


CONCEPT

Study protocol of translation into Spanish and cross-cultural adaptation and validation of the problem areas in diabetes—Pediatric version (PAID-Peds) survey

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Abstract

Aim: The metabolic and psychological management of paediatric type 1 diabetes mellitus (T1DM) can be challenging over time given that T1DM may cause a negative emotional burden and, consequently, result in poor metabolic control of the disease. The objectives of this study are to translate the Problem Area in Diabetes Survey—Pediatric version (PAID-Peds) into Spanish, adapt it culturally and validate it.

Design: Multicenter cross sectional study.

Methods: 636 patients aged 8–17 years, diagnosed with T1DM, under treatment with insulin and follow-up at the Miguel Servet University Hospital in Zaragoza (Aragón, Spain), the Ramón y Cajal University Clinical Hospital in Madrid (Spain) and at the Sant Joan de Déu Hospital in Barcelona (Catalonia, Spain) between 1 January 2023 and 31 December 2024 will be included. This study will consist of two phases: (1) Translation and cultural adaptation of the original PAID-Peds® survey into Spanish following eight steps; (2) Validation of the Spanish version of the PAIS-Peds® survey. The statistical analysis will be performed using Jamovi® 2.1.23. The reliability or internal consistency will be calculated using Cronbach's alpha index (considering an index higher than 0.8 to be good) and the test-retest will be evaluated using the intraclass correlation coefficient. For validity, confirmatory factor analysis will be calculated. This study has been approved by the ethics and research committees at each centre.

Results: The translation and validation into Spanish language of the Problem Area in Diabetes Survey—Pediatric version will be feasible, valid and reliable to detecting the youth-perceived burden of T1DM. Therapeutic education in diabetes—recommended by the WHO and the Diabetes Education Study Group—has shown encouraging results in glycaemia and psychosocial and behavioural factors in T1DM.

KEYWORDS

diabetes mellitus type 1, health surveys, quality of life, reproducibility of results

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1 | INTRODUCTION

Type 1 diabetes mellitus (T1DM) is characterized by the destruction of insulin-producing pancreatic beta cells. It is most prevalent in children and accounts for more than 90% of children and adolescents with DM (Mayer-Davis et al., 2018). Only 25% of cases occur in adulthood (Lawrence et al., 2021; Mayer-Davis et al., 2017).

Approximately 490,000 children in the world are diagnosed with T1DM (Desai & Deshmukh, 2020), with 10,000 new cases each year (Patterson et al., 2019) and the highest prevalence in the age range 5–7 years (Atkinson et al., 2012).

The transition from childhood to adolescence is a period of change in terms of the self-control and management of DM. This can result in a high psychological burden with immediate consequences such as poor metabolic control and, if persistent, long-term microvascular complications (Iturralde, Hood, et al., 2019; Stahl-Pehe et al., 2017).

Many young people diagnosed with T1DM experience emotional distress related to the daily burden of living with diabetes (Hagger et al., 2016), although there are also other problems inherent to this stage of life, namely parental overprotection, body image conflicts, eating disorders, etc. These problem situations lead to the psychological vulnerability of young people, which, in turn, is associated with worse adherence to treatment, decreased self-care and sub-optimal glycaemic control (Dennick et al., 2017; Hagger et al., 2016; Ruiz-Aranda et al., 2019). All this is inversely related to strengths in diabetes related to resilience, adaptive processes or attitudes that favour the achievement of results (Iturralde, Hood, et al., 2019).

Adolescence is a stage of important changes (hormonal changes, search for independence and autonomy and internal conflicts) that may trigger difficult situations and family conflicts. As such, it is a time of transition that generally involves poorer glycaemic control, poorer health care and increased risk of complications and, consequently, this stage poses a risk for diabetes (Iturralde, Hood, et al., 2019; Stahl-Pehe et al., 2017). The International Society for Pediatric and Adolescent Diabetes (ISPAD) Clinical Practice Consensus Guidelines 2018 recommend a set of specific educational care for this stage (Mayer-Davis et al., 2018).

Measures validated in children and adolescents in the paediatric age for early detection of diabetes-related emotional distress are required to design interventions that help to reduce the psychological problems that occur at this stage and thus improve the metabolic control and health-related quality of life of this population (Evans et al., 2019). In recent years, interest in this field has focused on the relationship between emotions and health (Chatterjee et al., 2018). Indeed, detection of the specific emotional burden of diabetes in childhood could favour early interventions to reduce anxiety and prevent worsening of distress, exhaustion, depressive symptoms and subsequent poor diabetes control (Hagger et al., 2018).

There is no validated scale in Spain to assess the burden of T1DM in diagnosed children and adolescents. This tool would allow early detection of emotional distress and interventions with these children

and adolescents, and also their families, to improve their emotional health, metabolic control and health-related quality of life.

The aims of this study are to translate into Spanish, adapt culturally and validate the paediatric version of the Problem Areas in Diabetes survey. This study will comprise two stages: (1) translation into Spanish and cultural adaptation of the PAID-Peds® survey; (2) validation of the Spanish version of the PAIS-Peds® survey.

2 | DATA SOURCE AND METHODOLOGY

2.1 | Design and research plan

2.1.1 | Translation into Spanish and cultural adaptation of the original PAID-Peds® survey

The PAID-Peds® survey was designed to assess the emotional health of children aged 8–17 years with T1DM and their families. This instrument was originally developed in English by Markowitz et al. to specifically measure the 'youth-reported burden related to type 1 diabetes management' (Markowitz et al., 2015, p. 1080). PAID-Peds® is a 20-item structured, self-administered tool. There are five response options on a 5-point Likert scale, with 0 being 'agree', 2 'neither agree nor disagree' and 4 'disagree'. The total score is obtained by inverting the scores of each item—with the original response value 0 being 4, 1 being 3, 2 being 2, 3 being 1 and 4 being 0—and averaging all the items. For a 100-point scale, the results must be multiplied by 25. Patients scoring 41 or higher may be at the level of 'emotional burnout' (Commissariat et al., 2018). The survey was validated with an internal consistency of 0.94 (Cronbach's alpha) and an intraclass correlation coefficient of 0.66 ($p < 0.0001$).

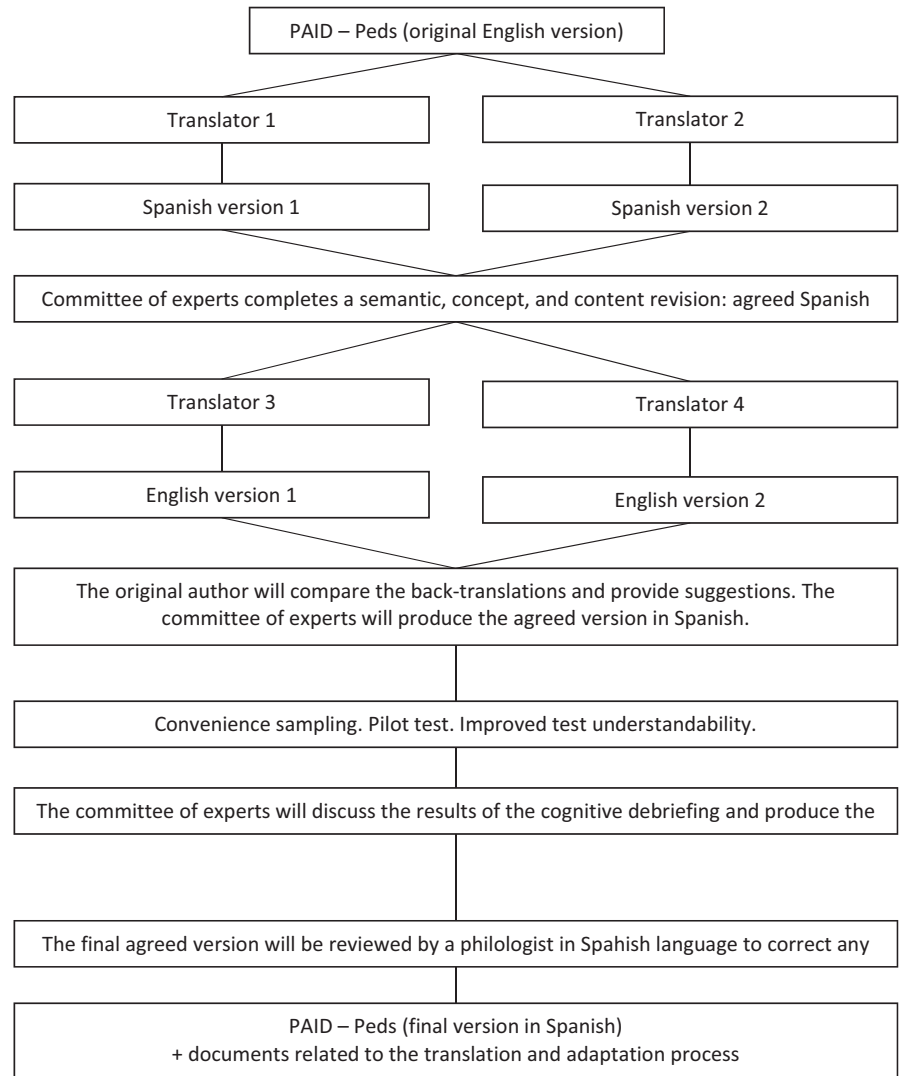
The translation and cultural adaptation of the instrument will consider semantics, concept, content and technical and criterion equivalence, and will follow the Principles of Good Practice for the Translation and Cultural Adaptation Process of the International Society for Pharmacoeconomics and Outcomes Research (Wild et al., 2005) (Figure 1):

Stage 1. Forward translation: Upon acceptance of the author, the PAID-Peds® survey will be translated into Spanish by two professional native Spanish translators, resulting in two initial translations.

Stage 2. Reconciliation and synthesis of the translations: An independent committee of experts (formed by two medical graduates specializing in paediatrics and paediatric endocrinology, and three nurses specializing in paediatric diabetes) will compare and merge 2 forward translation into a single forward translation.

Stage 3. Back translation into English: Two native English translators from the translation company Trasluz (Traducciones y Servicios de Mediación Lingüística S.L.) will complete two back translations of the new Spanish version into English.

FIGURE 1 Stages of translation into Spanish, cultural adaptation and validation of PAID-Peds® survey.



Stage 4. Comparison and harmonization of the back translations with the original: The committee of experts will compare the original instrument with the translated versions to detect translation problems and resolve them.

Stage 5. Cognitive debriefing: Testing the instrument to check the wording, understandability, interpretation and cultural adaptation at the Department of Educational Nursing in Paediatric Diabetes of the Miguel Servet University Hospital (Zaragoza), the Ramón y Cajal University Clinical Hospital (Madrid) and at the Sant Joan de Déu Hospital in (Barcelona). It is estimated that 30 patients diagnosed with T1DM aged 8–17 years and attending the Department of Educational Nursing in Paediatric Diabetes will participate in the pilot test.

Stage 6. Review of the cognitive debriefing: Evaluation of stage 5 for elaboration of the final Spanish PAID-Peds® version.

Stage 7. Proofreading, spelling and grammar revision: Final review of the translation, typographical and grammatical errors.

Step 8. Final report: Preparation of the report on how the PAID-Peds® survey was translated and adapted. Elaboration of the guidelines for the correct administration (type of population,

age, form of administration, etc.) and interpretation of the results of the survey.

2.1.2 | Validation of the Spanish version of the PAIS-Peds® survey. Subjects and sample

Cross sectional study with a sample size of 636 patients (95% confidence level and 5% margin of error) of patients diagnosed with T1DM, with >1 year of T1DM evolution, aged 8–17 years, under treatment with insulin therapy (multiple doses or continuous subcutaneous infusion pump) and under follow-up at the Miguel Servet University Hospital in Zaragoza (Aragón, Spain), the Ramón y Cajal University Clinical Hospital in Madrid (Spain) and the Sant Joan de Déu Hospital in Barcelona (Catalonia, Spain) between 1 January 2023 and 31 December 2024.

Patients diagnosed with disorders associated with intellectual diversity (chromosopathies, autism, cerebral palsy, etc.) and language difficulties will be excluded from the study.

2.2 | Variables, instruments and study description

The Spanish version of the PAID-Peds® survey will be used to assess the emotional health of children diagnosed with T1DM.

Patients will be recruited at the Department of Educational Nursing in Paediatric Diabetes of each participating hospital and will be asked the PAID-Peds® survey in Spanish version. The time to ask the survey will be monitored.

Upon inclusion, the nurse will explain the details of the study to the patients and their guardians and will hand them the information sheet. Inclusion of the children in the database will be confidential.

The data collected will be coded and pseudonymized and will comply with Spanish legal regulations on data confidentiality (Organic Law 3/2018, of December 5, on Personal Data Protection and guarantee of digital rights). With regard to the ethics of the participation process, upon written and verbal description of all information related to the study and its objectives (Participant Information Sheet), parents/guardians and children over 16 years will voluntarily agree to participate and sign the informed consent. National and international guidelines (ethics code, Declaration of Helsinki) will be followed during the study. In compliance with the European Charter for Hospitalized Children, approved by the European Parliament in 1986, which regulates the right of children to be accompanied by their parents, humanization of care will be promoted.

The independent variables are age, sex, type of family (nuclear: father-mother; single-parent; adoptive; separated; compound; homoparental and extended), years of evolution of diabetes, acute complications of diabetes (expected severe hypoglycaemia, episodes of diabetic ketoacidosis), chronic complications of diabetes (diabetic retinopathy, nephropathy and diabetic neuropathy), history of other autoimmune diseases (celiac disease, autoimmune thyroiditis, etc.), weight at the time of the study (in kg), height at the time of the study (in meters), body mass index (kg/m^2), glycosylated haemoglobin in % (by capillary puncture and estimated according to CGM (continuous glucose monitoring) or FMG (flash monitoring of glucose), at the beginning of the study and at 3, 6, 9 and 12 months previously), % time in range (<54 mg/dL, <70, >180 mg/dL and >250 mg/dL), coefficient of variation (standard deviation of glucose/mean glycemia $\times 100$) and type of insulin therapy: MDI (multiple doses of insulin) or CSII (continuous subcutaneous infusion of insulin).

2.3 | Research Ethics Committee approval

This study has been approved by the Ethics and Research Committees 'REDACTED'.

2.4 | Statistical analysis

Data will be analysed using Jamovi® 2.1.23. Qualitative variables will be presented using the frequency distribution of the percentages of each category. Quantitative variables will be explored using

the goodness-of-fit test for a normal distribution (Shapiro-Wilk test), and central tendency (mean or median) and dispersion (standard deviation or percentiles) indicators will be provided.

The reliability or internal consistency will be calculated using Cronbach's alpha index (Tavakol & Dennick, 2011) (considering an index higher than 0.8 to be good) and the test-retest will be evaluated using the intraclass correlation coefficient (Robinson et al., 1991). To assess the construct validity, confirmatory factor analysis will be calculated using the model chi-square, the comparative fit index (CFI), the Tucker-Lewis Index (TLI), the standardized root mean square residual (SRMR) and the root mean square error of approximation (RMSEA) (Bentler, 1990; Browne & Cudeck, 1992; Gefen et al., 2011; Mehta & Patel, 1983; Steiger, 1990; Tucker & Lewis, 1973).

A second evaluation of PAID-Peds will be conducted 3–4 weeks later to administer the questionnaire again. Interclass correlation coefficient will be used for test-retest reliability and for paired samples, Wilcoxon W test will be applied.

The association between the variables studied will be investigated using hypothesis contrast tests, with comparison of proportions when both variables are qualitative (chi-square, Fisher's exact test), comparisons of means when one variable is quantitative (Student's *t*, ANOVA and if the variables do not follow a normal distribution, the Mann-Whitney *U* test or the Kruskal-Wallis test) and bivariate correlations (Pearson's correlation coefficient) when both variables are quantitative. If necessary, appropriate tests for paired samples (before-after measures) will be applied. To study the relationship of each variable while controlling for the possible effect caused by third variables, the analysis will be completed by applying multivariate regression models. The effects will be considered statistically significant if $p < 0.05$, and the p values will be two-tailed. In case of multiple comparisons, the Bonferroni correction will be applied to the p -value.

3 | DISCUSSION

The main objective of this study was to provide a validated tool in Spanish that assesses the emotional burden/emotional distress that living with T1DM may cause at a paediatric age.

Several questionnaires assess the burden and health-related quality-of-life of having diabetes in adults and, mainly, in type 2 diabetes mellitus (Ishii et al., 2018; Polonsky et al., 1995; Trikkalinou et al., 2017). The Problem Areas in Diabetes (PAID) survey, created in 1990, is the most widely used international scale to assess the stress associated with living with diabetes in adults (Eilander et al., 2017) and has been associated with dysfunctional coping styles, poorer quality of life and depressive symptoms (Schmitt et al., 2016). However, there is no instrument in Spanish to assess the emotional burden of having diabetes in the paediatric population. The PAID survey was adapted for the paediatric age group (PAID-Peds) (Evans et al., 2019; Shapiro et al., 2018) and has clinical and research utility as a valid and acceptable measure of the type

of burden perceived by young people aged 8–17 years with T1DM (Markowitz et al., 2015).

The availability to evaluate the emotional distress on paediatric diabetes in Spanish Language is non-existent. There are numerous diabetes distress assessment tools as the appraisal of diabetes scale (ADS) (Carey et al., 1991), the Audit of Diabetes-Dependent QOL measure (ADDQOL) (Bradley et al., 1999), the Diabetes Health Profile (DHP) (Meadows et al., 1996) and Problem Areas in Diabetes (PAID) (Polonsky et al., 1995). These are excellent tools because there are more suitable for single-scale questionnaires when investigating one or more specific aspects of diabetes-specific quality of life (QOL) (Oluchi et al., 2021). However, PAID-tens assesses emotional distress between ages 13 and 19 years old. These tools are available, in Turkish (Sari et al., 2023) in German (Saßmann et al., 2023) and in Danish (Rahbæk et al., 2023) languages but not available for ages between 8 and 17 years old. All of these tools are valid, reliable and useful measures of diabetes-specific distress.

Only 25% of adolescents achieve the recommended levels of glycaemic control (Dennick et al., 2017; Ruiz-Aranda et al., 2019), which places them at risk for future microvascular and macrovascular complications (Iturralde, Rausch, et al., 2019). While new technologies (Markowitz et al., 2015) help to control diabetes, a considerable involvement of patients and their families is still required. Assessment of the psychological, social and emotional impact of diabetes in children and adolescents should be routinely included to detect needs and barriers to effective self-management, as recommended by ISPAD (de Wit et al., 2012) and there is evidence of a relationship between lower Hb1Ac and higher quality of life (Anderson et al., 2017).

The availability of the PAID-Peds survey in Spanish could be key to detecting the burden of having diabetes, facilitate early interventions to reduce anxiety and prevent the worsening of distress, exhaustion, depressive symptoms and subsequent poor diabetes control (Evans et al., 2019). Therapeutic educational interventions have shown encouraging results in terms of glycaemia and psychosocial and behavioural factors (Chatterjee et al., 2018; Sawtell et al., 2015; Speight et al., 2016).

Structured diabetes education comprises distinct and complex goals aimed at empowering patients to manage diabetes and the emotional challenges associated with their chronic disease. However, the multiple components of diabetes education cannot currently be assessed separately (Ehrmann et al., 2016), especially from the onset of adolescence (Sheehan et al., 2015).

Assessment of the psychological, social and emotional impact of diabetes in children and adolescents should be routinely included in daily clinical practice to detect needs and barriers to effective self-management, as recommended by ISPAD and the International Society for Pediatric and Adolescent Diabetes Clinical Practice Consensus Guidelines (Cameron et al., 2018; de Wit et al., 2012, 2022).

AUTHOR CONTRIBUTIONS

JOCM, ECM, MPFD, DGC and AAM conceptualized and design the research plan. ECM, MPFD, DGC, RYV, VPR, IGM and AAM are

responsible for recruiting participants and data collection. JOCM is responsible for data analysis and writing article. All authors read and approved the final article.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

Data sharing not applicable to this article as no datasets were generated or analysed during the current study.

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