Use of Opioid Medications for Chronic Noncancer Pain Syndromes in Primary Care

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OBJECTIVES: **To define the spectrum of chronic noncancer pain treated with opioid medications in 2 primary care settings, and the prevalence of psychiatric comorbidity in this patient population. We also sought to determine the proportion of patients who manifested prescription opioid abuse behaviors and the factors associated with these behaviors.**

DESIGN: **A retrospective cohort study.**

SETTING: **A VA primary care clinic and an urban hospital-based primary care center (PCC) located in the northeastern United States.**

PATIENTS: **A random sample of VA patients (n = 50) and all PCC patients (n = 48) with chronic noncancer pain who received 6 or more months of opioid prescriptions during a 1-year period (April 1, 1997 through March 31, 1998) and were not on methadone maintenance.**

MEASUREMENTS: **Information regarding patients' type of chronic pain disorder, demographic, medical, and psychiatric status, and the presence of prescription opioid abuse behaviors was obtained by medical record review.**

MAIN RESULTS: **Low back pain was the most common disorder accounting for 44% and 25% of all chronic pain diagnoses in the VA and PCC samples, respectively, followed by injury-related (10% and 13%), diabetic neuropathy (8% and 10%), degenerative joint disease (16% and 13%), spinal stenosis (10% and 4%), headache (4% and 13%) and other chronic pain disorders (8% and 22%). The median duration of pain was 10 years (range 3 to 50 years) in the VA and 13 years in the PCC sample (range 1 to 49 years). Among VA and PCC patients, the lifetime prevalence rates of psychiatric comorbidities were: depressive disorder (44% and 54%), anxiety disorder (20% and 21%), alcohol abuse/dependence (46% and 31%), and narcotic abuse/dependence (18% and 38%). Prescription opioid abusive behaviors were recorded for 24% of VA and 31% of PCC patients. A lifetime history of a substance use disorder (adjusted odds ratio [OR], 3.8; 95% confidence interval [CI], 1.4 to 10.8) and age (adjusted OR, 0.94; 95% CI, 0.89 to 0.99) were independent predictors of prescription opioid abuse behavior.**

CONCLUSIONS: **A broad spectrum of chronic noncancer pain disorders are treated with opioid medications in primary care settings. The lifetime prevalence of psychiatric comorbidity was substantial in our study population. A significant minority of patients manifested prescription opioid abusive behaviors, and a lifetime history of a substance use disorder and decreasing age were associated with prescription opioid abuse behavior. Prospective studies are needed to determine the potential benefits as well as risks associated with opioid use for chronic noncancer pain in primary care.**

KEY WORDS: **chronic pain; opioid analgesic use; primary care.**
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Chronic noncancer pain is common in primary care settings and is often associated with substantial disability and distress.[1–4] Depending on the source population, prevalence estimates for chronic noncancer pain range from 5% to 33% in primary care settings.[1,2] The costs associated with chronic noncancer pain are significant and include patient discomfort, decreased quality of life, and increased use of health services.[1–7]

A variety of nonpharmacologic and pharmacologic treatments are administered commonly to patients with chronic noncancer pain. Nonpharmacologic treatments include physical,[8] cognitive-behavioral,[9,10] exercise,[11] and relaxation therapies.[9] Pharmacologic treatments typically include peripherally acting agents such as acetaminophen[12] or nonsteroidal anti-inflammatory[13] medications, as well as centrally acting agents such as anti-depressant,[14] anticonvulsant,[15] or opioid[16] medications. In addition, invasive procedures (e.g., nerve blocks) may also be administered.[17]

The use of opioid medications for the treatment of chronic noncancer pain is controversial, due in part to the fact that the safety and efficacy of this treatment approach have not been established. Additional physician-related concerns regarding the use of opioid medications for the treatment of chronic noncancer pain include the potential for prescription opioid abuse by treated patients, and whether opioid treatment improves functional outcomes.[18,19] Despite these concerns, survey data indicate that the use of opioid medications for the treatment of chronic noncancer pain is increasing.[20,21] Moreover, a recent survey[18] found that a broad spectrum of physicians including both generalists and specialists prescribe opioid medications for patients with chronic noncancer pain. Although primary care physicians may prescribe opioids to patients with chronic noncancer pain, little information currently exists about this practice.

In the current study, we sought to define the spectrum of chronic noncancer pain treated with opioid medications in 2 primary care settings, the types of other pharmacologic

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and nonpharmacologic therapies received by opioid-treated patients, and the prevalence of psychiatric comorbidity in this patient population. We also determined the proportion of patients who manifested prescription opioid abuse behaviors, the factors associated with these behaviors, and the prevalence of opioid-related untoward events in our sample.

METHODS

Study Populations

Our study populations were drawn from 2 primary care practices and included: (1) patients enrolled in a primary care practice at the VA Connecticut Healthcare System (VACHS) located in West Haven, Connecticut, which provides longitudinal care to approximately 12,000 veterans; and (2) patients enrolled in the Primary Care Center (PCC), which is located at Yale–New Haven Hospital, New Haven, Connecticut. The PCC is an urban hospital-based primary care clinic with a total enrollment of approximately 7,000 patients. Both practices serve as training sites for internal medicine residents at Yale University School of Medicine.

Eligible patients included individuals at either primary care practice who received 6 or more months of opioid prescriptions during a 1-year period (April 1, 1997 through March 31, 1998) for noncancer pain and were not on methadone maintenance. The study protocol was approved by the institutional review board at the VACHS and at Yale University School of Medicine.

Identification of PCC and VA Patients. We first identified potentially eligible PCC patients by reviewing duplicate copies of all scheduled prescriptions written from April 1, 1997 through March 31, 1998 (duplicate copies of all prescriptions written for scheduled substances are kept on file). This search yielded a total of 54 PCC patients who received opioid prescriptions for 6 or more months during the defined time period.

To identify VA patients, we searched the VA pharmacy computer records and identified a total of 392 patients who received 6 or more months of opioid prescriptions over the 12-month period. A total of 60 potentially eligible VA patients were randomly sampled from this roster in order to obtain a final similar number of 50 participants. (This sample size represented the expected total number of eligible PCC patients.)

A total of 6 PCC patients were excluded due to opioid use for cancer-related pain, leaving a final sample of 48 PCC patients. Nine VA patients were ineligible due to the use of an opioid medication for cancer-related pain and 1 was on methadone maintenance, leaving a final sample size of 50 VA patients.

Based on the above numbers, the overall prevalence of opioid-treated chronic noncancer pain was estimated to be 48/7,000 (≈0.7%) and (50/60) × 392/12,000 (≈3%) in the PCC and VA primary care practices, respectively.

Data Abstraction

All data, including information regarding demographic status, were abstracted from patients' medical records. We recorded the type(s) of chronic noncancer pain present for each patient. In cases in which more than 1 chronic pain was present (e.g., low back and degenerative joint disease [DJD] of the knees) the most frequently recorded condition was selected as the "principal" chronic noncancer pain disorder. To estimate the temporal duration of patients' chronic pain, we used the date of onset recorded by the primary care physician (e.g., pain was first noted 5 years ago) as Time 0 and determined the difference between the Time 0 date and the last day of the study period (i.e., March 31, 1998). We recorded the number and type of patients' chronic medical conditions with the Charlson index.[22]

We recorded the number (and types) of other interventions including current prescription medications, specialty referrals (e.g., pain clinic) and other cotherapies (e.g., physical therapy) for each patient. The most recent opioid prescription was used to define type of opioid use, e.g., if a patient had received 6 months of oxycodone/acetaminophen followed by 6 months of morphine sulfate therapy, the patient was classified as receiving morphine sulfate.

Patients were classified as having a lifetime history of depression, anxiety, alcohol abuse or dependence, and narcotic abuse or dependence if any of these diagnoses were present in their medical records. Among those with a lifetime history of a substance use disorder (alcohol abuse or dependence and/or narcotic abuse or dependence), we also sought to determine how many had additional evidence of a current (or active) substance disorder, e.g., an admission for detoxification (e.g., alcohol, cocaine, etc.) or referral for detoxification that was declined by the patient.

We used the following criteria to determine the prevalence of prescription opioid abuse behaviors: (1) one or more reports of lost or stolen opioid medications (or prescriptions); (2) documented use of other sources (e.g., other physician practices, street purchases, etc.) to obtain opioid medications; and (3) requests for 2 or more early refills. The presence of 1 or more of these criteria in a patient's record was felt to be evidence of prescription opioid abuse.[23–25] Finally, we recorded information on all adverse events that were judged by clinicians to be opioid-related.

Reliability Appraisals

To determine the reliability of our record review process, 2 raters independently reviewed all 48 PCC records. Substantial interrater reliability was present, as evidenced by an observed agreement of 96% in the classification of chronic pain diagnoses, while percent agreement for the presence (or absence) of psychiatric diagnoses ranged from 86% to 93%, and κs varied from

0.72 to 0.88. To assess intrarater reliability, one reviewer reabstracted information on the types of chronic pain and psychiatric diagnoses for all 50 VA patients. Overall agreement on the classification of chronic pain diagnoses was 94%, while the levels of agreement for the presence or absence of a psychiatric disorder ranged from 89% to 96% with corresponding κs of 0.78 to 0.94, indicating substantial overall concordance.

Analysis

Bivariate associations between patient factors and the presence of prescription opioid abuse behavior were examined using χ^2 tests for categorical variables and *t* tests for continuous variables. Factors significantly associated ($P < .05$) with prescription opioid abuse behavior were subsequently entered into a multivariate logistic regression model to determine which predictors were independently associated with prescription opioid abuse behavior.

RESULTS

Table 1 shows that the median age was 54 and 55 years for VA and PCC patients, respectively, and that VA patients were predominantly male and white as compared with PCC patients. Low back pain was the most commonly recorded chronic pain disorder and was present in 44% and 25% of VA and PCC patients, while injury-related (10% and 13%), diabetic neuropathy (8% and 10%), DJD (16% and 13%), headache (4% and 13%), and spinal stenosis (10% and 4%) were less common (Table 1). The median estimated duration of pain was 10 years (range 3 to 50 years) in the VA sample and 13 years in the PCC sample (range 1 to 49 years).

The lifetime prevalence rates of individual psychiatric comorbidities were as follows: depressive disorder (44% and 54%), anxiety disorder (20% and 21%), alcohol abuse/dependence (46% and 31%), and narcotic abuse/dependence (18% and 38%) among VA and PCC patients.

A lifetime history of a substance use disorder was recorded for 23 VA and 18 PCC patients. Among these patients, evidence in support of a current (i.e., occurring while on an opioid medication) substance disorder was found in 9 VA and 5 PCC patient records, as demonstrated by 1 or more of the following: (1) admission for detoxification (e.g., alcohol, cocaine, etc.) or referral for detoxification that was declined by the patient; (2) tested positive for other substances (e.g., elevated blood alcohol level or urine screen positive for cocaine); and (3) recorded episodes of heavy or binge drinking in patients with a lifetime history of alcohol abuse or dependence.

Table 2 summarizes the types of opioids prescribed. Oxycodone/acetaminophen was the most commonly prescribed short-acting opioid, whereas extended-release morphine sulfate was the most commonly prescribed long-acting opioid. Of the total sample ($N = 98$), most patients ($n = 88$) were prescribed daily doses, while the remaining 10 patients received as-needed doses of opioids (e.g, for chronic headache).

Table 1. Characteristics of Study Population

	Primary Care Site	
Attribute	**VA (*n* = 50)**	**PCC (*n* = 48)**
Demographic		
Median age, y (range)	54 (33 to 84)	55 (26 to 80)
Male gender, %	92	33
Race, %		
White	88	52
African American	12	36
Hispanic	0	10
Married, %	52	35
Type and duration of chronic pain		
Low back, %	44	25
Injury-related*, %	10	13
Diabetic neuropathy, %	8	10
DJD (non–low back), %	16	13
Headache, %	4	13
Spinal stenosis, %	10	4
Other disorders†, %	8	22
Duration median, y (range)	10 (3 to 50)	13 (1 to 49)
Medical comorbidity		
Medical diseases‡, mean, *n* (SD)	2 (1.5)	2 (1.6)
Psychiatric comorbidity§, %		
Depression	44	54
Anxiety	20	21
Lifetime history of substance use disorder		
Alcohol abuse/dependence	46	31
Narcotic abuse/dependence	18	38

* *Includes crush injuries (*n *= 5), suboccipital neuralgia secondary to head trauma (*n *= 2), traumatic spine injuries (*n *= 2), poorly healed leg fracture (*n *= 1), and post-thoracotomy pain (*n *= 1).*

† *Includes avascular necrosis (*n *= 2), quadraplegia/paraplegia (*n *= 3), chronic abdominal pain (*n *= 2), chronic pancreatitis (*n *= 1), Crohn's arthropathy (*n *= 2), phantom limb (*n *= 2), fibromyalgia (*n *= 1), myofascial pain (*n *= 1), and scoliosis (*n *= 1).*

‡ *Represents the mean number of individual chronic medical diseases, as determined by the unweighted Charlson Index.*

§ *Represents the lifetime prevalence of individual psychiatric disorders.*

PCC, primary care center; DJD, degenerative joint disease.

Non-opioid analgesic agents received by VA and PCC patients included nonsteroidal anti-inflammatory (38% and 21%), anticonvulsant (30% and 15%), and tricyclic antidepressant (6% and 6%) medications and were prescribed concurrently with opioid medications. Nonpharmacologic treatments received by VA and PCC patients included physical therapy (38% and 38%), transcutaneous electrical nerve stimulation (12% and 11%), aquatic therapy (0% and 9%), chiropractic manipulation (2% and 4%), and acupuncture (2% and 0%).

Eighty percent of VA and 85% of PCC patients received 1 or more specialty evaluations. The specific types of evaluations and the relative proportion of VA and PCC patients that received each included: pain clinic (60% and 32%), neurosurgery or orthopedics (46% and 53%), behavioral medicine or health psychology (22% and 17%), neurology (16% and 15%), and rheumatology (12% and 13%), and represent nonmutually exclusive categories

Table 2. Types of Opioids Prescribed

	Primary Care Site	
	VA (*n* = 50)	PCC (*n* = 48)
Short-acting opioids, %		
Oxycodone/acetaminophen	46	31
Codeine (30 mg)/acetaminophen	14	5
Other*	0	10
Long-acting opioids, %		
Morphine sulfate†	6	23
Morphine sulfate + oxycodone/acetaminophen‡	16	13
Methadone	2	10
Methadone + oxycodone/acetaminophen‡	12	2
Other§	4	6

* *Includes proxyphene/acetaminophen (*n *= 1), hydrocodone/acetaminophen (*n *= 1), meperidine (*n *= 1), codeine (*n *= 1), codeine (60 mg)/acetaminophen (*n *= 1).*
† *Controlled-release preparations.*
‡ *Administered for breakthrough pain.*
§ *Includes morphine sulfate + propoxyphene/acetaminophen (*n *= 1), extended-release oxycodone (*n *= 3), and fentanyl + oxycodone/acetaminophen (*n *= 1).*
PCC, primary care center.

(i.e., some patients were evaluated in more than 1 specialty clinic.)

Prescription opioid abusive behaviors were recorded for 12 (24%) VA and 15 (31%) PCC patients. Reports of lost or stolen opioid medications (or prescriptions) were noted in 6 VA and 5 PCC records, documentation that patients were using multiple sources to obtain opioid medications was present in 2 VA and 4 PCC patient charts, while requests for 2 or more early refills were recorded in 7 VA and 8 PCC patient records. The median time to the onset of prescription opioid abuse behaviors was 24 months (range 3 to 72 months).

The bivariate associations between patient factors and the presence of prescription opioid abuse behaviors are shown in Table 3. Factors associated with prescription opioid abuse at the $P < .05$ level included age, the number of medical diseases, and a lifetime history of a substance use disorder. In a logistic regression model, the adjusted odds ratios (ORs) and corresponding 95% confidence intervals (CIs) for the 3 factors were age (OR, 0.94; 95% CI, 0.89 to 0.99), number of medical diseases (OR, 0.72; 95% CI, 0.45 to 1.1), and a lifetime history of a substance use disorder (OR, 3.8; 95% CI, 1.4 to 10.8).

In secondary analyses, we examined whether the odds of prescription opioid abuse varied among patients ($n = 14$) with evidence of both a current and a lifetime substance use disorder versus those with a lifetime history only ($n = 27$). Both exposures were associated ($P < .05$) with prescription opioid abuse behaviors in bivariate analyses. The associations remained significant in a logistic model that included age and number of medical diseases: adjusted OR for current + lifetime, 5.3; 95% CI, 1.2 to 22.7, and adjusted OR for lifetime only, 3.3; 95% CI, 1.1 to 10.3.

Possible untoward events secondary to opioid use were noted for 1 VA and 3 PCC patients. Inpatient admissions for opioid overdose occurred in 1 VA and 1 PCC patient. In addition, 1 PCC patient presented to the emergency room with mental status changes that corrected with Naloxone, while 1 PCC patient had recurrent falls that were felt to be opioid related.

DISCUSSION

Our results indicate that a broad variety of chronic noncancer pain conditions are treated with opioid medications in primary care settings. Although low back pain was the most common chronic noncancer pain disorder, injury-related, diabetic neuropathy, degenerative joint disease, and headache were also commonly represented.

Psychiatric comorbidity was common in our study populations. Among VA and PCC patients, lifetime prevalence rates ranged from 44% to 54% for depressive disorders, 20% to 21% for anxiety disorders, 48% to 31% for alcohol abuse or dependence disorders, and 18% to 38% for narcotic abuse or dependence. These lifetime prevalence estimates are 3 to 6 times higher than those found in other primary care populations.[26–30] Our results are consistent with prior studies[31–33] that have shown strong associations between chronic noncancer pain and psychiatric comorbidity.

Table 3. Bivariate Associations Between Patient Factors and Prescription Opioid Abuse

	Prescription Opioid Abuse		
Attribute	Yes (*n* = 27)	No (*n* = 71)	*P* Value
Demographic			
Mean age, y (SD)	47.9 (11.8)	57.7 (12.6)	<.01
Male gender, %	56	66	.33
White race, %	67	72	.62
Married, %	52	41	.23
Type and duration of chronic pain			
Low back, %	30	37	.52
Injury-related, %	11	11	.98
Diabetic neuropathy, %	7	10	.71
DJD (non–low back), %	15	14	.93
Headache, %	4	10	.32
Spinal stenosis, %	11	6	.31
Other disorders, %	30	17	.16
Duration, mean y (SD)	10.9 (7.7)	12.2 (8.4)	.52
Medical comorbidity			
Medical diseases, mean *n*, (SD)	1.3 (1.2)	2.2 (1.6)	<.01
Psychiatric comorbidity			
Depression	63	44	.09
Anxiety	15	23	.40
Lifetime history of substance use disorder*	63	34	<.01

* *Includes patients with a lifetime history of alcohol abuse or dependence and/or narcotic abuse or dependence.*
DJD, degenerative joint disease.

We found that a significant minority of patients (24% VA and 31% PCC) had documentation of prescription opioid abuse behaviors in their medical records. Prior studies of patients drawn from pain clinics have reported rates of prescription opioid abuse that varied from 0% to 90%.[34–37] The wide range in reported abuse behaviors reflects differences in the study populations as well as in the criteria used to define prescription opioid abuse.

While no gold standard exists for the diagnosis of prescription opioid abuse behavior, we employed criteria that have been recognized previously as indicators of prescription opioid abuse and that could be reliably applied in a medical record review,[23–25] including reports of lost or stolen opioid medications or prescriptions, use of other sources to obtain opioid medications, and multiple requests for early refills. It is possible in certain cases that repeated requests for early refills (or procuring opioid medications from multiple sources) occurred because of inadequately treated pain rather than prescription opioid abuse, a condition sometimes referred to as pseudoaddiction.[38] Pseudoaddiction was first described in a case report[38] involving a cancer patient who went to great lengths to obtain opioid medications due to undertreatment of pain. The extent to which pseudoaddiction occurs and can be distinguished from prescription opioid abuse among patients with chronic noncancer pain warrants further study.

We found that a lifetime history of a substance use disorder was a predictor of prescription opioid abuse behavior. It is possible that unmeasured factors, associated with both a history of a substance use disorder and prescription opioid abuse, could have been partially responsible for this finding. It is also possible that detection bias might partially explain the observed association. Because a history of a substance use disorder has been reported to be a risk factor for prescription opioid abuse,[23,24] clinicians may have been more vigilant about searching for and documenting evidence of prescription opioid abuse behaviors in this subgroup of patients.

Although the odds of prescription opioid abuse increased among patients with a history of both current and lifetime substance use disorders versus those with a lifetime history only, the confidence intervals vary widely around the estimates reflecting the small number of patients in both groups. These risk estimates should also be viewed with caution, given the potential for misclassification (e.g., other patients with lifetime substance use disorders may have had current disorders that were not detected by their treating physicians).

At least 2 retrospective studies[35,39] have reported associations between prescription opioid abuse and a history of a substance use disorder, while a third retrospective study[36] found that a history of a substance use disorder was not a risk factor for prescription opioid abuse among chronic noncancer patients receiving opioid medications. Prospective studies are needed to determine the extent to which this exposure increases the risk for prescription opioid abuse. Until such results are available, our findings indicate the need for extra caution when prescribing opioid medications for chronic noncancer pain patients with a history of a substance use disorder. Alternately, clinicians may opt to refer these patients to appropriate specialty services (e.g., addiction treatment specialists) for assistance in managing their substance use disorders.

We also found that decreasing age was associated with prescription opioid abuse behavior. To our knowledge, this relationship has not been demonstrated previously. Such an association could have occurred, however, if clinicians were more likely to search for evidence of prescription opioid abuse in their younger as opposed to older patients.

Documentation of untoward events secondary to opioid use was found in 4 patient records (4%) and included opioid overdoses, mental status changes, and falls. Despite their low prevalence in our study, the potential morbidity associated with these outcomes is significant. Additional studies are needed to define more accurately the magnitude of risk posed by opioid use among chronic noncancer pain patients in primary care settings.

Of note, in our study the vast majority of patients received opioid medications for noncancer pain. For example, only 9 of 60 (15%) VA and 6 of 54 (11%) PCC patients were prescribed opioid medications for cancer-related pain. Although our sample was restricted to 2 primary care practices located in the northeastern region of the United States, these findings suggest that most primary care patients on long-term opioid therapy are likely to have a noncancer-related diagnosis.

Our study has several limitations that deserve comment. First, we studied a largely male white population of veterans and an urban-based population with substantial minority representation. Our results may not be reflective of chronic noncancer pain patients in other primary care practices. Second, patients were drawn from 2 primary care sites that are affiliated with an academic medical center. Thus, our findings may not be reflective of practice patterns in nonacademic primary care settings. Third, we relied on a recorded diagnosis of an alcohol, narcotic, depressive, and/or anxiety disorder in patients' medical records in order to estimate lifetime prevalence rates for these specific disorders. Since we did not use formal criteria, e.g., Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition,[40] to validate these diagnoses, it is possible that our reported prevalence estimates overestimated the true prevalence of these disorders in our study samples (i.e., due to false positives). We contend that our prevalence estimates are probably conservative, however, since many patients may have had either lifetime or current disorders that were not recognized by their treating physicians. Fourth, we do not know whether patients who were prescribed opioid medications actually took these drugs. Finally, because clinicians may not have recorded all episodes of prescription opioid abuse or inquired about

possible opioid-related untoward events, our reported prevalence rates probably underestimate the true prevalence of these events.

In conclusion, our study has shown that a broad spectrum of chronic noncancer pain disorders are treated with opioid medications in primary care settings. The lifetime prevalence of psychiatric comorbidity was substantial in our study populations. A significant minority of patients manifested prescription opioid–abusive behaviors, and a lifetime history of a substance use disorder and decreasing age were associated with prescription opioid abuse behavior. Prospective studies are needed to determine the potential benefits as well as risks associated with opioid use for chronic noncancer pain in primary care.

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