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Implementation of a collaborative care management program with buprenorphine in primary care: A comparison between opioid-dependent patients and chronic pain patients using opioids non-medically

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Abstract

Objective—To implement a collaborative care management program with buprenorphine in a primary care clinic.

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Conflicts of interest: None

Design—Prospective observational study.

Setting—A busy urban academic primary care clinic affiliated with a tertiary care hospital.

Participants—Opioid dependent patients or chronic pain patients using opioids non-medically were recruited for the study. A total of 45 participants enrolled.

Interventions—Patients were treated with buprenorphine and managed by a supervising psychiatrist, pharmacist care manager and health coaches. The care manager conducted buprenorphine inductions and all follow-ups visits. Health coaches offered telephonic support. The psychiatrist supervised both the care manager and health coaches.

Main outcome measures—Primary outcomes were treatment retention at 6 months, and change in the proportion of aberrant toxicology results and opioid craving scores from baseline to 6 months. After data collection, clinical outcomes were compared between opioid dependent patients and chronic pain patients using opioids non-medically. Overall, 55.0% (25/45) of participants remained in treatment at 6 months. PCPs' attitudes about opioid dependence treatment were surveyed at baseline and at 18-months.

Results—Forty-three patients (95.6%) accepted treatment and 25 (55.0%) remained in treatment at 6 months. The proportion of aberrant urine toxicology results decreased significantly from baseline to 6 months ($p<0.01$). Craving scores significantly decreased from baseline to 6 months ($p<0.01$). Opioid dependent patients, as opposed to chronic pain patients using opioids non-medically, were significantly more likely to complete 6 months of treatment ($p<0.05$). PCPs' confidence in treating opioid dependence in primary care increased significantly from baseline to 18-months post-implementation ($p<0.01$).

Conclusion—Collaborative care management for opioid dependence with buprenorphine may be feasible in a primary care clinic. More research is needed to understand the role of buprenorphine in managing chronic pain patients using opioids non-medically.

Keywords

Opioid dependence; collaborative care management; buprenorphine; non-medical use of opioids; primary care

Introduction

In 2011, 11 million individuals in the United States used prescription opioids for non-medical reasons, and an estimated 2.5 million individuals met criteria for an opioid dependence(1). To address this public health problem, physicians have been allowed to prescribe buprenorphine (primarily as sublingual buprenorphine/naloxone tablets) from their offices to treat opioid dependence since 2002(2). Even though over 600,000 patients with opioid dependence received buprenorphine in 2009(3), more prescribers are needed, given that about 90% of individuals with a substance use disorder do not receive specialty addiction treatment in any given year (1).

Additionally, primary care physicians (PCP) are faced with the challenge of managing chronic pain patients receiving chronic opioid therapy—shown to benefit some patients but

also associated with adverse outcomes including non-medical use of opioids (e.g. using opioids to improve mood), opioid dependence, overdose, and diversion (4,5). The extensive literature on managing chronic pain patients supports the need for careful patient selection and close monitoring to maximize benefit while minimizing risk (6). Additionally, there is now emerging evidence that buprenorphine may play a role in managing chronic pain patients using opioids non-medically (7–10).

Lack of clinical support for PCPs is frequently reported as a barrier to their implementation of buprenorphine treatment(11). Other common barriers reported are lack of institutional support, payment or pharmacy issues, and being in a group practice(11). Similar concerns existed in our own institution's largest primary care clinic which prevented buprenorphine from being offered, even though some of the PCPs had completed the training to become buprenorphine prescribers. Given the heavy burden already placed on PCPs to manage a large number of patients with numerous chronic medical diseases, the clinic leadership recognized the need to find innovative strategies for providing treatment to opioid dependent patients as well as chronic pain patients suspected of using their opioids non-medically. To increase clinical support for PCPs in treating such patients, collaborative care management was proposed as a strategy(12,13). This approach typically integrates a nurse care manager and a supervising psychiatrist into the primary care clinic to help make treatment decisions and follow up on patients between PCP office visits. Collaborative care approaches have been shown to improve patient outcomes and increase patient access to treatment for a variety of behavioral health issues including depression(14,15), anxiety(16), chronic pain(17) and substance use disorders(18).

Therefore, a quality improvement project was proposed to implement a collaborative care management program for the treatment of opioid dependence and chronic pain patients using opioids non-medically. Our project aim was to offer buprenorphine treatment, using the collaborate care model, to 50 patients with opioid dependence or those found to be using opioids non-medically. Our primary improvement-related outcome was to examine the proportion of patients who remained in treatment at 6 months, and the change in aberrant urine toxicology results and craving scores from baseline to 6 months. In addition, clinical outcomes were compared between patients with opioid dependence and chronic pain patients using opioids non-medically.

Methods

Setting

The study was approved by the Partners HealthCare Human Research Committee. The project was conducted at a busy urban academic primary care clinic in Boston, MA. Office-based opioid dependence treatment with sublingual buprenorphine was not being offered in this practice prior to implementation of this program.

Participants

PCPs referred patients to the study who met these inclusion criteria: either a) DSM-IV diagnosis of opioid dependence, or b) a history of non-medical use of opioid medications

prescribed for chronic pain (i.e. repeated unsanctioned dose escalations, early refills, lost prescriptions, multiple emergency room visits seeking opioids, occasionally using pain medications to self-medicate moods or to get high, diverting medications, or urine toxicology results suggestive of illicit drug use) (1). Diagnosis of either opioid dependence or non-medical use of opioids was made clinically by the care manager who evaluated the patient; the diagnosis was then reviewed by the supervising psychiatrist. Any disagreements about diagnosis were resolved during the weekly team meeting. Those patients who did not have a PCP at the primary care clinic were excluded.

Program description

The care team was composed of a supervising psychiatrist, care manager, and health coaches. The care team met weekly for an hour to review patients in the program. A pharmacist with expertise in pain management was recruited to be the care manager, and was responsible for initial evaluations, buprenorphine inductions, and follow-up visits. The health coaches were undergraduate-level students who were responsible for maintaining the patient registry and contacting patients by telephone between office visits providing support using motivational interviewing. The coaches also relayed questions to other members of the team, and reminded patients of upcoming visits. The frequency of contact varied depending on clinical status, with more unstable and struggling patients receiving calls weekly, and stable patients receiving calls less frequently, between once or twice a month. Patients who continued to use illicit opioids, missed appointments, failed to give urine samples for testing, or reported significant cravings, depression, or anxiety were considered unstable and in need of closer follow-up. Health coaches were provided with at least 4 hours of training and monthly supervision in the use of motivational interviewing (MI), an evidenced-based approach to helping patients change unhealthy behaviors with demonstrated efficacy in a variety of health care settings (19–21). The training in MI was conducted by one of the authors (JS), a member of the Motivational Interviewing Network of Trainers. MI was used by health coaches to facilitate engagement and to help maintain patient motivation for treatment. Questions asked by health coaches helped to evoke from patients their own desire to get healthier (e.g., “If you were to be successful in stopping using heroin, how might you be successful?”, or “What are the three most important reasons to not use heroin?”). The supervising psychiatrist, board certified in addiction psychiatry and licensed to prescribe sublingual buprenorphine, supervised the pharmacist and health coaches and provided the buprenorphine prescriptions. The PCPs were kept informed about treatment progress on a regular basis through periodic emails summarizing patient progress with treatment. The patient registry was a database to track clinical data—medication dose, prescription and prior authorization information, urine toxicology results, and craving scores. The registry was used during the weekly team meetings to proactively make treatment decisions such as buprenorphine dosage and visit frequency.

Study procedures

Patients were initially screened by the care manager, and then scheduled for an induction visit. The induction onto buprenorphine followed standard procedures according to published practice guidelines(22). Patients were seen weekly at first. If patients were clinically stable for at least 4 weeks, then the visit frequency was decreased to every 2

weeks, then eventually every month. All patients, including chronic pain patients, were instructed to take buprenorphine in divided doses, typically three or four times day. The buprenorphine dose was titrated by the care manager and the supervising psychiatrist by examining opioid cravings, illicit opioid use, urine toxicology results, and pain scores. If pain was not managed adequately, patients were referred back their PCPs or a pain clinic. No formal protocol was in place to recommend adjunctive medications for pain. The prescription monitoring program for the State of Massachusetts was used to check for aberrant findings at regular intervals (e.g., multiple buprenorphine prescribers or prescriptions for controlled substances from other prescribers).

Assessments

1. Urine toxicology: Urine testing was performed monthly to be tested for common substances of abuse, including morphine, oxycodone, methadone, buprenorphine, cocaine, amphetamines, benzodiazepines, and tetrahydrocannabinol. The presence of non-prescribed opioids, the absence of buprenorphine, and the failure to provide a urine sample constituted aberrant urine toxicology results. Quantitative testing for both buprenorphine and norbuprenorphine was also performed to identify patients who are adultering urine samples with buprenorphine in order to conceal the diversion of their medications.

2. Pain: Brief Pain Inventory (23), a validated pain questionnaire, was used to obtain information about pain severity as well as the degree to which the pain interferes with daily activities, mood, and the enjoyment of life. The rating was obtained at baseline every 3 months thereafter. Pain severity (on a 0-10 scale) in the last 24 hours at its worst, least, average, and pain ‘‘right now” were combined to obtain an average pain severity score. This method of using a composite score has been reported to be superior to using either worst or best pain rating alone(24,25). The degree to which pain interfered with daily activities (on a 0-10 scale) in the past 24 hours was obtained in the following domains: general activity, mood, walking ability, normal work, relations with other people, sleep, and enjoyment in life. Similar to pain severity, scores were combined to obtain an average pain disability score.

3. Opioid craving: A 3-question craving questionnaire(26) was used to determine craving for opioids on a 10 point (0-9) scale: 1) “Please rate how strong your desire was to use an opioid during the last 24 hours,” 2) “Imagine yourself in an environment in which you’ve previously used drugs. If you were to be in this same environment again, what is the likelihood that you would use an opioid,” and 3) “Please rate how strong your urges are for the opioid of choice when something in the environment reminds you of it.” The scores were averaged to create a composite craving score for opioids ranging from 0 to 9.

4. Physician survey: All PCPs from the primary care clinic were invited to complete a survey at baseline prior to implementation, and then at follow-up 18 months after implementation. PCPs were asked if they “strongly agree,” “agree,” “disagree,” or “strongly disagree” with the following statements: 1) “It is important to treat opioid

dependence in primary care," and 2) "I am confident treating opioid dependence in primary care."

Analytic strategy

Descriptive statistics were used to describe the first 45 patients referred to the project. The proportion of patients remaining in treatment at 6 months was calculated. The difference in the proportion of positive urine toxicology results between baseline and 6 months was determined using chi-square. The difference in craving scores between baseline and 6 months was determined using t-test. PCP responses to the survey were collapsed to either "agree" or "disagree", and z-test was used to compare differences in proportions from baseline to follow-up. Demographic and clinical variables were compared between opioid dependent patients and non-medical users of opioids using chi-square and t-tests for categorical and ordinal variables, respectively (Minitab 16, State College PA). For opioid dependent patients and chronic pain patients using opioids non-medically separately, correlates of treatment retention at 6 months were examined using logistic regression analysis, using the following as independent variables: age, gender, ethnicity, history of heroin use, history of chronic pain, history of psychiatric illness, HIV, hepatitis C, cancer, maximum dose of buprenorphine during treatment, aberrant urine toxicology results at baseline, baseline craving score, baseline pain severity, and baseline pain disability.

Results

Results are summarized in **Table 1**. Overall, 55.6% remained in treatment at 6 months. The proportion of aberrant urine toxicology results decreased significantly from baseline to 6 months (69.2% vs 31.8%, z=3.02, $p<0.01$). Craving scores (on a 0-9 scale) significantly decreased from baseline to 6 months (4.1 vs 0.9, T=-3.09, $p<0.01$).

The results comparing opioid dependent patients and chronic pain patients using opioids non-medically are presented in **Table 2**. Opioid dependent patients, as opposed to non-medical user of opioids, were significantly more likely to complete 6 months of treatment (70.8% vs 38.0%, $\chi^2=4.94$, $p<0.05$), to be younger (38.9 vs 50.4, t=-3.85, $p<0.001$), to be non-white (66.7% vs 23.8%, $\chi^2=8.73$, $p<0.05$), and to have a history of heroin use (75.0% vs 28.6%, $\chi^2=10.06$, $p<0.01$), but were significantly less likely to have a history of chronic pain (45.8% vs 100.0%, $\chi^2=21.00$, $p<0.001$). Chronic pain patients with non-medical use of opioids were significantly more likely to have higher baseline pain severity scores at baseline and at 3 months (8.0 vs 3.1, t=3.83, $p<0.01$; 6.2 vs 0.9, t=4.86, $p<0.01$) and pain disability scores at baseline and at 3 months (8.5 vs 3.5, t=4.08, $p<0.01$; 5.4 vs 0.3, t=5.79, $p<0.01$). No differences were found in aberrant urine toxicology results or cravings scores at any time point.

PCP survey results are summarized in **Table 3**. The majority of PCPs agreed both at baseline and at follow-up that treating opioid dependence in primary care was important (89.5% vs 90.1%, NS). PCPs' confidence in treating opioid dependence in primary care increased significantly from baseline to follow-up (5.3% vs 25.0%, z=-2.64, p=0.008).

The results of the logistic regression analysis are summarized in **Table 4**. For opioid dependent patients, the only significant predictor of treatment retention was age (β=0.103, OR 1.11, 95%CI 1.00-1.23, p=0.044). For non-medical users of opioids, the only significant predictor of treatment retention was maximum buprenorphine dose during treatment (β =0.380, OR 1.46, 95%CI 1.01-2.12, p=0.047).

Discussion

The results of this quality improvement project suggest the feasibility of implementing a collaborative care management program in a busy urban primary care clinic that previously did not offer office-based opioid treatment with buprenorphine. PCPs were willing to refer appropriate patients to the program, and the vast majority (95.6%) of referred patients accepted buprenorphine. Patients who remained in treatment showed improvement in their opioid use patterns as demonstrated by decrease in the proportion of aberrant urine toxicology results, and reduction in opioid cravings scores. The overall treatment retention rates at 6 months was comparable to previous reports in similar settings(27,28). The follow-up survey indicated that PCPs' confidence in treating opioid dependence increased significantly following implementation of the project. The increase may be partly due to the clinical support provided to the PCPs, which may have influenced their confidence that opioid dependence can be treated successfully in the primary care setting.

This project enrolled not only patients with opioid dependence, but also chronic pain patients using opioids for non-medical reasons. Rosenblum and colleagues reported that some non-medical opioid users may benefit from sublingual buprenorphine as evidenced by the reduction in both average and worst pain scores from baseline to 3 months(10). In addition, studies also support using brief behavioral interventions for improving opioid use outcomes in chronic pain patients using opioids non-medically (29). We therefore originally hypothesized that non-medical users of opioids would benefit more from this treatment approach, while those with a diagnosis of opioid dependence would benefit less due to their more severe illness. However, contrary to our expectations, the results indicate that those with opioid dependence were significantly more likely to remain in treatment at 6 months compared to non-medical opioid users. Additionally, opioid dependent patients were significantly younger and more likely to have a history of heroin use—characteristics ordinarily associated with worse outcomes in buprenorphine treatment (30). Buprenorphine is an approved opioid analgesic for the treatment of chronic pain in the parenteral (Buprenex) and transdermal (Butrans) preparations. Although buprenorphine clearly exerts a ceiling effect for respiratory depression, empirical evidence suggests buprenorphine may be a full agonist for analgesia (32). However, in Rosenblum's study of sublingual buprenorphine for chronic pain patients, the majority (67%) dropped out before completing 3 months of treatment due to lack of efficacy or adverse effects (10). Indeed, our results indicate that 38.2% of the non-medical users discontinued sublingual buprenorphine due to lack of efficacy in treating their pain (19.1%) or adverse effects (19.1%), while none of the opioid dependent patients discontinued treatment for those reasons. Furthermore, compared to opioid dependent patients, non-medical users reported significantly higher pain severity and pain disability scores both at baseline and at 3 months. The regression analysis showed that chronic pain patients using opioids non-medically receiving higher doses of

buprenorphine were more likely to complete 6 months of treatment. This may suggest that chronic pain patients using opioid non-medically may require higher dose ranges than typically recommended for opioid dependent patients. Taken together, the results of this project suggest more research is needed to understand the potential role of buprenorphine in chronic pain patients using opioids non-medically.

Patients in this study were managed clinically by the PCPs, care manager and health coaches, but were not required to attend drug counseling unless the patients themselves requested those services. The literature on counseling for patients in office-based opioid treatment suggests that medical management may be sufficient to achieve good clinical outcomes(31,33,34).

There are a number of limitations to this study that deserve mention. Given the small sample size, our results remain tentative and preliminary. In addition, we cannot generalize our findings to all patients with either opioid dependence or non-medical use of opioids, nor can we generalize to other clinics or settings with differences in staff and resources. Even though the collaborative care approach may be a significant contributor to the improvement in clinical outcomes we observed, we cannot know for certain the extent to which buprenorphine alone would have produced similar results. Indeed, our results were not very different from other primary care based buprenorphine treatment without the use of collaborative care management. Additionally, while we made significant efforts to distinguish opioid dependent patients from those who are non-medical users of opioids, the distinction is exceedingly difficult to make on clinical grounds. As such, we may have either over- or under- diagnosed opioid dependence and non-medical use of opioids in this sample. Another limitation is that our participants were followed at varying frequencies—for example, unstable patients received more intensive treatment—and information obtained from participants was also inconsistent, resulting in missing data. In future studies, visit frequency and data collection would need to be better controlled so that differences between groups and missing data would be minimized. Finally, the care manager in our project was a pharmacist with expertise in pain management, and the supervising psychiatrist was board certified in addiction psychiatry, and many clinics may not have access to clinicians with those skills and experiences.

The results of this project are promising, as they demonstrate the feasibility of implementing a collaborative care approach for the treatment of opioid dependence using buprenorphine in a primary care clinic. More research is needed to understand the role of buprenorphine for chronic pain patients using opioids non-medically, and to identify strategies to increase the likelihood that primary care clinics will adopt office-based opioid treatment with buprenorphine.

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Table 1

Summary of demographic and clinical variables of participants.

	Total (n=45)
Age	44.3 (SD 11.7)
Gender	
Male:	57.8%
Ethnicity	
White:	53.3%
Hispanic:	22.2%
Black:	24.4%
Remaining in treatment at 6 months	25 (55.6%)
Reason for referral to program	
Opioid dependence:	24 (53.3%)
Non-medical user:	21 (46.7%)
Reason for discontinuing treatment	
Lost to follow-up:	6 (13.3%)
Lack of efficacy:	4 (8.9%)
Side effects:	4 (8.9%)
Refused treatment:	2 (4.4%)
Scheduled taper:	1 (2.2%)
Other:	3 (6.7%)
History of heroin use	24 (53.3%)
History of chronic pain	33 (73.3%)
Prescribed pain medications by PCP	36 (80.0%)
Oxycodone	17 (47.2%)
Hydromorphone	10 (21.3%)
Morphine	5 (13.9%)
Methadone	5 (13.9%)
Tramadol	3 8.3%)
Fentanyl	2 (5.6%)
Psychiatric Diagnosis	35 (77.8%)
Major depressive d/o	30 (85.7%)
Generalized anxiety d/o	18 (51.4%)

	Total (n=45)
Post-traumatic stress d/o	9 (25.7%)
Bipolar d/o	3 (8.6%)
Other	3 (8.6%)
Hepatitis C	16 (35.6%)
Diabetes Mellitus	7 (15.6%)
Cancer	6 (13.3%)
Buprenorphine maximum dose (mg)	20.8 (SD 8.4)
Aberrant urine toxicology results	
Baseline	27 (69.2%, n=39)
3 months	7 (25.0%, n=28)
6 months	7 (31.8%, n=22)
Cravings	
Baseline	4.1 (SD 3.1, n=14)
3 months	2.2 (SD 2.0, n=10)
6 months	0.9 (SD 1.8, n=8)
Pain severity	
Baseline	5.1 (SD 3.7, n=17)
3 months	3.3 (SD 3.3, n=11)
6 months	4.5 (SD 3.7, n=9)
Pain disability	
Baseline	5.5 (SD3.8, n=17)
3 months	2.7 (SD2.9, n=11)
6 months	4.4 (SD3.5, n=9)

Table 2

Summary comparing opioid dependent patients to chronic pain patients using opioids non- medically.

	Opioid dependent (n=24)	Non-medical user of opioids (n=21)
Age	38.9 (SD 12.0)	50.4 (SD 7.8)***
Gender		
Male:	14 (58.3%)	12 (57.1%)
Ethnicity		
White:	8 (33.3%)	16 (76.2%)*
Hispanic:	8 (33.3%)	2 (9.5%)
Black:	8 (33.3%)	3 (14.3%)
Remaining in treatment at 6 months	17 (70.8%)	8 (38.1%)*
Reason for discontinuing treatment		
Lost to follow-up:	3 (12.5%)	3 (14.3%)
Lack of efficacy:	0	4 (19.1%)
Side effects:	0	4 (19.1%)
Refused treatment:	2 (8.3%)	0
Scheduled taper:	1 (4.2%)	0
Other:	1 (4.2%)	2 (9.5%)
History of heroin use	18 (75.0%)	6 (28.6%)**
History of chronic pain	11 (45.8%)	21 (100%)***
Prescribed pain meds by PCP	17 (70.8%)	19 (90.5%)
Oxycodone	8 (47.1%)	9 (47.4%)
Hydromorphone	5 (29.4%)	5 (26.3%)
Morphine	1 (5.9%)	4 (21.1%)
Methadone	2 (11.8%)	3 (15.8%)
Tramadol	2 (11.8%)	1 (5.3%)
Fentanyl	0	2 (10.5%)
Psychiatric Diagnosis	19 (79.2%)	16 (76.2%)
Major depressive d/o	17 (89.5%)	13 (81.3%)
Generalized anxiety d/o	9 (47.4%)	9 (56.3%)
Post-traumatic stress d/o	5 (26.3%)	4 (25.0%)
Bipolar d/o	1 (5.3%)	2 (12.5%)

	Opioid dependent (n=24)	Non-medical user of opioids (n=21)
Other	2 (10.5%)	1 (6.3%)
HIV	3 (12.5%)	0
Hepatitis C	9 (37.5%)	7 (33.3%)
Diabetes Mellitus	3 (12.5%)	4 (19.1%)
Cancer	4 (16.7%)	2 (9.5%)
Buprenorphine maximum dose (mg)	20.2 (SD 7.1)	21.8 (SD 9.9)
Aberrant urine toxicology results		
Baseline	16 (76.2%, n=21)	11 (61.1%, n=18)
3 months	3 (18.8%, n=16)	4 (33.3%, n=12)
6 months	4 (28.6%, n=14)	3 (37.5%, n=8)
Cravings		
Baseline	4.0 (SD 3.0, n=9)	4.4 (SD 3.6, n=5)
3 months	3.4 (SD 1.8, n=5)	1.0 (SD 1.6, n=5)
6 months	1.2 (SD 2.0, n=6)	0 (n=2)
Pain severity		
Baseline	3.1 (SD 3.3, n=10)	8.0 (SD 2.1, n=7)**
3 months	0.9 (SD 2.0, n=6)	6.2 (SD 1.6, n=5)**
6 months	4.0 (SD 4.1, n=7)	6.3 (SD 0.2, n=2)
Pain disability		
Baseline	3.5 (SD 3.6, n=10)	8.5 (SD 1.2, n=7)**
3 months	0.3 (SD 0.6, n=6)	5.4 (SD 1.9, n=5)**
6 months	4.0 (SD 3.9, n=7)	5.8 (SD 1.1, n=2)

* $p<0.05$

** $p<0.01$

*** $p<0.001$

Table 3

Survey results of primary care physicians (proportion reporting “agree” or "“strongly agree”)

	Baseline (n=38)	18 months after implementation (n=44)
“It is important to treat opioid dependence in primary care”	89.5%	90.1%
“I am confident treating opioid dependence in primary care”	5.3%	25.0%*

*=p<0.01

Table 4

Predictors of treatment retention at 6 months using logistic regression

Opioid dependent			
Age	OR	95%CI	p
	1.11	1.00-1.23	0.044
Non-medical user of opioids			
Maximum buprenorphine dose	OR	95%CI	p
	1.46	1.01-2.12	0.047