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Buprenorphine/naloxone Treatment in Primary Care is Associated with Decreased HIV Risk Behaviors

Lynn E. Sullivan, M.D.^{*}, Brent A. Moore, Ph.D.[†], Marek C. Chawarski, Ph.D.[†], Michael V. Pantalon, Ph.D.[†], Declan Barry, Ph.D.[†], Patrick G. O'Connor, M.D., M.P.H.^{*}, Richard S. Schottenfeld, M.D.[†], and David A. Fiellin, M.D.^{*}

^{*}Department of Internal Medicine, Yale University School of Medicine, New Haven, CT

[†]Department of Psychiatry, Yale University School of Medicine, New Haven, CT

Abstract

Methadone treatment reduces HIV risk but the effects of primary care-based buprenorphine/naloxone on HIV risk are unknown. The purpose of the current study was to determine whether primary care-based buprenorphine/naloxone was associated with decreased HIV risk behavior. We conducted a longitudinal analysis of 166 opioid dependent persons (129 men and 37 women) receiving buprenorphine/naloxone treatment in a primary care clinic. We compared baseline, 12 and 24-week overall, drug-related and sex-related HIV risk behaviors using the AIDS/HIV Risk Inventory (ARI). Buprenorphine/naloxone treatment was associated with significant reductions in overall and drug-related ARI scores from baseline to 12 and 24-weeks. Intravenous drug use in the past 3 months was endorsed by 37%, 12%, and 7%, of patients at baseline, 12 weeks and 24 weeks, respectively; $p < 0.001$. Sex while you or your partner were “high” was endorsed by 64%, 13%, and 15% of patients at baseline, 12 weeks and 24 weeks, respectively; $p < 0.001$. Inconsistent condom use during sex with a steady partner was high at baseline and did not change over time. We conclude that primary care-based buprenorphine/naloxone treatment is associated with decreased drug-related HIV risk but additional efforts may be needed to address sex-related HIV risk when present. (ClinicalTrials.gov number, NCT00023283).

Keywords

Buprenorphine; HIV/AIDS; Risk Reduction Behavior; Treatment; Prevention

INTRODUCTION

Untreated opioid dependence plays a central role in HIV transmission internationally. HIV transmission results from both drug- and sex related-behaviors. Injection drug use accounted for 10% of the 4.2 million new HIV infections that occurred worldwide in 2003. (UNAIDS, 2003) High-risk sexual behaviors continue to be the driving force behind the global HIV/AIDS epidemic. (UNODC, 2005) An estimated 64% of the world’s population living with HIV resides in sub-Saharan Africa where transmission is primarily through heterosexual contact,

Correspondence to: Lynn E. Sullivan, M.D., Yale University School of Medicine, 333 Cedar St., P.O. Box 208025, New Haven, CT 06520-8025. Telephone: (203) 688-9105, Fax: (203) 688-4092 email: lynn.sullivan@yale.edu.

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(UNAIDS, 2006) and of the 5.7 million people living with HIV/AIDS in India, approximately 80% of HIV infections are acquired heterosexually. (CDC, 2006)

Buprenorphine is a partial mu-receptor agonist and is effective for the treatment of opioid dependence in primary care office-based settings. (D. A. Fiellin et al., 2002; Johnson et al., 1995; Ling et al., 1998) Prior research has demonstrated the effectiveness of methadone in reducing HIV risk behavior and seroconversion (Gowing, Farrell, Bornemann, Sullivan, & Ali, 2006; Marsch, 1998; Metzger, Navaline, & Woody, 1998; Prendergast, Urada, & Podus, 2001; Sorensen & Copeland, 2000) but there is no data on how primary care office-based buprenorphine/naloxone treatment impacts HIV risk behaviors. By providing effective office-based treatment for opioid dependent patients, primary care physicians may have an increased opportunity to engage patients with drug- and sex-related HIV risk behaviors into care. Therefore it is critical to examine how buprenorphine/naloxone impacts on these risk behaviors.

The purpose of the current study is to determine the impact of primary care office-based treatment of opioid dependence with buprenorphine/naloxone on HIV risk.

METHODS

Study Design

This study is an exploratory secondary analysis of data collected about HIV risk behaviors as part of a 24-week randomized clinical trial of two levels of psychosocial counseling in conjunction with buprenorphine/naloxone maintenance in a primary care clinic. Patients were randomly assigned to one of three psychosocial counseling and medication dispensing regimens: standard medical management (SMM) with either once-weekly or thrice-weekly medication dispensing or enhanced medical management (EMM) in conjunction with thrice-weekly medication dispensing. SMM was a brief (20 minutes), manual-guided, medically focused counseling provided by trained primary care nurses and focusing on drug counseling and maintenance of abstinence. EMM was similar in content but more extended in time (45 minutes) and consisted of manual-guided advice and counseling provided by the same trained nurses with additional content related to the consequences of addiction. EMM was provided along with thrice-weekly medication dispensing. The results of this trial, which did not demonstrate a difference in opioid abstinence between the three levels of counseling and medication dispensing, have been published elsewhere. (D.A. Fiellin et al., 2006) Of note, the counseling interventions did not specifically target HIV risk behaviors.

Setting and Subjects

The setting was the primary care clinic of a large, urban, academically affiliated hospital. One hundred and sixty-six patients met the following eligibility criteria: age ≥ 18 , DSM-IV criteria for opioid dependence, opioid positive urine, no dependence on alcohol, benzodiazepines or sedatives, no acute medical or psychiatric conditions, able to understand English, agreeing to adequate contraception and monthly pregnancy monitoring. This research was approved by the Yale University School of Medicine Human Investigational Committee, and all individuals signed an informed consent prior to participation.

Data Collection

HIV risk behaviors were assessed using the AIDS/HIV Risk Inventory (ARI), (Chawarski, Pakes, & Schottenfeld, 1998) (Chawarski, Mazlan, & Schottenfeld, 2006) at baseline and after 12 and 24 weeks of buprenorphine/naloxone treatment. The ARI is a structured interview that includes an assessment of both drug- and sex-related HIV risk behaviors and questions regarding communicable diseases, non-injection drug use, and motivation to change. We chose

the ARI because of its face validity and because it is designed to detect recent changes and changes during treatment. Drug-related behaviors include those associated with injection drug use such as needle sharing or lack of needle cleaning. Sex-related behaviors are divided into sex practices with a steady partner and those with any partner. Further, these behaviors include the following: 1) condom use; 2) trading sex for drugs, money, or gifts; 3) engaging in sex while intoxicated from drugs or alcohol; 4) engaging in casual sex with unknown people; and 5) engaging in sex with injection drug users. The overall score is a composite score of both drug-related and sex-related behaviors.

Data Analysis

All analyses used 2-tailed tests of significance and were performed using SPSS 14.0 (SPSS Inc., Chicago, Ill.), except as noted. P-values $<.05$ were considered statistically significant. Analyses of demographic and substance use characteristics at baseline used chi-square tests for categorical data (Fisher's exact tests were used for estimated cell sizes less than 5), and ANOVA for continuous measures to evaluate differences in individuals. Continuous outcome variables of the ARI overall, drug-related and sex-related sub-scale scores were evaluated using a mixed model repeated measures ANOVA with treatment assignment included as a fixed factor. The mixed model procedure was used since it allows for repeated measure design with missing data. For dichotomous variables we conducted autoregressive General Estimating Equation (GEE) modeling for repeated measures using SAS V9.1 (PROC GENMOD; SAS Institute, Cary, NC). Treatment group assignment was controlled for in all analyses except for those outcomes with low frequencies due to insufficient power.

RESULTS

Demographics and Substance Use Characteristics

The baseline demographic and substance use characteristics of patients who completed less than 12 weeks of follow-up, the 12-week follow-up and those who completed the 24-week follow-up are provided in Table 1. There were no significant differences between the three groups on any of the baseline measures. However, if patients who provided either 12 or 24-week follow-up data ($n = 101$) were compared to those who provided less than 12 weeks of follow-up data ($n = 65$), at baseline those who provided follow-up data were less likely to report sex in past 3 months with someone besides a partner (15% vs. 5%, $p = .04$) and less likely to report heroin use in the past 3 months (91% vs. 78%, $p = .04$). Those who provided one or more follow-ups also had lower ARI overall scores (21.5 vs. 16.5, $p = .05$).

Changes in HIV Risk Behaviors

For both the continuous and dichotomous outcome variables, treatment assignment (e.g. level of psychosocial counseling) was not significant as a main factor or as an interaction with follow-up on any of the outcome variables (all p values $> .13$), therefore the results presented in the table are collapsed across treatment group assignments. One hundred and fifty-five patients provided baseline data, 91 provided 12-week data, and 75 provided 24-week data (Table 2). The overall ARI score declined from baseline to 12 and 24-weeks, but the two follow-up periods did not differ significantly from one another. Similarly, the drug-related sub-scale score declined from baseline to both follow-up assessments but did not differ among follow-up periods. The 12-week sex-related subscale score did not differ from baseline (or 24 weeks), although the score at 24 weeks was lower than the baseline score.

Intravenous (I.V.) drug use in the past 3 months was endorsed by 37%, 12%, and 7%, of patients at baseline, 12 weeks and 24 weeks, respectively; $p < 0.001$. There was a non-significant reduction in sharing needles or works from baseline to 12 weeks and 24 weeks (8%, 4%, 1%); $p=.06$. Sex with your steady partner while you or your partner were "high" was endorsed by

64%, 13%, 15%, of patients at baseline, 12 weeks and 24 weeks, respectively; $p < 0.001$. Infrequent condom use (less than 50% of the time) with a steady partner was the only behavior that was prevalent at baseline (84%) and remained prevalent at 12 (87%) and 24 weeks of treatment (84%); $p = .87$. The low baseline prevalence of other sex risk behaviors remained unchanged with treatment. Frequencies for sex with someone besides a partner, unprotected sex with someone besides a partner or while high, were low at baseline and did not increase or decrease with treatment. In this cohort, trading sex for drugs was not reported by any participant at any assessment point.

DISCUSSION

Our study revealed that primary care office-based buprenorphine/naloxone treatment of opioid dependent patients is associated with a significant reduction in overall and drug-related HIV risk behaviors. Sex-related risk behaviors were lower at 24 weeks, but not 12, compared to baseline. The reduction in overall risk was primarily driven by a decrease in injection drug use and a decrease in having sex while intoxicated from drugs or alcohol. Of note, we also found that rates of non-condom use were high at baseline and remained high throughout the 24 weeks of buprenorphine/naloxone treatment. In comparing the patients who had completed the assessments and those who did not, we demonstrate that the non-completers were more likely to use heroin, inject drugs and had higher baseline sex-related risk behaviors indicating that this group is at higher risk. The lower baseline sex-related risk behaviors in the completer group made it difficult for us to detect a change in the sex-related behaviors over time.

Our findings, observed in primary care, are similar to studies providing methadone in specialized treatment programs. In a recent meta-analysis, methadone maintenance treatment was associated with significant reductions in drug- and sex-related behaviors including reports of multiple sex partners or exchanges of sex for drugs or money, but had little effect on condom use. (Gowing, Farrell, Bornemann, Sullivan, & Ali, 2006) Research examining the impact of methadone maintenance on sex-related behaviors have found that treatment with methadone was successful at reducing certain sex-related behaviors, even in the subset of patients who continued to inject drugs while in treatment. (Camacho, Bartholomew, Joe, Cloud, & Simpson, 1996; Camacho, Bartholomew, Joe, & Simpson, 1997; Gibson, Flynn, & McCarthy, 1999; Schroeder, Epstein, Umbricht, & Preston, 2006) Studies including two meta-analyses and two large-scale multi-site studies examining the impact of counseling and educational interventions targeting sex-related HIV risk behaviors concluded that behavioral interventions also result in a reduction of these behaviors in drug users who were in-treatment or out-of-treatment. (Gibson, Flynn, & McCarthy, 1999; Group, 1998; Kamb et al., 1998; Prendergast, Urada, & Podus, 2001; Semaan et al., 2002) In our study, both pharmacologic and counseling interventions were provided, but there was no specific intervention targeting HIV risk behaviors.

Our results present the first findings for HIV risk reduction with buprenorphine/naloxone in patients receiving treatment in primary care. A prior study that examined HIV risk behaviors in patients receiving buprenorphine (without naloxone) treatment in a specialized treatment program demonstrated that drug- and sex-related risk behaviors were reduced over six months. (Marsch, Bickel, Badger, & Jacobs, 2005) All participants in this study received lifestyle counseling which included HIV/AIDS education. This study, however, used a different buprenorphine formulation, was not conducted in a primary care office-based setting and did not provide any data on the specific risk behaviors that were reduced during the treatment period. A further study examining patients receiving either methadone, buprenorphine or levomethadyl acetate hydrochloride (LAAM) in a substance abuse treatment program revealed declines in drug-related risk behaviors in all three treatment groups but a reduction in sexual

risk behaviors only in the methadone group. (Lott, Strain, Brooner, Bigelow, & Johnson, 2006)

There are limitations to our study. All data on HIV risk behaviors were collected by self-report and without accompanying HIV serostatus determination and therefore do not provide information on actual HIV transmission. Self-report data is also limited because of well-documented reluctance on the part of study participants to reveal sensitive information and therefore there likely is underreporting of high-risk behaviors. (Catania, Gibson, Chitwood, & Coates, 1990; Coates et al., 1988; Latkin & Vlahov, 1998; Latkin, Vlahov, & Anthony, 1993; Saltzman, Stoddard, McCusker, Moon, & Mayer, 1987) Because we did not recruit specifically for patients with high-risk behaviors, we had less opportunity to observe reductions in these behaviors. Notably, the patients who were not retained had higher levels of HIV risk behaviors. Our analysis comparing the completer group and the non-completer group demonstrates that it might be possible to specifically recruit subjects with high levels of risk behaviors although there is a need to focus efforts on increasing retention among these patients. Our results provide information on relatively short-term outcomes and therefore the long-term impact of buprenorphine/naloxone on HIV risk will need to be evaluated.

While our study did demonstrate a significant decrease in the sex-related risk behavior of having sex with a partner while intoxicated, the rate of non-condom use was not affected with treatment. While all study patients received psychosocial counseling, the counseling contained no specific focus on HIV/AIDS risk reduction and our results demonstrated that there was no impact on HIV risk behavior based on the level of counseling that patients received. There is compelling evidence in the literature to support the efficacy of behavioral interventions in reducing specific HIV risk behaviors (for example needle-sharing, unprotected sex) however these types of interventions were not included in the current study and our results should not be interpreted to mean that these additional counseling efforts are not needed. Future efforts focused on counseling and education are needed to target further reductions in specific sex-related HIV risk behaviors in patients receiving buprenorphine/naloxone treatment.

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Table 1

Demographic and Substance Use Characteristics

Characteristic	Total (N= 166)	Completed fewer than 12 weeks of follow-up (n= 65)	Completed only 12 week follow-up assessment (n=26)	Completed 24 week follow-up assessment (n=75)	p value
Age, mean (SD)	36.0 (9.3)	35.0 (9.3)	37.3 (9.2)	36.5 (9.3)	.47
Male, % (n)	78% (129)	74% (48)	88% (23)	77% (58)	.32
White, % (n)	76% (127)	78% (51)	85% (22)	72% (54)	.38
Full-time employed, % (n)	38% (63)	30% (19)	35% (9)	47% (35)	.13
Monthly income, % >1000, (n)	46% (77)	40% (26)	46% (12)	52% (39)	.36
Never married, % (n)	58% (95)	62% (39)	62% (16)	53% (40)	.55
HCV Status, % positive (n)	28% (46)	21% (19)	15% (4)	31% (23)	.52
High school education or greater, % (n)	82% (134)	81% (51)	85% (22)	81% (61)	.92
Any heroin use in the past month, % (n)	83% (138)	91% (59)	77% (20)	79% (59)	.11
Any prescription drug use in the past month, % (n)	32% (53)	26% (17)	38% (10)	35% (26)	.41
Any current injection drug use, % (n)	32% (52)	39% (24)	15% (4)	32% (24)	.09
Any cocaine use in the past month, % (n)	37% (61)	42% (27)	31% (8)	35% (26)	.55
Any alcohol use in the past month, % (n)	49% (81)	42% (27)	50% (13)	55% (41)	.30
Years opioid dependence, mean (SD)	8.1 (8.0)	7.2 (7.0)	7.3 (8.1)	9.1 (8.6)	.34
Baseline IV drug use in the past 3 months, % Yes (n)	37% (58)	46% (28)	24% (6)	35% (24)	.14
Share needles or works in the past 3 months at baseline, % Yes (n)	8% (13)	12% (7)	8% (2)	6% (4)	.50
Baseline: In the past 3 months have you had sex with your steady partner while you or your partner were "high" on drugs or alcohol? % Yes (n)	64% (100)	64% (39)	64% (16)	65% (45)	.99
Baseline-Condom use less than 50% of the time with steady partner in last 3 month, % Yes (n)	85% (142)	80% (52)	92% (24)	88% (66)	.23
Baseline - Sex in past 3 months with someone besides partner or someone they just met, % Yes (n)	9% (14)	15% (9)	4% (1)	6% (4)	.13
Baseline - Unprotected sex in past 3 months with someone besides partner, % Yes (n)	7% (11)	8% (5)	8% (2)	6% (4)	.85

Table 2
HIV Risk Behaviors at Baseline, 12 Weeks, and 24 Weeks

	Baseline (n= 155)	12-week (n = 91)	24-week (n = 75)	p value
ARI Overall score, M (SD)	16.6 (14.5)	11.5 (11.9)	11.2 (15.5)	.02 <i>a,b</i>
ARI Drug Subscale score, M (SD)	6.5 (8.6)	2.3 (4.0)	1.9 (3.6)	<.001 <i>a,b</i>
ARI Sex Subscale score, M (SD)	9.0 (9.9)	7.4 (8.8)	6.0 (7.4)	.03 <i>c</i>
Injection-related behaviors				
IV drug use in the past 3 months, % Yes (n)	37% (58)	12% (11)	7% (5)	< .001 <i>a, b</i>
Share needles or works in the past 3 months, % Yes (n)	8% (13)	4% (4)	1% (1)	.06
Sex-related behaviors				
In the past 3 months have you had sex with your steady partner while you or your partner were "high" on drugs or alcohol? % Yes (n)	64% (100)	13% (12)	15% (11)	< .001 <i>a, b</i>
Condom use less than 50% of the time with steady partner in last 3 month, % Yes (n)	84% (131)	87% (79)	84% (63)	.87
Sex in past 3 months with someone besides partner or someone they just met, % Yes (n)	9% (14)	11% (10)	7% (5)	.63
Unprotected sex in past 3 months with someone besides partner, % Yes (n)	7% (11)	7% (6)	3% (2)	.39
Unprotected sex in past 3 months with partner when "high" on drugs or alcohol? % Yes (n)	3% (4)	0% (0)	3% (2)	.30
Suggested using a condom with partner in past 3 months, % Yes (n)	24% (38)	23% (21)	17% (13)	.46

^a 12 weeks ≠ baseline

^b 24 weeks ≠ baseline

^c 12 weeks ≠ 24 weeks