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Home- versus office-based buprenorphine inductions for opioid-dependent patients

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Abstract

Recent legislation permits the treatment of opioid-dependent patients with buprenorphine in the primary care setting, opening doors for the development of new treatment models for opioid dependence. We modified national buprenorphine treatment guidelines to emphasize patient self-management by giving patients the opportunity to choose to have buprenorphine inductions at home or the physician's office. We examined whether patients who had home-based inductions achieved greater 30-day retention than patients who had traditional office-based inductions in a study of 115 opioid-dependent patients treated in an inner-city health center. Retention was similar in both groups: 50 (78.1%) in office-based group versus 40 (78.4%) in home-based group, $p = .97$. Several patient characteristics were associated with choosing office- versus home-based inductions, which likely influenced these results. We conclude that opioid dependence can be successfully managed in the primary care setting. Approaches that encourage patient involvement in treatment for opioid dependence can be beneficial.

Keywords

Buprenorphine treatment; Buprenorphine induction; Opioid dependence; Primary care; Community health center

1. Introduction

New legislation permits buprenorphine, a partial opioid agonist, to be used for the treatment of opioid dependence in the primary care setting (Drug Addiction Treatment Act, 2000). This

provides opportunities to begin to develop and implement new treatment approaches for addiction care more generally. The Chronic Care Model (CCM), designed to improve long-term care for patients with chronic diseases (Wagner, 1998; Wagner et al., 2001), has great potential to guide new treatment strategies for opioid dependence in primary care. This model emphasizes the central role of patients and their relationship with their health care provider team to achieve optimal health outcomes. One aspect that is particularly relevant to the application of the CCM to addiction care is that it challenges the traditional notion that the physician is the sole person who directs care, and it directly engages patients in making treatment decisions. Although there are no published studies applying this model to the treatment of opioid dependence, successes in applying it to the treatment of alcohol abuse indicate its potential usefulness for addiction treatment in general (McEvoy & Barnes, 2007; Watkins, Pincus, Tanielian, & Lloyd, 2003). Our study is among the first to examine whether a key component of the CCM, increasing patient self-management, can be successfully integrated into buprenorphine treatment from opioid dependence in a community health center.

Buprenorphine treatment for opioid dependence consists of three phases: (a) induction, when the appropriate dose of buprenorphine is established with the goal of markedly reducing use of other opioids, cravings, and withdrawal symptoms; (b) stabilization, when patients are closely monitored to ensure appropriate ongoing dosing with the goal of completely eliminating opioid cravings and signs and symptoms of withdrawal; and (c) maintenance, when patients continue to take buprenorphine to manage their opioid dependence for an indefinite period (Center for Substance Abuse Treatment [CSAT], 2004). The most challenging phase is usually the few days of induction. During this time, patients are typically expected to present to a clinic setting in active opioid withdrawal, and physicians manage the induction process by repeatedly assessing patients' signs and symptoms of withdrawal while titrating the buprenorphine dose. This approach offers little to promote patients' self-management of their addiction and, for this and other reasons, has the potential to present substantial barriers to offering buprenorphine treatment in primary care settings. For example, patients may not be willing to relegate management of severe opioid withdrawal symptoms to a physician; patients and physicians may not be comfortable managing withdrawal symptoms in the primary care clinic setting; and the health care system may not have the capability or flexibility to allow patients to remain in the primary care clinic and be repeatedly assessed by a physician over several hours.

These challenges with office-based buprenorphine induction inspired us to modify the buprenorphine treatment guidelines from the Center for Substance Abuse Treatment, which specifies conducting office-based inductions (CSAT, 2004). We aimed to address the difficulties patients and their providers experience during office-based inductions in ways that were consistent with models used in primary care settings to manage other chronic diseases. Our modified induction protocol focuses on teaching patients to carry out the buprenorphine induction process at home and begin to independently manage opioid cravings over time. Several providers have begun to experiment with different home-based induction strategies that have ranged from telephone supported inductions by a nurse case manager to unsupported home-based inductions (Alford et al., 2007; Lee, Grossman, DiRocco, & Gourevitch, 2008; Mintzer et al., 2007). In each of these examples, patients are given instruction about the induction process, how to monitor signs and symptoms of withdrawal, how and when to take the initial buprenorphine doses, and when and who to contact in case of questions or emergencies. Thus far, studies report that the home-based induction process is safe and may be as effective as office-based inductions (Alford et al., 2007; Lee et al., 2008; Mintzer et al., 2007). However, to our knowledge, there have not been any direct comparisons of home- versus office-based inductions that were offered to comparable populations and that were carried out in the same clinical setting. Therefore, it remains uncertain whether home-based inductions, which encourage greater patient self-management of opioid dependence during the early stages

of treatment, can result in improved outcomes for primary care patients seeking buprenorphine treatment for opioid dependence.

In this observational study, we compare 30-day treatment retention between patients who had traditional office-based buprenorphine inductions and those who had home-based buprenorphine inductions in a single community health center. Based on the successes of programs that encourage patient self-management of various chronic diseases, we hypothesized that patients who had home-based inductions would be more likely to be retained in buprenorphine treatment than patients who had traditional office-based inductions.

2. Materials and methods

2.1. Patients

The study was conducted between 2005 and 2008 in a health center located in the Bronx, NY, a community profoundly affected by the growing epidemic of opioid dependence (Frank, 2000; New York City Department of Health and Mental Hygiene [NYC DOH], 2008). The health center serves an economically disadvantaged community that surrounds the health center.

Opioid-dependent people who presented to the health center for buprenorphine treatment were screened for clinical eligibility. In accordance with national guidelines (CSAT, 2004), the eligibility criteria were the following: (a) at least 18 years old, (b) *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV)* opioid-dependent, and (c) insured by a health plan accepted at the health center or ability to pay for treatment on a sliding scale fee. (Typically uninsured patients paid \$25 per visit, including laboratory and radiology tests, and \$5 per month for buprenorphine/naloxone prescriptions.) Patients were excluded if they were (a) hypersensitive to buprenorphine or naloxone, (b) pregnant, (c) *DSM-IV* alcohol-dependent, (d) *DSM-IV* benzodiazepine-dependent, (5) found to have serum aspartate aminotransferase (AST) or alanine aminotransferase (ALT) levels greater than five times normal, (6) diagnosed with severe, untreated psychiatric illness, or (7) taking more than 60 mg of methadone daily in the past month. During the study period, 298 people inquired about buprenorphine treatment, 171 (57.4%) were not interested in receiving treatment and did not return for full assessments, and 12 (4.0%) were deemed clinically ineligible. The remaining 115 (38.6%) people are included in our sample.

For the first 2 years of the program, all patients were given office-based inductions ($n = 28$). For the second 2 years, patients chose between office- or home-based inductions ($n = 87$). The decision about induction type was made through mutual agreements between the patients and their physicians. Among those given a choice, 51 patients (58.6%) had home-based inductions and 36 (41.4%) had office-based inductions.

2.2. Interventions

In general, as with other chronic disease management programs introduced to the health center, the buprenorphine treatment program was developed to be consistent with the CCM. One specific aspect of the CCM that was emphasized was encouragement of greater patient self-management of addiction. Below, we describe the two induction strategies that were offered—office-based inductions (traditional strategy) and home-based inductions. The latter strategy allows for greater patient self-management.

2.2.1. Office-based Inductions—Patients attended a preparatory office visit to obtain information about the buprenorphine treatment process, and those who remained interested and were eligible were given an appointment for the induction visit. They were told to present

to their appointment in opioid withdrawal. At that first induction visit, patients were assessed to ensure they were in adequate withdrawal and then given 1–2 tablets of 2/0.5 mg of buprenorphine/naloxone. (All patients were given buprenorphine/naloxone rather than buprenorphine monotherapy.) After this 20-minute visit, patients were told to wait in or around the health center for an additional 30–60 minutes so that they could be reassessed to determine their response to the initial buprenorphine/naloxone dose. When clinically appropriate, patients were subsequently given an additional 1–2 tablets of 2/0.5 mg of buprenorphine/naloxone. This process was repeated until patients' signs and symptoms of opioid withdrawal were substantially diminished or until a maximum of 12/3 to 16/4 mg of buprenorphine/naloxone was taken. In addition to prescribing buprenorphine/naloxone, physicians also prescribed ancillary medications (e.g., ibuprofen, clonidine, and loperamide hydrochloride) to help manage patients' symptoms as needed. All together, with repeated assessments, the initial induction visit lasted between 2 and 4 hours.

Patients were asked to return to the health center for their second induction visit within 1 to 2 days, during which time they were assessed for ongoing signs and symptoms of opioid withdrawal and buprenorphine/naloxone doses were titrated as needed. This second induction visit typically lasted 15–20 minutes. Patients were encouraged to contact their provider with questions or concerns that arose between the first and second induction visits; however, patients infrequently contacted providers between these visits. The duration of maintenance buprenorphine treatment was determined on a case-by-case basis and typically continued for an indefinite period.

2.2.2. Home-based inductions—Patients attended a preparatory office visit to obtain information and to assess their clinical eligibility for buprenorphine treatment. Eligible patients returned to the health center to plan their home inductions. This visit lasted 30 minutes, during which time patients were given information about buprenorphine/naloxone and the process of induction, the home induction kit, and instructions on how to use this kit. The home induction kit included an instruction sheet, 2/0.5 and 8/2 buprenorphine/naloxone pills, ibuprofen, clonidine, and loperamide hydrochloride (see Table 1). The instruction sheet had six sections that explained the contents of the kit, when to start taking buprenorphine/naloxone, things not to do, how to take buprenorphine/naloxone, plans to guide treatment and facilitate follow-up, and a log to track medications taken.

Patients were given a follow-up appointment within the week, at which time long-term maintenance was discussed, and as with those receiving office-based inductions, the duration of maintenance treatment was determined based on patients' needs and responses to medication. Patients were encouraged to contact their provider with questions or concerns that arose during the home induction, but, similar to patients with office inductions, patients with home inductions infrequently called providers.

2.3. Data collection

Data were extracted from medical records by a health care provider experienced in buprenorphine treatment. Standardized medical record extraction forms were used to collect data on sociodemographic information (age, gender, race/ethnicity, employment, and insurance status), substance use in the 30-day period prior to induction (opioid use, cocaine use, and sedative/benzodiazepine use), and substance abuse treatment history (methadone and buprenorphine treatment), induction outcomes, and treatment retention. Induction outcomes were defined as difficult versus routine. Difficult inductions included inductions that resulted in an acute worsening of withdrawal symptoms immediately following the first buprenorphine/naloxone dose (e.g., precipitated withdrawal) and inductions in which opioid withdrawal symptoms did not substantially improve within 48 hours of the first buprenorphine/naloxone

dose (e.g., protracted withdrawal). Data on severe adverse events that may have been associated with inductions were also recorded, including hospitalizations and hepatotoxicity (fivefold increases in baseline AST or ALT). Retention was defined as having at least one visit and an active buprenorphine/naloxone prescription 30 days after the first buprenorphine/naloxone dose was taken.

2.4. Data analyses

First, we describe our study sample in terms of sociodemographic and substance use patterns during the 30 days prior to induction. Second, we conducted bivariate analyses testing whether 30-day retention was similar by induction type (office vs. home). Because we used a convenience sample, we also conducted multivariable analysis to estimate the association between 30-day retention and induction type while adjusting for possible confounding factors. We identified sociodemographic characteristics and substance use patterns during the 30 days prior to induction that were associated with 30-day retention at the $p < .20$ level using chi-square tests (all variables were coded as categorical variables). Those factors were included in a logistic regression model with 30-day retention as our dependent variable and induction type as our main independent variable.

Finally, we compared the sociodemographic characteristics and substance use patterns during the 30 days prior to induction of patients choosing office- vs. home-based inductions during the second 2 years of our study to explore factors that might guide patient treatment decisions. We report those characteristics that were associated with induction type at $p < .05$ in bivariate analyses.

3. Results

Of the 115 patients treated with buprenorphine, the mean age was 44.9 years ($SD = 8.5$); most were men ($n = 85$, 73.9%), Hispanic or Black ($n = 103$, 89.5%), and unemployed ($n = 78$, 67.8%). Eighty-one (70.4%) used heroin; 12 (10.4%) used “street” prescription opioids (e.g., prescription opioids that were not prescribed to the patient); 18 (15.7%) used prescription opioids that were prescribed to the patient; 36 (31.3%) used “street” methadone (e.g., methadone not prescribed to the patient); and 35 (30.4%) used methadone that was prescribed to the patient. Fifty-four (47.0%) used more than one type of opioid in the past 30 days, and 3 (2.6%) did not use any opioids in the past 30 days (they met *DSM-IV* criteria for opioid dependence, but their last use was longer than 30 days prior). Eight-five (73.9%) had prior methadone treatment, and 31 (27.0%) had prior buprenorphine use (6 [5.2%] were prescribed buprenorphine, 21 [18.3%] took buprenorphine obtained from the “street,” and 4 [3.5%] took both prescribed and “street” buprenorphine). Overall, 51 (44.3%) had home-based inductions, and 64 (55.7%) had office-based inductions.

A similar proportion of people in each induction group experienced difficult inductions: 10 of 60 (16.7%) in office-based inductions versus 8 of 47 (17.0%) in home-based inductions, odds ratio (OR) = 0.98, 95% confidence interval (CI) = 0.35–2.70. Four patients with office-based inductions and 4 patients with home-based inductions had inadequate information to assess whether inductions were difficult. Only 1 patient (in the home-based induction group) was hospitalized immediately following induction; hospitalization was due to complications secondary to benzodiazepine abuse (which was underreported by the patient). None of the patients experienced clinically significant hepatotoxicity following inductions.

Thirty-day treatment retention was similar by induction type: 50 (78.1%) for office-based inductions versus 40 (78.4%) for home-based inductions, OR = 0.98, 95% CI = 0.40–2.40. Two characteristics were associated with 30-day treatment retention at the $p < .20$ level (see Table 2): insurance status and use of street methadone in the 30 days before induction. These

factors were also modestly associated with induction type in the full sample (data not shown). However, adjustment for these characteristics in multivariable regression did not substantially change the results (30-day retention for office- vs. home-based induction adjusted odds ratio [AOR] = 1.10, 95% CI = 0.43–2.78).

Using the subsample of 87 people who were induced during the second 2-year period when patients and providers chose the induction type, we compared patient characteristics for those receiving office- vs. home-based inductions. Hispanic ethnicity, unemployment, having Medicaid, crack/cocaine use in the past 30 days, and prior sedative/benzodiazepine use in the past 30 days were associated with choosing office-based inductions. Having had prior buprenorphine treatment was associated with choosing home-based inductions.

4. Discussion

In a health center that serves an economically disadvantaged community that is strongly affected by the opioid epidemic, people treated for opioid dependence with home-based buprenorphine inductions were as likely to be retained at 30 days as those with traditional office-based inductions. We hypothesized that home-based inductions would be associated with greater treatment retention based on research on chronic disease management that highlights the benefits of greater patient involvement and development of patient self-management skills (Bodenheimer, Lorig, Holman, & Grumbach, 2002; Hibbard & Cunningham, 2008; Lorig et al., 2001; Lorig, Sobel, & Stewart, 1999; Mosen et al., 2007). However, our data did not support this hypothesis and did not indicate superiority of either induction type on this short-term outcome in this observational study. There was also no indication of superiority of either induction type on experiencing difficulties with the induction process.

Because this was an observational study, in which patients and providers selected the treatment (office- vs. home-based induction) that they decided would be best, we believe the findings of this study reflects the success of the patients and providers in our study in selecting the buprenorphine induction type that was best suited to patients' needs, abilities, and beliefs about health care. Our results indicate that, in most cases, the decision about which induction type to use was made appropriately because 78.3% of the sample was retained at 30 days and approximately equal proportions were retained in each induction group. Given the importance of the induction process for longer term opioid addiction management, these data should be encouraging for providers who are considering treating opioid-dependent patients in the primary care setting. Most patients receiving office- or home-based inductions successfully completed the induction process.

We also did not detect differences in 30-day retention by induction type in multivariable analyses that adjusted for patient characteristics by induction type (AOR = 1.10, 95% CI = 0.43–2.78). We identified only two patient characteristics that were associated with 30-day retention: having an insurance type other than Medicaid and having used street methadone in the past 30 days. Patients who did not have Medicaid probably had fairly stable income sources (and therefore were privately insured or self-paid) and were more likely to be retained. Patients who used street methadone in the 30 days before induction were also more likely to be retained. We reported a similar result in an earlier evaluation of our buprenorphine treatment program (Cunningham et al., 2008) and believe that this finding is worthy of future exploration. Our clinical experiences with this population indicate that patients presenting for buprenorphine treatment who used street methadone rather than heroin or prescription opioids tended to describe their use as self-medication for opioid withdrawal symptoms rather than a desire to "get high." These patients tended to be highly motivated to find a better treatment approach for their opioid dependence. It will be important to examine whether these factors are also

associated with short-term retention in a buprenorphine treatment program in an experimental research design.

Unfortunately our study, based on post hoc medical record review data, was unable to assess fully the social and clinical factors that may have contributed to patient and provider decisions about the appropriate induction type. Factors such as level of support, stability, and severity of substance abuse should play a role in determining which patients will be comfortable and successful with a treatment strategy that draws on self-management skills (Street, Gordon, Ward, Krupat, & Kravitz, 2005; Tobias, Cunningham, Cunningham, & Pounds 2007) and therefore should influence decisions about the appropriate induction type for particular patients. Our study identified ethnicity, employment status, type of insurance, history of crack/cocaine or sedative/benzodiazepine use, and prior buprenorphine use as being associated with type of induction. These characteristics may be markers for the underlying factors mentioned above.

There were a number of limitations of this study, the primary one being the limited sample size and power to detect differences. Second, because our data were based on reviews of medical records of routine clinical care rather than data collected for research, we were limited by the type and number of factors that we could examine. For example, urine toxicology tests were conducted based on clinical judgment rather than a standardized research protocol; therefore, we could not compare the two groups of patients on other important outcomes like drug use behaviors. Third, as we follow patients over a longer period, it is possible that differences in outcomes between the two groups might emerge. For example, as patients face ongoing drug craving, interact with others who use opioids, and have challenging life experiences that were previously associated with drug use, the benefits of patient self-management may increase.

Finally, although an advantage of our study is that it compares induction strategies among patients recruited from the same health center population, it is possible that patients at this health center differ from the general population of opioid-dependent patients, and therefore, our study may not be generalizable to a larger target population. Therefore, the specific characteristics that are markers for level of support, stability, and severity of substance abuse might differ in different populations.

We conclude that both office- and home-based buprenorphine inductions are feasible in the primary care setting. In our study, treatment retention of 78.3% at 30 days is similar or greater than that reported in previous studies (e.g., Alford et al., 2007; Cunningham et al., 2008; Fiellin et al., 2002; Lee et al., 2008; Mintzer et al., 2007; O'Connor et al., 1998; Stein, Cioe, & Friedmann, 2005; Sullivan et al., 2006) and adds to the growing literature that demonstrates that patients can successfully undergo buprenorphine induction in office- or home-based settings. In contrast to our hypothesis that a strategy that encourages patient self-management from the earliest stage of treatment for opioid dependence would result in better retention, our data do not support either office- or home-based inductions as being superior with regard to short-term patient retention. Our evaluation of differences between patients who are retained at 30 days and who initially chose office- vs. home-based inductions indicate that, in most cases, patients and providers were able to appropriately assess patients' needs and self-management abilities and made appropriate induction strategy decisions.

It is crucial to continue to develop and evaluate innovative treatment models to successfully address the growing opioid epidemic. Providing buprenorphine treatment in the primary care setting offers opportunities to apply lessons from chronic disease management described in the CCM for treating opioid dependence.

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Table 1

Home-based buprenorphine induction kit

Contents			Purpose
<i>Instruction sheet</i>			
What's in the kit?			Guide to medications
When to start Suboxone			Guide to timing of treatment initiation
Things not to do			Guide to appropriate behaviors/treatment
How to take Suboxone			Facilitate correct dosing
Plan			Provide schedules and facilitate follow-up
What was taken?			Manage/Track medications taken
<i>Medications</i>			
No. of pills	Medication	Dose (mg)	
10	Buprenorphine/ Naloxone	2/0.5	Initiate buprenorphine treatment (Day 1)
4	Buprenorphine/ Naloxone	8/2.0	Continue buprenorphine treatment (Days 2–3)
6	Ibuprofen	200	Manage withdrawal symptoms: pain
6	Clonidine	0.1	Manage withdrawal symptoms: anxiety
6	Loperamide hydrochloride	2.0	Manage withdrawal symptoms: diarrhea

Table 2

Characteristics of 115 patients treated for opioid dependence in a community health center by 30 day retention status

	Retained at 30 days (<i>n</i> = 90)	Not retained at 30 days (<i>n</i> = 25)	
Characteristics	N (%)	N (%)	<i>p</i> ^a
Sociodemographic			
Age (younger than median, 46 years)	44 (48.9)	11 (44.0)	.67
Male gender	66 (73.3)	19 (76.0)	.79
Race			.44
Hispanic	59 (65.6)	19 (76.0)	
Non-Hispanic Black	20 (22.2)	5 (20.0)	
Non-Hispanic other	11 (12.2)	1 (4.0)	
Employed	31 (34.4)	6 (24.0)	.32
Have Medicaid	67 (74.4)	22 (88.0)	.15 ^b
Drug use behaviors			
Substance use in past 30 days			
Heroin	61 (67.8)	20 (80.0)	.24
Street methadone	31 (34.4)	5 (20.0)	.17 ^b
Methadone, prescribed in treatment	26 (28.9)	9 (36.0)	.49
Street prescription opioids	9 (10.1)	3 (12.5)	.72
Prescription opioids, prescribed in treatment	13 (14.6)	5 (20.0)	.54
Cocaine/Crack	36 (40.0)	11 (44.0)	.72
Sedative/Benzodiazepines	10 (11.6)	5 (20.8)	.31
Ever injected drugs	51 (57.3)	15 (62.5)	.64
Years using opioids ≥ median (≥22 years)	45 (53.6)	9 (39.1)	.22
Prior methadone treatment	66 (73.0)	19 (76.0)	.79
Prior buprenorphine use	25 (27.8)	6 (24.0)	.71
Treatment			
Home-based induction	40 (44.4)	11 (44.4)	.97

^a *p* value associated with chi-square test of difference in proportions for those retained at 30 days versus those not retained at 30 days for each characteristic.

^b *p* < .20, variable selected for inclusion in multivariable analyses.