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Original article

Psychometric analysis of the Spanish and Catalan versions of a questionnaire for hypoglycemia awareness☆

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ABSTRACT

Background and objective: Intensive insulin therapy with multiple insulin doses in subjects with type 1 diabetes mellitus (T1D) is associated with a higher risk of hypoglycaemic episodes. Repeated hypoglycemia results in a reduced ability/failure to recognise hypoglycemia symptoms and predisposes to severe episodes. In this context, it is crucial to work with specific questionnaires to diagnose and address this burden. Our study aimed to perform the psychometric analysis of Spanish and Catalan versions of Clarke et al. questionnaire for hypoglycemia awareness.
Patients and method: Psychometric analysis in patients with T1D of Spanish and Catalan versions of Clarke et al. questionnaire in three phases: (1) translation, back-translation and cultural adaptation of the English version; (2) analysis of internal, external and test–retest validity, and (3) assessing sensitivity to change in hypoglycemia perception.
Results: One-hundred and forty-four subjects with T1D answered the Clarke et al. questionnaire (mean age [SD] 36 [18] years, 46% men). We observed a Cronbach's α coefficient for internal validity of 0.75, a correlation coefficient for test–retest reliability of $r = 0.81$ and a correlation of the questionnaire score with the frequency of severe and no severe hypoglycemia events of $r = 0.47$ and $r = 0.77$, respectively. The analysis of 20 patients with T1D 24 months after the initiation of continuous subcutaneous insulin infusion showed a decrease in the frequency of non-severe hypoglycemia/week (from 5.40 [2.09] to 2.75[1.74]) and in the number of severe hypoglycaemic episodes/year (1.25 [0.44] to 0.05 [0.22]). This was associated with a decrease in scores of the translated versions of Clarke et al. questionnaire (from 5.45 [1.19] to 1.60 [2.03]).
Conclusions: Spanish and Catalan versions of Clarke et al. questionnaire display good psychometric properties and both could be considered a useful tool for evaluating hypoglycemia awareness in patients with T1D from our area.

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Análisis psicométrico de las versiones en lengua castellana y catalana de un cuestionario de percepción de la hipoglucemia

RESUMEN

Fundamento y objetivo: El tratamiento intensivo con múltiples dosis de insulina de los pacientes con diabetes mellitus tipo 1 (DT1) se asocia con la aparición de hipoglucemias. Su recurrencia condiciona la pérdida progresiva de los síntomas asociados a las mismas y predispone a la aparición de episodios graves. Es importante disponer de cuestionarios específicos y validados para identificar a los pacientes con este problema. Con este objetivo se realizó el análisis psicométrico de las versiones castellana y catalana del cuestionario de Clarke et al. destinado a valorar la percepción de hipoglucemias.

Pacientes y método: Análisis psicométrico en pacientes con DT1 de las versiones en castellano y catalán del cuestionario de Clarke et al. en 3 fases: 1) traducción, retrotraducción y adaptación cultural de la versión en inglés; 2) análisis de la consistencia interna, validez de constructo y test-retest del mismo, y 3) análisis de su sensibilidad al cambio en la percepción de hipoglucemias.

Resultados: Ciento cuarenta y cuatro pacientes con DT1 contestaron los cuestionarios en lengua castellana o catalana, según preferencias (edad media [DE] de 36 [18] años, 46% varones). Se obtuvo un coeficiente α de Cronbach para la consistencia interna de 0,75, un coeficiente de correlación para la fiabilidad test-retest de r = 0,81 y una correlación de la puntuación del cuestionario con la frecuencia de hipoglucemias no graves y graves de r = 0,47 y r = 0,77, respectivamente. El análisis de 20 pacientes con DT1 durante 24 meses tras el inicio de infusión subcutánea continua de insulina mostró una disminución de la frecuencia de hipoglucemias no graves/semana (de una media de 5,40 [2,09] a 2,75 [1,74]), así como del número de episodios de hipoglucemia grave/año (de una media de 1,25 [0,44] a 0,05 [0,22]). Esta reducción se asoció con una mejora en la percepción de la hipoglucemia, con una disminución de la puntuación del cuestionario de Clarke et al. (de 5,45 [1,19] a 1,60 [2,03]).

Conclusiones: Las versiones en lengua castellana y catalana del cuestionario de Clarke et al. tienen buenas características psicométricas y pueden ser un instrumento útil para evaluar la presencia de hipoglucemia desapercibida en pacientes con DT1 de nuestro entorno.

Introduction

Currently, intensive therapy using multiple insulin doses is the standard treatment for patients with type 1 diabetes (T1D) following diagnosis of the disease.[1,2] However, it is not free from secondary effects. One of the most important of these is its association with a three- or fourfold increase in incidence of non-serious and serious hypoglycaemia, as reported elsewhere.[1,3] In fact, this is now the principle side effect of this treatment and the main obstacle to its implementation in these patients.[4,5]

For as yet unknown reasons, in some patients recurrent episodes of non-serious hypoglycaemia condition the progressive loss of physiological, adrenergic and neuroglycopenic symptoms of response to an episode of hypoglycaemia.[6,7] In patients with T1D, episodes of so-called unnoticed or unseen hypoglycaemia multiply the risk of serious hypoglycaemia. Some studies have shown that abnormal perception of hypoglycaemia can lead to a sixfold increase in the risk of having an episode of this type.[8,9] Hence, in clinical practice, the use of specific questionnaires—validated in both the Spanish and Catalan languages—is essential if we are to identify patients with unnoticed hypoglycaemia.[9–11]

The objective of the present study was to conduct a psychometric analysis of the Spanish and Catalan versions of the Clarke et al. questionnaire to assess awareness of hypoglycaemia in patients with T1D.

Materials and methods

We chose the Clarke et al. questionnaire because it had already been validated in Spanish and Catalan.[10] It consists of eight questions about the patient's perception of hypoglycaemia, the frequency of serious and non-serious episodes, and the blood sugar level thresholds at which the patient experiences symptoms. Each answer is classified as normal (A) or abnormal (R). The total sum of R responses determines the level of awareness of hypoglycaemia: 1–2R = normal; 3R = indeterminate; >3R = abnormal. We requested and obtained authorisation to use the questionnaire from the authors of the English language version.

Our psychometric analysis of the Spanish and Catalan versions of the Clarke et al. questionnaire for patients with T1D was conducted in three stages. Stage 1 was based on a cross-sectional, observational, descriptive design. Stages 2 and 3 were longitudinal and observational.

Stage 1. Translation, back-translation and cultural adaptation of the English questionnaire for the Spanish and Catalan versions. The original version of the questionnaire was independently translated into Spanish and Catalan by three endocrinologists, two nurses specialised in diabetes and one psychologist specialised in psychometry. Subsequently, after a group discussion between the participating professionals, the different versions were merged into a single text. Both questionnaires were then independently back-translated into English by two native English translators. These were then compared with the original text and a new version of each questionnaire was produced. Twenty bilingual patients with T1D (aged 20–60 years) from our out-patient clinics (at the Endocrinology and Nutrition Service of the Hospital Clínic i Universitari de Barcelona) volunteered to participate in the study. Spanish was the mother tongue of 10 patients and Catalan the mother tongue of the other 10. All the participants answered the questionnaire to identify and modify terms and expressions that were difficult to understand or interpret. The final Spanish and Catalan versions of the questionnaire were produced using their observations.

Stage 2. Reliability: internal consistency, testing, re-testing and construct validity. This stage involved volunteer patients with T1D aged >18 years, receiving multiple insulin doses (MDI) or continuous subcutaneous insulin infusions (CSII), attending the Endocrinology and Nutrition out-patient clinics at the Hospital Clínic i Universitari de Barcelona and the Hospital Clínico de Madrid. This group included patients who the authors agreed were classified as being at high-risk of having unnoticed hypoglycaemia: patients with >10 years T1D, with a frequency of ≥3 episodes of non-serious hypoglycaemia per week during the previous 4 weeks and/or ≥1 episode of serious hypoglycaemia during the previous year (based on American Diabetes Association guidelines). Those patients who did not satisfy these criteria were classified as low-risk unnoticed hypoglycaemia patients. After receiving orientation about the study and signing the corresponding informed consent documents, patients completed the Clarke et al. questionnaire in the translated version of their individual language preference (51% Spanish). All participants provided sociodemographic data (age, gender, level of education) and clinical data (years of T1D progression, type of treatment, glycosylated haemoglobin [HbA$_{1c}$, determined by means of high-performance liquid chromatography using the Tosoh G8 Automated HPLC Analyser, Tosoh Bioscience Inc., South San Francisco, CA, USA, calibrated with the standard values of the Diabetes Control and Complications Trial; reference values 4–6%]) for the previous month, as well as data on the frequency of non-serious episodes of hypoglycaemia in the previous 4 weeks and serious episodes of hypoglycaemia in the previous year. All patients were provided with a second copy of the questionnaire and a post-paid envelope for them to complete and return this