



Examining the factor structure of the Clinical Opiate Withdrawal Scale: A secondary data analysis from the National Drug Abuse Treatment Clinical Trials Network (CTN) 0003



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ABSTRACT

Background: The Clinical Opiate Withdrawal Scale (COWS) is used to assess withdrawal in clinical trials and practice. The aims of this study were to examine the inter-item correlations and factor structure of the COWS in opioid-dependent men and women.

Methods: This is a secondary data analysis of the National Drug Abuse Treatment Clinical Trials Network 0003, a randomized clinical trial that compared buprenorphine/naloxone tapering strategies. The trial included 11 sites in 10 US cities. Participants were opioid-dependent individuals ($n = 516$) that had data on the COWS. The COWS at study baseline was analyzed in this study.

Results: Inter-item correlations showed weak to moderate relationships among the items. A 1-factor model did not fit the data for men (comparative fit index (CFI) = .801, root mean square error of approximation (RMSEA) = .073, weighted root mean square residual (WRMR) = 1.132) or women (CFI = .694, RMSEA = .071, WRMR = .933), where resting pulse rate was not related to withdrawal for men, and yawning and gooseflesh skin was not related to withdrawal for women. A reduced model comprised of only the 8 items that were significantly related to the construct of withdrawal in both men and women, and an exploratory 2-factor model, were also assessed but not retained due to inconsistencies across gender. **Conclusions:** When traditional psychometric models are applied to the COWS, it appears that the scale may not relate to a single underlying construct of withdrawal. Further research testing the hypothesized factor structure in other opioid-dependent samples is needed.

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1. Introduction

Opiate withdrawal scales were developed to examine the patient's physical dependence and physiological readiness prior to methadone or buprenorphine induction, and to compare treatments for withdrawal (Wesson and Ling, 2003). The Clinical Opiate Withdrawal Scale (COWS; Wesson and Ling, 2003) is a

common measure used to assess withdrawal in clinical trials and practice, and consists of 11 observed (clinician-rated) and subjective (patient-rated) items. The COWS has been used to assess withdrawal in buprenorphine/naloxone vs. clonidine treatment groups (Ling et al., 2005; Ziedonis et al., 2009) and 7-day vs. 28-day buprenorphine/naloxone tapering schedules (Ling et al., 2009). The COWS has also been used to measure opioid withdrawal severity, where those with high baseline COWS scores, and greater decreases in COWS scores, were more likely to have treatment success compared to those with low baseline COWS scores, regardless of treatment modality (Ziedonis et al., 2009). Interestingly, such relationships were not found in the Ziedonis et al. (2009) study when a patient-rated scale of opiate withdrawal, the Adjective

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Rating Scale of Withdrawal (Bickel et al., 1988a, 1988b; Amass et al., 2000) was used, suggesting that the clinician-rated items are of importance to capture withdrawal.

General clinical guidelines suggest that buprenorphine induction should occur when a patient is physically dependent on opioids and in mild to moderate withdrawal, or waiting for the patient to be in moderate to severe opiate withdrawal (Wesson and Ling, 2003). The items that make up the COWS have been validated in other instruments and the following cut-scores for the COWS have been offered: 5–12 = mild, 13–24 = moderate, 25–36 = moderately severe, and >36 = severe withdrawal (Wesson and Ling, 2003). Based on clinical experience, Wesson and Ling state that at a score on the COWS of ≥ 25 , buprenorphine is unlikely to precipitate withdrawal in patients who are physically dependent on opioids (2003).

It is noted that the COWS may be assessed repeatedly so that change in withdrawal due to treatment may be tracked over time. More recently, validation of the COWS was demonstrated as the scale was found to correlate with the Clinical Institute Narcotic Assessment (CINA) and two visual analog scales (VAS) (bad drug effect and feeling sick) in a sample of opioid-dependent individuals in mild withdrawal (mean peak COWS = 7.6) during a naloxone challenge session, while discriminant validity was demonstrated as the COWS did not correlate with a placebo (Tompkins et al., 2009). This study also reported good internal consistency of the COWS (Cronbach's $\alpha = .78$), and concludes that the COWS is a valid instrument to detect mild opiate withdrawal (Tompkins et al., 2009).

The COWS appears to be a useful tool for clinicians and researchers alike, and it may outperform other opiate withdrawal scales in assessing treatment effects (e.g., Ziedonis et al., 2009). To our knowledge it appears that the factor structure of the COWS has not been assessed. This examination would provide important information regarding the relationship of the COWS items as they make up the construct of withdrawal. Studies consisting of opiate-dependent men and women combined in one sample need verification that measurement properties of the COWS are consistent across gender. Specifically, while we are not testing if COWS levels differ across gender, we are testing the assumption that *measurement* of withdrawal is equivalent for men and women. Therefore, this study sought to advance prior work that utilized the COWS by examining inter-item correlations and the factor structure of the COWS for opioid-dependent men and women at pre-treatment in a clinical trial. As this was the first examination of the factor structure of the COWS, the goal was not to clinically refine the scale, but to apply traditional psychometric analyses to a clinically useful tool to guide future research.

2. Methods

2.1. Clinical Trials Network 0003

Participants were from the National Drug Abuse Treatment Clinical Trials Network (CTN) 0003 (Ling et al., 2009). Secondary data analysis employing this study has been reported in previous studies (McPherson et al., 2012, 2013; Barbosa-Leiker, 2014). This was a randomized, parallel-group, open-label study design for opioid-dependent individuals seeking treatment from 11 outpatient treatment facilities in 10 US cities. This secondary data analysis utilized data at baseline, prior to buprenorphine/naloxone induction, stabilization, and treatment (treatment consisted of two buprenorphine/naloxone taper periods). The COWS was administered by study physicians or nurses. Please see Ling et al. (2009) for a full description of the trial methodology.

2.2. Participants

The final intention-to-treat sample consisted of 516 participants who were potentially available for data collection. Sixty-seven percent of the sample was male (male = 347, female = 169). This sample was primarily Caucasian (Caucasian = 366, African American = 56, Hispanic = 35, Multiple = 45, Other = 13, Missing response = 1) with a mean age of 35.91 (SD = 10.45).

2.3. Measures

The COWS is an observed (clinician-rated) and subjective (patient-rated) scale of opiate withdrawal signs and symptoms (Wesson and Ling, 2003). The COWS items have been identified as 6 objective items (resting pulse rate, tremor, yawning, pupil size, gooseflesh skin, runny nose or tearing), 1 subjective item (anxiety or irritability), and 4 items that have both objective and subject components (GI upset, sweating, restlessness, bone or joint aches) (Tompkins et al., 2009). Various response categories are used to create individual ratings (e.g., 0–4 for pulse rate [0 = pulse rate 80 or below; 1 = pulse rate 81–100; 2 = pulse rate 101–120; 4 = pulse rate greater than 120]; 0–5 for pupil size [0 = pupils pinned or normal size for room light; 1 = pupils possibly larger than normal for room light; 2 = pupils moderately dilated; 5 = pupils so dilated that only the rim of the iris is visible]), and the ratings are summed to create a total score (Wesson and Ling, 2003). While not specified in study protocol, a pupillometer was used to assess pupil diameter. In this study, COWS total scores were 8.30 (SD = 4.01) for men and 8.86 (SD = 3.84) for women, indicating mild withdrawal for both men and women.

Previous research has reported a Cronbach's α of .78 in opioid-dependent individuals, indicating good internal consistency (Tompkins et al., 2009). Additionally, while most noted inter-item correlations have been found to be statistically significant, only restless with anxiety or irritability ($r = .67$), and runny nose/tearing with yawning ($r = .54$) had a moderate to strong correlation (Tompkins et al., 2009).

2.4. Statistical analyses

Inter-item correlations (Spearman's rho) were first assessed for the COWS items. Next, confirmatory factor analysis (CFA) was used to examine a 1-factor model of the COWS in the total sample, and then for men and women separately. This was chosen over exploratory factor analysis given the utility of the COWS total score in clinical and research practices, coupled with previous work on the validity and reliability of the COWS total scores. Therefore, the confirmation of the established use of the COWS was warranted. Additional factor models were explored post hoc.

Model fit was assessed using the comparative fit index (CFI; study criterion $\geq .900$), the root mean square error of approximation (RMSEA; study criterion $\leq .080$), and the weighted root mean square residual (WRMR; study criterion ≤ 1.00) (Brown, 2006; Yu, 2002). Additionally, standardized factor loadings were inspected to see which items accounted for at least 9% of the variance in the construct (factor loading of $\geq .30$) (Kline, 1994). Note that within WLSMV estimation, the factor loadings represent the correlation between y^* (underlying latent continuous distribution) and the latent continuous factor, which has a variance of 1 (Finney and DiStefano, 2013). Model fit and factor loadings were examined in the gender-specific models regardless of the fit of the model in the total sample to explore potential areas of model strain in the combined sample that may be due to gender differences. Factor loadings in the gender-specific models were examined alongside model fit to explore similarities and differences in the general pattern of significant factor loadings across men and women in order to help identify if each item was related to the construct of withdrawal across gender, a step used to assist with model revision.

All primary statistical testing was conducted in Mplus, Version 6 (Muthén, 1998–2010), using robust weighted least squares (WLSMV) estimator, appropriate in that it assumes that there is a continuous and normal latent response variable (i.e., withdrawal) underlying each ordinal manifest variable. Further, WLSMV is a distribution-free estimator and designed to handle ordinal items that may demonstrate a high level of skewness and/or kurtosis. For post hoc 2-factor exploratory factor models, WLSMV using Geomin rotation was used. Factor analyses were also estimated using robust maximum likelihood estimation (MLR); overall patterns of results were similar and therefore results are based on the WLSMV estimation.

3. Results

3.1. Inter-item correlations

Inter-item correlations and COWS items descriptive statistics (mean, variance, and number of zeros) are shown in Tables 1 and 2. Note that there does not appear to be large discrepancies in the prevalence of zeroes in item responses or item variances across gender. In the total sample (Table 1), most items significantly correlated with at least 5 other items. Of note was anxiety or irritability which significantly correlated with all other items, and pupil size, which correlated with all items but resting pulse rate. Conversely, resting pulse rate only significantly correlated with 4 other items (sweating, tremor, anxiety or irritability, and bone or joint aches) and yawning only correlated with 3 items (pupil size, anxiety or irritability, and runny nose or tearing). While most items demonstrated statistically significant relationships with the other items,

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