ORIGINAL RESEARCH

The World Health Organization Disability Assessment Schedule-2.0 (WHODAS 2.0) in a chronic pain population being considered for chronic opioid therapy

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Purpose: To examine the validity of the World Health Organization Disability Assessment Schedule 2.0 (WHODAS 2.0) for the assessment of function in a community-based sample of patients with chronic pain conditions undergoing evaluation for chronic opioid therapy.

Patients and methods: One hundred nine of 124 patients were evaluated for a chronic opioid therapy program between December 1, 2014 and April 10, 2015, inclusive, at one community-based interdisciplinary pain management practice. Measures included: demographic data; the WHODAS 2.0; a modified version of the Roland Morris Disability Questionnaire (RMDQ-m); the Patient Health Questionnaire-9 item (PHQ-9); the Screener and Opioid Assessment for Patients with Pain-Revised (SOAPP-R); the Current Opioid Misuse Measure (COMM), the Opioid Risk Tool (ORT); opioid dose. These data were collected as part of routine care, and this retrospective chart review study examined the data from this convenience sample, comparing the results of each assessment tool to the results of the WHODAS 2.0.

Results: Median score on the WHODAS 2.0 was 25.69 (IQR=16.01 to 35.28). WHODAS 2.0 score was significantly correlated with the RMDQ-m (r_s =0.69, p<0.001), the PHQ-9 (r_s =0.68, p<0.001), the COMM (r_s =0.52, p<0.001) and the SOAPP-R (r_s =0.51, p<0.001). There was no significant correlation between the WHODAS 2.0 and the ORT (r_s =0.14, p=0.12) or opioid dose (r_s =0.07, p=0.47).

Conclusions: The WHODAS 2.0 was significantly positively correlated with other measures, including measures of disability, risk of opioid misuse, and depression among patients being evaluated for chronic opioid therapy. The WHODAS 2.0 may be a useful measure of disability across a number of important domains when discussing expectations of both patients and providers at initiation of opioid therapy for chronic pain management. This assessment and discussion is crucial, particularly given the focus on function, rather than analgesia alone, when evaluating the effectiveness of opioid treatment.

Keywords: disability, chronic pain, opioids, function

Introduction

Chronic pain affects as many as 100 million Americans,¹ resulting in an estimated cost to society of US\$635 billion annually, with costs due to lost productivity and related disability found to be as high as \$335 billion annually.² With an estimated 13 million pain patients receiving long-term opioid treatment,³ chronic opioid therapy (COT) may contribute significantly to these costs. COT is reported to be associated with the development or exacerbation of substance use disorders,

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overdose/death, endocrinopathy, hyperalgesia, constipation, falls and fractures, motor vehicle accidents, cardiovascular events, and sleep apnea.^{4,5} The impact of COT on physical functioning is mixed, with some studies suggesting improvement and others describing diminishment across a range of domains.⁶⁻⁸ Accordingly, published guidelines have been increasingly calling for a shift of focus from pain reduction to functional improvement as the primary goal of COT.9 Unfortunately, assessing function in patients receiving COT is challenging as standardized, efficient, face valid measures that can be used across various pain conditions are generally lacking. Numerous self-report measures of disability and function with strong psychometric properties have been developed and/or validated in disease- and pain site-specific populations, including low back pain,¹⁰ neck pain,¹¹ foot pain,¹² osteoarthritis,¹³ fibromyalgia,¹⁴ rheumatoid arthritis,¹⁵ and migraine.¹⁶ Nonetheless, few disability measures have been validated across a variety of pain sites and conditions, with even fewer used cross culturally. Global measures such as the PROMIS PF CAT have received increasing attention in pain medicine;¹⁷ however, this group of measures has been challenged with respect to clinical utility.18

The World Health Organization Disability Assessment Schedule-2.0 (WHODAS 2.0) is a relatively short, facevalid measure of self-reported disability developed to measure disease burden across all psychiatric and medical diseases, and in all populations and cultures,¹⁹ and has been validated in populations suffering from myriad psychological and physical disease states.²⁰ The WHODAS 2.0 assesses six domains of function that correspond to the "activity and participation" dimension of the International Classification of Functioning, Disability, and Health (ICF): Cognition (understanding & communicating); mobility (moving & getting around); self-care (hygiene, dressing, eating & staying alone); getting along (interacting with other people); life activities (domestic responsibilities, leisure, work & school); participation (joining in community activities). Administration of the 36-item version requires approximately 15-20 mins. This measure can be scored using simple scoring (a more practical way to hand-score for daily clinical use), or complex scoring based in item response theory.¹⁹

Despite the number of studies employing the WHODAS 2.0, it has yet to be validated in a chronic pain patient population being considered for COT. As such, we present data examining the validity of the WHODAS 2.0 for the assessment of function in a community-based sample of

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Material and methods

for COT.

This study was reviewed and determined by the Tufts University Health Sciences Institutional Review Board to be not human subject research due to the retrospective, deidentified data gathered per the protocol. As such, no informed consent process was done. Electronic health record data was extracted for a convenience sample of 124 subjects who were evaluated for a COT program between December 1, 2014 and April 10, 2015, inclusive, at one communitybased interdisciplinary pain management practice located in a suburb of Boston, Massachusetts. The evaluation process for COT program is standardized for all patients, and included a psychological evaluation, standardized self-report measures described below, self-reported functional goals, urine drug toxicology, and review of prescription drug monitoring program data. All of this information is gathered on one day, over the course of a 2.5 hr evaluation with 3 specialist clinicians: psychologist/social worker, nurse practitioner, and chiropractor with expertise in functional assessment. This information is then presented in a weekly interdisciplinary team review meeting to determine risk of opioid misuse and potential benefit of COT, and finalize an interdisciplinary plan of care. Fifteen subjects' data were excluded from analyses due to apparent invalid or incomplete WHODAS 2.0 (Table 1), leaving 109 sets of data included in the data analysis.

Variables

Demographic data included age, gender, marital status, and work status (employed, retired, disabled, not employed, Worker's Compensation).

Table	I	Reasons	for	exclusion	for	15	excluded	subjects
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Reason	n	
Did not complete the evaluation visit	2	
Family member completed questionnaires	1	
No questionnaires completed due to blindness	1	
Entire WHODAS 2.0 measure incomplete	2	
Entire third page of WHODAS 2.0 measure incomplete	3	
5 items of WHODAS 2.0 incomplete ^a	1	
4 items of WHODAS 2.0 incomplete	3	
3 items of WHODAS 2.0 incomplete	2	

Notes: $\ensuremath{^a}\xspace{incomplete}$ item count does not include items in work/school section if left incomplete

Abbreviations: WHODAS 2.0, World Health Organization Disability Assessment Schedule 2.0.

Daily opioid dose

Daily opioid dose at the time of evaluation was extracted from the electronic health record. The pain center's electronic health record includes customized clinical encounter templates for opioid prescribing evaluation visits, including a built in calculator to convert any opioid prescription entered into to daily milligrams morphine equivalent (MME) using the conversions published by the Washington State Agency Medical Directors' Group.²¹

WHODAS 2.0

The WHODAS 2.0 36-item version was used to assess disability. Each item uses a 5-point Likert scale to rate the degree of difficulty completing various tasks over the past 30 days: 1=None, 2=Mild, 3=Moderate, 4=Severe, 5=Extreme or Cannot Do. It has demonstrated high concurrent validity with comparable instruments designed to measure disability in day-to-day functioning across activity domains.¹⁹ Internal consistency is high for the total measure (Cronbach's a=0.96) as well as each domain (Cronbach's α ranged from 0.79 to 0.98) and test-retest reliability was also good for the total measure (interclass correlation coefficient =0.98) as well as across items (interclass correlation coefficient ranged 0.69-0.89) and domains (interclass correlation coefficient ranged 0.93-0.96).¹⁹ The complex scoring method was used for this study wherein the summary score is converted to a metric ranging from 0=no disability to 100=full disability. The complex scoring program used for this study was downloaded from the WHO website (https://www.who.int/classi fications/icf/whodasii/en/), as advised in the WHODAS 2.0 manual. While the simple scoring method is recommended for daily clinical use, in part due to its ease with paper and pencil, the complex scoring method is recommended by WHO when conducting research.

Additional self-report measures

A modified version of the Roland Morris Disability Questionnaire $(RMDQ-m)^{22}$ was used to assess disability due to pain. The 24-item measure was modified from each item describing "back pain" to "pain" (eg, "I walk more slowly than usual because of my back" was modified to "I walk more slowly than usual because of my pain"). Similar modifications to the items have been described in the literature and supported by the authors of the RMDQ.²³ Scores range from 0 to 24, with 0 representing no disability from pain and 24 representing maximum disability from pain.

The Patient Health Questionnaire-9 $(PHQ-9)^{24}$ is a validated and reliable nine-item measure of the severity of depression symptoms. Scores range from 0 to 27, with scores of 10 or greater indicating the need for further evaluation of a major depressive episode.

The Screener and Opioid Assessment for Patients with Pain-Revised (SOAPP-R) is a 24-item measure designed to predict opioid misuse in patients with chronic pain for whom initiation of COT is being considered. Each item is rated on a 5-point Likert scale anchored at 0 with "never" and at 4 with "very often". A score of 18 or greater is used to indicate higher risk of opioid misuse. Previous studies have shown good psychometric properties in comparable subject populations.^{25–27}

The Current Opioid Misuse Measure (COMM) is a 17item measure assessing behaviors of patients on COT, with good reliability and validity reported in previous studies.^{28,29} A score of 9 or greater is used to indicate higher risk of opioid misuse.

The Opioid Risk Tool $(ORT)^{30}$ is one of the measures completed by the behavioral provider using information gathered from the patient's self-report during the clinical interview. Scores range from 0 to 26 with a score of 0–3 indicating low risk for opioid misuse, 4–7 as moderate risk, and 8 or greater as high risk.

Statistical analyses

Descriptive statistics (counts and percentages for categorical variables; medians, inter-quartile ranges, and ranges for discrete and continuous variables) were calculated. Associations between discrete/continuous variables were assessed via the Spearman rank-order correlation (r_s) due to non-normality of data. Employment statuses were compared in terms of disability measures using the Kruskal-Wallis test; post-hoc testing was conducted via the Mann-Whitney U test with the Bonferroni correction. The significance level was set at α =0.05, with the exception of tests in which the Bonferroni correction was employed. SPSS Version 24 was used in the analysis.

Results

Subjects included in data analysis (n=109) had a median age of 54 years (interquartile range [IQR]=48 to 61) and ranged in age from 25 to 88 years. Forty-five percent were male and 71% were married or partnered. The median total score on the WHODAS 2.0 was 25.69 (IQR=16.01 to 35.28). Median scores and ranges for clinical variables and self-report measures are reported in Table 2.

Variable	Median	First Quartile	Third Quartile	Range
MME	15.0	0.0	62.0	0-400
PHQ-9	6.0	3.0	11.0	0–23
SOAPP-R	14.0	9.0	21.0	0–70
СОММ	4.0	2.0	8.0	0–34
ORT	2.0	1.0	5.0	0–16
RMDQ-m	12.0	9.0	16.0	0–24
WHODAS 2.0	25.69	16.01	35.28	0–63.89
Communicating	4.17	0.00	20.83	0–75.00
Getting	50.00	30.00	65.00	0–90.00
Around				
Self-Care	12.50	0.00	25.00	0–75.00
Getting Along	10.00	5.00	20.00	0–75.00
Activities	31.25	18.75	50.00	0–93.75
Participation	31.25	18.75	46.88	0–93.75

Table 2 Clinical characteristics for all subjects (n=109)

Abbreviations: MME, milligrams morphine equivalent; PHQ-9, Patient Health Questionnaire- 9 item; SOAPP-R, Screener and Opioid Assessment for Patients with Pain- Revised; COMM, Current Opioid Misuse Measure; ORT, Opioid Risk Tool; RMDQ-m, modified Roland Morris Disability Questionnaire; WHODAS 2.0, World Health Organization Disability Assessment Schedule 2.0.

There was a statistically significant relationship between responses on the WHODAS 2.0 and RMDQ-m (r_s =0.69, p<0.001). Each of the 6 domains of the WHODAS 2.0 was significantly correlated with the WHODAS 2.0 total, the RMDQ-m, and each of the other WHODAS 2.0 domains at the 0.05 level (Table 3). Both the WHODAS 2.0 and the RMDQ-m were significantly correlated with the PHQ-9 (r_s =0.68, p<0.001 and r_s =0.60, p<0.001, respectively). Opioid dose was not significantly correlated with the WHODAS 2.0 (r_s =0.07, p=0.47) nor with any other self-report measure.

Subjects' employment status (excluding the Worker's Compensation group because there was only 1 subject in this group) and median disability measure scores are summarized in Table 4. Subjects' self-reported disability was greater for the disabled group when compared with the employed group on both the WHODAS 2.0 (p<0.001) and the RMDQ-m (p<0.001) and when compared with the retired group on both measures (p<0.001 and p=0.003, respectively). No other differences in perceived disability among groups reached statistical significance.

There was a statistically significant relationship between subjects' responses on the WHODAS 2.0 and responses on the COMM ($r_s=0.52$, p<0.001) and the SOAPP-R ($r_s=0.51$, p<0.001). There was no significant correlation between patients' responses on the WHODAS 2.0 and the ORT ($r_s=0.14$, p=0.12). Similarly, the correlation between the RMDQ-m and scores on the COMM ($r_s=0.45$, p<0.001) and the SOAPP-R ($r_s=0.42$, p<0.001) were statistically significant, but correlation with ORT did not reach significance ($r_s=0.03$, p=0.77).

Discussion

The results of this study demonstrated significant positive correlations between self-reported disability as measured by the WHODAS 2.0 and scores on the RMDQ-m. This correlation represents preliminary validation of the WHODAS 2.0 in a novel population of chronic pain patients being considered for COT. All of the 6 subscales were positively correlated to each other and the total WHODAS 2.0 score among our sample. There appears to be good feasibility of the measure for this sample; 109 of 124 patients completed the measure in entirety alongside 4 other screening measures administered. Results did reveal a possible burden as 5 patients left one or more pages incomplete, and another 6 patients left between 3–5 items incomplete, though this study did not gather data on the reasons for incomplete measures.

WHODAS 2.0 scores were not significantly correlated with opioid dose at the time of evaluation, a result consistent with the mixed literature on the impact of opioids on function.^{4–8} Those who had disabled employment status had significantly higher scores on both disability measures compared to employed and retired patients. While level of disability may lead to one applying for disability income, it may be the case that applying for disability income leads to self-perception of worse disability. There may also be other confounding dimensions such as physical impairment or psycho-social difficulties that are measured on the WHODAS 2.0 that affect one's employment status as well. These findings are consistent with a 2010 study in which WHODAS 2.0 scores were significantly different between those working and those not working due to their health condition.³¹

The scores on the WHODAS 2.0 correlated positively with the risk of opioid misuse as measured by the COMM and the SOAPP-R. The ORT screening failed to demonstrate a significant relationship with both disability measures, and may be explained by very recent findings of its questionable validity in a tertiary care chronic pain population.³² Consistent with earlier studies identifying a relationship between disability and depression,^{33–35} WHODAS 2.0 scores were positively correlated with PHQ-9 scores.

Given adequate psychometric properties evidenced in the many investigations of the WHODAS 2.0, clinical utility also should be evaluated when one considers the

	RMDQ-m	WHODAS 2.0	Communicating	Getting around	Self-care	Getting along	Activities	Participation
RMDQ-m	00.1	-	-	-	1	-	1	-
WHODAS 2.0	0.69**	00.1						
Communicating	0.36**	0.67**	00.1					
Getting around	0.68**	0.74**	0.23*	1.00				
Self-care	0.55**	0.77**	0.48**	0.57**	1.00			
Getting along	0.34**	0.62**	0.67**	0.22*	0.36**	1.00		
Activities	0.55**	0.77**	0.36**	0.52**	0.52**	0.36**	I.00	
Participation	0.54**	0.85**	0.61**	0.57**	0.56**	0.53**	0.59**	00.1
Notes: *Correlation is si Abbreviations: RMDQ-I	ignificant at the 0.05 I∉ m, modified Roland M	Notes: *Correlation is significant at the 0.05 level (2-tailed). ** Correlation Abbreviations: RMDQ-m, modified Roland Morris Disability Questionnaire	Notes: *Correlation is significant at the 0.05 level (2-tailed). ** Correlation is significant at the 0.01 level (2-tailed). Abbreviations: RMDQ-m, modified Roland Morris Disability Questionnaire; WHODAS 2.0, World Health Organization Disability Assessment Schedule 2.0.	-tailed). Organization Disability Assess	sment Schedule 2.0.			
				O Sameanon Livering a work				

Table 3 Disability measure Spearman correlations for all subjects (n=109, df=107)

employment status	
ures (median and IQR) by	
Table 4 Disability measur	

	Employed (n=42)	Retired (n=24)	Disabled (n=33)	Not Employed (n=9)	Difference Between Groups p
RMDQ-m	10.5 (7.0 to 13.0)	10.0 (7.5 to 15.5)	16.0 (13.0 to 19.0)	17.0 (11.0 to 20.0)	<0.001 ^a
WHODAS 2.0	20.12 (9.62 to 30.73)	17.31 (13.84 to 26.76)	33.58 (27.92 to 46.42)	30.31 (20.42 to 54.27)	<0.001 ^b
Notes: Worker's Compen	sation employment status has only I si	ubject and was excluded from analyse	s. ^a Post hoc analyses revealed significa	nt differences in RMDO-m scores betwee	Notes: Worker's Compensation employment status has only subject and was excluded from analyses. ^a Post hoc analyses revealed significant differences in RMDO-m scores between employed and disabled groups (p<0.001), and

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adoption of a self-report disability measure in the context of COT. The WHODAS 2.0 addresses face-valid disability domains that may greatly assist the clinician in goal-setting and measurement of discrete objective gains by the patient. However, other studies have shown that the WHODAS 2.0 suffers from the bias seen with many measures of self-reported disability in that it favors a medical model of disability, over social models or other interpretations, despite the apparent range of items across activities in an attempt to be consistent with the WHO ICF framework of disability.³⁶ It is clear that no single instrument can meet all of the required components of a thorough disability assessment, and limitations exist with the WHODAS 2.0 as with any self-report measure. Nonetheless, it remains a promising instrument for clinicians assessing chronic pain in patients receiving COT. In the clinical setting, a simple disability "score" is often inadequate, particularly as the literature and the findings of this study indicate that opioid dose was not correlated with scores on disability measures. Therefore, a disability measure should be considered a clinical tool to use as a component of a thorough disability evaluation to aid in treatment planning.

One of the strengths of this study is that it is the first to our knowledge evaluating the WHODAS 2.0 in a population of chronic pain patients being considered for COT. The study population reflects a broad community-based population seeking pain management at a multidisciplinary, tertiary care pain center for a range of pain complaints, rather than focused on a particular pain-related diagnosis population. Limitations are inherent in retrospective cohort studies, and one common limitation is missing data. This occurred for 12% of the sample and to address this issue, we used qualitative information about these patients to discuss the feasibility of using the WHODAS 2.0 in this population. Future research should evaluate the feasibility of the 36-item version compared to the 12-item version, particularly when administered alongside multiple other measures as is typical during opioid risk assessments. Another limitation is that we used the RMDQ-m, another self-report measure of disability, to validate the WHODAS 2.0 in this population, and future validation studies should consider including clinician ratings and/or objective measures of disability and impairment. Given that the use of opioids for chronic pain has been found to be predictive of higher levels of disability as measured by the RMDQ,³⁷ our hope is that future research on the WHODAS 2.0 will examine opioids' prediction of higher scores on this measure, as well. Last, this small validation study may not be generalizable to all patients seeking COT at pain management centers, and replication of this study in a larger sample and other settings such as academic hospitals or primary care offices is encouraged.

Conclusion

The results of this investigation revealed that the WHODAS 2.0 was significantly positively correlated with other measures, including disability, risk of opioid misuse, and depression among patients being evaluated for COT. While not a perfect measure of disability, the WHODAS 2.0 does appear to capture a disability rating based on a broader biopsychosocial definition of disability, as set forth by the WHO ICF. As such, it may be a more useful tool when discussing expectations of both patients and providers at initiation of COT for chronic pain management. This assessment and discussion is crucial, particularly given the focus on function, rather than analgesia alone, when assessing the effectiveness of opioid treatment.^{38,39}

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Disclosure

Dr Michael E Schatman is a consultant for Kaleo Pharma, outside the submitted work. The authors report no other conflicts of interest in this work.

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