# DOES ADHERENCE MONITORING REDUCE CONTROLLED SUBSTANCE ABUSE IN CHRONIC PAIN PATIENTS?

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Background: Opioids are used extensively for chronic pain management in the United States. The frequency of opioid use prior to presenting to interventional pain management settings and in interventional pain management settings has been shown to be above 90%. Given that controlled substance abuse and illicit drug use are prevalent phenomena, adherence monitoring of patients that are prescribed opioids is becoming common. Adherence monitoring is carried out by an appropriate history, periodic evaluation of appropriate intake of drugs, random drug testing, and pill counts. Crucial to adherence monitoring is an initial controlled substance agreement and repeated review of the terms of this agreement with on-going education. However,

the effect of adherence monitoring on drug abuse is unclear.

*Objective*: To identify controlled substance abuse through implementation of the terms of a controlled substance agreement, including periodic review and monitoring outside the organization.

*Study Design:* Prospective evaluation with historical controls.

*Methods*: Five hundred consecutive patients receiving prescription controlled substances were followed in a prospective manner. The evaluation consisted of a chart review to monitor controlled substance intake, with special attention to drugs obtained from outside the organization. Data collection for this purpose included information from records, pharmacies, referring phy-

sicians, and all the physicians involved in the treatment of the patient.

*Results*: Results from 500 consecutive patients were evaluated. Controlled substance abuse was seen in 9% of patients; overall, 5% of patients were obtaining controlled substances from other physicians, and 4% from illegal sources.

*Conclusion*: Adherence monitoring, including controlled substance agreements and various periodic measures of compliance was associated with a 50% reduction in opioid abuse.

*Key words*: Chronic pain, controlled substances, substance abuse, opioids, dependency, adherence monitoring

As many as 90% of patients in pain management settings have been reported to receive opioids for chronic pain management (1-20). Manchikanti et al (1) showed that 90% of patients were on opioids and 42% were on benzodiazepines prior to presenting to an interventional pain management center. The frequency of overall opioid use among individuals with back pain was reported at approximately 12% (21). A 2001 cross-sectional analysis of analgesic use by patients with low back pain showed that 55.5% of insurance plan members with low back pain were receiving analgesics, with 68% re-

From: Pain Management Center of Paducah, Kentucky Address Corresspondence: Laxmaiah Manchikanti, MD 2831 Lone Oak Road Paducah, KY 42003 E-mail: drm@apex.net Disclaimer: There was no external funding in preparation of this manuscript. Conflict of Interest: None Manuscript received on 11/23/2005 Revision submitted on 12/6/2005 Accepted for publication on 12/6/2005 ceiving an opioid (22). In addition, Medicaid patients were more likely to receive prescription drugs, particularly opioids (approximately 73% as compared to 40% with commercial insurance), for 30 days or longer and to visit the emergency room (23). Multiple authors in other studies also have reported widespread use of opioids in managing chronic pain (24-31).

Given that controlled substance abuse, and illicit drug use are prevalent phenomena, adherence monitoring of prescribed opioids to evaluate their appropriate use is common. Adherence monitoring is carried out by obtaining an appropriate history, periodic evaluation of appropriate intake of drugs, random drug testing, and pill counts (8-11, 32-39). Pivotal to adherence monitoring is an initial controlled substance agreement and repeated review of the terms of this agreement with the patient along with ongoing patient education.

In previous studies we reported the prevalence of prescription controlled drug abuse as 17.8% in a sample of 500 patients (11). In the present study, the role

of adherence monitoring was evaluated. We evaluated whether or not there was controlled substance abuse after the implementation of a controlled substance agreement, including periodic review of medications, urine testing, pill counts, and verification of medication information provided by the patient with treating physicians and pharmacies.

## METHODS

The study included 500 consecutive patients in a comprehensive, multi-disciplinary, interventional pain management center, all of whom were receiving prescription controlled substances. The exclusion criteria included patients refusing to follow the terms of the controlled substance agreement and refusing to submit to drug testing or pill counts. Following the initial selection, the evaluation consisted of a review of the charts and gathering of information with regards to controlled substance intake with special attention to receiving the drugs from outside the organization. The data collection for this purpose included information from records, pharmacies, referring physician, and all physicians involved in the treatment of the patient.

All the patients in the study signed consent and controlled substance agreements. This agreement included permission to contact pharmacies, physicians, etc., and to subject the patient to random drug screening and pill counts. All the patients were considered to be receiving stable doses of hydrocodone, oxycodone, methadone, or morphine as supplemental to their interventional techniques. Opioids were not the mainstay of treatment. Appropriate precautions were taken to protect the privacy and identity of patients participating in this evaluation.

Data were collected using a preprinted format with demographic information and drug history and were compared with all acquired information. Abuse was defined as a patient receiving controlled substances from any other place or source other than the prescribing physician at our center, with the exception of controlled substances for acute injuries unrelated to the problem being treated, or for emergencies. Data were tabulated and compared with results from historical controls published elsewhere (10,11).

Data were recorded in a database using Microsoft<sup>®</sup> or Access 97<sup>®</sup>. The SPS version 9.0 statistical package was used to generate the frequency tables

## RESULTS

#### Patient flow

Data were evaluated for the prevalence of controlled substance abuse in 500 patients. Overall, 566 patients were eligible to participate, but 66 patients refused to participate in the study.

## Demographic characteristics

Table 1 illustrates the demographic characteristics of the 500 patients included in the evaluation. The results showed that 59% of the patients were female, the mean age was 48.6 years, and the mean duration of pain was 10.7 years. Even though the mean age was  $48.6 \pm 0.55$  years, 48% of the patients were on Medicare.

#### Controlled substance abuse

Controlled substance abuse was identified as illustrated in Table 2. Over-

Table 1. Demographic	characteristics	
Gender	Male	41% (205)
	Female	59% (295)
Age	Mean $\pm$ SEM	$48.5 \pm 0.55$
Height (inches)	Mean <u>+</u> SEM	66.8 <u>+</u> 0.19
Weight (lbs.)	Mean $\pm$ SEM	184.5 <u>+</u> 2.24
Duration of Pain (years)	Mean <u>+</u> SEM	10.7 <u>+</u> 0.37
Mode of Onset	Gradual onset	38% (187)
	MVA	20% (100)
	Other Incident	20% (102)
	Sudden Onset	2% (11)
	Work Injury	20% (100)
Number of Pain Problems	1	36% (180)
	2	48% (240)
	3	16% (80)
History of Previous Spine Surgery		35% (176)
Employment Status	Disabled	38% (190)
	Working full-time	24% (120)
	Unemployment	18% (93)
	Retired or over 65	12% (59)
	Homemaker	8% (38)
Insurance Status	Medicare only or with third party	31% (154)
	Medicare and Medicaid	17% (85)
	Medicaid	14% (69)
	Third party	33% (166)
	No insurance	5% (26)

Table 2. Drug abuse characteristics

	% (No. patients)	
Doctor shopping	5% (25)	
Trafficking	4% (21)	
TOTAL	9% (46)	

all 9% of the patients were abusing prescription drugs, 5% by doctor shopping, and 4% by illegal acquisition involving drug trafficking. As reported elsewhere (10,11) this represents a 50% reduction in opioid abuse.

## DISCUSSION

This prospective evaluation suggests that adherence monitoring with a controlled substance agreement, periodic monitoring, periodic drug testing, pill counts, and education when necessary served to reduce controlled substance abuse. With those elements in place, this study identified controlled substance abuse among 9% of the patients in the study, in contrast to 17.8% in the past (11). In a previous study (11), Grade I, or low grade abuse was defined as receiving controlled substances from less than three physicians; Grade II, or moderate abuse, was defined as obtaining controlled substances from three or more physicians, patients on Schedule II substances with abuse of any controlled substances, abuse of Schedule II substances while on other controlled substances; and Grade III was defined as significant abuse including trafficking and overdosage. Our earlier study showed a prevalence of low grade abuse in 9.4% of the patients, moderate abuse in 6% of the patients, and high grade abuse in 2.4% of the patients with total abuse seen in 17.8% of the patients. In the present study, doctor shopping, which is categorized as both low grade and moderate abuse, was seen in 5% of the patients, while 4% of the patients obtained controlled substances by means of drug trafficking. None of the patients in the study were admitted with overdose during the time of the study. Consequently, the results can be classified as low grade and moderate abuse in 5% of the patients and high grade abuse in 4% of the patients.

Controlled substances can be diverted from their lawful purpose to illicit use at any point in the pharmaceutical manufacturing and distribution process. The diversion of prescription drugs among adults is typically described as occurring through one of the following: doctor shopping, illegal Internet pharmacies, drug theft, prescription forgery, and illicit prescriptions by physicians. Doctor shopping is one of the most popular methods of obtaining prescription drugs for legal and illegal use.

A recent publication of the National Center of Addiction and Substance Abuse at Columbia University (CASA) (40) presented alarming statistics, including that 15.1 million Americans have admitted to abusing prescription drugs – more than the combined number of those who admit to abusing cocaine (5.9 million), hallucinogens (4 million), inhalants (2.1 million) and heroin (0.3 million). The CASA report included a physician survey with highlights showing that physicians perceive the three main mechanisms of diversion to be: 1) 96.4% – doctor shopping in which patients obtain controlled drugs

from multiple doctors; 2) 87.8% - patient deception or manipulation of doctors; and 3) 69% - forged or altered prescriptions. In addition, 59.1% of physicians believe that patients account for the bulk of the diversion problem and 47.1% said that patients commonly try to pressure them into prescribing a controlled drug. Further, only 39.6% of physicians admitted that they received any training in medical school in identifying prescription drug abuse and addiction; 43.3% admitted that they do not ask about prescription drug abuse when taking a patient's health history; and 33% do not regularly call or obtain records from the patient's previous physician before prescribing controlled drugs on a long-term basis. Similarly, a survey of pharmacists also revealed that 51.8% of pharmacists believe that patients account for the bulk of the diversion problem; and drug-related emergency department visits also reveal that prescription drugs abuse is on the rise (41,42). From 1994 to 2002, mentions of pain medications during emergency department visits increased by 168%, whereas mentions of benzodiazepines increased by 42%. During the same time period, the percentage of increase mentioned by the Drug Abuse Warning Network (DAWN) for prescription pain relievers has been greater than the increase of marijuana, cocaine, and heroin.

Multiple investigators (1,7-12,14) have shown drug abuse in 18% to 41% of patients receiving controlled substances. The prevalence, comorbidities, and utilization of opioid abuse in a cohort of managed care patients with matched controls revealed that the prevalence of opioid abuse rose between years 2000 and 2002 (31). Opioid abuse was seen in 6.7 per 10,000 patients in 2002.

# CONCLUSION

This study showed that adherence monitoring was associated with a 50% decrease in opioid abuse among patients in chronic pain management settings. Adherence monitoring is carried out by appropriate history, periodic evaluation of appropriate intake of drugs, random drug testing, and pill counts. Further, pivotal to adherence monitoring is an initial controlled substance agreement and repeated review with the patient of the terms of the agreement, along with ongoing education.

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