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Psychometric evaluation of the 10-item Short Opiate Withdrawal Scale-Gossop (SOWS-Gossop) in patients undergoing opioid detoxification

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HIGHLIGHTS

- The 10-item SOWS-Gossop measures symptoms of opiate withdrawal syndrome.
- We examined the psychometric performance of the SOWS-Gossop.
- We analyzed data from clinical trials of patients undergoing opioid detoxification.
- Results supported the reliability and validity of the SOWS-Gossop.
- The SOWS-Gossop has excellent psychometric properties.

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ABSTRACT

Introduction: The Short Opiate Withdrawal Scale (SOWS)-Gossop is a 10-item questionnaire developed to evaluate opioid withdrawal symptom severity. The scale was derived from the original 32-item Opiate Withdrawal Scale in order to reduce redundancy while providing an equally sensitive measure of opioid withdrawal symptom severity appropriate for research and clinical practice. The objective of this study was to examine the psychometric properties and provide score interpretation guidelines for the SOWS-Gossop 10-item version.
Methods: Blinded, pooled data from two trials assessing the efficacy of lofexidine hydrochloride in reducing withdrawal symptoms in patients undergoing opioid detoxification were used to evaluate the quantitative psychometric properties and score interpretation of the SOWS-Gossop.
Results: Five hundred fifty-five ($N = 555$) observations were available at baseline with numbers decreasing to $n = 213$ at day 7. Mean (standard deviation) SOWS-Gossop scores were 10.4 (6.86) at baseline, 8.7 (6.49) on day 1, 10.5 (7.21) on day 2, and 3.1 (3.95) on day 7. Confirmatory factor analysis indicated that the SOWS-Gossop items loaded on a single factor consistent with a single total score. Intra-class correlations (95% confidence interval) were 0.78 (0.70–0.85) between baseline and day 1, 0.84 (0.79–0.89) between days 4 and 5, and 0.88 (0.83–0.91) between days 6 and 7, demonstrating good test-retest reliability. Mean SOWS-Gossop scores varied significantly ($p < 0.0001$) by Modified Clinical Global Impression severity groups supporting known-groups validity. Most correlations with conceptually similar instruments were over 0.4, providing evidence of construct validity. Results suggest that a change score of approximately 2–4 points is likely a small but meaningful improvement on the SOWS-Gossop Total Score.
Conclusions: The findings of this study indicate that the SOWS-Gossop includes concepts that are relevant to patients' experiences with opioid withdrawal and has excellent psychometric properties. The SOWS-Gossop is an appropriate, precise, and sensitive measure to evaluate the symptoms of acute opioid withdrawal in research or clinical settings.

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1. Introduction

Heavy and prolonged use of opioids in recreational or medical contexts can cause the occurrence of opioid withdrawal syndrome (OWS) when an individual discontinues opioid use (Doyon, 2004). OWS is classified into two phases: an initial phase in which acute withdrawal symptoms occur and a second phase that is characterized by chronic and more protracted signs of opioid abstinence (Tetrault & O'Connor, 2009). The acute withdrawal phase consists of a variety of signs and symptoms that differ in severity, time of onset, duration, and persistence, and may be modified by the degree of dependence and half-life of the opioids used (Doyon, 2004; Farrell, 1994; Tetrault & O'Connor, 2009). The earliest symptoms of OWS are increased levels of anxiety, dysphoria, agitation, increased sweating, thermoregulation disturbances, insomnia, yawning, lacrimation (flow of tears), and rhinorrhea (runny nose). These are typically followed by symptoms such as muscle and joint aches, piloerection (goose bumps), and gastrointestinal symptoms such as nausea, vomiting, diarrhea, and abdominal cramping (Doyon, 2004; Farrell, 1994; Tetrault & O'Connor, 2009).

There are a number of patient-reported outcome (PRO) measures that have been developed to measure the acute symptoms of OWS in adults, such as the Adjective Rating Scale for Withdrawal (ARSW) (Barbosa-Leiker, McPherson, Mamey, Burns, & Roll, 2014), the Opiate Withdrawal Scale (OWS) (Bradley, Gossop, Phillips, & Legarda, 1987), the Subjective Opioid Withdrawal Scale (SOWS) (Handelsman et al., 1987), and the Short Opioid Withdrawal Scale by Gossop (SOWS-Gossop) (Gossop, 1990). Together with the SOWS, the SOWS-Gossop is one of the most widely used instruments in clinical trials to evaluate OWS. The SOWS-Gossop is a 10-item PRO instrument based on the original 32-item OWS (Bradley et al., 1987) that underwent item reduction to remove redundancy while providing an equally sensitive and precise measure of opioid withdrawal symptoms appropriate for research and clinical practice (Farrell, 1994; Gossop, 1990). While there is information available about the measurement properties of the original OWS, the psychometric properties have not been confirmed for the 10-item SOWS-Gossop. Evaluation of the psychometric performance of a PRO instrument is an important part of the instrument development process (Food and Drug Administration, 2009). The objective of this study was to examine the psychometric properties and provide score interpretation guidelines for the SOWS-Gossop 10-item version.

2. Methods

2.1. Summary of development of the SOWS from the original OWS

Development of the SOWS-Gossop instrument was based on Bradley and colleagues previously validated 32-item OWS (Gossop, 1990). The final 10-item SOWS-Gossop scale that was tested in the content validity study described in Section 2.2 was established in three steps (see Fig. 1 for a diagram of item elimination). In the initial step, a 20-item scale was prepared from the original list of 32 items. The 12 items initially selected for elimination were due to low-loading in the original validation exercise (e.g., poor appetite and dry mouth), overlap with other items (e.g., vomiting was eliminated due to its overlap with feeling sick, which had a higher factor loading), or inability of patients to understand the symptom (e.g., feelings of unreality). In the next step, the resulting 20-item list was further evaluated and reduced to a 12-item scale, eliminating diarrhea (infrequent reporting); trembling hands, increased sweating, fatigue or tiredness, weakness, and sneezing (low loadings); hot and cold flushes (overlap with feelings of coldness); and runny nose (overlap with patient reports of runny eyes). Both the 20-item and the 12-item scales were prepared according to the same format as the original scale.

Principal components analyses were carried out on both the 20-item and 12-item sets of results for the day on which the peak withdrawal score was obtained (Gossop, Griffiths, Bradley, & Strang, 1989). The principal components analyses were performed on these peak withdrawal data in order to avoid distortion due to floor effects. In the 12-item scale, two factors emerged with an eigenvalue >1.0; however, a scree test indicated that a single factor solution was advisable. Correlation coefficients between each item and the main factor score were calculated. These were positive and significant for all items except gooseflesh and weakness ($r = 0.43$ and $r = 0.30$, respectively). A correlation of the sum of the items with the factor score was calculated, producing a result of $r = 0.70$. At this final stage, items 5 (Dry Mouth) and 9 (Headache) were dropped from the calculations, resulting in the final 10-item scale and a further principal components analysis was performed. This produced one main factor, which accounted for 61.4% of the total variance. Other factors all had eigenvalues <1.0. All 10 of the items contributed significantly toward the main factor.

2.2. Assessment of content validity

Prior to the quantitative evaluation, a qualitative study was conducted to assess the content validity of the SOWS-Gossop for use with patients experiencing opioid withdrawal. Institutional Review Board (IRB) approval was provided for the study by Schulman Associates IRB in November 2012. Semi-structured qualitative interviews were conducted with patients who had recently experienced unassisted short-acting opioid withdrawal. These interviews included both concept elicitation and cognitive interviewing on the content of the SOWS-Gossop.

2.3. Psychometric evaluation

2.3.1. Data source

Blinded, pooled data from two trials assessing the efficacy of lofexidine hydrochloride in reducing withdrawal symptoms in patients undergoing opioid detoxification were used to evaluate the quantitative psychometric properties and score interpretation of the SOWS-Gossop. The first trial (NCT00235729) was a randomized, multicenter, placebo-controlled, double-blind trial of 0.8 mg four times a day (QID) lofexidine or placebo QID for five days, plus an additional two-day placebo phase for both arms conducted in the United States (unpublished). Patients enrolled in this trial were adults experiencing withdrawal who met the Diagnostic and Statistical Manual for Mental Disorders Fourth Edition (DSM-IV) (American Psychiatric Association, 2000) criteria for current dependence on an opioid as determined by the structured clinical interview (First, Spitzer, Miriam, & Williams, 2002). Patients were on any opioid with a half-life similar to heroin or morphine, who reported use of heroin, morphine, or any opioid with a half-life similar to heroin or morphine for at least 21 of 30 days prior to screening and were seeking treatment for opioid dependence. IRB approval was provided for the study by Aspire IRB in November 2005. Data utilized from this study included all observed data from patients who were found eligible, were randomized, and completed at least a baseline assessment.

The second trial (NCT01863186) was a randomized, placebo-controlled, double-blind, parallel-group, dose-response study of 0.6 and 0.8 mg QID lofexidine or placebo QID for seven days, plus open-label treatment of variable doses as determined by the investigator of up to an additional seven days (ongoing at the time of this manuscript; unpublished). Patients enrolled in this trial were adults currently experiencing dependence, according to the Mini International Neuropsychiatric Interview (Sheehan et al., 1998), on any opioid with a half-life similar to heroin or morphine, who reported use of heroin, morphine, or any opioid with a half-life similar to heroin or morphine for at least 21 of 30 days prior to screening and were seeking treatment for opioid dependence. IRB approval was provided for the study by Aspire IRB in September 2012. Data utilized included all available observed data from patients who were found eligible, were randomized, and completed at least a baseline assessment. The data analysis for the second trial included a partial sample consisting of 303 patients, as patient enrollment was still ongoing at the time of the analysis. Only blinded