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Long-term outcomes of office-based buprenorphine/naloxone maintenance therapy

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Abstract

Background—Buprenorphine/naloxone was approved by the FDA for office-based opioid maintenance therapy (OMT), with little long-term follow-up data from actual office-based practice. 18-Month outcome data on the office-based use of buprenorphine/naloxone (bup/nx) and the impact of socioeconomic status and other patient characteristics on the duration and clinical effects of bup/nx are reported.

Methods—This retrospective chart review and cross-sectional telephone interview provide treatment retention of opioid-dependent patients receiving bup/nx-OMT in an office-based setting. 176 opioid-dependent patients from two different socioeconomic groups (high and low SES) were begun on bup/nx, started intensive outpatient treatment, and followed-up after a minimum of 18 months (18–42 months) by telephone interview to assess treatment outcome.

Results—110 subjects (67%) completed the interview, 77% remained on bup/nx with no difference in retention between high and low SES groups. Those on bup/nx at follow-up were more likely to report abstinence, to be affiliated with 12-step recovery, to be employed and to have improved functional status. Conclusions: Bup/nx-OMT is a viable treatment option and when coupled with a required abstinence oriented addiction counseling program is effective in

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Contributors

T. Parran consulted on the study development, supervised data collection, and wrote the final manuscript. C. Adelman developed the study design, provided clinical supervision and medical records access, supervised the IRB proposal and supervised all data collection. A. Mace compiled all data and wrote the initial draft of the report. M. Pagano provided data supervision, data analysis, and manuscript writing and editing. R. Ionescu provided data supervision, data analysis, and manuscript writing and editing. B. Merkin proposed the study, wrote the IRB protocol, developed the chart review forms, and edited the final manuscript. R. Defraco provided chart review services and conducted the phone interviews.

Conflict of interest

T. Parran is a member of the Speakers Bureau for ReckittBinckiser and a Buprenorphine Course Director and Faculty Member for ASAM, and a faculty mentor on the ASAM PCSS Buprenorphine web-service. C. Adelman is a member of the Speakers Bureau for ReckittBinckiser and a Buprenorphine Course Faculty Member for ASAM. B. Merkin has no disclosures to provide. R. Defranco has no disclosures to provide. A. Mace has no disclosure to provide. M. Pagano has no disclosures to provide. R. Ionescu has no disclosures to provide.

promoting abstinence, self-help group attendance, occupational stability, and improved psychosocial outcomes in both low SES and high SES patient populations over an 18–42-month period.

Keywords

Buprenorphine; Office-based; Abstinence; Outcomes; Follow-up; Socioeconomic status

1. Introduction

The buprenorphine/naloxone (bup/nx) sublingual tablet was approved by the FDA in 2002 and in early 2003 became available for use in the United States for office-based opioid maintenance therapy (OMT) for opioid-dependent patients (Johnson et al., 2003). This enabled major changes in the way opiate addiction is treated in the United States (Fiellin and O'Connor, 2002b; Fiellin et al., 2001; Jaffe and O'Keeffe, 2003). Substantial pre-release research demonstrated the safety, efficacy and comparability of bup/nx with previous forms of OMT like methadone. bup/nx also appears to have a good safety profile compared to methadone maintenance including a decreased risk with overdose or diversion, ease of dosage titration, possible ease and brevity for tapering, and possibly a decreased impact on the patient's cognitive function (Carrieri et al., 2006; Fiellin et al., 2004; Fiellin and O'Connor, 2002a; Fudala et al., 2003; Harris et al., 2000; Jasinski et al., 1978; Johnson et al., 2000, 1992; Ling et al., 1998, 1996; Mattick et al., 2003; Mendelson and Jones, 2003; Simoens et al., 2005; Strain et al., 1994; Walsh and Eissenberg, 2003).

This favorable safety profile of buprenorphine and the ability to move opioid agonist therapy to an office rather than addiction clinic setting has resulted in significant prescribing and a growing body of post-release bup/nx research and clinical experience (Bouchez and Vignau, 1998). Post-release studies have shown bup/nx to significantly reduce opioid withdrawal symptoms, improve retention in substance abuse treatment, and improve treatment completion roughly similar to methadone treatment (Amass et al., 1994; Caldiero et al., 2006; Fiellin et al., 2002; Gibson et al., 2003; Johnson et al., 1995; Krook et al., 2002; Moore et al., 2007; Stein et al., 2005; Auriacombe et al., 1994; Giacomuzzi et al., 2005; Johnson et al., 2000; Kakko et al., 2003; Kosten et al., 1993; Mattick et al., 2003; O'Connor et al., 1998; Strain et al., 1994).

There are several areas in which more research on OMT with bup/nx is needed including; outcomes with use in the actual private practice office setting, data on greater than 1 year follow-up (Alford et al., 2007; Fhima et al., 2001; Kornor et al., 2007; McLellan et al., 2000), and pre-induction patient characteristics as a predictor of long-term retention in treatment (Marsch et al., 2005). In addition very few studies have examined the long-term effectiveness of bup/nx in uninsured and underinsured populations (low socioeconomic status or low SES) (Mintzer et al., 2007).

This report provides outcome data on a large number of bup/nx maintained patients in an urban office setting with cross-sectional follow-up at a minimum of 18 months post-induction. Data include the impact of pre-treatment patient variables on patient outcomes including demographic, drug and alcohol use histories and socioeconomic status. The primary objective of the study was to assess retention on bup/nx treatment, drug use, morbidity from addictive disease and sobriety rates in 176 patients at least 18 months post-induction. The secondary objective was to analyze the impact of pre-induction patient characteristics including SES on the duration and outcome of bup/nx treatment at least 18 months post-induction.

2. Methods

The patient population consisted of 176 consecutively admitted opioid dependant adults age 19–65 who met the criteria for admission into the bup/nx treatment program (DSM-IV Opiate Dependence, multiple prior failed attempts at abstinence, lack of additional uncontrolled axis I diagnosis/psychosis, not homeless). Patients were admitted over a 30-month period of time. Initially only privately insured or full self-pay patients (the high SES group) were admitted to the bup/nx OMP. Starting in 2005 indigent and uninsured patients (the low SES group) were admitted under a treatment grant from the County Alcohol and Drug Abuse Services Board (ADASB). All patients had standardized addiction assessments performed and were induced on bup/nx doses between 12 and 16 mg/day (Caldiero et al., 2006).

Treatment was divided into a “primary phase” where all patients were followed by the investigators and an ongoing “outpatient phase” where many patients were referred to outlying primary care follow-up due to patient cap constraints. Primary treatment involved a 23–48 h inpatient admission for induction, participation in 5 weeks of intensive outpatient (IOP) counseling (3 h/day, 4 days/week), followed by 12 weeks of weekly once aftercare sessions (Caldiero et al., 2006). Following primary treatment, bup/nx office follow-up involved monthly visits with ongoing 12-step meeting attendance (three each week) and quarterly toxicology testing. The ADASB grant required low SES patients to participate in 1–2 months of half-way house level of care between the induction and IOP treatment phase.

Full adherence (attendance, participation and abstinence) to each level of treatment was required. Non-adherence or substance use resulted in referral back to the next highest level of care. Repeated substance use or non-adherence resulted in taper off of bup/nx and discharge.

After obtaining Human Subjects Committee review from the medical center IRB, chart reviews from hospital and outpatient clinic records were conducted by two Addiction Psychiatry Fellows using a standardized chart review form. A Fellow attempted to phone each patient at a minimum of 18 months (and a maximum of 42 months) after induction. Informed consent was obtained and the structured interview was conducted, including questions on opioid and other alcohol or drug use, continuous bup/nx medication use, and social, role and occupational function from the Shortened Inventory of Problems (SIP-AD).

Chart review and telephone interview forms were scanned into an SPSS database. Simultaneous equations were modeled to test hypothesized interrelationships between patient factors, treatment factors, and outcomes at least 18 months after bup/nx induction. Retention in bup/nx treatment was modeled by discrete time survival analysis (Muthén, 2001).

3. Results

Over 30 months 176 subjects were inducted on bup/nx and eligible for follow-up. 33% were female; 73% Caucasian, 21% Black, and 5% Hispanic, consistent with the overall racial characteristics of opioid-dependent patients in the region. 110 of 176 (63%) completed the follow-up telephone interview at least 18 months post-induction. Table 1 contains basic pre-induction demographic, drug use history, medical, legal, and psychosocial data. There were no significant differences in the baseline characteristic variables between subjects who completed the telephone interview and those who did not except that non-completers were more likely to have an arrest history ($\chi^2_{[1]}=4.96$, $p = 0.03$).

Table 2 presents data on the 110 follow-up patients regarding continuous bup/nx therapy, substance use, AA affiliation, employment, psychosocial functioning and several other demographic, socioeconomic, medical and legal variables. The majority of patients completing phone follow-up were Caucasian (73%), male (67%), and had a significant other (58%). 52% of subjects were low SES, 48% were high SES, and 88% were heroin users with 74% reporting I.V. use. Depression (41%) and hepatitis C (34%) were the most common medical comorbidities and 39% reported prior psychiatric treatment. 61% of patients reported prior legal problems with 35% having been incarcerated.

At follow-up, 77% of subjects reported that they had continuously remained on bup/nx. Patients on continuous bup/nx were significantly less likely to report using any substance ($\chi^2 = 6.26$, $p = 0.012$) and were less likely to report using heroin ($\chi^2 = 8.1$, $p = 0.004$). Continued bup/nx patients were significantly more likely to report AA affiliation ($\chi^2 = 5.49$, $p = 0.019$), including a “home group”, a “sponsor”, and attending 3+ 12-step meetings per week ($\chi^2 = 4.72$, $p = 0.029$). Those on bup/nx were significantly more likely to have been employed at baseline ($\chi^2 = 4.92$, $p = 0.027$) and at follow-up ($\chi^2 = 4.89$, $p = 0.027$).

Regarding psychosocial parameters, patients continuously on bup/nx were less likely to reported damaging a close relationship ($\chi^2 = 6.07$, $p = 0.014$), doing regretful or impulsive things ($\chi^2 = 4.89$, $p = 0.027$), hurting family ($\chi^2 = 8.52$, $p = 0.004$), experiencing negative personality changes ($\chi^2 = 4.43$, 0.035), failing to do things expected of them ($\chi^2 = 9.54$, $p = 0.002$), taking foolish risks ($\chi^2 = 11.36$, $p = 0.0008$), being unhappy ($\chi^2 = 9.27$, $p = 0.002$), and having money problems ($\chi^2 = 5.97$, $p = 0.015$). The study design did not allow these results to be controlled for opioid abstinence.

SES sub-group analysis indicated that high SES subjects were more likely to be from a minority background ($\chi^2 = 6.82$, $p = 0.009$) and were more likely to have a significant other ($\chi^2 = 12.36$, $p = 0.0004$). High SES subjects were more likely to be employed at baseline ($\chi^2 = 4.84$, $p = 0.028$), but not at follow-up. Low SES subjects were more likely to report still being on bup/nx at the time of follow-up. There was more substance use at follow-up in the low SES subjects ($\chi^2 = 4.09$, $p = 0.0432$).

4. Discussion

This study is one of the largest case series to date to report outcomes of office-based bup/nx maintenance with minimum 18-month follow-up data. The goals of the present study were to determine the proportion of subjects still using bup/nx at follow-up, to compare levels of functioning in continuously maintained bup/nx patients with those who dropped out, and to assess whether pre-treatment variables including SES were predictive of treatment retention.

At between 18 months and 4 years of follow-up, 85 of 110 of subjects contacted were still using bup/nx (77%), indicating that bup/nx can clearly be an effective long-term adjunct to a comprehensive abstinence oriented, 12-step treatment program. Subjects who remained on bup/nx reported dramatic improvement in many domains of quality of life and measures of sobriety when compared to drop outs including: less substance use, fewer psychosocial complications of addiction, more AA affiliation activities, and increased employment at follow-up. The major reason for drop out or discontinuation from bup/nx maintenance was failure to fully adhere with the abstinence based 12-step treatment or repeated evidence of substance use. Thus improved psychosocial functioning in bup/nx maintained patients was likely due to their marked decreased rate of substance use and not solely due to the bup/nx. Increasing levels of employment for patients remaining on bup/nx is very important given that long-term bup/nx therapy, especially if that therapy involves some degree of public funding, can hinge on a return to gainful employment and medication funding independence.

A secondary goal was to examine whether pre-treatment characteristics were associated with bup/nx retention. Factors associated with improved retention were being employed at entry into the study and the use of prescription opioids rather than heroin. This supports the prior observation that bup/nx outcomes may be improved in prescription opioid abusers over heroin abusers (Moore et al., 2007). A pre-treatment variable of special interest was patient SES. Slightly more low SES patients remained on bup/nx, the low SES patients demonstrated similar improvements in quality of life measures, and greater increases in employment status when compared to the high SES group. Despite the better retention in low SES patients and the fact that they received more treatment in the form of a half-way house residential stay, they were also slightly more likely (8%) to report substance use and hence relapse of addictive disease. Clearly, low SES patients can benefit greatly from bup/nx maintenance when combined with quality addiction counseling treatment.

This low SES patient group is a different population than reported on in other bup/nx studies. Previous reports on low SES groups have examined outcomes in homeless patient populations (Alford et al., 2007; Fiellin et al., 2006; Stein et al., 2005). All of the low SES patients in this study had stable housing, but were uninsured, mostly unemployed (89%), unmarried (86%), injection drug users (82%). None of our low SES patients could afford either the medications or the costs the treatment at entry to the program. The low SES patients in this study represent a large group of the US drug abusing population who are uninsured but are not truly homeless. As such they are a unique and important group to study.

This study has several important limitations. The study population is a clinical case series and a convenience sample derived from a clinical cohort stabilized on bup/nx as part of a private insurance and publicly funded treatment program, and was not part of any planned research protocol. The study was not prospective, with results obtained via retrospective chart review and cross-sectional telephone interview. Finally, while one strength of this study was its different SES patient populations, an important weakness was the necessity for different intensity of addiction treatment between the two groups. Because treatment of indigent subjects was publicly funded, these individuals were required by the funding agency to undergo 4–8 weeks of half-way house treatment that was not provided to any of the insured subjects. This created two potential biases: a treatment bias whereby indigent patients received longer and more intensive substance abuse treatment, and potentially a selection bias since this half-way house treatment was mandated and thus low SES patients unable or unwilling to go into the residential setting were not initiated on bup/nx.

Despite these limitations we believe the results of this study confirm that bup/nx can be effectively combined with a rigorous abstinence based 12-step treatment program and produce long-term improvements in sobriety and quality of life. These beneficial effects appear to be evident in low SES and high SES patient populations.

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Table 1

Demographic, drug use, and other intake variables shown for subjects initially enrolled in the study and the subset of those individuals available for follow-up.

Variable	Total (*N* = 176)	Subjects completing telephone interview (*N* = 110)
Ethnicity		
African American	37 (21%)	23 (21%)
Hispanic	8 (5%)	4 (4%)
White, non-Hispanic	129 (73%)	81 (74%)
Other	2 (1%)	2 (1%)
Female	58 (32%)	35 (32%)
Insurance status		
Insurance	72 (41%)	40 (37%)
Medicaid	10 (5%)	6 (5%)
Medicare	3 (2%)	2 (2%)
Self-pay	91 (52%)	62 (56%)
Significant other	76 (58%)	45 (66%)
Significant other using	15 (12%)	9 (13%)
Prescription opioid use	21 (12%)	12 (11%)
Route of administration		
Injection	130 (74%)	78 (71%)
Nasal	23 (13%)	18 (16%)
Oral	23 (13%)	14 (13%)
Medical history		
Abscess	13 (10%)	5 (8%)
Bacterial endocarditis	1 (1%)	0 (0%)
Depression	73 (41%)	43 (39%)
Hepatitis C	44 (34%)	20 (30%)
HIV	1 (1%)	0 (0%)
Injury	34 (27%)	13 (20%)
Overdose	5 (4%)	3 (5%)
Prior psychiatric treatment	69 (39%)	42 (38%)
Legal history		
Arrest	45 (35%)	17 (26%)
Prior legal problems	108 (61%)	66 (60%)

Table 2

Addiction related Intake and outcome variables by insurance status and continued bup/nx use at follow-up.

Variable (endorsed) Using bup/nx at follow-up	Total (*N* = 110)	Uninsured		Insured		Insured[a] 44% (48/110)		bup/nx at follow-up[b] 77% (85/110)	
		No (*N* = 12)	Yes (*N* = 50)	No (*N* = 13)	Yes (*N* = 35)	χ^2	*P*	χ^2	*P*
Intake variables									
Minority	27/110 (25%)	1 (8%)	9 (18%)	6 (46%)	11 (31%)	6.82	0.009	NS	
Female	35/110 (32%)	3 (25%)	12 (24%)	5 (38%)	15 (43%)	NS		NS	
Significant other	45/68 (66%)	2 (29%)	7 (44%)	11 (85%)	25 (78%)	12.4	0.0004	NS	
Who is using	9/67 (13%)	0 (0%)	1 (7%)	2 (15%)	6 (19%)	NS		NS	
Prescription opioid use	12/107 (11%)	0 (0%)	3 (6%)	2 (15%)	7 (20%)	NS		3.13	0.0768[c]
Route: injection	78/110 (71%)	10 (83%)	41 (82%)	9 (69%)	18 (51%)	NS		NS	
Medical comorbidity	21/64 (33%)	3 (50%)	7 (54%)	4 (31%)	7 (22%)	NS		NS	
Hepatitis C	20/64 (31%)	2 (33%)	7 (54%)	4 (31%)	7 (22%)	NS		NS	
Abscess	5/63 (8%)	1 (17%)	2 (15%)	0 (0%)	2 (6%)	2.77	0.0963[c]	NS	
Overdose	3/66 (5%)	0 (0%)	1 (7%)	0 (0%)	2 (6%)	NS		NS	
Depression	43/110 (39%)	7 (58%)	16 (32%)	6 (46%)	14 (40%)	NS		NS	
History of psychiatric treatment	42/110 (38%)	5 (42%)	18 (36%)	6 (46%)	13 (37%)	NS		NS	
Legal comorbidity	69/106 (65%)	9 (82%)	32 (67%)	7 (54%)	21 (62%)	NS		NS	
Arrest history	17/63 (27%)	4 (67%)	4 (31%)	3 (23%)	6 (19%)	NS		NS	
Any legal problems	66/106 (62%)	9 (82%)	32 (67%)	6 (46%)	19 (56%)	3.01	0.0827[c]	NS	
Outcome variables									
Substance use	16/110 (15%)	4 (33%)	7 (14%)	4 (31%)	1 (3%)	4.09	0.0432	6.26	0.0123
Alcohol	8/110 (7%)	3 (25%)	4 (8%)	1 (8%)	0 (0%)	4.95	0.026	3.8	0.0513[c]
Heroin	14/110 (13%)	4 (33%)	7 (14%)	3 (23%)	0 (0%)	7.97	0.0047	8.1	0.0044
Cocaine	8/110 (7%)	1 (8%)	5 (10%)	1 (8%)	1 (3%)	NS		NS	
AA affiliated	95/110 (86%)	9 (75%)	46 (92%)	7 (54%)	33 (94%)	NS		5.49	0.0191
Home group	83/110 (76%)	8 (67%)	41 (84%)	4 (31%)	30 (86%)	NS		3.40	0.0654[c]
Has sponsor	88/110 (80%)	9 (75%)	43 (86%)	5 (38%)	31 (89%)	NS		4.72	0.0298
3+ meetings/week	73/110 (66%)	6 (50%)	38 (76%)	6 (46%)	23 (66%)	NS		NS	

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Variable (endorsed) Using bup/nx at follow-up	Total (*N* = 110)	Uninsured		Insured		Insured[a] 44% (48/110)		bup/nx at follow-up[b] 77% (85/110)	
		No (*N* = 12)	Yes (*N* = 50)	No (*N* = 13)	Yes (*N* = 35)	χ^2	*P*	χ^2	*P*
Employment characteristics									
Employed—baseline	26/110 (24%)	1 (8%)	6 (12%)	4 (31%)	15 (43%)	4.84	0.0278	4.92	0.0266
Employed—follow-up	64/110 (58%)	2 (17%)	32 (64%)	7 (54%)	23 (66%)	NS		4.89	0.0271
Employment changes	n/a	n/a	n/a	n/a	n/a	NS		2.84	0.0918[c]
Still not employed	43/110 (39%)	10 (83%)	18 (36%)	5 (38%)	10 (29%)	n/a		n/a	
Still employed	23/110 (21%)	1 (8%)	6 (12%)	3 (23%)	13 (37%)	n/a		n/a	
Newly employed	3/110 (3%)	1 (8%)	26 (52%)	4 (31%)	10 (29%)	n/a		n/a	
No longer employed	41/110 (37%)	0 (0%)	0 (0%)	11 (8%)	2 (6%)	n/a		n/a	

Analyses control for baseline medical and legal comorbidity. Uninsured = Self-pay classification; Insured = Insured, Medicaid, Medicare (Medicaid and Medicare are considered insured by St. Vincent Charity Hospital standards). NS = not significant ($\alpha = p < 0.05$).

[a] Test statistics for group difference across insured and uninsured groups.

[b] Test statistics for group difference across those who did and those who did not report current bup/nx use at follow-up.

[c] Trend level observation ($p < 0.1$).