Italian translation and validation of the CGM satisfaction scale questionnaire

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Abstract

Aims Patient-reported outcomes (PROs) are increasingly important for assessing patient satisfaction with diabetes technologies. PROs must be assessed with validated questionnaires in clinical practice and research studies. Our aim was to translate and validate the Italian version of the continuous glucose monitoring (CGM) Satisfaction (CGM-SAT) scale questionnaire.

Methods Questionnaire validation followed MAPI Research Trust guidelines and included forward translation, reconciliation, backward translation, and cognitive debriefing.

Results The final version of the questionnaire was administered to 210 patients with type 1 diabetes (T1D) and 232 parents. The completion rate was excellent, with almost 100% of items answered. The overall Cronbach's coefficient was 0.71 and 0.85 for young people (patients) and parents indicating moderate and good internal consistency, respectively. Parent–young people agreement was 0.404 (95% confidence interval: 0.391–0.417), indicating moderate agreement between the two assessments. Factor analysis identified that factors assessing the "benefits" and "hassles" of CGM accounted for 33.9% and 12.9% of score variance in young people and 29.6% and 19.8% in parents, respectively.

Discussion We present the successful Italian translation and validation of the CGM-SAT scale questionnaire, which will be useful for assessing satisfaction with Italian T1D patients using CGM systems.

Abbreviations

T1D	Type 1 diabetes
CGM	Continuous glucose monitoring
rtCGM	Real time CGM
isCGM	Intermittent scanned CGM
CGM-SAT	CGM satisfaction
PROs	Patient-reported outcomes
MDI	Multiple daily injection
SD	Standard deviation
IQR	Interquartile range
JDRF	Juvenile Diabetes Research Foundation

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Introduction

According to the patient-centered care approach [1], the successful management of type 1 diabetes (T1D) is not limited to glycemic control but also includes patient-reported outcomes (PROs) such as quality of life and user satisfaction with treatments and technologies [2, 3]. Mindful of this, a recent European rapid health technology assessment (HTA) of continuous glucose monitoring (CGM) technologies using the HTA Core Model® [4] evaluated not only efficacy with regard to metabolic outcomes but also PROs using well known and validated questionnaires [5]. User satisfaction is an important factor in frequency and persistence of CGM use by patients [6]. Moreover, frequent CGM use is associated with improved glycemic control [7]. An objective analysis of user experiences and satisfaction with CGM is therefore desirable for clinical practice evaluation and research purposes.

The CGM Satisfaction (CGM-SAT) scale is a questionnaire designed to measure the impact of CGM on diabetes management in terms of family relationships, satisfaction, and the emotional, behavioral, and cognitive effects of CGM [8]. The questionnaire has only been used and validated in English. Therefore, the aim of this study was to translate and validate an Italian version of the CGM-SAT questionnaire from its original English version in pediatric patients with T1D wearing CGM.

Subjects, materials, and methods

Participants and procedure

The CGM-SAT questionnaire was designed for use in children and adolescents aged 8 to 18 years and their parents. Here, we tested internal reliability, impact, and satisfaction with an Italian version of the CGM-SAT on 210 consecutively enrolled patients and 232 parents attending 14 diabetes clinics in Italy for three-monthly scheduled visits. The pediatric diabetes centers participating in the study belonged to the Italian Pediatric Diabetes Technology Group and included Ancona, Bologna, Cremona, Genova, Messina, Milan S. Raffaele Hospital, Napoli G. Stoppoloni, Napoli Federico II University, Novara, Roma, Trento, Trieste, and Verona.

Inclusion criteria were: T1D; aged 8 to 18 years; diabetes duration ≥ 12 months; multiple daily injection (MDI) insulin therapy or insulin pump (sensor-augmented insulin pump, hybrid closed loop, and advanced hybrid closed loop); users of real-time CGM (rtCGM) and intermittent scanned CGM (isCGM) with alarms for at least three months; HbA1c < 10%; and fluent in Italian. Exclusion criteria were non-Italian-speaking subjects not fluent in Italian, complications related to T1D, or other major diseases or comorbidities.

Patients and parents were asked to complete the Italian CGM-SAT questionnaire version 1.2 (Supplementary Material S1). The pediatric diabetologist or one collaborator administered the questionnaire in each participating center.

The Clinical Research Ethics Committee (A787) of the coordinating center of Trento approved the study, which followed the Declaration of Helsinki. Written informed assents and consents were obtained by minors aged ≥ 12 years and all parents prior to study entry.

CGM-SAT scale

The original CGM-SAT was created by the Diabetes Research in Children Network (DirecNet) Study Group to measure levels of satisfaction with the use of CGM devices in young people aged 7–17; scores range from 37 to 185 [6, 9]. The Juvenile Diabetes Research Foundation Continuous Glucose Monitoring (JDRF–CGM) Study Group, in the JDRF Trial [10], designed a 44-item CGM-SAT questionnaire [8], with the first 37 items the same as the DirectNet Study group version. Patients (at least 8 but not yet 18 years old) and parents of young people < 18 years old report their degree of agreement or disagreement to questions on a 1–5 Likert scale (1 = strongly agree to 5 = strongly disagree), with two subscales referred to as "benefits" and "hassles" [7, 8, 11, 12]. Higher scores reflect a more favorable impact of, and satisfaction with, CGM use.

Translation process

"Cultural" validation was deemed unnecessary in this study because CGM-SAT was developed and validated for the American population, which is not unlike the Italian population when evaluating psychological outcomes from CGM use. Even though the questionnaire is not copyrighted, an author (RF) contacted the DirecNet consortium (Professors Roy Beck and William Tamborlane) before commencing the study to obtain permission to translate the CGM-SAT and use it after conducting linguistic validation.

Translation and validation were performed according to MAPI Research Trust guidelines (https://eprovide.mapi-trust.org/instruments/glucose-monitoring-experiences-questionnaire) and consisted of forward translation, backward translation, and patient testing.

Forward translation

The original version of the CGM-SAT was translated from the source language (English) into the target language (Italian) (versions 1.0a, 1.0b) by two native Italian translators bilingual in English who did not have a medical background (SP, MP). Translations were performed independently, and the translators were not permitted to contact each other during the translation process. A physician panel (RF, EM, and MM) compared the two translated versions in the Italian language (versions 1.0a, 1.0b), which were 95% identical in content. For 18 items, different wording with similar meaning was preferred, with the aim to facilitate patient understanding (for example: low blood sugar levels → "ipoglicemia," meaning hypoglycemia); no significant difference in meaning was found in the translation of the items; in item number 3, a different form of the verb was used. Reconciliation between the two translations into a single version was achieved after a panel meeting (version 1.1).

Backward translation

Version 1.1 underwent backward translation from Italian into English. This translation was conducted by a third

translator (DW), native English and bilingual in Italian, who had no contact with the original CGM-SAT. The result was compared by the physician panel to the original English version of the CGM-SAT, which was 93% identical in content. Minor issues were found with 27 different wordings but with similar meaning in 23 items and two different verb forms used. A significant difference was found in the translation of items 13 and 24, and an agreement was reached.

The physician panel did not change the 1.1 version of the Italian CGM-SAT after a second meeting, and the psychologist (AT) verified the intelligibility of the questionnaire items and confirmed this questionnaire version.

Cognitive debriefing

Version 1.1 of the questionnaire was evaluated by a small sample of the target audience: five Italian speaking patients with T1D and their parents. The psychologist (AT) asked the patients whether there were any clarity issues, culturally inappropriate expressions, or difficulties in understanding the questions. The debriefing interviews involved paraphrasing each question of the questionnaire and indicating whether the participants had any difficulty understanding the question or if any terms were confusing. Subsequently, the physician panel discussed the feedback from the five patients (two females, 8–16 years, HbA1c range 6.4–9.4, all using MDI; two using is CGM and three using rtCGM) and their parents (three females, levels of education from junior high school to university degrees). Patients and parents suggested simplifying some sentences. The panel accepted some proposals: 24 (4.7%) different wordings but with similar meaning in 11 items. The panel then performed a final check for spelling, grammar, and formatting and during a third meeting agreed upon a new version based on the issues raised (version 1.2).

Statistical analyses

Analyses were conducted using SAS v9.1.4. (SAS Institute Inc., Cary, NC). Items were measured using five category scales. Considering the single items as quantitative variables, means, standard deviations (SD), medians, and interquartile ranges (IQR) were calculated separately for young people and parents. Completeness at item level was evaluated. Factor analysis was conducted using minimum residuals on the correlation matrix approach to determine the model best describing the data, always separately for young people and parents. For choosing the number of factors, eigenvalues ≥ 1 were the criterion. A sample size of at least 210 participants was considered sufficient to perform factor analysis including at least five cases per item. Cronbach's α coefficient ($\alpha = k \times r/[1 + (k-1) \times r]$; with k = number of items and r = mean correlation) was calculated for each item and, for the total of the items, keeping only the records for which all answers relating to each section were present. The aggregating dimensions of the CGM-SAT Italian version were evaluated by factor analysis (principal components). Furthermore, Spearman correlations between each item and all others items were calculated to identify any significant correlations between pairs of variables, with a correlation coefficient > 0.70 considered strong [13]. Finally, agreement between young people and parent scores was calculated using Gwet's agreement coefficient (AC1 with 95% confidence intervals (CI)), which is considered more stable than Cohen's kappa.

Results

In total, 232 parents and 210 children–adolescents were recruited. Their characteristics are shown in Table 1.

Evaluation of completeness

Completeness was optimal for each item, both for patients and parents. The maximum percentage of missing values was 1.4 in the patient group (only for item 42) and 0.4 in the parent group (for only 7 items), with almost 100% of items answered (Supplementary Material S2).

Internal reliability

Cronbach's coefficients were > 70% for all 44 items in the young people group, while Cronbach's coefficients were > 80% for all 44 items in the parent group. Overall Cronbach's coefficients were 0.71 and 0.85, indicating moderate and good internal consistency, respectively.

Factor analysis

Two factors emerged for the CGM-SAT in both groups: benefits of CGM (21 items) and hassles of CGM (20 items). The remaining three items (4, 28, and 42) did not load on any factor (Table 2). After deleting the three items that did not load on a factor, the internal consistency of the total scale was alpha = 0.71 for patients and 0.85 for parents.

Correlation analysis

Correlation analysis showed positive correlations between couples of items > 0.30 in many cases, but never greater than 0.70. Despite some correlations, these items did not necessarily need to be eliminated due to their specific focus. The three items (4, 28, and 42) not loading on any factor were those with the lowest correlation coefficients.

Table 1 Patient characteristics ($n=210$)

Characteristic	
Female *n* (%)	104 (44.8)
Age at study enrollment (years) [mean ± SD (median)]	13.67 ± 2.9 (13.9)
Age at diabetes onset (years) [mean ± SD (median)]	7.0 ± 3.7 (7.0)
Age starting CGM [mean ± SD (median)]	10.4 ± 3.3 (11.0)
CGM experience (years) [mean ± SD (median)]	2.3 ± 1.9 (2.0)
CGM type n (%)	
Dexcom G6	155 (66.8)
Guardian 3	21 (9.1)
Guardian 4	21 (9.1)
Free Style Libre 2	35 (15.0)
Insulin treatment n (%)	
MDI	84 (36.2)
SAP	64 (27.6)
HCL	13 (5.6)
AHCL	71 (30.6)
Weight (kg) [mean ± SD (median)]	53.1 ± 15.4 (52.7)
Height (m) [mean ± SD (median)]	158.4 ± 13.8 (159.9)
BMI	20.67 ± 3.81 (20.13)
BMI z-score	0.23 ± 1.33 (0.25)
Stage of puberty n (%)	
Prepubertal	43 (18.5)
Pubertal	75 (32.3)
Postpubertal	114 (49.1)
Annual % HbA1c [mean ± SD (median)]	7.0 ± 0.8 (7.0)
Last value % HbA1c [mean ± SD (median)]	6.9 ± 0.8 (6.9)
Number of visits to clinic [mean ± SD (median)]	3.5 ± 1.2 (3.0)
Number of telemedicine visits [mean ± SD (median)]	0.6 ± 1.1 (0.0)
Total daily insulin dose (U/kg [mean ± SD (median)]	40.6 ± 20.2 (37.0)
Number of severe hypoglycemia events (last year) n (%)	
0	230 (99.1)
1	2 (0.9)
Number of severe DKA episodes (last year) n (%)	
0	231 (99.6)
1	1 (0.4)

Table 2 Factor analysis for the CGM-SAT

Measurement factor	Item loading	Eigenvalue	% variance	Alpha coefficient
Benefits of CGM	Item numbers: 2, 3, 6, 7, 9, 10, 11, 12, 13, 15, 17, 19, 20, 21, 22, 23, 24, 38, 41, 43, 44	9.52 (y) 8.36 (p)	33.9% (y) 29.6%	0.87 (y) 0.85 (p)
Hassles of CGM	Item numbers: 1, 5, 8, 14, 16, 18, 25, 26, 27, 29, 30, 31, 32, 33, 34, 35, 36, 37, 39, 40	3.63 (y) 5.58 (p)	12.9% (y) 19.8% (p)	0.88 (y) 0.91 (p)
No factor	Item numbers: 4, 28, 42			

y young people, *p* parents

Agreement analysis

Gwet's agreement coefficient (AC1) was 0.404 (95% CI 0.391–0.417), indicating moderate agreement between the two evaluations (young people and parents). The descriptive statistics and reliability indices for the CGM-SAT for young people and parents are summarized in Table 3.

Table 3 Descriptive statistics and reliability indices for the CGM-SAT for young people and parents

	Young people	Parents
N	212	232
Mean ± SD item score	2.9 ± 1.3	3.0 ± 1.2
Alpha coefficient	0.71	0.85
Parent–young people agreement AC1 (95% CI)	0.404 (0.391–0.417)	

Satisfaction with use of CGM was neutral, as indicated by a mean CGM-SAT score of 3.0 ± 1.2 for parents and 2.9 ± 1.3 for young people (possible score range 1 to 5, neutral score is 3.0). The mean scores for parents were 2.13 ± 0.52 (median 2.0) on the "benefits" subscale and 3.99 ± 0.92 (median 4.0) on the "hassles" subscale, while the mean scores for young people were 1.99 ± 0.84 (median 2.0) on the "benefits" subscale and 3.98 ± 1.00 (median 4.0) on the "hassles" subscale.

Discussion

This is the first study to translate and validate the CGM-SAT, which will be used to assess Italian patient satisfaction with CGM. We assessed the translation's reliability, conceptual equivalence, and content validity. General satisfaction (for both patients and parents) was neutral, as demonstrated by CGM-SAT scores lower than those described in the JDRF–CGM randomized controlled trial (mean item patient/parent scores 2.9/3.0 vs. 3.6/3.8) [8, 14], but mean scores on the "benefits" subscale were low for patients/parents (1.99/2.13), highlighting their agreement with the benefits of CGM systems. Mean scores on the "hassles" subscale were high (3.98/3.99, respectively), indicating that they do not regard CGM systems as causing hassles.

Overall, the Italian CGM-SAT demonstrated good psychometric properties, as confirmed by good internal reliability among patients and parents and agreement between parent–young people evaluations.

It was recently reported that CGM-SAT score and adherence to CGM use are significantly positively associated [9], and similar results were reported in the JDRF study, in which CGM satisfaction was higher in participants who used CGM consistently [7, 15]. In previous studies, the CGM-SAT questionnaire helped to show that participants who use CGM less frequently may be frustrated by multiple CGM sensor alarms. In contrast, compliant participants are likely to gain more benefits than drawbacks from CGM use [16].

Consistent with the validation study for the English version of the CGM-SAT, two primary measurement factors were identified: benefits of CGM (21 items) and hassles of CGM (20 items). Items 4, 28, and 42 did not load on any measurement factor and had the lowest correlation coefficients. In contrast to the English version validation, which reported 19 items as benefits, we found three more items (13, 15, and 19) that, according to their meaning, would be correctly categorized as benefits, while one that was miscategorized as a benefit (42). This last question asked "If possible, I want to use the device when the research study is over," which did not make any sense to patients in daily care rather than the research setting. A 41-item questionnaire without items 4, 28, and 42 would not change the internal consistency of the questionnaire.

Our study was limited by its cross-sectional design, and future studies should evaluate correlations between CGM-SAT scores and patient and/or technology characteristics.

In conclusion, our study provides the first validated Italian version of the CGM-SAT, which is a valuable resource for clinicians and researchers assessing CGM satisfaction in pediatric patients with T1D and their parents.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s00592-023-02043-w.

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Author contributions All persons who meet authorship criteria are listed as authors, and all authors certify that they have participated sufficiently in the work. RF, EM, AT, and MM designed the study. All authors except Riccardo Pertile (RP) enrolled patients in this study. RP performed statistical analyses. RF, EM, AT, and MM wrote the manuscript. All authors discussed, critically edited, and approved the manuscript.

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Data availability All databases generated for this study are included in the article.

Declarations

Conflict of interests The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Ethics approval The current study was approved by the local Institutional Review Board. The study was performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments.

Informed consent Written informed consent was obtained from each participant and parent/legal guardian.

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