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Research Paper

Psychometric Characteristics of the Persian Version of the Opiate Dosage Adequacy Scale (ODAS)

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ABSTRACT

Introduction: The opiate dosage adequacy scale (ODAS) is one of the most common assessment tools in studies on substance use disorders, which evaluates the "adequacy" of opiate medication doses in individuals recruited in maintenance approaches. There is no investigation on the Persian version of this questionnaire in Iran. This research validated a Persian version of the ODAS.

Methods: The Persian version of the ODAS was translated and revised based on the original scale presented by González-Saiz et al. The psychometric characteristics of the ODAS were assessed via direct interviews. Three trained interviewers questioned 250 patients treated in methadone maintenance clinics in Mazandaran Province (Northern Iran) for more than three months. Internal consistency and factor analysis were conducted using SPSS software, version 24.

Results: The internal consistency of ODAS was satisfactory (Cronbach's α=0.81). Across all items, considerable inter-rater reliability was discovered (kappa values between 0.90 and 1). A four-component structure was produced by the factor analysis that accounted for 77.5% of the total variance. Cronbach's α coefficients of the four components of Heroin craving and overmedication, Consumption, objective opiate withdrawal symptoms, and subjective opiate withdrawal symptoms were 0.84, 0.91, 0.83, and 0.74, respectively.

Conclusion: The reliability and validity of the Persian version of the ODAS were satisfactory in a sample of methadone maintenance subjects.

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Highlights

- The opiate dosage adequacy scale (ODAS) is a clinical tool for measuring the adequacy of methadone doses
- The Persian version of ODAS has good validity, internal consistency, and inter-rater reliability;
- The Persian version of the ODAS, as a valid and reliable tool, can be used for the Iranian people under methadone maintenance.

Plain Language Summary

In Iran, opioids are among the most common forms of illicit drugs. In opioid maintenance programs, the adequacy of methadone doses has an important effect on treatment outcomes. Clinicians typically assess the adequacy of doses based on the patient's response to the medication. Different tools are used in clinical studies to evaluate it. One of these tools is the ODAS, developed by González-Saiz et al. In the present study, we validated the Persian version of the ODAS for Iranian patients receiving methadone maintenance programs. The results confirmed the four-factor structure of the Persian ODAS and showed its good internal consistency and inter-rater reliability.

1. Introduction

More than 15 million individuals use illegal opiates, such as morphine, opium, and heroin worldwide. Each year, some people suffering from opiate use disorder die of complications resulting from drug use, and more need to seek addiction therapies. Among illegal narcotics, opiates are the most expensive in terms of treatment and medical care (Emmanuel & Attarad, 2006). In Iran, opiate use disorders are among the most common forms of illegal drug use (Amin-Esmaeili et al., 2016). Given the significant number of people worldwide who use opioids, the importance of an optimal maintenance program to treat the addictive issues of opioid use disorders is undeniable. Some benefits of such programs, like methadone maintenance treatment (MMT), include decreased illicit opioid consumption, improved treatment retention, reduced mortality rate, enhanced physical health, and reduced rate of infections, such as HIV (Heikman et al., 2017; Trafton et al., 2006). In opioid maintenance programs, the adequacy of the dose of the administered medication, such as methadone, has an important effect on treatment outcomes. Some critical criteria that must be fulfilled in this regard are suppressed opioid withdrawal symptoms and reduced illicit opioid-rewarding effects and craving (Bickel et al., 1988; Hammond et al., 2021).

Clinicians typically assess the appropriateness of an opioid medication dose by examining the patient's response to that medication. Different tools have been utilized in clinical studies to evaluate withdrawal signs (Trujols et al., 2010). The standard tools assess only a part of the factors involved in regulating the dose of the maintenance medication to reach the desired effects (Clark, 2003; Fudala et al., 2003). Exploration of individual predictive factors and setting variables that could influence the therapeutic responses are of high priority, as these data could help to improve the results of administered opioid medication and measure treatment effectiveness in different areas (Caplehorn et al., 1993; Condelli, 1993; Condelli & Dunteman, 1993; McLellan et al., 1993).

The opiate dosage adequacy scale (ODAS), suggested by González-Saiz et al. (González-Saiz, 2004), is a semi-structured interview mainly designed to be utilized in maintenance programs. The questionnaire is applied to approximate the adequacy of the dose of the opiate medication prescribed and assess patients' problems with these compounds in treatment programs. Another application of the questionnaire is measuring different aspects of the effectiveness of the treatment. Defining the proper dose of methadone for patients involved in MMT programs has several advantages: 1) The patient abuses no opiates or uses them only occasionally, 2) He or she will not experience long-lasting opiate withdrawal symptoms (OWS), and if he/she does only minimal problems are anticipated, 3) The patient does not experience recurrent incidents of opiate craving, 4) The patient will not have any subjective symptoms from heroin use, or would be mild (narcotic blockade or crossed tolerance), and 5) Constant symptoms of overmedication are not experienced by the patient (Farnum et al., 2021;

Trujols, et al., 2010). The ODAS is intended to assess how adequately the patients received their dose for the previous seven days.

It should be noted that ODAS is a tool to evaluate the pharmacological outcome of treatment, which means the best clinical outcome that is directly related to a specific dose of methadone. However, it is critical to make a distinction between the medication's pharmacological action and the patient's stabilization following a certain period of time on MMT. A reasonable dose of the maintenance medication is necessary but not sufficient to guarantee a considerable response to the treatment. Other prognostic factors, such as psychosocial elements and psychiatric comorbidities, should also be considered (González-Saiz et al., 2008).

In the present study, we validated the Persian version of the ODAS, a clinical tool created to measure the sufficiency of the administered dose of opioid medication (Artenie et al., 2019; González-Saiz et al., 2008). The validated version can be used for Iranian patients in maintenance programs as it has been used in several studies to determine the sufficient stable amount of the maintenance medication (Artenie & Bruneau, 2020; González-Saiz et al., 2008).

2. Materials and Methods

Study design

This observational, cross-sectional, and multi-centric research was performed in six MMT clinics in Mazandaran Province (Northern Iran). The participants were 250 male patients referring to clinics experiencing MMT. Inclusion criteria were an age range of 20-45 years and a record of at least three months on a continuous MMT program. Patients suffering from other psychiatric disorders, such as major depressive or personality disorder, or those who refused to provide written informed consent were excluded. The samples were randomly selected, but in such a way that each center was involved with a subsample proportional to the total number of subjects in MMT.

Measures

The opiate dosage adequacy scale (ODAS)

The 10-item ODAS assesses the appropriateness of the dose of opiate medicine given in the context of the patient's maintenance regimen in accordance with his or her specific needs. The ten items take into account six particular components of the "dose adequacy" paradigm (González-Saiz, 2004):

In addition, the questionnaire has five additional supplementary information items that are not a part of the appropriate ODAS and are not considered in scoring. The items assessing the frequency of symptoms are scored from one to five based on a Likert-type scale. An analogous visual scale with a comparable score range was used to check the questions that evaluate the severity of symptoms. Scores of the questionnaire could be explained in a dimensional (quantitative) or categorical (qualitative) model. Initially, each item's weighted summation score is combined to produce a final score. If the overall score is greater, the dose that was delivered is more "adequate". Second, the dose given to each patient can be classified as "adequate" or "inadequate" regarding a particular cut-off point.

The González-Saiz version served as the basis to create the ODAS in Persian (González-Saiz, 2004). It was translated by two separate translators whose areas of expertise were different scientific fields. Then, editors with experience in addiction research looked over and verified the document. The resulting questionnaire was then translated back into the original language and reviewed considering the primary English edition by editors who were native English speakers. The questionnaire was adjusted slightly if necessary. The alterations were mostly based on certain sociocultural and linguistic aspects of the Iranian language, such as phrasing or expressive style.

Self-reported opioid use

Participants reported the number of days, on which any amounts of opioids were consumed.

Procedures and analysis

Participants were evaluated by a research team, including physicians, psychologists, and nurses. First, a list of all subjects was prepared. The researchers randomly selected the samples, and a subsample was assigned to each of the six contributing centers. The researchers in each service scheduled meetings with chosen participants for an introduction interview individually described the research objectives, carried out the tests associated with the selection criteria, and asked each patient to sign the informed permission form. The information from the subject's clinical history and the data from the interview were then used by the researchers to finish the data logbook.

Data were analyzed using SPSS software, version 24. Cronbach's α was used to determine internal consistency, which is acceptable when the value is 0.6 or higher. Inter-rater reliability was evaluated through the follow-

ing procedure: The researcher interviewed the subject with the ODAS, and a nurse, at the same time, assigned a score to the patient's answers to questions in a parallel, blind questionnaire form that was discussed by the main questioner. All 250 patients underwent the process. The value of the weighted kappa coefficient, which illustrates the agreement between items when adjusted for chance agreement, was determined using reliability analysis item by item (Cohen, 1960) for each pair. The significance of the kappa value is divided into four categories: Poor (0 to 0.40), fair (0.41 to 0.59), good (0.60 to 0.74), and excellent (0.75 and above) (Cicchetti's criteria) (Cicchetti, 1994). Factorial analysis was carried out using an exploratory analysis (principal components analysis) to assess the ODAS's dimensionality. The Kaiser criteria were followed to define the number of factors to be extracted (Kaiser, 1970). The Stevens criteria were considered to choose the saturating items in each factor. Varimax rotation was utilized for solution transformation.

3. Results

Demographic characteristics

The sample included 250 male subjects. The mean age was 32.5±5.6 years (age range: 20–45 years). Most drug users (57.8%) had completed junior middle school, while 3% had a college or advanced degree. Besides, most subjects were unemployed (62.3%, n=155) (Table 1).

Table 2 shows the quantities for the items used in the reliability and validity tests.

Inter-rater reliability

According to Cicchetti's criteria (Cicchetti, 1994), all ODAS items fell into the "excellent" category, evidenced by the weighted kappa coefficients for each of the ODAS items, which supports the questionnaire's inter-rater reliability (Table 3).

Table 1. Demographic characteristics of the study population

Variables		Mean±SD/% Statistics	n
Age		32.5±5.6	250
Occupation	Owner	4.8	12
	Service	1.2	3
	Unemployed	62.3	155
	Staff	3.8	9
	Worker	24.2	60
	Farmer	1.5	4
	Other	2.2	7
Education	Primary school or lower	10.5	
	Junior middle school	57.8	
	Senior middle school	24.6	
	College or higher	7.1	
Marital status	Single	5.4	
	Married	57.2	
	Divorced/Widowed	37.4	

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Table 2. Description of the scores obtained on items used in the validity and reliability analyses.

ODAS	Mean±SD
1. Continued heroin use	4.96±0.18
2." Narcotic blockade" (crossed tolerance)	4.76±0.47
3a. Frequency of objective OWS[a]	4.88±0.36
3b. Intensity of objective OWS[a]	4.66±0.53
4a. Frequency of subjective OWS[a]	4.84±0.40
4b. Intensity of subjective OWS[a]	4.67±0.60
5a. Frequency of craving for heroin	4.76±0.43
5b. Intensity of craving for heroin	4.75±0.53
6a. Frequency of overmedication	4.92±30
6b. Intensity of overmedication	4.90±35

OWS[a]: Opiate withdrawal symptoms.

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Validity

The analysis revealed a four-factor ODAS structure. Clinically, it is easy to explain these four components, which all account for 77.5% of the variance. According to Table 4, factor 1 explained 39.73% of the variance, factor 2 explained 16.40%, factor 3 explained 11.27%, and factor 4 explained 10.11%. Because factor 1 (Lambda=3.87) included two questions that assessed heroin craving (5a and 5b) as well as two items that assessed the frequency and severity of overmedication (6a and 6b), we dubbed it the "heroin craving and overmedication" factor. Due to the inclusion of two items that assess recent heroin use 1) Continued heroin use and 2) Narcotic blockage (crossed tolerance), the second factor (Lambda=1.84) was classified as "consumption". Among all factors, this factor had the highest coefficient. "Objective OWS" refers to the third factor's clustering of the two items (3a and 3b) that measure the frequency and severity of objective OWS (Lambda=1.52). Finally, Factor 4 was identified as "subjective OWS" because it grouped the two items (4a and 4b) that assess the frequency and severity of subjective OWS (Lambda=1.01).

Table 3. Inter-rater reliability analysis and kappa coefficients.

ODAS	Weighted Kappa
1. Continued heroin use	1
2. "Narcotic blockade" (crossed tolerance)	0.90
3a. Frequency of objective OWS	0.99
3b. Intensity of objective OWS	0.99
4a. Frequency of subjective OWS	1
4b. Intensity of subjective OWS	0.98
5a. Frequency of craving heroin	0.96
5b. Intensity of craving heroin	0.97
6a. Frequency of overmedication	0.95
6b. Intensity of overmedication	1

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Table 4. Factorial analysis of items on the ODAS

ODAS	Factor 1	Factor 2	Factor 3	Factor 4
1. Continued heroin use	0.153	0.923*	0.164	0.105
2. "Narcotic blockade" (crossed tolerance)	0.126	0.915*	0.198	0.129
3a. Frequency of objective OWS	0.130	0.215	0.882*	0.145
3b. Intensity of objective OWS	0.180	0.147	0.889*	0.150
4a. Frequency of subjective OWS	0.249	0.324	0.132	0.789*
4b. Intensity of subjective OWS	0.165	-0.003	0.176	0.911*
5a. Frequency of heroin craving	0.801*	0.113	0.125	0.068
5b. Intensity of heroin craving	0.792*	-0.008	0.003	0.236
6a. Frequency of overmedication	0.683*	0.215	0.187	0.049
6b. Intensity of overmedication	0.757	0.088	0.118	0.169
Eigen value	3.87	1.84	1.52	1.01
Percentage of variance	39.73	16.40	11.27	10.11

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Note: Factor 1: Heroin craving and overmedication; Factor 2: Consumption; Factor 3: Objective OWS; Factor 4: Subjective OWS; OWS: Opiate withdrawal symptoms.*The greatest amount of variance coefficient in each factor.

Estimated reliability of the questionnaire

The questionnaire's Cronbach's α coefficient was calculated at 0.82, indicating that many ODAS components had sufficient covariance, which supported the scale's internal consistency. Cronbach's α coefficients of the factor dimensions were as follows: Heroin craving and overmedication: 0.84, consumption: 0.91, objective OWS: 0.83, and subjective OWS: 0.74.

4. Discussion

The findings regarding the Persian version of the ODAS provided adequate confirmation of the reliability and validity of assessments in the context of an MMT program, which could help to define the dose "adequacy" of the administered methadone. According to Nunnally (McLellan et al., 1992), the internal consistency of the scale is sufficient having Cronbach's α coefficient of 0.82, which coincides with reported data by González-Saiz (González-Saiz et al., 2008; González-Saiz et al., 2018). All ODAS's components are connected to one another in the same way. Inter-rater reliability is considerably high; thus, the observed agreement between raters is acceptable. This feature helps several clinicians reach a similar diagnosis using the questionnaire (Dyer & White, 1997). The reliable diagnosis and prescription of an adequate dose of methadone or another maintenance medication are essential in treatment strategies and critical to inhibiting patient relapse.

Factorial analysis of the ODAS in our study yielded four factors, similar to data reported by González-Saiz et al. All components seem to be "necessary" for describing and understanding the "adequacy" concept. However, the clustering of items in factors in our study is somehow different from factors reported by González-Saiz et al. In our study, the four factors observed were "heroin craving and overmedication", "consumption", "objective OWS", and "subjective OWS". The factors' percentages of the variance were 39.73, 16.4, 11.27, and 10.11, respectively. However, the factors reported by González-Saiz et al. (González-Saiz et al., 2008) were "OWS", "heroin craving", "overmedication", and "consumption", having percentage of variances of 29.73, 21.04, 18.16, and 11.65, respectively. However, other factors could also be involved in our factorial analysis, but the four mentioned factors are responsible for 77.5% of the ODAS variance. There were no differences in participants' educational level or marital status in validity and reliability parameters. According to the internal consistency, ODAS appears to measure a homogeneous

and multifaceted construct. Each of these dimensions exhibits a high degree of internal consistency in turn. The factorial analysis' distribution of the percentages of variance explained by each factor is another noteworthy finding. Percentages are well distributed, suggesting that all factors have an excellent "weight" within the framework.

The use of ODAS has been linked to improved methadone dosage adequacy and addiction severity characteristics (Trujols et al., 2017). Overall, it seems that the Persian version of the ODAS has sufficient validity and reliability for clinical use. The scale is a reliable tool for Iranian opioid-dependent individuals. It can be utilized extensively in addiction research fields, such as evaluating the dependence parameters in patients involved in MMT programs and evaluating the efficiency of the treatment.

It has many applications in the field of addiction research, including determining the levels of dependence in patients enrolled in MMT programs and gauging the success of the therapy.

Ethical Considerations

Compliance with ethical guidelines

The study protocol was evaluated and authorized by the Human Research Ethics Committee of Tehran University of Medical Sciences. Before the questionnaire survey, each subject provided a written statement of informed permission.

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Authors' contributions

All authors equally contributed to preparing this article.

Conflict of interest

The authors declared no conflict of interest.

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