Long-Term Opioid Contract Use for Chronic Pain Management in Primary Care Practice. A Five Year Experience

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BACKGROUND: The use of opioid medications to manage chronic pain is complex and challenging, especially in primary care settings. Medication contracts are increasingly being used to monitor patient adherence, but little is known about the long-term outcomes of such contracts.

OBJECTIVE: To describe the long-term outcomes of a medication contract agreement for patients receiving opioid medications in a primary care setting.

DESIGN: Retrospective cohort study.

SUBJECTS: All patients placed on a contract for opioid medication between 1998 and 2003 in an academic General Internal Medicine teaching clinic.

MEASUREMENTS: Demographics, diagnoses, opiates prescribed, urine drug screens, and reasons for contract cancellation were recorded. The association of physician contract cancellation with patient factors and medication types were examined using the Chi-square test and multivariate logistic regression.

RESULTS: A total of 330 patients constituting 4% of the clinic population were placed on contracts during the study period. Seventy percent were on indigent care programs. The majority had low back pain (38%) or fibromyalgia (23%). Contracts were discontinued in 37%. Only 17% were cancelled for substance abuse and noncompliance. Twenty percent discontinued contract voluntarily. Urine toxicology screens were obtained in 42% of patients of whom 38% were positive for illicit substances.

CONCLUSIONS: Over 60% of patients adhered to the contract agreement for opioids with a median follow-up of 22.5 months. Our experience provides insight into establishing a systematic approach to opioid administration and monitoring in primary care practices. A more structured drug testing strategy is needed to identify nonadherent patients.

INTRODUCTION

Chronic pain management is complex and is complicated by substantial psychological and functional impairment that can have a profound effect on quality of life. More than 75 million Americans suffer from some form of chronic pain that is unrelated to cancer, [1] and the number of these patients followed in primary care practices is rising.[2,3] Unfortunately, there is uncertainty on how to best manage these patients because the available research in this area is limited to reports of surveys and uncontrolled case series, largely from specialty pain clinics.[5,7,8] Few studies have examined the management of chronic pain in primary care settings.[1,3,4]

Opioid medications are known to be effective in relieving chronic pain and can improve mood and functional status as well.[5,6] Research suggests that patients with chronic noncancer pain can achieve satisfactory analgesia by using a stable (non-escalating) dose of opioids with a minimal risk of addiction.[10] Still, providers are cautious about prescribing opioids owing to concern about their addictive properties and side-effects, and concern about regulatory sanctions.[7–9]

As care of patients with chronic pain in the primary care setting increases, monitoring these patients for adherence to treatment plans, response to medication, and development of addiction has become critical.[9] A practical, standardized approach to prescribing opioids is needed in all medical settings, and particularly in primary care. Key organizations have published consensus statements and guidelines to assist physicians in prescribing opioids.[11–14] Use of a medication contract agreement is one method that might improve patient buy-in and monitor adherence to treatment plans.[15] A contract or a partnership agreement is defined as an "explicit bilateral commitment to a well-defined course of action".[16] Contracts are widely used in the chronic administration of potentially abusable drugs and behavior-linked problems.[17,18] Many academic pain management centers use an opioid contract as part of their standard practice, and some of their benefits and limitations have been described in these settings.[19,20] However to date, there has been little exploration of long-term contract use in improving adherence to chronic pain therapy, reasons for discontinuation of contracts, or its use in primary care practices.[19,21]

In the current study, we describe a 5-year experience using opioid contracts for chronic pain management in a large academic primary care practice. We determined the demographics of enrolled patients, chronic pain diagnoses, types of opioid medications prescribed, use of urine drug screens for monitoring use of illicit substances, and reasons for discontinuation of contract. We also looked at patient adherence to

contract agreements using a definition adapted from the pain literature, [9,19] which we defined as patients receiving stable doses of contracted medications at prescribed intervals and adhering to the conditions of the contract agreement.

STUDY METHODS

This study covers the period January 1, 1998 to December 31, 2003 in the General Internal Medicine Clinic at the Medical College of Wisconsin, an urban academic center and training site for Internal Medicine residents. During the study period the clinic had 8,644 enrolled patients. Ten board certified Internists and over 30 residents practiced at the site. The study protocol was approved by the Institutional Review Board at the Medical College of Wisconsin.

In 1998, the faculty practice group initiated a provider–patient agreement or medication contract protocol for patients started on long-term opioid medications for chronic pain. In 2000, by consensus of the faculty providers, this method became standard practice. All physicians including residents participated and were trained on use of the contract. Patient eligibility for a contract was determined by the primary provider. In general, if long-term opioid therapy was initiated, patients were asked to sign the medication contract agreement. Monthly prescriptions were then provided to the patient. Drug selection and dosing were determined by the physician. Patients who refused to sign a contract were not eligible to receive ongoing opioids through the practice. Whereas it is possible that not all eligible patients were placed on contract, every provider had a minimum of 2 patients enrolled in this system. Nurses were trained to assist the Faculty-resident teams in both implementation and ongoing follow-up care.

The medication contract is described in Figure 1 and included both patient and physician responsibilities. In addition to the diagnosis, type and dose of medication prescribed, it specified the conditions under which opioids would or would not be prescribed and patient responsibilities. Random urine drug screening would be performed if recommended by the physician to monitor adherence and possible use of illicit substances. Patients were informed that the contract would be discontinued if patient responsibilities were not met. Responsibilities of the physician and/or clinic staff included providing monthly prescriptions on the due date, monitoring the effects of therapy, and providing ongoing care.

Eligible patients included individuals with chronic non-cancer pain, who signed a medication contract agreement for long-term opioid medications during the study period. We performed a retrospective chart review of eligible patients and recorded patient demographics including age, sex, ethnicity, and type of insurance. Insurance status was determined from a billing database. If insurance changed, insurance type as of July 2003 was used. Insurance was divided into 1) Medicare only, 2) Medicaid with or without Medicare coverage, 3) county "insurance" for patients at or below the poverty line, 4) private insurance including preferred-provider, health maintenance organization, and private fee-for-service insurance, and 5) no insurance.

We recorded the etiologies of chronic pain for each patient. Cases were more than 1 chronic pain condition was present, the first recorded condition was selected as the principal diagnosis. Conditions were organized by diagnosis, including low back pain, degenerative joint disease (DJD), chronic pancreatitis, sickle cell anemia, and fibromyalgia or pain in multiple anatomic sites. A number of low volume diagnoses including headache, autoimmune disorders, peripheral neuropathy, avascular necrosis, phantom limb, and paraplegia were pooled into a single category called miscellaneous causes.

We defined the type of opioids used by documentation in the contract. They were categorized as long-acting, short-acting, and combination therapy (combination of long- and short-acting opioids). If the medication was changed in the contract, the most recent prescription was used. To estimate the duration of treatment with opioids, we used the date of onset of the contract as time 0. The end date was any of the following: 1) the last day of the study period (i.e., Dec 31, 2003), or 2) date the contract was terminated by the physician, or 3) last recorded date of prescription, if the patient discontinued follow up or did not receive any medications after July 1, 2003.

Urine toxicology screening (UTS) for monitoring therapy in this population was identified by chart audit and review of all laboratory studies from a computerized laboratory database. The results of UTS were examined and categorized as negative, positive for marijuana, cocaine, or positive for both. We chose not to label urine devoid of the prescribed opioid as a positive test, because of concerns of the accuracy of existing tests in detecting therapeutic concentrations of several commonly prescribed opioids.

We also determined the total number of contract cancellations, and reasons for cancellation as documented on the contract. The reasons for cancellation were adapted from prior literature on screening for problematic prescription opioid use [22,23] and information from our charts. They were categorized as: 1) positive UTS for cocaine and or marijuana, 2) prescription opioid abuse, which included procurement of opioids from multiple sources, prescription forgery, and use of opioids other than that prescribed, 3) contract rules violation (e.g., missed appointments, missed UTS and requests for early refills), and 4) other, including transfer of care to specialist. Cancellations in categories 1–3 were considered physician initiated cancellations in all analyses.

DATA ANALYSIS

The data were entered into a Microsoft Excel database and analyzed using SAS version 8 statistical software. Descriptive analysis of the data was used to summarize the demographic characteristics of the patient sample, chronic pain diagnoses, and type of opioid used and duration of treatment. The percentage of patients whose contracts were cancelled and the reasons for cancellation were determined. Differences in diagnosis, type of medication used, and demographic factors associated with contract cancellation were examined using the Chi-square test for independence. Variables with $p < 0.1$ were examined in a multivariate logistic regression model using backward regression to determine which predictors were independently associated with contract cancellation.

RESULTS

A total of 332 patients were placed on contract during the study period. Cancer patients ($n=2$) were excluded. The

Patient Name: _____

Diagnosis: _____

Since other treatments have not worked to control your pain, the physicians of General Internal Medicine (GIM) have decided to give you long-term opioids to help manage your pain better and improve your social and work activities. This is a serious decision. You must adhere to several conditions in order to continue with this type of treatment.

<u>Conditions:</u>
1. I will not use illegal substances, street drugs or abuse alcohol while taking controlled medications. I will not take opioids prescribed for other people.
2. I will not be involved in the sale, illegal possession, diversion, or transport of controlled substances like narcotics, sleeping pills, or nerve pills.
3. I agree to obtain drug screening tests, including blood alcohol levels, when my physician requests it.
4. I agree to obtain all prescriptions for opioids from one physician only at the GIM East Clinic and to take medications as prescribed by my doctor.
5. I agree to use only one pharmacy, _____
   Phone # _____, for filling prescriptions for opioids.
6. I agree to follow up every three months with my physician regarding pain control and to keep all scheduled clinic appointments regarding my chronic pain.
7. I agree to the hospital computer system containing information about the contract so that other doctors in the hospital are informed.
8. I agree to allow my physicians in GIM to communicate with other physicians and any pharmacists regarding pain management as deemed necessary.
9. I certify that I am not pregnant. I certify that I will use appropriate measures to prevent pregnancy during the course of my treatment with opioids.
10. I agree to contact GIM at 414-805-6850 within 24 hours if an unavoidable emergency occurs requiring a prescription for opioids, an ER visit, or an inpatient admission..
11. I understand that NO allowances will be made for lost prescriptions, drugs, or any problems I may have with transportation or dates of pick up.
12. I understand the possible adverse effects and dependencies associated with opioids as outlined on the Adverse Effects Sheet.
13. I agree to have _____ as a designated person to pick up my narcotic prescription in case I am unable. He/she will present a photo ID and my green clinic card to verify name and permission for pick up.
14. I agree to call 7 days in advance for all refills and to schedule an appointment for pick up.
15. I understand this mode of treatment will be stopped if any of the following occurs:
    a) I give away, sell, or misuse the drugs or use other peoples' drugs or illegal substances
    b) I am noncompliant with any of the terms of this agreement
    c) I disrespect or harass clinic personnel
    d) I do not follow up regularly or as requested by my physician.
16. Exceptions to the above include:

I have read this agreement, understand it, and have had all questions answered satisfactorily. I consent to the use of opioids under the terms outlined in this agreement.

_____   ___/____/_____   _____
GIM Physician   Witness

_____   _____
Signature   Date   Nurse

Figure 1. Medication agreement for the treatment of chronic pain with controlled medications (opioid medication).

remaining 330 patients constituted our study population, representing 4% (330/8644) of our primary care practice.

On average, 78 patients enrolled in the contract each year from 2001 to 2003. Median follow-up from initiation of opioid contract was 646 days. Table 1 summarizes the demographic data. The median age was 49 years; 52% were men. The population was evenly divided between whites and blacks. Seventy percent of the 330 patients were on indigent care programs. Low back pain was the most commonly recorded chronic pain diagnosis and was present in 37% of the patients. The next most common disorder was fibromyalgia and pain in multiple sites at 23%. Headache, DJD, and neuropathy were less common.

Table 2 summarizes the various types of opioids prescribed. These included long-acting opioids alone, short-acting opioids alone, or a combination of both. The most common prescribing pattern was combination therapy in 45%, followed by short-acting alone (38%) (Table 2). The most prescribed opioid overall was oxycodone/acetaminophen (22% of cohort). The most prescribed long-acting opioid was sustained-release oxycodone.

A total of 140 (42%) patients had a UTS performed during the course of the study. All physicians ordered toxicology screens for at least 2 of their patients, with no differences in the proportion of physicians' panels tested. Patients who were male (p=.044), younger (p=.02), who were taking long-acting or combination therapy (p<.001), or who had sickle cell anemia (p=.006) (compared with patients with low back pain) were

Table 1. Characteristics of Patients Enrolled in the Medication Contract and Overall Clinic Population

Patient Characteristics	Percent of contract population (N=330)	Percent of overall clinic population (N=8644)
Sex		
Male	52	38
Female	48	62
Race		
White	50	59
Black	48	35
Other	2	6
Age		
<40 yrs	33	24
40–55 yrs	42	34
>55 yrs	25	42
Insurance		
Medicare Only	11	35
Medicaid (with and without Medicare)	49	16
County insurance	21	12
Commercial	17	34
None	2	3
Diagnosis of chronic pain		
Low back pain	37	
Fibromyalgia and/or pain in multiple sites	23	
Degenerative joint disease	17	
Chronic pancreatitis	6	
Sickle cell anemia	5	
Miscellaneous*	12	

Includes headache, auto-immune disorders, phantom limb, and peripheral neuropathy.

Table 2. Type of Opioids Prescribed

Opioid Medications	N=330	Percent
Long-acting opioids alone	59	18
SR* oxycodone	24	
Morphine long acting	17	
Methadone	16	
Fentanyl Patch	2	
Short-acting opioids alone	124	38
Oxycodone/acetaminophen	74	
Hydrocodone/ acetaminophen	22	
Morphine	1	
Acetaminophen with codeine	20	
Propoxyphene+ acetaminophen	6	
Hydromorphone	1	
Combination therapy **	147	45
SR* Oxycodone + short acting	70	
Morphine long acting + short acting	51	
Fentanyl + short acting	9	
Methadone + short acting	17	

*SR=Sustained release; **Combination of long-acting and short-acting opioids.*

more likely to receive testing. Patients with degenerative joint disease were less likely to receive testing (p=.024). Among those tested, 38% had an illicit substance detected (n=53). Eighteen percent of patients tested were positive for cocaine, 14% for marijuana, and 6% were positive for both.

Over the 5 years 17% of contracts (n=54) were canceled by the physician. Twenty percent of patients (n=65), discontinued medications without cancellation. The most common reason for physician cancellation was positive UTS in 50% (n=27) of patients, followed by prescription drug abuse in 26% (n=14). Only 7% (n=4) of patients were terminated for contract rules violations, whereas 17% (n=9) were terminated for administrative reasons such as transfer of care to a specialist. No contracts listed negative drug screen for prescribed opioids as reason for cancellation.

We examined the association between patient or medication factors and contract cancellation (Table 3). For these analyses, contract cancellation was defined as positive UTS for cocaine or marijuana, prescription drug abuse, or contract rules violations (n=45 patients in total). It did not include administrative reasons for contract cancellation (n=9). Male sex and combination therapy were both significantly associated with contract cancellation in unadjusted analyses. There may have been a trend toward less cancellation among older (>55) patients, 6% of whom were cancelled as compared with 17% of those aged 40–55 and 16% of those <40 (p=.069). There was no difference in the number of patients canceled between users of long-acting morphine (19% cancelled), long-acting oxycontin (16%), nor reason for opioid use or insurance type.

When examined in analyses adjusted for patient age, male sex remained associated with contract cancellation. In addition, compared with users of short-acting medications alone, users of combination therapy had a greater chance of contract cancellation. There was no difference between users of combination therapy and users of long-acting medications alone.

DISCUSSION

To our knowledge, this is the first study in a primary care setting to describe long-term outcomes of a medication

Patient Characteristics	% Cancelled	Unadjusted *P* value	Adjusted Odds Ratio
Sex			
Male	18	0.015	1.9 (1.0, 3.9)
Female	9		-Reference
Age Group			
<40 yrs	16	0.069	0.4 (0.1, 1.2)
40–55 yrs	17		0.4 (0.1, 1.1)
>55 yrs	6		-Reference
Insurance			
Medicare Only	14	0.127	
Medicaid (with and without Medicare)	16		
County Insurance	8		
Commercial	9		
None	38		
Diagnosis of Chronic Pain			
Low Back Pain	13	0.658	
Fibromyalgia and/ or pain in Multiple sites	8		
Degenerative Joint Disease	15		
Chronic Pancreatitis	14		
Sickle Cell Anemia	20		
Miscellaneous*	18		
Drug Type			
Short-acting opioids	8	0.029	0.4 (0.2, 0.8)
Long-acting opioids	12		0.6 (0.2, 1.4)
Combination Therapy**	19		-Reference

Includes headache, auto-immune disorders, phantom limb, and peripheral neuropathy.
**Combination of long-acting and short-acting opioids.*

contract system for chronic noncancer pain. Our 5-year study followed over 300 patients in a primary care setting, with diverse demographic and clinical characteristics, for an average of 22.5 months.

Approximately 4% of our patient population was placed on contract for chronic pain during the 5 years. We know of no previous studies of patients followed long term on contract, so other estimates of prevalence of opioid use available in the literature are from computerized prescription records. Our results were similar to the 3% prevalence estimated in a VA study.[3]

A key finding was that over 60% of patients remained on contract during the study period, similar to average adherence rates of 43 to 78% among patients receiving treatment for chronic conditions noted in a recent review.[24] Physician-initiated contract cancellations were observed in only 17% of patients. Among those canceled, half were terminated for positive toxicology screens and a quarter for prescription drug abuse. More patients discontinued opioids voluntarily (20%) than were canceled in our study. We found no associations between contract cancellations and any patient characteristics or pain diagnoses. Whereas there was an association between use of combination therapy and contract cancellation, this finding is subject to selection bias in this observational study, and may reflect use of low doses of short-acting medications alone in patients with milder pain.

Comparing our results to 2 previous studies [1,3] of opioid use in single primary care systems we noted both similarities and differences. Sixty-seven percent of patients were female, with a median age of 53 years in the prior studies. In our study, the median age was 49 years, and we had a higher proportion of males. Low back pain was the most frequent pain diagnosis at 36% in our study, similar to other studies. In our study, 38% of patients received short-acting opioids for their chronic pain, with oxycodone/acetaminophen being the most commonly prescribed at 22%. In Adams [1] and Reid, [3] short-acting opioids were used in 60% and 46%, respectively, with oxycodone/ acetaminophen being the most common at 31%. However, sustained-release oxycodone was the most commonly prescribed long-acting opioid in our study compared to extended-release morphine in the other 2 studies, [1,3] perhaps reflecting secular trends and lack of a restricted formulary in most of our population. Other reasons may include patient request or pharmaceutical detailing. Physicians prescribed either long-acting medications alone or combination therapy, as recommended by multiple guidelines [11,13] for over 60% of patients.

Although many aspects of the contract system appear to have been successful, primary care physicians often did not monitor for contract adherence. Less than 45% (*n*=140) of patients received UTS. There was no standardized protocol for UTS in the clinic. UTS done at the discretion of the physician was positive for illicit drugs in 38% (53/140) of tested patients, and was the most frequent reason for contract cancellation. It is likely that clinicians ordered UTS in patients they suspected to be at higher risk for substance abuse. The ability of physicians in general to recognize nonadherence to treatment plans is poor.[24] In the absence of a clear guideline for drug screening, it is possible that some abuse was not recognized. Whereas drug screening is widely advocated, there is very little data on its use in clinical settings.[25,26] Nevertheless, limited data suggest that UTS may be more effective at identifying nonadherent patients than monitoring behaviors alone or self reports of drug use alone [27]. Reports from 2 academic medical centers with diverse population such as ours have noted 38% [3] and 32% [4] prevalence of substance misuse in their chronic pain population, consistent with our study. Given that we did not identify any clinical predictors of contract cancellation, a more structured testing strategy with defined criteria for interpretation of UTS would provide valuable information for both diagnostic and therapeutic decision making regarding substance misuse and contract discontinuation.

Our study has several limitations. First, it is a retrospective analysis of care delivered in a single site and local culture and trends may influence the nature of practice. Second, the decision to prescribe opioids, the type of opioids, use of a medication contract, and use of urine toxicology screening were all at the discretion of the individual physicians in our study. Our definition of contract adherence is also limited by the lack of systematic drug testing done by the physicians in our study. However, these limitations likely reflect real world practice. We defined our chronic pain diagnoses by the first listed diagnosis on the contract. Whereas this likely represents the most severe pain, some patients had more than 1 diagnosis listed, and therefore results of our comparisons by diagnosis should be interpreted with caution. Finally, pain outcomes for all patients, and in particular the outcomes for the 20% of patients who discontinued contract without cancellation, are unknown. It is possible that this reflects dissatisfaction with

the system, poor pain control, or change in insurance. Conversely, it may simply reflect the transient nature of this patient population. Despite the limitations, we believe that a medication contract system has great potential as a systems-based approach to management of pain in other academic primary care practices that serve diverse patient populations.

In conclusion, we believe opioid contract use can provide structure, support, and monitoring for long-term chronic pain management in a large primary care practice. Our experience can help provide insight in using such a tool more effectively. Potential interventions should include standardized guidelines for both pain assessment and monitoring therapy using pain scales and urine drug testing for both opioids and illicit substances. More research is needed to elucidate effective use of UTS in the management of chronic pain, as improved adherence monitoring may offer better control over pharmacological and psychological toxicity.

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