AIDS Behav (2008) 12:78–85
DOI 10.1007/s10461-006-9197-0

ORIGINAL PAPER

HIV Treatment Adherence and Sexual Functioning

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Published online: 13 February 2007

Abstract To our knowledge, no studies have considered the bidirectional relationship between HIV infected patients' social/sexual lives and HAART adherence. To determine it's potential impact the study sample consisted of 135 men starting HAART and being followed for 6 months. Twenty percent of men enrolled in the study self-reported non-adherence. Non-adherent patients reported a greater number and severity of adverse effects such as gastrointestinal and body changes. All participants were aware of these risks, requested support, and were advised by the health care providers. As many as 26% of the HIV infected men, at the second visit, reported sexual dysfunction and none received information regarding the possibility of this side effect. Of importance, patients reporting sexual dysfunction, were more likely to report not being fully adherent to the medication (RR = 2.46 95% CI 1.3–4.7; $P = 0.04$). Of most concern, none of the men reported looking for medical advice

Keywords HIV · AIDS · Adherence · HAART · Sexual dysfunction · BMI

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Introduction

Previously, the sex lives and functioning of those infected with HIV were secondary to the life-threatening aspects of the disease. Thus, with the exception of promoting condom use for HIV prevention, health care professionals and researchers rarely discussed sexuality issues.

The development and use of HAART have raised a host of behavioral questions that have significant implications for HIV prevention and treatment. Men and women receiving HAART are feeling well enough to resume and enjoy their social and sexual lives (Ippolito, Galati, Serraino, & Girardi, 2001). HAART has improved their quality of life, life expectancy, and physical appearance. By giving the impression of being healthy and reducing ''their infectivity,'' patients reported engaging in relationships without condom use more easily (Klitzman et al., 2004; Sheon & Crosby, 2004). However, to fully benefit from HAART, adherence must be strict (>95%) (Chesney, 2003; Halkitis, 2002; Tsasis, 2001). Given the need for near-perfect HAART adherence, several groups have investigated factors associated with poor adherence to determine modifiable targets for interventions to improve it (Ammasari et al., 2002; Moatti & Spire, 2003). Although factors associated with poor adherence are multiple, the association between medication side effects, which are common, and suboptimal adherence has been fairly consistent across studies (Monforte et al., 2000). Low compliance is often a consequence of persistent side effects such as nausea, vomiting, and gastrointestinal upset. In addition, side effects that directly affect personal appearance and functioning can discourage individuals from receiving

and adhering to HAART. For example, lipodystrophy can have a severe impact on people living with HIV by affecting their social and sexual lives (Ammasari et al., 2002; Collins, Wagner, & Walmsley, 2000; Guaraldi et al., 2003; Power, Tate, McGill, & Taylor, 2003). Multiple aspects of lipodystrophy extend beyond its clinical significance (Collins, Wagner, & Walmsley, 2000). For example, lipodystrophy can force patients to disclose their HIV status, as body changes mark them as infected (Collins, Wagner, & Walmsley, 2000; Power, Tate, McGill, & Taylor, 2003). In addition, lipodystrophy appears to have a negative impact on social and sexual esteem because individuals feel their body shape makes them look ''different'' and ''unattractive''(Persson, 2003). It is critical that we understand HAART side effects with socio-cultural implications on behaviors relevant to adherence and risk-taking behaviors. Greater insight will enrich theoretical models of HAART adherence, which tended to overlook some social dynamics.

The above mentioned effects of HAART toxicity have been extensively assessed in clinical trials (Collier et al., 2003; Hammer et al., 1997), but not all have been thoroughly evaluated in clinical settings. For men, low libido and erectile dysfunction have been reported as side effects associated with HAART, but are poorly discussed in the literature and with patients (Gordillo, Amo, Soriano, & Gonzalez-Lahoz, 1999; Lallemand et al., 2002; Lamba et al., 2004). Prevalence of sexual dysfunction is widespread with most (89%) HIV positive homosexual and bisexual men reporting a decrease or loss of libido, 86% having erectile dysfunction, 68% reporting orgasmic perturbation, and 59% reporting ejaculation difficulties (Lallemand et al., 2002). Although the mechanisms of these problems are still under investigation, in large studies these side effects are particularly prevalent in those receiving a regimen containing protease inhibitors (PIs) (27.1% vs. 3.8% for untreated patients) (Collazos, Martinez, Mayo, & Ibarra, 2002; Schrooten et al., 2001; Trotta et al., 2003). The data were more striking, as a significantly larger number of PI-experienced men reported sexual problems than antiretroviral naïve patients (Schrooten et al., 2001). Of interest, appearance of sexual dysfunction has also been reported, while switching across diverse antiretroviral regimens (Colebounders, Moerman, & Noestlinger, 2006). Despite this evidence and its potential impact on the patient's quality of life, health care professionals and researchers rarely address sexuality issues.

Another major area that has yet to be investigated is the relationship between HIV infected patients' social/sexual lives and HAART acceptance and adherence. Strengthening our understanding of these factors will improve long-term treatment responses and the patient's quality of life. To evaluate determinants, trends, and processes of HAART adherence and the negative physical, psychological, and social consequences of antiretrovirals' side effects, such as sexual dysfunction and the influence that health care providers could have on those parameters, we conducted a prospective study in patients starting a new antiretroviral regimen.

Methods

Participants

Participants aged 18–55 years, who had been diagnosed with HIV and had been receiving a new antiretroviral regimen for less than 10 weeks, were eligible to be enrolled in the Miami Alcohol Research Care for HIV (MARCH) study. Briefly, MARCH is a longitudinal observational study to evaluate the impact of alcohol use on health status of HIV infected men and women. The participants in this study were recruited from the University of Miami and Jackson Memorial clinics, where these individuals are being followed at regular intervals. Antiretroviral eligibility criteria were as follows: HIV infected men and women could be either (1) naïve or (2) have had prior exposure to antiretroviral therapy, but they must have discontinued HAART for at least six weeks prior to starting a new antiretroviral regimen. All stages of HIV infection were represented in this group of patients. Although the cohort included both HIV infected and uninfected men and women, sexual dysfunction was mainly reported by HIV infected men. Therefore, we decided to focus our analyses for this paper among HIV infected men.

Measures

Using standardized research questionnaires, the following data were collected at baseline and six months after treatment: (1) sociodemographic information, (2) drug, alcohol (AUDIT; Saunders, Aasland, & Babor, 1993), and the screening questionnaires of the Physician's guide NIAAA (Fleming 2000), and (3) tobacco use habits. The AUDIT and the Physician's guide questionnaires are screening instruments for alcohol use disorders that have been widely validated. In the AUDIT, items are scored 0–4, giving a total range between 0 (no problems) and 40 (severe problems). The questionnaire cover three domains: excessive alcohol intake, dependence and problems related to

drinking. All participants were questioned regarding past and current medical history including mood disorders. Additional information regarding any kind of medical prescriptions was documented. Individual signs and symptoms associated with antiretroviral adverse effects and not present before therapy were recorded closest to the date they initiated HAART and six months after. Individuals were questioned if their health care providers (i.e., physician, nurse, and/or pharmacist) advised them about potential antiretroviral side effects. Once all research forms and visit procedures had been completed, a medical chart and pharmacy records were abstracted and patient information was compared and validated.

Neurological Status The HIV Dementia Scale (HDS) was used as a valid screening tool to monitor cognitive status (von Giesen, Haslinger, Rohe, Koller, & Arendt, 2005). The HDS was selected because it is HIV specific, has been shown to have greater sensitivity (84%) and positive predictive value for recognition of dementia compared to the MMSE (72%), and seems to be relatively independent of age and education (Power et al., 1995). It consists of 4 subtests: a timed written alphabet, recall of 5 items at 5 min, cube copy time, and an anti-saccadic error task.

Depression We want to emphasize that depression is common in HIV infected individuals, and is one of the strongest correlates of poor treatment adherence for HIV and other illnesses (Mehta, Moore, & Graham, 1997). Therefore, patients were screened for depression with the Beck Depression Inventory for Primary Care (BDI-PC; Steer, Cavalieri, Leonard, & Beck, 1999). The BDI-PC is a 7-item questionnaire with each item rated on a 4 point scale (0–3). It is scored by summing the ratings for each item (range 0–21). Items are symptoms of sadness, pessimism, past failure, loss of pleasure, self dislike, self criticalness, and suicidal thoughts and wishes. Patients scoring ≥4 were considered depressed (Steer et al., 1999).

Adherence was established using standardized antiretroviral adherence questionnaires (ACTG), medical records, and virological and immunological responses. In the first questionnaire, patients reported the total number of missed antiretroviral doses during the previous month, week, and weekend from which we determined a categorical assessment of 100% adherence (i.e., no missed doses in the past month). Participants completed a 24-item questionnaire specifically created and validated for HAART and extensively used by multi-center studies, such as the ACTG. The questionnaire also investigates knowledge about the current HAART scheme, reasons for non-adherence, interruptions in drug supply, beliefs about treatment, perceived health status, psychological well-being, social/family/partner support, symptoms, and satisfaction with health care. The questionnaire required 15 min on average to complete.

Studies have shown that >95% adherence is necessary to achieve undetectable viral loads in >80% of treated patients (Low-Bear et al., 2000; Paterson et al., 2000). However, a number of studies have found that HAART adherence rates are frequently suboptimal (70–80%) (Haubrich et al., 1999; Rodriguez-Rosado et al., 1998; Thompson, Gold, & Sathasivam, 2000). Therefore, we classified a participant as adherent if he reported >85% adherence to his medication, viral loads at the second visit were undetectable, or if HIV RNA declined more than 1.5 log between visits. In case of a discrepancy between patient report and virological response, the patient was classified as non-adherent.

After completing the study questionnaires, a balance scale was used to measure body weight and height was measured using a wall-mounted vertical ruler. Body mass index (BMI) was calculated as the weight in kilograms divided by height in meters squared. A BMI of 27.8 for men is the cut-off point for obesity used in the National Health and Nutrition Examination Survey (NHANES II) and was used as a reference value.

Following the physical exam, blood was drawn to evaluate T lymphocyte profiles and viral load levels. Flow cytometry was used to establish the percentage and absolute numbers of T lymphocyte subset populations of CD3, CD4, and CD8. In addition, HIV viral burden was quantified in infected individuals using the Amplicor HIV monitor test (Roche Diagnostic System).

In addition, biochemical parameters such as liver enzymes, glucose, lipid profiles, total proteins, and albumin levels were obtained in all study participants.

Data Analyses

Following descriptive statistical analyses, mean variables were compared using student's *t* test and one-way ANOVA procedures; *P* values <0.05 were considered to be statistically significant. Associations between the main variables of interest were examined with Pearson's correlation coefficient analyses. Cognitive and mood status were included as dichotomous variables (yes vs. no).

Logistic regression analyses were used to evaluate the effects of sexual dysfunction and other potential risk factors on adherence. For longitudinal analyses, estimations of the relative risks (RR) of poor adherence according to side effects, including sexual dysfunction, were performed by the calculation of ratios and confidence intervals (CI) through multiple,

conditional, logistic regression analysis. Only subjects that reported no sexual dysfunction at baseline were included in the longitudinal analyses.

Results

Study Population Characteristics

Men living with HIV ranged in age from 24 to 54 years old (41 ± 7 years). Most of the participants were African-American (71%), with smaller proportions of Hispanics (21%), Caucasians (7%), and Asians (0.5%). The level of education varied between 2 and 20 years (11.3 ± 2.8); only 2% of the study participants reported less than five years of education, and 18% reported more than 13 years of education. Most participants were single (67%), divorced (2%), or widowed (5%). Only 19% were married or involved in a stable relationship. Fifty percent of the participants reported using alcohol, and 30% acknowledged currently abusing illicit drugs. The mean CD4 cell count of the cohort was 255 ± 193 at the baseline evaluation. Most of these participants were antiretroviral experienced and only 40% were naïve.

Adherence

At the six-month evaluation, 20% of the participants reported non-adherence and were more likely to have a detectable HIV RNA level (OR = 1.85; 95% CI: 1.05–3.13; $P = 0.03$) than those reporting to be adherent. Only 30% of the men reported complete adherence (100%) and achieved undetectable viral loads at the six-month follow-up.

We identified some participants' sociodemographic characteristics, beliefs, and psychosocial health associated with adherence (see Table 1). For example, non-adherence was significantly associated with no family/partner support to take the medications ($P < 0.05$), while partner support was strongly associated with adherence (RR = 3.9 95% CI: 0.9–9.1; $P = 0.05$). Another factor independently associated with HAART adherence was antiretroviral efficacy expectations (RR = 1.8; 95% CI: 1.0–3.1; $P = 0.04$). Patients who believed that the medications were going to help them were more likely to be adherent to HAART. Recent abstinence from drugs was also significantly associated with better adherence ($r^2 = 0.2$; $P = 0.02$). On the other hand, no significant effect of race/ethnicity, socioeconomic status, age, or alcohol use on adherence was observed.

A considerable percentage of the study participants (39%) reported depression, thus correlations between adherence and depression were examined. Univariate analyses indicated that depression reported at the time of HAART initiation was associated with missing doses during the six-month period compared to non-depressed patients (RR = 1.8; 95% CI: 1–3.2; $P = 0.04$).

Side Effects and Non-Adherence

Poorly adherent patients reported a variety of reasons for not taking their medication, but more than half were related to side effects/toxicity. All study participants were aware of the risk of gastrointestinal effects and body changes, as advised by their health care providers. Non-adherent patients reported a greater number and severity of overall adverse effects. Specific adverse effects (gastrointestinal, body changes, and BMI) were more likely than others to be associated with missing ARV medications. Twenty-two percent of those who reported missing doses did so because of gastrointestinal upset.

Other HAART side effects that deserved further attention were body weight and appearance changes. Weight gain associated with HAART affects general health and quality of life and can be difficult to manage. At baseline, 12% of the study participants had a BMI below 20, 56% of men exhibited normal BMI (21–27), 18% were overweight (28–30), and 14% were obese (>30). At the follow-up visit, a lower percentage (10%) of the men had a BMI

Table 1 Factors Associated with Poor Adherence

Variables	Univariate Analyses			Multivariate Analyses
	Relative Risk	95% Confidence Intervals	*p*-value	
Partner Support	3.9	1.3–5.3	0.05	
HAART Efficacy Expectations	1.8	1.0–3.1	0.04	
Depression	1.8	1.0–3.2	0.04	0.05
Body Mass Index <28	2.8	1.2–6.1	0.02	
Sexual Dysfunction	2.5	1.3–4.7	0.04	0.01

below 20, 27% of men exhibited normal BMI (21–27), the proportion of overweight doubled (36%), and more (25%) were obese. Interestingly, men at the six-month visit, who had BMI below 28, were more likely to be adherent (RR = 2.77; 95% CI: 1.2–6.1; $P = 0.02$). Patients who gained weight and/or had major body changes were more likely to skip doses than those who had low BMI or minor body changes (RR = 1.8; CI 0.9–4.5; 0.05). All patients requested support for the above mentioned side effects. The most frequent recommendations included dietary modification (60%) and 5% of the men received medications (anti-acids, statins, etc.).

Prevalence of Sexual Dysfunction among Men Receiving HAART

Eight percent of the participants at baseline and 26%of the sample at the follow-up visit reported sexual dysfunction. None received information regarding the possibility of this side effect. Of most concern, none of the men reported seeking medical advice for any sexual problem.

Of interest, men reporting sexual dysfunction were younger than those not reporting sexual problems (37.9 ± 6.4 vs. 41.6 ± 6.9 years, $P = 0.05$). Men experiencing sexual dysfunction were also more educated (12.4 ± 1.9 vs. 11.2 ± 2.7 years, $P = 0.05$). No significant difference in mean CD4 cell count was observed between patients with and without sexual dysfunction (253 ± 197 vs. 268 ± 194).

Depressed HIV infected men were also more likely to report sexual dysfunction (OR = 6.0; 95% CI: 1.8–19.6; $P = 0.005$) than non-depressed HIV infected men. Of importance, patients reporting sexual dysfunction at the second visit were more likely to report not being fully adherent to the medication (RR = 2.46; 95% CI: 1.3–4.7; $P = 0.04$). Moreover, patients indicating sexual dysfunction were four times more likely to have high viral loads at the follow-up visit, signifying poor adherence ($P = 0.03$).

Final Analysis

All variables found to be significantly associated with non-adherence in the univariate analysis were included in a multivariable logistic regression model. After controlling for CD4, viral load, and age, multivariate analyses indicated that being depressed and sexual dysfunction remained as predictors of adherence (see Table 1). Body changes, being single, partner/family support, and co-morbidities (alcohol and drugs) did not remain significant.

Discussion

Only a few studies have investigated the influence of beliefs about medication, and even fewer have described the importance of relationships and sexual lives in treatment decisions (Horne et al., 2004; Klitzman et al., 2004). To the best of our knowledge, no one has published a report of longitudinal relationships between adherence and sexual dysfunction. Although frequently ignored because of time and feelings of discomfort (Tindall et al., 1994), our results indicate that sexual dysfunction is prevalent among HAART-treated individuals and significantly affects antiretroviral medication adherence.

Our findings reveal that at least one-quarter of the men receiving HAART for six months reported sexual dysfunction after initiating treatment. Considering that this is a self-report, and the social connotation of the response, the prevalence of sexual dysfunction may be even higher than indicated. Our study results are consistent with previous research indicating that as many as 90% of men on antiretrovirals may experience sexual problems, such as reduced libido and erectile dysfunction (Collazos, Martinez, Mayo, & Ibarra, 2002; Lamba, Goldmeier, Mackie, & Scullard, 2004; Lallemand et al., 2002; Schrooten et al., 2001). Although HIV infection has been associated with sexual dysfunction, metabolic alterations, nerve damage, and hormone level abnormalities (Cove & Petrack, 2004), erectile dysfunction, opposed to sexual desire, doubled in men on HAART, suggesting a physiological link between HAART and sexual dysfunction (Collazos, Martinez, Mayo, & Ibarra, 2002; Lamba, Goldmeier, Mackie, & Scullard, 2004). Although the mechanisms involved in HAART-related sexual dysfunction have not been fully elucidated, PI and non-nucleoside medications may interfere with the liver's ability to metabolize fat, thus potentially causing sexual dysfunction (Bodawi, Cavalieri, & Rogan, 2001). This metabolic pathway is also implicated in generating and processing steroid hormones, such as testosterone and estradiol (Lamba, Goldmeier, Mackie, & Scullard, 2004).

Extending previous studies, our data indicate that sexual problems in people taking HAART are associated with poor adherence to their medications. The results were statistically significant after controlling for illegal drug use, alcohol, CDC stage, and use of other medications, indicating that sexual dysfunction was an important contributor to non-adherence. Sexual dysfunction is a common unwanted effect of many different types of drug therapy and of poor adherence to the prescribed therapies. Although not within HIV,

other studies have demonstrated that many patients with hypertension, depression, and psychiatric disorders discontinue their medication because of sexual side effects (Dinsmore, 2004; Loh, Leckband, Meyer, & Turner 2004; Nurnberg, 2001; Perkins, 2002; Wilks, 2003; Zajecka, 2001).

Unfortunately, the underlying mechanisms are poorly understood. Those few studies that have attempted to discover the mediating mechanisms consistently show an association between sexual dysfunction and autonomic side-effects of antipsychotic drugs or hyperprolactinemia. Different explanations can also be proposed to explain our findings. One can hypothesize from the literature in other diseases that missing doses may represent a logical attempt to moderate the risk of sexual dysfunction. Our data indicated a close relationship between depression, sexual dysfunction, and adherence. Sexual dysfunction can also have a significant impact on feelings of self-worth, contributing to emotional problems such as depression, which was previously associated with poor adherence (Aikens et al., 2005; Goldstein, 2000). Depression may decrease the ability to habituate to the aversive side effects of HAART, contributing to the maladaptive behavior to the treatment (Katon, 2003). Considering the prevalence of depression among the HIV infected population and its repeated association with poor adherence to HAART, psychological counseling, medical treatment, and coping strategies may be viable approaches for improving medication use during antiretroviral treatment.

Despite the widespread prevalence of sexual dysfunction, the lack of doctor-patient communication regarding such problems was overwhelming in our study. Fear of discrimination, misinformation, and taboo customs are some of the many factors that may be preventing men to look for medical treatment. Our findings are supported by previous studies indicating that the majority (56%) of Viagra users did not obtain the medication from a physician, but rather from friends, the internet, the street market, and other sources (Kim, Kent, & Klausner, 2002; Solomon, Man, Gill, & Jackson, 2002). The provider's barriers may include limited time, lack of skills to communicate in simple terms the information to their patient, or the perception that the problem of sexual dysfunction is not common.

Management and counseling regarding sexual dysfunction may be highly effective to help the patient make informed decisions and to increase adherence. It is also critical to prevent drug interactions because antiretrovirals and drugs such as Viagra or Cialis are metabolized by the P450 3A4 enzyme in the liver. Information on this problem is scarce, in part because people in clinical trials of HIV/AIDS drugs are not usually questioned about sexual dysfunction. In addition, physicians, researchers, subjects, and interviewers may not feel comfortable talking about this issue, so it has been seriously neglected. While we believe self-reports of sexual dysfunction and adherence in our study were susceptible to under-reporting, most of the data were confirmed with medical records. We are also aware that our data represent only our population area and are limited to the first six months of therapy. Thus, additional studies to confirm our findings are recommended.

In summary, non-adherence remains a difficult barrier in the management of HIV, with implications for the transmission of HIV to the community, transmission of drug-resistant strains, lost opportunity for health gain, and a waste of resources, as antiretrovirals are among the costliest medicines. Our data indicate that to be effective, physicians and researchers need to evaluate and address the potential of HAART-related sexual dysfunction with each man being prescribed medication from this class of drugs. Accordingly, education is urgently needed to address the gap between patient and physician communication that currently exists.

Acknowledgment The study was funded by the NIAAA of the United States (5R21AA13793-3 MJM).

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