95	---
Baseline CD4 (cells/µl) and Sex and pregnancy status				
Pregnant Women, CD4≤200	7 (20)	6.06 (2.20–16.71)	7 (20)	2.67 (1.12–6.35)
Pregnant Women, CD4>200	5 (7)	2.44 (0.80–7.46)	11 (16)	2.40 (1.14–5.05)
Non-pregnant Women, CD4≤200	19 (5)	1.66 (0.73–3.80)	36 (9)	1.37 (0.79–2.39)
Non-pregnant Women, CD4>200	12 (10)	2.91 (1.19–7.11)	22 (18)	2.29 (1.24–4.24)
Men	8 (3)	1.00	19 (7)	1.00

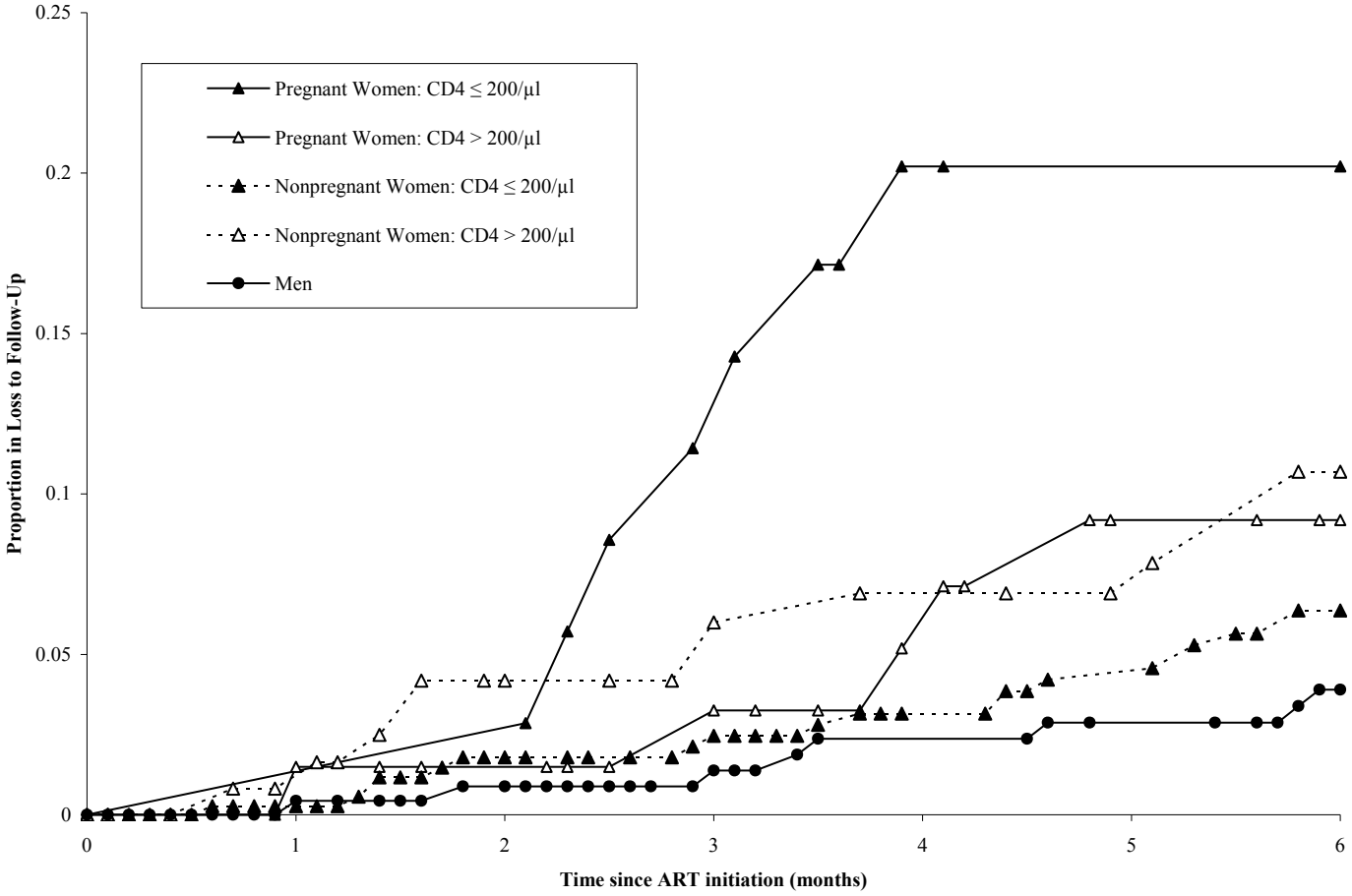
Clinic-based definition: failure to return for a scheduled consultation or medication pickup within 6 months after ART initiation; Data-based definition: missing any visit information for at least 6 months; LTFU: loss to follow-up; CI: confidence interval.

***% refers to the proportion of those LTFU among patients within each group.**

Legend for figure:

Figure 1. Cumulative probability of loss to follow-up 6 months from ART initiation, stratified by baseline CD4 and sex and pregnancy status. Differences among all groups are highly significant by Kaplan-Meier analysis.

Figure 1.


Pregnant Women: CD4 ≤ 200/µl
Pregnant Women: CD4 > 200/µl
Nonpregnant Women: CD4 ≤ 200/µl
Nonpregnant Women: CD4 > 200/µl
Men
Proportion in Loss to Follow-Up
0.25
0.2
0.15
0.1
0.05
0
0
1
2
3
4
5
6
Time since ART initiation (months)