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Validation of a Brief Opioid Compliance Checklist for Patients With Chronic Pain

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Abstract: There has been a need for a brief assessment tool to determine compliance with use of prescribed opioids for pain. The purpose of this study was to develop and begin the validation of a brief and simple compliance checklist (Opioid Compliance Checklist [OCC]) for chronic pain patients prescribed long-term opioid therapy. A review of the literature of opioid therapy agreements led to a 12-item OCC that was repeatedly administered to 157 patients who were taking opioids for chronic pain and followed for 6 months. Validation of the OCC was conducted by identifying those patients exhibiting aberrant drug-related behavior as determined by any of the following: positive urine toxicology screen, a positive score on the Prescription Drug Use Questionnaire interview or Current Opioid Misuse Measure, and/or ratings by staff on the Addiction Behavior Checklist. Of the original 12 items, 5 OCC items appeared to best predict subsequent aberrant behaviors based on multivariate logistic regression analyses (cross-validated area under the receiver operating characteristic curve = .67). Although further testing is needed, these results suggest that the OCC is an easy-to-use, promising measure in monitoring opioid adherence among persons with chronic pain.

Perspective: This study presents validation of a brief 5-item compliance checklist for use with chronic pain patients prescribed long-term opioid therapy. This measure asks patients about aberrant drug-related behavior over the past month, and any positive response indicates problems with adherence with opioids. Further cross-validation testing is needed.

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Key words: Substance abuse, chronic pain, opioids, compliance, adherence, aberrant drug behaviors.

etermining an individual's adherence with opioids is important in the evaluation and management of a patient with chronic pain. 16,18,24,25,30 Most providers who prescribe opioids for pain use an opioid therapy agreement that identifies patients' responsibilities when taking opioids for pain. 8,12,14,17,20,32,38 These responsibilities have included 1) taking opioids as prescribed, 2) using 1 pharmacy, 3) receiving opioids from only 1 provider, 4) not running

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© 2014 by the American Pain Society http://dx.doi.org/10.1016/j.jpain.2014.07.007 out of opioids early, 5) not missing scheduled medical appointments, 6) not borrowing opioid medication from others, 7) not using illicit substances, 8) taking precautions not to lose medication, 9) not driving when first starting to take an opioid, 10) agreeing to frequent monitoring and periodic urine screens, and 11) participating fully in the treatment plan and in other rehabilitation activities. Providers hope that the patient taking opioids would be completely honest about using the medication in a responsible manner, although this is not always the case. To make the patients fully aware of their responsibilities, they are frequently asked to sign an opioid agreement, and a signed copy is kept in their medical record. For some, a violation of this agreement would mean tapering and eventually discontinuing prescription opioids. Unfortunately, violations of this agreement can go unreported and often the treating physician has difficulty in tracking and verifying adherence.

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Chabal⁷ first developed a prescription abuse checklist of 5 criteria to document potential noncompliance with prescription opioids. These criteria included 1) overwhelming focus on opiate issues, 2) pattern of early refills, 3) multiple telephone calls or unscheduled visits, 4) episodes of lost or stolen prescriptions, and 5) evidence of supplemental sources of opioids. Patients who met 3 of the 5 criteria were considered to be opiate abusers. Similarly, Compton and colleagues¹⁰ developed an interview-screening tool for assessment of opioid noncompliance in patients with chronic pain and "problematic" substance use. The Prescription Drug Use Questionnaire (PDUQ) was created to identify subjects who are likely to be nonaddicted, substance-abusing, or substance-dependent. Responses of 52 "problematic" patients differed significantly from those of nonproblematic patients on multiple screening items, with the 2 groups easily differentiated by total questionnaire score. Although useful, these instruments were not directly based on the content of opioid therapy agreements that are commonly used for patients prescribed longterm opioid therapy.

There are a number of screening tools that have been developed to help identify patients who are at risk for opioid misuse (eg, Screener and Opioid Assessment for Patients with Pain-Revised [SOAPP-R], Opioid Risk Tool).3,5,6,42 These tools, however, assess correlates of misuse such as mood disorder, abuse history, and past behaviors. There are currently no widely accepted or used assessments for directly monitoring ongoing opioid adherence among chronic pain patients who have been on opioids, and few prospective studies have attempted to link these self-report variables with objective evidence of prescription opioid misuse. Furthermore, most physicians and care providers prescribing pain medication are busy and do not have time to administer a long assessment tool to determine opioid adherence in their chronic pain patients prescribed opioids for pain. The purpose of this study was to develop and validate a brief self-administered compliance checklist for chronic pain patients on long-term opioid therapy. The nature of items included in the Opioid Compliance Checklist (OCC) was based on the components of opioid therapy agreements used in the context of long-term opioid therapy for patients with chronic pain.8,12,17,20,32

Methods

Development of a Consensus-Based Measure

The OCC was designed to reflect the consensus of experts as to those components of an opioid therapy agreement that outline patients' responsibilities and clinic policies in prescribing opioids for chronic pain. To achieve such a consensus, we conducted a brief review of the literature to identify the main components of an opioid therapy agreement. We searched electronic databases including PubMed, The Cochrane Library, EMBASE, and Science Citation Index Expanded (ISI Web of

Science). We used the following combination of keywords: "contracts, patient agreement, opioids, and narcotics." Relevant articles were also identified by manual search of references from retrieved articles and available files. The titles and abstracts of potentially relevant articles were screened and were included if they addressed the content in opioid therapy agreements. The final selection of content of an opioid therapy agreement was based on the consensus of the investigators.

Following the literature review and investigator discussion and consensus, 12 items were created to form the initial version of the OCC. In this initial pool of items, each item was worded to reflect a yes and no response over the past month for aberrant drug-related behavior associated with the use of prescription opioids identified in a patient agreement.

Validation of the OCC

Once the initial pool of OCC items was constructed, the next steps involved 1) empirical selection of final OCC items by determining which of the 12 OCC items were predictive of patient compliance at a later date on the basis of other validated measures assessing opioid compliance, 2) examining the construct/convergent validity of the final set of OCC items by examining associations with other validated instruments assessing opioid compliance, 3) establishing the reliability (internal consistency, test-retest reliability) of the final OCC checklist items, and 4) establishing a cutoff and associated sensitivity and specificity of the scale. In order to accomplish these steps, the original items of the OCC were administered to chronic pain patients, and these patients were observed for at least a year to evaluate evidence of noncompliance and aberrant medication-related behavior.

Patient Participants

Inclusion/Exclusion

Patients with a diagnosis of chronic noncancer pain were recruited to participate in this 1-year trial. Patients were included if they 1) had chronic pain for > 6 months' duration, 2) averaged 4 or greater on a pain intensity scale of 0 to 10, 3) were able to speak and understand English, and 4) had been prescribed opioid therapy for pain. Patients were excluded from participation if they meet any of the following criteria: 1) current diagnosis of cancer or any other malignant disease, 2) acute osteomyelitis or acute bone disease, 3) present or past Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, diagnosis of schizophrenia, delusional disorder, psychotic disorder, or dissociative disorder that would be judged to interfere with study participation, 4) pregnancy, 5) any clinically unstable systemic illness judged to interfere with treatment, 6) a pain condition requiring urgent surgery, and 7) an active addiction disorder, such as cocaine or intravenous heroin use (positive on the Mini International Neuropsychiatric Interview; M.I.N.I. v.5.0³¹) that would interfere with study participation.

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