A CLINICAL TRIAL

DEVELOPMENT OF A SCREENING TOOL TO DETECT THE RISK OF INAPPROPRIATE PRESCRIPTION OPIOID USE IN PATIENTS WITH CHRONIC PAIN

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Background: Effective use of opioids in patients with chronic pain has been hindered by their potential for drug abuse. There are no reliable means to distinguish those who use the opioids in an inappropriate manner from those who do not.

Objective: To develop a screening tool to distinguish patients at risk for inappropriate prescription opioid use among patients with chronic pain.

Methods: We conducted a case-control study of adults with chronic pain. Patients dismissed from the pain clinic for inappropriate prescription opioid use were placed in the "inappropriate opioid use group". Randomly chosen patients with chronic pain on opioids, who did not have any evidence of inappropriate use were in the "control group". We performed a review of the clinical notes of all the patients enrolled in the study and extracted clinical criteria. We analyzed these criteria to identify independent predictors of inappropriate opioid use. Based on these criteria, a screening tool was developed to stratify patients into low-and high-risk categories. This screening tool was then applied to both groups.

Results: There were 107 patients in the inappropriate use group and 103 patients in the control group. On multivariate analysis, six criteria were significantly associated with inappropriate drug abuse. These included focus on opioids, opioid overuse, other substance use, nonfunctional status, unclear etiology of pain, and exaggeration of pain. A screening tool was developed by giving one point to each of these criteria so that a patient's score can range from 0 to 6. In the "inappropriate opioid use" group, 77% of patients scored more than 3 points as opposed to 16% in the control group. In the "inappropriate opioid use group", 23% scored 3 or less, in comparison to 84% in the control group.

Conclusion: We have identified six clinical criteria, which were significantly more prevalent in the 'inappropriate opioid use group'. Using these criteria, we have developed a screening tool that appears to predict inappropriate use of prescription opioids in patients with chronic pain.

Keywords: Screening tool, chronic pain, inappropriate opioid use, drug abuse

Management of chronic nonmalignant pain with opioids is currently one of the most challenging and controversial topics in the field of medicine. The rationale for advocating opioids is primarily because they can be effective in pain control in patients with chronic pain (1, 2) especially when other modalities have failed or have resulted in intolerable side effects. Additionally, there is evidence, based on opioid treatment of cancer pain that prolonged administration of moderate to high dose opioids does not lead to organ toxicity, unlike some non-opioid analgesics. Also in cancer pain patients, several reports have assured us that there is a low tendency for development of tolerance for analgesia.

Along with an awareness of a positive role of opioids in chronic pain and the subsequent increase in the use of opioids, a parallel escalation of prescription drug abuse has been noted. Recent reports from DAWN (Drug Abuse Warning Network) show that opioid abuse has increased to a significant extent (163%) over the last 7 years (3). The incidence of prescription opioid abuse in *chronic pain* ranges from 3% to 28% (4). Manchikanti et al (5) reported that drug abuse in patients in the interventional pain management setting varied from 18% to 24%. Chabal et al (6) using abuse criteria, found an incidence of abuse of 28% (6). Manchikanti et al (7) also showed that in patients without a history of drug abuse, the incidence of inappropriate use of opioids was 16%.

A questionnaire survey of physicians done by Potter et al (8) revealed that the greatest barrier for using opioids is the fear of dependence. The pain management community is in dire need of a screening tool, which can detect inappropriate prescription opioid use among patients with chronic pain (9). Existing tools in the psychiatric literature that address the issue of drug abuse were recently summarized by Robinson et al (9). In essence, most of these tools are limited by the fact that they are largely subjective and are not specifically designed to detect prescription drug abuse. Subjective screening tools may not be accurate as patients who use drugs inappropriately may not report in a truthful manner as they are concerned about the loss of prescription opioids (10, 11). Robinson et al (9) concluded that the area of screening for problematic drug behavior in chronic pain is still in its infancy. McQuay (12) in an editorial emphasized the lack of good tools to identify patients with potential for addictive behavior. Passik and Kirsch (13) also reiterated this opinion.

We conducted a study to identify clinician rated predictors of prescription opioid abuse among patients with chronic pain on opioids and to determine if such criteria could be used to develop a screening tool in order to stratify the risk of inappropriate opioid use among patients with chronic pain.

Methods

A case-control study was conducted at a community pain clinic. The study was comprised of patients treated between 1998-2001.

Due to retrospective nature of the study, no informed consent was obtained. All patients provided consent for urine drug testing and publication of results. Appropriate precautions were taken to protect the privacy and identity of patients included in the study. Patients included in this study were being treated with opioids for chronic pain (duration of pain > 6 months). All patients were more than 18 years old. Patients with acute pain and cancer pain were excluded from the study.

The patients were divided into two groups. The "Inappropriate opioid use group" consisted of 107 consecutive patients who were dismissed from the clinic for inappropriate use of prescription opioids. The reasons for dismissal included: inappropriate urine drug screen, intentional "doctor shopping" (seeking medications from different prescribers), alteration of the opioid prescription to obtain more opioids, and criminal activity involving prescription opioids. Most of these patients (89%) were included in this group because they had inappropriate urine drug screens.

The "Control Group" consisted of randomly chosen patients with chronic pain on opioids who did not exhibit any clinical evidence of inappropriate opioid use as described above. These patients were then subjected to random urine drug screen (UDS). The patients who passed the drug screen were placed into the control group and those who failed were transferred to the inappropriate opioid use group. A total of 103 patients constituted the control group.

Urine drug screening was preceded by completion of a questionnaire during which the patients were unaware that a drug screen was imminent. The following questions were addressed.
1. Are you taking pain medications regularly?
2. When was the last opioid dose taken?
3. Are you using any illicit drugs (Marijuana, Cocaine, PCP, Heroin)?
4. Are you taking pain medications from any other physician?

After the questionnaire was completed, patients were then informed about the UDS.

Table 1. *The description of six criteria utilized in the study*

1. Focus on opioids
- Not interested in non opioid modalities
- Not interested in workup of pain or referral for workup
- Physician feels that patient is focused on opioids
- Demanding opioids
- Angry if denied opioids
- Asking for higher doses of opioids
- Asking for opioids on the first visit
- Asking for and/or insisting for specific opioids
- Claim allergies to all/most non opioid analgesics

2. Opioid overuse
- Self dose escalations and asking for more
- ER visits for opioids
- Asking for opioids on weekends and after hours
- Stolen/lost prescriptions and asking for more
- Taking opioids from nonphysician sources
- Excuses to obtain additional opioids
- Hospitalization for unexplained exacerbation of the chronic pain

3. Other drug use
- Prior alcohol abuse or illicit drug abuse
- current use or asking for benzodiazepine/soma
- current use or asking for barbiturates
- current use or asking for stimulants

4. Low-functional status
- getting financial assistance(non-retirement) from the State
- getting disability benefits
- Applying for or planning to apply for disability benefits
- On BWC, but not working and getting financial assistance from BWC

5. Etiology of pain unclear
- History, physical exam and investigations unclear in explaining pain symptoms
- Nonphysiological pain patterns like diffuse pain, whole body hurting, pain radiating up or down the spine
- Inconsistent pain patterns
- Investigations normal
- Investigations don't explain or correlate with the symptoms
- Physician feels that the etiology of pain is unclear

6. Exaggeration of pain
- Exaggeration of pain symptoms
- Positive Waddell signs
- Unexplained moaning and groaning with slight movement
- Unexplained difficulty with movement
- Exaggerated facial expressions during physical exam
- Unexplained extreme limitation in the range of motion of the spine or joint
- Cannot clearly justify use of cane or walker or wheelchair
- Unexplained worsening of Pain after physical exam
- Cannot complete physical exam because of pain which cannot be justified
- More than expected tenderness in the area/areas of pain
- Pain out of proportion to the findings on investigations
- Physician feels that patient is exaggerating pain

Table 2. *Checklist for Screening Tool*

1. Focus on Opioids

- Is the patient requesting opioids on the first visit?
- Is patient not willing to try non opioid modalities like interventional therapy, nonopioid medications, physical therapy or behavioral therapy so that opioids are not needed
- Is the patient focused on opioids and/or insisting for opioids or repeatedly asking for higher doses?
- Is the patient not interested in workup?
- Is the patient upset when opioids are denied?
- Is the patient asking/insisting for particular opioid?

2. Opioid Overuse

- was the pain so severe that patient had to go the emergency room on more than one occasion in the last 6 months?
- Was the pain so severe that patient had to borrow opioids from friends or family?
- *Was the pain so severe that the patient had to overuse his medication and call for early refills?*

3.Other Substance Use

- does the patient feel that combination of opioids and benzodiazepines[Xanax, Valium,Ativan,Klonopin,Soma] would help with pain?
- Is the patient on benzodiazepines or soma currently or asking for them?
- Does the patient have history of drug or alcohol abuse in the past?
- Does the patient currently use marijuana and admit to it?

4. Nonfunctional

- is the patient on disability or applying or planning to apply for disability ?

5. Exaggeration of Pain

- does the patient have 'Waddell signs'?
- is the patient exaggerating pain in history or physical exam?
- Is the patient exhibiting 'Pain Behavior'?

6.Etiology of Pain Unclear

- Are the investigations normal or don't correlate with symptoms?
- Is the pain distribution nonphysiological?
- Is the pain 'everywhere'?

For this study purposes, the presence of any of following criteria constituted an inappropriate UDS:

1. Presence of any illicit drugs like cocaine, heroin, or phencyclidine
2. Presence of marijuana (if not reported by patient prior to testing)
3. Presence of opioids other than those prescribed by the treating physician (if not reported by patient prior to testing)
4. Inability to detect a prescribed opioid especially when the patient reports recent and regular use on the pre-drug screen questionnaire
5. Refusal to take the UDS
6. Any evidence of tampering with the urine specimen.

A detailed chart review was performed by the primary author to extract a number of demographic and clinical criteria. The clinical criteria were chosen based on the existing literature and our clinical experience. These chosen criteria included:

1. Focus on opioids
2. Opioid overuse
3. Other substance use
4. Low -functional status
5. Unclear etiology for pain
6. Exaggeration of pain.

The descriptions of these criteria are provided in Tables 1 and 2.

Statistical Analysis

Quality control procedures, database management, and statistical analyses were performed using SAS software. Basic descriptive statistics, including means, standard deviations (SD), ranges, and percentages, were used to characterize the study patients. Univariate analysis was conducted to identify statistically significant differences in the demographic and clinical characteristics between the inappropriate opioid use group and the control group. A multivariate analysis of the criteria with a P-value < 0.05 on the univariate analysis was conducted using step-wise logistic regression after controlling for age and gender of the cohort. Based on the criteria with P-values < 0.05 on the multivariate analysis, a screening tool was constructed to stratify patients into low and high risk for the presence of prescription opioid abuse. A P-value < 0.05 was considered to be statistically significant.

Results

Comparisons of demographic and selected clinical characteristics among both groups are shown in Table 3. On univariate analysis, there were no differences among the marital status, duration or intensity of chronic pain, or prevalence of anxiety or depression between the two groups. Statistically significant differences, however, were seen on analyses of age, gender, etiology of chronic pain, and the six clinical criteria.

When subjected to *multivariate analysis*, age, gender and etiology of chronic pain were not shown to be associated with inappropriate opioid use but *the clinical criteria, however, were shown to be independently associated with opioid abuse* (Table 4).

A screening tool was then developed in which one point was assigned to each of 6 clinical criteria listed so that an individual patient's score could range anywhere between 0 and 6 (Table 5). This screen-

Table 3. *Demographic characteristics controls*

	Inappropriate opioid use group (n=107)	Control Group (n=103)	P-value
Male/Female	60/47	34/69	0.00
Married (%)	60	67	ns
Age < 50 years (%)	82	47	0.00
Type of Pain (%) *Low Back Pain* *Neck Pain* *Diffuse*	 66 7 9	 71 9 7	 ns ns ns
Cause of Pain *NKC* *BWC* *MVA*	 30 30 20	 50 19 12	 0.02 ns ns
Duration of Pain (months)*	95 ± 87	89 ±100	ns
VAS Score*	7 ±1.5	6.7 ±1.6	ns
Psychiatric Illness (%)	38	28.1	ns
Focus on Opioids (%)	91	52	<0.001
Opioid Overuse (%)	61	18	<0.001
Other drug use (%)	78	37	<0.001
Low-functional status (%)	65	37	<0.001
Exaggeration of pain (%)	63	20	<0.001
Etiology of pain unclear (%)	77	41	<0.001
Total score per patient*	4.4 ± 1.2	2.0 ± 1.3	<0.001

* Expressed as mean ± sd; NKC: no known cause of pain, BWC: work related injury with Bureau of Worker's Compensation involved, MVA: motor vehicle accident, VAS: Visual analogue score

Table 4. *Illustration of criteria independently associated with opioid abuse with Multivariate Analysis*

Clinical criteria	Odds Ratio (95% CI)
1) Focus on Opioids	9.2 (95% CI 4.3 – 19.8)
2) Opioid overuse	6.8 (95% CI 3.6 – 12.9)
3) Other Drug use	5.9 (95% CI 3.2 – 10.9)
4) Low-functional status	3.1 (95% CI 1.8 – 5.5)
5) Exaggeration of pain	6.5 (95% CI 3.5 – 12.1)
6) Etiology of pain unclear	4.8 (95% CI 2.6 – 8.6)

CI – Confidence Interval

Table 5. *The Screening Tool*

> 3 points-High risk of Abuse		
≤ 3 points-Low risk of Abuse		
Criteria	**Points**	
	Yes	No
Focus on opioids	1	0
Opioid overuse	1	0
Other drug use	1	0
Low-functional status	1	0
Exaggeration of pain	1	0
Etiology of pain unclear	1	0
Total Score	6	0

score of > 3, whereas only 16% of the control group had a score > 3. Furthermore, patients with a score > 3 (high-risk group) were at a 17-fold increased risk for having inappropriate opioid use than those with a score of ≤ 3 (Odds ratio: 17, 95% CI; 8.3-33). Only 23% of patients in the inappropriate opioid use group scored 3 or less as opposed to 84% in the control group.

More patients in the inappropriate opioid use group when compared to the control group were receiving disability benefits ($P = 0.001$) and were on Medicaid (either primary or secondary) ($P =0.0006$) as seen in Table 8. Despite not having information about disability benefits on 22 patients in the inappropriate opioid use group (loss of patient contact after discharge from clinic), more patients in the inappropriate opioid use group were on disability when compared to the control group. Benzodiazepine use was significantly higher ($P = 0.0001$) in the inappropriate opioid use group.

Discussion

Opioid use in chronic pain can be very effective and at the same time challenging. Diagnosing and treating chronic pain with opioids and dealing with the side effects is relatively easy but the challenge is trying to differentiate between a patient seeking pain relief and a patient seeking drugs for the purpose of abuse. The majority of patients with chronic pain do well on opioids. However, a small but significant number of patients use them inappropriately. Opioids should not be the panacea. They are successful in chronic pain if used only in selected patients. Passik and Kirsh (13) in a commentary, highlighted the need to screen for and identify patients at risk for aberrant behavior among patients with chronic pain treated with opioids. They also stated that in the quest to provide adequate pain management the issues of addiction and aberrant behavior were initially swept under the carpet. Currently, there is no comprehensive, objective and practical screening tool designed to detect opioid abuse in chronic pain. Therefore, we conducted a case-control study and developed a screening tool that can potentially distinguish chronic pain patients who are likely to use opioids inappropriately from those who are less likely to abuse prescription opioids. Previous researchers have identified some criteria (overuse of opioids and overt focus on opioids), which are associ-

ing tool was then applied to both groups. The proportion of patients belonging to both groups with various scores is shown in Table 6.

There was a statistical difference between scores at each level between the groups as shown in Table 6. Based on the sensitivity, specificity, and predictive values, a cut-off score of 3 was considered optimal for separating patients into high- and low-risk for inappropriate prescription opioid use. Patients with a score ≤ 3 were classified as low risk and a score > 3 were classified as high risk for abuse (Table 7). For example, 77% of the patients in the inappropriate opioid use group had a

Table 6. *Proportion of patients belonging to various scoring cut-off value*

Total score	Inappropriate opioid use group N=107	Control Group N=103	P value	Odds Ratio
≤ 2	8% (8)	64% (66)	0.000	22.1 (95% CI 9.7 – 50.4)
> 2	92% (99)	36% (37)		
≤ 3	23% (25)	84% (86)	0.000	16.6 (95% CI 8.3 – 32.9)
> 3	77% (82)	16% (17)		
≤ 4	51% (54)	97% (100)	0.000	32.7 (95% CI 9.7 – 169.6)
> 4	49% (53)	3% (3)		
≤ 5	85% (91)	100% (103)	0.000	
> 5	15% (16)	0%		

CI – Confidence Interval

Table 7. *Proportion of patients belonging to various scoring cut-off value*

Score	Inappropriate opioid use group N=107	Control Group N=103	P value	Odds Ratio
> 3 (High Risk)	77%	16%	≤ 0.001	16.6 (95% CI 8.3 –33)
≤ 3 (Low Risk)	23%	84%		

*Implies that patients with a score > 3 have 17-fold increase in the risk for opioid abuse

CI – Confidence Interval

Table 8. *Prevalence of benzodiazepine use, disability benefits and Medicaid among both groups*

	Inappropriate opioid use group (n=107)	Control Group (n=103)	P value
Patients on Benzodiazepines	61% (65)	34% (35)	0.0001
Patients receiving Disability Benefits	60% (64)	36% (37)	0.0006
Patients on Medicaid Program (primary or secondary)	31% (33)	10% (10)	0.0001

ated with abuse of opioids (6). In addition to these criteria, we added 4 criteria, which we felt were linked to opioid abuse. Our analysis of the data clearly identified these 6 criteria to be independently associated with opioid abuse. The clinical criteria that were shown to be significantly associated with opioid abuse were:

1. Focus on opioids
2. Opioid overuse
3. Other substance use
4. Low-functional status
5. Unclear etiology of pain
6. Exaggeration of pain

A screening tool was designed using a point scoring system, 1 point being allocated to each criterion. Most of patients (77%) in the "inappropriate opi-

oid use" group scored > 3 and low scores (≤ 3) were seen in a significant proportion (84%) of patients in the "Control" group. Thus, this tool was able to visibly stratify the patients into categories of "High" or "Low" risk of inappropriate prescription opioid use.

No screening tool is perfect, especially when dealing with the complex issue of prescription opioid abuse in chronic pain. For instance, 23% of patients in the inappropriate opioid use group scored 3 or less points making them "low risk" for abuse. High scores (i.e., > 3) were, however, not seen in a significant proportion of patients (only 16%) in the control group.

There is considerable debate in the literature regarding the definition of addic-

tion in patients with chronic pain treated with opioids (9). Diagnostic and Statistical Manual of Mental Disorders (DSM III and DSM IIIR and DSM IV) diagnostic criteria, which are used to diagnose drug dependency in the general population cannot be applied to chronic pain patients because these criteria focus on physical dependence, tolerance and withdrawal, which are consistently seen in chronic pain populations treated with opioids. Most of chronic pain patients on opioids would be diagnosed as 'addicted', based on these criteria (9, 14). In contrast, abuse behaviors are frequently seen in this population (4) and can be relatively easily defined and detected. Physicians treating pain are not usually qualified to identify and treat addiction, but they can detect abuse behaviors. Therefore, diagnosing abuse behaviors is more important than detecting addiction in this population (14).

The risk of inappropriate prescription opioid use is probably high and opioids should not be used or used with extreme caution if a patient exhibits one of the following abuse behaviors:

1. Inappropriate UDS
2. Scores high on screening tools
3. Abnormal pill counts
4. Deceives physicians to obtain opioids
5. Uses illegal means to obtain opioids
6. Repeatedly takes more opioids than prescribed by the physician
7. Abuses alcohol and/or other drugs while using opioids
8. Uses opioids for psychological effects and not for pain relief
9. Is addicted (psychologically dependent) to opioids

Some may question the criteria we used to place patients in the inappropriate opioid use group. Their criticism is that this could be 'pseudoaddiction' (15) which is legitimate patients exhibiting abuse behaviors secondary to inadequate pain relief. The idea of pseudoaddiction was based on the experience of one cancer patient who was treated for acute pain in a hospital setting. Its relevance in chronic pain in an outpatient setting is unknown. It is possible that pseudoaddiction may exist in certain patients with chronic pain. Our experience, however, tells us that entertaining the concept of pseudoaddiction in chronic pain without considering the likelihood of opioid abuse may lead to a poor outcome. This view has been echoed by others (16). Chabal and Jacobson (16)

cautioned about the dangers of medicalization of the unproven concept of pseudoaddiction in chronic pain. If we ignore abuse and label it as pseudoaddiction, we may in fact be harming the patient. We realize that pseudoaddiction can sometimes be difficult to differentiate from abuse. In most of these cases, this screening tool can help distinguish between the two and in those where it cannot, the judgment of the physician along with the score can possibly resolve the issue.

Prospective studies are needed to further validate this screening tool. Interrater reliability of the criteria would also be necessary in future studies since some of these criteria are based on a subjective opinion of the physician. Four of the 6 criteria had similar odds ratio (ranging from 4.8 to 6.8) as seen in Table 4. One point was allocated to each of these 4 criteria. Despite the 'Low-functional status' criteria having a lower odds ratio of 3.1, it was still allocated one point because disability information was not available in 22 patients (22.5%) in the inappropriate opioid use group. We believe that the odds ratio for this criterion would have been closer to the other four criteria if we had the disability information in these 22 patients in the inappropriate opioid use group. The only criterion with a different odds ratio (9.1) was 'focus on opioids'. This was still allocated one point to make the screening tool user-friendly.

We would like to emphasize that if a patient is receiving disability benefits, which is one of the 6 clinical criteria, opioids should not be denied when necessary. But if 3 or more other clinical criteria exist in this patient, then opioid use should be prescribed with cautious. Clinical experience has revealed that it is not unusual for legitimate chronic pain patients to score 2 to 3 on our screening tool. This is consistent with the average score of 2 in the control group. However, if patients score 4 or more, it should raise a red flag.

More patients in the inappropriate opioid use group were on the Medicaid program (patients receiving Medicaid either as primary insurance or secondary insurance). More patients in the inappropriate opioid use group were receiving disability benefits compared to the control group (and thus receiving Medicaid as secondary insurance with Medicare as primary). This could explain the higher number of patients on Medicaid in the inappropriate opioid use group.

Along with patient selection, monitoring of patients who are on opioid therapy for chronic pain is vital. Passik and Weinreb (17) introduced a tool which assesses the 4A's (analgesia, activities of daily living, adverse effects, and aberrant behavior) which can aid in monitoring.

In summary, we have identified 6 clinical criteria that independently predict a high risk for prescription opioid abuse among patients with chronic pain. Based on these independent predictors, a screening tool with reasonable sensitivity and specificity was developed to stratify chronic pain patients into high and low risk for the presence of inappropriate prescription opioid use. If externally validated by prospective studies, this model would greatly help the management of patients with chronic pain by denying opioids to those who use them inappropriately and conversely making access easier to legitimate chronic pain patients.

Conclusion

Opioids have an important role in the management of chronic pain. The success of opioid therapy in this setting is largely based on patient selection. The area of screening for prescription opioid abuse is in infancy. This study resulted in the development of a screening tool which may prove to be reliable in chronic pain management. This may provide impetus for further research in this important area.

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