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Prescription opioid abuse, chronic pain, and primary care: A Co-Occurring Disorders Clinic in the chronic disease model

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ABSTRACT

Abuse of opioids has become a public health crisis. The historic separation between the addiction and pain communities and a lack of training in medical education have made treatment difficult to provide, especially in primary care. The Co-occurring Disorders Clinic (COD) was established to treat patients with co-morbid chronic pain and addiction. This retrospective chart review reports results of a quality improvement project using buprenorphine/naloxone to treat co-occurring chronic non-cancer pain (CNCP) and opioid dependence in a primary care setting. Data were collected for 143 patients who were induced with buprenorphine/naloxone (BUP/NLX) between June 2009 and November 2011. Ninety-three patients (65%) continued to be maintained on the medication and seven completed treatment and were no longer taking any opioid (5%). Pain scores showed a modest, but statistically significant improvement on BUP/NLX, which was contrary to our expectations and may be an important factor in treatment retention for this challenging population.

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1. Introduction

Unintentional opioid overdose is second only to motor vehicle deaths as an accidental cause of death, leading the Centers for Disease Control and Prevention to label prescription opioid overdose as a national epidemic. This epidemic is already widespread among the veteran population. Compared to the estimated 35% of American adults who experience chronic pain (National Research Council, 2011), 50% of veterans have chronic pain conditions (Clark, 2002). Among these veterans, 75% receive prescriptions for one or more analgesics, with 44% receiving opioids. A study conducted on 76 veterans receiving opioid therapy for CNCP in a pain clinic found that 34% met one criterion for opioid abuse or dependence and 28% met three or more of the authors' five-point checklist based on *DSM-IIIR* (Chabal, et al., 1997). In a recently published study, the rate of overdose among veterans treated with opioids was found to be 0.04% per year, a striking four times the national average (Bohnert, et al., 2011).

The CNCP patient with opioid dependence presents difficult therapeutic challenges to health care providers, especially those in primary care settings. Research shows that primary care physicians are ill-equipped to treat these patients because they receive little training in either pain management or addiction medicine (Miller, et al., 2001). Because many patients perceive their problems to be related to pain and not addiction, they may engage in treatment more readily if it is integrated into mainstream medical care. For patients with CNCP and opioid dependence, the chronic disease or continuing care approach may be the preferred model. Integrating addiction treatment in a medical setting not only reduces stigmatization, but also allows providers to simultaneously treat pain, addiction, and co-existing medical and psychiatric co-morbidities.

In 2000, the FDA designated buprenorphine as a schedule III controlled substance approved for the treatment of opioid dependence. The Drug Abuse Treatment Act of 2000 permits buprenorphine to be used in office-based settings such as primary care clinics with the appropriate Controlled Substance Act waiver. The implementation of office-based buprenorphine treatment was intended to allow non-specialist clinicians to treat patients with opioid addiction, including dependence on prescription medications, as they would other patients with chronic medical illnesses (Ling & Smith, 2002).

Buprenorphine is a partial mu opioid agonist and kappa antagonist, and when used to treat opioid dependence it reduces illicit opioid use, improves treatment retention, and increases negative urine toxicology screens (Johnson & McCagh, 2000; Johnson, et al., 2003). An important advantage of buprenorphine is its safety profile in overdose compared to full opioid agonists (Johnson, Fudala, & Payne, 2009). The epidemic of opioid overdose could potentially be reduced if buprenorphine was more widely prescribed for co-occurring

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chronic pain and opioid dependence. The risks of aberrant behavior, overdose, and opioid diversion might be further reduced when rigorous monitoring and psychosocial services accompany medication-assisted treatment.

Few studies have evaluated the effectiveness of the sublingual preparation of buprenorphine in patients with co-occurring CNCP and opioid addiction. One observational study set in a pain clinic used sublingual buprenorphine to treat 95 chronic pain patients who had failed conventional opioid therapy (Malinoff, et al., 2005). Overall, 82 patients reported substantial improvement and only 6 discontinued buprenorphine due to intolerable side effects. However, only 8% of patients enrolled in this study had opioid dependence by *DSM-IV* criteria. A small open-label study of 12 patients with CNCP and opioid addiction found that none of the 6 patients assigned to the buprenorphine detoxification and discontinuation arm could complete the protocol, while 5 of the 6 subjects assigned to the buprenorphine maintenance treatment arm successfully completed the program (Blondell, et al., 2010).

The present paper reports the results of a quality improvement project in primary care. We conducted a retrospective chart review evaluating outcomes from an innovative continuing care clinical model using buprenorphine to treat veterans with co-occurring CNCP and opioid dependence embedded in a primary care setting. We hypothesized that the major barrier to using buprenorphine to treat CNCP and co-occurring opioid dependence would be inadequate pain control, leading to discontinuation of BUP/NLX and return to opioid use.

2. Methods and materials

2.1. Setting and providers: the Co-occurring Disorders Clinic

The Co-occurring Disorders Clinic (COD) is a unique treatment setting embedded within the Primary Care Service of the tertiary care Raymond G. Murphy VA Medical Center in Albuquerque, NM. The COD was established in February 2009 to manage challenging patients with co-occurring chronic pain and substance abuse problems, including high-risk opioid use, substance use disorders, and high-dose or complex therapeutic pain management regimens.

2.2. Patient population, referral, and evaluation process

The COD clinic receives referrals from primary care providers, interventional pain management specialists, internal medicine and surgical sub-specialists, and the substance use disorder clinic.

During the intake visit, a detailed history of the patient's pain is obtained, including the standard parameters of pain and a detailed record of the efficacy and adverse effects of all past treatments. In addition, a comprehensive substance use history and a psychiatric evaluation are performed. We obtained information on psychiatric diagnoses from chart review, which were generally made by a psychiatrist or PCP before the patient presented to the COD clinic. However, the COD psychiatrist also made diagnoses based on the intake clinical interview. Physical examination focuses on the underlying pain condition, mental status examination, and signs of substance abuse. A Brief Pain Inventory (BPI) (Tan, et al., 2004), Screener and Opioid Assessment for Patients with Pain (SOAPP) (Butler, et al., 2004) and Diagnosis, Intractability, Risk and Efficacy (DIRE) (Belgrade, et al., 2006) screening tools are performed and scored. After these assessments, patient consent is obtained for urine toxicology screening and the New Mexico Prescription Monitoring Program Database that collects statewide data on controlled substances under the auspices of the New Mexico Board of Pharmacy (New Mexico Prescription Monitoring Program, 2010).

Approximately 70% of referrals are deemed appropriate for ongoing treatment in the COD clinic. About 30% of this group meet criteria for opioid dependence upon intake and are offered buprenorphine/naloxone (BUP/NLX). The remaining patients have a high risk for opioid dependence and significant pain problems, but the initial evaluation is insufficient to determine whether the primary issue is opioid dependence or inadequately treated pain. These patients are monitored one to two times a month for up to 12 months in Co-occurring Disorders Clinic. The monitoring protocol for both cohorts of patients includes regular urine toxicology screening, which includes enzyme immunoassay (EIA) screening for opioids (300 ng/ml detection threshold), benzodiazepines (200 ng/ml detection threshold), barbiturates (200 ng/ml detection threshold), cocaine (300 ng/ml detection threshold), cannibinoids (50 ng/ml detection threshold) and amphetamines (1000 ng/ml detection threshold). Additional testing with gas chromatography/mass spectrometry is performed on all initial and periodic follow up specimens and includes morphine (300 ng/ml detection threshold), codeine (300 ng/ml detection threshold), hydrocodone (100 ng/ml detection threshold), hydromorphone (100 ng/ml detection threshold) methadone (100 ng/ml detection threshold), buprenorphine (5 ng/ml detection threshold), oxycodone (50 ng/ml detection threshold) and oxymorphone (50 ng/ml detection threshold). Both cohorts are regularly assessed for compliance with recommended treatments through self-reports, review of emergency department (ED) visits, pharmacy refill records, state prescription monitoring program data, and pain score evaluation. If aberrant medication use continues, BUP/NLX is recommended.

2.3. Buprenorphine induction process

If patients are prescribed short-acting opioids for pain, buying short-acting opioids on the street or, using illicit opioids such as heroin, then BUP/NLX induction proceeds according to established guidelines provided in Treatment Improvement Protocol Series 40 (Center for Substance Abuse Treatment, 2004). Patients are instructed to abstain from short acting opioids 12 to 24 hours and from long acting opioids 24 to 36 hours prior to their initial dose of BUP/NLX. Patients prescribed long-acting opioid agonists for pain control by the New Mexico Veterans Administration Health Care System (NMVAHCS) are tapered to a dose below 90 mg morphine equivalents per day, and then switched to an equivalent dose of short-acting opioid for a period of 2 weeks to 1 month prior to induction. The induction instructions follow those of short-acting opioids.

Maintenance doses of BUP/NLX are prescribed between three and four times daily based on prior reports suggesting that the analgesic duration of action of buprenorphine is 6 to 8 hours and therefore should be dosed three times daily or four times daily for optimal analgesic effect (Heit & Gourlay, 2008), rather than the single day dosing utilized in treating opioid dependence only. A third visit occurs 7 days after the initial induction and further adjustments to the dosage may occur. Factors considered in dosage changes are cravings, pain relief, side effects, and opioid abstinence.

During the stabilization phase, patients are evaluated and receive prescriptions at monthly intervals. Patients on maintenance BUP/NLX are followed at twice-monthly intervals for the first 2 months following induction, then monthly for 6 months, and then every 1 to 3 months. At each visit, pain control and aberrant drug-taking behavior are assessed. Urine toxicology screens are obtained on random visits.

Patients are discontinued on BUP/NLX therapy if they return to opioid use without COD provider consent, have three or more urine toxicology screens positive for illicit drugs, miss three or more visits, or have more than two early refill requests. These patients are referred to more structured substance use disorder treatment programs within the NMVAHCS or to community methadone maintenance treatment programs. Patients are also discontinued from BUP/NLX if they experience intolerable side effects or uncontrolled pain on doses up to 28 mg of BUP/NLX and further treatment options are determined

including opioid agonist treatment with intensive monitoring for the treatment of pain or referral to specialized pain treatment programs.

Throughout the course of treatment, the patient's pain condition is treated as indicated with adjunctive measures all provided within the clinic as described in Table 1.

Patients may also be referred to interventional pain clinic, physical therapy, orthopedic surgery, or neurosurgery for more invasive procedures.

2.4. Data collection and statistical analysis

Between July 2009 and December 2011, the COD clinic initiated BUP/NLX treatment in 143 patients with comorbid opioid dependence and chronic pain. As part of a quality improvement project, we analyzed data for all 143 patients induced on BUP/NLX. We performed chart reviews and entered de-identified data into an Excel database. We stored these analytic files on a password-protected restricted-access computer drive. Our objective was to determine outcomes for patients prescribed BUP/NLX as treatment for both opioid dependence and chronic pain, and to attempt to identify possible reasons for success or failure of BUP/NLX treatment. We had assumed that one of the major barriers to retention of these patients on BUP/NLX would be inadequate pain control. We hypothesized that average pain scores in patients on BUP/NLX would be higher while on treatment than prior to induction, when most patients were taking prescribed or illicit opioid agonists. Descriptive statistics were collected and analyzed, including patient's opioid drug of choice, highest dosage used, pre-induction opioid dose, length of time and dosage of buprenorphine. Pre-induction opioid dosages were converted to morphine equivalents. Because of the variability in heroin purity and unreliability of patient reports, we did not convert heroin usage to morphine equivalents and did not include heroin users when calculating the average or mean morphine equivalents. Pain type and locations, comorbid psychiatric, medical, and substance use history, and reason for discontinuing treatment were also detailed. Analog scale (1–10) pain scores are recorded at all VA clinics as part of standard vital signs measurement. For this analysis, the five consecutive pain scores prior to the date of BUP/NLX initiation and the five consecutive pain scores after the date initiation were recorded for each patient. The 2 days of induction were not used because pain scores were expected to be fluctuating due to the need to stop all opioid medications. The five pain scores before and after BUP/NLX induction span a wide range of dates, from days to weeks to months, depending on how often the patient presented to a VA clinic. Mean pre- and post-BUP/NLX induction pain scores were calculated based on these five pre-induction and five post-induction pain scores. If five pain scores were not available (three cases) a value of 0 was used for pre-induction score and a value of 10 was entered for post-induction scores. A two-tailed Student's *t*-test was used to determine statistical significance for differences in pain scores. A relapse to opioid use was defined as a return to opioid agonist use without COD provider consent. We determined this by patient self-report, medical record review, pharmacy record review, state prescription monitoring report, and/or urine toxicology. Patients who discontinued buprenorphine treatment but remained in the NMVAHCS area continued to receive pain treatment—which in some cases involved opioid agonist therapy—through the COD.

Institutional review board approval was not obtained for this retrospective chart review because it was a quality improvement project. This determination was made in consultation with the Research Office of the NMVAHCS.

3. Results

All 143 patients induced on BUP/NLX met *DSM-IV* criteria for opioid dependence. Most were male (93%) and the mean age was 52 years (range: 26–75 years). Data on ethnicity were not collected for this project. The mean total daily dose was 16 mg buprenorphine (SD 5.4; range:6 to 28 mg). The three most commonly prescribed regimens were as follows: 38 patients (26%) were prescribed BUP/NLX 8 mg/2 mg twice a day, 28 patients (19%) were prescribed 8 mg/2 mg three times per day and 26 (18%) were prescribed 4 mg/1 mg three times per day.

3.1. Psychiatric and medical co-morbid conditions

Chart review found a high rate of psychiatric co-morbidity in this population, with 71% of patients carrying at least one psychiatric diagnosis (see Table 2). The most common psychiatric diagnoses included major depression (49% of patients) and PTSD (30% of patients). Both current and historical alcohol and illicit drug use was common in these patients, and there was a high rate of co-morbid chronic medical conditions, including hepatitis C, coronary artery disease, and diabetes (Table 2).

3.2. Opioid use history

Data showed that patients in the cohort had been on chronic opioids for a prolonged period of time, with a mean duration of

Table 1
Adjuvant pain medications (current).[a]

Antidepressant	No. of patients	NSAID	No. of patients	Anti-convulsant	No. of patients
Amitriptyline	3	Celecoxib	1	Gabapentin	31
Duloxetine	5	Ibuprofen	25	Pregabalin	9
Nortriptyline	1	Ketorolac	1		
Paroxetine	6	Meloxicam	4		
Venlafaxine	18	Naproxen	8		
		Salsalate	1		
		Tylenol	7		

Muscle Relaxant	No. of patients	Other	No. of patients
Baclofen	11	Capsaicin topical	7
Cyclobenzaprine	7	Epidural steroid	3
Methocarbamol	7	Joint steroid injection	13
Tizanidine	2	Lidocaine topical	5
		TENS Unit	10

[a] Number of current BUP/NLX patients concurrently using each adjuvant at the time of data analysis. Patients may be taking multiple adjuvant treatments. Does not indicate past use of the adjuvant.

Table 2
Psychiatric, substance use disorder and medical co-morbidities.

	n patients (% total)
Psychiatric diagnoses[a]	
Major depression	69 (49%)
PTSD	43 (30%)
Anxiety disorder (any)	16 (11%)
Bipolar (I or II)	4 (3%)
Panic disorder	3 (2%)
Medical diagnosis	
Hepatitis C	23 (16%)
Obstructive sleep apnea	9 (6%)
Coronary artery disease	15 (11%)
Diabetes mellitus	15 (11%)
Chronic kidney disease	3 (2%)
Seizure disorder	5 (3.5%)
Substance use disorder diagnoses[b]	
Alcohol abuse or dependence	59 (42%)
Cocaine abuse or dependence	38 (27%)
Amphetamine abuse or dependence	17 (12%)

[a] Current and lifetime diagnoses identified by chart review or clinical interview by a psychiatrist.
[b] Current and lifetime diagnoses identified by chart review of clinical interview by addiction medicine specialist.

115 months (median 105 months; range 3–240 months). At baseline, patients were taking relatively high doses of prescription or illicit opioids, with a mean dose in daily morphine equivalents of 184 mg (median 120 mg; range 30–375 mg). The most commonly used opioids were oxycodone (44%) and methadone (16%), and 11% were current heroin users. Retention rates and pain outcomes by pre-induction preferred opioid are given in Table 3.

3.3. Pain conditions

Most patients enrolled in COD had more than one pain complaint. A majority (56%) had purely musculoskeletal complaints, while 39% had mixed nociceptive and neuropathic pain. Seventy-nine patients (55%) had low back pain, 13 (9%) had chronic headaches and 7 (4%) had fibromyalgia.

3.4. Retention rates

Overall, 93 of the 143 patients (65%) started on BUP/NLX maintenance continued treatment with BUP/NLX and had not relapsed to opioid use (based on pharmacy records, state prescription monitoring, and frequent urine drug screens). Sixty (65%) of those 93 patients were on BUP/NLX for more than 6 months, 19 (21%) were on BUP/NLX for greater than 12 months, and 5 (6%) for greater than 18 months. These rates were higher than those reported in the literature for treatment of opioid dependence with buprenorphine in primary care which was a retention rate of 56.9% at 1 year (Soeffing, et al., 2009). Retention rates defined as treatment with BUP/NLX for >6 months without relapse to opioid use and pain outcomes are presented in Table 3 and are stratified by age group and preferred opioid. Differences across drug types and age groups were not statistically significant. Of the 50 patients who either discontinued BUP/NLX or were lost to follow up (Table 4), 21 (43%) were still engaged in treatment at the NMVAHCS and returned to opioid agonists therapy. Nine (18%) moved out of the area and it was unknown whether they remain on BUP/NLX, however, nearly all of these patients intended to remain on maintenance treatment when they re-located. Seven (14%) of the patients who discontinued BUP/NLX remained off all opioids. Of the remaining patients who discontinued BUP/NLX, eight (16%) did so due to ongoing pain complaints (many of these are included in the number of patients back on opioids), nine (18%) experienced side effects with BUP/NLX, six (12%) were released from clinic due to recurrent illicit drug screens, two (4%) are deceased (from non-drug related causes), one (2%) is on hospice, and two (4%) were lost to follow up. All patients who re-started opioid treatment due to ongoing pain or side effects from BUP/NLX were now on lower doses of chronic opioids than when they initially presented to COD.

Table 3
Retention rates and pain outcomes by preferred opioid and by age group.

	No. of patients	Mean diff pain[a]	No. of current (%)[b]
Preferred opioid			
Heroin	16	−0.7	10 (63%)
Methadone	23	−0.3	17 (74%)
Oxycodone	63	−1.0	40 (63%)
Hydrocodone	18	−0.1	13 (72%)
Fentanyl	9	−1.1	3 (33%)
Morphine	12	−1.2	9 (75%)
Codeine	1	−7.8	1 (100%)
Hydromorphone	1	+0.6	0 (0%)
Age group			
21–40 years	25	−1.1	15 (60%)
41–60 years	81	−0.7	51 (62%)
61–80 years	37	−0.9	27 (72%)

[a] Mean difference in pain scores before and after start of buprenorphine.
[b] Number and percent of patients retained on buprenorphine(currently being treated with BUP/NLX, mean treatment time greater than 6 months, and without relapse to opioid use).

Table 4
Reasons for discontinuation of buprenorphine treatment.

Reason for discontinuation	No. of patients (%)
Patient request[a]	13 (26%)
Moved	9 (18%)
Side effects	9 (18%)
Ongoing pain	8 (16%)
Noncompliance/illicit drugs	6 (12%)
Deceased	2 (4%)
Hospice	1 (2%)
Unknown	2 (4%)
Totals	50 (100%)

[a] Patient requested or self-stopped medication. Some of these patients returned to using opioids and some remained off all opioids.

3.5. Pain scores pre- and post-induction

Our original hypothesis was that BUP/NLX would not adequately treat chronic pain and would therefore be a significant barrier to treatment of opioid dependence with BUP/NLX and results were surprising in that those in treatment with BUP/NLX had a statistically significant improvement in pain scores. Before initiating BUP/NLX, the mean pain score (using an analog scale from 1 to 10) was 6.39 (95% CI 6.2 to 6.6), decreasing to 5.6 (95% 5.4 to 5.8) during treatment, $P<0.001$. Table 3 shows differences between pre-induction and during treatment with BUP/NLX pain scores and retention rates by preferred opioid and age group.

4. Discussion

4.1. Buprenorphine/naloxone (BUP/NLX) to treat co-occurring pain and opioid dependence

The high prevalence of chronic pain in patients with opioid dependence makes the treatment of both conditions challenging and complex. The favorable safety profile of buprenorphine in overdose makes the drug a promising alternative for the comorbid treatment of CNCP and opioid dependence, especially on prescription opioids. Little previous research has investigated whether BUP/NLX could be used to successfully treat co-occurring opioid dependence and CNCP simultaneously (Blondell et al., 2010).

This paper presents the outcomes from an innovative clinical model that suggests that both disorders can be successfully treated and that such treatment can be delivered in a primary care setting. Data from our clinic show that 93 of 143 (65%) patients induced on buprenorphine continued on the medication, and 60 of those 93 (65%) patients were on the medication for greater than 6 months. Of the 50 patients no longer prescribed BUP/NLX, 7 were no longer taking any opioids, and those who continued to require opioid agonists to manage their chronic pain condition were using lower doses than prescribed prior to BUP/NLX. In addition, contrary to our hypothesis, average pain scores did not increase and in some cases slightly decreased following induction with buprenorphine, even in those patients who had been prescribed greater than 200 mg of morphine equivalents per day of opioid agonists. Even though pain scores were not greatly reduced, the mere fact that they did not increase is a potentially significant contributor to lower relapse rates, higher retention in treatment, and most critically, fewer overdoses. Many of the patients treated in clinic with BUP/NLX for CNCP received adjunctive medications and non-pharmaceutical measures such as integrated treatment of psychiatric illness, and a supportive

therapeutic alliance that enhance the treatment of underlying pain issues and may minimize the return to opioid agonist treatment.

4.2. Integrated substance use and psychiatric disorder diagnosis and treatment

The majority of patients with co-occurring pain and opioid dependence also have comorbid psychiatric disorders (70%), and substance use disorders other than opioid dependence (65%), These comorbidities are not routinely addressed in traditional intervention-based pain clinics, yet represent some of the most significant obstacles to successful treatment of pain and opioid dependence. The COD clinic coordinates care for psychiatric, medical and substance use disorders into one integrated care model delivered in a single setting. Clinicians perform in-depth substance use disorder assessments, and can offer pharmacotherapy for opioid dependence, alcohol dependence, and tobacco cessation along with psychiatric assessments and pharmacotherapy and supportive therapy for comorbid anxiety and mood disorders.

4.3. Limitations

There are a number of important limitations that qualify the encouraging results reported here. First, this is a retrospective chart review rather than a prospective study. Second, there is no comparator control group. Third, and most significantly, the positive results cannot be conclusively attributed to BUP/NLX, due to multiple concomitant and thus confounding interventions. These include the use of adjunctive pharmacological and non-pharmacological pain treatments; the treatment of comorbid psychiatric and substance use disorders; the positive effects of a supportive therapeutic alliance, and finally the benefits of a coordinated and chronic disease model of care delivery. While pain scores either decreased or remained the same, functional outcome is at least as salient in the management of CNCP and no functional measures were utilized.

4.4. Conclusions

New approaches are needed to treat the increasing numbers of patients with CNCP who are also opioid dependent. Utilizing a chronic disease model of care with the risk management safeguards of ongoing monitoring and toxicology screening can enable the management of opioid dependence and chronic pain to be mainstreamed into primary care. The finding that chronic pain scores either stay the same or slightly decrease with BUP/NLX treatment may lead to improved retention and fulfill the promise of BUP/NLX as an office-based treatment for opioid dependence.

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