
Improved HIV and Substance Abuse Treatment Outcomes for Released HIV-Infected Prisoners: The Impact of Buprenorphine Treatment

Sandra Ann Springer, Shu Chen, and Frederick L. Altice

ABSTRACT *HIV-infected prisoners fare poorly after release. Though rarely available, opioid agonist therapy (OAT) may be one way to improve HIV and substance abuse treatment outcomes after release. Of the 69 HIV-infected prisoners enrolled in a randomized controlled trial of directly administered antiretroviral therapy, 48 (70%) met DSM-IV criteria for opioid dependence. Of these, 30 (62.5%) selected OAT, either as methadone (N=7, 14.5%) or buprenorphine/naloxone (BPN/NLX; N=23, 48.0%). Twelve-week HIV and substance abuse treatment outcomes are reported as a sub-study for those selecting BPN/NLX. Retention was high: 21 (91%) completed BPN/NLX induction and 17 (74%) remained on BPN/NLX after 12 weeks. Compared with baseline, the proportion with a non-detectable viral load (61% vs 63% log₁₀ copies/mL) and mean CD4 count (367 vs 344 cells/mL) was unchanged at 12 weeks. Opiate-negative urine testing remained 83% for the 21 who completed induction. Using means from 10-point Likert scales, opioid craving was reduced from 6.0 to 1.8 within 3 days of BPN/NLX induction and satisfaction remained high at 9.5 throughout the 12 weeks. Adverse events were few and mild. BPN/NLX therapy was acceptable, safe and effective for both HIV and opioid treatment outcomes among released HIV-infected prisoners. Future randomized controlled trials are needed to affirm its benefit in this highly vulnerable population.*

KEYWORDS *Buprenorphine, Substance abuse, Opioid dependence, HIV, AIDS, Prisoners, Incarceration, Prevention*

INTRODUCTION

In the USA, the prevalence of HIV among prisoners is approximately three times greater than in surrounding communities.¹ Indeed, 14% of all people living with HIV encounter the criminal justice system annually.² As such, prisons are an important place to detect HIV, treat it, and serve as a conduit to care after release. The availability of highly active antiretroviral therapy has transformed HIV into a chronically manageable condition, even for prisoners.^{3,4} Unfortunately for prisoners, including those with HIV, the 3-month period after release is a highly vulnerable time period, resulting in high rates of recidivism to prison,⁵ relapse to drug use,⁶⁻⁸ and overdose resulting in death.⁹ For those with HIV, decreased access to antiretroviral therapy,¹⁰ poor virological and immunological treatment outcomes,^{11,12} and high rates of HIV risk behaviors have been confirmed.¹³ Thus, researchers, practitioners, and policy makers have emphasized that the first 3 months

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after release to the community is a crucial period for newly released prisoners. If successful reintegration is not achieved during this period, it is not likely to occur.^{14–16}

These findings create an urgent need to adapt and test evidence-based transitional interventions for this population. Opioid agonist therapy (OAT), including methadone and buprenorphine/naloxone (BPN/NLX) therapy, decrease heroin use, time to relapse, criminal activity and HIV risk behaviors and increase retention in treatment and are cost-effective to society.^{17,18} Moreover, 85–90% of inmates with histories of opioid dependence relapse to heroin use within one year after release,^{6,7} yet OAT is rarely available.^{19–21} For unclear reasons, the criminal justice system has not adopted these effective treatments, particularly for those with HIV who might benefit most.²²

We therefore sought to establish acceptability, feasibility, and early HIV and substance abuse treatment outcomes after introducing BPN/NLX at the time of release from prison in HIV-infected patients receiving antiretroviral therapy. BPN/NLX, unlike methadone that is a full opioid mu-agonist, is a partial mu-agonist and was selected for its favorable safety profile, reduced likelihood for overdose and death and few pharmacokinetic drug interactions with antiretroviral medications.²³

METHODS

Recruitment All subjects were recruited from within a randomized controlled trial of directly administered antiretroviral therapy (DAART) among HIV-infected prisoners transitioning to the community within 90 days. Those who met DSM-IV criteria for opioid-dependence were assessed for interest in OAT with either methadone or BPN/NLX. Additional eligibility criteria included: (1) returning to either New Haven or Hartford; (2) age \geq 18 years; (3) a negative urine pregnancy test for women and willingness to use contraception; and (4) expressing an interest in BPN/NLX treatment. As part of the ongoing parent study, subjects were randomized 2:1 to receive DAART versus self-administered therapy (SAT).

Study Procedures Within 90 days before community-release, all subjects underwent informed consent, baseline assessments and chart review. Assessments included demographic information, mental illness and chemical dependence screening using the Mini-International Neuropsychiatric Interview (M.I.N.I),²⁴ Addiction Severity Index,^{25,26} and Alcohol Use Disorders Identification Test.²⁷ Alcohol and drug use questions referred to the pre-incarceration period to establish historical diagnoses, as no subject was actively using drugs or alcohol. Subjects underwent secondary consent procedures after release to avoid any perceived or real coercion. Additional post-release activities included baseline physical exam and weekly assessment of opiate craving (10-point Likert-scale), buprenorphine satisfaction (10-point Likert-scale), urine toxicology screening using the NIDA-6 (opiates, cocaine, methadone, benzodiazepines, marijuana, and methamphetamines), and separate urine tests for oxycodone and buprenorphine (Redwood Biotech, Santa Rosa, CA). Baseline and quarterly HIV-1 RNA levels (Amplicor 1.5; Roche) and CD4 lymphocyte counts (FACS; Quest) were obtained.

Buprenorphine Induction Process BPN/NLX induction was allowed up to 30 days post-release from prison; however, the day of release was targeted when possible. Due to low expected tolerance to opioids, subjects were initially administered

2.0 mg/0.5 mg BPN/NLX and increased by 2 mg/0.5 mg increments of BPN/NLX, as tolerated, to reduce the craving score to 1, while avoiding opiate agonist side effects. BPN/NLX dose, craving for opiates, opioid withdrawal symptoms, opioid-agonist side effects, and urine drug screening were all collected daily during the induction and weekly thereafter. All subjects received weekly, standardized, and manual-based counseling per protocol²⁸ for 45–60 min by a certified substance abuse treatment counselor. Study personnel linked counseling visits to collection of urine screens.

Buprenorphine Administration For those randomized to DAART, BPN/NLX was observed daily along with their antiretroviral therapy and other chronically prescribed medications. BPN/NLX dispensing, similar to the SAT group, was contingent upon attending weekly counseling sessions. For those in the SAT arm, BPN/NLX was contingent upon attending weekly counseling sessions where a voucher was provided to allow the pharmacy to release the BPN/NLX. Counselors provided a 7-day prescription voucher after providing a urine specimen and attending weekly counseling sessions. The voucher was not contingent on urine specimen results.

Follow-up Subjects were evaluated daily by the study clinician during the induction phase and at least monthly thereafter. Counselors met with subjects weekly, irrespective of study assignment, and assessed urine toxicology screening, opiate craving, BPN/NLX satisfaction, and adverse side effects. Structured interviews and phlebotomy for CD4 lymphocyte count and HIV-1 RNA level were conducted at weeks 4 and 12.

Analytic Strategy Outcomes from the first 12 weeks are reported for the first 23 subjects recruited. The primary HIV treatment outcome was the proportion with a non-detectable HIV-1 RNA level 12 weeks after prison-release since this is the most vulnerable time period. CD4 counts are similarly reported. The primary substance abuse treatment outcome was retention in BPN/NLX treatment. Secondary drug treatment outcomes included the percentage of opioid-free urine toxicology results over 12 weeks. Missing urine results were adjudicated in the following sequential manner: (1) self-report at weekly visits; and (2) last value carried forward only if a single missing value was noted; (3) for subjects who remained in the trial, missing consecutive urine values were considered positive. Therefore, the proportion of positive urine tests was calculated as the percent positive out of the number who remained in the trial for each week and included missing value adjudication. Craving and satisfaction scores were calculated as the mean for those individuals whose results were reported weekly.

Institutional Review Boards at both Yale University and the University of Connecticut and the Research Committee at the Connecticut Department of Correction approved the study; a Certificate of Confidentiality was also obtained. The parent study is registered at www.clinicaltrials.gov (NCT00786396).

RESULTS

Figure 1 depicts the disposition of the 69 subjects enrolled in the parent study; 70% ($N=48$) met DSM-IV criteria for opioid dependence. Of these, 14.5% ($N=7$) chose methadone, 37.5% ($N=18$) chose no form of OAT, and 48% ($N=23$) chose to be inducted on BPN/NLX.

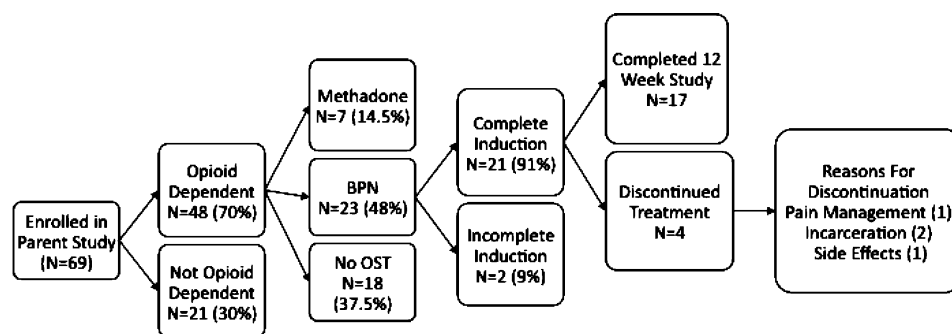


FIGURE 1. Subject allocation.

Table 1 describes the baseline characteristics for the 23 subjects choosing buprenorphine treatment. The 2:1 randomization of the parent study resulted in 16 receiving BPN/NLX as DAART and seven self-administering it. All subjects ($N=23$) had at least one Axis I disorder: 52% had thought disorders (i.e. schizophrenia and psychosis) and 78% had mood disorders (i.e. major depression, and bipolar disorder). The majority (61% of 23) with Axis I anxiety disorders (i.e. Post-Traumatic Stress Disorder, General Anxiety Disorder, Obsessive Compulsive Disorder) was also prescribed psychiatric medications.

For the primary HIV treatment outcome (see Figure 2), the proportion of subjects with a non-detectable HIV-1 RNA levels at 12 weeks did not differ from baseline (61% vs. 63%, $p=0.91$). The mean CD4 lymphocyte count (367 vs. 344, $p=0.89$) did not differ statistically either. For those subjects whose HIV-1 RNA level was

TABLE 1 Baseline characteristic of study participants ($N=23$)

Characteristic	
Mean age (years)	46.4
Gender (M/F), N (%)	18 (78):5 (22)
Race/ethnicity	
Black, N (%)	9 (39)
Hispanic, N (%)	12 (52)
White, N (%)	2 (9)
Co-morbid axis I mental disorders ^a	23 (100)
Thought disorders, N (%)	12 (52)
Mood disorders, N (%)	18(78)
Anxiety disorders, N (%)	14(61)
Prior opioid agonist treatment	
Methadone, N (%)	19 (82.6)
BPN/NLX, N (%)	5 (21.7)
Methadone and BPN/NLX, N (%)	5 (21.7)
Randomization (DAART/SAT)	16:7
Median months of incarceration (IQR)	7 (5–11)
Baseline AUDIT score	6.78 (± 7.71)
Mean baseline CD4+ lymphocytes (cells/mL)	344 (± 222)
HIV-1 RNA < 50 (%)	63
Mean HIV-1 RNA (among VL > 50, copies/mL)	4.11 log ₁₀

^aM.I.N.I prison diagnosis and/or psychiatric medications

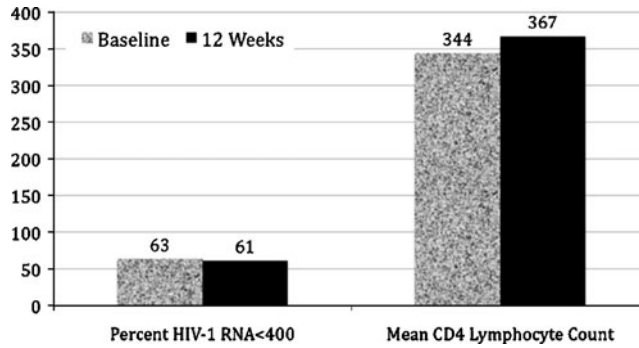


FIGURE 2. HIV treatment outcomes.

detectable, they similarly did not have a change in HIV-1 RNA levels (4.12 vs. 4.11 \log_{10} copies/mL).

Among the 23 subjects initiating BPN/NLX, 91% ($N=21$) completed the induction period. Two subjects left the study after a single dose of BPN/NLX and were subsequently lost to follow-up to both the BPN/NLX and the parent study. After induction, the mean daily BPN/NLX dose at which subjects were stabilized was 9.5 mg (range, 2 to 16 mg). There were no differences between the mean BPN/NLX dose for those treated and not treated with atazanavir-containing regimens (9.20 mg vs. 8.46 mg; $p=0.82$), yet there was a trend toward higher BPN/NLX dosage when co-administered with efavirenz-containing regimens (10.33 mg vs. 5.33 mg; $p=0.10$).

Compared to baseline, mean opioid craving scores decreased from 6 to 1.8 after induction completion (on average, 3 days) and remained 2.2 by the end of 12 weeks. The mean satisfaction with BPN/NLX treatment score was high at 9.5 throughout the 12-week period (see Figure 3) for the 17 retained subjects. Overall, retention was high at 12 weeks—74% for all 23 subjects and 81% for the 21 who completed induction. One successfully inducted subject withdrew from BPN/NLX because she required a prescribed narcotic for a pain-related syndrome; two were reincarcerated

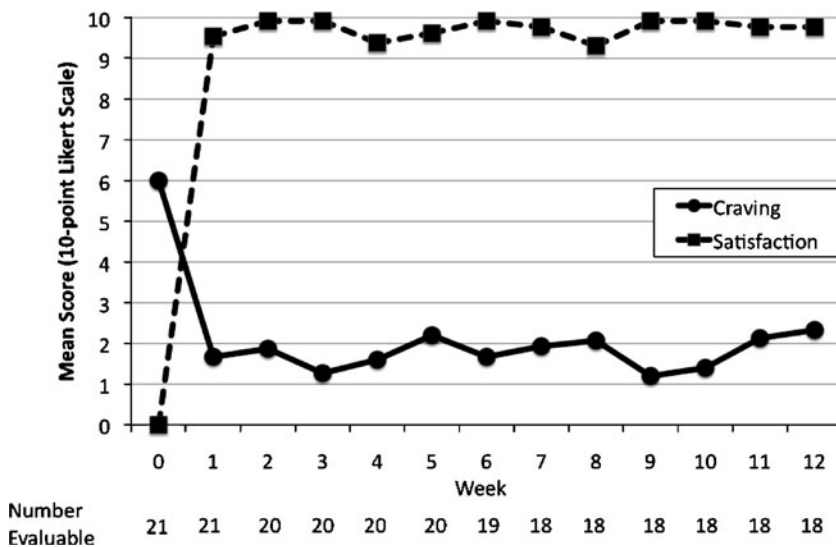


FIGURE 3. Opiate craving and satisfaction with buprenorphine treatment.

after cocaine-relapse (opiate screens remained negative); and one withdrew due to nausea, a side effect he attributed to BPN/NLX.

Figure 4 depicts the urine toxicology results for buprenorphine, other opioids and cocaine over the 12-week period. Urine opiate positivity decreased from 29% at baseline to 17% at the end of 12 weeks for the 17 subjects who completed 12 weeks; it was 20% for the 21 subjects who completed the 3-day induction. Similarly urine cocaine positivity ranged from 43% at baseline to 29% at 12 weeks. Receiving HIV and BPN/NLX medications as DAART vs. SAT did not significantly differ for retention between groups (72.2% vs 92.9%, $p=0.17$), but the study was underpowered to detect a difference.

The mean number of days between release from prison and receiving the first induction dose of BPN was 8.5 (range 0 to 30 days). The delay between release and starting buprenorphine resulted in positive urine testing at baseline. Comparing the 14 subjects who were inducted “early” (within the first 7 days of release), versus the nine inducted “later” (after 7 days of release), there was no statistical difference in the mean retention on treatment (11.0 vs. 10.6 weeks, $p=0.79$), the proportion completing all 12 weeks (84.6% vs. 87.5%, $p=1.00$), the percent of negative urine screens for opiates (70% vs. 86%, $p=0.47$) and cocaine (51.0 vs. 70.6%, $p=0.56$), and the mean BPN dose at the completion of induction (9.8 vs. 8.9 mg, $p=0.31$).

Adverse side effects, including constipation, headache, nausea and drowsiness from BPN/NLX during the 12 weeks of the study were considered mild and easily addressed by the treatment team. The one subject who withdrew from the BPN/NLX treatment for nausea refused treatment with anti-emetics. No subject experienced opioid withdrawal symptoms or overdose during the 12-week study period. Side effects were not associated with co-administration of atazanavir or efavirenz (data not shown).

DISCUSSION

Though small, this pilot feasibility study has important implications for both clinical care and research. First, it is the first study to demonstrate that HIV treatment outcomes persist during transition from prison and there were few adverse consequences. Second,

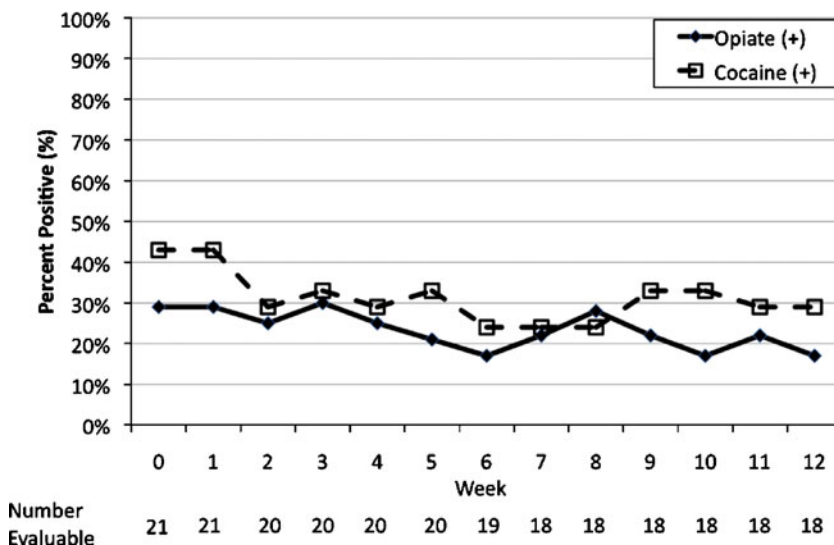


FIGURE 4. Percent of positive urine toxicology tests over time.

it is also the first study to demonstrate the feasibility of BPN/NLX treatment as relapse prevention for opioid-dependent, HIV-infected prisoners transitioning to the community. Last, this study demonstrates not only a high preference for BPN/NLX over methadone or no OAT among those with opioid dependence, but demonstrates high levels of acceptability and satisfaction.

Prison-release studies of HIV-infected patients, including those from Connecticut, confirm poor virological and immunological outcomes within 12 weeks of release.^{11,12} While case management interventions have successfully linked released prisoners to care, none have confirmed stability in HIV treatment outcomes. Recent data from Texas suggest that refilling prescriptions is low among released HIV-infected prisoners,¹⁰ but this obstacle was not present in this study since all prescriptions were continued for all study subjects. The Texas study, however, did not assess the reasons for not filling prescriptions, which might have resulted from relapse to drug use. Though these pilot data are not powered sufficiently to determine if BPN/NLX treatment alone led to these successful clinical endpoints, these data remain compelling and suggest that BPN/NLX was an important factor in stabilizing the lives of subjects, resulting in improved adherence to antiretroviral therapy. Though insufficiently powered, it is now necessary to recruit larger sample sizes to determine if DAART plays a role in retention and outcomes. Ultimately, buprenorphine treatment alone without DAART needs evaluation through the rigors of a randomized controlled trial to determine its effectiveness.

Similar to most correctional settings in the Northeast where HIV prevalence rates are highest, the majority (70%) of all released HIV-infected prisoners on antiretroviral therapy met DSM-IV criteria for opioid dependence. Not only did the majority of those with opioid dependence choose OAT over no pharmacological therapy, but also BPN/NLX was preferred over methadone. Though numerous explanations may be posited, the greater preference for BPN/NLX may reflect previous negative experiences with or perceptions about methadone among this population;²⁹ this finding is supported by the near universal (>80%) prior experience with methadone treatment (see Table 1). One of the misconceptions by prisoners who are no longer using illicit drugs is that “OAT would no longer be needed” after prolonged periods of forced abstinence. Absent from that perspective, however, is the recognition that opioid-relapse is high and approaches 85–90%⁶ even after prolonged imprisonment.

Though the sample size was small, BPN/NLX was feasible and efficacious. There are no other studies of BPN/NLX treatment for HIV-infected released prisoners, but compared with HIV-undifferentiated released prisoners, substance abuse outcomes are similar to other studies. Among opioid-dependent prisoners in Baltimore with unknown HIV status, the use of methadone resulted in retention, efficacy and urine toxicology results similar to ours three months after release.^{6,30} We extended their findings to HIV-infected subjects receiving antiretroviral therapy and demonstrated sustained HIV treatment response, high retention rates (>70%), low opiate- (17%) and cocaine-positive (29%) urine tests, and no associated adverse consequences between buprenorphine and HIV therapeutics. The retention rate of 74% ($N=17/23$), although potentially affected by the DAART intervention itself in this study, is higher than described in smaller studies of BPN/NLX treatment of HIV-infected persons in the USA³¹ and prisoners in Puerto Rico.³² This study also confirms findings reported from other small studies that have shown that BPN/NLX can be prescribed safely and effectively in HIV primary care settings;^{31,33} HIV-undifferentiated prisoners in Puerto Rico,³² and France.^{5,34,35}

Nine (39%) of the subjects had relapsed to opioid use within a week after release from prison, accounting for the high proportion of positive urine results at baseline. To avoid early relapse and potential overdose and death, relapse prevention strategies should be initiated prior to release from prison. This is particularly true since opioid tolerance is low and risk for overdose and death is high.⁹ Future studies should focus on initiating treatment prior to release.

In this study of opioid dependent subjects with prolonged periods of abstinence, BPN/NLX treatment was well tolerated, but required an extended induction period over 7 days. Dosing started lower than recommended by existing guidelines for chronic opioid-using patients,³⁶ and increases in dosage was slow and incremental. Fortunately, excess opioid-agonist effects were infrequent (17%) during the induction period (i.e., drowsiness, nausea, headache, constipation), extinguished by the end of the induction period. Induction did, however, require longer duration of induction due to the down-regulation of opioid receptors after prolonged periods of abstinence and potentially from known symptomatic pharmacokinetic interactions with ritonavir-boosted atazanavir.³⁷ Overall, tolerability remained high despite potential pharmacokinetic drug interactions reported between BPN/NLX and antiretroviral medications.^{23,37,38}

Last, this study represents a population of HIV-infected individuals who often have many unmet needs and co-morbidities, and who might not otherwise receive such treatment. The unexpected universal co-occurrence of mental illness (100% of subjects with documented Axis I disorders) suggests a particularly challenging population to treat. Indeed, collectively all subjects met criteria for triple diagnosis and their management has traditionally been fraught with multiple challenges.^{39,40} Left untreated, mental illness and substance use disorders contribute significantly to difficulty with maintaining appointments with medical professionals and often are associated with reincarceration.^{4,41,42} When effective support is offered, however, they can maintain clinical benefit from treatment.⁴³

BPN/NLX may offer added incentives to correctional settings that might result in increased use of OAT. These include decreased: (1) regulatory procedures and licensing; (2) concerns about diversion and overdose; and (3) concerns about opioid withdrawal symptoms if a subject is not effectively and immediately linked to community services.²² One of the major barriers to BPN/NLX treatment has been the actual cost of the medication, although it has been found to be similarly cost-effective as methadone.⁴⁴ This concern, however, may be obviated as the BPN/NLX patent ended in late 2009, potentially allowing for less expensive generics to emerge.

CONCLUSION

Buprenorphine induction and stabilization is a highly acceptable, tolerable and effective treatment to prevent relapse to opiate use in released HIV-infected prisoners. Importantly, it appears to be effective at maintaining HIV outcomes and potentially decreasing HIV-associated morbidity and mortality. This study initiated BPN/NLX after release from prison, but future studies, including randomized trials examining BPN/NLX induction before and after release are needed to determine the optimal timing for treatment. More importantly, better understanding of the impact that BPN/NLX treatment may have on recidivism, continuity of HIV care, ART adherence and HIV mortality through larger randomized controlled trials are urgently needed.

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