Behavioral Monitoring and Urine Toxicology Testing in Patients Receiving Long-Term Opioid Therapy

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No study has examined the role of urine toxicology in addition to behavioral monitoring in patients receiving opioid therapy for chronic pain. All patients maintained on chronic opioid therapy by the two senior authors at two university pain management centers were monitored for 3 yr with urine toxicology testing and for behaviors suggestive of inappropriate medication use. We retrospectively extracted demographic information, aberrant drug-taking behaviors, and urine toxicology information from the medical record. For 122 patients maintained on chronic opioid therapy, 43% ($n = 53$) had a "problem" (either positive urine toxicology or one or more aberrant drug-taking behaviors). Of patients with no behavioral issues, 21% ($n = 26$) had a positive urine screen for either an illicit drug or a nonprescribed controlled medication. Of patients with a negative urine screen, 14% ($n = 17$) had one or more behavioral issues. Monitoring both urine toxicology and behavioral issues captured more patients with inappropriate drug-taking behavior than either alone. Requiring a report of behavioral issues and urine toxicology screens for patients receiving chronic opioids creates a more comprehensive monitoring system than either alone.

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A recent bulletin from the American Pain Society revealed that 87% of physician American Pain Society members maintain patients with noncancer pain on opioids and support the long-term use of narcotic analgesics in patients with chronic noncancer pain (1). The decision whether to prescribe opioids remains controversial and involves medical, intellectual, emotional, and logistical factors (2). The safety of long-term opioid therapy for chronic noncancer pain is supported by studies that had multiple flaws, including small numbers of patients, single sites, short-term follow-up, open-label designs, retrospective reviews, and lack of a clear operational definition of addiction monitoring (3). Compliance with treatment guidelines and development of addiction have been identified as critical areas for patient monitoring (4). Of all the previously published studies on opioids for chronic noncancer pain, only one (5) has systematically defined how patients were monitored for addiction; this was done retrospectively by surveying patients for "addictive behaviors."

The doctor-patient relationship is traditionally based on the physician accepting the veracity of patient self-report. Many physicians monitor opioid therapy solely by patient self-report and by observing patients for addictive behavior. Unfortunately, patient care in the chronic pain setting is hampered by pervasive inaccuracies in patient self-report of drug use. Patients with chronic pain tend to underestimate their medication use (6). Chronic-pain patients regularly provide incorrect information on illicit drug use (7), which may be revealed by urine toxicology screens. The use of urine toxicology screens to supplement patient self-report is standard in the drug-abuse treatment setting (8). Opioid contracts in pain management centers usually require that patients submit to urine toxicology screens (9), but the only study that reviewed the effect of a signed contract on patient compliance found that there was no effect (5). We performed this study to describe the results of regular urine toxicology screens performed on all patients maintained on opioid therapy by the authors for chronic pain in two university pain centers, in comparison to monitoring for addictive behaviors.

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Methods

Approval for conducting this study was obtained from the IRBs of both Dartmouth-Hitchcock Medical Center (DHMC), Hanover, NH, and Brigham and Women's Hospital (BWH), Boston, MA. Since the authors retrospectively abstracted information from the medical record without altering usual practice and since no identifiable information about the patients was retained, patient consent was not required at either institution. All patients receiving long-term opioid therapy for chronic noncancer pain at the DHMC Pain Management Center and all the patients of one author (NPK) at BWH were monitored with urine toxicology screens. Patients at DHMC were monitored at least once annually; physicians had the option to monitor more frequently if they believed that it was indicated. At BWH, patients were expected to submit samples for urine toxicology screening at approximately every scheduled clinic visit during the period of the study (January 1997 to September 2000). During the study period, all patients who were prescribed opioids for chronic use had urine collected at least once for toxicology analysis.

Urine testing was performed in a two-step process. Initial screening was an enzyme-mediated immunoassay test that detected the following drugs: amphetamines, analgesics, anticonvulsants, antihistamines, barbiturates, benzodiazepines, cocaine metabolites, marijuana (tetrahydrocannabinol), methadone, opiates, phenothiazines, tricyclics, and volatiles (includes ethanol). All specimens were also sent for a gas chromatography/mass spectroscopy analytical method, which is a highly specific and sensitive test used to identify individual opioids. A patient was considered to have a "positive urine toxicology" if one or more of the following was identified in the urine sample: an illicit drug, a nonprescribed controlled drug, or ethanol. A patient who tested positive for one or more substances was categorized as having a single positive toxicology. Absence in the urine of the prescribed opioid was not considered a positive test.

Medical records were retrospectively reviewed by four of the authors (JV, SS, RJR, and GJF) for demographic information, drug-taking behaviors, and urine toxicology reports. Patients were screened for five selected behaviors that have been described as being suggestive of inappropriate drug-taking behaviors (5,10). These behaviors were reports of lost or stolen prescriptions, consumption in excess of prescribed dosage, visits without appointments, multiple drug intolerances and allergies, and frequent telephone calls. Patients who had one or more of these behavioral "issues" were categorized as having "behavioral issues."

Demographic features were tabulated descriptively. Descriptive statistics were used to describe the proportion of patients with positive urine toxicology screens and behavioral issues. Standard nonparametric tests were used for univariate comparisons. Logistic regression was used to model the effects of age, sex, and issues on urine toxicology. Goodness of fit was assessed by using diagnostic plots, changes in deviance, and the inclusion of interaction terms. A P value <0.05 was used to indicate statistical significance, and no adjustments were made for multiple comparisons. Ninety-five percent confidence intervals are reported.

Results

One-hundred-twenty-two patients with noncancer pain treated chronically with opioids were identified. The mean patient age was 45 ± 11 yr, with a range of 22 to 82 yr, and 51% (n = 62) were male (Table 1). Eighty-nine percent (n = 109) were non-Hispanic Caucasian, 0.8% (n = 1) were African American, 2% (n = 2) were other nonwhite, and race was not available for 8% (n = 10) of the patients. The leading diagnoses identified were failed back surgery syndrome (18%), low back pain (11%), neuropathic pain (7%), and lumbar radiculopathy (7%). Seventeen percent (n = 21) had a history of substance abuse; a substance abuse history was not available for 8% (n = 10) of the patients.

Table 2 depicts the number of patients who had positive and negative toxicology screens compared with patients with and without behavioral issues. Of the 122 patients, 22% (n = 27) had behavioral issues, and 29% (n = 36) had a positive urine toxicology screen. The percentage of patients with positive urine toxicology alone was 21% (n = 26); with behavioral issues alone, this was 14% (n = 17); and with both positive urine toxicology and behavioral issues, this was 8% (n = 10). Fifty-seven percent (n = 69) had neither behavioral issues nor positive urine toxicology.

A "problem" was defined as the presence of either a positive urine toxicology screen or behavioral issues. Monitoring both urine toxicology and behavioral issues identified more patients with a "problem" than either alone, such that each monitoring procedure identified patients missed by the other procedure. Of the 122 patients, 43% (n = 55) had a problem (Table 2). Of the 95 patients with no behavioral issues, 21% (n = 26) had a positive urine screen, compared with 29% (36 of 122) in the overall population. Of the 86 patients with a negative urine screen, 14% (n = 17) had one or more behavioral issues, compared with 22% (27 of 122) in the entire population. Monitoring patients with behavioral observations alone would have missed 49% of the patients with problems; monitoring with urine toxicology alone would have missed 32% of patients with a problem. Urine toxicology monitoring alone identified 26 (49%) of the 53 problem patients; behavioral monitoring alone identified 17 (32%) of the

Table 1. Demographic Summary of Patients Treated at Brigham and Women's Hospital (BWH) and Dartmouth Hitchcock Medical Center

Variable	BWH	Dartmouth	Total
Education			
No high school	0	1	1
Some high school	0	13	13
High school graduate	7	30	37
Some college	2	13	15
College graduate	7	16	23
Advanced degree beyond college	1	2	3
Information not available	29	1	30
Race			
Caucasian	34	75	109
African American	1	0	1
Other non-Caucasian	1	1	2
Information not available	10	0	10
Insurance			
Private	30	29	59
Medicare	8	17	25
Medicaid	0	17	17
None	8	9	17
Workman's compensation	0	3	3
Information not available	0	1	1
Diagnosis			
Failed back surgery syndrome	2	20	22
Low back pain	13	0	13
Neuropathic pain	6	3	9
Lumbar radiculopathy	2	6	8
Fibromyalgia	1	5	6
Other	22	42	64

53 problem patients. Thus, urine toxicology monitoring captured 17% more of the problem patients than monitoring of behavioral issues.

Fifteen percent ($n = 18$) of all patients had 1 behavioral issue, 5% ($n = 6$) had 2 issues, and 3% ($n = 3$) had 3 issues. Of the patients with one behavioral issue, the most prevalent was consumption in excess of the prescribed dosage, which occurred in 56% ($n = 10$) of this subgroup. Patients with at least one issue were 1.35 times more likely to have a positive toxicology screen (95% confidence interval, 0.75–2.44) (Fig. 1).

Fifty-seven percent ($n = 26$) of the 46 positive urine toxicology screens were positive for an illicit drug, and 37% were positive ($n = 17$) for a nonprescribed controlled drug (Table 3). Seventeen percent ($n = 8$) of these positive urine screens were positive for an opioid that was not prescribed. The only illicit drugs detected were cocaine and marijuana. Seven percent ($n = 3$) of these patients tested positive for ethanol. Twenty-two percent ($n = 10$) of the patients with a positive toxicology screen tested positive for two or more substances.

Fifty percent ($n = 31$) of men had a problem, compared with 37% ($n = 22$) of women ($P = 0.14$). Forty percent of men compared with 18% of women had positive urine toxicology ($P = 0.007$). The probability of a problem was greatest in the younger patient groups (Fig. 2), with 61% of the patients younger than 40 yr and 30% of those older than 60 yr having a problem ($P = 0.001$). A signed treatment contract, documented in 64% ($n = 78$) of the patients, stipulated the requirement for urine toxicology testing (information on the contract was not available for 8% [$n = 10$] of the patients). Of the patients with a contract, 46% ($n = 36$) had a problem; of those without a contract, 35% ($n = 12$) had a problem ($P =$ not significant). Of patients with a documented history of substance abuse (other than smoking), 52% ($n = 11$) had a problem, whereas 39% ($n = 37$) of patients without such a history documented had a problem ($P =$ not significant).

Table 2. Proportions of Patients with Behavioral Issues or Positive Urine Toxicology Screening

	Issues		
Urine toxicology	Yes	No	Totals
Positive	10 (8%)	26 (21%)	36 (29%)
Negative	17 (14%)	69 (57%)	86 (71%)
Total	27 (22%)	95 (78%)	122

Discussion

The primary aim of this report was to describe the results of urine toxicology screens and behavioral monitoring in patients with chronic noncancer pain prescribed opioids for daily use. Approximately 810,000 Americans regularly use heroin, and 3.6 million are regular cocaine users, according to the White House's Office of National Drug Control Policy (11). The use of these drugs is not a modern-day phenomenon. Opium has been used by humans since prehistoric times, and throughout the 19th century it was as widely used in Britain, Western Europe, and America as aspirin or acetaminophen are today (12). It is not surprising that the prevalence of drug abuse, dependence, or addiction in chronic-pain patients in the United States has been reported to range from 3.2% to 18.9% (13).

Extrapolating from other populations in an attempt to define a population baseline for marijuana use among chronic-pain patients is difficult. There are no prior reports of prevalence of marijuana use validated by urine testing in patients with chronic pain. A recent study showed that 4.3% of commercial tractor-trailer drivers tested positive for marijuana (14). This figure does not include the 19% of drivers who refused to supply an anonymous sample. Five percent of "low average risk" and 17% of "high average risk" adolescents tested positive in another study (15). Before September 11, 2001, 4.4% of a sample of adult residents of Manhattan, NY, anonymously reported marijuana use, compared with 5.7% after September 11; the increased use was presumably related to stress (16).

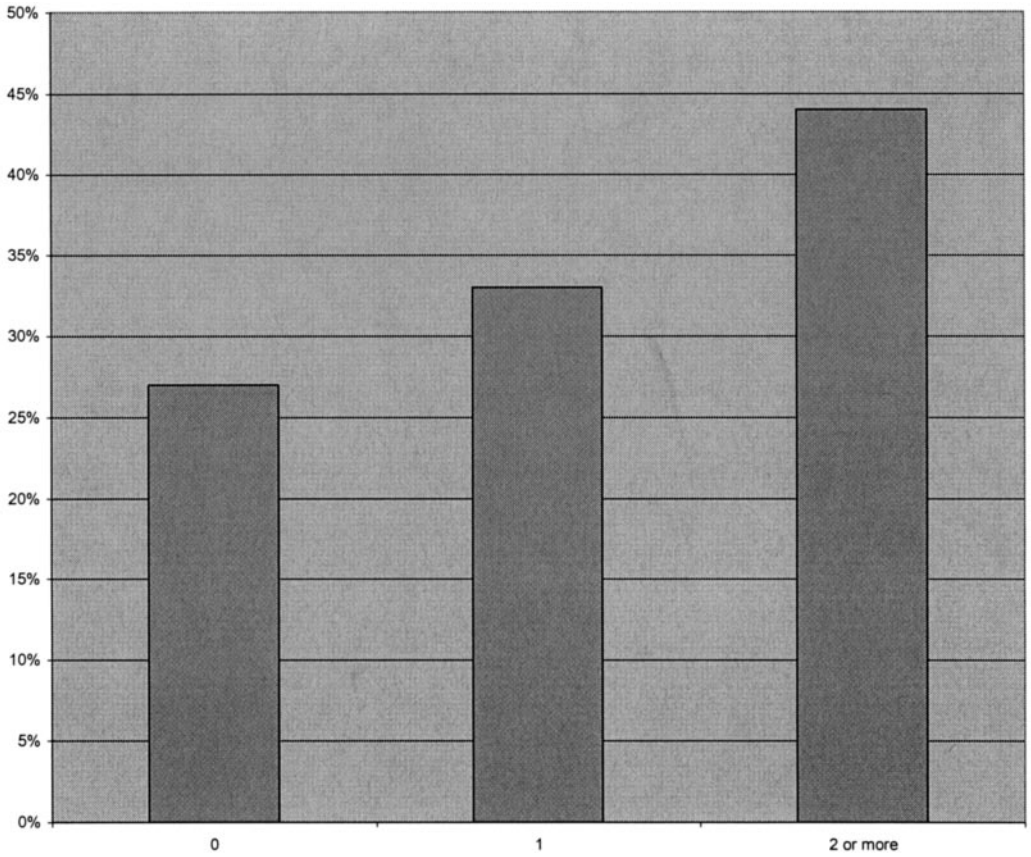

Figure 1. Probability of positive urine toxicology by number of issues ($P = 0.522$).

Table 3. Inappropriate Drugs Identified in Patients' Urine, Based on All Specimens: Patients May Be Represented More Than Once

Substance	Total
Illicit drugs	
Cocaine	6
Marijuana	20
Nonprescribed licit controlled drugs	
Opioids	8
Barbiturates	3
Benzodiazepines	5
Other	1
Ethanol	3
TOTAL	46

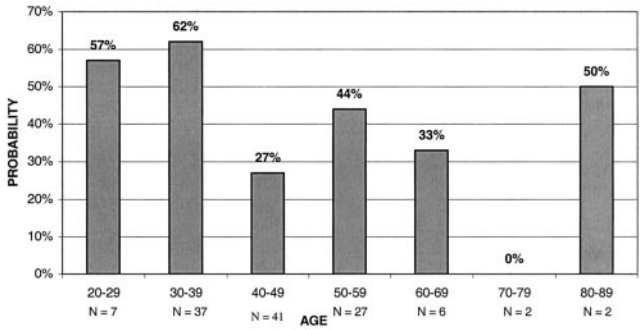

Figure 2. Probability of either a behavioral problem or inconsistent urine toxicology by age. The odds of either a behavioral problem or inconsistent urine toxicology were modeled as a function of age by using logistic regression. For each decade of age, the odds of both decreased by 0.71 (95% confidence interval, 0.50–1.01).

Twenty of 122 patients in this report had urine toxicology reports demonstrating the presence of marijuana. This prevalence of 16.4% seems to be more closely allied with the "high average risk" adolescent group than with a more normal population sample.

The long-term use of opioids for chronic noncancer pain is growing exponentially in the United States, particularly in the primary care setting. The increased willingness to prescribe opioids derives from a number of scientific, political, and cultural influences. These include scores of outcome studies in cancer and in acute pain suggesting safety and efficacy (17), a few outcome studies in chronic noncancer pain (10), regulatory imperatives to relieve pain (18), and the imperative to provide pain relief implicit in the discussion of euthanasia (19).

However, many physicians remain unconvinced of the safety of long-term opioid treatment in noncancer pain, mainly because of fears of addiction and tolerance (2). Physicians generally judge whether their

treatment is conferring benefit or harm by patient self-report, physical examinations, and laboratory tests. Unfortunately, each of these methods has serious inadequacies in determining the effect of opioids on chronic pain. Patient self-report of medication and drug use is unreliable (6,7), and neither physical examinations nor laboratory tests can measure pain or its relief (20). Patients may report inaccurately despite appropriate intentions or may actively seek to deceive for a variety of reasons (21,22). The published literature does little to reassure about the safety of opioids vis-à-vis addiction, because no published prospective outcome study has incorporated any specific definition of addiction or method of measuring addiction. Published guidelines on the use of opioids for chronic noncancer pain all agree that close patient monitoring for benefits and harm is important (23). Unfortunately, specific methods for monitoring patients for harm from opioids have not been validated.

The question arises: why is it important to recognize illicit or nonprescribed drug use in our chronic-pain patients being treated with opioids? It is important because our patients may suffer from the disease of addiction, and we may not have other means of making this important diagnosis. The diagnosis is important because treatment for addiction is possible and because we harm our patients by not identifying this disease and implementing the proper treatment. We harm our patients by prescribing opioids to them when they may need detoxification from opioids, inpatient drug treatment, and continuing treatment for their addiction.

Our patients may be diverting the drugs we prescribe to an illegal market, and by failing to identify patients who may be diverting opioids, we may be contributing to the sustenance of an underground criminal subculture. We may also be unintentionally responsible for opioid overdoses and deaths and for the possible addiction of persons who acquire these drugs illegally (24). Our patients may have a pseudoaddiction, or they may be self-medicating an unidentified anxiety disorder, bipolar disorder, or posttraumatic stress disorder, and identifying a marker, such as inconsistent urine toxicology results, may stimulate the provider to delve more deeply into the patient's problems.

It is at least equally as important and perhaps more important to include urine toxicology testing because it helps to validate and destigmatize (25) our patients with consistent urine results, with or without aberrant behaviors that have been poorly correlated or not correlated at all with the above conditions.

In this study, 43% ($n = 53$) of 122 patients receiving long-term opioid therapy for chronic nonmalignant pain had a "problem," defined as the presence of either a positive urine toxicology screen or at least one behavioral issue. Positive urine toxicology was defined as ethanol, an illicit drug, or a nonprescribed controlled drug. The behavioral issues we chose to monitor, based on previous work (5), were reports of lost or stolen prescriptions, consumption in excess of prescribed dosage, visits without appointments, multiple drug intolerances and allergies, and frequent telephone calls. We found that monitoring of urine toxicology was more effective at identifying problem patients (as we defined it) than monitoring behaviors alone and that monitoring behaviors alone would have resulted in missing approximately half of the patients with problems. An increased probability of positive urine toxicology with an increasing number of inappropriate behaviors supported the internal validity of this process. We chose not to label urine devoid of the prescribed opioid as a "positive" test, because of concerns about the accuracy of existing tests in detecting therapeutic concentrations of several commonly prescribed opioids.

Urine toxicology screening has an important potential role in the management of patients receiving chronic opioid therapy and is already standard in the addiction treatment setting (26,27). The relatively large proportion of patients in our sample with urine toxicology results divergent from their implied self-report suggests that self-report of compliance alone is an insufficient screening tool and that safety monitoring would be enhanced by routine urine toxicology screening. Furthermore, because the presence of behavioral issues did not predict urine toxicology results, our data do not support monitoring only patients selected on the basis of aberrant behaviors. Instead, our results suggest that all patients receiving long-term opioid treatment for noncancer pain should be monitored with urine toxicology testing.

Our results also question the validity of previous studies on the safety of long-term opioid therapy related to addiction, which have monitored patients for addiction solely on the basis of unspecified aberrant drug-taking behaviors (3,5,28–30). In this study, 72% (26 of 36) of patients with positive urine toxicology screens indicative of potential addiction or diversion did not evidence any of the behaviors thought to be useful screening tests for these disorders. This finding should lead to a reappraisal of previous research studies as perhaps less reassuring than previously thought.

Patients in this study were aware that urine toxicology screens would be obtained on most visits and had ample opportunity to appear compliant with their contracts by avoiding intake of inappropriate drugs for a few days or weeks before their visit, yet they did not do so. It is possible that the problems identified in this study represent a significant underestimate of inappropriate drug-taking behavior compared with what would be seen with more frequent testing.

There are many limitations to this study. The major limitation is that there is no accepted definition for addiction in the setting of opioid use for chronic pain (31). The predictive value of any screening test, such

as urine toxicology or behavioral screening for addiction, can be assessed only in comparison to a "gold standard" diagnostic test, which does not exist for addiction in the setting of chronic pain. In fact, there are multiple syndromes of concern that complicate opioid therapy (e.g., addiction, diversion, pseudoaddiction, and self-medication for psychological symptoms), which are quite different and which may well require different diagnostic approaches. It is therefore not possible to know the diagnostic value of either positive urine testing or our behavioral issues. For example, it is not possible to know whether a positive screen for marijuana represents a problem with the patient's analgesic regimen or whether a period of frequent telephone calls represents a problem with the patient or the clinic. It is also likely that somewhat different results would have been obtained with a different set of behavioral issues. Additional limitations include the retrospective nature of the study, the variability of monitoring regimens across centers and patients, and the limited sample size.

In conclusion, our patients receiving opioid therapy in two university pain management centers showed a significant prevalence of noncompliance with regard to consumption of nonprescribed medication and illicit substance use. A significant number of patients had positive urine toxicology screens in the absence of obvious aberrant drug-taking behavior. This study highlights the limitations of previous clinical trials and drug development programs that address the addiction risk of opioids. We recommend routine urine toxicology screens in the clinical management of all patients receiving opioid therapy and in clinical trials of opioids for chronic pain. Further research is needed to better define addiction and related complications of opioid therapy, to develop diagnostic procedures for these disorders.

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