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Treatment outcomes among a cohort of African American buprenorphine patients: Follow-up at 12-months

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Abstract

Background—Although buprenorphine/naloxone (bup/nal) is well established as a safe and effective treatment for opioid use disorders (OUDs), there are few studies reporting 12-month outcomes of patients receiving bup/nal in formerly drug-free outpatient programs.

Objectives—To examine 12-month outcomes by bup/nal treatment enrollment status among a cohort of African American patients enrolled in a clinical trial.

Methods—This analysis builds upon a randomized trial of 300 opioid-dependent African American bup/nal patients in two outpatient programs in Baltimore, Maryland. A subset of participants ($N=133$, $n=47$ female) were tracked for a 12-month follow-up interview.

Results—The participants receiving bup/nal at 12-months had significantly fewer opioid-positive urine screens (44% v. 73%) and days of self-reported heroin use ($M [SE] = 1.13 [0.34]$ v. $7.12 [1.44]$) than the out-of-bup/nal-treatment group (both $p < .001$). Similarly, those receiving bup/nal reported significantly fewer days of cocaine use ($M [SE] = 0.85 [0.23]$ v. $2.88 [0.75]$) and alcohol use ($M [SE] = 1.44 [0.38]$ v. $3.69 [1.04]$; both $p < .05$). There were no significant differences related to criminal activity, quality of life, and most ASI composite scores. Models adjusting for the baseline value, prior treatment experience, and assigned study condition largely confirmed these findings, except that participants in treatment had fewer days of crime and higher psychological quality of life scores compared to those out-of-treatment.

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Conclusion—Those receiving bup/nal at 12-months had significantly lower rates of illicit opioid use than those who were not. Approaches to improve bup/nal treatment retention and reengagement of patients with OUD are needed.

Keywords

buprenorphine; Medication-Assisted Treatment; pharmacotherapy; opioid use disorder

Introduction

Buprenorphine/naloxone (bup/nal) treatment for opioid use disorders (OUDs) has been shown to be efficacious in randomized clinical trials, and has been associated with increased treatment retention and reduced illicit opioid use compared to treatment without medication (1, 2). Bup/nal treatment, relative to no treatment or other forms of opioid treatment, has also been associated with reduced mortality (Kimber et al. 2015), reduced human immunodeficiency virus (HIV) risk behaviors (Saxon et al. 2013), as well as improved quality of life (3, 4).

Several United States (US) longitudinal outcome studies of bup/nal treatment have followed patients 12 months (5–9), or longer (2, 10–12). Nearly all of these reports were of patients treated in primary care (5, 7–10, 12). Hser and colleagues (2) conducted their recent study in an Opioid agonist Treatment Program (OTP), and found increased opioid use and decreased treatment retention among those randomized to bup/nal compared to methadone, after a long-term follow-up interview was conducted approximately 2–8 years post initial randomization. Another 12-month follow-up study (13), conducted in 1999 to 2000 prior to the Food and Drug Administration (FDA) approval of buprenorphine, compared opioid use outcomes and treatment retention across an OTP, an outpatient counseling program, and a private psychiatric practice. In this study, retention in treatment was significantly associated with a decrease in opioid use across each of the treatment modalities at 20 weeks. Although the study had a 48% disengage from treatment rate, approximately one-quarter of participants completed the 52 week study, while the remaining participants tapered off of the medication during the study period or left during the first week of treatment.

There are significantly more non-OTP outpatient programs in the US than any other type of substance abuse treatment modality (14). Given the presence of substance abuse counselors in these programs, they are a natural base upon which to build OUD pharmacotherapy capacity. This is of considerable importance given the current opioid epidemic and rise in opioid overdoses (15).

This study sought to fill the gap in knowledge regarding outcomes of bup/nal patients treated in non-OTP outpatient programs. It examined 12-month outcome data collected from African Americans adults who had enrolled in bup/nal treatment in Baltimore, MD as part of a trial comparing two levels of counseling for OUD. The present analysis compares the group of patients who reported receiving bup/nal treatment (in-Bup treatment group) to the group of patients who reported not receiving bup/nal treatment (out-of-Bup treatment group) at 12 month follow-up on substance use, quality of life, and Addiction Severity Index (ASI)

domain outcomes. We hypothesized that the in-Bup treatment group will have superior outcomes compared to the out-of-Bup treatment group.

Methods

Parent Study

The parent study was a parallel two-group randomized trial that compared standard outpatient and intensive outpatient levels of counseling for 300 African American patients newly admitted to bup/nal treatment in two programs that had not previously utilized opioid agonist therapy in Baltimore, Maryland (16). The sites were not opioid treatment programs (OTP), but dispensed bup/nal in an office-based setting. Eligibility requirements included having received at least one bup/nal dose and fewer than 8 hours of counseling prior to randomization. Participants were recruited into the study upon self-initiated entry into a bup/nal treatment program, so all patients began their study participation on bup/nal. Exclusion criteria included only severe cognitive disability or pregnancy. Participants were assessed at baseline, 3-, and 6-month follow-up visits. There were no significant differences between the intensive outpatient and standard outpatient conditions over the 6-month time period in terms of any of the outcome measures which included meeting Diagnostic and Statistical Manual of Mental Disorders 4 (DSM-IV) opioid and cocaine dependence, illicit opioid and cocaine use (urine test and self-report), self-reported criminal activity, retention in treatment, Quality of Life as measured by the World Health Organization (WHO) Quality of Life BREF, ASI composite scores, and HIV risk behaviors (16).

Present Study Procedures

The parent trial (run between 9/30/09–8/31/2012) was funded for a 3- and 6-month follow-up. Funding for extended data collection beyond the six months outlined in the parent trial was obtained at the end of recruitment from the Abell Foundation. The present 12-month follow-up study was approved by the Friends Research Institute Institutional Review Board (IRB). At the time of funding in September, 2011, 168 of the 300 participants were within the study follow-up window to be tracked and interviewed for 12-month follow-up. We were able to obtain consent and interview 142 (84.5%) of the 168 participants within their follow-up window. The remaining participants in the parent study (n=152) were excluded from this analysis because their 12-month follow-up window had passed before additional consent could be obtained. Of those not interviewed, sixteen were not found, eight were incarcerated, one was in a residential treatment program, and one was hospitalized. There were no significant differences between those interviewed and those lost-to-follow-up on the baseline characteristics shown in Table 1.

Measures

Buprenorphine/Naloxone Treatment Status at Follow-up.—The comparison groups of interest (in vs. out of treatment at follow-up) were composed based on the self-reported response to questions at 12-month follow-up regarding participants' use of doctor-prescribed bup/nal. Participants did not have to be enrolled at the original clinic in which they initiated bup/nal treatment in the parent study, but they did need to be receiving bup/nal from a prescribing physician. Participants who reported receiving doctor-prescribed bup/nal at 12

months may have disengaged from treatment and then reengaged during the study period. The only determining factor for group placement was the receipt of bup/nal from a prescribing physician at the time of the 12 month follow-up interview (in-Bup treatment), or not (out-of-Bup treatment). Participants who reported being enrolled in a methadone program at 12-months ($n=9$; 6%) were removed from the analysis because the focus of the study was on bup/nal and including methadone patients would confound the results. Participants in both groups may have also been receiving psychosocial treatment, but because this study targeted the effectiveness of bup/nal at 12-months, the groups reflected only their use of doctor-prescribed bup/nal.

Urine Screening Test.—A urine sample for research purposes was collected at follow-up. These samples were sent to a certified laboratory for analysis of drug metabolites by Enzyme-Linked Immunoassay Test (EMIT). For the current analysis, we examined urine test results for illicit opioids (morphine metabolites only) and cocaine (positive vs. negative).

Addiction Severity Index.—The 5th edition of the Addiction Severity Index (ASI) (17) was used to gather data on participant background and substance use characteristics. We examined group differences on the ASI self-reported number of days of opioid, cocaine, and alcohol use in the past 30 days; self-reported number of days engaging in criminal activity in the past 30 days; injection drug use status (injector vs. non-injector); and composite scores (mean) for each of the seven domains assessed by the ASI (medical, employment, alcohol, drug, legal, family/social, and psychological). Higher scores in each of these domains indicate more severe problems.

World Health Quality of Life BREF.—Quality of Life was assessed using the WHOQOL-BREF, a brief 32-item instrument developed by the World Health Organization that has been used in a wide variety of populations internationally (18–22) and has been found to have strong psychometric properties (23, 24). The WHOQOL-BREF produces scores ranging from 0 (low) to 100 (high) in four Quality of Life (QoL) domains: physical, psychological, social, and environmental. The WHOQOL-BREF also contains a single item, which is not incorporated into any of the four scale scores, asking participants to rate their overall QoL on a 5-point scale from very poor to very good.

Statistical Analyses

To examine group differences between in- and out-of-Bup treatment participants at 12-months regarding urine opioid and cocaine test results, self-reported days of heroin, cocaine, and alcohol use and criminal behavior, QoL measures, and ASI composite scores were analyzed separately as outcome variables using independent samples t-tests and likelihood ratio χ^2 tests. In addition, we examined statistical models using ordinary least squares regression for continuous outcomes (QoL domain scores and ASI composite scores), logistic regression for binary outcomes (urine test results), and over-dispersed Poisson models for count outcomes (days of heroin, cocaine, alcohol, and criminal activity). These analyses were also conducted holding constant the baseline value of each outcome variable, assigned condition in the parent study, and prior treatment experience with methadone and bup/nal. In almost all cases, these analyses gave only slightly different estimates of in- versus out-of-

Bup treatment effects and did not alter the conclusions. Thus, we only describe findings from these analyses for those variables for which they yielded different conclusions). All data were analyzed using Stata 14.2.

Results

Participants

Baseline study characteristics of participants are shown in Table 1 for the total sample who were interviewed at 12 months and then separately for the in- and out-of-Bup treatment groups. Analyses indicate that the only statistically significant baseline demographic or substance use characteristic differences between the in-Bup treatment versus the out-of-Bup treatment groups was prior enrollment in bup/nal or methadone treatment.

Treatment Retention—At 12-month follow-up, 82 (62%) of the sample reported being enrolled in bup/nal treatment.

12-Month Outcomes

Urine screening test results

At 12-months (see Table 2), the in-Bup treatment group had a significantly ($p=.001$) lower percentage of positive urine screens for opioids (44%) than the out-of-Bup treatment group (73%) [$OR=.30 (.14-.63)$]. However, the groups were not significantly different in terms of the percentage of cocaine-positive urine screens (39% vs. 43% for the in-Bup treatment and out-of-Bup treatment groups, respectively) [$OR=.84 (.41-1.72)$].

Days of substance use and criminal activity

The in-Bup treatment group reported significantly fewer days of self-reported heroin ($p<.001$), cocaine ($p=.002$), and alcohol ($p=.02$) use during the previous 30 days than did the out-of-Bup treatment group at 12-month follow-up [for the in-Bup treatment group: $M=1.13$ ($SE=.34$) for heroin, $M=.85$ ($SE=.23$) for cocaine, and $M=1.44$ ($SE=.38$) for alcohol; for the out-of-Bup treatment group: $M=7.12$ ($SE=1.44$) for heroin, $M=2.88$ ($SE=.75$) for cocaine, and $M=3.69$ ($SE=1.04$) for alcohol]. The groups did not significantly differ in the number of days of criminal activity reported for the previous 30 days (both $ps >.05$). Regression analyses generally confirmed these relationships; however, in the model controlling for prior treatment, baseline crime days, and assigned study condition, there was a significant negative association between bup/nal treatment status and days of self-reported crime ($b=-1.17$; $SE=.43$; $p<.01$).

Quality of life

QoL measures for the Physical, Psychological, Social, and Environmental domains were not significant for the in- ($n=82$) and out-of-Bup treatment ($n=51$) groups, as shown in the middle of Table 2. Similarly, the single-item QOL measure also did not differ between groups. Regression analyses confirmed the lack of a relationship between bup/nal treatment status and quality of life, with one exception: In the model controlling for baseline score, assigned study condition, and prior treatment experience, participants who were in bup/nal

treatment at 12 months had significantly higher psychological quality of life scores compared to those out-of-treatment ($b=4.22$; $SE=2.04$; $p<.05$).

ASI composite scores

There were no statistically significant differences between the in- vs. out-of-Bup treatment groups on 6 of the 7 ASI composite score domains, as shown at the bottom of Table 2. However, in-Bup treatment group had a higher mean ASI drug composite score than the out-of-Bup treatment group [$M=.05$ ($SE=.01$) v. $M=.15$ ($SE=.02$); $p<.001$]. Regression analyses confirmed the significant association between treatment status and the ASI drug score and the lack of association with other ASI domains, with one exception. In the regression analysis controlling for baseline employment/support ASI score, assigned study condition, and prior treatment experience, participants who were in bup/nal treatment at 12 months had significantly higher employment ASI scores compared to those out-of-treatment ($b=.06$; $SE=.03$; $p<.05$).

Discussion

The current study found that the group of patients who were enrolled in bup/nal treatment at 12- follow-up fared better than the group of patients who were not currently enrolled in bup/nal treatment. Urine test results and self-report at 12 months showed that participants in bup/nal had, on average, significantly less opioid use than patients who were not currently enrolled in bup/nal treatment, indicating superior outcomes on opioid use, the primary target of the medication. While self-reported days of cocaine use was significantly lower for the in-Bup treatment group, it is worth noting that urine cocaine screens were not significantly different. Furthermore, of note was the relatively low number of self-reported days of opioid and cocaine use and the relatively high rates of opioid and cocaine-positive urine tests. Although the interviews were conducted under research confidential conditions, it appears that participants may have been underreporting their drug use.

In this 12-month follow-up study of African Americans with OUD who initiated bup/nal treatment in an outpatient drug treatment program, 62% of participants were engaged in bup/nal treatment 12 months from treatment initiation, a rate that is consistent with another study that assessed bup/nal treatment retention longitudinally (61.6%) (6). The 12-month treatment retention rate was similar to the retention rate in a methadone treatment study conducted in Baltimore between 2008 and 2010 (25).

It is likely that among at least some of the participants in the out-of-Bup treatment group were self-medicating with bup/nal. Therefore, the fact that the in-Bup treatment group had better outcomes than the out-of-Bup treatment group is encouraging. A secondary analysis by Weiss and colleagues found that patients with a lifetime history of heroin use were more likely to be abstinent or near abstinent at the end of a 3 month trial of buprenorphine treatment (versus medical management alone) but only if they were adherent to treatment and thus had adequate exposure to counseling (26). These additional services may be helpful to some buprenorphine patients, as compared to those who self-medicate with bup/nal on the street.

Notwithstanding the superior outcomes of the in-Bup treatment group, a significant minority (44%) of participants had opioid positive urine tests and 39% had cocaine positive urine screens. Thus, a significant number of patients in treatment at 12 months could benefit from additional help. In one such possible approach, Stoller and colleagues (27) recommends transferring patients for stabilization to an OTP where bup/nal could be directly administered (to address potential non-adherence as a reason for opioid use). Once non-adherence was corrected, the bup/nal dose could be adjusted upward or the patient could be switched to methadone. This approach and others could be tested in future studies.

Haddad and colleagues (6) found a nearly 62% 12 month retention rate among patients treated with bup/nal in two federally qualified health center sites in Connecticut. These authors also found lower rates of opioid and cocaine-positive urine screens among those participants receiving vs. no longer receiving bup/nal treatment. Notwithstanding differences between the Haddad study and the present study, in type of treatment site and participant characteristics, these substance use outcomes were similar.

The in-Bup treatment group did not have significantly higher scores than the out-of-Bup treatment group on the QoL assessment domains. Interestingly, the parent study completed an analysis of treatment retention and QoL scores at earlier time points (3- and 6-months), and found that the group of participants who remained in treatment had significantly higher scores on two of the four QoL scales (psychological and environmental) compared to the group of participants who out-of-bup/nal treatment during the course of the study (27). At 6-month follow-up, the group remaining in treatment also had a higher single item QoL score than the group no longer in treatment (28). By 12-month follow-up, treatment enrollment status was no longer associated with higher QoL domain area scores. It is possible that perceptions of QoL may change over time for those who remain in treatment long-term, but this may also be attributable to sample differences and should be investigated in future studies.

The ASI composite scores in the psychological, social, legal, and health areas did not show a significant difference between the two groups at 12-month follow-up. Given that our in-Bup treatment group only included individuals who were currently taking bup/nal that a doctor prescribed, this could indicate that bup/nal treatment is effective in addressing opioid use, but had little impact on these other areas of patients' lives. This might present an opportunity to revise the way supplemental services are offered to bup/nal patients that might improve not only treatment retention, but also crime, vocational, and quality of life issues. Studies utilizing peer patient navigator services in addition to professional services have shown improvements in patients needing follow-up services for mental health (29). This may be an additional service that opioid treatment clinics could pilot in their programs.

OUD is often characterized as a chronic disease. Studies examining longitudinal outcomes for patients engaged in treatment for this disorder can shed light on patient response to treatment. Approximately 40% of the patients starting bup/nal treatment were no longer enrolled after 12 months. An examination of the factors that are associated with treatment retention and disengagement, as well as efforts to improve treatment retention and patient outcomes are needed. It is likely that some of the participants who were out of treatment

were continuing their use of bup/nal that they obtained outside of formal channels. Future research should examine the impact of such use of the medication.

This study has several limitations. The sample at 12-month follow-up constitutes a subset of participants from the parent study, which focused on African Americans receiving bup/nal treatment in a non-OTP outpatient program. This was an urban, low-income population. It is not known how well the findings would generalize to the broader population of adults in bup/nal treatment. The out-of-Bup treatment group may have been receiving non-bup/nal treatment such as naltrexone or outpatient counseling, taking non-prescribed bup/nal, or may have been engaged in recovery-oriented activities such as 12-step groups. Hence, the findings refer only to being in versus out of bup/nal treatment at longer-term follow-up, and may not reflect general substance use disorder treatment status. Importantly, the currently study makes comparisons based on treatment status at a single follow-up time point, and does not speak to more complex factors such as episodic treatment entry and re-entry, or substance use trajectories over time. Finally, it is not possible to draw causal inferences regarding the outcomes in the present study, because patients who remained in bup/nal may have had superior outcomes because of their willingness or ability to adhere to medication regimen.

Conclusion

Among urban, low-income African American participants who initiated bup/nal treatment, those who remained in treatment at 12-month follow-up had significantly lower rates of illicit opioid use than those who had discontinued treatment. However, approximately 40% of the participants had discontinued treatment and there were no significant differences in other measures of health and well-being including quality of life, psychological, social, legal, medical, physical, and environmental domains between in- and out-of-Bup treatment groups.

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Table 1.

Baseline characteristics of study participants.

	In-Bup Tx (n=82)	Out-of-Bup Tx (n=51)
Female Gender, n(%)	29 (35.36)	18 (35.29)
Age, mean (SD)	47.03 (6.05)	47.37 (7.17)
Married, n(%)	11 (13.41)	5 (9.80)
Full-time Employment Pattern, n(%)	25 (30.49)	13 (25.49)
Years of Education, mean (SD)	11.61 (1.61)	11.57 (1.71)
Number of lifetime hospitalizations, mean (SD)	2.32 (2.98)	3.02 (5.03)
No previous opiate agonist treatment, n(%)	18 (21.95)	15 (29.41)
Previous buprenorphine treatment only, n(%)	23 (28.05)	21 (41.17)
Previous methadone treatment only, n(%)	14 (17.07)	6 (11.76)
Previous buprenorphine and methadone treatment, n(%)	27 (32.93) ^{*1}	9 (17.65) ^{*1}
Injection drug user, n(%)	15 (18.29)	11 (21.57)
Cocaine use in last 30d, mean (SD)	5.28 (9.02)	7.55 (10.46)
Cocaine+ urine, n(%)	36 (43.90)	29 (58.00)
Opioid+ urine, n(%)	56 (68.29)	34 (68)
Days of heroin use (SD)	21 (9.48)	21.09 (9.58)
Days of cocaine use (SD)	5.28 (9.02)	7.55 (10.46)
Days of alcohol use (SD)	6.02 (9.32)	5 (8.64)
Days of crime committed (SD)	5.88 (9.82)	6.73 (11.2)
ASI component: medical (SD)	0.24 (0.37)	0.30 (0.40)
ASI component: emotional support (SD)	0.83 (0.21)	0.83 (0.21)
ASI component: alcohol (SD)	0.08 (0.14)	0.06 (0.10)
ASI component: drug (SD)	0.28 (0.10)	0.29 (0.10)
ASI component: legal (SD)	0.16 (0.20)	0.18 (0.23)
ASI component: family/social (SD)	0.10 (0.17)	0.08 (0.16)
ASI component: psychological (SD)	0.29 (0.24) ^{*2}	0.20 (0.24) ^{*2}
Quality of life score: overall	3.43 (0.93)	3.47 (0.78)
Quality of life score: physical (SD)	60.32 (19.72)	58.05 (18.96)
Quality of life score: psychological (SD)	65.85 (20.62)	72.30 (17.78)
Quality of life score: social (SD)	63.92 (22.53)	63.07 (24.34)
Quality of life score: environmental (SD)	59.57 (16.93)	60.17 (18.13)

^{*1}
p=.019

^{*2}
p=0.29

Table 2.Outcomes at 12-months ($N=133$) by buprenorphine treatment status

	In-Bup Tx (SE) (n= 82)	Out-of-Bup Tx (SE) (n=51)	<i>p</i>
<u>Urine Test, % positive</u>			
Opiates	44%	73%	.001
Cocaine	39%	43%	.64
<u>Self-Report, number</u>			
Days of heroin use	1.13 (.34)	7.12 (1.44)	<.001
Days of cocaine use	.85 (.23)	2.88 (.75)	.002
Days of alcohol use	1.44 (.38)	3.69 (1.04)	.02
Days of crime	.43 (.24)	1.41 (.76)	.14
<u>Quality of Life, mean</u>			
Single Item	3.91 (.09)	3.84 (.11)	.61
Physical	58.41 (1.20)	60.15 (1.43)	.36
Psychological	69.56 (1.55)	68.38 (1.77)	.63
Social	70.53 (2.34)	69.12 (2.41)	.69
Environmental	65.82 (1.86)	65.07 (1.86)	.79
<u>ASI Composite Scores, mean</u>			
Medical	.24 (.04)	.24 (.05)	.95
Employment	.88 (.02)	.82 (.03)	.09
Alcohol	.04 (.01)	.04 (.01)	.88
Drug	.05 (.01)	.15 (.02)	<.001
Legal	.09 (.02)	.12 (.02)	.42
Family/Social	.12 (.02)	.12 (.02)	.82
Psychological	.26 (.03)	.24 (.03)	.78