Patient Education and Counseling xxx (2018) xxx–xxx

Contents lists available at ScienceDirect

Patient Education and Counseling

journal homepage: www.elsevier.com/locate/pateducou

Patient perceived participation in decision making on their antipsychotic treatment: Evidence of validity and reliability of the COMRADE scale in a sample of schizophrenia spectrum disorders

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ARTICLE INFO

Article history:
Received 5 September 2017
Received in revised form 17 March 2018
Accepted 21 March 2018

Keywords:
Shared decision-making
Schizophrenia
Reliability
Validity
Patient participation
Risk communication

ABSTRACT

Objective: The aim of this paper is to provide evidence of the validity and reliability of the COMRADE scale (*Combined Outcome Measure for Risk communication And treatment Decision making Effectiveness*) in patients suffering from schizophrenia spectrum disorders.
Method: 150 patients recruited at five mental health centers were assessed using a cross-sectional study design. The COMRADE, WAIS-S (therapeutic alliance) and TSQM (satisfaction with medication) scales were used.
Results: Exploratory Factor Analysis identified three factors from the COMRADE (F1: "Risk communication"; F2: "Confidence in decision" and F3: "Knowledge of decisional balance") which explain 45.2, 8.5 and 6% of the variance, respectively. Statistically significant correlations were observed between the scores of the COMRADE subscales with the subscales of the WAI-S and the TSQM. The internal consistency observed for each of the factorial scores of the COMRADE were (Cronbach's alpha values) 0.90, 0.89 and 0.74, respectively.
Conclusion: The COMRADE scale offers appropriate psychometric properties for its use as a measure of perceived patient involvement in the shared decision making process in antipsychotic treatment.
Practice implications: The use of the COMRADE measure in psychiatric clinical practice and in research studies provides an outcome measure of interventions from the shared decision making model.

1. Introduction

Shared decision making (SDM) has been described as a collaborative process between patients and physicians [1–3]. SDM is situated in an intermediary point between a paternalistic model *based on the illness*, in which the physician carries out all of the decision making based on his clinical experience and the exploratory data, and a *patient-focused* model of greater autonomy, in which patients actively participate in their own care [4,5].

Although in the past the SDM model was primarily used with patients suffering from somatic illnesses, over the past decade, it has been progressively included in the mental health field [6–8]. This is due to both *ethical* as well as *practical* reasons [9]. First, there has been a prevailing respect for the autonomy of the psychiatric patient. Although decision making by this type of patients may be affected by their altered capacity, it is not abolished in all individuals suffering from serious mental disorders, or at all times, or for all possible decisions [10,11]. On the other hand, from a practical point of view, the SDM model may be applied to mental illnesses such as schizophrenia, given that for most therapeutic decisions, more than one option exists, these distinct options have diverse secondary effects and, given that treatment tends to be long, the inclusion of the patient perspective shall contribute to better adherence [12].

In a recent meta-analysis study, Stovell et al. [13] concluded that the implementation of SDM in patients with psychosis has a mild to moderate effect on different outcome measures such as

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https://doi.org/10.1016/j.pec.2018.03.018
0738-3991/

subjective empowerment or use of compulsory treatment. However, these observed results may be partly due to different methodological aspects related to the measurement; therefore, recent and current studies are focusing more on exploring distinct moments in which the SDM is carried out [14] or on using other measurement instruments [15]. Thus, several clinical tools for the measurement of different aspects of SDM process have been proposed [16]. Among them, the COMRADE scale (Combined Outcome Measure for Risk communication And treatment Decision making Effectiveness) [12] has the advantage of measuring the two fundamental elements of the SDM process; the information given to the patient, with pros and cons of different treatment options, and self-perceived satisfaction of their involvement in this decision. This scale relies on appropriate psychometric quality parameters in samples of patients with chronic medical illness [16–18]. Although the COMRADE scale has also been applied in a clinical trial with schizophrenia patients [12], to our knowledge, psychometric evidence has yet to be published on patients with psychosis. The aim of this paper is to provide evidence of the validity and reliability of the COMRADE scale in patients who have been diagnosed with disorders of the schizophrenic spectrum.

2. Methods

2.1. Setting and participants

Study inclusion criteria were as follows: a) being ≥18 years of age, b) fulfilment of DSM-IV criteria for schizophrenia, schizoaffective disorder, delusional disorder, brief psychotic disorder and schizotypal personality disorder diagnosis [19], c) having received antipsychotic treatment over the two last months and d) antipsychotic dose had not been modified over the week prior to the assessment. Exclusion criteria were: a) difficulty in responding to the interviewer's questions due to the acute decompensation of his/her psychosis, b) difficulty in responding to the interviewer's questions due to a low literacy level or due to a limited knowledge of the Spanish language and c) failure to accept the study procedures such as refusal to sign the informed consent form. The study protocol was approved by the Research Ethics Committee of the Hospital de Jerez.

2.2. Measures

2.2.1. Patient perceived participation in decision making

The COMRADE (*Combined Outcome Measure for Risk communication and treatment Decision making Effectiveness*) [16] is a self-administered scale made up of 20 items that were originally grouped in two factorially derived subscales of 10 items each. The response to each item is coded according to a Likert-type scale of 5 points, ranging from "strongly disagree" to "strongly agree". The first of the subscales is called *risk communication*, defined as an "open two-way exchange of information and opinion about risk, leading to better understanding and better (clinical) management decisions" [16,17]. This subscale assesses the perceived opinion of the patient on the quality of the information that is exchanged about risk and benefits of treatments or care. The second subscale is called *confidence (in decision)* assess the subjective perception of the patient participating in this decision as well as satisfaction with the decision that was made. Therefore, it is more similar to the general concept of shared decision making. The COMRADE has a good internal reliability and construct validity. Thus, it presents a high internal consistency (alpha co-efficient 0.92). Both subscales was inversely correlated with concern about the patient' condition. Confidence in decision subscale was associated with increased enablement and expectation to adherence to treatment [16]. In our study, we have used the Spanish version of the COMRADE measure, which we have developed previously [20,21].

2.2.2. Satisfaction with the antipsychotic as a medication

Satisfaction with the antipsychotic as a medication was assessed using the Treatment Satisfaction Questionnaire for Medication (TSQM version 1.4) scale [22]. The TSQM is a 14-item self-administered scale to measure patient satisfaction with treatment medication. This scale consists of 4 subscales, known as the Effectiveness subscale (items 1–3), the Side Effects subscale (items 4–8), the Convenience subscale (items 9–11), and the Global Satisfaction subscale (items 12–14). The item responses are coded according to a Likert-like scale of 5 and 7 points (range, 1 "extremely dissatisfied" to 7 "extremely satisfied"), with the exception of 1 item having a yes-no response option. The scores for each of the subscales are transformed into scores ranging from 0 to 100, with high scores being interpreted as having a higher degree of satisfaction with this dimension. In the Side Effects subscale, when the patient responded with "no" regarding experiencing secondary effects (item 4) this subscale scores with 100. The alpha co-efficient values of the subscales range from 0.88 to 0.90 and these explain 40–60% of the variation in patient's rating of their adherence to treatment. In our study, we have used the Spanish version of the TSQM (Quintiles, Inc).

2.2.3. Therapeutic alliance

The Working Alliance Inventory *short* ("WAI-S) by Tracey & Kokotovic [23] is the shorted version of the Working Alliance Inventory of Horvath and Greenberg [24]. Both versions are based on the theoretical proposal of Bordin [25] on the construct of therapeutic alliance as a basic element in the change process. The WAI-S is a 12-item self-administered scale coding by Likert-like scale of 7 points (range, 1 "Never" to 7 "Always"). It contains 3 subscales of 4 items each. The subscale known as "Goal Subscale" measures the degree to which the therapist and the patient share therapeutic process objectives. The "Task Subscale" measures the perception that each of the requested and expected tasks is achievable and has a relationship with the intervention objectives. Finally, the "Bond Subscale" measures aspects such as mutual perception of trust, understanding and care. The WAI-S has a 0.98 alpha co-efficient and an optimal correlation with other measures of therapeutic alliance (rho values greater than 0.75). In our study, we have used the patient version of the Spanish adaptation which includes adequate parameters of psychometric quality [26].

2.2.4. Adherence to the antipsychotic treatment

The Brief Adherence Rating Scale (BARS) [27] is a short, pencil and paper instrument that is administered by the clinician, for the assessment of adherence to the antipsychotic treatment. It consists of 4 items; 3 questions and a visual-analogue scale that measures the proportion of the dosage taken by the patient over the previous month. The total score of this instrument is derived directly from the visual-analogue scale and may be interpreted both quantitatively (0%–100%) and dichotomously, using a cut-off score. The BARS has a good internal reliability (alpha co-efficient 0.92) and a moderate-to-strong degree of test-retest reliability (co-efficients around 0.50–0.90). In relation to concurrent validity, BARS was significantly related to lower psychotic symptoms scores. This scale also demonstrated good sensitivity (73%) and specificity (74%) in identifying non-adherent patients [27].

2.2.5. Clinical global impression

The Clinical Global Impression-Schizophrenia Scale (CGI-SCH) [28] is a short instrument, administered by clinicians to assess the severity of the main symptomatic dimensions of schizophrenia through clinical judgment. It includes two subscales that measure

Please cite this article in press as: J. Pérez-Revuelta, et al., Patient perceived participation in decision making on their antipsychotic treatment: Evidence of validity and reliability of the COMRADE scale in a sample of schizophrenia spectrum disorders, Patient Educ Couns (2018), https://doi.org/10.1016/j.pec.2018.03.018