The Interface Between Pain and Drug Abuse and the Evolution of Strategies to Optimize Pain Management While Minimizing Drug Abuse

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Pain management is facing continued undertreatment of pain despite a growing problem with prescription opioid abuse. This has created a tension among prescribers and feelings of helplessness with regards to what constitutes appropriate practice. This article provides a review of pain management efforts and focuses on two key areas of potential interest. First, the emergence of prescreening tools for identifying appropriate candidates for opioid therapy are introduced and discussed, including the Opioid Risk Tool (ORT), the Screener and Opioid Assessment for Patients with Pain (SOAPP), and the Pain Assessment and Documentation Tool (PADT). In addition to these screening efforts, a novel concept of “in and out of the box” prescribing is presented, focusing on five areas of concern for judging whether one’s prescribing patterns are matching peer prescribing patterns. While more work needs to be done, the discussion of these areas should offer some questions for self analysis by physicians regarding their prescribing patterns. Overall, the authors must embrace the concept of rational pain management and assess patients for risk both before writing the first opioid prescription for them and thereafter. In addition, we must remember that good pain management should lead to some decreases in pain perception for the patient combined with a corresponding increase in ability to function. By reviewing these tools and proposed novel guidelines for in/out of the box prescribing and adopting them into practice as appropriate, the physician will take a significant step in providing effective pain management while minimizing risk of opioid misuse.

Keywords: pain, pain management, addiction, abuse, risk screening

Chronic pain continues to be a major health concern in the United States. Impacting approximately 75 million Americans, loss of productivity amounts to more than 60 billion dollars per year; quality of life often decreases for these patients; and they rarely experience significant pain relief for their condition (ABC News, 2008; American Pain Foundation, 2006; McCarrberg & Billington, 2006; Stewart, Ricci, Chee, Morganstein, & Lipton, 2003). Indeed, chronic pain affects physical, psychological, and social well being, and patients frequently experience sleep disturbance, depression, and anxiety (Argoff, 2007). Thus, despite advances in the knowledge of pain pathophysiology, the understanding of treatments, and the development of multidisciplinary approaches to pain management, pain care is still grossly inadequate.

Given the importance of pain and the prevalence of the problem, it might be surprising to think that many health care providers wish to avoid becoming involved with the concerns of the pain patient. However, there are several complicating factors that might explain the reluctance. First, the treatment of pain is complicated and often requires a multidisciplinary approach, which is becoming increasingly difficult to provide with poor reimbursement from managed care organizations. Second, chronic pain is not usually associated with sympathetic arousal and, therefore, the objective signs of physiological stress are often absent. Patients with chronic pain may not appear to be in physical pain, sometimes leading to skepticism by observers, which is particularly true when past histories of substance problems or the potential use of opioid medications are involved. Finally, with the souring of the regulatory climate and the growth of prescription drug abuse, there has been a trend for clinicians to shy away from using opioids (Cicero, Inciardi, & Munoz, 2005; Lipman, 2005).

In an effort to address the fears of clinicians, several instruments have been created to help with screening and ongoing management of pain patients being considered for opioid therapy. This does not answer all of the needs, however, and a novel set of guidelines and criteria are proposed that physicians can use to determine whether their prescribing patterns are within the guidelines of peer prescribing or of they are going outside the bounds of accepted opioid management. These concepts are the focus of the remainder of this article.

The Interface of Pain and Drug Abuse

Despite pain being undertreated in this country, we have seen a trend for an increase of prescribing in the country.
Almost every class of analgesia has had substantial increases in prescribing during the last three years, with hydrocodone compounds being the most widely prescribed medication in the United States (Volkow, 2008). With the wider availability of opioids has also come a much larger concern about public abuse. From 2002 to 2005, there were 190 million prescriptions for opioids in the United States, resulting in 9.4 billion doses (Substance Abuse and Mental Health Services Administration [SAMHSA], 2007b). In 2005, for the first time, opioids displaced marijuana to become the new illicit drug of choice (SAMHSA, 2006). A year later, the National Survey on Drug Use and Health data showed a minimum of 430 million abused doses (SAMHSA, 2006). Thus, clinicians are placed in a difficult position wherein they acknowledge on one hand that opioids are effective but are faced with the potential that they might be contributing to drug abuse and diversion on the other. Unlike any other medication class, opioid prescribing requires documentation of informed consent or a treatment agreement.

With the dilemma of treating pain while avoiding abuse and diversion, it is crucial that proper assessments be performed to help sort out genuine pain patients versus those more interested in the abuse potential of these medications. Chronic pain assessment should include a detailed assessment of the pain itself, including intensity, quality, location, and radiation of pain. In addition, identification of factors that increase and decrease the pain should be elicited as well as a review of the effectiveness of various interventions that have been tried to relieve the pain. Also, the impact of pain on sleep, mood, level of stress, and function in work, relationships, and recreational activities should be assessed, since improvement in these areas may be a goal of pain treatment and a measure of the efficacy of interventions. To aid in this endeavor, a number of general screening instruments, such as the Brief Pain Inventory, already exist for the clinical setting (Cleeland & Ryan, 1994; Kroenke, Spitzer, & Williams, 2001; Stratford et al., 1996).

While these tools are useful for a good generalized assessment, we have been sorely in need of screening instruments designed specifically for identifying patients who are more likely to misuse their opioid medications. To answer this, many researchers have recently flooded the literature with a wide variety of assessment tools to examine potential risk when prescribing opioid analgesics. A few of the more promising measures are discussed below.

Tools for Prescreening Patients

Most of the recent research has focused on screening tools which can be used to prescreen patients to determine level of risk when considering opioids as part of the treatment regimen. While mislabeling patients as either a good or bad risk can have negative consequences, safe opioid prescribing relies on proper risk stratification and the accommodation of that risk into a treatment plan. In addition, we must always keep in mind that a spectrum of nonadherence exists and that this spectrum is distinct for pain patients versus those who use these medications for nonmedical purposes (See Figure 1). Nonmedical users can be seen as self-treating personal issues, purely as recreational users, or as having a more severe and consistent substance use disorder or addiction. On the other hand, pain patients are more complex and their behaviors might range from strict adherence to chemically coping to a frank addiction. Thus, scores indicating increased risk on the following tools do not necessarily indicate addiction, but might be uncovering some of the gray areas of noncompliance.

Screener and Opioid Assessment for Patients With Pain

The Screener and Opioid Assessment for Patients with Pain (SOAPP) is a self-report measure with 14 items utilizing a 5-point scale (0 = never, to 4 = very often) and can be completed by patients while they are in the waiting room. Scores from each item are summed to create a total score, with a cutoff score of 8 or greater suggested as the cutpoint to determine risk (Akbik et al., 2006; Butler, Budman, Fernandez, & Jamison, 2004). The SOAPP has undergone a number of iterations and the relatively low cutoff score of 8 or greater was chosen partially to account for the underreporting of behaviors. The SOAPP is an accurate tool for assessing abuse potential in patients considered for opioid therapy and has good psychometric properties, although the data available to date are correlational and not causal in nature. In addition, few demographic and medical data were recorded in the validation of the SOAPP, raising the chance for differences to exist in the cutoff scores among different subpopulations. Despite this, the SOAPP has an active research program behind it and will likely emerge as a clinically relevant tool for years to come.

Opioid Risk Tool

The Opioid Risk Tool (ORT) is made up of 5 yes-or-no self-report items covering issues, such as family and personal history of substance abuse, age, history of preadoles-
cent sexual abuse, and psychological disease (Webster & Webster, 2005). A self-report version is available so that patients can complete it in the waiting room. Alternately, the clinician form can be completed during the patient visit and can be done briefly as part of the patient intake. Positive endorsements are given a score based on patient gender (i.e., a family history of alcoholism equates to a score of 3 for male patients and 1 for female patients), and then the scores are summed for a total score. Scores of 0–3 are associated with low risk, 4 to 7 with moderate risk, and 8 or more with high risk for addiction. The ORT was tested on 185 consecutive patients and displayed excellent discriminatory ability in both men and women for identifying patients who will go on to abuse their medications or develop an addiction, with observed c statistic values of 0.82 and 0.85, respectively. The ORT is useful due to its brevity and ease of scoring, but the face valid nature of the ORT brings up the issue of susceptibility to deception. For many, this will be an acceptable risk tool, but may not be sufficient for all.

Pain Assessment and Documentation Tool

To initiate follow-up once a patient has been started on opioid therapy, it is important to consider four major domains. These domains have been labeled the “4 A’s” (Analgnesia, Activities of daily living, Adverse effects, and Aberrant drug-related behaviors) for teaching purposes (Passik & Weinreb, 2000). The last A, aberrant drug-taking behaviors, is perhaps the most salient when considering whether a patient should remain a candidate for opioid therapy. In short, aberrant drug-taking behaviors is a term encompassing a range of behaviors that may or may not be indicative of addiction in a patient but definitely account for behaviors that need to be addressed and corrected. Examples of aberrant drug-taking behaviors less indicative of addiction can include increase in medication dose without authorization, requesting frequent early renewals, and appearing unkempt. More egregious aberrant drug-taking behaviors include doctor shopping, changing route of administration of medications, and forging prescriptions.

In application, Passik and colleagues (2004, 2005) set out to field test a short form that could be used as a charting note. The Pain Assessment and Documentation Tool (PADT) is a simple charting device based on the 4 As that focuses on key outcomes and provides a consistent way to document progress in pain management therapy over time. The PADT is a two-sided chart note that can be easily included in the patient’s medical record. It is designed to be intuitive, pragmatic, and adaptable to clinical situations. With regards to time burden, it took clinicians between 10 and 20 minutes to complete the original tool and the revised PADT is substantially shorter and only requires a few minutes to complete. The PADT does not provide strict scoring criteria, as it is meant as a charting tool, but evidence from the trials suggests that four or more aberrant behaviors in a 6 month period predicts abuse and possibly true addiction.

Prescribing in and out of the Box

Should the physician decide that a patient appears to be an acceptable risk for opioid therapy based off one or more of the above screening tools along with clinical judgment, another set of criteria should come into play. Medicine is a peer-practiced art and science and thus requires that some thought be given to what other physicians are doing in their own practices. Where possible, some form of consensus should be established as standards of care while still acknowledging that a great deal of variability exists between physicians’ philosophies and patients’ responses and analgesic requirements.

To this end, the authors propose a novel concept that may help afford clinicians prescribing opioids an early chance to review the status of a particular patient. This concept of monitoring opioid prescribing proposes that prescribing patterns can be viewed as either “in or out of the box.” Prescribing “in the box” refers to the prescribing of opioids in a usual and customary fashion similar to that of their colleagues. Conversely, prescribing “out of the box” refers to prescribing opioids in a manner that deviates from the usual prescribing habits of the majority of physicians writing opioid prescriptions. It is important to realize that there is nothing inherently wrong with prescribing “out of the box” and there may be excellent reasons to do so. However, this concept may be helpful as a mechanism to alert certain prescribers to the fact that they are no longer in line with the usual prescribing practice of the majority of their colleagues and so may decide to increase the degree, amount, or rigor of documentation.

It may be extremely appropriate to prescribe “out of the box” long-term for many decades on any given individual patient. The purpose of this label is not to highlight a prescriber as doing something wrong or aberrant but to serve to help notify prescribers that they are prescribing “out of the box” for a given patient to ensure that they are aware of this so that they can choose to act (only if appropriate) or do nothing. Although experienced experts in pain medicine may “know” when they are prescribing “out of the box,” novices and health care providers from other disciplines of medicine may not. Thus, we will arbitrarily create criteria that define “in and out of the box” prescribing in attempts to be helpful to those clinicians.

Factors Which Define Prescribing “In or out of the Box”

Five factors are proposed to be important in defining whether a clinician is prescribing “in or out of the box” (See Figure 2). Some of the factors have clear cut-points while others do not. The factors are discussed in turn below.

The first factor concerns the type of pain complaint. Is the pain complaint or syndrome controversial or less common when considering opioid therapy (e.g., headaches)? The second factor is whether or not the patient has active psychiatric or substance abuse issues. While not all psychiatric disorders will be complicating factors, things such as depression, bipolar disorder, any impulse control disorders, and substance use disorders will complicate care and may indicate out of the box prescribing. The third factor to
consider is whether the patient has a significant amount of contact with nonmedical users of opioids. While difficult to determine at times, physicians learning of this social influence need to consider whether this pushes prescribing into a different category. The fourth factor is patient age. While exceptions definitely exist, problems of abuse and addiction are usually associated with younger adults and this age group does increase risk of outside the box prescribing. Finally, the amount of opioid prescribed is the final factor to consider.

Of all the factors mentioned above, opioid amount is beginning to have the most clear cutpoint for determination of in or out of the box prescribing. The doses used in controlled studies are generally in the moderate range (up to 180 mg of morphine or a morphine equivalent per day), although a few patients received higher doses (Ballantyne & Mao, 2003; Haythornwaite, Menefee, Quatrano-Piacentini, & Pappagallo, 1998; Raja et al., 2002). Daily doses above 180 mg of morphine or a morphine equivalent duration involving patients with chronic noncancer pain have not been validated in clinical trials of significant size and, thus, may be considered the high watermark for appropriate prescribing among peer physicians as reported in the literature (Ballantyne & Mao, 2003).

Factors that may lead to opioid prescribing “out of the box” may include:

a) Progression of the patient’s painful condition;
b) Development of a new painful condition;
c) Development of opioid tolerance/hyperalgesia;
d) Increased spiritual/ emotional or socioeconomic suffering;
e) Chemical coping;
f) Pseudoaddiction: Drug-seeking behavior for the appropriate purpose of pain relief, rather than abuse or substance misuse (Weissman & Haddox, 1989). It is characterized by a demand for more medication for analgesic purposes, as well as by behaviors that appear similar to those seen in addicted patients (e.g., anger, hostility). Pseudoaddiction can be differentiated from drug misuse by increasing the dose by an appropriate amount and determining whether the complaints abate;
g) “Prescriber style” (e.g., aggressive opioid titration, perhaps with intent to entirely eliminate pain);
h) Pseudotolerance (e.g., increased physical activity, drug interactions): A situation in which opioid dose escalation occurs and appears consistent with pharmacological tolerance but, after a thoughtful evaluation, is better explained by a variety of other variables (Pappagallo, 1998);
i) Pharmacokinetic phenomena (e.g., ultrarapid metabolizers; Smith, in press);
j) Pharmodynamic phenomena (e.g., decreased efficiency of the signaling processes of the opioid receptor; Smith, in press);
k) Aberrant drug taking behavior.

Prescribing “out of the box” for any particular individual patient should not necessarily spark efforts to alter one’s prescribing in efforts to get back in the box. Although no specific action is necessary when prescribing “out of the box,” actions that prescribers may choose to take include a) consultation or referral to a pain specialist; b) close reevaluation of the patient’s clinical situation (e.g., repeat comprehensive history and physical examination and consideration for further medical work-up); c) careful review of how the prescribing became “out of the box” and over what period of time; d) investigation into the patient’s home and social environment as well as their contacts with nonmedical users and where their pain medications are stored (e.g., whether they are secured in a locked space and who may have access); or e) increase the degree of documentation and/or patient monitoring. Certain prescribers, such as pain specialists who care for complex challenging patients with persistent pain, may appropriately prescribe “out of the box” often.

If after careful consideration of the individual patient’s situation or discussion with a pain specialist a prescriber chooses to attempt to “get back in the box,” potential therapeutic options that may be helpful include opioid rotation; addition of other medications (e.g., anti-inflammatory agents, adjuvant analgesics like antidepressants and antiepileptic drugs); the addition of behavioral medicine treatment approaches; the addition of physical medicine treatment approaches; the addition of interventional treatment approaches; the addition of neuromodulation treatment approaches; a change to opioid administration intraspinally (with or without additional agents; Smith et al.,
in press); and/or the addition of complementary and alter-
native medicine treatment approaches.

Conclusion

Chronic pain issues are not going away and simply ig-
noring this health concern is not the answer. Over the past
two decades, clinicians have struggled to reach a consensus
on proper opioid prescribing, and physicians still fear the
risk of abuse or addiction as well as the potential legal
consequences of their prescribing. Therefore, we must em-
brace the concept of rational pain management and assess
our patients for risk both before writing the first opioid
prescription for them and thereafter. While the psychomet-
rics of various screening tools still require further evaluation
and the in/out of the box concept needs further refinement,
we must remember that good pain management should lead
to some decreases in pain perception for the patient com-
bined with a corresponding increase in ability to function.
By reviewing these tools and proposed novel guidelines for
in/out of the box prescribing and adopting them into prac-
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