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Improved Quality of Life for Opioid Dependent Patients Receiving Buprenorphine Treatment in HIV Clinics

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Abstract

Background—Opioid dependence and HIV infection are associated with poor health-related quality of life (HRQOL). Buprenorphine/naloxone (bup/nx) provided in HIV care settings may improve HRQOL.

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Methods—We surveyed 289 HIV-infected opioid-dependent persons treated with clinic-based bup/nx about HRQOL using the Short Form Health Survey (SF-12) administered at baseline, 3, 6, 9, and 12 months. We used normalized SF-12 scores which correspond to a mean HRQOL of 50 for the general U.S. population (SD 10, possible range 0–100). We compared mean normalized mental and physical composite and component scores in quarters 1, 2, 3, and 4 with baseline scores using GEE models. We assessed the effect of clinic-based bup/nx prescription on HRQOL composite scores using mixed effects regression with site as random effect and time as repeated effect.

Results—Baseline normalized SF-12 scores were lower than the general U.S. population for all HRQOL domains. Average composite mental HRQOL improved from 38.3 (SE 12.5) to 43.4 (SE 13.2) (β 1.13 [95% CI 0.72, 1.54]) and composite physical HRQOL remained unchanged (β 0.21 [95% CI −0.16, 0.57]) over 12 months follow-up. Continued bup/nx treatment across all four quarters was associated with improvements in both physical (β 2.38 [95% CI 0.63, 4.12]) and mental (β 2.51 [95% CI 0.42, 4.60]) HRQOL after adjusting for other contributors to HRQOL.

Conclusions—Clinic-based bup/nx maintenance therapy is potentially effective in ameliorating some of the adverse effects of opioid dependence on HRQOL for HIV-infected populations.

Keywords

Quality of life; Buprenorphine; HIV infections; Opioid-related disorders; Substance abuse; intravenous

INTRODUCTION

Health-related quality of life (HRQOL) is an important consideration in chronic illness management, particularly in the context of life-long therapy and management of complex co-morbidities. HRQOL is increasingly viewed as an essential patient-rated outcome for developing patient-centered treatment interventions for chronic illnesses.[1] HIV infection and substance use disorders are chronic illnesses that frequently co-occur. Approximately half of HIV-infected patients report past or current use of illicit drugs or hazardous alcohol use[2, 3] and injection drug use accounted for 14% of new U.S. HIV/AIDS diagnoses in 2007.[4] HIV disease and substance use disorders interact in complex ways to adversely impact HRQOL.

HIV disease decreases HRQOL.[5–8] In a nationally representative sample of HIV-infected persons in the United States, physical HRQOL for those with symptomatic HIV infection was lower than general population norms. Patients with all stages of HIV experienced lower mental HRQOL. Both physical and mental HRQOL were poorer compared with persons with other chronic conditions.[6] Mental and physical HRQOL decrease with more advanced stages of HIV disease[5, 6] and with an increasing number of HIV symptoms.[9, 10] While HRQOL may improve with treatment of HIV infection and symptoms,[9, 11–13] HIV-infected patients with low HRQOL experience decreased survival.[14–16] Improvements in the HRQOL of HIV-infected persons increase survival.[16]

Substance use disorders are associated with worse HRQOL for both HIV-infected[17–19] and uninfected individuals[20–22]. In a multi-center study of HIV-infected patients in care, current illicit drug users reported lower physical and mental HRQOL compared with non-users but HRQOL of illicit drug users who had not used in at least 6 months was comparable to non-users, suggesting that facilitating sobriety may improve HRQOL for these individuals.[17] Yet access to substance abuse treatment remains limited for many HIV-infected patients.[3, 23] The approval of buprenorphine/naloxone (bup/nx) for treatment of opioid dependence can expand access to treatment for opioid-dependent patients engaged in HIV care[24].

Buprenorphine/naloxone is preferred to methadone maintenance by some HIV-infected patients.[25]

Few studies of patients engaged in opioid agonist treatment assess changes in HRQOL over time.[26] Studies in non-HIV-infected opioid-dependent patients receiving bup/nx or methadone maintenance from specialty addiction treatment centers in Europe and Israel suggest that treatment with methadone or bup/nx maintenance can improve HRQOL.[27–30] To our knowledge, no prior studies have assessed the capacity of clinic-based bup/nx therapy to improve HRQOL in HIV-infected populations meeting DSM-IV criteria for opioid dependence. Treatment of opioid dependence in HIV-infected populations may have additional potential to benefit HRQOL by decreasing depressive symptoms,[31]and improving cognitive impairment,[32] and adherence to antiretroviral treatment, cellular immunity, and HIV-1 virologic suppression.[33, 34]

The objective of this study was to assess the effect of clinic-based bup/nx on HRQOL in a cohort of opioid-dependent HIV-infected persons receiving outpatient HIV care. We hypothesized that a) mental and physical HRQOL prior to initiating bup/nx treatment would be lower than general population norms, and that b) patients with greater exposure to clinic-based bup/nx over time would experience greater improvements in HRQOL compared with those with less exposure.

METHODS

Setting

As described in detail elsewhere[24, 35], from 2004–2009, the HIV/AIDS Bureau of the Health Resources and Services Administration (HRSA) funded, through its Special Projects of National Significance (SPNS), the development of demonstration programs that integrated HIV care and bup/nx treatment for opioid dependence at 10 HIV clinic sites across the U.S. HRSA also funded an Evaluation and Technical Assistance Center (Center) to coordinate the multi-site evaluation, provide clinical and evaluation support and technical assistance, and promote dissemination of findings. Data from nine of the ten sites were included in the current analysis. One site was excluded due to a limited number of patients prescribed clinic-based bup/nx. Each site and the Center obtained institutional review board approval for conducting this evaluation.

Participants

Potential study participants identified through provider referral, word of mouth, and community outreach were enrolled from 2005 through 2007. Eligible participants were HIV-infected, at least 18 years old, met DSM-IV criteria for opioid dependence, and spoke English or Spanish. Potential participants were excluded if they had unstable alcohol or benzodiazepine dependence or other severe medical or psychiatric conditions that constituted an imminent threat to participant safety, AST or ALT levels > 5 times normal, or were pregnant. All participants completed written informed consent prior to enrollment.

Data Collection Methods

Study participants completed baseline assessments that recorded demographic, social, substance use, and quality of life measures; research personnel conducted medical record abstraction to confirm substance abuse and medical treatment at baseline, 3, 6, 9, and 12 months follow-up. Data were entered electronically at participating sites and uploaded to the Center for collation and analysis.[35]

Measures

The primary independent variable for this analysis was persistence on bup/nx from baseline over the course of a year, as a measure of exposure to clinic-based bup/nx. Following bup/nx induction, maintenance doses ranged from 2mg to 24mg per day, according to site dosing protocols. A bup/nx clinical coordinator facilitated bup/nx treatment in HIV clinics. Participants were considered as being on bup/nx if quarterly chart abstraction demonstrated receipt of at least one prescription for bup/nx during that quarter. Participants were categorized according to the progressive number of quarters they continued being prescribed bup/nx in the year following baseline induction (persistent at quarter 1, quarters 1 and 2, quarters 1–3, and quarters 1–4).

Health Related Quality of Life—The main dependent variable of interest was HRQOL. HRQOL was assessed using the Medical Outcomes Study Short Form Health Survey (SF-12), version 2 that generates a physical composite summary score (composed of general health, physical functioning, physical role functioning, and bodily pain domains) and a mental composite summary score (composed of mental health, vitality, social functioning, and emotional role functioning).[36] We used standard norm-based scoring procedures that transform raw scores for comparison with the general U.S. population mean score of 50 and standard deviation of 10 (possible range 0–100).[37] The SF-12 has been previously validated in HIV-infected populations,[15, 38, 39] as well as in persons with current substance use disorders and other serious mental disorders,[40] low socioeconomic status,[39] homelessness,[41] and minority racial/ethnic groups[42, 43]—similar to the current study population.

Covariates—We examined potential covariates including gender (male, female), race/ethnicity (White, Black, Hispanic, Other), age in years at time of baseline survey, education level (< high school, high school graduate or GED, and at least some college), employment status (employed vs. not employed), housing status (homeless vs. not), Hepatitis C antibody status (positive/negative), and incarceration in the 30 days prior to baseline (yes/no). We used Addiction Severity Index (ASI)-lite drug and alcohol composite scores to assess addiction severity,[44, 45] and assessed self-reported time since HIV diagnosis (years), self-reported CD4 nadir prior to baseline (≤ 200 cells/mL^3, > 200 cell mL^3), and whether or not participants were prescribed HAART in each quarter (yes/no) as measures of HIV severity.

Analysis

We used descriptive statistics to describe patient characteristics at baseline. We compared mean normalized mental and physical composite scores and their subcomponent scores across 4 quarters using generalized estimating equation (GEE) models. We developed mixed effects regression models to test our hypothesis that clinic-based bup/nx prescription was associated with change from baseline in quality of life mental and physical composite summary scores over time. Site was included as a random effect and time was included as a repeated effect in all models. We considered covariates for inclusion in multivariate models if important in bivariate analysis ($p<0.10$) or of *a priori* importance.

RESULTS

Participant Characteristics

A total of 303 patients received bup/nx as part of the study. Of these, 289 had HRQOL scores at baseline and at least one subsequent quarter and were included in the current analysis. Table 1 shows baseline participant characteristics. Participants were primarily male (67.5%), African American (52.3%), heterosexual (81.1%), unemployed (74.4%), prescribed HAART (59.9%), Hepatitis C co-infected (77.3%) and had a mean age of 45.2 years (SD 8.2). At baseline, a quarter of participants were homeless and 13.5% had been incarcerated

in the previous 30 days. Baseline addiction severity scores were comparable to normative data for opiate-dependent populations[46] for both drug use (ASI-drug score .321, SD .129) and alcohol use (ASI-alcohol score .088, SD .121).

Health Related Quality of Life

Table 2 presents normalized mean physical and mental composite HRQOL scores for each domain over time. Normed scores were lower than those observed for the general U.S. population (mean 50, SD 10) at baseline for all domains. The average composite mental HRQOL score improved by more than 5 points during the follow-up period (β 1.13; 95% CI 0.72, 1.54). Average scores improved for all mental HRQOL sub-components (mental health β 0.96 [95% CI 0.55, 1.37]; vitality β 0.81 [95% CI 0.44, 1.17]; social functioning β 0.1.03 [95% CI 0.60, 1.47]; and emotional role β 0.84 [95% CI 0.41, 1.28]. While the average composite physical HRQOL score did not significantly improve over time, patients experienced improved general health (β 0.71 [95% CI 0.30–1.12]) and physical role functioning (β 0.60 [95% CI 0.23–0.97]). The majority of improvement for all HRQOL composite and component scores occurred during the first quarter of clinic-based bup/nx and then persisted throughout the follow-up period.

Participant Characteristics Associated with Quality of Life

Table 3 reports multivariate associations between patient characteristics and mental composite quality of life score. Persistence on bup/nx through all four quarters was associated with improved mental HRQOL (β 2.51 [95% CI 0.42, 4.60]), or a mean adjusted increase in mental HRQOL score of 2.51 points compared to baseline. This was comparable to the independent effect of taking HAART (β 2.81 [95% CI 1.20, 4.41]). Several baseline patient characteristics were associated with lower mental HRQOL, including female gender, White and Hispanic race/ethnicity (compared with Blacks), homelessness, incarceration in the 30 days prior to baseline, and higher drug use severity. Increased age at baseline was also associated with higher mental HRQOL.

Table 4 reports multivariate associations between patient characteristics and physical composite quality of life score. Persistence on bup/nx through three quarters (β 2.72 [95% CI 0.31, 5.14]), or four quarters (β 2.38 [95% CI 0.63, 4.12]) was associated with improved physical HRQOL. Being employed at baseline was associated with greater physical HRQOL. Patient characteristics at baseline predicting lower physical HRQOL included increased age, female gender, White, Hispanic and Asian/Other race/ethnicity (compared with Blacks), and homelessness.

DISCUSSION

The mental and physical HRQOL of HIV-infected study participants with opioid dependence improved over time with clinic-based bup/nx. Those continuing to receive bup/nx through all four quarters of follow-up experienced greater gains in both physical and mental HRQOL. Our findings suggest that clinic-based bup/nx maintenance therapy may potentially be effective in ameliorating some of the adverse effects of opioid dependence on HRQOL for HIV-infected populations.

Improvements in composite as well as all component mental HRQOL scores are consistent with findings from studies evaluating the effect of bup/nx treatment on HRQOL among HIV-uninfected patients receiving bup/nx maintenance from specialized addiction treatment centers.[27–30] Improvements were also observed for the general health and role physical component scores. Using different quality of life measures, Giacomuzzi, *et. al.* and Ponizovsky, *et. al.* both reported similar improvements in the physical health sub-domains

of their instruments for heroin dependent patients receiving bup/nx maintenance from addiction treatment centers.[28, 30] Though observed increases in HRQOL were numerically small in this and other studies, they correspond to potentially dramatic improvements in outcomes. In one study of patients with advanced HIV disease, a 1-point increase in the baseline composite physical or mental HRQOL score corresponded to a 4% decrease in risk of death.[16] This suggests the 5-point improvement in composite mental HRQOL observed in our data could potentially reflect improvements associated with decreased mortality.

Improvements in both mental and physical HRQOL in patients with longer retention in clinic-based bup/nx were observed even after adjusting for other significant determinants of HRQOL, suggesting that longer-term prescription of bup/nx maintenance may lead to greater improvements in HRQOL. Clinical trials of bup/nx maintenance vs. short-term bup/nx (supervised opioid withdrawal) demonstrate improved substance abuse treatment outcomes for long-term maintenance.[47, 48] Independent improvements in mental HRQOL due to remaining on bup/nx over time were comparable to the observed effect of remaining on HAART in multivariate models. Remaining on HAART over time is associated with decreased depressive symptoms, which may contribute to improved mental HRQOL.[31] Although these data cannot address this issue, successful and sustained integration of treatment for HIV and opioid dependence may further benefit patients' HRQOL by improving convenience, streamlining treatment decisions, increasing engagement in substance abuse and HIV treatment,[49] decreasing stigma, and providing a more patient-centered care experience.[25]

The current study contributes to calls for evaluation of more patient-centered approaches to treatment of substance use disorders[50] by directly evaluating HRQOL. U.S. federal agencies are increasing prioritizing patient-rated HRQOL as a key patient-centered outcome.[1, 51] Clinic-based bup/nx may be a tool for achieving better patient-centered outcomes for persons with opioid dependence and HIV-infection.[25]

Baseline patient characteristics, including age, gender, race/ethnicity, homelessness, incarceration, and HIV and drug use severity, were important contributors to mental and physical HRQOL, as has been reported previously in similar populations.[6, 19, 52–54] Despite the importance of and adjustment for these factors, persistence on bup/nx throughout four quarters of follow-up was associated with improvements in both mental and physical HRQOL. This is consistent with prior observations that substance use disorders likely eclipse other factors that contribute to HRQOL.[52] Our data suggest that addressing opioid dependence with clinic-based bup/nx treatment may mitigate these adverse baseline effects on HRQOL.

Our findings should be interpreted in the context of several potential limitations. First, we were unable to assess participant adherence to bup/nx, potentially biasing our findings toward the null hypothesis. Second, we did not consider substance abuse outcomes (e.g., urine drug screens) which may mediate observed improvements in HRQOL. Third, the number of participants with HRQOL data decreased from baseline through follow-up, potentially resulting in retention bias. An alternative explanation for observed improvements in HRQOL is that participants feeling well were more likely to continue on bup/nx. Fourth, participating HIV clinic providers and staff received substantial training and expert support in implementation of clinic-based bup/nx, and patients benefited from a grant-supported bup/nx clinical coordinator. Observed improvements in HRQOL may not be generalizable to HIV practice settings lacking such resources. Fifth, HIV clinic sites varied in their development of models for bup/nx integration.[55] Bup/nx was, however, typically administered by providers using standard bup/nx guidelines.[56] Finally, we relied on a single measure, the SF-12, to estimate HRQOL. Though the SF-12 has been well validated in HIV-

infected and substance abusing populations previously[15, 38–40], it does not include HIV or opioid dependence specific domains and is susceptible to "floor" effects (i.e., limited sensitivity in measuring lower levels of HRQOL).[57–59] Consequently, our results potentially underestimate the true effect of clinic-based bup/nx on HRQOL in this population with highly prevalent physical and mental health disorders.

In summary, the results of this observational cohort study suggest that clinic-based bup/nx maintenance therapy is potentially effective in improving HRQOL for HIV-infected patients with concurrent opioid dependence. Given the adverse impact of opioid dependence on HRQOL and often limited access to treatment, interventions that promote more widespread adoption of clinic-based bup/nx in HIV clinical care settings may contribute to substantial quality of life improvements for this highly vulnerable population.

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Table 1

Participant Characteristics at Baseline (n=289)

	n	%
Mean Age (SD)	45.2 (8.2)	
Female Gender	94	32.5
Race/Ethnicity		
Black	149	52.3
White	65	22.8
Latino	62	21.8
Other	9	3.1
Sexual Orientation		
Heterosexual	232	81.1
Gay/Lesbian	27	9.4
Bisexual	27	9.4
Education		
Less than high school	121	42.0
High school graduate or GED	101	35.1
College (some or graduated)	66	22.9
Unemployed	215	74.4
Jailed in 30 days prior to baseline	39	13.5
Homeless	73	25.3
CD4 nadir < 200 cells/mL^3	133	49.1
Hepatitis C antibody positive	174	77.3
On HAART at baseline	172	59.9
Mean years since HIV diagnosis (SD)	11.9 (6.5)	
Baseline ASI-Alcohol (SD)	.088 (.121)	
Baseline ASI-Drug (SD)	.321 (.129)	

Table 2

Mean Normalized Quality of Life Scores over Time Among All Participants.

	Normalized Scores (SE)					Average Change Across Quarters	
	Baseline (N=289)	**Q1 (N=212)**	**Q2 (N=193)**	**Q3 (N=178)**	**Q4 (N=185)**	**β coefficient**	**95% CI**
Physical Composite Score	42.1 (10.6)	43.1 (10.2)	42.3 (10.8)	43.9 (10.0)	42.5 (10.5)	0.21	−0.16, 0.57
General Health	38.4 (12.7)	41.2 (11.9)	41.0 (12.6)	42.6 (11.7)	41.2 (13.0)	0.71	0.30, 1.12
Physical Functioning	42.6 (11.7)	43.0 (11.8)	42.5 (12.1)	44.2 (10.7)	42.2 (12.0)	0.11	−0.28, 0.50
Role Physical	39.7 (10.4)	41.7 (11.0)	41.5 (11.0)	43.3 (10.2)	41.4 (10.9)	0.60	0.23, 0.97
Bodily Pain	40.1 (13.8)	42.3 (13.1)	41.5 (13.7)	42.0 (13.7)	42.2 (13.2)	0.42	−0.05, 0.89
Mental Composite Score	38.3 (12.5)	42.5 (12.5)	43.0 (12.7)	43.6 (12.0)	43.4 (13.2)	1.13	0.72, 1.54
Mental Health	39.3 (12.4)	42.5 (12.3)	42.8 (12.9)	43.6 (12.9)	43.6 (12.7)	0.96	0.55, 1.37
Vitality	44.2 (11.1)	47.6 (11.0)	47.3 (11.5)	47.8 (10.6)	47.9 (11.0)	0.81	0.44, 1.17
Social Functioning	37.9 (12.7)	41.0 (13.1)	40.1 (13.2)	42.5 (12.6)	42.2 (12.1)	1.03	0.60, 1.47
Role Emotional	36.4 (12.5)	39.4 (13.6)	40.5 (13.1)	41.1 (12.5)	39.5 (13.7)	0.84	0.41, 1.28

Table 3

Multivariate Associations with Mental Composite Quality of Life Score. β Coefficients indicate absolute difference in HRQOL score compared with referent category. For example, a β coefficient of 2.51 for persisting on Bup/nx through 4 quarters denotes a mean adjusted increase in mental HRQOL score of 2.51 points compared to baseline.

Parameter	β coefficient	95%CI
Prescribed Buprenorphine		
Baseline	reference	reference
Quarter 1	0.12	−3.33, 3.56
Quarters 1–2	2.39	−1.15, 5.93
Quarters 1–3	2.05	−0.86, 4.95
Quarters 1–4	2.51	0.42, 4.60
Age	0.14	0.03, 0.24
Female Gender	−2.60	−4.25, −0.94
Race/ethnicity		
Black	reference	reference
White	−3.34	−5.52, −1.16
Hispanic	−6.93	−9.06, −4.80
Asian/Other	−0.29	−4.88, 4.30
Homeless at baseline	−3.25	−5.10, −1.40
Education		
Less than high school	reference	reference
High school graduate or GED	1.44	−0.31, 3.20
Some college/graduate school	0.84	−1.16, 2.84
Jailed in 30 days before baseline	−4.75	−7.04, −2.46
Baseline ASI - Alcohol	4.02	−3.19, 11.2
Baseline ASI - Drugs	−11.4	−17.7, −5.05
On HAART (in quarter)	2.81	1.20, 4.41

Table 4

Multivariate Associations with Physical Composite Quality of Life Score. β Coefficients indicate absolute difference in HRQOL score compared with referent category. For example, a β coefficient of 2.38 for persisting on Bup/nx through 4 quarters denotes a mean adjusted increase in mental HRQOL score of 2.38 points compared to baseline.

Parameter	β coefficient	95%CI
Prescribed Buprenorphine		
Baseline	reference	reference
Quarter 1	−1.50	−4.35, 1.36
Quarters 1–2	−2.20	−5.07, 0.66
Quarters 1–3	2.72	0.31, 5.14
Quarters 1–4	2.38	0.63, 4.12
Age (years)	−0.21	−0.30, −0.12
Female Gender	−1.51	−2.91, −0.10
Race/ethnicity		
Black	reference	reference
White	−3.70	−5.58, −1.81
Hispanic	−2.00	−3.87, −0.13
Asian/Other	−9.80	−13.7, −5.89
Employed at baseline	3.84	2.37, 5.31
Homeless at baseline	−1.93	−3.45, −0.41
Baseline ASI - Alcohol	−2.72	−8.72, 3.29
Baseline ASI - Drugs	0.45	−4.78, 5.67
On HAART (in quarter)	0.16	−1.18, 1.50
HIV time from diagnosis	−0.07	−0.19, 0.04