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Translation and validation of the Depression Outcomes Module (DOM) in Greece

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ABSTRACT

In Greece, as in other countries, major depressive disorder is underdiagnosed. Its severity, implications and outcomes are often not adequately evaluated. The Depression Outcomes Module (DOM) was developed in order to meet the need for a global assessment of this disorder. The objective of the current study was to estimate the psychometric properties of DOM in a Greek population presenting depressive symptoms.

The DOM was translated into Greek. Patients were examined twice (baseline and follow-up assessment). The psychometric properties of DOM were calculated. Subjects were 83 psychiatric inpatients and outpatients presenting depressive symptoms. The measures used were DOM, Structured Clinical Interview for DSM III-R (SCID) and Hamilton Rating Scale for Depression (Ham-D). The results were: (a) baseline assessment: test-retest reliability k = 0.90, internal consistency 0.93, sensitivity 97%, specificity 90%; (b) follow up assessment: test-retest reliability k = 0.89, sensitivity 81% and specificity 67%. Recovery from depression detected by DOM at the follow-up was significantly correlated both with pharmacotherapy and with a combination of pharmacotherapy and supportive psychotherapy. It was concluded that the Greek version of DOM is a comprehensive, useful instrument for diagnosing, assessing depression and evaluating its outcomes.

Key words: Depression Outcomes Module (DOM), validation, Greece

Introduction

Major depressive disorder is a significant issue in mental healthcare. Its point prevalence reaches 5% in community surveys (Horwath and Weissman, 1995), ranges between 5% and 9% in primary care services (Kroenke, 2003) and between 8% and 13% among general hospital psychiatric inpatients (Martucci et al., 1999; Hansen et al., 2001). Although major depression is an important cause of suicide (Rihmer, 2001 and the WHO World Health Report 2001 at http://www.who.int/whr/2001/chapter2/en/index6.html), disability and poor quality of life (WHO World Health Report 2001 at http://www.who.int/whr/2001/chapter2/en/index4.html), and increases health care costs considerably (Carta et al., 2003), many cases are undiagnosed or poorly managed (Greden, 2003). General functioning, severity of the disorder, prognostic variables, treatment components and outcomes are either unreliably assessed or not assessed at all. For these reasons the cost-effectiveness of the management of this condition is far from optimal (Sturm, 1995).

In certain countries the above difficulties are also connected to the lack of appropriate instruments for objective and systematic assessment of depression. In Greece, there are structured psychiatric interviews and brief screening tests are available for this disorder. The use of these measures is important, especially concerning diagnostic or epidemiological aims, but they do not meet the need for global registration or for the evaluation of different factors (such as social, medical, psychological, therapeutic factors) related to the course of the disease. Moreover, an outcome measure of depression is necessary for conducting effectiveness research in mental health care (Sturm, 1995).

Considering the above, the authors of the present study decided to translate the Depression Outcomes

Module (DOM) into Greek and validate it. According to its manual, this measure can identify patients with major depressive disorder, evaluate the symptoms' severity, assess specific and generic outcomes of the disease, and register prognostic variables and relevant care elements. This measure has been used in the US in the clinical assessment of depressive patients and in outcome research projects (Rost et al., 1992; Smith et al., 1998; Smith et al., 2000).

Methods

Sample

The sample in this study consisted of 83 patients (46 women and 37 men) – 18 inpatients admitted in a psychiatric department, and 65 outpatients recruited from four different psychiatric outpatient units (two hospital clinics and two mental health centres). Among the 65 outpatients, 21 were referred by a primary care provider, and the 45 others contacted the outpatient unit on their own initiative. The criterion for inclusion in the sample was increased probability of active depression. This criterion is compatible with the main purpose of DOM (that is, the global assessment of depression and its outcomes). A similar criterion was used in the original validation of the scale (Rost et al., 1992).

The sampling procedure was carried out by a research team of two psychiatrists in collaboration with the medical staff of the psychiatric department and units. The two psychiatrists repeatedly visited each of the above settings on prearranged dates. At each visit they were provided with a list of all available patients presenting with depressive symptoms. The inpatients were recently admitted in the psychiatric department. The outpatients had an appointment with a psychiatric care provider in the outpatient unit. The first two patients listed in alphabetical order were asked to give their informed consent to participate in the present study. They were advised that the aim of the study was the validation of a psychological test and that their participation was optional and would be confidential. Out of 86 patients, 83 gave their consent and constituted the sample of the study. Three patients expressed fears about the confidentiality of the study and refused to participate.

The mean age of the sample was 34.78 ± 11.50 years and the median age was 34 years. Other demographic characteristics of the sample are shown in Table 1.

Table 1. Sociodemographic characteristics of the sample

	N (83)	%
Age		
≤30 years old	32	38%
>30 ≤ 60 years old	47	57%
>60 years old	4	5%
Sex		
Male	37	45%
Female	46	55%
Education		
6-9 years of studies	26	31%
10-12 years of studies	28	34%
>12 years of studies	29	35%
Income		
≤18000/year	49	59%
>18000/year	34	41%
Marital status		
Married	44	53%
Single	32	38%
Separated	4	5%
Widowed	3	4%

Measures

Depression Outcomes Module (DOM)

The DOM is used to assess the process of care and the characteristics of patients with major depressive disorder in primary care settings and in both inpatient and outpatient specialty care settings. Data collected by the DOM can be used to address research questions or to inform treatment decisions. The DOM can also be used as a part of an outcomes management system in order to monitor and improve patient's outcomes (Smith et al., 2000; Smith et al., 2002). It consists of five forms:

- Patient Screener (PS). This form consists of three questions completed by the patient in 2 minutes. It is a rough diagnostic screening tool.
- Patient Baseline Assessment (PBA). This comprises 79 items completed by the patient in about 25 minutes. It includes the Depression Arkansas Scale (D-ARK), which consists of 11 items, concerning 11 different depressive symptoms. The

scores of the four first items range from 1 to 4, (1 = no, 2–4 = yes). The scores of the next six items range between 1 and 4. (1 or 2 = no, 3–4 = yes). The score of the last item (suicidality) ranges between 1–2 (1 = no, 2 = yes). D-ARK measures (a) the existence of major depressive disorder (if there is a 'yes' answer to at least five items, including the item 'depressed mood' or the item 'loss of pleasure'); and (b) the severity of depression (the sum of the scores of all the 11 items). Attention has been paid to ensuring that the symptoms lead to the diagnosis of major depressive disorder according to the relevant criteria of DSM-IV. Other items of PBA measure various outcomes of care and prognostic characteristics such as social functioning, bed days, co-occurring physical or psychiatric problems, and quality of life (Ware et al., 1993), in order to examine how symptom severity and functioning change over time.

- Clinician Baseline Assessment (CBA). This is filled in, by a clinician aware of the patient symptoms, in 5 minutes. It provides information about (a) exclusion criteria for the diagnosis of major depressive disorder such as uncomplicated bereavement, depression caused by an organic disorder or by a side-effect of medication – if the clinician comes across an exclusion criterion, the diagnosis made by PBA is cancelled; (b) the depressive symptoms that the clinician is treating or considering in reaching a diagnosis; (c) prognostic characteristics; (d) prescribed medication.
- Patient Follow-up Assessment (PF-upA). This is completed by a patient with a diagnosis of major depressive disorder at baseline, usually 3 to 6 months after the baseline assessment. It is similar to PBA and provides additional information on treatment and outcome of care (for example, medication compliance, psychotherapeutic sessions, suicidality, work disability) during the follow-up period.
- Medical Record Review (MRR). This is completed by the clinician at every follow-up. It contains disease-specific outcomes or treatment incidents. In most cases, the treatment information comes from a major provider of care (for example the records of a clinic) during the follow-up period.

According to its guidelines, the DOM is designed either for patients who screen positive for depression according to PS or for patients who have received a preliminary diagnosis of depression by their care provider. Such patients are given a baseline assessment and if they receive a diagnosis of major depressive disorder they join a follow-up programme.

DOM is copyrighted but is available for free use for clinical care or research without charge to patients.

The DOM – translation

The DOM was translated from the English original text into Greek by a native Greek, speaking English fluently, and back translated into English by a native English-speaking Greek. Then the study team compared the translations. Before the final text was shaped, a qualitative analysis was performed, according to the following process. First, a convenience focus group of eight outpatients was created. These patients came from the same settings as the sample patients. In order to reduce selection bias we included patients from various social backgrounds, different ages and different educational levels. Another selection criterion was their availability to participate in the scheduled meetings of the focus group. Each of these patients, who were not included in the sample, completed the DOM separately. Immediately after completion, the patients were asked to comment on each item of the questionnaire. Meetings of the focus group were then held, with the participation of members of the research team. During these meetings questions were asked and the opinions of the participants about the interview were discussed. To improve its readability, the Greek translation of DOM was reviewed by a philologist for grammar or syntax errors.

Other measures

The following instruments were used as controls for the DOM's validity:

- The Structured Clinical Interview for DSM-III-R (SCID) (Spitzer and Williams, 1990), a semi-structured interview validated in Greece (Madianos et al., 1997). As SCID for DSM-IV is not yet validated in Greece, instructions for converting DSM-III-R diagnoses into DSM-IV diagnoses (First et al., 2004) were followed. The SCID served as the 'gold standard' against which the diagnoses of major depressive disorder derived from DOM were evaluated.
- The Hamilton Psychiatric Rating Scale for Depression (Ham-D) (Snaith, 1996) was used to

evaluate the D-ARK validity in assessing the severity of depression.

Study design

The final text of the translated DOM was administered to the patients of the sample at an initial baseline examination and at a 6-month follow-up examination.

At the baseline examination, a psychiatrist trained and experienced in using the SCID interviewed the participants and completed the CBA. Then, the patients filled in the PS and the PBA. Next, the same psychiatrist interviewed the patients with SCID and completed Ham-D. Another psychiatrist examined the same patients and completed the CBA. Seven days later, the PBA and the CBA were filled in again by the first interviewer and the same patients.

The 63 interviewees who, according to SCID, presented at baseline examination with major depressive disorder were registered in a 6-month follow-up programme. At the first follow-up examination the same procedure, concerning the administration of the measures, was repeated for 48 of the 62 registered interviewees. The other 14 were not found or did not attend the arranged appointments.

Statistics

Validity

The sensitivity and the specificity of the DOM were calculated by comparing the diagnoses of major depressive disorder set by the PBA and the PF-upA with those made by the SCID. Furthermore, the overall agreement of DOM was assessed using the Kappa coefficient.

Pearson correlations were conducted between the scores of D-ARK on the one hand and the scores of Ham-D or the number of the registered by SCID depressive symptoms on the other in order to evaluate the validity of DOM quantatively.

To further estimate the validity of DOM, different external validators were used depending on (a) the severity of depression, measured using quantitative criteria such as bed days during the last month, social, emotional and physical ability, health perception, and annoyance caused by bodily pains, and (b) the adequacy of the treatment (sufficient pharmacotherapy and/or psychotherapy).

Pearson correlations were calculated between the differences of the scores of each of the quantitative criteria mentioned above at the baseline and the follow-up assessments and the relevant differences of the scores of D-ARK. An analysis of covariance was performed on the treatment validators. It was expected that both sufficient pharmacotherapy and psychotherapy (which were the independent variables in the analysis) would positively influence the difference in the scores of D-ARK between the two assessments (baseline and follow-up). The demographic characteristics (sex, age and educational level) of the patients were the variables under control.

Reliability

The *test-retest* reliability of DOM was estimated by calculating:

- (a) the concurrence of diagnoses of major depressive disorder for each patient in the PBA and in the PF-upA, and also (b) the concurrence of suicidal ideation for each patient in the PF-upA, both using the Kappa coefficient;
- the agreement between the scores of D-ARK in the PBA and the PF-upA, using the intra-class correlation coefficient;
- the percentage agreement between patients' responses in the PF-upA and the clinician's reports in the MRR concerning the number of incidents of: (a) visits to a doctor, (b) psychotherapeutic sessions, (c) admissions to a psychiatric department, (d) visits to emergency departments.

The *inter-rater* reliability of DOM was estimated by calculating the number of depressive symptoms in the CBA using the intra-class correlation coefficient (ICC).

The *internal consistency* of the D-ARK was measured using the Cronbach α method.

Results

According to the SCID, 62 out of 83 interviewees (75% of the sample) presented with an active episode of major depressive disorder. Their mean score on Ham-D was 34.04 ± 7.13. The relevant score for the non-depressed interviewees was 13.04 ± 6.79. As many as 21 (34%) of the depressed patients had a history of a previous depressive episode. The depressed patients also presented the following comorbidity: 27 (44%)

had panic disorder with or without agoraphobia, 13 (21%) had other anxiety disorders, none had psychosis, and 4 (6%) had other disorders.

The 48 patients who completed the study presented at baseline assessment mean score in Ham-D 33.5±6.86 while the relevant score for the 14 dropouts was 35.92 ± 7.95. Patients who completed the study did not differ significantly from the dropouts in relation to sex, age, other demographic characteristics or the baseline assessment Ham-D scores.

Validity

The PS correctly screened 61 of the 62 patients classified as depressive by the SCID (sensitivity = 98%, 95% CI = 90–100) and 9 of the 21 patients classified by the SCID as non-depressed (specificity = 43%, 95% CI = 23–65). The Kappa coefficient for the overall agreement of the PS was 0.50 (95% CI = 0.28–0.72) (Table 2).

The PBA correctly diagnosed 60 of the 62 patients who were classified as depressive by the SCID (sensitivity = 97%, 95% CI = 88–99) and 19 of the patients who were classified as non-depressed by the SCID (specificity = 90%, 95% CI = 68–98). Kappa coefficient for the overall agreement of the PBA equals 0.87 (95% CI = 0.75–0.99) (Table 2).

The PF-upA diagnosed correctly 4 of the 6 patients who were classified as depressive by the SCID (sensitivity = 81%, 95% CI = 65–91) and 32 of the 42 patients who were classified as non-depressed by the SCID (specificity = 67%, 95% CI = 24–94). The Kappa coefficient for overall agreement of the PF-upA was 0.27 (95% CI = –0.01–0.56) (Table 2).

The baseline D-ARK score correlated strongly with the Ham-D score (r = 0.65, 95% CI = 0.51–0.76), as well as with the number of depressive symptoms in the SCID (r = 0.69, 95% CI = 0.56 to 0.79) (Table 2).

Table 2. The validity of Depression Outcomes Module (DOM) – Greek Version

	DOM
Patient Screener (Baseline Assessment (*N* = 83)	
Sensitivity (95% C.I.)	98% (90–100)
Specificity (95% C.I.)	43% (23–65)
Overall agreement (k[1], 95% C.I.)	0.50 (0.28–0.72)
Patient baseline assessment (N = 83)	
Sensitivity (95% C.I.)	97% (88–99)
Specificity (95% C.I.)	90% (68–98)
Overall Agreement (k[1], 95% C.I.)	0.87 (0.75–0.99)
Patient 6-month follow-up assessment (*N* = 48)	
Sensitivity (95% C.I.)	81% (65–91)
Specificity (95% C.I.)	67% (24–94)
Overall Agreement (k[1], 95% C.I.)	0.27 (–0.01–0.56)
Pearson correlation of D-ARK[2] (baseline) with: Ham-D[3] (*N* = 83)	r = 0.65 (95% CI = 0.51–0.76)
SCID[4] (number of symptoms) (*N* = 83)	r=0.69 (95% C.I = 0.56–0.79)

[1] Kappa coefficient.
[2] Depression Arkansas Scale.
[3] Hamilton Psychiatric Scale for Depression.
[4] Structured Clinical Interview for DSM-III-R.

The difference between the D-ARK scores at baseline and follow-up was highly correlated with the corresponding differences of the following validators: bed days (r = 0.52, 95% CI = 0.30 to 0.70), social functioning (r = –0.54, 95% CI = –0.71 to –0.29), emotional functioning (r = –0.50, 95% CI = –0.68 to –0.24). The correlations with physical functioning, bodily pain improvement and health perception were not significant (Table 3).

Sufficient pharmacological treatment (F = 38.705, p < 0.000) and the combination of sufficient pharmacotherapy with psychotherapy (F = 4.756, p = 0.035) constitute independent factors that contribute considerably to the recovery from depression at the follow-up examination. Other factors like supportive psychotherapy without pharmacotherapy (F = 1.336, p = 0.254), education (F = 0.327, p = 0.570), age (F = 1.117, p = 0.297) were not found to be significantly correlated with recovery from depression.

Test-retest reliability

The diagnoses of major depressive disorder that resulted from successive applications of the DOM to the same patient gave the following levels of agreement: PBA: k = 0.90 (SE = 0.052, p < 0.000), PF-upA: k = 0.89 (SE = 0.072, p < 0.000), existence of suicidal ideation at the follow-up examination: k = 0.78 (SE = 0.204, p < 0.000). The correlation for the scores of D-ARK was ICC = 0.97 (F = 71.47, DF = [80, 80,0], p < 0.000) for the PBA, and ICC=.92 (F = 24.31, DF = [47, 47,0], p < 0.000) for the PF-upA. The correlation of the numbers of depressive symptoms in the CBA was ICC = 0.93 (F = 27.43, DF= [82, 82,0], p < 0.000) (Table 4).

Table 3. Pearson correlations between the reduction of D-ARK[1] scores (6-month follow up vs baseline) and the changes in treatment characteristics (N=48)

Treatment Characteristics	D-ARK r (95% C. I.)
Bed days	52 (0.30 to 0.70)
Social functioning	–0.54 (–0.71 to –0.30)
Emotional functioning	–0.50 (–0.68 to –0.24)
Physical functioning	–0.074 (–0.34 to 0.22)
Bodily pain improvement	–0.25 (–0.49 to 0.04)
Health perception	–0.27 (–0.51 to 0.02)

[1] Depression Arkansas Scale.

Internal consistency

The items of the D-ARK scale gave a Cronbach α of 0.93 (Table 4).

Agreement for treatment incidents

The agreement between treatment incidents in the medical record reviews and in the patient follow-up assessments exceeded 95%, with the exception of the number of psychotherapeutic session (patient-rater agreement 79%, test-retest agreement 86%) (Table 5).

Discussion

Although the study team had held the opinion that the Greek population is not familiar with the use of instruments for psychiatric assessment, and would be reluctant to participate, a large majority of those examined collaborated willingly. The participants did not report difficulties during the process of completion. However, all the patients of the sample were at least primary school graduates.

According to the results, the Greek version of the DOM gave a test-retest reliability with a Kappa of > 0.80 for all but one, the relative statistical trials (Blacker and Endicott, 2000). Successive reports of incidents related to treatment coincided to a high degree. However, patients tended to report more psychotherapeutic sessions in the PF-upA than were reported in the MRR. A possible explanation is that patients considered contacts with health care providers as psychotherapeutic sessions, whereas the interviewers did not consider them as such.

The DOM's baseline sensitivity and specificity are satisfactory. It demonstrated superior specificity to screening tests validated in Greece, such as the GHQ or the SCL-90-R (Donias et al., 1991; Garyfallos et al., 1991).

However, the PF-upA presented a relatively lower sensitivity (81% versus 97% in the baseline assessment). This might be explained if patients at follow-up were presenting a clinical state nearing recovery and/or if they were underestimating their remaining symptoms. If this is the case, clinicians should take extra care because there is the danger of a premature interruption of treatment.

The external validators used confirmed the validity of DOM. The finding that medication, and medication combined with supportive psychotherapy, are reliable treatments for major depressive disorder is confirmed by the main body of modern research data

Table 4. The reliability of Depression Outcomes Module (DOM) - Greek Version

	DOM
Test - retest reliability Baseline (N=83)	
D-ARK [1] (diagnosis)	k [2]=0.90 [Std Error=0.052, p< 0.000]
D-ARK (severity)	ICC [3]=0.97 [F=71.47, DF=(80, 80,0), p< 0.000]
Follow-up (N=43) D-ARK (diagnosis)	k=0.89 [Std Error=0.072, p< 0.000]
D-ARK (severity)	ICC=0.92 [F =24.31, DF=(47, 47,0), p< 0.000]
Suicidal ideation (6-month follow up)	k=0.78 [Std Error=0.204, p<0.000]
Interrater reliability Baseline, N=83 CBA [4] (number of symptoms)	ICC= 0.93 [F = 270.43, DF=(82, 82,0), p < 0.000]
Internal consistency Baseline, N=83 D-ARK	α [5]=0.93

[1] Depression Arkansas Scale
[2] Kappa Coefficient
[3] Intraclass Correlation Coefficient
[4] Clinician Baseline Assessment
[5] Cronbach α

(Segal et al., 2001). Supportive psychotherapy *per se* was not found to be efficient in the present study. It is possible that this therapeutic method acts mainly as a backup for other therapies (Nierenberg, 2001) because it strengthens compliance with medical recommendations and/or because it can produce symptom alleviation (Vergouwen et al., 2003; Pampallova et al., 2004). However it is worth noting that the available psychotherapy for the patients of the present study was of a general supportive type. Other studies have brought evidence that specific structured psychiatric interventions such as cognitive-behavioural therapy (Beck, 1997) or interpersonal psychotherapy (Weissman and Markowitz, 1994) do have an independent therapeutic effect on depression.

The present study does have some limitations:

- As the distribution of the diagnoses is skewed, the method used to estimate some measures of reliability (Kappa coefficient) depends on marginals and the test might be biased to some degree (Spitznagel and Helzer, 1985).
- The sample consists of patients presenting at least some depressive manifestations; thus, it is not representative of a general population or of customers of a primary care centre. However, as already mentioned, DOM is used in protocols with depressive patients coming from various medical or psychiatric settings. In the present study we have followed one of the recommended methods for

Table 5. Agreement for treatment incidents at the follow up (N=48)

Treatment incidents	Agreement
Inter - rater	
Visits to a doctor	100%
Psychotherapeutic sessions	100%
Admissions to a psychiatric department	100%
Visits to the emergencies	100%
Test - retest	
Psychotherapeutic sessions	86%
Admissions to a psychiatric department	96%
Visits to the emergencies	98%
Patient - rater	
Psychotherapeutic sessions	79%
Admissions to a psychiatric department	96%
Visits to the emergencies	98%

creating such an homogenous sample of patients – a clinician's estimation that a depressive disorder might be present.

- The sampling method used here means that the reported properties of PS should be approached cautiously. A less homogenous initial sample (for instance, a random sample of primary care customers) would be more appropriate for the validation of a brief screening measure such as the PS.
- The specificity and the overall agreement of the PF-upA are not satisfactory. This might be due to the small number of cases in the follow-up assessment.

Conclusion

Despite the above limitations, the results of the present study support the view that the Greek version of DOM has satisfactory psychometric properties. Its use might (a) help clinicians to diagnose major depressive disorder more accurately in a global context, (b) help researchers to create protocols to better understand the factors related to the outcome of this disorder, and (c) help medical and mental health services to organize more effective secondary prevention interventions.

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