Abstract

Study design: We performed a cross-sectional study of HIV-positive patients from the Lusigetti Sub-County Hospital's Comprehensive Care Clinic (LCCC) to assess the adherence rate and potential barriers to Highly Active Antiretroviral Therapy (HAART).

Methods: Forty two percent of the clinic's adult patient population (102 of 243) was surveyed over the course of three months using the validated Simplified Medication Adherence Questionnaire (SMAQ), and ten additional questions (see appendix) to address barriers to adherence to HAART. Patient interviews were conducted in a private room, and responses to our survey were recorded without associated patient identifiers. Participation was voluntary, no incentives were provided to patients, and oral informed consent was obtained.

Results: Fifty three percent (53 of 100) of patients were identified as adherent to HAART. Univariate logistic regression analysis revealed that the odds of adhering increased 2.8 fold with each level of greater perceived ease of access to medication refills (p= 0.0021).

Conclusions: This study suggests patient adherence to HAART in Lusigetti Sub-county Hospital is much lower than expected based on previous patient viral load tests. Among the barriers assessed, poor access to medication was the only statistically significant barrier to adherence. Since other countries in sub-Saharan Africa have similar processes for HIV medication refill and delivery, effective solutions for optimizing medication access could be implemented across other African nations in order to increase HAART adherence and improve the control of HIV.

Introduction

In Kenya, 1.6 million adults (ages 15-49) are living with HIV (a prevalence of 4.7% of the adult population) [1]. However, this prevalence varies significantly between Kenya’s 47 counties with Wajir County at 0.1% to Siaya County at 21.0% of the population, and globally Kenya has the twelfth highest adult prevalence of HIV [2]. Nonetheless, in the past few decades, Kenya has been a success story in advancing HIV prevention efforts as one of the first to approve the use of pre-exposure prophylaxis and has led the way in providing voluntary medical male circumcision. AIDS-related deaths dropped from 53,900 in 2010 to 28,200 in 2017. This change is directly attributable to the government’s rollout of free Highly Active Antiretroviral Therapy (HAART) starting in 2003, and the adoption of the World Health Organization's (WHO) recommendations to immediately offer treatment to people diagnosed with HIV [3]. In order to effectively suppress viral load and prevent both the transmission of disease and the emergence of drug resistant strains, patients with HIV require adherence rates of 95% or greater, and studies of medication adherence to HAART in Kenya have shown adherence rates range between 43-90% [4-6].

Understanding the barriers to and predictors of HAART adherence is an important public health goal in helping to control HIV, particularly now that the WHO recommends HAART for all persons regardless of CD4 counts [4]. Thus, there is a need for more studies to understand the barriers to adherence based on geographical and population specific needs that are unique to the 47 counties in Kenya. This short communication summarizes adherence rates and presents a
quantitative analysis of barriers to adherence from a sample population of HIV-positive patients living in Lusigetti, a town in Kiambu County, Kenya. Understanding the obstacles to HAART adherence on a local level will ultimately improve the care of patients attending Lusigetti Sub–County Hospital’s Comprehensive Care Clinic (LCCC) and other healthcare settings in Kenya and more broadly in Africa.

Setting

Lusigetti’s Comprehensive Care Clinic (LCCC) had enrolled 250 HIV positive patients between the years of 2012 and 2019. The clinic primarily serves adults (N=243) but 7 children have also been treated there during this timeframe. The study population was comprised of 89 males (35.6%) and 161 females (64.4%) which was representative of the overall epidemiology related to gender distribution of HIV infection in Kenya. In 2019, sixty three percent of adults aged 15 or over living with HIV were women (UNAIDS Country Factsheets, Kenya 2019. Accessed June 1, 2021 https://www.unaids.org/en/regionscountries/countries/kenya).

Ethical considerations

This study was conducted after obtaining official approval from the Kiambu County Governor’s Office and the director of Lusigetti Sub–County Hospital. Participation was voluntary, no incentives were provided to patients, and oral informed consent was obtained from all who participated in the study; no patient identifiers were collected to protect patient privacy. This project was approved by the Stanford Institutional Review Board (Human Subjects).

Study design

Study patients were identified when they presented to LCCC for their scheduled refill appointment and invited to participate in this research project. Patients were excluded from participating in the study if they had been prescribed HAART fewer than three months prior to consent or if they were under 18 years of age. Informed consent was obtained through a scripted verbal informed consent process, which was also translated to Kiswahili. All patients who were invited and eligible, agreed to consent to the study and completed the survey, giving a response rate of 100%. To ensure patient anonymity and confidentiality, patient interviews were conducted in a private room, and responses to our survey were recorded without associated patient identifiers. The survey included the validated Simplified Medication Adherence Questionnaire (SMAQ), and ten additional questions (see appendix) to specifically address barriers to adherence [7]. The SMAQ classified patients as non–adherent when they answered any of the qualitative questions in a non–adherent manner, missed more than 2 doses over the past week, or over 2 days of total non–medication during the past 3 months [7].

Results

One hundred two patients were interviewed over the course of ten weeks, representing 41% of the clinic’s patient population. Two patients did not meet inclusion criteria as they were prescribed HAART less than 3 months prior to the interview and were not included in the study. According to the SMAQ component of the survey, 53% (n=53) of patients were adherent to their medication regimen. The questions within the SMAQ that frequently yielded non–adherent answers were, “Have you ever forgotten to take your medication?” (n=27) and, “When you feel bad, have you ever discontinued taking your medication?” (n=20).

Patients were asked to rank the ease of refilling their medication on a Likert scale: very difficult, difficult, easy, and very easy. Univariate logistic regression analysis revealed that the odds of adherence increased 2.8 fold with each level of greater perceived ease of access to medication refills (p=0.0021).

In order to assess patients’ perspectives on the importance of taking their medication regularly they were asked to select one of the following: not at all, indifferent, somewhat, and very. Furthermore, patients were asked to qualify how they think their health has changed since starting HAART: gotten worse, stayed the same, somewhat improved, improved a lot. Patients who believed taking their medication regularly was important presented 1.7 greater odds of believing that their health had changed for the better since starting HAART, but this was not statistically significant (p = 0.0688) (Table 1 for summary of results).

Comparison of mean time in years for the duration of being HIV–positive, time since first prescribed HAART, and the time difference between diagnosis and commencement of treatment between adherent and non–adherent patients.

Summary of the effects of barriers to adherence on the odds ratio that patients remain adherent to HAART.

Discussion

This study sought to determine the adherence rate and barriers to adherence in patients on HAART attending the LCCC. The high response rate of 100% in this study is in part likely due to the cultural excitement of interacting with a “mzungu,” meaning white or foreign person, often used affectionately and can contribute to patients’ eagerness to participate in a study by foreigners. In addition, the face to face nature of the interview can contribute to patients’ eagerness to participate in a study by foreigners.

Summary of Results.

| Table 1: Summary of Results. | Adherent Patients (mean # of years) | Non-adherent Patients (mean # of years) |
|-----------------------------|-----------------------------------|----------------------------------------|
| Duration HIV+               | 3.85                              | 4.54                                   |
| Time on HAART               | 3.44                              | 3.92                                   |
| Treatment Lag               | 0.41                              | 0.63                                   |

| Barrier to Adherence         | OR (95% CI)                        | p-value     |
|------------------------------|------------------------------------|-------------|
| Adherence vs. Time Since Diagnosis (Q7) | 0.942 (0.838 – 1.060) | 0.322       |
| Adherence vs. Treatment Lag (Q8) | 0.890 (0.659 – 1.201) | 0.445       |
| Adherence vs. Viewing Adherence as Important (Q10) | 1.4088 (0.768 – 2.687) | 0.2380      |
| Adherence vs. Refill Process Difficulty (Q13) | 2.817 (1.455-5.464) | 0.0021      |
| Perception of health change (Q9) vs. Belief in importance of taking medications (Q10) | 1.738 (0.958-3.151) | 0.0688      |

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and having the research study separated from the care patients received at LCCC were also essential in establishing trust and contributing to the high response rate.

Prior to this survey, the clinic staff believed 94% of their patients were adhering to their medication regimen, based on extrapolation from viral load tests. It is not uncommon for patients to improve their medication taking behavior around appointment time, a behavior described in the literature as white coat adherence where patients have improved medication adherence around the period of clinic visits and blood testing [8]. In anticipation of upcoming blood tests, patients prescribed HAART can achieve a viral load <400 copies/mL in under four weeks and give the impression they are adherent to their medications when they may not be taking their medications as prescribed at times outside of the 4 week clinic appointment times [9]. The healthcare teams at LCCC occasionally do pill counts to assess adherence, but this is also an unreliable means of measuring adherence as some patients are known to “pill dump” prior to appointments in an effort to appear more adherent to their medications. Sub-optimal adherence is unhealthy for patients as this can lead to treatment failure, poor survival outcomes, and drug resistance. There is also a threat to the community as high viral loads increase the risk of both HIV transmission to others and increases in HAART resistance [10].

Our results may be biased given patients were recruited at their clinic appointments and patients who adhere to clinic appointments are also more likely to adhere to their medications. Our measured adherence rates may therefore overestimate the true adherence rates in the general clinic population. One reason for the poorer adherence rates found in our study compared to previously reported adherence rates in Kenya might be that patients in our study were more willing to be forthcoming about missing doses due to the reasons mentioned above, and due to the fact that patients could remain anonymous and not identified by clinic staff. The SMAQ is also a sensitive instrument in identifying non-adherent patients given one positive response to the questionnaire classifies a patient as non-adherent. Our results are not much different to other region-specific studies of adherence in Kenya and from UNAIDS data from 2017 suggesting that only 51% of HIV-positive people living in Kenya have complete suppression of viral load. [6] This data is important for health care providers across Kenya as they consider including measures of adherence implemented in between clinic visits. Other options include using more objective measures such as Medication Event Monitoring System (MEMS) devices or using multiple modalities of adherence measures to more fully understand the medication taking behavior of patients.

Access to medication was the only statistically significant barrier to adherence, and gaps in care provision is a well-known factor impacting medication adherence. Anecdotal patient reports revealed that LCCC patients would prefer the option of refilling their medication in larger batches and less frequently to minimize their time off work to travel to the clinic; future research should focus on finding the other factors that make the refill process difficult for patients. This method of Multi-Month Scripting (MMS) is already in place at LCCC, however, more research needs to be done to improve the implementation of MMS and other processes to optimize delivery of medications to patients. Since other countries in sub-Saharan Africa have similar processes for the refill and delivery of HIV medications, effective solutions discovered through further research endeavors could be implemented across other African nations. We must empower patients with knowledge and resources for optimal medication management and provide them with the support they need to achieve the full benefit of these highly effective medications.

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