Incremental Validity of the Diagnostic Criteria for Psychosomatic Research – Revised (DCPR-R) to Clinical Assessment in Primary Care

INCREMENTAL VALIDITY OF THE DIAGNOSTIC CRITERIA FOR PSYCHOSOMATIC RESEARCH – REVISED (DCPR-R) TO CLINICAL ASSESSMENT IN PRIMARY CARE

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Abstract

Psychosocial problems are highly prevalent among primary care (PC) patients, but they often remain undetected using traditional classification systems. The aim of the present study was to test the incremental validity of the revised version of the Diagnostic Criteria for Psychosomatic Research (DCPR-R), in addition to standard psychiatric assessment based on DSM-5, with regard to the prediction of psychosocial functioning of PC patients. Two-hundred PC patients were consecutively recruited. A comprehensive assessment was performed using two clinical interviews and three self-rating questionnaires (the PsychoSocial Index [PSI], the Short-Form Health Survey [SF-12] and the Illness Attitude Scales [IAS]) for the assessment of psychopathology and psychosocial functioning. Adding the DCPR-R to DSM-5, the amount of explained variance significantly increased by 9% to 16% in the PSI subscales, by 13% in the SF-12 mental component summary, and by 2% to 6% in the IAS scales. The joint use of DCPR-R and DSM-5 thus significantly increased the prediction of psychosocial functioning of primary care patients. These findings further support the use of the DCPR-R in PC settings, particularly in patients who do not satisfy DSM-5 criteria and yet present with high psychological distress, maladaptive illness behavior, impaired psychological well-being and quality of life.

Keywords: Incremental Validity; Diagnostic Criteria for Psychosomatic Research – revised; Clinimetrics; Primary Care; Abnormal Illness Behavior; Psychological Distress.

1. Introduction

Mental disorders and psychosocial problems are highly prevalent among primary care patients (Carvalho and McIntyre, 2017; Roca et al., 2009; Toft et al., 2005; Wittchen et al., 2003), but they often remain unrecognized and undetected by physicians who rely on standard classification systems (Christensen et al., 2010). The Diagnostic and Statistical Manual of Mental Disorders (DSM-5) (APA, 2013) is one of the most widely used psychiatric classifications in primary care settings and so far has been considered the gold standard evaluation method (Carvalho and McIntyre, 2017).

There is, however, increasing awareness of the limited clinical utility of the DSM-5, particularly of its diagnostic rubric of Somatic Symptom and Related Disorders (SSD), which actually captures only a narrow spectrum of psychosocial variables affecting medical conditions (Cosci and Fava, 2019, 2016; Guidi et al., 2013; Hanel et al., 2009; Piolanti et al., 2019; Vanheule et al., 2014). Indeed, the DSM-5 does not provide a conceptual definition of illness behavior (Mechanic and Volkart, 1960) and of its abnormal manifestations (Pilowsky, 1986, 1978, 1969), which are very common among primary care patients and consist in a maladaptive mode of experiencing, perceiving, evaluating, and responding to one's own health status (Cosci and Fava, 2019, 2016). Studies also reported that rating scales based on DSM diagnostic algorithms were found to be not valid for sensitively detecting sub-threshold symptoms of psychological distress, which are often expressed in the form of somatic complaints by primary care patients (Fink et al., 2005; Hanel et al., 2009). Further, important clinical information such as patterns and sequence of symptoms, severity of illness, effects of comorbid conditions, rate of progression (staging), response to previous treatments, and many other clinical issues (e.g., levels of distress), which demarcate major

prognostic and therapeutic differences among primary care patients, are not included in the DSM-5 (Fava et al., 2012a).

There is, therefore, a need for assessment instruments, which display clinical validity for the evaluation of psychosocial aspects in primary care patients. Clinical validity represents a key concept in the clinimetric approach, a clinically based evaluation method for the measurement of a number of clinical issues, which do not find room in the traditional psychometric model (Bech, 2004; Carrozzino, 2019; Fava et al., 2018, 2012a, 2012b). Further, the choice of each psychological measurement is dictated by the clinimetric concept of incremental validity, which refers to the rating scale's unique contribution (or incremental increase) to the prediction of clinical information over and above standard assessment methods (Fava et al., 2012b; Hunsley and Meyer, 2003; Sechrest, 1963).

The Diagnostic Criteria for Psychosomatic Research were introduced in 1995 (Fava et al., 1995), whereas a revised version, the DCPR-R, was released in 2017 (Fava et al., 2017). The DCPR have been used and tested in various clinical settings and their clinical validity and utility have been largely documented (Basińska and Woźniewicz, 2016; De Caro et al., 2016; Desai and Chaturvedi, 2016; Porcelli and Guidi, 2015; Porcelli et al., 2009; Wise, 2009). The clinical usefulness of the DCPR-R in primary care settings has been recently reported (Piolanti et al., 2019). A number of studies showed that the joint use of the DCPR may yield important clinical information that standard psychiatric assessment cannot provide (Battaglia et al., 2018; Guidi et al., 2013; Grassi and Nanni, 2013; Huang and Liao, 2018; Leombruni et al., 2019; Offidani et al., 2016; Porcelli and Guidi, 2015; Tecuta et al., 2019).

The aim of the present study was to determine whether the DCPR-R criteria provide an incremental contribution to the prediction of psychosocial functioning of primary care patients over standard psychiatric assessment based on the DSM-5.

2. Methods

2.1. Participants

Two-hundred adult patients were consecutively recruited from a primary care setting in Northern Italy. Participants were excluded if they were < 18 or > 70 years old, had cognitive impairments, did not give written informed consent or had psychotic symptoms. Further details on recruitment procedure and patient characteristics have been provided elsewhere (Piolanti et al., 2019).

2.2. Assessment

A comprehensive assessment was performed using two clinical interviews and three self-rating questionnaires for the assessment of psychopathology and psychosocial functioning:

1. The Structured Clinical Interview for DSM-5 (SCID-5) (First et al., 2015), a semi-structured interview for obtaining DSM-5 diagnoses (APA, 2013).
2. The Semi-Structured Interview for Diagnostic Criteria for Psychosomatic Research – Revised version (SSI-DCPR-R) (Fava et al., 2017) to evaluate the presence of 14 psychosomatic syndromes. Eight of them cover clinical manifestations of abnormal illness behavior, i.e. hypochondriasis, disease phobia, thanatophobia, health anxiety, persistent somatization, conversion symptoms, anniversary reaction, and illness denial (Fava et al., 2017). Three DCPR-R syndromes (i.e.,

demoralization, irritable mood, and secondary somatic symptoms) refer to subclinical affective disturbances that are qualitatively different from traditional psychiatric disorders such as major depression and symptoms of anxiety (Fava et al., 2017). Two DCPR-R syndromes (i.e., Type A Behavior and Alexithymia) cover specific personality constructs that can potentially affect general vulnerability to disease (Fava et al., 2017). The remaining psychosomatic syndrome, the allostatic overload, refers to the cumulative effects of recent or chronic stressful experiences, which can lead to disease over time when they exceed the coping skills of an individual (Fava et al., 2019, 2017). Items of the interview for DCPR-R are scored through a yes/no response format. The interview for DCPR (Porcelli and Sonino, 2007) was developed according to clinimetric principles and was found to display excellent inter-rater reliability, construct validity and predictive validity for the assessment of psychosocial functioning and treatment outcome (Galeazzi et al., 2004). The SSI-DCPR-R allowed to formulate a higher rate of diagnoses compared to DSM-5 in migraine outpatients and showed a good criterion-related validity (Cosci et al., 2019). Diagnoses were formulated independently for DSM-5 and DCPR-R.

3. The PsychoSocial Index (PSI) (Piolanti et al., 2016; Sonino and Fava, 1998) is a 55-item self- rating scale, which was developed according to clinimetric principles and specifically designed to be used in busy clinical settings. The PSI provides a comprehensive assessment of stress, psychological distress, illness behavior, well-being and quality of life. Some questions of the PSI involve specific responses, most require a yes/no format answer, while others are rated on a 4-point Likert scale ranging from 0 (“not at all”) to 3 (“a great deal”) (Piolanti et al., 2016; Sonino and Fava, 1998). One item, measuring quality of life, is scored on a 5-point Likert scale ranging from 0 (“awful”) to 4 (“excellent”). The PSI has been used in different clinical populations and

showed high sensitivity, discriminating varying degrees of psychosocial impairment across different populations (Piolanti et al., 2016).

4. The 12-item Short Form Health Survey (SF-12) (Ware et al., 1996), which was derived from the SF-36 (McHorney et al., 1993; Ware and Gandek, 1994), is a self-rating questionnaire covering the following dimensions of health-related quality of life: physical functioning, role limitations (physical), bodily pain, general health vitality, social functioning, role limitations (emotional), and mental health. The SF-12 provides two aggregate summary measures of psychosocial functioning: the physical component summary and the mental component summary, both ranging from 0 to 100, whit higher scores indicating a higher level of quality of life. The SF-12 has been extensively validated and proved to be useful in sensitively discriminating between different groups of patients (Kontodimopoulos et al., 2007; Luo et al., 2003; Salyers et al., 2000; Ware et al., 1996).
5. Illness Attitude Scales (IAS) (Kellner, 1987; Sirri et al., 2008) include 9 self-rating scales specifically designed for the assessment of the following manifestations of maladaptive illness behavior: worry about illness, concerns about pain, health habits, hypochondriacal beliefs, thanatophobia, disease phobia, bodily preoccupations, treatment experience and effects of symptoms. Each scale consists of 3 items scored on a 5-point Likert scale ranging from 0 (“no”) to 4 (“most of the time”). The highest score is 12 for each scale and 108 for the total score. In both cases, higher scores indicate greater hypochondriacal symptoms (Sirri et al., 2008). The IAS showed high discriminant validity in differentiating patients with maladaptive illness behavior from control subjects (Sirri, 2014; Weck et al., 2010).

2.3. Data analysis

Data were analyzed using SPSS software version 20.0 for Windows (SPSS Inc., Chicago,

IL, USA). The sample size was determined using G*Power 3.1 according to the purpose of the study (Faul et al., 2009). The incremental contribution of the DCPR-R to the prediction of psychosocial functioning of primary care patients was tested using hierarchical multiple regression analyses. The dependent variables in the hierarchical regression models were the PSI, SF-12, and IAS scales. For all models, predictor variables in the first block (step 1) were age, gender, presence of a medical disease and presence of any DSM-5 disorder other than SSD (referred to hereafter as 'other DSM-5'). The presence of any SSD diagnosis (referred to hereafter as 'SSD') was entered as independent variable in the second block (step 2). Finally, the presence of at least one DCPR-R syndrome (referred to hereafter as 'DCPR-R') was added as independent variable in the third step of the hierarchical regression models. The increase in the explained variance from step 2 to step 3 served as a measure of the incremental validity of the DCPR-R.

Since our aim was to test to which extent the DCPR-R contributed over and above the DSM-5 to a significant increase in the prediction of psychosocial functioning of primary care patients, effect sizes were evaluated. According to Levine and Hullett (2002), a standardized effect size of 0.01 was considered as small, a value of 0.06 as medium and an effect size of 0.14 as large.

3. Results

Five hundred thirty-three consecutive primary care patients were approached to take part in the study. Of these, 200 (37.1%; 66% females; mean age: 46.5±14.5years) agreed to participate in the study and underwent the psychological interview. Eighty-two patients (41%) had an active medical disease, mostly cardiological (19%), endocrinological (12.5%) or pain disorders (7.5%). A total of 88 patients (44%) reported at least one DCPR-R syndrome. The most frequent DCPR-R

syndromes were allostatic overload (15.5%), alexithymia (13.5%), demoralization (13%), and irritable mood (11.5%). As to DSM-5 criteria, a total of 46 patients (23%) received at least one DSM-5 diagnosis. The most frequent DSM-5 diagnoses were SSD (10%), mood disorders (8%) and anxiety disorders (7.5%).

3.1. Incremental validity of the DCPR-R

As shown in Table 1, in the first model predictor variables accounted for a significant amount of variance in all the PSI subscales (step 1). Entering SSD into the model (step 2) significantly improved the prediction of the PSI subscale on psychological distress only ($p<0.001$). Adding DCPR-R to the model (step 3) accounted for a significant amount of incremental variance in all the PSI subscales. The explained variance increased by 11% in the PSI subscale on psychological distress, 13% in the stress subscale, 16% in the PSI well-being subscale and 9% in the PSI subscale on quality of life, with medium to large effect sizes.

The first model significantly predicted the SF-12 mental component summary (Table 2). Entering SSD into the model (step 2) significantly increased the percentage of explained variance in the SF-12 mental component summary ($p<0.01$). Adding DCPR-R to the model (step 3) accounted for a significant amount of incremental variance in the SF-12 mental component summary. The explained variance increased by 13%, with a large effect size.

The first model significantly predicted the IAS worry about illness ($p<0.05$), thanatophobia ($p<0.01$), treatment experience ($p<0.05$) and effects of symptoms scales ($p<0.001$) (Table 3). Entering SSD into the model (step 2) significantly improved the prediction of IAS scales. Adding DCPR-R to the model (step 3) accounted for a significant amount of incremental variance in the

IAS worry about illness, concerns about pain, thanatophobia, disease phobia, bodily preoccupations, treatment experience and effects of symptoms scales. The explained variance increased by 4% in the IAS worry about illness scale, 3% in the IAS concerns about pain scale, 6% in the IAS thanatophobia scale, 2% in the IAS disease phobia scale, 3% in the IAS bodily preoccupations scale, 2% in the IAS treatment experience scale and 6% in the IAS effects of symptoms scale, with effect sizes ranging from small to medium.

4. Discussion

The results of the present study showed that adding the DCPR-R to standard psychiatric assessment based on DSM-5 increased the amount of clinical information on psychosocial functioning in primary care patients. Indeed, the DCPR-R improved the prediction of psychosocial variables, which would have been otherwise undetected with the DSM-5 criteria. The added value of DCPR-R was found to be clinically significant regardless of the outcome measure, which was used as criterion variable.

As to PSI subscales, the DSM-5 diagnostic rubric of SSD contributed to the prediction of psychological distress only, while the DCPR-R provided unique clinical information in the assessment of additional psychosocial aspects such as stress, well-being, and quality of life. These findings are in line with a previous study (Guidi et al., 2013), in which the DCPR displayed greater sensitivity, compared to the DSM-5 diagnostic rubric of SSD, in detecting increased psychological distress and poorer psychosocial functioning among patients with congestive heart failure. Similarly, the DCPR-R were found to be clinically useful to unveil sub-threshold levels of

psychological distress, that would have been undetected based on DSM-5 classification, among primary care patients (Piolanti et al., 2019).

Further, the DCPR-R displayed an incremental predictive power with regard to the SF-12 mental component summary. Compared to DSM-5, the DCPR-R increased the amount of clinical information regarding functional impairment of primary care patients due to their mental health problems. The ability of the DCPR, when used jointly with standard psychiatric assessment based on the DSM, to enhance prediction of quality of life was reported in a previous study in the setting of consultation-liaison psychiatry (Porcelli et al., 2009). Evaluating patients' subjective perception of quality of life is particularly important in primary care, since it may help clinicians to understand how they function and feel in relation to their health condition or therapy (Concato and Feinstein, 1997; Fava et al., 2017).

As to the incremental predictive power of the DCPR-R on IAS scales, we found that, compared to DSM-5, the DCPR-R increased the amount of clinical information concerning abnormal illness behavior. The wide spectrum of clinical manifestations of abnormal illness behavior includes hypochondriasis, which was omitted in the DSM-5 classification (APA, 2013), whereas this information is included in the DCPR-R (Fava et al., 2017). Based on our findings, only the DCPR-R significantly predicted higher levels of impairment (effects of symptoms) and higher frequency of medical treatments, examinations and visits to the doctor (treatment experience). These results are in line with those of another study (Ferrari et al., 2008), which showed that frequent attenders in primary care reported significantly more DCPR diagnoses than average frequency attenders at the same clinic.

The present study has some limitations that may affect the generalizability of the results. The cross-sectional design does not allow for assessment of the temporal stability of psychiatric/psychosomatic diagnoses and of their associations with dimensional measures of psychological distress. In addition, we found a low participation rate, thus the sample composition might reflect specific characteristics of patients willing to participate in the study (Piolanti et al., 2019).

Nonetheless, our findings provide support to the incremental validity of DCPR-R in primary care settings, as suggested by the clinically significant contribution of the DCPR-R system to the prediction of patients' psychosocial functioning, over and above DSM-5 diagnoses. Adding DCPR-R to DSM-5 diagnostic criteria therefore may increase the amount of clinical information for a substantial number of primary care patients who do not satisfy DSM-5 criteria and yet present with high stress, psychological distress, impaired well-being and quality of life, as well as maladaptive illness behavior. The use of DCPR-R can be supplemented by other trans-diagnostic clinimetric indices according to the principle of incremental validity, such as euthymia (Carrozzino et al., 2019; Fava and Bech, 2016; Fava and Guidi, 2020) and mental pain (Fava, 2016; Fava et al., 2019; Guidi et al., 2019; Svicher et al., 2019), which may also add valuable information.

The DCPR-R can provide primary care practitioners with a sensitive and easy-to-use clinimetric tool for a comprehensive clinical assessment, expanding our understanding of patients' mental health status. The provision of an innovative classification method for psychological assessment, including both the DSM-5 and the DCPR-R, has the potential to form the basis for adequate referral and timely treatment of psychosocial distress in primary care.

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Table 1: Incremental contribution of the DCPR-R to the prediction of the PSI subscales in primary care patients (N=200)

Measures	Mean ± SD	Models	β	η_p^2	R^2	R^2 change	F
PSI psychological distress	8.98 ± 6.40	Model 1[a]			0.19		11.45***
		Other DSM-5	0.36***	0.13			
		Model 2			0.25	0.06	13.09***
		Other DSM-5	0.31***	0.10			
		SSD	0.25***	0.07			
		Model 3			0.36	0.11	18.62***
		Other DSM-5	0.20***	0.05			
		SSD	0.14*	0.03			
		DCPR-R	0.38***	0.15			
PSI stress	3.44 ± 2.49	Model 1[a]			0.06		3.26*
		Other DSM-5	0.12				
		Model 2			0.06	0.00	2.71
		Other DSM-5	0.11				
		SSD	0.05				
		Model 3			0.19	0.13	7.69***
		Other DSM-5	0.00				
		SSD	- 0.06				
		DCPR-R	0.41***	0.13			
PSI well-being	4.58 ± 1.45	Model 1[a]			0.07		3.75**
		Other DSM-5	- 0.23**	0.05			
		Model 2			0.10	0.03	4.60
		Other DSM-5	- 0.19*	0.03			
		SSD	- 0.19*	0.03			
		Model 3			0.26	0.16	11.59***
		Other DSM-5	- 0.07				
		SSD	- 0.06				
		DCPR-R	- 0.45***	0.17			
PSI quality of life	2.49 ± 0.82	Model 1[a]			0.10		6.61***
		Other DSM-5	- 0.31***	0.09			
		Model 2			0.11	0.01	6.08
		Other DSM-5	- 0.29***	0.08			
		SSD	- 0.13*	0.01			
		Model 3			0.20	0.09	9.65***
		Other DSM-5	- 0.19**	0.03			
		SSD	- 0.03				
		DCPR-R	- 0.35***	0.11			

[a] model also included age, gender and presence of a medical disease; * p<0.05; ** p<0.01; *** p<0.001

Table 2: Incremental contribution of the DCPR-R to the prediction of the SF-12 summary scores in primary care patients (N=200)

Measures	Mean ± SD	Models	β	ηp2	R2	R2 change	F
SF-12 mental component summary	45.63 ± 10.86	Model 1[a]			0.17		10.04***
		Other DSM-5	- 0.32***	0.10			
		Model 2			0.20	0.03	9.73***
		Other DSM-5	- 0.28***	0.08			
		SSD	- 0.17**	0.03			
		Model 3			0.33	0.13	16.57***
		Other DSM-5	- 0.16**	0.03			
		SSD	- 0.05				
		DCPR-R	- 0.43***	0.17			
SF-12 physical component summary	48.65 ± 8.92	Model 1[a]			0.03		1.95
		Other DSM-5	0.00				
		Model 2			0.04	0.01	1.64
		Other DSM-5	0.00				
		SSD	0.07				
		Model 3			0.04	0.00	1.37
		Other DSM-5	0.00				
		SSD	0.05				
		DCPR-R	0.02				

[a] model also included age, gender and presence of a medical disease; * p<0.05; ** p<0.01; *** p<0.001

Table 3: Incremental contribution of the DCPR-R to the prediction of the IAS scales in primary care patients (N=200)

Measures	Mean ± SD	Models	β	ηp2	R2	R2 change	F
IAS worry about illness	5.63 ± 2.87	Model 1[a]			0.06		3.11*
		Other DSM-5	0.03				
		Model 2			0.14	0.08	6.51***
		Other DSM-5	- 0.02				
		SSD	0.29***	0.08			
		Model 3			0.18	0.04	7.39***
		Other DSM-5	- 0.09				
		SSD	0.23**	0.05			
		DCPR-R	0.23**	0.05			
IAS concerns about pain	4.86 ± 2.56	Model 1[a]			0.04		2.26
		Other DSM-5	0.13				
		Model 2			0.15	0.11	7.10***
		Other DSM-5	0.06				
		SSD	0.34***	0.11			
		Model 3			0.18	0.03	7.19*
		Other DSM-5	0.01				
		SSD	0.28***	0.08			
		DCPR-R	0.19*	0.03			
IAS health habits	6.96 ± 2.94	Model 1[a]			0.03		1.60
		Other DSM-5	- 0.09				
		Model 2			0.03	0.00	1.34
		Other DSM-5	- 0.10				
		SSD	0.04				
		Model 3			0.03	0.00	1.11
		Other DSM-5	- 0.10				
		SSD	0.03				
		DCPR-R	0.01				
IAS hypochondriacal beliefs	1.27 ± 2.07	Model 1[a]			0.03		1.76
		Other DSM-5	0.17*	0.03			
		Model 2			0.06	0.03	2.70*
		Other DSM-5	0.14				
		SSD	0.17*	0.03			
		Model 3			0.07	0.01	2.73
		Other DSM-5	0.10				
		SSD	0.14				
		DCPR-R	0.13				
IAS thanatophobia	3.70 ± 3.44	Model 1[a]			0.08		4.34**
		Other DSM-5	0.13				
		Model 2			0.16	0.08	7.83***

		Other DSM-5	0.08				
		SSD	0.30***	0.09			
		Model 3			0.22	0.06	9.52***
		Other DSM-5	0.00				
		SSD	0.22**	0.05			
		DCPR-R	0.28***	0.07			
IAS disease phobia	2.15 ± 2.46	Model 1[a]			0.04		2.14
		Other DSM-5	0.12				
		Model 2			0.14	0.10	6.57***
		Other DSM-5	0.05				
		SSD	0.32***	0.10			
		Model 3			0.16	0.02	6.43*
		Other DSM-5	0.01				
		SSD	0.28***	0.07			
		DCPR-R	0.17*	0.02			
IAS bodily preoccupations	3.38 ± 2.49	Model 1[a]			0.03		1.81
		Other DSM-5	0.10				
		Model 2			0.10	0.07	4.48***
		Other DSM-5	0.05				
		SSD	0.26***	0.07			
		Model 3			0.13	0.03	5.20**
		Other DSM-5	0.00				
		SSD	0.20**	0.04			
		DCPR-R	0.21**	0.04			
IAS treatment experience	4.65 ± 2.46	Model 1[a]			0.06		3.06*
		Other DSM-5	0.09				
		Model 2			0.07	0.01	2.93
		Other DSM-5	0.07				
		SSD	0.10				
		Model 3			0.09	0.02	3.22*
		Other DSM-5	0.03				
		SSD	0.06				
		DCPR-R	0.16*	0.02			
IAS effects of symptoms	2.21 ± 2.71	Model 1[a]			0.11		6.36***
		Other DSM-5	0.24**	0.06			
		Model 2			0.13	0.02	6.19
		Other DSM-5	0.21**	0.04			
		SSD	0.15*	0.02			
		Model 3			0.19	0.06	7.70***
		Other DSM-5	0.13				
		SSD	0.07				
		DCPR-R	0.27***	0.06			

[a] model also included age, gender and presence of a medical disease; * p<0.05; ** p<0.01; *** p<0.001