

Original Article

Validation and Clinical Application of the Screener and Opioid Assessment for Patients with Pain (SOAPP)

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Abstract

The Screener and Opioid Assessment for Patients with Pain (SOAPP) is a brief, self-administered screening instrument used to assess suitability of long-term opioid therapy for chronic pain patients. This study presents preliminary data to examine the reliability and validity of the SOAPP as a measure of risk of opioid abuse for patients on opioid medication. Patients taking opioids for noncancer pain (n = 396) from two pain centers completed the SOAPP prior to being placed on opioids for pain. Demographic data, SOAPP scores, and results of urine toxicology screens from the patients' medical records were examined. Patients were divided into two groups of high and low risk of opioid abuse potential based on cutoff scores of 8 and higher on the SOAPP. Results showed that patients in the high-risk group were younger, more likely to be asked to give a urine screen, and had more abnormal urine screens compared with those in the low-risk group (P < 0.05). A combined factor analysis of the SOAPP revealed five factors labeled 1) history of substance abuse, 2) legal problems, 3) craving medication, 4) heavy smoking, and 5) mood swings. Preliminary support was found for the internal reliability and predictive validity of the SOAPP. Current limitations of the SOAPP and future directions for change are discussed. J Pain Symptom Manage 2006;32:287–293. © 2006 U.S. Cancer Pain Relief Committee. Published by Elsevier Inc. All rights reserved.

Key Words

Substance abuse, chronic pain, opioids, addiction, aberrant drug behaviors

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Introduction

There has been a growing use of opioids for the treatment of chronic pain, primarily by providers who prescribe them for chronic non-cancer pain.¹ It is also estimated that between 3% and 16% of the general population has an addiction disorder,²⁻⁵ and increasing attention has been given to the abuse of prescription opioid medication.^{1,6} Some pain centers where opioids are prescribed for pain are overwhelmed with problem patients, and many physicians prescribing pain medication have little training in addiction and/or aberrant drug-related behavior.⁷ These physicians prescribe opioids for patients with chronic pain without an indication of the level of risk for medication abuse.⁸ While substance abuse is prominent in the chronic pain population, there is also a greater potential for inadequate treatment of pain for patients with a history of substance abuse due, in part, to a reluctance of some physicians to address substance abuse issues.^{9,10} Optimal use of opioids must include an evaluation of risk associated with potential abuse of opioid medication.^{8,11}

A number of factors have been identified as potential predictors of substance abuse among chronic pain patients: 1) family history of substance abuse, 2) personal history of substance abuse, 3) history of criminal activity and/or legal problems, 4) regular contact with high-risk people, 5) problems with past employers, family members, and friends, 6) risk-taking or thrill-seeking behavior, 7) heavy tobacco use, 8) history of severe depression or anxiety, and 9) prior treatment in drug rehabilitation programs or Alcoholics Anonymous/Narcotics Anonymous.¹²⁻¹⁴

The use of urine toxicology results has been important in determining whether someone has a substance abuse problem. The results may consist of detection of illicit substance (e.g., cocaine), the presence of a nonprescribed opioid, and/or the absence of a prescribed opioid. Although there is the risk of a false positive, or negative, the use of urine screen results, in addition to self-report of aberrant behavior, can be most useful in identifying those patients at most risk for substance abuse.

There has been considerable interest in the development of a self-administered, brief screening tool to help providers plan

appropriate treatments for chronic pain patients. Several screening tools currently exist to help identify risk for abuse, including the Screening Instrument for Substance Abuse Potential,¹⁵ the Prescription Abuse Checklist,¹⁶ the Prescription Drug Use Questionnaire,¹⁷ the Pain Assessment and Documentation Tool,¹⁸ and the Pain Medication Questionnaire.¹⁹ Limitations of these measures have been identified, and no one scale has been determined to be superior in predicting substance abuse potential.¹² Some of these measures are time consuming, require administration of a structured interview by a trained specialist, or have yet to be validated.

The 14-item Screener and Opioid Assessment for Patients with Pain (SOAPP) was created as a promising brief self-report measure to capture important information in order to identify which chronic pain patients may be at risk for problems with long-term opioid medication (Table 1).¹² An expert panel was asked to identify and rate risk factors of potential problems with opioids in patients considered for opioid therapy. Concept mapping was used by the research team to construct items that represented each of eight conceptual clusters. A 24-item SOAPP (version 1.0) was developed based on this consensus and was administered to 175 patients who were taking opioids for chronic pain and followed for 6 months. Validation of the SOAPP was conducted by identifying those patients exhibiting aberrant drug-related behavior. Of the original 24 items, 14 SOAPP items appeared to predict subsequent aberrant behaviors, suggesting adequate sensitivity and specificity for a screening device. Initial findings suggest that the SOAPP may be a reliable and valid measure of risk potential for aberrant medication-related behavior among persons with chronic pain. The purpose of this study was to further validate the SOAPP among patients with noncancer chronic pain. It was predicted that predominant factors of the SOAPP would be reliably identified, and those with higher scores on the SOAPP would more likely have abnormal urine screens than those with lower SOAPP scores.

Methods

For purposes of this study, we adopted the following definitions accepted by the American

Table 1
Screener and Opioid Assessment for Patients with Pain

Please answer the questions below using the following scale: 0 = never; 1 = seldom; 2 = sometimes; 3 = often; 4 = very often

1. How often do you have mood swings?
2. How often do you smoke a cigarette within an hour after you wake up?
3. How often have any of your family members, including parents and grandparents, had a problem with alcohol or drugs?
4. How often have any of your close friends had a problem with alcohol or drugs?
5. How often have others suggested that you have a drug or alcohol problem?
6. How often have you attended an Alcoholics Anonymous or Narcotics Anonymous meeting?
7. How often have you taken medication other than the way that it was prescribed?
8. How often have you been treated for an alcohol or drug problem?
9. How often have your medications been lost or stolen?
10. How often have others expressed concern over your use of medication?
11. How often have you felt a craving for medication?
12. How often have you been asked to give a urine screen for substance abuse?
13. How often have you used illegal drugs (e.g., marijuana, cocaine) in the past 5 years?
14. How often, in your lifetime, have you had legal problems or been arrested?

Academy of Pain Medicine, the American Pain Society, and the American Society of Addiction Medicine.²⁰ Addiction is a primary, chronic, neurobiologic disease with genetic, psychological, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving. Physical dependence is a state of adaptation that is manifested by a drug class-specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, or decreasing blood levels of the drug and/or by administration of an antagonist. Abuse is the use of any drug in a manner other than how it is indicated or prescribed. Aberrant drug-related behaviors are those that suggest abuse or addiction.

Approval was obtained from the Human Subjects Review Board in each institution. Although the beta-version of the SOAPP contained 24 items, only the 14 items most predictive of aberrant drug behavior were used in this study.¹² Because the SOAPP was created for assessment of patients being considered for or taking opioids for pain, only patients who were eventually prescribed opioids for pain were included. Each of the items on the SOAPP are rated from 0 = "never" to 4 = "very often." Each questionnaire was scored by summing the 14 items. Demographic data and urine toxicology results were obtained from the patients' medical records. Available results of urine toxicology screens were used to identify patients using illicit substances or unprescribed opioids. All data were analyzed with SPSS (Statistical Package for the Social Sciences) v.11.0. Summed

SOAPP scores were used in the analyses, and subjects with missing items were excluded. Relations among demographic data and questionnaire data were analyzed with *t*-tests and Chi-squared analyses, as appropriate. Pearson product moment correlations were calculated, and reliability and principal component factor analyses were run on the combined data set to determine alpha reliability of the items and the number and content of primary factors of the SOAPP.

Results

Three hundred chronic pain patients at a tertiary hospital (Center A) completed the SOAPP; 238 were prescribed opioids for pain and were included in the analyses. A comparison group of 319 patients with chronic pain treated at a Veterans Administration (VA) Pain Center (Center B) also completed the SOAPP during their initial visit; 159 were prescribed opioids for their pain and were included in the analyses. Patients from Center A ranged in age from 18 to 88 years (mean 45.7 ± 10.6); 87.4% were Caucasian, 47.1% were male, and 43.9% reported low back as their primary pain site. Twenty-seven percent were taking both short- and long-acting opioids for pain. Patients from Center B ranged in age from 27 to 86 years (mean 59.4 ± 12.5); 98.1% were male and 33.5% reported low back as their primary pain site. Although specific data were not available on race, it was estimated by the staff at Center B that 70% of the population were Caucasian, 25% black, and 5% Hispanic. Sixty-six percent of these patients had a service-connected injury (i.e., pain resulted from

injuries incurred during active military service). Twenty-three percent were taking both short- and long-acting opioids for pain. Differences were found between centers, with patients in Center B being older and predominately male, and reporting back pain less often as their primary pain site compared with patients in Center A ($P < 0.05$). All patients completed the SOAPP with minimal difficulty. Forty-one patients left one or more SOAPP items blank and were not included in the analyses. No differences were found on demographic variables between patients who completed all the items on the SOAPP and those who left some blank. Only one subject with missing data was found to have an abnormal urine screen. The items that were omitted most often included how often they had been treated for alcohol or drug problems, how often medications had been lost or stolen, and how often the patients felt a craving for medication. A comparison of SOAPP scores between the centers showed higher scores for Center A, with comparable standard deviations and range (9.9 ± 6.4 ; range 0–31 vs. 8.3 ± 5.8 ; range 0–28). Total SOAPP scores for all subjects revealed a mean of 9.3 (SD = 6.2). Using the previously determined SOAPP cutoff score of 8, 164 patients with scores below an 8, identified as having a low abuse potential, were compared with 192 patients scoring an 8 or above and identified as having a high abuse potential.¹²

Urine toxicology analyses from medical records were available for 83 (34.7%) of the patients from Center A and 72 (45.6%) of the patients from Center B. Differences were assessed between those who had urine screen results and those who did not. Patients with urine toxicology results in Center A tended to be younger ($P < 0.05$) and male ($P < 0.05$) compared with patients who were not asked to give a urine sample. Patients found to have urine screen results in Center B tended to be younger ($P < 0.01$), but no other differences were noted on demographic variables. Among all patients, those who were found to have urine screen results in their medical record had higher total SOAPP scores compared with those who had no such results ($P < 0.001$). Of all subjects who were found to have results from a urine toxicology screen, 44 patients had evidence of illicit substances or abnormal findings. Twenty-seven subjects

showed traces of tetrahydrocannabinol, 11 had evidence of cocaine, and 11 were found to have other abnormalities (benzodiazepines, alcohol, or nonprescribed opioids). Differences in demographic variables and urine toxicology results in patients with low and high SOAPP scores are presented in Table 2. Patients with high SOAPP scores were younger, more likely to have urine screens, and more likely to have an abnormal urine screen result ($P < 0.05$).

Interitem correlations among the SOAPP items for all subjects were found to be positive and ranged between 0.02 and 0.61. Reliability analyses revealed an alpha coefficient of 0.75. Principal component factor analyses among the SOAPP items, using varimax rotation with Kaiser normalization for all the subjects ($n = 356$), revealed five extracted components after 10 iterations with an eigenvalue of >1.0 (Table 3.). These factors were labeled 1) family and personal history of substance abuse (24.6% of the variance), 2) history of legal problems (11.3%), 3) craving prescription medication (8.1%), 4) nicotine dependence (7.7%), and 5) mood swings (7.2%). A scree plot suggests that the first two factors are most important, although all 14 items added to the variance (Fig. 1).

Discussion

Results of this study show that the subjects easily completed the SOAPP without reporting difficulties, and the vast majority (90%) answered all 14 items. Those who scored an 8 or more on the SOAPP were found to be younger and to have given a urine screen more often, and had more abnormal urine screen results compared with those who had scores

Table 2
Differences in Demographic Variables and Urine Screen Results in Patients with SOAPP Scores Below 8, or 8 or Greater

	<8 (n = 164)	≥8 (n = 192)	P
Age, years	45.5 ± 9.3	40.7 ± 9.8	<0.05
Gender (% male)	62.8	70.2	NS
Race (% Caucasian)	84.8	87.1	NS
Pain site (% back)	38.7	40.3	NS
Urine screen taken (% yes)	31.1	46.4	<0.01
Abnormal urine (% yes)	27.5	33.7	<0.05

NS = nonsignificant.

Table 3
Results of Principal Component Factor Analyses
Among the SOAPP Items in the Centers
(n = 356)

Items	Extracted Components				
	I	II	III	IV	V
1					0.87
2				0.72	
3	0.74				
4	0.73				
5	0.60				
6	0.52				
7			0.63		
8		0.59			
9			0.69		
10			0.62		
11			0.76		
12		0.66			
13		0.69			
14		0.64			

Varimax rotation with Kaiser normalization.

below 8. Interitem reliability was found to be adequate, and five main factors were found through factor analyses. These results offer preliminary support for the reliability and validity of the SOAPP as a measure of opioid abuse potential.

In general, we found support for the clinical usability and predictive validity of the SOAPP among patients with chronic pain considered for opioid therapy. The comparative SOAPP scores require that the subject admit to the frequency of some potentially incriminating behaviors. The SOAPP was created with the assumption that patients would admit to some aberrant behaviors by rating items as "seldom," even though this would still be considered as a positive admission to an item. Even though our study shows a higher endorsement rate to individual SOAPP items than would be predicted in the general population (e.g., 30% admitting "sometimes," "often," or "very often" to the question "How often, in your lifetime, have you had legal problems or been arrested?"), individuals who believe that their responses may determine whether they are considered for opioid therapy may underreport their behavior. This is why the cutoff score of the SOAPP has been low (8 of 56). Patients may also be reluctant to respond to certain items because of concerns that their answers would be misconstrued. Although not incorporated in this study, our experience shows that patients are more willing to respond to items were

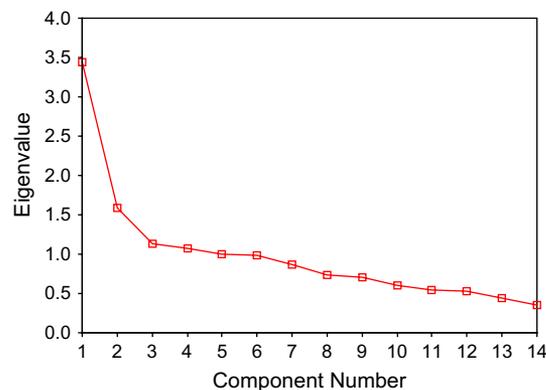


Fig. 1. Scree plot of the principal component factor analyses results of the combined SOAPP items.

previously left blank when the questions are asked by a staff member as part of a follow-up interview.

The results of this study offer information in determining which patients are at risk for opioid misuse. Patients who are younger and suspected to have a substance abuse problem (hence, were asked to give a urine screen) are at risk. A trend was also found to suggest that men are at greater risk for substance misuse than women, as shown in Center A. This is in agreement with addiction epidemiological data that show that abuse is highest among males and in those between the ages of 18 and 25.⁶ The combined data did not show significant differences between groups in gender, possibly because the vast majority of the patients from the Veterans Administration Hospital were male. No differences were found between groups based on race or pain site.

The factor analyses appeared to demonstrate five factors that make up the predominant constructs of the SOAPP. Past studies have supported similar constructs in predicting substance abuse, with particular emphasis on family history of substance abuse and a personal history of aberrant behavior problems.^{5,10,16,17} Although all items seem to add to the variance of the measure, two of the five factors consisted of single items. It is uncertain whether these analyses reflect meaningful content or whether artificial factors exist based on content similarity and similar response distributions. Thus, these factors are preliminary and require further replication.

Urine screen results can be helpful in determining whether someone has a substance

abuse problem.²¹ We recognize, however, that these results are not foolproof and other signs of aberrant prescription drug-related behavior should be monitored, including incidents of lost or stolen prescriptions, frequent running short of medication, unscheduled clinic and emergency room visits, and concern of friends and family members over use of opioid medication.¹⁰ Also, input from staff members, including clinic receptionists, is helpful in the assessment of serious drug behavior.¹² It should be emphasized that being at risk for aberrant drug-related behaviors does not necessarily indicate an addiction disorder. Also, for some individuals, having an addiction disorder does not mean that they cannot be successfully maintained on opioids for pain.

We believe that patients who have high scores on the SOAPP can be given advice similar to the advice given to at-risk individuals with an infectious disease to convey the correct comparison. This model is known as “universal precautions.”²² These patients can benefit from feedback that their total SOAPP score indicates that they may be at risk for problematic behavior and that careful attention is needed. Clinical practice suggests that all patients prescribed opioids for pain sign an opioid agreement and receive random urine screens. Careful monitoring of behavior through medical record documentation is essential. A further benefit of the SOAPP is when it is discovered that patients were not truthful to the SOAPP questions in their responses (e.g., choosing “never” to the question, “How often have you used illegal drugs in the past 5 years?”). In these cases, the suitability of continued use of opioids would be discussed.

There are some limitations of this study that deserve mention. First, these data are correlational and causal interpretations are not empirically supported. Also, not all patients were followed for a set period of time, which makes the results preliminary. Second, urine toxicology results were taken from past medical record information and not all subjects had toxicology screen data. Future validation studies need to follow patients for >6 months, with multiple urine toxicology results in order to more accurately document illicit substance use and aberrant drug-related behavior. Examination of practice differences in determining why urine screens are requested and limitations for

frequent screens (e.g., costs) should be addressed in future studies.

Third, additional demographic data that might have been helpful in determining differences between groups were not collected. Future studies may include pain duration, number of pain-related surgeries, history of mood disorder, employment and compensation status, and other important variables. Potentially valuable markers of aberrant drug behavior obtained through a structured interview and provider ratings were also not included. Fourth, differences may exist in the cutoff scores between subpopulations to determine whether a person is at risk for aberrant drug behavior. The published cutoff score for the SOAPP is 8 out of a possible 56. Bayes' theorem postulates that the predictive value of a screening test is not constant but must change with the proportion of patients who actually have the target disorder among those who undergo the diagnostic evaluation.²³ Thus, different cutoff scores may be needed for different subpopulations of pain patients. Fifth, 10% of the patients had missing items on the SOAPP. Interview follow-up with those patients with missing data would have supplied more complete data.

A longitudinal multicenter study to develop and validate a revised SOAPP (SOAPP-R) with the addition of subtle items is currently in progress. Plans are also under way to create a highly reliable brief (fewer than 10 items) screener to help identify patients with risk factors who may benefit from the full SOAPP-R. This is an important area of investigation, and further attempts to develop valid, reliable, and easily administered screening tools for the prescribing physician to help identify those individuals who are at risk for medication misuse are needed. Despite the limitations of this study, support was found for the use of the SOAPP for individuals with chronic pain who are being considered for opioid therapy.

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References

1. Joranson DE, Ryan KM, Gilson AM, Dahl JL. Trends in medical use and abuse of opioid analgesics. *JAMA* 2000;283:1710–1714.
2. Portenoy RK, Foley KM. Chronic use of opioid analgesics in non-malignant pain: report of 38 cases. *Pain* 1986;25:171–186.
3. Katon W, Egan K, Miller D. Chronic pain: lifetime psychiatric diagnoses and family history. *Am J Psychiatry* 1985;142:1156–1160.
4. Fishbain DA, Rosomoff HL, Rosomoff RS. Drug abuse, dependence, and addiction in chronic pain patients. *Clin J Pain* 1992;8:77–85.
5. Nedeljkovic SS, Wasan A, Jamison RN. Assessment of efficacy of long-term opioid therapy in pain patients with substance abuse potential. *Clin J Pain* 2002;18(Suppl):39–51.
6. Office of Applied Studies. Overview of findings from the 2002 National Survey on Drug Use and Health, DHHS Publication No. SMA 03-3774, NHSDA Series H-21. Rockville, MD: Substance Abuse and Mental Health Services Administration. <http://www.oas.samhsa.gov>. Accessed March 9, 2006.
7. Wasan AD, Wootton J, Jamison RN. Dealing with difficult patients in your pain practice. *Reg Anesth Pain Med* 2005;30:184–192.
8. Ballantyne JC, Mao J. Opioid therapy for chronic pain. *N Engl J Med* 2003;349:1943–1953.
9. Jamison RN, Kauffman J, Katz NP. Characteristics of methadone maintenance patients with chronic pain. *J Pain Symptom Manage* 2000;19:53–62.
10. Michna E, Ross EL, Hynes WL, et al. Predicting aberrant drug behavior in patients treated for chronic pain: importance of abuse history. *J Pain Symptom Manage* 2004;28:250–258.
11. Weaver M, Schnoll S. Abuse liability in opioid therapy for pain treatment in patients with an addiction history. *Clin J Pain* 2002;18(Suppl):61–69.
12. Butler SF, Budman SH, Fernandez K, Jamison RN. Validation of a screener and opioid assessment measure for patients with chronic pain. *Pain* 2004;112:65–75.
13. Savage SR. Assessment for addiction in pain-treatment settings. *Clin J Pain* 2002;18(Suppl):28–38.
14. Robinson RC, Gatchel RJ, Polatin P, et al. Screening for problematic prescription opioid use. *Clin J Pain* 2001;17:220–228.
15. Coombs RE, Jarry JL, Santhiapillai AC, Abrahamsohn RV, Atance CM. The SISAP: a new screening instrument for identifying potential opioid abusers in the management of chronic nonmalignant pain in general medical practice. *Pain Res Manag* 1996;1:155–162.
16. Chabal C, Erjavec MK, Jacobson L, Mariano A, Chaney E. Prescription opiate abuse in chronic pain patients: clinical criteria, incidence, and predictors. *Clin J Pain* 1997;13:150–155.
17. Compton PJ, Darakjian J, Miotto K. Screening for addiction in patients with chronic pain and “problematic” substance use: evaluation of a pilot assessment tool. *J Pain Symptom Manage* 1998;16:355–363.
18. Passik SD, Kirsh KL, Whitcomb L, et al. A new tool to assess and document pain outcomes in chronic pain patients receiving opioid therapy. *Clin Ther* 2004;26:552–561.
19. Adams LL, Gatchel RJ, Robinson RC, et al. Development of a self-report screening instrument for assessing potential opioid medication misuse in chronic pain patients. *J Pain Symptom Manage* 2004;27:440–459.
20. American Academy of Pain Medicine, the American Pain Society, and the American Society of Addiction Medicine. Definitions related to the use of opioids for the treatment of pain: A consensus document from the American Academy of Pain Medicine, the American Pain Society, and the American Society of Addiction Medicine. Chevy Chase, MD: ASAM, 2001.
21. Katz N, Fanciullo GJ. Role of urine toxicology testing in the management of chronic opioid therapy. *Clin J Pain* 2002;18(Suppl):76–82.
22. Gourlay DL, Heit HA, Almahrezi A. Universal precautions in pain medicine: a rational approach to the treatment of chronic pain. *Pain Med* 2005;6:107–112.
23. Meehl PE, Rosen A. Antecedent probability and the efficiency of psychometric signs, patterns or cutting scores. *Psychol Bull* 1955;52:194–216.