Pain Treatment and Antiretroviral Medication Adherence Among Vulnerable HIV-Positive Patients

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Abstract

Pain represents a significant source of morbidity, function loss, and decreased quality of life among people living with HIV. The present study examined the associations among pain, pain treatment, and ARV adherence among indigent, HIV-positive substance abusers. Participants were recruited via targeted sampling strategies, and completed a one-time computer-assisted personal interview. ANOVA and chi-square tests were used to analyze differences in demographics, health and psychological status, health behaviors, by pain and pain treatment status; a multivariate logistic regression model was constructed to examine the contribution of pain/treatment status to recent ARV adherence. Results indicated that those with untreated pain had lower odds of achieving gold-standard 95% ARV adherence as compared to the pain-free and treated pain groups; higher substance dependence symptoms were also associated with significantly lower odds of 95% ARV adherence. Findings suggest that pain management is critical to the health of people living with HIV, specifically those with high levels of co-morbid health and psychological problems. The prevalence of untreated pain was elevated among this group, and contributed to reduced ARV adherence. Providers of clinical care to disadvantaged HIV-positive patients should emphasize routine assessment and appropriate treatment of pain in order to provide comprehensive HIV care.

Introduction

PAIN IS COMMON AMONG PEOPLE living with HIV, with prevalence estimates indicating that some 40–80% of ambulatory HIV-positive patients endorse recent, clinically significant pain.^{1–4} The etiology of pain among HIV-positive individuals is varied, and includes infection-related inflammatory responses, secondary complications of progressive HIV disease, as well as adverse effects of treatment with antiretroviral (ARV) medications.⁵ Sensory neuropathy, for example, has been estimated to affect 40–60% of treated HIV-positive individuals,⁶ and often results in moderate to severe pain. Regardless of etiology, the experience of pain represents a significant source of morbidity, function loss, and decreased quality of life among individuals living with HIV,^{5,7,8} and has been associated with elevated levels of psychological distress, including depression, anxiety, and panic disorder, as well as greater HIV-related illness burden.^{5,8–10} Despite these indicators, recent literature suggests that pain is often under-recognized and under-treated in clinical care for HIV-positive individuals.^{11,12}

Many HIV-positive individuals suffer from co-morbid mood disorders and/or substance abuse problems,³ and pain management among these patients can present special challenges.¹² In particular, the risk for medication misuse may be heightened,¹³ and patients may require close monitoring; likewise, the under-treatment of pain may lead to aberrant drug-seeking behaviors.¹⁰ Despite these challenges, balanced and appropriate pain management among vulnerable HIV patients is critical to both individual and public health.⁷ A small but emerging body of literature suggests that pain experience among HIV-positive patients is associated with poor ARV adherence and reduced attendance at HIV-related care visits,^{2,3,14} both of which are key behavioral components of disease management to achieve viral suppression and prevent onward transmission.^{15,16} Although a handful of other studies has shown no link between pain and ARV treatment adherence,^{1,13} the dearth of research on this topic precludes consensus.

The purpose of this report is to examine the role that pain and its corresponding treatment may play in vulnerable patients' behavioral repertoires for HIV disease management.

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We recently documented substantial levels of ARV non-adherence, as well as the illicit diversion (selling and trading) of ARVs, among indigent substance abusing HIV-positive patients in South Florida.¹⁷ Prior research has not adequately examined the potential contribution of pain to these types of health risk behaviors, and to our knowledge, existing studies have been limited in investigating the influence of pain treatment as a potentially important moderator of these relationships. This article explores the associations of pain, pain treatment, ARV adherence, and diversion among a large, diverse sample of socioeconomically disadvantaged HIV-positive patients with high levels of co-morbid physical and psychological problems.

Methods

Study participants

Data were drawn from a large epidemiologic study designed to examine the patterns and predictors of ARV diversion among drug-involved people living with HIV in South Florida. Due to the focus on ARV diversion, we recruited a highly vulnerable sample of indigent HIV-positive substance users likely to have exposure to ARV street markets. Study eligibility criteria were: age 18 or older; cocaine or heroin use 12 or more times in the prior 3 months; documented HIV+ status; and current ARV prescription. In addition, diverters endorsed at least one occasion of ARV diversion in the prior 3 months.

Study recruitment

The study utilized targeted sampling techniques to guide recruitment.¹⁸ Study investigators identified specific geographic areas for recruitment based on publically available HIV prevalence and poverty-level indicator data. Initial recruitment efforts targeted the communities to the north of downtown Miami that are intersected by the highest rates of HIV/AIDS¹⁹ and highest poverty indices in Miami-Dade County. Over the life of the study, recruitment areas were expanded based on information from community key informants in the target areas (including treatment professionals, community outreach workers, HIV service providers, and street-level drug users). Professional field staff used direct outreach to distribute study information cards and flyers in a variety of street venues and community-based HIV service organizations within the identified target areas.

Study procedures

Potential participants were given information about the project, and were asked to participate in telephone screening for eligibility. Those meeting eligibility requirements were scheduled for an appointment at the field site, where they were re-screened by a research staff member. After eligibility was confirmed on-site, informed consent procedures were completed. 503 individuals were ultimately enrolled into the study; by design, we included approximately equal numbers diverting their ARV(s) ($n = 251$) and not ($n = 252$). Participants completed a single, standardized interviewer-administered questionnaire, which took approximately 1 h. Participants were paid a \$30 stipend for their time and travel costs to complete the interview. Research staff completed the requirements for National Institutes of Health (NIH) web-based

certification for protection of human subjects, and study protocols were subject to regular review by the University Institutional Review Board. A Certificate of Confidentiality from the National Institutes of Health was obtained and a copy was offered to participants.

Data collection and measures

Trained, bilingual research staff conducted computer-assisted personal interviews (CAPI) in either English or Spanish, according to the participant's language preference. The Global Appraisal of Individual Needs (GAIN, v. 5.4)²⁰ was the primary data collection instrument. The GAIN captures information on demographics, physical and mental health status, including DSM-IVR depression and anxiety measures, substance use and DSM-IVR dependence, and sexual risk behaviors, and has established reliabilities. Standardized instruments also assessed HIV diagnosis/treatment history,²¹ ARV adherence,²² and a newly developed instrument assessed ARV diversion.

Demographic information gathered on study participants included age, race/ethnicity, gender, and years since initial HIV diagnosis. As an indicator of economic need, we assessed food and housing insecurity with a single item adapted from a validated life stress scale.²³ "In the 3 months prior to interview, did you go without food, housing, or other necessities because you did not have the money?"

Health status was measured by five items. HIV-related health status was assessed by self-report of: (1) most recent CD4 count, and (2) most recent viral load. For the present analysis, viral load was dichotomized into undetectable versus not. Pain was assessed using a single item adapted from the Health Distress Scale of the GAIN instrument. Participants were asked, "During the past 90 days, have you had a lot of physical pain or discomfort?" A separate item queried related treatment: "Are you currently prescribed any pain medication?" If appropriate, participants were permitted to endorse multiple medications. Finally, we assessed other medical diagnoses among the target sample, excluding HIV. This included a range of chronic and acute health conditions; participants were instructed to endorse all current medical diagnoses.

Mental health subscales in the GAIN are based on DSM-IVR criteria: nine items assess depression symptoms, and twelve items assess anxiety symptoms over a 12-month period.^{20,24} In all cases, higher scores indicate greater problem severity. Alpha reliability coefficients for the depression and anxiety scales were 0.87 and 0.88, respectively. A separate item queried recency of depression and anxiety symptoms: "When was the last time, if ever, you had any of those *significant* nerve, mental or psychological problems that we just talked about?" To obtain a measure of current psychological distress, we dichotomized this variable into "within the past month" or "not within the past month."

Substance dependence in the past month was assessed using DSM-IVR criteria, which consists of seven items measuring drug problem severity (e.g., using more or longer than intended, withdrawal problems). The present analysis examined past month dependence symptom count as a

continuous variable. The alpha reliability coefficient for the DSM-IVR dependence scale was 0.85.

Participants self-reported ARV adherence in the past 7 days using the AIDS Clinical Trials Group instrument;²² information was gathered on total doses prescribed and total doses missed in the past week. ARV doses taken were computed and divided by total doses prescribed to generate an adherence percentile score. For this analysis, this variable was dichotomized into “95%+” or “<95%”. This cut-point was utilized in order to examine the proportions meeting the current gold-standard for HIV medication adherence. ARV diversion was measured by the following item: “When was the last time, if ever, that you sold or traded any of your HIV medications to another person for any reason?” For the present analysis, this variable was dichotomized into “within the past month” or “not within the past month”.

Data analysis

Data from the interview questionnaires were analyzed using *SPSS for Windows, Version 21*.²⁵ The primary independent variable of interest was recent pain and its associated pharmacological treatment. We constructed three analytic groups from the data: (1) pain-free: those individuals reporting no pain in the past 90 days; (2) pain/untreated: individuals reporting pain in the past 90 days and denying a current pain medication prescription; and (3) individuals endorsing both 90-day pain and a current prescription for pain medication. Descriptive statistics were calculated to describe the sample in terms of pain and treatment status. ANOVA and Chi-square tests were utilized to examine differences in socio-demographics (age, gender, race, food/housing insecurity, years HIV diagnosed); health status (CD4, viral load, other medical conditions); psychological status (depression, anxiety, current psychological problems, substance dependence), and health behavior domains (ARV adherence, ARV diversion) by pain and pain treatment status. Post-hoc Bonferroni tests were computed to identify specific group differences for significant ANOVA main effects.

Subsequently, a multivariate logistic regression model was constructed to examine the potential contribution of pain/treatment status to past week ARV treatment adherence, while controlling for all variables displaying significant associations in the initial bivariate analyses. To reduce the potential for multi-collinearity among our independent variables in the regression analysis, we included only the recency measure of past month psychological distress and eliminated past year symptom counts. For the regression analysis, 95% percent ARV adherence was the outcome of interest and was treated as a dichotomous variable. Variables were entered simultaneously into the logistic regression model.

Results

The median age of the sample was 46 years; 59.4% were male. More than three-quarters (81.4%) of study participants had monthly incomes below \$1000, and 39.2% reported homelessness in the prior 3 months. Self-reported ARV adherence in the past week was 95% or better among 54.1% of participants (data not shown).

The prevalence of recent pain among this sample of indigent HIV-positive substance users was 51.3%. Of those endorsing pain, 41.5% indicated no current prescription for

pharmacotherapy. Among those who reported medication treatment, 48.3% were prescribed an opioid, 39.1% a non-steroidal anti-inflammatory drug (NSAID), and 21.9% indicated another type of prescribed pain medication (data not shown). Participants could endorse multiple prescription types.

As shown in Table 1, pain experience and treatment status were associated with a number of health and psychosocial problems in this vulnerable sample. In terms of demographics, food/housing insecurity was more prevalent among both pain groups (treated and untreated) compared to the pain-free ($\chi^2=9.48$; $p=0.009$). No significant differences in HIV-related health status were observed between the groups.

Nearly three-quarters of the sample (74.6%) indicated diagnosis with at least one other medical condition (excluding HIV), and the mean number of health diagnoses in the sample was 2.2 (data not shown). The highest prevalence diagnoses included high blood pressure (31.2%), neuropathy (24.9%), high cholesterol (22.5%), sleep disorders (21.3%), and arthritis (20.3%). The presence of pain and its corresponding treatment status were associated with other diagnosed health problems endorsed by the sample. Higher illness burden was associated with pain experience ($F=61.0$; $p=0.000$), as both pain groups had significantly higher numbers of medical diagnoses than the pain-free group. Patients receiving pain treatment also reported significantly more medical diagnoses than their nontreated counterparts ($p=0.000$).

Analyses revealed disparities in mental health functioning associated with pain and treatment status. In this regard, both pain groups (treated and untreated) displayed significantly higher levels of psychological distress when compared with their pain-free counterparts, including past year symptoms of depression ($F=34.3$; $p=0.000$) and anxiety ($F=33.7$; $p=0.000$). Past month psychological symptoms were also more prevalent among those with pain ($\chi^2=35.1$; $p=0.000$), regardless of treatment status. Substance dependence symptoms in the prior month were elevated among those with untreated pain compared to both the pain-free and treated pain groups ($F=14.1$; $p=0.000$).

Pain was also associated with poorer disease management, as indicated by ARV diversion and adherence. Nearly 40% of those with untreated pain endorsed diversion of their ARV medications in the past month, which was a significantly higher proportion than either the pain-free or treated pain groups ($\chi^2=6.62$; $p=0.04$). Past week ARV treatment adherence levels were also reduced among HIV+ individuals with pain. The pain-free group displayed a higher likelihood of achieving 95% medication adherence than either pain group, regardless of treatment status ($\chi^2=11.81$; $p=0.003$).

Table 2 presents the results of the multivariate logistic regression model examining the impact of food and housing insecurity, pain and treatment status, other medical diagnoses, past month psychological problems, past month substance dependence symptoms, and past month ARV diversion on recent ARV adherence.

In the multivariate model, pain/treatment status, substance dependence symptoms, and ARV diversion demonstrated significant associations with ARV adherence. Those with untreated pain had 42% lower odds of achieving 95% medication adherence in the past week compared with the pain-free ($p=0.043$). Substance dependence symptoms adversely affected ARV adherence as well, with 11% lower odds of

TABLE 1. SAMPLE CHARACTERISTICS BY PAST 90-DAY PAIN AND TREATMENT STATUS AMONG INDIGENT HIV + PATIENTS IN SOUTH FLORIDA (N=503)

	<i>Pain (treated)</i> <i>N=151</i>	<i>Pain (untreated)</i> <i>N=107</i>	<i>No pain</i> <i>N=245</i>	<i>F- or chi-square</i>	<i>Sign. level</i>
Demographics					
Age, mean (SD)	46.9 (7.4)	46.8 (8.0)	45.3 (7.9)	2.50	0.08
Male gender, <i>n</i> (%)	79 (52.3)	64 (59.8)	156 (63.7)	5.01	0.08
African American, <i>n</i> (%)	101 (66.9)	71 (66.4)	169 (69.0)	0.32	0.85
Food/housing insecurity, <i>n</i> (%)	71 (47.0)	57 (53.3)	90 (36.7)	9.48	0.00
Years HIV diagnosis, mean (SD) ^a	13.5 (7.3)	13.7 (7.4)	12.9 (7.2)	0.56	0.57
Health status					
Current CD4, mean (SD) ^a	480.3 (293.9)	449.5 (264.0)	480.1 (285.3)	0.46	0.63
Undetectable viral load, <i>n</i> (%) ^a	65 (49.2)	48 (49.0)	103 (46.2)	0.39	0.82
Other medical conditions, mean (SD)	3.4 (2.4)	2.4 (2.2)	1.2 (1.4)	61.05	0.00
Psychological status					
Depression symptoms past yr., mean (SD)	6.3 (2.6)	6.4 (2.7)	4.3 (3.0)	34.34	0.00
Anxiety symptoms past yr., mean (SD)	5.8 (3.5)	5.9 (3.6)	3.3 (3.3)	33.70	0.00
Psychological symptoms past mo., <i>n</i> (%) ^a	122 (80.8)	87 (81.3)	138 (56.6)	35.13	0.00
Dependence symptoms past mo., mean (SD)	3.4 (2.5)	4.5 (2.5)	3.0 (2.4)	14.14	0.00
Health behaviors					
95% ARV adherence past week, <i>n</i> (%)	77 (51.0)	45 (42.1)	150 (61.2)	11.84	0.00
ARV diversion past month, <i>n</i> (%)	38 (25.2)	42 (39.3)	68 (27.8)	6.62	0.04

^aN=502; N=464, N=453, N=502

95% adherence per symptom endorsed ($p=0.007$). ARV diversion displayed a strong association with adherence; endorsement of past month HIV medication diversion resulted in 74% lower odds of achieving 95% adherence ($p=0.000$).

Discussion

Pain is estimated to affect some 30% of adults in the US, making it one of the most frequently occurring health disorders in the nation.^{26,27} Among indigent, HIV-positive substance abusers in South Florida, the present study documented recent pain prevalence of 51.3%. Although elevated with respect to the general population, this finding is in line with prior research on HIV-positive patients, which has gauged pain prevalence to be between 40% and 80%.¹⁻⁴ Our

data confirm that pain is an exceedingly common co-morbid health condition among HIV-positive individuals, including the non-elderly and those treated in an era of ARVs with lower side effect profiles.

Although this study did not gather information on pain intensity or duration, prescribed pharmacotherapy to treat pain was modest, with 41.5% of those endorsing pain being untreated. Pharmacotherapy for pain was more likely for those with more diagnosed medical conditions; nevertheless, those with untreated pain reported 2.4 medical diagnoses on average, not including HIV infection. These data would appear to indicate substantial levels of physical health co-morbidities among this vulnerable sample. Opioid therapy was most common among those prescribed pharmacotherapy at 48%, followed closely by NSAIDs at 39%. The relatively common selection of non-opioid medications may reflect

TABLE 2. MULTIVARIATE LOGISTIC REGRESSION MODEL PREDICTING 95% ARV ADHERENCE AMONG HIV + SUBSTANCE ABUSERS IN SOUTH FLORIDA (N=502)

	<i>B</i>	<i>Odds ratio</i>	<i>95% CI</i>	<i>Sign. level</i>
Demographics				
Food/housing insecurity ^a	-0.066	0.936	(0.628, 1.40)	0.744
Health status				
Pain ^a				
Untreated	-0.538	0.584	(0.346, 0.984)	0.043
Treated	-0.492	0.611	(0.372, 1.01)	0.052
No. of other medical conditions	0.037	1.037	(0.939, 1.15)	0.469
Psychological status				
Psychological symptoms past mo. ^a	-0.199	0.820	(0.526, 1.28)	0.380
No. of dependence symptoms past mo.	-0.113	0.893	(0.822, 0.970)	0.007
Health behaviors				
ARV diversion past month ^a	-1.322	0.266	(0.172, 0.413)	0.000

^aReference category is 'no'.

caution among health care providers and prescribers treating a population with known substance abuse issues.²⁸

Among our vulnerable sample of socioeconomically disadvantaged HIV-positive substance users, pain likely arose from multiple sources, including aging, long-standing participation in street lifestyles that entail drug use and exposure to violence, the presence of multiple chronic health conditions, as well as poverty-driven limitations on health care access and basic subsistence needs. Our bivariate analyses demonstrated that food and housing insecurity were significantly associated with pain endorsement. This finding is consistent with the notion that environmental living conditions, in this case inadequate access to food and safe housing, engender circumstances that may cause, exacerbate, or perpetuate pain. In this regard, prior research has linked housing instability to both high pain prevalence and multiple barriers to care.^{28–32}

Consistent with prior studies,^{33–35} bivariate analyses found that pain endorsement was strongly associated with psychological distress among this sample of substance users. Individuals with pain, regardless of treatment status, exhibited higher symptom levels for both depression and anxiety, compared to the pain-free. Depression and pain have often been linked in the scientific literature and are known to share biological pathways,³⁶ which would indicate that simultaneous treatment approaches may be required for improvement.

Our finding that untreated pain is associated with more problematic substance use may indicate that individuals with pain are attempting to self-medicate through illicit drug use, a phenomenon that has been documented by other researchers.³⁴ Alternatively, it may be that HIV-positive individuals who display more problematic substance use are less likely to receive pain treatment, possibly due to prescriber reluctance, or the patients' inability to comply with appointment schedules or other monitoring requirements. Additionally, disadvantaged HIV-positive patients with heavy substance use may not seek formal treatment for pain, particularly if they remain enmeshed in street lifestyles that limit their access to routine care.

One of the key findings of this study is the demonstration of a graduated improvement in recent ARV adherence corresponding to pain and treatment status. The pain-free group reported the highest adherence, with 61% achieving gold-standard 95% adherence, followed by those with treated pain at 51%, and untreated pain at 42%. Importantly, untreated pain retained a significant direct effect on ARV adherence in the multivariate analysis, even when controlling for other significant factors.

In the present study, participants were required to have an ARV prescription as an eligibility criterion, which indicates that they were seeing their HIV care provider regularly in order to maintain their access to ARVs. Within the context of HIV care visits, routine assessment for pain appears to be warranted. Many non-opioid pharmacotherapies present little risk for misuse and abuse, and regular assessments of pain type, severity, and functional impairment may indicate the need for treatment. Treating pain adequately may provide a mechanism to support improved ARV adherence, which can be especially critical for patients with high levels of competing needs who often struggle with medication regimen compliance. Improving

physical function and quality of life through effective pain management may assist in this regard.

This study has several limitations that should be considered when interpreting the results. First, the sample is not representative of HIV-positive patients. Given the study's focus on ARV diversion, recruitment was targeted to enroll indigent, substance abusing individuals who were located in specific geographic areas where the phenomenon of interest was occurring. This limits generalizability of the findings to other HIV-positive patient populations. A second limitation involves reliance on self-report data. It is possible that recall problems and social desirability biases influenced participant responses to the interview items; nevertheless, the high levels of substance use, ARV diversion, and low ARV adherence reported suggest that participants did not substantially under-report these behaviors. Measures of CD4 and viral load were also obtained from participant self-report; recall problems may have impacted the reliability of these measures and limited our ability to detect relationships in the data. An additional limitation is the cross-sectional nature of the interview data that were gathered; the lack of temporal data limits our ability to demonstrate causal relationships among the key variables. Finally, our measures of pain were limited, and no information was collected on pain intensity, duration, or etiology, so it is not definitive that medication therapy would have been indicated; similarly, it is unknown if patients were receiving alternative therapies for pain.

Our findings point to the need for further research on pain severity, functional impairment, ARV adherence, and diversion among vulnerable HIV-positive patients. In particular, future research may investigate the extent to which ARV diversion is undertaken with the goal of self-medication; that is, to gain access to analgesic medications through illicit sources. Investigation of the influence of untreated pain on positive coping skills is also warranted, as pain may render individuals less motivated to treat their HIV disease and lower compliance with ARV medication regimens.

We believe that this study provides compelling evidence that pain assessment and management warrant more attention among health care providers who serve disadvantaged HIV-positive patients. Given the competing needs of these vulnerable patients and limited access to both routine and specialized medical care,³⁷ the assessment and treatment of pain may fall to HIV care providers, particularly in locations that lack wrap-around services for HIV-positive individuals. The association of untreated pain with ARV non-adherence would appear to be clinically significant, and vulnerable patients may benefit from provider-initiated assessment and/or discussion of pain experience and its impact on the management of HIV. Raising provider awareness of pain as a significant risk factor for ARV non-adherence may lead to the implementation of other clinical intervention approaches for the treatment of pain among disenfranchised HIV-positive individuals as well.

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